JMIR Cardio

Electronic, mobile, digital health approaches in cardiology and for cardiovascular health
Volume 6 (2022), Issue 1 ISSN 2561-1011 Editor in Chief: Andrew Coristine, PhD, Scientific Editor at JMIR Publications, Canada

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Original Paper

Continuous mHealth Patch Monitoring for the Algorithm-Based Detection of Atrial Fibrillation: Feasibility and Diagnostic Accuracy Study

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Abstract

Background: The detection of atrial fibrillation (AF) is a major clinical challenge as AF is often paroxysmal and asymptomatic. Novel mobile health (mHealth) technologies could provide a cost-effective and reliable solution for AF screening. However, many of these techniques have not been clinically validated.

Objective: The purpose of this study is to evaluate the feasibility and reliability of artificial intelligence (AI) arrhythmia analysis for AF detection with an mHealth patch device designed for personal well-being.

Methods: Patients (N=178) with an AF (n=79, 44%) or sinus rhythm (n=99, 56%) were recruited from the emergency care department. A single-lead, 24-hour, electrocardiogram-based heart rate variability (HRV) measurement was recorded with the mHealth patch device and analyzed with a novel AI arrhythmia analysis software. Simultaneously registered 3-lead electrocardiograms (Holter) served as the gold standard for the final rhythm diagnostics.

Results: Of the HRV data produced by the single-lead mHealth patch, 81.5% (3099/3802 hours) were interpretable, and the subject-based median for interpretable HRV data was 99% (25th percentile=77% and 75th percentile=100%). The AI arrhythmia detection algorithm detected AF correctly in all patients in the AF group and suggested the presence of AF in 5 patients in the control group, resulting in a subject-based AF detection accuracy of 97.2%, a sensitivity of 100%, and a specificity of 94.9%. The time-based AF detection accuracy, sensitivity, and specificity of the AI arrhythmia detection algorithm were 98.7%, 99.6%, and 98.0%, respectively.

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Conclusions: The 24-hour HRV monitoring by the mHealth patch device enabled accurate automatic AF detection. Thus, the wearable mHealth patch device with AI arrhythmia analysis is a novel method for AF screening.

Trial Registration: ClinicalTrials.gov NCT03507335; https://clinicaltrials.gov/ct2/show/NCT03507335

(JMIR Cardio 2022;6(1):e31230) doi:10.2196/31230

KEYWORDS

atrial fibrillation; heart rate variability; HRV; algorithm; stroke; mobile health; mHealth; Awario analysis Service, screening; risk; stroke risk; heart rate; feasibility; reliability; artificial intelligence; mobile patch; wearable; arrhythmia; screening

Introduction

Background

Atrial fibrillation (AF) is globally the most common arrhythmia associated with significant morbidity and mortality, imposing a significant burden on patients, public health, and the health care budget [1,2]. The detection of AF is important in the decision to initiate anticoagulation therapy to prevent thromboembolic events [3,4]. Nonetheless, AF detection is still a major clinical challenge as AF is often paroxysmal and asymptomatic [5-8]. AF screening recommendations include opportunistic or systematic screening in patients ≥65 years of age or in those individuals with other characteristics pointing to an increased risk of stroke [3]. The European Heart Rhythm Association recommends multiple time points or over a prolonged time to increase diagnostic yield in AF screening with digital devices [9]. The popularities of well-being and taking personal responsibility for one's own health are reflected in the continuous development and growth of mobile health (mHealth) technologies. There are currently more than 400 wearable activity monitors and more than 100,000 mHealth apps already available [10]. mHealth technologies could provide an additional opportunity to diagnose AF, particularly its paroxysmal and asymptomatic forms [11]. Most mHealth technologies designed for AF detection include some form of automatic AF detection algorithm [12]. These novel mHealth technologies could provide a cost-effective solution for AF-screening [13].

Objective

A highly popular and evolving mHealth technology could reach the population to be screened at a relatively low cost and with little logistical effort, since well-being and personal health care monitoring is already a part of everyday life in many individuals. Several of these new devices produce heart rate variability (HRV) data, which have been widely used to assess a variety of well-being measures such as recovery and stress monitoring [14]. Furthermore, HRV monitoring could also be suitable for other health-related measurements such as AF detection [10,15]. Algorithm-based rhythm monitoring with devices designed for well-being and health-related measurements could enable straightforward, cost-effective, and reliable methods for AF screening. The specific aims of this study were to (1) evaluate the feasibility and quality of the HRV data using a single-lead electrocardiogram (ECG)–based mHealth patch device, and (2) assess the accuracy of an artificial intelligence (AI) arrhythmia detection algorithm in AF screening with 24-hour monitoring.

Methods

Study Setting and Participant Recruitment

The study was conducted as a single-center study between April 2018 and December 2019 in Kuopio University Hospital. The study patients were recruited from the hospital emergency care department. The inclusion criteria were AF or sinus rhythm (SR) based on a 12-lead resting ECG recorded during admission to the hospital. The exclusion criteria were as follows: (1) estimated stay in the hospital <24 hours; (2) BMI ≥35kg/m2; (3) left bundle branch block or right bundle branch block; (4) implanted cardiac pacemaker; and (5) a medical condition requiring immediate treatment. The clinical characteristics and symptoms prior to hospital admission of the patients were collected using a standardized data collection protocol and confirmed or complemented from the medical records. All participants provided written informed consent to participate in the study. All data were pseudonymized. Each subject was given an ID number, and the data were kept locked and encrypted in the study files. The measurement data did not include personal data. The research data collected in the study will be treated confidentially as required by the Personal Data Act.

HRV Measurements and Analysis

A single-lead ECG-based HRV device (Firstbeat Bodyguard 2, Firstbeat Technologies) was applied to the patient's chest with 2 adhesive patches as shown in Figure 1. The Firstbeat Bodyguard 2 device records ECG data, from which it stores beat-to-beat R-R intervals (time elapsed between two successive R-waves) to allow an HRV assessment. The target time for HRV measurement was 24 hours. Simultaneously registered 3-lead Holter ECG recording (Faros 360, Bittium) was used as the "gold standard" for rhythm classification (Figure 1). Both devices stored the data in the internal memory of the device.

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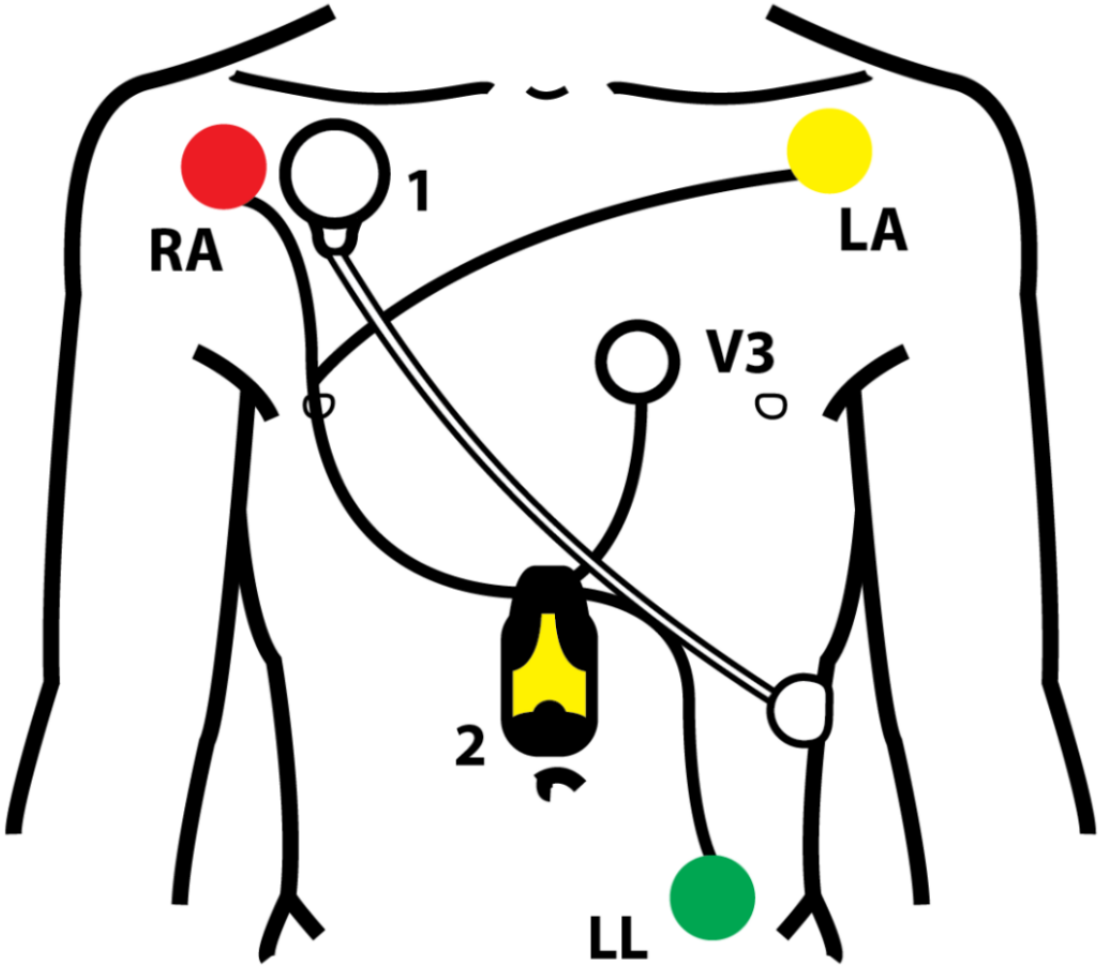
Figure 1. Heart rate variability (HRV) and electrocardiogram (ECG) recordings. Single-lead ECG-based HRV recording (1) and 3-lead Holter ECG recording (2). LA: left arm; LL: left limb; RA: right arm; V3: V3 lead in 12-lead ECG.



A commercial arrhythmia analysis software (Awario, Heart2Save) was used for automatic AF screening from the HRV data. The AI arrhythmia detection algorithm classified the HRV data in 30-second time windows into 3 categories: SR, AF, and uninterpretable. The accuracy of the AI-based rhythm classification from the HRV recording was further assessed by comparing it with the gold standard Holter ECG recording. Holter ECG recordings were analyzed using a Medilog Darwin Professional V2.8.1 software (Schiller Global). ECG recordings were reviewed independently by 4 investigators blinded to the initial 12-lead ECG and classified into either AF or non-AF rhythms.

Statistical Analysis

The size of the study sample was estimated as 200 observations with an assumed sensitivity of 95% and with a 3% margin error. The AF and control groups were compared using *t* test for continuous variables and $\chi 2$ test or Fisher exact tests for dichotomous variables. All HRV data were analyzed by the AI arrhythmia detection algorithm in 30-second time windows. The performance of the AI arrhythmia detection algorithm in AF detection from HRV recordings was quantified using accuracy, sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV). The performance of the AI arrhythmia detection algorithm was tested by (1) detecting AF per patient (subject-based) and (2) total accumulated AF duration across all patients (time-based). All significance tests were 2-tailed, and $P \leq .05$ was considered statistically significant. The data were analyzed using IBM SPSS statistics software, version 27. This study was registered in the ClinicalTrials.gov database (NCT03507335).

Ethics Approval

The study design was approved by Research Ethics Committee of the Northern Savo Hospital District (347/2018).

Results

Study Population

A total of 654 patients were assessed for eligibility. In the initial assessment for the study patients, 454 (69.4%) patients were excluded for the reasons summarized in Figure 2. A total of 200 eligible patients were included in study, of which 100 (50%) were assigned to the AF group and 100 (50%) with SR to the control group. Of the 200 eligible participants, 22 (11%) were further excluded (n=19, 10% were excluded due to missing data and n=3, 1.5% withdrew their consent). In addition, the rhythm of some patients had converted from the time of 12-lead ECG recording prior to study measurements. Consequently, the final rhythm classification made from Holter ECG recording reclassified 11 patients from the AF group into the control group and 1 patient from the control group into the AF group. Thus,

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the final study population consisted of 178 patients, of whom 79 (44%) were in the AF group and 99 (56%) in the control group.

Compared to the control group, patients with AF were older (77, SD 10 vs 68, SD 15 years; *P*<.001), presented more often with a history of paroxysmal AF (*P*<.001), hypertension (*P*=.02), congestive heart failure (*P*<.001), and previous heart surgery (*P*=.02), and were more often receiving anticoagulation (*P*<.001), beta-blocker (*P*<.001), and digoxin (*P*=.005) therapy. Patients with AF also more often reported palpitations (*P*=.005) and respiratory distress (*P*<.001), compared to the control group. These groups did not differ statistically with respect to the other recorded parameters (Table 1).

Figure 2. Study flow chart. AF: atrial fibrillation; HRV: heart rate variability.

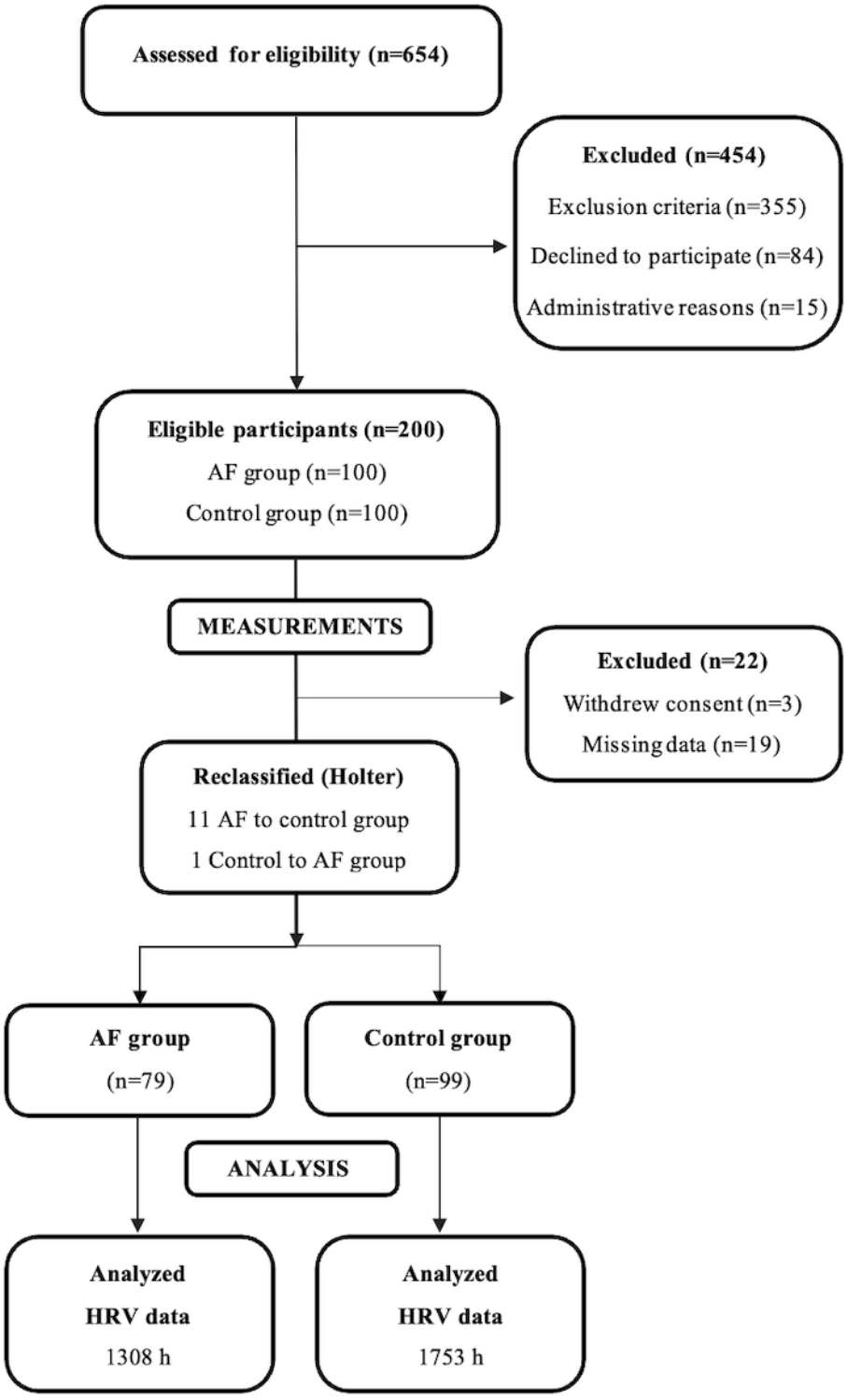

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Table 1. Patient demographics.

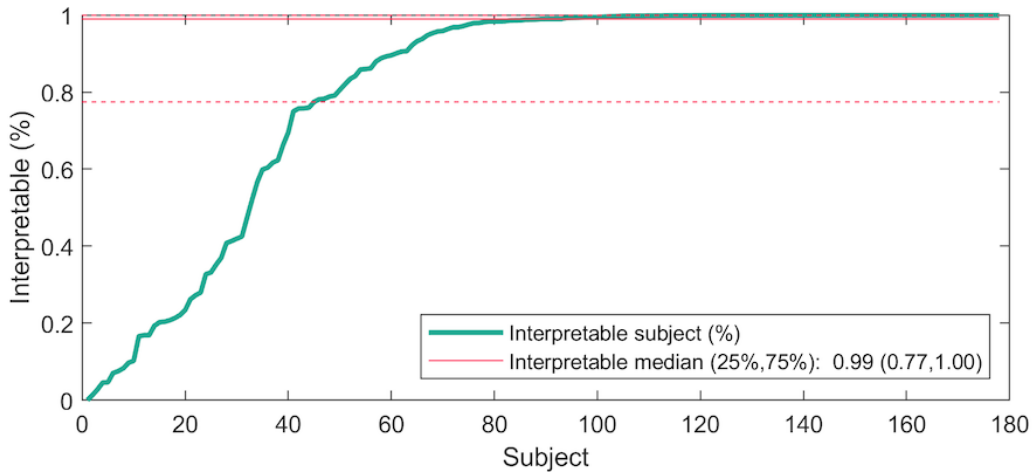
Characteristics and demographics	Control group (n=99)	AF[a] group (n=79)	Significance (2-sided)
Age (years), mean (SD)	68 (15)	77 (10)	<.001
BMI (kg/m^2), mean (SD)	26 (4)	27 (4)	.16
Sex, n (%)			.09
Male, n (%)	40 (40)	42 (53)	
Female	59 (60)	37 (47)	
Medical history, n (%)			
Earlier AF episode	21 (21)	63 (80)	<.001
Coronary heart disease	27 (27)	26 (33)	.41
Diabetes mellitus	21 (21)	19 (24)	.65
Hypertension	57 (58)	59 (75)	.02
Congestive heart failure	12 (12)	39 (49)	<.001
Previous heart surgery	7 (7)	15 (19)	.02
Medication, n (%)			
Anticoagulation therapy	26 (26)	67 (84)	<.001
Beta blocker	42 (42)	56 (71)	<.001
Digoxin	4 (4)	13 (17)	.005
Antiarrhythmic medication	1 (1)	1 (1)	>.99
Symptoms prior to hospital admission (%)			
Decrease in general condition	56 (57)	45 (57)	.96
Fatigue	51 (52)	47 (60)	.29
Palpitations	23 (23)	34 (43)	.005
Respiratory distress	26 (26)	39 (49)	<.001
Chest pain	17 (17)	18 (23)	.35

[a]AF: atrial fibrillation.

Quality of the HRV Data

In the automatic analysis of HRV data (all subjects), 3099 hours out of 3802 hours (81.5%) were estimated as being interpretable. In Holter ECG recordings, 3723 hours were deemed interpretable. Based on the evaluation of the AI arrhythmia detection algorithm, 1308/1543 hours (84.8%) of the AF group recordings and 1753/2180 hours (80.4%) of the control group recordings were estimated as being interpretable. The subject-based median for interpretable data was 99% (25th percentile=77% and 75th percentile=100%) (Figure 3).

Figure 3. Percentage of interpretable heart rate variability data in individual subject recordings. Subjects sorted by using automatic quality values.



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Accuracy of the AI Arrhythmia Detection Algorithm When Interpreting HRV Data

The accuracy of rhythm analyses was evaluated from the data deemed interpretable in both HRV and ECG recordings (3062 hours). The AI arrhythmia algorithm detected AF correctly in all the patients in the AF group and suggested the presence of AF in 5 patients in the control group (false-positive AF detection), resulting in a subject-based AF detection accuracy of 97.2% (173/178), a sensitivity of 100% (79/79), a specificity of 94.9% (94/99), PPV of 94.0% (79/84), and NPV of 100% (94/94) (Table 2). The values of the time-based accuracy, sensitivity, and specificity of the AI arrhythmia detection algorithm for identifying AF were 98.7% (3022/3062 hours), 99.6% (1304/1308 hours) and 98.0% (1718/1753 hours), respectively; the PPV was 97.4% (1304/1339 hours) for detecting the presence of AF, and the NPV was 99.7% (1718/1723 hours) for its absence (Table 3). We inspected for the reasons for false-positive AF detections, which were as follows: frequent (>10,000 per 24 hours) ventricular extrasystoles, atrioventricular block, a short section (12 minutes) with many ventricular extrasystoles, and in 2 cases they were attributable to undetected QRS complexes (Q wave, R wave, and S wave).

Table 2. Subject- and time-based AF detection accuracy, sensitivity, and specificity based on artificial intelligence arrhythmia detection algorithm.

Algorithm types	Accuracy, n/N (%)	Sensitivity, n/N (%)	Specificity, n/N (%)
Subject-based algorithm	173/178 (97.2)	79/79 (100)	94/99 (94.9)
Time-based algorithm (h)	3022/3062 (98.7)	1304/1308 (99.6)	1718/1753 (98.0)

Table 3. PPV[a] and NPV[b] based on artificial intelligence arrhythmia detection algorithm.

Algorithm types	PPV, n/N (%)	NPV, n/N (%)
Subject-based algorithm	79/84 (94.0)	94/94 (100)
Time-based algorithm (h)	1304/1339 (97.4)	1718/1723 (99.7)

[a]PPV: positive predictive value.

[b]NPV: negative predictive value.

Discussion

Principal Findings

We demonstrated the good feasibility and diagnostic performance of the mHealth patch device and AI arrhythmia detection algorithm for AF detection. The main findings were as follows: (1) the mHealth patch device designed for well-being and personal health care measurements produced interpretable HRV data from 24-hour recording; and (2) the AI arrhythmia detection algorithm achieved an accurate AF detection from the HRV data.

Comparison to Prior Work

ECG-based wearables, especially adhesive patches, are probably the most valuable approach for tracking HRV data [16]. In previous studies using adhesive patch devices, 92%-99% of the ECG or ECG-based HRV data have been reported to be analyzable with recording times ranging from 12 hours to several days [17-19]. In line with these reports, in our study of the HRV data produced by the ECG-based mHealth patch, 82% were analyzable, and in the subject-based analysis, the median of the data to be analyzed was 99%. However, interindividual differences were observed in the HRV data quality. In 32/178 patients (18%), less than 50% of the data were interpretable (Figure 3). According to a recent systematic review, although the correlation between HRV as measured by Holter and ECG-based wearable devices was excellent at rest, it declined down to 0.85 during movement or exercise [20]. In our study, mobilization of the study patients was not restricted. Despite this, the mHealth device provided high-quality ECG data for HRV monitoring.

The diagnostic accuracy of the AI arrhythmia detection algorithm used in this study to detect AF was comparable to other screening methods and devices. In the previous studies, the sensitivity of automatic AF detection ranged from 67% to 100% and the specificity from 84% to 100% depending on the mobile or digital technology and strategy used [21-36]. In our study, the sensitivity and specificity of AF detection were 100% and 94.9%, respectively. Although the new mHealth screening methods have a high sensitivity and specificity for AF detection, fals-positive AF detections (false alarm) remain a major concern, especially when low-risk individuals use these devices [37]. A false alarm can lead to anxiety, additional health care costs, and possibly even inappropriate treatment [37]. Nonetheless, it should be noted that some false alarms may be due to another arrhythmia or some other pathological condition, and in these cases, screened individuals may benefit from the AF screening program [38]. Our results support this idea since 3 (60%) of the 5 “false alarms” in our study were due to a true arrhythmia. Further, the threshold for confirming the arrhythmia diagnosis by a health care professional from an ECG recording should be low.

Future Directions

The current guidelines recommend AF screening for individuals at an elevated risk of stroke, such as those over 65 years of age [3]. However, there is no unambiguous guidance on the actual screening strategy to be adopted. According to the current guidelines of the European Society of Cardiology, the development of wearable technology is likely to provide cost-effective and practical alternatives for the detection of AF [3]. The popularity of well-being and personal health care

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monitoring is reflected in the continuous development and growth of the mHealth technologies [10]. However, most of these techniques have not been validated for clinical purposes [10]. Therefore, before using mHealth technologies, one should carefully consider whether the technology in question has been validated for clinical use [14]. Novel methods, such as the AI arrhythmia analysis used here, could provide reliable AF screening when combined with technologies designed for well-being and personal health care measurements. Firstly, a longer duration of rhythm monitoring is more sensitive compared to single recording in AF screening [39]. Secondly, the advantage of automatic AF screening helps to identify arrhythmia episodes from long-term ECG or HRV data, particularly in patients with paroxysmal and asymptomatic AF. Consequently, these techniques could enable the screening of patients at high risk for AF and stroke and the allow follow-up of patients after cardioversion and ablation as well as those recovering from stroke or transient ischemic attack.

Study Limitations

We acknowledge some limitations in our study. First, the presence of morbid obesity could degrade the signal quality and thus produce more failed measurements. In addition, in the right bundle branch block and left bundle branch block cases, the presence of broad 2-peak QRS complexes could result in a false R-R interval, and thereby, an erroneous AF detection by the automatic algorithm. For these reasons, these patients were excluded, and further studies will be needed in these subgroups. In the future, algorithm-based detection of AF with HRV mHealth patch devices will need to be conducted in an out-of-hospital setting to assess the signal quality and accuracy of AF detection in these scenarios.

Conclusions

The mHealth patch device provided good quality HRV data for accurate automatic AF detection from 24-hour monitoring. The AI arrhythmia detection algorithm detected AF with high accuracy, sensitivity, and specificity. Thus, the wearable mHealth patch device with AI arrhythmia analysis could represent a new, promising method for AF screening.

Acknowledgments

This work was supported by the Research Committee of the Kuopio University Hospital Catchment Area for the State Research Funding (project 5101137 and project 507T044). OES received research support from the Helsinki University Hospital fund, Department of Emergency Medicine and Services, Antti and Tyyne Soininen Foundation, Aarne Koskelo Foundation, The Finnish Foundation for Cardiovascular Research, and The Finnish Medical Foundation. We thank the nursing and medical staff of the Kuopio University Hospital and especially Menna Kuosmanen, Matias Rapo, Antti Redsven, Roope Sepponen, Salla Autio, and Vilppu Kekkonen for their work with data acquisition, Oona Silvennoinen for illustration assistance, and Tuomas Selander for statistical advice.

Authors' Contributions

All authors contributed to the study and preparation of this manuscript. TJM, JAL, HJ, MPT, JH, JEKH, TTR, OES, and ESV designed the study. OES and ESV were responsible for collecting the data. JAL, OES, ESV, TPL, and TML contributed to data analysis and figure and table preparation. OES, JH, HJ, TTR, MPT, TPL, TML, MC, ESV, OAR, NSN, JEKH, JAL, and TJM were responsible for editing and further improvements to the manuscript. OES was responsible for the literature search, drafting the first version of the manuscript, final editing, and preparation of the manuscript for submission. All authors read and approved the final manuscript.

Conflicts of Interest

OES, JAL, TTR, TJM, HJ, JH, ESV, and MPT are shareholders of a company (Heart2Save) that designs electrocardiogram-based software for medical equipment. JAL, MPT, and HJ report personal fees from Heart2Save.

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Abbreviations

AF: atrial fibrillation
AI: artificial intelligence
ECG: electrocardiogram
HRV: heart rate variability
mHealth: mobile health
NPV: negative predictive value
PPV: positive predictive value
SR: sinus rhythm

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Edited by T Leung; submitted 14.06.21; peer-reviewed by D Filos, O Pavliuk; comments to author 06.12.21; revised version received 27.12.21; accepted 02.05.22; published 21.06.22.

Please cite as:
Santala OE, Lipponen JA, Jäntti H, Rissanen TT, Tarvainen MP, Laitinen TP, Laitinen TM, Castrén M, Väliaho ES, Rantula OA, Naukkarinen NS, Hartikainen JEK, Halonen J, Martikainen TJ
Continuous mHealth Patch Monitoring for the Algorithm-Based Detection of Atrial Fibrillation: Feasibility and Diagnostic Accuracy Study
JMIR Cardio 2022;6(1):e31230
URL: https://cardio.jmir.org/2022/1/e31230
doi:10.2196/31230
PMID:35727618

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Original Paper

Smartphone Ownership and Interest in Mobile Health Technologies for Self-care Among Patients With Chronic Heart Failure: Cross-sectional Survey Study

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Abstract

Background: Heart failure (HF) is a highly prevalent chronic condition that places a substantial burden on patients, families, and health care systems worldwide. Recent advances in mobile health (mHealth) technologies offer great opportunities for supporting many aspects of HF self-care. There is a need to better understand patients' adoption of and interest in using mHealth for self-monitoring and management of HF symptoms.

Objective: The purpose of this study is to assess smartphone ownership and patient attitudes toward using mHealth technologies for HF self-care in a predominantly minority population in an urban clinical setting.

Methods: We conducted a cross-sectional survey of adult outpatients (aged ≥18 years) at an academic outpatient HF clinic in the Midwest. The survey comprised 34 questions assessing patient demographics, ownership of smartphones and other mHealth devices, frequently used smartphone features, use of mHealth apps, and interest in using mHealth technologies for vital sign and HF symptom self-monitoring and management.

Results: A total of 144 patients were approached, of which 100 (69.4%) participated in the study (63/100, 63% women). The participants had a mean age of 61.3 (SD 12.25) years and were predominantly Black or African American (61/100, 61%) and Hispanic or Latino (18/100, 18%). Almost all participants (93/100, 93%) owned a cell phone. The share of patients who owned a smartphone was 68% (68/100). Racial and ethnic minorities that identified as Black or African American or Hispanic or Latino reported higher smartphone ownership rates compared with White patients with HF (45/61, 74% Black or African American and 11/18, 61% Hispanic or Latino vs 9/17, 53% White). There was a moderate and statistically significant association between smartphone ownership and age (Cramér V [Φ_C]=0.35; P<.001), education (Φ_C=0.29; P=.001), and employment status (Φ_C=0.3; P=.01). The most common smartphone features used by the participants were SMS text messaging (51/68, 75%), internet browsing (43/68, 63%), and mobile apps (41/68, 60%). The use of mHealth apps and wearable activity trackers (eg, Fitbits) for self-monitoring of HF-related parameters was low (15/68, 22% and 15/100, 15%, respectively). The most popular HF-related self-care measures participants would like to monitor using mHealth technologies were physical activity (46/68, 68%), blood pressure (44/68, 65%), and medication use (40/68, 59%).

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Conclusions: Most patients with HF have smartphones and are interested in using commercial mHealth apps and connected health devices to self-monitor their condition. Thus, there is a great opportunity to capitalize on the high smartphone ownership among racial and ethnic minority patients to increase reach and enhance HF self-management through mHealth interventions.

(JMIR Cardio 2022;6(1):e31982) doi:10.2196/31982

KEYWORDS

mHealth; smartphone; mobile phone; heart failure; self-care; self-management

Introduction

Heart failure (HF) is a serious cardiovascular condition associated with substantial morbidity, mortality, and health care costs. In the United States, the estimated prevalence of HF is 6.5 million, and it is expected to increase to nearly 8.5 million by 2030 owing to the rapid growth of the aging population [1]. Despite improvements in patient outcomes with pharmacological therapy and surgical treatment, the clinical burden of HF remains high [2]. Approximately 25% of patients are readmitted to the hospital within 30 days, and up to 50% are readmitted within 6 months following HF-related hospitalization [3-5]. This results in significant, potentially avoidable costs for our already strained health care system [6,7]. In 2020, the direct and indirect costs of HF management were estimated to be US $43.6 billion [8]. Of these costs, 70% were attributed to direct medical expenditures because of hospitalizations for acute decompensated HF [8].

A large portion of the health care use costs and many HF-related deaths can potentially be prevented if patients consistently engage in effective self-care [9,10]. Evidence from clinical trials and systematic reviews shows that patients who adhere to their treatment plan and are actively engaged in their own care are more likely to have improved survival, decreased hospital readmission rates, and better quality of life [11-14]. HF self-care is defined as a naturalistic decision-making process comprised of 3 pillars: self-care maintenance, self-care monitoring, and self-care management. Self-care maintenance involves the choice of behaviors that maintain physiological stability, such as taking medications as prescribed, following a sodium-restricted diet, engaging regularly in physical activity or exercise, receiving an influenza vaccine or other necessary vaccinations, quitting smoking and drinking, and attending routine health care appointments. Self-care monitoring involves regular weighing and monitoring of vital signs and symptoms (eg, blood pressure, shortness of breath, and edema) as well as recognition and interpretation of these symptoms. Self-care management refers to the actions taken by the patient in response to HF symptoms and possible deterioration (eg, taking an extra diuretic dose and contacting the HF care team) and to the evaluation of the response to the treatment implemented. Clinical guidelines stress the importance of effective HF self-care as part of a successful treatment [10,15,16]. However, HF self-care is poor among patients with HF [9], especially minorities and people of low socioeconomic status [17,18]. Previous studies have shown that lack of adherence to prescribed medications, sodium-restricted diet, and self-monitoring of symptoms and weight is particularly high, with most studies citing rates of approximately 40% to 60% [19-22].

Rapidly evolving mobile health (mHealth) technologies such as smartphones, mHealth apps, SMS text messaging, wearable activity tracking devices, and other smart and connected health technologies have become increasingly ubiquitous, offering great opportunities for supporting many aspects of HF self-care. Through real-time collection and visualization of patient-generated health data, mHealth apps and connected health devices can enhance self-monitoring of HF signs and symptoms (eg, heart rate, weight, pulse oximetry, and blood pressure) and help patients become more aware of how their bodies work and what is normal and be alerted to health changes that may require medical attention. Furthermore, mHealth apps have the potential to improve self-care adherence through a variety of functionalities and behavior change tools such as medication reminders, behavioral prompts, electronic diaries, personalized feedback, patient education, and social networking [23]. SMS text messaging is another powerful mHealth tool that can be used to deliver behavior change interventions to improve self-management of HF [24,25] and other chronic diseases [26]. SMS text messaging is low-cost, does not require great technological expertise, is increasingly used by people from all socioeconomic classes and age groups [26], and has the advantage of being asynchronous (ie, it can be delivered as soon as the phone is turned back on and accessed by the recipient at any time). Several systematic reviews and meta-analyses have demonstrated the efficacy of mHealth interventions for self-management of long-term conditions (eg, HF [27,28], diabetes [29,30], and hypertension [31]). In the area of HF, a recent meta-analysis found that mHealth interventions involving data transmission to a clinical care team and a feedback loop to the patient can lead to significant reductions in all-cause mortality and HF-related hospitalizations and improve HF self-care and health-related quality of life [27]. However, it is important to note that not all mHealth technologies and interventions are effective. A Cochrane review of mHealth-delivered educational interventions for people with HF found evidence of little to no improvement in HF-related hospitalizations and self-care compared with usual care [32].

Given the increasing interest in the potential of mHealth technologies to improve self-care and reduce hospitalizations in patients with HF, there is a critical need to better understand the adoption and attitudes of patients with HF toward the use of commercial mHealth technologies for self-monitoring and management of HF symptoms—especially among racial and ethnic minority patients (eg, Black or African American and Hispanic or Latino), who have the highest incidence of HF across all age groups [1], and female patients, who have been underrepresented in HF research [33]. Previous mHealth trials [27] and survey studies in HF [34-36] have included primarily White, male patients and focused on *smart devices* in general

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[34] or smartphone ownership only [35], overlooking adoption of other important mobile technologies such as SMS text messaging and wearable activity trackers that can play an important role in self-monitoring and delivery of behavior change interventions to support HF self-care. We used a holistic approach to develop an mHealth questionnaire based on a review of previous studies and input from patients and clinicians to address this gap. Subsequently, we conducted a survey in a predominantly racial and ethnic minority HF population in an urban academic health care setting to assess patients' attitudes toward the use of smartphones, SMS text messaging, wearable devices, and other mHealth technologies that support functions of HF self-care. We also explore the relationship between mHealth adoption and socioeconomic characteristics, including educational status.

Methods

Study Design

The study was a single-site, cross-sectional survey of adult outpatients conducted between June and September 2018 at the outpatient HF clinic at the University of Illinois Hospital and Health Sciences System. Human research ethics approval was received from the University of Illinois, Chicago Institutional Review Board (research protocol 2017-0395).

Eligibility Criteria

Adults (aged ≥18 years) with a diagnosis of HF (confirmed by the attending cardiologist based on clinical evaluation and transthoracic echocardiography), able to speak English, and willing to participate in the study were eligible to participate in the survey. The exclusion criteria were patients with a diagnosis of major cognitive impairment (ie, dementia) documented in their medical records.

Survey Development

The cross-sectional survey used in this study (Multimedia Appendix 1) was designed based on a review of other mHealth surveys [37-40] and comprised 34 items across 4 sections. The first section (8 items) included questions about mobile phone ownership, use of SMS text messaging, and interest in receiving SMS text messages for HF self-care. The second section (10 items) included questions in relation to smartphone ownership and use, internet access and data plans, frequently used smartphone features, use of mHealth apps, and interest in specific smartphone app features for HF self-care. The third section (9 items) included questions in relation to ownership of other mobile and connected health technologies (eg, tablets and wearable activity tracking devices) as well as interest in using mHealth devices for HF self-monitoring and transmitting this information to their physician. The fourth section (7 items) comprised sociodemographic questions. The survey was anonymous (ie, no identifiable data were collected).

The survey was first reviewed by 2 physician researchers and 2 nurses who provided feedback for minor changes pertaining to the wording and order of the items. After improvements were made, the revised version of the questionnaire was pilot-tested with 5 patients with HF to ensure that the participants fully understood each question and were able to complete the survey within 15 to 20 minutes. No changes were made to the instrument after pilot-testing.

Participant Recruitment and Data Collection

Eligible patients were approached during routine clinical appointments by research assistants who provided information about the study protocol and asked patients for informed consent to participate in the study. All interviews were conducted in private examination rooms at the outpatient HF clinic. Survey questions were read aloud by research assistants, and responses were captured and saved in a REDCap (Research Electronic Data Capture) database using study laptops. REDCap is a secure web-based application for building and managing questionnaires and databases for the collection and entry of research data [41].

Statistical Analysis

Descriptive statistics (eg, frequency and percentage) were used to quantitatively analyze the adoption and use of mHealth technologies. Following the same approach as the Pew Internet Research study [42], we categorized the age groups as follows: <50 years, 50-64 years, and >65 years. Univariate analyses (chi-square tests) were used to examine associations between sociodemographic characteristics and mobile technology use across patients with HF, and the Cramér V (Φ_C) was used to assess the strength of these associations. The Cramér V ranges from 0 to 1, where 0 to <0.10 is a negligible association, 0.10 to <0.20 is a weak association, 0.20 to <0.40 is a moderate association, 0.40 to <0.60 is a relatively strong association, 0.60 to <0.80 is a strong association, and 0.80 to 1.00 is a very strong association [43]. Content analysis was used to assess the attitudes toward and perceptions of the use of commercially available smartphones and wearable sensor devices for remote monitoring and delivery of HF self-care support via SMS text messages.

Results

Demographics

Over a 4-month period, 144 patients were approached and asked to participate in the survey. A total of 100 eligible patients (mean age 61.3, SD 12.3; range 29-93 years) agreed to participate, yielding a response rate of 69.4% (100/144). As shown in Table 1, most patients (63/100, 63%) were women, self-identified as Black or African American (61/100, 61%), were aged 50-64 years (49/100, 49%), had high school education or lower (65/100, 65%), and reported being retired or on disability (55/100, 55%). Of the 100 patients, only 49 (49%) reported their annual income. Of those who did report their annual household income, 53% (26/49) made <US $25,000 per year.

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Table 1. Participant demographics (N=100).

Demographics	Values
Gender, n (%)	
Male	37 (37)
Female	63 (63)
Race, n (%)	
White (non-Hispanic)	17 (17)
Black or African American	61 (61)
Hispanic or Latino	18 (18)
Asian	1 (1)
Other	3 (3)
Age (years), mean (SD)	61.32 (12.3)
Age group (years), n (%)	
29-49	12 (12)
50-64	49 (49)
≥65	39 (39)
Education, n (%)	
Lower than high school	18 (18)
High school	47 (47)
Undergraduate	26 (26)
Graduate	9 (9)
Employment status, n (%)	
Employed	28 (28)
Unemployed	17 (17)
Retired or on disability	55 (55)
Income (US $), n (%)	
<25,000	26 (26)
25,000-49,000	12 (12)
50,000-74,999	6 (6)
75,000-99,999	0 (0)
>100,000	5 (5)
Not sure or declined to respond	51 (51)

Mobile Phone and Smartphone Ownership by Race and Age Group in Patients With HF

As shown in Table 2, most patients with HF owned a cell phone (93/100, 93%). The share of patients who owned a smartphone was 68% (68/100). Android smartphones (46/68, 67%) were owned at higher rates compared with iPhones (15/68, 22%) or other types of smartphones (7/68, 10%). Smartphone ownership was relatively higher in Black or African American participants (45/61, 74%) compared with White (9/17, 53%) and Latino or Hispanic participants (11/18, 61%). Adoption rates were twice as high in middle-aged adults (41/49, 84% ages 50-64 years) compared with people aged >65 years (16/39, 41%), illustrating a moderate association between age group and smartphone ownership (Φ_C=0.351; P<.001). Employed participants were significantly more likely to own a smartphone (25/28, 89%) compared with those who were unemployed (12/17, 71%) or retired (31/55, 56%; Φ_C=0.299; P=.001). Overall, the association between smartphone ownership and race (Φ_C=0.273), education (Φ_C=0.291), and income (Φ_C=0.274) was moderate, whereas it was weak with gender (Φ_C=0.122).

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Table 2. Profile and smartphone ownership of participants across demographic groups (N=100)[a].

Demographics	Participants with smartphone (n=68)[b], n (%)	Participants with mobile phone but not smartphone (n=25)[c], n (%)	Participants without mobile phone (n=7)[d], n (%)	Φ_C[e]	Chi-square (*df*)	*P* value
Gender				0.122	1.5 (2)	.48
Male	25 (68)	8 (22)	4 (11)			
Female	43 (68)	17 (27)	3 (5)			
Race				0.273	14.9 (8)	.06
White (non-Hispanic)	9 (53)	4 (24)	4 (24)			
Black or African American	45 (74)	15 (25)	1 (2)			
Hispanic or Latino	11 (61)	6 (33)	1 (6)			
Asian	1 (100)	0 (0)	0 (0)			
Other	2 (67)	1 (33)	0 (0)			
Age (years)				0.351	24.7 (4)	<.001
29-49	11 (92)	1 (8)	0 (0)			
50-64	41 (84)	8 (16)	0 (0)			
≥65	16 (41)	16 (41)	7 (18)			
Education				0.291	16.9 (6)	.01
Lower than high school	11 (61)	6 (33)	1 (6)			
High school	29 (62)	15 (32)	3 (6)			
Undergraduate	22 (85)	4 (15)	0 (0)			
Graduate	6 (67)	0 (0)	3 (33)			
Employment status				0.299	17.9 (4)	.001
Employed	25 (89)	1 (4)	2 (7)			
Unemployed	12 (71)	2 (12)	3 (18)			
Retired or on disability	31 (56)	22 (40)	2 (4)			
Income (US $)				0.277	7.5 (6)	.27
<25,000	17 (65)	8 (31)	1 (4)			
25,000-49,000	11 (92)	0 (0)	1 (8)			
50,000-74,999	4 (67)	2 (33)	0 (0)			
75,000-99,999	0 (0)	0 (0)	0 (0)			
>100,000	5 (100)	0 (0)	0 (0)			
Not sure	14 (54)	8 (31)	4 (15)			
Declined to respond	17 (68)	7 (28)	1 (4)			

[a]Percentages add up to 100 horizontally.

[b]Mean age 57.49 (SD 11.05) years.

[c]Mean age 67.32 (SD 10.54) years.

[d]Mean age 77.14 (SD 7.65) years.

[e]Cramér *V*

Most patients who owned a smartphone (60/68, 88%) reported having a data plan that allowed them to access the internet on their phones. Most of these patients (44/60, 73%) had an unlimited data plan. There were no significant differences in data plan ownership between age groups (Φ_C=0.143; χ^2_4=2.8; *P*=.59). However, people who reported being employed, retired, or on disability were significantly more likely to have an internet plan on their phone compared with those who reported being unemployed (Φ_C=0.324; χ^2_4=14.3; *P*=.007).

Text Messaging and HF Self-care

Of the 93 patients who owned a cell phone, 69 (74%) reported having an SMS text messaging plan. Most of them (61/69, 88%) had a plan that allowed them to send and receive an unlimited

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number of SMS text messages. Most patients with a cell phone (67/93, 72%) reported being somewhat comfortable or very comfortable with sending and receiving SMS text messages. Approximately half (43/93, 46%) said that they sent SMS text messages every day, whereas 30% (28/93) said they did not use the SMS text messaging feature. Frequency of and comfort with SMS text messaging use correlated with age. Patients aged ≥65 years reported sending SMS text messages less frequently (Φ_C=0.327; χ^2_6=19.9; *P*=.003) and feeling less comfortable using the SMS text messaging feature than younger and middle-aged adults (Φ_C=0.303; χ^2_6=17.1; *P*=.009). There was no significant relationship between SMS text messaging use and other demographic characteristics (eg, gender, race, education, or employment status). The patients were asked whether they would be interested in receiving weekly SMS text messages from the clinic to help them improve HF self-care and, if so, how many messages they would like to receive. A total of 68% (63/93) of patients said they would like to receive HF self-care messages. Most of them (34/63, 54%) said they would like to receive 1-2 messages per week. There were no significant differences in demographic characteristics (eg, age, gender, or race) between patients who expressed interest in receiving HF self-care messages on their cell phones and those who did not.

Frequently Used Smartphone Features and Interest in Using mHealth Apps for HF Self-care

The patients were asked to indicate which smartphone features they used regularly in addition to calling. As shown in Table 3, SMS text messaging was the most frequently used smartphone feature, followed by internet browsing, mobile apps, social media, emails, and appointment scheduling. Age group was significantly associated with this type of use (Table 3). Older adults (aged ≥65 years) were less likely to use these features than younger and middle-aged adults.

Table 3. Frequently used smartphone features and popular heart failure (HF) parameters that patients would like to self-monitor using mobile apps and connected health devices, grouped by age (N=68).

Item	Overall sample, n (%)	29-49 years (n=11), n (%)	50-64 years (n=41), n (%)	≥65 years (n=16), n (%)	Φ_C[a]	Chi-square (*df*)	*P* value
Most frequently used smartphone features							
SMS text messaging	51 (75)	11 (100)	31 (76)	9 (56)	0.313	6.7 (2)	.04
Internet browsing	46 (63)	11 (100)	25 (61)	7 (44)	0.366	9.1 (2)	.01
Mobile apps	41 (60)	9 (82)	26 (63)	6 (38)	0.291	5.8 (2)	.06
Social media	39 (57)	10 (91)	23 (56)	6 (38)	0.336	7.7 (2)	.02
Email	33 (49)	10 (91)	17 (42)	6 (38)	0.374	9.5 (2)	.009
Appointment scheduling	27 (40)	8 (73)	18 (44)	1 (6)	0.434	12.8 (2)	.002
Most popular HF parameters that patients would like to self-monitor using mobile apps and connected devices							
Physical activity tracking	46 (68)	11 (100)	25 (61)	10 (63)	0.304	6.3 (2)	.04
Blood pressure tracking	44 (65)	10 (91)	23 (56)	11 (69)	0.264	4.8 (2)	.09
Medication tracking	40 (59)	10 (91)	23 (56)	7 (44)	0.304	6.3 (2)	.04
Weight tracking	38 (56)	9 (82)	20 (49)	9 (56)	0.238	3.8 (2)	.15
Diet tracking	36 (53)	8 (73)	19 (46)	9 (56)	0.192	2.5 (2)	.28
Symptom tracking	35 (52)	8 (73)	20 (49)	7 (44)	0.191	2.5 (2)	.29
Sleep tracking	31 (46)	7 (64)	17 (42)	7 (44)	0.160	1.8 (2)	.42
Mood tracking	29 (43)	7 (64)	14 (34)	8 (50)	0.228	3.6 (2)	.17
Blood sugar or diabetes	28 (41)	8 (73)	14 (34)	6 (38)	0.283	5.5 (2)	.07

[a]Cramér *V*.

Of the 68 patients who owned a smartphone, 15 (22%) reported using ≥1 mHealth app for self-monitoring of HF and other health-related data, 36 (53%) said that they did not use mHealth apps but would be interested in doing so in the near future, and 17 (25%) said that they were not interested at all in using mHealth apps. There was a significant relationship between education and current use of mHealth apps (Φ_C=0.374; χ^2_3=9.5; *P*=.02).

Among those who reported using mHealth apps for HF self-care (15/68, 22%), frequently used apps included Fitbit, Apple Health, and Samsung Health for physical activity tracking (14/15, 93%); MyFitnessPal, Lose it!, and Eat24 for tracking of diet and low-sodium foods (11/15, 73%); and Apple Health or Samsung Health for monitoring of blood pressure (13/15, 87%) and glucose levels (6/15, 40%). Overall, as shown in Table 3, the most popular health parameters that patients with smartphones would like to self-monitor using mHealth apps were physical activity (46/68, 68%), blood pressure (44/68, 65%), medication intake (40/68, 59%), weight (38/68, 56%), and diet (36/68, 53%).

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Ownership of, Comfort With, and Interest in Other Mobile Devices and Technologies Among Patients With HF

Most participants reported having internet at home (73/100, 73%). Most (58/100, 58%) owned a PC or laptop, fewer participants owned a tablet (38/100, 38%), and even fewer owned a wearable activity tracking device (15/100, 15%). Of the participants who reported tablet ownership, Android or Apple tablets (26/38, 68%) were most frequently owned, whereas others reported Windows tablets (7/38, 18%), and some were unable to recall the tablet they owned (5/38, 13%). Most participants who owned tablets (n=38) reported being either comfortable or very comfortable (30/38, 79%) using a tablet. Of the 58 patients who owned a computer or laptop, 78% (45/58) reported being comfortable or very comfortable, and 22% (13/58) reported being somewhat or not comfortable using a computer. The interest in using wearables was high among patients who did not own an activity tracker (61/85, 72%). Also, the majority of study participants (76/100, 76%) reported willingness to transmit monitored data to their physician using mHealth devices.

Discussion

Principal Findings

In this study, we conducted a cross-sectional survey of 100 outpatients with HF (mean age 61.3, SD 12.25 years; 63/100, 63% women) at an urban academic hospital in the Midwest to investigate smartphone adoption and use of mHealth technologies for HF self-care. To our knowledge, this is the first study on mHealth adoption in a predominantly racial and ethnic minority HF population (61/100, 61% Black or African American and 18/100, 18% Hispanic or Latino). Our survey results showed that smartphone ownership was nearly ubiquitous (22/68, 85%) among younger and middle-aged patients with HF (aged 18-64 years) but significantly lower (16/39, 41%) among older adult patients (aged ≥65 years). The most common smartphone features used by the study participants were SMS text messaging (51/68, 75%), internet browsing (43/68, 63%), and mobile apps (41/68, 60%). The use of mHealth apps and wearable activity trackers (eg, Fitbits) for self-monitoring of HF-related parameters and management of symptoms was low (15/68, 22% and 15/100, 15%, respectively). However, 53% (36/68) expressed interest in using mHealth for HF self-care in the near future The most popular HF self-care measures the participants would like to monitor with the use of mHealth technologies were physical activity (46/68, 68%), blood pressure (44/68, 65%), and medication intake (40/68, 59%). Age, education, and employment status were significantly associated with smartphone ownership and mHealth uptake, whereas race, gender, and income were not.

Comparison With Other Studies

This study complements and expands on the findings of previous reports on mHealth adoption among patients with HF [34-36]. In a 2018 survey of 50 patients (mean age 64.5, SD 8.3 years; 32% women) conducted at a US-based University Health System, Sohn et al [36] found that 90% of patients with HF owned a smartphone, 49% owned a tablet, and 29% had an activity tracker or smartwatch. However, the study population consisted of mainly White, male patients aged 50-80 years with significantly higher education levels compared with our study. Thus, the higher adoption rates of mHealth devices reported by Sohn et al [36] may not be generalizable to the overall HF population.

In another survey study that was published in 2016 and included 100 patients with HF (mean age 60, SD 15 years; 31% women, no race reported), Dorsch et al [34] found that most participants (79%) owned a computer, and 44% owned a “smart device.” Contrary to our study, Dorsch et al [34] did not provide a definition or classification of smart devices nor reported the proportion of participants who owned a smartphone. These differences prevent further comparisons between studies.

Cajita et al [35] conducted a cross-sectional survey study on 129 older adults with HF (mean age 71.3, SD 4.6 years; 26.4% women, 56.6% White) and found that 57.4% of the participants owned a smartphone. In our study, smartphone ownership among older adults with HF (aged ≥65 years) was 41% (16/39) and varied substantially by age: 58% (10/17) of 65- to 69-year-old patients owned smartphones, but that share dropped to 36% (4/11) among 70- to 74-year-old patients and 18% (2/11) among patients in their mid-70s and beyond. These findings are consistent with the Pew Research Center survey on technology use among seniors [44] and confirm that, similar to the general population, there exists a digital divide between younger and older adult patients with HF in terms of smartphone ownership. However, the share of older adult patients with HF who owned a smartphone seems to follow that of the general senior population, which has more than doubled since 2013 when smartphone adoption among them was just 18%, rose to 46% in 2018 [44], and now stands at 61% [45]. Thus, it is safe to assume that the digital divide between younger, middle-aged, and older adult patients with HF will further decrease in the near future, creating new opportunities for mHealth research and care delivery methods in older adult patients with HF.

In a nationally representative sample of 3248 adults with or at risk for cardiovascular disease from the 2018 Health Information National Trends Survey, Shan et al [46] reported a high prevalence of smartphone ownership (73%) but low uptake of mHealth apps (48%) and wearables (39%) to track progress toward a health goal. Younger age, higher education, and higher income were associated with greater odds of smartphone ownership and mHealth uptake. In our study, smartphone ownership was significantly correlated with educational attainment and employment but not with income. More specifically, similar to other surveys [42,44], we found that patients with HF who had a bachelor’s or advanced degree and those who worked were significantly more likely to own a smartphone than those who had not completed high school or were retired or on disability. However, contrary to other studies [42,44,46,47], we did not find a statistically significant correlation between income and smartphone ownership. This could be because half of our study participants declined to answer the question about income, resulting in participation bias and, as a result, our sample size was not large enough to reach statistical significance.

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Racial and ethnic minorities that identified as Black or African American and Hispanic or Latino reported high smartphone ownership rates in our survey. This finding is consistent with a series of studies by the Pew Research Center among adults in the United States, which showed no statistically significant racial and ethnic differences in terms of smartphone ownership [42,45]. When accessing the internet, Black or African American and Latino or Hispanic adults may rely more on smartphones compared with White adults. Evidence illustrates that >25% of Hispanic and approximately 20% of Black or African American adults use smartphones as their only way to connect to the internet [48,49]. Black or African American and Hispanic or Latino patients with HF have the highest incidence and prevalence of HF, as well as worse clinical outcomes, compared with other racial and ethnic groups [1]. Thus, there is a great opportunity to capitalize on the high smartphone ownership and broadband access among racial and ethnic minority patients to enhance self-monitoring and management of HF through mHealth interventions that target key self-care behaviors for the most common reasons for HF readmissions (eg, medication and diet nonadherence) [50].

A key question when developing mHealth interventions to promote and facilitate self-management of chronic disease is which smartphone functionalities and features to use to deliver the intervention content to patients (eg, mobile apps, SMS text messages, and connected health devices). Our survey results indicate that the most frequently used feature among patients with HF was SMS text messaging. However, SMS text messaging is often overlooked by researchers compared with more sophisticated mHealth tools [51]. A recent systematic review and meta-analysis [27] found that, contrary to other conditions (eg, diabetes [29]), the efficacy of SMS text messaging for HF self-care remains largely underexplored. Virtually all trials of mHealth interventions to date have focused on testing technologically advanced interventions that involve remote patient monitoring with clinical feedback or interactive mHealth apps. However, it is important to consider that not all patients with HF are able to use such advanced technological solutions even if they have a smartphone and that this trend may further contribute to the digital divide and use gap that already exists between senior and younger patients. As *flip phones* and other nonsmart mobile phones are slowly phased out and replaced by smartphones, many senior patients find themselves with new and *shiny* technology that they do not know how to use. In fact, some older adult participants informed us during the survey that their children purchased the smartphones for them and that they did not know how to use apps or any other features besides calling and texting. This highlights 2 key aspects: (1) the importance of aligning mHealth interventions with the users' preferences, accessibility, and technology skills and (2) the need to provide new users with adequate support and training toward the adoption of novel digital health technologies, especially when there is evidence supporting their efficacy.

Our survey results show that, although 60% (41/68) of patients with HF used mobile apps in their daily lives, the use of mHealth apps and wearable activity trackers for self-monitoring of HF-related parameters was significantly low (15/68, 22% and 15/100, 15%, respectively). Previous research [52] has shown that this may be because of lack of interest or awareness of the existence of HF apps [23,53], including concerns about mHealth apps collecting and sharing identifiable data publicly. Some patients in our study openly expressed concerns regarding the use of wearable activity trackers and apps, stating that mHealth data might be used in the future to influence their premiums or deny them insurance coverage and shared with third-party companies without the patients' knowledge or previous consent. These concerns underpin the need to address privacy and security concerns with future HF interventions using mHealth technology. Notwithstanding these concerns, 53% (36/68) of study participants who owned a smartphone said that they would be interested in using mHealth apps for HF self-care if given the opportunity. This is consistent with the findings of Sohn et al [36] and highlights the prospect of more patients with HF experimenting with or using mHealth apps and wearables in the near future to self-monitor their condition.

Contrary to what one would expect, our data suggest that the most common HF-related measure patients were interested in monitoring was physical activity and not weight or HF symptom tracking, which are often monitored in mHealth or telehealth studies [27]. Previous research has shown that physical activity is the only nonpharmacological therapy that has proven to be effective in reducing mortality and hospitalizations in patients with HF [54,55]. Thus, physical activity is included as a recommendation in clinical guidelines and patient education materials [10,15,16]. Unlike other HF measures (eg, diet and symptoms), which require active monitoring, physical activity tracking is effortless with wearables as it can be monitored passively without requiring patients to perform any data entry [56]. This preference over mHealth technologies that perform passive monitoring is consistent with our observation in an ongoing clinical trial, in which we are seeing higher patient engagement with mHealth technologies that support passive monitoring and automated capturing of health data (eg, Fitbit wearable activity tracker) instead of active monitoring of symptoms, which requires manual data entry via an app [50]. Another reason that might explain this preference is that physicians and nurses often recommend the use of a pedometer or wearable activity tracker to patients to monitor and increase their steps. Wearable activity trackers and smartwatches have become popular over the years, and recent systematic reviews and meta-analyses have shown that they can help people increase their physical activity through self-monitoring and goal setting [57-59]. Other connected health devices such as smart weight scales and blood pressure monitors are less popular.

Limitations

There are several limitations that need to be considered in the interpretation of the results. First, the study was conducted at a single site in a large urban academic health system. Therefore, the results may not be generalizable to patients with HF who live in rural areas. Second, our sample comprised more women than men (63/100, 63% vs 37/100, 37%), although our HF clinic sees approximately 53% male patients with HF per year, which is similar to most data aggregates regarding the prevalence of HF [1]. It is likely that female patients were more receptive to participating in the survey, thus leading to a slight skew in our

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study cohort. However, we believe that this imbalance did not affect our study results, as previous studies have shown that there are no significant differences in smartphone and mHealth adoption between men and women [34,46].

Third, unlike other studies [36,60], we did not collect patients' HF clinical characteristics (eg, New York Heart Association Class or left ventricular ejection fraction) to explore potential relationships between HF severity and smartphone adoption or use. A similar study found that these characteristics were not associated with the adoption or perceptions of mHealth [36]. Therefore, we do not believe that the absence of these data had a major impact on the interpretation of our results. Fourth, our participant population did not include people with major cognitive impairments and comprised only English-speaking individuals because of limited resources. Finally, we did not assess digital literacy among smartphone owners. Despite relatively high ownership, it is likely that some participants were limited in their ability to use features such as mHealth apps, email, or social media apps.

Implications for Practice and Research

This study contributes to the mHealth literature by demonstrating smartphone ownership and mobile app use among a predominantly racial and ethnic minority population in an urban clinical setting in the Midwest. Smartphone ownership and use appear to cut across gender and race. We identified that participants used SMS text messaging and internet browsing at much higher rates than other more sophisticated features. Many mHealth interventions are built around complex remote monitoring apps; however, SMS text messaging interventions in HF remain underexplored. Health disparities exist among racial and ethnic minority populations, but we demonstrated a potentially innovative way to promote patient self-management because of high ownership and use of SMS text messaging. These factors may help address the disparate outcomes between racial groups with tailored SMS text messaging interventions. Furthermore, hospitals would be an important setting for promoting smartphone technology use to their patients. For example, patients may be trained to self-monitor symptoms, weight, or steps before discharge to prevent rehospitalizations. SMS text messages and mobile apps connect patients and providers to answer questions, address concerns, and provide guidance or education. We know that self-care is the key to improving outcomes in HF by leveraging existing technology. The results of this survey can guide future research to meet patients at their comfort level with smartphone technology rather than where we hope they would be.

Leveraging a scalable solution using smartphone technology in racial and ethnic minority populations would promote engagement and allow researchers to design future mHealth interventions. These important findings can support the creation of future interventions that rely on mHealth to monitor physical activity, blood pressure, weight, and medication adherence.

Acknowledgments

The authors would like to acknowledge their dear friend and collaborator Thomas Stamos, MD (deceased), for his help with the design and conduction of the study. They would also like to thank research assistants Atreya Mishra and Antonio Nieto for helping with data collection.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey of smartphones and wearable tracking devices in patients with heart failure.
[DOCX File , 20 KB - cardio_v6i1e31982_app1.docx]

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Abbreviations

HF: heart failure
mHealth: mobile health
REDCap: Research Electronic Data Capture

Edited by G Eysenbach; submitted 12.07.21; peer-reviewed by M Dorsch, J Portz, M Johansson; comments to author 27.08.21; revised version received 18.10.21; accepted 21.11.21; published 14.01.22.

Please cite as:
Leigh JW, Gerber BS, Gans CP, Kansal MM, Kitsiou S
Smartphone Ownership and Interest in Mobile Health Technologies for Self-care Among Patients With Chronic Heart Failure: Cross-sectional Survey Study
JMIR Cardio 2022;6(1):e31982
URL: https://cardio.jmir.org/2022/1/e31982
doi:10.2196/31982
PMID:35029533

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Original Paper

Developing and Implementing an mHealth Heart Failure Self-care Program to Reduce Readmissions: Randomized Controlled Trial

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Abstract

Background: Patients admitted with decompensated heart failure (HF) are at risk for hospital readmission and poor quality of life during the discharge period. Lifestyle behavior modifications that promote the self-management of chronic cardiac diseases have been associated with an improved quality of life. However, whether a mobile health (mHealth) program can assist patients in the self-management of HF during the acute posthospital discharge period is unknown.

Objective: We aimed to develop an mHealth program designed to enhance patients' self-management of HF by increasing knowledge, self-efficacy, and symptom detection. We hypothesized that patients hospitalized with HF would be willing to use a feasibly deployed mHealth program after their hospital discharge.

Methods: We employed a patient-centered outcomes research methodology to design a stakeholder-informed mHealth program. Adult patients with HF admitted to a large academic hospital were enrolled and randomized to receive the mHealth intervention versus usual care. Our feasibility outcomes included ease of program deployment, use of the clinical escalation process, duration of participant recruitment, and participant attrition. Surveys assessing the demographics and clinical characteristics of HF were measured at baseline and at 30 and 90 days after discharge.

Results: The study period was between July 1, 2019, and April 7, 2020. The mean cohort (N=31) age was 60.4 (range 22-85) years. Over half of the participants were men (n=18, 58%) and 77% (n=24) were White. There were no significant differences in baseline measures. We determined that an educational mHealth program tailored for patients with HF is feasibly deployed and acceptable by patients. Though not significant, we found notable trends including a higher mean quality of life at 30 days posthospitalization among program users and a longer duration before rehospitalization, which are suggestive of better HF prognosis.

Conclusions: Our mHealth tool should be further assessed in a larger comparative effectiveness trial. Our pilot intervention offers promise as an innovative means to help HF patients lead healthy, independent lives. These preliminary data suggest that patient-centered mHealth tools can enable high-risk patients to play a role in the management of their HF after discharge.

Trial Registration: ClinicalTrials.gov NCT03982017; https://clinicaltrials.gov/ct2/show/NCT03982017

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(JMIR Cardio 2022;6(1):e33286) doi:10.2196/33286

KEYWORDS

mHealth; heart failure; self-care; remote monitoring; telehealth; cardiology; hospital readmission; self-management; mobile health; patient-centered

Introduction

Patients hospitalized with decompensated heart failure (HF) are at risk for poor quality of life during the postdischarge period, hospital readmission within 30 days, and increased mortality [1,2]. Patient self-management of HF promotes better quality of life and longevity [3]. Preventing hospital readmission for HF is a mutual goal for patients, providers, and payers [2]. Chronic disease self-management requires patients to have self-efficacy, the knowledge to detect symptoms, and any necessary skills and tools [4,5]. Studies have shown that patient self-efficacy and symptom recognition are essential components of managing a chronic condition such as HF [3,6,7]. Additionally, interventions that develop self-management skills can improve patient knowledge and foster healthy lifestyle behaviors that are associated with improvements in quality of life [8].

Mobile health (mHealth) smartphone programs are facilitating the direct delivery of health information to patients [9]. In response, patients are becoming more knowledgeable about their conditions and are being equipped with the skills to care for themselves [9,10]. Nevertheless, the utility of mHealth for self-management among patients with HF is still under investigation. The older age of most patients with HF has been considered a barrier to the adaptation of smartphone technologies in this patient population [11]. Additionally, patients with HF may lack the physical capacity to follow an mHealth program during an exacerbation of their illness. On the contrary, research has demonstrated that patients with acute HF are at the highest risk for adverse outcomes and thus have the greatest need for additional support during the period after HF hospitalization [12]. Pragmatic research is needed to identify feasible mHealth methods for HF patients to care for themselves, especially after hospitalization.

Whether a smartphone program can assist patients in HF self-management during the immediate posthospital period within 30 days is unknown. Moreover, to design future comparative effectiveness trials, it is important to demonstrate that patients admitted with HF can be enrolled in such studies at discharge. Although other mHealth programs have been created for patients with stable HF [13], our goal was to develop an mHealth self-management program designed to enhance patient HF knowledge, self-efficacy, and symptom perception to prevent repeat exacerbation. We hypothesized that patients hospitalized with HF would be willing to use a feasible mHealth program.

Methods

Setting and Participants

The University of Pittsburgh Medical Center (UPMC) Presbyterian Hospital is a 900-bed academic hospital with inpatient cardiology and HF services. We included adult patients aged 18 years and older who were admitted to UPMC Presbyterian Hospital with acute decompensated HF as determined by a documented admission history. Patients with either systolic or diastolic left ventricular HF and who had a personal smartphone were eligible. We excluded patients with end-stage HF (eg, receipt of heart transplant, listed or under evaluation for heart transplant, inotrope dependence, under hospice care, and had a ventricular assist device or under evaluation for a ventricular assist device). Patients were excluded if they were discharged to a nursing home or were participants in other telemonitoring programs.

Ethical Considerations

This project was approved by the University of Pittsburgh Institutional Review Board and registered with National Clinical Trials (NCT03982017). Patients were enrolled and randomized after providing written informed consent. Participants were compensated US $40 upon study completion.

Heart Failure Self-care Mobile App to Reduce Readmissions Trial (HF-SMART) Program

We employed a patient-centered outcomes research (PCOR) methodology to design a stakeholder-informed program [14]. Key stakeholders comprised patients, physicians, nurses, platform developers, and patient education and mHealth experts. The intervention was designed to complement the care patients would typically receive at a posthospital follow-up cardiology visit. The mHealth program featured a patient-facing, internet-based platform for use on any smartphone and was designed in compliance with industry standards for mHealth programs [15]. The program consisted of a secure website with content tailored to patients with chronic HF, including educational videos and daily prompts, as can be seen in Figure 1. Patients were instructed to navigate to their unique link to access the program content [16]. Other key features included alerts that directed patients to contact medical personnel in the event of urgent health issues, active monitoring of patient HF data by nurses, interactive feedback of patients' symptom assessment with biometric tracking, and reminders for medication adherence.

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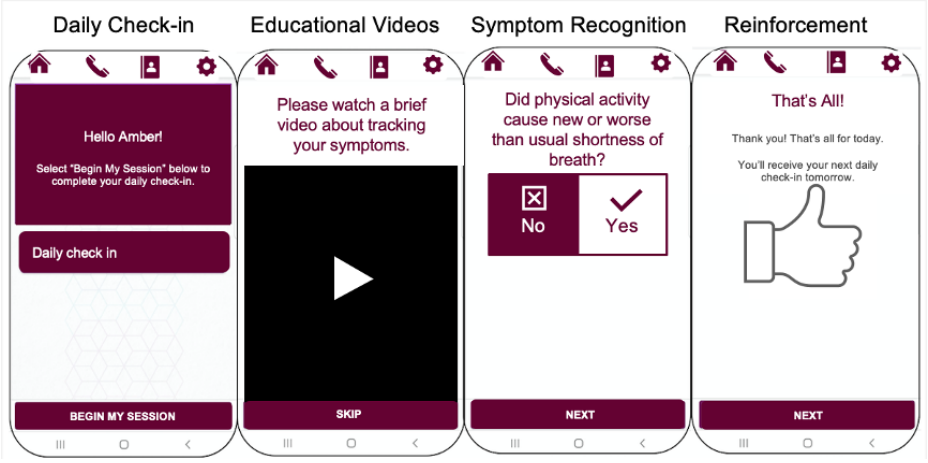
Figure 1. Depiction of the Heart Failure Self-care Mobile Application to Reduce Readmissions Trial (HF-SMART) program.



Study Design

This pragmatic feasibility study included patients with acute exacerbations of chronic HF with either reduced or preserved ejection fraction. Our primary objective was to determine the feasibility of developing, implementing, and assessing the HF-SMART mHealth program in patients with HF at hospital discharge compared with usual care. We assessed the following feasibility criteria: duration of participant recruitment, participant attrition, participant acceptability, ease of program deployment, and necessity of clinical escalation for participants requiring medical attention. Our secondary outcome was to determine patient satisfaction with the mHealth program.

Using a random number generator, the research coordinator randomized participants in a simple, unblinded 1:1 fashion to either the intervention arm—mHealth program plus usual HF care—or the usual care arm. At our institution, usual care consists of routine discharge planning that includes a review of the discharge medications and clinical discharge summary with the recommended follow-up appointments with the nurse. Occasionally, follow-up appointments are scheduled before discharge; however, more often, patients are responsible for scheduling their own appointments. At the discretion of the discharging provider, some patients may receive standard educational materials on their illness and postdischarge care. For example, the electronic medical record contains a congestive heart failure patient handout that can be printed for the patient at the time of discharge.

Survey Measures

A research assistant administered the baseline and demographic survey instruments at the bedside. Follow-up quality of life surveys were conducted via telephone at 30 and 90 days postdischarge. Survey measures were selected based on their validity in medical populations and their established psychometric properties. For those randomized to the intervention arm, we also measured postintervention participant satisfaction using a proprietary assessment (see Multimedia Appendix 1) with elements from other usability questionnaires [17,18], thus meeting face validity.

At baseline, all participants completed the 10-item Patient Activation Measure (PAM) [6,7], the 10-item Perceived Stress Scale [19], the 2-item Patient Health Questionnaire [20], and the 13-item Social Network Index [21]. Each of these measures has been shown to be associated with HF self-management and clinical cardiovascular outcomes [22-25]. Patient activation, a measure that incorporates self-efficacy, knowledge, and engagement, was measured with the PAM. The 13-item version of the PAM demonstrates good internal consistency overall (Cronbach α=.81) [6]. Higher scores on the PAM indicate more self-efficacy, knowledge, and engagement. The Perceived Stress Scale (higher score denotes greater stress), Patient Health Questionnaire (a score of 3 or higher denotes depression), and Social Network Index (higher score denotes greater social support) were included in the comprehensive baseline assessments of our participants to determine the psychological aspects known to be associated with cardiovascular outcomes [24,26,27]. Research examining the role of social support in chronic disease self-management indicates that social support improves adherence to medications and dietary regimens and lessens patient-reported depression [28].

Outcome Variables

Our independent variable was receipt of the mHealth program (yes or no). The primary outcome was feasibility. Our secondary outcome was patient satisfaction. We assessed the following exploratory outcome variables. Readmission was defined as a nonelective hospital admission via the emergency department, directly from the outpatient or residential setting, or transfer from another health system within 30 or 90 days. We dichotomized readmission (yes or no) and measured time to readmission as a continuous variable. Death was measured if it occurred within the study time frame.

Quality of life was measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ) at 30 and 90 days postindex hospital discharge. The KCCQ consists of 23 questions that use a Likert scale and features an intraclass correlation coefficient of 0.88 [29]. Subscales consist of physical limitation, symptom frequency, quality of life, and social limitation scores. A higher score on the KCCQ indicates a higher quality of life.

Covariates included age, self-reported race and ethnicity, binary (male/female) sex category, left ventricular ejection fraction, relevant laboratory results at the time of admission, clinically

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relevant comorbid conditions, and number of medications at the time of discharge.

Statistical Analysis

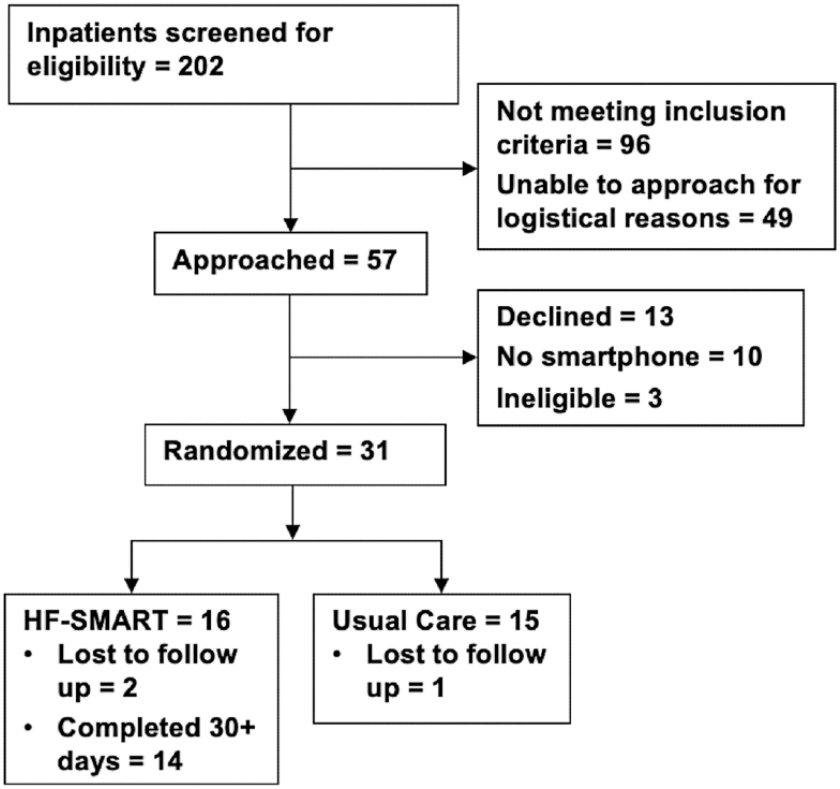
Although our study was not powered to detect statistical differences between groups, we conducted exploratory analyses on the available data. We used chi-square (or Fisher exact test) to assess if the intervention was associated with reduced readmission. We also used *t* tests to compare the mean time to readmission by intervention arm; time to readmission by race, sex, and systolic versus diastolic HF; and baseline PAM by race, sex, systolic versus diastolic HF.

Results

Setting and Participants

The study period was from July 1, 2019, to April 7, 2020. Participants were enrolled for a median of 2.2 (range 0.8-3) months with additional clinical assessments of up to 90 days. Unfortunately, the study was terminated prior to enrolling our prespecified goal of 50 participants due to institutional restrictions on clinical research secondary to the SARS-CoV-2 (COVID-19) pandemic. Figure 2 shows the patient flow for the study. Many patients were excluded from the study because they were discharged to a skilled nursing facility or with home care services. The largest barrier to recruitment was reaching, consenting, and enrolling the patients at their bedsides during the acute hospital stay. Nevertheless, 31 of the 57 (54.4%) patients that were approached agreed to participate, of which 16 were assigned to receive the program.

Figure 2. Patient flow diagram for the study.



Heart Failure Self-care Mobile Application to Reduce Readmissions Trial (HF-SMART) Program

The program deployment was uneventful with no need for clinical escalation of care, and there were no reported systems failures by participants, signifying that the website worked as intended. Retention in the program was satisfactory, with 14 of 16 (87.5%) participants completing at least 30 days of the program. Patient satisfaction was high, with all surveyed participants agreeing with the statements, “Overall, I am satisfied with my experience in the HF-SMART program” and “I would recommend this program to others.”

Survey Measures

Participant demographics and baseline clinical data are shown in Table 1. Groups were clinically similar based on laboratory data at the time of admission, type of HF (preserved vs reduced ejection fraction), and number of medications at discharge. The mean age was 60.4 (range 22-85) years. Over half of participants were men (n=18, 58%) and 77% (n=24) were White. There were no significant differences in baseline health psychology measures as indicated by the Patient Activation Measure, Perceived Stress Scale, Patient Health Questionnaire, and Social Network Index.

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Table 1. Baseline characteristics of the cohort.

	HF-SMART[a]	Usual care	*P* value
Patients, n	16	15	N/A[b]
Follow-up (days), mean (SD)	62.4 (23.4)	64.8 (24.9)	.78
Age (years) mean (SD)	60.1 (12.9)	60.7 (15.0)	.91
Male sex, n (%)	10 (62.5)	8 (53.3)	.61
White race, n (%)	12 (75)	12 (80)	.99
Hispanic, n (%)	2 (12.5)	0 (0)	.48
HF[c] with reduced ejection fraction, n (%)	10 (62.5)	7 (46.7)	.38
Positive admission troponin, n (%)	3 (18.8)	4 (26.7)	.99
Admission BNP[d], mean (SD)	623 (562.3)	739 (542.3)	.61
Admission hemoglobin, mean (SD)	12.2 (2.2)	12.5 (1.71)	.66
Admission creatinine, mean (SD)	1.4 (0.6)	1.3 (0.6)	.65
Number of discharge medications, mean (SD)	13.8 (5.2)	14.2 (7.2)	.84
Patient Activation Measure [5,6], mean (SD)	64.4 (12.3)	60.8 (14.5)	.48
Perceived Stress Scale [19], mean (SD)	18.1 (8.4)	17.7 (10.6)	.91
Positive Patient Health Questionnaire [30] Screen, n (%)	5 (31.3)	4 (26.7)	.99
Social Network Index [21], mean (SD)	5.3 (1.9)	6 (2.0)	.34

[a]HF-SMART: Heart Failure Self-care Mobile App to Reduce Readmissions Trial.

[b]N/A: not applicable.

[c]HF: heart failure.

[d]BNP: b-type naturetic protein

Outcome Variables

We collected longitudinal data for 29 of the initial 31 participants. Table 2 shows the clinical outcomes of treatment arms with respect to readmission, quality of life, and mortality. At 30 days, KCCQ scores were higher among the 6 participants who responded to the telephone survey in the intervention arm. We found that 5 patients were readmitted within 30 days for a readmission rate of 16.7% (n=3, 18.8% in the intervention group vs n=2, 13.3% in the usual care group). We also found that 9 patients were readmitted within 90 days for a readmission rate of 30% (n=5, 31.3% in the intervention group vs n=4, 28.6% in the usual care group). Only one person died during the study period and was in the usual care group. None of these differences were statistically significant.

Table 2. Characteristics of treatment arms with respect to readmission, quality of life, and mortality.

	HF-SMART[a] (n=16)	Usual care (n=14)	*P* value
Readmitted within 30 days, n (%)	3 (18.8)	2 (13.3)	.65
Readmitted within 90 days, n (%)	5 (31.3)	4 (28.6)	.70
KCCQ[b] at 30 days, n (%)	6 (37.5)	9 (64.3)	N/A[c]
KCCQ score at 30 days, mean (SD)	88.57 (15.89)	63.06 (31.34)	.09
KCCQ at 90 days, n (%)	3 (18.8)	3 (21.4)	N/A
KCCQ score at 90 days, mean (SD)	71.53 (16.83)	94.1 (7.69)	.10
Death, n (%)	0 (0)	1 (7.1)	N/A

[a]HF-SMART: Heart Failure Self-care Mobile App to Reduce Readmissions Trial.

[b]KCCQ: Kansas City Cardiomyopathy Questionnaire.

[c]N/A: not applicable.

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Discussion

Principal Results

We determined that an mHealth self-management program for HF patients is feasible and acceptable to patients. This pilot study was designed as a prospective, randomized controlled trial to assess the feasibility of deploying the intervention in our patient population. We also assessed patient outcomes in terms of readmission and quality of life. However, these clinical end points could not be assessed in a statistically meaningful way. Nevertheless, we found a higher mean quality of life among program users at 30 days and longer duration before readmission, which are suggestive of better HF management using a customary 30-day end point [31]. On the contrary, the mean KCCQ score at 90 days posthospitalization was higher in the usual care group despite high patient satisfaction, but the reliability of the 90-day findings is limited by the very small sample size. We infer from these encouraging data that our mHealth program has promise in further testing in a larger trial. These data provide evidence that patient-centered mHealth programs have a role in the management of high-risk HF patient populations. Our pilot intervention is a favorable and innovative tool to help HF patients lead healthier lives.

Comparison With Prior Work

Professional guidelines encourage short-interval follow-up (eg, less than 1 week) of HF patients once discharged from the hospital [1]. The posthospitalization period can be difficult for patients recovering from acute HF exacerbations due to the little support available to them as they transition from hospital to home and the limited in-person follow-up cardiology appointments [32]. Prior mHealth interventions, though successful at producing their prespecified clinical outcomes, have been heavily reliant on physician expertise to manage patients remotely [33,34]. Others have shown that interventions including community health workers can provide a support system for the HF patient population [35]. However, these prior efforts are resource intensive and require coordination of clinicians' and patients' time. During the COVID-19 pandemic, face-to-face interactions with clinicians and community health workers would have violated physical distancing recommendations, thus increasing the risk of COVID-19 infections, complications, or death. Patient-centered mHealth technologies offer a practical alternative to interpersonal interventions [36]. Our mHealth intervention was designed to complement the care patients would typically receive at an in-person clinic visit. The posthospitalization period has many obstacles for patients with HF, and self-management mHealth tools that increase self-efficacy and skills to implement the HF treatment plan by the cardiologist may reduce readmissions.

We add to the existing literature that the recruitment, enrollment, and implementation of a smartphone-based self-management intervention can be accomplished among patients with acute HF exacerbations. This timing of enrollment just prior to hospital discharge is critical for patients to take charge of their health and commit to self-management activities. Furthermore, the utility of enrolling inpatients not only proved feasible, but we also found that those recruited remained engaged in the intervention. These findings will be useful for future larger trials of similar interventions.

Researchers have described the potential barriers to the deployment of mHealth and the uptake of digital device use in an older patient population [37]. We found that lack of the requisite technology was not a reason for older patients to decline participation in this study. At the time of enrollment, all participants had smartphones and were motivated to use an HF self-care program. As the reliance on technological advancement for the provision of health services increases, there is growing support for underserved communities to receive equitable access to the necessary technological tools. These include mHealth technology, digital devices, and broadband internet for older adults [38]. Our findings should inspire future research on mHealth efficacy among older patient populations with chronic conditions.

Although patient engagement with mHealth, personalized medical technology, and patient-facing applications continues to grow, patient-centered mHealth has yet to be optimized [39]. The COVID-19 pandemic has facilitated a paradigm shift toward embracing telehealth technologies and empowering patients to manage more of their own care. Patients' experiences, skills, activation, and other unique contextual factors are all important to consider when developing mobile interventions for patients with HF [40].

In our cohort of high-risk patients with HF, we aimed to explore how psychosocial aspects at the time of HF hospitalization affected readmission and use of our mHealth program. Participants did not differ on baseline psychometric measures, and survey responses were not predictive of clinical outcomes, though underpowered to detect significance. Limitations of prior studies include no comparison group [13] and evaluations of only relatively low-risk, ambulatory cohorts [13,34]. Prior studies also evaluated the change in quality of life compared with baseline [13]. We did not assess quality of life at baseline because our patients were admitted to the hospital at the time of baseline assessment and because the KCCQ requires the patient to recall how they felt in the 2 weeks preceding the questionnaire. Being ill from acute decompensated HF likely decreases quality of life and biases a patient's response. Thus, an improvement in KCCQ above such a baseline is unlikely to be reflective of the intervention, rather reflecting the patient having recovered from their acute HF exacerbation.

Limitations and Strengths

There are several important limitations to this study. First, due to slow enrollment, our cohort was small. We planned to modify the study so that all participants would receive the intervention to further assess the intervention's effect; however, the study was terminated prior to modification due to restrictions related to the COVID-19 pandemic. Nevertheless, experts have suggested that pilot feasibility studies with a sample size of at least 12 participants provide valuable preliminary information when planning subsequent effectiveness trials [41]. Second, longitudinal data on health care utilization and medication adherence were not collected. Lastly, we were unable to determine the effect of inequitable access to technological advances in underserved communities due to the limited

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assessment of participant sociodemographic information and because smartphone ownership was an inclusion criterion. Despite these limitations, this study has several strengths. Our intervention had low attrition and several objectively measured positive outcomes for cardiovascular health, which are reflective of our formative work and prioritization of patient self-management. Another strength is that the program was developed with validated PCOR methods including stakeholder engagement to create a patient-centered program that increases the likelihood of the intervention being acceptable [14].

Conclusions

In conclusion, our pilot study showed that an educational HF self-management mHealth program was feasibly deployed and the patient experience was positive. Although we showed a trend toward a better 30-day quality of life, this study was not powered to detect differences between arms on account of early termination due to clinical research restrictions resulting from the COVID-19 pandemic. Nevertheless, we demonstrated that enhanced HF self-management is welcomed by patients and shows promise to improve quality of life posthospitalization. By demonstrating the proof of concept, this pilot study warrants further evaluation in a larger and more diverse cohort. Furthermore, this mHealth HF program can be modified to assist with the management of other chronic diseases.

Acknowledgments

We thank Michael Boninger, Lisa Hoff, Andrew Watson, Steven Orris, and collaborators from UPMC and Vivify for making this work possible. We thank Stacy Tessler Lindau for her valuable editorial comments.

This research was conducted with funding from the Agency for Healthcare Research & Quality (K12 HS019461) and was supported by the National Institutes of Health through grant UL1 TR001857.

EMD is supported by the National Institutes of Health research grant and is a member of the United States Preventive Services Task Force. This article does not necessarily represent the views and polices of the Task Force.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Usability survey.
[DOCX File , 15 KB - cardio_v6i1e33286_app1.docx]

Multimedia Appendix 2
CONSORT eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 360 KB - cardio_v6i1e33286_app2.pdf]

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Abbreviations

HF: heart failure
HF-SMART: Heart Failure Self-care Mobile Application to Reduce Readmissions Trial
KCCQ: Kansas City Cardiomyopathy Questionnaire
mHealth: mobile health
PAM: Patient Activation Measure
PCOR: Patient-Centered Outcomes Research
UPMC: University of Pittsburgh Medical Center
USPSTF: United States Preventive Services Task Force

Edited by G Eysenbach, T Leung; submitted 01.09.21; peer-reviewed by K Fitzner, JB Park; comments to author 03.01.22; revised version received 03.02.22; accepted 16.02.22; published 21.03.22.

Please cite as:
Johnson AE, Routh S, Taylor CN, Leopold M, Beatty K, McNamara DM, Davis EM
Developing and Implementing an mHealth Heart Failure Self-care Program to Reduce Readmissions: Randomized Controlled Trial
JMIR Cardio 2022;6(1):e33286
URL: https://cardio.jmir.org/2022/1/e33286
doi:10.2196/33286
PMID:35311679

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Original Paper

Physical Activity in Patients With Heart Failure During and After COVID-19 Lockdown: Single-Center Observational Retrospective Study

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Abstract

Background: The COVID-19 pandemic forced several European governments to impose severe lockdown measures. The reduction of physical activity during the lockdown could have been deleterious.

Objective: The aim of this observational, retrospective study was to investigate the effect of the lockdown strategy on the physical activity burden and subsequent reassessment in a group of patients with heart failure who were followed by means of remote monitoring.

Methods: We analyzed remote monitoring transmissions during the 3-month period immediately preceding the lockdown, 69 days of lockdown, and 3-month period after the first lockdown in a cohort of patients with heart failure from a general hospital in Lombardy, Italy. We compared variation of daily physical activity measured by cardiac implantable electrical devices with clinical variables collected in a hospital database.

Results: We enrolled 41 patients with heart failure that sent 176 transmissions. Physical activity decreased during the lockdown period (mean 3.4, SD 1.9 vs mean 2.9, SD 1.8 hours/day; $P<.001$) but no significant difference was found when comparing the period preceding and following the lockdown (–0.0007 hours/day; $P=.99$). We found a significant correlation between physical activity reduction during and after the lockdown ($R^2=0.45$, $P<.001$). The only significant predictor of exercise variation in the postlockdown period was the lockdown to prelockdown physical activity ratio.

Conclusions: An excessive reduction of exercise in patients with heart failure decreased the tolerance to exercise, especially in patients with more comorbidities. Remote monitoring demonstrated exercise reduction, suggesting its potential utility to encourage patients to maintain their usual physical activity levels.

(JMIR Cardio 2022;6(1):e30661) doi:10.2196/30661

KEYWORDS

heart failure; physical activity; COVID-19; remote monitoring; implantable cardiac device; monitoring; exercise; surveillance; lockdown; cardiovascular; heart; retrospective; burden

Introduction

The impact of the COVID-19 pandemic on health systems forced several European governments to impose severe lockdown rules to limit virus contagion. In Italy, since February 21, 2020 (the day of the first case identification), the dramatic spread of virus infection, particularly in the Lombardy region, induced the government to approve a national lockdown. The lockdown

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condition forbids people to travel and to frequent public spaces, except in cases of specific working conditions or for supplying food and essential goods.

Possible deleterious effects associated with these measures include economic slowdown, stop of schooling, and psychological distress [1]. Nevertheless, reducing the occupation of intensive care units is mandatory to limit the number of deaths due to COVID-19 [2].

In the lockdown period, the number of in-office visits was reduced due to patients' fear of contagion and to guarantee social distancing in the ambulatory waiting rooms.

Remote control is a well-defined follow-up system that expert consensus documents have endorsed as a possible alternative to in-office device control [3]. This technology was implemented in the last few years and became an important resource, even more so during the COVID-19 pandemic when patients were recommended to stay away from hospitals as much as possible [4,5].

Substantial information is available from device remote transmissions, including the quantification of patients' physical activity (PA). As the patient moves, a sensor detects body motion and generates a signal proportional to the amplitude and frequency of movement [6].

Regular training remains a low-appreciated therapy in patients with heart failure (HF) due to medical concern about safety for such patients and poor medical evidence of strong benefits [7]. Moreover, the patient can also be worried about engaging in PA owing to comorbidities, being elderly, and logistic considerations.

Nevertheless, the possible benefits of exercise include the preservation of sympathetic nerve and arterial baroreflex control, and improvement of the transport and utilization of oxygen in the skeletal muscle [8]. These physiological effects were associated with lower mortality and hospitalization in the HF-ACTION trial [9], although a subsequent meta-analysis failed to show a mortality benefit [10].

For these reasons, the reduction of PA during the lockdown could have been deleterious, in particular for patients with HF. It has been shown that a large portion of patients (49%) could fail to recover their usual PA after the lockdown period [11], and the frailty status of older patients could worsen because of stopping their cardiac rehabilitation [12].

The aim of this study was to investigate the effect of the lockdown strategy on the PA burden and subsequent reassessment in a group of patients with HF who were followed by means of remote monitoring.

Methods

Study Design

This was a retrospective, single-center, observational investigation on the impact of the lockdown strategy on average daily PA in patients with HF. We enrolled all 454 patients who were implanted with a device (cardiac resynchronization therapy [CRT] or implantable cardioverter defibrillator [ICD]) and were followed by means of remote monitoring in our center, located in the Milan area, Lombardy region, Italy.

We excluded 190 patients who had no history of HF. We only included devices implemented with the Cardiac Compass (Medtronic Inc) software, due to differences in the diagnostic tools for estimating PA by devices from other manufacturers. Thus, we analyzed the data from the remaining 112 patients.

Patients whose remote monitoring period started after December 8, 2019, were excluded (n=44), as well as those who stopped remote monitoring within 3 months after the end of lockdown for a nonclinical reason (n=21). We also excluded patients with very low PA in the 3 months before lockdown, arbitrarily defined as less than 0.5 hours/day, because of the supposed negligible effect of the limitation introduced by government measures (n=6).

We analyzed the average daily PA in patients with HF during a period that included the 3 months immediately preceding the onset of the lockdown (from December 8, 2019, to March 8, 2020), the 69 days of lockdown (March 8 to May 18, 2020), the 3 months after the end of lockdown (May 19 to August 18, 2020), and the same period in 2019 (May 19 to August 18, 2019).

Ethical Considerations

This is a retrospective analysis of data collected by previously implanted device. Before device implantation, every patient had a meeting with a medical doctor and signed a specific consent for device implantation and anonymized data collection for research purposes.

Data Collection

We collected demographics for all patients. Echocardiographic data were obtained from the hospital database. Clinical data such as hypertension, diabetes, atrial fibrillation (AF), and ischemic cardiac disease were collected from our database of hospital discharges, in-office visits, and emergency department accesses. The last blood examination available was considered if more recent than 6 months.

Measures

According to our follow-up protocol for remote monitoring, patients had scheduled periodical device remote transmissions (at least every 3 months) and the devices could send alarm transmissions due to prespecified alarm conditions. Alarms were delivered for any electrical malfunction, AF episodes lasting more than 6 hours, a high ventricular rate during AF (>90 beats per minute for >6 hours in a day), OptiVol index (Medtronic Inc) >60 Ω, ventricular arrhythmias activating device therapies, or reduction of the percentage of biventricular pacing (<90%).

Information available in remote transmissions include, behind PA: arrhythmias, average heart rate, thoracic impedance, and daily heart rate variability. These data were compared among the four periods of the study.

We considered the variation of PA during the study period as the primary outcome. We also compared baseline characteristics and clinical events to data available by means of remote

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transmissions. OptiVol episodes were considered as a surrogate of clinical events; the OptiVol algorithm was elaborated to identify thoracic fluid accumulation in an early phase and to monitor the duration of lower impedance episodes. Indeed, several studies have shown that variation in the content of fluid in the pulmonary vessels and tissues is associated with thoracic impedance changes [13,14]. Yu et al [15] demonstrated that during HF episodes, there is a relationship between pulmonary wedge pressure increase and the intrathoracic impedance.

Statistical Analysis

Statistical analysis was performed using SPSS PASW Statistics 18 software. The Student *t* test or Mann-Whitney *U* test was used to compare continuous variables, whereas the Fisher exact test and Pearson χ^2 were used to compare categorical variables.

To assess independent predictors of PA modification, a multivariable logistic regression was performed. Statistical significance was set at the α=.05 level.

Results

We enrolled 47 patients with HF; 6 (13%) patients were excluded because their daily activity was inferior to 0.5 hours/day before the lockdown period. Therefore, the study population included 41 patients with HF, 6 (15%) of whom were women. Ischemic etiology was present in 16 (39%) patients. In 17 (42%) patients, the device implanted was a CRT, whereas the remaining 24 (59%) patients had a single- or double-chamber ICD.

Every patient sent scheduled transmissions with data encompassing the whole study period; the overall number of transmissions was 176, including 61 (34.7%) alarm transmissions received during the study period.

During the lockdown period, the mean variation in daily PA compared with that in the prelockdown period was –16.6% (*P*<.001). The mean daily PA decreased during the lockdown period (mean 3.4, SD 1.9 vs mean 2.9, SD 1.8 hours/day; *P*<.001) and then increased to a mean daily activity of 3.4 (SD 2.0) hours/day (*P*<.001 vs lockdown period). As shown in Figure 1, the average daily PA was not different before and after the lockdown period (–0.0007 hours/day; *P*=.99). Furthermore, PA postlockdown was not different to that in the same period of the previous year (mean 3.4, SD 2.0 vs mean 3.5, SD 2.0 hours/day; *P*=.40)

The baseline features of the population are summarized in Table 1.

No patient died during the study; two patients were admitted to hospital, both for noncardiovascular reasons and one of them for COVID-19.

The number of OptiVol episodes (OptiVol value >60 Ω) did not change significantly before, during, and after the lockdown period (9 vs 5 vs 5; *P*=.66). There was also no significant difference in the number of days with an OptiVol value >60 Ω among the three study periods (mean 5.7, SD 14.2 vs mean 5.1, SD 14.2 vs mean 3.3, SD 14.3 days, respectively; *P*=.44).

In the 3 months after the lockdown period, no significant difference was found in the number of nonsustained ventricular tachycardia (VT) episodes (20 vs 33 vs 42, respectively; *P*=.19). Similarly, no difference was found regarding the burden of atrial arrhythmias, when available: 8 days with at least 6 minutes of atrial arrhythmias in the period preceding the lockdown, 7 days during the lockdown, and 5 days in the period after lockdown (*P*=.12). Average heart rate also remained similar during the study (61 vs 60 vs 59 beats/minute, respectively; *P*=.97).

A significant correlation between the variation in daily exercise during the lockdown and the postlockdown period was found by means of linear regression analysis (R^2=0.45; *P*<.001), as shown in Figure 2.

Figure 1. Daily physical activity amount in the three study periods. ns: not significant.

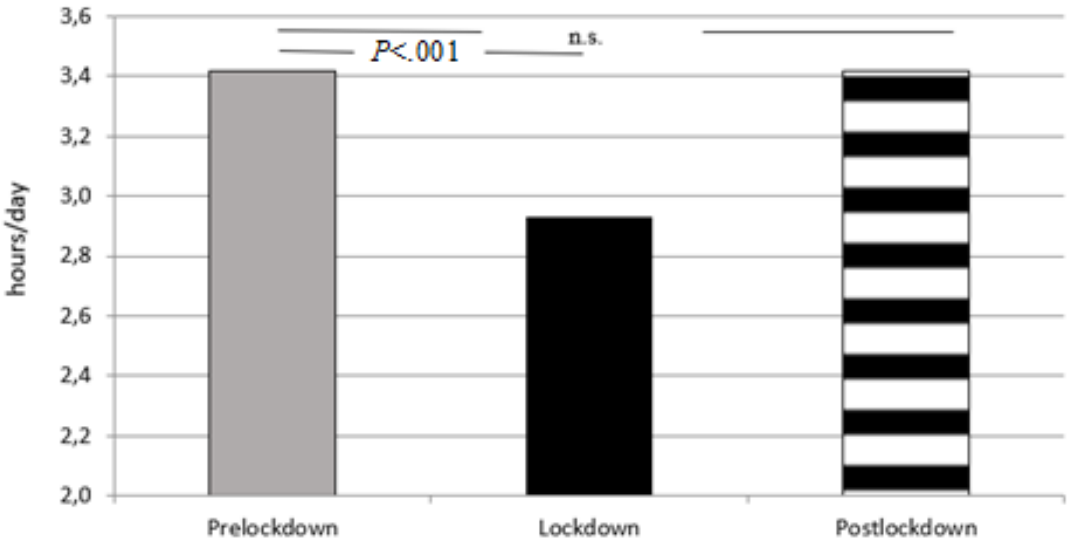

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Table 1. Baseline characteristics of the study population and comparison of physical activity variation between groups.

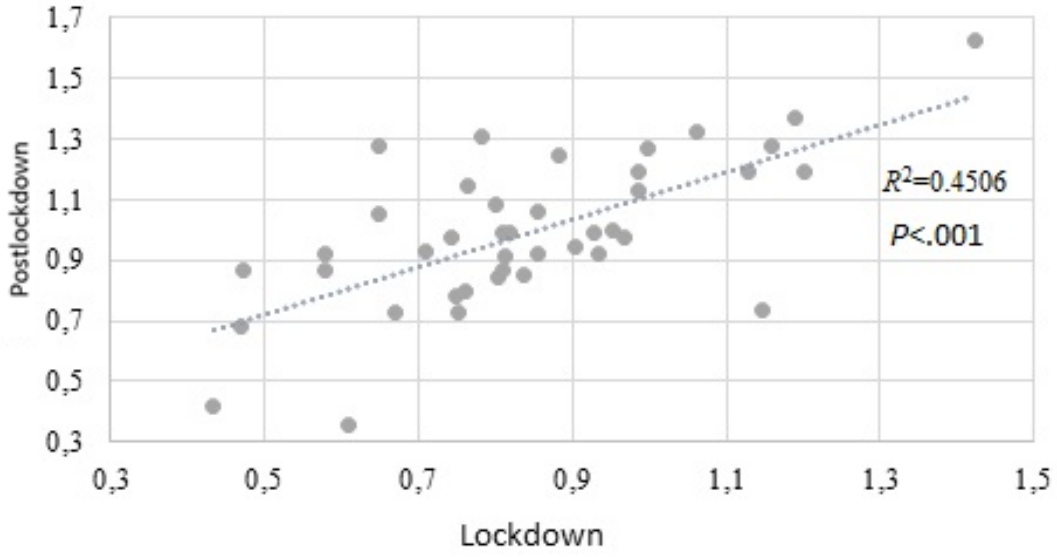
Characteristic	All participants (N=41)	Physical activity variation during lockdown (%), mean (SD)		Correlation	*P* value
Gender (female), n (%)	6 (15)	–25 (28)	–12 (22)	—[a]	.37
Hypertension, n (%)	15 (37%)	–26 (24)	–6 (20)	—	.03
Diabetes mellitus, n (%)	7 (17)	–25 (9)	–14 (25)	—	.06
History of atrial fibrillation, n (%)	12 (29)	–18 (25)	–12 (23)	—	.52
Ischemic etiology, n (%)	16 (39)	–10 (20)	–18 (27)	—	.32
Type of device (CRT[b]), n (%)	17 (42)	–14 (20)	–17 (23)	—	.70
Serum creatinine (mg/dL), mean (SD)	1.12 (0.3)	—	—	0.06	.77
Hemoglobin (g/dL), mean (SD)	13.8 (1.8)	—	—	0.03	.13
LVEF[c] (%), mean (SD)	39 (12)	—	—	0.02	.90
Age (years), mean (SD)	69.8 (12.6)	—	—	–0.06	.73

[a]Not applicable.

[b]CRT: cardiac resynchronization therapy.

[c]LVEF: left ventricular ejection fraction.

Figure 2. Correlation between relative variation in physical activity during the lockdown and postlockdown periods.



The study population was then separated in two groups: group A included all patients that showed daily activity variation above the average value (–0.7%) after the lockdown compared to the baseline and group B included those with a variation lower than the average.

As shown in Table 2, the patients in group B (24/41, 59%) had a higher prevalence of hypertension, history of atrial fibrillation, and a lower hemoglobin level compared with those of patients in group A. In addition, the reduction of PA during the lockdown period was significantly greater in group B than that in group A patients (mean –24.4%, SD 17.1% vs mean –3.2%, SD 21.0%; *P*=.001).

Patients in group B had a higher number of alarm transmissions compared with that of patients in group A (mean 3.4, SD 1.0 vs mean 2.5, SD 0.6; *P*=.05) due to VT, atrial arrhythmias, or OptiVol episodes; no specific alarm trigger defined a clear difference in the two main groups.

The only significant predictor of PA variation in the postlockdown period was the lockdown to prelockdown PA ratio (odds ratio 2.26, 95% CI 1.0-5.22; *P*=.05).

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Table 2. Comparison between patients with reduced and fully recovered physical activity after the lockdown.

Characteristic	Physical activity recovered (n=17)	Physical activity reduced (n=24)	*P* value
Age (years), mean (SD)	65.7 (14.4)	73.7 (14.5)	.08
Gender (female), n (%)	1 (6)	5 (201)	.18
Hypertension, n (%)	3 (18)	12 (50)	.03
Diabetes mellitus, n (%)	1 (6)	6 (33)	.08
History of atrial fibrillation, n (%)	2 (12)	10 (42)	.04
Ischemic etiology, n (%)	6 (35)	10 (42)	.68
LVEF[a] (%), mean (SD)	37 (15)	42 (7)	.26
Serum creatinine (mg/dL), mean (SD)	1.19 (0.3)	1.04 (0.3)	.20
Hemoglobin (g/dL), mean (SD)	14.7 (1.5)	12.9 (1.7)	.01
Type of device (CRT[b]), n (%)	10 (59)	7 (29)	.06

[a]LVEF: left ventricular ejection fraction.

[b]CRT: cardiac resynchronization therapy.

Discussion

This study investigated the effect of the COVID-19 lockdown on PA in patients with HF, focusing both on the lockdown period and on the postlockdown period. Similar studies had limited the comparison between prelockdown and lockdown periods [7] or included unselected patients [8], whereas information on postlockdown changes in patients with HF are lacking.

The main findings of this study are that the mean level of exercise in the period before the lockdown was recovered after the lockdown period, but the reduction in PA in the postlockdown period compared to the prelockdown period is a function of the entity of the PA reduction during the lockdown period.

These findings are partially in agreement with those reported by Cunha et al [11], showing difficult PA recovery in patients with low basal PA; however, they used a shorter study period and did not consider PA reduction during lockdown as a possible predictor of PA recovery failure.

As expected, in our study, the average daily PA decreased during the lockdown period, in line with previous reports [9,10]. PA then recovered, increasing to the same level as found in the prelockdown period. In a similar study, Bertagnin et al [16] performed a week-to-week analysis including 211 patients, and found that PA decreased (–25.9%, $P<.001$) during the prelockdown period. Of note, patients' perceptions about PA showed a very low correlation with remote monitoring–assessed PA levels ($R^2=0.035$, $P=.04$) [16].

Reduction of exercise and delay in medical visits during the holidays were suggested as some of the possible causes of the higher incidence of increased HF admission after the holidays [17]. According to this observation, in our study, the postlockdown period was also compared with the same period of the previous year. The mean PA was similar and no difference in hospitalization or death was found; however, the study is underpowered to state any definitive conclusion on such clinical outcomes.

The relationship between the level of PA and HF outcomes is controversial. Patel et al [18] showed that higher PA levels were associated with a lower frequency of HF episodes. Moreover, a reduction of daily PA has been associated with HF worsening and higher mortality in other studies [19,20]. Overall, exercise was shown to be a possible predictor of HF morbidity and mortality. In this study, patients with stable PA and those with reduced average daily activity did not show any significant differences in the number and duration of OptiVol episodes. However, the larger the reduction of PA during the lockdown period, the higher the number of alarm episodes, suggesting a negative effect of PA reduction, independent of the activation of a specific alarm. Unfortunately, this study was underpowered to investigate this issue.

Factors such as hypertension, anemia, and diabetes were significantly associated with a worse exercise recovery after the lockdown period. This could suggest that patients with more risk factors should be strictly monitored to endorse their PA recovery, because PA is an important step in lifestyle change for these patients.

We acknowledge that the study enrolled a very selected group of patients to carefully investigate a specific feature (ie, PA) in the three considered periods. Thus, results requiring larger samples to be demonstrated could not be found, as in the case of ventricular arrhythmias whose highest incidence was a mean of 0.09 (SD 1.2) episodes per patient per week in a previous study on the COVID-19 pandemic and remote monitoring [21].

All patients enrolled in this study were followed by means of a specific software made by a single manufacturer. Other devices have the capability to estimate PA; however, we focused on a single tool of remote monitoring to minimize diagnostic differences between different software types.

Both CRT and ICD patients were enrolled. These two groups of patients could have different perspectives, because a larger clinical benefit should be expected in CRT patients by the device

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itself [22]. Nevertheless, in the setting of this study that evaluated mainly PA in a limited period, the CRT per se should not be expected to have a significant role in that regard; the daily exercise level was indeed unchanged in the postlockdown period compared with that for the same period in the previous year.

In addition, the effect of COVID-19 infection was not assessed due to clinical and diagnostic limitations. The former depends on the low number of patients included in the study and, in particular, of patients with symptoms due to ascertained COVID infection; nevertheless, the low number of patients infected and the absence of death due to COVID-19 is a positive result in this high-risk population. The latter depends on the diagnostic strategy implemented in Italy during the first months of the pandemic that excluded asymptomatic patients from COVID-19 diagnostic research. Thus, the population could include patients who were infected, although the role of infection in the modification of exercise attitude and tolerance could not be evaluated.

In conclusion, an excessive reduction of PA due to lockdown measures in patients with HF decreased the tolerance to exercise, whose consequences should be investigated in larger studies. Patients with a higher prevalence of comorbidities appear to be at higher risk to fail in achieving full recovery of the basal PA level.

Implementation of a remote monitoring strategy could help patients with HF maintain an adequate level of PA in a critical period.

Acknowledgments

The authors wish to express their sincere thanks to the nurses and entire staff working at the Telemedicine Service of Department of Electrophysiology and Clinical Arrhythmology, Azienda Socio Sanitaria Territoriale Rhodense, Milan, Italy.

Conflicts of Interest

None declared.

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Abbreviations

AF: atrial fibrillation
CRT: cardiac resynchronization therapy
HF: heart failure
ICD: implantable cardioverter defibrillator
PA: physical activity
VT: ventricular tachycardia

Edited by G Eysenbach; submitted 14.06.21; peer-reviewed by H Gandhi, WF Khaw; comments to author 24.11.21; revised version received 03.12.21; accepted 19.12.21; published 19.04.22.

Please cite as:
Brasca FMA, Casale MC, Canevese FL, Tortora G, Pagano G, Botto GL
Physical Activity in Patients With Heart Failure During and After COVID-19 Lockdown: Single-Center Observational Retrospective Study
JMIR Cardio 2022;6(1):e30661
URL: https://cardio.jmir.org/2022/1/e30661
doi:10.2196/30661
PMID:35103602

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Original Paper

Use of Mobile Apps in Heart Failure Self-management: Qualitative Study Exploring the Patient and Primary Care Clinician Perspective

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Abstract

Background: Mobile apps have the potential to support patients with heart failure and facilitate disease self-management, but this area of research is recent and rapidly evolving, with inconsistent results for efficacy. So far, most of the published studies evaluated the feasibility of a specific app or assessed the quality of apps available in app stores. Research is needed to explore patients' and clinicians' perspectives to guide app development, evaluation, and implementation into models of care.

Objective: This study aims to explore the patient and primary care clinician perspective on the facilitators and barriers to using mobile apps, as well as desired features, to support heart failure self-management.

Methods: This is a qualitative phenomenological study involving face-to-face semistructured interviews. Interviews were conducted in a general practice clinic in Sydney, Australia. Eligible participants were adult patients with heart failure and health care professionals who provided care to these patients at the clinic. Patients did not need to have previous experience using heart failure mobile apps to be eligible for this study. The interviews were audio-recorded, transcribed, and analyzed using inductive thematic data analysis in NVivo 12.

Results: A total of 12 participants were interviewed: 6 patients (mean age 69 [SD 7.9] years) and 6 clinicians. The interviews lasted from 25 to 45 minutes. The main facilitators to the use of apps to support heart failure self-management were communication ability, personalized feedback and education, and automated self-monitoring. Patients mentioned that chat-like features and ability to share audio-visual information can be helpful for getting support outside of clinical appointments. Clinicians considered helpful to send motivational messages to patients and ask them about signs and symptoms of heart failure decompensation. Overall, participants highlighted the importance of personalization, particularly in terms of feedback and educational content. Automated self-monitoring with wireless devices was seen to alleviate the burden of tracking measures such as weight and blood pressure. Other desired features included tools to monitor patient-reported outcomes and support patients' mental health and well-being. The main barriers identified were the patients' unwillingness to engage in a new strategy to manage their condition using an app, particularly in the case of low digital literacy. However, clinicians mentioned this barrier could potentially be overcome by introducing the app soon after an exacerbation, when patients might be more willing to improve their self-management and avoid rehospitalization.

Conclusions: The use of mobile apps to support heart failure self-management may be facilitated by features that increase the usefulness and utility of the app, such as communication ability in-between consultations and personalized feedback. Also important is facilitating ease of use by supporting automated self-monitoring through integration with wireless devices. Future research should consider these features in the co-design and testing of heart failure mobile apps with patients and clinicians.

(JMIR Cardio 2022;6(1):e33992) doi:10.2196/33992

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KEYWORDS

mobile app; mHealth; heart failure; self-management; eHealth; telehealth

Introduction

Heart failure is one of the leading causes of hospitalization, morbidity, and mortality in the world and a major public health challenge [1]. Hospitalization for patients with heart failure is well known to be associated with an increased risk of death [2,3]. Good self-management can reduce rehospitalization and exacerbations [4-7]. Therefore, it is important for patients to know how to self-manage their condition at home, monitor early signs of congestion, and take the necessary action to avoid readmission [5,6].

Heart failure self-management involves adherence to specific behaviors (eg, medication compliance) and self-monitoring (eg, weight, blood pressure, signs, and symptoms) [4,5,8,9]. Self-management can be challenging for many patients due to lack of knowledge, symptoms recognition, motivation, and ability or confidence in performing it [9-12]. Heart failure impacts patients' lives in many ways and several physical and emotional factors may influence how patients respond to the challenges of self-management [11,13]. An analysis of self-management behavior in 15 countries showed that patients are poorly adherent to self-management tasks, and less than 50% of patients weigh themselves regularly [14]. Technology has the potential to facilitate the delivery and dissemination of self-management support and promote the ongoing surveillance and management of clinical deterioration in patients with heart failure.

Mobile technologies (eg, SMS text messaging, mobile apps, wireless monitoring devices) [15] are increasingly being used to support self-management of chronic diseases, either as part of telemonitoring programs or as stand-alone patient-facing interventions [16-18]. Interventions using mobile phone apps seem promising in cardiovascular disease self-management. Apps can automate the self-monitoring of physiological data, facilitate the tracking of symptoms, provide reminders, and offer personalized feedback to promote engagement [17,19-23].

However, in heart failure, the use of apps to support self-management is still in the early stages of research, with inconsistent results for efficacy [16]. So far, most of the published studies evaluate the feasibility of a particular app [24-31] or assess the quality of heart failure apps available in app stores [32-34]. Only a couple of qualitative studies [35,36] have analyzed users' perspectives on supporting heart failure self-management with mobile technologies, but they did not focus specifically on mobile apps, nor did they interview clinicians. Given the growing number of feasibility studies evaluating heart failure apps, research is needed to explore the patient and clinician perspective to guide app development, evaluation, and implementation. This study aims to explore the perspectives of patients and clinicians from a primary care center in a low socioeconomic setting in Sydney, Australia, exploring facilitators and barriers to the use of mobile apps to support heart failure self-management.

Methods

Study Setting and Participants

This is a qualitative phenomenological study involving face-to-face semistructured interviews. This study was conducted in a single primary care practice in Western Sydney (Mount Druitt Medical Centre), Australia, providing care to a population with low socioeconomic and educational level. The clinical team comprised general practitioners and allied health professionals (eg, dietician, psychologist, counselor, clinical pharmacist, and exercise physiologist). The clinic currently utilizes an electronic health record integrated with another system consisting of a clinician web-based platform for care coordination and a free patient-facing app (Multimedia Appendix 1). The patient app was not specific for heart failure self-management but allowed patients to send messages to their health providers, input and graphically visualize health data (eg, weight, blood pressure), and receive automated feedback. The practice and sample were selected using convenience methods. Eligible participants in this study were adult patients of the clinic with a confirmed diagnosis of heart failure (regardless of its classification or stage) and health care professionals who provided care to patients with heart failure at the clinic. Participants were eligible if they were able to communicate in English. Patients did not need to have previous experience using mobile apps, nor any knowledge about heart failure mobile apps. They also did not need to be users of the clinic's patient app to be eligible for this study. Participation in the study was voluntary and no incentive was provided.

Participant Recruitment

Patients were contacted by the clinic via phone and provided with details about the research study. Clinicians were contacted by the clinic director and informed about the study. Those who agreed to participate in the project were then contacted by the first author (LB) to schedule a face-to-face interview at the clinic. On the interview date, the eligible patients and clinicians received the hardcopy of the consent form, having the opportunity to read it and ask any questions they may have had about the study, before providing informed consent.

Data Collection

The interviews were conducted by LB, a Master of Public Health student, cardiologist by training, with previous experience in research and qualitative interviewing. Interview guides including demographic questions for patients and clinicians were developed and pilot tested by 2 researchers (LB and LL; Multimedia Appendices 2 and 3). The interview guides were developed based on relevant studies identified in the literature [28,37-40]. After informed consent was obtained, individual semistructured interviews were conducted and audio-recorded from February to March 2020. Field notes were taken during the interviews. Guided by the principle of thematic data saturation and existing literature indicating that a sample size ranging between 6 and 12 participants is adequate for a phenomenological study like ours, we aimed to recruit a

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minimum of 6 participants [41-45]. Additional individuals were recruited until the point when the researcher had the perception that no new themes or subthemes were emerging (ie, data saturation), a standard approach in qualitative research [46,47].

Patient interviews started with broad questions regarding their routine in managing their condition, challenges they faced in performing heart failure–related tasks, and the factors or strategies that could help with those tasks. Afterward, they were asked about their experience with mobile technology and the main barriers and potential facilitators to using an app for heart failure self-management support. Clinician interviews were initially focused on their usual consultations with patients with heart failure and the most important parameters they asked patients to monitor. Then, they were asked about their perspectives on the main difficulties their patients face to manage heart failure and how they thought mobile apps could potentially help patients deal with their condition.

Data Analysis

The interviews were transcribed and analyzed using the NVivo 12 software (QRS International Pty Ltd). The interview transcripts were analyzed by 2 investigators (LB and LL) using thematic data analysis. Themes were identified using an inductive data-driven approach (ie, inductive thematic analysis) [46]. Inductive thematic analysis is a process of coding the data without trying to fit them into a pre-existing coding frame or to analytic preconceptions so that the themes identified are strongly linked to the data themselves [46]. This analysis is in contrast to theory-driven analysis (ie, theoretical data analysis), where a specific theory or theoretical approach guides the analysis [46]. First, we selected relevant information in the data, generating open codes in our codebook (first-cycle coding) [47]. As the analysis progressed, several codes were added inductively. Second-cycle coding involved focused coding (ie, to find thematic similarity) and axial coding (ie, to find relations between codes) [47]. The initial codebook was developed by LB based on 4 interviews, at which point LL and LB discussed and revised the codebook. Subsequent revisions of the codebook by the authors occurred iteratively every 3 interviews through comparing and revising codes and emerging themes. Identification of themes occurred by sorting the different codes into potential themes, and collating all the relevant coded data extracts within the identified themes. Themes were identified at a semantic level, with analysis starting by organizing data to show patterns in semantic content, and then moving to the interpretation of the patterns and their broader meanings and implications [46]. After a candidate thematic “map” was reached, the data set was re-read to ensure the quality of the themes and refine them as needed. We reached data saturation when no new themes emerged from the data.

We then compared each theme with the literature, based on a systematic review on the same topic [48], searching for common and diverse themes, refining concepts, and reviewing the major themes. Finally, we analyzed the overall information content, selected extracts for quotes, and compiled the analysis report. Reporting follows the COnsolidated criteria for REporting Qualitative research (COREQ) checklist for reporting qualitative research (Multimedia Appendix 4) [49].

Ethics Approval

Ethical approval for this study was obtained from the Macquarie University Ethics Committee (Reference No: 52019612812569; Project ID: 6128).

Results

Sample Characteristics

We recruited 12 participants: 6 patients with heart failure and 6 clinicians. The patients’ age ranged from 57 to 79 years (mean 69 [SD 7.9] years) and 4 were women (Table 1). Most patients (n=5) had been diagnosed with heart failure for more than 3 years and 1 had been recently diagnosed. All participants owned a smartphone. The clinicians’ age ranged from 32 to 46 (mean 38 [SD 5.2] years), and 5/6 were women. The sample was composed of 2 general practitioners, a clinical pharmacist, a dietitian, an exercise physiologist, and a counselor. The average number of years working in the clinic was 5 years (SD 2.2).

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Table 1. Characteristics and self-monitoring behaviors of the interviewed patients (N=6).

Characteristics	Values
Age	
Mean (SD)	69 (7.9)
Range	57-79
Sex, n	
Women	4
Male	2
Marital status, n	
Single	1
Married	2
Divorced	2
Widowed	1
Occupation, n	
Retired	5
Unemployed/pensioner	1
Disease duration, n	
<1 month	1
3-6 years	4
7-10 years	1
Frequency of weight monitoring, n	
1× day	3
1× week/fortnight	2
1× month	1
Frequency of blood pressure/heart rate monitoring, n	
1× day	3
1-3× week	2
Never or seldom	1
Comorbidities[a]	
Diabetes	5
Hypertension	5
Pneumopathy	4
Walking impairment (arthropathy, neuropathy)	3
Atrial fibrillation	2

[a]A patient can have multiple comorbidities.

Qualitative Results

The interviews lasted from 25 to 45 minutes. Themes and subthemes emerging from the data are detailed below.

Facilitators to the Use of Apps to Support Heart Failure Self-management

Communication Features

Communication ability, particularly between patients and clinicians, was cited as one of the most helpful features in any app supporting heart failure self-management. Patients mentioned that chat-like features that facilitate communication outside of clinical appointments can be helpful for asking questions, receiving feedback, or requesting prescription renewal.

> *If I need to ask a question or need something, I can put it on [the app] and I know that they (clinicians) can see it, or at the Hospital. I can book appointments and speak to people.* [Female, 63]

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Clinicians also considered helpful to send motivational messages to patients, reminding them to maintain self-monitoring, or asking them about signs and symptoms.

> *I think that if we have constant communication with them it would help to motivate them and keep on track.*" [Clinician number 2]

> *I would ask him to do daily weight measurements (...) But also asking them how they feel regarding shortness of breath. [...].* [Clinician number 6]

In addition, the ability to share audio-visual information was mentioned as helpful by patients (eg, pictures of their food) and clinicians (eg, video instructions for exercises).

Personalized Feedback and Education

Patients and clinicians reported that personalized feedback and educational tools were very important to improve patients' awareness about their health status and the consequences of their behaviors.

> *When you have something wrong, then you have the feedback. It helps you to understand better what to do. (...) When that says 'you've lost weight, stay on your program'. (...) I'm doing a lot more things now than what I did before the app, you know?* [Male, 65]

Participants said that feedback in the form of color-coded risk assessment or trend graphs were helpful features, reassuring them when they were doing well, and alerting and guiding them when they were not within the normal ranges.

> *You know you're doing okay or not because of the colors. Green, yellow, and red. If I'm red I'm really out. If it happens, I just get in contact with my medical advisor. Or go to the hospital. And with this [the graphs] you can check if you are doing okay, if you're on track or not.* [Female, 63]

Clinicians mentioned the importance of personalizing the feedback and automated messages for each patient, as they believed this contributed to improve patients' motivation to better manage their condition.

> *Patients do learn from that interaction [automated feedback]. They become more able to self-manage or their family member is able to help. And they gain more knowledge of their conditions. They feel more self-sufficient or an active member (...) in health care rather than just passive. If the patient's weight or blood pressure are all on target, they will get a good message, 'you are on target, well done'. If they are getting a little bit out of range, the app automatically will send a message, 'please check your weight'. If it's not improving, come and see us, and the red message will do that. And that's set by the treating team for each patient, what the message and alert levels would be.* [Clinician number 3]

Participants mentioned that the ability for both patients and clinicians to monitor signs of deterioration allowed for timely action.

> *The app creates a graph that they can see and we can see. So that is pictorial as well. And it means that we can mitigate some exacerbation.* [Clinician number 4]

In addition, participants indicated a desire for personalized education features (eg, daily guide for diet and liquid intake) according to patients' age and health conditions, as well as tools to facilitate medication adherence.

> *I would like to have an app not only about calorie content, but more about the quality of their diet (...). It is important to increase patient awareness about what they eat. And probably more individualized, like their medication, other diseases, allergies, food intolerance.* [Clinician number 1]

> *They do get confused [...] We see patients accidently doubling up on doses because of generic and brand. It would be great if they could take a photo of the box or the barcode and it tells them if this is the same as that. That would be [an] ideal feature.* [Clinician number 3]

Automated Self-monitoring

Both patients and clinicians highlighted the helpfulness of automated self-monitoring of the main parameters in heart failure management (eg, blood pressure, weight). Patients reported that manually tracking their weight, blood pressure, and liquid intake were very burdensome tasks and that being able to automatically integrate data from devices (eg, fitness tracker) was very important.

> *What I find difficult to control is just everyday watching (...) the fluid I intake.* [Male, 57]

> *This doesn't cover one or two [diseases]. You want it to cover you entirely. COPD, blood pressure. [...] I use this, Fitbit. And they can see it [steps and heart rate] in the app.* [Male, 65]

Professionals expressed the need for connectivity with other monitoring devices (eg, glucose meters) and the ability to automatically track different activities (eg, riding a bike) and levels of intensity.

> *For example, some models of watches just do step counts and heartbeat. And some can really distinguish when you're going for an exercise or a run, (...) and this information goes directly to the smartphone. Well, it can say "you're only doing 30 minutes when you need to be 45" or "you are not doing the right time, duration, and frequency.* [Clinician number 2]

Patient-Reported Measures and Mental Health Tools

Professionals considered essential to enable patients to register their symptoms and other patient-reported measures, as well as patients' mental health and well-being. Clinicians saw mental health tools as a necessary feature to support patients in dealing with the disease burden and individual challenges. These participants suggested potential benefit in having a tool to collect and track the Patient Activation Measure [50], which measures a patient's level of activation (ie, knowledge, skill, willingness, and confidence to perform self-management of chronic diseases). This measure was perceived as potentially helpful to

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understand changes over time and identify self-management determinants.

> *It will create self-awareness, asking the patient what they're thinking, how they are (...) feeling today. And then you can actually do something about it. [...] But I think [it is important] to be mindful that not everybody works the same. So perhaps something tailored to suit each individual (...) and it can be done through a set of questions.* [Clinician number 5]

> *If I can add one thing, is probably tools to help with mental health. Because I find a lot of patients that feel that burden.* [Clinician number 1]

> *[I would add] probably things like overall well-being score, like a mood or depression score. So they can self-evaluate how they actually feel about their health, because that is a big marker of how they will cope with all the other things.* [Clinician number 3]

Barriers to the Use of Apps to Support Heart Failure Self-management

Patients' Digital Literacy and Willingness to Use Technology

Participants considered patients' lack of digital literacy and unwillingness to use technology as important barriers to the use of mobile apps. Patients mentioned seeing themselves as not being tech-savvy enough to use an app (mostly due to a perceived age barrier) and expected it would take them a long time and effort to learn how to use it properly.

> *I'm not really good with phones. (...) I try to use [the clinic's app] when my daughter is at my house. I mean, for us it's a lot harder, but I think it's a very good technology for the new generation.* [Male, 57]

According to professionals, patients with a stable or long-time condition would be less prone to engage in a new strategy with mobile apps to manage their condition, especially if they are not used to technology.

> *They [older patients] are a little bit stuck in their ways. They've sort of done things for a certain way for so long, that is hard to just [change]. In terms of the apps, they probably also are obviously not very technologically advanced.* [Clinician 2]

However, this barrier could be overcome by introducing the app soon after an exacerbation, when they might be more willing to improve their self-management practices.

> *I think when it comes to trying to motivate them, the ideal time would be when they have an exacerbation and we say "look, you don't need to come in every day while we watch this, you can get this from home, just set up with this app; this is how we're going to manage to get on a daily weight, right?". When they are stable, they don't want to do it. But when they have an exacerbation, that would be the time, when they are discharged from the hospital.* [Clinician 6]

Professionals added that learning how to use an app could be an additional burden to some patients but family or caregivers' support could be helpful.

> *Sometimes people go through a period where they are quite enthusiastic about their monitoring (...). Then they just lose interest. [...] They need to understand what is in there, how much information is there, input their data, send messages. I think they find that a bit overwhelming sometimes. So teaching them how to use the app is often problematic because they may do it whilst they're in the clinic and then they go home and they can't work it out again.* [Clinician 4]

> *I think it would be the combination of what else is happening in their lives. How busy are they? What family support do they have? Transport, all those all those factors (...), where's the priority? If they're busy looking [after] somebody else or kids.* [Clinician 5]

> *Time and that routine of checking it [the app] regularly [are difficult]. We always check our emails quite easily, but checking this other thing is a bit harder. [...]* [Female 79]

Clinician Workload, Remuneration, and Digital Literacy

Clinicians considered increased workload, lack of remuneration, and insufficient digital literacy as the main barriers to implementing a shared platform connected to a patient app. They said that managing patients' data and messages was time-consuming and not remunerated but may help avoid unnecessary visits to the clinic and optimize consultations.

> *We don't have to text them "your blood pressure's a little bit high" or something. The app does all that stuff. There's lots of (...) things that make it less labor-intensive for the clinicians. It makes patients understand (...) "I'm stable, I'm good", so it also allows other avenues because the ones that are stable know they don't need to come in. Then people who need quick access are able to come through the doors. And it's not just the doctors monitoring it. Our pharmacists and dieticians are part of the team, also taking responsibility. So they're actually monitoring it and helping alert us to any problems. It's a team-based monitoring. [...] So it's definitely a little bit more work, but not to the point where you're not answering messages. [...]* [Clinician 3]

Professionals mentioned the importance of all clinicians being able to access and respond to patients' data and messages, enabling them to share responsibilities and improve the team's problem-solving ability.

> *It also means that we can communicate with different team members as well. [...] So we all can make suggestions, contribute and send messages to each other.* [Clinician 4]

Associations Between Barriers and Facilitators to the Use of Apps to Support Heart Failure Self-management

There was a connection between patients' willingness to use technology and facilitators to the use of apps to support heart failure self-management. Participants mentioned the use of an app could be associated with an increase in the burden of managing heart failure. They explained that learning how to

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use the app and remembering to use it could be seen as an additional responsibility in people's already busy lives, which could be demotivating and lead to a lack of interest and decreased willingness to use the app over time. Hence, participants mentioned that it was very important for the app to be easy to use, such as by enabling automated self-monitoring through connected wireless devices instead of manual input of measures (eg, weight monitoring using a wireless scale connected to the app, physical activity monitoring using a fitness tracker). In addition, participants mentioned the app should be useful and provide value-added service, such as by enabling communication with clinicians and providing personalized feedback and education, instead of one-size-fits-all support.

Discussion

Principal Findings

This study identified the main facilitators and barriers to the use of mobile apps to support patients with heart failure self-management. The most important features mentioned by patients were communication between patients and clinicians, personalized feedback, automated self-monitoring, tracking of patient-reported measures, and mental health support. Participants suggested that those features could improve patient awareness about their condition, the ability to monitor their health status, and their understanding of the consequences of their behaviors, increasing their confidence and motivation to self-manage the disease. Lack of digital literacy and patients' unwillingness to engage in a new strategy to manage their condition using an app were seen as the most relevant barriers. Clinician workload and remuneration were also mentioned by clinicians as potential barriers.

Comparison With Prior Work

Our findings complement the results from 2 previous qualitative studies exploring patients' perspectives on the use of mobile technologies for heart failure self-management [35,36]. Although these studies did not focus specifically on mobile apps, there were some common findings with our study, namely, the importance of ease of use and usefulness [35,36,51]. In these qualitative studies, as in ours, participants mentioned specific facilitators enhancing ease of use (eg, automated self-monitoring) [35] and usefulness (eg, communication with clinicians, personalized education) [36]. Both studies found that lack of digital literacy and willingness to use the technology were the most frequently mentioned barriers, in line with our results [35,36].

Our findings are consistent with reviews of relevant mobile app features for self-management of other chronic diseases [52,53]. Common facilitators from these studies included ease-of-use, personalized features (including changes in goals or needs depending on the stages of the disease), tracking of self-management tasks with visualization and analysis of trends and progress, and support from the clinicians (communication). One study also alerted to the need to track patients' mental health, as suggested by some clinicians in our study [53]. Similar to these findings, the importance of integration with other platforms and devices and sharing information with other systems and supporting members (clinicians, family, caregivers) were also highlighted as important [52].

An interesting finding from our study was that clinicians highlighted the need for patient-reported measures and mental health tools to assess and address the psychological impact and emotional burden of heart failure [12]. Heart failure may affect patients' mental health and has been associated with depression, anxiety, and cognitive disorders [12,54,55]. Mental health problems increase the risk of hospital readmissions, hamper treatment compliance, and affect patients' quality of life [12,54,55]. Patient-reported outcomes can be collected through self-reported questionnaires assessing aspects such as general well-being, symptoms, functional impairment, or psychological status [56]. Patient-reported outcomes assessment might help clinicians to recognize and measure consistently the overall impact of heart failure and its treatment on patients' lives, adding strategies to reduce or manage this impact (eg, adjusting diuretic doses, targeting depression management), and assess their response [56,57]. Mental health support via smartphone apps has shown promise in previous studies [58] but the evidence is lacking regarding their use by patients with heart failure.

Strengths and Limitations

This study had several strengths and limitations. Interviewing different health care professional groups enabled us to gather perspectives on a variety of self-management aspects (eg, diet, physical activity, medication adherence, and mental health). Furthermore, recruitment of patients with and without experience using health apps enriched the understanding of the facilitators and barriers of adopting mobile apps for heart failure self-management. Main limitations of this study are as follows: first, the single practice setting and the lack of cardiologists among the clinicians interviewed; cardiologists could have enhanced the findings and raised new insights, and future studies should explore their perspectives. Second, the app and platform at use in the clinic were not specific for heart failure self-management, which may have limited the exploration of some features (eg, heart failure–specific education and alerts for early warning signs of decompensation). Third, the patients recruited to this study did not have previous experience with a heart failure–specific app, which allowed us to gather open-minded perspectives on potential facilitators and barriers and desirable features, but may have led to missed insights on some heart failure–specific app features. Fourth, the small sample did not allow comparison between patients using and not using the clinic's app. Finally, because we did not collect electronic health record data, we could not characterize patients according to severity of heart failure.

Future Directions

The design, evaluation, and implementation of apps to support heart failure self-management should focus on features enhancing their usefulness (eg, communication ability, personalized feedback, and education) and factors that facilitate ease of use (eg, automated self-monitoring). Chat-like functions may be an engaging way to support patients in-between clinical appointments, as well as may enable gathering information from patients on symptoms of heart failure decompensation. Other important health information to be monitored, such as weight

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and blood pressure, may be easily collected by wireless devices integrated with the app, to lessen self-management burden.

Finally, there seems to be a desire for features that help manage patients with heart failure not only physically or according to their tasks but also emotionally, providing mental health support. Although patient-reported outcomes have been largely used in clinical trials to evaluate quality of life, the adoption of patient-reported outcomes assessment in clinical care still needs development, and the use of mental health tools in mobile apps focused on heart failure is still largely unexplored.

Conclusion

Mobile apps have potential in supporting heart failure self-management, particularly if including features desired by patients and clinicians, such as communication in-between visits, automated self-monitoring, and personalized feedback. These features should be considered in the future co-design of apps focused on the self-management of heart failure. While this qualitative study focused on the primary care setting, future studies should also involve cardiologists and patient caregivers.

Acknowledgments

We thank Dr Kean-Seng Lim (Director, Mt Druitt Clinic) and Mt Druitt Clinic staff and patients for the opportunity to conduct the interviews and for their time and attention. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. LBG was funded by the MQRES/RTPi Scholarship (20191550).

Data Availability

Because of ethical and privacy issues, the data collected for this study are not available for sharing.

Authors' Contributions

LBG and LL were responsible for the conception and design of the work. LBG was involved in the planning and implementation, data collection, and preparation of first draft. LBG, LL, RR, JC, and CC were responsible for analysis and interpretation. LL, RR, JC, and CC were responsible for critical revision of drafts for important intellectual content. LBG, LL, RR, JC, and CC provided final approval of the version to be published.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of the CareMonitor app.
[DOCX File , 700 KB - cardio_v6i1e33992_app1.docx]

Multimedia Appendix 2
Interview guide for patients.
[DOCX File , 21 KB - cardio_v6i1e33992_app2.docx]

Multimedia Appendix 3
Interview guide for clinicians.
[DOCX File , 16 KB - cardio_v6i1e33992_app3.docx]

Multimedia Appendix 4
COnsolidated criteria for REporting Qualitative research (COREQ) checklist.
[DOCX File , 21 KB - cardio_v6i1e33992_app4.docx]

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Abbreviations

COREQ: COnsolidated criteria for REporting Qualitative research

Edited by T Leung; submitted 02.10.21; peer-reviewed by V Guan, A Tannoubi, H Mehdizadeh, Y Wu, M Abouzid, A Joseph; comments to author 03.11.21; revised version received 11.11.21; accepted 07.03.22; published 20.04.22.

Please cite as:
Bezerra Giordan L, Ronto R, Chau J, Chow C, Laranjo L
Use of Mobile Apps in Heart Failure Self-management: Qualitative Study Exploring the Patient and Primary Care Clinician Perspective
JMIR Cardio 2022;6(1):e33992
URL: https://cardio.jmir.org/2022/1/e33992
doi:10.2196/33992
PMID:35442205

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Original Paper

The Impact of Transitioning From In-Person to Virtual Heart Transplantation Selection Committee Meetings: Observational Study

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Abstract

Background: Heart transplant selection committee meetings have transitioned from in-person to remote video meetings during the COVID-19 pandemic, but how this impacts committee members and patient outcomes is unknown.

Objective: The aim of this study is to determine the perceived impact of remote video transplant selection meetings on usability and patient care and to measure patient selection outcomes during the transition period from in-person to virtual meetings.

Methods: A 35-item anonymous survey was developed and distributed electronically to the heart transplant selection committee. We reviewed medical records to compare the outcomes of patients presented at in-person meetings (January-March 2020) to those presented during video meetings (March-June 2020).

Results: Among 83 committee members queried, 50 were regular attendees. Of the 50 regular attendees, 24 (48%) were physicians and 26 (52%) were nonphysicians, including nurses, social workers, and coordinators; 46 responses were received, 23 (50%) from physicians and 23 (50%) from nonphysicians, with 41 responses fully completed. Overall, respondents were satisfied with the videoconference format and felt that video meetings did not impact patient care and were an acceptable alternative to in-person meetings. However, 54% (22/41) preferred in-person meetings, with 71% (15/21) of nonphysicians preferring in-person meetings compared to only 35% (7/20) of physicians (P=.02). Of the 46 new patient evaluations presented, there was a statistically nonsignificant trend toward fewer patients initially declined at video meetings compared with in-person meetings (6/24, 25% compared to 10/22, 45%; P=.32).

Conclusions: The transition from in-person to video heart transplant selection committee meetings was well-received and did not appear to affect committee members' perceived ability to deliver patient care. Patient selection outcomes were similar between meeting modalities.

(JMIR Cardio 2022;6(1):e35490) doi:10.2196/35490

KEYWORDS

telemedicine; transplantation; heart failure; physician; heart transplant; virtual meeting; interprofessional relations; health systems; selection committee

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Introduction

In 2020, 3658 heart transplants were performed in the United States, with an additional 3576 candidates remaining on the waiting list, reflecting the national scarcity of donor hearts and the challenging decisions made by transplant centers during organ allocation [1]. Thus, transplantation selection committees are typically large multidisciplinary groups, including physician and nonphysician members, that complete comprehensive patient evaluations to determine transplant listing eligibility [2].

The COVID-19 pandemic transformed clinical and administrative practices in heart transplantation. One fundamental change was the transition of heart transplant selection committee meetings from in-person to remote videoconference meetings to maintain social distancing requirements. Current data explore digital health in the remote monitoring of patients with heart failure and patients receiving heart transplants, but the impact of telemedicine on heart transplantation selection committee meetings has not been studied as extensively [3,4]. Furthermore, there is limited data on provider satisfaction with telemedicine and virtual collaborations among providers [5]. Thus, this report aims to (1) understand how the transition of heart transplant selection committee meetings from in-person to remote videoconference has affected committee members and the perceived impact on patient care and (2) determine the impact of in-person compared to remote meetings on patient selection outcomes.

Methods

Recruitment

A 35-item anonymous survey was developed and distributed electronically to individuals on the adult heart transplantation selection committee roster at a single tertiary care academic hospital in May 2020. The survey was adapted from the validated Telehealth Usability Questionnaire [6] and developed in reference to the institution's preferred videoconferencing system, Zoom (Zoom Video Communications Inc). Survey items included multiple-choice, Likert scale, and free-text responses and are available in Multimedia Appendix 1.

Selection committee meeting notes and electronic medical records were reviewed to obtain patient demographic characteristics, transplant listing status, and meeting outcomes. Data on the duration of meetings were not collected. Patients were included in the analysis if they were presented as a new evaluation to the adult heart transplant selection committee between January 3, 2020, and June 5, 2020, and had not already been chosen to receive a transplant by the start of the meeting. For patients whose decision was deferred, meaning they did not receive a decision at the initial meeting and were presented again at later meetings, their clinical course was followed beyond the original meeting to record the final decision and time to decision.

Ethics Approval

Informed consent was obtained from the committee members surveyed. The study protocol was approved by the University of California, Los Angeles Institutional Review Board (IRB#21-000084).

Statistical Analysis

Quantitative descriptive analyses were performed, including subgroup analyses stratified by physician and nonphysician respondents. Likert scale responses were analyzed as continuous variables and averaged. To test for differences between groups, *t* tests were used for normally distributed variables. For the patient selection outcomes data, we measured the proportion of patients who were accepted, declined, or received a deferred decision, as well as the time to decision, using the Wilcoxon rank-sum test for skewed variables and chi-square tests for categorical variables. Statistical analyses were performed using Stata (version 15.1; StataCorp). *P* values <.05 were considered statistically significant.

Results

Survey Data

The heart transplant selection committee included 83 members, 50 of whom were regular attendees; of the 50 regular attendees, 24 (48%) were physicians and 26 (52%) were nonphysicians. Overall, 46 anonymous responses were submitted and included in the participant demographic analysis; however, 1 physician response was excluded from additional analyses since the respondent had not attended any videoconference meetings in the preceding 6 months (by self-report). Of the 46 survey respondents, 23 (50%) were physicians and 23 (50%) were nonphysicians. Physicians from the departments of medicine, surgery, and anesthesia were represented, with cardiologists comprising the majority (11/23, 48%) of physician respondents (Table 1). Nonphysicians included cardiomyopathy nurses, pharmacists, transplant coordinators, social workers, and administrators. At the time of the survey, 91% (42/46) of respondents had attended more than one video meeting, and complete responses were received from 41 participants.

Overall, both physician and nonphysician respondents were satisfied with video meetings regarding ease of use, interface quality, and interaction ability. Respondents agreed that they could contribute effectively to the meeting and achieve their clinical and administrative goals through videoconference. The predominant positive attributes of in-person meetings were communication and clinical decision-making, while location was the predominant negative. The predominant positive attributes of video meetings were multitasking, technology integration, and location convenience, while communication was the predominant negative (Table 2).

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Table 1. Distribution of multidisciplinary committee member survey respondents by committee member subtype and physician subtype.

Selection committee member types	Value, n (%)
Professional role (N=46)	
Cardiomyopathy registered nurse/nurse practitioner	4 (9)
Transplant and pretransplant coordinator	6 (13)
Ventricular assist device coordinator	3 (7)
Physician	23 (50)
Pharmacist	1 (2)
Dentist	1 (2)
Quality assurance professional	2 (4)
Financial counselor/coordinator	1 (2)
Social worker	2 (4)
Other	3 (7)
Medical specialty[a] (n=23)	
Cardiology	11 (48)
Nephrology	1 (4)
Infectious diseases	5 (22)
Pulmonary	1 (4)
Anesthesiology	3 (13)
Surgery	2 (9)

[a]These data were collected from physician respondents.

Table 2. The proportion of respondents that identified each meeting attribute as a positive or negative aspect of in-person or video meetings (N=45).

Meeting type and attribute	Identified as positive, n (%)	Identified as negative, n (%)
In person meeting		
Location	11 (24)	18 (40)
Workflow	14 (31)	7 (16)
Communication	37 (82)	1 (2)
Multitasking	12 (27)	12 (27)
Clinical decision-making	28 (62)	1 (2)
Technology	5 (11)	13 (29)
Video meeting		
Location	28 (62)	1 (2)
Workflow	14 (31)	5 (11)
Communication	11 (24)	26 (58)
Multitasking	34 (76)	1 (2)
Clinical decision-making	12 (27)	12 (27)
Technology	24 (53)	5 (11)

Concerns with communication included the inability to see attendees (ie, from video cameras being turned off), audio interruptions, and barriers to communication flow. Compared to nonphysicians, more physicians cited workflow as a positive aspect of video meetings (11/22, 50% of physicians compared to 3/23, 13% of nonphysicians) and a negative aspect of in-person meetings (6/22, 27% of physicians compared to 1/23, 4% of nonphysicians). Additionally, physicians more frequently identified clinical decision-making as a negative aspect of video meetings (8/22, 36% of physicians compared to 4/23, 17% of nonphysicians).

Overall, committee members did not feel that video meetings impacted their ability to engage in patient care, such as by clarifying clinical questions, creating management plans, and

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determining or updating transplant listing status. However, compared to nonphysicians, physicians had consistently lower mean Likert scale scores for questions regarding patient care improvement with video meetings. Physicians did not agree that videoconference meetings improved their ability to clarify clinical questions, while nonphysicians agreed (2.79 mean physician score compared to 3.48 mean nonphysician score; *P*=.03). Physician responses were neutral or in agreement for other patient care tasks, such as creating management plans and determining or updating transplant listing status.

Respondents agreed that videoconferencing was an acceptable alternative to in-person meetings (3.98 mean Likert score) but did not agree that the 2 meeting formats were equivalent (2.98 mean Likert score). Among all respondents, 54% (22/41) preferred the in-person meeting format for future selection committee meetings. When stratified by committee member subtype, 71% (15/21) of nonphysicians preferred in-person meetings compared with 35% (7/20) of physicians (*P*=.02).

Patient Selection Outcomes

Of the 46 patients presented as new evaluations at heart transplant selection committee meetings from January to June 2020, the mean age was 54 (SD 2.1) years, 65% (n=30) were male, and 80% (n=37) were under consideration for single organ transplant (n=9, 20% were under consideration for multiple organ transplants). These characteristics were similar between in-person and video meetings. A total of 22 patients were presented during the in-person meeting phase (January-March 2020) and 24 patients were presented during the videoconferencing phase (March-June 2020).

As shown in Table 3, there was a numerical but statistically nonsignificant trend toward fewer patients initially declined at video meetings compared with in-person meetings (6/24, 25% compared to 10/22, 45%; *P*=.32), while more video patients were ultimately approved (16/24, 67% compared to 12/22, 55%; *P*=.40). Among the patients whose decision was deferred at the initial meeting, the median time to a final decision was 37 (IQR 21-124) days for in-person and 68 (IQR 27-97; *P*=.90) days for video meetings.

Table 3. Patient outcomes for both in-person and video selection committee meetings, N=46

Patient outcomes	In-person meetings (n=22)	Video meetings (n=24)	*P* value
Initial decision at time of meeting, n (%)			
Declined	10 (45)	6 (25)	.32[a]
Approved	5 (23)	9 (38)	
Decision deferred	7 (32)	9 (38)	
Final decision, n (%)			
Declined	10 (45)	8 (33)	.40[a]
Approved	12 (55)	16 (67)	
Time to final decision			
No delay in decision, n (%)	16 (73)	16 (67)	.66[a]
Time to decision[b] in days, median (IQR)	37 (21-124)	68 (27-97)	.90[c]

[a]*P* value obtained from the chi-square test.

[b]Among patients with a delayed decision (6 for in-person meetings and 8 for video meetings).

[c]*P* value obtained from the Wilcoxon rank-sum test.

Discussion

Principal Findings

The transition of heart transplant selection committee meetings from in-person to videoconference during the COVID-19 pandemic was well-received by committee members, though a higher proportion of physician members preferred video meetings than nonphysician members. Committee members perceived that video meetings did not impact patient care delivery. Patient selection outcomes for new patient evaluations did not significantly differ between the in-person and video meeting phases.

Comparison to Prior Work

This study was unique in focusing on a digital experience among heart transplant professionals, while prior work in the area of telemedicine and heart transplantation focused on patient-facing interventions [7,8]. A prior qualitative study on liver transplant selection committee members found that the main barriers to decision-making included a lack of written policies, difficulty maintaining the balance between advocating for a patient and promoting organ stewardship, inconsistent attendance, and lack of efficiency [2]. In this study, physicians preferred video selection committee meetings, while nonphysician members preferred in-person meetings, which may be influenced by physicians' perception of an improvement in efficiency when using videoconference. However, despite their preference for video meetings, physicians had lower agreement regarding whether video meetings improved patient care and more frequently cited clinical decision-making as a negative attribute of video meetings. In contrast, nonphysicians preferred in-person meetings, yet had higher agreement for questions relating to

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improvement in patient care delivery with video meetings. Collectively, these data highlight the nuanced nature of multidisciplinary heart transplant selection committee meetings and the perceived trade-offs of different meeting formats.

We observed numerical but statistically nonsignificant trends toward fewer immediately declined patients and more patients approved after some delay in the video meeting group. Given that respondents thought communication and clinical decision-making were easier with in-person meetings, a potential explanation may be a tendency to delay difficult clinical decisions in video meetings in favor of additional evaluation or monitoring over time.

Strengths and Limitations

This was a small, retrospective, single-center study, so findings should be considered hypothesis-generating. The quantitative survey methods allowed for measurement of the perceived impact of virtual meetings with comparison to observed patient outcomes. The voluntary aspect of the survey may have introduced selection bias, though the anonymous nature limited response bias. The observed response rate (46/83, 55%) was low; however, the number of respondents was similar to the number of regular meeting attendees (46 compared to 50), though survey anonymity precluded our ability to identify if respondents were indeed regular attendees. This survey evaluated committee members soon after the change in meeting format to videoconferencing; these initial preferences may have evolved over time. Finally, patient selection outcomes may have been affected by unmeasured confounders such as the unpredictable and evolving impact of the COVID-19 pandemic on programmatic transplant policies over time.

Future Directions

These observations warrant further investigation in larger studies. A sample size of 275 patients in each group (in-person and video meetings) would be required to detect the proportions observed in this pilot study in an adequately powered trial (80% power at a 2-tailed α of .05). Future studies should assess team interaction in virtual and in-person meetings, such as engagement with colleagues and ability to advocate for patients, as well as the impact on efficiency and attendance. Additionally, registry data to assess outcomes across multiple transplant centers could be incorporated.

Conclusions

The videoconferencing format for heart transplant selection committee meetings was generally well-received by the multidisciplinary members, though physicians reported a greater preference for video meetings compared to nonphysicians. Overall, video meetings do not affect committee members' perception of their ability to deliver patient care, which is corroborated by similar patient selection outcomes across both meeting modalities. Additional studies are needed to evaluate the impact of virtual meetings on care delivery systems and transplant-related patient outcomes.

Acknowledgments

RS and NVC participated in data analysis and writing of the manuscript. NVC, AA, AN, and RVP participated in study design. All authors contributed to conducting the research. The authors report no sources of funding.

Data Availability

Deidentified data can be accessed by contacting the corresponding author.

Conflicts of Interest

RVP receives research support from the American Heart Association, Janssen Pharmaceuticals, Infraredx Inc, and Abbott Laboratories, and consulting fees from Abbott Laboratories. The remaining authors report no conflicts of interest related to the contents of this manuscript.

Multimedia Appendix 1
Survey items (excludes demographic and free-text items).
[DOCX File , 16 KB - cardio_v6i1e35490_app1.docx]

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Edited by T Leung; submitted 06.12.21; peer-reviewed by S Choi, S Weinland; comments to author 18.02.22; revised version received 22.02.22; accepted 05.03.22; published 30.03.22.

Please cite as:
Shan R, Chandra NV, Hsu JJ, Fraschilla S, Moore M, Ardehali A, Nsair A, Parikh RV
The Impact of Transitioning From In-Person to Virtual Heart Transplantation Selection Committee Meetings: Observational Study
JMIR Cardio 2022;6(1):e35490
URL: https://cardio.jmir.org/2022/1/e35490
doi:10.2196/35490
PMID:35353041

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Original Paper

Relations Between BMI Trajectories and Habitual Physical Activity Measured by a Smartwatch in the Electronic Cohort of the Framingham Heart Study: Cohort Study

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Abstract

Background: The prevalence of obesity is rising. Most previous studies that examined the relations between BMI and physical activity (PA) measured BMI at a single timepoint. The association between BMI trajectories and habitual PA remains unclear.

Objective: This study assesses the relations between BMI trajectories and habitual step-based PA among participants enrolled in the electronic cohort of the Framingham Heart Study (eFHS).

Methods: We used a semiparametric group-based modeling to identify BMI trajectories from eFHS participants who attended research examinations at the Framingham Research Center over 14 years. Daily steps were recorded from the smartwatch provided at examination 3. We excluded participants with <30 days or <5 hours of smartwatch wear data. We used generalized linear models to examine the association between BMI trajectories and daily step counts.

Results: We identified 3 trajectory groups for the 837 eFHS participants (mean age 53 years; 57.8% [484/837] female). Group 1 included 292 participants whose BMI was stable (slope 0.005; *P*=.75), group 2 included 468 participants whose BMI increased slightly (slope 0.123; *P*<.001), and group 3 included 77 participants whose BMI increased greatly (slope 0.318; *P*<.001). The median follow-up period for step count was 516 days. Adjusting for age, sex, wear time, and cohort, participants in groups 2 and 3 took 422 (95% CI –823 to –21) and 1437 (95% CI –2084 to –790) fewer average daily steps, compared with participants in

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group 1. After adjusting for metabolic and social risk factors, group 2 took 382 (95% CI –773 to 10) and group 3 took 1120 (95% CI –1766 to –475) fewer steps, compared with group 1.

Conclusions: In this community-based eFHS, participants whose BMI trajectory increased greatly over time took significantly fewer steps, compared with participants with stable BMI trajectories. Our findings suggest that greater weight gain may correlate with lower levels of step-based physical activity.

(JMIR Cardio 2022;6(1):e32348) doi:10.2196/32348

KEYWORDS

mobile health; BMI; smartwatch; physical activity; cardiovascular diseases; cardiology; digital health; mHealth; mobile health apps

Introduction

The global prevalence of obesity is rising [1], with an estimated 573 million adults projected to be obese by the year 2030 [2]. Obesity is a significant public health problem, and increases the risk of cardiovascular disease (CVD), type 2 diabetes, cancer, and mortality [1,3]. Because obesity at younger ages is associated with negative health outcomes that persist into adulthood [4,5], early intervention may be useful in curbing the adverse outcomes associated with obesity. Lifestyle interventions such as dietary modification and increasing physical activity (PA) levels are used in the management of obesity [6]. Most previous studies that examined the relations between BMI and PA measured BMI at a single timepoint [7-11], ignoring the time-varying nature of BMI. In recent times, the use of trajectories has enabled researchers to track the trends of variables over periods [12,13]. A few studies have reported that BMI trajectories are associated with risk of CVD [14,15]; however, the association between BMI trajectories and PA is less well studied.

The relations between BMI and PA are complex. While some studies suggested an inverse relationship between BMI and PA [7,8,10,16], a few pedometer-based studies produced inconsistent results [7,17,18]. For example, in a study by Tudor-Locke et al [8] to determine the association between ambulatory activity and body composition, higher BMI was correlated with lower daily steps. However, another study by Walker et al [17] did not find any significant association between BMI and PA. Additionally, other studies assessing this relationship were interventional [16,17,19-21], and therefore, the findings may not represent habitual daily walking. Similarly, as most previous studies recruited fewer participants and had short follow-up duration [7,10], the results from these studies may not be generalizable to larger populations and longer follow-up periods. Furthermore, some step-based studies recommended 10,000 steps per day as a PA-promoting measure, and denoted step counts of 5000 or less per day as “sedentary lifestyle index” [22]. The relationship between long-term BMI and habitual step-based PA in community settings remains unclear.

It is thus important to examine the association between BMI trajectories and habitual step-based PA level. Advances in technology permit the use of smaller, light-weight, relatively accessible accelerometers, and allow accelerometer usage in large epidemiological studies [23,24]. As such, the aim of this study was twofold. First, we sought to identify BMI trajectory patterns over 14 years of middle-aged participants enrolled in the electronic cohort of the Framingham Heart Study (eFHS). Second, we aimed to determine the relations between BMI trajectories and daily step count retrieved from a smartwatch.

Methods

Study Sample

The details of the Framingham Heart Study (FHS) and the eFHS have been described previously [25,26]. In brief, the FHS enrolled participants in the Third Generation Cohort (Gen 3; n=4095), the multiethnic Omni Group 2 Cohort (n=410), and the New Offspring Spouse Cohort (n=103) from 2002 to 2005. These participants have attended examinations at the research center every 6-8 years. At the time of research examination 3 beginning in June 2016, participants were invited to participate in eFHS if they met the following eligibility criteria: spoke English, had a smartphone, lived in the United States, and were willing to permit notifications and share information with the FHS research center.

Participants who consented to the eFHS study were offered a study smartwatch beginning in November 2016 (Apple Watch Series 0). Of the 3521 participants who attended examination 3, we excluded 1370 who did not provide informed consent for eFHS, including those who had an incompatible phone, and those who had less than 12-month follow-up (n=203). Of the remaining 1948 participants who were enrolled in the eFHS, 1185 chose to participate with the Apple Watch and returned step data between November 2016 and January 2019. We excluded 213 participants who either wore the smartwatch less than 5 hours on any given day or those who returned smartwatch data for less than 30 days during the study period because these participants did not meet the definition for habitual PA previously published [27]. We also excluded 135 participants who did not attend the 3 examinations needed to build the BMI trajectory, participants with BMI values <18.5 or >60 kg/m^2 at any of the 3 research examinations, and participants who had a gastric bypass procedure. Eligibility and exclusion criteria are depicted in Multimedia Appendix 1.

Ethics Approval

The study protocol was approved by the Boston University Medical Center Institutional Review Board (H-36586 and H-32132). All participants provided informed consent.

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Body Mass Index Trajectories

At each examination visit in the FHS research center, trained personnel routinely measured participant's weight to the nearest pound and height to the nearest quarter-inch, using uniform measuring devices. BMI was calculated by dividing the participant's weight in kilograms by the square of the height in meters (kg/m^2). Normal weight was defined as BMI within the range of 18.5-24.9 kg/m^2, overweight as BMI between 25 and 29.9 kg/m^2, and obese as BMI ≥30 kg/m^2. To build the BMI trajectories, we included participants in eFHS with Apple Watch data who attended examination 1 (2002-2005), examination 2 (2008-2011), and examination 3 (2016-2019) [25,26]. The median age was 39 (IQR 33-45), 45 (IQR 40-51), and 53 (IQR 47-59) years at examinations 1, 2, and 3, respectively. The median follow-up time for the participants used in BMI trajectories was 14 years (IQR 13-14). We applied a semiparametric, group-based modeling strategy to identify latent homogeneity in BMI trajectories in eFHS participants during their middle adult life. The model assumes the study cohort consisted of a mixture of groups following homogenous developmental courses based on their BMI values [28]. Each participant's BMI values were centered using his/her baseline measurement to assess change in BMI from examination 1 to 3. The centered longitudinal BMI values were modeled as a mixture of several latent trajectories in a censored normal model (allowing for the lower [–19] and upper [20] BMI limits after centering) with a quadratic function of age. The trajectory models were adjusted for age, sex, and smoking status. We used the SAS "proc traj" program to develop the BMI trajectories. The preferred order of the polynomial (ie, linear or quadratic) for each trajectory and the number of trajectory groups were determined by the Bayesian information criterion (BIC) and the log Bayes factor [28-30]. To identify the optimal number of trajectory groups, we started with a single group, and added 1 more group one at a time. The BIC statistic was used to evaluate the model fit when adding groups.

Smartwatch Step Data

Participants who consented to the eFHS study using an iPhone were offered Apple Watches Series 0 starting in November 2016 through the end of enrollment. The study research technician assisted the participant with pairing the Apple Watch with her/his iPhone while in the Research Center or provided written instructions for participants who opted to set up the Apple Watch remotely. Participants who attended the research center prior to November 2019 were contacted and provided with the option to return to the Research Center for smartwatch setup or provided with materials for remote setup. Additionally, participants who owned an Apple Watch were permitted to participate using their own watch. The Apple watch has a built-in accelerometer that measures daily steps. All participants were instructed to wear the watch daily. We used daily step counts retrieved from the Apple Watch to assess PA.

Covariates Obtained at Examination 3

Age, sex, and race/ethnicity were ascertained at examination 1. Educational level and marital status were obtained from self-reports at examination 3. Participants who reported smoking in the year prior to the examination were defined as currently smoking [31]. Prevalent coronary heart disease, myocardial infarction, angina pectoris, stroke, intermittent claudication, and heart failure were classified as CVD, after adjudication by a panel of senior investigators using standard criteria and all available information including hospital records. We defined hypertension as the average of 2 resting blood pressure measurements of ≥140/90 mmHg or a report of antihypertensive medication usage [32]. Type 2 diabetes was defined as fasting glucose ≥126 mg/dL or a report of hypoglycemic agent usage [33]. Sleep apnea was determined based on the self-report of a diagnosis of sleep apnea by a health care professional from technician-administered respiratory questionnaire or the clinical diagnostic impression of the presence of sleep apnea from the standard medical history interview conducted by the nurse practitioner.

Statistical Analysis

Baseline characteristics of participants were reported as means and SDs for continuous variables and frequencies (percentages) for categorical variables stratified by BMI trajectory groups. We used analysis of variance to compare means of continuous variables and chi-square/Fisher exact test to examine differences in proportions between BMI trajectory groups. The BMI trajectories were created prior to steps assessment. The primary outcome was mean daily steps retrieved from the smartwatch, and BMI trajectories were the primary exposure of interest. We assessed the association between BMI trajectory groups and repeated measures of daily step counts, with BMI trajectory group 1 as the reference group. The statistical analysis was conducted with a generalized linear model that accounted for correlation between longitudinal daily step counts (PROC GENMOD in SAS). We also adjusted for potential confounders. In model 1, the covariates included age, sex, cohort, and wear time. In model 2, we adjusted for hypertensive status, diabetes status, smoking status, and prevalent CVD, in addition to covariates in model 1. In model 3, we adjusted for model 2 plus sleep apnea, education, and marital status. In sensitivity analyses to determine the effect of follow-up duration on daily step count, all models were additionally adjusted for follow-up duration. We used generalized estimating equations to investigate the association between BMI at examination 3 and daily mean steps, adjusting for the same covariates in models 1, 2, and 3.

To investigate whether uneven days of follow-up in the 3 trajectory groups may introduce bias in association analyses, we performed sensitivity analyses by investigating the average of unadjusted daily steps for the participants between the 3 BMI trajectory groups when restricting to a 90-day follow-up period. We performed association analyses between BMI trajectories and mean daily steps within the 90-day periods with model 2. All statistical analyses were performed using SAS version 9.4 (SAS Institute). We defined a 2-tailed P<.05 as statistically significant.

Results

The analyses included 837 participants (mean age 53 years; 57.8% [484/837] female) with a median follow-up of 516 days with the maximum follow-up of 1166 days in the eFHS after

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research examination 3 (ie, the baseline). Based on the comparison of the BIC values and the log Bayes factors from semiparametric group–based models with BMI values from research examinations 1 to 3, the 837 participants were grouped into 3 trajectory groups: group 1 consisted of 292 participants whose BMI remained unchanged (slope [change in BMI for each year] 0.005; standard error [SE] 0.017; *P*=.75) from examination 1 to 3; group 2 included the largest number of participants (n=468) whose BMI slightly increased (slope 0.123; SE 0.014; *P*<.001); and group 3, the smallest group, only included 77 participants who displayed the greatest change in their BMI (slope 0.318; SE 0.029; *P*<.001) from examination 1 to 3 (Table 1 and Figure 1).

Table 1. Baseline characteristics of 837 eFHS[a] participants, by BMI trajectory groups, at examination 3.

Variable	BMI trajectory groups[b]			
	Group 1 (n=292)	Group 2 (n=468)	Group 3 (n=77)	*P*-value[c]
Age (years), mean (SD)	54 (9)	53 (8)	50 (10)	<.001
Female, n (%)	166 (56.8)	264 (56.4)	54 (70.1)	.07
Race, n (%)				.44
European ancestry	257 (88.0)	425 (90.8)	70 (90.9)	
Other ancestries	35 (12.0)	43 (9.2)	7 (9.1)	
Hypertension, n (%)	67 (22.9)	116 (24.8)	37 (48.1)	<.001
Diabetes, n (%)	16 (5.5)	22 (4.7)	6 (7.8)	.52
Current smoking, n (%)	11 (3.8)	20 (4.3)	5 (6.5)	.58
Cardiovascular disease, n (%)	14 (4.8)	16 (3.4)	2 (2.6)	.59
Self-reported sleep apnea, n (%)				.01
Yes	29 (9.9)	55 (11.8)	18 (23.4)	
No	261 (89.4)	402 (85.9)	59 (76.6)	
Education, n (%)				.34
Bachelor’s degree or higher	197 (67.5)	327 (69.9)	47 (61.0)	
No college degree	94 (32.2)	140 (29.9)	29 (37.7)	
Marital status, n (%)				.53
Married	223 (76.4)	356 (76.1)	54 (70.1)	
Currently not married	66 (22.6)	110 (23.5)	22 (28.6)	
Physical Activity Index, mean (SD)	33.6 (4.4)	33.3 (4.9)	33.0 (5.4)	.51
BMI, n (%)				<.001
Normal weight	128 (43.8)	115 (24.6)	1 (1.3)	
Overweight	103 (35.3)	218 (46.6)	15 (19.5)	
Obese	61 (20.9)	135 (28.8)	61 (79.2)	

[a]eFHS: electronic cohort of the Framingham Heart Study.

[b]Group 1: Participants whose BMI remained stable over the study period; group 2: slight increase in BMI over the study period; group 3: large increase in BMI over the study period.

[c]*P*-value of chi-square test for categorical variables, and detecting if any of the groups are statistically different for continuous variables.

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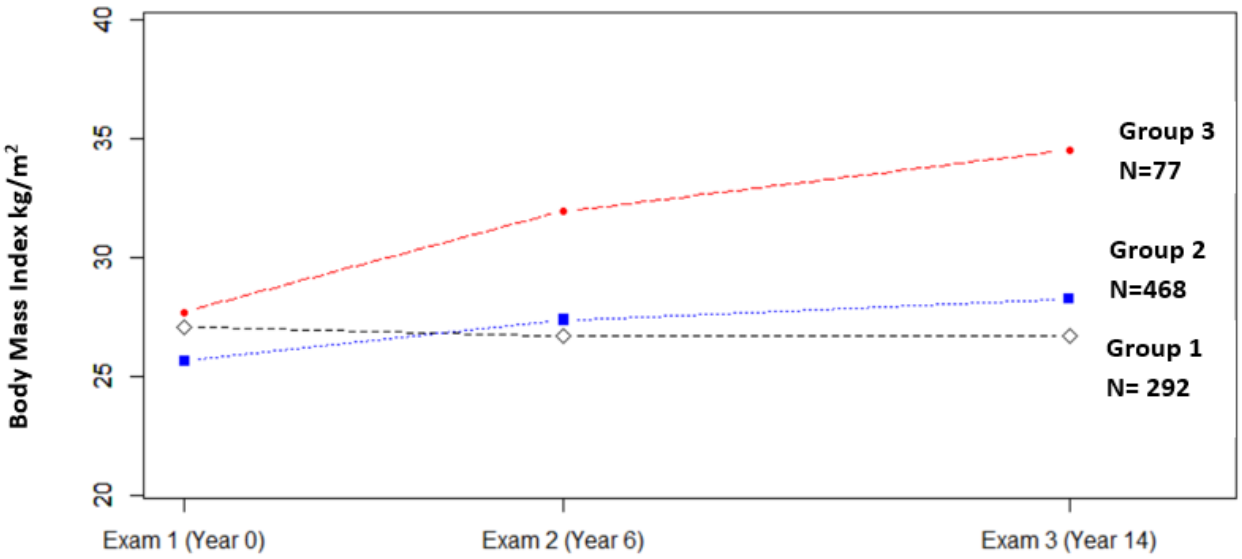
Figure 1. The three trajectory groups based on BMI measures at three health exams for 837 participants in eFHS. eFHS: electronic cohort of the Framingham Heart Study.



Of the 3 BMI trajectory groups, participants in group 3, on average, were the youngest (mean age 50 years), and contained the largest proportion of women (54/77, 70%). About 48% (37/77) of participants in group 3 had hypertension at baseline (examination 3). In addition, group 3 participants were more likely to have sleep apnea (Table 1). The median follow-up for participants in BMI trajectory group 1 was 576 days (IQR 322-843), for trajectory group 2 was 492 days (IQR 275-790), and for trajectory group 3 was 429 days (IQR 213-717).

A total of 13 participants had missing covariate data for self-reported sleep apnea, 3 had missing covariate data for education, and 6 had missing covariate data for marital status.

We compared the mean daily steps between BMI trajectory groups adjusting for covariates, using the complete case analysis approach (N=815; Table 2). Participants in BMI trajectory group 2 walked 422 fewer steps per day compared with participants in BMI trajectory group 1 (95% CI –823 to –21; *P*=.04), adjusting for age, sex, wear time, and cohort. Participants in BMI trajectory group 3 walked, on average, 1437 fewer steps per day compared with participants in BMI trajectory group 1 (95% CI –2084 to –790; *P*<.001). The effect sizes were slightly attenuated but remained significant after adjusting for cardiovascular risk factors and CVD (model 2; *P*=.04 and <.001 for groups 2 and 3, respectively). The effect sizes were further attenuated after additional adjustment for sleep apnea, education, and marital status (model 3): that is, compared with the reference, groups 2 and 3 walked 382 (95% CI –773 to 10; *P*=.06) and 1120 (95% CI –1766 to –475; *P*<.001) fewer steps per day, respectively (Table 2). The results did not substantially change after additional adjustment for follow-up duration (Multimedia Appendix 2).

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Table 2. Association between BMI trajectory groups and average daily step count[a].

Models and groups	Estimate	95% CI	*P*-value
Model 1[b]			
Group 1[c] (n=285)	Referent	—	—
Group 2 (n=455)	–422	–823 to –21	.04
Group 3 (n=75)	–1437	–2084 to –790	<.001
Model 2[d]			
Group 1	Referent	—	—
Group 2	–406	–800 to –12	.04
Group 3	–1258	–1908 to –609	<.001
Model 3[e]			
Group 1	Referent	—	—
Group 2	–382	–773 to 10	.06
Group 3	–1120	–1766 to –475	.001

[a]Complete case analysis: n=815.

[b]Model 1 covariates: age, sex, wear time, and cohort.

[c]Group 1: participants whose BMI remained stable over the study period; group 2: slight increase in BMI over the study period; group 3: large increase in BMI over the study period.

[d]Model 2 covariates: model 1 + hypertension, type 2 diabetes, current smoking, and cardiovascular disease.

[e]Model 3 covariates: model 2 + sleep apnea, education, and marital status

We assessed the association between BMI at examination 3 and mean daily steps (Multimedia Appendix 3). Higher BMI values were associated with lower mean daily step counts. For every kg/m^2 increase in BMI at examination 3, mean daily step count decreased by 146 (95% CI –182 to –111; *P*<.001) steps, after adjusting for age, sex, wear time, cohort, hypertension, diabetes, current smoking, CVD, sleep apnea, education, and marital status.

In sensitivity analyses, we investigated the daily median steps among the participants in BMI trajectory group 1, group 2, and group 3 during the 90-day follow-up without adjusting for covariates (Figure 2). BMI trajectory group 1 displayed the highest median step value within the 90-day period (6898 steps; IQR 4242-10298) and BMI trajectory group 3 participants had the least median daily steps (5707 steps; IQR 3335-8668; Figure 2). After adjusting for covariates, the differences in PA by BMI trajectory group remained similar during the 90-day follow-up period compared with the 12-month period. Within the 90-day interval, participants in BMI trajectory group 2 walked, on average, 659 fewer steps per day compared with those in BMI trajectory group 1 (95% CI –1124 to –194; *P*=.01), adjusting for age, sex, wear time, cohort, and cardiovascular risk factors. Similarly, participants in BMI trajectory group 3 walked, on average, 1006 fewer steps per day compared with participants in BMI trajectory group 1 (95% CI –1847 to –286; *P*=.01; Multimedia Appendix 4).

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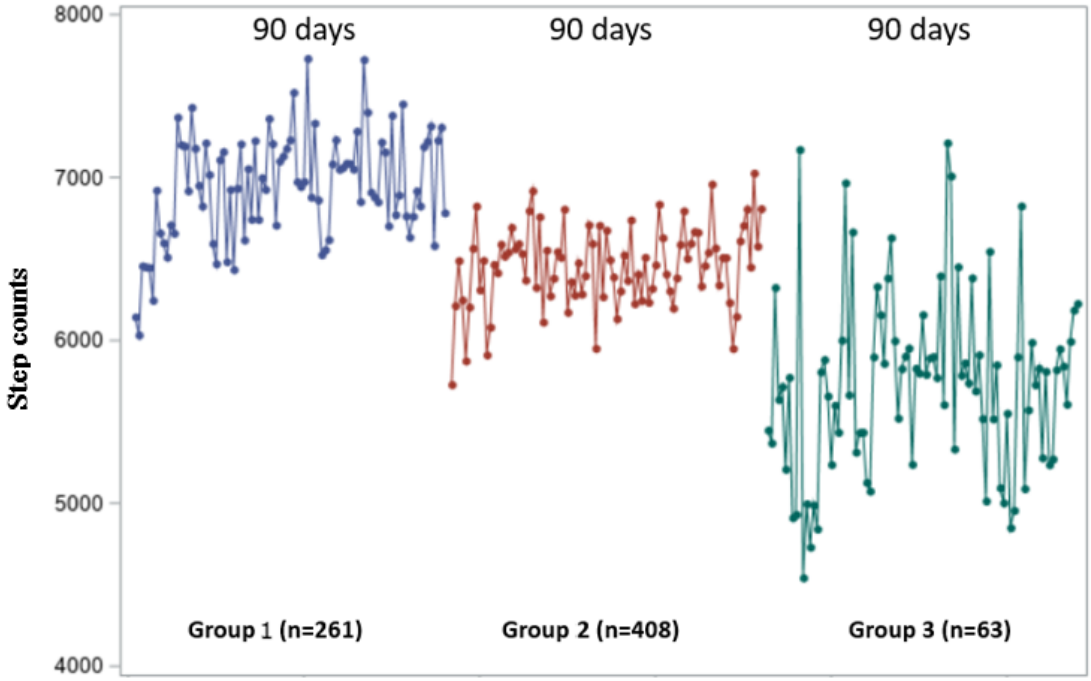
Figure 2. Median daily step distributions of BMI trajectory groups at 90-day window.



Discussion

Principal Findings

In this community-based electronic cohort of middle-aged and older participants, we examined the relations between BMI trajectories that were constructed at midlife and daily steps captured from a smartwatch worn over 1 year. We identified 3 distinct trajectory groups for BMI change over 14 years. The BMI change trajectory remained relatively stable for 34.9% (292/837) of participants; the majority of participants (468/837, 55.9%) had slight increments in BMI, whereas 9.2% (77/837) of participants had high increments in their BMI. We observed that in adjusted analyses, participants who had slight and greater increments in BMI took fewer steps per day, compared with participants whose BMI remained stable.

Our findings were consistent with previous studies demonstrating that individuals with higher weight took fewer mean daily steps compared with those with lower weight [7,18,34]. For instance, in an accelerometer-based cross-sectional study of 108 adults, participants with obesity took significantly fewer steps compared with those with normal weight [35]. Although the accelerometer usage overcame a major limitation of self-reported PA, BMI was measured from a single timepoint, and follow-up was relatively short. In another study of 1006 adolescents, Nesbit et al [36] demonstrated that participants within higher BMI trajectory groups were less physically active, compared with participants within healthy BMI trajectory groups. Similarly, a study of 3070 middle-aged Canadians showed that being physically active was associated with a lower risk of being in the overweight and obese trajectory groups [37]. In a more recent study, Laranjo et al [38] demonstrated that participants who were underweight/normal weight took significantly more steps per day over a 6-month period while those who were overweight/obese did not show any significant changes [38]. Although this study examined BMI and step count concurrently [38], the sample size may have been too small to detect significant changes among those in the overweight/obese group. In another study that found a negative association between daily step count and BMI, daily steps were measured over a relatively shorter period and BMI was measured only at 1 timepoint [39]. Although higher baseline BMI (at examination 3) was associated with significantly fewer mean daily steps, BMI trajectories factored in several objective measurements of BMI rather than self-reported height and weight in other published reports, or single BMI measurement. In addition, multiple objective measurement of step count, with a follow-up period of 1 year or more, adds more to understanding the relation between BMI and step-based PA. In this study, we show that higher levels of step-based PA are correlated with maintaining a stable BMI over time.

We observed that the smallest proportion of total participants (trajectory group 3) had the greatest (sharpest) increment in BMI over the period. This is consistent with the trend reported in previous trajectory studies [34,37,40,41]. For instance, in a recent study of 3271 young-to-middle-aged adults, 1.9% of participants were in the sharply rising BMI trajectory group, while about 46% of participants maintained a low-to-stable BMI [40].

Lifestyle factors may account for the different trajectories we observed. For example, in a 4-year lifestyle study of 120,887 men and women, Mozaffarian et al [42] found that diet, PA, alcohol, and smoking were associated with long-term weight gain. In our study, a greater proportion of participants in BMI trajectory group 3 were female and younger compared with the other BMI trajectory groups, and had a higher prevalence of hypertension. Furthermore, only 1 participant in BMI trajectory group 3 had normal weight and the rest of the participants were either overweight or obese. This is consistent with findings from some previous studies [34,40,41]. Life events such as pregnancy

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and motherhood may account for weight gain among young and middle-aged women [43]. Similarly, obesity is associated with hypertension [44], and may explain the high prevalence of hypertension among participants in BMI trajectory group 3. Because BMI trajectories in early adulthood increased risk for incident hypertension [40], early identification of individuals with higher risk of higher BMI trajectories may provide an opportunity to decrease obesity and reduce hypertension risk. It is possible that these lifestyle factors account for the trends we observed among participants who gained the most weight over the study period. Therefore, younger adults, particularly females, could benefit from early lifestyle interventions to prevent excessive weight gain over time.

This study included eFHS participants who had the opportunity to contribute at least one year of follow-up step data; however, due to the rolling enrollment design of the eFHS, some participants had the ability to contribute even longer data, while others may have dropped out during follow-up. As such, the follow-up duration was different among the BMI trajectory groups, with participants in BMI trajectory group 1 recording the longest follow-up duration (median 576 days), whereas those in trajectory group 3 the shortest (median 429 days). While it is possible that this observation may have an effect on the daily step count recorded, effect sizes were only slightly attenuated but remained significant after additional adjustment for follow-up duration in the models.

The strengths of this study include the moderate-size community-based sample of eFHS participants, the standardized and objective assessment of BMI used in building BMI trajectories over mid-adulthood, and step count data gathered with a smartwatch for a median of 1 year, providing abundant step data for analyses. Covariates were well characterized and directly measured at the FHS research center. Furthermore, because we excluded participants with BMI values <18.5 or >60 kg/m^2, as well as those who had a gastric bypass, we reduced the number of outliers in our analysis.

There are some limitations of our study to consider. First, because our analysis included a majority of European ancestry participants, our findings may not be generalizable to people of different race/ethnicity. Second, because eFHS participants were healthier, well educated, and had higher socioeconomic status compared with the overall FHS examination attenders, it is possible that their level of PA may differ from people of lower educational level and socioeconomic status. Moreover, because we excluded participants who returned data for <30 days, it is possible our findings may differ in this group. Although we adjusted for known confounders, our study may be subject to residual confounding. Because trajectories were created before comparison with step data, it is possible that other factors, besides PA, such as diet or illness, may have contributed to the trajectories we observed. As the study did not measure other types of PA besides step count, it is possible participants in the different BMI trajectory groups performed other types of PA that may affect weight change. Lastly, because the study was observational, causality cannot be inferred.

Conclusions

In this community-based study of eFHS participants, participants whose BMI trajectory increased greatly prior to step count measurement took significantly fewer daily steps, compared with participants with stable BMI trajectories. Our findings suggest that greater weight gain may be associated with lower levels of step-based PA during adulthood. Future research should investigate the long-term trends of other lifestyle factors such as diet and smoking, and assess the relationship between these factors and habitual PA.

Acknowledgments

This study was supported by an award from the Robert Wood Johnson Foundation (number 74624) and a grant from the National Heart Lung and Blood Institute (R01HL141434); Framingham Heart Study is supported by contract from NHLBI (PI VSR 75N92019D00031); the study investigators were supported by the following grants: R01HL126911 (EJB), 2R01 HL092577 (EJB), 1R01AG066010 (EJB), American Heart Association, 18SFRN34110082 (EJB), 2U54HL120163 (EJB), R01HL126911 (DMM), R01HL137734 (DMM), R01HL137794 (DMM), R01HL13660 (DMM), and U54-HL 143541 (DMM). The Apple watches were provided to Boston University by Apple Inc at no cost to the study.

Conflicts of Interest

DDM has received research support from Apple Inc, Bristol-Myers Squibb, Boehringer-Ingelheim, Pfizer, Flexcon, Samsung, Philips Healthcare, Biotronik; has received consultancy fees from Heart Rhythm Society, Bristol-Myers Squibb, Pfizer, Flexcon, Boston Biomedical Associates, and Rose Consulting; also declares financial support for serving on the Steering Committee for the GUARD-AF study (NCT04126486) and Advisory Committee for the Fitbit Heart Study (NCT04176926). JMM was a guest lecturer/consultant for Merck Research Laboratories. VK is the principal of CareEvolution. VK and CN are employees of CareEvolution, Inc., a healthcare technology company. Apple was not involved in the study design, analysis, interpretation, or reporting of study results. Starting 2020, NLS received funding from Novo Nordisk for an MD-initiated research grant unrelated to this study. JK received funding from the Marie Skłodowska-Curie Actions under the European Union's Horizon 2020 Research and Innovation Programme (Agreement No 838259). Other authors have no relevant disclosures.

Multimedia Appendix 1
Study sample selection.
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Multimedia Appendix 2
Association between BMI trajectory groups and average daily step count, additionally adjusted for follow-up duration.
[DOCX File , 13 KB - cardio_v6i1e32348_app2.docx]

Multimedia Appendix 3
Association between BMI at exam 3 and average daily step count.
[DOCX File , 13 KB - cardio_v6i1e32348_app3.docx]

Multimedia Appendix 4
Association between BMI trajectory groups and average daily step count for individuals at the 90-day window.
[DOCX File , 14 KB - cardio_v6i1e32348_app4.docx]

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Abbreviations

BIC: Bayesian information criterion
CVD: cardiovascular disease
eFHS: electronic cohort of Framingham Heart Study
FHS: Framingham Heart Study
SE: standard error

Edited by T Leung; submitted 23.07.21; peer-reviewed by D Filos, B Eshrati; comments to author 20.11.21; revised version received 14.01.22; accepted 14.03.22; published 27.04.22.

Please cite as:
Hammond MM, Zhang Y, Pathiravasan CH, Lin H, Sardana M, Trinquart L, Benjamin EJ, Borrelli B, Manders ES, Fusco K, Kornej J, Spartano NL, Kheterpal V, Nowak C, McManus DD, Liu C, Murabito JM
Relations Between BMI Trajectories and Habitual Physical Activity Measured by a Smartwatch in the Electronic Cohort of the Framingham Heart Study: Cohort Study
JMIR Cardio 2022;6(1):e32348
URL: https://cardio.jmir.org/2022/1/e32348
doi:10.2196/32348
PMID:35476038

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Original Paper

Virtual Reality Cardiac Surgical Planning Software (CorFix) for Designing Patient-Specific Vascular Grafts: Development and Pilot Usability Study

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Abstract

Background: Patients with single ventricle heart defects receive 3 stages of operations culminating in the Fontan procedure. During the Fontan procedure, a vascular graft is sutured between the inferior vena cava and pulmonary artery to divert deoxygenated blood flow to the lungs via passive flow. Customizing the graft configuration can maximize the long-term benefits. However, planning patient-specific procedures has several challenges, including the ability for physicians to customize grafts and evaluate their hemodynamic performance.

Objective: The aim of this study was to develop a virtual reality (VR) Fontan graft modeling and evaluation software for physicians. A user study was performed to achieve 2 additional goals: (1) to evaluate the software when used by medical doctors and engineers, and (2) to explore the impact of viewing hemodynamic simulation results in numerical and graphical formats.

Methods: A total of 5 medical professionals including 4 physicians (1 fourth-year resident, 1 third-year cardiac fellow, 1 pediatric intensivist, and 1 pediatric cardiac surgeon) and 1 biomedical engineer voluntarily participated in the study. The study was pre-scripted to minimize the variability of the interactions between the experimenter and the participants. All participants were trained to use the VR gear and our software, CorFix. Each participant designed 1 bifurcated and 1 tube-shaped Fontan graft for a single patient. A hemodynamic performance evaluation was then completed, allowing the participants to further modify their tube-shaped design. The design time and hemodynamic performance for each graft design were recorded. At the end of the study, all participants were provided surveys to evaluate the usability and learnability of the software and rate the intensity of VR sickness.

Results: The average times for creating 1 bifurcated and 1 tube-shaped graft after a single 10-minute training session were 13.40 and 5.49 minutes, respectively, with 3 out 5 bifurcated and 1 out of 5 tube-shaped graft designs being in the benchmark range of hepatic flow distribution. Reviewing hemodynamic performance results and modifying the tube-shaped design took an average time of 2.92 minutes. Participants who modified their tube-shaped graft designs were able to improve the nonphysiologic wall shear stress (WSS) percentage by 7.02%. All tube-shaped graft designs improved the WSS percentage compared to the native surgical case of the patient. None of the designs met the benchmark indexed power loss.

Conclusions: VR graft design software can quickly be taught to physicians with no engineering background or VR experience. Improving the CorFix system could improve performance of the users in customizing and optimizing grafts for patients. With graphical visualization, physicians were able to improve WSS percentage of a tube-shaped graft, lowering the chance of thrombosis.

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Bifurcated graft designs showed potential strength in better flow split to the lungs, reducing the risk for pulmonary arteriovenous malformations.

(JMIR Cardio 2022;6(1):e35488) doi:10.2196/35488

KEYWORDS

virtual reality; congenital heart disease; surgical planning; usability study; heart; surgery

Introduction

Congenital heart disease is the most common birth defect found in nearly 1% of births worldwide [1]. Those patients who are diagnosed with single ventricle heart defect (SVHD), a rare type of congenital heart disease, experience mixed circulation of oxygenated and deoxygenated blood flows. Patients with SVHD receive 3 stages of life-saving surgery—Norwood, Glenn, and Fontan—to direct the deoxygenated blood flow to the lungs without going through the heart. Stage I, or the Norwood procedure, reconstructs the aortic arch, connecting it to the right ventricle, and a systemic-to-pulmonary artery shunt is placed [2]. At stage II, the Glenn procedure, a superior cavopulmonary anastomosis is created by connecting the superior vena cava (SVC) to the right pulmonary artery (PA) [3,4]. Stage III, the Fontan procedure, involves suturing a vascular graft between the inferior vena cava (IVC) to the PA to allow passive flow of venous blood to the lungs for oxygenation. When post-Fontan surgery circulation does not provide ideal hemodynamics, patients may have increased risk of elevated PA pressure, anatomic abnormalities of the PAs, atrial-ventricular valve regurgitation, and poor ventricular function [4].

Advances in medical imaging scanning and 3D-printing techniques have been showing great potential for customizing Fontan grafts. One of the customization approaches is known as tissue-engineered vascular grafts (TEVGs), which uses biocompatible material to facilitate the growth of neotissue, including collagen, vascular muscle, and endothelial cells [5,6]. One of the prominent strengths of the growth of neotissue is the patency [7], allowing an implanted graft to grow over time along with patients [8]. It is also believed to be more thrombo-resistant and less infectious than are comparable synthetic grafts [9]. These characteristics could support long-term benefits for Fontan procedures. TEVGs involve 3D-printing techniques, such as casting, electrospinning, and modular construction, that can fabricate any shape of a TEVG scaffold [10]. Since synthetic grafts are conventionally limited to specific designs (ie, cylindrical tube-shaped and bifurcated), being able to fabricate a scaffold allows for more patient-specific operations.

3D-printed scaffolds can be modeled using various approaches including computer-aided design (CAD) software [11], graft modeling software (such as SURGEM [12]), and unconstrained clay modeling [13]. CAD software is the most widely used tool for parameterizing a graft design [11,14,15]. Despite its popularity, CAD's complex parametric design process requires extensive training and practice, which can be a significant challenge for physicians. SURGEM and unconstrained clay modeling are 2 great alternatives which enable physicians to perform the modeling tasks more easily and quickly. SURGEM is a tablet-based heart-specific surgical planning software [12]. It provides hole filling, stenosis repair, and Fontan graft design features. In SURGEM, the diameter, center line, and anastomosis region are defined, supporting the design of a cylindrical Fontan graft. The designed grafts using SURGEM may not match the size of the native IVC because they are limited to cylindrical designs [16]. Furthermore, since anatomies are complex and volumetric, lack of depth perception may challenge the design process. Unconstrained clay modeling involves molding physical clay onto a 3D-printed model of the total cavopulmonary connection (TCPC) anatomy [13]. This method does not require significant training to operate. However, relying on 3D-printed TCPC anatomy and clay makes it difficult for precise control, and small form changes can have dramatic consequences. Additionally, detailed viewing and reporting, design saving, and future edits are not straightforward with these techniques.

The ability to produce graft designs alone is not sufficient to optimize Fontan procedures. Without accounting for the flow inside each graft design, a patient may experience increased risk of medical complications. Multiple studies have emphasized the importance of a low indexed power loss (iPL) [17,18], a balanced hepatic flow distribution (HFD) [19,20], and a low nonphysiologic wall shear stress percentage (%WSS) [13]. High iPL is correlated with a greater chance of exercise intolerance [21], an unbalanced HFD is associated with pulmonary arteriovenous malformations [22], and low %WSS regions are associated with a higher chance of clot formation [23]. Evaluating these hemodynamic performances can be done using physical models or computational fluid dynamic (CFD) simulations. The physical setup entails 3D printing a modeled graft and running blood-mimicking fluid through it. Advanced imaging techniques, such as 4D flow magnetic resonance imaging, and optical imaging methods, such as particle image velocimetry [24], are used to measure the flow velocity field for computing WSS and HFD. iPL can be measured by pressure sensors at the boundaries on the printed grafts [25,26]. These approaches, however, require each design modification to be printed and tested. Thus, the physical setup for measuring hemodynamic performances is labor and time intensive. Physical testing is also limited by spatial resolution, signal noise, and segmentation errors. As a mathematical method for calculating fluid flow, CFD can reduce or even overcome these limitations [27,28]. It can visualize multiple flow properties inside any shape of grafts on a computer without the need to purchase any devices or print the actual models. The accuracy of CFD simulations is widely recognized and has been validated by multiple in vivo and in vitro studies [25,29-31]. However, there needs to be further development in tools that bridge 3D modeling and CFD. Most available tools for performing these tasks are complicated and require hours of

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training. In our previous study, we developed our first prototype of virtual reality (VR) vascular graft design software, CorFix [32]. The first prototype of CorFix integrated diagnosis, tube-shaped graft design, free-form graft design, and 3D export features. The diagnosis feature consisted of rotation, zoom in and out, anatomy clipping, annotation, and screenshot. The free-form graft design included pushing and pulling methods for manipulating a surface mesh of a designed tube-shaped graft. Even when the software was evaluated by engineers with extensive CAD training, CorFix outperformed CAD software in time and graft design quality. In this study, we developed a significantly improved second version of CorFix, modifying the VR interface and adding bifurcated graft design, design export and import, and CFD visualization features. Although engineers were proven capable of completing the graft design task, we focused here on enabling and evaluating the ability for physicians to manage the design task. By evolving the CorFix software, we expect to remove the uncertainty around the evaluation of surgical feasibility and preference. We also anticipate reducing communication and discussion times for patient-specific surgical planning by avoiding the back-and-forth communication between multiple parties. There are 2 objectives to this study: (1) to evaluate the use of the software by medical doctors and engineers and (2) to explore the impact of viewing hemodynamic simulation results in numerical and graphical formats. Our study included usability testing and design performance evaluations where we compared CorFix designs created by 4 medical doctors and 1 biomedical engineer for an actual surgical case.

Methods

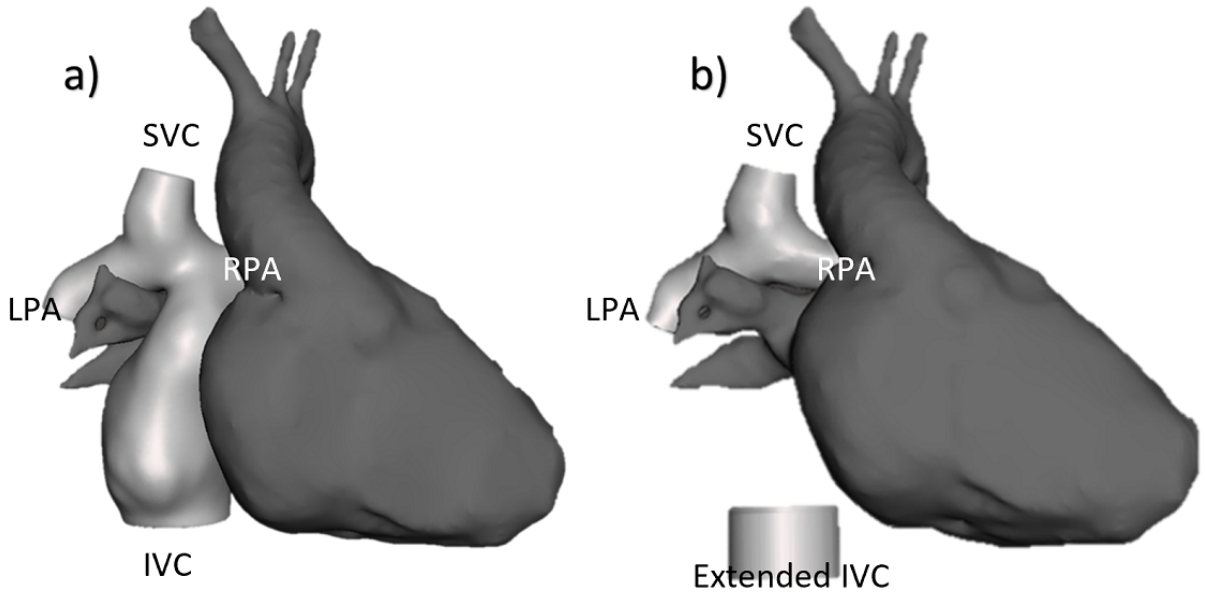
Ethics Approval

This study was approved by the investigational review board at Children's National Hospital (reference number: Pro00009721).

Medical Image Selection and Acquisition

One anonymized post-Fontan procedure imaging data set was acquired via magnetic resonance imaging. The data set was exported as a DICOM file and then manually segmented into two 3D models using Mimics software (Materialise): a (1) TCPC model and (2) a heart model without the TCPC anatomy (Figure 1a). CFD simulation was performed on the TCPC anatomy to evaluate its hemodynamic performance. For the experiment, the sutured vascular graft was virtually removed from the TCPC anatomy, resulting in 2 separate anatomies including the IVC and Glenn (ie, PA and SVC). The native IVC surface was extruded 10 mm inferiorly using SolidWorks software (Dassault Systèmes) to show the direction of the native IVC (Figure 1b).

Figure 1. Patient's Fontan anatomy. (a) The 3D models of the anonymized patient anatomy: heart (dark gray) and total cavopulmonary connection (light gray). (b) Patient anatomy with Fontan IVC to Glenn conduit removed and 10-mm inferior extrusion on the IVC. LPA: left pulmonary artery; IVC: inferior vena cava. RPA: right pulmonary artery; SVC: superior vena cava.



CorFix Development

The VR surgical planning software, CorFix, was developed based on the Unity 3D engine. The software-running platform was an Alienware Aurora R8 (Dell) with an Intel Core i7-9700 processor, a NVIDIA GeForce RTX-2080Ti, and 16 GB of RAM. An Oculus Rift S was used for displaying CorFix in full-immersive VR. Touch controllers (Oculus Rift) were integrated into the system for interacting with the interface. CorFix was previously designed to perform simple diagnosis (ie, zoom, rotation, label, ruler, and clipping) and modeling (ie, cutting vessels, parametric modeling, and free-form modeling) tasks. This version of CorFix had a modified user interface to accommodate clinicians untrained in VR, modeling software (eg, CAD), or CFD. The interface was adapted to allow users to intuitively design patient-specific vascular grafts in a short amount of time and integrate image analysis in the workflow.

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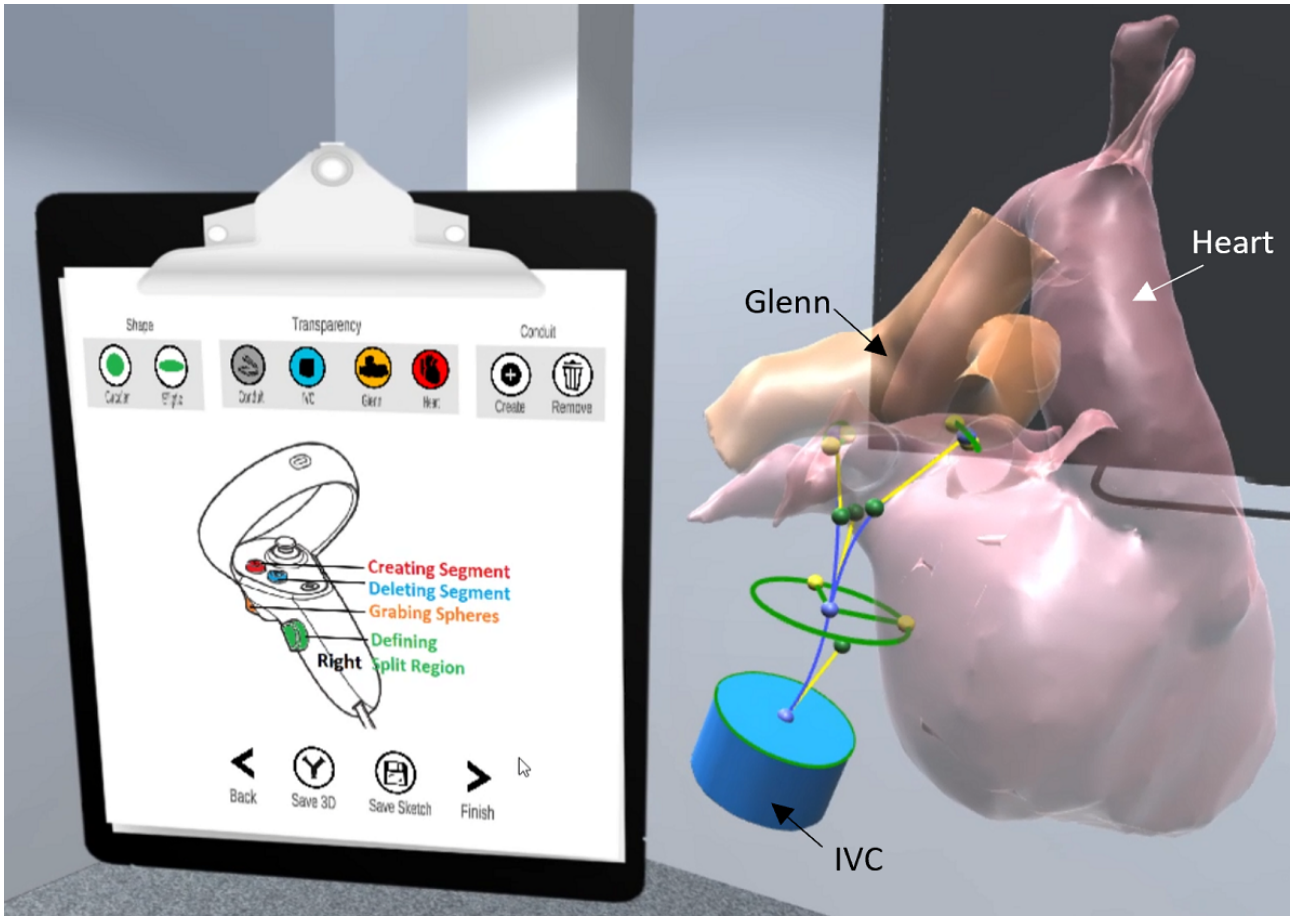
CorFix Interface for Graft Design

The Corfix interface was designed to support simple memory recall, allowing for a short, 1-time, 10-minute tutorial. A virtual clipboard was used as an access point for menu and Oculus controller information. The top row contained icons that support the designing of a tube-shaped or bifurcated graft. Icons were designed to match the color and shape of the corresponding geometry and anatomy. In the center of the clipboard, a diagram of the Oculus controller and its functionality were visualized. The bottom row contained menus that are necessary when the design process is completed (Figure 2). A "Save 3D" menu option was included for exporting the designed graft to a 3D-formatted OBJ file. The "Save Sketch" menu was included as a newly developed feature to save the current graft design for future edits.

Figure 2. Screenshot of a user creating a bifurcated graft using CorFix. IVC: inferior vena cava



Design Export and Import Feature

The import process saves all information needed to reconstruct the graft designs using the same algorithm used to construct the conduits. It first saves the transform information of the heart, Glenn, and the graft. The location and radii of the Bezier curve are then stored. These data are then exported into 1 CSV (comma-separated value) file in the aforementioned order. The design import feature works by parsing the saved file from top to bottom and then reconstructing the scene in that order.

Bifurcated Design Feature

The minimum design parameters for a bifurcated graft were 2 anastomosis regions and 1 split region (Figure 3a). For defining the anastomosis location, a center blue sphere was modified. Two yellow spheres were located near their respective geometry control points for defining the radii of the ellipse. These yellow spheres were grabbed and adjusted by the Touch controller. Subsequently, through use of a polar equation for an ellipse, multiple radii along the ellipse were then calculated and stored.

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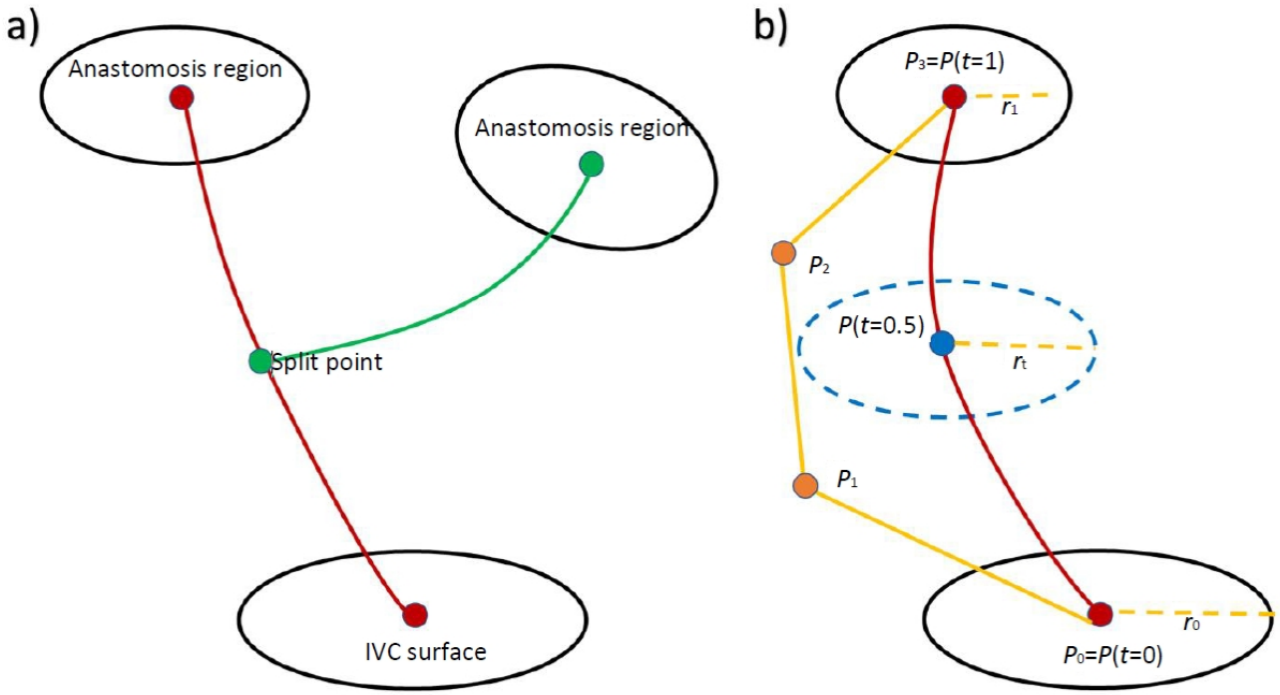
Figure 3. Schematic of Fontan graft designs. (a) Minimum design parameters for a bifurcated graft and (b) the cubic Bezier curve and radii interpolation diagram. IVC: inferior vena cava.



These calculated points were connected to the center of the ellipse to make triangular meshes, forming a surface. Two cubic Bezier curves were used to define the pathways and girths of the bifurcated graft. The first Bezier curve used the center of the native IVC surface and a user-defined anastomosis region. The second Bezier curve used the center of another anastomosis region and a user-specified split region of the graft. The formula for the pathways was as follows:

$$P(t) = P_0 (1 + t)^3 + P_1 (3t(1 - t)^2) + P_2 (3t^2 (1 - t)) + P_3 (t^3) \quad \textbf{(1)}$$

where P_0 and P_3 are anchor points which represent the center points of 2 different surfaces; and P_1 and P_2 are handles which define the direction and strength of the pathways, with the variable t ranging from 0 to 1 (Figure 3). Users were given an option to add as many anchor points as they wanted for more precise and complex control of the pathways. Adding an additional anchor point splits a single Bezier curve into 2 cubic Bezier curves. Two adjacent handles were automatically created at each anchor point. Connecting elliptic meshes and the native IVC surface along the pathway required the 3 following steps of interpolation:

$$\Delta = r_1 - r_0 \quad \textbf{(2)}$$

$$f(t) \quad \textbf{(3)}$$

$$r_t = r_0 + \Delta \cdot f(t) \quad \textbf{(4)}$$

where Δ is the difference between the radii from one center point to another. For example, r_1 could be one of the radii from the anastomosis region and r_0 could be one of the radii from the native IVC surface. $f(t)$ is the interpolation adjustment factor at t. The letter t represents any location on the Bezier curve. The center points of r_0 and r_1 are defined as 0 and 1 for t.

Hemodynamic Simulation Visualization

Hemodynamic simulation results were outputted in .h5 format. A data import and transform script was developed using MATLAB (MathWorks) since the .h5 format is not supported in Unity. The script consisted of 3 parts: data size, hemodynamic performance summary, and raw WSS values. The data size rows summarized the number of graft designs that were simulated and the total length of the raw WSS values. The hemodynamic performance summary contained information on iPL, %WSS, and HFD on each graft. The raw WSS values are composed of actual WSS values on each x, y, and z coordinate of a graft. These parts are concatenated into 1 CSV file, which is then imported into Unity. As a default, minimum and maximum WSS are set to 0 and 1, respectively. The maximum WSS can be changed by scrolling a slider on the clipboard towards the right. The maximum threshold of the slider is automatically identified by calculating the biggest WSS value from the CSV file. All points with nonzero WSS values are rendered using graphics processing unit acceleration and display relevant data regarding that point cloud. The graphics processing unit acceleration approach enables real-time point cloud rendering that corresponds to the slider. The rendered point cloud was grabbable and rotatable for users to study in detail or to match its orientation to their view of current designed graft (Figure 4).

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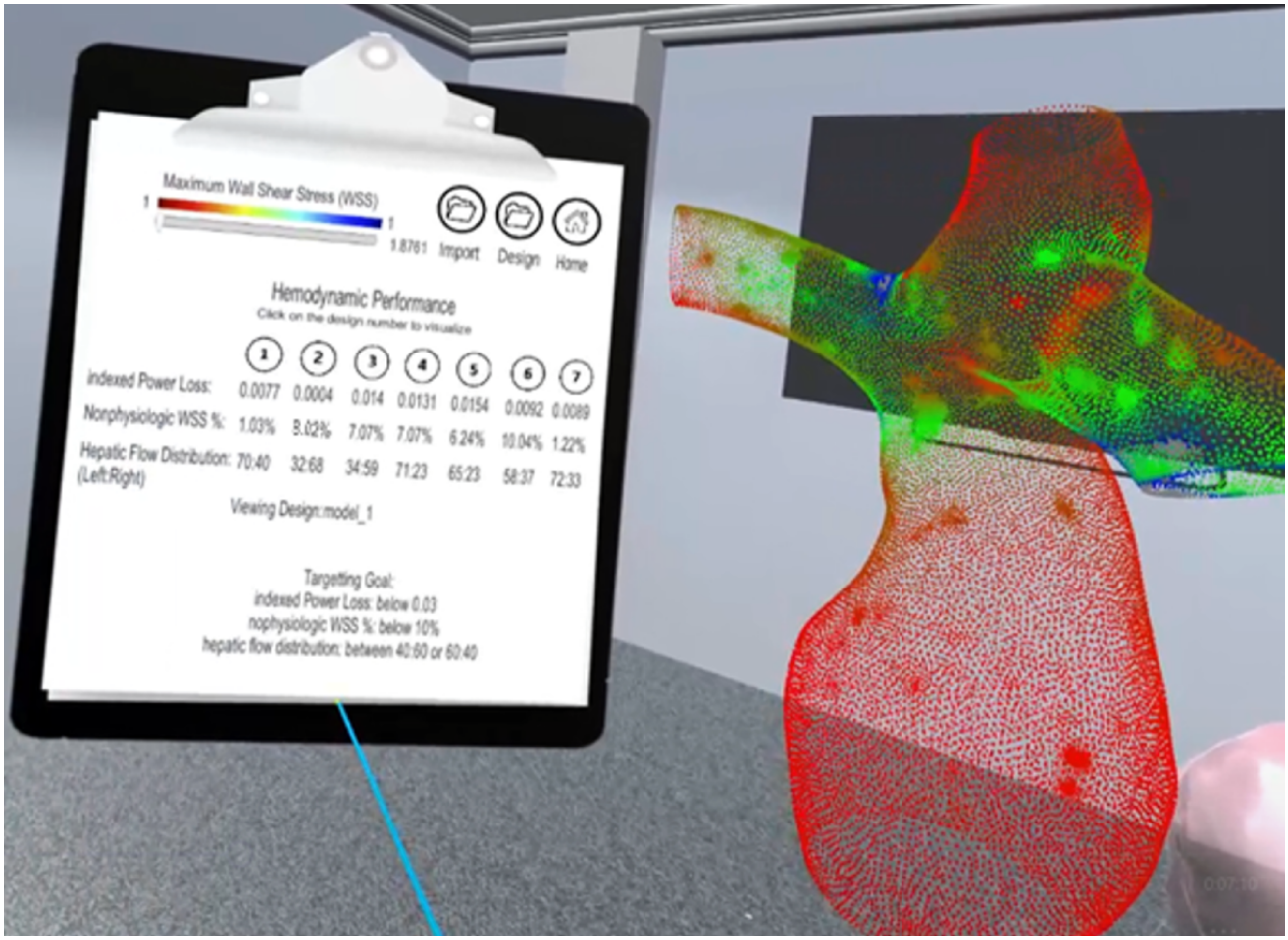
Figure 4. Screenshot of the hemodynamic simulation results of clipboard and point cloud rendering using the percentage of nonphysiologic wall shear stress output values.



CFD Simulations

Benchmark Hemodynamic Performance Parameters

The hemodynamic performance parameters included iPL, %WSS, and HFD. iPL is a dimensionless value of a pressure difference between the Fontan graft and the PA. It is normalized using a patient's body surface area. High iPL values have an increased chance of deteriorated cardiac performance and exercise capacity [33]. The iPL is calculated as follows:

$$iPL = \text{(5)}$$

where BSA is the body surface area of the patient, p is the static pressure, ρ is the density of the blood, v is the velocity, Q is the flow rate, and Q_s is the systemic venous flow that is equivalent to the sum of all inlet flow rates. The WSS is defined as a force created against the surface of the graft by the blood. A healthy physiologic range of venous WSS falls between 1 and 10 *dyne*/cm^2. If WSS is below the lower threshold, there could be an increased chance in thrombus formation on the surface of the graft [34]. The ratio of the areas that are below 1 *dyne*/cm^2 has been identified as the nonphysiologic regions. Its percentage against the total area was calculated for %WSS as follows:

$$\%WSS = \frac{N_A}{N} \times 100$$

where N_A is the number of WSS values below 1 *dyne*/cm^2 on the graft, and N is the total number of WSS values. The HFD is a ratio of the flow split to the PA from the Fontan. Unbalanced flow split may result in higher risk of pulmonary arteriovenous malformation [35]. HFD was calculated using a 1-way coupling Lagrangian particle-tracking method. This involves releasing massless infinitesimal particles at the IVC (N_{IVC}). The number of particles that pass through each side of the PA (N_{LPA} and N_{RPA}) is then counted as follows:

$$HFD_{LPA} = \frac{N_{LPA}}{N_{IVC}}$$

$$HFD_{RPA} = \frac{N_{RPA}}{N_{IVC}}$$

The number of total particles varies and depends on the surface area of the inlets. The particles are equally spaced from each other. This study set the healthy ranges of each benchmark parameter as below 0.03 for iPL, below 10% for %WSS, and within the range of 40% to 60% for the HFD ratio.

CFD Simulations

Ansys Fluent 19 (ANSYS Inc) was used to make extensions at inlet and outlet boundaries. The inlet, IVC, and SVC, were extruded by 10 times their largest diameter. The outlets, that is the left and right PA, were extruded by 50 mm. These extensions acted as a mechanism for developing a stable blood velocity

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profile. The CFD simulation was performed by solving steady 3D Navier-Stokes equations with Newtonian fluid and rigid wall assumptions. A calculation for the Reynolds number was implemented to assess the laminar flow of a patient's anatomy.

Pilot Usability Testing

Recruitment

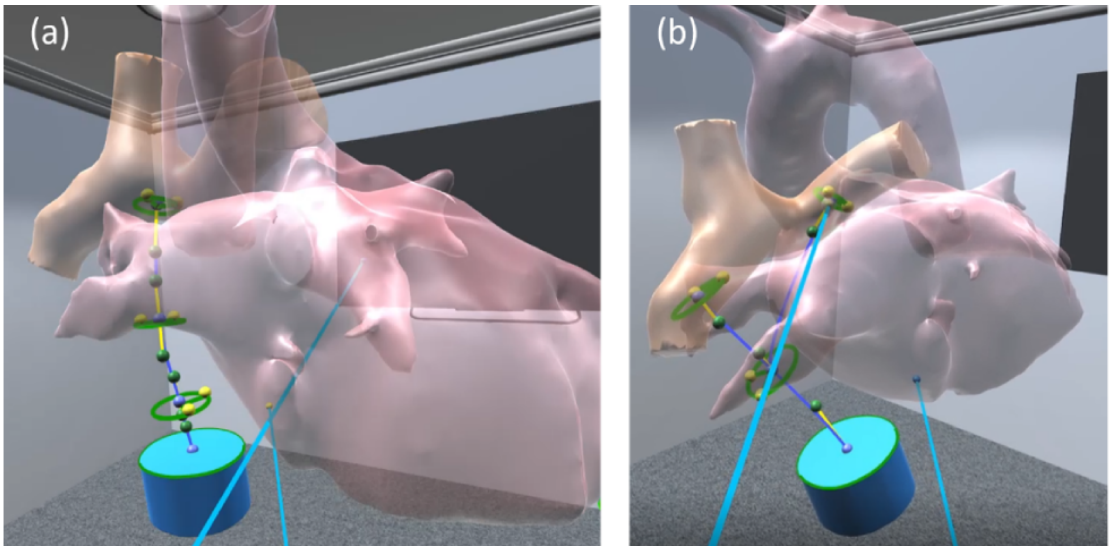
The institutional review board at the Children's National Hospital in Washington, DC, approved this study. The study was advertised by sending emails to the groups of residents, fellows, cardiac specialists, and medical engineers. A total of 5 voluntary participants were recruited including 1 fourth-year resident, 1 third-year cardiac fellow, 1 pediatric intensivist, 1 pediatric cardiac surgeon, and 1 biomedical engineer. All participants gave informed consent prior to their participation.

Experimental Process

Before the experiment, all participants were queried about their knowledge on the Fontan procedure and vascular grafts. Those who did not have a strong understanding about the topics were given a short tutorial. The tutorial covered anatomy of patients with SVHD, surgical repair for SVHD, and the shapes of Fontan grafts in 3 PowerPoint (Microsoft) slides. All participants then received a tutorial on the 3 benchmark parameters that would be calculated to identify the performance of their Fontan graft designs. This tutorial did not include any information about the relationships between each benchmark parameter and the graft design parameters. The participants were informed that %WSS is negatively correlated with iPL. Healthy ranges of each benchmark parameter were visually provided inside the VR environment as a reference. The last tutorial was for the CorFix interface and took about 10 minutes. None of the participants had prior experience with VR, requiring the CorFix tutorial to include information about the hardware (Oculus). During the CorFix tutorial, participants wore the gear and went through the following topics with verbal feedback: importing anatomies, interacting with the anatomies, designing basic tube-shaped and bifurcated Fontan grafts, making anatomies transparent, visualizing CFD results, and modifying the existing tube-shaped design.

After it was confirmed there were no further questions about the VR gear or CorFix software, participants created and exported 3D models of 1 bifurcated and 1 tube-shaped Fontan graft (Figure 5). There was no time limit for designing the graft. The second part of the experiment involved evaluating hemodynamic performances of the patient's anatomy along with 6 other anatomies that had 1 design parameter variation. The variations included the suturing region angled leftward, rightward, and upward; having a smaller anastomosis region; and offsetting the suturing region toward the left and right. None of these anatomies were optimal in any of the 3 benchmark parameters. All participants made individual decisions about the designs to find patterns or improvements for further modifying a previously designed tube-shaped graft. The participants were not required to modify their design. Three hard-printed surveys were provided at the end of the design modification. The entire experiment was scripted to provide a uniform experience.

Figure 5. A participant creating a (a) tube-shaped and a (b) bifurcated Fontan graft on CorFix during the experiment.



Surveys

All participants filled out a digital demographic survey prior to the experiment, including questions about their position, level of VR experience, knowledge and experience on the Fontan procedure, and the level of training on fluid dynamics. Three hard-printed surveys were provided at the end of the study. The System Usability Scale (SUS) and the Usefulness, Satisfaction, and Ease of Use Questionnaire (USE) were used to measure the usability of the system. To identify the level of sickness when using VR gear, the Simulator Sickness Questionnaire (SSQ) was provided.

Results

Design Times

Participants spent an average of 5.49 minutes creating 1 tube-shaped graft and 13.40 minutes creating 1 bifurcated graft. An average of 2.92 minutes was spent modifying the tube shape after it was created. This time includes reviewing the native

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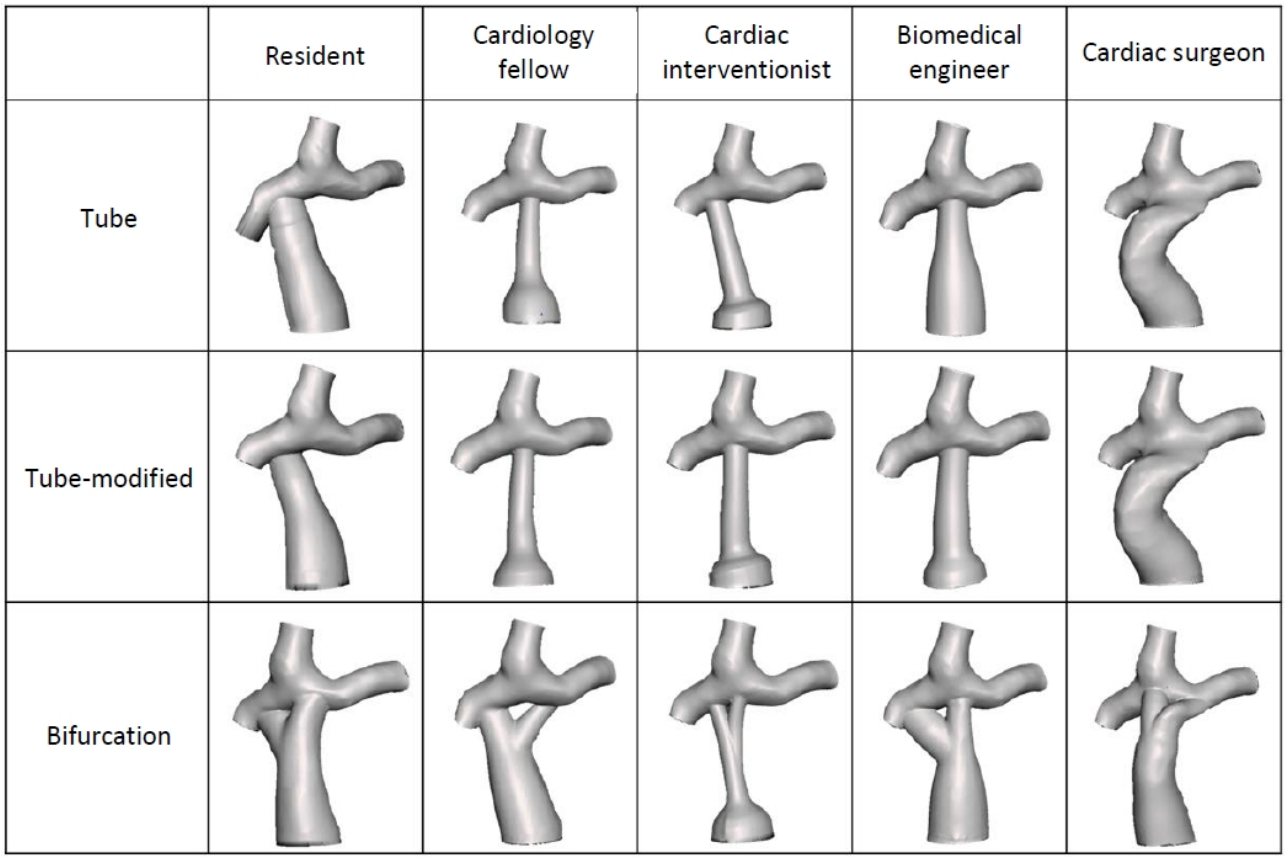
patient model and the 6 design variations. The summary of design times and actual designs are provided in Table 1 and Figure 6.

Table 1. Summary of graft design and modification times.

	Tube-shaped	Modified tube-shaped	Bifurcation
Time (min), mean (SD)	5.49 (2.35)	2.92 (1.67)	13.40 (3.48)
Minimum time (min)	2.50	2.49	9.45
Maximum time (min)	8.10	5.07	16.57

Figure 6. Summary figure of the Fontan graft designs.



Hemodynamic Performance

Native Fontan Patient

The patient Fontan data set without modifications showed suboptimal hemodynamic performance. with 55.36% of the Fontan anatomy under nonphysiologically optimal WSS, unbalanced HFD with 72.72% of hepatic flow going to the left PA, and an iPL of 0.0086, indicating minimal flow change within the anatomy (Figure 7).

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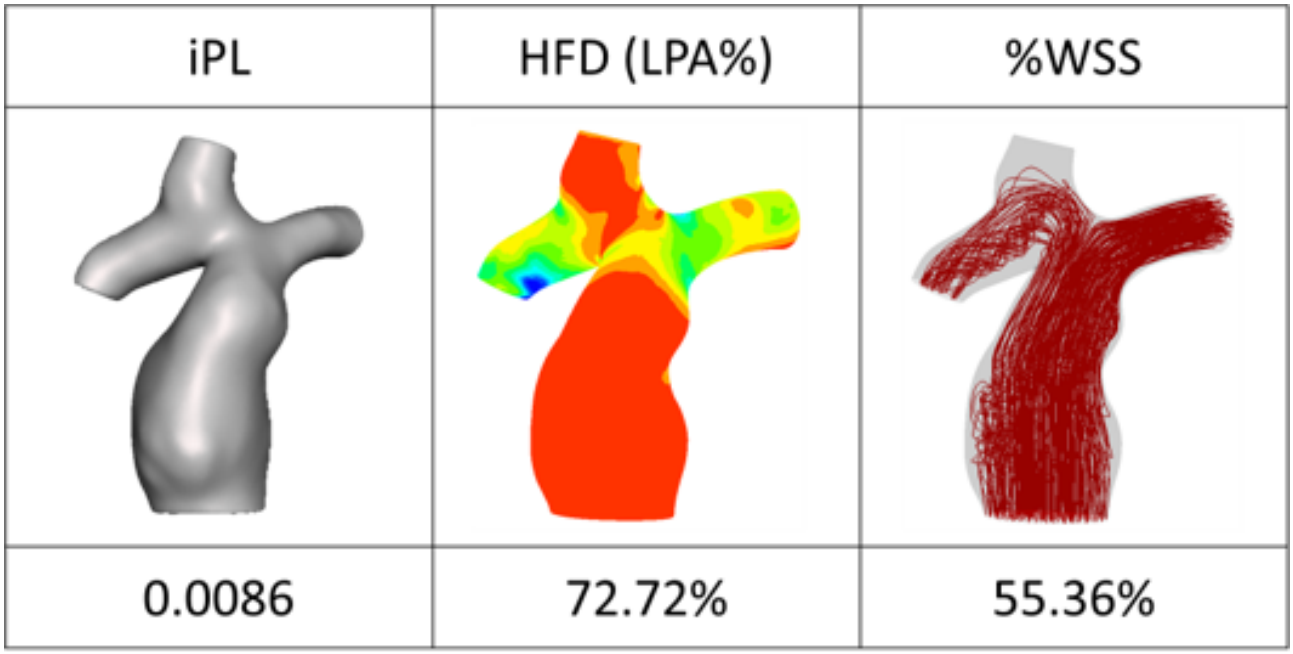
Figure 7. Hemodynamic performance of the provided Fontan data set without any modifications. %WSS: percentage of nonphysiologic wall shear stress; HFD: hepatic flow distribution; iPL: indexed power loss; LPA: left pulmonary artery.



Tube-Shaped and Bifurcated Grafts

Each participant produced 1 tube-shaped and 1 bifurcated Fontan graft. CFD simulations were performed on each of the graft designs. The detailed hemodynamic results are provided in Figure 8. Regardless of the shape of the graft, all participants were able to create designs that were much lower in %WSS compared to that of the surgical case. However, none of the designs were under the safe range of 10% or below. The bifurcated Fontan graft generally showed an optimal range of HFD, between 40% and 60%. All graft designs had higher iPL values than did the native Fontan surgical case.

Figure 8. Summary of computational fluid dynamics simulations on the participants' Fontan graft designs. %WSS: percentage of nonphysiologic wall shear stress; HFD: hepatic flow distribution; iPL: indexed power loss; LPA: left pulmonary artery.

	Resident		Cardiology fellow		Cardiac interventionist		Biomedical engineer		Cardiac surgeon	
	Tube	Bifurcation	Tube	Bifurcation	Tube	Bifurcation	Tube	Bifurcation	Tube	Bifurcation
iPL	0.0191	0.0095	0.0621	0.0168	0.0348	0.0521	0.0243	0.0155	0.0128	0.0161
HFD (LPA%)	22.95	43.14	67.71	28.21	29.44	36.45	57.59	40.78	66.04	52.47
%WSS	25.53	22.16	14.64	39.26	18.51	13.82	27.98	21.11	36.27	25.37

Tube-Shaped Graft Modification

All participants were asked to review 7 Fontan graft design variations based on the native Fontan surgical case. None of 7 design variations were considered optimal for the patient. The variations were created to assist the participants in identifying important design parameters that contribute to each hemodynamic benchmark parameter. After evaluating the design variations, the participants were given the freedom to modify their tube-shaped graft design to attempt to optimize the hemodynamic parameters. All those who modified their tube-shaped Fontan graft were able to reduce %WSS with an average improvement of 7.02%, ranging from 2.32% (cardiac interventionalist) to 13.28% (biomedical engineer; Figure 9).

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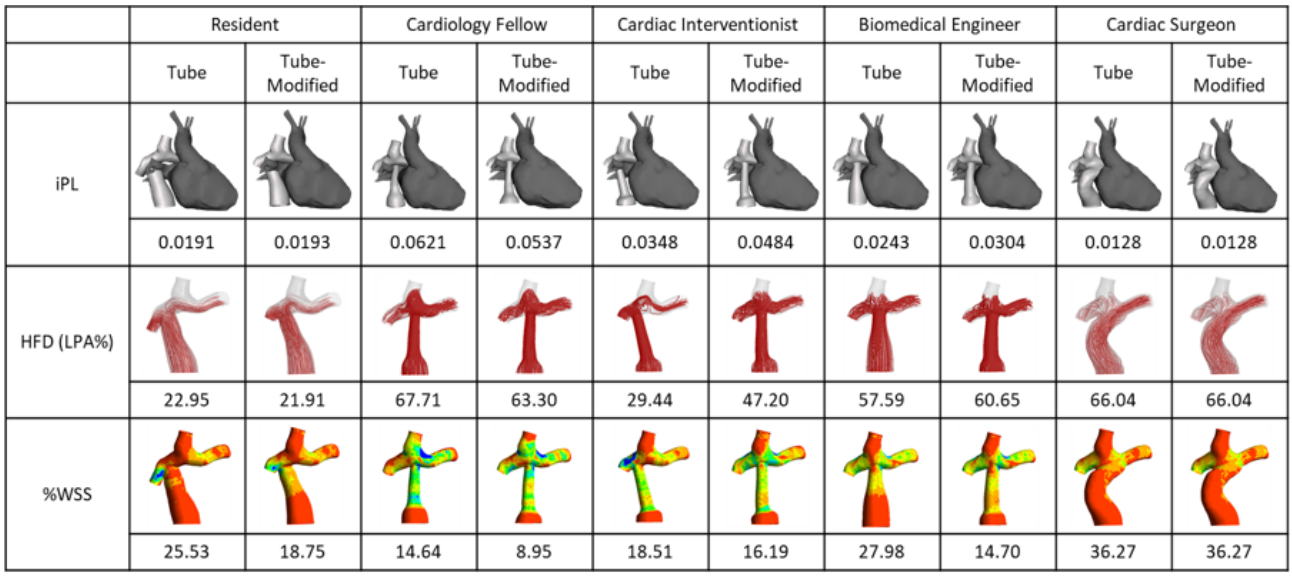
Figure 9. Summary table of computational fluid dynamic values after participants were presented with a set of prompt design variations; the %WSS values improved. %WSS: percentage of nonphysiologic wall shear stress; HFD: hepatic flow distribution; iPL: indexed power loss; LPA: left pulmonary artery.



Surveys

CorFix scored an average of 57 on the SUS questionnaire with a minimum score of 42.5 and a maximum of 67.5. The average SUS value suggests that the usability of our prototype was marginal. The average total score of USE (Table 2) for all participants was 4.38 out of a maximum of 7. This indicates that CorFix provides a good degree of usefulness, satisfaction, and ease of use. The results for the 4 dimensions associated with USE were (1) usefulness (mean 3.75, SD 1.03), (2) ease of use (mean 4.47, SD 1.38), (3) ease of learning (mean 5.10, SD 1.13), and (4) satisfaction (mean 4.60, SD 1.64).

The SSQ (Table 3) showed that using VR for designing, reviewing, and modifying Fontan grafts in less than 30 minutes could still cause a high level of nausea, oculomotor, and disorientation problems: on average, participants gave 11.45, 24.26, and 16.70 for each parameter of SSQ, respectively. The SD was 10.45, 26.48, and 30.18, respectively. The high SD of disorientation is due to 3 out of 5 participants reporting no disorientation problems.

Table 2. Summary table for the Usefulness, Satisfaction, and Ease of Use Questionnaire.

	Usefulness	Ease of use	Ease of learning	Satisfaction	Overall
Score, mean (SD)	3.75 (1.03)	4.47 (1.38)	5.10 (1.13)	4.60 (1.64)	4.38 (1.10)
Maximum score	2.63	2.36	3.25	1.71	2.57
Minimum score	5.38	5.64	6.00	5.71	5.53

Table 3. Summary table for the Simulator Sickness Questionnaire survey.

	Nausea	Oculomotor	Disorientation
Score, mean (SD)	11.45 (10.45)	24.26 (26.48)	16.70 (30.18)
Maximum score	0	0	0
Minimum score	28.62	68.22	69.60

Discussion

All participants were able to successfully design patient-specific conduits using the VR software with limited training. Although none of the participants had VR experience and CorFix was rated with marginal acceptable usability, designing tube-shaped and bifurcated grafts took less than 6 and 14 minutes, respectively. We used the time spent on a task as a surrogate for task difficulty and assessment of user adoption since there is sound literature indicating that among adult learners, time spent on a task is commensurate with task difficulty [36,37]. Even with design modification, less than 20 minutes could be spent to plan a Fontan procedure for each patient. Given the busy workload of surgeons and the urgent nature of patient care, being able to evaluate and customize a surgery for a patient in less than 20 minutes seems advantageous for the current surgical workflow. The study results mirror other recent studies for other surgical procedures demonstrating that VR is feasible and potentially useful but that satisfaction is limited by the technical limitations of the devices and the experience of disorientation [38-40].

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All participants expressed that if a real-time hemodynamic analysis of their designs were available, they would be able to better pinpoint the flaws of their designs. We, therefore, plan on further developing the CorFix software to add real-time simulation and visualization features. Our system has implemented button and pointer color changes and tactile feedback (ie, vibration) to bolster the interactivity inside the virtual scene. However, many participants struggled with depth perception and interactivity. Grabbing design control points or even clicking buttons on the virtual menu were frequently observed. Developing a feature or a device that could better support tactile feedback may enhance the usability and the innate learnability of the software.

The bifurcated graft designs were more successful in improving the hepatic flow distribution to a healthy range compared to the tube-shaped graft designs. During the experiment, all participants were asked to review 7 different tube-shaped Fontan grafts, which were derived from the actual surgical case although none of these design variations were surgically optimal. We hypothesized that the participants would be able to find patterns between design parameters and hemodynamic performance. Our study showed that when participants decided to modify their designs after reviewing other cases, they were able to design a more optimal graft by lowering %WSS. On average, %WSS was reduced by 7.02%. A biomedical engineer with a strong fluid dynamics education background showed the maximum %WSS reduction of 13.28%. Considering how lower %WSS is related to a lower risk of thrombosis for Fontan grafts, this design could provide a significant long-term improvement for the patient. We therefore infer that showing problematic regions in color, like a contour map, may help doctors without an engineering background to sufficiently identify low %WSS. iPL and HFD improvements were not consistent throughout the participants. Unlike %WSS, these hemodynamic parameters were presented only in numerical format. We hypothesize that with supplementary graphical visualization, users may be able to improve iPL and HFD more easily.

With the development of graft modeling and evaluation software like CorFix, physicians may be able to easily customize Fontan grafts and find an optimal graft configuration for long-term benefits. We plan to further develop CorFix by adding real-time CFD simulation and automatic graft optimization features for bolstering the graft design and evaluation process. Our next study will incorporate many of these changes and focus on recruiting more cardiac surgeons and testing against a larger number of patient surgical cases.

This study had a small sample for recruitment due to the limited number of doctors and their time availability despite 3 months of advertising and 2 additional months during the data collection period. We were able to include individuals with various levels of medical experience, which provides a broad spectrum of users and supports important preliminary insights. Our future study will involve greater participation and a larger number of patient cases to supplement the current results.

This paper reports the design of a VR software for patient-specific designs of vascular grafts that demonstrated feasibility and initial usability in a pilot usability study. All participants were able to create patient-specific graft designs with minimal training, needing on average only 5.49 minutes to design 1 tube-shaped graft and 13.40 minutes to design 1 bifurcated graft. Participants rated the design software with a good degree of usefulness, satisfaction, and ease of use. Further design improvements are needed to visualize hemodynamics during the design process, and a larger study is required to fully compare the VR design to current state-of-the-art surgical procedures.

Acknowledgments

This paper was supported by the National Institutes of Health (award #R01HL143468 and #R21HD090671).

Conflicts of Interest

BK, XL, and AK are founders of and hold shares of stock options in CorFix Medical, Inc. The results of the study discussed in this publication could affect the value of CorFix Medical Inc. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflict of interest policies.

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Abbreviations

%WSS: percentage of nonphysiologic wall shear stress
CFD: computational fluid dynamics
CSV: comma-separated value
HFD: hepatic flow distribution
iPL: indexed power loss
IVC: inferior vena cava
SSQ: Simulator Sickness Questionnaire
SUS: System Usability Scale
SVC: superior vena cava
TCPC: total cavopulmonary connection
USE: Usefulness, Satisfaction, and Ease of Use Questionnaire
VR: virtual reality
WSS: wall shear stress

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Edited by G Eysenbach; submitted 07.12.21; peer-reviewed by H Mehdizadeh, SS Amritphale; comments to author 05.02.22; revised version received 05.05.22; accepted 17.05.22; published 17.06.22.

Please cite as:
Kim B, Nguyen P, Loke YH, Cleveland V, Liu X, Mass P, Hibino N, Olivieri L, Krieger A
Virtual Reality Cardiac Surgical Planning Software (CorFix) for Designing Patient-Specific Vascular Grafts: Development and Pilot Usability Study
JMIR Cardio 2022;6(1):e35488
URL: https://cardio.jmir.org/2022/1/e35488
doi:10.2196/35488
PMID:35713940

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Original Paper

The Impact of a Mobile App on Participation in Cardiac Rehabilitation and Understanding Barriers to Success: Comparative Cohort Study

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Abstract

Background: Poor patient uptake of cardiac rehabilitation (CR) remains a challenge for multiple reasons including geographic, time, cultural, cost, and psychological constraints.

Objective: We evaluated the impact on CR participation rates associated with the addition of the option of mobile app–based CR (Cardihab) for patients declining conventional CR.

Methods: A total of 204 consecutive patients were offered CR following angioplasty; of these, 99 were in cohort 1 (offered conventional CR only) and 105 were in cohort 2 (app-based CR offered to those declining conventional CR). Patients in each cohort were followed throughout a 6-week CR program and participation rates were compared for both groups. Patients in cohort 2 declining both forms of CR were interviewed to assess reasons for nonparticipation.

Results: CR participation improved from 21% (95% CI 14%-30%) to 63% (95% CI 53%-71%) with the addition of the app (P<.001). Approximately 25% (9/39) of the group declining the app-based program identified technology issues as the reason for nonparticipation. The remainder declined both CR programs or were ineligible due to frailty or comorbidities.

Conclusions: Providing patients with the additional option of an app-based CR program substantially improved CR participation. Technology and psychological barriers can limit CR participation. Further innovation in CR delivery systems is required to improve uptake.

(JMIR Cardio 2022;6(1):e24174) doi:10.2196/24174

KEYWORDS

cardiac rehabilitation; digital health; smartphone app; Cardihab; participation rates; rehabilitation; cardiology; heart; app; barrier

Introduction

Although current guidelines recommend referral for cardiac rehabilitation (CR) following acute cardiac events, participation rates remain poor [1,2]. A recent estimate of the potential financial impact of increasing Australian CR participation rates from 30% to 50%-65% indicated net savings of Aus $46.7 million (US $33.9 million) to Aus $86.7 million (US $62.9 million) [2]. Clinical benefit is, however, more difficult to estimate, with some reviews questioning mortality benefit and others suggesting multicomponent CR programs may reduce overall mortality by up to 37% [3]. A Cochrane review of CR has confirmed lower rates of cardiovascular mortality and readmission among those who participate in exercise-based CR programs [4].

Conventional CR involves repeat attendance (usually 6-12 clinic visits) over a 6-week period. Previously described factors contributing to poor CR participation include issues of

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distance/transport, level of family support, gender roles, ethnicity, and cost [5-7]. Many currently available CR programs have not adapted to address these barriers. Additionally, changing patterns of treatment for acute events and much shorter hospital stays associated with more rapid return to work or home activities make prolonged conventional CR after an event less compatible with contemporary practice. Physical attendance may also be limited by a patient's body image, gender, cultural beliefs, comorbidity, and psychological factors [5], and the requirement for social distancing during the COVID-19 pandemic.

To determine if app-based CR might help to overcome some of these barriers, we conducted an observational study on patients referred for CR in our facility. We hypothesized that offering the additional option of app-based CR for those patients declining conventional CR would increase participation rates compared to offering conventional CR alone. Information on reasons for nonparticipation in CR were collected to increase understanding of barriers and help identify ways to improve CR uptake.

Methods

Study Design and Participants

This study was conducted as a before (cohort 1) and after (cohort 2) design. During an initial 3-month recruitment period (cohort 1), consecutive patients undergoing angiography in two cardiac hospitals (St Andrew's War Memorial Hospital and St Vincent's Private Hospital, Brisbane, Australia) were monitored by an experienced cardiac nurse. Uptake and completion of a 6-week conventional, face-to-face CR program was documented for patients with acute coronary syndrome or elective intervention with percutaneous coronary intervention. Patients referred for cardiac surgery were excluded from the study due to the likely delayed uptake of CR.

Following completion of the conventional CR program by cohort 1, a second series of patients (cohort 2) was monitored throughout a subsequent 3-month recruitment period. Those patients in cohort 2 who declined conventional CR were offered the option of participating in a digital CR program delivered via smartphone app (Cardihab). Following completion of the 6-week CR program by cohort 2, CR participation rates were compared for both cohorts. Patients were evaluated based on the mode of CR in which they initially agreed to participate.

Review of the study design was undertaken by a representative of the UnitingCare Health Human Research Ethics Committee, who determined the study was an extension of an existing clinical service using a validated tool and full ethics committee review was not required. Informed consent was obtained from all patients.

Description of App-Based CR Program

The app-based program consisted of an initial interview with a cardiac nurse, either face-to-face or remote, who admitted the patient to the web portal and collected baseline clinical data, including an assessment of prior physical activity levels and any constraints on physical activity. Patients with a compatible smart device (phone or tablet) were assisted to download either an iOS or Android version of the app. At first login, the 6-week program was activated and a series of daily and weekly tasks, based on the parameters entered during the admission interview, became visible in the app. Patients subsequently entered a variety of health measures, daily activity levels (type, intensity, and duration), and symptoms at regular intervals based on their specific clinical profile. The patient could visualize entered data in list or continuous graphical format. Activity reminders at scheduled intervals and encouragement messages were generated by the app.

Standardized education interventions were scheduled, with patient completion of these modules reported in the clinical portal. Patient understanding of the education modules was not assessed. Weekly telephone or video consultations were held between the patient and their cardiac nurse, who could review all app-derived data on relevant health measures, activity, and symptoms. Specific topics were scripted for weekly consultations along with discussion of clinical progress and barriers to completion of scheduled tasks.

Barriers to Uptake of CR

Patients declining either form of CR participated in a semistructured qualitative interview with their cardiac nurse; the interview included a set of baseline questions, with the flexibility for the nurse to explore patient responses in greater detail as required. Patient-reported reasons for nonparticipation were recorded and categorized.

Hospital Readmissions

For patients in cohort 2 (conventional CR, app-based CR, or no CR), the occurrence and cause of hospital readmissions within 12 months of the index cardiac event were retrospectively documented.

Statistical Analysis

Rates of participation in CR in cohort 1 and cohort 2 were compared with a Chi-square test or Fisher exact test depending on numbers. Comparison of continuous variables employed the Mann-Whitney *U* test. In all comparisons, a *P* value of <.05 was considered statistically significant. Confidence intervals for proportions were calculated using the Wilson score interval. The study was not powered to evaluate changes in other clinical endpoints such as weight, waist circumference, or systolic blood pressure, and no statistical analysis of these endpoints was performed.

Results

Principal Findings

A total of 204 patients were offered CR following a percutaneous coronary intervention; this included 99 patients in cohort 1 (74% male; median age: males 70 years, females 73 years) and 105 patients in cohort 2 (75% male; median age: males 66 years, females 71 years; Table 1). There was no difference in the gender distribution between the two groups (*P*=.81), however, comparison of age distributions within each gender showed that males were significantly younger in cohort 2 (*P*=.005). There was no significant difference in female ages between the two groups (*P*=.16).

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In cohort 1, a total of 21 patients (21%) undertook conventional CR, while in cohort 2, there were 43 patients (41%) that elected to undertake conventional CR (P=.002). Of the 62 patients (48 male) declining conventional CR in cohort 2, twenty-three (21 male) elected to participate in the app-based program. Overall, in cohort 2, there were 66 patients (63%) who undertook CR using either the conventional or app-based program. The increase in participation rate between cohort 1 and cohort 2 was statistically significant (P<.001).

As gender is a factor previously found to impact on CR participation [7], uptake by gender was evaluated. Participation by males in the CR program increased from 18% (n=13) in cohort 1 to 66% (n=52) in cohort 2 (P<.001). There was no significant difference apparent for females (8, 31% versus 14, 54%; P=.09). The increase in male participation arose from both an increased participation in the conventional program from 13 (18%) to 31 (39%), and a significant contribution from those taking up the app-based program (21/48, 44%).

Table 1. Summary of patient participation, age, and gender by mode of cardiac rehabilitation.

Variables	Cohort 1 (n=99)		Cohort 2 (n=105)		P value[a]
	Male	Female	Male	Female	
Patients approached, n (%)	73 (74)	26 (26)	79 (75)	26 (25)	.81
Median age (IQR)	70 (63-74)	73 (68-80)	66 (58-71)	71 (62-77)	Male: .005; female: .16
Conventional cardiac rehabilitation enrolled, n (%)[b]	13 (18)	8 (31)	31 (39)	12 (46)	.002
App-based cardiac rehabilitation enrolled, n (%)	N/A[c]	N/A	21	2	
Total cardiac rehabilitation uptake, n (%)[d]	13 (18)	8 (31)	52 (66)	14 (54)	.001

[a]P values for comparison between cohort 1 and cohort 2.

[b]Cohort one: 21 (21%, 95% CI 14%-30%); cohort two: 43 (41%, 95% CI 32%-51%). The Wilson score interval was used to calculate 95% CIs.

[c]N/A: not applicable.

[d]Cohort one: 21 (21%, 95% CI 14%-30%); cohort two: 66 (63%, 95% CI 53%-71%). The Wilson score interval was used to calculate 95% CIs.

Within cohort 2, patients participating in app-based CR were younger (median: 61 years versus 70 years, P=.005). Although the study was not powered to evaluate differences, trends were observed to higher weight (median: 90 kg versus 83 kg), higher BMI (median: 28.3 kg/m^2 versus 26.5 kg/m^2), and greater waist circumference (median: 105 cm versus 101 cm) in the app-based CR cohort.

There were 3 patients initially assigned to conventional CR who transitioned to app-based CR for completion of the program but they were counted as conventional CR based on their initial assignment. In addition, 2 patients in the conventional CR group and 1 in the app-based program commenced but did not complete CR.

Barriers to Uptake of CR

Patients declining CR in cohort 2 (n=39) were interviewed to elicit reasons for nonparticipation (Table 2). Of note, 9 (23%) identified technology issues (either device or operator) as reasons for not taking up app-based CR. Psychosocial reasons for nonparticipation were also recorded for 9 (23%) patients. In addition, 11 patients did not commence CR due to further scheduled cardiac procedures, with most indicating they would consider CR following completion of interventions.

Table 2. Patient-reported reasons for declining participation in cardiac rehabilitation (n=39).

Reason	Number (%)
Further cardiac procedure scheduled	11 (26)
Psychosocial issues	9 (23)
Technical concerns (device or operator) regarding app-based cardiac rehabilitation	9 (23)
Comorbidities (Alzheimer, hearing difficulties)	3 (8)
Unable to be interviewed or living outside Australia	3 (8)
Completed cardiac rehabilitation previously and feel another program will not be useful	2 (5)

Hospital Readmissions

Hospital readmissions within 12 months following the initial cardiac event for patients in cohort 2 are shown in Table 3. Readmissions were classified according to primary diagnosis as all-cause, cardiac-related, or bleeding-related. Although the study was not specifically designed to evaluate differences in readmission rates, cardiac readmission was observed to be very low (1/23, 4%) among the app-based (Cardihab) CR patients, considerably higher (13/43, 30%) for conventional CR patients, and 13% (5/39) for the patients who did not participate in any CR (P=.03). This may partly reflect a younger cohort in the app-based CR group (median age: 61 years, IQR 55-68 years versus conventional CR, median age: 70 years, IQR 62-74 years versus no CR, median age: 68 years, IQR 61-74 years).

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Table 3. Hospital readmissions within 12 months of index cardiac event.

Readmission data	No cardiac rehabilitation	Conventional cardiac rehabilitation	App-based cardiac rehabilitation
All participants			
Participants, n (% male)	39 (69)	43 (70)	23 (91)
Age (years), mean (IQR)	68 (61-74)	70 (63-74)	61 (56-69)
All readmissions			
Participants, n (% male)	10 (60)	21 (67)	5 (100)
Age (years), mean (IQR)	65 (61-75)	69 (63-73)	68 (66-70)
Proportion (95% CI)[a]	26 (15-41)	49 (35-63)	22 (10-42)
Cardiac readmissions			
Participants, n (% male)	5 (60)	13 (77)	1 (100)
Age (years), mean (IQR)[b]	66 (59-71)	69 (63-73)	68 (N/A[c])
Proportion (95% CI)[a]	13 (6-27)	30 (19-45)	4 (1-21)
Bleeding-related readmissions			
Participants, n (% male)	3 (67)	2 (100)	0 (0)
Age (years), mean (IQR)[b]	77 (N/A)	77 (N/A)	N/A
Proportion (95% CI)[a]	8 (3-20)	5 (1-15)	0 (0-14)

[a]Confidence intervals (95%) shown for proportions were calculated using the Wilson score interval.

[b]No IQR is provided where the number of cases is less than 5.

[c]N/A: not applicable.

Discussion

Principal Findings

Providing the additional option of an app-based CR program was associated with an increase in overall CR participation rate of 42%, from 21% (21/99) in cohort 1 to 63% (66/105) in cohort 2. The improved uptake in CR following the addition of an option for app-based CR suggests that a significant proportion of patients will benefit from the convenience and flexibility of a remotely delivered program.

A remote digital CR program using a smartphone app that communicates with a clinician portal can automate aspects of care delivery and standardize much of the content of conventional CR while tailoring a specific program for individual patient needs. A previous randomized controlled trial confirmed that an app-based program can deliver CR with at least comparable efficacy to conventional CR [8]. Other trials of digital CR programs using a mobile app have demonstrated improved participation and adherence to CR, improved exercise capacity [9], and reduced readmission rates over 12 months [10]. As patients may prefer conventional, digital, or blended models of care for a complex array of reasons, it is important to consider patient treatment preferences to help optimize completion rates. A recent Australian position statement addressing secondary prevention during the COVID-19 pandemic strongly recommended the use of eHealth strategies to continue delivering evidence-based therapies to patients [11].

Recent reviews of the potential of smart device apps in the long-term management of chronic diseases have concluded that apps have substantial potential to improve health outcomes [12-15]. One review noted, however, that significant improvements were recorded in 50% of the interventions that were solely app-based compared with 100% of the interventions where the app was a component of a clinical team management protocol [13]. The emphasis on continued close involvement by the clinical CR team is a likely key success factor for app-based CR and the inclusion of digital health apps should be considered as another tool in program delivery, rather than disruptive, for this model of care. Qualitative feedback from the app-based group in this study suggested patients placed a high value on continued monitoring from their clinical team.

Many patients attending CR sessions identify group dynamics and social interaction as positive motivating factors and will continue to select conventional, face-to-face CR as a preferred option. Future integration of virtual, private social media groups into app-based CR may reduce this preference effect. A recent randomized study using the WeChat social media platform to deliver CR demonstrated improved exercise capacity at 2 and 6 months, improvements at 12 months in coronary artery disease knowledge score, lower systolic blood pressure and heart rate, lower total and LDL cholesterol, and higher medication adherence in the digital CR group [16].

Addressing Barriers to CR Uptake

The provision of an app-based CR program can help overcome a number of the barriers associated with conventional CR, particularly the need for patients to travel long distances to attend, with the associated costs of transport and parking, as well as the barrier posed by social distancing restrictions implemented as a consequence of the COVID-19 pandemic. It

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also helps alleviate the time constraints associated with attending face-to-face CR, and has the capability to address cultural barriers associated with language and gender roles by providing programs in multiple languages, and the option for care coaches and family members to join the device program.

As previous experience [8] indicated that technology issues might be a significant factor limiting uptake of app-based CR, patients were interviewed to understand reasons for nonparticipation in CR. Technology issues were a substantial barrier for approximately 25% (9/39) of the cohort unable to undertake the app-based program, due to device issues or operator problems. Device issues included phones without internet connection or capability, problems with operating platforms, and older devices that did not support recent software versions. Operator problems included reluctance to use any type of app solution, difficulties with app downloads and account details, and a few instances of difficulty with manual data entry. Ongoing technology coaching by the CR team was required in some cases, supported by online video tutorials. Therefore, device suitability and a patient's technical literacy are important considerations for patient selection. Provision of loan or rental devices could help overcome device suitability issues. A worthwhile alternative to clinical staff providing technical support, suggested by patients to facilitate the adoption of a digital pulmonary rehabilitation program, is the creation of a peer-to-peer social learning environment to support patients with technology and motivation [17]. This approach could be considered for future app-based programs.

Anxiety or depression is present in at least 15% to 20% of patients after an acute cardiovascular event and this may be a barrier to the behavior change and adoption of a healthier lifestyle represented by CR [18]. These factors may also predispose patients to failure to complete CR, with a compounding effect on longer-term adverse outcomes [19]. It is likely that similar psychosocial factors contributed to the approximately 25% (9/39) of the cohort who declined taking up either modality of CR. App-based CR may alleviate some of the anxiety associated with conventional CR as activity levels can be customized and completed in private. Depression screening tools may also be incorporated into digital CR programs.

Hospital Readmissions

Readmission after major cardiac events is a significant and costly problem [1,3], with 30-day rates estimated between 6%-27% and 12-month rates estimated at 20%-30% [1,20]. This study was not powered to address differences in readmission rates but the very low rate of 4% observed for app-based CR compared to other groups is hypothesis generating. The younger and predominantly male app-based CR cohort may have had fewer comorbidities, which could partly explain this observation. This raises the important possibility of risk stratifying interventions to target higher risk groups and specifically measuring readmission outcomes in app-based CR compared to conventional approaches. Accurate assessment of risk status using a validated tool such as the PEGASUS-TIMI 54 score [21] in a larger prospectively designed trial employing app-based CR delivery should be considered.

Limitations

The findings of this work must be viewed in light of the study's limitations. As the effectiveness of the digital CR program had been tested in a previous randomized controlled trial [8], this study was intended to assess the real-world efficacy of a blended model of delivering CR. As a before-and-after study design without a control group, the outcomes are subject to biases associated with variations in patient characteristics and circumstances between cohort 1 and cohort 2. Although the basic distribution of males and females is similar in both cohorts, analysis suggests that the age of males in cohort 2 is significantly lower than that of males in cohort 1. This age disparity may account for some of the outcome differences noted in these two groups, particularly in terms of comorbidities that may have impacted hospital readmissions. Furthermore, the relatively small population involved in this study places significant limitations on any analysis involving subgroups.

Conclusion

A clinically validated app-based CR program can improve CR participation and should be considered as a standard component of a CR service, particularly for those patients who find conventional CR impractical, inconvenient, or unappealing. Study summary slides are available in Multimedia Appendix 1. Further trials are needed to assess the value of app-based risk factor modification on long-term clinical outcomes across the spectrum of coronary artery disease, from early diagnosis to long-term secondary prevention.

Acknowledgments

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Administrative and editorial support for manuscript development was provided by Donna Bartlett (DGB Health Communications) and funded by Cardihab Pty Ltd.

Conflicts of Interest

JTR and CS work within Queensland Cardiovascular Group, which is the clinical development partner for Cardihab Pty Ltd and a shareholder of Cardihab Pty Ltd. JC (deceased) worked within Queensland Cardiovascular Group. JTR is a director of Cardihab Pty Ltd. IS has no conflicts to declare.

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Multimedia Appendix 1
Study summary.
[PDF File (Adobe PDF File), 1161 KB - cardio_v6i1e24174_app1.pdf]

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Abbreviations

CR: cardiac rehabilitation

Edited by G Eysenbach; submitted 07.09.20; peer-reviewed by D Winchester; comments to author 29.09.20; revised version received 23.11.20; accepted 30.11.21; published 17.01.22.

Please cite as:
Rivers JT, Smith C, Smith I, Cameron J
The Impact of a Mobile App on Participation in Cardiac Rehabilitation and Understanding Barriers to Success: Comparative Cohort Study
JMIR Cardio 2022;6(1):e24174
URL: https://cardio.jmir.org/2022/1/e24174
doi:10.2196/24174
PMID:35037891

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Review

The Use of Mobile Apps for Heart Failure Self-management: Systematic Review of Experimental and Qualitative Studies

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Abstract

Background: Heart failure self-management is essential to avoid decompensation and readmissions. Mobile apps seem promising in supporting heart failure self-management, and there has been a rapid growth in publications in this area. However, to date, systematic reviews have mostly focused on remote monitoring interventions using nonapp types of mobile technologies to transmit data to health care providers, rarely focusing on supporting patient self-management of heart failure.

Objective: This study aims to systematically review the evidence on the effect of heart failure self-management apps on health outcomes, patient-reported outcomes, and patient experience.

Methods: Four databases (PubMed, Embase, CINAHL, and PsycINFO) were searched for studies examining interventions that comprised a mobile app targeting heart failure self-management and reported any health-related outcomes or patient-reported outcomes or perspectives published from 2008 to December 2021. The studies were independently screened. The risk of bias was appraised using Cochrane tools. We performed a narrative synthesis of the results. The protocol was registered on PROSPERO (International Prospective Register of Systematic Reviews; CRD42020158041).

Results: A total of 28 articles (randomized controlled trials [RCTs]: n=10, 36%), assessing 23 apps, and a total of 1397 participants were included. The most common app features were weight monitoring (19/23, 83%), symptom monitoring (18/23, 78%), and vital sign monitoring (15/23, 65%). Only 26% (6/23) of the apps provided all guideline-defined core components of heart failure self-management programs: education, symptom monitoring, medication support, and physical activity support. RCTs were small, involving altogether 717 participants, had ≤6 months of follow-up, and outcomes were predominantly self-reported. Approximately 20% (2/10) of RCTs reported a significant improvement in their primary outcomes: heart failure knowledge (P=.002) and self-care (P=.004). One of the RCTs found a significant reduction in readmissions (P=.02), and 20% (2/10) of RCTs reported higher unplanned clinic visits. Other experimental studies also found significant improvements in knowledge, self-care, and readmissions, among others. Less than half of the studies involved patients and clinicians in the design of apps. Engagement with the intervention was poorly reported, with only 11% (3/28) of studies quantifying app engagement metrics such as frequency of use over the study

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duration. The most desirable app features were automated self-monitoring and feedback, personalization, communication with clinicians, and data sharing and integration.

Conclusions: Mobile apps may improve heart failure self-management; however, more robust evaluation studies are needed to analyze key end points for heart failure. On the basis of the results of this review, we provide a road map for future studies in this area.

(JMIR Cardio 2022;6(1):e33839) doi:10.2196/33839

KEYWORDS

heart failure; self-management; mobile health; mobile app; secondary prevention; mobile phone

Introduction

Background

Heart failure affects approximately 40 million people worldwide [1]. A diagnosis of heart failure portends a poor prognosis, with a 12-month mortality rate of 17% for patients who are hospitalized and 7% for patients who are stable or ambulatory [2]. Hospitalization is associated with a 3-fold increased risk of death [3,4] and is preventable with good quality self-management [4-6], including symptom monitoring and taking prompt action when deterioration begins [4,7]. However, there are several barriers to achieving good quality self-management, such as lack of knowledge, symptom recognition, motivation, and confidence [8]. Addressing these can improve outcomes; yet, delivering such models for support at scale is challenging.

Mobile health (mHealth)—medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices [9]—has excellent potential for cardiovascular disease prevention [10-14]. In particular, app interventions seem promising as they can automate the self-monitoring of physiological data, facilitate symptom and medication tracking, and provide reminders and personalized feedback to promote patient engagement [15-17]. To date, no systematic reviews have focused exclusively on mobile apps to support self-management of heart failure. Previous mHealth systematic reviews on heart failure have mostly reported remote monitoring interventions using older technologies such as phone calls and interactive voice response to transmit data to health care providers, rarely focusing on supporting patient self-management [18-27]. A total of 3 nonsystematic reviews evaluated the content and quality of existing commercial heart failure apps and mHealth interventions without assessing their impact or patient perspectives [28-30].

Aims

This systematic review aims to examine the role of mobile apps in heart failure self-management, specifically, their impact on improving (1) clinical outcomes, (2) patient-reported measures, and (3) self-management knowledge and behaviors and in addition, examine the acceptability and feasibility of these interventions, as well as patient perspectives, needs, and preferences for specific app features.

Methods

Database Search

A systematic search of the literature was performed in October 2019 and updated in December 2021 on PubMed, Embase, CINAHL, and PsycINFO, using several search terms such as mobile apps, heart failure, and self-management (Multimedia Appendix 1). The reference lists of relevant articles and gray literature such as dissertations, theses, and conference proceedings were also screened to ensure that all eligible studies were captured. The search was limited from 2008 onward as app stores were launched in that year [31]. No language limits were applied.

Eligibility Criteria

Studies were included if they (1) focused on adult patients with heart failure, (2) involved an intervention comprising a mobile app to support heart failure self-management (ie, provision of education and support to increase patients' skills and confidence in managing their disease [32])—the mobile app could be a single component in the intervention or be combined with other intervention components (eg, wireless devices for remote monitoring)—(3) included any type or no comparison (eg, qualitative studies), (4) reported impact on any health outcome or patient-reported measure (eg, self-management and medication adherence) or focused on patients' perspectives, and (5) were a primary research study involving the use or testing of the mobile app intervention. Studies were excluded if they (1) did not involve the use of the app by patients with heart failure and (2) assessed interventions without a clear component of heart failure self-management (eg, patients using the app only to input data to be analyzed by health care professionals).

Screening

The screening form was piloted by 2 investigators before beginning the screening process. The 2 investigators independently screened studies based on the information in their titles and abstracts and then performed the full-paper screening. Disagreements were resolved through discussion between the reviewers or by a third reviewer. Cohen κ statistic was used to measure intercoder agreement in the initial and full-text screening [33].

Data Extraction and Synthesis

One of the reviewers extracted the following information from the included studies: author, year of publication, country, study design, sample size, population characteristics, study duration or intervention use time, intervention characteristics (eg,

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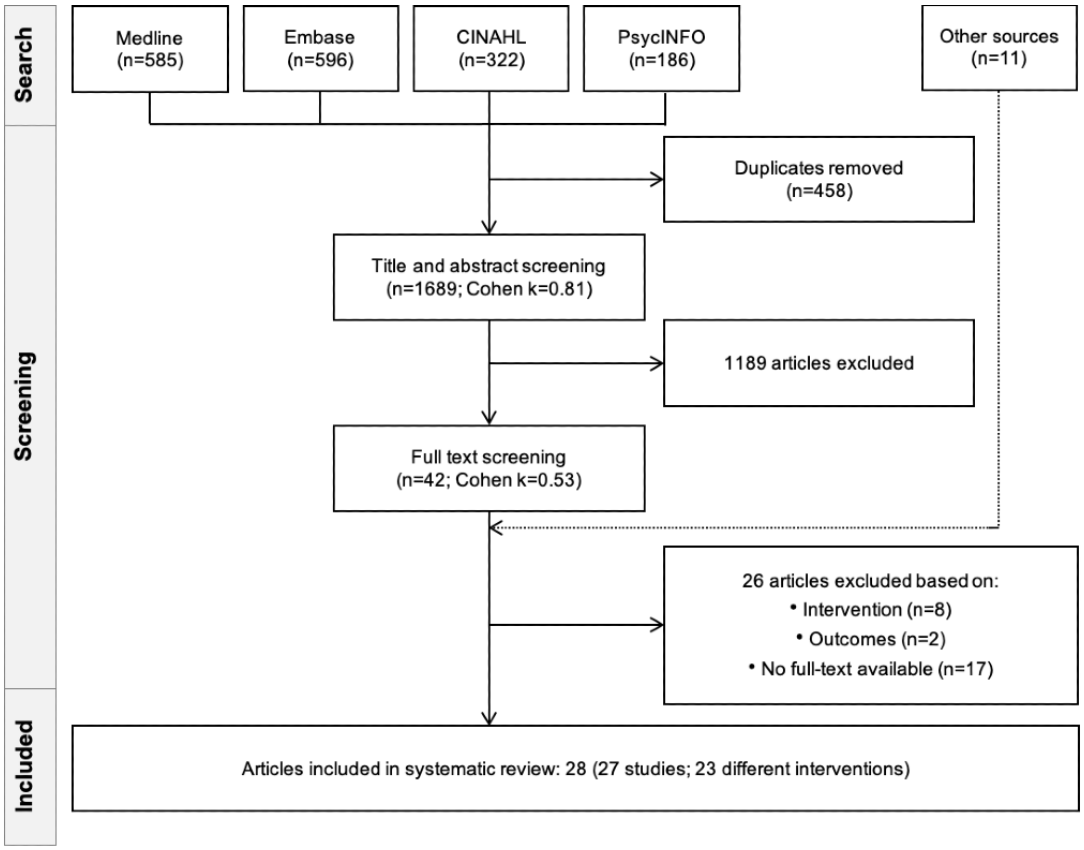
technology components and others, mobile app features, and presence or absence of personalization), comparison, outcomes, and main results. The 2 investigators reviewed the data extraction form for consistency. The coding of behavior change techniques (BCTs) according to the BCT taxonomy [34] was conducted by 1 researcher and reviewed by another. Studies' quality and risk of bias were appraised by 2 researchers using Cochrane's risk of bias tool [35] for randomized controlled trials (RCTs) and the *Risk Of Bias In Nonrandomized Studies of Interventions* [36] tool for other experimental studies. Disagreements were resolved by a third reviewer. We performed a narrative synthesis of the studies. The PRISMA (Preferred Reporting Item for Systematic Reviews and Meta-Analyses) 2020 statement was followed (Multimedia Appendix 2) [37], and the protocol was registered on PROSPERO (International Prospective Register of Systematic Reviews; CRD42020158041).

Results

Search and Screening Results

The database search retrieved 1689 citations, from which 458 (27.1%) duplicates were removed (Figure 1). After title and abstract screening of the 1689 articles, 1189 (70.4%) were excluded. Full-text screening was conducted for 42 articles, and a further 26 (62%) papers were excluded (see Multimedia Appendix 3 for reasons for exclusion). A total of 12 additional papers were identified—1 (8%) from the reference list of the included studies and 11 (92%) from database alerts and search updates—leading to the inclusion of 28 articles [38-65] for final analysis (corresponding to 27 studies, as 1 study was published in 2 different articles [38,65]). The Cohen κ statistic was 0.81 (excellent agreement) for the title and abstract screening and 0.53 (fair agreement) for the full-text screening before the consensus agreement was reached [66].

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the study selection process.



Study Characteristics

All 28 included articles [38-65] were published from 2012 onward and covered 27 studies and 23 interventions (n=4, 17% interventions were evaluated in ≥1 paper, using different study designs [39,44,47,52,56,59,63-65]). Of the 28 studies, there were 18 (64%) experimental studies [38-55], (n=10, 56% RCTs [38-47] and n=8, 44% quasi-experimental [48-55]; n=7, 39% with a qualitative component [38,44,46,49,51,52,54]; Table 1), 9 (32%) qualitative-only studies, 5 (18%) that included interviews [56-60], and 4 (14%) that involved a survey with open-ended questions (Table 2) [57-64]. Most studies were conducted in the United States (15/28, 54%) [39,40,44,45,48,50,52,54,56,58,60-64] and Canada (4/28, 14%) [47,51,55,59], and most were single-center, except for a few (5/28, 18%) [38,42,43,55,62]. There were 1397 participants (n=8-232 in experimental studies and 5-37 in qualitative studies), mean age was 63.4 years, 30% were women, 68% were White (from 15/28, 54% studies that reported on ethnicity), and the average education level was high (Multimedia Appendix 4 [38-65]). The study duration in the experimental studies ranged from 2 weeks to 12 months (average of 3.2 months). The 10 RCTs had a moderate risk of bias [35]; the quasi-experimental studies were of lower quality (Multimedia Appendix 5 [36,38-55]) [35].

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Table 1. Characteristics of experimental studies.

First author[a]	Study design	Follow-up (months)	Sample size (intervention; control)	Age (years), mean	Women (%)	Intervention	Control	Main results[b]
RCTs[c]								
Clays et al [38,65]	RCT + interviews	6	65 (38; 23)	63	23	App + devices (weight, BP[d], pill organizer, and wrist band): monitoring weight, BP, physical activity, and HR[e]; psychological support; education	Standard care	• Between-groups: improvement in depression and anxiety measures (P<.001) • NSf: between-groups quality of lifeg,h, self-careh,i, exercise capacity, illness perception • Intervention group: increase in self-care (P<.05) and decrease in sexual problems (P<.05)
Schmaderer et al [39]	RCT (3 arms)	3	74 (27; 26; 27)	56.3	54	App + wireless weight scale + Zoom visit with clinicians: monitoring medications and weight; automated feedback; graphical displays; education; clinician communication; reminders	App + wireless-weight scale: monitoring medications and weight	• Between-groups: decrease in rehospitalization (P=.02) • NS: quality of lifeh,j, EDk presentations, and hospitalizations
Wei et al [40]	RCT + interviews	1.5	28 (15; 13)	63	25	App + wireless weight scale: monitoring weight; manual input of diet sodium, and exercise, symptoms; automated feedback; graphical displays; education; clinician communication	Standard care + written education materials	• Intervention group: direct correlation between duration of app use and improvement in heart failure knowledgel (ρ=0.59; P=.04) and quality of life (ρ=0.63; P=.03)m • Feasibilityh and engagement: in the intervention group, 5 patients logged ≥1 interaction with the app per day on average, and 2 patients logged an interaction with the app every other day on average.
Yanicelli et al [41]	RCT	3	40 (20; 20)	52	20	Telemonitoring via app: monitoring (manual input) weight, BP, HR, and symptoms	Standard care	• Between-groups: increase in self-careh,n (P=.004) • NS: medication adherenceh
Rahimi et al [42]	RCT	6	202 (101; 101)	71.3	28	Telemonitoring via tablet app + devices (weight, BP, and HR): monitoring weight, BP, HR, and symptoms; automated feedback; EMR[o] integration; graphical displays; education; clinician communication; reminders	Tablet app + devices; no clinician communication	• Between-groups: decrease in systolic BP (P=.03) • NS: achieving optimal medical therapyh and physical well-being (self-assessed NYHAp class)

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First author[a]	Study design	Follow-up (months)	Sample size (intervention; control)	Age (years), mean	Women (%)	Intervention	Control	Main results[b]
Wonggom et al [43]	RCT	3	36 (17; 19)	67.5	19	App with avatar: education	Standard care	• Between-groups: increase in heart failure knowledgeh,q (*P*=.002) • NS: self-caren; general practitioner visits, ED presentations, and hospital readmission
Athilingam et al [44]	RCT + open-ended questionnaire	1	18 (9; 9)	53	56	App + chest-worn sensor: monitoring HR and physical activity, weight, and BP, and symptoms; automated feedback; graphical displays; medication adherence; education	Standard care	• Between-groups: increase in self-care management (*P*=.01) and confidence (*P*=.03)n, heart failure knowledgel (*P*=.04); <50% used the app daily • NS: quality of lifem, self-maintenance, medication adherence, and depression
Goldstein et al [45]	RCT (2×2 factorial) + questionnaire	1	60 (4 groups, 15 in each)	69	35	Arm 1: electronic pillbox; arm 2: arm 1 + medication reminder; arm 3: smartphone app; arm 4: arm 3 + medication reminder	Silent App or pillbox (no reminder)	• NS: medication adherenceh
Vuorinen et al [46]	RCT + questionnaire and interview	6	94 (47; 47)	58	17	Telemonitoring via app: monitoring (manual input) weight, BP, HR, and symptoms; automated feedback according to personal targets	Standard care	• Between-groups: increase in the use of nurse resources, unplanned clinic visits (both *P*<.001), medication change (increase in *P*=.042; decrease in *P*=.026). • NS: heart failure hospital daysh, ED visits, mortality, heart transplant, physiological parameters, and self-care behaviorn
Seto et al [47]	RCT	6	100 (50; 50)	54	21	Telemonitoring via app + devices (weight and BP): monitoring symptoms; automated feedback; reminders for daily readings; graphical displays	Standard care	• Between-groups: increase in self-maintenance (*P*=.03)h,i and quality of life (*P*=.05)g,h; increase in clinic visits • NS: self-confidence, self-management, brain natriuretic peptideh, left ventricular ejection fractionh, NYHAh, hospital days, readmissions, mortality, and ED visits
QE[r] studies								

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First author[a]	Study design	Follow-up (months)	Sample size (intervention; control)	Age (years), mean	Women (%)	Intervention	Control	Main results[b]
Heiney et al [48]	QE (1 arm)+questionnaire	1	12	NR[s]	42	App: monitoring (manual input) weight and symptoms; automated feedback; graphical displays; education	None	• NS: quality of lifet and self-carei
Guo et al [49]	QE (1 arm) + intervein + questionnaire	4	66	69	48	Telemonitoring via app + devices (weight, BP, and HR): monitoring symptoms + medication; EMR viewing; graphical displays; remote consultations, clinician communication; visit reminders	None	• Increase in consumption of low salt, fat, sugar diet (*P*=.046), fruits, vegetables (*P*=.02); increase in monitoring BP and weight (*P*<.001; *P*=.002); increase in medication adherence (*P*=.006); 60% used the app >1 time/week
Park et al [50]	QE (1 arm)	1	58	62	33	Telemonitoring via 2 apps + devices (weight and BP): monitoring symptoms and patient-reported outcomes; education; reminders; alerts	None	• Readmission rate after intervention: 10% (vs 25% national rates and 23% hospital rate)
Ware et al [51]	QE (1 arm) + questionnaire + interview	12	232; interview: 24	58; interview: 59	21; interview: 29	Telemonitoring via app + devices (weight, BP, and HR): monitoring symptoms; automated feedback; graphical displays; reminders	None	• Overall adherence (days when 4 readings taken/days enrolled): 73.6%. • Adherence first month 81.2%; 12 months: 63.1% • Age predicted better adherence (*P*=.04)
Foster [52]	QE (1 arm) + open-ended questionnaire	0.5	10	65	40	App: monitoring (manually) weight, BP, HR, and symptoms; automated feedback; medication reminders; education	None	• Increase in self-confidence (*P*=.04)i • NS: self-maintenance, self-management, and symptom awareness
Suthipong [53]	QE (2 arms not randomized)	3	120 (60; 60)	NR	28	App: monitoring (manually) weight, BP, symptoms, and liquid intake; automated feedback; medication adjustments; education; social support; clinician communication	Standard care	• Between-groups: decrease in readmission rates (*P*=.04) and pitting edema (*P*<.001); increase in 6-minute walking test (*P*=.01). • NS: BP
Alnosayan et al [54]	QE (1 arm) + interview + questionnaire	6	8	62	38	Telemonitoring via app + devices (weight, BP, and glucose): monitoring symptoms; reminders; education; graphical displays	None	• Good usability • NS: quality of lifeg
Radhakrishna et al [55]	QE (1 arm) + questionnaire	1	19	NR	11	Game for tablet: education (quiz and rewards); reminders and tips on self-management	None	• Usability: 100% found it easy and enjoyable; increase in heart failure knowledge (*P*=.007)l • NS: self-care behaviori

[a]Table is presented in the following order: RCTs first, then quasi-experimental studies, in chronological order of year of publication;

[b]Qualitative findings are included in the *Results* section.

[c]RCT: randomized controlled trial.

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[d]BP: blood pressure.

[e]HR: heart rate.

[f]NS: nonstatistically significant.

[g]Measured with the validated questionnaire Minnesota Living with Heart Failure Questionnaire [67].

[h]Indicates primary outcomes.

[i]Measured with the validated questionnaire Self-Care of Heart Failure Index, which measures three subcomponents: self-management, self-confidence, and self-maintenance [68].

[j]Measured with the validated questionnaire EuroQol–5 Dimensions.

[k]ED: emergency department.

[l]Measured with the validated questionnaire Atlanta Heart Failure Knowledge Test [69].

[m]Measured with the validated questionnaire Kansas City Cardiomyopathy Questionnaire score.

[n]Measured with the European Heart Failure Self-Care Behavior Scale.

[o]EMR: electronic medical record.

[p]NYHA: New York Heart Association functional classification.

[q]Measured with the validated questionnaire Dutch Heart Failure Knowledge Scale.

[r]QE: quasi-experimental.

[s]NR: not reported.

[t]Measured with the validated questionnaire Health-Related Quality of Life Scale 14.

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Table 2. Characteristics of qualitative studies.

First author and country	Methods	Sample size	Age (years), mean	Women, n (%)	Length of app use	Intervention
Schmaderer, United States [56]	Interviews	10	55.8	6 (60)	12 weeks	Same as Schmaderer [39] (Table 1)
Woods, Australia [57]	Questionnaire + interview	6	69	0 (0)	14 days	Smartphone app: monitoring weight, BP[a], HR[b], fluid intake, exercise, diet, medication, well-being, and symptoms; graphical display of data; plan setting; reminders and alerts; medical documentation repository, appointments, and care team contacts
Foster, United States [63]	Questionnaires + open-ended questions	10	65	4 (40)	2 weeks	Same as Foster [52] (Table 1)
Portz, United States [62]	Questionnaire + open-ended questions	30	66	18 (60)	NR[c]	Tablet app: monitoring weight and symptoms
Sebern, United States [61]	Focus group + open and closed ended questions	Patients: 4; caregivers: 4; clinicians: 7	Patients: 74; caregivers: 72; clinicians: 34	Patients: 1 (25); caregivers: 3 (75); clinicians: 6 (87)	NR	Tablet app: psychosocial intervention for partners (patients + their caregivers) based on share care, composed of communication (patients' and caregivers' preferences and values), decision-making and reciprocity; HF[d] education
Haynes, United States [60]	Interview (+ thinking aloud user observation)	Patients: 5; clinicians: 3	NR	NR	1 hour	Tablet app: monitoring weight, BP, and symptoms; medication tracking and reconciliation; care team contacts; appointment management
Srinivas, United States [58]	Interview + think-aloud user observation + questionnaire	5	61	2 (40)	60-90 minutes	Tablet app: monitoring weight, BP, HR, symptoms, physical activity, diet, and medication; HF education; daily behavior plan; motivational incentives and rewards
Athilingam, United States [64]	Questionnaires + open questions + user observation	Patients: 25; clinicians: 12	Patients: 58; clinicians: NR	Patients: 10 (40); clinicians: NR	1-2 hours	Same as Athilingam [44] (Table 1)
Seto, Canada [59]	Interview	Patients: 22; clinicians: 5	Patients: 57; clinicians: NR	Patients: 4 (18); clinicians: NR	6 months	Same as Seto [47] (Table 1)

[a]BP: blood pressure.

[b]HR: heart rate.

[c]NR: not reported.

[d]HF: heart failure.

Intervention Characteristics

Across the 23 apps, the app was provided via a smartphone in 17 (74%) [38-54,57,59,63,64] and via a tablet in 6 (26%) interventions [42,55,58,60-62]. In addition to the app, 35% (8/23) of interventions included telemonitoring (ie, remote monitoring), with transfer of data to health care providers [41,42,46,47,49-51,54], and 65% (15/23) were solely focused on self-management support [38-40,43-45,48,52,53,55,57,58,60-62]. Approximately 9% (2/23) of apps provided patient access to electronic medical records [42,49], and 22% (5/23) of apps allowed direct clinician communication [39,40,42,49,53]. Approximately 48% (11/23) of apps involved patient or clinician co-design [38,40,42-44,47,51,55,57,58,60]. For 39% (9/23) of apps [38,40-42,48,51,53,57,58], the authors reported the use of personalization, mostly in the form of feedback to self-monitored measures (Multimedia Appendix 6 [38-65]).

The most frequent app features were weight monitoring (19/23, 83%), [38-42,44,46,47,49-54,57-60,62-64], symptom monitoring (18/23, 78%) [40-42,44,46-55,57-60,62-64], and vital signs monitoring (blood pressure and heart rate: 15/23, 65%; Figure 2; Multimedia Appendix 7 [38-55,57-65]) [38,41,42,44,46,47,49-54,57-60,63,64]. Automated monitoring through external wireless devices (eg, weight scale, blood pressure, and heart rate monitor) was present in 43% (10/23) of apps [38-40,42,44,47,49-51,54,59,64]. Of these 10 apps, 6 (60%) were part of a telemonitoring system (ie, the apps were connected to a health care service or clinical provider) [42,47,49-51,54,59]. None of the interventions included implantable cardiac devices. Most apps recommended daily

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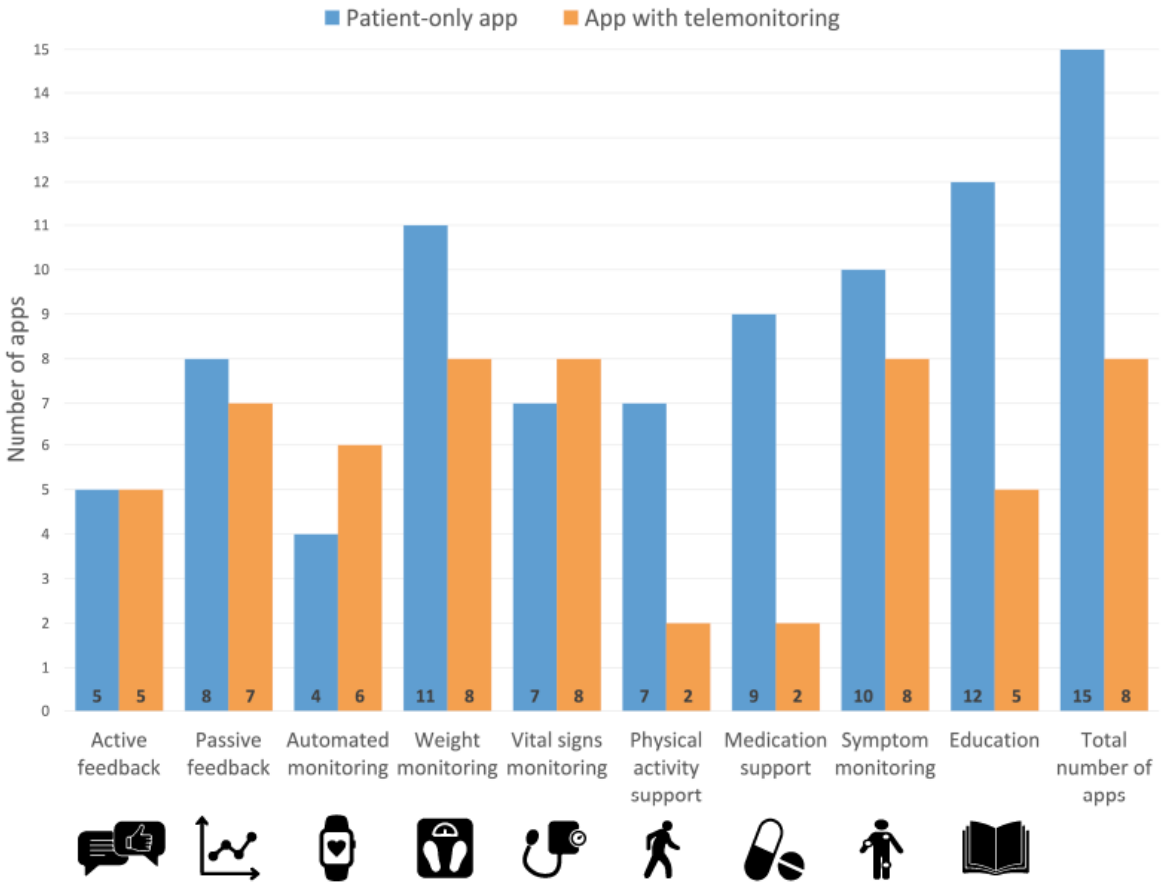
monitoring of symptoms and vital signs, and reminders for monitoring were mentioned in 52% (12/23) of interventions [38-42,44,47,51,53-55,57]. Few studies detailed the format or specifics of symptom monitoring except for 22% (5/23) of interventions [41,46,54,55,62], which allowed for the recording of the presence or absence of specific symptoms, with 20% (1/5) of them based on a validated questionnaire [54] and 60% (3/5) of them also providing symptom severity scales [41,54,62].

The most common BCTs presented in the studies were instructions on how to perform the behavior in 91% (21/23) of interventions [38-55,57-59,61,63,64], followed by self-monitoring of outcomes of behavior in 83% (19/23) [38-42,44,46-54,57-60,62-64], behavioral practice or rehearsal in 78% (18/23) [38-42,44,46-51,53-55,57,59,60,62,64], prompts or cues [38-42,44,45,47-51,53-55,57,59,60,64] and feedback on outcomes of behavior [38-42,44,46-51,53,54,57-59,62,64] in 74% (17/23) of interventions each. Feedback was *active* in 48% (11/23) of apps (ie, the app gave specific instructions to the patient in response to the individual information inputted by them) [40-42,44,46-48,51,53] and *passive* in 65% (15/23) of apps (ie, display of measurements in graphs) [38-40,42,44,47-51,54,57,58,62] (Multimedia Appendix 8 [38-55,57-65]).

Figure 2. Features present in apps of included studies, grouped by type of app (patient-only app and app with telemonitoring, ie, with transfer of data to health care providers).



Quantitative Results From Experimental Studies

The 10 included RCTs were small, often underpowered, with main outcomes self-reported, and the results were inconsistent. Approximately 20% (2/10) of RCTs found significant improvements in their primary outcomes: heart failure knowledge [43] and self-care [41]. One of the RCTs [47] reported several primary outcomes, showing improvements in self-care and quality of life. Approximately 40% (4/10) of RCTs did not show significant improvements in their primary outcomes (quality of life [38,39], self-care [38], achieving optimal medical therapy [42], medication adherence [45], and heart failure–related hospital days [46]). Approximately 20% (2/10) of RCTs indicated that their main aim was to assess feasibility [40,44].

Key clinical outcomes in heart failure were seldom reported (ie, mortality [46,47], emergency department visits [39,43,46,47], and hospital readmissions, [39,43,47,50,53]), with only 4% (1/28) of RCTs [39] and 7% (2/28) of quasi-experimental studies [50,53] showing a reduction in readmissions. Approximately 20% (2/10) of RCTs reported higher health care services use in the intervention groups than the control groups, including a higher number of unplanned clinic visits [46,47] and higher use of nurse resources (time and calls) and medication optimization [46].

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Other significant improvements were inconsistently reported across experimental studies: heart failure–specific knowledge [40,44,55], self-care [38,52], hospital readmissions [50,53], depression and anxiety measures [38], quality of life [40], systolic blood pressure [42], diet [49], self-monitoring (blood pressure and weight) [49], medication adherence [49], 6-minute walking test [53], and pitting edema [53]. Engagement with the mobile app was reported in 11% (3/28) of studies, 67% (2/3) indicating that less than half of the participants accessed the app daily as recommended by the investigators [40,44] and another showing that 60% of participants used the app more than once a week, as recommended [49].

User Experience and Qualitative Results From Experimental and Qualitative Studies

Overview

User experience was assessed in 68% (19/28) of studies using questionnaires, interviews, and focus groups [40,43-46,48,49,51,52,54,57-65]. The most commonly used questionnaires, apart from those created specifically by study authors, were the System Usability Scale [54,58] and the Unified Theory of Acceptance and Use of Technology questionnaire [51,65].

Of the 28 studies, qualitative analysis to assess acceptability and user perspectives was conducted in 14 (50%) studies (n=8, 57% qualitative-only studies [57-64] and n=6, 21% as part of an experimental study [38,44,46,49,51,52,54]). Common themes were automated self-monitoring and feedback, personalization, communication with clinicians and data sharing and integration, and digital literacy and technical issues.

Automated Self-monitoring and Feedback

Most study participants appreciated and noted the importance of automated self-monitoring (particularly through wireless device integration [49,51,54,57,59,60]) and feedback mechanisms with easy-to-understand objective visual displays that could also be tracked by family and friends [46,49,51,54,57,59,64]. They also mentioned that comparing their tracked measures and symptoms with their targets increased goal motivation, symptom awareness, and understanding of the relationship between their lifestyle or behavioral choices and health status, encouraging them to better self-manage their condition [56,59,63].

Personalization

Participants in 18% (5/28) of studies noted the need for personalization of the intervention and content provided [51,57,60,62,65] and their preference for more personalization in the ability to report symptoms and needs, which ideally would also generate more relevant feedback [51,57,60]. Specifically, some participants suggested adding a free-writing field [60], additional symptoms [62], and flexibility to input and change information (eg, medication changes) [57]. Personalization of feedback and data displays was also raised, given that some patients found it difficult to interpret longitudinal graphs, and others suggested the ability to increase the size of buttons and text as a desirable feature [57,58]. In addition, the perceived usefulness of the educational content was associated with previous educational level and duration of heart failure, also indicating the importance of personalized educational content [52,55,57]. Reminders for tasks and medication were mentioned as very relevant by most participants in several studies [49,60,62,64].

Communication With Clinicians and Data Sharing and Integration

Participants in several studies considered that the app could be an excellent tool for communicating with clinicians and helping with care planning [49,54,56,57,60,61], particularly if it allowed for data sharing and integration with electronic medical records [49,57,60]. Sharing data easily with clinicians, family, and caregivers during emergencies was commonly considered advantageous [49,57,60].

Digital Literacy and Technical Issues

Low digital literacy and technical challenges were reported as barriers to using the app in 14% (4/28) of studies [44,49,51,54,57,58,60], and in 4% (1/28) of studies, they were reported as an impassable barrier for older patients without additional technical support [60]. Technical challenges were mentioned as affecting app use and intervention fidelity and were mainly related to difficulties in using the app, such as downloading it, setting reminders, and inputting data [49,57,58,63].

Discussion

Principal Findings

In this first systematic review targeting exclusively mobile apps for heart failure self-management, we identified 23 unique apps evaluated in quantitative and qualitative designs, with 8 (35%) being part of telemonitoring systems and connected to health care services. Common features of apps were weight, symptom, and vital signs monitoring and provision of education, medication reminders, and graphical visualization of data. Overall, few had robust efficacy evaluation frameworks—only 10 RCTs involving 717 participants, with ≤6 months of follow-up, substantial heterogeneity in interventions and outcomes, and hence little quantitative evidence to indicate efficacy. Few studies involved patients and clinicians in the design of apps, and few quantified app engagement metrics such as frequency of use during studies. Qualitative studies identified the automation of self-monitoring tasks and feedback, personalization of content and format, communication with clinicians, and data sharing and integration capabilities as key enablers.

Comparison With Existing Literature

Similar to previous systematic reviews of other digital technologies in heart failure (focused on nonapp mobile technologies, such as SMS text messaging, personal digital assistants, interactive voice response, and phone calls), our findings were mixed, with high heterogeneity and lack of detailed reporting of intervention characteristics [18-27] likely because of poor evaluation frameworks. In these reviews, the interventions did not commonly offer self-management support (eg, education and feedback), merely involving remote

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monitoring with regular digital transmission of physiological and other disease-related data from the patient's home to a health care center. In addition, previous nonsystematic reviews seemingly with a focus on apps for heart failure self-management either only assessed the content and quality of commercially available apps [28-30] or broadened their inclusion criteria, including studies where the intervention was some type of mHealth technology but not an app (eg, SMS text messaging) [30]. In contrast, our systematic review is the first to focus exclusively on mobile apps for heart failure self-management (with or without clinician involvement via telemonitoring).

Despite the focus on heart failure self-management, the studies included in this review varied considerably in the types of self-management support features available in the apps. Core components of heart failure self-management programs, as defined in existing guidelines [2,5,70], include education, symptom monitoring, medication support, and physical activity support. Nevertheless, only 26% (6/23) of apps provided all these features [44,52,54,55,57,58], with more apps including features less supported by evidence in regard to their benefits in heart failure [5], such as daily weight monitoring. As a road map for future studies in this area, we encourage researchers and developers to follow the best available evidence [2,5,70] when designing and evaluating heart failure apps for self-management, focusing on features that have been systematically associated with improved outcomes. In addition, better reporting of intervention features is crucial to avoid what has been named as the *black box* of home telemonitoring [20], where the specific effective components of these interventions remain unknown.

Key outcomes in heart failure were seldom assessed in the included studies, hampering a complete evaluation of the impact of heart failure self-management apps. Overall, 1 RCT [39] and 2 quasi-experimental studies showed a significant reduction in readmissions [50,53], corresponding to the evaluation of 1 self-management app with telemonitoring and 2 without telemonitoring. Furthermore, 30% (3/10) of RCTs evaluated health care system use [43,46,47], with 67% (2/3) of them finding a higher number of unplanned clinic visits and medication optimization for participants in telemonitoring programs [46], although without significant changes in mortality, emergency department visits, or hospitalization [46,47]. Higher health care use may reflect earlier actions in the face of signs of worsening heart failure and provide opportunities for medication optimization. Such results may help explain the positive outcomes of telemonitoring interventions [26]. Longer and adequately powered studies measuring key clinical outcomes are needed to fully assess whether the potential benefits of self-management apps outweigh the costs of increased health care use.

Self-reported measures were commonly assessed in experimental studies, including validated questionnaires to measure heart failure knowledge, self-care, and quality of life [67-69]. Heart failure knowledge was significantly improved in 14% (4/28) of studies, all of which involved apps without telemonitoring [40,43,44,55]. Self-care was improved in 14% (4/28) of studies [38,41,47,52], 50% (2/4) of which involved apps with telemonitoring [41,47], and quality of life improved in 7% (2/28) of studies [40,47], 50% (1/2) of which involved telemonitoring [40]. There has been increasing recognition of the importance of including patient-reported outcomes as end points when evaluating interventions, as well as the benefits of collecting them routinely to improve care [71-73]. Digital technologies such as mobile apps can facilitate the capture of patient-reported outcomes, such as symptom status and severity [71], which can then be used by clinicians to guide care. Nevertheless, only one of the apps used a validated questionnaire for symptom monitoring [54]. The potential of mobile apps to collect patient-reported outcomes should be further explored in future studies, given their ability to promote patient-centered care and improve the quality of care for patients.

Overall, the evidence on the use of mobile apps for heart failure self-management is still lagging behind the large body of work supporting mHealth for remote monitoring, where significant reductions in all-cause mortality have been reported [19-22,26,27]. In our review, all included studies focused on supporting heart failure self-management, with 44% (8/18) of experimental studies including a telemonitoring component with clinician involvement [46,47,49-51,54]. Unfortunately, the small number, size, and quality of these studies do not enable us to draw conclusions regarding potential differences in efficacy between these 2 different types of mobile app interventions for heart failure self-management—with or without telemonitoring. Given the demonstrated benefits of self-management interventions more broadly [74] and remote monitoring [18-27], future research should explore the possibility that their combination may result in synergistic effects and higher efficacy in improving heart failure outcomes.

Personalization was valued in the studies included in this review, particularly personally relevant feedback and tailoring of the intervention to different levels of education and digital literacy. These findings are similar to those involving apps for other chronic diseases, showing that enabling customization (eg, editing information and choosing which aspects to track) is among the most appealing features and may enhance the usability, motivation, and engagement with the apps [17,75,76]. Future studies may explore the delivery of core BCTs (self-monitoring, feedback, and instruction on how to perform the behavior) and provide other techniques in a personalized manner, according to patient preferences and self-reported information [77] or based on machine learning algorithms using patient data collected over time (eg, from smartphone sensors or wireless monitoring devices) [78,79].

Limited experience in using technology can be a barrier to using mobile apps and may affect the utility and perceived benefit of mobile apps, as shown by our findings. The lack of confidence in using technology and perceived capability to benefit from it, as well as the workload required to learn how to use an app, are particularly challenging among older patients [80,81]. A study conducted to understand the main facilitators of and barriers to the use of mobile technology among older adults found that the most often mentioned barrier was the lack of knowledge on how to use it, whereas having previous experience of use was a facilitator [82]. However, older patients are willing to learn how to use mHealth technology and feel it may help them

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improve and maintain self-care behaviors [82,83]. Given that a large population of patients experiencing heart failure involves older adults, future app development needs to take into account specific characteristics of this population to design apps with simple navigation and ease of use [81].

Strengths and Limitations

This study presents several strengths. The PRISMA protocol was systematically followed. The screening process was pilot tested before its start, and there was good agreement between the independent reviewers. We also included both experimental and qualitative studies, enabling a better understanding of the impact, acceptance, and user preferences regarding mobile apps for heart failure self-management.

Some limitations should be considered in the interpretation of our results. First, given the heterogeneity between interventions and the small number of RCTs, a meta-analysis was not conducted. Second, the heterogeneity of study designs, sample sizes, follow-ups, interventions, and outcome measures among the experimental studies did not allow for consistent conclusions on the effectiveness of mobile apps in heart failure. Third, some studies in this review included analysis of adherence, acceptability, or usability of their interventions; however, although favorable trends were reported, the different measures and definitions used hindered reliable conclusions. Fourth, the socioeconomic and clinical characteristics of participants were rarely reported in the included studies; however, when reported, they suggested a high educational level and mild to moderate disease severity, potentially limiting the generalizability of the findings. Finally, the nature of this kind of research hampers the proper elucidation of the sociotechnical aspects of the interventions, which should be further evaluated in future studies (eg, using realist review methods).

Implications for Research, Clinical Practice, and Policy

Despite growing interest in the use of mobile apps for heart failure self-management, critical gaps remain in their design and evaluation, with lack of patient and clinician involvement and lack of robust evaluation to determine the populations that may benefit the most. Given the importance of patient preference and engagement in the successful delivery of heart failure interventions [26,27], co-design processes involving clinicians and patients and process evaluations assessing engagement and acceptability of the interventions are likely to improve intervention quality and consistency. Future studies should follow existing evidence in designing apps with features most likely to improve key patient-reported and clinical outcomes, adhering to recommendations derived from this study (Textbox 1). In addition, they should explore the efficacy and cost-effectiveness of mobile apps for heart failure self-management with and without a telemonitoring component. It is possible that self-management interventions without telemonitoring may be sufficient to improve outcomes in the early stages of disease in patients with a low risk of premature morbidity and mortality.

Textbox 1. Recommendations for researchers and developers regarding apps for heart failure self-management.

Recommendations for researchers and developers

Researchers and developers, when designing and evaluating apps, should consider the following:

- Follow the best available evidence
- Align with clinical guidelines
- Use co-design and pilot-testing to optimize products
- Enable automated self-monitoring and feedback, personalization, communication with clinicians, and data sharing and integration
- Report on specific functionalities and features of the apps
- Evaluate effectiveness on relevant outcomes to heart failure patients; for example, clinical outcomes, health service use, and clinical measures
- Report on adverse events or inadvertent effects; for example, increased health care use
- Patient-reported outcomes, including self-care and experiences, are also important; however, consider the ability to compare such measures among studies

Research is needed to better understand how these interventions can be implemented in the real world and integrated into existing models of care, such as collaborative care models involving shared care between heart failure nurses, general practitioners, and cardiologists [84-86]. Integrating these interventions into such services may increase their benefits and leverage partnerships between patients and clinicians, possibly leading to a more seamless implementation in practice. Perhaps a future model of care for heart failure patients can involve using mobile technology to improve patients' confidence and ability to manage their condition with greater autonomy, coupled with telemonitoring with clinician support for higher-risk patients.

Conclusions

This systematic review showed that research on the use of apps in heart failure self-management is still at an early stage, with limited evidence supporting its efficacy. RCTs are needed to fully ascertain the impact of these interventions. Future research should encompass greater involvement of end users and comprehensively measure patient engagement with the intervention.

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Acknowledgments

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. LBG was funded by the MQRES/RTPi Scholarship (20191550).

Authors' Contributions

LBG and LL were involved in the conceptualization and methodology, outcome data extraction, behavior change techniques coding, and risk of bias. LBG performed the database searching and writing of the original draft. Title, abstract, and full-text screening were performed by LBG, LL, and HLT. Validation, formal analysis, writing, review, and editing were performed by LBG, LL, HLT, RR, JC, CC, DK, JJA, and TS. LL, CC, RR, and JC provided supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 16 KB - cardio_v6i1e33839_app1.docx]

Multimedia Appendix 2
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File , 977 KB - cardio_v6i1e33839_app2.docx]

Multimedia Appendix 3
List of articles excluded after full-text review for not meeting inclusion criteria regarding the intervention, outcome, or unavailability of full-text.
[DOCX File , 18 KB - cardio_v6i1e33839_app3.docx]

Multimedia Appendix 4
Patients' clinical and socioeconomic characteristics.
[DOCX File , 22 KB - cardio_v6i1e33839_app4.docx]

Multimedia Appendix 5
Quality assessment of included studies.
[DOCX File , 20 KB - cardio_v6i1e33839_app5.docx]

Multimedia Appendix 6
Presence of personalization in included studies.
[DOCX File , 18 KB - cardio_v6i1e33839_app6.docx]

Multimedia Appendix 7
Intervention features of included articles.
[DOCX File , 21 KB - cardio_v6i1e33839_app7.docx]

Multimedia Appendix 8
Behavior change techniques present in the interventions of included articles.
[DOCX File , 31 KB - cardio_v6i1e33839_app8.docx]

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Abbreviations

BCT: behavior change technique
mHealth: mobile health
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: International Prospective Register of Systematic Reviews

Edited by A Mavragani; submitted 26.09.21; peer-reviewed by C Demers, T Greenhalgh, C Kruse, E Villalba-Mora; comments to author 22.11.21; revised version received 09.12.21; accepted 10.01.22; published 31.03.22.

Please cite as:
Bezerra Giordan L, Tong HL, Atherton JJ, Ronto R, Chau J, Kaye D, Shaw T, Chow C, Laranjo L
The Use of Mobile Apps for Heart Failure Self-management: Systematic Review of Experimental and Qualitative Studies
JMIR Cardio 2022;6(1):e33839
URL: https://cardio.jmir.org/2022/1/e33839
doi:10.2196/33839
PMID:35357311

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Review

Factors Affecting Patient and Physician Engagement in Remote Health Care for Heart Failure: Systematic Review

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Abstract

Background: Adult chronic heart failure mainly affects an elderly population with multiple comorbidities that often require frequent medical visits to prevent poor health outcomes. However, the heart failure disease process reduces their independence by reducing mobility, exercise tolerance, and cognitive decline. Remote care technologies can bridge the gap in care for these patients by allowing them to be followed up within the comfort of their home and encourage their self-care. However, patients, carers, and health care professionals need to engage with the technology for it to be useful.

Objective: This systematic review explores qualitative primary studies of remote care technologies used in heart failure, to determine the factors that affect user engagement with the technology. This is explored from the perspective of patients, carers, and health care professionals.

Methods: Relevant studies published between January 1, 1990, and September 19, 2020, were identified from EMBASE, Ovid MEDLINE, PubMed, Cochrane Library, and Scopus. These studies were then synthesized using thematic analysis. Relevant user experiences with remote care were extracted using line-by-line coding. These codes were summarized into secondary codes and core concepts, which were further merged into overarching themes that encapsulate user experience with remote care.

Results: The review included 47 studies, which led to the generation of 5 overarching themes that affect engagement: (1) “Convenience” relates to time saved by the intervention; (2) “Clinical Care” relates to perceived quality of care and health outcomes; (3) “Communication” involves feedback and interaction between patients, staff, and carers; (4) “Education” concerns the tailored information provided; and (5) “Ease of Use” relates to accessibility and technical barriers to engagement. Each theme was applied to each user base of patient, carer, and health care professional in a different manner.

Conclusions: The 5 themes identified highlight aspects of remote care that facilitate engagement, and should be considered in both future design and trials evaluating these technologies.

(JMIR Cardio 2022;6(1):e33366) doi:10.2196/33366

KEYWORDS

remote care technology; chronic adult heart failure; qualitative synthesis; thematic analysis; patient compliance; patient engagement; elderly population; carers; health care professionals; technology implementation

Introduction

The majority of people living with heart failure are elderly and have 3-5 severe comorbidities such as diabetes mellitus, chronic obstructive pulmonary disease, and ischemic heart disease [1]. The 1-year mortality from hospital admission is more than 30%, and 30%-50% of people living with heart failure are re-admitted to hospital each year [2]. Heart failure often leads to reduced mobility and shortness of breath on exertion. These manifestations can affect day-to-day living, reduce

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independence, increase the risk of falls, and impair access to health services [3].

Remote care technologies have the potential to benefit people living with heart failure by bridging the gap between clinical visits [4]. These technologies enable frequent observations in the home and give access to tools to aid self-care [5]. In the long term, personalized, community-based technology may reduce the burden of health care appointments and increase effective management of symptoms. Empowering self-management can enable early detection of health issues and promote interventions to prevent hospital admission [6]. However, only technologies which engage the users (including carers) can produce positive change. Engagement depends on the design and suitability of the technology to the cohort. Similarly, effective interventions must also engage health care professionals [7].

Non-engagement with health care technologies is widespread [7]. A meta-ethnography by Greenhalgh and colleagues [8] investigating technology-supported health programs generated the Non-adoption, Abandonment, Scale-up, Spread, Sustainability (NASSS) framework, which identifies 7 critical domains that impact whether a technology is adopted. These are the condition, the technology, the value proposition, the staff involved, the organization, the social/institutional context, and the interaction between domains. This approach gives valuable insights into the dynamic between users and medical technologies in general, but a more nuanced approach is needed to understand interventions in patients with heart failure having complex needs.

For instance, in the review by Simblett et al [7] regarding barriers to engagement of remote technology, a large proportion of dropouts from remote care studies were attributed to usability issues such as technical difficulties, over 5 times more than those that dropped out due to issues with their health status. In an unselected population this may be representative; however, in the cohort of patients with heart failure, patient barriers and priorities for engagement can be very different. Elderly populations are likely to have impairments in vision, dexterity, and hearing, which can impact usability in different ways. In addition, the higher incidence of comorbidities may mean more hospital admissions and variability in their health status. Therefore, a focused approach is needed to determine which factors play a greater role for engagement with this particular patient group so that future interventions can target these areas and incorporate the design elements that matter most. Otherwise, there is a risk of creating an intervention that is not well suited to the target population, which can lead to these large numbers of dropouts and disengagements.

The aim of this systematic review was to explore the use of remote distance technologies in heart failure. We focused on the effect that remote distance technologies have on engagement with care and investigated the perspectives of people living with heart failure, carers, and health care professionals interacting with the same technology. Our aim was to identify the unique contexts and issues found in this cohort, focusing on factors that influence adoption of, engagement with, and use of remote care interventions by people living with heart failure; and factors that affect the engagement of clinical staff with remote care intervention. We also considered which of the tensions identified in clinical trials became evident from examining patient and staff personal experiences.

Methods

Study Selection

Relevant studies published between January 1, 1990, and September 19, 2020, were identified from EMBASE, Ovid MEDLINE, PubMed, Cochrane Library, and Scopus (see Multimedia Appendix 1 for search history). Reference lists of all identified studies were manually searched for relevant publications.

Inclusion Criteria

- Primary studies using qualitative methodologies to collect or analyze data—defined as studies where participants can enter free-text comments or answer at least one open interview question.
- Studies that included patients diagnosed with adult chronic heart failure of all severities or their carers or the health care professionals involved in their care.
- Studies describing remote care programs—defined as any intervention accessible from the patient's home or local community, which provides the patient with education, assessment, investigation results, or otherwise replaces a service that would normally be offered within a formal clinical setting.

Exclusion Criteria

- Nonprimary studies.
- Studies with no qualitative element in the collection or analysis of data.
- Studies that did not include patients with adult chronic heart failure and neither their carers nor health care professionals.
- Non-English studies
- Interventions already established for heart failure care within national/international guidelines.
- Interventions involving implantable devices where user engagement is not a factor.

A random sample of 30% of abstracts were screened independently by 2 reviewers (AA and JD). The remaining abstracts were selected by a single reviewer (AA) using the double-screened sample as a foundation. Full texts were assessed for eligibility by 2 reviewers (AA and JD). Study characteristics were extracted using the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) statement [9], and with guidance from the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist [10]. We used the PROGRESS-Plus framework (ie, *p*lace of residence, *r*ace, *o*ccupation, *g*ender, *r*eligion, *e*ducation, socioeconomic status, *s*ocial capital, plus personal characteristics/relationships/time-dependent variables) [11] to create a more comprehensive review guideline for identifying health inequalities and characterizing populations [12]. Quality assessment of these studies ensured that the findings extracted were reliable and that bias was minimized [13]. Methodology of included literature was assessed using The National Institute

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for Health and Care Excellence (NICE) Quality Appraisal Checklist for Qualitative Studies [14-16]. Studies were designated excellent (++), good (+), or poor (–) quality. Rather than excluding the poor-quality studies, we opted for a more inclusive study design to better encompass the range of user experiences and reach a saturation point for first-order codes.

Thematic Synthesis Methodology

We applied the thematic analysis model of qualitative evidence synthesis [17]. Textual data from the *Results* or *Findings* sections of publications were extracted verbatim (EPPI-Reviewer 4, version 4.7.1.2) and line-by-line coding was used to generate first-order codes. First-order codes were grouped under second-order codes—umbrella terms that bridged commonalities between multiple first-order codes. Second-order codes were created independently by AA, JD, and a public advisor group, and the final list was determined by iterative consensus. Third-order, "core concept" codes were created based on patterns and inferences observed throughout the review. They involved a process of reflection and reiteration by the authors on all previously extracted data and codes within the context of the research question being asked, that is, what are the factors affecting engagement.

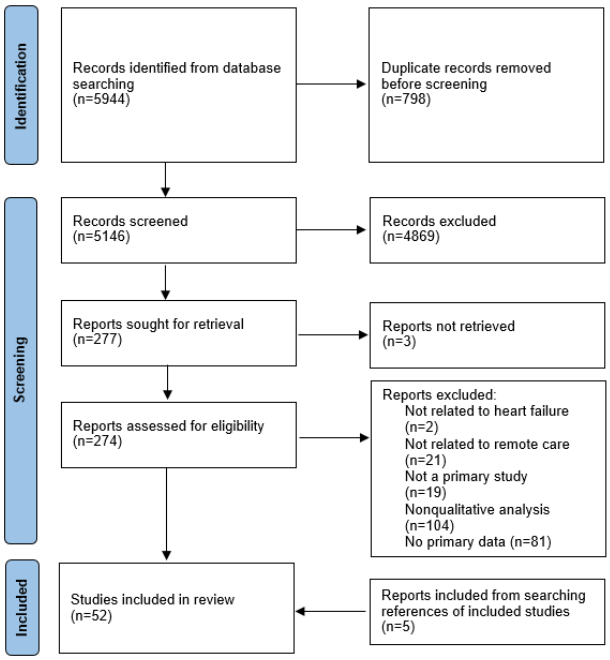
Core concepts and second-order codes were finally consolidated to create overarching themes, which were designed to be universal across patients, health care professionals, and carers, and to encapsulate all aspects of experiential user engagement. A patient participation group made up of several patients with heart failure was vital in establishing meaningful nomenclature for each of the themes and what they encompass. The title of each theme would then be intended to be interpreted in the context of its underlying description, based on its included secondary codes and core concepts, making it a unique thematic construction. At all stages of the review, the authors reflected on their own background and position and how it would affect the design, analysis, and interpretation of the research conducted [17].

Results

Study Selection

Our initial search criteria found 5944 matching studies, of which 798 were duplicates and 4869 did not match the inclusion criteria based on their title and abstract. A further 230 studies failed to meet the inclusion criteria when full texts were screened. The remaining 47 studies were included in the full review, in addition to 5 studies referenced by these papers (Figure 1). The PRISMA checklist (Multimedia Appendix 2) was used to analyze the included studies. Fifty-two studies were thus included in the final review (see Multimedia Appendix 3 for characteristics of studies table). The rationale for quality assessment scores is described in Multimedia Appendix 4.

Figure 1. PRISMA flow diagram for included studies. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



A total of 33 studies covered remote monitoring systems used to review a patient's status from their home [18-50]. Clinical decision tools, used to complement clinician management plans, were trialed in 4 studies [23,51-53]. As many as 4 studies involved patient health information platforms [23,54-56], 5 online patient self-management tools via an online portal, [23,56-59], and 4 educational tools delivering information for self-care through various means [23,58,60,61]. Community remote care, involving occasional home visits by nurses, comprised 2 studies [62,63], as did telephone consultations [48,64]. There was 1 instance each of a peer-support system [65] and a pharmacy-based consultation [66]; 2 studies delivered a concept of a remote care intervention and gathered opinions based on a theoretical design [46,67].

People living with heart failure, carers, and health care professionals are not equally represented in these sources: 9 studies included perspectives from health care professionals alone [31,37,39,44,45,48,51-53]; 29 included patients alone [18,19,21-24,28-30,33-35,38,40,41,46,47,54,56,57,59,60,62-65,67-69];

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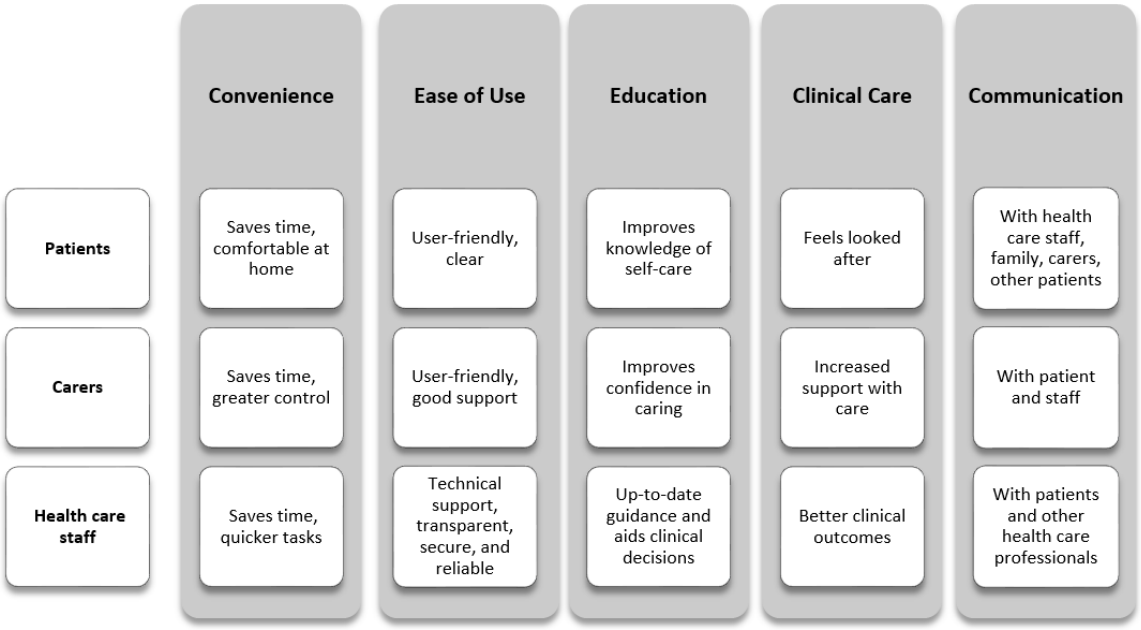
2 included patients and their carers [20,58]; 9 included patients and health care professionals [26,32,36,42,43,49,55,61,66]; and 3 included health care professionals, patients, and carers [25,27,50].

Themes

Overview

We extracted 110 separate primary descriptive codes from the *Results* sections of the included studies (Multimedia Appendix 5). We used a combination of grouping and reflective review to categorize these themes, which resulted in 30 secondary codes (Multimedia Appendix 6) and 13 core concepts. Secondary codes and core concepts were synthesized to give 5 themes that seek to encapsulate all aspects of user engagement: Convenience, Ease of Use, Education, Clinical Care, and Communication (Figure 2). Although themes are applicable across patients, carers, and health care professionals, they were associated with different secondary codes and core concepts.

Figure 2. Final thematic map representing the key points of each engagement theme and what they mean to each user group.



Convenience

Convenience is any aspect of the intervention that makes the user's life easier than the preintervention stage, by either time-saving or giving them the freedom to do more, or enhances their comfort in the current environment.

Positive patient experiences included those where the intervention had saved the patient travel time, or opened up new options for the patient to manage their care at home, and be comfortable in their home environment [20]. Negative experiences were associated with extra work, for example, in a complex self-monitoring system that takes time away from daily activities [35]. Loss of control was also commonly reported as a negative experience [35]:

> *I think you feel like you're not in control of your life...I just felt that, well, it certainly wasn't for me, and to, from how he explained it, um, you tended to have to do your blood test every single day...I try to be a bit more relaxed and...I just felt it, it did put a bit more pressure on me...you know, holidays or if I had to stay at my mum's, oh God, I've got to come home and do the machine.* [ID31]

For carers, positive aspects related to increasing options for managing care and increased freedom. Most carer experiences fell into negative codes regarding losing control of their tasks and increasing their workload and hence their stress. Throughout this theme, the concepts of workload, responsibility, and stress correlated with each other with regard to trialing a new intervention.

Positive experiences for health care professionals related to time-saving through faster and more efficient decision making. An example from Taylor and colleagues [37] showed how remote care technologies can help in understaffed situations:

> *We are being asked to see more patients with no additional resources.... How can we release a little bit of our capacity? Because our capacity is at absolute maximum all the time...I think telehealth helps from that point of view* [District Nurse 4, Site A]

Negative experiences related to the workload associated with implementing the intervention. After using the intervention, some health care professionals also reported that patients had become too dependent on the staff via the increased monitoring they provided [25]. Many clinical professionals were also reluctant to change as new methods were seen to restrict their preferred working pattern [39].

Ease of Use

This refers to the technical design elements of the intervention, and how user-friendly and accessible it was.

Positive patient experiences were associated with an easy-to-use intervention, with simple instructions and very few technical difficulties. Patient negative experiences involved devices that

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were intrusive, difficult to use, and had many technical difficulties. High costs and unreliability of the intervention made some technologies "less accessible." For example, Agrell and colleagues [18] described a remote care home hub with integrated stethoscope and blood pressure cuff, which proved difficult for sick patients to use.

Positive carer experiences centered around technology that was easy to use (eg, had a clear user interface) and reliable. Much of the negative feedback from carers was related to the stress caused by technical malfunctions of the device [54].

Health care professionals were positive about interventions that were easy to administrate and explain to patients and staff, or provided information in an intuitive manner. They favored interventions that took less time and effort to install and establish into current practice, such as a system that integrates remote monitoring into existing electronic patient records [52]. Negative feedback from health care professionals was associated with high cost, lack of security, poor user interface, lack of training provision, and unreliable results. An added issue for health care professionals was the lack of support and technical expertise to deal with problems [44].

Education

This relates to the ability of the intervention to provide appropriate, user-tailored information.

Positive patient experiences were reported in interventions that delivered self-care information in a simple, structured format, which was easy for patients to make use of. This helped increase their confidence in managing their condition, which in turn increased their engagement [55,64]. Negative patient experiences occurred where either useless or irrelevant information was given. This included remote care devices that give no immediate feedback, and websites or electronic health records that used medical jargon [55].

For carers, it was important to learn about the condition of the patient and understand disease progression. It was also important to access up-to-date information on the status of the patient. Remote interventions that made this easy for them generated positive feedback. When this information was difficult to access or mired in inaccessible jargon, it led to disengagement and discontentment [54].

For health care professionals, education centered on informative benefit that an intervention added to current practice. Positive experience involved interventions that provided guidelines or clinical suggestions to aid in patient management. Clinicians also identified the educational benefit on self-care habits of patients [27]. Education provided through a remote care intervention raises the standard of clinical treatment and involves the patient in their own management. This continuous benefit is valued by health care professionals. By contrast, the negative experiences of education involved insufficient, irrelevant, or poor-quality clinical information [22]. An intervention that did not provide feedback or allow patients to be updated on their health status provides little motivation for using the device or improving self-care, and this had a knock-on effect on health care professionals' perceptions of the usefulness of the device.

Clinical Care

This was a clearly defined theme that involved either improving or hindering the current clinical care provided for heart failure management. In most cases, the effects of this theme could be measured and observed in terms of patient outcome over the long term.

Patients valued interventions that supported better symptom control and improved confidence in their treatment management plan. They often commented that certain remote care interventions made them feel more "looked after" once they were aware that their measurements were being monitored from afar [22]. Negative experiences involved difficulty integrating the intervention into their daily lifestyle. Some patients felt that the intervention had no effect and that the technology was ultimately not needed [28].

Positive aspects for carers focused on them feeling more supported while using the intervention. The reassurance of extra clinical support helped them perform their task so that they felt they need not struggle alone [20,54]. Negative aspects of clinical care from carers were often found where patients already had sufficient care to meet their needs. Additionally, there were cases where the patients were too sick to be under an automated monitoring system and required personal supervision. Where carers mistrusted technology, its introduction was an extra source of stress [35].

For health care professionals, positive aspects involved being able to administer guideline-recommended management reliably and with less error. The ability to provide proactive treatment was also considered to be of great benefit. Often, increased monitoring frequency allowed the staff to identify deterioration more quickly and intervene earlier to prevent worsening outcomes. This improved the safety and quality of management and also fulfilled a "safety-netting" criteria that were found to be very valuable [22]. Remote care bridges the gap between primary and community care, where patients with heart failure are seen infrequently and may have periods of long stability, but may also be at risk of sudden deterioration. Negative aspects of clinical care for staff were equally impactful. They involved interventions that disrupted management, often by giving unreliable, incomplete, or false information, or simply made no difference to management decisions, or patient outcome. In the example by Sharma and colleagues [44], the remote care offered features such as home blood pressure monitoring, but did not provide enough information to assess for an infection. Health care providers perceived that some technology may hinder usual care in this way, and disrupt the current "face-to-face" care.

Communication

This theme encompasses the quality and frequency of interpersonal contact involved with the intervention.

When discussing communication, patients often referred to the frequency of contact with their nurse or doctor. In general, patients favored human contact to being monitored by a noninteractive device. Therefore, interventions that facilitated human contact appealed to patients [18,29]. Patients commented that greater human contact helped with their feelings of isolation and encouraged them to self-care. Remote care interventions

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that facilitated interaction with health care professionals were seen as valuable and worth the investment. Patients also liked interventions that could connect with their family and friends for further support. Some social interventions connected patients with each other and these showed widespread approval within this cohort of patients with heart failure. A chronic illness that reduces mobility often impacts the social activities of the patient and it is not surprising that this isolation can often be overlooked when considering these interventions [65].

Conversely, many of the remote care interventions led to reduced contact with physicians. Patients often missed the human contact element of regular clinic visits. Rather than having a device to provide information for them, they preferred being able to ask questions from staff members directly [18]. Without a human contact element, some felt more distant and perceived that something was lacking from the consultation. While remote care may obtain information efficiently, sometimes human contact is more reassuring and has a bigger impact on patient engagement.

For carers, "isolation" was predominantly related to the fear of leaving the patient on their own. The ability of remote care to mediate communication between both the patient and carer with health care professionals was seen as valuable and reassuring [26].

Health care professionals are often concerned with patient contact and with connection to specialists. Positive communication with other staff members is found in interventions that seamlessly connect multidisciplinary teams [37]. This in turn encouraged teamwork. Regarding staff to patient communication, health care professionals felt that frequent contact led to better awareness of the patient's tendencies and hence earlier and better decisions on their care [27,31]. The increased availability of communication with patients via remote care was felt to increase trust between the staff and their patients and staff felt their patients were more open to them. This fosters a good clinical environment, especially in the management of chronic disease where familiarity with the patient is vital to detecting early deterioration. Increased communication opportunities also motivate both parties to continue to use the device, for reassurance and safety-netting. Negative staff experiences with communication included systems that did not connect with other team members or caused a disruption in teamwork. An example was a remote monitoring system that provided the general practitioner with extra information but was unable to send this information on to heart failure hospital consultants, and thus made referrals harder [22]. Staff also found that interventions that reduced interaction with patients received much less support from both parties. Reduced face-to-face time due to remote intervention created a sense of distance with the patient, which was concerning to some staff [22].

Health Inequalities

Overview

In our review of interventions and the populations they were used on, various health inequality issues became apparent: usability, patient selection criteria, demographic distribution, and the potential to increase inequality gap through implementation of remote care.

Usability

In a heart failure cohort, interventions need to be usable by patients who have visual impairments or problems with dexterity [43]. If the intervention is not designed to take this into account, it can exclude the patients that might have benefitted the most. Riley and colleagues [34] recount an example of one such patient who struggled to use a remote care device, leading to undue stress:

> *I keep losing the finger contact and because of my sight I have to search hard to find it and that unfortunately sends my blood pressure up and then I have to redo the test.* [Edward]

In addition to co-ordination and visual problems, some patients were unable to use a weighing device because it required them to remain standing for several minutes [26].

Patient Selection

In any interventional trial, inequality may arise between patients who do and do not have access to remote interventions. Clinical decisions on which patients are most suited to the intervention can be subjective. The weight monitoring intervention in the study by Johnston and Weatherburn [26] demonstrated this selective service based on clinician opinion, creating a defined cohort of highly monitored patients above those of current care. With limited resources, clinicians may set up their own criteria for prioritizing access to remote care based on need, as they do with other treatments [22]. Over a short intervention trial period, some clinicians felt that monitoring was not useful in patients they deemed stable. However, this may lead to situations where patients are only provided with remote monitoring once deterioration has occurred.

Demographic Representation

In intervention trials, the criteria for proving the new remote care intervention are often decided a priori by the research group. Studies considered here show a distinct preponderance to White ethnicity and male gender. In addition, there is generally poor reporting on religion, socioeconomic status, social capital, disability, and vulnerable groups. It is therefore difficult to assess the impact of remote care integration on more disparate groups within populations.

Widening the Inequality Gap

Some clinicians showed anxiety that technology could widen the health inequality gap. The study by Earnest and colleagues [55] highlighted concerns around how remote care would translate in areas with fewer resources. Many remote care interventions take the form of highly technologically advanced, expensive devices, which, while rich with clinical data, are prohibitive for widespread use in terms of costs and resource drain. It is worth noting the impact of these interventions on the rest of the clinical care of the population, whether it creates a wider benefit to the whole or simply allows greater monitoring for those who have the most care in the first place.

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Discussion

Principal Findings

Throughout the endeavor to define engagement with heart failure remote care by patients, carers, and staff, this review has encompassed a wide range of possible interventions and environments, exploring the qualitative experiences from a vast array of users until the point of saturation. The experiential discoveries have been organized into 5 overarching themes that can be applied to each user base: Convenience, Ease of Use, Education, Clinical Care, and Communication. These themes go some way to giving insight to designers of such technology on how to tailor their intervention and improve uptake to create a greater benefit for their intended users.

Recently, the advent of COVID-19 has led to the prioritization of remote care as a way of managing vulnerable populations such as these while reducing the risk of in-person exposure [70]. While technology usability models for remote care have been explored [7,8], there are yet many clinical studies specific to heart failure remote care that emphasize more research into engagement for this patient group [71,72]. Hence the themes generated in this review aid to bridge the gap between generic usability models and the heart failure population, helping to apply existing knowledge in a more personalized way for more engaging interventions [73].

Implementing Engagement Themes Into Technology Design

Each theme has its own technological implications in the design of an intervention depending on the user group. Adding "Convenience" to a remote care intervention involves improving comfort or saving time in a way that has a significant impact on their daily life. This means that the user should be able to carry out typical tasks, such as patient self-care or a clinician's daily reviews, but in a more efficient manner or at a location more convenient for both parties.

Adding "Ease of Use" involves tailoring the experience with the user in mind. For elderly patients with heart failure, this means a simple and intuitive interface, requiring little or no technical knowledge. The closer the intervention reflects normal daily activity, the more seamless the transition toward its use. For clinicians, interventions should provide the necessary information for clinical decision making without unnecessary complexity. Technical difficulties are some of the most important barriers to effective implementations of remote care. Technologies that are reliable, easy to install, and integrate into current systems will earn the trust of staff.

Improving the "Education" of an intervention involves allowing it to provide information in a relatable way that is specific to the user's situation, for example, to aid patient self-care and to increase their sense of control and self-reliance [27]. For health care professionals, the intervention should help update staff on current guidelines and recommended practice. Information should be understandable and usable by all health care professionals from community nurses to heart failure specialists.

Adding the "Clinical Care" component for patients means improving the perception of greater care. These perceptions are enhanced by frequent feedback, contact with clinicians, and impactful changes to their lifestyle, which foster a sense of being "well looked after" [65]. For health care staff, clinical care relates to improving health outcomes. A robust series of clinical trials that demonstrate the clinical value of an intervention is vital to inform and justify implementation. Beyond this, clinicians will prioritize the interventions that address an unmet need in service provision. Overall, clinical care is a vital part of any remote care assessment, and must be assessed in the context of patients' needs, their current care, and the resources available to the staff.

Improving "Communication" is achieved by allowing further communication to take place, both between patients and staff and between peers, fostering a sense of more involved care [25]. Additionally, many patients value the option of having remote care to connect to their support network. Health care professionals highly value mechanisms in remote care that allow multiple specialties and services to integrate together and communicate. Many people living with heart failure are elderly and have multiple comorbidities necessitating a complex regimen of medication and outpatient health services to maintain their well-being. Too often, the flow of patient information between these services becomes lost or confused. This is an obstacle to communication that well-designed remote care can help overcome.

Implementation of Remote Care Within Clinical Trial Design

Based on our observations, we noted certain practices that need to be carefully considered during the design of remote care evaluation studies. Recorded experiences from users contrast and contradict each other even within the same study, and thus a sufficiently large sample size is important. The intervention must be distributed across a diverse ethnographical population, including those with poor literacy, and those with disabilities as well as diversity in gender and socioeconomic backgrounds. Selective inclusion or exclusion of patients with extremes of the condition may lead to bias. In our view, it is important to consider both the patient and health care professionals' viewpoint in the same study. This gives a good estimate as to how readily staff were able to use the intervention, and the impact that it has on their current care. It is also important to know where in the established care pathway the new technological intervention will sit; this affects who administers the device, to which cohort, and through which electronic systems. Interventions that do not consider the gaps in current care may cause disruption for staff and create additional steps that do not complement nor aid their current care environment [35]. Finally, in a few cases, patients and staff had negative experiences with the third-party support provided around the device's use. This could be improved with effective trial planning.

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Limitations

Limitations in Methodology

We have attempted to mitigate bias by double-coding, cross checking, and using grounded theory processes to construct a "blank-slate" perspective. However, in line-by-line coding some lines may have a double-meaning, fitting into multiple codes, and decisions on coding are subjective.

Limitations in Studies

The studies included were of a wide range of different methodological and analytical qualities. First-order codes from poor-quality studies may be subject to greater variability than high-quality studies. However, we included studies of all quality to avoid missing useful information and to achieve saturation. The wide range of study sizes may skew the experiences toward those that are mentioned in small sample sizes, as it increases the frequency of appearance of the related codes. We have listed the sample size of each study in the characteristics of studies table (Multimedia Appendix 1).

Limitations in Phenomena Studied

The researcher's reflexivity plays a role in the overall generation of the themes and can lead to first-degree bias. This process happens both inductively and intuitively and it cannot truly be distanced from preconceptions and beliefs of the reviewers themselves.

Conclusions

Overall, the 5 themes generated by this study overlap in many ways to create an engaging technology. Successful remote care interventions interact meaningfully with the user and thus instigate a change in self-care or in the working practice of health care professionals. Increased communication due to a remote care intervention leads to a perception of greater care from the patient. This in turn leads to improved feedback to the clinician and an improved perception of the devices' educational and clinical benefits. Likewise, convenience can be an important component contributing to ease of use. Successful and engaging interventions should combine these 5 elements into their design to increase the engagement of their users and lead to a greater benefit in this elderly comorbid population that needs this support the most.

Acknowledgments

This research was funded by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care North West Coast. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health. We acknowledge the invaluable input from the heart failure patient group at Liverpool Heart and Chest Hospital in naming the secondary codes and themes.

Authors' Contributions

AAN proposed the study concept; designed the methodology; conducted literature searches; and contributed to the data entry, interpretation of results, and drafting the manuscript. JD contributed to data entry, interpretation and analysis of results, and critical appraisal of the manuscript. KAS contributed to the layout of the draft and development of multimedia appendices as well as editing the manuscript for publication. All authors critically assessed and approved the final manuscript.

Conflicts of Interest

MP has received partnership funding for the following: MRC Clinical Pharmacology Training Scheme (co-funded by MRC and Roche, UCB, Eli Lilly, and Novartis); Joint PhD funding from EPSRC and Astra-Zeneca; and grant funding from VistaGen Therapeutics. He also has unrestricted educational grant support for the UK Pharmacogenetics and Stratified Medicine Network from Bristol-Myers Squibb. He has developed an HLA genotyping panel with MC Diagnostics, but does not benefit financially from this. MP is also part of the IMI Consortium ARDAT. None of these funding sources were used for the work presented in this paper.

Multimedia Appendix 1
Search history for systematic review.
[DOC File , 106 KB - cardio_v6i1e33366_app1.doc]

Multimedia Appendix 2
PRISMA 2020 checklist.
[DOC File , 77 KB - cardio_v6i1e33366_app2.doc]

Multimedia Appendix 3
Characteristics of studies included with the first order codes generated from each study.
[DOCX File , 101 KB - cardio_v6i1e33366_app3.docx]

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Multimedia Appendix 4
NICE quality appraisal.
[DOC File , 238 KB - cardio_v6i1e33366_app4.doc]

Multimedia Appendix 5
First-order codes identified in studies included in systematic review, with associated descriptions.
[DOC File , 201 KB - cardio_v6i1e33366_app5.doc]

Multimedia Appendix 6
Synthesis of second-order codes.
[DOC File , 241 KB - cardio_v6i1e33366_app6.doc]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
ENTREQ statement: Enhancing Transparency in Reporting the Synthesis of Qualitative Research statement
NASSS framework: Non-adoption, Abandonment, Scale-up, Spread, Sustainability framework
NICE: The National Institute for Health and Care Excellence
PROGRESS-Plus framework: place of residence, race, occupation, gender, religion, education, socioeconomic status, social capital, plus personal characteristics/relationships/time-dependent variables

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Edited by A Mavragani; submitted 05.09.21; peer-reviewed by L Ali, T Murphy; comments to author 04.12.21; revised version received 18.12.21; accepted 08.01.22; published 06.04.22.

Please cite as:
Al-Naher A, Downing J, Scott KA, Pirmohamed M
Factors Affecting Patient and Physician Engagement in Remote Health Care for Heart Failure: Systematic Review
JMIR Cardio 2022;6(1):e33366
URL: https://cardio.jmir.org/2022/1/e33366
doi:10.2196/33366
PMID:35384851

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Review

Smartphone Apps for Managing Antithrombotic Therapy: Scoping Literature Review

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Abstract

Background: Antithrombotic therapy is complex and requires informed decisions and high therapy adherence. Several mobile phone apps exist to either support physicians in the management of antithrombotic therapies or to educate and support patients. For the majority of these apps, both their medical evidence and their development background are unknown.

Objective: This review aims to investigate the available literature describing high-quality apps for managing antithrombotic therapy based on professional scientific information.

Methods: Keywords and Medical Subject Heading terms were used to search MEDLINE via PubMed and Ovid between December 2019 and January 2022. Inclusion criteria were the availability of full text and publications in the English language. Apps that solely focused on atrial fibrillation were excluded. Qualitative findings were thematically synthesized and reported narratively.

Results: Out of 149 identified records, 32 were classified as eligible. We identified four groups: (1) apps for patients supporting self-management of vitamin K antagonists, (2) apps for patients increasing therapy adherence, (3) educational apps for patients, and (4) apps for physicians in supporting guideline adherence.

Conclusions: Throughout the evaluated data, patients from all age groups receiving antithrombotic drugs expressed the desire for a digital tool that could support their therapy management. In addition, physicians using mobile guideline-based apps may have contributed to decreased adverse event rates among their patients. In general, digital apps encompassing both user-friendly designs and scientific backgrounds may enhance the safety of antithrombotic therapies. However, our evaluation did not identify any apps that addressed all antithrombotic drugs in combination with perioperative stratification strategies. Currently, strict regulations for smartphone apps seem to negatively affect the development of new apps. Therefore, new legal policies for medical digital apps are urgently needed.

(JMIR Cardio 2022;6(1):e29481) doi:10.2196/29481

KEYWORDS

anticoagulation; mobile app; telehealth; telemedicine; mHealth; smartphone; educational apps; digital tools; physician support

Introduction

Antithrombotic therapy, including both anticoagulation and platelet aggregation inhibition, is a common therapy for the treatment and prevention of atrial fibrillation (AFib)–related thromboembolic events [1], venous thromboembolism [2], and coronary artery disease [3]. European guidelines recommend oral anticoagulation (OAC) for most patients with AFib and platelet aggregation inhibitors for every patient diagnosed with coronary artery disease without contraindications [3,4]. Although AFib guidelines do not recommend OAC for low-risk patients, 75% of these patients receive antithrombotic therapy.

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On the other hand, 12% of patients at high risk for thromboembolic events do not receive adequate antithrombotic therapy [5]. The increasing number of new agents and drug combinations, as well as expanding indications for antithrombotic therapy, might contribute to inadequate management, putting these patients at risk for adverse events. Inadequate treatment might result in both bleeding and insufficient protection from thromboembolic events [6]. Several approaches were studied over the past years. However, mobile apps are constantly gaining in interest and also in clinical utility [7].

In 2021, the number of smartphone subscriptions worldwide reached the threshold of 6 billion, and that number is expected to reach 7.5 billion in 2026 [8]. Smartphones incorporate various hardware and software features. Furthermore, they enable wireless connectivity. In addition, the user can adapt the phone's software functions by individually installing apps. Apps are computer programs that run on the smartphone's mobile operating system (eg, Android and iOS).

The objective of this paper was to provide a comprehensive review of antithrombotic therapy apps that have been scientifically evaluated. Summarizing these results, our paper also offers suggestions for the future implementation of comparable apps.

Methods

We searched MEDLINE via PubMed and Ovid for predefined Medical Subject Headings and keywords in titles and abstracts. Searches in PubMed and Ovid were performed between December 8, 2019, and January 25, 2022, by an expert in the field of literature searching. The detailed search strategies are available in Multimedia Appendix 1. Additionally, we searched for publications about relevant apps.

Titles and abstracts were screened independently for eligibility by three authors (FP, BK, and TW). In the case of a disagreement, a fourth author (AM) was consulted. Full-text screening was performed independently by three authors (FP, BK, and TW).

Publications about smartphone apps concerning any aspect of antithrombotic therapy (eg, management, guidelines, risk assessment, or education) were considered eligible. Apps in this context were defined as smartphone software apps that must be installed on the device. Other features and hardware components were not defined as apps and, therefore, were among the exclusion criteria. Reviews, clinical studies, and protocols were included if their full text was available in English. "Epub ahead of print" articles were also included. There was no limit regarding publication date.

Data were collected from the publications by two authors (FP and TW). Information about the type of publication (eg, development of the app, user evaluation, and feasibility study); the name, target group, and aim of the app; study results; study funding; and country where the study was performed or where the app was developed were collected. Based on the main target group and the main aim of the app, the apps were assigned to groups. If not stated in the record, commercial availability of the apps was assessed by browsing Google Play and the Apple App Store.

Due to the heterogeneity of the publications, no meta-analysis or additional analyses were performed. Extracted data were analyzed descriptively.

Results

Overview

Our search revealed 149 records (147 from the databases and 2 from citation searching); this number was reduced to 32 records by excluding duplicates and applying inclusion and exclusion criteria, as shown in Figure 1. These 32 records were included in the qualitative synthesis. The 32 records reported on 23 different apps or app projects. Among them, 10 (31%) reported on the development of an app and 15 (47%) studied the efficacy of an app. Out of 32 records, 8 (25%) reported on evaluation of an app, another 4 (13%) were study protocols or were associated with a protocol, and 2 (6%) reported on app distribution and user statistics. Some reports covered more than one of these aspects. Only 1 (3%) report was a review. We identified four groups of smartphone apps concerning antithrombotic therapy: (1) apps for patients supporting self-management of vitamin K antagonists (VKAs), (2) apps for increasing patient treatment adherence, (3) apps for patient education, and (4) apps for supporting physicians with decision-making and guideline adherence. A comprehensive synthesis of the results is shown in Multimedia Appendix 2.

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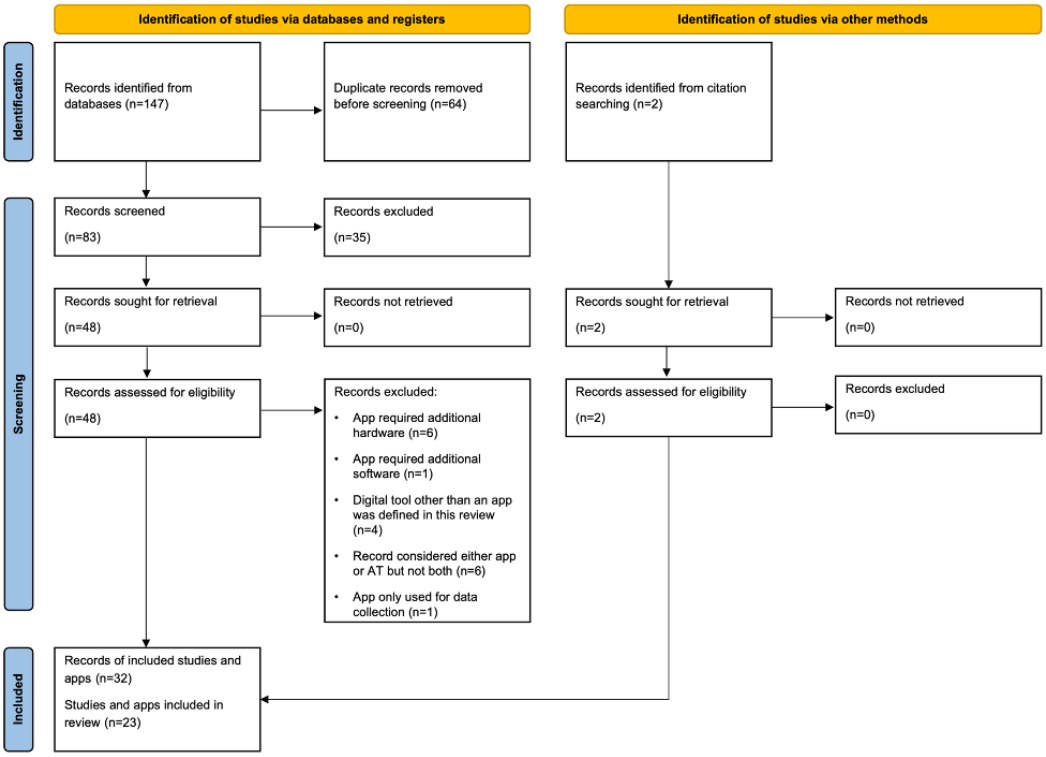
Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram showing the number of records identified, records included, and records excluded with the reasons for exclusion. AT: antithrombotic therapy.



Smartphone Apps for Patients Managing VKA Therapy

A report on the development and user evaluation of the app Warfarin Guide discussed a user-centered approach to design the app for patients taking warfarin, a VKA, to monitor their international normalized ratio (INR) measurements. Additionally, the app gives recommendations on warfarin dosages. After a co-design process, several usability tests were performed before app iteration [9,10]. In a study with 13 patients taking warfarin, a mean usability score of 85.0 (out of 100) was achieved based on the System Usability Scale [10]. A randomized controlled trial (RCT) validating the efficacy and effectiveness of Warfarin Guide was proposed. There was no funding declared.

An interdisciplinary team of computer scientists and cardiologists tracked INR measurements and recommended a VKA dosage from a technical point of view in an app (not named) based on two different machine learning algorithms [11]. A physician may access their patients' values via a web interface. Automated warnings are sent to the physician in case of threatening INR values. There was no funding reported.

The app Anticlot Assistant also gives dosage recommendations to patients taking warfarin based on INR measurements and a predefined target INR. Compliance with the app and time spent within the therapeutic range were evaluated prospectively in 30 patients. A positive prognostic factor for good compliance was having received an education of greater than 6 years (odds ratio 8.4; *P*=.03). Patients with good compliance spent significantly more time within the therapeutic range (mean 65.6%, SD 25.0% vs mean 40.0%, SD 21.0%; *P*=.009). The project received a grant from the China National Natural Science Foundation [12].

The Chinese app named XY was developed to aid patients in dosing warfarin [13]. Against the backdrop of the COVID-19 pandemic and associated limited access to professional INR monitoring, the app aims to improve the amount of time spent within the therapeutic range. Patients submit their self-measured INR to the app and receive a dosing recommendation. Contact is made by medical professionals in predefined conditions (eg, INR considerably out of target range or bleeding). The authors of the report presented the protocol of the validation study comparing users of the app against patients in the control group in an RCT. Enrollment began in March 2021. The study is sponsored by the Chinese Medical Board.

The Alfalfa app was developed by a multidisciplinary team and focuses on point-to-point remote monitoring of warfarin therapy [14]. The app is divided into a patient terminal and a medical staff terminal. Patients must provide necessary information about their medical history. After submitting their current INR and warfarin dose to their assigned doctor, they receive a response on dose adjustment and the suggested date of their next blood test. The app also includes reminder functions; access to a community, where patients can share their experiences; and an educational subsection. The usability and learnability of Alfalfa was evaluated in a retrospective study with 26 users by the System Usability Scale. The patient terminal and medical terminal reached scores of 61.8 and 82.7 (out of 100), respectively. The need for improving the usability of the patient terminal and the ease of learning for both terminals became evident. The Alfalfa app runs on the platform WeChat, a product of the Chinese telecommunication enterprise Tencent. According to the authors, reasons for choosing this platform included high development costs and long reviewing periods for apps at the Apple App Store and for Android apps at Google Play.

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Additionally, Alfalfa was tested in a retrospective, observational cohort study with 824 patients over 3 years to evaluate the effectiveness and safety of warfarin management via the Alfalfa app [15]. Clinical outcomes of patients using Alfalfa to adjust their warfarin dose and those of patients who attended regular hospital visits were compared. Alfalfa proved to be more effective than regular hospital visits in helping patients spend more time within the therapeutic range (79.35% vs 52.38%; *P*<.001), experience fewer major bleeding events (0.5% vs 3.0%; *P*=.005), and experience fewer warfarin-related emergency hospital admissions (0.2% vs 3.0%; *P*=.001).

The Yixing app was developed by hospital pharmacists who specialized in anticoagulation therapy. It includes functions such as reminders for drug intake, a personal health record, an educational program to raise the patient's awareness, and online counseling. The authors conducted a prospective study with 100 patients who had received a valve replacement; patients were distributed equally into an intervention group, who were using the Yixing app after receiving app-based training, and a control group, who would receive oral medication training but no further support after being discharged from the hospital [16]. The results revealed that using the app could increase the patient's awareness and days spent within the therapeutic range but did not have an influence on the number of days that warfarin was taken correctly or the incidence of anticoagulation-related complications.

Smartphone Apps for Educating Patients

In the systematic review conducted by Jang [17], the focus was on educational programs. A total of 12 studies were included in the analysis. The author focused on patients taking VKA in a hospital setting. Some of the solutions that were described were telephone-based programs. Three of the papers were described in our analysis as well [18-20]. The author concluded that mobile health (mHealth) apps improve adherence and patient's knowledge, but that bigger studies are required.

A group of cardiologists reported on an app (not named) that was developed by a multidisciplinary team based on current scientific literature. Inpatients diagnosed with AFib were given this app to educate themselves on thromboembolic and bleeding risk in AFib and on different treatments to improve shared decision-making [20]. The patient's knowledge on AFib was tested with a 20-item questionnaire before and after using the app. It showed a significant increase from a mean number of 4.7 (SD 1.8) to 7.2 (SD 1.0) correct answers (*P*<.001). However, perception of individual risks did not change significantly. The study was funded by internal budgets.

A similar approach was taken by a Philippine team. Based on focus group discussions and a literature review, they developed an app (not named) to support shared decision-making for or against OAC [21]. AFib patients use the app as part of their medical consultation to be educated about AFib and the different options regarding OAC. A pilot test with 37 patients showed a significant increase in AFib knowledge of 5 points (24-point knowledge tool; *P*<.001) and a significant decrease in decisional conflict of 35 points (100 point–scaled Ottawa PDA [patient decision aid] Decisional Conflict Scale; *P*<.001). Acceptance of the app by 37 patients and 30 physicians was mostly good to very good (92%-100% of patients in different categories; 67%-97% of physicians in different categories). The development of the app was funded by the pharmaceutical company Pfizer.

An interdisciplinary team reported on the development and evaluation of the Mobile Applications for Seniors to Enhance Safe Anticoagulation Therapy (MASS) [19,22]. MASS provides education on different anticoagulation therapies, their risks, and food recommendations for patients on VKA. Diary functions for INR, blood values, symptoms of bleeding, and reminders for medications are also included. In a co-design process, participants described their medication self-management and experience with digital health tools [22]. A feasibility study with 18 patients showed significant improvement of anticoagulation knowledge (*P*=.007). Other outcomes, such as therapy satisfaction, therapy adherence, and depressive or anxiety symptoms, did not change significantly [19].

The commercially available AFib 2gether app was designed to support AFib patients who are not yet receiving OAC therapy in shared decision-making. The app was developed by cardiologists in collaboration with Pfizer. Patients answer questions via the app to determine their thromboembolism risk using the CHA_2DS_2-VASc score (congestive heart failure, hypertension, age ≥75 years [doubled], diabetes mellitus, prior stroke, or transient ischemic attack [doubled], vascular disease, age 65-74 years, sex category) and select questions to ask physicians. The information is transmitted to physicians. In addition, educational content is available. The protocol of a single-arm intervention study to assess usability and perceived usefulness has been published [23]. The usability categories of functionality and aesthetics were rated as 4.51 and 4.26 out of 5 by 37 patients and 4.19 and 4.04 out of 5 by 13 physicians, respectively, using the Mobile App Rating Scale [24]. Perceived usefulness was reported by patients with 40% to 62% agreement and by physicians with 59% to 82% agreement in three categories each. After the intervention, 12 out of 37 patients (32%) initiated OAC therapy. Patient involvement in the decision-making process was demonstrated in just under half (48%) of the 25 recorded consultations; additional face-to-face consultations were not conducted due to the COVID-19 pandemic. The study was sponsored by Pfizer.

Smartphone Apps for Increasing Therapy Adherence

Platelet Inhibitors

Mobile4Meds is the protocol of an RCT comparing the ability of digital tools to increase adherence to antiplatelet therapy after acute coronary syndrome [25]. Prior to the RCT, the researchers assessed patients' perceptions regarding text messaging and the use of two different apps: Medisafe and Mango Health, both of which are commercially available. Six focus groups were moderated by professionals and had a specific topic, such as the patient's motivation to take their medication, presumed benefits and disadvantages of text messages and mobile apps, as well as the evaluation of the above-mentioned apps after testing each for a week [26]. Results showed that despite an average age of 66.9 years, all patients were regular smartphone users and described the use of mobile apps to enhance therapy

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adherence as useful. The reasons for nonadherence were forgetfulness and everyday distractions. Both text messaging and mobile apps were perceived to be able to address this issue effectively. Patients especially appreciated the interactive design of apps, the additional information about medication, the visualization of medication intake, and health parameters. One key finding was that most patients desired to share their results with their general practitioner, but data safety was a major issue. The project received funding from the National Institutes of Health (NIH), the University of California, and the US Department of Veterans Affairs.

A randomized feasibility study among 45 patients receiving dual antiplatelet therapy (DAPT) after percutaneous coronary intervention (PCI) over 3 months evaluated the impact of the mobile app MyIDEA (My Interventional Drug-Eluting Stent Educational App) on therapy adherence [27]. MyIDEA educates patients via short stories (ie, patient narratives). The authors discovered that patients show a high interest in smartphone-based support tools. However, they could not detect a significant difference in therapy adherence or anxiety levels between those who received traditional education materials and those who used the app. Limitations of the study were a small study population, a small local range, and low socioeconomic diversity.

The Me & My Heart app is not yet available in app stores, but the protocol of a prospective, randomized, multicenter, open-label interventional device study has been published regarding the app, which is CE (Conformité Européene) marked as a class I medical device [28]. It was developed by physicians and patients with sponsorship from AstraZeneca, the manufacturer of ticagrelor. The intended study compares two groups receiving DAPT with respect to medication adherence and lifestyle changes for 48 weeks after PCI. While both groups receive the same monthly evaluation questionnaires via the app, the intervention group also receives medication intake reminders, educational content, as well as motivational and supportive text messages. Therapy adherence is measured using either a self-developed questionnaire or a medication event monitoring system (MEMS) device. MEMS devices hold medication blister packs and register medication intake without displaying anything to the patient to minimize bias.

Wittig-Wells et al [29] described results from a prospective open-label trial evaluating the effects of a mobile app with reminders on adherence to antiplatelet therapy in patients after hip or knee alloplasty. There were 195 patients enrolled, and 122 completed the pill count at the end of the follow-up. No statistically significant differences were described between the two groups.

A prospective observational study conducted by Senoo et al [30] showed promising results in terms of adherence improvement in older adult patients with AFib. The Medisafe medication management app is a medication management platform, which includes the name of the medication and the dose. No detailed app description was provided. It has been underlined that mHealth technology, which emphasizes education, automatic reminders, and patient engagement, may be helpful. Additionally, reminders that do not require a doctor's involvement are a significant tool, which could enhance everyday care.

Anticoagulation Therapy

The app AFib Connect was developed by physicians and designers to support self-care and therapy adherence in patients taking direct oral anticoagulants (DOACs) for thromboembolic prophylaxis in AFib. It provides verified information on AFib, treatment options, and stroke risk. The app offers tools to track episodes of AFib and to document possible triggers, it includes a heart rate monitor that uses the phone camera to enable self-documentation, and it sends reminders for appointments and medications. The app's usability and usefulness were assessed by interviewing 12 patients with AFib [31]. The authors concluded with three key recommendations for successful app development: (1) understand your user group, (2) understand the users' workflow, and (3) assess required changes over time. Daiichi Sankyo Inc, a pharmaceutical company that manufactures the DOAC edoxaban, sponsored the study.

Physicians from New York teamed up with software developers to report on the efficacy of AiCure, a commercially available app using artificial intelligence to monitor adherence to anticoagulant intake and to provide reminders and specific instructions [18]. A randomized study with 28 patients compared adherence to anticoagulants when using AiCure to adherence when no monitoring device was used. App users had higher adherence than nonusers based on plasma levels of anticoagulants (100% vs 50%) and pill count (97.2% vs 90.6%). The project was funded by the NIH and sponsored by AiCure, LLC.

Smartphone Apps for Increasing Guideline Adherence and Decision Support

In a collaboration between Vanderbilt University and the American Society of Regional Anesthesia and Pain Medicine (ASRA), the ASRA Coags app was developed, which offers anesthesiologists decision support for the management of patients taking antithrombotic therapy and receiving regional anesthesia [32]. Users can choose from a broad variety of antithrombotic therapy, including antiplatelets and OACs; three different regional anesthesia procedures; and four different perioperative scenarios. Recommendations are based on the guidelines from the ASRA. An RCT with 259 anesthesiologists compared their performance with clinical scenarios related to ASRA guidelines, using either the ASRA Coags app; any other resource, such as the ASRA website; or no other resource. Participants using the ASRA Coags app gave significantly more correct answers than participants in the control group (mean 92.4%, SD 6.6% vs mean 68.0%, SD 15.8%; $P<.001$) [33]. ASRA Coags received grants from the Foundation for Anesthesia Education and Research for app development and from the Vanderbilt University Medical Center for the RCT [32,33]. After an update of the ASRA guidelines in April 2018, a study was conducted to evaluate how using the ASRA Coags app may facilitate guideline implementation. The authors stated that guideline alterations usually take about 17 years to be established in clinical use. Since 90% of all ASRA Coags users updated their apps within a month of the new guidelines being released, it has been postulated that mobile phone apps may be

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an effective tool to accelerate the implementation of new guidelines [34]. However, the authors had no information about whether the new information provided by the app was transferred to clinical use.

An unnamed app recommends OAC for patients with AFib based on CHA_2DS_2-VASc scores, according to US guidelines. Adherence to guidelines was compared among 10 cardiologists before and after the introduction of the app to 191 and 182 patients with newly diagnosed AFib, respectively. The use of OAC increased significantly from 37% to 51% (P=.01), and adherence to guidelines increased significantly from 46% to 66% (P<.001). The trial was funded by the authors' institution [35].

The commercially available app Management of Anticoagulation in the Periprocedural Period (MAPPP) was developed by a multidisciplinary team and provides physicians with evidence-based guidance on perioperative management of OAC therapy. Recommendations are based on the patient's medication and on the procedure's bleeding and thromboembolic risk as assessed by the physician. Warfarin (41%) and rivaroxaban (24%) were the most frequently selected medications [36]. Almost half of the queries included high bleeding risk procedures (49%) or high thromboembolic risk procedures (45%). The combination of high bleeding and high thromboembolic risk accounted for 30% of all queries. Due to the study design, it is unknown whether or not the documented user episodes were used in patient care.

A subsequent study investigated the effect of the integration of the MAPPP app into the electronic health record of patients receiving OAC therapy. Two cohorts were defined by the physician's decision to follow or decline the MAPPP app's advice. The two groups were compared in a 30-day follow-up after admission to the emergency department. The study revealed that physicians are more likely to follow the guidelines provided by the app with younger patients with normal renal function and who are taking DOAC medication, whereas they tend to trust their clinical expertise and deviate from the guidelines with older patients with impaired renal function and who are receiving warfarin therapy. The study showed a significantly lower rate of admissions to the emergency department for the cohort in which health practitioners accepted the app's advice than in the cohort where the advice was rejected (4.0% vs 8.3%; P=.02) [37].

The app PTT (Partial Thromboplastin Time) Advisor is a commercially available decision support tool for physicians with patients presenting with abnormal partial thromboplastin time and normal prothrombin time values. It recommends laboratory tests based on an algorithm created by the Centers for Disease Control and Prevention (CDC) [38]. The app Anticoagulation Manager succeeds PTT Advisor and provides multiple algorithms for patients with different conditions, such as venous thromboembolism or AFib. A user evaluation is planned. Anticoagulation Manager received funding from the CDC, the NIH, the Georgia Cancer Coalition, the Georgia Research Alliance, Hewlett-Packard Inc, and Microsoft Research [39].

A retrospective study on 274 patients with the indication for DOACs evaluated the support tool RecosDoc-MTeV, which was embedded in the hospital information system, alongside the Assistance Publique – Hôpitaux de Paris (AP-HP) clinical practice guidelines (CPGs) and a companion smartphone app, which was developed by the Parisian public hospitals [40]. Both clinical decision support systems analyzed the patient's clinical information with closed questions or validated scores. The recommended treatment was compared with the one received during hospital admittance. Both tools were congruent with their recommendations in 96.7% of all cases, whereas the received treatments varied between 67.2% and 72.3% from the recommendations provided by RecosDoc-MTeV and the AP-HP CPGs, respectively. Whenever received treatments and clinical decision support systems were not aligned, both tools recommended the same treatment. One limitation of the study was that only the type of anticoagulant was analyzed, whereas neither dosage nor period of treatment were analyzed.

Discussion

Principal Findings

We identified four groups of apps within the 32 eligible publications returned by this scoping literature review: (1) apps for patients supporting self-management of VKAs, (2) apps for patients increasing therapy adherence, (3) educational apps for patients, and (4) apps for physicians in supporting guideline adherence. This illustrates that such apps offer broad possibilities. Overall, most apps address OAC therapy for the most common indication, AFib. It is to be emphasized that within industrialized countries, the most frequent medications for AFib are DOACs, a group of drugs with high economic impact [41]. Interestingly, few sources reported on app projects addressing patients receiving antiplatelet therapy, although this medication is taken regularly by one-third to half of the adult population over 65 years [42-45]. Also, studies reveal that managing DAPT is challenging for medical professionals [46].

When apps for patients are grouped by the type of antithrombotic therapy they focus on, it is noticeable that many of them focus on one particular drug (eg, warfarin) or drug subgroup (eg, DOACs), rather than offering a broad selection of different antithrombotic therapy drugs. On the one hand, this might be due to the popularity of warfarin, especially in lower-income countries [47]. On the other hand, many of these apps are sponsored by pharmaceutical companies distributing such drugs. Benefits to this narrow approach are that maintaining these apps may be more cost-effective and that their features are tailored to their users' needs. The threat, however, is that medical apps are often known to be used as data collection mechanisms [48]. This is of high economic value to pharmaceutical companies. Data security is challenging for developers of medical apps [49]. The user may not be informed properly about the uses of collected data [50]. Also, sensitive personal and medical data are shared with third parties, potentially leading to serious damage to the user [50,51]. Antithrombotic therapy is a sensitive topic and, therefore, it is essential that medical staff and patients are provided with only the most up-to-date and precise information. Incorrect use of

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the medication might have life-threatening effects. There are also numerous apps for other indications (eg, type 1 diabetes, contraception, and more), but we have deliberately focused on antithrombotic therapy, as we are convinced that this topic, particularly in the perioperative setting, might bear a high risk of incorrect treatment decisions. In addition, most apps target diseases among younger patients, but this seems to overlook the fact that older adult patients are also increasingly using smartphones. Moreover, antithrombotic therapy management supported by computer-based technologies might increase the overall quality of treatment, translating into increased patient satisfaction [52].

User statistics from the MAPPP and the ASRA Coags apps show the need for high-quality and universal evaluation tools recommending periprocedural management of patients taking anticoagulants. They show that involvement of medical professionals as a quality predictor increases download numbers [53]. However, only 13% of medical apps targeting the general population have involved medical experts during development [54]. Yet, patients as medical laymen are hardly able to assess the quality of medical content. Publications on development and evaluation studies are one of the instruments potentially ensuring high-quality standards. This review revealed a relatively small number of scientific reports given the enormous number of apps in the app stores. Other instruments include compulsory or voluntary certifications that ensure quality standards for medical apps.

Secondary Findings

Interestingly, from all 32 records, only one reported on apps that were both developed by European research groups and commercially available on the common app platforms, the Apple App Store and Google Play [40]. Currently, within the European Union, the registration of an app as “Medical Device Software” has become a financial and administrative obstacle [55]. This is critical for most nonprofit apps since most public funding provides no funds for legal certification after the research and development phase. This hurdle may also be partly responsible for the discrepancy between peer-reviewed apps developed by renowned institutions and their availability.

In this review, most commercially available apps with a scientific background were developed in countries with lower data security [56]. For example, the United States and China are leading the field of app research but only hold rank 21 and 69, respectively, in the National Cyber Security Index released by the Estonian government and funded by the European Union; it is of note that other institutions provide other rankings.

Another issue is the maintenance of a published app that will guarantee not only the latest medical information but that the diverse technical needs for different phones and software will be met. This issue has also been addressed by the developers of the Alfalfa app, who decided to use the WeChat platform to evade the above-mentioned technical maintenance issues and requirements by the Apple App Store and Google Play. However, WeChat has been widely criticized for their data protection policy and entwinement with the Chinese government [57,58].

To overcome these obstacles, app developers need to seek strong financial partners. We argue that this might lead to a potential disadvantage for users with rare diseases or less financially potent drugs. In addition, a medication- or indication-based approach neglects the fact that many patients have several conditions that may require different kinds of antithrombotic therapy. However, a one-size-fits-all solution requires continuous maintenance by specialists, which may be less attractive for commercial distributors.

Strengths and Limitations

This scoping literature review provides extensive insight into the current state of scientific development and evaluation of medical apps that address antithrombotic therapy as their main topic. To our knowledge, this is the first review with this scope. We decided to focus on this medication because it also includes the obstacles of app development for older adults, is very frequently used, and offers a versatile spectrum of intended use for medical apps. Limitations of this study may be that the amount of information in the digital world is extensive, and a clear selection of data to enhance readability will always come at the cost of information loss. Taking into consideration the methodology, selection bias during full-text screening could occur since both inclusion and exclusion criteria leave some space for interpretation. On the other hand, this part was described in detail and, in case of any doubt, it was cleared by other authors. Moreover, it should be emphasized that a scoping review as such cannot show all the data, as this was not its objective. This review only targeted antithrombotic therapy apps with scientific evaluation, independently of the involvement of medical professionals or medical societies. Therefore, apps such as ManageAnticoag by the American College of Cardiology could not be included [59]. As already mentioned, AFib is the most common indication for anticoagulants, and there are several apps available for both patients and physicians concerning this indication. However, since the scope of this review was antithrombotic therapy and not AFib, publications focusing on AFib were not included, but they were reviewed elsewhere recently [60,61]. Therefore, papers that seemed relevant to the field at first sight were not included. Additionally, we only focused on apps that could be used by people where additional devices were not needed, which was an exclusion criterion but significantly limited the number of apps described.

Future Directions

Although the app market is constantly growing, only few solutions concerning antithrombotic therapy have been developed and evaluated following a scientific approach. In addition, the current legal situation might not facilitate independent, patient-orientated, and thoroughly validated apps. Despite diet management being a crucial aspect for patients receiving VKA therapy, no scientific records regarding such apps were retrieved by our search. The focus of most of the existing mobile phone apps is rather narrow, creating a need for many different apps. The desire for a certified and comprehensive solution seems unaddressed. Therefore, we propose the development of an app that has a wide target group, is based on scientific guidelines, and has supporting medical

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evidence and adequate data security. It should provide users with validated educational content, which will be constantly updated. Ideally, this app should address patients and doctors alike to create a common base for shared decision-making. Nonetheless, these solutions require further evaluation studies, which should be carried out prior to the commercial distribution of the app.

The approach to use apps to ameliorate clinical management and adherence to treatment is relatively new. Nevertheless, we see a great need for such instruments for both patients and physicians. Therefore, we advocate for more large prospective studies since we noticed many trial protocols but very few implementations. Positive results from studies could lead to broader inclusion in international guidelines. Our paper should be also regarded as a call for balance between studies and market access.

Acknowledgments

We acknowledge support by the Open Access Publication Fund of the University of Freiburg. The authors received funding from the German Federal Ministry of Research and Education (grant 01DS19010B) and the Polish National Centre for Research and Development (grant APP/2494/OP/CHASER/2018). AM received research funding from the Federal Ministry of Education and Research, Germany, and received coverage of travel expenses from the German Association of Urology, Germany, and the European Association of Urology, the Netherlands.

Conflicts of Interest

AM is an advisor for KLS Martin GmbH, Germany; Dornier MedTech Europe GmbH, Germany; Richard Wolf GmbH, Germany; KARL STORZ SE & Co. KG, Germany; LISA Laser OHG, Germany; Boston Scientific, USA; Medi-Tate Ltd, Israel; and B Braun New Ventures GmbH, Germany. AM is a reviewer for Ludwig Boltzmann Gesellschaft, Austria, and receives royalties from Walter de Gruyter, Germany, and Springer Science+Business Media, Germany.

Multimedia Appendix 1
Detailed search strategy.
[DOCX File , 21 KB - cardio_v6i1e29481_app1.docx]

Multimedia Appendix 2
Synthesis of results.
[DOCX File , 28 KB - cardio_v6i1e29481_app2.docx]

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Abbreviations

AFib: atrial fibrillation
AP-HP: Assistance Publique – Hôpitaux de Paris
ASRA: American Society of Regional Anesthesia and Pain Medicine
CDC: Centers for Disease Control and Prevention
CE: Conformité Européene
CHA_2DS_2-VASc: congestive heart failure, hypertension, age ≥75 years (doubled), diabetes mellitus, prior stroke, or transient ischemic attack (doubled), vascular disease, age 65-74 years, sex category
CPG: clinical practice guideline
DAPT: dual antiplatelet therapy
DOAC: direct oral anticoagulant
INR: international normalized ratio
MAPPP: Management of Anticoagulation in the Periprocedural Period
MASS: Mobile Applications for Seniors to Enhance Safe Anticoagulation Therapy
MEMS: medication event monitoring system
mHealth: mobile health
MyIDEA: My Interventional Drug-Eluting Stent Educational App
NIH: National Institutes of Health
OAC: oral anticoagulation
PCI: percutaneous coronary intervention
PDA: patient decision aid
PTT: Partial Thromboplastin Time
RCT: randomized controlled trial

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VKA: vitamin K antagonist

Edited by T Leung; submitted 08.04.21; peer-reviewed by E Opoku-Agyemang, E Caiani, DA Deacon; comments to author 21.05.21; revised version received 16.07.21; accepted 30.03.22; published 21.06.22.

Please cite as:
Praus F, Krzowski B, Walther T, Gratzke C, Balsam P, Miernik A, Pohlmann PF
Smartphone Apps for Managing Antithrombotic Therapy: Scoping Literature Review
JMIR Cardio 2022;6(1):e29481
URL: https://cardio.jmir.org/2022/1/e29481
doi:10.2196/29481
PMID:35727608

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Original Paper

Internet-Based Cognitive Behavioral Therapy and its Association With Self-efficacy, Depressive Symptoms, and Physical Activity: Secondary Analysis of a Randomized Controlled Trial in Patients With Cardiovascular Disease

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Abstract

Background: In patients with cardiovascular disease (CVD), knowledge about the associations among changes in depressive symptoms, self-efficacy, and self-care activities has been requested. This is because such knowledge can be helpful in the design of behavioral interventions aimed to improve self-efficacy, reduce depressive symptoms, and improve performance of self-care activities in CVD patients.

Objective: We aim to evaluate if internet-based cognitive behavioral therapy (iCBT) improves self-efficacy and explore the relationships among changes in depressive symptoms, self-efficacy, and physical activity, as well as the influence of iCBT on these relationships.

Methods: This study received funding in January 2015. Participant recruitment took place between January 2017 and February 2018, and the main findings were published in 2019. This study is a secondary analysis of data collected in a randomized controlled study evaluating the effects of a 9-week iCBT program compared to an online discussion forum (ODF) on depressive symptoms in patients with CVD (N=144). Data were collected at baseline and at the 9-week follow-up. Analysis of covariance was used to evaluate the differences in self-efficacy between the iCBT and ODF groups. Structural equation modeling explored the relationships among changes in depressive symptoms, self-efficacy, and physical activity, as well as the influence of iCBT on these relationships.

Results: At follow-up, a significant difference in the increase in self-efficacy favoring iCBT was found (P=.04, Cohen d=0.27). We found an indirect association between changes in depressive symptoms and physical activity (β=–.24, P<.01), with the change in self-efficacy acting as a mediator. iCBT had a direct effect on the changes in depressive symptoms, which in turn influenced the changes in self-efficacy (β=.23, P<.001) and physical activity (β=.12, P<.001).

Conclusions: Self-efficacy was improved by iCBT. However, the influence of iCBT on self-efficacy and physical activity was mostly mediated by improvements in depressive symptoms.

Trial Registration: ClinicalTrials.gov NCT02778074; https://clinicaltrials.gov/ct2/show/NCT02778074

(JMIR Cardio 2022;6(1):e29926) doi:10.2196/29926

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KEYWORDS

internet-based cognitive behavioral therapy; cardiovascular disease; depression; self-efficacy; physical activity; mental health; depression; digital health; online health; digital therapy; cognition; self-care; CVD; internet-based; cardiology; heart disease; cardiac health; cognitive behavioral therapy

Introduction

Depression is a serious health problem in patients with cardiovascular disease (CVD) (ie, atrial fibrillation/atrial flutter, ischemic heart disease, and heart failure). It is estimated that 20% to 40% of CVD patients experience depressive symptoms, leading to reduced health-related quality of life and increased risk of worse cardiovascular outcomes [1].

One possible mechanism behind these negative effects is that depressive symptoms are associated with biological changes such as overactivation of the sympathetic drive, chronic activation of the hypothalamic-pituitary-axis (HPA), and increased inflammation, all of which contribute to atherosclerosis, myocardial injury, and cell death [1,2], thus worsening CVD. Behavioral mechanisms are also important. In patients with different chronic conditions including CVD, depressive symptoms have been linked to poorer performance of self-care activities such as medication adherence and physical activity [3]. Furthermore, unhealthy behaviors such as sedentary lifestyles and smoking are more prevalent among CVD patients when compared to individuals without depressive symptoms [4]. Behavioral mechanisms, such as self-care, appear to play a role just as large as biological ones or an even larger role in cardiovascular outcomes [5].

Self-efficacy has an important role in the performance of adequate self-care behaviors [6]. In brief, self-efficacy stems from Bandura's social learning theory that was later renamed to social cognitive theory and refers to the beliefs of people in their capacity to carry out specific behaviors [6,7]. Self-efficacy influences how people feel about, think about, and motivate themselves. For example, people with low self-efficacy have difficulties in tolerating obstacles and give up easily when trying to accomplish self-care behaviors [8,9]. In CVD, low self-efficacy has been associated with more hyperlipidemia [10], whereas improvements in self-efficacy are associated with improved physical activity and healthy food choices [11,12]. A study on patients with heart failure [13] showed that higher levels of depressive symptoms led to lower self-efficacy, which in turn fully mediated lower treatment adherence. This result was based on cross-sectional data and cannot be interpreted as causal. However, a study based on the same patient population using a 6-month follow-up longitudinal design reported that an increase in self-efficacy and a decrease in depressive symptoms were associated with improvements in medical adherence [14]. Except for this study, there is a knowledge gap in the associations among changes in depressive symptoms, self-efficacy, and self-care activities in CVD patients [13]. Knowledge about these associations is important, as there have been requests for behavioral interventions that could improve self-efficacy, reduce depressive symptoms, and improve performance of self-care activities in CVD patients [14].

In a previous randomized controlled trial (RCT), we have reported that 9 weeks of internet-based cognitive behavioral therapy (iCBT) led to significantly lower levels of depressive symptoms compared to an online discussion forum (ODF) at the 9-week follow-up (–2.34, 95% CI –3.58 to –1.10, P<.001, and Cohen d=0.62) [15]. Furthermore, in a secondary analysis of data from the RCT, we found that iCBT improved physical activity and that a decrease in depressive symptoms needed to precede an increase in physical activity [16], but the effects of iCBT on self-efficacy and the influences of changes in self-efficacy on changes in depressive symptoms and physical activity were not evaluated. In the RCT, data regarding self-efficacy were also collected and therefore, we now aim to (1) evaluate if iCBT can improve self-efficacy in CVD patients with depression and (2) explore the relationship among changes in self-efficacy, depressive symptoms, and physical activity, as well as the influence of iCBT on these relationships.

Methods

Design and Study Participants

This study received funding in January 2015 (trial registration NCT02778074) . Participant recruitment took place between January 2017 and February 2018, and the main findings were published in 2019 [15]**.** Thus, this study is a secondary analysis of the data that were collected in an RCT evaluating the effect of a 9-week iCBT program on depressive symptoms in patients with CVD. A total of 144 CVD patients with at least mild depressive symptoms (ie, Patient Health Questionnaire-9 score>5) were included and randomized to 9 weeks of the iCBT (n=72) or the ODF (n=72) [15]. The iCBT program consisted of 7 modules, namely goal setting, psychoeducation, problem-solving, behavioral activation, part 1 (2 weeks) and part 2 (2 weeks), and a summary module. The program also included weekly homework assignments with feedback provided by nurses. The ODF consisted of 9 discussion topics moderated by a nurse. The discussion took place in writing.

Ethics Approval

The regional ethical review board of Linköping in Sweden approved the study (reference number 2016/72-31).

Assessments

Data for this analysis were collected at baseline and at follow-up at the end of the 9-week intervention period. All data were collected through questionnaires on the study website [15].

Self-efficacy

Self-efficacy was measured using the Swedish version of the General Self-efficacy Scale (GSES) [17]. The GSES consists of 10 items that are rated on a 4-point Likert scale ranging from 1meaning not at all true to 4 meaning exactly true. A higher score reflects higher self-efficacy. The instrument has proved a reliable and valid measure of self-efficacy in general

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populations [18] and has also been used in cardiac populations [10]. The Cronbach α for the GSES in this study was .93.

Depressive Symptoms

The Montgomery Åsberg Depression Rating Scale (self-rating version) (MADRS-S) was used to measure depressive symptoms. This instrument consists of 9 items rated on a 7-point scale with a maximum score of 54. Scores 13-19, 20-34, and >35 indicate mild, moderate, and severe depression, respectively [19]. The Cronbach α in this study was .78.

Physical Activity

The frequency and length of physical activity were measured using 2 modified items from the Physical Activity Questionnaire [20]. Frequency was scored between 0 (none of the days) to 3 (often, 5-7 days). Length was scored from 0 (0 minutes/day) to 4 (more than 60 minutes/day). In our analysis, we created a physical activity factor by multiplying the 2 items and this factor has been used in a previous paper published by our group [16]. In that study, physical activity was measured once a week from baseline to the 9-week follow-up, and the mean interweek correlation for the physical activity factor scale was 0.8 [16], suggesting it to be a stable and reliable measure of physical activity. Self-reports and single response items are considered reliable and valid estimates of physical activity [21,22].

Statistical Analysis

Descriptive statistics was used to describe the study population. Continuous variables were described as means and SDs, and categorical variables were described as numbers and percentages. All analyses were performed on original data, thus including participants with complete data at the 9-week follow-up (n=127). Analysis of covariance was used to evaluate if there was a significant difference in self-efficacy scores at the 9-week follow-up between the iCBT and ODF groups after adjustment for self-efficacy scores at baseline. The Cohen *d* was calculated for evaluating the effect of iCBT on self-efficacy. The associations among the changes in self-efficacy, depressive symptoms, and physical activity were explored by structural equation modeling (SEM). For these analyses, we calculated scores representing changes in self-efficacy, depressive symptoms, and physical activity between the baseline and 9-week follow-up measurements. To explore the influence of iCBT on these associations, we also added iCBT as an independent variable in the final SEM model. The associations/relationships obtained by SEM were described using their standardized coefficients (β). The chi-square value, the root mean square error of approximation (RMSEA), and comparative fit index (CFI) were used as goodness of fit indices of the SEM models. An insignificant chi-square would indicate a good model fit. An overall RMSEA below 0.06 indicates a good fit whereas a CFI ≥0.95 is considered a good fit, indicating that at least 95% of the covariation in the data is reproduced by the model. $P<.05$ indicates a significant value. Statistical analyses were performed with SPSS version 25.0 (IBM Corp) and the LISREL8 software (Scientific Software International) [23].

Results

Population

The mean age of the study population was 63 years. Among the 144 participants, 90 (62%) were males; almost 29 (20%) lived alone, and another 29 participants (20)% described their financial situation as problematic. Few participants were current smokers (ie, 4/144, 3%) or drank more than 10 units of alcohol per week (ie, 7/144, 5%). The median number of medications was 5 and approximately 48 participants had more than 1 comorbidity. Table 1 presents the characteristic of the study participants. The mean and SD values at baseline for self-efficacy, depressive symptoms, and physical activity as measured by the GSES, MADRS-S, and physical activity factor were 27.2 (6.3), 17.8 (6.7), and 4.8 (5.3) respectively. None of the variables presented in Table 1 differed significantly between those randomized to iCBT or the ODF.

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Table 1. Description of the study population at baseline.

Characteristics	Total N=144	iCBT[a] (n=72)	ODF[b] (n=72)	*P* value
Age in years, mean (SD)	63 (12)	61 (13)	64 (11)	.12
Gender, n (%)				.39
Male	89 (62)	47 (65)	42 (58)	
Female	55 (38)	25 (35)	30 (42)	
Living alone, n (%)	28 (19)	13 (18)	15 (21)	.67
Education, n (%)				.31
Elementary	19 (13)	7 (10)	12 (17)	
Upper secondary/high school	37 (26)	16 (22)	21 (29)	
Postsecondary education/college/university< 2 years	35 (24)	21 (29)	14 (19)	
University≥2 years	53 (37)	28 (39)	25 (35)	
Lifestyle, n (%)				
Smoking				.75
Never	69 (48)	33 (46)	36 (50)	
Ex-smoker	70 (49)	35 (51)	33 (46)	
Smoker	5 (3)	2 (3)	3 (4)	
Alcohol				.32
≤4 units/week	109 (76)	51 (71)	58 (81)	
5-9 units/week	27 (19)	17 (24)	10 (14)	
≥10 units/week	8 (5)	4 (5)	4 (5)	
Cardiovascular diagnosis, n (%)				
Myocardial infarction/angina	49 (34)	34 (47)	29 (40)	.4
Atrial fibrillation	65 (45)	40 (56)	41 (57)	.86
Heart failure	30 (21)	18 (25)	20 (28)	.70
>1 diagnosis	40 (28)	20 (28)	20 (28)	.73
New York Heart Association Class, n (%)				
I	41 (28)	23 (32)	18 (25)	
II	53 (37)	25 (35)	28 (39)	
III	50 (35)	26 (33)	26 (36)	
Medications				
Antidepressants, n (%)	20 (14)	7 (10)	13 (18)	.15
Antiplatelets/anticoagulants, n (%)	128 (88)	63 (88)	65 (90)	>.99
Beta-blockers, n (%)	110 (76)	55 (76)	55 (76)	>.99
Diuretics, n (%)	33 (23)	14 (19)	19 (26)	.32
Mineral receptor antagonists, n (%)	15 (8)	5 (7)	6 (8)	.75
Nitroglycerine, n (%)	30 (21)	15 (21)	15 (21)	>.99
RAAS[c] blockade, n (%)	69 (48)	34 (47)	35 (49)	.86
Statins, n (%)	69 (48)	36 (50)	33 (46)	.62
Number of medications, median (IQR)	5 (4-6)	5 (4-6)	5 (4-6)	.72
Comorbidities, n (%)				
Hypertension	76 (53)	36 (50)	40 (56)	.5

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Characteristics	Total N=144	iCBT[a] (n=72)	ODF[b] (n=72)	*P* value
Diabetes	21 (15)	8 (11)	13 (18)	.24
Pulmonary disease	15 (10)	7 (10)	8 (11)	.78
Transischemic attack/stroke	19 (13)	9 (12)	10 (14)	.81
Cancer	16 (11)	7 (10)	9 (12)	.6
>1 comorbidity	39 (27)	17 (24)	22 (31)	.35
Depressive symptoms, mean (SD)				
MADRS-S[d]	17.8 (6.7)	18 (7.2)	17.7 (6.2)	.31
Self-efficacy, mean (SD)				
General Self-efficacy Scale	27.2 (6.3)	27.0 (6.3)	27.4 (6.3)	.9
Physical activity, mean (SD)				
Physical activity factor	4.8 (3.5)	5.0 (3.7)	4.7 (3.4)	.7

[a]iCBT: internet-based cognitive behavioral therapy.

[b]ODF: online discussion forum.

[c]RAAS: renin-angiotensin-aldosterone system.

[d]MADRS-S: Montgomery Åsberg Depression Rating Scale (self-rating version)

Effect of the iCBT on Self-efficacy

At the 9-week follow-up, the mean self-efficacy scores and SD values for the iCBT group and the ODF group were 29.9 (5.8) and 28.2 (6.4), respectively. After adjustment for baseline scores, analysis of covariance showed a significant difference in the increase of self-efficacy in favor of iCBT (1.67, *P*=.04). The Cohen *d* was 0.27, indicating a small significant effect of iCBT on self-efficacy.

Associations Among Self-efficacy, Depressive Symptoms, and Physical Activity

For analyzing the associations among the changes in self-efficacy, depressive symptoms, and physical activity, we first explored an SEM model based on the mediation model reported by Maeda et al [13]. They initially analyzed the association between depression and medical adherence and then that between depression and self-efficacy, which were both statistically significant. After adding the association between self-efficacy and medical adherence to the model, the significant association between depressive symptoms and medical adherence disappeared. Thus, self-efficacy served as a full mediator between depression and medical adherence. Our model showing the relationships among depression, physical activity, and self-efficacy (Figure 1) had a perfect fit (χ^2_0=0, *P*>.99, CFI=1, and RMSEA=0), which indicates that the model completely explained the correlations. We found a significant direct effect (β=–.24, *P*<.01) among changes in depression, physical activity, and self-efficacy (β=–.64, *P*<.001). However, the association between the change in self-efficacy and change in physical activity was weak and not statistically significant (β=.11, *P*=.5). Consequently, in our model, self-efficacy was not a mediator between changes in depressive symptoms and physical activity.

However, the findings reported by Maeda et al [13] may also be interpreted as a simplex model, assuming that a change in depressive symptoms leads to a change in self-efficacy, which in turn leads to a change in physical activity. Given this assumption, self-efficacy could serve as a mediator between depressive symptoms and physical activity (Figure 2). This model had a perfect fit (χ^2_0=0, *P*>.99, CFI=1, and RMSEA=0). A summary of the associations is shown in Table 2. The model shows that a change in depressive symptoms has a significant relationship with the change in self-efficacy (β=–.64, *P*<.001), and a change in self-efficacy is significantly related to a change in physical activity (β=.49, *P*<.02). There was also an indirect association between the change in depressive symptoms and change in physical activity in which the change in self-efficacy served as a mediator (β=–.31, *P*<.01).

Furthermore, adding iCBT to our simplex model (Figure 3) showed that as expected, the iCBT had a direct and significant association with the changes in depressive symptoms (β=.37, *P*<.001) (χ^2_2=1.49, *P*=.47, CFI=1, and RMSEA=0). Table 3 summarizes these associations. The iCBT was also significantly and indirectly associated with the changes in self-efficacy (β=.23, *P*<.001) and physical activity (β=.12, *P*=.03). We also explored a reversed model in which the iCBT had a direct effect on the change in self-efficacy, which in turn influenced the changes in depressive symptoms and physical activity. The fit of the model was poor (χ^2_2=10.35, *P*=.005, CFI=0.82, and RMSEA=0.196), and the modification indices of the LISREL analysis strongly supported the model presented in Figure 3.

Performance accomplishment has been discussed as an important precursor of self-efficacy; if a person is successful at tasks, the feeling of efficacy will increase [6,7], which may indicate that an increase in self-efficacy leads to an increase in physical activity, which in turn increases self-efficacy. We added such

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a recursive association to the model presented in Figure 3. The fit of the model was good (χ^2_2=1.49, *P*=.47, CFI=1, and RMSEA=0) and showed that the relationship between self-efficacy and physical activity was significant (β=.5, *P*<.001) whereas the relationship between physical activity and self-efficacy was not (β=.27, *P*=.11). Accordingly, a significant recursive association was not found.

Figure 1. Model of the associations between changes in depressive symptoms, physical activity and self-efficacy based on the model by Maeda et al [13]. The associations in the model are described with the standardized coefficients (β). *P*<.05 indicates a significant value. The dotted line indicates a nonsignificant association. The fit of the model is perfect (χ^2_0=0, *P*>.99, CFI=1, and RMSEA=0). CFI: comparative fit index; RMSEA: root mean square error of approximation.

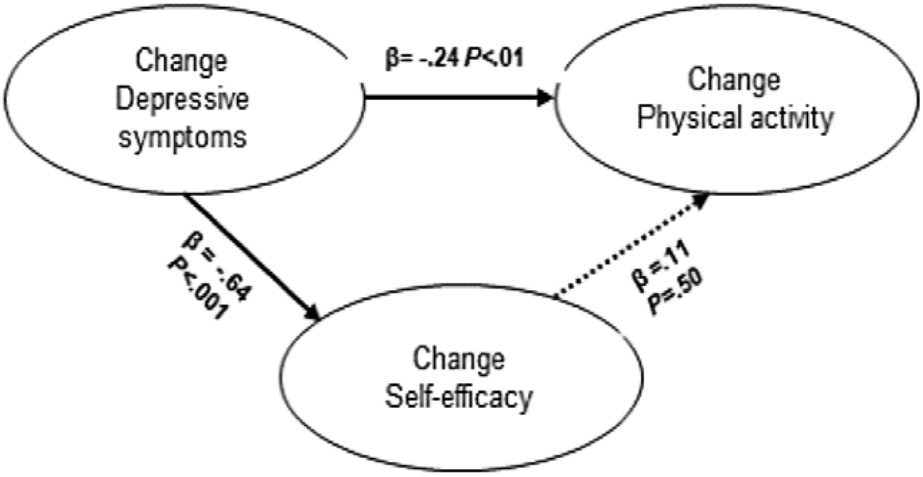

Figure 2. Simplex model describing the associations between changes in depressive symptoms, self-efficacy and physical activity. The model states that a change in depressive symptoms leads to a change in self-efficacy, which in turn leads to a change in physical activity. The thin grey dotted line indicates a significant indirect association between a change in depressive symptoms and a change in physical activity mediated by a change in self-efficacy. The associations in the model are described with the standardized coefficients (β). *P*<.05 indicates a significant value. The fit of the model is perfect (χ^2_0=0, *P*>.99, CFI=1, and RMSEA=0). CFI: comparative fit index; RMSEA: root mean square error of approximation.

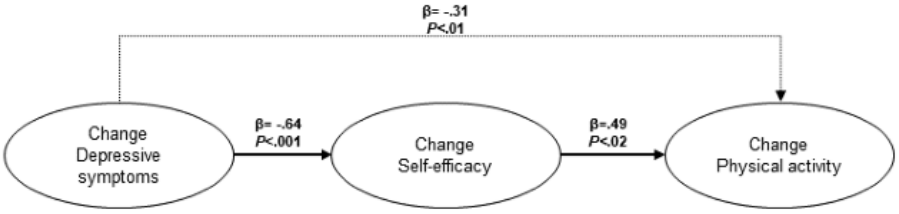

Table 2. Summary of the simplex model exploring the associations among changes in depressive symptoms, self-efficacy, and physical activity using the standardized coefficients (β).

	Change in depressive symptoms	Change in self-efficacy
Change in self-efficacy		
β	–.64	—[a]
P value	<.001	—
Change in physical activity		
β	–.31	.49
P value	<.001	.01

[a]Not applicable.

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Figure 3. Simplex model describing the associations among changes in depressive symptoms, self-efficacy, and physical activity as a function of iCBT. The dotted lines indicate significant and indirect associations between iCBT and changes in self-efficacy and physical activity as well as between the changes in depressive symptom and physical activity. The associations in the model are described with the standardized coefficients (β). *P*<.05 indicates a significant value. The fit of the model is good ($\chi^2$2=1.49, *P*=.47, CFI=1, and RMSEA=0). CFI: comparative fit index; iCBT: internet-based cognitive behavioral therapy; RMSEA: root mean square error of approximation.

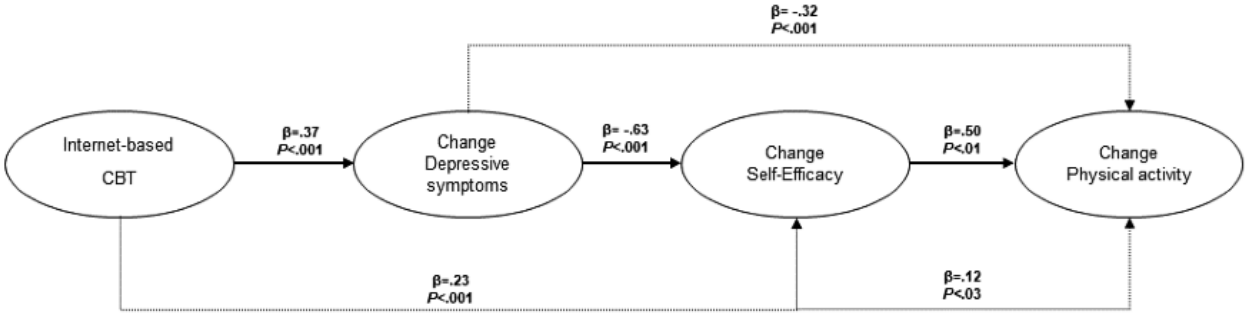

Table 3. Summary of the simplex model exploring the association of internet-based cognitive behavioral therapy with the changes in depressive symptoms, self-efficacy, and physical activity using the standardized coefficients (β).

	Internet cognitive behavior therapy	Change in depressive symptoms	Change in self-efficacy
Change in depressive symptoms			
β	.37	—[a]	—
P value	<.001	—	—
Change in self-efficacy			
β	–.23	–.63	—
P value	<.001	.001	—
Change in physical activity			
β	–.12	–.32	.5
P value	<.03	<.001	.01

[a]Not applicable.

Discussion

Principal Findings

The main findings of this study were that iCBT improved self-efficacy. However, the influence of iCBT on the improvement in self-efficacy and physical activity was mediated by improvements in depressive symptoms. Thus, self-efficacy was a mediator between improvements in depressive symptoms and physical activity.

In this study, we investigated the influence of self-efficacy on the changes in depressive symptoms and self-care through physical activity (ie, an aspect of autonomous self-care) [24]. To our knowledge, there is a lack of such studies involving CVD patients. In one of the few studies, Shen et al [14] showed that changes over 6 months in depressive symptoms (β=–.15, *P*=.05) and self-efficacy (β=.34, *P*<.001) were associated with medical adherence in patients with heart failure. However, in that study, only approximately 44% of the participants showed increased levels of depressive symptoms, and this may underestimate the results reported. Another study involving patients with heart failure reported that depression was negatively indirectly associated with poorer self-care through poorer self-efficacy [25], but this was a cross-sectionally designed study with no possibility to detect changes. Our study was performed on CVD patients with at least mild depression, and we found that a change from the baseline depressive symptoms was directly associated with the change in self-efficacy; this was indirectly associated with changes in physical activity, and thus self-efficacy had a mediating role in the relationship between changes in depressive symptoms and changes in physical activity. This highlights the importance of improvements in depressive symptoms in CVD patients. Such improvements are likely to be followed by improvements in self-efficacy and self-care, such as physical activity.

However, for such improvements to take place, an intervention is most likely needed. There have been requests for behavioral interventions that promote improvement of depressive symptoms, self-efficacy, and self-care in CVD patients [14]. In previous studies, we have found that an iCBT program for depression in CVD patients can improve depressive symptoms and increase physical activity [15,16]. This study now adds that iCBT can improve self-efficacy in depressed CVD patients as well. However, as observed in Figure 3, the impact of iCBT on self-efficacy is indirectly mediated by improvements in depressive symptoms. In Figure 3, the total effect of self-efficacy on physical activity is β=.5, but most of this is explained by the change in depressive symptoms (β=–.32); thus, the unique effect of self-efficacy on physical activity is β=.18 This suggests that only a minor part of the mediating role of self-efficacy between

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depressive symptoms and physical activity is related to self-efficacy itself. The model in which we analyzed if iCBT first led to changes in self-efficacy and then to changes in depressive symptoms was not valid, suggesting that improvements in depressive symptoms precede the increase in self-efficacy and physical activity. Moreover, we also explored if a change in self-efficacy leads to a change in physical activity, which in turn leads to changes in self-efficacy (ie, performance accomplishment). However, changes in physical activity had no significant effect on changes in self-efficacy (β=.27, *P*=.11).

Most digital interventional studies in cardiac rehabilitation focus on physical activity and counseling, with less focus on the core components such as psychological management [26]. However, our study suggests that in CVD patients with depressive symptoms, a digital intervention designed to improve self-efficacy and self-care such as physical activity should primarily focus on psychological management of depressive symptoms, for example, using iCBT. This does not contradict that the fact that such an intervention also includes physical activity counseling in the management of CVD and depression, and this can motivate the patients to perform physical activity when being involved in the iCBT program.

A limitation of this study is that this was a secondary analysis of data, and it did not primarily intend to investigate the effect of iCBT on self-efficacy or to explore the associations among changes in depressive symptoms, self-efficacy, and physical activity. Furthermore, data regarding physical activity were collected using only self-reports and not through objective measurements. This may have underestimated the level of physical activity measured [27] and may explain the nonsignificant association between self-efficacy and physical activity in Figure 1. However, in CVD patients with depression, there is a knowledge gap in the relationships among the changes in depressive symptoms, self-efficacy, and self-care such as physical activity and the influence of iCBT on these relationships. Therefore, we believe that despite the limitations, the results of this study provide interesting and useful information.

Conclusions

The iCBT program was more effective than the ODF in increasing self-efficacy in CVD patients. An increase in self-efficacy was the mediator between improvements in depressive symptoms and physical activity. Improvements in depressive symptoms mediated most of the influence of iCBT on the improvements in self-efficacy and physical activity. The findings are preliminary and replication in larger samples is needed.

Acknowledgments

This study received funding from the Swedish Research Council (grant 2015-02600), ALF grants from the Region Östergötland (grants LIO-600321 and LIO-687531), and Strategic fund from the Region Östergötland (grant LIO-719561). The funders of the study had no role in the study design, in the collection, analysis, and interpretation of the data, or in the writing of the manuscript. PJ and JL had full access to all the study data. All authors have approved the manuscript for publication.

Authors' Contributions

PJ, GA, ES, GM, and JL designed the study. PJ, GA, GM, and JL performed the study and obtained data. PJ and ES performed statistical analyses. PJ, GA, ES, GM, and JL interpreted the data. PJ, GA, ES, GM, and JL drafted the paper.

Conflicts of Interest

None declared.

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Abbreviations

CVD: cardiovascular disease
CFI: comparative fit index
GSES: General Self-efficacy Scale
HPA: hypothalamic-pituitary-axis
iCBT: internet-based cognitive behavioral therapy
MADRS-S: Montgomery Åsberg Depression Rating Scale
ODF: online discussion forum
RCT: randomized controlled trial
RMSEA: root mean square error of approximation
SEM: structural equation modeling

Edited by T Leung; submitted 26.04.21; peer-reviewed by S Chokshi, M Lewis; comments to author 26.04.22; revised version received 05.05.22; accepted 05.05.22; published 03.06.22.

Please cite as:
Johansson P, Lundgren J, Andersson G, Svensson E, Mourad G
Internet-Based Cognitive Behavioral Therapy and its Association With Self-efficacy, Depressive Symptoms, and Physical Activity: Secondary Analysis of a Randomized Controlled Trial in Patients With Cardiovascular Disease
JMIR Cardio 2022;6(1):e29926
URL: https://cardio.jmir.org/2022/1/e29926
doi:10.2196/29926
PMID:35657674

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Original Paper

Movement as Medicine for Cardiovascular Disease Prevention: Pilot Feasibility Study of a Physical Activity Promotion Intervention for At-Risk Patients in Primary Care

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Abstract

Background: Physical activity (PA) can reduce cardiovascular disease (CVD) risk factors, and although primary care settings offer a large reach to promote PA and reduce CVD risk, primary health care professionals may lack self-efficacy and tools to effectively promote PA in practice. Movement as Medicine for CVD Prevention is a suite of 2 theory-based, web-based behavioral interventions—one for health care professionals and one for patients—which may offer a pathway for promoting PA and reducing CVD risk in primary care.

Objective: This study aims to examine the feasibility and possible effects of Movement as Medicine for CVD Prevention.

Methods: This nonrandomized pilot study recruited participants from primary care organizations in the Northeast of England. Enrolled health care professionals followed a theory-based, web-based course on PA counseling and motivational interviewing techniques. After the course, health care professionals delivered behavior change consultations based on motivational interviewing to inactive individuals with >20% risk of developing CVD within 10 years. Patients were then given access to a website based on self-determination and self-regulation theories, which targeted increased levels of PA. Outcomes were assessed at baseline and after 3 months, and patient data were analyzed on an intention-to-treat basis in a multiple imputation data set.

Results: Recruitment rates of primary care organizations fell below expectations. A total of 11 health care professionals from 3 enrolled primary care organizations completed the web-based course and reported increases in important theoretical determinants of PA promotion in practice (eg, self-efficacy, Cohen *d*=1.24, 95% CI 0.67-1.80; and planning, Cohen *d*=0.85, 95% CI −0.01 to 1.69). A total of 83 patients were enrolled in the study, and 58 (70%) completed both the baseline and 3-month assessments. Compared with baseline, patients had higher levels of objective (Cohen *d*=0.77, 95% CI 0.13-1.41) but not subjective (Cohen *d*=0.40, 95% CI −0.03 to 0.83) moderate to vigorous PA at 3 months. Patients also reported higher levels of the PA determinants of intention, self-efficacy, intrinsic motivation, and action planning and action control at 3 months (effect sizes ranged from Cohen *d*=0.39 to 0.60).

Conclusions: The Movement as Medicine for CVD Prevention intervention seems to have the potential to improve patient PA behaviors and important determinants of health care professionals' PA promotion practices. However, the recruitment rates of

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primary care organizations in this study were low and would need to be increased to examine the efficacy of the program. This study offers several insights into improving the feasibility of this primary care PA promotion pathway.

Trial Registration: ISRCTN Registry ISRCTN14582348; http://www.isrctn.com/ISRCTN14582348

(JMIR Cardio 2022;6(1):e29035) doi:10.2196/29035

KEYWORDS

primary care; physical activity; cardiovascular disease; prevention; internet-based intervention; motivational interviewing; self-regulation

Introduction

Background

Cardiovascular disease (CVD) accounts for approximately one-third of all deaths in the United Kingdom and places a substantial economic burden on the UK National Health Service (NHS), with costs estimated at £14 (US $18.3) billion and rising [1]. Epidemiological and experimental studies have established strong links between low levels of occupational and leisure time physical activity (PA) and an increased risk of CVD [2-5], and this is supported by findings from a recent meta-analysis [6], which found significant associations between moderate occupational and leisure time PA and CVD risk in both men and women. In addition, a wealth of evidence demonstrates that participation in PA is associated with improvements in metabolic risk factors for CVD and CVD-related mortality [5,7,8].

PA affects the main risk factors for the development of CVD, including decreases in low-density lipoprotein [9] and maintenance of normal glucose tolerance [10]. In addition, there are protective effects resulting from weight loss or maintenance [11] and its effect on blood pressure in physically active individuals. There are negative physiological responses associated with a lack of PA and high levels of sedentary behavior [12,13]. Research has shown that prolonged sedentary behavior produces adverse effects on the cardiovascular system, involving cardiac function, stroke volume, cardiac output, heart rate, thromboembolic events [14,15], and glucose intolerance [16]. Taken together, these findings indicate that population-level increases in PA and reductions in sedentary behavior could be vital in reducing CVD incidence and mortality.

The importance of increasing PA and reducing sedentary behavior to prevent noncommunicable diseases has been highlighted by the Chief Medical Officers of England, Scotland, Wales, and Northern Ireland in the *Start Active, Stay Active* document [17]. The UK Department of Health currently recommends that adults should accumulate a minimum of 150 minutes of moderate-intensity PA each week to achieve tangible health benefits [17]. However, despite the well-known CVD-related and general benefits of PA, only a small percentage of adults meet these government guidelines, with >60% of men and >70% of women in England being insufficiently active to benefit their health [18].

At present, low levels of PA at the population level are partially addressed through primary care–based screening programs, including the NHS Health Checks program in the United Kingdom. Such health check programs screen for risk factors, including low PA, that contribute to the incidence of CVD and type 2 diabetes and then signpost individuals to appropriate interventions. For example, when low PA is identified during a health check, patients are signposted to interventions to increase PA. However, the PA interventions offered to individuals in these primary care settings rarely match the existing evidence on optimal methods for increasing PA behavior, and PA promotion is not a primary aim of primary care–based screening programs. Although PA prescription and advice giving are the most used methods of promoting PA in primary care settings [19], there is considerable evidence that these methods do not create lasting increases in PA [20,21], with up to 26 people needing to receive PA advice to meet the recommended levels of PA 6 months later [22]. In addition, even these minimal advice-giving approaches to PA promotion are only delivered to a small percentage of individuals for whom PA interventions are warranted [23,24], meaning that existing PA promotion interventions in primary care are suboptimal and delivered too infrequently.

The problems with PA promotion in practice may reflect deficits in the knowledge, skills, or motivation levels of health care providers (HCPs) regarding the delivery of effective behavior change interventions. Existing evidence indicates that interventions to increase PA are most likely to succeed when they include behavior change techniques (BCTs) derived from the Self-Regulation Theory [25], including self-monitoring, goal setting, action planning, feedback, and problem-solving. However, many HCPs working in primary care cite a lack of adequate training on how to deliver such self-regulatory interventions as a barrier to implementation [26]. Furthermore, HCPs may face additional barriers that limit the extent to which they offer PA promotion interventions to patients. For example, they may not be motivated to deliver PA promotion interventions in the first place; they may think that PA promotion is unimportant or not part of their role; or they may perceive barriers or conflicting priorities that prevent them from promoting PA, even if they are motivated to do so [27]. Helping HCPs overcome these barriers is crucial to ensuring that HCPs can deliver effective PA interventions in primary care.

As research from high-income countries indicates that approximately 70% to 80% of adults visit their general practice at least once a year [28] and that many individuals are willing to discuss changes in health behaviors with their primary health care professionals [29], primary care offers great potential for population-level PA promotion. To make full use of this reach, primary care HCPs need to have the necessary knowledge and skills to effectively target PA, be sufficiently motivated to do so, have sufficient self-efficacy for promoting PA, and have

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evidence-based tools at their disposal to assist patients as they attempt to increase their PA behavior. To this end, our group developed the Movement as Medicine for CVD Prevention (MaMCVD) program: a 2-tiered suite of behavior change interventions that aim to increase PA and thereby mitigate CVD risk.

Briefly, MaMCVD is a new PA promotion care pathway that comprises 2 theory-based behavior change interventions. The first intervention was delivered to health care professionals (eg, general practitioners [GPs], practice nurses, health care assistants, and health improvement practitioners) and is based on the Health Action Process Approach (HAPA) [30] and Self-Determination Theory (SDT) [31]. It aims to foster HCPs' self-efficacy and motivation for promoting PA in clinical practice and equip them with the knowledge and skills necessary to deliver behavior change interventions beyond traditional advice-giving and prescriptive approaches. The second intervention was delivered to patients and is based on the HAPA [30], SDT [31], and Self-Regulation Theory [32]. The patient intervention included techniques derived from motivational interviewing (MI) to increase patients' motivation for behavior change during primary care consultations and provided patients with a set of web-based tools with which they could self-regulate their efforts to become more physically active.

Aims

This study aims to examine the feasibility of MaMCVD as a PA promotion pathway in primary care settings, establish rates of recruitment and retention, and provide effect size estimates to potentially inform power calculations for a definitive randomized controlled trial (RCT). These aims are in line with phases 1 and 2 of the Medical Research Council framework for the development and evaluation of complex interventions to improve health [33].

Methods

Study Design

This nonrandomized pilot feasibility study aimed to examine a newly developed PA care pathway for individuals with an increased risk of developing CVD and involved data collection at both HCP and patient levels. The protocol was registered (ISRCTN14582348) and received approval from the Newcastle and North Tyneside 1 Research Ethics Committee (reference 14/ES/0032). All methods were performed in accordance with the relevant guidelines and regulations. Recruitment for the study began in June 2014, and the final study data were collected in May 2015.

The original protocol for this study specified an RCT; however, this changed to a nonrandomized trial because of difficulties in recruiting primary care organizations. In addition, the length of the study was shortened, and the primary outcomes were altered to better reflect the nature of this study as a feasibility trial. Full details of these changes are available in the trial registration record (ISRCTN14582348).

Setting and Participants

Overview

The study took place within primary care organizations typically tasked with delivering NHS Health Checks in the North of England (eg, general practices and NHS Foundation Trusts) and recruited both HCPs and patients. The intervention for HCPs was delivered via the internet, and the patient intervention was delivered face-to-face by the MaMCVD-trained HCPs in primary care settings and subsequently via a web-based platform.

Inclusion and Exclusion Criteria

To be included in the study, primary care organizations were required to meet the following inclusion criteria: willing to follow the intervention, committed to participating for up to 12 months depending on patient recruitment rates, at least 2 HCPs from the organization were willing and able to take part, capable and willing to identify and recruit patients meeting the eligibility criteria, and able to provide researchers with patient contact details to facilitate the mailing of questionnaires and accelerometers for data collection after a patient has provided informed consent. Individual HCPs were eligible for participation if they were normally part of a follow-up visit after an NHS Health Check (eg, nurses, physicians, allied health professionals, health visitors, and community health workers) and were willing to comply with the study protocol and complete the web-based training course for continuing professional development (CPD) credit.

Patients who had been identified as physically inactive with the General Practice PA Questionnaire [34] and who had at least a 20% risk of developing CVD in the next 10 years based on the QRISK2 cardiovascular risk algorithm [35] were eligible for inclusion in the study. In addition, patients needed to be aged between 18 and 75 years, have the capacity to provide informed written consent, be able to speak and read English without the support of an interpreter, have access to the internet, and be cleared to partake in PA according to the Physical Activity Readiness Questionnaire (PAR-Q) [36].

Study Interventions

The development of the MaMCVD primary care PA promotion pathway was informed by our group's previous work in developing a primary care PA promotion pathway for people with type 2 diabetes [37]. The core of MaMCVD was an integrated website with separate areas for HCPs and their patients, described in detail in the following sections.

Interventions for Health Care Professionals

After providing informed consent and completing baseline measures, health care professionals received a 20-minute motivational interview to elicit their reasons and motivations for potentially promoting PA with patients who have an increased risk of CVD and help strengthen their intentions to deliver behavior change interventions to such patients. These MI sessions took place in the HCPs' workplaces and were delivered by a trained MI trainer (KK). The BCTs [38] used in each phase of the MaMCVD intervention for HCPs are outlined in Table 1.

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Table 1. Description of the BCTs[a] delivered over the course of the study to health care professionals.

BCT	Before following the MaMCVD[b] course	As part of the web-based MaMCVD course	After following the MaMCVD course	After delivering the MaMCVD consultations[c]
Motivational interviewing	✓			
Provide normative information about others' consultation behaviors		✓		
Information on where or when to perform behaviors		✓		
Instruction on how to perform behaviors		✓		
Model or demonstrate the behaviors		✓		
Teach to use prompts or cues		✓		
Prompt practice		✓		
Provide reward contingent on completing the course			✓	
Provide feedback on performance				✓
Barrier identification or problem-solving				✓

[a]BCT: behavior change technique.

[b]MaMCVD: Movement as Medicine for Cardiovascular Disease Prevention.

[c]BCTs in this column were delivered after the effects of the intervention for health care providers were assessed. In other words, audit and feedback procedures were implemented to improve the quality of the motivational interview sessions delivered to patients during the study.

After the MI session, HCPs were given access to a web-based course comprising 11 interrelated modules on topics such as PA and sedentary behavior in relation to CVD, the processes involved in behavior change, and study-related procedures. Table 2 provides additional information about the topics of the modules, each of which was reviewed by experts in changing the clinical behaviors of HCPs. The course aimed to equip HCPs working in primary care with the knowledge and skills necessary to effectively promote PA among their patients and included static information about several key elements of MI [39] and self-regulation interventions [32]. Textual information, interactive info boxes, video demonstrations, and quiz questions aimed to prepare HCPs to confidently deliver the behavior change intervention to participating patients and help them overcome barriers to promoting PA in their day-to-day practice (ie, increase their self-efficacy for promoting PA). In total, the 11 modules took each practitioner approximately 4 hours to complete. HCPs were given 4 weeks to work their way through the intervention, and their log-in provided unlimited and ongoing access to the intervention content, including the web-based tools available to patients. After successful completion of the web-based course, including passing (≥80% correct) a 20-question multiple-choice end-of-course assessment, the HCPs received a certificate and CPD credit. HCPs were subsequently informed that they could begin delivering the MaMCVD intervention to their patients.

Initial sessions taking place between HCPs and patients who had both consented to have the consultations recorded were audio recorded. Recordings were then returned to the research team, who coded and assessed each consultation for clinician skill in delivering the intervention per protocol. From these recordings, researchers generated delivery feedback reports to assist the HCP in further improving their skills in MI and delivering behavior change interventions. This audit and feedback process highlighted areas of the consultation that went particularly well and were in line with what they had learned in the web-based course, as well as areas of the consultation that were delivered in a way that was not adherent to what was taught in the web-based course. For the areas of the consultation that were not delivered in line with the protocol, HCPs were prompted to identify what went wrong and think about ways of preventing similar mistakes from happening in future MaMCVD consultations. The feedback was provided in written form and was, in some cases, followed up by a telephone call or in-person visit to highlight or further explain points from the written feedback. To aid recall of the consultations upon which feedback reports were created, the research team aimed to provide HCPs with delivery feedback reports within 1 week. Therefore, HCPs were asked to stagger initial sessions with patients at 2-week intervals so that feedback could be delivered before the next set of sessions took place.

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Table 2. Descriptions of the contents and duration of the modules included in the Movement as Medicine web-based course for health care professionals.

Module number	Title	Description	Duration (min)
1	Introduction to Movement as Medicine for CVD[a] Prevention	• Video overview of course contents	5
2	Background of CVD	• Information about CVD prevalence, mortality, costs associated with the treatment of CVD, and costs of CVD to the UK economy or NHS[b]	15
3	PA[c] and CVD	• Information detailing the relationship between PA frequency or intensity and common CVD risk factors	15
4	Sedentary behavior and CVD	• Information detailing the relationship between sedentary behavior and CVD risk factors	10
5	An introduction to the process of behavior change	• Outline 2 distinct stages of behavioral change: motivation and action	10
6	Fostering motivation for change	• Introduction of the importance of change talk	20
7	Clinical skills—asking	• Learn skills to elicit change talk from patients	20
8	Clinical skills—listening	• Learn ways to reflect change talk back to patients	20
9	Clinical skills—informing	• Learn alternatives to information provision, such as using the elicit-provide-elicit structure	20
10	Use of patient self-regulation tools	• Provides rationale and evidence for the effectiveness of self-regulation approaches to behavior change • Provides full access to the web-based self-regulation materials available to patients in the trial, including walk-throughs and demos	30
11	Practical information for the Movement as Medicine trial	• Information about recruitment, timing of patient contacts, and feedback to be received about delivery	15

[a]CVD: cardiovascular disease.

[b]NHS: National Health Service.

[c]PA: physical activity.

Interventions for Patients

Over the course of the intervention, patients were scheduled to have one face-to-face and one telephone contact (of up to 30 minutes each) with their Movement as Medicine–trained HCP at baseline and 2 months, respectively. In addition, they were provided access to web-based behavior change resources and tools developed in line with the HAPA [30], SDT [40], and Self-Regulation Theory [32]. The BCTs [38] included in this intervention are enumerated on a per-component basis in Table 3, and screenshots of many web-based components are available in Multimedia Appendix 1. The patient intervention would include a maximum of 1 hour of contact time with an HCP, and participants could spend as much or as little time as they desired using the web-based behavior change resources and tools.

During a patient's first MaMCVD consultation, HCPs applied the key elements of MI in health care settings that they learned during the web-based MaMCVD course [39]. The goal of this initial consultation was to help patients form an intention to increase their PA behavior, and therefore, it also included techniques designed to target theoretical predictors of intention by fostering self-efficacy [41,42], addressing outcome expectancies and autonomous motivation for change, and providing information and advice only where necessary and in a way that supports patient autonomy and control [43]. During the session, HCPs obtained information about how PA fits into the patient's life, explored times in the past when the patient was more physically active, identified and weighed the pros and cons of potentially taking more PA, and helped patients work through this ambivalence. HCPs also aimed to create and appropriately respond to patient utterances of change talk and worked to elicit patients' motivations for change and long-term (outcome) goals. During the consultations, HCPs made efforts to adhere to the spirit of MI and use MI-adherent behaviors such as obtaining permission before providing advice or information, affirming the patient, emphasizing the patient's control, and supporting the patient with compassion or sympathy [39]. In addition, HCPs were instructed to avoid MI nonadherent behaviors such as advising without permission; confronting the patient; or directing the patient by giving orders, commands, or prescriptions [39], as a positive balance between MI-adherent and MI-nonadherent behaviors has been shown to predict favorable outcomes in consultations about PA behavior changes [44,45].

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Table 3. Description of the BCTs[a] delivered over the course of the MaMCVD[b] intervention for patients.

BCT	Consultation 1 (in person)	In the web-based MaMCVD materials	Consultation 2 (telephone)
Motivational interviewing	✓		✓
Prompt focus on past success	✓		✓
Individualized information on consequences of PA[c]	✓	✓	✓
Outcome goal setting	✓	✓	
Information on general consequences of PA		✓	
Behavioral goal setting		✓	
Action planning		✓	
Prompt self-monitoring of behavior		✓	
Barrier identification and problem-solving		✓	✓
Prompt review of behavioral goals		✓	✓
Prompt review of outcome goals		✓	✓
Relapse prevention or coping planning		✓	✓
Provide feedback on performance		✓	✓
Provide info on when and where to perform PA		✓	
Provide rewards contingent on behavior		✓	
Provide rewards contingent on progress		✓	
Teach to use prompts and cues		✓	
Use of follow-up prompts			✓

[a]BCT: behavior change technique.

[b]MaMCVD: Movement as Medicine for Cardiovascular Disease Prevention.

[c]PA: physical activity.

At the end of this initial session, a time and date for the follow-up telephone call were planned, and the HCP provided each patient with a pedometer, an activity log, and a unique log-in and password for the MaMCVD web-based behavior change tools. The primary aim of this patient website was to help people translate their intentions to be more physically active into actual PA behavior [46]. However, to accommodate patients who did not form an intention to increase their PA after their initial face-to-face consultation, the web-based behavior change tools also included techniques to promote intention formation.

Upon logging into the MaMCVD patient website, patients were directed to the *Decision Dashboard* preintentional portion of the site, which contained information pages and interactive assessments of patients' pros and cons of change and current PA levels. The information pages described the benefits of PA to health and well-being, government recommendations for PA, places in the community where participation in PA or sports was possible, and information about how to enjoy PA safely. The assessment of pros and cons took in users' own ideas about PA and provided tailored feedback about their intention strength. The assessment of current PA accepted user-recorded levels of PA based on 1 week of self-monitoring via the activity log and pedometer provided in the first session and provided tailored, autonomy-supportive feedback based on a comparison of patients' logged PA and current government guidelines for PA. Patients were free to explore these segments in any order they wished and could, at any time, click on a button within the *Decision Dashboard* to indicate to the system that they wished to launch the *Activity Dashboard* (ie, he or she had formed an intention to become more physically active).

After launching the *Activity Dashboard*, patients were asked to specify their motivation for wanting to become more physically active (ie, set an outcome goal). Patients who had difficulty specifying their motivation were offered a motivation assessment tool based on the Exercise Motivations Inventory [47]. In the motivation assessment tool, patients stated the strength of their desires to achieve the several outcomes that PA can produce (eg, vitality, health, and social) and subsequently received tailored feedback about the outcomes on which they scored the highest.

After choosing a motivation, users proceeded to the postintentional *Activity Dashboard* portion of the website, which contained several BCTs derived from Self-Regulation Theory (ie, self-monitoring, feedback, goal setting, action planning, and problem-solving). This set of techniques has been shown to play a vital role in increasing PA levels in previous research [25,48]. To establish a baseline level of PA, if they had not done so already in the *Decision Dashboard* portion of the website, patients were asked to self-monitor their behavior for a 1-week period. These data could be inputted by entering the duration and intensity of PAs they had engaged in or by entering the daily step counts from their pedometer. The system converted

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any activities entered into steps using metabolic equivalent values [49], which allowed for the entry of activities that could not be recorded by a pedometer (eg, swimming and cycling) and for the presentation of all activities using a common metric.

After 1 week of tracking to establish a baseline level of PA, patients were prompted to set a week-long PA goal for total steps or average steps per day. To reduce the risk of users failing to achieve their goals, as this could undermine self-efficacy and motivation [50], patients received visual feedback on the assumed difficulty of their new goal based on a comparison with their average activity level over the past 4 weeks. This gradual method of PA growth aimed to increase self-efficacy in PA [41].

After setting a goal, individuals were prompted to plan specific activities, times, durations, locations, and intensities of PA, which would lead them to achieve their weekly goal. Patients could also indicate whether they would like to receive reminders about their planned activities via email.

The *Activity Dashboard* also contained a problem-solving tool (based on the volitional help sheets of Armitage and Arden [51]) with which users could identify personally relevant barriers to PA participation, view common ways to overcome each barrier, brainstorm their own solutions, and make explicit links between their chosen barriers and solutions.

In engaging with the Movement as Medicine website, patients could use as many or as few of the self-regulation resources as they deemed necessary. Patients received rewards in the form of web-based badges for engaging with various aspects of the website, increasing PA in consecutive weeks, logging into the site in consecutive weeks, achieving their PA goals, achieving weekly or lifetime milestones, and meeting government guidelines for PA. In addition, users were prompted by email to revisit the site after a prolonged time between log-ins and were given tailored advice if they failed to achieve goals in successive goal periods.

After 2 months from the initial MI consultation (+1 week or –1 week), the patients received a follow-up phone call from their HCP to discuss their progress to that point. The structure of this consultation was flexible and tailored to reflect the extent to which each patient had formed an intention or engaged with the web-based self-regulation materials. For patients who still had not formed an intention to increase PA, the consultation would, in many ways, reflect the initial MI consultation, focusing on motivation for change and long-term outcome goals. For patients who had formed an intention and had engaged with the self-regulation materials, the call focused on providing technical assistance with the website, helping the patient talk through and overcome barriers to PA, and providing support for the patient's efforts. Regardless of the content, phone consultations were to be conducted in an MI-adherent way to continue to foster motivation for sustained behavioral change.

Outcome and Process Measures

Health Care Professional Measures

Overview

To assess the effects of the MaMCVD web-based course on HCPs' likelihood of effectively delivering PA promotion sessions in practice, we assessed important theoretical predictors of this outcome at baseline and after the completion of the course. These constructs included knowledge of the relationships between CVD and PA; self-efficacy, outcome expectancies, and intention to promote PA to patients in practice [52]; and autonomous motivation for delivering PA behavior change interventions to patients [53].

Evaluation of the Web-Based MaMCVD Course Materials

To obtain information about the acceptability of the web-based course, interviews were conducted with each HCP upon completion of the course to identify aspects of the course that required modification and were most or least useful, as well as to identify any technical problems encountered by HCPs while following the course. The interview topic guide is available in the Multimedia Appendix 1.

Patient Measures

Patient measures were assessed at baseline and 3 months. At both measurement points, the research staff mailed the patients an accelerometer and a guide for its use, a questionnaire booklet, and a stamped and addressed envelope to return the accelerometer and questionnaire pack to the research team.

PA Measures

Wrist-worn accelerometers (AX3, Axivity) [54] were used to capture 7-day monitoring of sedentary behavior and PA levels under free-living conditions. The AX3 is a triaxial accelerometer configured for sampling at 100 Hz [54]. The accelerometer was preprogrammed to start on disconnect and posted to the participant to start wearing the day after receiving the monitor, and instructions were provided on how to wear the accelerometer.

Accelerometer data were processed in R (R Foundation for Statistical Computing) [55] using the package GGIR [56]. The signals were inspected and corrected for calibration error [57]. The first and last hours of the measurement were excluded as they were expected to be influenced by the monitor distribution and collection procedure. Next, the average magnitude of wrist acceleration per 5-second epoch was calculated using the metric Euclidean Norm Minus One, as previously described [56]. The output from the metric Euclidean Norm Minus One is in milligram (1 mg=0.001 g=0.001×9.8 m/s^2=0.001×gravitational acceleration) [56]. Monitor nonwear was detected as described previously [56] and replaced by the average accelerometer data at similar time points on different days of the measurement [58,59]. The imputation procedure used was effectively the same as taking the average of all available data weighted by the number of available data points per time of the day. In contrast, taking the plain average of all available data points would cause unequal weighting of periods within the 24-hour cycle and result in an unstandardized estimate of PA. The resulting time series was used to derive the time spent in the acceleration categories

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per day. Moderate to vigorous PA (MVPA) was calculated using a ≥100 mg cutoff, and the outcome was displayed as an average for the week [60]. The average most and least-active 5-hour periods of each day were also calculated in milligrams. Only patients with at least 5 days of valid measurement (ie, at least 16 hours of wear time in a 24-hour period) in each assessment period were included in the analyses [61].

Patients' subjective PA levels were assessed using the short version of the International PA Questionnaire [62]. The primary outcome of interest from this questionnaire was the total MVPA (minutes per week). Self-reported leisure time MVPA (minutes per week) and sitting time (hours per day) are also reported.

Theoretical Predictors of PA

Predictors of PA derived from the HAPA [30] and SDT [40] were assessed among patients via postal questionnaires delivered at baseline and 3 months. The HAPA questionnaire [63] assessed risk perceptions (both absolute and relative), outcome expectancies, action planning, action control, and intention for PA with items using 4-, 5- and 7-point Likert scales. Means of the items were used to create the total score for each scale.

Self-efficacy for PA was assessed using the 18-item Exercise Self-efficacy Questionnaire developed by Bandura [64]. Each item presents a situation in which it may be difficult to engage in PA (eg, when busy and in bad weather) and allows participants to rate the likelihood that they could be physically active from 0 (not at all likely) to 10 (certainly). The mean of 18 items was used as the total self-efficacy score.

The Behavioral Regulation in Exercise Questionnaire was used to measure the continuum of behavioral regulation for PA [53]. It is a 19-item questionnaire that assesses intrinsic, identified, introjected, and external regulatory styles for exercise, with responses given on a 5-point Likert scale. The scales were calculated by taking the mean of the items within each regulatory style.

Depressive symptoms were assessed using the Patient Health Questionnaire [65], a validated brief self-report inventory commonly administered in primary care, which addresses the presence and severity of the 9 diagnostic criteria for major depressive disorder from the Diagnostic and Statistical Manual of Mental Disorders [66].

Control beliefs about developing CVD were assessed using a modified 6-item version of the Brief Illness Perceptions Questionnaire [67]. Patients' feelings of control from both personal and treatment-related sources were assessed on an 11-point Likert scale (0-10).

Use of Movement as Medicine Intervention Materials

Each patient's progress and interactions with the web-based MaMCVD intervention were anonymously logged by the system to identify the point at which patients proceeded to the postintentional website components and monitor the extent to which each patient viewed the information pages and engaged with the behavior change tools found on the website.

Trial Procedures

Practice Recruitment

Primary care organizations from the Northeast of England were approached to participate through meetings of clinical research networks within the NHS, as well as through local and regional meetings of general practice managers. In these meetings, researchers presented a rationale for the study, an outline of its procedures, and reimbursement schemes available to help practices cover the costs of treatment and recruitment. Primary care organizations were actively followed up by phone or email after these meetings, and those that responded favorably and expressed a capability to enroll at least two health care professionals in the study were included in the study. Recruitment of primary care organizations was planned to continue until 9 primary care organizations had been recruited or after 4 months of active recruitment.

HCPs from the recruited primary care organizations were given information sheets and asked to provide informed consent for the study. Participation was voluntary, and the HCPs were free to withdraw from the study at any time. In cases where HCPs withdrew from the study after contributing data, data already collected were included in the study report unless they were specifically requested to be removed.

Patient Recruitment

Patients were recruited through 2 possible streams of enrollment, and enrollment began after 2 HCPs from a participating primary care organization consented to participate in the study. In the first stream, a member of staff from each participating primary care organization accessed electronic patient record databases and selected a random sample of 200 or 400 patients (depending on the practice list size) who fulfilled the inclusion criteria and had at least a 20% risk of developing CVD over the next 10 years, as assessed by the QRISK2 algorithm [35]. The research staff then mailed a recruitment pack to each of these randomly selected eligible patients, which included an invitation letter, a patient information sheet, the PA Readiness Questionnaire [68], an informed consent form (all printed on paper headed with the details of that primary care organization), and a prepaid return envelope. In the second stream, patients who had recently undergone an NHS Health Check and who met the inclusion criteria were given the same abovementioned recruitment pack, with Movement as Medicine described as a brief PA intervention that fulfills Public Health England's Best Practice Guidance for the NHS Health Checks program [69]. Patient recruitment was planned to continue for 4 months at each site or until the overall target of 198 patients was reached. The target sample size of 198 was based on sample size calculations for multiple regression analyses to investigate processes within the intervention (α=.05; power=0.80; anticipating a medium effect size with 10 independent variables). Initial calculations in G*Power [70] indicated that 118 patients were needed to detect effects; however, after accounting for a potential dropout of approximately 20% and cluster effects based on primary care organization and HCP, the necessary sample size rose to 198 patients, recruiting 22 patients from each of the 9 recruited primary care organizations. This sample size was not achieved within the 4-month window of recruitment.

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Patients interested in taking part were asked to return the written informed consent form and the completed PAR-Q to the primary care organization in the prepaid envelope. If the patients failed the PAR-Q form by answering *yes* to any of the questions, they were required to obtain written approval from their GP before enrolling in the study. Upon arriving for their face-to-face consultation at the beginning of the study, patients had the chance to ask further questions and signed the consent form again in the presence of a member of staff to ensure that patients fully understood the study procedures. Patients who did not respond to the initial recruitment pack mail within 1 month were sent a second recruitment pack. If no response was received after this, no further efforts were made to recruit that patient. Primary care organizations continued to contact eligible patients in this manner for 4 months.

Patients were made aware that their participation in the study was entirely voluntary and that they could withdraw at any time without providing a reason and without their legal rights or health care being affected. In cases where participants withdrew from the study after contributing data, these data were used in the analyses unless they specifically requested that they be removed.

Patients who dropped out of the study were mailed a postcard with 3 very short questions to obtain their reasons for dropping out. The return of this postcard was entirely at the patients' discretion and was intended to gather important information that could be used to alter the program and procedures to reduce the likelihood of future dropouts for the same reasons.

Statistical Analyses

Paired *t* tests (2-tailed) in SPSS (SPSS Inc) were used to compare the baseline and follow-up levels of HCP outcomes. Multiple imputation (i=5) was undertaken to account for missing patient data at the 3-month follow-up. The imputation model used baseline demographic information and baseline and follow-up data of all study outcomes to predict the missing follow-up values of all study outcomes. Paired *t* tests were used to compare baseline and follow-up levels of patient outcomes in the pooled intention-to-treat data set. Cohen *d* effect sizes, and 95% CIs were also calculated to estimate the potential efficacy of the interventions and inform the sample size and power calculations for subsequent testing of this intervention [71]. Qualitative data from interviews with HCPs were examined using content analysis.

Ethics Approval and Consent to Participate

A favorable ethical opinion was granted by Newcastle and North Tyneside 1 NHS Research Ethics Committee (reference 14/ES/0032). Informed consent was obtained from all research participants.

Availability of Data and Materials

The data sets generated and analyzed during this study are not publicly available, as ethical approval for the sharing of data was not sought or obtained; however, these are available from the corresponding author on reasonable request.

Results

Recruitment

A total of 128 primary care organizations in the Northeast of England were approached for participation in the study. Of the 128 approached organizations, 5 (3.9%) primary care organizations (ie, n=4, 80% general practices and n=1, 20% community health organization) were willing to participate in the study. However, 50% (2/4) of the general practices dropped out of the study because of staff turnover and lack of available resources to administer the study.

Within the 3 remaining primary care organizations, recruitment packs were mailed to 827 patients. Of these 827 patients, 84 (10.2%) provided informed consent to participate in the study, with 83 (10%) subsequently completing baseline measures. Recruitment rates were 7%, 11%, and 12% across the 3 included primary care organizations. Detailed information on the flow of primary care organizations, HCPs, and individuals throughout the study can be found in Figure 1.

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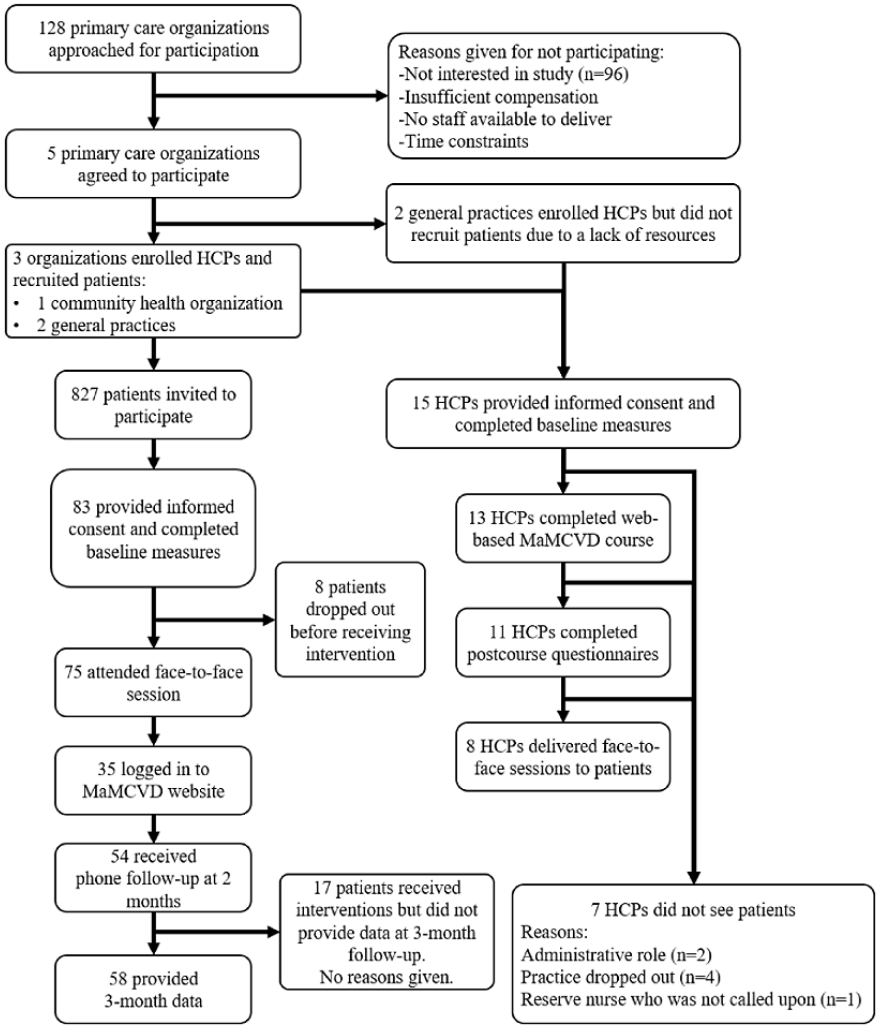
Figure 1. Flow of individuals through the study. HCP: health care provider; MaMCVD: Movement as Medicine for Cardiovascular Disease Prevention.



HCP Characteristics

A total of 11 HCPs completed the web-based course and postcourse questionnaires. Of these 11 HCPs, 7 (64%) were female, with a mean age of 38.8 (SD 9.9; range 28-52) years. Enrolled HCPs were PA specialists (5/11, 46%), practice nurses (3/11, 27%), health care assistants (2/11, 18%), and GPs (1/11, 9%) and had an average of 7.1 years in their current role. Of the 11 HCPs, 7 (64%) had previously received some form of training in behavior change methods or BCTs.

Acceptability of Web-Based MaMCVD Course Materials and Changes in HCP Outcomes

After completing the web-based course, the HCPs reported increases in self-efficacy for promoting PA in practice and for having concrete plans of how and where to promote PA in practice. Smaller increases in habit were also reported, whereas reported changes in attitudes toward PA promotion, intention for PA promotion, and goal conflict were negligible. Quantitative results for the HCP outcomes are presented in Table 4.

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Table 4. Effects of Movement as Medicine for CVD[a] Prevention on health care provider outcomes (N=11).

Outcome	Baseline, mean (SD)	Postcourse period, mean (SD)	*P* value[b]	Cohen *d* (95% CI)
Self-efficacy	3.91 (0.82)	5.03 (0.98)	.002	1.24 (0.67 to 1.80)
Attitudes	6.82 (0.34)	6.86 (0.26)	.69	0.13 (−0.40 to 0.66)
Intention	5.91 (0.77)	5.86 (1.23)	.91	−0.05 (−0.65 to 0.56)
Planning	4.48 (1.42)	5.45 (0.75)	.05	0.85 (−0.01 to 1.69)
Habit	4.93 (1.62)	5.55 (1.33)	.04	0.42 (0.02 to 0.80)
Goal conflict[c]	3.68 (1.33)	3.59 (1.53)	.76	−0.06 (−0.46 to 0.34)

[a]CDV: cardiovascular disease.

[b]*P* values reported are for paired *t* tests and are not corrected for multiple comparisons. Instead, we refer readers to the reported effect size estimates and CIs.

[c]For this outcome, a negative effect size indicates a favorable result of the intervention.

Qualitative interviews with HCPs indicated broad acceptability of the web-based course, with an appreciation for the demonstration videos of MI techniques and several of the interactive educational elements. Some HCPs were unable to access the web-based course from the computer workstations in their primary care practice because of outdated browsers still being in use. In these cases, HCPs completed the web-based course using their home computer or tablet.

Patient Characteristics

Of the 83 patients who provided data at baseline, 44 (53%) were female, and the average age was 57.5 (SD 10.2) years; 62 (75%) were married or cohabitating, and 41 (49%) were in part- or full-time employment, whereas 40 (48%) were unemployed or retired. Of the 83 patients, 15 (18%) had not completed high school or equivalent vocational education, whereas 25 (30%) had completed a university degree. Approximately 70% (58/83) of participants completed the 3-month follow-up measures, and there were no significant differences between patients who dropped out of the study and those who completed both baseline and follow-up assessments.

Changes in Patient Outcomes

Analyses of intention-to-treat data revealed a significant increase of 9.6 minutes per day in objectively measured MVPA from baseline to follow-up (effect size Cohen d=0.77). Participants also reported favorable increases in self-reported total MVPA and MVPA during leisure time, as well as small reductions in sedentary behavior, all with effect sizes >Cohen d=0.44. Of the psychological variables assessed, patients reported favorable changes in self-efficacy for PA, PA action planning, action control, and intrinsic motivation for PA, with effect sizes between Cohen d=0.46 and Cohen d=0.60. The effect sizes for most of the other outcomes were <Cohen d=0.30. Table 5 provides for the means, SDs, and effect sizes with CIs.

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Table 5. Effects of the Movement as Medicine for CVD[a] Prevention intervention on patient outcomes.

Outcome	Baseline, mean (SD)	3 months, mean (SD)	*P* value[b]	Cohen *d* (95% CI)
Objective PA[c,d]				
MVPA[e] (minutes per day)	83.1 (36.5)	92.7 (38.3)	.02	0.77 (0.13 to 1.41)
L5[f]	3.6 (0.7)	4.0 (2.5)	.32	0.32 (–0.31 to 0.94)
M5[g]	39.7 (9.2)	43.9 (11.5)	.01	0.94 (0.29 to 1.60)
ENMO[h] (mg)[i]	20.9 (4.8)	22.4 (5.2)	.01	0.83 (0.19 to 1.48)
Subjective PA				
IPAQ[j] total MVPA (minutes per week)	318 (203)	349 (172)	.18	0.30 (–0.14 to 0.74)
IPAQ leisure time MVPA (minutes per week)	36.5 (87.4)	58.2 (76.7)	.03	0.49 (0.05 to 0.93)
Sitting time (hours per day)[k]	5.85 (2.81)	5.24 (2.43)	.05	–0.44 (–0.88 to 0.002)
Determinants of PA from HAPA[l]				
Intention for PA	4.51 (1.24)	4.77 (1.09)	.09	0.39 (–0.06 to 0.84)
Self-efficacy for PA	4.61 (1.78)	5.19 (1.76)	.01	0.59 (0.14 to 1.03)
Action planning for PA	3.32 (1.84)	3.92 (1.67)	.01	0.60 (0.15 to 1.06)
PA outcome expectancies	3.50 (0.71)	3.44 (0.64)	.51	–0.15 (–0.60 to 0.30)
Perceived barriers to PA[k]	1.99 (1.04)	1.88 (1.10)	.52	–0.15 (–0.59 to 0.30)
Action control for PA	1.50 (0.78)	1.81 (0.80)	.02	0.54 (0.09 to 1.00)
Regulatory style				
Intrinsic motivation	2.08 (1.22)	2.36 (1.23)	.047	0.46 (0.01 to 0.91)
Identified motivation	2.36 (0.99)	2.59 (0.97)	.05	0.45 (–0.001 to 0.90)
Introjected motivation[k]	1.07 (0.95)	1.20 (0.89)	.35	0.21 (–0.23 to 0.65)
External motivation[k]	0.49 (0.69)	0.61 (0.71)	.27	0.25 (–0.19 to 0.70)
Amotivation[k]	0.47 (0.76)	0.48 (0.64)	.96	0.01 (–0.43 to 0.46)
Illness perceptions				
Personal control	6.10 (1.71)	6.63 (1.54)	.39	0.20 (–0.25 to 0.64)
Treatment control (PA)	7.88 (1.49)	7.24 (2.56)	.23	–0.27 (–0.72 to 0.17)
Concern	6.42 (2.50)	5.90 (2.65)	.19	–0.30 (–0.75 to 0.15)
Prevention comprehension	6.67 (2.15)	6.94 (2.12)	.54	0.14 (–0.31 to 0.58)
Other outcomes				
Depressive symptoms[k]	5.95 (5.83)	4.99 (4.58)	.16	–0.32 (–0.77 to 0.13)
Perceived CVD risk (relative)	3.08 (1.25)	3.45 (1.86)	.21	0.29 (–0.16 to 0.74)
Perceived CVD risk (%; absolute)	48.7 (21.0)	44.2 (26.8)	.38	–0.21 (–0.69 to 0.26)

[a]CVD: cardiovascular disease.

[b]*P* values reported are for paired *t* tests using pooled multiple imputation data and are not corrected for multiple comparisons. Readers are instead referred to the reported effect sizes and 95% CIs.

[c]PA: physical activity.

[d]Objective physical activity data are for individuals with at least 5 days of valid accelerometer wear time at both baseline and 3-month assessment periods (n=40). All other outcomes are reported for individuals who completed both baseline and 3-month questionnaires (n=58).

[e]MVPA: moderate to vigorous physical activity.

[f]Average least active 5-hour period of each day in mg.

[g]Average most active 5-hour period of each day in mg.

[h]ENMO: Euclidean Norm Minus One.

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[i]Average wrist acceleration.

[j]IPAQ: International Physical Activity Questionnaire.

[k]Lower scores are desirable for this outcome; thus, a negative effect size indicates a favorable result of the intervention.

[l]HAPA: Health Action Process Approach.

Use of Web-Based Tools

Of the 75 patients who attended a face-to-face session and received log-in credentials for the patient website, 35 (47%) logged in at least once. Among these 35 individuals, 7 (20%) logged into the system weekly for at least 10 consecutive weeks, and the mean number of log-ins during the 3-month study period was 19.6 (mean log-ins per week 1.5). The most active user during the study period logged in 156 times or an average of 12 times per week. Further data on the use of individual components of the web-based intervention are presented in Table 6.

Table 6. Numbers of patients who used the web-based components of the Movement as Medicine intervention (n=35).

Component	Users,[a] n (%)
Motivation-focused components	
Weighing pros and cons tool	5 (14)
Motivation assessment tool	3 (9)
Indicated a decision to become more physically active	15 (43)
Self-regulatory components	
Set at least one physical activity goal	11 (31)
Logged some self-monitored physical activity	10 (29)
Made at least one physical activity action plan	4 (11)
Formulated at least one coping plan using the problem-solving tool	4 (11)
Used self-monitoring plus at least one other self-regulatory component	10 (29)
Used all self-regulatory components	3 (9)

[a]Percentages indicate the proportion of individuals who logged into the patient website at least once (n=35) that used each component.

Discussion

Principal Findings

This nonrandomized pilot study assessed the feasibility of MaMCVD, a suite of 2 behavior change interventions for HCPs and patients to promote PA in primary care settings. MaMCVD was designed to provide HCPs with the skills required to increase motivation for PA among patients with CVD risk and help them address common barriers to promoting PA in primary care settings. In addition, it aimed to offer patients a set of theory- and evidence-based tools that they could use to self-regulate their efforts toward increasing PA and reducing CVD risk.

Feasibility of the MaMCVD Program

Among the patients approached for participation in this study, recruitment and retention rates were in line with expectations; however, recruitment of primary care organizations fell below expectations. This is attributable to several factors, including a major reorganization of primary care service delivery within the NHS just before the commencement of this study. In 2013, primary care trusts were disbanded and replaced by clinical commissioning groups, which created uncertainty as to whether and how participation in research studies would be reimbursed [72]. In addition, as this study was funded by a local (as opposed to a national or international) organization, it was not eligible for adoption by the National Institute for Health Research (NIHR) clinical research network [73]. Adoption to the NIHR portfolio would have provided additional financial compensation and logistical assistance to primary care organizations for taking part [74] beyond the CPD training and logistical assistance provided in this study. During recruitment, conversations with research leads from several primary care organizations indicated insufficient compensation and a lack of available staff as the most common reasons for nonparticipation in the study. Identifying additional compensation possibilities for practices and ensuring study adoption by primary care research networks will be key to improving the recruitment of primary care organizations when testing MaMCVD in a larger RCT.

The 30% rate of patient dropout in this study is similar to that reported in studies testing other (web-based) PA interventions among individuals with chronic diseases [75]. Although we attempted to gather information about the reasons why participants dropped out of the trial by mailing a postcard to those who did, none of these postcards were returned to the study team, and we were unable to gather such information. In any full-scale trial of MaMCVD, it might be worth including efforts to improve study retention, especially if outcomes are examined with a longer follow-up period. This could potentially include offering patients a choice of intervention components based on their preference (eg, web only, face-to-face only, or both options). For HCPs, the potential perceived burden of both receiving and delivering an intervention within the same study,

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as well as the share of total working time study-related obligations take up, should also be considered.

The web-based tools that constituted part of the MaMCVD intervention for patients were not used by all the participants. Approximately half of the participants who attended an MI session logged into the patient website, which is somewhat lower than the uptake reported in other internet-based PA interventions [76]. This could potentially be attributed to whether and how a patient's HCP introduced the website. As the study did not include any checks of whether patients received website log-in credentials from their HCP, it is possible that HCPs may have forgotten to deliver these to some patients. This element of intervention fidelity should be assessed in any further rollout of MaMCVD. In addition, audio recordings of MI sessions early in the trial revealed that some HCPs misinformed patients about the purpose of the patient website, referring to it simply as a place where patients could obtain additional information about PA. As much of the content of face-to-face MI sessions was already informational, patients may not have been interested in receiving even more information and may therefore have avoided logging in. In a future rollout of the MaMCVD intervention, the role of HCPs in referring patients to the web-based motivational and self-regulatory tools for patients will be emphasized more concretely, and sufficient patient numbers should be included to allow for investigating relationships between the use of web-based tools and PA outcomes. In addition, in future studies, the fidelity of MI sessions delivered to patients should be investigated as a potential moderator of subsequent engagement with web-based self-regulation tools and overall intervention effectiveness.

Effects of the Web-Based Course for Health Care Professionals

Following completion of the web-based course, HCPs participating in this study self-reported considerable increases in self-efficacy for promoting PA in practice. This indicates that the web-based course helped HCPs become more confident that they could overcome the common barriers to promoting PA in practice. The intervention also led to moderate increases in planning and habits for PA promotion, meaning that PA promotion became somewhat more routine for HCPs after they completed the web-based course. As self-efficacy, planning, and habits have previously been shown to be strong predictors of other preventive clinical behaviors (eg, HCP behaviors in diabetes care) [77], it is reasonable to assume that HCPs who followed this web-based course might be more likely to promote PA to their patients outside the context of this study. HCPs reported no changes in their attitudes or intentions to promote PA, perhaps because of ceiling effects from the high baseline levels of these variables. Taken together, the effect sizes obtained for increases in self-efficacy and habit indicate that the HCP-facing MaMCVD intervention could help to improve PA promotion in practice. However, given the small sample size, potential bias of self-report measures, and lack of a control group in this study, these results should be interpreted with caution. Therefore, future studies may wish to investigate whether changes in self-efficacy, planning, and habit translate into objective changes in HCPs' in-session PA promotion behaviors.

Effects of the Interventions for Patients

Between the baseline and posttreatment time points, objectively assessed MVPA increased by nearly 10 minutes per day among patients with an adequate accelerometer wear time. Subjective measures of PA corroborated these results, with the total self-reported MVPA increasing by approximately 45 minutes per week after the intervention. These 3-month effects on objective and subjective levels of MVPA are similar in magnitude to those obtained from primary care–delivered PA promotion interventions in general [78]. However, it should be noted that the sample of participants in this study was already highly active at baseline, with >80 minutes of objectively assessed MVPA per day. Future testing of MaMCVD should try to overcome this self-selection bias and recruit a less active sample to maximize the potential impact on CVD risk.

In addition to increases in PA, participants reported beneficial changes in important motivational and volitional predictors of PA behavior. Intention for PA, the seminal predictor of PA in many behavioral theories, also increased from baseline to posttreatment. This represents an important outcome of the intervention as, according to the Rubicon model [79], solid intentions to perform a behavior are prerequisites for engaging in self-regulatory behaviors, such as goal setting and action planning. Theoretically, this fits well with the increased use of action planning for PA participants reported between baseline and posttreatment time points. Although self-reported action planning did increase, this was not borne out in the objective data on patients' use of web-based self-regulatory tools, wherein only 11 participants set a goal or made an action plan. Therefore, self-reported increases in action planning more likely reflect individuals' mental conceptualizations of future PA-related actions, as opposed to any specific written action plans.

Patients also reported increases in action control for PA, which entails a greater focus on efforts to increase PA behavior. This, too, is an important finding, as self-regulatory efforts to change behavior require increased attention to the target behavior to be effective [32]. A recent meta-analysis indicated that coupling these self-regulatory techniques with opportunities for patients to engage in supervised PA could increase these effects on intention [80], a possible add-on for future iterations of the MaMCVD intervention.

Although most intervention effects occurred in the intended direction, several did not. Introjected motivation and external motivation, controlled forms of motivation that may undermine long-term PA participation [81], both increased between baseline and posttreatment time points. Participants also reported less concern about developing CVD after treatment than they did at baseline, as well as a decrease in the extent to which they thought PA could prevent CVD incidence. Although the magnitudes of these potential adverse effects were small, any subsequent iterations of MaMCVD should seek to mitigate these effects. This could be done by emphasizing and supporting participants' autonomy in their PA journeys by ensuring that participants engage with the educational content about the links between PA and CVD incidence and by clearly communicating CVD risk.

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Strengths and Limitations

This pilot study of the Movement as Medicine suite of behavior change interventions for HCPs and patients represents an important step in meeting the needs of HCPs tasked with promoting PA in primary care settings. The interventions were specifically designed to address HCPs' barriers to PA promotion in practice and were designed in line with theory and evidence on how to increase motivation and PA among patients. In addition, the study used objective measurements of PA to overcome social desirability and other response biases in PA intervention studies [82].

Despite these strengths, some limitations should be considered. First, no clinical outcomes were assessed as part of this study, as we did not expect changes in these within the short 3-month study period. The possibilities of sampling bias (eg, more motivated participants enrolling in the study), ceiling effects, and response desirability bias on subjective outcome measures should also be considered as limitations of this study. Common biomedical measures associated with CVD risk, such as blood pressure, cholesterol, weight, and waist circumference, as well as objective measures where possible, should be included in future tests of this intervention. Second, the recruitment of primary care organizations fell below anticipated targets, which limits the ability to generalize patient retention rates across sites. This low uptake among primary care organizations also led to deviations from the published trial registration and a reduction in the scope of the study from an RCT to a nonrandomized pilot feasibility study. As a result, patient recruitment too fell below the initial sample size targets, meaning that we were unable to investigate the extent to which changes in the theoretical determinants of PA and patient engagement with the MaMCVD intervention contributed to levels of PA at the end of the intervention in this study. More financial resources and adoption to the NIHR portfolio would likely improve the uptake of the intervention and allow for testing of these predictive hypotheses. Finally, as this was a single-group pilot study, the reported effect sizes for changes in the variables under study should not be interpreted as causal or as estimates of the true effects. Rather, these effect size estimates should be used to calculate the sample size needed to demonstrate between-group efficacy in a larger RCT.

Conclusions

The MaMCVD program sought to provide primary HCPs with new skills to promote PA during brief primary care consultations and, more broadly, to offer a follow-on PA treatment pathway for individuals with elevated CVD risk. The intervention improved self-efficacy for PA promotion among HCPs and may have had knock-on effects on their day-to-day practice. For patients participating in the study, MaMCVD offered web-based tools with which they could motivate themselves and self-regulate their efforts at PA behavior change. The intervention led to increases in the self-reported determinants of PA, including self-efficacy, intrinsic motivation, action planning, and action control, as well as increases in objectively assessed MVPA. Although these preliminary results indicate support for the program, the findings should be tempered, given the small sample size, absence of a control group, and use of self-report measures. In addition, feasibility problems around the uptake of the program by primary care organizations and national health research bodies need to be addressed before any broader rollout or testing of the program can take place. The results obtained here will be useful in improving these aspects of the MaMCVD program and can inform subsequent testing of the intervention in an RCT.

Acknowledgments

This research was funded by grant number 22034 from County Durham Sport to MIT. The funder had no role in the design of the study; collection, analysis, and interpretation of data; or in the writing of the manuscript.

The authors acknowledge Mike Lavender's contributions to the study and manuscript.

Authors' Contributions

MIT conceived the study and secured funding. KK, SO, MIT, FFS, and MC developed the *Movement as Medicine for Cardiovascular Disease Prevention* intervention. KK, SO, SJC, and LA conducted the study and collected the data. SJC cleaned and analyzed the objective physical activity data. KK cleaned and analyzed all other data. KK, SO, and SJC wrote the main manuscript. All authors critically revised the manuscript for important intellectual content and provided the final approval of the submitted version. All authors are accountable for all aspects of the work and ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

MIT is the founder and director of Changing Health, a digital behavior change company.

Multimedia Appendix 1
Supplementary materials, including screenshots of the websites for patients and health care providers, and the topic guide for interviews with health care providers.
[PDF File (Adobe PDF File), 1327 KB - cardio_v6i1e29035_app1.pdf]

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Abbreviations

BCT: behavior change technique
CPD: continuing professional development
CVD: cardiovascular disease
GP: general practitioner
HAPA: Health Action Process Approach
HCP: health care provider
MaMCVD: Movement as Medicine for CVD Prevention
MI: motivational interviewing
MVPA: moderate to vigorous physical activity
NHS: National Health Service
NIHR: National Institute for Health Research
PA: physical activity
PAR-Q: Physical Activity Readiness Questionnaire
RCT: randomized controlled trial
SDT: Self-Determination Theory

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Edited by A Mavragani; submitted 23.03.21; peer-reviewed by A McGuire, D Gürtler; comments to author 18.08.21; revised version received 08.12.21; accepted 27.12.21; published 29.06.22.

Please cite as:
Knittle K, Charman SJ, O'Connell S, Avery L, Catt M, Sniehotta FF, Trenell MI
Movement as Medicine for Cardiovascular Disease Prevention: Pilot Feasibility Study of a Physical Activity Promotion Intervention for At-Risk Patients in Primary Care
JMIR Cardio 2022;6(1):e29035
URL: https://cardio.jmir.org/2022/1/e29035
doi:10.2196/29035
PMID:35767316

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Original Paper

Comparing the Acceptance of Mobile Hypertension Apps for Disease Management Among Patients Versus Clinical Use Among Physicians: Cross-sectional Survey

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Abstract

Background: High blood pressure or hypertension is a vastly prevalent chronic condition among adults that can, if not appropriately treated, contribute to several life-threatening secondary diseases and events, such as stroke. In addition to first-line medication, self-management in daily life is crucial for tertiary prevention and can be supported by mobile health apps, including medication reminders. However, the prescription of medical apps is a relatively novel approach. There is limited information regarding the determinants of acceptance of such mobile health (mHealth) apps among patients as potential users and physicians as impending prescribers in direct comparison.

Objective: The present study aims to investigate the determinants of the acceptance of health apps (in terms of intention to use) among patients for personal use and physicians for clinical use in German-speaking countries. Moreover, we assessed patients' preferences regarding different delivery modes for self-care service (face-to-face services, apps, etc).

Methods: Based on an extended model of the unified theory of acceptance and use of technology (UTAUT2), we performed a web-based cross-sectional survey to explore the acceptance of mHealth apps for self-management of hypertension among patients and physicians in Germany. In addition to UTAUT2 variables, we measured self-reported self-efficacy, eHealth literacy, previous experiences with health apps, perceived threat to privacy, and protection motivation as additional determinants of mHealth acceptance. Data from 163 patients and 46 physicians were analyzed using hierarchical regression and mediation analyses.

Results: As expected, a significant influence of the unified theory of acceptance and use of technology (UTAUT) predictors on intentions to use hypertension apps was confirmed, especially for performance expectancy. Intention to use was moderate in patients (mean 3.5; SD 1.1; range 1-5) and physicians (mean 3.4, SD 0.9), and did not differ between both groups. Among patients, a higher degree of self-reported self-efficacy and protection motivation contributed to an increased explained variance in acceptance with R^2=0.09, whereas eHealth literacy was identified as exerting a positive influence on physicians (increased R^2=0.10). Furthermore, our findings indicated mediating effects of performance expectancy on the acceptance among patients but not among physicians.

Conclusions: In summary, this study has identified performance expectancy as the most important determinant of the acceptance of mHealth apps for self-management of hypertension among patients and physicians. Concerning patients, we also identified mediating effects of performance expectancy on the relationships between effort expectancy and social influence and the acceptance of apps. Self-efficacy and protection motivation also contributed to an increase in the explained variance in app acceptance among patients, whereas eHealth literacy was a predictor in physicians. Our findings on additional determinants of the acceptance of

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health apps may help tailor educational material and self-management interventions to the needs and preferences of prospective users of hypertension apps in future research.

(JMIR Cardio 2022;6(1):e31617) doi:10.2196/31617

KEYWORDS

patient acceptance of health care; mobile apps; blood pressure; mobile health; health applications; technology acceptance; patients; physicians; digital health

Introduction

Background

With 20 to 30 million out of approximately 82 million citizens affected in Germany alone, chronically increased blood pressure or hypertension represents a highly prevalent disease in working people, with a prevalence of 20%-25% in the age cohort of 40 to 49 years [1-3]. International studies also emphasize the role of hypertension as a leading risk factor for cardiovascular diseases as the most common cause of morbidity and mortality [4]. In addition, untreated or poorly treated chronically increased blood pressure can lead to life-threatening secondary diseases, such as heart attack or stroke. In Germany, approximately 20% of the people with high blood pressure are estimated to be unaware of their condition [5], whereas another study from the United States revealed that up to 36.2% of the concerned individuals are not aware that they suffer from hypertension [6].

Basically, hypertension results from the interaction of several factors, some of which cannot be changed, such as age or genetic disposition, whereas others can be influenced by stress, lifestyle, or health behavior [7] (eg, physical activity). Despite the availability of effective and relatively safe medication, only approximately half of the treated patients with high blood pressure are well adjusted, as indicated by epidemiological data [7]. Measuring one’s blood pressure values at home regularly is a further important prerequisite to control the disease because this promotes the patient's understanding of the disease and medication adherence [7]. Therefore, regular self-assessment or monitoring of blood pressure and a healthy lifestyle are recommended to patients [8]. All the described therapeutic approaches (self-assessment of blood pressure, taking medication regularly, and maintaining a healthy lifestyle) require a high degree of self-management by patients. Consequently, self-management represents important therapeutic potential for people suffering from hypertension [9]. However, self-management can pose high demands on patients with chronic conditions in daily life. Possible solutions include digital programs, such as disease management apps [10].

In general, mobile health (mHealth) apps are defined as digital apps on smartphones or tablets that provide health-related content and electronically record and evaluate the body data as well as behaviors of their users [11]. The features of these apps range from sending reminders via text messages to the measurement of, for example, blood pressure values via corresponding sensors. Health apps can be integrated into the everyday life of patients with hypertension and have the potential to positively influence the course of the disease in terms of improved long-term disease management, including medication reminders and monitoring [12-14]. In addition, the legal basis for integrating mHealth apps into routine care has been established in December 2019, making it possible to prescribe medical apps since October 2020, as statutory health insurance companies cover the expenses if apps are prescribed by physicians. However, despite an interest in using health apps among patients and physicians, their uptake requires considerable time to reach a population level, especially due to barriers such as the lack of knowledge about suitable options [15]. Accordingly, the acceptance of these apps, especially among patients without experience in using such apps whose functionalities vary considerably, depends highly on whether the disease-specific needs and patient preferences are met [10,12]. In addition, many studies have assessed acceptance of this technology only among patients as users or in terms of outcomes in clinical trials (eg, satisfaction), and they have not focused on early acceptance (eg, use intentions) of potential users such as patients and providers [16,17].

Determinants of the Acceptance of Health Apps

To improve the adoption of mHealth apps among smartphone users with hypertension, it is crucial to understand the determinants of acceptance and use. An approach for predicting acceptance (ie, intention to use) and usage of innovations such as health apps is the unified theory of acceptance and use of technology (UTAUT), including its core predictors namely performance expectancy, effort expectancy, social influence, and facilitating conditions [18]. Although the UTAUT model was developed in the business context, it is being extensively used to understand acceptance of new health care technologies [19], for instance, by assessing the usage intentions of a specific health technology among patients [20,21] and physicians [17,22]. The traditional UTAUT model was extended in 2012 to include hedonistic motivation, price value, and habit, subsequently called UTAUT2 [23], and it may be especially suitable to evaluate the acceptance of apps. Given the contextual sensitivity of acceptance, several extended UTAUT models and novel assumptions on mediating effects have been proposed, such as that of effort expectancy in relation to the other 3 UTAUT determinants (eg, performance expectancy) and intention to use a technology [20]. However, the remaining challenges in applying the UTAUT model include the unclarified mediating role of performance expectancy [20] along with the scarcity of UTAUT-related studies that clearly conceptualize and investigate the individual characteristics of technology acceptance [24].

In addition to the UTAUT2 determinants, self-efficacy has also been analyzed as a factor in various studies on the acceptance of innovations in health care, including electronic patient records

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[25], electronic mental health interventions [16,26], and hypertension apps [21].

Patient empowerment implies that patients are being increasingly recognized as the experts of their disease. However, making informed decisions on health apps require a broad range of skills and abilities, such as eHealth literacy. In the context of health apps for self-management of chronic diseases, a positive association with acceptance appears plausible because people with higher levels of eHealth literacy are expected to be more likely to find and use effective digital support for self-management [27] and cultivate preventive health behavior [28].

In addition to the outlined UTAUT determinants, personal beliefs or concerns regarding data protection in digital apps also appear to influence the intended use of health innovations, as mentioned earlier [29,30]. In contrast to the aforementioned factors, data protection and privacy concerns represent a barrier that is not commonly included in UTAUT-based research. According to Zhang et al [20], the perceived threat to privacy negatively influences the intention to use digital apps. In Germany, Heidel and Hagist [15] also confirmed that such concerns about data privacy and security are very strong or even stronger than those in many other countries.

Besides the UTAUT, factors such as the duration and therapy of hypertension, attitudes, and evaluation of the disease also play an important role in the context of hypertension as the determinant for the use of health apps. Illness-related predictors of health app adoption can be covered by the protection motivation theory (PMT) [31]. According to the PMT, the motivation to protect arises from the assessment of a threat and possible coping strategies. Protection motivation with respect to hypertension is mainly relevant for patients because this variable reflects beliefs about one's own health risk and not those of others. The influence of the PMT factors on the acceptance of eHealth solutions was confirmed, whereas the effect on the intention to use was found to be mediated by attitudes and moderated by age and gender [32].

However, little is known about the relative contribution of the subjective evaluation of one's disease and technology-related concerns regarding data protection aspects. Furthermore, most studies focus on 1 user group (patients or physicians), thus hampering the direct comparison of the acceptance factors between patients and health care providers (eg, prescribing medical apps).

In a prior study conducted by our work group [21], the perceived threat of the disease was identified as a significant determinant in an extended UTAUT model for hypertensive patients. However, with a total R^2=0.62 for the whole model, the explained variance indicated the existence of unconsidered additional determinants. Besides the UTAUT predictors of acceptance, other variables, especially self-efficacy and perceived health threat as well as the motivation to protect oneself from this threat of the disease, may be worth investigating. Furthermore, data security concerns or perceived threats to privacy may also play a major role in the acceptance of mHealth apps [33]. In addition, our prior work did not involve the perspectives of physicians who represent the "other side" of app acceptance, namely the perspective of potential prescribers of medical apps.

Patients and physicians differ in several aspects regarding their acceptance of hypertension apps, especially based on their motivations or reasons to use these apps. For patients, the focus is on managing their own disease to avoid health deterioration [12,34]. Thus, acceptance of health apps crucially depends on whether disease-specific needs are met [12,15]. Telemedicine is the main category for any eHealth solution that is used by physicians in health care.

To date, the adoption (or acceptance) of telehealth, including mHealth apps, by physicians has been studied primarily in terms of its benefits in supporting their work, such as reduced time and effort [35], rather than the potential benefits and risks to their patients with chronic conditions. Regarding specific differences, physicians have been found to report more open attitudes with less fear of risk compared to patients in Germany [36].

Hence, the present study investigates the acceptance of health apps for managing hypertension among patients and physicians. Thus, it addresses an area of research that has not yet been exhaustively investigated across different contexts, beyond the clinical testing of hypertension apps [16]. To improve the understanding of the efficient adoption of medical apps, the perspectives of patients and physicians or providers are important. Therefore, the present study examines similarities and differences between the 2 groups. In particular, it examines beliefs and expectations regarding the use of mHealth apps. To our knowledge, this is the first study that analyzes determinants for acceptance by both user groups in Germany.

Objectives

This study aims to complement existing research on mHealth acceptance by applying the extended UTAUT model and specifically focusing on other individual predictors related to hypertension and global user-related characteristics (eg, self-efficacy, eHealth literacy) [37], differentiated by personal use (patients) and clinical use (physicians). This is one of the few studies that investigates a possible disease-specific influence, examining patient and physician acceptance simultaneously to determine similarities and differences between these complementary user groups of mHealth apps [38]. Another goal is to explore the assumed underlying mechanisms (ie, mediator effects) in the relationships of the proposed extended UTAUT2 model [23], particularly regarding the role of performance expectancy. Although performance expectancy was only investigated as a predictor with a direct influence on the intention to use in the original UTAUT model, the extended UTAUT model for health care developed by Zhang et al [20] also found that performance expectancy plays a mediating role. Therefore, we explored the potential mediating effects of this construct because they are not yet fully understood.

Based on prior research and theoretical considerations, we propose the following research questions to analyze the predictors of acceptance.

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1. Which factors determine the acceptance (intention to use) of medical apps for self-management of hypertension among patients (personal use) and physicians (clinical use)?
2. Does the acceptance (intention to use) of hypertension apps differ between patients (personal use) and physicians (clinical use) based on varying cognitive attitudes, beliefs, and expectations (eg, UTAUT determinants like performance expectancy), and affective attitudes or beliefs (eg, concerns, perceived privacy threat, hedonic motivation)?
3. Does performance expectancy mediate the relationship between the other UTAUT determinants and acceptance among patients?

Methods

Study Design and Participant Recruitment

This study was designed as a cross-sectional web-based questionnaire study using the Unipark software (Questback Enterprise Feedback Suite Questionnaire, version 2019). Inclusion criteria were a minimum age of 18 years, fluency in written German, and being either a patient with self-reported hypertension (survey version 1, personal use) or a practicing physician regardless of specialty (survey version 2, clinical use). As some of the predictors were operationalized differently or not applicable to the 2 target groups (eg, duration of disease), 2 versions of the survey with different item sets were created and displayed after using an initial filter question (see Multimedia Appendix 1 for the version concerning the user group). Prior to data collection, a pretest with 7 people (4 patients and 3 physicians) was conducted. After this pretest, only semantic adjustments were made in the instructional texts, as some terms were not comprehensible to laypersons (eg, hypertension). An a priori power analysis was conducted to calculate the required sample size for multiple linear regression analyses with a maximum of 14 predictors and an expected moderate effect of f^2=0.15, resulting in an estimated sample size of 151 persons (with an α error probability of .05 and a power of 0.9) The data were collected anonymously between September 14, 2019, and October 31, 2019. Participation was voluntary. The overall completion time was 10 to 15 minutes on average. The 2 target groups (adult patients at least 18 years old with hypertension and physicians) were recruited primarily via social networks (eg, XING, Facebook, and Twitter), personal invitations in private and work environments (including medical conferences), emails, contributions in self-help forums and interest groups, and a university website. There was no monetary compensation. Undergraduate psychology students enrolled at the University of Hagen, a distance-learning university (patients or physicians in a second degree program), could be compensated with study credits via a virtual lab. As an incentive to participate in the study, a summary of the aggregated study results upon completion of the whole study was offered. The study was approved by the ethics committee of the University of Hagen prior to data collection (NR. EA_140_2019).

Measures

Acceptance

The dependent variable for patients and physicians is the acceptance of health apps, namely the intention to use health apps for managing chronic diseases (ie, hypertension) either as patients or physicians. This outcome was operationalized differently for both user groups. This study addressed the acceptance of hypertension apps in general, mainly in terms of the intention to use them (ie, not specific existing apps). For patients, the intention to use apps was assessed in line with a study by Breil et al [21] with 3 variables on a 5-level Likert scale from “do not agree at all” to “fully agree.” Among physicians, acceptance was operationalized as their intention to use health apps in their clinical practice and not manage their health in contrast to patients (ie, “I could imagine incorporating health apps into my work”) and whether they would recommend such health apps in general to their patients (“I would recommend patients use health apps”). For physicians, 4 items in a 5-point Likert scale were used to determine their intention to use health apps in their own work. [17].

As illustrated in Figure 1, we have adapted and extended the UTAUT2 research model. Only the price value in the UTAUT2 model was not considered due to the specific context (statutory health system in Germany) and the low familiarity with digital health in Germany [39]. The research model for physicians omits the PMT factors because this theory is only applicable to patients and not to physicians in their role as health care providers.

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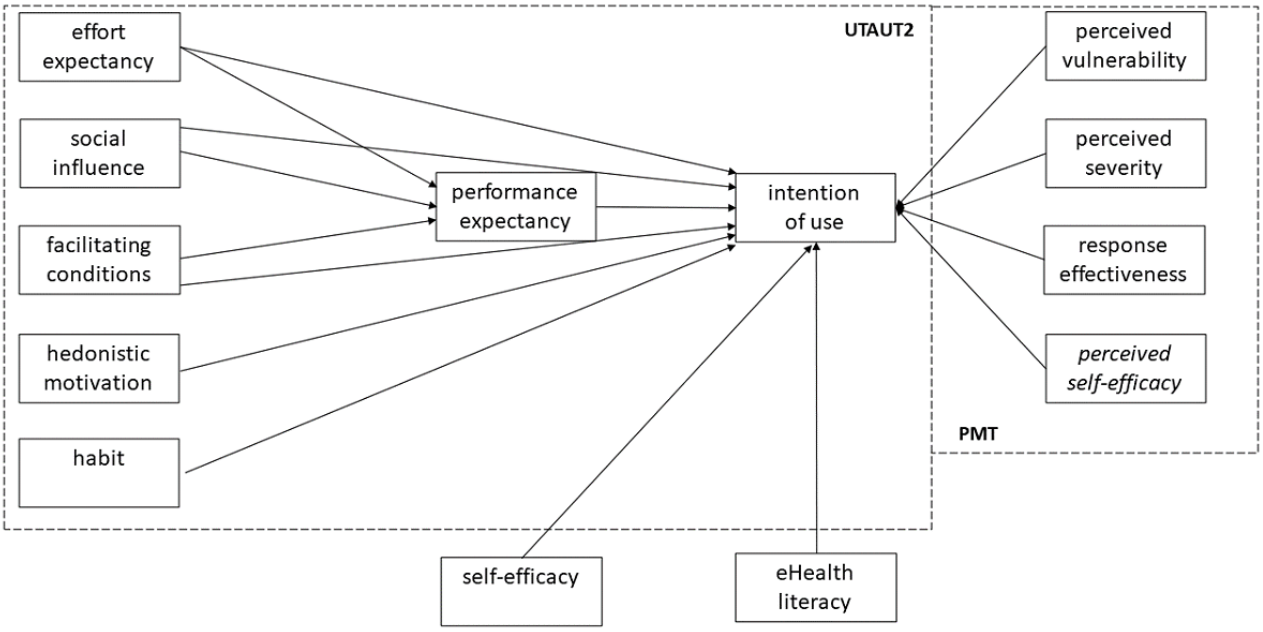
Figure 1. Research model depicting the acceptance of hypertension apps by patients. This study analyzes the influence of the determinants in the adapted UTAUT2 model and the protection motivation theory on the intention of using hypertension apps in addition to self-efficacy and eHealth literacy. eHealth: electronic health; PMT: protection motivation theory; UTAUT2: unified theory of acceptance and use of technology.



UTAUT2 Determinants of Acceptance

The operationalization of the UTAUT and UTAUT2 variables was based on the work of Zhang et al [20] with translations according to Hennemann et al [16], Breil et al [21], and Harboth and Pape [40]. The constructs hedonistic motivation and habit (UTAUT2) were additionally included in this study [23]. All UTAUT items were assessed on a 5-point Likert scale from “do not agree at all” to “fully agree.” The Cronbach α was in the acceptable to good range for all scales between .74 and .91, except for facilitating conditions for physicians (Cronbach α=.61). The complete questionnaire can be found in Multimedia Appendix 1.

Further Determinants of Acceptance

Self-efficacy was assessed using the General Self-Efficacy Short Scale with 3 items on a 5-point Likert scale ranging from “fully disagree” to “fully agree” [41]. The internal consistency of the scale was good (Cronbach α=.83).

Technology-Related Determinants

Norman et al [42] define eHealth literacy as the ability to search, find, understand, and evaluate health information from electronic sources and to use the knowledge thus gained to address or solve a health problem. eHealth literacy was operationalized with 8 items on a 5-point Likert scale ranging from “fully disagree” to “fully agree” using the electronic health literacy scale (eHEALS) [42] in German according of Soellner et al [43] (eg, “I know how to use the health information I find on the internet to help me“). Internal consistency of the scale was good with a Cronbach α=.89.

Perceived threat to privacy was operationalized according to Zhang et al [20]. Instead of the 7-point Likert scale, a 5-level Likert scale ranging from “strongly disagree” to “strongly agree” was used [20].

Experience With eHealth

Some studies have shown a significant positive influence of prior experience with web-based services on the acceptance of eHealth [44,45]. Even though most of the apps in the cited prior work were related to mental health services, a positive effect was also expected for hypertension apps in the present study. According to Venkatesh et al [23], experience is also a relevant moderating factor in other contexts; therefore, experience with health apps was also investigated in this study.

Contrary to the eHealth experience data collected for both user groups with the same items, the items for physicians were specifically adapted to the context of smartphone usage in a professional context with respect to clinical practice. The items were based on Albrecht et al [35] and included the use of apps in general (dummy coded, with 1=yes and 0=no), type of usage (professional, private), and types of the activities and concerns that prevent them from using smartphone apps.

In addition to the aforementioned constructs, the participants' age, gender, highest educational attainment, as well as the current country of residence and region (urban vs rural) were included as the control variables.

Health-Related Determinants

Information on the patients' own high blood pressure was obtained with 3 items. The durations of the disease and medication intake were recorded metrically in years. Comorbid diseases were chosen based on the list of chronic diseases provided by the Robert Koch Institute (ie, the German Higher Federal Authority for Infectious Diseases) [46] (multiple answers were possible).

Protection Motivation

Protection motivation was measured using the PMT questionnaire that is based on the following components [32]: Perceived vulnerability describes the probability of the

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occurrence of an illness-related event. Especially in the context of hypertension, several risk factors can be identified such as higher age as well as modifiable lifestyle factors, such as malnutrition and less physical activity. Perceived severity describes the extent to which a depicted event is perceived as harmful. Response effectiveness refers to specific protective behavior, such as the use of health apps and assessment of their effectiveness. As a fourth component, self-efficacy is investigated in terms of the skills needed to perform the protective behavior.

The PMT variables were operationalized according to Guo et al [32] with the 4 components, namely perceived vulnerability, perceived severity, response efficacy, and perceived self-efficacy. According to the PMT, protection motivation results from the subjective assessment of a threat and possible coping strategies. To ensure a concrete reference to high blood pressure, the sentence "Possible consequences of high blood pressure are various cardiovascular diseases (including heart attack, stroke), retinal damage, kidney damage, etc" was placed at the beginning of the questions.

The influence of the PMT variables was considered relevant only for the patients participating in this study and was thus not investigated among physicians.

Statistical Analysis

Only completed surveys were extracted from Unipark and analyzed (due to option of consent withdrawal by dropping out). The influence of the different UTAUT and PMT predictors on the intention to use self-management apps for hypertension (ie, acceptance) was computed using simple linear and multiple hierarchical regression analyses separately for the 2 user groups (ie, patients and physicians). The prerequisites for the parametric tests were examined and found to be sufficiently applicable.

To investigate the relative influence of variables, the significant determinants in the simple regression analyses were transferred to an overall model in 4 blocks, as shown in Table 3. This was done separately for both user groups due to the different determinants. First, the patients were considered. In multiple hierarchical regression, all significant single predictors were included in blocks. As the UTAUT determinants have already explained up to 70% of the intention to use in prior research [23], the UTAUT factors in this study were included as the first block or step of the hierarchical linear regression model followed by self-efficacy in the second block. In the third block, eHealth literacy was included, and the fourth block contained the items from the perceived threat to privacy. The fifth and last block comprised the 4 factors from the PMT. For each block, the increase in the coefficient of determination (ΔR^2) was determined. In line with Zhang et al [20], the effect of the other factors such as self-efficacy, privacy concerns, and factors from the PMT were analyzed in the subsequent blocks [20]. Differences in the acceptance scores between the 2 user groups were calculated through *t* tests for independent samples.

In addition to analyzing the intention to use health apps, we assessed preferences in terms of the willingness of patients to use health apps compared to face-to-face consultations with physicians, self-help groups, or internet-based information for managing high blood pressure.

To test the assumed mediation effects, 3 regression analyses were conducted for each of these assumptions. The first step of the regression model tested whether the predictor variables influenced the mediator variable performance expectancy. In the second step of the regression model, the direct effect of predictor variables on the dependent variable was determined, as already confirmed for all the 3 variables in the prior step. In the third step, the indirect effect was determined.

The analyses were performed using SPSS Statistics (version 25, IBM Corp). Conditional effects, especially related to the moderation hypotheses, as well as the indirect effects and the associated mediation hypotheses were calculated with PROCESS (version 3.4), a macro in SPSS [47]. Bootstrapping analysis was performed with 5000 bias-corrected samples to calculate the total direct and indirect effects of the variables. Hypotheses were tested twofold at $\alpha<.05$.

Results

Sample Characteristics

In the period mentioned earlier, 337 people accessed the internet-based survey, with 212 people giving their consent and completing the survey. This corresponds to a completion rate of 62.9%. However, 13 respondents did not start the survey at all, and 112 people did not finish it. Participants dropped out mainly because of not providing informed consent (26/337, 7.7%), not stating to which of the 2 user groups they belonged (42/337, 12.5%), and not providing demographic information (19/337, 5.6%). Moreover, 3 respondents were excluded after reviewing the raw data, as they had not answered the initial question regarding the user group (patient or physician) and thus had not answered the user group–specific questions (eg, on PMT variables).

The sample for the data analysis consisted of 209 participants including 163 patients and 46 physicians. The mean age was 35 years (mean 35.3 [SD 13.8] years), with slight differences between the user groups, as shown in Table 1. More women (126/209, 60.3%) participated in the survey than men. Differences between the user groups were apparent in terms of educational attainment, as shown in Table 1.

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Table 1. Demographic characteristics.

Characteristics	Total sample (N=209)	Patients (n=163)	Physicians (n=46)
Age (years)			
Mean (SD)	35.26 (13.8)	35.53 (14.9)	34.28 (8.6)
Range (median)	18-79 (33)	18-76 (32)	18-53 (34)
Sex, n (%)			
Female	126 (60.3)	98 (60.1)	28 (60.9)
Male	82 (39.2)	64 (39.3)	18 (39.1)
Not mentioned	1 (0.5)	1 (0.6)	0 (0)
Education, n (%)			
High school graduation	114 (54.5)	104 (63.8)	10 (21.7)
University degree	95 (45.5)	59 (36.2)	36 (78.3)

As shown in Table 2, 129 of the 209 participants (61.7%) stated that they already had experience using mobile health apps. Here, patients (103/163, 63.2%) differed only slightly from physicians (26/46, 56.5%) in terms of experience. Both groups had been using health apps for approximately 2.5 years on average (SD 2.9 and 3.1, respectively). There were clear differences in the way they used the apps. “Vital value measurements” (51/163, 31% vs 7/46, 15.2%) and “memories” (46/163, 28.2% vs 8/46, 17.4%) were used more frequently by patients, whereas every physician cited “Search for information” as the reason for use. Table 2 shows previous experience with health apps differentiated by user group. Under “Other use,” patients indicated that they also used “apps for measuring movement or physical activity (steps),” “menstruation cycle apps,” and “pregnancy apps.”

Table 2. Experience using electronic health apps.

	Total sample (N=209)	Patients (n=163)	Physicians (n=46)
Experience with health apps, n (%)			
Yes	129 (61.7)	103 (63.2)	26 (56.5)
No	74 (35.4)	55 (33.7)	19 (41.3)
Not specified	6 (2.9)	5 (3.1)	1 (2.2)
Purpose of using apps, n (%)			
Vital signs measurement	58 (27.8)	51 (31.3)	7 (15.2)
Reminder	54 (25.8)	46 (28.2)	8 (17.4)
Documentation	47 (22.5)	37 (22.7)	10 (21.7)
Electronic communication	50 (23.9)	35 (21.5)	15 (32.6)
Search for information	68 (32.5)	45 (27.6)	23 (50)
Relaxation	53 (25.4)	40 (24.5)	13 (28.3)
Other	24 (11.5)	17 (10.4)	7 (15.2)
App selection basis, n (%)			
Searched or found by self	126 (60.3)	103 (63.2)	23 (50)
Recommendation from friends	40 (19.1)	34 (20.9)	6 (13)
Recommendation from physicians	33 (15.8)	15 (9.2)	18 (39.1)
Advertising	16 (7.7)	15 (9.2)	1 (2.2)
Other	10 (4.8)	N/A[a]	N/A

[a]N/A: not applicable.

There were differences not only in the purpose, way, and frequency in which apps were used but also in the search and selection of apps. In both groups, apps were mainly searched for or found by the users themselves (98/163 patients and 28/46 physicians, 60.3%). Recommendations from friends were relevant for 20.9% (34/163) of patients and 13% (6/46) of physicians. Advertising was a reason for the selection of health

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apps for 9.9% (16/163) patients but only for 2.2% (1/46) of the physicians.

Patients' Preferences

Mobile health apps were stated as the second most preferred option to support hypertension management by 30.7% (50/163) of the patients. Only direct-contact physician care was regarded as more preferable for 36.8% (60) of the patients. In contrast, medical care via the internet 9.2% (15, 9.2%) and local face-to-face groups such as support groups (10, 6.1%) were the options mentioned much less frequently.

Previous Use of Smartphones by Physicians

Most physicians (35/46, 76.1%) reported using their smartphone for job-related electronic communication with patients or other professionals through email, chat, or messenger functions. The internet was also frequently used for searching literature in journals or databases by 60.9% (28) of the physicians. Other frequent responses included information on medication and treatment options given by 43.5% (20) and access to training content by 37% (17) of the physicians. Requests for laboratory tests (4, 8.7%) and access to patient records (5, 10.9%) were less frequently reported.

Physicians' Concerns When Using Health Apps

Physicians were asked about their concerns when using health apps. The main concerns were about the security of patient data (37/46, 80.4%), followed by the trustworthiness of content (23, 50%) and technical reliability of software (20, 43.5%). Concerns about hygiene were mentioned by only 23.9% (11) of the physicians. Concerns about reimbursement by German statutory health insurance companies (3, 6.5%), lack of or limited options for access by patients (4, 8.7%), and poor acceptance by patients (8, 17.4%) were relatively low.

Preliminary Analyses

Preliminary analyses were conducted to select significant determinants for the hierarchical regression model for patients. In simple linear regression, performance expectancy had a positive effect on the intention to use hypertension apps, with the highest explained variance of UTAUT determinants (R^2=0.44; β=.66; P<.001). There were also significant positive influences of effort expectancy (R^2=0.25;β=.50; P<.001), social influence (R^2=0.13; β=.36; P<.001), facilitating conditions (R^2=0.23; β=.48; P<.001), hedonistic motivation (R^2=0.15; β=.39; P<.001), and habit (R^2=0.13; β=.36; P<.001) on the intention to use. Subsequently, all significant UTAUT predictors were included in a multiple hierarchical model (Table 3). Of the 6 UTAUT factors, only performance expectancy had a statistically significant influence on patients (t_{156}=6.27, P<.001). Except for performance expectancy, the other predictors did not contribute significantly to the overall model of acceptance. Multimedia Appendix 2 presents the entire linear model.

Single regressions were conducted for analyzing the influence of the PMT variables. Perceived vulnerability (R^2=0.11; β=.33; P<.001), perceived severity (R^2=0.07; β=.27; P<.001), response efficacy (R^2=0.29; β=.54; P<.001), and perceived self-efficacy (R^2 =0.31; β=.56; P<.001) positively influenced the intention to use hypertension apps. In the multiple regression model, all factors except for perceived severity made a significant contribution (R^2=0.42). Multimedia Appendix 3 shows the multiple linear regression model of the PMT with all 4 factors and confidence intervals for β.

Next, simple regression analyses were also conducted for the physician user group. Performance expectancy had a positive effect on the intention to use (R^2=0.21; β=.46; P<.01). In contrast, effort expectancy, social influence, facilitating conditions (UTAUT1), hedonistic motivation, and habit (UTAUT2) did not prove significant in the simple regression model (P>.05).

Main Results

Research Question 1: Acceptance Determinants for Patients and Physicians

For the overall model regarding patients, the explained variance was R^2=0.56 (F_{15}= 12.53, P<.01). Of the 15 predictors in the 5 blocks, only 3 predictors were significant in the hierarchical regression (last step). Performance expectancy significantly contributed to the prediction of the intention to use hypertension apps (R^2=0.47). Among the remaining variables, only self-efficacy (ΔR^2=0.02) and protection motivation in terms of the PMT variables (ΔR^2=0.07) made significant contributions to the explained variance of the overall model for the patient group, as shown in Table 3.

Simple regression analyses showed that previous experience with health apps contributed to the acceptance of health apps for managing hypertension among patients (R^2=0.20, P<.01).

Determinants of hypertension app acceptance among physicians were then examined, as demonstrated in Table 4. The UTAUT variables form the first block. Among physicians, previous experience with health apps was not significant.

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Table 3. Overall model of the determinants for the intention to use hypertension apps in patients (n=162).

Predictor	B[a]	SE	95% CI	β	*P* value	ΔR^2
Constant	–1.85	1.58	–4.98 to 1.28		.25	
UTAUT[b] determinants						0.47
Performance expectancy	0.48	0.11	0.26 to 0.70	.42	<.001	
Effort expectancy	–0.03	0.10	–0.23 to 0.16	–.04	.73	
Social influence	–0.02	0.09	–0.19 to 0.15	–.02	.82	
Facilitating conditions	0.07	0.09	–0.11 to 0.24	.06	.46	
Hedonistic motivation	0.13	0.08	–0.03 to 0.28	.11	.10	
Habit	–0.10	0.08	–0.27 to 0.07	–.09	.24	
Self-efficacy						0.02
Self-efficacy expectation	0.19	0.10	0.00 to 0.38	.13	.05	
eHealth[c] literacy	–0.01	0.04	–0.10 to 0.07	.06	.73	<0.01
Threat of privacy						<0.01
Usage for other purpose	0.19	0.23	–0.26 to 0.65	.06	.40	
Loss/leakage of personal data	–0.10	0.25	–0.59 to 0.40	–.03	.70	
Misuse of personal data by criminals	–0.30	0.23	–0.75 to 0.16	–.10	.20	
Protection motivation						0.07
Perceived vulnerability	0.24	0.08	0.09-0.39	.20	<.001	
Perceived severity	0.03	0.08	-0.12-0.18	.03	.67	
Response efficacy	0.09	0.08	-0.08-0.18	.09	.29	
Perceived self-efficacy	0.19	0.11	-0.03-0.40	.17	.09	

[a]B: unstandardized β.

[b]UTAUT: unified theory of acceptance and use of technology.

[c]eHealth: electronic health.

Table 4. Hierarchical regression model of the determinants for the intention to use in physicians (n=46)[a].

Predictor	B[b]	SE	95% CI	β	*P* value	ΔR^2
Constant	4.31	4.30	–4.41 to 13.03	0	.32	
UTAUT[c] determinants						0.27
Performance expectancy	0.76	0.28	0.20 to 1.32	.54	.01	
Effort expectancy	–0.33	0.20	–0.74 to 0.07	–.29	.11	
Social influence	–0.29	0.28	–0.86 to 0.28	–.20	.30	
Facilitating conditions	–0.04	0.19	–0.43 to 0.34	–.04	.82	
Hedonistic motivation	0.05	0.22	–0.40 to 0.51	.04	.82	
Habit	0.06	0.22	–0.39 to 0.51	.06	.78	
eHealth literacy	0.30	0.11	0.07 to 0.53	.41	.01	0.10
Threat of privacy						0.05
Usage for other purposes	0.45	0.57	–0.71 to 1.62	.12	.43	
Loss or leakage of personal data	–1.03	0.60	–2.25 to 0.19	–.29	.09	
Misuse of personal data by criminals	0.38	0.50	–0.64 to 1.39	.11	.45	

[a]Data concerning self-efficacy and PMT were collected only for patients.

[b]B: unstandardized β.

[c]UTAUT: unified theory of acceptance and use of technology.

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Research Question 2: Differences Between Patients' and Physicians' Acceptance of Hypertension Apps

To test for differences between physicians and patients, all significant influences were transferred to a multiple regression model for each group and included in blocks. Self-efficacy had a significant influence only in the patient group and was therefore omitted in the multiple regression model. In the second block, eHealth literacy was included. The third and last block involved the perceived threat to privacy. For each block, the increase in the coefficient of determination (ΔR^2) was identified.

In the case of the patients, only 3 out of the 15 predictors in the 5 blocks were significant in the hierarchical regression. Performance expectancy contributed significantly to the prediction with R^2=0.47. Beyond that, only self-efficacy (ΔR^2=0.02) and PMT (ΔR^2=0.07) made significant contributions.

For physicians, all significant individual predictors were also included block wise in the multiple hierarchical regression. For the overall model, the coefficient of determination was R^2=0.42. The UTAUT2 factors explained under one-third of the variance explained by the overall model, with R^2=0.27. A further 10% increment in R^2 resulted from the addition of eHealth literacy and another 5% by accounting for privacy threat.

Direct comparison shows that the R^2 for patients is slightly higher and is largely determined by UTAUT2; therefore, the addition of other determinants resulted in a comparatively small increase in R^2. For physicians, the influence of factors outside of the UTAUT factors (eHEALS and privacy) is stronger.

Research Question 3: Mediation Effects in the Extended UTAUT Model for Patients

In line with the UTAUT assumptions, the UTAUT predictors effort expectancy, social influence, and facilitating conditions exerted a significant direct influence on performance expectancy, as illustrated in Figure 2. Performance expectancy had a significant direct effect on the intention to use hypertension apps and mediated the relationship between effort expectancy and intention to use (95% CI 0.04-0.23) as well as the relationship between social influence and intention to use (95% CI 0.04- 0.19).

The other 3 factors having a significant influence on the intention to use hypertension apps in the simple regression analyses (preliminary analyses) were used as covariates in this model. Table 5 presents the direct effects on the mediator performance expectancy as well as the direct and indirect effects on the intention to use hypertension apps.

Figure 2. Overall model showing the determinants of the intention to use hypertension apps in patients. Significant influence is shown with solid lines and corresponding beta values; influences that were investigated but not significant are shown with dashed lines. PMT: protection motivation theory; UTAUT2: unified theory of acceptance and use of technology.

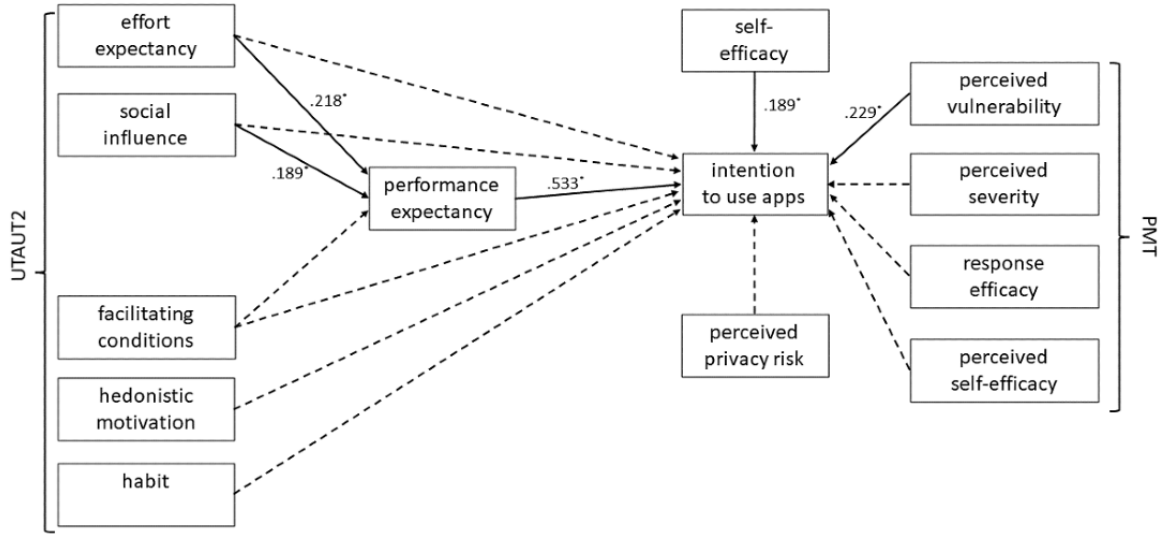

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Table 5. Overall model of determinants of intention to use among patients.

Predictor	Performance expectancy		Intention to use		
	β	*P* value	β	*P* value	95% CI
Effort expectancy					
Direct effect	.22	.004	–.02	.82	–0.21 to 0.17
Indirect effect	N/A[a]	N/A	.12		0.04 to 0.23
Total effect	.22	.004	.09	.36	–0.11 to 0.30
Social influence					
Direct effect	.19	.004	.00	.98	–0.17 to 0.17
Indirect effect	N/A	N/A	.10		0.04 to 0.19
Total effect	.19	.004	.10	.27	–0.08 to 0.27
Facilitating conditions					
Direct effect	.01	.93	.08	.38	–0.10 to 0.25
Indirect effect	N/A	N/A	.00		–0.10 to 0.08
Total effect	.01	.93	.08	.40	–0.11 to 0.27

[a]N/A: not applicable.

Discussion

The aim of this study was to determine the subjective factors that influence the acceptance of hypertension apps among patients and physicians in Germany. In addition to the UTAUT determinants that have already been investigated in health care research, protection motivation, threat to privacy, and self-efficacy expectations were also considered as further influencing factors on the intention to use hypertension apps.

Principal Findings and Comparison With Prior Work

As expected, a significant influence of performance expectancy on the acceptance of hypertension apps was found among patients and physicians. Among patients, self-efficacy and protection motivation, including perceived threat, further contributed to an increase in the explained variance of the extended UTAUT2 model.

The differences between the 2 user groups indicated that several factors had a statistically significant influence only in patients, such as self-efficacy. In the physician group, only performance expectancy proved significant. In addition to the UTAUT factors, a significant influence of eHealth literacy was identified only in physicians. Potentially, physicians had a more differentiated understanding of the meaning of eHealth literacy and were thus more critical in assessing their own skills than patients [48].

Another goal of this study was to gain insights into the role of performance expectancy as a mediating variable. Although numerous studies on the UTAUT model [49] have confirmed a direct influence of performance expectancy, they have not clarified whether this variable also mediates the influence of beliefs on the intention to use mHealth apps. Hence, a methodologically added value to the UTAUT2 model in this study can be observed in the demonstrated mediator role of performance expectancy, as shown earlier by Zhang et al [20]. Specifically, our study demonstrated the mediating effects of performance expectancy in the relationship between effort expectancy as well as social influence and the intention to use hypertension apps in patients. We also identified a direct effect of perceived vulnerability. Thus, the strong influence of performance expectancy and its mediating role may explain why the other UTAUT factors had no statistically relevant influence in the hierarchical linear model.

In contrast, the expected moderating effects of previous experience with health apps could not be identified in the group of patients, which should be interpreted considering the web-based survey and self-selection bias.

Contrary to our assumptions and previous research indicating data security concerns as a major barrier to using health apps [50], perceived threat to privacy had no significant influence on the acceptance of hypertension apps in our study. Potentially, the sample was already aware of certified disease management apps approved by statutory insurance companies and other trusted sources in Germany.

The explained variance of the UTAUT determinants that we applied in the extended UTAUT2 model in this study was R^2=0.47. In comparison, for all determinants, the explained variance regarding app acceptance by patients was only slightly higher with R^2=0.56 (ie, all 5 blocks in the regression model). This finding corresponds, for instance, to a study by Dou et al [51], which obtained an R^2 of 0.412 based on various determinants regarding the intention to use apps for self-management of chronic diseases.

More specifically, the predictive value in terms of the explained variance of the proposed determinants of acceptance is comparable to our previous study that served as a basis for this survey [21], which is interesting because of the integration of more illness-related variables in this study. In our related study [21], performance expectancy and effort expectancy proved to be significant predictors, explaining approximately 50% of the

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variance in the acceptance scores among patients. For direct comparison, the Illness Perception Questionnaire [52] that we used only in our previous study may have been a better choice for capturing the disease-specific acceptance of apps, as its contribution to the total variance was higher compared to the PMT factors. Instead, vulnerability was the only significant variable of the PMT block in the multiple regression model used in this study. Remarkably, threat to privacy, which had not yet been surveyed in our preliminary study [21], was thought to be another significant determinant in this study. However, we could not confirm this assumption, which may have been due to the rather young adults constituting our patient and physician samples.

Given the unexplained variance, patients' perspectives, especially regarding unmet needs and preferences, could be further explored using mixed methods and qualitative research methods. Accordingly, a qualitative study by Morrissey et al [53] also highlighted concerns regarding the risks of health apps used to improve medication adherence and the need for promote eHealth literacy among hypertensive patients. Regarding the real-world assessment of apps, a mixed methods study by Allessa et al [34] showed that apps for self-management of hypertension can be functional and acceptable to users, but they can also be considerably improved through training [34], which corresponds to UTAUT determinants like performance and effort expectancy as well as facilitating conditions.

Interestingly, one-third of the patients in our study stated that they preferred using health apps over physician contact and face-to-face self-help groups to manage hypertension. This finding indicates that for a relevant proportion of the patients, self-management via health apps can be the first choice, which can be seen as a starting point for the implementation and additional provision of medical apps. Nonetheless, in line with prior research [54,55], most patients in our study preferred personal contact with physicians over digital self-help using hypertension apps. Hence, further research is needed to determine how to increase the adoption of mobile solutions in conjunction with traditional face-to-face health care services (eg, blended or stepped care approaches). Regular blood pressure measurement supported by apps may help bridge the gap between the medical and lay perspectives of optimal and personalized hypertension treatments in practice and promote more effective disease management in the long run [56].

Overall, this corresponds to a study by Edwards et al [57] documenting considerable interest in using telemedicine services like apps among patients with chronic diseases, regardless of their health status, access difficulties, as well as age and many other sociodemographic factors.

Limitations

The present study is subject to several limitations. First, when considering the demographic distribution of the sample, various limitations apply that may help explain some of the consistent findings. For instance, the mean age of the physicians was considerably less at 34 years (mean 34.3 [SD 8.6] years, median 34 years) compared to all the physicians in Germany. According to the Federal Statistical Office, the average age of the physicians was 48 years in 2017 [58]. The respondents were thus considerably younger and therefore not representative of physicians in Germany. The patients in our sample were also relatively young, with the average age being 36 years (mean 35.5 [SD 14.9] years, median 32 years), and may therefore not necessarily reflect the views of most patients with hypertension, especially in terms of the acceptance and use of disease management apps. Further limitations concern the rather high educational level of the patients, with one-third holding an academic degree. Nonetheless, this group may represent a subgroup of patients that have been recently diagnosed and may thus be easily reached for prevention and health promotion initiatives.

Second, although the total sample size of 209 individuals was sufficiently powered for the conducted hierarchical regression analyses, this only applies to the analyses that concern the entire sample. Although the group of patients was sufficiently large with 163 participants, the group of physicians was relatively small (46 physicians), thus making it more difficult to identify effects. Despite including fewer determinants for the regression model measuring the acceptance of apps among physicians compared to the patient group, it would have been necessary to have a considerably higher number of physicians as participants. However, physicians are usually difficult to recruit via social media. In addition, the recruitment period of 1 month was considerably short. Therefore, the small sample size of the physician group is a major limitation.

Implications

Implications derived from this study, based on several significant and insignificant findings, especially concern the further extension and adaptation of the UTAUT2 model in the context of chronic diseases. Holden and Karsh [59] note that it is important to continuously adapt the acceptance models for the use of telemedicine, including health apps to mirror ongoing technological advances. Thus, future research may also consider further barriers to using hypertension apps. According to Schreiweis et al [60], potential barriers and drivers for eHealth applications can be divided into individual, organizational, and technical factors. In the current study, organizational and environmental [33] policy aspects were not investigated. Instead, we focused on individual acceptance-related factors such as eHealth literacy and beliefs such as performance expectancy as well as motivational factors (eg, hedonic motivation, protection motivation). Other potentially relevant aspects such as training of physicians or information on the availability of eHealth services [51] could also be considered in upcoming studies with a broader scope on the validation of an extended UTAUT2 model for assessing the acceptance of disease management apps among patients and physicians [48].

Another variable to consider in the investigation of hypertension apps may be resistance to change among patients [51]. Given the high prevalence of hypertension, it should be considered that there is a long-term demand for treatment support and at least a relevant proportion of patients indicates a preference for health apps [61]. However, other studies with hypertensive patients indicated ambivalent views on self-management apps [53]. Patient preferences for hypertension apps may also vary depending on the different features of such apps. For instance,

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some studies found reminders and personalization to be important features of hypertension apps [62]. In future studies, a differentiated assessment of app features, including trade-offs between preferred features, should be considered.

Given the forecast of the German National Association of Statutory Health Insurance, physicians state that the demand for medical care will increase by 2% by 2030, whereas the supply of medical care, especially in rural areas, will continue to decline [63]; health apps could be a solution accepted by relevant target groups, as this study has indicated. Nevertheless, knowledge on the most important determinants of mHealth acceptance is required to tailor information as well as interventions to the needs and preferences of future users. In this context, it is important to note that our study was conducted shortly before the global outbreak of the COVID-19 pandemic and the introduction of the directory for digital health applications in Germany (German name: Digitale Gesundheitsanwendung [DiGA]). DiGA are defined as low-risk medical products based on digital technologies that are intended, for example, to detect or alleviate illnesses or to support diagnosis using apps or browser-based applications. The DiGA directory [64] lists all the DiGA that have successfully undergone the assessment procedure that is regulated by the Federal Institute for Drugs and Medical Devices (German name: Bundesinstitut für Arzneimittel und Medizinprodukte). Interestingly, there is no app at present (as of October 2021) for hypertension management in the recently introduced DiGA directory among the 24 listed medical apps, which may change soon. In future, the provision of certified hypertension apps may change the views and uptake of such apps in health care.

In addition, it may be important for future research to consider the connection of remote and personal treatment assistance in the management of hypertension in terms of blended or hybrid treatments [11]. Transparent quality criteria represent another key strategy for the adoption of health apps. However, the quality of commercially or publicly available apps for hypertension management has been classified as overall poor [55]. Associations between the relevant features and outcomes of hypertension apps also remain inconclusive [65]. Therefore, implementation strategies and advances in (digital) health policy, such as the DiGA registry in Germany, are important steps to increase the dissemination of quality-approved medical apps for chronic diseases. With the ongoing diffusion of medical apps into routine care, research on the acceptance and use of these apps is required on a longitudinal basis.

Conclusions

In summary, this study identified several relevant determinants of the acceptance of hypertension apps among patients and physicians. The ongoing implementation of health apps into routine care and the COVID-19 pandemic emphasize the importance of acceptance-related research on disease management apps. One possible strategy is the targeted collection and prioritization of patient requirements [66]. Another strategy may be to increase the awareness of quality-approved self-management apps for hypertension through targeted information campaigns and training of physicians, such as general practitioners, which can be grounded on acceptance-based surveys like the present study.

Thus, the main contribution of this study lies in the identification of additional disease-related, context-sensitive determinants of the intention to use hypertension mHealth apps in terms of acceptance that complement the UTAUT determinants. In patients, protection motivation and perceived vulnerability made a significant explanatory contribution and should be thus further considered in efforts aimed at promoting mHealth acceptance. Furthermore, a deeper understanding of the underlying mechanisms in the theoretical model has been achieved by confirming performance expectancy as the mediator of the beliefs related to and intention to use mHealth apps.

Acknowledgments

The authors would like to thank all participants for contributing to this research.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire of the German online survey (including translation)–patient and physician versions.
[DOCX File , 42 KB - cardio_v6i1e31617_app1.docx]

Multimedia Appendix 2
Linear model and influence of the unified theory of acceptance and use of technology predictors on utilization in patients (n=163).
[XLSX File (Microsoft Excel File), 12 KB - cardio_v6i1e31617_app2.xlsx]

Multimedia Appendix 3
Linear model and influence of protection motivation theory predictors on patients' intention to use health apps (n=163).
[XLSX File (Microsoft Excel File), 12 KB - cardio_v6i1e31617_app3.xlsx]

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Abbreviations

DiGA: Digitale Gesundheitsanwendungen (German term for digital health applications)
eHEALS: electronic health literacy scale
mHealth: mobile health
PMT: protection motivation theory

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UTAUT: unified theory of acceptance and use of technology

Edited by G Eysenbach; submitted 01.07.21; peer-reviewed by K Matthias, B Sedlmayr, MDG Pimentel; comments to author 23.07.21; revised version received 11.09.21; accepted 27.11.21; published 06.01.22.

Please cite as:
Breil B, Salewski C, Apolinário-Hagen J
Comparing the Acceptance of Mobile Hypertension Apps for Disease Management Among Patients Versus Clinical Use Among Physicians: Cross-sectional Survey
JMIR Cardio 2022;6(1):e31617
URL: https://cardio.jmir.org/2022/1/e31617
doi:10.2196/31617
PMID:34989683

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Original Paper

A Preoperative Virtual Reality App for Patients Scheduled for Cardiac Catheterization: Pre–Post Questionnaire Study Examining Feasibility, Usability, and Acceptability

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Abstract

Background: Pre- and postoperative anxiety is a common phenomenon associated with negative postoperative outcomes. Symptoms of posttraumatic stress disorder, such as fear, nightmares, and sleep deprivation, are prevalent in approximately 30% to 50% of patients following discharge from intensive care units after cardiac surgery. Preliminary evidence suggests a promising role of virtual reality (VR) in preventing stress-related reactions using stress inoculation training. Such training enables cognitive preparation of individuals for stressful situations, thereby becoming more tolerant and resistant to stress, subsequently reducing the risk of potential negative psychological consequences. This study investigated a preoperative VR app—*Pre-View*—aimed at better informing and preparing patients for cardiac catheterization.

Objective: This study aims to assess the feasibility, usability, and acceptability of *Pre-View* in patients undergoing cardiac catheterization.

Methods: Eligible participants were adults scheduled for elective cardiac catheterization. *Pre-View* comprised an interactive virtual representation of the whole care process related to cardiac catheterization, from entering the hospital for admission to postprocedural stay and discharge. These processes were represented through 360° videos and interactive photos. Self-report questionnaires were completed at baseline (ie, before catheterization and after undergoing the VR experience) and after cardiac catheterization. Outcome measures included user experience and satisfaction, VR presence and immersive tendencies, and user friendliness. The perceived effectiveness was assessed exploratively.

Results: A total of 8 individuals, with a mean age of 67 (SD 7.5) years, participated in this study. Half of them underwent the VR experience at the hospital and the other half at home. Participants reported high levels of presence in the virtual environment (Presence Questionnaire score: mean 129.1, SD 13.4). The usability of *Pre-View* was well evaluated (System Usability Scale score: mean 89.1, SD 12.0), and patient satisfaction was high (Client Satisfaction Questionnaire score: mean 27.1, SD 3.2). Usability and satisfaction scores were higher for participants who underwent *Pre-View* at home versus those who underwent *Pre-View* at the hospital, although the latter group was significantly older; 72.8 versus 61.3, respectively. All participants reported *Pre-View* to be effective in terms of feeling better informed about the care process of cardiac catheterization. Most participants (7/8, 88%) reported *Pre-View* to be effective in terms of feeling better prepared for cardiac catheterization, acknowledging the potential of *Pre-View* in reducing negative psychological consequences after catheterization.

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Conclusions: The results provide initial support for the feasibility and acceptability of a preoperative VR app, creating a virtual environment that supports patient education and preparation for upcoming cardiac catheterization. More studies are needed to further investigate the effects of VR as a tool to better prepare patients for medical procedures, its effectiveness in reducing negative patient outcomes (eg, anxiety, stress, and postoperative recovery outcomes), and the generalizability of effects across different settings and patient populations.

(JMIR Cardio 2022;6(1):e29473) doi:10.2196/29473

KEYWORDS

virtual reality; cardiac catheterization; stress inoculation training; preoperative anxiety; acceptability; feasibility; presence; immersive tendencies; presence; patient education; mobile phone

Introduction

Background

Coronary artery disease is one of the 3 most common cardiovascular pathologies and plays a major role in mortality and morbidity worldwide [1]. The occlusion of coronary vessels can lead to myocardial infarction and eventually, death. Cardiac catheterization has evolved over many decades, drastically decreasing the number of deaths after acute myocardial infarction and relieving anginal complaints in an elective setting [2]. Overall, the clinical admission for such a procedure is short; however, psychological complaints regularly arise afterward. Approximately 30% to 50% of patients have been found to experience depression and symptoms of posttraumatic stress disorder (PTSD), such as fear, nightmares, and sleep deprivation, following cardiac surgery [3-6]. Such negative psychological outcomes can adversely affect patient recovery [3,7,8]. More specifically, studies have shown depression to be a strong risk factor for cardiac events, cardiac complications, and cardiac mortality following bypass surgery [3,9,10]. Furthermore, lower levels of quality of life and psychological functioning have been demonstrated in subgroups of patients reporting symptoms of PTSD after bypass surgery [5].

Previous research has demonstrated that preoperative education is a promising method to improve postsurgical outcomes, such as decreasing levels of anxiety and depression, improving recovery, and increasing patient satisfaction [11-15]. Preoperative patient education can be provided through verbal advice and written information. By informing and educating patients about the care process, such as surgery and hospital admission procedures, patients might feel more at ease and prepare for hospital admission and surgery accordingly.

The incorporation of multimedia tools has been suggested to be beneficial in terms of increasing patient satisfaction, perceived benefits, and understanding treatments [16-18]. New technologies such as virtual reality (VR) [19] is a successful tool in the education of patients [16-18]. Furthermore, VR can be used to desensitize patients to stressful events. VR exposure therapy is being increasingly used to treat PTSD and anxiety disorders [20-24]. Furthermore, preliminary evidence suggests that VR and stress inoculation training (SIT) can be successfully used to prevent stress-related reactions, such as PTSD. SIT can help prepare individuals for stressful situations (eg, as combat or battlefield stressors or medical emergencies or treatments) to reduce the risk of potential negative psychological consequences. When using VR during SIT, individuals can be pre-exposed to a stressor in a gradual and controlled manner. This is theorized to enable individuals to prepare themselves for an actual stressful event, thereby becoming more tolerant and resistant to stress. Indeed, using VR in the context of SIT, for example, has been shown to be a promising approach to prepare military personnel for combat situations [25-28], enhancing resilience, and potentially preventing PTSD-related symptoms.

In this study, a VR app—*Pre-View*—was used to investigate whether VR can be a useful medium in the preoperative management of cardiac patients undergoing elective cardiac catheterization. *Pre-View* combines preoperational education with virtual experience of the care process for elective cardiac catheterization in a Dutch university medical center. Using *Pre-View*, participants could virtually experience the whole process, from entering the hospital for admission until the moment of elective catheterization without showing the procedure itself, and to the postprocedural stay and discharge. The benefit of the VR experience over written or verbal information is that the patient is in control of the information he or she receives. The patient decides where to look and where to go to, and the app adjusts to that correspondingly. This increases the feeling of *being present* in the virtual environment, with *presence* referring to the subjective experience of being in a digital environment, while physically being in another [29]. The sense and quality of this presence are considered important factors for the efficacy of VR exposure therapy [30]. The quantification of presence can also be used as an evaluative measure for virtual experience [31].

Objectives

This pilot study aims to assess the feasibility and acceptability of using the VR app, *Pre-View*, as a medium to inform and prepare patients for their upcoming elective cardiac catheterization.

Methods

Participant Recruitment and Eligibility Criteria

Participants were recruited from the Cardiology Department of the Leiden University Medical Center (LUMC), where they were listed for elective cardiac catheterization. Patients were eligible to participate if they were (1) aged ≥18 years; (2) able to speak and understand the Dutch language; (3) scheduled for elective cardiac catheterization; (4) able to undergo a VR experience, that is, not having impaired eyesight and a known history of epilepsy; and (5) not having undergone a previous

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cardiac catheterization. Participants were recruited and enrolled between January 6, 2020, and February 27, 2020.

Ethical Considerations

The study was approved by the local medical ethics committee of the LUMC (protocol number: P19-068), and subsequently, a declaration of no objection was obtained from the Medical Ethics Review Committee. Interested participants received written information about the study and provided informed consent.

Procedure

Potentially eligible patients (ie, aged ≥18 years and not having undergone previous cardiac catheterization) were approached and informed by email or telephone by a research intern (author TW). Subsequently, the VR experience was planned 1 or 2 weeks before the scheduled elective cardiac catheterization. Participants could choose to either undergo VR experience at home or at the hospital. In the hospital, participants were welcomed at the outpatient clinic for heart disease at the LUMC. When participants chose to undergo the experience at home, the research assistant visited the patient at home. Other than location, the process of undergoing the VR experience was identical. Patients were informed on how to use the VR app, after which they could independently undergo the experience. The research assistant was present to assist with any technical difficulties. Directly after completion of the VR experience, participants were asked to fill out a set of paper questionnaires assessing sociodemographic characteristics (ie, age and gender), presence, immersive tendencies, and questions related to satisfaction and usability (for more details, see the *Measures* section). Patients' perceived effectiveness of *Pre-View* was assessed by a telephone call after cardiac catheterization to enable patients to reflect on whether and how *Pre-View* may have supported them during the process of preparation for the surgery, as well as during and after the catheterization.

VR Experience: Pre-View

Patients underwent VR experience via a head-mounted display, the Oculus Rift Go device (Figure 1). The headset was individually adjustable even for participants wearing glasses. Within the VR environment, patients were provided with an interactive representation of the whole care process related to cardiac catheterization; in general, they could experience the day of heart catheterization. This encompassed the patient journey from entering the hospital for admission to the postprocedural stay. Heart catheterization itself was not presented but the related processes were as follows: patients were virtually transferred in a hospital bed with wheels to the operating room, where the cardiologist would briefly explain the procedure. The experience was represented through both video and interactive photos, which were captured and recorded during the development process of the VR app. Topics such as "What will happen in the ward?", "What kind of clothing do I need?", and "Who are allowed to stay?" as well as topics such as "What medication is given after the procedure?" and "Can I eat before the surgery?" were addressed during the experience. The experience was fully interactive; patients could choose objects or persons (eg, nurses or cardiologists) to gain more information on relevant topics on the care process at every stage of the stay. To do so, patients simply had to gaze for a few seconds at the object or person to select it. Hence, there was no need to press a button on the controller physically. For example, patients could gaze at the personnel around them when virtually lying in the hospital bed, after which an explanation would be given about the type of personnel they were (eg, nurse or cardiologist) and what their role during the stay or catheterization would be (to perform the procedure, to assist, etc). Further interaction took place through short quizzes, for example, choosing the right floor in the virtual elevator when patients need to find their way through the hospital toward the cardiology department. A detailed overview of the total experience is provided in Table 1. An example of a 360° photo can be found in Multimedia Appendix 1. All images and videos shown were context-specific, meaning that they were captured and recorded at the LUMC with actual LUMC staff to enhance feelings of relevance and realism. The VR experience lasted approximately 20 minutes, depending on the time a patient spent in each module.

Figure 1. The Oculus Rift Go Virtual Reality headset was used in this study.

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Table 1. Overview of the virtual reality (VR) experience.

Virtual locations and procedures	Means	Description
Part 1: hospital admission		
Hospital entrance	P[a], I[b], and A[c]	The hospital's main entrance is shown, and the main menu and gaze function of the VR experience are explained.
Route to elevators	P, I, and A	The hospital's main hall is shown with the route to the hospital elevators being explained.
Elevator entrance and ride	P, I, and A	The elevator entrance is shown and the choice of floor leading to the nursing ward is explained.
Entrance of the cardiology ward	P, I, and A	The entrance of the cardiology ward is shown.
Part 2: admission to cardiology ward and precatheterization procedure		
Cardiology ward counter	V[d]	The user virtually walks toward the counter of the cardiology ward, where the desk clerk welcomes them. The desk clerk asks for a hospital card and personal identification. Hereafter, the user walks toward the entrance of the patient room.
Patient room: photo	P, A, and I	An interactive photo of the patient room is shown. Users need to collect items they will need to bring to the hospital (eg, clothing and phone-charger). After all items are found, the user is placed in a hospital bed.
Patient room: videos	V	Two short videos are shown of a nurse and cardiologist, respectively, explaining the upcoming procedures.
Transfer to operating room	V	The user is virtually being transferred in a hospital bed with wheels from the cardiology nursing ward to the operating room.
Part 3: operating room		
Operating room	P, V, and I	A photo is shown of the interior of the operating room containing explanations of specific devices (eg, radiology equipment). After this exploration, the patient can start a video of the scrub nurse and attending interventional cardiologist. They explain the upcoming procedure in general, including what they will do during the procedure and what is to be expected of the procedure (eg, duration).
Part 4: postcatheterization procedure at the cardiology nursing ward		
Patient room: inside hospital bed	V and P	A video is shown where the nurse and physician explain important aftercare issues and procedures. When the video is complete, the user can freely look around in the room and choose to be discharged when finished.
Discharge		
Exit cardiology ward	V and P	A short exit video shows all personnel and wishes the patient the best of luck and a healthy recovery. Hereafter, the VR experience is finished, and the user is placed outside in front of the hospital.

[a]P: photo.

[b]I: interactive feature.

[c]A: audio.

[d]V: video.

Measures

Presence

The participants' degree of presence and immersion in the virtual environment was assessed using the Presence Questionnaire (PQ) [29]. The PQ quantifies the amount of focus that a person expends on objects or tasks generated by a digital app—in this case, the VR app. The PQ is the most commonly used questionnaire for measuring presence [32]. It was developed based on factors widely believed to underlie presence and was found to be highly reliable and internally consistent with the Immersive Tendencies Questionnaire (ITQ) [29]. It consists of 22 questions covering different elements on the level of presence, such as the degree of realism and immersion, the degree of involvement, how compelling the sense of mobility was inside the virtual environment, and the degree of control over the virtual environment. All questions were answered on a 7-point Likert scale, with answers ranging from *not at all* to *completely*. The total scores varied between 22 and 154.

Immersive Tendencies

Immersion refers to a state in which an individual experiences an environment as an integral part of it, thus being enveloped in it and interacting with it naturally. Immersive tendencies relate to the tendencies to become immersed or involved easily in virtual or *make-believe* situations, quantifying a person's tendency to become immersed and focused in digital environments. In this study, the ITQ was used to quantify participants' immersive tendencies [29]. The ITQ consists of 18 questions, mostly assessing the degree of involvement and focus in common activities ("Do you ever become so involved

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in a movie that you are not aware of things happening around you?" or "When playing sports, do you become so involved in the game that you lose track of time?"). Answers were rated on a 7-point Likert scale ranging from *never/not very well* to *always/very well*. Higher cumulative scores (range, total score 18 and 126) represented a higher immersive tendency to become immersed or involved easily in the virtual situation.

Satisfaction

Patient satisfaction was assessed using the Client Satisfaction Questionnaire-8 (CSQ-8) [33]. The CSQ-8 is a short, 8-item standardized global satisfaction measure, and each item can be scored on a scale of 1 to 4, with total scores ranging from 8 to 32. The mean satisfaction level was computed for each individual. The CSQ-8 is widely used in health care studies and has good reliability and validity [34,35].

Several questions were asked to further assess the satisfaction levels. First, participants were asked to rate their satisfaction with *Pre-View* on a scale of 1 (extremely dissatisfied) to 10 (extremely satisfied) and to briefly summarize and clarify their scores subsequently. Second, participants were asked to what extent *Pre-View* met their need in terms of received information on a 5-point Likert scale (1 *definitely not* to 5 *definitely*) and to briefly summarize and clarify their score subsequently. Third, participants were asked whether they experienced any discomfort or side effects when undergoing the VR experience (yes or no) and if yes, to elaborate on these.

Usability

To assess the usability of *Pre-View*, participants were asked to complete the System Usability Scale (SUS) [36]. The SUS provides a quick and reliable tool for measuring the usability of a wide variety of products and services. It comprises a 10-item questionnaire with 5-point Likert scales ranging from *strongly agree* to *strongly disagree*. The total SUS scores ranged from 0 to 100. The SUS is a reliable and robust tool for assessing usability [37].

Perceived Effectiveness

Participants were asked to what extent they agreed with several statements, assessing their perceived effectiveness of *Pre-View* regarding (1) feeling better informed about the care process of cardiac catheterization, (2) feeling better prepared for the care process of cardiac catheterization, and (3) reduction or prevention of potential negative psychological consequences (eg, nightmares, anxiety, and symptoms of depression) after cardiac catheterization. The answer scales ranged from 1 (*totally do not agree*) to 5 (*totally agree*).

Statistical Analysis

All data were processed using SPSS (version 25). Descriptive analyses (ie, means, SDs, frequencies, and percentages) were used to describe the sociodemographic characteristics of the participants of the study population as well as to summarize the questionnaire data in terms of the measures described in the *Measures* section.

Results

Study Population

A total of 27 patients were approached to participate in this study, of whom 12 (44%) were interested in participating. Of the 27 patients, 1 (4%) patient dropped out of the study before undergoing the *Pre-View* because of fear of experiencing motion sickness. Furthermore, 11% (3/27) of patients were not included in the study because of cancelation of the VR appointment at the start of the COVID-19 pandemic and preventive measures that forced an early termination of study enrollment. This resulted in 30% (8/27) of patients who participated in this pilot study. Sociodemographic characteristics of each participant are shown in Table 2. The average age of the total study population was 67 (SD 7.5) years, including 75% (6/8) men and 25% (2/8) women. Half of the participants chose to undergo the VR experience at the hospital and the other half at home.

Table 2. Sociodemographic characteristics and outcome descriptives of individual participants.

Gender	Age (years)	Location	PQ[a] score	ITQ[b] score	CSQ-8[c] score	SUS[d] score
Male	73	Hospital	115.0	42.0	21.0	70.0
Male	77	Hospital	114.0	52.0	27.0	72.5
Female	73	Hospital	129.0	70.0	29.0	87.5
Male	68	Hospital	137.0	67.0	24.0	90.0
Male	60	Home	116.0	51.0	28.0	92.5
Male	69	Home	130.0	105.0	28.0	100.0
Female	59	Home	142.0	69.0	31.0	100.0
Male	57	Home	150.0	82.0	29.0	100.0

[a]PQ: Presence Questionnaire.

[b]ITQ: Immersive Tendencies Questionnaire.

[c]CSQ-8: Client Satisfaction Questionnaire-8.

[d]SUS: System Usability Scale.

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Presence and Immersive Tendencies

Patients reported high levels of presence in the virtual environment (Table 2), with an average PQ score of 129.1 (SD 13.4). At the individual item level, items that were scored lowest were related to how much one was able to control events (mean 4.3), the extent to which the visual display quality interfered or distracted one from performing assigned tasks or required activities (mean 4.6), and how much delay one experienced between their actions and expected outcomes (mean 4.9). Items that were scored highest related to how well one could concentrate on the assigned tasks or required activities rather than on the mechanisms used to perform those tasks or activities (mean 6.8), how involved one was in the virtual environment experience (mean 6.5), and how well one could actively survey or search the virtual environment (mean 6.5).

Regarding immersive tendencies, participants showed a mean score of 76.3 (SD 20.0), indicative of above average tendency of becoming immersed or involved in virtual or *make-believe* situations. Higher levels of immersive tendencies and presence were found in those who underwent VR experience at home (PQ mean 139.8; ITQ mean 80.8) than those who underwent VR experience at the hospital (PQ mean 118.5; ITQ mean 53.8); although, patients in the hospital group were, on average, approximately 10 years older than the home group; 73 years versus 61 years, respectively.

Satisfaction and Usability

As shown in Table 2, the usability of the *Pre-View* app was well evaluated by all participants, with a mean SUS score of 89.1 (SD 12.0) on a scale of 0 to 100. Patient satisfaction as assessed by the CSQ-8 was high, with an average score of 27.1 (SD 3.2) on a scale of 8 to 32. The results of the additional assessments of participant satisfaction are shown in Table 3. These results demonstrated acceptable to good satisfaction with *Pre-View*. Positive remarks were mostly about the clear explanation and visualization of the procedure day. A patient elaborated on his score of 6 on the item “Overall, how satisfied are you with *Pre-View*?” (Table 3); he was not able to see all the videos during the experience because of a technical error resulting in a black screen. Also, there were 2 remarks on identifying targets for improvements. A patient had missed seeing the actual catheterization. Another patient indicated that the cardiologist in the VR experience could perhaps elaborate a little more about the diversity of complaints that one could raise, as only chest pain was stated as the reason for visiting the cardiologist. Finally, none of the participants reported side effects during or after the VR experience.

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Table 3. Result in terms of satisfaction and perceived effectiveness of the virtual reality app.

Items	Answer scale	Values, n (%)	Values, mean (SD)
Satisfaction items			
	Overall, how satisfied are you with *Pre-View*?		8.6 (1.3)
	1=extremely dissatisfied	0 (0)	
	2	0 (0)	
	3	0 (0)	
	4	0 (0)	
	5	0 (0)	
	6	1 (13)	
	7	0 (0)	
	8	2 (25)	
	9	3 (38)	
	10=extremely satisfied	2 (25)	
	To what extent did *Pre-View* fulfill your need in terms of information received before the cardiac catheterization?		4.5 (0.5)
	1=not at all	0 (0)	
	2=not really	0 (0)	
	3=neutral or do not know	0 (0)	
	4=fairly well	4 (50)	
	5=really well	4 (50)	
	Have any side effects occurred while undergoing *Pre-View* (nausea, dizziness, headache, etc)?		2 (0)
	1=yes	0 (0)	
	2=no	8 (100)	
Perceived effectiveness items			
	***Pre-View* was effective in terms of feeling better informed about the cardiac catheterization care process**		4.5 (0.5)
	1=totally disagree	0 (0)	
	2=disagree	0 (0)	
	3=neutral or do not know	0 (0)	
	4=agree	4 (50)	
	5=totally agree	4 (50)	
	***Pre-View* was effective in terms of feeling better prepared for the care process of cardiac catheterization**		4.3 (0.7)
	1=totally disagree	0 (0)	
	2=disagree	0 (0)	
	3=neutral or do not know	1 (13)	
	4=agree	4 (50)	
	5=totally agree	3 (38)	
	***Pre-View* was effective, or could potentially be effective, in terms of reducing or preventing negative psychological consequences (eg, anxiety, nightmares, and symptoms of depression) after cardiac catheterization**		4.0 (0.9)
	1=totally disagree	0 (0)	
	2=disagree	0 (0)	
	3=neutral or do not know	1 (13)	
	4=agree	5 (63)	
	5=totally agree	2 (25)	

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When looking at usability and satisfaction scores separately for the patients who underwent *Pre-View* at home versus those who underwent *Pre-View* at the hospital, both scores were higher for the former group: 98 versus 80 for usability scores and 29 versus 25 for acceptability scores. These subgroups differed, however, not only in terms of where they underwent the VR experience but also in terms of age; those who underwent *Pre-View* at the hospital showed a higher mean age (mean 72.8 years, SD 3.7 years) than those who underwent it at home (mean 61.3 years, SD 5.3 years).

Perceived Effectiveness

As presented in Table 3, all patients agreed that *Pre-View* was effective in terms of feeling better informed about the care process of cardiac catheterization; half of the participants *totally agreed* with this statement, and the other half *agreed*. Furthermore, 7 (88%) of 8 patients agreed or totally agreed with the statement that *Pre-View* was effective in terms of feeling better prepared for the care process of cardiac catheterization. Overall, 25% (2/8) of patients who agreed elaborated: "If you know what is going to happen, you experience less stress" and "The more you know, the better." Finally, when asked whether *Pre-View* has been effective or could potentially be effective in reducing or preventing negative psychological consequences after cardiac catheterization, of the 8 patients, 2 (25%) participants *totally agreed*, 5 (63%) participants *agreed*, and 1 (13%) participant *disagreed*. The patient who disagreed elaborated as follows: "Even though you are better prepared for what is going to happen, you still do not know exactly what they are doing during the procedure. Nor does it completely remove the anxiety about what they will find, which so there is always some uncertainty." Another patient who agreed specifically remarked that even though he felt better informed and prepared, he still felt somewhat anxious and stressed before hospital admission for cardiac catheterization.

Discussion

Principal Findings

This pilot study investigated the feasibility, usability, and acceptability of a preoperative VR app (*Pre-View*) in the context of better informing and preparing patients for cardiac catheterization. Its feasibility was demonstrated by participants reporting high levels of presence in the virtual environment, and the VR experience was well tolerated without experiencing any side effects. Furthermore, the results indicate good user satisfaction and system usability. Finally, most participants self-reported *Pre-View* to have been effective in making them feel better informed, making them feel better prepared for the cardiac catheterization care process, and potentially reduce or prevent negative psychological consequences after cardiac catheterization.

The results of this study are promising in terms of feeling better informed about the hospital stay and corresponding elective cardiac catheterization. This is in line with previous literature suggesting that the incorporation of multimedia tools is beneficial for perceived benefits and understanding of upcoming treatments [16-18]. Our results also add to the body of literature underscoring the usefulness of VR as an engaging tool for patient education. For example, the results of a study by Pandrangi et al [38] showed that a VR experience modeling an abdominal aortic aneurysm for patients diagnosed with abdominal aortic aneurysm was perceived as beneficial in better understanding their health status and feeling more engaged in their health care. Another study demonstrated that patient education using VR training on radiotherapy increased knowledge and positive experiences of undergoing radiation therapy for patients with breast cancer [39]. Hence, the results of this pilot study underscore not only the acceptability and usability of using VR as a patient educational tool but also highlight the potential of using VR as a means to better inform patients about upcoming stressful treatment processes.

The preliminary results of this study suggest that *Pre-View* is potentially effective in preventing or reducing potential negative psychological consequences after surgery, which is compatible with the existing theory and body of literature indicating the potency of using VR technology as a means to desensitize individuals to stressful future events such as combat situations, thereby supporting resilience and preventing negative psychological symptoms [25-28]. Regarding hospital settings and surgery, few studies have investigated the effects of preoperative VR apps on patient outcomes. A single-blinded randomized controlled trial by Eijlers et al [40] investigated the effects of a child-friendly VR exposure to the operating theater on the day of children's surgery, aiming to get them familiarized with the upcoming medical procedures (eg, anesthesia procedures and transfer to the operating room) and corresponding environment. VR exposure did not have a beneficial impact on anxiety levels during anesthesia and after surgery or on the levels of postoperative pain and emergence delirium. Nevertheless, a subgroup of children who underwent more painful surgeries (ie, adenoidectomy and tonsillectomy) were significantly less often in need of rescue analgesia when having received VR exposure than those who had not. Another randomized controlled trial investigated the effects of preoperative VR experience in patients undergoing cranial and spinal surgery [41]. In comparison to usual preoperative procedures, the VR experience was found to lead to higher patient satisfaction, better preparedness, and lower levels of stress on the day of surgery. Thus, based on the results of our pilot study and the limited available research discussed above, VR seems to be an acceptable and feasible preoperative preparation tool for use in hospital settings before medical procedures. However, further research is needed to establish its effects on both physical and psychological outcomes.

Future studies could further explore the effects of using preoperative VR experiences across different contexts (eg, type of medical procedures in different types of illnesses) and different patient demographics (eg, age, immersive tendencies, and psychological well-being status). In addition, the role of presence in patient satisfaction and outcomes may be an interesting direction for future research: Is presence a necessary precondition or moderator of patient satisfaction and outcomes in the context of preoperative VR interventions? Not feeling *present* in the virtual environment has been found to be associated with higher levels of dropout in VR treatment for anxiety disorders; however, the same review did not find an

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effect of the degree of presence on patient outcomes [30]. A final interesting direction for future research is to investigate whether preoperative VR interventions can be effectively delivered via smartphones. In the literature, the feasibility of smartphone-based delivery of VR has already been demonstrated for various goals. The *Cardboard* platform by Google has been used to deliver VR experiences successfully for educational purposes [42] as well as in the context of a smoking cessation program [43]. Google Cardboard is a foldout cardboard viewer that provides the structure for a head-mounted display, while the display is provided by a smartphone that can be placed inside the cardboard viewer. Such smartphone-based delivery of VR experiences is of interest because of its possibility for less costly and timely VR experiences, thereby enabling easier and broad-scale implementation as it would be more convenient for individuals to start and walk through the experience whenever and wherever they choose or prefer to.

Limitations

The results of this pilot study should be interpreted in light of several limitations. The study sample size was small. Owing to the COVID-19 pandemic, appointments with included patients were canceled, and elective surgeries, including cardiac catheterization, at the time of study recruitment were postponed until further notice by the hospital. This led to premature termination of patient inclusion. The study was designed to assess the feasibility, usability, and acceptability of preoperative VR experience. Hence, no definitive statements can be made about the effectiveness of the VR experience in better informing and preparing patients for their upcoming hospital admission and corresponding procedures or in reducing negative psychological consequences afterward.

Conclusions

The current results provide initial support for the feasibility and acceptability of a preoperative VR app, creating a virtual experience that can support patient education and prepare patients for upcoming coronary catheterization. Further studies are needed to investigate the effects of VR as a tool to better prepare patients for medical procedures, its effectiveness in terms of reducing negative patient outcomes after such procedures, and its effects across different settings and patient populations.

Acknowledgments

The authors would like to acknowledge Andy Jansen, the founder of *Pre-View*, for the provision of the equipment (ie, virtual reality [VR] devices and experience) and for developing the VR experience in collaboration with the company Dutch VR. We would also like to thank all hospitals and medical staff for their cooperation in developing the VR experience and all the patients involved in this study. Finally, we would like to thank Marjolein Elderhorst for her support in the design and content of the VR experience.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Several examples of (360°) photos of the virtual reality experience.
[DOCX File , 2775 KB - cardio_v6i1e29473_app1.docx]

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Abbreviations

CSQ-8: Client Satisfaction Questionnaire-8
ITQ: Immersive Tendencies Questionnaire
LUMC: Leiden University Medical Center
PQ: Presence Questionnaire
PTSD: posttraumatic stress disorder
SIT: stress inoculation training
SUS: System Usability Scale
VR: virtual reality

Edited by T Leung; submitted 08.04.21; peer-reviewed by E Goldenhersch, M Engelen, J Urlings; comments to author 29.05.21; revised version received 30.07.21; accepted 29.12.21; published 22.02.22.

Please cite as:
Aardoom JJ, Hilt AD, Woudenberg T, Chavannes NH, Atsma DE
A Preoperative Virtual Reality App for Patients Scheduled for Cardiac Catheterization: Pre–Post Questionnaire Study Examining Feasibility, Usability, and Acceptability
JMIR Cardio 2022;6(1):e29473
URL: https://cardio.jmir.org/2022/1/e29473
doi:10.2196/29473
PMID:35191839

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Original Paper

Design of a Remote Coaching Program to Bridge the Gap From Hospital Discharge to Cardiac Rehabilitation: Intervention Mapping Study

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Abstract

Background: Remote coaching might be suited for providing information and support to patients with coronary artery disease (CAD) in the vulnerable phase between hospital discharge and the start of cardiac rehabilitation (CR).

Objective: The goal of the research was to explore and summarize information and support needs of patients with CAD and develop an early remote coaching program providing tailored information and support.

Methods: We used the intervention mapping approach to develop a remote coaching program. Three steps were completed in this study: (1) identification of information and support needs in patients with CAD, using an exploratory literature study and semistructured interviews, (2) definition of program objectives, and (3) selection of theory-based methods and practical intervention strategies.

Results: Our exploratory literature study (n=38) and semistructured interviews (n=17) identified that after hospital discharge, patients with CAD report a need for tailored information and support about CAD itself and the specific treatment procedures, medication and side effects, physical activity, and psychological distress. Based on the preceding steps, we defined the following program objectives: (1) patients gain knowledge on how CAD and revascularization affect their bodies and health, (2) patients gain knowledge about medication and side effects and adhere to their treatment plan, (3) patients know which daily physical activities they can and can't do safely after hospital discharge and are physically active, and (4) patients know the psychosocial consequences of CAD and know how to discriminate between harmful and harmless body signals. Based on the preceding steps, a remote coaching program was developed with the theory of health behavior change as a theoretical framework with behavioral counseling and video modeling as practical strategies for the program.

Conclusions: This study shows that after (acute) cardiac hospitalization, patients are in need of information and support about CAD and revascularization, medication and side effects, physical activity, and psychological distress. In this study, we present the design of an early remote coaching program based on the needs of patients with CAD. The development of this program constitutes a step in the process of bridging the gap from hospital discharge to start of CR.

(JMIR Cardio 2022;6(1):e34974) doi:10.2196/34974

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KEYWORDS

coronary artery disease; intervention mapping approach; information needs; support needs; eHealth; cardiac rehabilitation; remote coaching; e-coaching

Introduction

Cardiac rehabilitation (CR) is a cornerstone of secondary prevention and has been shown to reduce cardiovascular mortality and hospital readmissions and improve psychological well-being [1,2]. Although early enrollment in CR is advised, patients with coronary artery disease (CAD) generally wait 4 to 6 weeks after hospital discharge before starting physical CR [3,4]. This waiting period constitutes a gap between hospital discharge and the start of CR. Since patients are often discharged within 2 to 4 days, there is little room for patient education while patients are often in need of tailored medical information and support [5]. In addition, symptoms of anxiety are present in 28% and depression in 18% of patients entering CR, which negatively impacts adherence to CR [6]. While patients are sometimes offered educational support programs after hospitalization and prior to the start of CR that have been shown to increase knowledge and promote health behavior, these interventions are frequently neither initiated nor adhered to [7,8].

A potentially promising strategy for provision of information and support directly after hospital discharge is the use of a remote coaching program. In this study, remote coaching is defined as an online communication system used to provide medical, psychological, and social support to patients at home. Remote coaching programs, as part of a CR program, improve patients' physical capacity, clinical status, and psychosocial health [9]. Moreover, remote coaching has the potential of improving self-efficacy, which in turn is associated with improved CR adherence [10-12].

Nevertheless, it is unknown whether remote coaching meets patients' needs in the early phase (ie, gap) after hospital discharge. If the specific information and support needs in the early phase after hospital discharge are known, a remote coaching program to bridge the gap from hospital discharge to the start of CR can be developed.

Therefore, the objective of this study was to explore the information and support needs directly after hospital discharge among patients with CAD and develop an early remote coaching program to provide tailored information and support.

Methods

Study Design

In this study, we used the intervention mapping (IM) approach, a systematic and comprehensive methodology grounded in theory and developed in collaboration with key stakeholders (health care providers, patients, and informal caregivers) [13,14]. The 6 steps of the IM approach are (1) identification of the problem by performing a needs assessment, (2) identification of outcomes and change objectives, (3) selection of theory-based intervention methods and practical strategies, (4) development of an intervention, (5) generation of an adoption and implementation plan, and (6) generation of an evaluation plan. In this study, we completed the first 3 steps of the IM protocol.

The development of this remote intervention was performed on the existing platform of Cardiovitaal Cardiac Rehabilitation Amsterdam currently only used by patients who have started outpatient physical rehabilitation. This existing digital platform is used by patients to monitor physical (eg, blood pressure and steps per day) and psychological (symptoms of anxiety and depression) health. In addition, patients and health care providers use this platform to communicate using videocalling or the chat function. The design of the early coaching program was incorporated in the existing digital platform. At the beginning of this study, a multidisciplinary research group of health care providers comprised physical therapists (PK, ICDvD), physical therapist (Ilonka Pol), psychologist (VRJ), cardiologist (RAK), and registered nurse (Christine Dolman). All participants had expertise in the field of CR. The research group met on 3 occasions to discuss each step. The authors (PK and ICDvD) completed each step only after group consensus was reached. During each step the following tasks were completed.

Step 1. Logic Model of the Problem

The overall objective of step 1 was to define a logic model of the problem. The information and support needs of patients with CAD were investigated with an exploratory literature review and semistructured interviews with key stakeholders.

On the basis of these findings, a logic model of the problem was created using the Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation (PRECEDE) model, which is used as framework to identify intervention strategies [15]. After completion of the model, program objectives and outcomes were formulated by the research group. Based on these findings, outcomes and change objectives were formulated in step 2.

Step 2. Logic Model of Change

The overall objective of step 2 was to define a logic model of change. First, expected outcomes were formulated based on the results of step 1. These outcomes concern behavioral outcomes (outcomes related to the patient level) and environmental outcomes (outcomes related to the social network of the patient and health care setting). Second, based on the outcomes, we formulated program objectives. In the IM approach, these are formulated as performance objectives (outcomes that describe the desired behavior). Performance objectives were formulated at the patient and environmental level. Third, the research group selected determinants to influence during the intervention and created matrices of change objectives. Finally, a logic model of change was created. The logic model of change and matrices of change form the basis of this intervention and were further elaborated on in step 3 where they were matched with theory-based intervention methods and practical strategies.

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Step 3. Program Design

The overall objective of step 3 was to select theory-based intervention methods and practical strategies as ingredients for an intervention. As starting point for IM step 4, a preliminary design of an intervention was developed. Consecutive tasks were completed by the research group. First, based on the preceding steps, the overall themes, components, and sequence of the intervention were determined. Second, theory- and evidence-based change methods were selected and matched with the overall themes and components of the intervention. Third, the research group discussed and selected practical applications to deliver the intervention. Last, the design of the intervention was presented.

Study Population

For this study, patients were identified through an electronic patient file search of the Amsterdam University Medical Center and approached by telephone shortly after hospital discharge (2 to 4 days). We aimed to include a heterogenous sample to obtain a wide variety of viewpoints to increase the generalizability of our program.

We included patients with an acute coronary syndrome (ACS), coronary revascularization (percutaneous coronary intervention [PCI] or coronary artery bypass grafting [CABG]), or referral to CR. Patients were excluded if they had cognitive problems (Mini-Mental State Exam <24) or were unable to speak Dutch. Recruitment of patients ended when no new information was discovered in the data analysis (data saturation).

Ethics Approval

The Medical Ethics Committee of the Amsterdam University Medical Center approved the study protocol (NL65218.018.18).

Exploratory Literature Study

An exploratory literature review synthesizes the extant literature and usually identifies the gaps in knowledge that an empirical study addresses [16]. The objective of our exploratory literature review was to assess information and support needs after (acute) cardiac hospitalization. A comprehensive search was performed in PubMed to identify relevant studies concerning this topic. For this search, automatic term mapping was used to match the entered terms with Medical Subject Headings to enhance the search strategy. The following terms were used in the search builder: (coronary artery disease) OR (acute coronary syndrome) OR (percutaneous coronary intervention) OR (coronary artery bypass graft) AND (information needs OR support needs). The search strategy included terms occurring in the title and main text with no restrictions for date range but limited to the English language. During the screening process, articles were selected on title, abstract, and full text. The literature search was conducted by ICDvD and continuously discussed with PK and BV.

Semistructured Interviews

Semistructured interviews were conducted to assess patients' information and support needs. An interview guide was developed by the research group, in several rounds, until consensus was reached about the final version (Multimedia Appendix 1). These 30-minute interviews took place at the Amsterdam University Medical Center or at the patient's home. During the COVID-19 pandemic, interviews were continued by telephone. All patients gave informed consent for their personal data being used in this study. Interviews were performed by 2 physical therapists (PK and ICDvD), a physician assistant (Tarik Hoek Spaans), and 2 registered nurses (Bonita Meek and Miranda Balfoort).

All interviews were transcribed and were analyzed with qualitative data analysis software (MAXQDA 2018, VERBI GmbH). Three types of coding were used consecutively: open, axial, and selective. Initial codes were created by studying the segmented information. The codes were then abstracted into categories and subcategories. The underlying meanings of these categories were linked together to create overall themes. All data were independently coded for themes by 2 researchers (PK, ICDvD). A third researcher (BV) reviewed all codes and decided appropriate themes together with PK and ICDvD.

Results

Step 1. Logic Model of the Problem

The initial exploratory literature search identified 4606 electronic database papers. After removal of duplicates and non-English articles, the remaining papers were screened by title and abstract. After the screening procedure (see Figure 1 for flowchart), 38 articles were studied to identify the information and support needs of cardiac patients (see Multimedia Appendix 2 for an extraction table of our literature search).

Patients report a lack of (consistent) information after hospital discharge and that information needs were not always correctly perceived by health care providers [17-19]. The highest priority of information needs comprised information about medication and side effects, wound care, postoperative pain, physical activity, and dealing with emotions [20-28].

The greatest needs of information were found in young and middle-aged patients with a higher education [20,21]. No differences in type of information needs were found between men and women; however, women preferred to receive information before revascularization while men preferred it afterward [29,30]. Patients who were hospitalized after an acute coronary event were in greater need of information and emotional support than those treated electively [31].

High levels of anxiety were reported in the weeks after hospital discharge, especially in female patients and those with a lower education [32,33]. Patients reported distressing body signals, difficulties with sleeping, and insecurity about engaging in physical activity and returning to work [20,32,34-36]. Spouses reported high levels of psychological distress linked to anxiety, financial worry, and loneliness [37-39], highlighting a need to include spouses and informal caregivers in decision making and support programs [40-42].

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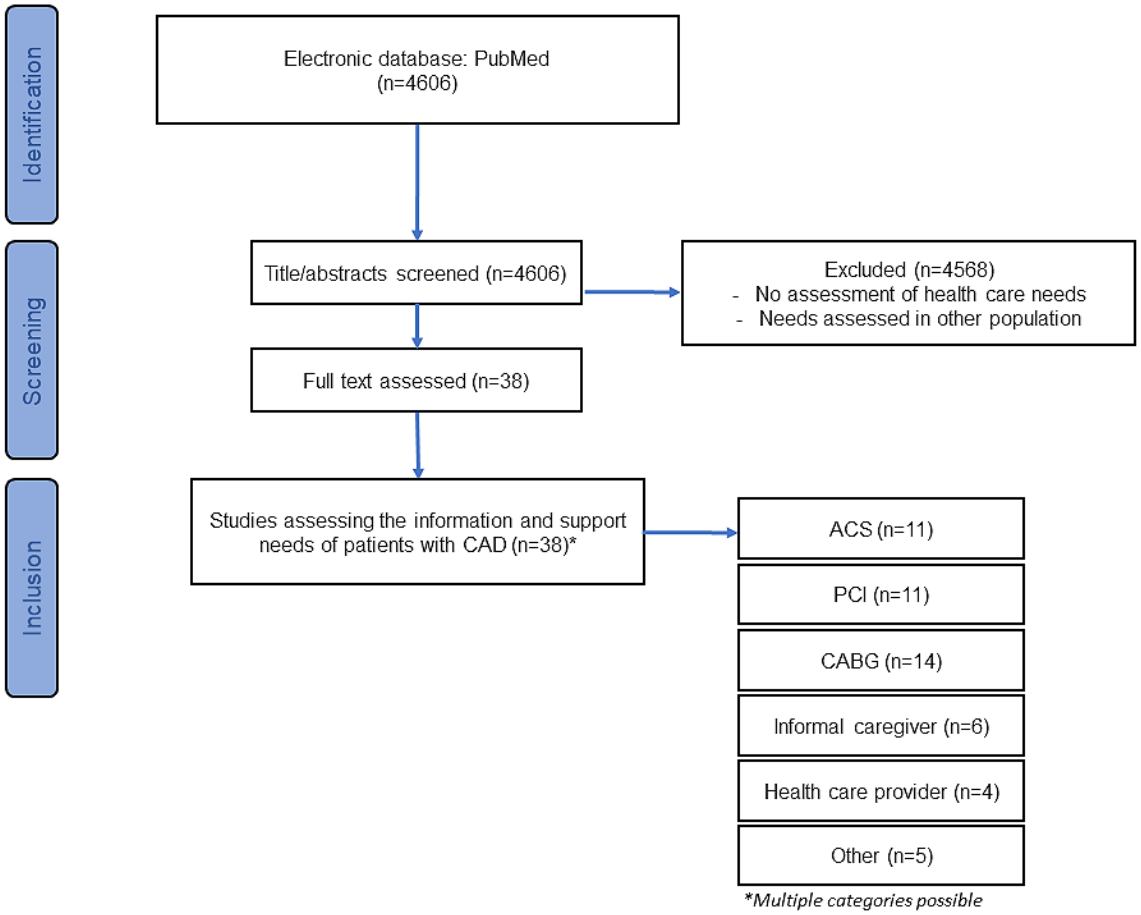
Figure 1. Flowchart of study. ACS: acute coronary syndrome; CABG: coronary artery bypass grafting; CAD: coronary artery disease; PCI: percutaneous coronary intervention.



In general, patient knowledge about risk factors and management of heart disease was limited, and patients often attributed the cause of their disease to nonmodifiable risk factors (ie, age, heredity) instead of lifestyle factors such as smoking, lack of physical activity, and unhealthy food choices [43-46]. However, reduction of mortality risk was rated as most important by patients with ACS [47].

In addition to having difficulties with understanding medical information, patients experienced problems with the referral process from hospital discharge to CR, which in turn led to a discontinuity in the health care process [48]. Those with a lower socioeconomic status felt especially excluded from CR while also having high information needs [49]. Moreover, these patients tended to have health beliefs that were not based on medical evidence, a predictor of nonadherence to CR [50,51]. Patients described advanced communication skills and pedagogical competences as important skills for health care providers [52]. Furthermore, the ability to build trust and tailor information to the individual were described by patients as important skills for health care providers [53,54].

Interviews

Data saturation was achieved after 17 eligible patients were included. Ten patients participated in an interview at the hospital or at home, and 7 patients took part in telephone interviews. Our total study population comprised 17 patients (9 females) with a median age of 64 years. Ten patients were diagnosed with ACS and 7 patients with angina pectoris. An overview of baseline characteristics is presented in Table 1.

Our data revealed 6 main themes: psychological distress, distressing body signals, lack of information at hospital discharge, passive coping style, disrupted health care process after hospital discharge, and social support. Qualitative findings with reference to individual patients can be found in Table 1.

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Table 1. Baseline characteristics.

Patient	Sex	Age range (years)	Diagnosis/intervention	Cardiac disease history	Comorbidity
1	Male	60-69	NSTEMI[a]/PCI[b]	Stroke, hypertension	HIV
2	Female	70-79	STEMI[c]/PCI	Hypertension, hypercholesterolemia	Hypothyroid
3	Male	80-89	NSTEMI/PCI	AF[d]	—[e]
4	Male	70-79	NSTEMI/PCI	Hypertension, hypercholesterolemia	Urothelial carcinoma
5	Male	50-59	STEMI/PCI	Hypertension, hypercholesterolemia	—
6	Male	60-69	STEMI/PCI	—	—
7	Female	70-79	AP[f]/PCI	Stroke	Hypothyroid, cholelithiasis
8	Female	50-59	STEMI/PCI	—	—
9	Male	60-69	NSTEMI/PCI	Diabetes mellitus, hypertension, OSAS[g]	Respiratory infection
10	Female	50-59	STEMI/PCI	Hypertension, hyperglycemia	—
11	Male	60-69	AP/CABG[h]	Stroke, hypertension	Rheumatic disease
12	Male	60-69	AP/CABG	—	—
13	Female	50-59	NSTEMI/PCI	Hypertension, hypercholesterolemia	Asthma, lumbar radicular syndrome
14	Female	50-59	AP/CABG	Stroke	Obesity
15	Female	60-69	AP/CABG	Complications during PCI, AF	—
16	Male	50-59	STEMI/PCI	—	Diabetes
17	Female	50-59	STEMI/PCI	—	Mixed connective tissue disease

[a]NSTEMI: non–ST-elevation myocardial infarction.

[b]PCI: percutaneous coronary intervention.

[c]STEMI: ST-elevation myocardial infarction.

[d]AF: atrial fibrillation.

[e]Not applicable.

[f]AP: angina pectoris.

[g]OSAS: obstructive sleep apnea syndrome.

[h]CABG: coronary artery bypass grafting.

Psychological Distress and Distressing Body Signals

After hospital discharge, patients reported having symptoms of anxiety and depression. In addition, patients reported needing information and support on dealing with body signals such as fatigue, palpitations, and wound pain after thoracotomy or PCI. These body signals often made patients afraid to engage in physical activity, which in some cases led to fear of bodily sensations and patients monitoring their heartbeat. See Multimedia Appendix 3 for the complete list of quotations.

> *I don't want to feel that pain anymore.* [P11, subcategory: wound pain/chest pain]
>
> *I don't dare to do anything.* [P16, subcategory: hypervigilance]
>
> *I monitor my heart rate.* [P17, subcategory: fear of bodily sensations]
>
> *Nothing will be the same again.* [P16, subcategory: depression]

Lack of (Consistent) Information at Hospital Discharge

Patients reported a lack of information at hospital discharge or stated that the information was vague or inconsistent. A major concern for patients was a lack of information about side effects of medication, which in some cases led to misinterpretation of body signals and revisiting the emergency room.

Patients also reported that they did not know the amount of physical activity they were allowed to engage in after hospital discharge, resulting in reluctance to engage in any physical activity whatsoever. Patients reported needing to be reassured about the chance of a new cardiac event before hospital discharge.

Not being reassured by a treating physician led, in some cases, to false beliefs about the procedure (eg, one patient believed a stent could shift in the artery by doing physical activity).

> *I felt a weird pressure on my chest, like my heart skipped a beat. I panicked, so I went back to the emergency room where they examined me. Afterward they told me it was a side effect of metropolol.* [P10, subcategory: side effects medication]
>
> *I don't know if I can do any physical activity and if I injure my body if do physical activity.* [P4, subcategory: physical activity]

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One health care provider tells me this, the other tells me that. [P1, subcategory: inconsistent information]

I really missed talking to my physician about what had happened to my heart before I left the hospital. [P7, subcategory: cardiac event]

Passive Coping Style

After hospitalization, patients often developed a passive coping style by spending all their time on the couch or in bed. In several cases, the informal caregiver performed all household chores and therefore felt overloaded. This maladaptive coping strategy was attributed to psychological distress and the inability to cope with distressing body signals.

I'd rather be in bed all the time. [P16, subcategory: inactivity]

I did not do anything for 6 weeks, I'm just staying in bed and on the couch, I can't do much more. [P9, subcategory: inactivity]

Disrupted Health Care Process After Hospital Discharge

Patients reported problems with continuity of care, especially about the long interval between hospital discharge and the start of CR. For some patients, the relevance of CR was unclear, which made them reluctant to participate in CR.

I think the time between discharge and CR is too long. [P12, subcategory: time until CR]

What is there to rehabilitate about the heart? [P2, subcategory: relevance of CR]

The referral to CR went completely wrong. It took ages before it was clear where I needed to go and what was expected. Thinking about this makes me short of breath again. [P4, subcategory: negative experience hospital]

Social Support

In the phase after cardiac hospitalization, patients received support from their informal caregivers. In some cases, the caregiver was overprotective and took all physical tasks out of the hands of the patient. Although well intentioned, this has a negative effect, since it is necessary that the patient undertakes activities for optimal recovery.

During the interviews, patients expressed their support needs and stated that receiving guidance and support, especially during physical activity or exercise, was paramount in regaining confidence.

If I do too much and I have complaints, my husband becomes angry and tells me to sit down. [P10, subcategory: hypervigilance informal caregiver]

My husband does all the groceries and cooking and tells me to relax. [P7, subcategory: hypervigilance informal caregiver]

I want to participate in CR to gain confidence so that afterward I can start exercising alone. [P5, subcategory: CR]

I would feel anxious if I started exercising without guidance. It's about confidence. I can do it, but it would not feel right. [P16, subcategory: CR]

Findings from the exploratory literature study and interviews were divided into the categories determinants, behavioral factors, health problems, and quality of life and compiled in the PRECEDE-based logic model of the problem by PK and IvD. After the research group discussed the model and proposed several adjustments, the final model was developed. The final model is presented in Figure 2.

Based on the logic model of the problem, the overall goal was determined by the research group. The overall goal of this intervention is to bridge the gap from hospital discharge to CR by stimulating self-management behavior and providing tailored illness management information and psychological support to patients and their informal caregivers by means of a remote coaching program.

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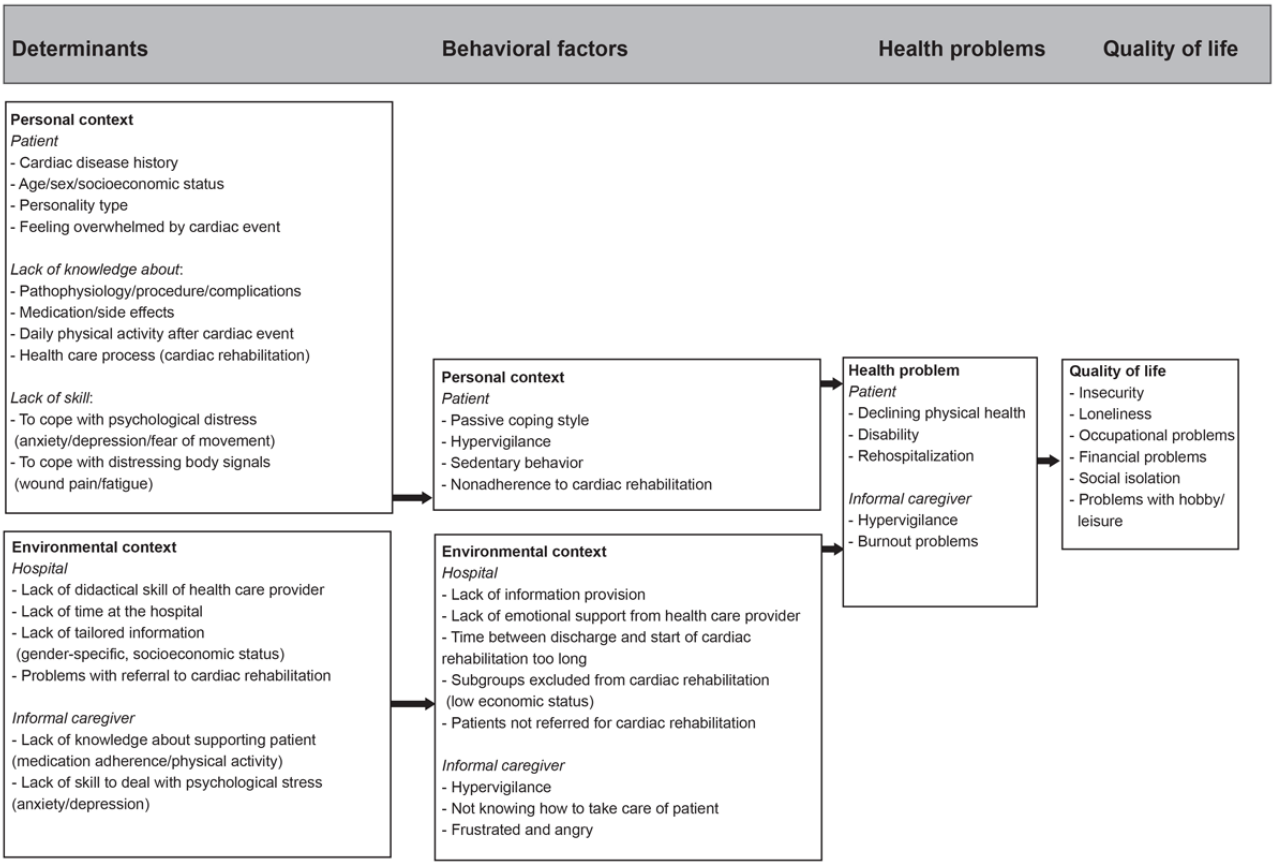
Figure 2. Logic model of the problem.



Step 2. Logic Model of Change

The logic model of change was developed based on the findings in step 1. First, behavioral and environmental outcomes were defined. Second, the influence of these outcomes on the health problem and quality of life was described. Third, performance objectives were formulated for the behavioral and environmental outcomes. Fourth, a theoretical framework and determinants to influence were selected. Last, a determinant matrix was developed that describes how each determinant is related to the performance objectives.

Behavioral Outcomes

Patients and informal caregivers actively prevent physical and psychological problems by adhering to a remote CR program in the first phase after hospital discharge.

Environmental Outcomes

The CR center supports patients and informal caregivers in the first 3 weeks after hospital discharge by providing tailored information and (emotional) support.

Program Objectives

Behavioral and Environmental Outcomes

For the behavioral outcomes, 4 performance objectives were formulated:

- Patients and informal caregivers gain knowledge on how CAD and revascularization affects their bodies and health
- Patients and informal caregivers gain knowledge about medications and side effects and adhere to their treatment plan
- Patients and informal caregivers know which daily physical activities they can and can’t do safely after hospital discharge and are physically active
- Patients and informal caregivers can deal with the psychosocial consequences of CAD

For the environmental outcomes, 2 performance objectives were formulated:

- In the 3 weeks after hospital discharge, patients and informal caregivers needs are assessed by the health care professional
- Health care providers give tailored information and coach cardiac patients and their informal caregivers in the first phase after hospital discharge

Theoretical Framework

The research group chose the theory of health behavior change (THBC) and theory of planned behavior (TPB) as the theoretical framework for this intervention. The THBC is presented in Figure 3.

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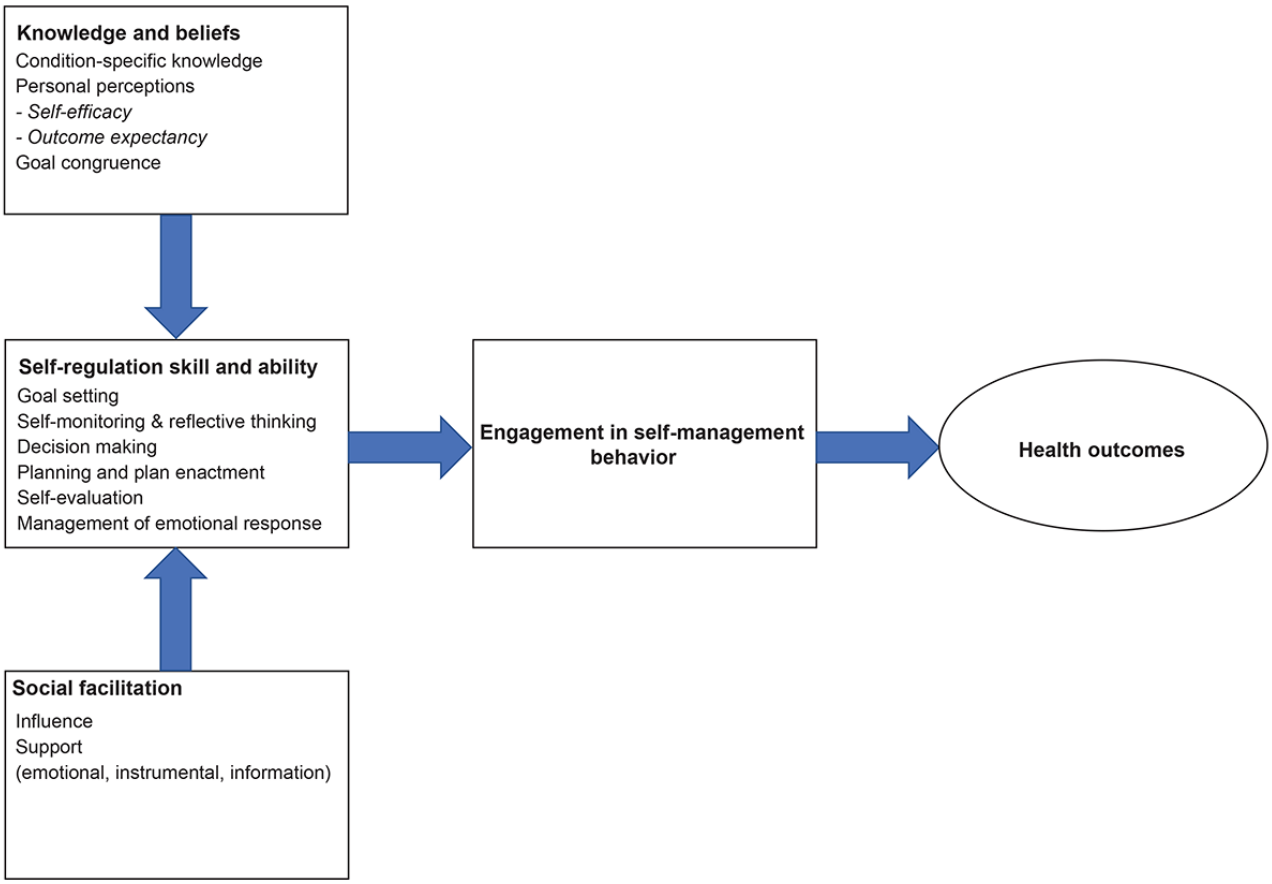
Figure 3. Theory of health behavior change.



According to THBC, 3 main determinants influence the adoption of self-management behavior [55]. These determinants are knowledge, self-regulatory skills, and abilities and social facilitation [55]. The TPB links beliefs to behavior and states that an individual's behavioral intentions are shaped by attitude, subjective norms, and perceived behavioral control [56]. According to these theories, knowledge is defined as part of an attitude toward a certain behavior, which in turn is based on personality traits, values, preference, and outcome expectancy. Self-regulatory skills refer to the process of incorporating behavior change in daily life [56]. In this study, self-regulatory skills can be described as patients monitoring themselves (eg, body signals, emotions), goal setting (eg, performing daily physical activity), reflective thinking (eg, effects of cardiac event of health and quality of life), planning (eg, medication adherence, appointments with physician), decision making (eg, lifestyle habits), plan enactment (eg, setting feasible goals), self-evaluation, and management of emotions arising as a result of behavior (eg, feeling anxious or depressed). Social facilitation is divided in social influence and social support and refers to the health care provider providing credible information and social support to the patient and informal caregiver.

Based on the core components of the THBC and TPB, the research group chose the following determinants of influence for the remote coaching program: knowledge, skills, attitude, social influence, and self-efficacy. These determinants were used to create a matrix where all performance objectives were described per determinant. A detailed description of all determinants is presented in Multimedia Appendix 4.

The last task of step 2 was to create a model of change which represents the relationship between the determinants, performance objectives, and desired outcomes (Figure 4).

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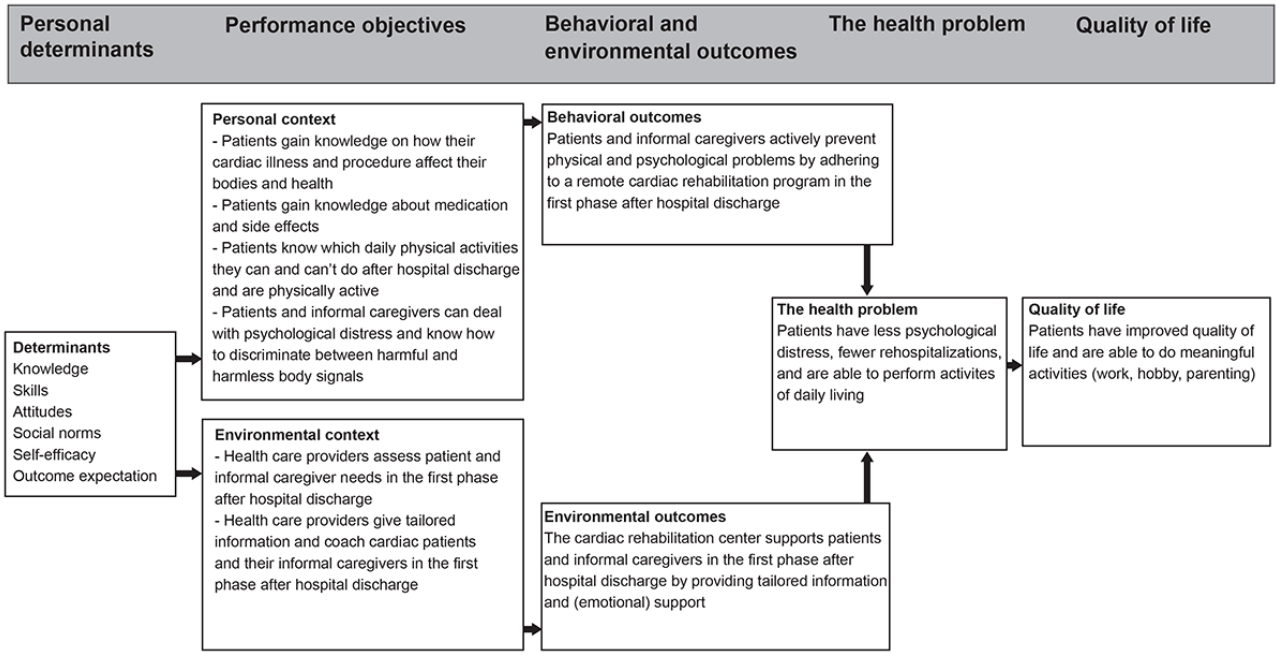
Figure 4. Logic model of change.



Step 3. Program Design

The results from step 2 were used to design the program. In this step, the research group matched the 6 determinants and performance objectives with theory-based and practical strategies, in line with the IM taxonomy [57]. The selection of theory-based strategies was based on the theoretical framework of Kok et al [57]; please see this paper for a detailed explanation of the theory-based strategies.

Selection of Theory-Based and Practical Strategies

Before specifically discussing the program objectives in relation to their determinants, the research group freely discussed the program design of this intervention based on the findings in step 1 and 2. The research group agreed that a remote coaching program to bridge the gap between hospital discharge and the start of CR was relevant. The research group defined 2 core elements of the program: behavioral counseling and increasing knowledge by using health video clips.

Behavioral Counseling

Health care providers will contact patients and informal caregivers within 2 days after hospital discharge using an eHealth platform. The use of an eHealth platform allows patients and informal caregivers to access information and support from the confines of their own home. During these counseling sessions, which last for about 60 minutes, informal caregivers are invited to join since many of them are in need of information and support. During these sessions, the health care provider assesses the information and support needs of patients and informal caregivers. Many informal caregivers struggle with feelings of psychological distress [37,38]. The role of the informal caregiver in these sessions is twofold. During the consultation sessions, the health care provider addresses the psychological stress in patients and informal caregivers. The emphasis is placed on influencing the participant's attitude by looking at negative situations and beliefs from a different perspective using shifting perspective and belief selection as the main behavioral change strategies. In addition, the informal caregiver is invited to stimulate healthy behavior in the patient (such as stimulating physical activity) by using "shifting away from unpopular behavior" as strategy. Self-regulation skills, such as goal setting and monitoring, are trained by using cognitive behavioral techniques and motivation interviewing.

Health Video Clips

The research group proposed the use of health video clips in addition to behavioral counseling to increase knowledge. These video clips provide basic knowledge about a variety of topics collected in step 1 and 2. Together with a cardiologist (RK), we created video clips about CAD and PCI, CAD and CABG, and medication and side effects. The physical therapist (Ilonka Pol) created a video clip about physical activity, and the psychologist (VJ) created a video clip about psychological distress. These video clips are used as a prerequisite to influence self-regulatory skills. All 5 health video clips are accessible for all patients at any time. The health care provider encourages the patient to access these clips before the coaching sessions. The knowledge obtained in the video clips is discussed during the remote coaching sessions and tailored to the specific situation and needs of the patient or caregiver. The theory-based strategies applied in the health video clips are persuasive communication, imagery, and elaboration. Based on the knowledge obtained by patients in these clips, the health care provider can apply the following strategies during consultation: setting goals, reattribution training, self-monitoring behavior, improving physical and emotional states, and setting graded tasks. A comprehensive overview of all strategies is presented in Multimedia Appendix 5.

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Intervention Plan

Remote Coaching Program

The eHealth platform can be accessed by patients using a personal computer or mobile device (smartphone or iPhone). Important prerequisites to using this eHealth platform are ability to use the camera on their device and some basic knowledge about accessing an internet platform. The research group proposes a 3-step coaching trajectory. In the first phase, the patients' and informal caregivers' needs are assessed, and additional information and support are provided depending on the patients' and informal caregivers' needs. After the first session, the patient can access the health information clips on the eHealth platform to obtain knowledge about a variety of topics (CAD and PCI/CABG, medication and side effects, physical activity, psychological distress, and distressing body signals). During the second session, the health care provider reflects on the obtained knowledge and tailors it to the needs of the patient and informal caregiver if needed. In addition, the health care provider challenges and helps the patient and informal caregiver to formulate short-term goals for the first phase after hospital discharge. In the last session, the health care provider and patient reflect on the patient's progress since hospital discharge and whether short-term goals are reached. During this session, the health care provider helps the patient in formulating long-term goals for after the CR program. If the patient needs more guidance after the third coaching session, more sessions will be planned. The final intervention plan is presented in Table 2.

Table 2. Intervention plan.

Strategies	Content	Target group
Before the intervention		
Assessing patients' needs	Mandatory workshop—objective: learning to perform a comprehensive assessment to assess the needs of patients and informal caregivers	Health care provider
Changing the behavior of patients	Mandatory workshop—objective: learning to coach patients and informal caregivers by using evidence-based behavior change techniques (such as motivational interviewing)	Health care provider
During the intervention		
Consulting health care provider	Coaching session 1—objectives: assessing information and support needs of patients and informal caregiver. Getting acquainted with coach, eHealth portal, and CR[a]	Patient and informal caregiver
Accessing digital health information	Health video clips—objectives: gaining detailed information about CAD,[b] medication, physical activity, psychological distress, and body signals	Patient and informal caregiver
Consulting health care provider	Coaching session 2—objectives: health care provider, patient, and informal caregiver reflect on health video clips and formulate short-term goals for the period between hospital discharge and starting CR	Patient and informal caregiver
Consulting health care provider	Coaching session 3—objectives: health care provider, patient, and informal caregiver reflect on short-term goals and progress. Health care provider and patient formulate long-term goals for during and after CR	Patient and informal caregiver

[a]CR: cardiac rehabilitation.

[b]CAD: coronary artery disease.

In summary, after hospital discharge, patients are approached by a health care provider and gain access to an eHealth platform. During the first session, the patients' information and support needs are assessed. On the eHealth platform, patients are coached by a health care provider and can access information videos. After the first 4 to 6 weeks, patients continue CR at the CR center or remotely. A flowchart of the intervention is presented in Figure 5.

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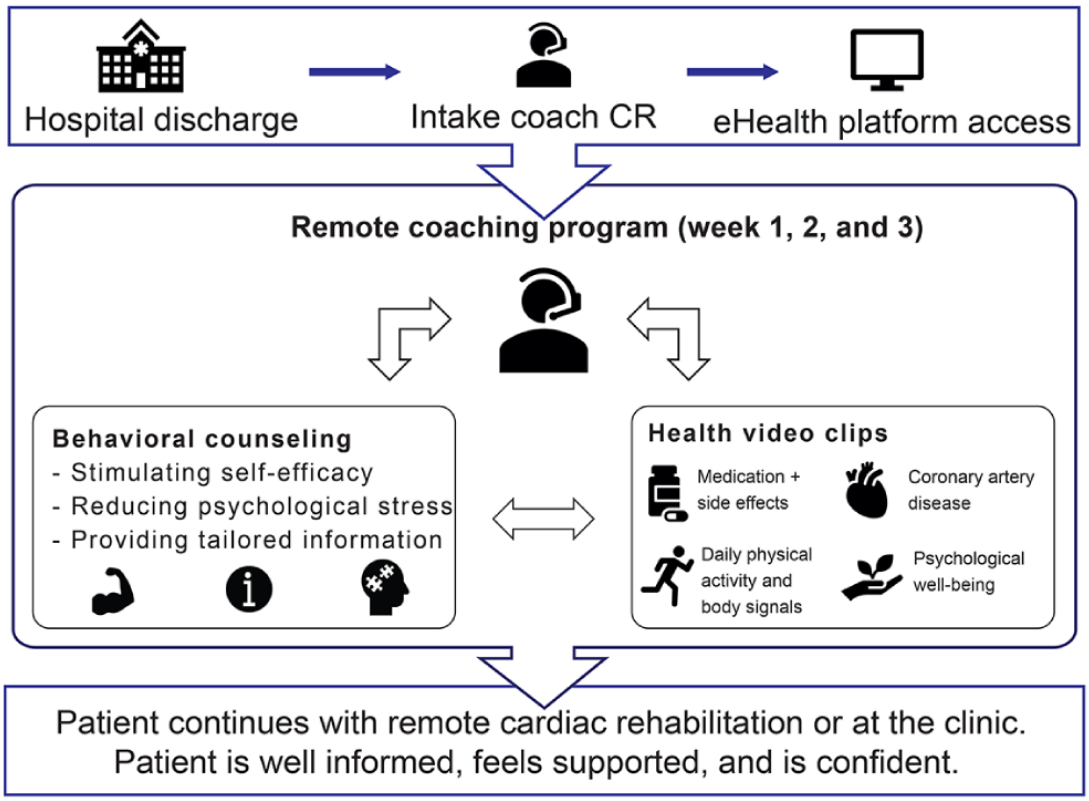
Figure 5. Remote coaching program. CR: cardiac rehabilitation.



Design and Implementation of the Intervention

After using the IM protocol to create the content of the program, the final intervention was developed. For this intervention, an existing eHealth app from Cardiovitaal Cardiac Rehabilitation Amsterdam was used. After hospital discharge, patients could access this platform to find information and consult with a health care provider before the start of the outpatient CR program. A screenshot of the eHealth platform is presented in Multimedia Appendix 6.

Five health video clips were created together with health care providers who work at the CR center:

- CAD and CABG
- CAD and PCI
- Physical activity after cardiac hospitalization
- Psychological distress after CR
- Medication and side effects

A screenshot of the video clip CAD and PCI is provided in Multimedia Appendix 7, and a screenshot of the video clip physical activity after cardiac hospitalization is provided in Multimedia Appendix 8.

Discussion

Principal Findings

The results of this study suggest that patients' needs after hospital discharge comprise information and support about the following topics: CAD, medication and side effects, daily physical activities, psychological distress, and body signals. In addition, we present a systematic approach to develop an early remote coaching program using the IM protocol.

The overall objective of this remote coaching program is to bridge the gap from hospital discharge to the start of center-based CR by stimulating self-management behavior and influencing the following determinants: knowledge, skills, social support, attitudes, and self-efficacy. We selected theory-based techniques that match these determinants, as research indicates the value of theory-based interventions [57,58]. Moreover, patients were actively involved in the development of this coaching program. To assure adoption of the intervention, patients have been asked to participate in the future refinement of the final intervention in step 4 of the IM approach.

Comparison With Prior Work

A recent systematic review reports that core components of CR, such as nutrition counseling and psychological and weight management are addressed in one-third of digital CR programs; less than one-third of these programs address management of lipids, diabetes, smoking cessation, and blood pressure [59]. Since our CR program aims to bridge the gap between hospital discharge and the start of CR, we chose to assess the needs of patients in the early phase after hospital discharge. Our study shows that in this phase patients value social support, disease specific information, and information about physical activities and psychological distress. Research shows that health care needs change over time. Nevertheless, knowledge about pathology and how to manage psychological distress remain important even after a 2-year follow-up period [60].

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Based on our results, we developed a comprehensive coaching program using remote counseling as the main strategy and considered its positive impact on psychosocial health, physical health, and clinical status [9-11]. In this study, we chose to complement behavioral counseling sessions with educational video clips. The use of video modeling has potential benefits such as facilitation of knowledge acquisition, improving self-care behaviors, and reducing psychological distress [61]. Moreover, video modeling is effective in patients with low health literacy and removes inconsistencies between health care providers [62,63].

Informal caregivers were invited to actively participate in this intervention since research shows that many informal caregivers suffer from psychological distress after their partner's hospitalization [37-42]. In addition, informal caregivers play an important role in the recovery of the patient; however, hypervigilance in informal caregivers can undermine patients' health and recovery [64]. It is therefore important to inform and support informal caregivers in their new role. A recent study shows that patients and informal caregivers prefer the same content and delivery formats for digital interventions (eg, health video clips, contact with health care provider) [65]. It is thus expected that informal caregivers can benefit from this remote coaching program.

For this coaching program to be successful, health care providers need to encourage patients to reflect on the obtained knowledge and skills and offer strategies to adopt behavior changes in daily life. Therefore, health care providers should be well trained in applying behavior change techniques and have the ability to build trust in patients.

Strengths and Limitations

First, we consider the use of the IM protocol a strength since digital health behavior interventions often lack theoretical grounding, as expertise from different scientific areas is often lacking in the design phase [66]. In line with the IM protocol, the development of this intervention was supported by researchers with expertise in various fields (cardiology, physical therapy, psychology, and nursing science), ensuring a firm theoretical approach.

Second, patients' needs and expectations were taken into account in the early phase of the design process, which contributed to the usability and utility of this intervention [67]. Results from our literature study and interviews indicated that the interval between hospital discharge and CR was too long and that patients wanted to be in contact with a health care provider to receive support and information. It remains unclear, however, if this remote coaching program is applicable for older adult cardiac patients with comorbidities, as they are often reluctant to use eHealth apps [68]. Nevertheless, a recent systematic review shows that older adults (aged 65 years and older) exhibited greater engagement with digital health interventions than younger adults (aged younger than 65 years). Despite the technological barriers, older adults might view digital coaching as social interaction, which is often desired by older adults. In addition, older adults might have more time to engage in digital technologies [69]. In this study, 17 patients with various ages, cardiac diagnoses, and comorbidities were included, and the results of the interviews supported the findings from the literature. It is therefore expected that this intervention is suitable for a wide variety of patients referred for CR. To assure adoption of this intervention by older adults, a thorough evaluation of the feasibility of this intervention should be conducted in step 4 of the IM approach.

Third, the use of a remote intervention is considered a strength since it can resolve several barriers at the patient level (distance to center, transportation) and health care system level (referral problems, limited facilities) [70]. In addition, this study shows that patients are in need of information and support directly after hospital discharge, despite current guidelines, which recommend initiation of CR within 4 to 6 weeks after hospital discharge [4,5]. Delayed participation in CR negatively impacts physical and psychological outcomes, while early initiation of CR positively impacts health outcomes [71-73]. An early remote coaching program starting directly after hospital discharge might help to overcome logistical issues and delays in CR initiation and is therefore well suited for the period between hospital discharge and the start of CR.

Finally, patients in this study were involved in the first steps of the intervention development. Due to the nature of this study, we used a small sample size to explore patients' needs. However, information obtained from the interviews was supplemented with data from our scoping literature study. We therefore expect that our results are generalizable to the greater cardiac population. Future studies should focus on program refinement (IM step 4) of this remote coaching program and assess its feasibility and effectiveness in studies with larger sample sizes. It would be interesting to assess the effectiveness of this early remote coaching program on symptoms of psychological distress and participation in outpatient CR.

Conclusion

This study shows that patients with CAD are in need of tailored information and support after hospital discharge. The main areas of information and support are CAD, medication and side effects, physical activity, psychological distress, and body signals. In addition, this study presents the development of a remote intervention, using the IM protocol, to bridge the gap from hospital discharge to the start of CR.

Acknowledgments

Data were collected by PK and ICDvD with assistance from Tarik Hoek Spaans, Miranda Balfoort, and Bonita Meek. The authors also thank Christine Dolman and Ilonka Pol for participating in the research group. Financial support was received via a personal grant (PK; 023.010.064) from the Dutch Research Council and grant RAAK.PRO02.083 from the Taskforce for Applied Research (RAAK-PRO). The funding bodies had no role in the design of the study; collection, analysis, and interpretation of data; or in writing the manuscript.

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Authors' Contributions

Data were interpreted by PK and ICDvD. RAK, VRJ, and BV made substantial contributions to the design of the work. PK was responsible for the first draft, which was revised by ICDvD, CHML, WJMSoR and BV. HTJ and BV made substantial revisions to the final version of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 15 KB - cardio_v6i1e34974_app1.docx]

Multimedia Appendix 2
Extraction table.
[DOCX File , 34 KB - cardio_v6i1e34974_app2.docx]

Multimedia Appendix 3
Participant quotations.
[DOCX File , 45 KB - cardio_v6i1e34974_app3.docx]

Multimedia Appendix 4
Determinant matrix.
[DOCX File , 17 KB - cardio_v6i1e34974_app4.docx]

Multimedia Appendix 5
Program strategy.
[DOCX File , 19 KB - cardio_v6i1e34974_app5.docx]

Multimedia Appendix 6
Screenshot of eHealth platform.
[PNG File , 233 KB - cardio_v6i1e34974_app6.png]

Multimedia Appendix 7
Screenshot of coronary artery disease and percutaneous coronary intervention.
[PNG File , 269 KB - cardio_v6i1e34974_app7.png]

Multimedia Appendix 8
Screenshot of physical activity after cardiac hospitalization intervention.
[PNG File , 660 KB - cardio_v6i1e34974_app8.png]

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Abbreviations

ACS: acute coronary syndrome
CABG: coronary artery bypass grafting
CAD: coronary artery disease
CR: cardiac rehabilitation
IM: intervention mapping
PCI: percutaneous coronary intervention
PRECEDE: Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation
RAAK-PRO: Taskforce for Applied Research
THBC: theory of health behavior change
TPB: theory of planned behavior

Edited by T Leung; submitted 15.11.21; peer-reviewed by L Happe, R Gallagher, P Savage; comments to author 25.12.21; revised version received 18.02.22; accepted 11.05.22; published 25.05.22.

Please cite as:
Keessen P, van Duijvenbode ICD, Latour CHM, Kraaijenhagen RA, Janssen VR, Jørstad HT, Scholte op Reimer WJM, Visser B Design of a Remote Coaching Program to Bridge the Gap From Hospital Discharge to Cardiac Rehabilitation: Intervention Mapping Study
JMIR Cardio 2022;6(1):e34974
URL: https://cardio.jmir.org/2022/1/e34974
doi:10.2196/34974
PMID:35612879

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Original Paper

The Effect of Wearable Tracking Devices on Cardiorespiratory Fitness Among Inactive Adults: Crossover Study

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Abstract

Background: Modern lifestyle is associated with a high prevalence of physical inactivity.

Objective: This study aims to investigate the effect of a wearable tracking device on cardiorespiratory fitness among inactive adults and to explore if personal characteristics and health outcomes can predict adoption of the device.

Methods: In total, 62 inactive adults were recruited for this study. A control period (4 weeks) was followed by an intervention period (8 weeks) where participants were instructed to register and follow their physical activity (PA) behavior on a wrist-worn tracking device. Data collected included estimated cardiorespiratory fitness, body composition, blood pressure, perceived stress levels, and self-reported adoption of using the tracking device.

Results: In total, 50 participants completed the study (mean age 48, SD 13 years, 84% women). Relative to the control period, participants increased cardiorespiratory fitness by 1.52 mL/kg/minute (95% CI 0.82-2.22; *P*<.001), self-reported PA by 140 minutes per week (95% CI 93.3-187.1; *P*<.001), daily step count by 982 (95% CI 492-1471; *P*<.001), and participants' fat percentage decreased by 0.48% (95% CI –0.84 to –0.13; *P*=.009). No difference was observed in blood pressure (systolic: 95% CI –2.16 to 3.57, *P*=.63; diastolic: 95% CI –0.70 to 2.55; *P*=.27) or perceived stress (95% CI –0.86 to 1.78; *P*=.49). No associations were found between adoption of the wearable tracking device and age, gender, personality, or education. However, participants with a low perceived stress at baseline were more likely to rate the use of a wearable tracking device highly motivating.

Conclusions: Tracking health behavior using a wearable tracking device increases PA resulting in an improved cardiorespiratory fitness among inactive adults.

(JMIR Cardio 2022;6(1):e31501) doi:10.2196/31501

KEYWORDS

activity tracking; cardiorespiratory fitness; mHealth; mobile health; motivation; physical activity; self-monitoring; wearable; cardio; fitness; cardiorespiratory; behavior change

Introduction

In the Western world, physical inactivity and sedentary behavior are increasing and accordingly, so are health-related problems and health care costs. Global Health Observatory data estimate that 37% of the adult population in high-income countries is insufficiently physically active [1]. In Denmark, 29% of the adult population report that they do not meet the World Health Organization's minimum recommendation for physical activity (PA), and of them, 71% want to be more physically active [2,3]. Starting and maintaining a physically active life is a great challenge for many people.

Wearable tracking devices (WTDs) have been suggested to support and motivate to a physical active behavior [4]. WTDs are small wearable computers with sensors that monitor different health-related parameters such as steps, physical intensity

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minutes, and heartbeat continuously under real-life conditions. Despite the promising features embedded in WTDs the results are mixed from studies investigating the effect of increasing PA with the use of these devices. Three recent reviews conclude that the use of a WTD improves daily step counts regardless of age, sex, and health status, but less consensus is found regarding the effect on moderate to vigorous PA (MVPA) [5-7]. Few studies have investigated the effect on cardiorespiratory fitness (CRF) despite low CRF has been reported to be a more powerful predictor of health issues than, for instance, inactivity [8,9]. Discrepancy exists between the few studies that have evaluated the effect on CRF after a WTD intervention [10-14]. The existing studies were all carried out at least 5 years ago and thereby conducted with older devices. Because a low CRF constitute a separate risk factor, the effect of utilizing a modern WTD on CRF is relevant to clarify [15]. In addition, not all individuals exhibit the same tendency for using a WTD, and recent studies suggest that individual differences may play a role in the adoption of using a WTD [4,16,17]. For instance, a study found that behavioral intentions to use a WTD is affected by personality traits, age, computer self-efficacy, and prior PA [18].

The purpose of this study was to investigate the effect of using a modern WTD on CRF and the relationships between the adoption of using a WTD and personal characteristics and health outcomes.

Methods

Participants

Participants were recruited from Naestved city, Denmark, through local advertisements in media (newspaper, television, radio, and the internet). Participants were required to be at least 18 years of age and to own a smartphone or tablet device. Only inactive participants who reported exercising less than the recommended 150 minutes per week [3] were eligible for the study.

The primary outcome was CRF, and the minimal difference of interest in Vo_2max was 2 O_2/kg/minute. With a significance level of P=.05 (2-sided), a total number of 56 participants should be included using an SD of 4.5 O_2/kg/minute to obtain a 90% power to detect the minimal difference of interest. The SD was based on the difference between 2 measures for the same participant obtained in a feasibility study [19]. Allowing for an attrition rate of 10%, 62 participants should be included.

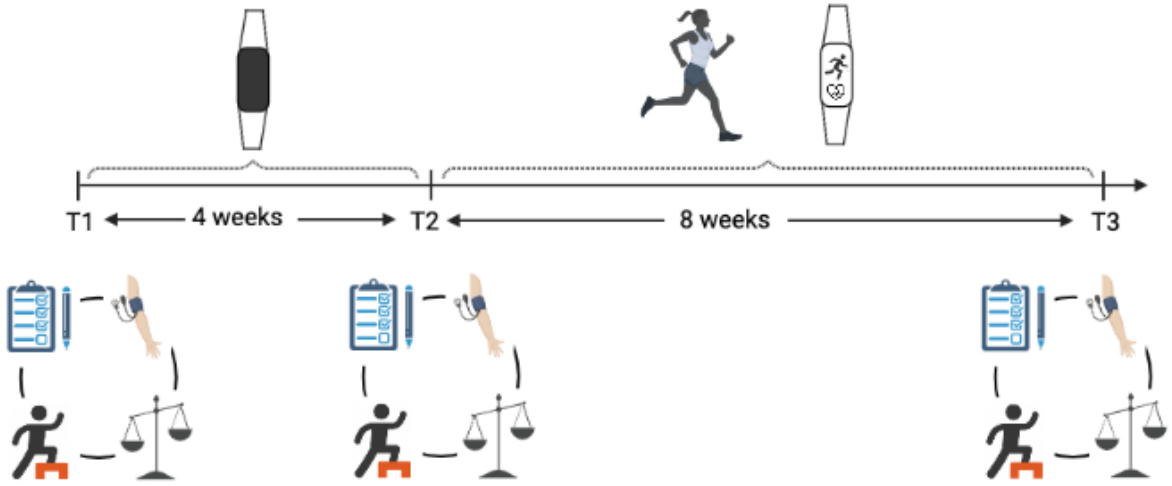
Ethics Approval

The study was approved by the ethics Committee of Region Zealand (protocol SJ-780) and was performed in accordance with the Declaration of Helsinki.

Experimental Protocol

Participants attended three test days: a baseline test day (T1) followed by 4 weeks of observation, a second test day (T2) followed by 8 weeks of intervention, and a third test day (T3) at the end of the intervention (Figure 1).

Figure 1. Experimental protocol (Created with BioRender.com).



A WTD (Garmin Vivosmart 4, CE marking) was handed out to all participants at T1. This WTD detects movement and heart rate via an embedded triaxial accelerometer, optical photoplethysmography signals, and associated algorithms. It automatically records intensity and the duration of different activity patterns, and estimates active kilocalories. It also attempts to obtain an objective estimate of stress on the basis of the root mean square of successive R-R intervals [20] and of sleep staging through a combination of accelerometer and photoplethysmography [21]. Participants were instructed to download a mobile app called “Garmin Connect” and set up a user account. Participants were required to wear the device on their wrist for the entire period of approximately 12 weeks. Between T1 and T2, participants were instructed to continue their usual lifestyle. During these first 4 weeks participants were asked to refrain from looking at their data. The screen on the WTD was customized to display only the clock. After 4 weeks of observation, participants had an extended introduction to the WTD and the accompanied Garmin Connect mobile app in which they were able to follow their health behaviors. Between T2 and T3, participants were instructed to increase their PA level to a least 150 intensity minutes per week and to use the

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WTD to register and follow their PA behavior. The WTD was installed in collaboration with participants and the number and type of received notifications were individualized in accordance with the participants' own wish. All participants were instructed to upload their data via Garmin Connect at least once a week.

Outcome Measures

Personal characteristics of participants were collected from a survey during T1 and included age, gender, years of education, family status, and smoking. The survey also included three validated questionnaires:

1. The NEO Five Factor Inventory questionnaire (NEO-FFI-3): this questionnaire consists of 60 items and provides a measure of the 5 domains of personality (neuroticism, extraversion, openness, agreeableness, and conscientiousness). The internal consistency for the NEO-FFI-3 ranges from 0.79 to 0.86 [22].
2. The Nordic Physical Activity Questionnaire-short is a 2-item questionnaire and provides a measure of MVPA in minutes per week (Spearman ρ=0.33 between self-reported and objectively measured PA levels) [23].
3. The Perceived Stress Scale [24] assess subjective stress levels and comprises 10 items. Scores range from 0 to 40, with higher composite scores indicating greater levels of perceived stress.

The latter 2 questionnaires were also completed at T2 and T3 to explore changes in self-reported measures. At T3, the participants were also asked to evaluate the motivational impact of using a WTD (self-reported adoption) on a 5 ordered level ranging from 4=highly motivated to 0=not helpful. A short web-based survey was sent out 6 months post study participation with questions of current PA behavior.

Height was measured with a stadiometer (Leicester portable height measure Tanita HR 001). Body composition, including body weight (in kg), fat percentage, and skeletal muscle (in kg) were assessed through bioelectrical impedance analysis using the monitor Tanita DC 430 SMA [25]. Blood pressure was monitored in a sitting position with an automated oscillatory device (Omron M3) after the participant had rested for 5 min. The lowest mean arterial pressure of 3 readings was used. Finally, the new step test was conducted and used to estimate participants CRF [26]. The step test is a progressive test based on the principle that the energy cost of stepping with a known step height and pace is relatively independent of age, gender, and training status. The test starts with a slow stepping frequency (0.2 steps per second), which increases gradually to a very fast stepping frequency (0.8 steps per second) after 6 minutes. The CRF is estimated on the basis of the stopping time; that is, the time when the pace can no longer be followed.

The following health parameters were exported from the WTD: steps, MVPA, active kilocalories, resting heart rate (HR), stress scores, and total sleep time. Compliance of wearing the WTD is important for the accuracy of the measurements and was calculated on the basis of automatically registered HR measures relative to the study duration. More than 10 minutes of continuous missing HR data were registered as missing data. Thus, the percentage of available HR data was used as a proxy for the percentage of time participants wore the WTD.

Analysis and Statistics

Baseline characteristics are presented as mean (SD) or n (%) values. All data were imported to MATLAB (R2017_b) for analysis. Statistical processing of the data was carried out with R statistical program (RStudio; version 1.2.5033, packages: nlme, clubSandwich). For analyses of the primary outcome (CRF), we used a linear mixed model for repeated measures over time to analyze the difference among the 3 test days. Time was considered a fixed effect, and participants was considered a random effect, and the maximum likelihood method was applied. A similar procedure was used for secondary outcomes such as body composition, blood pressure, and self-reported PA. For nonnormally distributed variables, cluster-robust variance estimators with "CR2" adjustment were applied [27].

Daily measures obtained with the WTD included step count, MVPA active kilocalories, resting HR, stress score, and total sleep time. A calibration period for the WTD was recommended; hence, the first 7 days in the control period were excluded from further analysis. The mean of each measure was calculated for the control and the intervention period, respectively. A 2-tailed Student *t* test was used to test for differences in the normally distributed variables. Objectively measured MVPA was compared with self-reported PA with a Pearson correlation analysis.

The influence of personal characteristics and health outcomes on the adoption of using a WTD was explored by fitting a linear model. The adoption of WTD was based on the participants subjective evaluation of the motivational impact of using a WTD at T3. This response variable was chosen as we believe perceived motivation is the best prediction of future use. The following baseline variables were included inspired by previous studies [16,17,28]: personal characteristics (age, gender, education, and personality) and current individual health status at T1 (BMI, fat percentage, CRF, self-reported PA, perceived stress, daily step count, and active kilocalories). Moreover, changes in health outcomes at T3 (changes in CRF, fat percentage, BMI, self-reported PA, perceived stress, daily step count, and active kilocalories) were also included in the analysis to explore if improvements of health parameters were specifically related to adoption of WTD. One subject was excluded from the analysis owing to 36% of missing values. Other observations with missing values were imputed using k-nearest neighbors. All the predictor variables were standardized, such that they have a mean of 0 and SD of 1. Feature selection was applied using Partial Least Squares [29] to reduce the effect of variables with multicollinearity. The number of significant components was then determined by The Weight Randomized Test [30]. For the significant number of components, The Variable Importance in Projection was calculated to select variables with a score greater than 1 for further analysis [31]. Principal components analysis was performed on health parameters to secure independents. The score from the principal components analysis was used as predictor variables for the linear regression model. To obtain a

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model solely on the basis of significant effects, stepwise regression was performed for the linear model.

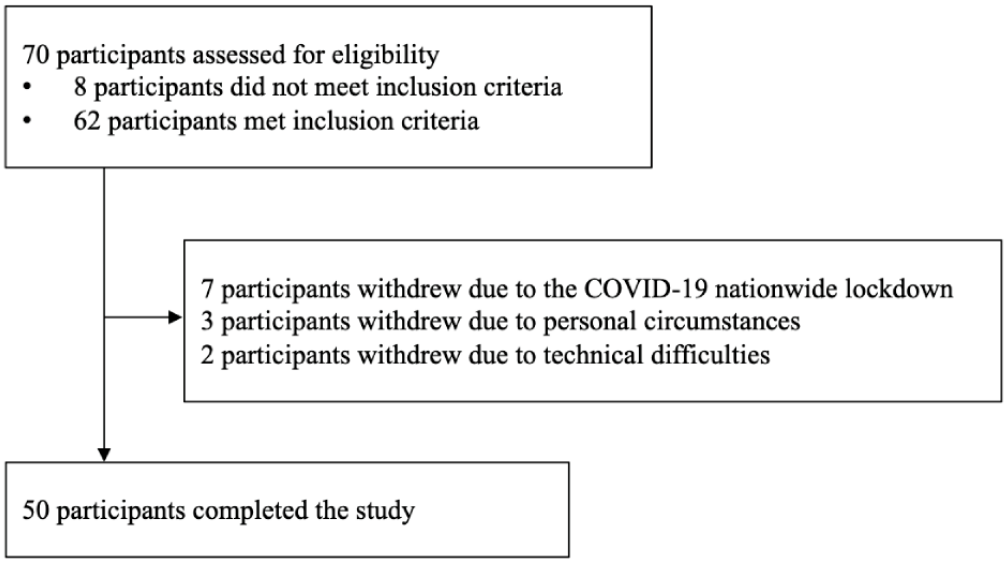
Results

Participants' baseline characteristics are shown in Table 1. Data collection was initiated in October 2019 and ended 1 year later. In total, 16 participants were paused in March 2020 owing to a nationwide COVID-19 lockdown, of whom 7 completely withdrew from the study, 2 completed T3 on the internet, and 7 restarted their intervention period after the lockdown end of April 2020. The incidence of COVID-19 cases increased during fall 2020, which led to gradual restrictions on physical training facilities and size of participation in teams sport and group exercises toward the end of the study period. In addition, during the data collection, 3 participants withdrew owing to personal circumstances (not related to the study or the COVID-19 pandemic), and 2 withdrew owing to technical difficulties. A flow diagram is presented in Figure 2.

Table 1. Participants' baseline characteristics.

Baseline characteristics	All participants (N=62)	Analyzed population (n=50)
Age (years), mean (SD)	50 (14)	48 (13)
Female, n (%)	51 (82)	42 (84)
Male, n (%)	11 (18)	8 (16)
Education (years), mean (SD)	2 (14)	2 (14)
Married or living together, n (%)	37 (60)	32 (64)
Children at home under 16 years of age, n (%)	22 (35)	20 (40)
Current smoker, n (%)	7 (11)	3 (6)
Neuroticism, mean (SD)	44 (10)	44 (10)
Extraversion, mean (SD)	51 (11)	52 (11)
Openness, mean (SD)	54 (9)	53 (9)
Agreeableness, mean (SD)	57 (10)	58 (11)
Conscientiousness, mean (SD)	56 (10)	56 (11)

Figure 2. Flow diagram of participant inclusion.



The duration of the control and intervention period were 30 (SD 5) days and 61 (SD 6) days, respectively. The results of objective and self-reported health parameters are shown in Table 2. One participant did not conduct the step test at T1 owing to guidelines for marked elevated hypertension (BP>180/105 mm Hg) [32]. Because of the COVID-19 lockdown, 4 patients solely completed the web-based survey on one of the test days with no measures of body weight, BP, or CRF. Moreover, one participant did not conduct the step test either at T2 and T3 owing to hip pain aggravated by the step test, and 4 participants did not conduct the final step test at T3 owing to temporary knee pain and dizziness, respectively. Finally, 2 participants had their antihypertensive medication adjusted during the study (not related to study activities) and were therefore excluded from the BP analysis.

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Table 2. Results of the linear mixed model on objective and self-reported health parameters.

Parameter (n)	Estimated mean (SE)	*P* value	95% CI
Cardiorespiratory fitness (mL/kg/minute) (50)			
Intercept T1	26.42 (0.85)		24.75 to 28.09
Difference from T1 to T2	0.89 (0.35)	.01[a]	0.21 to 1.57
Difference from T2 to T3	1.52 (0.36)	<.001[a]	0.82 to 2.22
BMI (kg/m^2) (50)			
Intercept T1	27.88 (0.82)		26.26 to 29.49
Difference from T1 to T2	–0.02 (0.06)	.81	–0.14 to 0.11
Difference from T2 to T3	–0.12 (0.08)	.13	–0.29 to 0.04
Fat percentage (%) (50)			
Intercept T1	32.63 (1.00)		30.67 to 34.59
Difference from T1 to T2	0.05 (0.15)	.72	–0.24 to 0.34
Difference from T2 to T3	–0.48 (0.18)	.009[a]	–0.84 to –0.13
Muscle mass (kg) (50)			
Intercept T1	50.50 (1.39)		47.77 to 53.23
Difference from T1 to T2	0.03 (0.12)	.83	–0.20 to 0.25
Difference from T2 to T3	0.11 (0.16)	.51	–0.21 to 0.42
Systolic blood pressure (mm Hg) (48)			
Intercept T1	124.69 (2.51)		119.75 to 129.62
Difference from T1 to T2	–2.22 (1.37)	.11	–4.92 to 0.47
Difference from T2 to T3	0.71 (1.46)	.63	–2.16 to 3.57
Diastolic blood pressure (mm Hg) (48)			
Intercept T1	81.23 (1.48)		78.31 to 84.15
Difference from T1 to T2	–1.70 (0.85)	.047[a]	–3.36 to –0.04
Difference from T2 to T3	0.93 (0.83)	.27	–0.70 to 2.55
Moderate to vigorous physical activity (minutes per week) (49)			
Intercept T1	94.18 (11.6)		70.9 to 117.4
Difference from T1 to T2	7.24 (14.9)	.63	–22.8 to 37.3
Difference from T2 to T3	140.19 (23.3)	<.001[a]	93.3 to 187.1
Difference from T2 to 6 months	58.62 (23.6)	.02[a]	10.6 to 106.6
Difference from T3 to 6 months	–81.6 (29.2)	.008[a]	–140 to –22.6
Perceived Stress Scale score (50)			
Intercept T1	13.54 (0.87)		11.79 to 15.29
Difference from T1 to T2	–3.14 (0.57)	<.001[a]	–4.29 to –1.99
Difference from T2 to T3	0.46 (0.66)	.49	–0.86 to 1.78

[a]Values are significant at $P<.05$.

A significant increase in CRF of 0.89 mL/kg/minute ($P=.01$) was observed already at T2. CRF increased further during the intervention period with 1.52 mL/kg/minute ($P<.001$; see Table 2). No change was observed in BMI and muscle mass, while the fat percentage decreased from T2 to T3 by 0.48% ($P=.009$). No change was observed in systolic BP, while diastolic BP decreased with 1.7 mm Hg ($P=.047$) during the control period with no further change during the intervention period. Perceived stress decreased from T1 to T2, with a reduction of 3.14 in the Perceived Stress Scale score ($P<.001$), while no change was observed between T2 and T3. The result from the self-reported PA questionnaire was omitted for one participant owing to an

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incorrect completion of the questionnaire (the participant reported a higher number of vigorous active minutes per week than total MVPA minutes per week). Self-reported PA behavior from the remaining 49 participants was unchanged between T1 and T2 and increased during the intervention period with 140 minutes per week (P<.001). In total, 26 (50%) participants replied to the 6-month follow-up survey from which it appeared that self-reported exercise behavior was significantly higher than that before the intervention (59 minutes, P=.02), but also significantly lower than that at the end of the intervention (82 minutes, P=.008). Of note, a distinct variation in PA behavior among participants was observed after 6 months in the associated 95% CIs (see Table 2).

Throughout the intervention period, the participants wore the WTD device 94% (SD 5%) of the time. The daily step count increased by 982 steps per day (P<.001) from the control to the intervention period, objectively measured MVPA by 107 minutes per week (P<.001), and active kilocalories by 180 kilocalories per day (P<.001). Resting HR decreased from 58 to 57 beats per minute from the control to the intervention period (P=.002), while no change was observed in daily stress scores or total sleep time (Table 3). Objectively measured MVPA significantly correlated with self-reported PA in the intervention period, where participants were encouraged to register PA on the WTD (r=0.38, P=.008). A similar correlation was not observed in the control period, where participants were instructed to refrain from actively using the WTD (r=–0.03, P=.86).

Table 3. Average measures obtained with wearable tracking device use (stress scores ranged from 0=low to 100=high and are based on the root mean square of successive R-R intervals).

Wearable tracking device measures	Control period, mean (SD)	Intervention period, mean (SD)	*P* value	Mean difference (95% CI)
Steps per day	8196 (2446)	9178 (2735)	<.001[a]	982 (492 to 1471)
Moderate to vigorous physical activity per week	86 (187)	193 (190)	<.001[a]	107 (74 to 140)
Active kilocalories per day	332 (222)	512 (257)	<.001[a]	180 (129 to 231)
Resting heart rate (beats per minute)	58 (8)	57 (7)	.002[a]	–1 (–1.3 to –0.3)
Stress score per day	31 (9)	31 (6)	.77	0 (–2.2 to 1.6)
Total sleep time per night (hours:minutes)	07:42 (46)	07:49 (42)	.10	00:07 (–1.3 to 14.0)

[a]Values are significant at P<.05.

Participants rated the motivational impact of using a WTD on a 5 ordered level ranging from 4=highly motivated to 0=not helpful. In total, 16 participants rated the impact with “4,” 16 participants rated “3,” 9 participants rated “2,” 7 participants rated “1,” and 2 participants did not find the WTD helpful (score=0). The motivational impact of using a WTD (the response variable) and predictor variables (personal characteristics, current individual health status, and health outcomes) revealed (via partial least squares regression) a significant first component after applying the Weight Randomized Test. In this first component, the following variables displayed a Variable Importance in Projection scores of >1: age, baseline perceived stress, BMI, and active kilocalories as well as changes in fat percentage, active kilocalories, step count, and BMI. Principal components analysis was performed for the latter 6 variables. Age, baseline perceived stress, and scores for each principal component were used as predictors in the linear model. After stepwise regression, the final model contained an intercept and the estimated effects of baseline perceived stress and the first principal component (see Table 4). The loadings of the first principal component are shown in Table 5.

Table 4. The estimated effects of the linear model.

Parameters	Estimate (SE)	*P* value
Intercept	2.7143 (0.13865)	6.069×10^{-24}
Perceived stress at T1	–0.36159 (0.14028)	.01
First principal component	0.38181 (0.088732)	8.716×10^{-05}

Table 5. The loadings of the first principal component.

Variable	Changes in variables					
	Fat percentage	Step count	BMI	Active kilocalories	T1 active kilocalories	T1 BMI
Loading	–0.542	0.485	–0.485	0.429	–0.229	–0.024

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Discussion

Principal Findings

Results from this study suggest that the use of WTDs can increase CRF and PA and decrease fat percentage after an intervention of 8 weeks. The primary outcome measurement was CRF, which is less studied in relation to the use of WTDs. In this study, we used an updated, simple, and user-friendly version of a WTD. Previous studies have reported mixed results on CRF after the use of a WTD. Two studies reported significant improvements of 1.8 mL/kg/minute after 6 months [10] and 2 years [13], while 3 studies found no effect after respectively 3 months and 1 year usage of a WTD [11,12,14]. However, these 5 studies were all conducted for more than 5 years ago with quite different activity trackers than currently available. Thus, our finding of an increase in CRF of 1.52 mL/kg/minute after the use of a modern WTD contributes new knowledge in an area of current sparce and mixed results. Improvements in CRF of 3.5 mL/kg/min have been associated with 8% to 35% reductions in mortality [9]. From this perspective, an average increase of 2.4 mL/kg/minute in CRF after the control and intervention period combined suggest a noteworthy health benefit if the participants maintain the increase of PA behavior in future.

We observed an increase of 982 steps per day in the intervention period compared to the control period. Two recent meta-analyses report a positive effect for step count equivalent to approximately 500-627 more steps per day in intervention groups compared to control groups [5,6]. The step count is one of the more validated and accurate measures registered by modern WTDs [33], and the feature is easy for the user to comprehend and track. This could explain the general positive effect.

The effect of WTD on activity minutes is less clear ranging from no significant difference [5] to a mean increase of 75 minutes per week among recent studies [6]. In this study, we observed a convincing increase of 140 minutes per week in self-reported MVPA and of 107 minutes per week in objectively measured MVPA during the intervention period compared to the control period. Self-reporting is known to overestimate PA [34], which may explain part of the discrepancy observed in previous studies and in this study. Moreover, in the literature, some studies obtain the objective measurement of MVPA via validated accelerometers and other studies directly from the commercial WTD, which was carried out in this study. On a WTD, the timely resolution and accuracy of MVPA often depends on user activation of PA. This may explain the lack of correlation between self-reported and objectively measured MVPA in the control period in this study. Thus, part of the discrepancy between current studies, investigating the use of a WTD on MVPA, may relate to application of different methods to assess MVPA.

In this study, a decrease in fat percentage of 0.48% was observed, similar to that reported in a recent randomized controlled trial including 135 adults [35]. In this study, 32 out of 50 (64%) participants were overweight, as assessed from their fat percentage [36]. In line with a previous study investigating 9 months of WTD use, the decrease in fat percentage was more pronounced among overweight participants compared to average or lean participants (0.59% vs 0,16%) [37]. Most previous studies have investigated weight loss and not changes in body composition. There is currently no evidence for the use of WTDs in weight loss among healthy inactive or overweight adults [7,38], and this study confirms this finding.

The effect of the use of a WTD on blood pressure is mixed. A study by Thorndike et al [39] found that systolic BP decreased 3 mm Hg, while diastolic BP did not change after 12 weeks among young medical residents. Another study involving older patients diagnosed with type 2 diabetes showed a significant decrease of 6.7 mm Hg (P<.01) in systolic BP and 2.9 mm Hg in diastolic BP (P<.05) [40]. In contrast and in line with our results, Finkelstein et al [41] found no improvement in BP among adult employees after the use of a WTD.

The positive effect of PA on stress levels is well documented [42]. However, we solely observed a decrease in perceived stress levels after the control period. The increase in CRF after the control period may have affected stress levels positively. Moreover, the low stress scores (10.4, SD 5.6) observed at T2 seem to represent a ceiling effect, which reduce the potential for improvement.

The effect of the use of a WTD on different health parameters is mixed and is challenged by the fact that many studies are carried out using older versions of WTDs. The technology is developing at a fast pace, and further research is needed to determine the efficacy of the latest devices. Furthermore, current literature evaluating the health benefit of using WTDs differs in study designs, duration of interventions, outcome measures, and participant characteristics.

The Motivational Impact of Using a WTD

In this study, no associations were found between adoption of the WTD and age, gender, personality, or education (explored with partial least squares regression analysis). This is in contrast to a study from 2018, which indicated that older people (aged >50 years) were less likely to use a WTD, as they perceived the usability as low [18]. It could be speculated that the use of a very simple WTD and the instruction of achieving a clear goal (minimum 150 MVPA minutes per week) positively influenced the perceived utility among participants above 50 years of age in this study. Rupp et al [18] further found that personality traits such as agreeableness, conscientiousness, and extraversion were associated with high intention to use WTDs. However, Attig and Franke [43] could not find these associations, concurrent with our findings. Thus, more research is needed to reveal how personal characteristics are associated with adoption of activity tracking technology.

Adoption of the use of a WTD has also been linked to dynamic variables such as current individual health status. We observed that participants with low perceived stress at T1 were more likely to rate the use of a WTD highly motivating at T3 (Table 4), suggesting that sufficient resources are important for successful adoption. Rupp et al [18] reported that physically active individuals have higher desire to use a WTD, as they are more likely to find such a device motivating [44]. We also

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observed that participants who were more physically active during the intervention and reduced their fat percentage were more likely to rate the use of a WTD as motivating (Table 5). Similar to this finding, Su et al [28] reported a significantly larger decrease in their primary outcome (change in hemoglobin A_{1c} levels) in active users of an mHealth app compared to that of nonactive users among patients with diabetes.

Limitations

Some limitations need to be acknowledged. First, we used a commercial WTD with software updates and proprietary algorithms, which only allows access to already processed data and not the raw data. This limits the interpretations of the data since the threshold of different activities are unknown. Second, 28 of 50 participants were tracking their PA behavior via the accompanied Garmin Connect app during the control period, although specifically instructed not to. The information may have affected their behavior and may explain the observed increase in CRF from T1 to T2. However, behavioral outcomes may also be affected simply by the awareness of being monitored [45]. Third, we used an indirect but validated step test to estimate CRF. Fourth, the included sample size was not powered to investigate associations between adoption of a WTD and personal characteristics and health outcomes. Thus, these findings should be interpreted with caution. Fifth, the study was conducted during the COVID-19 pandemic and temporal changes in PA patterns cannot be excluded owing to different home or work patterns and periodic restrictions on physical training facilities. Finally, generalization of our results is limited by the unequal distribution of gender, with 42 women out of 50 participants in our study. However, gender effects are not identified as an influential factor for the use of a WTD in a recent review [16].

Conclusions

Tracking health behavior using a modern WTD increases PA, leading to an improved cardiorespiratory fitness among inactive adults. The motivational impact of the use of a WTD varied among participants. No associations were observed between personal characteristics (such as age and personality) and self-reported adoption, but participants with a low perceived stress at baseline were more likely to rate the use of a WTD as highly motivating. Furthermore, participants who were more physically active and who reduced their fat percentages during the intervention were also more likely to perceive the WTD as motivating, which suggests that the device contributed significantly to the observed health benefits.

Acknowledgments

The study was supported by the European Union via Interreg, which is funded by the European Regional Development Fund. We thank medical student Nanna Jung Mouritzen, supported by the Lundbeck Foundation, for assistance in data collection.

Conflicts of Interest

None declared.

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Abbreviations

BP: blood pressure
CRF: cardiorespiratory fitness
HR: heart rate
MVPA: moderate to vigorous physical activity
NEO-FFI-3: NEO Five Factor Inventory questionnaire
PA: physical activity
WTD: wearable tracking device

Edited by T Leung; submitted 24.06.21; peer-reviewed by ML Mauriello, J Golbus, HL Tam; comments to author 06.11.21; revised version received 23.11.21; accepted 09.02.22; published 15.03.22.

Please cite as:
Larsen LH, Lauritzen MH, Sinkjaer M, Kjaer TW
The Effect of Wearable Tracking Devices on Cardiorespiratory Fitness Among Inactive Adults: Crossover Study
JMIR Cardio 2022;6(1):e31501
URL: https://cardio.jmir.org/2022/1/e31501
doi:10.2196/31501
PMID:35289763

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Original Paper

Changes in Blood Lipid Levels After a Digitally Enabled Cardiometabolic Preventive Health Program: Pre-Post Study in an Adult Dutch General Population Cohort

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Abstract

Background: Despite widespread education, many individuals fail to follow basic health behaviors such as consuming a healthy diet and exercising. Positive changes in lifestyle habits are associated with improvements in multiple cardiometabolic health risk factors, including lipid levels. Digital lifestyle interventions have been suggested as a viable complement or potential alternative to conventional health behavior change strategies. However, the benefit of digital preventive interventions for lipid levels in a preventive health context remains unclear.

Objective: This observational study aimed to determine how the levels of lipids, namely total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol, and triglycerides, changed over time in a Dutch general population cohort undergoing a digital preventive health program. Moreover, we looked to establish associations between lifestyle factors at baseline and lipid levels.

Methods: We included 348 adults from the Dutch general population who underwent a digitally enabled preventive health program at Ancora Health between January 2020 and October 2021. Upon enrollment, participants underwent a baseline assessment involving a comprehensive lifestyle questionnaire, a blood biochemistry panel, physical measurements, and cardiopulmonary fitness measurements. Thereafter, users underwent a lifestyle coaching program and could access the digital application to register and track health behaviors, weight, and anthropometric data at any time. Lipid levels were categorized as normal, elevated, high, and clinical dyslipidemia according to accepted international standards. If at least one lipid marker was high or HDL was low, participants received specific coaching and advice for cardiometabolic health. We retrospectively analyzed the mean and percentage changes in lipid markers in users who were remeasured after a cardiometabolic health–focused intervention, and studied the association between baseline user lifestyle characteristics and having normal lipid levels.

Results: In our cohort, 199 (57.2%) participants had dyslipidemia at baseline, of which 104 participants were advised to follow a cardiometabolic health–focused intervention. Eating more amounts of favorable food groups and being more active were associated with normal lipid profiles. Among the participants who underwent remeasurement 9 months after intervention completion, 57% (17/30), 61% (19/31), 56% (15/27), 82% (9/11), and 100% (8/8) showed improvements at remeasurement for total, LDL, HDL, and non-HDL cholesterol, and triglycerides, respectively. Moreover, between 35.3% and 77.8% showed a return to normal levels. In those with high lipid levels at baseline, total cholesterol decreased by 0.5 mmol/L (7.5%), LDL cholesterol decreased by 0.39 mmol/L (10.0%), non-HDL cholesterol decreased by 0.44 mmol/L (8.3%), triglycerides decreased by 0.97 mmol/L (32.0%), and HDL increased by 0.17 mmol/L (15.6%), after the intervention.

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Conclusions: A cardiometabolic screening program in a general population cohort identified a significant portion of individuals with subclinical and clinical lipid levels. Individuals who, after screening, actively engaged in a cardiometabolic health–focused lifestyle program improved their lipid levels.

(JMIR Cardio 2022;6(1):e34946) doi:10.2196/34946

KEYWORDS

cholesterol; lifestyle intervention; prevention; hypercholesterolemia; digital health

Introduction

The morbidity and mortality burden associated with cardiovascular disease (CVD) continues to increase globally [1]. With prevalent cases of CVD having nearly doubled since 1990 to almost 523 million cases worldwide, it is now the leading cause of global mortality and a major contributor to disability [1]. The etiology of CVD is multifold, including genetic predisposition, socioeconomic and environmental factors, and lifestyle [2]. In fact, approximately 50% of CVD risk is attributable to modifiable lifestyle factors, such as an unhealthy diet, lack of physical activity, and smoking, which subsequently lead to metabolic imbalances and overweight or obesity [1-3].

Dyslipidemia, defined as elevated levels of total cholesterol, low-density lipoprotein (LDL) cholesterol, or triglycerides, or low levels of high-density lipoprotein (HDL) cholesterol, is a major risk factor for CVD [4]. As with other CVD risk factors, genetic risk plays a role in the development of dyslipidemia, such as in familial hypercholesterolemia; however, the majority of cases are due to unhealthy lifestyle behaviors [5,6]. As such, lifestyle interventions are central to dyslipidemia prevention and are recommended for all patients before pharmacotherapy is prescribed, and even after pharmacotherapy initiation [5]. Lifestyle changes that have been shown to be beneficial for dyslipidemia are simple and well-known to the general public, such as following a diet emphasizing the intake of vegetables, fruits, legumes, and whole grains, and minimizing the intake of processed meats, refined carbohydrates, and sweetened beverages, as well as doing sufficient daily low-intensity activity [7-9]. Although most national and international guidelines consider both healthy lifestyle behaviors and preventive medication as cornerstones of CVD primary and secondary prevention, there is a lack of effective strategies promoting risk reduction through these lifestyle factors [9,10]. This is because primary care providers often struggle to implement advice and referral structures for lifestyle promotion and individuals fail to successfully change and maintain favorable health behaviors that modify these risk factors [11-13]. The reasons for the latter vary greatly from limiting social constructs, such as work hours, family duties, and socioeconomic factors, to personal factors, such as low self-efficacy, motivation, and lack of perceived benefit [14,15].

A growing number of digital application–based programs that can support individuals in addressing these challenges are being developed and are both publicly and commercially available [16,17]. Previous studies have demonstrated the benefits of digital applications for improving medication adherence and reducing cardiovascular risk in patients at higher cardiovascular risk and in patients living with CVD [18-20]. Therefore, these applications can broaden access to prevention strategies and care outside of traditional care [20]. Yet, there is scarce robust data on the effectiveness of such applications for modulating lifestyle-related risk factors, such as lipid profiles, and few, if any, studies have demonstrated the effects of a digitally enabled lifestyle intervention in a presumably healthy general population cohort [21,22].

The Ancora Health platform is a digital application that supports a preventive health screening and lifestyle coaching intervention. Individuals undergo a health assessment, and receive a Personal Health Passport (PHP) with their data and the outline of the intervention. Then, they go through a 16-week coaching program, initiated with a 30-minute video consultation by a medical doctor. This initiation session consists of counselling on health insights (risks in aspects of physical and mental health); recommendation of targeted lifestyle medicine actions (which can also be tracked by individuals in their PHP); and getting a buy-in to undertake these actions for the following period. Coaching is primarily digital, one-on-one, chat-based digital coaching (optional audio/video call alongside this) from either a lifestyle coach, personal trainer, dietitian, or psychologist. This is complemented by weekly progress reports with feedback. Through this approach, participants are provided peer-support and motivation, are coached on how to acquire and maintain healthy habits, learn how to overcome barriers encountered during behavior change, and receive tips/tricks on how to implement new behaviors into daily practice.

In this study, we assessed the prevalence of dyslipidemia in a Dutch general population cohort undergoing health screening, and measured the effect of the subsequent digitally enabled lifestyle program on participants' lipid profiles in the first cohort of individuals undergoing this program.

Methods

Study Sample

As of October 2021, more than 500 users had enrolled in an Ancora Health Lifestyle program, with many getting their lipid markers (total cholesterol, HDL cholesterol, LDL cholesterol, non-HDL cholesterol, total/HDL cholesterol ratio, and triglycerides) measured through venipuncture. Of those, 100 users also came for a remeasurement after concluding the program. We excluded participants whose first or second measurement was done using a point-of-care device. Our final sample size was 348 participants who had their blood lipid levels determined via venipuncture at both timepoints. An overview of the study flow is given in Figure 1.

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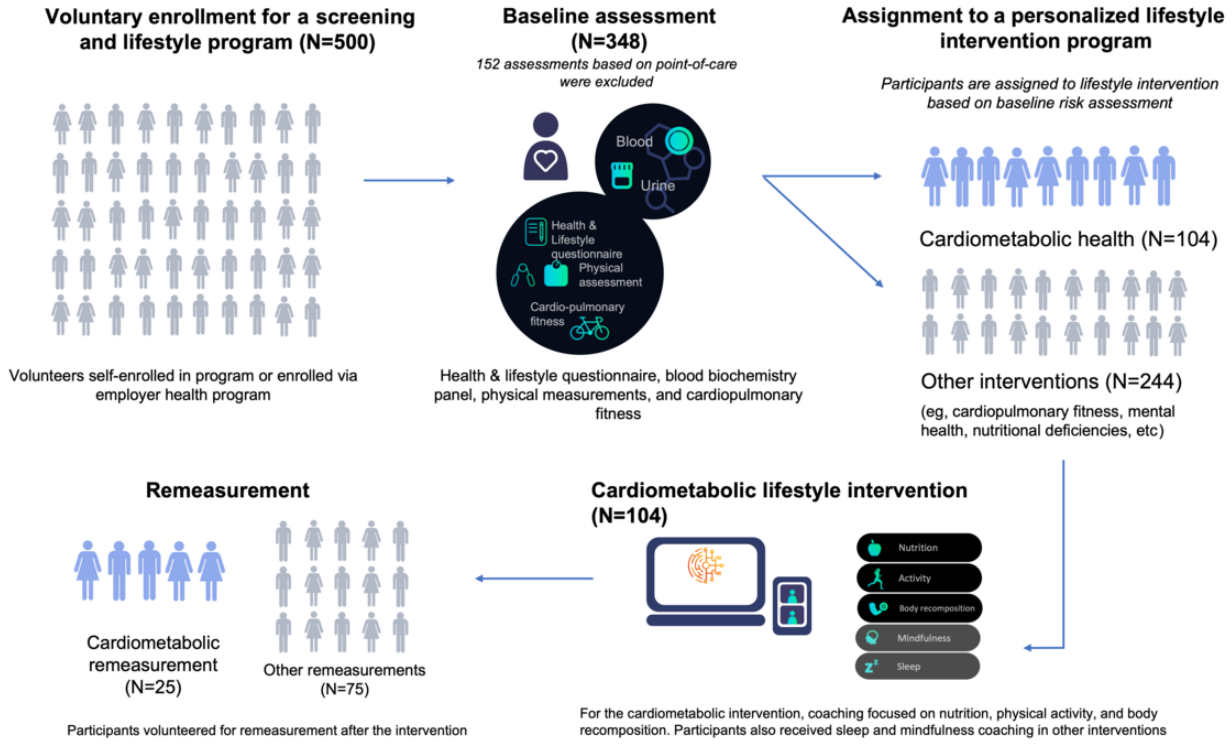
Figure 1. Overview of the study flow, including sample size at each stage. Changes in lipid values presented in the results are derived from the cardiometabolic remeasurement group (N=25).



The Platform

The Ancora Health PHP is a certified Class I medical device that presents individuals their current health status and possible future health risks based on a broad assessment of body, mind, and lifestyle. Participants undergo a physical intake, where blood biomarkers, including cardiometabolic markers, physical measurements, and cardiopulmonary fitness measurements are assessed. Additionally, individuals provide diet- and activity-related information through a Health and Lifestyle Questionnaire, as well as previous medical and family history. The PHP uses these inputs to stratify individual risk, placing individuals on a gradient between health (no elevated risk based on the absence of measurable risk factors) and disease (beyond clinical threshold based on clinical guidelines). Based on this stratification, participants are provided lifestyle coaching on nutrition, physical activity, and other health behaviors. The goal of the program is to create lasting behavior change through motivation, education, and personalized recommendations, to modulate the identified modifiable risk factors.

The Ancora Health application is available in The Netherlands directly to the consumer, and through selected health plans and employers.

Measurements at Intake, During the Program, and After the Program

Upon enrollment to the program, participants underwent a baseline assessment involving a comprehensive lifestyle questionnaire, a blood biochemistry panel, physical measurements, and cardiopulmonary fitness measurements. After the baseline assessment, users could access the digital web application to register and track their health behaviors, and modify weight and anthropometrics data at any time during the intervention. At follow-up after the intervention, the subset of blood biochemistry parameters found to be abnormal at baseline, and the lifestyle questionnaire and physical measurements, with or without cardiopulmonary fitness assessment, were remeasured.

We defined the following prespecified cutoffs for all lipid markers: normal, elevated, high, and clinical threshold for dyslipidemia, which, if crossed, would result in advice to discuss the findings with a care practitioner. For total cholesterol, the thresholds for “normal,” “elevated,” “high,” and “clinical dyslipidemia” were <5.1 mmol/L, 5.1-6.2 mmol/L, 6.2-8.0 mmol/L, and ≥8 mmol/L (the clinical threshold leading to referral), respectively; for LDL cholesterol, the same thresholds were <3.0 mmol/L, 3.0-4.1 mmol/L, 4.1-4.9 mmol/L, and ≥4.9 mmol/L, respectively; and for triglycerides, the same thresholds were <1.8 mmol/L, 1.8-2.3 mmol/L, 2.3-5.6 mmol/L, and ≥5.6 mmol/L, respectively [23,24]. For HDL cholesterol, levels <1 mmol/L were considered low, those between 1 and 1.2 mmol/L were considered suboptimal, those between 1.2 and 2.3 mmol/L were considered normal, and those above 2.3 mmol/L were considered elevated [25]. The same thresholds were applied to the remeasured values at follow-up. Not all individuals with dyslipidemia followed a cardiometabolic health–focused intervention. Only individuals in whom at least one marker was high or HDL cholesterol was low received specific coaching and advice. For instance, individuals with low HDL cholesterol received advice to consume more healthy fats (ie, fatty fish, nuts and seeds, and avocado, depending on their dietary restrictions), while individuals who needed to reduce total or LDL cholesterol were advised to consume more fiber-rich foods and limit saturated and transsaturated fats, and were coached

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specifically on how to implement and maintain these nutritional habits. Others with normal or only elevated lipid levels underwent an intervention with coaching on a variety of other aspects, from mental health to endurance training. In these cases, no specific cardiometabolic advice was given unless proactively requested by the participant.

Changes in lipid markers from baseline were calculated by subtracting the first reported values from the end values, and the percentage change was calculated by dividing the observed change by the baseline value. We also examined values of the cholesterol ratio (total/HDL cholesterol), with a threshold of ≥5 considered elevated [26]. BMI was calculated at baseline and remeasurement as weight in kilograms divided by height in meters squared (kg/m^2).

Dietary Assessment

Food group consumption was assessed by means of web-based weekly dietary questionnaires, filled in upon enrollment in the program and at remeasurement. Thresholds for unusually low or high portion sizes were defined a priori per food group based on the Dutch Nutritional Guidelines, with the number of portions per week being entered as multiple choice, to minimize incorrect entries. Changes in food group consumption were calculated as the difference between baseline and remeasured self-reported consumption. Participants were assigned a classification between insufficient and excessive consumption for food groups seen as favorable or neutral for improving lipid profiles (pulses and beans, fatty fish, dark chocolate, coffee or tea, low fat dairy, whole grain foods, fruit, leafy greens, herbs, nuts and seeds, poultry, unsaturated fats and oils, meat substitutes, shellfish, soy products, and lean fish) and food groups unfavorable to lipid profiles (eggs, full-fat dairy, red meat, processed meat, sweetened beverages, refined grains, saturated fats and oils, sweets, and fast food) based on national guidelines and the literature [27,28].

Statistical Analysis

Descriptive statistics were calculated to characterize the population at baseline, in terms of demographics and lipid markers. Additional analyses were conducted in the group of patients who had elevated or high lipid levels at baseline and subsequently underwent remeasurement. In this group, we calculated the mean start value, mean end value, and mean absolute and percentage changes of total cholesterol, total/HDL cholesterol ratio, HDL cholesterol, LDL cholesterol, and triglycerides. All categorical variables were reported as percentage (%) and continuous variables were reported as mean and SD. For differences in categorical variables, the chi-square test was used, and the analysis of variance test was used for continuous variables. We considered a P value <.05 as statistically significant for differences in biomarkers. All data analyses were performed using R software v4.0.3 (The R Project for Statistical Computing). We also computed the percentage of participants by category of change in lipid parameters from baseline to after the intervention period, from clinical threshold values to normal values. The Pearson linear correlation factor, R, was used to assess the linear associations of baseline food group consumption, physical activity (self-reported low/moderate and high-intensity physical activity, as well as strength training), and type of occupational activity (sedentary or active in different extents) with cholesterol levels. P values for the associations of dietary factors and other lifestyle factors with lipid levels were adjusted for multiple comparisons.

Ethics Statement

The study was declared exempt from institutional review board approval through a waiver issued by the Medical Ethical Committee of the University Medical Centre Groningen (waiver number: METC#2021/488). All analyses were performed in accordance with relevant guidelines and regulations.

Results

Baseline Characteristics

Baseline characteristics of the total study sample are shown in Table 1. We found that 199 participants (57.2%) had dyslipidemia at baseline, of which 39 (19.6%) crossed the clinical threshold. Additionally, 104 of the 199 had at least one high lipid marker or low HDL, and were therefore advised to follow a cardiometabolic health–focused intervention. Nine to 10 months after completion of the intervention, 100 participants underwent a remeasurement, of which 25 had partaken in the cardiometabolic health–focused intervention. Participants from this cardiometabolic subgroup were older, had higher lipid levels, and had higher weight and BMI compared to participants following interventions with other focuses, such as mental health and endurance training (Table 1).

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Table 1. Baseline characteristics of the total study sample.

Characteristic	Baseline (N=348)	Cardiometabolic intervention group[a] (N=104)	*P* value[b]
Demographics			
Age (years), mean (SD)	44.6 (11.1)	49.4 (9.0)	.02
Sex (female), n (%)	195 (56.0%)	38 (36.5%)	.09
Anthropometrics			
Weight (kg), mean (SD)	77.2 (14.4)	83.5 (12.2)	.02
BMI (kg/m^2), mean (SD)	25.0 (4.7)	26.6 (2.9)	.01
Body fat percentage, mean (SD)	24.9 (9.8)	26.7 (7.7)	.26
Lipids			
Total cholesterol level (mmol/L), mean (SD)	5.10 (1.06)	6.00 (1.01)	<.001
LDL[c] cholesterol level (mmol/L), mean (SD)	3.13 (0.94)	4.19 (0.84)	<.001
Triglyceride level (mmol/L), mean (SD)	1.12 (0.69)	1.88 (1.30)	.007
HDL[d] cholesterol level (mmol/L), mean (SD)	1.60 (0.42)	1.33 (0.40)	.003
Total/HDL cholesterol ratio, mean (SD)	3.37 (1.12)	4.65 (1.09)	<.001
Non-HDL cholesterol level (mmol/L), mean (SD)	3.49 (1.07)	4.64 (0.89)	<.001

[a]Participants with high lipid values at baseline who underwent a cardiometabolic health–focused intervention.

[b]Unpaired *t* test between the entire cohort and the cardiometabolic remeasurement group.

[c]LDL: low-density lipoprotein.

[d]HDL: high-density lipoprotein.

Baseline Lipid Levels and Association With Lifestyle Factors

Of 348 individuals at baseline, 199 (57.2%) had dyslipidemia. In particular, 162 users (46.6%) had elevated or high total cholesterol, 172 (49.4%) had elevated or high LDL cholesterol, 36 (10.3%) had elevated or high triglycerides, and 54 (15.5%) had low or suboptimal HDL cholesterol. More than half of these individuals (104/199, 52.3%) had at least one relevantly abnormal lipid marker, with 53 (15.2%) having high total or LDL cholesterol and 54 (15.5%) having low to suboptimal HDL cholesterol; high triglycerides were found in 22 (6.3%) participants. In addition to these, 39 (11.2%) participants were found to have at least one lipid marker beyond the clinical threshold: 2 (0.6%) with total cholesterol above 8 mmol/L, 18 (5.2%) with LDL cholesterol above 4.9 mmol/L, 18 (8.9%) with a total/HDL cholesterol ratio ≥5, and 1 (0.3%) with triglycerides above 5.6 mmol/L.

The regression analysis between food group consumption and baseline lipid levels revealed a significant positive correlation between the consumption of several favorable food groups and having normal lipid levels (Figure 2). Consuming more portions of nuts and seeds was associated with a better lipid profile across all markers, with significant associations for all markers other than total cholesterol (R=−0.19 to −0.21; *P*<.001). Consuming more fresh fruits was associated with better lipid values across the board, and was significantly associated with an improved total/HDL cholesterol ratio (R=−0.15; *P*=.03). Higher vegetable consumption was also highly associated with normal lipid levels across all markers except triglycerides (R=−0.20 to −0.23; *P*<.001). On the other hand, consumption of unfavorable food groups was associated with higher lipid levels. Higher red meat consumption was associated with higher lipids across the board, especially the total/HDL cholesterol ratio (R=0.17; *P*<.001). Consuming more take-out/fast food was also associated with higher triglycerides (R=0.11; *P*=.03) and lower HDL cholesterol (R=−0.19; *P*<.001). Interestingly, consumption of sweetened beverages was markedly associated with lower HDL cholesterol and a higher total/HDL cholesterol ratio (R=−0.25 and 0.19, respectively; *P*<.001).

For physical activity, an association was found between more days of brisk walking and HDL cholesterol (R=0.25; *P*<.001) and the total/HDL cholesterol ratio (R=−0.18; *P*<.001) (Figure 3). Additionally, there was an association between doing or not doing strength training and lower total cholesterol, non-HDL cholesterol, and triglyceride levels (R=−0.19 to −0.15; *P*=.005). The number of days doing strength training per week showed no further association. Lastly, doing frequent physical activity outside working hours was also associated with normal lipid values (R=−0.17 to −0.12; *P*=.003).

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Figure 2. Associations between baseline food group consumption and lipid levels at baseline. HDL: high-density lipoprotein; LDL: low-density lipoprotein.

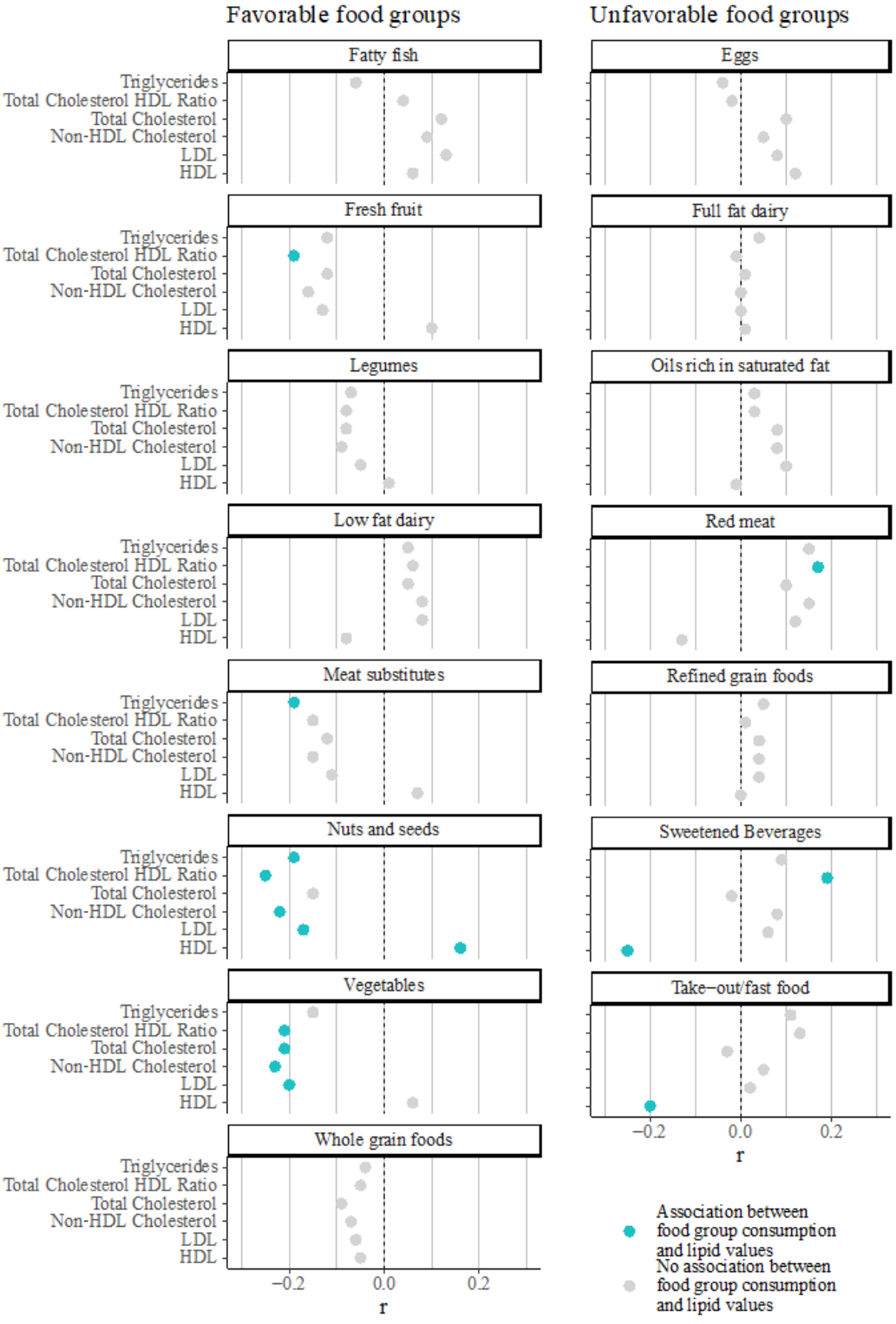

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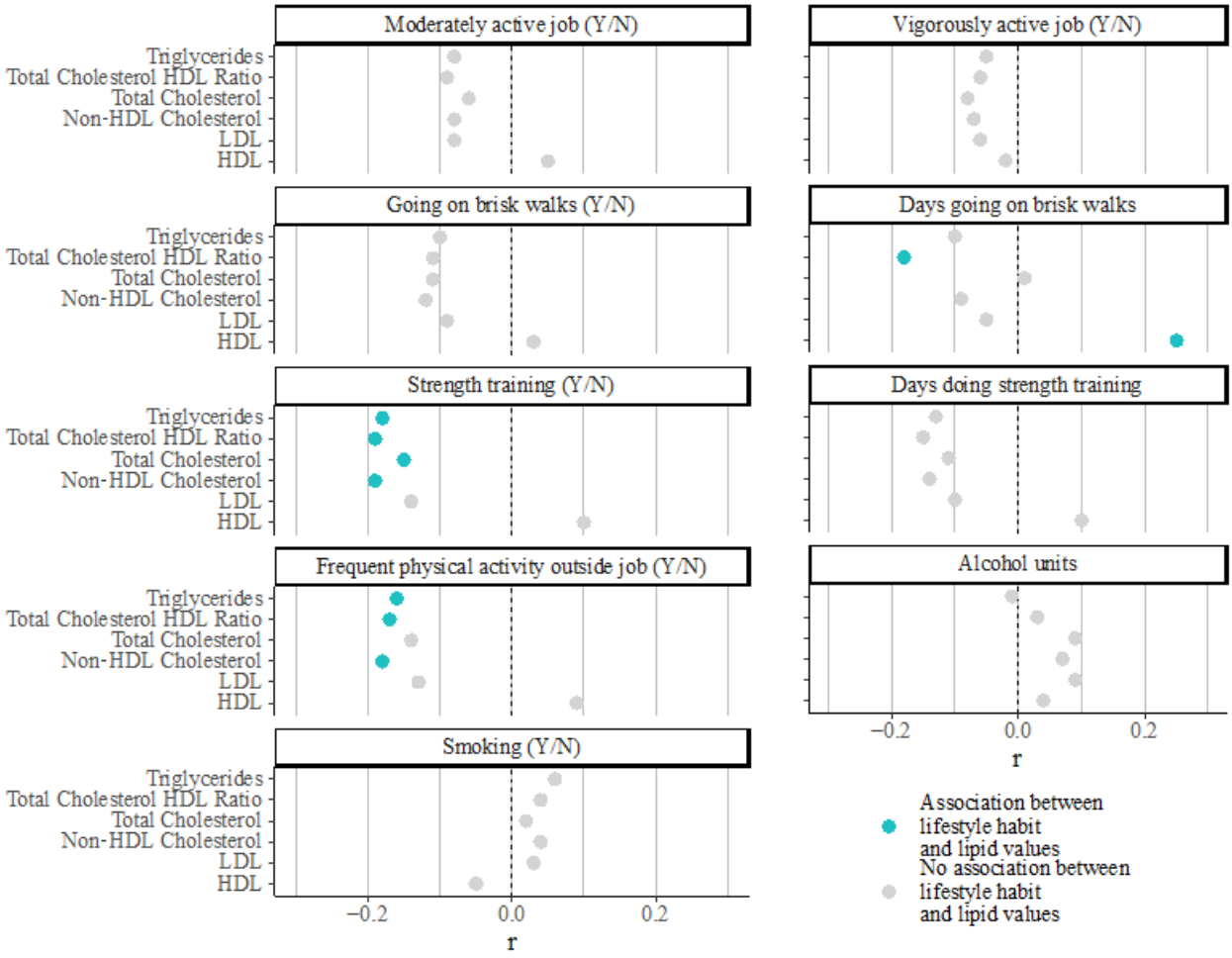
Figure 3. Associations of baseline physical activity levels and other lifestyle factors with lipid levels at baseline. HDL: high-density lipoprotein; LDL: low-density lipoprotein.



Changes in the Lipid Profile

There were 30 participants with elevated or high total cholesterol levels at baseline who underwent remeasurement. Of these, 17 (57%) showed a decrease at remeasurement, with 65% (11/17) showing at least a meaningful decrease and 35% (6/17) returning to within the normal range. On average, the total cholesterol reduction for those who underwent the intervention focused on cardiometabolic health was 0.50 (SD 0.71) mmol/L (P=.01; Table 2). There were 31 participants with elevated or high LDL cholesterol levels at baseline who underwent remeasurement. Of these, 19 (61%) showed a decrease at remeasurement, with 68% (13/19) showing at least a meaningful decrease and 37% (7/19) returning to within the normal range. In the cardiometabolic intervention group, this translated to a mean decrease of 0.30 (SD 0.59) mmol/L in LDL cholesterol after follow-up (P=.04; Table 2). Accordingly, significant differences were also found for non-HDL cholesterol, where of the 27 participants with elevated or high non-HDL cholesterol levels at baseline who underwent remeasurement, 15 (56%) showed a decrease at remeasurement, with 67% (10/15) showing at least a meaningful decrease and 47% (7/15) returning to within the normal range. On average, the non-HDL cholesterol reduction was 0.44 (SD 0.74) mmol/L (P<.05; Table 2). Eleven remeasured participants had abnormal HDL cholesterol levels at baseline. Of these, 9 (82%) showed an improvement at remeasurement, with 89% (8/9) showing at least a meaningful improvement and 78% (7/9) returning to within the normal range (P<.001; Table 2). Lastly, 8 participants with elevated or high triglyceride levels at baseline underwent remeasurement. All 8 participants showed a decrease in triglycerides, with 88% (7/8) showing at least a meaningful decrease and 50% (4/8) returning to within the normal range. In the intervention group, the average reduction was 0.97 (SD 0.31) mmol/L (P=.02).

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Table 2. Changes in the lipid profile after the cardiometabolic intervention.

Variable	Value before the intervention	Value after the intervention	Absolute and relative (%) change	*P* value[a]
Total cholesterol level (mmol/L)	6.68	6.18	−0.50 (7.5%)	.01
LDL[b] cholesterol level (mmol/L)	4.39	4.00	−0.30 (6.9%)	.04
Triglyceride level (mmol/L)	3.02	2.05	−0.97 (32.1%)	.02
HDL[c] cholesterol level (mmol/L)	1.09	1.26	0.17 (15.6%)	<.001
Total/HDL cholesterol ratio	3.7	3.6	−0.1 (2.7%)	.31
Non-HDL cholesterol level (mmol/L)	5.31	4.87	−0.44 (8.3%)	.045

[a]Paired *t* test.

[b]LDL: low-density lipoprotein.

[c]HDL: high-density lipoprotein.

Discussion

Principal Findings

In this study, of 348 users participating in a digitally enabled combined lifestyle intervention program, we found that 57.2% had dyslipidemia, 29.9% had at least one relevantly abnormal lipid marker, and 8.9% had a lipid marker crossing a clinical threshold requiring referral. Eating more amounts of favorable food groups and being more active were associated with normal lipid profiles. Of those who had their levels remeasured after the intervention, more than 56% showed a decrease at remeasurement, and between 35.3% and 77.8% showed a return of the levels to within the normal range. These preliminary findings suggest that participating in a digitally enabled lifestyle intervention targeting behavioral change across multiple lifestyle factors associated with abnormal lipid levels leads to improvements in lipid markers. This may therefore be a scalable approach to cardiometabolic risk reduction at the population level.

Comparison With Prior Work

The positive effect of lifestyle programs on cholesterol levels is well established, with reductions in total and LDL cholesterol varying from 7% to 20% and increases in HDL cholesterol varying from 10% to 15%, using interventions of different intensities and complexities [29,30]. Evidence for digital interventions targeting the reduction of cardiometabolic risk and CVD has been accumulating over the last 5 to 10 years, yet it is still sparse. A recent review showed that primarily mobile digital interventions targeting populations with high cardiovascular risk led to meaningful decreases in total and LDL cholesterol [20]. In line with this, a 2015 review and meta-analysis had already shown the great potential of these interventions to positively impact risk factors for CVD and subsequently also reduce CVD outcomes [31]. Across a variety of studies, reductions in CVD outcomes of up to 40% were documented, mediated by decreases in individual risk factors such as weight, BMI, and lipids. In particular, total cholesterol and LDL cholesterol improved on average by 0.13 to 0.14 mmol/L, while triglycerides showed no improvement. This provides a good comparison metric to the intervention deployed in our study, since in this review, most interventions were web-based. The reductions in LDL and total cholesterol achieved in our study were thus more substantial than those reported in the review, likely due to the blended nature of the intervention (eHealth combined with human coaching), rather than the primarily educational character of previous interventions. In fact, the effect of this web-based intervention was more comparable to studies focused on nutritional and/or exercise coaching provided via a mobile platform [20].

Since the first step of a targeted preventive health program is to stratify risk and define which modifiable parameters individuals should focus on, in this study, we also analyzed which lifestyle factors assessed at baseline were associated with abnormal lipid levels. We found that higher consumption of food groups generally seen as favorable for cardiovascular risk and, in particular, lipid level reduction was indeed associated with lower baseline lipid levels and a higher HDL cholesterol level. Evidence for the role of plant-based or low-meat diets in reducing cholesterol levels is increasing, with diets, such as the Portfolio Diet from the early 2000s, being shown to lower LDL cholesterol and CVD risk [32]. This is potentially mediated through an increase in dietary fiber consumption associated with plant-rich or low-meat diets, and is in line with our findings that higher consumption of legumes and vegetables was linked to lower levels of most lipid parameters. Moreover, some, but not all, food groups with anti-inflammatory properties, such as nuts and seeds or fatty fish rich in monounsaturated and polyunsaturated fats, were associated with higher HDL cholesterol levels [33,34]. The opposite was also true for food groups usually seen as unfavorable, with consumption of, for example, oils rich in saturated fat and red meat being associated with higher baseline levels of most lipid parameters, which is in line with the findings of previous studies that established a link between consumption of these food groups and CVD risk and mortality [35,36]. For triglycerides, associations were less present, though higher consumption of food groups, such as legumes and meat substitutes, was associated with lower levels. Interestingly, we did not find higher consumption of certain food groups, such as eggs, to be associated with CVD, despite previous epidemiological evidence of this [37]. Overall, despite the association between nutritional habits, such as consumption of certain food groups, and lipid levels having long been established, we showed that even in an otherwise healthy general population cohort, nutritional habits are associated with high preclinical lipid levels and therefore constitute a prime target

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for digitally enabled combined lifestyle interventions geared at reducing cardiometabolic risk factors and adding healthy life years to participants' lives.

The identification of critical nutritional habits associated with higher lipid levels and cardiovascular risk is, however, only the first step. We showed that providing tailored nutritional and physical activity advice and coaching through a digital lifestyle platform resulted in measurable improvements in lipid levels. Few previous studies have demonstrated this, with a handful of studies summarized in reviews showing that interventions applying theoretical frameworks or models for behavioral change, some of which were technology based, were more effective at increasing adherence to healthy lifestyle habits than standard advice [38,39]. In particular, this framework led to improved cholesterol levels when used for cardiometabolic risk management [40]. Two studies reported on the effectiveness of nutrition-only platforms. In one, the effect of a digital nutritional tracking and meal planning platform on lipid markers in individuals with dyslipidemia was assessed, showing improvement in all parameters [41]. In the second study, a mixture of online and offline engagement was used, with participants who underwent the complete prevention program showing improved cholesterol levels [42]. Additionally, one study analyzed the effect of a mobile app providing health education and step counting on multiple cardiovascular risk factors in a presumably healthy population [43]. In the study, an increase in the daily step count attributed to the use of the app was associated with a reduction of 0.07 mmol/L in LDL cholesterol and an increase of 0.05 mmol/L in HDL cholesterol [43]. With this study, we contribute to the, for now, scarce body of evidence on the usefulness of digital lifestyle programs for cardiovascular risk reduction through improvement in lipid profiles. Together with the other studies in clinical populations, the findings from this study, which was focused on individuals with elevated lipid levels without overt dyslipidemia, underscore the potential usefulness of lifestyle interventions, especially when delivered digitally, for both the primary and secondary prevention of cardiometabolic risk. In fact, effective digital lifestyle interventions appear to magnify the therapeutic benefit of cholesterol-lowering medication in those already past the clinical threshold and receiving medication, because of the complementary effects of the pharmacological and lifestyle interventions [44].

Lastly, we need to address the point of the high attrition rate registered for the intervention. Of the 104 individuals stratified to the cardiometabolic health intervention, only 25 opted to be remeasured within the reported study period. Attrition rates in mobile health (mHealth) studies and real-world applications are known to be high, with previous research having identified that up to 80% of all participants in mHealth interventions may engage in only minimal use of these interventions and that the lowest user dropout rate was 40%, even in a trial setting [45,46]. The results presented here are, as stated, preliminary, and there is certainly room for improvement in the digital engagement strategies deployed in this version of the intervention. For example, the intervention will shortly be released in mobile app form, which will support more high quality and more frequent digital engagement due to integrations with suites, such as Apple Health Kit, Google Fit, and more [47]. However, despite these limitations, we consider the results reported for the subpopulation that underwent remeasurement to be sufficient to provide an answer to the research question we set out to investigate, namely, whether a digital lifestyle intervention can improve cardiometabolic risk factors in engaged individuals.

Limitations

This study has several limitations. First, the sample size of the remeasured population was small. Second, there may be some selection bias in this remeasured population, as remeasurement was optional and voluntary. Participants who came for a remeasurement could represent a more engaged subpopulation or represent a group who actively worked on behavioral change and therefore expected results. Third, participants were required to return to the health center for a remeasurement of blood chemistry outcome parameters. This prevented us from assessing the changes verified in those who did not remeasure but may have nonetheless conducted lifestyle changes. We are currently evaluating several possibilities to overcome this. On the one hand, we are considering adapting our digital infrastructure to allow for input of self-measured blood values. However, this possibility needs to be weighed against the risk of inaccurate measurements due to interlaboratory analytical variability. On the other hand, we are studying options to structurally offer remeasurements at fixed time points. We believe this will help overcome the low remeasurement rate, which is likely to stem from the culture of health checks every 2 years in the Netherlands, both self-initiated and offered through employer health plans. Lastly, we did not account for socioeconomic factors, which are potential confounders in assessing the effect of the intervention.

Conversely, one strength of the study is that medication information was gathered at baseline and follow-up. This allowed us to verify that participants with improved lipid levels did not initiate cholesterol-lowering medications. In addition, few studies have reported on real-world applications of digital interventions targeting health behavior change and the effects on health parameters such as lipid levels. Using a database of users of the Ancora Health platform, we evaluated real-world data to analyze the changes in lipid levels before and after a digitally enabled lifestyle intervention, and find associations that support the usefulness and effectiveness of commercial digital applications of health behavioral change for cardiometabolic risk factor reduction. Additionally, the data gathered in the database spanned across multiple lifestyle domains. Few other studies reported on a broad range of lifestyle factors and their influence on lipid levels.

Conclusions

While the positive effects of healthy lifestyle changes on lipid levels are well established in the literature, this is one of the first studies to examine changes in lipid profiles among individuals of the general population participating in a digitally enabled lifestyle program with personalized dietary and physical activity recommendations delivered through the combination of eHealth and human coaching protocols rooted in behavioral science. We confirmed findings from previous studies regarding the link between certain nutritional patterns/other health

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behaviors and lipid levels, even in a general population cohort. Importantly, we showed that digital interventions can achieve lipid level reductions comparable to other traditional lifestyle interventions. A high rate of attrition remains a potential problem for mHealth interventions, primarily those that are web-based, which may limit adoption at scale. These preliminary findings contribute to expanding the body of evidence on the potential of digital therapeutic platforms providing lifestyle coaching for improving lipid levels and thereby contribute to cardiovascular risk reduction.

Acknowledgments

As the funder, Ancora Health BV provided support in the form of salaries for all employees.

Authors' Contributions

JCF: main contributor to all aspects of the manuscript. RG: original ideation of the manuscript, and significant contributions to the drafting of the manuscript. PF: main contributor to the data analysis, and the methods and results sections of the manuscript. SK: original ideation. SM and JH: contributor to the methods and discussion sections of the manuscript. SvD: contributor to the methods, results, and discussion sections of the manuscript. All authors gave input and approved the final manuscript.

Conflicts of Interest

All authors are employed by Ancora Health BV. Additionally, JCF, RG, SK, and SvD own shares of Ancora Health BV.

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Abbreviations

CVD: cardiovascular disease
HDL: high-density lipoprotein
LDL: low-density lipoprotein
mHealth: mobile health
PHP: Personal Health Passport

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Edited by T Leung; submitted 23.12.21; peer-reviewed by A Akinosun, R Hamaya; comments to author 31.12.21; revised version received 12.01.22; accepted 05.03.22; published 23.03.22.

Please cite as:
Castela Forte J, Gannamani R, Folkertsma P, Kumaraswamy S, Mount S, van Dam S, Hoogsteen J
Changes in Blood Lipid Levels After a Digitally Enabled Cardiometabolic Preventive Health Program: Pre-Post Study in an Adult Dutch General Population Cohort
JMIR Cardio 2022;6(1):e34946
URL: https://cardio.jmir.org/2022/1/e34946
doi:10.2196/34946
PMID:35319473

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Original Paper

The Impact of Health Literacy–Sensitive Design and Heart Age in a Cardiovascular Disease Prevention Decision Aid: Randomized Controlled Trial and End-User Testing

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Abstract

Background: Shared decision-making is an essential principle for the prevention of cardiovascular disease (CVD), where asymptomatic people consider lifelong medication and lifestyle changes.

Objective: This study aims to develop and evaluate the first literacy-sensitive CVD prevention decision aid (DA) developed for people with low health literacy, and investigate the impact of literacy-sensitive design and heart age.

Methods: We developed a standard DA based on international standards. The standard DA was based on our existing general practitioner DA. The literacy-sensitive DA included simple language, supporting images, white space, and a lifestyle action plan. The control DA used Heart Foundation materials. A randomized trial included 859 people aged 45-74 years using a 3 (DA: standard, literacy-sensitive, control) ×2 (heart age: heart age + percentage risk, percentage risk only) factorial design, with outcomes including prevention intentions and behaviors, gist and verbatim knowledge of risk, credibility, emotional response, and decisional conflict. We iteratively improved the literacy-sensitive version based on end-user testing interviews with 20 people with varying health literacy levels.

Results: Immediately after the intervention (n=859), there were no differences in any outcome among the DA groups. The heart age group was less likely to have a positive emotional response, perceived the message as less credible, and had higher gist and verbatim knowledge of heart age risk but not percentage risk. After 4 weeks (n=596), the DA group had better gist knowledge of percentage risk than the control group. The literacy-sensitive DA group had higher fruit consumption, and the standard DA group had better verbatim knowledge of percentage risk. Verbatim knowledge was higher for heart age than for percentage risk among those who received both.

Conclusions: The literacy-sensitive DA resulted in increased knowledge of CVD risk and increased fruit consumption in participants with varying health literacy levels and CVD risk results. Adding heart age did not increase lifestyle change intentions or behavior but did affect psychological outcomes, consistent with previous findings. This tool will be integrated with additional resources to improve other lifestyle outcomes.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12620000806965; https://tinyurl.com/226yhk8a

(JMIR Cardio 2022;6(1):e34142) doi:10.2196/34142

KEYWORDS

decision aids; shared decision-making; risk communication; heart age; cardiovascular disease prevention; behavior change; health literacy

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Introduction

Background

Prevention of cardiovascular disease (CVD) includes lifestyle interventions and medication for those at highest risk who are most likely to benefit. An absolute risk approach is supported by clinical evidence and endorsed by many national guidelines worldwide [1-5]. The absolute risk of a heart attack or stroke in the next 5-10 years can be assessed using widely available calculators [1]; however, these tools are substantially underused in practice [6-11]. Providing medication to high-risk and not low-risk patients is a cost-effective approach [6]. However, up to 75% of high-risk patients do not receive recommended medication to prevent death and disability from CVD, whereas 25% of low-risk patients take medication they are very unlikely to benefit from [7]. Recent guideline changes have led to calls for a shared decision-making approach to ensure that medication prescription for blood pressure and cholesterol is more in line with patient values [12-14].

Health literacy also plays a role in CVD prevention. Low health literacy is common in many countries, with estimates ranging from 36% to 60% of the population in Australia, Europe, and the United States [15-17]. This is associated with poorer self-management, less access to the health system, increased incidence of chronic diseases, including CVD, and increased mortality [18]. Therefore, it is important to engage this group in communication strategies for CVD prevention. This requires changes to the design of web-based patient resources, as many Australians seek health information on the web [19,20], but fewer than 1% of health information websites meet the recommended readability levels. Grade 8 is recommended to meet the needs of people with varying health literacy [21,22].

Some countries have used web-based CVD risk assessment tools for absolute risk and heart age to engage consumers in CVD prevention, with millions of users worldwide [23-26]. However, our systematic review of 73 web-based CVD risk assessment tools available to consumers found that they were not suitable for people with lower health literacy: their readability level was too high; they frequently used unexplained medical terms; few used best practice risk communication formats such as frequencies in icon arrays; and they rated poorly on actionability (ie, clarity in instructions of what actions or steps to take), which makes it difficult for the average person to know what to do about the risk assessment result [27]. Our review of 25 web-based decision aids (DAs) for CVD prevention found similar issues with understandability and actionability [28], and few included lifestyle changes as an option to reduce risk, with many focusing on medication only.

There are several evidence-based strategies to address the issue of communicating CVD risk to people with lower health literacy, such as:

1. Use literacy-sensitive design to improve the readability of health information and reduce the cognitive load of action plans for behavior change [29-31].
2. Use best practice risk communication formats to explain abstract probabilities (eg, 16%) using icon arrays and more concrete frequencies (eg, 16 out of 100 people like you) [32-35].
3. Use patient DAs to improve understanding and decision-making, including both lifestyle change and medication, as clear actions that patients can take to reduce their CVD risk [29,36,37].

Objectives

This study aims to develop and test a new consumer engagement tool for CVD prevention based on the aforementioned strategies to address the needs of Australians with different levels of health literacy. It builds on our previous development of a general practitioner (GP)-focused risk calculator and DA [38] and evaluation of the national heart age calculator [26].

Methods

Ethics Approval

This study received ethics approval from the Human Research Ethics Committee of the University of Sydney (project number 2019/774).

Stage 1: Develop Consumer Engagement Tool

In stage one, we developed a literacy-sensitive version of our existing GP DA [39], which calculates 5-year risk of a CVD event based on current guidelines [1] and shows the effects of 9 lifestyle, medication, and supplement interventions [38]. This was based on previous reviews and evaluations of 73 CVD risk calculators and 25 CVD prevention DAs, which identified tools for many different CVD models, but none that matched Australian guidelines and best practice communication principles [27,28]. We added heart age to the Australian absolute CVD risk calculation based on published methods from New Zealand, both of which use the 5-year Framingham equation [40]. The literacy-sensitive design included simple language, supporting images, and white space to improve readability and understandability [30]. The text within this DA was evaluated using the Sydney Health Literacy Editor, a tool that automatically applies readability and actionability criteria to the text [41]. On the basis of this feedback, the final tool met the recommended grade 8 level. The literacy-sensitive version also included a novel action plan format developed by our team, which has been shown to reduce unhealthy lifestyle behaviors among people with low health literacy [31]. We added options for physical activity and smoking to the existing tools to reduce unhealthy snacking, drawing on previous literature on effective if-then plans in these areas. If-then plans help people identify an important environment context or trigger in which they find that they often carry out an unwanted behavior and to identify a new behavior that can be substituted for the unwanted behavior. These 2 components are formulated into an *if-then* statement or plan; for example, *If I find myself eating unhealthy snacks when drinking a cup of tea, then I will eat a piece of fruit instead.* In this study, we used an if-then format called a *volitional help sheet*, which prompts the person with predefined *if* and *then* statements [42-44].

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Stage 2: Randomized Trial to Identify Best Formats for Low Versus High Health Literacy Design

Overview

The randomized trial was based on a 3×2 factorial, between-subject design to test the effect of literacy-sensitive design (literacy-sensitive DA, standard DA, or control: Heart Foundation patient information) and risk format (explaining CVD risk only [as a percentage risk], or CVD risk percentage+heart age) on psychological and behavioral outcomes. See Table 1 and Figure 1 for study design and Figure 2 and Multimedia Appendix 1 for example intervention content. The trial was preregistered at the Australian New Zealand Clinical Trials Registry (ACTRN12620000806965).

Table 1. The 2×3 study design.

Group	Risk results	Decision aid (DA)	Action plan
Control HF[a] information—risk percentage (+heart age)	Absolute percentage risk shown in the design of HF risk calculator results [45]. For participants in the heart age group, heart age also shown in the design of HF heart age calculator.	In the design of the National Vascular Disease Prevention Alliance risk calculator [45], participants can change any risk factors and are then presented with their risk percentage compared with their *updated risk* based on the changes they made to the risk factors. They are then advised to book in for a heart health check with their doctor.	Participants receive feedback on their blood pressure, cholesterol, and BMI. Then they are prompted to select a topic to see more information about (diet, exercise or smoking). This information is taken from the HF website [46-48].
Standard DA—risk percentage (+heart age)	Absolute percentage risk shown alongside an icon array, with the number of icons in red (out of 100 gray icons), demonstrating the risk percentage. For participants in the heart age group, heart age also shown in the design of HF heart age calculator.	Participants were asked to choose an option to reduce their risk, out of nine potential options in three categories (medication, lifestyle changes, and supplements). Once they chose an option, they were shown an icon array with the new risk in red and the difference between their current and new risk in green. They were then shown information from our current CVD[b] risk website about the option they chose as well as a table of the benefits and harms of that choice [39].	Participants had to choose a lifestyle behavior change to make (smoking, exercise, or diet) and then create a goal. They were then guided through creating a *SMART*[c]*goal* design plan, taken from our current CVD risk website [39].
Literacy-sensitive DA—risk percentage (+heart age)	Absolute percentage risk shown alongside an icon array, with the number of icons in red (out of 100 gray icons), demonstrating the risk percentage. For participants in the heart age group, heart age also shown with more explanation than control and standard DA conditions.	The same as for the standard DA; however, the information and benefits and harms were edited to be appropriate for all levels of health literacy; for example, by introducing white space, images, and reducing the readability level.	Participants were prompted to change their smoking, exercise, or snacking habits. They were then guided through creating an action plan based on implementation intentions or *if-then* plans. The snacking action plan was previously developed by our team [31], and the exercise and smoking plans were in the same design using research in those areas [42,43].

[a]HF: Heart Foundation.

[b]CVD: cardiovascular disease.

[c]SMART: Specific, Measurable, Achievable, Realistic, and Timely.

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Figure 1. Study design. NVS: Newest Vital Signs.

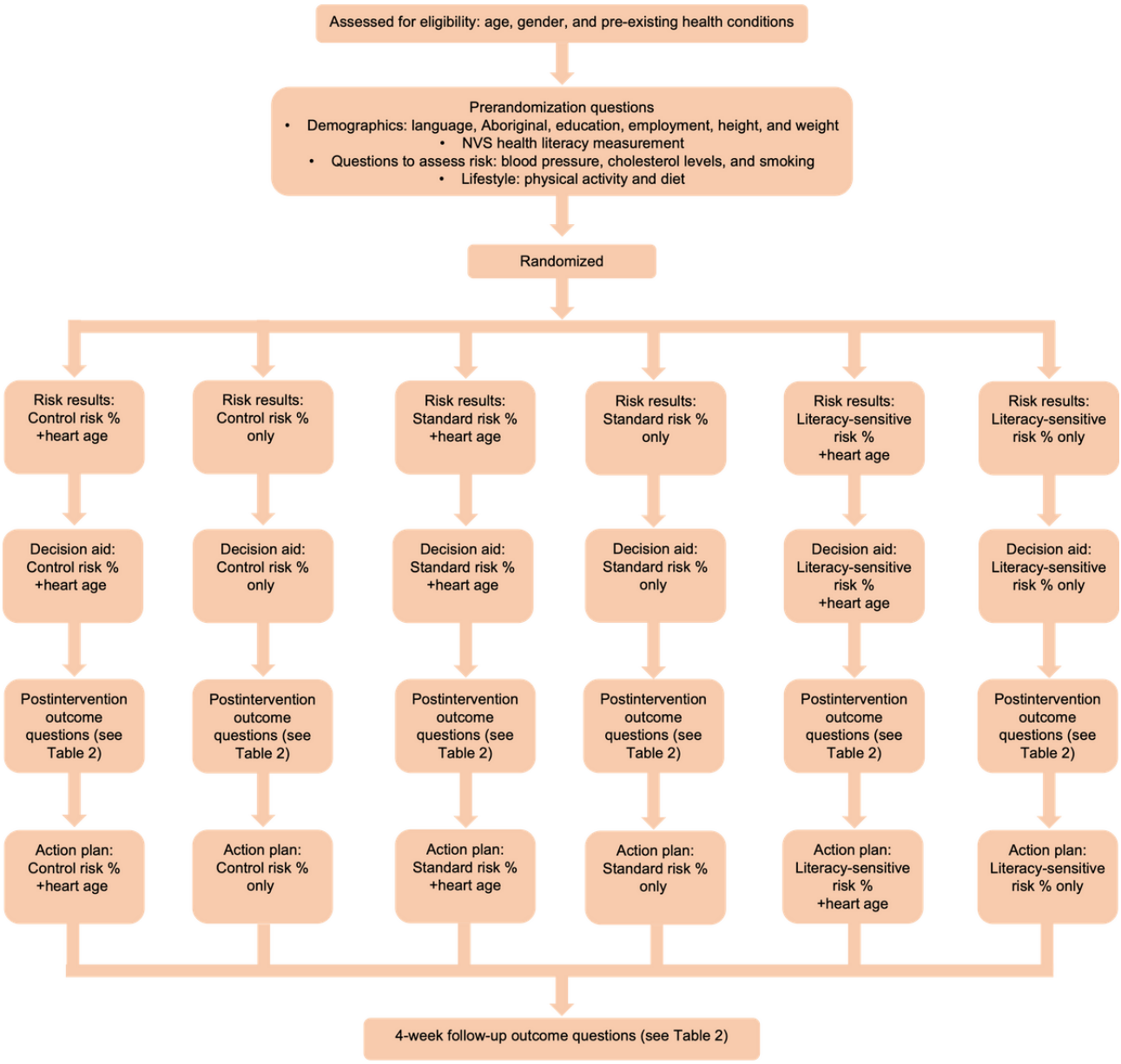

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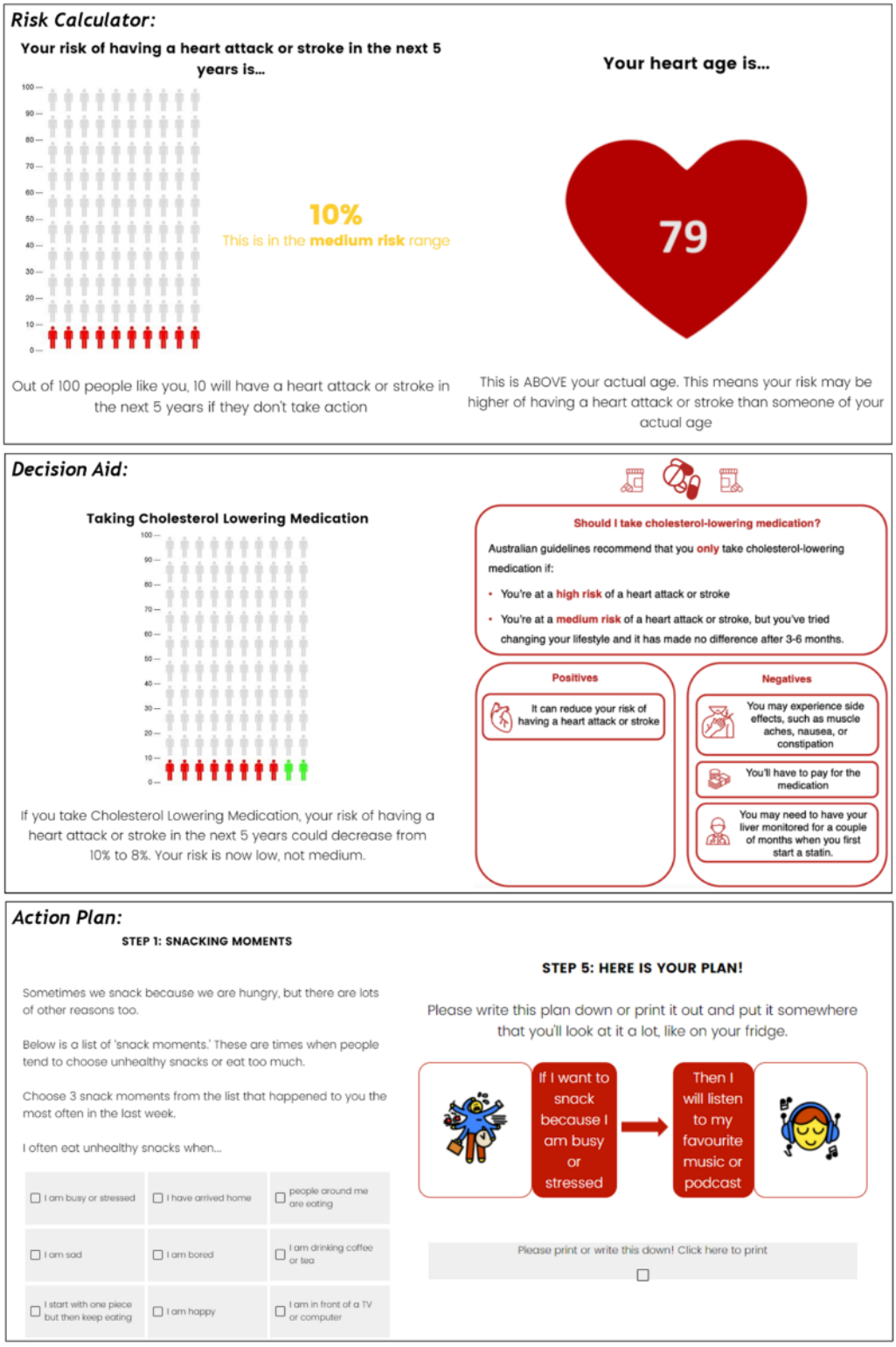
Figure 2. Example risk calculator, decision aid, and action plan (literacy-sensitive heart age version).



Recruitment

A national sample was recruited through Qualtrics (Qualtrics Inc), a web-based social research agency, with stratified sampling based on gender and age groups (5-year age groups from 45 to 74 years). Participants completed a CVD risk assessment based on the Australian guidelines and New Zealand approach to calculate heart age [1,40]. If blood pressure or cholesterol were not known, the average by age and gender based on non-diabetic participants in the AusDiab cohort was used (accessed via author JD), and all participants were advised to see a GP for a more accurate risk assessment. Participants with established CVD or those taking CVD prevention medications were excluded. Duplicate IP addresses were replaced, and stratified sampling was relaxed with additional quality checks added if hard-to-reach groups did not reach the quota after 2 weeks.

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Measures

Established measures were used for the primary outcome of behavioral intentions (validated theory of planned behavior scale applied to smoking, diet, exercise, and GP visit) [49-51]. Secondary outcomes included self-reported behavior after 4 weeks compared with national guidelines for diet and physical activity [50,51], gist and verbatim knowledge (absolute risk percentage and heart age), emotional response using a validated scale (3 positive emotions, eg, hopeful, and 3 negative emotions, eg, anxious) [52], credibility of the information (that the information is personally relevant) [53], and decision conflict scale (uncertainty in decision-making) [54]. Details are presented in Table 2.

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Table 2. Psychological and behavioral outcomes measured in the analyses.

Outcome and items	Response scale	Immediately after the intervention	4-week follow-up
Lifestyle intentions [49]			
I intend to smoke less/improve my diet/increase the amount of physical activity I do in the next 4 weeks (average 2-3 items depending on smoking)	1=strongly disagree to 7=strongly agree	✓[a]	
Medication intentions [49]			
I intend to talk to my GP[b] about taking blood pressure lowering medication/cholesterol lowering medication/aspirin in the next 4 weeks (average 3 items)	1=strongly disagree to 7=strongly agree	✓	
Supplement intentions [49]			
I intend to take fish oil/multivitamin/antioxidant supplements in the next 4 weeks (average 3 items)	1=strongly disagree to 7=strongly agree	✓	
Credibility [53] (Cronbach α=.89)			
I felt that the numbers received were "my numbers";	1=strongly disagree to 7=strongly agree	✓	
I found the results to be written personally for me;			
I felt that the information was relevant to me;			
I felt that the information was designed specifically for me			
Emotion (positive Cronbach α=.81; negative Cronbach α=.85) [52]			
My results made me feel: Positive subscale: hopeful/optimistic/enthusiastic; Negative subscale: afraid/anxious/worried	0=none of this feeling to 10=a lot of this feeling	✓	.
Gist knowledge of percentage risk			
My risk level for having a heart attack or stroke in the next 5 years was	Low/medium/high/I don't know	✓	✓
Verbatim knowledge of percentage risk			
My percentage risk of having a heart attack or stroke in the next 5 years was	Numerical/I don't know	✓	✓
Gist knowledge of heart age			
My heart age result was	Below my actual age/the same as my actual age/above my actual age/I wasn't shown my heart age/I don't know	✓	✓
Verbatim knowledge of heart age			
My heart age was	Numerical/I don't know	✓	✓
Decisional conflict [54]			
Do you feel sure about the best choice for you?	Yes/no	✓	
Do you know the benefits and risks of each option?	Yes/no	✓	
Are you clear about which benefits and risks matter most to you?	Yes/no	✓	
Do you have enough information to make a choice?	Yes/no	✓	
Smoking[c]			
Do you currently smoke cigarettes?	Yes/no		✓
In the last week, how many cigarettes did you usually smoke per day?	Numerical (if yes)		✓
Physical activity [50][c]			
In the last week, how many times did you do 20 minutes or more of vigorous-intensity physical activity that made you sweat or puff and pant?	0-10+ (assessed as adequate/inadequate against Australian diet guidelines)		✓

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Outcome and items	Response scale	Immediately after the intervention	4-week follow-up
In the last week, how many times did you do 30 minutes or more of moderate-intensity physical activity or walking that increased your heart rate or makes you breathe harder than normal?	0-10+ (assessed as adequate/inadequate against Australian diet guidelines)		✓
Diet [51][c]			
In the last week, how many serves of fruit did you usually eat per day?	0-10+ (with examples of serves provided; assessed as adequate/inadequate against Australian diet guidelines)		✓
In the last week, how many serves of vegetables did you usually eat per day?	0-10+ (with examples of serves provided; assessed as adequate/inadequate against Australian diet guidelines)		✓
In the last week, how many serves of unhealthy snacks did you usually eat per day?	0-10+ (with examples of serves provided; assessed as adequate/inadequate against Australian diet guidelines)		✓
In the last week, how much soft drink, cordial or sports drinks do you usually drink per day?	0-10+ (with examples of serves provided; assessed as adequate/inadequate against Australian diet guidelines)		✓
Seeing a doctor			
Have you discussed your risk of heart disease with a doctor in the last 4 weeks? (including blood pressure, cholesterol or lifestyle change)	Yes/no		✓
Have you made an appointment to discuss your risk of heart disease with a doctor? (including blood pressure, cholesterol or lifestyle change)	Yes/no		✓
Helpline			
Have you used the Heart Foundation helpline for more lifestyle change support?	Yes/no		✓

[a]The tick demonstrates in which survey this outcome was measured.

[b]GP: general practitioner.

[c]Also asked before the intervention, with preintervention behavior controlled for in the analyses.

Analysis

A priori sample size calculations determined that 85 participants per randomized group (total n=510) would yield 90% power to detect a moderate effect size of Cohen *d*=0.5 (a standardized difference; this generic effect size estimate was selected because of the absence of similar trials on which to base calculations) in the primary outcome of intention to change lifestyle or any of the secondary outcomes, assuming a 2-sided Cronbach α of .05. We aimed to recruit an additional 20% more cases to account for potential missing values, totaling 600 participants (100 per group) at follow-up. This sample was inflated for recruitment to 850 participants to account for potential attrition of up to 30% between the intervention and follow-up.

Continuous outcome variables were modeled using linear regression. Dichotomous outcomes were analyzed using modified Poisson regression (using a log-link function with robust error variances). Ordinal logistic regression was used to analyze the ordered categorical outcomes. Count outcomes were modeled using negative binomial regression. All regression models included the DA group (literacy-sensitive DA, standard DA, or basic Heart Foundation patient information) and risk format (CVD risk percentage only or CVD risk percentage+heart age) as categorical variables and controlled for health literacy adequacy (categorical based on the Newest Vital Signs measure [55,56]: low, moderate, or adequate) and absolute risk (percentage). Postintervention and follow-up outcomes were analyzed separately, with follow-up analyses controlling for preintervention values where available. Pairwise comparisons were conducted to test these hypotheses. We also conducted exploratory analyses of potential differences in DA effects between health literacy levels by including a literacy-sensitive-by-DA interaction term and heart age category for heart age groups (younger or same vs older in stratified analyses). Chi-square test for paired proportions by McNemar was used to compare knowledge of heart age versus percentage risk among those who saw both. Analyses were conducted using Stata (version 16.1; StataCorp). No adjustments were made for multiple comparisons.

Hypotheses

1. The two DA formats will be more effective (ie, increase lifestyle change intentions or behavior and knowledge of risk without reducing credibility) than the standard Heart Foundation information.
2. The literacy-sensitive DA will be more effective than the standard DA for everyone (not just people with lower health literacy).

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3. Adding heart age to absolute risk will be more effective than absolute risk alone.

Stage 3: Iterative End-User Testing With Varying Health Literacy Levels

As part of the follow-up survey, participants in the trial were invited to opt-in to a *think aloud* interview to provide further end-user testing and feedback for the literacy-sensitive version of the intervention. From the 27 participants who provided email addresses, 20 (74%) participants were selected to represent a range of ages, genders, risk levels, and health literacy levels. Participants went through the risk calculator in full while saying out loud everything they were thinking; for example, any areas of confusion. Further questions were asked to prompt more discussion or elaboration. Transcripts were thematically coded and discussed after each set of 4-5 interviews, and improvements were made to the intervention before the next set of interviews. We conducted 2 rounds of interviews with people with low health literacy as our key target group (8/20, 40%) and then tested the improved tool with people who had higher health literacy to ensure that it was suitable for these users in another 2 rounds (12/20, 60%).

Results

Stage 1

We used the question format and style of the current national heart age calculator as the basis for the risk factor questions in all groups, as well as the heart age presentation on that tool. The CVD risk results and DA were presented based on (1) our existing GP DA tool [39] (standard DA group), (2) a simplified version of the standard DA with supporting images (literacy-sensitive DA group; Figure 2), and (3) the current risk calculator from the National Vascular Disease Prevention Alliance [45]. See Multimedia Appendix 1 for example intervention content in each group.

Stage 2

Overview

The CONSORT (Consolidated Standards of Reporting Trials) diagram is shown in Figure 3, and the characteristics of all the participant groups in the intervention are shown in Table 3. We conducted a soft launch with 100 participants to check that we had an adequately low health literacy sample and adequate follow-up considering the COVID-19 disruptions in 2020 before proceeding with the full trial with no changes to the preregistered method. We recruited 859 participants for the intervention (including the 100 in the soft launch), with a target of 600 at the 4-week follow-up, for which we recruited 596 participants. The characteristics were similar among the groups for age and gender but some differences were observed for health literacy (relating to education) and absolute risk (relating to smoking and heart age); therefore, these 2 factors were controlled for in the analyses. In terms of dropout, there was no difference in the randomized DA group (P=.71), randomized to heart age (P=.91), health literacy level (P=.69), CVD risk level (P=.56), or heart age result (P=.30) between those who returned for follow-up and those who did not. The outcomes by trial group are shown in Table 4, and the analyses for each of the 3 hypotheses are shown in Tables 5-7.

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) diagram.

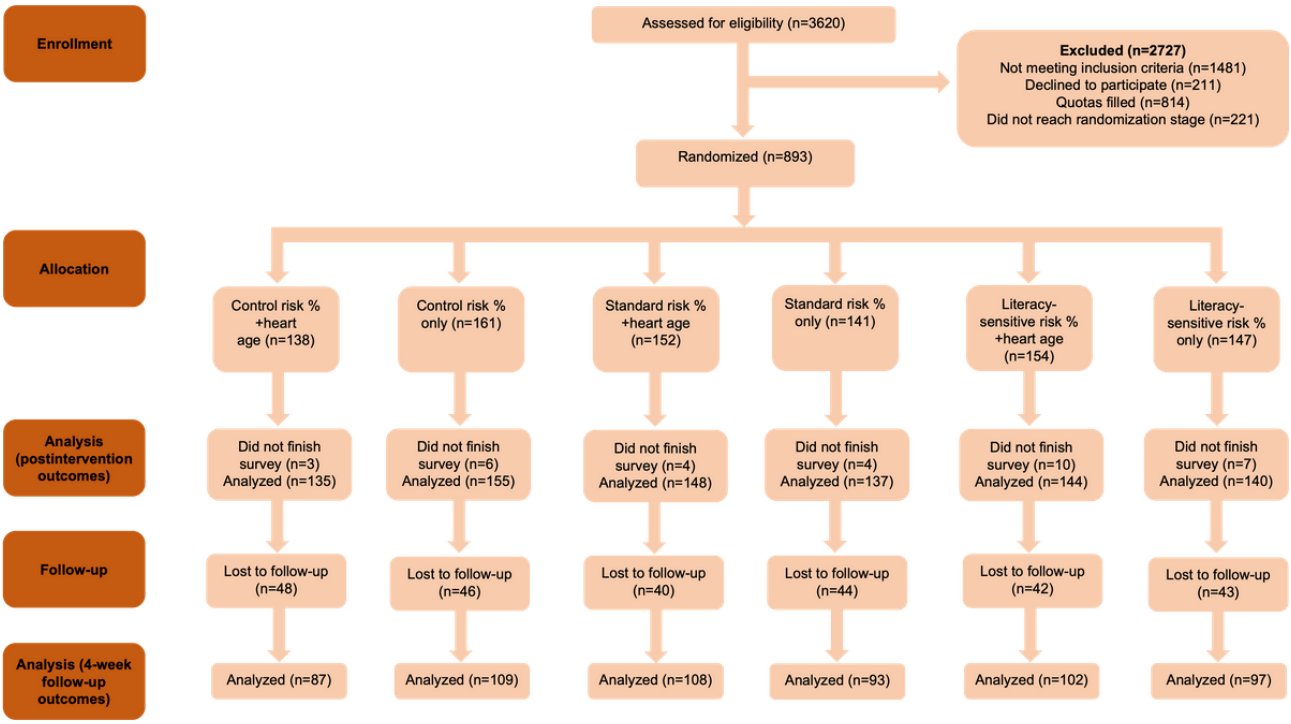

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Table 3. Trial participant characteristics by randomized group.

Characteristics	Decision aid group			Heart age group	
	Control (n=290)	Standard (n=285)	Literacy-sensitive (n=284)	Risk percentage only (n=432)	Risk percentage+heart age (n=427)
Demographics					
Age (years), mean (SD)	59.9 (8.7)	59.6 (8.2)	58.3 (8.7)	58.8 (8.6)	59.8 (8.5)
Heart age (years), mean (SD)	60.7 (14.7)	60.9 (13.1)	58.5 (13.7)	58.9 (14.0)	61.2 (13.7)
Sex					
Male, n (%)	137 (47.2)	147 (51.6)	142 (50)	213 (49.3)	213 (49.9)
Female, n (%)	153 (52.8)	138 (48.4)	142 (50)	219 (50.7)	214 (50.1)
Education (university degree), n (%)	149 (51.4)	133 (46.7)	145 (51.1)	218 (50.5)	209 (48.9)
Inadequate health literacy, n (%)	63 (21.7)	77 (27)	66 (23.2)	103 (23.8)	103 (24.1)
Clinical characteristics					
Knew their cholesterol, n (%)	41 (14.1)	41 (14.4)	34 (12)	59 (13.7)	57 (13.3)
Total cholesterol[a] (mg/dL), mean (SD)	4.9 (1.3)	4.9 (1.5)	4.4 (1.4)	4.6 (1.3)	4.8 (1.5)
High-density lipoprotein cholesterol[a] (mg/dL), mean (SD)	2.6 (1.3)	2.6 (1.2)	2.8 (1.3)	2.8 (1.3)	2.6 (1.2)
Knew their blood pressure, n (%)	102 (35.2)	106 (37.2)	98 (34.5)	162 (37.5)	144 (33.7)
Systolic blood pressure[a] (mm Hg), mean (SD)	123.9 (15.1)	127.0 (14.8)	124.9 (14.8)	123.9 (14.7)	126.8 (15.1)
Diastolic blood pressure[a] (mm Hg), mean (SD)	83.1 (11.7)	83.3 (12.0)	82.3 (13.0)	82.4 (12.7)	83.5 (11.8)
Overweight BMI[b] (kg/m^2), n (%)	172 (59.3)	175 (61.4)	161 (56.7)	260 (60.2)	248 (58.1)
Behavior+lifestyle characteristics					
Adequate diet[b], n (%)	73 (25.2)	75 (26.3)	67 (23.6)	113 (26.2)	102 (23.9)
Adequate exercise[b], n (%)	165 (56.9)	150 (52.6)	162 (57)	239 (55.3)	238 (55.7)
Smokers, n (%)	38 (13.1)	42 (14.7)	35 (12.3)	48 (11.1)	67 (15.7)
Risk results					
Older heart age[c], n (%)	164 (56.6)	171 (60.0)	153 (53.9)	230 (53.2)	258 (60.4)
Absolute risk, mean (SD)	5.3 (4.8)	5.4 (4.1)	4.9 (4.1)	4.9 (4.5)	5.5 (4.2)
Low risk, n (%)	248 (85.5)	235 (82.5)	238 (83.8)	375 (86.8)	346 (81.0)
Medium risk, n (%)	37 (12.8)	44 (15.4)	39 (13.7)	49 (11.3)	71 (16.6)
High risk, n (%)	5 (1.7)	6 (2.1)	7 (2.5)	8 (1.9)	10 (2.3)

[a]If known.

[b]Overweight BMI: >25 kg/m^2; adequate diet: at least 2 servings of fruit and 5 servings of vegetables per day in the past week [51]; adequate physical activity: 3 vigorous sessions per week, 5 moderate sessions per week, or 1-2 vigorous sessions plus 3-4 moderate sessions per week [50].

[c]Older heart age: heart age result is higher than chronological age.

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Table 4. Trial outcomes by randomized group.

Outcome	Decision aid group			Heart age group	
	Control	Standard	Literacy-sensitive	Risk percentage only	Risk percentage+heart age
Immediately after the intervention	(n=290)	(n=285)	(n=284)	(n=432)	(n=427)
Intention to change lifestyle[a], mean (SD); 1 (strongly disagree) to 7 (strongly agree)	4.5 (1.4)	4.7 (1.2)	4.6 (1.4)	4.6 (1.3)	4.6 (1.4)
Intention to take medication, mean (SD); 1 (strongly disagree) to 7 (strongly agree)	2.5 (1.4)	2.5 (1.4)	2.5 (1.5)	2.5 (1.4)	2.5 (1.4)
Intention to take supplements, mean (SD); 1 (strongly disagree) to 7 (strongly agree)	3.2 (1.6)	3.1 (1.6)	3.1 (1.6)	3.1 (1.6)	3.1 (1.6)
Decisional conflict, n (%); 4 (yes to all 4 questions; therefore, any score <4 indicates decisional conflict)	34 (11.7)	34 (11.9)	37 (13)	46 (10.6)	59 (13.8)
Positive emotion, median (IQR); 0 (none of this feeling) to 10 (a lot of this feeling)	7 (5-8.3)	7.3 (5.3-8.3)	7 (5.3-8.5)	7.3 (5.7-8.7)	6.7 (5-8)
Negative emotion, median (IQR); 0 (none of this feeling) to 10 (a lot of this feeling)	1.3 (0-4)	2 (0-5)	2 (0-4.3)	1.2 (0-4)	2 (0-4.7)
Credibility, mean (SD); 1 (strongly disagree) to 7 (strongly agree)	5.0 (1.2)	5.0 (1.1)	4.9 (1.2)	5.1 (1.1)	4.9 (1.2)
Gist knowledge of risk percentage after the intervention, n (%)	256 (88.3)	253 (88.8)	241 (84.9)	379 (87.7)	371 (86.9)
Inflated risk, n (%)	19 (6.6)	16 (5.6)	22 (7.7)	23 (5.3)	34 (8)
4-week follow-up (a positive difference means higher levels at follow-up)	(n=196)	(n=201)	(n=199)	(n=299)	(n=297)
Difference in smoking[b], mean (SD)	0.4 (2.1)	−1.4 (7.5)	0.2 (3.2)	0.8 (3.3)	−1.0 (5.7)
Difference in moderate exercise[b], mean (SD)	0.03 (2.2)	−0.1 (2.3)	−0.04 (2.3)	−0.1 (2.3)	0.04 (2.3)
Difference in vigorous exercise[b], mean (SD)	−0.2 (2.2)	−0.1 (2.1)	−0.1 (2.5)	−0.3 (2.1)	0.01 (2.4)
Adequate exercise[c], n (%)	102 (52.0)	103 (51.2)	115 (57.8)	152 (50.8)	169 (56.9)
Difference in whether exercise met adequate levels[b], %	−4.9	−1.4	0.8	−4.5	1.2
Difference in daily fruit serves[b], mean (SD)	−0.4 (2.4)	−0.2 (2.3)	0.5 (2.5)	−0.1 (2.7)	0.01 (2.2)
Difference in daily vegetable serves[b], mean (SD)	−0.4 (2.6)	−0.2 (2.4)	0.1 (2.6)	−0.3 (2.6)	−0.1 (2.5)
Difference in daily unhealthy snack serves[b], mean (SD)	−0.4 (2.2)	−0.3 (2.1)	−0.2 (2.3)	−0.3 (2.2)	−0.4 (2.1)
Difference in daily soft drinks[b], mean (SD)	0.03 (1.6)	−0.1 (1.7)	−0.1 (2.0)	0.1 (1.8)	−0.2 (1.7)
Adequate diet[c], n (%)	39 (19.9)	50 (24.9)	50 (25.1)	68 (22.7)	71 (23.9)
Difference in whether diet met adequate levels[b], %	−5.3	−1.4	1.5	−3.5	0
Seen a doctor in the last 4 weeks, n (%)	14 (7.1)	16 (8)	23 (11.6)	27 (9)	26 (8.8)
Made an appointment to see a doctor, n (%)	8 (4.1)	7 (3.5)	6 (3)	8 (2.7)	13 (4.4)

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Outcome	Decision aid group			Heart age group	
	Control	Standard	Literacy-sensitive	Risk percentage only	Risk percentage+heart age
Called the Heart Foundation helpline in the last 4 weeks, n (%)	1 (0.5)	4 (2)	3 (1.5)	5 (1.7)	3 (1)
Gist knowledge of heart age at follow-up, n (%)	44 (22.4)	57 (28.4)	54 (27.1)	40 (13.4)	115 (38.7)
Verbatim knowledge of heart age at follow-up, n (%)	16 (8.2)	11 (5.5)	9 (4.5)	2 (0.7)	34 (11.4)
Gist knowledge of risk percentage at follow-up, n (%)	76 (38.8)	108 (53.7)	102 (51.3)	139 (46.5)	147 (49.5)
Verbatim knowledge of risk percentage at follow-up, n (%)	6 (3.1)	19 (9.5)	14 (7)	21 (7)	18 (6.1)

[a]Primary outcome.

[b]Difference score: follow-up score minus preintervention score; positive: more at follow-up.

[c]Adequate diet: at least 2 servings of fruit and 5 servings of vegetables per day in the past week [51]; adequate physical activity: 3 vigorous sessions per week, 5 moderate sessions per week, or 1-2 vigorous sessions plus 3-4 moderate sessions per week [50].

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Table 5. Hypothesis 1: the decision aid (DA) groups will improve outcomes versus the control group.

Outcome	Literacy-sensitive DA vs control		Standard DA vs control		Main effect, *P* value
	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value	
Immediately after the intervention					
Intention to change lifestyle[a]	0.07 (−0.15 to 0.29)	.52	0.17 (−0.05 to 0.39)	.12	.30
Intention to talk to a doctor about medication	0.01 (−0.21 to 0.24)	.90	0.00 (−0.23 to 0.22)	.97	.99
Intention to take supplements	−0.10 (−0.36 to 0.16)	.43	−0.09 (−0.34 to 0.17)	.52	.70
Decisional conflict[b]	1.12 (0.72 to 1.73)	.62	0.98 (0.63 to 1.54)	.93	.82
Positive emotion	0.16 (−0.23 to 0.55)	.43	0.31 (−0.08 to 0.70)	.12	.29
Negative emotion	0.28 (−0.11 to 0.68)	.16	0.20 (−0.19 to 0.60)	.31	.34
Credibility	−0.12 (−0.30 to 0.07)	.22	0.01 (−0.18 to 0.19)	.95	.34
Gist knowledge of risk percentage after the intervention[c]	1.22 (0.74 to 2.02)	.44	1.05 (0.63 to 1.73)	.85	.72
Inflated risk[b]	1.10 (0.63 to 1.92)	.74	0.74 (0.39 to 1.38)	.34	.42
Follow-up (after 4 weeks, controlling for preintervention)					
Daily smoking (number of cigarettes smoked)[d]	0.41 (−2.34 to 3.16)	.77	−1.48 (−4.17 to 1.20)	.28	.29
Weekly vigorous exercise sessions[d]	0.23 (−0.15 to 0.62)	.24	0.00 (−0.38 to 0.38)	.99	.39
Weekly moderate exercise sessions[d]	0.03 (−0.36 to 0.42)	.89	−0.03 (−0.42 to 0.36)	.87	.95
Whether exercise met adequate levels[b]	1.10 (0.95 to 1.28)	.19	1.04 (0.89 to 1.21)	.64	.41
Daily fruit serves[d]	0.69 (0.32 to 1.06)	<.001	0.21 (−0.13 to 0.55)	.23	<.001
Daily vegetable serves[d]	0.38 (−0.03 to 0.78)	.07	0.04 (−0.36 to 0.43)	.85	.13
Daily unhealthy snack serves[d]	0.11 (−0.17 to 0.40)	.43	0.02 (−0.26 to 0.31)	.87	.71
Daily soft drink serves[d]	0.12 (−0.10 to 0.35)	.28	0.05 (−0.17 to 0.27)	.65	.55
Whether diet met adequate levels[b]	1.23 (0.87 to 1.74)	.23	1.16 (0.83 to 1.62)	.37	.48
Follow-up only (after 4 weeks)					
Has seen a doctor in the last 4 weeks[b]	1.60 (0.85 to 3.02)	.14	1.04 (0.52 to 2.07)	.92	.23
Intends to see a doctor at follow-up[b]	0.75 (0.27 to 2.10)	.58	0.86 (0.31 to 2.41)	.78	.86
Has called the Heart Foundation helpline in the last 4 weeks[b]	3.00 (0.31 to 29.07)	.34	3.81 (0.45 to 32.25)	.22	.47
Gist knowledge of heart age at follow-up[b]	1.12 (0.80 to 1.56)	.51	1.16 (0.84 to 1.61)	.36	.65
Verbatim knowledge of heart age at follow-up[b]	0.47 (0.22 to 1.03)	.06	0.58 (0.28 to 1.20)	.14	.12
Gist knowledge of risk percentage at follow-up[b]	1.28 (1.04 to 1.58)	.02	1.41 (1.14 to 1.74)	.002	.006
Verbatim knowledge of risk percentage at follow-up[b]	2.34 (0.91 to 6.05)	.08	3.25 (1.31 to 8.07)	.01	.04

[a]Primary outcome.

[b]Analysis by modified Poisson regression, data shown as incidence rate ratios.

[c]Analysis by ordered logistic regression, data shown as odds ratio of being in next highest (relative to group shown Heart Foundation information only).

[d]Analysis by negative binomial regression, data shown as differences in the predicted counts.

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Table 6. Hypothesis 2: the literacy-sensitive decision aid (DA) will improve outcomes versus the standard DA regardless of health literacy level.

Outcome	Standard DA (vs literacy-sensitive DA)		Newest Vital Signs score×group interaction, *P* value
	Estimated difference (95% CI)	*P* value	
Immediately after the intervention			
Intention to change lifestyle[a]	0.10 (−0.12 to 0.32)	.37	.22
Intention to talk to doctor about medication	−0.02 (−0.24 to 0.21)	.87	.02
Intention to take supplements	0.02 (−0.24 to 0.28)	.90	.10
Decisional conflict[b]	0.88 (0.57 to 1.36)	.56	.53
Positive emotion	0.16 (−0.24 to 0.55)	.44	.01
Negative emotion	−0.08 (−0.48 to 0.32)	.69	.006
Credibility	0.12 (−0.06 to 0.31)	.20	.11
Gist knowledge of risk percentage after the intervention[c]	0.86 (0.52 to 1.41)	.55	.007
Inflated risk perception (above actual level)[b]	0.70 (0.37 to 1.23)	.20	.72
Follow-up (after 4 weeks, controlling for preintervention measurement)			
Daily smoking (number of cigarettes smoked)[d]	−1.90 (−4.33 to 0.53)	.13	.90
Weekly vigorous exercise sessions[d]	−0.23 (−0.62 to 0.16)	.24	.20
Weekly moderate exercise sessions[d]	−0.06 (−0.45 to 0.32)	.76	.50
Whether exercise met adequate levels[b]	0.94 (0.81 to 1.09)	.43	.35
Daily fruit serves[d]	−0.48 (−0.86 to −0.11)	.01	.15
Daily vegetable serves[d]	−0.34 (−0.74 to 0.06)	.10	.10
Daily unhealthy snack serves[d]	−0.09 (−0.38 to 0.20)	.53	.97
Daily soft drink serves[d]	−0.07 (−0.30 to 0.16)	.53	.77
Whether diet met adequate levels[b]	0.94 (0.69 to 1.28)	.71	.90
Follow-up (after 4 weeks)			
Has seen a doctor in the last 4 weeks[b]	0.65 (0.35 to 1.19)	.16	.75
Intends to see a doctor at follow-up[b]	1.15 (0.39 to 3.36)	.80	Not tested (insufficient variability)
Has called the Heart Foundation helpline in the last 4 weeks[b]	1.27 (0.26 to 6.09)	.77	<.001
Gist knowledge of heart age at follow-up[b]	1.04 (0.77 to 1.41)	.81	.61
Verbatim knowledge of heart age at follow-up[b]	1.24 (0.53 to 2.89)	.62	.27
Gist knowledge of risk percentage at follow-up[b]	1.10 (0.92 to 1.30)	.29	.83
Verbatim knowledge of risk percentage at follow-up[b]	1.39 (0.71 to 2.69)	.33	<.001

[a]Primary outcome.

[b]Analysis by modified Poisson regression, data shown as incidence rate ratios.

[c]Analysis by ordered logistic regression, data shown as odds ratio of being in next highest (odds in standard, relative to low health literacy).

[d]Analysis by negative binomial regression, data shown as differences in the predicted counts.

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Table 7. Hypothesis 3: adding heart age to percentage risk will improve outcomes versus percentage risk only.

Outcome	Heart age shown vs not shown					
	Across all participants		Older heart age result		Same or younger heart age result	
	Estimated mean difference (95% CI)	*P* value	Difference (95% CI)	*P* value	Difference (95% CI)	*P* value
Immediately after the intervention						
Intention to change lifestyle[a]	−0.04 (−0.22 to 0.14)	.64	−0.11 (−0.34 to 0.13)	.36	0.02 (−0.25 to 0.30)	.87
Intention to take medication	.04 (−0.15 to 0.22)	.70	0.11 (−0.13 to 0.36)	.37	−0.14 (−0.41 to 0.13)	.31
Intention to take supplements	0.00 (−0.21 to 0.21)	.99	0.07 (−0.21 to 0.35)	.63	−0.14 (−0.47 to 0.19)	.41
Decisional conflict[b]	1.27 (0.89 to 1.83)	.19	1.08 (0.72 to 1.62)	.71	1.72 (0.81 to 3.67)	.16
Positive emotion	−0.56 (−0.88 to −0.24)	.001	−0.75 (−1.19 to −0.31)	.001	−0.25 (−0.70 to 0.20)	.28
Negative emotion	0.26 (−0.06 to 0.58)	.12	0.57 (0.12 to 1.02)	.01	−0.27 (−0.71 to 0.17)	.23
Credibility	−0.20 (−0.35 to −0.05)	.01	−0.29 (−0.49 to −0.09)	.005	−0.06 (−0.29 to 0.17)	.60
Gist knowledge of risk percentage after the intervention[c]	2.03 (1.33 to 3.08)	.001	2.12 (1.32 to 3.41)	.002	1.60 (0.58 to 4.37)	.36
Inflated risk[b]	1.60 (0.98 to 2.61)	.058	1.70 (0.93 to 3.13)	.09	1.38 (0.57 to 3.36)	.47
Follow-up (after 4 weeks, controlling for preintervention measurement)						
Daily smoking (number of cigarettes smoked)[d]	−0.77 (−2.93 to 1.40)	.49	Not estimated (n=4 not shown)	Not estimated	−0.66 (−2.94 to 1.61)	.57
Weekly vigorous exercise sessions[d]	0.29 (−0.02 to 0.60)	.07	0.58 (0.09 to 1.07)	.02	0.04 (−0.37 to 0.44)	.85
Weekly moderate exercise sessions[d]	0.05 (−0.26 to 0.37)	.74	0.45 (−0.01 to 0.91)	.056	−0.26 (−0.72 to 0.20)	.27
Whether exercise met adequate levels[b]	1.16 (0.99 to 1.26)	.08	1.23 (1.05 to 1.45)	.01	1.03 (0.86 to 1.24)	.74
Daily fruit serves[d]	0.02 (−0.28 to 0.31)	.92	0.42 (−0.06 to 0.89)	.08	−0.26 (−0.63 to 0.11)	.17
Daily vegetable serves[d]	0.30 (−0.02 to 0.63)	.07	0.57 (0.05 to 1.09)	.03	−0.14 (−0.28 to 0.56)	.51
Daily unhealthy snack serves[d]	−0.05 (−0.28 to 0.18)	.68	0.22 (−0.15 to 0.58)	.25	−0.28 (−0.58 to 0.02)	.07
Daily soft drink serves[d]	−0.14 (−0.33 to 0.04)	.13	0.03 (−0.22 to 0.27)	.83	−0.34 (−0.61 to −0.07)	.01
Whether diet met adequate levels[b]	1.14 (0.87 to 1.50)	.34	1.48 (1.00 to 2.18)	.048	0.95 (0.66 to 1.38)	.79
Follow-up (after 4 weeks)						
Has seen a doctor in the last 4 weeks[b]	0.99 (0.60 to 1.63)	.96	0.81 (0.37 to 1.80)	.61	1.15 (0.58 to 2.26)	.69
Intends to see a doctor at follow-up[b]	1.61 (0.67 to 3.84)	.29	0.67 (0.17 to 0.27)	.58	4.17 (0.90 to 19.32)	.07
Has called the Heart Foundation helpline in the last 4 weeks[b]	0.65 (0.17 to 2.53)	.54	1.23 (0.25 to 6.03)	.80	2.66 (1.76 to 4.03)	<.001

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Outcome	Heart age shown vs not shown					
	Across all participants		Older heart age result		Same or younger heart age result	
	Estimated mean difference (95% CI)	*P* value	Difference (95% CI)	*P* value	Difference (95% CI)	*P* value
Gist knowledge of heart age at follow-up[b]	2.90 (2.10 to 3.99)	<.001	3.38 (2.05 to 5.55)	<.001	6.67 (1.50 to 32.41)	.01
Verbatim knowledge of heart age at follow-up[b]	18.13 (4.36 to 75.48)	<.001	Not estimated (n=2 not shown)	Not estimated	Not estimated (n=2 not shown)	Not estimated
Gist knowledge of risk percentage at follow-up[b]	1.11 (0.95 to 1.30)	.20	1.09 (0.91 to 1.29)	.35	1.16 (0.87 to 1.55)	.31
Verbatim knowledge of risk percentage at follow-up[b]	0.82 (0.44 to 1.50)	.52	1.02 (0.40 to 2.57)	.97	0.68 (0.31 to 1.52)	.35

[a]Primary outcome.

[b]Analysis by modified Poisson regression, data shown as incidence rate ratios.

[c]Analysis by ordered logistic regression, data shown as odds ratio of being in next highest (odds in heart age, relative to not shown).

[d]Analysis by negative binomial regression, data shown as differences in predicted counts and unstable estimate: 1.7% (5/299) individuals who were not shown heart age used the helpline compared with 1.0% (3/297) who were shown heart age.

Postintervention Differences Among DA Groups

Immediately after the intervention, there were no differences among the 3 DA groups for the primary outcome of lifestyle intentions or secondary outcomes of risk perception, credibility, emotional response, or decisional conflict. For hypothesis 1, the combined DA groups did not differ from the control group for any outcome (Table 5). For hypothesis 2, there was no difference between standard and literacy-sensitive DAs for any outcome (Table 6). There were significant interactions between DA and health literacy for intention to talk to a doctor about medication (*P*=.02) and emotional responses (positive *P*=.01; negative *P*=.006). Participants with lower health literacy who received literacy-sensitive DA had a more negative or less positive emotional response and had stronger intentions to see a doctor about medication compared with the other groups (Table 6).

4-Week Differences Among DA Groups

At follow-up after 4 weeks, there were no significant differences between the control and DA groups for most self-reported behaviors. However, the literacy-sensitive DA group had higher fruit consumption compared with both the control (difference in predicted counts=0.69, 95% CI 0.32-1.06; *P*<.001) and standard DA groups (difference in predicted counts=0.48, 95% CI 0.11-0.86]; *P*=.01). The DA groups were more likely to know whether their risk was low, medium, or high than the control group (literacy-sensitive DA: incident rate ratio [IRR]=1.28, 95% CI 1.04-1.58; *P*=.02 and standard DA: IRR=1.41, 95% CI 1.14-1.74; *P*=.002). The standard DA group was more likely to know their exact risk percentage result compared with the control group (IRR=3.25, 95% CI 1.31-8.07; *P*=.01; Table 5). There were significant differences among DA groups by health literacy levels for self-reported calls to the Heart Foundation helpline (*P*<.001) and verbatim knowledge of CVD percentage risk at follow-up (*P*<.001). None of the participants with low health literacy reported calling the helpline or remembered their exact CVD risk in the control group. Standard DA increased both outcomes in all health literacy groups, and literacy-sensitive DA increased both outcomes in the low and high health literacy groups but not in the medium group (Table 6).

Postintervention Differences Among Heart Age Groups

Immediately after the intervention, there were no differences between the 2 heart age groups in the primary outcome of lifestyle intentions or secondary outcomes of risk perception or decisional conflict. For hypothesis 3, the heart age group was less likely to have a positive emotional response (mean difference −0.56, 95% CI −0.88 to −0.24; *P*=.001; Cohen *d*=0.23), less likely to perceive the message as credible (mean difference −0.20, 95% CI −0.35 to −0.05; *P*=.01; Cohen *d*=0.17), and more likely to know whether their risk was low, medium, or high (odds ratio 2.03, 95% CI 1.33-3.08; *P*=.001), compared with the percentage risk only group (Table 7). When the heart age result was older, there were significant differences indicating less positive (mean difference −0.75, 95% CI −1.19 to −0.31; *P*=.001; Cohen *d*=0.31) and more negative (mean difference 0.57, 95% CI 0.12 to 1.02; *P*=.01; Cohen *d*=0.23) emotional responses, lower credibility (mean difference −0.29, 95% CI −0.49 to −0.09; *P*=.005; Cohen *d*=0.25) and higher perceived risk level (odds ratio 2.11, 95% CI 1.31-3.39; *P*=.002) when heart age was shown. No such differences were found in those who received the same age or younger results (Table 7).

4-Week Differences Among Heart Age Groups

At the 4-week follow-up, there were no significant differences among the heart age groups in terms of lifestyle behavior change, seeing a doctor for a heart health check, or gist knowledge of risk level (Table 7). Unsurprisingly, being shown heart age led to greater gist knowledge of heart age (IRR 2.90, 95% CI 2.10-3.99; *P*<.001) and verbatim knowledge of heart age (IRR 18.13, 95% CI 4.36-75.48; *P*<.001) compared with those who were not shown their heart age, but there was no

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difference between the heart age and percentage risk only groups for knowledge of percentage risk. Within the heart age group that saw both risk formats, participants were more likely to have verbatim knowledge of their heart age (11%) than their percentage risk (6%, chi-square test for paired proportions by McNemar: χ^2_1=6.1; *P*=.01, difference in proportions 5.4%, 95% CI 0.8%-10.0%). When the heart age result was older, there were significant differences indicating more vigorous exercise (mean difference 0.58, 95% CI 0.09-1.07; *P*=.02), more vegetable serves (mean difference 0.57, 95% CI 0.05-1.09; *P*=.032), higher chance of meeting guidelines for exercise (IRR 1.23, 95% CI 1.05-1.45; *P*=.01) and diet (IRR 1.48, 95% CI 1.00-2.18; *P*=.048), when heart age was shown. When the heart age result was the same or younger than their current age, there were significant differences, indicating fewer soft drink serves (mean difference −0.34, 95% CI −0.61 to −0.07; *P*=.012) and a higher chance of calling the Heart Foundation helpline (IRR 12.66, 95% CI 1.76 to 4.03; *P*<.001), when heart age was shown (Table 7).

Stage 3

Participant interviews were conducted in 4 stages so that any user feedback from the interviews could be discussed among the team (C Bonner, C Batcup, and JA) and then implemented into the calculator for the next interviews in an iterative process. The issues addressed in each round of interviews are shown in Multimedia Appendix 2.

Discussion

Principal Findings

We used both a mixed method development and evaluation process to produce a CVD DA that is effective for improving verbatim and gist knowledge of CVD risk and fruit consumption after 4 weeks. The resulting intervention is a scalable eHealth tool suitable for people with varying levels of health literacy. This consumer tool will supplement a GP version for use within consultations [38,39], providing GPs with a clear action for their patients to follow up when lifestyle change is recommended. This paper provides an example of how to apply literacy-sensitive design principles to evidence-based decision-making and behavior change tools. The results show that literacy-sensitive DAs can support people with lower health literacy in making informed decisions, while still being suitable for the general population.

Comparison With Previous Work

A recent review of DAs for people with lower health literacy [57,58] showed that DAs that use health literacy design strategies lead to improved knowledge, decisional conflict, and decision-making outcomes. Furthermore, DAs that used explicit strategies to reduce cognitive burden showed greater improvements in knowledge for people with low health literacy and from disadvantaged backgrounds [58]. The review highlighted the need for more consideration of health literacy in DA development. This study addresses these findings in the context of CVD prevention for the first time.

We observed several interactions with health literacy, showing the importance of considering this as a covariate when investigating shared decision-making and behavior change outcomes. The literacy-sensitive version of the DA produced more negative emotional responses and greater intention to speak to a doctor about medication options to reduce CVD risk among those with lower health literacy. This may reflect risk and choice awareness in this group if they had not previously considered themselves to have risk factors for heart disease that could be addressed with preventive medication. As this sample was predominantly low-risk, we would not want a DA to lead to greater actual medication uptake in this group; however, speaking with a physician about risk and how to reduce it may be a positive outcome in line with guidelines to assess risk in this age group [1]. We replicated previous DA studies by finding increased knowledge of risk among the DA groups compared with the control group [37]. We also replicated our previous finding that a literacy-sensitive action plan can improve diet outcomes across different levels of health literacy, although this was more marked for people with low health literacy [31,59].

This study also replicated several heart age effects found in reviews of previous research, in that it leads to a more negative emotional response, increased gist and verbatim knowledge of heart age, but not percentage risk, and reduced credibility, but is neutral for lifestyle change overall [60,61]. Our subgroup analyses suggest that more nuanced study designs are required to better understand the effects of heart age. First, among those who were shown their heart age, gist knowledge of percentage risk initially improved, but after 4 weeks, gist and verbatim knowledge were higher for heart age than for percentage risk. Previous studies have shown that people who receive an older heart age may react defensively and focus on other information, such as a low short-term risk level, which in turn may reduce their credibility of the risk result [26,62]. Analyses of people who received an older heart age result suggest that it may be useful as a marketing tool to gain attention and initiate behavior change, but knowledge of heart age did not translate to knowledge of risk. For the intended purpose of a DA to be used in a clinical context, the focus must be on validated risk results to make informed decisions about medication. Therefore, we decided to use the non–heart age version of the literacy-sensitive DA in future research in general practice. However, web-based heart age tools can incorporate DA and action plan elements with no detrimental effects.

Future Directions

Future trials need to be designed to isolate older heart age results and follow-up behavior over time. In considering how to power such trials, researchers will need to consider how the specific heart age tool they use is calibrated for the intended population (eg, approximately 50% older in our sample using the New Zealand method vs approximately 80% in the Australian/United Kingdom Heart Foundation tool [25,26]). The primary outcomes also need to be considered carefully. Most heart age research has been conducted with a primary outcome of immediate lifestyle change intentions, where we found no differences. More research could be done to verify the self-reported behavior change among people receiving older heart age results we

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observed after 4 weeks, using more objective measures such as pedometers.

The end-user interviews were helpful for improving simple navigation and wording issues in the literacy-sensitive version of the DA, but there were some larger issues that could not be resolved using a web-based tool. Most users did not know their blood pressure or cholesterol results; however, even if they had been assessed recently, they had difficulty understanding where different numbers should be entered. This was particularly difficult for cholesterol results in pathology test reports. Therefore, we will test the final revised tool in clinical practice to address the issue of unknown blood pressure and cholesterol, which reduces the accuracy and limits the display of options in line with the current medication guidelines. This tool will be integrated with additional Heart Foundation resources to improve other lifestyle outcomes.

Strengths and Limitations

A major strength of this study is that we were able to recruit a large, diverse sample in terms of health literacy and risk results. We had sufficient follow-up to run the study per protocol despite the COVID-19 disruptions and observed no difference in dropouts for key variables. A limitation is that the web-based panel sample may not be representative of the general population and may better reflect users of web-based heart age tools than patients presenting to primary care for CVD risk assessment. Furthermore, many participants did not know their blood pressure and cholesterol levels, which may have affected their response to the DA because of a less accurate CVD risk result. However, the use of averages reflects the approach used in currently available consumer tools for CVD risk assessment [26-28]. Different countries also use different CVD risk models or heart age algorithms, which may affect the results given the differences we observed in the older heart age sample. We conducted a large number of analyses on multiple outcomes; however, given the exploratory nature of the study, we did not make adjustments for multiple comparisons. The study was powered by moderate effect sizes and therefore may have lacked the power to detect more subtle differences; however, these findings will be useful for informing sample size calculations for future studies. Finally, we used validated outcomes where possible but behavior changes were self-reported. Future research on heart age should use objective measures over time.

Conclusions

This study shows the value of combining health-literacy–sensitive design with best practice risk communication and behavior change tools. Although aimed at addressing the needs of people with lower health literacy, this approach improved knowledge of CVD risk, heart age, and behavior in a sample with varying health literacy levels. The role of heart age remains somewhat unclear, with both advantages and disadvantages; however, there is no clear evidence of an effect on lifestyle change intentions or behavior overall. Further research should investigate implementation pathways for integrating such consumer tools with clinical practice and distinguish between older and younger heart age results.

Acknowledgments

This study was funded by a Vanguard grant from the National Heart Foundation of Australia (ID 102215).

Conflicts of Interest

C Bonner advises the Heart Foundation on health literacy and risk communication issues.

Multimedia Appendix 1
Example intervention content.
[XLSX File (Microsoft Excel File), 2328 KB - cardio_v6i1e34142_app1.xlsx]

Multimedia Appendix 2
Issues addressed in each round of interview feedback.
[XLSX File (Microsoft Excel File), 13 KB - cardio_v6i1e34142_app2.xlsx]

Multimedia Appendix 3
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1286 KB - cardio_v6i1e34142_app3.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
CVD: cardiovascular disease
DA: decision aid
GP: general practitioner
IRR: incident rate ratio

Edited by T Leung; submitted 07.10.21; peer-reviewed by E Hass, M Kopka; comments to author 16.12.21; revised version received 10.02.22; accepted 05.03.22; published 15.04.22.

Please cite as:
Bonner C, Batcup C, Ayre J, Cvejic E, Trevena L, McCaffery K, Doust J
The Impact of Health Literacy–Sensitive Design and Heart Age in a Cardiovascular Disease Prevention Decision Aid: Randomized Controlled Trial and End-User Testing
JMIR Cardio 2022;6(1):e34142
URL: https://cardio.jmir.org/2022/1/e34142
doi:10.2196/34142
PMID:35436208

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Letter to the Editor

Using Caution When Interpreting Gender-Based Relative Risk. Comment on “The Effect of Cardiovascular Comorbidities on Women Compared to Men: Longitudinal Retrospective Analysis”

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Abstract

(JMIR Cardio 2022;6(1):e34647) doi:10.2196/34647

KEYWORDS

gender gap; sex differences; cardiovascular diseases; acute myocardial infarction; chronic ischemic heart disease; gender; diabetes; smoking; risk factors; comorbidities; relative risk; interaction

Dervic et al [1] have conducted an impressive, comprehensive analysis of Austrian health records to compare the relative risks of comorbidities for cardiovascular disease (CVD) among men and women. Based on the higher relative risks observed for most comorbidities among women, the authors suggested that “women appear to be more affected” by these comorbidities and that their findings may have public health relevance in designing screening and prevention strategies. However, theoretical epidemiological works have clearly shown that the heterogeneity of relative risks alone generally does not allow causal inference for interaction between exposures or evaluation of public health implications [2,3].

Consider the following intuitive example: in contrast to CVD or other diseases of complex multifactorial origin where the causes for individual cases are practically always obscure, let us consider a “disease” with a clear origin, namely homicide. In this example, we have an imaginary country with a northern and southern region. In both regions, there are 20 million inhabitants with an equal distribution of men and women (ie, 10 million men and 10 million women in each region). Normally, in both regions, 1 woman per million per year dies of homicide in this country; the corresponding number is 2 per million for men. However, last year, a serial killer started to operate exclusively in the northern region. He is a sniper shooting from far away; hence, he cannot see the sex of his victims. It follows that he does not discriminate between men and women. Last year, he killed 20 northerners: 10 men and 10 women. Thus, last year, the relative risk of being killed when we compare northerners to southerners will be 2 for women and 1.5 for men. Despite the higher relative risk for women, the sniper is clearly equally dangerous to both men and women.

When interpreting the findings of Dervic et al [1], we need to take into account the considerably higher baseline risk, that is, the excess risk of CVD without the respective comorbidities

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for the men in their study. Depending on the degree of male excess risk among the unexposed, the lower relative risk for CVD with comorbidities observed by the authors among men can also indicate no difference in the effect of these factors between the sexes or an even more detrimental effect in men compared with women.

Conflicts of Interest

None declared.

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Abbreviations

CVD: cardiovascular disease

Edited by T Leung; submitted 02.11.21; this is a non–peer-reviewed article;accepted 14.03.22; published 25.03.22.

Please cite as:
Janszky I
Using Caution When Interpreting Gender-Based Relative Risk. Comment on "The Effect of Cardiovascular Comorbidities on Women Compared to Men: Longitudinal Retrospective Analysis"
JMIR Cardio 2022;6(1):e34647
URL: https://cardio.jmir.org/2022/1/e34647
doi:10.2196/34647
PMID:35333181

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Letter to the Editor

Authors' Reply to: Using Caution When Interpreting Gender-Based Relative Risk. Comment on "The Effect of Cardiovascular Comorbidities on Women Compared to Men: Longitudinal Retrospective Analysis"

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Related Articles:

Comment on: https://cardio.jmir.org/2021/2/e28015

Comment on: https://cardio.jmir.org/2022/1/e34647

Abstract

(JMIR Cardio 2022;6(1):e36801) doi:10.2196/36801

KEYWORDS

gender gap; sex differences; cardiovascular diseases; acute myocardial infarction; chronic ischemic heart disease; gender; diabetes; smoking; risk factors; comorbidities; relative risk; interaction

We thank Janszky [1] for their time and observations on our paper [2]. We appreciate the comments.

Our analysis was done on a large data set of hospital diagnoses from 1997 to 2014. We developed a systematic approach to detect all significant gender differences across all comorbidities associated with cardiovascular disease (CVD). In our paper [2], we reported all risk factors and calculated sex differences as a measure of differences using logarithmic odds ratios between male and female patients in units of pooled standard errors. As a limitation, we pointed out that we cannot rule out specific unobserved confounders as well as the limitations of our in-hospital data set. We thank Janszky [1] for providing an illustrative example of how such a confounding influence could work.

It is clear that correlation is not causation, and we did not make any statement on causality. We analyzed the order of diagnoses by conducting a "time directionality analysis," and our results showed us which diagnoses were "typically diagnosed before."

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In the *Limitations* section, we emphasized this as well: “Given the purely observational nature of our dataset, no statements on causality can be made based on this analysis.” Janszky’s [1] comment clearly shows why it is important to repeatedly stress such limitations.

The motivation behind our work is to increase awareness of the need for gender-specific medicine. It has been well described that the female sex overall is protective in the development of CVD due to biological and psychosocial factors but that metabolic diseases like diabetes attenuate this protective effect [3]. Yet, our knowledge on potential sex-dimorphic pathophysiological mechanisms remains limited, in particular in relation to CVD. With our work, we aim to show how observational data can be used to rapidly generate hypotheses regarding sex differences in disease risk at scale and thereby initiate further research that aims to clarify their potential causal mechanisms.

Conflicts of Interest

None declared.

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Abbreviations

CVD: cardiovascular disease

Edited by T Leung; submitted 26.01.22; this is a non–peer-reviewed article;accepted 14.03.22; published 25.03.22.

Please cite as:
Dervic E, Deischinger C, Haug N, Leutner M, Kautzky-Willer A, Klimek P
Authors’ Reply to: Using Caution When Interpreting Gender-Based Relative Risk. Comment on “The Effect of Cardiovascular Comorbidities on Women Compared to Men: Longitudinal Retrospective Analysis”
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URL: https://cardio.jmir.org/2022/1/e36801
doi:10.2196/36801
PMID:35333178

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Original Paper

Surveillance of Arrhythmia in Patients After Myocardial Infarction Using Wearable Electrocardiogram Patch Devices: Prospective Cohort Study

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Abstract

Background: Acute myocardial infarction may be associated with new-onset arrhythmias. Patients with myocardial infarction may manifest serious arrhythmias such as ventricular tachyarrhythmias or atrial fibrillation. Frequent, prolonged electrocardiogram (ECG) monitoring can prevent devastating outcomes caused by these arrhythmias.

Objective: We aimed to investigate the incidence of arrhythmias in patients following myocardial infarction using a patch-type device—AT-Patch (ATP-C120; ATsens).

Methods: This study is a nonrandomized, single-center, prospective cohort study. We evaluated 71 patients who had had a myocardial infarction and had been admitted to our hospital. The ATP-C120 device was attached to the patient for 11 days and analyzed by 2 cardiologists for new-onset arrhythmic events.

Results: One participant was concordantly diagnosed with atrial fibrillation. The cardiologists diagnosed atrial premature beats in 65 (92%) and 60 (85%) of 71 participants, and ventricular premature beats in 38 (54%) and 44 (62%) participants, respectively. Interestingly, 40 (56%) patients showed less than 2 minutes of sustained paroxysmal atrial tachycardia confirmed by both cardiologists. Among participants with atrial tachycardia, the use of β-blockers was significantly lower compared with patients without tachycardia (70% vs 90%, *P*=.04). However, different dosages of β-blockers did not make a significant difference.

Conclusions: Wearable ECG monitoring patch devices are easy to apply and can correlate symptoms and ECG rhythm disturbances in patients following myocardial infarction. Further study is necessary regarding clinical implications and appropriate therapies for arrhythmias detected early after myocardial infarction to prevent adverse outcomes.

(JMIR Cardio 2022;6(1):e35615) doi:10.2196/35615

KEYWORDS

myocardial infarction; arrhythmia; wearable electronic device; wearable; ECG; electrocardiogram; patch; patch devices; atrial fibrillation; heart; rhythm; cardiology; cardiologist; cohort study; tachycardia; beta-blocker

Introduction

Acute myocardial infarction is a common cardiac emergency associated with high potential for mortality and a substantial risk of complications [1]. The majority of patients with acute myocardial infarction develop some form of arrhythmia during or immediately after the events, and more than 10% of these patients manifest serious arrhythmias such as ventricular tachyarrhythmias or atrial fibrillation, which may cause disabling stroke and sudden cardiac death [2,3]. These adverse events most frequently occur during the first months after myocardial infarction [4]. Therefore, close electrocardiographic

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(ECG) monitoring during this period is extremely important to avoid severe outcomes.

However, conventional ECG monitoring devices such as multilead portable ECG monitoring or Holter monitoring devices are not useful for continuous monitoring of ECG signals for longer than 24 hours, particularly after discharge from the hospital [5]. In addition, implantable loop recorders allow for a longer duration of ECG monitoring [6] but require an invasive procedure, making patients vulnerable to infection and discomfort. Due to these technical and other difficulties, data regarding types and frequencies of arrhythmia after acute myocardial infarction are scarce.

To compensate for these drawbacks, a new generation of ECG monitoring devices with advanced technologies have been developed [7]. The Zio Patch (iRhythm Technologies), a single-use, patch-type continuous ECG monitoring device, can continuously monitor the patient's ECG signals for 2 weeks and has been applied to more than 400,000 patients [8]. This device enables a longer duration of monitoring, as well as wireless data transfer and unlike conventional ECG monitoring devices, does not interrupt the daily life of patients [9].

A wearable ECG monitoring patch device can detect ECG rhythm disturbances in patients with postmyocardial infarction. In this study, we investigated the incidence of arrhythmias in patients with postmyocardial infarction using another new wearable patch-type device—AT-Patch (ATP-C120; ATsens).

Methods

Recruitment

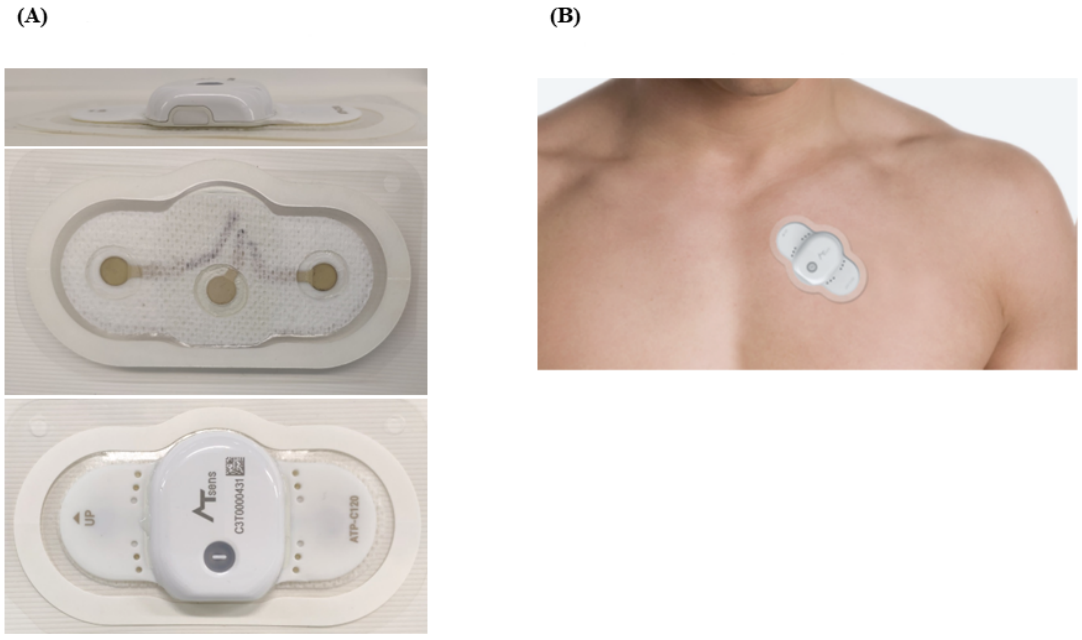
This study is a nonrandomized, single-center, prospective cohort study. We evaluated patients who had been admitted to our hospital for myocardial infarction and discharged after treatment. Eligible patients had a history of acute myocardial infarction and provided written informed consent to participate. Exclusion criteria were as follows: (1) previously diagnosed with atrial fibrillation, (2) implanted pacemaker, cardioverter-defibrillator, or any electrical devices, and (3) skin problems such as allergic contact dermatitis. Our prospective study enrolled 73 adults aged 55 years or older from April 2020 to November 2020. Among them, 2 participants dropped out due to loss of the device before data acquisition.

The Experimental Wearable Patch-Type Device

ATP-C120 is a single-lead ECG monitoring device that can continuously monitor the ECG signals for as long as 14 days (11 days if the device is connected to a smartphone via Bluetooth) when attached to the skin over the area of the heart (Figure 1). The device weighs about 13 g, with dimensions of 95.0 × 50.6 × 8.3 mm. This is the smallest of the contemporary wearable patch devices worldwide.

When the device is attached to the patient, several predefined methods are used to prevent the occurrence of noise or signal loss. First, the skin is cleansed and disinfected using a 70% ethanol solution. Skin hair is removed if necessary. Subsequently, the protective film is removed from the patient-side surface of the device. The device is placed at the left third intercostal space, tilted inward 45 degrees. A continuous ECG signal is recorded to a memory card for 11 days. Subsequently, the device is linked to a computer and the data are downloaded and analyzed by a specific program (AT-report) provided by ATsens.

Figure 1. The appearance of ATP-C120 (A) The actual photographs of the ATP-C120 (image courtesy of ATsens). (B) The placement of the ATP-C120 patch (image courtesy of ATsens).



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Trial Schedule

According to institutional Good Clinical Practice for medical devices, we attached the experimental ATP-C120 device to participating patients. We obtained demographic data, as well as past and present medical and drug administration history, and conducted physical examinations (height, body weight, and vital signs such as systolic and diastolic blood pressure and pulse). In addition, laboratory parameters (complete blood count, electrolyte, blood urea nitrogen, creatinine, estimated glomerular filtration rate, liver function tests, lipid panel, fasting blood sugar, and glycated hemoglobin A_{1c} or HbA_{1c}) and the 12-lead ECG results before the attachment of the ATP-C120 device were obtained. We detached the device after 11 (SD 5) days and recorded the date and time. Two independent cardiologists analyzed the recorded data for arrhythmic detection.

Sample Size Calculation

We hypothesized that ATP-C120 could detect 10% of new-onset atrial fibrillation in patients with postmyocardial infarction. We set the type I error as .05 and confidence limit as 5%. Application of these parameters resulted in 139 participants. The attrition rate was set as 5% and, thus, the final sample size was 146 participants. However, we only enrolled 73 patients because of limited enrollment time and funding, which was adjusted by the project manager of the Korean Health Industry Development Institute.

Statistical Analyses

Data are presented as numbers and frequencies for categorical variables and as mean (SD) for continuous variables. The incidence of atrial fibrillation followed by myocardial infarction is described as proportions and 95% CIs. A 2-sided *P* value of <.05 was indicative of a statistically significant difference. To evaluate interobserver reliability and interdevice reliability, Cohen κ coefficient was calculated. For comparisons between patients with or without atrial tachycardia, chi-square test (or Fisher exact test when any expected count was <5 for a 2 × 2 table) was performed for categorical variables. Statistical analyses were performed using R (version 3.1.0; The R Foundation for Statistical Computing).

Ethics Approval

The study was reviewed and approved by the Institutional Review Board of Seoul National University Bundang Hospital (B-2003/603-002).

Results

Baseline Characteristics

A total of 71 patients who had a history of acute myocardial infarction were included in the analyses. The baseline characteristics are shown in Table 1. The mean age was 67.6 (SD 8.3) years, and 59 (83%) patients were men. Among the study population, 23 (32%) patients were clinically diagnosed with ST-segment elevation myocardial infarction, and 40 (56%) participants were attached with the ATP-C120 device within 6 months of acute myocardial infarction. Patients with previous heart failure were not enrolled in this study. The average left ventricular ejection fraction (LVEF) was 57.1% (SD 8.2%), and pro–B-type natriuretic peptide level was 370.3 (SD 505.3) pg/L. For medication, 61 (86%) participants received aspirin, whereas 37 (52%) participants received P2Y12 inhibitor. In addition, among the study population, 56 (79%) patients received β-blockers, 23 (32%) patients received renin-angiotensin system inhibitors, and 18 (25%) patients received calcium channel blockers.

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Table 1. Profile of study population (N=71).

Characteristics	Values
Age (years), mean (SD)	67.6 (8.3)
Gender, n (%)	
Male	59 (83)
Female	12 (17)
Systolic blood pressure (mm Hg), mean (SD)	129.8 (18.6)
Diastolic blood pressure (mm Hg), mean (SD)	73.5 (11.3)
Heart rate (beats/min), mean (SD)	71.6 (11.8)
BMI (kg/m^2), mean (SD)	24.3 (3.0)
Clinical diagnosis of STEMI[a], mean (SD)	23 (32)
Post myocardial infarction period, n (%)	
<6 months	40 (56)
6-12 months	3 (4)
≥12 months	28 (39)
Previous heart failure, n (%)	0 (0)
Hypertension, n (%)	50 (70)
Diabetes, n (%)	29 (41)
Dyslipidemia, n (%)	66 (93)
Smoking, n (%)	
Current smoker	14 (20)
Former smoker	32 (45)
Nonsmoker	21 (30)
Unknown	4 (6)
History of stroke, n (%)	3 (4)
Chronic kidney disease, n (%)	3 (4)
Echocardiography	
LVEF[b] (%)	57.1 (8.2)
LAVI[c] (mL/m^2)	37.0 (29.3)
Laboratory test	
Creatinine (mg/dL)	0.9 (0.3)
Total cholesterol (mg/dL)	150.6 (42.3)
LDL[d] (mg/dL)	89.7 (28.6)
ProBNP[e] (pg/L)	370.3 (505.3)
Troponin I (ng/mL)	8.8 (14.8)
CK-MB[f] (mg/dL)	20.7 (39.5)
Discharge medication	
Aspirin	61 (86)
P2Y12 inhibitor	37 (52)
β-blocker	56 (79)
RAS inhibitor[g]	23 (32)
Calcium channel blocker	18 (25)

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Characteristics	Values
Statin	71 (100)

[a]STEMI: ST-segment elevation myocardial infarction.

[b]LVEF: left ventricular ejection fraction.

[c]LAVI: left atrial volume index.

[d]LDL: low-density lipoprotein.

[e]ProBNP: pro–B-type natriuretic peptide.

[f]CK-MB: creatine kinase-MB.

[g]RAS inhibitor: renin-angiotensin system inhibitor.

Clinical Outcomes

The incidence of arrhythmias as detected by ATP-C120 and confirmed by 2 cardiologists (C1 and C2) is shown in Table 2. One participant was concordantly diagnosed with atrial fibrillation by both cardiologists (Figure 2A). The cardiologists determined that atrial premature beats occurred in 65 (92%) (C1) and 60 (85%) patients (C2), and ventricular premature beats occurred in 38 (54%) (C1) and 44 (62%) patients (C2). No ventricular fibrillation was recorded and only 1 nonsustained ventricular tachycardia event was noted by both cardiologists (Figure 2B). Remarkably, 40 (56%) patients (according to both C1 and C2) showed paroxysmal atrial tachycardia, which was sustained less than 2 minutes (Figure 2C).

In Table 3, additional analyses of patients with atrial tachycardia are shown.

In general, there were no significantly different characteristics between patients with atrial tachycardia and those without atrial tachycardia. The timing of monitoring after acute myocardial infarction was not significantly different (55% vs 45%; *P*=.56). The LVEF (mean 56.1%, SD 8.6% vs mean 57.9%, SD 7.8%; *P*=.35) and the size of left atrium or left atrial volume index (mean 32.3, SD 8.9 vs mean 35.6, SD 12.9; *P*=.31) were not significant contributors to atrial tachycardia. However, among medications, the use of β-blockers made a significant difference (70% vs 90%; *P*=.04) (Table 3). Furthermore, when we analyzed participants based on different β-blocker dosages, there were no significant differences (Table 4).

Lastly, reported adverse events associated with the ATP-C120 patch are described in Table 5. Among the participants, 21 (30%) complained of itching during the patch monitoring period, 2 (3%) experienced abrasion (Figure 3A), 1 experienced bullae (Figure 3B), and 1 showed erosion but fully recovered without scarring or altered pigmentation (Figure 3C).

Table 2. Incidence of arrhythmias during follow-up.

Incidence of arrhythmias	Participants (N=71)	
	Cardiologist 1, n (%)	Cardiologist 2, n (%)
Atrial premature beats	65 (92)	60 (85)
Ventricular premature beats	38 (54)	44 (62)
Atrial tachycardia	40 (56)	40 (56)
Nonsustained ventricular tachycardia	1 (1)	2 (3)
Ventricular fibrillation	0 (0)	0 (0)
Atrial fibrillation	1 (1)	1 (1)

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Figure 2. Examples of the detected arrhythmia (A) Atrial fibrillation. (B) Nonsustained ventricular tachycardia. (C) Atrial tachycardia.

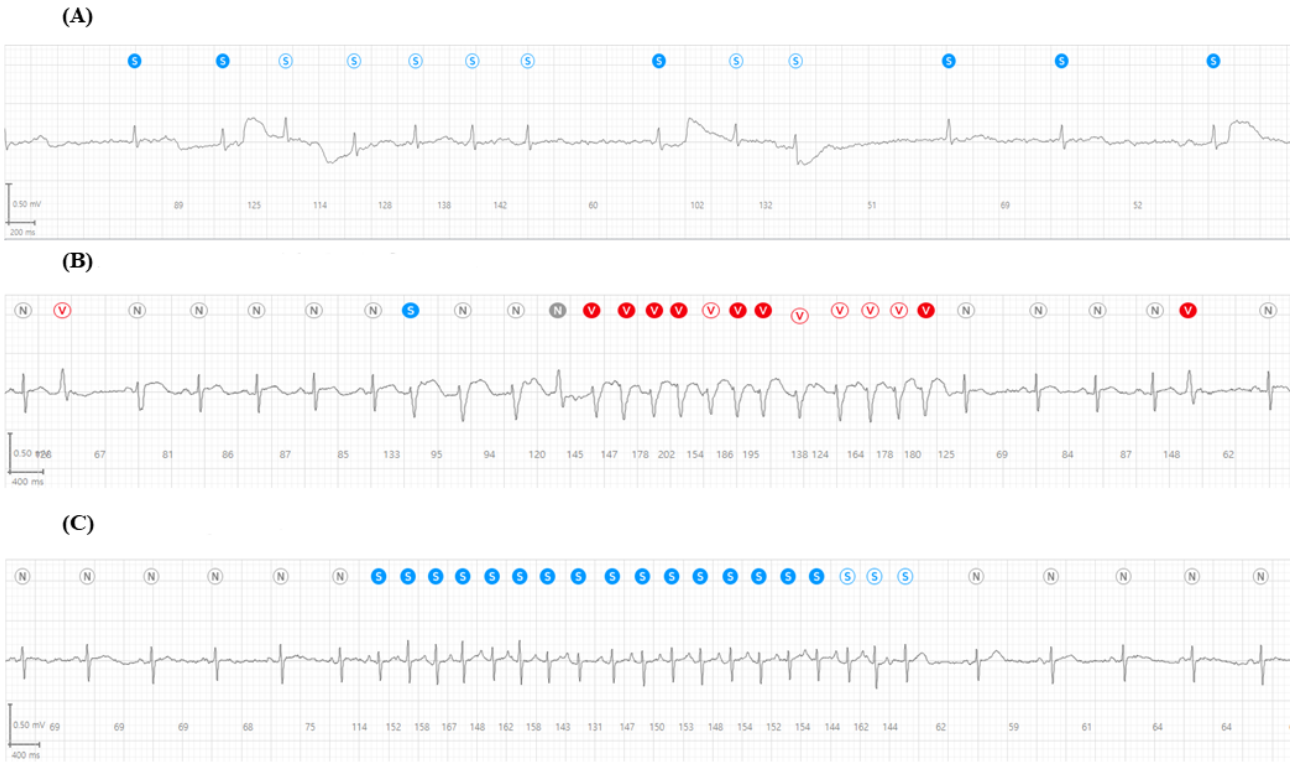

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Table 3. Characteristics of patients with atrial tachycardia (N=71).

Characteristics	Atrial tachycardia		
	Yes (n=40)	No (n=31)	*P* value
Age (years), mean (SD)	68.7 (7.7)	66.2 (8.9)	.22
Male, n (%)	32 (80)	27 (87)	.65
BMI (kg/m^2), mean (SD)	24.2 (2.9)	24.4 (3.1)	.73
Systolic blood pressure (mm Hg), mean (SD)	128.2 (18.2)	131.8 (19.2)	.43
Diastolic blood pressure (mm Hg), mean (SD)	73.2 (11.3)	71.5 (16.5)	.64
Heart rate (beats/min), mean (SD)	73.2 (11.3)	71.8 (11.2)	.93
Hypertension, n (%)	28 (70)	22 (71)	>.99
Diabetes mellitus, n (%)	18 (45)	11 (35)	.57
Dyslipidemia, n (%)	38 (95)	28 (90)	.65
Smoking, n (%)			.74
Current smoker	7 (19)	7 (23)	
Former smoker	17 (46)	15 (50)	
Nonsmoker	13 (35)	8 (27)	
History of stroke, n (%)	0 (0)	3 (10)	.08
Chronic kidney disease, n (%)	3 (8)	0 (0)	.25
Diagnosis of STEMI[a], n (%)	7 (23)	16 (40)	.19
Postmyocardial infarction period, n (%)			.92
<6 months	22 (55)	18 (58)	
6-12 months	2 (5)	1 (3)	
≥12 months	16 (40)	12 (39)	
Echocardiography, mean (SD)			
LVEF[b] (%)	56.1 (8.6)	57.9 (7.8)	.35
LAVI[c] (mL/m^2)	32.3 (8.9)	35.6 (12.9)	.31
Laboratory test, mean (SD)			
Creatinine (mg/dL)	1.0 (0.4)	0.9 (0.2)	.34
Total cholesterol (mg/dL)	148.0 (40.0)	153.8 (45.4)	.58
LDL[d] (mg/dL)	87.2 (28.1)	93.3 (29.4)	.41
ProBNP[e] (pg/L)	298.1 (316.5)	464.7 (683.0)	.43
Troponin I (ng/mL)	7.7 (9.7)	10.3 (19.6)	.61
CK-MB[f] (mg/dL)	16.0 (20.4)	26.5 (55.0)	.51
Discharge medications, n (%)			
RAS inhibitor[g]	9 (23)	14 (45)	.04
β-blocker	28 (70)	28 (90)	.04
Calcium channel blocker	8 (20)	10 (32)	.24
CHA_2DS_2-VASc[h] score, mean (SD)	2.3 (1.2)	2.6 (1.4)	.22

[a]STEMI: ST-segment elevation myocardial infarction.

[b]LVEF: left ventricular ejection fraction.

[c]LAVI: left atrial volume index.

[d]LDL: low-density lipoprotein.

[e]proBNP: pro–B-type natriuretic peptide

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[f]CK-MB: creatine kinase-MB.

[g]RAS inhibitor: renin-angiotensin system inhibitor.

[h]CHA_2DS_2-VASc: congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke, vascular disease, age 65-74 years, sex category.

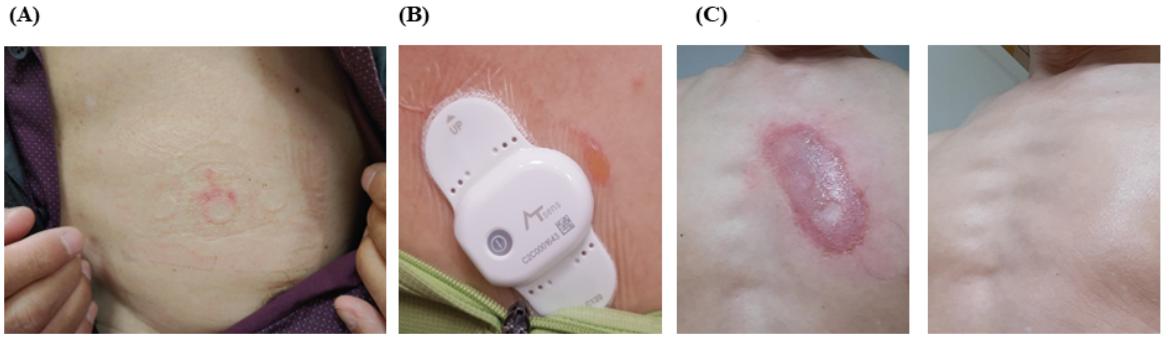
Table 4. Comparison of incidence of atrial tachycardia with use of different dosages of β-blockers (N=71).

β-blocker	Atrial tachycardia		
	Yes (n=40), n (%)	No (n=31), n (%)	*P* value
No	12 (30)	2 (7)	.03
Low	13 (33)	15 (48)	.27
Intermediate	9 (23)	9 (29)	.73
High	6 (6)	5 (16)	>.99

Table 5. Adverse events associated with the ATP-C120 patch.

Reported adverse events	Participants (N=71), n (%)
Itching	21 (30)
Pricking	2 (3)
Abrasion	2 (3)
Erosion	1 (1)
Bullae	1 (1)

Figure 3. Adverse events from use of ATP-C120 patch.



Discussion

Principal Findings

In this study, we analyzed 71 patients' ECG signals after myocardial infarction for 11 days. Several studies reported that myocardial infarction may be associated with new-onset arrhythmias. In particular, some fatal arrhythmic events such as ventricular tachyarrhythmia often occur during or immediately after acute myocardial infarction [2,3]. Prolonged conventional ECG monitoring increases the detection rate of arrhythmic events [10]. Therefore, we designed the study to detect arrhythmias in patients with postmyocardial infarction, using the ATP-C120, a new patch device. This device is a single-lead ECG monitoring device that can continuously monitor the ECG signal for up to 11 days. The ATP-C120 has recently demonstrated that its diagnostic capability and safety compares to conventional ECG monitoring systems [11].

In this study, potentially fatal arrhythmias such as ventricular tachyarrhythmias or atrial fibrillation, which can produce devastating events, were scarcely detected. However, a moderate number of participants with postmyocardial infarction had nonsustained atrial tachycardia events. Several studies reported that nonsustained atrial tachycardia and paroxysmal atrial fibrillation share similar electrical stimulating pathways [12]. Other studies reported that episodes of atrial tachycardia may cause the remodeling of the pulmonary vein cardiomyocytes and the left atrium, and that atrial tachycardia is potentially related to arrhythmogenesis of paroxysmal atrial fibrillation [13]. Although in our study the device only detected 1 exact paroxysmal atrial fibrillation, a moderate number of nonsustained atrial tachycardia episodes were recorded, indicating the unstable hemodynamic and electrical impulses of the atria after myocardial infarction.

β-Blocker therapy after myocardial infarction is necessary for survival [14]. Therefore, guidelines based on randomized controlled and large observational studies recommend β-blocker therapy for all patients after myocardial infarction [15,16]. In our study, nonsustained atrial tachycardia was more frequently found in patients who were not receiving β-blocker therapy.

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The antiarrhythmogenic effect of β-blocker therapy may stabilize atrial electrophysiology. Therefore, this study suggests that long-term β-blocker therapy after myocardial infarction for prevention of atrial degeneration and new-onset atrial fibrillation needs to be further investigated. Interestingly, the dose of β-blocker did not affect the incidence of paroxysmal atrial tachycardia. This implies that β-blockers may be important when used at any tolerable dose after acute myocardial infarction.

Strengths and Limitations

This study was a comprehensive analysis of the incidence of postmyocardial infarction arrhythmias. One major limitation of our study was the small number of patients. Therefore, only a few clinically important arrhythmic events were recorded. However, this does not indicate that prolonged monitoring after myocardial infarction only shows trivial arrhythmic episodes. This study showed that there was an interestingly high incidence of supraventricular arrhythmic events. This infers the need for further investigation regarding the progression to atrial fibrillation and fatal complications after arrhythmic episodes.

Conclusions

A wearable ECG monitoring patch device is easy to apply and can detect ECG rhythm disturbances in patients with postmyocardial infarction. Further study is necessary regarding clinical implications and therapeutic approaches for early detected arrhythmias after myocardial infarction to prevent adverse outcomes among patients.

Acknowledgments

This work was supported by the “Supporting Project to evaluation New Domestic Medical Devices in Hospitals” funded by the Ministry of Health and Welfare (MOHW) and the Korea Health Industry Development Institute (KHIDI) (grant number HI20C1456 and HI19C0655).

Conflicts of Interest

CHY owns stock in ATsens, in Seongnam, Korea. The other authors declare no conflicts of interest.

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Abbreviations

ECG: electrocardiogram
LVEF: left ventricular ejection fraction

Edited by T Leung; submitted 10.12.21; peer-reviewed by D Seshadri, SS Amritphale; comments to author 01.02.22; revised version received 09.03.22; accepted 30.04.22; published 09.06.22.

Please cite as:
Kwun JS, Yoon CH, Kim SH, Jeon KH, Kang SH, Lee W, Youn TJ, Chae IH
Surveillance of Arrhythmia in Patients After Myocardial Infarction Using Wearable Electrocardiogram Patch Devices: Prospective Cohort Study
JMIR Cardio 2022;6(1):e35615
URL: https://cardio.jmir.org/2022/1/e35615
doi:10.2196/35615
PMID:35679117

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