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Original Paper

Feasibility of Artificial Intelligence–Based Electrocardiography Analysis for the Prediction of Obstructive Coronary Artery Disease in Patients With Stable Angina: Validation Study

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Abstract

Background: Despite accumulating research on artificial intelligence–based electrocardiography (ECG) algorithms for predicting acute coronary syndrome (ACS), their application in stable angina is not well evaluated.

Objective: We evaluated the utility of an existing artificial intelligence–based quantitative electrocardiography (QCG) analyzer in stable angina and developed a new ECG biomarker more suitable for stable angina.

Methods: This single-center study comprised consecutive patients with stable angina. The independent and incremental value of QCG scores for coronary artery disease (CAD)–related conditions (ACS, myocardial injury, critical status, ST-elevation myocardial infarction, and left ventricular dysfunction) for predicting obstructive CAD confirmed by invasive angiography was examined. Additionally, ECG signals extracted by the QCG analyzer were used as input to develop a new QCG score.

Results: Among 723 patients with stable angina (median age 68 years; male: 470/723, 65%), 497 (69%) had obstructive CAD. QCG scores for ACS and myocardial injury were independently associated with obstructive CAD (odds ratio [OR] 1.09, 95% CI 1.03-1.17 and OR 1.08, 95% CI 1.02-1.16 per 10-point increase, respectively) but did not significantly improve prediction performance compared to clinical features. However, our new QCG score demonstrated better prediction performance for obstructive CAD (area under the receiver operating characteristic curve 0.802) than the original QCG scores, with incremental predictive value in combination with clinical features (area under the receiver operating characteristic curve 0.827 vs 0.730; $P<.001$).

Conclusions: QCG scores developed for acute conditions show limited performance in identifying obstructive CAD in stable angina. However, improvement in the QCG analyzer, through training on comprehensive ECG signals in patients with stable angina, is feasible.

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KEYWORDS

artificial intelligence; AI; coronary artery disease; coronary stenosis; electrocardiography; stable angina

Introduction

Coronary artery disease (CAD) is a major global health issue, with increasing prevalence and incidence worldwide [1]. Although electrocardiography (ECG) has been used as a primary noninvasive modality in patients with suspected CAD, its diagnostic value is limited to acute coronary syndrome (ACS), such as ST-elevation myocardial infarction (STEMI) [2]. In patients presenting with stable angina, the initial ECG often shows nonspecific or normal findings, resulting in a low-diagnostic accuracy [2,3]. Therefore, in most cases,

additional tests, such as exercise ECG, single-photon emission computed tomography, and coronary computed tomography angiography, are required regardless of the initial ECG findings.

In previous decades, several attempts have been made to develop automated algorithms using artificial intelligence (AI) to analyze ECG signals to identify CAD [4]. For clinical use, most of these AI-ECG "digital biomarkers" were developed for the rapid evaluation of patients presenting with acute chest pain, especially for ACS screening [5-10]. However, for nonacute conditions, there is a paucity of data regarding the use of such AI algorithms. Accordingly, there is a large knowledge gap regarding whether algorithms developed for acute ischemia can be used in chronic stable conditions.

We hypothesized that the AI-ECG biomarkers originally developed for acute ischemia might also provide valuable information regarding the presence and severity of CAD in patients presenting with stable angina. However, we also considered the possibility that a dedicated score for stable angina may be more suitable. Therefore, the objectives of this study were 2-fold: (1) to evaluate the utility of ECG digital biomarkers that were originally developed for acute conditions, such as ACS, in the risk stratification of patients presenting with stable angina; and (2) to evaluate the feasibility of developing a new ECG biomarker for stable angina by reusing the deep features of an existing AI system.

Methods

Study Population

We retrospectively screened consecutive patients who visited the outpatient clinic with symptoms indicative of stable angina and underwent invasive coronary angiography at the Seoul National University Bundang Hospital (SNUBH) between 2018 and 2020. Symptomatic patients with suspected CAD and available records on clinical risk factors and baseline examinations (blood tests, chest X-ray, ECG, and echocardiography) were included. Patients who were asymptomatic, had a previous history of CAD or coronary revascularization (including percutaneous coronary intervention and bypass surgery), underwent emergent or urgent coronary angiography with suspected ACS, or underwent an ergonovine provocation test with suspected variant angina were excluded. Finally, 723 patients were analyzed.

Ethics Approval

The study protocol was approved by the institutional review board of SNUBH (B-2211-790-102) and conducted in compliance with the principles of the Declaration of Helsinki. The requirement for informed consent was waived by the review board due to the retrospective study design.

Clinical Features and Invasive Coronary Angiography

Baseline characteristics were obtained through a dedicated review of electronic health records. Patient symptoms were classified as typical or atypical chest pain according to their nature. Additionally, patients without documented chest pain but with relevant symptoms indicative of ischemic heart disease (eg, dyspnea, diaphoresis, or extreme fatigue) were categorized as having angina-equivalent symptoms. The presence of clinical risk factors, including hypertension, diabetes mellitus, dyslipidemia, and stroke, were determined by clinical diagnoses or medical therapy records.

All patients underwent invasive coronary angiography, and obstructive CAD was defined as the presence of any stenosis with ≥50% diameter stenosis in major epicardial coronary arteries (left main [LM], left anterior descending artery, left circumflex artery, or right coronary artery [RCA]), or major branches of each artery. The number of vessels with obstructive CAD was counted as 1, 2, or 3 (1 vessel with obstructive CAD [VD], 2VD, or 3VD), and obstructive CAD at the LM was considered equivalent to 2VD. Therefore, 3VD was defined as the presence of obstructive CAD in all 3 epicardial coronary arteries (left anterior descending artery, left circumflex artery, and RCA) or in both the LM coronary artery and RCA.

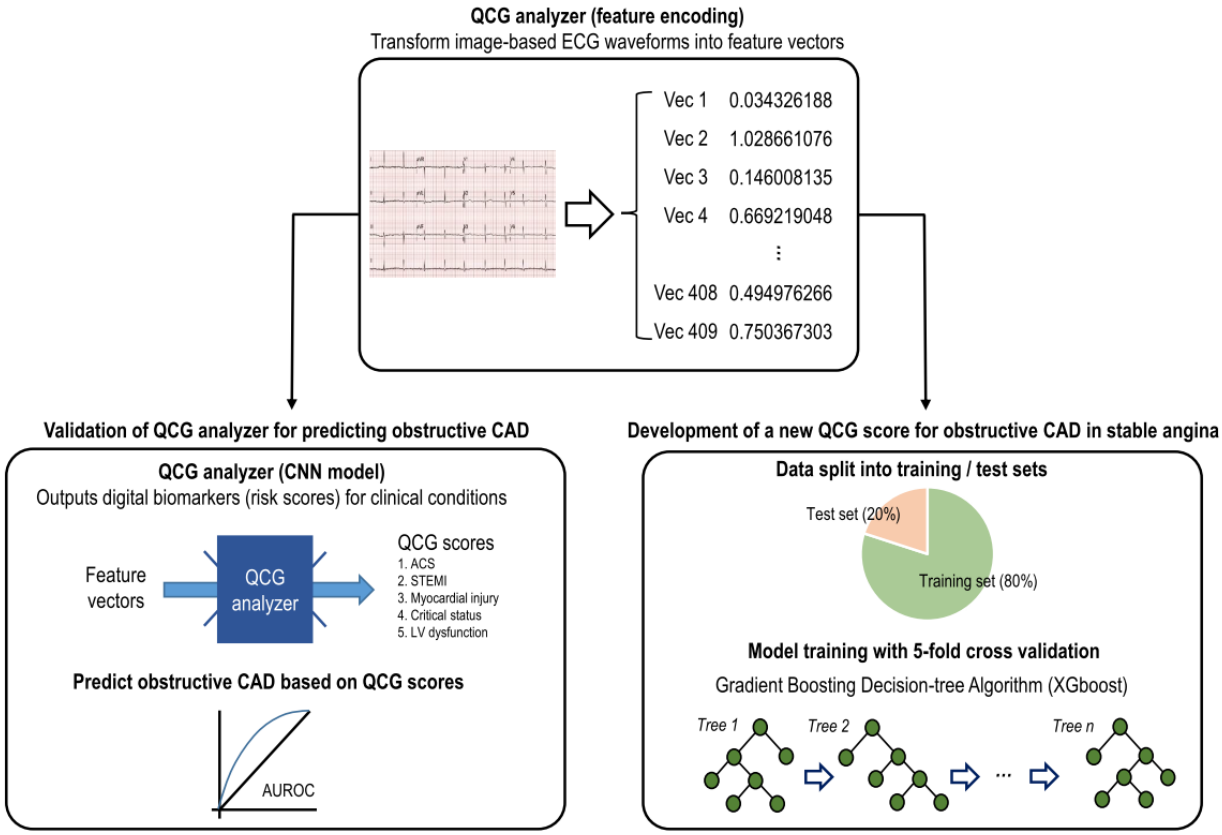
AI-Based Quantitative Electrocardiography (QCG) Analysis

The development process for the QCG analyzer (Figure 1), which operates on a mobile platform as a smartphone app, has been reported previously [5,6]. The QCG analyzer is composed of an encoder and various task-specific artificial neural network layers. The encoder is a deep learning algorithm pretrained on various open ECG data sets (49,731 recordings total) using self-supervised learning techniques and can be used with or without fine-tuning for various tasks. It was first integrated into a smartphone AI app developed to screen various emergency conditions using 47,194 annotated ECG images of over 32,968 patients who were admitted to the SNUBH emergency department between 2017 and 2019. The encoder part has a signal extraction submodule applying a series of morphological operation procedures on the input data and a ResNet-based convolutional neural network submodule with 16 layers of convolution layers with squeeze-excitation blocks and a nonlocal network block. The encoder serves as a signal extractor and both submodules can be jointly optimized further through fine tuning for the specific tasks it is applied for. The task-specific layers of the QCG analyzer were optimized with Adam optimizer with focal loss function using a supervised training scheme, and the output probability from the sigmoid function was calibrated using the temperature scaling method. The QCG analyzer outputs 10 digital biomarkers (QCG scores ranging from 0 to 100) representing the risk of 10 medical conditions that may require emergent management (ACS, STEMI, myocardial injury, critical status, left ventricular [LV] dysfunction, pulmonary edema, pulmonary hypertension, right ventricular dysfunction, pericardial effusion, and hyperkalemia).

In this study, the QCG analyzer was used in the following 2 AI-ECG analyses (Figure 1). First, to evaluate whether the original QCG analyzer trained on acute-phase patients admitted to the emergency department could be used for the evaluation of patients presenting with stable angina, we derived 5 QCG scores related to CAD (ACS, STEMI, myocardial injury, critical status, and LV dysfunction). We then examined the independent association and predictive value of each QCG score for the presence of (1) any obstructive CAD and (2) 3VD as study outcomes. Second, to develop a new QCG score for the detection

of any obstructive CAD that is more suitable for stable angina, we extracted the encoded feature vectors from input ECG images using the QCG analyzer, which were then used as input features.

Figure 1. Artificial intelligence (AI)–based quantitative electrocardiography (QCG) analysis. The diagram summarizes the study flow. The QCG analyzer transforms image-based electrocardiography (ECG) data into vectorized signal features. To validate the original QCG analyzer in patients with stable angina, we derived 5 QCG scores related to coronary artery disease (CAD) and evaluated their predictive value for the presence of obstructive CAD. Additionally, we developed a new QCG score that is more suitable for identifying obstructive CAD in stable angina by using a tree-based AI algorithm, XGboost, with the extracted vectors as input features. ACS: acute coronary syndrome; AUROC: area under the receiver operating characteristic curve; CNN: convolutional neural network; LV: left ventricular; STEMI: ST-elevation myocardial infarction.



Statistical Analysis

All statistical analyses were performed using R software (version 4.2.1; R Core Team). Continuous variables were presented as medians (IQR; categorical variables were presented as numbers (percentages). A 2-sided $P<.05$ was considered statistically significant.

Evaluation of Original QCG Scores for Predicting Obstructive CAD in Patients With Stable Angina

QCG scores for 5 CAD-related conditions were plotted according to the number of vessels affected to evaluate their distribution according to the CAD burden in patients with stable angina. Significant associations between QCG scores and study outcomes were examined using logistic regression analysis, with independence determined by multivariate adjustment for clinical features. The discrimination performance of QCG scores for the study outcomes was evaluated by the area under the receiver operating characteristic curve (AUROC). To evaluate the incremental predictive value of QCG score over clinical features, we constructed the clinical model using multivariate logistic regression analysis with baseline clinical variables (age, sex, BMI, symptom type, hypertension, diabetes mellitus, dyslipidemia, smoking, stroke, and family history of cardiovascular disease). Compared with the baseline performance of the clinical model, significant improvement in AUROC was assessed by adding QCG scores with clinical features in the prediction model.

Development of a New Risk Score for Obstructive CAD in Stable Angina

To derive a new QCG score suitable for stable angina, the entire data set was divided into a training set (80%) and a test set (20%). For model development, we employed an existing AI algorithm using a tree-based ensemble technique, XGboost, which has shown satisfactory performance in disease classification problems across various cardiovascular fields [11]. The final prediction model was derived from the training set with hyperparameter optimization. We applied a 5-fold cross-validation technique for this hyperparameter tuning process by randomly dividing the training set into 5 folds. During the cross-validation, the model was fitted among the 4 folds and validated on the remaining fold, and this step was repeated 5 times. Then the final model performance on outcome prediction was verified in the test set, expressed as AUROC. Additionally, the incremental predictive value of the new QCG score was assessed among the test set. The baseline clinical model was constructed with clinical features that were the same as those used for assessing the incremental value of the original QCG score.

Results

Baseline Clinical Features

The clinical features of 723 patients (age: median 68 years, IQR 60-75 years; male: 470/723, 65%; BMI 25.1 kg/m^2, IQR 23.3-27.1 kg/m^2) are summarized in Table 1. Obstructive CAD was found in 497 (69%) patients, 132 (18%) of whom had 3VD. Patients with obstructive CAD tended to be male, presented more frequently with typical chest pain, and had a higher prevalence of clinical risk factors than those without obstructive CAD. These trends were more pronounced in patients with 3VD (Table 1).

Table 1. Baseline characteristics.

Variables	Total population (N=723)	No obstructive CAD[a] (n=226)	Any obstructive CAD (n=497)	*P* value (vs no obstructive CAD)	3-vessel obstructive CAD (n=132)	*P* value (vs no obstructive CAD)
Demographics						
Age (years), median (IQR)	68 (60- 75)	68 (59-74)	68 (60-75)	.39	69 (61-76)	.28
Male, n (%)	470 (65)	125 (55.3)	345 (69.4)	<.001	98 (74.2)	<.001
BMI (kg/m^2), median (IQR)	25.1 (23.3-27.1)	25.3 (23.2-27.5)	25.1 (23.4-27.1)	.46	25.3 (23.6-27.1)	.90
Clinical features, n (%)						
Symptoms						
Typical chest pain	486 (67.2)	125 (55.3)	361 (72.6)	<.001	111 (84.1)	<.001
Atypical chest pain	163 (22.5)	70 (31)	93 (18.7)	—[b]	12 (9.1)	—
Angina equivalent	74 (10.2)	31 (13.7)	43 (8.7)	—	9 (6.8)	—
Hypertension	459 (63.5)	130 (57.5)	329 (66.2)	.03	98 (74.2)	.002
Diabetes mellitus	221 (30.6)	55 (24.3)	166 (33.4)	.02	55 (41.7)	.001
Dyslipidemia	245 (33.9)	71 (31.4)	174 (35)	.39	51 (38.6)	.20
Stroke	41 (5.7)	8 (3.5)	33 (6.6)	.13	9 (6.8)	.25
Family history of CAD	59 (8.2)	10 (4.4)	49 (9.9)	.02	10 (7.6)	.31
Smoking	68 (9.4)	19 (8.4)	49 (9.9)	.63	13 (9.8)	.79
Invasive coronary angiography, n (%)						
Obstructive CAD						
Left main	56 (7.7)	—	56 (11.3)	—	38 (28.8)	—
Left anterior descending artery	402 (55.6)	—	402 (80.9)	—	125 (94.7)	—
Left circumflex artery	218 (30.2)	—	218 (43.9)	—	119 (90.2)	—
Right coronary artery.	248 (34.3)	—	248 (49.9)	—	132 (100)	—

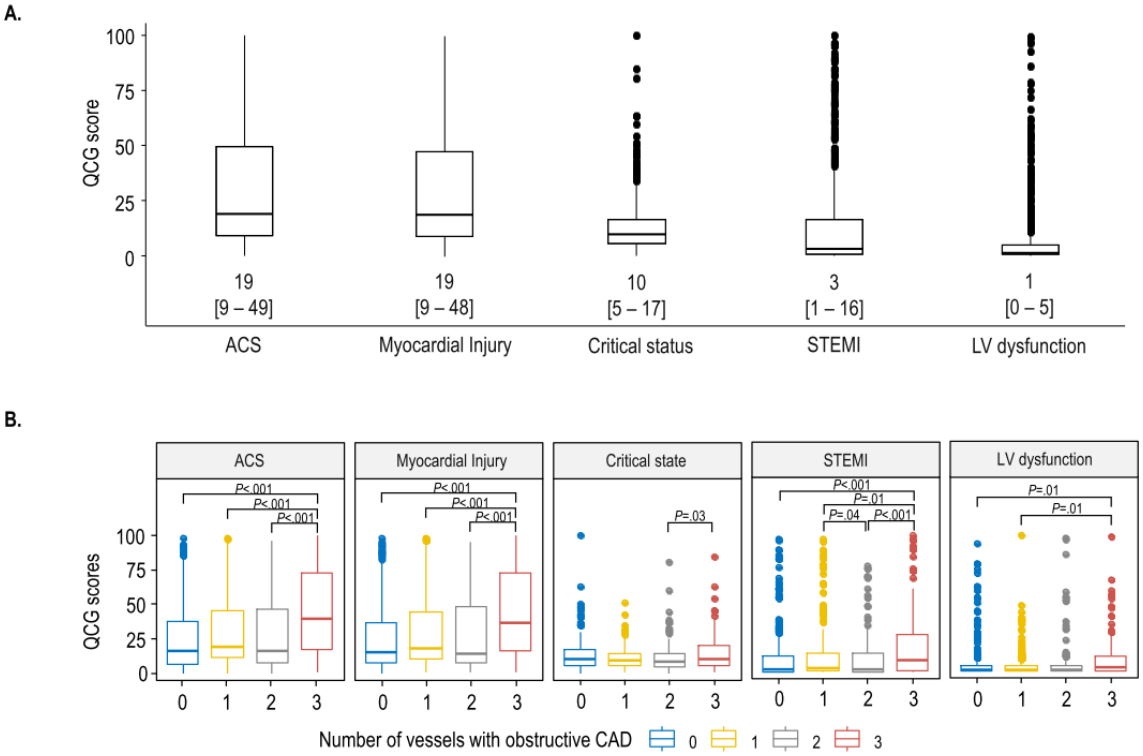
[a]CAD: coronary artery disease.

[b]Not applicable.

Distribution of the Original QCS Scores in Patients Presenting With Stable Angina

The distributions of 5 QCG scores in the study population are shown in Figure 2. Among these, the scores for ACS (median 19, IQR 9-49) and myocardial injury (median 19, IQR 9-48) had the highest values (Figure 2A). When stratified by the number of vessels with obstructive CAD, these 2 scores did not significantly differ between patients with 1VD or 2VD and those without obstructive CAD (Figure 2B). However, the 3VD group demonstrated significantly higher ACS and myocardial injury QCG scores compared to those in other groups (all *P*<.01).

Figure 2. Distribution of the quantitative electrocardiography (QCG) scores. (A) Among the 5 QCG scores, those for acute coronary syndrome (ACS) and myocardial injury exhibited the highest values. (B) When the QCG scores were stratified by the number of vessels with obstructive coronary artery disease (CAD), patients group with 3-vessel disease showed significantly higher scores for ACS and myocardial injury than those in the other groups. LV: left ventricular; STEMI: ST-elevation myocardial infarction.



Predictive Value of the Original QCG Scores

On univariate analysis, only the QCG scores for ACS (odds ratio [OR] 1.11, 95% CI 1.05-1.18 per 10-point increase; *P*<.001) and myocardial injury (OR 1.10, 95% CI 1.04-1.17 per 10-point increase; *P*=.002) showed significant associations with the presence of obstructive CAD (Table 2). However, all 5 QCG scores demonstrated significant associations with 3VD. These trends were maintained after multivariate adjustment for clinical features (age, sex, BMI, type of chest pain, hypertension, diabetes, dyslipidemia, smoking, stroke, and family history of premature CAD). Only QCG scores for ACS and myocardial injury showed independent associations with the presence of obstructive CAD (OR 1.09, 95% CI 1.03-1.17 per 10-point increase; *P*=.006; and OR 1.08, 95% CI 1.02-1.16 per 10-point increase; *P*=.01; respectively) (Table 3); however, all 5 QCG scores were independently associated with the presence of 3VD. The QCG scores for ACS (OR 1.19, 95% CI 1.11-1.27 per 10-point increase; *P*<.001) and myocardial injury (OR 1.19, 95% CI 1.10-1.26 per 10-point increase; *P*<.001) demonstrated stronger associations with 3VD than other QCG scores (Table 3).

Although both scores for ACS and myocardial injury showed significant discriminative performance for obstructive CAD (AUROC 0.589 and 0.576, respectively), their performance was lower than that for clinical features (AUROC 0.672; *P*=.005 and *P*=.001, respectively) (Figure 3A). However, for the prediction of 3VD, both scores demonstrated moderate performance (AUROC 0.652 and 0.648, respectively), comparable to that for clinical features (AUROC 0.686; *P*=.31 and *P*=.27, respectively), and provided significant incremental predictive value in combination with clinical features (AUROC 0.724 and 0.723; *P*=.02 and *P*<.001, respectively) (Figure 3B).

Table 2. Univariate analysis for obstructive coronary artery disease (CAD).

Variables	Any obstructive CAD		3-vessel obstructive CAD	
	Univariate OR[a] (95% CI)	*P* value	Univariate OR (95% CI)	*P* value
Clinical features				
Age (per 10-year increase)	1.10 (0.95-1.27)	.20	1.10 (0.92-1.31)	.29
Male	1.83 (1.33-2.54)	<.001	1.70 (1.11-2.59)	.02
BMI (per 1 kg/m^2 increase)	0.97 (0.92-1.01)	.15	1.00 (0.94-1.06)	.99
Typical chest pain	2.14 (1.54-2.98)	<.001	3.04 (1.85-5.00)	<.001
Hypertension	1.45 (1.05-2.00)	.03	1.84 (1.20-2.81)	.005
Diabetes mellitus	1.56 (1.09-2.23)	.02	1.83 (1.24-2.70)	.002
Dyslipidemia	1.18 (0.84-1.65)	.34	1.29 (0.87-1.90)	.20
Stroke	1.94 (0.88-4.27)	.10	1.28 (0.59-2.75)	.53
Family history of CAD	2.36 (1.17-4.75)	.02	0.91 (0.45-1.84)	.79
Smoking	1.19 (0.68-2.08)	.54	1.06 (0.56-2.01)	.85
QCG[b] scores (per 10-point increase)				
Acute coronary syndrome	1.11 (1.05-1.18)	<.001	1.20 (1.12-1.27)	<.001
Myocardial injury	1.10 (1.04-1.17)	.002	1.19 (1.12-1.27)	<.001
Critical status	0.94 (0.82-1.08)	.40	1.21 (1.04-1.41)	.02
STEMI[c]	1.04 (0.97-1.12)	.30	1.13 (1.05-1.21)	.002
Left ventricle dysfunction	0.98 (0.88-1.09)	.71	1.14 (1.02-1.27)	.02

[a]OR: odds ratio.

[b]QCG: quantitative electrocardiography.

[c]STEMI: ST-elevation myocardial infarction.

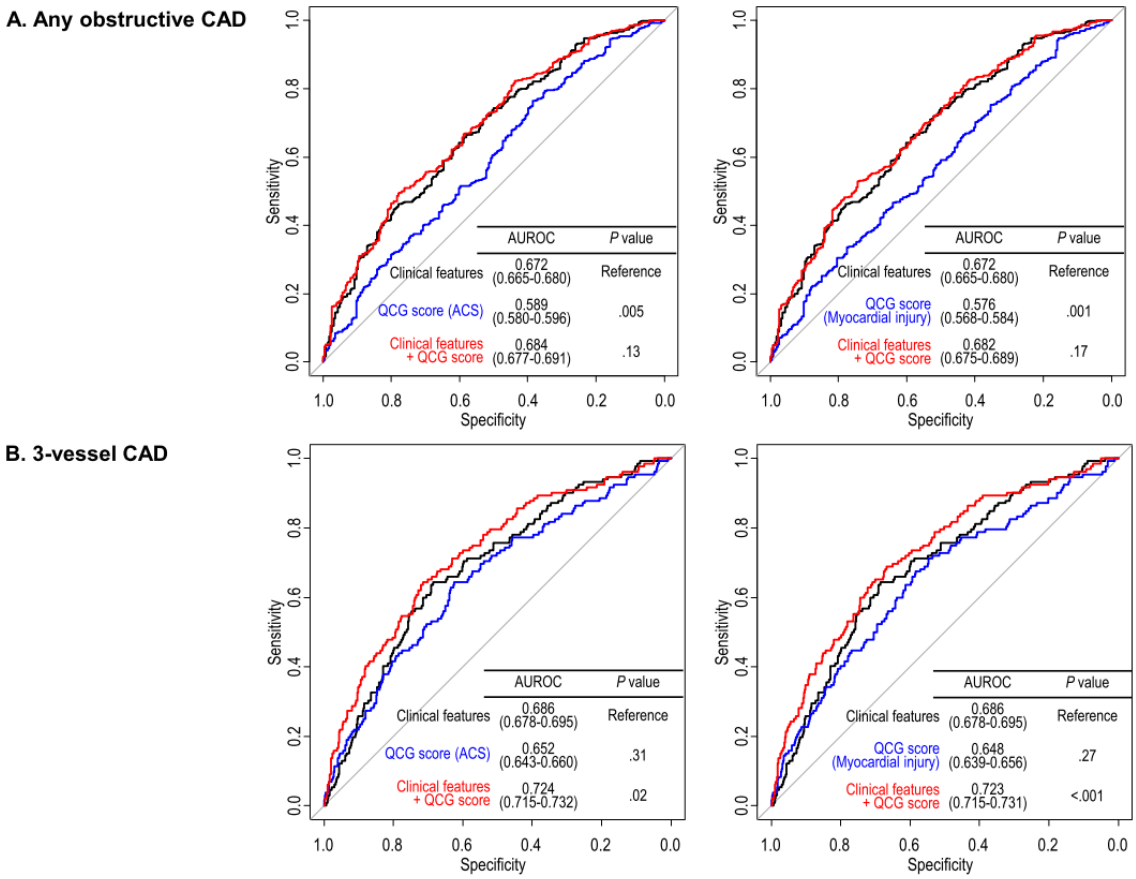
Table 3. Multivariate analysis of the quantitative electrocardiography (QCG) scores for obstructive coronary artery disease (CAD).

Variables	Any obstructive CAD		3-vessel obstructive CAD	
	Multivariate OR (95% CI)[a]	*P* value	Multivariate OR (95% CI)	*P* value
QCG scores (per 10-point increase)				
Acute coronary syndrome	1.09 (1.03-1.17)	.006	1.19 (1.11-1.27)	<.001
Myocardial injury	1.08 (1.02-1.16)	.01	1.19 (1.10-1.26)	<.001
Critical status	0.92 (0.79-1.06)	.24	1.19 (1.01-1.40)	.04
STEMI[b]	1.03 (0.95-1.11)	.52	1.13 (1.04-1.22)	.004
Left ventricle dysfunction	0.95 (0.85-1.06)	.37	1.13 (1.01-1.27)	.04

[a]Multivariate odds ratios (ORs) are estimated with adjustment for age, sex, body mass index, typical symptoms, hypertension, diabetes mellitus, dyslipidemia, stroke, family history of CAD, and smoking.

[b]STEMI: ST-elevation myocardial infarction.

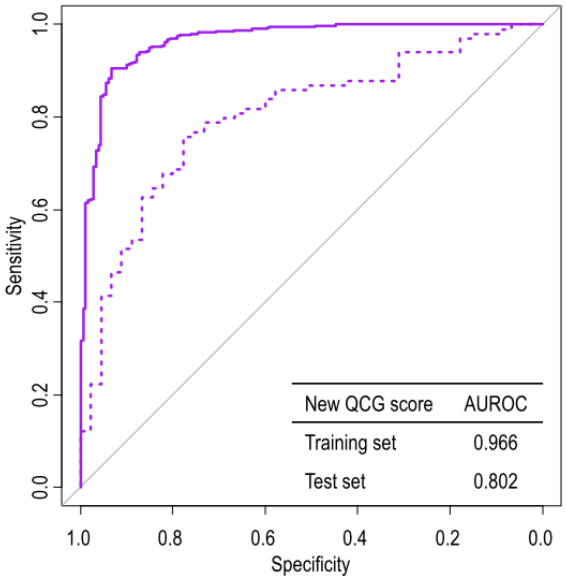
Figure 3. Incremental predictive value of the original quantitative electrocardiography (QCG) scores for obstructive coronary artery disease (CAD). (A) The QCG scores for acute coronary syndrome (ACS) and myocardial injury demonstrated significant predictive performance for obstructive CAD, despite lower performance than that of clinical features. (B) In contrast, both scores showed moderate predictive performance for 3-vessel disease, comparable to that for clinical features, and provide incremental predictive value in combination with clinical features. AUROC: area under the receiver operating characteristic curve.



A New QCG Score for Obstructive CAD in Stable Angina

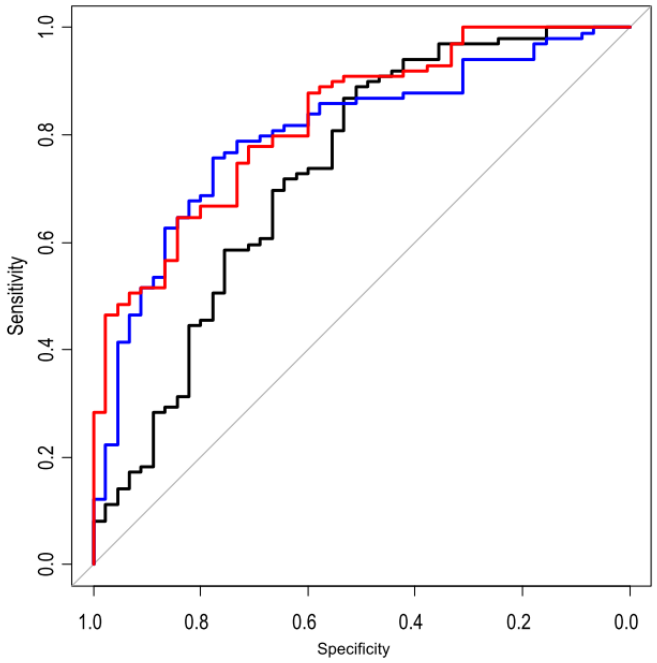
Based on the above results, a new QCG score for any obstructive CAD more suitable for patients presenting with stable angina was deemed appropriate. The clinical characteristics of the training and test sets are summarized in Table S1 in Multimedia Appendix 1. Although the median age was slightly higher in the training set than in the test set (median 69 years, IQR 60-75 years vs median 65 years, IQR 58-73 years), no significant differences were observed in other clinical features between the training and test sets. The distribution of our new QCG score in the training and test sets is shown in Figure S1 in Multimedia Appendix 2. The new QCG score was significantly higher in patients with obstructive CAD than in those without obstructive CAD. Further, the new QCG score demonstrated improved performance for identifying obstructive CAD (AUROC 0.966 and 0.802 in the training and test sets, respectively) compared to that for the original QCG scores of ACS and myocardial injury (Figure 4). When patients were categorized by the optimal cutoff value of the new QCG score (score of 66 in both training and test sets), the sensitivity, specificity, and accuracy for obstructive CAD were 90.5%, 91.7%, and 90.8% in the training set and 75.8%, 75.6%, and 75.7% in the test set, respectively (Figure 4). In addition, the new QCG score provided incremental predictive value in combination with clinical features (AUROC 0.730 vs 0.827; $P<.001$) (Figure 5).

Figure 4. Prediction performance of the new quantitative electrocardiography (QCG) score for any obstructive coronary artery disease (CAD). This figure summarizes the discrimination performance of the new QCG score in the training and test sets. After categorizing the patients by the optimal cutoff values of the new QCG score (score of 66 in both training and test sets), the accuracy for obstructive CAD was 90.8% and 75.7% in the training and test sets, respectively. AUROC: area under the receiver operating characteristic curve; NPV: negative predictive value; PPV: positive predictive power.



	Training set	Test set
Sensitivity	90.5%	75.8%
Specificity	91.7%	75.6%
PPV	96.0%	87.2%
NPV	81.4%	58.6%
F1 score	0.93	0.81
Accuracy	90.8%	75.7%

Figure 5. Incremental predictive value of the new quantitative electrocardiography (QCG) score for any obstructive coronary artery disease in the test set. In the test set, the new QCG score showed significantly higher predictive performance for obstructive CAD than that for clinical features, and provided incremental predictive value in combination with clinical features. AUROC: area under the receiver operating characteristic curve.



Model	AUROC	*P* value
Clinical features	0.730 (0.713-0.747)	Reference
New QCG score	0.802 (0.788-0.815)	.001
Clinical features + New QCG score	0.827 (0.815-0.839)	<.001

Discussion

Overview

In this study, we evaluated the utility of ECG digital biomarkers developed for acute conditions, known as QCG scores, in the risk stratification of patients with stable angina. Although the discriminative power for the detection of any obstructive CAD was inferior to that for clinical features, CAD-related QCG scores showed independent and incremental predictive value for the presence of 3VD. In addition, to improve the risk stratification of patients with stable angina, we developed a new

ECG biomarker for the detection of obstructive CAD in stable angina by using the deep features of the QCG analyzer.

Challenges in Diagnosing Stable Angina With ECG

ECG has provided valuable insights into the physiological and structural conditions of the heart and has long been used as a primary diagnostic tool for various cardiovascular diseases. In addition to its advantages of low cost, rapidity, and simplicity, ECG acquisition is well standardized and reproducible. However, the human interpretation of ECG images is highly dependent on experience and expertise. Although computer-generated interpretation techniques have been used, they are based on predefined rules and do not capture all of the complex information contained in ECG [12]. In patients with stable angina, the diagnostic value of ECG is often limited because of nonspecific or normal findings in the resting state [3,13,14]. The diagnostic accuracy of ECG in detecting obstructive CAD in the epicardial artery was reportedly low, ranging from 59% to 62% [3]. Nevertheless, it is still possible that there are ECG features relevant to stable angina, but they are so subtle that visual interpretation would inevitably be limited. There is growing evidence that AI techniques using deep-learning convolutional neural networks enable the detection of subtle signals and patterns from ECG that are unrecognizable by the human eye or conventional computer-based analysis [12]. Although they do not fit traditional knowledge, these approaches may allow the prediction of diseases that were previously unpredictable with ECG, such as stable angina. Their usage extends beyond the traditional roles of ECG, such as the identification of the current rhythm, to include novel areas, such as the prediction of subsequent atrial fibrillation events or poor LV ejection fraction [15].

Potential of AI-ECG Models for Identifying Obstructive CAD in Stable Angina

In terms of CAD, previous studies have demonstrated the feasibility and fine performance of AI-ECG models as a rapid screening tool for ACS in patients presenting with acute chest pain [6-8]. Although various model structures with different AI algorithms have been used, these models have focused on the prediction of ACS. Although it is also conceivable that a well-trained AI-ECG model might be able to detect stable obstructive CAD, there is a paucity of investigations extrapolating the clinical utility of these AI models for identifying obstructive CAD in patients with stable angina. In this study, we hypothesized that predeveloped QCG scores trained on acute-phase patients could also be applied to patients with stable angina. Among 5 QCG scores related to CAD, ACS and myocardial injury QCG scores showed independent associations with the presence of any obstructive CAD. However, their prediction performance was low, and they did not significantly improve the prediction performance over that with clinical features. This is not surprising given that the original QCS scores were derived by a deep-learning process capturing ECG signals of patients in an acute setting. Nevertheless, both scores exhibited moderate performance in predicting obstructive 3VD and showed incremental predictive value in combination with clinical features. Our results suggest that these predeveloped QCG scores also have some potential in capturing ECG changes in patients presenting with stable angina, especially in those with extensive CAD, indicating a higher burden of ischemia, such as 3VD.

Feasibility of the QCG Analyzer in Stable Angina

Because ECG findings in patients with stable angina are more subtle and nonspecific than those observed in ACS, an accurate prediction of obstructive CAD would be best achieved by a dedicated model for stable angina. Therefore, we proceeded to develop a new QCG score for the presence of obstructive CAD in patients with stable angina based on ECG wave signals vectorized by the QCG analyzer, applying a boosting tree algorithm. The new QCG score performed better than the original QCG scores in predicting obstructive CAD. Notably, the new QCG score showed better performance for the identification of patients with obstructive CAD than the model with conventional clinical risk factors, as well as additive value over that with clinical features.

There have been several reports on AI-ECG models for patients with suspicion of stable CAD. A recent study reported that AI-ECG may predict underlying coronary artery calcification [16]. Another study by Huang et al reported an AI-ECG model for obstructive CAD (defined as >70% diameter stenosis) with an overall accuracy of 90%, which is higher than that in this study (75.7% in the test set) [17]. However, the accuracy in the previous study was only 56% among those without an ECG diagnosis of acute myocardial infarction or ischemia. Additionally, the study population comprised patients with obstructive CAD who underwent percutaneous coronary intervention and control patients without documented or suspected CAD. Therefore, the AI performance was likely overestimated, as the study population comprised extremes (ACS patients with STEMI, who would be easily diagnosed on ECG, and asymptomatic control patients who did not require invasive coronary angiography), and its usefulness may inevitably be limited in clinical practice. In contrast, we enrolled consecutive patients who visited our outpatient clinic with symptoms indicative of stable angina and underwent invasive angiography to confirm the presence of obstructive CAD. Although our study population was limited to a single tertiary center, it is highly representative of our daily clinical practice. Furthermore, the additive value of an AI-ECG analysis of clinical features to detect obstructive CAD could provide valuable insights to clinicians regarding when to consider invasive coronary angiography.

Another study presented a deep-learning model for obstructive CAD (defined as >50% diameter stenosis) in patients with stable angina, similar to that in this study [18]. However, their analysis was based on billing reports and included patients with known CAD (58.3%), including those who underwent coronary revascularization (previous percutaneous intervention [27.4%]; previous coronary artery bypass graft [19%]). Although their model showed higher accuracy for obstructive CAD (overall accuracy of 89.9%) than that in this study, the results may have been affected by high-risk patient profiles, leading to more representative ischemic ECG findings. In this study, we excluded patients with a history of CAD or coronary

revascularization, enabling us to demonstrate the feasibility of the QCG analyzer in a population that requires better stratification, and thus benefits from the AI-ECG analysis.

Several AI-ECG models have been developed for commercially available platforms [12]. Although the underlying driving mechanisms may differ between models, they are commonly fed by ECG signals that are preprocessed as 1D or 2D matrix arrays [18]. Therefore, there may be difficulties in applying these AI-ECG models in daily clinical practice, as additional software may be required for input signal transformation. In comparison, the QCG analyzer allows 12-lead ECG image data as input, extracting wave signals and vectorizing them through the initial encoding step [5,6]. Previous reports have validated the consistent performance of the QCG analyzer for printed ECG images and ECG photographs obtained as screenshots from a smartphone [5]. Currently, the QCG analyzer is available as a smartphone app, which can be directly applied on the ECG images obtained by either smartphone cameras or screenshots. Given its user-friendly interface, the QCG analyzer has the potential to be used in both well-equipped hospitals with digital ECGs and more resource-limited settings with paper ECGs. Furthermore, the QCG analyzer can incorporate ECG images obtained from conventional ECG recorders, enabling more effective training in a new disease category. Through further training on a high volume of patients with stable angina, the QCG analyzer can also be an effective screening tool in primary clinics, which initially assess patients with chest pain.

Limitations

This study has several important limitations. Although we enrolled consecutive patients who visited the outpatient clinic with symptoms indicative of stable angina and underwent invasive coronary angiography, the number of patients was relatively small, limited to a single tertiary center. Because we evaluated the QCG analyzer in symptomatic patients who underwent invasive coronary angiography, our study population may have presented a relatively higher incidence of obstructive CAD compared to previous studies. Furthermore, the performance of the new QCG score, which was derived in this study, was only internally validated. Therefore, the generalizability of our results is limited. Nevertheless, we observed the possibility of detecting obstructive CAD through ECG in patients with stable angina. Therefore, we are planning for further external validation on a larger number of patients to refine the new QCG score and validate it in patient groups with diverse clinical features. We hope we can share the results in the near future.

Conclusions

As a quantitative AI-ECG algorithm, the QCG analyzer shows the feasibility of predicting obstructive CAD in patients with stable angina. Although predeveloped QCG scores for CAD-related conditions showed limited performance for the detection of obstructive CAD in stable angina, they still demonstrated independent and incremental predictive value for the presence of 3VD. Furthermore, we developed a new QCG score by using the ECG wave signals vectorized by the QCG analyzer, which outperformed the conventional model with clinical features. With further expanded training on stable angina, the QCG analyzer could be a more accurate and cost-effective AI tool for screening obstructive CAD in these patients.

Acknowledgments

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Data Availability

Data cannot be made publicly available due to ethical restrictions set by the institutional review board of Seoul National University Bundang Hospital; that is, public availability would compromise patient confidentiality and participant privacy. Please contact the corresponding authors (yeonyeeyoon@snubh.org or cho_y@snubh.org) to request the anonymized data set.

Conflicts of Interest

JK developed the QCG analyzer and founded the start-up company ARPI Inc. YC holds shares in, and received consulting fees from, ARPI Inc. The remaining authors declare no conflicts of interest.

Multimedia Appendix 1
Patient characteristics in training and test sets.
[PDF File (Adobe PDF File), 119 KB - cardio_v7i1e44791_app1.pdf]

Multimedia Appendix 2
Distribution of the new quantitative electrocardiography score.
[PDF File (Adobe PDF File), 151 KB - cardio_v7i1e44791_app2.pdf]

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Abbreviations

ACS: acute coronary syndrome
AI: artificial intelligence

AUROC: area under the receiver operating characteristic curve
CAD: coronary artery disease
ECG: electrocardiography
LM: left main
LV: left ventricular
OR: odds ratio
QCG: quantitative electrocardiography
RCA: right coronary artery
SNUBH: Seoul National University Bundang Hospital
STEMI: ST-elevation myocardial infarction
VD: vessel with obstructive CAD

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Original Paper

High-Throughput Assessment of Real-World Medication Effects on QT Interval Prolongation: Observational Study

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Abstract

Background: Drug-induced prolongation of the corrected QT interval (QTc) increases the risk for Torsades de Pointes (TdP) and sudden cardiac death. Medication effects on the QTc have been studied in controlled settings but may not be well evaluated in real-world settings where medication effects may be modulated by patient demographics and comorbidities as well as the usage of other concomitant medications.

Objective: We demonstrate a new, high-throughput method leveraging electronic health records (EHRs) and the Surescripts pharmacy database to monitor real-world QTc-prolonging medication and potential interacting effects from demographics and comorbidities.

Methods: We included all outpatient electrocardiograms (ECGs) from September 2008 to December 2019 at a large academic medical system, which were in sinus rhythm with a heart rate of 40-100 beats per minute, QRS duration of <120 milliseconds, and QTc of 300-700 milliseconds, determined using the Bazett formula. We used prescription information from the Surescripts pharmacy database and EHR medication lists to classify whether a patient was on a medication during an ECG. Negative control ECGs were obtained from patients not currently on the medication but who had been or would be on that medication within 1 year. We calculated the difference in mean QTc between ECGs of patients who are on and those who are off a medication and made comparisons to known medication TdP risks per the CredibleMeds.org database. Using linear regression analysis, we studied the interaction of patient-level demographics or comorbidities on medication-related QTc prolongation.

Results: We analyzed the effects of 272 medications on 310,335 ECGs from 159,397 individuals. Medications associated with the greatest QTc prolongation were dofetilide (mean QTc difference 21.52, 95% CI 10.58-32.70 milliseconds), mexiletine (mean QTc difference 18.56, 95% CI 7.70-29.27 milliseconds), amiodarone (mean QTc difference 14.96, 95% CI 13.52-16.33 milliseconds), rifaximin (mean QTc difference 14.50, 95% CI 12.12-17.13 milliseconds), and sotalol (mean QTc difference 10.73, 95% CI 7.09-14.37 milliseconds). Several top QT prolonging medications such as rifaximin, lactulose, cinacalcet, and lenalidomide were not previously known but have plausible mechanistic explanations. Significant interactions were observed between demographics or comorbidities and QTc prolongation with many medications, such as coronary disease and amiodarone.

Conclusions: We demonstrate a new, high-throughput technique for monitoring real-world effects of QTc-prolonging medications from readily accessible clinical data. Using this approach, we confirmed known medications for QTc prolongation and identified potential new associations and demographic or comorbidity interactions that could supplement findings in curated databases. Our single-center results would benefit from additional verification in future multisite studies that incorporate larger numbers of patients and ECGs along with more precise medication adherence and comorbidity data.

(JMIR Cardio 2023;7:e41055) doi:10.2196/41055

KEYWORDS

electrocardiogram; QT prolongation; pharmacovigilance; drug toxicity; electronic health records; ECG; EHR; medication monitoring; medication effects; clinical data monitoring; demographic interaction; comorbidity interaction; monitoring; clinical data; accessibility; assessment

Introduction

Prolongation of the corrected QT interval (QTc) increases the risk for malignant ventricular tachyarrhythmias such as Torsades de Pointes (TdP), which can degenerate into ventricular fibrillation and cause sudden cardiac death [1-3]. Medications are the most frequent cause of QTc prolongation and include a number of commonly prescribed drugs such as antiarrhythmics, antipsychotics, antibiotics, and antidepressants [4].

Given the high prevalence of drugs with QTc-prolonging risks, immense effort has been dedicated to maintaining databases of such medications [5]. Currently, most knowledge of the QTc prolonging effects of medications stems from highly controlled individual drug studies as well as regulatory or case reports. However, neither of these approaches offers the ability to systematically monitor QTc prolongation effects in real-world settings, where a medication's effects may be modulated by patient demographics and comorbidities, as well as with the use of other concomitant medications [6-8].

To address these gaps, we used clinical electrocardiogram (ECG) and electronic health record (EHR) data from a large academic health care system to screen medications for their real-world effects on the QTc. Using this high-throughput approach comparing the same patients before and after initiation of drug therapy, we clarify the associations between medications and QTc prolongation, as well as potential interacting effects from demographics and comorbidities.

Methods

Overview

We analyzed QTc durations from all ECGs performed from September 30, 2008, to December 31, 2019, at Cedars-Sinai Medical Center, a large academic medical system in Los Angeles, California, which provides quaternary care and completes more than 800,000 outpatient visits a year. We excluded inpatient ECGs because of high uncertainty and variations in medication history while patients are hospitalized. Given the known limitations of QTc quantification at extremes of interval lengths and heart rate, we included only ECGs in sinus rhythm with a heart rate of 40-100 beats per minute (bpm), QRS duration of <120 milliseconds, and QTc duration between 300 and 700 milliseconds [9,10]. QTc durations were automatically calculated using the Bazett formula [11]. We additionally calculated QTc durations using the Fridericia (QTc = QT / [$RR^{1/3}$]), Hodges (QTc = 0.00175 [60 / RR – 60]), Framingham (QTc = QT + 0.154 [1 – RR]), and Rautaharju (QTc = QT + 0.0185 [RR – 1] + 0.006 for men) formulae [10]. We used medication data from the Surescripts pharmacy database. Surescripts is an electronic prescription clearing house, which routes prescriptions between EHRs and pharmacies, with an estimated coverage of >95% of US pharmacies. We also used medication lists from all outpatient visits and hospitalizations captured by the Epic EHR system during the same time period. We studied the 300 most frequently prescribed medications in the Surescripts database plus all outpatient cardiovascular medications. We further limited our list to only those medications that are systemically active and are not taken on an as-needed basis.

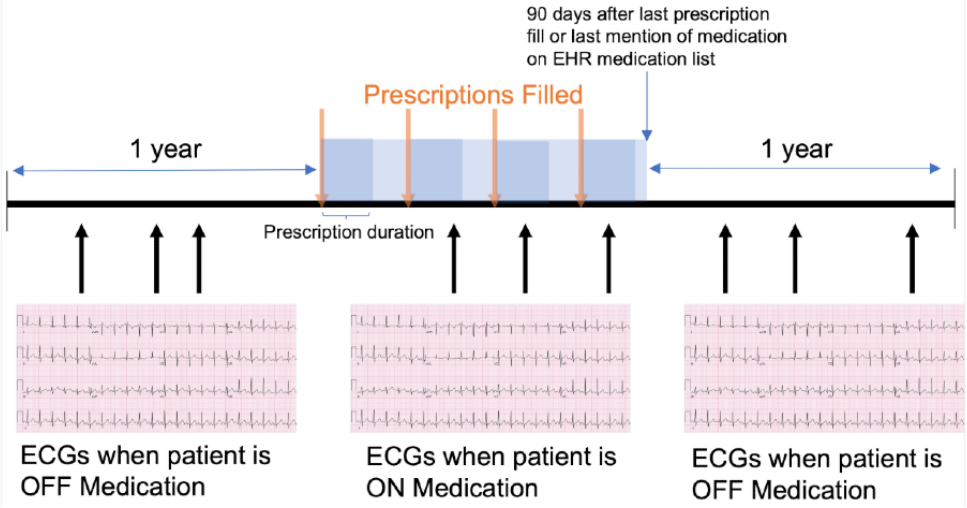
A patient was considered to be taking a particular medication if the date of the ECG obtained was within a filled medication prescription duration (Figure 1). A patient was considered to not be taking a medication if the ECG date was before the earliest prescription date of that medication or more than 90 days after the last prescription date of the medication. We required that patients "not on a medication" be restricted to only those who had been or would be prescribed the medication within 1 year. This condition was implemented to ensure that ECGs obtained from patients on a medication and those who are off a medication were derived from the same population to reduce confounding by indication. A single ECG could be used for multiple medications given that patients were often taking multiple medications simultaneously at the time of an ECG.

We assessed the difference in the mean QTc duration between ECGs when patients were likely to be taking the medication and those when patients were likely to not be taking the medication. We calculated 95% CIs for QTc differences by bootstrapping with 1000 replications. We visualized medications in accordance with their known risk of TdP per the publicly available database at CredibleMeds.org, which was founded in 2000 with the support of the Agency for Healthcare Research and Quality [5].

We additionally studied the interaction of patient-level demographics and clinical comorbidities with the QTc-prolonging effects of the top QTc-prolonging medications identified by at least 3 of the 5 QTc formulae. Demographics (age, sex, and race and ethnicity) and comorbidities (hypertension, coronary artery disease [CAD], heart failure, diabetes, chronic kidney disease, liver disease, and chronic obstructive pulmonary disease [COPD]) were determined from the EHR. Comorbidities were derived from International Classification of Diseases, Tenth Revision, codes associated with patient visits and problems lists per previously published methods [12,13]. We first performed simple univariate linear regressions modeling the associations of each demographic or comorbidity with QTc. Next, for each medication, we performed linear regressions across each demographic or comorbidity of the following form:

$$QTc = a + b \times medication + c \times (demographic\ or\ comorbidity) + d \times medication \times (demographic\ or\ comorbidity)$$

Figure 1. Method for determining electrocardiograms (ECGs) of patients who are on and off a particular medication. EHR: electronic health record.



Significant interaction coefficients were displayed using a heat map. All hypothesis testing was 2-sided, and results were evaluated with a significance level of α=.05 after Bonferroni correction for multiple comparisons for each medication.

Data analysis and visualization was performed with R statistical software (version 3.4.1; R Project for Statistical Computing).

Ethics Approval

This study was approved by the institutional review board of Cedars-Sinai Medical Center (STUDY00001506).

Results

A total of 310,335 ECGs from 159,397 individuals taking a total of 272 medications met our inclusion criteria (Table 1). The average age of patients at the time of ECG was 59.81 (SD 18.67) years with 44.6% (N=135,364) of ECGs obtained from non-White patients. Patients represented a relatively healthy outpatient cohort, although cardiovascular comorbidities were common, with 23.1% (n=71,715) of participants having hypertension, 10.9% (n=33,900) of them having CAD, 10.3% (n=32,005) of them having diabetes, 7.6% (n=23,570) of them having heart failure, and 8.8% (27,427) chronic kidney disease at the time of ECG. The mean QT was 400.54 (SD 36.05) milliseconds and heart rate was 73.20 bpm (SD 12.56) milliseconds with a QTc of 437.44 (SD 29.41) milliseconds by the Bazett formula.

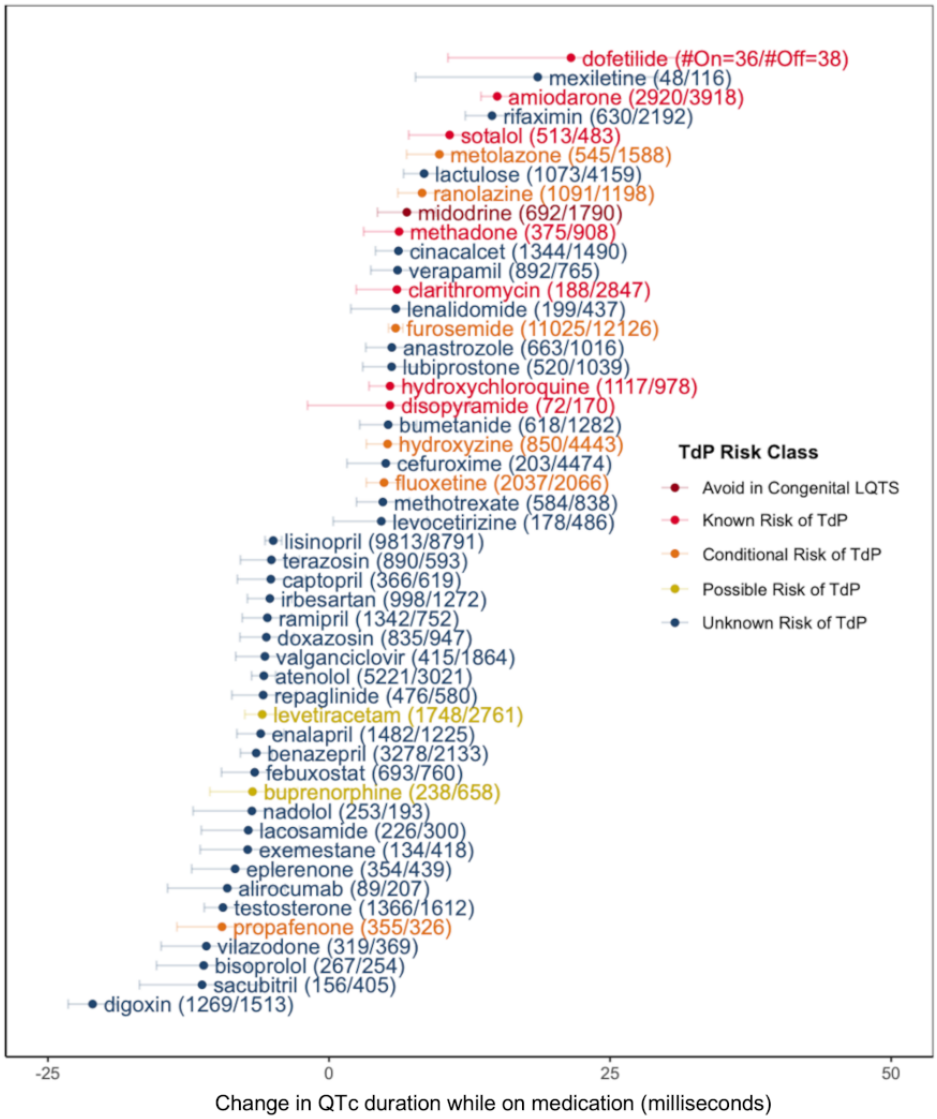
We identified medications associated with the greatest change in mean QTc (Figure 2). Overall results across all studied medications are provided in Multimedia Appendix 1. Medications associated with the greatest QTc prolongation when comparing patients on versus those off the medication at the time of ECG included dofetilide (mean QTc difference 21.52 , 95% CI 10.58-32.70 milliseconds), mexiletine (mean QTc difference 18.56, 95% CI 7.70-29.27 milliseconds), amiodarone (mean QTc difference 14.96, 95% CI 13.52-16.33 milliseconds), rifaximin (mean QTc difference 14.50, 95% CI 12.12-17.13 milliseconds), and sotalol (mean QTc difference 10.73, 95% CI 7.09-14.37 milliseconds). Medications associated with the greatest QTc shortening included digoxin (mean QTc difference –21.02, 95% CI –23.20 to –18.85 milliseconds), sacubitril or valsartan (mean QTc difference –11.29, 95% CI –16.86 to –5.90 milliseconds), bisoprolol (mean QTc difference –11.15, 95% CI –15.34 to –7.11 milliseconds), vilazodone (mean QTc difference –10.91, 95% CI –14.94 to –6.92 milliseconds), and propafenone (mean QTc difference –9.52, 95% CI –13.53 to –5.55 milliseconds). Notably, certain identified medications, such as rifaximin, lactulose, cinacalcet, lenalidomide, mercaptopurine, and ritonavir, were not previously known to be associated with QTc prolongation. Our real-world approach was consistent with known classifications, as the average QTc prolongation by TdP class, according to CredibleMeds.org, decreased as expected when comparing across meds with known TdP risk (mean 3.68, SD 5.96 milliseconds) to avoid congenital long QT syndrome (mean 1.71. SD 3.05 milliseconds), conditional risk (mean 1.60, SD 3.75 milliseconds), possible risk (mean 0.65, SD 2.99 milliseconds), and unclassified risk (mean –0.65, SD 4.05 milliseconds).

Table 1. Baseline patient and electrocardiogram (N=310,335) characteristics.

Characteristics	Values
Age (years), mean (SD)	59.81 (18.67)
Sex, n (%)	
Female	160,757 (53.5)
Male	149,578 (46.5)
Race, n (%)	
American Indian	540 (0.2)
Asian	17,868 (5.8)
Black	56,825 (18.3)
Hispanic	33,146 (10.7)
Non-Hispanic White	174,971 (56.4)
Pacific Islander	611 (0.2)
Other	26,374 (8.5)
Comorbidities, n (%)	
Hypertension	71,715 (23.1)
Coronary artery disease	33,900 (10.9)
Heart failure	23,570 (7.6)
Diabetes mellitus	32,005 (10.3)
Chronic kidney disease	27,427 (8.8)
Liver disease	4803 (1.5)
Chronic obstructive pulmonary disease	8349 (2.7)
QRS duration (milliseconds), mean (SD)	88.14 (11.16)
QT interval (milliseconds), mean (SD)	400.54 (36.05)
Heart rate (beats per minute), mean (SD)	73.20 (12.56)
QTc[a] Bazett (milliseconds), mean (SD)	437.44 (29.41)
QTc Fridericia (milliseconds), mean (SD)	424.97 (26.78)
QTc Framingham (milliseconds), mean (SD)	400.56 (36.03)
QTc Hodges (milliseconds), mean (SD)	400.56 (36.03)
QTc Rautaharju (milliseconds), mean (SD)	428.13 (26.92)

[a]QTc: corrected QT interval.

Figure 2. Medications with largest QTc-lengthening and -shortening effects. Mean change in QTc duration while on medication versus while off medication. Intervals represent 95% CIs. TdP risk class is in accordance with classifications by CredibleMeds.org. LQTS: long QT syndrome; TdP: Torsades de Pointes; #On: number of electrocardiograms of patients on medication; #Off: number of electrocardiograms of patients off medication; QTc: corrected QT interval.



There was also consistency in medications assessed to have the most QTc prolongation across different QTc assessment methods (Figure 3). However, in contrast to the Bazett, Fridericia, and Rautaharju formulae, the Framingham and Hodges formulae showed no substantial QTc prolongation for several medications known to have a TdP risk.

The QTc was lengthened by all major demographics and comorbidities including age (mean QTc difference 2.5, SD 0.03 milliseconds per 10 years), female sex (mean QTc difference 7.20, SD 0.11 milliseconds), non-White race (mean QTc difference 1.08, SD 0.11 milliseconds), hypertension (mean QTc difference 6.93, SD 0.13 milliseconds), CAD (mean QTc difference 4.70, SD 0.17 milliseconds), heart failure (mean QTc difference 17.1, SD 0.20 milliseconds), diabetes (mean QTc difference 8.57, SD 0.17 milliseconds), chronic kidney disease (mean QTc difference 14.7, SD 0.18 milliseconds), liver disease (mean QTc difference 16.4, SD 0.43 milliseconds), and COPD (mean QTc difference 6.89, SD 0.33 milliseconds). The QTc prolongation effects of several individual medications were significantly modified by demographics and comorbidities (Figure 4). The top 6 positive interactions between demographics or comorbidities and QTc-prolonging medication were between age and dofetilide, hypertension and lenalidomide, chronic kidney disease and methotrexate, COPD and ranolazine, COPD and lithium, and CAD and amiodarone. As one example of these interactions, we show the distribution of QTc duration for patients with and those without CAD before and after taking amiodarone (Figure 5).

Given that QTc can be associated with heart rate, we performed a limited analysis of medications with the most QTc prolongation showing minimal changes in heart rate for most medications when comparing ECGs of patients who are on versus those who are off medication (Multimedia Appendix 2).

Figure 3. Comparison of medications with largest QT interval (QTc) effects across different QTc formulae.

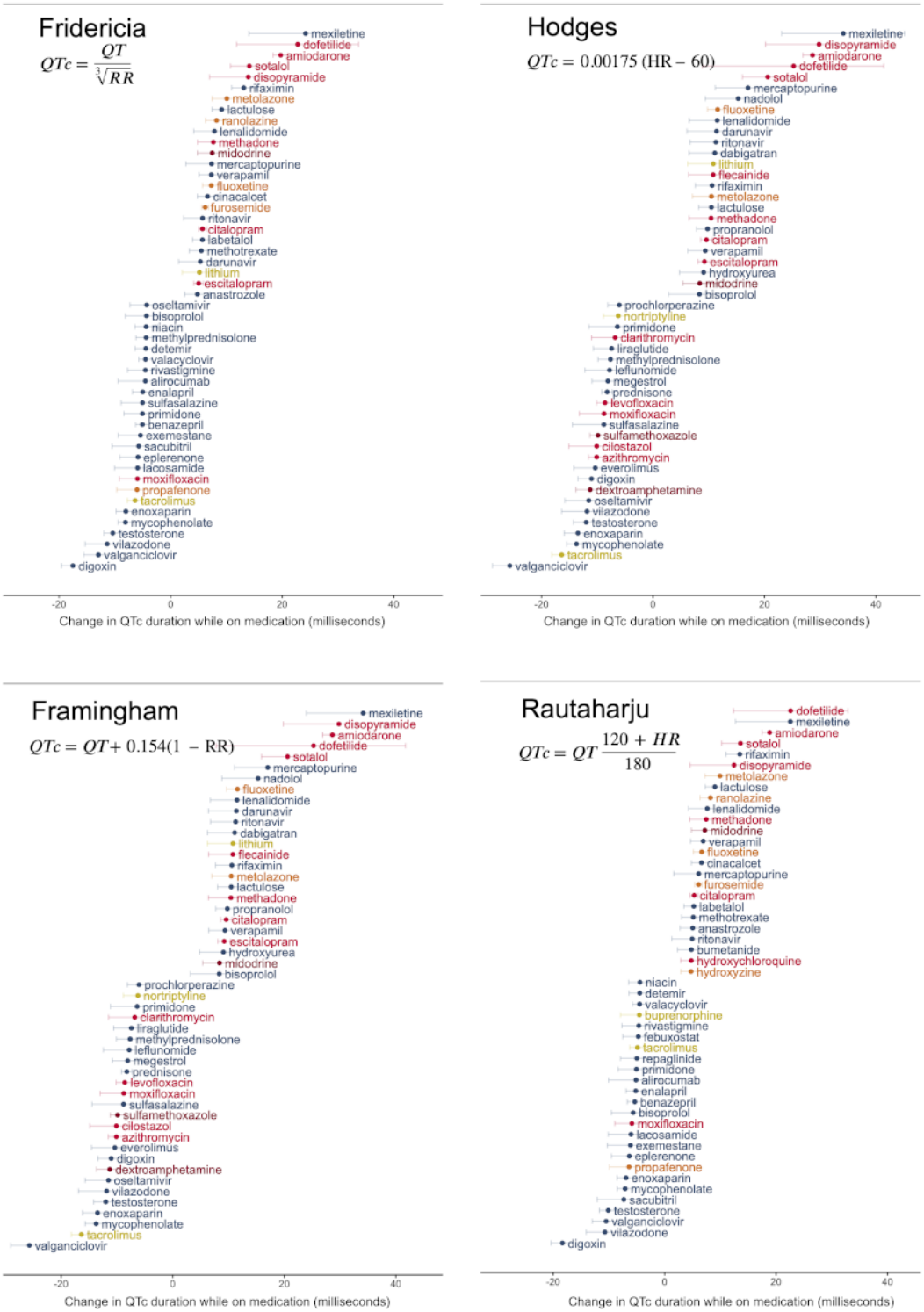


Figure 4. Interaction of demographics and comorbidities on medication with QTc-prolonging effects. For each medication, we performed linear regressions across each demographic or comorbidity of the form: QTc change = a + b × medication + c × demographic/comorbidity + d × medication × demographic/comorbidity. Significant interaction coefficients are displayed using a heat map. All hypothesis testing was 2-sided, and results were evaluated with a significance level of α=.05 after Bonferroni correction for multiple comparisons. CAD: coronary artery disease; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; HF: heart failure; QTc: corrected QT interval.

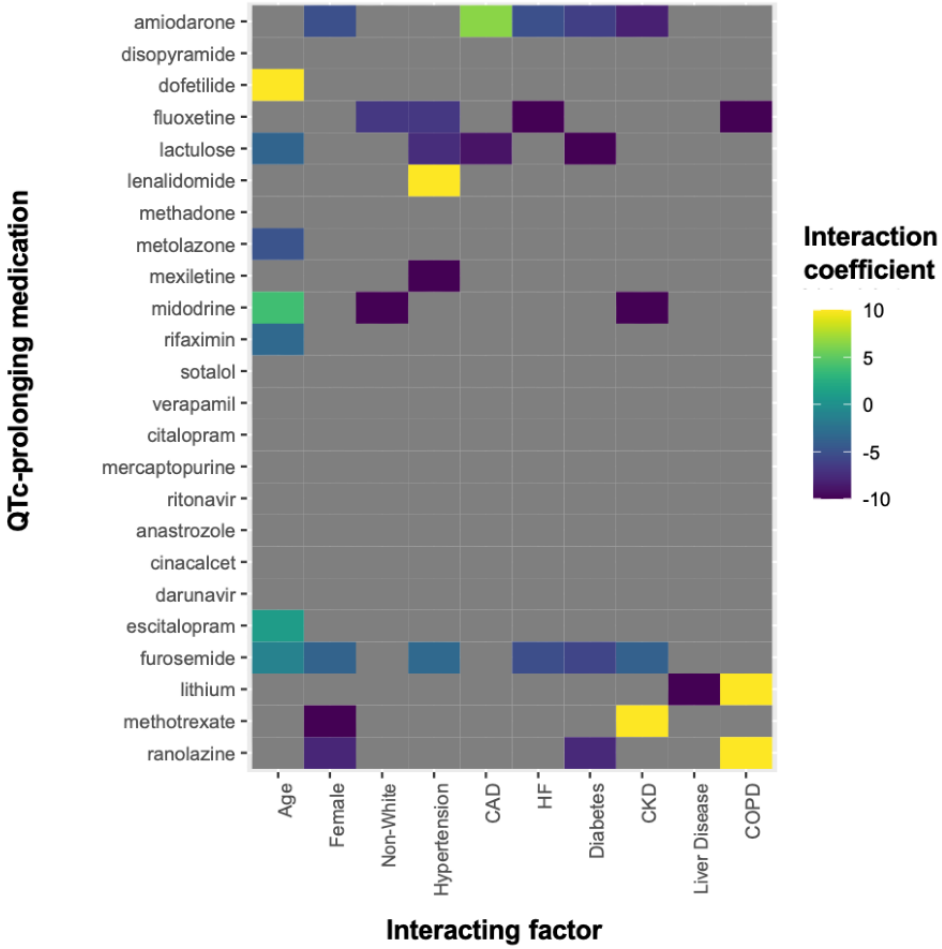
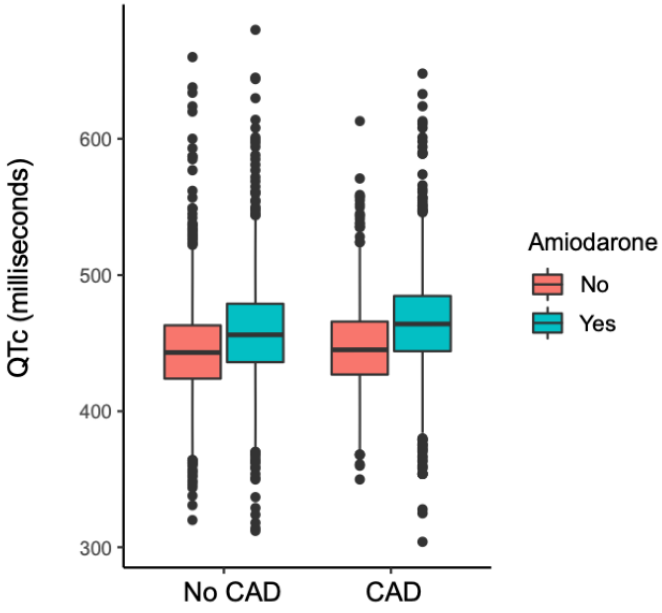


Figure 5. Interaction between amiodarone and CAD on QTc duration. CAD: coronary artery disease; QTc: corrected QT interval.



Discussion

Principal Findings

We demonstrate a new, high-throughput technique for identifying and monitoring real-world medication-related QTc prolongation effects using readily accessible clinical data. Using this approach, we confirmed previously known medications associated with QTc prolongation as well as identified potential new medications not identified in curated databases. While considerable effort has been made to maintain well-researched lists of potentially dangerous medications using data from highly controlled studies, little has been published about the real-world effects of medications on QTc duration. It is well known that demographics, comorbidities, and drug-drug interactions may have profound effects on QTc but may not be represented in conventional drug study data [6-8]. We envision that applying our described technique across multiple centers could be used for (1) identifying high-TdP-risk medications that may have little prior data but require further study, (2) confirming or disputing case reports of medications associated with TdP, and (3) understanding how individual drug QTc prolongation effects may be modulated by demographics, comorbidities, and other medications.

Comparison to Prior Work

Our analysis was able to distinguish drugs with known QTc-prolonging effects, including antiarrhythmics (dofetilide, amiodarone, sotalol, and disopyramide), antibiotics (clarithromycin), and antidepressants (fluoxetine, citalopram, and escitalopram). Interestingly, we also identified medications such as rifaximin, lactulose, cinacalcet, lenalidomide, mercaptopurine, and ritonavir, for which there are few data about QTc prolonging effects, but which may deserve additional study. Cinacalcet, for example, has been shown, in very small-scale studies, to be associated with QTc prolongation beyond what might be expected from chronic kidney disease, possibly through its effects on serum calcium levels [14,15]. Lenalidomide, a drug used to treat hematologic malignancies often in older patients with comorbidities, has known cardiovascular toxicities but has only been studied on the basis of its effects on ECGs in 60 healthy, young male volunteers [16,17]; it has also been understudied in Black individuals [18]. Other medications such as mercaptopurine were introduced to drug formularies long before drug trials with QTc prolongation safety analyses were standard of practice. It is also possible that the QTc prolongation observed with some medications such as rifaximin and lactulose may reflect underlying comorbidities such as liver disease, which may prolong the QTc [19,20]. Other medications, such as ritonavir and verapamil, are cytochrome P450 3A4 isozyme inhibitors and may have QTc effects via prominent drug-drug interactions. We did note that mexiletine, a sodium channel blocker known to shorten the QTc and used to treat congenital long QT syndrome type 3, was associated with QTc prolongation. This may be due to mexiletine being prescribed either in combination with QTc-prolonging agents such as amiodarone or as treatment for patients with prolonged QTc [21]. In our cohort, 27 of 48 (57%) patients taking mexiletine were also taking amiodarone, and a simple linear regression revealed that the QTc-prolonging effect of mexiletine was not significant after accounting for amiodarone.

We found that our technique was relatively uninfluenced by the QTc assessment method in identifying medications at the highest risk for QTc prolongation. While prior studies suggested that some methods may perform better at certain heart rate ranges or may better predict even mortality, we found that the effects of QTc-prolonging medications were still observable regardless of the QTc method used [9,10]. This may have been partially due to our deliberate choice to limit our cohort of ECGs to those with a heart rate between 40 and 100 bpm. We did find, however, that the Hodges and Framingham methods, which are known to underestimate QTc prolongation relative to the Bazett formula, seemed to underdetect QTc prolongation with several medications that have known QT-prolonging effects [10].

Demographics and comorbidities all increased the average QTc duration. Consistent with risk factors that are included in the frequently used Tisdale Risk Score for QTc prolongation, we found that age, female sex, heart failure, and CAD were associated with particularly significant increases in QTc [8]. Liver disease and chronic kidney disease were also notably associated with prominent QTc increases. Demographics and comorbidities, not surprisingly, therefore had significant modifying influences on the QTc prolonging effects of many individual medications. While on average, QTc increases with age, age was additionally associated with increased QTc prolongation of dofetilide and decreased QTc prolongation from metolazone, lactulose, or rifaximin [22]. Women, on average, have longer QTcs and a higher risk of experiencing TdP while on QTc-prolonging medications [23,24]. Tisdale et al [8] found that female sex had an odds ratio of 1.5 for QTc prolongation (defined as a QTc of >500 milliseconds or an increase of >60 milliseconds). Interestingly, we observed that in women, there may actually be less change in QTc associated with several of our identified medications. It could be that even if some medications do not change the QTc by as much in female patients, women on average start with a longer QTc and therefore still end up more frequently with a QTc of >500 milliseconds. Race was also a significant interacting factor, which adds emphasis to potential gaps in our current understanding of the QTc-prolonging effects of medications in non-White populations due to lack of racial diversity in drug studies [25,26]. With regard to the effects of comorbidities, all of the major chronic conditions studied were associated with interacting effects with certain medications. This may be due to altered medication metabolism or electrolyte disturbances in cases of kidney or liver disease or due to other interacting effects such as autonomic modulation that may affect QTc duration in patients with COPD [27]. The QTc-prolonging effects of amiodarone were different in patients with coronary disease and those with heart failure, which suggest the influence of cardiac structural change on drug-induced QTc prolongation.

Limitations and Future Directions

Several limitations of this study warrant consideration. Although QTc prolongation correlates with TdP risk, prolongation in itself is not fully predictive of TdP. As such, identifying medication that prolong QTc is likely a first step in truly understanding a

medication's effects on TdP risk. While we believe that our method for identifying whether a patient was on or off a medication was quite rigorous, using both Surescripts pharmacy and EHR data, medication adherence remains challenging to assess, and patients could still receive prescriptions from external sources. Both of these cases (nonadherence and external prescription) would bias our results to the null. We pooled ECGs from patients both before as well as after they were on medication to create our off-medication cohorts. This increased the number of ECGs that could be used and did not significantly change whether a medication prolonged the QTc when compared to using only ECGs from patients before starting a medication (Multimedia Appendix 3). However, future studies could consider limiting the off-medication cohort to only ECGs from patients before starting a medication. As this was a relatively healthy population, some of the interaction effects between less common comorbidities (eg, liver disease) and medications (eg, dofetilide, disopyramide, and mexiletine) may be less reliable and should be confirmed in cohorts with larger numbers. We additionally acknowledge that there can be inaccuracies in identifying comorbidities and demographics when relying on EHR data and International Classification of Diseases, Tenth Revision, coding. Future studies using more rigorously adjudicated registries could add precision. Lastly, there remains many possible co-occurring confounding reasons for a medication to be associated with QTc prolongation: patient demographics, comorbidities, electrolyte abnormalities, and drug-drug interactions. However, even if a certain medication tends to be used among patients with other QTc-prolonging risk factors, we still hold that such information is useful as a real-world reflection of QTc prolongation risk. To control for some of these confounders, we ensured that for each medication, ECGs were compared only among patients who were prescribed that medication at some point in time, thereby ensuring that ECGs of patients on and those of patients off the medication were drawn from the same patient population. Nevertheless, the associations uncovered by our methodology are meant to be exploratory and require dedicated prospective studies for confirmation.

Conclusions

In this study, we demonstrate a high-throughput method using accessible clinical data to identify and monitor the real-world QTc prolongation associations of all commonly prescribed medications. Such a technique might be easily deployable across multiple medical centers for identifying and confirming suspected medications with QTc-prolonging risks and the demographic and comorbidity factors that may enhance or mitigate such risks.

Acknowledgments

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Data Availability

Given the potential identifying nature of the intersection of a patient's ECG, demographics, comorbidities, and medications, the entire data set will not be made publicly available. However, a limited subset of deidentified data may be made available upon reasonable request to the corresponding author.

Conflicts of Interest

None declared.

Multimedia Appendix 1
QTc changes (ms) across all medications studied.
[DOCX File , 44 KB - cardio_v7i1e41055_app1.docx]

Multimedia Appendix 2
Change in heart rate when comparing ECGs on versus off of medication.
[DOCX File , 14 KB - cardio_v7i1e41055_app2.docx]

Multimedia Appendix 3
Changes in QTc when on a medication compared to when off a medication before or after being on the medication.
[DOCX File , 15 KB - cardio_v7i1e41055_app3.docx]

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Abbreviations

bpm: beats per minute
CAD: coronary artery disease
COPD: chronic obstructive pulmonary disease
ECG: electrocardiogram
EHR: electronic health records
QTc: corrected QT interval
TdP: Torsades de Pointes

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Original Paper

Data Quality Degradation on Prediction Models Generated From Continuous Activity and Heart Rate Monitoring: Exploratory Analysis Using Simulation

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Abstract

Background: Limited data accuracy is often cited as a reason for caution in the integration of physiological data obtained from consumer-oriented wearable devices in care management pathways. The effect of decreasing accuracy on predictive models generated from these data has not been previously investigated.

Objective: The aim of this study is to simulate the effect of data degradation on the reliability of prediction models generated from those data and thus determine the extent to which lower device accuracy might or might not limit their use in clinical settings.

Methods: Using the Multilevel Monitoring of Activity and Sleep in Healthy People data set, which includes continuous free-living step count and heart rate data from 21 healthy volunteers, we trained a random forest model to predict cardiac competence. Model performance in 75 perturbed data sets with increasing missingness, noisiness, bias, and a combination of all 3 perturbations was compared to model performance for the unperturbed data set.

Results: The unperturbed data set achieved a mean root mean square error (RMSE) of 0.079 (SD 0.001) in predicting cardiac competence index. For all types of perturbations, RMSE remained stable up to 20%-30% perturbation. Above this level, RMSE started increasing and reached the point at which the model was no longer predictive at 80% for noise, 50% for missingness, and 35% for the combination of all perturbations. Introducing systematic bias in the underlying data had no effect on RMSE.

Conclusions: In this proof-of-concept study, the performance of predictive models for cardiac competence generated from continuously acquired physiological data was relatively stable with declining quality of the source data. As such, lower accuracy of consumer-oriented wearable devices might not be an absolute contraindication for their use in clinical prediction models.

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KEYWORDS

wearables; time series; data reliability; prediction models; hear rate; monitoring; data; reliability; clinical; sleep; data set; cardiac; physiological; accuracy; consumer; wearables; device

Introduction

There are numerous devices available within hospital settings to continuously monitor patients' physiological signs, track disease progression, or perform diagnostics. In recent years, there has been increased interest in extending the use of these devices to the outpatient setting [1]. For this purpose, such devices are well accepted by patients and physicians and are generally seen as an important component of future clinical protocols [1-3]. There are two major categories of outpatient monitoring device: medical-grade and consumer-oriented devices. The advantages of consumer-oriented devices are obvious—they are often less expensive, they are ubiquitous, and their use is not dependent on a person's medical need. Moreover, such devices allow data to be acquired continuously,

passively, and without the need for standardized protocols or deviation from normal daily routine—all factors that have been associated with reduced adherence to outpatient monitoring [4]. However, contrary to their medical-grade counterparts, which are made to replicate the functionality and reliability of in-hospital devices, consumer-oriented devices are built for other purposes, which may affect the quality of the data that they generate. Numerous studies have shown limited equivalence between the data generated from consumer-oriented devices and the data acquired using standardized protocols involving their medical-grade counterparts [5-8]. Given these limitations, and although the reliability of data from newer consumer-oriented devices has greatly increased, some have advocated caution in the use of consumer-grade wearable devices for clinical monitoring when the intent is to integrate the data directly into care management [9]. One emerging application of data generated from physiological-monitoring devices is using them to produce features in prediction models based on machine learning algorithms, as opposed to the detection of abnormalities and direct integration in care management pathways [10]. In this context, the effect of decreasing data quality and reliability has not been previously studied. In this study, our aim was to investigate the practicality of using consumer-grade monitoring devices in medical care by determining the effect of various common forms of time-series data degradation on the performance of the predictive models generated using those data.

Methods

Study Data

Data were obtained from the open-access Multilevel Monitoring of Activity and Sleep in Healthy People (MMASH) data set made available by Rossi et al [11] on PhysioNet [11,12]. These data were collected through a collaboration between BioBeats and researchers at the University of Pisa. The MMASH data set includes 1 day of activity and sleep data for 22 healthy young adult males. During the 24-hour data collection period, the participants wore a heart rate (HR) monitor (Polar H7) and an activity monitor (ActiGraph wGT3X-BT). The participants were also asked to record specific times and categories (eg, sleeping, sitting, and heavy exercise) of activity that they performed throughout the day [11]. For the purposes of this secondary analysis, pertinent raw data from this data set included demographic information, step count data from the activity monitor, beat-to-beat intervals (or N-N intervals [NNIs]) from the HR monitor, and activity categories as reported by participants. One of the participants was removed from the analysis due to incomplete information.

Data Processing and Feature Extraction

All MMASH data were downloaded from PhysioNet. The first 5 minutes of the activity monitor and HR monitor data were removed to account for the initial placement and adjustment of the devices. Per-minute step count (PMSC) was calculated for each participant by summing the number of steps taken in sequential 60-second periods. PMSC data during sleep hours for all of the participants was removed from the analysis, as these time series were flat and did not provide predictive value. Three features were used to summarize the PMSC data for each participant, which were maximum PMSC, median PMSC, as well as 25th and 75th percentiles in PMSC. HR measurements were calculated as the quotient of 60 divided by the NNI values. These HR values were then transformed to beats per minute by averaging them in sequential 60-second periods. Any values in the HR time series less than 35 beats per minute were set equal to 35 (lowest plausible value in the data set). Next, various HR variability statistics were calculated for each participant based on the Python code published by the research team responsible for the MMASH data set [13]. Time-domain features were calculated relating to NNIs (median, mean, standard deviation, root mean square, range, and percentage of differences greater than 50) and HRs (maximum, minimum, mean, and standard deviation) recorded by the HR monitor. Various frequency-domain features relating to HR variability were also computed for each participant, such as very low-frequency power (0.003 to 0.04 Hz), low-frequency power (0.04 to 0.15 Hz), high-frequency power (0.15 to 0.40 Hz), ratio of low-frequency power to high-frequency power, normalized low-frequency power, and normalized high-frequency power. Lastly, several features were extracted from a Poincaré plot of the NNIs, as follows: standard deviation of a projection onto the line perpendicular to the line of identity, standard deviation of the projection onto the line of identity, and the ratio of these two standard deviations [13].

Two R packages, *tsfeatures* and *tsfeaturex*, were employed to extract various higher-dimensional features from the time-series data including per-minute HR, NNIs, and PMSC. The extracted features included autocorrelation, partial and differential autocorrelations, probabilities of acute changes when the time series is lagged, and time series quantiles. A total of 87 features were extracted for each time series feature using these packages.

Study Outcome

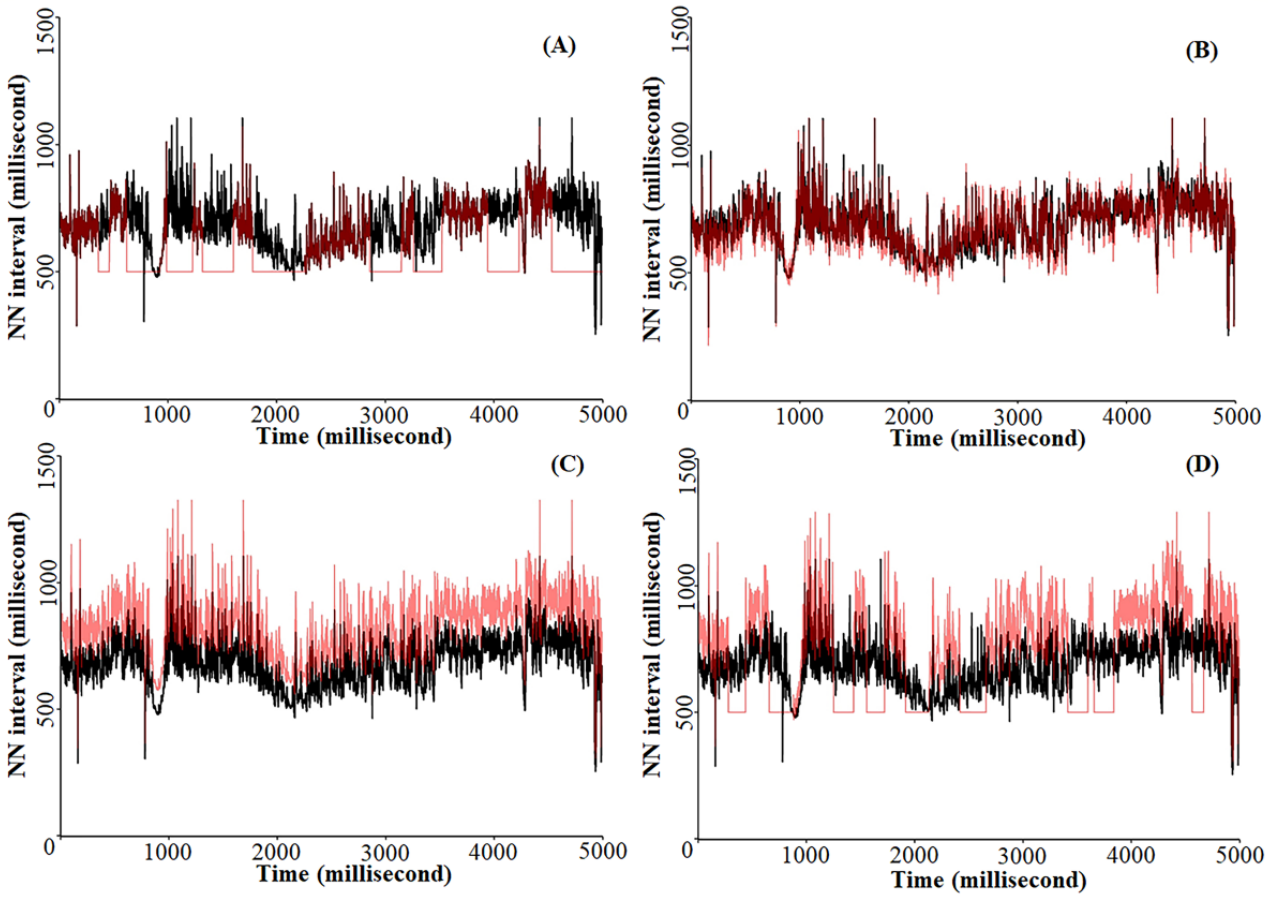
For each patient, we calculated the cardiac competence index (CCI) to be used as the target for prediction models. The CCI used in this study is based on the concept for cardiac competence limit proposed by Wu et al [14]; however, it was modified to be calculable with the data available in this study. In short, using activity information, data were isolated for periods of rest (ie, lying down or sitting) and periods of heavy exercise. Baseline HR was defined as the minimum of a rolling 2-minute mean of HR during periods of rest, whereas peak HR was calculated as the maximum of a rolling 2-minute mean of HR during heavy exercise (ie, the modification from Wu et al [14], which used maximal HR during an exercise test). Predicted HR was calculated by subtracting patient age from 220. CCI was then calculated for each participant as the ratio between their respective subtraction of peak, baseline HR values, and subtraction of predicted, baseline HR values.

Parameters of the Simulation

To simulate real-world conditions that may affect HR and activity monitor data, 3 perturbations were individually added to each participant's raw data, including NNI, HR, and PMSC time-series data. HR data were extracted from raw NNI time-series data in the initial analysis steps. Postextraction, HR, and NNI data were analyzed separately adding the perturbations.

First, gaps of varying length and frequency were added to the HR monitor and activity monitor data (Figure 1A). This perturbation was achieved by randomly selecting segments of HR, NNI, and PMSC values for periods of 1 to 5 minutes in length and removing them. The proportion of the entire data set that was removed was varied from 5% to 95% in increments of 1.2% (75 steps). In this analysis, HR and NNI values in the removed proportion of the data set were set to 35 beats per minute and 500 milliseconds, respectively. Secondly, flicker (ie, pink) noise in the HR monitor and activity monitor data was simulated using the power law noise generator function in R (R Foundation for Statistical Computing; Figure 1B). Next, the amount of noise added to HR, NNI, and PMSC values was varied between 0% and 150% (in 2% increments) of the mean value for that feature. After the noise was added to the time series, negative values for HR and NNI were transformed to positive by taking their absolute and then both HR and NNI values less than 1 were set equal to 1. For the third perturbation, a positive systematic bias ranging between 0% and 150% (in 2% increments) was added to the HR, NNI, and PMSC data (Figure 1C). PMSC values less than 0 were set equal to 0 after the addition of any perturbation. Finally, all 3 types of perturbations were combined in a final simulation, with each perturbation being applied at an equivalent level varying between 0% and 150% in increments of 2% for noise and bias, and between 5% and 95% in increments of 1.2% for missingness (ie, 75 steps for each of the 3 perturbations; Figure 1D). A total of 75 perturbed data sets were created for each participant and analyzed in this study.

Figure 1. Visual depiction of 4 simulated perturbations for a typical participant, where the black line represents the unperturbed data and the transparent red lines represent the following perturbations: (A) 20% of data missing, (B) noise with magnitude equal to 20% of mean, (C) a positive bias of 20%, and (D) all 3 perturbations combined.



Prediction Models

Features were extracted for the unperturbed raw data and each of the data sets with a simulated perturbation. A total of 285 features (282 continuous and 3 categorical) were extracted from the HR, NNI, and PMSC time-series data for each participant. After variable preselection, 18 out of 285 features were reserved to predict the CCI. The remaining 267 features were eliminated from the analysis based on (1) low correlation with the CCI variable and (2) features that remained consistent across all data sets (perturbed and unperturbed) and as such were deemed uninformative. Pearson correlation coefficient was computed to quantify the association between the CCI and each feature and considered only features with $P \leq .10$ for the analysis to filter out features weakly correlated with the CCI outcome. Next, the *rfcv* [B1] function from the *randomForest* library in R was used to create a random forest model predicting CCI in each data set, and to output 3-fold cross-validated prediction performances in the form of the root mean squared error (RMSE) between the actual and predicted CCI values. The default parameters were left unchanged for each of the developed random forest models, allowing for direct comparability. Given the small amount of data and the resultant variability in the results of a single 3-fold cross-validation, the assessment of prediction performance was

repeated 25 times for each data set. The mean and standard error of the RMSE achieved by each model were then outputted and compared between each of the simulated conditions. Baseline RMSE (RMSE for a random classifier) was calculated by considering the mean of the actual CCI values as predicted and obtaining the standard deviation of the prediction errors. All analyses were performed using R (v4.1.1).

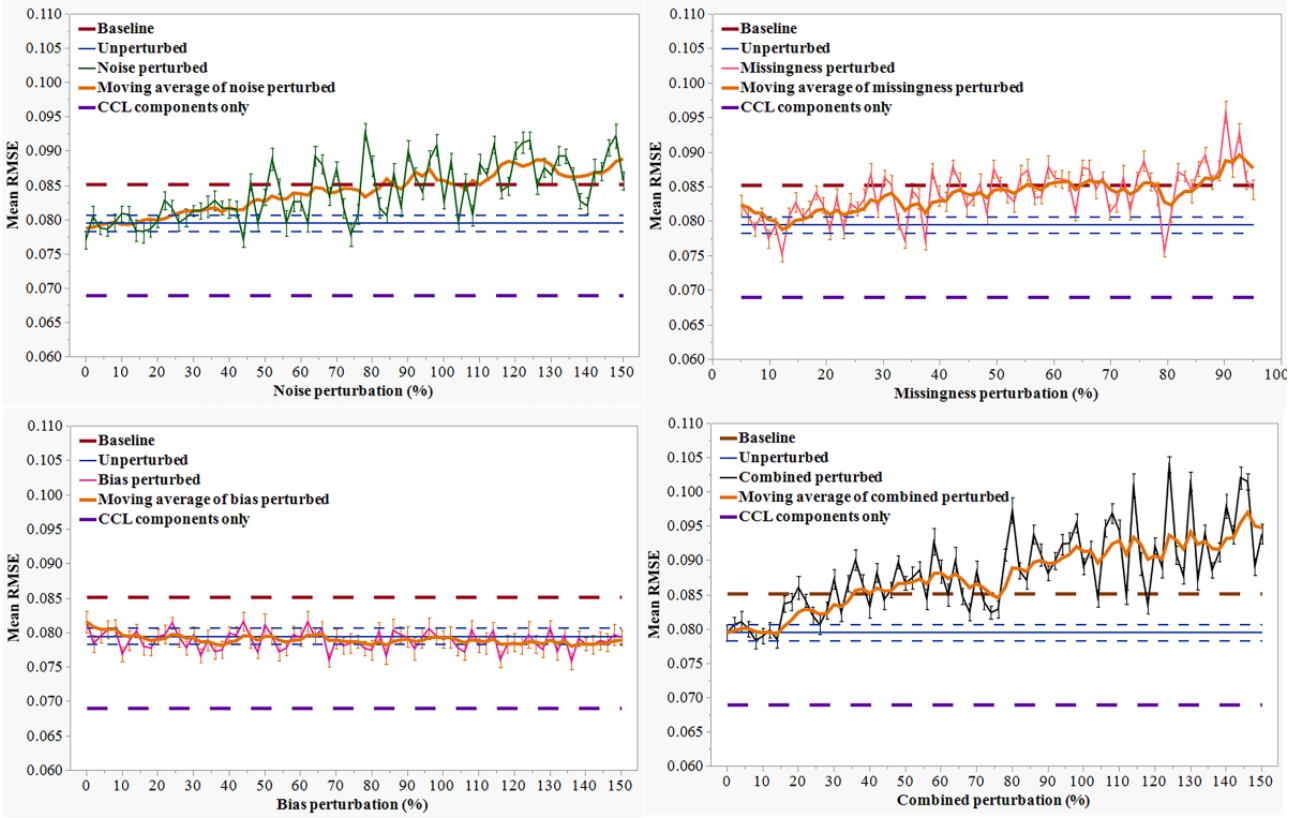
Ethics Approval

Research ethics approval was not needed for this study as it is a secondary use of publicly available data. The original data for this study were collected with participant consent after approval from the Ethical Committee of the University of Pisa (#0077455/2018) [11,12].

Results

Prediction performance was assessed for a total of 76 conditions (1 unperturbed and 75 perturbed simulations). The prediction model for CCI, created using the unperturbed data set, achieved a mean RMSE of 0.079 (SD 0.001) versus a baseline RMSE of 0.085 (SD 0.001). RMSE for prediction model for CCI, when using the maximum and minimum HR terms included in the calculation of CCI, was 0.069 (SD 0.006). Both the noise perturbation and degree of missingness showed stability at the low end of the perturbation spectrum with increasing RMSE starting with medium-high degrees of perturbation. For the noise perturbation (Figure 2), the RMSE remained stable up to a 20% perturbation. Thereafter, RMSE increased up to an 80% noise perturbation at which point the RMSE was no better than the baseline model. A similar pattern was seen for missingness with a stable RMSE up to a 20% data missingness, degrading performance up to a 50% missingness and loss of predictive ability thereafter. Introducing bias in the time series had no effect on the RMSE at any level. The progression of RMSE for the combined perturbations showed a similar pattern as noise and missingness, with stability up to a 20% perturbation, followed by performance degradation and a loss of predictive ability at a ~35% perturbation.

Figure 2. Progression of root mean squared error (RMSE) for prediction of cardiac competence index (CCI) using 3-fold cross-validated predictive performance over multiple iterations with increasing level of perturbations in source data (top left: noise; top right: missingness; bottom left: bias; and bottom right: combined). CCL: cardiac competence limit.



Discussion

Principal Findings

In this study, we used continuous step count and HR data acquired using a standardized protocol and thoroughly validated wearable devices [15,16] and simulated the effect of data degradation on a predictive model. We showed that the performance of the prediction models for CCI remained stable up to a 20% feature degradation (for all types). Thereafter, model performance decreased with increasing perturbation of up to 40%-50% feature degradation, at which point the models were no longer predictive. Should these findings be replicated in other contexts, it follows that the moderate decrease in data reliability associated with consumer-grade wearable devices might not be a contraindication to the use of the data generated from these devices being used in prediction models.

Methodological Considerations

The results from this study show that prediction models created using machine learning based on the features derived from time-series data can be relatively resistant to the low-moderate degree of degradation in the quality of the underlying data. There are numerous aspects of our simulation that warrant further discussion. First, we focused only on step count and HR as those are 2 of the most common types of data acquired through consumer-based wearables devices. Recently released devices now continuously measure other physiological indices such as pulse oximetry, breathing rate, or HR variability. Thus, the same type of simulation study will be needed for each of these measurements to establish the degree of reliability needed to maintain the performance of prediction models derived from these data. Second, we decided to run the simulations far beyond the range of perturbations that have been previously reported for these devices. We used this approach to both observe the behavior of the prediction models over the expected range of perturbations and the degree of perturbations needed for model's performance to degrade up to the point where it is no longer predictive. Future studies assessing other physiological markers might not need to investigate behavior over such a large range given that the upper limit is clearly outside of the realistic range. Finally, it is important to note that the effect of feature degradation might not be the same with all machine learning methods that can be used to create prediction models. The ability of random forest models to effectively integrate continuous variables with highly abnormal distributions might make such models uniquely suited to resist the effects of degradation in the underlying features in a way that other methods could not replicate. Future studies will be needed to compare the effect of data degradation on different prediction models.

The use of machine learning to handle continuous monitoring data, particularly in contexts where data reliability and acquisition could be an issue, is appealing. In a traditional, probabilistic-based, predictive modeling approach, the accuracy and reliability of the predictors is highly important. However, with machine learning, the paradigm can be different. Machine learning uses secondary, data-derived features for predictions, and model performance is predicated on the stability and characteristics of those features and less so on the reliability of the underlying data. This is particularly true for time-series data, where features are created from multiple data points, something which tends to reduce their variability. Prediction models created using machine learning also have 3 additional major advantages in this context. First, many machine learning algorithms create higher-order features (features created through the combination of other features in a process akin to statistical interactions); meaning that the features predicting the outcomes are even further removed from the raw data, and thus, are less sensitive to small perturbations. Second, the ability of machine learning models to use higher-order features also allows for predictive models to use features specific to different segments of the population. Third, machine learning models are able to take into consideration far more features in making a prediction than their probabilistic counterparts. Thereby, data perturbations need to affect more features and be more pronounced to derail model performance, since the algorithm can still make predictions based on the more stable features.

Comparison With Prior Work

There are 2 main challenges with the use of consumer-oriented devices to acquire data to be used for clinical applications—the accuracy of the data generated and the use of surrogate measurements. Previous studies of activity trackers have generally found limited accuracy in step count, the measurement of which is prone to substantial noise, particularly in high physical activity situations [5-8]. A systematic review on the subject has found that consumer-grade devices meet acceptable accuracy standards for step count half the time, overestimating higher intensity activity while underestimating medium intensity activity. Additionally, wrist-worn devices are more prone to high levels of noise and a greater amount of data missingness, given that the data acquisition is free-living and not standardized [17]. On the other hand, the accuracy of HR measurements, something much less sensitive to data perturbations, was found to be reasonably accurate albeit with an overall negative bias and lower accuracy when patients were not in sinus rhythm. For this metric, accuracy was lowest during high-intensity activity [18,19].

An additional common criticism of the use of commercially available wrist-worn devices for the clinical monitoring of patients is that the majority of devices do not directly measure the physiological features of interest but instead use surrogate, more easily measurable features to approximate or predict those features. For example, many wrist-worn devices do not measure HR directly. They use a method called photoplethysmography, which looks at rapid changes in red and green light absorption in the wrist to estimate HR [20]. Cardiac pulsations and the associated forward blood flow reflect red light and absorb green light, and consequently, there is less green light absorption in between heart beats. The speed of variation between red and green light absorption is used to estimate HR. The use of surrogate markers can have the following 2 drawbacks: first, the approximation or prediction can be associated with a higher error rate than a direct measurement and thus have lower reliability, and second, some important features might be missed. For example, in the case of HR measurements by photoplethysmography, since the device does not measure a full electrocardiogram signal, not all possible cardiac intervals can be assessed, which may result in missing clinically important features [17,21-23]. Moreover, HR detection with photoplethysmography is dependent on having a sufficient volume of ejected blood with each cardiac cycle (ie, perfusion) to generate a detectable flow in the extremity where the device is worn. In some heart rhythms and in some heart conditions, stroke volume may be inadequately low for detection in certain cardiac cycles leading to the underestimation of HR [24,25].

The use of data acquired from wearable devices in prediction models is still relatively new, so much so that a systematic review found only 8 published models based on wearable data between 1997 and mid-2019 [26]. In a recent systematic review of wearable sensors used in Parkinson disease in a clinical area with a long history of sensor-based monitoring, only 7 out of 74 studies reported the creation of prediction models from these

data. The development of those models was dependent on the use of increasingly complex machine learning algorithms that required the combination of diverse sets of higher-order features to achieve a high performance [10]. The same trend toward increasing the use of machine learning has been observed in the area of continuous glucose monitoring for patients with diabetes [27,28]. None of those previous investigations addressed the potential effect of data accuracy and data degradation on the performance of prediction models.

Study Limitations

This study must be considered in light of some limitations. First, given that the outcome (ie, CCI) and predictive features were derived from the same HR and physical activity data, it is possible that the prediction models may overperform compared to prediction models for outcomes not derived from the underlying data. Additionally, it is worth noting that the calculation to obtain the CCI was modified based on the data available in this study, and, as such, it is only an approximation of true CCI. Second, the limited sample size from a single data set and the single modeling approach used here preclude treating this study as definitive. That being said, this study provides a proof of concept aimed at raising an important question related to the reliability of the data obtained from consumer-grade monitoring devices. Future studies will need to focus on large cohorts, on more remote outcomes, and on exploring different modeling strategies that may be more or less resistant to the degradation of source data.

Conclusions

In conclusion, in this proof-of-concept study, we showed that the performance of predictive models for CCI generated from continuous devices is relatively stable to degradation in the quality of the underlying data. This finding, while needing confirmation in larger studies, suggests that by itself, lower accuracy of measurements may not be an absolute contraindication for the use of data from consumer-oriented monitoring devices in prediction models intended to inform clinical management.

Data Availability

All data used for this study are publicly available from the PhysioNet database [11,12].

Authors' Contributions

Study concept was developed by CM, DGS, JH, and JVdE. Data analysis was conducted by JH, JVdE, and BC. Manuscript drafting was done by JH, BC, and CM. All authors were involved in the interpretation, critical revisions, and final approval of the study.

Conflicts of Interest

None declared.

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Abbreviations

CCI: cardiac competence index

HR: heart rate
MMASH: Multilevel Monitoring of Activity and Sleep in Healthy People
NNI: N-N interval
PMSC: per-minute step count
RMSE: root mean square error

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Original Paper

Corrected QT Interval (QTc) Diagnostic App for the Oncological Routine: Development Study

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Abstract

Background: Numerous antineoplastic drugs such as chemotherapeutics have cardiotoxic side effects and can lead to long QT syndrome (LQTS). When diagnosed and treated in time, the potentially fatal outcomes of LQTS can be prevented. Therefore, regular electrocardiogram (ECG) assessments are critical to ensure patient safety. However, these assessments are associated with patient discomfort and require timely support of the attending oncologist by a cardiologist.

Objective: This study aimed to examine whether this approach can be made more efficient and comfortable by a smartphone app (QTc Tracker), supporting single-lead ECG records on site and transferring to a tele-cardiologist for an immediate diagnosis.

Methods: To evaluate the QTc Tracker, it was implemented in 54 cancer centers in Germany. In total, 266 corrected QT interval (QTc) diagnoses of 122 patients were recorded. Moreover, a questionnaire on routine ECG workflow, turnaround time, and satisfaction (1=best, 6=worst) was answered by the centers before and after the implementation of the QTc Tracker.

Results: Compared to the routine ECG workflow, the QTc Tracker enabled a substantial turnaround time reduction of 98% (mean 2.67, 95% CI 1.72-2.67 h) and even further time efficiency in combination with a cardiologic on-call service (mean 12.10, 95% CI 5.67-18.67 min). Additionally, nurses and patients reported higher satisfaction when using the QTc Tracker. In particular, patients' satisfaction sharply improved from 2.59 (95% CI 2.41-2.88) for the routine ECG workflow to 1.25 (95% CI 0.99-1.51) for the QTc Tracker workflow.

Conclusions: These results reveal a significant improvement regarding reduced turnaround time and increased user satisfaction. Best patient care might be guaranteed as the exposure of patients with an uncontrolled risk of QTc prolongations can be avoided by using the fast and easy QTc Tracker. In particular, as regular side-effect monitoring, the QTc Tracker app promises more convenience for patients and their physicians. Finally, future studies are needed to empirically test the usability and validity of such mobile ECG assessment methods.

Trial Registration: ClinicalTrials.gov NCT04055493; https://classic.clinicaltrials.gov/ct2/show/NCT04055493

(JMIR Cardio 2023;7:e48096) doi:10.2196/48096

KEYWORDS

telemedicine; mobile health; mHealth; eHealth; tele-cardiology; cardiology; long QT syndrome; prolonged QT interval; electrocardiography; ECG; telehealth; app; application; oncology; cancer; diagnosis; diagnostic; heart; arrhythmia; cardiotoxic; side effects; adverse effects

Introduction

The potentially fatal long QT syndrome (LQTS) is one of the main cardiotoxic side effects of cancer drugs [1], including arsenic trioxide [2-6], selective cyclin-dependent kinase 4 and 6 inhibitors such as ribociclib [7-12], tyrosine kinase inhibitors such as vandetanib [13-18], or histone deacetylase inhibitors such as depsipeptide [19,20]. This syndrome is characterized by a prolongation of the corrected QT interval (QTc), which may induce life-threatening arrhythmias, including torsade de pointes (TdP), and can lead to sudden cardiac death [21]. The outcome of LQTS is not necessarily fatal when diagnosed and treated in time, as the medically induced prolongation of the QTc is reversible [22]. Multiple risk factors may contribute to the development of QTc prolongation. Increasing age as well as female sex, for example, are associated with a higher risk of prolonged QTc [23-27].

The normal average QTc for male individuals is approximately <430 ms, whereas the normal average QTc for female individuals is approximately <450 ms. A borderline QTc can be 431-450 ms for male individuals and 451-470 ms for female individuals, whereas a prolonged QTc is considered >450 ms for male individuals and >470 ms for female individuals [28]. An increased QTc of 10 ms contributes to a 5% to 7% exponential increased risk to develop the life-threatening arrhythmia TdP. Thus, a QTc of 540 ms exposes the patient to a 63% to 97% higher TdP risk than a QTc of 440 ms, but there is no QTc value at which TdP certainly occurs [29-31]. In the case of drug-induced LQTS with a QTc increased to >500 ms or a QTc prolongation of >60 ms above the baseline, treatment discontinuation or alternative therapies should be considered [1].

Regular QTc assessment is associated with additional effort for the attending physician and patient. In the context of oncologic treatments, QTc examination commonly requires the consultation of a cardiologist in addition to the attending oncologist, as many oncologists do not have the ability to record and diagnose electrocardiograms (ECGs) directly on-site. This situation forces the typically older patients with cancer to additionally visit a cardiologist, which in turn exposes them to more stress and endangers susceptible patients. Even if the oncologists can conduct an ECG themselves, this does not guarantee the correct QTc assessment, as only <25% of noncardiologists can correctly classify a QTc as prolonged or normal [32]. Additionally, a 12-lead ECG in general requires the patient to undress and lay down, which is especially uncomfortable for older patients. For example, antiembolism stockings can significantly impede the undressing process for an older patient, and putting the stockings back on after the measurement is often difficult for them [33]. Ultimately, all these mentioned challenges and disadvantages may contribute to the known underuse of ECG monitoring in routine patients in oncology [34]. Therefore, the aim of this study was to examine whether this conventional procedure can be made more efficient and comfortable by a smartphone app (QTc Tracker; version 4.27.30; CANKADO GmbH), supporting single-lead ECG records on site and transferring to a tele-cardiologist for an immediate diagnosis.

Methods

Participants and Study Procedure

In total, 54 centers in Germany with 122 patients participated in the study, and 266 QTc diagnoses were recorded. A questionnaire on routine ECG workflow, turnaround time, and satisfaction was answered by the centers before and after the implementation of the QTc Tracker. The turnaround time of the QTc Tracker was accessed from the software itself. All participating patients were diagnosed with early breast cancer and were on ribociclib-based therapy. Since ribociclib can lead to drug-induced LQTS as an adverse drug reaction, patients were monitored by ECG via at least 3 points every 2 weeks at the start of therapy.

Ethical Considerations

The study was conducted according to the Declaration of Helsinki, and all participants provided informed written consent prior to the measurements. Ethical approval was provided by the West German Study Group (study ID: WSG-AM08). Participation was free and included no further risks. Participants were randomly assigned to numerical codes, so that data could be handled anonymously. The study is part of a registered trial (ClinicalTrials.gov; NCT04055493).

Questionnaire

The questionnaire used was developed from our own experiences and can be found in Multimedia Appendix 1. It comprised 11 questions about the routine ECG workflow, turnaround time, and satisfaction. Answers were given from nurses' and patients' perspectives as free text and rated between 1 (best) and 6 (worst). All centers provided information about their routine ECG workflow and how they routinely receive the QTc diagnosis (paper based or digital).

KardiaMobile and Kardia App

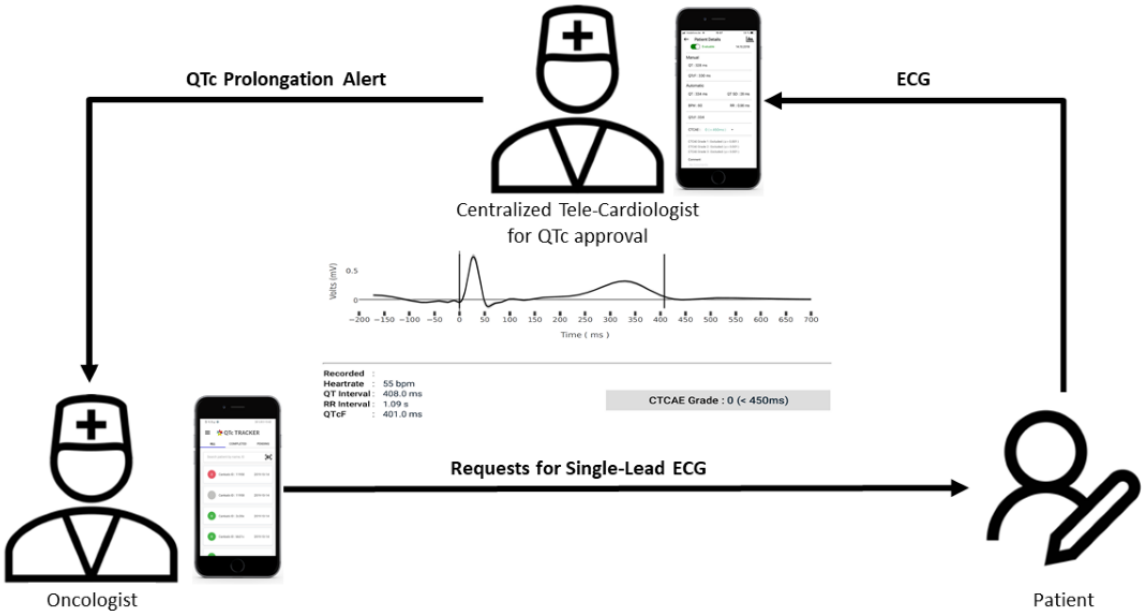
The portable ECG device KardiaMobile (model AC-009; AliveCor Inc) was used to record the single-lead ECGs. The device has US Food and Drug Administration and European Union clearance and Conformité Européenne labeling as a medical device and can be used to calculate QT intervals and monitor drug-mediated QTc prolongation [35-37]. The device comprises 2 electrodes that are used to measure a single-lead ECG between both hands (Figure 1). The ECG recording is transmitted wirelessly to the respective Kardia App (version 5.7.4; AliveCor Inc).

Figure 1. Recording of an electrocardiogram (ECG) with the KardiaMobile Device connected to the Kardia App. The single-lead ECG is recorded by laying the fingers on the electrodes of the KardiaMobile ECG device. A smartphone is connected to the device and records the ECG.

QTc Tracker

During a routine check-up, the patient records a single-lead ECG on site at the cancer center with the KardiaMobile single-lead ECG device. A PDF file is created with the Kardia App and transferred to the QTc Tracker of the attending oncologist. The assignment of an ECG file to the corresponding patient's record—either a new or an already existing patient—is guided using a unique patient ID. The QTc Tracker interface for oncologists shows each recorded ECG in an individual row. Next to the patients' ID is a colored circle, which represents the status of the QTc diagnosis request. If the diagnosis is still pending, the circle is gray. After diagnosis, the circle changes its color according to the Common Terminology Criteria for Adverse Events (CTCAE) grade of the QTc diagnosis. In the case of a normal QTc with a CTCAE grade of 0, the circle is green. If the QTc is pathologic, the color is either orange for a CTCAE grade of 1 or red for a CTCAE grade of 2 or higher (Figure 2).

Figure 2. Overview of the general QTc Tracker workflow. Immediate corrected QT intverval diagnosis via smartphone app supporting single-lead ECG record on-site and transfer to tele-cardiologist.



When the oncologist requests the QTc diagnosis of the ECG file, both the request and the ECG data are transferred to a tele-cardiologist, who then receives a push notification. The QTc Tracker also comprises an interface for the tele-cardiologist (Figure 2). This interface includes an overview of all pending QTc diagnosis requests sorted by the time of receipt. It is structured similar to the interface of the oncologist, with each row representing one request containing the unique patient's

ID and the color-coded circle for the diagnosis status. A gray circle symbolizes a pending ECG diagnosis, whereas a green circle symbolizes the completed diagnosis. The tele-cardiologist is able to open specific requests and view the original ECG file recorded by the Kardia App for revision and diagnosis. Although the QT interval, QT SD, beats per minute, RR interval, QTc using the Fridericia formula (QTcF), and CTCAE grade are calculated automatically, the cardiologist is able to graphically adjust the QTc (Figure 2). The different elements of the ECG are extracted, so the ECG cycles can be identified and further analyzed. For each cardiac cycle, the QT interval is determined according to Martínez and colleagues [38] and corrected for the heart rate with the Fridericia formula (QTcF) as recommended by the European Society of Cardiology [1]. The correction formula according to Fridericia [39] is as follows:

The RR interval is the interval between the R waves of 2 adjacent heart cycles. By determining the QRS onset and T offset (Figure 2), the QTcF is calculated automatically. An overlay plot of all cardiac cycles of an ECG is produced, displaying the mean cardiac cycle and the SD. The mean QTcF is also calculated and displayed.

According to *CTCAE version 5.0* [40,41], QTc prolongations are classified as follows: grade 1 is defined as an average QTc of 450-480 ms; grade 2 is defined as an average QTc of 481-500 ms; grade 3 is defined as an average QTc of >500 ms or a >60 ms change from baseline; and grade 4 is defined as the presence of TdP, polymorphic ventricular tachycardia, or serious arrhythmia [40,41]. After the completion and submission of a diagnosis, the diagnostic report is generated as a PDF file and cannot be changed anymore. Additionally, a comment can be inserted by the tele-cardiologist into the diagnostic report. The details of a diagnostic report are saved in the electronic patient record and transmitted to the oncologist, who subsequently receives a push notification too. The QTc Tracker directly displays the CTCAE grade of a diagnosed ECG in the patient overview. For further details, the oncologist can view the complete diagnostic report. They also have the possibility to download the whole diagnostic report, print it, and add it to the local patient records.

Results

General Workflow

The fundamental principle of the telecardiology application QTc Tracker was the on-site ECG measurement at the cancer center and the direct transfer of the ECG data from the smartphone of the oncologist to the tele-cardiologist (Figure 2).

Routine ECG

The overall results of the questionnaire before the tracker's implementation are shown in Table 1. Not all centers answered all questions about the turnaround times of their routine ECG assessments. Information about the waiting time for an ECG appointment and the time span between ECG measurement and QTc diagnosis were obtained from 91% (49/54) and 87% (47/54) of the centers, respectively. The total turnaround time was obtained from 81% (45/54) of the centers, wherein both the waiting time for an ECG appointment and the time span between ECG measurement and QTc diagnosis were obtained.

Table 1. Overview of the different centers that participated in the study.

Group	Centers (N=54), n (%)	Diagnosis format, n/N (%)		Time to appointment, mean (95% CI)	Time to diagnosis after appointment, mean (95% CI)	Total turnaround time, mean (95% CI)
		Paper based	Digital			
Group 1[a]	21 (39)	21/21 (100)	0/21 (0)	12.45 (2.90-22.00) d	3.79 (0.60-6.97) d	12.77 (2.83-22.70) d
Group 2[b]	9 (17)	6/9 (67)	3/3 (33)	2.64 (0.13-5.14) d	1.14 (0.86-1.42) d	2.16 (0.23-4.08) d
Group 3[c]	24 (44)	21/24 (88)	3/24 (12)	25.08 (15.50-34.65) min	51.98 (18.45-85.51) min	72.52 (36.84-108.20) min
Total	54 (100)	48/54 (89)	6/54 (11)	4.76 (1.12-8.40) d	1.64 (0.34-2.94) d	5.44 (1.43-9.45) d

[a]Group 1: centers without cardiologist.

[b]Group 2: centers with cardiologist who did not receive the corrected QT interval diagnosis on the same day.

[c]Group 3: centers with cardiologist who received the corrected QT interval diagnosis on the same day.

The 54 centers had a mean total turnaround time of 5.44 (95% CI 1.43-9.45) days, which was composed of a mean waiting time for an ECG appointment of 4.76 (95% CI 1.12-8.40) days and a mean time span between ECG measurement and QTc diagnosis of 1.64 (95% CI 0.34-2.94) days. Due to the high variation of the turnaround times, the centers were classified into 3 groups. Group 1 included centers without an in-house cardiologist (21/54, 39% of centers). Group 2 consisted of centers with their own cardiologist who did not receive the QTc diagnosis on the same day (9/54, 17%). Group 3 included centers with their own cardiologist who received the QTc diagnosis on the same day (24/54, 44%).

QTc Tracker

The second part of the questionnaire about the workflow and turnaround time of using the QTc Tracker was answered by 12 centers. The total turnaround time of the QTc Tracker was retrieved from the system itself and comprised 266 QTc diagnoses, of which 223 (83.8%) were evaluable. Due to the sample size, the QTc Tracker results were not subdivided into groups but evaluated as a whole; therefore, group 4 represents all centers using the QTc Tracker. The mean turnaround time of the QTc Tracker until the receipt of the diagnostic report by the oncologist was 2.67 (95% CI 1.72-2.67) hours. The time

reduction from the mean turnaround time of all centers of 5.44 days to 2.67 hours equals to a reduction of 98%.

Further, a cardiologic on-call service was implemented as a trial to perform the QTc diagnosis. This workflow is constituted as group 5. Thereby, the mean turnaround time was further decreased to 12.10 (95% CI 5.67-18.67) minutes. In contrast to the routine ECG workflow, the mean total turnaround time was reduced by over 99%. The combination of the QTc Tracker with a cardiologic on-call service was tested for 28 QTc diagnoses.

Satisfaction

The majority of the centers (47/54, 87%) completed all questions about their satisfaction. Again, for the questions about the workflow and turnaround time, the second part of the questionnaire about satisfaction with the QTc Tracker workflow was answered by 12 centers.

The overall mean satisfaction grade of the nurses improved from 2.57 (95% CI 2.31-2.84) for the routine ECG workflow to 2.21 (95% CI 1.55-2.86) for the QTc Tracker workflow. The overall mean satisfaction grade of the patients improved from 2.65 (95% CI 2.41-2.88) for the routine ECG workflow to 1.25 (95% CI 0.99-1.51) for the QTc Tracker workflow. Common feedback from the study centers was relief from the patients as it was not necessary to visit a cardiologist in addition to the oncologist. Another positive feedback was the simplicity of the single-lead ECG measurement, especially because the patient does not need to undress for the procedure.

Discussion

Principal Findings

Since many medications ranging from antiarrhythmics to oncologic agents may prolong the QTc, it is necessary to search for a more comfortable and time-effective solution to monitor for QTc prolongation. Aside the conventional 12-lead ECG method, smartphone-dependent ECG devices were developed in recent years using a more convenient mode to measure ECGs without the need to undress. The versatility of mobile phones and the general accessibility to the internet enabled the possibility to use newly developed, smartphone-based heart rhythm monitors to assess the QTc directly on site with real-time tele-cardiologic QTc diagnosis, which in turn allows the practitioners to directly react in case of a prolongation.

Previous research confirmed the suitability of using single-lead ECGs recorded by the smartphone-based heart rhythm monitor KardiaMobile to evaluate the QTc in various age and disease groups [35,37,42]. This new technology was shown to be very promising for outpatient QTc monitoring [36]. In general, the market of mobile and smartphone-based ECG devices is constantly expanding, with the perspective that such devices would be implemented into routine care in the next few years [37]. Apart from QTc prolongations as considered in this study, other heart rhythm disturbances can also be diagnosed including atrial fibrillation and atrial flutter [43].

To date, a change in the interaction between attending physicians and cardiologists for QTc diagnosis using single-lead ECGs was not an objective of previous research. The QTc Tracker is the first tele-cardiologic solution for QTc diagnosis using single-lead ECGs recorded by a KardiaMobile device. The field of telemedicine is a constantly evolving science that, according to the World Health Organization, comprises the provision of clinical support by connecting geographically separated users with modern information and communication technologies to improve health outcome [44]. Telemedicine was assessed as an important health care aspect that is under constant progress, with the perspective of it being implemented as a gold-standard technique in the future [45,46]. Currently, the majority of telemedicine systems address the topics of radiology and stroke care [46]. Especially regarding the recent COVID-19 pandemic, telemedicine is becoming more and more relevant [47,48], and therefore, more usable and efficient alternatives are needed.

However, some constraints are limiting our study. The first limitation is the dependency on technical support. In rural regions, internet support in general as well as technical support are not always given as needed for using the QTc Tracker. Another limitation is that we did not assess the accuracy of the measurements in this study but instead aimed for the usability of the assessment method. Therefore, further analysis of the accuracy of the QTc Tracker measurements is necessary. As the tool is promising for regular side-effect monitoring, it is currently integrated into several phase III-IV clinical trials in Germany. In the future, it is planned to use the QTc Tracker not only in combination with a central cardiology service but also to support the centers with their own cardiologists to conduct the diagnosis themselves.

Conclusions

The QTc Tracker provided a significant improvement for the cancer centers, enabling a highly reduced turnaround time and improved user satisfaction for QTc diagnoses. Finally, future studies should not only establish but also empirically test the usability and validity of such mobile ECG assessment methods.

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Data Availability

The data sets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' Contributions

TS and AS contributed to the conceptualization of the manuscript. KK wrote the original draft. NH and YJP conducted the investigation. TS and AS contributed to writing—review and editing. All authors have read and agreed to the final version of the manuscript.

Conflicts of Interest

TS is the owner and managing director of CANKADO GmbH. The other authors declare that they have no conflicts of interest.

Multimedia Appendix 1
Questionnaire used in the study.
[DOCX File , 11 KB - cardio_v7i1e48096_app1.docx]

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Abbreviations

CTCAE: Common Terminology Criteria for Adverse Events
ECG: electrocardiogram
LQTS: long QT syndrome
QTc: corrected QT interval
QTcF: QT interval corrected for heart rate using the Fridericia formula
TdP: torsade de pointes

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Original Paper

Pilot Investigation of Blood Pressure Control Using a Mobile App (Cardi.Health): Retrospective Chart Review Study

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Abstract

Background: The high prevalence of hypertension necessitates effective, scalable interventions for blood pressure (BP) control. Self-monitoring has shown improved adherence to medication and better BP management. Mobile apps offer a promising approach with their increasing popularity and potential for large-scale implementation. Studies have demonstrated associations between mobile app interventions and lowered BP, yet real-world data on app effectiveness and engagement remain limited.

Objective: In this study, we analyzed real-world user data from the Cardi.Health mobile app, which is aimed at helping its users monitor and control their BP. Our goal was to find out whether there is an association between the use of the mobile app and a decrease in BP. Additionally, the study explored how engagement with the app may influence this outcome.

Methods: This was a retrospective chart review study. The initial study population comprised 4407 Cardi.Health users who began using the app between January 2022 and April 2022. After applying inclusion criteria, the final study cohort comprised 339 users with elevated BP at the baseline. The sample consisted of 108 (31.9%) men and 231 (68.1%) women (*P*=.04). This retrospective chart review study obtained permission from the Biomedical Research Alliance of New York Institutional Review Board (June 2022, registration ID 22-08-503-939).

Results: The study's main findings were that there is a possible relationship between use of the Cardi.Health mobile app and a decrease in systolic BP. Additionally, there was a significant association between active use of the app and systolic BP decrease (χ^2_1=5.311; *P*=.02). Finally, active users had an almost 2 times greater chance of reducing systolic BP by 5 mm Hg or more over 4 weeks (odds ratio 1.932, 95% CI 1.074-3.528; *P*=.03).

Conclusions: This study shows a possible relationship between Cardi.Health mobile app use and decreased BP. Additionally, engagement with the app may be related to better results—active use was associated with an almost 2-fold increase in the odds of reducing BP by 5 or more mm Hg.

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KEYWORDS

mobile app; Cardi.Health; blood pressure; engagement; app; pilot study; hypertension; effective; blood pressure control; self-monitoring; medication; management; engagement; users; use

Introduction

The prevalence and burden of hypertension are exceptionally high. It is estimated that in the United States, nearly half of all adults have hypertension, and of those, only approximately 1 in 5 achieve adequate control of their blood pressure (BP) [1]. Elevated BP is one of the most significant risk factors for ischemic heart disease and stroke and thus is a leading preventable cause of cardiovascular disease and heart failure [2-4]. Accordingly, reducing the prevalence of hypertension is a worldwide target for preventing and controlling noncommunicable diseases [5].

Despite the many strategies available for hypertension management, sufficient blood pressure control in the population

is evidently lacking. Thus, there is a growing need to establish and test scalable interventions to achieve said control [6,7]. In addition, research has noted that self-monitoring of BP leads to better control and improves adherence to medication [8-10]. One recognized way of promoting the self-management of BP is mobile apps [11]. It is thought that by providing an organized overview of BP data, information about hypertension, the correct ways to measure BP, and relevant lifestyle modifications, mobile apps may make it easier for patients to understand and adequately control their BP [12]. Importantly, considering the growing popularity of mobile phones and health apps [12], mobile technology interventions are a way of disseminating information that may potentially be scaled for large populations.

Existing studies demonstrate an association between mobile app interventions and lowered BP. For example, in a large cohort study, engagement in a BP self-management program that used a mobile app with automated lifestyle coaching was associated with lower BP within a follow-up period of 3 years [6]. Similarly, systematic reviews of mobile app BP interventions note that most controlled studies report associations with lowered BP [13-15]. Nevertheless, there is still relatively little real-world data about the effectiveness of and engagement with mobile BP apps. More research about the features, mechanisms of BP control, engagement factors, and effectiveness of mobile app interventions targeting BP in various settings and populations is still required.

In this study, we aim to analyze real-world user data of the Cardi.Health mobile app, with the specific objectives of determining whether there is an association between the use of the mobile app and a decrease in BP and how engagement with the app may influence this outcome. We hypothesize that increased engagement with the Cardi.Health mobile app will be associated with a significant decrease in blood pressure among its users. We hope to provide insight into the effectiveness of mobile interventions in real-world settings, thus adding to the growing body of knowledge about this promising field of mobile health.

Methods

Ethical Considerations

This retrospective chart review study received research ethics approval from the Biomedical Research Alliance of New York Institutional Review Board in June 2022 (22-08-503-939). The need for patient consent was waived due to the retrospective nature of the investigation. The study was conducted according to the guidelines of the Declaration of Helsinki.

Participants

The initial study population comprised 4407 Cardi.Health users who began using the app between January 2022 and April 2022. Users who met the following criteria were included for further investigation: they entered their age, gender, height, and starting weight; they had at least one active day per week with valid app-related activities (eg, they documented activities, entered data, completed an exercise from the app, or looked for nutrition information in the app) for 4 consecutive weeks; they entered blood pressure measurement results at least once a week; and they had less than 30 active days overall. After applying the inclusion criteria, the final study cohort comprised 339 users with elevated BP at the baseline. The sample consisted of 108 (31.9%) men and 231 (68.1%) women (P=.04). Detailed descriptive data are presented in Table 1.

Table 1. Descriptive data of the final cohort (n=339).

	Men	Women	*P* values
Users, n (%)	108 (31.9)	231 (68.1)	.04
Users in starting blood pressure category, n (%)			
Elevated	39 (31.2)	86 (68.8)	.29
High	33 (27.5)	87 (72.5)	.72
Very high	36 (38.3)	58 (61.7)	.77
Active days, median (IQR)	23 (11)	21 (9)	.42
Total time of use (days), median (IQR)	47 (59)	43 (54)	.63

Intervention

Cardi.Health is available for download from the App Store and the Google Play store. The app serves as a tool for the daily monitoring and management of cardiovascular diseases. It enables users to track their condition by receiving regular reminders to check their vital signs (recommendations and instructions about the proper techniques for self-measurements, such as BP, are also provided) and to log their symptoms (Figure 1) and medications (Figure 2), and it provides actionable insights and reminders (Figure 3). In addition, the app features personalized insights, condition trackers, daily reminders for medication, insight action plans, and meal and activity plans, and, finally, generates reports for a scheduled physician check-up (Figure 4). The app was developed in collaboration with cardiologists working clinically and the American Heart Association's Center for Health Technology and Innovation.

Figure 1. Cardi.Health mobile app screen for symptom logging.

Figure 2. Cardi.Health mobile app screen for medication logging.

Figure 3. Cardi.Health mobile app giving a reminder.

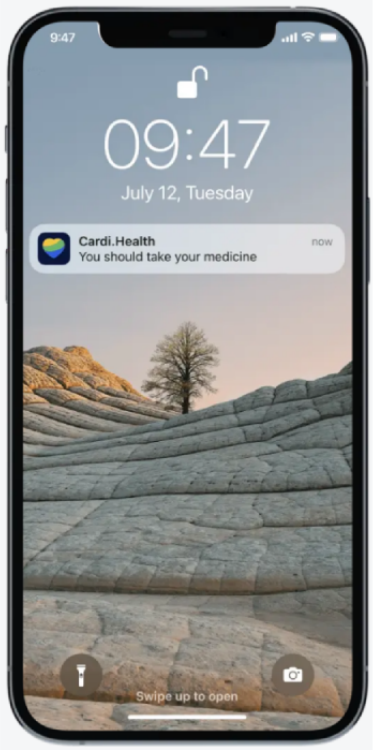
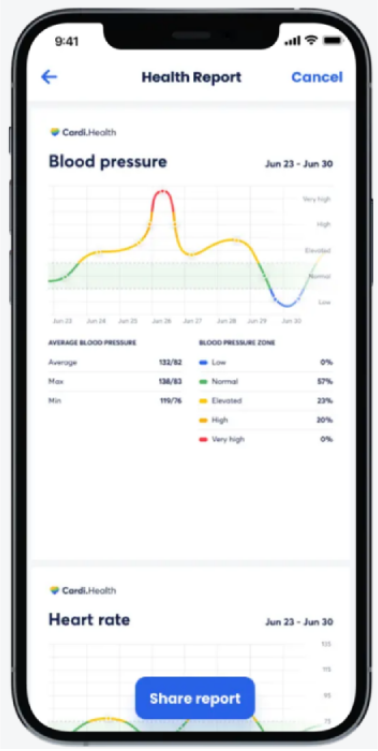


Figure 4. Generated report for a scheduled physician check-up.



Measures

Systolic BP values were used to assess the effectiveness of the app in managing users' BP levels over a consecutive 4-week period. Users were classified into 3 groups based on their mean systolic BP values during their first week of app use: elevated (120-129 mm Hg), high (130-139 mm Hg), and very high (140 mm Hg or higher) [16].

To assess user engagement over the 4-week period, an "activity ratio" was calculated. This ratio was obtained by dividing the number of active days (ADs) by the total time (TT) the app was used. Both ADs and TT are measured in days. The activity ratio ranged from 0.04 to 1, with a score of 1 indicating that the user had the app for x number of days and was active and engaged with the app on all x number of days. The activity ratio allowed the identification of users who frequently used the app during

the 4-week period. Furthermore, it enabled comparing 2 user groups based on their activity ratio: users who frequently used the app during the 4-week period and those who used it for 4 weeks but were less active.

Statistical Analyses

The statistical analysis of the data was performed using GraphPad Prism (version 9; GraphPad Software). The normality of continuous variables was assessed using the Shapiro-Wilk test. For related nonnormally distributed samples, the Wilcoxon signed-rank test was used to analyze paired or unpaired samples. A chi-squared analysis was used to investigate the relationship between activity ratio and users who lowered their systolic BP by 5 mm Hg or more over 4 weeks. The sample was divided into 2 groups based on activity ratio: active (activity ratio ≥0.75) and nonactive (activity ratio <0.75). The frequency distribution of users who achieved the systolic BP reduction threshold was calculated for each group. A significance level of .05 was chosen for all analyses.

Furthermore, a logistic regression model was used to examine significant differences between mean systolic BP values during the first and fourth weeks of app use. The change in systolic BP values was selected as the dependent variable and coded as follows: users whose systolic BP decreased by 5 mm Hg or more over 4 weeks were coded as 1, while those whose systolic BP decreased by less than 5 mm Hg or increased were coded as 0. The covariates included the users' activity level, categorized as nonactive or active based on the activity ratio (where an activity ratio of 0.75 or higher indicated an active user). A logistic regression model was constructed to investigate the effect of the independent variables (covariates) on the dependent variable.

Results

The statistical analysis using the Wilcoxon signed-rank test showed that both groups significantly reduced systolic BP within the elevated, high, and very high BP categories. It is worth mentioning that active users did not experience a statistically significant change in systolic BP in the elevated BP category (Table 2). However, we observed a tendency toward decreased BP (P=.09).

The chi-squared test results (χ^2_1=5.311; P=.02) indicate a significant association between activity and systolic BP decrease. The active group had a higher proportion of participants who decreased systolic BP over 4 weeks by more than 5 mm Hg than the nonactive group.

Finally, based on the activity ratio, a logistic regression model was created to predict the likelihood of reducing systolic BP by 5 mm Hg or more over 4 weeks. The model showed that users with an activity ratio equal to or more than 0.75 had an almost 2 times greater chance of reducing systolic BP by 5 mm Hg or more over 4 weeks than users with an activity ratio less than 0.75 (odds ratio [OR] 1.932, 95% CI 1.074-3.528; Table 3).

Table 2. Systolic blood pressure results at baseline and 4 after weeks of use of the app.

Blood pressure category	Systolic blood pressure (mm Hg), mean (SD)			*P* value
	Week 1	Week 4	Difference	
Elevated				
Nonactive (n=107)	125.6 (2.88)	124.6 (9.58)	–1.06 (9.18)	.02
Active (n=18)	125.1 (3.21)	121.9 (7.85)	–3.18 (7.70)	.09
High				
Nonactive (n=93)	134.5 (2.87)	129.7 (11.32)	–4.79 (11.44)	<.001
Active (n=27)	134.5 (2.64)	127.1 (8.28)	–7.42 (8.71)	<.001
Very high				
Nonactive (n=81)	150.2 (10.33)	140.3 (14.22)	–9.91 (15.73)	<.001
Active (n=13)	146.2 (6.46)	134.0 (12.21)	–12.17 (12.22)	.006

Table 3. Logistic regression model predicting the likelihood of reducing systolic blood pressure by 5 mm Hg or more.

Variable	Coefficient	SE	*P* value	Odds ratio (95% CI)
Nonactive vs active	0.652	0.302	.03	1.932 (1.074 to 3.528)

Discussion

Principal Findings

The primary finding of this study is a potential association between the use of the Cardi.Health mobile app and a reduction in systolic BP. Across all participant groups, there was a discernible trend toward decreased BP associated with app use. Notably, among active users, engagement with the app was linked to a decrease in systolic BP of over 5 mm Hg during the 4-week period. Furthermore, the logistic regression model indicated that active users had nearly double the likelihood of experiencing a decrease in BP of 5 mm Hg or more (OR 1.932, 95% CI 1.074-3.528).

The use of mobile apps in the field of BP control has become increasingly popular in recent years. These apps provide a convenient and accessible way for individuals to monitor their BP levels on a regular basis. A recent randomized control trial (RCT) conducted by Gazit et al [6] showed promising results for further use of such apps. The use of a mobile app designed for improved BP control led to reductions in mean systolic BP of 7.2 (SE 0.4) mm Hg, 12.2 (SE 0.7) mm Hg, and 20.9 (SE 1.7) mm Hg in groups with elevated BP, stage 1 hypertension, and stage 2 hypertension, respectively, in comparison with baseline measurements. Additionally, the authors found that engagement with the app was associated with lower BP (131.2, 133.4, and 135.5 mm Hg for low-, medium-, and high-engagement groups, respectively; $P<.05$). On the other hand, in an RCT by Persell et al [17], there was no statistically significant difference between intervention and control groups when comparing BP differences after 6 months of intervention (–2 mm Hg, 95% CI –4.9 to 0.8; $P=.16$). However, the intervention group's self-confidence in controlling BP was statistically significantly higher (0.4 points on a 5-point scale, 95% CI 0.2-0.5; $P<.001$).

Our results show a similar trend and a possible relationship between app use and a decrease in BP. Users in all BP groups (except for the active elevated BP group, where the tendency was observed but was not statistically significant) statistically significantly lowered their BP during the time they used the app. Such results may be explained by the fact that mobile apps increase adherence to medication and diet, which was shown in a study by Bozorgi et al [18], who reported that mobile intervention increased treatment adherence by 5.9 points (95% CI 5.03-6.69) based on the Hill-Bone scale. Similar conclusions were drawn by 2 systematic reviews, whose authors found that mobile apps tend to increase adherence to medications and subsequently decrease BP [19,20].

It is worth mentioning that more engaged use was associated with a higher chance of reducing BP by 5 mm Hg or more in our study. We speculate that a few effects may be in play to explain such an observation. First, a mobile app for BP control can help increase awareness of one's BP levels, leading to better control [13]. Additionally, by allowing users to track and monitor their BP levels over time, mobile apps can offer users valuable insights into how their BP responds to various activities and medications throughout the day [21]. This can empower users to make informed decisions about their lifestyle choices and medication use, ultimately improving their ability to manage their BP. Finally, dedicated BP control apps can provide users with educational resources and support [22]. These resources can include tips for managing BP and information about lifestyle changes.

Limitations

As with all similar investigations, the retrospective nature of this study design may introduce the possibility of recall bias, where participants may not accurately remember or record all relevant information in the mobile app. Secondly, the study may be subject to selection bias, as the data were obtained from a self-selected group of mobile app users. This may limit the generalizability of the findings, as the study sample may not be representative of the broader population of individuals with high BP. Additionally, a significant limitation of our study is the requirement of payment to use the app. This creates a potential health equity issue, as it may inadvertently exclude individuals from lower socioeconomic backgrounds, who may not be able to afford the app. This is particularly concerning given that hypertension and other noncommunicable diseases disproportionately affect individuals from lower socioeconomic backgrounds. Therefore, our findings primarily represent individuals who can afford the app and may not be generalizable to the broader population. This limitation underscores the importance of considering affordability and accessibility when developing and implementing digital health interventions. Future research and intervention development should prioritize inclusivity and explore alternative funding models, such as subsidies or free versions with in-app purchases, to ensure that mobile health apps are accessible to a broader audience, thereby addressing health equity more thoroughly. Moreover, as the information we could obtain about the app users was limited, we faced challenges in establishing causality between mobile app use and BP control, as the data may not account for other factors that could influence BP control, such as medication adherence, lifestyle habits, and comorbidities. Furthermore, we are unable to confirm whether the users were using a clinically validated BP device. Most BP devices available on the market are not validated for clinical accuracy, which raises concerns about the accuracy and reliability of the BP data entered by the users. While the app provides recommendations and instructions about the proper techniques for self-measurements of BP, it does not have the capability to confirm the accuracy or validation status of the devices used by the users. This limitation raises the possibility that some of the BP data entered into the app may not be clinically accurate, which could potentially impact the findings and conclusions of this study. Finally, a significant limitation is the frequency of BP measurements, as the users were only required to enter their BP data at least once per week. This is inconsistent with clinical guidelines for self-monitoring of BP, which recommend a minimum of 3 days per week of BP measurements, and ideally, daily measurements to calculate the average for assessing significant BP changes or control [23]. This discrepancy may affect the accuracy and clinical relevance of the BP data collected and analyzed in our study.

Conclusions

Despite the increasing popularity of mobile app interventions and the increasing number of studies analyzing the results such apps generate, their results should be interpreted with a grain of salt. Considering all possible limitations, this study shows a possible relationship between Cardi.Health mobile app use and decreased BP. Additionally, engagement with the app may be related to better results—active users were associated with an almost 2-fold increase in the odds of reducing their BP by 5 or more mm Hg. An RCT will be initiated to test these results and provide more robust conclusions on the efficacy of the Cardi.Health app.

Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

JJ contributed to conceptualization, visualization, and original draft preparation. MN contributed to methodology and formal analysis. JJ and KA contributed to validation. JJ, SV, and MN contributed to investigation. KA contributed to resources, data curation, supervision, project administration, and funding acquisition. SV, KA, MN, and JJ contributed to review and editing of the manuscript. All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors except for JJ are Kilo.Health employees. The Kilo.Health administration had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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Abbreviations

AD: active day
BP: blood pressure
OR: odds ratio
RCT: randomized control trial
TT: total time

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Original Paper

Diagnostic Accuracy of Single-Lead Electrocardiograms Using the Kardia Mobile App and the Apple Watch 4: Validation Study

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Abstract

Background: To date, the 12-lead electrocardiogram (ECG) is the gold standard for cardiological diagnosis in clinical settings. With the advancements in technology, a growing number of smartphone apps and gadgets for recording, visualizing, and evaluating physical performance as well as health data is available. Although this new smart technology is innovative and time- and cost-efficient, less is known about its diagnostic accuracy and reliability.

Objective: This study aimed to examine the agreement between the mobile single-lead ECG measurements of the Kardia Mobile App and the Apple Watch 4 compared to the 12-lead gold standard ECG in healthy adults under laboratory conditions. Furthermore, it assessed whether the measurement error of the devices increases with an increasing heart rate.

Methods: This study was designed as a prospective quasi-experimental 1-sample measurement, in which no randomization of the sampling was carried out. In total, ECGs at rest from 81 participants (average age 24.89, SD 8.58 years; n=58, 72% male) were recorded and statistically analyzed. Bland-Altman plots were created to graphically illustrate measurement differences. To analyze the agreement between the single-lead ECGs and the 12-lead ECG, Pearson correlation coefficient (r) and Lin concordance correlation coefficient (CCC_{Lin}) were calculated.

Results: The results showed a higher agreement for the Apple Watch (mean deviation QT: 6.85%; QT interval corrected for heart rate using Fridericia formula [QTcF]: 7.43%) than Kardia Mobile (mean deviation QT: 9.53%; QTcF: 9.78%) even if both tend to underestimate QT and QTcF intervals. For Kardia Mobile, the QT and QTcF intervals correlated significantly with the gold standard (r_{QT}=0.857 and r_{QTcF}=0.727; P<.001). CCC_{Lin} corresponded to an almost complete heuristic agreement for the QT interval (0.835), whereas the QTcF interval was in the range of strong agreement (0.682). Further, for the Apple Watch, Pearson correlations were highly significant and in the range of a large effect (r_{QT}=0.793 and r_{QTcF}=0.649; P<.001). CCC_{Lin} corresponded to a strong heuristic agreement for both the QT (0.779) and QTcF (0.615) intervals. A small negative correlation between the measurement error and increasing heart rate could be found of each the devices and the reference.

Conclusions: Smart technology seems to be a promising and reliable approach for nonclinical health monitoring. Further research is needed to broaden the evidence regarding its validity and usability in different target groups.

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KEYWORDS

accuracy; electrocardiography; eHealth; mHealth; mobile health; app; applications; mobile monitoring; electrocardiogram; ECG; telemedicine; diagnostic; diagnosis; monitoring; heart; cardiology; mobile phone

Introduction

Digitalization and technological progress are extending to more and more areas of life, including the fitness and health care sectors. The number of digital apps for smartphones, fitness trackers, or smartwatches that allow users to assess and evaluate individualized fitness, health, and lifestyle data is constantly increasing [1]. With the release of the Apple Watch 4 as one of the first smartwatches to include electrocardiogram (ECG) function in 2018, smartphone-based systems that enable users to record single-lead ECGs on their own have become very popular [2]. Such devices are designed to help prevent cardiovascular diseases, for example, by identifying cardiac arrhythmia at an early stage and thereby preventing a stroke.

According to the German Stroke Foundation [3], around 270,000 people endure a stroke in Germany every year. This is why strokes and their health consequences are the third most common cause of death in Germany and even one of the most common causes of death worldwide [4]. In the age group of over 60 years, the quota of those affected amounts to almost 80% [3]. One of the reasons for this high mortality rate is, among other things, that cardiac arrhythmias such as atrial fibrillation are detected too late. This in turn might be due to the fact that atrial fibrillation can be asymptomatic and, therefore, is often unnoticed. In addition, it occurs only intermittently in many cases, which is also why it is difficult to detect. However, atrial fibrillation can increase the risk of enduring a stroke by up to 5 times [5]. In total, 15% to 20% of all strokes are due to this type of cardiac arrhythmia. This means that a stroke due to atrial fibrillation happens almost every 10 seconds [5]. Any cardiac arrhythmia can be detected by ECG diagnostics, and consequently, suitable and timely treatment by a doctor can prevent a stroke.

As stated, affordable compact devices for recording a single-lead ECG at home entered the market recently [6]. Unlike the conventional ECG, a diagnosis is no longer dependent on the symptoms to occur at the time of measurement in a doctor's office. Rather, a patient may notice symptoms such as tachycardia or shortness of breath and is able to carry out an ECG measurement immediately him- or herself.

Especially in sports science, the ECG is also one of the most important diagnostic tools in terms of the determination of the individual physical performance, the reproduction of loads, or the exclusion of contraindications referring to the cardiovascular system [7]. Hereby, it is important to distinguish athletes' usual training-related changes from unusual and nontraining-related potentially pathological abnormalities. For example, in endurance athletes, ECG changes in the form of sinus arrhythmias and sinus bradycardia are most common. Further, changes in the ventricular complexes or during repolarization, as well as earlier repolarization, can occur [8].

The 12-lead ECG is the current reference method ("gold standard") for recording cardiovascular parameters. Although the 12-lead ECG is used in clinical settings, its complex structure presents certain economic and practical limitations that need to be considered [9,10]. From a sports cardiological perspective, single-lead ECGs have the potential to be an alternative to the established 12-lead ECG. The improvement of wearable devices' measured value density and quality is the main reason for this assessment [11,12]. Comparably, compact single-lead ECGs for smartphones and smartwatches are much easier and more time-efficient to use by assessing all relevant heart (rate) parameters [13]. Although the manufacturers claim that this smart technology can be used in both clinical and nonclinical settings, less is known about the measurements' validity and reliability from a scientific perspective [14,15]. Therefore, we aimed to examine the measurements' accuracy of the Kardia Mobile App and the Apple Watch 4 in comparison to a 12-lead gold standard ECG. Aside, we analyzed whether the devices' measurement error correlates with an increasing heart rate.

Methods

Participants

Data collection took place in our laboratory. Participants were recruited via advertisement. In order to participate, individuals must be at least 18 years old and in good physical health. Persons with cardiovascular diseases were excluded from this study. In total, 100 adults took part, with 81 complete measurements that could be incorporated in the statistical analysis. The age of the sample ranged between 19 and 78 (mean 24.89, SD 8.58) years; of the 81 participants, 23 (28%) were female and 58 (72%) males.

Study Procedure

This study was designed as a prospective quasi-experimental 1-sample measurement, in which no randomization of the sampling was carried out. Each data collection began with the gluing of disposable electrodes to the chest and limbs and the cabling of the 12-lead ECG. If the signal was free of interference, a 10-second measurement was started in the lying position. After this successful reference measurement, the following measurement via the Kardia Mobile was carried out. Finally, the last measurement via the Apple Watch was conducted. This study's procedure respective measurement order as well as the lying position were the same for all subjects. To address the possibility of bias due to a consistent test order, several measurements were conducted as a pretest for the final study procedure. The design of this study is based on the recommendations for implementing validation studies of diagnostic devices [16,17].

Ethical Considerations

This study was conducted according to the guidelines of the Declaration of Helsinki and approved by the ethics committee of the University of the Bundeswehr Munich, Germany (June 4, 2018). Informed consent was obtained from all subjects participating in this study. This included comprehensive information about the course of this study, data storage and use, and possible health risks during or after the examination. Participants consented to the collection, storage, and analysis of their personal data. Each participant was given the opportunity to withdraw from this study at any time and for any reason. This includes the complete deletion of all data already collected from the participant and copies thereof unless they

have already been anonymized. No compensation of any kind was provided for participation in this study.

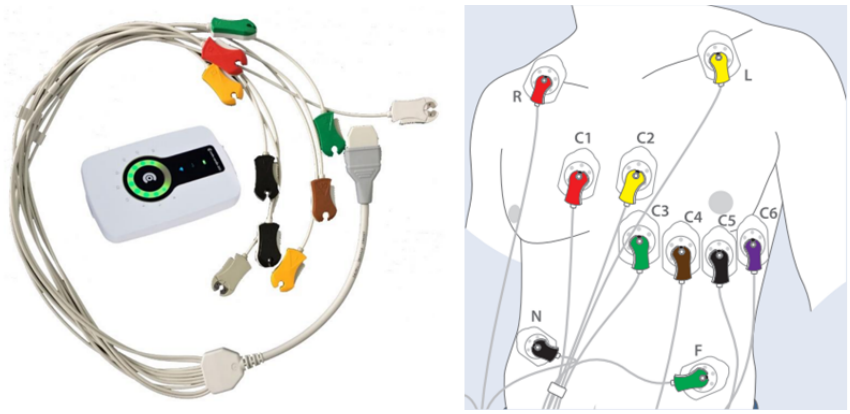
Materials

Custo Cardio 300

We used the Custo Cardio 300, a valid 12-lead ECG, as the reference device in our study (Figure 1) [18]. It is manufactured for medical centers and hospitals by the German company custo med GmbH and is linked to their foreign analysis software *custo diagnostic*.

The device records the individual's ECG via 12 leads comprising of 6 leads of the limbs (I, II, III, augmented vector left, augmented vector right, and augmented vector foot) and 6 leads of the chest wall (C_1, C_2, C_3, C_4, C_5, and C_6) [19]. Referring to Goldberger [20], the disposable electrodes for the limb leads were placed at the wrists and ankles. According to Wilson [21], the chest wall leads were placed as follows: C_1 in the fourth intercostal panel at the right side of the sternum, C_2 in the fourth intercostal panel at the left side of the sternum, C_3 between C_2 and C_4 on the fifth rib, C_4 in the fifth intercostal panel at the intersection with the left midclavicular line, C_5 at the same level as C_4 on the anterior axillary line, and C_6 at the same level as C_4 on the midaxillary line. The electrodes are connected to the ECG device by a 10-wire patient cable with colored clips. The integrated LED ring of the device provides visual information about the signal quality of each individual lead. If electrodes are not applied to the subject, the relevant LEDs light up red. If every lead is correctly applied, the corresponding LEDs light up green. The recording of the ECG can be started by either using the button on the device or setting it in manually via the software on the computer. Data can be transferred via Bluetooth, wireless local-area network, or USB port. When the 10-second-resting-ECG mode is completed, the recording is automatically ended, saved, aligned, and displayed in the software.

Figure 1. 12-lead ECG device Custo Cardio 300 (left) and placement of its disposable electrodes (right). ECG: electrocardiogram.



Kardia Mobile and Kardia App

The second device we used was the single-lead ECG Kardia Mobile combined with the associated app for any smartphone or tablet (Figure 2) [22]. Its manufacturer AliveCor is a medical device and artificial intelligence company that sells ECG hardware and software for mobile devices. The company is the first company that has US Food and Drug Administration (FDA) approval for a medical device accessory for the Apple Watch and pioneered the development of FDA-approved machine learning techniques. The Kardia Mobile was approved by the FDA in December 2012 and is Conformité Européene marked [13]. According to AliveCor, it is one of the most clinically validated mobile compact ECG on the market. The Kardia Mobile together with the Kardia app can record, display, and transmit a single-lead ECG. Its algorithm has been approved by the FDA solely for the analysis to detect atrial fibrillation and a normal sinus rhythm, although it also claims to indicate whether bradycardia or tachycardia is present. The device measures 8.2 cm (length) 3.2 cm (width) 0.35 cm (depth) with a weight of 18g (including a 3.0V, CR2016 battery). The 2 square stainless-steel electrodes comprise an area of 9cm^2. Via the supplied mounting plate, it can directly be attached to the back of the smartphone. With normal use, the device has an operating time of about 200 hours or 12 months and an estimated shelf life of 2 years.

To record an ECG, a smartphone or tablet running the Kardia app is needed. For the measurement, first, the "Record ECG" option in the app needs to be selected. Then, the index and middle fingers are placed on the electrodes of the device with the right hand on 1 electrode and the left hand on the other electrode. As soon as there is good contact with the electrodes, the app starts recording automatically. Kardia Mobile transmits the data wirelessly via ultrasound to the smartphone, displaying real-time heart rate as well as an ECG waveform similar to lead I of a 12-lead ECG. According to the manufacturer, the device should be at a distance of up to 30 cm from the smartphone or tablet. Normally, the recording lasts 30 seconds. Immediately after completion, an evaluation is available stating whether the ECG is within the normal range, it cannot be classified, atrial fibrillation is detected, or if the recording is unreadable. The app classifies the ECG as normal if the heart rate is between 50 and 100 beats per minute (bpm); none or only a few abnormal beats are present; and if form, timing, and duration correspond to a sinus rhythm. Finally, the Kardia app allows us to export the ECG as a PDF file in order to save and send it via email to the user oneself or his or her health care provider.

Figure 2. Recording of an ECG with the Kardia Mobile device connected to the Kardia App. ECG: electrocardiogram.

Apple Watch 4

As third, we used the *Apple Watch Series 4*, which is, without further gadgets, also able to record a single-lead ECG (Figure 3) [23].

For the ECG recording, an Apple Watch 4 or later running at least watchOS 5.2 as well as an iPhone running at least iOS 12.2 are needed. The device is the standard model and measures 4.0 cm (length) 3.4 cm (width) 1.07 cm (depth) with a weight of 30.01 g. It has a battery life of up to 18 hours. The required electrodes for the ECG are integrated with the so-called "Digital Crown," for example, the small rotary knob on the side and on the back of the watch. By touching the Digital Crown with the index finger of the other hand, the circuit between the heart and the arms is closed so that the electrical impulses of the heart can be measured, comparable to lead I according to Einthoven [23]. The Apple Watch's ECG provides information on heart rate and heart rhythm and, thus, enables the classification of sinus rhythm and atrial fibrillation. Unlike the automatic heart rhythm monitoring several times a day via the optical pulse sensor, the ECG function must be actively started. Meanwhile, the 30 seconds of recording, a typical ECG curve, a countdown, and the heart rate are displayed on the watch. Afterward, a classification is apparent, and the data are directly transmitted to the app on the smartphone. In line with the Kardia Mobile, the ECG is classified as normal if the heart rate is between 50 and 100 bpm and a stable sinus rhythm could be detected. The results of the ECG recording can be viewed via the health app on the smartphone or exported as a PDF file.

Figure 3. Single-lead ECG Apple Watch 4. BPM: beats per minute; ECG: electrocardiogram.

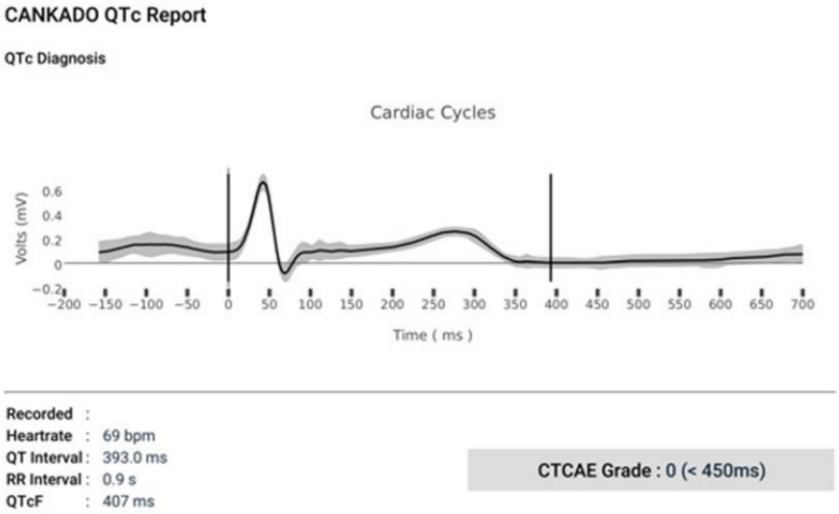
Data Analysis

Data Export

We exported the recordings of the 12-lead ECG via the custo diagnostic software. As this PDF export already provides all relevant parameters such as QT, QT interval corrected for heart rate using Fridericia formula (QTcF) intervals, and heart rate, no further data processing was required. The QT interval comprises the time from the start of the Q wave to the end of the T wave. Based on Fridericia formula [24], the heart rate corrected QT interval (QTc) can be determined [25]. The data export of the compact single-lead ECGs was similar for both devices. Besides the heart rate and the classification of the ECGs, the created PDFs also comprised the 30-second recording only as a graph with a waveform comparable to a lead I ECG. Therefore, it was necessary to calculate the QT and QTcF intervals from these graphical ECG waves with the help of appropriate software. Hereby, we used the Beta version of the

app *QTc Tracker* by CANKADO GmbH, which is specially designed to extract data from single-lead ECGs. The app's algorithm is the winning algorithm of the "2017 PhysioNet/CinC Challenge" [26]. The app matches all data points of 1 measure and averages them as an ECG curve while deviating data points are presented as gray area around the averaged curve (Figure 4) [27]. Furthermore, the program suggests the beginning and the end of the QT interval, which can be manually corrected if needed. If both markers have been set, it finally calculates the RR, the QT, and the QTcF intervals. The QTc Tracker's output function is limited to the parameters mentioned, preventing the evaluation of other ECG parameters such as the P wave or ST segment. A first description and examination of the QTc Tracker in the oncological routine has recently been published [28].

Figure 4. ECG Analysis via QTc Tracker. The algorithm of the QTc Tracker is based on Fridericia formula, which calculates the quotient from the QT interval and the cube root of the RR interval (QT/(RR) 1/3). CTCAE: Common Terminology Criteria for Adverse Events; ECG: electrocardiogram; QTc: QT interval corrected for heart rate.



Statistical Analysis

Statistical Analysis was carried out using the data processing programs Microsoft Excel and SPSS (version 27; IBM Corp). After the descriptive analysis, we first graphically analyzed the agreement between the single-lead and the reference ECG via Bland-Altman plots [29,30]. The x-axis is the mean of both devices, and the y-axis represents the 12-lead minus the single-lead ECG with the line of equality (LoE) plotted at zero. The dotted lines (LoA [limit of agreement]) are 1.96 SDs from the mean, and the thin lines are the 95% CI of the mean. Second, to examine the correlation between the devices, we calculated Pearson correlations and interpreted the results according to Cohen [31]. The level of significance was set a priori at $\alpha<.05$. However, the Pearson correlation coefficient does not consider the location shift (parallel shift of the degrees of regression compared to the bisecting line) nor the scale shift (rotation of the regression line so that it has a different slope than the bisecting line), and further allows no conclusion about the intraindividual concordance (agreement of measured values of the same person) [32]. Therefore, third, we calculated Lin concordance correlation coefficient (CCC_{Lin}) as it includes both aspects. CCC_{Lin} weights the correlation coefficient r according to Pearson with a correction term that, including mean and SD, corresponds to the deviation from the bisecting line (see equation 1 below) [33]. The results were classified in addition to Cohen κ [34]. If the ECG devices were completely in agreement, both the location and scale shift (accuracy) would be 0, and the precision (correlation) $r=1$, that is, $CCC_{Lin}=1$. Mathematical formula for CCC_{Lin} is as follows:

(1)

Results

Descriptive Analysis

We included the heart rate and QT and QTcF intervals in our analysis. Referring to the 12-lead ECG, the participants heart rate ranged between 38 and 98 (mean 66.44, SD 11.52) bpm. Descriptive statistics of QT and QTcF are presented in Table 1. The mean QT interval of the 12-lead reference device was 387.89 (SD 27.1) ms. On average, the Kardia Mobile deviated 37.27 ms from the reference, which was up to 9.53% (SD 3.62%) mean deviation. The Apple Watch differed on average by 25.89 ms, which was with 6.85% (SD 4.02%), a smaller mean deviation. Regarding QTcF, the reference device measured 399.09 (SD 18.2) ms while both single-lead ECGs assessed shorter interval durations. The Kardia Mobile differed on average by 39.04 ms, which means a 9.78% (SD 3.76%) deviation. The Apple Watch differed on average by 29.52 ms, which means with 7.43% (SD 4.17%), a smaller deviation from the reference device. Taken together, the single-lead ECGs tend to underestimate both the QT as well as the QTcF intervals compared to the 12-lead gold standard.

Table 1. Descriptive statistics of QT and QTcF[a] intervals. Quasi-experimental 1-sample measurement with no randomization (81 healthy adults; mean age 24.89, SD 8.58 years). Norm values for QT range between 350 and 400 ms; QTcF values should be <450 ms (men) and <460 ms (women) [25].

Device	QT (ms)			QTcF (ms)		
	Value, mean (SD)	Value, range	Deviation (%), mean (SD)	Value, mean (SD)	Value, range	Deviation (%), mean (SD)
Custo Cardio 300	387.89 (27.17)	325-478	—[b]	399.09 (18.16)	360-445	—
Kardia Mobile	350.62 (26.53)	296-440	9.53 (3.62)	360.05 (22.00)	313-411	9.78 (3.76)
Apple Watch 4	362.00 (27.17)	303-474	6.85 (4.02)	369.57 (22.11)	323-417	7.43 (4.17)

[a]QTcF: QT interval corrected for heart rate using Fridericia formula.

[b]Not available.

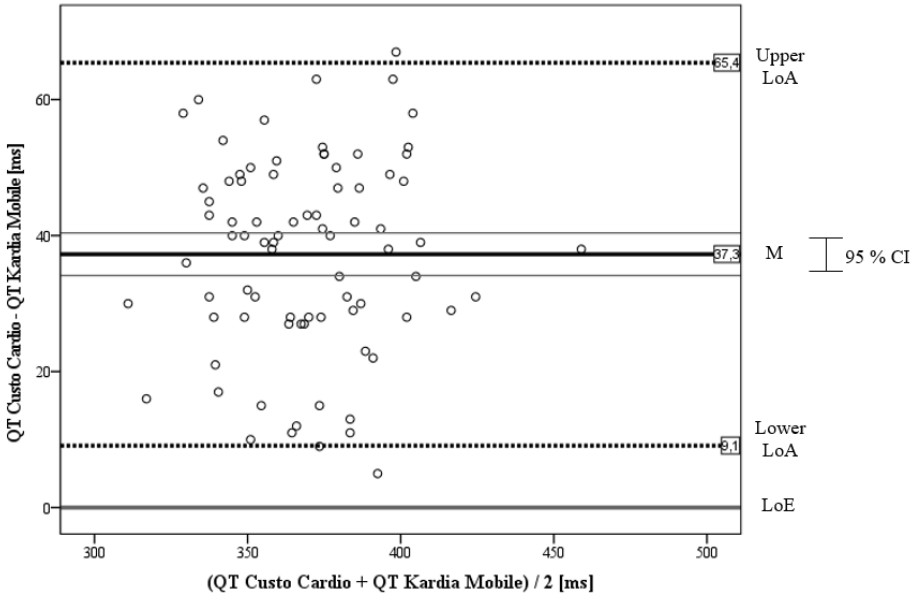
Agreement Between Kardia Mobile and 12-Lead Gold Standard ECG

QT interval

For the inferential statistical analysis, we first created a Bland-Altman plot to gain graphical knowledge about the agreement between the Kardia Mobile and Custo Cardio (Figure 5). The mean difference of QT intervals of both ECGs was mean 37.3 (SD 14.4) ms, which is above the LoE. As the LoE is outside the CI of the mean difference, the bias can be considered significant. Furthermore, the LoE lies outside the LoAs, which are SD 28.2 ms around the mean difference. Obviously, there is also 1 outlier above and 1 below the LoAs. In sum, all values are above the LoE; so, it can be concluded that the Kardia ECG tends to systematically underestimate the QT interval compared to the reference device. Finally, as the scatter in the graph is consistent, there seems no discernible trend in relation to the amplitude of the QT interval.

When correlating the measures of both devices, we found a significant positive agreement of r=0.857 (P<.001). This result was strengthened by the calculation of CCC_{Lin}=0.835, which also can be interpreted as almost perfect agreement between the Kardia Mobile and the 12-lead reference.

Figure 5. Bland-Altman plot for QT interval of Kardia Mobile versus Custo Cardio. LoA: limit of agreement; LoE: line of equality; M: mean.

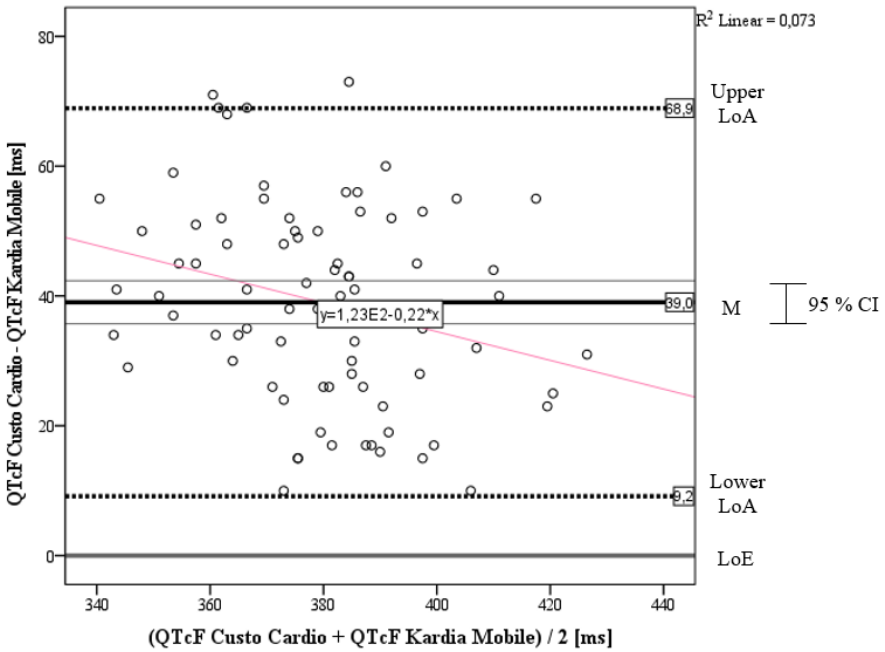


QTcF Interval

The Bland-Altman plot for the QTcF interval comparing the Kardia Mobile and Custo Cardio graphically showed an obvious deviation, although nearly all values are within the LoAs (Figure 6). The average difference of the QTcF intervals of the ECGs was mean 39.0 (SD 15.3) ms, which is above the LoE. Again, the bias can be considered significant as the LoE is outside the CI of the mean difference. The LoE also lies outside the LoAs, which are SD 34.3 ms around the mean difference. Notably, all values are positive and none comes close to the LoE. The scatter seems to increase in the low and high range of QTcF intervals. In sum, it can be concluded that the Kardia Mobile seems to systematically underestimate QTcF intervals compared to the 12-lead reference. Furthermore, we found a slight trend in dispersion, indicated by the pink regression line, whereby the deviation seems to decrease with increasing QTcF interval.

When correlating the measures of both devices, we found a significant positive agreement of r=0.727 (P<.001). This result was strengthened by the calculation of CCC_{Lin}=0.682, which also can be interpreted as strong agreement between Kardia Mobile and the 12-lead reference.

Figure 6. Bland-Altman plot for QTcF interval of Kardia Mobile versus Custo Cardio. LoA: limit of agreement; LoE: line of equality; M: mean; QTcF: QT interval corrected for heart rate using Fridericia formula.



Measurement Error

In addition to the accuracy of the measurements, we tested whether the deviation of the compact ECG increased with increasing heart rate. Therefore, we computed the deviation as a quotient subtracted from 1 and correlated it with the heart rate. For QT intervals, we found a small negative but significant effect of r=–0.291 (P<.01), while for QTcF intervals, the effect was even smaller and not significant (r=–0.181; P>.05). Thus, the hypothesis that the deviation of the measurement error of the Kardia Mobile might increase with increasing heart rate could be disclaimed for both QT and QTcF intervals.

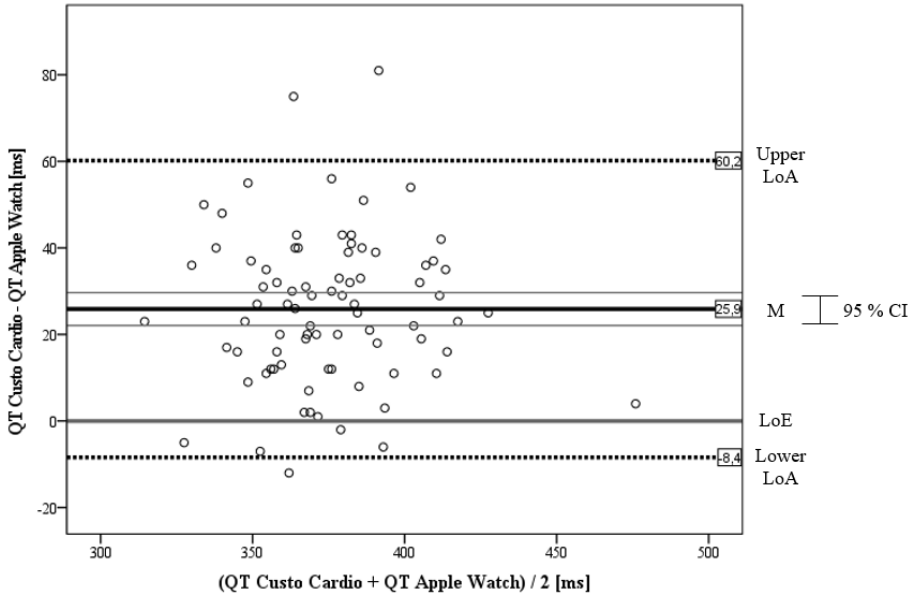
Agreement Between Apple Watch and 12-Lead Gold Standard ECG

QT Interval

Also, for the Apple Watch, we began the inferential statistics with the graphical analysis via the Bland-Altman plot for QT intervals comparing the Apple Watch with Custo Cardio (Figure 7). On average, the difference of the ECGs was mean 25.9 (SD 17.5) ms, which is above the LoE. Here, the bias is apparently smaller than the one of the Kardia Mobile but can also be considered significant as the LoE is outside the CI of the mean difference. In contrast to the Kardia Mobile, the LoE is within the LoAs, which are SD 34.3 ms around the mean difference. Although the range of the LoAs is the highest, a total of 3 outliers could be identified in the figure. Unlike the Kardia ECG, not all values are above the LoE and 5 values are negative. Another difference is the plotting of some values near the zero line, which indicates their approximate agreement. Nevertheless, in sum, it can be concluded the Apple Watch also tends to systematically underestimate the QT intervals compared to the 12-lead reference. Finally, as the scatter in the graph is consistent, there seems to be no trend in relation to the amplitude of the QT interval.

When correlating the measures of both devices, we found a significant positive agreement of r=0.793 (P<.001). This result was strengthened by the calculation of CCC_{Lin}=0.779, which also can be interpreted as almost perfect agreement between the Apple Watch and the 12-lead reference.

Figure 7. Bland-Altman plot for QT interval of Apple Watch versus Custo Cardio. LoA: limit of agreement; LoE: line of equality; M: mean.

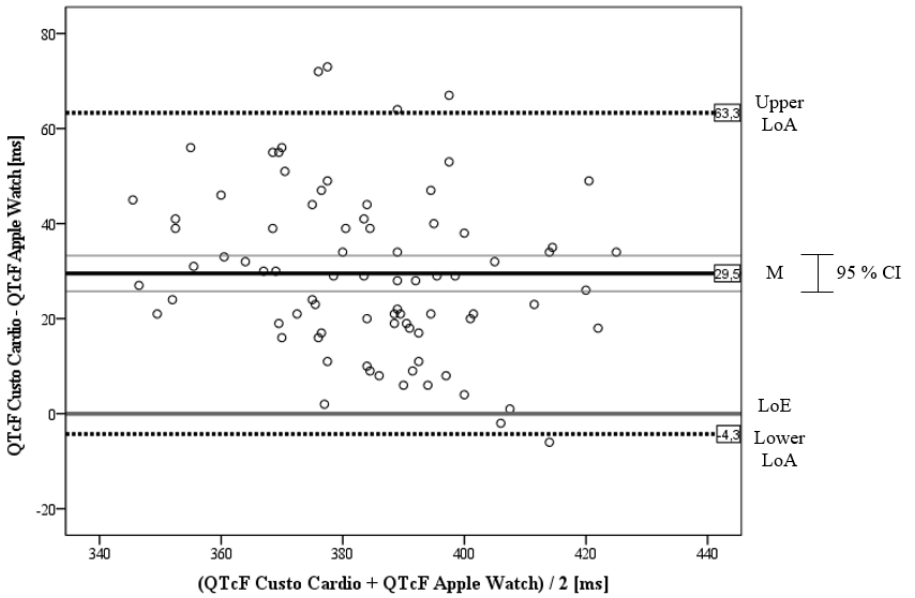


QTcF Interval

The Bland-Altman plot for the QTcF interval comparing the Apple Watch and Custo Cardio showed an obvious deviation with some values outlying LoAs (Figure 8). The mean difference of the ECGs was mean 29.5 (SD 17.2) ms, which is above the LoE. As the LoE is outside the CI of the mean difference, the bias can be considered significant. Although the deviation is clearly visible, the LoE is within the LoAs, which are SD 33.8 ms around the mean difference and are similar to the LoAs of the QT interval. There are 4 outliers above the upper LoA and 1 below the lower LoA. Except for 2 values, all values are above the LoE. The few values touching the LoE reached the highest agreement. In sum, it can be concluded that the Apple Watch systematically underestimates the QTcF intervals compared to the 12-lead reference. Again, as the scatter is consistent, there seems to be no trend related to the amplitude of the QTcF interval.

When correlating the measures of both devices, we found a significant positive agreement of r=0.649 (P<.001). This result was strengthened by the calculation of CCC_{Lin}=0.615, which also can be interpreted as a strong agreement between the Apple Watch and the 12-lead reference.

Figure 8. Bland-Altman plot for QTcF interval of Apple Watch versus Custo Cardio. LoA: limit of agreement; LoE: line of equality; M: mean; QTcF: QT interval corrected for heart rate using Fridericia formula.



Measurement Error

Regarding the measurement error in correlation with increasing heart rate, again, some very small effects could be calculated. For QT intervals, we found a negative significant effect of r=–0.289 (P<.01), while for QTcF intervals, the effect was a little smaller but also negatively significant (r=–0.231; P<.05). Thus, when relying on the small, but observable, statistical significance, a relationship between the increasing deviation of

the measurement error of the Apple Watch by increasing heart rate seems possible.

Discussion

Principal Findings

This study aimed to validate mobile single-lead ECGs compared to the 12-lead gold standard. Basically, standard QT measurement uses the longest QT interval of the 12-lead ECG. This is mostly lead II. The single-lead ECG of the Kardia Mobile and the Apple Watch are obtained in a somewhat different position. However, referring to Salvi et al [35], an alternative lead can be used, that is, if lead II is not available. Lead I seems appropriate for determining the QT interval.

According to our findings, the ECG of the Kardia Mobile differed in the measured QT as well as QTcF intervals by an average of less than 10% from the reference device. The deviations in both parameters could be seen clearly in the Bland-Altman plots. Thus, the Kardia Mobile tended to systematically underestimate both parameters. While there was no discernible trend in the magnitude of the difference in the QT interval, the underestimation seemed to decrease slightly with increasing QTcF time. The measured QT values correlated significantly and strongly positive with each other and also showed an almost perfect agreement to the Lin correlation coefficient. The calculated QTcF values generally showed a somewhat lower correlation and a slightly larger deviation compared to the reference device. Further, the correlation was numerically lower but can still be interpreted as a strong agreement, that is, based on our results it can be assumed that the Kardia Mobile measures concordantly when compared to the 12-lead reference device.

However, relating this finding to the current state of research seems problematic as most of the studies examine the general sensitivity (true positive) and specificity (true negative) of the diagnosis of atrial fibrillation but not the measurement accuracy of the different parameters themselves. The sensitivity of the detection of atrial fibrillation ranges from 54.5% to 100%, with most studies calculating values of >87% [36,37]. In 2019, the National Institute for Health and Care Excellence examined in a review comprising 9 studies the accuracy of 4 single-lead ECGs (Kardia Mobile, imPulse, MyDiagnostick, and Zenicor-ECG) [38]. All devices were tested for their sensitivity and specificity of detecting atrial fibrillation. In total, the devices reached a pooled sensitivity of 90.8% (95% CI 83.8%-95%) and a pooled specificity of 95.6% (95% CI 89.4%-98.3%). The validity of Kardia Mobile has been confirmed by 4 studies in this review. It gained a pooled sensitivity of 94% (95% CI 85.1%-97.7%) and a pooled specificity of 96.8% (95% CI 88%-99.2%). The single-lead ECGs also have an algorithm that enables them to deduce diagnostic suggestions. The accuracy of this algorithm was reviewed in the paper of National Institute for Health and Care Excellence [38], too. Here, a sensitivity of 88% (95% CI 32.3%-99.1%) and a specificity of 97.2% (95% CI 95.1%-98.5%) was found for the Kardia Mobile. However, future studies are needed, as the evidence of the available studies is not sufficient for recommending the routine adoption of single-lead ECG devices for atrial fibrillation detection [38]. According to Hnatkova et al [39], the differences that are still tolerable for the clinical context are SD 15 ms. In our study, the Kardia Mobile excelled this cutoff by more than twice. However, in sports science or in general in nonclinical conditions, setting such high standards as in the clinical context is obsolete. Suitable reference values, that is, to what extent deviations are still within the tolerance range and from when the measurement difference is too high to obtain usable results, should be developed. Another aspect that affects the usability of such devices is their manageability. We experienced problems in approximately 20% (16/81) of the measurements with the Kardia Mobile. Often the measurements were interrupted due to a lack of connection, so several trials were necessary wherein the finger position or the contact pressure was varied. Furthermore, the Kardia Mobile has no display of its own and can only be used together with a smartphone, which in turn needs to be close to the ECG device. Contrary to the manufacturer's claimed 30-cm distance, according to our own experiences, a distance of 10 cm to the smartphone should not be exceeded. Especially in a lying position, it is problematic to find an optimal positioning of the ECG in which no artifacts due to little finger muscle contractions occur. We suggest sitting at a table for the measurement, but we were unable to do so for the sake of a standardized comparison of measurement methods in this study. When looking at the Apple Watch, we also found a difference in both parameters from the reference device. Compared to the Kardia Mobile, this corresponds to a smaller deviation of approximately 28% for QT and 24% for QTcF intervals. However, the ECG of the Apple Watch tends to underestimate the assessed parameters, too. Again, compared to the Kardia Mobile, the Bland-Altman plots showed an about 10 ms lower but still considerable difference. These differences were also significantly higher than the clinically tolerable deviation of 15 ms. Unlike the Kardia Mobile, some of the differences were negative values, and also, some of them could be plotted near the zero line, which in turn refers to a higher agreement. In both cases, no trend in the scatter in terms of a possible time dependency could be found. Regarding the correlation with the reference device, a strong significant effect was computed. In line with the Lin concordance coefficient, the Apple Watch's ECG agreed almost perfectly with Custo Cardio's ECG, although correlations were numerically smaller than those of the Kardia Mobile.

Discussing these findings from the Apple Watch with respect to the current state of the literature is even more difficult than from the Kardia Mobile, as barely any representative studies about the smartwatch's validity exist. The only representative study was sponsored by Apple [40]. Accordingly, the sensitivity of 98.3% and specificity of 99.6% postulated by Apple should be seen critically, since these calculations exclude all ambiguous and nonclassifiable values. If these values were included, the sensitivity would be 90.5% and the specificity 85.2%, which differs significantly from the values primarily mentioned. Regarding Apple's ECG algorithm, a sensitivity of 95.5% and a specificity of 97.1% was calculated [40]. Thus, also here, suitable reference values for classifying the range of deviation and their tolerance limits are missing and should be considered in future studies. The German Cardiac Society [41] has described the Apple Watch's ECG function as "a valuable

monitoring tool for establishing important information for patients and their doctors." However, they have also pointed out that results should be attested by experienced health care providers. As single-lead ECGs are somewhat concordant but do not become 100% close to the 12-lead medical standard, those recordings are not able to replace the visit at the doctor's office, especially in patients with preexisting cardiovascular illness [41].

Furthermore, the aspect of manageability should also be addressed at this point. In about 5% (4/81) of the trials, we had a few problems when recording an ECG with the Apple Watch, so the measurements failed. In significantly more cases (12/81, 15%), difficulties occurred when lying down to find an adequate arm position in which the ECG is not triggered by action potentials of muscle contractions. Again, it is advisable to carry out the measurement at a table in a seated position in order to provide support for the arms. Contrary to the Kardia Mobile, the Apple Watch can record the ECG without a smartphone connection. The visual representation on the watch is simple and easy to understand.

The question of whether the measurement error of the compact ECGs increases with increasing heart rate cannot be denied in total. For all parameters, both for the Kardia Mobile and for the Apple Watch, we found negative correlations with a weak effect. Except for the QTcF time of the Kardia Mobile, the results were also significant. However, it should be kept in mind that most of the participants were young and athletic, which can have an impact on their heart rate.

Overall, compact single-lead ECG devices, for example, for the smartphone or the smartwatch, seem to be a good alternative to the previous standard 12-lead ECGs in terms of algorithmic detection of atrial fibrillation and imaging of the ECG wave [42,43]. Furthermore, the advantage is that the ECG recording need not take place in the doctor's office. Further, it can easily be sent as a PDF file via an email requesting for evaluation by a specialist personnel. While AliveCor has already conducted few studies regarding the validity of their ECG products, less is known about the Apple Watch's validity for ECG recording. For example, on the website of AliveCor, a clinical research section with various peer-reviewed papers is available [44]. The problem with many of these studies, however, is that they refer to an "AliveCor device," which is often not specified in more detail. AliveCor has several ECG-enabled devices on the market such as the Kardia Mobile, the Kardia Mobile 6L, or the Kardia Band for the Apple Watch. Thus, it is unclear in which study which of the devices were proven for their accuracy and usability. As described above, the only validation study of the Apple Watch's ECG was sponsored and commissioned by Apple [40]. To our knowledge, another representative validation of the device in its ECG function is not available. Thus, further empirical research is needed.

Given the fact that the available consumer technology is proceeding rapidly, the number of smartphone apps and gadgets for recording, visualizing, and evaluating physical performance as well as health data is constantly growing. The greatest effort of such smart devices as the ones used in this study is that they are innovative, reliable, and time- and cost-efficient. Although the mobile compact ECGs seem not to fulfill the validity criteria as medical or clinical diagnostic device, they have a high practical usage potential. The most beneficial or practical use of this new health technology is to be found in home-based health care, especially in terms of cardiovascular disease prevention and health monitoring in everyday life. This is in line with the findings of the increasing number of studies examining the effects of mobile health interventions [45,46]. Finally, some could assume that the role of artificial intelligence systems in health technology (such as the QTc Tracker app used here) will also be greatly increased in the future [47].

Limitations

There are some constraints limiting our study. As only healthy and mainly young adults took part in this study, the results might be to some extent limited and not generalizable. Further, we assessed the individuals' ECGs comprehensively but did not include parameters such as the P- or T-wave in our analysis. Therefore, future studies should investigate these parameters as well as the measurement error in dependence on the pulse rate. Further, clustering participants according to a pulse range or to age groups would be interesting. We validated the mobile ECGs in a lying, resting position. Regarding their practical usability, comparable measurements during or after exercising are required. Finally, from a methodological perspective, it should be mentioned that the observed correlations and their statistical significance are limited. Although high correlations are positive findings, they do not necessarily indicate high test accuracy. In line with previous research, we relied on Cohen classification, but his suggestions on acceptable correlations and effect sizes were based on his research in the social sciences, that is, when assessing physiological functions or bioelectrical signals where the value of correlations is discussable. Furthermore, there is a potential bias from multiple comparisons. The most useful and informative data to rely on when determining acceptability of the testing mechanisms rather seem to relate to the Bland-Altman plots. Thus, with regard to a comprehensive methodological and analytical approach as well as in order to strengthen the measurements' concordance, the combination of correlative or regressive with Bland-Altman analyses is recommended.

Conclusions

In medicine and science, 12-lead ECGs are the gold standard for cardiovascular diagnostics. As their usability is quite extensive and, beyond that, the technological progress offers smart time- and cost-efficient tools, consumers prefer mobile ECGs in nonclinical conditions. In this study, we thus validated the single-lead ECGs of the Kardia Mobile and the Apple Watch 4. Besides single-digit deviation from the 12-lead reference, concordant ECGs were recorded. To conclude, mobile compact ECGs are an innovative and reliable approach, especially in terms of cardiovascular disease prevention and health monitoring in everyday life. However, to date, they seem not to fulfill the validity criteria as a medical or clinical diagnostic device.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

LG and AS conceptualized this study; LG conducted the investigation and was in contact with participants; LG and TS curated the data; KK and LK carried out statistical analysis and further wrote the original draft; and AS reviewed and edited the writing. All authors read and approved the final paper.

Conflicts of Interest

TS is the owner and managing director of CANKADO GmbH. The other authors declare that they have no conflicts of interest.

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Abbreviations

bpm: beats per minute
CCCLin: Lin concordance correlation coefficient
ECG: electrocardiogram
FDA: Food and Drug Administration
LoA: limit of agreement
LoE: line of equality
r: Pearson correlation coefficient
QTc: QT interval corrected for heart rate
QTcF: QT interval corrected for heart rate using Fridericia formula

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Original Paper

Guideline-Based Cardiovascular Risk Assessment Delivered by an mHealth App: Development Study

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Abstract

Background: Identifying high-risk individuals is crucial for preventing cardiovascular diseases (CVDs). Currently, risk assessment is mostly performed by physicians. Mobile health apps could help decouple the determination of risk from medical resources by allowing unrestricted self-assessment. The respective test results need to be interpretable for laypersons.

Objective: Together with a patient organization, we aimed to design a digital risk calculator that allows people to individually assess and optimize their CVD risk. The risk calculator was integrated into the mobile health app HerzFit, which provides the respective background information.

Methods: To cover a broad spectrum of individuals for both primary and secondary prevention, we integrated the respective scores (Framingham 10-year CVD, Systematic Coronary Risk Evaluation 2, Systematic Coronary Risk Evaluation 2 in Older Persons, and Secondary Manifestations Of Arterial Disease) into a single risk calculator that was recalibrated for the German population. In primary prevention, an individual's heart age is estimated, which gives the user an easy-to-understand metric for assessing cardiac health. For secondary prevention, the risk of recurrence was assessed. In addition, a comparison of expected to mean and optimal risk levels was determined. The risk calculator is available free of charge. Data safety is ensured by processing the data locally on the users' smartphones.

Results: Offering a risk calculator to the general population requires the use of multiple instruments, as each provides only a limited spectrum in terms of age and risk distribution. The integration of 4 internationally recommended scores allows risk calculation in individuals aged 30 to 90 years with and without CVD. Such integration requires recalibration and harmonization to provide consistent and plausible estimates. In the first 14 months after the launch, the HerzFit calculator was downloaded more

than 96,000 times, indicating great demand. Public information campaigns proved effective in publicizing the risk calculator and contributed significantly to download numbers.

Conclusions: The HerzFit calculator provides CVD risk assessment for the general population. The public demonstrated great demand for such a risk calculator as it was downloaded up to 10,000 times per month, depending on campaigns creating awareness for the instrument.

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KEYWORDS

cardiovascular disease; cardiovascular risk assessment; HerzFit; mobile health app; mHealth app; public information campaigns; prevention; risk calculator; mobile phone

Introduction

Cardiovascular disease (CVD) risk is mostly driven by modifiable risk factors such as hypercholesterolemia, arterial hypertension, diabetes mellitus (DM), and smoking. An unhealthy lifestyle favors many of these risk factors and is therefore deemed to play a major role in CVD. Thus, the promotion of a healthy lifestyle and the effective treatment of modifiable risk factors are essential for CVD prevention [1]. In reality, however, many people are unaware of opportunities to improve their health and life expectancy. Identifying these individuals at risk and ensuring CVD prevention remains challenging. Systematic screening programs might offer a solution for this problem. However, such programs tend to be expensive and have inconsistent clinical outcomes [2,3]. Self-identification of modifiable risk factors could increase the awareness of health risks. Digital applications, including mobile health (mHealth) apps, could play a role in this regard by providing risk assessment software. In recent years, web-based cardiovascular risk calculators demonstrated great public interest [4]. Clinical validity and understandability have been shown to be critical for the usefulness of such tools. Most of the available web-based calculators base their prediction on well-validated 10-year CVD risk scores [5]. As absolute risk percentages have been found to be difficult to understand for laypersons, calculators presenting a heart age instead have become increasingly popular worldwide [6-9]. These calculators compare the individual risk level to the average risk level. The individual heart age matches the age of a person with the same predicted risk but with average levels of modifiable risk factors [10,11]. If the cardiovascular risk is increased, the estimated heart age exceeds the chronological age. The potential loss of life years is intended to motivate users to better control their risk factors and to adhere to a healthier lifestyle [9]. Simple risk scores such as the Framingham Risk Score (FRS) for 10-year risk of CVD have been shown to be capable of identifying at-risk individuals and can be used for such self-assessment tools [5,12]. As the FRS covers risk only for primary prevention in an age spectrum from 30 to 74 years, other scores are needed to cover a wider age range as well as individuals with previous CVD events. Finally, these scores come from different regions such that the application in a specific region requires recalibration. Here, we report the development of a risk calculator for self-assessment recalibrated to the German population and usable for a wide range of age groups in both primary and secondary prevention.

Methods

Overview

The HerzFit risk calculator was developed together with the Deutsche Herzstiftung eV (German Heart Foundation), which is the largest nonprofit and independent patient advocacy group in the field of heart disease in Europe (>100,000 members). The scientific basis of the risk calculator, including the selection of risk scores, was determined together with the scientific advisory board of the German Heart Foundation. Ideas for the practical implementation of the risk calculator, including its communication strategy, were developed together with representatives of the potential target group. These were invited to an interdisciplinary workshop together with our team of physicians from the German Heart Center Munich, medical informaticians from the Technical University of Munich, representatives of the German Heart Foundation, and app designers.

CVD Risk Assessment

The HerzFit risk calculator provides CVD risk assessment for both primary and secondary prevention. For people without known atherosclerotic disease, the European Society of Cardiology Systematic Coronary Risk Evaluation 2 (SCORE2; applicable to individuals aged 40-69 years) and SCORE2–Older Persons (SCORE2-OP; applicable to individuals aged 70-89 years) models for moderate-risk regions were used. The SCORE2 models base their age-specific, sex-specific, and risk region–specific estimations on systolic blood pressure (SBP), smoking status, and cholesterol levels. The SCORE2-OP version additionally considers DM as a predictor [13,14]. For younger people (aged <40 years), a recalibrated version of the original FRS for 10-year risk of CVD was applied. In addition to age and sex, the FRS uses SBP, antihypertensive treatment, smoking status, diabetic status, and cholesterol levels as predictors [11]. Recalibration was performed by calculating the baseline survival and mean risk factor values from a Bavarian population–based cohort study (Cooperative Health Research in the Region Augsburg, KORA-S4) [15]. All 3 scores predict the 10-year CVD risk.

The FRS defines CVD as coronary artery disease (CAD; coronary death, myocardial infarction, coronary insufficiency, and angina), cerebrovascular events (ischemic stroke, hemorrhagic stroke, and transient ischemic attack), peripheral arterial disease (PAD; intermittent claudication), and heart failure [11]. SCORE2 and SCORE2-OP define CVD as the

composite of cardiovascular mortality (including death because of CAD, heart failure, stroke, and sudden death), nonfatal myocardial infarction, and nonfatal stroke [13,14]. In contrast to the FRS and SCORE2-OP model, the SCORE2 model does not consider the DM as a predictor. Therefore, the FRS is used for all diabetics <70 years of age. The models, their predicted outcomes, and the parameters used are highlighted in Table 1. If users were not aware of their SBP or cholesterol levels, age- and sex-specific mean values were used instead. These mean values were derived from the Bavarian KORA-FF4 cohort.

Table 1. Risk scores used in the HerzFit risk calculator[a].

	Origin	Age range used in HerzFit (years)	Predictors	Predicted outcome	Special points
Framingham Risk Score[b] [11]	United States	30-39[c]	• DM[d] • Smoking • SBP[e]+BP[f] treatment[g] • TC[h]+HDL-C[i]	10-year risk of CVD[j]	Recalibrated to the Bavarian population [15].
SCORE2[k] [13]	Europe	40-69	• Smoking • SBP • TC+HDL-C	10-year risk of CVD	Version for moderate-risk region is used.
SCORE2-Older Persons [14]	Europe	70-89	• DM • Smoking • SBP • TC+HDL-C	10-year risk of CVD	Version for moderate-risk region is used.

[a]All 3 risk scores base their risk estimation on sex and age.

[b]Framingham Risk Score for 10-year risk of cardiovascular disease.

[c]For individuals with diabetes, the Framingham Risk Score ranged from 30 to 69 years.

[d]DM: diabetes mellitus.

[e]SBP: systolic blood pressure.

[f]BP: blood pressure.

[g]Denotes antihypertensive treatment.

[h]TC: total cholesterol.

[i]HDL-C: high-density lipoprotein cholesterol.

[j]CVD: cardiovascular disease.

[k]SCORE2: Systematic Coronary Risk Evaluation 2.

For individuals who already had a CVD event, the 10-year risk of recurrent events was estimated using the Secondary Manifestations Of Arterial Disease (SMART) risk score. Established CVD is defined as the presence of CAD (angina pectoris, myocardial infarction, or coronary revascularization), cerebrovascular disease (transient ischemic attack, cerebral infarction, amaurosis fugax or retinal infarction, or a history of carotid surgery), PAD (symptomatic and documented obstruction of the distal arteries of the leg or angioplasty, bypass, or amputation of the leg), or abdominal aortic aneurysm. Recurrent events were defined as the composite of cardiovascular death, ischemic or hemorrhagic stroke, and myocardial infarction. The SMART risk score was developed on the basis of the SMART study in the Netherlands. The model is based on sex, age, as well as the underlying type of CVD (CAD, cerebrovascular disease, PAD, or aortic aneurysm) and the years since the first event. Smoking status, DM, SBP, total cholesterol (TC) and high-density lipoprotein cholesterol (HDL-C) levels, glomerular filtration rate, and high-sensitivity C-reactive protein level were used as predictors [16].

CVD Risk Communication

In primary prevention, CVD risk is reported as an individual's heart age. The heart age is calculated by comparing the individual risk with average risk levels at a given age and thus matching the age of a person with average risk at that age in the population (Table 2). In secondary prevention, the risk calculator provides an individual absolute risk of recurrence instead of the heart age. The same applies to individuals with excessive risk factor levels in primary prevention. In these cases, the heart age of a person would otherwise drastically exceed the biological age (eg, heart age >100 years).

Table 2. Average risk factor levels used for heart age estimation. Heart age was estimated by comparing the individual risk with average risk levels. Heart age matches the age of a person with the same predicted risk but with average risk factor levels.

Risk factors	Primary prevention
Smoking	Nonsmoker
Diabetes mellitus	Nondiabetic
Systolic blood pressure	130 mm Hg
Blood pressure treatment[a]	No
Total cholesterol	200 mg/dL
High-density lipoprotein cholesterol	50 mg/dL

[a]Denotes antihypertensive treatment.

Individual risk was compared with the mean risk and optimal risk in both primary and secondary prevention. Mean risk was derived from the Bavarian KORA-FF4 (for individuals without CVD) and F4 (for individuals with CVD) cohorts. The optimal risk was obtained by estimating someone's risk at the same age but with optimal risk factor levels (Table 3). In addition to traditional risk factors (eg, SBP, DM, and cholesterol levels), the HerzFit risk calculator asks users about their habits related to diet, exercise, and stress management. As these factors are not included in the risk models used for prediction, they do not directly affect the results. However, they are used for individualized recommendations within the app.

Table 3. Optimal risk factor levels used for comparison of individual and optimal risk. The HerzFit calculator compares individual risks with the optimal risk level. These parameters were used to obtain the optimal risk. In secondary prevention, the optimal risk is estimated for individual-specific underlying cardiovascular disease and the individual time span since the first event.

	Primary prevention	Secondary prevention
Smoking	Nonsmoker	Nonsmoker
Diabetes mellitus	Nondiabetic	Nondiabetic
Systolic blood pressure	120 mm Hg	120 mm Hg
Blood pressure treatment[a]	No	—[b]
Total cholesterol	150 mg/dL	110 mg/dL
High-density lipoprotein cholesterol	50 mg/dL	50 mg/dL
Glomerular filtration rate	—	80 mL/min
C-reactive protein	—	0.1 mg/dL

[a]Denotes antihypertensive treatment.

[b]Not applicable; information not needed for risk estimation.

Automatic Updates and Trends

The risk calculator was integrated into the mHealth app HerzFit, which allows people to monitor their vital and laboratory parameters. Every time novel risk factor levels are implemented (eg, when a new SBP value is transferred to the HerzFit app), the risk assessment automatically updates itself. This enables users to see how changes in risk factor levels can lead to improvements in their cardiovascular risk, without repeating the assessment every time. Obtaining a more accurate risk prediction, not a single but the mean value of the last 7 measurements of SBP was used for risk estimation. The HerzFit app is available free of charge for both the iOS and Android platforms in Germany, Austria, and Switzerland.

Data Security

All data (that are or were) entered into the HerzFit risk calculator, and the HerzFit app remained locally on the users' smartphones. The risk analysis was performed directly on the users' devices. This privacy by design concept ensures data security for users; however, it limits the statistical evaluation of its use. The strategy was communicated and aligned with the Bavarian Data Protection Commissioner (Landesdatenschutzbeauftragter).

Ethical Considerations

In this study, the download numbers of HerzFit were extracted from the respective iOS and Android developer accounts. These data cannot be associated with specific individuals and are therefore considered anonymized and fall outside the scope of the European Data Protection Regulation [17]. No institutional review board approval was obtained for our retrospective analysis of these anonymized data [18].

Results

Risk Assessment

For primary prevention, neither FRS (applicable to individuals aged ≥30 years) nor SCORE2 models (SCORE2 applicable to individuals aged 40-69 years; SCORE2-OP applicable to individuals aged ≥70 years) can be used for the complete range

of age and spectrum of risk factors. As we had to integrate these instruments into a single calculator, we had to harmonize the transition zones between the respective risk scores. Moreover, because of differences in their underlying study populations, the absolute risks derived from the FRS differed from the absolute risks derived from the SCORE2 model. Despite being recalibrated to the German population, the FRS still tends to calculate higher absolute risks compared with the SCORE2 model. This difference in absolute risk was more prominent in higher-risk individuals. Presenting a heart age instead of absolute risks is intended to mitigate this problem and ensure smoother transitions between the FRS and the SCORE2 model. Despite the similarities in the underlying study populations and mathematical calculations, differences in the predicted absolute risks were also evident in the transition from SCORE2 to SCORE2-OP. Similar to the transition between the FRS and SCORE2, the differences were more pronounced in the high-risk groups. Using a heart age instead of absolute risks helped to overcome these differences and ensured a smooth transition between the scores. To illustrate the differences in absolute risk and heart age for individuals with different risk profiles, Figures 1 and 2 and Table 4 illustrate the transition zones between the different scores for 3 example personas: 1 unhealthy persona (smoker, SBP 155 mm Hg, TC 250 mg/dL, and HDL-C 40 mg/dL), 1 average persona (nonsmoker, SBP 130 mm Hg, TC 200 mg/dL, and HDL-C 50 mg/dL), and 1 healthy persona (nonsmoker, SBP 125 mm Hg, TC 170 mg/dL, and HDL-C 70 mg/dL).

Figure 1. Correlation of age and 10-year risk of cardiovascular disease for different personas. This figure demonstrates the correlation between age and 10-year risk of cardiovascular disease for unhealthy, average, and healthy personas for Framingham Risk Score (FRS), Systematic Coronary Risk Evaluation 2 (SCORE2), and SCORE2–Older Persons (SCORE2-OP) in their respective age ranges used in the HerzFit risk calculator. Healthy persona: male, nonsmoker, nondiabetic, systolic blood pressure (SBP) 125 mm Hg, no blood pressure (BP) treatment, total cholesterol (TC) 170 mg/dL, and high-density lipoprotein cholesterol (HDL-C) 70 mg/dL. Average persona: male, nonsmoker, nondiabetic, SBP 130 mm Hg, no BP treatment, TC 200 mg/dL, and HDL-C 50 mg/dL. Unhealthy persona: male, smoker, nondiabetic, SBP 155 mm Hg, no BP treatment, TC 250 mg/dL, and HDL-C 40 mg/dL.

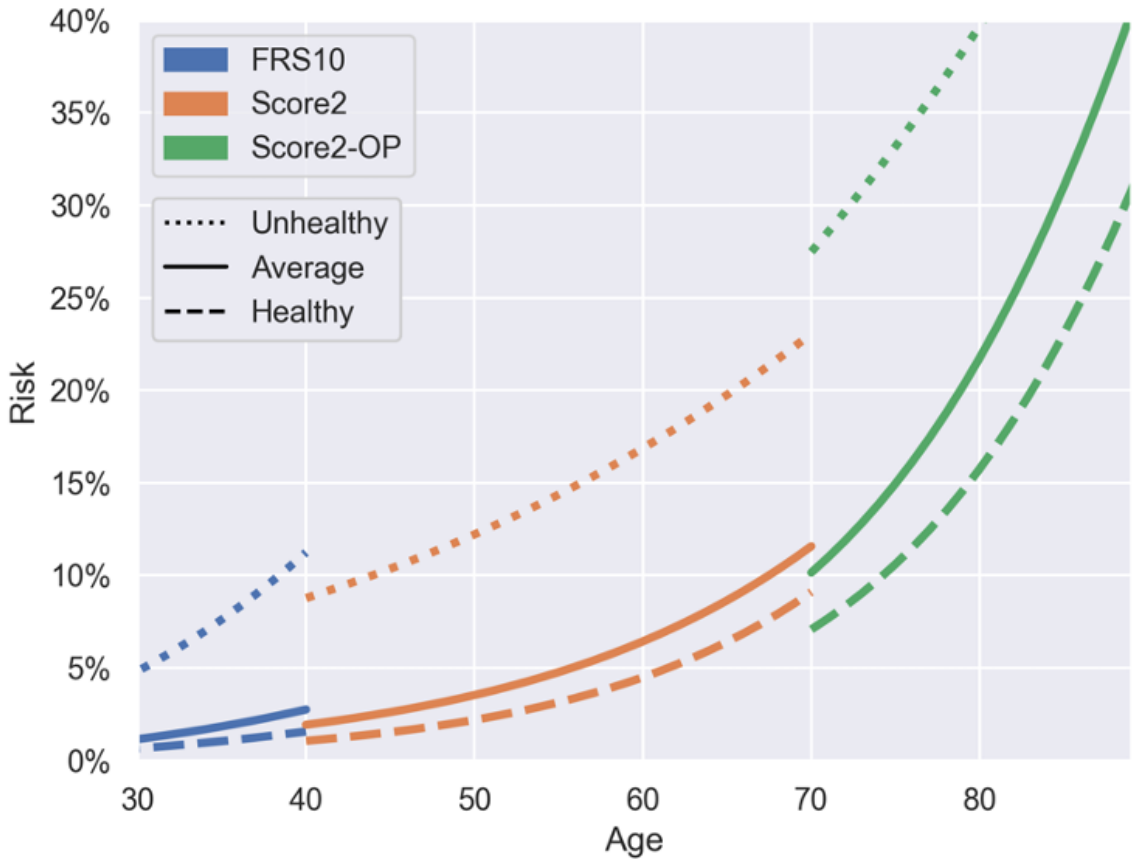


Figure 2. Correlation of age and heart age in the HerzFit risk calculator. This figure demonstrates the correlation of real age and heart age for unhealthy, average, and healthy individual personas for Framingham Risk Score (FRS), Systematic Coronary Risk Evaluation 2 (SCORE2), and SCORE2–Older Persons (SCORE2-OP) in their respective age ranges used in the HerzFit risk calculator. Healthy persona: male, nonsmoker, nondiabetic, systolic blood pressure (SBP) 125 mm Hg, no blood pressure (BP) treatment, total cholesterol (TC) 170 mg/dL, and high-density lipoprotein cholesterol (HDL-C) 70 mg/dL. Average persona: male, nonsmoker, nondiabetic, SBP 130 mm Hg, no BP treatment, TC 200 mg/dL, and HDL-C 50 mg/dL. Unhealthy persona: male, smoker, nondiabetic, SBP 155 mm Hg, no BP treatment, TC 250 mg/dL, and HDL-C 40 mg/dL.

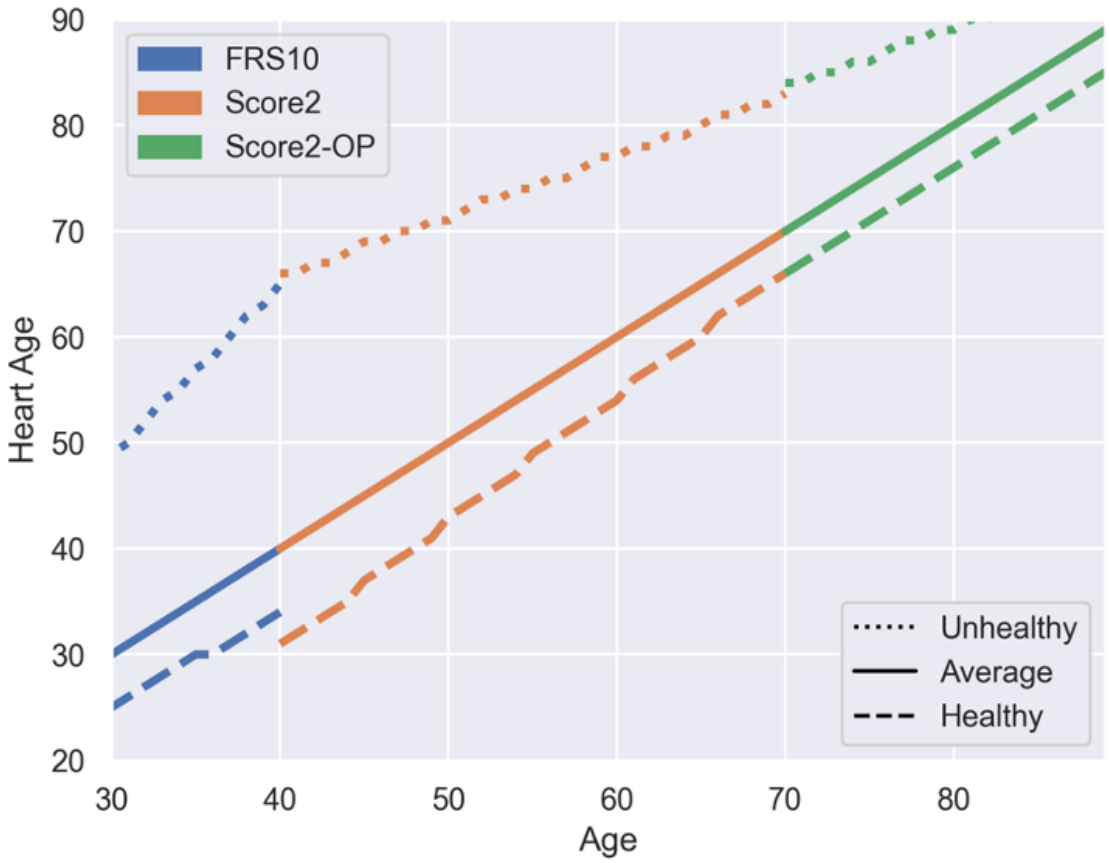


Table 4. Risk score transition—differences in absolute risk and heart age[a].

Biological age (years)	Risk score	Healthy persona[b]		Average persona[c]		Unhealthy persona[d]	
		Absolute 10-year risk (%)	Heart age (years)	Absolute 10-year risk (%)	Heart age (years)	Absolute 10-year risk (%)	Heart age (years)
37	FRS[e]	1.23	31	2.17	37	8.96	60
38	FRS	1.33	32	2.35	38	9.68	62
39	FRS	1.44	33	2.54	39	10.44	63
40	SCORE2[f]	1.06	31	1.92	40	8.77	66
41	SCORE2	1.14	32	2.04	41	9.07	66
42	SCORE2	1.22	33	2.17	42	9.37	67
67	SCORE2	7.38	63	9.72	67	21.02	81
68	SCORE2	7.91	64	10.30	68	21.68	82
69	SCORE2	8.49	65	10.92	69	22.36	82
70	SCORE2-OP[g]	7.07	66	10.15	70	27.49	84
71	SCORE2-OP	7.68	67	10.98	71	28.56	84
72	SCORE2-OP	8.33	68	11.87	72	29.67	85

[a]For primary prevention, Framingham Risk Score, Systematic Coronary Risk Evaluation 2 (SCORE2), and SCORE2 in Older Persons were used for risk estimation. Differences in absolute risk estimates were apparent in the transition zones between scores, particularly in high-risk individuals. Estimating the heart age instead of the absolute risk numbers helped smooth the transitions between scores.

[b]Healthy persona: male, nonsmoker, nondiabetic, systolic blood pressure 125 mm Hg, no blood pressure treatment, total cholesterol 170 mg/dL, high-density lipoprotein cholesterol 70 mg/dL.

[c]Average persona: male, nonsmoker, nondiabetic, systolic blood pressure 130 mm Hg, no blood pressure treatment, total cholesterol 200 mg/dL, high-density lipoprotein cholesterol 50 mg/dL.

[d]Unhealthy persona**:** male, smoker, nondiabetic, systolic blood pressure 155 mm Hg, no blood pressure treatment, total cholesterol 250 mg/dL, high-density lipoprotein cholesterol 40 mg/dL.

[e]Framingham Risk Score.

[f]SCORE2: Systematic Coronary Risk Evaluation 2.

[g]SCORE2-OP: Systematic Coronary Risk Evaluation 2–Older Persons.

Risk Communication

Before users are able to assess their risk, the concept and limitations of risk estimation are explained to the user. It is pointed out that the risk calculator can only estimate but not exactly predict the cardiovascular risk.

After entering the required parameters, the heart age (in primary prevention) or the risk of recurrence (in secondary prevention) and the comparison to the mean and optimal risk are depicted (Figure 3). If risk factor levels change (eg, someone stops smoking or takes better care of blood pressure [BP] levels), individual risk and thereby heart age automatically adapt. Figure 4 uses the 3 example personas described above (1 healthy, 1 average, and 1 unhealthy) to illustrate how different risk profiles affect the heart age. For the average persona, who does not smoke, has no diabetes, and has normal BP and cholesterol levels, biological age and heart age match. The healthy persona, who has even better BP and cholesterol levels than the population average, has a younger heart age than the biological one. This persona shows a potential gain in life years. The unhealthy persona, on the other hand, who smokes and has elevated BP and cholesterol levels, is given an increased heart age. This persona is made aware of the possible loss of life years.

Figure 3. Presentation of heart age and risk in primary and secondary prevention. For individuals without cardiovascular disease, the HerzFit calculator estimates an individual's heart age. The 10-year risk of recurrent events was estimated for people with established cardiovascular disease. In addition, the individual risk is compared with the mean and optimal risk. The screenshots were translated from German.

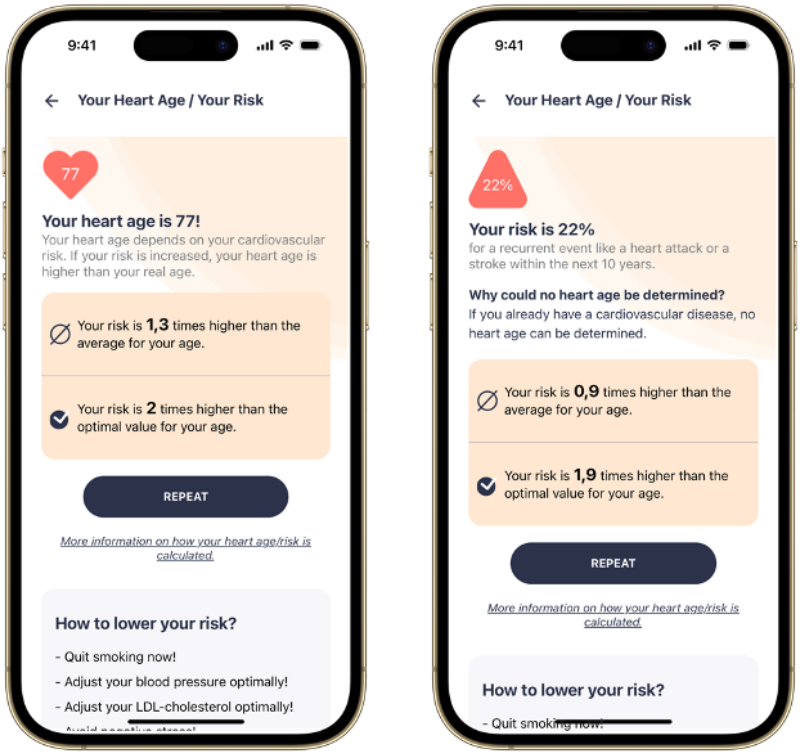
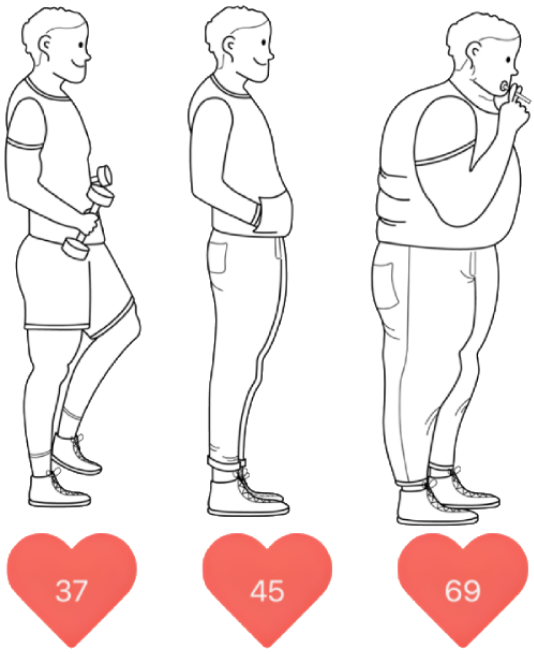


Figure 4. The effect of different risk profiles on heart age. This figure shows the effects of cardiovascular risk factors on heart age. Although a healthy man aged 45 years has a heart age of 37 years, and an average man of the same age has a heart age of 45 years, an unhealthy man of the same age can already have a heart age of 69 years. Healthy persona: nonsmoker, nondiabetic, systolic blood pressure (SBP) 125 mm Hg, no blood pressure (BP) treatment, total cholesterol (TC) 170 mg/dL, and high-density lipoprotein cholesterol (HDL-C) 70 mg/dL. Average persona: nonsmoker, nondiabetic, SBP 130 mm Hg, no BP treatment, TC 200 mg/dL, and HDL-C 50 mg/dL. Unhealthy persona: smoker, nondiabetic, SBP 155 mm Hg, no BP treatment, TC 250 mg/dL, and HDL-C 40 mg/dL.

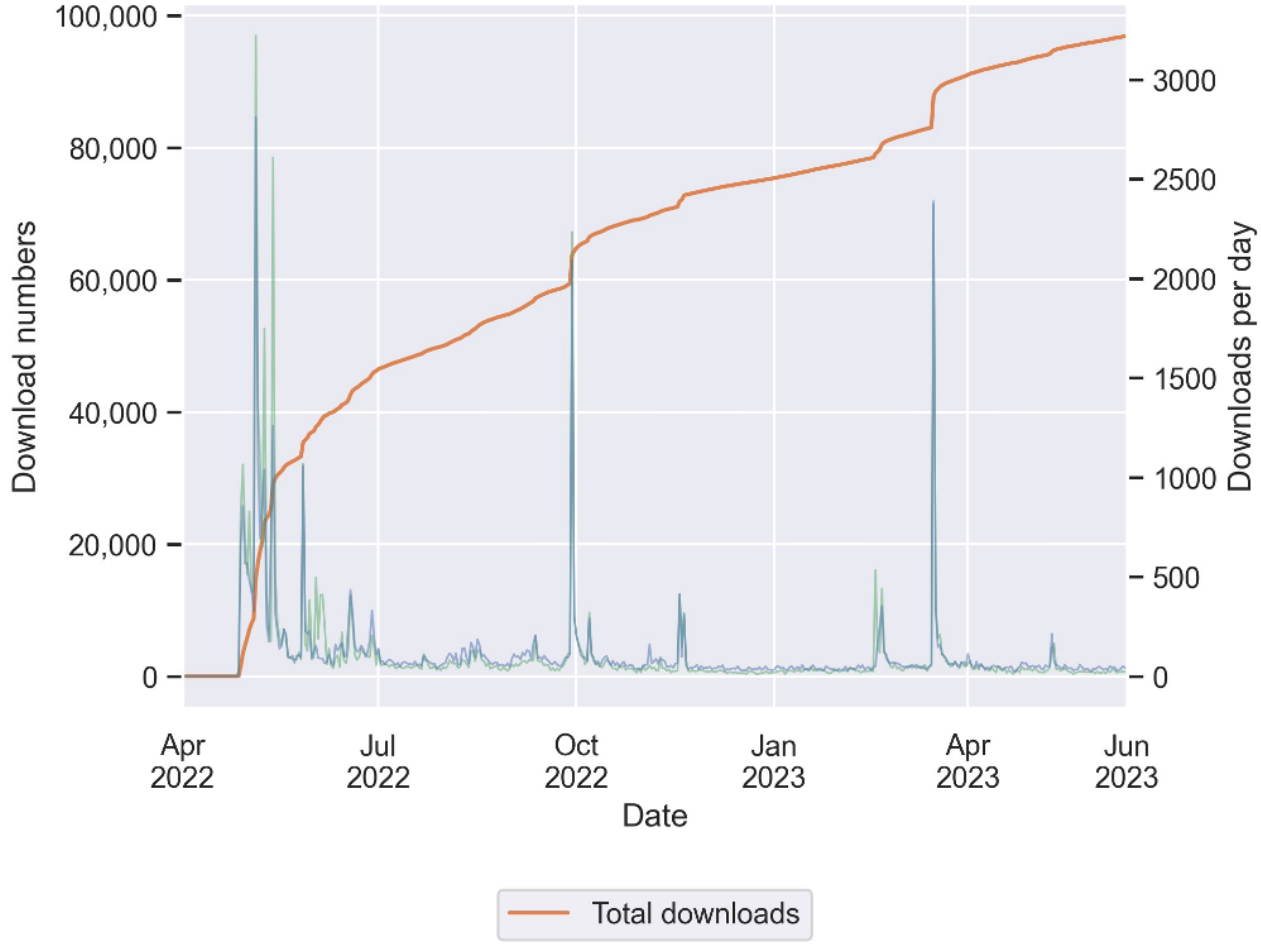


Raising Awareness

Within the first 14 months, the HerzFit app and its risk calculator were downloaded more than 96,000 times. In addition to a steady increase in the number of users, several download peaks were evident (Figure 5). The greatest increase in the number of users occurred in the months following the release in April 2022. Before and immediately after the release, many marketing activities were carried out by the State of Bavaria, the German Heart Foundation, the Digitized Medicine in Bavaria (DigiMed

Bavaria) Consortium, a cooperating health insurance company, and a health magazine. In addition, the HerzFit app and its risk calculator were promoted as part of a large-scale heart health campaign (Hand aufs Herz Kampagne) funded by the Bavarian State Ministry of Health and Care. After the first 3 months, a slower but steady increase in the number of users was observed. The next major download peak was evident in the fall of 2022, when the German Heart Foundation presented the risk calculator at several events for the World Heart Day. In addition, a scientific symposium organized by the DigiMed Bavaria Consortium took place, which subsequently led to broader attention for the risk calculator in the media. Finally, a third major peak in downloads could be observed in the spring of 2023 when the German Heart Foundation and a health magazine once again promoted the HerzFit risk calculator.

Figure 5. HerzFit downloads from April 2022 to June 2023. Since its release in April 2022, the HerzFit app and risk calculator have been downloaded more than 96,000 times. The orange curve represents the total number of downloads. The green and blue curves mark the downloads per day on iOS and Android devices, respectively. In addition to a continuous increase in the total download numbers, repeated peaks in daily downloads were evident. This finding could be correlated with previous marketing campaigns and events.



Discussion

Principal Findings

This study indicates the feasibility of and public demand for a calculator that indicates the risk of CVD. The main findings of our study are as follows: offering a calculator that covers a broad range of ages for both primary and secondary prevention required use of multiple instruments. For individuals covered by >1 established risk assessment instrument, estimates may differ significantly, which implies the need for harmonization to cover a broad range of age and risk profiles in a single tool. Providing plausible estimates that can be interpreted by laypersons is essential for risk communication. Depending on public campaigns that create awareness, the public shows great interest in a CVD self-assessment tool.

A novel aspect of this study is the integration of multiple primary and secondary preventive risk scores into a single instrument for laypersons. Previous self-assessment tools were mostly based on a single primary preventive score such as the FRS or the QRESEARCH cardiovascular risk algorithm model [7,19]. As a result, certain groups of age and risk profiles, as well as individuals with preexisting CVD, were excluded from the risk estimation. More complex risk assessment instruments, such as the web-based U-Prevent tool or the European Society of Cardiology CVD Risk Calculation App, provide risk assessment for people in both primary and secondary prevention. However, they were not developed as a self-assessment tool for laypersons but rather as a clinical decision support platform for physicians [20,21]. Given these limitations, we integrated several primary and secondary preventive scores into a single instrument for laypersons. Following the current guideline

recommendations, SCORE2 models and the SMART risk score form the basis of the HerzFit calculator [1,13,14]. A recalibrated version of the FRS complements our tool by providing risk estimation for younger individuals and those with preexisting diabetes [15,22]. Designed as a self-assessment tool for laypersons, the HerzFit calculator automatically uses the appropriate risk model based on the individual information on risk factors and disease history. Similar to previous self-assessment tools, mean values are automatically provided to ensure risk estimation when individuals are unaware of their laboratory values [7]. Combining different primary and secondary preventive risk models, the HerzFit calculator covers a broad range of age and risk profiles as well as patients with previous cardiovascular events [23]. This approach was encouraged by our cooperating patient organization, the German Heart Foundation, as a large proportion of their members already have CVD. It was also supported by the Bavarian State Ministry of Health and Care, which needed a widely applicable risk assessment and awareness tool for a large-scale heart health campaign.

The integration of multiple scores with different underlying study populations requires recalibration and harmonization to obtain consistent and plausible estimates. In primary prevention, calculating the heart age instead of absolute risks ensured the harmonization of results. Presenting a heart age also promised to facilitate risk communication, as percentage risk formats have been shown to be difficult for laypersons to understand [24]. Several randomized trials have compared the effects of communicating the heart age instead of absolute risk percentages. The study by Soureti et al [24] showed that heart age had greater emotional impact in individuals at higher cardiovascular risk. The study by Lopez-Gonzalez et al [25] found that a heart age tool led to greater reduction in CVD risk compared with conventional 10-year risk percentages. However, the literature also indicates that high-risk individuals were less accepting of their heart age results and perceived them as less credible [26,27]. Given these limitations, an additional comparison of expected to mean and optimal risk levels using risk ratios was implemented in the HerzFit calculator. Risk ratios and peer group risk estimates have been shown to increase risk perception and intention to adhere to a healthier lifestyle [28]. In contrast to other apps, we refrained from showing absolute 10-year risks in addition to the heart age [29]. Especially younger users, who may already have an increased relative risk and heart age because of modifiable risk factors, could otherwise be misled by low absolute risk numbers. A graphical representation of the estimated risk as in other CVD risk estimation apps has not yet been implemented in the HerzFit risk calculator [23,29].

Another specialty of the HerzFit risk calculator is how it is delivered. Previous self-assessment tools were mostly web based or developed as stand-alone apps for risk assessment [7,19,20,23,29]. In contrast to these delivery methods, the HerzFit risk calculator was developed as a smartphone tool and integrated into an mHealth app. This app not only provides respective background information but also encourages its users to better manage their health based on the individual risk assessment. In this way, the HerzFit calculator could not only help identify individuals at risk but also help them optimize their cardiovascular profile.

Finally, our study demonstrated great public interest in the German-speaking population for a CVD self-assessment tool. This result is consistent with those of previous studies conducted in the United States and the United Kingdom [7,19]. With up to 10,000 downloads per month, public information campaigns have had a significant impact on download numbers. This also supports previous studies reporting increased disease and risk factor awareness following public information campaigns [19,30-32].

Strengths and Limitations

This study has several strengths. To the best of our knowledge, the HerzFit calculator is the first smartphone-based tool to offer guideline-based CVD risk estimation for laypersons in German-speaking countries. The integration of 4 internationally recommended scores allows risk estimation for individuals aged 30 to 90 years with or without CVD. Recalibration and harmonization ensure plausible estimates based on individual risk profiles. Presenting a heart age and comparing the expected to mean and optimal risk levels promise better risk comprehension among users. Finally, the calculator is implemented into an mHealth app that provides the respective background information and is delivered free of charge on both the iOS and Android platforms.

The following limitations of this study must be addressed. First, due to the data protection regulations, there has been no statistical evaluation of the user profile of the HerzFit calculator. It remains unclear whether HerzFit reaches at-risk individuals and whether it has an impact on their behavior. However, recent studies have revealed a great interest in CVD self-assessment tools among all risk groups and showed considerable improvement in risk factor control when heart age was communicated [19,24,25]. Developed with the functionality to collect scientific data, the HerzFit app may soon provide further evidence in this regard. With user consent, anonymized data on individual risk factors, comorbidities, and estimated risks shall be analyzed in the future. The results could even be used to guide future campaigns to create awareness for the instrument. Second, risk scoring in general faces limitations when it comes to individuals with extreme risk factor levels (eg, familial hypercholesterolemia) [33]. Conventional risk scoring tools such as ours might underestimate the risk of these persons. This also emphasizes that the HerzFit calculator is not intended to replace a professional health care consultation. Nevertheless, self-assessment tools can be seen as a way to provide information, direct people toward traditional preventive measures, and empower them in their health management. Finally, the HerzFit calculator is only available in German language so far, which could lower user rates in non–native-speaking groups.

Conclusions

The HerzFit calculator provides a guideline-based CVD risk assessment for the general population in Germany, Austria, and Switzerland. With more than 96,000 downloads within the first 14 months, the great public demand for such a self-assessment

tool was demonstrated. Public information campaigns were largely responsible for creating awareness about the instrument.

Acknowledgments

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Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

BP: blood pressure
CAD: coronary artery disease

CVD: cardiovascular disease
DM: diabetes mellitus
FRS: Framingham Risk Score
HDL-C: high-density lipoprotein cholesterol
mHealth: mobile health
PAD: peripheral arterial disease
SBP: systolic blood pressure
SCORE2: Systematic Coronary Risk Evaluation 2
SCORE2-OP: Systematic Coronary Risk Evaluation 2–Older Persons
SMART: Secondary Manifestations Of Arterial Disease
TC: total cholesterol

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Original Paper

Feasibility and Acceptability of a Combined Digital Platform and Community Health Worker Intervention for Patients With Heart Failure: Single-Arm Pilot Study

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Abstract

Background: Heart failure (HF) is one of the leading causes of hospital admissions. Clinical (eg, complex comorbidities and low ejection fraction) and social needs factors (eg, access to transportation, food security, and housing security) have both contributed to hospitalizations, emphasizing the importance of increased clinical and social needs support at home. Digital platforms designed for remote monitoring of HF can improve clinical outcomes, but their effectiveness has been limited by patient barriers such as lack of familiarity with technology and unmet social care needs. To address these barriers, this study explored combining a digital platform with community health worker (CHW) social needs care for patients with HF.

Objective: We aim to determine the feasibility and acceptability of an intervention combining digital platform use and CHW social needs care for patients with HF.

Methods: Adults (aged ≥18 years) with HF receiving care at a single health care institution and with a history of hospital admission in the previous 12 months were enrolled in a single-arm pilot study from July to November 2021 (N=14). The 30-day intervention used a digital platform within a mobile app that included symptom questionnaire and educational videos connected to a biometric sensor (tracking heart rate, oxygenation, and steps taken), a digital weight scale, and a digital blood pressure monitor. All patients were paired with a CHW who had access to the digital platform data. A CHW provided routine phone calls to patients throughout the study period to discuss their biometric data and to address barriers to any social needs. Feasibility outcomes were patient use of the platform and engagement with the CHW. The acceptability outcome was patient willingness to use the intervention again.

Results: Participants (N=14) were 67.7 (SD 11.7) years old; 8 (57.1%) were women, and 7 (50%) were insured by Medicare. Participants wore the sensor for 82.2% (n=24.66) of study days with an average of 13.5 (SD 2.1) hours per day. Participants used the digital blood pressure monitor and digital weight scale for an average of 1.2 (SD 0.17) times per day and 1.1 (SD 0.12) times per day, respectively. All participants completed the symptom questionnaire on at least 71% (n=21.3) of study days; 11 (78.6%) participants had ≥3 CHW interactions, and 11 (78.6%) indicated that if given the opportunity, they would use the platform again in the future. Exit interviews found that despite some platform “glitches,” participants generally found the remote monitoring platform to be “helpful” and “motivating.”

Conclusions: A novel intervention combining a digital platform with CHW social needs care for patients with HF was feasible and acceptable. The majority of participants were engaged throughout the study and indicated their willingness to use the intervention again. A future clinical trial is needed to determine the effectiveness of this intervention.

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KEYWORDS

heart failure; digital platform; remote monitoring; home-based care; community health worker; social needs care; community health work; care; monitoring; pilot study; heart; feasibility; acceptability; community; heart rate; oxygenation; willingness; mobile phone

Introduction

Heart failure (HF) is one of the most common causes of hospitalization and generates significant expense and hardship for patients [1,2]. Numerous adverse clinical (eg, low ejection fraction, elevated natriuretic peptide, and complex disease comorbidities) [3,4] and social needs care factors (eg, transportation, food security, housing stability, and access to care) [5,6] have been associated with HF exacerbations leading to hospitalization along with rising cost of HF care [7]. Growing pressure to provide more effective clinical support to patients with HF at home and reduce total costs of care has resulted in increased interest in biometric monitoring with digital solutions paired with wearable devices that can track data for patients and care teams [8]. Similarly, home-based interventions addressing social needs care from a navigator or community health worker (CHW) have shown promise addressing gaps in social needs care while impacting clinical outcomes in chronic disease populations [9,10].

Digital platforms can offer a suite of remote biometric monitoring such as continuous heart rate and oxygenation monitoring, and measurement of blood pressure and body weight via digital devices [11-13]. Machine learning algorithms may also contribute to framework accuracy and alert specificity [14]. Use of digital platforms to determine early clinical decline (eg, changes in baseline weight, activity tolerance, heart rates, and blood pressure) via biometric and symptom-linked monitoring has the potential to benefit HF home care. However, broad adoption and implementation of digital platforms for patients with HF have lagged for a variety of reasons stemming from institutional and provider-related challenges to logistical constraints in tech-challenged settings and aging populations [15]. Even in settings that are able to support digital solutions, there are patient barriers to digital platform use such as knowledge gaps, lack of willingness to adopt new skills, reluctance to use technologies, and challenges with internet connectivity and access [16,17]. As a result, concerns about the exclusion of digital platform use in low-resourced or less technology savvy populations persist [18]. A number of these identified patient barriers could be addressed by integrating a home-based human resource with the capacity to guide patients through platform use while also addressing any unmet social needs care.

As lay professionals trained with basic knowledge of chronic conditions, such as HF, home-based CHW staff spend time with patients, often addressing social care needs [6] (eg, economic, educational, and behavioral factors) that influence clinical outcomes such as unplanned hospital readmissions and emergency department (ED) visits. These activities could include supporting patients in the logistics of navigating digital platform use and connectivity as it relates to home monitoring [19]. As such, home-based CHW roles [9,10,20,21] are uniquely positioned to support digital platform use and engagement by also supporting patients with any needed resources such as connectivity, transportation, nutrition education, or psychosocial support [22].

In this study, we explore a combined remote monitoring and CHW intervention designed for patients with HF and unmet social needs who had at least 1 hospitalization in the prior 12 months. We conducted a single arm pilot study to determine the feasibility and acceptability of this intervention as preliminary data for a larger clinical trial.

Methods

Setting and Study Design

We enrolled 14 participants who had a diagnosis of HF (July 2021 through November 2021) and at least 1 hospitalization in the prior 12 months. A 15th participant was initially enrolled but later excluded due to the inability to sustain connectivity of the digital platform at home despite the trial use of multiple sets of platform hardware; this was thought to be due to interference related to connectivity of other devices within the home. Study participants were identified using 6 outpatient primary care and cardiology clinic panels of clinicians at Massachusetts General Hospital (MGH). MGH is a 999-bed academic medical center in Massachusetts. Further, 15 MGH primary care clinics and the MGH Corrigan Minehan Heart Center support over 27,000 cardiac patients each year; many of whom have a HF diagnosis. A HF diagnosis was defined as having this condition (systolic or diastolic HF) listed in the electronic health record (EHR) problem list.

Ethical Considerations

Institutional review board approval was obtained from the Massachusetts General Brigham Human Research Committee on September 22, 2020 (2018P002014). All enrolled participants provided written consent for study enrollment. It was given prior to this study. All methods were carried out in accordance with guidelines and regulations outlined by the Mass General Brigham institutional review board. All participants were provided US $250 of remuneration for study participation.

Participants

Eligibility criteria were developed based on findings from prior qualitative studies focused on perspectives on hospital to home care transitions and home-based care that includes HF orts [23-25]. Specifically, in prior interviews with patients with HF who had a history of prior hospitalization, themes related to difficulty adhering to diet and medication instructions outlined by primary care or cardiology specialists and willingness to participate in digital platform interventions emerged. Based on this, study participants with HF were recruited from outpatient cardiology and internal medicine clinic panels. Participants had to be ≥18 years old, live within a 30-mile radius of MGH, have a diagnosis of HF listed in the EHR problem list, have a history of ≥1 hospitalizations within the previous 12 months, a clinician managing their HF, smartphone use familiarity, ability, and willingness to participate in the intervention, and English fluency. Patients were ineligible if they were experiencing homelessness, had an active alcohol or substance use disorder, were living in a long-term care facility, were unable to provide consent due to cognitive impairment, or had invoked health care proxy or prisoner status.

Enrollment

Research staff called patients expressing prior interest in study involvement by phone to describe the study, establish eligibility, and enroll participants. Patients were called up to 3 times if they were unsure or unable to be contacted on initial outreach. If interested, patients agreed to meet study staff at MGH main campus for enrollment and were enrolled after consent processes were completed. Enrolled participants were introduced to the digital platform (Biofourmis) [26] features: a HF mobile phone app on an Android phone that included a daily checklist of patient to-do items, educational HF videos, a portal for messaging the assigned CHW, and a daily symptom questionnaire (see Multimedia Appendix 1). In addition, participants were provided with a digital blood pressure monitor, a digital weight scale, and a sensor attached to a lightweight arm band worn on the nondominant arm tracking basic biometrics (heart rates, oxygenation, and steps taken; see Multimedia Appendix 2). The digital platform was designed for patients with HF by the platform developers and specific aspects of the platform dashboard layout and alert deployment were modified for CHW use by platform developers prior to study start. These modifications were led by a CHW staff member trained to guide patients in navigation of the platform as well as members of the research team (eg, JC and NS). The CHW contacted participants via phone within 24 weekday hours of enrollment.

Intervention Care

Participants were given access to the digital platform, BiofourmisRPM, along with instruction on the use of all devices for the 30-day intervention. Participants were encouraged to wear the sensor via armband for up to 24 hours daily and check blood pressure and weight daily. Participants were encouraged to complete a daily symptom questionnaire and view American Heart Association HF educational videos using the mobile app. Baseline biometrics were established by participant use of the digital platform on hospital discharge (whereupon baseline heart rates, oxygenation rates, and steps taken along with blood pressures and body weights were established). A machine learning algorithm within the mobile app generated a daily Biovitals Index for the CHW team dashboard with alerts sent to the CHW team dashboard indicating if participants were at, moving away from, or moving toward their clinical baseline in terms of symptoms, biometrics, and functionality. The team also applied a color schematic, red (recommendation for immediate clinical attention; score ≥1.0), yellow (recommendation for clinical attention within 24 hours; score 0.8-0.9), green schematic (no clinical attention required; score 0.7), which was used to further categorize patient status and needed actionability. No mobile app-generated feedback was given to patients based on abnormal biometrics or symptoms.

Specifically, CHWs were trained to assess scores and alerts generated by the digital platform. Any scores or alerts indicating that participants were moving away from their baseline were discussed with a CHW project manager (ie, trained intensive care unit nurse). When indicated, the CHW staff connected with patients whose biometric data or symptoms were within the yellow or red zones within 4 workday hours of occurrence. Patients were instructed to use on-call clinical team or urgent or emergent care as they normally would if they developed new symptoms or concerning changes in biometric measurements after workday hours or on weekends. The CHW was also trained to assist patients with the technology set up and trouble shooting. Any unreconciled technical difficulties were addressed by research study staff and the platform vendor, as needed.

Participants received routine calls and contacts from their assigned CHW to address barriers to social needs care as well as patient knowledge gaps or challenges with adherence to clinical care plans. Social care needs included any issues related to transportation, insurance benefits, food security, rental, or housing assistance (or any unmet need related to the social determinants of health), as well as psychosocial support. Further, 1 CHW with expertise in CHW core competencies [27] (motivational interviewing, goal-setting, behavior change, and psychosocial support) delivered the intervention and was trained to assist participants with the digital platform. The CHW documented all encounters in the EHR (eg, enrollment notes, progress notes for all contacts) as well as completing the CHW interaction by logging in a REDCap database. Preexisting clinical team members were copied on all EHR notes and contacted directly by the CHW or supervisory staff during the intervention when needed.

In total, 1 CHW staff member was involved in this intervention as a hospital employee. This CHW completed extensive training in self-management as part of an 80-hour course associated with CHW certification supported by the local public health commission. Focused case-based learning specific to the digital platform use and HF home care led by the principal investigator (JC) and a CHW supervisor, clinically trained as a critical care nurse, was conducted prior to the study. Training on the digital platform and HF care occurred over a 2 week period (6 hours in total) culminating with skill-based proficiency assessments.

Measures or Outcomes

All study participants completed an enrollment questionnaire to establish baseline habits and patient experience adapted from previous survey instruments [23,24]. This questionnaire was derived from standard established measures of patient experience for benchmarking as well as validated questions generated by prestudy qualitative interviews with patients and discussions with physicians caring for patients with HF. The enrollment questionnaire included items about health-related habits, understanding of the care plan, smartphone knowledge, quality of life, perceptions of physical and mental health, unmet social needs, loneliness, and depression. At study end, participants completed an exit interview focused on their experiences with the technology and an acceptability questionnaire focused on the digital platform and their experiences with the CHW. For the usability and acceptability interview questions, components of the System Usability Scale [28], Post Study System Usability Questionnaire [29], Technology Assessment Model Measurement Scales [30], and Usefulness, Satisfaction, and Ease Questionnaire [31] were adapted as described by Ben-Zeev et al [32] for the purposes of this study. For the acceptability questionnaire, the responses were “very true,” “somewhat true,” and “not true.” For the CHW experience, responses ranged on a scale from “satisfied” to “neutral” to “not satisfied.” The questionnaires were initially pretested with 3 patients and no additional changes were made. The exit interview and all questionnaires were verbally administered by study staff. Basic demographics, insurance status, and major medical and psychiatric comorbidities were collected via EHR chart review. The primary outcomes were feasibility and acceptability of the combined digital remote monitoring and CHW intervention designed for patients with HF. Feasibility outcome measures included daily use rates of the biometric sensor (average hours per day), the digital blood pressure monitor (average times per day), the weight scale (average times per day), and completion of the symptoms questionnaire (average times per day). The acceptability outcome measure was captured by patients’ response to the statement that if given the opportunity, they would use the digital platform again in the future (response options: very true, somewhat true, or not true).

Demographic data and survey item responses were captured in REDCap (Research Electronic Data Capture; Vanderbilt University). These items were summarized, and univariate analysis was completed for any domains connected to the outcomes. Structured medical record review data extracted from the EHR were also captured in a REDCap database.

Statistical Analysis

Univariate analysis included demographic covariates of participants and intervention use frequencies, means, and SDs related to feasibility and acceptability outcomes. A brief 4-item qualitative exit interview guide probing the participant experience was administered at the end of the study and framework analysis was used to identify main themes [33]. We conducted coding and analysis using verbatim transcription. The transcripts were uploaded into Dedoose (software version 8.3.47B.exe; SocioCultural Research Consultants, LLC) for analysis.

Results

Overview

In total, 14 participants with HF were enrolled and included in the analysis (Table 1) in this observational study between July and November 2021. Participants (n=14) were 68.7 (SD 11.7) years old; 8 (57.1%) were women, and 7 (50%) were insured by Medicare. Of those enrolled, 6 (42.8%) had HF with a reduced ejection fraction (≤40%; Table 1). All participants completed the enrollment and exit questionnaires or interview.

Table 1. Patient characteristics (N=14).

Participant characteristics	Value
Female sex, n (%)	8 (57.1)
Age (years), mean (SD)	68.7 (11.7)
Race and ethnicity, n (%)	
Asian, non-Hispanic	0 (0)
Black, non-Hispanic	1 (7.1)
Hispanic or Latin	0 (0)
White, non-Hispanic	13 (92.9)
Primary insurance, n (%)	
Medicare	7 (50)
Commercial or private	6 (42.9)
Medicaid	1 (7.1)
Highest level of education, n (%)	
≤High school	3 (21.4)
≥Some college or more	11 (78.6)
Heart failure, n (%)	
Ejection fraction <40%	6 (42.8)
Ejection fraction ≥40%	8 (57.1)
Medical history, n (%)	
Hypertension	11 (78.6)
Hyperlipidemia	6 (42.9)
Atrial fibrillation	5 (35.7)
Diabetes	5 (35.7)
Chronic kidney disease	5 (35.7)
Non-ST elevation myocardial infarction	4 (14.8)
≥2 or more chronic conditions	14 (100)
Usage or needs, mean (SD)	
Hospitalizations in 12 months prior to enrollment	1.2 (0.47)

Feasibility

All participants used the digital platform throughout the 30-day study interval and wore the sensor for 82.2% (n=24.66) of study days with an average of 13.5 (SD 2.1) hours per day (Figure 1). Participants used the digital blood pressure monitor and digital weight scale at a mean of 1.2 (SD 0.17) times per day and 1.1 (SD 0.1) times per day, respectively. All participants completed the symptom questionnaire on at least 71% (n=21.3) of study days.

Overall, 11 (78.6%) of participants had ≥3 CHW interactions (Table 2), and all participants had at least 2 CHW interactions. Of the 311 total patient-CHW interactions occurring during the study interval, the most frequent CHW activities were related to reinforcement of the general care plan (n=113, 36.3%), psychosocial support (n=45, 14.5%), salt or nutrition education (n=40, 12.9%), making clinical appointments (n=22, 7.5%), case management referrals (n=18, 5.8%), and creating reliable transportation (n=14, 4.5%).

Figure 1. Description of Biofourmis mobile app function for 14 study participants over a 30-day study period. The mobile app included educational videos and articles from the American Heart Association, the ability to record weight and blood pressure, and a daily 4-question symptom questionnaire. AHA: American Heart Association; CHW: community health worker.

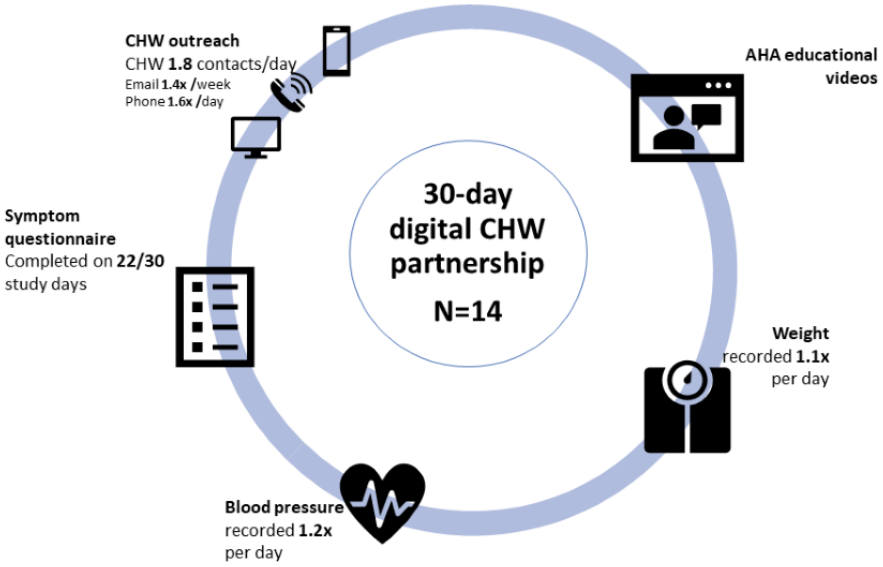


Table 2. Types of community health worker-patient interactions (N=311).

Interactions	Value, n (%)
Medical needs	
Reinforcement of general adherence	113 (36.3)
Making or confirming clinical appointments	22 (7.1)
Assessment of need of case management services	18 (5.8)
Assisted patient with insurance or eligibility inquiries	10 (3.2)
Referral to a health agency	1 (0.3)
Arranging for access to medications	2 (0.6)
Other	1 (0.3)
Coaching or teaching	
Psychosocial support	45 (14.5)
Education on salt, fluid, or other aspects of dietary intake or nutrition	40 (12.9)
Education on activity	11 (3.5)
Education on medications	7 (2.3)
Education on other aspects of general health	4 (1.3)
Social or basic needs	
Transportation for clinical care	14 (4.5)
Referral to a social service agency	8 (2.6)
Referral to social work	7 (2.3)
Assistance with basic needs (eg, housing, food, and electricity)	6 (1.9)
Financial counseling or eligibility for program assistance	2 (0.6)

Acceptability

All participants completed exit questionnaires. Overall, 10 (71.4%) participants responded that the statement "I found that the different parts of the [digital platform] worked well together" was very true or somewhat true. Furthermore, 11 (78.6%) participants indicated that the statement "If I have access to the [digital platform] moving forward, I will use it" was very true or somewhat true, and 9 (64%) indicated that the statement "I think I would need the support of a technical person" to use the digital platform was very true or somewhat true. In total, 12

(86%) participants indicated that their CHW interaction was satisfying.

Four themes emerged from patient exit interviews (Textbox 1): (1) patients with HF value access to data via remote monitoring at home, (2) participants experienced inconsistencies with the accuracy and precision of the digital platform, (3) patients viewed the CHW role as beneficial in terms of motivation, connection to resources, and assistance with insurance, and (4) patients with HF see digital platform use as generally helpful with little inconveniences.

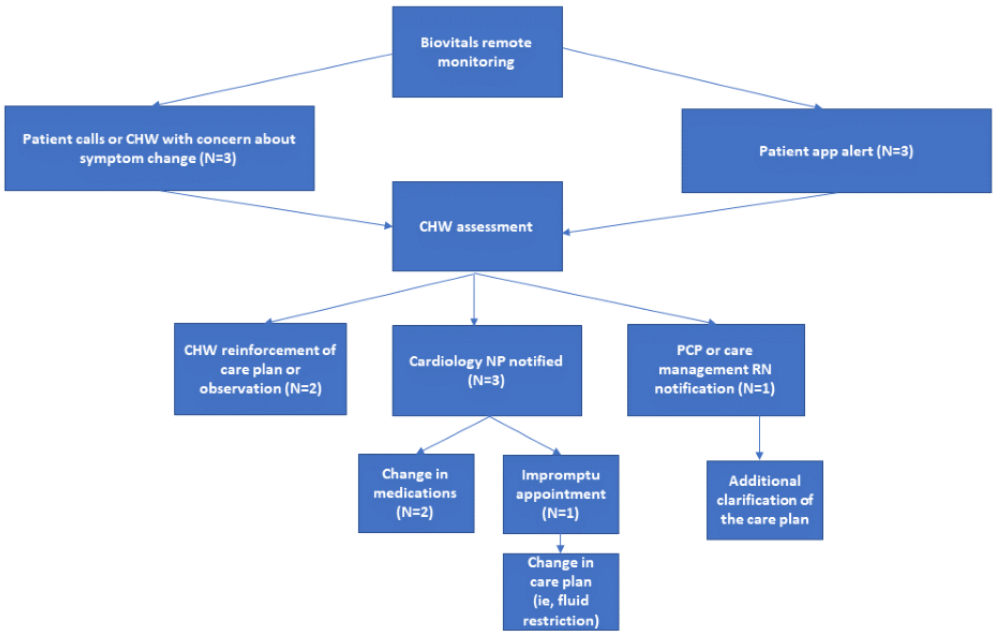
Textbox 1. Major themes associated with illustrative quotes from poststudy interviews with participants with heart failure.

- Data: *patients with heart failure value access to data via remote monitoring at home*
  - "Well, I think that it's a positive thing to have it in the home. It gives you a lot of information, and it's not intimidating."
  - "And the cuff thing, I found out a lot of information. Because I have CPAP, that I hate."
  - "[In the past] with my doctor.. I was forwarding her exactly what was happening with you guys' and technology, but I was doing it by taking a picture and sending it to her through the Gateway. So it was a little archaic now that I've done this. It seems very archaic and it would have been simple …if this technology was available, it really would have been a lovely thing because I did it twice a day before.."
  - "Okay. I found it okay. I mean, watching my weight, that was great. Watching my blood pressure was even better, because I [have] problems."
  - "Yeah. I mean….it was extremely informative. It was helpful. It gave your blood pressure. It gave your oxygen level. It gave your skin temperature."
- Digital issues: *participants experienced inconsistencies with the accuracy and precision of the digital platform.*
  - "I mean, my device had to be restarted every so often which was inconvenient."
  - "[The digital scale] had me from 176 to 224 to 233 back down to 170s-- so it was all over the place one day."
  - "I mean, if it was not for the few glitches, then I would say that it works perfectly for me."
- Community health worker (CHW): *patients viewed the CHW role as beneficial in terms of motivation, connection to resources, and assistance with insurance.*
  - "I think that [the CHW] motivated me to follow up with my senior center … because there seems to be a number of classes that I could take."
  - "Like I say, I really appreciated that [the CHW] sort of walked me, held my hand as we went through a couple of the application processes. Yeah, it was very good."
  - "[The CHW] was excellent. She helped me with some upcoming things that I have to deal with, Medicare specifically. There's some other things I had asked [the CHW] help about, right away, [the CHW] obtained the information for me and shared it with me, the resources. Yeah, [the CHW] was very good."
- Platform use: *patients with heart failure see digital platform use as generally helpful with little inconveniences.*
  - "So the device, I honestly didn't really notice much of a difference in my normal life, except something obviously on my arm. But that really wasn't a problem for me. I normally take my blood pressure often and my weight often. So that wasn't anything new to me, except to record it. So that really wasn't a problem."
  - "The phone that I used was different from an iPhone, but it came up easy enough for me to find the menus and to do what I needed to do on them.."
  - "It was great. I loved it. You know what I mean."

Exploratory Findings

Exploratory analysis also demonstrated that there were 6 occurrences where the intervention may have assisted in preventing clinical decline, ED visits, or hospital admissions (Figure 2). These occurrences were identified by biometric changes generated by the digital platform as well as patient symptoms spurring CHW assessment. Further, 4 of these occurrences resulted in care team communications, encounters, and changes in clinical care plans. These changes potentially addressed factors that may have otherwise resulted in ED visits or hospital readmissions. Examples of how clinical teams were notified of patient decline are described in detail in Figure 2.

Figure 2. Examples of care team notification of patient decline. Occurrences were initiated due to a change in patient symptoms identified by machine learning algorithm Biovitals alerts. Both a change in patient symptoms reported to their CHW via phone and generated Biovitals dashboard alerts from remote monitoring resulted in CHW assessment. From there, the appropriate steps were taken as identified by the study team. This often resulted in CHW reinforcement of care, notification of the patient's cardiology team, or notification of the patient's primary care team which lead to medication changes, impromptu appointments, care plan changes, and care plan clarification. CHW: community health worker; NP: nurse practitioner; PCP: primary care physician.



Discussion

Principal Findings

In this single arm study assessing the feasibility and acceptability of digital platform use combined with CHW care for patients with HF, we found that the intervention was both feasible and acceptable. The digital platform was designed for patients with HF and modified for use by a CHW staff member trained to guide patients in navigation of the platform. This patient-centered and comprehensive home-based HF management intervention was both feasible and acceptable to patients.

Prior studies have demonstrated the willingness of patients with HF to engage with digital platforms, and this was consistent with our findings [34]. Although the biometrics of the digital platform such as heart rate, steps taken, oxygenation, and blood pressure were generally accurate, qualitative interviews suggested that some participants initially experienced weight scale errors due to an incomplete mobile app update that was subsequently corrected. This finding underlines the importance for measurement accuracy and precision in home-based HF interventions where clinical status often hinges on narrow margins of change in weight or other biometrics [35,36]. The effect of care plan reinforcement or other categories of CHW-patient interactions seen here in this study have not been well studied in digital remote monitoring interventions. However, the impact of these types of CHW activities is strongly supported in prior general medicine and disease-specific CHW studies [12,37,38].

There were some unexpected findings in this study. First, most participants indicated in the poststudy questionnaire that they would need in-person support in order to use the digital platform. This finding is supported in at least 1 prior observational study [32] and reflects patient perceptions about the technological challenges of digital platform use in this older and chronically ill population of patients. Most participants indicated in the poststudy questionnaire that they "needed to learn a lot of things before using the digital platform." This supports the use of embedding assistance in the form of a CHW as a necessary component of digital platform use and engagement [33,39].

In exit interviews, participants also identified aspects of the digital platform that could be improved. These included improving weight scale precision and accuracy, optimizing digital platform connectivity, and streamlining the mobile app layout. Addressing these participant-identified areas of improvement may avoid patient-perceived logistical and technical inconveniences associated with using the digital platform and further enhance patient engagement and intervention adoption.

We identified several examples where the intervention resulted in additional CHW assessment, clinical care team coordination, or care plan changes without resulting in acute care use or hospitalization. These examples, triggered by patient symptoms or digital platform alerts, resulted in continued observation, medication changes, or an impromptu appointment. Subsequent involvement of the patient clinical home occurred on a case-by-case basis. Future study of these pathways can identify additional opportunities for intervention and determine if the

intervention helps to prevent emergency visits or hospitalizations.

Limitations

Since this was an observational single-arm study, we cannot establish effectiveness of the intervention. Furthermore, our sample size was small, mostly White, and limited to a single academic institution; these results may not be generalizable to other settings. Despite this, we believe that the novel intervention and use of patient response data gathered from questionnaires and exit interviews provides meaningful context for the acceptability and feasibility of the intervention. Furthermore, given the timing of the study with performance during the height of the COVID-19 pandemic, enrollment in the outpatient setting may have been affected by patients who were isolating in their homes versus those who were unable to be contacted due to living elsewhere at that time.

Conclusions

Use of a digital platform combined with a CHW is both feasible and acceptable for delivering home-based HF care. Given the significant burden for patients with HF living at home, this intervention could help predict early decline, guide intervention prior to clinical deterioration, and prevent hospital admissions and ED visits. A future randomized controlled trial is needed to test the preliminary effectiveness of this intervention in improving clinical outcomes.

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Data Availability

Deidentified data may be obtained upon request by contacting the corresponding author with a descriptive proposal stating the purpose of the data request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Digital platform symptom questionnaire.
[DOCX File , 15 KB - cardio_v7i1e47818_app1.docx]

Multimedia Appendix 2
Digital platform biosensor on wristband.
[DOCX File , 125 KB - cardio_v7i1e47818_app2.docx]

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Abbreviations

CHW: community health worker
ED: emergency department
EHR: electronic health record
HF: heart failure
MGH: Massachusetts General Hospital
REDCap: Research Electronic Data Capture

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Original Paper

Patterns in the Use of Heart Failure Telemonitoring: Post Hoc Analysis of the e-Vita Heart Failure Trial

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Abstract

Background: Research on the use of home telemonitoring data and adherence to it can provide new insights into telemonitoring for the daily management of patients with heart failure (HF).

Objective: We described the use of a telemonitoring platform—including remote patient monitoring of blood pressure, pulse, and weight—and the use of the electronic personal health record. Patient characteristics were assessed in both adherent and nonadherent patients to weight transmissions.

Methods: We used the data of the e-Vita HF study, a 3-arm parallel randomized trial performed in stable patients with HF managed in outpatient clinics in the Netherlands. In this study, data were analyzed from the participants in the intervention arm (ie, e-Vita HF platform). Adherence to weight transmissions was defined as transmitting weight ≥3 times per week for at least 42 weeks during a year.

Results: Data from 150 patients (mean age 67, SD 11 years; n=37, 25% female; n=123, 82% self-assessed New York Heart Association class I-II) were analyzed. One-year adherence to weight transmissions was 74% (n=111). Patients adherent to weight transmissions were less often hospitalized for HF in the 6 months before enrollment in the study compared to those who were nonadherent (n=9, 8% vs n=9, 23%; *P*=.02). The percentage of patients visiting the personal health record dropped steadily over time (n=140, 93% vs n=59, 39% at one year). With univariable analyses, there was no significant correlation between patient characteristics and adherence to weight transmissions.

Conclusions: Adherence to remote patient monitoring was high among stable patients with HF and best for weighing; however, adherence decreased over time. Clinical and demographic variables seem not related to adherence to transmitting weight.

Trial Registration: ClinicalTrials.gov NCT01755988; https://clinicaltrials.gov/ct2/show/NCT01755988

(JMIR Cardio 2023;7:e41248) doi:10.2196/41248

KEYWORDS

heart failure; telemonitoring; adherence; eHealth; remote monitoring; electronic personal health record; patient monitoring

Introduction

The COVID-19 pandemic has put pressure on health care systems worldwide, and it sparked new interest in home telemonitoring. In heart failure (HF) care, it could help monitor HF signs and symptoms, reduce face-to-face consultations, and improve patient empowerment [1]. It may include remote patient monitoring or an electronic personal health record or a combination of remote patient monitoring and an electronic personal health record [2]. A personal health record is an electronic application through which individuals can access, manage, and share their health information in a private, secure, and confidential environment [3]. A personal health record may also include self‐management support, patient‐provider communication, information about illness, peer support, or monitoring health behavior data [4].

Randomized trials evaluating the effectiveness of noninvasive telemonitoring in HF, with HF hospitalization or death as end point, were either neutral or positive. Different results can be explained, at least partly, by the variety in telemonitoring approaches used and the level of usual care in the comparator arm [5-7]. Furthermore, blood pressure and heart rate are often captured in conjunction with weight in telemonitoring systems, but the additional prognostic potential of daily measurements of these biometric values in providing information on upcoming hospitalizations for worsening HF has not been explored thoroughly [8]. On the other hand, several research groups reported that simple rules of sudden weight change in patients with HF demonstrated to generate many alerts with poor sensitivity, and therefore, remote patient monitoring of weighing alone seems of limited value [9-12]. However, these results may be driven by insufficient or inadequate use of telemonitoring by patients. These studies lacked reporting on the daily use and adherence of participants to telemonitoring. In addition, both applications (ie, remote patient monitoring and personal health record) are rarely used in trials, while this can provide valuable new insights in understanding how patients want to use telemonitoring systems [13].

We already know that a small number of patients will not use telemonitoring at all (2%-14%) and that, in general, the use of telemonitoring decreases over time [14-16]. Studies that reported on adherence to telemonitoring in HF mainly focused on adherence to the number of biometric measurements per week [14,15]. Less is known about the relation between patient and their characteristics, the level of adherence to remote patient monitoring, and the use of a personal health record in a single telemonitoring system. The analysis of log data (ie, actual and continuous information about real-time usage behavior of a noninvasive telemonitoring device) can provide objective insights into the actual use and adherence to remote patient monitoring [17]. Deterioration of HF may lead to rapid weight gain as a consequence of fluid retention, and if uncorrected, it can lead to hospitalization and ultimately death. Obviously, weight management is important, and it is recommended by the European Society of Cardiology that patients should be trained to self-adjust their diuretic dose based on monitoring of signs or symptoms of HF deterioration and daily weight measurements [18].

The aim of this study was to quantify the use of telemonitoring (both remote patient monitoring and personal health record) in patients with stable HF and to assess whether patient characteristics were related to adherence or nonadherence to weight transmissions.

Methods

Procedure

We used the data of the e-Vita HF study. The design and results of the e-Vita HF study were reported elsewhere [1,19]. In short, the e-Vita HF study was a 3-arm parallel randomized trial in patients with stable chronic HF (337/450, 75% of the entire study population was self-assessed New York Heart Association [NYHA] class I or II) who were managed for at least 3 months in one of 9 heart failure outpatient clinics in the Netherlands; the study compared an eHealth-adjusted care pathway with (1) usual care and (2) usual care plus guided access to the heartfailurematters.org website [1,19]. Patients were followed up for 1 year. Patients were individually randomized by computerized block randomization (maximum of 9 patients per block) to one of the 3 groups (150 patients in each group) [1,19].

The eHealth-adjusted care pathway included an interactive platform for HF disease management with (1) a remote patient monitoring facility for weight, blood pressure, and pulse; and (2) a personal health record [1,19].

This post hoc analysis includes the data of all 150 patients randomized to the eHealth-adjusted care pathway arm.

Ethics Approval

All patients provided written informed consent, which was obtained during the first study visit at the HF outpatient clinic before any study procedure was undertaken. The study was approved by the Medical Ethics Committee of the University Medical Center Utrecht (number 12/456), and the e-Vita HF trial was registered on ClinicalTrials.gov (NCT01755988).

Patient Population

Patients were eligible if they were 18 years of age or older, had an established diagnosis of HF for more than 3 months, were managed at a participating HF outpatient clinic, and had sufficient cognitive function [1,19]. Exclusion criteria were as follows: (1) nonavailability of internet and email; (2) inability of the patients or their family to work with internet and email; and (3) inability of the patients, their family, or caretakers to read and understand Dutch [1,19].

Components of the eHealth-Adjusted Care Pathway

In the eHealth-adjusted care pathway, an interactive platform for HF disease management (the e-Vita platform) was used. The e-Vita HF platform consisted of a remote patient monitoring platform for biometric values plus a medical and health

information website (ie, personal health record), and therefore, it was not integrated in a mobile phone app.

When logging on for the first time to the personal health record, every patient saw a pop‐up with a brief explanation about the website and the services that could be found on there. After the pop‐up, every patient was directed to the home page. From there, patients were able to access all

functionalities of the website. It consisted of the following set of interrelated services, which could be accessed via the home page: (1) self‐monitoring personal health values, where patients could view (previous) biometric values and, if needed, manually add extra measurements in addition to the values received by Bluetooth (eg, blood pressure, pulse, and weight); (2) the website heartfailurematters.org was also a feature of the home page (with a smooth operating link to the freely accessible website); (3) medicine chart, where patients could add their medication; and (4) account settings, where patients could change personal information.

In addition, the specialist HF nurses instructed the patients and their caregivers on how to use the remote patient monitoring elements of the e‐Vita platform, including guidance on the heartfailurematters.org website. Patients learned to record biometric measurements (ie, weight, blood pressure, and pulse) on a fixed time point every day. Blood pressure and pulse were measured with the same device (a Bluetooth-enabled electronic blood pressure monitor). Weight was measured on a Bluetooth-enabled scale. The measurements were automatically forwarded to the e‐Vita website with Bluetooth. If recordings of weight, blood pressure, or pulse were outside of personally adjusted limits (to reduce redundant alerts) or if measurements were not recorded, the specialist HF nurse received an alert via the e-Vita platform. If deemed necessary, the nurse contacted the patient by phone to explore symptoms and, if needed, adjusted the individual management or asked the patient to visit the outpatient clinic. The study team and help desk of the e-Vita platform were available by phone and email during office hours to provide help when patients or health care professionals experienced technical problems with the e-Vita HF platform or any other technical issue.

Measurements

Demographic and Disease-Specific Characteristics

Demographic and disease-specific characteristics were collected from electronic patient records at baseline. The NYHA class was patient reported. Self-care behavior was measured at baseline and after 12 months with the European Heart Failure Self-care Behaviour Scale. It consists of 9 items that were scored on a 5-point Likert scale with standardized scores from 0 to 100 and with a higher score meaning better self-care [20,21].

Participants' Use of Log Data of the Personal Health Record

When logging onto the web-based personal health record, every patient had to tick off a box to accept the general conditions, including a paragraph about tracking their use of the personal health record for research purposes. With accepting these general conditions, patients gave permission for collecting their usage data. The developers of the personal health record facilitated the collection of log data. All data were stored and processed following the actual privacy regulations. The log data of the personal health record were collected from October 9, 2013, to December 25, 2015.

For every patient, sessions (ie, the actions taken between logging on and logging out) were identified first. All actions that were performed within half an hour after the last action were considered to be part of the same session [22].

During the e-Vita HF study, the following log data were collected: (1) the time and date of the action, (2) identification of the action, and (3) optional additional information (eg, what information was viewed by the patients, or which personal goal was added).

The log data were divided into 2 time periods, that is, 0-6 and 6-12 months from baseline, to describe the change over time of the use of features of the personal health record other than the home page. The log data used were as follows: (1) clicking on "enter biometric measurements," (2) views of "graphs biometric measurements," (3) opening "previous measurements," (4) opening "my target biometric values," (5) opening "disease information," (6) opening "my medication," and (7) clicking on "add medication."

Because log data do not provide information concerning who used the personal health record (patient or caregiver), we analyzed the question "How many times have your family, friends and/or caregivers visited the personal health record on average in the past 3 months?" from the self-administrated "use of personal health record" questionnaire (measured at 3, 6, and 12 months). The questionnaire consisted of 17 questions, which were scored on an 8-point Likert scale (1=never and 8=daily).

Log Data of Remote Patient Monitoring

Log data were collected on weight, blood pressure, and pulse. The developers of the e-Vita heart failure remote patient monitoring system facilitated the collection of log data. All data were pseudonymized, stored, and processed following the current privacy regulations.

The log data of the biometric measurements were collected from October 9, 2013, to December 25, 2015. During the e-Vita HF study, the following log data of remote patient monitoring were collected: the date, time, values, alert triggers, and problems with measurements.

The population was divided into adherent and nonadherent based on adherence to weight transmission to assess whether patient characteristics were related to adherence or nonadherence to weight transmissions. Because there is no "gold standard" measure for telemonitoring adherence, we defined adherence as transmitting weight ≥3 times per week for at least 42 weeks in 1 year (ie, 80% of the time). Most patients mentioned to be in NYHA class I at the start of the study. In addition to the fact that all participants were in a stable phase of their disease, we did not define adherence as daily transmitting weight but as at least 3 times a week transmission of weight, similar to what the "Telemonitoring to Improve Heart Failure Outcomes" study used (intended use of 3 times per week) [14]. We used the

criteria of at least 42 weeks, since patients did not use remote patient monitoring during hospitalizations and holidays.

We measured adherence for the complete set of biometric measurements (blood pressure, pulse, and weight) and for each biometric measurement separately. We also compared the adherent and nonadherent patients with regard to hospitalizations the year before participation and during the study as well as their self-care behavior based on the European Heart Failure Self-care Behaviour Scale at baseline and at the end of the study (ie, 12 months).

Statistical Analyses

Descriptive statistics were used to describe the actual use of the e-Vita HF home page by patients during 1 year. To univariably compare the demographic and clinical characteristics between patients adherent and nonadherent to weight transmissions, the chi-square test was used for categorical variables, the independent 2-tailed *t* test was used for continuous variables in case of normal distributions, and the Mann-Whitney *U* test was used in case of skewed distributions. Nominal variables were expressed as n (%). Continuous variables were expressed as means with SDs or medians with IQRs. Data were extracted to IBM SPSS Statistics for Windows (version 26; IBM Corp) for statistical analysis.

Results

Demographic and Disease-Specific Characteristics

The mean age of the 150 patients studied was 67 (SD 11) years, and 25% (n=37) were female. The mean left ventricular ejection fraction was 36% (SD 11%), and the majority were in self-reported NYHA class I and II (I: n=49, 46%; II: n=54, 36%; III: n=18, 12%; and IV: n=9, 6%).

Actual Use of Remote Patient Monitoring Over Time (Transmission of Blood Pressure, Pulse, and Weight)

In a period of a year, 111 (74%) patients were adherent to weight transmissions (Table 1), and 101 (67%) were adherent to transmitting data on all three biometric values. Individual adherence showed to be dynamic, changing over time.

In the first 6 months, patients were most adherent to weight transmissions (n=129, 86% vs n=109, 73% between 6 and 12 months; Figure 1). The percentage of patients adherent to remote patient monitoring per month varied over time (Figure 1). Weight transmission varied between 95% (n=143) and 81% (n=122), blood pressure and pulse between 91% (n=137) and 73% (n=110), and all three (ie, weight, blood pressure, and pulse) between 91% (n=137) and 71% (n=107) per month over the period of 1 year.

A total of 6 (4%) patients never used the e-Vita HF platform (ie, remote patient monitoring and e-Vita HF website). Another 2 (1%) patients never used the remote patient monitoring facilities; they only logged on to the personal health record during follow-up.

In total, 85% (128/150) of the measurements were done between 6 and 10 AM, and during that period, 26% (39/150) of patients visited the home page of the personal health record (Figure 2). Transmitting biometric values did not differ between the weekdays or the different months of the year.

Table 1. Baseline characteristics of the 150 patients divided into adherent and nonadherent to weighing during a year. The italicized *P* value is significant.

Characteristics	Adherent[a] (n=111)	Nonadherent (n=39)	*P* value
Demographics			
Age (years), mean (SD)	67.3 (9.9)	64.8 (13.6)	.23
Female, n (%)	29 (26)	8 (20)	.20
Educational level, n (%)			.39
Low	24 (22)	10 (26)	
Middle	54 (45)	14 (45)	
High	33 (30)	15 (39)	
Living alone, n (%)	25 (22)	10 (26)	.21
BMI, mean (SD)	27.8 (5.0)	28.2 (7.0)	.67
Current smoking, n (%)	12 (11)	9 (23)	.06
Comorbidity			
ACS[b], n (%)	51 (46)	21 (54)	.40
Atrial fibrillation, n (%)	50 (45)	16 (41)	.66
Hypertension, n (%)	45 (40)	20 (51)	.24
Diabetes mellitus, n (%)	31 (28)	9 (23)	.56
COPD[c], n (%)	26 (23)	10 (26)	.78
Depression, n (%)	23 (21)	3 (8)	.06
Anxiety disorder, n (%)	18 (16)	5 (13)	.61
Heart failure and clinical characteristics			
Duration of HF[d] (months), median (IQR)	25 (12-51)	33 (11-59)	.48
LVEF[e], mean (SD)	36.4 (11.2)	34.9 (10.9)	.47
Hospitalization due to HF in the 6 months before the start of the study, n (%)	9 (8)	9 (23)	*.02*
NYHA[f] class at baseline, n (%)			.87
I	51 (46)	18 (46)	
II	40 (36)	14 (36)	
III	11 (10)	7 (18)	
IV	9 (8)	0 (0)	
Questionnaires			
EHFScBS[g] total score, median (IQR)	72 (61-83)	72 (64-80)	.97

[a]Adherent with weight transmissions ≥3 times a week for at least 42 weeks in 1 year.

[b]ACS: acute coronary syndrome.

[c]COPD: chronic obstructive pulmonary disease.

[d]HF: heart failure.

[e]LVEF: left ventricular ejection fraction.

[f]NYHA: New York Heart Association.

[g]EHFScBS: European Heart Failure Self-care Behaviour Scale.

Figure 1. Percentage of patients adherent to remote monitoring per month.

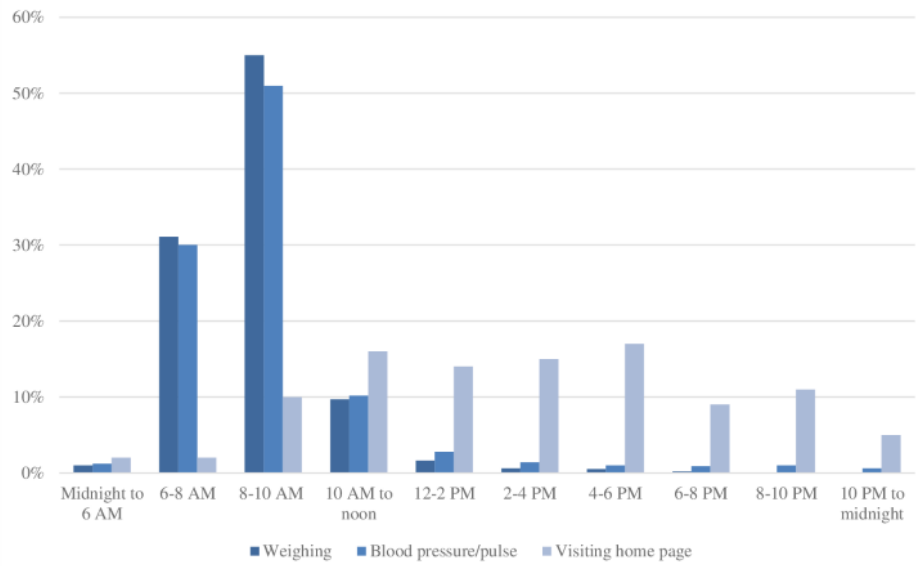
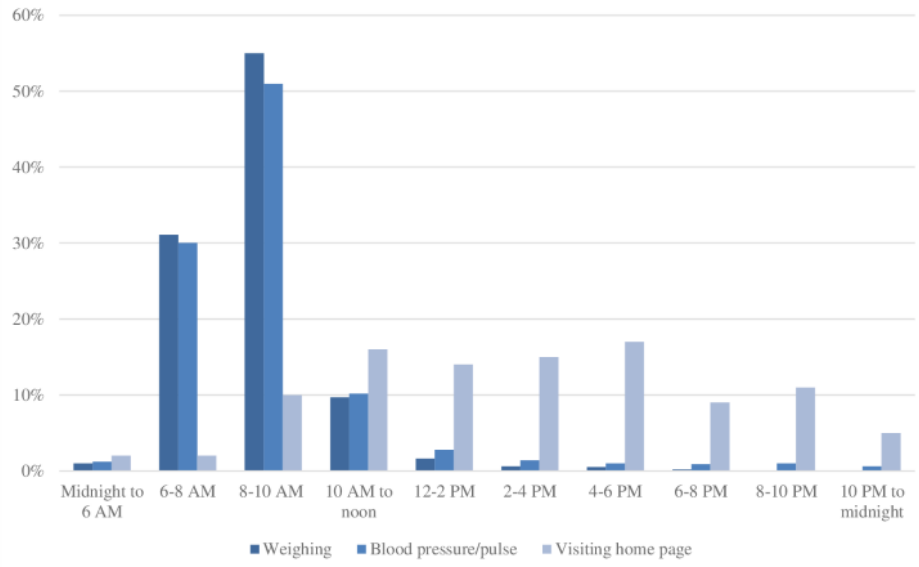


Figure 2. Time of the day for weighing, blood pressure and pulse measurements, and visiting the home page of the electronic personal health record.



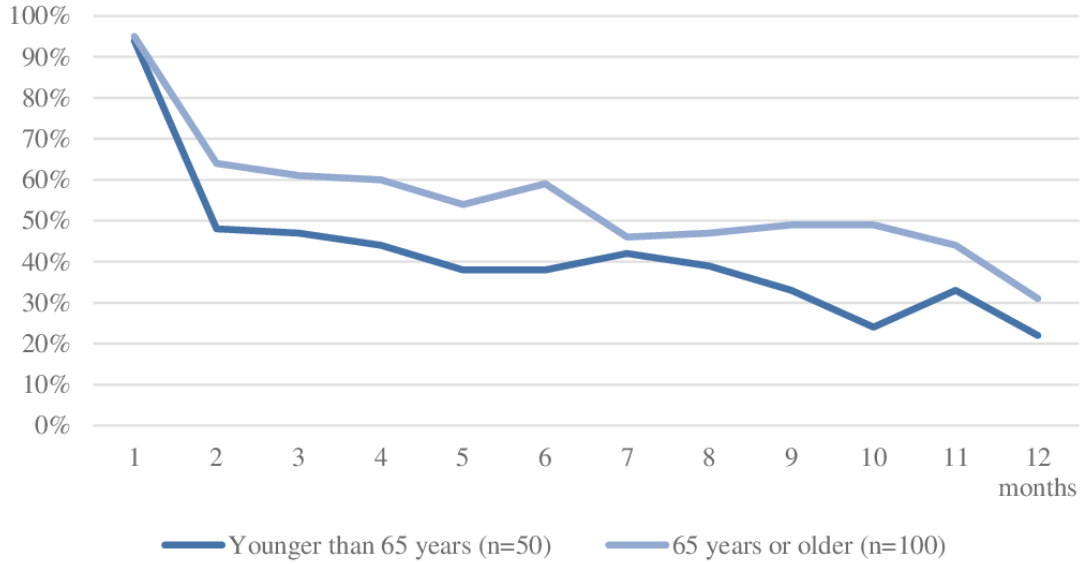
Clinical Characteristics of Patients Adherent to Weight Transmissions

The mean age of the 111 adherent patients was 67 (SD 10) years, and 29 (26%) were female (Table 1). Patients adherent to weighing were less often hospitalized for worsening of HF in the 6 months *before* enrollment in the study (adherent patients: n=9, 8% vs nonadherent patients: n=9, 23%). There was no difference between the adherent and nonadherent patients in the number of hospitalizations during the study; in the adherent group, 4 (3.6%) patients had more than one hospitalization compared to 1 (2.6%) patient in the nonadherent group. Furthermore, there was no difference in the total European HF Self-care Behaviour Scale scores between the groups at baseline or at 12 months.

Use of the Personal Health Record

In the first month, 142 (95%) patients visited the home page of the personal health record with a median number of 21 (IQR 7-54) visits. The number of patients visiting the home page declined over time, most rapidly in the first 2 months of follow-up (Figure 3).

Figure 3. Decline of over-the-year visits to the home page of the electronic personal health record of patients <65 years and patients ≥65 years of age.



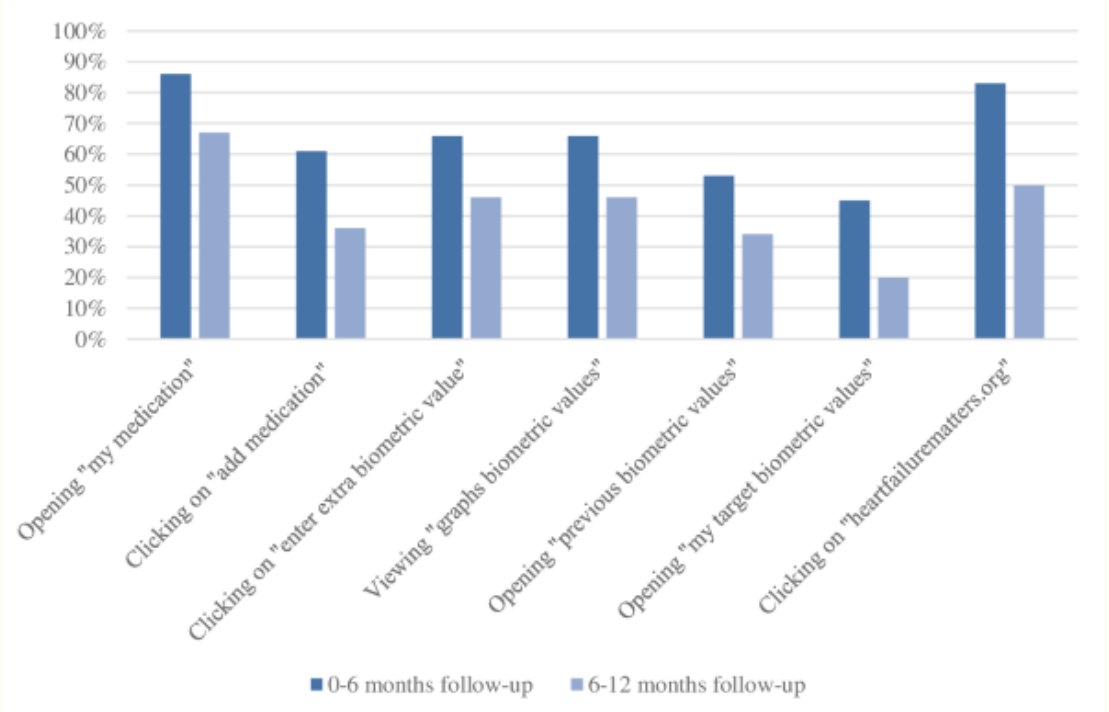
A total of 20 (13%) caregivers visited the personal health record at least once during 12 months. There was no difference between caregivers of adherent patients and caregivers of nonadherent patients.

The home page was most frequently visited in December (n=20, 13% of the visits) and least frequently visited in June (n=6, 4%); it was visited most often on Wednesdays (n=26, 17%) and less often on weekends (both weekend days; n=15, 10% of the visits). This was not related to the month or day of enrollment in the study. Between 10 AM and 6 PM, the home page was most often visited (n=93, 62% of the visits; Figure 2). Over time, older patients logged on to the personal health record more often than younger patients (Figure 3). There was no difference in sex related to logging on to the home page of the platform.

In the first 6 months, the most frequent action on the personal health record—after visiting the home page—was "opening my medication" (n=129, 86% of the patients), followed by visiting the heartfailurematters.org website (n=125, 83% of the patients; Figure 4). In the last 6-12 months of follow-up, the personal health record was less used compared to the first 6 months.

Patients adherent to weight transmissions visited the home page of the personal health record significantly more often in the last 3 months of follow-up compared to nonadherent patients (n=71, 64% vs n=8, 20%; *P*<.001).

Figure 4. Percentage of patients visiting features of the electronic personal health record 0-6 months versus 6-12 months of follow-up (n=150).



Discussion

Principal Findings

We quantified the use of telemonitoring in patients with stable HF and assessed whether patient characteristics correlated with adherence or nonadherence to weight transmissions. Overall, adherence to transmitting biometric values (ie, weight, blood pressure, and pulse) was high, ranging from 90% (n=135) at the start of the study to 71% (n=107) after 12 months. In addition, the use of personal health record was high at the start (n=143, 95%) but dropped to 25% (n=38) at 12 months.

Adherence to weight transmissions was rather high (on average n=111, 74% over the year), with the highest adherence during the first 6 months (n=131, 87%).

Of note, patients adherent to weight transmissions were less often hospitalized for HF in the 6 months before enrollment in the study and nonsignificantly so during the follow-up period of the study. This finding may be a coincidental finding but may also be related to the "healthy adherer effect." In any case, the main reason for using telemonitoring in patients with stable HF may not be the reduction of HF hospitalizations but to safely reduce routine health care utilization, including face-to-face contacts with a specialist HF nurse.

Clinical and demographic variables seemed not related to adherence to transmitting weight. This is in line with a recent systemic review that concluded that symptom severity, comorbidity, sex category, and marital status were inconclusively associated with better adherence to telemonitoring for any of these factors [23].

Monitoring vital signs is a key component of self-care for patients with HF, but the relationship between self-care behavior and age, gender, education, and left ventricular ejection fraction values is inconsistent [24].

The decline of adherence over time is a common finding with transmitting biometric values, and as such, it is also reported in previous telemonitoring HF studies [25,26]. Adherence rates in remote patient monitoring ranged from 40% to 90% in previous eHealth heart failure studies, which is similar to our study [6,14,26-32]. Interpreting our results, it is important to realize that adherence to remote patient monitoring is dependent on the telemonitoring system used, such as interactive voice response–based interventions and eHealth apps on mobile phones that leverage devices already familiar to patients [27]. Second, the remote patient monitoring interventions vary in intensity of contacts with HF professionals, for example, remote patient monitoring on top of usual care and remote patient monitoring including interactive and intensive coaching modules. Third, adherence is defined and measured inconsistently across studies and in diverse patient populations. In our study, we used a definition similar to the one the "Telemonitoring to Improve Heart Failure Outcomes" study used (intended use of 3 times per week) [14]. To correct the number of weeks for holidays and hospitalizations, we used an adherence percentage of 80% over 1 year (ie, 42 weeks). Fourth, adherence is a dynamic measure that often changes within patients. Adherence can vary per day, week, or month, and it is influenced by social and economic factors as well as factors that are related to the health care system, the condition of the patient, therapy, and other factors related to the patient [33].

Adherence to weight transmission was higher than adherence to transmitting blood pressure and pulse. This is in line with the "Trans-European Network–Home-Care Management System" study [31]. One of the reasons can be that weighing was already a habit for patients before the start of the study, whereas measuring blood pressure and pulse were not. Furthermore, measuring blood pressure is more time consuming than weighing and can be unpleasant; it may give a tinkling feeling in the arm and hand. Another explanation might be that patients had insufficient knowledge on the relevance of these parameters. Moreover, patients who are stable might not see any changes over time or a direct link between small changes in blood pressure and heart rate and their symptoms. Finally, an explanation could be that patients with HF in NYHA class I-II may feel less urgency to monitor the worsening of HF because they remain stable over a long period of time and may not experience substantial limitations due to their HF in their daily life. An important finding in this study regarding the use of a personal health record is that patients did not look at their (previous) biometric measurements very often, and therefore, it seems that most of the patients did not really use the personal health record for monitoring their own HF. This can be partly explained by the personal health record being mainly introduced in light of the evaluation study, and the training of the HF nurses predominantly focused on how to collect the data for this study. As a result, HF nurses did not know what was expected from them with regard to using the services of the personal health record. This caused HF nurses to find it difficult to motivate their patients in using the personal health record. Importantly, however, limited use of the personal health record is a rather common finding in eHealth studies [34-36]. Several systematic reviews focusing on the implementation of complex telemonitoring interventions and personal health records stress that the (perceived) fitting of telemonitoring technologies within the current working routines and the interoperability with other systems are key factors for a successful implementation [36-39].

In this study, a digital platform with automatic transmission was used, whereas a mobile phone app may be easier to use by patients.

Limitations

The study sample was rather small and too small for multivariable regression analysis, and this post hoc analysis of the e-Vita HF trial was observational in nature. In addition, we were unable to account for days when patients experienced technical problems with the remote patient monitoring equipment. However, technical problems occurred rarely and could be solved by a help desk we had in place. Therefore, it is unlikely that technical problems affected the degree of adherence. Nevertheless, this is one of the few studies that both evaluated remote patient monitoring and personal health record in patients with HF.

Conclusions

Adherence to transmitting biometric values was high among stable outpatients with HF who were participating in an eHealth study, and it was best for weight; however, adherence decreased over time. Clinical and demographic variables seem not related to adherence to transmitting weight.

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Data Availability

The data used to support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

HF: heart failure
NYHA: New York Heart Association

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Original Paper

Cardio4Health Study, a Cardiac Telerehabilitation Pilot Program Aimed at Patients After an Ischemic Event: Cross-sectional Study

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Abstract

Background: Center-based cardiac rehabilitation programs (CRPs) reduce morbidity and mortality after an ischemic cardiac event; however, they are widely underused. Home-based CRP has emerged as an alternative to improve patient adherence; however, its safety and efficacy remain unclear, especially for older patients and female patients.

Objective: This study aimed to develop a holistic home-based CRP for patients with ischemic heart disease and evaluate its safety and impact on functional capacity, adherence to a healthy lifestyle, and quality of life.

Methods: The 8-week home-based CRP included patients of both sexes, with no age limit, who had overcome an acute myocardial infarction in the previous 3 months, had a left ventricular ejection fraction of ≥40%, and had access to a tablet or mobile device. The CRP was developed using a dedicated platform designed explicitly for this purpose and included 3 weekly exercise sessions combining tailored aerobic and strength training and 2 weekly educational session focused on lifestyle habits, therapeutic adherence, and patient empowerment.

Results: We initially included 62 patients, of whom 1 was excluded for presenting with ventricular arrhythmias during the initial stress test, 5 were excluded because of incompatibility, and 6 dropped out because of a technological barrier. Ultimately, 50 patients completed the program: 85% (42/50) were male, with a mean age of 58.9 (SD 10.3) years, a mean left ventricular ejection fraction of 52.1% (SD 6.72%), and 25 (50%) New York Heart Association functional class I and 25 (50%) New York Heart Association II-III. The CRP significantly improved functional capacity (+1.6 metabolic equivalent tasks), muscle strength (arm curl test +15.5% and sit-to-stand test +19.7%), weekly training volume (+803 metabolic equivalent tasks), adherence to the Mediterranean diet, emotional state (anxiety), and quality of life. No major complications occurred, and adherence was excellent (>80%) in both the exercise and educational sessions. In the subgroup analysis, CRP showed equivalent beneficial effects irrespective of sex and age. In addition, patient preferences for CRP approaches were equally distributed, with one-third (14/50, 29%) of the patients preferring a face-to-face CRP, one-third (17/50, 34%) preferring a telematic CRP, and one-third (18/50, 37%) preferring a hybrid approach. Regarding CRP duration, 63% (31/50) of the patients considered it adequate, whereas the remaining 37% (19/50) preferred a longer program.

Conclusions: A holistic telematic CRP dedicated to patients after an ischemic cardiac event, irrespective of sex and age, is safe and, in our population, has achieved positive results in improving maximal aerobic capacity, weekly training volume, muscle strength, quality of life, compliance with diet, and anxiety symptoms. The preference for a center- or home-based CRP approach is diverse among the study population, emphasizing the need for a tailored CRP to improve adherence and completion rates.

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KEYWORDS

cardiac rehabilitation; web-based platform; telemedicine; remote care; ischemic heart disease

Introduction

Background

The cardiac rehabilitation program (CRP) is a comprehensive, multidisciplinary, secondary prevention program for optimizing cardiovascular health. Multifaceted programs can address the psychosocial, physical, nutritional, and emotional aspects of cardiovascular health. Supervised CRP is beneficial and safe for different populations of patients with cardiovascular diseases, such as those who have experienced an ischemic event [1,2], cardiac surgery [3], or heart failure [4]. Thus, international guidelines recommend, with a maximum level of evidence *1A*, CRPs for cardiovascular pathologies [5,6].

The beneficial effects of CRP on the abovementioned cardiovascular diseases include a considerable improvement of functional capacity [7], greater adherence to a healthy lifestyle [8], and lower incidence of disease-associated anxiety and depression [9], all of which improve the quality of life of the patient [10]. Furthermore, CRP reduces cardiovascular morbidity and mortality mid- to long-term in patients who have experienced an ischemic event [1,11]. Over the last decade, supervised CRP has been increasingly used for patients who have experienced an ischemic event; however, the percentage of patients benefiting from these programs is still far from 100% [12].

CRP implementation has been mainly hindered by the associated costs [12] and low adherence of eligible patients [13], which may be because of their incompatible working hours [14]. Many patients who have experienced an ischemic event continue working and cannot attend the CRP, which is usually performed during the usual consultation hours (morning and half an afternoon). Other variables associated with low adherence are difficulty traveling to the CRP center, low socioeconomic status [13], and frailty with concomitant pluripathology. In contrast, female individuals traditionally have a higher familial burden and lower physical activity levels than male individuals, leading to a decline in their reduced CRP participation [15].

Technological advancement over the last decade has allowed the development of a novel web-based CRP designated as cardiac telerehabilitation. Such programs are effective and safe for patients following an ischemic event [16]. However, most of the currently available evidence comes from selected populations, including middle-aged male patients with a high degree of motivation to undertake the program and excluding those expected to have lower adherence, such as female patients [15], patients aged >75 years, rural residents [17], and patients with multiple comorbidities [18].

The development of telematic CRP is significant in the past scenario of the COVID-19 pandemic. Such programs would allow the continuation of CRPs while minimizing the contagion risk.

However, many CRPs focus only on physical training (PT), disregarding interventions for the emotional sphere [19], nutrition [20], and medication adherence [8], which are essential for improving patient adherence to a healthy lifestyle. In addition, PT in several CRPs includes only aerobic exercise, despite the safety and synergistic effect of strength training in improving functional capacity [21].

In this study, we developed a web-based cardiac telerehabilitation platform, specifically designed for patients following ischemic events. The holistic telematic CRP includes PT and interventions to improve the emotional sphere and adherence to a healthy lifestyle.

Objectives

The primary objective of this pilot study was to evaluate the result of the cardiac telerehabilitation program in terms of increasing the aerobic functional capacity, evaluated using the metabolic equivalent tasks (METs) achieved in a maximal exercise test, and strength, measured through repetitions of sit-to-stand and arm curl tests.

The secondary objectives were to assess the following:

- Feasibility of the program and the designed platform
- Safety of the program: assessing whether major or minor events (cardiovascular or other types, if relevant) occurred within 24 hours after PT
- Quality of life using the European health questionnaire combining quantity and quality of life (EuroQoL) [22]
- Adherence to the program
- Adherence to the Mediterranean diet using the Mediterranean diet and lifestyle (*Prevención con Dieta Mediterránea* [PREDIMED]) questionnaire [23]
- Emotional state using the Hospital Anxiety and Depression Scale (HADS) [24].

Methods

Study Design

This was a single-center prospective study with participant recruitment from the Cardiovascular Institute of the Hospital Clínic (*Institut d'Investigacions Biomèdiques August Pi i Sunyer*) at the University of Barcelona, Spain, conducted between December 2020 and January 2022.

All participants provided verbal and written consent.

The variables listed below were included on the web platform used for the cardiac telerehabilitation program. The program researchers collected data and were anonymous in all cases.

Ethics Approval

The Ethical Committe for Research on Medicines at the Hospital Clinic of the Universitat de Barcelona approved this study in November 2020 (ethics ID: HCB/2020/1021), which aligned with the Helsinki Declaration.

Variables Analyzed

Variables Related to the Study Population

The following data were collected from the study population:

- Age
- Sex
- Weight, height, BMI, and abdominal circumference
- Family history
- History of cardiovascular pathology and comorbidities
- Socioeconomic data: employment status and educational level
- Systolic and diastolic blood pressures were measured under normal daily conditions (nonfasting state and with antihypertensive treatment administered if previously prescribed, as described in the 2018 European Society of Cardiology/European Society of Hypertension guidelines for the management of arterial hypertension) [25].
- Heart rate (HR) at rest.
- Cardiovascular medication record: therapeutic adherence was assessed using a personalized interview and by counting the number of pills between the inclusion visit and end of the program.
- Physical activity: pre- and postprogram physical activity levels were assessed using the International Physical Activity Questionnaire–Short Form (IPAQ-SF) [26].

Variables Related to Functional Capacity and Strength Assessment

The variables related functional capacity and strength assessment were as follows:

- METS at maximal effort and indirect anaerobic threshold
- HR at maximal exertion and indirect anaerobic threshold
- Systolic and diastolic blood pressures at maximal exertion and indirect anaerobic threshold
- The perceived sensation of exertion was assessed using the Borg scale at maximal effort and indirect anaerobic threshold [27].
- Lower- and upper-extremity strengths: sit-to-stand and arm curl tests were used to estimate maximal strength in 1 repetition with a linear transducer (encoder).

Variables Related to a Healthy Lifestyle

The variables related to a healthy lifestyle used in this work were as follows:

- Adherence to the Mediterranean diet: PREDIMED questionnaire
- Quality of life: EuroQoL questionnaire
- Anxiety and depression: HADS questionnaire
- Tobacco and other drug use
- Blood tests (measured in a fasting state as described in the European Society of Cardiology guidelines for the management of diabetes mellitus and dyslipidemia) [28,29]
- Glycosylated hemoglobin, total cholesterol, and low- and high-density lipoproteins

Variables Related to the Implementation of the Cardiac Telerehabilitation Program

The variables related to the program implementation were as follows:

- For the PT sessions, HR was measured using a Fitbit device range of devices with activity trackers, the Fitbit Ionic smartwatch, that transferred the data directly to the platform via Bluetooth with a 3- to 4-minute interval, and the sensation of perceived effort (Borg scale 1-10) [30] was recorded after questioning the patient at the end of each exercise series during the web-based training session.
- For the educational sessions, daily intake was recorded once weekly.

Recruitment of the Patients: Inclusion and Exclusion Criteria

The study population included patients of both sexes, with no age limits, who had experienced an acute myocardial infarction in the previous 3 months; who had access to mobile phones, computers, or tablets with internet access; and who had not previously participated in a CRP (face-to-face or telematic). Conversely, patients who met the high-risk criteria for exercise-induced cardiovascular events according to the European guidelines for cardiac rehabilitation and exercise prescriptions for patients with cardiovascular diseases were excluded. Specifically, these criteria included left ventricular ejection fraction (LVEF) of <40%, New York Heart Association class >III, ischemia or significant arrhythmias documented during the inclusion stress test, and the placement of an implantable automatic device within 6 weeks before the start of the program. In addition, those with significant anemia (hemoglobin level <10 mg/100 mL), grade IV chronic obstructive pulmonary disease, or requiring home oxygen therapy were excluded from the study.

Development and Implementation of the Program

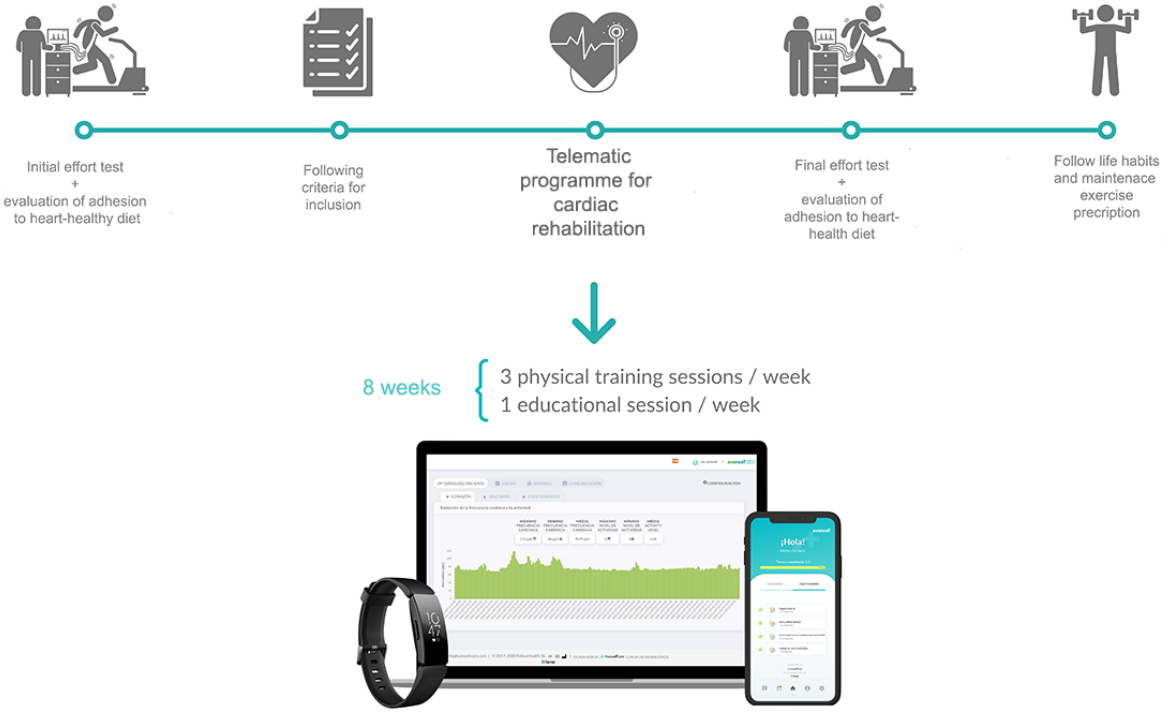
Overview

During their first visit, the potential participants were evaluated for cardiovascular risk factors, adherence to the Mediterranean diet (PREDIMED questionnaire), and emotional status (HADS). In addition, quality of life and exercise training volume were evaluated using the EuroQoL and IPAQ-SF questionnaires, respectively.

Muscle strength was evaluated using the 30-second sit-to-stand (lower limb) and arm curl (upper limb) tests. The intensity prescribed was based on the basal characteristics of each patient and the maximum HR reached on the initial stress test on the treadmill using the Bruce protocol. In some cases with limited functional capacity, we used the modified Bruce protocol [31]. The 85% of maximum HR obtained in the stress test was the maximum HR allowed by the Fitbit device to guide the exercises, as described in the 2020 European Society of Cardiology Guidelines on Sports Cardiology and Exercise in Patients with Cardiovascular Disease [32].

The holistic CRP included 3 weekly exercise sessions and 1 weekly session regarding lifestyle habits, therapeutic adherence, and patient empowerment (Figure 1) for a duration of 8 weeks.

Figure 1. Scheme of the pilot cardiac telerehabilitation program.



The sessions were performed by a physiotherapist or nurse expert in nutrition in groups of 8 patients. The sessions took place after working hours to increase patient adherence and to be compatible with normal hospital activities.

Exercise Sessions

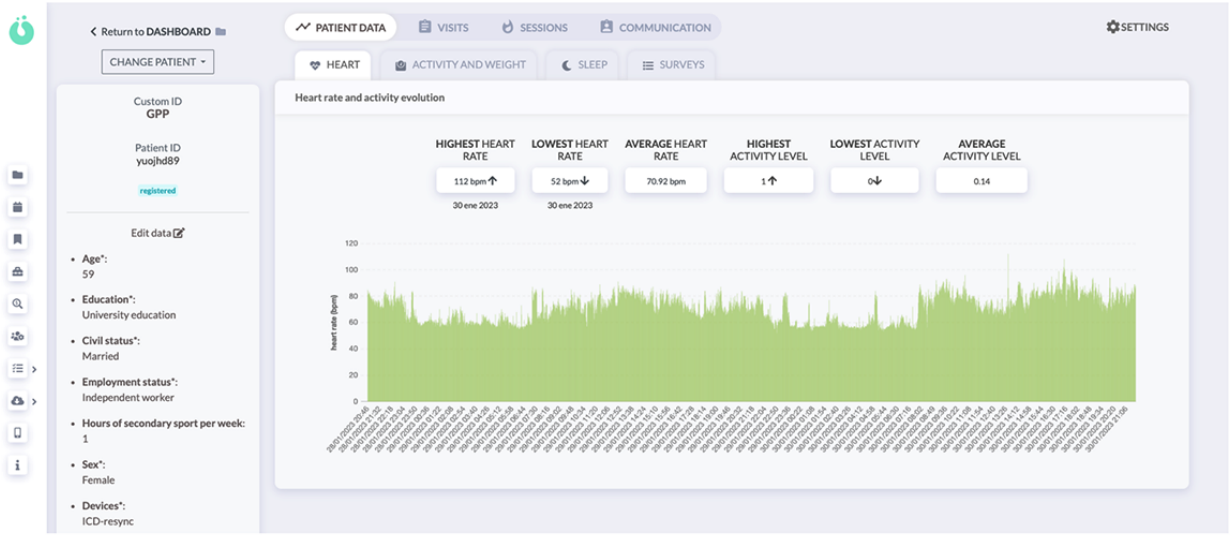
Each participant completed 24 thrice weekly PT sessions, each lasting 1 hour. The sessions were conducted live via the platform, with guidance from a physiotherapist and cardiologist.

Exercise training consisted of aerobic and prescribed strength training based on the exercise testing and strength assessment; the HR and perceived exertion scale regulated the exercise intensity. The HR was monitored during the PT sessions using a Fitbit Inspire 2 device, which complied with the privacy shield policy. The training load was then increased overnight.

Patients directly contacted their assigned physiotherapist during and up to 30 minutes after the training sessions. In all sessions, there was a responsible cardiologist on call, in case of need. If any complication occurred within the indicated time, the physiotherapist initiated the medical emergency circuit, which consisted of contacting *112* (medical emergency telephone number) and detailing the complication to ensure prompt evaluation of the patient. The cardiologists were simultaneously informed of the adverse event.

All patients were instructed to bring along a family member during the PT sessions. In addition, before starting, all patients and their relatives (partners or caregivers) had to complete a workshop, which was offered live on the platform, on cardiopulmonary resuscitation and warning signs. Moreover, patients could forward their queries and messages through chat. The program physiotherapist reviewed these messages and questions daily and referred the patients to the medical team when necessary (Figure 2).

Figure 2. HumanITcare dashboard: heart rate over the time control panel.



Educational Sessions

A specialized nurse accredited in nutrition conducted weekly group sessions through the web-based platform to address issues such as smoking, the Mediterranean diet, patient empowerment, therapeutic adherence, and psychological support, including strategies for acceptance of the disease, to comprehensively improve the quality of life and encourage a healthy lifestyle. In addition, all patients had individual monthly sessions during which the concepts covered during the group sessions were reinforced.

The last visit at the end of the program included a maximal exercise test: upper and lower extremity strength assessments. In addition, questionnaires assessing adherence to the Mediterranean diet, emotional state, quality of life, and medication count were also repeated.

Adherence to Exercise and Educational Sessions

We defined correct adherence if the patient completed the established and individualized protocol and the assistance was >80% of the session's educational and exercise.

Statistical Analysis

Data were entered into an anonymized database, and statistical analyses were performed using Stata software (version 15.1; StataCorp LLC). Quantitative variables are expressed as mean (SD) or median according to their normality, as assessed using the Shapiro-Wilk test. Qualitative variables are expressed as n (%). Data were compared using Student 2-tailed *t* test for unpaired data if they followed a normal distribution and the Mann-Whitney *U* test if they did not. Statistical significance was set at $P<.05$.

Subgroups Analysis: Sex and Age Differences

Our CRP included patients of both sexes with no age limit, so a comparison could be made in terms of feasibility; safety; and results in exercise, educational sessions, and adherence.

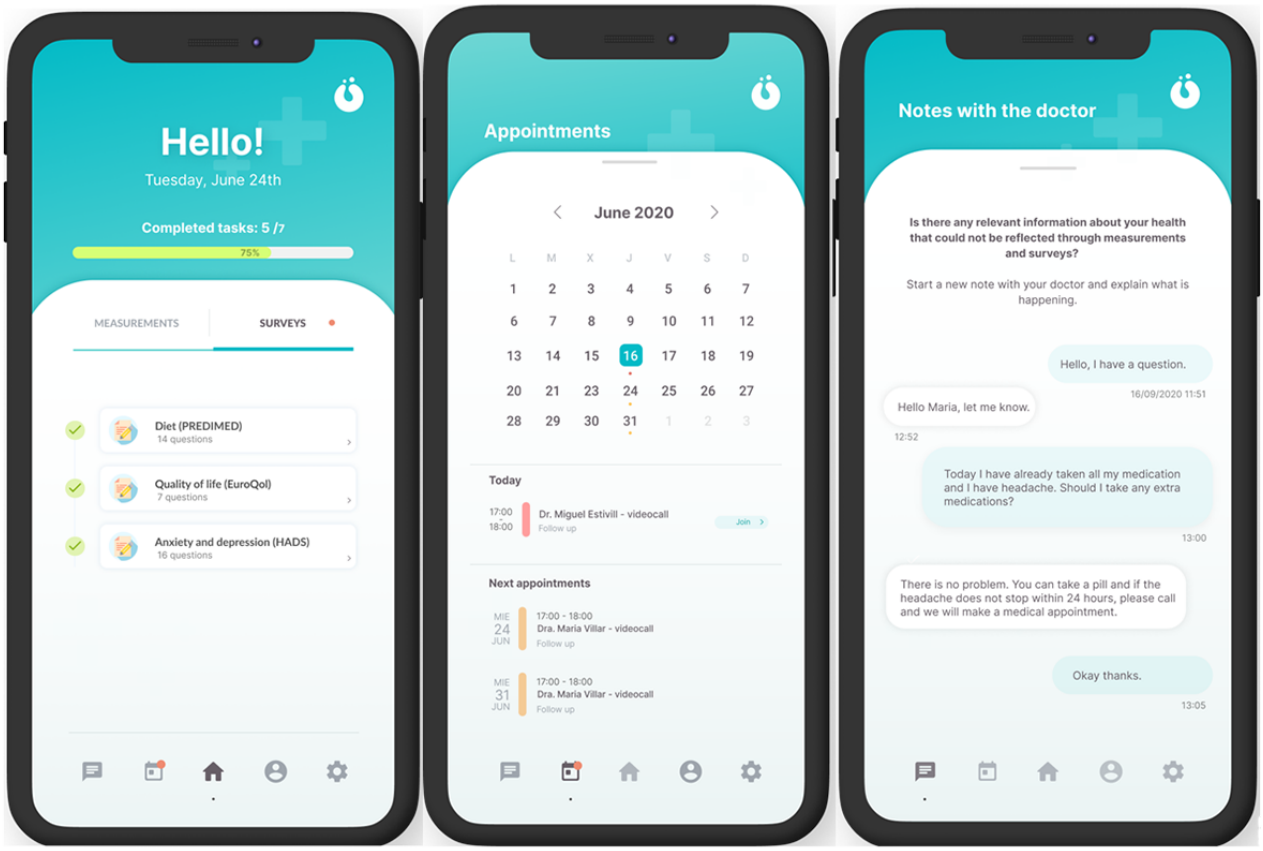
Designed Platform: HumanITcare Solution—Subjective Evaluation of the Patients of the CRP

The cardiac telerehabilitation program was carried out using the HumanITcare (SME Technology Co) platform [33], a telemedicine and telemonitoring platform for remotely monitoring chronic patients through integrated portable devices.

HumanITcare is an application programing interface–based solution comprising a medical website for health care professionals and a mobile app for patients (Figure 3; available for Android and iOS). The website includes a medical portal to personalize each follow-up care plan, where medical professionals can access a dashboard with data collected from all patients. However, patients have to download an app to follow their care plans. The app allows automatic data collection through Bluetooth-linked sensors, integrated devices, and self-reported questionnaires. In addition, all data are transmitted to the cloud in real time; therefore, they can be analyzed, processed, and simultaneously displayed on the medical web portal.

Data security and privacy are essential to such solutions. Each patient had a username and a personal password to access the app. The company responsible for this platform is FOLLOWHEALTH S.L. (HumanITcare), which has servers in Ireland and complies with the General Data Protection Regulation of May 25, 2018, and the Data Protection Law (Organic Law on the Protection of Personal Data, Spain). Each participant in the study was assigned an ID consisting of 8 random characters (eg, d4w192bg), and participant data could only be reviewed using this ID.

Figure 3. The app screen for the patient. PREDIMED: Prevención con Dieta Mediterránea.



Participant data were encrypted on the access platform for the researchers, technical administrators, and server. When the patient registered on the platform through the app, the following legal notice regarding data protection appeared on the screen to obtain consent from the patient for data processing:

> *This tool does not provide medical advice. It is only intended for information purposes for healthcare professionals. Do not use it as a substitute for professional medical advice, diagnosis, or treatment. Your doctor will review your responses and contact you, if necessary. Confidentiality of your data is important to us. Therefore, we have complied with the established data protection regulations. For more information, please read the detailed legal terms and conditions.*

To improve satisfaction with the usability of the platform, feedback was collected from all users (patients and health professionals) during the study to enhance the different aspects of the tools used during the CRP, including reminders, bug reporting, and data visualization during sessions.

Material was provided to the patients to allow them to perform the program from home. This material included rehabilitation equipment and a wearable device to collect continuous data on patient habits during the program, specifically during the rehabilitation sessions.

After completion of the CRP, patients were also asked to complete a questionnaire to evaluate their satisfaction with the program, its duration, and the designed platform.

Results

Study Design, Variables Analyzed, and Recruitment of Patients

Between December 2020 and January 2022, 62 patients were included in the CRP; 2 were initially excluded (one because of ventricular arrhythmias during the initial stress test and the other because of technological incapacity). Therefore, 60 patients began the program, of whom 5 dropped out because of technical barriers and 5 dropped out because of schedule incompatibility.

Ultimately, 50 patients completed the program, 42 (85%) of whom were male, with a mean age of 58.9 (SD 10.3) years. In addition, the mean LVEF was 52.1% (SD 6.72%). According to the New York Heart Association functional classes, 50% (25/50), 40% (20/50), 10% (5/50), and 0% (0/50) of patients had classes I, II, III, and IV heart failure, respectively. No major or minor complications occurred during the course of the CRP (Figure 1).

Development and Implementation of the Program: Exercise and Educational Sessions—Evaluation of Adherence

Exercise Sessions

CRP significantly improved the maximal and submaximal aerobic capacities, weekly training volume, and muscle strength. In addition, no changes in blood pressure values were observed at rest or during exercise (Table 1).

Table 1. Exercise stress test and muscle strength evaluation before and after the cardiac rehabilitation program (CRP) in the study population.

	Baseline participants, mean (SD)	Participants after the CRP, mean (SD)	*P* value
Maximal aerobic capacity (METs[a])	8.3 (2.7)	9.8 (2.9)	.04
Weekly training volume (METs for week)	954 (629)	1757 (952	.03
METs VT1[b]	5.4 (1.6)	6.04 (1.7)	.03
METs VT2[c]	8.6 (2.3)	9.4 (2.5)	.04
Basal DBP[d] (mm Hg)	76.99 (7.1)	75.7 (7.5)	.10[e]
DBP at maximal exercise (mm Hg)	78.4 (2.8)	78.4 (3.9)	.08
Basal SBP[f] (mm Hg)	123.9 (15.49)	122.1 (11.4)	.09
SBP at maximal exercise (mm Hg)	168.1 (17)	167 (19)	.11
Arm curl test (repetitions)	19.4 (4.9)	22.4 (5.8)	.03
Sit-to-stand test (repetitions)	13.7 (2.8)	16.4 (3.9)	.04

[a]MET: metabolic equivalent task.

[b]VT1: first ventilator threshold.

[c]VT2: second ventilator threshold.

[d]DBP: diastolic blood pressure.

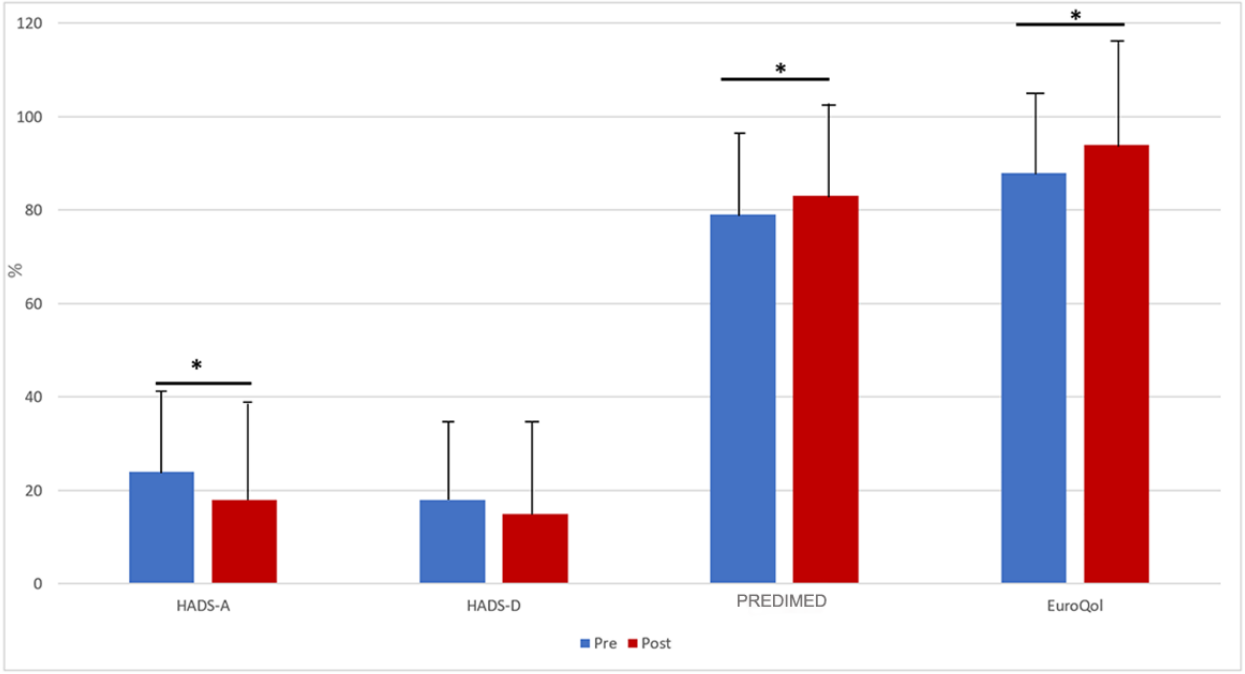
[e]Not significant.

[f]SBP: systolic blood pressure.

Educational Sessions

CRP significantly increased adherence to the Mediterranean diet, promoted a better quality of life, and improved the emotional state by reducing anxiety symptoms; however, no changes were observed in the depressive symptoms (Figure 4).

Figure 4. Adherence to the Mediterranean diet, emotional state, and quality of life before and after the program in the study population. *P*<.05 values significantly different between the indicated groups. HADS-A: *P*=.03; HADS-D: *P*=.09; PREDIMED: *P*=.04; EuroQol: *P*=.006. EuroQoL: European health questionnaire combining quantity and quality of life; HADS-A: Hospital Anxiety and Depression Scale–Anxiety; HADS-D: Hospital Anxiety and Depression Scale–Depression; PREDIMED: Prevención con Dieta Mediterránea—Mediterranean diet using the Mediterranean diet and lifestyle.



Adherence to Exercise and Educational Sessions

Adherence to the exercise (85.3%) and educational (86.6%) sessions was excellent. Additionally, there were no significant differences between male and female participants (exercise sessions: *P*=.10; educational sessions: *P*=.21; Table 2).

Table 2. Comparison between male and female participants in the adherence to nutritional and exercise sessions.

	Global participants, mean (SD)	Male participants, mean (SD)	Female participants, mean (SD	*P* value
Adherence to nutritional sessions (%)	86.6 (3.5)	84.2 (4.3)	96.7 (1.7)	.21
Adherence to exercise sessions (%)	85.3 (3.6)	82.9 (4.3)	95.6 (1.8)	.10

Subgroup Analysis

Sex Differences

This CRP pilot study included 50 patients after an ischemic event, 42 (85%) of whom were male.

Subgroup analysis showed an equivalent impact of the CRP on maximal aerobic capacity and muscle strength. Similar results were observed for adherence to the Mediterranean diet, quality of life, and depression symptoms, with a greater impact on improving anxiety symptoms (Table 3).

Table 3. Comparison between male and female participants in the study population showed the increasing parameters of stress test, muscle strength, Mediterranean diet and lifestyle (Prevención con Dieta Mediterránea [PREDIMED]), Hospital Anxiety and Depression Scale (HADS), and EuroQoL evaluation before and after the cardiac rehabilitation program (CRP).

	Baseline male participants, mean (SD)	Male participants after the CRP, mean (SD)	Difference between before and after the CRP in male participants, mean (SD)	Baseline female participants, mean (SD)	Female participants after the CRP, mean (SD)	Difference between before and after the CRP in female participants, mean (SD)	*P* value of the difference between before and after the CRP in male vs female participants
Maximal aerobic capacity (METs[a])	8.9 (0.4)	9.9 (0.6)	1.0 (0.2)[b]	6.9 (0.2)	7.8 (0.7)	0.9 (0.5)[b]	.14[c]
Weekly training volume (MET/wk)	1010 (112)	1900 (158)	890 (46)[b]	723 (93)	1169 (219)	446 (126)[b]	.21
METs VT1[d]	6.03 (0.5)	9.14 (0.6)	3.1 (0.2)[b]	4.2 (0.8)	5.9 (0.6)	1.7 (0.6)	.03
METs VT2[e]	8.9 (0.5)	9.6 (0.6)	0.7 (0.1)[b]	7.6 (1.3)	7.6 (3.1)	0.1 (0.0)	.04
Basal DBP[f] (mm Hg)	76 (1.3)	75.1 (1.2)	−0.17 (0.2)	80 (0.9)	77.2 (0.7)	−3.2 (0.2)	.13
DBP at maximal exercise (mm Hg)	78 (1)	78.6 (0.8)	−0.6 (0.3)	80 (2)	77 (1.5)	−3 (0.5)	.31
Basal SBP[g] (mm Hg)	121.8 (2.3)	121.2 (1.9)	−0.6 (0.4)	132 (6.8)	125 (3.1)	−7 (3.7)	.26
SBP at maximal exercise (mm Hg)	169 (3.1)	169 (3.0)	−0.2 (0.1)	162.2 (4.9)	158.9 (6.1)	−3.3 (1.2)	.28
Arm curl test (repetitions)	20.2 (0.8)	23.4 (0.9)	3.2 (0.1)[b]	16.7 (1.8)	18.7 (1.8)	2.0 (0.0)[b]	.11
Sit-to-stand test (repetitions)	14.1 (0.5)	17 (0.7)	2.0 (0.2)[b]	12.1 (1.1)	14.1 (1.7)	2.0 (0.6)[b]	.12
HADS-A[h]≥10 (%)	23 (2.4)	7 (1.3)	−15 (1.1)[b]	50 (2.1)	25 (1.70)	−25 (0.4)[b]	.03
HADS-D[i]≥10 (%)	12.9 (0.5)	7.8 (0.4)	−5.1 (0.1)	15 (8)	10 (1.9)	−5 (7.1)	.14
PREDIMED≥8 (%)	75 (0.5)	81.3 (0.8)	6.3 (0.6)[b]	100	100	0	.09
EuroQoL (%)	87.9 (2.8)	95.7 (2.9)	7.8 (0.1)[b]	82.2 (2.5)	89.2 (2.4)	7.0 (0.1)[b]	.08

[a]MET: metabolic equivalent task.

[b]Statistically significant result among the subgroups.

[c]Not significant.

[d]VT1: first ventilator threshold.

[e]VT2: second ventilator threshold.

[f]DBP: diastolic blood pressure.

[g]SBP: systolic blood pressure.

[h]HADS-A: Hospital Anxiety and Depression scale–Anxiety.

[i]HADS-D: Hospital Anxiety and Depression scale–Depression.

Age Differences

Among the 50 participants who completed the program, 6 (12%) were aged >75 years. In total, 45% (22/50) of the older population initially recruited dropped out because of technical issues, whereas none of the younger participants did so for this reason (Table 4).

Table 4. Comparison among participants aged <75 years and ≥75 years in the study population showed the increasing of different parameters.

	Baseline participants aged <75 years, mean (SD)	Participants aged <75 years after the CRP[a], mean (SD)	Difference between before and after the CRP in participants aged <75 years, mean (SD)	Baseline participants aged ≥75 years, mean (SD)	Participants aged ≥75 years after the CRP, mean (SD)	Difference between before and after the CRP in participants aged ≥75 years, mean (SD)	*P* value of the difference between before and after the CRP participants aged <75 years vs ≥75 years
Maximal aerobic capacity (METs[b])	8.9 (0.4)	9.9 (0.6)	1.0 (0.2)[c]	6.9 (0.2)	7.8 (0.7)	0.9 (0.5)[c]	.14[d]
Weekly training volume (METs per week)	1010 (112)	1900 (158)	890 (46)[c]	723 (93)	1169 (219)	446 (126)[c]	.21
METs VT1[e]	6.03 (0.5)	9.14 (0.6)	3.1 (0.2)[c]	4.2 (0.8)	5.9 (0.6)	1.7 (0.6)	.03
METs VT2[f]	8.9 (0.5)	9.6 (0.6)	0.7 (0.1)[c]	7.6 (1.3)	7.6 (3.1)	0.1 (0.0)	.04
Basal DBP[g] (mmHg)	76 (1.3)	75.1 (1.2)	−0.17 (0.2)	80 (0.9)	77.2 (0.7)	−3.2 (0.2)	.13
DBP at maximal exercise (mmHg)	78 (1)	78.6 (0.8)	−0.6 (0.3)	80 (2)	77 (1.5)	−3 (0.5)	.31
Basal SBP (mmHg)	121.8 (2.3)	121.2 (1.9)	−0.6 (0.4)	132 (6.8)	125 (3.1)	−7 (3.7)	.26
SBP[h] at maximal exercise (mmHg)	169 (3.1)	169 (3.0)	−0.2 (0.1)	162.2 (4.9)	158.9 (6.1)	−3.3 (1.2)	.28

[a]CRP: cardiac rehabilitation program.

[b]MET: metabolic equivalent task.

[c]Statistically significant result among the subgroups.

[d]Not significant.

[e]VT1: first ventilator threshold.

[f]VT2: second ventilator threshold.

[g]DBP: diastolic blood pressure.

[h]SBP: systolic blood pressure.

Designed Platform: HumanITcare Solution (Subjective Evaluation of the Patients of the CRP, Its Duration, and the Designed Platform)

Upon completion of the CRP, 78% (39/50) of the study population reported improved functional capacity and therapeutic adherence. In addition, 56% (28/50) of the participants stated that they were much closer to a healthier lifestyle and found themselves less anxious and more empowered about their disease.

Moreover, all patients reported a good rapport with the CRP team and considered the management of the program to be excellent.

Regarding CRP duration, 63% (31/50) of the patients considered it adequate, whereas the remaining 37% (18/50) preferred a longer program. In addition, 29% (14/50), 34% (17/50), and 37% (18/50) of patients showed a preference for face-to-face, telematic, and hybrid strategies, respectively.

Regarding the usability of the designed platform, 51% (26/50) of the patients described the platform as easy to use, whereas 34% (17/50) and 15% (7/50) faced minor and significant technical problems, respectively. In addition, 83% (41/50) of patients aged >75 years and 40% (20/50) of younger patients faced technological difficulties when using the platform.

Discussion

Principal Findings

Overview

In this pilot study, we developed a holistic telematic CRP dedicated to patients after an ischemic cardiac event, including patients of both sexes with no age limit. Our results can be summarized into four key findings: (1) telematic CRP, including tailored aerobic and strength training sessions, improved maximal and submaximal aerobic capacities and muscle strength; (2) a holistic approach, including educational sessions and emotional support, significantly improved adherence to the Mediterranean diet, emotional state, and quality of life; (3) CRP was beneficial irrespective of age and sex; and (4) the telematic CRP strategy was safe and feasible for our study population, although there were differences in the preferences of patients in terms of duration and type of strategy.

Exercise Sessions: Improvement in Functional Capacity and Muscle Strength

In the overall study population, our telematic CRP led to an improvement of 1.6 METs. This increase is equivalent to the reported face-to-face CRP conducted in comparable study populations and with a similar training protocol (a combination

of aerobic and resistance training) [34]. In contrast, it was superior to that observed after CRPs that involved only independent aerobic PT during the telematic or face-to-face strategy. Strength training is safe for patients with ischemic heart disease and is synergistic with aerobic exercise training [35]. Furthermore, our PT protocol significantly increased the results of the arm curl (15.5%) and sit-to-stand (19.7%) tests, indirectly measuring the arm and leg muscle strength resistance, respectively. Both aerobic and strength training are essential for exercise-induced beneficial metabolic effects [36]. In addition, muscle strength is known to be strongly correlated with quality of life and autonomy, especially in older adult patients [37]. Therefore, on-site or telematic strength training should be part of all PT protocols in CRPs.

Educational Sessions: Adherence to Mediterranean Diet, Emotional State, and Quality of Life

Our comprehensive telematic CRP included nutritional counseling, educational sessions, and emotional support. These interventions enhance patient empowerment by promoting a healthy lifestyle [38,39]. In a recent meta-analysis [40], CRP reduced anxiety and depression rates without differences between face-to-face and telematic strategies. In our study, patients were made cognizant of their disease, after which their anxiety levels significantly decreased. However, no significant changes were observed in depressive symptoms. A meta-analysis reported that the prevalence of depression after acute coronary syndrome in round 14 improved to 3% after cardiac rehabilitation [41]. However, the COVID-19 pandemic increased this percentage to 34% [42]. Our study population had average depression rates of 16.9% preintervention and 15% postintervention; therefore, we hypothesize that this nonsignificant improvement in the post-CRP depression score could have resulted from the COVID-19 pandemic. Meanwhile, anxiety levels positively and significantly improved after the program (23% preintervention and 17% afterward), possibly because of greater empowerment of the patient and improved cognition regarding their disease.

In compliance with the previously mentioned meta-analysis, our holistic CRP, including individual and group nutritional counseling, significantly improved compliance with the Mediterranean diet, which is the best-studied and most evidence-based diet for preventing ischemic events and is considered the gold standard for healthy eating [43]. Moreover, it reduces the risk of repeated cardiovascular events, as evidenced by a previous randomized controlled trial [44]. Therefore, CRP must include nutritional assessments, possibly with the PREDIMED score, and more complements to medical treatment.

Furthermore, home-based CRP significantly improved quality of life, concordant with similar studies on telematic cardiac rehabilitation [45] and center-based CRP [46]. This may be because of patient empowerment regarding their cardiac condition, which allows them to resume their previous daily activities without fear and provides tools for the management of cardiac symptoms and stress.

Sex Differences: Feasibility and Safety of the Telematic CRP

This CRP pilot study included 50 patients after an ischemic event, 42 (85%) of whom were male. This percentage was similar to that of other studies, and US surveys have shown that following a heart attack, 14.3% of female individuals participated in CRPs compared with 22.1% of male individuals [47]. Female individuals are less likely to engage in CRP than male individuals because of less encouragement from practitioners and psychosocial barriers, such as familial obligations, lack of support, and misperception of the disease [48]. Furthermore, they are usually older and have more comorbidities, increased anxiety and depression, worse functional capacity, and worse CRP results, compared with male individuals [15]. Specific interventions, such as automatic referral, strong physician recommendation, psychological support, and home-based or tailored programs, can increase adherence and improve results in female individuals [49,50].

Our pilot telematic CRP attempted to provide the flexibility of a tailored intervention for female patients and psychological support, which resulted in an equivalent impact of CRP on maximal aerobic capacity and muscle strength and better impact on improving anxiety symptoms (Table 2). Although female patients had higher levels of anxiety preintervention, it could be easier in this group to achieve positive scores, highlighting the special importance of psychological sessions in female patients. Conversely, CRP adherence was similar among male and female patients (Table 3), which differed from the superior adherence observed among male individuals in traditional center-based studies [51].

Age Differences: Feasibility and Safety of the Telematic CRP

Of the study participants, 12% (6/50) were aged >75 years and 24% (12/50) had an LVEF of <50%. Although both represented a small percentage of the entire group, these patients had no complications during the intervention. However, CRP use among older patients remains low despite evidence suggesting lower mortality, hospitalization rates, and Medicare costs and improved symptomatology [52]. This may be because of multiple comorbidities; psychosocial factors, such as denial of disease severity and depression; and other difficulties, such as transportation to the CRP centers [53]. Newer CRP models include home-based approaches to overcome these barriers [54]. In addition, CRP benefits patients with low LVEF [55], in whom exercise training is not associated with adverse effects on left ventricular remodeling, and most patients have improved functional capacities despite the LVEF [56]. Both older patients and those with a low LVEF and poor functional class are associated with frailty, which is increased in patients who undergo CRP for acute coronary syndrome [57].

In the subgroup analysis (Table 4), patients aged >75 years had an increase of 1.7 (SD 0.9 METs) in maximal aerobic capacity, which reached statistical significance despite the small study subgroup. Furthermore, CRP induced significant improvements in adherence to the Mediterranean diet and emotional state, and these improvements were better than those observed in younger individuals. No major or minor complications occurred during

the intervention in this subgroup. Moreover, no minor or major complications were observed in this study population. Although these results are promising in terms of positive values of CRP for the older population, the feasibility of the telematic approach is low, as 45% of the older population recruited for the program dropped out because of technical issues, whereas none of the younger participants did so for this reason. Overall, these results emphasize that CRP for older patients must be tailored to individual clinical complexities to obtain better outcomes of functional capacity, nutritional status, comorbidities, cognitive status, and socioeconomic support.

Designed Platform: HumanITcare Solution (Subjective Evaluation of the Patients of the CRP, Its Duration, and the Designed Platform)

Regarding the designed platform, 50% (25/50) of the patients adequately handled it; however, 15% (7/50) still required help. In addition, 83% (41/50) of patients aged >75 years and 40% (20/50) of younger patients faced technological difficulties when using the platform.

Feedback collected from patients and health professionals during the study could enhance the different aspects of the tools that have already been implemented, whereas others will soon be incorporated. In this manner, our solution can be better adapted for people with different technological backgrounds, allowing the inclusion of more patients in such telematic programs.

However, wearable devices do not provide real-time data, which are crucial for monitoring the maximum HR of a patient during telematic rehabilitation sessions.

Therefore, we plan to incorporate new wearable devices into our platform in the future to resolve this problem. If different brands of wearable devices are available to collect data on the platform, patients may already be using them; thus, offering a "bring your own device" approach would be helpful. In addition, some of these devices allow third-party apps to record HRs in real time or with minor delays.

Regarding the preferences for CRP strategies, one-third of the patients preferred the face-to-face approach, one-third preferred the telematic approach, and one-third were comfortable with both strategies. These results emphasize the need for a tailored CRP program that offers different approaches and durations based on patient characteristics and preferences.

Finally, regarding the duration of CRP, one-third of our study population considered a longer CRP necessary for better results. Phase 3 (maintenance) intervention, usually developed between general practitioners and the cardiology team, helps patients maintain their physical activity levels and reduces the risk of new cardiovascular events [58]. However, costs, coordination among different teams, and patient motivation are crucial for its development, which remains a challenge for further improvement.

Comparison With Prior Work

As mentioned above, there are few studies in the literature about the telematic cardiac rehabilitation approach, which is effective and safe for patients following an ischemic event [16]. However, most of them came from selected populations, excluding female patients [15], patients aged >75 years [17], and patients with multiple comorbidities [18].

In this study, we developed a cardiac telerehabilitation platform, specifically designed for patients after a cardiac ischemic event, with no sex or age limitation. The CRP included PT (aerobic and strength) and interventions for improving the emotional sphere and adherence to a healthy lifestyle.

Strengths and Limitations

This pilot CRP after an ischemic cardiac event configures a holistic approach. It includes patients of both sexes with no age limit and is safe in all subgroups. It achieved positive results in improving maximal aerobic capacity, weekly training volume, muscle strength, quality of life, compliance with diet, and anxiety symptoms.

This study has a few limitations. First, the small sample size of the patients included in this pilot study limited statistical power. Second, only 15% (7/50) of the participants were female and 12% (6/50) were older patients; therefore, our results regarding the impact of age and sex on the beneficial effects of CRP should be considered cautiously. Regarding these 2 facts, this was a small study but included patients of all ages and both sexes, being safe and achieving positive results in all subgroups. It is necessary to corroborate these results in larger programs.

Third, follow-up was not conducted; thus, the evolution of functional capacity, adherence to a healthy lifestyle, and clinical events following the completion of the program remain unknown. Nevertheless, these data combination allows a better understanding of the medical conditions of the patients, thereby improving the diagnosis or treatment provided. An algorithm that enables patients to make lifestyle recommendations, thereby improving their quality of life after acute myocardial infarction, can be implemented.

Finally, when it came to including patients in the program, a significant limitation was at the technological level. Patients needed a cell phone with an updated operating system to access all functions of the app accurately. In addition, patients required basic skills to manage the platform or an environment that could support them in this regard. Although the technological education of the older population is improving, there is still a gap with that of the current generation.

Conclusions and Future Directions

Moreover, most of them do not have a holistic approach as they do not incorporate interventions with demonstrated positive impact on CRP, such as the emotional sphere [19], nutrition [20], and medication adherence [8]. Moreover, exercise sessions do not include strength training, with synergic effect with aerobic exercised.

Future studies with more patients will be needed, with a higher percentage of individuals who are fragile and aged >75 years, as well as female patients. Improvements to the technological approach should be made. The preference for a face-to-face or telematic CRP varied among the study population, which emphasizes the need for a tailored CRP offering telematic, on-site, and hybrid models to improve adherence and completion

rates. Short- and long-term follow-up should be performed to confirm these results.

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Data Availability

The data sets used and/or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

MS-dlG and MS conceived the idea for this study and designed it in collaboration with NP. NP and the HumanITcare team designed the platform in close collaboration with MS and MS-dlG. Patients were recruited by RAR, CF, MR, and GY. MC-L, MS-dlG, and DG performed the initial and final cardiac rehabilitation program visits. JM, JS, MS-dlG, and MC-L performed the maximal exercise tests during the initial and final visits. RA conducted the physical training sessions. GY, JS, and JM conducted the educational sessions. MC-L and MS-dlG performed statistical analyses and wrote the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CRP: cardiac rehabilitation program
HADS: Hospital Anxiety and Depression Scale
HR: heart rate
IPAQ-SF: International Physical Activity Questionnaire–Short Form
LVEF: left ventricular ejection fraction
MET: metabolic equivalent task
PREDIMED: Prevención con Dieta Mediterránea
PT: physical training

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Original Paper

Continuous Data-Driven Monitoring in Critical Congenital Heart Disease: Clinical Deterioration Model Development

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Abstract

Background: Critical congenital heart disease (cCHD)—requiring cardiac intervention in the first year of life for survival—occurs globally in 2-3 of every 1000 live births. In the critical perioperative period, intensive multimodal monitoring at a pediatric intensive care unit (PICU) is warranted, as their organs—especially the brain—may be severely injured due to hemodynamic and respiratory events. These 24/7 clinical data streams yield large quantities of high-frequency data, which are challenging in terms of interpretation due to the varying and dynamic physiology innate to cCHD. Through advanced data science algorithms, these dynamic data can be condensed into comprehensible information, reducing the cognitive load on the medical team and providing data-driven monitoring support through automated detection of clinical deterioration, which may facilitate timely intervention.

Objective: This study aimed to develop a clinical deterioration detection algorithm for PICU patients with cCHD.

Methods: Retrospectively, synchronous per-second data of cerebral regional oxygen saturation (rSO_2) and 4 vital parameters (respiratory rate, heart rate, oxygen saturation, and invasive mean blood pressure) in neonates with cCHD admitted to the University Medical Center Utrecht, the Netherlands, between 2002 and 2018 were extracted. Patients were stratified based on mean oxygen saturation during admission to account for physiological differences between acyanotic and cyanotic cCHD. Each subset was used to train our algorithm in classifying data as either stable, unstable, or sensor dysfunction. The algorithm was designed to detect combinations of parameters abnormal to the stratified subpopulation and significant deviations from the patient's unique baseline, which were further analyzed to distinguish clinical improvement from deterioration. Novel data were used for testing, visualized in detail, and internally validated by pediatric intensivists.

Results: A retrospective query yielded 4600 hours and 209 hours of per-second data in 78 and 10 neonates for, respectively, training and testing purposes. During testing, stable episodes occurred 153 times, of which 134 (88%) were correctly detected. Unstable episodes were correctly noted in 46 of 57 (81%) observed episodes. Twelve expert-confirmed unstable episodes were missed in testing. Time-percentual accuracy was 93% and 77% for, respectively, stable and unstable episodes. A total of 138 sensorial dysfunctions were detected, of which 130 (94%) were correct.

Conclusions: In this proof-of-concept study, a clinical deterioration detection algorithm was developed and retrospectively evaluated to classify clinical stability and instability, achieving reasonable performance considering the heterogeneous population of neonates with cCHD. Combined analysis of baseline (ie, patient-specific) deviations and simultaneous parameter-shifting (ie, population-specific) proofs would be promising with respect to enhancing applicability to heterogeneous critically ill pediatric populations. After prospective validation, the current—and comparable—models may, in the future, be used in the automated detection of clinical deterioration and eventually provide data-driven monitoring support to the medical team, allowing for timely intervention.

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KEYWORDS

artificial intelligence; aberration detection; clinical deterioration; classification model; paediatric intensive care; pediatric intensive care; congenital heart disease; cardiac monitoring; machine learning; peri-operative; perioperative; surgery

Introduction

Critical congenital heart disease (cCHD)—requiring a cardiac intervention (cardiac surgery or therapeutic cardiac catheterization) in the first year of life for survival—globally occurs in 2-3 of every 1000 live births [1-3]. In the critical perioperative period, intensive multimodal monitoring at a pediatric intensive care unit (PICU) is warranted as their organs, especially the brain, may be severely injured due to changes in blood flow and oxygenation caused by hemodynamic and respiratory events [4-7]. As such, clinical data streams that include regional cerebral oxygen saturation (rSO_2) using near-infrared spectroscopy, as well as vital parameters (eg, heart rate and blood pressure), are continuously acquired in these critical patients and produce substantial amounts of high-frequency data for medical assessment purposes.

However, integrated assessment of these clinical data streams—condensing data to comprehensible information—can be especially challenging in the cCHD population due to their unique and dynamic physiology. For example, an oxygen saturation (SpO_2) varying from 60% to 90% can be normal in some forms of cyanotic cCHD, such as hypoplastic left heart syndrome [8], where it can be deadly in different forms of cCHD. Adding up to the challenge, the overall intensive care unit and PICU architecture is increasingly shifting toward single-person rooms, promoting privacy and family-centered care. However, this also results in decreased immediate visibility of the patient and subsequently raises the threshold to combine monitoring data with hands-on bedside input (ie, visual, tactile, and response to stimuli).

With the rapid growth in both computing power and data storage over the last decade, the potential benefits of advanced data science algorithms, such as machine learning (ML), have greatly increased for health care [7,9-11]. Clinicians may benefit from the ML-assisted continuous interpretation of these large quantities of monitoring data at the PICU, as it can provide them with data-driven remote monitoring support through automated detection of clinical deterioration. At times of suspected deterioration, staff may be notified in a timely manner, allowing for medical evaluation and possible treatment in an effort to reduce the risk of injury.

Most of the previously published models aimed at providing data-driven monitoring support do so through a prognostic early warning score for a certain population and consider both static (eg, diagnosis or age) and dynamic (eg, vital signs) parameters. These were recently reviewed by Muralitharan et al [10] and included postoperative patients or those in step-down wards [12,13], emergency departments [14,15], and adult intensive care [16,17].

To date, ML-based early warning algorithms in the pediatric population are overall scarce (eg, Park et al [18]) and very sporadic in the congenital heart disease (CHD) population in the PICU (eg, Ruiz et al [19]), whereas none have been reported as being currently in use. In the specific case of cCHD, the heterogeneity of the population, both with respect to the normal values in different age groups [20] and the spectrum of underlying diseases, together with the limited amount of critically ill pediatric patients, provide substantial challenges for the application of advanced data science [21].

This study aimed to develop a diagnostic model using transparent ML, which is capable of continuously detecting clinical deterioration in patients with cCHD admitted to the PICU while considering their unique hemodynamic physiology. The model's internal architecture is demonstrated, its performance evaluated in comparison to expert opinion, and the future implementation discussed, along with recommendations provided for similar research.

Methods

Patient Population and Parameters

Infants younger than 1 year with cCHD admitted perioperatively to the PICU of the University Medical Centre Utrecht between 2002 and 2018 were included based on the availability of time-synchronous data streams. We collected data from 5 vital parameters in a frequency of 1 measurement per second, namely SpO_2, regional cerebral saturation (rSO_2) in both hemispheres, invasive mean arterial blood pressure (IBP), respiratory rate (RR), and heart rate (HR), as well as current mechanical ventilation status. Patients were excluded if less than 12 hours of complete data were available or due to low birth weight (<2000 g).

Ethical, Distributional, and Guideline Statements

As fully anonymized data were used, the medical ethical review committee of the Wilhelmina's Children Hospital waived informed consent (application number 22/822). In manuscript preparation, the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) checklist [22] was used (Multimedia Appendix 1).

Data Preprocessing

RR was measured through thoracic movement as a result of electrocardiographic impedance derivation with the electrocardiographic leads from the Philips Intellivue MP70 monitor. Because infants, especially neonates, can have considerable fluctuations of RR within minutes, a trend movement was examined rather than absolute values: a 300-second moving average for RR was implemented preceding each time point *t*. Cerebral rSO_2 was measured with near-infrared spectroscopy with the Medtronic INVOS 5100 monitor using 2 pediatric cerebral sensors. If both probes recorded a value, their mean was used in model calculations.

At our institution, end-tidal carbon dioxide ($EtCO_2$) is considered in all mechanically ventilated patients to monitor the efficacy of ventilation; therefore, $EtCO_2$ was extracted to determine the current mechanical ventilation status at each time point (ie, currently mechanically ventilated if $EtCO_2$>0 at time *t*). No imputation was performed to account for missing values in these parameters. To account for the underlying varying physiology of CHD, patients were stratified into 2 subsets based on average SpO_2 during admission (ie, <90% versus ≥90%), as measured with oximetry using the Philips Intellivue MP70 monitor (FAST technology with the Nelcor sensor). As SpO_2 is a parameter in the model and therefore directly influences predictive performance, we decided to use data-driven stratification of CHD in order to accurately represent the spectrum of underlying diseases throughout the stratified group regardless of clinical diagnosis.

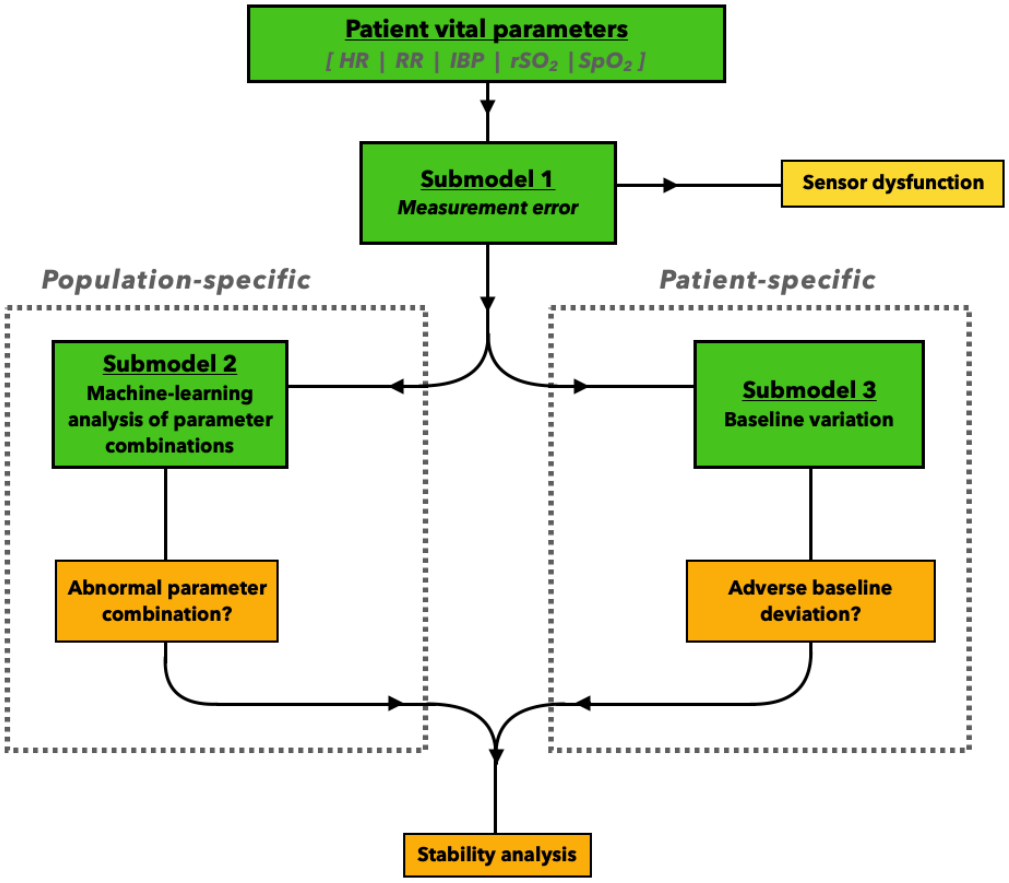
Model Architecture

To facilitate future clinical use, our model was developed using explainable methods (ie, through methods allowing clinicians to understand what features and assets contribute to the output) as opposed to the so-called "black box" models (eg, deep neural networks), where their methodological foundation and feature derivation remains beyond grasp to most clinicians. The model's internal architecture consisted of 3 separate models, which were integrated to coordinate a classification response of either sensor dysfunction or stable or unstable patient status (Figure 1). Each of the 3 models relied on a specific analysis: sensorial dysfunction (submodel 1 in Figure 1), classification of normal and abnormal vital parameter combinations (submodel 2 in Figure 1), and detection and analysis of significant patient-specific baseline deviations (submodel 3 in Figure 1).

An analyzed time point *t* was deemed unstable if no sensorial dysfunction was detected, and either submodel 2 or 3—or both—classified the time point *t* to be unstable. The continuous data points were converted to episodes through a 5-minute moving time frame, where an episode was considered unstable when classified thus in at least 4 minutes (ie, ≥80%) out of any 5-minute time frame. If less than 4 (nonconsecutive) minutes of the episode (ie, <80%) were deemed unstable, the time frame was consequently classified as stable. To allow for baseline build-up (submodel 3), the first hour of admission was analyzed without triggering a classification response.

All models were built using RStudio (version 1.4; R Foundation for Statistical Computing). The packages used in construction, as well as the source code, can be found on the website of our research group [23].

Figure 1. Flowchart depicting the model's analytic process of detecting deterioration through submodel 1 (sensor dysfunction), submodel 2 (machine learning analysis of parameter combinations), and submodel 3 (analysis of baseline deviations). HR: heart rate; IBP: invasive mean blood pressure; RR: respiratory rate; rSO_2: regional cerebral oxygen saturation; SpO_2: oxygen saturation.



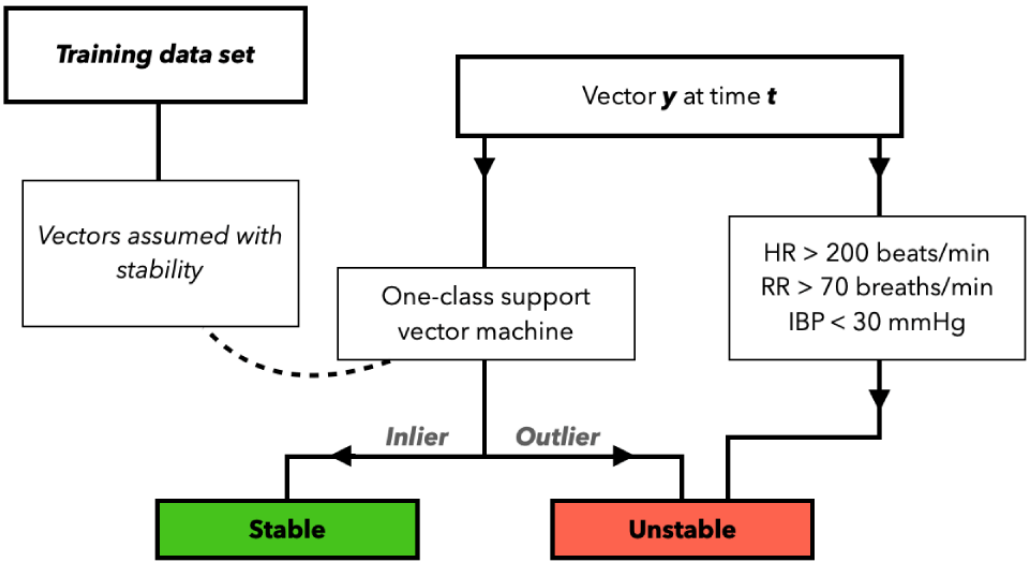
Submodel 1: Sensor Dysfunction

To reduce the faulty classification of patient status due to sensor errors, dysfunctions of IBP, SpO_2, rSO_2, and RR were evaluated. HR sensor dysfunction was not included as no reliable distinction between, for example, cardiac arrest (HR=0 beats per minute) and sensor error, could be made. IBP and SpO_2 dysfunction was determined as a difference of >25 points on their respective scales compared to the previously measured value (at time point *t*–1). The lower and upper limits of the rSO_2 scale (≤15% and ≥95%, respectively) were noted as measurement error as these values are unlikely to be a valid measurement and rather emerge due to escaping sensor-light emission. An RR sensor malfunction was considered to be a rate below 5 breaths per minute. Upon detection, measurements in the minute preceding the first detection (at time point *t*–60 seconds) up to the minute proceeding (at time point *t*+60 seconds) the last detection (*t*) were considered unfit for adequate classification and consequently classified as sensor dysfunction.

Submodel 2: Machine Learning Analysis of Parameter Combinations

Combinations of parameters were analyzed and classified to either be stable or unstable. Each vector of the parameters (RR, HR, IBP, rSO_2, and SpO_2) was normalized and reduced to a single principal component using the Mahalanobis method [24], with respect to the stratified subset–specific (SpO_2<90% versus SpO_2≥90%) mean, variance, and correlation matrices (Multimedia Appendix 2). Vectors with a corresponding Mahalanobis distance greater than the 80th percentile were deemed unstable and discarded from the subset. The remaining vectors were divided into a random 80:20 train:test partition and used to train a one-class support vector machine (SVM). We used a square-exponential radial basis function kernel with a 5% soft margin (μ) to prevent overfitting. As the SVM was trained using, presumably, stable vectors of parameters, any nonresemblant vector was classified as unstable by the SVM. Additionally, singular parameters were considered unstable when exceeding static cutoff values determined by the consensus of pediatric intensivists (Figure 2).

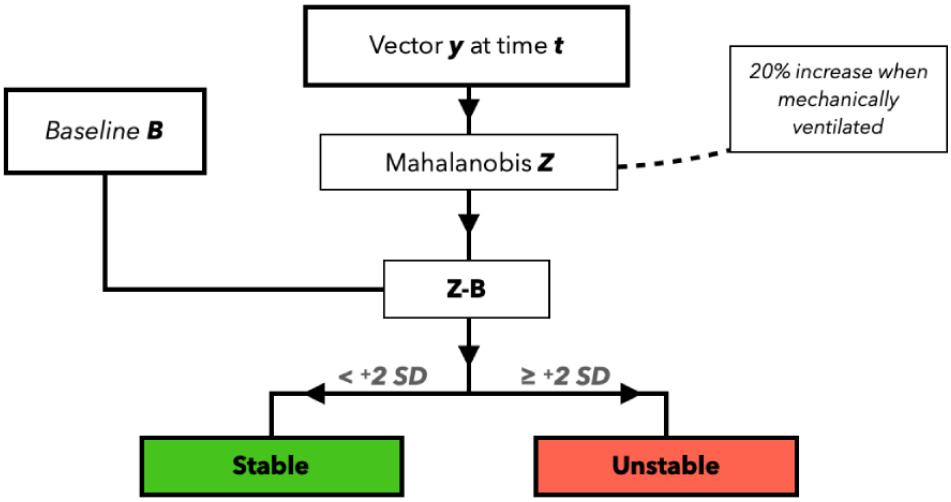
Figure 2. Flowchart depicting the layout of submodel 2, where stability and instability is detected through both support vector machine learning of population-specific parameter instability as well as through predefined static cutoff values of HR, RR, and IBP. HR: heart rate; IBP: invasive mean arterial blood pressure; RR: respiratory rate.



Submodel 3: Baseline Variation

Baseline variation analysis focused on the detection of abnormal parameter deviations in comparison to the patient's unique baseline (Figure 3). A vector of parameters (HR, RR, IBP, rSO_2, and SpO_2) was reduced to a single principal component using the earlier introduced Mahalanobis distance [24] and increased by 20% at times of mechanical ventilation (ie, $EtCO_2$>0) due to the consequent iatrogenically diminished variation in parameters. The current Mahalanobis trend (Z), through a 300-second moving median preceding time point *t*, was subsequently compared to the patient's unique baseline (B, median of all Mahalanobis distances preceding *t*). As Mahalanobis distance is calculated using normalized values, trend movement toward subset mean values (Z–B<0) was assumed to be related to clinical improvement, where a significant trend drifting ≥2 SDs from both the subset mean values, as well as the baseline, was deemed to result from instability (Z–B≥+2SD). SD was calculated after the removal of the upper 20th percentile of the baseline corrected Mahalanobis distance (ie, the SD in supposedly stable time points) with respect to chronologicity.

Figure 3. Flowchart depicting the layout of submodel 3 in the process of determining stability through baseline deviation analysis.



Model Performance

Novel, unseen data from the 5 parameters (HR, RR, IBP, SpO_2, and rSO_2), along with the model's classification, were visualized in detail (Multimedia Appendix 3). Two experienced pediatric intensivists (JN and EK) reviewed these charts, each noting independently, being blinded from each other, whether they agreed with the model classification. Any difference in opinion was resolved by an independent third expert. The performance of the algorithm was consequently based on expert opinion, noting both time-percentual correctness as well as episodic performance. Episodes were counted with a maximum duration of 2 consecutive hours to prevent shifting results based on episode length.

Results

Patient and Parameter Characteristics

In total, 92 patients were initially identified with time-synchronized parameters in their data sets, of whom 14 (15%) were excluded (<12-hour data: n=11, 79%; birthweight<2000 g: n=3, 21%). The remaining 78 patients were stratified into 2 subgroups based on mean SpO_2 during admission: SpO_2<90% (n=26, 33%) and SpO_2≥90% (n=52, 67%). The group characteristics are shown in Table 1. A list of cardiac diagnoses and performed surgical interventions on included patients is provided in Multimedia Appendix 4.

Table 1. Baseline characteristics of stratified subsets with an average oxygen saturation (SpO_2) of <90% versus those with an SpO_2 of ≥90%.

Characteristics	SpO_2<90% (n=26)	SpO_2≥90% (n=52)
Study population		
Male gender, n (%)	21 (81)	35 (67)
Birth weight (kg), median (IQR)	3.4 (3.1-4.0)	3.3 (3.0-3.6)
Age at *t*=0 (days), median (IQR)	7.0 (2.3-11)	9.0 (5.0-17.3)
Available data (hours), median (IQR)	63.1 (46.4-98.9)	44.0 (23.8-61.6)
Vital parameters, median (IQR)		
Heart rate (beats per minute)	159 (147-170)	146 (132-158)
Respiratory rate in (breaths per minute)	34 (30-38)	35 (30-40)
SpO_2 (%)	77 (70-81)	97 (95-100)
Regional cerebral oxygen saturation (%)	55.0 (49.0-63.0)	71.5 (63.5-80.0)
Mean Invasive blood pressure (mm Hg)	51 (47-57)	53 (47-60)

Model Performance

A total of 209 hours of data from 10 patients across the SpO_2<90% group (n=5, *t*=98 hours) and SpO_2≥90% group (n=5, *t*=111 hours) were classified by our algorithm for performance analysis.

Patients With an Average SpO_2 of <90%

In the subgroup with an average SpO_2 of <90%, a total of 77 stable episodes occurred, where 66 (86%) were correctly classified. These 77 episodes lasted 90 hours, where 87 (97%) hours were correctly analyzed. Unstable episodes occurred 21 times for a total of 8 hours. In total, 17 (81%) of these episodes were correctly classified, adding up to 4 (51%) hours. Further,

2 (12%) of the unstable episodes were correctly detected; yet, algorithmic labeling did not cover the full length of the episode.

Patients With an Average SpO_2 of ≥90%

Across the subgroup with an average SpO_2 of ≥90%, stable episodes occurred 76 times, of which 68 (89%) were correctly classified. Stable episodes lasted a total of 91 hours, where 84 (92%) hours were correctly classified. Across 36 unstable episodes adding up to 20 hours, 18 (86%) hours in 29 (81%) episodes were classified accordingly. Out of the 29 correctly detected unstable episodes, 8 (28%) were partially correct.

Overall Performance

Considering both groups, 134 of the 153 (88%) stable episodes were correctly labeled (171 of 181 hours, 93%). Unstable episodes were correctly labeled in 46 of the 57 (81%) observed episodes (22 of 29 hours, 77%). A total of 12 unstable episodes were missed by the model in testing. Sensor dysfunction occurred a total of 138 times, of which 130 (94%) were accurately labeled (Table 2).

Table 2. Performance analysis overview of the aberration detection algorithm when compared to expert consensus, depicted in either episodic or time occurrence.

Model performance	SpO_2[a]<90% (n=5)	SpO_2≥90% (n=5)	Total (n=10)
Stable moment			
Episodic occurrence, n	77	76	153
Episodic correctness (%), n (%)	66 (86)	68 (89)	134 (88)
Time occurrence (hours), n	90	90	181
Time correctness (hours), n (%)	83 (92)	84 (93)	171 (93)
Unstable moment			
Episodic occurrence, n	21	36	57
Episodic correctness, n (%)	17 (81)	29 (81)	46 (81)
Time occurrence (hours), n	8	20	29
Time correctness (hours), n (%)	5 (63)	17 (83)	22 (77)
Sensor dysfunction			
Episodic occurrence, n	57	81	138
Episodic correctness, n (%)	56 (98)	74 (91)	130 (94)

[a]SpO_2: oxygen saturation.

Discussion

Principal Findings

In this proof-of-concept study, we have developed and retrospectively evaluated an advanced data science algorithm for PICU patients with cCHD aimed at automated detection of clinical deterioration during their critical perioperative period. Through 2-fold analysis of vital parameters, both in relation to each other and in comparison to the patient's unique baseline parameters, a tailored approach was demonstrated to monitor complex and hemodynamically challenging patients. Overall, our model accurately detected clinical stability and deterioration in, respectively, 88% and 81% of expert-confirmed episodes. Sensor dysfunction occurred 138 times, of which 94% were rightfully detected.

Clinical Relevance

The population of patients with cCHD has been shown to be at substantial risk of deterioration in their perioperative period, as they are susceptible to a range of hemodynamic and respiratory events, especially in the postoperative period [4-7]. These disturbances in (cerebral) blood flow and oxygenation may eventually result in damage to internal organs, such as the gut and the brain [7,25]. Brain injury, for example, is observed in up to 60% of postoperative patients with cCHD and is known to cause severe neurodevelopmental impairment, significantly impacting quality of life [26,27]. Adequate detection of patient deterioration could facilitate timely intervention and may, eventually, prevent the onset of novel (brain) injury. However, adequate and timely detection of ongoing deterioration is becoming increasingly difficult through the ever-growing amount of complex and dynamically interpretable data inherent to the cCHD population, posing a 24/7 monitoring challenge to the medical team. Additionally, previous research has noted subtle variations in vital parameters to precede adverse events [7] as well as significant phenotype differences in cCHD related to an adverse outcome [4]. Through mixed-effects regression analysis, Nicoll et al [4] described independent associations between elevated HR (P=.003) and elevated systolic BP (P=.02) with novel brain injury in the first 72 hours after surgery. These physiological differences were most significant directly postoperatively and decreased with time, again highlighting the importance of adequate and intensive perioperative monitoring to identify patients at higher risk of deterioration. However, paying attention to these different physiological phenotypes and subtle parameter variations requires 24/7 vigilance from staff, greatly increasing their cognitive load. With algorithmic

condensation of clinical data streams toward comprehensible information, the cognitive load on clinicians and nurses will likely be decreased, providing support to both patients and the medical team.

Comparison to Previous Work

Overall, research classifying current patient status in CHD—rather than predicting a future adverse event—is very scarce. To the best of our knowledge, diagnostic AI models classifying current patient status in CHD and cCHD have yet to be published. A fair comparison of predictive versus diagnostic models in CHD is limited due to their different aims and setup; however, their methodological comparison is possible to some degree.

In 2013, Clifton et al [14] proposed an algorithm for adults in the emergency department through the use of an integrated monitoring system that combines high-frequency physiological data to predict upcoming escalation of care. Here, they have developed and tested several ML methods against an existing evidence-based early warning score. The different approaches to predicting escalation of care had mixed results, where the SVM had a high detection rate (>85%, time frame–dependent), yet, also, a high false positive rate (27%). If their algorithm were applied to, for example, the population of patients with cCHD, their inherent dynamic circulation would not be taken into account, most likely decreasing the detection rate.

In this study, it is argued that the 2-fold analysis of stability (ie, parameters in relation to each other and with different time points) is of significant value to the monitoring or predicting of outcomes in heterogeneous populations, such as pediatrics, using high-frequency physiological data. As such, future studies aiming to monitor, classify, or predict outcomes in the pediatric population are encouraged to evaluate the need for adjustment to their patients' dynamic physiology and consider their model's resilience to these dynamic conditions. However, it must also be acknowledged that robust statistical methods for transparent advanced data science models, such as those proposed in this study, remain scarce to this date, especially in complex clinical time-series data.

Additionally, a multitude of "black box models" (eg, deep neural networks) have shown spectacular results in various fields, including the prediction of clinical deterioration [10,16,19]. In 2022, Ruiz et al [19] demonstrated their retrospective data-driven extreme gradient boosted model aimed at predicting clinical deterioration (defined as adverse events, such as intubation, cardiopulmonary resuscitation or initiation of extracorporeal membrane oxygenation) in cCHD over a time frame up to 8 hours. Through the model's assessment of 1028 variables (eg, medication, vital parameters, laboratory values, etc), they have achieved accurate predictions and good calibrations with at least 4 hours prior to intubation (area under the receiver operating characteristic curve 0.927, 95% CI 0.825-0.994) or cardiopulmonary resuscitation and extracorporeal membrane oxygenation (area under the receiver operating characteristic curve 0.914, 95% CI 0.796-0.991).

However, the methodological foundations of such complex models remain beyond the grasp of most clinicians. It is likely that models with explainable methods are more likely to be implemented in daily practice and, therefore, explainable modeling techniques were used in this study. The clinical usefulness of our proof of concept, however, has yet to be proven as it is currently limited by its underpowered sample size and the retrospective analysis of model performance. In the near future, the model will be trained and evaluated on a more heterogeneous population to increase performance and versatility, boosting the chances of successful (external) validation while maintaining a sharp clinical perspective: how can the algorithm be most valuable to both patients (eg, early intervention and reduced risk of injury) as well as the medical team (eg, reduced cognitive load)?

Strengths and Limitations

Several other limitations to this proof-of-concept study must be addressed. First (and foremost), selection bias was introduced through the inclusion of patients with cerebral rSO_2 measurements, as well as IBP. Cerebral rSO_2 monitoring is currently not available as a standard of care in global (cardiac) PICUs, and as such, the clinical value of our model will decrease outside the research institution. Additionally, a relatively high sample rate of 1 Hz was used to extract data. As not all parameters are transmitted at the same frequency, internal sampling or resampling is inevitable, possibly affecting data quality.

Second, we have chosen a retrospective approach to analyze model performance. Analyzing patient stability solely based on retrospective parameters remains particularly challenging, even for medical experts. Increases or decreases in parameter values may, for example, originate for a number of reasons, such as feeding or movement, and may have little to no clinical significance. The classification of episode stability or sensor dysfunction was evaluated by expert consensus based on the same data available to the model. However, no hard judgments can be made on the clinical relevance of that episode, as the data were not labeled prospectively (ie, containing labeled events). Arguably, prospective validation with members of the medical team performing a simultaneous bedside evaluation on agreement with the model will be one of the future goals.

Third, in the stability analysis of parameter combinations, an SVM was trained to recognize stability across 5 dimensions. In selecting presumably stable parameter combinations, an 80th percentile split of the vector's corresponding Mahalanobis distance was made, partially based on earlier work by Clifton et al [14]. However, since no explicit labeling was possible in the data set, the chosen cutoff percentile remains arbitrary. Additionally, through the use of normalized data, an assumption is made that any deviation from subset-specific mean values reflects an adverse development. However, for some parameters, an increase or decrease does not necessarily reflect an adverse event, which may result in an overestimation of clinical status and aid in the induction of alarm fatigue. Future research may point out different methods to be more effective.

Future Directions

Several steps must be taken to progress this model—and others alike—toward implementation in daily clinical practice [28,29].

Primarily, a data infrastructure is required to enable real-time or near–real-time data availability to AI models, allowing their prospective validation. In the near future, such a platform will be constructed, speeding up the qualitative performance analysis of data science models while promoting guideline adherence, such as the TRIPOD guidelines [22]. Eventually, AI models will be implemented into the daily workflow, aiding the medical team and likely decreasing their cognitive load, which is beneficial for, in this instance, the continuous interpretation of clinical data streams in hemodynamically challenging patients.

Conclusions

In this study, a proof-of-concept algorithm aimed at detecting clinical deterioration in patients with cCHD at the PICU was developed and retrospectively evaluated, achieving reasonable performance considering the heterogeneous population of neonates with cCHD. Combined analysis of baseline (ie, patient-specific) deviations and simultaneous parameter-shifting (ie, population-specific) proofs to be promising with respect to enhancing applicability to heterogeneous critically ill pediatric populations.

Although performance should be improved and prospectively validated, advanced data science models such as the one presented here may, in the future, be used in automated detection of clinical deterioration, providing real-time data-driven monitoring support in the case of hemodynamically challenging patients and allowing for timely intervention.

Acknowledgments

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Data Availability

The data sets presented in this paper are not readily available due to confidentiality restrictions preventing their distribution. Requests to access the data may be directed to the corresponding author.

Conflicts of Interest

EK has received consulting or speaker honorarium from Philips, GE healthcare, Getinge, and B Braun in the past. The other authors declare that they have no competing interests.

Multimedia Appendix 1
TRIPOD (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) checklist.
[DOCX File , 22 KB - cardio_v7i1e45190_app1.docx]

Multimedia Appendix 2
Mean, standard deviation, and correlation matrices of stratified subgroups.
[DOCX File , 20 KB - cardio_v7i1e45190_app2.docx]

Multimedia Appendix 3
Clinical deterioration detection visualized.
[DOCX File , 646 KB - cardio_v7i1e45190_app3.docx]

Multimedia Appendix 4
Overview of cardiac diagnosis and performed surgical procedures of included patients.
[DOCX File , 19 KB - cardio_v7i1e45190_app4.docx]

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Abbreviations

cCHD: critical congenital heart disease
CHD: congenital heart disease
$EtCO_2$: end-tidal carbon dioxide
HR: heart rate
IBP: invasive mean arterial blood pressure
ML: machine learning
PICU: pediatric intensive care unit
RR: respiratory rate
rSO_2: regional cerebral oxygen saturation
SpO_2: oxygen saturation
SVM: support vector machine
TRIPOD: Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Original Paper

Smartphone-Based Remote Monitoring in Heart Failure With Reduced Ejection Fraction: Retrospective Cohort Study of Secondary Care Use and Costs

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Abstract

Background: Despite effective therapies, the economic burden of heart failure with reduced ejection fraction (HFrEF) is driven by frequent hospitalizations. Treatment optimization and admission avoidance rely on frequent symptom reviews and monitoring of vital signs. Remote monitoring (RM) aims to prevent admissions by facilitating early intervention, but the impact of noninvasive, smartphone-based RM of vital signs on secondary health care use and costs in the months after a new diagnosis of HFrEF is unknown.

Objective: The purpose of this study is to conduct a secondary care health use and health-economic evaluation for patients with HFrEF using smartphone-based noninvasive RM and compare it with matched controls receiving usual care without RM.

Methods: We conducted a retrospective study of 2 cohorts of newly diagnosed HFrEF patients, matched 1:1 for demographics, socioeconomic status, comorbidities, and HFrEF severity. They are (1) the RM group, with patients using the RM platform for >3 months and (2) the control group, with patients referred before RM was available who received usual heart failure care without RM. Emergency department (ED) attendance, hospital admissions, outpatient use, and the associated costs of this secondary care activity were extracted from the Discover data set for a 3-month period after diagnosis. Platform costs were added for the RM group. Secondary health care use and costs were analyzed using Kaplan-Meier event analysis and Cox proportional hazards modeling.

Results: A total of 146 patients (mean age 63 years; 42/146, 29% female) were included (73 in each group). The groups were well-matched for all baseline characteristics except hypertension (P=.03). RM was associated with a lower hazard of ED attendance (hazard ratio [HR] 0.43; P=.02) and unplanned admissions (HR 0.26; P=.02). There were no differences in elective admissions (HR 1.03, P=.96) or outpatient use (HR 1.40; P=.18) between the 2 groups. These differences were sustained by a univariate model controlling for hypertension. Over a 3-month period, secondary health care costs were approximately 4-fold lower in the RM group than the control group, despite the additional cost of RM itself (mean cost per patient GBP £465, US $581 vs GBP £1850, US $2313, respectively; P=.04).

Conclusions: This retrospective cohort study shows that smartphone-based RM of vital signs is feasible for HFrEF. This type of RM was associated with an approximately 2-fold reduction in ED attendance and a 4-fold reduction in emergency admissions over just 3 months after a new diagnosis with HFrEF. Costs were significantly lower in the RM group without increasing outpatient

demand. This type of RM could be adjunctive to standard care to reduce admissions, enabling other resources to help patients unable to use RM.

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KEYWORDS

heart failure; remote monitoring; smartphone care; telemonitoring; self-management; admission prevention; cohort study; hospitalization; noninvasive; smartphone; vital signs; diagnosis

Introduction

Despite proven effective medical therapies, chronic heart failure with reduced ejection fraction (HFrEF) has a prognosis worse than most cancers [1] and accounts for a substantial health-economic burden [2]. A major driver of these high costs is frequent clinical decompensations requiring emergency department (ED) attendance and urgent hospital admissions [3]; reducing these is a primary target for remote monitoring (RM) interventions [4,5].

Community-based management by a heart failure specialist nurses (HFSNs) decreases hospitalizations but relies on high-frequency monitoring of vital signs and regular symptom review via serial face-to-face outpatient appointments [6]. In practice, these appointments are often too infrequent to capture rapid changes in a patient's clinical status and allow early intervention. Patients may recognize their condition is deteriorating, but there is no systematic way of corroborating this with objective clinical data (eg, self-measurement of vital signs) or a convenient line of communication with clinicians who can intervene. This potentially misses a window of opportunity for early intervention, which may instead lead to ED attendance and admissions [7].

RM aims to optimize care and the implementation of guideline-directed medical therapy for HFrEF by providing a platform for the collection and transmission of clinical data at a higher frequency and more conveniently than serial face-to-face appointments. By leveraging clinical data submitted by patients remotely at their convenience, RM aims to facilitate timely community-based clinical intervention and avoid admissions to secondary care [4].

Existing research into RM in heart failure has yet to influence clinical guidelines due to a lack of consensus regarding which type of RM is most impactful [8,9]. Noninvasive RM of vital signs (rather than invasive data from implanted devices) has minimal risks to patients and is often cheaper than other strategies, so it can be applied to a greater proportion of heart failure patients [10]. The majority of noninvasive RM for HFrEF uses telephone-based strategies [11], which fail to harness the wide adoption of smartphone technology or meet the acceleration of demand for remote care brought about by the COVID-19 pandemic [12]. The impact of modern smartphone platforms that combine noninvasive RM of vital signs, messaging, and patient-focused e-learning is unknown. The risk of rehospitalization is highest after initial diagnosis, an opportune window for RM-based intervention [13]. Modifying what happens to patients during this period is often most relevant to patients and health systems considering whether RM is clinically and economically beneficial.

In this study, we present a clinical and economic evaluation of Luscii, a novel smartphone-based RM platform for HFrEF patients that have demonstrated feasibility for monitoring patients with other conditions [14,15]. Our primary objective was to conduct a secondary care health use and health-economic evaluation for patients with HFrEF using smartphone-based noninvasive RM and compare it with matched controls receiving usual care without RM.

Methods

Overview

We performed a retrospective clinical and health economic evaluation of a novel type of smartphone-based, noninvasive RM platform for patients with HFrEF. The platform combined a smartphone app with noninvasive self-measurement of blood pressure, pulse rate, and body mass that is transmitted to a cloud-based server. It also enabled self-reporting of heart failure symptoms, pill use, and messaging functionality to communicate with clinicians, together with a suite of tailored e-learning modules. We compared the impact of this type of RM to a matched group of controls receiving standard heart failure care without RM. We compared secondary health care use and associated costs over a 3-month period following a new diagnosis of HFrEF.

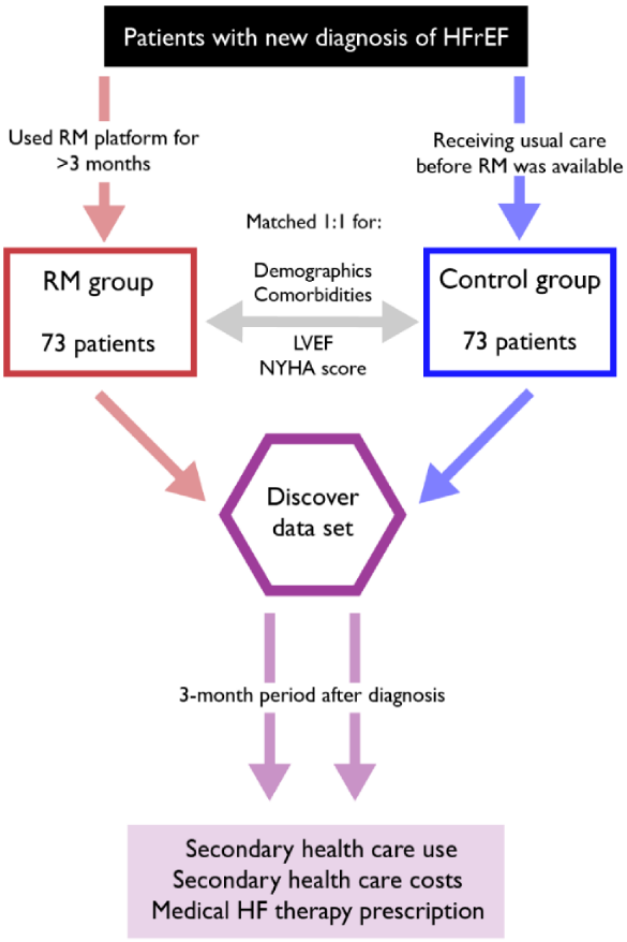
Ethics Approval

This study was approved by the Imperial College Health Care audit and quality and improvement committee (CAR/077) and the North West London Sub-Data Research Access Group committee (sDRAG; ID-186). Study data were deidentified. Participants were not compensated for their involvement.

Study Design

We performed a retrospective analysis of 2 cohorts (the RM group and the control group) with a new diagnosis of HFrEF, defined as heart failure and a left ventricular ejection fraction (LVEF) <50%. This cutoff combined patients in the "mildly reduced" and "reduced" ejection fraction groups as defined by international clinical guidelines [16]. The study design is summarized in Figure 1.

Figure 1. Study design. HF: heart failure; HFrEF: heart failure with reduced ejection fraction; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; RM: remote monitoring.



Setting

We studied adult patients with a new diagnosis of HFrEF who were referred to our heart failure service in northwest London between October 2020 and November 2021.

Participants

The RM group was defined by new HFrEF patients who were onboarded to the RM platform between April and November 2021 and used it for at least 3 months. The inclusion criteria included participants (1) with a new diagnosis of HFrEF (LVEF <50%), (2) who agreed to use the RM platform, (3) who used the platform for at least 3 months, and (4) with regular platform use (submitting at least 2 measurements per week).

The control group was defined as a group of consecutive new patients with HFrEF who were referred to our service before RM was available (October 2020 to March 2021). These patients were identified from our registry of heart failure referrals. These patients all received standard heart failure care without RM in accordance with international clinical guidelines [16]. From this group, a set of patients (the same number as in the RM group) were selected by matching to the RM group for a range of factors (see below). The ratio of RM to control patients was 1:1.

Sample Size

The sample size was determined by the number of patients fulfilling the inclusion criteria above. The size of the control group was determined by the size of the RM group by 1:1 matching. We envisaged that the distribution of health care use and costs would be nonparametric. We calculated that detecting a change in the probability of ED attendance, hospital admission, and outpatient clinic attendance of 0.15 (with the null hypothesis assuming that there is no difference between groups, that is, probability of RM decreasing use=0.5), at an α of .05 and power of 80% would require at least 58 patients per group [17].

The Remote Monitoring Intervention

Overview

The RM intervention in this study used the Luscii (Luscii Healthtech BV) platform. This is a commercially available smartphone-based RM platform. None of the authors of this study are employed by Luscii or were involved in the development of the platform. No employees of Luscii were involved in our analyses. The intervention combined 3 modules within a single smartphone app.

Measurements Module

Patients were given a digital sphygmomanometer, pulse rate monitor, and body mass scales, which were connected to the smartphone app via Bluetooth. Patients were prompted to submit measurements daily, with no upper limit on the number of

allowable measurements. All previously submitted measurements were viewable by the patient and clinicians in graphical and tabulated formats. Patients could also complete optional questionnaires about heart failure symptoms, pill use, anxiety, and depression (Figure S1 in Multimedia Appendix 1 shows a screenshot).

Self-Care Module

e-Learning modules written by HFSNs in our department were uploaded to the Luscii app. These covered topics such as prognostic heart failure medication, information about different cardiac investigations, and device therapy (Figure S2 in Multimedia Appendix 1 shows a screenshot).

Messages Module

Patients had the option to add free-text comments to their measurements, which were sent to clinicians in the form of a message. In this module, clinicians (typically HFSNs) could respond to these messages or send new messages as unstructured free text. HFSNs were available to interact with patients using this module between 9 AM and 5 PM, Monday to Friday (Figure S3 in Multimedia Appendix 1 shows a screenshot).

Standard of Care Received by the Control Group (Usual Care)

The heart failure care received by the control group was the usual standard provided to all patients before we started using RM. It consisted of a comprehensive clinical and biochemical assessment in accordance with international guidelines [16]. Upon diagnosis of new HFrEF, every patient is allocated a named consultant and HFSN. They have appointments face-to-face and by telephone to check their symptoms and up-titrate their medical therapy. At each face-to-face appointment, the patient's blood pressure, pulse, and weight are measured. The frequency and interval of these appointments are individualized depending on the clinical condition, response to therapy, blood test results, and patient wishes. Typically, patients will initially be seen weekly after the diagnosis and then move to longer intervals as they enter the chronic stage of the condition. In terms of educational material, all patients are provided with leaflets about the condition and a pack of web-based resources compiled by heart failure charities. Heart failure specialist nurses proactively provide opportunistic education and information to patients and their caregivers with each clinical encounter.

Variables for Cohort Matching

From the pool of patients with a new diagnosis of HFrEF referred to our heart failure service in the months before RM, a control group was selected using propensity matching in a 1:1 ratio with the RM group for the following categories: demographics (age, sex, and ethnicity); socioeconomic status as measured by indices of multiple deprivations (IMDs; income, employment, and education) [18]; medical comorbidities (ischemic heart disease, hypertension, atrial fibrillation, stroke, type 2 diabetes mellitus, chronic obstructive pulmonary disease, and chronic kidney disease); and heart failure severity as measured by LVEF and the New York Heart Association (NYHA) classification at the time of referral.

Outcome Variables

The measured outcome variables were the number of ED attendances, unplanned hospital admissions, elective hospital admissions, and cardiology outpatient appointments for each group. The total costs associated with each type of hospital activity were also measured.

Data Sources and Measurement

The variables for cohort matching, including demographics, cause of heart failure, LVEF, NYHA score, and medical comorbidities, were extracted from the electronic health record.

The outcome variables were extracted from the Discover data set [19]. The Discover data set was accessed via the Discover-NOW Health Data Research Hub for Real World Evidence through their data scientist specialists and information governance committee-approved analysts, hosted by Imperial College Health Partners.

Data were extracted for health care use over a 3-month time period, starting with either onboarding to the RM platform (for the RM group) or referral to our service (for the control group). The costs associated with each type of activity were also extracted. For the RM group, the platform costs were added to the health care use costs.

Statistical Methods

The effectiveness of the propensity matching was confirmed using 2-tailed *t* tests for continuous variables and Fisher exact test for discrete variables (or nonparametric equivalents) to detect differences in baseline characteristics between the RM and control groups.

Differences in health care use and associated costs were analyzed using Wilcoxon rank sum tests. Kaplan-Meier analysis with Cox proportional hazards modeling was used to analyze the probability of avoiding ED attendance, unplanned admission, elective admission, and cardiology outpatient clinic use between the 2 groups. Univariate Cox proportional hazard modeling was performed for any baseline variables found to be significantly different between the 2 groups.

Results

Overview

A total of 146 patients (42/146, 29% female, mean age 63.8 years) with HFrEF were included. The RM group included 73 patients with a new diagnosis of HFrEF who were onboarded to the RM platform and used it for at least 3 months. The control group included 73 patients with a new diagnosis of HFrEF from the period just before RM was available, matched to the RM group for age, sex, ethnicity, IMD, medical comorbidities, LVEF, and NYHA score at baseline. The baseline characteristics of the 2 groups are shown in Table 1. The groups were well-matched for demographics, IMD, heart failure severity, and comorbidities except for hypertension (RM group 27/73, 36%; control group 41/73, 55%; *P*=.03).

Table 1. Baseline characteristics. Baseline characteristics in the RM and matched control groups.

Baseline characteristic	RM[a] group (n=73)	Control group (n=73)	*P* value
Demographics			
Age (years), mean (SD)	63.0 (13.2)	64.5 (13.0)	.48
Female, n (%)	21 (29)	21 (29)	>.99
IMD[b] decile, mean (SD)	3.40 (2.18)	3.87 (2.26)	.22
Ethnicity, n (%)			
White	40 (55)	42 (58)	.87
Black	13 (18)	11 (15)	.82
Asian	7 (10)	7 (10)	>.99
Mixed	5 (7)	7 (10)	.76
Other	8 (11)	11 (15)	.62
Medical comorbidities, n (%)			
Ischemic heart disease	24 (32)	23 (31)	>.99
Atrial fibrillation	22 (29)	24 (32)	.86
Hypertension	27 (36)	41 (55)	.03
Stroke	5 (<7)	7 (9)	.76
Type 2 diabetes mellitus	13 (17)	24 (32)	.06
COPD[c]	10 (13)	13 (17)	.65
Chronic kidney disease	8 (11)	11 (15)	.62
Heart failure parameters, %			
LVEF[d], mean (SD)	33 (10)	32 (9)	.53
NYHA[e] classification, n (%)			
I	11 (15)	14 (19)	.66
II	36 (49)	33 (45)	.74
III	22 (30)	25 (34)	.72
IV	4 (5)	1 (1)	.37

[a]RM: remote monitoring.

[b]IMD: indices of multiple deprivation.

[c]COPD: chronic obstructive pulmonary disease.

[d]LVEH: left ventricular ejection fraction.

[e]NYHA: New York Heart Association.

Secondary Health Care Use

Over the 3-month follow-up period, there were significantly fewer ED attendances in the RM group compared to the control group (16 vs 46, *P*=.01). The RM group also had fewer unplanned hospital admissions (4 vs 21, *P*=.01). There was no difference in elective (planned) hospital admissions (6 vs 5, *P*=.99) between the 2 groups. The RM group had a trend toward more cardiology outpatient use than the control group, but this difference did not reach statistical significance (77 vs 48, *P*=.10; Table 2).

Kaplan-Meier analyses (Figure 2) and Cox proportional hazard modeling (Table 3) showed that patients in the RM group had a significantly lower chance of attending an ED (unadjusted hazard ratio [HR] 0.43; 95% CI 0.21-0.88; *P*=.02) and having an unplanned hospital admission (unadjusted HR 0.26; 95% CI 0.09-0.80; *P*=.02). These findings were sustained by a univariate model that adjusted for hypertension (the one baseline characteristic that was unequal between the 2 groups): ED attendances (adjusted HR 0.43; 95% CI 0.21-0.89; *P*=.02) and unplanned hospital admissions (adjusted HR 0.29; 95% CI 0.09-0.89; *P*=.03).

Table 2. Secondary health care use and costs: The amount of secondary health care use and associated costs (categorized by type of encounter) by patients in the RM and control groups during a 3-month follow-up period. Use values are total counts of the number of events that took place in each category for each group. Cost values are the total spend in each category for each group (ie, not per patient). *P* values were calculated from Wilcoxon rank sum tests between median values for each group.

	RM[a] group (n=73)	Control group (n=73)	*P* value
Secondary health care use (total number of events in 3 months), n			
Emergency department attendances	16	46	.01
Unplanned admissions	4	21	.01
Elective admissions	6	5	.99
Cardiology outpatient attendances	77	48	.10
Secondary health care costs (GBP £, total)[b]			
Emergency department cost	2562	6673	.04
Unplanned admissions cost	11,321	108,906	.02
Elective admissions cost	5053	13,175	>.99
Cardiology outpatient cost	8827	6320	.07

[a]RM: remote monitoring.

[b]A currency exchange rate of GBP £1=US $1.25 is applicable.

Figure 2. Event analysis for secondary health care use. Kaplan-Meier curves comparing the probability of not using different secondary health care services between RM and control groups. RM: remote monitoring.

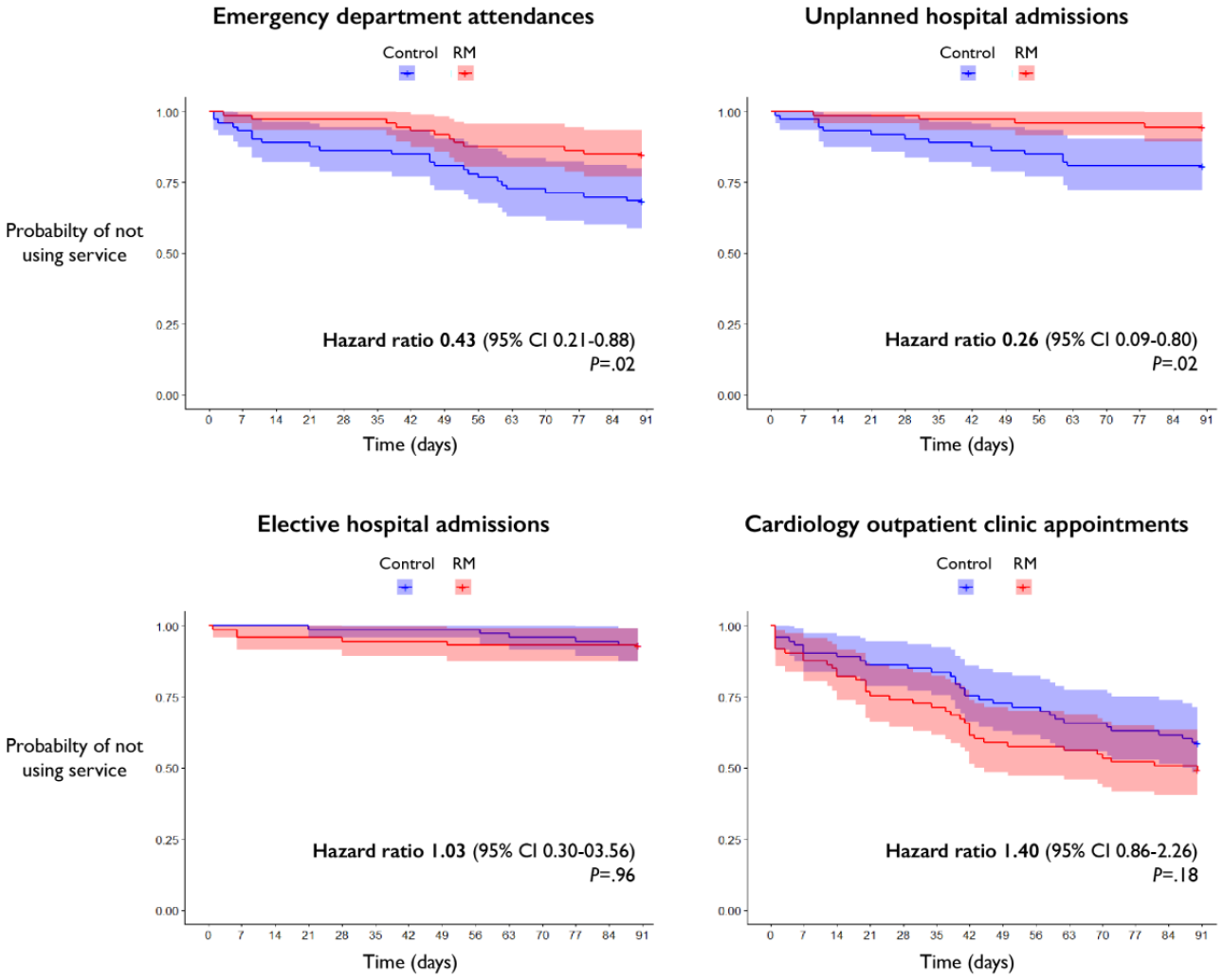


Table 3. Cox proportional hazard modeling for secondary health care use: hazard ratios (unadjusted and adjusted for hypertension) for different types of secondary health care use during a 3-month period. Hazard is calculated for the remote monitoring group with respect to the control group.

Type of health care use	Unadjusted		Adjusted for hypertension	
	HR[a] (95% CI)	*P* value	HR (95% CI)	*P* value
Emergency department attendance	0.43 (0.21-0.88)	.02	0.43 (0.21-0.89)	.02
Emergency admission	0.26 (0.09-0.80)	.02	0.29 (0.09-0.89)	.03
Elective admission	1.03 (0.30-3.56)	.96	1.17 (0.33-4.16)	.80
Cardiology outpatient	1.40 (0.86-2.26)	.18	1.34 (0.82-2.19)	.24

[a]HR: hazard ratio.

Secondary Health Care Costs

The secondary health care costs were largely in line with the amount of use. Over 3 months, the RM group had significantly lower cumulative ED attendance costs (total GBP £2562, US $3214.07 vs GBP £6673, US $8371.39; *P*=.04) and cumulative emergency hospital admissions (total GBP £11,321, US $14,202.38 vs GBP £108,906, US $136,624.32; *P*=.02). Although the RM group had lower total costs associated with elective hospital admissions and higher total outpatient costs than the control group, these differences did not reach statistical significance (Table 2).

When all 4 categories of secondary health care use over the 3-month period were considered, including (for the RM group) the cost of RM over this period, the RM group had a significantly lower mean cost per patient (GBP £465, US $583.35 vs GBP £1850, US $2320.85; *P*=.04).

Discussion

Primary Findings

The key findings of this study are that in the 3 months after HFrEF diagnosis, smartphone-based noninvasive RM was associated with a reduced hazard of ED attendance and unplanned hospital admissions by 57% and 74%, respectively, which was not explained by an increase in elective admissions or outpatient use. Over a 3-month period, the RM group had overall lower secondary health care costs than the control group, even after accounting for the cost of RM.

Comparison With Previous Studies

Our results add evidence in support of smartphone-based noninvasive RM of vital signs in patients with HFrEF. To date, this is the largest study investigating the impact of a smartphone-based RM platform combining vital signs monitoring, patient-focused e-learning, and instant messaging with clinicians in this population. Our findings build on previous studies, which found that this type of RM was feasible and beneficial but was limited by low numbers [20,21] or the lack of matched controls [22]. Our findings also agree with a meta-analysis of telephone-based RM (which has been much more extensively researched for heart failure) that found it to reduce hospitalizations [23].

Many randomized trials of telephone-based RM such as BEAT-HF (Better Effectiveness After Transition–Heart Failure) and Tele-HF are limited by low adherence and high dropout (almost half at 6 months) [24,25]. By contrast, there was a very low dropout rate in our study; 87 patients were onboarded altogether, of whom 11 were excluded because they had under 3 months' platform use at the time of analyses, and 3% (3/87) dropped out (2 stopped using and 1 died). This is in line with previous work for smartphone-based RM platforms [13]. There are a number of possible explanations. First, a smartphone app-based platform allows the flexibility of asynchronous communications, meaning patients can use it at a time convenient for them rather than a scheduled phone call [26]. Second, this type of RM enables vital sign and symptom self-reporting more frequently than face-to-face outpatient appointments but is not as intrusive as daily telephone calls; this data collection and trend analysis could aid therapy optimization and intercept clinical decompensation without burdening patients with fixed activities that may risk disengagement [7]. Third, we studied a self-selecting group who agreed to have RM and use the smartphone platform. This group was younger (mean age 63 years) than the average HFrEF patient, and almost all patients were able to use the technology without dropping out. This is similar to the average age of the RM cohort in another study [13], and it highlights the importance of the careful selection of the most appropriate patients for this type of RM: those who can use the technology and therefore stand to benefit from it [7].

Smartphone-Based RM Combines Multiple Interventions Into a Single Platform

The RM technology used in this study packages together monitoring, education, self-care, and messaging features in a single smartphone app interface. It is difficult to tease apart which of these were most responsible for the reduction in acute secondary care use and costs that we observed. Simply having a direct line of communication with HFSNs may enable rapid, ad hoc decision-making such as temporary up-titration of diuretic doses, which could prevent admission. An instant messaging intervention has previously been found to reduce symptoms and improve quality of life [27]. Similarly, access to a nurse-led heart failure education program could increase patient activation, understanding, and self-management sufficiently to reduce the need for other health care services [28]. It is more likely that the additive benefit of all these features rather than any single one and the convenience of a "one-stop-shop" RM user interface are responsible for the differences between RM and control groups. Further follow-up is required to determine whether these differences are sustained in the long term.

Secondary Health Care Economic Impact of RM

A key finding of this study is that the cost savings associated with lower ED attendance and unplanned hospital admissions in the RM group were not offset by higher use of elective and outpatient secondary care. This adds depth to previous findings that RM reduced hospitalizations but could not say whether use (and costs) were simply diverted to other parts of the health system [13,21,22]. Previous economic analyses of RM in heart failure have not accounted for RM platform costs, but this is a very important factor for decision makers considering the cost-effectiveness of RM. In our study, we added the RM platform costs to the secondary health care costs and found that the cost savings were sustained. We found that the largest difference in costs between the RM and control groups was for unplanned admissions rather than ED attendances. This might be because patients in the RM group had a shorter length of hospital stay than those in the control group due to being more optimized to start with.

Impact on Other Medical Comorbidities

It is likely that the benefits of noninvasive vital sign RM extend beyond just the optimization of heart failure. Blood pressure, body mass, and heart rate are key parameters reflecting the optimization of other conditions such as hypertension, chronic kidney disease, obesity, and atrial fibrillation [26]. Optimizing these parameters is known to reduce the risk of ischemic heart disease and stroke [29]. It is intuitive to conclude that optimizing one condition using this method of RM has added benefits to patients' comorbidities (which, as we observed, were highly prevalent in both groups in this study). Furthermore, since smartphone-based RM platforms also enable the delivery of educational material, the resulting increase in patient activation and self-management is likely to have far-reaching benefits beyond just heart failure care. Smartphone-based vital sign RM could be an effective holistic intervention to optimize care across a range of syndromes for multimorbid patients carefully selected based on their comorbidities and ability to use the technology effectively [7,26].

Hypotheses for Improved Clinical Outcomes in the RM Group

There are a number of possible reasons why better clinical outcomes were observed in the RM group in this study. First, the RM platform may enable earlier recognition of clinical deterioration by monitoring physiological parameters (heart rate, blood pressure, weight, and symptoms) more frequently than is possible with traditional models of care using face-to-face appointments [30]. Second, previous research has shown that nurses have twice as much activity with RM patients as controls [31]. This closer attention may enable more aggressive up-titration of prognostic medical therapy (eg, on a daily rather than weekly basis), leading to fewer hospital admissions. Patients in the control group would typically have to wait for their next face-to-face appointment or telephone consultation or seek emergency medical care if their symptoms or measurements worsened. Third, the RM platform provided patients with more opportunities to engage in their health care both passively (when inputting their parameters) and actively (when engaging with specialists via the instant messaging platform or undertaking the learning modules). This may lead to increased medication adherence, as seen in previous studies [32]. Finally, the RM platform might make information previously available to patients in the form of leaflets more accessible to patients. Nurse-led education is known to reduce readmissions and improve quality of life, which may be linked to the clinical outcomes observed in our study [33].

Limitations

The primary limitation of this study is the retrospective, nonrandomized design. As a retrospective cohort study, this study may have selection bias compared to a randomized controlled trial. We accounted for this by matching the RM group with a control group matched for a wide range of demographic, socioeconomic, and clinical features. This design is novel compared to other studies investigating noninvasive RM of vital signs in HF [13,21,22]. Our matching process was effective (Table 1) for all categories except hypertension. We further accounted for this with a univariate Cox proportional hazards model that controlled for hypertension (Table 3). Importantly, since socioeconomic status and education level are linked to smartphone use, we controlled for the 7 IMDs: income, employment, education, health, crime, housing, and living environment. Both groups were well-matched for IMDs (P=.22); therefore, we assert that these factors do not confound our results. Although there may be other minor confounders, these are likely to be equally distributed between both groups. Our fastidious approach to cohort matching may explain the positive findings in our study, despite it not being a randomized design. We believe this is an important contribution to the literature to stimulate more rapid adoption of these types of technologies so that patients can start benefiting from them sooner. We strongly recommend the formal evaluation of the long-term efficacy of this type of RM by means of a randomized controlled trial.

It is possible that the patients in the RM group were more proactive and engaged with their care than the control group, even before they used the RM. This may in part explain our results. However, if this were the case, it would typically be driven by previous experience using digital technologies and smartphone ownership. The primary determinants of smartphone ownership are income, education, and socioeconomic category, which we controlled. Therefore, it is unlikely that this was a significant source of bias that explains our results. Our aim in sharing the results of this study is to stimulate further adoption of this type of technology in clinical practice. We recommend future researchers verify our findings via large randomized controlled trials.

We used propensity score matching to match patients between the RM and control groups in a 1:1 ratio. This method of matching may introduce minor bias to the results of conventional Cox regression modeling due to a lack of independence between the 2 groups [34]. In the absence of consensus on this topic, it is statistically more conservative to assume the groups are independent, and our analyses support this. We encourage future researchers to account for time-dependent exposure by adjusting propensity scores for this to potentially enable unbiased estimates [35].

The study duration was only 3 months. This follow-up length is similar to other studies [13,22], but ours includes more patients and a matched control group. We focused on patients with a new diagnosis of HFrEF. Registry data show that the risk of decompensation—and therefore the largest window for RM intervention—is in the weeks after diagnosis [36]. 3 months is therefore an appropriate timeframe to evaluate the impact of RM on the optimization of care as measured by health care use, costs, and prescribing.

The patients in both cohorts in this study had an average age younger than that of all-comers with HFrEF (64 years). Although this does not confound our results (because the groups are matched), it reflects the fact that older patients (in general) did not opt for this RM strategy. This may be because they are unwilling or unable to use the technology or do not own a smartphone, as has been reported by previous researchers [21]. It is important that RM technologies do not worsen health inequalities, in particular for groups that may not have access to smart devices or reliable internet connections [37]. As a result, we recommend that RM be viewed as a supplement to, not a replacement for, standard clinical care. A major contribution of RM technologies may be to optimize management remotely for those for whom it is possible and desirable, enabling redistribution of resources to enhance standard care for those who are unwilling or unable to have RM [7].

Conclusions

This study demonstrates that smartphone-based noninvasive RM of vital signs combined with a messaging platform and e-learning is feasible for patients with HFrEF. In the 3-month period after diagnosis, RM was associated with significantly lower ED attendance and unplanned hospital admissions without placing extra demand on elective care or outpatient clinics. The secondary health care costs of the RM group were significantly lower than standard care without RM, even after accounting for the costs of RM itself.

Based on these findings, RM has significant benefits for patients and health systems in the early period after a diagnosis of HFrEF. Noninvasive RM should be viewed as an adjunct to standard care to reduce admissions and enable other complementary resources to be directed toward patients who are unable to use RM.

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Data Availability

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of the remote monitoring intervention smartphone app.
[DOCX File , 6722 KB - cardio_v7i1e45611_app1.docx]

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Abbreviations

BEAT-HF: Better Effectiveness After Transition–Heart Failure
ED: emergency department
HFrEF: heart failure with reduced ejection fraction
HFSN: heart failure specialist nurse
HR: hazard ratio
IMD: index of multiple deprivation
LVEF: left ventricular ejection fraction
NYHA: New York Heart Association
RM: remote monitoring

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Original Paper

Barriers and Facilitators Associated With Remote Monitoring Adherence Among Veterans With Pacemakers and Implantable Cardioverter-Defibrillators: Qualitative Cross-Sectional Study

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Abstract

Background: The Heart Rhythm Society strongly recommends remote monitoring (RM) of cardiovascular implantable electronic devices (CIEDs) because of the clinical outcome benefits to patients. However, many patients do not adhere to RM and, thus, do not achieve these benefits. There has been limited study of patient-level barriers and facilitators to RM adherence; understanding patient perspectives is essential to developing solutions to improve adherence.

Objective: We sought to identify barriers and facilitators associated with adherence to RM among veterans with CIEDs followed by the Veterans Health Administration.

Methods: We interviewed 40 veterans with CIEDs regarding their experiences with RM. Veterans were stratified into 3 groups based on their adherence to scheduled RM transmissions over the past 2 years: 6 fully adherent (≥95%), 25 partially adherent (≥65% but <95%), and 9 nonadherent (<65%). As the focus was to understand challenges with RM adherence, partially adherent and nonadherent veterans were preferentially weighted for selection. Veterans were mailed a letter stating they would be called to understand their experiences and perspectives of RM and possible barriers, and then contacted beginning 1 week after the letter was mailed. Interviews were structured (some questions allowing for open-ended responses to dive deeper into themes) and focused on 4 predetermined domains: knowledge of RM, satisfaction with RM, reasons for nonadherence, and preferences for health care engagement.

Results: Of the 44 veterans contacted, 40 (91%) agreed to participate. The mean veteran age was 75.3 (SD 7.6) years, and 98% (39/40) were men. Veterans had been implanted with their current CIED for an average of 4.4 (SD 2.8) years. A total of 58% (23/40) of veterans recalled a discussion of home monitoring, and 45% (18/40) reported a good understanding of RM; however, when asked to describe RM, their understanding was sometimes incomplete or not correct. Among the 31 fully or partially adherent veterans, nearly all were satisfied with RM. Approximately one-third recalled ever being told the results of a remote transmission. Among partially or nonadherent veterans, only one-fourth reported being contacted by a Department of Veterans Affairs health care professional regarding not having sent a remote transmission; among those who had troubleshooted to ensure they could send remote transmissions, they often relied on the CIED manufacturer for help (this experience was nearly always positive). Most nonadherent veterans felt more comfortable engaging in RM if they received more information or education. Most veterans were interested in being notified of a successful remote transmission and learning the results of their remote transmissions.

Conclusions: Veterans with CIEDs often had limited knowledge about RM and did not recall being contacted about nonadherence. When they were contacted and troubleshooted, the experience was positive. These findings provide opportunities to optimize strategies for educating and engaging patients in RM.

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KEYWORDS

cardiac implantable electronic device; electrophysiology; pacemaker; remote monitoring; veterans; adherence

Introduction

Cardiovascular implantable electronic devices (CIEDs: pacemakers and implantable cardioverter-defibrillators [ICDs]) are life-saving devices that provide heart rhythm therapy for patients at risk or with malignant brady- or tachyarrhythmias. CIEDs also generate important diagnostic information, which can be transmitted to clinicians through remote monitoring (RM). RM is strongly recommended by the Heart Rhythm Society (class 1, level of evidence A) and is the standard of care for all patients with CIEDs [1,2]. This is because RM has been demonstrated in randomized clinical trials and large observational studies to improve several important patient-centered outcomes, including reducing mortality [3-5], hospitalizations [4,6,7], and inappropriate ICD shocks [8]. Studies have also demonstrated that RM is associated with high levels of patient acceptance and satisfaction [9-11]. However, this research has only studied patients who are engaged in RM [9-11].

Unfortunately, adherence to RM is suboptimal. Within the Department of Veterans Affairs (VA), the largest US health system performing RM, caring for more than 60,000 veterans with CIEDs who are monitored centrally by the Veterans Affairs National Cardiac Device Surveillance Program (VANCDSP), fewer than one-third of veterans had complete adherence to scheduled transmissions over a 2-year period [12]. For patients to achieve the benefits of RM, they must be adherent to sending RM transmissions. Additionally, patients with wireless devices should ideally be consistently and continuously connected to their transmitter [2]. Ideally, patients would be informed before their CIED implantation about the purpose and benefits of RM, counseled about the importance of adherence, and provided directions about how to activate and send transmissions [2]. Patients must also be educated about steps to troubleshoot challenges with RM [2]. This ideal intervention of education, counseling, and directions may not uniformly occur because of the stress of device placement, or it may not be provided at a level individualized to patient comprehension [2].

To improve RM adherence among patients with CIEDs, we must first understand the reasons for nonadherence. Although previous research has quantitatively examined RM adherence, data about patient perspectives are limited to a single focus group study of 9 patients from 1 county in the Midwestern US [13]. To better understand patient perspectives, we conducted structured telephone interviews about potential barriers and facilitators to RM adherence with adherent and nonadherent veterans who were followed by the VANCDSP.

Methods

Veteran Population

Using the VANCDSP database of all veterans with CIEDs who had agreed to participate in RM as of October 23, 2020, we created this study's sample. Veteran contact information was identified through the Veterans Affairs Corporate Data Warehouse. According to best practices for qualitative methods, our goal was to select a representative sample of veterans to understand their perspectives about barriers and facilitators associated with RM, and we continued this study until we reached saturation of information to ensure adequate data [14].

Veterans were stratified into 3 groups based on their adherence to RM transmissions over the past 2 years: fully adherent (≥95%), partially adherent (≥65% but <95%), and nonadherent (<65%). Each time that a veteran sent an RM transmission, the veteran was considered adherent for the past number of days equivalent to their transmission interval, plus an additional 10 days in order to provide a buffer for any brief delays in transmission [12]. Thus, adherence was determined based on the past 631 days (since nearly all veterans have a 90-day transmission window, and an additional 10-day buffer leads to 100 fewer days compared with the 730 days in a 2-year period).

Among the entire population of veterans who had agreed to participate in RM, we randomly selected veterans from each of the 3 groups (fully, partially, and nonadherent) in a 2:6:3 ratio, respectively, through purposive sampling [15]. First, we included a limited number of veterans who were fully adherent; as our focus was to understand challenges with RM adherence, we did not anticipate learning as much about barriers, but we wanted to have some data from these veterans. Our primary focus was veterans who were partially adherent to RM (as this group of veterans comprises most of the nonadherent veterans), and, thus, we sampled 3 times as many of these veterans in this study. Finally, we know that there are also many patients who are supposed to be engaged in RM but are nonadherent; accordingly, we included this group of veterans, but half as many as those who were partially adherent. Saturation was reached more quickly in the group of fully adherent veterans. We included veterans with both wireless-capable CIEDs and those who must manually send remote transmissions; this latter group receives a postcard reminder from the VANCDSP before their scheduled transmission date.

Structured Interview Guide Development and Testing

The structured interview guide was developed to learn about veteran experiences with care for CIEDs. In developing the interview guide, we sought input from clinicians with expertise in RM and researchers with expertise in qualitative methods.

The structured interview guide used a fixed order and number of questions with predetermined categorical answer choices. A few questions allowed for open-ended responses to dive deeper into themes. The interview guide was pretested on 3 randomly selected veterans to determine acceptability, improve clarity, and fine-tune length.

Interview Domains

Veteran interviews covered 4 predetermined domains: knowledge, satisfaction, reasons for nonadherence, and preferences for health care engagement. The first domain asked all veterans about their understanding of RM and its benefits. The second domain asked veterans who were fully or partially adherent about their perspectives, satisfaction, and adherence to RM. The third domain was limited to veterans who were partially or nonadherent to RM; these questions asked about reasons for nonadherence, contact with the health care system or CIED manufacturer, and reminders about missed transmissions. The final CIED-related domain asked questions about preferences for engagement around home monitoring, including stopping in-person clinic visits, confirmation of transmission success, and learning the results of remote transmissions. We also asked veterans about demographics, social determinants of health, and location of care. Veterans could decline to answer any questions.

Interview Protocol

All veterans were mailed a letter in November 2020 stating that they would be reached by phone to understand their experiences and perspectives of RM technology as well as possible barriers. They were also provided with contact information if they wanted to schedule an interview.

Approximately 1 week after the letters were mailed, veteran contact began. Veterans were reached at one of their 2 primary numbers within the electronic health record, one of which is usually a mobile phone number. Attempts were made to reach veterans a minimum of 3 times, leaving a message after the first attempt with a call-back number.

The structured interviews were conducted by 1 author (SM), who has experience conducting telephone interviews with veterans. Once saturation across responses was reached, no further interviews were conducted. During the interview, veterans were also provided with education about RM, and those who were not actively transmitting were provided reference information to support starting or restarting remote transmissions.

Data Analysis

Study data were analyzed deductively using content analysis within the 4 study domains. The data are presented using descriptive statistics. Where available, quotations are used to illustrate themes.

Ethical Considerations

This project did not constitute research. In accordance with the VA's Office of Research & Development Program Guide: 1200.21, "VHA (Veterans Health Administration) Operations Activities That May Constitute Research," data were collected as part of a quality improvement study to assess and improve the quality of RM care for veterans with CIEDs and did not require institutional review board approval. Veterans consented to participation; no compensation was provided.

Results

Overall, we contacted 44 veterans (6 fully adherent, 28 partially adherent, and 10 nonadherent). A total of 2 veterans declined to be interviewed, and another 2 could not be reached despite multiple attempts. We concluded participant recruitment after reaching saturation.

Among the 40 veterans interviewed (6 fully adherent, 25 partially adherent, and 9 nonadherent—of whom 7 had never sent an RM transmission), the mean age for veterans was 75.3 (SD 7.6) years, and 98% (39/40) were men (Table 1). A total of 30 veterans (75%) self-reported White race, 4 (10%) Black or African American, 3 (8%) American Indian or Alaskan Native, 3 (8%) other, and 3 (8%) declined to answer. A total of 27 veterans (68%) were married, and 1 (2%) reported difficulty with housing.

Table 1. Characteristics of interviewed veterans receiving cardiovascular implantable electronic device care within US Department of Veterans Affairs, October 2020.

Characteristics	Fully adherent (n=6)	Partially adherent (n=25)	Nonadherent (n=9)	Total (n=40)
Age (years), mean (SD)	78.2 (6.7)	76.3 (8.1)	70.5 (4.3)	75.3 (7.6)
Male sex, n (%)	6 (100)	24 (96)	9 (100)	39 (98)
Race, n (%)				
White	5 (83)	19 (76)	6 (67)	30 (75)
Black or African American	0 (0)	2 (8)	2 (22)	4 (10)
Asian	0 (0)	0 (0)	0 (0)	0 (0)
American Indian or Alaskan Native	0 (0)	2 (8)	1 (11)	3 (8)
Native Hawaiian or other Pacific Islander	0 (0)	0 (0)	0 (0)	0 (0)
Other	1 (17)	2 (8)	0 (0)	3 (8)
Declined to answer	0 (0)	2 (8)	1 (11)	3 (8)
Highest education attained, n (%)				
Less than high school	2 (33)	6 (24)	1 (11)	9 (22)
High school degree or completion of general educational development test	0 (0)	3 (12)	1 (11)	4 (10)
Some college or associate degree	2 (33)	12 (48)	4 (44)	18 (45)
Bachelor's degree	1 (17)	3 (12)	2 (22)	6 (15)
Higher than a bachelor's degree	1 (17)	1 (4)	0 (0)	2 (5)
Declined to answer	0 (0)	0 (0)	1 (11)	1 (2)
Marital status, n (%)				
Married	4 (67)	18 (72)	5 (56)	27 (68)
Living with a partner	1 (17)	1 (4)	1 (11)	3 (8)
Widowed, separated, or single	1 (17)	6 (24)	2 (22)	9 (22)
Declined to answer	0 (0)	0 (0)	1 (11)	1 (2)
Housing difficulty, n (%)				
No difficulty with housing	6 (100)	24 (96)	9 (100)	39 (98)
Difficulty with housing	0 (0)	1 (4)	0 (0)	1 (2)
CIED[a] information, n (%)				
Pacemaker	2 (33)	15 (60)	5 (56)	22 (55)
Implantable cardioverter-defibrillator	4 (67)	10 (40)	4 (44)	18 (45)
Duration of time (years) CIED has been in place	4.3 (3.1)	4.8 (3.0)	3.4 (2.1)	4.4 (2.8)
Number of CIED generators in veteran's history	2.3 (0.8)	1.4 (0.7)	1.3 (0.5)	1.6 (0.7)
Wireless versus manual transmission, n (%)				
Wireless-capable generator	5 (83)	15 (60)	7 (78)	30 (75)
Manual transmission only	1 (17)	10 (40)	2 (22)	10 (25)
Cardiology care location, n (%)				
All cardiology care within VA[b]	6 (100)	23 (92)	8 (89)	37 (92)
Some cardiology care provided outside VA	0 (0)	2 (8)	1 (11)	3 (8)
Overall health care location, n (%)				
At least half of the health care is provided within VA	6 (100)	24 (96)	9 (100)	39 (98)
Less than half of health care is provided within VA	0 (0)	1 (4)	0 (0)	1 (2)

[a]CIED: cardiovascular implantable electronic device.

[b]VA: Department of Veterans Affairs.

Of the 40 veterans, a total of 22 (55%) had pacemakers, and 18 (45%) had ICDs. A total of 30 (75%) CIEDs were wireless-capable, while 10 (25%) were manual transmission only. The veterans had been implanted with their current CIED for an average of 4.4 (SD 2.8) years and had a mean of 1.6 (SD 0.7) generators in their history. Of the 40 respondents, 37 (92%) received all their cardiology care within VA, and all but one received at least half of their health care within VA.

Domain 1: Understanding of Remote Monitoring and Clinical Benefits

Of the 40 veterans, 23 (58%) reported that home monitoring had been discussed with them, and 5 (12%) were not sure. Among these 23 veterans, only 5 (22%) recalled learning about RM at the initial implant, with 14 (61%) learning about it at follow-up for in-person CIED checks (Table 2). The person who discussed RM with the veteran was a physician for 4 (17%), a nurse for 7 (30%), a CIED manufacturer representative for 5 (22%), and unknown for 7 respondents (30%). An additional 2 veterans reported learning about RM by reading a pamphlet. Only 8 (35%) veterans were accompanied by a friend, family member, or caregiver when RM was initially discussed with them; the majority of partially adherent or nonadherent veterans reported being unaccompanied. Of the 23 veterans with whom RM had been discussed, 20 (87%) reported being satisfied or very satisfied with this discussion.

Table 2. Veteran-reported characteristics of remote monitoring education among interviewed veterans receiving cardiovascular implantable electronic device care within US Department of Veterans Affairs who recalled being informed about remote monitoring.

Characteristics	Fully adherent (n=5), n (%)	Partially adherent (n=11), n (%)	Nonadherent (n=7), n (%)	Total[a] (n=23), n (%)
Time of veteran's education about remote monitoring				
At initial implant	2 (40)	2 (18)	1 (14)	5 (22)
At follow-up for in-person CIED[b] checks	2 (40)	8 (73)	4 (57)	14 (61)
At other times	0 (0)	1 (9)	2 (29)	3 (13)
Unknown	1 (20)	0 (0)	0 (0)	1 (4)
Remote monitoring educator				
Physician	2 (40)	0 (0)	2 (29)	4 (17)
Nurse	0 (0)	4 (36)	3 (43)	7 (30)
CIED manufacturer representative	2 (40)	2 (18)	1 (14)	5 (22)
Unknown	1 (20)	5 (45)	1 (14)	7 (30)
Social support at remote monitoring education				
Accompanied by friend, family member, or caregiver	3 (60)	4 (36)	1 (14)	8 (35)
Unaccompanied	1 (20)	6 (55)	4 (57)	11 (48)
Not sure or unknown	1 (20)	1 (9)	2 (29)	4 (17)
Satisfaction with remote monitoring education				
Satisfied or very satisfied	4 (80)	10 (91)	6 (86)	20 (87)
Not very satisfied	1 (20)	1 (9)	1 (14)	3 (13)

[a]An additional 17 veterans did not recall being informed about remote monitoring.

[b]CIED: cardiovascular implantable electronic device.

Only 18 (45%) of the 40 veterans thought that they had a good understanding of RM. However, when these 18 veterans were asked an open-ended question to describe their understanding, some potential misconceptions were identified. A veteran said, "machine (remote transmitter) will buzz, call (name of clinician) at the VA." Other veterans did have an understanding:

"Every 90 days, transmitter reads ICD, transmits to Boston Scientific. They decode and send results to (the) doctor."

When these 40 veterans were asked to describe the clinical benefits of RM, 19 (48%) reported detection of abnormal rhythms and 5 (12%) reported detection of device malfunction. However, 8 (20%) veterans were unable to report any benefits. Of the 40 veterans, 33 (82%) recognized that it was safer to be participating in RM than not participating, while 4 (10%) felt that it was the same, and 3 (8%) declined to answer.

Domain 2: Perspectives and Satisfaction With Remote Monitoring

Among the 31 fully or partially adherent veterans, a total of 27 (87%) were satisfied with RM (Table 3). Of these 31 veterans, a total of 28 (90%) stated that they would recommend RM to other veterans with a CIED. When these veterans were asked an open-ended question as to why they would recommend RM,

they provided a variety of reasons, most commonly that it provided “peace of mind” and a sense of security, as well as the need for fewer in-person visits.

Table 3. Veteran satisfaction with remote monitoring among interviewed veterans receiving cardiovascular implantable electronic device care within US Department of Veterans Affairs who were fully or partially adherent to remote monitoring.

	Fully adherent (n=6), n (%)	Partially adherent (n=25), n (%)	Total[a] (n=31), n (%)
Veteran’s satisfaction with remote monitoring			
Satisfied	6 (100)	21 (84)	27 (87)
Not sure	0 (0)	4 (16)	4 (13)
Veteran remote monitoring referral disposition			
Would recommend remote monitoring	6 (100)	22 (88)	28 (90)
Not sure	0 (0)	3 (12)	3 (10)
Veteran notification of any transmission results			
Notified	2 (33)	9 (36)	11 (35)
Not notified	3 (50)	16 (64)	19 (61)
Not sure	1 (17)	0 (0)	1 (3)

[a]An additional 9 veterans were nonadherent.

Of these 31 veterans, 11 (35%) reported having ever been told the results of a remote transmission. Only 18 (58%) veterans had an idea of the next steps if their RM transmitter was not working; approximately half said that they would contact their VA clinic and the other half would contact the manufacturer of their CIED.

Domain 3: Adherence to Remote Monitoring

Of the 25 veterans who were partially adherent to RM, when asked about possible barriers to adherence, a total of 3 (12%) reported forgetting about monitoring, and 3 (12%) reported losing a monitor (Table 4). A total of 2 veterans reported preferring in-person visits, and none reported other concerns. No veterans reported concerns about privacy or not knowing how to engage in RM.

Table 4. Communication and barriers to remote monitoring among interviewed veterans receiving cardiovascular implantable electronic device care within US Department of Veterans Affairs who were partially adherent or nonadherent to remote monitoring.

	Partially adherent (n=25), n (%)	Nonadherent (n=9), n (%)	Total[a] (n=34), n (%)
Barriers to remote monitoring			
Do not know how	0 (0)	4 (44)	4 (12)
Do not recall being informed about remote monitoring	0 (0)	4 (44)	5 (15)
Privacy	0 (0)	1 (11)	1 (3)
Prefer in-clinic visits	2 (8)	2 (22)	4 (12)
Difficulties with use (either patient-specific constraints, disabilities, or technology difficulties)	0 (0)	1 (11)	1 (3)
Forgetting about remote monitoring	3 (12)	2 (22)	5 (15)
Losing monitor	3 (12)	0 (0)	3 (9)
Veteran contacted about missed remote monitoring transmission			
Contacted	6 (24)	4 (44)	10 (29)
Not contacted	18 (72)	5 (56)	23 (68)
Not sure	1 (4)	0 (0)	1 (3)
Veteran-manufacturer communication about remote monitoring			
Called manufacturer	14 (56)	3 (33)	17 (50)
Positive experience when called manufacturer	12 (86)	2 (67)	14 (82)
Negative experience when called manufacturer	2 (14)	1 (33)	3 (18)
Have not called manufacturer	10 (40)	6 (67)	16 (47)
Not sure	1 (4)	0 (0)	1 (3)

[a]An additional 6 veterans were fully adherent.

Among these 25 veterans, only 6 (24%) reported being contacted by a VA health care professional regarding not having sent a transmission, and the same number recalled being offered help in transmitting. A total of 14 (56%) veterans had called the manufacturer of their CIED about RM, and all but 2 reported a positive experience; one of them asked for a new remote transmitter but reported that the request was declined, and the other replied that they were unable to reach anyone.

Among 9 veterans who were nonadherent, the barriers identified were not knowing how to transmit (n=4), not recalling being informed about RM (n=4), preferring in-person visits to RM (n=2), forgetting (n=2), privacy concerns (n=1), and difficulty with using a home monitor (n=1).

Of these 9 veterans, only 4 reported that they had been contacted by a VA health care professional about not sending a transmission. However, a total of 5 veterans felt that they would feel more comfortable engaging if they received more information or education; all 5 preferred to learn from VA clinicians, and an additional 2 were amenable to informational postcards. Of these 9 veterans, a total of 3 had called the manufacturer of their CIED; of which 2 reported positive experiences, while 1 reported that no solution was possible because of a lack of cell coverage. Of these 9 veterans, a total of 3 were not sure about their interest in starting RM, and 1 was not interested in starting RM, stating, “If it’s my time, it’s my time.”

Domain 4: Additional Possibilities With Remote Monitoring

When all 40 veterans were offered the hypothetical possibility of stopping routine in-person CIED evaluations in favor of an RM-only approach, a total of 10 (25%) were interested in the possibility, while 25 (62%) were not, another 4 (10%) were not sure, and 1 (2%) declined to answer (Table 5). A majority of the veterans who were nonadherent were interested in this option.

Table 5. Interest in remote monitoring engagement among interviewed veterans receiving cardiovascular implantable electronic device care within US Department of Veterans Affairs.

	Fully adherent (n=6), n (%)	Partially adherent (n=25), n (%)	Nonadherent (n=9), n (%)	Total (n=40), n (%)
Interest in complete substitution of remote monitoring for in-person visits				
Interested	1 (17)	4 (16)	5 (56)	10 (25)
Not interested	4 (67)	19 (76)	2 (22)	25 (62)
Not sure	1 (17)	2 (8)	1 (11)	4 (10)
Declined to answer	0 (0)	0 (0)	1 (11)	1 (2)
Interest in receiving a transmission reminder	5 (83)	22 (88)	6 (67)	33 (82)
Preferred format for remote monitoring transmission reminder				
SMS text message	2 (40)	4 (18)	4 (67)	10 (30)
Email	1 (20)	6 (27)	0 (0)	7 (21)
Mobile app	0 (0)	0 (0)	0 (0)	0 (0)
Phone call	1 (20)	7 (32)	2 (33)	10 (30)
Other: letter	1 (20)	0 (0)	0 (0)	1 (3)
Multiple combinations	0 (0)	5 (23)	0 (0)	5 (15)
Interest in successful transmission notification	3 (50)	16 (64)	6 (67)	25 (62)
Interest in learning remote monitoring results	6 (100)	21 (84)	6 (67)	33 (82)
Level of detail interested about remote monitoring results				
Normal or abnormal	6 (100)	15 (71)	5 (83)	26 (79)
All device details	0 (0)	6 (29)	1 (17)	7 (21)
Preferred format for learning remote monitoring results				
SMS text message	2 (33)	4 (19)	2 (33)	8 (24)
Email	1 (17)	8 (38)	0 (0)	9 (27)
Mobile app	0 (0)	3 (14)	1 (17)	4 (12)
Letter or phone call	2 (33)	4 (19)	2 (33)	8 (24)
Multiple options	1 (17)	2 (10)	1 (17)	4 (12)

Of the 40 veterans, a total of 25 (62%) were interested in a smartphone or tablet app notifying them of a successful transmission, and 24 (60%) had a smartphone or tablet. And 33 (82%) veterans, including majorities in all 3 categories, were willing to receive a reminder if they had missed their transmission by at least 3 days. A total of 34 respondents (all of those who said "yes" and an additional veteran who was "not sure") reported their preferred mechanism: SMS text messaging (n=12), email (n=11), phone call (n=13), and n=1 each through a letter or a mobile app.

A total of 33 (82%) veterans were interested in learning the results of their remote transmissions; of these, a total of 26 (79%) wanted to know just if the transmission was normal or abnormal, while 7 (21%) were interested in all device details. When these 33 veterans were asked the mechanism through which they would like to learn these results, 8 (24%) stated SMS text message, 9 (27%) email, 4 (12%) mobile app, 8 (24%) other and reported that they wanted either a letter or phone call, and 5 (15%) mentioned multiple options.

Among the 13 veterans who needed to send manual transmissions, a total of 10 (77%) were interested in electronic reminders through either SMS text message, email, or both. Similarly, among the 27 veterans with wireless CIEDs, a total of 22 (81%) were interested in a reminder the day before their automatic scheduled transmission, and some of these veterans were also interested in a phone call or letter reminder.

Discussion

Principal Results

In this qualitative study of veterans with CIEDs, we found that most veterans reported being satisfied with RM, but they often had limited understanding about the need for and clinical benefits of RM. Some veterans did not recall receiving counseling about RM. Among veterans who were not fully adherent to RM, few recalled being contacted by clinicians about nonadherence. Nonadherent veterans welcomed the opportunity to learn more about RM and engage in monitoring. These findings are important because they demonstrate gaps in veterans' knowledge about RM and opportunities to support

veterans in increasing RM engagement so that they can achieve the many clinical outcome benefits of RM that lead to its strong professional society recommendation [1,2].

Comparison With Previous Work

Previous single-center survey and interview research has shown that patients have limited understanding about their CIED [16,17]. This study extends these findings to a larger population and asked more specific questions about barriers and facilitators to RM. A focus group study found that patients not engaged in RM did not understand RM or have confidence in their ability to send a transmission [13], and we add more detail to these findings in a larger number of patients. This is also the first study of veterans' perspectives and understanding of RM.

A previous survey of patients in CIED clinics found variation in the amount of detail patients request about their remote transmissions, ranging from most patients being interested in learning about battery life to a smaller proportion being interested in sensing and impedance data [16]. To date, only 1 pilot study of 10 patients has provided granular CIED data directly to patients; overall, patients appreciated access to the data but had questions about its interpretation [18]. This study demonstrates that veterans are usually interested in learning at least if a remote transmission has been received, whether it is normal or abnormal, and, less frequently, additional details.

Patient Education at Device Implant

To ensure minimal knowledge gaps about RM among patients, the standard of care should be patient education before device implant, as recommended by the Heart Rhythm Society [1,2]. In this study, fewer than 15% of veterans recalled learning about RM at CIED placement. However, veterans were interviewed an average of almost 5 years after the placement of their current CIED. Thus, it is possible that they may not have retained that information given the stress and often overwhelming nature of hospitalization and CIED placement, as well as accompanying factors such as sedation. Therefore, the importance of RM should be reinforced in the outpatient setting and through a variety of other strategies that are individualized to patients, such as pamphlets or digital information made available through patient portals, to ensure that patients understand the multiple benefits and need to engage in RM. Including family members, when able, could also help support patients in monitoring. The inaccurate or incomplete understanding of the benefits of RM that we found for some patients is also likely to be addressed if they receive accurate information before, during, and after the implant; it is possible that some of these knowledge gaps may also lead to suboptimal adherence.

Addressing Nonadherence to Remote Monitoring

Our findings also demonstrate that patients should be informed about nonadherence. The Heart Rhythm Society gives a Class 1 recommendation for device clinics to have an established process with dedicated clinic staff to facilitate reconnection [2]. However, clinicians usually have competing priorities, such as addressing alerts [19] and the overall deluge of transmissions [20]; thus, adequate staffing is imperative [2]. Although troubleshooting RM nonadherence through patient contact can take significant amounts of time in busy clinical schedules [21,22], RM reduces the need for in-person visits [23,24] and is associated with significant cost savings [7]. Therefore, in addition to established patient benefits, these clinician efforts are worthwhile; however, given busy clinical schedules, these ideally would be supported by additional strategies to inform patients about lost connectivity or missed transmissions. Most veterans in this study reported positive experiences receiving help from CIED manufacturers over the phone, and clinicians may just need to refer patients to manufacturers for assistance. Veterans were also amenable to a variety of, primarily digital, methods to alert them about a missed transmission.

Context for Improving Remote Monitoring Adherence

Addressing these gaps in patient education and addressing nonadherence is particularly important because the number of patients implanted with CIEDs has been growing globally [25]; more than 350 per 100,000 Medicare beneficiaries received a CIED-related procedure in 2019 [26]. Continuous RM is also recommended if patients have a CIED component under safety advisory; the number of safety advisories has been increasing in recent years and RM is necessary to allow quicker detection and response [2]. Furthermore, during the COVID-19 pandemic, RM was strongly recommended by professional societies with the goal of minimizing unnecessary in-person visits [27,28]. Similarly, the VHA has placed increasing emphasis on digital care [29]. Achieving these goals for the increasing number of veterans with CIEDs will require ensuring patients are empowered with knowledge about RM through appropriate counseling and reinforcement of information, as appropriate.

Further Opportunities for Improving Remote Monitoring Care

We also found that veterans were interested in learning about their remote transmissions—both if a transmission was successfully received and varying levels of details about the transmissions. In 2019, the Heart Rhythm Society issued a Call to Action about transparent sharing of digital health data, including data from CIEDs [30], and this was reinforced by a Class IIa recommendation in the 2023 Heart Rhythm Society Expert Consensus that the results of all remote transmissions be shared with patients, based on preferences for content, mode of communication, and clinic workflows [2]. Sharing this information could also help reduce additional patient-initiated transmissions [31]. This trend follows the larger goal of providing patients with increased access to their own health care data, which has been supported by legislation and regulation and is hoped to empower patients to better manage their health care [32]. Notification if a patient with a wireless device is connected and transmitting is now available for some Bluetooth-capable CIEDs, but not all veterans have a smartphone or tablet [33]. This means that while communicating CIED data to patients is important, research must delineate the relevant parameters and provide assurance that patients can comprehend the findings; if so, this holds the potential to maximize the clinical benefits of RM [2].

Limitations

Our findings should also be considered within the context of their limitations. First, this study is limited to 40 randomly

selected veterans followed by the VA and may not generalize to other populations. However, as there are more than 60,000 veterans with CIEDs followed by VA, these findings generalize to a large population, and we had a 91% response rate among veterans who we attempted to reach. Additionally, patients outside VA may face financial burdens for participating in RM. Second, this study population was enriched for veterans with intermittent or low adherence and may not reflect the views and perspectives of more adherent veterans, although veterans who are not fully adherent are those for whom understanding barriers and facilitators is most important. Third, social desirability bias may have led participants to provide answers that are inconsistent with their true viewpoints. Future studies can directly address patient viewpoints, such as through a validated questionnaire about satisfaction with RM [34].

Conclusion

Among a population of veterans with CIEDs enriched for those intermittently or nonadherent, we found that veterans often had limited understanding of RM. Most veterans did not recall being contacted about nonadherence, but when they were contacted and troubleshooted, they found the experience to be positive. These findings demonstrate important opportunities to engage patients in RM, thereby improving both their quality of care and clinical outcomes.

Acknowledgments

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Data Availability

Data sharing is not applicable to this article, as no research data sets were generated or analyzed. The results describe qualitative patient interviews that were conducted for quality improvement purposes.

Conflicts of Interest

LR reports receiving consultancy fees from Pfizer and Biotronik. All other authors have no conflicts to declare.

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Abbreviations

CIED: cardiovascular implantable electronic device
ICD: implantable cardioverter-defibrillator
RM: remote monitoring
VA: Department of Veterans Affairs
VANCDSP: Veterans Affairs National Cardiac Device Surveillance Program
VHA: Veterans Health Administration

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Original Paper

The Association Between Mobile App Use and Change in Functional Capacity Among Cardiac Rehabilitation Participants: Cohort Study

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Abstract

Background: Cardiac rehabilitation (CR) is underused in the United States and globally, with participation disparities across gender, socioeconomic status, race, and ethnicities. The pandemic led to greater adoption of telehealth CR and mobile app use.

Objective: Our primary objective was to estimate the association between CR mobile app use and change in functional capacity from enrollment to completion in patients participating in a CR program that offered in-person, hybrid, and telehealth CR. Our secondary objectives were to study the association between mobile app use and changes in blood pressure (BP) or program completion.

Methods: We conducted a retrospective cohort study of participants enrolled in CR at an urban CR program in the United States. Participants were English speaking, at least 18 years of age, participated in the program between May 22, 2020, and May 21, 2022, and downloaded the CR mobile app. Mobile app use was quantified by number of exercise logs, vitals logs, and education material views. The primary outcome was change in functional capacity, measured by change in 6-minute walk distance (6MWD) from enrollment to completion. The secondary outcome was change in BP from enrollment to completion. We estimated associations using multivariable linear or logistic regression models adjusted for age, sex, race, ethnicity, socioeconomic status by ZIP code, insurance, and primary diagnosis for CR referral.

Results: A total of 107 participants (mean age 62.9, SD 13.02 years; 90/107, 84.1% male; and 57/105, 53.3% self-declared as White Caucasian) used the mobile app and completed the CR program. Participants had a mean 64.0 (SD 54.1) meter increase in 6MWD between enrollment and completion (P<.001). From enrollment to completion, participants with an elevated BP at baseline (≥130/80 mmHg) experienced a significant decrease in BP (systolic BP –11.5 mmHg; P=.002 and diastolic BP –7.7 mmHg; P=.003). We found no significant association between total app interactions and change in 6MWD (coefficient –0.03, 95% CI –0.1 to 0.07; P=.59) or change in BP (systolic coefficient 0.002, 95% CI –0.03 to 0.03; P=.87 and diastolic coefficient –0.005, 95% CI –0.03 to 0.02; P=.65). There was no significant association between total exercise logs and change in 6MWD (coefficient 0.1, 95% CI –0.3 to 0.4; P=.57) or total BP logs and change in BP (systolic coefficient –0.02, 95% CI –0.1 to 0.06; P=.63 and diastolic coefficient –0.02, 95% CI –0.09 to 0.04; P=.50). There was no significant association between total app interactions and completion of CR (adjusted odds ratio 1.00, 95% CI 0.99-1.01; P=.44).

Conclusions: CR mobile app use as part of an in-person, hybrid, or telehealth CR program was not associated with greater improvement in functional capacity or BP or with program completion.

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KEYWORDS

cardiac rehabilitation; mobile application; functional capacity; blood pressure; telemedicine; mHealth; telehealth assessment; e-health; youth; adolescence; EHR; electronic health record

Introduction

Cardiovascular disease remains the leading cause of death globally and in the United States for men, women, and most racial and ethnic groups [1,2]. The United States spent US $320.1 billion in cardiovascular-related costs in 2016, with an overall increase in spending driven mostly by inpatient and ambulatory care [3,4]. Cardiac rehabilitation (CR) is a multidisciplinary exercise training customized to help patients with heart disease to recover, improve, and prevent future cardiac events [5-7]. Exercise-based CR studies have shown reductions in mortality and hospital admissions as well as improvement in quality of life [5-7]. However, CR is highly underused around the globe [7-9]. Globally, uptake of eligible patients ranges from 10% to 60%, with an uptake of 24% in the United States [7,10-14]. With barriers such as transportation, cost, and participation disparities across sex, gender, socioeconomic status (SES), race, and ethnicity, new delivery strategies are needed to increase accessibility and participation in CR [7,8,13,15].

The role of digital devices has significantly increased with the increasing trend of digitalization [16-18]. As mobile phone use increases, advancement in mobile technology and its application have the potential to transform health care delivery and support vulnerable populations [18-20]. Mobile health apps can organize and present relevant information and facilitate clinician-patient communication [16,21]. Prior studies have shown the potential of mobile health apps in transforming CR, showing that it is feasible to use mobile health apps to help deliver CR. [22-24]. With the COVID-19 pandemic, programs began to implement telehealth and hybrid approaches to delivering care, including the use of mobile apps [25,26]. However, it is unclear whether the extent of engagement with mobile apps is associated with important CR outcomes, such as functional capacity or blood pressure (BP).

The primary objective of this study was to estimate the association between CR mobile app use—measured by total app interactions—and change in functional capacity—measured by change in 6-minute walk distance (6MWD)—between enrollment and completion. We hypothesized that among patients using a CR mobile app, greater mobile app use would be associated with greater change in 6MWD. Secondary objectives included studying the association between total app interactions and changes in BP, physical activity logs and change in 6MWD, frequency of BP logs and change in BP, as well as the association between total app interactions and completion of CR. The study has the potential to quantify the impact of a mobile app on clinical outcomes in CR programs.

Methods

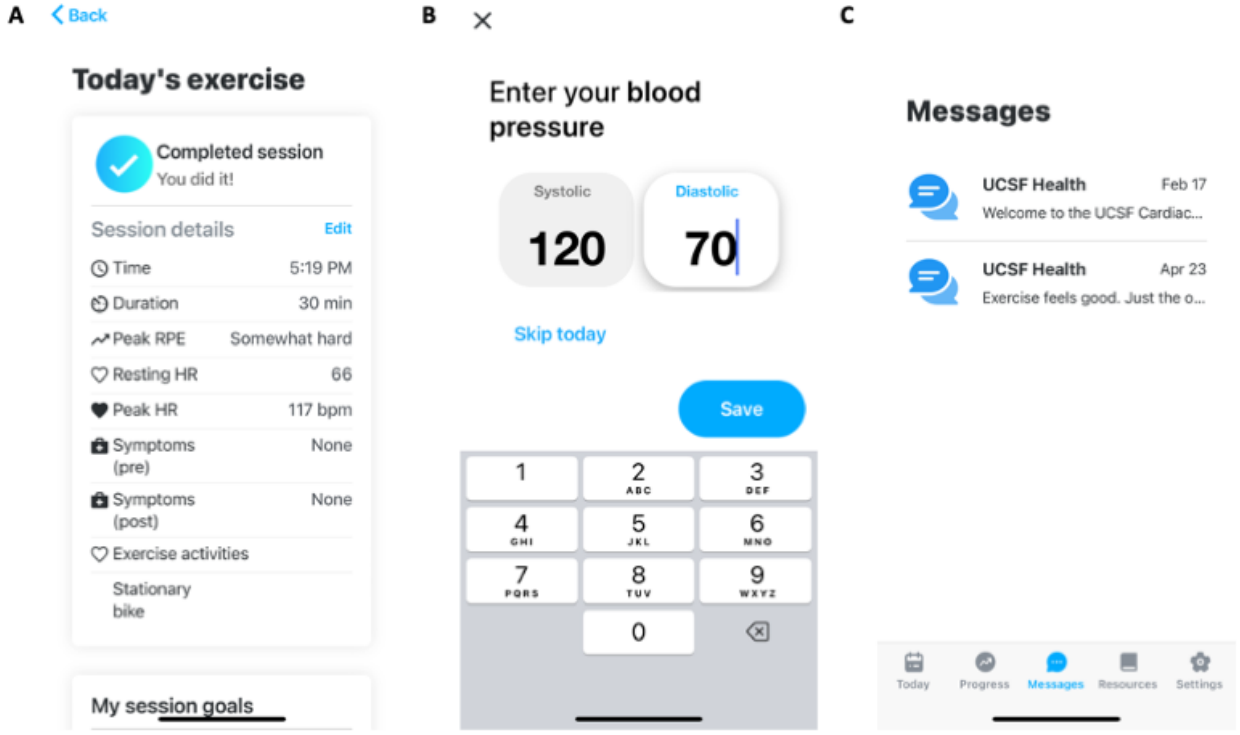
Design and Participants

We conducted a retrospective cohort study of adult participants enrolled in CR at University of California, San Francisco (UCSF) CR from May 22, 2020 (when use of the mobile app began) until May 21, 2022. For the primary study analysis, we included all participants aged ≥18 years who were enrolled in CR and downloaded the mobile app. Since the mobile app was only available in English, the study only included English-speaking participants. For the primary outcome analysis, we included only participants with 6MWD measurements at both enrollment and completion. For participants who enrolled in CR multiple times during this period (n=16), we analyzed the first episode of participation in CR.

CR Program and Mobile App

Participants enrolled in CR at UCSF can participate in in-person, telehealth, or hybrid CR [26]. Use of a mobile app (Chanl Health; Figure 1) is offered to all CR patients in all modes of participation but is optional. The mobile app allows patients to log exercise activities and vitals, view educational materials, set medication reminders, and message CR staff. CR staff include doctors, nurses, exercise physiologists, pharmacists, a nutritionist, and a mental health provider. Concomitantly, CR staff can view patient logs and activities. Eligible patients were informed of the mobile app and taught how to use the app by a CR staff member using task-based training on entering vital signs, entering an exercise session, viewing an education module, messaging with providers, and setting up medication reminders (if desired). There was no cost to the patient associated with using the app.

Figure 1. Screenshots of a mobile app used by patients in a retrospective cohort study of cardiac rehabilitation patients at University of California, San Francisco from May 22, 2020, to May 21, 2022. Features of the mobile app include (A) exercise log, (B) blood pressure log, and (C) chat with staff.



Mobile App Use

Patient app interaction was retrieved from mobile app use logs. Patient app interactions included exercise logs, vital sign logs (eg, BP, weight, blood glucose, and oxygen saturation), education material views, and chat with providers. Data were manually entered into the app by patients. Total app interaction was measured as the sum of total exercise logs, vital sign logs, and education material views. For analysis of BP measurements recorded in the app, when multiple measurements were present with the same date and time, B*P* values were averaged.

Outcomes

The primary outcome was change in functional capacity between enrollment and completion of the CR program, measured by change in 6MWD. At enrollment and completion, participants completed a 6-minute walk test on a standard course at the UCSF CR center [27]. The secondary outcome was change in BP between enrollment and completion of the CR program. At enrollment and completion, systolic and diastolic BP were measured with a standard BP cuff at the UCSF CR center. Measurements of 6MWD and BP were recorded by CR staff in CR Quality Improvement data and entered into the electronic health records, which served as the data sources for outcome measurements.

Other Measurements

Participant characteristics were obtained from structured electronic health record data, including age, sex assigned at birth, race, ethnicity, insurance, SES by zip code, and primary reason for CR referral. Sex assigned at birth was used since it was the only available data. Insurance was categorized as either private or public (eg, Medicare, Medicaid, and other city- or state-sponsored health plans). SES by zip code was established using the UCSF Health Atlas, where zip codes across California are rated between 1 (lowest quintile) to 5 (highest quintile) of socioeconomic advantage [28]. The UCSF Health Atlas uses neighborhood data system from a census tract-level data accounting for 7 factors (eg, percentage of people aged ≥25 years with college, high school, or less than high school education level; percentage of people with blue-collar jobs; percentage of people aged ≥16 years in the workforce, but without a job; and percentage of people below 200% of the federal poverty level, median household income, and median rent) [28]. The primary diagnosis associated with the CR referral was used as the primary reason for referral, categorized as coronary artery disease, valvular disease, heart failure, or other diseases. If a coded referral diagnosis was not present, reason from referral was determined from chart review of the patient's individualized treatment plan for CR.

Clinical CR measurements at enrollment and completion were obtained from CR Quality Improvement data, including BMI, waist-to-hip ratio, General Anxiety Disorder (GAD)-7, and Patient Health Questionnaire (PHQ)-9. BMI was calculated through weight and height recorded in the health electronic record, and waist-to-hip ratio were measured in person by CR staff using standardized methods. PHQ-9 was scored 0-27, with higher scores representing more severe depressive symptoms; GAD-7 was scored 0-21, with higher scores representing more severe anxiety symptoms. Laboratory test values were obtained from structured electronic health record data, including hemoglobin A_{1c}, total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides. Enrollment laboratory values were defined as the measurements prior to the participant's first day in the CR program. Completion

laboratory values were defined as a recorded measurement 3 to 6 months after enrollment.

Statistical Analysis

We included all patients within the study period who fit our inclusion criteria; therefore, sample size was not calculated a priori. Patient characteristics, app interactions, and clinical test results were summarized using descriptive statistics, mean (SD) for normally distributed characteristics, and median (IQR) for nonnormally distributed characteristics. Changes in clinical characteristics were calculated by subtracting enrollment values from completion values and compared using a paired *t* test (2-tailed). Linear regression was used to evaluate the association between change in 6MWD and total app interactions, change in 6MWD and total exercise logs, change in BP and total app interactions, and change in BP and total BP logs. We also examined, among all people enrolled in CR who downloaded the app, whether total app interactions were associated with completion of CR using logistic regression. Regression models were adjusted for confounders including age, sex assigned at birth, race, ethnicity, SES by zip code, insurance, and primary diagnosis. Significance was considered $P<.05$. With our sample size, we would have >70% power to detect a difference of 25 meters (the minimum clinically important difference) per 100 app uses [29]. All statistical analyses were performed using Stata (version 17.0; StataCorp).

Ethics Approval

This study was approved by the UCSF Institutional Review Board (21-33754), who waived the requirement of informed consent for this retrospective study. All identifiable data were stored on secure cloud servers. From identifiable raw data, deidentified data sets were created for analysis. There was no compensation to patients.

Results

Between May 22, 2020, and May 21, 2022, a total of 107 adult English-speaking patients enrolled and completed the UCSF CR program and downloaded the CR mobile app. Mean participant age was 62.9 (SD 13.02) years, with 90/107 (84.1%) participants having male sex assigned at birth, 57/105 (53.3%) self-declared as White Caucasian, 96/105 (91.4%) self-declared as non-Hispanic, 75/107 (70.1%) with private insurance, and 62/106 (58.5%) categorized as the highest quintile of SES by zip code (Table 1) . The leading primary reason for CR referral was coronary artery disease with 76/107 (71.0%) participants.

Participants had a mean 64.0 (SD 54.1; $P<.001$) meter increase in 6MWD between enrollment and completion (Table 2). Among all participants, there was not a significant change in systolic BP or diastolic BP from enrollment to completion. However, participants with an elevated BP at baseline (³130/80 mmHg) experienced a significant decrease in BP from enrollment to completion (Table 2).

Participants had a median of 92 (IQR 20-200) total app interactions, a median of 19 (IQR 1-57) exercise logs, and a median of 26 (IQR 4-67) BP logs. Of 107 participants, 17 (15.9%) had no exercise logs, 4 (3.7%) had no app interactions (only downloaded the app), and 8 (7.5%) had no BP logs. Logged BPs were stable over time among all participants but demonstrated a decrease over time among participants with initially elevated BP (n=26; Figure 2).

Evaluating the association between total app interactions and change in 6MWD with a linear regression model adjusted for age, sex, race, ethnicity, SES by zip code, insurance, and primary diagnosis revealed no significant association (Table 3). There was no association between total exercise logs and change in 6MWD. Similarly, we did not observe associations between total app interactions or total BP logs and change in BP (Table 3).

We conducted a sensitivity analysis examining the adjusted association between chat messages and change in functional capacity, finding no association (coefficient 0.48, 95% CI –0.84 to 1.80; $P=.47$). Adding chat messages to total app interactions did not meaningfully change the adjusted association between total app interactions and functional capacity (coefficient –0.04, 95% CI –0.1 to 0.06; $P=.43$). Representing total app interactions as quartiles of use also demonstrated no association between quartile of app interactions and functional capacity.

Analyzing the data of 149 patients, who were ≥18 years of age, enrolled in the CR program between May 22, 2020, and February 21, 2022 (since program completion of patients has an average of 4 months), and downloaded the mobile app, we found no significant association between total app interactions and program completion (odds ratio 1.00; 95% CI 0.99-1.00; $P=.10$), even after adjustment for age, sex, race, ethnicity, SES by zip code, insurance, and primary diagnosis (odds ratio 1.00; 95% CI 0.99-1.01; $P=.44$).

Table 1. Characteristics of patients using a mobile app in a retrospective cohort study of patients in cardiac rehabilitation at University of California, San Francisco from May 22, 2020, to May 21, 2022.

Characteristics	Values
Age in years (n=107), mean (SD)	62.9 (13.02)
Sex at birth (n=107), n (%)	
Male	90 (84.1)
Female	17 (15.9)
Race (n=105), n (%)	
African American	2 (1.9)
Asian	29 (27.6)
Pacific Islander	1 (1)
White Caucasian	57 (53.3)
Multirace	4 (3.7)
Others	12 (11.4)
Ethnicity (n=105), n (%)	
Hispanic	9 (8.6)
Non-Hispanic	96 (91.4)
Socioeconomic status by zip code (n=106), n (%)	
1 (lowest)	0 (0)
2	2 (1.9)
3	11 (10.4)
4	31 (29.3)
5 (highest)	62 (58.5)
Insurance (n=107), n (%)	
Public insurance	32 (29.9)
Private insurance	75 (70.1)
Primary diagnosis (n=107), n (%)	
Coronary artery disease	76 (71)
Heart failure	13 (12.2)
Valvular	14 (13.1)
Other	4 (3.7)
Mobile app use (n=107), median (IQR)	
Total app interactions	92 (20-200)
Total exercise logs	19 (1-57)
Total blood pressure logs	26 (4-67)

Table 2. Clinical results of patients using a mobile app in a retrospective cohort study of patients in cardiac rehabilitation at University of California, San Francisco from May 22, 2020, to May 21, 2022 (n_e represents number of participants at enrollment, and n_c represents number of participants at completion).

Characteristics	Enrollment	Completion	Change	*P* value
6-minute walk distance (meters; n=107), mean (SD)	447.1 (85.1)	510.8 (99.3)	64 (54.1)	<.001
Elevated BP[a] (³130/80 mmHg; n_e=101; n_c=67), n (%)	26 (25.7)	14 (20.9)	N/A[b]	N/A
Systolic BP (mmHg; all patients; n_e=101; n_c=67), n (%)	119.5 (11.7)	117.2 (12)	–2.7 (11.9)	.07
Diastolic BP (mmHg; all patients; n_e=101; n_c=67), n (%)	73.9 (7.6)	71.6 (9.4)	–2 (8.3)	.06
Systolic BP (<130/80 mmHg at enrollment; n_e=75; n_c=50), n (%)	115.1 (8.3)	116.4 (12.6)	0.2 (10.2)	.92
Diastolic BP (<130/80 mmHg at enrollment; n_e=75; n_c=50), n (%)	70.9 (5.8)	70.8 (9.3)	–0.1 (7.1)	.90
Systolic BP (≥130/80 mmHg at enrollment; n_e=26; n_c=17), n (%)	132.4 (10.6)	121.1 (10.7)	–11.5 (12.4)	.002
Diastolic BP (≥130/80 mmHg at enrollment; n_e=26; n_c=17), n (%)	82.5 (80.1 to 86.7)	74.8 (65.5 to 81.1)	–7.7 (–14 to –0.4)	.003
BMI (kg/m^2; n=107), n (%)	26.7 (4.4)	26.9 (4.5)	0.3 (1.4)	.03
Waist-to-hip ratio (n=107), n (%)	0.9 (0.07)	0.9 (0.08)	0 (0)	<.001
GAD-7[c] (n=107), median (IQR)	1 (0 to 5)	1 (0 to 3)	–1.2 (–3 to 0)	<.001
PHQ-9[d] (n=107), median (IQR)	3 (1 to 6)	1 (0 to 3)	–1.9 (–3 to 0)	<.001
Hemoglobin A_{1c} (%; n_e=60; n_c=33), median (IQR)	5.6 (5.3 to 5.9)	5.6 (5.4 to 6.1)	–0.1 (–0.2 to 0.3)	.70
Total Cholesterol (mg/dL; n_e=68; n_c=46), n (%)	154.7 (47.8)	134.2 (45.1)	–22.5 (51.3)	.01
LDL[e] (mg/dL; n_e=67; n_c=44), n (%)	89.2 (41)	74.4 (35.7)	–21.7 (43.8)	.006
HDL[f] (mg/dL; n_e=68; n_c=45), n (%)	43.7 (13.7)	45.4 (16.4)	3.9 (16.6)	.16
Total triglyceride (mg/dL; n_e=72; n_c=45), n (%)	107.9 (52.2)	94.4 (42.9)	–10.2 (53.3)	.25

[a]BP: blood pressure.

[b]N/A: not applicable.

[c]GAD-7: General Anxiety Disorder-7.

[d]PHQ-9: Patient Health Questionnaire-9.

[e]LDL: low-density lipoprotein.

[f]HDL: high-density lipoprotein.

Figure 2. Average blood pressure over time of patients using a mobile app in a retrospective cohort study of patients in cardiac rehabilitation at University of California, San Francisco from May 22, 2020, to May 21, 2022. (A) Average blood pressure of all patients at enrollment (n=101). (B) Average blood pressure of patients with elevated blood pressure (≥130/80 mmHg) at enrollment (n=26). (C) Average blood pressure of patients with normal blood pressure (<130/80 mmHg) at enrollment (n=75).

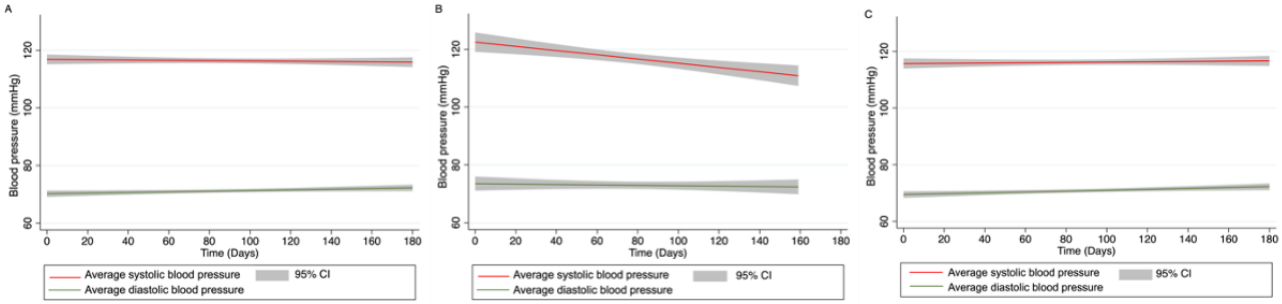


Table 3. Associations between clinical outcomes and mobile app use in patients using a mobile app in a retrospective cohort study of patients in cardiac rehabilitation at University of California, San Francisco from May 22, 2020, to May 21, 2022 (models were adjusted for age, sex assigned at birth, race, ethnicity, socioeconomic status by zip code, insurance, and primary diagnosis).

Clinical outcome	Coefficient (95% CI)	*P* value
Change in 6-minute walk distance		
Total app interactions	–0.03 (–0.1 to 0.07)	.59
Total exercise logs	0.1 (–0.3 to 0.4)	.57
Change in systolic blood pressure		
Total app interactions	0.002 (–0.03 to 0.03)	.87
Total blood pressure logs	–0.02 (–0.1 to 0.06)	.63
Change in diastolic blood pressure		
Total app interactions	–0.005 (–0.03 to 0.02)	.65
Total blood pressure logs	–0.02 (–0.09 to 0.04)	.50

Discussion

Principal Results

In this study of 107 patients participating in CR with the use of a mobile app, we found no association between the amount of app use and improvement in clinical outcomes, including 6MWD and BP. We also did not observe an association between app use and completion of CR.

Comparison With Prior Work

Previous research has shown that CR programs using mobile apps can achieve similar or improved outcomes compared to traditional CR programs [26]. However, there has been a lack of published research on associations between patient interaction with CR mobile apps and clinical outcomes. In their study, Widmer et al [30] found that digital health interventions in which patients interact with the app through reporting dietary and exercise habits showed a nonsignificant reduction in cardiovascular-related rehospitalizations [30]. In a randomized study, Rosario et al [31] found no statistically significant difference in 6MWD, waist measurement, RPE, and resting heart rate comparing hospital-based CR patients with and without a smart phone app, portable BP monitor, and weight scale [31]. In our nonrandomized study, we found no association between total app interactions and change in functional capacity (change in 6MWD) or change in BP.

In a systematic review of 6 randomized control trials of CR mobile apps, Tuttle et al [32] found inconsistent clinical results. Analysis suggested improved outcomes with apps that incorporated automated data collection, such as automatic step counters, automatic information logs, correctional goal setting, and real-time feedback [32]. Meanwhile, apps without automatic data collection and feedback were not successful [32]. The app used by patients in this study required manual data entry and did not provide automated feedback; moreover, its use was not associated with improved outcomes, which is consistent with the systematic review findings.

Nonetheless, with the larger use of smartphones comes an inherent shift of mobile app incorporation into clinical care. In addition, there is a high interest of mobile app use for health care delivery among patients and clinicians [9,33]. With this interest, technologies such as mobile apps can provide flexibility, scalability of care, accessibility of information, and communication among teams and patients [16,20-23]. As we have learned during the COVID-19 pandemic, mobile apps provided a mechanism to facilitate CR care and information exchange between patients and providers in a hybrid and remote setting, with no significant difference in clinical outcomes from in-person CR programs [26]. Patient experience is considered an important predictor for health care quality affecting clinical outcomes, medical adherence, and hospital retention [34-37]. Similarly, provider experience, although less studied, has been shown to affect patient outcomes and successful integration of programs [36,38]. However, little research is done on the role of mobile apps in improving patient and provider experiences [39,40]. This study did not capture measures of patient and provider satisfaction with mobile app use. Future studies should examine the impact of mobile app use on patient and provider experience.

Limitations

Certain limitations must be considered. Generalizability may be limited since the cohort was enrolled and completed the program during the COVID-19 pandemic. Other factors that may affect generalizability include underrepresentation across sex assigned at birth, race, ethnicity, and SES since the cohort was mostly male, White Caucasian, non-Hispanic, living in neighborhoods associated with high SES, and with private insurance. SES by zip code incompletely captures individual-level SES factors.

This study only examined mobile app use among people who chose to download a mobile app and cannot account for differences between this population and people who did not choose to download the mobile app. Moreover, the patient population was only from a single center with a limited sample size. Additionally, in this observational study, using data collected during the routine course of health care, we could not account for all potential unmeasured confounders.

Conclusions

In a population of patients participating in CR and using a mobile app, this study found no associations between total app

interactions and changes in functional capacity, total exercise logs and changes in functional capacity, total app interactions and program completion, total app interactions and changes in BP, and total BP logs and changes in BP. Mobile app use was not associated with completion of the program. Given the lack of association between mobile app use and clinical outcomes, we encourage further study of the impact of mobile app use on patient and provider experience. Importantly, this research should be conducted in a diverse population to address existing disparities.

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Data Availability

Since data derive from identifiable data and there is a risk of reidentification, access to data sets is limited. A deidentified data set may be available upon request and execution of a data use agreement.

Conflicts of Interest

ALB was formerly employed by (2018-2019) and held stock in (2019-2021) Apple Inc and was formerly on the board of the American Association of Cardiovascular and Pulmonary Rehabilitation (2020-2021). ALB has received research support from the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Mental Health (NIMH), unrelated to this manuscript topic.

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Abbreviations

6WMD: 6-minute walk distance
BP: blood pressure
CR: cardiac rehabilitation
GAD-7: General Anxiety Disorder
PHQ-9: Patient Health Questionnaire (PHQ)-9
SES: socioeconomic status
UCSF: University of California, San Francisco

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Original Paper

Cardiac Rehabilitation Facebook Intervention: Feasibility Randomized Controlled Trial

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Abstract

Background: The adherence to cardiac rehabilitation is low. Social media has been used to improve motivation and cardiac rehabilitation completion, but the authors did not find Facebook interventions for these purposes in the literature.

Objective: The purpose of this study was to determine the feasibility of the Cardiac Rehabilitation Facebook Intervention (Chat) for affecting changes in exercise motivation and need satisfaction and adherence to cardiac rehabilitation.

Methods: The Behavioral Regulation in Exercise Questionnaire-3 and Psychological Need Satisfaction for Exercise were used to measure motivation and need satisfaction (competence, autonomy, and relatedness) before and after the Chat intervention. To support need satisfaction, the intervention included educational posts, supportive posts, and interaction with peers. The feasibility measures included recruitment, engagement, and acceptability. Groups were compared using analysis of variance and Kruskal-Wallis tests. Paired *t* tests were used to assess motivation and need satisfaction change, and Pearson or Spearman correlations were used for continuous variables.

Results: A total of 32 participants were lost to follow-up and 22 were included in the analysis. Higher motivation at intake (relative autonomy index 0.53, 95% CI 0.14-0.78; *P*=.01) and change in need satisfaction-autonomy (relative autonomy index 0.61, 95% CI 0.09-0.87; *P*=.02) were associated with more completed sessions. No between-group differences were found. Engagement included “likes” (n=210) and “hits” (n=157). For acceptability, mean scores on a 1 (not at all) to 5 (quite a bit) Likert scale for feeling supported and in touch with providers were 4.6 and 4.4, respectively.

Conclusions: Acceptability of the Chat group was high; however, intervention feasibility could not be determined due to the small sample size. Those with greater motivation at intake completed more sessions, indicating its importance in cardiac rehabilitation completion. Despite challenges with recruitment and engagement, important lessons were learned.

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International Registered Report Identifier (IRRID): RR2-10.2196/resprot.7554

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KEYWORDS

cardiac rehabilitation; motivation; exercise; social media; cardiology; adherence; physical activity; satisfaction; rehabilitation; Facebook; peer support

Introduction

Background

Cardiac rehabilitation (CR) is an evidence-based clinical standard due to reported benefits for functional capacity, psychosocial health, and mortality [1]. Cardiac rehabilitation referral is a class IA recommendation by the American Heart Association and American College of Cardiology for patients with recent myocardial infarction [2], coronary artery bypass graft surgery [3], and percutaneous coronary intervention [4]. The Centers for Medicare and Medicaid Services have also approved CR for patients who had heart valve repair or replacement or those who had heart or heart and lung transplant [5]. Additionally, patients with heart failure can benefit from outpatient exercise-based CR (phase II), which has been shown to improve oxygen uptake, muscle health, and left ventricular ejection fraction in this population [1]. Despite these and other benefits, uptake, adherence, and completion of 12-week phase II CR programs remain poor.

Cardiac Rehabilitation Adherence

Cardiac rehabilitation referral rates vary by location; however, many hospitals automatically refer all patients with a qualifying diagnosis [6]. Nevertheless, researchers continue to report numerous barriers to CR uptake and adherence, and only 34% of those who are referred actually attend CR [7]. For many, barriers are access related and include cost and lack of transportation [8,9]. Patients may also experience disparate access related to gender, race, ethnicity, and poor physical health [9]. Unfortunately, solutions addressing barriers have not always been effective; however, low-cost approaches have been recommended [9]. Supervia et al [10] reported that relationships with CR staff and other patients were important to those who completed the program. Other researchers described that, for women, motivation to complete the program included a friendly attitude and reinforcement by the CR staff [11]. These patients completed the program despite encountering multiple barriers [11], suggesting that support from the staff may have been an important factor in their program completion.

Technology-Driven Solutions

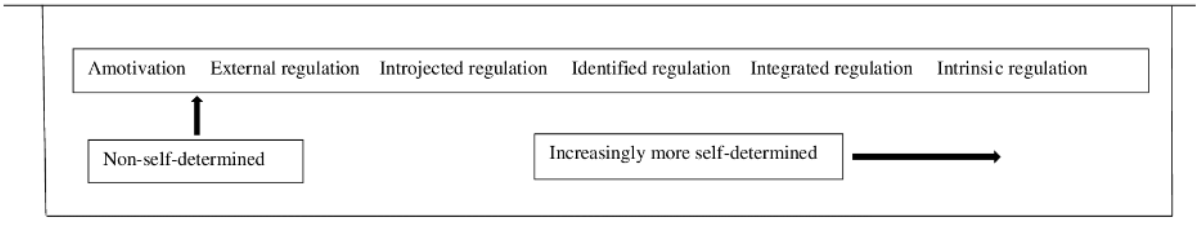
For patients who begin CR, technology-driven solutions may be helpful for providing additional support and reinforcement to ensure completion [12]. For example, patients attended more sessions when they used a mobile technology app that tracked their metrics, provided educational materials, and enabled communication with the CR team compared to patients in usual care CR [13]. Researchers also showed that patients from low-income households found social media platforms acceptable for targeting lifestyle changes [14]. In China, a WeChat social media intervention combined with a 12-week center-based CR program was successful at improving adherence and completion, with the intervention group attending at least 75% of sessions [15]. Additionally, perceived health scores and 6-minute walk test improved [15]. Motivational factors may play a role in technology-supported CR. In a comparison between telerehabilitation (home-based) and traditional center-based CR, perceived competence increased in both groups, and the telerehabilitation group had an initial increase in motivation; however, there was no difference in motivation over the long term, demonstrating that a more intense intervention might be needed for motivation to be internalized [16].

No Facebook interventions for cardiac rehabilitation adherence were found in the literature. Nevertheless, patients with greater Facebook capability were receptive to the idea of using the platform for a closed CR group and peer support [17]. Other researchers posited that applications such as Facebook may be valuable CR tools to enhance social connectedness [18]. Since Facebook is free and widely used (70% of American adults report regular and often daily use) [19], it may be a promising supplement to CR for the purposes of information sharing and support, with the potential to improve motivation for exercise and CR adherence.

Theoretical Framework

The Cardiac Rehabilitation Facebook Intervention (Chat) was grounded in self-determination theory (Figure 1). Self-determination theory was successfully used in prior CR research that used pedometers to support self-determined motivation [20]. Further, researchers investigated self-determination theory in a content analysis on Facebook in older adults [21]. According to the theory, motivation is on a continuum, ranging from amotivation (no intention to do the activity) to intrinsic motivation (may do the activity just for the joy of doing it) [22]. According to Ryan and Deci [22], to achieve self-determined motivation (internalized), 3 psychological needs must be met: competence, autonomy, and relatedness [21]. Competence can be supported through structure, positive feedback, and realistic goals [23,24]. Autonomy can be supported by assisting with decision-making for personal reasons and providing minimal pressure to help with making choices [23-25]. Relatedness can be supported by helping a person feel socially included [22,24,26].

Figure 1. Self-determination theory and motivation continuum.



Purpose

The primary purpose of this study was to determine the feasibility of the Chat Facebook intervention, providing education, peer support, and provider support, for affecting change in motivation and self-determination for exercise, and adherence to CR in patients with heart disease during a 12-week phase II CR program compared to a control group who received educational handouts and emails. Feasibility was predicated on the effectiveness of the recruitment strategy, the success of the intervention, participant engagement (number of visits to the group, "hits," and "likes"), and acceptability of intervention (comments). We hypothesized that Chat would improve motivation for exercise, and participants in the Chat intervention would complete a higher percentage of CR sessions compared to the control. Additionally, we hypothesized that engagement in Chat would predict a higher percentage of CR sessions and would provide evidence of feasibility. Feasibility was also determined by recruitment or sample size and retention.

Methods

Design

This was a randomized controlled pilot trial to evaluate the feasibility of using Chat to affect change in motivation for exercise and adherence to cardiac rehabilitation.

Ethics Approval

This feasibility study was approved as minimal risk research by the hospital's institutional review board (IRB) (16-1456) and was registered with ClinicalTrials.gov (NCT02971813). Written informed consent was obtained, and each participant was adequately informed about the research. All participants included in the study voluntarily agreed to participate. The consent document included details on randomization to groups, surveys, and participation in the Chat group or the control. Possible risks included in the consent were loss of personal information, computer viruses, and malicious software, as well as steps the researchers would take to minimize these risks. All postings, data collection, storage, and analyses were conducted using a password-protected hospital computer in the locked office of the principal investigator. Participants were also informed that they could withdraw from the study at any time. No compensation was provided, and participants incurred no cost for participating in the study.

Sample and Setting

A sample size of 30 per group was chosen in order to facilitate a large intervention group since the value of the intervention depended on the interaction among the participants. The researchers conducted an a priori power analysis and determined that an estimated sample size of 60 total participants for randomization would provide 86% power to detect large effect sizes (Cohen d=0.8) for the outcomes of interest. We determined that feasibility would be unlikely if a sample of 30 per group could not be obtained in the first year. Participants qualified for participation if they planned to attend the outpatient CR (center-based program) at the main campus and 3 regional hospitals of a large hospital system in Ohio. This 36-session phase II CR program was exercise based and included electrocardiogram-monitored and supervised exercise, and education on diet, stress reduction, and behavioral counseling.

Participants also qualified for the study if they were regular Facebook users (defined as logging in at least twice per month), had a cardiac diagnosis, and had been referred to the cardiac rehabilitation program at the hospital's main campus or 3 of the regional campuses. Regular use was defined as logging into the Chat group at least 2 times in the last month. Other inclusion criteria included adults who were age 18 years or older, were able to read and speak English, and lived within 100 miles of the cardiac rehabilitation center at the hospital's main campus. No other exclusions applied.

Recruitment and Randomization

Recruitment took place during patients' inpatient stay, intake visit for cardiac rehabilitation, or via phone call within a week after hospital discharge. In order to ensure there were participants with whom to interact in the Chat group, the first 8 volunteers were allocated to Chat, and no data were collected for these participants. After the first 8, participants were randomized to the Chat versus the control groups using blocked randomization, an appointment was scheduled to discuss the study and obtain consent. For convenience, this appointment often occurred just prior to their first CR session, in a private space near the exercise room, and was always at a date and time prior to beginning the CR program. Written informed consent was obtained from each participant. Participants were randomized at the time of consent. As described in the published protocol, randomization was to take place after consent and completion of preintervention questionnaires [27]. However, the extra time required to fill the questionnaires interfered with the start of their first CR visit, so this was changed with the IRB amendment so that participants were randomized and then given the questionnaires via email. A link was emailed to the participants and included the baseline Behavioral Regulation in Exercise Questionnaire-3 (BREQ-3) [28], Psychological Need Satisfaction for Exercise (PNSE) scale [25], and instructions for joining the private Chat group if applicable. The control group was given the same baseline questionnaires and was informed they would be receiving weekly emails. They were also given the opportunity to join the Facebook group after CR completion.

Study Procedures

Overview

Study procedures were described previously in the published protocol [27]. The principal investigator independently completed all recruitment, consent, administration of questionnaires, and intervention implementation. The CR team regularly handed out study flyers to inpatients who were in phase I CR.

Intervention Group

Chat was designed to promote increasingly higher self-determined motivation. The intervention, which was participation in the Chat group, included educational posts (to support competence), supportive provider posts (to support autonomy), and opportunities to interact with peers (to support

relatedness). Supporting competence, which refers to self-efficacy in learning new information, requires the provision of structure in the information provided, offering participants positive feedback, and helping them to set realistic goals [23-25]. Educational posts were created to support competence and covered 12 topics, offering a variety of suggestions and encouragement for making personal health care choices. Provider posts included topics such as motivational quotes, contained reminders to exercise independently, and provided support for individual decision-making with minimal pressure [23-25]. Peer interaction in the Chat group served to support relatedness and took place as frequently as the participants freely chose to do so. Situations that are conducive to social interaction with peers can help facilitate intrinsic motivation [22]. The educational and provider posts were standardized such that they contained a consistent message for each topic. Content was then posted on the Chat group, 1 each week, then reposted again every 12 weeks to account for rolling enrollment. Per IRB request, all postings were IRB approved prior to being posted on the Chat group.

Control Group

The control group received the same educational and provider support materials as the intervention group but in the form of an email. Like the Chat group, the control group participated in the same 12-week phase II CR and received the usual care and education through the CR program.

Measures and Outcomes

Overview

The outcomes for this study were (1) change in motivation for exercise, (2) change in self-determination for exercise (competence, autonomy, and relatedness), (3) adherence to the 12-week CR program, and (4) measures of feasibility (recruitment strategy, success of the intervention, engagement, and acceptability).

Engagement

Engagement, defined as participation in the Chat group, was determined by the number of "likes" and "hits" in the group. "Likes" (the number of times a participant clicked "like" on any of the Facebook posts) were counted. The number of "hits" was self-report using a postintervention questionnaire.

Acceptability

Acceptability of the intervention was determined from a post questionnaire, which had a section for additional comments. The post questionnaire also included questions about feeling supported, changing behaviors, and feeling healthier as a result of participation in the Chat group. Responses were on a 5-point Likert scale (1: "not at all" to 5: "quite a bit").

Participant Characteristics

Participant characteristics were collected from the electronic medical record and included age, sex, race, and diagnosis. In addition, intake functional capacity was collected. Functional capacity was measured in metabolic equivalents and obtained from the intake stress test prior to CR.

Motivation

Change in motivation for exercise was measured using the BREQ-3, a 24-question instrument based on self-determination theory that measures intrinsic and extrinsic regulation of exercise behavior [28]. Cronbach α reliabilities for the BREQ-3 subscales (regulations) were: amotivation (.83), external regulation (.79), introjected regulation (.80), identified regulation (.73), and intrinsic regulation (.86). Each question in the BREQ-3 can then be weighted (ranging from −3 to +3) and summed, giving a single score of self-determination for exercise known as a relative autonomy index (RAI). The RAI is useful for determining an individual's motivational subtype (behavioral regulation) from amotivated (lacking intention to exercise) to intrinsically motivated (self-determined or autonomously motivated).

Psychological Need Satisfaction

Perception of psychological need satisfaction was measured with the PNSE to determine the extent to which participating in exercise promoted feelings of competence, autonomy, and relatedness, which are the 3 subscales of the PNSE [25]. The PNSE consists of 18 items on a 6-point Likert scale from 1 (false) to 6 (true). Higher scores for each latent factor indicate higher competence (eg, I feel confident in my ability to perform exercises that personally challenge me), autonomy (eg, I feel like I am the one who decides what exercises I do), or relatedness (eg, I feel connected to the people who I interact with while we exercise together). Cronbach α was >.90 [25]. Normative data, collected from a sample of Canadian university exercise class participants, are also available [29]. Adherence to the CR program was reported as a percentage of cardiac rehabilitation sessions attended and was measured by dividing the number of sessions attended in a 12-week period by the total number of sessions allowed by insurance and multiplying by 100.

Analysis

Categorical variables were described using frequencies and percentages, and analyses comparing the control and the Chat groups used Pearson chi-square or Fisher exact tests. Normally distributed continuous variables were described using means and SDs, and analyses comparing control and Chat groups used analysis of variance models. Nonnormally distributed continuous variables were described using medians and quartiles, and analyses comparing the control and the Chat groups used Kruskal-Wallis tests. Paired *t*-tests were used to assess RAI and PNSE change within groups. The relationship between RAI change and continuous variables was assessed using Pearson or Spearman correlations (for the number of sessions, which was not normally distributed) with 95% CI. For categorical measures, means and SDs with *P* values from analysis of variance models. The relationships between the number of sessions with continuous variables were assessed using Spearman correlations with 95% CI, while medians and quartiles are presented for categorical factors. Internal consistency was determined with Cronbach α. Analyses were performed using SAS software (version 9.4; SAS Institute, Inc). A significance level of .05 was assumed for all tests.

Results

Recruitment and Participants

After removing those who were participating in CR for noncardiovascular disease–related reasons, 210 potential participants were screened for eligibility. Of 54 (26%) who agreed to take part in the study, 28 were randomized to intervention and 26 to the control group. See Table 1 and Figure 2 for additional recruitment and participant characteristics. There were no differences between groups on personal characteristics at baseline. Of the final analyzed sample, diagnoses included aortic aneurysm repair (n=2), myocardial infarction (MI) (n=7), coronary artery bypass graft without MI (n=1), percutaneous coronary intervention without MI (n=1), Takotsubo's cardiomyopathy (n=1), valve repair or replacement (n=3), heart transplant (n=2), and other (n=5). Of additional participant medical conditions, 64% had hypertension, 14% had diabetes, 14% had hypertriglyceridemia (>150 mg/dL), 32% had elevated low-density lipoprotein (≥100 mg/dL), and 45% had low high-density lipoprotein (<60 mg/dL). The mean functional capacity for participants at intake to CR was 5.9 (SD 2.4) METS. Data for exit metabolic equivalents were not analyzed as they were only available for 3 participants. Of the 14 remaining in the intervention group, 6 (43%) completed the exit questionnaires compared to 7 (87%) in the control group.

Table 1. The relationship between group and demographic variables.

Factor	Overall (N=22)	Control (n=8)	Facebook (n=14)	*P* value
Age (years), mean (SD)	57.8 (11.0)	60.6 (7.2)	56.2 (12.6)	.38[a]
Sex, n (%)				.19[b]
Male	9 (41)	5 (62)	4 (29)	
Female	13 (59)	3 (37)	10 (71)	
Race, n (%)[c]				.99[b]
Black	6 (28.6)	2 (25)	4 (31)	
White	15 (71)	6 (75)	9 (69)	
RAI[d] intake, mean (SD)	39.4 (23.5)	32.9 (14.9)	43.1 (27.0)	.34[a]
Intake METS[e,f]	5.9 (2.4)	6.5 (2.2)	5.6 (2.6)	.52[a]
Diagnosis categories, n (%)				.08[g]
CAD[h]	14 (64)	7 (87)	7 (50)	
Other	8 (36)	1 (12)	7 (50)	
CR[i] sessions out of 36, median (IQR)	26.0 (4.0-36.0)	22.0 (3.5-27.0)	32.5 (10.0-36.0)	.21[j]

[a]Analysis of variance.

[b]Fisher exact test.

[c]Race was reported for 8 participants in the control and 13 in the Facebook group, for a total of 21.

[d]RAI: relative autonomy index.

[e]METS: metabolic equivalents.

[f]Intake METS was reported for 6 participants in the control and 10 in the Facebook group, for a total of 16.

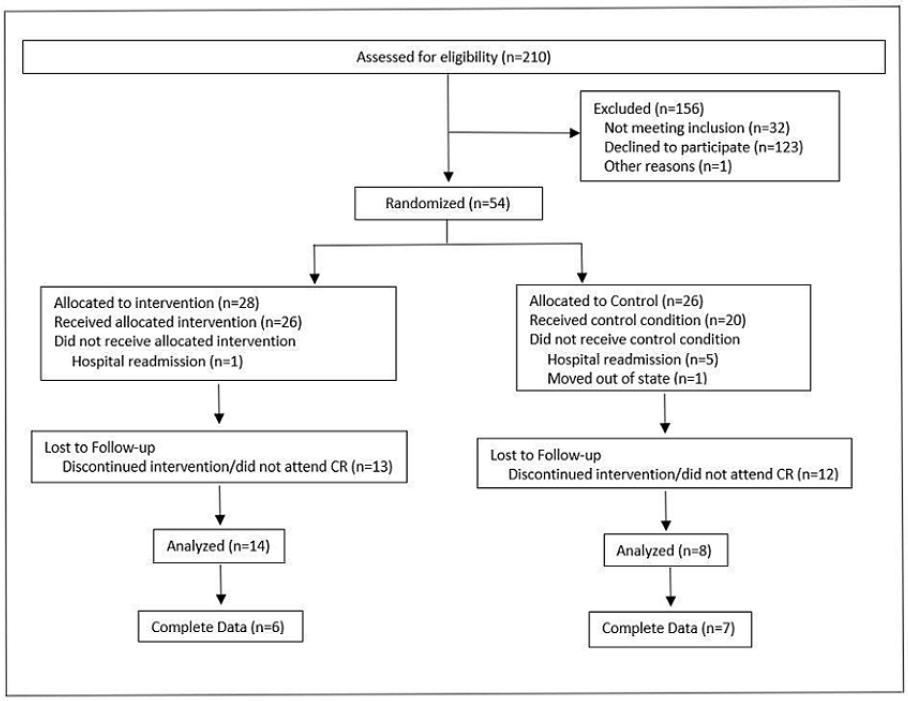
[g]Pearson chi-square test.

[h]CAD: coronary artery disease.

[i]CR: cardiac rehabilitation.

[j]Kruskal-Wallis test.

Figure 2. Consort diagram for recruitment. CR: cardiac rehabilitation.



Intervention

Across both groups, higher motivation (RAI) at intake was associated (95% CI) with the greater number of completed sessions (RAI 0.53, 95% CI 0.14-0.78; *P*=.01). Change in PNSE need satisfaction-autonomy from pre-to-post intervention was also associated with a higher number of completed sessions (RAI 0.61, 95% CI 0.09-0.87; *P*=.02). No between-group differences were found for change in motivation, need satisfaction, or sessions completed. There was no relationship between demographic variables and change in motivation, need satisfaction, or sessions completed.

Engagement

There were 210 “likes” and 157 “hits” in the Chat group. Comments in the Chat group (n=21) were positive (86%) and the other 14% of comments were neutral. Exit questionnaires for the Chat group indicated that 4 participants logged into the group (hits) a total of only 1-5 times, one logged in 6-10 times, and 1 participant never logged in to the group.

Acceptability

Comments on the post questionnaire included “Very interesting, informative and educational” and “I loved the videos.” Some commented specifically on the cardiac rehabilitation sessions. These statements included: “I thoroughly enjoyed being with my group in cardiac rehab!” “We cared about each other and laughed together, as we worked hard at completing our exercise programs,” “I love going,” and “The staff was wonderful!” For those who dropped out of CR, statements included: “I prefer to do it on my own,” “I just don’t have the time,” and “I’m overwhelmed with my health and all of my appointments.”

The mean response for feeling supported by the Chat group and feeling more in touch with their CR health care team was 4.6 (SD 0.89) and 4.4 (SD 0.89), respectively, both with a range of 3-5 on a 5-point Likert scale. When asked how often they talked with other Chat members in the web-based group, responses ranged from “not at all” to “rarely” except for one participant who stated “frequently” (mean 2.2, SD 1.64). Mean response to whether they made changes to their exercise or diet after being in the Chat group was 3.4 (SD 1.5) for both, with a range from 1 to 4. The mean for perceptions of overall health as a result of being in the Chat group was 4 (SD 1.4) with a range of 2-5.

Discussion

Principal Findings

Despite that recruitment was challenging and we did not meet recruitment goals, there were many positive lessons to be learned from this feasibility study. First, while the sample was small, the Chat intervention was acceptable to the participants based on postintervention feedback. Additionally, there were associations between motivation at intake and greater number of CR sessions, and improvement in perceived competence and a greater number of CR sessions for both groups. No between-group differences were found possibly due to the limited statistical power related to the small sample size. Although no change scores for functional capacity were available due to the lack of exit exercise tests, participants were very poorly conditioned at intake with a mean of 5.9 (SD 2.4) METS, which is very poor for this age group [30]. All of these findings provide helpful information for future research using social media to improve motivation for exercise and CR adherence.

There was a unique opportunity to learn from 2 participants, who were identical twins. During their time in CR, they lived together and provided each other with additional support. They had identical diagnoses, the same surgery at the same time, the same fasting blood sugar, and at intake to CR, functional

capacity (metabolic equivalents) was identical. They also scored exactly the same on the pre-RAI, and both had similar positive statements postintervention. However, their homes were far apart. One twin lived out of state, and at the end of her CR sessions, had to return to her out-of-state home. Interestingly, her RAI scores from pre to post went down, while her sister's scores went up. It may be that the time they had together supported motivation for the out-of-state twin, and since she was not intrinsically motivated at intake and had to stop her sessions 2 weeks before completion, the loss of support accounted for her drop in autonomy scores. A similar phenomenon was cited in the literature, in which researchers posited that a longer intervention time may have been needed to improve motivation for CR participants [16].

Recruitment

A slowing rate in recruitment coincided with social media privacy issues in national news. For this reason, we chose to continue the study in hopes that recruitment would improve over time. However, 9 months after the start of the study, the research team determined that recruitment was going to be an ongoing issue. It is possible that there was a lack of trust in Facebook or other concerns about privacy that affected the choice to participate or not. It is also possible that potential participants were hesitant to participate due to concerns that they might be randomized to the control group. Only 26% of those who were approached agreed to participate, and of those who were randomized to control, some expressed disappointment, even though they were informed they could join the Facebook group after completing CR. Additionally, 5 in the control group were lost to medical issues at the start, and we were unable to determine if they were later eligible to participate in CR or the study.

Consistent with low CR retention rates nationwide, retention in the Chat intervention was poor. One participant in this study stated that they dropped out of CR and Chat due to feeling overwhelmed with all of their health problems. Others stated that they preferred to exercise on their own or that time was a barrier to CR attendance. Two patients with recent heart transplants encountered medical complications, resulting in CR and study dropout. Previous work revealed that heart failure was associated with a greater likelihood of CR dropout [16], providing further evidence that the sickest patients may have difficulty adhering to the program. It is possible that, given time and support, some of the aforementioned participants would have continued with CR as well as the Chat intervention. Recent reports showed that patients in CR require reassurance, validation, and interaction with staff and other patients in order to complete the program [11]. Therefore, adjustments to the Chat intervention may be needed if it is to provide the required interaction to support CR adherence.

Additionally, motivational support provided via social media platforms could be helpful in post phase II CR programs when patients may be more receptive to additional help and support. Thus, provision of Chat or similar groups should be piloted in phase III and IV programs in which patients are in higher intensity exercise programs and long-term management of heart disease.

Intervention

Although there were no between-group differences in change in motivation for exercise nor need satisfaction as a result of the Chat intervention, among those in both groups, results showed that those who had an increase in perceived competence were more likely to complete more sessions. Furthermore, those with higher motivation at intake completed more sessions. These findings demonstrate the important role of motivation and competence in CR completion. Nonetheless, we encountered unique issues with the Chat intervention. The IRB determined they had to approve all posts prior to posting. This limited the variety of posts and resulted in a number of IRB amendments. Furthermore, the requirement for IRB prescreening of posts made it difficult for researchers to interact with the participants since any reply that the researchers posted had to be cleared by the IRB first, ultimately limiting communication. These same obstacles prevented the CR staff from posting in the Chat group. In previous research, effective 2-way communication between the patient and CR staff was a vital component of the electronic intervention, which demonstrated improved adherence [13]. Recently, participants in a social media group (WeChat) completed more CR sessions (>75%) compared to the control, and participants were able to regularly communicate with providers through the group's chat function [15]. Unlike this study in which 2-way communication was limited, the WeChat group was highly interactive [15].

Other researchers suggested that a technology-based intervention was an external motivator [16]. We do not know if this was the case with Chat; only that the intervention was not successful in changing motivation for exercise. A larger study in which participants and researchers can freely communicate may show different results.

Engagement

The number of "likes" and comments in the group was low. Participants logged into the Chat group rarely and few chatted with other group members. Engagement was likely affected by the limitations of the interventions previously mentioned. Since platforms such as Facebook can provide abundant social connectedness and provider support [18], it is imperative that researchers find ways to engage those who can benefit the most from groups like Chat.

Acceptability

Overall, the acceptability of the intervention was positive for those who participated. Although there were few comments on the Facebook group, none of them were negative in nature. Acceptability of social media interventions may be higher if individualized for the participant. In a recent systematic review, researchers concluded that a one-size-fits-all approach to social media or other e-based lifestyle interventions is not optimal [14]. Unfortunately, we were not able to individualize the Chat intervention due to IRB restrictions. The post questionnaire revealed that scores were high for "feeling supported" and "feeling in touch with providers"; nevertheless, it is likely that additional support was needed for those who dropped out of CR and the Chat intervention.

Summary and Future Research

This study provides a number of lessons learned that can be incorporated into the design of future social media research and programming. It is possible the reasons given for poor CR uptake, adherence, and completion are the same reasons for low recruitment, engagement, and postintervention follow-up in the Chat intervention. Similar to this study, lack of time and feeling overwhelmed with health problems were previously reported [10], which reinforces the need for additional support for CR attendees. With the proper support, patients are more likely to attend and complete phase II CR despite obstacles [11]. However, the support provided in Chat may have been more effective with an alternative social media platform and methodology to improve the interaction between participants and providers.

Recruitment

Recruitment was suboptimal in this study and might be improved in future research. First, recruiting participants from Facebook, rather than from a limited cohort within a single hospital system, might offer the benefit of sampling from a large number of volunteers. While recruiting from Facebook is more likely to bias the sample toward those who have strong feelings or motivation, it allows for a larger and more diverse group of volunteers. It is possible that recruiting from multiple hospital systems while also including those who have never been on Facebook might increase recruitment numbers but would also add the need to provide social media instruction for nonusers. Acceptability of the group was positive overall; however, it would likely be received more eagerly if there was communication between larger numbers of participants.

Engagement

Most of the participants in this sample were in their 50s and 60s. Thus, alternative platforms need to be considered for engaging adults over the age of 60 years. Although Facebook use here in the United States was 73% for those aged 50-64 years in 2021 [31], it may be that participants in this sample did not find it useful for the Chat intervention. Other social media apps and platforms are not as popular as Facebook among older adults [31]; however, WhatsApp, which has end-to-end encryption, may improve privacy and increase trust for app-based interventions [32]. Currently, WhatsApp is popular among Hispanic American people, but its use is low among non-Hispanic Black and White people [31]. YouTube on the other hand is popular among a broad demographic and is the most used platform in the United States [31], making it a potential venue for future research.

Engagement may also be influenced by the availability and use of specific devices. Although smartphone, computer, and tablet ownership among older adults was less than 15% a decade ago, those numbers have been rapidly increasing [33]. Of those 65 years of age and older, 61% owned a smartphone in 2021 and 44% owned a tablet [33]. Regardless, several issues with engagement will need to be addressed for future studies. There might have been more activity in the Facebook group if the postings were more frequent and more personalized. One person commented that they would have liked notifications when new posts were added. Additionally, if each post must be approved by the IRB, it would be important to have a large number of articles and interesting videos for posting prior to the IRB application. One of the participants stated that the videos were helpful; therefore, more active and interactive content would likely be well received.

The feasibility of the intervention could not be determined for this study due to the small sample. As a result, future research using innovative recruitment techniques may be required before a determination of feasibility can be made. A future intervention should allow for freer communication, greater interaction, and include entertaining content. In addition, researchers should consider ways to personalize social media posts in order to improve engagement. Alternative platforms may be more acceptable and should be examined for a larger CR social media intervention. Finally, the length of the pre-post questionnaires should be considered moving forward. It may be that the questionnaires for this study were too burdensome, which is also evidenced by unanswered questions and missing data.

Limitations

This study had limitations. The sample size was small, creating a high risk for type II error and a risk of bias related to unequal group sizes. The unequal group sizes resulted in unequal variances between groups, affecting the types of analyses that could be performed. Although comments in the Chat group were positive overall, given the nature of social media, it is possible that low participation rates in this study were due to privacy concerns. To address potential privacy concerns, alternative social media platforms should be considered. Furthermore, the sample was limited to 4 hospitals within a single organization. A more diverse population will be required for a larger study to improve generalizability. No between-group differences were found for any of the hypothesized outcomes since the study was underpowered. This was a feasibility study and a large sample size was not planned; however, a larger study will be required to determine whether the Chat intervention is feasible. Finally, “likes” were used as a surrogate measure of engagement; however, it is possible that participants valued a post and did not “like” it.

Conclusions

Acceptability of the Facebook group was high for support and feeling in touch with providers. Despite challenges with recruitment and engagement, many important lessons were learned from this feasibility study. No between-group differences were found for motivational or need satisfaction scores. The small sample size likely affected the ability to find between-group differences and determine intervention feasibility. Nevertheless, among both groups, participants with greater exercise motivation at CR intake and greater improvement in perceived competence, completed more sessions, indicating that these are important factors for CR completion. More research is needed to find ways to engage those who have low motivation, and innovative recruitment methods may be required to ensure an adequate sample size. Researchers considering conducting social media research should consider various platforms for intervention delivery.

Data Availability

The data sets generated and analyzed during this study are not publicly available due to institutional policy but are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 90 KB - cardio_v7i1e46828_app1.pdf]

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Abbreviations

BREQ-3: Behavioral Regulation in Exercise Questionnaire-3
Chat: Cardiac Rehabilitation Facebook Intervention
CR: cardiac rehabilitation
IRB: institutional review board
MI: myocardial infarction
PNSE: Psychological Need Satisfaction for Exercise
RAI: relative autonomy index

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Original Paper

Outcomes of a Remote Cardiac Rehabilitation Program for Patients Undergoing Atrial Fibrillation Ablation: Pilot Study

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Abstract

Background: Risk factor modification, in particular exercise and weight loss, has been shown to improve outcomes for patients with atrial fibrillation (AF). However, access to structured supporting programs is limited. Barriers include the distance from appropriate facilities, insurance coverage, work or home responsibilities, and transportation. Digital health technology offers an opportunity to address this gap and offer scalable interventions for risk factor modification.

Objective: This study aims to assess the feasibility and effectiveness of a 12-week asynchronous remotely supervised exercise and patient education program, modeled on cardiac rehabilitation programs, in patients with AF.

Methods: A total of 12 patients undergoing catheter ablation of AF were enrolled in this pilot study. Participants met with an exercise physiologist for a supervised exercise session to generate a personalized exercise plan to be implemented over the subsequent 12-week program. Disease-specific education was also provided as well as instruction in areas such as blood pressure and weight measurement. A digital health toolkit for self-tracking was provided to facilitate monitoring of exercise time, blood pressure, weight, and cardiac rhythm. The exercise physiologist remotely monitored participants and completed weekly check-ins to titrate exercise targets and provide further education. The primary end point was program completion. Secondary end points included change in self-tracking adherence, weight, 6-minute walk test (6MWT), waist circumference, AF symptom score, and program satisfaction.

Results: The median participant age was 67.5 years, with a mean BMI of 33.8 kg/m^2 and CHADs2VASC (Congestive Heart Failure, Hypertension, Age [≥75 years], Diabetes, Stroke/Transient Ischemic Attack, Vascular Disease, Age [65-74 years], Sex [Female]) of 1.5. A total of 11/12 (92%) participants completed the program, with 94% of expected check-ins completed and 2.9 exercise sessions per week. Adherence to electrocardiogram and blood pressure tracking was fair at 81% and 47%, respectively. Significant reductions in weight, waist circumference, and BMI were observed with improvements in 6MWT and AF symptom scores (P<.05) at the completion of the program. For program management, a mean of 2 hours per week or 0.5 hours per patient per week was required, inclusive of time for follow-up and intake visits. Participants rated the program highly (>8 on a 10-point Likert scale) in terms of the impact on health and wellness, educational value, and sustainability of the personal exercise program.

Conclusions: An asynchronous remotely supervised exercise program augmented with AF-specific educational components for patients with AF was feasible and well received in this pilot study. While improvements in patient metrics like BMI and 6MWT are encouraging, they should be viewed as hypothesis generating. Based on insights gained, future program iterations will include particular attention to improved technology for data aggregation, adjustment of self-monitoring targets based on observed adherence, and protocol-driven exercise titration. The study design will need to incorporate strategies to facilitate the recruitment of a diverse and representative participant cohort.

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KEYWORDS

atrial fibrillation; behavior modification; cardiac rehabilitation; catheter ablation; exercise; remote exercise supervision; weight loss

Introduction

Atrial fibrillation (AF) is one of the most common arrhythmias affecting adults, with a projected prevalence in the United States of 12.1 million by 2030. With nearly 5 million office visits and 700,000 emergency department visits annually, AF is associated with a significant burden on the health care system that is expected to grow in the coming years [1-3]. In recent years, increasing attention has been paid to the prevention of AF and associated complications through lifestyle and risk factor modification [4].

Several studies have explored the utility of exercise programs for the outcomes associated with AF. Programs focused on aerobic exercise and fitness, particularly when associated with weight loss, have been shown to improve arrhythmia burden and associated symptoms in patients with AF [5-7].

Cardiac rehabilitation (CR) is a supervised exercise program paired with health education. In the United States, CR is currently recommended for patients with a recent myocardial infarction, recent percutaneous coronary intervention or bypass surgery, cardiac valve surgery, or congestive heart failure. Several studies have investigated the effect of these programs on patients with AF, with generally favorable results for symptom reduction and arrhythmia control but mixed results for mortality and hospitalization [8-17].

CR is, however, practically limited by the lack of insurance coverage in the United States for patients with AF. Another limitation is the requirement for participants to physically report to gymnasiums or health care centers to participate in exercise sessions under the supervision of health care personnel. The resource intensiveness of these models limits their scalability, and in-person design limits accessibility for patients who may be working or live remotely from centers offering these services. As a result, it remains that CR as a therapy has a low penetrance, even among patients for whom it is currently indicated and covered. There is, however, growing interest in the evaluation of alternative models of delivery, strategies to improve access, and the evidence-based evolution of program design [18].

Our center has been offering remote CR services for patients indicated for traditional CR but unable to participate for personal reasons such as work or distance. In this pilot study, we sought to evaluate the feasibility of offering a 12-week asynchronous remotely supervised exercise program, modeled on CR programs, augmented with digital health tools and AF-specific educational material to patients with AF undergoing catheter ablation.

Methods

Patient Cohort

All patients referred for catheter ablation for AF at a tertiary care center were considered for enrollment. The inclusion criteria were (1) age 18 years or older, (2) access to a smartphone compatible with the provided digital health equipment, (3) access to exercise equipment or space, (4) low to moderate risk based on the American Association of Cardiovascular and Pulmonary Rehabilitation criteria, and (5) presence of 1 additional risk factor, including obesity (BMI >30 kg/m^2), sedentary lifestyle, hypertension, diabetes mellitus, dyslipidemia, or obstructive sleep apnea. The exclusion criteria included (1) the inability to provide informed consent, (2) major procedural complications, (3) pulmonary disease requiring home oxygen, (4) gait instability, or (5) history of previous falls.

A total of 12 patients were enrolled in this pilot study. An additional 14 patients were screened but not enrolled, 12 of whom were male. A patient met exclusion criteria on further review. A total of 6 patients could not be reached for review of the study, and 2 canceled their procedures. Among the remaining 5 patients who declined, 1 was due to relocation and the remaining patients did not provide a specific reason.

Intervention Design

All patients were provided with a weight scale, a blood pressure cuff, and a Kardia Mobile 6L electrocardiogram (ECG) device (AliveCor). All participants were enrolled in KardiaPro (AliveCor) for ECG review and storage. Patients were also enrolled in the patient portal of the electronic medical record (EMR), where the ability to enter self-recorded data was enabled with subsequent display in a patient-generated data flowsheet.

As summarized in Figure 1, all patients underwent a 1-week postablation follow-up visit with an electrophysiology advanced practice provider, at which point they were cleared for return to normal activity. An in-person intake visit was then scheduled for a visit with an exercise physiologist in the CR gymnasium, and the patient completed the Atrial Fibrillation Effect on Quality-of-Life Questionnaire.

During the intake visit, baseline weight, blood pressure, and waist circumference were checked. The patient then completed a 6-minute walk test (6MWT) on a treadmill or on the track. The exercise physiologist discussed a home exercise plan and fitness goals with each patient. The exercise physiologist also reviewed an exercise target heart rate range and rating of perceived exertion (RPE) to help guide their home exercise. Each patient was shown how to track exercise minutes, blood pressure, and weight to track their health within Epic (Epic Systems Corp), the electronic health record (EHR) system. If available, a participant's Fitbit (Fitbit Inc) or Apple Watch (Apple Inc) was set up and synced with Epic to help with tracking. Each patient was given the opportunity to try a variety of aerobic equipment in the CR gymnasium. The personalized exercise program was modeled on the recommendations provided during standard CR programs, and a remote CR program at our institution was offered to patients who met the criteria for ambulatory CR programs but were unable to participate. During this visit, patient education was provided

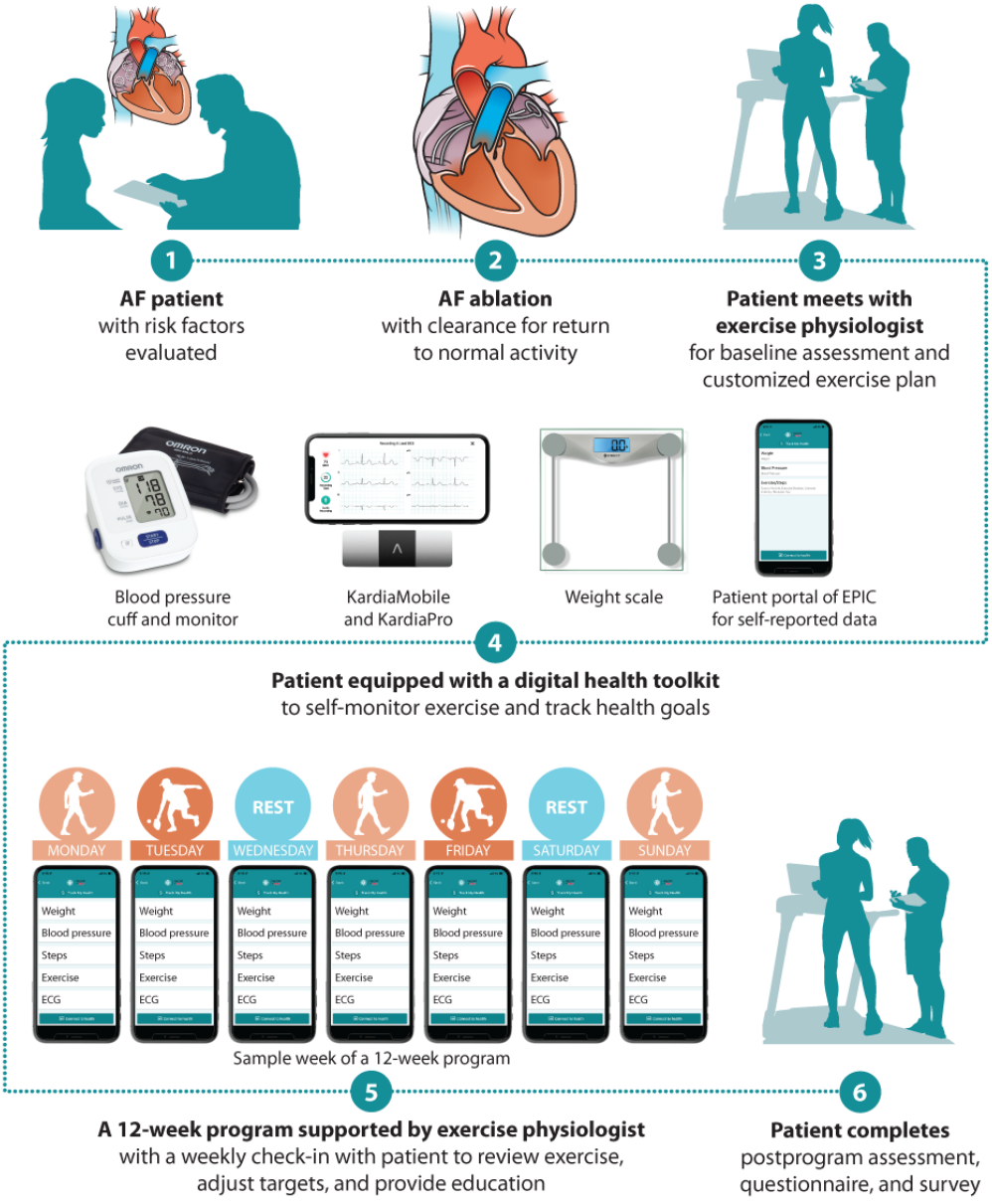
directly by the exercise physiologist and through print material regarding diet, exercise, and self-monitoring, such as techniques for appropriate blood pressure measurement.

The exercise physiologist made phone calls to follow up with patients on a weekly basis. The physiologist discussed (1) how often the patients were exercising, (2) how they were progressing, and (3) if they were having any symptoms. Patients were given an opportunity to ask questions about their home exercise routine. The exercise physiologist would review the data tracked in Epic and follow up with patients regarding their self-tracking. Exercise targets were adjusted by the exercise physiologist based on the data review, particularly the RPE, and discussion with the participant. The specific changes were not protocolized but included both duration and intensity adjustments in parallel when made. Throughout the 12-week intervention, additional education was provided through direct patient communication with the exercise physiologist and print materials.

During the program, patients were asked to record their weight and blood pressure on a daily basis and exercise minutes as performed; the data were recorded in the patient portal of the EHR. Participants were asked to record ECGs on a daily basis and with symptoms; the ECGs were reviewed and stored in KardiaPro. Patients with an iPhone (Apple Inc) had Apple Health (Apple Inc) sharing enabled them to allow automatic data flow from their devices into the EHR. After the completion of the 12-week program, patients were permitted to continue entering data at their discretion.

At the end of 12 weeks, patients participated in an exit evaluation, including measurements of weight, waist circumference, 6MWT, and Atrial Fibrillation Effect on Quality-of-Life survey (AFEQT) questionnaires. At least 3 months after completion of the program, participants were asked to complete a 4-question survey using a Likert scale on their experience and also to indicate interest in patient advisory roles for future program development and study. Both AFEQT and RPE have been validated in previous literature [19,20].

Figure 1. Overview of a remotely supervised exercise program for patients with atrial fibrillation (AF). ECG: electrocardiogram.



Outcomes

The primary end point of this study was program completion, specifically participation through completion of the exit visit. Secondary end points included self-tracking adherence, weight, 6-minute walk test, waist circumference, change in AFEQT score, and program satisfaction survey. Finally, during the first 3 months of the study after enrollment of the first patient, the exercise physiologist time applied toward the program was recorded for the assessment of personnel requirements. Except for weekly patient tracking, all of the other patient data were collected and stored in an encrypted REDCap (Research Electronic Data Capture; Vanderbilt University) database. Patient self-tracking data were abstracted from the EMR and cloud-based ECG storage system for analysis.

Statistical Analysis

Descriptive statistics were calculated for patients' demographics and comorbidities and presented as mean (SD) or median (range) or counts (percentages), as appropriate. Outcome data were tested for the normal distribution using the Shapiro-Wilk test. A 2-tailed, paired *t* test for normally distributed data or a Wilcoxon rank sum test for not normally distributed data was performed to assess the differences between pre- and postintervention measures. Median change or mean change with SE were reported, as appropriate. All statistical analyses were performed using SAS Enterprise Guide 7.1 (SAS Institute). A *P* value of <.05 was considered statistically significant.

Ethical Considerations

This study was reviewed and approved by the Atrium Health Institutional Review Board (IRB number: IRB00082393). All participants provided informed consent before being enrolled in the study. All protected health information collected was managed in accordance with institutional data protection protocols. Protected health information, including identifiable data, was stored on institutional servers secured according to institutional protocols. There was no compensation provided for participation in the study.

Results

Baseline Demographics

Baseline characteristics are summarized in Table 1. Half of the participants (6/12, 50%) were female, with a median age of 67.5 (range 47-79) years. The mean BMI was 33.8 kg/m^2. Most of the patients had associated medical comorbidities. The median CHADs2VASC (Congestive Heart Failure, Hypertension, Age [≥75 years], Diabetes, Stroke/Transient Ischemic Attack, Vascular Disease, Age [65-74 years], Sex [Female]) was 1.5 (range 1-5). Slightly more than half of participants (7/12, 58%) had paroxysmal AF, while the remainder had persistent AF.

Table 1. Baseline characteristics of participants (N=12).

Participants	Frequency
Sex (female), n (%)	6 (50)
Race (White), n (%)	10 (83)
Age (years), median (range)	67.5 (47-79)
BMI (kg/m^2), mean (SD)	33.78 (5.03)
AF[a] type, n (%)	
Paroxysmal	7 (58)
Persistent	5 (42)
Diabetes, n (%)	2 (17)
Hypertension, n (%)	10 (83)
Heart failure, n (%)	1 (8)
Coronary artery disease, n (%)	2 (17)
Peripheral vascular disease, n (%)	1 (8)
Cerebrovascular accident, n (%)	1 (8)
CHADs2VASC[b], median (range)	1.5 (1-5)
Obstructive sleep apnea, n (%)	6 (50)

[a]AF: atrial fibrillation.

[b]CHADs2VASC: Congestive Heart Failure, Hypertension, Age (≥75 years), Diabetes, Stroke/Transient Ischemic Attack, Vascular Disease, Age (65-74 years), Sex (Female).

Program Adherence and Time Intensity

Program adherence and engagement with exercise physiologist is summarized in Table 2. In total, 92% (11/12) of participants completed the 12-week program through the exit visit. One patient was lost to follow-up during the program. Over the course of the 12-week program, 94% of expected patient contacts between the exercise physiologist and the participant were made, with a total of 136 patient contacts of an expected 144 contacts. The contact type, either telephone or email, was

evenly distributed between email and telephone calls. The majority of contacts included educational content (123/136, 90%), while a smaller segment included support for self-tracking (48/136, 35%) and an adjustment of exercise targets (20/136, 15%).

For self-tracking, the cohort of 12 participants recorded 487 blood pressure measurements, 824 ECGs, and 418 exercise sessions over the 12-week program. This accounted for approximately 3.4 blood pressure measurements, 5.7 ECGs, and 2.9 exercise sessions per patient per week. For the requested daily recording of blood pressure and ECG, this frequency is associated with a 48% adherence rate and an 81% adherence rate, respectively.

There were no program-related adverse events. One patient developed COVID-19 during the program and had to pause participation.

In the 3 months of the study, the period in which exercise physiologist time was specifically tracked, a total of 48.7 hours of exercise physiologist time was required. The number of patients enrolled in the study and time per biweekly period are shown in Figure 2. The average time per week required was 2 hours, or an average of 0.5 hours per patient enrolled per week.

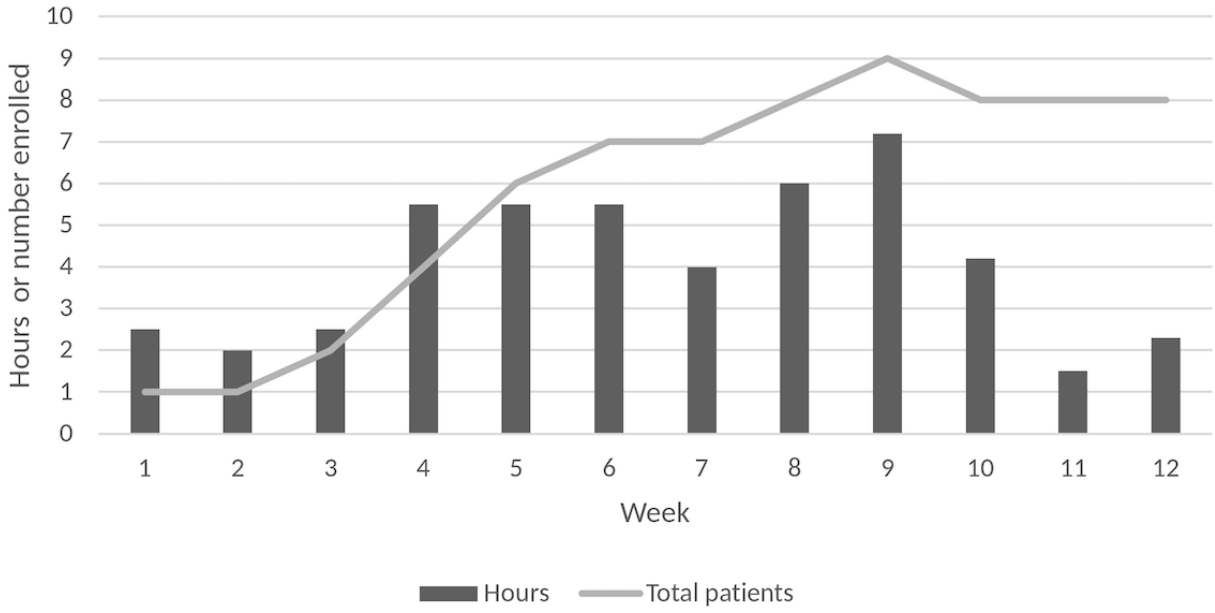
Table 2. Participant adherence to self-tracking and weekly contacts with the exercise physiologist.

Patient-reported metrics	Total	Frequency
Blood pressure, median (range)	537	49 (0-83)
Electrocardiogram, median (range)	824	72.5 (32-92)
Exercise sessions, median (range)	418	36 (0-69)
Participant contacts		
Total contact	136	94%[a]
Phone	66	45%[a]
Email	70	49%[a]
Contact content		
Education	123	90%[b]
Self-tracking	48	35%[b]
Exercise targets	20	15%[b]

[a]Percentage expected.

[b]Percentage total.

Figure 2. Exercise physiologist time use.



Health Outcomes and Patient Satisfaction

Program outcomes are summarized in Table 3. Overall, there were significant improvements seen across all measured domains. The average waist circumference reduced from 45.5 to 44.0 (P=.001). Weight reduced from 215.8 lbs to 211.94 lbs (P=.04). BMI also improved from 34.1 to 33.4 kg/m^2 (P=.04). The 6-minute walk tests also improved from 0.31 km to 0.38 km (P=.01). AF symptoms, as assessed by the AFEQT questionnaire, also improved from 40.6 to 80.0 (P<.001).

The postprogram surveys were returned by 8 participants (Table 4). Among the participants responding, the program assessment was favorable. Participants overall strongly agreed that the program improved their overall health and wellness (8.75/10). They also strongly agreed that they would recommend this program to other patients with AF (9.13/10). Finally, they strongly agreed that they would be able to apply the education they received to future decisions about their health and that they could sustain the established exercise program going forward (9/10 and 8.215/10, respectively).

There were no intervention-related adverse events. One patient developed COVID-19 during the intervention, requiring an interruption of exercise.

Table 3. Health outcomes of a remotely supervised exercise program.

	Preprogram measurement, mean (SD)	Postprogram measurement, mean (SD)	Absolute change, mean (SD)	P value
Waist circumference (inches)	45.5 (4.9)	44 (4.4)	1.5 (1.2)	.002
Weight (lbs)	217.8 (36.1)	213.3 (33.5)	4.6 (6.2)	.04
BMI (kg/m^2)	34.1 (5.2)	33.4 (5.2)	0.7 (1)	.03
6-minute walk test (km)	0.3 (0.1)	0.4 (0.1)	–0.1 (0.1)	.02
AFEQT[a] score	40.6 (21.2)	80.1 (17.3)	–39.5 (20.6)	<.001

[a]AFEQT: Atrial Fibrillation Effect on Quality-of-Life survey.

Table 4. Patient feedback on a remotely supervised exercise program.

Question (1=strongly disagree and 10=strongly agree)	Mean score
This program improved my overall health and wellness	8.75
I would recommend this program to other patients with atrial fibrillation	9.125
I will be able to apply the education to my future decisions about exercise and health	9
I will be able to sustain the exercise program I established going forward	8.125

Discussion

In this study of an asynchronous remotely supervised exercise program augmented with disease-specific education in patients undergoing catheter ablation of AF, we found that there was a high rate of program adherence without significant program-associated adverse events and high levels of patient satisfaction.

Several studies have investigated the utility of exercise programs for patients with AF. In the CopenHeartRFA study, Risom et al [15] randomized 210 patients undergoing catheter ablation for AF to CR versus usual care. While a significant difference in peak oxygen consumption was found, there was no difference in quality of life as assessed by the 36-Item Short Form Health Survey questionnaire [15]. Kato et al [10] observed similar findings in their study of 61 patients randomized to CR versus usual care. In the extended follow-up of this cohort, Risom et al [16] reported persistence of this effect at 1 year as well as lower levels of anxiety in the intervention cohort at 2 years, though no differences in hospitalization or mortality were observed. Aoyama et al [9] evaluated the effect of CR among patients with heart failure undergoing catheter ablation of AF. In that study, no significant outcome difference was observed over 18 months of follow-up in AF recurrence or hospitalization. Overall, data specifically on the impact of CR are limited and conflicting in terms of impact on arrhythmia burden and outcomes [13,14].

Other studies have more generally evaluated risk factor modification programs, including components focused on exercise. In the CARDIO-FIT study, 308 patients were enrolled in a risk factor modification program that included elements focused on comorbidities including obesity, hypertension, glucose intolerance, and sleep apnea. Participants underwent exercise stress testing, and a tailored exercise program was designed for each participant. Participants with >2 metabolic equivalent improvement in fitness had the greatest arrhythmia-free survival at follow-up (89% vs 40%, P<.001). Interestingly, participation in a separate risk factor clinic was strongly associated with the achievement of improvement in cardiorespiratory fitness (83% vs 39%, P<.001), suggesting significant value for reinforcement and observation from health care providers. Patient education has also been demonstrated to be an important component in the care of patients with AF. In HELP-AF, Gallagher et al [21] evaluated an in-home educational program including an educational pamphlet designed with patient feedback and demonstrated a reduction in subsequent AF hospitalizations. Isakadze et al [22] recently described the development of educational material delivered

through a smartphone app using patient-centered design processes as well, which could offer a far more scalable approach to patient education.

In comparison with these previous investigations, this study offers several strengths. First, the use of digital care models with digital health tools, patient-reported data through EMR interfaces, and remote follow-up can help improve scalability and accessibility. Several factors, including the distance from appropriate facilities and socioeconomic barriers, have been identified as contributing to the poor rates of participation in CR among eligible patients [23,24]. Second, the inclusion of remote monitoring of participation could help improve adherence. As Pathak et al [6] noted, there was a substantial improvement in the impact of their exercise intervention among patients who had participated in a risk factor clinic. Similarly, weekly check-ins with an exercise physiologist associated with the arrhythmia team may help motivate patients and improve the effectiveness of the intervention. Additionally, pairing with the periablation period may help leverage routine patient contacts to reinforce the importance of exercise in AF management. Finally, the time requirement for staff engagement, specifically the exercise physiologist, was low per patient and may help improve the feasibility of implementation in a health care environment where staffing is more challenging.

There are several limitations worth noting. First, the sample size was small, and so all findings should be viewed as hypothesis generating and informative for future investigations. A contributing factor to the small sample size was several COVID-19 surges, which led to the cessation of research enrollment for extended periods. Nonetheless, this pilot study provided several insights into future iterations and further studies, such as staffing requirements, participant self-monitoring adherence in several areas, and technological gaps to be addressed. Also, it was a homogeneous cohort, and future studies will need to focus on improvement in size and diversity of the enrolled population. A structured assessment of health literacy, technological sophistication, and disease-specific knowledge would also be useful to help assess the intervention's impact and the generalizability of results.

Second, effects on AF-associated symptoms are confounded by the postablation status of the cohort. While mitigated somewhat by the baseline AFEQT being done several weeks after catheter ablation, the effect on AF symptoms would be better assessed with a control group. Additionally, while ECG monitoring was performed during the study, there was neither a specific recommendation to check before exercise nor a restriction that exercise should not be performed if in AF. Furthermore, while heart rate targets were provided, these were not adjusted for rhythm, so it is possible that participants limited exercise based on elevated heart rates in AF if they occurred during exercise. In future iterations of program design, rhythm assessment with the adjustment of rate targets accordingly would be an important consideration. Finally, the collection of physiologic data during the intervention was primarily exploratory to assess adherence and feasibility. No conclusions can be made in regard to the impact on those measures from the intervention.

There are several observations that were noted through the course of this pilot study that will help inform future intervention design. First, 50% of potential candidates, excluding the 2 patients who canceled their procedure and therefore were no longer candidates, were enrolled in the program. For most patients who declined to participate, no specific reason or barrier beyond preference was identified. It is also important to recognize that disparities exist in patient referrals for catheter ablation for patients of certain minority groups [25]. As such, interventions targeted at patients reaching this stage will inherit these disparities, and expansion beyond this cohort will be important to ensure equitable access.

Second, a more robust data aggregation infrastructure will be required. The embedded functionality for patient-generated data within the EMR performed poorly due to (1) poor visualization tools, (2) system stability issues with large quantities of data, and (3) lack of tools for data export for analysis requiring manual abstraction. Functionality for exercise tracking beyond patient self-report was limited as well, despite the availability of more robust activity tracking tools. For such programs to be feasible, a single data management and software solution will be critical to ensuring the efficiency and scalability required to clinically implement this type of program. Third, some patients expressed a preference for access to the exercise facilities at the CR center, even outside of the directly supervised programs currently available but for which they were not candidates.

There are several opportunities to improve the scalability of this type of intervention. Automated tools for longitudinal tracking of patients will be needed to support the durability of the changes made during the intervention. Additionally, protocol-driven feedback and adjustments to exercise regimens based on the collected data could help improve outcomes; further validation of these protocols, however, would be important. Lastly, the need for an in-person visit to a CR center may be a barrier both in terms of access and cost; future iterations will need to explore alternative models for program intake and exercise prescription development.

In summary, this asynchronous remotely supervised exercise program augmented with AF-specific educational components for patients with AF appears feasible in terms of patient adherence as well as resources required for implementation and warrants further iterative development and study. Further iteration of data collection strategies, including both implementation of aggregation tools outside the EHR and more focused self-monitoring recommendations, will need to be developed. Particular attention to the recruitment of diverse cohorts of patients for future studies will be important to evaluate strategies to overcome barriers that may be presented by socioeconomic, racial, geographic, and technological disparities. In comparison to traditional care paradigms currently available, this type of intervention can offer scalable strategies for risk factor modification across large patient cohorts dispersed across broad geographic areas and warrants further investigation.

Acknowledgments

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

6MWT: 6-minute walk test
AF: atrial fibrillation
AFEQT: Atrial Fibrillation Effect on Quality-of-Life survey
CHADs2VASC: Congestive Heart Failure, Hypertension, Age (≥75 years), Diabetes, Stroke/Transient Ischemic Attack, Vascular Disease, Age (65-74 years), Sex (Female)
CR: cardiac rehabilitation
ECG: electrocardiogram
EHR: electronic health record
EMR: electronic medical record
REDCap: Research Electronic Data Capture
RPE: rating of perceived exertion

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Review

Digital Transformation in the Diagnostics and Therapy of Cardiovascular Diseases: Comprehensive Literature Review

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Abstract

Background: The digital transformation of our health care system has experienced a clear shift in the last few years due to political, medical, and technical innovations and reorganization. In particular, the cardiovascular field has undergone a significant change, with new broad perspectives in terms of optimized treatment strategies for patients nowadays.

Objective: After a short historical introduction, this comprehensive literature review aimed to provide a detailed overview of the scientific evidence regarding digitalization in the diagnostics and therapy of cardiovascular diseases (CVDs).

Methods: We performed an extensive literature search of the PubMed database and included all related articles that were published as of March 2022. Of the 3021 studies identified, 1639 (54.25%) studies were selected for a structured analysis and presentation (original articles: n=1273, 77.67%; reviews or comments: n=366, 22.33%). In addition to studies on CVDs in general, 829 studies could be assigned to a specific CVD with a diagnostic and therapeutic approach. For data presentation, all 829 publications were grouped into 6 categories of CVDs.

Results: Evidence-based innovations in the cardiovascular field cover a wide medical spectrum, starting from the diagnosis of congenital heart diseases or arrhythmias and overoptimized workflows in the emergency care setting of acute myocardial infarction to telemedical care for patients having chronic diseases such as heart failure, coronary artery disease, or hypertension. The use of smartphones and wearables as well as the integration of artificial intelligence provides important tools for location-independent medical care and the prevention of adverse events.

Conclusions: Digital transformation has opened up multiple new perspectives in the cardiovascular field, with rapidly expanding scientific evidence. Beyond important improvements in terms of patient care, these innovations are also capable of reducing costs for our health care system. In the next few years, digital transformation will continue to revolutionize the field of cardiovascular medicine and broaden our medical and scientific horizons.

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KEYWORDS

cardiovascular; digital medicine; telehealth; artificial intelligence; telemedicine; mobile phone; review

Introduction

From Digitization to a Digital Transformation

Digitization is the conversion of analog information into a digital signal consisting of discrete values. Beyond the obvious advantage of storing data for the future, it also provides the potential for further IT processing. In general, the use of digitization to facilitate and optimize processes is referred to as digitalization. With the introduction of the first universally programmable computer by Konrad Zuse in 1941, a path was initiated that led us to an age at the end of the 20th century since when digital technologies have become omnipresent [1-4].

Over the years, the original term digitalization has expanded to a new strategic alignment of entire industries, as it nowadays also refers to the megatrend of digital transformation in all areas of life. Similar to how the Industrial Revolution shaped the

transition from an agrarian to an industrial society 200 years ago, we are now experiencing a rapidly progressing digital revolution [2-4].

Digital Medicine and Digital Health

Digitalization has become increasingly important in the field of medicine over the last 3 decades. The constantly growing volume of patient data makes the use of digital management systems inevitable. Redundant examinations must be avoided to ensure patient safety as well as from a health economics perspective. Data should be easily accessible in a digital patient file regardless of the location and should be provided to the attending physician upon patient consent. Moreover, there are innovative concepts in informatics, such as the implementation of artificial intelligence in the health care sector, that can decisively enrich the quality of medicine. Today, we are in the process of digital transformation, as digitalization has essentially transformed the entire medical sector as an industry.

Digital health, as a subdiscipline of digital medicine, describes a transformation toward patient-centered recordings of medical information including vital signs and simple diagnostics such as electrocardiograms (ECGs). It improves the security of supply and access to medical facilities, as it is separated from any local medical institution. A growing shortage of physicians in rural regions and restrictions due to the COVID-19 pandemic over the past 3 years have shown us how quickly critical medical care bottlenecks can occur. Telemedicine and digital remote diagnostics and treatments can provide enormous benefits in these situations [5].

Smart Technologies and Lifestyle

The increasing integration of medical digital technology in everyday life in the form of digital health diaries, smartphones, smartwatches, and personal health monitoring systems has made the technical possibilities more tangible.

Even though smartphones have been in use since 1999, the launch of the first iPhone in 2007 triggered a noticeable change. Today, an estimated 4 billion people, or half of the world's population, use a smartphone [6].

As a mobile minicomputer, the phone accompanies most people around the clock, and many of them can no longer imagine life without a smartphone. Specialized apps have been developed for a wide range of tasks including health care. Although these were purely informative in the first few years, there has been an increasing rethinking of how these data can be used in everyday patient care. As approximately 500 million people worldwide live with cardiovascular diseases (CVDs), it becomes obvious that smart technologies have enormous potential for prevention, diagnostics, and therapy monitoring [7].

A growing number of people continuously wear mobile minicomputers on their wrists (so-called wearables) to record activity data or vital signs. Prominent representatives of this class are smartwatches or fitness trackers. As with smartphones, the collected data are far more than just informative and have the potential to improve patient care. The most important parameters that can be recorded today are ECGs, heart rate, number of steps, oxygen saturation, and blood pressure or blood sugar values via special additional modules [8,9].

CVD Diagnostics and Therapy

CVDs are highly interesting from the perspective of digital medicine because they have a very high lifetime prevalence, with approximately 500 million people affected worldwide, and they are responsible for approximately one-third of all deaths worldwide [7,10]. In fact, the World Health Organization assumes an even higher number of CVDs, as a significant proportion (potentially >50%) of people have not yet been diagnosed, especially in the case of arterial hypertension [7,10].

Cardiology involves the management of a broad spectrum of diseases ranging from chronic diseases such as heart failure or valvular heart diseases to highly acute pathologies such as acute myocardial infarction or cardiac arrhythmias. In addition, the technology of smartwatches and other so-called wearables consistently captures cardiovascular functional parameters such as heart rate, physical activity, or even blood pressure. For these reasons, great efforts have been made to make cardiovascular medicine as digital as possible to optimize patient care and treatment through innovative technologies.

The aim of this literature review was to present a comprehensive overview of the historical and technical development of digital technologies in relation to diagnostics and therapy for CVDs over the last few decades.

Methods

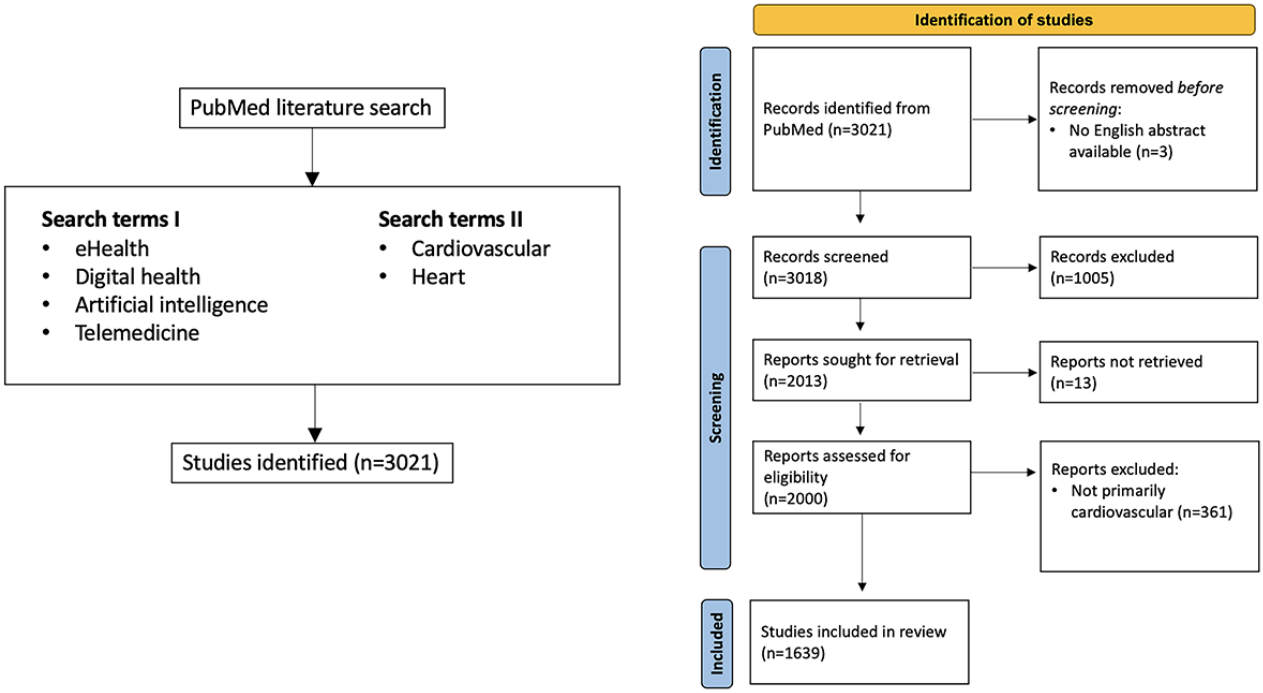
Literature Review

The aim of this study was to conduct a comprehensive literature review investigating digital transformation in the diagnostics and therapy of CVDs. The focus was on the direct application of digital technologies in patient care, whereas early phase technical innovations or IT solutions without direct clinical use were excluded. Therefore, we conducted an extensive literature search in the PubMed biomedical database, which provides ideal coverage of the publications of interest.

Our search strategy was based on two major components: (1) all studies that contained the terms "ehealth," "digital health," "artificial intelligence," or "telemedicine" in the title or abstract were identified, and (2) the studies were narrowed down to the cardiovascular field by the simultaneous presence of the terms "cardiovascular" or "heart" in the title or abstract, resulting in the following search term: "((ehealth[Title/Abstract]) OR (digital health[Title/Abstract]) OR (artificial intelligence[Title/Abstract]) OR (telemedicine[Title/Abstract])) AND ((cardiovascular[Title/Abstract]) OR (heart[Title/Abstract]))." The choice of the above-mentioned search terms was the result of a survey of experienced cardiologists involved in digital cardiology at the University Hospital of Ludwig Maximilian University of Munich, Germany. Our search did not restrict any article types; therefore, review articles and comments were found among the results in addition to original articles. Furthermore, there was no thematic restriction within the cardiovascular field, and all studies up to the cutoff date (March 16, 2022) were included.

The review yielded 3021 studies, all of which were then screened and processed in a structured manner. Within this framework, 1018 (33.77%) of the 3021 studies were excluded because they were not directly related to digital technologies in medicine or because they could not be retrieved. In addition, 361 (11.95%) of the 3021 studies were excluded because they did not focus on CVDs, although they addressed digital technologies. Studies from interdisciplinary research areas such as diabetes mellitus as a major cardiovascular risk factor or dietary behavior as a preventive aspect were also excluded. The final analysis included 1639 studies of which 1273 (77.67%) were original articles and 366 (22.33%) were reviews or comments. In addition to studies on CVDs in general, 829 (50.58%) of the 1639 studies included in the final analysis could be assigned to a specific CVD with a diagnostic or therapeutic approach (Figure 1).

Figure 1. Literature search strategy and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



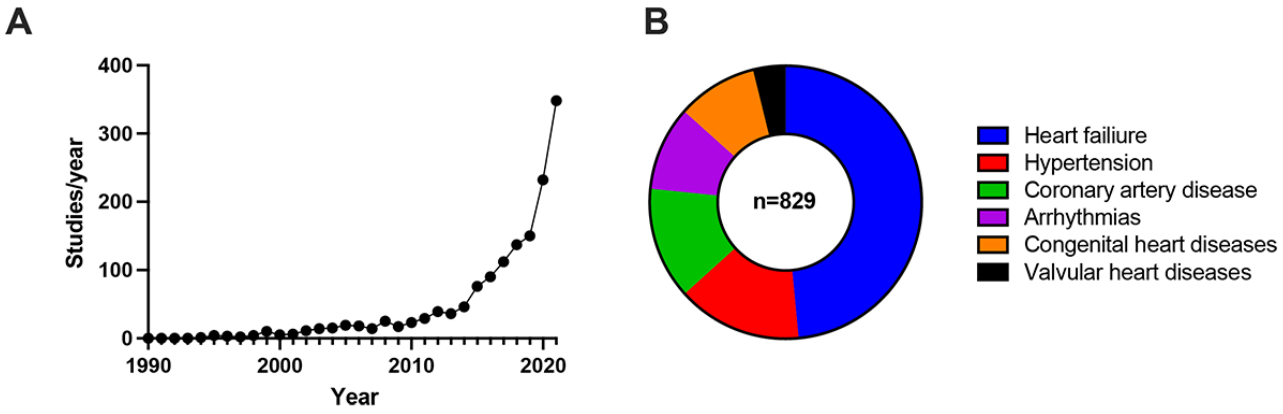
Qualitative Structured Analysis

Qualitative analysis and structuring of the available sources were performed using ATLAS.ti software (version 22; ATLAS.ti Scientific Software Development GmbH). In the process, the so-called “codes” in the form of keywords were assigned to individual studies to reflect their content. The main keywords assigned here refer to the CVD pattern, type of digital application, and data processing methodology used in respective studies. In addition, the studies were separately labeled as dealing with new digital prototypes, thus indicating possible future applications.

Building on the qualitative structuring described in the previous paragraph, content analysis was performed. All the 829 disease-specific publications were grouped by linking them to the following fields of cardiovascular medicine: (1) heart failure, (2) arterial hypertension, (3) coronary artery disease, (4) cardiac arrhythmias, (5) congenital heart diseases, and (6) valvular heart disease (Figure 2). In the *Results* section, a brief introduction to the disease itself and use cases of digital medicine are presented and underlined by the scientific data. For this purpose, the results of the screened studies are summarized. In the *Discussion* section, possible future projects and perspectives are outlined.

For visualization, we chose the evaluation of word frequencies, following established concepts of qualitative reporting [11-13]. As heart failure is the most extensively investigated condition, multiple randomized controlled trials have been published. A summary of the results is presented in Multimedia Appendix 1 [14-41] according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.

Figure 2. Publications in the field of digital cardiology. Depicted are (A) publication rates per year for studies on digital medicine in cardiology as well as (B) the respective area of cardiovascular medicine.



Results

CVDs in Digital Medicine

A total of 829 studies in the field of digital medicine could be assigned to a specific CVD, with subsequent grouping into 6 major categories (Table 1 and Figure 2). All major areas of cardiology are covered by these studies, leaving no significant thematic gap between the prevalence of CVD patterns and digital implementation. Of note, the focus of research has shifted over the decades; whereas the focus was mainly concentrated on congenital heart defects and valvular heart diseases in the early days of cardiovascular digital medicine in the 1990s, current emphasis is on chronic diseases such as heart failure, coronary artery disease, and arterial hypertension. Another aspect of cardiovascular digital research focuses on the diagnosis of cardiac arrhythmias, which is certainly due to the growing use of wearables (Table 1).

Table 1. Grouping of digital cardiovascular research in the last decades (n=829).

	Published studies, n (%)			
	1990s (n=16)	2000s (n=87)	2010s (n=376)	2020s (n=350)
Heart failure	2 (12.5)	32 (36.8)	204 (54.3)	164 (46.9)
Hypertension	0 (0)	15 (17.2)	51 (13.6)	57 (16.3)
Coronary artery disease	1 (6.3)	10 (11.5)	48 (12.8)	51 (14.6)
Arrhythmias	0 (0)	2 (2.3)	33 (8.8)	48 (13.7)
Congenital heart diseases	11 (68.8)	24 (27.6)	27 (7.2)	17 (4.9)
Valvular heart diseases	2 (12.5)	4 (4.6)	13 (3.5)	13 (3.7)

In the following sections, individual cardiovascular clinical features are briefly introduced. This is followed by a concise description of the current diagnostics and therapy. On the basis of available evidence, digital health concepts are presented and critically evaluated, and potential future perspectives are highlighted.

Heart Failure

Heart failure is defined as the inability of the heart to provide sufficient blood flow through the body, that is, cardiac output. This is usually due to reduced cardiac contractility, namely, systolic heart failure. The underlying pathomechanism is mostly lack of oxygen supply due to coronary artery disease [42]. Ischemic heart disease including heart failure accounts for almost 10 million deaths per year, making it the leading cause of death worldwide [10]. In the early stages, the 1-year mortality rate is <10% per year; it rises to up to 50% per year with disease progression and is thus far higher than that for most cancers. Heart failure is a chronic disease that requires consistent long-term therapy. In addition to the treatment of triggering underlying diseases, such as high blood pressure, there are defined therapy recommendations that have a clear focus on drug treatment.

Heart failure is one of the most important diseases in terms of health economics, and it has affected the lives of about 70 million people worldwide for many years [7,10]. It is not surprising that heart failure is the most intensively investigated condition in terms of digitalization in the cardiovascular field (Table 1 and Multimedia Appendix 1). A total of 402 studies, including 289 (71.9%) original articles and 113 (28.1%) reviews or comments, focused on digital options in diagnostics and therapy. Looking at the 10 most frequently used words in the titles of these publications, it is evident that telemedical management in the home environment has a strong focus (Textbox 1).

Textbox 1. Title words from studies on digital cardiology. Depicted are the 10 most frequently used words from titles of studies on indicated cardiovascular research areas in descending order.

Heart failure

- Heart
- Failure
- Patients
- Chronic
- Management
- Care
- Telemedicine
- Study
- Monitoring
- Health

Hypertension

- Pressure
- Blood
- Hypertension
- Telemedicine
- Health
- Management
- Monitoring
- Patients
- Study
- Based

Coronary artery disease

- Disease
- Patients
- Health
- Coronary
- Heart
- Based
- Cardiovascular
- Trial
- Telemedicine
- Chronic

Arrhythmias

- Atrial
- Fibrillation
- Cardiac
- Smart
- Study
- Heart
- Health

- Monitoring
- Detection
- Patients

Congenital heart diseases

- Heart
- Congenital
- Disease
- Telemedicine
- Pediatric
- Fetal
- Remote
- Cardiology
- Diagnosis
- Health

Valvular heart diseases

- Heart
- Sound
- Telemedicine
- Auscultation
- Monitoring
- Stethoscope
- Development
- Study
- Based
- Cardiac

Living with a diagnosis of heart failure requires consistent use of prescribed medications over many years. Simultaneously, changes in vital signs, blood values, and cardiac function must be monitored regularly. As it is known that the maximum tolerated dose ensures the longest survival, a fine and regular adjustment of the current therapy is necessary. Furthermore, it is essential to check one's body weight regularly, as this can indicate water retention in case of decompensated heart failure before more pronounced symptoms such as shortness of breath or a decrease in physical performance occur. Telemedicine offers excellent opportunities to provide urgently needed care, especially in medically underserved areas or, as recently, during the COVID-19 pandemic [43,44].

Studies that investigated telephone and telemedical care systems in an outpatient setting were able to demonstrate a significant reduction in hospitalization rates, whereas a trend toward reduced mortality did not reach statistical significance [14,45,46]. Large, randomized follow-up studies such as *Telemonitoring to Improve Heart Failure Outcomes* (Tele-HF), *Telemedical Interventional Monitoring in Heart Failure* (TIM-HF), or *Baroreflex Activation Therapy for Heart Failure* (BEAT-HF) could not confirm the reduction in hospitalization rates. The authors concluded that patient selection may have a crucial impact on success and that it needs to be critically evaluated in the future [15,16]. Meta-analyses on this topic have identified a slight reduction in all-cause mortality and heart failure–associated hospitalizations [47-49]. Recent trials that have optimized their concepts in terms of technology and patient selection, such as TIM-HF2 or *A New Model of Medical Care With Use of Modern Methods of Non-invasive Clinical Assessment and Telemedicine in Patients With Heart Failure* (AMULET), showed a reduction in hospitalization rates as well as all-cause mortality (TIM-HF2) and cardiovascular mortality (AMULET) [17,18]. This has led the European Cardiology Society to provide telemedical procedures for the treatment of heart failure, with a recommendation grade IIB in its guidelines [42] (Multimedia Appendix 1).

It is clear that in the field of heart failure, the focus is less on diagnostics and more on optimized monitoring of therapy using modern digital tools. Most studies on digital technologies in heart failure use telemedical applications to care for patients in their home environment. This reduces on-site visits and allows for earlier discharge of patients from the hospital, with telemedical support during the transition phase. Several studies

have demonstrated a significant reduction in the 30-day rehospitalization rate from 24% to 17% to 18% [50,51]. In-depth heart failure education is provided to patients as part of their respective telemedicine programs [52,53]. In addition, telemedical services facilitate communication and involve psychological factors such as increased social attention, which should not be neglected [54,55]. Vital signs and body weight can be recorded autonomously via wearables or similar devices that transmit data to the attending physician or heart failure nurse [56]. Moreover, individual medications can be evaluated and adjusted using telemedicine applications [19,20,57]. Current experimental studies have attempted to integrate telemedicine ultrasound diagnostics by trained nonphysician staff or the patients themselves [58,59]. In addition to these conventional digital methods, artificial intelligence algorithms that have the potential to automate therapy adjustments based on transmitted data are being developed [60,61].

In patients with special pacemakers for cardiac resynchronization or those with implanted cardiac defibrillators, further data can be collected via remote monitoring systems without direct physician-patient contact. These include physical activity and heart rate profiles, detection of possible arrhythmias, and impedance-guided detection of water balance in the body [62]. Studies on this monitoring mechanism have been controversial; whereas SENSE-HF, OptiLinkHF, and *Remote Management of Heart Failure Using Implanted Electronic Devices* (REM-HF) failed to show a clear benefit [21,22,63], a reduction in hospitalizations was demonstrated in the *Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators* (EVOLVO) and *Influence of Home Monitoring on Mortality and Morbidity in Heart Failure Patients With Impaired Left Ventricular Function* (IN-TIME) studies [23,24]. Regardless of the latter discussion, the establishment of remote monitoring allows for cost savings during routine follow-ups [25,64] (Multimedia Appendix 1).

In addition to these implanted devices with primarily therapeutic intention, there are also purely diagnostic monitoring tools such as loop recorders for the detection of arrhythmias or devices for the real-time measurement of pulmonary arterial pressure as a surrogate for hemodynamics in patients with heart failure [65]. For example, the *CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association Class III Heart Failure Patients* (CHAMPION) trial for the CardioMEMS system demonstrated that the pulmonary arterial pressure could be lowered, and cardiac symptoms and hospitalization rates were reduced by using this monitoring device [26]. A technologically comparable approach to measuring pulmonary arterial pressure in heart failure is currently being investigated using the Cordella system, although the final study results are still pending [66]. Possible approaches to these systems are not only the early detection of heart failure decompensations but also a more differentiated therapy control including an automated adjustment of left ventricular assist devices [67].

Patients with heart failure clearly benefit from adapted fitness programs such as those offered in rehabilitation clinics or special cardiac training groups, despite their limited exercise capacity. Given the increased baseline risk, monitoring vital signs, with subsequent transmission to the attending physician or an intelligent system, offers tremendous opportunities for improved exercise planning. Other tools provide specific exercise recommendations and guidance for patients with heart failure via web platforms or smartphones. These telemedicine fitness offerings, especially those for rehabilitation, have a positive impact on patient compliance and quality of life and are noninferior to on-site programs in their effectiveness [68-70].

Overall, digital technologies have become a major tool in guiding patients with heart failure and offer enormous potential for optimized therapy adjustments while substantially reducing planned and unplanned medical consultations in inpatient and outpatient settings. Although the use of digital technologies is associated with additional costs, numerous studies have shown that these systems perform positively in the overall cost balance and reduce financial burdens for health care systems by 10% to 35% while increasing patient comfort [71,72].

Arterial Hypertension

Arterial hypertension is defined as blood pressure >140 mm Hg systolic or >90 mm Hg diastolic blood pressure as measured in the physician's office. The estimated prevalence according to the World Health Organization is approximately 1.3 billion people worldwide, whereas more than half of them have not been diagnosed yet [73].

Depending on the severity of hypertension and individual cardiovascular risk factors, the initial treatment strategies for mild forms of hypertension can mainly focus on lifestyle changes. These include reduced stress, regular physical activity, and a healthy diet. If these measures fail, drug therapy is initiated according to the current guideline recommendations. For rare cases in which a secondary form of hypertension is present, the first-line treatment involves managing the underlying causes [74].

Digital medicine finds its application in both diagnostics and therapy of hypertension in 123 studies (including 26 reviews or comments). Keywords in the titles of these studies predominantly describe the remote monitoring of blood pressure by telemedicine systems using wearables (Textbox 1).

Autonomously performed outpatient blood pressure measurements, which are forwarded to a physician using a digital system, can be important for identifying and treating patients with hypertension. Various factors play a decisive role here: blood pressure measurements should be as uncomplicated and accurate as possible. To this end, various systems that allow measurements via smartphone-connected devices have been validated [75]. Although these systems used to be predominantly cuff based, modern alternatives do not require the classic pressure cuff. The common basis for this is photoplethysmography in which light is registered differently depending on the blood flow by a photosensor in the form of a pulse wave. This is performed either via a smartphone camera or contactless via webcams and comparable devices. In combination with intelligent algorithms, blood pressure can be calculated accurately to approximately 5±8 mm Hg either from the waveform or the pulse transit time (rarely also oscillometrically or via the detection of heart sounds) [76].

Artificial intelligence is used to further increase the reliability and measurement accuracy [76,77]. Although current cuff-free systems have not yet found widespread use and certainly need to be optimized, there is great potential for identifying and monitoring patients with hypertension or detecting fluctuations in blood pressure over the course of the day using smartphone-based self-measurement systems [78]. The latest devices have incorporated pressure sensors in special textiles to record blood pressure changes, and they are barely noticeable [79,80]. The technology of continuous autonomous measurements allows the evaluation of blood pressure variability and therefore helps further specify the individual cardiovascular risk [81,82].

Blood pressure monitoring also plays a crucial role in hospitals. In specialized centers or intensive care settings, blood pressure is automatically recorded at specific intervals and sent to a central monitoring unit. As an alternative to conventional monitoring systems, institutions first started to use cost-effective wearables to monitor selected patients [83].

In addition to the diagnosis of hypertension, therapy planning and management are also of major importance. Especially in primary care, blood pressure therapy is a significant topic, and it is not always easy to identify the best therapy according to current recommendations for the individual patient. The first pioneering study used intelligent decision support systems to optimize guideline-based therapy, which was regarded as helpful by most treating physicians [84]. Continuous adjustment of blood pressure medication to recorded values and monitoring of possible side effects require close medical supervision. However, personal visits might become dispensable if blood pressure measurements are performed autonomously, followed by digital adjustments of the respective medication. This is particularly appealing in medically underserved areas [85,86]. Telemedical systems for blood pressure monitoring and therapy adjustment have also proven useful in the transition from inpatient care to outpatient therapy [87].

Several randomized controlled trials have shown inconsistent data on the success of telemedicine interventions for the treatment of arterial hypertension. The type of intervention ranges from simple text messages for educational purposes, over internet platforms and smartphone apps, to detailed telemedical consultations in video conferences with physicians [88-90]. Depending on the type of intervention, meta-analyses have shown an additional reduction in systolic blood pressure of up to 4 mm Hg compared with conventional therapy. Interestingly, the increased interactivity of telemedicine care was associated with increased therapeutic success [91,92].

The high prevalence of hypertension and associated outpatient consultations or hospital admissions suggests that telemedicine systems can save costs. Although there is a tendency for an overall reduction in costs, a conclusion is still missing and needs to be addressed in future studies [93].

Coronary Artery Disease

Coronary artery disease involves the pathology of the heart vessels (coronaries) that ultimately impairs circulation and thus leads to a potential reduction in the supply of oxygen to the heart muscle as is typically found in myocardial infarction. The causes of the development of coronary heart disease are high blood pressure, elevated blood lipid levels (cholesterol), smoking, diabetes mellitus, and a family history of associated diseases. In industrialized nations, coronary heart disease is the leading cause of death (responsible for approximately 20% of all cases) and ranks among the top 3 worldwide [10]. Currently, more than 200 million people worldwide are affected by ischemic heart disease [7].

The mainstay of treatment for coronary heart disease is to reduce the risk of CVDs. If these methods fail and the coronary vessel is narrowed to an extent that significantly limits blood flow, it is reopened by percutaneous coronary intervention. For selected patients with the most severe forms of coronary artery disease, bypass surgery must also be considered to ensure coronary perfusion [94].

For these reasons, coronary artery disease has been a major focus in the field of digital medicine, with 110 publications (including 42 reviews or comments) investigating this domain. Thematic focuses that are based on the keywords of the study titles concern both acute and chronic telemedical care of coronary artery disease for primary and secondary prevention (Textbox 1).

Diagnostic apps offer a broad screening potential and the chance to identify high-risk patients [95]. Cardiovascular risk factors such as immobility, elevated blood pressure, or obesity can be easily detected by smartphones and associated devices to generate an awareness of the potential risk. With modern algorithms, in addition to heart rate variability, pulse wave velocity can be determined as an early marker of cardiovascular changes using photoplethysmography technology [96-98].

Even more important, however, is the role of digital diagnostics through wearable devices and telemedicine in secondary prevention. Patients can use smart technologies to monitor their health status based on vital signs, obtain information about their illness, manage and adjust their digital medication plans, and maintain regular web-based communication with their responsible physicians [99,100]. At the same time, there are programs that enable patients to autonomously manage their disease and obtain relevant information using apps or the web [101]. In particular, the transition from inpatient to outpatient care can also be significantly improved by telemedicine care, and any uncertainties that may arise early can be quickly eliminated [102,103]. Medical care is improved while saving costs by reduced rehospitalizations at the same time [104]. This also applies to rehabilitation therapy, where telemedicine measures allow the monitoring of vital signs during physical activity. Intensive engagement with the disease can be promoted, facilitating the transition to a normal everyday life. Several meta-analyses have demonstrated significant benefits of the use of telemedicine systems in cardiac rehabilitation, particularly in terms of physical performance, quality of life, and disease education [105-107].

Time is often critical when acute cardiac symptoms occur. Typical ECG changes (ST-segment or T-wave alterations) that occur in life-threatening myocardial infarction can be detected very quickly. Artificial intelligence algorithms are applied to

accelerate and simplify this crucial diagnostic procedure, which can even be performed when no physician is present [108-110]. In this way, we can obtain highly relevant clinical information, and the necessary therapeutic steps can be initiated as early as possible. This applies not only to the transmission of data collected by the patient through smartphones or other wearables but also to ECG transmissions in the context of emergency medical services. Typical ECG changes in myocardial infarction and arrhythmias can be recorded, or vital signs such as blood pressure or oxygen saturation can be transmitted [9]. A meta-analysis showed that telemedical ECG transmission reduces the door-to-balloon time (time from hospital admission to reopening of the infarct vessel) by up to 30 minutes, which reduces mortality in the short- and long-term [111,112]. Especially in rural areas, where medical services are often less accessible, the use of telemedical systems can offer an enormous advantage [113]. Even during the COVID-19 pandemic, digital medicine filled important gaps in patient care, as many patients avoided medical contact whenever possible [114]. Beyond the obvious benefits of optimized care for coronary artery disease, telemedicine systems offer a relevant saving potential in terms of health economics [115].

Arrhythmias

Under physiological conditions, cardiac action is triggered by the sinus node. From there, the cardiac action spreads through the atrial tissue to the atrioventricular node, from where it is transmitted to the ventricle. When this system is disturbed or in cases of automaticity, fibrosis, or scarring, cardiac arrhythmias occur, originating in either the atrium or the ventricle.

To detect cardiac arrhythmias, an ECG must be recorded whenever possible. If an episode of arrhythmia was not documented, a long-term ECG over 24 to 48 hours can be performed or the patient can be connected to permanent monitoring devices in the inpatient setting. If a cardiac arrhythmia can be confirmed, the therapy depends entirely on the type of arrhythmia. In the context of this review, we have limited ourselves to atrial fibrillation because other forms are rarely covered by studies in the field of digital cardiology.

Atrial fibrillation requires anticoagulation therapy to prevent the development of stroke. In addition, a strategy of rate control can be pursued, in which one accepts atrial fibrillation and uses only β-blocker therapy to counteract periods of rapid cardiac action. An alternative therapy goal is the conversion to normal sinus rhythm, the so-called rhythm control strategy. This can be performed by either electrical cardioversion or cardiac ablation (pulmonary vein isolation) [116].

Digital medicine offers far-reaching possibilities for the diagnosis of cardiac arrhythmia. The steady availability of spontaneous ECG recordings through smartwatches and other wearables has significantly facilitated the detection of rare rhythm events or assignment of symptoms to ECG images. A total of 83 publications, including 13 reviews or comments, addressed the applications of digital medicine in cardiac arrhythmias. Keywords from these papers map the monitoring and detection of arrhythmias, especially atrial fibrillation, by wearables as priority topics (Textbox 1).

The focus of digital applications in relation to cardiac arrhythmias is diagnostics. The current standard for the detection of arrhythmias is long-term ECG recordings or, in selected cases, the implantation of a loop recorder. Typical indications are unexplained syncope, the identification of atrial fibrillation in patients after (cryptogenic) stroke, or arrhythmias of any kind in the phase after an acute myocardial infarction [117]. However, today's technology has set a path for significant change in the near future. Modern wearables offer recordings of cardiac rhythm mainly by photoplethysmography as well as ECGs with high resolution [118,119]. Using special algorithms based on heart rate variability and artificial intelligence, atrial fibrillation can be detected automatically in many cases, reaching a positive predictive value of ≥90% [120-122]. Large screening examinations for congenital arrhythmias or for monitoring of cardiomyopathies are feasible via telemedicine devices [123,124]. In addition, recent technical innovations have enabled rhythm diagnostics via special electrodes in shirts [125].

Patients with implanted pacemakers or defibrillators require regular follow-up. To reduce costs and increase patient comfort, this can be performed at least partially via remote monitoring [25]. Furthermore, it allows for intensified monitoring and earlier detection of possible malfunctions or cardiac arrhythmias.

In the therapeutic field, the applications of digital medicine for cardiac arrhythmias are still limited. First, there is certainly frequency monitoring in patients with atrial fibrillation [126]. Particularly in medically underserved areas or during the COVID-19 pandemic, digital procedures were able to ensure guideline-compliant patient care, which also led to an overall increase in the quality of life of affected patients [127]. In addition, there are now some smartphone apps that remind patients to take their anticoagulation therapy to prevent stroke, provide information about the therapy, and in some cases even provide specific recommendations for dose adjustments [128]. There are also approaches to smart medication lists beyond anticoagulation, which can improve both patient comfort and the medical treatment itself [129]. Similar to other CVDs, the transition from inpatient care during ablation treatment to outpatient care for patients with atrial fibrillation can be improved by telemedicine techniques: patients gain quality of life, recurrences are detected earlier, and overall, there is an increase in physical performance [130].

In the future, the detection of cardiac arrhythmias using smartwatches and other wearables will become more important. However, when detecting atrial fibrillation via optical sensors (photoplethysmography), as they are used in the Apple Watch, for example, we should always keep in mind that false alarms may occur and demand diagnostic confirmation via ECG recordings [122]. Nevertheless, the wide applicability offers a great advantage in arrhythmia detection that cannot be achieved by alternative methods [121,131].

Congenital Heart Diseases

Almost 1% of newborns in industrialized countries have congenital heart defects. A basic distinction is made between cyanotic (blue skin in the presence of hypoxia) and acyanotic heart defects. The most common pathologies include defects in

the ventricular or atrial septum (acyanotic), tetralogy of Fallot (cyanotic), and patent ductus arteriosus (acyanotic).

The most relevant cardiac defects are diagnosed during the prenatal examinations. However, it also happens that individual defects are detected only during birth. The essential examination procedures for the diagnosis of cardiac defects include auscultation of heart murmurs and echocardiography to confirm the diagnosis. Depending on the anatomical characteristics and severity of the defect, most corrections are performed via cardiac surgery or interventional procedures by the treating pediatric cardiologists. The only exception is patent ductus arteriosus, which can usually be closed using targeted drug therapy.

Diagnosis of congenital heart defects was the pioneering area of digital medicine in the field of cardiology (Table 1). Initial work on this topic was published in the early 1990s and totaled 79, including 12 reviews or comments [132]. Keywords from these publications focused on the telemedicine diagnosis of congenital heart defects using ultrasound (Textbox 1).

Timely diagnosis of congenital heart defects is crucial for the treatment of affected individuals. Therefore, high medical standards and a wealth of experience are of particular importance. Especially in smaller hospitals, in rural areas, or during the COVID-19 pandemic, bottlenecks in care can be compensated for by specialized physicians via telemedicine consultations or using artificial intelligence approaches [133,134]. Although the transmission of auscultation findings characterized the initial phase of digital cardiology, telemedicine specialist–guided ultrasound examinations dominate the field today [132,135,136]. This ensures high-level diagnostics regardless of the location, and, at the same time, training is provided to physicians who have less experience with relevant clinical pictures [137,138]. These modern approaches can not only reduce severe disease progression with long hospital stays by about 50% but also facilitate the early detection of cardiac defects, allowing significant cost savings [139].

Patients with congenital heart defects often require special care throughout their life. This is especially true in stressful situations such as surgery and physical activities. Telemedicine has enabled a unique network in outpatient care; affected persons can be closely monitored via wearables in their home environment and always have the option of obtaining further information or consulting a physician directly [140]. Initial investigations of home care suggested that the mortality of patients with congenital heart defects can be slightly reduced [141,142]. In addition, telemedicine in combination with wearables makes it possible to provide patients with individual training programs, thus increasing not only performance but also quality of life under controlled conditions [143,144].

Valvular Heart Diseases

Heart valve diseases are defects in the closing or opening functions of at least one of the 4 heart valves. Indicators of potential heart valve defects can be obtained from auscultation using a stethoscope. The definite diagnosis is confirmed by ultrasound examination of the heart, which also allows for severity quantification. Valvular heart diseases are usually treated conservatively until they reach a relevant degree of severity. Therefore, patients with valvular defects need to be evaluated regularly with respect to exercise capacity, vital signs, laboratory parameters, and echocardiography findings to detect possible deterioration over time. Once the relevant severity of the defect is reached, younger patients are usually treated surgically, and older patients are usually treated by an interventional approach in the cardiac catheterization laboratory [145].

Acquired valvular heart diseases play important roles in everyday medical practice. A total of 32 publications, including 4 reviews, investigated digital technologies in this field. Similar to keywords related to congenital heart defects, the keywords focus on telemedical remote diagnostics using echocardiography (Textbox 1).

Beyond technical innovations in the field of image acquisition and processing, telemedicine remote diagnosis of echocardiography and artificial intelligence algorithms for automated analyses have yielded promising results [146-148]. In vitro model experiments have used special flow sensors in the ascending aorta; via continuous measurement techniques, these sensors were able to independently indicate the development of valvular heart diseases that require treatment [149]. Although this method is still far from use in humans, it offers insights into future diagnostic potential. In the context of the COVID-19 pandemic, in medically underserved areas, or to increase the quality of care in emergency departments, the use of digital technology in ultrasound examinations has experienced a significant upswing [150,151]. In parallel with the increasing use of remote telemedicine diagnostics by consulting experts, robotic systems have been tested to perform echocardiography [152,153]. Technological innovations such as automated acquisition of myocardial stiffness, among other measures of diastolic function, are being tested and show promising initial results [154].

The therapeutic applications of digital medicine in valvular heart diseases are limited. Nevertheless, the application of intelligent decision support systems seems to gain increasing clinical importance. In addition to technical data and guideline recommendations, past experience and patient preferences can be incorporated [155].

Discussion

Overview

Digital medicine in diagnostics and therapy for CVDs has experienced considerable upswing, particularly in the last 10 to 15 years. Political measures, such as adapted legislation, and special funding programs have laid a significant foundation for medical digitalization. In addition, there is a growing affinity among the population for innovative technical solutions and a more differentiated view of data protection concerns.

Beyond the structural conditions described in the previous paragraph, external circumstances have provided an additional boost to digital medicine. These factors include the shortage of physicians in rural areas and the COVID-19 pandemic during the last 3 years. Finally, the increased use of digital medicine is attributed to the advancing technology with the widespread

use of smartphones and other wearables as well as the exchange of information via the internet and video conferences as part of our everyday lives [156]. In the medical sector, in particular, digitalization is rapidly expanding, even if the interoperability of the existing systems and interfaces as well as a lack of standardization still represent significant obstacles.

This review provides an overview of all the present digital technologies in the cardiovascular field. This illustrates an enormous increase in knowledge and investigations in recent years with respect to optimized diagnostic and therapeutic strategies (Figure 3 and Table 2). We should not hesitate to face these opportunities and challenges in maintaining patient care at the highest possible standard. Thematic reappraisal, as previously described, is indispensable. Today, we are in a comfortable position to actively restructure and optimize our daily medical work.

Figure 3. Digital medicine in cardiology.

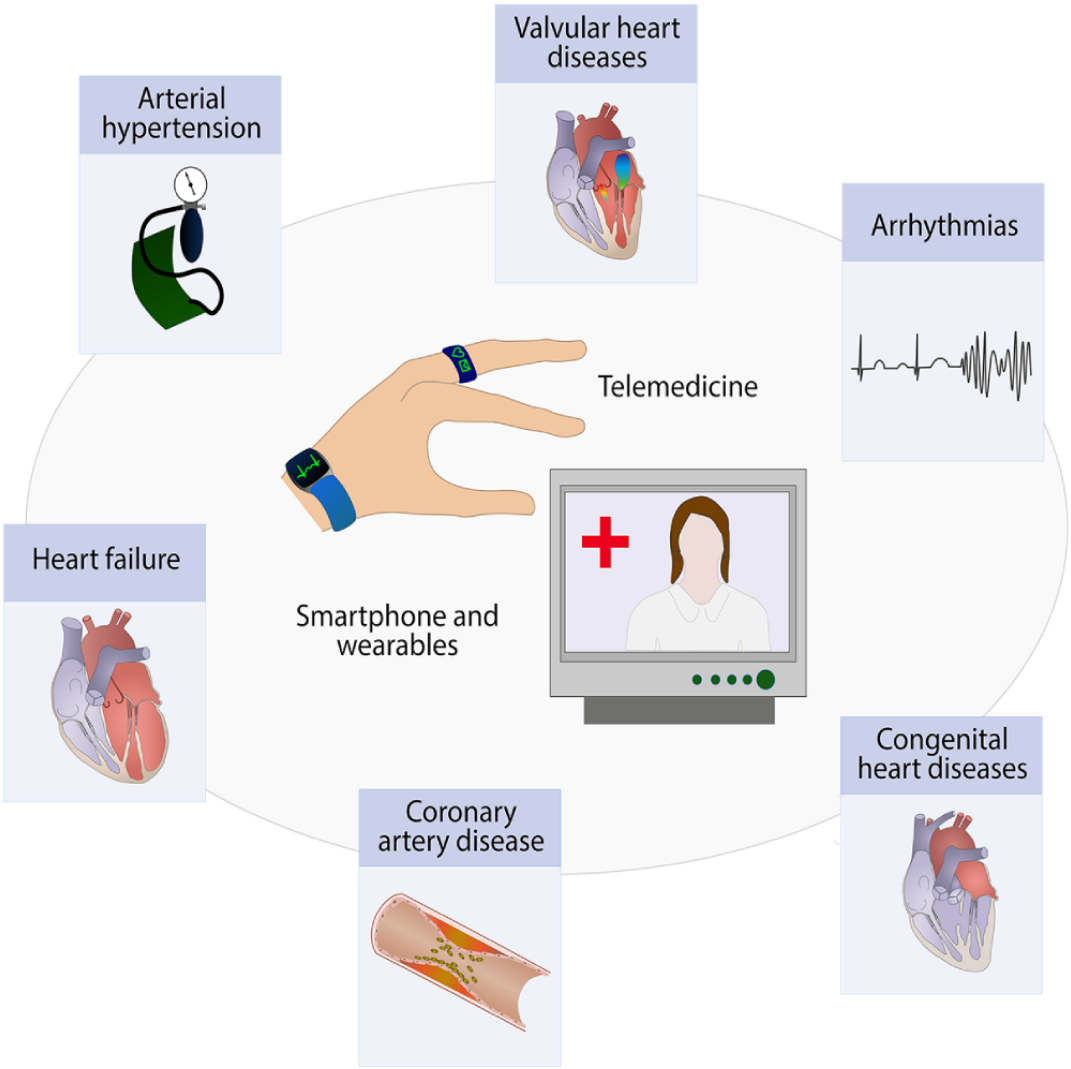


Table 2. Diagnostic and therapeutic use of digital technologies[a].

	Diagnostics		Therapy						
	Remote diagnosis	Events detection	Medication plan	Patient education	Remote rehabilitation	Training control	Prevent rehospitalization	Mortality	Costs
Heart failure	−	++	+++	++	++	++	++	+	−
Hypertension	+++	++	++	++	+	−	+	−	+
CAD[b]	+	++	+	++	+++	++	++	+	+
Rhythm[c]	+++	+++	+	+	−	+	+	−	+
CHD[d]	+++	−	−	−	−	++	−	+	+
VHD[e]	++	+	−	−	−	−	−	−	−

[a]+++, ++, and + indicate the degree of scientific evidence for positive effects on patient care, whereas − indicates negative results or missing data.

[b]CAD: coronary artery disease.

[c]Rhythm refers to arrhythmias.

[d]CHD: congenital heart disease.

[e]VHD: valvular heart disease.

Acute disease patterns such as myocardial infarction or sudden-onset arrhythmias can be documented via wearables and made accessible to remote telemedical diagnostics. With these modern methods, we have the unique opportunity to record short-term health conditions on demand or, as in the case of myocardial infarction, to save important time in the emergency cascade and thus reduce mortality.

The second major domain of digital technology in CVDs is related to diagnostics. Currently, it is possible to consult highly specialized medical experts for all types of questions regardless of the location. This was also the origin of digital technology in the cardiovascular field in the 1990s, when congenital heart defects were diagnosed via telemedicine expert consultations including guided echocardiography (Table 1). These remote diagnostic methods have been extended to many other cardiac pathologies and enable a very high medical standard even in rural areas or under the COVID-19–related restrictions.

In terms of cardiovascular therapy, digital technologies are expected to provide significant changes. Chronic diseases such as heart failure and arterial hypertension and secondary prophylaxis in coronary heart disease have huge health economic importance. Due to their high mortality, regular medical contact is essential for checking vital signs, adjusting medications, and detecting possible deterioration. Telemedicine offers a unique opportunity to replace these visits, at least in part, with digital consultations. Although immediate personal contact is certainly important and lost to some extent by telemedicine, more attention can be paid to the individual patient, travel time is reduced, and more patients can be treated by an individual physician. Detailed data records from wearables can be evaluated in a partially automated manner, highly up-to-date information about one's own illness can be made available, medication plans can be managed and adjusted digitally, and methods of artificial intelligence can be used to optimize treatment strategies. The transitional phases from inpatient to outpatient care or to rehabilitation therapy can also be decisively supported by digital systems. Patients report not only an improved quality of life but also better performance, although it is possible to register any early recurrences of diseases or other adverse events in a timely manner.

Nevertheless, the possible risk of a decline in routine personal visits or the complete avoidance of physician contact may also have negative effects and potentially harm the patient. In an individual case, a human second assessment of the digital diagnostics remains essential and beneficial, especially for evaluating potential erroneous conclusions of digital algorithms.

Finally, both the patient and the treating physician must be aware that a considerable amount of sensitive patient data are made available to companies involved in digital medicine. As long as the product is not medically or scientifically approved, protected and sensitive handling of patient data is not guaranteed, as opposed to insurance companies or medical institutions.

In terms of evidence-based facts, heart failure is the best-investigated field in digital cardiovascular research. Proper patient selection provided by telemedicine monitoring systems has been shown to cause a slight but significant reduction in hospitalization and mortality [17,18]. Moreover, the 30-day rehospitalization rate of patients with heart failure was significantly reduced from 24% to 17% to 18% [50,51]. Evidence for arterial hypertension programs is limited, but initial meta-analyses have shown an additional reduction in systolic blood pressure by approximately 4 mm Hg [91,92]. In the group of coronary artery disease, remote diagnostics and telemedicine ECG transmission have proven the potential to reduce the door-to-balloon time by up to 30 minutes in acute myocardial infarction; this has direct implications on mortality due to reduced cardiac ischemia time [111,112]. Telemedicine offers optimized diagnostics in 3 other cardiovascular domains, including arrhythmias, congenital heart diseases, and valvular heart diseases, whereas its effects on mortality have not been proven in larger trials so far.

Conclusions

Digitalization in cardiovascular medicine will certainly continue to gain importance in the near future, and it will be crucial to make the best possible use of these technologies. Today, the field of digital cardiovascular medicine has a strong focus on telemedicine technologies, as a lack of interoperability and standardization still limits applications such as automation and intelligent decision support systems, as well as modern medical IT-based research tools. Continual efforts will not only improve patient care but also have significant health economic saving potential for various CVD patterns. It is therefore important not to cling obsessively to old systems but to embrace innovations and actively help to shape them.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of randomized controlled trials on heart failure.
[DOCX File , 23 KB - cardio_v7i1e44983_app1.docx]

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Abbreviations

AMULET: A New Model of Medical Care With Use of Modern Methods of Non-invasive Clinical Assessment and Telemedicine in Patients With Heart Failure
BEAT-HF: Baroreflex Activation Therapy for Heart Failure
CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association Class III Heart Failure Patients
CVD: cardiovascular disease
ECG: electrocardiogram
EVOLVO: Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators
IN-TIME: Influence of Home Monitoring on Mortality and Morbidity in Heart Failure Patients With Impaired Left Ventricular Function
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
REM-HF: Remote Management of Heart Failure Using Implanted Electronic Devices
Tele-HF: Telemonitoring to Improve Heart Failure Outcomes
TIM-HF: Telemedical Interventional Monitoring in Heart Failure

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Review

Characterizing Real-World Implementation of Consumer Wearables for the Detection of Undiagnosed Atrial Fibrillation in Clinical Practice: Targeted Literature Review

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Abstract

Background: Atrial fibrillation (AF), the most common cardiac arrhythmia, is often undiagnosed because of lack of awareness and frequent asymptomatic presentation. As AF is associated with increased risk of stroke, early detection is clinically relevant. Several consumer wearable devices (CWDs) have been cleared by the US Food and Drug Administration for irregular heart rhythm detection suggestive of AF. However, recommendations for the use of CWDs for AF detection in clinical practice, especially with regard to pathways for workflows and clinical decisions, remain lacking.

Objective: We conducted a targeted literature review to identify articles on CWDs characterizing the current state of wearable technology for AF detection, identifying approaches to implementing CWDs into the clinical workflow, and characterizing provider and patient perspectives on CWDs for patients at risk of AF.

Methods: PubMed, ClinicalTrials.gov, UpToDate Clinical Reference, and DynaMed were searched for articles in English published between January 2016 and July 2023. The searches used predefined Medical Subject Headings (MeSH) terms, keywords, and search strings. Articles of interest were specifically on CWDs; articles on ambulatory monitoring tools, tools available by prescription, or handheld devices were excluded. Search results were reviewed for relevancy and discussed among the authors for inclusion. A qualitative analysis was conducted and themes relevant to our study objectives were identified.

Results: A total of 31 articles met inclusion criteria: 7 (23%) medical society reports or guidelines, 4 (13%) general reviews, 5 (16%) systematic reviews, 5 (16%) health care provider surveys, 7 (23%) consumer or patient surveys or interviews, and 3 (10%) analytical reports. Despite recognition of CWDs by medical societies, detailed guidelines regarding CWDs for AF detection were limited, as was the availability of clinical tools. A main theme was the lack of pragmatic studies assessing real-world implementation of CWDs for AF detection. Clinicians expressed concerns about data overload; potential for false positives; reimbursement issues; and the need for clinical tools such as care pathways and guidelines, preferably developed or endorsed by professional organizations. Patient-facing challenges included device costs and variability in digital literacy or technology acceptance.

Conclusions: This targeted literature review highlights the lack of a comprehensive body of literature guiding real-world implementation of CWDs for AF detection and provides insights for informing additional research and developing appropriate tools and resources for incorporating these devices into clinical practice. The results should also provide an impetus for the active involvement of medical societies and other health care stakeholders in developing appropriate tools and resources for guiding the real-world use of CWDs for AF detection. These resources should target clinicians, patients, and health care systems with the goal of facilitating clinician or patient engagement and using an evidence-based approach for establishing guidelines or frameworks for administrative workflows and patient care pathways.

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KEYWORDS

arrhythmias; atrial fibrillation; clinical workflow; consumer wearable devices; smartwatches; wearables; remote patient monitoring; virtual care; mobile phone

Introduction

Background

Consumer wearable devices (CWDs) are increasingly being used to monitor fitness and personal health in daily life. Many of these devices have also incorporated medical technology and algorithms to provide alerts for specific physiological changes or abnormalities. There has been early recognition of the potential value of wearable devices in the cardiology setting, especially for cardiac arrhythmias, and key issues have been raised on establishing workflows to process and act on the obtained data [1]. Despite this early recognition, the infrastructure and processes for implementing these devices into clinical practice have not been fully developed.

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting an estimated 3 to 6 million individuals in the United States and approximately 46 million people worldwide [2]. Older age has been identified as a primary predisposing factor for AF, and thus, its prevalence is expected to increase owing to the aging of the population [2]. Of particular clinical relevance is that AF is associated with a 4- to 5-fold increase in the risk of stroke [2], which is a leading cause of disability and results in substantial morbidity, mortality, and socioeconomic burden [3,4]. Consequently, the clinical focus on early detection and appropriate management of AF is considered an important component in reducing the subsequent risk and burden of cerebrovascular events, with evidence suggesting that early AF detection and treatment can lead to a 70% reduction in the risk of stroke [5].

Early detection of AF may be especially relevant as it is underrecognized and often undiagnosed because of the frequently asymptomatic nature of this arrhythmia [6,7]; as many as one-third of individuals with AF may be asymptomatic. However, the clinical consequences of asymptomatic AF are likely to be at least similar to those of symptomatic AF, with AF commonly diagnosed based on the occurrence of stroke or other AF sequelae [6]. It has also been reported that asymptomatic AF may be associated with an approximately 3-fold higher risk of cardiovascular and all-cause mortality than symptomatic AF even after adjusting for confounding factors, such as age and CHA2DS2-VASc (congestive heart failure, hypertension, age 75 years and older, diabetes, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex category) score, calculated as congestive heart failure, hypertension, age 75 years and older, diabetes, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex category [8]. Despite the underrecognition of AF and the increased risk of stroke, current evidence on the benefits and harms of AF screening is considered insufficient to determine whether widespread screening should be conducted [9].

Several CWDs have been cleared by the US Food and Drug Administration (FDA) for irregular heart rhythm detection suggestive of AF, including Apple Watch (Apple) [10,11], Galaxy (Samsung) [12], Fitbit (Google) [13], ScanWatch (Withings) [14], and Venu 2 Plus (Garmin) [15]. Although FDA clearance language for CWDs is to detect “irregular heart rhythm suggestive of atrial fibrillation” [10], the use of the term “AF notification” is generally accepted nomenclature in both the medical and lay literature when referring to notifications from CWDs that could be suggestive of AF. Although FDA approval requires rigorous evaluation of the safety and efficacy of pharmaceutical and biological products for high-risk medical devices (class 3), FDA clearance is used for class-2 devices such as CWDs that are considered to be of moderate risk. FDA clearance is granted when the manufacturer has demonstrated that their product is “substantially equivalent to a legally marketed predicate device that does not require premarket approval.” Class-2 devices are also subject to special controls such as specific testing or labeling requirements [16].

The use of mobile devices may be dependent on the type of device and the population [17]. Results from the Apple Heart Study [18] and the Fitbit Heart Study [19] demonstrated that these devices have the ability to identify individuals in the general population who are likely to have AF on subsequent electrocardiogram (ECG) patch monitoring. However, evaluation in patients with known AF has indicated variability in the sensitivity of the Apple device [20,21], which was also supported by a real-world validation study of 5 smart devices that suggested their reduced sensitivity and specificity [22]. Furthermore, the overall value of the widespread use of CWDs such as the Apple Watch for AF detection in the general population has been questioned, with a suggestion that accessing clinical and demographic data from electronic health records (EHRs) could help target these devices to a population that would obtain higher potential benefit of use [23].

Although the value of CWDs for early AF detection to improve outcomes is being further evaluated [24], the potential application of CWDs within the context of AF detection has received limited recognition by medical societies at least in part because of the relatively new nature of this innovative technology and a still developing body of evidence. Although the Heart Rhythm Society (HRS), in a published white paper, provided a meaningful discussion of the benefits and uncertainties of CWDs relevant to specific clinical scenarios encompassing a variety of patient situations [25], they also indicated that more research is needed on how CWDs could best be used. Similarly, a position paper from the European Society of Cardiology (ESC) working group on e-cardiology [26] as well as a collaborative statement from the International Society for Holter and Noninvasive Electrocardiology (ISHNE)/HRS/ European Heart Rhythm Association (EHRA)/and Asia Pacific HRS (APHRS) [27] described the potential role and limitations of these devices in relation to the existing status and operational challenges of mobile health technologies in arrhythmia management. The EHRA also published a practical guide that focused on when and how to

use various digital technologies, including CWDs, to detect and manage arrhythmias in different clinical scenarios [28].

The aforementioned papers highlight the need for detailed guidelines on how primary care physicians or cardiologists should use, interpret, or act on information from wearables and are consistent with the key issues that have been previously raised [1]. In a broader sense, these papers underscore that widespread availability of support for real-world implementation of CWDs into clinical and administrative workflows has been lacking as the infrastructure for guiding workflow and subsequent pathways for clinical decisions has not been uniformly established. Thus, greater characterization of these gaps and how they can be filled can facilitate the development of tools for informing patients and clinicians on the use of CWDs and providing guidance to clinicians on data management and appropriate patient follow-up. Such tools could potentially guide the establishment of pathways of administrative workflow among stakeholders, including patients, clinicians, and health care systems.

Objectives

As a step toward bridging these gaps, our objective was to conduct a targeted literature review to identify articles on CWDs that would enable us to determine the extent of current knowledge on how CWDs can be used for AF detection. Our focus was on three targeted questions: (1) "What is the current state of wearable technology in the use of AF detection?" (2) "What are the operational and technical approaches to implementing wearable technology into clinical workflows?" and (3) "How do healthcare providers and patients view wearable technology for patients with risk of AF?" Rather than reviewing clinical or validation studies on CWDs, these questions were derived with the intent of gleaning information that may be actionable for developing processes and pathways for implementing these devices in clinical practice.

Methods

Search Strategy and Selection Criteria

Initial searches were conducted in October 2021 and November 2021 using a combination of Medical Subject Heading (MeSH) terms and keywords (words in the title or abstract), including "remote monitoring," "telemonitoring," "wearable device," "wearable," "smart watch," "heart rate," "arrythmia," and "atrial fibrillation." To provide an update, additional searches were conducted in August 2023. All authors contributed to developing search terms under the guidance of JKS and SNH. A full list of the search terms and strings that were used for the searches addressing each of the questions is provided in Tables S1-S4 in Multimedia Appendix 1. The searches were for articles in English only that were published between January 2016 and July 2023. The databases that were searched were MEDLINE via PubMed and the gray literature sources ClinicalTrials.gov, UpToDate Clinical Reference, and DynaMed. For citations considered potentially relevant based on a review of titles and abstracts, the full-text articles were obtained for further review.

Our focus was on articles that applied to real-world implementation of CWDs for AF detection, especially the processes or pathways enabling such implementation. Articles exclusively reporting on or discussing ambulatory monitoring tools, tools available by prescription (eg, Zio Patch monitors), or handheld devices (eg, KardiaMobile) were excluded, as were articles that only tested or reported on detection algorithms or discussed CWDs within the general context of mobile health or digital technology. Other reasons for exclusion of returned citations were the citations being meeting abstracts, validation or clinical studies, study protocols, or deemed out of scope; the reasons for exclusion of full-text articles were insufficient discussion of CWDs or failure to address the targeted questions.

Collection and Extraction

One author (EK) conducted the searches and reviewed the first-pass results with another author (MA). After this initial assessment, all authors met weekly to review the results and discuss the articles for inclusion or exclusion based on the aforementioned criteria. Subsequent weekly meetings focused on article review and data extraction. The bibliographies of the included articles were further reviewed for any additional potential articles of interest. A qualitative analysis of the included articles was conducted, and we identified emerging themes deemed to be relevant for addressing the 3 targeted questions posed as our study objectives.

Results

Search Results

On the basis of the search terms in Tables S1-S4 in Multimedia Appendix 1 and as shown in the flow diagram (Figure 1), the initial search strategies returned 2871 citations, and the updated searches returned another 3381 citations (Figure 1). After deletion of 12.96% (810/6252) of duplicates and review of the remaining records, of the 6252 citations, 85 (1.36%) articles were identified for full-text review, of which 26 (31%) were identified for final inclusion, with another 4 identified from bibliographic review (Table 1). Of these 31 articles, 7 (23%) were reports or guidelines from medical societies [27-33], 4 (13%) were general reviews [1,2,34,35], 5 (16%) were systematic reviews [5,36-38], 5 (16%) were health care provider surveys [39-43], 7 (23%) were consumer or patient surveys or interviews [44-48], and 3 (10%) were analytical reports [49-51]. Of these 31 articles, 3 (10%) were from AF-SCREEN, which is a professional organization that advocates for discussion and research on screening for unrecognized or undertreated AF and included a white paper published in 2017 [29], a health care provider survey published in 2020 [39], and a review or report published in 2022 [32].

Figure 1. Flow diagram of the included articles. *Reasons for exclusion included the articles being algorithm studies, meeting abstracts, validation or clinical studies, study protocols, or out of scope. **Reasons for exclusion included insufficient discussion of customer wearable devices and failure to address the targeted questions.

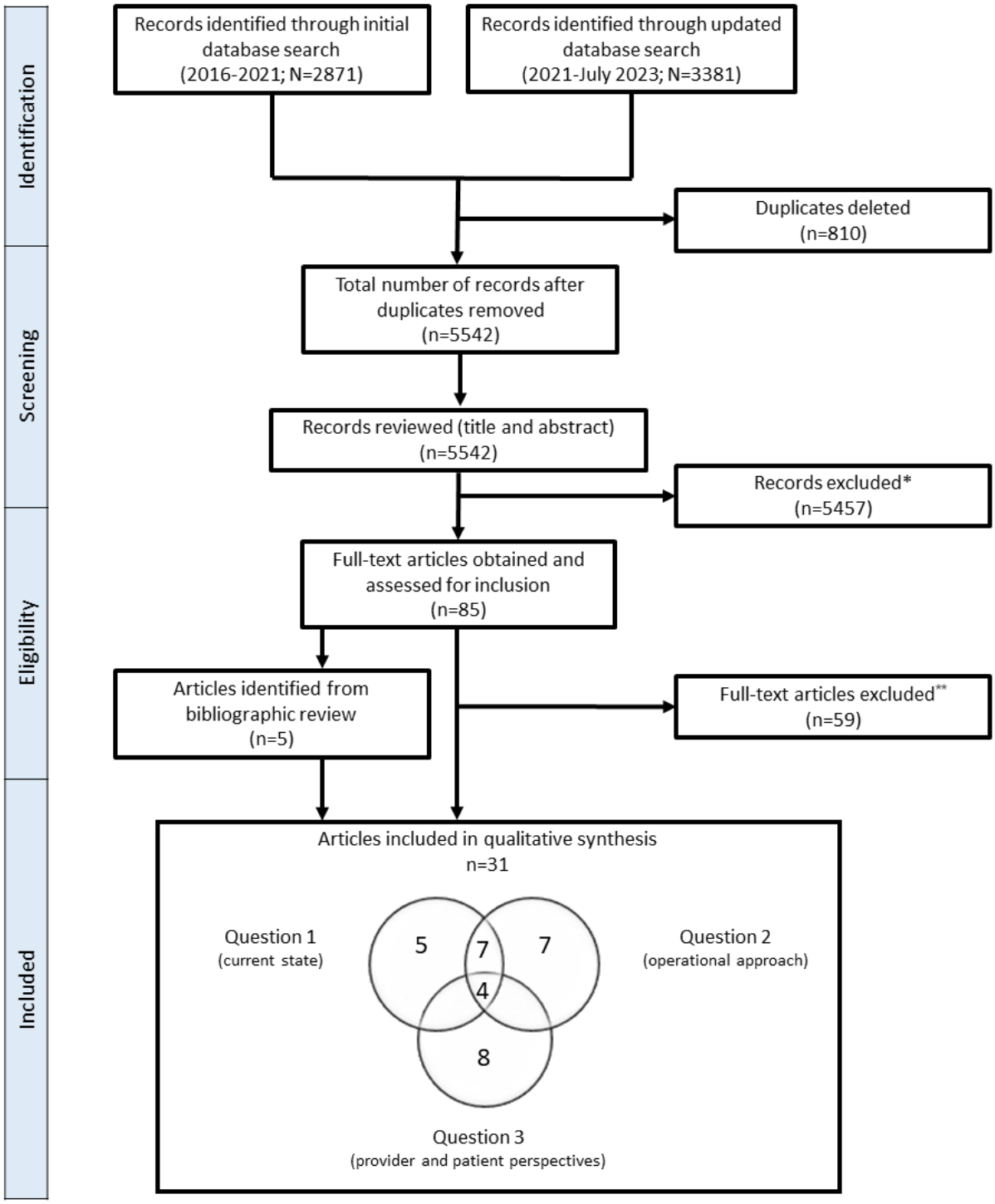

Table 1. Chronological list of the 31 articles identified for final inclusion.

Study, year	Article type	Targeted question addressed[a]
Freedman et al [29], 2017	Medical society report	2
Scott Kruse et al [36], 2018	Systematic review	2
Al-Alusi et al [1], 2019	General review	1 and 2
January et al [30], 2019	Medical society guideline	2
Boriani et al [39], 2020	Provider survey	1, 2, and 3
Chandrasekaran et al [44], 2020	Consumer survey	3
Ding et al [34], 2020	General review	1 and 2
Ding et al [40], 2020	Provider survey	1, 2, and 3
Inui et al [50], 2020	Analytical report	2
Kornej et al [2], 2020	General review	1
MacKinnon and Brittain [35], 2020	General review	1 and 2
Manninger et al [41], 2020	Provider survey	1, 2, and 3
Predel and Steger [49], 2020	Analytical report	1
Hills [46], 2021	Patient survey	3
Hindricks et al [31], 2021	Medical society guideline	2
Lopez Perales et al [17], 2021	Systematic review	1
Manninger et al [42], 2021	Provider survey	1, 2, and 3
Nazarian et al [37], 2021	Systematic review	1
Nuvvula et al [45], 2021	Patient survey	3
Prasitlumkum [5], 2021	Systematic review	1
Smuck et al [51], 2021	Analytical report	2
Varma et al [27], 2021	Medical society report	2
Boriani et al [43], 2022	Provider survey	3
Brandes et al [32], 2022	Medical society report	1 and 2
Ding [52], 2022	Clinical trial with patient survey	3
Faro et al [47], 2022	Patient survey	3
Hermans et al [38], 2022	Systematic review	1 and 2
Leclercq et al [33], 2022	Medical society report	1 and 2
Shih et al [48], 2022	Consumer interviews	3
Svennberg et al [28], 2022	Medical society guidance	1 and 2
Dhingra et al [53], 2023	Cross-sectional population survey	3

[a]Targeted question 1: "What is the current state of wearable technology in the use of AF detection?"; targeted question 2: "What are the operational and technical approaches to implementing wearable technology into clinical workflows?"; targeted question 3: "How do health care providers and patients view wearable technology for patients with risk of AF?"

Targeted Question 1: What Is the Current State of Wearable Technology in the Use of AF Detection?

Technology Options

Detection of AF has traditionally involved the use of a 12-lead ECG or ambulatory ECG monitors such as 24-hour Holter monitoring, and implantable cardioverter defibrillators may be used for long-term monitoring of patients [5,35,37]. However, the value of these methods, especially short-term monitoring for detection, is limited because of the episodic and transient nature of AF as the episodes may not necessarily be captured within the investigation period. The American College of Cardiology, American Heart Association, and HRS guidelines on AF developed before the introduction of CWDs emphasized the potential need for prolonged or frequent monitoring to detect episodes of asymptomatic AF [5,54]. The advent of digital technology has introduced a wide range of mobile devices, including handheld devices, implantable loop recorders, ECG patches, and CWDs, that may be appropriate for use in the cardiology setting under a variety of scenarios [28]. CWDs offer a passive and near-continuous approach to health monitoring

that can set individuals on a path toward the recognition of AF and identify those who may have asymptomatic presentation of AF. CWDs also allow patients to play a greater role in disease detection [37], with diagnosis ultimately confirmed by their clinician. This approach may also be considered cost-effective for individuals aged >65 years, with calculated cost-effectiveness ratios substantially below conventionally used thresholds indicative of cost-effectiveness [34].

The ability of CWDs to detect AF relies on photoplethysmography (PPG) sensors or a single-lead ECG sensor (Textbox 1), with some CWDs having both systems. PPG is an optical measurement technique that uses a light source and a photodetector, whereas ECG sensors are based on the detection of electric signals. In contrast to ECG, PPG has the potential advantage of passive, near-continuous monitoring [34]. In devices with both PPG and ECG, a PPG notification can be followed by the individual actively conducting an ECG on the device to characterize the waveform, which can then be shown to and interpreted by a clinician during a follow-up. Therefore, these devices may be especially useful for improving early diagnosis in individuals with asymptomatic or paroxysmal AF with short episodes [2]. A review by Al-Alusi et al [1] in 2019 described the early landscape of wearable monitors in the cardiology setting, including a discussion of key questions and challenges that need to be addressed for their implementation. On the basis of the digital technology landscape, the EHRA practical guide provided a flowchart with suggestions for when and how to screen for AF using wearable devices in different populations and clinical scenarios [28].

Textbox 1. Summary of sensor technology used in consumer wearable devices (CWDs) to detect atrial fibrillation (AF).

Electrocardiogram (ECG) sensors (Apple Watch, Fitbit, Galaxy, ScanWatch, and Venu 2 Plus)

- They measure electrical activity of the heart.
- Single-lead ECG devices may represent a cost-effective method for AF detection.
- Using the ECG sensor requires a person to touch the dial (electrode) on the device using their other hand.

Photoplethysmographic (PPG) sensors (Apple Watch, Fitbit, and ScanWatch)

- They use light to measure volume changes in microvasculature to monitor heart rate.
- CWDs may have either 2 or 4 PPG sensors.
- The ability for near-continuous monitoring may be an advantage of PPG sensors relative to ECG sensors.

CWD Confidence and Concerns

Reviews of digital health technology mentioned the importance of evaluating and establishing the accuracy of such devices [1,27,28,32-34,38]. In particular, the accuracy of CWDs in detecting arrhythmia consistent with AF is integral for instilling confidence in these devices, and this concern was also expressed in some manner in clinician surveys [39-42]. Although randomized controlled trials (RCTs) represent the gold standard for assessment, the number of RCTs that measured the accuracy of CWDs was limited. However, systematic reviews and meta-analyses of non-RCT studies have reported good accuracy. In one meta-analysis that included 5 observational studies of smartwatches, the sensitivity and specificity were 93% and 94%, respectively, and PPG provided slightly better diagnostic accuracy than single-lead ECG, although there was heterogeneity among the studies [5]. Another review of 18 studies, nearly all of which used PPG, estimated that the sensitivity, specificity, and accuracy of smartwatches for the detection of cardiac arrhythmias were 100%, 95%, and 97%, respectively [37]. These analyses support the high diagnostic accuracy of this technology for the detection of cardiac arrhythmias and can convey an increased level of confidence in their use. Both analyses also emphasized the need for further evaluation of "clinical implications and generalizability," especially given that the technology is noninvasive [5], and the need "to clearly define the ideal population for the use of these systems, as well as to help form specific guidance on the conduct of device-detected disease" [37]. Other systematic reviews of mobile health technologies for AF detection also emphasized the need to target appropriate populations and evaluate clinical outcomes, especially as, despite their generally favorable accuracy, there is the potential for variability depending on how and in whom the device is used [17,38]. This variability further suggests that the comparative effectiveness of the devices should be established in appropriately designed studies [17].

Because of new and novel use of CWD technology for AF notifications, there are few published studies on incorporating these devices into clinical workflows even though the importance of and need for developing the infrastructure for such workflows was recognized in an early review of this technology [1]. In particular, Nazarian et al [37] highlighted that guidance is lacking on what the clinician is expected to do when an individual receives and reports an AF notification. Associated with this lack of guidance is that, even with the high reported accuracy of CWDs, concerns have been raised regarding the potential for false positive rates for AF, which may lead to anxiety, additional health care costs, and potentially inappropriate treatment [34,49]. This type of notification calls into question how to manage the patient population, and recommendations for such management have included the development of appropriate criteria and tools or the use of existing tools such as the Cohorts for Heart and Aging Research in Genomic Epidemiology model for AF (CHARGE-AF) to further guide detection and diagnosis [34]. Other suggestions have been to prioritize individuals at high risk or use threshold criteria that could include age or other risk factors [34], although the use of age-related criteria may represent its own challenge as an older age group may be less accepting of new technology

[34,49]; a recent estimate suggests that, in the United States, only 4.6% of smartwatch users are aged ≥65 years [49].

Several articles indicated that there are limited pragmatic studies measuring real-world applications of CWDs [32,34,37,51]. Furthermore, of the few available studies, many excluded data because of insufficient PPG signal quality or were conducted in settings in which individuals were supervised and provided with instructions, thereby introducing potential bias and reducing real-world generalizability [37]. Consequently, as reported by Ding et al [34], there is a need for additional studies to evaluate the deployment, support, and communication strategies for successful AF detection programs using mobile or digital technologies. The review of consumer-led screening for AF published by AF-SCREEN in 2022 also indicated the need for evaluating clinical outcomes associated with consumer-led screening as these outcomes currently remain unknown [32]. This lack of hard end points in the evaluation of CWDs for AF detection has been previously noted in the ISHNE/HRS/EHRA/APHRS statement [27].

Targeted Question 2: What Are the Operational and Technical Approaches to Implementing Wearable Technology Into Clinical Workflows?

Current Approaches

Established or recommended operational and technical guidelines for incorporating CWD AF notifications into the clinical workflow may facilitate consistent patient follow-up and disease management and concomitantly reduce the administrative burden. A specific need for appropriate infrastructure to accommodate workflow was recognized [1], and the updated American College of Cardiology, American Heart Association, and HRS guidelines for management of patients with AF acknowledged that “a role in screening for silent AF may also exist for remote electrocardiographic acquisition and transmission with a ‘smart’ worn or handheld WiFi-enabled device with remote interpretation” [30]. However, these guidelines do not provide specific recommendations for AF detection or practical considerations guiding the incorporation of notifications from such worn or handheld devices into the clinical workflow. Similarly, the ISHNE/HRS/EHRA/APHRS statement mentioned clinical workflow as a component for incorporating mobile health technologies into clinical care but did not offer any recommendations for establishing infrastructure or processes [27].

In the AF-SCREEN white paper from 2017, a proposed screening framework was considered with the additional suggestion of linking to existing workflows [29]. In total, 2 international surveys by Manninger et al [41,42], one published in 2020 and the other in 2021, yielded more practical insights on how clinicians, including electrophysiology specialists, electrophysiology team leaders, cardiologists, and other clinicians, approach incorporating CWDs into clinical practice. In the earlier survey of 417 clinicians, respondents reported that tracings from CWDs suggestive of AF would likely trigger further diagnostic steps, although these “steps” were unspecified in the survey. In the later survey of 539 clinicians comprising the same specialties as the earlier survey, respondents generally reported that they relied on a 12-lead ECG as the next step. AF tracing notifications from a CWD in a symptomatic individual with AF would more likely result in the initiation of anticoagulation treatment than in an asymptomatic individual (59% vs 21%; $P<.001$), whereas PPG recordings would rarely trigger therapeutic intervention. However, the absence of studies assessing therapeutic consequences “from an incidentally diagnosed AF” has also been noted [38].

Subsequent to the studies by Manninger et al [41,42], the 2022 review by AF-SCREEN provided one of the first proposals for a diagnostic clinical pathway following a mobile health AF notification and expanded on the next steps by emphasizing the need for appropriate follow-up regardless of whether the notification was from an ECG or PPG device [32]. The pathway also provided guidance to clinicians depending on whether AF was confirmed (initiate integrated care) or refuted (reassure the patient). The need for guidance on wearable devices was also recognized by the EHRA [28], which proposed pathways that encompassed several important components such as guiding decisions on when and how to choose an appropriate device stratified by patient risk; digital management of AF; and describing the patient’s digital journey, including assessment, AF confirmation, workup and education, and longer-term management. However, the lack of details on how to operationalize wearable devices into clinical and administrative workflows (eg, integrating wearable data with EHR documentation) warrants additional resource development to guide health care systems and other stakeholders.

In the second survey by Manninger et al [42], respondents additionally recognized the need for integration of CWD data into the clinical workflow as well as a need for reimbursement policies to compensate health care providers for collecting and interpreting data. Respondents generally preferred manual incorporation into the workflow: 63% added descriptions of the recordings to the patient’s record, 53% manually uploaded recordings, and only 15.5% used an external platform to access the data. Despite the caveat regarding the lack of workflow recommendations, most respondents (74%) supported systematic screening for AF using CWDs and would diagnose AF based on single-lead ECG (83%) rather than PPG (27%). In contrast, the 2022 AF-SCREEN report did not discuss specific processes necessary for the implementation of CWDs into clinical and administrative workflows, although it did recognize that consumer-led screening could potentially facilitate the early diagnosis of AF and indicate the need for regulatory pathways [32].

Challenges and Barriers

The purpose of the published ISHNE/HRS/EHRA/APHRS statement was to define current mobile health technology and outline important challenges and barriers to its incorporation into the clinical workflow [27]. Not surprisingly given the newness of CWDs for AF detection and the lack of pathways guiding their clinical use, the challenges and barriers identified were similar to those consistently noted in other reviews [1,32,33,38]. One of the main barriers was related to workflow, specifically calling out that implementation of mobile health

"will require defined aims and fundamental changes to existing workflows and responsibilities" [27]; the need for redefining workflows rather than leveraging current systems has also been suggested to avoid volume overload [1]. Transparency of information was another challenge that affects all stakeholders but may be of particular importance to consumers using these devices as the process of data transparency and accessibility was considered likely to improve engagement between the consumer and the health care system even in the absence of direct actionability by the consumer [27]. In addition to data transparency, the need for ensuring data security and privacy was considered an important challenge for the implementation of wearable devices from the perspective of all stakeholders, including patients [1,27,28,32,33,38].

A systematic review by Scott Kruse et al [36] identified barriers to the implementation of telemedicine such as leadership buy-in, clinician confidence in effectiveness, educating staff, and teaching consumers how to use the technology and access telemedicine. These factors, especially the issue of confidence in effectiveness (ie, accuracy), were also generally recognized as barriers by clinicians in the clinician surveys published subsequent to the review [39-42]. The review further ranked organizational- and consumer-related barriers based on frequency of report [36]. Interestingly, neither workflows nor implementation models were among the top 5 organizational barriers, which included cost, reimbursement, legal liability, privacy or confidentiality, and security of data. However, although most of the studies included in the review were from the United States, other geographic regions were represented that may not necessarily reflect the perspectives of the US health care system. The top 5 barriers that may impede consumer implementation included age, level of education, computer literacy, internet availability, and unawareness of telemedicine products and services. Individual devices may also be associated with specific challenges owing to differences in methods of data collection and device performance [50]. Many of these challenges were echoed in the review or report of digital technology resulting from an ESC roundtable workshop [33].

Overcoming Challenges and Barriers

The same ISHNE/HRS/EHRA/APHRS statement that identified challenges and barriers also considered several operational factors that need to be met to overcome these barriers to the successful implementation of mobile health technologies into clinical care [27]. A key factor, which was considered as yet unresolved, was the transmission of data to the clinician, with concerns regarding both logistics (manner of transmission) and practicality (potential for data overload). Other operational needs involved information sharing owing to the lack of organized infrastructure for receiving and managing data as well as for transmitting data and instructions to consumers. Such issues of information sharing likely require a closer interface with EHRs, including the development of defined pathways for sharing and incorporating data. Resolving issues related to cybersecurity was also considered integral to allaying concerns of health care systems and consumers regarding safety and privacy. Although reimbursement is a ubiquitous issue in new health care technologies that require linking potential cost savings to improved outcomes, it was also noted that responsibilities for reimbursement for mobile health technologies "may extend beyond traditional parties in healthcare and drive novel pathways" [27]. However, consumer costs were not specifically discussed, although the affordability of devices has been raised as a crucial consideration, with a need for discussion among patient advocacy groups, health care systems, and insurers for subsidizing their use to limit disparities in care across vulnerable populations [34]. Appropriate solutions to these challenges should be strategically incorporated into the clinical workflow to address information sharing in a way that minimizes burden on clinicians, maximizes confidence, and ensures transparency across multidisciplinary teams. In the survey by Manninger et al [41], 34% of the respondents indicated that they would want the tracing data to be transmitted to a specialized center, whereas 29% and 18% would transmit data directly to the responsible clinician or to the recommending clinician, respectively; only 9% would transmit data to a third party for interpretation.

In a study by Smuck et al [51], 2 successful digital health intervention programs were assessed, albeit for hypertension and diabetes rather than AF, to identify features that they had in common and that could potentially provide a framework to help guide digital health programs in general. Seven common features were identified: (1) a defined role of the wearables within the disease state, (2) integration into the EHR and incorporation of data into the existing data architecture, (3) technology support for consumers, (4) a personalized approach involving support teams rather than just technology solutions, (5) a user-friendly experience for clinicians, (6) a defined reimbursement model, and (7) physician champions and stakeholder opt-in programs. Although potential solutions were provided for factors 2 to 7, these features and their solutions would need to be further evaluated and developed to more specifically address issues related to AF that may be different from those of diabetes and hypertension.

Despite the screening framework and diagnostic pathway proposed by AF-SCREEN [29,32], neither of those publications discussed processes for specifically incorporating CWDs into health care delivery. Although the EHRA provided additional guidance [28], the lack of detailed processes suggests a remaining need for wider recognition and discussion on the implementation and ongoing use of these devices. The ESC report proposes a collaborative approach among stakeholders, including partnership between technology developers and industry leaders, and lists key factors for implementation as well as steps being taken by professional societies [33]. Nevertheless, the processes for facilitating the implementation of CWDs in cardiology have yet to be fully explicated and formalized, although pathways such as those proposed by EHRA [28] can provide a basis for eliciting consensus among health care stakeholders on the development of additional tools and resources for implementing CWDs in clinical practice.

Targeted Question 3: How Do Health Care Providers and Patients View Wearable Technology for Patients at Risk of AF?

Provider Perspectives

Although we sought studies that surveyed the perceptions and practices of providers in the area of CWDs and AF, the surveys that we found were international in scope and mainly represented electrophysiology specialties [39-43]. Many respondents in these surveys believed that CWDs have a role in the potential diagnosis of AF, and they generally knew, used, and recommended such devices. Although 68% of respondents in one survey recognized that CWDs could assist in diagnosis, similar proportions also expressed concern about data overload (69%) [41], suggesting that efficient workflow management of these devices was needed. Most respondents (62%) in that survey also indicated that they would want clear recommendations, such as those from medical societies, on using CWDs and incorporating them into clinical practice. Similar opinions regarding the need for guidance from professional societies were expressed in the other surveys [39,40,42]. However, these surveys were conducted before the 2021 ISHNE/HRS/EHRA/APHRS collaborative statement, although as previously mentioned, even that statement provided few recommendations on workflow. A more recent survey among members of the ESC indicated that, although only a small proportion of respondents (3.5%) reported a lack of trust in digital devices for use in cardiology, there remains a low awareness of the administrative and regulatory aspects of the use of digital devices as well as a need for care pathways for a referral [43]. This survey also highlighted the concerns of clinicians regarding reimbursement issues, although such issues did not preclude the management of presenting patients.

There appeared to be an overall consensus that the available guidelines are not clear on the best clinical practice after AF notification [27,29,31]. All the surveys supported the need to develop appropriate pathways for managing notifications, and most emphasized the importance of defining the population that would most benefit from CWDs as an approach to monitoring for AF [39-43]. Toward this definition, 74% of respondents in one of the surveys supported the use of CWDs based on age and CHA2DS2-VASc scores, starting at medians of 60 years and a score of 2, respectively [42].

Many of these provider perspectives were also summarized in the ESC review of digital technology [33], and although this review also mentioned several potential solutions, there was little discussion of specific initiatives for operationalizing CWD implementation in the cardiology setting.

Consumer Perspectives

Even though the overall use of CWDs is driven by consumers, our search identified few studies characterizing consumer perceptions of these devices for use in AF detection. However, a medical society review or report on digital technology summarized some of the key challenges to consumer uptake of such devices, including issues of digital literacy, data privacy, costs, and uncertainty of steps to take subsequent to a notification [33]. Among the surveys, one national survey not specific to the cardiology setting explored the prevalence of CWD use for health care among adults in the United States and evaluated factors that may be predictive of such use [44]. This survey found that 30% of the 4551 respondents indicated use of CWDs, and of these, 47% reported daily use [44]. Although the low prevalence of use may suggest an untapped potential for these devices in health care, the survey also provided information on the demographic using these devices. Interestingly, there was no statistically significant difference in use between those with and without chronic conditions, but the prevalence of use was greater among those with higher education, technology proficiency, and household income, suggesting a need for digital skill development and financial support. Importantly, from a clinical perspective, 82% of respondents indicated a willingness to share data with their clinicians, but other perceptions and needs regarding these devices were not captured.

In a more relevant population of individuals who self-reported the presence or risk of cardiovascular disease, less than one-quarter reported the use of CWDs, and of those who used such devices, approximately 81% did state a willingness to share wearable data with their physicians even though less than half reported daily use [53]. However, the use of CWDs decreased with age and varied according to other demographic factors, including educational attainment and household income, suggesting demographic disparities in availability and use.

Patient use and perspectives on CWDs were also reported in a survey of a focused population of 424 cancer survivors with or at risk of AF [47]. In that survey, 31.8% of respondents reported owning a commercial wearable device, and 79.7% of patients also endorsed arrhythmias as the most important heart condition for detection by such a device. Furthermore, 89.4% of these patients agreed that it would give them peace of mind to know that a commercial wearable device will detect a heart problem. Peace of mind and a sense of security were also attributes associated with wearing a smartwatch by participants in a clinical trial evaluating the accuracy of a smartwatch-smartphone app dyad for the detection of AF among older stroke survivors [52]. However, these patients indicated that in-person training and support enhanced their experience, suggesting the need for a more patient-centric approach to incorporating these devices into clinical practice. A simpler device interface and longer smartwatch battery life were also reported as desirable goals that would improve usability.

The consumer-driven nature of CWDs for AF detection was discussed in a study consisting of interviews with 19 Apple Watch users [48]. These consumers used the device to take ECG readings that ranged in frequency from several times a week to a few times a year and reported that they liked the technical sophistication of performing a function that would normally occur in a clinical setting but were ambivalent about the potential for false positive results that might prompt an unnecessary clinical visit. Although the authors of the study interpreted the consumer reports to some extent as potentially leading to medicalization of CWDs shaped by marketing, these interviews also highlight the need for development of educational materials on the appropriate use of these devices.

Two studies focused on AF surveyed specific populations, with one study conducted at an academic medical center that stratified survey participants by those diagnosed with AF (n=327) and those at risk of AF (n=895), defined as being aged ≥65 years with a CHA2DS2-VASc score of >2 [45]. The other study was conducted among patients with AF by a patient advocacy organization (N=763) [46]. In the former survey, consumers already diagnosed with AF were more likely to share data with their clinician than those at risk of developing AF, although both groups reported similar ownership and use of such devices. In the latter study, most of the patients (71%) were already using CWDs to "monitor or manage their heart rate or rhythm," although they also expressed concerns regarding accuracy and lack of interest among their clinicians. Although both of these studies were limited by a potential lack of generalizability because of the specificity of the populations, they consistently indicated the existence of knowledge gaps regarding the use of devices and data sharing subsequent to a notification [45,46], further suggesting the importance of developing specific recommendations and broad educational initiatives targeting consumers.

Discussion

Principal Findings

Although our goal was to review and summarize the current knowledge of the processes and pathways for implementing CWDs for AF detection in clinical practice, the availability of articles for inclusion in this targeted review was limited, likely because such use of CWDs is relatively new. Even when the search was updated, few relevant articles were identified, and overall, most of the returned citations indicated that CWDs remain an investigational field with less practical discussion on operationalizing their use for AF detection in real-world practice.

The articles that we reviewed in our qualitative analysis emphasize the concerns and needs for effective incorporation of CWDs for AF detection into clinical practice from the perspectives of clinicians and patients. Economic value was also suggested in several articles that indicated that CWDs are likely to be cost-effective for AF detection when used appropriately in populations at risk [29,31,34,41], which has been further supported by a more recent economic simulation model [55].

Several overarching themes were gleaned from this targeted literature review (Table 2), and many of these themes appear to be concerns regarding the use of digital technology in AF detection and cardiology in general [33,38]. A main theme was that, even though professional societies recognize a potential role for these devices, there remains a lack of guidance on the processes that would facilitate the incorporation of incoming data from CWDs. Furthermore, several of the articles, especially clinician surveys, explicitly requested specific guidance and recommendations by professional organizations on workflow and patient management. However, it should also be noted that the current lack of such guidance may be due to another theme that emerged from this review, that is, the fact that there has been limited pragmatic evaluation of real-world applications and outcomes when CWDs for AF detection are incorporated into the clinical workflow. Thus, additional real-world implementation studies are required to determine the best methods for deploying and supporting strategies for successful AF detection based on CWD-derived data. The lack of organized infrastructure for receiving, managing, and communicating CWD data further indicates the technical considerations that need to be addressed to facilitate the incorporation of such data into the EHR.

Another main theme was the need for the development and dissemination of educational resources directed toward clinicians and consumers. In particular, the lack of tools such as care pathways that can both inform clinician engagement with the patient who received a notification and guide subsequent clinical decision-making was considered an important barrier to the use of CWDs. Overcoming this barrier could also be of benefit in addressing the criticism that consumer use of CWDs for health monitoring may be driven by marketing [48,49,56] and would ideally be accomplished via evidence-based pathways developed in conjunction with professional organizations, such as those proposed by the EHRA [28], which can provide a basis for expansion into more detailed clinical pathways and administrative workflows. An integral component of such pathways would be defining who engages with the patients as well as when and how such engagements occur (eg, virtual vs clinic visits); cardiologists and electrophysiologists reported that the use of virtual visits substantially increased as a result of the COVID-19 pandemic [42]. Indeed, the COVID-19 pandemic resulted in a substantial increase in the use of digital health technology by electrophysiology professionals, who also reported concerns regarding an overall lack of supportive infrastructure, including guidelines on clinical workflow [57].

When engaging with patients, there is also a need for educational materials that clearly explain the benefits and limitations of CWDs and what to do should they receive an AF notification on their device. In addition, patient education should unambiguously explain that an AF notification only means that the CWD has detected an irregular heart rhythm and clinician follow-up is required to determine its clinical relevance. As these notifications may result from other sources, including irregular rhythms other than AF, device artifacts, or sudden changes in movement or body position, AF notifications may be open to misinterpretation by patients. Therefore, from the patient's perspective, clarity regarding the context and meaning of a notification is important for reducing anxiety and informing patients that they should not only provide the notification to their clinician but should also report the circumstances surrounding the notification (ie, when it occurred and what they were doing). In addition, educating patients to capture a single-lead 30-second ECG tracing that accompanies a potential AF notification and then sharing this with the clinician can help determine the appropriate path forward by distinguishing among potential AF, "noise," or other types of arrhythmias. Such education and follow-up are also important from the clinician's perspective as these can enable determination of the most appropriate pathway for patient follow-up. Operationally, decisions will need to be made, but who will make the decisions and based on what criteria still needs to be determined. Educational resources should be both proactive to help manage

expectations from CWDs and reactive to facilitate engagement and postnotification follow-up.

The range of clinician perspectives on the utility of CWD notifications (PPG vs ECG vs conventionally used technology) and how to manage patients who receive a notification further emphasizes the importance of clinician education on the meaning of an AF notification and establishing diagnostic pathways that consider the potential for false positives, especially in individuals at low risk. False positives also relate to clinicians' concerns about the potential for data overload from AF notifications as the notification is only for an irregular heart rate, which can arise from different causes (other cardiac rhythm irregularities and circumstantial events) and may not necessarily be an occurrence of AF. These concerns were further reflected by clinicians' reported desire for tools such as diagnostic and organizational pathways for data management, which would simplify both the workflow and the decision-making process. These tools would provide guidance on when and in whom further follow-up may be appropriate using strategies such as prioritizing patient populations and stratifying by risk. As the clinical implications of an AF notification with regard to diagnosis, treatment, and outcomes are not yet fully understood, additional clinical trials and real-world studies can expand the body of evidence, potentially informing diagnostic pathways and clinical decisions. It should also be noted that issues regarding reimbursement for receiving, analyzing, and responding to CWD data were raised in an international survey of clinicians [42], and clinician reimbursement was a specific focus in a European survey [39], although these issues did not appear to be a barrier to follow-up and patient management. Nevertheless, given the differences in the US health care system, reimbursement policies may need to be considered as part of the frameworks for incorporating CWDs into patient care pathways.

Table 2. Themes gleaned from the targeted literature review on the status of consumer wearable devices for detection of atrial fibrillation.

Theme	Description	Needs for resolution
Guidance or recommendations	Lack of guidance on processes for using CWDs[a] and determining appropriate patient follow-up subsequent to an AF[b] notification.	Professional societies should play a larger role in providing guidance or endorsement.
Patient age	Age of patients at risk of AF may be relevant to their knowledge and motivation to use new technologies such as CWDs and the internet, along with clinicians' views of those qualities in their patients.	Develop patient education resources.
Detection methods	Traditional AF detection methods involve 12-lead electrocardiograms and ambulatory monitoring; however, owing to the episodic nature of AF, devices such as CWDs may be able to uncover more cases of irregular heart rhythm.	Conduct clinical trials and real-world studies comparing effectiveness (sensitivity and specificity) and outcomes between traditional detection methods and CWDs.
False positives (accuracy)	How to manage the potentially high rate of notifications of irregular heart rhythm across the patient population.	Identifying patients at risk may help provide balance between screening the general population and addressing all irregular heart rhythm notifications (which are less likely to be undiagnosed AF for low-risk populations); development of diagnostic pathways; guidance or recommendations from professional organizations on workflow and patient management.
Data overload	Organizations may not be able to address the volume of CWD notifications or have mechanisms to triage notifications and follow-up appropriately.	Initiate appropriate organizational infrastructure to address managing notifications and follow-up.
Lack of care pathways	The availability of clinical tools such as care pathways and detailed guidelines for CWDs is limited.	Develop diagnostic pathways and provide guidance from professional societies.

[a]CWD: consumer wearable device.

[b]AF: atrial fibrillation.

Previous surveys evaluating the clinicians' perspective were from international studies, and although they included clinicians in the United States, the results were not stratified by country. Therefore, it would be valuable to more specifically survey clinicians in the United States as results from international studies may not necessarily reflect their needs and priorities or issues that may be specific to the US health care system. Furthermore, most participants in the surveys were from electrophysiology specialties. As electrophysiologists are potentially more familiar with and confident regarding the use of wearable technology for irregular heartbeat detection, potentially biasing the survey findings and limiting generalizability, a wider range of specialties should be surveyed, including primary care physicians, who are often the main health care contact for patients.

Similar patient-related issues and challenges regarding technology access and acceptance as well as costs were identified by clinicians and in the 2 patient surveys. However, as the patients surveyed represented specific populations, these surveys were likely confounded by selection bias that reduced generalizability [45,46], suggesting that the perspective of patients on the use of CWDs requires further exploration.

A more comprehensive approach to evaluating the effectiveness of CWDs across the patient population may be necessary to determine the potential for care pathways. Such an evaluation

of specificity and sensitivity may be especially important with regard to race and ethnicity as there have been equivocal reports on whether skin tone may contribute to the inaccuracy of optical heart rate sensors (ie, PPG) [58].

There is also likely to be varying digital literacy among those at risk of AF as both digital literacy and technology acceptance may vary according to social determinants of health such as age and geographic regions. The age of patients may be especially relevant to their knowledge and acceptance of new technologies [59], as also supported by the results of the survey by Dhingra et al [53], which reported that, among demographic groups with known worse cardiovascular outcomes, those aged ≥65 years have the lowest use of CWDs. As patient-targeted educational resources are lacking for explaining CWD use, guiding expectations, and understanding the meaning of an AF notification, such resources can be developed. These patient-facing educational materials should focus on AF risk factors, use and capabilities of CWDs, and the meaning of an AF notification to allay potential anxiety regarding the receipt of such a notification. The importance of providing sufficient information on the notification to enable the clinician to determine appropriate next steps should also be emphasized in these materials, as should informing the patient of what may be expected for follow-up.

Study Limitations

The main limitation of this targeted review, as previously mentioned, is that there are few published studies that have evaluated the various stakeholder perspectives on the use of CWDs and how they may be incorporated into clinical practice. It should also be considered that the character of the published literature is still maturing and currently consists mainly of pilot studies or early explorations of the topic that may vary in focus with few RCTs, further emphasizing the emerging nature of CWDs in the cardiology setting. This limitation increases the complexity of making the comparisons that are needed to gather "themes" representing the current state of the evidence. As this was a targeted review rather than a more formal systematic review, it is also possible that we missed some relevant studies.

Conclusions

This targeted literature review underscores the current lack of a comprehensive body of literature guiding the real-world implementation of CWDs for potential AF detection. Our results provide insights for informing additional research and developing appropriate tools and resources for incorporating CWDs for AF detection into clinical practice. The identified gaps and challenges can provide a focus for surveys and interviews to elicit additional feedback from clinicians and other stakeholders, such as health care systems that have already incorporated CWDs into clinical pathways. Such surveys and interviews will be useful for confirming and prioritizing the most important issues and, when combined with the information gleaned from the targeted literature search, can inform the development of appropriate tools and educational resources. The results of this review should also provide an impetus for the active involvement of medical societies and other health care stakeholders in developing appropriate tools and resources for guiding the real-world use of CWDs for AF detection. These resources should be tailored by stakeholder, such as clinicians, health care organizations, technical and operational staff, and patients. The goals of the resources provided to stakeholders would include establishing guideline-based frameworks for addressing alerts and recommendations for incorporating alerts into administrative workflows and patient care pathways, as well as facilitating clinician or patient engagement. Efforts to fill these gaps and address the identified needs are ongoing and will be reported in future publications. As the use of CWDs in practice increases and the body of medical literature on CWDs grows, expanding the landscape of these devices, development of frameworks and workflows may be able to rely on a more evidence-based approach for incorporating the use of these devices into clinical practice.

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Data Availability

The processes for identifying the articles evaluated in this review are included in this published paper and its supplementary files.

Authors' Contributions

JKS and SNH designed and conceptualized this study and oversaw all aspects. EK and CP performed the searches and conducted the initial review and writing. All authors reviewed the results weekly and contributed to thematic review and discussion.

Conflicts of Interest

JKS and SNH are employees and shareholders of Pfizer Inc. MA, EK, and CP report no other competing interests.

Multimedia Appendix 1
Search strategy for wearables for atrial fibrillation, provider perceptions, patient perspectives, and provider acceptance.
[PDF File (Adobe PDF File), 76 KB - cardio_v7i1e47292_app1.pdf]

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Abbreviations

AF: atrial fibrillation
APHRS: Asia Pacific Heart Rhythm Society
CHA2DS2-VASc: congestive heart failure, hypertension, age 75 years and older, diabetes, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex category
CHARGE-AF: Cohorts for Heart and Aging Research in Genomic Epidemiology model for atrial fibrillation
CWD: consumer wearable device
ECG: electrocardiogram
EHR: electronic health record
EHRA: European Heart Rhythm Association
ESC: European Society of Cardiology
FDA: Food and Drug Administration
HRS: Heart Rhythm Society
ISHNE: International Society for Holter and Noninvasive Electrocardiology
MeSH: Medical Subject Heading
PPG: photoplethysmography
RCT: randomized controlled trial

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Review

Efficacy of eHealth Technologies on Medication Adherence in Patients With Acute Coronary Syndrome: Systematic Review and Meta-Analysis

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Abstract

Background: Suboptimal adherence to cardiac pharmacotherapy, recommended by the guidelines after acute coronary syndrome (ACS) has been recognized and is associated with adverse outcomes. Several randomized controlled trials (RCTs) have shown that eHealth technologies are useful in reducing cardiovascular risk factors. However, little is known about the effect of eHealth interventions on medication adherence in patients following ACS.

Objective: The aim of this study is to examine the efficacy of the eHealth interventions on medication adherence to selected 5 cardioprotective medication classes in patients with ACS.

Methods: A systematic literature search of PubMed, Embase, Scopus, and Web of Science was conducted between May and October 2022, with an update in October 2023 to identify RCTs that evaluated the effectiveness of eHealth technologies, including texting, smartphone apps, or web-based apps, to improve medication adherence in patients after ACS. The risk of bias was evaluated using the modified Cochrane risk-of-bias tool for RCTs. A pooled meta-analysis was performed using a fixed-effect Mantel-Haenszel model and assessed the medication adherence to the medications of statins, aspirin, P2Y12 inhibitors, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and β-blockers.

Results: We identified 5 RCTs, applicable to 4100 participants (2093 intervention vs 2007 control), for inclusion in the meta-analysis. In patients who recently had an ACS, compared to the control group, the use of eHealth intervention was not associated with improved adherence to statins at different time points (risk difference [RD] –0.01, 95% CI –0.03 to 0.03 at 6 months and RD –0.02, 95% CI –0.05 to 0.02 at 12 months), P2Y12 inhibitors (RD –0.01, 95% CI –0.04 to 0.02 and RD –0.01, 95% CI –0.03 to 0.02), aspirin (RD 0.00, 95% CI –0.06 to 0.07 and RD –0.00, 95% CI –0.07 to 0.06), angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (RD –0.01, 95% CI –0.04 to 0.02 and RD 0.01, 95% CI –0.04 to 0.05), and β-blockers (RD 0.00, 95% CI –0.03 to 0.03 and RD –0.01, 95% CI –0.05 to 0.03). The intervention was also not associated with improved adherence irrespective of the adherence assessment method used (self-report or objective).

Conclusions: This review identified limited evidence on the effectiveness of eHealth interventions on adherence to guideline-recommended medications after ACS. While the pooled analyses suggested a lack of effectiveness of such interventions on adherence improvement, further studies are warranted to better understand the role of different eHealth approaches in the post-ACS context.

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KEYWORDS

medication adherence; eHealth; secondary prevention; acute coronary syndrome; heart disease; text messaging; mobile app; cardiology; cardioprotective; prevention; efficacy; statins

Introduction

Acute coronary syndrome (ACS) occurs due to the blockage of 1 or more coronary arteries, which often leads to chest pain, myocardial infarction, and other serious complications. It has a high recurrence rate among individuals who previously had ACS [1,2], necessitating the need for a range of pharmacotherapeutic interventions during and post incident [3]. As such, people with ACS typically require multiple medications including aspirin, β-blockers, and statins to prevent future cardiac events [4]. Current guidelines recommend the long-term use of 5 classes of medications in secondary prevention following ACS: aspirin, statins, β-blockers, angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs), and in addition P2Y12 inhibitors for 1 year to reduce future ACS incidents and associated cardiac complications. Further, people with ACS may also require medications to manage symptoms like chest pain or to prevent disease complications including blood clots and myocardial infarction, resulting in an overall increase in medication burden.

Adherence to medications is defined as "The process by which patients take their medications as prescribed, composed on initiation, implementation and discontinuation [5]." While there remains a lack of consensus on what is considered an adequate level of medication adherence [6], evidence indicates that suboptimal adherence to chronic medications is a widely recognized clinical challenge that places a significant burden on health care expenditure [7]. Reports showed that medication nonadherence is a highly prevalent clinical problem, which varies based on the disease condition, age, study setting, and definition of medication adherence [8]. Evidence from a systematic review and meta-analysis shows that adherence to secondary prevention pharmacotherapy ranges between 54% and 86% within 1 year of discharge from the hospital for ACS [9], with no consistent predictors of nonadherence identified across all cardiac medication classes. This is further supported by another meta-analysis that also reported poor adherence to secondary prevention medications in people with coronary heart disease, with little differences among medication classes [10].

While poor medication adherence could be a conscious decision in certain circumstances, unintentional nonadherence, for example, due to cognitive and memory issues, plays a significant role in predicting poor medication adherence [11]. Factors contributing to unintentional nonadherence are considered amenable to changes through appropriate interventions. eHealth-based interventions are emerging as an integral component of health care service delivery and are contributing to improved health outcomes. Web-based eHealth technologies like SMS text messages or interactive voice response, mobile apps, and calls as modes of providing adherence telefeedback have been successfully tested on a range of medical conditions, leading to improved adherence to long-term medications [12].

Emerging evidence from studies on the efficacy of eHealth interventions in improving medication adherence in people with ACS has led to inconclusive findings [13-17]. Therefore, in this study, we aim to (1) conduct a systematic review and meta-analysis to investigate the effectiveness of eHealth interventions in improving medication adherence in people with recent history of ACS and (2) examine any subgroup differences in the effectiveness of such interventions based on their application on different medication classes prescribed to manage ACS or method of adherence assessment.

Methods

Study Design

The study involves a systematic review and meta-analysis of randomized controlled trials (RCTs) and was designed in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) statements (Multimedia Appendix 1) [18].

Data Search Strategy

Electronic data searches of PubMed, Embase, Scopus, and Web of Science were conducted between May and October 2022, with an update in October 2023 to identify RCTs focusing on eHealth interventions to improve pharmacotherapy adherence in patients who had an ACS incident. Articles published from January 2000 to October 2023 were considered for screening. The following search keywords or concepts and relevant synonyms words were used combined via appropriate Boolean operators: Mobile health, text messages, smartphones, eHealth, and mobile applications in combination with cardiovascular disease, secondary prevention, adherence, medication adherence, medication nonadherence, coronary artery disease, acute coronary syndrome, myocardial infarction, and cardiac rehabilitation. The detailed keywords and search strategies used in different databases are presented in Multimedia Appendix 2.

The Population Intervention Comparison Outcome(s) Study design statement for this systematic review was as follows: participants: patients with post-ACS; intervention: eHealth technology (telehealth, eHealth, smartphone, texting, mobile health [mHealth], phone apps, etc); comparisons: standard or usual care; outcomes: adherence to guidelines-recommended post-ACS pharmacotherapy; and study design: RCTs.

Selection Criteria

For this systematic review, studies were included if they investigated the effectiveness of eHealth technologies (eg, mobile phone app, a web-based app, a smartphone app, an electronic device, or texting) in an RCT for a duration of at least 12 weeks. The studies were focused on improving adherence

to various classes of guideline-recommended cardioprotective medications, such as aspirin, statins, β-blockers, P2Y12 inhibitors, and ACEIs or ARBs, among patients after ACS. The studies, to be included in the meta-analysis, had to provide information on the number of subjects or proportion of use for the 5 classes of medications indicated for secondary prevention after ACS in both the intervention and control groups at baseline as well as at follow-up periods. Studies that examined eHealth interventions for the treatment of obesity, hypertension, dyslipidemia, secondary lifestyle factors, and smoking cessation in patients without ACS were excluded. Articles published in non-English language results were also excluded. Additionally, abstracts, case reports, editorials, and conference presentations were not considered for this systematic review.

Screening Process

Titles and abstracts found through the electronic database searches were imported into the Covidence systematic review software (Veritas Health Innovation Ltd). A total of 2 reviewers (ASB and WT) independently screened the abstracts. Studies not meeting the predetermined selection criteria were excluded. After reviewing the abstracts of identified studies, the full texts of eligible publications were subsequently evaluated by the same 2 independent reviewers for potential inclusion in the final analysis. In addition, bibliographies of relevant publications were also examined to identify any articles missed during the original database searches. Any disagreements regarding article inclusion and exclusion of the article were resolved through collaborative review. The final results were reviewed by all authors.

Data Extraction and Critical Appraisal

A total of 2 authors (ASB and WAA) independently extracted the data into a predetermined Excel (Microsoft Corp) spreadsheet, and the third author (WT) evaluated the collected data. Study characteristics (authors, year of publication, country, registration, design, and duration of the trial protocol); patient demographics (mean age, sex, size, and type of control condition); design parameters (type of intervention and length of intervention); eHealth intervention features (type of electronic device, messaging frequency, and a web-based app), and outcomes (method and frequency of assessment for adherence and type of medication) were extracted.

Risk of Bias of Individual Studies

A total of 2 independent authors evaluated the risk of bias within individual studies using the modified Cochrane risk-of-bias tool for RCTs [19], a 7-item instrument that assesses selection bias, allocation concealment, implementation bias, measurement bias, follow-up bias, reporting bias, and others. Any discrepancies were resolved by consensus.

Outcomes

The primary outcome includes overall adherence to cardioprotective medication classes (statins, aspirin, P2Y12 inhibitors, ACEI or ARBs, and β-blockers) in patients with ACS following eHealth interventions. The secondary goal is to evaluate the effectiveness of eHealth interventions on medication adherence at 6-month and 12-month follow-up periods.

Data Analysis

The included trials reported the extent of medication nonadherence, including to specific drug classes, using both self-report questionnaires and objective methods like medication possession ratio or prescription claims data at different time intervals (3-, 6- or 12-months post intervention). When trials reported multiple follow-up assessments, we pooled the relevant data to determine the effect of the intervention at 6-month and 12-month time points. To analyze the data, effect sizes were estimated using standardized risk differences (RD) between the intervention and control groups, as well as RD for each cardiovascular medicine in the study and weighted pool estimates. We considered variations in outcome measurement across studies by applying appropriate statistical methods (ie, fixed effects for heterogeneity level of ≤25% and random effects when heterogeneity level was >25%) to generate meta-analytic estimates of intervention effect and presented as RD [19]. A chi-square test was used to assess homogeneity between studies and a homogeneity *P* value of less than .10 was considered statistically significant [20]. Subgroup analyses were performed using self-report and objective adherence assessment methods to determine the effectiveness of intervention on adherence to individual or all drug classes both at 6-month and 12-month follow-ups. Due to the small number of studies meeting our inclusion criteria, publication bias was not assessed [21]. All statistical analyses were performed using STATA MP statistical software (version 16.1; StataCorp). The results were expressed as an "RD" with 95% CI. A *P* value less than .05 was considered a statistically significant difference between the intervention and the controls.

Results

Overview

The database search resulted in 831 titles and abstracts, while the bibliographic search of these articles did not result in any other articles. Of the 831 articles screened, 779 articles were considered for screening and 40 articles met the eligibility criteria, but most of these RCTs did not have data on medication adherence or follow-up (n=24), no specific data on ACS (n=5), were not an eHealth intervention (n=4), and other reasons (n=4). Finally, 5 peer-reviewed journal articles met the inclusion criteria (Figure 1) [13-17] and their features are summarized in Table 1.

All RCTs were published in English between the years 2020 and 2022. A total of 3 of the included studies were from China, while 1 was conducted in Australia and another 1 in New Zealand. The 5 studies included 4100 participants, with 2093 and 2007 people included in the intervention and control groups, respectively. The majority of the targeted participants were male, with their average age ranging from 57 to 64.8 years.

Adherence to statins, aspirin, P2Y12 inhibitors, ACEIs or ARBs, and β-blockers was evaluated using text message, WeChat, and smart phone–based app interventions. Both self-report [13-15,17] and objective [13,15] adherence measurement methods were used by the included studies to determine the level of nonadherence to prescribed medications. For example, 2 studies used the 8-item Morisky medication adherence scale

(MMAS-8) to determine the proportion of medication nonadherence [15,17], while other studies used self-reports along with objective methods like prescription claims data [13], or a medication possession ratio [15]. Patients were deemed adherent, for example, if at different time points, they had a medication possession ratio of ≥80% (determined based on the number of days patients are in possession of the dispensed drugs divided by the number of days used for follow-up) [15] or self-report of medication use >80% of the time in the previous 30-days (24/30 days) [13]. People were also considered adherent based on having a score of ≥6 using the MMAS-8 scale, which was obtained mainly from "yes" and "no" responses and 1 Likert-based question [17].

Figure 1. Covidence PRISMA flow diagram showing article screening and selection criteria. ACS: acute coronary syndrome; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis.

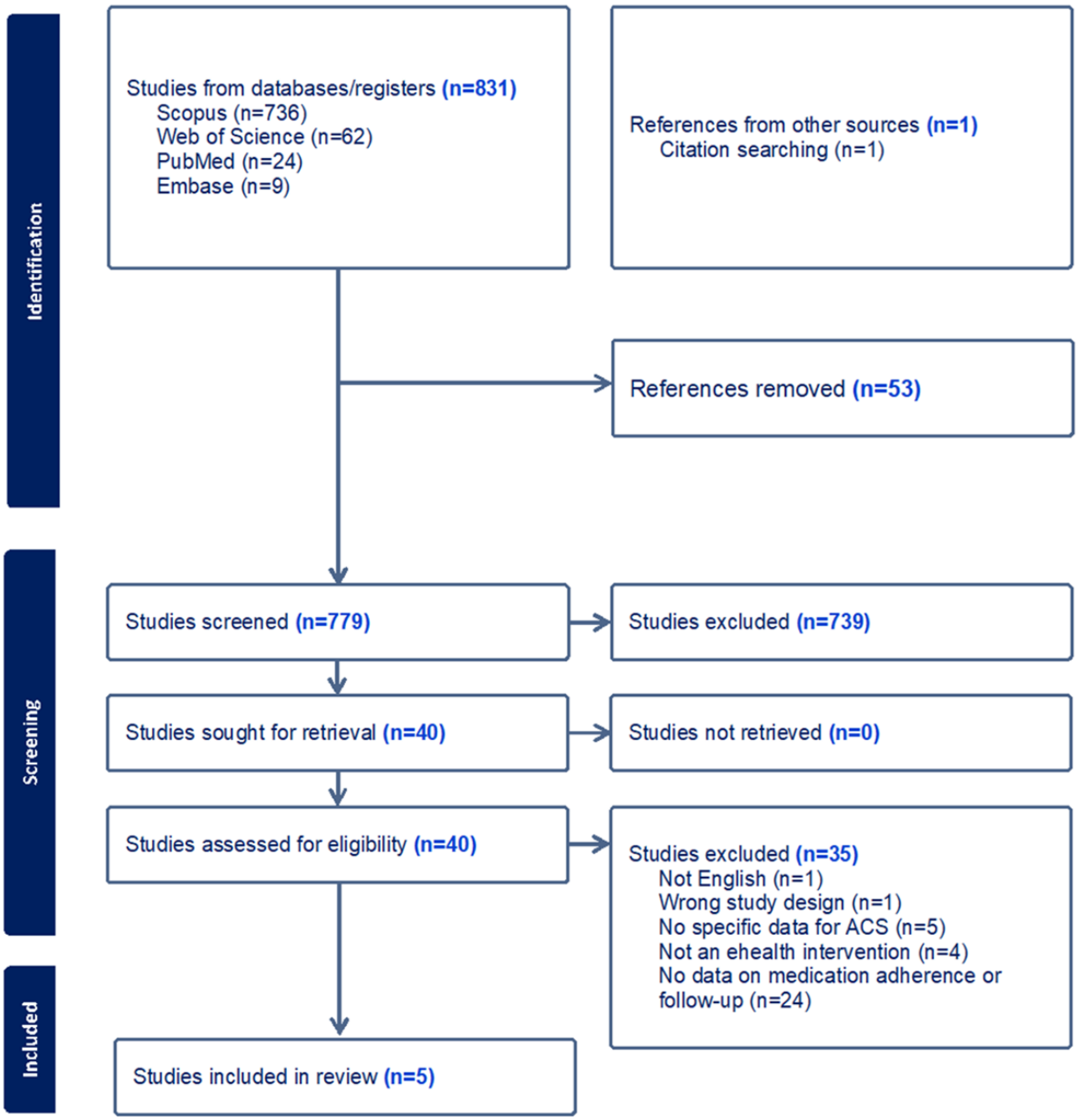


Table 1. Characteristics of included studies in the meta-analysis.

Study	Year	Country	Participants, n		Mean age, mean (SD)	Male, %	Randomization, n:n	eHealth intervention type and frequency	Medications	Assessment method	Adherence cut-off, %	Duration of intervention, months
			Intervention	Control								
Chow et al [13]	2022	Australia	716	708	58.0 (10.7)	79.2	1:1	A 1-year program of customized SMS text messages (4 per week in the first 6 months, followed by 3 per week in the subsequent 6 months)	Statins, other antiplatelet[a], aspirin, ACEI[b] or ARB[c], and β-blockers	Prescription claims data (PBS[d]). Self-report on medication use over past 30 days	>80	6 and 12
Wang et al [14]	2022	China	81	83	62 (12.4)	82.8	1:1	Provision of information related to medications and lifestyle factors coupled with a 12-month WeChat app-based follow-up	Statins, aspirin, and ACEI or ARB	Interviewer-led questionnaire	>80	6 and 12
Maddison et al [15]	2021	New Zealand	153	153	61 (11)	77.1	1:1	Personalized, automated self-management program delivered via SMS text messages (1 message per day for 24 weeks plus 35 additional messages in the first 12 weeks)	Statins, aspirin, ACEI or ARB, and β-blockers	MPR[e] and MMAS-8[f]	80	6 and 12
Shi et al [16]	2021	China	642	564	64.8 (10.6)	72.6	1:1	Provision of health lifestyle recommendations and medication advice with a WeChat-based telemedicine management app for follow-up	Statins, antiplatelet, ACEI or ARB, and β-blockers	Self-report	90	1, 3, 6, and 12
Yu et al [17]	2020	China	501	499	57.3 (9.0)	85.5	1:1	Provision of information using a smartphone app (Heart Health) on medications, including reminders post discharge	Statins, antiplatelet, ACEI or ARB, and β-blockers	MMAS-8	N/A[g]	3 and 6

[a]P2Y12 antagonists or ticagrelor.

[b]ACEI: angiotensin-converting enzyme inhibitors.

[c]ARB: angiotensin receptor blocker.

[d]PBS: Pharmaceutical benefits scheme.

[e]MPR: medication possession ratio.

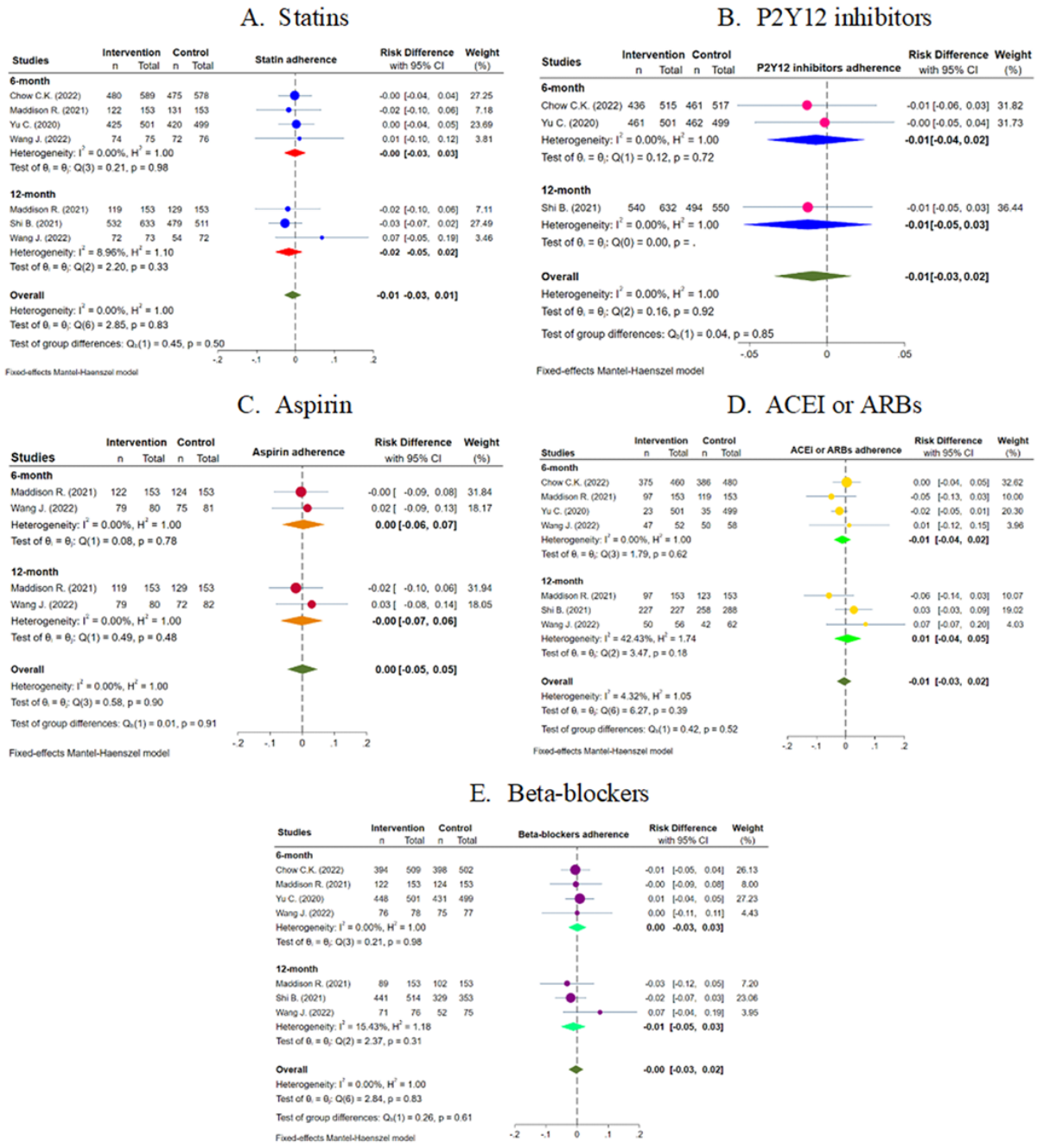
[f]MMAS-8: 8-item Morisky Medication Adherence Scale.

[g]N/A: not applicable.

The Effectiveness of eHealth Intervention on Adherence to Cardioprotective Medications

Figure 2 shows the weighted RD between the intervention and the control groups for statins, P2Y12 inhibitors, ACEIs or ARBs, β-blockers, and aspirin. A total of 4 studies provided data for intervention on adherence to statins, showing that eHealth intervention was not associated with significant improvement in adherence both at 6 months (RD –0.00, 95% CI –0.03 to 0.03; I^2=0.0%) and 12 months (RD –0.02, 95% CI –0.05 to 0.02) post intervention. Similarly, no improvements in the medication adherence following eHealth intervention were observed for other classes of medications, such as P2Y12 inhibitors (RD –0.01, 95% CI –0.04 to 0.02; I^2=0.0% at 6 months and RD –0.01, 95% CI –0.05 to 0.03; I^2=0.0% at 12 months), aspirin (RD 0.00, 95% CI –0.06 to 0.07; I^2=0.0% at 6 months and RD 0.00, 95% CI –0.07 to 0.06; I^2=0.0% at 12 months), ACEIs or ARBs (RD –0.01, 95% CI –0.04 to 0.02; I^2=0.0% at 6 months and RD 0.01, 95% CI –0.04 to 0.05; P=.18; I^2=42.4% at 12 months), and β-blockers (RD 0.00, 95% CI –0.03 to 0.03; I^2=0.0% at 6 months and RD –0.01, 95% CI –0.05 to 0.03; P=.31; I^2=15.4% at 12 months).

Figure 2. Effect of eHealth intervention on medication adherence after acute coronary syndrome. ACEI: angiotensin-converting enzyme inhibitor; ARB: angiotensin receptor blocker [13-17]. For a higher-resolution version of this figure, see Multimedia Appendix 3.



Subgroup Analyses for the Effect of Interventions Based on Adherence Assessment Method

A subgroup analysis of the effectiveness of eHealth interventions on medication adherence at 6 months' and 12 months' time points post intervention was conducted based on the adherence assessment methods used (self-report vs objective). The findings showed no significant combined RDs in overall medication adherence between intervention and control groups both at 6-month and 12-month follow-up periods, irrespective of the type of medication adherence assessment method applied (see detailed analyses in Multimedia Appendix 4). Heterogeneity among studies was high for most analyses, except when using the objective adherence assessment method. Furthermore, the studies that provided data for pooled estimation of the effect of the intervention on adherence to all drug classes also revealed no improvement in adherence both at 6 months (RD 0.01, 95% CI –0.00 to 0.02; I^2=92.3%) and 12 months (RD 0.00, 95% CI –0.01 to 0.01; I^2=1.00%).

Quality Assessment of Included Studies

Overall, all studies showed a low risk of bias, and only 1 study did not provide a description of the blinding of outcome assessment. In Table 2, we reported the methodological quality assessment of individual studies as per the modified Cochrane risk of bias tool for RCTs.

Table 2. Risk of bias in included studies[a].

Study	Selection bias		Performance bias	Detection bias	Attrition bias	Proportion bias	Outcome bias	Reporting bias	Treatment bias
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Groups balanced at baseline	Group received same intervention	Selective reporting	Intention-to-treat analysis
Chow et al [13]	Low	Low	Low	Low	Low	Low	Low	Low	Low
Wang et al [14]	Low	Low	Low	Low	Unclear	Low	Low	Low	Low
Maddison et al [15]	Low	Low	Low	Low	Unclear	Low	Low	Low	Low
Shi et al [16]	Unclear	Low	Unclear	Unclear	Low	Low	Low	Low	Unclear
Yu et al [17]	Low	Low	Low	High	Low	Low	Low	Low	Low

[a]Risk of bias: review authors' judgments about each risk of bias item for the included studies.

Discussion

Principal Findings

This work presents a systematic review and quantitative analysis of randomized trials evaluating the effect of eHealth interventions on adherence to medications acting on the cardiovascular system in people who experienced ACS. The findings of this review revealed that eHealth-based intervention was not associated with significant improvements in adherence to guideline-recommended medications such as statins, P2Y12 inhibitors, aspirin, or hypertension medications or overall medication classes after ACS incidents. At 6 and 12 months' time points after the intervention, no significant improvements in cardioprotective medication adherence were observed, irrespective of the methods of adherence assessment used.

Previous evidence from a meta-analysis of 16 randomized controlled trials found that sending medication-related reminders in the form of SMS doubled medication adherence across a range of chronic conditions [22]. This is in contrast to the findings of our review, which focused on patients with an acute medical condition on top of preexisting chronic diseases. ACS is a life-threatening condition that may require a specialized intervention plan. Consistent postdischarge assistance and education for long-term secondary prevention of ACS remain a health care service challenge. eHealth-based interventions are hypothesized to have the potential to improve the implementation and accessibility of nonpharmacological modalities for promoting the long-term secondary prevention of ACS [23]. These low-cost, easy-to-implement, and scalable eHealth interventions may have used as a consolidated source of information. Neither do they require extra investment or extensive clinician involvement.

Despite being low-cost and scalable, however, the contents of eHealth messages may not be enough to elicit behavioral changes in patients with ACS. This is particularly difficult in contexts where there are competing health goal priorities affecting medication adherence, like in case of patients experiencing acute illnesses superimposed on chronic conditions.. Similar initiatives that were published in the past, that addressed a single behavior, for example, such as exercise or smoking cessation, reported the success of eHealth intervention [24,25]. Targeting multiple behaviors simultaneously may be burdensome for patients demanding both acute and chronic medical care. SMS text messaging program alone may not satisfy participants' needs for more personalized interventions [26].

Prior research demonstrates that eHealth technologies can address extrinsic social and economic factors to improve

medication adherence after ACS [27-29]. For example, the study by Redfern et al [27] highlighted how an iterative, theory-based development process for texting interventions can inform optimized eHealth tools to enhance post-ACS pharmacotherapy adherence. Their user-centered approach integrating behavior change techniques suggests that future eHealth interventions could benefit from participatory design tailored to patient needs and preferences.

Applying such standardized methodology grounded in guidelines and tailored content may advance the effectiveness of eHealth adherence promotion after ACS. In addition, another pilot study by Riegel et al [29] tested a personalized telehealth intervention using behavioral economics and financial incentives to promote maintained aspirin adherence after ACS hospitalization, representing a participatory approach tailored to patient motivations that showed promising trends versus declining adherence in the controls.

From our pooled analysis, the findings revealed that the implemented eHealth programs were not significantly more effective than usual care in improving cardioprotective medication adherence in people who experienced recent ACS, regardless of the adherence assessment method used. This may point to the need for a redesign of eHealth interventions' contents or components as well as their delivery. Based on the literature, for interventions to be more effective, the design should be theory-driven, iteratively designed, and culturally tailored to provide educational and motivational information to patients who experienced ACS. A successful intervention outcome may result from incorporating personalized intervention during a design process [29]. Most of the studies included in our analyses did not use theory-driven interventional materials, which are found to be effective in improving self-management practices and adherence in certain health conditions and patient populations [30-32]. The application of theory-based interventions provided in the right context may lead to improved adherence to treatments. However, it is important to note that the given patients, who were included in the targeted studies, were enrolled at or soon after their hospital discharge, they are more likely to have higher adherence and lifestyle adjustments, regardless of the implementation of an intervention.

This review synthesized evidence from published studies of relatively high quality, with all included studies being RCTs. Due to the rigor of their study designs, the majority of articles included in the meta-analysis had a minimal risk of bias. However, our evidence from the systematic review should be interpreted in the context of several major limitations. Variations in study participants' characteristics, definitions of medication adherence, and sample sizes may account for the wide range of reported risk reductions. More importantly, the small number of studies from only 3 countries (Australia, China, and New Zealand) limits the generalizability of the findings to other settings. The methods used to assess adherence were different among the included studies, making it difficult to fully understand the effectiveness of the implemented interventions on adherence. This is particularly important given the absence of a gold-standard adherence measurement or adequate level of adherence that could predict health outcomes. In the literature, there are different types, measurement tools, and definitions of what constitutes medication adherence, bringing substantial heterogeneity between clinical studies [33,34]. Generating evidence from this meta-analysis may have been affected by these differences, depending on the amount to which these variations were present. Therefore, owing to the limited number of studies with strict inclusion criteria, variations in the ways interventions were delivered, and differences in health service delivery, the overall generalizability of our findings is limited. Finally, as only English-language papers were selected, it is possible that some important studies may have been missed during the literature search.

Conclusions

The current meta-analysis revealed that there is limited evidence on the effectiveness of eHealth interventions on adherence to guideline-recommended medications after ACS compared to controls. Although prior studies demonstrate the use of eHealth tools for modifying cardiovascular risk factors, our pooled analysis of RCTs specific to people who had ACS did not find a significant association between eHealth interventions and medication adherence across 5 standard drug classes at 6- and 12-month follow-ups. This highlights the need for further studies to better understand the role of different eHealth approaches, including those beyond text messaging, to enhance post-ACS pharmacotherapy adherence and potentially resultant cardiovascular outcomes.

Acknowledgments

No artificial intelligence assistance was used for data analysis and writing the study.

Data Availability

All data generated or analyzed during this study are included in this published article.

Authors' Contributions

ASB contributed to the conceptualization. WAA, TMA, and SA contributed in the data curation. ASB contributed to the formal analysis. ASB and WT contributed to the methodology. ASB, TMA, WAA, SA, and WT contributed in writing the original paper. ASB, WAA, and WT contributed in writing review and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA checklist.
[PDF File (Adobe PDF File), 66 KB - cardio_v7i1e52697_app1.pdf]

Multimedia Appendix 2
Search strategy.
[DOCX File , 22 KB - cardio_v7i1e52697_app2.docx]

Multimedia Appendix 3
Effect of eHealth intervention on medication adherence after acute coronary syndrome. ACEI: angiotensin-converting enzyme inhibitor; ARB: angiotensin receptor blocker [13-17].
[PNG File , 1712 KB - cardio_v7i1e52697_app3.png]

Multimedia Appendix 4
Subgroup analysis: effect of eHealth intervention on medication adherence to cardioprotective therapies at 6 and 12-month.
[DOCX File , 719 KB - cardio_v7i1e52697_app4.docx]

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Abbreviations

ACEI: angiotensin-converting enzyme inhibitor
ACS: acute coronary syndrome
ARB: angiotensin receptor blocker
mHealth: mobile health
MMAS-8: 8-item Morisky medication adherence scale
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT: randomized controlled trial
RD: risk difference

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Original Paper

Determining Optimal Intervals for In-Person Visits During Video-Based Telemedicine Among Patients With Hypertension: Cluster Randomized Controlled Trial

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Abstract

Background: Introducing telemedicine in outpatient treatment may improve patient satisfaction and convenience. However, the optimal in-person visit interval for video-based telemedicine among patients with hypertension remains unreported in Japan.

Objective: We determined the optimal in-person visit interval for video-based telemedicine among patients with hypertension.

Methods: This was a cluster randomized controlled noninferiority trial. The target sites were 8 clinics in Japan that had a telemedicine system, and the target patients were individuals with essential hypertension. Among patients receiving video-based telemedicine, those who underwent in-person visits at 6-month intervals were included in the intervention group, and those who underwent in-person visits at 3-month intervals were included in the control group. The follow-up period of the participants was 6 months. The primary end point of the study was the change in systolic blood pressure, and the secondary end points were the rate of treatment continuation after 6 months, patient satisfaction, health economic evaluation, and safety evaluation.

Results: Overall, 64 patients were enrolled. Their mean age was 54.5 (SD 10.3) years, and 60.9% (39/64) of patients were male. For the primary end point, the odds ratio for the estimated difference in the change in systolic blood pressure between the 2 groups was 1.18 (90% CI –3.68 to 6.04). Notably, the criteria for noninferiority were met. Patient satisfaction was higher in the intervention group than in the control group. Furthermore, the indirect costs indicated that lost productivity was significantly lesser in the intervention group than in the control group. Moreover, the treatment continuation rate did not differ between the intervention and control groups, and there were no adverse events in either group.

Conclusions: Blood pressure control status and safety did not differ between the intervention and control groups. In-person visits at 6-month intervals may cause a societal cost reduction and improve patient satisfaction during video-based telemedicine.

Trial Registration: UMIN Clinical Trials Registry (UMIN-CTR) UMIN000040953; https://tinyurl.com/2p8devm9

(JMIR Cardio 2023;7:e45230) doi:10.2196/45230

KEYWORDS

hypertension; Japan; lost productivity time; patient satisfaction; telemedicine

Introduction

The introduction of telemedicine in outpatient treatment may improve patient satisfaction and convenience [1,2]. Moreover, it can overcome several challenges related to in-person visits in outpatient care. One of the challenges in treating lifestyle-related diseases in outpatient clinics is treatment dropout [3]. A widespread use of telemedicine can help prevent such treatment dropouts among working people. Notably, the COVID-19 pandemic has caused many interruptions in medical care. For example, in a survey of 30,000 Japanese workers, the treatment of 11% of the patients requiring regular hospital visits was interrupted during the pandemic [4]. Under these circumstances, the wide use of telemedicine is expected to prevent the interruption of medical visits owing to the pandemic.

Many studies in the relevant literature have reported the effectiveness of telemedicine [5-9]. In Japan, a previous study involving a 1-year follow-up of patients with hypertension randomized into 2 groups (standard care or telemedicine) revealed that the mean weekly systolic blood pressure at the end of the study was significantly lower in the telemedicine group [10]. However, telemedicine has not been widely adopted in Japan, partly because of the national medical fee system. Moreover, in Japan, reimbursement for telemedicine is <50% of the reimbursement for normal in-person visits [11]. Considering that the standard reimbursement for telemedicine is equal to or greater than the reimbursement for in-person visits worldwide, lesser reimbursement in the Japanese fee system is a major challenge. Another challenge is the interval between in-person visits. Until March 2022, in-person visits were required once every 3 months for insured patients who were using telemedicine in Japan [11]. This short interval between in-person visits may be a barrier to the widespread use of telemedicine in Japan. Since April 2022, the restrictions on in-person visit intervals in telemedicine have been relaxed, and the obligation of conducting such visits every 3 months has been abolished; in addition, there are no longer any restrictions on in-person visit intervals. However, this change was not based on evidence-based medicine but was largely attributed to the COVID-19 pandemic.

To our knowledge, there are no studies in Japan on the optimal in-person visit interval for telemedicine in patients with hypertension based on a multifaceted evaluation, including health economics and patient satisfaction assessments. Therefore, this study's aim was to generate evidence regarding the optimal in-person visit intervals for patients with essential hypertension during the video-based telemedicine.

Methods

Study Design

This was a cluster randomized controlled trial conducted as a noninferiority trial.

Site Selection

A total of 8 clinics in Japan with a video-based telemedicine system at study initiation were included in this study. Notably, a clinic was defined as a place where physicians practiced medicine for the public, or a specified number of people who did not have facilities for admitting patients or had facilities for admitting ≤19 patients.

Study Population

Study participants were included in each clinic. The inclusion criteria were as follows: adult patients receiving outpatient telemedicine or who were about to start receiving outpatient telemedicine; those diagnosed with essential hypertension and prescribed with antihypertensive medication for ≥3 months; those with stable hypertension (ie, no change in the antihypertensive medication prescription for over 3 months) and stable comorbidities; those who could visit outpatient departments in the third and sixth months after enrollment; and those who provided their free written consent to participate in the study after receiving a full explanation of the study requirements. The exclusion criteria were as follows: patients with drug allergies; patients who were pregnant; patients with visual impairment or other problems that could interfere with telemedicine; patients with end-stage renal failure; patients with cancer who were receiving anticancer drug therapy; patients with chronic respiratory diseases, such as obstructive lung disease, who were receiving home oxygen therapy; patients participating in other clinical trials; patients who required frequent visits to the hospital for blood tests to manage comorbidities; and patients whose participation was deemed medically or scientifically inappropriate by the principal investigator and coinvestigators.

During patient recruitment, the study purpose and details were explained using an informed consent form. Patients who provided informed consent were enrolled. Moreover, we ensured that patients could withdraw their consent even after participating in the research.

Procedures

Among patients receiving video-based telemedicine, those who underwent in-person visits at 6-month intervals were included in the intervention group, and those who underwent in-person visits at 3-month intervals were included in the control group. Stratified cluster randomization was performed using clinic location (23 wards of Tokyo [urban] vs outside the 23 wards of Tokyo [suburban]) and the target number of cases as allocation factors.

Prescriptions for antihypertensive medications could be changed during the study period as needed at the discretion of the physician in charge. Moreover, medication status was assessed through self-report at the time of enrollment and at follow-up in both groups.

Patient Enrollment and Follow-up Period

Physicians recruited the patients during their first in-person visits. After recruitment by a physician, each patient spoke with a clinical research assistant who used an explanatory document to outline the study to the patient. The originally planned patient enrollment period was 3 months, but the COVID-19 pandemic led to some delays; hence, the patient enrollment period was extended to 8 months. The registration period for the first half group (3 clinics) was from May 29, 2020, to January 31, 2021, and that for the second half group (5 clinics) was from July 31, 2020, to March 31, 2021. Notably, the follow-up period for both groups was 6 months. Follow-up was planned for the 3rd and 6th months after patient enrollment.

Blood Pressure Measurement

Blood pressure was measured using an upper-arm digital automated sphygmomanometer (HEM-8712) from Omron in both intervention and control groups. Two blood pressure measurements were taken at rest in a sitting position for each patient. The interval between the first and second measurements was ≥2 minutes, and the average of the 2 measured values was used for this study. During the remote examination, the patient reported the blood pressure measurements taken on the day of the examination through video, and the doctor confirmed the blood pressure values visually.

End Points

The primary end point of the study was the change in systolic blood pressure (6-month value – baseline value). Secondary end points were the treatment continuation rate at 6 months, patient satisfaction ratings (Ministry of Health, Labor, and Welfare [MHLW] survey for behavior at the outpatient visit [Question 15; Multimedia Appendix 1], and EuroQol 5 Dimensions 5 Level [EQ-5D-5L]), a health economic evaluation, and a safety evaluation (adverse events). Furthermore, we examined whether the patient attended in-person visits for hypertension management outside the scheduled timing.

Health Economics Evaluation Questionnaire

Although the health care costs are expected to be lower for telemedicine than for normal in-person visits, their clinical outcomes may be comparable. Therefore, we performed a cost-minimization analysis of telemedicine (intervention group) versus normal in-person visits (control group). The analysis was conducted from the perspective of public health care based on the Guidelines for Analysis of Cost-Effectiveness Evaluation in the Central Social Insurance Medical Council, 2nd edition [12]. Given that the use of telemedicine may directly affect patient productivity, an additional analysis was performed to include productivity loss in terms of cost using a patient questionnaire (Multimedia Appendices 2 and 3), which comprised questions regarding employment status, occupation, and annual income.

Patients' Backgrounds

At patient enrollment, in addition to blood pressure, the following data were collected: sex, age, height, weight, pulse rate, the presence of dyslipidemia, the presence of diabetes, smoking and alcohol consumption status, family history (hypertension in parents), and use of antihypertensive medications. Patient satisfaction and health economic evaluation questionnaires were administered at enrollment and at 3- and 6-month follow-up examinations.

Sample Size Calculation

The target sample size of the study was 70. If the SD of blood pressure after the antihypertensive medication is considered 7.9 mm Hg based on the report by Chow et al [13], the SD of the change in systolic blood pressure is 7.9 mm Hg when the correlation coefficient between the pre- and postvalues is set at 0.5. Based on this assumption, when the noninferiority margin was set at –5.0 mm Hg, the required sample size was determined to be 64 cases (1-sided α=.05, power 80%). The choice of –5.0 mm Hg as the margin for our work was based on a discussion by 3 internal medicine specialists. The sample size of the *t* test was used for the above calculations because the assumption of 0 for the intracluster correlation is equivalent to that for the *t* test. The dropout rate was set at 10% (3 patients each in the intervention and control groups), and the target total number of patients was set at 70. If the correlation coefficient between the pre- and postvalues was >0.5, the SD reduced, thereby reducing the required sample size.

Statistical Analysis

Using the baseline and 6-month data, we used the time point, allocation group, and their interaction terms as the explanatory variables in a linear mixed model, whereas the systolic blood pressure (ie, the mean of two measurements) was used as the response variable. In this model, the change from the baseline value (ie, the primary end point) was estimated as the effect of the interaction term. Further, the covariates sex, age, and baseline blood pressure values were estimated as fixed effects, and the interaction term between the baseline blood pressure values and time points, allocation factors, and cluster were estimated as random effects. Kenward–Roger method was used to estimate the degrees of freedom. Further, variance components were specified for the variance–covariance structure

of the random effects. First, the correlation structure of time points among participants was specified as unstructured, but because the model did not converge, it was specified as first-order autoregressive (1) [14]. A *P* value of <.05 was considered statistically significant. All statistical analyses apart from the health economic evaluation were performed using SAS (version 9.4; SAS Institute).

Data Management

An electronic data capturing system, REDCap (Research Electronic Data Capture), was used for data management [15].

Ethical Approval

This study was approved by the Ethics Committee of Juntendo University Hospital (reception 20-038) and was conducted in accordance with the principles of the Declaration of Helsinki. The study was registered in the University Hospital Medical Information Network (UMIN) Clinical Trials Registry system [UMIN Clinical Trials Registry (UMIN-CTR)]. The UMIN study ID was UMIN000040953.

This study enrolled patients who fully understood the study purpose, signed a written consent form, and were willing to participate. Patient anonymity is maintained in this paper, including in the text, tables, and figures.

Results

Overview

No clinic participating in this clinical trial had the capacity to admit more than 20 patients. Patients in the intervention group visited 5 clinics, including 2 and 3 in urban and suburban areas, respectively. Patients in the control group visited the other 3 clinics, including 1 and 2 in urban and suburban areas, respectively. Overall, 31 and 33 patients were included in the intervention and control groups, respectively. However, 1 patient in the control group dropped out of the study before the 3-month visit after withdrawing consent. The mean age of participants was 54.5 (SD 10.3) years, and 60.9% (39/64) of the participants were male. Patient characteristics, including diabetes, dyslipidemia, smoking, alcohol drinking, and family history of hypertension, did not significantly differ between the 2 groups. However, the use of antihypertensive medication was significantly different between these groups. Table 1 summarizes the patient characteristics. Trends in blood pressure in both groups are shown in Table 2.

Table 1. Patient characteristics.

Characteristics	All patients (n=64)	Telemedicine practice group (intervention group) (n=31)	In-person visit group (control group) (n=33)	*P* value
Age (years), mean (SD)	54.5 (10.3)	51.5 (7.4)	57.2 (11.9)	.02[a]
Male, n (%)	39 (60.9)	17 (54.8)	22 (66.7)	.44
Height (cm), mean (SD)	165.4 (9.2)	165.2 (9.4)	165.7 (9.1)	.79
Weight (kg), mean (SD)	71.0 (17.0)	71.6 (18.6)	70.5 (15.6)	.74
Pulse rate per minute (bpm), mean (SD)	73.3 (11.9)	73.8 (11.2)	72.8 (12.7)	.74
Diabetes, n (%)	4 (6.3)	2 (6.5)	2 (6.1)	>.99
Dyslipidemia, n (%)	25 (39.1)	12 (38.7)	13 (39.4)	>.99
Smoking (current smoker), n (%)	10 (15.6)	3 (9.7)	7 (21.2)	.31
Alcohol drinking, n (%)	41 (64.1)	21 (67.7)	20 (60.6)	.77
Family history of hypertension, n (%)	26 (40.6)	16 (51.6)	10 (30.3)	.19
Drug adherence (complied with physicians' instructions), n (%)	61 (95.3)	29 (93.5)	32 (97)	.60
Antihypertensive medication, n (%)				
ACE-I[b]	2 (3.1)	0 (0)	2 (6.1)	.49
ARB[c]	25 (39.1)	15 (48.4)	10 (30.3)	.20
CCB[d]	35 (54.7)	8 (25.8)	27 (81.8)	<.001[a]
β-blocker	4 (6.3)	2 (6.5)	2 (6.1)	>.99
α-blocker	0 (0)	0 (0)	0 (0)	>.99
Diuretics	5 (7.8)	5 (16.1)	0 (0)	.02[a]
Combination drug	16 (25)	13 (41.9)	3 (9.1)	.003[a]
ARB+CCB	15 (23.4)	12 (38.7)	3 (9.1)	.007[a]
ARB+diuretics	1 (1.6)	1 (3.2)	0 (0)	.48

[a]*P*<.05.

[b]ACE-I: angiotensin-converting enzyme inhibitor.

[c]ARB: angiotensin II receptor blocker.

[d]CCB: calcium-channel blocker.

Table 2. Trends in blood pressure.

	All patients (n=64), mean (SD)	Telemedicine practice group (Intervention group) (n=31), mean (SD)	In-person visit group (Control group) (n=33), mean (SD)	*P* value
At time of registration (mm Hg)				
Systolic blood pressure	132.6 (14.3)	128.8 (13.1)	136.3 (14.7)	.03[a]
Diastolic blood pressure	87.3 (9.3)	85.3 (9.6)	89.2 (8.8)	.09
Follow-up at 3 months (mm Hg)[b]				
Systolic blood pressure	129.8 (13.7)	125.4 (10.8)	134.1 (15.0)	.01[a]
Diastolic blood pressure	86.0 (8.9)	82.2 (6.6)	89.7 (9.4)	<.001[a]
Follow-up at 6 months (mm Hg)[b]				
Systolic blood pressure	133.7 (12.1)	130.9 (10.8)	136.4 (12.9)	.07
Diastolic blood pressure	87.4 (9.2)	85.6 (10.2)	89.2 (7.9)	.12

[a]*P*<.05.

[b]The number of patients at 3- and 6-month follow-ups was 63 because 1 patient in the control group withdrew from this study.

Primary End Points

A linear mixed model was used to estimate the difference in the change in systolic blood pressure between the 2 groups (odds ratio [OR] 1.18, 90% CI –3.68 to 6.04). The lower limit of the CI was the noninferiority margin of –5, which met the criteria for noninferiority in this study (Figure 1). Additionally, 1 patient in the intervention group made a nonscheduled in-person visit for hypertension management. Nonetheless, even after this patient was excluded from the analysis, the criterion for noninferiority was met, with a between-group (intervention and control group) difference (OR 0.51, 90% CI –4.68 to 5.69). Figure 2 shows the adjusted relative change in systolic blood pressure estimated by the linear mixed model.

Figure 1. Differences in the change in systlic blood pressure estimated using linear mixed model. Lower confidence limit (one-sided 95%) of the difference exceeded noninferiority margin of -5 mm Hg. The point estimate was odds ratio (OR) 1.18 (90% CI -3.68 to 6.04).

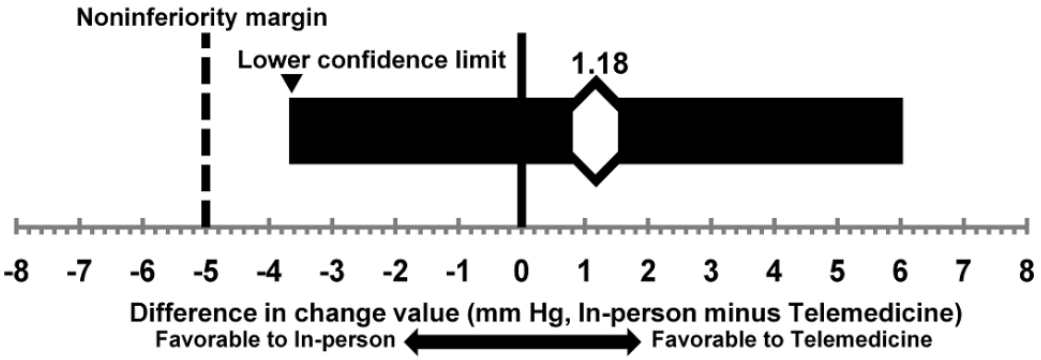
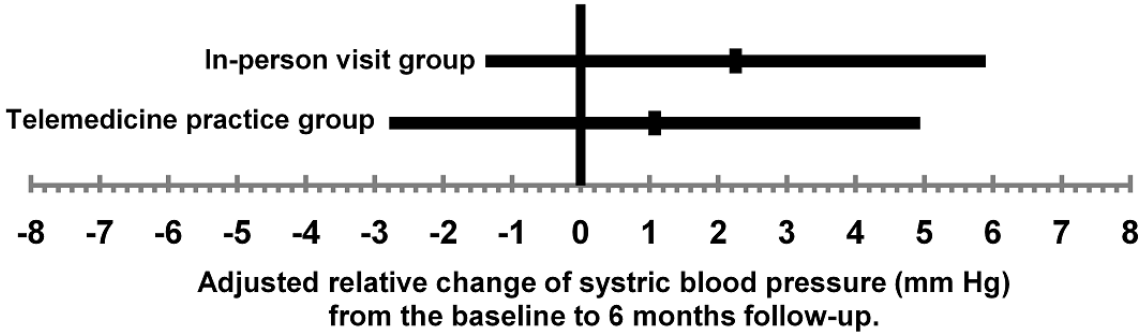


Figure 2. The adjusted relative change in systolic blood pressure estimated using a linear mixed model. The short vertical lines centered in the long lines represent the point estimates. Long lines indicate the 90% CI of the point estimates.



Secondary End Points

There were no differences in the treatment continuation rate at the 6-month follow-up between the intervention (31/31, 100%) and control (32/33, 97%) groups (P=.51). Moreover, there were no adverse events in either group. There was no significant difference in terms of in-person visits for hypertension management at unscheduled times between the 2 groups (only 1 patient in the intervention and no patients in the control group; P=.48). The results of patient satisfaction are shown in Table 3. Although there was no difference in the EQ-5D-5L results between the two groups, patient satisfaction was partially higher in the intervention group than in the control group, as assessed by the MHLW survey for behavior at the outpatient visit (question 15). In particular, responses to questions about consultation time and conversation with the physician showed that patient satisfaction was higher in the intervention group. A boxplot graph of the MHLW survey results is shown in Figure S1 in Multimedia Appendix 4. The raw data regarding patient satisfaction are shown in Table S1 in Multimedia Appendix 5. The health economic evaluation results indicated no significant difference in the 3-month average direct medical costs between the 2 groups. The indirect costs (calculated by converting lost productivity hours into Japanese Yen) indicated significantly lower lost productivity in the intervention group than in the control group (Table 4).

The number of patients at the 3- and 6-month follow-ups was 63 because 1 patient in the control group withdrew from this study.

Table 3. Difference in the change in patient satisfaction (n=63).

	Estimated difference in change value[a] (control group minus intervention group)	95% CI (lower limit to upper limit)	*P* value
EuroQol 5 Dimensions 5 Level			
Anxiety and depression	0.08	–0.14 to 0.30	.51
Mobility	0.02	–0.09 to 0.12	.72
Pain/discomfort	–0.06	–0.21 to 0.10	.54
Self-care	N/A[b]	N/A	N/A
Usual activities	–0.03	–0.09 to 0.03	.37
Visual analog scale	–4.46	–9.32 to 0.40	.12
Ministry of Health, Labor, and Welfare survey for behavior at the outpatient visit (question 15)			
Q1. Are you satisfied with the waiting time for consultation?	0.18	–0.11 to 0.47	.30
Q2. Are you satisfied with the consultation time?	0.29	0.09 to 0.48	.01[c]
Q3. Are you satisfied with the content of the medical examination and treatment provided by the physician?	0.14	–0.04 to 0.32	.19
Q4. Are you satisfied with conversation with the physician?	0.21	0.04 to 0.37	.04[c]
Q5. Are you satisfied with the hospital staff other than physicians?	0.23	0.03 to 0.43	.05
Q6. Are you satisfied with the privacy protection measures during the consultation?	0.19	–0.25 to 0.64	.37
Q7. Overall, are you satisfied with this hospital?	0.30	0.14 to 0.46	.002[c]

[a]These results were estimated by linear mixed model.

[b]N/A: not available.

[c]*P*<.05.

Table 4. Health economics evaluation (¥1=US $0.0074).

	All patients (n=64)	Telemedicine practice group (intervention group) (n=31)	In-person visit group (control group) (n=33)	*P* value
Direct medical cost (¥), mean (SD)				
At the time of registration	7561.7 (4461.3)	7674.8 (3404.7)	7455.45 (5319.1)	.84
Follow-up at 3 months	5006.8 (2048.5)	4568.4 (2357.9)	5431.56 (1623.0)	.09
Follow-up at 6 months	8189.1 (4513.8)	9131.0 (4589.7)	7276.56 (4314.6)	.10
Indirect costs calculated by converting lost productivity hours into Yen (¥), mean (SD)				
At the time of registration	32,734.8 (33,372.6)	31,733.1 (33,202.2)	33,675.78 (34,018.8)	.81
Follow-up at 3 months	18,728.6 (24,435.6)	9102.3 (13,082.6)	27,771.52 (28,999.6)	.002[a]
Follow-up at 6 months	28,170.9 (28,174.7)	26,918.0 (26,157.0)	29,347.80 (30,305.9)	.73
Societal costs (total of direct medical costs and indirect costs) (¥), mean (SD)				
At the time of registration	40,391.4 (33,574.4)	39,441.9 (33,343.5)	41,283.30 (34,282.0)	.82
Follow-up at 3 months	23,697.5 (25,030.7)	13,670.7 (14,319.0)	33,116.62 (29,195.6)	.001[a]
Follow-up at 6 months	36,292.6 (28,756.4)	36,065.1 (26,242.5)	36,506.35 (31,341.6)	.95

[a]*P*<.05.

Discussion

Overview

The results of this study indicated no difference in blood pressure between the intervention and control groups. The health economics evaluation results showed that costs were lower for the intervention group than for the control group when productivity losses (social costs) were considered. Furthermore, patient satisfaction, mainly with consultation time and conversation with the physician, was higher in the telemedicine group.

Blood pressure values differed between the 2 groups at registration, and this could have affected the primary end point, although the outcome was the change in systolic blood pressure from baseline. The systolic blood pressure at registration was adjusted in a statistical model while evaluating the primary end point as per major guidelines, such as the European Medicines Agency guidelines [16]. Regarding patient background, the medications used were different among all patients (Table 1). Moreover, physician preferences for antihypertensive drug prescriptions may have varied among the participating clinics. This bias may be attributed to cluster randomization with an insufficient number of clusters. However, the primary end point of the study was the stability of systolic blood pressure in real world, regardless of the medication used, and this study demonstrated noninferiority of the primary end point in patients with stable essential hypertension. Therefore, the 3-month follow-up did not necessarily have to be an in-person visit, suggesting that, under certain conditions, continued treatment is also possible with in-person visits at 6-month intervals during video-based telemedicine.

Doctor-patient communication is crucial for improving both health outcomes and treatment adherence in patients. However, physicians tend to interrupt patients' complaints in an outpatient setting [17]. Moreover, insufficient doctor-patient communication was recognized by patients as a critical cause of treatment dissatisfaction [18]. In this study, in the patient satisfaction evaluation through the MHLW survey for behavior at outpatient visits (question 15), the intervention group reported greater satisfaction with consultation time and conversation with the physician. The satisfaction with consultation time may be attributed to the better accessibility of web-based treatment. Notably, good accessibility is a convenient and major factor in increasing patient satisfaction, and this has been a particularly important factor during the COVID-19 pandemic [19,20]. The intervention group reported higher scores in satisfaction with the conversation with the doctor, which may indicate characteristics of telemedicine as it is a one-to-one interaction with a doctor (in a private room) that allows for a more in-depth and pleasant conversation with the doctor than is possible in a regular outpatient clinic. Moreover, increasing patient satisfaction can have a positive effect on health outcomes [21]. The results of the question "Are you satisfied with the waiting time for consultation?" were not significantly different between the two groups. The reasons behind the answers to this question may differ according to the operational system of each medical facility. Therefore, the specific implications of these results are not clear from this question. Further studies are required to address these issues.

The relationship between telemedicine and cost-effectiveness has been reported in various clinical fields [22-25]. For instance, the report of the Victorian Stroke Telemedicine intervention contained an estimation of the cost per quality-adjusted life year (QALY) gained from stroke telemedicine. At 12 months, the QALYs were estimated to be 0.43 per person in the control period and 0.5 per person in the intervention period. After 1000 bootstrapping iterations, the Victorian Stroke Telemedicine intervention period, compared with the control period, was more effective and cost saving in 50.6% of iterations and cost-effective (US $0 and US $33,357.9 per QALY gained) in 10.4% of iterations, potentially contributing to the further implementation of telemedicine for acute stroke care in Australia [25]. In this study, a comparison of societal costs, which are the sum of productivity losses and direct medical costs converted into monetary values, revealed that the costs were lower in the intervention group than in the control group. Notably, the calculation of productivity losses included patient and family transportation expenses and labor productivity loss (workforce productivity loss). These results indicate that telemedicine is effective in reducing societal costs after accounting for productivity losses. To our knowledge, this is the first study to report the usefulness of video-based telemedicine for societal cost reduction. In addition to noninferiority in blood pressure control, safety, and higher patient satisfaction of telemedicine versus in-person visits, the reduction in societal costs suggests that telemedicine is more cost-effective in a society-based analysis. Thus, telemedicine is valuable from health economics and medical perspective.

This study has some limitations. First, the number of participating facilities was small; hence, the data obtained from 8 included facilities may not represent overall telemedicine in Japan. Second, the study cohort was limited to patients with stable essential hypertension. Therefore, the study results may not be generalizable. Third, the COVID-19 pandemic posed difficulty in patient recruitment; hence, the patient recruitment period was extended from 3 to 8 months. Consequently, the seasons for patient registration varied, and the difference in season may have affected blood pressure [26]. Fourth, there was 1 unscheduled patient visit for hypertension management in the intervention group, which possibly influenced the blood pressure findings by affecting the change in systolic blood pressure. However, the noninferiority criteria in this study were met even after excluding this patient. Fifth, the observation period was short. We have only demonstrated the usefulness of video-based telemedicine for at least 6 months of follow-up. It would be desirable to evaluate the usefulness of the video-based telemedicine in clinical trials with follow-up periods of 6 months or more. Sixth, the study did not directly assess the prevention of cardiovascular events. The original and primary purpose of blood pressure control is to prevent cardiovascular events [27]. A study design with cardiovascular events as the primary end point is desirable but not feasible because a long observation period is required to evaluate cardiovascular events. Further studies are required to address this issue. Seventh, the timing of the start of outpatient telemedicine could affect the patient satisfaction rating. In this study, we did not evaluate the relationship between the patient satisfaction and timing of the start of the outpatient telemedicine. In future work, we would like to consider the mean time from the start of the outpatient telemedicine.

Conclusions

Switching in-person visit intervals from 3 to 6 months in patients with stable essential hypertension did not cause any difference in the status of blood pressure control or safety in video-based telemedicine. Moreover, the use of video-based telemedicine is expected to have a social societal cost reduction effect and improve patient satisfaction.

Acknowledgments

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Data Availability

Because we did not obtain consent from patients for their data to be shared publicly, the data are not available. The corresponding author will respond to inquiries on the data analysis in this study.

Authors' Contributions

YN and M Nojima had full access to all data in the study and took the responsibility for the integrity of the data and accuracy of the data analysis. YN, DS, and RW undertook the study concept and design. HK, SI, SO, CW, RW, HN, M Nagao, and KO were responsible for the acquisition, analysis, or interpretation of data. YN, HK, SI, M Nojima, DS, RW, YK, and KO worked on manuscript drafting. HN, HK, GT, and KO were involved in critical revision of the manuscript for important intellectual content. M Nojima worked on statistical analysis. YN, M Nagao, and KS undertook administrative, technical, or material support. YN, HW, and GT supervised the study.

Conflicts of Interest

This study was conducted in cooperation with Medley, Inc, and the collaborators included people who hold shares in the company (GT) and employee of this company (YK). However, Medley, Inc only managed the collaboration of the participating facilities and was not involved in data analyses. Monitoring and auditing were conducted by the Clinical Research and Trial Center, Juntendo University Hospital; hence, the study results were not manipulated by Medley, Inc.

Multimedia Appendix 1
Ministry of Health, Labor, and Welfare (MHLW) survey for behavior at the outpatient visit (Question 15).
[DOCX File , 13 KB - cardio_v7i1e45230_app1.docx]

Multimedia Appendix 2
Questionnaire for patients to investigate the health care economic impact of telemedicine (at the time of registration).
[DOCX File , 15 KB - cardio_v7i1e45230_app2.docx]

Multimedia Appendix 3
Questionnaire for patient to investigate the health care economic impact of telemedicine (3-month and 6-month follow-ups).
[DOCX File , 13 KB - cardio_v7i1e45230_app3.docx]

Multimedia Appendix 4
The results of the Ministry of Health, Labor, and Welfare (MHLW) survey for patients satisfaction.
[PNG File , 165 KB - cardio_v7i1e45230_app4.png]

Multimedia Appendix 5
Raw data for patient satisfaction.
[DOCX File , 20 KB - cardio_v7i1e45230_app5.docx]

Multimedia Appendix 6
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1064 KB - cardio_v7i1e45230_app6.pdf]

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Abbreviations

EQ-5D-5L: EuroQol 5 Dimensions 5 Level
MHLW: Ministry of Health, Labor, and Welfare
OR: odds ratio
QALY: quality-adjusted life year
REDCap: Research Electronic Data Capture
UMIN: University Hospital Medical Information Network

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Original Paper

Prediction of Outcomes After Heart Transplantation in Pediatric Patients Using National Registry Data: Evaluation of Machine Learning Approaches

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Abstract

Background: The prediction of posttransplant health outcomes for pediatric heart transplantation is critical for risk stratification and high-quality posttransplant care.

Objective: The purpose of this study was to examine the use of machine learning (ML) models to predict rejection and mortality for pediatric heart transplant recipients.

Methods: Various ML models were used to predict rejection and mortality at 1, 3, and 5 years after transplantation in pediatric heart transplant recipients using United Network for Organ Sharing data from 1987 to 2019. The variables used for predicting posttransplant outcomes included donor and recipient as well as medical and social factors. We evaluated 7 ML models—extreme gradient boosting (XGBoost), logistic regression, support vector machine, random forest (RF), stochastic gradient descent, multilayer perceptron, and adaptive boosting (AdaBoost)—as well as a deep learning model with 2 hidden layers with 100 neurons and a rectified linear unit (ReLU) activation function followed by batch normalization for each and a classification head with a softmax activation function. We used 10-fold cross-validation to evaluate model performance. Shapley additive explanations (SHAP) values were calculated to estimate the importance of each variable for prediction.

Results: RF and AdaBoost models were the best-performing algorithms for different prediction windows across outcomes. RF outperformed other ML algorithms in predicting 5 of the 6 outcomes (area under the receiver operating characteristic curve [AUROC] 0.664 and 0.706 for 1-year and 3-year rejection, respectively, and AUROC 0.697, 0.758, and 0.763 for 1-year, 3-year, and 5-year mortality, respectively). AdaBoost achieved the best performance for prediction of 5-year rejection (AUROC 0.705).

Conclusions: This study demonstrates the comparative utility of ML approaches for modeling posttransplant health outcomes using registry data. ML approaches can identify unique risk factors and their complex relationship with outcomes, thereby identifying patients considered to be at risk and informing the transplant community about the potential of these innovative approaches to improve pediatric care after heart transplantation. Future studies are required to translate the information derived from prediction models to optimize counseling, clinical care, and decision-making within pediatric organ transplant centers.

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KEYWORDS

explainable artificial intelligence; machine learning; mortality; outcome prediction; organ rejection; organ transplantation; pediatrics; United Network for Organ Sharing

Introduction

Background

The rates of survival for pediatric solid organ transplant recipients continue to improve. Overall, the 5-year survival rate for pediatric heart transplant (HT) recipients was 81.5% between 2009 and 2013 [1]. Despite these improvements, ongoing concerns remain regarding the rates of late acute rejection (LAR) and hospitalization within this population [2-5]. Increased number and frequency of LAR episodes and hospitalizations reduce health-related quality of life of these patients and their families owing to multifactorial reasons [6-9]. Therefore, any insight to help stratify those patients at higher risk of posttransplant complications will allow better resource allocation and focused interventions to reduce morbidity and mortality.

With the advent of machine learning (ML) methodologies, predictive modeling has entered a new era, leveraging latent information from a large number of data points that was previously not practical. Despite advancements in research using ML and its predictive utility for prediction of posttransplant health outcomes, widespread use and clinical application are still limited in pediatric transplant recipients [10-12]. In addition, the currently available research into posttransplant health outcomes in pediatric patients has suffered from a lack of rigorous statistical approaches, small sample sizes comprising samples from single transplant centers with limited generalizability, and other methodological limitations [13-15]. Furthermore, general linear modeling or Cox proportional hazards regression approaches are prevalent in this research, offering limited predictive utility [16-18].

Data-driven modeling and ML approaches have had limited application in prediction of outcomes in pediatric heart transplantation despite the availability of robust databases of patient electronic health records (EHRs) and longitudinal data [19-21]. Among these few studies, the use of ML approaches in pediatric transplantation has resulted in limited success in predicting health outcomes [10,15,16]. However, the use of advanced ML approaches with these data are unexplored and can inform care and decision-making.

ML and deep learning (DL) approaches can identify unique risk factors as well as their complex relationship with outcomes using prediction modeling. Results from these approaches can thereby aid in identifying patients considered to be at high risk and provide a solid foundation for improved clinical care and risk stratification as well as enhance decision-making. In our previous work, DL and traditional ML techniques were applied to United Network for Organ Sharing (UNOS) patient data from a single large pediatric transplant center in the southwestern United States. Despite having to work with a relatively small sample, we demonstrated that traditional ML models can predict hospitalizations across liver, kidney, and heart transplantations with moderate accuracy [15]. This study sought to take a step further by testing and examining the utility of ML and DL models for predicting LAR and mortality at 1, 3, and 5 years after transplantation using national UNOS data on pediatric HT recipients. To the best of our knowledge, this is the first study that uses national registry data to evaluate ML-based prediction models for multiple post–heart transplantation outcomes across multiple prediction windows. In addition, the use of DL approaches with national UNOS data represents an important innovation for the prediction of posttransplant outcomes in pediatric patients. The long-term goal of this endeavor is to continue to improve the ability of pediatric transplant teams to identify patients early on who are at higher risk of poor posttransplant outcomes. Using the information gained from these modeling techniques will directly translate into the development of clinical decision-making support tools for pediatric transplantation teams and allow an opportunity to perform targeted interventions to potentially improve outcomes.

The remainder of this paper is organized as follows: in the *Related Work* subsection, we review the recent literature on building prediction models for outcomes of pediatric organ transplantation. In the *Methods* section, we describe the data set, problem setting, outcome definition, selection of variables, data preprocessing, ML and DL modeling, and model interpretation. In the *Results* section, we present the characteristics of the patient cohort, performance of the prediction models, and interpretation of the models. In the *Discussion* section, we discuss the principal findings, clinical meaningfulness of model interpretation, ways to improve modeling, and limitations, followed by a *Conclusions* subsection.

Related Work

To identify related work in the literature, we searched PubMed for these terms in all text over the last 10 years: *[(heart transplant*) AND (pediatric* or paediatric* or child* or adolescen*) AND (machine learning)]*. A total of 123 studies were imported into Covidence (Veritas Health Innovation Ltd), a web-based software platform that facilitates conducting systematic reviews of research literature. Among the 123 studies, Covidence identified 22 (17.9%) duplicates. Next, we screened the remaining 101 studies using titles and abstracts and excluded 83 (82.2%) as irrelevant. Full-text review was conducted by multiple reviewers on the remaining 18 studies, of which 14 (78%) were ultimately excluded (n=7, 50%, did not use a pediatric sample or subsample; n=4, 29%, were not conducted using data from HT recipients; and n=3, 21%, did not use some form of ML or similar predictive modeling approach). Thus, of the initial 123 studies, 4 (3.3%; Table 1) were ultimately identified that predicted posttransplant health outcomes using ML with patient EHR data or administratively collected medical data of pediatric HT recipients. The literature search is documented in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart shown in Figure S1 in Multimedia Appendix 1.

Table 1. Related work in the literature.

Study	Prediction methods	Sample	Sample size, n	Outcomes	AUROC[a], best (95% CI)	AUROC, best (outcome)
Gupta et al [11], 2022	Stepwise logistic regression, gradient boosting, and random forest	Pediatric Heart Transplant Society database; aged <18 years; heart transplantation; discernible discharge date; transplanted between January 2005 to December 2018	4414	Prolonged length of stay (>30 days) after transplantation	0.750 (0.720-0.780)	N/A[b]
Killian et al [15], 2021	Logistic regression, multilayer perceptron, sequential minimal optimization algorithm polynomial kernel, random forest, and deep learning	UNOS[c] data for a single transplant center; aged 0-18 years; heart transplant; transplanted between 1988 and May 31, 2017	193	Hospitalization owing to rejection over 1-, 3-, and 5-year posttransplant periods	N/A	0.740 (5‐year hospitalization)
Miller et al [12], 2019	Artificial neural networks, classification and regression trees, and random forest	UNOS data; aged <18 years; heart transplant; transplanted between January 2006 and December 2016	2802	Mortality over 1-, 3-, and 5-year posttransplant periods	N/A	0.720 (1‐year mortality)
Miller et al [22], 2022	Random forest, XGBoost[d], and L2 regularized logistic regression	UNOS data; aged <18 years; heart transplant; transplanted between January 1994 and December 2016	8349	1-year and 90-day all-cause mortality	0.836 (0.823-0.849)	N/A

[a]AUROC: area under the receiver operating characteristic curve.

[b]N/A: not applicable.

[c]UNOS: United Network for Organ Sharing.

[d]XGBoost: extreme gradient boosting.

Miller et al [12] conducted a study that involved pediatric patients from the UNOS database who underwent heart transplantation and aimed to predict mortality within 1, 3, or 5 years using artificial neural networks (NNs), classification and regression trees, and random forest (RF), and the area under the receiver operating characteristic curve (AUROC) values of the testing data were 0.72, 0.61, and 0.60, respectively. All models displayed poor sensitivity in identifying positive cases, and the authors explained that the ML algorithm tended to be biased toward the common outcomes rather than toward the rarities. In a more recent study, Miller et al [22] used 3 binary classification algorithms (RF, extreme gradient boosting [XGBoost], and L2 regularized logistic regression [LR]) and 3 survival models (random survival forest, survival gradient boosting, and L2 regularized Cox regression) to predict 1-year and 90-day mortality after heart transplantation. The study used shuffled 10-fold cross-validation (CV) and rolling CV where each fold is a transplantation year, and training data are from at least 1 transplantation year before the evaluated year. In the shuffled CV, RF was the best-performing model, and it achieved a much better performance (AUROC 0.893, 95% CI 0.889-0.897) than XGBoost, which was the best model in the rolling CV (AUROC 0.657, 95% CI 0.647-0.667), indicating that the overprediction performance is limited by the temporal shift in the data. Our study differs from the work by Miller et al [22] in that we compared the performance of mortality and organ rejection prediction models. We also used Shapley additive explanations (SHAP), a post hoc explanation method, to rank the features by their importance.

Gupta et al [11] analyzed the data in the Pediatric Heart Transplant Society database and identified factors that are related to the prolonged length of stay (>30 days) after heart transplantation among pediatric patients. This study evaluated stepwise LR, gradient boosting, and RF when building the risk-prediction model for prolonged length of stay. The final prediction model achieved an AUROC value of 0.75 (95% CI 0.72-0.78) for the overall population. Killian et al [15] extracted the data of pediatric patients who underwent heart, kidney, or liver transplantation from UNOS data from a single transplant center in the United States and focused on the prediction of hospitalization within the observation windows of 1, 3, and 5 years after each patient's first organ transplantation using both traditional ML methods (RF, LR, multilayer perceptron [MLP], and support vector machine [SVM]) and a simple feed-forward NN model. The overall performance of DL was not better than that of the traditional ML methods. The best-performing model was the RF model for 5-year hospitalization prediction (AUROC 0.74). Our study differs from the work by Killian et al [15] in three aspects: (1) we used national UNOS data for the modeling, (2) we built models to predict organ rejection and mortality outcomes and compared them, and (3) we used the observation data collected up to the time of the transplantation procedure to predict the outcomes.

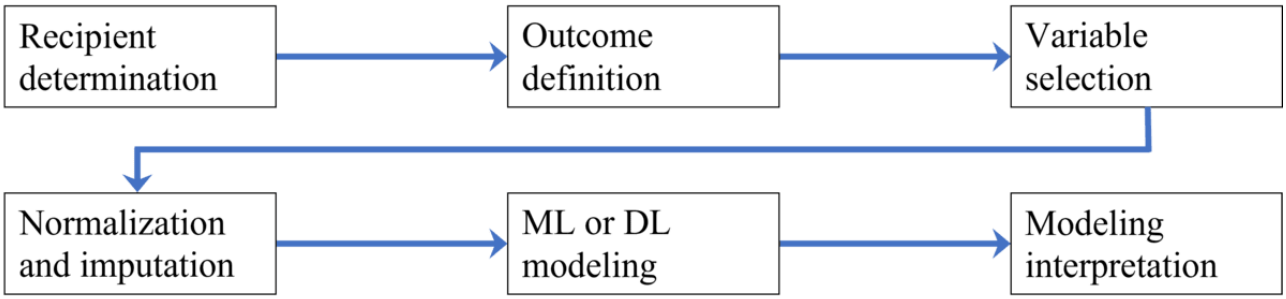
Methods

UNOS Data

For this study, we used national UNOS data from 1987 to 2019 [23]. This database contains pretransplant medical information and long-term and posttransplant health outcomes of organ transplant recipients at the national and center level. A record of each recipient in the UNOS data is established when the recipient is registered as a candidate for an organ transplant. Each recipient's record includes their pre- and posttransplant medical and health data completed at 3 time points: being listed for a transplant (ie, transplant candidate registration), at the time of the transplant procedure (ie, transplant recipient registration), and annually as a posttransplant follow-up (ie, transplant recipient follow-up [TRF]). Information related to pretransplant conditions, medical data concerning the transplant procedure, posttransplant complications, and long-term health outcomes are also collected and reported by the transplant centers. These data were stored in the corresponding variables, which were then used as predictors and responses for different ML and DL models.

The overall workflow for this study is shown in Figure 1. After the identification of the patient cohort, we defined the prediction outcomes and chose the observation and prediction windows. Relevant variables were selected based on previous studies [17,24-31] and chosen by a medical expert from the available data as potential predictors. Subsequently, data normalization and imputation were performed, followed by ML and DL modeling and modeling interpretation. Details of each step are explained in the following subsections.

Figure 1. Overall workflow. DL: deep learning; ML: machine learning.



Recipient Determination

The target recipients for this study are primary pediatric HT recipients aged 0 to 18 years. The exclusion criteria were as follows: retransplantation, records with missing follow-up dates, no follow-up information during the prediction window, and patients with unknown or missing values in their outcome variables. Table 2 shows the basic demographic characteristics of the entire cohort.

Table 2. Characteristics of the entire patient cohort.[a]

Recipient	Overall (N=8201)	Alive or unknown (n=5887)	Deceased (n=2314)	*P* value
Age (years), mean (SD)	6.78 (6.48)	6.39 (6.38)	7.76 (6.62)	<.001
Sex (female), n (%)	3577 (43.62)	2558 (43.45)	1019 (44.04)	.63
Race, n (%)				<.001
American Indian or Alaska Native	41 (0.5)	25 (0.42)	16 (0.69)	
Asian	287 (3.5)	235 (3.99)	52 (2.25)	
Black or African American	1591 (19.4)	970 (16.48)	621 (26.84)	
Native Hawaiian or other Pacific Islander	29 (0.35)	13 (0.22)	16 (0.69)	
White	4781 (58.3)	3505 (59.54)	1276 (55.14)	
Multiracial	150 (1.83)	113 (1.92)	37 (1.6)	
Ethnicity (Hispanic), n (%)	1317 (16.06)	1023 (17.38)	294 (12.71)	<.001
BMI (kg/m^2), mean (SD)	17.64 (4.92)	17.53 (4.8)	17.91 (5.2)	.002
Height (cm), mean (SD)	110.28 (44.42)	107.70 (43.88)	116.80 (45.12)	<.001
Education, n (%)				<.001
None	102 (1.4)	76 (1.37)	28 (1.46)	
Grade school (grades 0-8)	2044 (28)	1551 (27.87)	543 (28.24)	
High school (grades 9-12) or GED[b]	1149 (15.74)	809 (14.54)	370 (19.24)	
Attended college or technical school	32 (0.44)	22 (0.4)	14 (0.73)	
Associate or bachelor's degree	1 (0.01)	1 (0.02)	0 (0)	
N/A[c] (aged <5 years old)	3886 (51.9)	2986 (53.66)	900 (46.8)	
Prior cardiac surgery, n (%)	404 (8.79)	270 (9.95)	134 (7.12)	<.001
Diabetes, n (%)				.13
No	7021 (97.7)	5284 (97.91)	1737 (97.09)	
Type 1	16 (0.22)	12 (0.22)	4 (0.22)	
Type 2	8 (0.11)	7 (0.13)	1 (0.06)	
Serum creatinine (mg/dL), mean (SD)	0.64 (1.23)	0.6 (1.08)	0.77 (1.6)	<.001
CMV[d]+, positive, n (%)	2286 (30.63)	1768 (32.39)	518 (25.84)	<.001
EBV[e]+, positive, n (%)	2977 (50.03)	2321 (49.37)	656 (52.48)	<.001
ABO[f] match, n (%)				<.001
Identical	6353 (77.47)	4536 (77.05)	1817 (78.52)	
Compatible	1616 (19.7)	1154 (19.6)	462 (19.97)	
Incompatible	232 (2.83)	197 (3.35)	35 (1.51)	
Primary diagnosis, n (%)				
Cardiomyopathy	4272 (52.09)	3092 (52.52)	1180 (50.99)	.21
CHD[g]	3638 (44.36)	2590 (44)	1048 (45.29)	.29
Other	291 (3.55)	205 (3.48)	86 (3.72)	.61
Secondary diagnosis, n (%)				
CHD with HLHS[h]	85 (1.04)	65 (1.10)	20 (0.86)	.33
CHD with prior surgery	1700 (20.73)	1388 (23.58)	312 (13.48)	<.001
Dilated myopathy	3588 (43.75)	2554 (43.38)	1034 (44.68)	.29
Hypertrophic cardiomyopathy	228 (2.78)	175 (2.97)	53 (2.29)	.09

Recipient	Overall (N=8201)	Alive or unknown (n=5887)	Deceased (n=2314)	*P* value
Restrictive myopathy	442 (5.39)	349 (5.93)	93 (4.02)	.001
Ventricular assist device, n (%)				<.001
None	4180 (78.19)	3401 (78.45)	779 (77.05)	
LVAD[i]	761 (14.23)	650 (14.99)	111 (10.98)	
RVAD[j]	16 (0.3)	12 (0.28)	4 (0.4)	
TAH[k]	6 (0.11)	6 (0.14)	0 (0)	
LVAD + RVAD	214 (4)	178 (4.11)	36 (3.56)	
LVAD, RVAD, or TAH unspecified	169 (3.16)	88 (2.03)	81 (8.01)	
Year of transplant (range), n (%)				<.001
1987-1990	387 (4.73)	202 (3.43)	185 (8)	
1991-1995	1074 (13.1)	523 (8.88)	551 (23.82)	
1996-2000	1150 (14.03)	658 (11.18)	492 (21.26)	
2001-2005	1255 (15.3)	807 (13.72)	448 (19.37)	
2006-2010	1548 (18.88)	1185 (20.13)	363 (15.68)	
2011-2015	1877 (22.88)	1652 (28.05)	225 (9.73)	
2016-2018	910 (11.09)	860 (14.61)	50 (2.16)	
Days listed, mean (SD)	95.33 (196.89)	99.43 (209.3)	84.92 (160.5)	.003
Days listed as status 1A[l], mean (SD)	32.92 (61.31)	37.71 (61.94)	20.73 (57.93)	<.001

[a]Nonmissing values are used to calculate summary statistics, frequency, and percentages.

[b]GED: General Educational Development Test.

[c]N/A: not applicable.

[d]CMV: cytomegalovirus.

[e]EBV: Epstein-Barr virus.

[f]ABO: the 4 main blood types are A, B, O, and AB; for a blood transfusion, the ABO blood group system is used to match the blood type of the donor and the person receiving the transfusion.

[g]CHD: congenital heart defect.

[h]HLHS: hypoplastic left heart syndrome.

[i]LVAD: left ventricular assist device.

[j]RVAD: right ventricular assist device.

[k]TAH: total artificial heart.

[l]Status 1A: the United Network for Organ Sharing status code 1A is the most severe designation for need for transplantation. Candidates on the waiting list at this level are critically ill and are receiving some form of mechanical circulatory support.

Outcome Definition

In this study, we studied 2 prediction outcomes: rejection and mortality after transplantation. For each prediction outcome (rejection or mortality), we considered 3 different outcome prediction windows of 1, 3, and 5 years after transplantation. The observation window used was the information from baseline data collected at listing or registration for a transplant and immediately after the transplant procedure. The data collected from the observational window were used as the predictors. For the prediction window of 1-year outcomes, we used the last TRF information of each patient within 1 year after transplantation to determine the 1-year outcomes. Similarly, for the prediction window of 3-year outcomes, outcomes were determined using the annual follow-up information of each patient from the time of transplantation until 3 years after transplantation. For the prediction window of 5-year outcomes, outcomes were determined using the annual follow-up information of each patient from the time of transplantation until 5 years after transplantation. Figure 2 illustrates the observation window and the outcome prediction windows for this study.

In the UNOS data, rejection outcome was defined by 2 variables jointly: *hospitalized for rejection during follow-up period* (HOSP_REJ) and *episodes of acute rejection* (ACUTE_REJ_EPI). In the study period, UNOS used these variables at different times: HOSP_REJ from April 1, 1994, and ACUTE_REJ_EPI from June 30, 2004. Therefore, we used these variables as such to define presence or absence of rejection. Therefore, rejection was determined with HOSP_REJ before June 30, 2004; after June 30, 2004, the rejection outcome was positive if either HOSP_REJ or ACUTE_REJ_EPI was *Yes* and negative otherwise. Mortality was determined using

the corresponding variables from the UNOS thoracic follow-up data set. The latest collection date for pediatric HT recipients was February 28, 2019, in the data set. Tables 3 and 4 show the number of valid recipients with known prediction outcome in each prediction window. Table 5 shows the number of patients included in data sets for predicting outcomes in multiple prediction windows.

Figure 2. Observation window and outcome prediction windows.

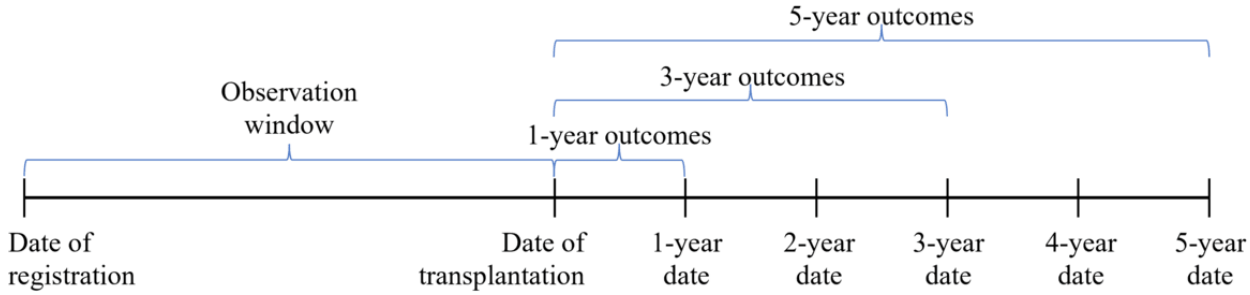


Table 3. Number of valid recipients with known rejection prediction outcome in each prediction window.

Rejection	1-year prediction window (n=2882), n (%)	3-year prediction window (n=2582), n (%)	5-year prediction window (n=2709), n (%)
No	2100 (72.87)	553 (21.42)	225 (8.31)
Yes	782 (27.13)	2029 (78.58)	2484 (91.69)

Table 4. Number of valid recipients with known mortality prediction outcome in each prediction window.

Mortality	1-year prediction window (n=6035), n (%)	3-year prediction window (n=3306), n (%)	5-year prediction window (n=2237), n (%)
No	5608 (92.92)	2388 (72.23)	969 (43.32)
Yes	427 (7.08)	918 (27.77)	1268 (56.68)

Table 5. Patients appearing in data sets for different prediction windows.

Characteristics	Outcomes	
	Rejection, n	Hospitalization, n
Have outcomes in year 1 and year 2 or 3 but not in year 4 or 5	47	116
Have outcomes in year 1 and year 4 or 5 but not in year 2 or 3	10	35
Have outcomes in year 2 or 3 and year 4 or 5 but not in year 1	61	174
Have outcomes in year 1, year 2 or 3, and year 4 or 5	66	277

Selection of Variables

Through literature review, we selected common features in UNOS data in prediction models for transplantation outcome predictions [17,24-31]. The variables were selected from donor, recipient, and donor-recipient variables. In addition, a medical expert and coauthor (DG) reviewed the list of identified features and determined the ones that were clinically relevant and should be used in predictive modeling. In addition, *diagnosis* was selected as a variable and included congenital heart defect (CHD), CHD with hypoplastic left heart syndrome, cardiomyopathy, CHD with prior surgery, dilated cardiomyopathy, hypertrophic cardiomyopathy, restrictive myopathy, and other. Any variables with >50% missing values were excluded from analysis.

Normalization and Imputation

The selected variables included categorical and continuous numerical variables. Categorical variables were coded into numerical variables for computation. The values of all continuous numerical variables were normalized between 0 and 1. Because of missing values, we conducted a missing data imputation using multivariate imputation by chained equations [32]. After normalization and imputation, variables that were collinear with other variables were excluded. This process resulted in a list of the 69 selected variables in different groups. Description and type of each variable are provided in Table S1 in Multimedia Appendix 1. Details of coding for each categorical variable can be found in Table S2 in Multimedia Appendix 1.

ML and DL Modeling

In this study, 7 ML models and 1 DL model were tested. The ML models were XGBoost, LR, SVM, RF, stochastic gradient descent, MLP, and adaptive boosting (AdaBoost). We used the *scikit-learn* package in Python (Python Software Foundation) for the implementation of all ML models. All ML models were implemented with default settings. The DL model was

implemented with the Python packages of *TensorFlow* and *Keras*. After experimenting with different hyperparameters, the selected DL model included 2 hidden layers with 100 neurons and a rectified linear unit (ReLU) activation function followed by batch normalization for each and a classification head with a softmax activation function. The model used the adaptive gradient algorithm with a learning rate of 0.01 as optimizer and used cross-entropy as loss function. We trained the DL model for 50 epochs at most, with batch size of 32 and early stopping. The evaluation metrics reported include weighted precision, weighted recall, weighted F_1-score, weighted AUROC values, and area under the precision-recall curve (AUPRC) values. AUROC measures the model's ability to distinguish between positive and negative classes, whereas AUPRC measures the trade-off between precision and recall. AUPRC is often considered when the data sets used to build the models are imbalanced. We used 10-fold CV to evaluate all ML models. In each fold, a random sample of 90% of the instances were used for training, and the remaining 10% of the samples were used for testing. All evaluation metrics were computed using 10-fold CV for all models. The performances of the tested ML and DL models are reported in the Results section.

Modeling Interpretation

Prediction results of ML and DL models are often considered difficult, and sometimes even impossible, to interpret for both users and developers. With the widespread application of ML and DL, understanding why a model makes a certain prediction becomes even more important. This has led to many research studies in the field of explainable artificial intelligence [33]. These studies have proposed, developed, and tested a wide range of methods for interpreting prediction results of ML and DL models. Among these methods, SHAP provides a state-of-the-art unified framework for explainable artificial intelligence.

SHAP is an additive feature attribution approach for interpreting prediction results of an ML or DL model [34]. It assigns an importance value to each feature for a particular prediction using the classic Shapley values from game theory and their related extensions. SHAP values are attributed to the change in the expected model prediction compared with the base model fitted on background data when conditioning on each feature. The implementation of SHAP is publicly available on GitHub [35]. In this study, we used SHAP to interpret prediction results of the best-performing ML model: RF. We used the SHAP *TreeExplainer* for the interpretation of RF predictions in terms of predicted probabilities. Details of interpretation are explained in the *Results* section.

Ethical Considerations

In this study, we used publicly available deidentified UNOS data. Therefore, it was determined as exempt by the institutional review board of Florida State University.

Results

Characteristics of the Patient Cohort

Our cohort consisted of 8201 patients (UNOS data from 1987 to 2019), of whom 5887 (71.78%) were alive at the time of analysis. The characteristics of the overall patient cohort are shown in Table 2. Overall, the mean age of the cohort was 6.78 (SD 6.48) years, and 43.62% (3577/8201) of the patients were female. Interestingly, important differences were observed in race distribution, prior cardiac surgeries, and frequency of renal dysfunction between the patients who were deceased and those who were alive. There were significantly more Black or African American patients in the deceased group than the alive group (621/2314, 26.84% vs 970/5887, 16.48%; P<.001). No statistically significant difference was observed with a primary diagnosis of CHD (P=.29) or cardiomyopathy (P=.21) as the reason for transplantation. Furthermore, the diagnosis of CHD with prior surgeries (P<.001), prior cardiac surgery (P<.001), and restrictive cardiomyopathy (P=.005) was seen more frequently in the alive group. However, the number of valid recipients for each prediction window of the 2 different outcomes varied (Tables 3 and 4); for example, there were 2882 recipients with regard to the question on rejection within 1 year, of whom 2100 (72.87%) had no episodes of rejection, whereas 782 (27.13%) had episodes of rejection. Overall, the frequency distributions of episodes of rejection at 1, 3, and 5 years after transplantation were 27.13% (782/2882), 78.58% (2029/2582), and 91.69% (2484/2709), respectively (Table 3). Similarly, the frequency distributions of 1-, 3- and 5-year mortality outcomes were 7.08% (427/6035), 27.77% (918/3306), and 56.68% (1268/2237), respectively (Table 4).

Performance of the Predictive Models

The performance details of each of the tested models are reported in Table 6. We observed that there was a variation in the type of model performance with some of the models performing better than others for some outcomes. When considering AUROC as the key performance evaluation measure, RF outperformed other ML and DL algorithms in predicting 5 of the 6 outcomes (all except 5-year rejection; AUROC 0.664 and 0.706 for 1-year and 3-year rejection, respectively, and AUROC 0.697, 0.758, and 0.763 for 1-year, 3-year, and 5-year mortality, respectively). For the 5-year rejection prediction, the AdaBoost model achieved the best performance (AUROC 0.705).

Table 6. Performance of different prediction models for rejection and mortality.

Prediction models	Precision	Recall	F_1-score	AUROC[a]	AUPRC[b]
Rejection					
At 1 year					
XGBoost[c]	0.688	0.726	0.691	0.641	0.576
LR[d]	0.698	0.737	0.679	0.648	0.576
SVM[e]	0.531	0.728	0.614	0.485	0.614
RF[f]	0.695	0.735	0.677	0.664	0.575
SGD[g]	0.641	0.611	0.623	0.547	0.592
MLP[h]	0.662	0.712	0.668	0.627	0.578
AdaBoost[i]	0.699	0.735	0.696	0.648	0.576
NN[j]	0.610	0.699	0.629	0.504	0.604
At 3 years					
XGBoost	0.717	0.768	0.728	0.695	0.739
LR	0.709	0.779	0.711	0.692	0.737
SVM	0.617	0.785	0.691	0.480	0.663
RF	0.724	0.785	0.707	0.706	0.738
SGD	0.680	0.677	0.679	0.523	0.668
MLP	0.697	0.766	0.712	0.675	0.733
AdaBoost	0.717	0.769	0.728	0.703	0.734
NN	0.673	0.780	0.694	0.491	0.664
At 5 years					
XGBoost	0.873	0.915	0.881	0.697	0.888
LR	0.841	0.916	0.877	0.685	0.885
SVM	0.841	0.917	0.877	0.462	0.841
RF	0.841	0.917	0.877	0.676	0.882
SGD	0.853	0.816	0.833	0.526	0.851
MLP	0.847	0.905	0.873	0.667	0.882
AdaBoost	0.866	0.911	0.880	0.705	0.887
NN	0.853	0.915	0.877	0.484	0.847
Mortality					
At 1 year					
XGBoost	0.878	0.926	0.896	0.663	0.838
LR	0.899	0.929	0.895	0.669	0.835
SVM	0.863	0.929	0.895	0.502	0.868
RF	0.863	0.929	0.895	0.697	0.834
SGD	0.875	0.912	0.891	0.534	0.859
MLP	0.887	0.928	0.897	0.652	0.837
AdaBoost	0.886	0.926	0.898	0.667	0.838
NN	0.863	0.927	0.894	0.493	0.868
At 3 years					
XGBoost	0.725	0.745	0.729	0.737	0.567

Prediction models	Precision	Recall	F_1-score	AUROC[a]	AUPRC[b]
LR	0.709	0.739	0.699	0.719	0.566
SVM	0.626	0.722	0.607	0.574	0.584
RF	0.718	0.745	0.706	0.758	0.569
SGD	0.646	0.596	0.614	0.564	0.584
MLP	0.707	0.735	0.707	0.711	0.567
AdaBoost	0.720	0.744	0.720	0.738	0.565
NN	0.603	0.677	0.623	0.503	0.600
At 5 years					
XGBoost	0.688	0.690	0.689	0.748	0.575
LR	0.668	0.671	0.669	0.718	0.559
SVM	0.577	0.588	0.555	0.613	0.530
RF	0.717	0.718	0.717	0.763	0.574
SGD	0.599	0.604	0.600	0.596	0.521
MLP	0.636	0.638	0.622	0.683	0.550
AdaBoost	0.692	0.692	0.692	0.735	0.562
NN	0.508	0.534	0.501	0.517	0.514

[a]AUROC: area under the receiver operating characteristic curve.

[b]AUPRC: area under the precision-recall curve.

[c]XGBoost: extreme gradient boosting.

[d]LR: logistic regression.

[e]SVM: support vector machine.

[f]RF: random forest.

[g]SGD: stochastic gradient descent.

[h]MLP: multilayer perceptron.

[i]AdaBoost: adaptive boosting.

[j]NN: neural network.

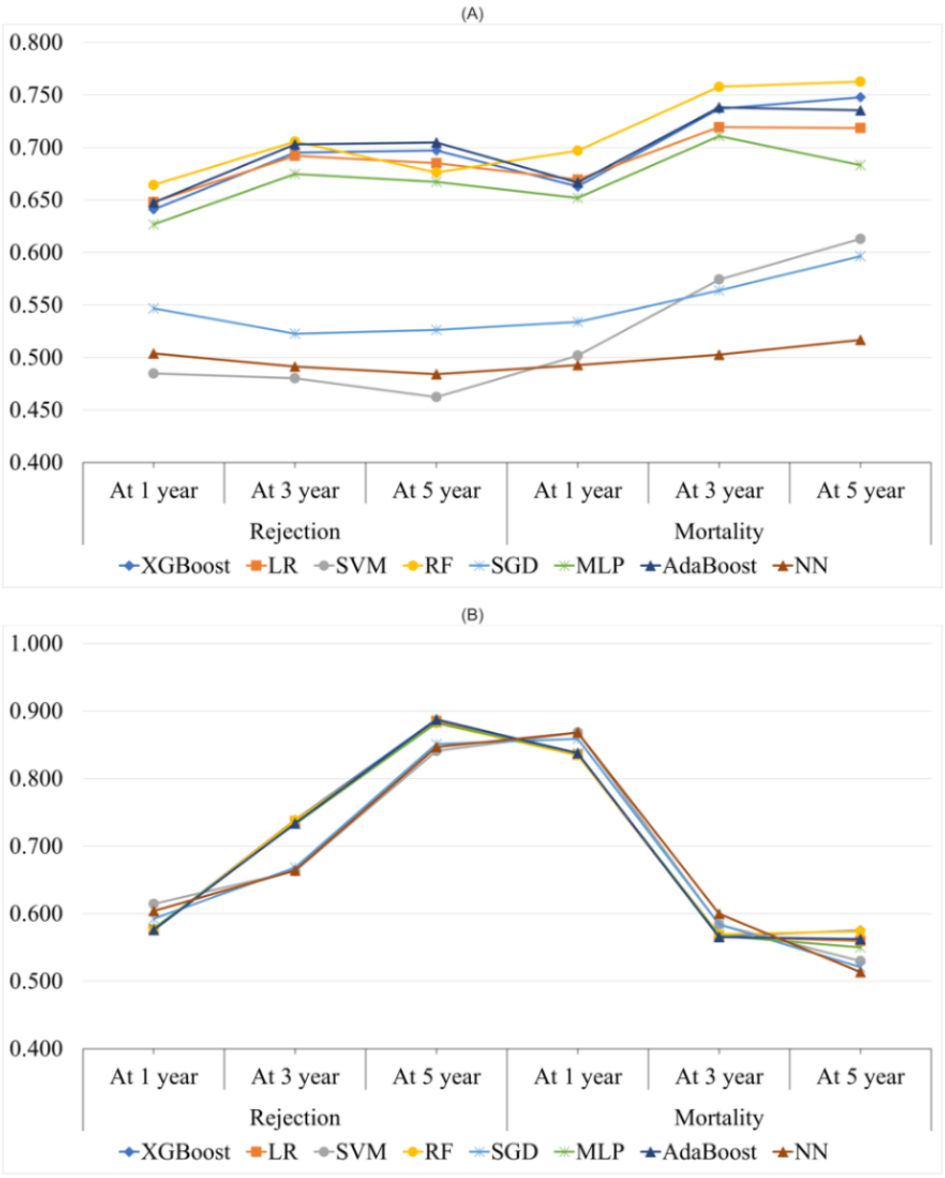
When examining the performance of the tested models across different prediction outcomes, the AUROC values for models predicting mortality were considerably higher than those of models predicting rejection (mean AUROC for rejection prediction 0.610, SD 0.090, and mean AUROC for mortality prediction 0.648, SD 0.091; $P<.001$).

When comparing the performance of the tested models across different prediction windows of each outcome, there is no significant difference among the AUROC values of the models for different prediction windows of rejection at significance level of .01. However, the AUROC value of the models for the 1-year prediction window of mortality is lower than the AUROC values of the models for the 3-year and 5-year prediction windows of mortality.

With respect to AUPRC values, XGBoost outperformed the other models in 3 of the 6 outcomes (ie, AUPRC 0.739 for 3-year rejection, AUPRC 0.888 for 5-year rejection, and AUPRC 0.575 for 5-year mortality). The NN outperformed other models in 2 outcomes (ie, AUPRC 0.868 for 1-year mortality and AUPRC 0.600 for 3-year mortality). For the 1-year rejection prediction, the SVM performed slightly better than the NN (AUPRC 0.614). Among all outcomes, the prediction of 1-year mortality and 5-year rejection showed significantly better performance than the prediction of other outcomes (mean AUPRC for 1-year mortality prediction 0.847, SD 0.015, and mean AUPRC for 5-year rejection prediction 0.870, SD 0.020).

In Figure 3, we show a comparison of the performances of different models across different prediction windows and outcomes. When we evaluated the AUROC values of different algorithms across different prediction windows and outcomes, we observed that the DL model consistently had worse performance than the other algorithms. This finding is also consistent with our previous analysis, which used data from a single transplant center in the southwestern United States [15].

Figure 3. (A) Area under the receiver operating characteristic curve values of different machine learning and deep learning algorithms for different outcomes. (B) Area under the precision-recall curve values of different machine learning and deep learning algorithms for different outcomes. AdaBoost: adaptive boosting; LR: logistic regression; MLP: multilayer perceptron; NN: neural network; RF: random forest; SGD: stochastic gradient descent; SVM: support vector machine; XGBoost: extreme gradient boosting.

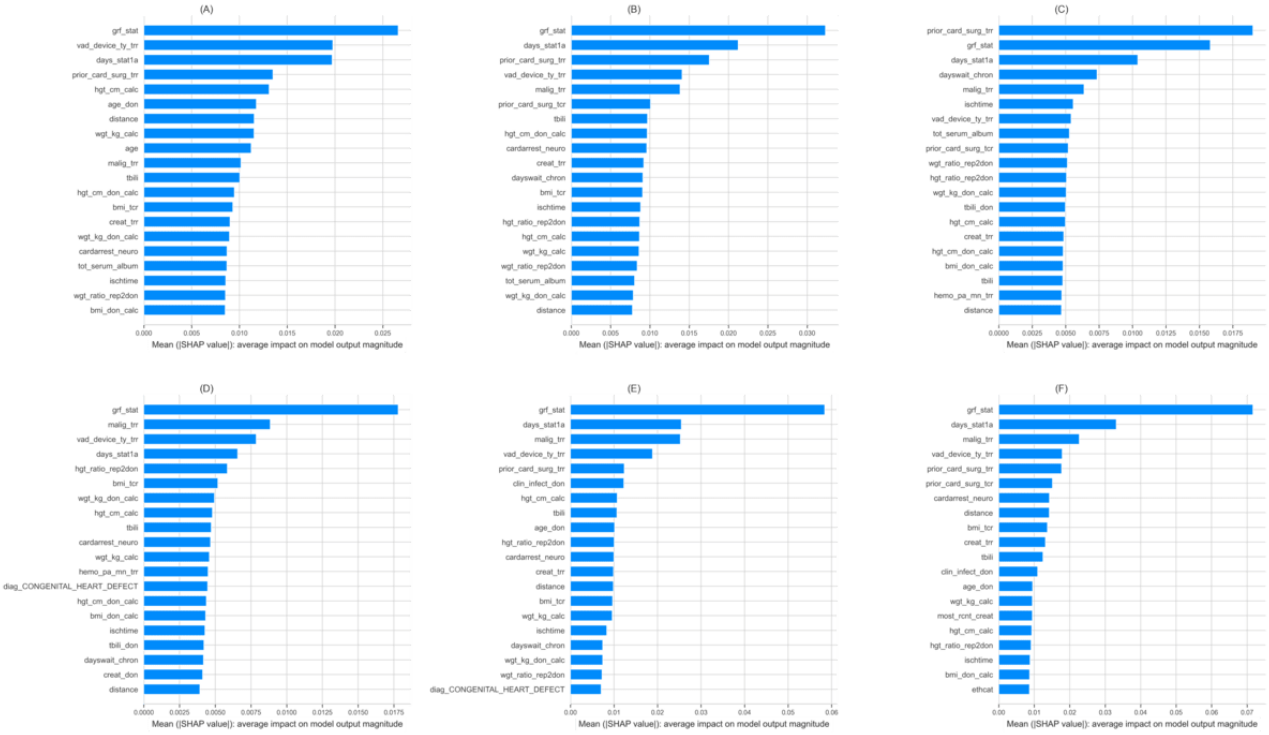


Interpretation of the Best-Performing Models by SHAP Value

Figure 4 demonstrates the impact of 20 predictor variables in terms of mean (|SHAP value|) on the outcome prediction results of RF models. The length of each bar indicates the strength of the impact the corresponding variable has on the model prediction. An examination of the impact of the predictor variables in terms of mean (|SHAP value|) across all RF models suggests that, overall, the recipient variables of graft status after transplantation, education, any known malignancies since listing for transplantation, ethnicity, and height, as well as donor height and weight, have a higher impact on prediction. In addition, graft status immediately after the transplantation was a salient predictor in nearly every model and often the most predictive per SHAP value. Pretransplant medical factors such as prior cardiac surgeries, the diagnosis of a congenital heart condition, and the use of ventricular assist devices and mechanical ventilation before the transplant procedure were important predictors across models and outcomes. Patient medical factors that were shown to be predictive included weight; a history of prior malignancies; and albumin, bilirubin, and creatinine levels. Furthermore, factors such as donor cause of death, ischemic time, waitlist duration, and duration of time listed as status 1A (the UNOS status code 1A is designated for candidates on the waiting list who have the highest priority on the basis of medical urgency; patients may be listed as status 1A for 30 days at any time after left ventricular assist device implantation when they are clinically stable) were found to be predictive.

Table S3 in Multimedia Appendix 1 shows the predictor variables that have higher impact on prediction by outcome, prediction window, and ML algorithm according to SHAP value.

Figure 4. Impact of the top 20 variables on rejection and mortality prediction by mean (|SHAP value|) for the random forest model. (A) Rejection: 1-year window. (B) Rejection: 3-year window. (C) Rejection: 5-year window. (D) Mortality: 1-year window. (E) Mortality: 3-year window. (F) Mortality: 5-year window. SHAP: Shapley additive explanations. For a higher-resolution version of this figure, see Multimedia Appendix 2.



Discussion

Principal Findings

In this study, we compared 7 ML models and 1 DL model and examined their ability to predict rejection and mortality 1, 3, and 5 years after pediatric heart transplantation. There has been increasing use of advanced mathematical modeling using large data sets to predict outcomes in pediatric transplantation [10-12]. However, despite initial experience, much work needs to be done to further evaluate and refine the best strategies and modeling techniques to optimally use these methods for advancing clinical care. In this study, RF, XGBoost, and AdaBoost demonstrated the highest AUROC values throughout the posttransplant outcomes across the 3 observation windows. As a decision tree–based ensemble ML algorithm, RF has been shown to yield the best performance in many other studies on small, tabulated data sets, which is also the case in our study. A possible reason is that RF generally performs well when the data set has a mix of categorical and numeric features; in addition, RF is less influenced by outliers than other algorithms. Nonetheless, based on best practice in ML modeling, one would need to experiment with multiple ML algorithms on a particular data set to see which ML model works best. In our study, when AUPRC was used as the primary performance measure, XGBoost outperformed other models in 3 of the 6 outcomes and yielded slightly better performance than RF. The NN slightly outperformed other models in 2 outcomes. Most importantly, the use of SHAP values to evaluate the relative importance of predictors in these models adds to the clinical interpretability, utility, and potential translation into clinical care. We also observed that the DL model consistently had worse performance than the ML algorithms, which may be related to the small amount of data available because, empirically, DL models perform better with a large number of data points. This can also suggest that DL modeling in this clinical scenario may not be the most appropriate strategy. This finding is also consistent with our previous analysis, which used data from a single transplant center in the southwestern United States [15]. However, further research is needed to validate this conclusion.

The results from this modeling demonstrate the important challenges of using registry and administrative data to model adverse medical events during posttransplant care of pediatric HT recipients. Prior research and modeling of posttransplant data in pediatric care similarly found poor-to-fair predictive utility and sensitivity using classification and regression trees, RF, and artificial NN approaches [10-12]. Previous research using RF has identified key factors in predicting ideal posttransplant outcomes 3 years after liver transplantation [10]. However, results from ML models in pediatric transplantation across kidney, liver, and heart recipients from 1 center were similarly suboptimal [15]. In adult populations, predictive validity with ML approaches has not achieved encouraging results [28,36-43]. Many of these studies have focused only on mortality in adult HT recipients, offering little insight for pediatric transplant teams managing instances of other important outcomes such as rejection in a much more heterogenous population. Despite the UNOS being the largest registry of data for pediatric transplant patients, there are inherent data quality issues that may limit the optimal use of these analytical approaches. Therefore, urgent efforts are needed to improve quality of data entry and reduce the amount of missing data.

Model Interpretation

SHAP values [34] were used in this study to provide greater interpretability of the results and to quantify the relative influence of individual variables within these models. Our data highlight the importance of graft status immediately after transplantation as being a salient predictor in nearly every model. Graft function immediately after transplantation is affected by a complex interplay of donor, preservation, recipient, and perioperative factors. These factors are unique in individual patients; however, the presence of suboptimal graft function immediately after transplantation is a strong predictor of 1-, 3-, and 5-year rejection and mortality. This observation does not necessarily change clinical management currently; however, it highlights the importance of in-depth evaluation and optimization of donor, recipient, and transplantation factors, which can influence graft function and the strength of its influence on important clinical outcomes; for example, donor myocardial function, ischemic time, and sensitization are a few factors that can influence graft function after transplantation. Other factors such as pretransplant use of ventricular assist devices and mechanical ventilation are important factors in predicting clinical outcomes as well. Furthermore, liver or kidney dysfunction and being listed as status 1A, all of which can be considered surrogate markers for a patient who is sicker, have important predictive influence on the outcomes. Various donor factors such as weight, height, and BMI, as well as recipient-to-donor weight ratio, influenced the predictive models. We hypothesize that these factors were likely related to the smaller children who are more likely to have CHD and, in addition, may have a larger impact owing to the donor-recipient size discrepancy in thoracic cavity. Likewise, other factors such as pretransplant medical factors, including the number of prior cardiac surgeries and a diagnosis of CHD, were important predictors across various models and outcomes. Previous studies have shown that a single-ventricle physiology secondary to hypoplastic left heart syndrome influences outcomes; however, this was not the case in our study. In addition, longer waitlist duration likely secondary to medical or surgical factors, such as organ dysfunction, human leukocyte antigen sensitization or mismatch, and the need for other procedures were important factors in the predictive models. These medical factors have been similarly identified in prior research using ML approaches in other transplantation data, including those of adult populations [15,28,41-43]. Patient social factors predicting outcomes across the time frames in this study included age, ethnicity, level of education, and sex, which have been reported as important predictors in prior research [15,28,41-43]. Female and adolescent patients have been shown to be at greater risk for rejection episodes [44-46] and mortality than male or younger patients [47-51]. Our study also highlighted that recipient ethnicity was an important predictor for 5-year mortality. Obviously, it is difficult to predict why that is the case, but it does call for a need to further understand the complex interplay of various psychosocial factors.

Improving Future Modeling

Our modeling efforts build on prior studies through the inclusion of posttransplant data through subsequent observation windows using TRF data. Despite this, posttransplant health outcomes for children and adolescents remain challenging to predict with better-than-modest accuracy. The UNOS data constitute a large and valuable registry of transplant patients nationally, yet this administrative database *as is* may not be optimal for prediction of specific posttransplant health outcomes owing to the lack of granularity at important clinical time points [43]. Importantly, these data sets also lack important data collected on psychological, social, and environmental factors, which can help predict long-term outcomes. In addition to medical factors, psychosocial variables and family functioning are well-known to influence outcomes [52-54]. Usually, psychosocial variables and family functioning are not well represented in these databases, limiting an important aspect of care, which affects opportunities for effective predictive modeling. Despite the importance of psychological and social determinants of posttransplant pediatric heart transplantation outcomes, these valuable data are not available in the UNOS database or in similar transplant data sets, such as the Studies of Pediatric Liver Transplantation [55] and Scientific Registry of Transplant Recipients [56] databases. The absence of such parameters can likely affect the predictive ability of these models; for example, previously, UNOS data captured physician- or transplant team–reported nonadherence (UNOS variable: *recipient noncompliant during this follow-up period* [PX_NCOMPLIANT]), but this variable has been excluded from TRF forms since 2007. Although physician proxy reports, reports, or opinion of patient medication adherence have inherent measurement issues [13], the lack of this critical predictor from these data sets and our inability to include these in modeling algorithms is a major loss in predictive utility, especially because of the known strong association between medication nonadherence and numerous posttransplant outcomes [2-5,50,57,58]. To overcome these limitations, the inclusion of granular longitudinal structured and unstructured clinical and psychosocial data within the patient EHR (eg, text from clinical notes) using these advanced analytical methods is the next step to refine the modeling algorithms, thereby increasing chances of better predictive capability.

Limitations

This study has several limitations, including the inherent ones related to the use of database and registry data; for example, all rejections were treated as though they were of the same grade. In this work, we treated the 3 outcomes independently, although 1 outcome may in fact be a cause of another. Nonetheless, we built different models for different outcomes. In future work, we will build multiclass models with different combinations of outcomes as the prediction outcome. In this work, we grouped together patients in the UNOS database from 1987 to 2019. In future work, we will account for era and changes in clinical practice and ways to determine outcomes. This work aims to demonstrate the promise and limitations of using ML compared with using registry data in predicting posttransplantation outcomes in pediatric recipients. Because of the number of models and algorithms we evaluated, we used default parameters for the ML algorithms. With further hyperparameter tuning, we may be able to further improve the prediction performance of these models. We also converted categorical variables to numeric variables when building the prediction models. Another

approach would have been to use a one-hot coding scheme for all categorical variables. However, because of the small sample size, number of categorical variables, and number of categories in these variables, one-hot coding would have resulted in a very sparse data set. Nonetheless, we created one-hot variables for 8 important diagnoses for transplantation outcome prediction.

Conclusions

This study evaluates the approaches of 7 ML models and 1 DL model to predict posttransplant health outcomes using patient-level data and demonstrates the advantages and limitations of current methods to inform pediatric heart transplantation care. Important outcomes can be predicted with reasonable accuracy using various modeling techniques, and our study presents a comprehensive comparison of these techniques. We evaluated the approaches of these 8 models for 6 post–heart transplantation outcomes (organ rejection and mortality at 1, 3, and 5 years). Among the models for predicting these 6 outcomes, XGBoost yielded better AUPRC values than the other models in 3 of the 6 outcomes (ie, AUPRC 0.739 for 3-year rejection, AUPRC 0.888 for 5-year rejection, and AUPRC 0.575 for 5-year mortality). The NN outperformed other models in 2 outcomes (ie, AUPRC 0.868 for 1-year mortality and AUPRC 0.600 for 3-year mortality). The SVM performed slightly better than the NN in 1-year rejection prediction (AUPRC 0.614). Currently, the DL methods have not demonstrated additional predictive accuracy compared with the SVM, RF, and MLP methods. Future research should continue to seek out rich data sources such as EHRs to improve granularity and integrate them with existing registry data, using advanced analytical methods for predictive modeling of outcomes for pediatric HT recipients. Moreover, clinical notes in EHRs contain a wide range of social determinants of health for patients. We will develop a natural language processing pipeline to extract such information and enrich the prediction models for social risk stratification.

Acknowledgments

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Data Availability

The data underlying this paper cannot be shared publicly owing to privacy concerns because the data contain private health information of individuals receiving care from a single transplant center in the southwestern United States. However, these data are contained within the national Organ Procurement and Transplantation Network (US Department of Health and Human Services) database [59].

Authors' Contributions

ZH and MOK conceived and designed the study. MOK collected the data. AX performed data extraction and cleaning. ST implemented the models and performed the data analysis. DG provided medical domain knowledge regarding the study design. DH and XW helped with the review of the literature. ZH, ST, and MOK interpreted the data analysis results. ST, MOK, and ZH drafted the manuscript. All authors reviewed and edited the final manuscript before publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) chart for identifying the related work; description of variables; coding for categorical variables; and the rank and significance of top 20 variables having higher impact on prediction by outcomes, prediction windows, and machine learning (ML) algorithms according to Shapley additive explanations (SHAP) values.

[PDF File (Adobe PDF File), 338 KB - cardio_v7i1e45352_app1.pdf]

Multimedia Appendix 2

Impact of the top 20 variables on rejection and mortality prediction by mean (|SHAP value|) for the random forest model. (A) Rejection: 1-year window. (B) Rejection: 3-year window. (C) Rejection: 5-year window. (D) Mortality: 1-year window. (E) Mortality: 3-year window. (F) Mortality: 5-year window. SHAP: Shapley additive explanations.

[PNG File , 1201 KB - cardio_v7i1e45352_app2.png]

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Abbreviations

AdaBoost: adaptive boosting
AUPRC: area under the precision-recall curve
AUROC: area under the receiver operating characteristic curve
CHD: congenital heart defect
CV: cross-validation
DL: deep learning
EHR: electronic health record
HT: heart transplant
LAR: late acute rejection
LR: logistic regression
ML: machine learning
MLP: multilayer perceptron
NN: neural network
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

ReLU: rectified linear unit
RF: random forest
SHAP: Shapley additive explanations
SVM: support vector machine
TRF: transplant recipient follow-up
UNOS: United Network for Organ Sharing
XGBoost: extreme gradient boosting

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Original Paper

The Information Needs and Experiences of People Living With Cardiac Implantable Electronic Devices: Qualitative Content Analysis of Reddit Posts

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Abstract

Background: Cardiac implantable electronic devices (CIEDs) are used to treat a range of cardiovascular diseases and can lead to substantial clinical improvements. However, studies evaluating patients' experiences of living with these devices are sparse and have focused mainly on implantable cardioverter defibrillators. In addition, there has been limited evaluation of how people living with a CIED use social media to gain insight into their condition.

Objective: This study aims to analyze posts from web-based communities called subreddits on the website Reddit, intended for people living with a CIED, to characterize the informational needs and experiences of patients.

Methods: Reddit was systematically searched for appropriate subreddits, and we found 1 subreddit that could be included in the analysis. A Python-based web scraping script using the Reddit application programming interface was used to extract posts from this subreddit. Each post was individually screened for relevancy, and a register of participants' demographic information was created. Conventional qualitative content analysis was used to inductively classify the qualitative data collected into codes, subcategories, and overarching categories.

Results: Of the 484 posts collected using the script, 186 were excluded, resulting in 298 posts from 196 participants being included in the analysis. The median age of the participants who reported this was 33 (IQR 22.0-39.5; range 17-72) years, and the majority had a permanent pacemaker. The content analysis yielded 5 overarching categories: use of the subreddit by participants, questions and experiences related to the daily challenges of living with a CIED, physical sequelae of CIED implantation, psychological experiences of living with a CIED, and questions and experiences related to health care while living with a CIED. These categories provided insight into the diverse experiences and informational needs of participants living with a CIED. The data predominantly represented the experiences of younger and more physically active participants.

Conclusions: Social media provides a platform through which people living with a CIED can share information and provide support to their peers. Participants generally sought information about the experiences of others living with a CIED. This was often done to help overcome a range of challenges faced by participants, including the need to adapt to living with a CIED, difficulties with navigating health care, psychological difficulties, and various aversive physical sequelae. These challenges may be particularly difficult for younger and physically active people. Health care professionals may leverage peer support and other aid to help people overcome the challenges they face while living with a CIED.

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KEYWORDS

implantable cardioverter defibrillator; pacemaker; cardiac resynchronization therapy; social media; patients; peer support; content analysis; experiences

Introduction

Background

Cardiovascular diseases present a global health burden, with conditions such as atrial fibrillation being experienced by 37 million people globally [1] and heart failure experienced by 60 million people globally [2]. Cardiac implantable electronic devices (CIEDs) represent a growing treatment option for these conditions and a range of other cardiovascular diseases [3,4]. There are 3 common types of CIEDs: permanent pacemakers (PPMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy devices. In addition, novel CIEDs including subcutaneous ICDs (S-ICDs), and leadless PPMs have been developed (refer to the study by Steffen et al [4] for a detailed review). Qualitative studies have been particularly useful for elucidating the experiences of patients living with a CIED; however, the current literature has disproportionately focused on the experiences of people living with an ICD.

Systematic reviews of qualitative studies indicate that living with an ICD presents a number of psychological and physical challenges for patients owing to both the physical form and functions of these devices [5,6]. This includes experiences of anxiety owing to the defibrillatory shocks administered by a patient's ICD, a well-documented phenomenon [7]. In addition, qualitative studies have evaluated decisions regarding the discontinuation of ICD-administered therapies during end-of-life care [8]. It has been postulated that the disproportionate focus on experiences with ICDs in the literature is owing to the perception that patients living with these devices experience greater treatment burdens and poorer health [9]. This focus is problematic as it obscures the experiences of the vast majority of patients living with a CIED, who generally receive a PPM [10].

The limited qualitative evidence suggests that other CIEDs present several substantial challenges for patients. Living with a PPM may lead to several lifestyle changes [11,12], issues of identity and body image for women [13], and disruptions in social participation and emotional state [14]. Despite this, many patients are able to adapt to living with their PPM [11-13], and some regain their desired way of life [14]. Furthermore, patients living with a S-ICD may experience a similar range of challenges as well as shock-related anxiety [15,16].

A patient's knowledge about their CIED may be particularly important for overcoming these challenges and adapting to their device [17]. Systematic reviews suggest that patients living with an ICD feel that they lack sufficient knowledge about their device, which may be detrimental to their health management [5,6]. Similar concerns regarding knowledge deficits have been observed in people living with PPMs [18] and S-ICDs [15]. When faced with knowledge deficits, patients are increasingly turning to social media to gain insight into their conditions and to seek advice from their peers [19,20].

Objectives

To date, limited research has assessed how patients living with a CIED interact with social media. There is evidence to suggest the utility of web-based peer support for patients living with a CIED, as studies indicate that patients living with an ICD desire lived experience groups to address knowledge deficits [21-23]. Web-based forums and social media for people with ICDs may allow for the provision of information and peer support [24,25], and this information may decrease experiences of shock-related anxiety [26]. However, social media information about ICDs can lack quality and overestimate the risks associated with living with these devices [27]. To understand the experiences of people living with a CIED and their interactions with social media, this study aimed to characterize the experiences and questions that patients posted to CIED-related communities hosted on the social media website Reddit.

Methods

Reddit as a Data Source

Reddit is a popular web-based social media platform that allows users who have created an account to submit, share, and discuss content. All content submitted to Reddit must be categorized into designated *subreddits*, each serving as a user-curated and managed community centered around distinct themes, interests, or subjects. The curated nature of these communities has been of particular interest to researchers, as subreddits have been used as a valuable resource for in-depth investigations into specific topics [28]. Reddit was selected as the focus of this study because data collection could be constrained to subreddits intended for the discussion of experiences with a CIED. Other social media platforms either lack this degree of curation or resort to private communities for discussing such topics. Accessing data from these private groups can raise ethical issues related to consent.

Ethical Considerations

Participants in this study were considered to be Reddit users who had posted to subreddits related to CIEDs. This study received low-risk research ethics approval from the University of Adelaide School of Psychology Human Research Ethics Sub-Committee (22/27). As publicly available posts made to web-based communities can be considered textual documents [29-31], consent was not required from participants. However, unique ethical challenges are associated with the collection of web-based data [29,32]. Thus, ethics approval was granted on the grounds that all posts were publicly available, no contact was made with participants, and participants remained anonymous. Consequently, subreddits with specific rules prohibiting the collection of user data were excluded from this study, personal information was removed from the reported extracts, and each participant's username was converted into a numeric pseudonym.

Subreddit Selection and Data Collection

Reddit's internal search engine was used to systematically identify suitable subreddits, and only those intended for people living with a CIED were included in the analysis (Multimedia Appendix 1). One subreddit intended for people with a CIED to discuss their experiences, questions, and concerns was identified and included in this study. At the time of data collection (April 17, 2022), the subreddit consisted of >1100

members, 484 top-level posts, and 4036 comments. Discussions of experiences related to living with a CIED may have occurred on subreddits related to more general medical issues. However, observation and searching of posts in these communities indicated that discussions on such topics were rare, making it difficult to include these posts given the data collection method used.

Consistent with Reddit's terms of service, the website's application programming interface was used to collect all top-level posts made to the subreddit [28]. Top-level posts, also known as initial posts, are the messages created by users to initiate a discussion thread on a specific topic within a subreddit. Only top-level posts were collected to develop an overview of the experiences shared by participants and how they engaged with the subreddit. Upon being granted access to the application programming interface, a script was created using Python (version 3.9.7) and the Python Reddit Application Programming Interface Wrapper (version 7.5.0) [33], which could systematically collect every top-level post made to the subreddit in chronological order (Multimedia Appendix 2). The script collected the title of each post, content, time of posting, and poster username.

After posts were collected using the Python script, they were each individually read to facilitate the exclusion of irrelevant posts. Only posts made by people who clearly indicated that they were currently living with a CIED were included in the analysis. Posts from people awaiting CIED implantation or caregivers were not included and will be used in subsequent analyses that aim to specifically represent their experiences. During the exclusion process, a register of participant demographic information was created based on their explicitly declared age, gender, type of CIED, and time lived with a CIED declared in each post. We considered each Reddit username as representing a distinct participant.

Data Analysis

Conventional qualitative content analysis [34] was used to systematically classify the textual data from the collected posts into codes, subcategories, and categories. This was done to create a hierarchical framework that described the questions and experiences of participants. The analysis was inductive in nature and guided by the following research question: "What questions, and information about their experiences, do people living with a CIED post to communities intended for them on the social media website Reddit?" Each stage of the analysis was conducted using NVivo 12 Plus software (version 12.6.1.970; Lumivero), which allows researchers to organize and code qualitative data to identify meaningful insights. Captions for each code, subcategory, and category were determined by the authors based on the meaning and data contained within each analysis unit. As part of the conventional qualitative content analysis process, frequencies of occurrence were calculated based on how many participants produced textual data to which each unit of analysis applied. As participants could not be contacted for feedback, to enhance the credibility of the study, both the second and third authors (experienced health psychologists) evaluated the analysis. Typographical errors were corrected in all reported quotations.

Results

Data Collection

Of the 484 posts collected using the script, 186 were excluded. The excluded posts included 118 made by participants who did not have a CIED, 42 that were not usable in the analysis (eg, spam, links, or memes without context), and 26 made by participants who did not specify if they had a CIED. After exclusion, 298 posts that were made by 196 participants were included. The posting dates of the included posts ranged from January 24, 2018, to April 17, 2022 (the data collection date).

Demographic Information

Table 1 illustrates the reported demographic characteristics of participants and their current CIED.

Table 1. Demographic characteristics reported by participants living with a cardiac implantable electronic device (CIED; N=196).

Characteristic	Value
Gender, n (%)	
Men	26 (13.3)
Women	19 (9.7)
Not reported	151 (77)
Age (years)	
Values, median (range)	33 (22.0-39.5; 17-72)
Not reported, n (%)	117 (59.7)
Time lived with CIEDs (years), n (%)	
<1	45 (23)
1-5	16 (8.2)
5-10	9 (4.6)
10-15	6 (3.1)
15-20	8 (4.1)
20-25	3 (1.5)
25-30	3 (1.5)
30-35	3 (1.5)
Not reported	103 (52.6)
Current CIED type, n (%)	
PPM[a]	101 (51.5)
ICD[b]	61 (31.1)
S-ICD[c]	9 (4.6)
CRT[d] device	6 (3.1)
Leadless PPM	4 (2)
Not reported	15 (7.7)

[a]PPM: permanent pacemaker.

[b]ICD: implantable cardioverter defibrillator.

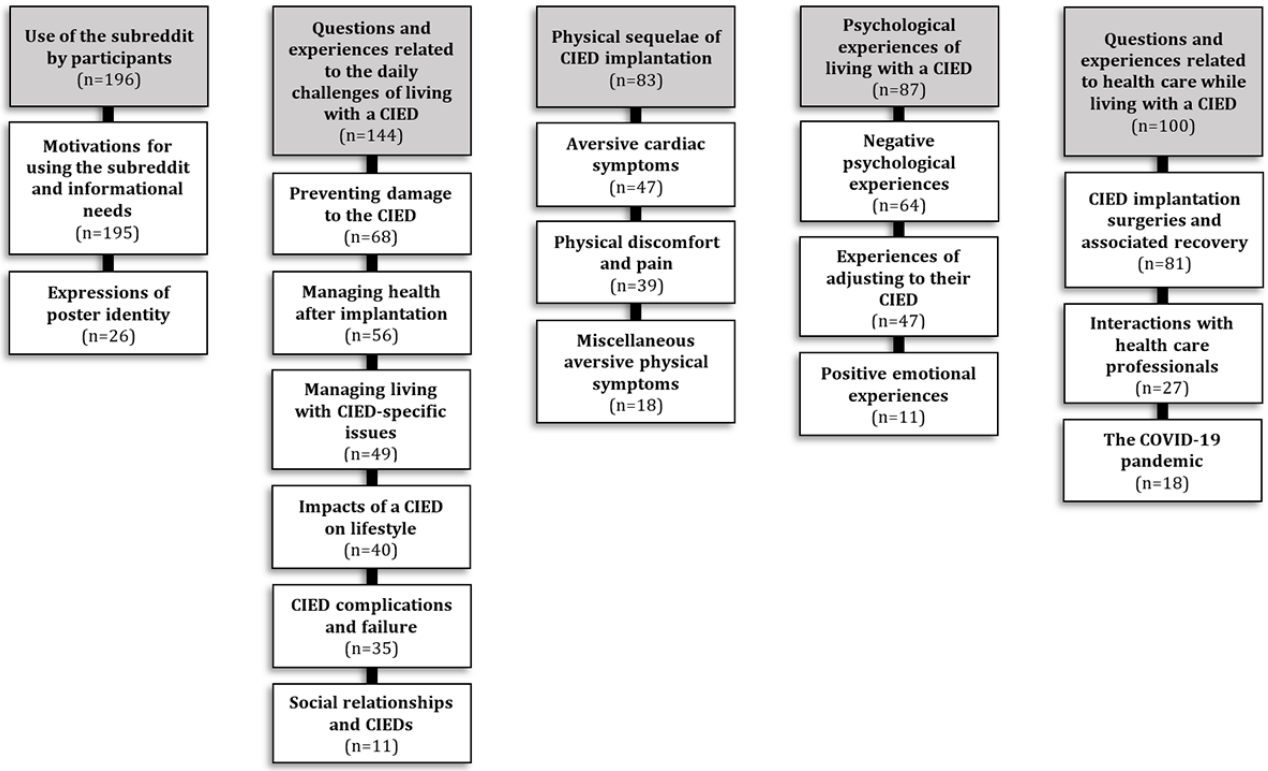
[c]S-ICD: subcutaneous implantable cardioverter defibrillator.

[d]CRT: cardiac resynchronization therapy.

Analysis Structure: Categories, Subcategories, and Codes

Posts made to the subreddit were classified into 104 codes that were condensed into 17 subcategories and 5 overarching categories (refer to Multimedia Appendix 3 for the full analysis structure). The overarching categories and associated subcategories, with frequencies of occurrence for each, are shown in Figure 1.

Figure 1. The experiences and questions of participants (N=196) with cardiac implantable electronic devices (CIEDs). Overarching categories (colored grey) and accompanying subcategories with occurrence frequencies.



Use of the Subreddit by Participants

The first category captured how participants engaged with the subreddit. The most frequent subcategory captured the participants' declared motivations for posting and their associated informational needs. Most participants sought experiential knowledge of living with a CIED, followed by advice for dealing with their problems and answers to technical questions. The inability to find information about CIEDs, such as potentially sensitive topics or how to best live with these devices, also motivated participants to post:

> *I got a leadless pacemaker about a month ago. I am still confused about what I can do or not. Anyone else have one? I haven't found much information on them either.* [Participant 171]

In addition to fulfilling their informational needs, the participants sought affirmation by asking the subreddit whether their experiences were normal and posted to thank the community for the help they had received. Participants were also motivated to post by an often explicitly stated desire to help others by sharing their experiences of living with a CIED:

> *I know there are a lot of emotions that go along with being different than "what's normal," and I would be more than happy to share my experiences, the challenges I've overcome and my philosophy on what it means to have such an amazing device.* [Participant 21]

The second subcategory captured how the participants expressed their identities on the subreddit. Younger participants specifically described themselves as such, and others described themselves as cyborgs or as belonging to a special club:

> *Have y'all ever realized that we're basically cyborgs since our hearts are run by a piece of technology?* [Participant 141]

Questions and Experiences Related to the Daily Challenges of Living With a CIED

The second category captured discussions and questions related to the intricacies and daily challenges faced while living with a CIED. The most frequent subcategory captured participants' experiences of, and questions about, preventing damage to their CIED. Concerns about electromagnetic interference, especially from emergent consumer technologies such as smartwatches, were most common. Participants discussed the restrictions placed on their physical activities to prevent damage to their CIED, such as discontinuing contact sports, and different methods of protecting their device from harm:

> *Were you able to continue the sports you were doing before? I understand contact sports are a no-no to avoid any blow to the ICD (but I'm guessing with protection it should be fine?)* [Participant 88]

Concerns about damage also stemmed from the use of recreational or prescription drugs, and the participants expressed a lack of information regarding these topics:

> *I know illegal substances are bad for you and we shouldn't take them. But I still just want the information and can't find any online. What would happen to my heart if I did a single line of cocaine? Or if I took molly once? Like, would I drop dead or*

> *get shocked? I searched online and couldn't find any answers.* [Participant 160]

The second subcategory captured how participants evaluated and managed their health after implantation. Participants reported either improvements or declines in their health status. Most posts were related to exercise, and participants generally asked questions about the types of activities that were possible with a CIED. In addition, the participants reported their experiences with deliberate weight loss and associated pain-related complications owing to CIED protrusion:

> *One thing I'm noticing is that as I've started to slim down, my ICD is causing me more and more discomfort. Not via shocks or anything, just by kinda poking out. I can feel pressure on it whenever I lie down, whenever I sit in a chair or in the car, and it's uncomfortable for a while, then gradually starts to become painful.* [Participant 156]

The third subcategory captured discussions related to the management of issues specific to being implanted with a CIED. Participants discussed ICD shocks, rubbing from external objects (eg, bra straps or seatbelts), CIED battery life, automated CIED checks, discomfort caused by CIED warning alarms, and medical alert identification information. Changes in CIED settings were reported to help alleviate some of the problems experienced by participants. Participants most frequently discussed the monitoring of device functioning using health tracking applications, CIED remote monitoring services, and consumer heart rate monitors. These efforts were often reported as a source of confusion:

> *I have 2 oximeters. I use them to take my pulse. Sometimes when I feel bad (with a lack of air feeling), I take my pulse. It has been in the 40s or 140s (too low or too high) sometimes during those episodes.... I've told my dr but he says that everything is ok because my PPM isn't recording those events.... Is the oximeter accurate enough for us? Should I trust more the PPM than the oximeter?* [Participant 86]

The fourth subcategory captured the actual and potential impacts of having a CIED on the lifestyles of the participants. This subcategory included a diverse range of reciprocal impacts between having a CIED and work, driving, sleep, simple activities, school, sex and masturbation, diet, and pregnancy. The reported impacts of living with a CIED could be caused by its direct physical presence or the limitations of current technology:

> *I am a marine engineer and electrical engineer, currently looking for a work. I can no longer work with magnets or transformer stations, which has already led to me having to avoid certain job options. I'm scared of telling anyone outside my closest family, because employers might consider me damaged goods and reject me.* [Participant 35]

The fifth subcategory captured discussions related to the complications and failures of the participants' CIEDs. The participants expressed concerns about lead dislocation or failure, device dislocation, and CIED malfunction. In addition, the participants reported their experiences of lead failure and CIED-related infections. Lead failures were perceived as impactful and were more commonly reported by younger and physically active participants:

> *Once I got to high school I ripped or broke my lead and feel like I have been accidentally doing this over the years because of my lead placement over my collar bone...I used to be very active so I have limited my activity and no longer do things like weightlifting. I am extremely careful and always conscious of my PPM.* [Participant 168]

The final subcategory captured the described perceptions of others toward CIEDs and the positive impacts of social support. Two participants raised concerns about the insensitive and negative perceptions of others toward their CIED:

> *I was out for dinner with my OH [other half] and 2 old friends and he drew attention to my PPM wound. They were all laughing and saying it looked like a mouth and that they could animate it and make it look funny.... They didn't mean it maliciously, but it was really crushing and has massively knocked my confidence, just posting here because I'm struggling to find anyone who understands.* [Participant 163]

Physical Sequelae of CIED Implantation

The third category encompassed the physical consequences of having a CIED. The first subcategory captured the discussion of aversive CIED-related cardiac symptoms. This included the discussion of aversive heart rates, palpitations, shortness of breath, feelings of lightheadedness or fainting, loss of consciousness, feelings of dizziness, and fluid retention. Generally, participants sought the experiences of others and guidance on whether to seek medical care:

> *All of a sudden these past few days I am feeling dizzy all the time. Getting out of bed, laying in bed, outside, etc; has anyone else experienced anything similar to me? Should I contact my doctor? I get slightly lightheaded and my head starts to space out.* [Participant 179]

The second subcategory captured codes related to the discussion of the different experiences of pain and discomfort. Pain and discomfort were related to the direct physical presence of the CIED generator or leads, the surgical site, and the heart or chest. Participants also reported general experiences of bodily pain; these combined sensations were often complex and overlapping:

> *This stabbing/poking sensation in my heart has been present every moment of every day since my PPM was put in. Some positions hurt worse than others, such as leaning on your shoulder in bed at 3 am. The pain radiates up my jaw and into my molar. It's driving me literally crazy.* [Participant 12]

The last subcategory captured miscellaneous aversive physical experiences that were not directly pain or cardiac related. The participants reported changes in body temperature, physical tiredness, bruising, feeling weak, twitching sensations, restlessness, excessive sighing or yawning, stomach problems, tingling sensations, and feeling shaky. Participants often inquired

as to whether these symptoms had been experienced by other people and whether they should be concerned:

> *I recently got a PPM (a couple of months ago), and I've noticed my chest on the left side "twitches" or kind moves every time my heart beats. Has anyone else experienced this?* [Participant 9]

Psychological Experiences of Living With a CIED

The fourth category was related to the emotional and psychological aspects of living with and adapting to a CIED. The first subcategory captured the aversive psychological aspects of living with a CIED. Participants reported being worried, fearful or scared, anxious, depressed or sad, frustrated, traumatized or experiencing posttraumatic stress disorder, stressed, emotionally tired, feeling lost or empty, and cognitively impaired from their experiences. In addition, participants with an ICD reported anxiety related to potential shocks from their device. Experiences of worry and anxiety from having a CIED were often compounded by other aspects of their lives:

> *I'm 21, and I just got mine inserted yesterday.... I've been more anxious about almost everything and it doesn't help that it's my last semester of college so I'm also worrying about school work on top of trying to recover. I've had two different anxiety attacks just today.* [Participant 38]

The second subcategory captured how participants adapted to the challenges of living with a CIED. Participants discussed experiences with, and asked questions about, ways of coping with a CIED, returning to a normal lifestyle after implantation, trying to rebuild their confidence, and learning to trust their CIED and body. Participants expressed that their lives had changed after implantation, and 1 participant stated that they had become emotionally attached to their CIED. Not all participants were able to adapt to their CIED, and some participants even wanted theirs removed or deactivated. Similarly, some participants expressed hatred and resentment toward their CIED:

> *Need a battery change, haven't made the appointment. Why? I hate this and I'm miserable. I'm afraid of it, it doesn't make me feel safer, it's taken my dreams of military service and flying away from me, I can't do cool hobbies I'm interested in. When I bring this up to people they don't get it. They think I should be thankful and appreciate that it might save my life. I don't care. A longer life feels pointless when I don't get to be happy.* [Participant 5]

Moreover, younger and more active participants expressed difficulties with accepting their CIED, which were unique to their age and health status:

> *I read the other posts and I guess I'm struggling with the whole "why me" crap. I live a healthy lifestyle, never smoked, and am in good health (besides having a battery in my chest). Like a lot of the other posts have stated, it's more of a mind fuck than anything.* [Participant 97]

The least frequent subcategory captured positive emotional experiences related to living with a CIED. Participants reported being happy with or excited for having a CIED, proud of some aspect of living with a CIED, or grateful for being implanted with a CIED. Participants most often expressed positive emotions when their CIED presented clear benefits over undesirable alternatives:

> *Got the all clear to send back the LifeVest to Zoll [a wearable external defibrillator] after the longest 5 months of my life.... Cheers to life beyond the vest, and freedom from the electrodes, garments, and all the cords! I am most excited about my re-expanded wardrobe options and not lugging that box around my waist anymore.* [Participant 115]

Questions and Experiences Related to Health Care While Living With a CIED

The final category captured the experiences of, and questions about, health care after CIED implantation. The most frequent subcategory consisted of questions and experiences related to CIED surgeries and associated recovery. Topics included CIED replacement, implantation surgery, lead replacement and removal, implantation complications, additional surgeries to support heart function, costs associated with CIED surgeries, and bandages. Although many participants who discussed recovering from implantation surgery only described their experiences, those scheduled for a CIED replacement often expressed apprehension:

> *I am now scheduled to see an electrophysiologist this Thursday and I'm just.... Shocked. And really scared. I don't know what to expect or how technology has changed.... I guess I just need to vent to people who understand but would also like some advice on recovery times, restrictions etc. Are PPMs like they were 17 years ago?* [Participant 129]

The second subcategory captured the interactions of participants with health care professionals. Participants discussed the medical advice they had received and their appreciation for some of the professionals with whom they had interacted, and 1 female participant expressed discomfort discussing sexual activity with her male physician. Participants most frequently expressed a sense of perceived ambivalence held by their health care professionals, and some participants disagreed with them about their symptoms:

> *The doctor says nothing is wrong with it and I shouldn't be feeling it [pulsating heart pain and aversive cardiac symptoms] but yet I still do. I'm not getting any answers or help from the cardiologist, so I just don't know what to think anymore.* [Participant 169]

The third subcategory captured the impact of the COVID-19 pandemic on the experiences of participants, such as public health restrictions limiting health care opportunities. In addition, participants reported possible complications from the COVID-19 vaccine and raised questions about who can access it or concerns about potential side effects:

> *Has anyone had any discussions with their cardiologist or GP regarding receiving Pfizer of Astra Zeneca vaccinations for COVID-19? I have complete heart block, and I have some preliminary concerns about receiving the vaccination in the fear that it may not have been adequately tested.* [Participant 154]

Discussion

Principal Findings and Comparison With Prior Work

To the best of our knowledge, this is the first study to explore how people living with a CIED use the social media website Reddit. One subreddit analyzed was used by participants living with a CIED to find information, share a range of experiences, and render support to their peers through the provision of knowledge and affirmation. A number of insights are presented, including how participants engaged with the subreddit, their experiences of living with a CIED, the impacts of physical activity and age on their experiences, and their experiences during the COVID-19 pandemic.

The ability to receive and share information formed the central way users engaged with the subreddit. Participants with different types of CIED posted to the subreddit to receive experiential knowledge, advice to overcome the challenges they faced, fill unmet educational needs, and have their experiences affirmed by others living with a CIED. Similar patterns of information seeking have been observed in people living with an ICD [25]. In addition, CIED ownership was demarcated as a unifying group identity, and participants expressed a desire to provide support to others living with these devices. Taken together, these patterns of behavior are consistent with theoretical conceptualizations of peer support [35,36] and build on research that has explored the natural occurrence of these phenomena in social media contexts [37,38].

The experiences described by participants who were predominately implanted with a PPM largely concurred with previous qualitative studies that have explored the challenges faced by people living with ICDs [5,6], who represent one of the most studied CIED patient groups [9]. The findings were also consistent with the previously reported experiences of patients living with PPMs [11-14] and S-ICDs [15]. As previous studies have almost exclusively used interview-based methodologies with in-hospital and community populations, this suggests that the concerns expressed by people with a CIED may be comparable between web-based platforms and face-to-face investigations. This said, social media serves as a way for people living with a CIED to ask questions about sensitive topics that they may not feel comfortable discussing in formalized research contexts. The finding that the subreddit was used to discuss drug use was a novel contribution to the existing literature, underscoring the need for enhanced education in this specific domain.

Compared with previous literature and available demographic data, participants in this study appeared to be younger and more physically active than the average person living with a CIED [10]. In the current literature, this population represents a novel demographic that may be linked to the web-based nature of Reddit, which necessitates a higher level of technological literacy for engagement. As an indication of the unique demographics present in the sample, no discussion regarding the end-of-life discontinuation of device treatments was observed, although this is a common topic in the current CIED literature [8]. This was most likely owing to the younger age and greater physical activity levels observed across the data. In addition, individuals with a PPM, the most prevalent subgroup in our sample, may have had a more favorable prognosis compared with other device populations. Interestingly, the discussion of end-of-life considerations was observed in posts from caregivers who were excluded from the analysis. We plan to conduct subsequent analyses of the posts made by caregivers to provide comprehensive insight into their experiences.

The reduced age and increased activity level of participants provide a number of novel insights into the experiences of patients living with a CIED. Similar to previous studies of people living with an ICD, restrictions placed on participation in physical activities could be substantially impactful for the experiences of participants with any CIED [6,21,22,39]. To overcome these restrictions, participants discussed a range of efforts to protect their CIED from damage. This included prevention efforts, such as limiting physical activity and avoiding danger, and protection efforts through the use of sports guards. Protection also involved participant comfort, with cushioned pads reported as being used to assist with external objects rubbing against the device; this included seatbelts [40] and bra straps [16], which have been previously reported as sources of discomfort. Furthermore, participants often saw their CIED as at risk of failure and deemed it necessary to monitor the functioning of their device through various domestically available technologies. We are unaware of previous studies that have evaluated these topics.

Despite these activity restrictions and associated difficulties, the participants viewed the continuation of exercise to stay healthy as important. Participants did not discuss CIED-related body image concerns, which is a common topic in the literature [13,16,41-43]. Instead, body image concerns focused on deliberate postimplantation weight loss attempts, often in the context of exercise. Participants attempting to lose weight reported pain and discomfort caused by the thinning of tissue around their implantation site, and the medical literature has previously drawn associations between decreases in BMI and this phenomenon [44]. We are unaware of previous studies evaluating the experiences of deliberate weight loss while living with a CIED.

The experiences of individuals living with a CIED during the COVID-19 pandemic emerged as a notable topic of discussion on the subreddit. This topic has received little attention in the current literature. Delays in accessing health care and the difficulties created by public health approaches used to manage the pandemic were discussed. In addition, there is a need for targeted pandemic-related information for people living with a CIED, as questions were posted about the availability of vaccines and possible complications from vaccination.

Limitations

The results should be interpreted within the context of the limitations posed by the methodology and sample used. Proferes

et al [28] asked whether Reddit data only provides insight into phenomena specific to the characteristics of the website. The findings of this study may reflect the specific qualities of the subreddit analyzed, as it could have been the last resort for people unable to receive adequate health services. Reddit users also tend to be younger than the general population [45], and social media data may overrepresent people of higher socioeconomic status [46]. Furthermore, participants could not be contacted to clarify their postings, and they may have inaccurately recounted their experiences [47]. Although this may be the case, this study used a novel systematic approach for the collection of naturalistic data, which allowed deep insight into the experiences and needs of the participants.

Implications

The findings present several implications for the improvement of care and outcomes for patients living with a CIED. Participants living with a CIED experienced numerous biological, psychological, and social challenges associated with their device; thus, an understanding of postimplantation quality of life should consider holistic perspectives. In doing so, health care professionals and researchers must develop appropriate patient resources and supports that address the diversity of patient experiences, which could include the use of educational interviews tailored to the lifestyles of patients [48]. As a majority of participants desired experiential knowledge, the creation of formalized peer support networks should also be explored, as they have demonstrated benefits for people living with chronic health conditions [49,50]. Further work is needed to explore the nuances and differences in patient experiences between devices.

Conclusions

This study analyzed posts from a community on the social media website Reddit intended for people living with a CIED to characterize the informational needs and experiences of patients. In this context, participants expressed a desire for a range of information, with the majority requesting experiential information. Participants living with a CIED experienced a range of challenges, including the need to adapt to living with a device, difficulties with navigating health care, psychological difficulties, and various aversive physical sequelae. These challenges were often most deeply impactful for younger and more physically active participants. This study demonstrated that social media represents a way in which people living with a CIED may engage in peer support to help address the diverse and unique challenges that they may face. Health care professionals may wish to draw on peer support and other forms of aid to help their patients overcome the challenges of living with these devices.

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Data Availability

The data collected and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Systematic search terms and exclusion criteria.
[DOC File , 29 KB - cardio_v7i1e46296_app1.doc]

Multimedia Appendix 2
Data collection Python script using the Python Reddit Application Programming Interface Wrapper.
[DOC File , 29 KB - cardio_v7i1e46296_app2.doc]

Multimedia Appendix 3
Structure of the categories, subcategories, and associated codes, with occurrence frequencies calculated for the 196 participants living with a cardiac implantable electronic device.
[DOC File , 175 KB - cardio_v7i1e46296_app3.doc]

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Abbreviations

CIED: cardiac implantable electronic device
CRT: cardiac resynchronization therapy
ICD: implantable cardioverter defibrillator
PPM: permanent pacemaker
S-ICD: subcutaneous implantable cardioverter defibrillator

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Original Paper

Implementation and User Evaluation of an eHealth Technology Platform Supporting Patients With Cardiovascular Disease in Managing Their Health After a Cardiac Event: Mixed Methods Study

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Abstract

Background: eHealth technology can help patients with cardiovascular disease adopt and maintain a healthy lifestyle by supporting self-management and offering guidance, coaching, and tailored information. However, to support patients over time, eHealth needs to blend in with their needs, treatment, and daily lives. Just as needs can differ between patients, needs can change within patients over time. To better adapt technology features to patients' needs, it is necessary to account for these changes in needs and contexts of use.

Objective: This study aimed to identify and monitor patients' needs for support from a web-based health management platform and how these needs change over time. It aimed to answer the following research questions: "How do novice and more advanced users experience an online health management platform?" "What user expectations support or hinder the adoption of an online health management platform, from a user perspective?" and "How does actual usage relate to user experiences and adoption?"

Methods: A mixed methods design was adopted. The first method involved 2 rounds of usability testing, followed by interviews, with 10 patients at 0 months (round 1) and 12 patients at 6 months (round 2). In the second method, log data were collected to describe the actual platform use.

Results: After starting cardiac rehabilitation, the platform was used frequently. The patients mentioned that they need to have an incentive, set goals, self-monitor their health data, and feel empowered by the platform. However, soon after the rehabilitation program stopped, use of the platform declined or patients even quit because of the lack of continued tailored or personalized advice. The reward system motivated them to log data, but most participants indicated that being healthy should be the main focus, not receiving gifts. A web-based platform is flexible, accessible, and does not have any obligations; however, it should be implemented as an addition to regular care.

Conclusions: Although use of the platform declined in the longer term, patients quitting the technology did not directly indicate that the technology was not functioning well or that patients no longer focused on achieving their values. The key to success should not be user adherence to a platform but adherence to healthy lifestyle habits. Therefore, the implementation of eHealth should include the transition to a stage where patients might no longer need support from a technology platform to be independently

and sustainably adherent to their healthy lifestyle habits. This emphasizes the importance of conducting multi-iterative evaluations to continuously monitor whether and how patients' needs and contexts of use change over time. Future research should focus on how this transition can be identified and monitored and how these insights can inform the design and implementation of the technology.

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KEYWORDS

patient needs; health behavior; lifestyle support; user-centered design; implementation; evaluation; cardiovascular disease; app; web-based platform; intervention

Introduction

Background

Supporting patients with cardiovascular disease (CVD) in adopting and maintaining a healthy lifestyle is a challenging and ongoing process. A healthy lifestyle is often not limited to one action or change but requires ongoing attention. eHealth technology can help patients with CVD in tackling this challenge by supporting self-management and offering guidance, coaching, and information. eHealth enables patients to access their health data [1] and receive feedback on their behavior and health [2] and provides tips and support to improve their health. These insights and feedback increase the self-management ability of patients [1], which is necessary to adopt and maintain a healthy lifestyle even at home when cardiac rehabilitation has ended. In addition, the possibility of sharing self-monitored data with health care professionals provides more insights into patients' health than would be possible during a consultation [3], which could result in more personalized treatment choices. However, achieving long-lasting effects of eHealth is possible only if patients (or users) feel engaged, and even if they do, it does not mean that they are adherent [4,5]. To improve patients' engagement and adherence and thus be able to assist them over time, the eHealth technology needs to blend in with their treatment and daily lives [6-8]. This emphasizes the importance of intertwining implementation (to identify and tackle potential challenges) within the development of eHealth [9].

In this study, we focus on the user-centered development and implementation of a particular web-based lifestyle platform: the Vital10 Personal Health Platform (Vital10 PHP). This platform aims to support patients with CVD with adopting and maintaining a healthy lifestyle in their own home situation [10]. The theoretical framework behind the user-centered design approach adopted in this study is the CeHRes Roadmap, a holistic and participatory approach for eHealth development, implementation, and evaluation [9]. This road map emphasizes the importance of stakeholder involvement (eg, patients as users), which includes the identification of their values and needs and translation of these values to specific requirements for the design of the eHealth technology. A key principle of the CeHRes Roadmap is that user-centered design involves a continuous, multi-iterative process of user evaluation rather than a one-size-fits-all approach. In a previous study, we identified the values of patients with CVD for support from a web-based health management platform [6]. These values (ranging from the need for security, support, and reduction in anxiety to the need for the tailoring of treatment and personalized and accessible care) informed the development of the Vital10 PHP. Although all the (design) features of the Vital10 PHP are based on these identified values, continued monitoring among users during implementation is essential to assess the extent to which the platform satisfies these values [9]. Moreover, just as needs and preferences can differ between patients, needs may vary within patients over time [6]. If we want to better adapt technology features to the needs of patients, we need to account for these changing preferences, needs, and contexts of use. To account for such dynamics, a long-term perspective on eHealth design, as indicated by the CeHRes Roadmap, is preferred and will contribute to the likelihood of sustainable implementation of the health management platforms.

Goal of This Study

Therefore, the aim of this study was to identify and monitor patients' needs for support from a web-based health management platform and how these needs change over time. Compliant with the CeHRes Roadmap, we investigated how the Vital10 PHP fits patients' rehabilitation goals and day-to-day activities. We included user expectations and experiences and actual use data to explain the implementation process of the platform from a user perspective, as the uptake and acceptance of the platform are prerequisites for its implementation. In addition, we considered the domains of the Nonadoption, Abandonment, Scale-up, Spread, Sustainability (NASSS) framework to identify potential factors impeding or facilitating the adoption and continued use of the Vital10 PHP [11]. Although the NASSS framework contains 7 domains in total, only the domains of condition, technology, and adopter were considered relevant to this study. However, in this study, we only included the perspectives of patients (users) as adopters. The findings of our study will provide input for platform redesign and implementation strategies for lifestyle-supporting eHealth tools. In addition, it will show how use patterns will develop over time. We aimed to answer the following research questions: "How do novice and more advanced users experience an online health management platform?" "What user expectations support or hinder the adoption of an online health management platform?" and "How does actual usage relate to user experiences and adoption?"

Methods

Study Design

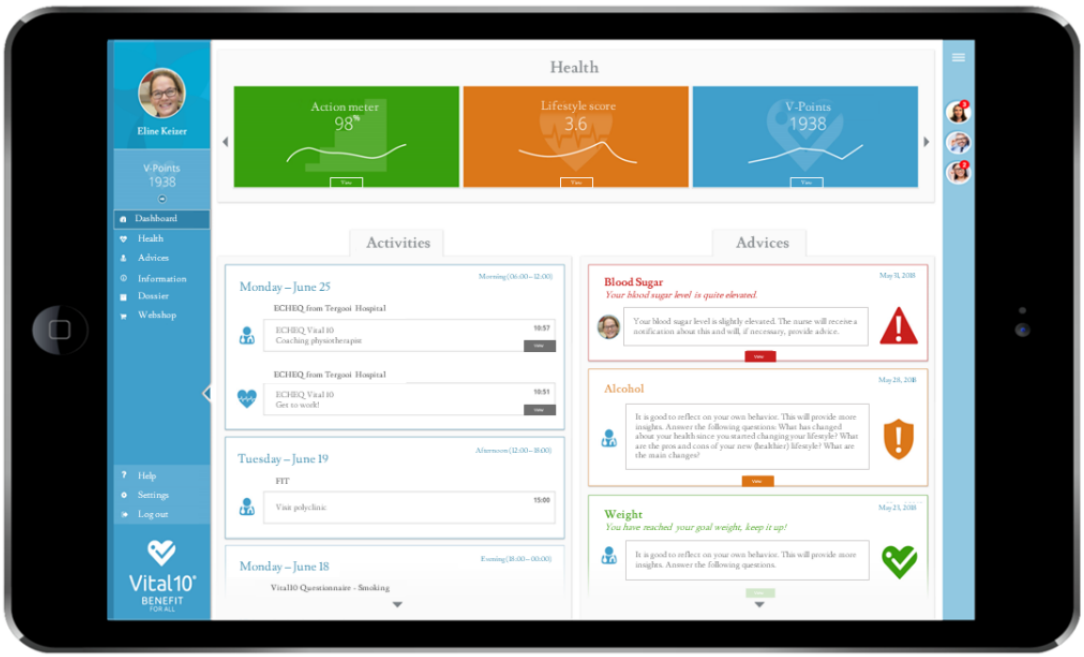
This mixed methods study combined a 2-round usability study with a log data analysis. The usability study consisted of 2 rounds of web-based usability tests with additional interviews,

inspired by the NASSS framework [11]. The usability tests were conducted using a scenario-based think-aloud method [12] and were captured by video and audio recordings. The first round was conducted before the participants used the Vital10 PHP (0-month group), and the second round was conducted after they used the Vital10 PHP for 6 months (6-month group). The first round was conducted between July and October 2020, and the second round was conducted between April and May 2021. Both usability rounds were held on the web via Microsoft Teams (Microsoft Corp) because of COVID-19 restrictions. Conducting 2 different rounds of usability testing in distinct phases of platform use and cardiac rehabilitation enabled us to identify patients' needs, expectations, and experiences and evaluate whether and how these might change over time. In addition, testing scenarios in 2 different rounds over time enabled us to study the fulfillment of the needs of the patients both prospectively and retrospectively because in the first round, the primary focus was on usability, whereas in the second round, the focus was on engagement and adherence. In addition, in the second round, we included both patients who participated in the first round and new patients. In this manner, the change in participants' experiences over 6 months (within person) was captured, without the influence of a t0 (study of the 0-month group) assessment. The log data analysis was conducted with a data set from the users of the Vital10 PHP from January 3, 2020, to March 15, 2021 (437 consecutive days). The log data analysis enabled us to study the actual use patterns of the patients over time, which made it possible to compare objective use behavior with the users' self-reported experiences and intended use as envisioned by the Vital10 PHP developers.

The Vital10 PHP

The usability tests were performed with the Vital10 PHP, a platform developed to support patients with CVD during and after cardiac rehabilitation [10]. The development of this platform was initiated by the BENEFIT consortium, which consists of researchers, cardiologists, general practitioners, eHealth experts, and data scientists. The BENEFIT consortium aims to create a national ecosystem with embedded evidence-based interventions that promote a healthy lifestyle and reward patients for taking actions that contribute to a healthy lifestyle [13]. The intended platform is currently hosted by Vital10, an organization established by a team of multidisciplinary information communication technology and health care professionals who aim to support people with their health [14]. The Vital10 PHP is a dynamic platform in which both patients and health care providers (eg, cardiologist, physiotherapist, dietician, and psychologist), as well as several nonmedical stakeholders such as intervention providers (eg, quit smoking program providers and personal trainers) and loyalty partners (eg, those who provide discount on products), are involved. See Figure 1 for a screenshot of the Vital10 PHP's dashboard. Additional screenshots of the Vital10 PHP are presented in Multimedia Appendix 1.

Figure 1. Screenshot of the dashboard of the Vital10 Personal Health Platform.



The dashboard displays the menu on the left hand (in blue). The green (*Action meter*), orange (*Lifestyle Score*), and blue (*V-points*) blocks are lifestyle modules with the patient's data. "Activities" shows tasks that the patients have to do on the platform and reminders of visits to health care professionals. "Advices" shows automatically generated advice or personal feedback from a linked professional based on the health- and lifestyle-related data. In the blue border on the right site, chat windows with health care workers (eg, their lifestyle coach) are displayed.

Several persuasive features from the Persuasive Systems Design model [15] were added to the design of the Vital10 PHP (eg, self-monitoring of data, rewards, reminders, and suggestions) to make it more appealing to users and motivate them to improve

their lifestyle. In addition, several evidence-based interventions to promote a healthy lifestyle are embedded in the platform. The platform includes different modules, such as weight, blood pressure, alcohol, stress, sleep, and physical activity. The platform is characterized by the provision of rewards to patients for taking actions that contribute to a healthier lifestyle [13]. For example, patients set goals to improve their lifestyle (eg, focusing on increasing physical activity levels or aiming for a healthier diet), and they can log their health data (eg, weight and blood pressure) and behavioral data (eg, step count and daily food intake). Every time patients set goals and log their data, they receive *points*. Saved points can be used in a web shop to *buy* health-stimulating products (eg, diet and lifestyle books and a heart rate monitor) as well as luxury products (eg, hotel trips). In addition, the Vital10 PHP provides features that support patients' motivation (eg, goal feedback and reminder messages) and provides an overview of medical and lifestyle information. For example, when patients set goals and log data, the Vital10 PHP automatically provides feedback on their progress and offers advice. The automatically generated feedback is based on the cutoff values predetermined by Vital10, based on clinical practice guidelines for cardiac health care. The Vital10 PHP also provides a to-do list with tasks to be performed on the platform and an overview of their historical and future medical appointments. In addition, patients can reach out to a real-life coach to ask questions and for advice via the chat function and video consultation.

Ethics Approval

The University of Twente's Ethical Committee from the Faculty of Behavioural, Management and Social Sciences (BCE200180) approved this study.

Consent to Participate

The participants were informed of the voluntary nature of their participation, and confidentiality was guaranteed. All participants verbally provided consent for participation in a voice recording before the start of the usability session.

Web-Based Usability Tests With Interviews

Participants

Two rounds of usability testing were conducted with patients with CVD. In the first round, patients who had just started or were about to start cardiac rehabilitation and, therefore, had been recently introduced to the Vital10 PHP were included. In the second round, patients with CVD who had started cardiac rehabilitation in the past 6 months and had used the Vital10 PHP during their rehabilitation process were included. For both rounds, participants were recruited via convenience sampling from Vital10 users. Participants in the first round who indicated willingness to participate in future research were approached first. Overall, 40% (4/10) of participants took part in both rounds, whereas most participants (4/12, 33%) were included only in round 1 or 2.

Procedure

In the first round, the patients who underwent cardiac rehabilitation at Vital10 were sent digital surveys ("V-cheqs") within the Vital10 PHP, conforming to the Vital10 procedure. In these surveys, their Vital10 coach added the question of whether the patients were willing to be contacted about participation in a research study. If the patients agreed, their Vital10 coach provided the researchers with the patients' contact details, and they were contacted by a researcher (BEB) via telephone. In this call, the nature and aims of the study were explained, and if the patients agreed to participate, web-based appointments were scheduled. For the second round, the Vital10 coach added the question of whether the patients were willing to be contacted about participation in this study in the V-cheq that the patients had to fill in at that particular moment of cardiac rehabilitation, conforming to the Vital10 procedure. Establishing contact and scheduling web-based appointments were similar to the first round and were done by another researcher (CS).

Both rounds of usability testing took place on the web via Microsoft Teams because of the COVID-19 restrictions that were in force. For both rounds, the same usability test and interview protocols were used. During the digital meeting, the participants provided verbal informed consent after the recording was initiated by the researcher. After the recording started, the patients were asked in the first part of the meeting to provide information on their demographic characteristics, digital skills, and cardiac health if they were willing to.

In the second part (usability session), several core functions of the Vital10 PHP were evaluated by the participants using scenarios. The scenarios were determined based on the Vital10 PHP Patient Journey (including intended use of the platform), which was developed during brainstorm sessions of the BENEFIT research group and based on adherence and log data literature [16], focusing beyond general use belief of "more is better." In fact, a more realistic use of the PHP was formulated, considering rehabilitation goals as well as accounting for personal use preferences and personal needs, among other things. For example, the participants were asked to fill in some of the provided V-cheqs, set goals, log (fictive) health data, view their (fictive) progress, and view some of the provided feedback and advice, which were generated automatically by the Vital10 PHP based on the self-monitored data. See Multimedia Appendix 2 for an overview of the scenarios. During the scenarios, the researchers intervened as little as possible because the participants had to show how they would navigate the platform by themselves. They were prompted to think aloud [12]. They could log in via newly made accounts of fictitious users during the test so that they did not have to show their own (medical) data and goals on the Vital10 platform.

In the third part (interview questions), the patients were asked about the uptake and use of the Vital10 PHP in their daily lives. For example, they were asked when the Vital10 PHP should be introduced to inexperienced users, whether informal caregivers should be involved, how they perceive the role of health care professionals within the Vital10 PHP, and what they need to achieve their healthy lifestyle goals in their daily life. After closing the interview, the recording was stopped. Subsequently, the patients were mailed a gift certificate via post to thank them for participating. See Multimedia Appendix 2 for an overview of the interview scheme.

Data Analysis

After the usability and interview sessions in round 1, the recordings of the usability sessions were pseudonymized and stored in a secure data server at the University of Twente. These data were accessible only to the researchers involved. The recordings of 3 participants from round 1 were not stored correctly owing to technical errors; therefore, these patients were excluded from the study (round 1 participants 4, 7, and 12). The recordings were transcribed verbatim, and all the transcripts were analyzed by BEB to identify fragments about experiences with the Vital10 PHP and the needs and requirements for the design and implementation of eHealth technology. Relevant fragments were labeled with the main codes "experiences," "design," and "implementation" in Atlas.ti (version 9, ATLAS.ti Scientific Software Development GmbH) [17]. The fragments within the main codes were analyzed axially to link fragments to each other and create new subcodes within each main code. The analysis of the first round was performed by BEB before the analysis of the second round. The coding scheme of the first round was revised several times by BEB and JW, and the fragments were reread and recoded if necessary. This coding scheme was also used as a foundation for the extraction of data from the second round. In the second round, data were analyzed by BEB and CS similarly to how data were analyzed in the first round. The coding scheme of the second round was revised several times by BEB, CS, and JW, and the fragments were reread and recoded if necessary.

Log Data Analysis

Data Set

This study used a secondary set of data collected before the beginning of the study (from January 3, 2020, to March 15, 2021; 437 days). All users were invited by their health care professionals to use the Vital10 PHP after they experienced a cardiovascular event. The users had to agree to the terms of use, which included the guarantee that anonymized log data would be used only for research purposes, before they could first access the platform. These log data do not include any demographic or medical data but solely use-related data.

Data Analysis

The data set was prepared and analyzed using R (R Foundation for Statistical Computing, version 1.3.1056). The original variables were timestamp, user ID, http method, and apicall. Sessions of use were created when a session lasted for at least 60 seconds. After 30 minutes of inactivity, a new session began. The following new variables were created: session number, total sessions, total time used, days between sessions, lapse, session length, mean total days used, and platform component. See Table 1 for an overview of the variables.

For descriptive analysis, only long-time users were considered. Research shows that many users stop using eHealth within 3 weeks [18]. Any user who used it for >3 weeks was either adherent or nonadherent. To be defined as adherent, we needed a definition for intended use. Members of the BENEFIT consortium envisioned this as follows: *minimum of both once per week log-in and filling in the vitality score*. This was defined by the BENEFIT project team in a brainstorming session, and based on earlier studies in the area of intended use and adherence [16] and the research team's assessment of the platform and rehabilitation goals. Every user can have some lapse in adherence, as this is common [19]. Therefore, not every user who has 1 lapse is labeled as nonadherent. Users who (1) have too many lapses, relative to their total time using the platform; (2) have 4 weeks of nonuse; or (3) stop using the platform qualify as nonadherent. Consequently, users to whom none of these variables apply are considered adherent. In Table 2, the operationalization of adherence variables is summarized.

Table 1. Variables for log data analysis.

Variable	Explanation
Timestamp	Date and time
User ID	Unique user ID
http method	GET[a] for receiving information from the platform and POST[b] for posting information on the platform
Apicall	The activity performed
Session number	Count of sessions for a user
Total sessions	Maximum number of sessions a user performed on the platform
Total time used	Total number of days of using the platform
Days between sessions	Number of days between 2 sessions
Lapse	Gap of >7 days between sessions
Session length	The length of a session in minutes
Mean of total days between sessions	The sum of *days between sessions* divided by *session number*, which indicates the average time in days between using the platform
Platform component	Indicates whether a platform component was used; for example, "Advice"=yes explains that the user did use the advice

[a]GET: an action performed by the user on the platform to receive information from the platform.

[b]POST: an action performed by the user on the platform to post or upload information on the platform.

Table 2. Operationalization of nonadherence.

Variable	Operationalization
4 weeks of nonuse	• Gap of >28 days between sessions
Too many lapses	• The total number of lapses is higher than allowed for the "total time used" based on the following formula: "total time used"[a] 0.034< "lapse"; 0.034 means that one lapse is allowed every 30 days (1 month) • Too many lapses = 0.034 total time used<lapse
Stopped using	• The last "timestamp" is earlier than February 15, 2021, (4 weeks before the end of the log data) or "total time used"<364 (1 year)

[a]Only one of the variables must be true to be labeled as nonadherent.

Results

Usability Tests and Interviews

First-Round Sample (0 Months)

Participants

In total, 10 participants were included at 0 months. The sample comprised 80% (8/10) of males. The mean age of the patients was 62 (range 48-76) years. The most reported cardiovascular condition was myocardial infarction. The participants reported that they started to improve their lifestyle after the cardiac incident by focusing on maintaining a healthier diet and increasing their physical activity. However, some of them mentioned that they already focused on a healthy lifestyle (mainly diet and physical activity) before the cardiac event. The participants wished to return to the life they had before the event and wanted their anxiety and insecurity about their health condition to be taken away. For example, they indicated a strong feeling of insecurity about their health after they were discharged from the hospital. An overview of the participant characteristics is presented in Table 3.

Table 3. Characteristics of the participant sample at 0 months.

Participant number	Sex	Age (years)	Cardiovascular condition
Participant 1	Male	48	Heart surgery
Participant 2	Male	62	Heart surgery
Participant 3	Male	66	Aorta aneurysm
Participant 5	Male	63	Myocardial infarction
Participant 6	Male	70	Arrhythmia
Participant 8	Male	52	Congestive heart failure
Participant 9	Female	76	Myocardial infarction
Participant 10	Male	72	Congenital heart defect
Participant 11	Female	DNS[a]	Myocardial infarction with complications (cardiac arrest or arterial bleeding)
Participant 13	Male	52	Myocardial infarction

[a]DNS: did not state.

Expectations and Experiences at 0 Months

The 0-month usability test showed that half of the participants (5/10, 50%) had not started using the platform. They had filled in a few introduction questionnaires, for example, but they did not start exploring the platform by themselves. These participants indicated that they had no need for technological support to monitor their data. The indicated reasons were, for example, that they thought that they already had a healthy lifestyle or that they did not feel comfortable using technology. Others indicated that they were open to being supported by technology. In general, the participants stated that support by a technological platform does not have any obligation and is flexible, which they appreciated because it makes the platform accessible for them:

> *[Researcher: How desirable is it for you to be supported by a platform instead of a real person?] It is easier. [Researcher: Easier, because?] Because you can use it if you feel like it and want to make time for it. If you are confronted with a real person, then you must make all kinds of agreements, all kinds of obligations, and yes...I hate all kind of obligations. I like that I can use the platform whenever I want.* [Participant 6]

During the scenarios, the participants noticed that it was interesting to monitor their own health data and view their progress. It was indicated that *watching their progress* would motivate them to adopt or maintain a healthy behavior:

> *It gives stimulation when you see it descend, the line, which gives extra motivation* [Participant 1]

In addition, they were positive about the possibility of revising older data and advice, and they appreciated that all their data, appointments, and to-dos were accessible on one page. However, the participants indicated that it is important for the platform to use all health data when providing feedback (eg, historical data). At that moment, they indicated that they only received feedback from the platform on a snapshot of data and that the platform did not consider the progress since the last logged data when providing feedback to the user:

> *Below you can see all the advice that is currently provided on your input. I have the idea that it is just a snapshot, that advice, and that it does not revise the data history [...] For example, alcohol consumption: every now and then during the week I drink some glasses, but in the weekend, I fill in zero glasses. And then you see 'congratulations, you're doing well, you didn't drink alcohol.' Then I think, hey, it does not look at the history of the past few days...* [Participant 10]

There were contradictory attitudes toward the use of reminders. It was mentioned that the frequency of *receiving reminders* was annoying or overwhelming, whereas others indicated that it helped them with remembering what still needed to be done (eg, daily tasks).

Needs and Requirements for Support From a Health Management Platform

During the interview sessions, several possibilities of what could be provided on the platform were discussed. For example, the participants wished to *have an incentive (*"a stick behind the door") to monitor their data, and they appreciated the option to set goals on the platform:

> *It gives you an overview, but it is also a big incentive to keep measuring your health. Rehabilitation is not just training.* [Participant 5]

A reward system, such as that provided on the Vital10 PHP, was generally considered undesirable or unnecessary by the participants. They stated that gaining or regaining their health was their aim, not receiving rewards. One of the participants also indicated that the platform should provide fitness exercises or other tips for physical activity for this specific patient group. In addition, the participants preferred *personalized advice.* For example, although a participant had already lost considerable weight, he or she was still too heavy. Therefore, the platform provided the feedback that this person should lose weight. This was very demotivating for the participant because he or she was already trying hard, and it would have been appreciated if the progress he or she made was also reviewed and mentioned.

> *Well, you know...at some point you had a heart attack and then you are sent home. And then you receive rehabilitation guidance, because you must start exercising again and regain confidence. So, then I do not pay attention to getting gifts. I think those goals, my health goals are sufficient for me to be motivated to start, do you understand?* [Participant 5]

The participants indicated their need for visualization of their data. Insight into their own data and progress was experienced as an added value. For example, the use of colors or graphs makes it immediately clear what the current health status is. However, it was also noted that this could be confrontational. The advice the platform provides based on health data was interesting for some participants, whereas others mentioned that it was patronizing and that they did not need advice from a platform or person other than their health care professional:

> *I clicked once on it [Provided advice] and it was a bit patronizing. And very brief, considerably basic information.* [Participant 3]

The participants appreciated that the platform provided additional information about their disease and how to change their lifestyle. They indicated that sometimes, there was no time to discuss this with their health care professionals during appointments or that they were afraid to ask questions:

> *[Researcher: What do you think about this kind of information being here?] It is incredibly wise, because people see upper and lower blood pressure...usually, you have to be quiet during the doctor's examination and then you do not ask what those different things are. So, I like that it is explained in here* [Participant 10]

The participants indicated needing *reliable information* on the platform or a reference to another reliable source. It was mentioned that the information provided should be concise because an overload of information can be overwhelming. In addition to the information in the text, they also wished to have direct and personal contact, for example, for asking questions without urgency.

The participants mentioned *that it was not clear what role health care professionals* play on the platform. They indicated that they wanted their health data on the platform to be visible to health care professionals. They thought that it would be useful if they can show their logged data to, for example, their cardiologist during appointments. However, it was also mentioned that the participants did not feel comfortable with *sharing health data via technology,* but they suggested that they could show their data easily to their health care professional if they could print an overview of their progress. These participants appreciated logging data such as body weight and blood pressure on the platform but did not want all their medical history to be shown (such as prescribed medication, medical incidents, and previous appointments). In addition, they expected health care professionals to *contact them after their logged data becomes* "red" (eg, if high blood pressure is too high, the module will be colored red) or for the platform to automatically alert the health care professional in such a case:

> *There should be a notification system that if, for example, your blood pressure is an increasing pattern, then the cardiologist receives automatically a notification with "that patient is not doing so well."* [Participant 8]

Needs and Requirements for the Adoption of a Health Management Platform

Several other needs and requirements were indicated to help patients adopt the platform in their daily lives. The participants

mentioned that they need the *platform to be introduced* and explained to inexperienced users while they are still in the hospital (before discharge). It should then be clarified *for how long the use of the platform* is expected and what the intended use is. They indicated that the strategy of implementation should be tailored to different target groups because different patients *might have different digital skills*. For example, the participants indicated that they feel uncomfortable with only digital support and preferred a combination of digital support and real-life support:

> *There is a distinction between the younger, middle-aged, and older patients. I can imagine that there are some older people who have a little more trouble using a platform, and there will be, for example, a little more guidance desired.* [Participant 1]

A *combination of support by health care professionals and a technological platform* is appreciated because this is perceived as a more personal approach. In addition, the participants thought that *an app would fit better in their daily life* than a web page. They also preferred to *connect measuring equipment* (eg, Fitbit [Fitbit Inc] and iWatch [Apple Inc]) to the platform to automatically monitor data. The participants indicated that they did not need their family or friends to be involved on the platform.

Second-Round Sample (6 Months)

Participants

In total, 12 participants were included at 6 months. The study sample comprised 92% (11/12) of males. The mean age of the patients was 59 (range 48-74) years. The most reported cardiovascular conditions were myocardial infarction and cardiomyopathy. All the participants reported that they started improving their lifestyle after the cardiac incident by increasing their physical activity and mainly by focusing on a healthier diet, for example, eating less salt, unhealthy fats, and red meat and consuming more fruit and vegetables. In addition, the participants mentioned that they also focused on reducing stress (factors), increasing their quality of sleep, lowering their alcohol consumption, and maintaining a healthy weight. An overview of the participant characteristics is presented in Table 4.

Table 4. Characteristics of the participant sample at 6 months.

Participant number	Sex	Age	Cardiovascular condition
Participant 1	Female	DNS[a]	Congenital heart defect
Participant 2[b]	Male	63	Heart surgery
Participant 3[b]	Male	64	Myocardial infarction (2 times)
Participant 4	Male	66	Myocardial infarction (3 times)
Participant 5	Male	63	Heart surgery
Participant 6[b]	Male	49	Heart surgery
Participant 7[b]	Male	58	Myocardial infarction
Participant 8	Male	74	Preventive vascular surgery + stent
Participant 9	Male	48	Myocardial infarction with complication (cardiac arrest)
Participant 10	Male	48	Cardiomyopathy
Participant 11	Male	64	Cardiomyopathy and multiple myocardial infarctions
Participant 12	Male	52	Inherited cardiac conditions and angina pectoris

[a]DNS: did not state.

[b]These participants were also included in the round 1 sample (0 months).

Expectations and Experiences at 6 Months

After using the platform for multiple months, the participants stated that it was motivating and easy to log data. The colors and signs provided *a direct and clear overview of data* (Figure 1). Tracking data and progress stimulated and motivated the participants, and *setting goals made them more aware of the focus on their lifestyle*. However, the participants mentioned that it was a challenge to get all the lifestyle values on the dashboard to turn "green" (eg, in case of a healthy weight or blood pressure, the module will become green). The chat is *easy and accessible for quick contact* with a health care professional, although some participants preferred personal contact. However, the reward system was not valuable to most participants. They indicated that rewards motivated them to log data, but most participants mentioned that they must *be intrinsically motivated to improve their health, not to gain rewards*. In addition, some advice and information on the platform were impersonal or basic, which gave the participants a bad feeling. It was also noted that there was a lack of support at the beginning of their use of the system, which was demotivating for them:

> *Then I get the feeling that it is a general story and not specifically intended for you.* [Participant 6]

Needs and Requirements for Support From a Health Management Platform

A platform should have a *calm and consistent appearance*, and features should be prominently placed and easy to find. In

addition, the participants wanted the option to *save interim data while logging, performing tasks, or filling in questionnaires*. They also preferred to review and adjust their data after saving it. They indicated that setting goals helps them improve their lifestyle step by step. It was mentioned that they would prefer it if they could *set several goals at the same moment*, for example, not only diet-related goals but also exercise and quit smoking goals. They wanted the platform to *provide information about a healthy lifestyle*. They needed an incentive ("a stick behind the door") to adopt and maintain new, healthy behaviors. In addition, they mentioned that they wished to have *peer-contact* on the platform:

> *I would not be into having contact with other heart patients because treatment and recovery greatly differ between conditions. It would be interesting though to read about how other patients deal with experiences of limitations or changes in lifestyle.* [Participant 5]

The provided information should be complete, correct, and personalized to the user's needs and interests. The participants noticed that the current information and advice were not applicable to them. They indicated that they will be more motivated to use the platform if the *information and advice were applicable and reliable*. In addition, they indicated that the information was not inspiring:

> *I also kept track of my data for a while, but that slowly stopped because I was not necessarily happy with all the advice I received, or just the advices I did not receive, so that's why.* [Participant 9]

The participants indicated their wish for *feedback not only on self-monitored data* but also on their activities. This was especially true during the COVID-19 pandemic (because of the lockdown, there was no real-life physical activity rehabilitation) when the participants *missed receiving feedback* on their physical performance, and they needed some reassurance about what their body was capable of doing.

The participants needed an *overview of all their medical health data*. Although it was mentioned that a commercial platform is not the right place for saving medical data, most participants indicated that they wanted to exchange data with health care professionals. Some want to make their data *accessible for the health care professional* on the platform, whereas others wished to show their logged data on the platform by themselves during appointments:

> *Well, it is useful if all medical data is put together, but I do not know If this platform is the right place. I do not know whether a commercial organization such as I see this [Vital10 PHP]...whether I would consider that as the right place. I would prefer to have that at for example my general practitioner or the hospital.* [Participant 9]

Needs and Requirements for the Adoption of a Health Management Platform

The Vital10 PHP participants indicated that one of the requirements for the adoption of the platform is that it should be *introduced and explained before their discharge from the hospital* or at the start of the (live) cardiac rehabilitation:

> *Nowadays you are no longer in the hospital for ten days, before you know it you are home again. And then? Then it is especially useful if you get it from the hospital, go look for it, you are working on it, you can give it a place, you can describe it in your goal, so you can look back on what did I do wrong. Of course, it does not have to, it can also just be a physical thing. You will be helped a bit with that and triggered to think about it, but you can also do something with it. Otherwise, I will come home and then there will be nothing, yes, continue to live happily, but at least that is what I experienced from cheerfully to live on, there are still some steps needed.* [Participant 3]

They suggested this timing of introduction because they mentioned that it was important that patients or users be informed in person about the platform and *have the possibility of asking questions or receiving help while using it*. For less digitally skilled participants, it was difficult to understand how to use the platform or what was expected from them. Moreover, the participants indicated that the platform should be provided in addition to usual cardiac care. They mentioned that the platform supports them, but they wished that it be implemented not only as an addition to cardiac rehabilitation but also as an addition to regular (cardiac) care. It should support them but should not replace usual care or personal contact with health care professionals.

The participants indicated that it was irritating that it was not clear whether the platform could interoperate with other measurement equipment, such as Fitbit or iWatch. They were bothered by the fact that they had to log the data manually on the platform and preferred an automatic synchronization of these data. In addition, the participants indicated that they need to receive triggers for using the platform. The current reminders sent by the Vital10 PHP were helpful for some of the participants, although others thought that these were irritating and would like the possibility of changing the settings related to the frequency of receiving reminders:

> *I think it [Vital10 PHP] should trigger usage...The rehabilitation trajectory is 6 weeks, and the platform could for example after 10 or 12 weeks send you a notification asking: "How are you now?" Or not even a question, but just a notification which triggers you to look at the platform and fill in some data. The trajectory stops after 6 weeks, period. Then you must do it by yourself. That is true, but I still have questions after 10 weeks...* [Participant 3]

Log Data Analysis

Use Statistics

A total of 762 users were invited to use the platform. Of these, 69.6% (506/762) of users were long-term users (>3 weeks of use) and were thus included in the analysis. In total, 10,285 sessions were performed, of which 9606 (93.4%) sessions were performed by nonadherent users. On average, it took the users 14 minutes per session. This average session length decreased from 37.6 minutes for the first session to 11.5 minutes for the

eighth session and beyond. Half of the users (300/506, 59.2%) quit using the platform during the first 11 sessions. Over 49% of the users had a total number of sessions that represent at least 1 session per week. The platform was most used between 9 AM to 12 PM, with an average gap of 6.5 days between the sessions. Table 5 provides an overview of the general use statistics.

Table 5. General use statistics by long-term users (n=506).

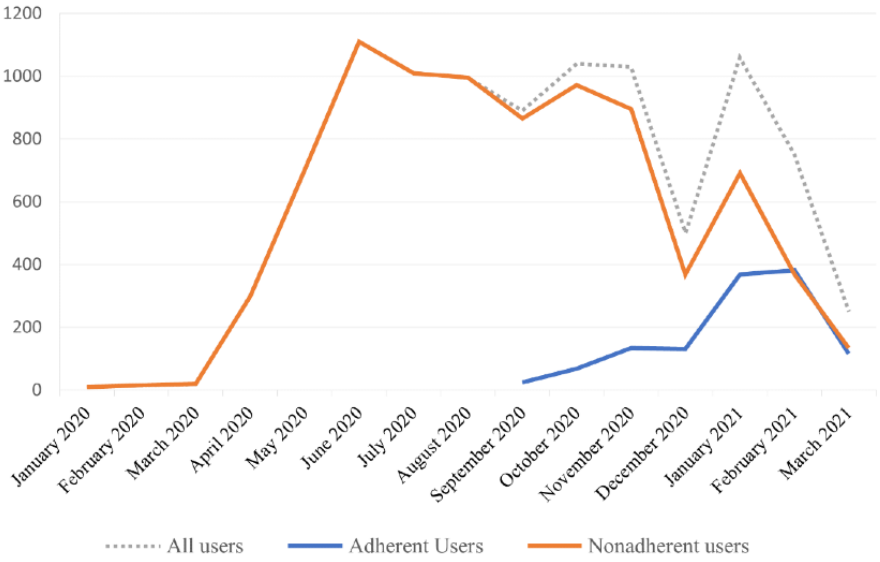
	Average	Range
Number of sessions	19[a]	2-283
Session length (minutes)	14[a]	1-241
First session length (minutes)	37.6[a]	1-241
Length of the eighth session and beyond (minutes)	11.5[a]	1-113
Total time used (days)	100[a]	21-381
Lapses	2.7	0-15
Mean total days used	110	21-392

[a]Variables are averages.

Long-term Use Pattern of the Vital10 PHP

Over the entire study period (437 consecutive days from January 3, 2020, to March 15, 2021), each patient visited the Vital10 PHP an average of 19 times, for approximately 110 days (range 21-381 days). An overall decline in use was observed over time (Figure 2). Most sessions were performed by nonadherent users, who make up 93.4% (n=712) of all users.

Figure 2. Long-term use of the Vital10 Personal Health Platform by all the included users.



Long-term Use Pattern of the Components of the Vital10 PHP

The platform consists of different components. Table 6 shows the different components and reports the number of users who used these components at least once.

Figure 3 displays the long-term use patterns of the different Vital10 PHP components for all the included users. The components “Advice” and “Indicator” were used the most by both adherent and nonadherent users, followed by “V-cheq” and “Health.” “Care doc” and “resources” were used rarely or not at all used by both groups.

Table 6. Platform component use.

	Total number of users who visited the component at least once, n (%)		If yes, the percentage of sessions the component was used in
	Yes	No	
Advice	506 (100)	0 (0)	98.2
Challenge[a]	452 (89.3)	54 (10.7)	9.2
Mission[a]	408 (80.6)	98 (19.4)	22.9
Health[b]	331 (65.4)	175 (34.6)	56.4
Record[c]	322 (63.6)	184 (36.4)	11.5
History[c]	432 (85.4)	74 (14.6)	21.5
Care doc[c]	233 (46)	273 (54)	6.8
Indicator[d]	506 (100)	0 (0)	96.4
Information[d]	267 (52.8)	239 (47.2)	10.8
Resources	13 (2.6)	493 (97.4)	0.3
Reminders	200 (39.5)	306 (60.5)	18.3
V-cheq	499 (98.6)	7 (1.4)	47.6

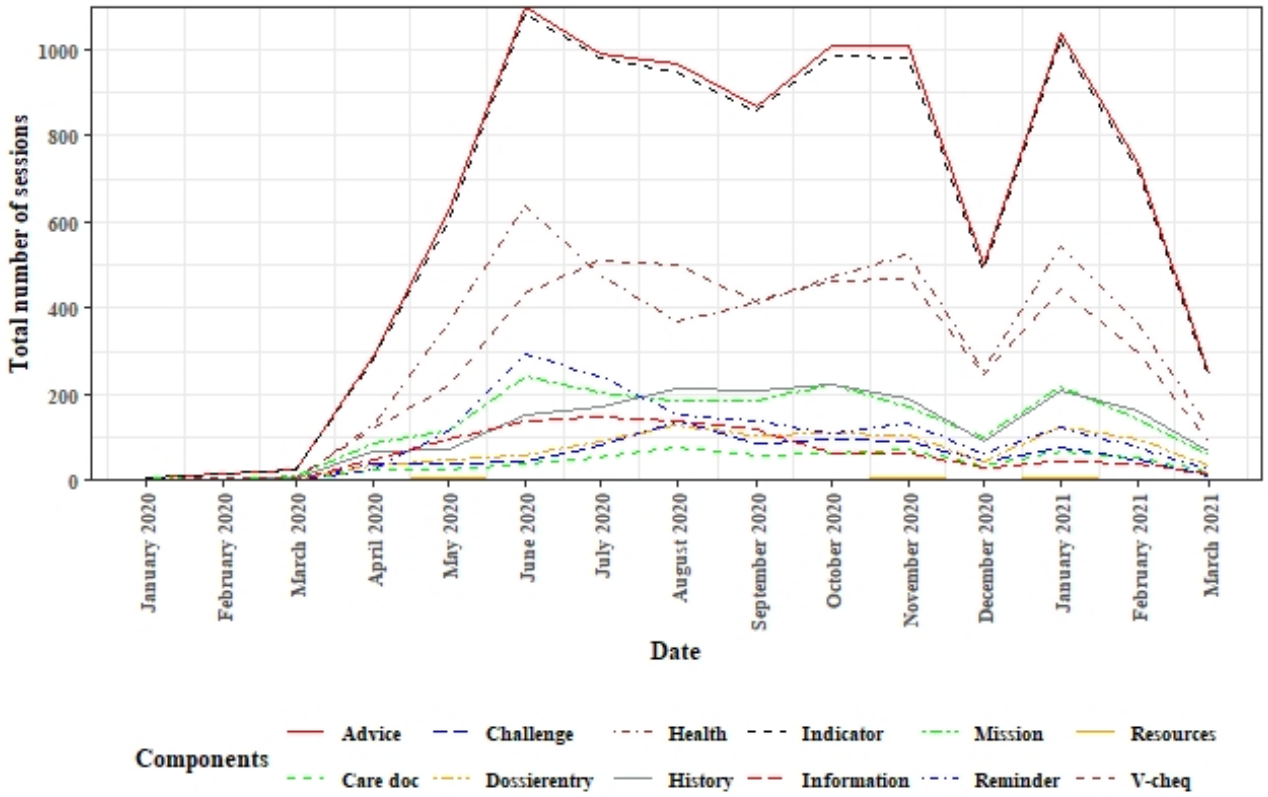
[a]Challenge and mission refer to goal setting.

[b]Health refers to self-monitoring.

[c]Record, history, and care doc refer to medical records.

[d]Indicator and information refer to information.

Figure 3. Long-term use of the different components of the Vital10 Personal Health Platform by all the included users.



Discussion

Principal Findings

The aim of this study was to identify and monitor patients' needs for support from a web-based health management platform and how these needs change over time. On the basis of these findings, we can conclude that after the start of cardiac rehabilitation, a health management platform can support patients with CVD in adopting and maintaining a healthy lifestyle by helping them self-monitor data, watching their progress, and be (kept) motivated and reminding of their personal goals. The lack of continued tailored or personalized advice 6 months after cardiac rehabilitation made the platform appear less useful to patients. We noted that most patients easily learned how to use the platform and were interested and motivated by logging their data and viewing their progress. After months of using the platform, patients learned and understood how to use the functions on the platform; None of the usability issues hindered them gravely, nor were they a reason to quit using the system. However, soon after the cardiac rehabilitation program stopped (after approximately 3 months), the use of the platform declined, or patients even quit. Earlier studies showed a similar decline in adherence to supporting technologies in cardiac rehabilitation during the first 3 to 6 months [20,21], and approximately 90% of the patients quit using the technology within a year [22]. However, other studies that used eHealth as follow-up after regular cardiac rehabilitation (eg, with features such as reminders and a personal approach) showed positive effects on adherence to the technology [23-25].

An interesting finding of this study pertains to the incentive system included in the Vital10 PHP, which aims to motivate patients to achieve their goals. The need for "having a stick behind the door," an overview of personal health data, and receiving personalized care were earlier identified as values for patients with CVD [6]. Moreover, in earlier research within the BENEFIT consortium [26], patients indicated that they want to be extrinsically motivated (eg, with rewards) to accomplish goals. Providing feedback and a personalized approach seem to have a positive effect on adherence [27-29], and our study confirms that a lack of personalization discourages the use of the platform. However, in contrast to earlier findings, our study showed that a reward system is generally not regarded as valuable by patients. In the current version of the Vital10 PHP, most of the implemented rewards were luxury items (eg, handbags and discounts for holiday trips). However, these incentives seemed inappropriate to the patients. These incentives were insufficiently linked to the core value of regaining health. However, we can confirm that patients need a positive trigger or reward because they claimed that their reward was becoming healthy again. In this sense, the regained health that they experience is the positive trigger or reward. This finding provides the insight that patients may initially have a need for extrinsic motivation in the short term; however, in the long term, a shift to focusing on intrinsic motivation is needed to support them. Nevertheless, becoming healthy again is a long-term effect, and a lack of short-term effects can demotivate patients [30-32]. Therefore, it is recommendable to focus on health-related rewards (eg, products in the web shop) to contribute to positive health-related changes (promote a healthy lifestyle). Earlier research showed that using eHealth can improve levels of confidence and self-efficacy in a brief time track in comparison with usual rehabilitation programs [23,33].

Most Vital10 PHP users did not use the platform as intended by the BENEFIT research group. However, this does not necessarily mean that the users did not benefit from the platform. The study showed that patients visit the platform and perform the tasks that are assigned to them. However, as soon as the coaching support stops and the patient has to continue independently (eg, use the functions by themselves and seek support by themselves), the platform use declines. We question whether it is a negative outcome that patients quit using the platform at a certain moment. Quitting the platform does not directly mean that the platform is not functioning well or that patients no longer focus on lifestyle improvement. However, it provides insight into the extent to which patients need support at this stage of improving and maintaining their lifestyle. For example, if patients quit using the platform, it could be possible that the platform was successful in providing the support the patients needed to acquire the skills necessary to improve and maintain a healthy lifestyle and is, therefore, no longer needed. By contrast, although patients might think that they no longer need technological support, previous research shows that a sustainable change in (health) behavior after implementing interventions is limited [34,35]. In the latter case, quitting the platform would be a negative result because it would mean that the platform was not successful (yet) in teaching the patient how to maintain their changed behavior. Therefore, more extensive research is needed into how health and health behaviors change after cardiac rehabilitation with the help of the platform. Future research should identify whether patients who discontinued using the platform were, indeed, capable of maintaining a healthy behavior themselves or whether they missed a personal component or supporting guidance in the longer term.

Recommendations

Currently, we see that the focus of researchers, developers, and health care institutions is on building a guiding and supportive relationship with patients and on encouraging patients to sustain the use eHealth technologies to improve their health. However, it should be kept in mind that the key to success should not be user adherence to an eHealth technology but adherence to healthy lifestyle habits. Therefore, we recommend not focusing on improving adherence to eHealth as a goal in itself but rather focusing on fulfilling the patients' values: achieving a healthier lifestyle in real life. eHealth is not a stand-alone support but should be integrated into daily life and treatment processes. Therefore, "off-boarding" from a platform should be encouraged if it helps patients independently and sustainably adhere to their healthy lifestyle habits. In this regard, eHealth can still play a role in the patients' lives as (back-up) support, especially in cases of relapse or health-related questions, with a focus on helping the participants live healthier lives and making them aware of the products and services in the neighborhood that can support them.

Consequently, if we assume that this "off-boarding" is a transition from needing support from an eHealth technology to using the technology as a back-up, how will we be able to identify or monitor this transition? What will happen to the patients after this transition? Will they no longer identify themselves as patients? How and to what extent can or should we (still) support them? In particular, less is known about how technology can support patients in this transition from short-term lifestyle changes to long-term maintenance [3]. We suggest that future research focus on this "off-boarding" transition and how the insights derived in this regard can be taken into account in the design and implementation of an eHealth technology. In addition, use patterns provide insight into which content or functionalities of an eHealth technology are used and could, therefore, identify when, and to what extent, patients' needs are fulfilled. From a methodological perspective, it is interesting to note that this study included a mix of participants who took part in only the 0-month or the 6-month iteration as well as participants who took part in both iterations. It remains to be tested in future research what sampling approach best suits a multi-iterative user evaluation.

We want to emphasize the importance of conducting multi-iterative user evaluations that conform to the CeHRes Roadmap. It enabled us to identify changes in the users' needs and contexts of use, and continuously evaluating the eHealth technology enabled us to respond to these changes in the design or redesign and implementation of the technology. The NASSS framework is complementary to this because it provides guidance on what aspects need to be considered for successful implementation. Thus, the NASSS framework helps focus on what should be done, whereas the CeHRes Roadmap defines how, when, and where. However, in this study, we focused on development and implementation from an end-user perspective. eHealth is not a stand-alone tool, and its integration within daily life and health care will involve multiple stakeholders other than patients as well as a business plan [6]. Therefore, future research should also focus on a more ecological implementation of eHealth by considering the other domains of the NASSS framework, such as additional adopters (eg, other stakeholders such as health care professionals), organizational factors (eg, working routines and capacity to innovate), and the wider system (eg, political, regulatory, or legal processes).

Strengths and Limitations

A strength of this mixed methods approach is that by performing both a log data analysis and usability tests with interviews, we were able to collect details on the users' (patients') experiences with a web-based health management platform and their perspectives on the needs and requirements for the platform and its implementation. We were able to complement this with the data on the actual use of the platform. This allowed us to identify the use patterns of adherent and nonadherent users; furthermore, it could help explain why users quit at certain moments of time or why they do not use certain features (anymore). In addition, conducting 2 rounds of usability testing with interviews enabled us to see differences in the needs and requirements for receiving support from a web-based platform over time. During the first round, the cardiac event had just occurred, and participants may have indicated short-term needs based on their anxiety or uncertainty. During the second round, they had probably processed the cardiac event and already adjusted their lifestyle, which could have given them the opportunity to focus on the long-term needs.

This study also has some limitations. Owing to the COVID-19 pandemic, multiple restrictions were implemented in the Netherlands. Especially during the 0-month iteration, the first month after the COVID-19 outbreak, the cardiac rehabilitation centers of Vital10 were shut down and restricted to web-based care only. The participants were offered different rehabilitation programs (with fewer or even without physical appointments), which might have affected their motivation or willingness to use the platform. Owing to the COVID-19 restrictions, we also had to adjust our recruiting and study procedure to conduct them on the web instead of offline. Considering that our target group just had a life-changing cardiac event during a pandemic, it was quite difficult to include patients during this part of our study. In this qualitative study, we focused on the how and why of platform use and not on quantitative results. However, although we included 10 patients, instead of 12, in the 0-month iteration, we observed data saturation in the interviews. In addition, selection bias may have occurred and caused a more homogenous participant group. Most participants were relatively young compared with the general CVD population. However, by including relatively young patients as well as older patients with CVD, we were able to include both more and less digitally skilled participants. In addition, considering privacy protection, during the recruitment, we as researchers only received the contact details of patients who indicated willingness to be contacted by us. Therefore, the response rate of our recruited sample was unknown.

Conclusions

We can conclude that the support approach of health management platforms should be personalized: there is no one-way solution, and eHealth is not a stand-alone tool. In the short term, it is important to provide supporting tools to patients because they need to learn how to improve their lifestyle and to feel safe and secure about their health again. However, in the long term, the focus should not be on user adherence to the eHealth technology but on adherence to the values of patients for which the eHealth technology was initially developed, such as having healthy lifestyle habits. Although the underlying core value of platform use is becoming healthy, the more practical needs for which patients (or their context of use) require support from the technology may change over time. Hence, quitting the use of eHealth does not directly mean that the technology is not functioning well or that the patients no longer focus on achieving their value. It could mean that their value is fulfilled or that current content or features of the technology do not contribute anymore to supporting them in achieving a healthy lifestyle. This emphasizes the importance of conducting multi-iterative evaluations to continuously examine whether the technology still meets patients' need for support to achieve their value. These evaluations enable developers to respond to the changing needs in the design or redesign and implementation of eHealth. Therefore, the implementation of eHealth should also include the transition to a stage where patients might no longer need support from the eHealth technology to achieve and maintain

a healthy lifestyle and might be independently and sustainably adherent to their healthy lifestyle habits. Future research should focus on how this transition can be identified and monitored and how these insights can be considered in the design and implementation of the technology. However, in this study, we focused on development and implementation from a user perspective. eHealth is not a stand-alone tool, and its integration within daily life and health care will involve multiple stakeholders other than patients as well as a business plan. The NASSS framework also aids in determining which other stakeholder perspectives as well as organizational or legal aspects of implementation need to be considered for the successful implementation of eHealth technology.

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Data Availability

The transcribed data are not publicly available because of privacy restrictions but are available from the corresponding author upon reasonable request.

Authors' Contributions

All the authors contributed to the study design. BEB, JW, CS, and LDB participated in the coordination of the usability tests and recruitment of the participants. BEB and JW were responsible for the creation of the protocols for the usability tests and interviews, which were conducted by BEB and CS. BEB analyzed the data of the first-round sample, and BEB and CS together analyzed the data of the second-round sample. The findings were discussed and revised with JW. BEB wrote the first draft of the manuscript. JW, LDB, MEP, and LvG-P contributed to the manuscript by providing feedback and discussing the interpretation of the results. All the authors read and approved the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots and core attributes of the Vital10 Personal Health Platform.
[DOCX File , 8691 KB - cardio_v7i1e43781_app1.docx]

Multimedia Appendix 2
Usability test and interview protocols with scenarios.
[DOCX File , 26 KB - cardio_v7i1e43781_app2.docx]

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Abbreviations

CVD: cardiovascular disease
NASSS: Nonadoption, Abandonment, Scale-up, Spread, Sustainability
Vital10 PHP: Vital10 Personal Health Platform

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Original Paper

Engagement in Self-measured Blood Pressure Monitoring Among Medically Underresourced Participants (the Reach Out Trial): Digital Framework Qualitative Study

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Abstract

Background: Mobile health (mHealth) interventions serve as a scalable opportunity to engage people with hypertension in self-measured blood pressure (SMBP) monitoring, an evidence-based approach to lowering blood pressure (BP) and improving BP control. Reach Out is an SMS text messaging–based SMBP mHealth trial that aims to reduce BP among hypertensive patients recruited from the emergency department of a safety net hospital in a low-income, predominately Black city.

Objective: As the benefits of Reach Out are predicated on participants' engagement with the intervention, we sought to understand participants' determinants of engagement via prompted SMBP with personalized feedback (SMBP+feedback).

Methods: We conducted semistructured telephone interviews based on the digital behavior change interventions framework. Participants were purposively sampled from 3 engagement categories: high engagers (≥80% response to SMBP prompts), low engagers (≤20% response to BP prompts), and early enders (participants who withdrew from the trial).

Results: We conducted interviews with 13 participants, of whom 7 (54%) were Black, with a mean age of 53.6 (SD 13.25) years. Early enders were less likely to be diagnosed with hypertension prior to Reach Out, less likely to have a primary care provider, and less likely to be taking antihypertensive medications than their counterparts. Overall, participants liked the SMS text messaging design of the intervention, including the SMBP+feedback. Several participants across all levels of engagement expressed interest in and identified the benefit of enrolling in the intervention with a partner of their choice. High engagers expressed the greatest understanding of the intervention, the least number of health-related social needs, and the greatest social support to engage in SMBP. Low engagers and early enders shared a mixed understanding of the intervention and less social support compared to high engagers. Participation decreased as social needs increased, with early enders sharing the greatest amount of resource insecurity apart from a notable exception of a high engager with high health-related social needs.

Conclusions: Prompted SMBP+feedback was perceived favorably by all participants. To enhance SMBP engagement, future studies could consider greater support in the initiation of SMBP, evaluating and addressing participants' unmet health-related social needs, as well as strategies to cultivate social norms.

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KEYWORDS

mobile health; mHealth; cardiovascular disease; hypertension; blood pressure; semistructured interviews; intervention engagement; social determinants of health; DBCI framework

Introduction

Hypertension, the most important modifiable cardiovascular risk factor, affects nearly half of the adult population in the United States [1-5]. Many Americans have uncontrolled blood pressure (BP). In 2018, about 116.4 million (46%) adults had hypertension [6-8]. Black Americans have the highest prevalence of hypertension of any racial or ethnic group in the United States and are less likely to have their BP controlled than White Americans [8]. Hypertension disparities are also evident among low-income Americans, who have a higher prevalence, less awareness, and less treatment of BP and poorer BP control than other Americans [9]. Self-measured blood pressure (SMBP) monitoring is the regular measurement of BP by an individual outside of the clinical setting [10]. SMBP is effective in lowering BP and improving BP control, particularly when combined with other strategies, including behavioral counseling, education, and training [11-13].

Given the high penetrance of mobile phones, estimated at nearly 97% of Americans, mobile health (mHealth) interventions serve as a scalable opportunity to engage people with hypertension [14]. mHealth strategies can include reminders to measure BP, BP feedback, visualization tools, and telemonitoring. Specifically, telemonitoring allows people to obtain their BP readings, and these BP readings can also be transmitted to patients' care teams, which has been shown to be more effective than SMBP alone [13,15].

The benefits of SMBP are predicated on engagement. It has been suggested that a standardized definition of engagement with digital behavior change interventions (DBCIs) may be based on the extent of usage and the subjective experience of the participant [16]. Within the confines of this qualitative study, we defined engagement as the frequency with which participants responded to prompts to self-report their BP via SMS text message. Using this initial objective measure of engagement (ie, SMBP), we then explored the more subjective experiences and measures of engagement. Despite many people having a home BP cuff, engagement in SMBP may be low [17-19]. Researchers have explored age, family history of hypertension, use of antihypertension medication, BMI, and smoking as factors associated with SMBP [20]. In this context, we sought to understand the determinants of engagement with SMBP based on the DBCI conceptual framework among patients with hypertension. These patients were recruited from the emergency department (ED) of a safety net hospital located in a low-income, predominantly Black city and were enrolled in Reach Out, a 1-year mHealth clinical trial to lower BP [16].

Methods

Overview

We conducted theory-based, semistructured interviews with participants in the Reach Out trial to understand their engagement with SMBP. The interviews were conducted following the conclusion of the Reach Out trial from June to September 2021. Interviews were between 30 and 60 minutes long.

Reach Out Trial and SMBP

Reach Out was an SMS text messaging–based factorial clinical trial assessing behavioral interventions to reduce BP among the safety net ED patient population [21]. Participants of the Reach Out trial were required to have texting capability and were informed during the consent process that standard SMS text messaging rates could apply, depending on their cellular plan. Participants were randomized into 1 of 8 component arms consisting of varying intensity levels: (1) healthy behavior SMS text messaging (daily vs none), (2) SMBP monitoring (daily vs weekly), and (3) facilitated primary care provider appointment scheduling and transportation (yes vs no). Regarding SMBP monitoring, during ED enrollment, a BP cuff was distributed, and participants underwent training on BP cuff use and how to format their BP text message responses to be recognized by the SMS text messaging system as a BP reading (eg, 140/90). They were also given written materials about how to properly send text messages, take their BP, and the significance of hypertension. Participants were able to tailor the time of their text messages based on their preferences (ie, morning, afternoon, or evening). Participants were prompted to take their BP and text responses of their BP at daily or weekly intervals, depending on their randomized group assignment. If participants randomized to weekly intervals did not respond with an SMBP reading, they receive up to 2 additional reminders during the week. Each week, participants received a tailored feedback message based on their recent self-reported BP compared to normal BP thresholds (130/80 mmHg). Herein, the combination of these mechanisms will be referred to as SMBP+feedback. Additionally, participants may prompt the SMS text messaging system to provide a graph or list of their self-reported BP readings since their randomization. Graphs were sent through multimedia messaging services (a text message containing audiovisual material) only requiring the availability of a cellular network.

Participants

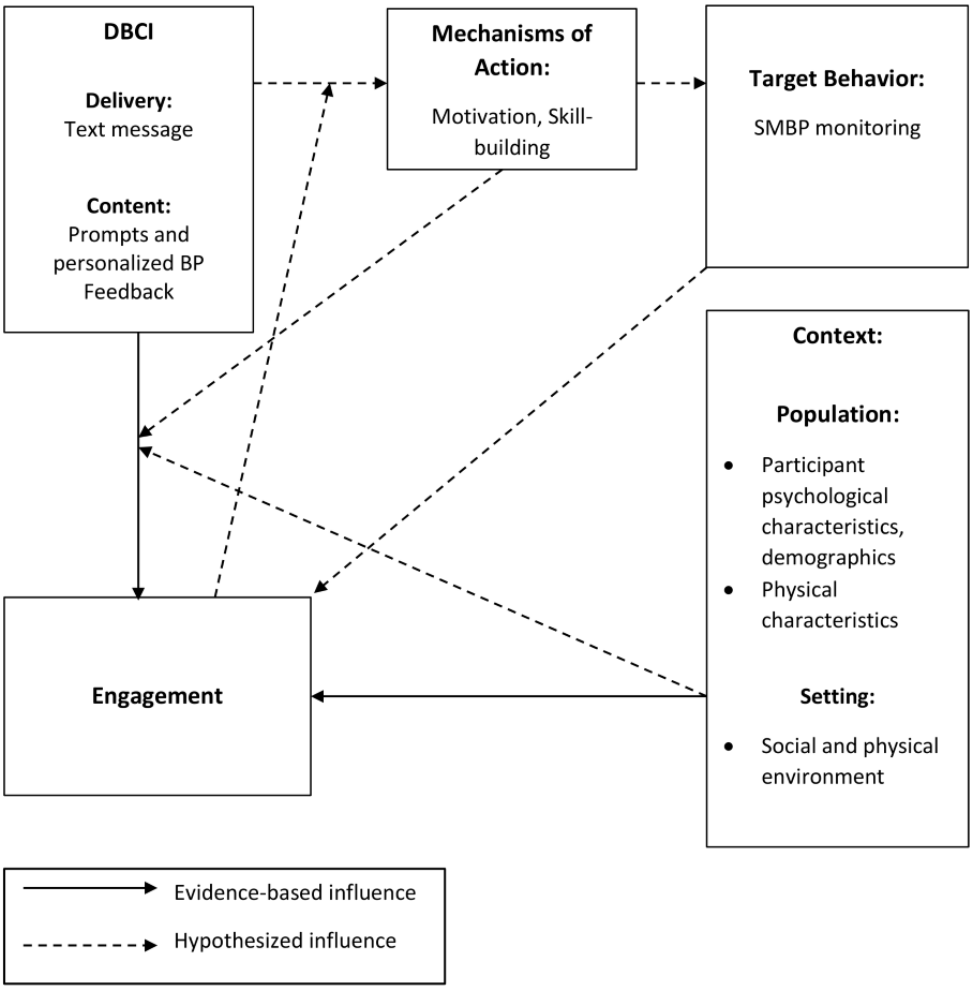
We contacted 31 Reach Out trial participants randomized to the weekly or daily SMBP prompts, of which 13 (42%) participated in the semistructured telephone interviews. We performed purposeful sampling with an emphasis on variation in engagement to understand the determinants of engagement across trial participants [22]. Thus, we enrolled participants from 3 separate engagement categories: high engagers, low engagers, and early enders. High engagers were defined as participants who responded to 80% or more (n= 292+ responses for daily prompt recipients, n=42+ responses for weekly prompt recipients) of the SMBP prompts, while low engagers were defined as participants who responded to 20% or less (n= 73- responses for daily prompt recipients, n=10- responses for

weekly prompt respondents) of the SMBP text prompts. Early enders were participants who formally withdrew themselves from the study, either by texting "STOP" or by directly contacting the research team, before their 12-month end date.

Interview Guide

We developed an interview guide based on a conceptual framework of engagement with DBCIs that was created from a synthesis of 117 articles (Multimedia Appendix 1). The framework proposes that engagement is directly influenced by the DBCI itself, including its content and delivery, as well as contextual factors pertaining to the user [16]. A simplified and tailored model of the DBCI framework is presented in Figure 1. For the development of our interview guide, we focused on the delivery and content of the intervention; the user's physical and social environment; and demographic, physical, and psychological factors. We specifically queried: (1) intervention mode of delivery and complexity; (2) health-related social needs and their digital/general literacy levels; (3) users' perception and experience engaging in SMBP; (4) users' confidence to engage in SMBP; (5) the effects of community and familial support; and (6) access to quality cell-phone service, time/responsibilities, and digital redlining.

Figure 1. Simplified and tailored digital behavior change intervention (DBCI) framework. BP: blood pressure; SMBP: self-measured blood pressure.



Data Collection

Participants were given the option to complete the interviews either through web-based Zoom meetings approved by HIPAA (Health Insurance Portability and Accountability Act) or by telephone. All interview participants chose to complete the interview via telephone, which was conducted by a primary interviewer (author CW). A second study team member (author MCR) served as a real-time data collector who utilized a structured data collection form to conduct real-time transcription and note verbal clues such as sarcasm during the interviews [23]. All interviews were audio recorded and transcribed verbatim for analysis.

Ethics Approval

This study was approved by the University of Michigan Institutional Review Board (HUM00138470). The Reach Out Trial was registered on ClinicalTrials.gov (NCT03422718). Informed consent was obtained from all participants.

Data Analysis

We developed a codebook based on the DBCI engagement framework and conducted thematic analysis using ATLAS.ti qualitative data analysis software (ATLAS.ti Scientific Software Development GmbH). To establish intercoder agreement, 2 authors (AKH and AC) double-coded 4 (30%) of the transcripts and compared their results. Discrepancies in coding were discussed by the coders until an agreement was reached. With

a shared understanding of the coding schema, the remainder of the transcripts were coded. The intercoder agreement was .98 Krippendorff c-alpha binary.

Results

Participant Characteristics

We conducted interviews with 13 participants, almost equally divided between White and Black participants. Characteristics of individuals who participated in the interviews, declined, or were unable to be reached, along with those of the Reach Out trial population, are shown in Table 1.

Given the nature of the semistructured interviews, not all questions may have been asked or answered by all participants; thus, the denominators in the results section may fluctuate.

Table 1. Participant characteristics[a].

Characteristics	Interviewed participants (n=13)			Declined (n=18)	Reach Out study (n=488)
	High engagers (n=4)	Low engagers (n=4)	Early enders (n=5)		
Age (years), mean (SD)	65.8 (9.3)	50.25 (12.1)	46.6 (9.7)	44.2 (9.6)	45.5 (12.4)
Race, n (%)					
Black/African American	1 (25)	3 (75)	3 (60)	8 (44)	262 (54)
White/European American	3 (75)	1 (25)	2 (40)	8 (44)	201 (41)
Gender, n (%)					
Female	3 (75)	2 (50)	4 (80)	12 (67)	299 (61)
Male	1 (25)	2 (50)	1 (20)	6 (33)	189 (39)
Education, n (%)					
High school/GED[b]/ or less	0 (0)	3 (75)	2 (40)	10 (55)	227 (46)
Some college/trade school	2 (50)	1 (25)	2 (40)	3 (17)	169 (35)
University/advanced degree	2 (50)	0 (0)	1 (20)	5 (28)	92 (19)
Health status, n (%)					
Diagnosed with hypertension prior to Reach Out	4 (100)	3 (75)	4 (80)	14 (78)	385 (79)
Routine PCP[c]	4 (100)	3 (75)	5 (100)	13 (72)	380 (78)
Antihypertension medication (baseline)	4 (100)	2 (50)	4 (80)	7 (39)	273 (56)

[a]Totals not equaling to total n indicate data that were missing or not applicable.

[b]GED: General Educational Development (a high school equivalency credential).

[c]PCP: primary care provider.

Target Behavior

Most high engagers (3/4, 75%) and a couple of low engagers (2/4, 50%) had tried SMBP monitoring prior to participating in Reach Out either at home or at a pharmacy. On the other hand, most early enders (4/5, 80%) shared that they had not tried self-monitoring before, stating that they never thought they needed to, did not have a BP cuff, or forgot.

DBCI Delivery and Content

Understanding of Intervention

All high engagers (3/3, 100%) stated that they understood how the intervention worked, whereas only a couple of low engagers (2/4, 50%) and early enders (2/5, 40%) reported understanding the intervention, both in terms of how to self-measure their BP and the frequency with which they were supposed to report their BPs. As 1 low engager shared:

> *No [I didn't understand], I just did it when...whenever I got texted to do it (giggle). I mean, I understood when I was texted, but I couldn't tell you if it was like once a month or, you know…*

Mode of Delivery

Mode of delivery refers to the method in which the intervention was administered to the participants; in the Reach Out trial, it was via SMS text messaging. All participants (12/12, 100%) expressed being comfortable with text messaging and using a mobile phone in general.

Feedback

All high engagers (4/4, 100%) and early enders (5/5, 100%) and most low engagers (3/4, 75%) expressed liking the DBCI's feedback messages that their BP reading had been received by the research team, sharing that these messages gave them a sense of confirmation and social support:

> *Well, I mean it-I think it was good. You know that was good for reassurance that I made…that I sent it in..because every once in a while, I'd have to go back and check, Oh, did I send my blood pressure in?* [High engager]

> *I felt like I had somebody with me that wasn't present that was still on my team.* [Early ender]

Similarly, all high engagers (4/4, 100%) and early enders early enders (5/5, 100%) and most low engagers (2/3 67%) expressed liking feedback messages that interpreted their BP reading, letting them know if the BP they texted in was high, normal, or low. They said that these messages allowed them to reflect, provided them with a call to action to manage their BP, gave them a sense of reassurance, and generally equipped them with knowledge about their condition:

> *Um… [the messages were] great. Um...that way I knew I had to work a little bit better at either lowering or you know everything was okay.* [High engager]

> *Um, I appreciated those [messages]. I did. And then I was like, 'What? Did I take my medicine or if I was eating too much salt, you know, it just kind of made me take a look at what I was doing.* [Early ender]

> *…That was helpful because, you know, I may've been eatin' something I ain't got no business [eating] (laughter).* [Low engager]

Control Features

Control features are defined as aspects of the DBCI that participants can adjust, and in doing so, provide a sense of control over their engagement. Only 1 (20%) early ender stated that they would have wanted more input into the types of messages they received. Similarly, another early ender shared that they would have wanted more input regarding the frequency of messages they received, stating they would have liked more messages.

Social Support Features

Social support features are aspects of the DBCI that provide assistance via interpersonal interaction. Participants were asked if they would have liked to participate in Reach Out with a partner. Among them, 2 (50%) high engagers shared that they already felt as though they had a partner participating with them because their spouse would encourage them to take their BP or take their BP with them. As 1 high engager stated:

> *Well, my…my wife stays on top of me when I do it, so I mean, I guess I already got [a partner], and I don't complain.*

Other participants shared diverse opinions on having a partner participate with them. Most early enders (3/5, 60%), a couple of low engagers (2/4, 50%), and 1 (25%) high engager shared that they would have liked a partner or noted the value of a partner. As the high engager put it, a partner would have provided them with additional support and would have added a sense of fun and competition to the intervention:

> *Um...it would've been great (laughing) to have someone doing it while I was doing it. […] Yeah. More support and … um…uh...yeah support and, you know making a game out of it, making it where it was challenging.*

Participants who shared not wanting a partner cited that a partner would be unnecessary, unhelpful, or would not have made a difference in their participation. One high engager said:

> *It wasn't necessary to have anybody doing it with me. I am doing it for myself.*

An early ender declared:

> *Nah, it wouldn't have mattered. I'd have done [Reach Out] anyways.*

Professional Support Features

Professional support features are aspects of the DBCI that provide assistance via professional interaction. A couple of high engagers (2/4, 50%) and most early enders (3/5, 60%) expressed wanting more interaction with the research team. Early enders specified that they would have liked more in-person instruction on how to use the BP cuff and other BP-related resources:

> *I went through a lot of stress putting the pressure…you know learning how to use it, even with the instructions…so, I feel about if I came in and then they had shown me personally. Like I'm more of a visual type of guy…so, you would put it on for me and shown me how to put it on, then I'm good right there other than me turning it this way, or thinking it goes this way and it was uncomfortable this way. You know what I'm sayin'?* [Early ender]

Most (3/4, 75%) low engagers, however, stated that they would not have wanted more interaction with the research team. As 1 low engager put it, they would not have wanted more interaction because managing their BP is a behavior they engage in independently:

> *Um…I think [the amount of interaction I had with the research team] was fine because I pretty much maintain, you know, my blood pressure and all that kind of stuff. I can pretty much maintain myself, so, you know, but I like when y'all…when I talked to you guys. I enjoy it. I enjoy talking to you guys, you know, but…I don't need nobody to come out and check on me and all that.*

Participant Context

Physical Context

Physical context refers to participants' basic and technological resources, and the term cellular resources refers to participants' capability to access and use mobile cellular technology. Nearly all participants (11/12, 92%) reported owning a smartphone, either an iPhone or Android, except for 1 (8%) participant, an

early ender who owned a flip phone. All low engagers (3/3, 100%) and most high engagers (3/4, 75%) shared that it would be easy to obtain a new cell phone if theirs were to break, saying that they have insurance for their phones and easy access to a store. As 1 high engager said:

> *Well [replacing my phone would be] fairly easy. I mean, we've got the insurance on the phone, and there's offices all over town here, so it wouldn't be that hard.*

However, another high engager stated that getting a cell phone would be a challenge due to financial constraints:

> *Um... [it would be] difficult (laughing). Um, because I'm considered low income and that's a bill that I could…I probably wouldn't have a cell phone on. My…I'm strapped most every month.*

Most early enders (3/5, 60%) said that it would be challenging to obtain a new cell phone due to cost. As 1 early ender said:

> *[It's] not very easy [to get a new phone]. You got to have money.*

All high engagers (4/4, 100%) and early enders (4/4, 100%) and most low engagers (2/3, 67%) shared that there are many cell phone providers in their area. None of the high nor low engagers reported struggling to keep their cell phone service active. A couple of early enders (2/5, 40%) mentioned struggling to keep their service active, with one early ender citing it was because they forget to pay their bill. None of the participants from any engagement group reported changing their cell phone provider often.

Physical Resources

Physical resources are basic resources (ie, housing, transportation, and food) that significantly influence individuals' quality of life and health outcomes. All participants (13/13, 100%) shared that they have stable housing.

Transportation

Most high engagers (3/4, 75%) and all early enders (5/5, 100%) shared that they have access to regular transportation; however, 1 (25%) high engager shared that their transportation had been "shaky." Low engagers reported mixed access to transportation, with a couple (2/4, 50%) saying that they sometimes have trouble accessing transportation. As a low engager put it:

> *Yes, transportation is a problem sometimes, yes 'cause I don't…I don't drive. I don't know how to drive (laughter). I have to rely on my kids, my neighbor, somebody.*

Food

A couple of high engagers (2/4, 50%) and most of the early enders (3/5, 60%) shared that they worried that their food would run out before they got money to buy more. In contrast, most (3/4, 75%) low engagers reported not worrying that their food would run out. Most high (3/4, 75%) and low (3/4, 75%) engagers shared that they never actually ran out of food. On the other hand, most early enders (3/5, 60%) did experience running out of food.

Utilities

None of the high engagers expressed receiving notice that their utilities would be turned off. In contrast, 1 (25%) low engager and a couple of early enders (2/5, 40%) shared they had received notice that their utilities would be turned off. Two participants, 1 (25%) low engager and 1 (20%) early ender, went on to clarify that they were able to avoid the services being shut off.

Social Context

Social context is defined as the participants' cultural and social normative environment in relationship to SMBP.

Perception of Others Wanting Them to Engage in SMBP Monitoring

All participants (12/12, 100%) shared that they believe that the people who care about them want them to monitor their BP. Participants shared that they believed others wanted them to self-monitor their BP for a variety of reasons, including their current health status and behaviors ("They're worried about how high my blood pressure is and I'm [...] not taking medications for it right now,") a near-death experience ("They almost lost me...uh, a year ago), wanting to make sure they will stay healthy in the future ("Uh, yeah, yeah…'Cause they don't want nothing to happen to [me]. They don't want [me] to die), and their relationship with the people who care about them ("Because they're my children and I'm their mother.")

SMBP Monitoring Social Normative Environment

Most high engagers (3/4, 75%) shared that they know others who also engage in SMBP monitoring; however, most low engagers (3/4, 75%) and early enders (3/5, 60%) did not know anyone engaging in SMBP monitoring. All high engagers (4/4, 100%) and the majority of low engagers (3/4, 75%) and early enders (4/5, 80%) stated that their friends and family knew about their participation in Reach Out and were supportive of their participation:

> *Oh, yes, they did [know about my participation]…They thought it was good and they also...um, each time that you all sent a graph…they wanted a copy, so we had a thread going and so they got a chance to see the up and down as well.* [High engager]

> *Uh…everyone was kinda like glad that I was doing something about [my blood pressure]. Glad that somebody was showing me how to wear my cuff, reminding me to take my press…blood pressure medicine, and-and let me see that it could be higher or lower. You know what I'm saying? […] So, it was a lot of people that was…that was kind happy that-that I was able to [participate].* [Early ender]

Psychological Context

Psychological context refers to the participants' mental and emotional state in relationship to SMBP.

Perceived Importance of Self-monitoring

Overall, most high engagers (3/4, 75%) and all early enders (5/5, 100%) said that checking their BP was important to them:

> *...Checking my blood pressure is important to me 'cause…uh if it gets too high or it gets too low, I could be in trouble and…um blood pressure is the easiest way for black men to die these days from heart attacks, so it's important that you keep up with your blood pressure.* [Early ender]

> *[Checking blood pressure is important]…um just to make sure your blood pressure is, you know do-doing great. You know, you don't want it to be too high because, you know…With me, sometimes mine elevates high…really high…And…uh, you know if mine's too high and my medicine does not control it, I'm gonna go to the hospital.* [High engager]

In contrast, low engagers reported mixed perceived importance of taking their BP; half of the low engagers (2/4, 50%) shared that they found checking their BP was important, while the other half (2/4, 50%) expressed that monitoring their BP is less important to them. As 1 low engager put it, monitoring their BP was less important because their BP had improved:

> *Five [out of 10 important]…'cause I just feel like, you know, checking it when you...when you...when you need to check it, but if nothing's wrong with you, why would you be checking it?*

All participants (12/12, 100%) shared that their health is very important to them.

Experience of Self-monitoring

All high engagers (4/4, 100%) and early enders (3/4, 75%) and most (3/4, 75%) low engagers shared that SMBP monitoring makes them feel positive or neutral emotions, including good, secure, aware, and responsible:

> *It made me feel really more responsible…'Cause…uh, I don't have really no kids, like I just picked up some bills that I have to be responsible for now, but it made me more responsible because…uh you know you could just take a pill and eat the wrong thing and your blood pressure goes up. You know what I'm saying? That's-that's harmful, so it made me make sure I take my pressure every day, sometimes three times a day. You know what I'm saying? It made me pay attention to it, and I had the cuff from-from y'all to even take it…[Early ender]*

> *It makes me feel good that I'm actually, you know, taking control of it a little bit there and makin' sure I'm doing what I'm supposed to be doing and I'm not gonna have a stinkin' stroke, you know?* [Early ender]

A few participants across all levels of engagement noted that how they feel while self-monitoring is dependent on their BP reading. One high engager said:

> *Well, when it's where it should be, it makes me feel pretty darn good, but...it kind of bothers me when it's like it was today, okay?*

Self-perceived Barriers

Most low engagers (3/4) did not self-identify barriers to their participation in Reach Out. One low engager identified not being home as a barrier:

> *Sometimes...Sometimes if I'm not home, I might wait, that's...that's the only thing that, you know.*

In contrast, the majority of early enders (3/5, 60%) identified barriers to their participation, including work and comorbidities ("depending on what time of the day it was, if I was working or not"). Another early ender said:

> *Just physical…during the study a couple of times, I had a hand surgery and an elbow surgery…So it was kinda hard then.*

A visual comparative summary of these results between engagement groups is shown in Table 2.

Table 2. Comparison of engagement groups.

Variables	High engager	Low engager	Early ender
Target behavior			
Tried SMBP[a] monitoring prior to Reach Out	+[b]	+/–[c]	–[d]
Design and delivery			
Understanding of the intervention	+	+/–	–
Mode of delivery	+	+	+
Feedback messages	+	+	+
Control features	+	+	+
Interaction with the research team	+/–	+	–
Social support (enroll with partner)	+	+/–	+
Physical context			
Smartphone ownership	+	+	+
Ease of obtaining a new cell phone	+	+	–
Cell phone providers in the area	+	+	+
Stable cell phone service	+	+	+
Stable housing	+	+	+
Transportation access	+	+/–	+
Food security	+/–	+	–
Utility services	+	+	+
Social context			
Believe others want them to self-monitor their BP[e]	+	+	+
Know others who self-monitor their BP	+	–	–
Others know about their participation in Reach Out	+	+	+
Psychological context			
Importance of overall health	+	+	+
Importance of monitoring BP	+	+/–	+
Experience self-monitoring BP	+	+	+
Absence of perceived barriers to participation	+	+	–

[a]SMBP: self-measured blood pressure.

[b]+: majority satisfaction/agreement/have resource.

[c]+/–: split satisfaction/agreement/resources attainment.

[d]–: majority dissatisfied/disagree/absence of resource.

[e]BP: blood pressure.

Discussion

Principal Results

We conducted a qualitative study to understand engagement with a prompted SMBP+feedback mHealth intervention among people with hypertension who were recruited from a safety-net ED. Overall, participants perceived their overall health and SMBP as important, were satisfied with the SMBP+feedback design of the DBCI, and did not have barriers to SMS text messaging access. Our results suggest that addressing factors including the capacity for personalization, enhanced SMBP monitoring enrollment procedures, and additional social and health-related social needs support may increase SMBP engagement.

Challenges in digital health literacy and mHealth are particularly prevalent among demographic groups adversely impacted by disparities in cardiovascular care [24]. These inequities can be further exacerbated by digital redlining, which presents unique challenges ranging from the affordability of individual technologies to the absence of basic infrastructure in marginalized communities, particularly notable with mobile applications [25]. A strength of Reach Out is that it was SMS text messaging–based and did not require a smartphone.

Despite employing a community-based participatory research approach for the design of SMBP instructions and SMBP prompts and feedback [26], some low engagers and early enders did not understand the purpose, frequency, or how to use the BP cuff. High engagers, in comparison to low engagers and early enders, expressed the greatest understanding of how SMBP was intended to help lower their BP. High engagers also represented the group with the highest level of completed formal education and had participated in SMBP monitoring previously. Thus, the enrollment strategies we used to introduce SMBP may be best suited for individuals with high levels of formal education or those who engaged in SMBP in the past. These conclusions further support the need to examine elements of enrollment to make them more suitable for individuals of all education levels and SMBP experience. Further, optional longitudinal technical support may be needed to increase engagement.

Participants' unmet health-related social needs emerged as a theme associated with SMBP engagement. Early enders experienced more health-related social needs, including food insecurity and financial resources, as demonstrated by the ease of obtaining a new cell phone, than their counterparts. Unmet social needs may serve as additional barriers to SMBP monitoring by creating stress, introducing competing priorities, and reducing leisure time [27]. However, 1 (8%) of the participants had many unmet health-related social needs but was highly engaged in SMBP. Thus, unmet health-related social needs do not preclude engagement with SMBP. Our findings from the early enders suggest that additional resources to address unmet health-related social needs, such as information on community resources or community health worker support [28-31], may be needed for some participants.

Social norms may be another factor that influences participation. High engagers differed from low engagers and early enders in that most high engagers knew someone who engages in SMBP monitoring. Knowing others who engage in self-monitoring may aid in creating social norms that encourage participants to check their own BP. Future strategies to encourage SMBP could include support within participants' social networks or support from others engaging in SMBP.

Limitations

Our study has several limitations. First, women were overrepresented across all engagement levels. Men experience unique social norms that have reverberating impacts on other facets of life. The information gained from these interviews may not fully capture the barriers and facilitators that impact men's engagement in SMBP. The study had a small sample, which limits some of the generalizability. With this small sample size of interviewed participants, this is a hypothesis-generating study. Further studies are needed to confirm the findings with a larger number of participants across each of the engagement groups. Consequently, we did not explore certain topics such as differences in engagement by smartphone type or digital literacy. However, within this small sample, different themes were identified between engagement groups. Finally, there is very little literature defining engagement categorization; thus, thresholds in determining engagement categorization were based on the best available literature [18] but ultimately not determined with statistical methods.

Conclusions

Participants found this SMS text messaging–prompted SMBP+feedback mHealth intervention to be satisfactory. The tailored BP feedback was particularly appreciated. Participants who were high engagers knew others who engaged in SMBP, and overall, participants were open to engaging in SMBP with a partner. In fact, many had done so independently of Reach Out. The importance of hypertension literacy and the skills to measure BP are critical to ensuring engagement with SMBP. Finally, overall unmet health-related social needs increased as SMBP engagement decreased. Thus, prompted SMBP+feedback with the capacity for personalization, enhanced enrollment procedures, and additional social and health-related social needs support may further facilitate participant engagement in SMBP.

Acknowledgments

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Data Availability

The data sets generated and/or analyzed during this study are available from the corresponding author upon request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Participant interview guide.
[DOCX File , 14 KB - cardio_v7i1e38900_app1.docx]

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Abbreviations

BP: blood pressure
DBCI: digital behavior change intervention
ED: emergency department
HIPAA: Health Insurance Portability and Accountability Act
mHealth: mobile health
SMBP: self-measured blood pressure
SMBP+feedback: self-measured blood pressure with personalized feedback

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Original Paper

Initial Implementation of the My Heart, My Life Program by the National Heart Foundation of Australia: Pilot Mixed Methods Evaluation Study

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Abstract

Background: Coronary heart disease (CHD) remains the leading cause of death in Australia, with a high residual risk of repeat events in survivors. Secondary prevention therapy is crucial for reducing the risk of both death and other major adverse cardiac events. The National Heart Foundation of Australia has developed a consumer-facing support program called My Heart, My Life (MHML) to address the gap in the secondary prevention of CHD in Australia. The MHML pilot program supplies advice and support for both patients and their caregivers, and it was conducted over 8 months from November 2019 to June 2020.

Objective: This study aims to describe and examine the implementation of a novel multimodality secondary CHD prevention pilot program called MHML, which was delivered through booklets, text messages, emails, and telephone calls.

Methods: This pilot study consists of a mixed methods evaluation involving surveys of participants (patients and caregivers) and health professionals, in-depth interviews, and digital communication (SMS text message, electronic direct mail, and call record analytics). This study was performed in people older than 18 years with acute coronary syndrome or angina and their caregivers in 38 Australian hospitals from November 2019 to June 2020 through the National Heart Foundation of Australia web page. The main outcome measures were reach, accessibility, feasibility, barriers, and enablers to implementation of this program.

Results: Of the 1004 participants (838 patients and 164 caregivers; 2 missing), 60.9% (608/1001) were males, 50.7% (491/967) were aged between 45 and 64 years, 27.4% (276/1004) were from disadvantaged areas, 2.5% (24/946) were from Aboriginal or Torres Strait Islander background, and 16.9% (170/1004) reported English as their second language. The participants (patients and their caregivers) and health professionals reported high satisfaction with the MHML program (55/62, 88.7% and 33/38, 87%, respectively). Of the 62 participants who took the survey, 88% (55/62) used the text messaging service and reported a very high level of satisfaction. Approximately 94% (58/62) and 89% (55/62) of the participants were satisfied with the quick guide booklets 1 and 2, respectively; 79% (49/62) were satisfied with the monthly email journey and 71% (44/62) were satisfied with the helpline calls. Most participants reported that the MHML program improved preventive behaviors, that is, 73% (45/62) of them reported that they maintained increased physical activity and 84% (52/62) reported that they maintained a healthy diet even after the MHML program.

Conclusions: The findings of our pilot study suggest that a multimodal support program, including digital, print, phone, and web-based media, for the secondary prevention of CHD is useful and could be a potential means of providing customized at-scale secondary prevention support for survivors of acute coronary syndrome.

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KEYWORDS

cardiology; prevention; digital health; heart; text message; text messaging; SMS; health communication; demographic; preventative; cardio

Introduction

Coronary heart disease (CHD) causes the greatest burden of disease and remains the leading cause of death in Australia [1]. The risk of a repeat major adverse cardiac event (MACE) in survivors of acute coronary syndrome (ACS), which includes a repeat myocardial infarction or stroke, is more than 20% in a 2-year period [2]. Secondary prevention therapies in the form of medications and cardiac rehabilitation are crucial for reducing the risk of both death and MACE [3]. Unfortunately, research from Australia demonstrates a decline in the use of secondary prevention medication therapy from as soon as 6 months after discharge [3]. Many patients are discharged without advice on secondary prevention and do not adhere to medications; moreover, only 1 in 3 eligible patients attend cardiac rehabilitation [4]. Developing innovative methods to improve this situation is urgently required to reduce the burden of this disease.

The benefits of secondary prevention programs for CHD, which include counselling, education, and exercise components, have been proven to reduce the risk of repeat MACE [5]. Aligned with this, the National Heart Foundation of Australia (NHFA) has developed a consumer-facing support program called as My Heart, My Life (MHML) to address the gap in the secondary prevention of CHD in Australia. The MHML pilot program supplies advice and support for both patients and their caregivers and was conducted over 8 months from November 2019 to June 2020.

The MHML program was initiated to complement existing support programs such as cardiac rehabilitation and was designed to improve patients' access to health information and support Australians during and after their cardiac events to facilitate safer transitions of care and enhanced access to secondary prevention support [3]. This program is expected to contribute to improvements in multiple outcomes over time. These include increasing the confidence and knowledge of self-management of CHD by patients, improving health behavior and quality of life of people with CHD, and raising awareness of the NHFA resources. This paper outlines the implementation of the pilot program and the barriers and enablers, with the aim to assess feasibility and guide improvements to successfully expand the program.

The specific objectives of this study were to (1) describe the uptake of the MHML program, including reach and accessibility, (2) describe the characteristics of participants accessing the MHML program, (3) examine and report the implementation of the MHML pilot program with regard to feasibility, (4) provide insight into the acceptability of the patient support journey, and (5) provide information on the barriers and enablers to wide-scale implementation of this program.

Methods

Ethics Approval

This study received ethics approval from the University of Sydney Human Research Ethics Committee (approval 2021/771) for the project title "My Heart, My Life Support Program Pilot Evaluation."

Study Design

This study had a mixed methods design involving quantitative and qualitative data collection. The term participants refers to patients and their caregivers in this paper.

MHML Program

The MHML is a multimodal program, merging existing and new resources, delivered at no cost to participants, as outlined in Table 1 and Multimedia Appendix 1. The goal of the MHML program is to support and provide information at critical points in the patient journey with different modalities to allow individualization of exposure to key messages. The NHFA also aims to overcome barriers to secondary prevention, including geography, cardiac rehabilitation access, digital technology, and health literacy. Onboarding was initially intended to be facilitated by hospital staff caring for patients with ACS; however; for a short period, self-enrollment was allowed via the NHFA website.

Print resources were provided through 2 booklets. Part 1: "Your Quick Guide to Heart Attack and Angina," which was given in the hospital, was designed to provide individualized information upon discharge. The booklet contained a record-keeping tool for documentation of risk factors, nearest cardiac rehabilitation program, driving restrictions, and individual goals. Part 2 "Living Well With Heart Disease: Heart Attack and Angina" was mailed to the enrolled participants only. This booklet contained detailed information on long-term risk factor management, nutrition, physical activity, psychosocial well-being, and returning to pre-event quality of life.

The digital resources consisted of 2 components. The first component was a mobile phone text messaging program based on the Heart Foundation grant-in-aid–supported TEXT ME (tobacco exercise and diet messages) [6] and delivered via the TextCare platform [7]. This text messaging program comprised 4 heart health text messages per week for 6 months with message content customized to a participant's risk factors. Messages included prompts and tips to encourage heart-healthy behaviors and habits and web links to further information (eg, diet, exercise, blood pressure/cholesterol, other risk factors including smoking as relevant). The second component was an email journey comprising 8 customized emails sent over 6 months, which included links to key heart health information, advice, narratives, recipes, and support services.

Table 1. Summary of the resources used for My Heart, My Life program.

Resource	Description
First patient educational booklet: part 1	A 50-page booklet called "Your Quick Guide to Heart Attack and Angina" was provided to patients by the health professionals in hospitals or health services, which covered individual details, including hospital team, information on coronary heart disease, risk factors, cardiac rehabilitation, medications, warning signs of angina and myocardial infarction, follow-up plans, and a heart dictionary. Examples of excerpts from the guide are given in Multimedia Appendix 1.
Second patient booklet: part 2	A 48-page booklet called "Living Well With Heart Disease: Heart Attack and Angina" was delivered by mail to the patient's home. This booklet provides help with managing clinical and lifestyle risk factors, emotional and social well-being, and resuming everyday activities after a cardiac event or diagnosis.
A health information–based text message service	Participants received 4 heart health text messages per week for 6 months in their mobile phones. The SMS text message content prompted heart-healthy behaviors and habits and included links to other important health information. It was based on the TEXT ME (tobacco exercise and diet messages) [6] program and delivered via the TextCare platform (University of Sydney). The intervention provided semipersonalized text messages with advice, motivation, and information related to healthy eating patterns, increased physical activity, and if applicable, encouraging smoking cessation. Examples of SMS text messages sent to participants are given in Multimedia Appendix 1.
Helpline outbound support calls	Two helpline outbound calls were provided by trained health professionals, with the first call being within 2-4 weeks of enrollment. The calls explored the patient/caregiver health admission, provided support and reassurance, delivered information, including modifying risk factors, discussed questions relating to posthospital care, and assisted with navigating the health system. The second phone call offered at 3 months was to check on recovery and answer any outstanding information needs.
Email support	An email journey commenced soon after patients or caregivers enrolled in the program, which included 8 bespoke emails delivered over a 6-month period. Three emails were delivered in the first month, and then monthly emails were delivered. The emails provided links to key heart health information and advice, narratives, recipes, and support services.

The enrolled participants also received 2 calls by trained health professionals from the NHFA helpline. The calls provided individualized support and reassurance based on the NHFA's "six steps to cardiac recovery" resource. The first call, within 2-4 weeks of enrollment, discussed the hospital admission, rehabilitation options, information on risk factors, and navigating the health system. The second phone call at 3 months was to address outstanding information needs. If the first call was unanswered, an SMS text message was sent to allow the participant to return the call at their convenience. The COVID-19 pandemic decreased face-to-face interactions in the hospital and reallocation of resources at NHFA. This reduced the opportunity for promotion and engagement with hospitals and therefore patient and caregiver recruitment and initial delay by 2 weeks in meeting helpline call-timing goals.

Setting and Participants

In this pilot program, 38 Australian hospitals (Multimedia Appendix 2) from diverse locations participated. The NHFA supported the hospitals by delivering local education sessions regarding information for the program and provided health professional conversation guides to prioritize key messages after a CHD admission. The inclusion criteria for the program included adults and their caregivers older than 18 years presenting to the hospital with a non–ST-segment elevation myocardial infarction, ST-segment elevation myocardial infarction, or angina within the last 12 months. Caregivers were family or friends involved in the cardiac journey of the participants and could also be enrolled. Health professional staff in hospital recruited these participants during their admission by making them aware of the MHML program, and once aware, participants and their caregivers could choose to (1) send a text message to a designated mobile number, which automatically provided a link to a web-based enrollment form; (2) phone the helpline to verbally complete the enrollment form; and (3) access the web-based form directly with a link. Other participants were alerted to the pilot program via a pop-up prompt on targeted pages of the NHFA website and were provided with the web-based form link for 3 months of the recruitment phase.

Data Collection

Data were collected by the NHFA insights team, which was separate from the MHML implementation team. Participant data were collected at baseline, at 3 months, and toward the end of the pilot study across an 8-month evaluation period. Not all participants completed the 3-month survey, as the evaluation occurred 8 months into onboarding. Surveys comprised questions on acceptability, usefulness, knowledge, behavior change, and usage of intervention components (Table S1 of Multimedia Appendix 3). The interviews explored if the program enhanced participant knowledge and provided support to positively influence their recovery and ongoing management and collected data on barriers and enablers to implementation. Health professionals, including cardiac nurses and doctors, were interviewed at 4-6 months to assess the accessibility, improvements, degree of integration into practice, and feedback on program content (Table S2 of Multimedia Appendix 3).

Data Analysis

Quantitative data analysis used descriptive statistics. Chi-square goodness-of-fit tests were used to compare the MHML sample with the general population to assess representativeness for various demographic variables (significance set at $P<.05$). Analytics reports from the TextCare text messaging platform, email journey, and helpline were analyzed, and the feedback log was analyzed according to themes. Thematic analysis was

performed to survey open-ended questions and interviews. A results matrix was used to triangulate the different data sources and methods by each of the key evaluation questions. This matrix was used to assess where there were similarities or any differences by data source and by method and enabled the development of overarching key findings.

Results

Participant Demographics

A total of 1004 participants (2 missing data), consisting of patients (838/1002, 83.6%) and caregivers (164/1002, 16.3%), were enrolled in this pilot study (Figure 1). Most participants were males (608/1001, 60.9%) and were aged 45-64 years (491/967, 50.7%). Most of them (763/1004, 76%) had recent (in the last 12 months) ACS (Table 2).

Of the total patient population, 69.8% (584/836) were males (2 preferred not to answer), while 85.9% (140/164, 1 missing) of the caregivers who enrolled were females. The proportion of the male patients in this program is representative of the male hospitalization data, which is higher for CHD, and suggested that the program was well accessed by both men and women. Overall, 27.6% (276/1004) of the patients lived in disadvantaged areas, 2.5% (24/946) were Aboriginal or Torres Strait Islander people, and 16.9% (170/1004) reported English as their second language. The ratio of men to women in this study was similar to that of the national heart disease hospitalized population [1,8]. The MHML sample population appeared younger (P<0.001) (Figure 2) and less disadvantaged (P<0.001) than the overall population with CHD in Australia (Figure 3).

Figure 1. Evaluation of the participants and data sources. Response rate was calculated based on those who had been involved in the pilot program for 3 months or more at the end of the pilot period.

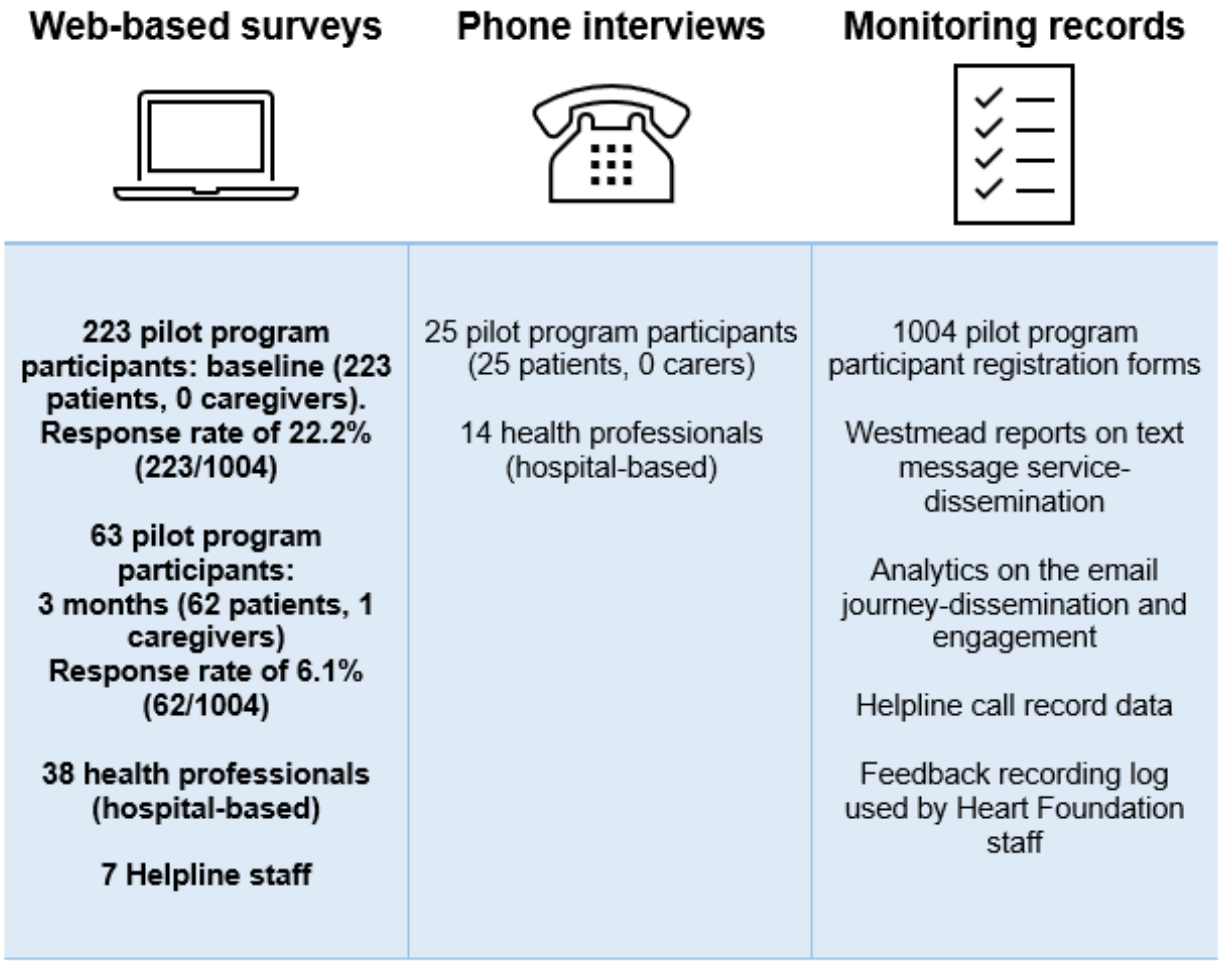


Table 2. Demographics of the pilot study population (N=1004).

	Values, n (%)
Males (n=1001)	608 (60.7)
Age group (years) (n=967)	
<45	139 (14.4)
45-64	491 (50.7)
65+	337 (34.9)
Aboriginal or Torres Strait Islander (n=946)	24 (2.5)
English as a second language[a] (N=1004)	170 (16.9)
Myocardial infarction (n=1001)	765 (76.4)
Angina (n=1001)	236 (23.5)
Patients (n=1002)	838 (83.6)
Caregivers (n=1002)	164 (16.3)

[a]The most frequently reported languages other than English were Hindi, Mandarin, Italian, Greek, and Arabic.

Figure 2. Age and sex distribution of pilot program participants relative to the national hospitalization rates for coronary heart disease. AIHW: Australian Institute of Health and Welfare; CHD: coronary heart disease.

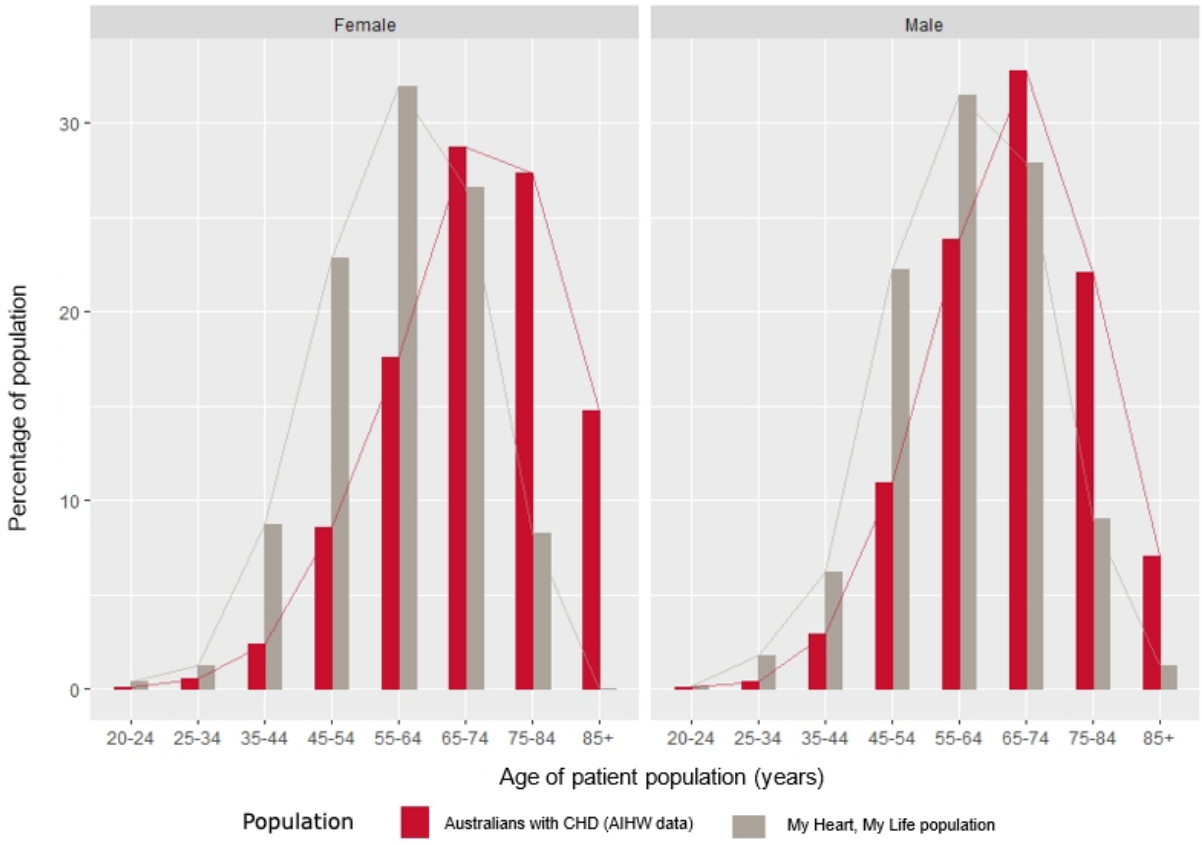
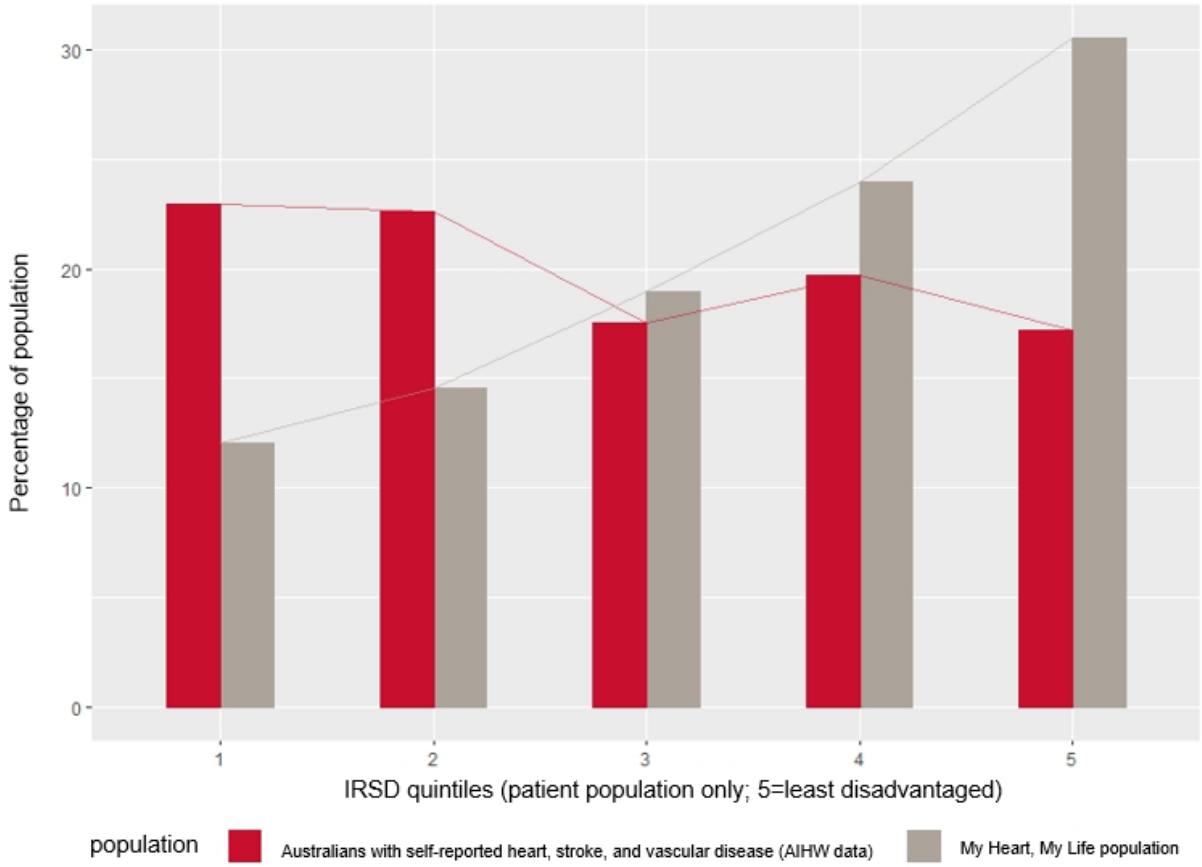


Figure 3. Distribution of the pilot program participants based on the Index of Relative Socioeconomic Disadvantage Quintiles relative to the national population of people with cardiovascular disease [8]. AIHW: Australian Institute of Health and Welfare; IRSD: Index of Relative Socioeconomic Disadvantage.



Participant Enrollment

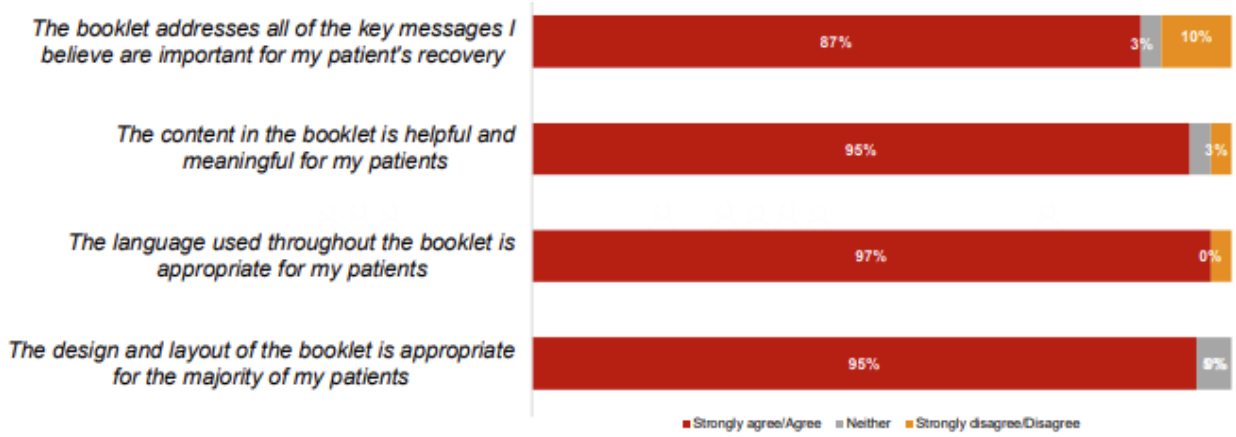
Overall, 17,820 part 1 booklets were distributed to hospitals to be provided to patients and caregivers, and participants had to complete a web-based enrollment form to receive subsequent components of the program. The conversion rate from booklets provided to actual enrollments was low, as only 1187 part 2 booklets were distributed to the enrolled participants. Most enrollments occurred following a hospital admission (733/1004, 73%), and 26.9% (275/1004) self-registered via the NHFA website.

Participants who had successfully completed the web-based registration form reported that web-based registration was simple. Health professionals and helpline staff reported barriers to onboarding, including confidence with technology, web-based form length, unclear information of the registration process, and absence of an email address (particularly for Aboriginal or Torres Strait Islander peoples). Health care staff, participants, and helpline staff reported that enablers may include (1) simplification and shortening of the web-based form, (2) providing feedback or monthly report to health professionals about enrolled patients to help maintain the program's profile, (3) bedside enrollment by health professionals, and (4) raising awareness among health professionals, patients, and caregivers. The majority (34/38, 90%) of the health professionals reported that it was realistic to promote this program. The encouragement by health professionals was important to participants and was a key driver for the enrollment noted during participant interviews.

Booklets

Overall, 94% (58/62) of the participants reported a high level of satisfaction with part 1 booklets and 89% (55/62) of them were satisfied with part 2 booklets. Most health professionals (35/38, 92%) reported that the part 1 booklet assisted with patient education and agreed that it addressed key messages, provided meaningful and helpful content, had appropriate language, and was well-designed (Figure 4). The hard copy version allowed professionals to fill information during the hospital journey at a time when patients absorb less information (Multimedia Appendix 1). Participants valued the hard copy format, diagrams, record-keeping tools, risk factor information, simple language, volume, and appropriate coverage of topics. One participant reported that "they're informative about what to expect and if anything's about to happen it gives you a little run-down on symptoms…I had no idea of any of that before." The booklet helped the helpline staff who emphasized key information, for example, warning signs. Factors to be strengthened include the title, which was deemed less engaging than other NHFA resources, and minor changes to information about medications, triglycerides/cholesterol levels, alcohol consumption and driving, and stents.

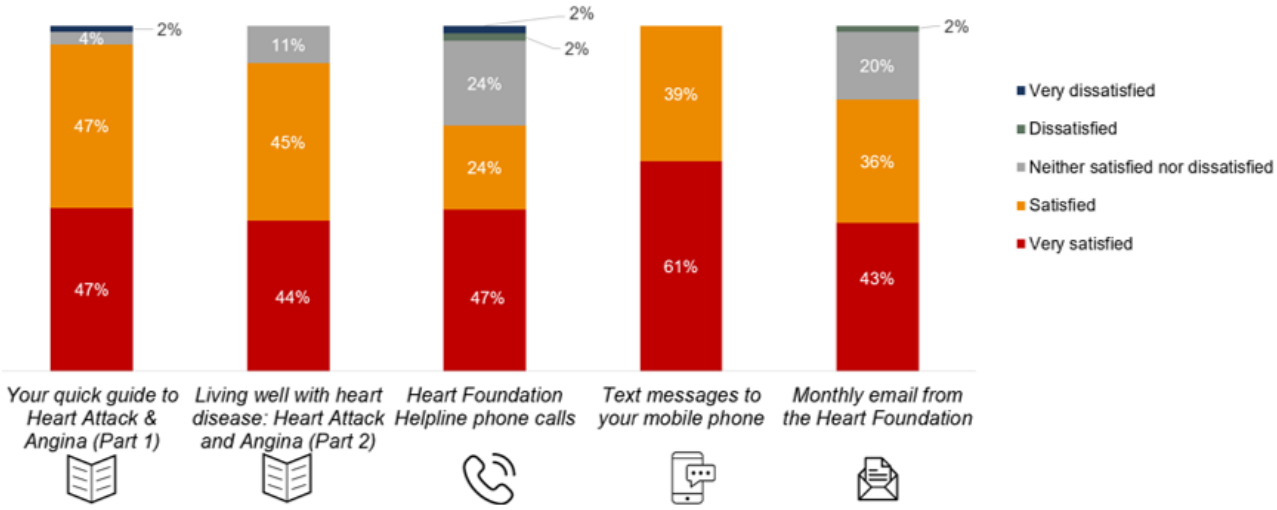
Figure 4. Responses to the question, "Below is a list of statements about the in-hospital booklet quick guide to heart attack and angina. Please indicate how strongly you agree or disagree with each statement." (n=38 health professionals).



Text Messaging

Approximately 73% (733/1004) of the participants commenced the text messaging service, with 9% (90/1004) opting out. Reasons for opting out included feeling that messages were repetitive and were common sense. The majority (667/733, 90.9%) continued receiving messages until the end of the pilot period. Of those who responded to the survey, 88% (55/62) used the text messaging service and reported a very high level of satisfaction (Figure 5). The strengths of the text messaging service included emphasis on self-management through reminders, "And I keep getting tips about eating fruit and walking upstairs instead of taking elevators," and "The little pointers are sort of helpful reminders that you need to keep exercising." Minor suggestions included reducing repetitiveness across messages and providing links to further information, given that the texts were often succinct.

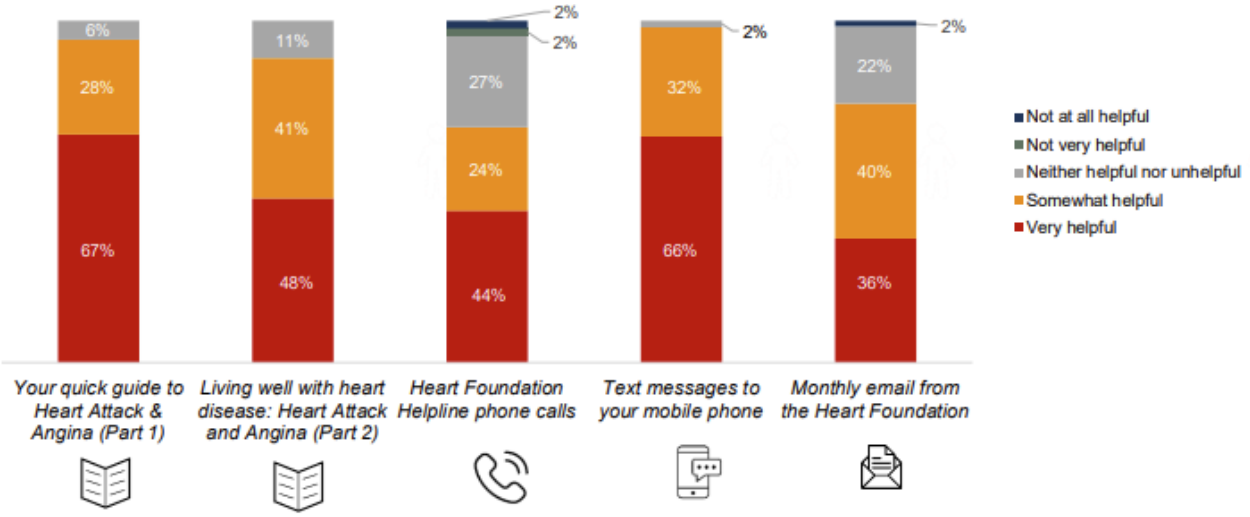
Figure 5. Response to the question, "How satisfied are you with the following elements of the Australian National Heart Foundation's My Heart, My Life program?" (by participants at 3 months) (n=62).



Helpline

Outbound calls were provided to 978 participants, with 1691 calls made. Half of the participants who partook in the 3-month survey reported using this service, with 68% (42/62) reporting that it was helpful (Figure 6). The average call duration was 26 minutes (based on 1325 calls), with the first phone call taking 20 minutes or more. The helpline was unique in that it was individually tailored to participant circumstances, and participants liked that the helpline staff initiated the phone call. Suggestions for improvement included tailoring the frequency and duration of calls according to individual needs and removing the time limit.

Figure 6. Response to the question, "In your opinion, how helpful have you found the following elements of the Australian National Heart Foundation's My Heart, My Life program?" (by participants at 3 months) (n=62).



Emails

The data of email opening rates and clicking on content showed that there was good engagement of 964 participants with the email journey. Most continued on the journey, with only 11 participants opting out. Engagement rates in the first 2 emails were higher than those in subsequent emails. The MHML open rate (802/1129, 70.9%) and click-to-open rate (644/1129, 57.3%) (Figures S2 and S3 in Multimedia Appendix 4) were comparable to health care industry standards (24.3% and 11.2%, respectively) [9]. Participant interviews revealed that emails were helpful, as they provided useful information and helpful reminders, including the benefits of healthy eating patterns and recipes.

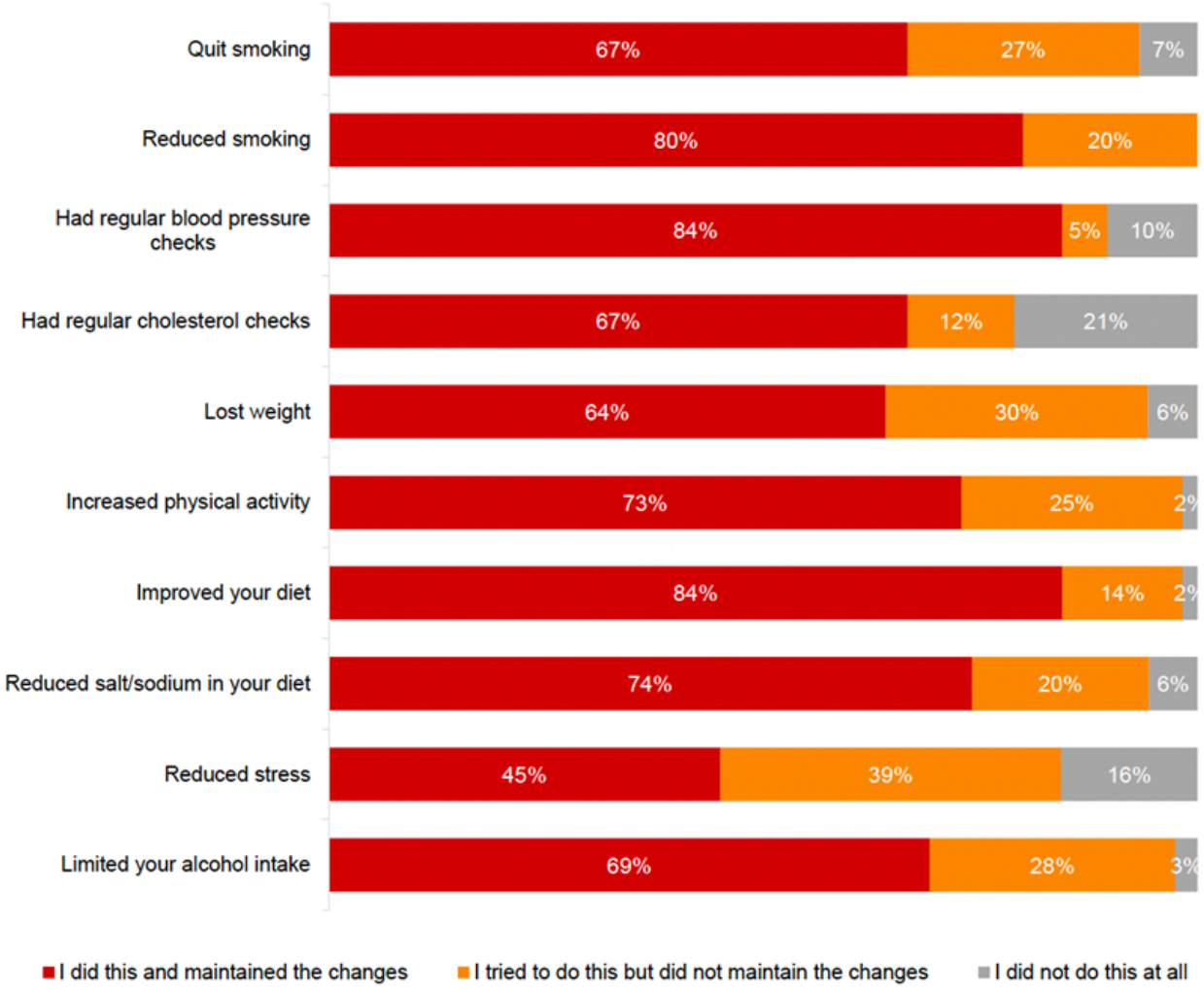
Program Acceptability

At the 3-month survey, both participants and health professionals reported high levels of satisfaction with MHML (55/62, 88.7% and 33/38, 87%, respectively). All of them (62/62) reported being satisfied with the text message journey: 94% (58/62) and 89% (55/62) were satisfied with booklets 1 and 2, respectively; 79% (49/62) were satisfied with the monthly email journey; and 71% (44/62) were satisfied with the helpline calls. (Figure 4). All interviewed participants reported that they would definitely recommend the MHML program to others, as it provided a support for their recovery journey with information and resources complimenting cardiac rehabilitation, medical consultations, and health coaching. Suggestions from participants included adding webinars or forums delivered by health professionals, a peer support program for motivation and accountability, as well as a smartphone app with focus on healthy eating. Text messages and booklets were rated as the most helpful, followed by emails and calls (Figure 5). Health professionals supported continuation and expansion of the program. Improvements suggested by health professionals included expanding resources, especially for Aboriginal or Torres Strait Islander patients and cultural and linguistically diverse patients, including more hospitals, expanding to other cardiac conditions, and ensuring adequate staffing for rollout.

Progress Toward Short-Term Outcomes

The self-assessed knowledge and confidence of the participants to manage their heart conditions were gauged at baseline, at the 3-month survey, and during interviews. Many participants reported trying to implement lifestyle behavior changes after joining the MHML, and a large proportion reported maintaining these changes after the program, for example, 73% (45/62) maintained increased physical activity and 84% (52/62) maintained a healthy diet (Figure 7).

Figure 7. Participant lifestyle changes after the My Heart, My Life intervention program.



Discussion

CHD Secondary Prevention Programs

MHML is a unique health care program delivered by the NHFA. Other organizations, including the British Heart Foundation and American Heart Association, promote telephone hotlines, web-based forums, and patient information pamphlets; however, a national, individualized, and multimodal program for CHD secondary prevention is yet to be implemented [10,11]. Economic modelling has shown that increasing referrals by 65% to secondary prevention support services such as cardiac rehabilitation could result in a saving of US $86.7 million over 10 years in health care costs [12]. Secondary prevention programs for cardiovascular diseases delivered by text messages have demonstrated to be potentially cost-effective [6,13]. The MHML program provides an additional comprehensive tailored support option without charge to those with CHD and their caregivers.

Principal Findings

The pilot MHML program was well-received by participants and health professionals, the majority of whom reported that the program was easy to use (55/62, 88.7% of the participants and 33/38, 87% of the health professionals). Of note, much of the implementation of this pilot program was during the COVID-19 pandemic, thereby demonstrating the utility of alternative methods of support to patients with CHD at an otherwise vulnerable time point. The at-scale delivery of secondary prevention programs is challenging, and despite the knowledge that these programs are effective, little improvement has been made across the years in achieving comprehensive engagement of survivors of ACS in secondary prevention programs. The strengths of this program include the multimodal delivery of cardiac information by a centralized and respected organization, thereby supplementing existing care while encouraging self-management in secondary prevention.

Self-management strategies often lead to sustained behavioral change, and supporting patients on this journey to empower them is crucial [14]. Multiple behavior change techniques are more effective than a single technique with differences in individual preference and response [14]. By receiving a comprehensive and individualized program with physical booklets, program-initiated telephone support calls, text messages, and an email journey, participants in the MHML program were able to utilize multiple forms of communication to aid behavior changes. The uptake of this program was equivalently distributed across genders relative to the burden of CHD in these populations, wherein secondary prevention is

underprescribed and underutilized in women, who have poorer cardiovascular outcomes [15]. This program appeared more accessible to a younger age group, and although many of lower socioeconomic status and some people of Aboriginal or Torres Strait Islander background accessed this program, it is important to optimize access for these population groups who historically have had poorer access to secondary prevention programs.

With regard to the feasibility of this program, there was overall satisfaction and acceptability in the feedback from health care professionals. The benefits of the MHML program were clearly expressed with the primary concern of implementation related to staffing of the service.

Comparison to Other Studies

The participants found most aspects of the MHML program acceptable and helpful. Of note, they particularly valued the text messaging program, which has previously shown to alter cardiovascular outcomes in randomized controlled studies [6]. Given the relative ease of implementation at a pilot level, the NHFA MHML program should continue to expand to intensify the benefits of these complementary secondary prevention methods. Additional barriers such as COVID-19 were identified, and these barriers will continue to require innovative strategies to overcome the challenges. Alternative ways to reach patients and caregivers will need to be explored to allow widespread implementation of this program.

Future Directions

Given the high levels of satisfaction regarding this pilot program, future directions should include a broader rollout of the MHML program. In particular, additional tools should be provided to support patient recovery (eg, webinars, smartphone apps), specific resources should be provided for patients of Aboriginal and Torres Strait Islander descent in addition to those from culturally and linguistically diverse backgrounds, and the program should be expanded to other hospital locations and include other types of cardiac conditions such as heart failure.

Limitations

We acknowledge that the participants of the evaluation may have been more engaged with the program than those who had not engaged with the program. The invitation to participate in the surveys was distributed by email; therefore, participants who had responded may have been more skilled with technology than those who had not responded.

Conclusions

The NHFA MHML pilot program was widely accepted by participants and health professionals. The NHFA is dedicated to improving recovery after a cardiac event and aims to improve and expand MHML by using evaluation findings. Future evaluations will consider more quantitative and clinical outcomes such as medication adherence and risk factor management to have an impact on the rates of unplanned rehospitalizations and the quality of life of participants.

Acknowledgments

We acknowledge that since the time of writing this paper, the My Heart, My Life program piloted by the National Heart Foundation of Australia has undergone comprehensive review and redesign. We are excited to soon share the revised patient support program that has been informed by this pilot and over 18 months of needs assessment work. We would also like to thank the participants of this research who shared their time and provided invaluable insights throughout this project. Together, we are working toward an Australia free of heart disease.

Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Examples of the different components of the My Heart, My Life program.
[DOCX File , 1621 KB - cardio_v7i1e43889_app1.docx]

Multimedia Appendix 2
List of hospitals participating in the My Heart, My Life pilot program.
[DOCX File , 16 KB - cardio_v7i1e43889_app2.docx]

Multimedia Appendix 3
Summary of data of participants of the My Heart, My Life program collected by the Australian National Heart Foundation.
[DOCX File , 1388 KB - cardio_v7i1e43889_app3.docx]

Multimedia Appendix 4
My Heart, My Life program open rate and click-to-open rate data.
[DOCX File , 278 KB - cardio_v7i1e43889_app4.docx]

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Abbreviations

ACS: acute coronary syndrome
CHD: coronary heart disease
MACE: major adverse cardiac event
MHML: My Heart, My Life
NHFA: National Heart Foundation of Australia
TEXT ME: tobacco exercise and diet messages

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Original Paper

Patient-Facing Clinical Decision Support for High Blood Pressure Control: Patient Survey

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Abstract

Background: High blood pressure (HBP) affects nearly half of adults in the United States and is a major factor in heart attacks, strokes, kidney disease, and other morbidities. To reduce risk, guidelines for HBP contain more than 70 recommendations, including many related to patient behaviors, such as home monitoring and lifestyle changes. Thus, the patient's role in controlling HBP is crucial. Patient-facing clinical decision support (CDS) tools may help patients adhere to evidence-based care, but customization is required.

Objective: Our objective was to understand how to adapt CDS to best engage patients in controlling HBP.

Methods: We conducted a mixed methods study with two phases: (1) survey-guided interviews with a limited cohort and (2) a nationwide web-based survey. Participation in each phase was limited to adults aged between 18 and 85 years who had been diagnosed with hypertension. The survey included general questions that assessed goal setting, treatment priorities, medication load, comorbid conditions, satisfaction with blood pressure (BP) management, and attitudes toward CDS, and also a series of questions regarding A/B preferences using paired information displays to assess perceived trustworthiness of potential CDS user interface options.

Results: We conducted 17 survey-guided interviews to gather patient needs from CDS, then analyzed results and created a second survey of 519 adults with clinically diagnosed HBP. A large majority of participants reported that BP control was a high priority (83%), had monitored BP at home (82%), and felt comfortable using technology (88%). Survey respondents found displays with more detailed recommendations more trustworthy (56%-77% of them preferred simpler displays), especially when incorporating social trust and priorities from providers and patients like them, but had no differences in action taken.

Conclusions: Respondents to the survey felt that CDS capabilities could help them with HBP control. The more detailed design options for BP display and recommendations messaging were considered the most trustworthy yet did not differentiate perceived actions.

(JMIR Cardio 2023;7:e39490) doi:10.2196/39490

KEYWORDS

high blood pressure; hypertension; clinical decision support; shared decision-making; blood pressure control; decision-making support; patient engagement; patient support tool

Introduction

Overview

High blood pressure (HBP) is a common condition in the United States, affecting roughly 47% of adults [1]. Persistently elevated blood pressure (BP)—hypertension—is a primary predictive factor for heart disease and stroke, which are among the most common causes of death in the United States [2]. Despite its prevalence, hypertension often goes underdiagnosed and undertreated [3]. The evidence base for the benefits of identifying HBP and reducing it through behavioral and lifestyle changes, medications, and careful monitoring is strong [4]; adherence to recommendations remains less than 50% for the population overall, and BP control has worsened through the COVID-19 pandemic, especially for vulnerable populations [5,6].

Significance

As part of a project to develop an effective patient-facing CDS tool for hypertension management, we needed to understand how best to engage and motivate patients to use this tool through behavior science by understanding the knowledge, attitudes, and anticipated responses of potential patients to CDS systems.

Background

There are many challenges to controlling HBP, especially when it is diagnosed as hypertension. First, hypertension is known as the "silent killer" [7] as elevated BPs are asymptomatic, leading to a lack of engagement from patients. Second, measuring BP requires frequent measurements and attention to protocol to assess control; home BP monitoring is frequently recommended yet rarely followed, leading to uncertainty about control and increased risk of adverse events from overtreatment [8]. Third, the therapeutic index in controlling BP can be narrow; a large BP trial, the Systolic Blood Pressure Intervention Trial [9], showed a 25% relative reduction in cardiovascular events in the tightly controlled BP group compared to that in the less intensive group (<120/80 vs 140/90 mm Hg, respectively) but a substantial increase in adverse events such as dizziness, falls, electrolyte disturbances, and acute kidney injury. Lastly, and perhaps most pressing, the role of the patient is crucial in BP control: behavioral and lifestyle changes can reduce BP by more than 15 mm Hg in most patients [10]. Given that most people lack symptoms for HBP, patient engagement and motivation remain a substantial issue.

An understudied area is taking recommendations from CDS and making them patient-centered. Work in patient-centered CDS explores the best way to engage patients beyond self-management support, sharing and translating recommendations and providing them directly to patients [11]. A patient-facing tool with robust CDS—providing the right information at the right time in the right format through the right channel [12]—may afford a way to better help patients both self- and comanage their BP and related conditions [13]. Encouraging patients to set goals (eg, smoking cessation, physical activity, diet and salt or sodium intake, weight, and alcohol intake), recognize when medications may be of help, and recognize adverse events can promote patient agency and engagement in BP management while also helping their care teams to obtain a more complete understanding of the patient's cardiovascular health [14,15].

Goals, treatment preferences, and personal priorities may vary considerably, making recommendations difficult to implement. Assessing patient perceptions of priorities for goal setting is critical for designing CDS tools for engaging patients in treating HBP. Moreover, engaging people to set and follow goals requires behavioral change: behavior science has both cognitive precepts such as self-efficacy and behavioral economics concepts such as choice architecture, structured incentives, prosocial messaging, and social trust that may improve motivation and engagement [16,17]. Choice architecture is the ordering of options or defaults to help people make decisions more easily [18] and structured incentives—such as loss avoidance—help maintain motivation [19]. Social trust may be enhanced through well-sourced information and clinician recommendations [20]. Prosocial messaging encourages people to consider the beneficiaries of their behaviors when changing behaviors [21]. Focusing on others can be strong motivation: a review of older adults and people making changes after heart attack or stroke showed that team-based engagement with challenges and achievements were more effective in encouraging healthy behaviors [22-25]. However, studies of behavior science to guide CDS, especially with patients, are limited and results are mixed despite their promise [26].

The purpose of this study was to examine perspectives and experiences of people diagnosed with hypertension, particularly around health literacy, self-management strategies and other treatments, and general attitudes toward shared decision-making and CDS tools.

Methods

Overview

This work had two phases: (1) survey-guided interviews with a limited cohort and (2) a nationwide web-based survey. Participation in each phase was limited to adults aged between 18 and 85 years who had been diagnosed with hypertension.

Ethics Approval

The Oregon Health & Science University's institutional review board (IRB) approved this study (STUDY00020522).

Phase 1: Guided Synchronous Interviews—Development and Recruitment

We recruited English-speaking participants from internal medicine patients at a primary care clinic. Initial contact was made via email, in which patients were told that the focus of this study was to assess attitudes and preferences for hypertension treatment. Participants were consented to record the interview and to a review of their medical record to identify medications and BP measurements. Interviews were conducted over 30-60 minutes via videoconference with screen sharing. Participants were given the opportunity to ask questions and make additional comments throughout the interview.

The phase 1 interview questions were derived from the 5 rights of CDS, attempting to help identify the right information,

person, format, channel, and time, essentially attempting to understand patient perception of their role in the process [27]. In addition, we used cognitive and behavioral economics theories to drive questions, focusing on where choice architecture and social trust may be helpful in building the tool [22-25]. Topics in the phase 1 interviews included demographic questions and current HBP knowledge. We also sought to understand whether defaults could be set through questions about home monitoring and self-management strategies such as lifestyle changes, drawn directly from the guidelines, and general attitudes toward shared decision-making and CDS tools. Finally, patients were presented with recommendation-based case studies and asked what each patient should do: these were matched with questions asked of providers to understand alignment. The interview also used a modified version of the High Blood Pressure-Health Literacy Scale instrument to assess patient health literacy: this survey has a set of scenarios with structured and open-ended answers [28]. High literacy was defined as >80% correct, the top quartile from validation sample in the scale's development. The interview questions were implemented as a Qualtrics survey and the interviewer filled out the survey during each session (Multimedia Appendix 1).

Phase 2: Web-Based Patient Survey

A 10-minute web-based English language survey was deemed necessary to better identify generalizable trends. We developed the survey based closely on the interview guide, retaining many of the questions, albeit revising for clarity in the absence of an interviewer. The survey included questions that assessed goal setting, treatment priorities, medication load, comorbid conditions, satisfaction with BP management, and attitudes toward CDS (Multimedia Appendix 2).

We also included 3 sets of paired information displays, based on work by Shaffer et al [29] and the results of phase 1. The main goal was to assess whether questions with more information that enhanced social trust (with authoritative references) or provided clearer defaults were more likely to enhance trust and guide actions than those with less information. The displays were shown in randomized order and consisted of low (A) and high (B, ie, A/B testing) information tailoring, where low tailoring provided the recommendations within minimal additional information and high tailoring increased the amount of information overall [30].

The first set of displays compared 2 options for representing the patient's recent BP history. The first option (shown in the results shown in Figure 1) overlayed a current average BP (systolic and diastolic) onto colored bars representing ranges for healthy, borderline, and high; these were intended to simplify the choice to take action through choice architecture. The second option provided a line graph of the recent BP history with colored bands representing the healthy and borderline ranges; the additional data were intended to enhance trust by providing more data.

The second set of displays (see results shown in Figure 2) compared suggested behavioral change goals with and those without added messaging around social norms. For example, a suggested goal of reducing smoking would have a higher amount of social trust enhancement with a message such as "80% of providers and patients identified this as a top priority."

The third set of displays (see results shown in Figure 3) compared messaging around suggesting pharmacologic interventions. The low information tailoring option provided a simple message that one's doctor may prescribe medications to help manage BP. The higher information option cited a survey of general provider preferences for particular drug classes and drug names and also referenced care guidelines supporting the pharmacologic option.

Figure 1. Visualizing the comparison of blood pressure history.

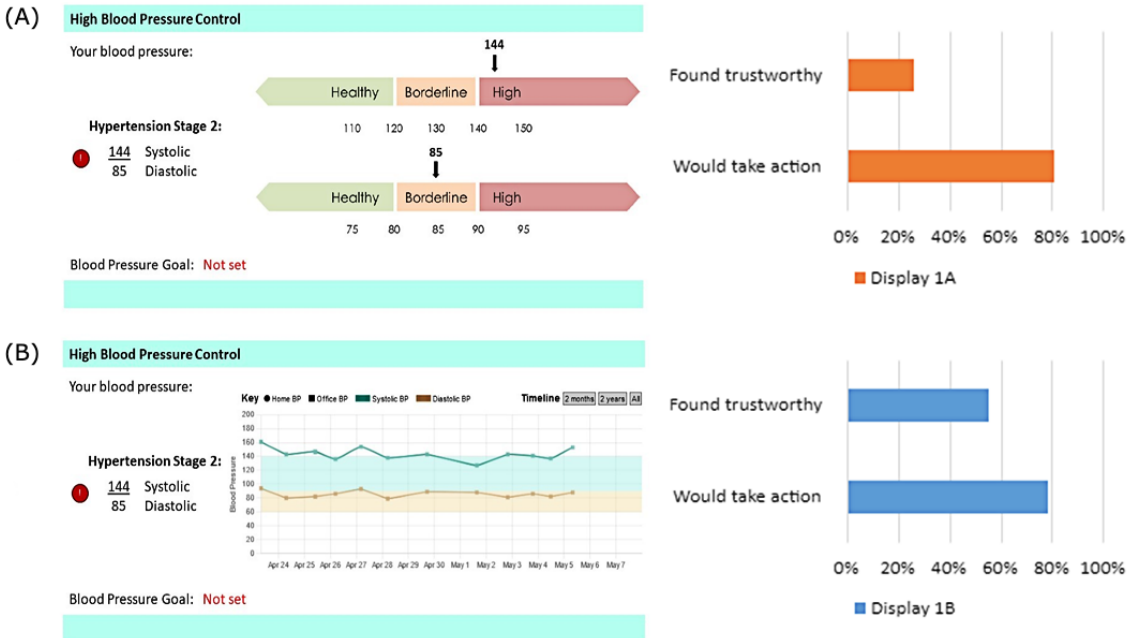
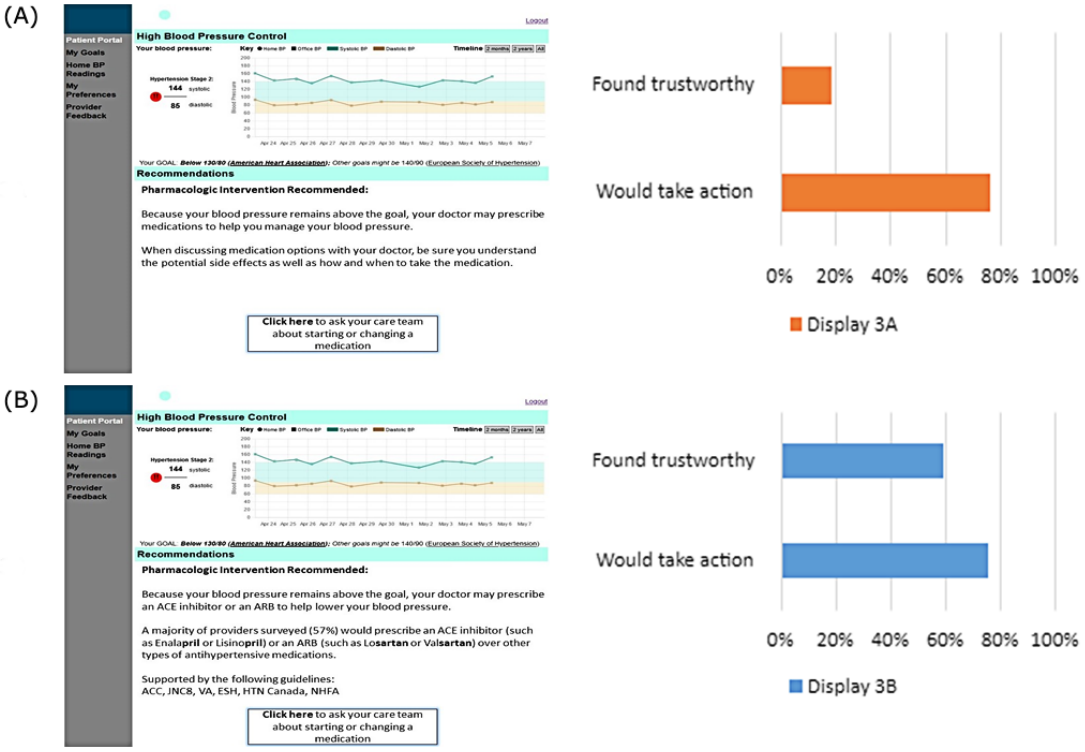


Figure 2. Lifestyle change goals with or without advice from clinicians regarding priorities.

Figure 3. Potential hypertension medications with and without specific medications and supporting guidelines.



Phase 2: Recruitment

With IRB approval, we contracted Qualtrics to gather 500 survey responses from patients aged between 18 and 85 years with a diagnosis of hypertension. IRB-approved recruitment language was provided to Qualtrics, and we incorporated their survey design expertise while finalizing our survey. Participants received credit toward a reward, administered by Qualtrics in accordance with their agreement with survey participants. Recruitment was stratified to include roughly equal proportions of male and female participants, as well as increased distributions from racial and ethnic minorities to collect a more generalizable sample set.

Analysis

From the phase 1 survey–guided interviews, we summarized results using descriptive statistics, focusing on the most frequent and highest-priority responses. We also performed content analysis on the open-ended questions to understand the most common responses; these questions were largely focused on

suggestions for display improvement or feedback about the HBP tool. Analysis was solely focused on extracting the ideas from each comment and summarizing them. For the phase 2 survey, we summarized results by frequency of answer selection. Likert scales were used for the paired visualizations requiring respondents to select one display as more trustworthy than the other, as defined by their own sense of trust, and the likelihood of taking action based on each display (actionability). Each used a 1-7–point range and the responses were summarized by the percentage of responses in the top 3 categories. Since trustworthiness was a dichotomous choice between 2 displays, the percentage selected was compared with a sign test. Categorical responses were compared with a chi-squared test for significant variations in response at the P=.05 level.

Results

Survey-Guided Patient Interviews

In total, 18 patients with hypertension were interviewed, out of 38 patients contacted, with 1 patient excluded from the analysis due to technical challenges preventing the interviewee from viewing the shared screen. Of the 17 remaining participants, summarized in Table 1, all identified as White, with a mean age of 69.2 years. This was a health literate group, with a mean modified HTN-HLS score of 84.9%, and 15 of 17 having scores of >80% (high literacy). All 17 participants reported having measured BP at home either currently or in the past. None were current tobacco smokers, though 7 (41.2%) reported having previously smoked. Only one patient (5.9%) was a heavy drinker. Overall, 35% of patients reported having atherosclerotic cardiovascular disease (ASCVD), although they did not remember having a heart attack or stroke. One (5.9%) participant reported a diagnosis of heart failure, 3 (17.7%) reported diagnoses of diabetes, and 2 (11.8%) reported diagnoses of prediabetes. In total, 16 of 17 (94.1%) participants reported currently taking one or more medication to manage their BP, with 12 (70.6%) participants reporting having experienced at least 1 adverse reaction to antihypertensive medication.

When asked about making lifestyle changes for HBP management, all 17 participants indicated that making changes required significant patient effort, with 16 (94.1%) having indicated that making these changes was important for managing BP. In total, 14 of 17 (82.4%) participants indicated that patient input was important when lifestyle change counseling is provided for BP control. Furthermore, 10 of 17 (58.8%) participants indicated that they often do not implement lifestyle changes for BP control. The majority of interviewees (88.3%) would be “extremely” or “somewhat” comfortable using a smartphone app, patient portal, or computer program that could make recommendations for treatment. The vast majority (88.9%) also felt it “extremely” or “somewhat likely” that the tool would improve patient outcomes.

Table 1. General characteristics of surveyed populations.

Demographic characteristics	Survey-guided interview participants (n=17)	Survey participants (N=519)
Female sex, n (%)	9 (52.9)	260 (50.1)
Age (years), mean (SD)	69.2 (9.1)	41.2 (14.7)
Age groups (years), n (%)		
18-39	0 (0)	272 (52.4)
40-59	4 (23.5)	172 (33.1)
60-69	3 (17.7)	46 (8.9)
70-79	8 (47.1)	26 (5.0)
80+	2 (11.8)	3 (0.6)
Race and ethnicity, n (%)		
White	17 (100)	343 (65.0)
African American	0 (0)	93 (17.6)
Asian	0 (0)	23 (4.4)
Latino or Hispanic	0 (0)	50 (9.5)
Related conditions, n (%)		
Diabetes	3 (17.7)	153 (26.2)
Prediabetes	2 (11.8)	90 (15.4)
Heart failure	1 (5.9)	47 (8.1)
Chronic kidney disease	0 (0)	33 (5.7)
Past myocardial infarction	0 (0)	79 (15.2)
Past stroke	0 (0)	58 (11.2)
Have ASCVD[a]	6 (35.3)	119 (22.9)
Age with ASCVD (years), mean (SD)	75.5 (4.8)	41.1 (14.8)
Age without ASCVD (years), mean (SD)	64.8 (8.7)	41.2 (14.7)
Antihypertensive medications, n (%)		
None	1 (5.9)	101 (19.5)
1	3 (17.6)	190 (36.6)
2	5 (29.5)	128 (24.7)
3	6 (35.3)	61 (11.8)
4	2 (11.8)	31 (6.0)
Blood pressure goals and control, n (%)		
Participants with a blood pressure goal	17 (100)	427 (82.3)
Participants who chose a goal in consultation with a doctor	7 (41.2)	276 (64.6)
Participants who have monitored blood pressure at home	17 (100)	426 (82.1)
Participants who were satisfied with blood pressure control	13 (76.5)	383 (73.8)
Participants for whom blood pressure control was a high priority	16 (94.1)	429 (82.7)
Comfort with decision support systems, n (%)		
Extremely comfortable	8 (47.1)	195 (37.6)
Somewhat comfortable	7 (41.2)	211 (40.7)
Neither comfortable nor uncomfortable	0 (0)	90 (17.3)
Somewhat uncomfortable	2 (11.8)	17 (3.3)
Extremely uncomfortable	0 (0)	6 (1.2)

[a]ASCVD: atherosclerotic cardiovascular disease.

Patient Survey

In all, 541 participants completed the survey. We excluded 22 incomplete responses. The 519 remaining responses are summarized in Table 1. Demographically, 260 (50.1%) participants identified as female, with a much younger mean age of 41.2 years as compared to the interviewees (69.2 years). The majority of participants (n=272, 52.4%) were younger than 40 years, with only 75 (14.5%) participants aged 60 years or older. We compared the groups (Multimedia Appendix 3 and Table 1) and noted a higher burden of disease in the younger adults than is usually reported. A majority (n=343, 65.0%) of participants identified as White.

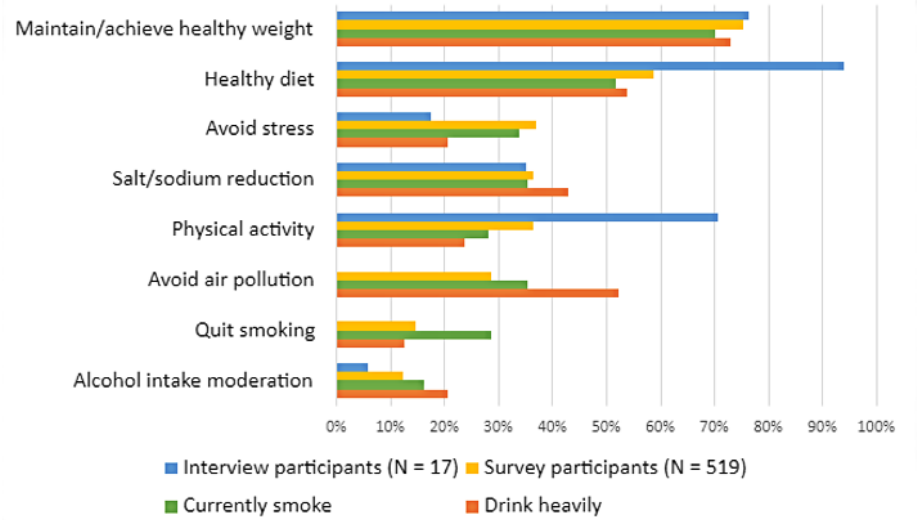
These participants reported generally good HBP control and 73.8% (383/519) of them were satisfied with the control. Most, 82.3% (427/519) of participants, reported having a specific BP goal, with 64.6% (276/519) of those having selected that goal in consultation with a doctor. Overall, 82.1% (426/519) of participants reported having monitored their BP at home either currently or previously. A large majority, 82.7% (n=429) of participants, reported that controlling their BP was a high or very high priority.

Significant comorbidities were reported by these participants, with 26.2% (n=153) of them having reported a diabetes diagnosis, 15.4% (n=90) of them having reported a prediabetes diagnosis, 8.1% (n=47) of them having reported a heart failure diagnosis, and 5.7% (n=33) of them having reported a chronic kidney disease diagnosis. Major adverse cardiovascular events were also reported, with 15.2% (n=79) of them having reported a past heart attack and 11.2% (n=58) of them having reported a past stroke. Based on self-report of one of heart failure diagnosis, past myocardial infarction, or past stroke, we determined that 22.9% (119) of survey participants have ASCVD. A minority of patients, 19.5% (n=101) of them, reported taking no medication to manage their BP, while 36.6% (190) of them took one medication and 24.7% (n=128) of them took 2 medications.

Participants were asked to arrange lifestyle change recommendations for HBP management into their personal order of priority. Participants could only include quitting smoking or moderating alcohol intake in their priority list if they indicated that they currently smoked tobacco or drank alcohol, respectively.

As shown in Figure 4, we examined the top 3 selected priorities for each response. Maintaining or achieving a healthy weight was the most common priority among all participants (391/519, 75.3%) among the top 3 priorities, followed by eating a healthy diet (305/519, 58.7%). Among participants who currently smoke, only 28.7% (76/265) of them identified smoking cessation as one of their top 3 priorities. Among those who can be classified as drinking heavily, alcohol intake moderation was one of the top 3 priorities for 20.6% (13/63) of participants.

Figure 4. Percentage of participants' top 3 selections for lifestyle changes prioritized. Patients were considered to be drinking heavily if they consume >8 drinks per week if female and >15 drinks per week if male. The currently smoke category includes all current smokers, including those trying to quit.



When asked about their comfort with using systems, such as smartphone apps, patient portals, and computer programs that provide recommendations based on a person's BP history, 37.6% (195/519) of participants reported being "extremely comfortable," with 40.7% (211/519) of them having reported that they were "somewhat comfortable."

The first comparison (Figure 1) asked participants to consider whether a BP average display or a BP history chart was more trustworthy. The BP history chart was considered more trustworthy than the thermometer style display by 55.7% (289/519; 26.6%, sign test P=.002), though participants reported a similar likelihood to take action based on both charts: 80.9% (420/519) for average display versus 78.2% (406/519) for BP history chart (chi-square P=.28).

The second comparison (Figure 2) asked patients whether a display with lifestyle change goals prioritized by clinician priorities for hypertension treatment was more trustworthy than a display presenting lifestyle change goals without additional advice. Most participants, 60.9% (316/519), considered the display that included clinician advice more trustworthy, while

16.4% (85/519) of them considered the display without clinician prioritization more trustworthy (sign test, $P<.001$). Again, patients reported similar likelihood to take action based on both displays ($P=.56$).

The third comparison (Figure 3) asked participants to consider whether a display providing examples of specific potential antihypertensive medications that a doctor may prescribe and the guidelines supporting the use of those medications was more trustworthy than a display that advised patients to discuss medication options and potential side effects with their doctor. A majority of participants, 59.2% (307/519) considered the display that provided specific examples of medications and the supporting guidelines more trustworthy, while 18.5% (96/519) of them considered the latter display more trustworthy ($P<.001$). As with the other comparisons, participants reported similar likelihood to take action based on both displays ($P=.77$).

Discussion

Principal Findings

In both the interviews and the survey, we found favorable attitudes toward controlling BP through CDS applications. Most participants had monitored their BP at home and considered BP control a personal health priority. This experienced and motivated patient population spanned multiple demographics and indicates that there is a high perceived need for tools that better engage patients in hypertension care.

Survey participants had reported a high level of knowledge about BP goal setting. They also indicated a preference for more complete information presentation, including information about BP history, clinician-endorsed goals, and potential pharmacologic treatments for hypertension. Social or relational information, such as what clinicians would recommend or what other patients would do, was deemed particularly trustworthy.

Participants reported weight management and healthy dieting as their top priorities for lifestyle change-related goal setting. Among smokers and those who drink heavily, smoking cessation and alcohol intake moderation, 2 interventions that are known to help reduce both BP and ASCVD risk, were not highly prioritized. This is an opportunity for CDS tools to encourage patient goal setting by presenting these options as suggested priorities, as patients indicated receptiveness to suggested prioritization of lifestyle changes in A/B testing.

Limitations

This research has several limitations. A major concern is that the population was not representative of those with HBP in the United States. The population was skewed toward younger, more technologically literate, and was less representative of underserved communities. This is an issue to be addressed in future work: to understand how better to engage these communities. Self-reported comorbidities require good health literacy to be accurate; our prior studies have shown reasonable accuracy in this group [31]. The rate of heart attack and stroke among adults younger than 40 years was much higher than expected; however, this group is growing rapidly [3]. Future surveys may address these concerns through health literacy screening and by stratifying survey participant subpopulations to achieve overall distributions closer to the population. Future versions of the tool could be created by engaging users historically marginalized by health care in a human-centered design process.

Comparison With Prior Work and Future Research Needs

CDS interventions require engagement by different stakeholders. CDS can remind patients of their goals and promote adherence to those goals. Our survey results suggest that patients perceive they would act on information and recommendations displayed by the tool; however, significant previous work has shown that people overestimate their own actions [32]. By using displays that provide patients with more complete information about their BP history and options for goal setting and treatment, patients may better trust the recommendations provided by the tool. Providers have high fatigue with alerts, but may be able to transfer trust in CDS to patients, as we found in a previous survey [33]. Given the high priority that patients in the survey assigned to HBP management, CDS tools may be used to better engage patients in shared decision-making with their care team.

Engaging patients with these tools continues to be a challenge, however. Substantial work to understand how to engage patients, especially those who are historically underserved, has been undertaken, but disparities remain [34-36]. Additions of coaching and other supports may help key populations engage in CDS [15]. Similarly, improving the visualizations of the data and the manner in which recommendations are delivered was identified by patients as being important to engage in the CDS. Previous work has highlighted the importance of simple, clear, consistent design in CDS tools; the apparent contradiction of wanting more information and having limited attention make acting on these suggestions more difficult. Rapid cycle testing may help resolve these contradictions.

Conclusions

Overall, this digitally literate group of patients was ready to engage with CDS tools and provided substantial guidance on the optimization of these tools through meaningful visualizations with context provided through evidence and from trusted groups. Next steps include expanding the population to those with lower digital literacy and testing the visualizations, reminders, and tailored messages in the real world through a pragmatic trial.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Hypertension patient interview questionnaire.
[PDF File (Adobe PDF File), 462 KB - cardio_v7i1e39490_app1.pdf]

Multimedia Appendix 2
Hypertension patient survey (revised).
[DOCX File , 43 KB - cardio_v7i1e39490_app2.docx]

Multimedia Appendix 3
These are the data for the survey, de-identified, and with specific worksheets for the breakdown of key populations as requested.
[XLSX File (Microsoft Excel File), 255 KB - cardio_v7i1e39490_app3.xlsx]

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Abbreviations

ASCVD: atherosclerotic cardiovascular disease
BP: blood pressure
CDS: clinical decision support
HBP: high blood pressure
IRB: institutional review board

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Original Paper

Long-Term Results of a Digital Hypertension Self-Management Program: Retrospective Cohort Study

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Abstract

Background: Digital health programs that incorporate frequent blood pressure (BP) self-monitoring and support for behavior change offer a scalable solution for hypertension management.

Objective: We examined the impact of a digital hypertension self-management and lifestyle change support program on BP over 12 months.

Methods: Data were analyzed from a retrospective observational cohort of commercially insured members (n=1117) that started the Omada for Hypertension program between January 1, 2019, and September 30, 2021. Paired *t* tests and linear regression were used to measure the changes in systolic blood pressure (SBP) over 12 months overall and by SBP control status at baseline (≥130 mm Hg vs <130 mm Hg).

Results: Members were on average 50.9 years old, 50.8% (n=567) of them were female, 60.5% (n=675) of them were White, and 70.5% (n=788) of them had uncontrolled SBP at baseline (≥130 mm Hg). At 12 months, all members (including members with controlled and uncontrolled BP at baseline) and those with uncontrolled SBP at baseline experienced significant mean reductions in SBP (mean –4.8 mm Hg, 95% CI –5.6 to –4.0; –8.1 mm Hg, 95% CI –9.0 to –7.1, respectively; both *P*<.001). Members with uncontrolled SBP at baseline also had significant reductions in diastolic blood pressure (–4.7 mm Hg; 95% CI –5.3 to –4.1), weight (–6.5 lbs, 95% CI –7.7 to –5.3; 2.7% weight loss), and BMI (–1.1 kg/m^2; 95% CI –1.3 to –0.9; all *P*<.001). Those with controlled SBP at baseline maintained within BP goal range. Additionally, 48% (418/860) of members with uncontrolled BP at baseline experienced enough change in BP to improve their BP category.

Conclusions: This study provides real-world evidence that a comprehensive digital health program involving hypertension education, at-home BP monitoring, and behavior change coaching support was effective for self-managing hypertension over 12 months.

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KEYWORDS

hypertension; digital health program; home measurement; self-management; behavior change

Introduction

Hypertension, which is defined as systolic blood pressure (SBP) ≥130 mm Hg or diastolic blood pressure (DBP) ≥80 mm Hg, impacts nearly 1 in 2 adults in the United States and increases the risk for heart disease and stroke, 2 of the leading causes of death both in the United States and globally [1,2]. While hypertension is one of the most common primary care diagnoses [3], the Centers for Disease Control and Prevention estimates that just 1 in 4 adults (24%) with hypertension have their condition under control (defined as SBP <130 mm Hg and DBP <80 mm Hg) [4]. A strong relationship exists between rising SBP and DBP and increased risk of cardiovascular disease, including a 2-fold increased risk of death from stroke or heart disease for every 20 mm Hg increase in SBP [5].

Various interventions that incorporate evidence-based behavioral strategies such as self-monitoring of blood pressure (BP) [6-9] and healthy lifestyle changes, such as dietary modifications and increased physical activity [10-13] in conjunction with pharmacological treatments [1], have demonstrated effectiveness in the treatment of hypertension. To improve BP control at scale, translatable innovative solutions are needed that provide support for hypertension management both during traditional in-person office visits as well as at home, where individuals spend the majority of their time [14-19].

In support of using home blood pressure as part of the management of hypertension, the American Heart Association (AHA) and the American Medical Association reviewed the evidence for the use of home blood pressure monitoring (HBPM) [6]. HBPM is a stronger predictor of cardiovascular risk than office-based BP measurements [6,7]. In order to demonstrate clinically meaningful BP reductions that reduce the risk of developing a cardiovascular event [20,21], HBPM typically requires the use of education, human-led coaching interventions, and intensive clinical support [8,9].

Digital health and mobile health solutions combine the advantages of HBPM and the provision of data-driven insights with programs designed to support patients through self-management, goal setting, behavior change, and healthy lifestyle education [22]. Some digital solutions automate this support through artificial intelligence or other conversational technology (eg, texting) and self-service functions; however, automation has struggled with replicating the elements of building personal connection and promoting engagement found in human-led coaching programs [23-26].

As health care grapples with hypertension as a persistently undertreated and costly chronic disease, more pragmatic solutions are needed to address the significant time required to support lifestyle modifications, improve HBPM adherence, and respond to the real-time data being collected through HBPM to ensure that appropriate and timely care is being delivered.

The Omada for Hypertension program is a digital health behavior change solution that combines HBPM with human-led coaching support and a comprehensive lifestyle modification curriculum. A recent pilot study demonstrated that Omada for Hypertension members improved BP control after 3 months [27]; however, longer-term results of the program have yet to be investigated. The primary objective of this analysis is to examine the change in SBP between baseline and 12 months among Omada for Hypertension members. The secondary objectives are to (1) measure SBP change at 12 months compared to baseline among members whose SBP was uncontrolled at baseline (≥130 mm Hg [uncontrolled] and among members whose SBP was controlled at baseline <130 [controlled]); (2) examine weight change at 12 months overall and by SBP control status at baseline; and (3) assess change in DBP at 12 months compared to baseline overall and among those with uncontrolled BP at baseline.

Methods

Study Design

This was a nonrandomized, retrospective observational cohort study evaluating the clinical outcomes from baseline to 12 months among commercial health plan members enrolled in the Omada for Hypertension program. To enroll in the Omada for Hypertension program, individuals were required to meet the following criteria: (1) have coverage from their employer or health insurance plan for the benefit; (2) be ≥18 years old; (3) have a self-reported diagnosis of hypertension; and (4) not have any medical contraindications. All members self-enrolled in the program and were not compensated for their participation.

To be included in the current analysis, members met the following criteria: (1) previously or currently enrolled in the Omada for Hypertension program; (2) completion of baseline and 12-month home BP readings (following the procedures described in the Measures section below); and (3) a program start date (defined as the date of first home BP reading uploaded) between January 1, 2019, and September 30, 2021.

Ethical Considerations

The study was a secondary analysis of previously collected deidentified commercial data and thus was deemed exempt from ethics approval by the WCG institutional review board (confirmation ID: 45104379).

Program Description

The Omada for Hypertension program is a digitally delivered hypertension self-management program that pairs asynchronous human support through health coaches and hypertension education specialists with a virtual platform that is accessed either through a website or through an app available on web-enabled devices (eg, smartphone and tablet). The program offers both a hypertension education curriculum and comprehensive lifestyle self-management support using behavior change techniques, in addition to a cellularly connected BP cuff for HBPM (BodyTrace, Inc) and a cellularly connected digital scale (Greater Goods, LLC or BodyTrace, Inc).

Program members are paired with an Omada care team, which includes a health coach and a hypertension education specialist (ie, Certified Diabetes Care and Education Specialist trained for hypertension) who communicate with members through an asynchronous messaging platform. Members are instructed to take BP measurements at home on a monthly basis (per the

protocol described in the Measures section below), as well as prior to a scheduled visit with their doctor, after a change in medication, and according to their doctor's instructions. The health coach supports members' progress throughout the program, provides feedback to members regarding HBPM, encourages medication adherence, and prepares members for their doctor visits. The hypertension education specialist reviews members' BP data and provides individual feedback and counseling on nonpharmacological treatment for BP pattern management as needed.

Additional program components include hypertension education content, lifestyle modification advice (eg, physical activity and individualized dietary support), social support, goal-setting tools, self-monitoring capabilities via cellularly connected devices, feedback on self-monitoring data, BP pattern management, and check-ins with members to encourage communication with their health care providers when adjustments to medication or care may be needed. Recommendations made by the Omada care team are done in alignment with the member's care plan created by their regular treating provider. In addition, members are placed in a virtual peer support group and can communicate with other program members through a secure group discussion board.

Measures

Blood Pressure

Members measure their BP (mm Hg) with a Food and Drug Administration-cleared cellularly connected BP device, which is connected to the member's account and requires no additional setup. Members also had the option of using their own BP device and manually reporting their readings in the app or website, but only approximately 2% of members used this option. Members were provided with instructions for how to perform accurate BP measurements at home [28] and were instructed to establish a baseline BP reading by choosing a 3-day window where they measured their BP twice in the morning and twice in the evening for each of the 3 consecutive days. Additionally, members were encouraged to take monthly BP readings using the same protocol as above as part of the self-monitoring hypertension program.

Members' BP measurements were averaged if the measurements met the following minimum criteria at baseline and 12-month follow-up: (1) 3 or more measurements taken over at least 3 days with at least ≥1 measurement collected per day or (2) ≥4 or more measurements taken over at least 2 days with ≥2 measurements collected per day [29]. The baseline and 12-month BP data were calculated as the average of the BP measurements meeting the minimum criteria closest to the program start date and up to 30 days after the program start date and closest to 12 months and up to 15 months from the program start date, respectively. At baseline, uncontrolled SBP was defined as ≥130 mm Hg (controlled <130 mm Hg), and uncontrolled DBP was defined as ≥80 mm Hg (controlled <80 mm Hg) [30]. BP measurements were used to categorize members into HBPM categories that correspond with current AHA/American College of Cardiology 2017 recommendations and are appropriate thresholds for HBPM [30].

To keep consistent with AHA/American College of Cardiology–recommended treatment goals for those with hypertension, the normal and elevated HBPM categories were consolidated into an "At Goal" category. Thus, HBPM categories were defined as (1) At Goal: SBP<130 mm Hg and DBP<80 mm Hg, (2) Stage 1: SBP between 130 and 134 mm Hg or DBP between 80 and 84 mm Hg, and (3) Stage 2: SBP ≥135 mm Hg or DBP≥85 mm Hg [30]. If a member's BP falls into 2 different categories, the member is assigned to the higher HBPM category. Consistent with recent meta-analyses, a clinically meaningful change in SBP over the study period was defined as a 5 mm Hg reduction [20,21].

Body Weight

Body weight (lbs) was collected with an Omada-provided cellularly connected digital scale, which is linked to the member's account. The baseline and 12-month data were calculated as the average of all weight measurements on the day with at least 1 weight measurement closest to the program start date within the window of 7 days prior to and 30 days post the program start date and within an 11- to 13-month window from the program start date, respectively. Absolute change in body weight and percent weight loss from baseline to 12 months was calculated. BMI was calculated from self-reported height and measured weight and categorized into an obesity indicator variable (obesity ≥30 kg/m^2 vs without obesity <30 kg/m^2).

Member Characteristics

Members self-reported their demographic information, including sex (male and female), race and ethnicity (White, Black, Hispanic, Asian, and other), annual income (>US $50,000 and ≤US $50,000), and educational attainment (college education and above and less than college education), upon enrollment in the program. Self-reported medication usage was collected during account setup and further categorized into a 2-level variable for whether members were taking hypertension-related medications versus not at baseline [31].

Program Engagement

Program engagement was measured by counts of actions taken within the program app or website each week in the program and included six components: (1) number of conversations started on a group discussion board; (2) number of comments (replies to conversations) made on the group discussion board; (3) number of hearts (likes) shared on the group discussion board; (4) number of messages sent to their Omada care team; (5) number of meals tracked; and (6) number of lessons completed. The median of the average weekly activities for all members was used as the cutoff point for high versus low engagement (ie, high engagement ≥4 activities per week, normal or low engagement <4 activities per week).

Additionally, activities related to self-monitoring behaviors were captured by the average number of times per week that members recorded a physical activity as well as the average number of times per week that members recorded weight. BP engagement was assessed by the average times per month that members used their BP cuff or manually entered BP readings.

Statistical Analysis

Differences in baseline demographic characteristics and clinical measures between members with uncontrolled (≥130 mm Hg) versus controlled (<130 mm Hg) SBP at baseline were tested using chi-square and *t* tests. Changes in clinical outcomes (SBP, DBP, weight, and BMI) from baseline to 12 months were assessed using paired *t* tests. Differences in the proportion of hypertension members within each stage (At Goal, Stage 1, and Stage 2) were analyzed using a marginal homogeneity test of symmetry to determine whether there was a significant shift of members within each stage from baseline to 12 months. Linear regression was used to model the change in SBP at 12 months overall and stratified by SBP control status at baseline. Unadjusted, minimally adjusted (age, sex, and race and ethnicity), and fully adjusted models (minimally adjusted covariates, program engagement, and obesity status) were fit. Model assumptions and goodness of fit tests were assessed, and the fully adjusted model was selected as the final model. All analyses used 2-sided hypothesis testing and were conducted in R (version 4.1; R Foundation) and Stata (version 17.0; StataCorp).

Results

Sample Characteristics

The final sample size for Omada for Hypertension members with baseline and 12-month BP data over the analysis period was 1117 members, including 788 members with uncontrolled SBP (≥130 mm Hg) at baseline and 329 with controlled SBP (<130 mm Hg) at baseline (Figure 1). The mean age of the overall sample was 50.9 (SD 9.6) years old, with approximately half of the overall sample self-identifying as female, 60.5% (n=675) of them self-identifying as White, and the majority reporting incomes over US $50,000 with at least a college education (Table 1).

Approximately two-thirds (n=724, 66.9%) of members were classified as obese, and 77% (n=860) of them had Stage 1 or 2 hypertension based on baseline SBP or DBP measurements. Stratified by SBP control at baseline, those with uncontrolled SBP were significantly more likely to be male and had significantly higher mean weight, BMI, and DBP at baseline (all $P<.05$; Table 1).

Figure 1. Omada for Hypertension member enrollment and study participation flow chart. SBP: systolic blood pressure.

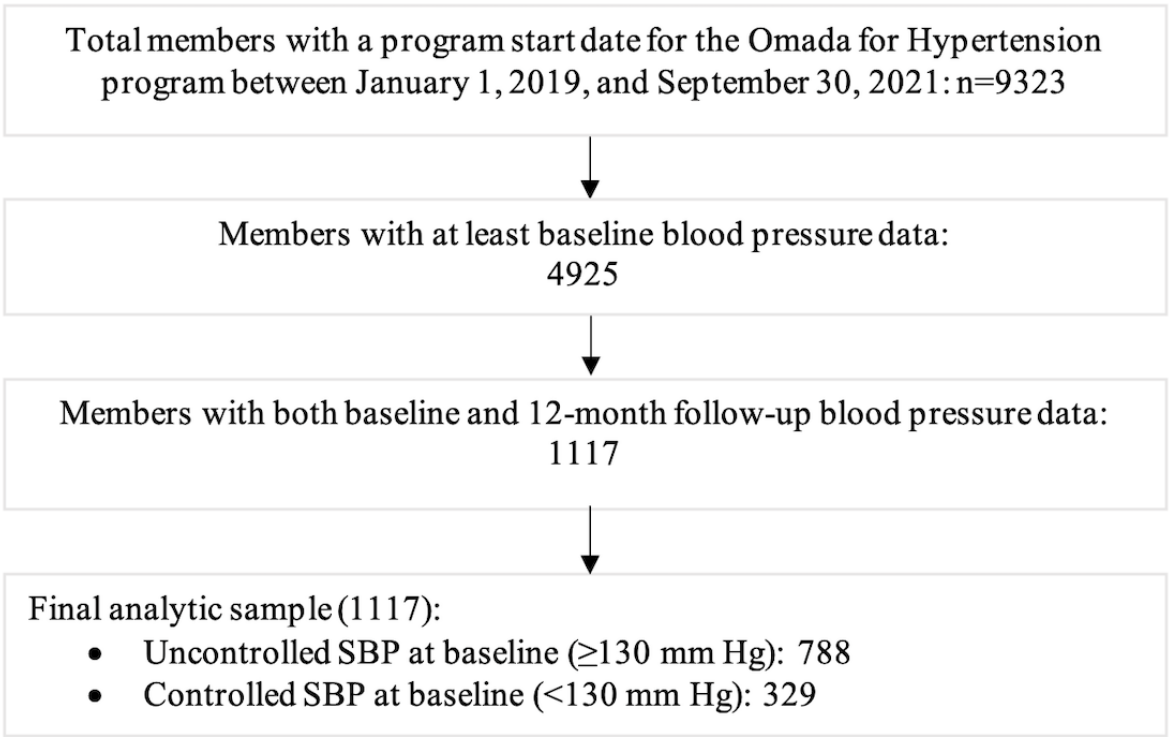


Table 1. Demographic characteristics, weight, and blood pressure overall and by systolic blood pressure (SBP) control status at baseline (uncontrolled SBP ≥130 mm Hg vs controlled <130 mm Hg).[a]

	Overall (n=1117)	SBP[b] ≥130 (n=788; 70.5%)	SBP <130 (n=329; 29.5%)	*P* value
Demographic characteristics				
Age (years), mean (SD)	50.9 (9.6)	51.2 (9.5)	50.3 (10.0)	.13
Age distribution (years), n (%)				.63
18-44	284 (25.4)	194 (24.6)	90 (27.4)	
45-64	768 (68.8)	548 (69.5)	220 (66.9)	
≥65	65 (5.8)	46 (5.8)	19 (5.8)	
Sex, n (%)				*.02*
Female	567 (50.8)	382 (48.5)	185 (56.2)	
Male	550 (49.2)	406 (51.5)	144 (43.8)	
Income, n (%)				.28
>US $50,000	600 (75.3)	435 (76.3)	165 (72.7)	
≤US $50,000	197 (24.7)	135 (23.7)	62 (27.3)	
Race and ethnicity, n (%)				.06
White	675 (60.5)	474 (60.5)	201 (61.3)	
Black	187 (16.8)	147 (18.7)	40 (12.2)	
Hispanic	114 (10.2)	76 (9.7)	38 (11.6)	
Asian	99 (8.9)	64 (8.1)	35 (10.7)	
Other	40 (3.6)	26 (3.3)	14 (4.3)	
Education, n (%)				.18
College education and above	645 (66.3)	451 (65.0)	194 (69.5)	
Less than a college education	328 (33.7)	243 (35.0)	85 (30.5)	
Clinical measures				
Weight (lbs), mean (SD)	219.9 (51.1)	226.4 (52.0)	204.6 (45.2)	*<.001*
BMI (kg/m^2), mean (SD)	35.2 (9.4)	36.3 (9.7)	32.7 (8.1)	*<.001*
Obesity status (kg/m^2), n (%)				*<.001*
BMI≥30 kg/m^2	724 (66.9)	544 (71.2)	180 (56.6)	
BMI<30 kg/m^2	358 (33.1)	220 (28.8)	138 (43.4)	
Hypertension medications, n (%)				.69
Yes	620 (86.1)	434 (85.8)	186 (86.9)	
No	100 (13.9)	72 (14.2)	28 (13.1)	
SBP (mm Hg), mean (SD)	136.5 (13.4)	142.6 (10.8)	122.0 (5.6)	*<.001*
DBP[c] (mm Hg), mean (SD)	82.4 (9.1)	85.4 (8.6)	75.1 (5.3)	*<.001*
DBP control (mm Hg), n (%)				*<.001*
≥80 mm Hg (uncontrolled)	676 (60.5)	604 (76.7)	72 (21.9)	
<80 mm Hg (controlled)	441 (39.5)	184 (23.4)	257 (78.1)	
HBPM[d] hypertension categories (based on baseline SBP and DBP), n (%)				*<.001*
At Goal	257 (23.0)	0	257 (78.1)	
Stage 1	383 (34.3)	323 (41.0)	60 (18.2)	
Stage 2	477 (42.7)	465 (59.0)	12 (3.7)	

[a]Italicized *P* values are significant.

[b]SBP: systolic blood pressure

[c]DBP: diastolic blood pressure.

[d]HBPM: home blood pressure monitoring.

Program Engagement

Overall, 55.5% (n=620) of members were classified as "highly engaged" with the program (mean weekly activities ≥4) versus 44.5% (n=497) as "less engaged" (weekly activities <4). Meal tracking accounted for 82% of the mean weekly engagement metric. There was no significant difference in program engagement by uncontrolled versus controlled SBP at baseline (*P*=.08). With regard to BP engagement, members used their BP cuff or manually entered BP values an average of 13.4 (median 8.7) times per month over 12 months. For self-monitoring related app or website activities, members weighed in on average 4 times per week and tracked their physical activity on average 3.7 times per week.

Clinical Outcomes

As shown in Table 2, overall members had significant unadjusted mean reductions in SBP and DBP from baseline to 12 months (mean –4.8, 95% CI –5.6 to –4; mean –3.0, 95% CI –3.5 to –2.5, both *P*<.001, respectively). In addition, members with uncontrolled SBP at baseline experienced clinically meaningful reductions in SBP and DBP from baseline to 12 months (mean –8.1, 95% CI –9.0 to –7.1; mean –4.7, 95% CI –5.3 to –4.1, both *P*<.001, respectively). Nearly all members (604/676, 89%) with uncontrolled DBP (≥80 mm Hg) at baseline also had uncontrolled SBP at baseline. Members with uncontrolled DBP experienced clinically meaningful unadjusted mean reductions in DBP from baseline to 12 months (n=676; mean –5.7; *P*<.001). Members with controlled SBP at baseline experienced mean increases in SBP and DBP from baseline to 12 months (n=329; mean 3.1, 95% CI 2.0-4.2; 1.0, 95% CI 0.2-1.8, both *P*<.05, respectively), but these increases were not clinically significant (Table 2).

Table 2. Mean (95% CI) change over time in clinical outcomes from baseline to 12 months overall and by systolic blood pressure (SBP) control status at baseline (≥130 mm Hg vs <130 mm Hg; n=1117).[a]

Variable	Baseline, mean (95% CI)	12 months, mean (95% CI)	12-month change, mean (95% CI)	*P* value
Overall				
SBP (mm Hg; n=1117)	136.5 (135.8 to 137.3)	131.8 (131.0 to 132.5)	–4.8 (–5.6 to –4.0)	<.001
DBP[b] (mm Hg; n=1117)	82.4 (81.9 to 83.0)	79.4 (78.9 to 79.9)	–3.0 (–3.5 to –2.5)	<.001
Weight (lbs; n=973)	220.5 (217.4 to 223.7)	214.3 (211.2 to 217.4)	–6.2 (–7.2 to –5.3)	<.001
BMI (kg/m^2; n=966)	35.3 (34.8 to 35.9)	34.3 (33.8 to 34.9)	–1.0 (–1.2 to –0.9)	<.001
Uncontrolled SBP ≥130 mm Hg at baseline				
SBP (mm Hg; n=788)	142.6 (141.9 to 143.4)	134.6 (133.7 to 135.4)	–8.1 (–9.0 to –7.1)	<.001
DBP (mm Hg; n=788)	85.5 (84.9 to 86.1)	80.8 (80.1 to 81.4)	–4.7 (–5.3 to –4.1)	<.001
Weight (lbs; n=685)	226.8 (222.9 to 230.6)	220.3 (216.5 to 224.1)	–6.5 (–7.7 to –5.3)	<.001
BMI (kg/m^2; n=681)	36.3 (35.6 to 37.1)	35.3 (34.6 to 36.0)	–1.1 (–1.3 to –0.9)	<.001
Controlled SBP <130 mm Hg at baseline				
SBP (mm Hg; n=329)	122.0 (121.4 to 122.6)	125.1 (124.0 to 126.2)	+3.1 (+2.0 to +4.2)	<.001
DBP (mm Hg; n=329)	75.1 (74.6 to 75.7)	76.2 (75.3 to 77.0)	+1.0 (+0.2 to +1.8)	.01
Weight (lbs; n=288)	205.7 (200.6 to 210.8)	200.1 (195.3 to 204.9)	–5.6 (–7.3 to –3.9)	<.001
BMI (kg/m^2; n=285)	33.0 (32.1 to 33.9)	32.1 (31.2 to 33.0)	–0.9 (–1.2 to –0.6)	<.001

[a]12-month change=12 months–baseline; negative 12-month change indicates improvement in clinical outcomes.

[b]DBP: diastolic blood pressure.

The final multivariable regression models were consistent with unadjusted estimates (data not shown). Overall, in fully adjusted models, average marginal estimates of SBP significantly decreased by 4.8 mm Hg from baseline to 12 months (95% CI –5.6 to –4.0; *P*<.001), and among those with uncontrolled SBP at baseline, average marginal estimates of SBP significantly decreased by 8.0 mm Hg at 12 months (95% CI –9.0 to –7.1; *P*<.001). Among members with uncontrolled SBP at baseline, program engagement was significantly related to a 12-month change in SBP with highly engaged members experiencing greater mean reductions than less engaged members (–4.4 mm Hg; 95% CI –6.4 to –2.5; *P*<.001). Additionally, members with obesity had significantly greater reductions in SBP compared to those who did not have obesity (*P*=.02).

Both overall and among those with uncontrolled SBP or DBP at baseline, the percentage of members within each HBPM hypertension category (ie, At Goal, Stage 1, and Stage 2) showed significant improvement from baseline to 12 months as shown

in Figure 2 (*P*<.001). Overall, 13% (146/1117) of members shifted from Stage 1 to At Goal, 9% (103/1117) from Stage 2 to At Goal, and 15% (169/1117) from Stage 2 to Stage 1. Additionally, among those with uncontrolled BP at baseline, 17% (146/860) of members shifted from Stage 1 to At Goal, 12% (103/860) from Stage 2 to At Goal, and 19.7% (169/860) from Stage 2 to Stage 1.

The mean change in BP by HBPM stage among those with uncontrolled SBP and DBP at baseline is shown in Figure 3. Members with Stage 2 SBP and DBP at baseline demonstrated clinically meaningful and statistically significant reductions in BP at 12 months (–10.3 and –7.5 mm Hg, respectively; both *P*<.001); furthermore, the mean DBP at 12 months moved to the At Goal category for those with Stage 1 DBP at baseline (Figure 3).

Overall, members lost on average 6.2 lbs at 12 months (95% CI –7.2 to –5.3; *P*<.001) and approximately 2.6% weight loss. Both members with uncontrolled and controlled SBP at baseline experienced significant weight loss from baseline to 12 months (–6.5 lbs, 95% CI –7.7 to –5.3; –5.6 lbs, 95% CI –7.3 to –3.9, respectively; both *P*<.001); the mean percent weight loss among those with uncontrolled versus controlled SBP at baseline were 2.7% and 2.4% at 12 months, respectively (Table 2).

Figure 2. Home blood pressure monitoring hypertension category percentages at baseline and 12 months overall (n=1117) and among those with uncontrolled SBP (≥130 mm Hg) or DBP (≥80 mm Hg) at baseline (n=860). The figure on the left represents all members in the study (n=1117) and the figure on the right includes only those with uncontrolled SBP or DBP at baseline (n=860); *P* value <.001 overall and by SBP control status at baseline using marginal homogeneity test for shift in ordered proportion of members within home blood pressure monitoring hypertension stages at 12 months compared to baseline; home blood pressure monitoring categories were defined as: (1) At Goal: SBP<130 mm Hg and DBP<80 mm Hg, (2) Stage 1: SBP between 130 and 134 mm Hg or DBP between 80 and 84 mm Hg, and (3) Stage 2: SBP ≥135 mm Hg or DBP≥85 mm Hg. DBP: diastolic blood pressure; SBP: systolic blood pressure.

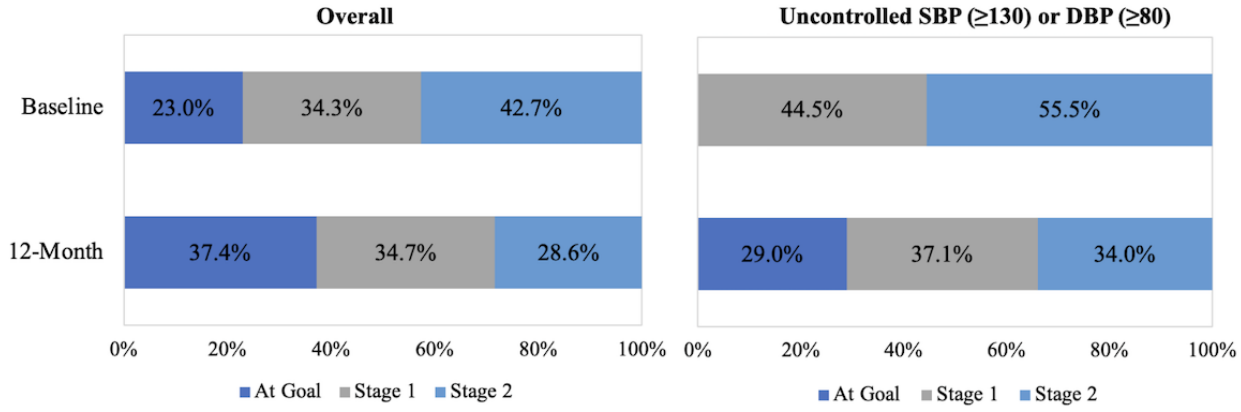
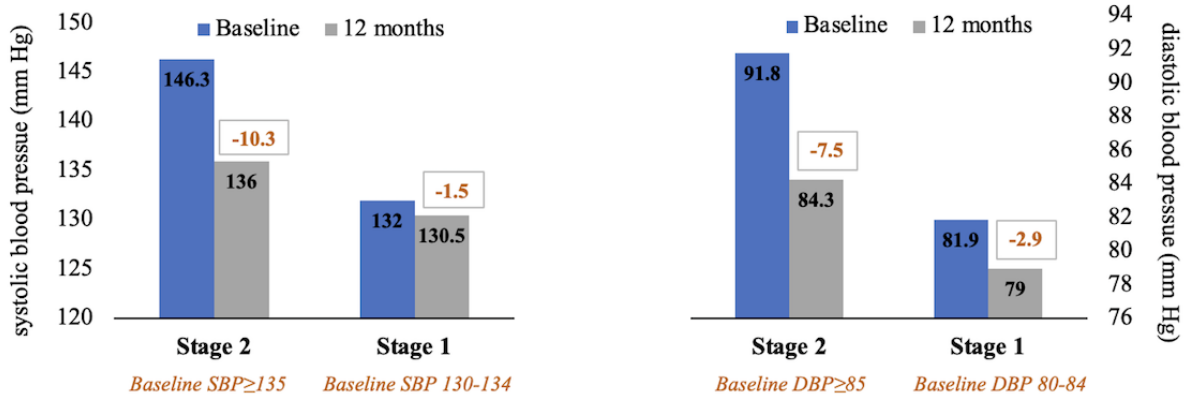


Figure 3. Mean 12-month reduction in SBP and DBP by baseline hypertension categories among those with uncontrolled SBP (≥130 mm Hg) or uncontrolled DBP (≥80 mm Hg) at baseline (n=860). Within category change *P* values all <.001. DBP: diastolic blood pressure; SBP: systolic blood pressure.



Discussion

Principal Findings

Members with uncontrolled BP at baseline experienced significant and clinically meaningful mean reductions in SBP and DBP from baseline to 12 months. When examining clinical improvement through the lens of shifting hypertension categories, more than 48% (418/860) of members with uncontrolled SBP or uncontrolled DBP at baseline experienced a large enough improvement in BP to shift down by 1 or more categories. Weight and BMI addressed in the program through diet, physical activity, and behavior change support also showed statistically significant reductions during the study period. Program engagement was also evident in this study, with over half of members being classified as “highly engaged” (mean weekly activities ≥4). These members experienced significantly greater reductions in SBP compared to those that were less engaged in the program, supporting current literature on the effectiveness of engagement on interventions for hypertension self-management [32,33].

Although members with SBP and DBP within the goal range at baseline experienced statistically significant increases in BP at 12 months, the magnitude of the changes was not clinically meaningful, and the mean of this group still fell within the At Goal HBPM category at 12 months. These increases may be due to regression to the mean, random variability in the data, or from disease progression as members’ age in the program. Moreover, these members also lost nearly as much percent body weight as members with uncontrolled BP at baseline, demonstrating that they also benefited from the program from a weight loss perspective.

While there have been a number of studies examining different models of digital health solutions for the management of hypertension [22,34], few have investigated real-world outcomes in programs that incorporate the three specific components included in the Omada for Hypertension program: (1) self-monitoring of BP through HBPM, (2) comprehensive lifestyle education and behavior change interventions, and (3) human-led health coaching to support behavior change [35-38]. The spectrum of digital health interventions may also include the involvement of licensed clinicians as part of the care team (eg, pharmacists and physicians), automated education or direct medication reminders via text, electronic pill box or medication bottles, physical activity trackers, and other wearable devices.

In a review of the literature, 1 previous cohort study of a hypertension self-management program offered through an employer health plan also found that higher engagement with the app was associated with greater reductions in SBP [38]. The program intervention in that study and the Omada for Hypertension program are similar in that they both offer hypertension self-management with a BP monitor and connected smartphone app; however, a difference is that the former uses an automated lifestyle coaching platform, whereas the Omada program uses human-led behavior change coaching. Likewise, in the HOME BP trial [39], which examined a digital intervention for hypertension with self-monitoring of BP and guided self-management, SBP control status was improved after 1 year compared to usual care. In the HOME BP intervention, however, all members received a BP medication review by a clinician with an individualized drug titration plan, directly addressing the issue of therapeutic inertia. These examples show that the Omada for Hypertension program outcomes are consistent with other studies; however, direct comparisons in the literature are difficult to make due to the variety of intervention designs.

Limitations

There are limitations to this study. First, the study population was composed primarily of commercially insured and middle-aged adults, with a lower representation than the national average of members who identify as Hispanic. All members had access to internet connectivity, a smartphone app, a web OS platform, a computer or tablet, and sufficient technology literacy. These demographics limit the generalizability of our findings to other populations including Medicaid, Medicare, or uninsured populations, which currently have lower adoption of technology.

Second, members were enrolled in the program based on a self-reported diagnosis of high BP or hypertension, and access to medical records was not available to further validate the diagnosis. An assessment of usual medical care and the presence of medication adherence issues and treatment inertia was also not possible due to the lack of longitudinal medication data. In addition, we accounted for normal variation in BP by calculating a mean BP using clinical best practices rather than relying upon a single BP measurement [29]; yet, the potential for measurement error may remain. Moreover, as a nonrandomized, observational cohort study, the lack of a control group may introduce confounding variables and bias, and findings could be attributable in part to regression to the mean.

Due to the real-world digital delivery of this program, about one-quarter of members with a baseline BP measurement also had a valid 12-month BP follow-up measurement. However, there were only a few differences between those with complete 12 months of data versus those without or excluded from the study; excluded members due to missing follow-up data were more likely to be Black and female (both $P<.001$). Additionally, some members may have been engaged with the program even if they did not report BP data or chose to only report limited BP data at 12 months, thus not meeting the minimum criteria to be included in the study (per the protocol discussed in the measures section of the methods).

Lastly, the mean weekly engagement metric included a wide range of activities that do not carry equal weight in terms of the amount of activation required and the evidence supporting their effectiveness. Nevertheless, we summed all 6 measures of action-oriented engagement to create a total mean weekly engagement metric for a number of reasons: members may uniquely benefit from different types of content and interactions to help promote behavior change and clinical improvements and may have more opportunities to engage in some engagement metrics than others (ie, can log 3+ meals per day but only have the opportunity to complete 1 lesson per week).

Future Directions

Future research should examine the implementation of similar digital health programs into the health care ecosystem including bidirectional data exchange and care coordination. More evidence for the applicability of digital programs to other populations (eg, Medicare and Medicaid) and how a digital solution might reduce the burden on the primary care team would further bolster the evidence for a widespread adoption of this approach to hypertension management.

The cost-effectiveness and the long-term impact of a digital health program on the health economics of hypertension management were not directly assessed in this study. However, a recent study showed that patients with hypertension had a US $432 decrease in health care expenditures in the year following a decrease in 1 BMI unit inflated to 2022 dollars [40]. Thus, further analysis of the economic impact and potential savings of digital hypertension self-management programs is warranted.

Conclusions

The current management of hypertension in the United States is in need of innovative solutions that can scale to reverse the alarming trend of worsening disease and unsustainable costs related to hypertension in the health care system. Digital health solutions have shown promise in allowing more care to be shared by the patient in a self-management program and less time required by the physician to deliver lifestyle counseling and behavior change support. This study provides evidence that a digital solution, coupled with human-led health coaching, is associated with improved SBP control over a sustained period of time.

Acknowledgments

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Conflicts of Interest

JW, JN, SL, MN, and CBJ are employees of Omada Health, Inc and receive salary and stock options. MT receives salary and equity from Google and Omada Health, Inc and is a consultant for Guidepoint. JJ receives consulting fees from Omada Health, Inc.

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Abbreviations

AHA: American Heart Association
BP: blood pressure
DBP: diastolic blood pressure
HBPM: home blood pressure monitoring
SBP: systolic blood pressure

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Original Paper

Automated Messaging Program to Facilitate Systematic Home Blood Pressure Monitoring: Qualitative Analysis of Provider Interviews

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Abstract

Background: Hypertension is a leading cause of cardiovascular and kidney disease in the United States, yet blood pressure (BP) control at a population level is poor and worsening. Systematic home BP monitoring (HBPM) programs can lower BP, but programs supporting HBPM are not routinely used. The MyBP program deploys automated bidirectional text messaging for HBPM and disease self-management support.

Objective: We aim to produce a qualitative analysis of input from providers and staff regarding implementation of an innovative HBPM program in primary care practices.

Methods: Semistructured interviews (average length 31 minutes) were conducted with physicians (n=11), nurses, and medical assistants (n=6) from primary care settings. The interview assessed multiple constructs in the Consolidated Framework for Implementation Research domains of intervention characteristics, outer setting, inner setting, and characteristics of individuals. Interviews were transcribed verbatim and analyzed using inductive coding to organize meaningful excerpts and identify salient themes, followed by mapping to the updated Consolidated Framework for Implementation Research constructs.

Results: Health care providers reported that MyBP has good ease of use and was likely to engage patients in managing their high BP. They also felt that it would directly support systematic BP monitoring and habit formation in the convenience of the

patient's home. This could increase health literacy and generate concrete feedback to raise the day-to-day salience of BP control. Providers expressed concern that the cost of BP devices remains an encumbrance. Some patients were felt to have overriding social or emotional barriers, or lack the needed technical skills to interact with the program, use good measurement technique, and input readings accurately. With respect to effects on their medical practice, providers felt MyBP would improve the accuracy and frequency of HBPM data, and thereby improve diagnosis and treatment management. The program may positively affect the patient-provider relationship by increasing rapport and bidirectional accountability. Providers appreciated receiving aggregated HBPM data to increase their own efficiency but also expressed concern about timely routing of incoming HBPM reports, lack of true integration with the electronic health record, and the need for a dedicated and trained staff member.

Conclusions: In this qualitative analysis, health care providers perceived strong relative advantages of using MyBP to support patients. The identified barriers suggest the need for corrective implementation strategies to support providers in adopting the program into routine primary care practice, such as integration into the workflow and provider education.

Trial Registration: ClinicalTrials.gov NCT03650166; https://tinyurl.com/bduwn6r4

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KEYWORDS

mHealth; digital intervention; qualitative research; provider stakeholders; hypertension; home blood pressure monitoring; implementation research; short-messaging system; remote monitoring; qualitative analysis; messaging program; blood pressure; monitoring; cardiovascular; disease; text messaging; text mining; self-management; mobile phone

Introduction

Hypertension is the leading cause of morbidity worldwide [1]. It affects 100 million US adults, most of whom have uncontrolled hypertension [2]. Many factors contribute to uncontrolled hypertension but particularly vexing are patient nonadherence to prescribed medications and lifestyle modifications, and provider reluctance to advance pharmacotherapy, termed *therapeutic inertia* [3,4]. Therapeutic inertia is exacerbated by uncertainty regarding data accuracy, as patients either do not record any blood pressure (BP) data at home or fail to organize readings in a manner that is verifiable and serviceable by providers [4-6]. Providers recognize several barriers to home BP monitoring (HBPM), some of which might be addressed using new technologies [7].

Interventions to facilitate collection and reporting of HBPM more reliably and systemically may combat therapeutic inertia by improving provider confidence in submitted HBPM readings. Some programs include ancillary self-management supports such as BP measurement reminders, automated feedback, and educational resources [8-10]. Critically, systematic reviews of randomized clinical trials have shown that HBPM coupled with a supporting resource lowers BP [11]. Due to its promise and advantages, US guidelines now broadly recommend HBPM in the diagnosis and management of hypertension [12,13]. However, implementation has not been systematized and practicality is uncertain. Some tested programs have employed pharmacists to manage pharmacotherapy, while others used case managers who followed up on readings by calling patients and offering verbal education [11]. These resource-intensive interventions have limited scalability and lack clear benefit to cost ratios [10,11]. Programs that are automated may have superior utility provided they are effective in engaging patients in systematic HBPM and supporting disease self-management. Still, designers must consider barriers to engagement with technologically based HBPM programs, particularly among older, rural, and other disadvantaged communities.

Automated communication programs using mobile phones to link patients and their providers have shown promise [14-18], including among underserved populations [19-22]. Previous work has highlighted that awareness of BP status and goals can enhance adherence to lifestyle recommendations and medication [23,24]. Widespread cell phone ownership with unlimited texting (SMS text messaging) makes SMS text messaging an attractive conduit through which automatic programs can operate without reliance on broadband, local Wi-Fi or uploaded apps [25]. SMS text messaging–based programs also have other benefits such as being simple and proactive that allow for high user engagement.

The goal of our program, MyBP, is to support both patient and provider in the management of hypertension through the above measures and ultimately control BP. The core feature is an automated SMS text messaging program systematically collecting longitudinal HBPM data and providing tailored BP feedback. MyBP also includes educational videos and provider reports summarizing BP trends [8]. MyBP has been developed in 3 phases spanning focus groups and feasibility studies using varied clinical settings [8]. Throughout this process, the developers of MyBP have received both formal and informal stakeholder feedback. In a qualitative analysis of patient interviews, participants reported improved understanding of, and motivation surrounding, healthy behaviors [26]. Objective engagement with MyBP over a period of 25 weeks further supports usefulness and implementation feasibility [27].

The goal of the current study was to collect and analyze providers' perception of the barriers to and facilitators of MyBP implementation in primary care. Using semistructured interviews, we sought to identify unmet needs by current HBPM practices, areas of refinement within the MyBP program, and strategies for implementation. Artificial intelligence was not used in any part of the research or in writing this paper.

Methods

Study Design

In a qualitative analysis of stakeholder input from primary care providers and staff, this study assesses strengths and weaknesses of the current MyBP program, particularly the facilitators and barriers to implementation in primary care practices. Textbox 1 provides a summary of the MyBP program. Our methods relied on an implementation-focused formative evaluation using the Stetler et al [28] typology. The goals were primarily to identify actionable barriers to implementation while also identifying facilitating factors for implementation that could potentially be augmented. A convenience sample of primary care physicians, nurses, and medical assistants from local practices were recruited. Participants received an information packet providing a general overview of all the functions of the MyBP program and an example of the provider BP report. Some providers had had personal experience with MyBP while others had knowledge of the program only through printed materials and oral description. Interviews were conducted either in-person or via telephone by one of the authors (JE or TI) between January 2018 and September 2019.

Textbox 1. MyBP program overview.

MyBP is a patient-facing, automated, bidirectional SMS text messaging program providing support of hypertension self-monitoring and self-management. It also generates blood pressure summary reports for providers. The program is delivered to patients via any text-capable phone and requires no internet connection or special equipment. Patient-submitted blood pressure readings are sent via SMS text messaging and collected in a secure server for processing.

- Upon enrollment, participants were given access and instructed to watch several health-education videos on hypertension by Emmi Solutions, Inc.
- Once enrolled, MyBP sent text messages supporting personalized and scheduled morning and evening blood pressure self-measurement.
- Each submitted prescheduled reading prompted confirmation and personalized blood pressure feedback.
- Patients received periodic tips to promote better health behaviors and were provided with continued access to educational videos.
- General guidance is offered when extremely low or high blood pressure readings are submitted.
- Monthly blood pressure reports were faxed automatically to primary care provider offices.

Interview Development

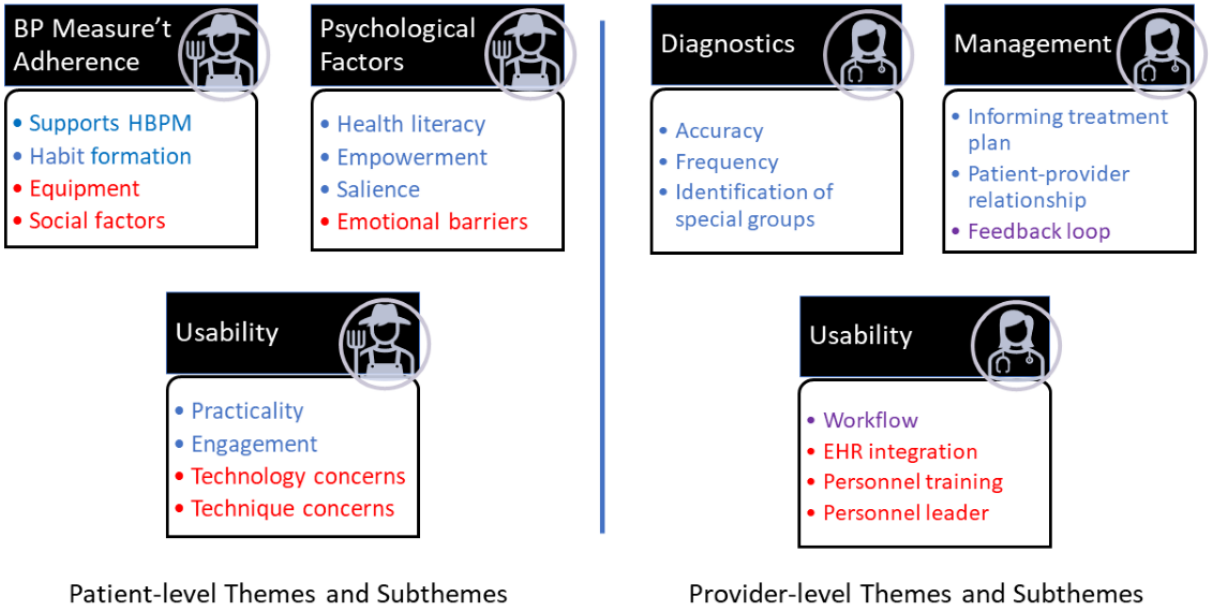
The Consolidated Framework for Implementation Research (CFIR) was used to formulate interview questions [29]. This practical and theory-based guide for systematically assessing potential barriers and facilitators is used to either tailor implementation strategies and adaptations for the innovation being implemented or to explain outcomes of implementations. The CFIR includes 5 domains: characteristics of the intervention, the characteristics of individuals, implementation process, and the inner and outer settings or contexts. Each domain contains multiple constructs. It is not practical to cover every construct in an interview, so a group deliberation strategy was used between authors MFM and SSR to determine the most relevant constructs to address given the innovation under study in the context of primary care office practice. The selected CFIR constructs are listed in Multimedia Appendix 1. These CFIR constructs and definitions were then used to compose the interview questions and additional probes to elucidate details depending on the initial responses received. The interview text is found in Multimedia Appendix 1.

Coding and Analysis

All interviews were recorded and transcribed verbatim by the investigators. Transcripts were thematically analyzed using an inductive coding approach [30,31]). This was accomplished through multiple in-depth readings of the transcripts by investigators (JE and ARM) to find meaningful excerpts related to the implementation of MyBP. These excerpts were then coded and grouped into categories based upon similar semantic or explicit content. The same investigators reviewed the transcripts and coded material independently. The unique coded excerpts were then discussed in detail to reach a consensus and add or subtract from the agreed-upon list of coded segments of text. If a new code was developed, all previously reviewed interviews were reanalyzed to determine the presence or absence of the new code.

After this consensus was reached, the codes were analyzed to form an illustration or "mind map" of the interrelationships of the underlying thoughts and ideas related to each code (Figure 1). This was done without any a priori model or framework (ie, without reference to CFIR). The activity required iterative discussions between investigators to agree upon themes and subthemes based upon similarities between codes to develop a patterned response from the data set [30]. Themes and subthemes were refined to ensure that they were internally consistent and distinct from one another. As a second step, codes and themes were then reviewed and aligned to the CFIR framework. Representative examples were then selected from interview transcripts to denote findings. The data sets generated during this study are available from the corresponding author on reasonable request.

Figure 1. Patient- and provider-level themes and subthemes for codes generated by inductive transcript analysis of primary care provider interviews. Implementation facilitators are indicated by blue font, barriers by red font, and purple represents subthemes that may act as both barriers and facilitators. BP: blood pressure; EHR: electronic health record; HBPM: Home Blood Pressure Monitoring; Measure't: measurement.



Ethical Considerations

This study was approved by the University of Pittsburgh investigational review board (STUDY19050151). Participants received no payment, and all provided signed, informed consent. Personal identifying information is retained in a password protected file and paper documents in a locked cabinet.

Results

Overview

A total of 17 providers agreed to participate and were interviewed for an average of 31 (range 16 to 56) minutes. Participants included 11 physicians and 6 nurses or medical assistants from urban and suburban practices in the Pittsburgh metropolitan area. All 17 interviews were transcribed and included in the analysis. Inductive analysis was applied to generate a mind map of themes and subthemes without any a priori organization or model. This thematic analysis is displayed in Figure 1. Next, unmapped codes were aligned with CFIR. CFIR is organized in 5 domains, each of which contains multiple defined constructs. All 5 CFIR domains were represented in our results below and within each heading we list the subset of constructs under which those findings align.

Innovation Domain: Relative Advantage, Complexity, and Design

Providers perceived a relative advantage for MyBP, reporting that implementing MyBP would offer patients broad support in adhering to systematic HBPM. Further, 1 provider (senior male physician, medium size urban practice) mentioned adherence with HBPM has "… gotta be over 90% I would assume…" compared to the "…50-60% compliance rating on patients without MyBP." MyBP was envisioned as a tool providers could easily imagine using to broadly support BP measurement adherence. Other providers felt that MyBP would assist their patients in setting up a routine and then support adherence. Habit formation was frequently mentioned as another benefit of MyBP, helping patients incorporate systematic HBPM into their daily activities. Using such a set schedule for HBPM gives the patient "… a pretty clear standardized process for the patients to see …" in routinizing their measurement of BP. A senior male physician (small size rural practice) believed that creating a "stable schedule and also sending them messages to remind them to do it is even better… Because you know, you would have a certain amount that would say 'Oh, I was going to do it but I forgot.'" Another provider (senior male physician, large academic practice) suggested that the utility of the MyBP program structure was to "[remind] the patient this is something important … help[ing] with compliance." Providers thought that MyBP would help patient motivation.

By providing between-visit care, MyBP was felt to increase the daily salience of BP control to patients. This program ensured that they would continue to measure and remain aware of their BP despite long gaps between primary care appointments. A senior female physician (large academic practice) noted: "It gets them more involved. It helps them see what the point is ... it just makes their health stay on their radar a little bit more. I said 'out of sight out of mind', it's kind of on them too as soon as they walk out of my office they don't see me again often for 3 or 4 months." By taking continuous measurements, patients may take more notice of and further understand the importance of these values. An early career female physician (large academic practice) noted, that MyBP "gives the patient something they can see, like a running tally …" and that "having the averages come back is helpful because they can see that and they know what's happening with their BP." Allowing patients to measure their BP in a convenient manner, within the comfort of their home was also considered a relative advantage: "[MyBP offers] convenience for the patients to take a BP reading whenever it's reasonable for them. Not having to drive somewhere else to get it done" (female nurse, small suburban

practice). MyBP was viewed as a practical method of obtaining the necessary BP data. A female nurse (large academic practice) stated that, "… it keeps the person on top of their numbers so that they know what they need to do, if they need to adjust their treatment or get treatment." It was emphasized that using patients' desire for more immediate and concrete feedback was an added benefit of MyBP: "…people like the idea of having interaction … they want to do good … You want to get the A, you want reinforcement…" (midcareer female physician, medium size urban practice).

Many thought these measurements obtained from home were a more reliable source of information and were better able to support management decisions. MyBP was noted by providers to enhance their diagnostic precision while managing hypertension. It helped that "the patients … were compliant and even though [their BP readings] were high here in the office, they got good readings at home" (midcareer female physician, medium size urban practice). Further, 1 provider remarked that MyBP helped to confirm a patient's response to medication that was doubted after elevated in-office readings: "the numbers I was getting were actually better than um, I think the patients had been doing during clinic visits. And so, it seems like the blood pressures came down" (senior male physician, large academic practice). This helped providers to clarify the management of patients with previously inappropriately categorized or overtreated hypertension, including those with white coat hypertension. A senior male physician (medium size urban practice) found that MyBP influenced their treatment plans to manage hypertension: it "did a good job…and it did influence my treatment [plan]." Another senior male physician (medium size suburban practice) offered that MyBP "often times it makes the difference between starting somebody on medication or adjusting medication" due to the availability of program-generated home BP data. A senior male physician (medium size urban practice) observed that MyBP aided in some decision-making "in terms of who to treat or who to treat more aggressively, who not to treat more aggressively," and another senior male physician (medium size suburban practice) noted the program "would be very very beneficial … [in] identifying overtreatment as well." These promising insights indicated that providers felt comfortable modifying drug therapy with the help of the program.

In terms of complexity from the provider perspective, when discussing MyBP's features, a female nurse (large academic practice) noted that [MyBP] "is a pretty simple format that … [is] not cutting into my busy schedule" and "I think that that would … enhance maybe compliance with this." However, complexity was also seen as a barrier from the patient perspective. Overall, it was felt that MyBP was easy for patients to use. The same nurse noted that, "I think it's great because I think it is simple… And I think folks need simple." An early career female physician (small suburban practice) added, "I'm someone who isn't super tech savvy, but I think I could easily do this … it seems pretty simply designed." However, there was concern that patients struggling with other self-management behaviors may have difficulty using MyBP. A female nurse (large academic practice) observed, "you have to have an engaged patient who wants to take care of themselves and wants to learn more in order to use the tool that's there and if they don't see the benefit, they're not gonna use it."

Outer Setting Domain: External Pressure, Societal Pressure, and Financing

There were several outer setting barriers that providers noted at the societal level. An early career female physician (small suburban practice) stated, "we already have some barriers to controlling their blood pressure, and I don't know if this would necessarily address… concerns about being able to afford medications, not going for refills, those kinds of things." A senior female physician (large academic practice) used the story of a particular patient to model a larger point, explaining that she is at the "crux of one of our greatest challenges in our healthcare system … the source of the tremendous difficulty isn't medical; it's her life, it's social…" Finally, she expressed skepticism: "I don't know if at the level of MyBP we can address the hot spotter population."

Likewise, insurance policies were considered to be a potential outer setting barrier to the implementation of MyBP. Access to a personal BP monitor was a repeatedly mentioned barrier: "not having a blood pressure cuff and acquiring a blood pressure cuff is a barrier … even if we jump through hoops and so forth, very few people get a blood pressure cuff through their insurance" (female nurse, large academic practice). This provider continued to explain that often those most impacted by socioeconomic barriers are the ones most in need of access to tools such as the BP device, further highlighting the interplay between access to resources and differences in health outcomes.

Individuals' Roles Domain: Need, Capability, Opportunity, and Motivation

Providers perceived that patients have low motivation or capability. Further, 1 midcareer female physician (medium size urban practice) said, "often they [patients] don't get the cuff when you ask them to, or they don't know where to get the cuff at." Although some providers mentioned patient health literacy as a potential barrier to MyBP (capability), they reported that the educational tools provided by the program could address this barrier. MyBP's educational videos assisted with learning "… about how to check proper pressures, and how to do … the proper technique, and uh just explaining the meanings behind those numbers …" This senior male physician (medium size suburban practice) continued, "in the 27 years I've been doing this … I've realized the more that you explain to people and give them information to use the less likely they are to have problems, and … when they do, they understand … what the issue is."

Providers perceived that patients were motivated but that education would be needed to ensure that this did not result in anxiety: "When they're getting a bunch of numbers and they're not really understanding what those numbers mean, I think a potential is there for people to get um scared or excited or something…" (female nurse, large academic practice). Therefore, ensuring that patients have the context to interpret these values and manage adverse emotional responses was of great importance to the success of MyBP. Another provider noted a similar barrier when patients become overly fixated on

knowing their BP at any given point in time: "I mean some are really—some are really diligent, I mean some, some- some people I think kinda overdo it. And they take their blood pressure more than I think they need to" (senior male physician, large academic practice). In summation, providers foresaw circumstances where MyBP could cause stress that may deter patients from a constructive HBPM experience.

Other interviewees noted concern about the technology's capability for some patients. While they viewed texting as convenient, an early career female physician (small suburban practice) was still unconvinced "… about the folks that aren't tech-savvy enough." This same provider felt the interface "would be difficult for them to manage," and a senior male physician (small size rural practice) went on to say "Well, there will be a group that doesn't want to fool around with that. But, um, I mean I still have mine that come in with written pressures all the time..." An adjacent concern included the belief that the use of texting within the MyBP program could lead to input errors. While MyBP was designed to avoid reliance of automated data collection (eg, with Bluetooth), several providers viewed the step of inputting the BP reading or interfacing with MyBP via SMS text messaging as a barrier.

Patient measurement technique error was also a concern as an inability to verify proper technique for each BP measurement. A female nurse (small suburban practice) voiced that "I'd wonder about accuracy overall. I'm sure there's still room for patient error." A senior female physician (large academic practice) felt that using the tool raised more questions: "[there was] more that I would've wanted to know when I got the reports … Was she seated at rest for five minutes? Was she checking in her left arm? Was she checking her blood pressure properly?" While providers felt MyBP would be beneficial in increasing the amount of BP data they could use to inform their treatment plan, the lack of contextual information could lower confidence in the BP data.

They did report that MyBP increased patient opportunity to check BP and increase accuracy. "It's more accurate BP readings than what we get in the hospital. More accurate and more frequent. [*pause*] That they get to record their BPs more, than just once when they come to the hospital…" (female medical assistant, large academic practice).

Inner Setting Domain: Informational Technology Infrastructure, Work Infrastructure, Relational Concerns, Communications, Structural Characteristics, Recipient-Centeredness, Deliverer-Centeredness, Tension for Change, Compatibility, and Available Resources

MyBP was adaptable, which addressed inner setting barriers including time. Providers also found that MyBP helped to elucidate a patient's "true" BP: "patients are able to do it on their time … in a relaxed setting. You get a better picture of their blood pressure. It's hard for us to do that whenever they only come in at a specific time" (female nurse, small suburban practice). They noted confounding variables with in-office measurements, such as when the patient is "so out of breath of just came up 2 flights of steps or something like that" (female nurse, large academic practice).

In addition, providers felt that MyBP enhanced their relationship with their patients, improving their ability to develop rapport. This was noted through a senior male physician's (medium size urban practice) observation that patients "were asking me whether I had seen the reports…and they wanted to know what I thought" with another provider (early career female physician, large academic practice) observing their patients "were pretty excited to show what they've been doing with their BPs." The program reports gave patients an opportunity to engage with their providers and interact beyond typical care interactions. The program provided a platform for patients to not only be held accountable themselves for their HBPM measurements, but also to keep the clinical team accountable, through asking if they had received faxes and initiating more dialogue about their BP.

Patient-provider feedback loops were frequently discussed, not only in terms of how they were improved by the program but also how some issues persisted despite it. A female nurse (large academic practice) felt that they were "getting results in a timely fashion," which is important because "you can't fix what you don't see." Another female nurse (large academic practice) mentioned that the program allowed for "an opportunity for earlier intervention, for medication changes as opposed to waiting, again, another 3 or 6 months." They felt that the between-visit care was improved by virtue of additional data points to overcome clinical and diagnostic inertia. Treatment teams appreciated the advantage of the communication channels offered by the program, especially in its lowering of the required investment of patient time and effort to receive at least some BP information and guide therapy.

There were several providers that noted positive tension for change, such as a senior male physician (small size suburban practice) saying "I think, it will just kind of make more structure to something that I'm doing … Anything to support that or give structure to something, I feel is important … could be helpful." Another senior male physician (small size rural practice) reflected that the data from the program "would be just nice and more formalized." They would already have "the data aggregated so that I wouldn't have to be calculating averages myself" (early career female physician, small suburban practice) as opposed to the current status quo, in which data collection is more piecemeal and nonaggregated, taking "additional time … away from the nurses" (female nurse, small suburban practice). Providers felt that the ability of the program to quickly aggregate and make useful conclusions about BP data offered a significant benefit from a time and effort standpoint.

However, interviewees did believe that uptake of the fax reports and updating clinical practice patterns would take some effort. Speaking to concerns about compatibility with the current clinic flow, a senior male physician (large academic practice) pointed out, "the clinic staff already has a million things to do and so the process would have to be streamlined somehow," and that "you kind of have to … modify that process to what would work in an actual clinic." Providers felt a significant push would be needed to overcome the inertia within clinical practices and

begin to change workflow. Regarding fax reports an early career female physician, small suburban practice, said, "I do get worried about getting information by fax … I'm [away from the clinic] for 2 weeks and … I [c]ould miss something that I would want to see." While a senior male physician (medium size rural practice) commented "And now we're buried in paper again." Interviewed providers believed that direct electronic health record (EHR) integration would aid in implementation of the platform.

Barriers to clinical implementation of MyBP also extended to personnel issues such as the need to expand office staff. A senior male physician (medium size urban practice) reflected that "if we had the staff then I would say we were we we [*sic*] could implement it but we need some additional sta—team members to help us do it" and that hiring new staff presents a "tremendous workload." A female nurse (small suburban practice) felt the "training for staff" was the most important issue facing her practice, as it was difficult for her to make "sure that staff were also properly aware of application of the cuff and all of that …It just goes back to staff education."

Implementation Process Domain: Teaming, Planning, Engaging Innovation Deliverers, and Adapting

It was believed a local "champion" for MyBP would be beneficial in establishing enthusiasm and having the program started at each site. A female nurse (small suburban practice) liked the idea of having a "point person for it so somebody is keeping the list [of enrolled patients] together…" or (senior female physician, large academic practice) if a "MyBP person was housed on site … and summed up the BP reports inter-visit…" Having dedicated MyBP personnel to help with the normal workflow of the program and assist with troubleshooting seemed overall to be beneficial.

There were also safety concerns regarding implementation, speaking to the need for a process for data return. Instead of the monthly report cycle, a midcareer female physician (large academic practice) expressed that they "would have liked more feedback sooner… Sometimes I didn't get it for a while and making a change took time." This thinking also applied to more urgent patient scenarios, in which an early career female physician (small suburban practice) expressed that they would feel concerned "…if I miss data that tells me someone has had very high blood pressures, and no one has checked in to see about symptoms or no one has made a move to try to control their blood pressure better." Although providers saw the between-visit BP data as an advantage compared to standard follow-up, they had persistent concerns that symptoms or extreme BP values would go unnoticed by office staff for several weeks.

Discussion

Principal Findings

This study qualitatively assessed providers' perceptions of the implementation of MyBP, a text-message based program designed to engage patients in ongoing hypertension self-management focused on systematic and continuous HBPM. Given the near-universal competency in using text messaging including among older adults, mobile health (mHealth) using automated SMS text messaging may be effective for population health interventions [32] and specifically in disadvantaged patient populations [27,33]. This report complements patient stakeholder evaluation of MyBP based upon 40 interviews [26]. Here, the transcripts of semistructured interviews to physicians, nurses, and medical assistants were analyzed using pattern identification of concepts to generate de novo codes and themes classified as pertaining to either the patient experience or the practice or provider experience. We then returned to the initial codes and themes to map the findings onto the 5 CFIR domains [29].

Providers felt that MyBP would offer strong foundational support in a patients' efforts to systematically monitor their BP at home. They believed SMS text messaging would facilitate sustainable health-behavior habits without infringing into patients' schedules. This is enhanced by patients' access to video-based educational materials and improved health literacy. As such, providers believed the program helped patients feel more in control of their BP, and in turn view their high BP as more manageable. Providers also stated that the program is practical for patients to use as it connects patients to their health care from the comfort of their homes. This decreased the need to spend time or money on travel to a clinic for BP checks, further supporting a patient's engagement with their BP management. These themes relate to the CFIR Innovation Domain constructs of relative advantage and design. This evidence corroborates patients' reports that MyBP may strengthen their self-efficacy [26], and our quantitative evidence of continued engagement with systematic HBPM aided by the program [27].

Nonetheless, providers saw barriers to implementation. One of the most voiced concerns was patients' difficulties securing personal BP devices. As insurance generally does not provide coverage for BP cuffs, low-income patients are particularly affected. There was also concern that the attention given to HBPM could cause some patients to become fixated on their BP readings. Providers worried that such hypervigilance would become a source of distress. Notably, the MyBP program design discourages fixation by not accepting extra readings or readings outside of the self-selected time windows.

Regarding the basic design of MyBP, providers worried that deploying messaging through SMS text messaging would impede use by patients who do not wish to or are unable to use this technology. Patient self-submitted measurements via SMS text messaging may contain errors if done incorrectly. Alternatives include automated data uploading using a Bluetooth enabled monitor paired to the patient's smartphone and newer cuffless, wearable devices. These approaches are limited by the digital divide and are likely to exacerbate health disparities. Furthermore, providers had concerns about the HBPM measurement technique. As patients would be taking their BP unsupervised, providers wondered if lack of oversight could result in unreliable BP readings.

From the providers' perspective, their experience with MyBP was most notable for a perceived improvement in their ability to diagnose and manage hypertension. The increased number

of measurements and more realistic setting in which the measurements were captured provides valuable data to guide intervisit care, as evidenced by providers' repeated mention of the ease of navigation of the BP reports organized as successive 2-week averages. They expressed that their current practice team lacked a method for organizing large swaths of BP data into a digestible format. The program was also felt to help identify when patients were being over- or under-treated for hypertension, especially in the case of white-coat hypertension, all while improving provider confidence to overcome therapeutic inertia [34]. Providers also saw that patients involved in the program were likely to discuss their BP and use the application interface as a jumping off point for more health-related dialogue, taking more initiative in their hypertension management. In this sense, the program may increase accountability between provider and patient in a bidirectional manner.

Providers expressed concern about implementing the MyBP program within existing clinical workflows. They thought that the BP fax reports may prove cumbersome to sort through given their large patient volume and ongoing transition to paperless records, hindering the quick review of BP data. Often discussion of the fax reports led to an appeal for the integration of BP data directly into the EHR, though there was some skepticism regarding interoperability. Providers varied in their suggestions about where such HBPM data should be located within the EHR (ie, vitals, outside documents, or reports).

A desire for more dedicated training was frequently voiced. The goal would be to improve staff awareness and management of the program, as well as designation of a dedicated team member as the program "champion." These concerns were exacerbated by the worry that with the reports generated monthly, there could be dangerously high or low BP values that were not addressed expeditiously. This may require close monitoring and scrutiny through additions to staff workflow. Collectively, the above themes constitute barriers to the implementation spanning CFIR Innovation Design and Cost, Inner Setting Work Infrastructure and Communications, and Implementation Process Teaming and Adapting.

Future iterations of the program should thus focus on these barriers of workflow integration and staff training, possibly including a local champion. Program modification to enable automated transfer of BP data into the EHR requires improved interoperability, although all values are already digitized and contain 2-week BP averages. These BP report summaries could be generated automatically in plain text and routed to that section of the EHR dictated by program design or user preference. Notably, incoming actionable health data can impact medicolegal liability. The barriers identified highlight that despite numerous advantages of the program in improving the diagnosis and management of hypertension via utilitarian patient interface, there is still a significant need for implementation supports and related resources. On the other hand, the application's operation is more automated, efficient, and scalable than most other programs that support patients in HBPM [10].

The report contributes to an otherwise underdeveloped literature on implementation of programs for systematic HBPM. Prior qualitative research indicates many positive aspects of mHealth hypertension programs leading to improved self-management [35], whereas without a well-designed tool to assist with systematic home BP measurement patients often fail to comply with collection and reporting of HBPM data [36]. Even the best resourced and tested mHealth intervention for hypertension management was rated by providers as more challenging to implement than paper-based BP reports from patients [37].

Study limitations include the relatively small number of providers interviewed. Furthermore, some interviewed providers had had no direct experience with MyBP, though they did have patients performing HBPM. Further, most of those interviewed worked within the same health care network, such that their opinions may have limited generalizability. Stakeholder input from providers in diverse communities and clinical settings would generate additional stakeholder insight.

Conclusions

Uncontrolled hypertension is a serious and highly prevalent condition for which new approaches are needed. Primary care providers felt that a program such as MyBP can support and improve patient engagement with HBPM and engagement with self-managing their hypertension, while concurrently gathering and organizing actionable data to guide prescribed pharmacotherapy. Notwithstanding this, providers also identified clinical and patient-centric barriers to implementation of the program in office practice settings. The themes of increased data quality and support for healthy habit formation in patients were lauded. Providers collectively described the need for additional supports and resources as well as adaptations to the program itself. These included staff training and workflow adjustments, better reporting flexibility and EHR interface, and parallel resources to cover the out-of-pocket cost of BP monitors. Given the widespread challenge of uncontrolled hypertension further health services research should advance the design and deployment of technology-leveraged programs supporting systematic HBPM and self-management support.

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Conflicts of Interest

Author MFM is the founder of a start-up company exploring commercialization of MyBP. The authors have no other potential conflicts of interest.

Multimedia Appendix 1
Supplementary materials.
[DOCX File , 26 KB - cardio_v7i1e51316_app1.docx]

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Abbreviations

BP: blood pressure
CFIR: Consolidated Framework for Implementation Research
EHR: electronic health record
HBPM: home BP monitoring
mHealth: mobile health

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Original Paper

Comparing Explainable Machine Learning Approaches With Traditional Statistical Methods for Evaluating Stroke Risk Models: Retrospective Cohort Study

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Abstract

Background: Stroke has multiple modifiable and nonmodifiable risk factors and represents a leading cause of death globally. Understanding the complex interplay of stroke risk factors is thus not only a scientific necessity but a critical step toward improving global health outcomes.

Objective: We aim to assess the performance of explainable machine learning models in predicting stroke risk factors using real-world cohort data by comparing explainable machine learning models with conventional statistical methods.

Methods: This retrospective cohort included high-risk patients from Ramathibodi Hospital in Thailand between January 2010 and December 2020. We compared the performance and explainability of logistic regression (LR), Cox proportional hazard, Bayesian network (BN), tree-augmented Naïve Bayes (TAN), extreme gradient boosting (XGBoost), and explainable boosting machine (EBM) models. We used multiple imputation by chained equations for missing data and discretized continuous variables as needed. Models were evaluated using C-statistics and F_1-scores.

Results: Out of 275,247 high-risk patients, 9659 (3.5%) experienced a stroke. XGBoost demonstrated the highest performance with a C-statistic of 0.89 and an F_1-score of 0.80 followed by EBM and TAN with C-statistics of 0.87 and 0.83, respectively; LR and BN had similar C-statistics of 0.80. Significant factors associated with stroke included atrial fibrillation (AF), hypertension (HT), antiplatelets, HDL, and age. AF, HT, and antihypertensive medication were common significant factors across most models, with AF being the strongest factor in LR, XGBoost, BN, and TAN models.

Conclusions: Our study developed stroke prediction models to identify crucial predictive factors such as AF, HT, or systolic blood pressure or antihypertensive medication, anticoagulant medication, HDL, age, and statin use in high-risk patients. The explainable XGBoost was the best model in predicting stroke risk, followed by EBM.

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KEYWORDS

stroke; machine learning; risk prediction model; explainable artificial Intelligence; risk factor; cohort study; high-risk patient; hypertension

Introduction

Cardiovascular disease, especially stroke, is a major cause of death globally. Many risk factors for stroke include nonmodifiable (eg, ethnicity, age, and sex) and modifiable risk factors (eg, hypertension [HT], diabetes mellitus [DM], dyslipidemia [DLP], smoking, and alcohol consumption) [1]. Improved understanding of disease prediction and risk stratification are active epidemiological research areas to help clinicians target preventive treatment to those most likely to benefit.

The American Heart Association or American Stroke Association defines ischemic and hemorrhagic stroke [2]. Ischemic stroke is defined as an episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction. A hemorrhagic stroke is characterized by an intracerebral hemorrhage, which involves bleeding within the brain tissue (parenchyma) or ventricular system. This condition, which is not caused by trauma, encompasses instances of spontaneous parenchymal hemorrhages or those occurring following a brain infarction. The rapid development of neurological dysfunction symptoms is a defining consequence of this internal bleeding.

There are 2 common sources of ischemic stroke: atherosclerotic stroke and cerebral embolism [3], with the former being more common. Atherosclerosis within a significant cerebral blood vessel can vary in severity from small changes in diameter to severe stenosis that can cause clotting at the site of the atherosclerotic plaque leading to blood flow obstruction, causing a stroke [4]. While a cerebral embolism can originate from other regions of the body, sometimes as a consequence of atrial fibrillation (AF), the emboli travel and obstruct the distal cerebral arteries preventing brain tissue perfusion leading to ischemia.

There are multiple risk factors for stroke given the various pathological pathways involved [5]. The Framingham Stroke Risk Profile is a composite vascular risk score that predicts 10-year stroke risk based on 8 risk factors, that is, age, systolic blood pressure (SBP), antihypertensive therapy, DM, cigarette smoking, cardiovascular disease, AF, and left ventricular hypertrophy [6]. The INTERSTROKE consortia identified 10 modifiable risk factors associated with 90% of the stroke population-attributable risk [7,8]. HT is regarded as the most important modifiable risk factor for hemorrhagic stroke, while recent smoking, DM, apolipoproteins, and cardiac causes are more critical factors associated with ischemic stroke.

Risk or prognostic prediction models of stroke have been developed using conventional statistical methods (such as multiple logistic regression [LR] or Cox proportion hazard [CPH] models) based on linear relationships with the outcome measure, allowing for 2-way interactions between risk factors [5,6,9-11]. In reality, the interaction between risk factors may be more complex, of a higher order, or nonlinear. Machine learning (ML) models free from prior hypotheses have been recently used for disease prediction given their ability to better consider the interactions present, including nonlinear relationships [12]. However, the causal inference of these methods remains questionable, in particular, whether these ML models actually reflect the underlying relevant biology or simply improve prognostic performance.

Many ML models (eg, decision tree, tree ensembles, support vector machines, and neural networks) and deep learning approaches have been compared to conventional statistical models to assess their ability to detect nonlinear associations and multifaceted interactions [13-17]. Deep learning models are composed of multiple hidden layers that include millions of parameters without clear mechanistic meaning, representing "black-box" models with little transparency [18,19]. To address this shortcoming, explainable ML approaches have become popular by improving features such as understandability, comprehensibility, interpretability, explainability, and transparency [18]. Explainable models include Bayesian network (BN) and tree-augmented Naïve Bayes (TAN) models, both of which are probabilistic graphical models [20]. An explainable boosting machine (EBM) is based on a generalized additive model and is considered a "glass-box" model given its improved transparency and interpretability [21]. These models excel in capturing complex relationships and dependencies among features, providing a more comprehensive understanding of the data structure and interplay between different risk factors when compared with the traditional statistical LR model. Furthermore, extreme gradient boosting (XGBoost) is considered a state-of-the-art approach for evaluating tabular data [22].

Therefore, this study used real-world cohort data and explainable ML models to identify risk factors for stroke occurrence in high-risk patients. The importance and ranking of risk factors were used as a proxy for explainability.

Methods

Study Design

This study is a retrospective cohort analysis of high-risk patients with stroke treated at Ramathibodi Hospital in Bangkok, Thailand, from January 2010 to December 2020. The study included patients aged 18 years or older with at least 1 diagnosis of HT, AF, DM, or DLP. Participants were excluded if they had a prior stroke at the initial hospital visit or had only 1 visit during the study period.

The patient cohort was identified from Ramathibodi Hospital's electronic database using the International Classification of Diseases, 10th Revision (ICD-10) codes for risk factors and clinical features, such as HT (I10-I16), DM (E08-E13), AF (I48), and DLP (E78). The primary end points of interest were the development of ischemic stroke (I63) and hemorrhagic stroke (I61), as indicated by their respective ICD-10 codes. The features and criteria used in this study can be found in Multimedia Appendix 1.

Predictive Features and Outcome

Each patient was followed up until stroke occurrence, loss to follow-up, or censoring at study end (December 31, 2020). The latter 2 events were censored on their final visit or study end date, respectively.

Baseline study predictive features included age, sex, AF, HT, DM, DLP, SBP, plasma glucose (PG), serum creatinine, BMI,

low-density lipoprotein and high-density lipoprotein (HDL), triglyceride level, and medications (antihypertensives, antiplatelets, oral hypoglycemics and insulin, statin and nonstatin lipid-lowering drugs, and anticoagulants). These baseline features were identified and retrieved when patients were first identified in our electronic medical records. The missing data in this study, assumed to be missing at random, were filled in using multiple imputation by chained equations via scikit-learn's IterativeImputer [23,24]. The percentage of missing data and features used in multiple imputation by chained equations for each imputed variable are detailed in Table S1-S3 in Multimedia Appendix 1. Continuous data were categorized on the basis of previous literature to improve interpretation and as a requirement of the BN model [25]. Details of discretization are provided in Table S4 in Multimedia Appendix 1. We randomly separated the data by hospital numbers into development and test sets with a ratio of 80:20; each patient appeared in only 1 data set to maintain independence between the data sets. Characteristics of patients between the 2 data sets are comparable, see Table S5 in Multimedia Appendix 1.

Model Construction

We compared model performance and explainability between LR, CPH, BN, TAN, XGBoost, and EBM. We normalized continuous variables and used recursive feature elimination to select features in the LR model, whereas feature selection in XGBoost and EBM included self-selecting features during node splitting [26]. We manually selected features in the BN and TAN based on stroke pathophysiology and considered the appropriate network structure.

Scikit-learn served as the ML library for LR and XGBoost, with hyperparameter tuning using grid and random searches with successive halving (HalvingGridSearchCV and HalvingRandomSearchCV) and assigned imbalance ratio as weights to counter imbalanced class effects. We extracted LR coefficients and XGBoost's features' importance together with Shapley Additive Explanations (SHAP) to represent their explainability [27]. We constructed EBM using the open-source package *InterpretML* (Microsoft) [21]. Variable and interaction effects were plotted to determine their impact on the outcome.

We built a BN using GeNIe Modeler (BayesFusion, LLC) software based on the known causal pathways of disease [28] and trained it using discretized data. TAN structures were also determined using the training data and GeNIe (BayesFusion, LLC) software. The architectural details of the BN and TAN are shown in Multimedia Appendix 2. Models were evaluated with C-statistics and F_1-scores. C-statistics, or area under receiver operating characteristics curve (AUC-ROC), provide a measure of a models' ability to accurately distinguish between positive and negative classes (0.5 being no predictive ability beyond chance and 1 being perfect prediction), while the F_1-score represents a measurement of the balance between precision and recall in binary classification, which computes by harmonic mean between precision and recall.

Ethical Considerations

The data were anonymized to ensure confidentiality and privacy protection. This study was approved by Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University (COA. MURA2021/255). The committee waived the need to obtain consent for the collection, analysis, and publication of the retrospectively obtained and anonymized data for this noninterventional study.

Results

A total of 275,247 high-risk patients were included in this cohort, of whom 9659 (3.5%) experienced a stroke. Specifically, 7874 patients had an ischemic stroke, and 2427 patients had a hemorrhagic stroke. The patient cohort included 19,324 (7%) patients with AF, 98,836 (36%) with DM, 228,055 (83%) with DLP, and 211,430 (77%) with HT. Table 1 presents the baseline characteristics, revealing significant differences between the stroke and nonstroke groups for almost all variables, except for DLP (P=.70). The data set was divided into development and validation sets, comprising 220,198 and 55,049 patients, respectively.

Table 1. Cohort summary statistics.

	Stroke (N=9659)	Nonstroke (N=265,588)	*P* value
Age (years), mean (SD)	64.7 (13)	58 (14.1)	<.001
Sex			<.001
Male, n (%)	5107 (0.05)	101,700 (0.95)	
Female, n (%)	4552 (0.03)	168,440 (0.97)	
Medication, n (%)			
Antihypertensive medication			<.001
Yes	4096 (0.03)	141,188 (0.97)	
No	5563 (0.04)	124,400 (0.96)	
Hypoglycemic medication			<.001
Yes	1659 (0.03)	59,150 (0.97)	
No	8000 (0.04)	206,438 (0.96)	
Lipid-lowering medication (nonstatin)			<.001
Yes	913 (0.02)	38,580 (0.98)	
No	8746 (0.04)	227,008 (0.96)	
Statin medication			<.001
Yes	3369 (0.03)	126,508 (0.97)	
No	6290 (0.04)	145,370 (0.96)	
Antiplatelet medication			<.001
Yes	2868 (0.05)	54,992 (0.95)	
No	6791 (0.03)	217,387 (0.97)	
Anticoagulant medication			<.001
Yes	622 (0.06)	10,015 (0.94)	
No	9037 (0.03)	255,573 (0.97)	
Vital signs, mean (SD)			
Systolic blood pressure (mm Hg)	138 (22.7)	133.6 (20.9)	<.001
Diastolic blood pressure (mm Hg)	77.5 (11.1)	78 (10)	.002
BMI (kg/m^2)	25.2 (4.4)	25.5 (4.8)	<.001
Risk factors, n (%)			
Atrial fibrillation			<.001
Present	2591 (0.13)	16,733 (0.87)	
Absent	7068 (0.02)	248,855 (0.98)	
Dyslipidemia			.70
Present	8017 (0.04)	220,038 (0.96)	
Absent	1642 (0.03)	45,550 (0.97)	
Hypertension			<.001
Present	8936 (0.04)	202,494 (0.96)	
Absent	723 (0.01)	63,094 (0.99)	
Diabetes mellitus			<.001
Present	4202 (0.04)	94,634 (0.96)	
Absent	5457 (0.03)	170,954 (0.97)	
Laboratory values, mean (SD)			
Plasma creatinine (mg/dL)	1.2 (1.4)	1.14 (1.7)	.001

	Stroke (N=9659)	Nonstroke (N=265,588)	*P* value
Blood sugar (mg/dL)	128.3 (64.2)	111.6 (46)	<.001
Hemoglobin A_{1c} (%)	6.7 (1.7)	6.4 (1.5)	<.001
Low-density lipoprotein (LDL) (mg/dL)	119.9 (43.2)	128.3 (41.1)	<.001
High-density lipoprotein (HDL) (mg/dL)	45.7 (13.5)	50.9 (14)	<.001
Triglyceride (md/dL)	142 (96.7)	136.1 (94.8)	<.001

In terms of discriminative performance, the XGBoost model yielded the highest C-statistic (0.89, 95% CI 0.88-0.90) and F_1-score (0.80), followed by EBM and TAN with C-statistics of 0.87 (95% CI 0.86-0.87) and 0.83 (95% CI 0.82-0.83), respectively. LR and BN models demonstrated similar performances, with C-statistics of 0.80 (95% CI 0.79-0.81). These results are presented in Table 2.

Table 2. Model performance of stroke risk prediction over a 10-year period.

Model	C-statistics (95% CI)	F_1-score
Logistic regression	0.80 (0.79-0.81)	0.73
Bayesian network	0.80 (0.79-0.81)	0.73
Explainable boosting machine	0.87 (0.86-0.87)	0.78
XGBoost[a]	0.89 (0.88-0.90)	0.80
Tree-augmented Naïve Bayes	0.83 (0.82-0.83)	0.73

[a]XGBoost: extreme gradient boosting.

The LR model identified several factors significantly associated with stroke including AF (odds ratio [OR] 5.93, 95% CI 5.86-5.99), HT (OR 5.14, 95% CI 5.1-5.18), antihypertensive medication (OR 0.3, 95% CI 0.24-0.35), antiplatelets (OR 3.01, 95% CI 2.96-3.07), HDL (OR 0.76, 95% CI 0.74-0.78), and age (OR 1.31, 95% CI 1.29-1.33) as shown in Table 3. Based on feature importance ranking and SHA*P* values, the XGBoost model identified AF, SBP, HDL, PG, antihypertensive medication, HT, and antiplatelets as significant factors associated with stroke occurrence (Figure S1 in Multimedia Appendix 3). The EBM model identified PG, antihypertensive medication, SBP, HDL, HT, and AF as significant features, with interaction terms providing no additional predictive power (Multimedia Appendix 4). For the BN and TAN models, advanced age (>75 years) combined with AF were the strongest factors. Overall, AF, HT, and antihypertensive medication emerged as common significant factors across most models. Notably, AF was the strongest factor in the LR, XGBoost, BN, and TAN models. Receiver operating characteristic and precision-recall curves of each model are provided in Multimedia Appendix 5.

Table 3. Odds ratio (OR) of variables from multivariate logistic regression model.

	OR (95% CI)
Categorical variable	
AF[a]	5.93 (5.86-5.99)
HT[b]	5.14 (5.1-5.18)
antiHT[c]	0.3 (0.24-0.35)
antiPL[d]	3.01 (2.96-3.07)
antiDM[e]	0.51 (0.43-0.6)
DLP[f]	1.86 (1.78-1.93)
Statin	0.61 (0.56-0.67)
antiDLP[g]	0.67 (0.59-0.75)
antiCoag[h]	0.68 (0.58-0.79)
isMale[i]	1.4 (1.36-1.44)
DM[j]	1.31 (1.25-1.36)
Continuous variable	
HDL[k] (mg/dL)	0.76 (0.74-0.78)
Age (years)	1.31 (1.29-1.33)
PG[l] (mg/dL)	1.31 (1.29-1.32)
Cr[m] (mg/dL)	0.89 (0.87-0.91)
SBP[n] (mmHg)	1.11 (1.09-1.13)
BMIcalc[o] (kg/m^2)	0.94 (0.92-0.96)
LDL[p] (mg/dL)	1.04 (1.02-1.07)
TG[q] (mg/dL)	0.97 (0.95-0.99)

[a]AF: atrial fibrillation.
[b]HT: hypertension.
[c]antiHT: antihypertensive medication.
[d]antiPL: antiplatelet medication.
[e]antiDM: hypoglycemic medication.
[f]DLP: dyslipidemia.
[g]antiDLP: nonstatin lipid-lowering medication.
[h]antiCoag: anticoagulant medication.
[i]isMale: male.
[j]DM: diabetes mellitus.
[k]HDL: high-density lipoprotein.
[l]PG: plasma glucose.
[m]Cr: serum creatinine.
[n]SBP: systolic blood pressure.
[o]BMIcalc: body mass index.
[p]LDL: low-density lipoprotein.
[q]TG: triglycerides.

Discussion

Principal Findings

We investigated a retrospective cohort of patients at high risk of developing stroke to develop prediction models for stroke occurrence. The models identified AF, HT, or SBP or antihypertensive medication, anticoagulant medication, HDL, age, and statin use as important features in predicting stroke using both conventional LR and ML models. Our findings provide robust, transparent, and explainable ML models for stroke risk prediction using routinely collected clinical data accessible in general health care settings.

Explainability

Explainability and transparency of risk prediction models are important for facilitating the prescribing of individualized treatments (precision medicine) in real-world clinical settings [29]. Improved patient understanding also leads to empowerment and improved medication or treatment adherence [30]. Improved understanding and use of ML models in both prehoc and post hoc analyses are growing. According to Arrieta et al [18], LR, CPH, BN, TAN, and EBM models are considered transparent and understandable in themselves, while XGBoost requires post hoc analysis to improve explainability, including local interpretable model-agnostic explanations [31], SHAP, partial dependence plots, feature importance [32], or DeepLIFT [17,18,33]. Explainability can be classified into 3 types: application-grounded, human-grounded, and functionality-grounded [34]. Application- and human-grounded categories involve human interpretability, that is, models that are easily comprehensible to a layperson, without the need for specialized technical knowledge or expertise; functionality grounded refers to the methods or algorithms used and their quantitative evaluation.

Some studies have explored the benefits of white-box ML prediction models, such as BN and EBM. For example, Park et al [35] used BN with a TAN algorithm to predict 3-month functional outcomes after stroke with an AUC-ROC of 0.889. Kanwar et al [36] used a BN-derived risk prediction model that improved the prediction of 1-year survival in patients with pulmonary arterial HT compared to the Kaplan-Meier method in REVEAL (version 2.0), with an AUC-ROC of 0.8 versus 0.76 [37,38]. Lou et al [39] showed that EBM approaches could achieve accuracy close to that provided by random forest models while providing good interpretability. White-box EBM approaches are also known as “glass-box” models that allow for interaction terms between variables within the model. All of these models performed well, and their white-box nature enables transparency, making them useful for clinicians to explain and translate medical knowledge for a more confident application in clinical settings. A previous study compared multiple ML models to predict stroke and address the class imbalance problem using a multilayer perceptron classifier to achieve the lowest false-negative rate (18.60%) and SHAP to investigate the impact of risk factors on stroke prediction [40]. However, this approach was considered a post hoc analysis and not representative of a white-box model.

To date, investigation of the predictive capabilities of multiple explainable models in the context of stroke risk assessment using real-world data has been limited. Our study addresses this knowledge gap through a novel approach that compares the performance metrics for several explainable models, resulting in significantly improved predictive accuracy, further informing the existing literature. ML models generally outperform traditional statistical methods, supported by AUC-ROCs that represent sufficient improvement to be clinically actionable, that is, AUC-ROCs over 0.80-0.85. This does not mean that all ML methods are superior to traditional statistical methods in all applications, and users should keep an open mind. Another benefit of transparent and explainable models is the rational and selective approach to the choice of predictors. Data mining methods used without regard to causative pathways can include variables that cause collider bias and reduce model performance or may lead to embedded bias within the observational data.

We seek to further contextualize our study findings in relation to the existing literature while also acknowledging the unique characteristics of our study population. The significant features we identified as contributing to stroke risks, such as AF and HT, have been extensively reported previously, providing validation of our findings [41]. However, it is important to note that our study offers additional insight into the strength and interaction of these risk factors to improve our understanding of stroke risk. They also show the potential to improve model performance over traditional approaches even when starting with an identical data set.

The integration of these models into clinical workflows could provide real-time, personalized risk assessments, guiding clinicians toward more targeted and effective interventions. For instance, a patient identified as high risk could be prioritized for aggressive preventive measures, such as rigorous lifestyle modification, counseling, or intensified medication regimens. Conversely, if a patient is predicted to have a lower stroke risk, they may avoid unnecessary treatments and potential side effects, or they might require less intensive follow-up within the hospital setting. This individualized approach would enhance the personalization of stroke prevention strategies, potentially improving patient outcomes.

In addition, the interpretability of the models used helps health care professionals to better understand the key drivers of the predicted stroke risk. This transparency could facilitate more informed and confident decision-making, bridging the gap between complex ML algorithms and their practical application in a clinical setting. Ultimately, these advances could lead to more efficient and effective personalized health care, underpinned by evidence-based, data-driven decisions.

Limitations

There were several limitations to our study. First, other important epidemiological factors, such as smoking status, education, and alcohol consumption, were not included within our risk prediction models as the information was not recorded in the electronic medical records. Many variables rely on the accuracy of ICD-10 coding, which may be subject to miscoding or misdiagnosis that would reduce model performance. Our study cohort encompassed a somewhat narrow demographic

range of an “at-risk” population. We recognize that stroke risk factors may vary across different populations, highlighting the need for externally validating our stroke prediction model in the future before wider application.

Conclusions

Our study demonstrates predictive accuracy and explainability for stroke risk prediction models in high-risk patients. The key findings highlight the impact of AF, HT, and blood pressure control as significant risk factors for stroke emphasizing the potential benefits of screening and early detection, especially within patients for whom these risk factors are prominent. Furthermore, our findings confirm the robustness and interpretability of ML models such as XGBoost, EBM, and BN in handling complex, real-world health data and the potential to improve model performance even when starting with the same data set as traditional approaches.

Looking ahead, we anticipate significant opportunities for further research using these approaches. The continued evolution of ML techniques provides an avenue for refining prediction models, possibly by incorporating additional or alternative feature sets. Moreover, future studies could explore the effects of different interventions on stroke risk, such as lifestyle modifications or novel therapeutic agents. In doing so, our understanding of stroke prevention and management may be enhanced, potentially improving patient outcomes. By pushing the boundaries of explainable ML in health care, these findings hold the potential to revolutionize clinical practice, empowering physicians and patients with clear, actionable insights for better health outcomes.

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Data Availability

Further use of data can be requested from the corresponding author.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Data management.
[DOCX File , 27 KB - cardio_v7i1e47736_app1.docx]

Multimedia Appendix 2
Bayesian network and tree-augmented Naïve Bayes.
[DOCX File , 723 KB - cardio_v7i1e47736_app2.docx]

Multimedia Appendix 3
Extreme gradient boosting.
[DOCX File , 61 KB - cardio_v7i1e47736_app3.docx]

Multimedia Appendix 4
Explainable boosting machine.
[DOCX File , 60 KB - cardio_v7i1e47736_app4.docx]

Multimedia Appendix 5
Receiver operating characteristic curve and precision-recall curve from baseline models.
[DOCX File , 110 KB - cardio_v7i1e47736_app5.docx]

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Abbreviations

AF: atrial fibrillation
AUC-ROC: area under receiver operating characteristics curve
BN: Bayesian network
CPH: Cox proportional hazard
DLP: dyslipidemia
DM: diabetes mellitus
EBM: explainable boosting machine
HDL: high-density lipoprotein
HT: hypertension
ICD-10: International Classification of Diseases, 10th Revision
LR: logistic regression
ML: machine learning
OR: odds ratio

PG: plasma glucose
SBP: systolic blood pressure
SHAP: Shapley Additive Explanations
TAN: tree-augmented Naïve Bayes
XGBoost: extreme gradient boosting

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Original Paper

Remotely Delivered Cardiac Rehabilitation Exercise for Coronary Heart Disease: Nonrandomized Feasibility Study

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Abstract

Background: Exercise-based cardiac rehabilitation (CR) is recommended for coronary heart disease (CHD). However, poor uptake of and poor adherence to CR exercise programs have been reported globally. Delivering CR exercise classes remotely may remove some of the barriers associated with traditional hospital- or center-based CR.

Objective: We have developed a bespoke platform, Eastern Corridor Medical Engineering Centre–Cardiac Rehabilitation (ECME-CR), to support remotely delivered CR exercise. This pilot trial sought to test the ECME-CR platform and examine the efficacy and feasibility of a remote CR exercise program compared to a traditional center-based program.

Methods: In all, 21 participants with CHD were recruited and assigned to either the intervention or control group. Both groups performed the same 8-week exercise program. Participants in the intervention group took part in web-based exercise classes and used the ECME-CR platform during the intervention period, whereas participants in the control group attended in-person classes. Outcomes were assessed at baseline and following the 8-week intervention period. The primary outcome measure was exercise capacity, assessed using a 6-minute walk test (6MWT). Secondary outcomes included measurement of grip strength, self-reported quality of life, heart rate, blood pressure, and body composition. A series of mixed between-within subjects ANOVA were conducted to examine the mean differences in study outcomes between and within groups. Participant adherence to the exercise program was also analyzed.

Results: In all, 8 participants (male: n=5; age: mean 69.7, SD 7.2 years; height: mean 163.9, SD 5.4 cm; weight: mean 81.6, SD 14.1 kg) in the intervention group and 9 participants (male: n=9; age: mean 69.8, SD 8.2 years; height: mean 173.8, SD 5.2 cm; weight: mean 94.4, SD 18.0 kg) in the control group completed the exercise program. Although improvements in 6MWT distance were observed from baseline to follow-up in both the intervention (mean 490.1, SD 80.2 m to mean 504.5, SD 93.7 m) and control (mean 510.2, SD 48.3 m to mean 520.6, SD 49.4 m) group, no significant interaction effect ($F_{1,14}$=.026; P=.87) nor effect for time ($F_{1,14}$=2.51; P=.14) were observed. No significant effects emerged for any of the other secondary end points (all P>.0275). Adherence to the exercise program was high in both the intervention (14.25/16, 89.1%) and control (14.33/16, 89.6%) group. No adverse events or safety issues were reported in either group during the study.

Conclusions: This pilot trial did not show evidence of significant positive effect for either the remotely delivered or center-based program. The 6MWT may not have been sufficiently sensitive to identify a change in this cohort of participants with stable CHD. This trial does provide evidence that remote CR exercise, supported with digital self-monitoring, is feasible and may be considered for individuals less likely to participate in traditional center-based programs.

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KEYWORDS

cardiac rehabilitation; exercise; coronary heart disease; CHD; coronary; cardiovascular; virtual rehabilitation; remote rehabilitation; digital health; heart; rehabilitation; cardiac; digital platform; digital; intervention; program; physical activity; fitness

Introduction

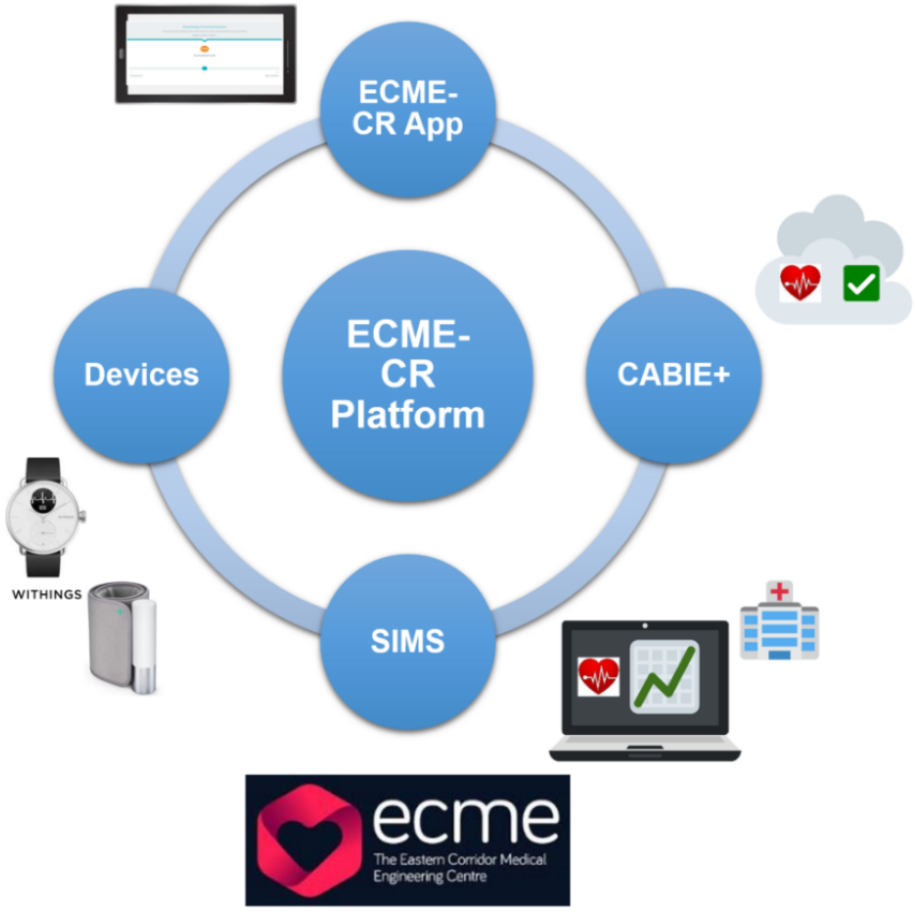
Coronary heart disease (CHD) is the most common cause of death globally, responsible for 16% of the world's total deaths in 2019 [1]. Cardiac rehabilitation (CR) is a multidisciplinary intervention and is well recognized as the standard of care in CHD management. CR typically involves risk factor education, supervised exercise training, and psychological support. Numerous studies have shown that CR can aid in the recovery from an acute cardiac event and help to prevent further illness and mortality [2]. Although models vary, CR usually consists of 4 phases: phase I (in-hospital patient period; consists of education about CHD risk factors and early mobilization, with the goal of achieving functional independence at the time of discharge); phase II (postdischarge from hospital; continuing to mobilize and gradually increase functional capacity); phase III (structured exercise and education program); and phase IV (maintenance; patients receive encouragement toward maintaining an active and healthy lifestyle and continuing their exercise program). Phase III and IV CR is usually delivered in a clinical setting at hospital outpatient departments, rehabilitation clinics, or community centers. Structured exercise training is the cornerstone of both phase III and IV CR.

The benefits of exercise have been widely established in the literature, playing a key role in the primary and secondary prevention of not only CHD but a wide range of other chronic diseases such as diabetes, cancer, and depression [3-5]. CR exercise has been shown to significantly reduce all-cause and cardiac mortality compared to standard medical care without structured exercise training or advice [6]. However, despite the reported benefits, referral to and uptake of exercise-based CR are poor [7]. Multiple barriers to participation exist, such as long commutes, transportation issues, inconvenient scheduling, and work or family responsibilities [8-10]. A more recent review examined CR models based in the United States and highlighted that the reasons for low CR participation are multifactorial, with physician-, patient-, and system-related factors all being cited [11]. A suggested alternative to the traditional hospital-, clinic-, or center-based model of CR is home-based CR, where components of CR are delivered directly into the person's home. Home-based CR increases patient accessibility and overcomes many of the obstacles that may be present with traditional center-based CR [11]. A scientific statement from the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, and the American College of Cardiology advocated for home-based CR for low-to-moderate risk patients [12], and evidence from systematic reviews comparing home- and center-based CR concluded that home-based CR programs were not inferior to center-based programs [13,14]. Using technology to deliver home-based CR has received increased interest the past decade, and this was furthered heightened with the onset of the COVID-19 pandemic.

The pandemic had a severe impact on CR services worldwide. A global survey gave an indication of the scale of the impact that COVID-19 had on CR, with approximately 75% of CR programs temporarily ceasing and other programs ceasing the initiation of new patients and reducing components delivered [15]. Many CR services changed the mode of delivery and began delivering home-based cardiac tele-rehabilitation to patients via videoconferencing platforms to curb the spread of COVID-19 infections. Cardiac tele-rehabilitation can be defined as the use of information and communication technologies, such as the internet, telephone, or videoconferencing, to deliver the components of CR completely outside of the traditional hospital, clinic, or center environment. A number of reviews have been conducted outlining the effectiveness of cardiac tele-rehabilitation intervention; however, these predominately used telephone calls for patient monitoring [16,17]. A more recent systematic review and meta-analysis have shown that home-based cardiac tele-rehabilitation is at least as effective as traditional center-based CR and, in some cases, more effective for improving exercise capacity, physical activity, quality of life, and depression scores in a population with CHD [18]. The trials included in this review largely used web-based platforms and smartphone apps delivering comprehensive home-based CR, including CHD risk factors management, physical activity, smoking cessation, medication adherence, and stress management. However, the physical activity prescription in these trials largely involved individualized physical activity programming and advice. To our knowledge, little work has been undertaken examining the remote delivery of structured CR exercise classes.

We have developed a bespoke, innovative solution to support the web-based delivery of CR exercise classes. The Eastern Corridor Medical Engineering Centre–Cardiac Rehabilitation (ECME-CR) digital health platform (Figure 1) has been fully described elsewhere [19]. Briefly, the platform consists of a web-based app (ECME-CR), which is used during exercise classes for guidance, monitoring, and support. Two off-the-shelf consumer devices—the Withings ScanWatch and the Withings BPM Connect—are integrated with the platform and are used to collect health and well-being data during web-based CR exercise classes as well as during the intervention period. CABIE+ is a data collection and aggregation system, which is used by the platform to organize and store the data acquired from the ECME-CR app and Withings devices. SIMS is an information management system, which is used for viewing the data collected from the app and the Withings devices in near-real time.

Figure 1. Overview of the Eastern Corridor Medical Engineering Centre–Cardiac Rehabilitation (ECME-CR) Digital Health Platform.



A pilot trial was conducted to examine the effectiveness of a remotely delivered CR exercise program supported by the ECME-CR platform in adults with CHD. We compared the effectiveness outcomes of those participating in the remotely delivered CR exercise program to a control group who participated in a traditional center-based CR exercise intervention. The protocol for this study has been described in detail elsewhere [19]. We hypothesized that the remotely delivered CR exercise program would not be inferior to the traditional center-based program.

Methods

Study Design

We conducted a pilot trial to examine the efficacy of a remotely delivered CR exercise program supported by the ECME-CR platform. The published protocol for this trial outlined a randomized controlled trial; however, due to the COVID-19 pandemic, a more pragmatic approach was adopted.

Participant recruitment initially commenced in August 2021; however, at this time, COVID-19 restrictions had been introduced in Ireland, which resulted in a slower-than-anticipated recruitment rate. In addition, the COVID-19 restrictions prohibited indoor group exercise classes. For this reason, those enrolled in the study at this time were not randomly allocated and participated in the remotely delivered CR exercise classes. Data collection and intervention delivery with this cohort took place between September and December 2021. In January 2022, COVID-19 restrictions had eased, and participant recruitment recommenced. This cohort of participants was randomly allocated to either the intervention or the control group, and data collection and intervention delivery took place between January and April 2022.

Ethical Approval

The study protocol was approved by the Health and Science Ethics Committee in Dundalk Institute of Technology, and all procedures were conducted in accordance with the Declaration of Helsinki 1974 and its later amendments. All participants provided written informed consent before entering the study.

Population and Group Allocation

The study population included participants eligible to participate in community-based phase IV CR. Participants were recruited through advertisements placed in local general practices, health clinics, and local media and through posts on social media. Potential participants made contact by telephone with the study team and were screened for their eligibility to take part by a member of the research team, over the phone, using the study eligibility criteria (Textbox 1).

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Men or women with documented coronary heart disease eligible to participate in a community-based cardiac rehabilitation (CR) program (phase IV CR)
- Aged 40-85 years
- Medically stable with regard to symptoms and no change in pharmacotherapy in the previous 4 weeks
- Clinical approval from their treating physician to enroll in the CR program

Exclusion criteria

- Living in a nursing home or other long-term care facility
- Have any contraindications to exercise (adapted from the American College of Sports Medicine's Guidelines for Exercise Testing and Prescription [20]):
  - Unstable angina
  - Uncontrolled hypertension (ie, resting systolic blood pressure >180mmHg or resting diastolic blood pressure >110mmHg)
  - Orthostatic blood pressure drop of >20 mmHg with symptoms
  - Significant aortic stenosis (aortic valve area <1.0 cm2)
  - Acute systemic illness or fever
  - Uncontrolled atrial or ventricular arrhythmias
  - Uncontrolled sinus tachycardia (heart rate >120 beats per minute)
  - Acute pericarditis or myocarditis
  - Uncompensated heart failure
  - Third-degree (complete) atrioventricular block without pacemaker
  - Recent embolism
  - Acute thrombophlebitis
  - Resting ST segment displacement (>2 mm)
  - Uncontrolled diabetes mellitus
  - Severe orthopedic conditions that would prohibit exercise
  - Other metabolic conditions, such as acute thyroiditis, hypokalemia, hyperkalemia, or hypovolemia (until adequately treated)

Cardiac Rehabilitation Exercise Program

Overview

Both study groups performed the same exercise program over an 8-week intervention period. Details of the exercise program are outlined elsewhere [19]. Each 60-minute session consisted of a 15-minute warm-up, 30 minutes of circuit style aerobic and strength exercises, and a 10-minute cooldown. Exercise intensity was assessed during the exercise class using the Borg scale of perceived exertion [21]. The Borg scale ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion." Heart rate was measured during each exercise class using the Withings ScanWatch. The ScanWatch was worn on the participants' nondominant wrist, and for the duration of each exercise class, the ScanWatch was used in the workout mode. The intervention group undertook the exercise program in their own home, joining the CR exercise classes using Zoom videoconferencing software (Zoom Video Communications, Inc.). The control group attended a sports center in the institution to undertake their rehabilitation exercise classes.

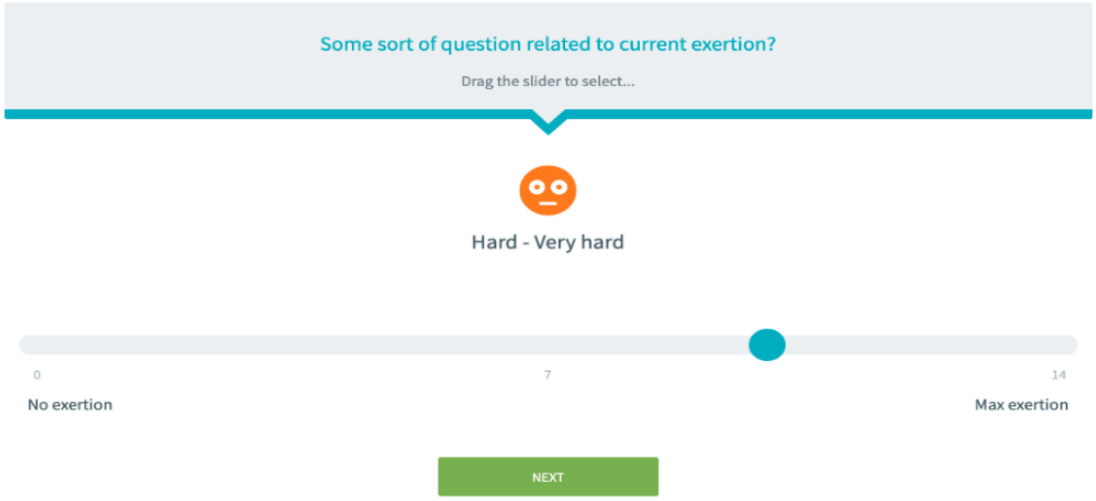
Intervention Group

Participants were provided with an iPad (Apple iPad, 8th Gen, 10.2-inch, Wi-Fi, 32GB; Apple Inc.) preloaded with the ECME-CR app, the Withings devices, as well a set of free weights to use during the exercise classes. Participants received an equipment familiarization session in person at the research center, which included how to operate the iPad and the ECME-CR app, use the monitoring equipment, and record measurements. An equipment manual with written and pictorial instructions was also supplied. Participants were also provided with a mobile Wi-Fi device for the duration of the study if they did not have an established broadband internet connection in their home.

Participants used the ECME-CR app during the class to record their exertion levels on the Borg scale (Figure 2). The class instructor was able to visualize and monitor in real time the exertion levels recorded by all participants simultaneously on SIMS. The instructor provided coaching and feedback on exertion when required via Zoom. Before each class, participants measured their resting heart rate and blood pressure using their

BPM Connect device. This data was synchronized with the ECME-CR app and was also available for review by the instructors on SIMS before the class began, ensuring it was safe for the participant to exercise. This process was repeated at the end of the exercise class, following the cooldown period. Participants wore the Withings ScanWatch in workout mode to measure heart rate during the class. The heart rate data provided by the watch were not monitored in real time during the class. However, after each class, a summary of the heart rate data obtained was reviewed by the instructor.

Figure 2. Eastern Corridor Medical Engineering Centre–Cardiac Rehabilitation (ECME-CR) app: Borg rating of perceived exertion.



Control Group

Each participant's resting heart rate and blood pressure were checked using the Withings BPM Connect device before beginning each exercise class and again following the cooldown period. Participants were provided with a ScanWatch to wear for the duration of the class for continuous heart rate measurement. Self-reported exertion levels were monitored at regular intervals using the Borg scale and were manually recorded by a member of the research team.

Outcome Measures

Outcome measures were assessed at baseline (week 0) and repeated following the intervention period (week 8). The primary outcome was cardiopulmonary exercise capacity as assessed using a 6-minute walking test (6MWT) [22]. Secondary end points were grip strength, self-reported quality of life assessed using the 12-Item Short Form Survey [23], and physical health related outcome measures, including measurement of heart rate at rest, blood pressure, and body composition. Participant adherence to the exercise program (ratio of exercise sessions completed versus prescribed) was also analyzed.

Data Analysis

Data collected at baseline and week 8 were collated using Microsoft Office Excel (Microsoft Corp) and analyzed using SPSS software (IBM Corp). Demographic characteristics were analyzed using descriptive statistics. A series of 2 × 2 mixed ANOVAs were conducted to examine the mean differences in study outcome measures between groups (intervention group and control group) and to examine the impact of time (within subjects factor: week 0 and week 8). The Shapiro-Wilk test was applied to assess normality, and although the data were not normally distributed, ANOVA was used as it is considered to be robust to violations of nonnormality and with small sample sizes [24]. As the number of variables with missing data was low, the SPSS default for mixed within-between subjects ANOVA, listwise deletion, was used. The false discovery rate approach was used to control for type 1 error associated with making multiple comparisons [25]. Using this procedure, the *P* value was reduced by multiplying it by ([n + 1] / 2n), where n is the number of tests. This approach is recommended as it is less conservative and has greater power than the Bonferrroni correction, where *P* is divided by the number of tests [26]. A significance level of $P<.0275$ was therefore applied.

Results

Flow of Participants Through the Study

A total of 59 people responded to our advertisements, and 54 were contacted and screened for eligibility. In all, 28 participants satisfied the study eligibility criteria. The reason for exclusion included being unsuitable due to the use of the Withings ScanWatch in this study (ie, having a pacemaker or other implanted electronic device; n=6), uncontrolled atrial fibrillation (n=14), spontaneous coronary artery dissection (n=1), not having a CHD (n=4), or currently enrolled in a CR program (n=1). Further, 7 participants who were deemed eligible to participate were subsequently unable to enroll in the study due to family or work commitments. Of the remaining 21 participants with CHD who enrolled, 14 underwent a percutaneous coronary intervention (PCI), 3 underwent a coronary artery bypass graft, 1 underwent an aortic valve replacement and PCI, 1 underwent a PCI and coronary artery bypass graft, and 2 were treated with medication only during their hospitalization. All participants enrolled in the intervention group were urban-dwelling and had

an established internet connection in their homes prior to the trial.

In all, 11 participants were allocated to the intervention group and 10 were allocated to the control group. One participant in the intervention group was unable to attend follow-up testing due to personal reasons and was thus lost to follow-up. Two participants in the intervention group dropped out, due to family reasons and changing work commitments. One participant in the control group withdrew from the study prior to baseline measurements due to a lower limb injury. The remaining 9 participants in the control group completed the intervention. A flowchart of participants through the study is presented in Figure 3, and baseline demographics for those participants completing the intervention are presented in Table 1. Medication at baseline is also outlined in Table 1. One participant in the intervention group had a change in medication dosage (reduced dose of angiotensin-converting enzyme inhibitor) during the intervention period; all others were unchanged.

Figure 3. Flow of participants through the trial. CHD: coronary heart disease; SCAD: spontaneous coronary artery dissection.

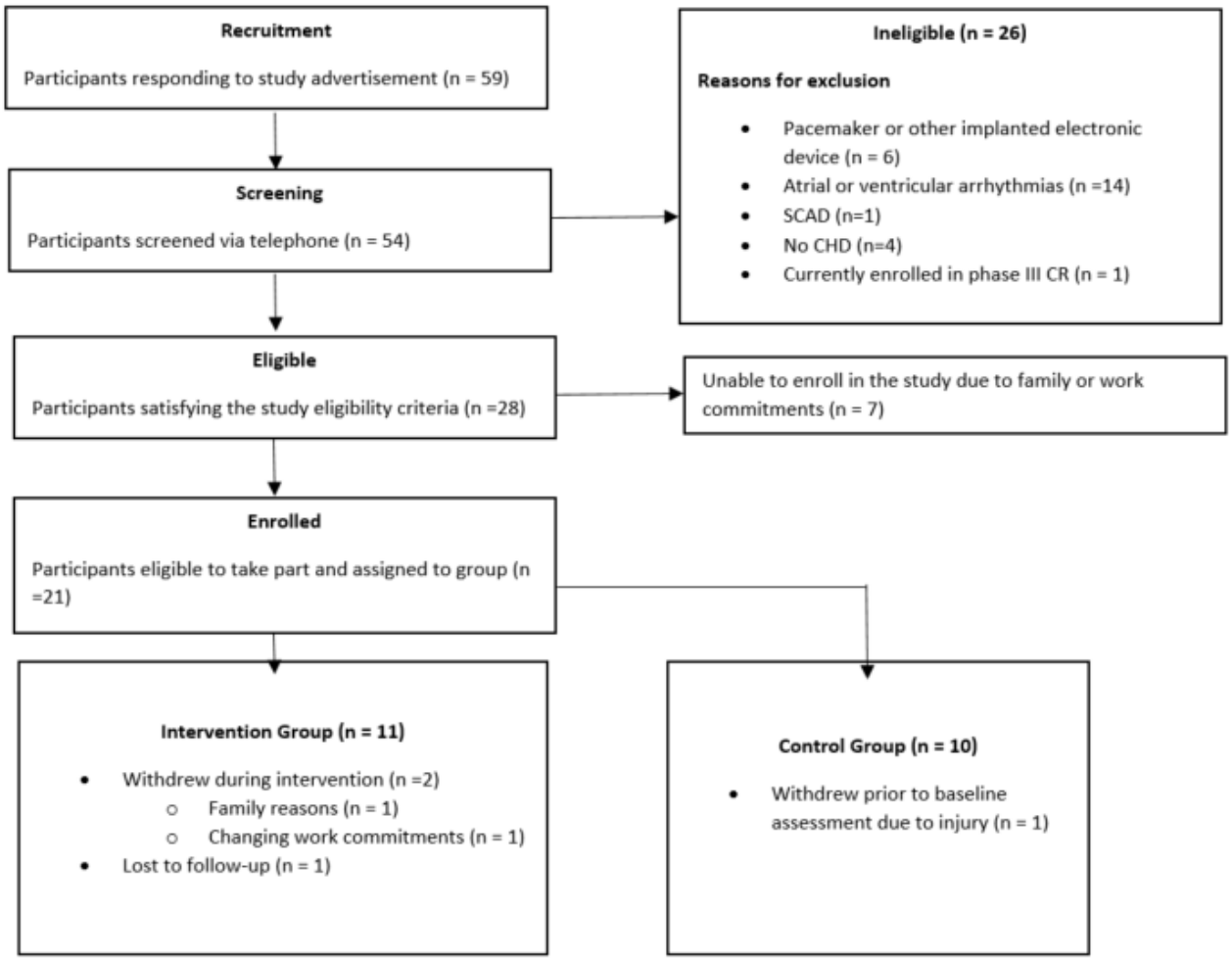


Table 1. Participant demographics at baseline.

Characteristic	Intervention group (n=8)	Control group (n=9)
Sex, n (%)		
Male	5 (62)	9 (100)
Female	3 (38)	0 (0)
Age (years), mean (SD)	69.7 (7.2)	69.8 (8.2)
Ethnicity, White, n (%)	8 (100)	9 (100)
Height (cm), mean (SD)	163.9 (5.4)	173.8 (5.2)
Weight (kg), mean (SD)	81.6 (14.1)	94.4 (18.0)
BMI (kg/m^2), mean (SD)	30.4 (5.4)	31.1 (5.1)
CHD[a] diagnosis, n (%)		
PCI[b]	8 (100)	4 (44)
CABG[c]	0 (0)	2 (22)
AVR[d] and PCI	0 (0)	1 (11)
PCI and CABG	0 (0)	1 (11)
Medication only	0 (0)	1 (11)
Medication, n (%)		
Beta-blockers	6 (75)	6 (67)
Statins	7 (88)	9 (100)
Anti-platelets	8 (100)	8 (89)
ACE[e] inhibitors or ARB[f]	7 (88)	8 (89)
Nitrates	1 (12)	1 (11)

[a]CHD: coronary heart disease.

[b]PCI: percutaneous coronary intervention.

[c]CABG: coronary artery bypass graft.

[d]AVR: aortic valve replacement.

[e]ACE: Angiotensin-converting enzyme.

[f]ARB angiotensin II receptor blockers.

Effect of the Intervention

Table 2 shows the outcome measures assessed at baseline (week 0) and after the 8-week intervention. The primary outcome was exercise capacity as assessed using the 6MWT. One participant in the intervention group was unable to perform the 6MWT at week 8 due to a rheumatic flare-up, and therefore, these results are presented only for 7 participants in this group. The 2-way ANOVA performed revealed that there was not a statistically significant interaction effect for 6MWT distance ($F_{1,14}$=.026; P=.87). Simple main effects analysis for the impact of time showed no statistically significant effect on 6MWT distance ($F_{1,14}$=2.51; P=.14). No significant differences were observed following the 8-week intervention in any of the secondary outcome measurements of grip strength (right: P=.78; left: P=.29), quality of life (SF-12 physical component score: P=.24; SF-12 mental component score: P=70), resting heart rate (P=.89), diastolic blood pressure (P=.27), and body composition (weight: P=.17; body fat: P=.06; waist circumference: P=.55; Table 2). As no significant main effects were observed, post hoc tests were not conducted. The duration of each exercise class ranged from 50 to 60 minutes (including warm-up and cooldown), and the intensity level ranged from 6 to 14 on the Borg scale of perceived exertion.

Table 2. Summary of mixed between-within subject ANOVA for the intervention and control group.

	Intervention group, mean (SD)		Control group, mean (SD)		Interaction		Main effect	
	Week 0	Week 8	Week 0	Week 8	*F* test (*df*)	*P* value	*F* test (*df*)	*P* value
6MWT[a] distance (m)	490.0 (80.2)	504.5 (93.7)	510.2 (48.3)	522.0 (49.4)	.026 (1.14)	.87	2.51 (1.14)	.14
Grip strength, right (kg)	27.9 (7.8)	26.8 (7.0)	35.3 (7.6)	35.8 (7.0)	.576 (1,15)	.46	.079 (1,15)	.78
Grip strength, left (kg)	28.5 (9.2)	28.6 (9.7)	34.6 (5.9)	36.4 (7.4)	.906 (1,15)	.36	1.323 (1,15)	.29
Weight (kg)	81.6 (14.1)	82.9 (14.2)	95.0 (17.0)	94.9 (16.7)	3.154 (1,15)	.10	2.106 (1,15)	.17
Body fat (%)	33.9 (9.8)	34.5 (9.3)	27.6 (2.4)	27.9 (2.7)	.936 (1.14)	.35	4.372 (1.14)	.06
Waist circumference (cm)	103.6 (12.8)	103.8 (12.4)	107.0 (10.1)	105.8 (12.3)	.731 (1,15)	.41	.382 (1,15)	.55
Resting heart rate (BPM[b])	65.8 (10.1)	63.4 (8.2)	60.4 (13.8)	63.3 (10.8)	2.124 (1,15)	.17	.020 (1,15)	.89
Systolic BP[c] (mmHg)	125.5 (11.5)	136.3 (12.0)	145.8 (21.3)	149.9 (25.7)	.293 (1,15)	.60	1.470 (1,15)	.24
Diastolic BP (mmHg)	78.1 (7.0)	78.3 (7.5)	87.9 (10.8)	82.0 (14.7)	1.436 (1,15)	.25	1.139 (1,15)	.27
SF12[d]-PCS[e]	43.8 (10.6)	41.9 (12.2)	49.7 (4.3)	46.1 (9.3)	.136 (1,15)	.72	1.500 (1,15)	.24
SF12-MCS[f]	57.9 (4.7)	56.4 (6.5)	54.1 (7.5)	57.1 (3.4)	1.381 (1,15)	.26	.153 (1,15)	.70

[a]6MWT: 6-minute walk test.

[b]BPM: beats per minute.

[c]BP: blood pressure.

[d]SF12: 12-Item Short Form Survey.

[e]PCS: physical component score

[f]MCS: mental component score.

Program Adherence

In total, 8 (73%) of the 11 participants assigned to the intervention group completed the exercise program, attending on average 14.25 (range 12-16; adherence rate: 89.1%) out of the 16 web-based CR exercise classes delivered. In contrast, 9 (90%) of the 10 participants assigned to the control group completed the program, attending on average 14.33 (range 11-16; adherence rate: 89.6%) CR exercise classes over the 8-week intervention period. There was no significant difference in the adherence rate between the 2 groups (*P*=.84).

Safety of the CR Exercise Intervention

There were no adverse events reported in either group participating in the CR exercise program. We did not observe any adverse cardiovascular signs or symptoms during any CR exercise class. No musculoskeletal injuries related to the intervention were reported. The need to discontinue the intervention or urgently stop exercising did not occur for any participant in this study.

Technical Issues

Some technical issues were experienced by participants in the intervention group during the 8-week intervention period, and a log of all technical issues was maintained by the research team. The key issues encountered included difficulty logging on to Zoom for the exercise class, difficulty navigating and interacting with the features on Zoom during the exercise class (turning camera on and muting-unmuting), difficulty interacting with the Withings ScanWatch device as required during the exercise class (starting or stopping workout mode), issues synchronizing the Withings BPM Connect with the app, and difficulties interacting with the ECME-CR app as required during the exercise class. No issues with internet connection were reported by participants.

Discussion

Principal Findings

This pilot study sought to examine the effectiveness of a remotely delivered CR exercise program for people with CHD and compare it with a control group who participated in a traditional center-based CR exercise class. After the 8-week intervention period, neither the intervention group nor the control group showed a statistically significant improvement in 6MWT distance from baseline, which was the primary outcome measure in this study. No significant difference was found in either group in the secondary outcomes of grip strength, body composition, resting heart rate, and self-reported quality of life following the intervention period. Although weight, percentage body fat, and systolic blood pressure measurements were observed to increase from week 0 to week 8 in the intervention group, no significant effect for time emerged in this group nor in the control group.

Comparison to Prior Work

A major trial conducted to examine the effectiveness of remotely monitored exercise-based cardiac tele-rehabilitation compared to conventional center based CR in people with CHD found that exercise capacity was comparable after a 12-week intervention period in both groups [27]. Another randomized controlled trial provided evidence of the effectiveness of a smartphone- and social media–based CR program in people with CHD [28]. Other trials have also demonstrated greater

improvements in exercise capacity after home-, tele-rehabilitation–, and center-based CR [29,30]. In this study, although mean improvements in 6MWT distance of 14 m and 12 m were observed in the intervention group and the control group, respectively, at the 8-week follow-up, these improvements were not clinically significant. A 25-m improvement in the 6MWT distance has been considered clinically meaningful for patients with CHD undergoing CR [31]. This threshold was established in patients recovering from an acute cardiac event, and for patients with stable CHD, a higher threshold is likely to be required to be clinically significant. A possible explanation for the nonclinically significant improvement in this study is that the duration of the intervention or the frequency of exercise sessions may not have been sufficient to achieve an effect comparable to the results seen in other studies. Second, the age profile of participants in this trial is older (mean age: 69.5 years) than previous similar trials [18]. Previous reports have shown that improvements in exercise capacity in older adults with CHD is not as large as those observed in individuals aged <65 years [32]. Third, the inability of this study to produce significant improvements in exercise capacity compared to previous studies may indicate that the measurements used in this study were not sufficiently sensitive to identify a change in the cohort included. A previous study that examined the effect of home-based CR program in an older population with CHD also used a change in exercise capacity determined by the 6MWT as the primary outcome measure [29]. This study did demonstrate significant increases in 6MWT distance following the 3 month home-based CR program; however, the participants included had a much lower exercise capacity at baseline and therefore had a greater potential to change. Another large randomized controlled trial, which also used 6MWT distance as the primary end point, found significant improvements in 6MWT distance in participants following an 8-week smartphone-based CR program [33]. However, the trial was evaluating an early physical activity program after an acute cardiac event, where again the potential for improvement is much greater.

In this study, we observed adherence rates of >89% to the exercise program across both groups, which can be classified as high adherence [34]. Participants enrolled in this study were self-referred and were not referred by their physician, which may explain the high adherence rate observed in this study. The level of completion, that is, the number of participants with outcome data at the 8-week follow-up, was higher in the control group who were attending the center-based CR exercise class. Although a number of technical issues were experienced by participants in this group, these technical issues were not cited as a reason for withdrawal. All control group participants completed the intervention. This may be explained by the fact that COVID-19 restrictions had just been lifted when the center-based CR exercise classes were taking place. Anecdotally, participants reported that they enjoyed attending the classes as it was seen as an enjoyable social activity after a long period of social restrictions.

No serious adverse events were reported during the CR program in either group. Other investigators have found a similarly low rate of exercise-related complications during home-based CR [35]. Although some technical issues were experienced by participants in the intervention group during the exercise classes and the intervention period, these were quickly addressed and rectified by the research team. Our study, therefore, indicates that remotely delivered CR exercise at home is feasible and should still be considered for its potential for increasing overall access to CR for all eligible patients who face obstacles to traditional means of participation.

Strengths and Limitations

This study has some limitations that should be acknowledged. First, this study was a single-center pilot trial, with a small sample size, which limits the establishment of any strong conclusions. Sample size calculations were not conducted in this pilot trial; future trials conducted will be adequately powered to determine the treatment effect. Second, few female participants participated in the study (<20%), and all participants were from the majority ethnic group in Ireland (White, Settled or non-Traveler). Although most patients attending CR and those included in other CR trials are male [36,37], the results of this trial cannot be generalized to female participants and those of other ethnicities. In this study, no participant assigned to the control group was female, and this difference, along with the differences in conditions and blood pressure between the groups, should also be acknowledged as a weakness that limits our ability to draw firm conclusions. Third, all participants included in this trial were of low-to-moderate risk, with stable CHD. The results should therefore be interpreted with caution and cannot be generalized to patients with high-risk CHD or those after an acute coronary event. Fourth, all participants in this study were self-referred and volunteered to take part. Participants referred by their physician may adhere to CR programs differently than those who self-refer, and therefore, the feasibility of our approach in a physician-referred cohort was not established. Finally, this study did not include a long-term follow-up of participants; this will be considered in future investigations. Despite these limitations, this trial provides preliminary information on remotely delivered CR exercise program supported by the ECME-CR platform.

Conclusions

Remotely delivered CR has been suggested as an alternative to center-based CR, especially during the COVID-19 pandemic. In this trial, although both groups demonstrated improvements in the primary outcome measure of exercise capacity from baseline to 8-week follow-up, these improvements were neither clinically nor statistically significant. As previous studies have shown overwhelmingly positive outcomes for both telehealth- and center-based CR interventions, it suggests that the measurement of exercise capacity used in this study may not have been sufficiently sensitive to identify a change in the cohort of participants with stable CHD included in this study. Future work will review the exercise program delivered to both groups and use measurements that may be more sensitive to identify a change. Nonetheless, this trial provides preliminary evidence to suggest that a remotely delivered CR exercise program, supported with digital self-monitoring, is feasible and may serve as an alternative delivery model for CR for individuals less likely to participate in traditional center-based programs.

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Data Availability

The data that support the findings of this study are available as a supplementary file (Multimedia Appendix 1).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Data that supports the findings of this study.
[XLSX File (Microsoft Excel File), 91 KB - cardio_v7i1e40283_app1.xlsx]

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Abbreviations

6MWT: 6-minute walk test
CHD: coronary heart disease
CR: cardiac rehabilitation
ECME-CR: Eastern Corridor Medical Engineering Centre–Cardiac Rehabilitation
PCI: percutaneous coronary intervention

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Original Paper

Accuracy of Artificial Intelligence–Based Automated Quantitative Coronary Angiography Compared to Intravascular Ultrasound: Retrospective Cohort Study

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Abstract

Background: An accurate quantitative analysis of coronary artery stenotic lesions is essential to make optimal clinical decisions. Recent advances in computer vision and machine learning technology have enabled the automated analysis of coronary angiography.

Objective: The aim of this paper is to validate the performance of artificial intelligence–based quantitative coronary angiography (AI-QCA) in comparison with that of intravascular ultrasound (IVUS).

Methods: This retrospective study included patients who underwent IVUS-guided coronary intervention at a single tertiary center in Korea. Proximal and distal reference areas, minimal luminal area, percent plaque burden, and lesion length were measured by AI-QCA and human experts using IVUS. First, fully automated QCA analysis was compared with IVUS analysis. Next, we adjusted the proximal and distal margins of AI-QCA to avoid geographic mismatch. Scatter plots, Pearson correlation coefficients, and Bland-Altman were used to analyze the data.

Results: A total of 54 significant lesions were analyzed in 47 patients. The proximal and distal reference areas, as well as the minimal luminal area, showed moderate to strong correlation between the 2 modalities (correlation coefficients of 0.57, 0.80, and 0.52, respectively; $P<.001$). The correlation was weaker for percent area stenosis and lesion length, although statistically significant (correlation coefficients of 0.29 and 0.33, respectively). AI-QCA tended to measure reference vessel areas smaller and lesion lengths shorter than IVUS did. Systemic proportional bias was not observed in Bland-Altman plots. The biggest cause of bias originated from the geographic mismatch of AI-QCA with IVUS. Discrepancies in the proximal or distal lesion margins were observed between the 2 modalities, which were more frequent at the distal margins. After the adjustment of proximal or distal margins, there was a stronger correlation of proximal and distal reference areas between AI-QCA and IVUS (correlation coefficients of 0.70 and 0.83, respectively).

Conclusions: AI-QCA showed a moderate to strong correlation compared with IVUS in analyzing coronary lesions with significant stenosis. The main discrepancy was in the perception of the distal margins by AI-QCA, and the correction of margins improved the correlation coefficients. We believe that this novel tool could provide confidence to treating physicians and help in making optimal clinical decisions.

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KEYWORDS

artificial intelligence; AI; coronary angiography; coronary stenosis; interventional ultrasonography; coronary; machine learning; angiography; stenosis; automated analysis; computer vision

Introduction

Coronary angiography is a key step in defining the coronary anatomy and severity of coronary arterial stenosis [1]. Percent diameter stenosis (%DS) based on a 2D image is usually used as evidence of ischemia or guidance for further physiology study [2]. Despite advances in intravascular imaging and physiology, coronary intervention is mostly performed based on coronary angiography alone [3].

Efforts have been made to analyze coronary angiography images quantitatively and objectively [4]. Human eyeball assessments are known to have a high interobserver variability [5]. Quantitative coronary angiography (QCA) has proven reproducibility and accuracy and is thus considered the standard [6]. Moreover, 3D QCA has been developed, which showed a better correlation with coronary hemodynamics and intravascular anatomy than the 2D QCA [7,8]. However, its clinical adoption is low because it is time consuming and labor intensive.

Intravascular ultrasound (IVUS) offers detailed 3D tomographic views of coronary plaques and reference vessels. Anatomical information obtained by IVUS can help identify the clinical relevance of the lesion and enable optimal stent implantation [9]. Studies have suggested that the use of IVUS can reduce adverse cardiovascular events such as mortality, myocardial infarction, target lesion revascularization, and stent thrombosis, especially in complex coronary interventions, including left main intervention and long coronary stenting [10-12]. Limitations of intravascular imaging still exist, such as the additional time and cost as well as the invasiveness of the additional procedure.

Artificial intelligence (AI) has been shown to automatically analyze medical images with accuracy and consistency as high as human experts [13]. A novel software (MPXA-2000, Medipixel) has been developed that uses a deep learning algorithm to segment and analyze coronary angiography images. An AI-assisted real-time QCA that automatically provides quantitative information has the potential to support clinical decisions and improve patient outcomes. In this study, we validated the performance of AI-based QCA (AI-QCA) compared with IVUS in patients with coronary artery disease.

Methods

Study Design and Patient Selection

This was a retrospective analysis of patients with coronary artery disease who underwent coronary intervention at a single tertiary center. Fifty patients who underwent IVUS-guided percutaneous coronary intervention (PCI) in Uijeongbu Eulji University Hospital between October 2021 and July 2022 were included. Patients with total or subtotal occlusion and ST-segment elevation myocardial infarction were excluded from the study. Baseline characteristics, clinical diagnosis, and laboratory data were collected via medical record review.

Ethical Considerations

The study protocol was approved by the Eulji University Hospital Institutional Review Board (no. 2022-07-009). Written informed consent was waived because of the retrospective study design and minimal risk to the patients. Personal information and study data were anonymous and deidentified. The data will not be used for any purpose other than this research, and compensation for participants is not applicable. The study complied with the principles of the Declaration of Helsinki, revised in 2013.

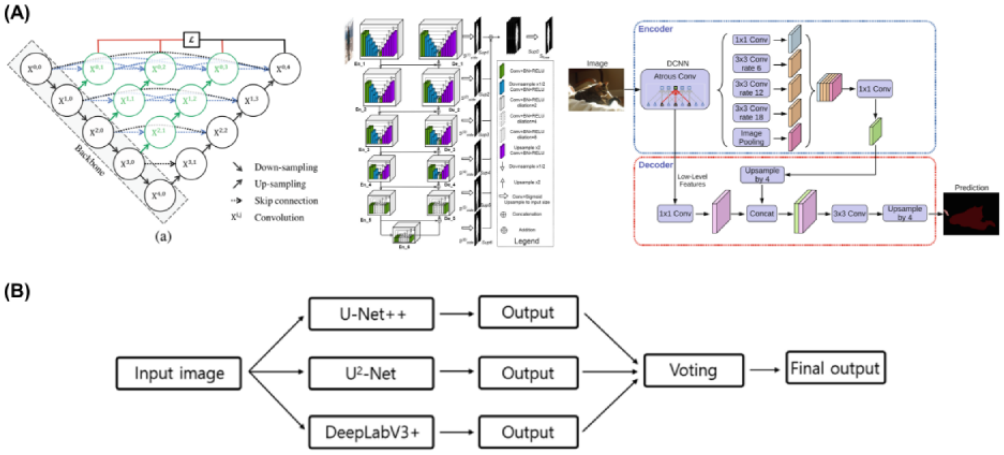
AI-QCA Analysis

AI-QCA analysis was performed using the MPXA-2000 software. The algorithm used in MPXA-2000 was developed based on an ensemble architecture that integrated 3 neural networks for semantic segmentation (U-Net++, U2-Net, and DeepLabV3+; Figure 1) [14-16]. A hard voting classifier was also employed to improve the overall performance. A classification head for the target vessel of angiography is included at the end of each encoder in the 3 networks. In the training stage, the algorithm was trained to segment vessel mask, classify the mean vessel and side branches into 1 of the 3 types, and localize the region of interest. In an unpublished test, the average dice similarity coefficient of this segmentation algorithm was reported as 0.92, and the overall accuracy of vessel classification was 0.99. The software was authorized by the Korean Food and Drug Administration. Each image was calibrated using automatic calibration based on the isocenter calibration factor, which can be extracted from the header of the Digital Imaging and Communications in Medicine file. The best frame was automatically chosen from each video clip using densitometry. Based on 2D images, vessel segmentation, region of interest choice, vessel classification, and quantitative analysis can be performed without human intervention.

Information such as proximal and distal reference vessel diameters, minimum lumen diameter, %DS, and lesion length (LL) was provided within several seconds. Users can switch the analysis frame and modify the lesion and the segmented mask contours. Reference areas and percent area stenosis (%AS) were derived from the values estimated by AI-QCA using the following formula:

The first set of analyses was performed using the values from the fully automated AI-QCA. Data on proximal reference diameter, distal reference diameter, minimum lumen diameter, %DS, and LL were collected without any intervention from the investigators. Second, the proximal and distal borders of AI-QCA were adjusted to match those of IVUS to compare the 2 methodologies for the same coronary locations. As will be described later, geographic mismatch was the biggest cause of the discrepancy between AI-QCA and human analysis using IVUS. Third, we compared proximal-and-distal-border–adjusted AI-QCA and manual QCA.

Figure 1. (A) Three main network architectures: U-NET++, U2-Net, and DeepLabV3+. (B) The ensemble method process. Conv: convolution; DCNN: deep convolutional neural network.



IVUS Analysis

IVUS was performed using 60 MHz OPTICROSS HD catheter (Boston Scientific) after intracoronary nitroglycerin administration. The proximal and distal reference areas, minimal luminal area (MLA), percent plaque burden, and LL were measured by human experts with more than 5 years of experience. IVUS analysis followed the consensus recommendations [17].

Variables and Statistical Analysis

The study variables included proximal reference area, distal reference area, MLA, %AS, and LL. Continuous variables were expressed as mean and SD, and categorical variables as numbers and percentages. The association between the 2 methods was tested by plotting a scatter plot and measuring Pearson correlation coefficient. A correlation coefficient between 0.10 and 0.39 was considered weak, that between 0.40 and 0.69 moderate, that between 0.70 and 0.89 strong, and that between 0.90 and 1.00 very strong [18]. Bland-Altman plots were constructed to test the agreement between the 2 methods by plotting the average of the AI-QCA and IVUS measurements on the x-axis and the difference between the AI-QCA and IVUS on the y-axis. All statistical analyses were performed using R programming version 4.1.2 (The R Foundation for Statistical Computing).

Results

Among the 50 patients initially included, AI-QCA did not work properly in 3 patients due to overlapping coronary arteries. Finally, we analyzed 54 lesions in 47 patients who underwent PCI under IVUS guidance. The baseline patient characteristics are shown in Table 1. The average age was 64.7 (SD 10.5) years. Of the 47 patients, 33 (70.2%) were male, and 24 (51%) had acute coronary syndrome. The left anterior descending, right coronary, and left circumflex arteries comprised 59.3% (n=32), 27.8% (n=15), and 13.0% (n=7) of the lesions, respectively (Table 2). Reflecting the complex study population of IVUS-guided PCI, 61.1% (n=33) of the lesions were in the bifurcation, and 35.2% (n=19) were heavily calcified lesions.

First, we compared the values from the fully automated AI-QCA with IVUS. Figure 2 shows the scatter plots of the study variables. Measurements for the reference and lesion areas showed moderate to strong correlations between the 2 modalities (correlation coefficients of 0.57 for proximal reference, 0.80 for distal reference, and 0.52 for MLA; P<.001). Meanwhile, %AS and LL showed a weaker correlation (correlation coefficient of 0.29 and P=.03 for %AS and correlation coefficient of 0.33 and P=.02 for LL). The Bland-Altman plots for agreement between the AI-QCA and IVUS measurements are shown in Figure 3. The AI-QCA measured reference areas smaller than human observers using IVUS with no systematic proportional bias. Most observations were within an error margin of 4 mm^2. The AI-QCA tended to measure LL shorter than human observers with IVUS.

%AS showed the weakest correlation among the variables. We divided the patients into 2 groups, with high and low agreement in %AS. The low agreement group, which is a group with a difference of more than 10% of %AS measured by AI-QCA and IVUS, had numerically lower heavy calcified lesions (Table S1 in Multimedia Appendix 1). The difference of less than 10% of %AS does not affect the decision to perform PCI.

The weak correlation for LL was driven by the geometric mismatch of lesion identification between the human observers and the AI-QCA (Figure 4). The proximal border identified by AI-QCA was mostly within 10 mm of that identified by human observers in 48 (88.7%) lesions. However, the distal border showed a greater discrepancy—AI-QCA identified the distal border more proximally than human observers guided by IVUS. As a result, AI-QCA generally estimated a shorter LL compared with IVUS.

Next, we adjusted the proximal and distal margins detected by AI-QCA to align with those determined by human observers under IVUS guidance. The proximal and distal reference areas and MLA showed numerically greater correlation coefficients than the initial analysis (0.70 for proximal reference area, 0.83 for distal reference area, and 0.59 for MLA; P<.001), while %AS still showed weak correlation (0.21, P=.13; Figure 5). Bland-Altman plots (Figure S1 in Multimedia Appendix 1) show that the mean differences in reference areas and MLA

between AI-QCA and IVUS were smaller than those between fully automated AI-QCA and IVUS.

AI-QCA showed strong correlation with manual QCA except proximal reference diameter (Figure S2 in Multimedia Appendix 1). Figure S3 in Multimedia Appendix 1 shows the correlation coefficients measured by IVUS and manual QCA. Correlation coefficients between AI-QCA and IVUS were similar to those between manual QCA and IVUS (0.70 vs 0.76 for proximal reference area, 0.83 vs 0.82 for distal reference area, 0.59 vs 0.59 for MLA, 0.21 vs 0.22 for %AS, and 1.00 vs 0.98 for LL).

Figure 6 shows a representative case in which AI-QCA showed a good correlation with IVUS. LL was estimated to be 39.0 mm with AI-QCA and 37.1 mm with IVUS. %DS by AI-QCA was 76.7%, and plaque burden on IVUS was 78%. Figure 7 shows another representative case in which AI-QCA identified the distal border more proximally than IVUS. AI-QCA separated the distal right coronary artery lesion into 2 segments, which was considered a single continuous lesion under IVUS guidance.

Table 1. Patient characteristics.

Variables	Values
Age (years), mean (SD)	64.7 (10.5)
Sex, n (%)	
Male	33 (70.2)
Female	14 (29.8)
Smoking history, n (%)	
Nonsmoker	24 (51.1)
Previous smoker	10 (21.3)
current smoker	13 (27.7)
Clinical diagnosis, n (%)	
Myocardial infarction	12 (25.5)
Unstable angina	12 (25.5)
Stable angina	16 (34.0)
Heart failure, others	7 (14.9)
Underlying disease, n (%)	
Hypertension	29 (61.7)
Diabetes mellitus	27 (57.4)
Dyslipidemia	15 (31.9)
Chronic kidney disease	6 (12.8)
Stroke (ischemic and hemorrhagic)	6 (12.8)
Previous coronary artery disease	6 (12.8)
Laboratory findings, mean (SD)	
Hemoglobin (g/dL)	13.5 (2.0)
Fasting glucose (mg/dL)	157.0 (65.4)
Creatinine (mg/dL)	1.7 (2.5)
Total cholesterol (mg/dL)	159.2 (50.2)
Triglyceride (mg/dL)	150.7 (83.7)
HDL[a]-cholesterol (mg/dL)	37.9 (9.2)
LDL[b]-cholesterol, mg/dL	103.8 (53.5)
Hemoglobin A_{1c} (%)	6.8 (1.9)

[a]HDL: high-density lipoprotein.

[b]LDL: low-density lipoprotein.

Table 2. Lesion characteristics.

Characteristics	Values, n (%)
Location	
Left anterior descending artery	32 (59.3)
Right coronary artery	15 (27.8)
Left circumflex artery	7 (13.0)
Bifurcation	33 (61.1)
Heavy calcified lesion	19 (35.2)
Ostial disease	8 (14.8)
Long lesion	9 (16.7)
Disease extent	
One-vessel disease	16 (29.6)
Two-vessel disease	20 (37.0)
Three-vessel disease	18 (33.3)

Figure 2. Scatter plots and Pearson correlation coefficients for (A) proximal and (B) distal reference areas; (C) minimal lumen area, (D) % area stenosis, and (E) lesion length measured by artificial intelligence–based quantitative coronary angiography (AI-QCA) and intravascular ultrasound (IVUS).

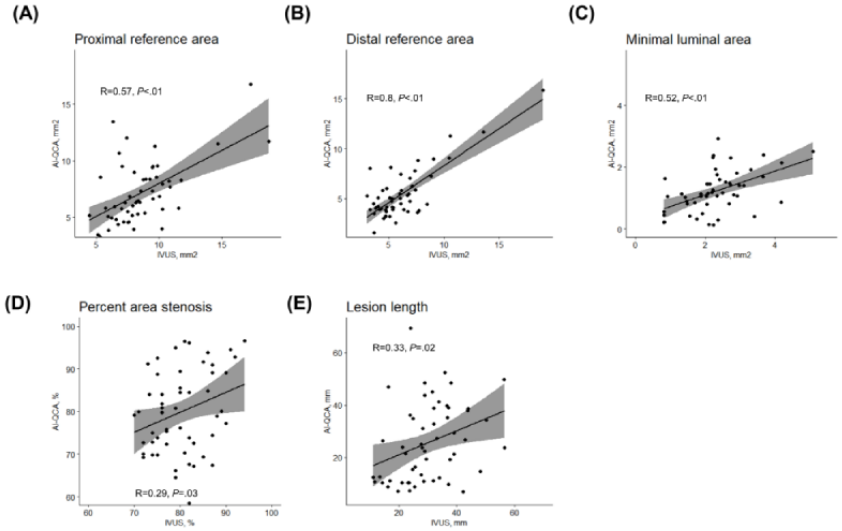


Figure 3. Bland-Altman plots showing the agreement between artificial intelligence–based quantitative coronary angiography (AI-QCA) and intravascular ultrasound (IVUS) for (A) proximal and (B) distal reference areas; (C) minimal lumen area, (D) % area stenosis, and (E) lesion length. The x-axis is the average of variables measured by AI-QCA and IVUS, and the y-axis is the difference of AI-QCA minus IVUS.

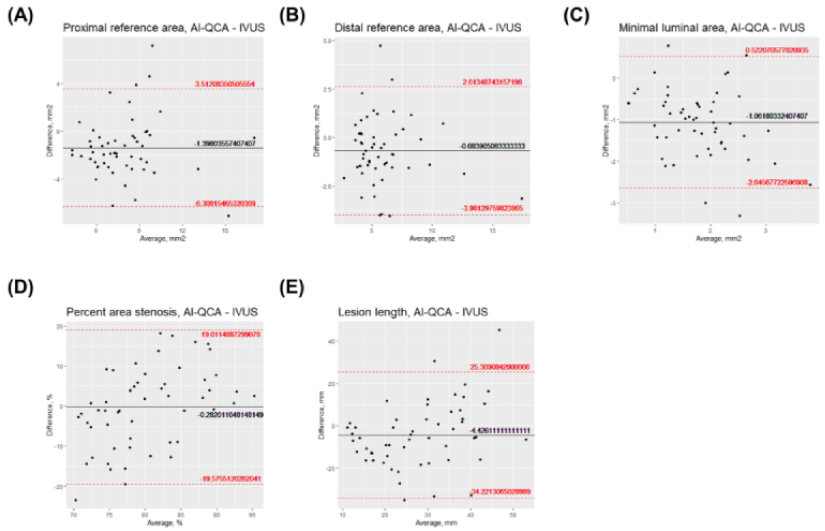


Figure 4. Geographic mismatch in lesion identification between artificial intelligence–based quantitative coronary angiography (AI-QCA) and human observers under intravascular ultrasound (IVUS) guidance. The reference point of y-axis is the proximal and distal margin determined by IVUS. A positive value means the margin determined by AI-QCA is more distal than that by IVUS.

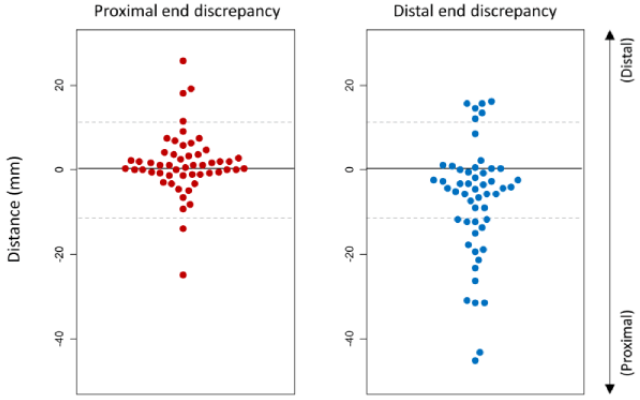


Figure 5. Scatter plots and Pearson correlation coefficients for (A) proximal and (B) distal reference areas; (C) minimal lumen area, (D) % area stenosis, and (E) lesion length measured by artificial intelligence–based quantitative coronary angiography (AI-QCA) and intravascular ultrasound (IVUS) after adjusting proximal and distal margins.

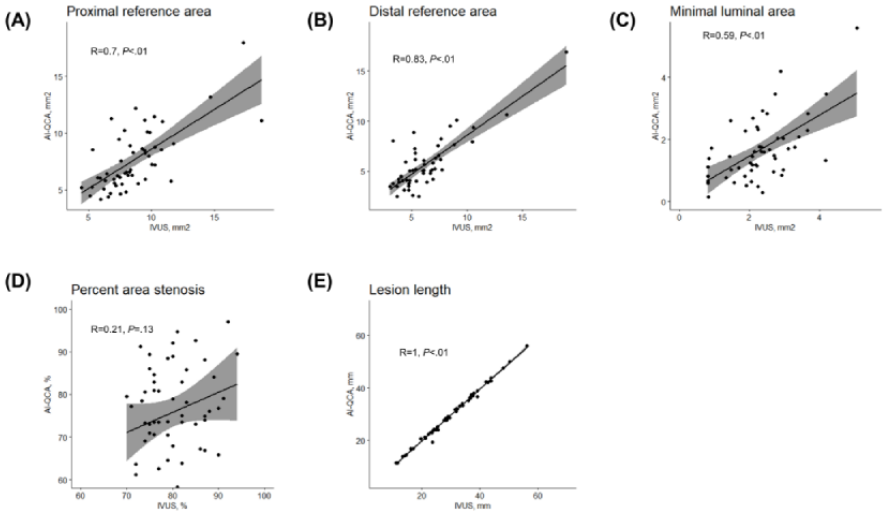


Figure 6. A representative case in which artificial intelligence–based quantitative coronary angiography (AI-QCA) showed a good correlation with intravascular ultrasound (IVUS) observation. %DS: percent diameter stenosis; DRD: distal reference diameter; LAD: left anterior descending artery; LCX: left circumflex artery; MLD: minimal luminal diameter; PRD: proximal reference diameter; RCA: right coronary artery; Ref.D: reference diameter.

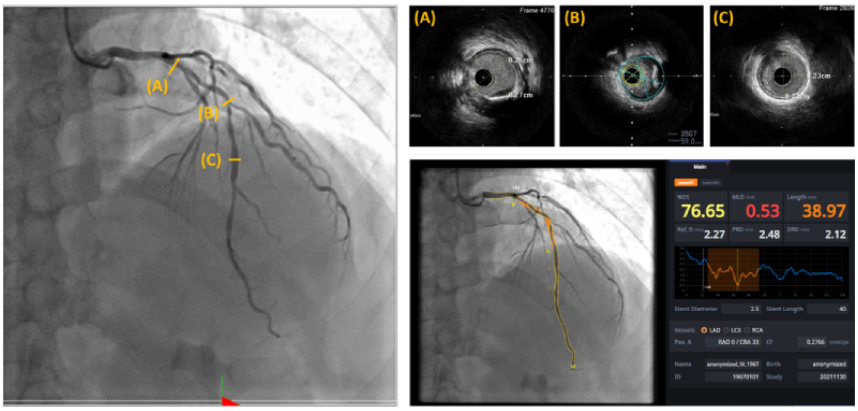
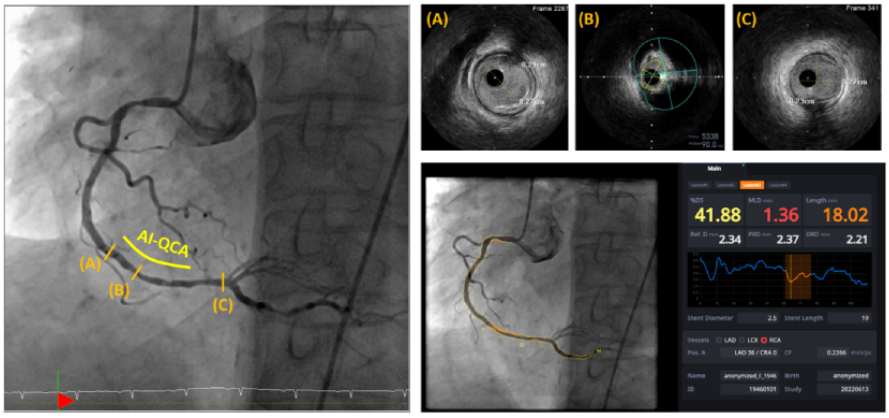


Figure 7. A representative case in which artificial intelligence–based quantitative coronary angiography (AI-QCA) measured lesion length shorter than intravascular ultrasound (IVUS). AI-QCA identified mild atherosclerotic lesion at distal as normal. %DS: percent diameter stenosis; AI-QCA: artificial intelligence–based quantitative coronary angiography; DRD: distal reference diameter; LAD: left anterior descending artery; LCX: left circumflex artery; MLD: minimal luminal diameter; PRD: proximal reference diameter; RCA: right coronary artery; Ref.D: reference diameter.



Discussion

Principal Findings

In this study, we found that the AI-QCA showed a moderate to strong correlation with human assessment guided by IVUS. The reference vessel size and stenosis severity were moderately correlated. Geographic mismatch was present in certain cases, indicating that there was discrepancy in the proximal or distal lesion margins between AI-QCA and IVUS. Discrepancies were frequently observed at distal margins.

Strengths of This Study

The application of AI is expanding in various fields of medicine. Machine learning and computer vision were introduced first and have proven their roles in radiology and pathology [19,20]. The adoption of medical AI has been slow in cardiology, partly due to the 3D nature and video format of cardiology images. Several recent studies have tested the application of AI in echocardiography, owing to recent advances in computing power and machine learning algorithms [21,22]; however, research has been scarce in the field of coronary angiography [23,24].

Interpretation of Results

The observation of this study, that AI-QCA underestimates vessel size compared to IVUS, is in line with the findings from previous studies. Studies have shown that QCA measurements are usually smaller than intracoronary imaging including optical coherence tomography and IVUS [25]. A postmortem study also found that intracoronary imaging overestimates the lumen area compared with the histomorphometry [26]. IVUS measurements are generally larger than those obtained using optical coherence tomography.

Since there are scarce data on AI-QCA, the relationship between coronary artery calcification and AI-QCA measurements is not well known. In this study, heavy calcification may have affected the AI-QCA measuring %AS, although not statistically significant. The finding that AI-QCA estimates an LL shorter than IVUS does can be partly explained by the tomographic images provided by IVUS. Observers can identify mild atherosclerotic changes with IVUS that appear normal on the angiography [27]. It is well known that physicians tend to use longer and larger stents during IVUS-guided PCI [28].

This study showed a relatively good correlation with MLA, but a weaker correlation with %AS. One possible reason for this is that positive remodeling is reflected in IVUS. Positive remodeling and vessel wall expansion occur during the early phase of atherosclerosis to maintain lumen size despite plaque accumulation. %DS is calculated only based on the reference diameter assumed by the interpolation of proximal and distal normal-looking segment diameters. In addition, reference diameters can be underestimated because proximal and distal reference segments may not be free of atherosclerosis, as discussed above. The plaque burden assessed by IVUS is greater than the %AS by QCA [29]. This study population represented complex coronary diseases—61% with bifurcation and 35% with heavily calcified lesions. A previous study also found intercore lab variability in the analysis of %DS for bifurcation lesions [30]. In this study, we calculated %AS from %DS from 2D images using the previously mentioned equation (Methods section). It is anticipated that 3D QCA may improve the accuracy of lesion severity.

Clinical Implication

Physicians performing PCI require considerable experience to accurately assess the characteristics of coronary arteries and the burden of atherosclerotic plaques. IVUS is the most commonly used intravascular imaging tool for optimizing coronary stenting [31,32]. This study showed a moderate to strong correlation between an AI-QCA that automatically analyzed 2D angiography images and IVUS analysis. Physicians could consult AI-QCA during PCI and consider a one-step larger diameter stent, as this study suggested AI-QCA tended to underestimate reference vessel area. In addition, physicians should be aware that AI-QCA may underestimate mildly atherosclerotic lesion as normal.

The AI-QCA tested in this study was based on deep learning algorithms intended to mimic the QCA process by human experts. This tool may be helpful for interventional cardiologists who feel less confident in determining stent size based on angiography alone when intravascular imaging is not available.

Limitations

This study is not free from limitations. First, this was a single-center study with a small sample size; therefore, caution should be exercised when extrapolating the findings to other studies. Since this study population represents a significant coronary disease that requires complex coronary intervention, the findings cannot be extrapolated to mild to intermediate coronary lesions. While the software was developed as a real-time coronary intervention assistance tool, the AI-QCA was performed separately because of the retrospective nature of this study. Second, IVUS was performed after predilatation in some cases because of the delivery failure of IVUS catheter, which may lead to larger MLA than the initial angiography. Third, even though the qualitative component of coronary artery, such as calcification or tortuosity, is the important value for clinicians to make the right decision, AI-QCA cannot assess the characteristics of coronary arteries. Correlation with IVUS measurements may not be a gold standard indicator for evaluating the accuracy of AI-QCA.

Future studies are required to address the utility of the software in real world clinical practice.

Conclusion

In this study, AI-QCA showed moderate to strong correlation accuracy compared with IVUS measurements in patients with coronary artery disease who underwent coronary intervention. This study provides supporting evidence that the AI-QCA can be safely used in clinical practice. Automated real-time analysis of coronary angiography may help practitioners make clinical decisions with greater confidence. Further prospective studies are needed to confirm AI-QCA's clinical utility and safety.

Acknowledgments

We thank Medipixel employees for their help in data collection.

Data Availability

The data sets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

S-H Kang owns stock options of and receives counseling fee from Medipixel. ITM, S-H Kim, JYC, SHP, C-HY, T-JY, and I-HC declare no conflicts of interest.

Multimedia Appendix 1

Table S1. Lesion characteristics of high and low agreement groups in percent area stenosis. Figure S1. Bland-Altman plots of proximal and distal reference areas, minimal luminal area (MLA), percent area stenosis (%AS), and lesion length (LL). The x-axis is the average of variables measured by artificial intelligence–based quantitative coronary angiography (AI-QCA) and intravascular ultrasound (IVUS); the y-axis is the difference value of AI-QCA minus IVUS. Figure S2. Scatter plots and Pearson correlation coefficients for (A) proximal and (B) distal reference diameters; (C) minimum lumen diameter, (D) % diameter stenosis, and (E) lesion length measured by AI-QCA and manual quantitative coronary angiography (QCA). Figure S3. Scatter plots and Pearson correlation coefficients for (A) proximal and (B) distal reference areas; (C) minimal lumen area, (D) % area stenosis, and (E) lesion length measured by IVUS and manual QCA.
[DOCX File , 453 KB - cardio_v7i1e45299_app1.docx]

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Abbreviations

%AS: percent area stenosis
%DS: percent diameter stenosis
AI: artificial intelligence
AI-QCA: artificial intelligence–based quantitative coronary angiography
IVUS: intravascular ultrasound
LL: lesion length
MLA: minimal luminal area
PCI: percutaneous coronary intervention
QCA: quantitative coronary angiography

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Original Paper

Effective Prediction of Mortality by Heart Disease Among Women in Jordan Using the Chi-Squared Automatic Interaction Detection Model: Retrospective Validation Study

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Abstract

Background: Many current studies have claimed that the actual risk of heart disease among women is equal to that in men. Using a large machine learning algorithm (MLA) data set to predict mortality in women, data mining techniques have been used to identify significant aspects of variables that help in identifying the primary causes of mortality within this target category of the population.

Objective: This study aims to predict mortality caused by heart disease among women, using an artificial intelligence technique–based MLA.

Methods: A retrospective design was used to retrieve big data from the electronic health records of 2028 women with heart disease. Data were collected for Jordanian women who were admitted to public health hospitals from 2015 to the end of 2021. We checked the extracted data for noise, consistency issues, and missing values. After categorizing, organizing, and cleaning the extracted data, the redundant data were eliminated.

Results: Out of 9 artificial intelligence models, the Chi-squared Automatic Interaction Detection model had the highest accuracy (93.25%) and area under the curve (0.825) among the build models. The participants were 62.6 (SD 15.4) years old on average. Angina pectoris was the most frequent diagnosis in the women's extracted files (n=1,264,000, 62.3%), followed by congestive heart failure (n=764,000, 37.7%). Age, systolic blood pressure readings with a cutoff value of >187 mm Hg, medical diagnosis (women diagnosed with congestive heart failure were at a higher risk of death [n=31, 16.58%]), pulse pressure with a cutoff value of 98 mm Hg, and oxygen saturation (measured using pulse oximetry) with a cutoff value of 93% were the main predictors for death among women.

Conclusions: To predict the outcomes in this study, we used big data that were extracted from the clinical variables from the electronic health records. The Chi-squared Automatic Interaction Detection model—an MLA—confirmed the precise identification of the key predictors of cardiovascular mortality among women and can be used as a practical tool for clinical prediction.

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KEYWORDS

coronary heart disease; mortality; artificial intelligence; machine learning; algorithms; algorithm; women; death; predict; prediction; predictive; heart; cardiology; coronary; CHD; cardiovascular disease; CVD; cardiovascular

Introduction

Background

Cardiac disease covers a range of cardiac conditions, including heart attacks and coronary artery disease [1]. Heart disease is sometimes considered a male illness, but the fact that women die of heart disease at the same rate as men each year contradicts this notion [2]. According to the Centers for Disease Control and Prevention, about 56% of women recognize that heart disease is their leading cause of death [3]. Heart disease was reported to be the primary cause of death among women in the United States in 2020 [4]. For more precise results, it has been found that the most prevalent form of heart disease, coronary heart disease, affects approximately 1 in 16 (6.2%) women aged 20 years and older [5]. Recent data indicate a stall in the declines in coronary heart disease incidence and mortality, especially in younger women aged <55 years [6]. Furthermore, new issues had emerged in transitional countries as a result of globalization, which increased risk factors and sedentary lifestyle adoption, having sharply increased cardiovascular mortality rates [7].

Sex chromosomes alter gene expression, which may then be further altered by sex-specific hormonal variations, resulting in sex-specific cardiovascular gene expression and function [6]. These differences result in variations in the prevalence and manifestation of cardiovascular disorders, including those related to autonomic regulation, hypertension, diabetes, and vascular and cardiac remodeling [8].

Age, smoking, obesity, high blood pressure, pulse, mean arterial pressure, diabetes, cholesterol, poor diet, and lack of physical activity are the primary risk factors for heart disease [9]. Many clinical examinations are available to diagnose coronary heart disease, including electrocardiography, cardiac enzyme assays, x-ray imaging, and angiography [10]. The data stored in the electronic health system of a health care organization generates a vast amount of unanalyzed raw data that aid in the prevention and treatment of cardiovascular disease [11].

Currently, machine learning algorithms (MLAs), as a specific artificial intelligence modality, are playing an important role in the field of disease prediction including cardiology mortality prediction, big data storage, acquisition, and recovery as primary prevention strategies [12,13]. A widespread MLA data set is used to predict mortality among women—through what is known as data mining—to determine significant features of variables that assist in detecting the main causes of mortality in this target group of the population since such risk prediction is an integral aspect according to the international guidelines of primary prevention of heart disease [14,15]. Thus, understanding the unique aspects of predicting mortality due to heart disease in women, including a lower incidence of heart disease due to a later age of heart disease occurrence, development of new prediction models, and differences in the effects of laboratory data—known as biomarkers—are critical factors in predicting mortality due to heart disease. However, there is a scarcity of studies that effectively predict mortality caused by heart disease among women. Hence, this study aims to effectively predict heart disease among women, using the MLA data set.

Research Questions

Our research questions are as follows: (1) what are the risk factors for the development of heart disease in Jordanian women, that are related to death versus a life status? (2) What is the best model to use to generate the best performance metrics based on the data extracted from electronic health records (EHRs)?

Methods

Study Design

The study used a retrospective design in retrieving data from Electronic Health Solutions (EHS) for Jordanian women with heart disease. Data were collected for Jordanian women who were admitted to public hospitals from 2015 to 2021.

Study Variables

Patients' age, geographic location (governorate), medical diagnosis based on the International Classification of Disease, Tenth Revision (ICD-10), laboratory findings including high-density lipoprotein (HDL), lactate dehydrogenase (LDH), cholesterol level, fasting blood sugar (FBS), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were obtained from the health data analytics department for the admitted patients for the period of 2015 to the end of 2021. Data were downloaded as Excel (Microsoft Corp) sheets in many files for health data analysis. None of the data on age, medical diagnosis, and place of residence were missing. However, there were numerous missing values for variables of LDH, HDL, cholesterol, glycated hemoglobin (HbA_{1c}), creatinine, FBS, and vital signs including oxygen saturation (measured with pulse oximetry), heart rate, SBP, and DBP. Mean arterial pressure (MAP) and pulse pressure were calculated. Data were merged in a single file using the SPSS program [16] and then sorted and cleaned.

Data Source

After receiving approval to extract the necessary data, which took about 6 months, the health data analytics department that stores the EHRs was contacted. Unfortunately, we encountered some extraction challenges that made it difficult to gather all necessary data. Electrocardiography and catheterization reports are 2 examples of data that could not be obtained because they require a natural language processing method that is not available in the EHR system. In terms of physical information, the system lacked the patients' height, weight, and ejection fraction (percent), as well as information on occupation and dietary habits.

Data Analysis

Data Processing

Using frequency analysis and outlier detection, the data were examined for noise, inconsistency, and missing values. A large number of redundant data were removed after sorting, cleaning, and organizing the extracted data.

Data Transformation

The researchers chose the most relevant attributes of coronary heart disease using data visualization. Moreover, SPSS Modeler

(version 18.0; IBM Corp) [16] was used for manipulating, analyzing, and visualizing the data, which provides the features of presenting the data with high statistical power and predictive analysis and data management for descriptive and predictive modeling [17]. Descriptive modeling was used to identify the main risk factors for heart disease that lead to death. Furthermore, predictive modeling was used to build the appropriate model based on the overall accuracy and area under the curve (AUC).

Building Appropriate Model

This study applied the SPSS Modeler software application (IBM Corp) that helps users build and deploy predictive models. Data were imported and prepared after processing and transformation. Thereafter, SPSS Modeler offers a wide range of modeling techniques and algorithms to choose from, including decision trees, neural networks, regression, clustering, association rules, and more. The appropriate model was selected on the basis of data quality, problem type, and goals of the study. Once the model (Chi-squared Automatic Interaction Detection [CHAID]) was selected, the SPSS Modeler interface was configured to build the model. This involved specifying the input variables, target variables, and model parameters. Performance metrics including accuracy and AUC were used to evaluate the selected model.

However, the model in this study could be improved if the missing data were handled properly using proper imputation techniques. Overall, SPSS Modeler provides a comprehensive platform for data preparation, model building, evaluation, and deployment, making it a popular choice for data mining and predictive analytics tasks.

Ethical Considerations

The Committees of Scientific Research and Ethics of Research at the School of Nursing, The University of Jordan, as well as the ethics committee at the Ministry of Health (#MOH/REC/2022/3) provided their approval for the study to be carried out in a manner that complies with ethical standards. In addition, the Health Data Analytical Department at EHS provided their approval to the study. Patients' records were handled with confidentiality and anonymously using an ID as the distinguishing characteristic of each record. The data that were extracted were stored in a separate file that was locked up and stored in a secure location within the researchers' office.

Results

Sample Characteristics

The participants' average age was 62.6 (SD 15.4) years. In the extracted file of the women, angina pectoris was the most common diagnosis (n=1264, 62.3%), followed by congestive heart failure (n=764, 37.7%). The majority of the women lived in Amman, the capital of Jordan (n=1308, 64.5%), followed by Zarqa (n=257, 12.7%) and Irbid (n=153, 7.5%), which constituted the country's northern areas. A smaller percentage of women lived in Karak (n=66, 3.3%), Maam (n=24, 1.2%), and Aqaba (n=21, 1.0%), which constitute the southern regions of the kingdom (Table 1).

The laboratory findings, including LDH, HDL, cholesterol, HbA_{1c}, creatinine, and FBS, were recorded. Vital signs, including oxygen saturation (measured with pulse oximetry), heart rate, SBP, DBP, pulse pressure, and MAP were used to stratify the patients' outcomes. Unfortunately, not all patient health records had all the workup results in their EHR. Table 2 displays the minimum, maximum, mean, and SD values of the clinical and laboratory results.

Table 1. Sample characteristics (N=2028).

Characteristics	Values
Age (years), mean (SD)	62.6 (15.4)
Medical diagnosis, n (%)	
Angina pectoris	1264 (62.3)
Congestive heart failure	764 (37.7)
Governorate, n (%)	
Irbid	153 (7.5)
Ajloun	2 (0.1)
Jarash	24 (1.2)
Mafraq	20 (1.0)
Balqa	104 (5.1)
Amman	1308 (64.5)
Zarqa	257 (12.7)
Ma'daba	48 (2.4)
Karak	66 (3.3)
Tafilah	1 (0.01)
Maan	24 (1.2)

Table 2. Work-up results and vital signs of the patients.

Findings	Participants, n	Minimum value	Maximum value	Values, mean (SD)
Lactate dehydrogenase (IU\L)	57	124.0	816.0	246 (141.5)
High-density lipoprotein (mg/dL)	41	11.9	69.30	26.8 (14.2)
Cholesterol (mg/dL)	54	46.4	319.0	127 (64.4)
Glycated hemoglobin (%)	191	2.15	22.30	3.98 (2.55)
Creatinine (mg/dL)	228	0.02	122.0	2.29 (10.24)
Fasting blood sugar (mmol/L)	271	18.0	977.1	136.9 (110.7)
Oxygen saturation (%)	421	36	100.0	93.9 (6.59)
Heart rate (beats per minute)	1440	19	170.0	81.4 (14.4)
Systolic blood pressure (mm Hg)	2028	72	250.0	149.5 (26.5)
Diastolic blood pressure (mm Hg)	2028	41	165.0	82.6 (15.7)
Pulse pressure (mm Hg)	2028	17	137.0	66.9 (21.6)
Mean arterial pressure (mm Hg)	2028	60.6	183.0	104.7 (17.2)

Predictive Model

The CHAID model demonstrates the most accurate model, out of 9 models, to predict death versus life status among women with heart disease, with an overall accuracy of 93.25% and AUC of 82.5% (Table 3).

The CHAID model helps in analyzing the given data to understand the main characteristics that are mostly associated with a given outcome or being a member of a target group. The results of the CHAID model are presented skillfully for interpretation as a decision tree graph [18]. The CHAID model merges the values of the target variable that is deemed to be statistically homogeneous while retaining all heterogeneous values. The first branch of the decision tree is then constructed using the best predictor, with each child node containing a set of uniform values from the selected field. The statistical test that is used depends on the target field's level of measurement, and this process is repeated until the tree is fully developed [19]. In addition, this model is similar to the other MLA as it divides the sample data into 70% (testing data set) and 30% (training data set) to determine whether the model generates reliable results.

Table 3. Seven models built for the study data.

Model	Overall accuracy (%)	Area under the curve
CHAID[a]	93.25	0.825
C5	93.09	0.500
Quest	93.09	0.500
C&R[b] tree	93.09	0.500
Discriminant	75.35	0.733
Decision list	46.79	0.699
Bayesian network	17.85	0.657
Neural network	17.26	0.534
Logistic regression	16.96	0.481

[a]CHAID: Chi-squared Automatic Interaction Detection.

[b]C&R: Classification and Regression.

The 17-node model was created using the SPSS Modeler. Multimedia Appendix 1 shows that the graph of the study, as produced by the interactive CHAID tree's beginning node, branched to 4 nodes (nodes 1-4) based on tissue oxygenation (measured with pulse oximetry) with a cutoff value of 93% since women who had an oxygen saturation of ≤93% were at a high risk of death caused by heart disease (n=34, 27.87%). In node 2, women who had an oxygen saturation of 93% and 95% had a mortality rate of 4.3%, node 3 shows that women who with an oxygen saturation of 95% and 96% had a death rate of 27.1%, and node 4 shows that women who had an oxygen saturation of >96% had the lowest mortality rates (12.9%; χ^2_3=140.7; *P*<.001).

Further, in the model, node 1 was split into 2 nodes, nodes 5 and 6, based on the pulse rate with a cutoff value of 97 beats per minute. Women who had a pulse rate of >97 beats per minute were at a higher risk of death (n=1257.14%; χ^2_1=10.8; *P*=.19). Node 2 split into 3 nodes based on age: nodes 7-9. Women who were older than 72 years were at a higher risk of death (n=45, 10.0%; χ^2_3=56.4; *P*<.001). Node 7 split into 2 nodes, nodes 12 and 13, based on SBP with a cutoff value of >187 mm Hg and a mortality rate of 8.5% (χ^2_1=23.4; *P*<.001). Node 4 split into 2 nodes, nodes 10 and 11, based on the pulse rate (heart rate) with a cutoff value of 97 beats per minute. Women with a pulse rate of >97 beats per minute had a higher mortality rate (n=8, 38.1%; χ^2_1=13.7; *P*=.004).

Node 9 split into 2 nodes based on medical diagnosis: nodes 14 and 15. Women diagnosed with congestive heart failure were at a higher risk of death (n=31,16.58%) than those with angina pectoris (n=14, 5.32%; χ^2_1=15.4; *P*<.001). Moreover, node 14 split into 2 nodes, nodes 16 and 17, based on pulse pressure with a cutoff value of 98 mm Hg. Women who had a pulse pressure of >98 mm Hg had a higher mortality rate (19.4%; χ^2_1=13.7; *P*=.002).

Discussion

Principal Findings

Several independent variables emerged as predictors of mortality caused by heart disease among the study participants, using the decision tree approach of the CHAID model. The CHAID model is a data mining technique that highly facilitates graphical presentation that provides an easy way for data interpretation in the medical field, with notable advantages over other models such as logistic regression analysis. In addition, it provides the ability to deal with multiple nodes, since it emerges all variables in a given data set [20].

Retrospective data were extracted from the EHRs and used to effectively predict death versus life status among Jordanian women who had heart disease. The built model predicts several predictor variables to identify women with heart disease who were at a high risk of death.

This study concluded that oxygen saturation (measured with pulse oximetry) is the most important predictor of death versus life status among female patients. We found that women with low tissue oxygen saturation had higher mortality rates than those with normal oxygen saturation. This finding is consistent with that of Cahyati et al [21] since they mentioned that lack of oxygenated blood in the myocardium is caused by atherosclerosis or plaque formation that blocks blood supply to the heart muscle. In turn, this leads to the formation of blood clots in the narrowing arteries, thus preventing blood flow to the cardiac system. This blockage can disrupt oxygen supply throughout the body, and the patient experiences shortness of breath, which, in turn, reduces oxygen saturation.

Second, pulse rate (heart rate) is the leading factor driving an increase in mortality among women. We found that women with a heart rate of >97 beats per minute are at a high risk of death. Many studies reported that heart rate is an independent risk factor for cardiovascular death [22,23]. Another large follow-up study and meta-analysis conducted by Tadic et al [24] supported the relationship between heart rate and cardiovascular morbidity and mortality among the general population; they reported that heart rate has a negative effect

on both cardio- and cerebrovascular mortality, and that it is recommended to reduce the heart rate among these populations in order to prevent the primary and secondary effect of cardiac events.

The third factor was related to aging, which increases the risk of death, particularly among women. This result is consistent with those of other studies that explored the association between the aging process and the risk of death caused by cardiovascular disease. Rodgers et al [25] and Woodward [26] reported that age is an independent risk factor for the development of cardiovascular events owing to corresponding reductions in sex hormones (primarily estrogen), which plays an important role in protecting against heart disease.

Systolic blood pressure is the fourth leading cause of the increased risk of mortality among women. Our results show that any woman who has an SBP of >187 mm Hg was at a high risk of death due to heart disease. This finding paralleled that of Razo et al [27], who reported the substantial causal relationship between SBP and the development of ischemic heart disease at a cutoff point of 165 mm Hg. This finding could be attributed to the aging process that is associated with many devastating lifestyle changes such as increased sodium intake, decreased intake of fruits and vegetables, increase cholesterol level, and decreased physical activity, which lead to a substantial increase in SBP.

The fifth-ranking predictor, medical diagnosis of women, contributed as a risk factor of death since we found that women who had congestive heart failure were at higher risk of death than those who had coronary heart diseases such as angina pectoris and acute myocardial infarction. Many previous studies verified that female patients with heart failure experience persistent death and high mortality due to a reduced ejection fraction [28]. The statistical analysis conducted by the American Heart Association reported that heart attacks and coronary heart diseases were the main causes of death among individuals with cardiovascular disease [29].

As the sixth-ranking predictor of mortality risk among women, pulse pressure was the last factor in this study in the built model. Our model predicted that a pulse pressure of >98 mm Hg increased the risk of death among women. Previous reports have shown that pulse pressure is an important determinant of, and greatly influences, the development of heart diseases since it increases arterial stiffness resulting from the loss of elastin and collagen, leading to increases in the SBP and pulse pressure velocity [30,31].

Implications in Clinical practice

Health care professionals must have a thorough understanding of the risk factors for heart disease in order to identify those women who are more susceptible to the development of heart disease and to implement the appropriate preventative measures. Outlined below are a few outcomes of risk factors in the treatment of heart disease.

Risk Assessment

Health care professionals can use risk assessment techniques to determine an individual woman's overall risk of developing heart disease. Oxygen saturation (measured with pulse oximetry), age, SBP, medical diagnoses, and pulse pressure are just a few of the risk factors taken into account by these instruments. By assessing a person's risk, medical professionals can determine whether additional diagnostic procedures and actions are necessary.

Patient Education

Finding and communicating risk factors for developing heart diseases in women is an essential part of clinical practice. Health care professionals can educate patients about risk factors that can be altered, such as blood pressure control and avoiding conditions that result in a particular medical diagnosis. They can provide guidance on how to implement necessary lifestyle changes such as adopting a heart-healthy diet, engaging in regular physical activity, quitting smoking, and skillfully managing stress.

Screening and Monitoring

Certain risk factors may necessitate routine screening and monitoring in clinical practice. This study provides critical proactive management strategies. For instance, patients with hypertension must routinely keep their blood pressure under control to prevent further complications of fatal heart diseases.

Strengths

This study provides an important proposed model that can help physicians in precise decision-making that reflects the clinical consequences of the main risk factors for the development of cardiovascular events; thus, primary prevention strategies can be initiated to optimize the recurrence of cardiovascular events. Second, follow-up of the main variables and clinical features as predictors can be taken into account as a risk management strategy.

Limitations

This study has the following limitations. First, missing, inconsistent, and noisy data were extracted from the EHS system. Second, several variables that could influence our results could not be obtained, such as smoking status, BMI, and the socioeconomic status of the population.

Conclusions

Cardiovascular heart disease remains the leading cause of death globally. In this study, the most important variables were predicted using big data that were extracted from the clinical variables from the EHRs. The CHAID model as an MLA verified the accurate identification of the main predictors of cardiovascular mortality among women and can be used as a convenient tool for clinical prediction. Besides, follow-up of the main variables of oxygen saturation, pulse rate, SBP, and pulse pressure provides strategic measures of primary prevention of further complications of cardiovascular events.

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Data Availability

Data will be made available upon request while preserving the study participants' privacy and confidentiality.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Predictive model of death versus a life outcomes among Jordanian women.
[DOCX File , 37 KB - cardio_v7i1e48795_app1.docx]

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Abbreviations

AUC: area under the curve
CHAID: Chi-squared Automatic Interaction Detection
DBP: diastolic blood pressure
EHR: electronic health record
EHS: Electronic Health Solutions
FBS: fasting blood sugar
HbA_{1c}: glycated hemoglobin
HDL: high-density lipoprotein
ICD-10: International Classification of Disease, Tenth Revision
LDH: lactate dehydrogenase
MAP: mean arterial pressure
MLA: machine learning algorithm
SBP: systolic blood pressure

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Original Paper

Digital Health Secondary Prevention Using Co-Design Procedures: Focus Group Study With Health Care Providers and Patients With Myocardial Infarction

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Abstract

Background: Myocardial infarction (MI) is a debilitating condition and a leading cause of morbidity and mortality worldwide. Digital health is a promising approach for delivering secondary prevention to support patients with a history of MI and for reducing risk factors that can lead to a future event. However, its potential can only be fulfilled when the technology meets the needs of the end users who will be interacting with this secondary prevention.

Objective: We aimed to gauge the opinions of patients with a history of MI and health professionals concerning the functions, features, and characteristics of a digital health solution to support post-MI care.

Methods: Our approach aligned with the gold standard participatory co-design procedures enabling progressive refinement of feedback via exploratory, confirmatory, and prototype-assisted feedback from participants. Patients with a history of MI and health professionals from Australia attended focus groups over a videoconference system. We engaged with 38 participants across 3 rounds of focus groups using an iterative co-design approach. Round 1 included 8 participants (4 patients and 4 health professionals), round 2 included 24 participants (11 patients and 13 health professionals), and round 3 included 22 participants (14 patients and 8 health professionals).

Results: Participants highlighted the potential of digital health in addressing the unmet needs of post-MI care. Both patients with a history of MI and health professionals agreed that mental health is a key concern in post-MI care that requires further support. Participants agreed that family members can be used to support postdischarge care and require support from the health care team. Participants agreed that incorporating simple games with a points system can increase long-term engagement. However, patients with a history of MI emphasized a lack of support from their health care team, family, and community more strongly than health professionals. They also expressed some openness to using artificial intelligence, whereas health professionals expressed that users should not be aware of artificial intelligence use.

Conclusions: These results provide valuable insights into the development of digital health secondary preventions aimed at supporting patients with a history of MI. Future research can implement a pilot study in the population with MI to trial these recommendations in a real-world setting.

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KEYWORDS

co-design; digital health; myocardial infarction; qualitative; participatory; mobile health

Introduction

Myocardial Infarction

Myocardial infarction (MI) is the leading cause of morbidity and mortality globally [1]. Experiencing an MI increases the likelihood of a subsequent MI, resulting in 30% higher mortality rates than the general population [1]. Secondary prevention strategies can be implemented to support patients with a history of MI, particularly when regular contact with their health care provider is no longer feasible. These strategies have the potential to facilitate patients with a history of MI self-manage their condition in alignment with health providers' recommendations and promote positive, heart-healthy behaviors. Cardiac rehabilitation programs are a traditional form of secondary prevention used to encourage positive behavior change after MI and are found to reduce readmission and mortality [2,3]. However, the attendance and engagement of patients with a history of MI in these programs is low [4]. Studies have identified several barriers to cardiac rehabilitation, including concerns about engaging with the content, travel time, fees, or conflicting schedules [4-6]. Therefore, other forms of secondary prevention are needed to promote the lifestyle changes required to manage MI risk factors.

Key protective factors for MI include smoking cessation, increased physical activity, and a healthy diet [7]. However, a global study on cardiovascular disease using data spanning between 2003 and 2009 from 153,996 adults determined that only 4.3% of adults with cardiovascular disease adopted all 3 positive lifestyle behaviors [8]. To substantiate this, an 11-year longitudinal study found that 79% of MI events could be prevented in men who adhere to 5 protective factors: a healthy diet, reasonably low alcohol consumption, smoking cessation, high physical activity, and the absence of a high waist circumference [7]. Despite its clear importance, there is a markedly low level of adherence to protective factors in the cardiovascular population, indicating that other efforts need to be made to assist patients with a history of MI in changing negative health behaviors.

Digital Health

Digital health has become an increasingly feasible modality for implementing behavior change support in a clinical population in a cost-effective manner [9,10]. It can directly address the shortcomings of traditional cardiac rehabilitation. Namely, ensuring that content is engaging with each user, eliminating the need for travel, reducing fees, aligning with patient schedules, and being easy and accessible so that patients can easily implement lifestyle changes [4-6]. Digital health technologies have been widely supported among scientific and health care communities, with the American Heart Association encouraging the use of mobile health (mHealth) for cardiovascular disease prevention [11]. Their stance was based on multiple randomized controlled trials using mHealth, which resulted in weight loss, physical activity, smoking cessation, blood glucose management, hypertension management, and lipid management [11]. Digital health has been successfully used to reduce cardiovascular disease risk factors and outcomes, with secondary preventions leading to a 40% reduction in the relative risk of cardiovascular disease outcomes and reduced morbidity and mortality [12]. Specifically, digital health secondary preventions led to significant reductions in systolic blood pressure, reduced antiaggregant medication nonadherence by 69%, and reduced rehospitalization by 55% compared with standard care [13]. This risk reduction is greater than that of other common preventive measures, such as statins, aspirin, and blood pressure reductions with β-blockers [12]. Ultimately, the all-cause mortality rate is reduced by 49% when comparing those who used digital health secondary preventions compared with standard care, showing the utility of digital health in cardiovascular disease secondary prevention [13].

mHealth, a subset of digital health, is a highly used health care tool owing to its intuitive implementation, with most people in Western countries owning an mHealth device [14]. mHealth interventions have been shown to significantly improve lifestyle cardiovascular risk factors, including improvements in systolic-diastolic blood pressure levels, smoking cessation, medication adherence, BMI, patient satisfaction, and quality of life after 1 year compared with usual care [15,16]. mHealth is a useful tool as patients with a history of MI carry mobile phones throughout the day, making daily mHealth interventions possible, such as implementing timely SMS text messages [17-19]. SMS text messaging interventions can provide advice, motivational reminders, and lifestyle behavior change support and have been found to decrease low-density lipoprotein cholesterol levels, systolic blood pressure, BMI, and smoking and improve physical activity and medication adherence [17-19]. Therefore, there are marked clinical and behavioral indicators showing utility in digital health and mHealth approaches [20], yet they have not been widely adopted [21,22].

Key barriers to the adoption of digital health are a lack of technology usability and user involvement during the design of the technology [21]. One way to improve technology usability is to use machine learning algorithms, which aim to learn from existing data and adapt their output using mathematical models [23]. Machine learning is based on big data (which are becoming increasingly available using mobile tracking) and can be used to predict individual health behavior and tailor the technology to the life and context of patients with a history of MI [24]. In addition, designing digital health technology with the advice of end users can mitigate these barriers by gaining insight into how users would practically use technology to support their health needs [25].

Co-Design Research

This approach to intervention development is known as co-design or participatory research [22]. The following co-design principles allow researchers to understand the needs of the target population, enhance communication and cooperation between stakeholders, and increase user satisfaction and loyalty [26]. Each of the parties involved in the co-design should provide valuable insights into their expertise. The early stages of co-design are used extensively in novel intervention development [27]. The architecture of these early stages of co-design is mostly studied using focus group discussions (FGDs) and interviews with the stakeholders of the solution, that is, the user and health professionals (HPs) [27,28].

This Study

Our study, deemed MiSmartHeart, aimed to identify the core needs of patients with a history of MI in the context of the prevention of subsequent MI events and explain how these can be addressed using features of a digital health solution, as identified by both patients with a history of MI and HPs.

Methods

Design

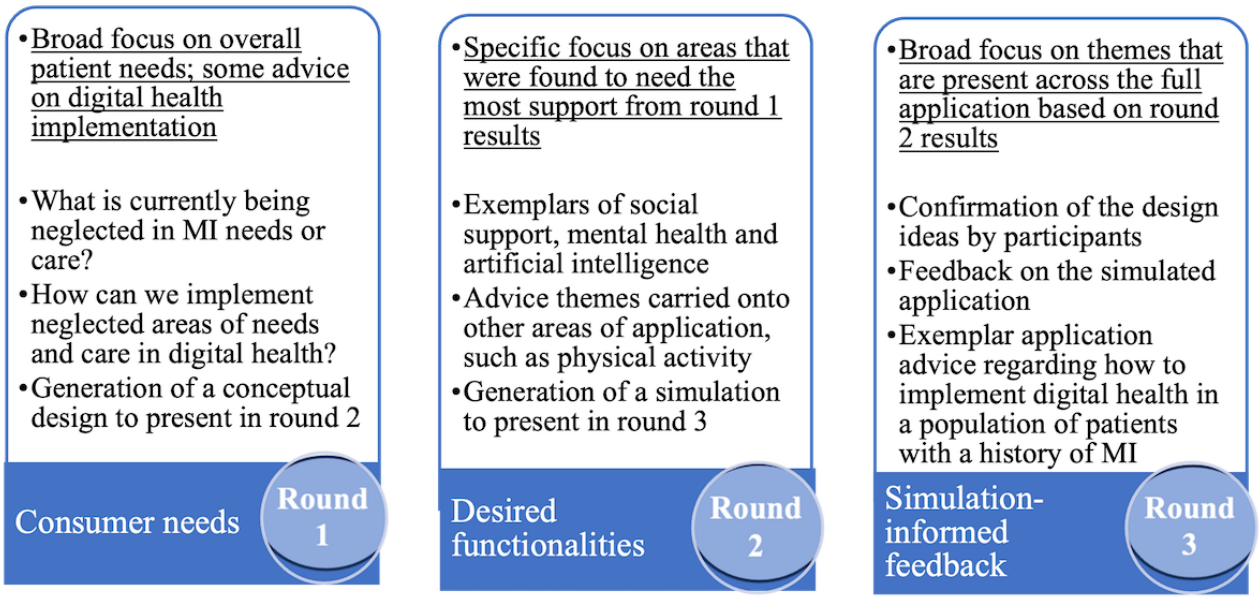
The MiSmartHeart study used a qualitative and iterative approach to refine the essential components of MI secondary prevention informed by end users. This study uses similar co-design applications as those reported in the specialized co-design literature [29,30]. For instance, this study involves iteratively obtaining opinions and advice from multiple stakeholders using FGDs and interviews across multiple rounds of discussion, which leads to mock-ups of the solution [27]. These rounds of discussion can refute, refine, build on, or confirm advice from the previous rounds. This study comprised 3 iterative phases deployed via 3 rounds of FGDs. The 3 rounds are defined as follows:

Round 1 was titled "consumer needs." In this round, we attempted to determine what the overall population needs are by discussing real-world issues with involved parties, that is, patients with a history of MI and HPs. Round 1 was broad and exploratory, and the findings were consolidated by identifying overarching unmet needs. The results of this round led to an initial conceptual design developed by the research team.

Round 2 was titled "desired functionalities," and it involved obtaining more information about the core unmet needs identified in round 1 and methods to address these needs. Participants were shown visual conceptual designs created based on the advice from round 1. The research team explained to participants that these designs were intended to relay core concepts of possible digital health features identified in round 1, rather than depicting a visual mock-up of a designed intervention. Round 2 was more structured and less broad than round 1, as the discussion focused on elaborating on a few key unmet needs identified in round 1. The research findings were consolidated by identifying categories and subcategories and drawing conclusions into a simulated design. The results of this round led to the creation of an in-depth simulation displaying each feature of the proposed app to be discussed in the next round of FGDs.

Round 3 was titled "simulation-informed feedback," and it involved providing an example simulation to generate new ideas to address the problem and to gain additional feedback. The results of this round provided a comprehensive overview of the additional features and functions needed in a self-management app to support patients with a history of MI. These insights are broad and not bound to the key unmet needs elaborated on in round 2. These insights can be integrated into a fully digital health intervention. The key anticipated outcomes for each round have been described in Figure 1.

Figure 1. Anticipated outcomes for each round of focus group discussions. MI: myocardial infarction.



Participants

A total of 38 participants were recruited across the 3 focus group rounds, with 11 participants recruited in multiple rounds. Inclusion criteria were (1) aged ≥18 years and (2) self-reported experience of an MI for which they were subsequently hospitalized or self-reported involvement in the care of patients with a history of MI. Participants were excluded if they could not speak English, did not reside in Australia, or did not own a device to allow communication with the research team (ie, mobile phone or computer).

Round 1 included 8 participants (4 patients with a history of MI and 4 HPs). As this round was primarily intended as an initial scope to enable further exploration in future rounds, this sample size is within acceptable standards for the exploratory stages of co-design according to the specialized literature [28].

Round 2 included 24 participants (11 patients with a history of MI and 13 HPs). Round 3 included 22 participants (14 patients with a history of MI and 8 HPs). As rounds 2 and 3 required more idea generation and evaluation, we aimed to recruit a larger number of participants. In round 3, we intended to recruit more patients with a history of MI than HPs. This is because patients with a history of MI would be the primary consumer of the digital health intervention; therefore, they would be best able to advise and evaluate the final simulated prototype. Within each round, there were no repeat interviews or FGDs. Considering repeated participation across rounds, we engaged with the participants a total of 54 times. Participants' demographics were explained across the 3 rounds (Table 1).

Table 1. Participant information across 3 rounds of focus group discussions.

Participant types and characteristics	Round 1 (consumer needs)	Round 2 (desired functionalities)	Round 3 (simulation-informed feedback)
Patient			
Age (y), mean (SD)	• 40.75 (13.36)	• 51.82 (12.43)	• 49 (10.59)
Female sex, n/N (%)	• 3/4 (75)	• 5/11 (45)	• 7/14 (50)
Retained from previous round	• N/A[a]	• 2 patients retained from round 1	• 5 patients retained from round 1 or 2
Highest education	• 2 certification or accreditations 3 or 4 • 2 diploma or advanced diploma	• 5 certification or accreditations 3 or 4 • 2 diploma • 2 bachelor • 1 postgraduate • 1 no answer	• 4 certification or accreditations 3 or 4 • 4 diploma • 2 no answer • 1 postgraduate • 1 bachelor • 2 high school
Race or ethnicity	• 3 Australian participants • 1 Asian participant	• 10 Australian participants • 1 other participant	• 11 Australian participants • 3 other participants
HP[b]			
Female sex, n/N (%)	• 3/4 (75)	• 9/13 (69)	• 7/8 (88)
Retained from previous round	• N/A	• 4 HPs retained from round 1	• 5 HPs retained from round 1 or 2
Profession	• 1 GP[c] • 1 physiotherapist • 1 aged care emergency attendant • 1 rehabilitation consultant	• 5 cardiac rehabilitation specialists • 4 cardiac nurses • 2 GPs • 1 physiotherapist • 1 aged care emergency attendant	• 4 cardiac rehabilitation specialists • 4 cardiac nurses

[a]N/A: not applicable.

[b]HP: health professional.

[c]GP: general practitioner.

We intended to recruit both new and existing participants in the study for various reasons. First, existing participants were needed in the study to amend or confirm that our representation of their advice from the previous round was accurate and achieved its intended purpose. However, new participants were recruited to reduce the potential for participant bias, that is, confirming the outcome because it is based on their advice rather than critiquing the outcome of their advice. New participant recruitment was also needed for a greater likelihood of generating new ideas and concepts that were not explored in the previous rounds. Amending and confirming previous participant advice with newly recruited participants provided more reliability in that the shared ideas represent opinions held by this population.

Procedure

This study was conducted between November 2020 and December 2021. The researchers conducted data analysis and obtained the results after each round to implement insights into the following round.

Researchers conducted FGDs and qualitative interviews with patients with a history of MI and HPs (eg, general practitioners, nurses, and cardiac specialists). Participants were people living in Australia who were aged ≥18 years. Eligibility criteria was as follows: the patients with a history of MI must have a history of hospitalization for MI and HPs must have experience treating patients with a history of MI. Participants were consecutively sampled with either web-based advertisements on various cardiology-focused Facebook pages and social media websites, or in person, with flyers delivered to cardiology clinics and

assisted living villages in Victoria, Australia. Advertisements prompted participants to fill out an expression of interest form, after which the researchers emailed the participants. Participants had no prior relationship with the researchers but understood that the study was a part of PhD research concerning behavior change.

Semistructured FGDs and interviews were also conducted. FGDs were organized based on availability, with FGDs preferred over interviews to allow the exchange of ideas between participants. If the participant schedules did not align or they did not feel comfortable speaking with other participants, an interview was conducted instead. FGDs and interviews were delivered on either Zoom (Zoom Video Communications), a popular videoconference system, or a phone call with the participant if they could not use Zoom. All attendees in these FGDs and interviews were recruited as participants for this study. A question guide was created based on the research team's expert knowledge of digital health, behavior change, and cardiovascular disease. The question guides from rounds 2 and 3 were created considering the advice provided from the previous round, with an emphasis on exploring the previously mentioned topics with more granularity. The full question guides outlining discussion topics for each round are available (Multimedia Appendix 1). FGDs were held with a maximum of 5 people in the session, along with 2 interviewers (duration: 60 min). Most focus group sessions included 2 or 3 participants. The interviews consisted of 1 patient with a history of MI or an HP, along with 2 interviewers (duration: 40-60 min). One male interviewer had an extensive background in digital health for chronic disease (FF); the other female PhD student had experience in clinically interviewing cardiology patients in a hospital setting (MLP). Together, these interviewers conducted FGDs and interviews across all rounds. Recruitment continued until the researchers agreed that data saturation for that round was reached. Audio and video were recorded on Zoom with the participants' consent and then transcribed. Transcripts and results were not sent to participants for confirmation.

Ethical Considerations

The Monash University Human Research Ethics Committee approved this study (reference: 25035, 22/7/2020), and all participants provided informed consent. Participants were reimbursed with an Aus $30 (US $19.12) shopping e-voucher. All data was deidentified upon data analysis and writeup.

Data Analysis

Our descriptive data analysis involved a flexible approach, which was found to be effective in obtaining rich data [31]. The qualitative methods use the tenants of naturalistic inquiry, with a primary interest in studying humans in their natural state without the constraints of preexisting theoretical underpinnings [32]. For all transcribed focus group and interview discussions, data were extracted into NVivo (version 20.5; Lumivero). Here, participants were separated into "patients with a history of MI" and "HP" to establish initial codes based on the data. Once codes were created, categories that encompassed the codes for each patients with a history of MI and HP group were defined.

Multiple iterations were performed to determine which groups of categories were the most representative of the data. Each category consisted of subcategories (grouped codes under a category). When a consensus among the 2 researchers (ie, the first and second authors) was reached, key data were extracted into an Excel (Microsoft Corporation) sheet based on these key categories and subcategories. From here, categories were sorted from the most common to least commonly mentioned, which was used to prepare the results. The frequency of each category for each patients with a history of MI and HP group, along with illustrative quotes from the participants, was included.

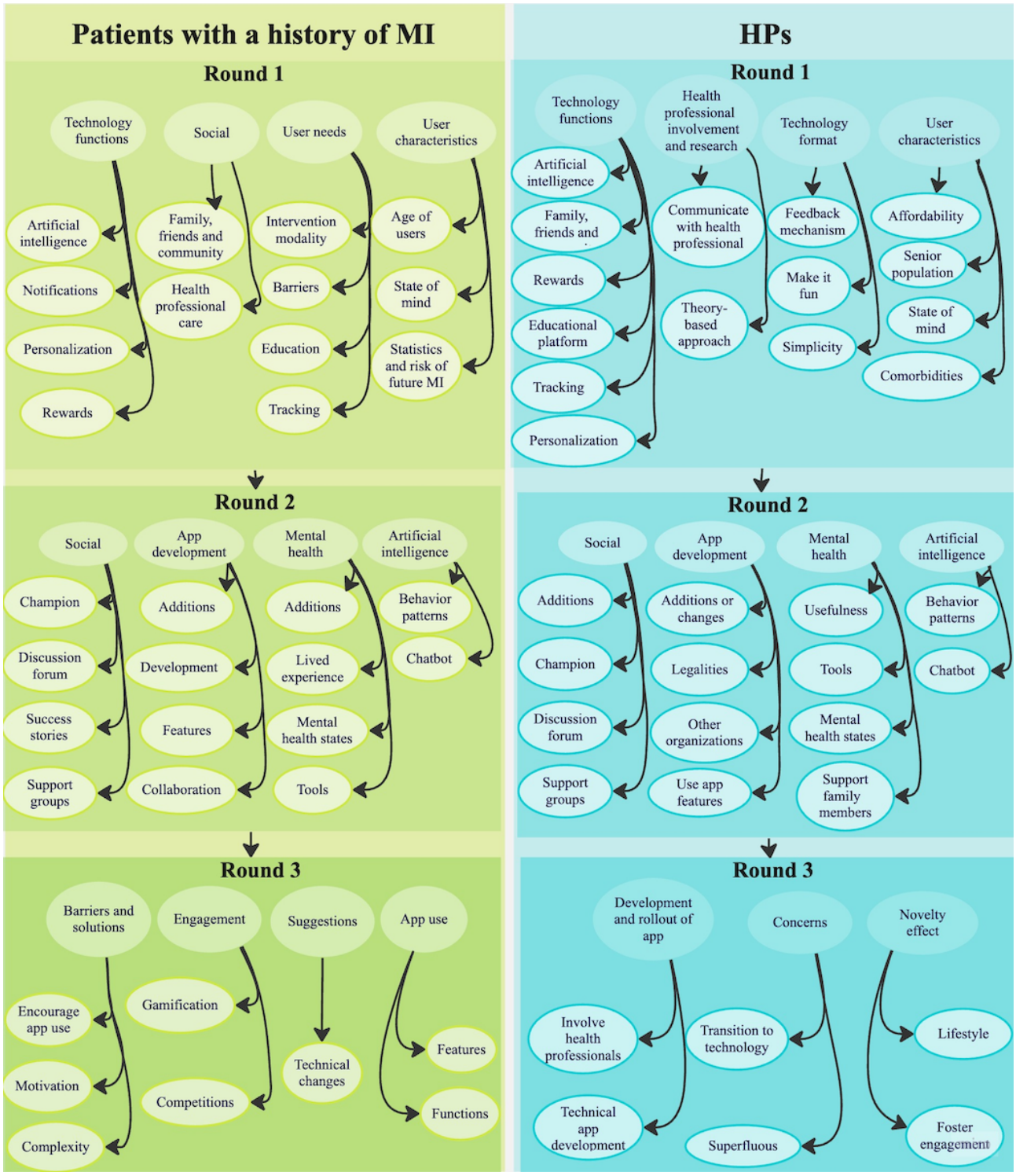
Results

Round 1: Consumer Needs

Overview

Discussions for patients with a history of MI fell under four primary categories: (1) *technology functions*, (2) *social*, (3) *user needs*, and (4) *user characteristics* (n=133). HP discussions fell under four different categories: (1) *technology functions*, (2) *HP involvement and research*, (3) *technology format*, and (4) *user characteristics* (n=65). These were sorted from most commonly to least commonly mentioned. Feedback from round 1 (consumer needs) informed the discussions planned for the subsequent round 2 (desired functionalities). The subcategories for each round are listed under each category (Figure 2). A detailed breakdown of the advice throughout each round is provided in Multimedia Appendix 2.

Figure 2. Categories and subcategories in rounds 1 to 3 for patients with a history of myocardial infarction (MI) and health professionals (HPs).



Patients With a History of MI Advice From Round 1

Patients with a history of MI discussed *technology functions* most extensively concerning artificial intelligence, notifications, personalization, and rewards (n=47). Patients with a history of MI mentioned that they would trust the general advice provided by artificial intelligence but would check specific advice with an HP:

> *Does this tablet interact with something else? Asking a chat bot would be fine because they would know...if it's something a little bit more to do with you personally I think you'd want to rely on a health professional rather than chatbots.* [patient with a history of MI 1, interview]

Notifications were recommended primarily for medication and should be personalized according to users' clinical characteristics, such as time since the MI, and users' performance on the app, such as the rate of goal achievement. Points should be used in a rewards system, and patients with a history of MI explained how social competition and fundraisers can increase intrinsic satisfaction:

> *It gives me little stars and rewards...you could get money or raise money or anything like that, but it was displayed on your page I guess for anyone who was sponsoring you to see.* [patient with a history of MI 2, interview]

Patients with a history of MI discussed *social elements* regarding family, friends and the community, and HP care (n=30). They expressed a need for support groups and peer support, which are currently unmet: "You could find people in your area to go on a walk or you could find a local sports club" (patient with a history of MI 3, interview). Patients with a history of MI would use an interface with no HP interaction and would like the option to set reminders about what to ask their HP on their next visit. When asked if they would use a technology without HP interaction, 1 participant said, "You know, that would be good," and later, "when you go in there you just blank out, you know when you go and see a medical professional" (patient with a history of MI 4, interview).

Patients with a history of MI also discussed *user needs*, including intervention modality, barriers, education, and tracking (n=30). Most patients with a history of MI preferred a simple app modality over other modalities because of its convenience. Barriers included the user's technical ability to set up and use an app, containing relevant information for individual users, and the user's motivation:

> *It was just so complicated. I just didn't have the strength or the ability to go out and try and work out how to use an Apple Watch and then coordinate it to my heartbeat and then send it to him. So that was all in the too-hard basket.* [patient with a history of MI 4, interview]

Education on the effects of surgeries and medication, risk factors, exercise, cardiopulmonary resuscitation, and diet guidelines and the next steps in the users' journey were identified as a facilitator for app use: "Sodium and stuff like that, what are good, what are levels sort of OK to have?" (patient with a history of MI 2, interview). Tracking was highly emphasized, including sleep, pain symptoms, medication, diet, exercise, smoking, pulse, oxygen levels, steps, calories, blood pressure, cardiac blues and mood, and weight.

Finally, patients with a history of MI advised on *user characteristics*, including the age of users, state of mind, and statistics of a future MI (n=26). Patients with a history of MI advised that some older adults would not have an issue with technology use and that experiencing an MI is often motivation enough to change negative lifestyle behavior:

> *It's really hard in terms of like motivating, without having had...that big scare.* [patient with a history of MI 2, interview]

> *Everything is going is all digital...look at it more rather than if you go and gave them a pamphlet.* [patient with a history of MI 1, interview]

Patients with a history of MI were keen to receive statistics concerning the risk of recurrent MI episodes to stimulate behavior change. They would also welcome prompts that emphasize the need for behavior change in addition to surgical and medication treatments. Patients with a history of MI emphasized extreme depression, anxiety, and loneliness after their MI:

> *A lot of anxiety that people may have never had, especially when you learn to be on your own after a heart attack and you've got to be prepared if you have another one...the people who are alone might need that extra support.* [patient with a history of MI 4, interview]

HP Advice From Round 1

HPs discussed *technology functions* most extensively regarding the use of artificial intelligence; rewards; personalization; tracking; and provision of education and support from family, friends, and the community (n=36). Some HPs were unsure whether patients with a history of MI would understand artificial intelligence: "I think 50/50 [would use artificial intelligence]...I think we give the person the choice" (HP 1, interview). They suggested catering to education levels by providing relatively easy content to understand. HPs suggested that a family member of a patient with a history of MI can be made into a "champion" over the app, where they can keep track of the user's health goals. Patients with a history of MI can have a "champion in their app that they connect the patient to one of your family or friends and they get like a very good message, supportive and motivational from their supporters, from their champion. This is one of the ways that we can like reinforce their behaviour change as well" (HP 2, FGD). An incentives program would motivate patients with a history of MI with rewards, including a fruit hamper or a personal training session. The app should be personalized based on time since MI and specific user goals:

> *The most important element is time. What sort of information or education the person needs in the first 24-48 hours after discharge...[where] we do expect recurrence of the heart attack much more than what would happen in the months after.* [HP 3, FGD]

HPs mentioned that tracking capabilities should include a digital Webster pack and daily diary.

HP involvement and research were discussed, including communication with an HP and using a theory-based approach (n=11). They emphasized the importance of the output being clinically sound and interpretable by HPs: "It should be clinically sound and logical, so the information they get should be meaningful and interpretable by a healthcare professional" (HP 3, FGD). They also suggested that theoretical approaches are necessary, such as the "diffusion of innovation theory" (HP 3, FGD), which tailors different approaches to patient technology adoption behaviors [33]:

> *We can incorporate different theories, behaviour change theories. And we need to start involving and engaging patient in the design.* [HP 2, FGD]

HPs emphasized an appropriate *technology format*, including a feedback mechanism, making it fun and simple (n=9). HPs encouraged feedback loops based on user behavior to improve motivation. This feedback loop "gives them hope and it gives them an understanding as to how they are they're doing" (HP 3, FGD). Simple formatting with a hierarchical structure that

incorporates visuals and games, such as a visual of a tree thriving when app use is high or suffering if app use is low, would make the app appealing:

> *That application about time management...when you know you're not able to finish that [study] time of 45 minutes that you already plan, it's like someone is cutting a tree, that it makes you somehow guilty.* [HP 4, FGD]

Finally, certain *user characteristics* should be considered in app development, such as socioeconomic demographics, older adult population, comorbidities, and users' state of mind (n=9). To make the app affordable for all socioeconomic groups, developers should consider whether subscriptions or one-time purchases are appropriate. Some older adults would need to be guided on how to download an app. HPs stated that health needs should be determined based on each user's comorbidities, and self-care, uncertainty, and mental health symptoms such as health-related stress should be supported. It is common that patients with a history of MI will "not know what to do about the condition. Frightened to ask for more care. Lacking confidence and continuing to be independent" (HP 1, interview).

Round 2: Desired Functionalities

Overview

The advice from round 1 (consumer needs) was discussed with patients with a history of MI and HPs concerning round 2 (desired functionalities). In round 2, we walked participants through a conceptual design and asked for specific advice about features that were emphasized in round 1, such as social support. Example screenshots of this design are available in Multimedia Appendix 3. The desired functionalities were determined from the previous round to be unmet needs or opportunities. We organized the discussion points from the desired functionalities round into four primary categories: (1) *social*, (2) *app development*, (3) *mental health*, and (4) *artificial intelligence.* These were sorted from most to least commonly discussed. These categories were applicable to both patients with a history of MI (n=230) and HPs (n=256) because the targeted line of questioning was designed to elicit specific and detailed responses.

Patients With a History of MI Advice From Round 2

Patients with a history of MI detailed *social* support features, including the creation of a "champion," discussion forum, success stories, and support groups (n=76). Patients with a history of MI preferred the term "buddy" to champion, stating that a buddy should have experienced an MI and can communicate with the user over the app:

> *Somebody who's actually had the experience, because my wife's holding me accountable. She doesn't understand how I feel half the time.* [patient with a history of MI 5, FGD]

An artificial intelligence buddy was suggested for users who wanted only information and reminders rather than a personal connection: "If you want total objective-type support then an automated agent would be really good" (patient with a history of MI 5, FGD). Patients with a history of MI had a high interest in the discussion forum, suggesting filtering discussions based on conditions and receiving personalized notifications about liked threads. They mentioned the importance of short success stories and support groups with consistent scheduling systems. Patients with a history of MI preferred the support groups to be structured with presentations from HPs, followed by a patients with a history of MI–led question and answer session:

> *I would prefer the presentation and then people can join in and ask questions...that will really get people talking.* [patient with a history of MI 2, interview]

Patients with a history of MI discussed *app development*, including additional features, development, app features, and collaboration (n=57). Additional features include explicit references to personalization capability, links to social media, journaling functions, and further tracking features, including blood pressure, oxygen, subjective pain, and other sicknesses. Patients with a history of MI expressed the need for developers to store large files on a server or YouTube to reduce phone storage requirements: "Make the app not chunky with megabytes...there's premium space on a lot of phones" (patient with a history of MI 6, FGD). Features included downloading a report to show their HP and GPS tracking for the user to avoid their personal, habitual smoking or alcohol locations. One patient with a history of MI said the GPS tracking can inform users to "'Quit, turn around. Go the other way. Avoid at all costs.' Probably a warning of some form could pop up" (patient with a history of MI 7, interview). Finally, collaborating with a corporate partner would facilitate app development and rollout.

Patients with a history of MI spoke about the importance of *mental health*, including additional features, lived experience, mental health states, and tools (n=51). Additions include fun exercises that can raise mood, progressive muscle relaxation to improve sleep, and encouraging hobbies (eg, gardening): "'Have you done your exercises today?' just because you know, that releases the endorphins or something and makes you feel good" (patient with a history of MI 7, interview). Patients with a history of MI stated that isolation is particularly anxiety-inducing because of the looming fear of death. Along with anxiety, patients with a history of MI mentioned other mental states that should be addressed, including mood, depression, social uncertainty (eg, loved ones coping with their condition), sleep, maintaining positivity, mortality, and memory loss: "A lot of it's the focus on how do you cope with your condition? But we have to think about the people we interact with, how they cope with the condition?" (patient with a history of MI 5, FGD). Mental health modules should address these issues and can be organized based on the lived experience. Mindfulness exercises should emphasize the perception of the body and heartbeat so that patients with a history of MI can notice heartbeat abnormalities. Mindfulness of the body can help patients with a history of MI to "go and get help earlier. Probably a simple equation, you know something's not right and get it fixed. Get it looked at and in doing that, that's what saved my heart muscle" (patient with a history of MI 8, interview).

Finally, *artificial intelligence* was discussed, including behavior patterns and a chatbot (n=46). Visualizing user patterns of

behavior can motivate improvement, with diet, exercise, mental health, smoking, and drinking identified as the most important to visualize. Patients with a history of MI are willing to use the chatbot, particularly for subjectively uncomfortable or embarrassing questions that they would not ask an HP. For example, asking "a question you think is a really dumb question, or you're not sure. You can start with the chatbot and you get a response and you don't feel like you're embarrassing yourself because it's just a machine" (patient with a history of MI 5, FGD). The chatbot should use links and information from trusted sources and should mostly answer general questions, "as long as they're not sending me links to Wikipedia" (patient with a history of MI 9, interview). Patients with a history of MI stated that it should be adaptive, for example, if a low mood is recorded, it should suggest an intervention for low mood. However, patients with a history of MI would seek an HP's opinion regardless of the chatbot, and there is a concern that the chatbot may not understand the user's questions: "If I get stuck in a vicious cycle, the chatbot should somehow be configured to understand that it's caught in a loop...then issue an alternative resource link or number" (patient with a history of MI 10, FGD).

HP Advice From Round 2

HPs detailed *social* support, including additional features, a "champion," a discussion forum and a support group (n=95). Additions include outdoor activities such as park runs and promoting healthy restaurants to try with friends. HPs labeled the "champion" as a "buddy" who should undergo training, have a positive attitude toward change, and be matched to the user based on needs. This can include the "opportunity to have a little bit of training about motivational interviewing, etc. Like, you don't want someone saying, 'Oh, you know, that's hopeless. How come you started smoking again?'...maybe they'd have access to a 'be a champion app,' which would give them hints what to do when someone's not achieved a goal" (HP 5, FGD). They suggested that users can find a buddy from the support groups or discussion forums rather than appointing a family member (to reduce familial conflict) or use the chatbot as their buddy. They emphasized the need for a disclaimer on the discussion forum for potential misinformation and the ability to flag an item to be removed. The support groups should be a combination of (1) an open forum to share experiences and (2) presentations from an HP with a question-and-answer session. There should be group polls to choose discussion topics and a calendar for these recorded sessions running with an HP moderator: "Ahead of [the] week, we can ask them couple of questions and ask them which topic they prefer to talk in the next session" (HP 2, interview). The app should include an introductory recorded session to encourage users to participate.

HPs discussed *app development* including additional features or changes, legalities, other organizations, and the use of app features (n=66). Additions include a simple daily plan, blood pressure tracking, a monthly report, and a road map for the future:

> *Having that long-term vision and knowing that they're on the right pathway and they're doing the right things can be really beneficial. I'm all for having a really clear plan.* [HP 6, FGD]

HPs advised on further visual appeals, such as larger headings and videos. HPs emphasized privacy regulations and consent if support groups are recorded and suggested involving cardiac rehabilitation staff for advertisements:

> *People aren't going to stumble across it. Yeah, and maybe you should think about getting it as endorsed as a product through ACRA or Heart Foundation or linking with some of those organisations so that people are actually channelled there.* [HP 6, FGD]

GPS tracking to avoid the habitual smoking or drinking locations of patients with a history of MI is very novel and could be useful with large warnings to alert the user when nearing these locations.

HPs discussed *artificial intelligence*, including behavior patterns and a chatbot (n=49). Artificial intelligence should not be labeled or obvious to users. Personalized behavior patterns are likely to be used and should report on overall health, for example, patterns for chest pain symptoms and types of exercise. HPs suggested that the chatbot should both (1) enable specialist appointment booking and (2) answer both general and specific questions tailored to the user. The addition of an avatar can make the chatbot more personable: "Have an avatar and make it look like a person" (HP 7, interview). Overall, many patients with a history of MI will not completely trust the chatbot but may use it:

> *To me a chatbot is another tool in a large toolbox, so people may not use it. You don't need a screwdriver every single day. But you may need a screwdriver one day, and if you know how a screwdriver works, then you will refer back to it.* [HP 3, interview]

Finally, HPs discussed *mental health*, including mental health states, support from family members, tools, and usefulness (n=46). Patients with a history of MI can struggle with mental health more than with physical health:

> *Being in cardiac rehab for the many years...this is the biggest part of it. Now, it's going to always be more mental than physical.* [HP 8, FGD]

The feelings of patients with a history of MI of being broken, uncertain, and alone, along with the effect of quitting smoking and a changed sex life, should be addressed. HPs stated the app should support family members, who may also experience declined mental health, with dedicated modules (potentially in a "family member" app or section of the app):

> *Cover family emotions as well...because there's often been a bigger event for the family than it has been for the client, which sounds funny, but it's because they obviously don't remember any of it. Whereas, the family, say a wife who's witnessed it, or maybe done CPR and stuff like that, it's been a really horrific event for her.* [HP 9, interview]

Mental health modules should have problem-focused outcomes based on the experiences of patients with a history of MI. HPs stated that mindfulness exercises should be tailored to mental

health states, for example, different audio recordings for depression and anxiety. Overall, mental health was highly regarded by the HPs.

Round 3: Simulation-Informed Feedback

Overview

The advice provided from round 2 (desired functionalities) was extrapolated into a simulated design that was critiqued in round 3 (simulation-informed feedback). In round 3, we showed participants a mock-up prototype that they could interact with and asked for advice about features that apply to the full application, such as engagement features. The information derived from round 3 is presented in the following sections. Results from the patients with a history of MI were displayed in four primary categories: (1) *barriers and solutions*, (2) *app use*, (3) *engagement*, and (4) *suggestions* (n=286). Whereas HP discussions fell under three categories: (1) *development and rollout*, (2) *novelty effect*, and (3) *concerns* (n=96). Feedback from round 3 is listed in subsequent sections, sorted from most to least commonly discussed.

Patients With a History of MI Advice From Round 3

Patients with a history of MI discussed *barriers and solutions to these barriers*, including complexity, privacy, encouraging app use, and motivation (n=112). Patients with a history of MI suggested gradually introducing new features based on progress, for example, "Somebody who started off perhaps with the simple concept, once they got the hang of it and became familiar with it and comfortable, would then step up to the next level" (patient with a history of MI 11, FGD). Users should be able to choose a specific page that automatically loads every morning. Patients with a history of MI mentioned that upon setup, the app should ascertain features that users would use and only display these features. Push notifications can be used especially during extensive idle periods, for example, "It's been a month since you last did a health check. Would you like to go to the to the quick check page?" (patient with a history of MI 12, FGD). Organizational health sponsors can provide patients with a history of MI with a percentage of their product if goals are achieved.

Patients with a history of MI also discussed *app use*, including its features and functions (n=101). Many web-based resources are based on standards from other countries, for example, the United States; Australian standards and education are required: "It'd be good to have an Aussie one because the nutritional information is quite different" than American information (patient with a history of MI 9, FGD). Patients with a history of MI mentioned that their family members and carers should have their own app log-in to receive relevant support and education. Correlational graphs could show the link between biometric health data and activity levels or medication use:

> *So just being able to add different things into this section is good as well...then it shows you know, if you've missed a tablet, the effect of missing that tablet is your blood pressure goes up.* [patient with a history of MI 13, FGD]

Patients with a history of MI spoke about increasing *engagement*, including competitions, gamification, and rewards (n=51). Patients with a history of MI were unsure if they would compete with a large group. Rather, they would play a game or a competition against themselves or a buddy. The app should provide participation achievements rather than specific outcomes (eg, step count) because "everybody's different in their ability, in what they'd be able to do" (patient with a history of MI 15, FGD). Overall goal achievement across the app can mitigate negative self-talk, for example, "62% of users reach their food goals, gives you an indication that that's okay. It's literally only just over half. Therefore, the fact that I didn't reach my food goals is probably not that big a deal. But by the same token, you know, hey, it'd be nice to be in that 62%" (patient with a history of MI 14, interview). Patients with a history of MI suggests that with consistent app use, the user can earn a gamified level, such as "guru," displayed on the discussion forum. Rewards can include obtaining a percentage of certain brands, entry to a relevant health conference, or a one-on-one with the app's HP:

> *Medals are good, but they tend to have the lifespan is not great...in the long run, it's just an achievement on an app...especially if you're dangling like bigger, will say the carrot or fruit in front of it, you can have a one-on-one with a cardiologist...which is very, very valuable even the private system and in the public system.* [patient with a history of MI 13, FGD]

Concern that users would cheat led to a discussion on nontangible rewards. Nonmonetary rewards could involve expressive emojis, and medals were perceived as childish.

Patients with a history of MI provided additional *suggestions*, including added content to the app and technical changes (n=22). Content should include other contributors that affect physical symptoms (eg, the effect of weather on the heart): "It's the inflammation [caused by] I think the variations in climate that we get from all in one day" (patient with a history of MI 16, FGD). Patients with a history of MI suggested including a page for resources and emergency contacts for each user. The app should be relatively small and enabled to synchronize with the cloud, the phone's calendar system, family members' calendars, the Apple or Samsung Health app, Bluetooth devices, and other fitness apps. The app should allow the recording of heart rates for enabled phones.

HP Advice From Round 3

HPs discussed the *development and rollout of the app*, including the involvement of HPs, the likelihood of app use, and technical app development (n=39). An HP should be able to communicate with patients with a history of MI through the app for a check-up:

> *You know, building in those specialist follow ups, and maybe that would be something that when you talk about the journey, that that may be something that we could build into that journey as well, because it is able to be tailored and customized.* [HP 5, FGD]

The app should be introduced during or near the end of standard cardiac rehabilitation and framed as ongoing support. The app

can "be that sort of bridge for when people do finish [cardiac rehabilitation], that they've got somewhere else to go and you know, some of the options available to them" (HP 10, FGD). HPs stated that patients with a history of MI can meet potential app buddies with others involved in cardiac rehabilitation, creating a personal connection. Notifications should decrease in frequency over time and be titrated to determine how often the patients with a history of MI complete their goals.

HPs discussed ways to overcome the *novelty effect*, including fostering engagement and integrating the app into the user's lifestyle (n=33). Competitions without associated disappointment can foster engagement with the app, but if the leaderboard becomes demotivating, it can be removed:

> *My concern is for those people that are lower down on the leaderboard each time. Is that going to be something where they start to go, "oh, well, I'm not achieving like those people" and set them up for that disappointment.* [HP 5, FGD]

The app should have the functionality to see friends' activity levels to motivate the activity levels of patients with a history of MI. Points can tie in with a heart-healthy sponsor for discounts, but HPs are unsure whether patients with a history of MI require this external reward for effective behavior change. Upon installation, videos of a navigator should be used to guide new users through activities and modules. Patients with a history of MI "wanted somebody to guide them through what each stage meant, and what they would get out of it. So that they went into each section of [a] module and, perhaps the same for this, knowing what they expect to get out of it" (HP 11, FGD). This navigator should be a "patient. It's actually a consumer, consumer who's guiding people through" (HP 11, FGD). HPs suggested integrating goals on an adaptive figure of a heart that changes based on goal progress, for example, a healthy heart is displayed if goals are achieved.

Finally, HPs discussed *concerns*, including interest, motivation, superfluous features, and the transition to technology (n=24). They suggested that a dedicated health care team presenting content not otherwise available would maintain the interest of patients with a history of MI in the app: "Are you actually going to be doing your own videos?...I think it'd be great if, yeah, as much as possible" (HP 11, FGD). HPs stated that no features or functions are superfluous, although reducing manually entered information, visual clutter, and redundant notifications could maintain the interest of patients with a history of MI:

> *No, I don't think it's overwhelming...I think it's better to have more than less, I think sometimes you go on apps, and you think I'd just like to have this but it's just not available* [HP 10, FGD]

A companion website could simplify manual data entry, but the transition to technology will depend on each user with variability in affinity with technology. One participant asked if "you have to do it all on your phone, like you can't go online and enter stuff in?...I'm just thinking practically, like, you've got people [that] don't want to be typing on their phone" (HP 6, FGD).

Discussion

Principal Findings

This study aimed to specify the key needs identified by patients with a history of MI and HPs for the secondary prevention of MI using digital health technology. The results from the 3 rounds of FGDs provide rich information about the various primary needs of end users, the methods and structures on how to provide these needs in digital health technology, and the practicalities of rolling out the app to patients with a history of MI. We will organize the discussion of findings according to two main themes: (1) topics that patients with a history of MI and HPs agreed on and (2) topics on which patients with a history of MI and HPs had differing opinions. For theme 1, these topics included addressing mental health; the fit of the intervention within current health care (ie, the timing of app disbursement); and features of the app, including a focus on family members and engagement. For theme 2, these topics included a lack of social support and the use of artificial intelligence to deliver support. We start by discussing theme 1 in the context of prior research.

Comparison With Prior Work

Research emphasizes the impact of MI on the exacerbation of mental health problems and that decreased mental health can lead to poorer heart health outcomes [34,35]. However, our participants stated that there is a lack of support for mental health and a strong desire for greater support. Participants emphasized specific areas of mental health, including normalizing feelings of depression, anxiety, loneliness and not feeling "whole;" providing education to patients with a history of MI, such as awareness of warning signs for mental health issues; tools to assess and track mental health; intervention techniques, such as mental health modules and mindfulness activities; and using social formats, such as discussion forums. These needs have also been stressed in the mental health literature [36] but not incorporated into cardiology-related interventions. Therefore, our findings provide specific approaches for improving mental health in patients with a history of MI by using digital health tools.

Both patients with a history of MI and HPs agreed that incorporating the app during or immediately after cardiac rehabilitation would ensure the best likelihood of habit formation and long-term use of the app. A similar app provided directly after cardiac rehabilitation was able to demonstrate this habit maintenance and low attrition (n=2) after a 1-year follow-up, with improved peak oxygen uptake, exercise performance and habits, and self-perceived goal achievement in comparison with a control [37]. Participants in this study mentioned that users may consider the app to be an extension of cardiac rehabilitation, contributing to their earnest and consistent long-term use of the app.

Both patients with a history of MI and HPs agreed that family members of patients with a history of MI are often neglected in postdischarge care. By incorporating app modules or a version of the app designed for family members with a focus on promoting education and mental health for these family members, they will be best able to provide frequent support to

patients with a history of MI in their recovery journey. This need is reflected in previous research, in which cardiac rehabilitation educational programs for patients and family members have been theoretically developed [38]. The involvement of family members in each stage of rehabilitation was found to result in improved exercise tolerance, quality of life, perceived stress, and state anxiety [39]. Therefore, there is merit in involving family members in the care of patients with a history of MI that can potentially alleviate poor reported mental health symptoms.

Finally, strategies to increase engagement with digital health were similarly discussed between patients with a history of MI and HPs. There is limited research addressing engagement in the MI literature, but research on engagement (eg, leader boards and points systems) to increase physical activity has shown promise [40,41]. Patients with a history of MI and HPs advised the use of a simple game with a points system that levels up the user's profile, which is displayed on the discussion forum. They stated that points can also be earned together with a buddy when both users achieve their goals, aimed at eliciting a social responsibility to achieve goals [41]. Competitions were viewed less favorably, with both patients with a history of MI and HPs stating that it can easily become demotivating and can potentially be omitted. Therefore, implementing engaging games rather than competitions is a well-valued strategy for improving long-term engagement. We now discuss the contrasts in advice between patients with a history of MI and HPs.

Patients with a history of MI emphasized the lack of support from their health care team and a lack of understanding from their family and community more strongly than HPs. Negative health outcomes are exacerbated in patients with a history of MI without a support network [42,43]. However, many participants reported no awareness of support groups, despite their desire to attend a support group. Participants agreed with previous research that implementing a real-time support group using videoconferencing can maintain patient involvement [44]. Both patients with a history of MI and HPs stated that introducing a buddy system will provide patients with a history of MI with a real connection to combat feeling alone in their disorder. However, HPs particularly emphasized that the buddy should not be a personal relationship of the patients with a history of MI, whereas the patients with a history of MI stated that the buddy should be anyone who has also experienced an MI. Therefore, social support as a critical facet of postdischarge care is highly significant for the population of patients with a history of MI, who strongly emphasized this unmet need.

Artificial intelligence is increasingly used in cardiology research [45]. Patients with a history of MI expressed some openness to intentionally experimenting with artificial intelligence, whereas HPs stated that patients with a history of MI should not know that artificial intelligence is being used, expressing it would work more efficiently in the back end of the app. Artificial intelligence chatbots have been shown to have high efficacy in promoting health behavior change among diverse populations, including promoting healthy lifestyles, smoking cessation, or treatment or medication adherence and reducing substance misuse but with poor feasibility, usability, and acceptability [46]. Therefore, co-designed approaches, as in this study, may be needed to develop an acceptable chatbot for patients with a history of MI. Patients with a history of MI particularly emphasized the importance of the chatbot appearing on the side of the app screen at relevant and opportune times. For example, after tracking low mood, the chatbot can appear and suggest modules to support mood. This builds on previous research findings that chatbots should provide real-time reinforcement and on-demand support [46]. Finally, HPs expected personalized responses from the chatbot. However, patients with a history of MI stated that general information is more trustworthy because it is less likely to be affected by chatbot interpretation and that general responses are preferred compared with having no chatbot functionality.

Strengths and Limitations

A strength of this study was its iterative approach, with key needs being refined and confirmed with both participant groups multiple times. Participants involved in subsequent rounds were either the same participants from the previous rounds—where their comments could be clarified using a visual design—or new participants, where new advice could be provided. Therefore, the information derived from the rounds was rich with new insights and feedback provided in each round.

Participants were relatively young for an MI target population. The mean age of patients with a history of MI across all rounds was 47 (SD 12.13) years, whereas the average age at the first MI was 65.2 years [47]. The web-based advertisements and videoconference format likely led those who are more technologically literate, perhaps younger, to express an interest in the study. Therefore, the results should be interpreted based on the age range of the participants. The number of participants in each focus group (maximum=5) was relatively small compared with the reported median of 10 participants [48]. This may limit discussion between many participants but allowed us to overcome the issue of fragmented communication inherent with web-based videoconferencing. Finally, round 1 only contained advice from 8 participants. However, considering that all rounds included 38 participants, the study included an adequate number of participants compared with other studies [28].

Conclusions

We gathered insights from patients with a history of MI and HPs regarding the need for a digital health solution for the secondary prevention of MI. Both patients with a history of MI and HPs highlighted focusing on mental health, collaborating with heart health organizations, involving family members in postdischarge care, and increasing engagement in simple games. These results can inform the development of a valued digital health secondary prevention strategy for patients with a history of MI. Future research should conduct a pilot study using the findings of the MiSmartHeart study to guide intervention development.

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Data Availability

The data sets generated during and analyzed during this study are not publicly available because of the sensitive and personal information divulged in the discussions but are available from the corresponding author upon reasonable request.

Authors' Contributions

All authors contributed to conducting the underlying research and drafting of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Full focus group and interview question guide.
[DOCX File , 20 KB - cardio_v7i1e49892_app1.docx]

Multimedia Appendix 2
Advice provided in each round.
[XLSX File (Microsoft Excel File), 26 KB - cardio_v7i1e49892_app2.xlsx]

Multimedia Appendix 3
Example screenshots of conceptual and simulated designs.
[DOCX File , 1453 KB - cardio_v7i1e49892_app3.docx]

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Abbreviations

FGD: focus group discussion
HP: health professional
mHealth: mobile health
MI: myocardial infarction

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Original Paper

A Web-Based Application for Risk Stratification and Optimization in Patients With Cardiovascular Disease: Pilot Study

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Abstract

Background: In addition to aspirin, angiotensin-converting enzyme inhibitors, statins, and lifestyle modification interventions, novel pharmacological agents have been shown to reduce morbidity and mortality in atherosclerotic cardiovascular disease patients, including new antithrombotics, antihyperglycemics, and lipid-modulating therapies. Despite their benefits, the uptake of these guideline-directed therapies remains a challenge. There is a need to develop strategies to support knowledge translation for the uptake of secondary prevention therapies.

Objective: The goal of this study was to test the feasibility and usability of Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CVD), a point-of-care application that was designed to facilitate knowledge translation by providing individualized risk stratification and optimization guidance.

Methods: Using the REACH (Reduction of Atherothrombosis for Continued Health) Registry trial and predictive modeling (which included 67,888 patients), we designed a free web-based secondary risk calculator. Based on demographic and comorbidity profiles, the application was used to predict an individual's 20-month risk of cardiovascular events and cardiovascular mortality and provides a comparison to an age-matched control with an optimized cardiovascular risk profile to illustrate the modifiable residual risk. Additionally, the application used the patient's risk profile to provide specific guidance for possible therapeutic interventions based on a novel algorithm. During an initial 3-month adoption phase, 1-time invitations were sent through email and telephone to 240 physicians that refer to a regional cardiovascular clinic. After 3 months, a survey of user experience was sent to all users. Following this, no further marketing of the application was performed. Google Analytics was collected postimplementation from January 2021 to December 2021. These were used to tabulate the total number of distinct users and the total number of monthly uses of the application.

Results: During the 1-year pilot, 47 of the 240 invited clinicians used the application 1573 times, an average of 131 times per month, with sustained usage over time. All 24 postimplementation survey respondents confirmed that the application was functional, easy to use, and useful.

Conclusions: This pilot suggests that the STOP-CVD application is feasible and usable, with high clinician satisfaction. This tool can be easily scaled to support the uptake of guideline-directed medical therapy, which could improve clinical outcomes. Future research will be focused on evaluating the impact of this tool on clinician management and patient outcomes.

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KEYWORDS

atherosclerotic cardiovascular disease; guideline-directed medical therapy; mHealth; mobile health; risk stratification; secondary prevention; web application

Introduction

Atherosclerotic cardiovascular disease (ASCVD) is a leading cause of morbidity and mortality among adults in North America [1,2]. Historically, guidelines have focused on a 3-pronged approach with antithrombotic therapy, lipid-lowering therapy, and antihypertensive therapy [1]. Despite this, there remains a residual risk for cardiovascular events such as acute coronary syndrome, congestive heart failure, and cardiovascular death [3,4].

Recent landmark trials have resulted in a paradigm shift in the management of patients with ASCVD [2]. The Canadian Cardiovascular Society incorporated these into a recent guideline on evidence-based secondary prevention [2]. In addition to usual antithrombotic therapies, dual pathway inhibition with vascular-dose rivaroxaban is recommended for patients with polyvascular disease (defined as the presence of atherosclerosis in 2 or more arterial beds, including coronary artery disease, cerebrovascular disease, and peripheral arterial disease) [5]. In addition to statin therapy, ezetimibe [6] and proprotein convertase subtilisin/kexin type 9 inhibitors [7,8] are recommended for patients with persistently elevated lipid levels. For those with elevated triglycerides, icosapent ethyl [9] is also recommended. Sodium glucose cotransporter-2 inhibitors [10-12] and glucagon-like peptide-1 agonists [13,14] are also indicated as oral hypoglycemic agents to reduce risk in diabetics with ASCVD. Nonpharmacological interventions, including smoking cessation [15], weight reduction, increased physical activity, dietary changes, and stress and depression management, remain vital [2]. Cardiac rehabilitation referrals are encouraged [16].

Despite the established benefit of guideline-directed medical therapy (GDMT), uptake of these therapies remains a challenge in patients with ASCVD [17-20]. This results in worse clinical outcomes for patients [21]. There is an urgent need to develop strategies to support knowledge translation for the uptake of GDMT.

To support this, our team developed a novel, easy-to-use, point-of-care, provider-facing web-based application. The primary aim of the Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CVD) application was to stratify and optimize patients by incorporating a simplified guideline-based algorithm of care based on patient demographics. The purpose of this quality improvement (QI) project is to demonstrate the feasibility and usability of this tool among physicians providing care for patients with ASCVD.

Methods

Application Development

We developed a free, web-based application using PHP: Hypertext Preprocessor. Google Analytics was integrated to track usage. No individual user data was collected or stored. The application was developed to be accessible on desktop and mobile devices running all available operating systems.

Risk Calculator

The REACH (Reduction of Atherothrombosis for Continued Health) Registry was a large cross-sectional study that included 67,888 patients with ASCVD in 44 countries [22]. Predictive modeling identified key demographic and medical history factors to estimate cardiovascular events and cardiovascular deaths at 20 months [23]. These include age, sex, current residence location, smoking status, body mass index, and 1 or more of the following (current and history of): (1) cardiovascular event in the previous 12 months, (2) atrial fibrillation, (3) polyvascular disease, (4) aspirin therapy, and (5) statin therapy.

Our team leveraged this to create an interactive risk calculator, which was incorporated into the STOP-CVD application. Figure S1 in Multimedia Appendix 1 displays a screenshot of the user interface of the risk calculator. The application additionally displays the risk of cardiovascular events and cardiovascular death as a bar graph (Figure S2 in Multimedia Appendix 2). A hypothetical patient with matched age, gender, and location demographics with no additional risk factors is displayed by the application in order to illustrate a patient's potential "intervenable risk" to target with optimal risk factor control (for educational purposes).

Risk Factor Modification Algorithm

We developed an algorithm for the initiation of GDMT based on a review of landmark clinical trials, systematic reviews, and the 2020 Canadian Cardiovascular Society Secondary Prevention guideline update [2]. To aid in visualization and use, the algorithm was displayed graphically in a flowchart in the STOP-CVD application (Figure S3 in Multimedia Appendix 3). This algorithm outlines the foundational therapies recommended for all patients with ASCVD along with novel therapies for risk factor optimization.

Based on an individual patient's risk factors (identified in the risk calculator portion of the STOP-CVD application), personalized recommendations for additional therapies based on the risk factor modification algorithm are provided by the application. The indication, drug name, dosing (for pharmacological therapies), and summary of the supporting evidence are included (Figure S4 in Multimedia Appendix 4). Citations and links to the primary literature sources are provided as reference material.

Privacy and Security

No identifiable patient or clinician user information was used or stored in the STOP-CVD application. There were no privacy or security concerns identified for patients or clinicians.

Recruitment

The STOP-CVD application was implemented from the Cambridge Cardiac Care Center (CCC), a tertiary cardiovascular clinic in Cambridge, Ontario. It was soft-launched on the internet

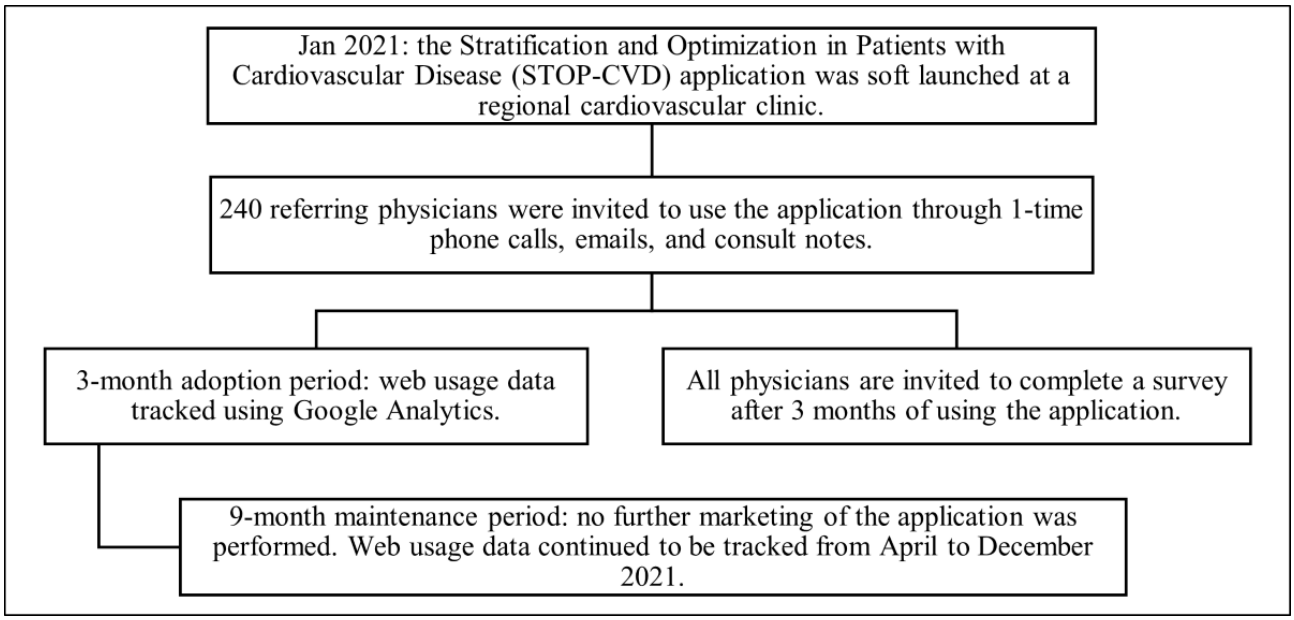
free of charge [24]. All physicians who referred patients to CCC in 2020 were invited to use the STOP-CVD application to help risk stratify and optimize their patients with ASCVD. The specialties of referring physicians included family medicine, internal medicine, emergency medicine, endocrinology, and cardiology. One-time invitations were sent in January 2021 through email or telephone, depending on the preferred means of communication by the referring physician. The website link was also included in all consult notes sent to referring physicians by physicians at CCC. No further marketing or reminders were used.

Data Collection

Google Analytics was collected postimplementation from January 2021 to December 2021. These were used to tabulate the total number of distinct users and the total number of monthly uses of the application. All physicians who referred patients to CCC in 2020 were invited to complete a QI survey 3 months postintervention if they had used the application. This survey was administered using their preferred means of communication (email or telephone). The target population was those physicians who had used the application to provide feedback on their experience.

All respondents were asked 3 yes-or-no questions: (1) “Is the application functional?” (2) “Is the application easy to use?” (3) “Is the application useful?”. This 3-question survey was designed to answer the “3 measures of usability:” effectiveness, efficiency, and satisfaction, from the seminal book on usability testing, *Usability Evaluation in Industry* [25]. Additional qualitative feedback was solicited from all survey respondents. No participant identifiers were collected. See Figure 1 for details on study recruitment and data collection.

Figure 1. Flow diagram of the STOP-CVD application implementation and evaluation.



Evaluation of the Application

The feasibility and usability of this application were evaluated through the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework [12]. Reach and adoption were assessed based on the number of unique users and frequency of application use within the first 3 months. Implementation was evaluated based on users’ survey responses. Maintenance was assessed based on sustained usage of the application after the initial 3-month adoption phase. During the 9-month maintenance phase, physician users were not contacted further about the application. Effectiveness was not assessed in this study to maintain patient and physician confidentiality.

Ethical Considerations

The Ottawa Health Science Network Research Ethics Board Research or Quality Improvement checklist was completed. Based on these guidelines, this project was deemed to be a QI project. As such, formal research ethics board approval was deemed not to be necessary and was not obtained.

No identifiable patient or provider data was collected. All aggregate analytic data collected was anonymous. Surveys were anonymous and conducted on an invitation-only basis.

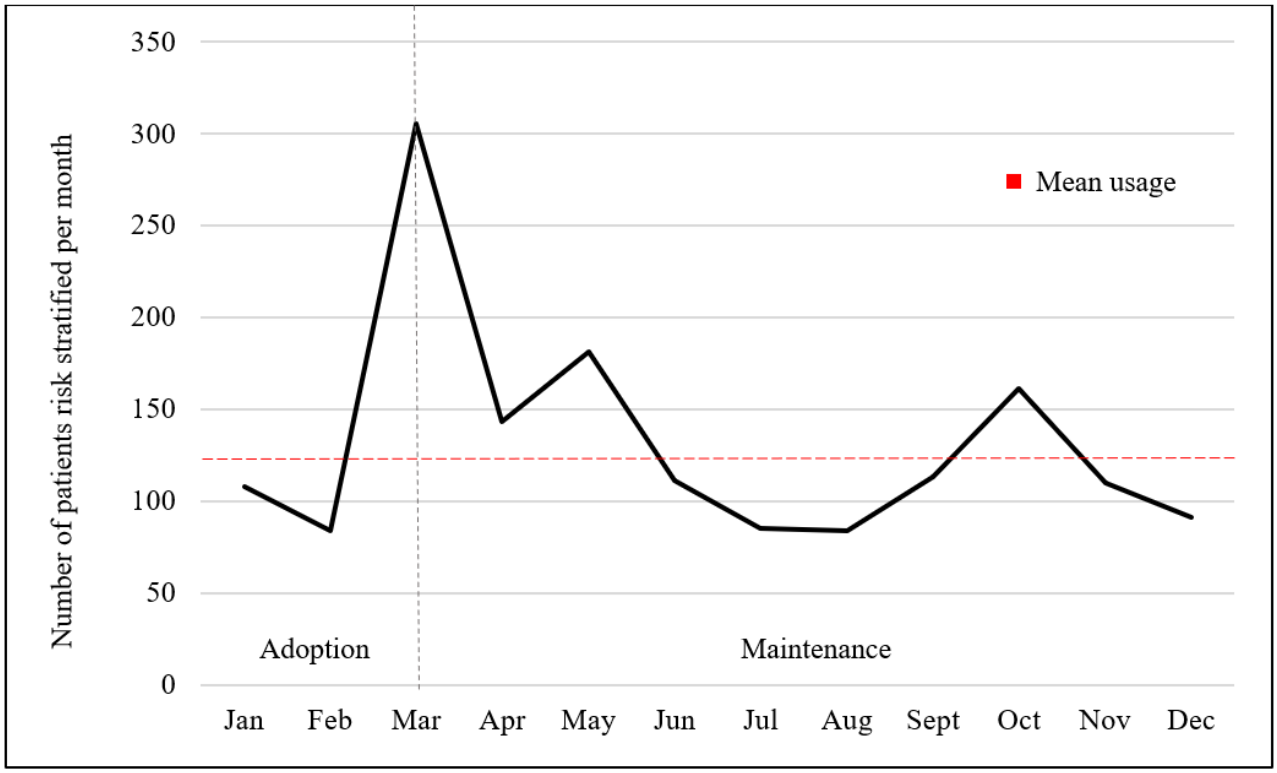
Results

Application Usage

The STOP-CVD application was launched on January 1, 2021. A total of 240 physicians were invited to use the application; 47 unique clinicians used the application. Over the year of implementation, the application was used 1573 times, an average of 131 times per month. During the first 3 months (adoption phase), the application was used for a total of 494 patients, an average of 165 patients per month. Peak usage occurred in March 2021, when it was used for 305 patients.

Over the subsequent 9 months (maintenance phase), the application continued to be used 1079 times, an average of 120 patients per month. See Figure 2 for application usage data.

Figure 2. Monthly usage of the Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CVD) application 1 year post implementation.



User Satisfaction and Feedback

A total of 24 physicians who used the STOP-CVD application agreed to complete the brief postintervention survey. All participants (24/24, 100%) answered "yes" to each of the 3 survey questions: (1) "Is the application functional?" (2) "Is the application easy to use?" (3) "Is the application useful?"

Qualitative feedback was solicited from all survey respondents. A total of 4 users provided qualitative statements. Users stated that the application was "useful for discussions with patients," "helpful for optimizing patients," and "similar to a mini cardiology consult."

One user suggested increased functionality: "It would be helpful for the application to generate a report, which could be added to a patient's electronic medical record (EMR)." This feedback was implemented after month 3 during the maintenance phase. A printable report function was added to the application (though no patient information was stored in the STOP-CVD application).

Discussion

Principal Results

In this QI initiative, we designed and implemented a web-based application that enables evidence-based risk stratification and individualized guidance for the optimization of patients with ASCVD. The STOP-CVD application provides a unique opportunity to use technology to support simplified, algorithm-based knowledge translation of guideline recommendations among clinicians. This pilot project indicates that such a tool is feasible to develop and implement among clinicians. Surveys of clinicians 3 months postimplementation unanimously suggest that the application was highly functional, easy to use, and useful in their clinical practice. Qualitative feedback was obtained and adopted by allowing clinicians to print a report that could be uploaded into the patient's EMR. These are important findings as they confirm that point-of-care applications aimed at clinicians have the potential to facilitate knowledge translation and use of GDMT, thus improving patient outcomes.

Comparison With Previous Work

This project seeks to address the significant care gaps among patients with ASCVD. Large studies have demonstrated that patients with known ASCVD are often not prescribed appropriate secondary prevention therapy [26]. Retrospective analysis of 1,489,745 American patients with ASCVD in the National Cardiovascular Data Registry demonstrated that 9% were not prescribed ASA, 20% were not prescribed statins, and 41% were not prescribed angiotensin-converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) therapy [26]. Even among patients with ASCVD appropriately prescribed these foundational secondary prevention therapies (antiplatelet therapies, statins, and ACE-I or ARB therapy), the risk of morbidity and mortality remains elevated. A 2020 retrospective cohort study found that patients with postmyocardial infarction (MI) prescribed dual antiplatelet therapy, high-intensity statins, beta-blockers, and ACE-I or ARB therapy had an adjusted hazard ratio of 1.15 for all-cause mortality and 9.56 for hospitalization for MI when compared to the general population [27]. The addition of novel risk factor modification therapies, including antihyperglycemics, lipid optimizing therapies, and dual pathway inhibition, has

demonstrated a reduced risk of recurrent cardiovascular events and mortality in multiple landmark clinical trials. Improved uptake of these therapies may improve outcomes among patients with ASCVD [2].

On review of the literature, 3 other tools for secondary risk stratification of patients with established ASCVD were identified: the SMART (Second Manifestations of Arterial Disease) Risk Score [28], SMART-REACH Model [29], and SMART2 Risk Score [30]. Additional tools exist for primary prevention of ASCVD but would not be applicable in this population. Similar to our application, each of these tools used large studies to develop a risk calculator aimed at predicting the risk of future ASCVD events and mortality. However, in addition to a risk calculator, our application provides a simplified algorithm based on risk factors to help clinicians identify what treatments the patient should be initiated on, the indication, dosing, and a summary of available evidence for further reading. This functionality is not provided by other ASCVD risk assessment tools.

There is no literature on the rates of uptake or usage of physician-facing applications for ASCVD secondary prevention or any other form of clinical prediction tool. Historically, physician participation in QI initiatives has been shown to be poor. A cross-sectional survey of Norwegian physicians showed 17% of physicians reported participating in QI during working hours [31]. Among members of the American Board of Family Medicine, 38% of physicians reported participation in a QI activity over the previous year [32]. A total of 20% of participants' physicians were engaged with the STOP-CVD QI initiative, which appears to be in line with typical physician participation.

Although not assessed in this QI project, previous studies have demonstrated improved GDMT uptake through clinician-facing decision aids. A systematic review of 99 trials found that 70% of physician education interventions improved physician performance metrics [33]. Among studies examining secondary prevention for ASCVD, there is also evidence of the benefit of digital tools for physician education [34]. Vani et al implemented a clinical decision support tool as a part of an EMR and demonstrated an improvement in the prescription of GDMT [34]. Taken together, these studies highlight the potential for using digital tools such as the STOP-CVD application to improve the prescription of GDMT and clinical outcomes.

Limitations

There are several limitations to this study. First, this is a feasibility and usability study, and therefore no causal conclusions can be derived. Second, no identifying information was obtained, such as clinician demographics or specialty. Due to this, we are unable to perform subgroup analyses of clinicians. Those with a larger roster of patients with ASCVD may use the tool more frequently, but for a smaller proportion of their patients, given comfort with secondary prevention guidelines. Nevertheless, this was a conscious decision to maximize feasibility, usability, and security. Third, this study did not evaluate physician knowledge, prescription practice, or patient outcomes pre- and postintervention. While not the focus of this study, future studies can build on the results of this study.

One limitation to adoption is that this tool currently operates as a web-based application external to EMR. Placing this tool within the EMR workflow as a clinical decision support tool may help to increase adoption (as shown in previous studies) [34]. We chose a web-based application design in order to maximize accessibility to physicians practicing in a variety of clinical environments (including outpatient clinics, which may not use sophisticated EMR systems with clinical decision support capabilities). The application was also optimized for both desktops and mobile phones for ease of use and convenience purposes.

It is important to recognize that volunteer bias and nonresponder bias may affect the validity of our results. A subset of clinicians who were invited (47 of 240) decided to participate in the study, and just over half (24 of 47) completed the postintervention survey. Nonetheless, there was sustained usage and overwhelmingly positive responses by those who completed the postintervention survey.

Despite these limitations, we accomplished the objectives of this study, which were to demonstrate the feasibility and usability of the STOP-CVD application among clinicians from diverse clinical backgrounds providing care for patients with ASCVD. Future research can build on the findings of this study by using rigorous methodology to evaluate the impact of the STOP-CVD tool on clinician knowledge, practice, and patient outcomes.

Conclusions

Recent landmark trials have shifted the management paradigm for patients with ASCVD. Despite their benefits, the uptake of recommendations remains a challenge. The STOP-CVD application is a novel, point-of-care, easy-to-use, provider-facing web-based application that supports knowledge translation by providing individualized risk factor stratification and optimization guidance. This pilot project indicates that such a tool is feasible to develop and implement among clinicians. This tool can be easily scaled to support the uptake of GDMT, which could improve clinical outcomes. Future research will be focused on the evaluation of the impact of this tool in a randomized, controlled setting. We hope to evaluate its impact on physician and trainee knowledge, prescribing patterns, and patient outcomes.

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An unrestricted educational grant was provided by Bayer, Inc. Supporting sources were not involved in the application development, content, study design, analysis, interpretation, writing of the results, or the decision to submit the report for publication.

Authors' Contributions

AP was responsible for the development of the Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CV) application, study design, and manuscript writing. MMDS was responsible for the launch and circulation of the STOP-CVD application to physician users. ASP was responsible for the development of the STOP-CVD app and the launch and circulation of the STOP-CVD app to physician users. HM was responsible for study design and manuscript writing.

Conflicts of Interest

AP and ASP are the creators of the Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CVD) application. ASP has received speaker honoraria from the CPD (Continuing Professional Development) Network Association, Amgen, AstraZeneca, CHRC, Boehringer Ingelheim, Merck, Novartis, Novo Nordisk, Pfizer, Purdue Pharma, Servier, HLS Therapeutics, and Sunovion. ASP has received research grants from Amgen, Sanofi, AstraZeneca, Pfizer, Merck, Boehringer Ingelheim, Sunovion, Bayer, and Servier. MMSD and HM report no conflicts of interest.

Multimedia Appendix 1
Screenshot from the Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CVD) application showing the physician-facing REACH (Reduction of Atherothrombosis for Continued Health) risk calculator user interface.
[DOCX File , 71 KB - cardio_v7i1e46533_app1.docx]

Multimedia Appendix 2
Screenshot from the Stratification and Optimization in Patients With Cardiovascular Disease) STOP-CVD application showing the REACH (Reduction of Atherothrombosis for Continued Health) risk calculator prediction of risk of cardiovascular event and cardiovascular death compared to a patient with the same age, sex, and location demographics without additional risk factors.
[DOCX File , 76 KB - cardio_v7i1e46533_app2.docx]

Multimedia Appendix 3
Screenshot from the Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CVD) application showing the STOP-CVD secondary prevention algorithm for incorporating guideline-directed medical therapy and lifestyle modification.
[DOCX File , 1500 KB - cardio_v7i1e46533_app3.docx]

Multimedia Appendix 4
Screenshot from the Stratification and Optimization in Patients With Cardiovascular Disease (STOP-CVD) application showing personalized recommendations for additional therapies based on clinical trials and Canadian Cardiovascular Society guidelines with a summary of the available evidence.
[DOCX File , 71 KB - cardio_v7i1e46533_app4.docx]

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Abbreviations

ACE-I: angiotensin-converting enzyme inhibitors
ARB: angiotensin receptor blocker
ASCVD: atherosclerotic cardiovascular disease
CCC: Cambridge Cardiac Care Center
EMR: electronic medical record
GDMT: guideline-directed medical therapy
MI: myocardial infarction
QI: quality improvement
REACH: Reduction of Atherothrombosis for Continued Health
RE-AIM: Reach, Effectiveness, Adoption, Implementation, Maintenance
SMART: Second Manifestations of Arterial Disease
STOP-CVD: Stratification and Optimization in Patients With Cardiovascular Disease

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Original Paper

The Impact and Perception of England's Web-Based Heart Age Test of Cardiovascular Disease Risk: Mixed Methods Study

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Abstract

Background: It is well documented that individuals struggle to understand cardiovascular disease (CVD) percentage risk scores, which led to the development of heart age as a means of communicating risk. Developed for clinical use, its application in raising public awareness of heart health as part of a self-directed digital test has not been considered previously.

Objective: This study aimed to understand who accesses England's heart age test (HAT) and its effect on user perception, knowledge, and understanding of CVD risk; future behavior intentions; and potential engagement with primary care services.

Methods: There were 3 sources of data: routinely gathered data on all individuals accessing the HAT (February 2015 to June 2020); web-based survey, distributed between January 2021 and March 2021; and interviews with a subsample of survey respondents (February 2021 to March 2021). Data were used to describe the test user population and explore knowledge and understanding of CVD risk, confidence in interpreting and controlling CVD risk, and effect on future behavior intentions and potential engagement with primary care. Interviews were analyzed using reflexive thematic analysis.

Results: Between February 2015 and June 2020, the HAT was completed approximately 5 million times, with more completions by men (2,682,544/4,898,532, 54.76%), those aged between 50 to 59 years (1,334,195/4,898,532, 27.24%), those from White ethnic background (3,972,293/4,898,532, 81.09%), and those living in the least deprived 20% of areas (707,747/4,898,532, 14.45%). The study concluded with 819 survey responses and 33 semistructured interviews. Participants stated that they understood the meaning of high estimated heart age and self-reported at least some improvement in the understanding and confidence in understanding and controlling CVD risk. Negative emotional responses were provoked among users when estimated heart age did not equate to their previous risk perceptions. The limited information needed to complete it or the production of a result when physiological risk factor information was missing (ie, blood pressure and cholesterol level) led some users to question the credibility of the test. However, most participants who were interviewed mentioned that they would recommend or had already recommended the test to others, would use it again in the future, and would be more likely to take up the offer of a National Health Service Health Check and self-reported that they had made or intended to make changes to their health behavior or felt encouraged to continue to make changes to their health behavior.

Conclusions: England's web-based HAT has engaged large number of people in their heart health. Improvements to England's HAT, noted in this paper, may enhance user satisfaction and prevent confusion. Future studies to understand the long-term benefit of the test on behavioral outcomes are warranted.

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KEYWORDS

heart age; cardiovascular disease; CVD prevention; web-based risk assessment; CVD risk; qualitative research; cross-sectional design; cardiology; risk assessment; cardiovascular risk; heart health; user perception; risk knowledge; engagement; web-based

Introduction

Background

Cardiovascular disease (CVD) remains the leading cause of death globally [1], with one-fourth of all deaths in England reportedly owing to heart and circulatory disease alone [2]. Communicating the risk of CVD to patients is challenging [3], and is influenced by several factors including patient understanding, health literacy, and personality traits [4]. There is evidence that patients and practitioners struggle to interpret traditional risk formats such as short-term percentage risk scores that are used to communicate risk [5-9], which limits their potential to encourage individuals to adopt CVD risk–reducing behaviors [5]. In recent years, other CVD risk formats, including heart age calculators, have been developed to support health care professionals with CVD risk communication. Heart age is a reflection of lifetime risk, whereby an individual's chronological age is compared with someone of the same age, sex, and ethnicity but with optimum modifiable risk factors [10]. If an individual has ≥1 risk factors (ie, cholesterol level and blood pressure) that are less than optimal, their heart age will be higher than their chronological age. There is evidence that use of heart age improves risk perception and recall and is more emotionally impactful [10-22], compared with other risk communication methods, such as percentage risk scores.

A web-based version of the Joint British Societies–derived heart age test (HAT) [23], developed by Public Health England, British Heart Foundation, Joint British Societies for the prevention of cardiovascular disease, and NHS Digital, was first introduced in 2015, known as the HAT [24]. The HAT is freely accessible on the National Health Service (NHS) website [25] and can be used to identify CVD risk among people aged >30 years who do not have preexisting CVD. The test was created to raise awareness and increase understanding of CVD risk, provide information and direct individuals to resources, improve health literacy, and encourage individuals to take up the offer of an NHS Health Check (vascular risk assessment offered to those aged 40-74 years who have not been diagnosed with CVD, kidney disease, dementia, and diabetes) [26]. Early assessment of HAT use shows >500,000 completions between February 2015 and July 2015, broadly representing the population demographic of England [24]. Other heart age calculators have also been developed, which have been used by millions of individuals worldwide. These include the heart age tool developed by Unilever, accessed across 13 countries between 2009 and 2011 [27]; *Your Heart Forecast*, used to promote clinical guidance in New Zealand [28]; Framingham version of heart age, used to identify population estimates of heart age in the United States and China [29,30]; and Australia's heart age calculator [31], created during a national consumer awareness campaign in 2019.

Despite their popularity, it has been noted that web-based CVD risk calculators (ie, including heart age calculators) produce variable risk estimates, often fail to disclose the models upon which they were based, can result in limited understanding and concern regarding CVD risk, and lead to poor behavioral intentions [13,32]. There is also the risk that heart age calculated based on incomplete data owing to poor user awareness of physiological risk information is also poor [24,27] and can lead to underestimation or overestimation of CVD risk [19,27], doubts about the credibility of the risk calculator [13,33], and unnecessary primary care visits and clinical testing [31,34]. Evaluation of Australia's heart age calculator suggested that it provoked a positive emotional response and led to self-reported health behavior change (ie, improvement in diet, physical activity, and weight loss) and clinical checks for more than half of the survey respondents [31]. Despite such suggestions that communication of chronic risk through *age concepts* may improve behavioral outcomes over percentage risk scores (ie, low blood pressure, change in cholesterol level, and intentions to improve diet and increase exercise), a recent systematic review concluded that evidence remains limited [13,20].

There has been little research on England's web-based HAT, despite its apparent popularity based on data published in 2016 [24]. This study provides a necessary contribution to understand its use and possible impact.

Aim

The aim of the study was to understand who is accessing England's HAT and its effect on knowledge and understanding of CVD risk, future intentions toward health behavior change, and potential engagement with primary care services.

Methods

Design

A mixed methods design was used in this study. Data were collected in one of the following three ways: (1) HAT user data (aggregate data provided by Public Health England), (2) open web-based survey, and (3) semistructured interviews.

Ethics Approval

Ethics approval was obtained from Staffordshire University (reference SU20-085/096/101). The procedures followed were in accordance with the ethical standards of the institutional committee and with the Helsinki Declaration of 1975. Participants were informed that completion of the web-based survey was deemed informed consent. Written and audio-recorded verbal consent was obtained from those who participated in a follow-up interview.

Settings and Participants

As it is a web-based tool, there is no geographical constraint on who can access the test; therefore, HAT user data cannot be attributed to only those living in England.

Participants were adults (aged ≥30 years) who had completed the HAT. The study setting was England, the United Kingdom.

The test was completed via the web [25]. According to the purposes of the study, participants who completed the web-based survey and follow-up interviews were required to be living in England at the time of participating in the study.

Processes and Procedures

Recruitment

Information about the study (including the purpose, estimated time to complete the survey, data storage, and details about the research team) and how to participate was presented to potential participants before survey completion, through a URL shared via several web-based platforms (ie, Facebook, Twitter, university website [used by university staff and prospective and preexisting students and academics], and the university's Centre for Health and Development newsletter). A pop-up was also created by NHS Digital and displayed on the HAT results page (on the NHS website; used by the general population to obtain health information) to promote the study. The survey was voluntary. Survey respondents were invited to provide their contact information at the end of the web-based survey if they wished to participate in a follow-up interview to discuss their experience in more detail. Contact information was stored separately from the data collected in a secure laptop and destroyed after the study was completed. Both the web-based survey and interview were incentivized to encourage individuals to participate (through a prize draw and individual retail vouchers, respectively). Owing to COVID-19 restrictions and the geographical distribution of participants, interviews were conducted via telephone.

Data Collection and Analysis

User Data

Aggregate quantitative data about HAT users were obtained from Public Health England by the research team in March 2021. The data were summarized to profile users of the HAT.

Open Web-Based Survey

Data were collected between January 2021 and March 2021, through a web-based survey, whereby participants were asked to complete the HAT before answering questions about their experience and impact of the test, future behavior intentions, and demographic profile. Nonvalidated survey questions were created based on the aim of the study, through discussions among authors and the project steering group, and based on a previously unpublished survey created by Public Health England to understand the value of the HAT. Questions were presented across 5 pages (on average, 5 items per page), in the same order for all participants, but using survey logic to omit certain questions where appropriate. Completeness checks were not conducted, and participation and completion rates were not recorded and therefore cannot be reported.

To meet the objectives of the evaluation, responses were analyzed descriptively, and a summary of the findings is outlined.

Follow-up Interviews

A subsample of survey respondents participated in a semistructured, one-to-one, telephone interview to talk about their experience and the effect of the tool on future behavior intentions. An interview topic guide was used to support the discussion; it was informed through discussions among authors and the HAT steering group (including colleagues from NHS Digital, University College London, and British Heart Foundation) and a previously unpublished survey created by Public Health England to understand the value of the HAT. All participants who completed the interview were offered a web-based retail voucher worth £20 (US $25) in appreciation of their time. Interviews were audio-recorded following participant consent and transcribed verbatim.

Data were analyzed using inductive, reflexive, thematic analysis [35,36]. This was appropriate for this type of inquiry and the size of the sample [37] and allowed for purposive sampling (from the subsample of survey respondents who expressed interest in participating in an interview), such that the interview sample was broadly reflective of the typical HAT user population (based on age, sex, ethnicity, and deprivation). Processes followed those described by Braun and Clarke [35]. Overall, 2 researchers (first and third authors) familiarized themselves with the data through extensive reading before preliminary codes and themes were identified. A subsample of transcripts (1 in every 5 transcripts; 20% overall) were independently dual coded by both researchers to check the reliability of coding. Dual-coded transcripts were manually checked for discrepancies and indicated excellent coding consistency. Both researchers reviewed all preliminary codes before agreeing on initial themes. Themes were checked to ensure that they were data-driven and discussed with the second author before being finalized.

England's HAT

England's web-based HAT is based on the Joint British Societies' risk calculator [23]. The calculator's algorithm uses QRISK data to estimate individual 10-year CVD risk, lifetime risk, and heart age. Users are required to input information about their age, sex, ethnicity, postcode (to derive deprivation estimate), smoking status, height, weight, blood pressure, cholesterol level, family history of CVD, and other information about their current health status (eg, diagnosis of type 2 diabetes mellitus and rheumatoid arthritis). This information is used to estimate and present heart age and age at first CVD event (ie, CVD event–free survival age; Multimedia Appendix 1).

Heart age is calculated by comparing the user with someone of the same sex and ethnicity but with no individual elevated risk factors (ie, blood pressure, cholesterol level, and family history of CVD). If the user is unable to provide information about their blood pressure and cholesterol level, UK national averages are included to calculate their risk. Following the results, the test also provides the user with advice tailored to the individual's risk factor profile (eg, smoking status, weight, cholesterol level, and blood pressure; refer to Multimedia Appendix 2 for an example screenshot of risk-tailored information and advice around smoking presented in HAT output).

Results

User Data

Between February 2015 and June 2020, there were 4,898,532 calculated HAT cases (the test can be completed more than once by the same individual). Users were most commonly men (2,682,544/4,898,532; 54.76%), aged between 50 and 59 years (1,334,195/4,898,532; 27.23%), and classified as having a White ethnic background (3,972,293/4,898,532; 81.09%). Ethnicity data showed that more cases were recorded as Indian or other ethnic background than any other minority ethnic group captured by the HAT. This is broadly representative of the national population aged between 30 and 90 years in England (sex [female]: 18,426,236/35,715,368, 51.59%; age [most commonly aged between 50 and 59 years]: 7,578,112/35,715,368, 21.22%) [38] and ethnicity data for England and Wales (ethnicity: 86% White, 7.5% Asian, 3.3% Black African or Black Caribbean, 2.2% mixed, and 1% other) [39]. Cases by deprivation based on the Index of Multiple Deprivation (IMD) 2019 (where quintile 1 [Q1] is the most deprived) [40] indicated more HAT completions among those living in the least deprived areas (quintile 5 [Q5]: 707,747/4,898,532; 14.45%), but there was representation across the strata (quintile 4 [Q4]: 611,793/4,898,532, 12.49%; quintile 3 [Q3]: 521,251/4,898,532, 10.64%; quintile 2 [Q2]: 402,331/4,898,532, 8.21%; and Q1: 267,897/4,898,532, 5.47%).

Calculated heart age was typically estimated to be 1 to 4 years older than the user's chronological age (in 1,668,499/3,658,814, 45.60% of cases), followed by 5 to 9 years older than (684,793/3,658,814, 18.72%) and 1 year younger than or the same as the user's chronological age (545,197/3,658,814, 14.90%), irrespective of year of completion.

HAT users often did not enter information about blood pressure or cholesterol level. More than half (n=4,898,532, 52.9%) of the cases were completed without blood pressure, more than three-fourths (n=4,898,532, 76.6%) were completed without cholesterol level, and approximately half (n=4,898,532, 48.6%) lacked both cholesterol level and blood pressure information.

Open Web-Based Survey

The web-based survey yielded 819 responses. For those who provided demographic information (804/819, 98.2%), most were women (585/819, 71.4%), from a White ethnic background (755/819, 92.2%), and living in areas within the least deprived IMD quintile (Q5: 212/819, 25.9%; Table 1). Compared with the HAT user population, a high proportion of women and those from White ethnic background participated, but the distributions for age and deprivation were broadly representative of those who typically engage with the test.

Survey respondents understood that an estimated heart age that was older than their chronological age indicated that they were at an increased risk of a heart attack or stroke in the future (685/819, 83.6%). More respondents reportedly felt concerned or surprised by their estimated heart age than those who felt happy, satisfied, and reassured (Multimedia Appendix 3).

Approximately two-thirds (520/819, 63.5%) of the respondents stated that their heart age was higher than what they expected (Table 2). However, at least half of the respondents reported increase in their understanding of CVD risk (458/819, 55.9%), risk factors (414/819, 50.2%), and actions that can be taken to reduce risk (410/819, 50.1%) following completion of the HAT (Table 2). Similarly, approximately half of the respondents also reported increase in confidence related to understanding (453/819, 55.3%) and controlling (443/819, 54.1%) CVD risk (Table 2).

Most respondents reported that they intended to take some action following the completion of the test (Table 2). Intentions to set a goal to lose weight (374/819, 45.7%), followed by a goal to increase physical activity (302/819, 36.9%) and eat more healthily (283/819, 34.6%) were most commonly selected by respondents. The most common reason for not intending to take action was that their heart was healthy for their age and "other" (eg, COVID-19 restrictions and continuing healthy behavior adopted before completion of the test).

Acceptability of attending a preventative health assessment (ie, NHS Health Check) was high following completion of the test (624/819, 76.2%). Most respondents stated that they would probably (264/819, 32.2%) or definitely (375/819, 45.8%) engage with the test again in the future to assess their heart health. Those (144/819, 17.6%) who reported that they would probably or definitely not engage with the test again in the future reported that their estimated heart age was a lot (59/144, 40.9%) or a little higher (44/144, 30.5%) than what they expected.

Table 1. Characteristics of individuals who completed the web-based survey (N=819) compared with those of typical users of HAT[a].

Characteristics	Individuals who completed the web-based survey, n (%)
Age range (years)	
30-35	65 (7.9)
36-40	69 (8.4)
41-45	52 (6.3)
46-50	90 (10.9)
51-55	108 (13.2)
56-60	128 (15.6)
61-65	121 (14.8)
66-70	87 (10.6)
71-74	47 (5.7)
≥75	37 (4.5)
Missing	15 (1.8)
Sex	
Male	219 (26.8)
Female	585 (71.4)
Missing	15 (1.8)
Ethnic group	
White	755 (92.2)
Indian	13 (1.6)
Pakistani	4 (0.5)
Bangladeshi	1 (0.1)
Other Asian	3 (0.4)
Black Caribbean	4 (0.5)
Black African	5 (0.6)
Chinese	3 (0.4)
Other	13 (1.6)
Prefer not to answer	3 (0.4)
Missing	15 (1.8)
Deprivation (IMD[b] quintiles)	
1	75 (9.2)
2	115 (14.4)
3	148 (18.1)
4	170 (20.8)
5	212 (25.9)
Missing	99 (12.1)
Last contact with GP[c]	
In the past week	88 (10.7)
In the past month	118 (14.4)
In the past 3 months	150 (18.3)
In the past 6 months	89 (10.9)
In the past 12 months	94 (11.5)

Characteristics	Individuals who completed the web-based survey, n (%)
>12 months ago	265 (32.4)
Missing	15 (1.8)
Have a longstanding illness, disability, or disorder	
Yes	259 (31.6)
No	527 (64.3)
Prefer not to answer	18 (2.2)
Missing	15 (1.8)

[a]HAT: heart age test.

[b]IMD: Index of Multiple Deprivation.

[c]GP: general practitioner (or physician).

Table 2. Expectations, understanding, confidence, and actions following completion of the heart age test (N=819).

Categories, statements, and responses	Values, n (%)
Expectations	
Estimated heart age	
A lot higher than expected	238 (29.1)
A little higher than expected	282 (34.4)
As expected	162 (19.8)
A little lower than expected	59 (7.2)
A lot lower than expected	16 (1.9)
No expectation	62 (7.6)
Understanding (following completion of the heart age test, has it helped to understand more about...)	
Your chance of having a heart attack or stroke	
Not at all	99 (12.1)
About the same as before	262 (31.9)
A little more	240 (29.3)
Somewhat more	130 (15.9)
A lot more	88 (10.7)
Factors that can increase your chance of having a heart attack or stroke	
Not at all	67 (8.2)
About the same as before	338 (41.3)
A little more	202 (24.7)
Somewhat more	127 (15.5)
A lot more	85 (10.4)
Factors that can reduce your chance of having a heart attack or stroke	
Not at all	75 (9.2)
About the same as before	333 (40.7)
A little more	201 (24.5)
Somewhat more	127 (15.5)
A lot more	83 (10.1)
Actions you could take to reduce your chance of having a heart attack or stroke	
Not at all	92 (11.2)
About the same as before	317 (38.7)
A little more	179 (21.9)
Somewhat more	140 (17.1)
A lot more	91 (11.1)
Confidence (following completion of the heart age test, how confident are you...)	
Understand what risk factors could increase your chance of having a heart attack or stroke	
Not at all	32 (3.9)
About the same as before	334 (40.8)
A little more	93 (11.4)
Somewhat more	130 (15.9)
A lot more	230 (28.1)
Understand how to change your chance of having a heart attack or stroke	
Not at all	48 (5.9)

Categories, statements, and responses	Values, n (%)
About the same as before	315 (38.5)
A little more	114 (13.9)
Somewhat more	150 (18.3)
A lot more	192 (23.4)
Have control over your chance of having a heart attack or stroke	
Not at all	59 (7.2)
About the same as before	317 (38.7)
A little more	123 (15)
Somewhat more	168 (20.5)
A lot more	152 (18.6)
Can reduce your chance of having a heart attack or stroke	
Not at all	48 (5.9)
About the same as before	311 (37.9)
A little more	132 (16.1)
Somewhat more	165 (20.1)
A lot more	163 (19.9)
Have the skills or support you need to reduce your chance of having a heart attack or stroke	
Not at all	75 (9.2)
About the same as before	327 (39.9)
A little more	119 (14.5)
Somewhat more	164 (20)
A lot more	134 (16.4)
Actions	
Having found out your estimated heart age, do you intend to take any of the following actions...	
Blood pressure check by a GP[a], nurse, or pharmacist	127 (15.5)
Check my blood pressure myself (home blood pressure monitor)	211 (25.8)
Book an appointment to get my cholesterol levels checked	236 (28.8)
Set a goal to attempt to quit smoking	17 (2.1)
Set a goal to lose weight	374 (45.7)
Set a goal to eat more healthily	283 (34.6)
Set a goal to get more active (i.e., going for a walk a day)	302 (36.9)
Look for more information about heart health	111 (13.6)
I do not intend to take any action	146 (17.8)
Something else	107 (13.1)

[a]GP: general practitioner (or physician).

Follow-up Interviews

Overview

Semistructured telephone interviews were conducted with a subsample of survey respondents (33/819, 4%; mean duration 21, SD 6 minutes). Most participants were aged between 51 and 60 years (10/33, 34%), women (19/33, 58%), from a White ethnic background (27/33, 82%), and living in areas ranked among the most deprived 50%, nationally (19/33, 58%; Table 3). The average duration between completion of the test and the interview was 8 (SD 3; range 2-13) days.

Analysis of interview data produced 4 themes: *emotional response to estimated heart age*, *perceived understanding of CVD risk*, *perception of the HAT*, and *making a change?* Each theme is examined in turn and evidenced by interview transcripts (eg, each extract is labeled to indicate participant number, age, sex, IMD quintile, and ethnicity).

Table 3. Interview participants' characteristics (n=33).

Characteristics	Values, n (%)
Sex	
Male	14 (42)
Female	19 (58)
Age range (years)	
30-35	1 (3)
36-40	5 (15)
41-45	4 (12)
46-50	2 (6)
51-55	5 (15)
56-60	6 (18)
61-65	4 (12)
66-70	3 (9)
71-75	2 (6)
>75	1 (3)
Ethnic group	
White	27 (82)
Ethnic minority[a]	6 (18)
Deprivation	
Most deprived (IMD[b] 1-5)[c]	14 (42)
Least deprived (IMD 6-10)[c]	19 (58)
Last contact with GP[d]	
In the past week	4 (12)
In the past month	5 (15)
In the past 3 months	8 (24)
In the past 6 months	3 (9)
In the past 12 months	4 (12)
>12 months ago	9 (27)
Have a longstanding illness, disability, or disorder	
Yes	15 (45)
No	18 (55)

[a]Includes those from Chinese, Indian, Black Caribbean, and other ethnic background.

[b]IMD: Index of Multiple Deprivation.

[c]IMD 1=most deprived to IMD 10=least deprived.

[d]GP: general practitioner (or physician).

Emotional Response to Estimated Heart Age

Following completion of the HAT, many participants were "a little bit surprised" when their result did not equate to expectations "because [they were] really active, [they] do a lot of exercise" (participant 25; aged 36-40 years; female; Q5; White) and "because [their] blood pressure is good, [their] weight is good" (participant 24; aged 41-45 years; female; Q5; White). Some of these participants felt frustrated that they "didn't see [their] biological age" (participant 32; aged 51-55 years, male; Q2; ethnic minority) as it did not "fit with [their] experience of most people [their] age" (participant 7; aged 56-60 years; female; Q4; White). Others considered the estimated heart age to be a "real wake-up call" (participant 21; aged 66-70 years; female; Q2; White) and "a bit of a boost to say actually 'yeah I do need to understand these levels'...I could do better with my own lifestyle" (participant 9; aged 30-35 years; male; Q3; White).

Some participants were "pleasantly surprised that [they weren't] more unhealthy" (participant 4; aged 36-40 years; female; Q5; White). This was owing to recognition of lack of engagement in healthy behaviors:

> *I don't do much exercise as I used to, or I would like to.* [Participant 12; aged 41-45 years; male; Q3; White]

Those who received an estimated heart age equal to or lower than their chronological age found that their result "was actually quite pleasing" (participant 10; aged 61-65 years; male; Q3; White) and it "reassured [them that] 'oh there is a point to [a healthy lifestyle]'" (participant 11; aged 71-75 years; male; Q5; White) choosing to "los[e] some weight" (participant 5; aged 46-50 years; male; Q5; White) before taking the test.

In summary, participants reported both positive and negative emotional responses following completion of the HAT, particularly when their result did not meet expectations. For some, the test served as a wake-up call and encouraged them to re-evaluate their behavior.

Perceived Understanding of CVD Risk

Participants perceived to have a good understanding of their estimated heart age, with some suggesting that the test indicated their heart was older than their chronological age:

> *...Basically, I am a 79-year-old person.* [Participant 20; aged 66-70 years; male; Q2; White]

Those with an estimated heart age older than their chronological age understood that "there is obviously a little bit more [they] could do to look after [themselves]" (participant 25; aged 36-40 years; female; Q5; White), whereas those with an estimated heart age equal to their chronological age thought that their "behaviour, what [they are] eating, doing, isn't making [their] heart necessarily any worse" (participant 4; aged 36-40 years; female; Q5; White).

Understanding of CVD risk was also perceived to be high, as participants stated that they were already aware of factors that can increase their risk of a heart attack or stroke as a result of information from "social media and previous knowledge" (participant 15; aged 66-70 years; female; Q4; White) or from "family members that have had issues with their hearts" (participant 9; aged 30-35 years; male; Q3; White).

Results from the HAT also provide users with their CVD event–free survival age (Multimedia Appendix 1; presented in HAT as "on average, someone like you can expect to live to the age of XX without having a heart attack or stroke"). A small number of participants struggled to interpret this information:

> *I was predicted to die at 77.* [Participant 5; aged 46-50 years; male; Q5; White]
>
> *From age 53, I should be expecting to have a heart attack. That is how I read it.* [Participant 32; aged 51-55 years; male; Q2; ethnic minority]

Others found it difficult to determine which factors were increasing their estimated heart age:

> *I don't know whether it's the cholesterol figure I put in, that is the only thing I can think of at the minute.* [Participant 8; aged 56-60 years; female; Q4; White]

This was concerning for a small number of participants, and therefore, the interviewer had to explain the result to provide some reassurance.

In summary, most interview participants perceived that they had a good understanding of estimated heart age and CVD risk before completing HAT owing to information obtained from social media and personal experience. Few participants struggled to interpret CVD event–free survival age presented in HAT, which led to some concern and confusion about their results and CVD risk.

Perception of the HAT

Most participants thought that the HAT was "easy to use and interesting" (participant 2; aged 51-55 years; female; Q2; White) or "very clear and concise" (participant 9; aged 30-35 years; male; Q3; White). The HAT was perceived to be "quite informative" (participant 14; aged 51-55 years; female; Q1; White) and would be helpful to those who need to improve their health behavior, "like my mum" (participant 6; aged 51-55 years; female; Q5; White).

However, most comments referred to the fact that heart age was estimated from limited information:

> *I don't think it had much to go on.* [Participant 5; aged 46-50 years; male; Q5; White]

Participants expected to be asked about other factors such as alcohol or physical activity:

> *[It] didn't ask me like alcohol intake...that sort of surprise[d] me.* [Participant 10; aged 61-65 years; male; Q3; White]
>
> *I don't remember there being an exercise question.* [Participant 8; aged 56-60 years; female; Q4; White]

Others questioned the accuracy of the test when an individual is unable to report their blood pressure and cholesterol information:

> *With those answers [blood pressure and cholesterol] it may have been more precise, or maybe a bit more accurate.* [Participant 23; aged 61-65 years; female; Q2; ethnic minority]
>
> *They are fairly important measurements to put in aren't they?* [Participant 4; aged 36-40 years; female; Q5; White]

Owing to this reason, a small proportion of participants whose estimated heart age was older than their chronological age chose to "discount the whole thing because you just don't believe it, it's how it is, isn't it. They have got it wrong" (participant 11; aged 71-75 years; male; Q5; White).

Nevertheless, some participants had already recommended the test when interviewed:

> *My son is 33 and I said to him you need to be doing this now. My niece, I rang her and told her and my*

sister. [Participant 21; aged 66-70 years; female; Q2; White]

Others reported that they would recommend the test "to some, not to all, it probably depends on where I think they are at, at the time" (participant 30; aged 41-45 years; female; Q4; ethnic minority). This was mostly owing to feeling that it is not their "job [to discuss health behaviour choices with someone]...It is quite a delicate subject" (participant 16; aged 51-55 years; male; Q4; White).

In summary, participants liked the simplicity of the test, but some questioned its accuracy owing to the amount of information required and when they were unable to provide information about their blood pressure and cholesterol level. However, most participants would recommend or had already recommended the HAT to others. This implies a perceived benefit regardless of their reservations about HAT's accuracy.

Making a Change?

Following completion of the HAT, most participants reported that the test prompted them to consider "doing more exercises" (participant 6; aged 51-55 years; female; Q5; White), "calorie intake" (participant 25; aged 36-40 years; female; Q5; White), and weight loss of "certainly 3[kgs]" (participant 10; aged 61-65 years; male; Q3; White). Participants also suggested that the HAT could be a catalyst to engage with primary care, for example, either "just have a check-up" (participant 9; aged 30-35 years; male; Q4; White) or "to find out [what their cholesterol level and blood pressure numbers were]" (participant 30; aged 41-45 years; female; Q4; ethnic minority). However, some questioned "whether [their] motivation [would] persist" (participant 1; aged 36-40 years; male; Q4; White) once the burden of the COVID-19 pandemic became more manageable for general practice and they could subsequently book a checkup.

Some participants reported that they had already made changes to their health behavior including "doing more regular exercise" (participant 3; aged 41-45 years; female; Q1; White) and researching "about food portions...checking calories, how much do you need" (participant 27; aged 36-40 years; female; Q5; ethnic minority). Only 3% (1/33) of the participants would prefer to ask a health professional if they could have their cholesterol level and blood pressure checked through a routine blood test for a preexisting condition and were surprised to learn that their blood pressure was high:

> *The doctor rang me...he said because you have got a rheumatoid flame up at the moment, that would put your blood pressure up...if I hadn't done that survey I wouldn't have had a clue.* [Participant 21; aged 66-70 years; female; Q2; White]

This low level of follow-up among users may be explained by the COVID-19 pandemic, as participants felt that it was "probably not the right time" (participant 30; aged 41-45 years; female; Q4; ethnic minority) to ask their GP for follow-up tests. Another participant stated that the HAT had encouraged them to reconsider their smoking habit:

> *It brought it home a bit more to me...it was just the test that really said to me..."Hang on [name], do you have to have a cigarette now" and that has been "no," so it is just breaking habits.* [Participant 20; aged 66-70 years; male; Q2; White]

Changes to behavior were largely reported to be a result of completing the HAT and "because of [their] family history" (participant 24; aged 41-45 years; female; Q5; White) or influences from family members:

> *My little lad...to hear him say "you know mum that has put so many years on your [heart] which means you are going to lose those years." That was...a big factor hearing my little boy say that.* [Participant 3; aged 41-45 years; female; Q1; White]

Those without intentions to change their behavior explained that it was because they did not "feel there are massive life changes to be made as a result of what was in the test" (participant 1; aged 36-40 years; male; Q4; White) or because "[their] heart age [was] only slightly above [their] real age" (participant 22; aged 56-60 years; male; Q3; ethnic minority). However, participants stated that they would attend an NHS Health Check following the completion of the HAT as "it would be nice to understand more about...the actual health of [their] heart" (participant 26; aged 36-40 years; female; Q5; White).

In summary, most participants had intentions to change or had already made changes to their health behavior following completion of the HAT. Those who had already taken action to improve their health before completing the test reported that it had encouraged them to maintain those changes. Although behavioral intentions and changes were reportedly owing to the HAT, most participants had already made changes to their health behavior before completing HAT, which indicates that participants were already invested in improving their health.

Discussion

Principal Findings and Comparison With Previous Studies

To the best of our knowledge, there is limited evidence of the effect of England's HAT from a sample of users. With approximately 5 million completions up to June 2020, the findings suggest that there is considerable public interest in heart health. Overall, users who engaged with the test were most commonly men, aged between 50 and 59 years, classified as having White ethnic background, and living in the least deprived areas, similar to a previous descriptive study published in 2016 [24]. This contrasts with other heart age calculators that have typically reported high proportions of female users [27,31]. This may be explained by a campaign in 2018, which led to a surge in HAT engagement, particularly from men.

Analysis of the web-based survey and interview data suggested that the HAT provoked a negative emotional response when the score did not meet expectations, reflective of findings reported elsewhere [31]. Participants also stated that they understood the significance of estimated heart age being higher than their chronological age and self-reported at least some improvement in understanding of their CVD risk and confidence in understanding and controlling their CVD risk. Compared with percentage risk scores, there is evidence that heart age is

more emotionally impactful and improves risk perception and recall [10-12,15-22]. However, CVD event–free survival age (presented in HAT—refer to Multimedia Appendix 1) was reportedly difficult to interpret, which led to some concern and confusion about why their estimated heart age was higher than their chronological age for some participants. There is little evidence of the impact of CVD event–free survival age, but poor understanding from both patients and practitioners has been reported elsewhere [5,41], suggesting the need for great caution and clarity when presenting risk information in this format.

Participants questioned the accuracy of the HAT, largely owing to the small amount of information required from which heart age was estimated and the implications of not knowing their blood pressure or cholesterol level to inform this estimate. Concerns that heart age can overestimate CVD risk are well reported [19,27,31,33,34] and have led to calls for caution in its application [17,34]. Nevertheless, most participants stated that they would recommend or already had recommended the HAT to others, would engage with the test again in the future, and would be more likely to take up the offer of an NHS Health Check and self-reported that they had made or intended to make changes to their health behavior (ie, lose weight, be more active, and eat more healthily) or were encouraged and motivated by the test to maintain the changes made to their health behavior.

Researchers have suggested that estimated heart age can increase motivation for individuals to make changes to their health behavior [10-12,19-22,31] and perform clinical checks [20,31]. As with Australia's heart age calculator, participants most commonly self-reported changes or intentions to improve their diet, lose weight, and be more active following completion of the HAT [31]. However, a recent systemic review that explored the effects of heart age interventions concluded that there is limited evidence to suggest that heart age alone can lead to positive behavioral outcomes [13]. In this study, participants reported some engagement in healthy behaviors before completing the HAT, and their motivation to reduce their CVD risk also resulted from other factors including supportive family and friends and family history of CVD. Therefore, heart age calculators may be a method that can be used in combination with other behavioral strategies to encourage individuals to re-evaluate their current health behavior and to increase intentions to improve their heart health. The long-term outcomes from HAT are yet to be explored.

Strengths and Limitations

To the best of our knowledge, this is the first study of England's HAT to explore user experiences and intentions to action. Strengths of this study include the use of multiple data sources, which allowed for cross-validation of findings and participant experiences. The survey sample differed in some aspects but still represented the sociodemographic range of the population of England, with participants from various age, sex, ethnic background, and deprivation levels. Interview participants were purposively sampled to be representative of the typical profile of HAT users, with overrepresentation of those from ethnic minority backgrounds to ensure that a range of views and experiences were captured. A subsample of interviews was independently coded by 2 qualitative researchers, which led to a robust examination of the data.

Several limitations are acknowledged. First, deprivation could not be determined for approximately half (2,387,513/4,898,532, 48.74%) of HAT users. Users may have completed the HAT with fictitious data, and those with no postcode could reside outside of England, which could undermine assertions about the HAT user population. Second, the self-selecting sample introduces a degree of bias to be reflective of those who typically engage with digital self-checking tests (ie, ecologically valid). This may be arguably great in the interview sample, representing those who are more knowledgeable and positive about their health. However, both positive and negative views and experiences were described by participants, which suggests this had a limited influence on the findings. Third, to be representative of typical HAT users, few older participants were recruited for follow-up interviews. Owing to their age, these individuals are predisposed to an increased CVD risk, which may be likely to affect their perception of the test and future behavioral intentions. Their limited inclusion in the study may have influenced the findings. Fourth, there is underrepresentation of those living in the most deprived areas. Although this is representative of those who typically engage with the HAT, it limits the conclusions that can be drawn in this sample of individuals. Further studies are needed to understand the impact of heart age on those who are most deprived. Fifth, many participants self-reported that their intentions to change or actual changes to their health behavior resulted from completing the HAT (Table 2). However, as most participants reported at least some engagement in healthy behaviors before completing the test, these outcomes cannot be attributed to the HAT alone. Therefore, participants' future engagement in healthy behaviors cannot be attributed to competing the HAT alone. Future studies could explore the impact of HAT on those who are not currently engaged in risk-reducing behaviors. Sixth, data were collected during a period of national lockdown (England; January 2021 to March 2021), which may have affected participant responses (ie, self-reported intentions to change or actual behavior change and access to health care services). This may have led to individuals underreporting or overreporting their intentions to change behavior and may have reduced access to health care services.

Future Directions

Completion of England's HAT elicited a negative emotional response when the result did not match previous risk perception. Although this served as a wake-up call for most participants, the credibility of the test was questioned by all participants who were interviewed and subsequently dismissed by some. Therefore, adequate direction to resources and more information about how estimated heart age is calculated is needed to support users who may feel confused or concerned about their result. Clear information about the accuracy of the result is also warranted, especially if the user was unable to provide physiological risk factor information (ie, blood pressure and cholesterol level).

Most participants reportedly had a good understanding of the meaning of high estimated heart age, suggesting that heart age

calculators may be a good way to improve the population's understanding of CVD risk. However, given the misinterpretation of CVD event–free survival age, great caution and clarity are needed when presenting risk information in this format. Participants also self-reported changes to their health behavior and intentions to make healthy behavior choices and engage with primary care services (ie, arrange a blood pressure or cholesterol check) upon completion of the test. However, it could not be determined if these participants were estimated to have a heart age that was older than their chronological age, as few participants shared their result during interview. Nevertheless, web-based tests such as HAT may be a good way to encourage individuals to manage their own health by self-checking their heart health. Where clinically appropriate, some users reported intending to see a health care professional for blood pressure and lipid assessments. This could support a range of incentives recently introduced in England to enable individuals aged >40 years to get their blood pressure checked.

The number of HAT completions reported here (approximately 5 million from February 2015 to June 2020) suggests considerable public interest in heart health. However, there was a pattern of underrepresentation of those living in the most deprived areas in this study, which suggests a need to further explore the extent of inequalities, regarding both reach or access and how the potential benefits are distributed across the socioeconomic strata.

Conclusions

With approximately 5 million completions up to June 2020, findings from our evaluation of England's HAT in a subgroup of users suggest that there is considerable public interest in heart health. The test was shown to elicit a more negative emotional response when estimated heart age did not equate to previous risk perceptions. The test reportedly led to an increased understanding of high estimated heart age and at least some improvement in understanding of CVD risk and confidence in understanding and controlling CVD risk. Despite concerns resulting from the limited information needed to complete the test or missing physiological risk factor information (ie, blood pressure and cholesterol level), participants stated that they would recommend or had already recommended the test to others, would use it again in the future to check their heart health, and would be more likely to take up the offer of an NHS Health Check and self-reported that they had made or intended to make changes to their health behavior or felt encouraged and motivated by the HAT to continue the changes made to their health behavior. However, many participants self-reported at least some engagement in healthy behaviors before completing the test; therefore, some of these outcomes cannot be attributed to the HAT alone. A web-based self-checking test such as England's HAT may be a good way to raise awareness about CVD risk and encourage individuals to self-check their heart health and consider healthy behavior choices in combination with other behavioral strategies. However, more adequate direction to support and information about how estimated heart age is calculated and presentation of CVD event–free survival age should be considered to avoid user confusion and improve satisfaction.

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Data Availability

The data sets generated and analyzed during this study are not publicly available because consent was not obtained from participants during data collection.

Conflicts of Interest

The heart age test was jointly developed by Public Health England, British Heart Foundation, Joint British Societies, and NHS Digital. The funder (Public Health England) collaborated in the study design and the write-up of this paper.

Multimedia Appendix 1
Screenshot of heart age and cardiovascular disease (CVD) event-free survival age presented in heart age test (HAT) output.
[PNG File , 55 KB - cardio_v7i1e39097_app1.png]

Multimedia Appendix 2
Screenshot of risk tailored information and advice presented in heart age test (HAT) output.
[PNG File , 61 KB - cardio_v7i1e39097_app2.png]

Multimedia Appendix 3
Participants' emotional response to estimated heart age.

[PNG File , 97 KB - cardio_v7i1e39097_app3.png]

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Abbreviations

CVD: cardiovascular disease
HAT: heart age test
IMD: Index of Multiple Deprivation
NHS: National Health Service
Q1: quintile 1
Q2: quintile 2
Q3: quintile 3
Q4: quintile 4
Q5: quintile 5

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Original Paper

Preliminary Efficacy, Feasibility, and Perceived Usefulness of a Smartphone-Based Self-Management System With Personalized Goal Setting and Feedback to Increase Step Count Among Workers With High Blood Pressure: Before-and-After Study

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Abstract

Background: High blood pressure (BP) and physical inactivity are the major risk factors for cardiovascular diseases. Mobile health is expected to support patients' self-management for improving cardiovascular health; the development of fully automated systems is necessary to minimize the workloads of health care providers.

Objective: The objective of our study was to evaluate the preliminary efficacy, feasibility, and perceived usefulness of an intervention using a novel smartphone-based self-management system (DialBetes Step) in increasing steps per day among workers with high BP.

Methods: On the basis of the Social Cognitive Theory, we developed personalized goal-setting and feedback functions and information delivery functions for increasing step count. Personalized goal setting and feedback consist of 4 components to support users' self-regulation and enhance their self-efficacy: goal setting for daily steps, positive feedback, action planning, and barrier identification and problem-solving. In the goal-setting component, users set their own step goals weekly in gradual increments based on the system's suggestion. We added these fully automated functions to an extant system with the function of self-monitoring daily step count, BP, body weight, blood glucose, exercise, and diet. We conducted a single-arm before-and-after study of workers with high BP who were willing to increase their physical activity. After an educational group session, participants used only the self-monitoring function for 2 weeks (baseline) and all functions of DialBetes Step for 24 weeks. We evaluated changes in steps per day, self-reported frequencies of self-regulation and self-management behavior, self-efficacy, and biomedical characteristics (home BP, BMI, visceral fat area, and glucose and lipid parameters) around week 6 (P1) of using the new functions and at the end of the intervention (P2). Participants rated the usefulness of the system using a paper-based questionnaire.

Results: We analyzed 30 participants (n=19, 63% male; mean age 52.9, SD 5.3 years); 1 (3%) participant dropped out of the intervention. The median percentage of step measurement was 97%. Compared with baseline (median 10,084 steps per day), steps per day significantly increased at P1 (median +1493 steps per day; *P*<.001), but the increase attenuated at P2 (median +1056 steps per day; *P*=.04). Frequencies of self-regulation and self-management behavior increased at P1 and P2. Goal-related self-efficacy tended to increase at P2 (median +5%; *P*=.05). Home BP substantially decreased only at P2. Of the other biomedical characteristics, BMI decreased significantly at P1 (*P*<.001) and P2 (*P*=.001), and high-density lipoprotein cholesterol increased significantly only at P1 (*P*<.001). DialBetes Step was rated as useful or moderately useful by 97% (28/29) of the participants.

Conclusions: DialBetes Step intervention might be a feasible and useful way of increasing workers' step count for a short period and, consequently, improving their BP and BMI; self-efficacy–enhancing techniques of the system should be improved.

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KEYWORDS

behavior change; blood pressure; feasibility studies; goal setting; mobile health; mHealth; self-control; self-efficacy; self-regulation; smartphone; step count; walking; workplace; mobile phone

Introduction

Background

Cardiovascular diseases (CVDs) are the leading cause of death worldwide [1]; they also affect patients' quality of life and health care expenditures. High blood pressure (BP) is one of the major risk factors for CVDs [2,3]. BP levels have dose-response associations with mortality from CVDs in Japanese cohorts [4]. Aerobic exercise, such as brisk walking, is effective [5] and recommended for lowering BP [6,7]. However, physical inactivity remains as a critical public health issue worldwide [8,9]. In Japan, although the second term of the National Health Promotion Movement in the 21st Century has established goals for steps per day (9000 steps for men and 8500 steps for women who are aged 20-64 years) [10], the mean steps per day has been gradually decreasing since 2000 [11] and falls short of the goals.

Mobile health (mHealth) is expected to increasingly support people's self-management for improving cardiovascular health, such as physical activity promotion and BP control [12]. mHealth interventions with feedback from care providers were associated with significant reduction in BP [13]. A meta-analysis of mobile phone–based weight loss interventions suggested that personal contact between participants and intervention staff and more frequent interactions were associated with weight reduction [14]. However, interventions needing time investment from care providers or intervention staff may prevent scalability under the limited workforce in the current superaged society. In our previous studies of a smartphone-based self-management system for workers with abdominal obesity [15,16], creating monthly feedback reports including lifestyle advice placed a heavy burden on health care providers. Therefore, the development of mHealth systems with fully automated feedback and individualized advice is necessary to minimize their workloads.

Theory is helpful in guiding hypothesized mechanisms of behavior change during the development and evaluation of interventions [17]. The Social Cognitive Theory (SCT) [18] has been used most frequently as a framework for interventions targeting CVD risk factors [19] because it specifies techniques for changing the core determinant of health behavior, namely self-efficacy [20]. Interventions based on the SCT had significant effect on increasing physical activity in survivors of cancer [21]. However, few mobile apps focusing on physical activity have been developed and evaluated based on the SCT.

Objective

We developed automated feedback and individualized advice functions to increase step count based on the SCT. We added them to the extant smartphone app (DialBeticsLite) [15,16], which facilitates the recording of physical parameters (BP, body weight, and blood glucose) and health behavior related to CVD prevention (diet, exercise, and daily step count) and provides brief evaluation messages about physical parameters and general diet advice. We focused on daily step count because it is the best-known and objectively measurable key indicator of aerobic physical activity. Longitudinal studies have demonstrated that great daily step counts were associated with low risk of all-cause mortality [22,23] and CVDs [23]. This paper describes the system development and a pilot study of workers with high BP aiming to evaluate the preliminary efficacy, feasibility, and perceived usefulness of an intervention using the new system (DialBetes Step) in increasing step count.

Methods

System Development

Theoretical Framework

We used the SCT and the *stages of change* in the Transtheoretical Model [24,25] as the theoretical basis of DialBetes Step.

We focused on 3 constructs of the SCT to create new functions to increase step count: *self-efficacy*, *self-regulation*, and *behavioral capability*. *Self-efficacy* is the conviction that one can successfully perform a behavior that leads to an outcome, which can be changed through certain techniques (eg, mastery experience by *performance accomplishments* and *verbal persuasion*) [26]. *Self-regulation* is the process through which an individual observes their own behavior (self-monitoring), judges it by comparison with personal standards (self-set goals), and gives self-evaluative or tangible self-reactions (self-reward) to modify their own behavior [18,27]. Interventions combining self-monitoring of behavior with at least one of the other self-regulation techniques (eg, goal setting and feedback) were more effective in increasing physical activity [28].

Self-regulation techniques partly overlap with techniques that improve self-efficacy [29]. For example, graded goal setting contributes to accumulating mastery experience, and feedback is a means of verbal persuasion [30]. Therefore, we hypothesized that the enhancement of self-regulation would increase physical activity not only directly but also by mediating improvements in self-efficacy [31,32].

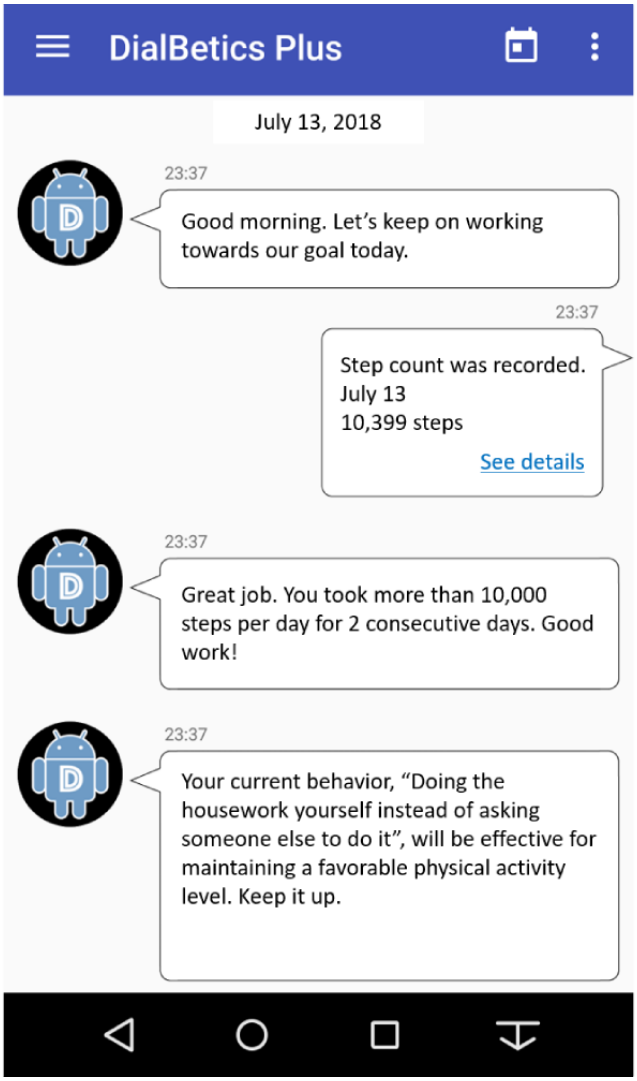
Finally, we developed personalized goal-setting and feedback functions, focusing on daily step count to support users' self-regulation and enhance their self-efficacy. We intended for users to set step goals in gradual increments to have many mastery experiences through goal achievement. We also included information delivery functions to enhance users' *behavioral capability* (ie, knowledge and skill) [27].

The *stages of change* were used to define the system's target population. We selected people in the *contemplation* stage (in which they are seriously thinking about overcoming a problem) and the *preparation* stage (in which they intend to change behavior in the very near future or are engaging in small behavior changes) as our target population. Patients in these stages were more likely to be willing to use a self-management tool based on information and communication technology than those in the precontemplation stage [33].

Development Process

We decided on the conceptual framework described previously, content, and algorithms of the new functions by reviewing the literature, including previous information and communication technology–based intervention studies [34-48] on increasing physical activity based on the SCT. We also had continuous discussions within the interdisciplinary team of medical and nursing researchers, such as a registered nurse (TS), endocrinologists (KW and KM), a cardiologist, and a specialist in behavioral medicine. We made an interactive timeline screen on which users could see messages from the system (Figure 1). After the implementation of new functions in DialBeticsLite, the authors (TS, AI, and NYM) and 5 healthy volunteers tested the user interface of the timeline screen and the accuracy of the new function algorithms.

Figure 1. An example of the timeline screenshot of the DialBetes Step app. We copied and transformed the Google material (Android robot) following the Creative Commons 3.0 Attribution license. "DialBetics Plus" was the name of the app when the study was conducted.



The New Functions

The functions for increasing step count in DialBetes Step were divided into self-monitoring, information delivery, and personalized goal setting and feedback. Overall, DialBetes Step included 18 behavior change techniques defined in the Behavior Change Technique Taxonomy version 1 [49] (Multimedia Appendix 1).

DialBeticsLite already has functions to record daily step count and show them as a list and a graph (self-monitoring function). Information delivery functions comprise general information to increase step count, individualized advice to promote physical activity, and individualized information for safe physical activity. When starting the use of the new functions, users can see general information (an action list consisting of 12 actions [50,51]; Textbox S1 in Multimedia Appendix 2) for increasing the step count. We created individualized advice to promote physical activity by modifying the physical activity–related algorithms of Lifestyle Intervention Support Software for Diabetes Prevention [52]. When the user does not meet their step goal, the system recommends one of the behaviors the user "never" or "rarely" does from the items of the "evaluation scale for self-management behavior related to physical activity of type 2 diabetic patients" (ES-SMBPA-2D) [53].

Functions of personalized goal setting and feedback consist of 4 components: goal setting for daily steps, positive feedback, action planning, and barrier identification and problem-solving.

First, DialBetes Step helps users set their own step goals once a week. The process of goal setting involves system-suggested goals, self-setting of goals, and system-suggested goal adjustments according to the user's self-efficacy in goal achievement. As there were insufficient studies for a way to calculate appropriate step goals automatically, we made algorithms for goal suggestion by simulation using data from our previous study [54]. Therefore, the system-suggested goals are based on the user's daily step counts at baseline (P0; at week 1) or the number of days in the previous week the user achieved their step goal (at and after week 2) [45,55]. The maximum goal the system suggests and the user can input are both 15,000 steps per day. Users input their confidence in achieving the goal on >4 days of the week, from 0% to 100%. If their confidence level is from 70% to 90%, the system judges the goal as appropriate [41]; otherwise, the system recommends changing the goal. Thus, DialBetes Step allows users to set challenging yet attainable goals that they were likely to achieve with a little more effort [56,57].

Second, DialBetes Step gives users various types of positive feedback to recognize their efforts in increasing their step count: daily feedback about the user's step goal achievement (Figure 1), feedback about the user's favorable physical activity behaviors (Figure 1), and weekly feedback. We created feedback about the user's favorable physical activity behaviors by modifying the algorithms of Lifestyle Intervention Support Software for Diabetes Prevention [52]. When the user meets their step goal, the system displays a message that recognizes one of the behaviors from the ES-SMBPA-2D the user does "often" or "always" as favorable and that encourages them to continue the behavior. For the other types of feedback, we created algorithms with conditional equations to select one of the messages automatically. Weekly feedback includes the mean steps per day, the number of days on which the user achieved the step goal, mean values of physical parameters in the past week, and feedback messages about changes in each parameter.

Third, DialBetes Step helps users make and review an action plan to achieve their step goal once a week after a step goal is determined. Users choose as many actions from the action list (Textbox S1 in Multimedia Appendix 2) as they plan to accomplish or input any other action in a free write-in column.

In addition to action planning, DialBetes Step helps users identify barriers to walking and think of possible solutions. Users rate current or future barriers instead of reviewing their action plan, depending on their mean steps per day and the number of days the user achieved their step goal in the past week. Even if the step goal is reached, it is essential for users to think of possible barriers to walking in the future, to maintain behavior and prevent relapse [58]. We created lists of common current and future barriers to walking from previous studies [59-62] and lists of possible solutions for each barrier (Tables S1 and S2 in Multimedia Appendix 2).

Design of the Feasibility Study

We conducted a single-arm pilot study of workers at Tokyu Department Store Health Insurance Society in Tokyo, Japan. The primary objective of this study was to evaluate the short-term efficacy, feasibility, and perceived usefulness of DialBetes Step in 6 weeks. We assumed a clinically meaningful change in steps per day to be 1000 steps, as the Japanese physical activity guideline recommends a 10-minute increase in physical activity per day [51], and 100 steps per minute is an estimate for moderate-intensity walking [63]. We hypothesized that the clinically meaningful change would be reached in 6 weeks based on the system's goal-setting algorithms. We also assessed whether the short-term efficacy continued after 24 weeks of using DialBetes Step.

This study was registered in the University Hospital Medical Information Network Clinical Trial Registry (UMIN000037970).

Participants

Employees of 4 private enterprises whose systolic BP had been ≥140 mm Hg at a workplace health checkup in the fiscal year 2017 and who were working in the Tokyo metropolitan area were included in this study. All 4 enterprises were in the service industry (eg, department store) and belong to Tokyu Department Store Health Insurance Society. Employees who had been given nationwide lifestyle intervention [16,64] in the fiscal year 2018 were excluded.

A collaborator in the health insurance society sent written recruitment documents to all candidates via workplace mail. Candidates who judged themselves to meet the 3 entry criteria (not walking enough in general, being willing to increase physical activity through walking, and able to engage in moderate physical activity) applied for participation. Recruitment was continued by the collaborator via telephone or email and by an industrial physician (KW) at the employee

outpatient clinic until the number of applicants reached the target described in the following section.

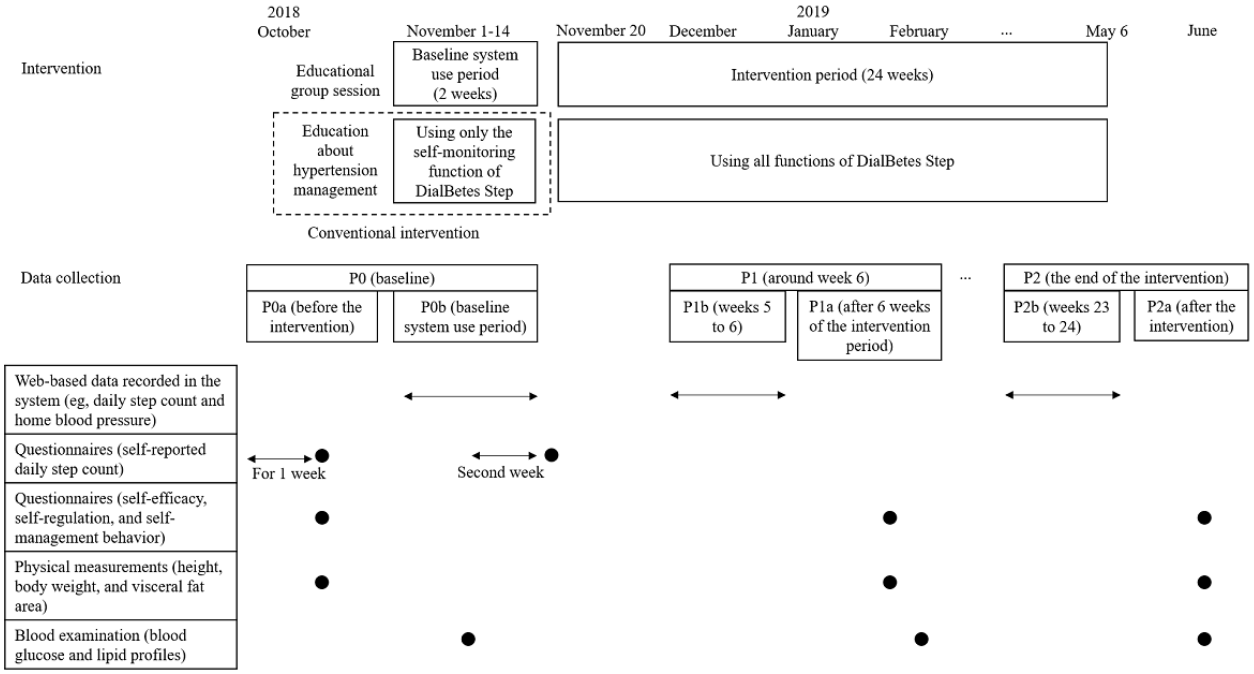
We confirmed the applicants' eligibility for the study based on the results of their health checkups and a baseline questionnaire. Exclusion criteria were the following: systolic BP of ≥180 mm Hg; recent hemoglobin level <10 g/dL; diabetes other than type 2; experience of any hypoglycemic events within the past 3 months; and pregnancy, lactation, or pregnancy plans in the near future. We consulted another industrial physician to judge the applicants' eligibility if we had difficulty in making a decision.

We collected data both via the web (data recorded in DialBetes Step) and offline (paper-based questionnaires, physical measurements, and blood examinations; Figure 2). Participants attended group sessions for offline data collection at the University of Tokyo Hospital at P0, after 6 weeks of the intervention period (P1a), and after the intervention (P2a). Questionnaires at P1a and P2a were sent via email and collected at each group session. Blood samples were collected for examination at the outpatient clinic of the health insurance society at P0 and P1a and during the group session at P2a.

As baseline characteristics, we obtained sex and the date of birth from the health insurance society. The baseline questionnaire before the intervention (P0a) included questions about the participant's stages of change in increasing step count [65]; outpatient visits for hypertension and diabetes; and routine measurement of home BP, body weight, and step count. Office BP was measured using an automated sphygmomanometer (Omron; HEM-7271T).

After the completion of the study, we compensated the participants with a paper-based report on the results of physical measurements and blood examinations with comments from a registered nurse (TS).

Figure 2. Timeline of the intervention and data collection for outcome evaluation in the before-and-after study among workers with high blood pressure. P0: baseline; P0a: before the intervention; P0b: baseline system use period; P1: around week 6; P1b: weeks 5 to 6; P1a: after 6 weeks of the intervention period; P2: the end of the intervention; P2b: weeks 23 to 24; P2a: after the intervention.



Ethics Approval

This study was approved by the research ethics committee of the Graduate School of Medicine, the University of Tokyo—approval 11902-(2). We obtained informed consent through 2 processes. Participants initially provided written informed consent to data collection for the short-term evaluation in 6 weeks. At the P2a group session, we informed participants about the remaining data collection through a document and verbal explanation; participants could opt out at their own discretion. We deidentified all study data to protect the participants' privacy and confidentiality.

Interventions

Educational Group Session (Conventional Intervention)

All participants attended a 2-hour group session in October 2018. The group session included the initial informed consent, baseline data collection, a 40-minute lecture on hypertension management, and a 60-minute lecture with a practice session on how to use DialBetes Step based on a user manual.

Use of DialBetes Step

All participants used the system for 26 weeks from November 2018. The study team loaned participants a device set to use the system: a smartphone (Fujitsu; F-02H) in which necessary apps were installed, a home sphygmomanometer (Omron; HEM-7271T), a weight and body composition scale (Omron;

HBF-255T), a glucometer (Terumo; MS-FR201B), and a triaxial accelerometer (Terumo; MT-KT02DZ).

For the first 2 weeks, all participants used only the self-monitoring function of DialBetes Step (conventional intervention) for baseline data collection (baseline system use period [P0b]). They measured BP twice a day (before breakfast [morning] and before bedtime [night]) and body weight once a day (morning). Participants whose hemoglobin A_{1c} (glycated hemoglobin) level was ≥6% or fasting blood glucose was ≥100 mg/dL at the latest health checkup also measured blood glucose levels once or twice a day (Multimedia Appendix 3). They recorded the data into the system through Bluetooth communication using a free app (Omron; OMRON connect) or near field communication. All participants wore the accelerometer in a clothes pocket or bag during all waking hours, except when swimming or taking a shower. Participants sent daily step count and calories burned by activity to the system through near field communication every night. Participants also input information about every meal and exercise not recorded by the accelerometer. We asked participants to live their daily life as usual (ie, not to increase physical activity intentionally) during this period.

After the 2-week P0b and a 5-day interval, all participants began using all functions of DialBetes Step for 24 weeks (intervention period). They received the same evaluation messages about physical parameters and diet advice as in the original DialBeticsLite [15,16] and used the new functions.

Participants contacted the study team via telephone or email when they had any trouble with using the system. We monitored the recorded data of the participants through the server every weekday. If a participant did not record accelerometer data for 3 consecutive days, the first author emailed them a reminder.

Process Evaluation

We calculated percentages for the measurement and recording of each parameter in DialBetes Step during P0b and intervention period. The percentages were calculated by dividing the number of days data were measured and recorded by the number of days in each period. We excluded days without data owing to recording failures, for which participants were not responsible, from the denominator.

We summarized the number of contacts between participants and the study team in each period, including email reminders to record accelerometer data and problems with system use. We categorized problems according to the functions of DialBetes Step.

Participants completed a paper-based questionnaire to evaluate the system during the P1a group session. Participants rated the usefulness and user-friendliness of the overall system and each function on a 4-point Likert scale (good, somewhat good, somewhat bad, or bad). They also responded to modified items about the overall system evaluation [54].

Outcome Evaluation

Primary Outcome

The primary outcome was the change in the mean steps per day recorded in DialBetes Step between P0b and weeks 5 to 6 (P1b) of the intervention period. We also assessed the long-term change between P0b and weeks 23 to 24 (P2b). We excluded data from days on which the participant did not wear the accelerometer according to their self-report or had daily step count <100 steps [66].

To assess the change in the mean steps per day presumably caused by the conventional intervention, participants also recorded daily step count for a week before the educational group session (ie, P0a) and during the second week of P0b on questionnaires if they had measured it using their own devices (eg, smartphones). The P0b questionnaire was sent to participants and returned via email.

Secondary Outcomes

Secondary outcomes included changes in another physical activity measure, biomedical outcomes, and antecedent factors of physical activity. We assessed short-term changes between P0 and around week 6 (P1: P1b for web-based data or P1a for offline data) and long-term changes between P0 and the end of the intervention (P2: P2b for web-based data or P2a for offline data) in each outcome. Detailed information about measuring instruments and scales is summarized in Multimedia Appendix 4.

We assessed the changes in the mean calories burned by activity per day (measured using the triaxial accelerometer [67]) and the mean home BP (for morning and night) using the web-based data recorded in DialBetes Step.

Other biomedical outcomes included changes in body weight, BMI, and visceral fat area (VFA) measured in the morning during each group session. Height and body weight were measured using an automatic height-and-weight scale (A&D; AD-6228AP), which subtracted 0.5 kg as the tare from the body weight. The first author or a clinical laboratory technician measured participants' VFA using DUALSCAN (Omron Colin; HDS-2000), which uses the dual impedance method [68,69].

Blood samples collected in the morning were sent to and examined by LSI Medience Corporation, Tokyo, Japan. We evaluated changes in the levels of hemoglobin A_{1c}, fasting blood glucose, triglycerides, and high-density lipoprotein (HDL) cholesterol. We used non-HDL cholesterol as an indicator of hypercholesterolemia instead of low-density lipoprotein cholesterol calculated using the Friedewald formula, as some participants had a triglyceride level of >400 mg/dL at P2a.

We assessed the changes in antecedent factors of physical activity using the questionnaire at P0a, P1a, and P2a, including 2 types of self-efficacy, self-regulation, and self-management behavior related to physical activity. First, we assessed self-efficacy in achieving goals for daily steps (goal-related self-efficacy [70]). On the basis of the scales of self-efficacy for physical activity [71-73], we set 4 levels of incremental step goals (6000, 8000, 10,000, and 12,000 steps per day). Participants rated their degree of confidence in achieving each

goal by writing a percentage from 0% to 100%. The score was calculated as the average of the confidence estimates for each goal. Second, we assessed self-efficacy in walking behavior [74]. Participants rated their degree of confidence in engaging in regular walking during 4 difficult situations (when tired, when in a bad mood, when feeling as if they did not have the time, and when it was raining or snowing) on a 5-point Likert scale. Self-regulation was assessed using the Japanese version of the 12-item Physical Activity Self-Regulation scale [75,76]. The scale consists of 6 factors (eg, self-monitoring, goal setting, reinforcements, time management, and relapse prevention), with 2 items each, rated on a 5-point Likert scale. Self-management behavior was assessed using the ES-SMBPA-2D, which consists of 9 factors, with a total of 32 items rated on a 5-point Likert scale [53].

Adverse Events

Adverse events were assessed using questionnaire. First, as DialBetes Step encouraged participants to increase physical activity, we assessed changes in body pain, using 4 items categorized in the body pain cluster in the 25-question Geriatric Locomotive Function Scale [77]. Participants rated those items on a 5-point Likert scale at P0a, P1a, and P2a. Second, we asked participants whether they experienced any changes in their condition or subjective symptoms during system use in the P1a and P2a questionnaires.

Population for Analyses and Sample Size

We included all participants in the assessment of problems with system use and adverse events. In contrast, we defined the suitable population for the other evaluation (eg, outcome evaluation) as the theoretical target population of DialBetes Step (ie, the contemplation and the preparation stages in the Transtheoretical Model). First, we excluded participants categorized in the precontemplation stage using the P0a questionnaire. Second, we excluded participants who were already taking >15,000 steps per day (equal to the maximum step goal users can set) during P0b because the system encouraged them to maintain that step count rather than increase it.

To calculate the sample size for outcome evaluation, we used the aforementioned clinically meaningful change in steps per day (1000 steps [51,63]) and estimated the SD to be 1800 based on our previous study of DialBeticsLite in Tokyu Department Store Health Insurance Society (K Waki, unpublished data, September 2017). We estimated the necessary sample size to be 28 to detect 0.55 SD of change, with 80% power at the 5% significance level, using G*Power 3.1.9.2 (Heinrich-Heine-Universität) [78]. Anticipating the dropout and ineligibility of a certain number of participants, we set a recruitment target of at least 35 participants.

Statistical Analyses

Changes in outcomes between P0 and P1 or P2 were tested using the Wilcoxon signed rank test owing to the small sample size and the skewed distribution of variables. We calculated distribution-free 95% CIs of the median using the *ciquantdf* option of the Base SAS 9.3 univariate procedure [79]. As we conducted 2 tests (short-term and long-term analyses) for each outcome, we set the significance level using the 2-tailed test at .025 based on the Bonferroni method.

We excluded participants who did not complete data collection and those without valid data (eg, having breakfast before the physical measurement) from analyses of each outcome. If responses to items of the ES-SMBPA-2D were missing, we substituted the participant's mean item score in each factor at the same time point for the missing values. If participants reported the start of new medications or increase in dose of any medication for hypertension or dyslipidemia in the P1a or P2a questionnaires, they were excluded from analyses of home BP or lipids, respectively.

We conducted post hoc subgroup analyses to assess whether the changes in steps per day were modified by baseline steps. We divided the participants into 2 groups using the median of the mean steps per day during P0b (<10,000 and >10,000 steps per day) and tested the step changes in each group.

We used SAS Studio 3.8 (SAS Institute) for all analyses.

Results

Participant Flow and Baseline Data

Figure 3 shows a flow diagram of participants. Although we could not determine the actual number of candidates who had been sent recruitment documents, 13.2% (34/257) or 13.1% (34/259) of them provided the initial informed consent. All participants were considered to be eligible for inclusion in the study. We included 88% (30/34) participants who met the qualifications for our theoretical target population in the process and outcome evaluation (the main population for analyses). A participant who had plans to be hospitalized for the treatment of arrhythmia at week 5 of the intervention period was excluded from the short-term analyses of the web-based data. We could not inform 9% (3/34) of the participants about data collection after P1; a total of 31 participants (n=29, 94% in the main population) were included in the long-term analyses.

Table 1 shows the baseline characteristics of participants in the main population. Most participants (21/30, 70%) were not overweight or obese.

Figure 3. Flow diagram of participants in the before-and-after study. P1: around week 6; P1a: after 6 weeks of the intervention period; P0b: baseline system use period; P2a: after the intervention; P2: the end of the intervention.

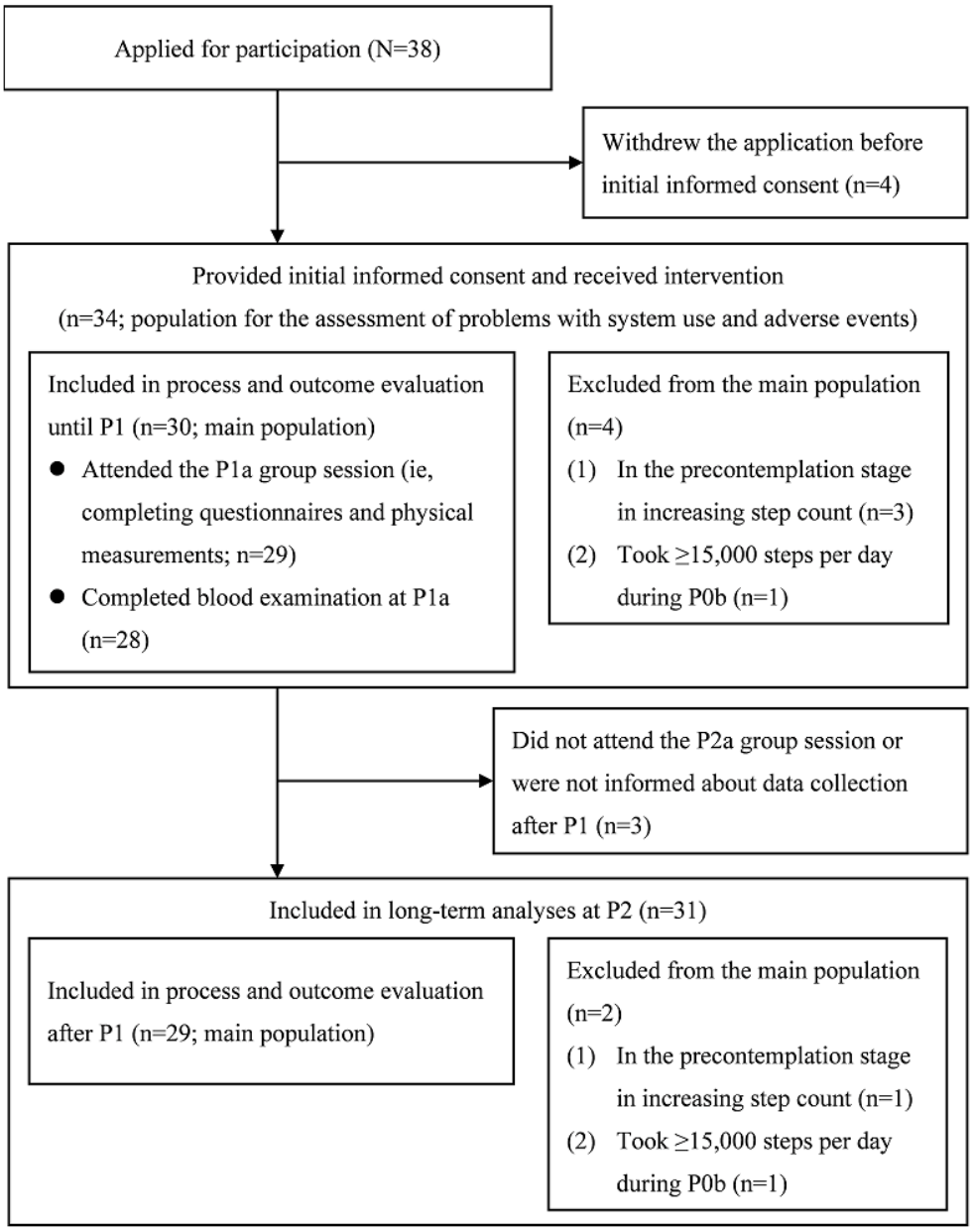


Table 1. Baseline characteristics of the main population for analyses in the before-and-after study among workers with high BP[a] (n=30).

Characteristics	Values
Sex (male), n (%)	19 (63)
Age (years), mean (SD)	52.9 (5.3)
Systolic BP at hospital (mm Hg), median (IQR)	146 (137-155.5)
Diastolic BP at hospital (mm Hg), median (IQR)	96 (91.5-105)
BMI (kg/m^2), median (IQR)	23.5 (20.9-25.1)
≥25 (overweight or obesity), n (%)	9 (30)
<25, n (%)	21 (70)
Visceral fat area (cm^2), median (IQR)	56 (42-88)
≥100 (abdominal obesity), n (%)	5 (17)
<100, n (%)	25 (83)
Stages of change in increasing step count, n (%)	
Contemplation	5 (17)
Preparation	17 (57)
Action	3 (10)
Maintenance	5 (17)
Regular outpatient visits for hypertension (yes), n (%)	8 (27)
Regular outpatient visits for type 2 diabetes (yes), n (%)	1 (3)
Routine measurement of home BP (yes), n (%)	13 (43)
Routine measurement of body weight (yes), n (%)	19 (63)
Routine measurement of step count (yes), n (%)	11 (37)

[a]BP: blood pressure.

Process Evaluation

The median percentages for daily step count measurement were 96.4% (IQR 85.7%-100%) during P0b and 97% (IQR 88.7%-100%) during the intervention period. The median measurement and recording percentages for the other parameters were >85% throughout the study (Table S1 in Multimedia Appendix 5). Only 23% (7/30) of the participants recorded any exercise during the intervention period.

During the study, we sent a total of 37 email reminders to 40% (12/30) of the participants. In total, 79% (27/34) of the participants had a total of 62 problems with system use (Table S2 in Multimedia Appendix 5). Half (31/62, 50%) of them were related to measurement and recording of daily step count (eg, recording failure through near field communication); however, there was no inquiry about the other functions designed to increase step count.

Most participants rated the overall system as useful (16/29, 55%) or somewhat useful (12/29, 41%) for self-management (Table S3 in Multimedia Appendix 5). The function that most participants rated as useful in increasing step count was measurement and recording (25/29, 86%), followed by goal setting (15/29, 52%), weekly feedback (14/29, 48%), and educational group session (11/29, 38%). In contrast, >20% of participants rated the user-friendliness of measurement and recording of daily step count (6/28, 21%), action planning (6/28, 21%), and barrier identification and problem-solving (7/28, 25%) as somewhat bad or bad. Similarly, 76% (22/29) of the participants rated the overall system interface as easy to use (Table S4 in Multimedia Appendix 5). Participants spent an average of 16.5 (SD 11.2; range 3-60) minutes per day in using the system; 90% (26/29) of them reported that the system was worth the time they spent.

Outcome Evaluation

Primary Outcome

The median of the mean steps per day during P0b was >10,000 steps (Tables 2 and 3). They significantly increased at P1b compared with P0b (median +1493 steps per day; P<.001). However, the increase attenuated and did not remain significant under the significance level of this study at P2b (median +1056 steps per day; P=.04). Week 6 of the intervention period was during the end of the year, and P2b contained many Japanese national holidays, which may have changed participants' daily activities during those periods. Steps per day significantly increased when we compared P0b and week 5 only (median +1497 steps per day; P=.003) or weeks 21 to 22 (median +1005 steps per day; P=.008; Multimedia Appendix 6).

Owing to the high number of baseline steps, we conducted post hoc subgroup analyses to assess whether the increases in steps per day were significant in less-active participants, who were more consistent with the theoretical target population of

DialBetes Step (Tables S5 and S6 in Multimedia Appendix 5). Steps per day increased at P1b significantly only in the less-active group (median +1451; 95% CI +111 to +3220 steps per day; *P*=.005 vs median +1958; 95% CI −544 to +3055 steps per day; *P*=.05 in the more active group). Both groups did not significantly change steps per day at P2b.

Only 30% (9/30) of the participants were included in the comparison of steps per day between P0a and P0b. The median was 9578 (IQR 8433-10,326) steps per day at P0a and did not change until P0b (median +53 steps per day; *P*=.82).

Table 2. Short-term changes from P0[a] to P1[b] in outcome variables in the before-and-after study among workers with high BP[c] (n=30).

Variables	P0a[d], median (IQR)	P0b[e], median (IQR)	Changes from P0 to P1	
			Median (95% CI)	*P* value[f]
Physical activity				
Mean steps per day[g]	N/A[h]	10,020 (8548-11,519)	+1493 (+131 to +2584)	<.001
Mean calories burned by activity (kcal per day)[g]	N/A	265 (248-331)	+50 (+6 to +83)	<.001
Mean home BP (mm Hg)[g]				
Morning—systolic	N/A	131.1 (126.3-141.4)	−0.2 (−3.4 to +2.4)	.66
Morning—diastolic	N/A	89.7 (83.2-95.3)	−0.6 (−2.6 to +1.8)	.30
Night—systolic[i]	N/A	126.1 (119.1-136.4)	−3.1 (−6.2 to +2.7)	.23
Night—diastolic[i]	N/A	80.3 (77.3-84.5)	−1.2 (−5.0 to +1.1)	.44
Results of physical measurement[j]				
Body weight (kg)	66 (57.7-72.4)	N/A	−1.2 (−1.9 to −0.4)	<.001
BMI (kg/m^2)	23.7 (21.1-25.1)	N/A	−0.4 (−0.7 to −0.1)	<.001
Visceral fat area (cm^2)[k]	56.5 (46-88)	N/A	−1 (−8 to +3)	.18
Results of blood examination[l]				
Hemoglobin A_{1c} (%)	N/A	5.4 (5.1-5.5)	0 (0 to +0.1)	.94
Fasting blood glucose (mg/dL)	N/A	88 (82-92)	+0.5 (−1 to +2)	.38
Triglycerides (mg/dL)	N/A	104 (52-149)	−10 (−29 to +9)	.27
HDL[m] cholesterol (mg/dL)	N/A	63 (48.5-79)	+3.5 (+1 to +8)	<.001
Non-HDL cholesterol (mg/dL)	N/A	157.5 (129.5-189)	−3.5 (−18 to +6)	.20

[a]P0: baseline.

[b]P1: around week 6.

[c]BP: blood pressure.

[d]P0a: before the intervention.

[e]P0b: baseline system use period.

[f]Analyzed using Wilcoxon signed rank test.

[g]A participant who was hospitalized during week 5 was excluded (n=29).

[h]N/A: not applicable.

[i]A participant without measured data at P0b was excluded (n=28).

[j]Overall, 10% (3/30) of the participants were excluded—3% (1/30) did not take physical measurements, and the other 7% (2/30) had breakfast on the day of the measurement at P1 (n=27).

[k]An additional participant was excluded because of inability to use the abdominal belt owing to pain (n=26).

[l]Overall 7% (2/30) of the participants who did not take blood tests at P1 were excluded (n=28).

[m]HDL: high-density lipoprotein.

Table 3. Long-term changes from P0[a] to P2[b] in outcome variables in the before-and-after study among workers with high BP[c] (n=29).

Variables	P0a[d], median (IQR)	P0b[e], median (IQR)	Changes from P0 to P2 Median (95% CI)	*P* value[f]
Physical activity				
Mean steps per day[g]	N/A[h]	10,002 (8486-11,908)	+1056 (−651 to +2286)	.04
Mean calories burned by activity (kcal per day)[i]	N/A	264 (243-331)	+26 (−21 to +69)	.07
Mean home BP (mm Hg)[j]				
Morning—systolic[k]	N/A	132.3 (126.3-141.4)	−3.3 (−9.8 to +2)	.07
Morning—diastolic[k]	N/A	90.3 (82.3-95.3)	−1.6 (−6.2 to +0.1)	.02
Night—systolic[k,l]	N/A	125.5 (117-136)	−4.4 (−8.9 to +0.6)	.02
Night—diastolic[k,l]	N/A	79.6 (76.2-84.3)	−2.4 (−5.8 to −0.9)	<.001
Results of physical measurement[m]				
Body weight (kg)	66.8 (57.6-73.1)	N/A	−1.4 (−2.7 to −0.2)	.001
BMI (kg/m^2)	23.7 (21.1-25.2)	N/A	−0.5 (−1.2 to −0.1)	.001
Visceral fat area (cm^2)	56.5 (45-89)	N/A	−0.5 (−7 to +7)	.60
Results of blood examination[m]				
Hemoglobin A_{1c} (%)	N/A	5.4 (5.15-5.6)	+0.1 (0 to +0.1)	.22
Fasting blood glucose (mg/dL)	N/A	88 (84-92.5)	+2.5 (−1 to +6)	.16
Triglycerides (mg/dL)[n]	N/A	105 (59-144)	−13 (−30 to +5)	.50
HDL[o] cholesterol (mg/dL)[n]	N/A	63 (49-73)	+3 (0 to +7)	.23
Non-HDL cholesterol (mg/dL)[n]	N/A	158 (130-186)	−6 (−22 to +5)	.25

[a]P0: baseline.

[b]P2: the end of the intervention.

[c]BP: blood pressure.

[d]P0a: before the intervention.

[e]P0b: baseline system use period.

[f]Analyzed using Wilcoxon signed rank test.

[g]A participant without measured data at P2 owing to accelerometer trouble was excluded (n=28).

[h]N/A: not applicable.

[i]Overall, 7% (2/29) of the participants without measured or valid data at P2 owing to accelerometer trouble were excluded (n=27).

[j]A participant who intensified their antihypertensive treatment after P1 was excluded (n=28).

[k]Overall, 7% (2/28) and 4% (1/28) of the participants without measured data at P2 for morning and night, respectively, were excluded (n=26 for morning, n=27 for night).

[l]A participant without measured data at P0b was excluded (n=26).

[m]A participant was excluded because he had breakfast on the day of the measurement and blood tests at P2 (n=28).

[n]An additional participant who started taking a cholesterol medication after P1 was excluded (n=27).

[o]HDL: high-density lipoprotein.

Secondary Outcomes

As is the case with steps per day, calories burned by activity per day significantly increased only at P1b compared with P0b (Tables 2 and 3). Home BP did not change significantly between P0b and P1b (all *P*>.025); however, it decreased significantly at P2b (all *P*<.025), except for systolic BP in the morning (*P*=.07). Overall, 7% (2/29) of the participants reported decrease in the dose of antihypertensive medications during system use. Body weight and BMI decreased significantly at both P1a (*P*<.001) and P2a (*P*=.001) compared with that at P0a; however, VFA did not change significantly over time (both *P*>.025). The median percentage decrease in body weight was 1.8% at P1a and 2.1% at P2a. For metabolic outcomes, HDL cholesterol increased significantly at P1a compared with that at P0b

(*P*<.001); however, the change from P0b to P2a was not significant (*P*=.23).

The median score of goal-related self-efficacy was 72.5% at P0a (Table 4); the baseline score of 21% (6/29) of the participants was 100%. Although it did not change between P0a and P1a, it tended to increase at P2a compared with that at P0a (*P*=.05), but this was not statistically significant. Self-efficacy in walking behavior did not change over time. The total score of self-regulation and scores for self-monitoring, goal setting, reinforcements, and time management significantly increased at both P1a and P2a (all *P*<.025); the score for relapse prevention significantly increased only at P2a (*P*=.02). Scores for most of the factors of self-management behavior significantly increased at both P1a and P2a, except for selecting a suitable place or time for physical activities and creating situations to enhance active behavior. Items in "exercising to stimulate the enjoyment of eating" are not recommended behaviors; however, the corresponding score significantly increased at P1a (*P*=.005).

Table 4. Changes in antecedent factors of physical activity in the before-and-after study among workers with high blood pressure (n=29).[a]

Variables	P0a[b], median (IQR)	Changes from P0a to P1a[c]		Changes from P0a to P2a[d]	
		Median (95% CI)	*P* value[e]	Median (95% CI)	*P* value[e]
Self-efficacy					
Goal-related self-efficacy (%)[f]	72.5 (63.8-92.5)	0 (−7.5 to +12.5)	.38	+5 (−5 to +15)	.05
Self-efficacy in walking behavior[g]	11 (8-16)	0 (−2 to +2)	.68	0 (−2 to +3)	.48
Self-regulation[h]					
Total score	20 (16-25)	+5 (+2 to +10)	<.001	+4 (+3 to +13)	<.001
Self-monitoring	4 (2-5)	+2 (+1 to +3)	<.001	+1 (+1 to +2)	<.001
Goal setting	4 (2-4)	+1 (0 to +2)	.002	+2 (+1 to +3)	<.001
Eliciting social support	2 (2-2)	0 (0 to 0)	.09	0 (0 to 0)	.14
Reinforcements	5 (4-6)	+1 (0 to +2)	.005	+1 (+1 to +2)	<.001
Time management	4 (2-5)	+1 (0 to +2)	<.001	0 (0 to +2)	.007
Relapse prevention	2 (2-4)	0 (0 to +2)	.11	0 (0 to +2)	.02
Self-management behavior related to physical activity (range)[i]					
Shopping (0-16)	1 (0-5)	+2 (+1 to +4)	<.001	+2 (0 to +4)	<.001
Household activities (0-16)	4 (0-6)	+1 (0 to +3)	.006	+1 (0 to +4)	<.001
Exertion (0-16)	7 (5-9)	+2 (0 to +3)	.002	+1 (+1 to +3)	.004
Commuting activities (0-16)	6 (4-8)	+2 (+1 to +4)	<.001	+2 (+1 to +4)	<.001
Suitable place or time (0-20)	8 (6-10)	+1 (0 to +3)	.18	+1 (−1 to +4)	.05
Self-monitoring (0-12)	0 (0-5)	+7 (+5 to +10)	<.001	+4 (+2 to +7)	<.001
Making a habit (0-12)	2 (0-5)	+2 (+1 to +4)	.001	+1 (0 to +2)	.007
Exercising for eating (0-8)	1 (0-3)	0 (0 to +1)	.005	0 (0 to +1)	.18
Creating situation (0-12)	2 (0-4)	+1 (0 to +2)	.07	+1 (0 to +3)	.002

[a]A participant who did not respond to the questionnaire at P1a was excluded (n=29).

[b]P0a: before the intervention.

[c]P1a: after 6 weeks of the intervention period.

[d]P2a: after the intervention.

[e]Analyzed using Wilcoxon signed rank test.

[f]Average of the self-efficacy in achieving 4 incremental step goals (6000; 8000; 10,000; and 12,000 steps per day; range 0-100). A participant with an invalid response at P0a was excluded (n=28).

[g]Measured using the self-efficacy scale for walking behavior (range 4-20). High score indicates high self-efficacy.

[h]Measured using the Japanese version of the 12-item Physical Activity Self-Regulation scale (range 2-10 for each factor and range 12-60 for the total score). High score indicates high frequency of self-regulation.

[i]Measured using the evaluation scale for self-management behavior related to physical activity of type 2 diabetic patients. High score indicates high frequency of self-management behavior.

Adverse Events

The score of the body pain cluster did not change over time (Table S7 in Multimedia Appendix 5). The item score of lower limb pain (Table S8 in Multimedia Appendix 5) increased by at least one point in 21% (7/33) of the participants at P1a and 19% (6/31) of the participants at P2a. A participant's item score was 3 points ("considerable pain") at P1a and P2a (+1 point from P0a). She took >15,000 steps per day during P0b and further increased the steps per day at P1b.

A participant reported daytime sleepiness (at P1a and P2a) and dizziness upon standing (at P1a) as negative changes in their condition during system use. He attributed these symptoms to his short sleeping hours. His home BP did not change between P0b and P1b. In contrast, 15% (5/33) and 16% (5/31) of the participants at each time point, respectively, reported positive changes, such as their body feeling light.

Discussion

Principal Findings

We evaluated the preliminary efficacy, feasibility, and perceived usefulness of the intervention using DialBetes Step, a novel smartphone-based self-management system with personalized goal-setting and feedback functions and information delivery functions designed to increase step count among workers with high BP. Participants rarely missed the measurement and recording of data, and there was a low level of attrition. Despite frequent problems with measurement and recording, the system's interface was rated as easier to use than that of the original DialBeticsLite [15]. Participants increased their mean steps per day along with engaging more frequently in self-regulation and self-management behaviors related to physical activity. Although the increase in steps per day attenuated at P2b, BP and body weight decreased by the end of the study. Intervention using DialBetes Step may be useful in increasing the step count for a short period and improving cardiovascular risk.

After using the new functions in DialBetes Step, most participants increased their step count by >1000 steps per day, an expected clinically meaningful change [51,63] at both P1b and P2b. Previous reviews suggested significant effects of activity trackers on step count and body weight, with moderate certainty of evidence [80]. The median increases in this study were less than those measured in behavior modification interventions using pedometers (approximately 2000-2500 steps per day on average) [63]. Previous studies showed negative correlation between the increase in steps per day and baseline steps [81,82]. Participants in our study were considered to be physically active [63] at P0, and the post hoc subgroup analyses supported these previous findings. Thus, their potential to increase physical activity may have been lower than that of sedentary people. Similarly, physical activity and daily step count have seasonal variation, in that they tend to decrease in winter [83]. Therefore, the increase from P0b (early November) to P1b (late December) in this study is likely to be more meaningful than the observed value.

Home BP decreased significantly only at P2b. BP is also subject to seasonal variation, as it is highest in winter (middle to late January in Japan) and lowest in summer [84]; the observed changes in home BP in P1b might be underestimated. Of the other biomedical outcomes, body weight, BMI, and HDL cholesterol level improved significantly, even though the median values at P0 were within the normal range. These improvements were almost the same as or better than previous pedometer-based interventions in which participants increased their step count by 2183 steps per day and decreased systolic BP by 3.8 mm Hg, diastolic BP by 0.3 mm Hg, and BMI by 0.38 kg/m^2 from baseline on average [81]. Most of the meta-analyses have reported no statistically significant effect of walking on HDL cholesterol [81,85-87]. The improvement in biomedical outcomes in this study could be associated not only with the increase in physical activity but also with changes in diet.

Most aspects of self-regulation were enhanced both at P1a and P2a. It is possible that enhancement of self-regulation itself, rather than the mediating effect of self-efficacy, may have led to an increase in step count. Factors of the 12-item Physical Activity Self-Regulation scale, except social support, correspond with each function of DialBetes Step; for example, functions of positive feedback, action planning, and barrier identification and problem-solving were targeted for reinforcements, time management, and relapse prevention, respectively. Previous reviews revealed that interventions with a goal-setting component had large effects on physical activity [70,81,88]. Although it is difficult to identify the active components of such a complex intervention [17], our results including the subjective usefulness of each function suggest that goal setting [89], weekly feedback [90], and self-monitoring [31,89] were useful in increasing step count.

Despite the significant increase in steps per day in the short-term analysis, attenuation was observed at P2b. Even in weeks 21 to 22 before the long holidays, in which the increase was statistically significant, the median change from P0b was less than that during P1b. Previous studies often reported a trend toward a slight decrease in step count after the peak around the second or third month of interventions [66,91-94]. Self-efficacy is reported to be a mediator for the effects of interventions on physical activity [31], including future habituation [43]. Our participants' inability to maintain the increase in step count may be attributed to the insufficient improvement in self-efficacy. Action planning is reported to be significantly associated with positive changes in self-efficacy [95,96]; however, our participants' rating of action planning was relatively low. Moreover, interventions providing vicarious experience and feedback by comparison with others' performance and the user's past performance produced large effects on self-efficacy [30]. It will be necessary to improve the action planning function and add social functions in future versions of the system to enhance users' self-efficacy.

The results of adverse event assessment suggest a need for some other improvement in the system. Despite no apparent adverse effects caused by using DialBetes Step, a participant experienced considerable pain in their lower limbs. Countermeasures against the worsening of body pain should be implemented, such as

periodic pain assessment and advising against increase in physical activity when necessary. Another participant's symptoms caused by insufficient sleep indicated that the system use was a burden on busy workers. The mean time spent in using the system in this study was not different from that in our previous study of the original DialBeticsLite [15]; participants used most of their time for measurement and recording; therefore, we should try shortening that time by using easy recording platforms and minimizing difficulties.

To the best of our knowledge, there are few SCT-based mobile apps designed to promote physical activity. We developed original goal-setting algorithms that intended to enhance users' self-efficacy by automatically suggesting incremental goals tailored for each user. Our future exploration of the participants' goal-setting processes might add new findings to the currently limited evidence of appropriate step goals [97].

Limitations

This study has some limitations. First, participants in this study were not consistent with the initially defined theoretical target population of DialBetes Step. Despite an entry criterion of "not walking enough in general," most participants (21/30, 70%) had already reached the national goal of steps per day [10] at P0b. Although their self-reported frequencies of self-regulation at P0a were lower than those of general workers across Japan [76], they may have been physically active because of their workplace and commuting environment where workers have many opportunities to walk (ie, department store in metropolitan Tokyo). Goal-related self-efficacy at P0a was also high; therefore, the changes might have been underestimated because of the ceiling effect. Although the post hoc subgroup analyses suggested that less-active participants were more likely to increase their steps per day for a short period, subsequent studies should evaluate the effects of the system in sedentary people.

Second, the results of outcome evaluation might be biased for various reasons. First, a few participants were lost to follow-up or those without data were excluded from analyses. As a previous review attributed the risk of bias partly to high levels of attrition [98], we should consider a possibility that the positive results were overestimated because the excluded participants were likely to have low adherence to the intervention. Nevertheless, we had a low level of attrition than previous interventions [98], which is a strength of this study. Second, measuring each outcome variable at a slightly different point in time made it difficult to interpret the results. For example, we had 2 time points (P0a or P0b) for baseline data collection; however, we asked participants not to change their behavior, and their steps per day did not change during P0b. We should note that the participants' status would be different, even in the same period of outcome evaluation. Third, the intervention included not only mHealth system use but also face-to-face group sessions, which increased participants' commitment to and utility of human resources in health care. This might limit the generalizability and scalability of the intervention.

Third, there might have been measurement errors in the accelerometer used in this study, which was reported to be less accurate in counting the number of steps than other frequently used pedometers and accelerometers in research settings [99]. The accuracy of the accelerometer had been examined only under controlled conditions using a treadmill at speeds between 70 and 120 m/min, not in uncontrolled environments [67]. The accelerometer might not have counted an irregular gait in daily activities precisely and might have counted hand movement as steps.

Finally, we could not assess the change in the intensity of walking. The intensity of physical activity is just as important as the amount [100,101]. Physical activity and clinical guidelines recommend moderate-intensity activity, such as moderate walking [6,102]. In the future, a function to record the parameters of walking intensity should be added for a more comprehensive assessment of physical activity.

Conclusions

The intervention using DialBetes Step may be feasible and useful for increasing workers' step count through self-regulation enhancement for a short period and, consequently, improving their BP and BMI. However, without significant change in self-efficacy, the increase in steps per day attenuated at the end of 24-week intervention. Future studies should improve the system with more self-efficacy–enhancing techniques and evaluate the effectiveness of the SCT-based new functions through a randomized controlled trial.

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Data Availability

The data sets generated and analyzed during this study are not publicly available because we did not obtain consent from participants for data sharing. They will be available from the corresponding author upon reasonable request and after approval by the research ethics committee.

Authors' Contributions

TS created the new functions, tested the new system, designed the feasibility study, provided the intervention, collected and analyzed the data, and wrote the manuscript. KW discussed the new functions, designed and supervised the feasibility study, and recruited some participants. KM reviewed the contents of the new functions and collected data. AI and NYM tested the new system and advised about the study design and analyses. YT provided advice on statistical analyses. AS, MS, TY, MN, and KO contributed to the discussion. All authors reviewed the manuscript and approved the final version of the manuscript.

Conflicts of Interest

KW and KM were members of the Department of Ubiquitous Health Informatics when this study was conducted. TS was a fellow and YT was an assistant professor of the Graduate Program for Social ICT Global Creative Leaders when this study was conducted. KW is an industrial physician at Tokyu Department Store Health Insurance Society. YT has received consultant fees from EPARK, Inc and lecture fees from SAS Institute Japan Ltd.

Multimedia Appendix 1
Outline of behavior change techniques used in the intervention.
[DOCX File , 32 KB - cardio_v7i1e43940_app1.docx]

Multimedia Appendix 2
Lists of actions for increasing step count, current and future barriers to walking, and possible solutions for each barrier provided by DialBetes Step.
[DOCX File , 24 KB - cardio_v7i1e43940_app2.docx]

Multimedia Appendix 3
Flowchart of deciding the frequency of blood glucose level measurements.
[PPTX File , 48 KB - cardio_v7i1e43940_app3.pptx]

Multimedia Appendix 4
Detailed information about measuring instruments and scales used in the study.
[DOCX File , 22 KB - cardio_v7i1e43940_app4.docx]

Multimedia Appendix 5
Supplementary tables about the results of the study.
[DOCX File , 43 KB - cardio_v7i1e43940_app5.docx]

Multimedia Appendix 6
Distribution of changes in the mean steps per day from the baseline system use period.
[PNG File , 15 KB - cardio_v7i1e43940_app6.png]

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Abbreviations

BP: blood pressure
CVD: cardiovascular disease
ES-SMBPA-2D: evaluation scale for self-management behavior related to physical activity of type 2 diabetic patients
HDL: high-density lipoprotein
mHealth: mobile health
P0: baseline
P0a: before the intervention
P0b: baseline system use period
P1: around week 6
P1a: after 6 weeks of the intervention period
P1b: weeks 5 to 6
P2: the end of the intervention
P2a: after the intervention
P2b: weeks 23 to 24
SCT: Social Cognitive Theory

VFA: visceral fat area

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Original Paper

Evaluation of Machine Learning Approaches for Predicting Warfarin Discharge Dose in Cardiac Surgery Patients: Retrospective Algorithm Development and Validation Study

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Abstract

Background: Warfarin dosing in cardiac surgery patients is complicated by a heightened sensitivity to the drug, predisposing patients to adverse events. Predictive algorithms are therefore needed to guide warfarin dosing in cardiac surgery patients.

Objective: This study aimed to develop and validate an algorithm for predicting the warfarin dose needed to attain a therapeutic international normalized ratio (INR) at the time of discharge in cardiac surgery patients.

Methods: We abstracted variables influencing warfarin dosage from the records of 1031 encounters initiating warfarin between April 1, 2011, and November 29, 2019, at St Michael's Hospital in Toronto, Ontario, Canada. We compared the performance of penalized linear regression, k-nearest neighbors, random forest regression, gradient boosting, multivariate adaptive regression splines, and an ensemble model combining the predictions of the 5 regression models. We developed and validated separate models for predicting the warfarin dose required for achieving a discharge INR of 2.0-3.0 in patients undergoing all forms of cardiac surgery except mechanical mitral valve replacement and a discharge INR of 2.5-3.5 in patients receiving a mechanical mitral valve replacement. For the former, we selected 80% of encounters (n=780) who had initiated warfarin during their hospital admission and had achieved a target INR of 2.0-3.0 at the time of discharge as the training cohort. Following 10-fold cross-validation, model accuracy was evaluated in a test cohort comprised solely of cardiac surgery patients. For patients requiring a target INR of 2.5-3.5 (n=165), we used leave-p-out cross-validation (p=3 observations) to estimate model performance. For each approach, we determined the mean absolute error (MAE) and the proportion of predictions within 20% of the true warfarin dose. We retrospectively evaluated the best-performing algorithm in clinical practice by comparing the proportion of cardiovascular surgery patients discharged with a therapeutic INR before (April 2011 and July 2019) and following (September 2021 and May 2, 2022) its implementation in routine care.

Results: Random forest regression was the best-performing model for patients with a target INR of 2.0-3.0, an MAE of 1.13 mg, and 39.5% of predictions of falling within 20% of the actual therapeutic discharge dose. For patients with a target INR of 2.5-3.5, the ensemble model performed best, with an MAE of 1.11 mg and 43.6% of predictions being within 20% of the actual therapeutic discharge dose. The proportion of cardiovascular surgery patients discharged with a therapeutic INR before and following implementation of these algorithms in clinical practice was 47.5% (305/641) and 61.1% (11/18), respectively.

Conclusions: Machine learning algorithms based on routinely available clinical data can help guide initial warfarin dosing in cardiac surgery patients and optimize the postsurgical anticoagulation of these patients.

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KEYWORDS

algorithm; anticlotting; anticoagulant; anticoagulation; blood thinner; cardiac; cardiology; develop; dosage; international normalized ratio; machine learning; medical informatics; pharmacology; postoperative; predict; prescribe; prescription; surgery; surgical; validate; validation; warfarin administration and dosage; warfarin

Introduction

Warfarin is a commonly prescribed oral anticoagulant for patients who have undergone cardiac surgery and remains the only guideline-endorsed anticoagulant for patients with mechanical heart valves. However, considerable interindividual variability exists in the response to warfarin, with patient age, BMI, concomitant medications, and genetic status imparting considerable influence on warfarin maintenance dose requirements [1-5]. Complicating matters in cardiac surgery patients is an exaggerated sensitivity to the effects of warfarin in the immediate postoperative period, predisposing individuals to supratherapeutic international normalized ratio (INR) values and bleeding [3,6,7]. Consequently, close monitoring and frequent dosage adjustments are needed to optimize warfarin therapy and prevent thromboembolic events and bleeding in these patients [8].

Warfarin dosing prediction algorithms are commonly used by clinicians to optimize treatment and reduce the unpredictability of warfarin responses [9,10]. Recently, machine learning methods have been used for developing and validating algorithms that leverage patient information to guide warfarin dosing and facilitate individualized treatment [11-16]. A systematic review of 266 studies describing 433 warfarin dosing algorithms found that most algorithms were derived using both clinical and genetic variables (344/433, 79.4%), emphasized dose initiation (373/433, 86.1%) rather than discharge or maintenance doses, and presented a regression formula that could be used to compute a weekly or daily dose (239/433, 55.2%) [17]. The most commonly reported outcomes were the mean absolute and mean prediction errors, with few algorithms undergoing external validation or clinical utility assessment to gauge their performance in a clinical setting relative to clinicians. Moreover, the majority (280/433, 64.7%) of algorithms were developed using linear regression and may therefore not accurately characterize the complex relationships between warfarin dosing and patient features [17].

Considering the complex relationship between warfarin and patient characteristics, predictive dosing algorithms have been developed using machine learning methods that can more readily accommodate nonlinear relationships and interactions between features. A recent systematic review summarized the characteristics and quality of 23 studies investigating nonlinear machine learning algorithms for warfarin dose prediction [13]. Most (78%) of the studies were conducted in Asia or at sites associated with the International Warfarin Pharmacogenetics Consortium, with China being the most represented single country among the included studies (9/23, 39%). The most common demographic and clinical predictors were age (21/23, 91%), weight (17/23, 74%), height (12/23, 52%), and concomitant administration of amiodarone (11/23, 48%), while CYP2C9 (14/23, 61%), VKORC1 (14/23, 61%), and CYP4F2 (5/23, 22%) were the most common genetic predictors. The most reported outcome measures were the mean absolute error (MAE) and whether the predicted dose was within 20% of the actual dose, derived in 91% (21/23) and 83% (19/23) of studies, respectively. The majority (16/23, 70%) of studies focused on model development with internal validation only. In addition, the studies were found to be at high risk of bias, with poor handling of missing data (20/23, 87%) and a small sample size (15/23, 65%) being the factors most commonly contributing to bias.

Recent studies have evaluated more advanced methods for guiding warfarin dosing in cardiac surgery patients. Specifically, a study of 13,639 eligible patients identified in the Chinese Low Intensity Anticoagulant Therapy after Heart Valve Replacement database compared the performance of a previously described 3-layer Back Propagation Neural Network (BPNN) model with multiple linear regression for predicting the warfarin maintenance dose in patients undergoing heart valve replacement [14,15]. Results demonstrated a slightly improved performance for the BPNN model, with a MAE in the external validation group of 0.740 (95% CI 0.671-0.810) compared with 0.750 (95% CI 0.673-0.814) with multiple linear regression [14]. The percentage of patients in the external validation group whose predicted absolute error between the predicted and actual doses was within 20% of the actual dose was also slightly better with the BPNN algorithm (59.7%) compared with multiple linear regression (56.6%).

A recent study has also examined the potential for reinforcement learning in predicting the daily warfarin dose required for patients undergoing surgical valve replacement [18]. The study was conducted in China and involved 10,408 patients, partitioned into training (n=8216), validation (n=932), and test (n=1260) data sets. The primary outcome was the proportion of patients in the test data set categorized as excellent responders, defined as the absence of an INR >3.0 during the entire postoperative stay and having a discharge INR within the target range of 1.8-2.5. The individual components of the primary outcome, defined as the proportion of test patients who were safety responders (ie, no INRs >3.0 after warfarin initiation) and target responders (ie, discharge INR within 1.8-2.5), were examined in secondary analyses. Comparisons were made between the reinforcement learning algorithm, clinician practice, and other machine learning algorithms. Overall, the reinforcement learning algorithm outperformed clinician practice with respect to the proportion of the test set patients being excellent responders (80.8% vs 41.6%; P<.001). For the secondary outcomes, the safety responder ratio (RR; 83.1% vs 99.5%; RR 0.83, 95% CI 0.81-0.86; P<.001) and the target responder ratio (49.7% vs 81.1%; RR 0.61, 95% CI 0.58-0.65; P<.001) were lower for clinicians relative to the reinforcement learning algorithm. Similarly, performance for all outcomes was significantly better with the reinforcement learning algorithm relative to other machine learning approaches. This study therefore demonstrated the potential for

applying reinforcement learning to improve outcomes in patients undergoing cardiac surgery who are treated with warfarin. However, the generalizability of these findings to other settings may be limited by the generally lower anticoagulation intensity examined in this study relative to clinical practice in Western countries.

Our center, St Michael's Hospital, is a large, inner-city academic hospital in Toronto, Ontario, Canada, that performs over 1000 cardiac surgeries per year. Pharmacists and clinicians caring for cardiac surgery patients identified challenges discharging warfarin-treated patients with a therapeutic INR as a problem potentially amenable to machine learning-based solutions for the hospital health care analytics team. However, generalizing the findings from existing literature to our setting and patient population was considered infeasible and inappropriate for several reasons. First, St Michael's Hospital treats a diverse inner-city population that was not reflected in the studies conducted to date, with most algorithms developed and validated in predominantly Asian and White populations [13,17]. Second, the clinical utility of many algorithms, particularly in cardiac surgery patients, has not been evaluated. It is therefore unclear how these algorithms compare to existing clinical practice [13]. Third, many algorithms rely on the use of pharmacogenetic information that is not readily available in most clinical settings, including ours [16,19]. In addition, although neural networks and reinforcement learning are promising approaches for predicting warfarin dose in cardiac surgery patients, the large sample sizes required for their derivation and validation were prohibitive at our site. There was therefore a need to develop an algorithm using routinely available patient data that respected our data limitations and allowed for more complex relationships between patient variables and warfarin dose. Considering these needs, we developed and validated algorithms for predicting the warfarin dose required to attain a therapeutic INR at the time of discharge among patients who have undergone cardiac surgery using commonly available clinical and demographic data.

Methods

Setting

We conducted a retrospective algorithm development and validation study using the data of all patients initiating warfarin during a hospital admission at St Michael's Hospital between April 1, 2011, and November 29, 2019. Warfarin dosing in cardiac surgery patients at St Michael's Hospital is led primarily by team pharmacists under a medical directive. The study was undertaken as a collaboration between clinical staff and the data scientists of the Data Science and Advanced Analytics team, a service-based–health care analytics group at St Michael's Hospital with expertise in machine learning.

Data Sources

We used the St Michael's Hospital Enterprise Data Warehouse (EDW), which integrates and stores structured and unstructured data at the patient level from several hospital electronic databases, including inpatient and outpatient electronic medical charts, inpatient pharmacy records, and results of laboratory and medical imaging investigations [20]. The EDW is updated daily using automated algorithms that abstract, clean, and link data from separate hospital sources using a patient's unique medical record number.

Study Population and Outcomes

Our base population included all patients newly initiating warfarin during the course of hospital admission between April 1, 2011, and November 29, 2019, regardless of indication. From within this cohort, we included individuals administered warfarin and undergoing INR testing on at least three separate occasions during a 7-day period. Next, we excluded individuals admitted for palliative care and those who died during their admission, patients transferring to and from the mental health inpatient unit during their admission, and individuals with discharge dispositions undermining outcome ascertainment, including leaving against medical advice and not returning to the hospital following an authorized pass. Finally, we retained only those individuals discharged with a therapeutic INR, defined in this study as ranging from 2.5 to 3.5 for patients receiving mechanical heart valves and from 2.0 to 3.0 for all other patients [21].

Outcome Measures and Features

Our primary outcome was the warfarin dose needed to attain a therapeutic INR at the time of discharge following cardiovascular surgery. The specific procedures included mechanical mitral valve surgery (target INR 2.5-3.5), mechanic aortic valve surgery (target INR 2.0-3.0), prosthetic or tissue mitral or tricuspid valve surgery (target INR 2.0-3.0), and new-onset atrial fibrillation of more than 48 hours duration following aortic surgery or coronary bypass surgery (target INR 2.0-3.0), with target INRs based on clinical practice guidelines [22-24]. We identified demographic and clinical determinants of the final warfarin dose from past research and consultation with experts and included those variables that could be abstracted from patient records as features in our predictive models (Textbox 1). To account for heterogeneity in warfarin sensitivity and dosing requirements, we also included the change in INR and warfarin dose from their immediately preceding values, as well as multiplications of the warfarin dose and its subsequent INR measurement, as model features.

Textbox 1. Model features and descriptions.

Model features and descriptions:

- Warfarin 1: First postoperative warfarin dose (mg/day)
- Warfarin 2: Second postoperative warfarin dose (mg/day)
- Warfarin 3: Third postoperative warfarin dose (mg/day)
- Warfarin difference 1: The absolute difference between the 1st and 2nd warfarin doses
- Warfarin difference 2: The absolute difference between the 2nd and 3rd warfarin doses
- Warfarin difference 3: The absolute difference between the 1st and 3rd warfarin doses
- International normalized ratio (INR) 1: First postoperative INR measurement following warfarin administration.
- INR 2: Second postoperative INR measurement following warfarin administration.
- INR 3: Third postoperative INR measurement following warfarin administration.
- INR difference 1: The absolute difference between the 1st and 2nd INR measurements.
- INR difference 2: The absolute difference between the 2nd and 3rd INR measurements.
- INR difference 3: The absolute difference between the 1st and 3rd INR measurements.
- Times 1: The multiplication of Warfarin 1 and INR 1
- Times 2: The multiplication of Warfarin 2 and INR 2
- Times 3: The multiplication of Warfarin 3 and INR 3
- Sex: Patient's sex.
- Age: Patient's age at time of admission.
- Indication: Binary indicators for one of the following procedure types that the patient received: cardiac valve replacement, cardiac valve replacement except percutaneous transluminal approach, coronary artery bypass graft, and others.
- Comorbidities: Binary indicators for the presence of any of the following comorbidities: myocardial infarction (MI), peripheral vascular disorders (PVD), congestive heart failure (CHF), rheumatic heart disease, diabetes, renal disease, peptic ulcer disease (PUD), HIV, and stroke.
- Medication groups: Binary indicators for the presence of any of the following medication groups: aspirin, clopidogrel, ticagrelor, amiodarone, fibrates, nonsteroidal anti-inflammatory drugs (NSAIDs), selective serotonin reuptake inhibitor (SSRIs), phenytoin, carbamazepine, fluconazole, fluoroquinolones, metronidazole, rifampin, and trimethoprim-sulfamethoxazole.

Statistical Models

We compared the performance of 5 different models to predict the warfarin dose required to attain discharge INRs of 2.0-3.0 and 2.5-3.5. Specifically, we examined penalized linear regression, k-nearest neighbors (kNN), random forest regression, gradient boosting, and multivariate adaptive regression splines (MARS). Penalized linear regression is an extension of ordinary least squares that includes a regularization constraint in the model to shrink coefficient values toward zero relative to the least squares estimates [25,26]. Random forest regression is an ensemble of independent decision trees created by using random bootstrap samples of the training observations and random subsets of the candidate variables in each split of the tree [27,28]. The final prediction is obtained by calculating the mean of the predictions from the individual trees comprising the forest. In contrast to random forest, which is an ensemble of independent trees, gradient boosting involves the stepwise construction of many small regression trees from the pseudoresiduals of previous trees [25,29,30]. MARS is a nonparametric modeling method that avoids the questionable linearity assumption of regular linear regression. Specifically, MARS approximates the nonlinear relationship between response and predictor variables by fitting the data into piecewise linear regression functions [31]. kNN regression is a nonparametric algorithm that makes predictions by averaging the outcomes of the observations most similar to the target, weighted by the inverse of their distance [25]. We also determined the performance of an ensemble model combining the predictions of the 5 regression models. For each model, we used grid search to tune hyperparameters, trying multiple parameter settings over a predefined range of values and selecting the values of each hyperparameter providing the best prediction (Table S1 in Multimedia Appendix 1). We also used cross-validation to estimate model performance and generalizability with unseen data. In this study, we used 2 distinct cross-validation strategies tailored to the characteristics of our patient groups. For patients within the target INR range of 2.0-3.0, we implemented a 10-fold cross-validation approach. This method divides the data into 10 subsets, or "folds," and iteratively uses 9 folds for training and 1 fold for validation, ensuring comprehensive model assessment while mitigating overfitting by repeating this process 10 times with different validation sets. This approach was selected for its balance between robustness and computational efficiency. Conversely, for patients with a target INR of 2.5-3.5, who were characterized by a notably limited data set, we adopted leave-p-out cross-validation with p=3 to ensure even splits of the 165 observations. Leave-p-out cross-validation is particularly advantageous in scenarios with limited data, as it systematically

excludes p data points at a time, creating multiple validation sets. This approach was crucial because the small size of the data set made it impractical to create a separate testing set, thus allowing us to make the most of the available data while achieving reliable results.

We quantified model performance using the MAE, defined as the absolute value of the difference between the true and predicted doses of warfarin required to attain the required discharge INR. A predicted dose within 1 mg of the predicted dose is considered a reasonable measure of predictive ability [32]. We also determined the proportion of predictions within 20% of the true warfarin dose. We selected these measures because they are commonly used in studies of warfarin dosing algorithms, thereby allowing us to facilitate a comparison with past research [13,17,33,34]. In addition, we compared our findings with clinical algorithms developed by Gage and colleagues [33] and the International Warfarin Pharmacogenetics Consortium [34]. We specifically chose these algorithms because they are among the most externally validated and clinically assessed algorithms. Moreover, the Gage algorithm has been operationalized as a freely available web-based calculator [35] that is commonly used for estimating warfarin doses in various clinical settings, including heart valve replacement. Because of the skewed distribution of warfarin doses, we replicated our analyses using a logarithmic transformation of the warfarin dose and compared these findings with those generated by models predicting the untransformed dose.

Model Creation

Because the intensity of postsurgical anticoagulation required for a given patient is determined by the nature of cardiac surgery performed, we developed and validated separate models for predicting the warfarin dose required for achieving a discharge INR of 2.0-3.0 in patients undergoing all forms of cardiac surgery other than mechanical mitral valve replacement (ie, prosthetic tissue valve replacement, postsurgical atrial fibrillation, and mechanical aortic valve replacement) and a discharge INR of 2.5-3.5 in patients receiving a mechanical mitral valve replacement.

We selected 80% of encounters (n=780) who had initiated warfarin during their hospital admission and had achieved a target INR of 2.0-3.0 at the time of discharge as the training cohort. Following 10-fold cross-validation, model accuracy was evaluated in the test cohort, comprising the remaining 20% (n=195) of patients. To ensure we had an adequate number of patients for model training, we included patients initiating warfarin for reasons unrelated to cardiac surgery (eg, thromboembolic disease) in the training cohort. This approach is similar to that of past studies developing warfarin dosing algorithms for a specific target INR, with subsequent dosing tools based on these algorithms incorporating clinical indication as one of several variables for predicting a warfarin dose [13,17,33,34]. However, because our primary motivation was to determine a tool that could guide warfarin dosing specifically in cardiac surgery patients, our test cohort consisted solely of cardiac surgery patients, thereby ensuring that the performance of the final model would be determined with the target study population. The cardiac surgery patient cohort was defined as any patient whose service was cardiovascular surgery or patients with the following procedures: cardiac valve replacement, cardiac valve repair, or coronary artery bypass graft (Table 1). The model with the lowest MAE in the test cohort was selected as the final model for predicting the stable warfarin dose needed to attain a discharge INR of 2.0-3.0.

Because cardiac surgery patients requiring a target INR of 2.5-3.5 represent those individuals requiring a mechanical mitral valve replacement, we did not include noncardiac surgery patients in this data set, resulting in a smaller sample of 165 patients for model training and validation. These 165 patients all had cardiac valve replacements. Consequently, rather than partitioning the data into 2 separate training and test sets, we used leave-p-out cross-validation, where p=3 observations, to estimate model performance. Figure 1 outlines the study cohort, data splits, and validation strategies.

Table 1. Characteristics of encounters initiating warfarin while hospitalized between April 1, 2011, and November 29, 2019.

Characteristics	INR[a] 2.0-3.0		INR 2.5-3.5
	Training and validation (n=780)	Testing (n=195)	Training and validation (n=165)
Age (years), median (IQR)	67 (56-78)	67 (58.5-76)	65 (55-75)
Sex (male), n (%)	466 (59.7)	125 (64.1)	98 (59.4)
Procedure, n (%)			
Cardiac valve replacement	156 (20)	122 (62.6)	165 (100)
Cardiac valve repair[b]	21 (2.7)	18 (9.2)	0 (0)
Coronary artery bypass graft (new onset atrial fibrillation)	41 (5.3)	40 (20.5)	0 (0)
Other[c]	562 (72.1)	15 (7.7)	0 (0)
Service[d], n (%)			
Cardiovascular surgery	120 (15.4)	195 (100)	110 (66.7)
Cardiology	144 (18.5)	0 (0)	32 (19.4)
Intensive coronary care	59 (7.6)	0 (0)	12 (7.3)
Intensive care cardiovascular	16 (2.1)	0 (0)	10 (<6.1)
Other[e]	441 (56.5)	0 (0)	10 (<6.1)
Potentially interacting medications, n (%)			
Amiodarone	230 (29.5)	121 (62.1)	105 (63.6)
Fluoroquinolones	164 (21)	35 (17.9)	26 (15.8)
Clopidogrel	97 (12.4)	14 (7.2)	16 (9.7)
Trimethoprim/sulfamethoxazole	52 (6.7)	6 (3.1)	5 (3)
Phenytoin	49 (6.3)	13 (6.7)	6 (3.6)
Metronidazole	47 (6)	<5 (<2.6)	<5 (<3)
Fluconazole	16 (2.1)	<5 (<2.6)	<5 (<3)
Ticagrelor	15 (1.5)	0 (0)	<5 (<3)
Fibrates	7 (0.9)	<5 (<2.6)	<5 (<3)
Rifampin	6 (0.8)	<5 (<2.6)	0 (0)
Carbamazepine	<5 (<0.6)	0 (0)	0 (0)
Aspirin	<5 (<0.6)	<5 (<2.6)	<5 (<3)
Comorbidities, n (%)			
Congestive heart failure	310 (39.7)	59 (30.3)	62 (37.6)
Stroke	123 (15.8)	16 (8.2)	17 (10.3)
Myocardial infarction	121 (15.5)	22 (11.3)	15 (9.1)
Peripheral vascular disorders	95 (12.2)	21 (10.8)	26 (15.8)
Renal disease	134 (17.2)	16 (8.2)	15 (9.1)
Rheumatic heart disease	17 (2.2)	<5 (<2.6)	<5 (<3)
Peptic ulcer disease	25 (3.2)	0 (0)	0 (0)
HIV	11 (1.4)	<5 (<2.6)	<5 (<3)
Diabetes	261 (33.5)	50 (25.6)	46 (27.9)
Warfarin doses (mg/day), median (IQR)			
First dose	5 (3-5)	3 (2.5-5)	3 (2.5-5)
Second dose	5 (3-5)	3.5 (2.75-5)	4 (2.5-5)

Characteristics	INR[a] 2.0-3.0		INR 2.5-3.5
	Training and validation (n=780)	Testing (n=195)	Training and validation (n=165)
Third dose	5 (3-5)	3 (2-5)	4 (2.5-5)
Final warfarin dose[f]	3.5 (2.5-5)	3 (2-5)	3 (2.5-4)
INR measurements, median (IQR)			
INR after first Warfarin dose	1.31 (1.18-1.60)	1.3 (1.19-1.52)	1.35 (1.22-1.52)
INR after second Warfarin dose	1.57 (1.34-2.09)	1.6 (1.375-2)	1.66 (1.345-2.09)
INR after third Warfarin dose	1.98 (1.59-2.48)	1.94 (1.62-2.45)	2.06 (1.69-2.6)
Discharge INR	2.41 (2.22-2.62)	2.42 (2.2-2.625)	2.85 (2.63-3.12)

[a]INR: international normalized ratio.

[b]Excludes percutaneous transluminal approach.

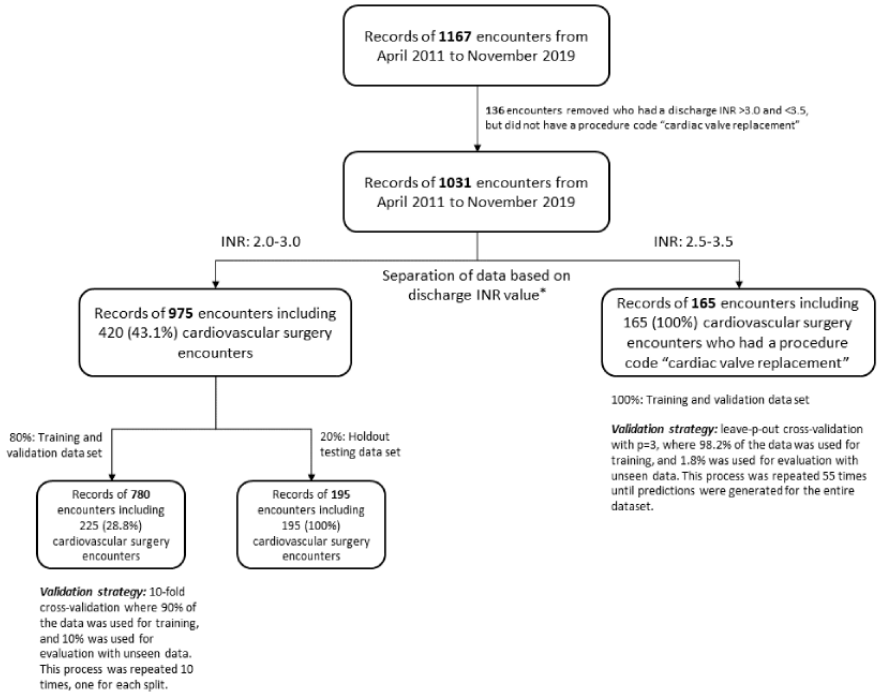
[c]Procedures in the "Other" category are all other procedures and conditions not listed above, including but not limited to pulmonary embolism, heart failure without coronary angiogram, and ischemic events of the central nervous system.

[d]Patients who have had a cardiac surgery procedure may not always have "cardiovascular surgery" as their service.

[e]Services in the "Other" category are all other services not listed above, including orthopedics, intensive care medical, general medicine, vascular surgery, intensive care trauma, neurosurgery, general surgery acute care, and other hospital services with less than 2% of total patients.

[f]The dose required to achieve therapeutic INR at discharge following cardiac surgery.

Figure 1. Model development study design outlining cohort, data splits, and model validation strategies. INR: international normalized ratio. *There are 109 encounters who are represented in both INR groups of 2.0-3.0 and 2.5-3.5. These were cardiovascular surgery encounters who had a procedure code "cardiac valve replacement" and had a discharge INR value between 2.5-3.0.



Retrospective Case Series

On September 6, 2021, the algorithm was deployed as a web-based dosing calculator for predicting the warfarin dose required to attain a therapeutic INR at the time of discharge among patients undergoing cardiovascular surgery. To preliminarily ascertain how the algorithm performed in clinical practice, we retrospectively determined the proportion of cardiovascular surgery patients discharged with a therapeutic INR before (April 2011 and July 2019) and following (September 2021 and May 2, 2022) the implementation of the web-based calculator. We also reviewed the charts of patients with discrepancies between the dose predicted by the algorithm and the actual discharge warfarin dose and patients who were not discharged with a therapeutic INR to identify whether specific patient features (eg, smoking history and BMI) not included in the development and validation of the algorithm could be undermining the performance of the web-based calculator in clinical practice.

Ethical Considerations

This study was approved by the Research Ethics Board of Unity Health Toronto, Ontario, Canada (reference #16-371). Because

fully anonymized data were used, the need for informed consent was waived by the Research Ethics Board.

Results

Algorithm Validation

We identified 1031 encounters initiating warfarin while hospitalized between April 1, 2011, and November 29, 2019, who met the inclusion criteria, of whom 334 (32.4%) received a cardiac valve replacement and 142 (13.8%) underwent other forms of cardiac surgery. The majority (628/1031, 60.9%) of patients were male, and the median age was 67 (IQR 56-77) years (Table 1).

In our analysis predicting the warfarin dose for a discharge INR of 2.0-3.0, random forest regression was the best performing model in the test set of cardiac surgery patients, with an MAE of 1.13 mg and 39.5% of predictions falling within 20% of the actual dose (Table 2, Figure S1 in Multimedia Appendix 1).

The MAEs for the penalized linear regression, MARS, gradient boosting, kNN regression, and ensemble models were 1.22 mg, 1.25 mg, 1.15 mg, 1.26 mg, and 1.16 mg, respectively, with the proportion of predicted doses falling within 20% of the actual dose ranging from 32.8% to 36.9% (Table 1). Logarithmic transformation of the warfarin dose did not result in a better-performing model than random forest regression of the untransformed dose (Table 2).

For predictions of the warfarin dose required for a discharge INR of 2.5-3.5, the ensemble model combining the results of the 5 regression models performed best among patients undergoing mechanical mitral valve replacement. Specifically, the MAE for the ensemble model was 1.11 mg, with 43.6% of predictions being within 20% of the actual dose. The mean average errors for the penalized linear regression, random forest regression, MARS, gradient boosting, and kNN regression models were 1.17 mg, 1.16 mg, 1.30 mg, 1.27 mg, and 1.26 mg, respectively, with 37.0%-41.2% of predictions being within 20% of the actual dose (Table 3, Figure S2 in Multimedia Appendix 1). Logarithmic transformation of the warfarin dose did not improve model performance.

Table 2. Model performance for predicting the warfarin dose for a discharge international normalized ratio (INR) of 2.0-3.0 using validation and testing data sets.

Model	Outcome transformation	Mean absolute error (MAE; mg), 95% CI		Proportion of predictions within 20% of true dose (%), 95% CI		Correlation coefficient, 95% CI	
		Validation	Test	Validation	Test	Validation	Test
Penalized regression	None	1.15 (1.07-1.23)	1.22 (1.08-1.37)	46.9 (43.5-50.4)	35.9 (28.7-42.6)	0.728 (0.688-0.772)	0.550 (0.466-0.629)
MARS[a]	None	1.20 (1.12-1.29)	1.25 (1.10-1.41)	42.6 (39.0-46.2)	33.3 (26.2-39.5)	0.720 (0.678-0.767)	0.548 (0.447-0.639)
kNN[b]	None	1.50 (1.41-1.59)	1.26 (1.09-1.41)	33.2 (29.7-36.5)	35.4 (28.2-42.0)	0.569 (0.521-0.621)	0.462 (0.353-0.573)
Random forest regression	None	1.17 (1.09-1.25)	1.13 (0.99-1.27)	44.5 (40.9-48.1)	39.5 (32.8-46.2)	0.728 (0.686-0.773)	0.579 (0.489-0.672)
Gradient boosting	None	1.25 (1.17-1.34)	1.15 (1.01-1.29)	41.7 (38.2-45.0)	36.9 (29.7-43.6)	0.690 (0.640-0.743)	0.596 (0.498-0.697)
Ensemble model	None	1.13 (1.04-1.21)	1.16 (1.02-1.29)	48.2 (44.5-51.5)	32.8 (26.2-39.5)	0.742 (0.701-0.786)	0.582 (0.494-0.665)
Penalized regression	Logarithm	1.18 (1.09-1.27)	1.21 (1.04-1.35)	43.7 (40.3-47.4)	34.4 (27.7-41.0)	0.716 (0.673-0.763)	0.535 (0.440-0.621)
MARS	Logarithm	1.14 (1.05-1.22)	1.18 (1.02-1.33)	46.3 (42.9-50.0)	34.9 (28.2-41.5)	0.732 (0.690-0.776)	0.568 (0.470-0.659)
kNN	Logarithm	1.48 (1.38-1.58)	1.34 (1.17-1.50)	32.7 (29.2-35.8)	33.3 (26.7-39.5)	0.569 (0.519-0.622)	0.433 (0.326-0.541)
Random forest regression	Logarithm	1.16 (1.08-1.25)	1.16 (1.01-1.31)	45.3 (41.7-48.7)	34.9 (28.2-41.5)	0.727 (0.685-0.774)	0.574 (0.487-0.665)
Gradient boosting	Logarithm	1.23 (1.15-1.32)	1.23 (1.07-1.38)	42.6 (39.0-46.0)	32.3 (25.6-39.0)	0.690 (0.644-0.740)	0.539 (0.435-0.641)
Ensemble model	Logarithm	1.12 (1.04-1.19)	1.14 (0.99-1.27)	47.6 (44.0-51.3)	33.8 (27.2-40.0)	0.750 (0.709-0.796)	0.578 (0.487-0.663)

[a]MARS: multivariate adaptive regression splines.

[b]kNN: k-nearest neighbors.

Table 3. Model performance for predicting the warfarin dose for a discharge international normalized ratio (INR) of 2.5-3.5 using validation data set.

Model	Outcome transformation	Mean absolute error (MAE), milligrams, 95% CI	Proportion of predictions within 20% of true dose (%), 95% CI	Correlation coefficient, 95% CI
Penalized Regression	None	1.17 (1.00-1.33)	41.2 (33.9-48.5)	0.502 (0.401-0.615)
MARS[a]	None	1.30 (1.13-1.47)	38.8 (30.9-46.1)	0.373 (0.228-0.554)
kNN[b]	None	1.26 (1.08-1.44)	38.2 (30.9-44.8)	0.339 (0.194-0.481)
Random Forest Regression	None	1.16 (0.99-1.33)	38.8 (31.5-46.7)	0.519 (0.408-0.642)
Gradient boosting	None	1.27 (1.07-1.46)	37.0 (29.7-44.2)	0.338 (0.209-0.469)
Ensemble Model	None	1.11 (0.94-1.27)	43.6 (35.8-50.9)	0.545 (0.442-0.660)
Penalized Regression	Logarithm	1.12 (0.94-1.29)	43.0 (35.2-50.3)	0.525 (0.419-0.641)
MARS	Logarithm	1.18 (0.99-1.35)	44.2 (35.8-51.5)	0.497 (0.372-0.650)
KNN	Logarithm	1.23 (1.03-1.42)	40.0 (32.1-47.3)	0.359 (0.244-0.472)
Random Forest Regression	Logarithm	1.19 (1.00-1.37)	42.4 (34.5-49.7)	0.464 (0.352-0.581)
Gradient boosting	Logarithm	1.30 (1.10-1.50)	38.2 (30.9-44.8)	0.361 (0.240-0.487)
Ensemble Model	Logarithm	1.16 (0.98-1.33)	41.2 (33.3-48.5)	0.507 (0.395-0.635)

[a]MARS: multivariate adaptive regression splines.

[b]kNN: k-nearest neighbors.

Retrospective Case Series

The uptake of the warfarin dosing tool is illustrated in Figure 2.

Because of COVID-19–associated reductions in surgical volumes at our institution, we identified only 18 warfarin-naïve patients who underwent cardiovascular surgery and were discharged on warfarin between September 2021 and May 2, 2022. Overall, 61.1% (11/18) of these patients were discharged with a therapeutic INR with a warfarin dose within the range predicted by the algorithm (Figure 3). In contrast, 47.5% (305/641) cardiovascular surgery patients were discharged with a therapeutic INR before the development and implementation of the web-based calculator (April 2011 to July 2019; *P*=.37 for pre- and postcomparison).

In a review of 7 patients with discrepancies between the predicted and actual discharge warfarin dose, a total of 2 patients were discharged with a therapeutic INR but with discharge doses lower than those predicted by the algorithm. Another 3 patients were not discharged with a therapeutic INR using the dose predicted by the algorithm. Of these patients, 2 were discharged with INRs that were nearly therapeutic (1.90 and 1.93; target INR 2.0-3.0), and 1 was discharged with an INR of 1.65 and therapeutic bridging with a low molecular weight heparin. The final 2 patients were not discharged with a therapeutic INR and were discharged with warfarin doses that differed from those predicted by the algorithm. A review of patient charts did not identify any factors that could account for discrepancies between actual and predicted discharge doses.

Figure 2. Warfarin dosing tool usage by St Michael's Hospital cardiac surgery service, September 6, 2021, to September 18, 2023. INR: international normalized ratio.

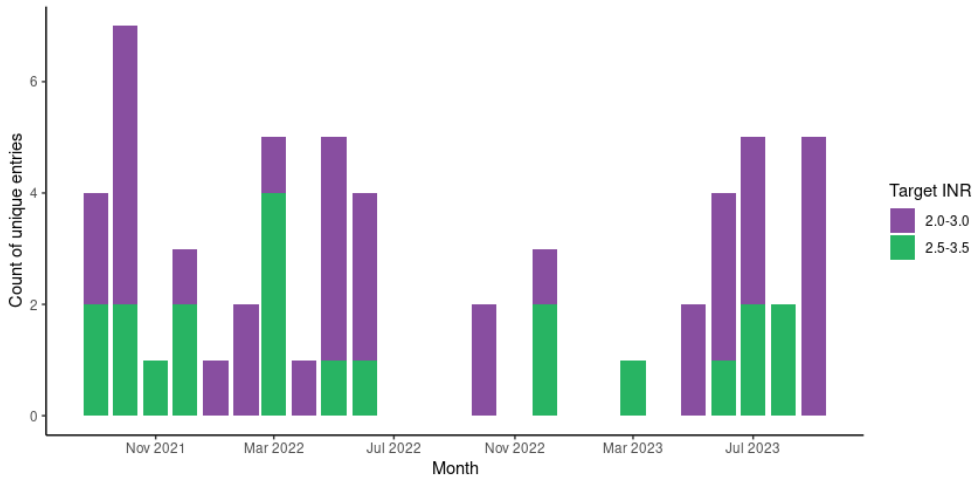
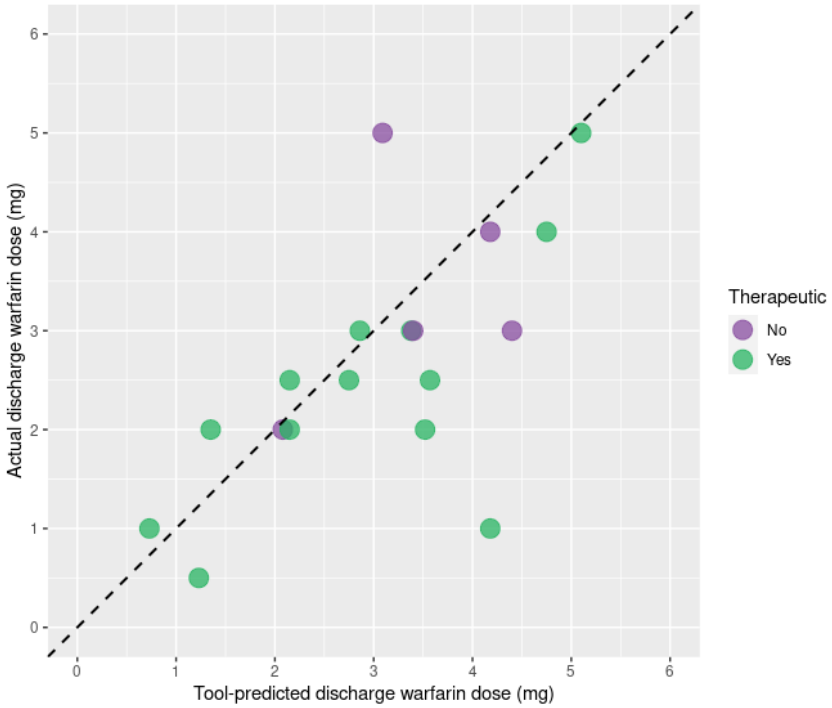


Figure 3. Predicted and true discharge warfarin doses for patients in the retrospective case series with indicators for whether their discharge international normalized ratio (INR) was therapeutic.



Discussion

In this study, we found that machine learning models trained on readily available demographic and clinical data could predict the warfarin dose needed to discharge cardiac surgery patients with a therapeutic INR. Overall, random forest regression and ensemble models performed best for patients requiring discharge INRs of 2.0-3.0 and 2.5-3.5, respectively, with approximately 40% of predictions being within 20% of the actual dose. Based on our findings, a web-based tool was developed and deployed to the cardiovascular surgery unit of the hospital to facilitate warfarin dosing in the postoperative period. A preliminary evaluation found a numerically higher proportion of patients discharged with a therapeutic INR using the warfarin discharge dose predicted by the algorithm relative to historical controls. However, this evaluation was based on a small sample of patients, with additional evaluations being required.

Our findings are consistent with previous studies demonstrating the use of machine learning approaches for supporting personalized warfarin dosing in cardiac surgery patients. This is important because of the heightened sensitivity to warfarin in cardiac surgery patients during the postoperative period, thereby increasing the risk of bleeding and death or prolonging the length-of-stay because of delayed epicardial pacer wire removal [7,8,36,37]. Moreover, warfarin remains the only anticoagulant indicated for patients with mechanical mitral heart valves and remains commonly used following other forms of cardiac surgery [21-24,38]. In addition, our predictive algorithms were derived using clinical information that is routinely collected during the care of cardiac surgery patients. In contrast, some previous studies have integrated pharmacogenetic information accounting for up to 40% of individual variation in warfarin dosing with clinical data when developing and validating warfarin dosing algorithms [13,16,18,19,39]. Although a combination approach may improve model performance, these gains may be offset by the resources associated with obtaining pharmacogenetic data in all patients and the lack of availability of this information in most settings. Moreover, meta-analyses of randomized controlled trials comparing genotype-guided and clinical dosing algorithms have found inconsistent results with respect to time in the therapeutic range and bleeding risk, with no difference in mortality or thromboembolism risk [40,41]. However, the time to attain a therapeutic INR may be shortened by genotype-guided approaches [41]. Further, while cross-study comparisons are challenging, the MAEs for our best-performing models were similar to those of other studies incorporating pharmacogenetic data, with similar proportions of predictions falling within 20% of the true value. Specifically, the median MAEs of warfarin dosing algorithms were 1.20 (95% CI 0.37-3.70) [17] and 1.47-10.86 [13] in separate systematic reviews. Although this is higher than the MAE derived using a BPNN (0.740 mg) [14], our sample size limited us from exploring the performance of more advanced models. In addition, the median proportion of patients with the predicted dose within 20% of the true value was 48% from 14 studies describing the development of algorithms using clinical data only [17]. Our findings are also consistent with those of the Gage and International Warfarin Pharmacogenetics Consortium clinical algorithms, with a median and MAE of 1.50 and 1.41 mg/day, respectively [33,34].

Several limitations of this study merit emphasis. First, our sample size was small, potentially limiting the ability of models to recognize patterns and make predictions. However, this reflects our stringent inclusion criteria and emphasis on developing a warfarin dosing algorithm for a specific patient population. Moreover, we used expert knowledge and past research to select a parsimonious number of features for our

predictive models. Further, our best-performing models had MAEs of approximately 1.1 mg, which is only slightly higher than the value of 1 mg considered to represent reasonable predictive ability [32]. Second, we lacked information on some variables known to affect warfarin sensitivity, such as smoking [42], ethnicity [43], and herbal medications [44]. Third, our case series examining the impact of our algorithms on clinical outcomes comprised a small number of patients because of COVID-19–associated reductions in surgical volumes. We were therefore likely underpowered to detect statistically significant differences in the proportion of patients discharged with a therapeutic INR following the implementation of the tool. Finally, we did not evaluate deep learning methods for algorithm development. However, we chose to avoid these methods because of the small number of observations in our data sets [14,15].

In conclusion, we found that a random forest regression and ensemble model based on routinely available clinical data provided accurate predictions to guide initial warfarin dosing in cardiac surgery patients requiring discharge INRs of 2.0-3.0 and 2.5-3.5, respectively. These algorithms can be harnessed to provide personalized warfarin dosing and optimize the postsurgical anticoagulation of these patients.

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Data Availability

The data sets presented in this paper are not publicly available due to confidentiality restrictions preventing their distribution. Requests to access the data may be directed to the corresponding author.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional information about each model.
[DOCX File , 199 KB - cardio_v7i1e47262_app1.docx]

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Abbreviations

BPNN: Back Propagation Neural Network
EDW: Enterprise Data Warehouse
INR: international normalized ratio
kNN: k-nearest neighbors
MAE: mean absolute error
MARS: multivariate adaptive regression splines
RR: responder ratio

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Original Paper

A Smartwatch System for Continuous Monitoring of Atrial Fibrillation in Older Adults After Stroke or Transient Ischemic Attack: Application Design Study

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Abstract

Background: The prevalence of atrial fibrillation (AF) increases with age and can lead to stroke. Therefore, older adults may benefit the most from AF screening. However, older adult populations tend to lag more than younger groups in the adoption of, and comfort with, the use of mobile health (mHealth) apps. Furthermore, although mobile apps that can detect AF are available to the public, most are designed for intermittent AF detection and for younger users. No app designed for long-term AF monitoring has released detailed system design specifications that can handle large data collections, especially in this age group.

Objective: This study aimed to design an innovative smartwatch-based AF monitoring mHealth solution in collaboration with older adult participants and clinicians.

Methods: The Pulsewatch system is designed to link smartwatches and smartphone apps, a website for data verification, and user data organization on a cloud server. The smartwatch in the Pulsewatch system is designed to continuously monitor the pulse rate with embedded AF detection algorithms, and the smartphone in the Pulsewatch system is designed to serve as the data-transferring hub to the cloud storage server.

Results: We implemented the Pulsewatch system based on the functionality that patients and caregivers recommended. The user interfaces of the smartwatch and smartphone apps were specifically designed for older adults at risk for AF. We improved our Pulsewatch system based on feedback from focus groups consisting of patients with stroke and clinicians. The Pulsewatch system was used by the intervention group for up to 6 weeks in the 2 phases of our randomized clinical trial. At the conclusion of phase 1, 90 trial participants who had used the Pulsewatch app and smartwatch for 14 days completed a System Usability Scale to assess the usability of the Pulsewatch system; of 88 participants, 56 (64%) endorsed that the smartwatch app is “easy to use.” For phases 1 and 2 of the study, we collected 9224.4 hours of smartwatch recordings from the participants. The longest recording streak in phase 2 was 21 days of consecutive recordings out of the 30 days of data collection.

Conclusions: This is one of the first studies to provide a detailed design for a smartphone-smartwatch dyad for ambulatory AF monitoring. In this paper, we report on the system's usability and opportunities to increase the acceptability of mHealth solutions among older patients with cognitive impairment.

Trial Registration: ClinicalTrials.gov NCT03761394; https://www.clinicaltrials.gov/ct2/show/NCT03761394

International Registered Report Identifier (IRRID): RR2-10.1016/j.cvdhj.2021.07.002

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KEYWORDS

atrial fibrillation; stroke; smartwatch app; smartphone apps; wearable devices; user experience; older adults; mobile phone

Introduction

Background

Atrial fibrillation (AF) is the most frequent cardiac arrhythmia [1], and the prevalence of AF in the United States is increasing, from an estimated 5.2 million in 2010 to a projected 12.1 million in 2030 [2]. AF, whether paroxysmal, persistent, or permanent, and whether symptomatic or silent, significantly increases the risk of thromboembolic ischemic stroke [3]. Owing to the difficulty in diagnosis, paroxysmal AF (pAF) is the most common AF pattern found in all patients presenting with acute ischemic stroke [4]. Diagnosing pAF remains critically important and often requires monitoring for >24 hours [5]. The popularity of noninvasive wearable devices and user-friendly, informative mobile apps may play an important role in long-term heart rhythm monitoring for the population at high risk of pAF [6]. In addition, the COVID-19 pandemic has fundamentally altered the landscape of clinical care in the United States, with many older adults and their clinicians shifting to internet-based visits and increasing the acceptability of wearable devices as medical monitors. Because the prevalence of AF increases with age, reaching 9% in people ≥80 years [7], the ideal population to screen for AF is of older adults. However, familiarity with wearable devices remains low among older adults. Physical, as well as cognitive, impairments can interfere with the ability of older adults to use mobile health (mHealth) apps and commercial wearables [8]. We aimed to design a system for AF monitoring that would be highly usable by older adults by incorporating their feedback into the design of a smartphone app.

Traditional electrocardiogram (ECG) monitoring uses hydrogel-based adhesive electrodes, which leads to poor patient acceptance and usability in long-term monitoring apps. Most current mobile noninvasive technologies with automated pulse or ECG acquisition have highly accurate AF detection, calculated from embedded advanced signal processing algorithms [6]. However, initial manifestations of this technically required an individual to perform self-checks by placing fingers on a smartphone camera lens or pairing them with an ECG unit for 30 seconds to 2 minutes of recording. This *spot-check* approach does not provide the continuous, passive monitoring needed to detect brief episodes of AF in high-risk populations, such as those with cryptogenic stroke.

Prior Work

A better method to monitor pAF passively and near-continuously is to use a photoplethysmography (PPG) sensor on the back of a smartwatch to record pulse information. Recently, Apple Heart study [9,10], Huawei Heart study [11,12], and Fitbit Heart study [13] evaluated systems that use this approach to monitor pAF. However, all 3 studies targeted users who already owned each brand's smartphones and smartwatches. Therefore, the Apple Heart study, Huawei Heart study, and Fitbit Heart study were skewed toward younger participants. In fact, each study included only 5.9%, 1.8%, and 12.5% of the total cohort of participants aged ≥65 years, respectively. No details were provided on whether the apps were specifically designed by or for older adults, and no details on the design of the rhythm collection system have been described [10-13]. In addition, Including the details of the design is important, as long-term monitoring that generates enormous data could overload wearable devices that have limited storage.

Goal of This Study

As with any novel technological development, end user guidance in design and development is paramount. This is especially true for pAF monitoring because the target population of older stroke patients is unique, slower to adopt new technology, and understudied. Accordingly, in our clinical trial [14], we collaborated with survivors of stroke and their clinicians to develop Pulsewatch, an innovative smartwatch-based AF detection mHealth system. This comprised a Samsung smartwatch for long-term (up to 6 weeks), near-continuous (24 h/d) pulse monitoring and on-demand ECG into which we embedded our novel algorithms for noise elimination, contact sensing, and automated AF detection and which communicated with a smartphone app with user interface (UI). In this study, we provide the details of our system design and its acceptability among older survivors of stroke or transient ischemic attack (TIA).

Methods

In this section, we discuss the design of the functionalities of the Pulsewatch system. Details of the final implementation of the Pulsewatch system are provided in the *Results* section.

Overview of the Functionality of the Pulsewatch System

The Pulsewatch system consisted of a pair of smartphone and smartwatch apps and was intended to be used for at least 6 weeks in an at-home ambulatory setting by older adults who survived a stroke or TIA [14]. The aim of the Pulsewatch system was to provide a passive AF monitoring solution with minimal user attention required during recording with real-time display of the monitoring results. Importantly, owing to the cognitive

impairment of our target population, pulse monitoring had to be passive, wherein the participants were only asked to hold still when a rhythm abnormality was detected. Although the system required no action on the part of the user, users can access historical data through the Pulsewatch app. Users can input symptoms or notes for their clinicians, as the system was designed to facilitate the sharing of information about the AF status between the user and their clinicians. The participants' clinicians can also remotely check the Pulsewatch system's wearing time information, user symptoms, and AF detection results.

The Pulsewatch system was designed to be used by 3 groups of users, as described in Textbox 1.

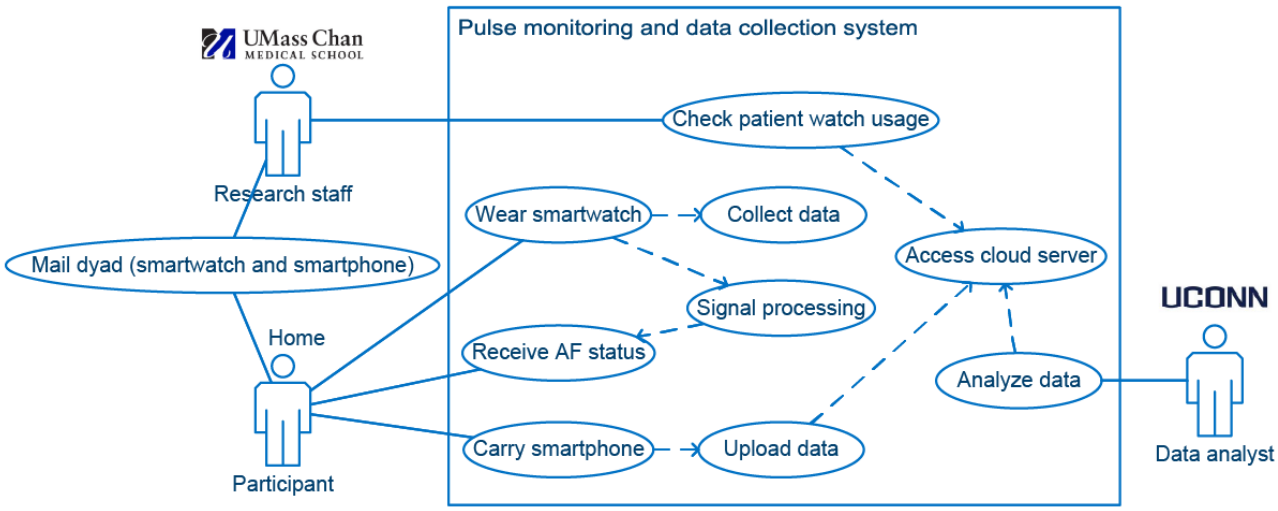
During the design process of the Pulsewatch app, inputs from both patients and their clinicians were taken to facilitate communication. Our patients' focus group consisted of 5 screened patients with a history of stroke or TIA at the University of Massachusetts Chan Medical School's (UMass Chan) Stroke Prevention Clinic, whereas our clinicians' focus group participants consisted of 5 clinicians (neurologists and cardiologists) from the UMass Chan Neurology and Cardiology groups. Developers (algorithm developer and software engineer) also joined the hack-a-thon and agile programming team meeting at UMass Chan to finalize the Pulsewatch system to be deployed in the clinical trial.

The use case diagram [15] depicted in Figure 1 shows the main functionalities provided by our Pulsewatch system. The Pulsewatch experiment began with a smartwatch app that could automatically and independently detect AF. After a participant received the dyad composed of the smartwatch and smartphone, turned on the devices, and donned the smartwatch, the data collection and signal processing procedure automatically started without any configuration needed from the participant. We believe that this is the most feasible way to start monitoring AF in older adult participants.

Textbox 1. The 3 user groups for the Pulsewatch system .

1. Participants (end users): Participants were identified using electronic health records based on diagnostic codes and then approached by our research staff at the time of a clinic visit for potential enrollment. Eligible participants had to be aged ≥50 years with a history of stroke or transient ischemic attack within the past decade. A detailed description of the target user, sample size, hypothesis of the study, and inclusion and exclusion criteria was previously described by Dickson et al [14]. If participants were interested, they provided informed consent to participate in the study and were subsequently randomized to determine whether they had received the Pulsewatch system. The study staff provided the smartwatch and smartphone devices, extensive training, and written information detailing device operation. Participants could only use the smartwatch and the smartphone assigned to them for the study.
2. Research staff (the web admin): After the initial training, the study staff provided technical and operational support over the phone when required by patients. In addition, the study staff used the user interface of the Pulsewatch web system to examine the pulse data collected from the enrolled participants (ie, they accessed the data tracking websites that we described in the *Results* section and implemented data tracking website on the cloud server), to check the secured cloud server and to provide on-time feedback for the phase 1 experiment.
3. Data analysts (the local administrator): Data analysts from the University of Connecticut had access to the entire Pulsewatch system, including the secured cloud server for administrative management and future data processing.

Figure 1. Use case diagram of the data collection system. AF: atrial fibrillation; UConn: University of Connecticut; UMass Chan: University of Massachusetts Chan Medical School.



Ethics Approval

Formal ethical approval for this study was obtained from the Institutional Review Board of the UMass Chan's Institutional Review Board (Approval Number H00016067). Written informed consent was obtained from all patients involved in the hack-a-thon and clinical trials. Verbal consent was obtained from clinicians enrolled in the hack-a-thon development phase. Because of the unprecedented challenges posed by COVID-19 regarding in-person human participant research, we adopted an alternate protocol to allow for all study encounters to occur over

the phone [14]. The consent form was adopted for telephone and approved by the Institutional Review, and eligible participants were contacted via their contact information in the electronic health record and consented [14]. This alternate remote protocol was initiated in July 2020, and all participants who had been approached over the phone were also offered the option to participate in person as per the original study protocol [14].

All participants' identifiable information was deidentified by the UMass team. The authors designed the study and gathered and analyzed the data according to the Helsinki Declaration guidelines for human research.

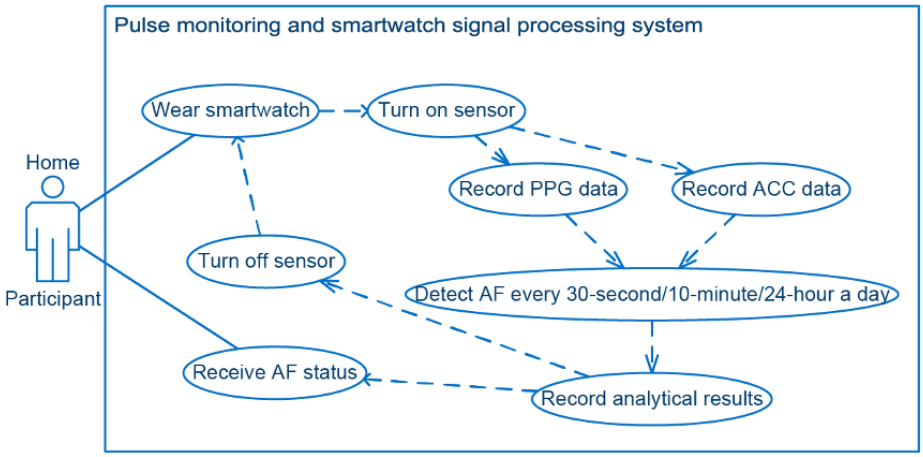
The 5 patient participants who completed the hack-a-thon were each awarded a US $50 visa gift card. During the clinical trial, enrolled participants received a US $100 visa gift card after completing the baseline questionnaire for phase 1 of the study and another US $100 gift card for completing the follow-up questionnaire. Participants who were randomly selected for a usability interview received an additional US $60 visa gift card. After completing phase 2 and the 44- day follow-up questionnaire, the participants were compensated with a US $50 visa gift card.

Functionality of Independent AF Detection on Smartwatch

Figure 2 illustrates the core functionality and highlights of the Pulsewatch system, that is, the signal processing system on the smartwatch.

We designed a novel sensor modulation program to turn the sensor on every 10 minutes to preserve the smartwatch battery while maximizing the monitoring span. The duration of the sensor-on stage was 5 minutes but could be extended based on the instantaneous AF detection results [14].

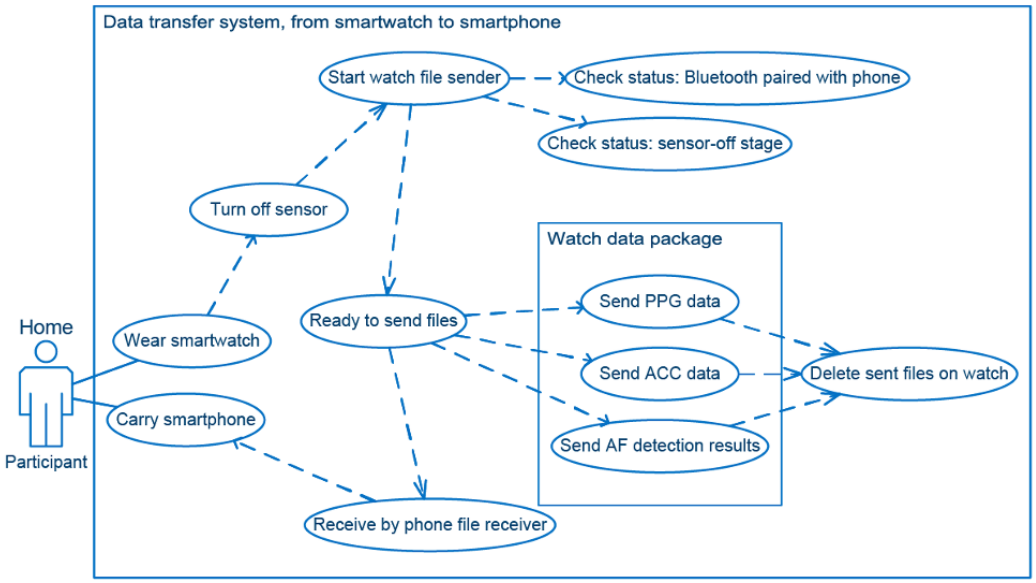
Figure 2. Use case diagram of pulse monitoring (smartwatch signal processing) system. ACC: accelerometry; AF: atrial fibrillation; PPG: photoplethysmography.



Functionality of Automated File Transferring Between Smartwatch and Smartphone

Once data were collected and processed on the smartwatch, the next critical step was when and how to upload them to the smartphone so that the storage on the watch could be freed. As shown in Figure 3, the file transferring procedure initiated by the watch occurred immediately when the sensor was turned off, thereby ensuring that no new files were created. The file sender program inside the smartwatch app first confirmed that a Bluetooth connection was established between the smartwatch and the paired smartphone. When the criteria were met, a file transfer process was initiated. Three types of data were transferred from the watch to the phone: PPG raw data, accelerometry (ACC) raw data, and results of signal processing and AF detection methods. Details of the output data are provided in the *Results* section. Once the smartphone successfully received the watch data, the watch app deleted the transferred data to free the storage space for future data collection. The smartphone app file receiver application programming interface (API) continuously ran in the background of the smartphone to ensure that any spontaneous file uploading requests were received from the watch.

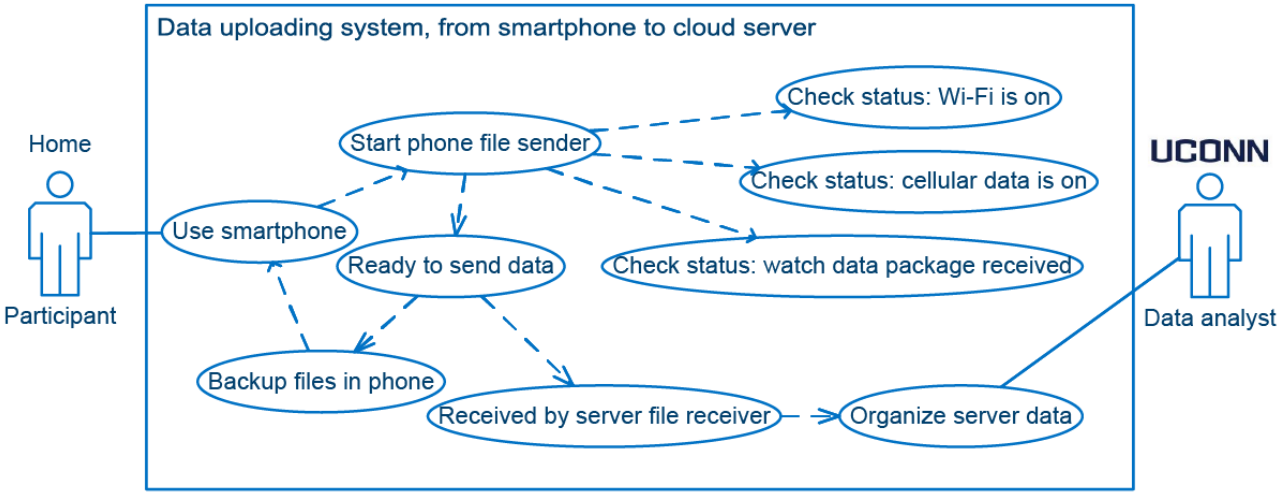
Figure 3. Use case diagram for phone-watch file transfer system. ACC: accelerometry; AF: atrial fibrillation; PPG: photoplethysmography.



Functionality of Automated File Backup Between the Smartphone and the Cloud Server

Even if the smartphone received data transferred from the smartwatch, the physical dyad could be damaged or lost at any moment. To address this, we designed a Pulsewatch system to ensure that the data were backed up to the cloud server. As shown in Figure 4, when the smartphone was turned on, the file sender in the Pulsewatch phone app automatically ran in the background constantly to ensure that files were uploaded to the cloud at any given moment. Before uploading unsent files to the server, the file sender must establish internet connection, either through Wi-Fi or cellular data. Once a file was uploaded through the internet connection successfully, the phone app did not delete it but instead moved it to another folder to have a second local backup. This was because during transfer, the data could be corrupted, and therefore, it was critical to keep the original files in the phone.

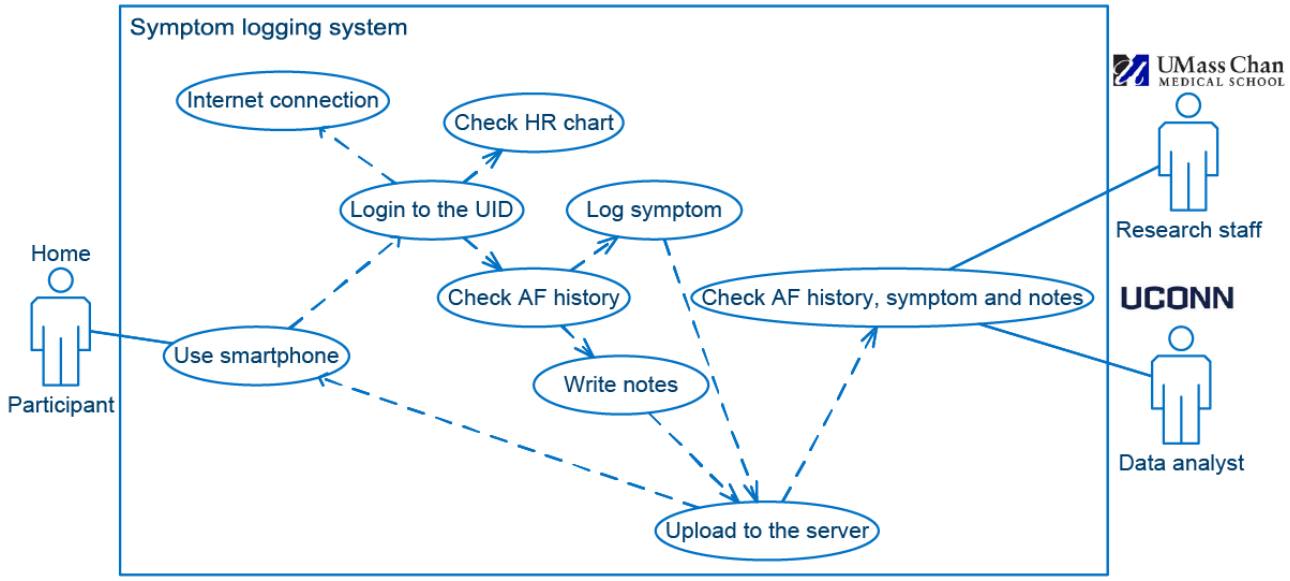
Figure 4. Use case diagram of the phone-server file transfer system. UConn: University of Connecticut.



Functionality of Symptom Logging in the Smartphone

An important functionality required by cardiologists, as shown in Figure 5, was participants' symptom tracking within the Pulsewatch smartphone app, which mirrors the same functionality as clinical heart rhythm monitors. Regardless of the AF status results in the phone app, participants were able to select predefined symptoms or log free text in the smartphone app at any time to inform their clinician. To separate different participants' inputs on the cloud, the participants had to first log-in to the phone app with their user ID (UID) and password. This log-in process required internet connection to contact the cloud server for log-in credentials. After log-in, the participants used the start time point from when the watch sensor was turned on every 10 minutes to input their symptoms and notes. Once the participant clicked the save button, all edits were automatically uploaded to the server through an internet connection. The UMass research staff could read the participant's symptom input immediately on the webpage.

Figure 5. Use case diagram of the symptom logging system. AF: atrial fibrillation; HR: heart rate; UConn: University of Connecticut; UID: user ID; UMass Chan: University of Massachusetts Chan Medical School.



Results

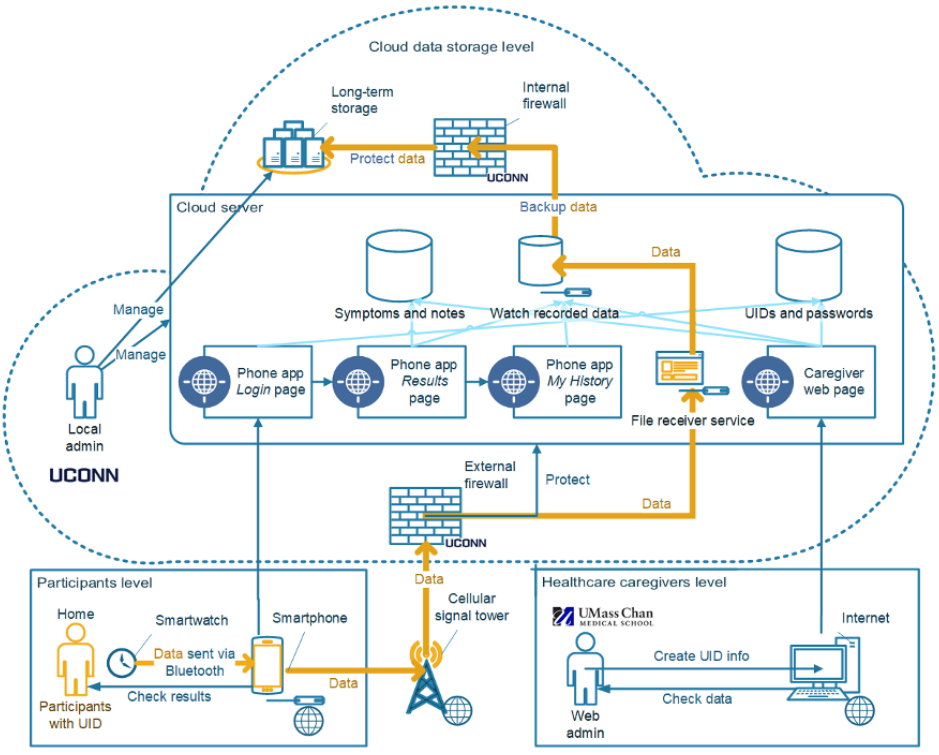
In this section, we explain the implementation of all the functionalities proposed in the *Methods* section for our Pulsewatch system. We then describe the output of our Pulsewatch clinical trial, including the total number of recordings collected from the Pulsewatch system and the usability ratings of our system among our participants.

Implemented Structure of the Pulsewatch System

On the basis of the functionality mentioned in the *Overview of the Functionality of the Pulsewatch System* in the *Methods* section, we designed the structure of our Pulsewatch system, as shown in Figure 6.

At near real-time speed (<1 s), the smartwatch processed the recorded data and displayed an AF status (normal or abnormal) on the watch UI, together with the time of day. There was no notification of AF status other than the watch face color and text, reflecting the preferences of older adult patients. After collecting and processing the data, they were transferred to the paired smartphone via self-initiated communication within the dyad. The data were backed up both in the phone's local storage and on the cloud server through the phone app.

Figure 6. Structure of the Pulsewatch system. Admin: administrator; UConn: University of Connecticut; UID: user ID; UMass Chan: University of Massachusetts Chan Medical School.

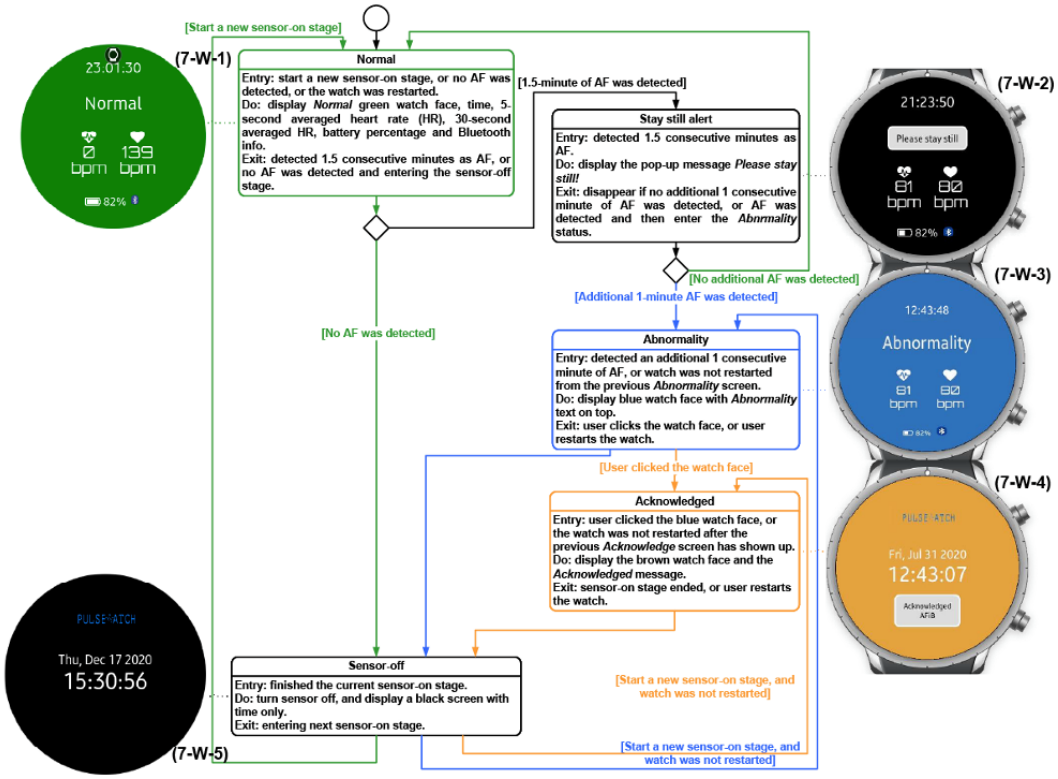


Implemented UI of the Smartwatch App

On the basis of the functionality requested in Figure 2, we implemented the logic as shown in Figure 7. During the sensor-on stage, PPG and ACC data were recorded, and AF detection was performed [16,17] based on the PPG heart rate value [18] from clean PPG segments [16]. The results of AF detection were displayed accordingly on the watch face. The enrolled participants were able to observe the AF status from the smartwatch face passively when they checked the time displayed on the watch. If the system detected AF, the status lingered on the watch face until the participant clicked the watch face to acknowledge it. This AF detection cycle was repeated all day while the watch was powered on.

For the watch app UI shown in Figure 7, the AF status was displayed with the watch face color and text at the top, based on suggestions from the patient focus group members in the hack-a-thon [14]. To avoid inducing worry among participants, the watch face color for abnormality was deliberately chosen as blue (in lieu of a red color). Color blindness was considered and factored into the choice of warning color, following a suggestion by clinician participants in the hack-a-thon [14]. In addition to the AF status (normal, possible AF active, possible AF previously detected), the watch face also displays the time and 2 distinct heart rate features. Details of the smartwatch UI are provided in Multimedia Appendix 1. As the sensor was turned off half of the time, we used the darkest color for the background to minimize the brightness of the watch face and disturbance to participants' sleep. The frequency of *normal* watch face could be high as well, if the participant did not have long episodes of AF or had lots of motion artifact; thus, we used a darker green color in (4-W-1) of Figure 7, compared with the dazzling green color on the watch face shown in the *normal* screen of Figure 3 in [14]. We did not design any night mode for the watch face in case participants preferred to be woken up at night for any AF alert. To indicate the Bluetooth connection and the remaining battery percentage, we added 2 icons at the bottom of the watch face to help participants debug the file transferring issue if the study staff had not seen their data for several days in phase I.

Figure 7. The state machine of the Pulsewatch smartwatch app. AF: atrial fibrillation; bpm: beats per minute; HR: heart rate.



Implementation of Smartwatch App

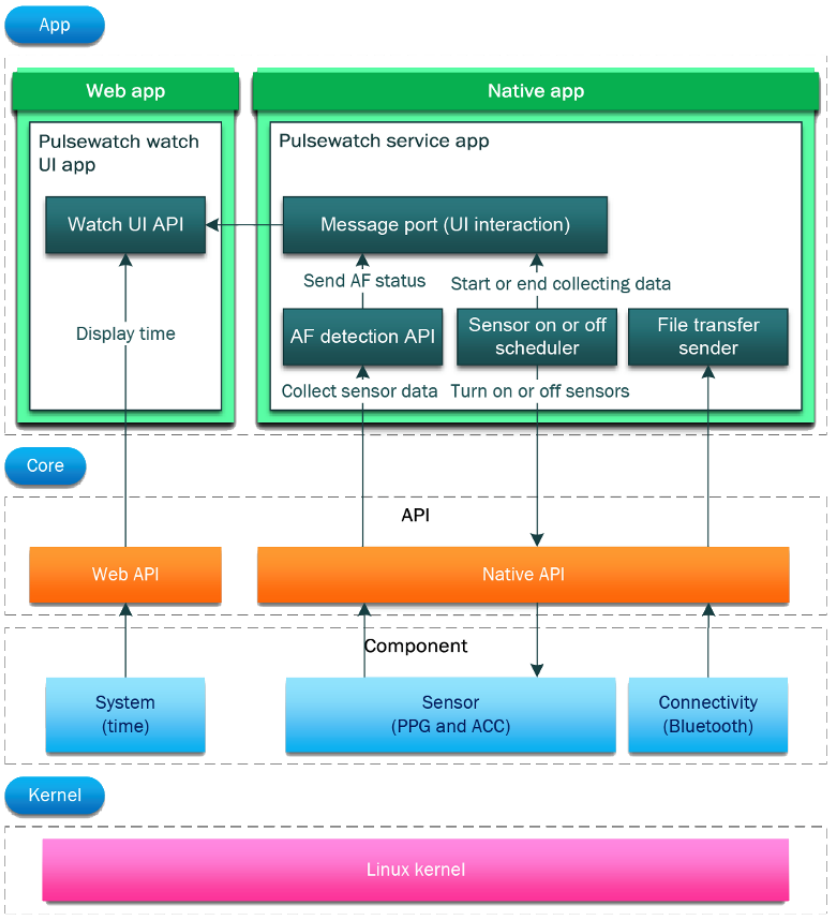
Before we introduced the final implementation of the watch app, we needed to provide background knowledge on the paradigms of mobile watch apps. On the basis of the required functionalities, we designed the watch app architecture shown in Figure 8 [19]. The Pulsewatch watch application uses both types of apps that the Samsung Tizen (Samsung) Wearable OS supports: a web app, which is for the watch face application, and a native application, which is for the Pulsewatch service application—a job manager for calling the sensors to collect data or calling the algorithm to process the data. The watch face application, written in web language (ie, HTML, Cascading Style Sheets, and JavaScript), is a special type of application that runs automatically and consistently on the home screen of a watch with the Samsung Tizen Wearable OS when the watch is turned on. The watch faces shown in Figure 7 are the only apps that the participants could see. All automated procedures are described below for both native and service apps.

According to the designed functionality of the watch app (signal processing functionality in Figure 2, UI changes in Figure 7, and file transferring functionality in Figure 3), we summarize the workflow of our watch app as follows. As mentioned previously, every time the smartwatch was powered on, the

watch face application ran first, followed by the native application. The watch face color or pattern changes according to the input sent from our service application through the message port. Our service application then initialized all APIs equipped and started the AF detection procedure. A service application turns on the watch sensors through the sensor scheduler and then sends the initiated sensor status to the watch face application through the same message port. Then, the AF detection API collects and processes all sensor data and transmits the AF detection results to the watch face application through the same message port. Finally, when the 5-minute sensor-on stage is completed, the sensor scheduler turns off the sensor and updates the sensor status on the watch face application through the same message port.

Every smartwatch model was powerful enough to process the pulse signal and detect AF in near real time. The initial model of the smartwatch was Gear S3 Classic (2016). After nearly a year of heavy use in the clinical trial, the battery health of the Gear S3s degraded significantly and could not support more than 3 hours of use, and this older model was discontinued by the manufacturer. We replaced it with a Galaxy Watch 3 (41 mm; 2020) watch, which had better sensors for data collection and larger RAM and internal storage compared with Gear S3. Both Gear S3 and Galaxy Watch 3 run an open source Samsung Tizen Wearable operating system (OS) from the Linux Foundation [20], allowing researchers to have access to the original sensor data using a free open-source API without any commercial license fees to Samsung [21].

Figure 8. The architecture of the Pulsewatch smartwatch app. ACC: accelerometry; AF: atrial fibrillation; API: application programming interface; PPG: photoplethysmography; UI: user interface.



Implementation of Smartphone App

When deploying a mobile phone app, which is slightly different from the deployment of the mobile watch app, we decided to use a hybrid application [22], where we display content using the web application and then fit it inside the native application structure. The reasons for this are presented in Table 1.

We structured the relationships between pages and other content components [23] of the Pulsewatch phone app in a top-down informational architecture, as shown in Figure 9. After log-in, the user entered the home page, which consisted of 4 large buttons for 4 main categories: “My Preferences,” “Results,” “My History,” and “Get Help.” These 4 main pages can also be navigated quickly using the side menu (screenshots 10-17 in Figure 10). Details of the content displayed on each page are provided in the Multimedia Appendix 1.

The “Login,” “Results,” and “My History” pages are actually 3 web-based apps that run on the cloud server. We chose this application type mainly because the large amount and importance of the content displayed on these 3 pages led to many UI revisions. Thus, compared with using a native app paradigm, using web apps significantly reduced the developer’s burden and end user’s pain in reinstalling the apps. However, if the cloud server was shut down for maintenance, no users

could use the phone app. Therefore, it was necessary to schedule a time slot for server maintenance (eg, around 3 AM to 5 AM), because not many users were logged in and used the app during these hours.

The design of the "Login" page can shorten the dyad cleaning time (eg, removal of patient information and data) between any 2 participants in the experiment for UMass study staff. When the app was first used by a participant, the phone app required a 1-time log-in for the participants to input their UID and passwords. This process could also be performed by the study staff to reduce app use difficulties before handing out the dyad. All the data recorded from the smartwatch will be tagged with this UID. Once the experiment was finished, the UMass study coordinators were able to manually log out the current participant in the side menu from any page to prepare the dyad for the next participant. Once the current UID was logged out, the next user could not see any history of information from previous users, and the newly recorded data can be isolated from the previous data with a different UID.

Table 1. Decision of using hybrid application paradigm.

Factors	Native apps	Web apps	Requirements
Hardware features	Have all the access.	No access.	Bluetooth connection with smartwatch.
System features	Have all the access.	No access.	Push notifications and run smartphone app on the background.
UI[a] Style	Match seamlessly with the system UI.	May looks less *authentic* to users.	No strict requirement on unity with system UI.
Publishing of app	Publish on app stores such as Google Play and Samsung Galaxy app store or rely on manual installation.	In-browser web page, no installation needed.	Rely on manual installation and cannot use App Store because of study confidentiality.
App updates	Must perform reinstallation.	Remotely update the content on web page, no need for reinstallation.	As few reinstallations as possible.
Internet connection	No internet required if data were all stored locally on the phone. Content display speed is fast.	Must have internet connection. Content display speed relies on internet speed.	Should not work in offline mode, must ask user to use internet so data can be backup on the cloud.
Developing time	Lengthy as more code libraries are involved.	Fast.	As fast as possible.
Cost	High.	Low.	As low as possible.

[a]UI: user interface.

Figure 9. The information architecture of the Pulsewatch smartphone app. AFib: atrial fibrillation; HR: heart rate; UID: user ID.

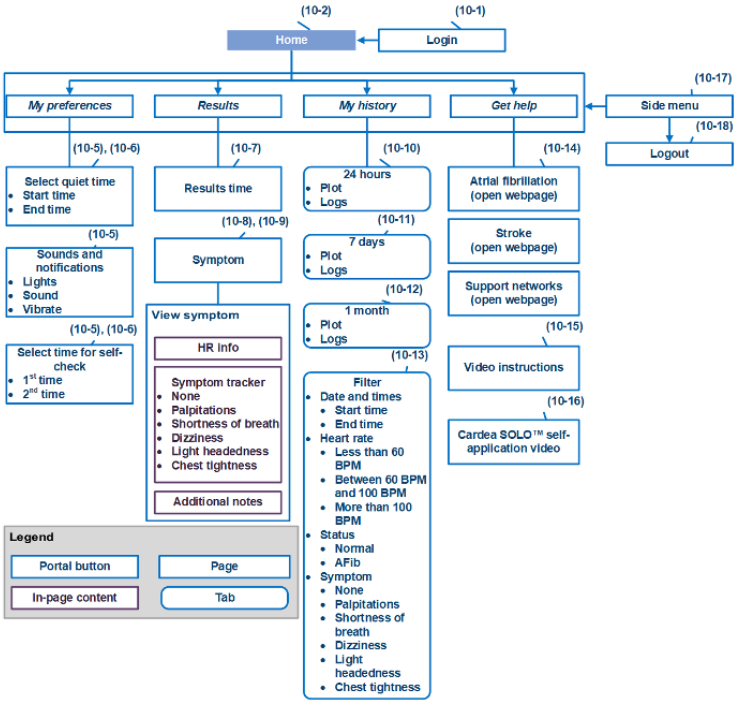
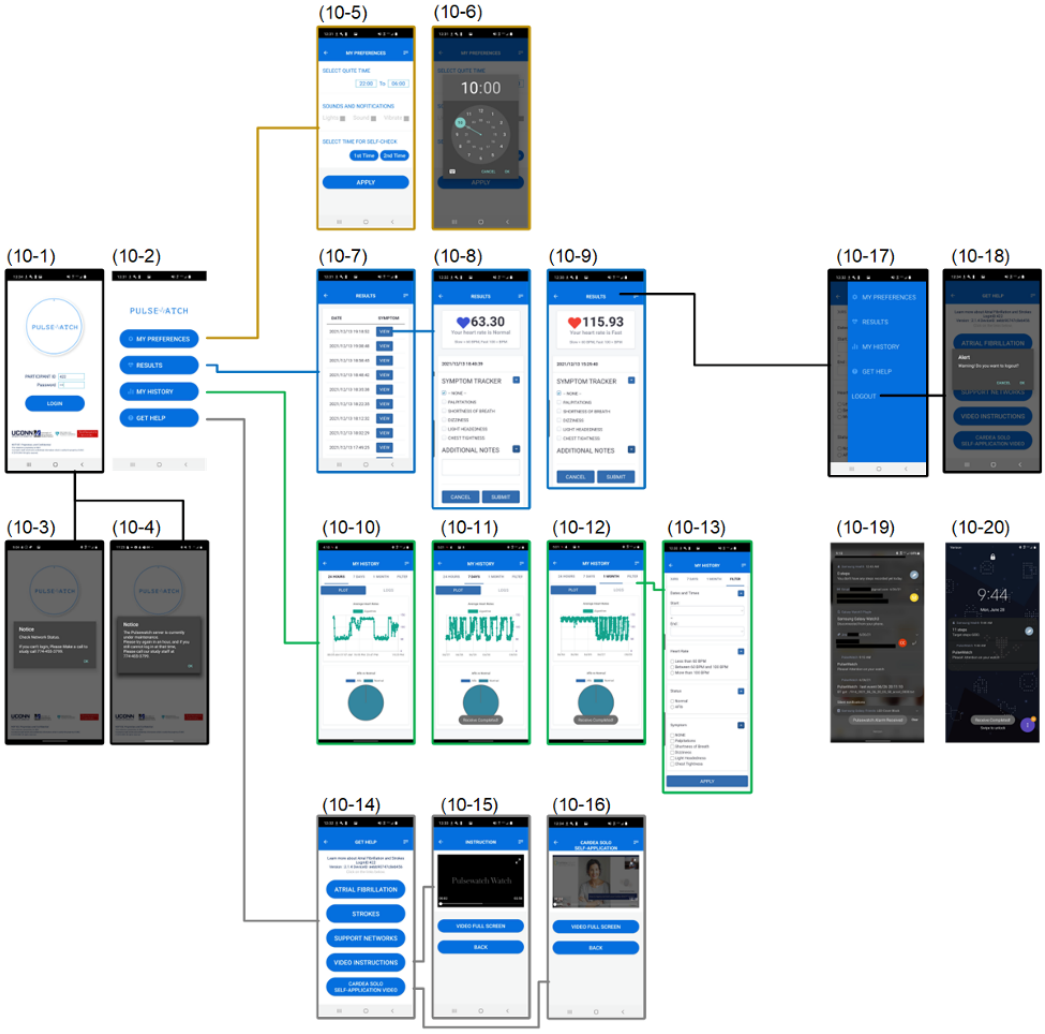


Figure 10. The final implemented web-based phone app user interface.



The “My Preferences” and “Get Help” pages are native app pages because they need access to system-level features and have to work offline. The “My Preferences” page was mainly designed to let a user set up twice daily self-check alarms. This allows users to set the time and notification types for self-check alarms. The number of acceptable prompts that Pulsewatch can deliver per day was determined by the patient focus group participants in the hack-a-thon [14]. In addition to alarm time, users could also set a do-not-disturb time to avoid unwanted interruptions from the Pulsewatch app. Notification options such as flashlights, sound, and vibration could also be turned on or off. Self-check alarms appeared in the notification center to allow the user to tap it and open our Pulsewatch phone app quickly. This alarm could be deleted using either a swipe left or right action.

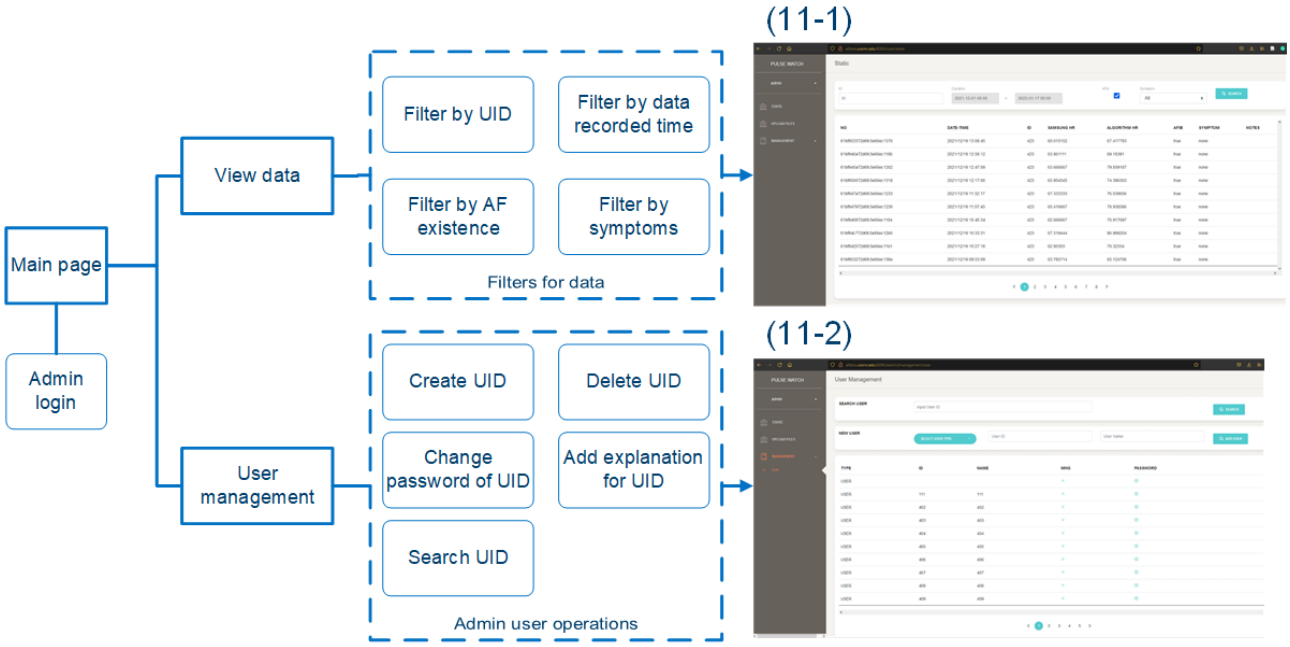
For the phone UI shown in Figure 10, a larger font size and capitalized letters were appreciated by end users [14], many of whom had visual impairments. In the phone app, a pie chart on the results page was added, as one of the participating clinicians suggested [14] that it would be important for clinicians to have a report that showed the AF burden recorded by the system.

As some active participants might wonder if the watch files were successfully uploaded to the phone, we placed a steady notification banner, using the native app structure, in the notification center to show the last time that a file was transferred from the watch to the phone. This notification banner was not visible unless the participants swiped down the notification center.

Implemented Data Tracking Website on the Cloud Server

Most electronic health records are now web and client-server–based and use relational databases [24]. Although not indispensable, it is state-of-the-art to provide a web service for clinicians and research staff to track the status of data uploading on the cloud. The details of our data tracking website are provided in Figure 11 and Multimedia Appendix 1.

Figure 11. The information architecture of the data tracking website and the final implementation of the data tracking website. AF: atrial fibrillation; UID: user ID.



Large Data Collected From the Pulsewatch System

In total, our Pulsewatch system collected 33,207,780 seconds (approximately 9224.38 h) and 182 GB of physiological recordings from the 90 participants who participated in phase 1 in the intervention group of 14 days and the 60 participants who participated in phase 2 (30 days).

For the functionality of the Pulsewatch system, as described in Figure 7, we recorded the raw PPG and ACC data for post hoc analysis because of the scarcity of smartwatch data sets for those with AF. The details of our output files from the Pulsewatch system are provided in the Multimedia Appendix 1.

As a staggering number of files were generated during the 44 days of continuous monitoring of the clinical trial, we had to consider the size of each file, as the cumulative size could be massive and pose challenges for the smartwatch, smartphone, and even the cloud server storage. The final file sizes were recorded during our clinical trial, and were found to be as large as 10 GB per participant if the Pulsewatch app was used daily. This amounts to a significantly large data storage requirement, considering that as many as 60 subjects could wear our Pulsewatch system for the entire study, lasting 44 days.

Because the quantity of data was quite substantial, we had to seek a large, long-term storage space on the cloud storage with a lower cost because the original storage space on the cloud server shown in Figure 6 is faster in read and write speed but costs much more. Details of the storage are described in Multimedia Appendix 1.

Usability of the Pulsewatch System

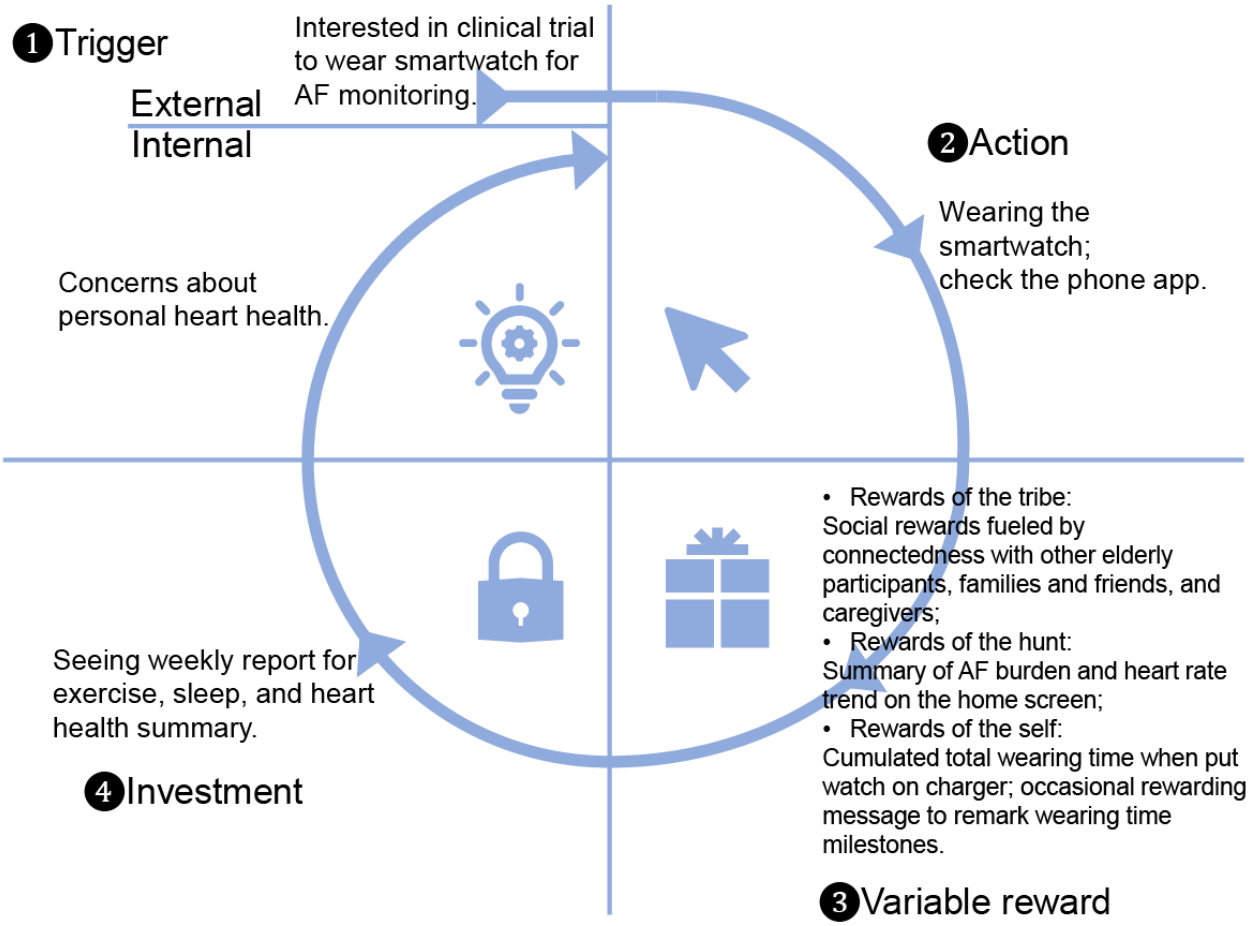
Before phase 1 started in this clinical trial, we held a hack-a-thon meeting [14] to optimize the interactivity and usability of Pulsewatch, guided by information gleaned from 2 focus groups. From the hack-a-thon, the patients unanimously agreed that the UI layout shown above for both the phone and watch was clear and preferable to other options that were discussed.

After phase 1, researchers at UMass Chan studied the human factor aspects of our Pulsewatch system by surveying 90 patients who used it [25]. The participants used the System Usability Scale to quantify usability [25]. As documented in [25], patients (n=90) who received the Pulsewatch system had an average age of 65 years, 41% (37/90) were female individuals, and 87% (78/90) were of a White racial background. The baseline characteristics of the participants can be found in Table 1 of the study by Ding et al [25]. A total of 39% (32 /83) of patients found the system to be highly usable (System Usability Scale>68; [26]). For the watch app, 64% (56/88) of patients agreed or strongly agreed that it was easy to use. When considering only the phone app, 52% (46/88) of patients agreed or strongly agreed that it was easy to use. In addition, 42% (37/88) of patients felt that using Pulsewatch made them feel more connected to their clinicians. About one-eighth of the patients thought it was stressful to use the devices (11/88, 13% patients), but more than half enjoyed their experience using the system (45/88, 51% patients) [25].

Formation of Smartwatch Wearing Habit

On the first day of phase 2, 44 out of 57 (77%) participants in the intervention group wore the smartwatch of the Pulsewatch system [27]; however, it quickly dropped to only 14 out of 57 participants (25%) on the last day of phase 2. This fading enthusiasm for wearing a smartwatch for AF monitoring suggests that engineers and clinicians must consider the burden of the Pulsewatch system before designing its functionalities and user groups. In their book [28], Eyal described the “Hook” model to build user’s habit-forming products. In Figure 12, we illustrate how to use the Hook model to increase Pulsewatch system use among the targeted older adult population.

Figure 12. The Hook model forms the habit of using the Pulsewatch system. AF: atrial fibrillation.



The Hook model consists of 4 steps to form the habit of using a new product. The first step is *trigger*, which means the actuator of a user's behavior. An external trigger could be the health caregiver approaching the participant, and an internal trigger could be the participant's concern for their health after stroke or TIA. We believe that all the enrolled participants experienced strong external and internal triggers in this study.

After the trigger comes the *action* step, which is defined as the user's behavior in anticipation of a reward. The simple action in this study was to wear the Pulsewatch watch and sporadically check the AF results on the Pulsewatch phone app. This step could be challenging because the watch battery lasted only for 8 hours of recording. Consequently, participants may have lost patience with the frequent need to charge the watch. This situation will improve if developers have root access to the OS of smartwatches to shut down irrelevant smartwatch services for better battery management, and the battery capacity will increase as technology advances.

The third step is the *variable reward*, which is the key part that we believe should be improved upon. There are 3 variable types of rewards, and we believe that we can let end users select one or more types of rewards when they start to use the phone app. For rewards of the tribe, that is, when the users prefer to be supported by a community, they can see other participants' wearing times and encourage other older adults to participate and adhere to the guidelines. If the caregivers or the users' beloved families and friends are interested in helping the users, they can also join and provide in-app encouragement to the user. The momentum of wearing a watch can be continuously driven by social connections with others.

For those users who prefer rewards of the hunt, meaning they want information-intensive material, our phone app should provide a summary of AF burden and heart rate trends on the home screen that is easy for participants to find. Providing straightforward information reduces fatigue and encourages better adherence to data collection.

For users who prefer rewards of the self, that is, the need for intrinsic rewards of mastery, competence, and completion, one of the best ways to reward is to show the cumulative wearing time every time the user places the smartwatch on its charger. This is also helpful for participants with impaired cognitive function, as we could tailor some customized audio announcements to passively inform them of their accomplishments and health status. To increase the entertainment value of self-reward, we could provide occasional pop-up rewarding messages to remark on certain milestones of wearing time.

In the last step, which is the investment step, we can introduce a weekly report to the users summarizing their daily events, including exercise, sleep, heart health, and information on the time and effort the users have invested to leverage a new round of triggers.

Discussion

Principal Findings

As one of the first studies to provide a detailed design for a smartphone-smartwatch dyad for ambulatory AF monitoring, we successfully designed and implemented an innovative smartwatch-based AF monitoring mHealth solution for the older adult population with feedback from patients with AF and their clinicians. The usability of the system indicated an increase in the acceptability of mHealth solutions among older patients with cognitive impairment.

Comparison With Prior Work

Although few manuscripts describe designs for health monitoring apps, Chae et al [29] described an approach to the design of a web-based upper limb home-based rehabilitation system using a smartwatch and smartphone for chronic stroke survivors. From the brief description of the system design by Chae et al [29], the recording of smartwatch data was initiated by touching the start button on the smartphone app, which required considerable attention from older adult patients. This was found to be difficult for the older adult participants to adhere to. Moreover, the frequency of rehabilitation exercises was as low as a few times a day; thus, the recording length was incomparable with the near-continuous recording of PPG data for AF monitoring in this study. Data processing was performed using the phone's microprocessor, and not the watch, which would be an issue for real-time AF detection if Bluetooth is disconnected. Lutze et al [30-32] designed a stand-alone smartwatch app using the Samsung Simband smartwatch to handle health hazards for older people. However, other than simple tasks such as at-home checking through Wi-Fi connection, health reminders, and emergency calling, it neither performed other complicated tasks nor collected a large amount of data. Others have attempted to design combined smartphone and smartwatch apps as a diary self-management tool for diabetics [33]. The design of the app involved diabetic patients, but because the daily diary recording was discrete, the amount of data collected was minimal when compared with our AF monitoring; hence, cloud-based storage requirements were not needed. None of the above studies could provide a solution for freeing storage after recording a large amount of data, which is crucial for long-term monitoring, as storage space is limited in smartwatches (<8 GB).

Limitations

The Pulsewatch system was designed to collect data for long-term monitoring, and the smartwatch file transfer process proceeded smoothly when the Bluetooth connection between the smartwatch and the smartphone was stable. However, several issues were encountered. For example, our longest recording streak among all participants was only 21 days during the combined 44 days of the phase 1 and phase 2 experiments. This was caused by improper functioning of the smartphone app during the 30-day phase 2. For example, the smartphone app could be terminated by the smartphone OS because of high battery consumption, or the participants may have their own smartphone device; therefore, they tend to forget to carry the study phone to maintain the Bluetooth connection of the Pulsewatch system. Consequently, the storage of the smartwatch became full, resulting in the loss of newly recorded information. In the future, smartwatch apps should have a data loss prevention mechanism when the watch storage is full. If the smartwatch app notices that the user has not maintained Bluetooth connectivity, and no files are uploaded to the smartphone for more than 3 or 4 days, it should automatically start a procedure to compress all existing files into a zip file, followed by deleting the original files to free up the data storage space. With this approach, we can save approximately 80% of the storage space, as the compression ratio for text files can be as high as 80% [34]. If this data compression functionality is implemented in the future, even without a Bluetooth connection to the phone, the Gear S3 smartwatch could record 24 days of data, and the Galaxy Watch 3 could record 64 days of data.

When we calculated the wearing time after the clinical trial was finished, we found that although obvious signs of wearing (eg, step counts) were observed in the Samsung Health smartwatch data, our Pulsewatch did not record any data. This could be caused by several factors, including full smartwatch storage. Although our watch app was tested to continuously and automatically operate on the watch, users could still terminate the running of our Pulsewatch app. Users can terminate our Pulsewatch app if they long press the watch face and switch to another built-in watch face. They could even accidentally delete our Pulsewatch app after long press the watch face. The Samsung Tizen Wearable OS has a battery use monitor, and it often asks users to stop running smartwatch apps that drain the battery. Furthermore, it automatically asks users to enter the *power saving* mode when the remaining battery is <20%. This power-saving mode is problematic because it terminates the operation of all third-party apps. Unless the watch is rebooted, our Pulsewatch app cannot automatically rerun again, even if users exit this mode after charging the watch. The Pulsewatch App must be active for rhythm detection, which has important implications for monitoring AF over an extended period.

In addition to wearing our Pulsewatch system, participants were also asked to wear the US Food and Drug Administration–approved, Cardea SOLO Wireless ECG Patch (Cardiac Insight). This served as the gold standard reference in phase 1 of the clinical trial to validate the accuracy of the AF monitoring algorithms for PPG. It should be noted that including a sample-level timestamp is crucial for any wearable system, especially on the reference device, as it is used to validate the accuracy of PPG data, such as peak detection comparison or heart rate variability analysis between the 2 devices. We added the sample-level timestamp for the Pulsewatch system after realizing that this capability was not enabled in the reference device when we enrolled 35 participants. Finally, we obtained the precise sample-level timestamp from the Cardiac Insight during the secondary analysis. Details of the sample-level timestamp issues are provided in Multimedia Appendix 1.

Clinical Prospects

In this study, we detail potential issues in the design, development, and execution of a clinical trial that implements a novel digital health care system designed to monitor older stroke survivors for potential AF. The technical challenges

encountered during the design and deployment process outlined in this study provide a foundational blueprint for future work in the area, both in research and clinical spaces, allowing for a more streamlined resource allocation and data management. In turn, this would lead to an improvement in patient outcomes. Our study also illustrated a successful and agile shift to internet-based recruitment in the context of the COVID-19 pandemic, providing a poignant example of how to adapt clinical trial protocols while maintaining data integrity and patient safety. Our study will enrich a diverse and inclusive pipeline of digital health and informatics professionals to address new pandemic-induced public health, medical, and scientific issues.

Conclusions

As one of the first studies to provide a detailed design for a smartphone-smartwatch dyad for ambulatory AF monitoring, our team of engineers, programmers, clinicians, and patients successfully designed a system that has been used in a randomized clinical trial. The reported usability of our Pulsewatch system may increase the acceptability of mHealth solutions among older adult patients with cognitive impairment. Our proposed mHealth system overcomes some of the limitations of many prior devices for long-term AF monitoring. The Pulsewatch app was rated highly usable by over half of the stroke survivors in our study. All AF detection was performed solely on the smartwatch, and the smartphone served as a data transfer hub between the cloud and smartwatch. Clinicians organized the participant UIDs on the cloud and checked the collected data, including symptoms and notes logged by the participants on the Pulsewatch phone app. The Pulsewatch system successfully recorded raw data for subsequent data mining and machine-learning applications for AF detection.

Acknowledgments

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Data Availability

The data collected from the Pulsewatch study are in the analysis phase; therefore, access to the data will be available once the study is completed. Once all data analyses have been completed, we will release the data to the public on our laboratory's website [35]. The smartwatch and smartphone apps contain patented algorithms developed by the authors; therefore, they are not available on Google App stores or any open-source code repository.

Conflicts of Interest

EYD was supported by F30HL149335 from the National Heart, Lung, and Blood Institute. K-VT was supported by K23HL161432 from the National Heart, Lung, and Blood Institute. KHC was supported by R01 HL137734. DDM was supported by R01HL126911, R01HL137734, R01HL137794, R01HL135219, R01HL136660, U54HL143541, and 1U01HL146382 from the National Heart, Lung, and Blood Institute; and reports receiving honorary fees, speaking and consulting fees, or research grants from FLEXcon, Heart Rhythm Society, Rose Consulting, Bristol Myers Squibb, Pfizer, Boston Biomedical Associates, Avania, VentureWell, Samsung, Phillips, CareEvolution, Boehringer Ingelheim, Biotronik, Otsuka Pharmaceuticals, and Sanofi, and declares financial support for serving on the Steering Committee for the GUARD-AF study (ClinicalTrials.gov identifier NCT04126486) and the Advisory Committee for the Fitbit Heart Study (ClinicalTrials.gov identifier NCT04176926). He also reports nonfinancial research support from Apple and Fitbit. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Details of the implementation of the Pulsewatch system.
[DOCX File , 1401 KB - cardio_v7i1e41691_app1.docx]

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Abbreviations

ACC: accelerometry
AF: atrial fibrillation
API: application programming interface
ECG: electrocardiogram
mHealth: mobile health
OS: operating system
pAF: paroxysmal atrial fibrillation
PPG: photoplethysmography
TIA: transient ischemic attack
UI: user interface
UID: user ID
UMass Chan: University of Massachusetts Chan Medical School

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Original Paper

Accuracy, Usability, and Adherence of Smartwatches for Atrial Fibrillation Detection in Older Adults After Stroke: Randomized Controlled Trial

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Abstract

Background: Atrial fibrillation (AF) is a common cause of stroke, and timely diagnosis is critical for secondary prevention. Little is known about smartwatches for AF detection among stroke survivors. We aimed to examine accuracy, usability, and adherence to a smartwatch-based AF monitoring system designed by older stroke survivors and their caregivers.

Objective: This study aims to examine the feasibility of smartwatches for AF detection in older stroke survivors.

Methods: Pulsewatch is a randomized controlled trial (RCT) in which stroke survivors received either a smartwatch-smartphone dyad for AF detection (Pulsewatch system) plus an electrocardiogram patch or the patch alone for 14 days to assess the accuracy and usability of the system (phase 1). Participants were subsequently rerandomized to potentially 30 additional days of system use to examine adherence to watch wear (phase 2). Participants were aged 50 years or older, had survived an ischemic stroke, and had no major contraindications to oral anticoagulants. The accuracy for AF detection was determined by comparing it to cardiologist-overread electrocardiogram patch, and the usability was assessed with the System Usability Scale (SUS). Adherence was operationalized as daily watch wear time over the 30-day monitoring period.

Results: A total of 120 participants were enrolled (mean age 65 years; 50/120, 41% female; 106/120, 88% White). The Pulsewatch system demonstrated 92.9% (95% CI 85.3%-97.4%) accuracy for AF detection. Mean usability score was 65 out of 100, and on average, participants wore the watch for 21.2 (SD 8.3) of the 30 days.

Conclusions: Our findings demonstrate that a smartwatch system designed by and for stroke survivors is a viable option for long-term arrhythmia detection among older adults at risk for AF, though it may benefit from strategies to enhance adherence to watch wear.

Trial Registration: ClinicalTrials.gov NCT03761394; https://clinicaltrials.gov/study/NCT03761394

International Registered Report Identifier (IRRID): RR2-10.1016/j.cvdhj.2021.07.002

(JMIR Cardio 2023;7:e45137) doi:10.2196/45137

KEYWORDS

accuracy; atrial fibrillation; cardiac arrhythmia; design; detection; diagnosis; electrocardiography; monitoring; older adults; photoplethysmography; prevention; remote monitoring; smartwatch; stroke; usability

Introduction

Atrial fibrillation (AF) is a common heart rhythm disorder that affects over 6 million Americans and more than 30 million individuals worldwide [1,2]. Individuals diagnosed with AF are at increased risk for myriad adverse health outcomes, including dementia, heart failure, and myocardial infarction [3]. AF is associated with a 5-fold increase in ischemic stroke risk, and AF-related strokes are clinically more severe than those not associated with AF [4]. Oral anticoagulation is highly effective for stroke prevention in AF patients [5]. Unfortunately, nearly one-fifth of the strokes attributable to AF are diagnosed at the time of stroke presentation, highlighting a critical need for improvement in AF detection [6].

Over the last decade, consumer wearable technologies capable of detecting AF have transformed how health care providers and their patients diagnose and manage heart rhythm disorders [7,8]. Several large-scale observational studies, including the Apple Heart Study, Huawei Heart Study, Fitbit Heart Study, and Health eHeart Study, have shown that, in large groups of smartwatch owners, a wearable can offer moderate-to-vigorous accuracy for detecting AF [9-12].

Despite the large number of participants in these studies, relatively few participants were at high risk for AF based on age or comorbidities. Furthermore, all participants were existing smartwatch owners, limiting the generalizability to most older populations in which digital technologies are less commonly used [13,14]. Stroke survivors have a significantly increased risk of having undiagnosed AF than the general population, yet no previous study has examined the use of smartwatches in older stroke survivors [15]. Additionally, stroke survivors often have physical and cognitive impairments, like loss of vision, that may limit smartwatch adoption or impede successful use.

We present the primary findings of the Pulsewatch study (NCT03761394), a randomized trial conducted to evaluate the accuracy and usability of a novel smartwatch-smartphone dyad designed for AF detection among stroke survivors. The Pulsewatch smartphone and smartwatch app were designed on the Android operating system by researchers with significant patient and provider input. The primary aims of this study were to (1) examine the accuracy and usability of a smartwatch for the detection of AF over 14 days compared with a comparator standard electrocardiogram (ECG) patch monitor and (2) describe the extent of adherence to wearing a smartwatch throughout the monitoring period.

Methods

Study Population and Setting

All participants were enrolled from ambulatory neurology and cardiovascular clinics affiliated with the University of Massachusetts Memorial Health Care (UMMHC), an academic tertiary care center in central Massachusetts, from September 2019 to August 2021. Ambulatory patients were eligible for participation if they were aged 50 years or older, had a history of ischemic stroke or transient ischemic attack (TIA) within the past decade, were willing to use the Pulsewatch system for at least 44 days, and were proficient in written and spoken English. Exclusion criteria included an absolute contraindication to the receipt of anticoagulation therapy (ie, major intracranial hemorrhage), the inability to provide informed consent, a known allergy or hypersensitivity to medical-grade hydrocolloid adhesives or hydrogel, the presence of a life-threatening arrhythmia that required in-patient monitoring for immediate analysis, and having an implantable pacemaker.

Study Design

The Pulsewatch study is a clinical trial with 2 phases, both involving randomized assignment of participants to intervention versus control. The first phase is designed to evaluate Pulsewatch system accuracy versus a comparator standard (a 14-day ECG patch) and usability, followed by a second 30-day phase intended to evaluate adherence to wearing the smartwatch daily as the primary study outcome. The Pulsewatch study protocol, including more detailed calculations with regard to sample size and randomization, has been described previously [16].

Study Procedures

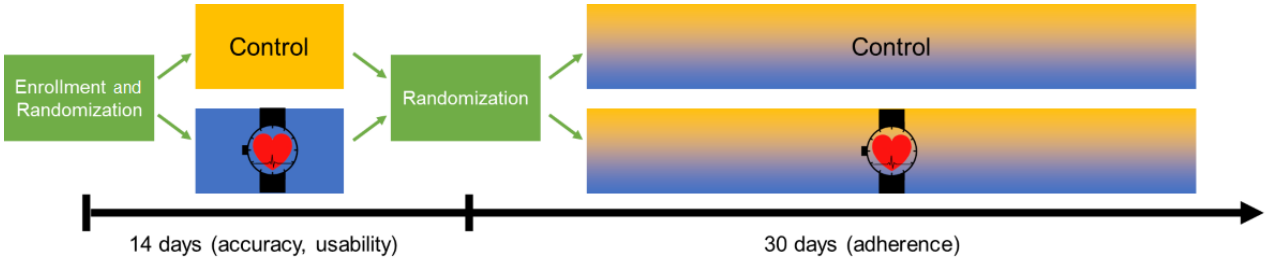
Trained research staff screened electronic medical records for eligible patients with upcoming neurology and cardiology clinic appointments from September 2019 to May 2021. An invitation letter providing a description of the Pulsewatch study as well as contact information was mailed to all participants in case they wished to ask questions or opt out of the study. Patients were then approached in person by research coordinators at the time of their ambulatory clinic visit to gauge interest in the study and obtain informed consent, if appropriate. Upon enrollment, participants were asked to complete a baseline questionnaire and were then randomized to either the control or intervention groups in a 1:3 ratio. The random allocation sequence was generated a priori by statisticians, to which all other study staff were blinded. Both groups received a comparator standard US Food and Drug Administration (FDA)–cleared ECG patch (Cardea Solo, Cardiac Insight) and were asked to wear the patch daily over 14 days, whereas participants in the intervention group received the same ECG patch and instructions for use plus a Pulsewatch system (Samsung Gear S3 or Galaxy Watch 3 with accompanying Samsung smartphone). Participants were asked to wear the smartwatch daily and to keep the smartwatch and smartphone charged regularly. Research staff provided training to all intervention group participants, as well as to any caregiver or family member who accompanied the participant to the study visit, and all participants were provided a training packet with detailed instructions for the successful use of the patch and the Pulsewatch system (Multimedia Appendix 1).

During the 14-day follow-up period for phase 1 of the study, research staff contacted participants on days 3 and 7 to

encourage the use of the Pulsewatch system, address any questions or concerns expressed by participants, and troubleshoot any technical challenges the participant may be experiencing. This training was designed to improve wear time and ensure adequate sampling to evaluate the accuracy of the Pulsewatch system.

Upon completion of the 14-day follow-up period, participants returned for a study visit, at which time they completed a follow-up questionnaire to assess key domains, including device use experience and a multitude of psychosocial factors, and those in the intervention arm were asked about their experience with the smartphone, app, and smartwatch. At this time, all participants, irrespective of their initial assignment to intervention or control, were randomized in a 1:1 fashion to be provided the Pulsewatch system for an additional 30 days. This 30-day follow-up period was designed to evaluate longer-term adherence to smartwatch use. During this phase of the study, the research staff did not initiate any calls with participants. The staff did, however, provide advice and instructions to participants who called the study hotline during the follow-up period. An overview of the study design is presented in Figure 1.

Figure 1. Pulsewatch study design and randomization process.



Pulsewatch System

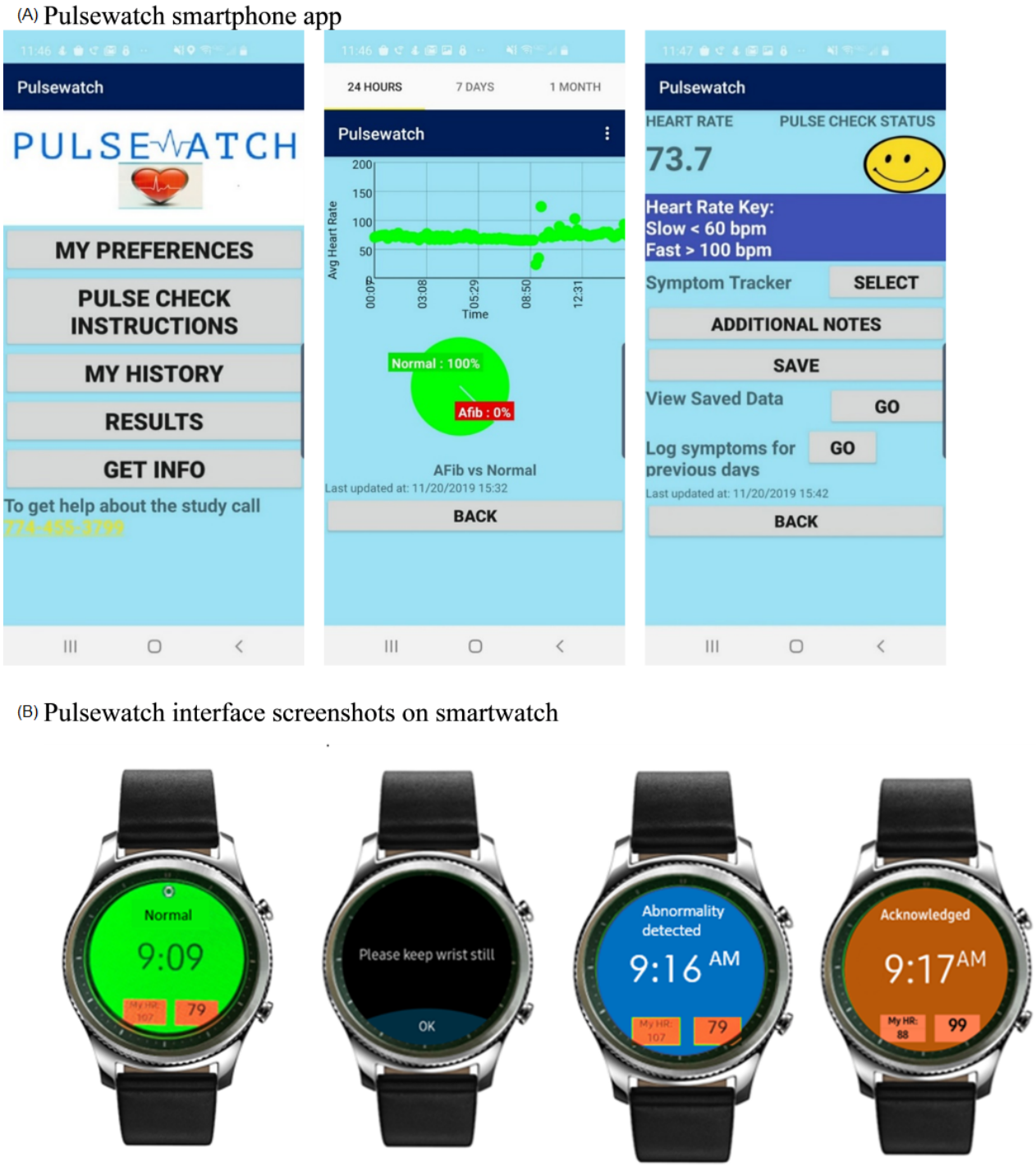
The Pulsewatch system consists of 2 apps developed for the Android operating system for use on the Samsung smartphone and smartwatch. The Pulsewatch user interface was designed through an iterative process involving participants who consented to participate in focus groups and a Hack-a-thon. Participants included stroke survivors, their caregivers, and health care providers. Development and programming took place over the course of a year, and 4 focus groups were held with patients and their caregivers. During these sessions, iterations of the app interface were presented to the participants to elicit their feedback and refine the app for better usability.

Upon completion of the focus groups, additional patients and their caregivers, together with local cardiologists, cardiac electrophysiologists, stroke neurologists, and the primary engineering and app development teams, were invited to a day-long programming event where participants reviewed the prototype app, offered their perspectives, and made suggestions for improvement.

The final version of the Pulsewatch smartwatch app shows the user their heart rate, the time, and their rhythm status based on the recordings of the participants' pulse (5-minute recordings are used to assess rhythm). If at least 90 consecutive seconds of potential AF are detected during a 5-minute detection window, the watch app displays an alert asking the user to "please stay still" along with an accompanying audio or vibration notification. After this alert, if another 60 consecutive seconds of AF are detected, the user is presented with an alert on the watch that reads "abnormality detected." This approach was designed to reduce the likelihood of motion noise artifact simulating AF and the number of false positives among participants. "Abnormality detected" was our primary outcome, indicating Pulsewatch's detection of AF.

The Pulsewatch smartphone app pulls pulse data from the smartwatch, allows users to label arrhythmia episodes with any symptoms they may be experiencing, provides informational links regarding AF, and allows participants to review their heart rate ranges. Screenshots from the final version of the smartphone and smartwatch apps are presented in Figure 2.

Figure 2. Representative screenshots of Pulsewatch apps.



Study Measures and Primary Outcomes

Participant demographic characteristics and medical history information were abstracted from the electronic medical record by trained research staff. Accuracy of the smartwatch's "abnormality detected" (or AF detection) was determined by comparing whether a participant received any AF alerts over the 2-week monitoring period compared to whether AF was adjudicated as present based on a cardiologist's over-read of all possible AF episodes detected on the FDA-cleared ECG patch monitor. Raw ECG data from these patches were extracted, and each episode categorized as AF by the patch monitor's built-in FDA-approved AF detection algorithm was divided into 30-second segments. Each 30-second segment was reviewed by a noncardiologist physician (SN), and those determined to be potentially AF were reviewed by a board-certified cardiologist (MFG) for confirmation. Any segments on which the reviewers disagreed were reviewed by another board-certified cardiologist (KVT) as a tiebreaker. If any participant failed to wear the Pulsewatch smartwatch during the 14-day study period, they were excluded from the device accuracy analysis.

Usability was measured at the 14-day study examination by the System Usability Scale (SUS), a validated scale ranging from 0 to 100, with scores of 68 or greater indicating high usability, and investigator-generated Likert scale usability questions specific to smartwatch use [17]. Pulsewatch system adherence was defined by the number of hours of daily smartwatch wear time over the 30-day monitoring period. Participants were considered to have worn the watch during a given hour if they had either more than 50 recorded steps or any heart rate data recorded during that hour. Mean wear time was calculated for each day of the study, and daily adherence was operationalized in 2 ways: wearing the watch for at least 1 hour and wearing the watch for at least 5 hours.

COVID-19 Protocol Adaptations

Due to the unprecedented challenges presented by the COVID-19 pandemic, this study protocol was adapted in June 2020 and approved by the Institutional Review Board to be performed entirely through remote means to ensure the safety of study participants, research staff, and clinic staff. All in-person study visits were replaced by phone encounters, including informed consent, enrollment, baseline visit, and follow-up visits for both phases of the study. All participants approached after June 2020 were given the option of interfacing with study staff in person per the original study protocol or entirely remotely as described above. The only questionnaire that could not be administered over the phone as it was in person was the Montreal Cognitive Assessment (MoCA) [18]. A validated version of the MoCA designed for administration through telephone was administered to assess patients' cognitive status as part of our COVID-19 protocol [19].

Data Management

Deidentified pulse data collected from the smartwatches were transferred to the paired smartphone through Bluetooth in real time, and these data were transmitted to secure study servers for storage. All patient identifiers, questionnaire data, and information extracted from medical records were stored on Health Insurance Portability and Accountability Act (HIPAA)–compliant secure servers at UMMHC.

Data Analysis

Descriptive statistics were calculated for all participant demographic, medical history, and psychosocial characteristics. The performance of the Pulsewatch system for AF detection was determined at the individual participant level and presented as sensitivity, specificity, and accuracy compared to the comparator standard. For usability questions, Likert scale responses of "strongly agree" and "agree" were collapsed, as were responses of "strongly disagree" and "disagree." Descriptive statistics of usability questions were calculated. Overall device wear time in hours was quantified for each participant and descriptive statistics were calculated. A Cuzick rank sum test for the trend of ordered groups was used to assess the linear trend in daily adherence (binary outcome). All analyses were completed using Stata 14.0 and SAS 9.3.

Ethics Approval

Pulsewatch has been approved by the UMass Chan IRB (Approval Number H00016067). Written informed consent was collected from all participants, and all study data has been deidentified. Study participants were compensated US $100 for their participation in phase 1, then another US $100 for phase 2. A small convenience sample of participants was selected for qualitative interviews about their experience in the study and compensated US $60 for their time.

Results

Overview

A total of 90 participants were randomized into the intervention arm of phase 1 of the trial and 57 into the phase 2 intervention group. The average age of study participants in the first phase was 65.1 (SD 9.3) years, 41% (37/90) were female, most were non-Hispanic White (78/90, 87%), 56% (46/82) were college graduates, and 35% (27/77) had an income higher than US $100,000. More than 3 out of 4 participants had been previously diagnosed with hypertension and hyperlipidemia, and 2 out of every 5 were cognitively impaired. Most owned smartphones (74/89, 83%) and engaged with apps on their devices daily (54/80, 68%), though a much smaller proportion of participants owned smartwatches (22/89, 25%). The characteristics of participants randomized into the phase 2 intervention group were similar. Participant characteristics are further detailed in Tables 1 and 2.

Table 1. Baseline medical characteristics of study participants randomized to use the Pulsewatch smartphone app and smartwatch.

Demographics	Phase 1 (n=90)	Phase 2 (n=57)
Age (years), mean (SD)	65.1 (9.3)	64.1 (8.8)
Female, n (%)	37 (41)	22 (39)
Race, n (%)		
White	78 (87)	52 (91)
More than one race	6 (7)	2 (4)
Black	1 (1)	1 (2)
Asian or Pacific Islander	1 (1)	1 (2)
Other	4 (4)	1 (2)
Non-Hispanic ethnicity, n (%)	87 (97)	57 (100)
Married or living as married, n (%)	61 (69)	37 (66)
Education, n (%)		
Less than high school	4 (5)	3 (5)
High school degree or equivalent	38 (43)	24 (44)
College degree	28 (32)	15 (27)
Postgraduate degree	18 (20)	14 (25)
Income (US $)		
Less than 50,000	29 (35)	15 (29)
Between 50,000 and 99,999	27 (33)	18 (34)
More than 100,000	27 (33)	19 (37)
Medical history, n (%)		
History of ischemic stroke	71 (79)	46 (81)
History of TIA[a]	26 (29)	18 (32)
Congestive heart failure	6 (7)	4 (7)
Cardiac arrhythmias	12 (13)	8 (14)
Valvular disease	9 (10)	9 (16)
Hypertension	70 (78)	41 (72)
Chronic pulmonary disease	7 (8)	7 (12)
Diabetes	25 (28)	7 (12)
Vascular disease	24 (27)	13 (23)
Renal disease	4 (4)	3 (5)
Previous major bleed	5 (6)	5 (9)
Previous MI[b]	16 (18)	10 (18)
Hyperlipidemia	77 (86)	48 (84)
Sleep apnea	25 (28)	14 (25)
Percutaneous coronary intervention	11 (12)	6 (11)
Medication use, n (%)		
Antiarrhythmic	2 (2)	1 (2)
Beta blocker	40 (44)	19 (33)
Calcium channel blocker	62 (69)	42 (74)
Anticoagulant	11 (12)	12 (21)
Antihypertensive	51 (57)	31 (54)

Demographics	Phase 1 (n=90)	Phase 2 (n=57)
Antiplatelet	79 (88)	45 (79)
Statin	82 (91)	53 (93)
Vitals, mean (SD)		
BMI	32 (21)	30 (10.3)
Systolic BP[c]	131.4 (16.7)	129.4 (15.2)
Diastolic BP	76 (8.6)	75.8 (9.4)
Heart rate	73.1 (14.7)	74.8 (13.9)

[a]TIA: transient ischemic attack.

[b]MI: myocardial infarction.

[c]BP: blood pressure.

Table 2. Psychosocial characteristics of study participants randomized to use the Pulsewatch smartphone app and smartwatch.

Characteristics	Phase 1, n (%)	Phase 2, n (%)
Residual neurological deficit	28 (31)	17 (30)
Alcohol use	7 (8)	5 (9)
Cognitive impairment[a]	26 (30)	19 (34)
Vision impairment	48 (54)	23 (40)
Hearing impairment	26 (29)	16 (28)
Depressive symptoms		
None (0-4)	49 (54)	32 (56)
Mild (5-9)	27 (30)	19 (33)
Moderate (10-14)	8 (9)	3 (5)
Moderately severe (15-19)	3 (3)	2 (4)
Severe (>20)	3 (3)	1 (2)
Anxiety symptoms		
None or minimal (0-4)	62 (69)	37 (65)
Mild (5-9)	16 (18)	12 (21)
Moderate (10-14)	7 (8)	6 (11)
Severe (>15)	5 (6)	2 (4)
Technology engagement		
Device ownership		
Tablet	60 (67)	42 (74)
Smartphone	74 (83)	48 (84)
Smartwatch	22 (25)	18 (32)
Basic cellphone (SMS-enabled)	30 (34)	14 (25)
App use frequency (excluding call or text)		
Daily	54 (68)	36 (72)
A few days a week	12 (15)	4 (8)
At least once a week	5 (6)	4 (8)
Less than once a week	2 (3)	1 (2)
Once a month	3 (4)	2 (4)
Never	4 (5)	3 (6)

[a]Montreal Cognitive Assessment (MoCA) <23 for in-person, <17 for phone version.

Atrial Fibrillation Burden

AF was detected in 6 out of the 90 participants (incidence 6.67%). Participants with AF detected varied widely with regard to the number of episodes and the total AF burden (time spent in AF), ranging from a minimum of 2 episodes lasting a total of 16 minutes to 5012 episodes lasting a total of 1712 minutes (Table 3). However, despite this wide variation in total AF, the length of the longest episode was less than 30 minutes in duration (mean 14.6, SD 8). Notably, 1 participant did not wear the watch at all and was thus excluded from subsequent accuracy analysis.

Table 3. Burden of atrial fibrillation (AF) detected in participants in Pulsewatch.

Participant ID	AF episodes, n (%)	Total AF burden (minutes)	Longest AF episode (minutes)
005	2 (0)	16	9.6
017	400 (2)	451	20.5
026	1133 (3)	322	5
051	5012 (15)	1712	10.1
075	215 (5)	426	26.8
082	9 (0)	52	15.7

Accuracy

The Pulsewatch system detected AF correctly in 3 out of the 5 participants who were determined to have AF by cardiologist overread of the ECG patch monitors (60% sensitivity, 95% CI 14.7-94.7) and correctly indicated no AF in 76 of the 80 participants determined to be free from AF based on cardiologist overread of the ECG patch monitors (95% specificity, 95% CI 87.7-98.6). Overall, the smartwatch exhibited an accuracy of 92.9% for AF identification in our 14-day study (Tables 4 and 5).

Although a participant may be wearing the watch, the Pulsewatch app may not have been constantly running in the background, most often due to accidental termination of the app by the participant or activation of power-saving mode to conserve battery. Thus, active rhythm recording did not occur for the entirety of watch wear time for all participants. Accuracy analysis is therefore limited to the duration that the Pulsewatch app was on and recording pulse (Table 3).

Table 4. Smartwatch-detected atrial fibrillation (AF) compared with an electrocardiogram (ECG) patch over 2-week monitoring period.

	ECG patch, n		Total
	AF	No AF	
AF alerts on smartwatch, n			
Alerts	3	4	7
No alerts	2	76	78
Total	5	80	85

Table 5. Accuracy of smartwatch-detected atrial fibrillation (AF) compared with an electrocardiogram (ECG) patch.

Statistic	Value (%) (95% CI)
Sensitivity	60 (14.7-94.7)
Specificity	95 (87.7-98.6)
Positive predictive value	42.9 (18.5-71.2)
Negative predictive value	97.4 (92.8-99.1)
Accuracy	92.9 (85.3-97.4)

Usability

The average Pulsewatch SUS was 62.8 out of a possible 100, and 37.5% (33/88) of participants reported the system as highly usable (SUS ≥68). When asked about the watch and phone apps separately, 63.6% (56/88) of participants agreed or strongly agreed that the watch app was easy to use, while 52.3% (46/88) indicated the same for the phone app. Around 42% (37/88) of participants agreed or strongly agreed that using the Pulsewatch system made them feel more connected to their doctor. Most participants did not experience anxiety or worry because of using the Pulsewatch system (60/88, 68.2% disagreed or strongly disagreed), and 58% (51/88) of participants indicated a willingness to use the system daily for 6 months for heart rhythm monitoring. Overall, more than one-half of participants, 51.1% (45/88), agreed or strongly agreed with the statement that they enjoyed using the system over the course of the study. All 90 participants who used the Pulsewatch system

indicated that they would be comfortable allowing their doctors access to health information collected by this device.

Participant Adherence to Smartphone App and Smartwatch Use Over the 30-Day Phase 2 Period

During the second phase of the study, participant adherence remained steady overtime (Figure 3). Initially, 73% (37/51) of participants wore the watch, while on day 30, this slightly decreased to 63% (32/51) of participants (Figure 4A) ($P<.05$). Similarly, about 55% (28/51) of participants wore the watch for at least 5 hours on day 30 of the study (Figure 4B). Participants wore the watch for 21.2 (SD 8.3) days (out of the 30 possible days), but they kept the watch on for the majority of waking hours during those days (average 11.5, SD 5.1 hours).

Figure 3. Distribution of days of watch wear over course of study.

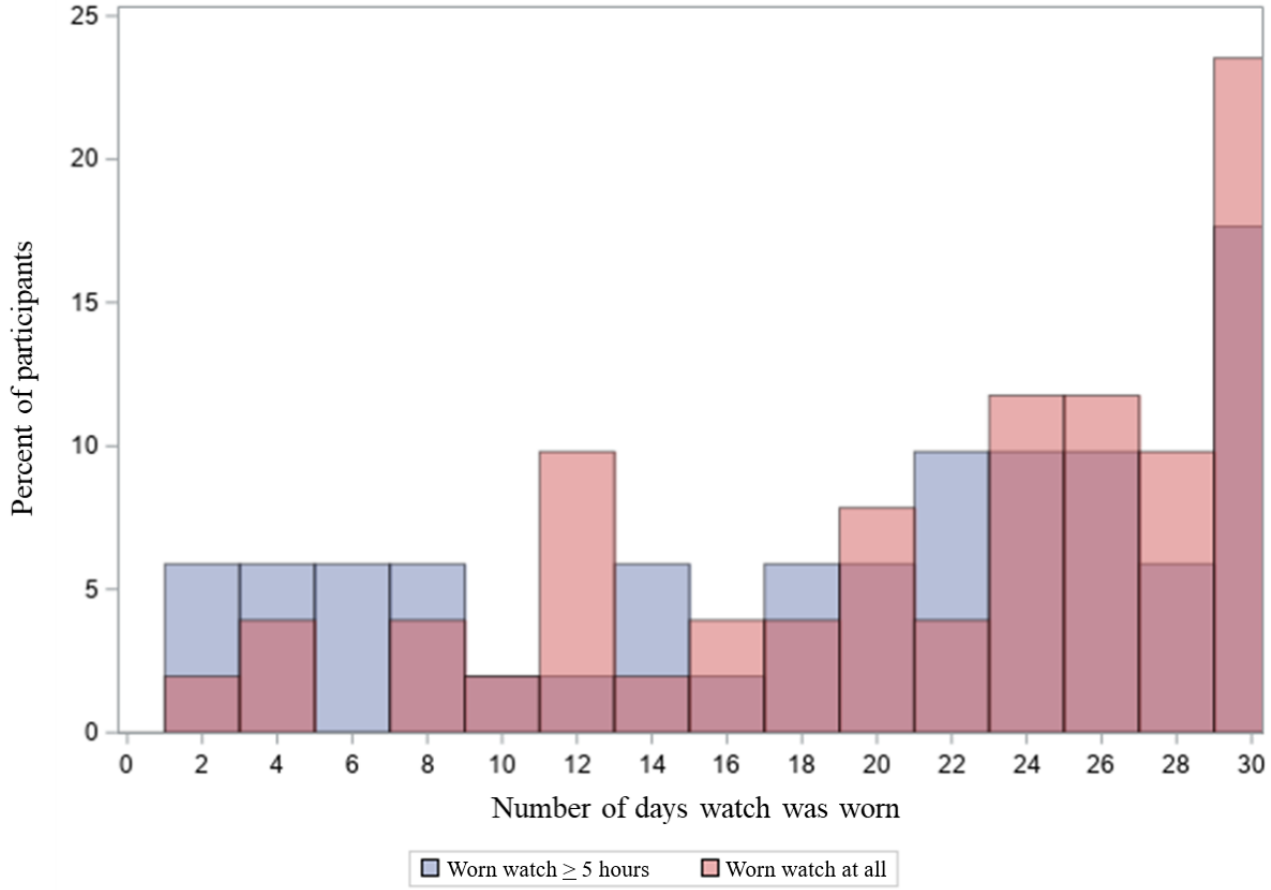
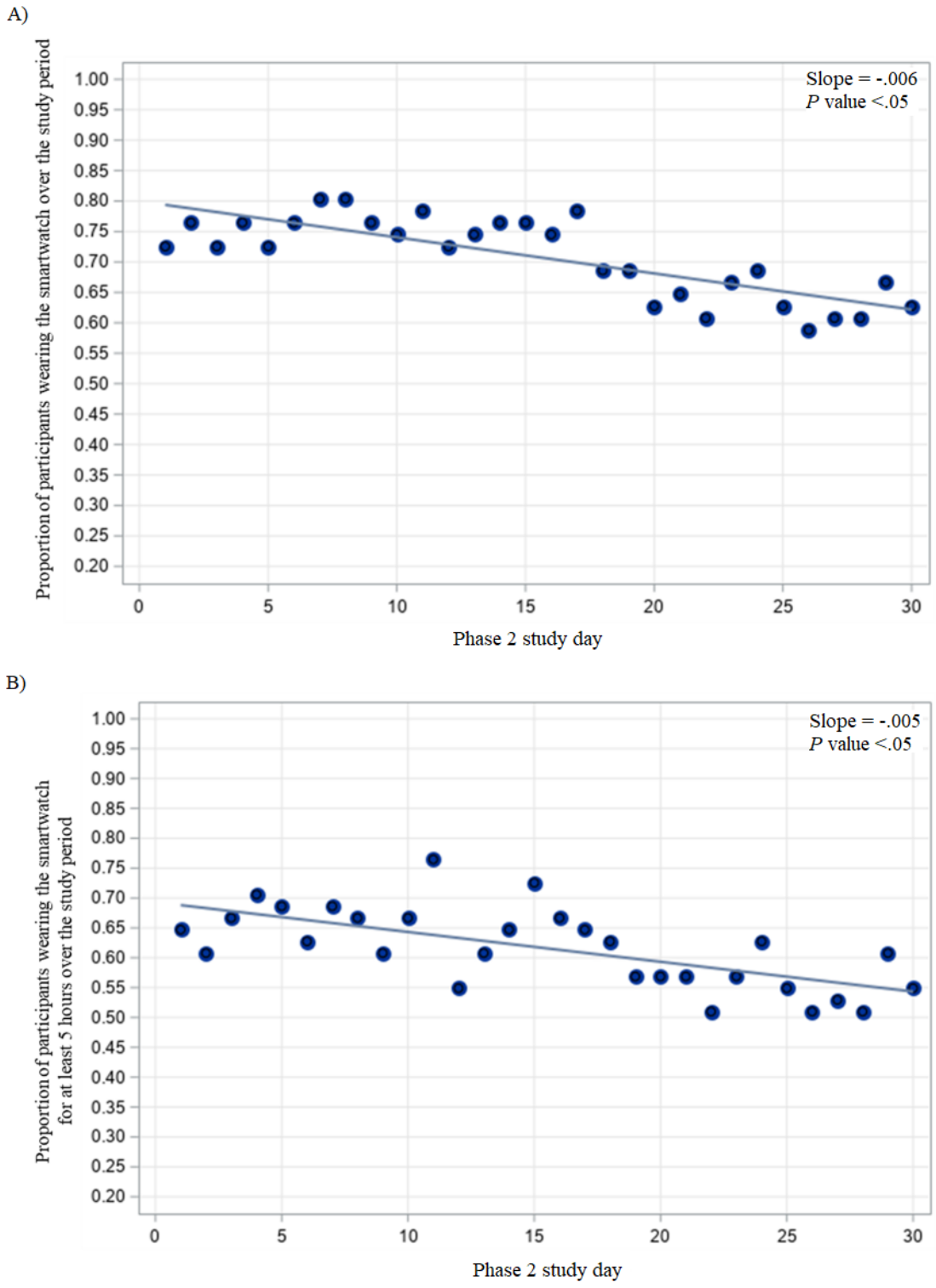


Figure 4. Proportion of participants wearing the Pulsewatch smartwatch (A) at all or (B) over 5 hours on each day of the 30-day phase 2 follow-up period.



Discussion

Overview

In this manuscript, we describe the accuracy and usability of a novel smartphone-app smartwatch system for detecting undiagnosed AF designed with and for stroke survivors. Compared to a gold-standard cardiologist's over-read of ECG patch recordings, the Pulsewatch app and smartwatch dyad demonstrated 93% accuracy at the participant level over the 2-week monitoring period. Approximately half of the participants found the Pulsewatch system to be highly usable, and over half of the participants reported that they would be interested in using the smartphone-app smartwatch for AF monitoring after study completion. In contrast to previous studies, we observed a slight decline in adherence to watch wear over 30 days, with several participants opting to keep the watch

on after the study [20]. Our findings suggest that a smartphone app and smartwatch system for AF detection is accurate and has reasonable participant adherence to watch wear to serve as a clinical method of AF detection. However, the slight decline in adherence observed in this study suggests that clinical deployment of smartwatches for AF detection may benefit from further development of strategies to enhance adherence to watch wear.

Accuracy of the Smartphone App-Smartwatch Dyad (Pulsewatch System) for Atrial Fibrillation Detection

In this randomized study of older stroke survivors, we observed high patient-level accuracy in detecting undiagnosed AF. The incidence of AF in the Pulsewatch cohort was relatively high during the 14-day follow-up (6.67%) compared to similar cohorts. A meta-analysis of 50 studies examining AF diagnosis poststroke demonstrated a yield of 15.3% with mobile cardiac outpatient telemetry (MCOT) devices [21]. However, AF incidence in this study is still within the confidence interval (5.3%-29.3%). Furthermore, Pulsewatch included participants without diagnosed AF whose stroke occurred up to a decade ago. Thus, most individuals in our cohort have undergone extensive work-up post stroke to identify AF as a potential source of their stroke, thus any arrhythmia we identify is occult AF that has been refractory to detection up to this point, in some cases many years after their stroke. This is further exemplified by the relatively low burden of AF among all participants in whom AF was detected and the longest episode being 27 minutes.

The Pulsewatch algorithm for AF detection was designed to minimize false-positive alerts to avoid introducing patient anxiety. This is particularly important in the context of our recent finding that smartwatch alerts for AF negatively impact patients' perceptions of physical health [22]. In this study, we developed a patient-centric smartwatch monitoring system that has high negative predictive value and low false positives, demonstrating a viable option for AF detection that does not cause undue stress due to excessive false positive alerts.

Our analysis of concurrent watch and patch wear demonstrated that while a portion of the hours in which AF was detected on the patch were not detected by the smartwatch, it was still able to identify AF in 3 of the 5 participants who had this condition over the 2-week monitoring period. This further highlights the importance of adequate duration of monitoring, which may be significantly higher for a smartwatch than a traditional ECG monitor affixed to a patient's chest, as a smartwatch may need to analyze more episodes of AF to detect the condition, as observed in this study. We observed that 55% (28/51) of participants in this study wore the watch for greater than 5 hours daily at 30 days, suggesting that in real-world use, smartwatches would be worn for an adequate duration to allow for AF detection, albeit with a slight decline in adherence over time.

Few studies have examined the accuracy of wearable devices among older adults, and fewer still among those naïve to technologies at baseline. The Apple Heart Study recruited individuals who already owned an Apple Watch (average age 41 years, 57% male), asked them to use the device's built-in pulse analysis feature, and sent ECG patch monitors to all participants who received a potential AF alert on their smartwatch [9]. Among the 450 users who returned their ECG patches, 34% had AF identified on their clinical gold-standard patches, and participants who were of age 65 years or older had the highest rate of AF identified. The Huawei Heart Study used a similar design to that of the Apple Heart Study, and of the 262 participants with "suspected AF" notifications on their smartwatch who had subsequent clinical workups, 87% had confirmed AF [10]. Similarly, the study found that older adults had the highest rate of AF being confirmed as present among those who received alerts on their watches. While neither of these studies specifically addressed smartwatch use among older adults or patients with stroke, they reinforce the high incidence of AF and illustrate the potential for wearables to detect undiagnosed AF that is clinically significant. Fortunately, there are ongoing efforts to focus on this understudied but high-risk population. The Liverpool-Huawei stroke study is an ongoing prospective study that plans to enroll 1000 stroke patients and monitor them for 4 weeks using a Huawei wearable device [23]. Eligibility criteria are quite similar compared to Pulsewatch, and it will be quite interesting to compare the incidence of AF between the studies.

Perceptions of Smartwatch Usability

Older adults are a particularly understudied population with respect to digital health and telemedicine, and information on the perceptions of smartwatch usability among this population is scant. A systematic review of wearable sensors deployed in older adults found that studies largely focus on the systems and technical performance aspects of technology and that few existing studies address usability and acceptability challenges encountered by older adults [24].

A preliminary feasibility study we conducted in a small cohort of older adults (n=40, mean age 71 years) using a smartwatch for cardiac rhythm monitoring found an average SUS score of 73 [13]. In the general population, SUS scores for various smartwatch models are typically in the range between 60 and 70, depending on the specific model or app scenario [25,26]. Furthermore, a usability study of older adults (aged between 66 and 88 years) using the Samsung Galaxy Gear S3 to administer assessments of pain, mood, and fatigue showed that 73% of participants reported being satisfied with the smartwatch, and another 73% reported that they were likely to use the device daily in the context of a research study for a year [27]. Similarly, a qualitative study of 19 adults over the age of 65 years with osteoarthritis found that 74% of participants indicated a willingness to use a smartwatch for a year for pain symptom tracking [28]. Pulsewatch participants were generally less amenable to long-term device engagement (60% of participants indicated a willingness to use the system daily for 6 months), but this difference may stem from differences in the populations under study and their reasons for smartwatch use. Both previous studies focused on using smartwatches for pain assessment in patients with osteoarthritis, a condition that can drastically diminish quality of life and thus may be perceived by participants as a health priority more so than heart rhythm monitoring [28]. Overall, our data is promising with regard to the long-term use of smartwatches as a viable option for rhythm monitoring with regard to perceived usability.

Adherence to Smartwatch Use

Initial adherence to the Pulsewatch app and smartwatch was high but declined marginally over the course of the 30-day monitoring period. Our findings are consistent with other studies that prescribe the use of commercial wearables among older adults with risk factors for stroke. For example, in a substudy of the mHealth Screening to Prevent Strokes (mSToPS) trial, which consisted of 230 participants with numerous risk factors for AF (median age 71 years; 24% female), it was observed that 43% of participants who received a smartwatch to monitor their heart rhythm did not record any data on the device despite initial enthusiasm for receiving such a device [29]. The distribution of device usage over a follow-up period of 4 months in mSToPS showed that 43% of participants never transmitted any data. In this study, all participants wore the watch for at least 2 days; more than one-fifth wore the watch at least once a day, and over a tenth wore it for more than 5 hours a day for the entirety of the 30-day study period. This is likely a direct result of the highly specialized and intensive training Pulsewatch participants received at the initial study visit, along with on-call technical support, which was not part of the protocols for previous studies. This further highlights the importance of personnel support when deploying wearable devices in older adults, as though it is extremely resource-intensive, the level of support required to address barriers to device use in this population is high.

Our results illustrate the opportunities for using wearables for AF detection but also highlight gaps that may impede the successful integration of smartwatches for long-term arrhythmia monitoring in at-risk populations that do not regularly use such devices. As discussed in the recent European Heart Rhythm Association (EHRA) position paper on AF screening and detection, photoplethysmograph-based wearables potentially provide a useful means of initial screening but should not guide anticoagulation therapy without further investigation [30]. Since the performance of the system for AF monitoring is predicated on adherence to watch wear, our observations suggest that systems must be refined and supported for them to perform as well as implantable monitors or other devices designed for longer-term arrhythmia monitoring. Further research is needed to identify whether certain baseline characteristics (eg, familiarity with technology, smartwatch ownership, marital status, or social support) may identify populations better able to use prescribed smart devices over longer periods. Furthermore, with the rise in holistic, integrated AF treatment centers that focus on behavior change and healthy lifestyle promotion, research into whether support from clinical teams can reengage and sustain wearable use for AF monitoring is necessary [31]. The “Atrial Fibrillation Better Care” (ABC) pathway introduced by the mAFA-II and Huawei Heart Study investigators is a prominent example of the potential of well-designed and executed models, achieving excellent outcomes in terms of anticoagulation rates for patients diagnosed with AF [32].

Limitations

Our results should be examined in light of several limitations. First, our small sample size and subsequent low rate of AF result in large confidence intervals for the accuracy of AF detection, and thus the accuracy values should be interpreted with this in mind. Additionally, watch wear time in the study was relatively low and may have resulted in inadequate coverage to capture AF in subjects with arrhythmia, further complicating accuracy calculations. Finally, this study population is rather homogenous, including a high proportion of individuals of high socioeconomic status, which may not be representative of other populations.

Conclusions

A smartphone-app smartwatch dyad designed with and for patients with a previous stroke demonstrates high accuracy for detecting undiagnosed AF and was found to be highly usable by stroke survivors. Daily adherence to the system declined over a 30-day unsupported monitoring period, suggesting that the use of commercial wearables for AF detection outside of populations who previously owned such devices will require new strategies to improve adherence for effective integration of wearables into clinical settings.

Acknowledgments

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Data Availability

The data sets generated during or analyzed during this study are not publicly available. Please contact the corresponding author for inquiries regarding data access.

Conflicts of Interest

DDM has received honorary, speaking, and consulting fees or grants from Flexcon, Rose Consulting, Bristol-Myers Squibb, Pfizer, Boston Biomedical Associates, Samsung, Phillips, Mobile Sense, CareEvolution, Flexcon Boehringer Ingelheim, Biotronik, Otsuka Pharmaceuticals, and Sanofi. He also declares financial support for serving on the Steering Committee for the GUARD-AF study (NCT04126486) and the Advisory Committee for the Fitbit Heart Study (NCT04176926).

Multimedia Appendix 1
Supplemental materials and information regarding the Pulsewatch RCT.

[DOCX File , 2553 KB - cardio_v7i1e45137_app1.docx]

Multimedia Appendix 2
CONSORT diagram detailing study enrollment and retention.
[PNG File , 105 KB - cardio_v7i1e45137_app2.png]

Multimedia Appendix 3
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1156 KB - cardio_v7i1e45137_app3.pdf]

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Abbreviations

ABC: Atrial Fibrillation Better Care
AF: atrial fibrillation
ECG: electrocardiogram
EHRA: European Heart Rhythm Association
HIPAA: Health Insurance Portability and Accountability Act
MCOP: mobile cardiac outpatient telemetry
MoCA: Montreal Cognitive Assessment
mSToPS: mHealth Screening to Prevent Strokes
RCT: randomized controlled trial
TIA: transient ischemic attack
UMMHC: University of Massachusetts Memorial Health Care

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Original Paper

Patients' Experiences With the Fit of Virtual Atrial Fibrillation Care During the Pandemic: Qualitative Descriptive Study

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Abstract

Background: In-person health care has been the standard model of care delivery for patients with atrial fibrillation (AF). Despite the growing use of remote technology, virtual health care has received limited formal study in populations with AF. Understanding the virtual care experiences of patients in specialized AF clinics is essential to inform future planning of AF clinic care.

Objective: This qualitative descriptive study aimed to understand patients' virtual AF clinic care experiences during the COVID-19 pandemic.

Methods: Participants were recruited from a pool of patients who were receiving care from an AF clinic and who were enrolled in a larger survey study. A total of 8 virtual focus groups (n=30) were conducted in 2 waves between March 2021 and May 2021. Facilitators used a semistructured discussion guide to ask participants questions about their experiences of virtual care and the perceived quality of virtual care and technology support. Three team members initially open coded group data to create a preliminary coding framework. As the analysis progressed, with subsequent focus groups, the code clusters were refined.

Results: The participants were primarily male (21/30, 70%), aged ≥65 years (20/30, 67%), and college graduates (22/30, 73%). Patients found virtual care to be highly beneficial. Central to their experiences of virtual care was its fit or lack of fit with their health needs, which was integrally connected to communication effectiveness and their preferred virtual care future. Practical benefits included flexibility, convenience, and time and cost savings of virtual care. Virtual care fit occurred for small, quick, and mundane issues (eg, medication refills) but was suboptimal for new and more complex issues that patients thought warranted an in-person visit. Fit often reflected the effectiveness of communication between patient and provider and that of in-clinic follow-up. There was near-complete agreement among participants on the acceptability of virtual communication with their providers in addressing their needs, but this depended on adequate reciprocal communication. Without the benefit of in-person physical assessments, patients were uncertain and lacked confidence in communicating the needed, correct, and comprehensive information. Finally, participants described concerns related to ongoing virtual care with recommendations for their preferred future using a hybrid model of care and integrating patient-reported data (ie, blood pressure measurements) in virtual care delivery.

Conclusions: Virtual care from a specialty AF clinic provides practical benefits for patients, but they must be weighed against the need for virtual care's fit with patients' needs and problems. The stability and complexity of patients' health needs, their management, and their perceptions of communication effectiveness with providers and clinics must be considered in decisions

about appointment modality. Patients' recommendations for future virtual care through use of hybrid models together with systems for data sharing have the potential to optimize fit.

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KEYWORDS

atrial fibrillation; virtual care; patient experience; qualitative; communication; quality of care

Introduction

Background

In-person health care has been the standard model of specialty care for patients with atrial fibrillation (AF). However, there have been steady advancements in technology for remote arrhythmia detection, such as electrocardiogram patch monitoring via mail and other app-based patient heart rate and rhythm monitoring systems, which have been highly effective [1]. However, virtual care has received limited research attention [2,3]. Virtual care has been defined as any interaction between patients or members of their circle of care occurring remotely, using any form of communication or information technology with the aim of facilitating or maximizing the quality and effectiveness of patient care [4,5].

Virtual care was used to a limited extent in AF care [6] before COVID-19, with a few studies showing similar levels of satisfaction between virtual and in-person consultations [2,7-9]. Although the acute phase of the COVID-19 pandemic radically transformed care delivery models to virtual care as the new normal, there continues to be limited research exploring the use of virtual AF care delivery and none from a patient perspective. For example, the European TeleCheck-AF project combining the use of remote app-based heart rate and rhythm monitoring before teleconsultations reported that patients found the app easy to use and install and that it provided a feeling of safety [10], but patients' experiences with the teleconsultations were not addressed. A Canadian survey study, which was not specific to AF, found that 88% (n=45) of patients who had had a virtual visit with a cardiology health care provider during COVID-19 were satisfied (13% somewhat satisfied, 30% satisfied, and 45% very satisfied) with the virtual format, but there was no in-depth exploration of patients' experiences or their perceptions of the quality of their virtual care [11].

Objective

In Canada, structured, integrated, multidisciplinary, and patient-focused care that can be delivered by specialized AF clinics is recommended by consensus guidelines [12], and AF clinics are increasing in prevalence [13,14]. As virtual care is projected to continue following the acute pandemic, the future and sustainability of virtual AF care remain unknown. It is essential to understand the virtual care experiences of patients in specialized AF clinics and their views of deficits and successes with virtual care to help inform future planning of virtual AF clinic care. Therefore, this qualitative study, part of a larger cross-sectional study exploring the AF clinic's virtual care delivery, aimed to understand patients' perceptions and experiences of virtual AF clinic care during the pandemic.

Methods

Design

Qualitative description was used to produce a detailed and nuanced interpretation that stayed close to the participants' data and their everyday language [15]. Consistent with the constructivist paradigm, which views reality as socially constructed, it allowed for an in-depth understanding of patients' experiences with specialty virtual care. The conduct and reporting of the study followed the Consolidated Criteria for Reporting Qualitative Studies guidelines for qualitative research reporting [16].

Ethics Approval

This study received joint approval from the University Behavioural Research Ethics Board and the Health Authority (certificate #H19-03601).

Setting

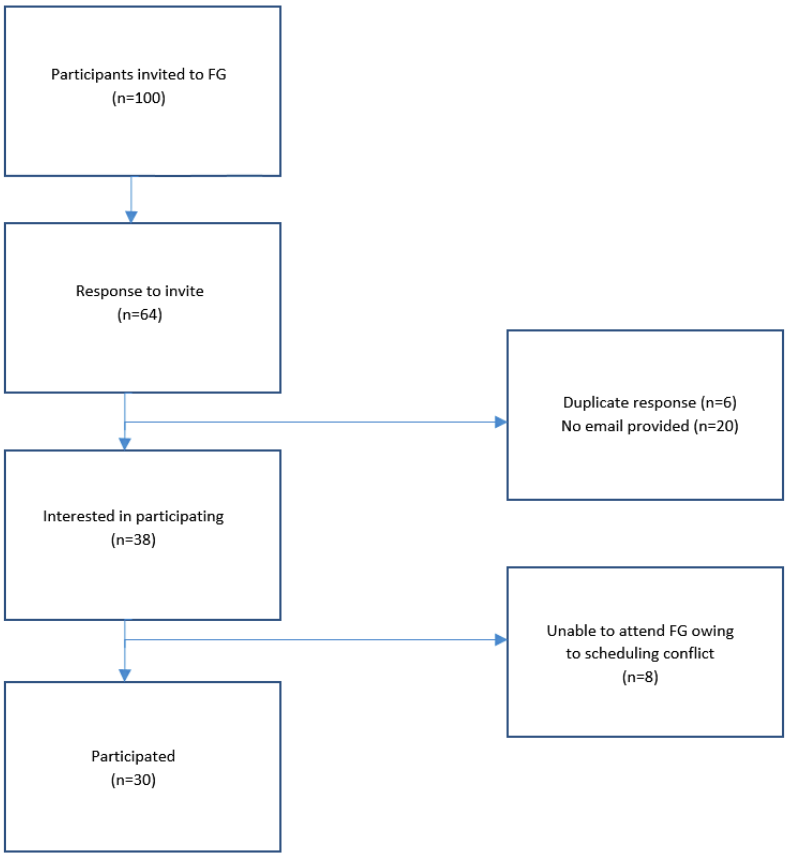
This study was conducted in partnership with the largest tertiary urban-based specialty AF clinic in Western Canada. The clinic is 1 of the 5 provincial AF clinics and serves approximately 1900 patients on average every year. The clinic is provincial in scope and comprises a multidisciplinary team of nurse practitioners, pharmacists, registered nurses, cardiologists, and electrophysiologists. The mandate of the clinic is to provide specialized care for patients with newly diagnosed or established AF or atrial flutter, focusing on acute or short-term interventions, chronic disease management, and advanced procedural or electrophysiological care such as ablation. Once a patient's treatment is optimized (usually within 6-12 months), patients are returned to their primary care clinician for ongoing follow-up. In March 2020, the clinic implemented COVID-19 protocols that restricted appointments to virtual mode only, and as of January 2023, the AF clinic continues to restrict all appointments to telephone, except when providers request in-person appointments.

Sampling and Recruitment

The study participants were recruited from a pool of patients aged >18 years who had consented to a larger study. For the larger study, the booking clerk initially notified all eligible patients about the study using scripted communication (by email or mail) and that a member of the research team would be contacting them. Patient contact information was shared with the research team through secure file transfers. Subsequently, a research assistant (a physician or a licensed practical nurse) who had no previous relationship with the participants contacted the patients by telephone.

Focus group recruitment occurred during recruitment for the larger study, with researchers sending patients who had consented and completed the survey (as of March 2021, n=100) an email invitation to participate in the focus groups. The email included a link to indicate availability from 4 midweek dates and times (Figure 1), and if in conflict, their interest in possible future focus group participation. Interested patients received an email including a link to a web-based consent form and focus group questions in preparation—a strategy recommended to avoid "GroupThink," or thinking like other group members, that may not reflect individual thinking. When no additional insights were provided by the last focus group, no further focus groups were conducted [17] as agreed by the investigators.

Figure 1. Recruitment flowchart. FG: focus group.



Data Collection

Consistent with the qualitative description, focus groups were an efficient way to obtain a broad range of information (who, what, and where) about the nature and shape of virtual care experiences [18] through facilitated discussion. Focus groups allowed participants to exchange ideas and information; react, build on, stimulate, or challenge each other's thinking to generate a range of perceptions, insights, and experiences about virtual AF care; and avoid acquiescence and transference effects while maintaining rapport [19]. Consistent with our purpose, we used semistructured questions and facilitated the group interaction to productively generate content while paying careful attention to the general amount of agreement and disagreement between participants as well as the level of emotion (eg, enthusiasm, indifference, and dispassion) [19].

A total of 8 focus groups (ranging in size from 2-5 participants) were conducted over 3 months (March 2021-May 2021), with participants joining from their homes or workplaces using Zoom videoconference software (Zoom Video Communications). Trained facilitators (KLR, RW, and LB) followed a semistructured interview guide (Multimedia Appendix 1), asking questions about participants' experiences of virtual care and their perceptions of virtual care quality and technology support. Facilitators used prompts and probes to encourage greater clarification, elaboration, and depth in detailing their experiences. Facilitators also asked contextual questions such as participants' distance from the clinic and employment status. Only researchers and participants were present during and after the focus groups to take field notes of the focus groups. The recorded focus groups lasted 1 to 1.5 hours. The team debriefed following each focus group to discuss any new insights gained and from whom and determined the need for a second wave of recruitment 1 month following the first wave to maximize sample diversity and to explore new and emerging ideas. It was anticipated that additional focus groups would expand the opportunities to recruit women and visible minority individuals who were underrepresented in earlier groups. In addition, data sharing emerged in early focus groups, and it became a more focused line of exploration in subsequent focus groups.

Additional information including demographics, health history, and consultation type (follow-up, new, or ablation) were extracted from the participants' previous survey responses. Geographic distance from the clinic was determined using a

combination of previous survey responses and focus group discussions.

Data Analysis

NVivo-transcribed (QSR International) focus group audio recordings were checked for accuracy against recordings (SS) and subsequently analyzed thematically. The transcribed data were coded following each focus group. Data from the first 2 focus groups were initially open coded by 3 team members (KLR, LB, and SS) who met to discuss and cluster similar codes into themes and subthemes to generate a preliminary coding framework. A research assistant used the preliminary framework to code the data using NVivo (version 12; QSR International). As the analysis progressed with subsequent interviews, codes were created, modified, and in some cases, collapsed and renamed. NVivo was used to recode the data. Maintaining an audit trail and involving multiple team members in the data analysis were used to enhance trustworthiness of the data. The researchers engaged in ongoing reflexivity and reflection to avoid influencing the research process and data analyses. Demographics and health history were analyzed descriptively using R software (R Foundation for Statistical Computing).

Results

Overview

In total, 30 patients participated in the focus groups. Participants were primarily male (21/30, 70%), ≥65 years (20/30, 67%), and living within the clinic's greater metropolitan area (21/30, 70%; Table 1), similar to the clinic demographics in which patients were primarily male (4004/6566, 60.98%), ≥65 years (3742/6566, 56.99%), and living within the clinic's greater metropolitan area (4793/6566, 72.99%). Male participants in the sample were significantly younger and had higher incomes than female participants (Table 1). Patients had, on average, 2 chronic diseases inclusive of AF and primarily rated their health (19/30, 63%) and mental health (27/30, 90%) as good or excellent. The reasons for virtual appointments were follow-up (16/30, 53%), new consultation (8/30, 27%), and ablation (6/30, 20%), and they were primarily conducted by telephone (27/30, 90%).

Patients often described their experiences and perceptions of virtual care relative to in-person care. They lauded the practical benefits of virtual care. Despite perceived benefits, central to patients' experiences of virtual AF care was its fit or lack of fit with their health needs, which was integrally connected to communication effectiveness and their preferred virtual care future.

Table 1. Participant demographics.

	Overall (N=30)	Female (n=9)	Male (n=21)	*P* value[a]
Age (years), mean (SD)	66 (9)	73 (6)	63 (8)	.004
Age group (years), n (%)				.01
<65	10 (33)	0 (0)	10 (48)	
≥65	20 (67)	9 (100)	11 (52)	
Marital status, n (%)				.15
Common Law	1 (3)	1 (11)	0 (0)	
Widowed	1 (3)	1 (11)	0 (0)	
Single (never married)	4 (13)	1 (11)	3 (14)	
Married or remarried	24 (80)	6 (67)	18 (86)	
Ethnicity, n (%)				>.99
Asian	3 (10)	1 (11)	2 (9.5)	
White	27 (90)	8 (89)	19 (90)	
Education, n (%)				.66
Completed high school	2 (7)	0 (0)	2 (10)	
Some college	3 (10)	0 (0)	3 (14)	
College or university graduate	22 (73)	8 (89)	14 (67)	
Other (specify)	3 (10)	1 (11)	2 (10)	
Income (CAD $; CAD $1 = US $0.75), n (%)				.002
<25,000	3 (10)	2 (22)	1 (5)	
25,000-50,000	4 (13)	4 (44)	0 (0)	
51,000-75, 000	6 (20)	1 (11)	5 (24)	
>75,000	17 (57)	2 (22)	15 (71)	
Housing, n (%)				.054
Apartment or condo	7 (23)	0 (0)	7 (33)	
Detached home	22 (73)	8 (89)	14 (67)	
Other (specify)	1 (3)	1 (11)	0 (0)	
Living arrangement, n (%)				.17
Live alone	4 (13)	1 (11)	3 (14)	
Live with children	5 (17)	0 (0)	5 (24)	
Live with other family members	3 (10)	0 (0)	3 (14)	
Live with partner	18 (60)	8 (89)	10 (48)	

[a]Wilcoxon rank-sum test; Fisher exact test.

Practical Benefits of Virtual Care

Participants were unanimous in their opinion to use virtual care during COVID-19 to ensure the protection of both patients and staff. Patients described several practical benefits of virtual AF care, including convenience, cost and time savings, reduced stress, and opportunities for family participation. The participants described virtual care as less disruptive and more convenient than in-person care. For example, rather than the interruption of going for an office visit, they could easily integrate a virtual visit into their daily lives, whether it was during a workday, a family vacation, or while running errands. A participant described the freedom and flexibility of phone use when scheduling appointments ahead of time:

> *...you have the freedom to keep doing what you're doing and then just set that time aside when you're expecting a phone call.* [P6, male aged 68 years, follow-up]

Participants expressed that unlike in-person visits, virtual appointments did not keep the patients waiting in a crowded waiting room reading magazines and interacting with others (and being exposed) if the provider was late, which in some cases could be quite substantial (eg, an hour).

All the patients lauded the benefit of virtual care in terms of time and cost savings. For participants who lived in rural areas and at significant distances from the AF clinic (approximately 150-2400 km), virtual care reduced travel, ferry, parking, and in some cases, accommodation costs. A participant who lived some distance from the clinic (approximately 200 km) and had a lower income elaborated as follows:

> *I live over in [a rural community], and over the 10 years I've had atrial fibrillation, I've had made anywhere from two to four checkup visits to [the clinic] every year to see [cardiologist], who is an absolutely charming man. So I didn't mind going for the checkups. I could usually squeeze in a visit to friends and other things. However, a lot of the times the checkups are very routine and mostly done by a student. So I could have just as easily done that on Zoom and I would save myself a couple of days of time each visit. So I think Zoom, for me it looks like a technology that I hope stays around for a while.* [P13, female aged 81 years, follow-up]

Participants living within the metropolitan area with travel times up to 1 hour similarly highlighted the benefit of virtual care:

> *...it's just so much more convenient that you don't have to drive to the office.* [P26, male aged 67 years, follow-up]

Having family members to be able to attend appointments that otherwise they may not be able to attend in person was also viewed by patients as an added benefit to the virtual consultations.

Fit of Virtual Care With Patients' Health Needs and Problems

Overview

Patients often gauged the quality of their virtual care experiences according to its fit in meeting their health needs and problems. When they perceived that the virtual modality suitably aligned with their various needs, it was a fit; however, when they were not aligned, they regarded it as a suboptimal fit. They described fit as dependent on the nature and complexity of their health problems, stability of their AF, and extent of decision-making related to their disease management.

Fit

When the health problem or need was simple, uncomplicated, straightforward, and easy to resolve, patients deemed virtual care to be a good fit. Fit extended to the management of the need, which included medication prescription refills, laboratory requisitions, quick questions, and other short inquiries, and this was evident in the sentiments of 2 participants:

> *So if it's mundane stuff that doesn't require an in-depth discussion, I would just as soon be on Zoom.* [P9, male aged 69 years, new consultation]

> *I think it [virtual] works very well for things like medications and just the questions* [P27, female aged 74 years, ablation]

Another patient echoed that a virtual appointment works as long as the providers have all the information they need:

> *EKGs and Holter monitors and all the other information is coming from other places. So you don't really need to be there.* [P6, male aged 68 years, follow-up]

Suboptimal Fit

In contrast, patients viewed a virtual appointment as a suboptimal fit for a new or serious AF diagnosis, for a changing health situation (eg, concerning symptoms), when making important health decisions, or when experiencing postprocedural complications (eg, after the ablation). They described these complex situations as requiring more in-depth discussions, such as one participant who described serious diagnosis-related discussions as being more appropriate for in-person and not Zoom:

> *If I'm sitting down with a physician and I'm discussing a diagnosis and some serious issues as to choices that must be made, I think I'd prefer a face-to-face discussion.* [P9, male aged 69 years, new consultation]

Another patient echoed the need for in-person appointments to facilitate compassionate care when dealing with a new issue or diagnosis:

> *If you've got some like a new issue or a previously undiagnosed like I think that having that in person is probably going to have a bit more comfort, to it. I think you have to think about the...I don't want to say compassion, you just have to be able to have the other person and the tone and the voice and just the physical body language would make, I think myself feel at ease if, you know, obviously that's something really serious and you can read it in a doctor's body language or even in a nurse's body language. I think that those visual cues you definitely can't have over the phone or through even a video perspective. Right? So that's something that would help from a patient, even from a long-term patient, just having that compassion and just being able to hear that from a doctor.* [P20, male aged 48 years, ablation]

Virtual care was seen as a suboptimal fit for meeting the needs of newly diagnosed patients or patients new to the clinic. Patients described new patients to the clinic as lacking a context for their care and established connections with the clinic team and whose condition was often unstable. For example, patients described the impact of virtual care on new patients' orientation to the team, facilities, and workflow and trust gain as follows:

> *...the people that you're putting your life in their hands.* [P27, female aged 74 years, ablation]

One of the sequelae of the pandemic for newly diagnosed patients (9/30, 30%) was receiving all their care virtually and never having seen the physical space that housed the clinic slowing their familiarity with the workflow and making the clinic appear as a "...giant black box..." New patients expressed

a strong and unmet need to know the treatment pathways and options, as expressed by a male participant in his mid-50s:

> *If I'm coming into the system, I want to know what the paths are to get me through it. And I never had that sense. I had to create it myself.* [P14, male aged 58 years, new consultation]

Virtual appointments were not always seen to be a good fit for information exchange and patient education, particularly when patients needed more explanation and education. Although several participants were satisfied with the explanations about pending procedures (eg, ablation) and opportunities for questions during virtual appointments, others found the virtual modality to be more limited in this regard. Unlike in-person appointments, virtual care was found to be restrictive by several patients in situations when providers communicated information that was complex, "over my head," and "very technical" in nature. They expressed their need for simplified explanations ("putting in more of a layperson's terms") and the use of supplementary means, such as visual diagrams to help them understand their health condition, and recounted their specialists' drawing diagrams that were easier to do in person than over the phone.

Communication

Overview

Communication was a critical facet of patients' overall perceptions of their virtual care experiences and its fit in meeting their needs. There was near-complete agreement from participants who found virtual communication with their providers acceptable in making them feel "cared for" and having their needs and questions addressed and not constrained by time. For example, one participant described their virtual care as follows:

> *I've had Zoom calls and telephone calls and I have felt surprisingly well cared for without seeing anybody in person. I felt like everything was covered in the appointments and that people had time for me* [P22, female aged 67 years, ablation]

Patients were variable in their use of specific virtual modalities, with some using the phone exclusively, whereas others used a combination of phone and Zoom; some had a choice of modality, whereas others did not. The patients described two specific areas of communication that had an impact on their overall virtual care experience: (1) provider-patient communication effectiveness and (2) follow-up communication with the clinic. Although virtual communication with the clinic and providers was highly effective overall, patients also relayed the challenges they experienced.

Provider-Patient Communication Effectiveness

Patients varied in their perceptions of virtual communication effectiveness with their providers. Patients described communication effectiveness as dependent (1) on their ability to focus and adequately communicate their needs and concerns and (2) on the provider's ability to listen, interpret the information, and act on it to address their concerns. A 72-year-old female patient who had a telephone appointment captured these vital elements of effective communication:

> *My observation is that virtual care is really only as good as a patient's ability to communicate issues and successes they may have had. And it's also only as good as the provider's ability to listen and in the end, interpret.* [P1, female aged 72 years, follow-up]

Some patients who could describe their situation and symptoms, and how they were feeling and who had the provider interpret the information found the virtual modality very effective and a good fit in addressing their concerns. A participant who had fluctuating heart rates was very pleased with the communication by phone appointment in resolving her problem:

> *Dr. called me up and I discussed with him my situation. And he gave me he said, you know what? I think your medication is a little too much...So he said, you know what we'll adjust it, he said try it. And then if there's a problem, get back to us. And voila, it disappeared. Whatever problems I had, I thought, my goodness, this is really good, even though it was a phone call, right? It was a phone call. I described what I was feeling and the situation. And he said he totally understood what I meant because he had all the paperwork in front of him, all my tests previously.* [P23, female aged 74 years, follow-up]

Other patients found virtual care to be a suboptimal fit in communicating their needs and concerns compared with in-person care. Without the benefit of in-person physical assessments and having their providers look, listen, or feel, they lacked confidence, reassurance, and validation of their symptoms, what they were feeling, and their symptom analysis. A participant expressed self-doubt about her communication adequacy over the telephone:

> *I did feel that quite a lot initially because I never did have an in-person consult. So I was a little bit nervous initially that I wasn't being seen and having my blood pressure done. And somebody listen to my heart and all that kind of physical stuff because I was having to describe my symptoms. And, you know, it's I wasn't sure I was covering everything and if anything was being missed. So, yeah, I was a little concerned that I wasn't being actually physically seen some of the time* [P8, female aged 65 years, new consultation]

Furthermore, without the hands-on examination, patients doubted and questioned whether their descriptions of signs and symptoms were correct, whether they were communicating the necessary information, or whether they were correctly judging the symptoms that were the most relevant (eg, leg swelling) to share with their providers:

> *The only disadvantage, I think, is the lack of actual hands-on examination just to, I guess, reassure you that what you're describing [over the phone]. Is this correct?* [P8, female aged 65 years, new consultation]

Another patient expressed not receiving enough information during the phone appointment and wondered if he did not ask the right questions. In some cases, patients tolerated symptoms such as leg swelling rather than disclosing them during the video visit:

> *I just have to judge for myself and put up with it* [P19, female aged 82 years, new consultation]

This self-doubt about the adequacy of their communication left patients concerned that things were being missed.

At the same time, participants were also concerned that virtual care limited their providers' ability to assess and interpret their issues. They questioned whether their providers' interpretation of their clinical symptoms would be the same over the telephone compared with an in-person visit:

> *[During in-person visits, a provider could] take your pulse and throw you on a Holter monitor or monitor you for a period, they might not come to the same conclusion.* [P15, male aged 54 years, follow-up]

In some cases, patients found the virtual back and forth with phone calls and emails that did not allow providers to "see" for themselves so inadequate and inefficient in resolving the issue, that they gave up and resorted to an in-person appointment. A patient who found that talking about his symptoms on the telephone did not work concluded as follows:

> *I think that if there are clinical signs, it's important to actually be seen in person.[P27, female aged 74 years, ablation]*

Patients' activities during telephone appointments influenced their perceptions of the adequacy of their communication with providers. Patients who treated their virtual appointment like an in-person appointment and prepared ahead of time by making notes optimized communication:

> *...stay[ing] home to dedicate that time to the phone call...I just have to do that. I can't do these things while I'm being distracted.* [P8, female aged 65 years, new consultation]

In contrast, patients who took phone appointments while multitasking (working, driving, or grocery shopping), whether by choice or owing to provider delays, were distracted and found it difficult to focus on the appointment. A patient who had telephone appointments during work hours reported suboptimal communication:

> *You are not concentrating during work because it's during your work time...I am distracted by millions of things, you know, and you can concentrate when you go to the office [Dr's], you get this personal touch, like maybe a little bit more attention to detail and you don't forget things so.* [P17, male, aged 50 years, follow-up]

Patients who had used a combination of telephone and Zoom described the greater connection and engagement with providers using Zoom than telephone:

> *I still feel more connected, through the actual zoom call. And I think it allows you to probably get everything over because you kind of fully engage with that person.* [P24, male aged 49 years, follow-up]

Follow-up Communication With the Clinic

Patients had mixed responses regarding the adequacy of follow-up communication with the clinic in meeting their needs in a timely and efficient manner. Some patients experienced few to no problems and found that the clinic was highly responsive to the immediacy of their needs. One patient appreciated the clinic's rapid response to their AF compared with a 2-month wait for an injured hip ultrasound:

> *With your heart, you can't you can't kind of wait. So you need to be able to talk to somebody really, really fast. And so I appreciated the responsiveness. I think that's come out of this. I'd trade responsiveness for the in person. In terms of quality of care, I guess.* [P4, male aged 57 years, follow-up]

Another patient similarly described a timely response to his informational needs as follows:

> *I've never had any trouble getting, talking to somebody, you know, within a day or two or getting some information, but end up talking more to the nurse practitioners and pharmacists than I actually do the doctor. And they know their stuff* [P6, male aged 68 years, follow-up]

Other patients encountered challenges with follow-up communication, including unmet expectations about clinic-initiated follow-up appointment scheduling and inefficiencies in their self-initiated efforts in reaching clinic staff for various reasons. Some patient participants described anticipating clinic-initiated follow-up communication about treatment options following an initial consultation or scheduling a 6-month appointment after ablation, but such communication had not occurred. A female participant who lived the farthest from the clinic described her uncertainty about who initiates the communication for a follow-up appointment:

> *And so I guess that's one thing that I would say is maybe not as clear for those of us who aren't more on site than others. And that is who initiates the calls. So, as I say, I've waited.* [P1, female aged 72 years, follow-up]

The reciprocal challenge for other participants was their unproductive self-initiated efforts in accessing clinic staff when they wanted to discuss changes in their health situation such as postprocedural complications, failed treatments (cardioversion and ablation), or following an emergency department visit for an AF episode. They did not know whether they should contact the clinic, who to contact, or how. One participant who was trying to follow-up after an unsuccessful cardioversion in the emergency department said of his efforts at calling:

> *...then you're kind of in the feedback loop trying to get a hold of somebody.* [P15, male aged 54 years, follow-up]

Some participants, following ablation or with new symptom onset, found that they had to be more persistent in making their needs known when using the telephone, as one participant voiced the following:

> *I have to do a little more poking and following up to kind of make the next step happen.* [P4, male aged 57 years, follow-up]

Preferred Virtual Care Future

Looking to the future, patients were highly supportive of the continued use of virtual AF care but were concerned that it might become usual care. Their concerns stemmed from perceived challenges with scheduling in-person appointments and with expanding practices and the potential for patients being underserved. One patient whose in-person visit with the nurse practitioner expedited ablation and cardioversion expressed this concern:

> *But my concern is that. If the more it becomes the norm, the more when you actually do want to see him [physician], it'll be harder to do. So that'll be my big concern. So I'd be very disappointed to see virtual appointments become the norm such that you can't get in to see somebody.* [P21, male aged 71 years, ablation]

One participant voiced concerns about provider availability:

> *I can see that that's my only trepidation with virtual care, is that if doctors get more [patients], a bit more busier, they're going to have less time for some of their oldest and most long term patients.* [P20, male aged 48 years, ablation]

Participants addressed their concerns about the future by offering suggestions and recommendations for optimizing fit of virtual care in meeting and managing their overall care needs. Patients had 2 primary recommendations for optimizing fit: use of a hybrid model of care and integration of patient-reported data in virtual care delivery.

Use of Hybrid Model of Care

As patients projected to the future, they advocated a mix of in-person and virtual appointments and not just virtual care:

> *Virtual care is great, but there's always a place, there's always a place for it and there's always a place for in-person visits. So it has to be a mix. Definitely* [P17, male aged 50 years, follow-up]

Patients described specific uses of a hybrid model with the combination of in-person and virtual visits depending on the newness of their AF diagnosis, stability of their condition, and treatment-related issues. They preferred a predominantly virtual approach with periodic in-person visits when they were more comfortable with AF and their AF was stable but preferred in-person visits during the period of initial or early diagnosis and during periods of disease instability.

Patient capacity was an important consideration in participants' advocacy for a hybrid virtual AF model. They identified several barriers limiting patient capacity that would need to be addressed to prevent exclusion of some patients with AF. The barriers included patient age, technology literacy and comfort, and memory capacity. Participants suggested that patients who were uncomfortable using virtual modalities might opt not to receive care at all and the potentially distracting nature of virtual care was unsuitable for those with memory loss. Furthermore, they viewed patients who lacked infrastructure, such as inadequate cell signal or internet access and privacy and security issues, as a disadvantage in using virtual care.

In describing the hybrid model, patients thought it was important that they have an in-person option with the suggestion that the choice of virtual versus in-person approach needed to rest with the patient, and there needed to be clearly laid out expectations agreed on by physician and patient for the virtual aspect of the hybrid model:

> *I wonder if it makes sense, like I'm not sure if it's there at this point, but if there is something like a patient's rights or something, where there's something where both doctors and patients kind of agree in this kind of virtual care, what's to be expected? It's just mainly setting expectations. I think to make it easier on both sides...so if there is some sort of way of getting expectations set or some sort of, you know, patient, I don't want to say patient rights because that seems very legal and stuff, but it's just an understanding and that we're both sides are both going to try and do our best to make sure that the patient's interests are still being protected and being looked after. That's all we really want as patients.* [P20, male aged 48 years, ablation]

Integration of Patient-Reported Data in Virtual Care Delivery

As patients considered continuing the use of virtual care and optimizing its fit with their needs, they described making better use of the biometric data they collected. Several patient participants described actively tracking, monitoring, and recording a range of biometric data, such as blood pressure, pulse, oxygen levels, wearable 6-lead electrocardiogram, and weight. They tended to collect these data using Apple Watches (Apple Inc) and blood pressure cuffs (self-measured or measured at a pharmacy) and used both paper (eg, Excel spreadsheet) and electronic approaches to record.

Patients described using the data they collected both to share with their providers and to give them a sense of personal control in self-managing their AF, as one patient described as follows:

> *Well, what happens is I know that I have it on Omron. I have just transferred it to my phone. I have all my records. I can tell her [provider] whether she wants to know, you know, and that is really good. That is valuable for me too. I used to write on these cards at the drugstore. A spare piece of paper.* [P19, female aged 82 years, new consultation]

Another patient described self-monitoring to detect abnormal readings and potential problems to self-initiate contact with providers as needed:

> *So having that device at home is very reassuring because I can if I'm having problems, I know immediately that I should contact someone.* [P13, female aged 81 years, follow-up]

However, patients raised privacy concerns regarding sharing these data with the clinic through insecure email or faxes and requested a secure way of transmitting their health information.

Other patients contemplated the purchase of wearables or other devices that would allow them to transmit real-time biometric data to the AF clinic as a complement to remote care:

> *One of the things since I had my ablation in the end of December this year, I still have brief episodes of irregularity, my heart rate and it is possible to go to a local lab and have an EKG done because I have a standing order, but however, it's not that easy to do. And also these events tend to be quite short lived sometimes. And I'm wondering about the use of some of these new technologies that have been developed recently, like the AliveCor devices that connect to your phone and they can actually do a six lead ECG. And I was thinking that I would maybe purchase one of these things so that when I have one of these episodes, I could make a record of it and send it to the clinic. And I'm thinking something like that might be extremely useful for this kind of remote care.* [P5, male aged 73 years, ablation]

Patients highlighted the importance of sharing the information they were tracking with providers. One participant spoke of the benefit of such sharing:

> *The more information that we track ourselves and that we make available to the cardiologist is to our benefit.* [P18, male aged 63 years, ablation]

However, despite their data tracking, patients acknowledged limited use of the data in their care. The patients described a need for integrating their existing monitoring practices with the AF clinic:

> *It would be good if the AF Clinic had some way of getting some of these metrics in into their system. As we are recording all of the time, I'm always recording. I know exactly what my blood pressure is all the time. I know what my heart rate is. I record my heart rate all of the time. If I have a spike, I know immediately all of that stuff. And it's because of the wearable technology. And I do that for myself because I want to know myself. But it would be interesting if they had some way of using those data in the clinic as well.* [P30, male aged 69 years, follow-up]

Discussion

Principal Findings

Patients described the benefits of virtual care, including convenience, time and cost savings, reduced stress, and opportunities for family participation. However, central to their experiences with virtual care was its fit with their needs that was integrally connected to communication effectiveness and their preferred virtual care future. Patients considered virtual care a fit for simple, uncomplicated, straightforward, and easy-to-resolve issues but a suboptimal fit for new, changing, and complex issues such as important health decisions and postprocedural complications. Patients gauged fit according to the effectiveness of their communication with providers and the clinic. Without the benefit of in-person physical assessments, patients experienced uncertainty, self-doubt, and lack of confidence in communicating their needs appropriately. Finally, patients' preferred virtual care future to address their concerns about virtual care becoming usual care was as a hybrid model, with ongoing access to in-person care, while optimizing the integration of electronic data sharing into routine practice.

Comparison With Previous Work

Findings from this study show that overall, patients were positive about their experiences with virtual AF care. In their review of remote cardiology clinic visits during COVID-19, Mishra and Edwards [20] found evidence for the potential of telemedicine to be used to adequately address cardiac conditions such as AF and cited a study that revealed that internet and technology access were not significant barriers to telehealth use [21]. However, the patients with AF in our study expressed some concerns and reservations about virtual care fit with their needs and the impact on communication with their providers.

Consistent with previous research with both cardiac and noncardiac populations [20], patients described many practical benefits of virtual care, such as flexibility, convenience, and time and cost savings. Patients also expressed feeling cared for during virtual visits by members of their care team. However, patients raised concerns about access to in-person visits if virtual visits became usual care rather than augment them and worries about whether communication using virtual visits can be as effective as in-person visits. A US survey of American households found that of 42% of households where a family member had used telehealth, 64% would have preferred an in-person visit despite high satisfaction (82%) [22]. A unique finding of this study was the issue of distraction during virtual visits, including conducting them while a patient was driving. There are few recommendations to guide virtual cardiac care in Canada [6], and guidelines for both patients and providers are needed regarding timeliness (eg, responsiveness and being on time), safety, and ways to promote effective communication during virtual visits.

Patients supported virtual care's fit for small, quick, and mundane issues (eg, medication refills) but found it suboptimal for new and serious issues that are more appropriate for an in-person visit. Patients' perspectives aligned with a survey of Canadian cardiologists (n=26) who identified the need for in-person visits for patients who were very sick, had communication challenges, required physical assessment to inform care options, required hands-on tasks, or were new patients [11]. National and provincial virtual care policy and guidelines direct care providers to limit virtual encounters to those requiring only history, gross inspection, or data that patients can gather with cameras or other devices. According to these guidelines, any new or significant symptoms require in-person care rather than virtual care [23]. Although patients thought they should be able to choose the modality for their appointments, the physician's clinical judgment must also be considered, and this collaborative decision-making is important to consider in negotiating patient and provider virtual care expectations.

Patients suggested greater sharing of patient-reported data with their providers to enhance the benefits of virtual care visits and to better meet their health needs. Jamieson et al [24] regarded

virtual care as creating the preconditions for truly empowered patients and patient-centric care—the equivalent of other life activities such as banking and shopping. Such data sharing has the potential for expanding the scope of virtual care. Patients in this study gravitated toward a hybrid model of AF care and made several recommendations for optimizing care using this model. For example, patients recommended supplementing their care with the use of tools and technology to send their providers biometric data. Similarly, in a survey of Canadian patients who had had a virtual visit with a cardiology health care provider, 72% of patients preferred a hybrid model, with 68% indicating interest in using an electronic tool (eg, email or mobile app) to share nonurgent health information with their health care provider [11]. Patient satisfaction with virtual care was high in a study that had patients upload vital signs (heart rate, blood pressure, blood glucose, weight, and temperature) to the virtual platform before their face-to-face video call with the clinical nurse specialist at the technology-enabled arrhythmia clinic [7].

The patients also raised concerns about the effectiveness of virtual communication with their providers. To date, little is known about the effectiveness of patient-provider communication during telemedicine or virtual encounters [25], generally or specific to cardiovascular care [20]. However, evidence has shown that interventions targeting patient-provider communication improve population health, patient and provider experiences, and costs [26]. Study participants emphasized the importance of effective communication—the patient relaying the information accurately and comprehensively and the provider receiving and interpreting it [27]—but often felt a greater weight of responsibility, lack of confidence, and limited validation in virtual communication with their specialists. Similarly, a study on patients' contributions during virtual gastrointestinal consultations found that patients assumed increased agency in their contributions, as few were explicitly doctor driven [28]. Frankel and Beckman [29] described patients and providers as relational units with shared responsibility in coproducing more efficient and effective interactions. These interactions can be enhanced by improving patients' health literacy through digital approaches to education [30] and self-management support [31].

Some of the participants' communication concerns may reflect the high use of the telephone (27/30, 90%) as the primary modality in this study, and such use is consistent with the finding from another Canadian study of virtual cardiology care [11]. Telephone affords only the use of audio communication without the benefit of visual cues that play an important role in complementing the verbal message, especially when virtual care does not permit physical and hands-on examination, and compared with virtual care, it has been linked to lower-quality patient-provider virtual communication [26]. Furthermore, evidence suggests that videoconference may offer improved initial diagnostic accuracy compared with the telephone [32]. Virtual care practice resources and toolkits developed for Canadian physicians that have emphasized patients' technological readiness or preparation for a virtual video appointment [23] may need to be balanced with consideration of communication issues relevant to both patients and providers. Patients also experienced some communication challenges with the clinic more generally when they were seeking to initiate contact for a variety of reasons but particularly in booking follow-up to procedures, when they relapsed, or had unexpected health events. A directory made available for patients being seen at the clinic could help avert dual stress for patients of being unable to access clinic personnel and experiencing unwanted AF challenges.

Limitations

This study has some limitations. First, the findings are limited to patients from only one urban AF clinic, but it has a large reach and overlapping catchment service area with other AF clinics because of its advanced specialized care. Second, despite a robust sample size for a qualitative study, there is potential for selection bias, as recruitment may have attracted participants more positive about their experiences with virtual care and those who had also participated in the larger study survey. Third, the group effect of using focus groups may have limited individual insights, but the relatively small size of the focus groups facilitated more in-depth sharing of individual experiences. Finally, the lack of diversity may limit the transferability of the findings beyond the population represented, although other researchers and users will need to make that determination. However, our sample did represent a similar composition of patients to the clinic demographics.

Conclusions

Virtual care from a specialty AF clinic provides practical benefits for patients but must be weighed against the need for virtual care's fit with the complexity of this patient population's ever-changing needs and problems. Participants clearly defined when virtual care aligned with their needs and when it did not, and this reflected the complexity of their health needs and their management; these are important considerations in decisions about appointment modality. Virtual care fit was often gauged by patients' perceptions of the effectiveness of their communication with providers and the timeliness of follow-up. Greater attention to the quality and timing of virtual communication may help optimize the fit. Patients recommended that the use of virtual care as a supplement for in-person care in the form of hybrid approaches integrating patient-generated data, video, and digital tools is a better fit with their preferences and needs.

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Authors' Contributions

KLR, PL, JGA, and LM contributed to the study design. KLR, LB, and RW contributed to data collection, and KLR, LB, and SS analyzed the data. KLR drafted the manuscript. All authors have critically revised and approved the manuscript for publication.

Conflicts of Interest

JGA reports grants from Medtronic and the Heart and Stroke Foundation of Canada during the conduct of this study; personal fees from Medtronic and Biosense Webster Inc, outside the submitted study. The other authors have no conflicts to declare.

Multimedia Appendix 1
Interview guide.
[DOCX File , 68 KB - cardio_v7i1e41548_app1.docx]

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Abbreviations

AF: atrial fibrillation

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Original Paper

AI Algorithm to Predict Acute Coronary Syndrome in Prehospital Cardiac Care: Retrospective Cohort Study

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Abstract

Background: Overcrowding of hospitals and emergency departments (EDs) is a growing problem. However, not all ED consultations are necessary. For example, 80% of patients in the ED with chest pain do not have an acute coronary syndrome (ACS). Artificial intelligence (AI) is useful in analyzing (medical) data, and might aid health care workers in prehospital clinical decision-making before patients are presented to the hospital.

Objective: The aim of this study was to develop an AI model which would be able to predict ACS before patients visit the ED. The model retrospectively analyzed prehospital data acquired by emergency medical services' nurse paramedics.

Methods: Patients presenting to the emergency medical services with symptoms suggestive of ACS between September 2018 and September 2020 were included. An AI model using a supervised text classification algorithm was developed to analyze data. Data were analyzed for all 7458 patients (mean 68, SD 15 years, 54% men). Specificity, sensitivity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for control and intervention groups. At first, a machine learning (ML) algorithm (or model) was chosen; afterward, the features needed were selected and then the model was tested and improved using iterative evaluation and in a further step through hyperparameter tuning. Finally, a method was selected to explain the final AI model.

Results: The AI model had a specificity of 11% and a sensitivity of 99.5% whereas usual care had a specificity of 1% and a sensitivity of 99.5%. The PPV of the AI model was 15% and the NPV was 99%. The PPV of usual care was 13% and the NPV was 94%.

Conclusions: The AI model was able to predict ACS based on retrospective data from the prehospital setting. It led to an increase in specificity (from 1% to 11%) and NPV (from 94% to 99%) when compared to usual care, with a similar sensitivity. Due to the retrospective nature of this study and the singular focus on ACS it should be seen as a proof-of-concept. Other (possibly life-threatening) diagnoses were not analyzed. Future prospective validation is necessary before implementation.

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KEYWORDS

cardiology; acute coronary syndrome; Hollands Midden Acute Regional Triage–cardiology; prehospital; triage; artificial intelligence; natural language processing; angina; algorithm; overcrowding; emergency department; clinical decision-making; emergency medical service; paramedics

Introduction

Overcrowding of emergency departments (ED) and hospitals is a concerning problem in many countries and is associated with increased mortality, delays in the initiation of critical care and dissatisfied patients and health care workers [1,2]. The causes of overcrowding are multifactorial, such as a large and growing supply of patients due to ageing, and insufficient capacity in hospitals due to personnel and resource shortages. Cardiovascular disease is the most common cause of mortality and morbidity, and as such contributes enormously to overcrowding. In 2019 there were an estimated 5.8 million new cases of ischemic heart disease in Europe [3]. Therefore, a large volume of patients presented to the hospital (around 1.95 million per year in the Netherlands [4]) are presented with symptoms of possible cardiac origin. However, not all patients visiting the ED need to be admitted to the hospital. For example, 80% of patients visiting the ED because of chest pain do not have an acute coronary syndrome (ACS) and can be reassured and discharged after a short analysis [5,6]. If these patients could be identified before visiting the ED, this could relieve pressure from EDs and prevent time-consuming and stressful ED visits for patients.

While there is extensive experience with prehospital triage in patients with trauma, the experience with prehospital triage in patients with cardiac symptoms is still limited. Recently, the FamouS Triage [7], ARTICA [8] and Hollands Midden Acute Regional Triage–cardiology [9,10] studies focused on improving triage of cardiac patients when patients contact the emergency medical services (EMS). These studies focused on selecting “low risk” patients who could safely stay at home after paramedic assessment. The FamouS and ARTICA studies used prehospital point-of-care troponin assessments, while the Hollands Midden Acute Regional Triage–cardiology study implemented a novel triage platform combining prehospital and hospital data.

Of note, the decision whether a patient can stay at home or should be transported to an ED in these studies was a purely human decision by health care professionals. The accuracy of these decisions is therefore highly dependent of training and expertise. Within these processes enormous amounts of data were gathered, processed, evaluated, and analyzed.

Artificial intelligence (AI) could be useful in analyzing data in medicine [11,12]. In cardiology, AI has mostly been used in integration and analysis of cardiovascular imaging [13]. However, there is potential to aid health care professionals in clinical decision-making such as certain apps do [14]. AI could be useful in making predictions or risk scores by learning from the available data. It might then be possible to identify low-risk patients through these AI generated risk scores in the prehospital setting. Patients could be reassured and safely stay at home, instead of being presented to the hospital.

The aim of this study was to develop an AI model able to predict ACS from prehospital data in patients presenting to the EMS. The AI model may be used as a proof of concept for future research on prehospital decision-making. In order to be a reliable tool, the AI model should have an increased specificity and at least a similar sensitivity as compared to regular care, as this could lead to an increase in patients staying at home after EMS consultation.

Methods

Study Design and Patient Population

The retrospective cohort study included all adults (aged 18 years or older) presenting to the regional EMS Hollands-Midden, servicing around 800,000 inhabitants in a mostly urban area, between September 2018 and September 2020 for symptoms suspected to be of cardiac origin. Patients were recruited in the prehospital setting by nurse paramedics. All data were acquired by a nurse paramedic and noted in AMBUFORMS (Topicus). Baseline characteristics are shown in Table 1.

Patients experiencing out-of-hospital cardiac arrest, (cardiac) shock, or patients visited by the EMS for noncardiac symptoms were excluded. The final diagnoses for ACS (defined as ST elevation myocardial infarction, non-ST elevation myocardial infarction, or unstable angina pectoris [15]) from all referrals to the ED were acquired through hospital billing data.

Table 1. Baseline characteristics of all recruited patients divided between patients who were ultimately presented to the hospital and patients who stayed at home after EMS[a] consultation in this retrospective cohort study analyzing an AI algorithm in prehospital cardiac care.

Characteristic	Hospital (n=7386)	Home (n=72)
Women, n (%)	3991 (54)	37 (51)
Age (year), mean (SD)	68 (15)	67 (12)
Distance to hospital (km), mean (SD)	11.6 (8.3)	14.3 (12.0)
Day of presentation, n (%)		
Monday	1414 (19)	20 (28)
Tuesday	1412 (19)	13 (18)
Wednesday	1224 (17)	15 (21)
Thursday	1196 (16)	5 (7)
Friday	1260 (17)	10 (14)
Saturday	438 (6)	5 (7)
Sunday	442 (6)	4 (6)
Chest pain at presentation, n (%)	2741 (37)	31 (43)
ACS[b] diagnosis, n (%)	980 (13.3)	4 (5.6)

[a]EMS: emergency medical service.

[b]ACS: acute coronary syndrome.

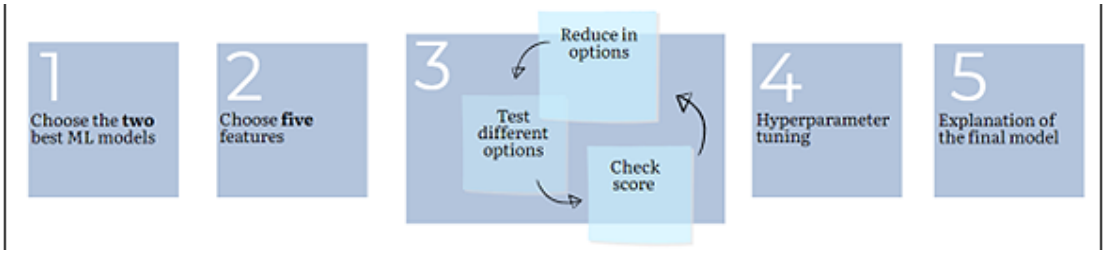
AI Model

Separate columns of data points, or features, were filled by paramedics for every patient. Patient data were stored on an external secure database AMBUFORMS. Patient data comprise quantitative data such as oxygen saturation, blood pressure, and heart rate and textual data created by the paramedic, such as the patient's medical history, medication use, current symptoms, and physical examination. Table S1 in Multimedia Appendix 1 shows an overview of all available features evaluated by the AI model.

The 5 steps toward developing the final AI model are shown in Figure 1. The model was developed using Python (version 3; Python Software Foundation). At first, a machine learning (ML) algorithm (or model) was chosen, afterwards the features needed were selected and then the model was tested and improved using iterative evaluation and in a further step through hyperparameter tuning. Finally, a method was selected to explain the final AI model.

In the first step, the *2* best ML models (or algorithms) were selected from 4 algorithms, namely support vector machine (SVM), random forest (RF), k-nearest neighbor (KNN) and logistic regression (LR). These models were preselected because they are well known when applying natural language processing (NLP) [16,17].

Figure 1. In total, there are 5 steps toward developing the final artificial intelligence (AI) model in this retrospective cohort study analyzing an AI algorithm in prehospital cardiac care. ML: machine learning.



The *SVM model* converts the input to a vector in space. If all inputs are plotted, a hyperplane will be created. This plane is able to separate 2 classes of input from each other. The *RF model* is a classification algorithm consisting of many decisions trees. It creates an uncorrelated forest of decision trees from building individual decision trees. The forest of trees is more accurate than any individual tree. The *KNN model* finds distances between queries and examples in the data, selecting the specified number (K) closest to the query. Then the model votes for the most frequent label in the case of classification.

The *LR algorithm* can be used for regression as well as classification tasks, for our model the classification tasks are used. LR has a binary response variable, which belongs to one of the classes. It is used to predict categorical variables with the help of dependent variables. Every model generated an Fβ score by analyzing all available data points. The most appropriate models were selected based on their respective Fβ score. The Fβ score was calculated as (1+β^2) × ((precision × recall) / ((β^2 × precision) + recall)).

Features (or columns of data) were selected in the second step. Further, 3 new features were created; a selection of all available data (CompiledALL), a selection of all textual data (CompiledTEXT), and a selection of all data thought to be relevant by a consulted cardiologist (CompiledSELECT). The CompiledSELECT feature was a combination of medical history, current symptoms, and electrocardiogram description, all of which were textual data noted by a nurse paramedic on the scene. Based on the Fβ and recall scores, commonly used within AI, the most relevant features were selected.

In the third step, separate parts of the algorithm were tested, after which highest scores were compared and other options were reduced or eliminated. In the first phase of this "loop" the 2 remaining models are tested, and the model with the lowest recall scores was eliminated. In the second phase, the selected features from step 2 were preprocessed and analyzed. The final feature was selected for the model. Then the threshold for the algorithm was analyzed and determined to find the correct false negative (FN) score.

The fourth step is fine-tuning the hyperparameters. In ML models settings can be altered to change the behavior of the model, and make predictions more accurate. Each model has one or multiple of these settings, called hyperparameters. For example, the SVM model has only 1 hyperparameter, named C. This hyperparameter has the options: 0.01, 0.1, 1, 10, 100, and 1000. During the previous steps, the default settings were used. By changing these settings, through trial-and-error, the final AI model can be optimized and the outcomes altered.

A *Python* package called "Explain Like I'm 5" (ELI5) was used to improve understanding of the model [18]. ELI5 explains classifiers and predictions in NLP by scoring the importance of words in text. The higher the importance of a word, the more influence it has on the eventual output of the AI model.

Statistics

The following metrics were used to test reliability of the final AI model: precision, recall, and Fβ score. The Fβ score combines precision and recall, and the "beta" highlights the importance of one of the 2 metrics. A beta of 1 means both metrics were equally important, a beta lower than 1 means precision was more important, and a beta higher than 1 means recall was more important.

These metrics were clinically correlated using sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV). Sensitivity (=recall) is the ability to correctly identify patients with a disease, in this case meaning no ACS were missed. Specificity is the ability to correctly identify patients without the disease, for the purpose of this study meaning no patients were unnecessarily presented to the hospital. NPV predicts the likelihood of a correct decision to leave patients at home and PPV (=precision) predicts the likelihood of a correct decision to present a patient to the hospital. The equations are given in Table S2 in Multimedia Appendix 2. All these parameters were calculated using true positives (*TP*), false positives (*FP*), true negatives (*TN*), and *FN*. *TP* was defined as a patient who was presented to the hospital who ultimately experienced ACS. *FP* was defined as a patient presented to the hospital who did not experience ACS. A *TN* was a patient who could stay at home and did not experience ACS, and a *FN* was defined as a patient who stayed at home but ultimately did experience ACS.

Ethical Considerations

This study complies with the Declaration of Helsinki and the triage method was approved by the Hospital's Medical Ethics Committee (P18.213). Patients were requested to provide verbal informed consent for participating in the triage method. Data were analyzed anonymously, all patient data were deidentified.

Results

Study Population

In total, 7458 patients (mean 68, SD 15 years, 54% men) were included in this study. For every patient, 270 features were available for the AI model. The primary presenting symptom was chest pain in 4686 (63%) patients, while 2772 (37%) patients had other symptoms (such as dyspnea, palpitations, or near-collapse). The EMS nurse paramedics decided that 72 patients could stay at home (1%): these patients were consequently not transported to the ED. Accordingly, in 7386 patients a medical analysis was performed at the ED: this showed an ACS in 980 patients. From the patients who stayed at home ultimately 4 were diagnosed with ACS within 30 days of staying at home.

AI Model

The RF model had a mean Fβ score of 0.61, and the LR model had a mean Fβ score of 0.63. The 2 best models were the SVM model with an Fβ score of 0.71 and the KNN model with an Fβ of 0.88. The Fβ had a beta of 2 because this would mean that FN, an important outcome for the final model, had a higher weight. Table S3 in Multimedia Appendix 3 shows the outcomes from all AI models per feature.

Second, the 5 most relevant features were selected. The Fβ (again with a beta of 2) scores of all 17 features were between 0.75 and 0.89 for both the KNN and the SVM model. The recall scores were used to reduce the starting 17 features to 5. The "CompiledSELECT"-, physical examination–, physical survey–, differential diagnosis–, and control room note features had the highest recall scores. For the SVM model these were 0.6, 0.85, 0.71, 0.79, and 0.61, respectively. The KNN model had recall scores of 0.13, 0, 0.02, 0.01, and 0.05.

In the third step recall and FN score of both models for the 5 selected features were calculated. The recall scores for SVM were higher (as seen in step 2) and therefore the KNN model was eliminated. In the second phase the 5 remaining features were preprocessed, reducing the model to 1 single feature. The feature with the highest recall and FN score was "CompiledSELECT." Lastly a threshold was selected for the model. A threshold of 0.955, 0.983, and 0.991 gave recall scores of 0.95, 0.995, and 1, respectively.

The final step of the model, step 4, is the tuning of hyperparameters. As mentioned before, the SVM model has 1 hyperparameter, or setting, named C. Recall scores were highest when this hyperparameter was set to 0.1.

The results from analyzing the textual data by the final AI model were shown through ELI5 in Figures 2 and 3. The AI model recognized words that are linked to myocardial infarction in green and words that are not linked to myocardial infarction in red. All textual data were analyzed this way. The final AI model resulted in a recall score of 1.00 and precision score of 0.15 as compared to 1.00 and 0.12 in usual care respectively.

Figure 2. Global explanation of the artificial intelligence (AI) model in this retrospective cohort study analyzing an AI algorithm in prehospital cardiac care. Green shows words which correlate with patients who experienced myocardial infarction, whereas red correlates with patients who did not experience myocardial infarction. acs: acute coronary syndrome; ecg: electrocardiogram; pci: percutaneous coronary intervention; pob: chest pain; STEMI: ST-elevation myocardial infarction.

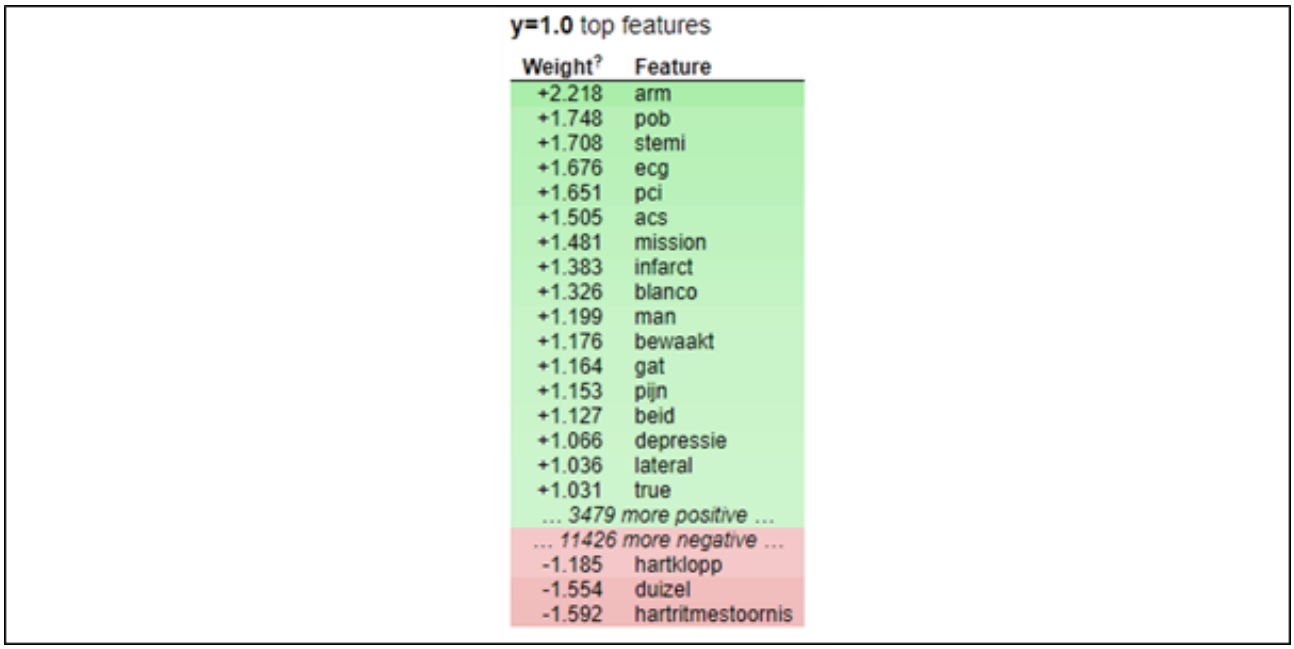
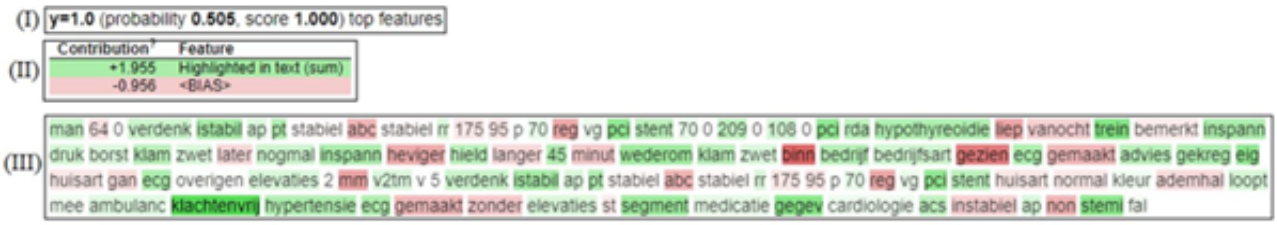


Figure 3. Explanation by ELI5 where red words represent the class "myocardial infarction" and green "no-myocardial infarction" in this retrospective cohort study analyzing an AI algorithm in prehospital cardiac care. ELI5: "Explain Like I'm 5.".



Clinical Results

The AI model was able to identify 713 TNs (patients who could stay at home without experiencing ACS) as compared to 68 TNs in usual care. There were 4 FNs (patients who stayed at home but did experience ACS) in the usual care group and 4 in the AI model, meaning a total of 645 patients could potentially stay at home without missing more ACS. This is an increase in TNs of 945% (n=577). Subsequently, the FPs (patients presented at the hospital without experiencing ACS) decreased by 10% (n=645) as there were 5761 patients identified in the AI model and 6406 patients in usual care. TPs remained similar when comparing usual care with the AI model, both comprised of 980 patients.

The AI model had a specificity of 11% and a sensitivity of 99.5% whereas usual care had a specificity of 1% and a sensitivity of 99.5%. The PPV of the AI model was 15% and the NPV was 99%. The PPV of usual care was 13% and the NPV was 94%.

Discussion

Principal Findings

This study evaluates a newly developed AI model to predict ACS in patients presenting to the EMS. The model was developed as a proof of concept for prehospital triage based on large amounts of EMS data. This study demonstrates that the AI model is able to predict ACS with a similar sensitivity and a higher specificity as compared to usual care, which means more patients can stay at home and a low number of ACS are missed.

Resources in health care are scarce, the shortages in health care personnel are increasing and hospitals and ED's are increasingly (at risk of being) overcrowded. With an ageing population more patients are expected in the near future, putting even more strain on the existing health care resources. It is of utmost importance to correctly allocate (or triage) these scarce resources to the right patient, preferably as early as possible in the health care process, thus, ideally, before patients are presented to the ED.

Selecting the appropriate patient to safely stay at home can prevent stressful and time-consuming ED visits for patients. Risk scores developed and analyzed by AI could be useful since the current forms of prehospital triage [8,9,19-21] all depend on health care personnel, such as EMS paramedics, cardiologists, or general practitioners. AI models could reduce costs and decrease the amount of personnel needed while maintaining high quality health care. As a last point, (human) experience-based triage has the potential for errors, whereas AI, by definition, has a lower interobserver variability. Implementation of AI may therefore potentially limit these errors.

AI within the field of cardiology has mainly been applied in automating the interpretation of cardiac imaging [13,22] and electrocardiography [23]. It has also proven to be useful in predicting events in asymptomatic patients and in patients following ACS [24,25], or, when using textual data, by determining cardiovascular disease risk from social media [26]. In-hospital AI, outside of the field of cardiology, has been able to identify patients admitted to the ED at risk of clinical deterioration [27], and identify low-severity patients for quick discharge [28]. However, the evidence for the use in prehospital triage is scarce. In the prehospital setting, there have been some studies where AI was able to predict the need for critical care or hospital admission for all patients [29,30], and in mass casualty incidents [31]. However, prehospital triage for cardiac symptoms with the intention for patients to stay at home after EMS consultation has not been described.

Because of the retrospective nature of this study, the binary outcome (ACS or no ACS) was known and thus supervised ML classification was used. The 4 presented algorithms (SVM, RF, KNN, and LR) are most commonly used [16,17] when using supervised classification and analyzing textual data (and thus when applying NLP). Ultimately, the SVM algorithm was implemented in the final AI model.

The model had a specificity of 11% and a sensitivity of 99.5% whereas usual care had a specificity of only 1% and a sensitivity of 99.5%. The AI model led to an 1100% increase in specificity as compared to regular care. The AI model was able to identify more TPs, meaning more patients without ACS could stay at home after EMS consultation. Both methods had a very high sensitivity, meaning there were (almost) no FNs. Thus, a very small number of patients (<0.5% or n=4) were left at home who ultimately experienced ACS. This is important, as delayed care in patients with ACS results in higher mortality and disability rates [32]. To the best of our knowledge there are no examples of studies within the field of cardiology that describe the specificity and sensitivity of the clinical use of their AI algorithm as described in this study. As mentioned above, in clinical practice the specificity of prehospital triage for cardiac symptoms is very low, as ACS is a diagnosis that is not to be missed. Of note, sensitivity and specificity of all patients in this study, low-risk, medium-risk and high-risk combined, are comparable to the sensitivity and specificity of only the low-risk patients in the HEART score (<2), which had a sensitivity of 98.9% and a specificity of 14.7% [33].

This study is the first study to evaluate an AI model in prehospital triage of cardiac patients. The model analyzed routinely collected data from prehospital EMS care and, when applied, could be a useful tool to aid in triage for first responders. The AI model could easily be trained for other purposes, such as different symptoms or cardiac symptoms in different countries. An AI based model is futureproof, since, when available, more advanced techniques, models, and approaches could be built in to the model. The complexity and amount of medical data (and patients) is expected to increase in the future; therefore, advanced pattern finding by AI can be hugely beneficial. It seems that an AI model which uses text classification could be useful for other medical specialties as well. Prehospital triage of surgical patients could possibly be improved by an AI model. The model could analyze the textual data from a nurse paramedic and assess whether patients need to be transported and, importantly, which hospital might be best suited for that specific patient. For instance, patients with fever and specific abdominal pain could be presented to a hospital with surgical capabilities, where patients with shortness of breath and a history of coughing up blood could be assessed in a hospital with the capabilities of treatment of pulmonary embolism, thereby improving prehospital triage. Furthermore, it is far less dependent on the (scarcely) available professional workforce. For future research, validation, and eventual implementation it is important to streamline the methods of data collection and analysis. By structuring medical data AI models could be of even greater benefit. Of importance, health care professionals should always have the final say in the decision.

This study has some limitations. The most important limitation is that the AI model was only able to predict ACS or “no ACS,” a sort of pseudo-diagnosis. It does not take into account important, possible life-threatening causes of chest pain, such as pulmonary embolism or aortic dissection. Therefore, it cannot be said with surety that patients can be left at home if ACS is ruled out. Future research should include all of these possible causes and look for stronger end points such as hospital admission for other causes or even 30-day mortality. It is important to note that an AI model should always be used as a tool, or aid, in prehospital decision-making. It should never be used to overrule decisions made by clinicians who are with the patients.

Furthermore, the AI model has only been able to identify patients in a retrospective manner, validation and further research is needed in a prospective setting. Herein also lies the practical limitation, as it is still very difficult to prospectively validate AI models, especially in the prehospital setting. Furthermore, the model needs to be trained regularly and there will always be cases which the model hasn’t seen before making it possibly prone to errors.

Conclusions

This retrospective study is a proof-of-concept of an AI model which was developed to identify patients with ACS in the prehospital setting based on textual data. The model had a similar sensitivity and an 1100% increased specificity as compared to usual care.

Acknowledgments

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Data Availability

The data sets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Table S1. List of features used in the AI model, originally in Dutch translated to English.
[DOCX File , 18 KB - cardio_v7i1e51375_app1.docx]

Multimedia Appendix 2
Table S2. Equations of metrics used in the presented study.
[DOCX File , 14 KB - cardio_v7i1e51375_app2.docx]

Multimedia Appendix 3
Table S3. Fβ score of the four different models per Dutch feature (translation in English) used in the AI algorithm.
[DOCX File , 16 KB - cardio_v7i1e51375_app3.docx]

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Abbreviations

ACS: acute coronary syndrome
AI: artificial intelligence
ED: emergency department
ELI5: Explain Like I'm 5
EMS: emergency medical services
FN: false negative
FP: false positive
KNN: k-nearest neighbor
LR: Logistic Regression
ML: machine learning
NLP: natural language processing
NPV: negative predictive value
PPV: positive predictive value
RF: Random Forest
SVM: support vector machine
TN: true negative
TP: true positive

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Original Paper

Physician- and Patient-Elicited Barriers and Facilitators to Implementation of a Machine Learning–Based Screening Tool for Peripheral Arterial Disease: Preimplementation Study With Physician and Patient Stakeholders

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Abstract

Background: Peripheral arterial disease (PAD) is underdiagnosed, partially due to a high prevalence of atypical symptoms and a lack of physician and patient awareness. Implementing clinical decision support tools powered by machine learning algorithms may help physicians identify high-risk patients for diagnostic workup.

Objective: This study aims to evaluate barriers and facilitators to the implementation of a novel machine learning–based screening tool for PAD among physician and patient stakeholders using the Consolidated Framework for Implementation Research (CFIR).

Methods: We performed semistructured interviews with physicians and patients from the Stanford University Department of Primary Care and Population Health, Division of Cardiology, and Division of Vascular Medicine. Participants answered questions regarding their perceptions toward machine learning and clinical decision support for PAD detection. Rapid thematic analysis was performed using templates incorporating codes from CFIR constructs.

Results: A total of 12 physicians (6 primary care physicians and 6 cardiovascular specialists) and 14 patients were interviewed. Barriers to implementation arose from 6 CFIR constructs: complexity, evidence strength and quality, relative priority, external policies and incentives, knowledge and beliefs about intervention, and individual identification with the organization. Facilitators arose from 5 CFIR constructs: intervention source, relative advantage, learning climate, patient needs and resources, and knowledge and beliefs about intervention. Physicians felt that a machine learning–powered diagnostic tool for PAD would improve patient care but cited limited time and authority in asking patients to undergo additional screening procedures. Patients were interested in having their physicians use this tool but raised concerns about such technologies replacing human decision-making.

Conclusions: Patient- and physician-reported barriers toward the implementation of a machine learning–powered PAD diagnostic tool followed four interdependent themes: (1) low familiarity or urgency in detecting PAD; (2) concerns regarding the reliability of machine learning; (3) differential perceptions of responsibility for PAD care among primary care versus specialty physicians; and (4) patient preference for physicians to remain primary interpreters of health care data. Facilitators followed two interdependent themes: (1) enthusiasm for clinical use of the predictive model and (2) willingness to incorporate machine learning into clinical care. Implementation of machine learning–powered diagnostic tools for PAD should leverage provider support while simultaneously

educating stakeholders on the importance of early PAD diagnosis. High predictive validity is necessary for machine learning models but not sufficient for implementation.

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KEYWORDS

artificial intelligence; cardiovascular disease; machine learning; peripheral arterial disease; preimplementation study

Introduction

Peripheral arterial disease (PAD) afflicts over 8 million Americans and is associated with an increased risk of major cardiac events, major limb events, and all-cause mortality [1]. In the current diagnostic approach, physicians perform an ankle brachial index (ABI) on patients in whom PAD is suspected based on risk factors or symptomatology; an ABI less than 0.9 is suggestive of PAD. Cross-sectional studies suggest PAD is underdiagnosed, with only 10%-30% of patients presenting with stereotypical symptoms and less than 50% of patients and primary care physicians reporting awareness of the disease [2,3].

Machine learning (ML) algorithms may improve PAD detection by identifying high-risk patients who would benefit from ABI testing. By integrating diverse data sources in the electronic health record, such as genomics, wearable data, and medical history, in nonlinear ways, ML may ease the cognitive workload of diagnosis while assisting clinical decision-making. Previously reported algorithms have demonstrated greater than 90% sensitivity and specificity, exceeding that of logistic regression [4,5].

Despite superlative diagnostic performance, previously reported barriers to ML implementation in health care include low acceptability among physicians due to alert fatigue and a lack of algorithmic transparency [6,7]. Patients have also voiced concerns that ML will interfere with the patient-physician relationship and increase the risk of data misuse or privacy violations [8,9]. Ultimately, improving PAD detection requires stakeholder acceptance of and investment in novel diagnostic approaches. A qualitative assessment of patients' and physicians' perceptions of a novel ML-powered diagnostic intervention for PAD is needed to better inform implementation strategies. In this study, we evaluate physician- and patient-elicited barriers and facilitators to the implementation of an ML-based PAD screening tool in outpatient clinics affiliated with a quaternary care teaching hospital.

Methods

Setting

This project was conducted jointly with Stanford University's Divisions of Primary Care and Population Health, Vascular Medicine, and Cardiology. Interviews were conducted from September 2021 to May 2022. This quality improvement project received a nonresearch determination by the Stanford University Institutional Review Board (Eprotocol-62076).

We have previously described the development of an ML model based on the Stanford Medicine Research Data Repository, which contains clinical practice data from over 4 million adult patients from 1998 to 2020. This model outperformed Duval et al's [10] traditional nomogram for PAD diagnosis and logistic regression with respect to sensitivity, specificity, and discrimination. The objective of this study is to solicit patients' and physicians' perspectives regarding the integration of this model into the electronic health record to notify physicians to consider PAD screening in patients with a high risk of PAD.

Theoretical Framework

The Consolidated Framework for Implementation Research (CFIR) integrates metrics from previous implementation frameworks into 5 domains: intervention, outer setting, individual characteristics, inner setting, and process [11]. CFIR was chosen as the framework for this study because it allows identification of barriers and facilitators among diverse stakeholders and has been shown to be useful in guiding rapid-cycle evaluations of clinical interventions [12].

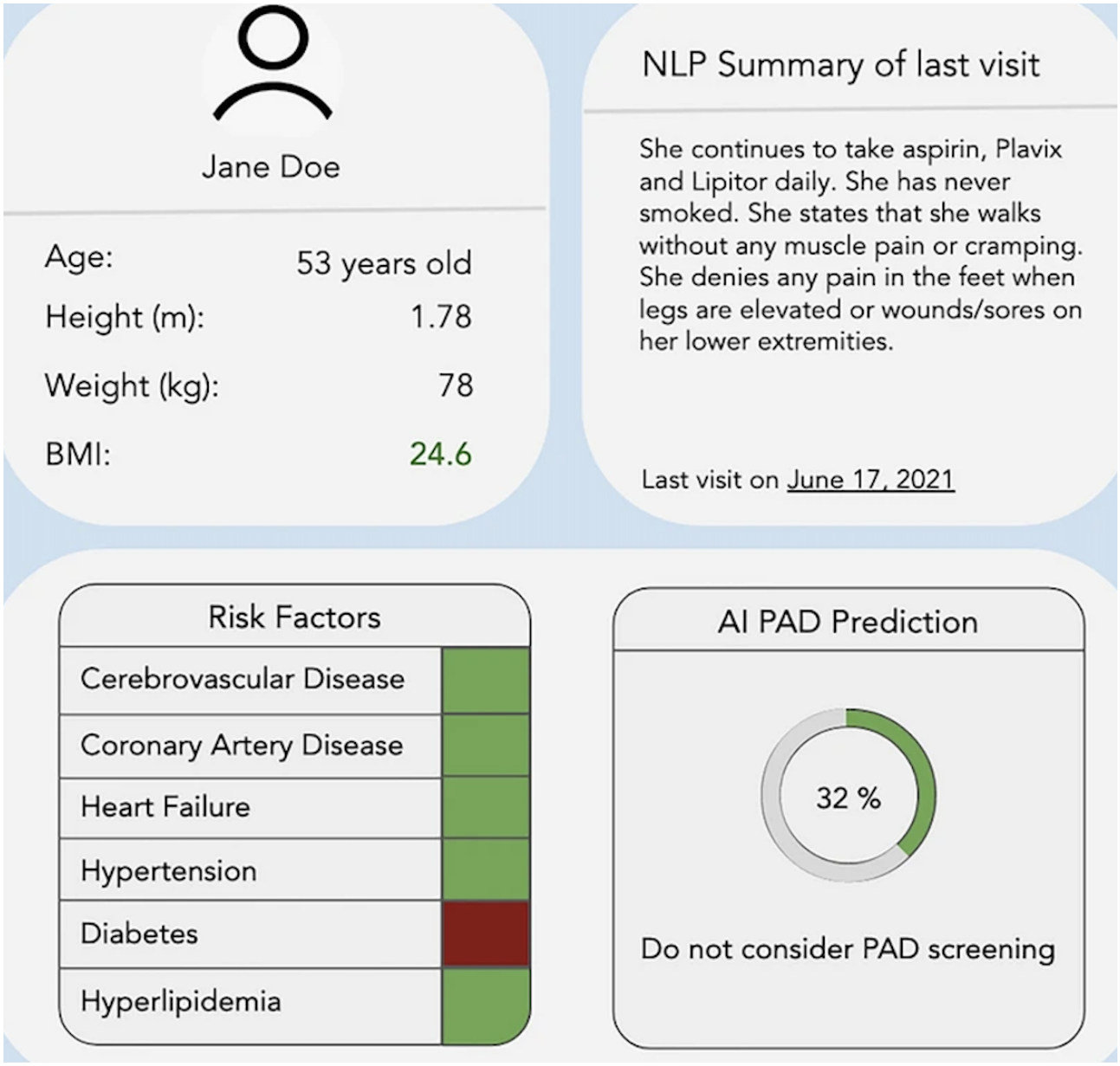
Participants and Study Design

A semistructured interview guide was developed to contextualize the vignettes within barriers and facilitators from the CFIR domains. Vignettes and interview guides were pretested with 3 cardiovascular physicians who were excluded from the list of prospective interviewees to ensure appropriate clinical relevance and formatting. Vignettes were designed to simulate environments in which patients have a moderate pretest probability of PAD, with comorbidities that are established risk factors such as diabetes, hypertension, and old age. The order in which vignettes were administered was randomized between participants. An interview guide for physician participants containing patient vignettes and prompts is provided in Multimedia Appendix 1.

For the physician evaluation, semistructured interviews were conducted with faculty in cardiology, vascular medicine, and primary care to represent the variation of physicians who typically diagnose PAD. The study team sent an email to each department seeking volunteers for participation and arranged interviews with respondents. One author (VH) conducted interviews through videoconferencing with previous verbal consent.

After discussing their current approach to diagnosing PAD, participants listened to a simulated patient vignette and were prompted to navigate an ML-powered dashboard containing the patient's information and PAD risk prediction score while thinking aloud. A total of 2 simulated patient vignettes were used, one in which screening was recommended and one in which screening was not recommended. Figure 1 depicts the output of the PAD screening tool alongside summarized fictional patient data.

Figure 1. Peripheral arterial disease screening tool output presented to physician interviewees. NLP: natural language processing.



For the patient evaluation, participating cardiovascular physicians were asked for permission to contact patients who had been seen by them on an outpatient basis in the past 2 months. Physicians who gave verbal consent to proceed were also given the opportunity to identify patients who should not be contacted for study participation. A list of all eligible patients was then generated and randomized. Semistructured interviews were then sequentially conducted through telephone, with a total of 42 calls made without leaving voice messages to yield 14 patient interviews. One female researcher (VH) with previous postdoctoral clinical training in vascular surgery and no previous contact with study participants conducted interviews, prompting patients to discuss their current perceptions and previous experiences regarding ML and PAD with previous verbal consent. The researcher's clinical background in vascular surgery was disclosed to physician interviewees but not to patient interviewees.

Interviews continued until thematic saturation was reached, defined as the inflection point after which new interviews ceased to surface new themes or perspectives. All interviews were performed with only the researcher and interviewee present, and no repeat interviews were performed. Transcripts were not made available to participants after the fact. An interview guide for patient participants is provided in Multimedia Appendix 2.

Qualitative Analysis

As per standard rapid analytic methods, template summaries were used to summarize each interview transcript into structured one-page documents that captured major a priori themes [13,14]. Template summaries are frequently used in rapid qualitative analyses, allowing for an expedited review process without formal coding (Multimedia Appendix 3). Summaries were then analyzed with deductive and inductive approaches, allowing for subsequent organization by CFIR domain. Deductive themes were derived from outcomes of interest, while emergent barriers and facilitators were identified inductively. Subsequent analysis and reporting conformed to the COREQ (Consolidated Criteria

for Reporting Qualitative Research) standardized guidelines (Multimedia Appendix 4).

Ethical Considerations

This study was deemed not to constitute human participant research by the Stanford University institutional review board as a quality improvement study (IRB code 62076). All study data were anonymized and stored locally on an encrypted institutional device. All physician research participants were awarded a US $25 gift card for participation, while patient research participants were not offered any compensation.

Results

A total of 12 physicians (6 primary care and 6 cardiovascular specialists) and 14 patients were interviewed. Table 1 provides key sample characteristics for participating physicians. There was an equal distribution of male and female physicians, with the majority of interviewees having less than 10 years of practice experience. Table 2 provides key sample characteristics for participating patients. The majority of patients were male, greater than 50 years of age, and used Medicare as their primary insurance plan.

Out of the 37 CFIR constructs, 5 emerged as barriers to implementation, 4 emerged as facilitators, and 1 construct had both barrier and facilitator attributes. Table 3 summarizes the relevant CFIR domains, constructs, and subthemes.

Table 1. Key sample characteristics for participating physicians.

Characteristics	Values, n (%)
Gender	
Male	6 (50)
Female	6 (50)
Other or decline to state	0 (0)
Race	
Asian American	4 (33)
Hispanic or Latino	1 (8)
Non-Hispanic African American or Black	1 (8)
Non-Hispanic White	6 (50)
Highest level of postdoctoral education	
Residency	6 (50)
Fellowship	6 (50)
Medical practice (years)	
0-5	4 (33)
5-10	4 (33)
10-20	1 (8)
>20	3 (25)

Table 2. Key sample characteristics for participating patients.

Characteristics	Values, n (%)
Gender	
Male	9 (64)
Female	5 (35)
Other or decline to state	0 (0)
Age (years)	
Less than 30	0 (0)
30-50	2 (14)
50-70	10 (71)
>70	2 (14)
Race	
Asian American	2 (14)
Hispanic or Latino	3 (21)
Non-Hispanic African American or Black	3 (21)
Non-Hispanic White	6 (42)
Primary insurance	
Private	4 (28)
Medicare	10 (71)
Other	0 (0)

Table 3. Patient and physician interview themes.

CFIR[a] domain	Barriers	Facilitators
Intervention characteristics	• Complexity: physicians' and patients' perceptions of machine learning as difficult • Evidence strength and quality: lack of physician and patient awareness regarding PAD[b]	• Intervention source: endorsement from vascular surgeons • Patient preference for physicians to remain the primary interpreters of health care data • Relative advantage: patients' and physicians' perceptions of machine learning as a useful decision-making adjunct
Inner setting	• Relative priority: physician-reported low urgency regarding PAD screening	• Learning climate: physician willingness to incorporate clinical decision support into workflows
Outer setting	• —[c]	• External policies and incentives: institutional support for precision medicine
Individual characteristics	• Knowledge and beliefs about intervention: patient concerns regarding data security and privacy • Individual identification with organization: specialty physicians' perception that PAD management is not their responsibility	• Knowledge and beliefs about intervention: physicians' perceptions that an ML[d]-powered PAD tool would improve their ability to care for PAD patients

[a]CFIR: Consolidated Framework for Implementation Research.

[b]PAD: peripheral arterial disease.

[c]Not available.

[d]ML: machine learning.

Intervention Characteristics Domain

Intervention source refers to the perception of key stakeholders regarding whether the intervention is externally or internally developed. Among physicians, primary care physicians responded positively to the affiliation of the study group within the Stanford University Division of Vascular Surgery. These participants felt that having specialists who frequently treat PAD involved in the implementation process demonstrated stakeholder investment that increased the legitimacy of the intervention.

> *If [the intervention] came from our vascular surgery team or someone that I trusted used it I'd think about implementing it.* [Physician 3]

Relative advantage is defined by stakeholders' perceptions regarding the benefit of implementing the intervention against an alternative. Most physicians felt that the intervention would improve their ability to diagnose PAD.

While most patients were comfortable with their physician using this tool in their care, only many did not feel comfortable making decisions about their health based on an ML-powered tool alone. Many patients who were interested in making decisions based on the proposed intervention stipulated that they would want to ensure that their doctors agreed with the model's recommendation, making their physician the primary interpreter of health care data and the ultimate decision maker regarding the conclusions of any proposed screening model.

> *I think artificial and human intelligence should be balanced, with 75% human and 25% artificial intelligence.* [Patient 4]

> *I think [the intervention] could start good conversations, and if there was something that it flagged I'd discuss it further with my physician.* [Patient 12]

Complexity refers to the perceived difficulty of the intervention. While few stakeholders had first-hand experience with ML, both providers and patients expressed concerns that the difficulty of performing ML tasks accurately could lead to unreliable results.

> *What goes into [the intervention]? I don't like to take numbers and data without underlying evidence that this algorithm is validated.* [Physician 3]

> *I've heard about [machine learning], but for it to be used in healthcare it must be really mature… unless it's very well trained and matured you cannot guarantee the results.* [Patient 13]

Aside from the technical complexity, patients also expressed concerns that the intervention could complicate the physician-patient relationship, creating opportunities for misunderstandings or mistakes in care coordination.

> *I could see [the intervention] being good in healthcare because it has the most up to date technology, but it could be bad… in that it changes your interaction with the doctor, or if the doctor doesn't understand what [the intervention] is saying and the two aren't communicating… that's bad. There could be a glitch or misinterpretation.* [Patient 1]

Evidence strength and quality is a subdomain describing stakeholders' perceptions of the validity of evidence supporting the intervention's success. Most providers were not aware of guidelines advocating or discouraging testing patients without lower extremity symptoms for PAD.

> *I don't think there's really established guidelines for screening for asymptomatic PAD.* [Physician 1]

Only 1 provider directly referenced current guidelines and ultimately felt there was a potential benefit to PAD screening.

> *I think there is a potential benefit [to testing asymptomatic patients for PAD]. American College of Cardiology, American Heart Association and vascular surgery guidelines would say potential benefit… I think the United States Preventative Task Force would say it's not clear if there's a benefit.* [Physician 11]

Analogously, only 2 of the 14 interviewed patients were familiar with PAD. One patient was a retired physician, and the other had heard of PAD from friends who were in the health care industry.

Inner Setting Domain

Relative priority entails stakeholders' perceptions about the importance of the implementation. Among providers, most felt that early diagnosis of PAD was not urgent compared to other diseases for which screening is routinely performed. Of the 6 primary care doctors, 3 said that PAD was less urgent than cardiac disease.

> *[PAD] is unlike heart disease in that there's such a thing as a heart attack, so missing screening for heart disease has grave implications. Patients who have risk factors for PAD typically have cardiovascular risk factors and are being treated aggressively anyway.* [Physician 4]

Similarly, 1 physician felt that they already had many tests to request of patients, such that PAD screening may not always feel appropriate:

> *I have to put [the] risk benefit ratio [of PAD screening] in the context of everything else. So if they haven't had their colonoscopy, or their mammogram… do I send them for that if they have limited bandwidth?* [Physician 4]

Learning climate describes a setting in which stakeholders feel that there is enough time, space, and psychological safety to try new practices. Multiple physicians cited familiarity with similar clinical decision support interventions and a willingness to incorporate the intervention.

> *I know there's tools like this and others being created for heart failure risk prediction, so I think it's interesting how we can have these show up on schedules and outpatient records to help us more consistently screen people.* [Physician 7]

Outer Setting Domain

External policies and incentives are strategies to spread interventions, including policies and regulations, external mandates, recommendations, and guidelines. Multiple physicians referenced broader initiatives at Stanford in precision medicine and artificial intelligence as a reason why they were familiar with and interested in the intervention.

> *Stanford has really gone in on precision medicine, you know finding ways to use technologies to assist us in doing our jobs. I haven't been approached about such tools specifically before you but I think it's good that there is a general enthusiasm about it and investment to bring this to reality.* [Physician 1]

Individual Characteristics Domain

Knowledge and beliefs about the intervention reflect individual familiarity with facts, truths, and principles related to the intervention. All providers stated that they diagnosed PAD based on clinical suspicion driven by traditional risk factors such as hypertension, diabetes, smoking history, and symptoms including lower extremity pain or wounds. Most providers believed that PAD was relatively underdiagnosed; even providers who did not think the intervention would benefit their practice believed that patients were being missed based on current diagnostic approaches.

> *PAD, we didn't get that much teaching on it. Everyone thinks so much about coronary artery disease and I feel PAD seems more subtle and we know less about it. I could tell you so much about [coronary artery disease] and I think I know less for PAD.* [Physician 12]

Furthermore, most providers had positive perceptions of ML in health care.

> *I'm all for machine learning in the record to help me be a better doctor. It's going to help me not miss diseases, and its going to help me manage diseases better.* [Physician 4]

Patients' perceptions of ML in health care were generally positive. Some patients associated ML and artificial intelligence with previous innovations they viewed favorably, including robotic surgery and learning software for autistic children.

> *I'm all for technology; I think I've heard about using artificial Intelligence to do surgery, and I don't know much about it but I think it's a good tool.* [Patient 7]

> *I have [artificial intelligence], I hire programmers, my kids use AI-powered software for their autism. I like AI.* [Patient 6]

Some patients objected to the phrase "artificial intelligence" and voiced concerns about its use by nonphysician entities.

> *The wording is scary. 'Artificial intelligence' sounds like it comes from aliens, like not human. The wording should be switched… how it comes off is very strange.* [Patient 3]

> *There's a lot of potential really good stuff you can use machine learning for. On the other hand, if you put it in the hands of insurance companies for them to put together their predictive algorithms I think you may have issues.* [Patient 15]

Individual identification with an organization refers to how individuals perceive the organization and their relationship and degree of commitment with that organization. Among cardiovascular specialists, some providers felt that diagnosing PAD was the responsibility of primary care providers. This led to concerns regarding whether they would be open to using the intervention.

> *To take on PAD screening would be kind of an additional thing outside my normal workflow… I would prefer for the local physician to do the evaluation.* [Physician 8]

Conversely, primary care physicians cited a tension between specialists seeking to screen for a specific disease of interest and primary care physicians who are responsible for managing the whole patient:

> *No offense, but everybody comes to primary care and says, 'Could you screen for my disease?' Whether it be incontinence or prostate cancer, and then they want us to use a specific separate tool.* [Physician 4]

Discussion

Summary of Findings

In this qualitative analysis of patients' and physicians' attitudes toward the development of an ML-powered PAD diagnostic tool, barriers to implementation followed four interdependent themes: (1) low familiarity or urgency in detecting PAD; (2) concerns regarding the reliability of ML; (3) differential perceptions of responsibility for PAD care among primary care versus specialty physicians; and (4) patient preference for physicians to remain primary interpreters of health care data. Facilitators followed two interdependent themes: (1) enthusiasm for clinical use of the predictive model and (2) willingness to incorporate ML into clinical care.

Low physician and patient awareness of PAD is well documented. In separate surveys, 26% of patients expressed familiarity with PAD, while only 49% of physicians knew when their patients had a previous PAD diagnosis [3,15]. Physicians' perceptions that PAD is not as serious as other cardiovascular diseases may fuel downstream care disparities; in a registry evaluation of over 68,000 outpatients with cardiovascular disease, patients with PAD were less likely to be receiving adequate risk factor management compared to patients with coronary or cerebrovascular disease [16]. Our findings suggest that these attitudes persist in a quaternary academic care setting, but there are also opportunities for stakeholder education given the interest expressed by multiple respondents in learning more about PAD. In our sample, physician awareness of PAD may be impacted by the extent of clinical experience, with most physicians having less than 10 years of clinical practice.

While stakeholders were generally interested in leveraging ML to identify patients with PAD, they sought assurances about the algorithm's reliability and scope. Physicians requested accompanying citations and explanatory text about the algorithm's development and accuracy; this feedback has since been incorporated into further iterations of the ML tool interface [5]. Patients stipulated that the tool should be an adjunct rather than a replacement for human judgment; one specifically disliked the term "artificial intelligence" because it implied that machines would outlearn and replace people. Emphasizing that doctors would be using the intervention as one of many diagnostic tools was central to patient acceptability, which has been similarly reported in qualitative studies soliciting patients' perceptions of ML tools in general [17].

Physician interviews also revealed ambiguity regarding who should be responsible for diagnosing PAD. Primary care physicians reported less familiarity with PAD and difficulty balancing the need to screen and treat a wide variety of diseases.

Cardiovascular specialists were more knowledgeable about PAD but felt that the diagnosis was better left to the primary care physicians. While ambiguity regarding the practice domain of generalists and specialty providers is often influenced by cultural norms, patient comorbidities, and local resources, facilitating communication between specialists who suspect PAD and their primary care providers may improve diagnosis rates [18,19].

Facilitators for implementation included institutional and interventional support for improved methods of PAD diagnosis. In 2015, Stanford Medicine introduced a precision health framework reflecting a strategic focus toward leveraging data science, ML, and predictive analytics into clinical care. Institutional investment in these methods, in addition to endorsement of the algorithm from our Division of Vascular Surgery, which specializes in medical and surgical management of patients with PAD, were perceived as facilitators by stakeholders.

This study had several limitations. First, our sample was limited to a single quaternary academic center, which may limit the broad applicability of the results. However, interviewees included physicians and patients across departments, providing a rich perspective from multiple specialties. Second, since interviews were performed on a voluntary basis, it is possible that stakeholders who did not volunteer would have different perceptions of the intervention. However, interviews were conducted until thematic saturation, providing as broad a range of viewpoints as possible. Third, limited participant demographic information was collected as part of this quality improvement project. While identifying a patient's primary insurance provider offers some insight into their socioeconomic status, there are many other variables that influence patients' perceptions of PAD, ML, and the subsequent acceptability of the proposed intervention.

Conclusion

In this qualitative analysis of patients' and physicians' attitudes toward the development of an ML-powered PAD diagnostic tool, barriers to implementation followed four interdependent themes: (1) low familiarity or urgency in detecting PAD; (2) concerns regarding the reliability of ML; (3) differential perceptions of responsibility for PAD care among primary care versus specialty physicians; and (4) patient preference for physicians to remain primary interpreters of health care data. Facilitators followed two interdependent themes: (1) enthusiasm for clinical use of the predictive model and (2) willingness to incorporate ML into clinical care. Implementation of ML-powered diagnostic tools for PAD should leverage institutional and interventional support while simultaneously educating stakeholders on the importance of early PAD diagnosis.

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Data Availability

The data sets generated during or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide for physicians participating in the study.
[DOCX File , 26 KB - cardio_v7i1e44732_app1.docx]

Multimedia Appendix 2
Interview guide for patients participating in the study.
[DOCX File , 22 KB - cardio_v7i1e44732_app2.docx]

Multimedia Appendix 3
Template summary example of de-identified participant quotations contextualized in study themes and subthemes.
[PDF File (Adobe PDF File), 45 KB - cardio_v7i1e44732_app3.pdf]

Multimedia Appendix 4
Checklist designating manuscript conformation to Consolidated Criteria for Reporting Qualitative Research standardized guidelines (COREQ).
[PDF File (Adobe PDF File), 416 KB - cardio_v7i1e44732_app4.pdf]

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Abbreviations

ABI: ankle brachial index

CFIR: Consolidated Framework for Implementation Research
COREQ: Consolidated Criteria for Reporting Qualitative Research
ML: machine learning
PAD: peripheral arterial disease

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Review

Electrocardiogram Devices for Home Use: Technological and Clinical Scoping Review

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Abstract

Background: Electrocardiograms (ECGs) are used by physicians to record, monitor, and diagnose the electrical activity of the heart. Recent technological advances have allowed ECG devices to move out of the clinic and into the home environment. There is a great variety of mobile ECG devices with the capabilities to be used in home environments.

Objective: This scoping review aimed to provide a comprehensive overview of the current landscape of mobile ECG devices, including the technology used, intended clinical use, and available clinical evidence.

Methods: We conducted a scoping review to identify studies concerning mobile ECG devices in the electronic database PubMed. Secondarily, an internet search was performed to identify other ECG devices available in the market. We summarized the devices' technical information and usability characteristics based on manufacturer data such as datasheets and user manuals. For each device, we searched for clinical evidence on the capabilities to record heart disorders by performing individual searches in PubMed and ClinicalTrials.gov, as well as the Food and Drug Administration (FDA) 510(k) Premarket Notification and De Novo databases.

Results: From the PubMed database and internet search, we identified 58 ECG devices with available manufacturer information. Technical characteristics such as shape, number of electrodes, and signal processing influence the capabilities of the devices to record cardiac disorders. Of the 58 devices, only 26 (45%) had clinical evidence available regarding their ability to detect heart disorders such as rhythm disorders, more specifically atrial fibrillation.

Conclusions: ECG devices available in the market are mainly intended to be used for the detection of arrhythmias. No devices are intended to be used for the detection of other cardiac disorders. Technical and design characteristics influence the intended use of the devices and use environments. For mobile ECG devices to be intended to detect other cardiac disorders, challenges regarding signal processing and sensor characteristics should be solved to increase their detection capabilities. Devices recently released include the use of other sensors on ECG devices to increase their detection capabilities.

(JMIR Cardio 2023;7:e44003) doi:10.2196/44003

KEYWORDS

electrocardiogram; mobile ECG; home use ECG; wearables; medical devices; ECG clinical validation, ECG technical characteristics

Introduction

Background

Cardiovascular diseases are the leading cause of mortality, accounting for approximately 31% of all deaths worldwide [1]. The leading contributors to cardiovascular death are ischemic heart disease, ischemic stroke, hemorrhagic stroke, hypertensive heart disease (which ultimately results in heart failure), cardiomyopathy, rheumatic heart disease, and atrial fibrillation (AF) [2]. To perform cardiovascular assessments, physicians require diagnostic tools such as the electrocardiogram (ECG) [3].

The ECG records the electrical signals generated by the heart's electrical activity; the electrical currents arise owing to potential differences that spread to the surface of the body when cardiac impulses pass through the heart [4]. The traditional 12-lead ECG is recorded via electrodes placed on the limbs and chest wall [3]. The ECG is a tool used in the everyday practice of clinical medicine, with >300 million ECGs obtained annually [5].

The 12-lead ECG is the clinical gold standard and is reminiscent of the original recordings by Einthoven, which refers to the placement of 3 limb electrodes, from which 2 leads are measured, and other 4 leads are calculated, allowing 6 limb leads and creating a view of the heart in the vertical plane [6]. In addition, the 6 precordial leads (V1-V6) provide a view of the horizontal plane of the heart, using the Wilson central terminal as a reference [3]. Technological advances such as the miniaturization of electronic components, innovations in sensor technologies, and progress in mobile and communication technology have allowed innovations in mobile health devices. New technologies allow general practitioners or ambulance staff to record ECGs as routine in chest pain, whereas patients can perform self-monitoring at home. Thus, the ECG is moving from the clinical to the domestic environment [7].

Previous review studies on mobile ECG devices have focused primarily on wearable sensors that can be used in and outside of the clinic, the technological taxonomy of ECG devices, an analysis of single- and 3-lead devices, adhesive ECG patch devices, and devices focused only on diagnosing rhythm disorders and conduction system diseases; the studies' secondary focus has been on the future of ECG technologies, including the necessary steps for integration in clinical infrastructures [7-13]. The published reviews have shown that a majority of mobile ECG devices are focused on screening for AF or other rhythm disorders [7,8,11,13]. The reviews partly cover the potential applications of mobile ECG devices. There is a gap in how the available devices in the market can be selected for use based on device characteristics, purpose, and clinical evidence.

Objectives

This review aimed to provide an overview of the mobile ECG devices that are available in the market, including the technology used, their intended clinical use, and the published clinical evidence used for validation. In this review, we defined the gaps and pitfalls in commercially available and discontinued devices to provide the reader with a comprehensive overview of the current landscape of mobile ECG devices as well as their clinical purposes, clinical outcomes, and benefits. In addition, we addressed the disadvantages per type of device to highlight the most promising devices or technology used and the areas where there is room for improvement.

Methods

Device Searches

First, we performed a PubMed database search for ECG devices. We searched for articles published between September 6, 2012, and September 6, 2022. Article titles, keywords, and abstracts were searched using the following search terms: "Wearable Electronic Devices" (medical subject headings [MeSH] term) AND ("Electrocardiography" [MeSH term] OR "electrocardiography, ambulatory" [MeSH term]). We only included articles published in English, and the identified devices needed to be capable of recording ECGs. We excluded devices that are only capable of recording photoplethysmography.

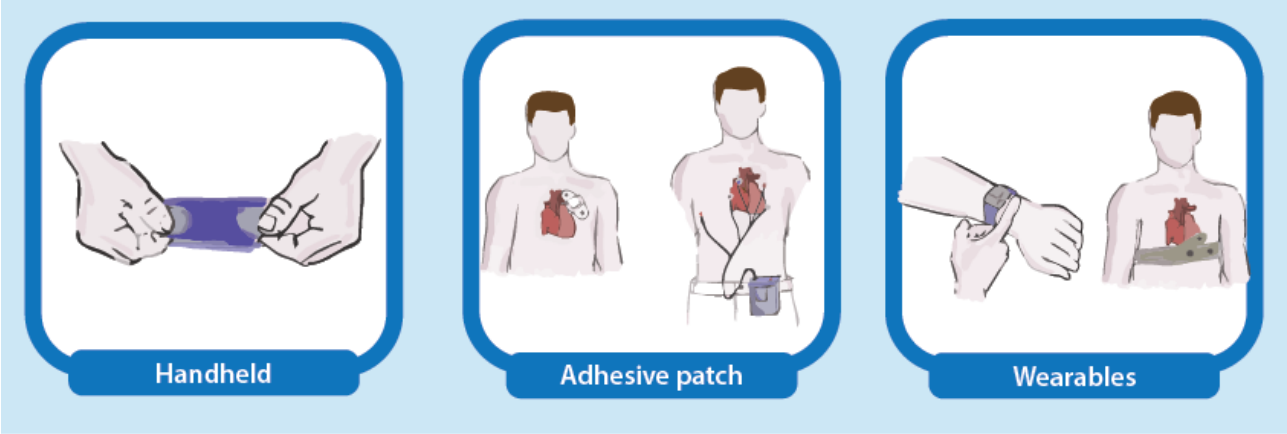
In addition, internet searches for mobile ECG devices using the Google search engine were performed. The search words used were "electrocardiography" combined with "mobile," "wearable," or "handheld." Only ECG devices were included.

Device Characteristics

Once the mobile ECG devices were identified, we consulted their manufacturer websites to gather technical datasheets as well as user manuals and then summarized their characteristics and technical and user specifications. We also consulted the Food and Drug Administration (FDA) 510(k) Premarket Notification database and ClinicalTrials.gov to review data on devices when no data were available from the manufacturers.

After we identified the ECG devices, based on their characteristics, all devices found were classified into three types of mobile ECG devices: (1) handheld, (2) patch, and (3) wearable (as summarized in Figure 1 and Textbox 1).

Figure 1. Presentation of mobile electrocardiogram device categories.



Textbox 1. Types of mobile electrocardiogram (ECG) devices.

Handheld devices

- These devices, which have embedded dry electrodes, are required to be carried separately by users. To perform ECG recordings, users place the device on their chest or hold the device in their hands. This type of device performs ECG recordings when it is activated by users. Users perform intermittent recordings lasting <1 minute.

Patch devices

- These devices, which have disposable embedded electrodes or disposable surface electrodes, are usually attached to the left chest of patients. They can perform continuous recordings for up to 30 days.

Wearables

- These devices, which use dry metal, textile, or single-use electrodes, are used for continuous wearing during normal daily activities. Wearables are worn on the chest as a garment (eg, T-shirt), as a harness, or on the wrist as a smartwatch. Depending on the area of measurement, these devices can perform for 24 hours or obtain recordings lasting <1 minute.

For each device, we identified the intended use, recording time, and number of electrodes (instead of leads because the number of leads was not specified for some devices; it should be noted that for 3-electrode devices, 6 leads could be obtained from the calculation of the limb leads). We also detailed whether the device is stand-alone.

We registered the user characteristics (user environment, multiple areas of measurement, and setup difficulty), as well as technical characteristics (sampling rate, sampling resolution, and signal bandwidth) and compliance characteristics for use, such as the level of protection of the device against the ingress of hazardous parts and water (the ingress protection [IP] rating).

Clinical Evidence

Finally, we searched for available clinical information by performing a search per device with the aim to identify the available clinical evidence regarding its capabilities. We identified the type of studies performed per device, whether the device had been validated for detection of certain heart conditions, and whether these studies had compared the device against 12-lead ECG devices or other mobile ECG devices.

We also analyzed the feasibility of these devices for home use while guaranteeing the safety of patients. We looked at home use compliance as well as analyzed the available clinical evidence for detection of heart disorders.

Results

Overview

With the PubMed search, we identified 434 articles (Figure 2), of which we excluded 317 (73%) owing to publication date as well as not being written in English and after an examination of titles and abstracts, leaving 117 (27%) for analysis. Of these 117 publications, 73 (62.4%) were excluded because they referred to prototype devices (n=35, 48%), non-ECG devices (n=17, 23%), and design and validation of artificial intelligence algorithms (n=17, 23%) or were opinion articles (n=4, 5%). From the remaining articles (44/117, 37.6%), we identified 48 ECG devices, of which 22 (46%) were patch-based devices, 8 (17%) were handheld devices, and 18 (38%) were wearables. Subsequently, from the internet search, another 33 devices were identified: 16 (49%) were patch-based devices, 11 (33%) were handheld devices, and 6 (18%) were wearables. In total, 82 devices were identified for this review (Figure 2). For 58 (70%) of these 82 devices, we were able to find characteristics from manufacturer websites. We summarized and grouped the devices into continuous recording devices and intermittent recording devices (Figure 3).

Figure 2. Schematic view of the methodology used for the scoping review and the internet search results. AI: artificial intelligence; ECG: electrocardiogram.

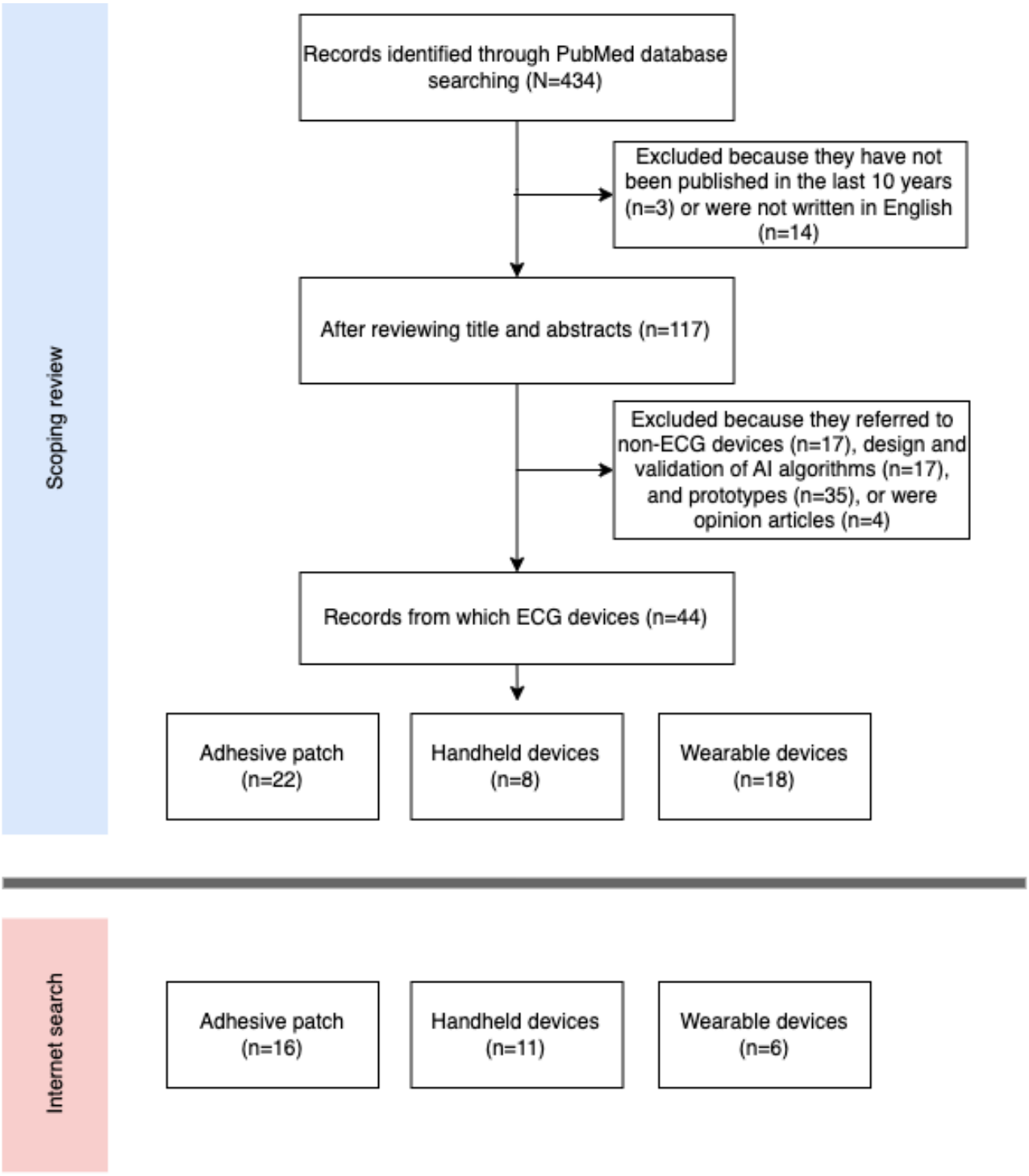
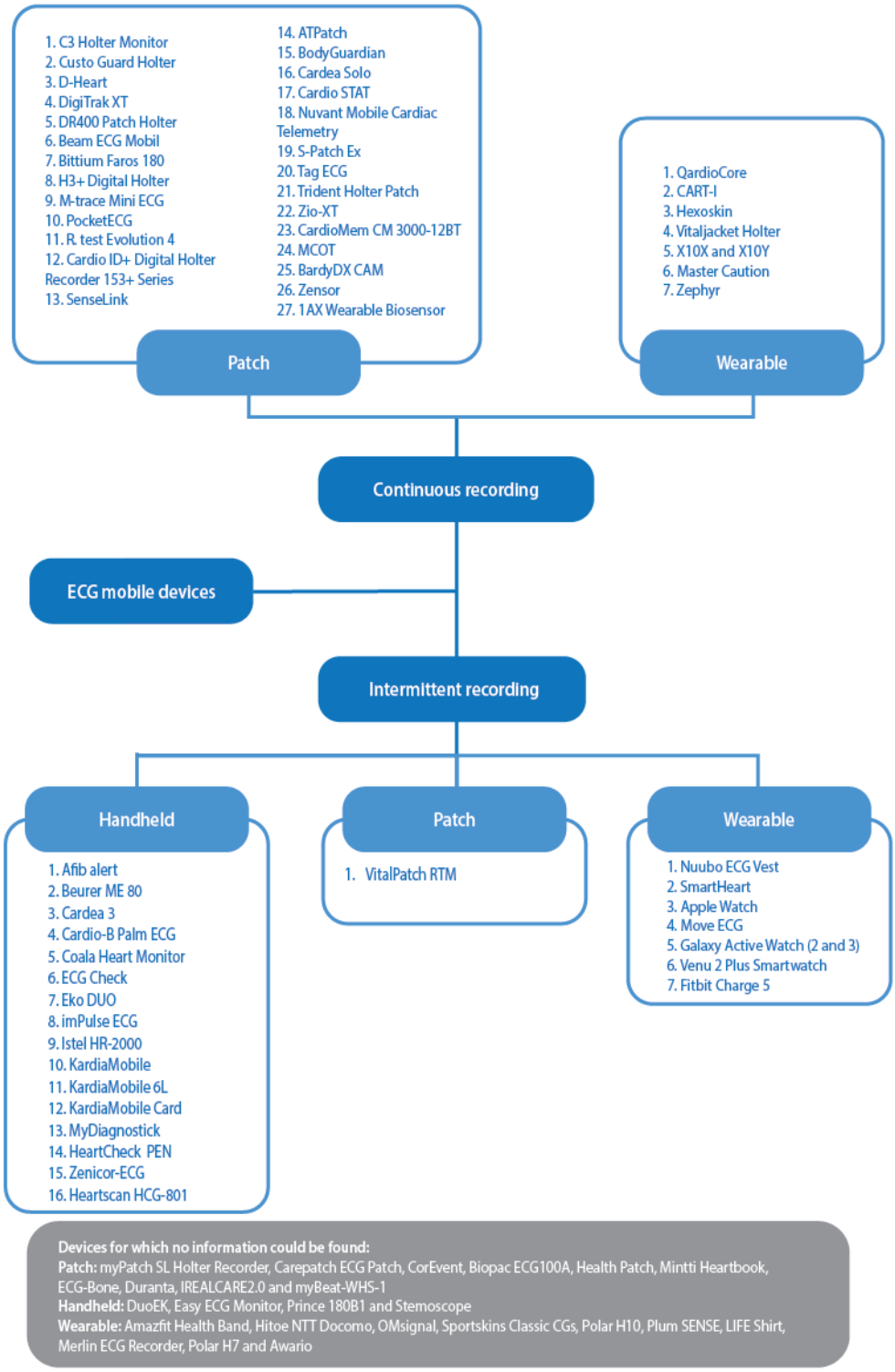


Figure 3. Electrocardiogram (ECG) device classification based on type of recording and type of device.



Clinical Purpose

For 3% (2/58) of the devices, the intended use information was not available from the manufacturer (Tables 1 and 2). Of the 58 devices, 21 (36%) do not state intended use regarding the detection of rhythm disorders; they are intended to be used for measuring and recording ECGs in general. However, more than half (31/58, 53%) of the devices are intended to be used when there is suspicion of arrhythmias (25/58, 43%), more specifically AF (6/58, 10%).

Table 1. Functionality characteristics per device (continuous recording devices).

Device	Manufacturer	Intended use	Recording time	Number of electrodes	Stand-alone	Source of clinical evaluation evidence
Patch						
C3 Holter Monitor[a]	Cortrium ApS	M+R[b]	1 week	3	Yes	Clinical trials website[c]
Custo Guard Holter[a]	Custo Med GmbH	M+R+PMD[d]	>1 day	4	Yes	—[e]
D-Heart	D-Heart Srl	M+R	1 day	6	No	—
DigiTrak XT	Koninklijke Philips NV	M+R+HRD[f,g]	1 week	5	Yes	Clinical trials website[c] and PND[h]
DR400 Patch Holter	NorthEast Monitoring Inc	ER[i]+AD[j]	>1 week	3	Yes	PND
Beam ECG Mobil[a]	IEM GmbH	M+R+ER[g]	>1 minute	8	Yes	—
Bittium Faros 180	Bittium	M+R+AD[g]	>1 week	2	Yes	PND
H3+ Digital Holter[a]	Welch Allyn	M+R+AD	>1 day	5	Yes	PND
M-trace Mini ECG[a]	M4Medical	M+R+AD[g]	1 minute	4	Yes	Clinical trials website[c]
PocketECG[a]	Medicalgorithmics SA	M+R+AD	1 day	3	Yes	Clinical trials website[c] and PND
R.Test Evolution 4	Novacor	AD	>1 month	2	Yes	Clinical trials website and PND
Cardio ID+ Digital Holter Recorder 153+ Series	Rozinn	M+R	>1 day	3	Yes	PND
SenseLink[a]	Temeco	AD+ER	>1 week	5	Yes	—
Zensor	Renew Health Ltd	AD	>1 week	7	Yes	Clinical trials website[c] and PND
1AX Wearable Biosensor[a]	LifeSignals Inc	M+R	>1 day	6	No	Clinical trials website[c] and PND
ATPatch	Atsens	AD	>1 week	3	No	Clinical trials website and PND
BodyGuardian	Preventice Technologies Inc	AD	1 day	4	No	Clinical trials website and PND
Cardea Solo[a]	Cardiac Insight Inc	AD	1 week	2	Yes	Clinical trials website[c] and PND
Cardio STAT	Icentia Inc	AD	>1 week	2	Yes	Clinical trials website
Nuvant Mobile Cardiac Telemetry Monitor	Corventis	AD+CD[k]	>1 week	—	—	Clinical trials website[c] and PND
S-Patch Ex[a]	Wellysis	M+R	>1 day	2	No	Clinical trials website[c]
Tag ECG[a]	Welch Allyn	AD	1 week	2	Yes	—
Trident Holter Patch[a]	TZ Medical Inc	M+R[g]	1 week	—	Yes	—
Zio XT	iRhythm Technologies Inc	M+R	>1 week	2	Yes	Clinical trials website and PND
CardioMem CM 3000-12BT[a]	GE Healthcare	AD	>1 day	12	Yes	Clinical trials website and PND
MCOT[a]	Koninklijke Philips NV	AD	>1 day	4	No	Clinical trials website[c]

Device	Manufacturer	Intended use	Recording time	Number of electrodes	Stand-alone	Source of clinical evaluation evidence
BardyDX CAM[a]	Bardy Diagnostics Inc	AD	>1 week	2	Yes	PND
Wearable						
QardioCore[a]	Qardio Inc	M+R	1 day	4	No	PND
CART-I[a]	Sky Labs Inc	AFD[l]	1 day	—	No	Clinical trials website[c]
Hexoskin	Carré Technologies Inc	Research[g]	>1 day	—	No	Clinical trials website[c]
VitalJacket Holter	BioDevices SA	AD+CD	>1 day	6	Yes	—
X10X and X10Y	L.I.F.E. Italia Srl	—	1 day	8	Yes	Clinical trials website[c]
Master Caution	HealthWatch Ltd	M+R	—	12	No	Clinical trials website[c] and PND
Zephyr	Medtronic	M+R	>1 day	2	Yes	PND

[a]Device found via internet search.
[b]M+R: measure and record electrocardiogram.
[c]No results available.
[d]PMD: pacemaker detection.
[e]Not available.
[f]HRD: heart rate detection.
[g]Data found via internet search.
[h]PND: Food and Drug Administration 510(k) Premarket Notification database.
[i]ER: event recorder.
[j]AD: arrhythmia detection.
[k]CD: conduction disorder detection.
[l]AFD: atrial fibrillation detection.

Table 2. Functionality characteristics per device (intermittent recording devices).

Device	Manufacturer	Intended use	Recording time	Number of electrodes	Stand-alone	Source of clinical evaluation evidence
Handheld						
Afib Alert	Lohman Technologies LLC	AFD[a]	<1 minute	2	Yes	PND[b]
Beurer ME 80	Beurer GmbH	AD[c]	<1 minute	1	Yes	—[d]
Cardea 3[e]	Human Medical Solutions Inc	AD	<1 minute	4	No	—
Cardio-B Palm ECG[e]	Shanghai International Holding Corp	M+R[f]	<1 minute	2	Yes	—
Coala Heart Monitor	Coala Life AB	AFD	<1 minute	3	No	Clinical trials website and PND
ECG Check[e]	Cardiac Designs Inc	AD	<1 minute	2	No	PND
Eko DUO[e]	Eko Devices Inc	M+R	>1 minute	2	No	Clinical trials website and PND
Impulse ECG	—	—	<1 minute	2	No	—
Istel HR-2000[e]	Diagnosis SA	M+R	<1 minute	4	No	Clinical trials website
KardiaMobile	AliveCor, Inc	AD	<1 minute	2	No	Clinical trials website and PND
KardiaMobile 6L	AliveCor, Inc	AD	<1 minute	3	No	Clinical trials website and PND
KardiaMobile Card	AliveCor, Inc	AD	<1 minute	2	No	Clinical trials website and PND
MyDiagnostick	MyDiagnostick Medical BV	AFD	1 minute	2	Yes	Clinical trials website
HeartCheck PEN	CardioComm Solutions, Inc	AD	<1 minute	2	No	PND
Zenicor-ECG	Zenicor Medical Systems	M+R	<1 minute	2	No	Clinical trials website
Heartscan HCG-801[e]	Omron	M+R	<1 minute	3	Yes	Clinical trials website
Patch						
VitalPatch RTM[d]	VitalConnect Inc	M+R	<1 week	2	Yes	PND
Wearable						
Nuubo ECG Vest	Nuubo Wearable Technologies	M+R	>1 week	4	Yes	Clinical trials website
SmartHeart[e]	SHL Telemedicine International Ltd	M+R	<1 minute	18	No	PND
Apple Watch	Apple Inc	AFD	<1 minute	2	Yes	Clinical trials website and DND[g]
Move ECG[e]	Withings	AFD	<1 minute	2	No	Clinical trials website and PND
Galaxy Active Watch (2 and 3)[e]	Samsung Electronics Co, Ltd	AFD	<1 minute	2	Yes	Clinical trials website and PND
Venu 2 Plus Smartwatch[e]	Garmin Ltd	AFD	<1 minute	2	Yes	PND
Fitbit Charge 5 [e]	Alphabet Inc	AFD	<1 minute	2	Yes	Clinical trials website and PND

[a]AFD: atrial fibrillation detection.

[b]PND: Food and Drug Administration 510(k) Premarket Notification database.

[c]AD: arrhythmia detection.

[d]Not available.

[e]Device found via internet search.

[f]M+R: measure and record electrocardiogram.

[g]DND: Food and Drug Administration 510(k) De Novo database.

Use Characteristics

Adhesive patch devices are intended to be placed either at the left side (11/28, 39%) or center of the chest (17/28, 60%). Table 2 shows that these devices require setup for positioning the devices on patients, with the steps including skin preparation (shaving and removal of nonconductive skin layer via skin abrasion) as well as templates for the correct device placement, and for performing successful patient recordings. These steps are performed once because these devices are used on a longer-term basis (from >1 day up to >30 days). There are 2 types of patch devices: those in which the whole system, including 2 or 3 electrodes, is embedded in the patch and those that use disposable single electrodes attached through a cable. In the latter case, the devices aim to provide recordings that resemble 12-lead clinical ECG recordings. Patch devices are usually managed by health care centers, and analyses are performed by the manufacturer, specialized companies, or at health care centers.

The wearables category has shown to be more versatile because some of the devices (7/14, 50%) in this category are intended for intermittent use, whereas others (7/14, 50%) are intended for continuous recording. Devices in the former category are often used as daily accessories, such as the Apple Watch (Apple Inc), Amazfit Band (Zepp Health Corporation), and CART-I smart ring (Sky Labs Inc). As for the wearable devices that offer continuous recording, they can be used as garments such as T-shirts. These devices have embedded textile electrodes and can perform recordings lasting 24 hours. Although these devices offer prolonged recordings compared with the accessory wearables, only 2 (29%) of the 7 devices allow simultaneous recording and analysis.

Handheld devices are designed for patients, both for clinical and home use. Of the 14 devices, 11 (79%) rely on limb (including lower limbs) recordings, whereas 3 (21%) perform chest recordings. To record ECGs using handheld devices, no extra steps are required for preparing the area of contact, and ECGs can be recorded in <1 minute.

Technical Characteristics

Patch and wearable devices can be used for at least 24 hours continuously, and these devices can include the feature to detect cardiac events automatically. By contrast, handheld devices have recording durations, initiated by patients, ranging from 15 to 120 seconds. Patients are typically instructed to perform recordings at the onset of symptoms or at specified times.

Handheld devices record ECGs via dry electrodes. These metal electrodes are manufactured from stainless steel, copper, silver or silver chloride (Ag or AgCl), or other unspecified materials. By contrast, patch devices use disposable electrodes, either commercially available or as part of the product.

Of the 58 devices with available manufacturer information, 43 (74%) are intended to be used at home. Of these 43 devices, only 21 (49%) disclosed their IP rating. Of these 21 devices, 5 (24%) have been tested for IP22 (protected from touch by fingers and objects >12 mm and protected from water spray <15° from the vertical) and 10 (48%) for higher IP, whereas 6 (29%) devices have been tested only for water IP (Tables 3 and 4).

Table 3. Technical characteristics per device (continuous recording devices).

Device	Use environment	Multiple measures	Requires setup	Ingress protection rating	Sampling rate (Hz)	Resolution (bits)	Signal bandwidth (Hz)
Patch							
C3 Holter Monitor	Home and clinical	N/A[a]	✓	—[b]	256	24	—
Custo Guard Holter	Clinical	✓	✓	65	533	18	0-105
D-Heart	Home and clinical	N/A	✓	—	640	—	—
DigiTrak XT	Home	N/A	✓	—	175	10	0.05-60
DR400 Patch Holter	Home	✓	✓	44	180	12	0.05-70
Beam ECG Mobil	Home	✓	✓	—	200	12	Event: 0.3-75; loop: 0.1-75
Bittium Faros 180	Home	✓	✓	67	100	—	—
H3+ Digital Holter	Clinical	N/A	✓	—	180	12	—
M-trace Mini ECG	Home	N/A	✓	—	1000	24	0.5-100
PocketECG	—	N/A	✓	22	300	—	0.05-60
R.Test Evolution 4	—	N/A	✓	X4	200	10	—
Cardio ID+ Digital Holter Recorder 153+ Series	—	N/A	N/A	—	1024	12	0.05-60
SenseLink	Home and clinical	N/A	✓	22	1000	16	—
Zensor	—	N/A	✓	22	360	12	0.67-40
1AX Wearable Biosensor	Home	N/A	✓	24	244.14	16	0.2-40
ATPatch	Home	N/A	✓	57	250	10	0.05-40
BodyGuardian	Home	✓	✓	X4	256	12	—
Cardea Solo	Home	N/A	✓	—	—	—	—
Cardio STAT	Home	N/A	N/A	—	—	—	—
Nuvant Mobile Cardiac Telemetry Monitor	—	N/A	✓	—	200	10	—
S-Patch Ex	—	N/A	✓	55	256	12	—
Tag ECG	Home	✓	✓	X7	250	—	0.05-65
Trident Holter Patch	—	N/A	N/A	—	—	—	—
Zio XT	—	✓	✓	X4	200	10	0.05-30
CardioMem CM 3000-12 BT	Home	N/A	✓	20	1024	12	0.05-120
MCOT	Home	N/A	✓	X4	250	12	—
BardyDX CAM	Home	N/A	✓	23	171	—	0.67-25
Wearable							
QardioCore	Home	N/A	N/A	65	600	16	0.05-40
CART-I	Home	N/A	N/A	58	—	—	—
Hexoskin	Home	N/A	N/A	—	256	12	—
VitalJacket Holter	—	N/A	✓	—	500	10	0.03-150
X10X and X10Y	—	N/A	N/A	—	—	—	—
Master Caution	Home	N/A	N/A	—	1000	—	—
Zephyr	Home	N/A	N/A	55	250	12	—

[a]N/A: not applicable.

[b]Not available.

Table 4. Technical characteristics per device (intermittent recording devices).

Device	Use environment	Multiple measures	Requires setup	Ingress protection rating	Sampling rate (Hz)	Resolution (bits)	Signal bandwidth (Hz)
Handheld							
Afib Alert	Home	✓	✓	__[a]	—	—	—
Beurer ME 80	Home	✓	N/A[b]	—	256	—	—
Cardea 3	Home and clinical	N/A	N/A	—	500	—	1-75
Cardio-B Palm ECG	Home	✓	N/A	—	—	—	1-40
Coala Heart Monitor	Home and clinical	✓	N/A	22	1000	24	—
ECG Check	Home	N/A	N/A	—	200	—	0.5-25
Eko DUO	Clinical	N/A	N/A	55	—	—	—
Impulse ECG	Home	N/A	N/A	—	—	—	—
Istel HR-2000	Home	N/A	N/A	22	160, 320, and 640	24	0.05-32, 0.05-35, and 0.05-130
KardiaMobile	Home	N/A	N/A	64	300	16	0.5-40
KardiaMobile 6L	Home	✓	N/A	22	300	16	0.5-40
KardiaMobile Card	Home	N/A	N/A	X8	300	16	0.5-40
MyDiagnostick	Clinical	N/A	N/A	24	—	—	—
HeartCheck PEN	Home	✓	N/A	—	250	—	1-40
Zenicor-ECG	Home	N/A	N/A	22	—	—	—
Heartscan HCG-801	Home	✓	N/A	20	125	—	0.05-40
Patch							
VitalPatch RTM	Home and clinical	✓	✓	24	—	—	—
Wearable							
Nuubo ECG Vest	Home and clinical	N/A	N/A	22	250	—	0-65
SmartHeart	Home	N/A	✓	—	—	—	0.05-150
Apple Watch	Home	N/A	N/A	—	—	—	—
Move ECG	Home	N/A	N/A	—	—	—	—
Galaxy Active Watch (2 and 3)	Home	N/A	N/A	—	—	—	—
Venu 2 Plus Smartwatch	Home	N/A	N/A	—	—	—	—
Fitbit Charge 5	Home	N/A	N/A	—	—	—	—

[a]Not available.

[b]N/A: not applicable.

Clinical Evidence

Through the individual searches with regard to all 58 devices for which we were able to find characteristics from manufacturer websites, we found articles (n=36) that covered 22 (38%) of the devices, demonstrating their capabilities to record cardiac disorders. Of these 22 devices, 8 (36%) are handheld devices, 8 (36%) are patch devices, and 6 (28%) are wearables (Tables 5 and 6).

Table 5. Summary of device study objectives (continuous recording devices).

Device, study, heart disorder or ECG[a] abnormality	Comparators	Participants, n	Sensitivity, %	Specificity, %	Accuracy, %
Patch					
D-Heart					
Maurizi et al [14]					
Quality recordings	12-lead device	117	—[b]	—	—
Bittium Faros 180					
Müller et al [15]					
AF[c]	PPG[d] devices	144	90	84.2	—
R.Test Evolution 4					
Eysenck et al [16]					
AF	Zio XT, Nuubo ECG Vest, and BardyDX CAM	21	—	—	30-second recording: 50.8; 6-minute recording: 77.3
CardioSTAT					
Nault et al [17]					
AF	12-lead Holter	212	—	—	99
Zio XT					
Eysenck et al [16]					
AF	Zio XT, Nuubo ECG Vest, BardyDX CAM, and R.Test Evolution 4	21	—	—	30-second recording: 86.7; 6-minute recording: 80.8
Hannun et al [18]					
AF and flutter	—	53,549	71	94.1	—
AVB[e]	—	53,549	73.1	98.1	—
Bigeminy	—	53,549	82.9	99.6	—
EAR[f]	—	53,549	38	99.3	—
IVR[g]	—	53,549	61.1	99.1	—
Junctional rhythm	—	53,549	63.4	98.4	—
Noise	—	53,549	74.9	98.3	—
Sinus rhythm	—	53,549	90.1	85.9	—
SVT[h]	—	53,549	40.8	98.3	—
Ventricular tachycardia	—	53,549	65.2	99.6	—
Wenckebach	—	53,549	54.1	98.6	—
BardyDX CAM					
Eysenck et al [16]					
AF	Zio XT, Nuubo ECG Vest, BardyDX CAM, and R.Test Evolution 4	21	—	—	30-second recording: 99.9; 6-minute recording: 95.3
ATPatch					
Choi et al [19]					
Quality recordings	12-lead device	10	—	—	0.1
BodyGuardian					
Bruce et al [20]					
Quality recordings	—	10	97	77	—

Device, study, heart disorder or ECG[a] abnormality	Comparators	Participants, n	Sensitivity, %	Specificity, %	Accuracy, %
Wearable					
Amazfit					
Chen et al [21]					
AF	PPG devices	451	87.3	99.2	94.76
Zhang et al [22]					
Rhythm disorders and AF	12-lead device	291	93.3	95.3	—
PAC[i]	12-lead device	291	84	96.6	—
PVC[j]	12-lead device	291	89.3	93.9	—
First-degree AVB	12-lead device	291	32.1	97.7	—

[a]ECG: electrocardiogram.
[b]Not available.
[c]AF: atrial fibrillation.
[d]PPG: photoplethysmography.
[e]AVB: atrioventricular block.
[f]EAR: ectopic atrial rhythm.
[g]IVR: idioventricular rhythm.
[h]SVT: supraventricular tachycardia.
[i]PAC: premature atrial contraction.
[j]PVC: premature ventricular contraction.

Table 6. Summary of device study objectives (intermittent recording devices).

Device, study, heart disorder or ECG[a] abnormality	Comparators	Participants, n	Sensitivity, %	Specificity, %	Accuracy, %
Handheld					
Beurer ME 80					
Nigolian et al [23]					
AF[b]	12-lead device	16	100	94	96
AVB[c]	12-lead device	13	85	97	94
LBBB[d]	12-lead device	7	71	100	96
RBBB[e]	12-lead device	10	90	100	98
LVH[f]	12-lead device	5	80	100	98
ST-segment elevation	12-lead device	11	64	93	87
ST-segment depression	12-lead device	13	54	95	85
Prolonged QTc	12-lead device	4	50	91	88
Coala Heart Monitor					
Insulander et al [24]					
AF	__g	1000	95.1	97.6	97.3
ECG Check					
Aljuaid et al [25]					
AF	Holter	90	100	97	—
Eko DUO					
Bokma et al [26]					
CHD[h]	12-lead device, Move ECG, KardiaMobile	176	100	99	—
Bachtiger et al [27]					
LVEF[i] of ≤40%	12-lead device	1050	91.9	80.2	—
Istel HR-2000					
Krzowski et al [28]					
Sinus rhythm	12-lead device and KardiaMobile	98	91.5	84.6	—
AF	12-lead device and KardiaMobile	98	77.3	98.7	—
KardiaMobile					
Krzowski et al [28]					
Sinus rhythm	12-lead device and Istel HR-2000	98	88.1	89.7	—
AF	12-lead device and Istel HR-2000	98	86.4	97.4	—
Palà et al [29]					
AF	WatchBP, MyDiagnostick, and FibriCheck	359	80	95.5	—
Lau et al [30]					
AF	12-lead device	109	97.5	92	94.5
Desteghe et al [31]					
AF (cardiology ward)	12-lead device and MyDiagnostick	445	54.5	97.5	—
AF (geriatric ward)	12-lead device and MyDiagnostick	445	78.9	97.9	—
Bokma et al [26]					

Device, study, heart disorder or ECG[a] abnormality	Comparators	Participants, n	Sensitivity, %	Specificity, %	Accuracy, %
CHD	12-lead device, Move ECG, and Eko DUO	176	100	99	—
Scholten et al [32]					
AF	12-lead device, Apple Watch, and Move ECG	220	99	97	—
Bumgarner et al [33]					
AF	12-lead device	100	99	83	—
Ford et al [34]					
AF	Apple Watch	125	94	90	91
Wasserlauf et al [35]					
AF	Implantable Cardiac Monitor	24	83.3	83.3	—
Himmelreich et al [36]					
AF and AFL[j]	12-lead device	23	100	100	—
AF	12-lead device	44	90.9	93.5	—
AF	12-lead device	28	46.4	100	—
MyDiagnostick					
Tieleman et al [37]					
AF	12-lead device	192	100	95.9	—
Palà et al [29]					
AF	WatchBP, KardiaMobile, and FibriCheck	359	76.9	97.1	—
Verbiest-van Gurp et al [38]					
AF	12-lead device and WatchBP	4339	90.1	97.9	—
Vaes et al [39]					
AF	12-lead device	191	94	93	—
Yeo et al [40]					
AF	12-lead device	671	100	96.2	—
Karregat et al [41]					
Paroxysmal AF	12-lead Holter	270	66.7	68.8	—
Desteghe et al [31]					
AF (cardiology ward)	12-lead device and KardiaMobile	445	81.8	94.2	—
AF (geriatric ward)	12-lead device and KardiaMobile	445	89.5	95.7	—
Zenicor-ECG					
Doliwa et al [42]					
AF	12-lead device	49	96	92	—
Wearable					
Apple Watch					
Abu-Alrub et al [43]					
AF	Galaxy Watch Active 3, and Move ECG	100	87	86	—
Nasarre et al [44]					
Cardiac abnormalities and cardiac arrest	12-lead device	67	100	100	—
Brugada Syndrome	12-lead device	67	92	100	—

Device, study, heart disorder or ECG[a] abnormality	Comparators	Participants, n	Sensitivity, %	Specificity, %	Accuracy, %
Long QT	12-lead device	67	80	100	—
HCM[k]	12-lead device	67	92	85	—
ARVC/D[l]	12-lead device	67	100	99	—
Caillol et al [45]					
Bradyarrhythmias	12-lead device	40	96	91	—
Tachyarrhythmias	12-lead device	40	25	99	—
Cardiac Ischemia	12-lead device	40	7	100	—
Spaccarotella et al [46]					
Measurements of the QT interval	12-lead device	—	69	88	—
Scholten et al [32]					
AF	12-lead device, Move ECG, and KardiaMobile	220	96	94	—
Ford et al [34]					
AF	KardiaMobile	125	68	93	87
Move ECG					
Bokma et al [26]					
CHD	12-lead device, KardiaMobile, and Eko DUO	176	100	98	—
Abu-Alrub et al [43]					
AF	Apple Watch, Galaxy Watch Active 3	100	88	81	—
Scholten et al [32]					
AF	12-lead device, Apple Watch, and KardiaMobile	220	95	95	—
Nuubo ECG Vest					
Eysenck et al [16]					
AF	Zio XT, Nuubo ECG Vest, BardyDX CAM, and R.Test Evolution 4	21	—	—	30-second recording: 97; 6-minute recording: 89.7
Fitbit					
Rajagopalan [47]					
AF	12-lead device	475	98.7	100	—
Galaxy Active Watch					
Yang [48]					

Device, study, heart disorder or ECG[a] abnormality	Comparators	Participants, n	Sensitivity, %	Specificity, %	Accuracy, %
AF	12-lead device	544	98.1	100	—

[a]ECG: electrocardiogram.
[b]AF: atrial fibrillation.
[c]AVB: atrioventricular block.
[d]LBBB: left bundle branch block.
[e]RBBB: right bundle branch block.
[f]LVH: left ventricular hypertrophy.
[g]Not available.
[h]CHD: congenital heart defect.
[i]LVEF: low ventricular ejection fraction.
[j]AFL: atrial flutter.
[k]HCM: hypertrophic cardiomyopathy.
[l]ARVC/D: arrhythmogenic right ventricular cardiomyopathy/dysplasia.

Of the 36 articles, 24 (66%) evaluated the devices' capabilities to diagnose rhythm disorders [15-17,21,24,25,29-35,37-43,49-56], whereas 7 (20%) reported on capabilities to detect rhythm disorders and other heart conditions, such as cardiomyopathy, conduction disorders, and cardiac ischemia [18,22,23,28,36,45,57]. Finally, for 3 (14%) of the 22 devices, the evidence found was regarding the evaluation of the quality of the signals recorded by them [14,19,20].

In 23 (63%) of the 36 articles, the feasibility to detect AF was studied. Studies on the Istel HR-2000 (Diagnosis SA), AliveCor heart monitor (AliveCor Inc), MyDiagnostick (MyDiagnostick Medical BV), Apple Watch (Apple Inc), Amazfit (Zepp Health Corporation), and Move ECG (Withings France SA) have reported sensitivities of <94% (range 54.5%-94%) for the detection of AF [21,28,29,31,34,43]. The Apple Watch, KardiaMobile (AliveCor), Bittium Faros 180 (Bittium), and Move ECG studies reported specificities of <90% (range 81%-86%) for AF detection [15,33,43]. For other rhythm disorders, the studies reported specificities of >85% (range 85.9%-99,6%), whereas the sensitivities ranged from 25% to 96% [18,22,45]. For cardiac ischemia detection, the Apple Watch and Beurer ME 80 (Beurer GmbH) were evaluated, and the studies reported specificities of >90% (range 93%-100%) and sensitivities of <65% (range 7%-64%); these studies included 40 and 13 participants, respectively [23,45].

Discussion

Overview

The aim of this review was to provide an overview of the mobile ECG devices available in the market, including the technology used, their clinical application, and the published clinical evidence. In this review, we have identified 58 mobile ECG devices with available manufacturer information and observed that the main intended use of these devices is the detection of rhythm disorders, more specifically AF. We analyzed the relation of the technical characteristics and how these design decisions influence the capabilities of the devices to record cardiac disorders. In terms of clinical evidence, upon reviewing 2 FDA databases, we noted that most of the devices (33/58, 57%) did not require clinical validation because they have been found to be equivalent to other ECG devices in the market or to their previous versions. The published studies we found focused on the evaluation of the devices for the detection of rhythm disorders, more specifically AF.

Clinical Purpose and Technical Capabilities of ECG Devices

To detect rhythm disorders, especially AF, one may only need to be able to capture basic heart rhythms. However, according to the European Society of Cardiology guidelines for the diagnosis of AF, an irregular R-R interval, absence of distinct repeating P waves, and irregular atrial activations indicate AF [58]. For home monitoring devices, it is not completely clear whether the detection of AF is solely based on the detection of irregular R-R intervals or whether they include P-wave detection as well.

For the diagnosis of AF, a 12-lead ECG is recorded only if the physician suspects AF, and the diagnosis will be provided if the ECG records an AF episode [59]. With our analysis, it is also possible to note that continuous monitoring devices show better performance in terms of sensitivity and specificity than intermittent monitoring devices. By using continuous recording systems, the chances of recording AF events are high, but it is necessary to consider that the amounts of data generated while continuous recordings could make it cumbersome to see when the AF events have been detected, as recordings are performed over periods higher than 24 hours.

For wearable devices with continuous recording systems, 16% of the recordings have been considered inconclusive by cardiologists, according to third-party comparisons [60]. It has also been reported that owing to signal processing and algorithm settings, devices such as the Apple Watch are limited in terms of diagnosing and misdiagnosing AF in comparison with medical grade devices [61]. This brings into question the value of using wearable devices with continuous recording systems for early detection of AF because these devices add more challenges to already stressed health care systems and clinical workflows [12].

Considering the clinical importance of the detection of AF as well as cardiac ischemia, the difference in the number of devices that can detect either condition is striking. The overwhelming

number of devices is aimed at detecting AF, whereas no devices are intended for the detection of ischemia, and only 2 (9%) of the 22 devices have published studies for the detection of ST-segment elevation. From a technical point of view, many of the devices may not be completely limited in their capability to detect ischemia.

To detect other cardiac disorders such as ischemia, one also needs to be able to capture morphological details of the ECG. For either case, there are some technical challenges that require further discussion and are discussed in the following paragraphs.

A low number of electrodes and limited measurement area impose restrictions on the detection of all heart diseases [45,62,63]. Caillol et al [45] have shown how single-lead devices such as the Apple Watch could miss ST-segment elevation caused by ischemia in specific parts of the heart. The authors were able to demonstrate that ST-segment elevations and depressions were visible for lateral and inferior infarction, but when they attempted to record an anterior infarction, no ST-segment elevations or depressions were visible on the recordings [45]. Samol et al [64] demonstrated that performing ECG recordings with the Apple Watch (placed on the chest) allowed 6 precordial channels to be recorded in a serial manner [64]. A study using the AliveCor heart monitor showed that with only 2 electrodes, the device is capable of recording ST-segment elevations, once again by performing serial recordings [65,66]. The other device studied for ischemia detection (Beurer ME 80) also requires serial measurements. Considering the acute nature of the condition, we do not see any feasible application of this method of measuring ECGs for ischemia detection.

There is a need for ECG devices intended to detect ischemic diseases, but, as our search has shown, there are no devices intended for this purpose available in the market. There is evidence showing that methods for measurements and technologies are moving toward the detection of ischemic diseases; for example, the RELF method (in which the RELF leads record the voltage differences from the right shoulder [R] to an exploratory electrode [E], to the left shoulder [L], and to the left iliac crest [F]) has been developed using a 3-lead detection system, and when this device was tested for the detection of acute coronary artery occlusion, it showed a specificity of 96% during daily life recordings, and when ST-segment elevation myocardial infarction (STEMI) criteria on a 12-lead ECG device were observed during the interventions, the RELF method had a sensitivity of 100% [67,68].

For heart diseases other than rhythm disorders, single-lead devices allow preliminary recordings to be made, but to obtain a deeper understanding and to allow physicians to provide a diagnosis, more information should be recorded. However, one can imagine that performing studies on conditions such as myocardial infarction in acute settings, is more complex. Furthermore, the approval of a device aiming to detect a high-risk cardiac disorder would require compliance with more stringent requirements; for example, upon the detection of heart disorders such as acute coronary syndrome, it is necessary to provide rapid attention and therapy for patients. If such disorders are undetected, the life and quality of life of patients will be highly affected.

Other characteristics such as signal processing and acquisition may affect the capabilities of the device to detect various cardiac disorders. Applying filters to the captured ECG affects the waveform, which could lead to misinterpretation and misdiagnosis. Signal processing is a design characteristic that has been specified in the International Electrotechnical Commission (IEC) standard [69]. For the detection and interpretation of ischemic diseases, devices need to be able to record changes in the ST segment. The suggested update on the current standard for ECG devices specifies that devices that contain a filter with a high-pass cutoff frequency of 0.67 Hz can detect ST-segment deviations as long as filters are not modifying the phase of the ECG signal [70]. Bailey et al [71] have performed measurements to demonstrate that zero-phase filters indeed do not modify the phase of the ECG recordings. For 45% (26/58) of the devices that specify signal bandwidth, the lower limit ranges from 0.03 to 1 Hz, whereas the upper limit ranges from 25 to 1000 Hz. According to the suggested update of the standard, 17 (65%) of the 26 devices would be suitable for ischemia detection. In addition, the applied filter (zero phase or not) will influence the ability to detect ischemia; however, this is not specified for any of the devices.

Regarding signal acquisition, one of the influencing factors is the sampling frequency, which refers to the time interval of the discrete digital points transformed from the cardiac biopotentials [72]. In general, mobile ECG devices have a sample frequency of at least 250 samples per second. The applicable standard for home use does not specify the required sample frequencies [73]. The general standard for ECG devices used in the clinical environment recommends sample frequencies of at least 500 samples per second (there is no specification for devices used at home) [69,74]. According to Kligfield et al [72], most of the diagnostic information in the ECG is contained below 100 Hz in adults. We noted that all devices analyzed are capable of recording cardiac biopotentials at adequate sample rates.

Besides sampling frequency, signal resolution influences the quality of the ECG. The signal resolution refers to how biopotential signals are expressed in digits into which the input signal can be converted, based on the number of discrete steps. When a device has a resolution of 16 bits, it means that the number of measured steps between the minimum and maximum values that can be recorded is 2^{16}=65,536. In other words, if a device can only capture signals between −2.5 V and +2.5 V (5 V at full-scale deflection), the detail that can be recorded at a resolution of 24 bits is 0.298 µV, also referred to as the least significant bit (LSB). Thus, the combination of full-scale deflection and resolution determine how little of the heart biopotentials can be captured. In fact, the question is this: what is the maximum value of the LSB that provides enough detail on the morphology of the ECG signals (the standard defines an LSB of ≤1 µV [69])?

The relationship of sampling frequency and signal resolution is relevant for diagnosis because of the added information that these features provide to physicians; for example, regarding the relationship of fragmented QRS (fQRS) and heart disorders,

fQRS can only be observed when the sample rate and resolution are sufficient to capture the detailed signals. It has been demonstrated that the use of fQRS is a key feature for detecting myocardial scars in patients [75-77].

Device Features and Technical Characteristics

It is observed that the prioritization of a device's characteristics depends upon its intended use. For handheld home-use devices, usability and easy-of-use characteristics are a priority in comparison with patches, where the recording is a priority and the comfort of the patient is secondary.

We believe that the prioritization regarding users starts from design decisions, such as the selection of electrodes. Adhesive patch devices use wet electrodes, whereas handheld devices and wearables use a mix of electrodes, ranging from embedded metal dry electrodes to textile electrodes that do not require skin preparation. According to electrode comparisons and reviews, wet gel electrodes provide good signal quality for short-term recordings because the gel improves the electrode-skin contact, allowing the formation of a conductive path between skin and electrode [78,79]. However, it has also been noted that long-term use of these types of electrodes can cause skin irritation, and the signal quality decreases as the conductive gels dry out [80]. Hickey et al [81] have reported that by using devices that include multiple adhesive electrodes or patch-type devices, user compliance is diminished owing to application and wearing complexity. Dry electrodes do not require a medium for conduction because the substrate is in direct contact with the skin. This metal-skin interface has been reported to influence the quality of recorded signals owing to movement artifact and charge sensitivity [79]. When biocompatible, the use of dry electrodes prevents undesirable chemical effects and skin irritation on patients [78,82].

For home-use medical electrical devices, their enclosures should provide the user protection against access of hazardous parts inside the enclosure and against harmful effects owing to ingress of water [83]. To designate a device's degree of protection, the IP rating is disclosed. Devices must comply with the minimum IP rating of 22, which is applicable to medical home-use and health care devices [73]. Compliance with the features specified in the standard helps to guarantee the essential device performance as well as basic device safety to users and patients. Of the 38 devices meant for home use, only 14 (37%) have disclosed their IP rating in compliance with the applicable IEC standard. For the remaining devices (24/38, 63%), the IP rating has not been registered on the available device patient information; however, this requirement might be covered by the checklist of general safety and performance requirements. Of note, the devices carry the Conformité Européenne (CE) marking and meet the requirements specified by IEC standards [73,84].

Clinical Evidence

Of the 58 devices with available manufacturer information, only 18 (31%) have published feasibility and reliability studies on diagnosing heart conditions. Patch devices are used as the benchmark for comparison in clinical studies, specifically if these devices have a continuous recording function (Holter devices). As for other devices with published clinical evidence, these devices perform recordings in positions that are not similar to those of the 12-lead clinical ECG. The studies are part of the clinical evidence on the route to compliance with medical device regulations for clinical testing to show the capability of the device to achieve its intended purpose, clinical performance, and benefits [85]. Upon performing the search in the FDA 510(k) Premarket Notification database, we noted that most devices do not include clinical evidence in the submissions because they show evidence of their similarities to other devices in the market or previous versions of the device in question. However, for recently released devices, such as the Apple Watch, we were able to see detailed clinical evidence summaries. We believe that because compliance requirements for new devices have become more stringent, we can expect to see more clinical evidence for new devices. Our belief is also based on the changes made to the European Union regulations governing medical devices; as other researchers have pointed out, the new regulations focus on the need for more clinical data for all medical devices [86,87].

In 2017, the medical device directive was updated to a new version, which is more stringent and aims to improve the safety and effectiveness of medical devices. One of the main changes made to the regulations concerns the additional emphasis placed on the clinical evidence of medical devices [83] to ensure their safety and effectiveness [85]. For devices without available clinical evidence, we could argue that for them to be available in the market, an important step is the clinical evaluation. Before 2017, owing to their similarities to other products already available in the market, these devices' clinical investigations could have been based on the clinical evidence presented by similar devices. This is specifically the case if these devices have been certified before May 2021, when the European Union Medical Device Regulation became fully applicable. Nowadays, another source of information regarding the performance and safety of medical devices as well as the risks involved in using them is the postmarket surveillance; however, these activities are normally confidential, which could be the reason for the lack of available public clinical data for these devices [88].

The studies have shown promising evidence of the capabilities of the ECG devices, but they have been tested on small populations, which is a limitation in terms of investigating their full functionality and use in broader scenarios. As has been specified in the guidance regarding sufficient clinical evidence, these types of publications could be sufficient if there are no concerns regarding the safety of the patient and performance of the device [88].

For handheld devices, another observation concerned the design of the studies owing to the use characteristics of these devices. In the study by Magnusson et al [89], the recordings were limited and scheduled at certain times of the day, limiting the comparison with patch devices, which were used on a continuous basis, whereas in another study, the approach was based on patient management, with patients instructed to perform recordings when symptoms were present, which, as Doliwa et al [90] have shown, is an improvement with regard to detecting paroxysmal AF in patients who have had a recent stroke. These data were confirmed by other studies with similar

approaches and outcomes [41,91]. The design of clinical studies should take into account user case scenarios that approximate to the intended use of the device in daily life. By designing studies based on user scenarios, it would be possible to compare the capabilities of handheld devices with those of patch devices when their performance is evaluated for the detection of symptomatic cardiac diseases. There is a marked lack of studies for the vast majority of the devices (35/58, 60%) included in this review, with, as mentioned previously, only 38% (22/58) of the devices having been investigated in studies regarding their capabilities to detect cardiac disorders.

Limitations

To the best of our ability, we tried to perform an exhaustive search to identify all available devices; however, we cannot guarantee that all were indeed identified. In terms of the analysis performed, we were not able to summarize all technical and clinical information related to the devices owing to the lack of availability of data for such devices.

As this review shows, there is a wide range of mobile ECG devices available for home use, but as mentioned, technologies are moving toward the use of other sensors. One limitation of this review is that we have not analyzed other devices containing other types of sensors used for cardiac monitoring, such as photoplethysmography or consumer electronics not intended for detection of cardiac disorders such as the Fitbit (Google LLC); however, this was a choice because we decided to include only ECG devices.

Finally, in our analysis, we decided not to include the fact that for some devices (ie, KardiaMobile and Fitbit), users are required to sign up for subscription services to obtain further diagnosis of ECGs. We decided not to analyze the availability of these types of services because they depend on location, and prices may change over time.

Future Perspectives

We believe that the inclusion of other sensors will help to improve ECG devices' capabilities to detect disorders. As noted by Sana et al [92], certain heart conditions are difficult to detect with ECG recordings [92]. Structural heart abnormalities can potentially be diagnosed with the help of other sensors (eg, by analyzing sound, accelerometer, and gyroscope recordings), which suggests that phonocardiograms or seismocardiograms could be added to the ECG recording [92]. We noted that, of the 58 devices included in this review, a few (n=2, 3%), such as the Eko DUO (Eko Devices Inc) and Coala Heart Monitor (Coala Life AB), already include these features. We also noted that there is a trend toward acquiring more information on the heart. During the systematic search, we came across prototypes, which included microphones, accelerometers, and gyroscope sensors, that are currently in development and in early stages of testing [93-97].

Conclusions

In this review, we have explored the current scope of mobile ECG devices available in the market for use at home. We have summarized the usability, technical, and clinical characteristics that could allow selection of an ECG device for patients and home use. Devices available in the market are mainly intended for the detection of arrhythmias, more specifically AF, but no devices are intended for the detection of cardiac ischemic disorders. We showed that this is due to the capabilities of the devices, such as the limited measurement areas, limited number of electrodes, and recording capabilities. Clinical research concerning the devices has been primarily focused on rhythm disorders, with few studies focusing on other heart disorders, involving small test populations. Trends in the development of mobile ECG devices are inclusion of other sensors on ECG devices to increase cardiac information collected by them and a movement toward the inclusion of embedded algorithms, allowing the diagnosing of rhythm disorders.

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Conflicts of Interest

PAD is cofounder of HeartEye BV. All other authors declare no other conflicts of interest.

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Abbreviations

AF: atrial fibrillation
CE: Conformité Européenne
ECG: electrocardiogram
FDA: Food and Drug Administration
fQRS: fragmented QRS
IEC: International Electrotechnical Commission
IP: ingress protection
LSB: least significant bit
MeSH: medical subject headings
STEMI: ST-segment elevation myocardial infarction

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