JMIR Cardio

Electronic, mobile, digital health approaches in cardiology and for cardiovascular health
Volume 5 (2021), Issue 2 ISSN 2561-1011 Editor in Chief: Andrew Coristine, PhD, Scientific Editor at JMIR Publications, Canada

Contents

Original Papers

User Perceptions and Experiences of a Handheld 12-Lead Electrocardiographic Device in a Clinical Setting: Usability Evaluation (e21186)
Kam Wong, Aravinda Thiagalingam, Saurabh Kumar, Simone Marschner, Ritu Kunwar, Jannine Bailey, Cindy Kok, Tim Usherwood, Clara Chow. 4

Moderation of the Stressor-Strain Process in Interns by Heart Rate Variability Measured With a Wearable and Smartphone App: Within-Subject Design Using Continuous Monitoring (e28731)
Herman de Vries, Wim Kamphuis, Hilbrand Oldenhuis, Cees van der Schans, Robbert Sanderman. 20

Validation of Heart Rate Extracted From Wrist-Based Photoplethysmography in the Perioperative Setting: Prospective Observational Study (e27765)
Eveline Mestrom, Ruben Deneer, Alberto Bonomi, Jenny Margarito, Jos Gelissen, Reinder Haakma, Hendrikus Korsten, Volkher Scharnhorst, R Bouwman. 35

Effects of Urban Green Space on Cardiovascular and Respiratory Biomarkers in Chinese Adults: Panel Study Using Digital Tracking Devices (e31316)
Lin Yang, Ka Chan, John Yuen, Frances Wong, Lefei Han, Hung Ho, Katherine Chang, Yuen Ho, Judy Siu, Linwei Tian, Man Wong. 46

The Effects of a Digital Mental Health Intervention in Adults With Cardiovascular Disease Risk Factors: Analysis of Real-World User Data (e32351)
Robert Montgomery, Eliane Boucher, Ryan Honomichl, Tyler Powell, Sharelle Guyton, Samantha Bernecker, Sarah Stoeckl, Acacia Parks. . . 60

Patient-Reported Outcomes From Patients With Heart Failure Participating in the Future Patient Telerehabilitation Program: Data From the Intervention Arm of a Randomized Controlled Trial (e26544)
Cathrine Skov Schacksen, Anne-Kirstine Dyrvig, Nanna Henneberg, Josefine Dam Gade, Helle Spindler, Jens Refsgaard, Malene Hollingdal, Lars Dittman, Kim Dremstrup, Birthe Dinesen. 77

Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation (e27720)
Amber Seiler, Eliana Biundo, Marco Di Bacco, Sarah Rosemas, Emmanuelle Nicolle, David Lanctin, Juliette Hennion, Mirko de Melis, Laura Van Heel. 89

Experiences and Perceptions of Patients and Providers Participating in Remote Titration of Heart Failure Medication Facilitated by Telemonitoring: Qualitative Study (e28259)
Veronica Artanian, Patrick Ware, Valeria Rac, Heather Ross, Emily Seto. 106

Real-World Experience of mHealth Implementation in Clinical Practice (the Box): Design and Usability Study (e26072)
Tom Biersteker, Alexander Hilt, Enno van der Velde, Martin Schalij, Roderick Treskes. . . . 117

Financial Incentives for Healthy Living for Patients With Cardiac Disease From the Perspective of Health Care Professionals: Interview Study (e27867)
David de Buisonjé, Jessica Van der Geer, Mike Keesman, Roos Van der Vaart, Thomas Reijnders, Jobke Wentzel, Hareld Kemps, Roderik Kraaijenhagen, Veronica Janssen, Andrea Evers. . . . 131

Transitions in Technology-Mediated Cardiac Rehabilitation and Self-management: Qualitative Study Using the Theoretical Domains Framework (e30428)
Shreya Tadas, Claudette Pretorius, Emma Foster, Trish Gorely, Stephen Leslie, David Coyle. . . . 139

Toward the Value Sensitive Design of eHealth Technologies to Support Self-management of Cardiovascular Diseases: Content Analysis (e31985)
Roberto Cruz-Martínez, Jobke Wentzel, Britt Bente, Robbert Sanderman, Julia van Gemert-Pijnen. . . . 173

Efficacy of Telemedicine in Hypertension Care Through Home Blood Pressure Monitoring and Videoconferencing: Randomized Controlled Trial (e27347)
Junichi Yatabe, Midori Yatabe, Rika Okada, Atsuhiro Ichihara. . . . 191

The Effects of Lifestyle Intervention Using the Modified Beliefs, Attitude, Subjective Norms, Enabling Factors Model in Hypertension Management: Quasi-Experimental Study (e20297)
Resti Villarino, Christopher Arcay, Maria Temblor, Maureen Villarino, Rosita Bagsit, Lanndon Ocampo, Paquito Bernard. . . . 199

Patient Perspectives on Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure (ITEC-CHF): Usability Study (e24611)
Sheau Chen, Iain Edwards, Rajiv Jayasena, Hang Ding, Mohanraj Karunanithi, Alison Dowling, Jamie Layland, Andrew Maiorana. . . . 209

The Effect of Cardiovascular Comorbidities on Women Compared to Men: Longitudinal Retrospective Analysis (e28015)
Elma Dervic, Carola Deischinger, Nils Haug, Michael Leutner, Alexandra Kautzky-Willer, Peter Klimek. . . . 219

Values of Importance to Patients With Cardiovascular Disease as a Foundation for eHealth Design and Evaluation: Mixed Methods Study (e33252)
Britt Bente, Jobke Wentzel, Rik Groeneveld, Renée IJzerman, David de Buisonjé, Linda Breeman, Veronica Janssen, Roderik Kraaijenhagen, Marcel Pieterse, Andrea Evers, Julia van Gemert-Pijnen. . . . 229

The Danish Future Patient Telerehabilitation Program for Patients With Atrial Fibrillation: Design and Pilot Study in Collaboration With Patients and Their Spouses (e27321)
Birthe Dinesen, Josefine Dam Gade, Cathrine Skov Schacksen, Helle Spindler, Andi Eie Albertsen, Lars Dittmann, Mads Jochumsen, Dorthe Svenstrup Møller. . . . 241

Usability and Perceived Usefulness of the AFib 2gether Mobile App in a Clinical Setting: Single-Arm Intervention Study (e27016)
Alok Kapoor, Anna Hayes, Jay Patel, Harshal Patel, Andreza Andrade, Kathleen Mazor, Carl Possidente, Kimberly Nolen, Rozelle Hegeman-Dingle, David McManus. . . . 257

A Patient Decision Aid for Anticoagulation Therapy in Patients With Nonvalvular Atrial Fibrillation: Development and Pilot Study (e23464)
Kim de Castro, Harold Chiu, Ronna De Leon-Yao, Lorraine Almelor-Sembrana, Antonio Dans. . . . 269

Short Paper

Initial Outcomes of CardioClick, a Telehealth Program for Preventive Cardiac Care: Observational Study (e28246)
Neil Kalwani, Austin Johnson, Vijaya Parameswaran, Rajesh Dash, Fatima Rodriguez. 99

Review

Interventions Using Heart Age for Cardiovascular Disease Risk Communication: Systematic Review of Psychological, Behavioral, and Clinical Effects (e31056)
Carissa Bonner, Carys Batcup, Samuel Cornell, Michael Fajardo, Anna Hawkes, Lyndal Trevena, Jenny Doust. 156

Original Paper

User Perceptions and Experiences of a Handheld 12-Lead Electrocardiographic Device in a Clinical Setting: Usability Evaluation

Kam Cheong Wong[1,2,3,4], BEng, MBBS, MSc; Aravinda Thiagalingam[1,2,5], MBChB, PhD; Saurabh Kumar[1,2,5], MBBS, PhD; Simone Marschner[1], BSc, MSc; Ritu Kunwar[1], MBBS, MPH; Jannine Bailey[3], BSc, PhD; Cindy Kok[6], MBBS, MPH, PhD; Tim Usherwood[1,2,7], BSc, MBBS, MD; Clara K Chow[1,2,5,7,8], MBBS, PhD

[1]Westmead Applied Research Centre, Faculty of Medicine and Health, The University of Sydney, Westmead, Australia

[2]Westmead Clinical School, Faculty of Medicine and Health, The University of Sydney, Westmead, Australia

[3]Bathurst Rural Clinical School, School of Medicine, Western Sydney University, Bathurst, Australia

[4]School of Rural Health, Faculty of Medicine and Health, The University of Sydney, Orange, Australia

[5]Department of Cardiology, Westmead Hospital, Westmead, Australia

[6]Faculty of Medicine and Health, The University of Sydney, Sydney, Australia

[7]The George Institute for Global Health, Sydney, Australia

[8]Charles Perkins Centre, The University of Sydney, Sydney, Australia

Corresponding Author:
Kam Cheong Wong, BEng, MBBS, MSc
Westmead Applied Research Centre
Faculty of Medicine and Health
The University of Sydney
Level 6, Block K, Entrance 10, Westmead Hospital
Hawkesbury Road
Westmead, 2145
Australia
Phone: 61 2 8890 3125
Email: kam.wong@sydney.edu.au

Abstract

Background: Cardiac arrhythmias are a leading cause of death. The mainstay method for diagnosing arrhythmias (eg, atrial fibrillation) and cardiac conduction disorders (eg, prolonged corrected QT interval [QTc]) is by using 12-lead electrocardiography (ECG). Handheld 12-lead ECG devices are emerging in the market. In tandem with emerging technology options, evaluations of device usability should go beyond validation of the device in a controlled laboratory setting and assess user perceptions and experiences, which are crucial for successful implementation in clinical practice.

Objective: This study aimed to evaluate clinician and patient perceptions and experiences, regarding the usability of a handheld 12-lead ECG device compared to a conventional 12-lead ECG machine, and generalizability of this user-centered approach.

Methods: International Organization for Standardization Guidelines on Usability and the Technology Acceptance Model were integrated to form the framework for this study, which was conducted in outpatient clinics and cardiology wards at Westmead Hospital, New South Wales, Australia. Each patient underwent 2 ECGs (1 by each device) in 2 postures (supine and standing) acquired in random sequence. The times taken by clinicians to acquire the first ECG (efficiency) using the devices were analyzed using linear regression. Electrocardiographic parameters (QT interval, QTc interval, heart rate, PR interval, QRS interval) and participant satisfaction surveys were collected. Device reliability was assessed by evaluating the mean difference of QTc measurements within ±15 ms, intraclass correlation coefficient, and level of agreement of the devices in detecting atrial fibrillation and prolonged QTc. Clinicians' perceptions and feedback were assessed with semistructured interviews based on the Technology Acceptance Model.

Results: A total of 100 patients (age: mean 57.9 years, SD 15.2; sex: male: n=64, female n=36) and 11 clinicians (experience acquiring ECGs daily or weekly 10/11, 91%) participated, and 783 ECGs were acquired. Mean differences in QTc measurements of both handheld and conventional devices were within ±15 ms with high intraclass correlation coefficients (range 0.90-0.96),

and the devices had a good level of agreement in diagnosing atrial fibrillation and prolonged QTc (κ=0.68-0.93). Regardless of device, QTc measurements when patients were standing were longer duration than QTc measurements when patients were supine. Clinicians' ECG acquisition times improved with usage (P<.001). Clinicians reported that device characteristics (small size, light weight, portability, and wireless ECG transmission) were highly desired features. Most clinicians agreed that the handheld device could be used for clinician-led mass screening with enhancement in efficiency by increasing user training. Regardless of device, patients reported that they felt comfortable when they were connected to the ECG devices.

Conclusions: Reliability and usability of the handheld 12-lead ECG device were comparable to those of a conventional ECG machine. The user-centered evaluation approach helped us identify remediable action to improve the efficiency in using the device and identified highly desirable device features that could potentially help mass screening and remote assessment of patients. The approach could be applied to evaluate and better understand the acceptability and usability of new medical devices.

(JMIR Cardio 2021;5(2):e21186) doi:10.2196/21186

KEYWORDS

handheld; electrocardiogram; ECG; acceptability; usability; user perception; user experience; atrial fibrillation; long QT; screening

Introduction

Cardiac arrhythmias are a leading cause of death in Australia [1] and internationally [2]. The mainstay method for diagnosing arrhythmias is 12-lead electrocardiography (ECG), and it is commonly used in the community and in primary care to screen and assess for atrial fibrillation and cardiac conduction abnormalities such as prolonged corrected QT interval (QTc) [3]. Atrial fibrillation has been increasing in prevalence and is an important contributor to risk of stroke [4]. A recent systematic review and meta-analysis [5] reported that prolonged QTc is associated with an increased risk of atrial fibrillation. Patients with atrial fibrillation who take antiarrhythmic medication to control their heart rhythm face the potential risk of QTc prolongation, particularly at the start of antiarrhythmic drug therapy [6]. Prolonged QTc is also a marker for long QT syndrome, which increases the risk of sudden cardiac death [7]. Early detection of prolonged QTc in patients would allow clinicians to modify or treat the underlying cause and could potentially reduce the risk of sudden cardiac death [8].

Conventional 12-lead ECG machines have practical limitations to use in community and remote geographic settings due to their bulky size and portability [9]. Portable mobile handheld technologies have a positive impact on accessibility of health care devices at point of care and demonstrate the greatest benefits in contexts where time efficiency and timely clinical decision making are crucial [10]. In the context of timely diagnosis of cardiac abnormalities, there is a need for more portable ECG devices. Handheld or wearable ECG devices (such as AliveCor Kardia, MyDiagnostick, Omron, and the Apple Watch) have become increasingly prevalent in the market. However single-lead handheld ECGs are limited in their ability to detect arrhythmias, and there is minimal evidence of their utilization in clinical practice [3]. Furthermore, most single-lead handheld ECG devices cannot automatically report QTc measurements [11]. QTc measurements in single-lead rhythm strips produced by Apple watches were validated against those from conventional 12-lead ECGs to enable remote assessment of patients [12]. Remote assessment was particularly important during the coronavirus disease 2019 pandemic. Clinicians manually measured and calculated the QTc using the single-lead ECG trace [12]. Manual calculation of QTc is time-consuming, particularly when QTc varies with variation in heart rate caused by change in body position (supine and standing) [13,14]. Portable 12-lead ECG devices that automatically report QTc and other ECG parameters could improve clinicians' ability to diagnose prolonged QTc and other cardiac abnormalities.

In tandem with an increasing number of technology options to acquire ECG in various clinical settings, evaluation of device usability should go beyond validation of the device in a controlled laboratory setting. A recent review [15] on mobile health technology acceptance reported that assessment of users' experiences is crucial because assessments of user experiences provide insights and opportunities to improve the device, and user experiences can affect intention to use the device. However, common approaches for evaluating medical devices [16] were assessing product performance at research and development stage and compliance with regulatory requirements and they lack focus on user training, lack focus on efficiency in using the device, and lack assessment of users' perceptions and experiences in clinical settings.

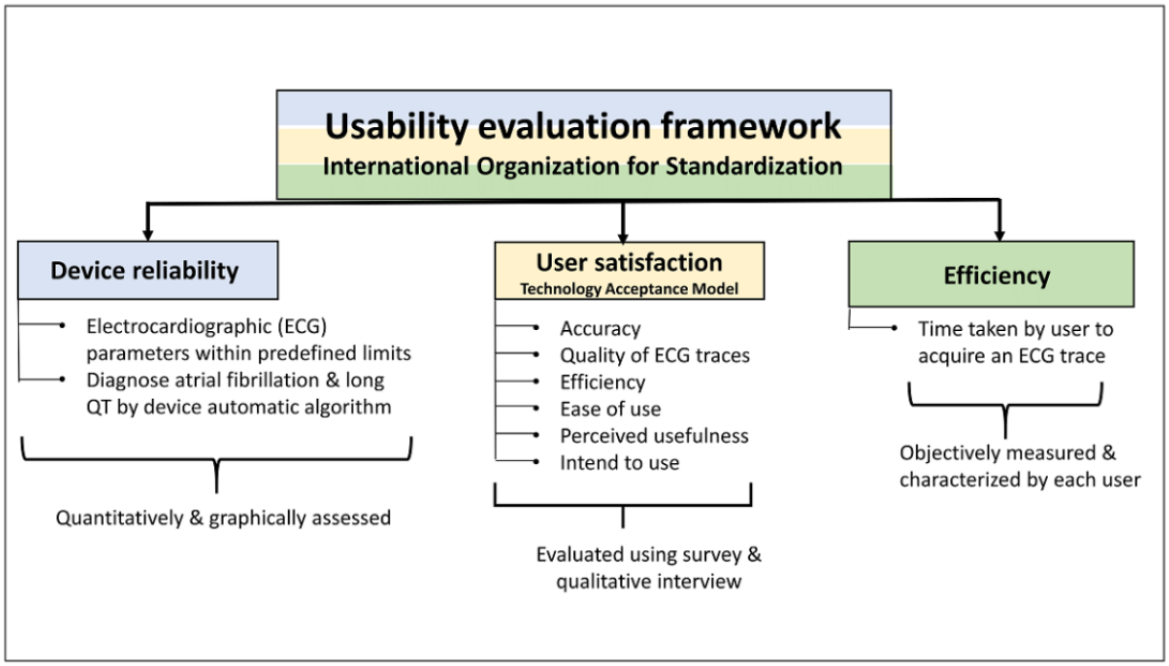
We aimed to pragmatically evaluate ECG devices within the setting in which they will be used, by assessing (1) device reliability in producing key ECG parameters and diagnosing atrial fibrillation and prolonged QTc for 2 patient postures (supine and standing) in a clinical setting, (2) user time efficiency, (3) patients' experiences with the device, and (4) clinicians' perceptions of and feedback on potential use of the device for clinician-led mass screening.

Methods

Study Design, Setting, and Participants

We used a mixed methods approach [17] to evaluate device usability. The framework (Figure 1) for assessing device usability was based on International Organization for Standardization Guidelines on Usability [18] and included reliability of the device, efficiency when using the device, and user satisfaction with the device [19].

Figure 1. Usability evaluation framework.

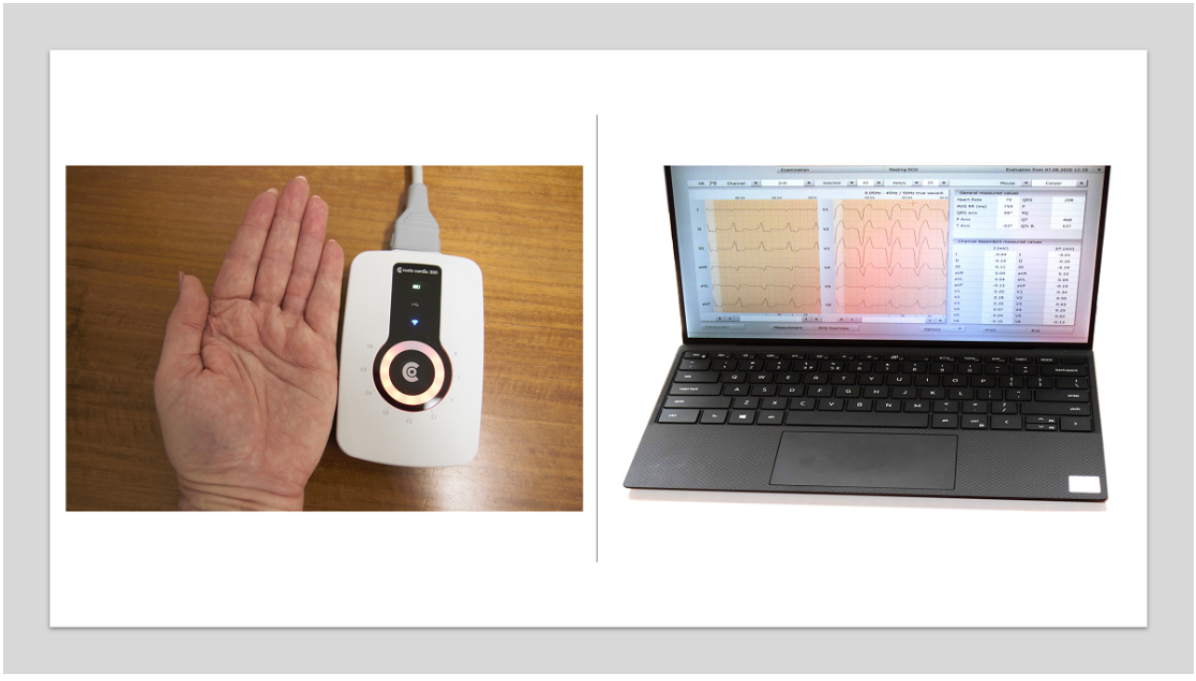


The study was conducted in an outpatient cardiology clinic and inpatient cardiology ward at Westmead Hospital, New South Wales, Australia. The hospital setting was selected because patients with various arrhythmias and cardiac diseases present to the hospital and require ECG assessment. Patients (age ≥18 years) and their clinicians were recruited. Patients who were too ill or unable to provide consent were excluded. Users were clinicians who applied the device to acquire ECGs and patients who were connected to the device.

Handheld and Conventional 12-Lead ECG Devices

A handheld 12-lead ECG device (Cardio 300, custo med GmbH [20]; Australian Register of Therapeutic Goods number 302423) (Figure 2) was selected because of its small size (length by width by thickness: 11.5 cm × 7.5 cm × 1.8 cm; weight: 430 g) and ability to transmit ECG data via Bluetooth. It was compared with the routinely used conventional 12-lead ECG machine at each clinic site—Mortara Eli 280 (Welch Allyn Inc) in the outpatient cardiology clinic and Mac 5500 (General Electric) in the inpatient cardiology ward.

Figure 2. Handheld electrocardiography device and graphical interface on a laptop computer.



Reliability

Device reliability [21] is defined as its ability to reproduce measurements (QT interval, QTc interval, heart rate, PR interval, and QRS interval) consistently within an acceptable limit in a clinical setting. We chose QTc interval as the primary measurement because of its importance in assessing prolonged QTc—which is defined as an individual QTc measurement ≥460 ms in females and an individual QTc measurement ≥450 ms in males [5]. There are guidelines for an acceptable limit of variation in QTc measurements [22]. A clinically noteworthy change in QTc from baseline is defined as 30 ms to 60 ms [22,23]. We defined acceptable limits of mean difference for QTc as within ±15 ms. Both devices produced QTc readings using the Bazett formula [24]. Agreement between devices' automatic ECG interpretation algorithms for diagnosing atrial fibrillation was also assessed.

Efficiency

Efficiency was measured as the total time taken by the clinician to place electrodes on a patient and acquire the first ECG trace. A research assistant measured the time taken by the clinician to place electrodes while the patient was supine. The electrodes were left in place on the patient during device change over. The time taken by the clinician to connect each ECG device to the electrodes and acquire the first ECG trace was measured separately for each device.

User Satisfaction

Clinician satisfaction was measured using 5-point Likert scales (for device accuracy, quality of ECG traces, ease of use, and efficiency). In addition, semistructured interviews were conducted for feedback and to assess clinicians' acceptance of the device; semistructured interview guides were based on the Technology Acceptance Model [25,26] (ie, ease of use, perceived usefulness, and intention to use the device). Patient satisfaction with the device connected to them was assessed using a 5-point Likert scale.

Sample Size

The required sample size of patients was calculated (Sealed Envelope, Sealed Envelope Ltd) based on the primary objective to evaluate device reliability using within- and between-device variabilities in producing QTc measurements within the predefined acceptable limit of ±15 ms. With a power of 80% and α=5%, the required sample size was 96, which we rounded up to 100.

Data Collection Procedures

A research assistant provided in-person training to clinicians to demonstrate how to use the handheld device to acquire ECGs. In addition, clinicians could opt to watch a short introductory video about how to use the handheld device. For each patient, ECGs were acquired twice while supine and while standing using each device. ECG acquisition order was randomized with block sizes of 2 and 4 using SAS (version 9.4; SAS Institute). The randomized sequences, participants' demographic data and ECG parameters (QT, QTc, heart rate, PR and QRS) were recorded in REDCap [27]."

Survey Questionnaire and Semistructured Interview

Patient's satisfaction while connected to the devices were surveyed using 5-point Likert scale (1, strongly disagree to 5, strongly agree). Before using the handheld device, clinicians were asked whether they had previously used a similar device (yes or no); if yes, we asked the name of the device. Using 5-point Likert scales, the clinicians rated importance (1, strongly disagree to 5, strongly agree) and satisfaction (1, not satisfied to 5, very satisfied) with respect to accuracy, quality of the ECG trace, ease of use, and efficiency. We also asked clinicians whether they found the handheld device easier to use than the routinely used conventional ECG machine, whether using the handheld device in their current workflow could increase their productivity, and assuming they had continual access to the handheld device, whether they intended to use it. In semistructured interviews, we asked clinicians if they found the handheld device useful and to explain their response, if their needs were met when using the handheld device (probing questions: what were their needs and what could the device do to better serve their needs), and if the handheld device could be applied for clinician-led mass screening (probing question: how to make the device suitable for clinician-led mass screening?).

Statistical Analysis

Demographic data are presented using descriptive statistics. Reliability, in terms of agreement between devices in diagnosing atrial fibrillation and prolonged QTc, was assessed using the κ statistic [21], for which κ=0.41 to κ=0.60 is generally considered to demonstrate moderate agreement and κ>0.61 considered to demonstrate good agreement. Within- and between-device reliability in QTc measurements was assessed using the intraclass correlation coefficient (ICC); ICC ≥0.7 demonstrates good reliability [21]. The within-device variability for QTc was assessed by the difference in QTc in the first and second ECG acquired immediately one after another by the same device on the same patient. The between-device variability was assessed by the difference in QTc in the first ECG produced by the 2 devices. The between-device variability over a range of QTc intervals was examined using Bland-Altman plot [28]. The within-device and between-device variabilities in QTc compared with the predefined acceptable limits of ±15 ms were examined by plotting the mean of the differences in QTc and their 95% confidence intervals in forest plots. Similarly, within-device and between-device variability in other key ECG parameters (QT interval, heart rate, PR interval, and QRS interval) were examined using forest plots.

The differences in clinicians' ECG acquisition times using the devices were assessed using a scatter plot. A logarithmic transformation was used for the frequency of usage because the time difference due to a unit of increment of usage from first to second usage was not proportional to a unit of increment in subsequent usages (ie, the change in time difference levelled off as the frequency of usage increased). These time differences were analyzed using linear regression analysis. The impact of the randomized sequence of using the devices on the ECG acquisition times was analyzed using a 2-tailed *t* test. Quantitative data were analyzed using SPSS statistical software (version 25; IBM Corp), except linear regression analysis, which

was performed using R software (R Foundation for Statistical Computing). Normality of distribution was assessed with a Shapiro-Wilk test [29]. Nonparametric testing (Wilcoxon signed ranked test using the Hodges-Lehman method to compute 95% CI of the median difference) was used for nonnormal distributions. A *P* value <.05 was considered significant.

Semistructured interviews were recorded and transcribed verbatim for inductive thematic analysis. Two investigators (KW and JB) coded the interview transcripts independently, generated a draft codebook, and then convened to reach consensus on the final codebook. Any discrepancy in coding was resolved by discussion. Interview transcripts were thematically analyzed using NVivo (version 12; QSR International).

Ethics

The study was approved by Western Sydney Local Health District Human Research Ethics Committee (ethics approval number 5929).

Results

General

A total of 100 patients were recruited and participated from July to December 2019. The mean age of patients was 57.9 years (SD 15.2). Participant demographics, morbidities, and medication profiles are shown in Table 1.

Table 1. Characteristics of the patients.

Characteristic	Total (n=100)
Sex, n (%)	
Male	64 (64)
Female	36 (36)
Age (years)	
Mean (SD)	57.9 (15.2)
Range	18-88
Median (IQR)	61.0 (20.0)
Preexisting morbidity[a] , n (%)	
Heart diseases	
Ischemic heart disease	27 (27)
Cardiomyopathy	7 (7)
Valvular disease	6 (6)
Heart blocks	6 (6)
Pacemaker	6 (6)
Arrhythmia	
Atrial fibrillation	14 (14)
Paroxysmal atrial fibrillation	3 (3)
Atrial flutter	3 (3)
Supraventricular tachycardia	1 (1)
Hypertension	63 (63)
Hypercholesterolemia	42 (42)
Diabetes	27 (27)
Medications[a] , n (%)	
Antihypertensive medication	53 (53)
Anticoagulant/antiplatelet	47 (47)
Lipid lowering medication	43 (43)
Oral hypoglycemic	18 (18)
Diuretics	15 (15)
Antiarrhythmic medication	9 (9)
Insulin	3 (3)

[a]The total exceeds 100% because many patients had more than 1 morbidity or took more than 1 medication.

A total of 11 clinicians (nursing staff: n=10; clinical trial coordinator: n=1) participated. Prior ECG experience was high, with 10 of the clinicians routinely acquiring ECGs daily or weekly and 1 clinician routinely acquiring ECGs fortnightly. Among the clinicians, 8 were from outpatient cardiology clinics, and 3 were from inpatient cardiology wards (Table 2). Most clinicians (9/11, 82%) opted to receive a demonstration of how to use the handheld device from the research assistant while the remaining 2 clinicians (clinicians 1 and 6) opted to watch a short video demonstration. Clinicians 1, 2, 3, and 6 were nurses working in cardiology outpatient clinics, and they acquired ECGs daily and recruited 18, 16, 19, and 20 patient participants, respectively.

Table 2. Characteristics of the clinicians.

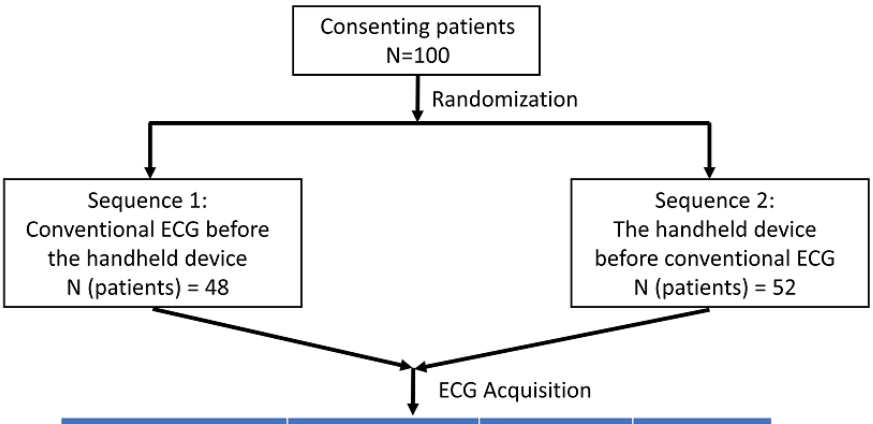
Characteristic	Total (n=11)
All, n	
Outpatient	8
Inpatient	3
Role, n (%)	
Nurse	7 (63.6)
Nurse educator	3 (27.3)
Clinical trial coordinator	1 (9.1)
Gender, n (%)	
Male	4 (36)
Female	7 (64)
How often do you acquire an ECG[a]? n (%)	
Daily	6 (55)
Weekly	4 (36)
Fortnightly	1 (9)
Monthly	0 (0)
Have you used the 12-lead handheld ECG device before? n (%)	
Yes	0 (0)
No. If no, have you used similar device before? n (%)	11 (100)
Yes[b]	1 (9)
No	10 (91)
Number of patients recruited per clinician	
Mean	9
Median	6
Range	1-20

[a]ECG: electrocardiography.

[b]Clinician 10 had used wireless electrocardiography before but not the handheld device used in this study.

A total of 783 ECGs were collected (Figure 3). The randomized sequence for ECG device order resulted in the handheld device being connected first for 52 patients and the conventional ECG machine being connected first for 48 patients.

Figure 3. Patient randomization and number of electrocardiograms (ECG) acquired. ECG traces could not be acquired due to loss of connection for (a) 1 patient, (b) 1 patient, (c) 3 patients, (d) 7 patients, (e) 2 patients, and (f) 3 patients.



	Handheld device	Conventional ECG machine	Total
1st Supine ECG, n	99[a]	100	199
2nd Supine ECG, n	99[b]	100	199
1st Standing ECG, n	97[c]	98[e]	195
2nd Standing ECG, n	93[d]	97[f]	190
Total, N	388	395	783

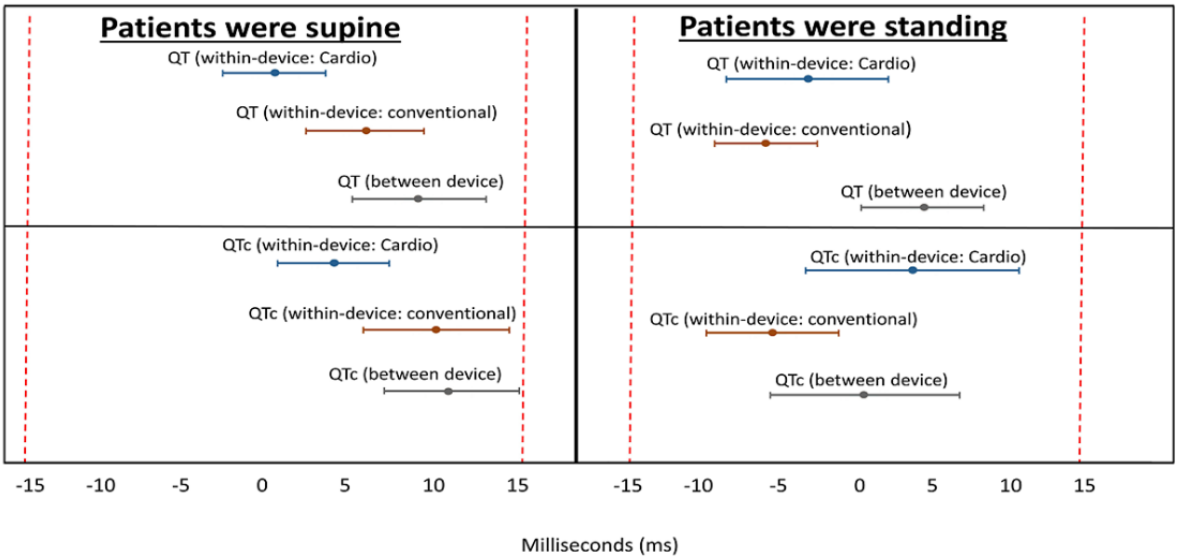
Note: ECG traces couldn't be acquired due to loss of connection between the device and computer in the following patients:
a: patient #79, b: patient #79, c: patients #38, #56 and #69, d: patients #1, #15, #27, #29, #38, #56 and #69, e: patients #42 and #69, f: patients #42, #69 and #76.

Reliability

The within- and between-device mean differences for QT and QTc while patients were supine and standing were consistently within ±15ms for both handheld and conventional devices (Figure 4).

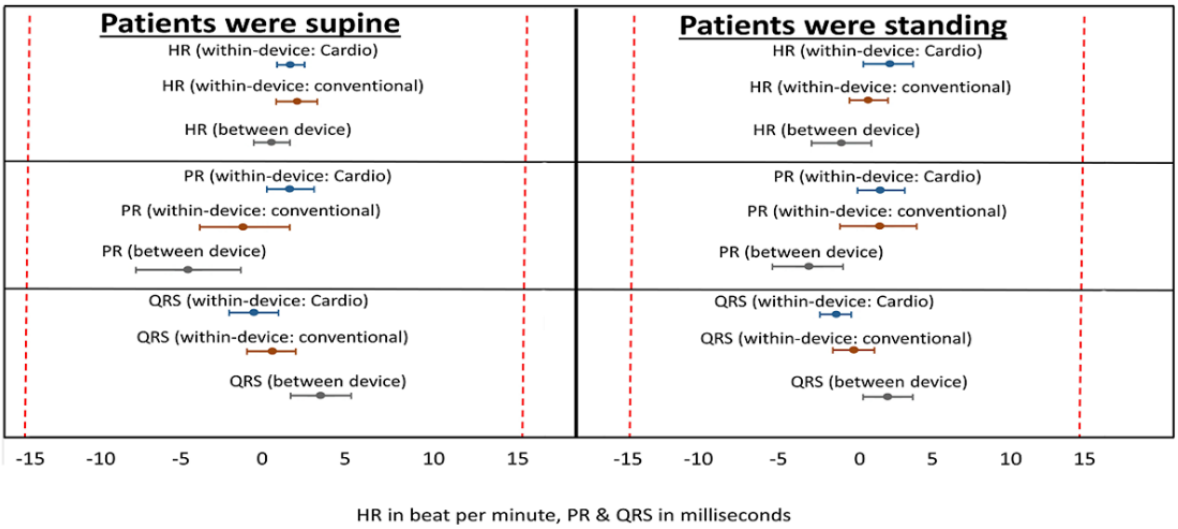
Both devices had good reliability in producing heart rate, PR interval, and QRS interval measurements while patients were supine and standing. The within- and between-device mean differences in heart rate, PR interval, and QRS interval measurements were ±5 bpm, ±10 ms, and ±10 ms (Figure 5).

Figure 4. Within- and between-device variability of QT interval and corrected QT interval by patient posture. Mean differences and 95% confidence intervals. Dashed red lines indicate predefined acceptable limits.



Cardio: the handheld ECG device, QT: the time from the onset of ventricular depolarization to the end of ventricular repolarization, QTc: the QT corrected for heart rate. Each horizontal line represents the mean difference with its 95% confidence interval.

Figure 5. Within- and between-device variability of heart rate, PR interval, and QRS interval by patient posture. Mean differences and 95% confidence intervals. Dashed red lines indicate predefined acceptable limits.

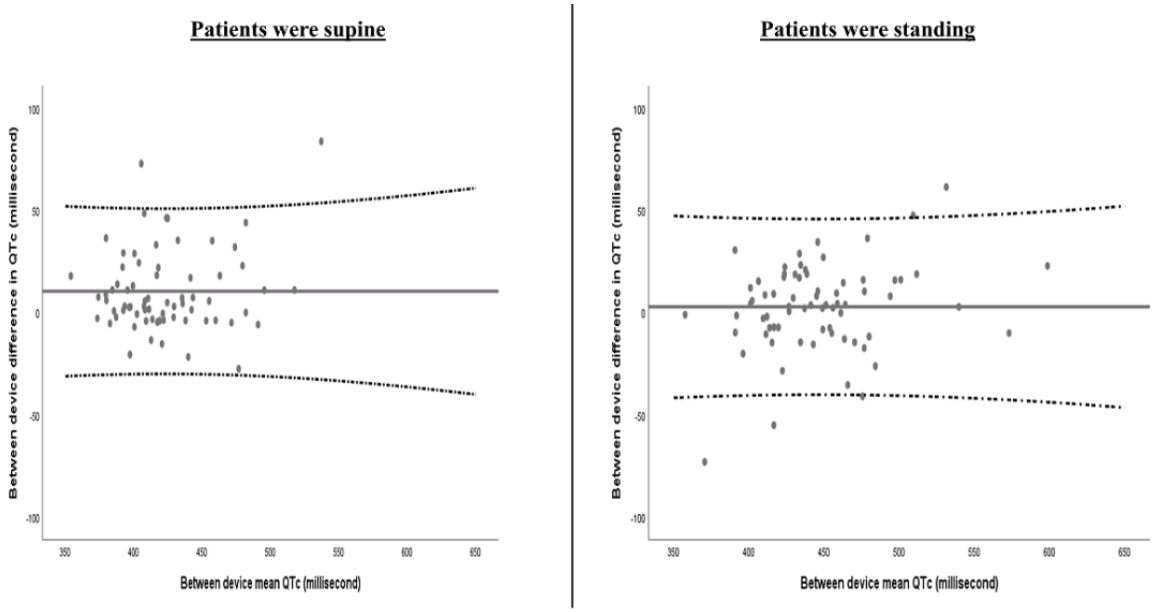


Cardio: the handheld ECG device, HR: heart rate, PR: the time between the onset of atrial depolarization and the onset of ventricular depolarization, QRS: the time duration of ventricular depolarisation. Each horizontal line represents mean difference with its 95% confidence interval.

Variability of the differences in QTc measurements between the handheld device and conventional ECG machines were randomly distributed (Figure 6). For conventional ECG, the difference between standing (median 436.4 ms, IQR 46.0 ms) and supine QTc measurements (median 410.3 ms, IQR 49.0 ms) was significant (P<.001). The median of the difference between QTc standing and QTc supine was 20.7 ms (95% CI 15.3-25.6). For the handheld device, the difference between standing (median 446.0 ms, IQR 50.0 ms) and supine QTc measurements (median 420.0 ms, IQR 48.0 ms) was significant (P<.001). The median of the difference between QTc standing and QTc supine was 14.5 ms (95% CI 10.5-19.0).

The devices had good agreement in diagnosing atrial fibrillation and prolonged QTc (within- and between-device κ=0.68-0.93) (Table 3). The within- and between-device reliabilities for QTc measurements were high (ICC 0.90-0.96) (Table 3).

Figure 6. Bland-Altman plots for differences between (first handheld device and conventional) individual corrected QT interval measurements.



Horizontal dotted lines represent 95% limits of agreement between the devices.

Table 3. Within- and between-device agreement in diagnosing atrial fibrillation and prolonged QTc. Reliability of QTc measurements.

Variable[a]	Within-device κ or ICC[b,c] (95% CI)		Between-device κ or ICC[c] (95% CI)
	Handheld device	Conventional machine	
Atrial fibrillation			
Patients were supine	0.82 (0.58-1.00)	0.79 (0.50-1.00)	0.90 (0.71-1.00)
Patients were standing	0.68 (0.40-0.97)	0.84 (0.62-1.00)	0.93 (0.78-1.00)
Prolonged QTc[d]			
Patients were supine	0.84 (0.68-0.99)	0.75 (0.55-0.94)	0.92 (0.81-1.00)
Patients were standing	0.71 (0.54-0.88)	0.77 (0.61-0.93)	0.69 (0.51-0.86)
QTc measurements			
Patients were supine	0.96 (0.93-0.97)[c]	0.92 (0.88-0.95)[c]	0.92 (0.88-0.95)[c]
Patients were standing	0.90 (0.84-0.94)[c]	0.95 (0.92-0.97)[c]	0.94 (0.90-0.96)[c]

[a]Clinicians mistakenly reprinted the second conventional ECG from the first ECG in the first 20 patients, and 8 other patients declined repeating ECG acquisition after several attempts. These 28 patients were excluded from this analysis resulting in a sample size of 72.

[b]ICC: intraclass correlation coefficient.

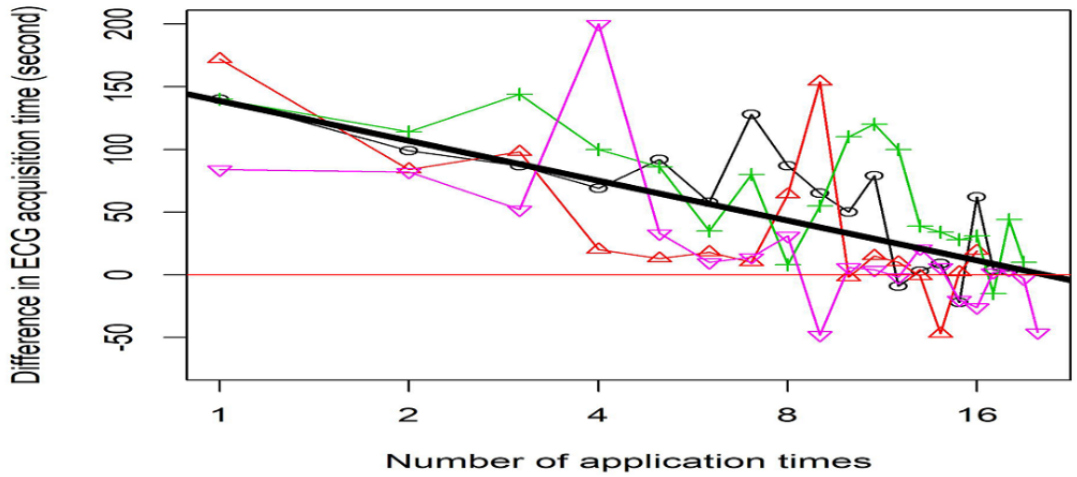
[c]These values are ICCs.

[d]QTc: corrected QT interval.

Time Efficiency

The mean time taken to place electrodes on patients (regardless of ECG device) was 42.2 seconds. The mean times taken by clinicians to acquire the first ECG using the handheld device and conventional ECG machine were 144.6 seconds and 103.5 seconds, respectively. On average, the total times taken by clinicians to acquire an ECG using the handheld device and conventional ECG machine were 186.8 seconds and 145.7 seconds. The median of the difference between the clinicians' ECG acquisition time using the handheld device and conventional ECG machine was 39.5 seconds (95% CI 27.0-51.0). These times excluded the time taken to prepare the patient (eg, the time taken by the patients to undress themselves for the procedures). The randomized sequence of applying the devices had insignificant effect on the difference in ECG acquisition time (conventional: P=.51; handheld: P=.97). ECG acquisition times improved with the number of time clinicians used the devices (P<.001) (Figure 7). The difference in clinicians' ECG acquisition times using the devices approached 0 after clinicians had used the device 18 times (Figure 7).

Figure 7. Difference in the time taken by clinicians to acquire 12-lead electrocardiography measurements using the handheld device and conventional machine by usage frequency.



Black circle: Clinician 1 applied 18 times, red upright triangle: Clinician 2 applied 16 times, green cross: Clinician 3 applied 19 times, pink inverted triangle: Clinician 6 applied 20 times.

User Satisfaction and Acceptance

Clinicians' expectations of the handheld device before and satisfaction after are shown in Table 4 and Figure 8. Patients' experiences are also shown in Table 4.

Table 4. Clinician and patient satisfaction.

Survey item	Rating, mean (SD)
Clinicians' expectations before using the handheld device and their satisfaction after using it	
Accuracy	
Before[a]	5.0 (0.0)
After[b]	4.0 (0.8)
Quality of ECG[c] trace	
Before[a]	5.0 (0.0)
After[b]	4.0 (0.8)
Ease of use	
Before[a]	4.7 (0.5)
After[b]	3.9 (0.9)
Efficiency	
Before[a]	4.9 (0.3)
After[b]	3.5 (1.0)
Clinicians' response after using the handheld device	
Compared to conventional ECG, I found the handheld device easier to use[d]	3.4 (0.8)
Using the handheld device in my job increased my productivity[d]	3.1 (0.5)
Assuming I had continual access to the handheld device, I intended to use it[d]	3.6 (0.5)
Patients' experience with the handheld device compared to the conventional ECG machine	
Patient felt comfortable while connected to the device and lying down	
The handheld device[d]	3.2 (0.6)
Conventional ECG[d]	3.0 (0.3)
Patient felt comfortable while connected to the device and standing up	
The handheld device[d]	3.2 (0.5)
Conventional ECG[d]	3.1 (0.4)

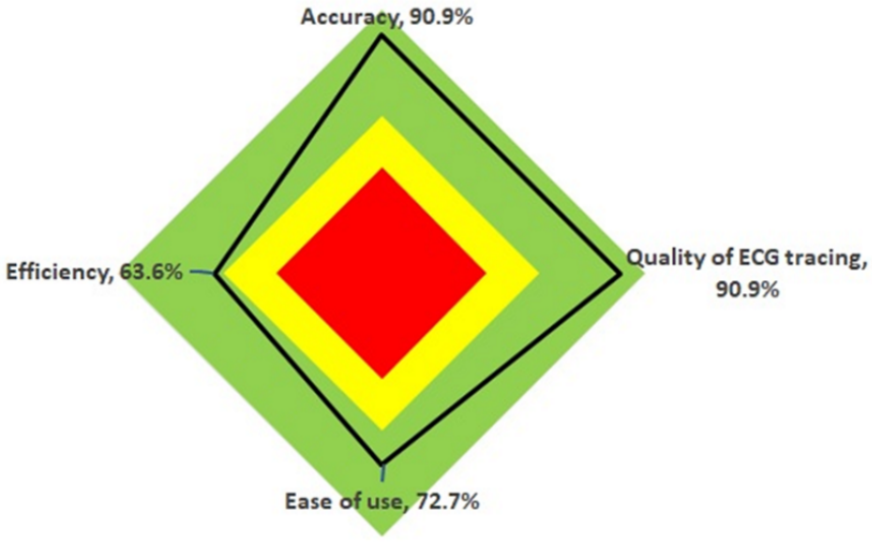
[a]5-point Likert scale ranging from 1 (not important) to 5 (very important).

[b]5-point Likert scale ranging from 1 (not satisfied) to 5 (very satisfied).

[c]ECG: electrocardiography.

[d]5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Figure 8. Radar chart of clinician satisfaction after using the handheld device. ECG: electrocardiogram.



Thematic Analysis of Interviews With Clinicians

Overview

Most (10/11) clinicians attended a 1-to-1 interview. One clinician was on leave and could not attend the interview. When asked about their needs, satisfaction, and useful features of the handheld device, clinicians frequently mentioned the following features: quality of the ECG traces, ease of use, efficiency, accuracy, small size, and portability.

Main Themes

When asked about their needs regarding an ECG device, clinicians expressed that they wanted a device that was easy to use, efficient (took short time to acquire an ECG), accurate, and produced good-quality ECG traces. Clinicians reported satisfaction with the accuracy and quality of the ECG traces produced by the handheld device, however, were equivocal about the efficiency due to the extra time they took to acquire an ECG.

> *My needs are to do ECG quick and efficient as possible, and better quality ECG. Quality-wise it is good, but I am slightly satisfied with the efficiency of the device.* [Clinician 1]
>
> *I am satisfied with the quality and accuracy of the device. I also find it easy to use. But usually, it takes more time than the old device.* [Clinician 6]
>
> *My needs are to acquire accurate and better quality ECGs. I am satisfied with accuracy, efficiency and quality of the device.* [Clinician 8]

Feedback about interference (loss of connection between the device and computer) varied between clinicians in cardiology inpatient wards and outpatient clinics. Clinicians in inpatient wards reported less interference in the handheld device than that in a conventional ECG machine, however, clinicians in outpatient clinics found the opposite.

> *There is a lot of interference with the connection of the device. The connection gets lost multiple times in between while doing ECGs, especially for standing one.* [Clinician 3, cardiology outpatient clinic where patients had ECG acquired before seeing cardiologist]
>
> *It has less interference mainly while doing standing ECGs compared to conventional device.* [Clinician 8, cardiology inpatient ward]
>
> *The aspects that I liked about this device is it's clear, less interference with cardiac monitors, small, light-weight, easy to carry and chargeable.* [Clinician 11, cardiology inpatient ward]

Clinicians specified portability as a desired feature of the handheld ECG device. The wireless transmission of ECG trace from the device to a laptop computer was an added advantage; however, the need to carry a laptop computer to connect with the ECG device could be a drawback.

> *I do find it useful as far as portability wise it is good. However, it takes more time compared to the old device. Few aspects of the device, I like are it's handy, easy to carry, save lots of space and ECG are saved within the laptop so less chance of loss of ECG. Also, no damage to papers and no extra cost for papers.* [Clinician 1]
>
> *I like the most about this device is it is portable, small and quite fast picking up ECG sometimes. But, most of the times we need to wait a few more seconds to get a satisfactory ECG. The thing I don't like about this device is it is attached to the laptop. The device is smaller and easy to carry everywhere, but along with this, we should also carry a laptop everywhere. I feel for our clinic (Rapid Access Cardiac Clinic) paper is more efficient.* [Clinician 6]

Most clinicians (9/11) agreed that the handheld device was suitable for clinician-led mass screening; 1 clinician was unsure, and 1 clinician stated “yes” with suggested enhancements to the device. Suggestions for enhancements included improving efficiency in using the device to acquire ECG by increasing user training,

> *As it is small in size and not bulky and easy to carry everywhere, it can be used for mass screening. But, firstly, clinicians who will be using this device for mass screening purpose should be properly and adequately trained.* [Clinician 3]

and improving wireless transmission of ECG trace to a computer (increasing the range of wireless transmission to allow patient isolation for infection control and remote assessment of patients).

> *Long range would help for infection control use. ie receiver on patient and device outside the room for an isolated patient.* [Clinician 10]
>
> *It is a small device so we can easily carry this device everywhere, even in remote areas. So, I think it is more convenient for mass screening in rural settings where it is difficult to carry the old device.* [Clinician 2]

Discussion

Principal Findings

The results suggested that the handheld device had high reliability in producing key ECG parameters and had good levels of agreement with the conventional ECG machines in diagnosing prolonged QTc and atrial fibrillation using the device automatic algorithm. The clinicians' efficiency in using the devices improved with usage, which was demonstrated by ECG acquisition times. This user-centered approach helped us identify remediable action to improve user efficiency with training. Highly desirable device features, such as portability (small size and lightweight) and wireless ECG transmission (enhancement in the wireless range of ECG transmission from the device to computer) allow clinician-led mass screening and remote assessment of patients to be feasible. However, the mass screening should be clinician-led because users require the skill to apply electrodes correctly on the body.

The mixed methods approach allowed us to explore diverse perspectives in the usability of the handheld device. Quantitative evaluation of clinicians' ECG acquisition times provided an objective measurement of time efficiency and characterized the trend of improvement in efficiency with the number of usage (Figure 7). In this study, we found that differences in ECG acquisition times between the devices approached 0 after the users used the devices 18 times. Quantitative measurements of ECG acquisition times revealed the learning curves of different users. With qualitative evaluation of user perceptions and experiences in using the device, we identified their training needs, desired device features, and suggestions to make the device suitable for clinician-led mass screening and remote assessment of patients. This mixed methods approach addressed gaps in the common approaches to medical device evaluation, which lack evaluation of user perceptions, experiences, and efficiency [16].

The devices had high reliability in producing key ECG parameters while patients were supine and standing. This was consistent with findings in previous research. Madias and colleagues [30] evaluated a standard 12-lead ECGs recorded in patients in supine and standing positions and concluded that the ECG results in supine and standing were comparable. This comparability may allow ECG recording in busy clinical setting to be more cost-effective—ECGs could be acquired while patients are standing. Despite high reliability, we should note that QTc measurements (regardless of device) while patients were standing compared to those when supine were longer, which was consistent with the literature [13,14]. Compared with QTc measurement when supine, QTc measurement while standing was more accurate in distinguishing patients with long QT syndrome from individuals without long QT syndrome [14]. Lengthened QTc while standing could assist clinicians to diagnose long QT syndrome. Researchers should evaluate the effect of change in body position when comparing device reliability.

Clinician perceptions of efficiency were affected by their familiarity with the device. It was expected that users would take a longer time using the newly introduced handheld device to acquire an ECG than when using a familiar conventional ECG machine because users lacked familiarity with the new device. It is worthwhile to note that the time measured in this study excluded the time to prepare the patients (eg, time for patients to remove their top clothing and get ready for the procedure). The clinicians' ECG acquisition times were less than the 10.6 minutes reported by Somerville and colleagues [31] (which included the time taken for preparing the patients) using conventional 12-lead ECG in general practice. The clinicians in our study were mainly nursing staff working in the cardiology clinic and ward, and they acquired ECGs daily or weekly. The clinicians' familiarity with acquiring ECG could differ in comparison to those in general practice setting, and this factor should be taken into consideration when formulating a training program.

Clinician experience in using the device was contextual. In the inpatient cardiology ward, clinicians reported that there were less artefacts on the ECGs because of less interference between the handheld device and the other monitors to which patients were connected, but clinicians in the outpatient cardiology clinic reported that there were several incidences of lost Bluetooth connection between the handheld device and laptop computer resulting in multiple attempts to reacquire ECGs. Thus, the experiences and resulting perceptions on ease of use of the device varied depending on the environment in which the device was used. Patient satisfaction was mainly focused on their comfort when connected to the devices. Most of the patients felt comfortable during ECG acquisition with both handheld and conventional devices.

Strengths and Limitations

The strengths of this study included the application of quantitative and qualitative methods to evaluate devices using a usability evaluation framework that integrated the International Organization for Standardization Guidelines on Usability [18] and the Technology Acceptance Model [25,26], and the use of forest plots to examine within- and between-device variabilities to complement the use of other quantitative indices (ICC and κ). However, because of time constraints, we did not evaluate the variability of ECGs while patients were sitting, we did not

explore in-depth views of patients, and most ECGs were acquired by 4 clinicians.

Conclusions

The handheld 12-lead ECG device was comparable to routinely used conventional 12-lead ECG machine in its reliability and usability. The device's small size, light weight, and wireless ECG transmission coupled with improved efficiency via training make the device a potential tool for clinician-led mass screening and remote assessment of patients. Patient body position should be included in the evaluation of device reliability because QTc lengthening secondary to standing offers diagnostic information. The user-centered evaluation framework utilized in this study could be applied to evaluate and better understand the acceptability and usability of new medical devices.

Acknowledgments

We would like to acknowledge and thank the clinicians and participants of the study. We would also like to thank Mr. Lucas Bao Thu Nguyen for his assistance in producing the forest plots. The study was funded by the University of Sydney Industry Engagement Seed Fund, custo med GmbH, and Cardio-Jenic Pty Ltd. The funders were not involved in study design, analysis, and interpretation of results.

Authors' Contributions

KCW, CKC, SK, and AT initiated conceptualization of the study. KCW and SM established the statistical analysis plan including randomization sequence and sample size computation. KCW drafted the research protocol, which was reviewed and approved by CKC, SK, AT, and SM. KCW and RK performed data collection and data management. RK assisted in transcribing interview transcripts. KCW and JB performed thematic analysis on interviews. KCW performed statistical analysis, and SM reviewed the analysis. KCW drafted the manuscript, which was reviewed, revised, and approved by all authors.

Conflicts of Interest

None declared.

References

1. Australia's leading causes of death, 2015. Australian Bureau of Statistics. URL: https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/3303.0~2015~Main%20Features~Australia's%20leading%20causes%20of%20death,%202015~3 [accessed 2021-08-09]
2. Srinivasan N, Schilling RJ. Sudden cardiac death and arrhythmias. Arrhythm Electrophysiol Rev 2018 Jun;7(2):111-117 [FREE Full text] [doi: 10.15420/aer.2018:15:2] [Medline: 29967683]
3. Wong KC, Kok C, Marschner S, Usherwood T, Chow CK. Screening for atrial fibrillation and other arrhythmias in primary care. BMC Fam Pract 2020 May 06;21(1):79 [FREE Full text] [doi: 10.1186/s12875-020-01151-8] [Medline: 32375662]
4. Roth GA, Mensah GA, Johnson CO, Addolorato G, Ammirati E, Baddour LM, GBD-NHLBI-JACC Global Burden of Cardiovascular Diseases Writing Group. Global burden of cardiovascular diseases and risk factors, 1990-2019: update from the GBD 2019 study. J Am Coll Cardiol 2020 Dec 22;76(25):2982-3021 [FREE Full text] [doi: 10.1016/j.jacc.2020.11.010] [Medline: 33309175]
5. Zhang N, Gong M, Tse G, Zhang Z, Meng L, Yan BP, et al. Prolonged corrected QT interval in predicting atrial fibrillation: a systematic review and meta-analysis. Pacing Clin Electrophysiol 2018 Mar 16;41(3):321-327. [doi: 10.1111/pace.13292] [Medline: 29380395]
6. Kirchhof P. The future of atrial fibrillation management: integrated care and stratified therapy. Lancet 2017 Oct 21;390(10105):1873-1887. [doi: 10.1016/S0140-6736(17)31072-3] [Medline: 28460828]
7. Schwartz PJ, Ackerman MJ, Antzelevitch C, Bezzina CR, Borggrefe M, Cuneo BF, et al. Inherited cardiac arrhythmias. Nat Rev Dis Primers 2020 Jul 16;6(1):58 [FREE Full text] [doi: 10.1038/s41572-020-0188-7] [Medline: 32678103]
8. Waddell-Smith KE, Skinner JR, members of the CSANZ Genetics Council Writing Group. Update on the diagnosis and management of familial long QT syndrome. Heart Lung Circ 2016 Aug;25(8):769-776. [doi: 10.1016/j.hlc.2016.01.020] [Medline: 27262388]
9. Walker A, Muhlestein J. Smartphone electrocardiogram monitoring: current perspectives. Adv Health Care Technol 2018 Jun;4:15-24. [doi: 10.2147/AHCT.S138445]
10. Prgomet M, Georgiou A, Westbrook JI. The impact of mobile handheld technology on hospital physicians' work practices and patient care: a systematic review. J Am Med Inform Assoc 2009;16(6):792-801 [FREE Full text] [doi: 10.1197/jamia.M3215] [Medline: 19717793]
11. Nguyen HH, Silva JN. Use of smartphone technology in cardiology. Trends Cardiovasc Med 2016 May;26(4):376-386. [doi: 10.1016/j.tcm.2015.11.002] [Medline: 26686266]
12. Strik M, Caillol T, Ramirez FD, Abu-Alrub S, Marchand H, Welte N, et al. Validating QT-interval measurement using the Apple Watch ECG to enable remote monitoring during the COVID-19 pandemic. Circulation 2020 Jul 28;142(4):416-418 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.120.048253] [Medline: 32478565]

13. Adler A, van der Werf C, Postema PG, Rosso R, Bhuiyan ZA, Kalman JM, et al. The phenomenon of "QT stunning": the abnormal QT prolongation provoked by standing persists even as the heart rate returns to normal in patients with long QT syndrome. Heart Rhythm 2012 Jun;9(6):901-908 [FREE Full text] [doi: 10.1016/j.hrthm.2012.01.026] [Medline: 22300664]
14. Viskin S, Postema PG, Bhuiyan ZA, Rosso R, Kalman JM, Vohra JK, et al. The response of the QT interval to the brief tachycardia provoked by standing: a bedside test for diagnosing long QT syndrome. J Am Coll Cardiol 2010 May 04;55(18):1955-1961 [FREE Full text] [doi: 10.1016/j.jacc.2009.12.015] [Medline: 20116193]
15. Nadal C, Sas C, Doherty G. Technology acceptance in mobile health: scoping review of definitions, models, and measurement. J Med Internet Res 2020 Jul 06;22(7):e17256 [FREE Full text] [doi: 10.2196/17256] [Medline: 32628122]
16. Park J, Kim E, Shin K. Developing an evaluation framework for selecting optimal medical devices. J Open Innov Technol Mark Complex 2019 Aug 28;5(3):64. [doi: 10.3390/joitmc5030064]
17. Shorten A, Smith J. Mixed methods research: expanding the evidence base. Evid Based Nurs 2017 Jul 14;20(3):74-75. [doi: 10.1136/eb-2017-102699] [Medline: 28615184]
18. International Organization for Standardization. BS EN ISO 9241-11:2018 Ergonomics of human-system interaction. Usability: Definitions and concepts. The British Standards Institution. 2018. URL: https://landingpage.bsigroup.com/LandingPage/Standard?UPI=000000000030319071 [accessed 2021-08-13]
19. Bevan N, Carter J, Harker S. ISO 9241-11 revised: what have we learnt about usability since 1998? In: Kurosu M, editor. Human-Computer Interaction: Design and Evaluation Lecture Notes in Computer Science, vol 916. Cham: Springer; 2015:143-151.
20. Hardware, description of device for custo cardio 300. Custo Med GmbH. 2018. URL: https://www.customed.de/DownloadDoc?v=1.1.95 [accessed 2021-08-13]
21. Streiner DL, Norman GR, Cairney J. Reliability. In: Streiner DL, Norman GR, Cairney J, editors. Health Measurement Scales: A Practical Guide to their Development and Use. Oxford: Oxford University Press; 2008.
22. Darpo B, Nebout T, Sager PT. Clinical evaluation of QT/QTc prolongation and proarrhythmic potential for nonantiarrhythmic drugs: the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use E14 guideline. J Clin Pharmacol 2006 May;46(5):498-507. [doi: 10.1177/0091270006286436] [Medline: 16638733]
23. Mert KU, Turk UO, Gorenek B. A statistical perspective to the QTc interval in the treatment of COVID-19. J Electrocardiol 2021 May;66:48 [FREE Full text] [doi: 10.1016/j.jelectrocard.2021.03.002] [Medline: 33770647]
24. Dahlberg P, Diamant UB, Gilljam T, Rydberg A, Bergfeldt L. QT correction using Bazett's formula remains preferable in long QT syndrome type 1 and 2. Ann Noninvasive Electrocardiol 2021 Jan;26(1):e12804 [FREE Full text] [doi: 10.1111/anec.12804] [Medline: 33070409]
25. Gagnon MP, Orruño E, Asua J, Abdeljelil AB, Emparanza J. Using a modified technology acceptance model to evaluate healthcare professionals' adoption of a new telemonitoring system. Telemed J E Health 2012 Jan;18(1):54-59 [FREE Full text] [doi: 10.1089/tmj.2011.0066] [Medline: 22082108]
26. Rahimi B, Nadri H, Lotfnezhad Afshar H, Timpka T. A systematic review of the technology acceptance model in health informatics. Appl Clin Inform 2018 Jul 15;9(3):604-634 [FREE Full text] [doi: 10.1055/s-0038-1668091] [Medline: 30112741]
27. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
28. Bland J, Altman D. Comparing methods of measurement: why plotting difference against standard method is misleading. The Lancet 1995 Oct;346(8982):1085-1087. [doi: 10.1016/s0140-6736(95)91748-9]
29. Yap BW, Sim CH. Comparisons of various types of normality tests. J Stat Comput Simul 2011 Dec;81(12):2141-2155. [doi: 10.1080/00949655.2010.520163]
30. Madias JE. Comparability of the standing and supine standard electrocardiograms and standing sitting and supine stress electrocardiograms. J Electrocardiol 2006 Apr;39(2):142-149. [doi: 10.1016/j.jelectrocard.2005.07.006] [Medline: 16580409]
31. Somerville S, Somerville J, Croft P, Lewis M. Atrial fibrillation: a comparison of methods to identify cases in general practice. Br J Gen Pract 2000 Sep;50(458):727-729 [FREE Full text] [Medline: 11050790]

Abbreviations

ECG: electrocardiography
ICC: intraclass correlation coefficient
QTc: corrected QT interval

Edited by G Eysenbach; submitted 19.01.21; peer-reviewed by HC Lin, W Sun; comments to author 17.03.21; revised version received 23.03.21; accepted 27.07.21; published 26.08.21.

Please cite as:
Wong KC, Thiagalingam A, Kumar S, Marschner S, Kunwar R, Bailey J, Kok C, Usherwood T, Chow CK
User Perceptions and Experiences of a Handheld 12-Lead Electrocardiographic Device in a Clinical Setting: Usability Evaluation
JMIR Cardio 2021;5(2):e21186
URL: https://cardio.jmir.org/2021/2/e21186
doi:10.2196/21186
PMID:34435958

Original Paper

Moderation of the Stressor-Strain Process in Interns by Heart Rate Variability Measured With a Wearable and Smartphone App: Within-Subject Design Using Continuous Monitoring

Herman de Vries[1,2,3], MSc; Wim Kamphuis[2], PhD; Hilbrand Oldenhuis[1], PhD; Cees van der Schans[3,4,5], PhD; Robbert Sanderman[3,6], PhD

[1]Professorship Personalized Digital Health, Hanze University of Applied Sciences, Groningen, Netherlands
[2]Department of Human Behaviour & Training, TNO, Soesterberg, Netherlands
[3]Department of Health Psychology, University Medical Center Groningen, Groningen, Netherlands
[4]Department of Rehabilitation Medicine, University Medical Center Groningen, Groningen, Netherlands
[5]Research Group Healthy Ageing Allied Health Care and Nursing, Hanze University of Applied Sciences, Groningen, Netherlands
[6]Department of Psychology, Health and Technology, University of Twente, Enschede, Netherlands

Corresponding Author:
Herman de Vries, MSc
Professorship Personalized Digital Health
Hanze University of Applied Sciences
Zernikeplein 11
Groningen, 9747 AS
Netherlands
Phone: 31 0031 50 5953572
Email: h.j.de.vries@pl.hanze.nl

Abstract

Background: The emergence of smartphones and wearable sensor technologies enables easy and unobtrusive monitoring of physiological and psychological data related to an individual's resilience. Heart rate variability (HRV) is a promising biomarker for resilience based on between-subject population studies, but observational studies that apply a within-subject design and use wearable sensors in order to observe HRV in a naturalistic real-life context are needed.

Objective: This study aims to explore whether resting HRV and total sleep time (TST) are indicative and predictive of the within-day accumulation of the negative consequences of stress and mental exhaustion. The tested hypotheses are that demands are positively associated with stress and resting HRV buffers against this association, stress is positively associated with mental exhaustion and resting HRV buffers against this association, stress negatively impacts subsequent-night TST, and previous-evening mental exhaustion negatively impacts resting HRV, while previous-night TST buffers against this association.

Methods: In total, 26 interns used consumer-available wearables (Fitbit Charge 2 and Polar H7), a consumer-available smartphone app (Elite HRV), and an ecological momentary assessment smartphone app to collect resilience-related data on resting HRV, TST, and perceived demands, stress, and mental exhaustion on a daily basis for 15 weeks.

Results: Multiple linear regression analysis of within-subject standardized data collected on 2379 unique person-days showed that having a high resting HRV buffered against the positive association between demands and stress (hypothesis 1) and between stress and mental exhaustion (hypothesis 2). Stress did not affect TST (hypothesis 3). Finally, mental exhaustion negatively predicted resting HRV in the subsequent morning but TST did not buffer against this (hypothesis 4).

Conclusions: To our knowledge, this study provides first evidence that having a low within-subject resting HRV may be both indicative and predictive of the short-term accumulation of the negative effects of stress and mental exhaustion, potentially forming a negative feedback loop. If these findings can be replicated and expanded upon in future studies, they may contribute to the development of automated resilience interventions that monitor daily resting HRV and aim to provide users with an early warning signal when a negative feedback loop forms, to prevent the negative impact of stress on long-term health outcomes.

(JMIR Cardio 2021;5(2):e28731) doi:10.2196/28731

KEYWORDS

stress; strain; burnout; resilience; heart rate variability; sleep; wearables; digital health; sensors; ecological momentary assessment; mobile phone

Introduction

Background

Psychological stress is associated with increased risk of several forms of cancer [1], musculoskeletal diseases [2], periodontal diseases [3], type 2 diabetes mellitus [4], stroke [5], cardiovascular disease [6], and recurrent cardiovascular disease [7]. In an occupational setting, psychosocial risk factors such as high job demands are estimated to increase the risk of stress-related diseases (eg, burnout) by 60%-90% [8]. Occupational stress can therefore cause absenteeism, organizational dysfunction, and decreased productivity, and it has a large economic burden [9].

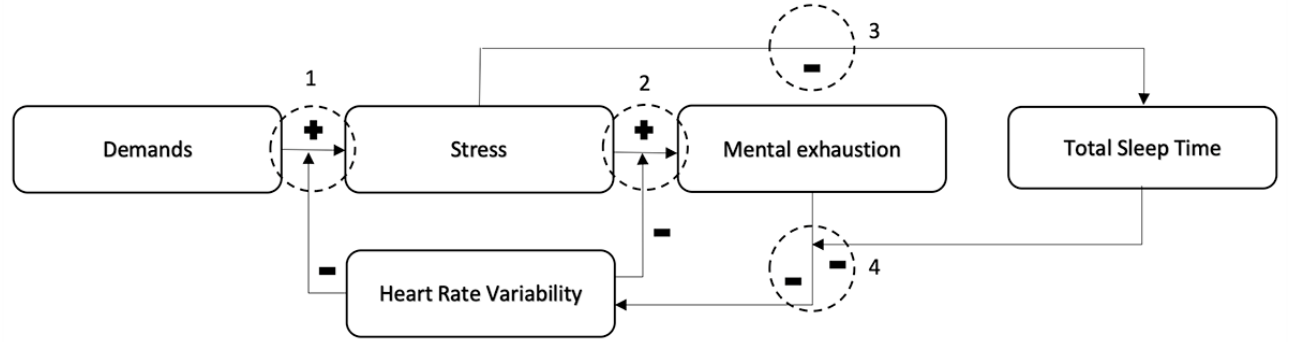
Stress occurs when the brain subconsciously appraises a demand as threatening because of a lack of resources to cope with it [10]. This threat appraisal that we refer to as stress is sometimes referred to as *distress*, whereas demands for which sufficient coping resources are available are appraised as a challenge or as *eustress*. Therefore, stress can be seen as a psychological state that is the result of a divergence between demands on an individual and the individual's perceived capacity to cope with them. Stress causes an imbalance in the body's biological equilibrium (homeostasis), which requires a neural, neuroendocrine, and neuroendocrine-immune adaptation to restore it (allostasis) [11,12]. Although acute stress can have negative effects, it is particularly the cumulative wear and tear on bodily systems (allostatic load) caused by excessive stress or inefficient management of the systems that promote adaptation that is detrimental to long-term health and well-being [13]. In addition, lifestyle-related factors such as obesity, sleep, and substance abuse can also contribute to allostatic load [14]. Allostatic load is therefore considered a measure of the cumulative biological burden on health [15].

To complement this biological and neuroendocrinological perspective on the negative long-term health effects of stress and provide a framework for how short-term spillover effects of stress accumulate the need for a recovery concept be introduced [16]. A need for recovery arises when an individual has problems using resources to adaptively cope with demands that induce stress [17]. Need for recovery is a conscious emotional state that is related to the temporal depletion of resources following effort to meet demands and is characterized by feelings of mental exhaustion [18]. As the availability of resources is assessed during appraisal and the use of resources may be needed during coping, the Conservation of Resources Theory states that an initial loss of resources can lead to a negative feedback loop that increases one's vulnerability to stress [19]. Such a loss spiral may become even more distinct if stress negatively impacts the recovery process itself, for instance, by negatively impacting sleep quality [20] and psychological detachment [21]. Resilience, which can be defined as the process of positively adapting to adverse events [22], is a term describing this process from a positive perspective. During a resilient process, the aforementioned loss spiral is prevented by using resources to adaptively cope with demands and stress to limit long-term strain and its related negative consequences on health and well-being from developing [23]. Resilience is therefore an ongoing process that influences the extent to which adverse events that occur on a small timescale have an impact on mid- to long-term health outcomes.

Heart Rate Variability

A challenge for resilience research that focuses on resilience-related associations on timescales is that it requires continuous data collection, making it relatively labor-intensive for participants to do so. Over the past decade, the emergence of smartphones and wearable sensor technologies has enabled the easy and unobtrusive measurement of physiological and psychological data related to an individual's resilience [24]. A promising example of such a metric is heart rate variability (HRV), which refers to the variation in interbeat intervals of the heartbeats [25]. HRV is a plausible, noninvasive, and easily applicable biomarker for resilience that may serve as a global index of an individual's flexibility and adaptability to stressors [26,27]. HRV is negatively correlated with allostatic load, illustrating its use as an overall health risk indicator [28]. Stress is also known to decrease HRV, particularly with reduced parasympathetic activation [29-31]. Although an acute decline in HRV may be indicative of increased acute stress levels, HRV can remain lowered during rest and sleep after stress or mental exhaustion [32-35]. Conversely, having a lower trait resting HRV has been linked to increased sensitivity to stress via appraisal when faced with demands [36] and to suboptimal emotion regulation that may result in mental exhaustion [37,38]. Therefore, resting HRV can be seen as a physiological resource that is addressed during the appraisal of demands and coping with stress. Therefore, resting HRV can be hypothesized to have a buffering effect on the positive associations between demands and stress, as well as between stress and mental exhaustion. These two hypothesized buffering effects are depicted as circles 1 and 2 in Figure 1, which represent the conceptual model for this study and were based on a previous publication [39]. The model is based on the Transactional Model of Stress and Coping [10], the Job Demands-Resources Model of Burnout [40], the Effort-Recovery Model [17], and the Conservation of Resources Theory [19]. In short, it depicts that demands are appraised as stress when resources are low, that stress leads to mental exhaustion when resources to cope with the demands are lacking, and that mental exhaustion limits resources to deal with future demands, unless there are sufficient recovery opportunities. In this study, HRV is the resource of interest, whereas sleep, operationalized as total sleep time (TST), represents the model's recovery process.

Figure 1. The conceptual model for this study and the four hypotheses that will be tested.



Sleep

Besides resting HRV, sleep is also a relevant potential indicator for the accumulation of the negative consequences of stress and predictor of spillover need for recovery. In the literature, stress has been consistently shown to decrease slow-wave sleep, rapid eye movement sleep, and sleep efficiency, as well as to increase the number of awakenings that may impact the overall sleep duration [20]. Therefore, stress can be hypothesized to negatively affect the TST, which is the total time during a sleep episode in which one was not awake (Figure 1; hypothesis 3). In contrast, sleep has important homeostatic functions that are essential during recovery from both physiological and psychological strains [41]. Sleep deprivation therefore has been linked to an increase in allostatic load [42] and has been linked to decreased HRV in some studies [43,44]. As mental exhaustion may result in decreased resting HRV [34,35] and sleep is an essential aspect of the recovery process, TST can be hypothesized to buffer against the negative association between mental exhaustion and resting HRV (Figure 1; hypothesis 4).

Aims of This Study

HRV measurement is regularly used as a biofeedback tool in mobile health (mHealth) interventions that target acute stress relief [45-47] but may also be useful for interventions that aim to provide users with feedback on their resilience over a longer timeframe. A recent literature review confirmed that HRV has potential as a biomarker for resilience but suggested that more longitudinal studies are needed that use wearable sensors to observe HRV in a naturalistic context of real-life and associate it with resilience-related outcomes, as most of the evidence is based on cross-sectional population studies [27]. Therefore, this study longitudinally assessed the aforementioned hypotheses in a free-living context using consumer-available wearable sensors. Exploring these will provide insight into the potential causal pathways of the within-day accumulation of the negative consequences of stress. Gained insights may therefore be beneficial to the future development of (automated) resilience interventions that target the prevention of stress-related health problems.

Methods

The study protocol was approved by the ethical committee of the Hanze University of Applied Sciences Groningen (heac.2018.008) in the Netherlands.

Participants

Students in applied psychology, social work, and physiotherapy who were about to start their first full-time internship were invited to participate via a message on the school's digital learning environment and email. This population was anticipated to be at risk of experiencing stress because of the potentially stressful nature of these internships, as well as the fact that this was the first internship in the participants' curriculum. A maximum of 15 participants could be simultaneously recruited because of the availability of materials. The recruitment and data collection processes were therefore divided into two waves that started in September 2018 and September 2019, respectively. The students were sent an email with an information letter that described the goal of the study, a description of the measurement protocol, and management of the collected data; the email also stated that participation would be unrelated to their internship or educational progress, that participation would occur on a voluntary basis, and that they could stop at any time without negative consequences. Some of the researchers were employed by the university in which the students were enrolled but had no other associations with the invited students (eg, via education). The participants provided written informed consent before participation. Participants who collected complete data on at least 84 days during the formal participation period were rewarded with a €25 (US $27.50) gift voucher to facilitate recruitment and optimize adherence during participation. This reward threshold represents an adherence of at least 80% over a data collection period of 15 weeks (105 days). The threshold was solely used as a cutoff point for the reward and not for statistical analyses.

Data Collection

Participants were assisted in installing the required apps on their smartphones and were instructed on how to use the devices used for data collection. The data collection period started immediately after the measurement instructions, after which participants collected data for 15 weeks. Some participants completed additional daily measurements on a voluntary basis until their appointment was planned to return the used materials. At this appointment, an additional 20-minute conversation was held about how they experienced the daily measurements and to learn about potential improvements for future studies. During the study, anonymized user accounts were used for the applied consumer-available wearables in order to protect the participants' privacy on the companies' cloud servers, before

being exported and deleted by the researchers after completing their participation.

Main Variables

Resting HRV was measured daily using a consumer-available Polar H7 Bluetooth chest strap in combination with the Elite HRV app that is freely available in the iOS App Store and Google Play Store. The Polar H7 chest strap has been shown to accurately measure resting HRV when compared with an electrocardiogram [48]. The Elite HRV app was chosen because it is easy to use for daily HRV measurements in a consumer setting and allows data export on an interbeat interval level. Participants were instructed to perform a 2-minute HRV measurement in a supine position after awakening before getting out of bed. This is consistent with existing standards and recommendations that suggest a measurement duration of 1-5 minutes and consistent circumstances with as little influence as possible from circadian rhythms, meals, smoking, posture changes, and before significant mental or physical exertion [49,50]. We considered sitting or standing resting HRV measurements to account for the possible presence of parasympathetic saturation in case we recruited an elite endurance athlete [51]. However, we opted for supine measurements immediately after awakening in order to limit the potential influence of posture changes, physical activity, meals, and smoking as recommended by the aforementioned guidelines, as well as to ensure that all participants performed the measurement at a similar postawakening time and in a similar context.

The wrist-worn Fitbit Charge 2 activity tracker was used to measure *TST*, which tends to slightly overestimate but for which has acceptable measurement accuracy in diverse populations [52-54]. Participants were instructed to continuously wear the Fitbit during the day and night and charge it at least once every 5 days.

Before bedtime (available between 08 PM and 06 AM), participants completed a short ecological momentary assessment (EMA) questionnaire using an internally developed smartphone app to measure *demands*, *stress*, and *mental exhaustion*. The daily EMA questionnaire data were stored on premise. In the absence of a single item or full scale that was relevant for the study setting, demands were scored on the self-composed diary question, “How demanding was your day?” These demands represent the contextual circumstances that exerted pressure on the participant, whereas stress reflected the resulting threat appraisal that these evoked within the individual. Stress was scored on a validated single-item scale [55]: “How much stress did you perceive today?” Mental exhaustion is an aspect of the need for recovery concept and was based on item 3 of the Need for Recovery Scale [56], which was chosen because it appropriately represents strain within the context of the used conceptual model [39]: “I felt mentally exhausted as a result of my activities.” All three items were scored on a 11-point numeric rating scale ranging from 0 (*not at all* for demands and stress and *strongly disagree* for mental exhaustion) to 10 (*extremely* for demands and stress and *strongly agree* for mental exhaustion).

Control Variables

Although the Fitbit Charge 2 was chosen for its accuracy in measuring TST, its data on *moderate-to-vigorous physical activity (MVPA)* and *sedentary time* were also used during analysis as potential confounders. MVPA is defined as the total amount of daily minutes where the participant was physically active at an intensity of 3 metabolic equivalents or more, where 1 metabolic equivalent represents the resting metabolism. In previous studies, MVPA was negatively associated with state anxiety [57], mental strain [58], and HRV recovery [59], as well as positively associated with TST [60]. Similarly, sedentary time was positively associated with depression and anxiety [61] and negatively associated with TST [62] and HRV [63]. Finally, Fitbit-measured TST was also used as a control variable in the analyses for stress and mental exhaustion because intraindividual variability in accelerometer-measured TST has been associated with increased stress [64].

In addition, *alcohol consumption* during the previous day was measured in a morning questionnaire (available between 6 AM and 3 PM) for use as a potential confounder. In previous literature, alcohol consumption has been negatively associated with wearable-measured TST [65] and reduced HRV [66]. Alcohol consumption was scored as a numeric variable by asking for the number of alcoholic beverages consumed during the previous day. Although the absolute amount of alcohol in different types of beverages may deviate, asking for the number of alcoholic beverages consumed is both convenient for daily inquiry and consistent with the widely used AUDIT-C questionnaire [67].

Data Analysis

All data management and analyses were performed in RStudio [68] and R [69].

Data Management

For HRV data management, the RHRV package [70] was used. Interbeat interval data of all daily observations were filtered for artifacts using the algorithm in the RHRV package. The respective algorithm is described fully in a complementary book written by the authors of the RHRV package [71]. The algorithm is too comprehensive to be fully described here but is summarized by the authors to apply an adaptive threshold to reject beats whose interbeat interval value differs from previous and following beats, and from a mobile mean more than a threshold value, as well as beats that are not within acceptable physiological values. Subsequently, the root mean square of the successive differences (RMSSD) was calculated for every observation by first calculating each successive difference between heartbeats in milliseconds, then squaring these values, averaging that result, and finally taking its square root [72]. However, algorithmic artifact correction can only distinguish potential measurement errors on an interbeat interval level and can result in abnormally high RMSSD values if there are too many measurement errors present. As this study was performed in free-living conditions, it was not possible to verify if participants performed the daily measurements exactly as instructed. Therefore, a second filtering method was applied to filter out HRV observations with extreme RMSSD values for

that specific participant. To achieve this, within-subject RMSSD outliers of daily observations with a value that lies more than 1.5 IQR below the first quartile or 1.5 IQR above the third quartile for all available data of the respective participant were removed [73]. Finally, the RMSSD values were logarithmically transformed to improve the distribution for parametric statistical modeling of resting HRV.

The TST data were filtered for episodes that started after filling in the evening EMA questionnaire and ended before the morning questionnaire was filled in to obtain the nighttime TST. When more than one TST episode was present between the evening and the subsequent morning EMA questionnaire, they were combined. No outliers were removed from the EMA data because no unfeasible values were identified.

Because of the different scales of the resting HRV, TST, and EMA data, centering and standardizing the data was necessary to prevent potential multicollinearity and allow comparability of the coefficients of the independent variables. As the level 1 association between the aforementioned main variables is the primary interest in this study, centering within subject is recommended as opposed to centering at the grand mean [74]. Therefore, all data were centered and standardized within subjects by subtracting the subject's mean value over all daily observations from each value and dividing it by the subject's SD over all daily observations. The z-scores that were used during analysis therefore reflect the degree to which a daily observation differed from the individual's own mean. As the mean z-scores for each variable in each individual were zero, there was no between-subject variance left in the data. Therefore, multiple regression analysis was performed instead of the multi-level modeling that we originally planned to undertake, despite the observations being nested within subjects (Linear Mixed Modeling with fixed effects and random slopes using the within-subject standardized values resulted in the same outcomes and conclusions on all analyses but had a boundary [singular] fit and no differences in the within- and between-subject explained variance because there was no between-subject variance. As these multi-level models had no benefit, the results of our multiple regression analyses were presented in this study).

Statistical Analysis

To test the four hypotheses described in the Introduction, four statistical analyses were performed. In the first analysis, stress was first modeled based on the control variables MVPA, sedentary time, and previous-day TST, after which the main variables demands, resting HRV, and the interaction effect of demands and resting HRV were added to create the full model. In the second analysis, a control variable model for mental exhaustion was first developed based on MVPA, sedentary time, and previous-night TST, after which a full model was created by adding the main effects of stress and resting HRV, as well as the interaction effect between stress and resting HRV. For analysis three, the control variable model for TST contains previous-day MVPA, sedentary time, and alcohol consumption, with previous-day stress being added to the full model. Finally, the fourth analysis first modeled resting HRV based on control variables previous-day MVPA, sedentary time, and alcohol consumption before adding the main effects of previous-evening mental exhaustion and previous-night TST, as well as the interaction effect between previous-evening mental exhaustion and previous-night TST. To compare the explained variance and statistical significance of the control variable and full models, the difference in the adjusted R-squared value and F statistic was calculated for all four analyses.

Results

Overview

A total of 26 participants were recruited for this study. The participants were predominantly women (n=24). Most participants studied applied psychology (n=19), followed by social work (n=6) and physiotherapy (n=1). The participants were aged between 19.2 and 33.2 years (median 22.6). The participants collected TST data on 2129 days (per participant range 10-119; median 94), 1731 morning EMA questionnaires (range 5-109; median 74), 1653 evening EMA questionnaires (range 7-111; median 73), and HRV data on 1443 days (range 6-115; median 53). In total, for 1004 of the 2379 days (42.2%) on which a participant collected data, the participant collected complete data containing all required TST, HRV, and EMA data. The descriptive statistics for and intercorrelations between the main and control variables are presented in Table 1. Three participants did not complete the full (105 days) measurement period because they lost motivation for the daily measurements, and one participant stopped the daily measurements because of skin rash related to wearing the Fitbit. All three participants who did not complete the full measurement period contributed daily measurements and were thus still included in the analyses. During the exit conversations, several participants stated that they found it difficult to adhere to the HRV measurement, because the need to apply a moistened chest strap and lay still for 2 minutes after awakening while they wanted to continue with their day was inconvenient. Missing Fitbit data were primarily ascribed to forgetting to charge it, particularly when participants were away from home. Finally, participants mostly attributed missing EMA data to simply forget to act on the smartphone notification as they were busy at that time.

Table 1. Descriptive statistics for and intercorrelations between the main (1-5) and control (6-8) variables.

Variable	HRV[a]	TST[b]	Demands	Stress	Mental exhaustion	MVPA[c]	Sedentary time	Alcohol use	Value, mean (SD)
HRV									75.3 (49.9)
Correlation	__[d]	—	—	—	—	—	—	—	
P value	—	—	—	—	—	—	—	—	
TST									7.3 (1.4)
Correlation	−.03	—	—	—	—	—	—	—	
P value	.36	—	—	—	—	—	—	—	
Demands									4.6 (2.4)
Correlation	.06	−.01	—	—	—	—	—	—	
P value	.03	.68	—	—	—	—	—	—	
Stress									3.6 (2.4)
Correlation	.06	.02	.53	—	—	—	—	—	
P value	.03	.42	<.001	—	—	—	—	—	
Mental exhaustion									3.6 (2.4)
Correlation	.004	−.03	.55	.64	—	—	—	—	
P value	.89	.31	<.001	<.001	—	—	—	—	
MVPA									33.9 (37.0)
Correlation	−.05	−.11	.04	−.05	−.06	—	—	—	
P value	.10	<.001	.13	.06	.02	—	—	—	
Sedentary time									687.2 (220.7)
Correlation	−.13	−.48	−.07	.06	.03	−.24	—	—	
P value	<.001	<.001	.004	.02	.18	<.001	—	—	
Alcohol use									1.3 (2.8)
Correlation	−.04	−.28	−.21	−.10	−.06	.10	.08	—	
P value	.13	<.001	<.001	<.001	.03	<.001	.002	—	

[a]HRV: heart rate variability (in milliseconds).

[b]TST: total sleep time (in hours).

[c]MVPA: moderate-to-vigorous physical activity (in minutes).

[d]Not applicable.

Analysis 1: Stress

A two-step hierarchical multiple regression model explaining stress scores was developed (Table 2). After controlling for MVPA, sedentary time, and previous-night TST, demands were positively associated (*P*<.001) with stress. In addition, the interaction effect of demands and resting HRV significantly (*P*=.044) buffered against this positive association. This means that participants tended to report higher stress scores on days that they also considered to be more demanding, but this relationship was weaker on days where the participant woke up with a relatively high resting HRV. The positive association between demands and stress, as well as the buffering effect of resting HRV, confirms hypothesis one. Furthermore, the control variable MVPA was positively associated with stress (*P*=.044), which means that participants reported higher stress scores on days where they were more physically active. In the control variable model, TST was a negative predictor of stress (*P*=.03), but this effect was no longer significant in the full model. The control variable model of analysis explained 2.0% of the within-subject variance in the daily stress scores, whereas the full model had an explained variance of 21.7%, which is a significant increase from the control variable model.

Table 2. Hierarchical multiple regression model for stress (analysis 1).

Independent variable	Stress			
	Step 1 (n=953)[a]		Step 2 (n=953)[b]	
	β	*P* value	β	*P* value
Intercept	.05	.14	.00	.96
TST[c]	−.09	.03	.00	.89
MVPA[d]	.12	<.001	.06	.04
Sedentary time	.02	.75	.05	.29
Demands	—[e]	—	.47	<.001
HRV[f]	—	—	.01	.70
Demands×HRV	—	—	-.06	.04

[a]Adjusted R-squared 0.02; $F_{3,949}$=7.541.

[b]Adjusted R-squared 0.22; $F_{6,946}$=44.86; Δ adjusted R-squared 0.20; Δ $F_{6,949}$=37.32.

[c]TST: total sleep time (in hours).

[d]MVPA: moderate-to-vigorous physical activity (in minutes).

[e]Variable is not included in step 1.

[f]HRV: heart rate variability (in milliseconds).

Analysis 2: Mental Exhaustion

A two-step hierarchical multiple regression model explaining mental exhaustion scores was developed (Table 3). After controlling for MVPA, sedentary time, and previous-night TST, stress was positively associated (*P*<.001) with mental exhaustion. In addition, the interaction effect of stress and resting HRV significantly (*P*=.029) buffered against this positive association. This means that participants tended to report higher mental exhaustion scores on days that they were also considered stressful, but this relationship was weaker on days where the participant woke up with a relatively high resting HRV. The positive association between stress and mental exhaustion, as well as the buffering effect of resting HRV confirm hypothesis two. In the control variable model, MVPA was also positively associated with mental exhaustion (*P*=.017), but this effect was no longer significant in the full model. The control variable model of analysis two explains 1.4% of the within-subject variance in the daily mental exhaustion scores, whereas the full model has an explained variance of 31.6%, which is a significant increase from the control variable model.

Table 3. Multiple regression model for mental exhaustion (analysis 2).

Independent variable	Mental exhaustion			
	Step 1 (n=953)[a]		Step 2 (n=953)[b]	
	β	*P* value	β	*P* value
Intercept	.05	.12	.02	.37
TST[c]	−.06	.15	−.01	.68
MVPA[d]	.09	.02	.02	.58
Sedentary time	.09	.09	.07	.09
Stress	—[e]	—	.55	<.001
HRV[f]	—	—	−.04	.15
Stress × HRV	—	—	−.06	.03

[a]Adjusted R-squared 0.01; $F_{3,949}$=5.42.

[b]Adjusted R-squared 0.32; $F_{6,946=}$74.17; Δ adjusted R-squared 0.31; Δ $F_{6,946}$=68.75.

[c]TST: total sleep time (in hours).

[d]MVPA: moderate-to-vigorous physical activity (in minutes).

[e]Variable is not included in step 1.

[f]HRV: heart rate variability (in milliseconds).

Analysis 3: Total Sleep Time

A two-step hierarchical multiple regression model explaining nighttime TST was developed (Table 4). After controlling for previous-day MVPA, sedentary time, and alcohol consumption, previous-day stress did not predict TST, unlike our expectation based on hypothesis 3. However, the control variables previous-day MVPA and alcohol consumption were negatively associated with TST, whereas sedentary time was positively associated with TST. This means that participants had a lower TST on days where they were relatively physically active, consumed alcohol, and had limited sedentary time. The control variable model of analysis three explains 3.8% of the within-subject variance in TST, whereas the full model has an explained variance of 4.6%, which is not a statistically significant increase from the control variable model.

Table 4. Multiple regression model for TST (analysis 3).

Independent variable	TST[a]			
	Step 1 (n=1285)[b]		Step 2 (n=1285)[c]	
	β	*P* value	β	*P* value
Intercept	−.03	.32	−.03	.33
MVPA[d]	−.07	.01	−.07	.01
Sedentary time	.08	.01	.08	.01
Alcohol consumption	−.20	<.001	−.20	<.001
Stress	—[e]	—	−.01	.64

[a]TST: total sleep time (in hours).

[b]Adjusted R-squared 0.05; $F_{3,1281}$=21.88.

[c]Adjusted R-squared 0.05; $F_{4,1280}$=6.46; Δ adjusted R-squared 0.0; Δ $F_{4,1280}$=−5.42.

[d]MVPA: moderate-to-vigorous physical activity (in minutes).

[e]Variable is not included in step 1.

Analysis 4: Heart Rate Variability

A two-step hierarchical multiple regression model explaining resting HRV was developed (Table 5). After controlling for previous-day MVPA, sedentary time, and alcohol consumption, previous-evening mental exhaustion negatively predicted (*P*<.001) resting HRV, but previous-night TST did not buffer against this negative association. Therefore, these results partially support hypothesis four. Among the control variables, previous-day alcohol consumption negatively predicted resting HRV (*P*<.001). The control variable model explained 2.3% of the within-subject variance in resting HRV, whereas the full model had an explained variance of 3.6%, which was not a statistically significant increase from the control variable model.

Table 5. Multiple regression model for HRV (analysis 4).

Independent variable	HRV[a]			
	Step 1 (n=948)[b]		Step 2 (n=948)[c]	
	β	*P* value	β	*P* value
Intercept	−.00	.98	.00	.96
MVPA[d]	−.06	.06	−.05	.10
Sedentary time	.02	.53	.03	.40
Alcohol consumption	−.18	<.001	−.19	<.001
Mental exhaustion	—[e]	—	−.12	<.001
TST[f]	—	—	.02	.52
Mental exhaustion × TST	—	—	−.00	.92

[a]HRV: heart rate variability (in milliseconds).

[b]Adjusted R-squared 0.02; $F_{3,944}$=8.42.

[c]Adjusted R-squared 0.04; $F_{6,941}$=6.956; Δ adjusted R-squared 0.02; Δ $F_{6,941}$=−1.46.

[d]MVPA: moderate-to-vigorous physical activity (in minutes).

[e]Variable is not included in step 1.

[f]TST: total sleep time (in hours).

Discussion

Principal Findings

This study aimed to test the hypotheses that (1) demands are positively associated with stress and resting HRV buffers against this association, (2) stress is positively associated with mental exhaustion and resting HRV buffers against this association, (3) stress negatively impacts subsequent-night TST, and (4) previous-evening mental exhaustion negatively impacts resting HRV, while previous-night TST buffers against this association. By assessing these associations based on longitudinal data that were collected using consumer-available wearables and smartphone apps in a free-living context, this study provides insight into the potential pathways of the within-day accumulation of the negative consequences of stress. The results of this study support hypotheses one and two and partially support hypothesis four.

Heart Rate Variability as an Index of Resilience

As hypothesized, having a high resting HRV buffered against the positive associations between demands and stress (hypothesis 1), as well as between stress and mental exhaustion (hypothesis 2). Similarly, mental exhaustion negatively predicted resting HRV, as expected (hypothesis 4). These findings suggest that waking up with a relatively high intraindividual resting HRV decreases an individual's sensitivity to stress when faced with demands, as well as the likelihood of being mentally exhausted during a stressful day. In addition, as the accumulation of mental exhaustion negatively impacts an individual's resting HRV, an increase in mental exhaustion negatively impacts this (psycho) physiological resource and thus potentially creates a negative feedback loop that can lead to a loss spiral. These results therefore confirm our hypothesis that a decline in resting HRV is indicative of the accumulation of the negative consequences of stress, as well as the continued accumulation of negative consequences of stress. Therefore, resting HRV can be seen as a biomarker for or an index of resilience, where a decline in resting HRV may signal that buildup of allostatic load is present and suggests that the individual's readiness to face new demands may at least be temporarily decreased.

As highlighted in a recent literature review, most studies to date investigating the role of HRV as an index for resilience have a cross-sectional nature and assess relationships at the between-subject level [27]. To our knowledge, this study is the first to apply a nested longitudinal design and assess the potential of resting HRV as an index of resilience to stress on a within-subject level. Previous studies that investigated between-subject differences identified similar relationships between resting HRV and mental health outcomes. For instance, a recent study with school teachers concluded that 48-hour trait HRV buffered the effect of emotional demands on exhaustion [75]. Another recent study cross-sectionally assessed a population of young female adults and found that having a high resting HRV buffered against the positive association between emotion regulation difficulties and depressive symptoms [76]. Resting HRV has also been reported to buffer against the negative effects of chronic stress on sleep quality, which in turn is related to greater depressive symptoms [77]. Finally, high stress-induced HRV was shown to buffer against the negative effect of hostility on cortisol sensitivity [78]. Therefore, the within-subject findings of this study align with previous studies that also reported favorable between-subject effects of resting HRV on diverse mental health outcomes.

The Role of Sleep in the Within-Day Stressor-Strain Process

Contrary to our hypothesis, stress did not negatively affect TST (hypothesis 3). The absence of a negative association between stress and TST conflicts with previous literature that consistently links experimental stress to decreased slow-wave sleep, rapid eye movement sleep, sleep efficiency, and increases in awakenings [20]. A possible explanation for this could be the difference in context, as those studies examined the influence of experimental stress on polysomnographically measured sleep, whereas this study investigated daytime stressors and TST in a natural free-living context. Because of the increasing capabilities and performance of consumer wearables to measure sleep and the resulting rise in the use of consumer wearables in sleep research, future studies may increase insights into the potential relationship between daily stressors and TST in a natural free-living context [79].

TST also did not buffer against the negative association between mental exhaustion and resting HRV, as expected (hypothesis 4). This expectation was based on the rationale that sleep has important homeostatic functions that are essential during recovery from strain [41], and that sleep deprivation has been linked to an increase in allostatic load [42] and a decrease in HRV [43,44]. As mental exhaustion was measured during the evening and resting HRV during the morning, we expected TST to potentially have a buffering effect, meaning that the negative impact of mental exhaustion on resting HRV would be smaller if the participant slept well that night. This buffering effect was not present in these findings, but TST was also not positively associated with resting HRV, as might be expected based on the aforementioned literature. A possible explanation for this could be that the relationship between sleep deprivation and HRV in previous literature seems to be particularly present in studies assessing a longer sleep deprivation period [80], which might suggest that the nuanced day-to-day differences in TST are too small to significantly impact the resting HRV. Future studies investigating the impact of TST on resting HRV or the recovery from strain in a natural free-living context in which such long periods of sleep deprivation are relatively uncommon, assessing the impact of multi-day trends in TST might help increase insight on this topic.

Notable Effects of MVPA, Sedentary Time, and Alcohol Consumption

The effects of most of the control variables that were significantly associated with the outcomes of the four analyses were as expected, but some of the effects seem to conflict with previous literature. For instance, MVPA was negatively associated with TST, but a recent study found a positive association between MVPA and TST [60]. Similarly, sedentary time was positively associated with TST in this study, whereas a negative association with TST was reported in another recent study assessing obese adults [62]. A possible explanation can

be found in the reported significant correlations between MVPA, sedentary time, and alcohol consumption (Table 1). This young student population spends part of their leisure time enjoying the local nightlife, in which dancing and alcohol consumption are common. It is therefore possible that this will have caused the low sedentary time, high MVPA, and alcohol consumption that were associated with low TST.

Strengths and Limitations

The strengths of this study are its longitudinal design and large sample of nested observations, optimizing the within-subject variance. Moreover, the use of consumer-friendly wearable sensors and smartphone apps allowed for relatively unobtrusive monitoring in a free daily living context, optimizing the generalizability for similar settings. A limitation of this study was the need to apply relatively coarse algorithmic artifact correction and rule-based outlier filtering during HRV data management. Because of the choice to use a consumer-available sensor and app for long-term daily measurements in free-living conditions, electrogram-level data were unavailable, and it was impossible to verify if participants performed the measurements as instructed. As the applied algorithmic artifact removal method can only filter out interbeat interval artifacts within an HRV measurement, it has no rules to decide whether an observation should be removed altogether, filtering out extreme within-subject RMSSD outliers was necessary. Furthermore, algorithm-based artifact correction was preferred over manually adjusting interbeat interval artifacts to make the findings of this study applicable to the context of an automated resilience intervention that does not rely on human interference during data management. In addition, the use of single-item scales in the evening EMA questionnaire forms a limitation of comprehensiveness at which the concepts can be measured. Therefore, validated single-item scales or items with the most favorable psychometric properties in existing validated scales were used where available [39]. As single-item scales have consistently been found to be valid measures for diverse concepts in comparison to full scales [81-84] and have become common good in EMA research, the applied EMA methods can still be considered appropriate. The participants also received some feedback on their sleep, physical activity, and HRV because of the use of the consumer-available Fitbit and Elite HRV apps, which might have influenced their behavior. Nevertheless, any such influence was not considered a problem because this study observes the natural relationship between several variables and does not reflect on the behaviors themselves. Finally, only 3.6% of the within-subject variance in resting HRV could be explained, and the buffering effect of resting HRV was relatively modest.

Generalizability

The HRV-related results can be generalized to young and employed female adults who track their resting HRV upon awakening. As 92% (24/26) of the participants were female and HRV can be related to menstrual cycle changes [85], further research on young males is necessary to improve the generalizability of these findings to young adults regardless of gender. As the resting HRV was measured upon awakening in this study, the influence of a phenomenon called the cortisol awakening response (CAR) might have played a role. Upon awakening, cortisol levels start to increase and peak approximately 30-45 minutes thereafter because of the CAR, where 1%-3.6% of its variance can be explained by psychosocial factors [86]. Although the CAR is associated with postawakening changes in HRV, these changes appear to be unrelated to perceived stress and measures of emotion regulation [87]. Therefore, it is possible that measuring HRV during sleep could yield similar results. An advantage of measuring resting HRV during sleep is that participants would not need to apply a moistened chest strap and lay still in a supine position upon awakening to collect their resting HRV data. As multiple participants described that this procedure negatively impacted their adherence to the measurement protocol, unobtrusively measuring the resting HRV during sleep might improve adherence and thus increase statistical power. Future research is needed to confirm whether resting HRV during sleep can be used to yield similar results.

Implications

To our knowledge, this study is the first to report a significant within-subject buffering effect of resting HRV on the positive associations between demands and stress, as well as between stress and mental exhaustion and a negative association between mental exhaustion and resting HRV. Replication of these findings in future studies is needed. As the combined findings form a feedback loop, it is possible that multi-day trends in resting HRV could be linked to longitudinal mental health outcomes in future studies. Furthermore, exploring the use of time series analysis to create within-subject models in which multi-day trend data are used to assess the daily outcomes could potentially improve the accuracy of the presented models.

Future studies are advised to use passive monitoring techniques that require little to no user attention whenever possible to improve participant adherence and optimize statistical power.

If the findings of this study can indeed be replicated and expanded upon, it would show that longitudinally monitoring resting HRV as a biomarker of or index for resilience may be useful in the context of prevention. In this context, a structural increase or decline in resting HRV could provide an early warning signal that a positive or negative feedback loop is formed. When used in a consumer wearable–based automated resilience intervention, these signals can be used to prompt user feedback. For instance, users could be rewarded when a positive feedback loop is recognized or suggested to perform cognitive behavioral therapy–based self-reflection exercises or relaxation techniques when a negative feedback loop occurs. Such an automated resilience intervention that unobtrusively monitors the user's resting HRV for the early recognition of (un)favorable feedback loops and generation of just-in-time feedback may therefore limit the buildup of allostatic load and improve long-term health outcomes.

Acknowledgments

The authors thank Dr Heather Young (TNO) for performing the backward translations for the EMA items, Dr Arie van Roon (University Medical Center Groningen) for his advice on the HRV data management, and Dr Tanja Krone (TNO) for her advice on the applied data analysis method. This work was supported by internal funding of TNO, the Hanze University of Applied Sciences Groningen, and the University Medical Center Groningen.

Conflicts of Interest

None declared.

References

1. Yang T, Qiao Y, Xiang S, Li W, Gan Y, Chen Y. Work stress and the risk of cancer: a meta-analysis of observational studies. Int J Cancer 2019;144(10):2390-2400 [FREE Full text] [doi: 10.1002/ijc.31955] [Medline: 30484859]
2. Buscemi V, Chang W, Liston MB, McAuley JH, Schabrun SM. The role of perceived stress and life stressors in the development of chronic musculoskeletal pain disorders: a systematic review. J Pain 2019;20(10):1127-1139. [doi: 10.1016/j.jpain.2019.02.008] [Medline: 30797962]
3. Decker A, Askar H, Tattan M, Taichman R, Wang H. The assessment of stress, depression, and inflammation as a collective risk factor for periodontal diseases: a systematic review. Clin Oral Investig 2020;24(1):1-12 [FREE Full text] [doi: 10.1007/s00784-019-03089-3] [Medline: 31677052]
4. Sui H, Sun N, Zhan L, Lu X, Chen T, Mao X. Association between work-related stress and risk for type 2 diabetes: a systematic review and meta-analysis of prospective cohort studies. PLoS One 2016;11(8):e0159978-e015997- [FREE Full text] [doi: 10.1371/journal.pone.0159978] [Medline: 27513574]
5. Booth J, Connelly L, Lawrence M, Chalmers C, Joice S, Becker C, et al. Evidence of perceived psychosocial stress as a risk factor for stroke in adults: a meta-analysis. BMC Neurol 2015;15:233 [FREE Full text] [doi: 10.1186/s12883-015-0456-4] [Medline: 26563170]
6. Magnavita N, Capitanelli I, Garbarino S, Pira E. Work-related stress as a cardiovascular risk factor in police officers: a systematic review of evidence. Int Arch Occup Environ Health 2018;91(4):377-389. [doi: 10.1007/s00420-018-1290-y] [Medline: 29344727]
7. Li J, Zhang M, Loerbroks A, Angerer P, Siegrist J. Work stress and the risk of recurrent coronary heart disease events: a systematic review and meta-analysis. Int J Occup Med Environ Health 2015;28(1):8-19 [FREE Full text] [doi: 10.2478/s13382-014-0303-7] [Medline: 26159942]
8. van der Molen HF, Nieuwenhuijsen K, Frings-Dresen MH, de Groene G. Work-related psychosocial risk factors for stress-related mental disorders: an updated systematic review and meta-analysis. BMJ Open 2020;10(7):e034849 [FREE Full text] [doi: 10.1136/bmjopen-2019-034849] [Medline: 32624469]
9. Béjean S, Sultan-Taïeb H. Modeling the economic burden of diseases imputable to stress at work. Eur J Health Econ 2005;6(1):16-23. [doi: 10.1007/s10198-004-0251-4] [Medline: 15452742]
10. Lazarus RS, Folkman S. Transactional theory and research on emotions and coping. Eur J Pers 1987;1(3):141-169. [doi: 10.1002/per.2410010304]
11. McEwen B. Stress, adaptation, and disease. Allostasis and allostatic load. Ann N Y Acad Sci 1998;840:33-44. [doi: 10.1111/j.1749-6632.1998.tb09546.x] [Medline: 9629234]
12. McEwen BS. Protective and damaging effects of stress mediators: central role of the brain. Dialogues Clin Neurosci 2006;8(4):367-381 [FREE Full text] [doi: 10.31887/DCNS.2006.8.4/bmcewen] [Medline: 17290796]
13. Seeman TE, Singer BH, Rowe JW, Horwitz RI, McEwen BS. Price of adaptation--allostatic load and its health consequences. MacArthur studies of successful aging. Arch Intern Med 1997;157(19):2259-2268. [Medline: 9343003]
14. Suvarna B, Suvarna A, Phillips R, Juster R, McDermott B, Sarnyai Z. Health risk behaviours and allostatic load: a systematic review. Neurosci Biobehav Rev 2020;108:694-711. [doi: 10.1016/j.neubiorev.2019.12.020] [Medline: 31846655]
15. Seeman TE, McEwen BS, Rowe JW, Singer BH. Allostatic load as a marker of cumulative biological risk: MacArthur studies of successful aging. Proc Natl Acad Sci U S A 2001;98(8):4770-4775 [FREE Full text] [doi: 10.1073/pnas.081072698] [Medline: 11287659]
16. Sluiter JK, de Croon EM, Meijman TF, Frings-Dresen MH. Need for recovery from work related fatigue and its role in the development and prediction of subjective health complaints. Occup Environ Med 2003;60(Suppl 1):i62-i70 [FREE Full text] [doi: 10.1136/oem.60.suppl_1.i62] [Medline: 12782749]
17. van Veldhoven M. Need for recovery after work: an overview of construct, measurement and research. In: Houdmont J, Leka S, editors. Occupational Health Psychology: European Perspectives on Research, Education & Practice. Nottingham, United Kingdom: Nottingham University Press; 2008:1-25.
18. Sonnentag S, Zijlstra FR. Job characteristics and off-job activities as predictors of need for recovery, well-being, and fatigue. J Appl Psychol 2006;91(2):330-350. [doi: 10.1037/0021-9010.91.2.330] [Medline: 16551187]
19. Hobfoll SE. The influence of culture, community, and the nested‐self in the stress process: advancing conservation of resources theory. Appl Psychol 2001;50(3):337-421. [doi: 10.1111/1464-0597.00062]

20. Kim E, Dimsdale JE. The effect of psychosocial stress on sleep: a review of polysomnographic evidence. Behav Sleep Med 2007;5(4):256-278 [FREE Full text] [doi: 10.1080/15402000701557383] [Medline: 17937582]
21. Sonnentag S, Kuttler I, Fritz C. Job stressors, emotional exhaustion, and need for recovery: a multi-source study on the benefits of psychological detachment. J Vocat Behav 2010 Jun;76(3):355-365. [doi: 10.1016/j.jvb.2009.06.005]
22. Cosco TD, Kaushal A, Hardy R, Richards M, Kuh D, Stafford M. Operationalising resilience in longitudinal studies: a systematic review of methodological approaches. J Epidemiol Community Health 2017;71(1):98-104 [FREE Full text] [doi: 10.1136/jech-2015-206980] [Medline: 27502781]
23. Britt TW, Shen W, Sinclair RR, Grossman MR, Klieger DM. How much do we really know about employee resilience? Ind Organ Psychol 2016;9(2):378-404. [doi: 10.1017/iop.2015.107]
24. Drury RL. Wearable biosensor systems and resilience: a perfect storm in health care? Front Psychol 2014;5:853. [doi: 10.3389/fpsyg.2014.00853] [Medline: 25147531]
25. Thayer JF, Ahs F, Fredrikson M, Sollers JJ, Wager TD. A meta-analysis of heart rate variability and neuroimaging studies: implications for heart rate variability as a marker of stress and health. Neurosci Biobehav Rev 2012;36(2):747-756. [doi: 10.1016/j.neubiorev.2011.11.009] [Medline: 22178086]
26. An E, Nolty A, Amano S, Rizzo A, Buckwalter J, Rensberger J. Heart rate variability as an index of resilience. Mil Med 2020;185(3-4):363-369. [doi: 10.1093/milmed/usz325] [Medline: 31642481]
27. Perna G, Riva A, Defillo A, Sangiorgio E, Nobile M, Caldirola D. Heart rate variability: can it serve as a marker of mental health resilience?: special section on "Translational and Neuroscience Studies in Affective Disorders" section editor, Maria Nobile MD, PhD. J Affect Disord 2020;263:754-761. [doi: 10.1016/j.jad.2019.10.017] [Medline: 31630828]
28. Viljoen M, Claassen N. Allostatic load and heart rate variability as health risk indicators. Afr Health Sci 2017;17(2):428-435 [FREE Full text] [doi: 10.4314/ahs.v17i2.17] [Medline: 29062338]
29. Jarczok MN, Jarczok M, Mauss D, Koenig J, Li J, Herr RM, et al. Autonomic nervous system activity and workplace stressors--a systematic review. Neurosci Biobehav Rev 2013;37(8):1810-1823. [doi: 10.1016/j.neubiorev.2013.07.004] [Medline: 23891906]
30. Järvelin-Pasanen S, Sinikallio S, Tarvainen MP. Heart rate variability and occupational stress-systematic review. Ind Health 2018;56(6):500-511 [FREE Full text] [doi: 10.2486/indhealth.2017-0190] [Medline: 29910218]
31. Kim H, Cheon E, Bai D, Lee YH, Koo B. Stress and heart rate variability: a meta-analysis and review of the literature. Psychiatry Investig 2018;15(3):235-245 [FREE Full text] [doi: 10.30773/pi.2017.08.17] [Medline: 29486547]
32. Hall M, Vasko R, Buysse D, Ombao H, Chen Q, Cashmere JD, et al. Acute stress affects heart rate variability during sleep. Psychosom Med 2004;66(1):56-62. [doi: 10.1097/01.psy.0000106884.58744.09] [Medline: 14747638]
33. Hynynen E, Konttinen N, Kinnunen U, Kyröläinen H, Rusko H. The incidence of stress symptoms and heart rate variability during sleep and orthostatic test. Eur J Appl Physiol 2011;111(5):733-741. [doi: 10.1007/s00421-010-1698-x] [Medline: 20972879]
34. Uusitalo A, Mets T, Martinmäki K, Mauno S, Kinnunen U, Rusko H. Heart rate variability related to effort at work. Appl Ergon 2011;42(6):830-838. [doi: 10.1016/j.apergo.2011.01.005] [Medline: 21356531]
35. van Amelsvoort L, Schouten E, Maan A, Swenne C, Kok F. Occupational determinants of heart rate variability. Int Arch Occup Environ Health 2000;73(4):255-262. [doi: 10.1007/s004200050425] [Medline: 10877031]
36. Park G, Van Bavel JJ, Vasey MW, Thayer JF. Cardiac vagal tone predicts inhibited attention to fearful faces. Emotion 2012;12(6):1292-1302. [doi: 10.1037/a0028528] [Medline: 22642338]
37. Park G, Thayer JF. From the heart to the mind: cardiac vagal tone modulates top-down and bottom-up visual perception and attention to emotional stimuli. Front Psychol 2014;5:278 [FREE Full text] [doi: 10.3389/fpsyg.2014.00278] [Medline: 24817853]
38. Williams DP, Cash C, Rankin C, Bernardi A, Koenig J, Thayer JF. Resting heart rate variability predicts self-reported difficulties in emotion regulation: a focus on different facets of emotion regulation. Front Psychol 2015;6:261 [FREE Full text] [doi: 10.3389/fpsyg.2015.00261] [Medline: 25806017]
39. de Vries H, Kamphuis W, Oldenhuis H, Van Der Schans C, Sanderman R. Modelling employee resilience using wearables and apps: a conceptual framework and research design. Int J Adv Life Sci 2019;11(3-4):110-117 [FREE Full text]
40. Bakker AB, Demerouti E. The Job Demands ‐ Resources model: state of the art. J Manag Psychol 2007;22(3):309-328. [doi: 10.1108/02683940710733115]
41. McEwen BS. Sleep deprivation as a neurobiologic and physiologic stressor: allostasis and allostatic load. Metabolism 2006;55(10 Suppl 2):S20-S23. [doi: 10.1016/j.metabol.2006.07.008] [Medline: 16979422]
42. McEwen BS, Karatsoreos IN. Sleep deprivation and circadian disruption: stress, allostasis, and allostatic load. Sleep Med Clin 2015;10(1):1-10. [doi: 10.1016/j.jsmc.2014.11.007] [Medline: 26055668]
43. Virtanen I, Kalleinen N, Urrila AS, Leppänen C, Polo-Kantola P. Cardiac autonomic changes after 40 hours of total sleep deprivation in women. Sleep Med 2015;16(2):250-257. [doi: 10.1016/j.sleep.2014.10.012] [Medline: 25634644]
44. Zhong X, Hilton HJ, Gates GJ, Jelic S, Stern Y, Bartels MN, et al. Increased sympathetic and decreased parasympathetic cardiovascular modulation in normal humans with acute sleep deprivation. J Appl Physiol (1985) 2005;98(6):2024-2032 [FREE Full text] [doi: 10.1152/japplphysiol.00620.2004] [Medline: 15718408]

45. Kizakevich PN, Eckhoff RP, Lewis GF, Davila MI, Hourani LL, Watkins R, et al. Biofeedback-assisted resilience training for traumatic and operational stress: preliminary analysis of a self-delivered digital health methodology. JMIR Mhealth Uhealth 2019;7(9):e12590 [FREE Full text] [doi: 10.2196/12590] [Medline: 31493325]
46. Chang I, Cheng W, Kung W. A stress relief app intervention for newly employed nursing staff: quasi-experimental design. JMIR Mhealth Uhealth 2019;7(12):e15785 [FREE Full text] [doi: 10.2196/15785] [Medline: 31850848]
47. Munster-Segev M, Fuerst O, Kaplan SA, Cahn A. Incorporation of a stress reducing mobile app in the care of patients with type 2 diabetes: a prospective study. JMIR Mhealth Uhealth 2017;5(5):e75 [FREE Full text] [doi: 10.2196/mhealth.7408] [Medline: 28554881]
48. Plews DJ, Scott B, Altini M, Wood M, Kilding AE, Laursen PB. Comparison of heart-rate-variability recording with smartphone Photoplethysmography, Polar H7 chest strap, and electrocardiography. Int J Sports Physiol Perform 2017;12(10):1324-1328. [doi: 10.1123/ijspp.2016-0668] [Medline: 28290720]
49. Heart rate variability. Standards of measurement, physiological interpretation, and clinical use. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Eur Heart J 1996;17(3):354-381. [Medline: 8737210]
50. Quintana DS, Heathers J. Considerations in the assessment of heart rate variability in biobehavioral research. Front Psychol 2014;5:805 [FREE Full text] [doi: 10.3389/fpsyg.2014.00805] [Medline: 25101047]
51. Plews D, Laursen P, Buchheit M. Day-to-day heart-rate variability recordings in world-champion rowers: appreciating unique athlete characteristics. Int J Sports Physiol Perform 2017;12(5):697-703. [doi: 10.1123/ijspp.2016-0343] [Medline: 27736257]
52. de Zambotti M, Goldstone A, Claudatos S, Colrain IM, Baker FC. A validation study of Fitbit Charge 2™ compared with polysomnography in adults. Chronobiol Int 2018;35(4):465-476. [doi: 10.1080/07420528.2017.1413578] [Medline: 29235907]
53. Liang Z, Chapa-Martell MA. Accuracy of Fitbit wristbands in measuring sleep stage transitions and the effect of user-specific factors. JMIR Mhealth Uhealth 2019;7(6):e13384 [FREE Full text] [doi: 10.2196/13384] [Medline: 31172956]
54. Tedesco S, Sica M, Ancillao A, Timmons S, Barton J, O'Flynn B. Validity evaluation of the Fitbit Charge2 and the Garmin vivosmart HR+ in free-living environments in an older adult cohort. JMIR Mhealth Uhealth 2019;7(6):e13084 [FREE Full text] [doi: 10.2196/13084] [Medline: 31219048]
55. Littman AJ, White E, Satia JA, Bowen DJ, Kristal AR. Reliability and validity of 2 single-item measures of psychosocial stress. Epidemiology 2006;17(4):398-403. [doi: 10.1097/01.ede.0000219721.89552.51] [Medline: 16641618]
56. van Veldhoven M, Broersen S. Measurement quality and validity of the "need for recovery scale". Occup Environ Med 2003;60(Suppl 1):i3-i9 [FREE Full text] [doi: 10.1136/oem.60.suppl_1.i3] [Medline: 12782740]
57. Ensari I, Greenlee TA, Motl RW, Petruzzello SJ. Meta-analysis of acute exercise effects on state anxiety: an update of randomized controlled trials over the past 25 years. Depress Anxiety 2015;32(8):624-634. [doi: 10.1002/da.22370] [Medline: 25899389]
58. Chatzitheodorou D, Kabitsis C, Malliou P, Mougios V. A pilot study of the effects of high-intensity aerobic exercise versus passive interventions on pain, disability, psychological strain, and serum cortisol concentrations in people with chronic low back pain. Phys Ther 2007;87(3):304-312. [doi: 10.2522/ptj.20060080] [Medline: 17284546]
59. Michael S, Graham KS, Davis GM. Cardiac autonomic responses during exercise and post-exercise recovery using heart rate variability and systolic time intervals-a review. Front Physiol 2017;8:301 [FREE Full text] [doi: 10.3389/fphys.2017.00301] [Medline: 28611675]
60. Lee A, Lin W. The effects of physical activity on sleep quality. Med Sci Sport Exerc 2002 Jun;34(5):S70-S49. [doi: 10.1097/00005768-200205001-00384] [Medline: 25596964]
61. Teychenne M, Stephens LD, Costigan SA, Olstad DL, Stubbs B, Turner AI. The association between sedentary behaviour and indicators of stress: a systematic review. BMC Public Health 2019;19(1):1357 [FREE Full text] [doi: 10.1186/s12889-019-7717-x] [Medline: 31647002]
62. Liao Y, Robertson M, Winne A, Wu I, Le TA, Balachandran DD, et al. Investigating the within-person relationships between activity levels and sleep duration using Fitbit data. Transl Behav Med 2021;11(2):619-624 [FREE Full text] [doi: 10.1093/tbm/ibaa071] [Medline: 32667039]
63. Hallman D, Sato T, Kristiansen J, Gupta N, Skotte J, Holtermann A. Prolonged sitting is associated with attenuated heart rate variability during sleep in blue-collar workers. Int J Environ Res Public Health 2015;12(11):14811-14827 [FREE Full text] [doi: 10.3390/ijerph121114811] [Medline: 26610534]
64. Veeramachaneni K, Slavish DC, Dietch JR, Kelly K, Taylor DJ. Intraindividual variability in sleep and perceived stress in young adults. Sleep Health 2019;5(6):572-579 [FREE Full text] [doi: 10.1016/j.sleh.2019.07.009] [Medline: 31575485]
65. Devenney LE, Coyle KB, Roth T, Verster JC. Sleep after heavy alcohol consumption and physical activity levels during alcohol hangover. J Clin Med 2019;8(5):752 [FREE Full text] [doi: 10.3390/jcm8050752] [Medline: 31137775]
66. Quintana DS, McGregor IS, Guastella AJ, Malhi GS, Kemp AH. A meta-analysis on the impact of alcohol dependence on short-term resting-state heart rate variability: implications for cardiovascular risk. Alcohol Clin Exp Res 2013;37(Suppl 1):E23-E29. [doi: 10.1111/j.1530-0277.2012.01913.x] [Medline: 22834996]

67. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Arch Intern Med 1998 Sep 14;158(16):1789-1795. [doi: 10.1001/archinte.158.16.1789] [Medline: 9738608]
68. RStudio: Integrated Development for R. RStudio. URL: http://www.rstudio.com [accessed 2021-08-17]
69. The R project for statistical computing. R Core Team. URL: https://www.r-project.org [accessed 2021-08-17]
70. Rodriguez-Linares L, Vila X, Lado M, Mendez A, Otero A, Garcia CA, et al. RHRV: Heart Rate Variability Analysis of ECG Data. CRAN - R Project. 2020. URL: https://cran.r-project.org/web/packages/RHRV/ [accessed 2021-03-01]
71. Quintana AO, Rodríguez-Liñares L, Vila XA. Heart Rate Variability Analysis With the R Package RHRV. Basel, Switzerland: Springer; 2017.
72. Shaffer F, Ginsberg JP. An overview of heart rate variability metrics and norms. Front Public Health 2017;5:258 [FREE Full text] [doi: 10.3389/fpubh.2017.00258] [Medline: 29034226]
73. Mowbray FI, Fox-Wasylyshyn SM, El-Masri MM. Univariate outliers: a conceptual overview for the nurse researcher. Can J Nurs Res 2019;51(1):31-37. [doi: 10.1177/0844562118786647] [Medline: 29969044]
74. Enders CK, Tofighi D. Centering predictor variables in cross-sectional multilevel models: a new look at an old issue. Psychol Methods 2007;12(2):121-138. [doi: 10.1037/1082-989X.12.2.121] [Medline: 17563168]
75. Schmid RF, Thomas J. Teachers' ambulatory heart rate variability as an outcome and moderating variable in the job demands-resources model. Anxiety Stress Coping 2020;33(4):387-402. [doi: 10.1080/10615806.2020.1746286] [Medline: 32228186]
76. Fantini-Hauwel C, Batselé E, Gois C, Noel X. Emotion regulation difficulties are not always associated with negative outcomes on women: the buffer effect of HRV. Front Psychol 2020;11:697 [FREE Full text] [doi: 10.3389/fpsyg.2020.00697] [Medline: 32425846]
77. da Estrela C, McGrath J, Booij L, Gouin JP. Heart rate variability, sleep quality, and depression in the context of chronic stress. Ann Behav Med 2021;55(2):155-164 [FREE Full text] [doi: 10.1093/abm/kaaa039] [Medline: 32525208]
78. Murdock KW, LeRoy AS, Fagundes CP. Trait hostility and cortisol sensitivity following a stressor: the moderating role of stress-induced heart rate variability. Psychoneuroendocrinology 2017;75:222-227 [FREE Full text] [doi: 10.1016/j.psyneuen.2016.10.014] [Medline: 27838516]
79. de Zambotti M, Cellini N, Menghini L, Sarlo M, Baker FC. Sensors capabilities, performance, and use of consumer sleep technology. Sleep Med Clin 2020;15(1):1-30 [FREE Full text] [doi: 10.1016/j.jsmc.2019.11.003] [Medline: 32005346]
80. Quintana DS, Elvsåshagen T, Zak N, Norbom LB, Pedersen P, Quraishi SH, et al. Diurnal variation and twenty-four hour sleep deprivation do not alter supine heart rate variability in healthy male young adults. PLoS One 2017;12(2):e0170921 [FREE Full text] [doi: 10.1371/journal.pone.0170921] [Medline: 28151944]
81. Wanous JP, Hudy MJ. Single-item reliability: a replication and extension. Organ Res Methods 2001;4(4):361-375. [doi: 10.1177/109442810144003]
82. Bergkvist L, Rossiter JR. The predictive validity of multiple-item versus single-item measures of the same constructs. J Mark Res 2007;44(2):175-184. [doi: 10.1509/jmkr.44.2.175]
83. Finkel EJ, Burnette JL, Scissors LE. Vengefully ever after: destiny beliefs, state attachment anxiety, and forgiveness. J Pers Soc Psychol 2007;92(5):871-886. [doi: 10.1037/0022-3514.92.5.871] [Medline: 17484610]
84. Spörrle M, Bekk M. Meta-analytic guidelines for evaluating single-item reliabilities of personality instruments. Assessment 2014;21(3):272-285 [FREE Full text] [doi: 10.1177/1073191113498267] [Medline: 23996850]
85. Schmalenberger KM, Eisenlohr-Moul TA, Jarczok MN, Eckstein M, Schneider E, Brenner IG, et al. Menstrual cycle changes in vagally-mediated heart rate variability are associated with progesterone: evidence from two within-person studies. J Clin Med 2020;9(3):617 [FREE Full text] [doi: 10.3390/jcm9030617] [Medline: 32106458]
86. Boggero IA, Hostinar CE, Haak EA, Murphy ML, Segerstrom SC. Psychosocial functioning and the cortisol awakening response: meta-analysis, P-curve analysis, and evaluation of the evidential value in existing studies. Biol Psychol 2017;129:207-230 [FREE Full text] [doi: 10.1016/j.biopsycho.2017.08.058] [Medline: 28870447]
87. Stalder T, Evans P, Hucklebridge F, Clow A. Associations between the cortisol awakening response and heart rate variability. Psychoneuroendocrinology 2011;36(4):454-462. [doi: 10.1016/j.psyneuen.2010.07.020] [Medline: 20732747]

Abbreviations

CAR: cortisol awakening response
EMA: ecological momentary assessment
HRV: heart rate variability
MVPA: moderate-to-vigorous physical activity
RMSSD: Root Mean Square of the Successive Differences
TST: total sleep time

Edited by G Eysenbach; submitted 12.03.21; peer-reviewed by S Tedesco, N Brasier; comments to author 08.06.21; revised version received 14.07.21; accepted 27.07.21; published 04.10.21.

Please cite as:
de Vries H, Kamphuis W, Oldenhuis H, van der Schans C, Sanderman R
Moderation of the Stressor-Strain Process in Interns by Heart Rate Variability Measured With a Wearable and Smartphone App: Within-Subject Design Using Continuous Monitoring
JMIR Cardio 2021;5(2):e28731
URL: https://cardio.jmir.org/2021/2/e28731
doi:10.2196/28731
PMID:34319877

Original Paper

Validation of Heart Rate Extracted From Wrist-Based Photoplethysmography in the Perioperative Setting: Prospective Observational Study

Eveline Mestrom[1], MD; Ruben Deneer[2,3,4], MSc; Alberto G Bonomi[5], PhD; Jenny Margarito[5], MSc; Jos Gelissen[5], MSc; Reinder Haakma[5], PhD; Hendrikus H M Korsten[1,6], PhD, MD; Volkher Scharnhorst[2,3,4], PhD; R Arthur Bouwman[1,6], PhD, MD

[1]Department of Anesthesiology, Catharina Hospital Eindhoven, Eindhoven, Netherlands

[2]Clinical Laboratory, Catharina Hospital Eindhoven, Eindhoven, Netherlands

[3]Department of Biomedical Engineering, Eindhoven University of Technology, Eindhoven, Netherlands

[4]Expert Center Clinical Chemistry Eindhoven, Eindhoven, Netherlands

[5]Department of Personal Health, Philips Research, Eindhoven, Netherlands

[6]Department of Electrical Engineering, Eindhoven University of Technology, Eindhoven, Netherlands

Corresponding Author:
Eveline Mestrom, MD
Department of Anesthesiology
Catharina Hospital Eindhoven
Michelangelolaan 2
Eindhoven, 5623 EJ
Netherlands
Phone: 31 646067638
Email: eveline.mestrom@catharinaziekenhuis.nl

Abstract

Background: Measurement of heart rate (HR) through an unobtrusive, wrist-worn optical HR monitor (OHRM) could enable earlier recognition of patient deterioration in low acuity settings and enable timely intervention.

Objective: The goal of this study was to assess the agreement between the HR extracted from the OHRM and the gold standard 5-lead electrocardiogram (ECG) connected to a patient monitor during surgery and in the recovery period.

Methods: In patients undergoing surgery requiring anesthesia, the HR reported by the patient monitor's ECG module was recorded and stored simultaneously with the photopletysmography (PPG) from the OHRM attached to the patient's wrist. The agreement between the HR reported by the patient's monitor and the HR extracted from the OHRM's PPG signal was assessed using Bland-Altman analysis during the surgical and recovery phase.

Results: A total of 271.8 hours of data in 99 patients was recorded simultaneously by the OHRM and patient monitor. The median coverage was 86% (IQR 65%-95%) and did not differ significantly between surgery and recovery (Wilcoxon paired difference test P=.17). Agreement analysis showed the limits of agreement (LoA) of the difference between the OHRM and the ECG HR were within the range of 5 beats per minute (bpm). The mean bias was –0.14 bpm (LoA between –3.08 bpm and 2.79 bpm) and –0.19% (LoA between –5 bpm to 5 bpm) for the PPG- measured HR compared to the ECG-measured HR during surgery; during recovery, it was –0.11 bpm (LoA between –2.79 bpm and 2.59 bpm) and –0.15% (LoA between –3.92% and 3.64%).

Conclusions: This study shows that an OHRM equipped with a PPG sensor can measure HR within the ECG reference standard of –5 bpm to 5 bpm or –10% to 10% in the perioperative setting when the PPG signal is of sufficient quality. This implies that an OHRM can be considered clinically acceptable for HR monitoring in low acuity hospitalized patients.

(JMIR Cardio 2021;5(2):e27765) doi:10.2196/27765

KEYWORDS

validation; heart rate; photoplethysmography; perioperative patients; unobtrusive sensing

Introduction

Timely recognition of deterioration in hospitalized patients is important because early intervention improves clinical outcomes of mortality and unplanned intensive care unit (ICU) admissions and reduces length of stay [1]. Especially in perioperative care, complications related to surgery limit effectiveness of the surgery and are associated with increased mortality and costs [2,3]. From previous studies, it is known that vital signs such as heart rate (HR) and respiratory rate are important indicators of critical illness and are often altered long before a deterioration is clinically apparent [4-6]. In general, patients' vital signs are assessed multiple times a day in general wards. However, patients may deteriorate between the scheduled measurements [1]. Therefore, both remote and continuous monitoring of HR and respiratory rate is considered a promising tool for early detection of patient deterioration in the low acuity or home setting.

The gold standard for measurement of HR in the perioperative setting is the multiple-lead electrocardiogram (ECG). However, there are practical limitations to continuous measurements of vital signs using ECG due to the obtrusiveness and limited mobility of patients. Novel solutions to monitor vital signs have been proposed in the literature [7]. One of these novel solutions is the wrist-based optical heart rate monitor (OHRM). The OHRM has the advantage of offering unobtrusive, remote, and continuous monitoring. The photopletysmography (PPG) sensor in the OHRM has shown potential to provide robust peak detection from which HR may be calculated [8,9]. Validation studies have been presented on the accuracy of these devices in healthy participants [10-17]. However, it remains unclear whether these tools are also reliable for monitoring vital signs in patients during hospital stay. The robustness of an OHRM should be studied in hospitalized patients before it can be reliably adopted in a clinical setting. Few studies have been performed in hospitalized patients, and these included mainly stable ward patients [13,18,19]. To check the accuracy of the OHRM in the acute phases of disease, the study population should ideally experience some deterioration in HR during the study period. Hospitalized patients are a heterogeneous population where HR can be influenced by all kinds of pathologies, particularly during surgery, which induces hemodynamic, metabolic, endocrine, and immunological alterations [20,21]. The objective of this study was to assess the agreement between the HR extracted from a PPG sensor–based OHRM and that of the gold standard 5-lead ECG connected to the patient monitor during surgery and recovery.

Methods

Study Design

We used a prospective, nonrandomized, observational, single-center study design to examine the perioperative period. The study was performed in the Catharina Hospital in Eindhoven, the Netherlands, a tertiary hospital that performs an average of 20,000 surgical procedures annually. The study was reviewed and approved by the Medical Research Ethics Committees United (study #NL65134.100.18).

Study Population

All adult patients scheduled for noncardiac surgery were screened by anesthesiologists for inclusion in the study. Patients were selected by the anesthesiologist on a weekly basis and informed of the study prior to the surgical procedure. In total, 203 patients were eligible for inclusion, and 100 patients signed informed consent. Cardiac surgeries were excluded since the required extracorporeal circulation and scheduled ICU admission would complicate analysis.

To obtain a representative case mix of patients undergoing surgery, patients were categorized and stratified based on the American Society of Anesthesiologists Physical Status Classification (ASA class) [22] and risk of the surgery [23]. Patients were divided into 2 groups: (1) low risk (ASA score I or II and low- or intermediate-risk surgery) and (2) high risk (ASA score III or IV and intermediate- or high-risk surgery). If the ASA score and risk were discordant (eg, ASA score IV and low-risk surgery), the ASA score took precedence over the surgical risk.

Study Procedure

The measurements on the OHRM started as soon as the device was placed on the patient's wrist in the holding area. The choice of wrist depended on the placement of the blood pressure cuff. Unless not otherwise possible, the OHRM was placed on the wrist of the arm opposite to the blood pressure cuff to prevent disturbance in the optical measurements of the cardiac pulse. The vital sign measurement started upon arrival in the operating room when sensor modules were connected to the patient monitor. Measurements continued during surgery (surgical phase). After completion of the surgery, the patient was disconnected from the patient monitor located in the operating room and transferred to the recovery room. Upon arrival in the recovery room, the patient monitor was reconnected to the patient monitor located in the recovery room, and measurements continued (recovery phase) until the patient was transferred to the general ward. Upon transfer, the patient monitor was disconnected, and the OHRM was removed from the patient's wrist.

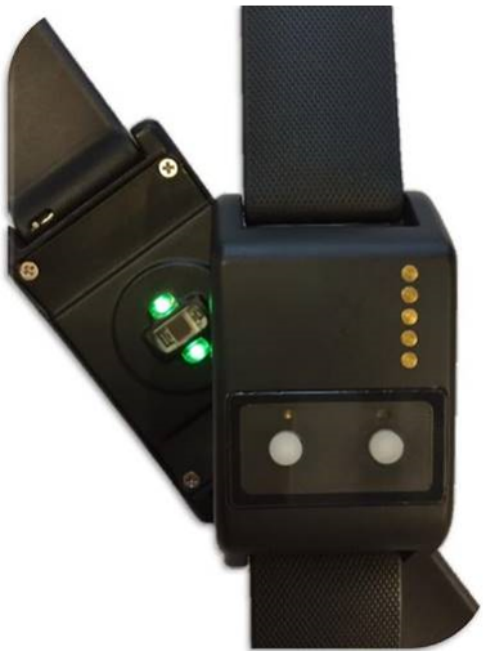
Data Collection

The wrist-worn OHRM was developed by Philips and equipped with a Philips Cardio and Motion Monitoring Module, which integrates a PPG and accelerometer sensor (Figure 1). PPG is an optical technique used to detect volumetric changes in blood in peripheral circulation. It continuously measures the reflectivity of the skin in the green part of the light spectrum in combination with the 3-axial acceleration of the body part where it is located. Accelerometry is a technique used to quantify movement patterns through the detection of rotational and translational acceleration. The sampling frequency of both the PPG and accelerometer sensors was 32 Hz [24]. The patient monitor in both the operating and recovery room was a Carescape B850 (GE Healthcare) connected to a 5-lead ECG, pulse oximeter, body temperature sensor, and oscillometric cuff for noninvasive blood pressure measurements or an arterial line for invasive blood pressure measurements. All patient monitors were linked to a patient data collection system which logged

data for every patient. The application used for logging data was AnStat (CarePoint). AnStat logs trends and waveforms with a sampling frequency of 100 Hz and events like administration of drugs.

Data on patient demographics were extracted from the electronic medical records.

Figure 1. The wrist-worn optical heart rate monitor.



Data Processing

The HR from the 5-lead ECG was derived by the Carescape B850 patient monitor software. The HR from the OHRM was extracted from the logged PPG signal using an algorithm that was previously validated in healthy volunteers in various conditions of rest and physical activity [25]. In brief, the algorithm processed the PPG and motion signal simultaneously to derive HR and a quality index (QI) for the HR measurements with a 1-second interval. Both HR and QI were assessed in real time. The algorithm provided an output every second, but the data were processed using a sliding window of 5 seconds. The HR measurements from the ECG and PPG were synchronized using a cross-correlation function and visual inspection of the resulting overlapped time series. The QI characterized the confidence in the provided metric estimated by the algorithm itself. It was represented on a 5-point scale (from 0-4), where 0 denoted "lowest confidence/output unavailable" and 4 denoted "highest confidence." The QI was determined by proprietary methods and used to provide a monotonically increasing relation between availability and reliability. The QI of the HR was typically influenced by the signal-to-noise ratio of the PPG signal, the ability of the algorithm to cope with motion artifacts, and the periodicity of the detected pulse signal.

A PPG-based arrhythmia detection algorithm [26] was also used to identify periods in which the PPG signal was not in accordance with a normal sinus rhythm. In brief, the arrhythmia detection algorithm first identifies interpulse intervals (IPIs) in a 30-second interval from the PPG signal and then rejects the IPI in presence of motion during the IPI period. The final set of IPIs in the 30-second period are then processed by a Markov Model to define the probability of atrial fibrillation (AF). In our study, if >50% of the detected IPIs in the 30-second interval were rejected by the algorithm, the interval was labeled as arrhythmia. For measurement intervals during which events of arrhythmias were detected by this algorithm, the QI was set to 0. To summarize the PPG signal coverage, each HR measurement was assigned to 1 of 3 categories: (1) good quality (QI=4), (2) low quality (QI≤3), and (3) arrhythmia. Only HR data associated with QI=4 were used in the agreement analysis. Coverage was measured as the ratio between the measurements with good quality and the entire measurement duration for a patient. If patients had less than 5 minutes of coverage during surgery or recovery, the session was excluded from analysis. The hospital health records were screened to find potential causes for patients that were excluded since this would indicate that the OHRM was not usable for these patients.

Bland-Altman plots were made to visualize the agreement between ECG and PPG HR [27]. Limits of agreement (LoA) and CIs of the LoA were calculated by taking into account both within- and between-patient variability [28]. The modified Bland-Altman method that estimates the limits of agreement with repeated measurements where the true value varies, as described by Zou [29], was used. The CIs of the LoAs were constructed using the method of variance estimate recovery (MOVER). In short, a 1-way random-effects model was used to model the difference d_{ij} of the j-th measurement for the i-th patient as follows:

$$d_{ij} = d + a_i + e_{ij}$$

Where d is the unknown true difference between the ECG and PPG HR. The difference d is either the difference between the PPG and ECG HR (ie, $d = HR_{PPG} - HR_{ECG}$) or the percentage

difference calculated by $d = d_{\%} =$. a_i and e_{ij} are zero-mean normally distributed, with variance and corresponding to the true between- and within-patient variances, respectively. The bias is estimated by , where and and m_i is the number of pairs per patient. The between- and within-patient variances were estimated by and where . and were summed to obtain an estimate of the total variance . The 95% LoA values were then calculated by . CIs around the LoA values were estimated by the MOVER [29]. Bland-Altman analysis was conducted for both absolute difference and the percentage difference in HR between PPG and ECG. The HR evaluation was compared to the reference standard [30], which requires an accuracy of –5 bpm to 5 bpm or –10% to 10% (whichever is largest).

Results

Characteristics and Coverage

A total of 100 patients were included. One patient was excluded because the patient monitor data were missing due to technical difficulties. Recovery data of 1 patient were missing because this patient was transferred to the ICU immediately after surgery. Three patients had too few (<5 minutes) good quality PPG measurements during both the surgery and recovery phase and were therefore omitted from the agreement analysis. Another 12 patients had <5 minutes of good quality measurements during either the surgery or recovery phase, but only the respective phase was omitted from the agreement analysis. Patient demographics are shown in Table 1.

An example of the data that were captured for each patient in the study is shown in Figure 2. In total, 159.08 hours of data were captured during surgery, 76.5% (121.7/159.1 hours) of which were of good quality (QI = 4), and 112.59 hours of data were captured during recovery, 74.4% (83.8/112.6 hours) of which were of good quality. Coverage varied between patients (Figure 3). Median coverage was 86% (IQR 65% to 95%) and did not differ significantly between surgery and recovery (Wilcoxon paired difference test P=.17). Coverage statistics are shown in Table 2.

Table 1. Patient demographics.

Demographic variable	Value
Total participants, n	99
Age in years, median (IQR)	58.0 (44.5-68.0)
Male, n	36
BMI (kg/m2), median (IQR)	28.7 (24.8-37.1)
ASA-PS[a] score, n	
I	10
II	39
III	45
IV	5
Surgical risk, n	
High	9
Intermediate	63
Low	27
Diabetes, n	7
Hypertension, n	37
Hypercholesterolemia, n	21
Previous stroke or TIA[b], n	13
Structural heart disease, n	8
Atrial fibrillation, n	8
Wrist device location, n	
Left	45
Right	53
Unknown	1
Surgery type, n	
Bariatric	22
Gastroenterological	8
Neurological	3
Orthopedic	31
Plastic	7
Thyroid	1
Urogenital	17
Vascular	10
Surgery duration (min), median (IQR)	87.0 (48.0-115.0)
Recovery duration (min), median (IQR)	58.0 (41.2-78.0)

[a]ASA-PS: American Society of Anesthesiologists Physical Status.

[b]TIA: transient ischemic attack.

Figure 2. Example of data captured for a representative patient in the study. The ECG signal is represented by the gray line and the individual PPG measurements by the colored points. The QI of the PPG signal is represented by a different color which ranges from 0 (lowest quality) to 4 (highest quality). bpm: beats per minute; ECG: electrocardiogram; HR: heart rate; PPG: photopletysmography; QI: quality index.

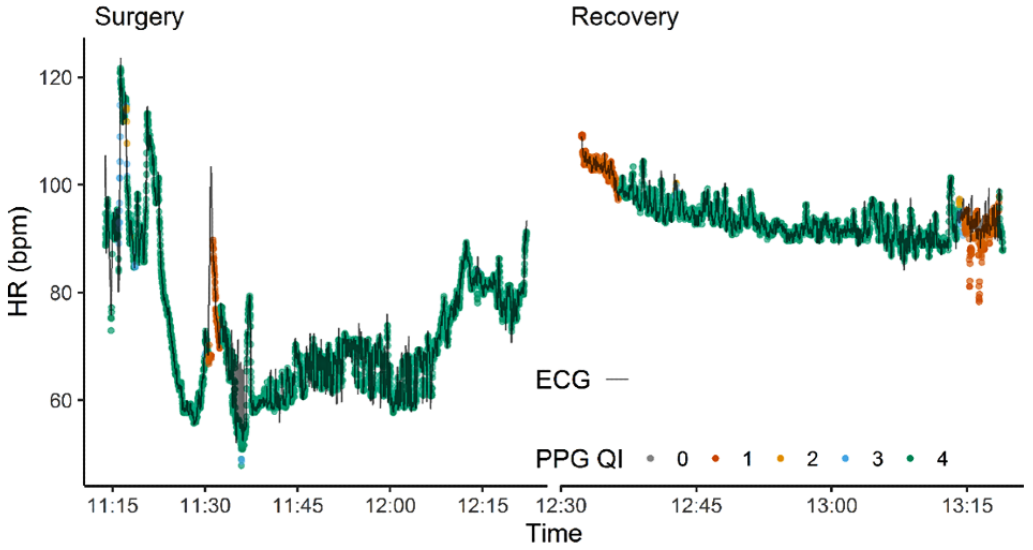


Figure 3. Histogram with distribution of coverage fraction (ie, proportion of recorded data that corresponds to a photopletysmography signal with good quality).

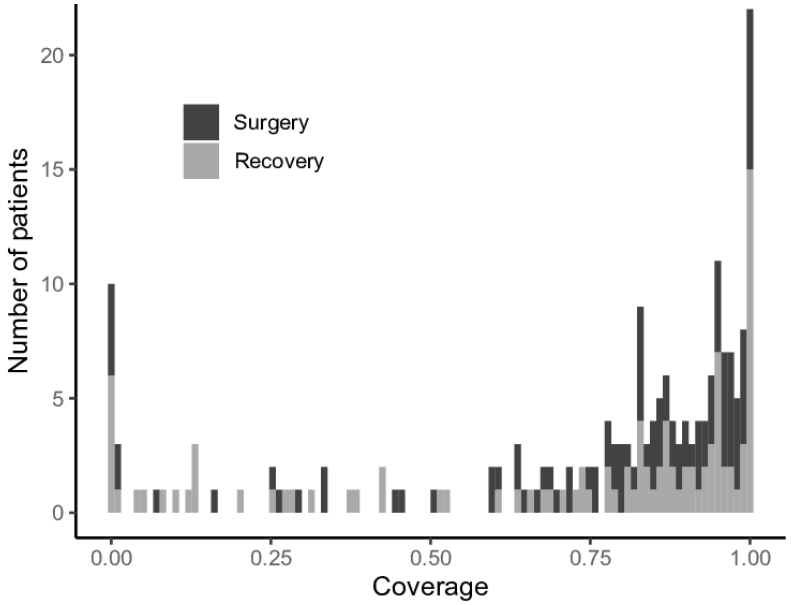


Table 2. Coverage statistics of total hours for analyses including all patients.

Characteristics of the collected data	Surgery	Recovery	Surgery and recovery
Total hours, n	159.6	112.2	271.8
Good quality PPG[a] (hours), n (%)	124.1 (78.0)	83.8 (74.4)	207.9 (76.5)
Low quality PPG (hours), n (%)	33.3 (21.0)	28.7 (25.5)	62.0 (22.8)
Arrhythmia (hours), n (%)	1.7 (1.1)	0.2 (0.2)	1.9 (0.7)

[a]PPG: photopletysmography.

Bland-Altman Analysis During Surgery

The mean bias was –0.15 (SD 0.05) bpm and –0.20% (SD 0.06) for the PPG-measured HR compared to the ECG-measured HR, where the LoA (including the SE) fell within the reference standard of –5 bpm to 5 bpm and –10% to 10% (Table 3).

Table 3. Bland-Altman analysis results during surgery.

Results	Difference in bpm[a]	Difference in percentage
Bias, mean (SE)	–0.15 (0.05)	–0.20 (0.06)
SD of differences	1.50	2.34
Lower LoA[b] (95% CI)	–3.08 (–2.99 to –3.19)	–4.79 (–4.92 to –4.66)
Upper LoA (95% CI)	2.79 (2.69 to 2.89)	4.39 (4.26 to 4.53)
Within-patient variance	2.04	5.12
Between-patient variance	0.20	0.37
Intraclass correlation coefficient	0.09	0.07

[a]bpm: beats per minute.

[b]LoA: limits of agreement.

Bland-Altman Analysis During Recovery

The mean bias was –0.10 bpm (SD 0.04) and –0.14% (SD 0.04) for the PPG-measured HR compared to the ECG-measured HR, where the limits of agreement (including the SE) fell within the reference standard of –5 bpm to 5 bpm and –10% to 10% (Table 4).

Table 4. Bland-Altman analysis results during recovery.

Results	Difference in bpm[a]	Difference in percentage
Bias, mean (SE)	–0.10 (0.04)	–0.14 (0.04)
SD of differences	1.38	1.93
Lower LoA[b] (95% CI)	–2.80 (–2.72 to –2.87)	–3.92 (–3.83 to –4.01)
Upper LoA (95% CI)	2.59 (2.52 to 2.67)	3.64 (3.56 to 3.74)
Within-patient variance	1.78	3.56
Between-patient variance	0.11	0.16
Intraclass correlation coefficient	0.06	0.04

[a]bpm: beats per minute.

[b]LoA: limits of agreement.

Discussion

A wrist-worn OHRM may be able to provide continuous unobtrusive HR monitoring in the low acuity care or home settings. To determine this, the validity of OHRM-derived HR must first be assessed in a representative target population and compared to the gold standard 5-lead ECG. In this study, the agreement between the HR derived from an OHRM and a 5-lead ECG connected to a patient monitor was assessed for a representative patient population during the perioperative period. The OHRM could provide an accurate HR (–5 bpm to 5 bpm and –10% to 10% compared to the ECG-derived HR) during both the surgical and recovery phase when the PPG signal was of good quality. A vast majority (121.7/159.1 hours, 76.5%) of the PPG signal was good quality.

Given the hemodynamic changes during the perioperative period and the diversity in surgical procedures, a technical validation, as performed in this study, is essential before the OHRM can be introduced into clinical practice. Very few studies were found in the literature that validated wrist-worn OHRMs in hospitalized patients. One study with a goal of early warning detection using an OHRM was performed in patients during and after discharge from the ICU [13]. The OHRM was a personal fitness tracker, and 24 hours of monitoring started in the ICU while patients were still being monitored by means of a continuous ECG. The authors concluded that personal fitness tracker–derived HRs were slightly lower than those derived from continuous ECG monitoring and not as accurate as pulse oximetry-derived HRs. A feasibility study was performed by the same research group regarding bradycardia and tachycardia detection in the same population [18]. The authors stressed in both studies the importance of subgroup analysis of patients not in sinus rhythm since this negatively impacted measurement accuracy. This corresponds to the findings in our study where measurements during arrhythmia were of low quality.

Another study was designed for AF detection, but also showed good results in sinus rhythm in patients undergoing elective cardioversion for AF [31]. There were fewer patients (N=20) included than in our study, and the agreement analysis was based on QRS intervals as the reference, with a mean difference of 1.3 ms being found between ECG and PPG. Other studies were performed in healthy participants and focused on assessing accuracy during physical activity [11,12,14,16,17,32-34]. However, the results obtained in these studies cannot be translated to our results since surgery was the underlying cause for changes in HR in our study and not physical activity. Factors

influencing HR during surgery are hemodynamic changes induced by anesthesia, intraoperative factors such as blood loss and hypothermia, or involvement of vital organs in the area of surgery. Results of previous studies did conclude that motion artifacts remain a challenge in OHRMs. In this study, motion artifacts were less likely to occur since patients were mostly immobilized. Nevertheless, motion artifacts are relevant to consider if the OHRM is to be used in the future for remote monitoring of patients.

The agreement between the ECG- and PPG-derived HR was within the LoA of –5 bpm to 5 bpm and –10% to 10% (whichever was largest) both during surgery and recovery. However, this only applied when the quality of the PPG signal was labeled as "good." Moreover, a vast majority (during surgery: 121.7/159.1 hours; during recovery: 76.5%; 83.8/112.6, 74.4%) of the PPG signal was good quality. Ideally, the coverage should be 100%, but this may not be realistic since a poor signal-to-noise ratio in the PPG measurements can perturb the detection of a sinus rhythm. Arrhythmias such as ectopic beats, AF, premature ventricular or atrial complex, and paced beats also contributed to a reduction of measurement coverage of the OHRM. This is confirmed by the fact that patients with a medical history of AF had lower overall coverage compared to patients without previous diagnosis of AF, resulting in 25% versus 85% overall coverage, respectively. This was also true for those patients with severe congenital heart disease where median coverage was 47% versus 85% for patients without structural heart disease. Finally, a very small group of patients had an extremely low coverage, but a consequently large influence on the mean coverage. Median coverage was higher, with 85% being good quality data. Exclusions of patients in this study should be taken into account as well when clinical applicability of the OHRM is assessed. Furthermore, 3 patients were excluded since <5 minutes of data were captured in total, which could be explained in 1 case by serious congenital heart disease which involved aberrant anatomy. Another 12 patients with <5 minutes of good quality data during surgery or recovery were also excluded. As the reference standard, ECG is considered capable of providing 100% coverage. However, in clinical practice, this is most likely not the case since ECG HR detection can also fail in the presence of the aforementioned abnormalities.

The limitations of this study are the following. Despite a heterogeneous group of elective procedures and hospital setting, no general ward patients were included. Nevertheless, translation of our findings to patients in the general ward is reasonable as patients are transitioning from immobile to a more moveable state during stay in the recovery room. By using a 1-way random-effects model, the between- and within-patient variance was quantified to explore the effect of heterogeneity of the study group. As indicated by Hamilton and Lewis [35], not accounting for repeated measures can lead to a falsely narrow LoA, mainly with a small number of patients and a large number of measurements per patient. Both the mean bias and between-patient variance are weighted according to the number of observations available for each patient. Hence, patients with more observations will contribute more to the final results. As the distribution of observation times was not normal, some patients contributed substantially more than did others, and results could have been biased to these patients. It is also worth mentioning the assumptions underlying the 1-way random-effects model. Specifically, the model assumes that repeated differences on a single patient are independent and that the within-patient variance of these differences is constant and the same for all patients. First, the independence assumption could have been too strong since hemodynamic changes occurred during surgery or recovery which could have led to autocorrelation in the HR and subsequent differences arising between the PPG- and ECG-derived HR. The effect of autocorrelation on the within-patient variance is unknown, and further studies are needed to take autocorrelation into account [28]. Second, the assumption of homoscedasticity was not formally tested, and it could have been the case that the variance of the differences increased with higher HR. Finally, the possible influence of surgery-specific factors, such as electrosurgical instruments causing interference was not investigated.

With this study in hospitalized patients, we gained knowledge on the influence of the oscillometric blood pressure cuff which disturbs the measurements by compromising the blood flow. Although both nurses and patients experience the wireless and unobtrusive wristband as an advantage, the OHRM will still have to find a way into local workflow. Before early warning systems can be incorporated into timely detect deterioration, clinical studies to define the predictive value of continuous HR monitoring for deterioration in hospitalized patients other than the ICU or operating room are first needed. Although our own and previous studies might not have found equal accuracy compared to the gold standard, there is still more opportunity to produce benefit during the acute phases of illness, which otherwise may go unnoticed in the general ward with monitoring of the HR 2 to 3 times daily. Although the use of an ORHM for deterioration detection seems less time-consuming for nurses, it still remains uncertain what the false alarm rate will be or how much time practical procedures, such as charging the battery of the OHRM, will take. From a practical point of view, placement of the wristband is made problematic by intravenous or arterial lines, identification bands, or bandages on the wrists.

In summary, the current study found that the OHRM is clinically acceptable when good quality data are captured and in settings when high-intensity monitoring, such as in the ICU or operating room, is not mandatory. The OHRM seems less suitable for patients with congenital anatomical changes of the heart or patients with arrhythmias. When the OHRM captures a significant amount of low-quality data in a patient, the suggestion would be to use another monitoring type to ensure safe monitoring. Since the OHRM can report the quality of the PPG signal instantaneously, the decision to switch to ECG monitoring can be made immediately. The reliability of an OHRM to measure HR in patients known to suffer from arrhythmias or structural heart disease requires further research.

In conclusion, this study shows that an OHRM equipped with a PPG sensor can measure HR within the ECG reference standard of –5 bpm to 5 bpm and –10% to 10% in the perioperative setting when the PPG signal is of sufficient quality. This implies that an OHRM can be considered clinically acceptable for HR monitoring in low acuity hospitalized patients

and may provide the basis for future studies for remote, unobtrusive, continuous monitoring for timely recognition of deterioration.

Acknowledgments

We would like to express our gratitude for the valuable help of Marleen van Aartrijk in the design and collection of data for this study. This research was funded by Rijksdienst voor Ondernemend Nederland, Ewatch (grant # ITEA161006).

Authors' Contributions

RD, RH, JG, VS, HHMK, and RAB conceptualized the study. RD, RS, and RAB devised the methodology. RD and AGB performed the validation. RD conducted the formal analysis. RD and EM were responsible for execution of the study protocol. JG, RD, and EM obtained the resources. AGB and JM were responsible for data curation. RD and EM prepared the original draft. AGB, JM, JG, RH, HHMK, VS, and RAB performed the draft review and editing. RD was responsible for visualization. RD and JG were responsible for project administration. RH and VS were responsible for funding acquisition. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

AGB, JM, JG, and RH are employed at Royal Philips Netherlands. RAB and HHMK are clinical consultants for Philips Research Netherlands.

References

1. Cardona-Morrell M, Prgomet M, Turner RM, Nicholson M, Hillman K. Effectiveness of continuous or intermittent vital signs monitoring in preventing adverse events on general wards: a systematic review and meta-analysis. Int J Clin Pract 2016 Oct;70(10):806-824. [doi: 10.1111/ijcp.12846] [Medline: 27582503]
2. Ahmad T, Bouwman RA, Grigoras I, Aldecoa C, Hofer C, Hoeft A, International Surgical Outcomes Study (ISOS) group. Use of failure-to-rescue to identify international variation in postoperative care in low-, middle- and high-income countries: a 7-day cohort study of elective surgery. Br J Anaesth 2017 Aug 01;119(2):258-266 [FREE Full text] [doi: 10.1093/bja/aex185] [Medline: 28854536]
3. Noordzij PG, Poldermans D, Schouten O, Bax JJ, Schreiner FAG, Boersma E. Postoperative mortality in The Netherlands: a population-based analysis of surgery-specific risk in adults. Anesthesiology 2010 May;112(5):1105-1115 [FREE Full text] [doi: 10.1097/ALN.0b013e3181d5f95c] [Medline: 20418691]
4. Walston JM, Cabrera D, Bellew SD, Olive MN, Lohse CM, Bellolio MF. Vital signs predict rapid-response team activation within twelve hours of emergency department admission. West J Emerg Med 2016 May;17(3):324-330 [FREE Full text] [doi: 10.5811/westjem.2016.2.28501] [Medline: 27330665]
5. Fieselmann JF, Hendryx MS, Helms CM, Wakefield DS. Respiratory rate predicts cardiopulmonary arrest for internal medicine inpatients. J Gen Intern Med 1993 Jul;8(7):354-360. [Medline: 8410395]
6. Taenzer AH, Pyke JB, McGrath SP, Blike GT. Impact of pulse oximetry surveillance on rescue events and intensive care unit transfers: a before-and-after concurrence study. Anesthesiology 2010 Feb;112(2):282-287. [doi: 10.1097/ALN.0b013e3181ca7a9b] [Medline: 20098128]
7. Suaste-Gómez E, Hernández-Rivera D, Sánchez-Sánchez AS, Villarreal-Calva E. Electrically insulated sensing of respiratory rate and heartbeat using optical fibers. Sensors (Basel) 2014 Nov 14;14(11):21523-21534 [FREE Full text] [doi: 10.3390/s141121523] [Medline: 25405510]
8. Vadrevu S, Manikandan MS. A robust pulse onset and peak detection method for automated PPG signal analysis system. IEEE Trans. Instrum. Meas 2019 Mar;68(3):807-817. [doi: 10.1109/tim.2018.2857878]
9. Chang KM. Pulse rate derivation and its correlation with heart rate. Journal of Medical and Biological Engineering 2009;29(3):132-137.
10. Sartor F, Papini G, Cox LGE, Cleland J. Methodological shortcomings of wrist-worn heart rate monitors validations. J Med Internet Res 2018 Jul 02;20(7):e10108 [FREE Full text] [doi: 10.2196/10108] [Medline: 29967000]
11. Valenti G, Westerterp K. Optical heart rate monitoring module validation study. : Jan 11-14, 2013; 2013 Presented at: IEEE International Conference on Consumer Electronics (ICCE); 2013; Las Vegas, NV, USA. [doi: 10.1109/icce.2013.6486856]
12. Gillinov S, Etiwy M, Wang R, Blackburn G, Phelan D, Gillinov AM, et al. Variable accuracy of wearable heart rate monitors during aerobic exercise. Med Sci Sports Exerc 2017 Aug;49(8):1697-1703. [doi: 10.1249/MSS.0000000000001284] [Medline: 28709155]
13. Kroll RR, Boyd JG, Maslove DM. Accuracy of a wrist-worn wearable device for monitoring heart rates in hospital inpatients: a prospective observational study. J Med Internet Res 2016 Sep 20;18(9):e253 [FREE Full text] [doi: 10.2196/jmir.6025] [Medline: 27651304]

14. Delgado-Gonzalo R, Parak J, Tarniceriu A, Renevey P, Bertschi M, Korhonen I. Evaluation of accuracy and reliability of PulseOn optical heart rate monitoring device. 2015 Presented at: The 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC); Aug 25-29, 2015; Milan, Italy. [doi: 10.1109/embc.2015.7318391]
15. Parak J, Korhonen I. Evaluation of wearable consumer heart rate monitors based on photopletysmography. 2014 Presented at: The 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; Aug; Aug, 26-30, 2014; Chicago, IL, USA. [doi: 10.1109/embc.2014.6944419]
16. Shcherbina A, Mattsson CM, Waggott D, Salisbury H, Christle JW, Hastie T, et al. Accuracy in wrist-worn, sensor-based measurements of heart rate and energy expenditure in a diverse cohort. J Pers Med 2017 May 24;7(2):3-3 [FREE Full text] [doi: 10.3390/jpm7020003] [Medline: 28538708]
17. Spierer DK, Rosen Z, Litman LL, Fujii K. Validation of photoplethysmography as a method to detect heart rate during rest and exercise. J Med Eng Technol 2015;39(5):264-271. [doi: 10.3109/03091902.2015.1047536] [Medline: 26112379]
18. Kroll RR, McKenzie ED, Boyd JG, Sheth P, Howes D, Wood M, et al. Use of wearable devices for post-discharge monitoring of ICU patients: a feasibility study. j intensive care 2017 Nov 21;5(1):64-64. [doi: 10.1186/s40560-017-0261-9]
19. Hochstadt A, Havakuk O, Chorin E, Schwartz AL, Merdler I, Laufer M, et al. Continuous heart rhythm monitoring using mobile photoplethysmography in ambulatory patients. J Electrocardiol 2020;60:138-141. [doi: 10.1016/j.jelectrocard.2020.04.017] [Medline: 32361522]
20. Lord JM, Midwinter MJ, Chen Y, Belli A, Brohi K, Kovacs EJ, et al. The systemic immune response to trauma: an overview of pathophysiology and treatment. Lancet 2014 Oct 18;384(9952):1455-1465 [FREE Full text] [doi: 10.1016/S0140-6736(14)60687-5] [Medline: 25390327]
21. Manou-Stathopoulou V, Korbonits M, Ackland GL. Redefining the perioperative stress response: a narrative review. Br J Anaesth 2019 Nov;123(5):570-583 [FREE Full text] [doi: 10.1016/j.bja.2019.08.011] [Medline: 31547969]
22. Doyle D, Goyal A, Bansal P, Garmon E. American Society of Anesthesiologists Classification (ASA Class). Treasure Island, FL, USA: StatPearls Publishing; 2020.
23. Kristensen SD, Knuuti J, Saraste A, Anker S, Bøtker HE, De Hert S, Authors/Task Force Members. 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management: The Joint Task Force on non-cardiac surgery: cardiovascular assessment and management of the European Society of Cardiology (ESC) and the European Society of Anaesthesiology (ESA). Eur J Anaesthesiol 2014 Oct;31(10):517-573. [doi: 10.1097/EJA.0000000000000150] [Medline: 25127426]
24. Papini GB, Fonseca P, van Gilst MM, Bergmans JWM, Vullings R, Overeem S. Wearable monitoring of sleep-disordered breathing: estimation of the apnea–hypopnea index using wrist-worn reflective photoplethysmography. Sci Rep 2020 Aug 11;10(1):13512. [doi: 10.1038/s41598-020-69935-7]
25. Kathirvel P, Sabarimalai Manikandan M, Prasanna SRM, Soman KP. An efficient R-peak detection based on new nonlinear transformation and first-order Gaussian differentiator. Cardiovasc Eng Tech 2011 Oct 12;2(4):408-425. [doi: 10.1007/s13239-011-0065-3]
26. Bonomi AG, Schipper F, Eerikäinen LM, Margarito J, van Dinther R, Muesch G, et al. Atrial fibrillation detection using a novel cardiac ambulatory monitor based on photo-plethysmography at the wrist. J Am Heart Assoc 2018 Aug 07;7(15):e009351 [FREE Full text] [doi: 10.1161/JAHA.118.009351] [Medline: 30371247]
27. Bland JM, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986 Feb 08;1(8476):307-310. [Medline: 2868172]
28. Bland JM, Altman DG. Agreement between methods of measurement with multiple observations per individual. J Biopharm Stat 2007;17(4):571-582 [FREE Full text] [doi: 10.1080/10543400701329422] [Medline: 17613642]
29. Zou GY. Confidence interval estimation for the Bland-Altman limits of agreement with multiple observations per individual. Stat Methods Med Res 2013 Dec;22(6):630-642 [FREE Full text] [doi: 10.1177/0962280211402548] [Medline: 21705434]
30. ANSI/AAMI. Cardiac monitors, heart rate meters,alarms, american national standard (Revision of ANSI/AAMI EC13). Association for the Advancement of Med. Instrum, Arlington, VA. Tech. Rep 2002:1.
31. Hochstadt A, Chorin E, Viskin S, Schwartz AL, Lubman N, Rosso R. Continuous heart rate monitoring for automatic detection of atrial fibrillation with novel bio-sensing technology. J Electrocardiol 2019;52:23-27. [doi: 10.1016/j.jelectrocard.2018.10.096] [Medline: 30476634]
32. Dobbs WC, Fedewa MV, MacDonald HV, Holmes CJ, Cicone ZS, Plews DJ, et al. The accuracy of acquiring heart rate variability from portable devices: a systematic review and meta-analysis. Sports Med 2019 Mar;49(3):417-435. [doi: 10.1007/s40279-019-01061-5] [Medline: 30706234]
33. Wallen MP, Gomersall SR, Keating SE, Wisløff U, Coombes JS. Accuracy of heart rate watches: implications for weight management. PLoS One 2016 May;11(5):e0154420 [FREE Full text] [doi: 10.1371/journal.pone.0154420] [Medline: 27232714]
34. Wang R, Blackburn G, Desai M, Phelan D, Gillinov L, Houghtaling P, et al. Accuracy of wrist-worn heart rate monitors. JAMA Cardiol 2017 Jan 01;2(1):104-106. [doi: 10.1001/jamacardio.2016.3340] [Medline: 27732703]
35. Hamilton C, Lewis S. The importance of using the correct bounds on the Bland-Altman limits of agreement when multiple measurements are recorded per patient. J Clin Monit Comput 2010 Jun;24(3):173-175. [doi: 10.1007/s10877-010-9230-8] [Medline: 20306289]

Abbreviations

AF: atrial fibrillation
ASA-PS: American Society of Anesthesiologists Physical Status
bpm: beats per minute
ECG: electrocardiography
HR: heart rate
ICU: intensive care unit
IPI: interpulse interval
LoA: limits of agreement
MOVER: method of variance estimate recovery
OHRM: optical heart rate monitor
PPG: photoplethysmography
QI: quality index

Edited by G Eysenbach; submitted 05.02.21; peer-reviewed by F Sartor, M O'Brien; comments to author 14.04.21; revised version received 08.06.21; accepted 27.07.21; published 04.11.21.

Please cite as:
Mestrom E, Deneer R, Bonomi AG, Margarito J, Gelissen J, Haakma R, Korsten HHM, Scharnhorst V, Bouwman RA
Validation of Heart Rate Extracted From Wrist-Based Photoplethysmography in the Perioperative Setting: Prospective Observational Study
JMIR Cardio 2021;5(2):e27765
URL: https://cardio.jmir.org/2021/2/e27765
doi:10.2196/27765
PMID:34734834

Original Paper

Effects of Urban Green Space on Cardiovascular and Respiratory Biomarkers in Chinese Adults: Panel Study Using Digital Tracking Devices

Lin Yang[1], PhD; Ka Long Chan[2], MSc; John W M Yuen[1], PhD; Frances K Y Wong[1], PhD; Lefei Han[1,3], PhD; Hung Chak Ho[4], PhD; Katherine K P Chang[1], PhD; Yuen Shan Ho[1], PhD; Judy Yuen-Man Siu[5], PhD; Linwei Tian[6], PhD; Man Sing Wong[2], PhD

[1]School of Nursing, The Hong Kong Polytechnic University, Hong Kong, Hong Kong

[2]Department of Land Surveying and Geo-Informatics, The Hong Kong Polytechnic University, Hong Kong, Hong Kong

[3]School of Global Health, Chinese Center for Tropical Diseases Research, Shanghai Jiao Tong University School of Medicine, Shanghai, China

[4]Department of Urban Planning and Design, The University of Hong Kong, Hong Kong, Hong Kong

[5]Department of Applied Social Sciences, The Hong Kong Polytechnic University, Hong Kong, Hong Kong

[6]School of Public Health, The University of Hong Kong, Hong Kong, Hong Kong

Corresponding Author:
Frances K Y Wong, PhD
School of Nursing
The Hong Kong Polytechnic University
Hung Hom Campus
GH519
Hong Kong
Hong Kong
Phone: 852 2766 6419
Fax: 852 2364 9663
Email: frances.wong@polyu.edu.hk

Abstract

Background: The health benefits of urban green space have been widely reported in the literature; however, the biological mechanisms remain unexplored, and a causal relationship cannot be established between green space exposure and cardiorespiratory health.

Objective: Our aim was to conduct a panel study using personal tracking devices to continuously collect individual exposure data from healthy Chinese adults aged 50 to 64 years living in Hong Kong.

Methods: A panel of cardiorespiratory biomarkers was tested each week for a period of 5 consecutive weeks. Data on weekly exposure to green space, air pollution, and the physical activities of individual participants were collected by personal tracking devices. The effects of green space exposure measured by the normalized difference vegetation index (NDVI) at buffer zones of 100, 250, and 500 meters on a panel of cardiorespiratory biomarkers were estimated by a generalized linear mixed-effects model, with adjustment for confounding variables of sociodemographic characteristics, exposure to air pollutants and noise, exercise, and nutrient intake.

Results: A total of 39 participants (mean age 56.4 years, range 50-63 years) were recruited and followed up for 5 consecutive weeks. After adjustment for sex, income, occupation, physical activities, dietary intake, noise, and air pollution, significant negative associations with the NDVI for the 250-meter buffer zone were found in total cholesterol (–21.6% per IQR increase in NDVI, 95% CI –32.7% to –10.6%), low-density lipoprotein (–14.9%, 95% CI –23.4% to –6.4%), glucose (–11.2%, 95% CI –21.9% to –0.5%), and high-sensitivity C-reactive protein (–41.3%, 95% CI –81.7% to –0.9%). Similar effect estimates were found for the 100-meter and 250-meter buffer zones. After adjustment for multiple testing, the effect estimates of glucose and high-sensitivity C-reactive protein were no longer significant.

Conclusions: The health benefits of green space can be found in some metabolic and inflammatory biomarkers. Further studies are warranted to establish the causal relationship between green space and cardiorespiratory health.

(JMIR Cardio 2021;5(2):e31316) doi:10.2196/31316

KEYWORDS

green space; biomarker; cardiovascular disease; respiratory disease

Introduction

Background

Previous studies have demonstrated the health benefits of the natural environment and urban green space on mental health [1,2], perceived stress [3-5], sleep quality [6,7], and cardiovascular and respiratory health [8]. The health benefits of green space in neighborhoods may be due to increased physical activity, reduced air pollution exposure, and relief of stress from work and life [9-12]. A prospective cohort study in the United States also showed that people living in communities with higher green space coverage had a lower mortality rate, and this association was likely mediated by physical activity and air pollution [13]. However, to date, the underlying mechanism remains unexplored in the literature, which hinders the establishment of a causal relationship between green space exposure and cardiorespiratory health. In environmental health studies, the panel study design has often been adopted to investigate the short-term impacts of environmental factors on cardiovascular and respiratory health by comparing the levels of metabolic, inflammatory, and oxidative biomarkers of the same cohort of volunteers at different time points [14-16]. The panel study design features repeated collection of samples from the same individuals at different times, with the aim to demonstrate the changes in biomarkers at various exposure levels. As each individual serves as their own control, this study design minimizes the confounding of time-invariant factors (such as demographics and health-seeking behavior) but is subject to the confounding of other temporal factors, such as air pollution [17]. In addition, a panel study requires good-quality personal exposure data, which are often absent in many regions. Fortunately, this obstacle has been diminished by the recent research development of combining personal tracking devices with satellite images to estimate individual exposures to air pollution and actual access to green space [18].

Objective

With the aim to explore the effects of green space on respiratory and cardiovascular biomarkers to provide evidence for the underlying biological pathways, we conducted a panel study using personal tracking devices to continuously collect the individual exposure data in healthy Chinese adults aged 50 to 64 years living in Hong Kong. Using these data, we estimated the independent effects of green space exposure on different metabolic, inflammatory, and oxidative biomarkers for cardiovascular and respiratory health.

Methods

Study Design and Participants

The target population was Chinese adults aged 50 to 64 years who had been living in Hong Kong for the past 2 years. This age group was chosen because of their high risk of preclinical chronic conditions [19]. Inclusion criteria were nonsmoker or no exposure to secondhand smoke at home or work; generally healthy without any diagnosed chronic diseases or regular taking of medicines; no need of walking assistance; and staying at the same residential address during the whole study period. We recruited participants using convenience sampling via posters and social media and through snowball sampling by inviting participants to refer their friends to us.

Using the formula for mixed models with repeated measurements [20], we calculated the sample based on the results from one previous study on indoor and outdoor air pollution [21], which used a similar study design. We assumed that the mean concentration of 8-hydroxy-2'-deoxyguanosine (8-OHdG) measurements was 4.0 ng/mL, with a standard deviation of 2.3. The sample size of 30 could achieve 90% power to detect an effect size of 0.8, under the assumption that the autocorrelation of repeated measurements was 0.9. Given the 20% attrition rate during the repeated measurements, we decided to recruit 38 to 40 participants for this study.

The participants were recruited and followed up for 5 consecutive weeks during October to December 2017. On the same weekday of each week during the study period, each individual participant was invited to visit the Integrative Health Clinic (IHC) of the Hong Kong Polytechnic University for blood sample collection and physical examination. Each participant had a total of 6 visits during the whole study period (1 at enrollment and 5 at follow-up). These visits were scheduled on early mornings (8 AM-10 AM) of the same weekday to reduce the bias caused by the diurnal change of biomarkers. If participants took any medication, experienced allergies in the preceding 7 days, or worked a night shift on the day before their scheduled visit, these visits would be postponed for 1 week.

A summary of the data collection procedure at the clinic visits is shown in Table S1 in Multimedia Appendix 1. At recruitment (the first visit to the IHC), each participant signed a consent form and took a self-administered questionnaire, with the support of research assistants if needed. The questionnaire collected their demographic information (age, gender, years living in Hong Kong), socioeconomic characteristics (education, household income, occupation, housing type), lifestyle information (alcohol drinking, physical activity), and residential address.

Personal Exposure Assessment

Access to Green Space

At the first visit, a GPS device (BT-Q1000XT, Qstarz International Co Ltd) was distributed to each participant. Research assistants provided the participants with both verbal and paper instructions on device use. The GPS device logged the participant's location coordinates, date, and time at 1-minute epochs, and the real-time data were automatically collected by a server on the university campus. Raw GPS data were first screened in ArcGIS software (Esri) for missing or suspicious

data by comparing them with the daily activity log. Days with less than 600 minutes of GPS data recorded were regarded as missing and excluded from subsequent analysis. The research assistants regularly checked the GPS data collected on the server to ensure the completeness of these data. The participants showed good compliance and yielded no missing data.

We matched cleaned GPS data to a map of the normalized difference vegetation index (NDVI) in the entire territory of Hong Kong to calculate the urban greenness within a 100-, 250-, and 500-meter–radius buffer zone of individual GPS coordinates, based on a Satellite Pour l'Observation de la Terre (SPOT) 6 image obtained in 2016. The NDVI is a normalized ratio of infrared and red bands ranging between –1 and 1, with higher numbers indicating more green vegetation [22]. The NDVI has been widely used in previous environmental studies on the health impacts of green space [23,24]. The average NDVI of individuals was weighted by the daily hours spent in and outside the home.

Exposure to Air Pollution and Traffic Noise

We also estimated individual exposure to two ambient air pollutants, nitrogen dioxide (NO_2) and particulate matter with a diameter less than 2.5 μm ($PM_{2.5}$), by matching the raw GPS coordinates with the hourly maps of $PM_{2.5}$ and NO_2 at 10-meter spatial resolution. These hourly maps were remodeled from temporal information reported by the Kwai Chung Monitoring Station and adjusted by the spatial patterns of air pollutants reported in previous local studies [25,26]. Weekly average concentrations of NDVI, $PM_{2.5}$, and NO_2 were calculated from raw data estimated at 1-minute epochs.

The annual average household exposure to road traffic noise was estimated by matching the residential addresses with a 3D-built environment database in Hong Kong that was validated using real-time field data in a local study [27].

Physical Activity and Dietary Intake Measurements

At the first visit, an accelerometer data logger (ActiGraph GT3X, ActiGraph LLC) was also distributed to each participant, and the research assistants reminded them to wear the accelerometer on the wrist of their nondominant hand all the time during the study period to continuously record their physical activities. Raw accelerometer data were collected at 1-minute epochs. Individual daily physical activities were calculated from the vector magnitudes of the cleaned data. The cutoff points of light, moderate, and vigorous physical activity were determined according to a formula validated in a Chinese population [28].

We asked each participant to record their daily dietary intakes in weeks 2 and 5 using a standard dietary journal widely used in nutritional studies [29]. Food items and consumed amounts collected from the dietary journals were analyzed with the software Food Processor, version 11.3 (ESHA). The Food Processor database is composed of over 72,000 food items from sources including the United States Department of Agriculture Standard Reference database, Food and Nutrient Database for Dietary Studies, and different manufacturers' data. Food items, especially local and Chinese food items, which could not be found in the Food Processor database were searched using the Nutrient Information Inquiry System developed by the Centre for Food Safety, the Taiwan Food and Nutrient Database developed by the Food and Drug Administration of Taiwan, or the manufacturers' webpages. If the nutrition information of the food items still could not be found, the most appropriate food items available were chosen for the analysis. The daily amounts of energy and nutrients consumed, including total calories, calories from fat and saturated fat, protein, carbohydrates, and total fiber, were calculated for individual participants using the Food Processor software.

The above collected data were converted into weekly averages by taking the arithmetic mean—with the exception of the weekly average access to green space, which was calculated using the geometric mean of the NDVI—in the corresponding period between two visits of each participant.

Outcome Measurements

At each visit, participants first measured their body weight and height, systolic blood pressure, diastolic blood pressure, and heart rate (HR). Lung function tests were conducted using a spirometer (microQuark, COSMED), following the guidelines of the American Thoracic Society [30]. Individual data pertaining to the forced expiratory volume in the first second (FEV1) and forced vital capacity (FVC) were included in the analysis. Each participant donated 5 ml fasting blood at each visit, which was collected in a heparinized tube by a qualified phlebotomist following a standard venipuncture procedure. Specimens were maintained on ice and transported to the laboratory, where blood samples were immediately centrifuged (3000 rpm for 10 minutes at 4 ^{o}C) and stored in two 1.0 to 1.5 ml aliquots at –80 ^{o}C for batch testing later. The above procedure was completed within 30 minutes of the participant's arrival at the laboratory to minimize damage to the biomarkers.

We chose a panel of biomarkers used in previous environmental studies on the cardiovascular health effects of green space and air pollution [21,31-34]: (1) metabolic biomarkers: glucose, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein (LDL-C), total cholesterol (TC), and triglyceride (TG); (2) inflammatory biomarkers: high-sensitivity C-reactive protein (hs-CRP), interleukin-6 (IL-6), tumor necrosis factor α (TNF-α), and soluble platelet selectin (sP-selectin); and 3) oxidative stress biomarkers: 8-hydroxy-2'-deoxyguanosine (8-OHdG), malondialdehyde (MDA), copper-zinc superoxide dismutase (Cu,Zn-SOD), and glutathione peroxidase 1 (GPx-1). The metabolic biomarkers and hs-CRP were measured by an AU480 chemistry analyzer (Beckman Coulter) with corresponding assay kits. The remaining biomarkers were measured using enzyme-linked immunosorbent assay (ELISA) kits purchased from various commercial sources.

Data Analysis

Spearman coefficients were calculated to assess the correlations between variables. A generalized linear mixed-effects model (GLME), which includes two components, namely, a fixed effect (green space effects and confounding) and a random effect (within-subject variations), was used to estimate the association between green space exposure and biomarker levels or lung

functions. The potential confounding factors, including sex, total household income, occupation, physical activities, and household traffic noise exposure, were included as fixed effects in the model. Because there were categorical confounding factors, the generalized version of the variance inflation factor (VIF) was used to detect multicollinearity [35]. A generalized VIF of more than 10 would indicate multicollinearity, and the confounding variables would be removed from the models [36]. Subject numbers were fitted as a random effect variable to account for within-subject variations of repeated measurements.

We fit 4 different models to the weekly measurements of each biomarker to estimate the independent effects of green space. In model 1, the NDVI was added as the only explanatory factor; in model 2, variables of sex, physical activity (moderate to vigorous physical activity levels), occupation, household income, and traffic noise exposure were added to model 1 as confounding factors; in models 3 and 4, $PM_{2.5}$ and NO_2 were respectively added to model 2 to assess the independent effects of green space exposure with adjustment for ambient air pollutants; and in model 5, daily consumption amounts of protein and carbohydrates were added to model 2 to adjust for the confounding effects of dietary intake. The effects of green space were quantified by the percentage changes of biomarker concentrations associated with a per interquartile range increase of the NDVI. The goodness of fit was evaluated by the Akaike information criterion (AIC), with the minimum indicating the best fit. The likelihood ratio tests of full and partial models were used to show the statistical significance of the variables. All data analysis was conducted using R software, version 3.6.2 (R Foundation for Statistical Computing). The statistical significance was set to $P<.05$. Multiple testing of biomarkers was controlled by the Bonferroni correction.

Ethical Statement

This project was approved by the Human Subjects Ethics Subcommittee of the Hong Kong Polytechnic University. All participants signed a consent form, and no personal information except residential address was collected in this study.

Results

Participant Characteristics

We recruited 40 participants during October to December 2017. One participant withdrew from the study after the first week due to unforeseen family issues. The remaining 39 participants finished all the scheduled visits. The 39 participants had a mean age of 56.4 years (range 50-63 years); 27 (69%) were women, 31 (80%) were married, 35 (90%) were living with family members (family size range 1-6 people), and 14 (36%) received postsecondary education (Table 1).

Table 1. Baseline characteristics of the participants (N=39).

Characteristics	Value
Age (years), mean (SD)	56.4 (3.5)
Sex, n (%)	
Male	12 (31)
Female	27 (69)
Housing type, n (%)	
Self-owned	25 (64)
Rent	14 (36)
Living condition, n (%)	
Alone	4 (10)
With family member	35 (90)
Household size, mean (SD)	3.1 (1.2)
Education level, n (%)	
Secondary	25 (64)
Postsecondary	14 (36)
Occupation, n (%)	
Working	21 (54)
Homemaker and retired	18 (41)
Household income (HK $)[a], n (%)	
Low (10,500 or below)	21 (54)
Medium (10,501-23,000)	13 (33)
High (23,001 or above)	5 (13)
Marital status, n (%)	
Married	31 (80)
Single	4 (10)
Widowed/divorced	4 (10)
BMI, mean (SD)	23.0 (3.4)

[a]HK $1=US $0.13.

Outcome Measurements

The weekly average NDVIs at the 100-, 250-, and 500-meter buffer zones were –0.54 (IQR 0.34), –0.61 (IQR 0.25), and –0.61 (IQR 0.25), respectively (Table 2). The weekly average concentrations of $PM_{2.5}$ at the 100-, 250-, and 500-meter buffer zones were 25.57 μg/m^3 (SD 1.28), 29.26 μg/m^3 (SD 1.12), and 29.25 μg/m^3 (SD 1.01). The weekly average concentrations of NO_2 were 23.46 μg/m^3 (SD 12.89), 39.73 μg/m^3 (SD 5.30), and 39.78 μg/m^3 (SD 5.21) at the 100-, 250-, and 500-meter buffer zones, respectively.

Table 2. Weekly average of green space exposure and air pollution for the 3 buffer zones, as well as BMI and physical activity at the 250-meter buffer zone, in the 5-week follow-up period.

Variable	Value, mean (SD)					
	Overall	Week 1	Week 2	Week 3	Week 4	Week 5
NDVI[a]						
100-m buffer zone	–0.54 (0.33)	–0.67 (0.35)	–0.53 (0.34)	–0.53 (0.29)	–0.46 (0.35)	–0.51 (0.33)
250-m buffer zone	–0.61 (0.22)	–0.70 (0.29)	–0.61 (0.19)	–0.59 (0.17)	–0.57 (0.21)	–0.61 (0.21)
500-m buffer zone	–0.61 (0.22)	–0.70 (0.29)	–0.60 (0.19)	–0.59 (0.17)	–0.57 (0.21)	–0.60 (0.21)
$PM_{2.5}$[b] (μg/m^3)						
100-m buffer zone	25.57 (1.28)	25.60 (1.62)	25.68 (1.20)	25.46 (1.22)	25.67 (1.42)	25.46 (1.07)
250-m buffer zone	29.26 (1.12)	29.07 (1.47)	29.25 (1.00)	29.17 (1.05)	29.44 (1.07)	29.35 (1.02)
500-m buffer zone	29.25 (1.01)	29.04 (1.44)	29.25 (0.82)	29.18 (0.95)	29.41 (0.89)	29.33 (0.93)
NO_2[c] (μg/m^3)						
100-m buffer zone	23.46 (12.89)	23.58 (14.84)	23.48 (13.26)	23.63 (12.38)	22.78 (11.82)	23.84 (13.36)
250-m buffer zone	39.73 (5.30)	40.43 (8.19)	39.78 (4.00)	39.44 (4.64)	39.08 (4.19)	40.00 (5.20)
500-m buffer zone	39.78 (5.21)	40.47 (7.81)	39.83 (4.09)	39.52 (4.56)	39.12 (4.34)	40.03 (5.09)
BMI (kg/m^2)	22.83 (3.26)	22.85 (3.30)	22.78 (3.35)	22.89 (3.30)	22.91 (3.29)	22.73 (3.25)
MVPA[d] (minutes)	177.61 (76.64	180.77 (79.75)	184.02 (79.01)	176.64 (77.24)	172.96 (77.39)	173.91 (73.37)

[a]NDVI: normalized difference vegetation index.

[b]$PM_{2.5}$: particulate matter with a diameter less than 2.5 μm.

[c]NO_2: nitrogen dioxide.

[d]MVPA: moderate to vigorous physical activity.

Table 3 shows the weekly means and variations of the outcome measures. Overall, these biomarkers show small variations across visits and between individuals, except for the systemic inflammatory biomarkers and some oxidative stress biomarkers. The biomarkers had low to moderate correlations except for the metabolic biomarkers, which had high correlations (Figure S1, Multimedia Appendix 1).

Table 3. Summary statistics of the outcome measurements at the weekly visits.

Variable	Outcome, mean (SD)				
	Week 1	Week 2	Week 3	Week 4	Week 5
Lung functions					
FVC[a] (%)	100.69 (9.65)	99.85 (8.39)	99.67 (10.26)	100.66 (10.06)	98.84 (9.54)
FEV1[b] (%)	103.76 (10.43)	102.11 (9.48)	102.01 (11.19)	103.01 (10.62)	101.17 (10.30)
FEV1/FVC ratio	103.11 (5.02)	102.33 (5.63)	102.37 (5.29)	102.44 (5.90)	102.44 (5.46)
Heart rate (beats per minute)	71.67 (10.13)	69.46 (9.17)	69.44 (9.25)	71.05 (9.68)	70.28 (9.12)
Blood pressure (mm Hg)					
Systolic	127.64 (15.78)	123.59 (16.28)	124.08 (14.24)	122.77 (16.98)	122.92 (13.02)
Diastolic	79.90 (12.30)	77.46 (9.60)	77.46 (10.50)	76.18 (10.18)	75.82 (9.07)
Metabolism biomarkers					
Total cholesterol (mmol/L)	5.86 (0.91)	5.72 (1.02)	5.77 (1.07)	5.78 (1.09)	5.52 (1.05)
Triglycerides (mmol/L)	1.48 (0.82)	1.43 (0.80)	1.44 (0.72)	1.53 (0.86)	1.45 (0.74)
LDL-C[c] (mmol/L)	3.83 (0.84)	3.73 (0.92)	3.76 (0.97)	3.73 (0.95)	3.57 (0.92)
HDL-C[d] (mmol/L)	1.47 (0.34)	1.44 (0.34)	1.45 (0.33)	1.45 (0.36)	1.38 (0.32)
Total cholesterol/HDL-C ratio	4.19 (1.12)	4.17 (1.15)	4.16 (1.10)	4.18 (1.10)	4.17 (1.11)
Triglycerides/HDL-C ratio	1.15 (0.88)	1.14 (0.91)	1.12 (0.76)	1.20 (0.86)	1.18 (0.85)
LDL-C/HDL-C ratio	2.77 (0.90)	2.75 (0.95)	2.74 (0.92)	2.72 (0.89)	2.72 (0.89)
Glucose (mmol/L)	5.75 (0.82)	5.60 (0.78)	5.59 (0.72)	5.63 (0.68)	5.45 (0.74)
Systemic inflammatory biomarkers					
hs-CRP[e] (mg/L)	1.98 (3.11)	1.56 (3.20)	1.01 (0.76)	1.07 (1.20)	1.05 (0.82)
IL-6[f] (pg/mL)	1.72 (2.40)	1.78 (2.58)	1.31 (1.66)	1.74 (2.26)	1.25 (1.75)
TNF-α[g] (pg/mL)	1.6 (1.22)	1.65 (1.25)	1.49 (1.22)	1.73 (1.45)	1.50 (1.27)
sP-selectin[h] (ng/ml)	3.51 (2.62)	3.20 (2.14)	2.90 (1.98)	3.27 (1.89)	3.24 (1.92)
Oxidative stress biomarkers					
MDA[i] (μM)	40.85 (22.26)	31.83 (21.24)	30.11 (18.88)	36.35 (23.69)	31.75 (19.76)
8-OHdG[j] (ng/mL)	1.32 (0.54)	1.41 (0.54)	1.22 (0.39)	1.37 (0.49)	1.47 (0.55)
SOD[k] (U/μL)	0.77 (0.38)	0.74 (0.35)	0.77 (0.32)	0.79 (0.36)	0.80 (0.50)
GPx-1[l] (ng/mL)	3.25 (7.06)	3.17 (6.91)	2.79 (6.31)	2.54 (5.84)	4.25 (10.8)

[a]FVC: forced vital capacity.

[b]FEV1: forced expiratory volume in the first second.

[c]LDL-C: low-density lipoprotein cholesterol.

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

[e]hs-CRP: high-sensitivity C-reactive protein.

[f]IL-6: interleukin-6.

[g]TNF-α: tumor necrosis factor-α.

[h]sP-selectin: soluble platelet selectin.

[i]MDA: malondialdehyde.

[j]8-OHdG: 8-hydroxy-2'-deoxyguanosine.

[k]SOD: superoxide dismutase.

[l]GPx-1: glutathione peroxidase 1.

We compared the AICs of the different GLME models and found that model 3 with the 100-meter NDVI, model 1 with the 250-meter NDVI, and model 1 with the 500-meter NDVI generally returned smaller AICs for most biomarkers than the

rest of the models (Table S2, Multimedia Appendix 1). The majority of the generalized VIF values of the variables for all the models was below 2, indicating the absence of collinearity (data not shown). The effect estimates of the NDVI for the 250-meter and 500-meter buffer zones were more consistent between different models, with a few exceptions (TC/HDL ratio and 8-OHdG) (Figures 1 and 2, Tables S3-S5 in Multimedia Appendix 1). Positive associations with NDVI were found for the FEV1/FVC ratio, IL-6, TNF-α, MDA, and SOD, whereas negative associations were found for TC, TG, LDL-C, HDL-C, TG/HDL, LDL/HDL, glucose, and hs-CRP. However, only some estimates reached statistical significance (P<.05) at the 250-meter buffer zone, including TC (–21.6% per IQR increase in NDVI, 95% CI –32.7% to –10.6%), LDL-C (–14.9%, 95% CI –23.4% to –6.4%), HDL-C (–4.9%, 95% CI –8.0% to –1.9%), glucose (–11.2%, 95% CI –21.9% to –0.5%), hs-CRP (–41.3%, 95% CI –81.7% to –0.9%), and TNF-α (41.5%, 95% CI 20.9% to 62.0%). The effect estimates of the 100- and 500-meter buffer zones were similar to those of the 250-meter buffer zone except for glucose and hs-CRP, which did not reach statistical significance (P>.05) at the 100-meter buffer zone. After adjustment for multiple testing by Bonferroni correction, the estimates remained statistically significant for TC, LDL-C, HDL-C, and TNF-α at the 250- and 500-meter buffer zones (P<.002).

Figure 1. Percentage change in metabolic biomarker concentrations associated with per IQR increase in normalized difference vegetation index (NDVI) at (A) the 100-meter buffer zone, (B) the 250-meter buffer zone, and (C) the 500-meter buffer zone. Vertical bars are 95% CI. Note: model 1: outcome ~ NDVI; model 2: outcome ~ NDVI + covariates (sex, income, occupation, moderate to vigorous physical activity, noise); model 3: outcome ~ NDVI + covariates + $PM_{2.5}$; model 4: outcome ~ NDVI + covariates + NO_2; model 5: outcome ~ NDVI + covariates + protein + carbohydrates. hs-CRP: high-sensitivity C-reactive protein, IL-6: interleukin-6, TNF-α: tumor necrosis factor α, 8-OHdG: 8-hydroxy-2'-deoxyguanosine, SOD: superoxide dismutase, GPx-1: glutathione peroxidase.

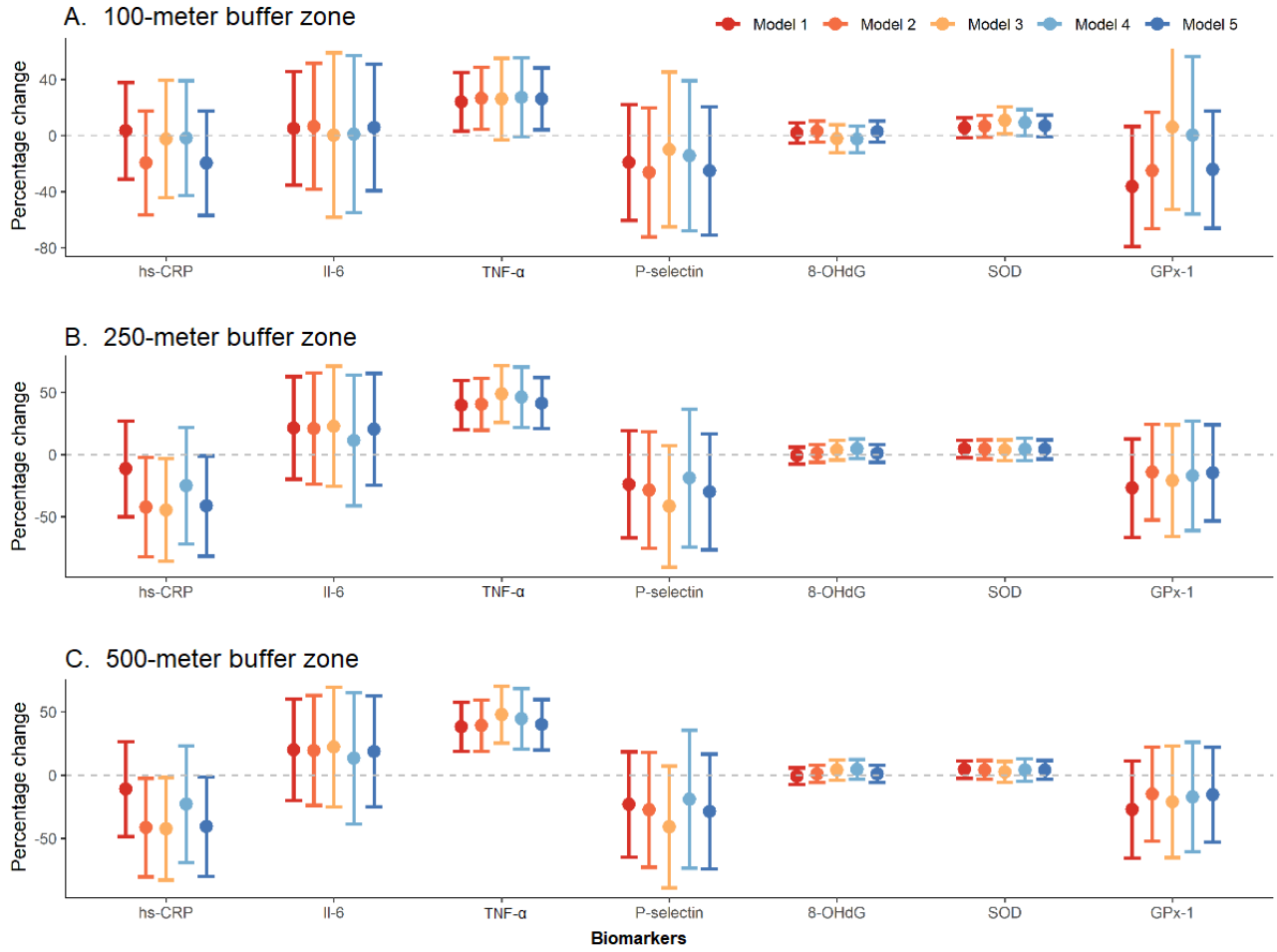
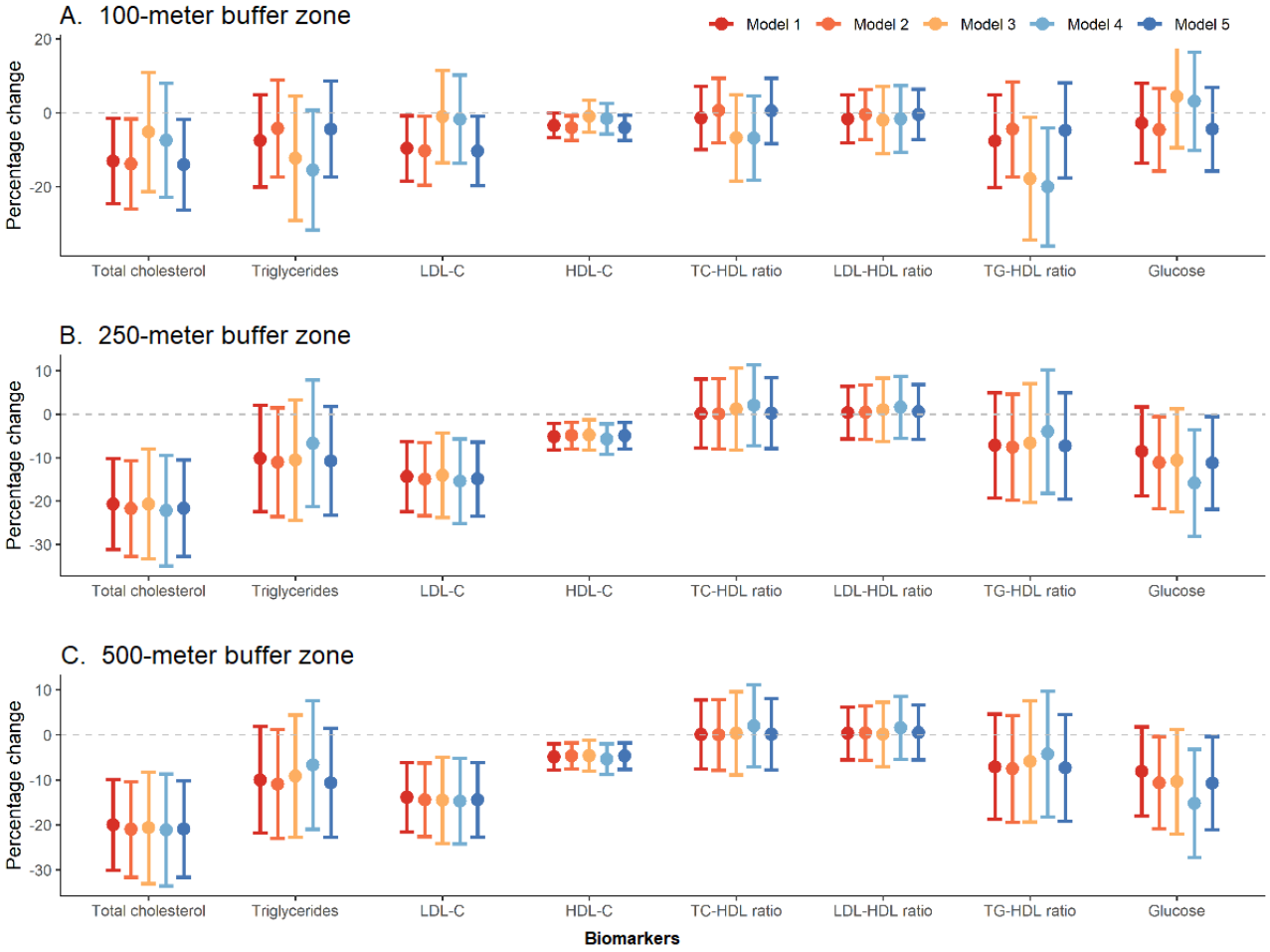


Figure 2. Percentage change in inflammatory and oxidative biomarker concentrations associated with per-IQR increase in normalized difference vegetation index (NDVI) at (A) the 100-meter buffer zone, (B) the 250-meter buffer zone, and (C) the 500-meter buffer zone. Vertical bars are 95% CIs. Note: model 1: outcome ~ NDVI; model 2: outcome ~ NDVI + covariates (sex, income, occupation, moderate to vigorous physical activity, noise); model 3: outcome ~ NDVI + covariates + $PM_{2.5}$; model 4: outcome ~ NDVI + covariates + NO_2; model 5: outcome ~ NDVI + covariates + protein + carbohydrates. LDL-C: low-density lipoprotein, HDL-C: high-density lipoprotein, TC: total cholesterol, TG: triglyceride.



Discussion

Principal Findings

In this panel study, we found a negative association of NDVI exposure with different metabolic and inflammatory biomarkers. The findings were generally consistent with the beneficial effects of neighborhood green space on biomarkers of respiratory and cardiovascular health in the literature [32], but our study was among the first to use personal tracking devices to objectively and continuously collect individual data of weekly exposure to green space. Different from previous studies using residential greenness as long-term exposure, we adopted a longitudinal study design to explore the effects of weekly exposure to green space on biomarkers of cardiorespiratory health in healthy adults. This reflects subclinical signs for the beneficial or detrimental effects of green space, which could shed light on underlying biological mechanisms that remain unexplored in the literature.

After adjustment for air pollution, physical activities, and dietary intake, we found that lower levels of TC, LDL-C, and fasting glucose were associated with higher green space exposure. Our findings are consistent with 2 cross-sectional studies and 1 cohort study in Chinese populations, which reported that a larger amount of green space in working places or residential areas was associated with lower levels of TC, TG, LDL-C, and fasting glucose [15,37,38]. Our effect estimates are also similar to those reported in a large sample of 15,477 adults in China [37]. However, we found that HDL-C also slightly increased in those with higher green space exposure; this is in contrast to the findings of these two studies, although the LDL/HDL, TG/HDL, and TC/HDL ratios remained unchanged. The simultaneous increase of HDL-C and LDL-C could be due to an intake of high-cholesterol food in some participants, as some previous studies have observed [39]. Hence, the negative associations of all lipid biomarkers may be due to inadequate adjustment for physical activities and dietary intake. Further studies with a larger sample size are needed to elucidate the controversial results of the lipid profile.

Compared to the metabolic biomarkers, the associations of green space and proinflammatory biomarkers were less significant and inconsistent in our study. We found negative associations between green space exposure and hs-CRP, although they were not statistically significant. This echoes the findings of a cohort study of school-aged children in Portugal [40]. Our findings are consistent with a previous study conducted in deprived

communities in the United Kingdom that demonstrated an association of residential greenness with hs-CRP [41]. Mao et al [42] conducted an intervention study in 24 older patients with essential hypertension and found that those who stayed in a forest for 7 days and nights had significant reductions in IL-6 but no significant changes in TNF-α. Similar findings were reported in a trial among 20 patients with chronic obstructive pulmonary disease (COPD) after a 1-day forest trip [43]. However, we did not observe any significant effects of green space on IL-6, whereas TNF- levels were consistently higher among those with more green space exposure. The reliability and validity of inflammatory biomarkers to reflect the risk of cardiovascular diseases associated with green space require further study. Other inflammatory biomarkers, such as interleukin-1β, interleukin-8, vascular endothelial growth factor, and soluble tumor necrosis factor-α receptor II [44], could be considered as alternatives in future studies on the health effects of green space.

Elevated MDA and lower SOD levels have been linked to increased risks of coronary artery disease, heart failure, and other chronic diseases [45,46]. It has been proposed that residential green space can reduce oxidative stress and increase angiogenic capacity in patients with cardiovascular diseases [47]. Several experimental studies in patients with hypertension or COPD or in college students found that forest bathing could significantly elevate SOD and lower MDA, despite small sample sizes [48,49]. Our study, however, did not observe significant associations of daily exposure to green space with these oxidative biomarkers. This discrepancy may be due to differences in the study designs and sampling populations.

We did not find any significant effects of green space on lung functions, except FEV1/FVC. This could be due to the fact that the participants were relatively healthy, without any pre-existing chronic respiratory conditions. Sinharay et al [50] conducted a randomized crossover study and found a significant reduction in FEV1 and FVC among patients with COPD, but not among healthy volunteers. Future studies may consider using more sensitive biomarkers for airway inflammation, such as fractional exhaled nitric oxide and differential frequency-dependent respiratory resistance at 5 Hz and 20 Hz, which have used in recent environmental epidemiology studies [50].

Similar to previous green space studies [51,52], we calculated 100-, 250- and 500-meter buffer zones to obtain a comprehensive view of the green space exposure. It is interesting to note that the effect estimates of the 250- and 500-meter buffer zones tend to have consistent patterns but differ from those of the 100-meter buffer zone. By contrast, in a study in Mexican American children in the United States, it was found that children living in residential areas with a higher NDVI had lower odds of dry cough and asthma, and such associations were consistently found across the 3 buffer zones [51]. Other similar studies in children also reported significant associations in the 100-meter buffer zone but not in the larger buffer zones [53]. The daily activity zones of adults are much wider than those of children, which may also explain the lack of significant association of greenness with biomarkers in the 100-meter buffer zone in our adult participants. We speculate that this could also be due to the highly crowded living conditions of Hong Kong, with numerous high-rise residential buildings. Hence, the 250- and 500-meter buffer zones probably better represent community greenness exposure among adults in a metropolitan city such as Hong Kong.

Limitations

Our study had several limitations. First, the small sample size may render low statistical power, which could explain the few significant effect estimates and wide confidence intervals. Therefore, additional studies with a larger sample size are needed to further elucidate the inconsistent findings. Second, green space exposure was measured by daily average NDVI, which could not reflect the activities performed by participants around the green spaces. Nevertheless, we simultaneously collected the physical activities by personal trackers, which can reduce the confounding effect of these activities. Third, due to a limited budget, we only tested a selected panel of biomarkers, although we attempted to cover a wide range of biomarkers for metabolism, respiratory functions, oxidative stress, and proinflammation. Future studies could adopt more biomarkers to gain a comprehensive understanding of the pathways involved in health effects of green space. Last but not least, sampling bias may exist due to the convenience sampling approach we used in this study. The volunteers tend to be healthier and more educated than the general population, as shown in Table 1. However, the time-invariant characteristics of the participants (such as demographic, lifestyle, and socioeconomic factors) have been well adjusted for in the panel study, because each participant served as their own control. Nevertheless, the weekly green space exposure of these participants had enough variations (as shown in Table 2) to allow us to investigate the effects of green space on different biomarkers. In the future, a large-scale study with a more representative sample of participants could provide more evidence for the health benefits of green space exposure in urban settings.

Conclusions

By combining data collected via personal tracking devices with green space GIS data, we were able to demonstrate that higher exposure to green space was associated with a better lipid profile and lower inflammatory biomarkers; however, no significant associations were found with respiratory and oxidative biomarkers. The findings of this study provide more clues to the potential biological pathways for the health benefits of green space. From the public health perspective, the health effects of green space identified from this study will also aid the design of future intervention programs to improve the quality of life of the general public.

Acknowledgments

We thank Fiona Y Wong and Shi Zhao for their assistance in data analysis.

This work was supported by the Faculty of Health and Social Science Dean's Reserve Fund from the Hong Kong Polytechnic University.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary materials.
[DOCX File , 3779 KB - cardio_v5i2e31316_app1.docx]

References

1. Francis J, Wood LJ, Knuiman M, Giles-Corti B. Quality or quantity? Exploring the relationship between Public Open Space attributes and mental health in Perth, Western Australia. Soc Sci Med 2012 May;74(10):1570-1577. [doi: 10.1016/j.socscimed.2012.01.032] [Medline: 22464220]
2. Astell-Burt T, Mitchell R, Hartig T. The association between green space and mental health varies across the lifecourse. A longitudinal study. J Epidemiol Community Health 2014 Jun;68(6):578-583. [doi: 10.1136/jech-2013-203767] [Medline: 24604596]
3. van den Berg AE, Maas J, Verheij RA, Groenewegen PP. Green space as a buffer between stressful life events and health. Soc Sci Med 2010 Apr;70(8):1203-1210. [doi: 10.1016/j.socscimed.2010.01.002] [Medline: 20163905]
4. Stigsdotter UK, Ekholm O, Schipperijn J, Toftager M, Kamper-Jørgensen F, Randrup TB. Health promoting outdoor environments--associations between green space, and health, health-related quality of life and stress based on a Danish national representative survey. Scand J Public Health 2010 Jun 22;38(4):411-417. [doi: 10.1177/1403494810367468] [Medline: 20413584]
5. Ulrich RS, Simons RF, Losito BD, Fiorito E, Miles MA, Zelson M. Stress recovery during exposure to natural and urban environments. J Environ Psychol 1991 Sep 21;11(3):201-230. [doi: 10.1016/S0272-4944(05)80184-7]
6. Astell-Burt T, Feng X, Kolt GS. Does access to neighbourhood green space promote a healthy duration of sleep? Novel findings from a cross-sectional study of 259 319 Australians. BMJ Open 2013 Aug 13;3(8):e003094 [FREE Full text] [doi: 10.1136/bmjopen-2013-003094] [Medline: 23943772]
7. Yang L, Ho JY, Wong FK, Chang KK, Chan KL, Wong MS, et al. Neighbourhood green space, perceived stress and sleep quality in an urban population. Urban Forestry & Urban Greening 2020 Oct;54:126763. [doi: 10.1016/j.ufug.2020.126763]
8. Tischer C, Gascon M, Fernández-Somoano A, Tardón A, Lertxundi Materola A, Ibarluzea J, et al. Urban green and grey space in relation to respiratory health in children. Eur Respir J 2017 Jun;49(6):1502112 [FREE Full text] [doi: 10.1183/13993003.02112-2015] [Medline: 28642307]
9. Gatrell J, Jensen R. Growth through greening: developing and assessing alternative economic development programmes. Appl Geogr 2002 Oct;22(4):331-350. [doi: 10.1016/s0143-6228(02)00049-8]
10. Liu H, Shen Y. The impact of green space changes on air pollution and microclimates: a case study of the Taipei Metropolitan Area. Sustainability 2014 Dec 03;6(12):8827-8855. [doi: 10.3390/su6128827]
11. Kabisch N, Qureshi S, Haase D. Human–environment interactions in urban green spaces — A systematic review of contemporary issues and prospects for future research. Environmental Impact Assessment Review 2015 Jan;50:25-34. [doi: 10.1016/j.eiar.2014.08.007]
12. Markevych I, Schoierer J, Hartig T, Chudnovsky A, Hystad P, Dzhambov AM, et al. Exploring pathways linking greenspace to health: Theoretical and methodological guidance. Environ Res 2017 Oct;158:301-317. [doi: 10.1016/j.envres.2017.06.028] [Medline: 28672128]
13. James P, Hart JE, Banay RF, Laden F. Exposure to greenness and mortality in a nationwide prospective cohort study of women. Environ Health Perspect 2016 Sep;124(9):1344-1352 [FREE Full text] [doi: 10.1289/ehp.1510363] [Medline: 27074702]
14. Egorov AI, Griffin SM, Converse RR, Styles JN, Sams EA, Wilson A, et al. Vegetated land cover near residence is associated with reduced allostatic load and improved biomarkers of neuroendocrine, metabolic and immune functions. Environ Res 2017 Oct;158:508-521 [FREE Full text] [doi: 10.1016/j.envres.2017.07.009] [Medline: 28709033]
15. Tsao T, Tsai M, Wang Y, Lin H, Wu C, Hwang J, et al. The health effects of a forest environment on subclinical cardiovascular disease and heath-related quality of life. PLoS One 2014;9(7):e103231 [FREE Full text] [doi: 10.1371/journal.pone.0103231] [Medline: 25068265]
16. Mena C, Fuentes E, Ormazábal Y, Palomo-Vélez G, Palomo I. Effect of straight-line and road network distances to parks and markets on anthropometric measurements, biochemical markers, and a healthy lifestyle in adult people. Sport Sci Health 2015 Dec 18;12(1):55-61. [doi: 10.1007/s11332-015-0253-x]
17. Møller P, Loft S. Oxidative damage to DNA and lipids as biomarkers of exposure to air pollution. Environ Health Perspect 2010 Aug;118(8):1126-1136 [FREE Full text] [doi: 10.1289/ehp.0901725] [Medline: 20423813]

18. Wong CM, Lai HK, Tsang H, Thach TQ, Thomas GN, Lam KBH, et al. Satellite-based estimates of long-term exposure to fine particles and association with mortality in elderly Hong Kong residents. Environ Health Perspect 2015 Nov;123(11):1167-1172 [FREE Full text] [doi: 10.1289/ehp.1408264] [Medline: 25910279]
19. Madsen C, Rosland P, Hoff DA, Nystad W, Nafstad P, Naess OE. The short-term effect of 24-h average and peak air pollution on mortality in Oslo, Norway. Eur J Epidemiol 2012 Sep;27(9):717-727. [doi: 10.1007/s10654-012-9719-1] [Medline: 22836233]
20. Davis C. Statistical Methods for the Analysis of Repeated Measurements. New York, NY: Springer; 2002.
21. Day DB, Xiang J, Mo J, Li F, Chung M, Gong J, et al. Association of ozone exposure with cardiorespiratory pathophysiologic mechanisms in healthy adults. JAMA Intern Med 2017 Sep 01;177(9):1344-1353 [FREE Full text] [doi: 10.1001/jamainternmed.2017.2842] [Medline: 28715576]
22. Goward SN, Markham B, Dye DG, Dulaney W, Yang J. Normalized difference vegetation index measurements from the advanced very high resolution radiometer. Remote Sensing of Environment 1991 Feb;35(2-3):257-277. [doi: 10.1016/0034-4257(91)90017-z]
23. Ho HC, Lau KK, Yu R, Wang D, Woo J, Kwok TCY, et al. Spatial variability of geriatric depression risk in a high-density city: a data-driven socio-environmental vulnerability mapping approach. Int J Environ Res Public Health 2017 Aug 31;14(9):994 [FREE Full text] [doi: 10.3390/ijerph14090994] [Medline: 28858265]
24. Rugel EJ, Henderson SB, Carpiano RM, Brauer M. Beyond the Normalized Difference Vegetation Index (NDVI): Developing a Natural Space Index for population-level health research. Environ Res 2017 Nov;159:474-483. [doi: 10.1016/j.envres.2017.08.033] [Medline: 28863302]
25. Lee M, Brauer M, Wong P, Tang R, Tsui TH, Choi C, et al. Land use regression modelling of air pollution in high density high rise cities: A case study in Hong Kong. Sci Total Environ 2017 Aug 15;592:306-315. [doi: 10.1016/j.scitotenv.2017.03.094] [Medline: 28319717]
26. Barratt B, Lee M, Wong P, Tang R, Tsui T, Cheng W. A dynamic three-dimensional air pollution exposure model for Hong Kong, Research Report 194. Health Effects Institute 2018 Feb:1-65 [FREE Full text]
27. Guo M, Huang J, Yuxuan Ni M. 3D built-environment attributes and household road traffic noise exposure in Hong Kong. In: IOP Conference Series: Earth and Environmental Science. 2019 Sep 24 Presented at: Sustainable Built Environment Conference 2019 Wales: Policy to Practice; September 24-25, 2019; Cardiff, Wales p. 012012. [doi: 10.1088/1755-1315/329/1/012012]
28. Lee P, Tse CY. Calibration of wrist-worn ActiWatch 2 and ActiGraph wGT3X for assessment of physical activity in young adults. Gait Posture 2019 Feb;68:141-149. [doi: 10.1016/j.gaitpost.2018.11.023] [Medline: 30476691]
29. Lee R, Nieman D. Nutritional Assessment, 7th Edition. Boston, MA: McGraw-Hill Education; 2019.
30. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al. Standardisation of spirometry. Eur Respir J 2005 Aug;26(2):319-338 [FREE Full text] [doi: 10.1183/09031936.05.00034805] [Medline: 16055882]
31. de Oliveira BFA, Chacra APM, Frauches TS, Vallochi A, Hacon S. A curated review of recent literature of biomarkers used for assessing air pollution exposures and effects in humans. J Toxicol Environ Health B Crit Rev 2014 Dec 12;17(7-8):369-410. [doi: 10.1080/10937404.2014.976893] [Medline: 25495790]
32. Twohig-Bennett C, Jones A. The health benefits of the great outdoors: A systematic review and meta-analysis of greenspace exposure and health outcomes. Environ Res 2018 Oct;166:628-637 [FREE Full text] [doi: 10.1016/j.envres.2018.06.030] [Medline: 29982151]
33. Day DB, Xiang J, Mo J, Clyde MA, Weschler CJ, Li F, et al. Combined use of an electrostatic precipitator and a high-efficiency particulate air filter in building ventilation systems: Effects on cardiorespiratory health indicators in healthy adults. Indoor Air 2018 May;28(3):360-372 [FREE Full text] [doi: 10.1111/ina.12447] [Medline: 29288500]
34. Huang W, Wang G, Lu S, Kipen H, Wang Y, Hu M, et al. Inflammatory and oxidative stress responses of healthy young adults to changes in air quality during the Beijing Olympics. Am J Respir Crit Care Med 2012 Dec 01;186(11):1150-1159 [FREE Full text] [doi: 10.1164/rccm.201205-0850OC] [Medline: 22936356]
35. Fox J, Monette G. Generalized collinearity diagnostics. J Am Stat Assoc 1992 Mar;87(417):178. [doi: 10.2307/2290467]
36. Dormann CF, Elith J, Bacher S, Buchmann C, Carl G, Carré G, et al. Collinearity: a review of methods to deal with it and a simulation study evaluating their performance. Ecography 2012 May 18;36(1):27-46. [doi: 10.1111/j.1600-0587.2012.07348.x]
37. Yang B, Markevych I, Heinrich J, Bloom MS, Qian Z, Geiger SD, et al. Residential greenness and blood lipids in urban-dwelling adults: The 33 Communities Chinese Health Study. Environ Pollut 2019 Jul;250:14-22. [doi: 10.1016/j.envpol.2019.03.128] [Medline: 30981931]
38. Lin B, Yen Y, Lao XQ, Chen Y, Chan T. Association between neighborhood greenspace and fasting plasma glucose from a large cohort study in Taiwan. Urban Forestry & Urban Greening 2019 Aug;44:126439. [doi: 10.1016/j.ufug.2019.126439]
39. Greene CM, Zern TL, Wood RJ, Shrestha S, Aggarwal D, Sharman MJ, et al. Maintenance of the LDL cholesterol:HDL cholesterol ratio in an elderly population given a dietary cholesterol challenge. J Nutr 2005 Dec;135(12):2793-2798. [doi: 10.1093/jn/135.12.2793] [Medline: 16317122]

40. Ribeiro AI, Tavares C, Guttentag A, Barros H. Association between neighbourhood green space and biological markers in school-aged children. Findings from the Generation XXI birth cohort. Environ Int 2019 Nov;132:105070 [FREE Full text] [doi: 10.1016/j.envint.2019.105070] [Medline: 31387021]
41. Chaparro MP, Benzeval M, Richardson E, Mitchell R. Neighborhood deprivation and biomarkers of health in Britain: the mediating role of the physical environment. BMC Public Health 2018 Jun 27;18(1):801 [FREE Full text] [doi: 10.1186/s12889-018-5667-3] [Medline: 29945580]
42. Mao G, Cao Y, Lan X, He Z, Chen Z, Wang Y, et al. Therapeutic effect of forest bathing on human hypertension in the elderly. J Cardiol 2012 Dec;60(6):495-502 [FREE Full text] [doi: 10.1016/j.jjcc.2012.08.003] [Medline: 22948092]
43. Jia BB, Yang ZX, Mao GX, Lyu YD, Wen XL, Xu WH, et al. Health effect of forest bathing trip on elderly patients with chronic obstructive pulmonary disease. Biomed Environ Sci 2016 Mar;29(3):212-218 [FREE Full text] [doi: 10.3967/bes2016.026] [Medline: 27109132]
44. Fang SC, Mehta AJ, Alexeeff SE, Gryparis A, Coull B, Vokonas P, et al. Residential black carbon exposure and circulating markers of systemic inflammation in elderly males: the normative aging study. Environ Health Perspect 2012 May;120(5):674-680 [FREE Full text] [doi: 10.1289/ehp.1103982] [Medline: 22336131]
45. Kotur-Stevuljevic J, Memon L, Stefanovic A, Spasic S, Spasojevic-Kalimanovska V, Bogavac-Stanojevic N, et al. Correlation of oxidative stress parameters and inflammatory markers in coronary artery disease patients. Clin Biochem 2007 Feb;40(3-4):181-187. [doi: 10.1016/j.clinbiochem.2006.09.007] [Medline: 17070511]
46. Landmesser U, Merten R, Spiekermann S, Büttner K, Drexler H, Hornig B. Vascular extracellular superoxide dismutase activity in patients with coronary artery disease: relation to endothelium-dependent vasodilation. Circulation 2000 May 16;101(19):2264-2270. [doi: 10.1161/01.cir.101.19.2264] [Medline: 10811593]
47. Yeager R, Riggs DW, DeJarnett N, Tollerud DJ, Wilson J, Conklin DJ, et al. Association between residential greenness and cardiovascular disease risk. J Am Heart Assoc 2018 Dec 18;7(24):e009117 [FREE Full text] [doi: 10.1161/JAHA.118.009117] [Medline: 30561265]
48. Im SG, Choi H, Jeon Y, Song M, Kim W, Woo J. Comparison of effect of two-hour exposure to forest and urban environments on cytokine, anti-oxidant, and stress levels in young adults. Int J Environ Res Public Health 2016 Jun 23;13(7):625 [FREE Full text] [doi: 10.3390/ijerph13070625] [Medline: 27347982]
49. Mao GX, Lan XG, Cao YB, Chen ZM, He ZH, Lv YD, et al. Effects of short-term forest bathing on human health in a broad-leaved evergreen forest in Zhejiang Province, China. Biomed Environ Sci 2012 Jun;25(3):317-324 [FREE Full text] [doi: 10.3967/0895-3988.2012.03.010] [Medline: 22840583]
50. Sinharay R, Gong J, Barratt B, Ohman-Strickland P, Ernst S, Kelly FJ, et al. Respiratory and cardiovascular responses to walking down a traffic-polluted road compared with walking in a traffic-free area in participants aged 60 years and older with chronic lung or heart disease and age-matched healthy controls: a randomised, crossover study. The Lancet 2018 Jan;391(10118):339-349. [doi: 10.1016/s0140-6736(17)32643-0]
51. Eldeirawi K, Kunzweiler C, Zenk S, Finn P, Nyenhuis S, Rosenberg N, et al. Associations of urban greenness with asthma and respiratory symptoms in Mexican American children. Ann Allergy Asthma Immunol 2019 Mar;122(3):289-295. [doi: 10.1016/j.anai.2018.12.009] [Medline: 30557617]
52. Hartley K, Ryan P, Brokamp C, Gillespie GL. Effect of greenness on asthma in children: A systematic review. Public Health Nurs 2020 May 03;37(3):453-460. [doi: 10.1111/phn.12701] [Medline: 31899558]
53. Lambert KA, Bowatte G, Tham R, Lodge C, Prendergast L, Heinrich J, et al. Residential greenness and allergic respiratory diseases in children and adolescents - A systematic review and meta-analysis. Environ Res 2017 Nov;159:212-221. [doi: 10.1016/j.envres.2017.08.002] [Medline: 28803150]

Abbreviations

8-OHdG: 8-hydroxy-2'-deoxyguanosine
AIC: Akaike information criterion
COPD: chronic obstructive pulmonary disease
Cu,Zn-SOD: copper–zinc superoxide dismutase
ELISA: enzyme-linked immunosorbent assay
FEV1: forced expiratory volume in the first second
FVC: forced vital capacity
GLME: generalized linear mixed-effects model
GPx-1: glutathione peroxidase
HDL-C: high-density lipoprotein
HR: heart rate
hs-CRP: high-sensitivity C-reactive protein
IHC: Integrative Health Clinic
IL-6: interleukin-6
LDL-C: low-density lipoprotein

MDA: malondialdehyde
NDVI: normalized difference vegetation index
NO_2: nitrogen dioxide
$PM_{2.5}$: particulate matter with a diameter less than 2.5 μm
sP-selectin: soluble platelet selectin
SPOT: Satellite Pour l'Observation de la Terre
TC: total cholesterol
TG: triglyceride
TNF-α: tumor necrosis factor α
VIF: variance inflation factor

Edited by G Eysenbach; submitted 17.06.21; peer-reviewed by Z Xu, A Guttentag; comments to author 25.08.21; revised version received 28.10.21; accepted 16.11.21; published 30.12.21.

Please cite as:
Yang L, Chan KL, Yuen JWM, Wong FKY, Han L, Ho HC, Chang KKP, Ho YS, Siu JYM, Tian L, Wong MS
Effects of Urban Green Space on Cardiovascular and Respiratory Biomarkers in Chinese Adults: Panel Study Using Digital Tracking Devices
JMIR Cardio 2021;5(2):e31316
URL: https://cardio.jmir.org/2021/2/e31316
doi:10.2196/31316
PMID:34967754

Original Paper

The Effects of a Digital Mental Health Intervention in Adults With Cardiovascular Disease Risk Factors: Analysis of Real-World User Data

Robert M Montgomery[1], MA; Eliane M Boucher[1], PhD; Ryan D Honomichl[1], PhD; Tyler A Powell[1], MS; Sharelle L Guyton[1], MS; Samantha L Bernecker[1], PhD; Sarah Elizabeth Stoeckl[1], BS; Acacia C Parks[1], PhD

Happify Health, New York, NY, United States

Corresponding Author:
Robert M Montgomery, MA
Happify Health
51 E 12th St 5th floor
New York, NY, 10003
United States
Phone: 1 917 261 6933
Email: robmontgomery@happify.com

Abstract

Background: The American Heart Association has identified poor mental health as a key barrier to healthy behavior change for those with cardiovascular disease (CVD) risk factors such as high blood pressure, high cholesterol, and diabetes. Digital mental health interventions, like those delivered via the internet to computers or smartphones, may provide a scalable solution to improving the mental and physical health of this population. Happify is one such intervention and has demonstrated evidence of efficacy for improving aspects of mental health in both the general population and in users with chronic conditions.

Objective: The objectives of this analysis of real-world data from Happify users with self-reported CVD risk factors, including high blood pressure and cholesterol, diabetes, and heart disease, were to examine whether these users would report improvements in subjective well-being and anxiety over time (H1) and use of Happify as recommended would be associated with significantly greater improvement in subjective well-being and anxiety over time compared to less-than-recommended usage (H2).

Methods: Data were obtained from existing Happify users who reported the aforementioned CVD risk factors. The sample included 1803 users receiving at least 6 weeks' exposure to Happify (ranging from 42 days to 182 days) who completed at least one activity and two assessments within the app during that time. Subjective well-being was assessed with the Happify Scale, a 9-item measure of positive emotionality and life satisfaction, and anxiety was assessed with the Generalized Anxiety Disorder 2 (GAD-2). To evaluate H1, changes over time in both outcomes were assessed using mixed effects linear regression models, controlling for demographics and usage. For H2, an interaction term was added to the models to assess whether usage as recommended was associated with greater improvement over time.

Results: Both hypotheses were supported. For both the Happify scale and GAD-2, the initial multivariable model without an interaction demonstrated an effect for time from baseline, and the addition of the interaction term between time and recommended use was significant as well.

Conclusions: This analysis of real-world data provides preliminary evidence that Happify users with self-reported CVD risk factors including high blood pressure or cholesterol, diabetes, and heart disease experienced improved well-being and anxiety over time and that those who used Happify as recommended experienced greater improvements in these aspects of mental health than those who completed fewer activities. These findings extend previous research, which demonstrated that engagement with Happify as recommended was associated with improved well-being among physically healthy users and in those with chronic conditions, to a new population for whom mental health is especially critical: those at risk of developing CVD.

(JMIR Cardio 2021;5(2):e32351) doi:10.2196/32351

KEYWORDS

digital mental health; digital health; mobile apps; mobile health; internet-based intervention; happiness; subjective well-being; anxiety; cardiovascular health; high blood pressure; high cholesterol; diabetes; cardiovascular disease risk; real-world data

Introduction

Background

Cardiovascular diseases (CVDs) are the leading cause of death and disability worldwide, causing nearly one-third of all global deaths in 2019 [1] and trillions of dollars in projected global annual health care costs [2,3]. All told, in the United States, where health care expenditures are the greatest in the world, CVD is responsible for 17% of national health care expenditure [2,4]. Hypertension, or high blood pressure, as well as dyslipidemia (high cholesterol) and uncontrolled blood sugar (prediabetes or diabetes), are 3 of the most prevalent preventable risk factors for CVD, affecting 31%, over 50%, and 16.7% of adults worldwide, respectively [5-7]. Combined, high blood pressure, high cholesterol, and diabetes are responsible for the vast majority of cardiovascular-related deaths [8]. The Framingham Risk Function calculator, which models the contribution of various risks to the incidence of CVD, relies primarily on these 3 factors, in addition to age, gender, and smoking status, for producing risk estimates [9]. Economically, high blood pressure alone accounts for approximately 10% of global health care spending [10], with per capita annual health care costs estimated between US $4871 and US $11,238 [11]. Diabetes is estimated to cost US $827 million annually for global disease care [12], and the global burden of high cholesterol is estimated to be nearly US $4 billion annually [13]. Consequently, mitigating risk factors like high blood pressure, high cholesterol, and diabetes is critical to reducing the overall burden associated with CVD [14].

Self-management of physical health and psychological well-being is critical for reducing CVD risk and improving cardiovascular health [15-18]. The current first-line recommendation for managing CVD risk is adopting healthy lifestyle behaviors, including eating a healthy diet, not smoking, being physically active, and managing weight [19]. Additionally, consistent medication management, access to professional care, social support, and psychological health have been identified as important factors for success [1,16,17,20-23]. However, there are many barriers that can interfere with self-management [24,25]. In particular, poor mental health has been found to compromise many self-management behaviors, including medication adherence, adherence to cardiac rehabilitation programs, exercise, and healthy diet [26-30].

Mental Health and Cardiovascular Health

The American Heart Association has identified poor mental health in particular as a key barrier to health behavior change [17]. Mental health has been defined as both the absence of psychological distress, including symptoms of anxiety, depression, stress, and associated mental disorders, and the presence of positive psychological well-being, which includes factors like life satisfaction, optimism, and positive emotion [31-33]. Research has demonstrated that psychological distress and positive psychological well-being are related, but distinct constructs that uniquely contribute to the prediction of various health outcomes [34,35], including cardiovascular health [36,37], and therefore a complete description of mental health and its relationship with CVD risk should include both.

There is a large body of research establishing a relationship between CVD and psychological distress [38]. Psychological distress is elevated for populations with poor cardiovascular health relative to those with better cardiovascular health [39], and mental disorders are more prevalent in those with CVD than in the general population [38]. Approximately 20%-30% of people with CVD or CVD risk factors may experience elevated symptoms of psychological distress, including depression or anxiety [40,41]. There is evidence that the relationship between psychological distress and cardiovascular health is bidirectional, such that elevated psychological distress negatively impacts cardiovascular health [42] and poor cardiovascular health increases the risk of psychological distress and even mental illness [43-46]. This may be explained, in part, by the finding that psychological distress impairs self-management and self-care activities, such as healthy eating and exercise, thereby undermining cardiovascular health [47]. Simultaneously, CVD risk factors may upregulate the intensity of the body's inflammatory response system [48-51], which in turn, increases perceived stress and reduces psychological resilience [52].

There is also a well-established relationship between cardiovascular health and various aspects of positive psychological well-being, such as optimism, life satisfaction, and positive emotion [53]. Psychological well-being is lower for those with CVD risk factors than in those without such risk factors [54], and the frequent experience of positive emotion has been found to impact the successful prevention, management, and treatment of CVD [36,37]. In fact, positive psychological well-being has been found to protect against CVD risk, independent of common risk factors and psychological distress [53]. This may be because positive mood increases the frequency of key self-care and management activities in patients with chronic illnesses [55], including CVD [56]. It is clear that mental health, including both the absence of psychological distress and the presence of positive psychological well-being, is critically important to cardiovascular health.

Although there is ample research supporting the effectiveness of psychological interventions such as cognitive behavioral therapy (CBT) [57] for improving mental health [58,59], fewer studies have assessed whether mental health–focused interventions can positively affect cardiovascular health in patients at risk for CVD [60-63]. A meta-analysis including 35 randomized controlled trials (RCTs) examining psychological interventions in patients with chronic heart disease suggested that such interventions reduced the risk of cardiac mortality by an estimated 21% [64]. However, the authors noted that there was significant heterogeneity in quality and outcomes across studies and that there is still uncertainty regarding the magnitude of effects and the particular interventions or techniques that may benefit this population [64]. Another review found that, among face-to-face psychological interventions, CBT demonstrated the strongest evidence of positive impact on mental health and cardiovascular health in patients with CVD risk factors [62]. Mindfulness-based interventions and interventions promoting positive psychological well-being may also reduce CVD risk, though more research is needed to determine the details of when, why, and how they may do so

[65-67]. There is some evidence to suggest that greater subjective well-being is associated with a number of positive physiological outcomes, such as increased longevity [67], though the strength and consistency of this association may vary across populations and contexts [68]. Even if the direct effect of most mental health interventions on CVD risk is small, the benefits of improved self-care behaviors and quality of life make these interventions indispensable to those with CVD risk factors [36].

Barriers to Care and the Importance of Digital Interventions

Numerous barriers, including cost, stigma, and availability, limit people's access to effective mental health interventions [69]. Digital interventions, like those delivered via the internet to computers or smartphones, can circumvent many of these barriers and may provide a scalable solution to supporting the physical and mental health of patients with CVD risks [70-74]. There are a number of digital health interventions that directly target self-management of CVD risks such as smartphone apps and wearable devices that focus on lifestyle behavior change, some of which have demonstrated efficacy in improving cardiovascular health outcomes [75-77]. Unfortunately, these interventions do not address the barriers introduced by mental health issues and may therefore be less effective for the increasing proportion of the population suffering from mental health difficulties each year [78-80]. As such, there is a need for scalable mental health interventions that are effective for this population. There is ample evidence indicating that digital mental health interventions such as internet-based CBT are safe and effective in general populations [81-83], but few of these interventions have demonstrated efficacy in improving aspects of mental health in patients with CVD risk factors [84-86]. One example is an internet-based CBT program that was adapted to patients with CVD and at least mild depression, which had a moderate to large effect on depression scores over 9 weeks (ds=0.62-0.86) compared with an online forum control group [86]. Other studies have evaluated the characteristics of digital mental health app users with CVD risk factors [77] and explored the feasibility and usability of digital interventions for mental and cardiovascular health [87]. However, most of these interventions lack evidence regarding their safety and effectiveness, and those that do have empirical support are generally not widely accessible [88,89]. Therefore, more research is needed on scalable, widely accessible digital mental health interventions in populations with CVD risk factors.

Happify is a mobile and web-based digital intervention designed to support mental and physical health through engagement with a variety of activities drawn from evidence-based treatments. Prior research has demonstrated Happify's effectiveness in improving mental health and well-being. One RCT showed the positive mental health effects of Happify in a general population of US adults, finding that participants who completed a minimum 16 activities over 8 weeks improved their psychological resilience by 20.8% and reduced depression and anxiety symptoms by over 25%, effects twice as large as those observed in the active psychoeducation placebo control condition [90]. Additionally, a real-world naturalistic study of Happify in those with and without self-reported chronic conditions found that users with a chronic condition experienced significant improvement in subjective well-being over time (42-182 days from baseline) and that the trajectory of this change did not differ from those without a self-reported chronic condition [91]. Consistent with previous research, users who completed more activities, regardless of chronic condition status, had greater improvements in subjective well-being.

Study Objectives

Although extant research suggests Happify users with chronic physical conditions experience significant improvements in subjective well-being over time [91], the previously published study combined all users with self-reported chronic conditions into a single group, and therefore, the specific impact on subpopulations, such as those with CVD risk factors, could not be observed. The previous study also only evaluated changes in positive aspects of mental health (subjective well-being) but not negative features (eg, anxiety) [91]. Therefore, the objective of this analysis of real-world user data was to expand on previous research by examining changes in both subjective well-being and anxiety over time in Happify users with self-reported CVD risk factors, including high blood pressure and cholesterol, diabetes, and heart disease. We hypothesized that (H1) Happify users with CVD risk factors will experience significant improvements in both subjective well-being and anxiety over time and (H2) users who engage with Happify at the recommended level (an average of 2 or more activities per week) will report significantly greater improvements in these mental health outcomes over time than those who completed fewer activities. While demonstrating improvement over time is a necessary first step, the second question is especially important as it would support stronger inferences about the relationship between engagement with Happify and improvements in mental health outcomes.

Methods

Recruitment

The sample consisted of users who found Happify via the Apple App Store or Google Play Store, internet search, digital advertisements, employee and health plan benefits programs, or other channels and signed up of their own accord. This study included data for 3 different subgroups of existing Happify users: consumer guests, who had free access to a limited version of the app; premium users, who paid for full access to the platform; and enterprise users, who received full access via their employer or health plan. The onboarding process for all new Happify users involves the following steps. After downloading the app or accessing the Happify website, all users complete an onboarding questionnaire, which contains questions about the user's demographic characteristics as well as common intra- and interpersonal problems. One of these questions asks users to select all that apply from a list of conditions, including high blood pressure or cholesterol, heart disease, diabetes, migraine, psoriasis, rheumatoid arthritis, psoriatic arthritis, insomnia, eczema (atopic dermatitis), asthma, multiple sclerosis, cancer, arthritis, chronic pain, postpartum depression, or other. This item was used as a screening criterion for this study. Next, users receive an algorithmically generated recommendation for a "track" (a group of activities with a common theme) based on

the challenges or conditions they reported during onboarding, though they are free to engage with any of the hundreds of available tracks in any order. After selecting a track, users can begin to complete activities.

Upon sign-up for Happify, users must agree to the terms of service and privacy policy, which includes the following statement: "Information that we collect about you also may be combined by us with other information available to us through third parties for research and measurement purposes, including measuring the effectiveness of content, advertising, or programs." All data analyzed in this study were real-world data entered or generated by app users as part of the standard user experience and stored on secure company servers. Only anonymized data were extracted from the user database, and no personal data were submitted for scientific evaluation. Users were not offered any compensation to complete activities or assessments.

Participants

Data were drawn from registered Happify users who reported having one or more of the following conditions: "High blood pressure or cholesterol," "Diabetes," or "Heart disease." Data from users aged 18 years and older who created accounts between November 5, 2018 and May 31, 2021 (when data were queried) were considered for inclusion in the analysis (users were not asked about high blood pressure/cholesterol, diabetes, or heart disease prior to November 5, 2018). Users also had to meet the following inclusion criteria: complete at least 1 activity, complete no more than 3 activities before their baseline assessment, and complete at least 1 assessment in addition to baseline within 42-182 days (6 weeks to 6 months) from signup. This time window aligns with the time window used in our previous analysis of Happify users with self-reported chronic conditions [91], facilitating comparison. Naturalistic studies can yield notoriously messy data [92], and these criteria were selected in order to increase the interpretability of the results. Specifically, users who completed no activities were removed because any improvements they experienced could not be due to the use of Happify; users who completed more than 3 activities before the baseline were removed because their scores may not accurately represent their initial state before using Happify; and users without a follow-up assessment within the time window were removed because change over time cannot be assessed with only a single timepoint.

Between November 5, 2018 and May 31, 2021, there were 254,312 new sign-ups, among whom 18,905 reported at least one of the heart-related conditions. Of these, 4262 users completed at least 1 activity, at least 2 assessments, and no more than 3 activities before the first assessment. Restricting the sample to those with an assessment in the 42-182–day window reduced the sample to 2107. Finally, users who were missing multiple demographic variables due to a server error were removed, leaving a final sample of 1803.

Intervention Description

A detailed description of the Happify platform, including screenshots, is available in previous research [90]. Briefly, Happify is a digital intervention designed to support mental and physical health through engagement with a variety of activities drawn from evidence-based treatments, including CBT [57], positive psychology [93], and mindfulness-based stress reduction [94]. These activities are generally brief, ranging from 2 minutes to ≥15 minutes, and are delivered in 5 media formats: (1) written activities, some of which are guided by a US-patented digital artificial intelligence coach (chatbot) called Anna; (2) audio recordings; (3) video recordings; (4) quizzes; and (5) cognitive training games. Some activities can be completed fully within the app (eg, psychoeducational quiz about happiness), while others require action outside of the app (eg, calling a friend or practicing a more adaptive response to an upsetting event or situation). Activities are grouped into 6 skills: savoring (eg, mindfulness-based activities), thanking (eg, gratitude-based activities), aspiring (eg, optimism and goal-setting activities), giving (eg, kindness and forgiveness activities), empathizing (eg, self-compassion and perspective-taking activities), and reviving (eg, physical activities). These activities are organized into 4-week tracks that address particular challenges or symptoms (eg, addressing negative thoughts or reducing stress). Each track contains approximately 30-40 activities subdivided into 4 parts. Users select a track of interest but can switch tracks anytime and can also access activities on-demand, separate from any track.

Previous research on Happify has indicated that completing at least 16 activities over 8 weeks, or an average of ≥2 activities per week, is associated with moderate increases in mental health outcomes, and thus, this is considered the minimum recommended level of use [90,95]; however, users are not directed or required to use Happify at a particular frequency. Two new activities are available each day, with the option to unlock a third new activity if at least one activity is completed that day, though users may complete as many instant play activities as desired.

Outcome Measures

Happify includes regular assessments of different aspects of mental health, including anxiety and subjective well-being, and provides visual feedback to users via a graph that tracks their subjective well-being over time. One day after registering and every 2 weeks thereafter, all Happify users are invited to complete a well-being assessment called the Happify Scale and the Generalized Anxiety Disorder-2 (GAD-2) assessment [90,96,97]. Assessments are optional, and thus, there is considerable variability in the frequency and timing of assessment completion of these measures in the data analyzed for this study.

Subjective Well-Being

The Happify Scale has been described in detail in other publications [91,97]. Briefly, the Happify Scale is a 9-item measure with 2 subscales: a 4-item positive emotionality scale and a 5-item life satisfaction scale [97]. Items on the positive emotionality subscale are rated on a 5-point scale from "Never" to "Very often (almost every day)," and items on the life satisfaction subscale are rated on a 7-point scale from "Very dissatisfied" to "Very satisfied." Scores are converted into percentages and thus range from 0 to 100, where higher scores on each subscale indicate greater positive emotionality and life

satisfaction. Subscale scores are typically averaged together such that higher composite scores indicate greater subjective well-being. Scale validation using a general population sample from Amazon's Mechanical Turk showed that scores between 46 and 49 corresponded to the 25th percentile, scores between 61 and 63 corresponded to the 50th percentile, and scores between 75 and 77 corresponded to the 75th percentile of the Happify Scale. Internal validation data indicated that composite scale scores had acceptable reliability (α=.89) and was strongly correlated with subjective happiness (r=0.78) [98] and anticorrelated with a measure of depressive symptoms (r=−0.7) [99].

Anxiety Symptoms

The GAD-2 is a 2-item initial screening tool for generalized anxiety disorder that consists of the first 2 questions of the GAD-7 [100]: "Over the last two weeks, how often have you been bothered by the following: (1) Feeling nervous, anxious, or on edge and (2) Not being able to stop or control worrying." Responses are Likert-style from 0 to 3 (0=not at all, 1=several days, 2=more than half the days, and 3=nearly every day). The scores for both items are summed for a total score range of 0-6. A total score of ≥3 is recommended as a cut-off for detecting generalized anxiety disorder in the general population, though clinical interviews are generally required for diagnostic purposes [101]. Though the GAD-2 is most often used as a screening tool, it has also been used to measure responsiveness to treatment effects in both clinical study and primary care settings [102]. Staples and colleagues [102] compared the short-form against the full version of several common mental health measurement tools, including the GAD-7, and found that the percentage change and within-person effect sizes were of similar magnitude across the 2 versions of the measure. Therefore, the GAD-2 may be a practical and effective means of measuring change in anxiety symptoms over time in the context of an intervention study.

Statistical Analysis

To test both hypotheses, linear mixed effects (LME) models were fitted for each outcome, with time from baseline (in days) as a level 1 fixed effect predicting each assessment score. LME is capable of modeling change over time in longitudinal data that have a high degree of variability and heterogeneity [103]. As is typical with real-world data [103,104], our data were highly variable regarding the frequency and timing of assessments, and thus, LME was used to account for these factors. The Akaike information criterion was used to identify the best random effects model, and ultimately, all LME models were fitted with a random intercept and random slope for time. Because users had varying numbers of assessments at unequally spaced times, a continuous autoregressive error structure of order 1 was used.

To test the first hypothesis, that Happify users with CVD risk factors would experience significant improvements in mental health outcomes over time, models were fit to examine the fixed effect of time—that is, the coefficient representing whether and how quickly users decreased in anxiety and increased in subjective well-being—while controlling for person-level (ie, level 2) covariates. Person-level predictors included the total number of chronic conditions reported by the user at baseline (which could include heart-related conditions and other conditions), gender, age category, baseline GAD-2 or Happify Scale composite score (each predicting the other measure; eg, [91]), relationship status, whether the user had any minor-aged children, and a dichotomous variable that indicated whether a user completed the recommended use of an average of ≥2 activities per week. That is, a user was categorized as having reached the recommended use if the total number of activities completed between first and last assessment, divided by the number of weeks between assessments, was ≥2. This cutoff has been established in previous research as an approximate threshold for the minimum amount of engagement required to produce meaningful effects [90,91]. Coefficients for these person-level predictors represent whether they are associated with higher or lower mental health overall, but not whether they are associated with how quickly a person's mental health improves.

To test the second hypothesis, that users who engage with Happify at the recommended use report significantly greater improvements in these mental health outcomes over time than those who use it less, an interaction between the user's recommended use status and time was added to the model. The coefficient for this interaction represents how the change in mental health over time (ie, the time slope) differs between those who used at the recommended level and those who did not.

Assumptions of final models were evaluated via visual inspection of residual plots. For all predictors and covariates, no variance inflation factor was higher than 2, suggesting multicollinearity was not an issue. Models were fit in R [105] within the maximum likelihood framework using the lme function from the nlme package [106]. All test statistics were two-sided, and P values <.05 were considered statistically significant.

Results

Baseline Sample Characteristics

Sample characteristics are presented in Table 1. Hypertension/high cholesterol was the most common heart-related condition, and comorbid heart disease and diabetes was the least common. Users reported an average of 2 chronic conditions; other than the 3 heart-related conditions, the most commonly selected categories were insomnia, chronic pain, and "other." Approximately three-quarters of users were female, and the most frequent age category was 45-54 years old. Mean total duration of time between first and last assessments was approximately 100 days, and the average number of activities completed per week between a user's first and last assessments was 2.9 (SD 4.6), with a range of 0.04-29.94. In total, 636 users (636/1803, 35.27%) achieved the recommended use of 2 activities averaged per week.

Table 1. Baseline sample characteristics (N=1803).

Characteristics	Users
Heart conditions, n (%)	
Hypertension/high cholesterol	1180 (65.44)
Diabetes	361 (20.00)
Hypertension/high cholesterol and diabetes	169 (9.37)
Heart disease	69 (3.83)
Heart disease and diabetes	24 (1.33)
Gender, n (%)	
Female	1348 (74.76)
Male	447 (24.79)
Other	8 (0.44)
Age group (years), n (%)	
18-24	61 (3.38)
25-34	228 (12.65)
35-44	394 (21.85)
45-54	646 (35.83)
55-64	474 (26.29)
User is in a relationship, n (%)	1340 (74.32)
User has at least one minor child, n (%)	569 (31.56)
Total chronic conditions, mean (SD)	2 (1)
Total chronic conditions, n (%)	
Arthritis	222 (12.31)
Asthma	201 (11.15)
Cancer	40 (2.22)
Chronic pain	419 (23.24)
Eczema	106 (5.88)
Insomnia	473 (26.23)
Migraine	238 (13.20)
Multiple sclerosis	15 (0.83)
Postpartum depression	39 (2.16)
Psoriasis	60 (3.33)
Rheumatoid arthritis	50 (2.77)
Other conditions	480 (26.62)
Total time between baseline and last assessment (days), mean (SD)	101 (43)
Total number of assessments, mean (SD)	4 (2)
Days between assessment, mean (SD)	50 (36)
Happify score at baseline, mean (SD)	46 (21)
GAD-2[a] score at baseline, mean (SD)	3 (2)
Number of activities per week, mean (SD)	2.9 (4.6)
Recommended use[b], n (%)	636 (35.27)

[a]GAD 2: Generalized Anxiety Disorder-2.

[b]Users met criteria for recommended use if they completed an average of 2 or more activities per week between their first and last assessments.

Changes in Well-Being and Anxiety Over Time

For the Happify scale, the initial multivariable model without an interaction demonstrated an effect for time from baseline (b=0.049; 95% CI 0.041 to 0.057; P<.001), supporting our first hypothesis that users would report significant improvements in subjective well-being over time. Specifically, users were predicted to improve 0.049 points per day, amounting to about 2.1 points over 6 weeks or 8.8 points over 6 months.

There was also a main effect of whether a user completed the recommended number of activities: Those who used as recommended had higher Happify scale scores overall (b=9.071; 95% CI 7.563 to 10.578; P<.001). The interaction term between time and whether a user met the recommended use was significant as well (b=0.047; 95% CI 0.032 to 0.063; P<.001), supporting the second hypothesis that those who used Happify at or above the recommended use would experience significantly greater improvements in well-being over time than those who completed fewer activities. Individuals who averaged at least 2 activities per week would be expected to improve by 0.077 points per day (about 3.2 points over 6 weeks or 13.9 points over 6 months), whereas users who did not use as recommended would only be predicted to improve 0.028 points per day (about 1 point over 6 weeks or 5 points over 6 months). The interaction is depicted in Figure 1. Additionally, users with higher GAD-2 scores at baseline scored lower on the Happify scale overall, users with more chronic conditions scored lower, and users in a relationship scored higher. Table 2 presents estimates for both models.

For the GAD-2, there was also a significant main effect for time (b=–0.003; 95% CI –0.004 to –0.003; P<.001) for the initial model, supporting the first hypothesis that users would report significant improvements in anxiety over time. Specifically, users were predicted to improve by 0.003 points per day, amounting to 0.126 points over 6 weeks or 0.54 points over 6 months. There was also a main effect of whether a user completed the recommended number of activities: Those who met recommended use had lower GAD-2 scores overall (b=–0.362; 95% CI –0.484 to –0.239; P<.001).

The inclusion of the interaction term between time and recommended use was also significant (b=–0.002; 95% CI –0.004 to –0.001; P=.001), supporting the second hypothesis: Those who used Happify at or above the recommended use level experienced significantly greater reductions in anxiety over time compared with those who completed fewer activities. Individuals who averaged at least 2 activities per week would be expected to improve by 0.004 points per day (about 0.17 points over 6 weeks or 0.72 points over 6 months), whereas users who did not use as recommended would only be predicted to improve 0.002 points per day (about 0.084 points over 6 weeks or 0.36 points over 6 months). The interaction is depicted in Figure 2.

Additionally, female users scored higher (greater anxiety) on the GAD-2 overall, users with higher Happify Scale scores at baseline scored lower on the GAD-2, users with more chronic conditions scored higher, and users in a relationship scored lower. Finally, users aged 18-24 years, users aged 25-34 years, and users aged 35-44 years all reported higher overall anxiety scores than those aged 45-54 years. Users aged 55-64 years reported lower scores than those aged 45-54 years. Table 3 presents the estimates for both models.

Figure 1. Change in predicted subjective well-being scores over time by recommended use.

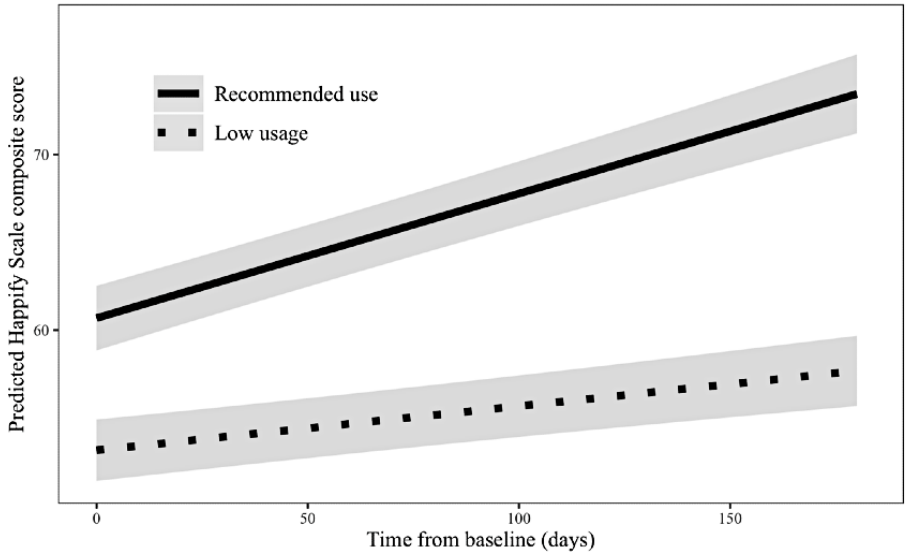


Table 2. Linear mixed effect model of main effects and interaction between recommended use and time for Happify Scale scores.

Predictor	Main effects–only model		Interaction model	
	Model estimate (95% CI)	*P* value	Model estimate (95% CI)	*P* value
Intercept[a]	60.474 (57.721 to 63.226)	<.001	61.037 (58.277 to 63.796)	<.001
Recommended use	9.071 (7.563 to 10.578)	<.001	7.636 (6.053 to 9.219)	<.001
Time from baseline (days)	0.049 (0.041 to 0.057)	<.001	0.03 (0.021 to 0.04)	<.001
Total chronic conditions	–2.168 (–2.693 to –1.642)	<.001	–2.168 (–2.694 to –1.643)	<.001
GAD-2[b] score at baseline	–5.267 (–5.657 to –4.877)	<.001	–5.26 (–5.65 to –4.871)	<.001
Female gender	0.676 (–1.001 to 2.354)	.43	0.691 (–0.987 to 2.368)	.42
Age group (years)				
18-24	–0.512 (–4.714 to 3.69)	.81	–0.509 (–4.709 to 3.692)	.81
25-34	–1.354 (–3.727 to 1.019)	.26	–1.366 (–3.739 to 1.007)	.26
35-44	–0.759 (–2.739 to 1.221)	.45	–0.768 (–2.747 to 1.212)	.45
45-54	-[c]	-[c]	-[c]	-[c]
55-64	1.131 (–0.769 to 3.031)	.24	1.131 (–0.769 to 3.031)	.24
User is in a relationship	6.093 (4.39 to 7.797)	<.001	6.106 (4.403 to 7.809)	<.001
User has at least one minor child	–1.035 (–2.755 to 0.684)	.24	–1.024 (–2.743 to 0.695)	.24
Recommended use by time from baseline	N/A[d]	N/A	0.047 (0.032 to 0.063)	<.001

[a]Represents the score for a male user aged 45-54 years at baseline with 0 chronic conditions, no anxiety symptoms, not in a relationship, with no children, and who did not meet the recommended use of an average of 2 activities per week.

[b]GAD-2: Generalized Anxiety Disorder-2.

[c]Reference group.

[d]N/A: not applicable to the first model.

Figure 2. Change in predicted Generalized Anxiety Disorder-2 (GAD-2) scores over time by recommended use status.

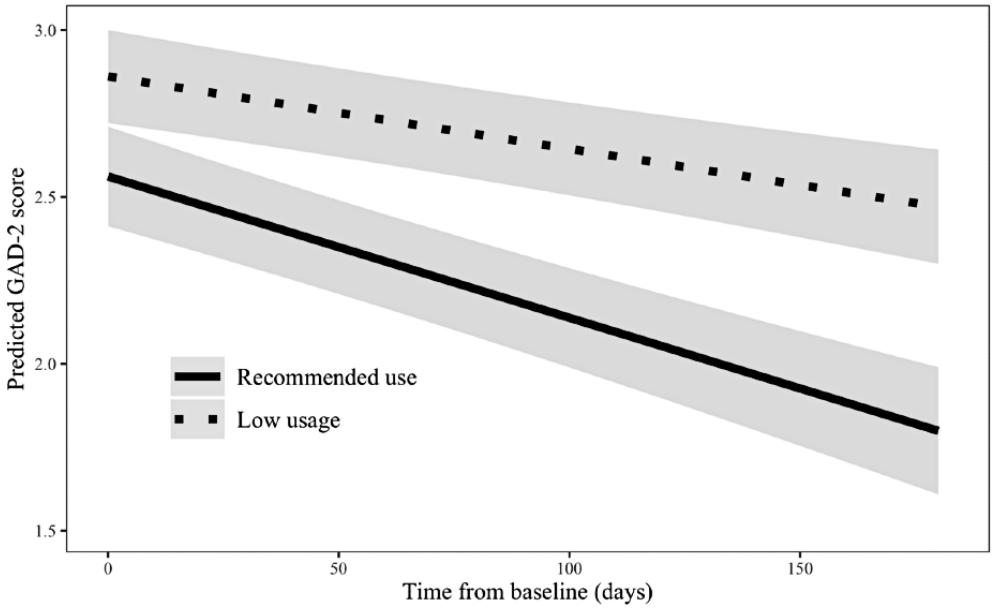


Table 3. Linear mixed effect model of main effects and interaction between recommended use and time for anxiety scores on the Generalized Anxiety Disorder-2 (GAD-2).

Predictor	Main effects–only model		Interaction model	
	Model estimate (95% CI)	*P* value	Model estimate (95% CI)	*P* value
Intercept[a]	4.165 (3.914 to 4.416)	<.001	4.075 (3.821 to 4.33)	<.001
Recommended use	–0.362 (–0.484 to –0.239)	<.001	–0.28 (–0.421 to –0.139)	<.001
Time from baseline (days)	–0.003 (–0.004 to –0.003)	<.001	–0.002 (–0.003 to –0.001)	<.001
Total chronic conditions	0.135 (0.092 to 0.178)	<.001	0.137 (0.094 to 0.18)	<.001
Happify score at baseline	–0.041 (–0.043 to –0.038)	<.001	–0.039 (–0.042 to –0.036)	<.001
Female gender	0.161 (0.026 to 0.297)	.02	0.165 (0.029 to 0.301)	.02
Age group (years)				
18-24	0.615 (0.274 to 0.955)	<.001	0.622 (0.278 to 0.965)	<.001
25-34	0.378 (0.186 to 0.569)	<.001	0.383 (0.191 to 0.576)	< .001
35-44	0.246 (0.086 to 0.405)	.003	0.241 (0.08 to 0.401)	.003
45-54	-[b]	-[b]	-[b]	-[b]
55-64	–0.163 (–0.316 to –0.01)	.04	–0.159 (–0.313 to –0.005)	.04
User is in a relationship	0.181 (0.043 to 0.32)	.01	0.164 (0.025 to 0.304)	.02
User has at least one minor child	–0.007 (–0.146 to 0.132)	.93	0.003 (–0.137 to 0.143)	.96
Recommended use by time from baseline	N/A[c]	N/A	–0.002 (–0.004 to –0.001)	.001

[a]Represents the score for a male user aged 45-54 years at baseline with 0 chronic conditions, a score of 0 on the Happify Scale, not in a relationship, with no children, and who did not meet the recommended use of an average of 2 activities per week.

[b]Reference group.

[c]N/A: not applicable to the first model.

Discussion

Principal Findings

The objective of this analysis of real-world data from Happify users with self-reported CVD risk factors, including high blood pressure and cholesterol, diabetes, and heart disease, was to examine whether (H1) these users would report improvements in subjective well-being and anxiety over time and (H2) use of Happify as recommended would be associated with significantly greater improvement in subjective well-being and anxiety over time compared with less-than-recommended usage. Both hypotheses were supported. As predicted, users experienced significant improvement in subjective well-being and anxiety over time. However, in single-arm studies, such improvements could be attributed to factors other than the intervention, including regression to the mean, spontaneous remission, changes in a person's medication or treatment regimen, or any number of other factors. We also found a significant interaction between recommended use (ie, completing at least 2 activities per week or not) and time for both subjective well-being and anxiety, which provides preliminary evidence that the changes in mental health outcomes may be due, at least in part, to the engagement with the intervention itself (though it is not, of course, dispositive). As shown in Figures 1 and 2, the *rate of improvement* was greater (faster) for those who met or exceeded the recommended use criteria compared with those who did not. This suggests that the observed improvements in mental health outcomes were not due to the passage of time alone, thereby reducing the influence of one potential confound and increasing the likelihood that the observed changes were due at least in part to the intervention.

Strengths and Limitations

This study provided important extensions to prior research and included many strengths, but also several limitations. First, as this was a study of real-world data from Happify users, there was no opportunity to assign participants to a control group, and thus, we cannot determine whether the observed changes in outcomes were simply due to the passage of time, chance, or any number of other confounding factors. However, though RCTs are considered the gold standard for assessing the efficacy and safety of therapeutic interventions, naturalistic studies provide important insight into the performance of these interventions in real-world settings [107]. Real-world studies are free from many of the constraints imposed by more controlled research, such as strict eligibility criteria, which can limit the diversity of participants and the generalizability of the results [108]. As such, real-world studies have been recognized for their value by regulatory bodies such as the Food and Drug Administration [109]. This sample consisted of existing Happify users and so was not limited to those who could be reached via traditional research recruitment channels, nor was compensation given to users for participating in the study or using the app, removing the potential for such incentives to influence users' behaviors. Therefore, this naturalistic analysis yields results

that are more readily generalizable to the broader population of users than would be the case for a more controlled trial.

Second, despite these advantages regarding generalizability, the users retained for analysis may not be representative of Happify users as a whole. Although these data provide important insights into real-world use, users could easily stop using the app with little friction, resulting in a high dropout rate. This means that only a small proportion of potentially eligible users was included in the analysis, and they may systematically differ from other Happify users in their behaviors or dispositions. Unfortunately, this is a widespread issue, as the majority of open-access, digital mental health interventions are plagued by low usage and retention rates, with the median app losing 97% of its users within 30 days [110]. Studies of such interventions also suffer from high attrition and dropout, especially for observational or real-world evidence studies [111].

Another challenge to the generalizability of the study is regarding the gender balance within the sample. Approximately three-quarters of the sample were women, a trend that is common across many studies of digital mental health interventions [112] and consistent with prior research of Happify [90]. This may reflect the fact that proportionally more women are affected by a number of mental health issues than men [113] and/or that women may be more willing to engage with digital mental health interventions [114,115]. However, men, on average, are at higher absolute risk of developing CVD than women (although the relative risk of CVD morbidity and mortality is higher in women than men) [116]. Therefore, our study undersampled men relative to the proportion of men who experience CVD risk in the general population, and future studies should seek more representative samples. At the same time, the sample is likely biased toward those who are naturally more inclined to use digital mental health interventions, and consequently, our sample may be more closely representative of the people with CVD risk factors who would be most likely to actually use digital mental health interventions.

Despite these difficulties, this study demonstrated fairly high rates of usage relative to other studied interventions. After excluding those who merely downloaded the app but did not use it, which was only 3.51% (664/18,905) of the initial sample of users with CVD risk factors, we found that the average number of activities per week completed between a user's first and last assessments was 2.9 and that 35.27% (636/1803) of the sample met criteria for recommended use. This is actually quite high, especially considering that in this and prior research, a significant improvement has been observed in those who complete as few as 2 activities per week over 6-8 weeks [90,91]. Most Happify activities take between 2 minutes and 15 minutes to complete. Given the many demands on people's time, in particular those with poor cardiovascular health, who may experience higher stress levels [117] and impaired physical function [118], digital mental health interventions that are effective with minimal usage and time commitment are especially valuable.

Third, we were limited to the use of only 2 brief, self-reported measures of mental health capturing subjective well-being and anxiety that were part of the general user experience of the existing Happify product. These 2 measures alone are clearly not representative of all features of mental health, but we were unable to add other measures due to the naturalistic nature of the study. Although the Happify Scale has been observed to be highly correlated (r=–0.70) with validated measures of depression [97], it is not a direct measure of depression or other important mental health factors, like stress. Additionally, the GAD-2 is less responsive to change than a longer, more sensitive measure of anxiety like the GAD-7 [119] and therefore more precise and potentially larger effects for anxiety might have been observed had we used a more psychometrically robust measure. Finally, all other data was self-reported, and thus, we cannot confirm whether users' conditions were official diagnoses.

Future Directions

Additional research is needed to address these limitations and more fully understand how Happify and other digital mental health interventions can improve mental and physical health outcomes in patients with CVD risks. Existing research suggests that interventions designed to improve mental health may also lead to reduced CVD risk [64], but to determine whether an intervention like Happify has a direct causal impact on cardiovascular health, an RCT would be necessary. Additionally, the version of Happify studied here was not specially tailored or personalized to the particular population of users with CVD risks. Tailored interventions have been shown to improve outcomes over and above nontailored ones [120], and thus, there is an opportunity to create and test an intervention that addresses the unique challenges and concerns of users with CVD risk factors. Furthermore, there is great potential in the integration of sensors and wearable technology into interventions for CVD risk monitoring and prevention, which allow for greater insight into health behaviors and opportunity to impact users in real time [121]. Other technology, such as artificial intelligence, could be used to process this large influx of data and provide ongoing recommendations that are tailored to meet individual user's needs without dramatically increasing the burden of care [75]. These and other technologies should be further explored to determine what kinds of interventions best serve this population. Future RCTs and other studies should also expand the measures of mental health beyond those studied here to include validated measures of quality of life, depression, and stress, all of which have been associated with CVD risk [122], and there is a further opportunity to address some of the weaknesses associated with self-reported measures by incorporating data from wearables or other devices like home blood pressure monitors on physiological outcomes [19]. Finally, future research should evaluate the impact of digital mental health interventions on mental health and CVD risk factors beyond the current window of 6 months to establish the long-term trajectory and durability of the effects.

Conclusions

This retrospective analysis of real-world data provides preliminary evidence that Happify users with self-reported CVD risk factors including high blood pressure or cholesterol, diabetes, and heart disease experienced improved well-being and anxiety over time and that those who used Happify at or

above the recommended level experienced greater improvements over time in these aspects of mental health than those who completed fewer activities. This study assessed data from a publicly available digital mental health product, and consequently, the regularity of data collection and consistency of usage were highly variable. Although greater Happify usage was significantly associated with greater improvements in mental health (thereby reducing the likelihood that observed changes were due to maturation effects), the lack of a control group nevertheless makes it impossible to draw direct causal links between Happify usage and improvements in mental health. Acknowledging these limitations, our findings extend previous research, which demonstrated that engagement with Happify as recommended was associated with improved well-being among physically healthy users [90,123] and in those with chronic conditions [91], to a new population for whom mental health is especially critical: those at risk of developing CVD. Also, by including both subjective well-being and anxiety symptoms as outcomes, this study provides insight into a broader understanding of mental health than assessed in previous naturalistic studies of Happify [91]. Understanding how to increase positive experiences and reduce negative ones is essential to achieving the flourishing of the "whole person" [124], and digital mental health interventions appear to be a promising means of supporting people, including those with CVD risk factors, in this pursuit [125].

Acknowledgments

This study was funded by Happify Health.

Conflicts of Interest

The authors are employees of Happify Health, a company that designs and deploys software that can improve mental health, physical health, and well-being across the continuum of care. Emplyees have stock options with Happify Health; however, they are not compensated for publishing or producing favorable results. ACP was involved in the development of the Happify software and intervention.

References

1. Roth GA, Mensah GA, Johnson CO, Addolorato G, Ammirati E, Baddour LM, GBD-NHLBI-JACC Global Burden of Cardiovascular Diseases Writing Group. Global Burden of Cardiovascular Diseases and Risk Factors, 1990-2019: Update From the GBD 2019 Study. J Am Coll Cardiol 2020 Dec 22;76(25):2982-3021 [FREE Full text] [doi: 10.1016/j.jacc.2020.11.010] [Medline: 33309175]
2. Mensah GA, Moran AE, Roth GA, Narula J. The global burden of cardiovascular diseases, 1990-2010. Glob Heart 2014 Mar 01;9(1):183-184 [FREE Full text] [doi: 10.1016/j.gheart.2014.01.008] [Medline: 25432128]
3. Benjamin EJ, Virani SS, Callaway CW, Chamberlain AM, Chang AR, Cheng S, American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics-2018 update: A report From the American Heart Association. Circulation 2018 Mar 20;137(12):e67-e492 [FREE Full text] [doi: 10.1161/CIR.0000000000000558] [Medline: 29386200]
4. Heidenreich PA, Trogdon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, American Heart Association Advocacy Coordinating Committee, Stroke Council, Council on Cardiovascular Radiology and Intervention, Council on Clinical Cardiology, Council on Epidemiology and Prevention, Council on Arteriosclerosis, Thrombosis and Vascular Biology, Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation, Council on Cardiovascular Nursing, Council on the Kidney in Cardiovascular Disease, Council on Cardiovascular Surgery and Anesthesia, Interdisciplinary Council on Quality of Care and Outcomes Research. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation 2011 Mar 01;123(8):933-944 [FREE Full text] [doi: 10.1161/CIR.0b013e31820a55f5] [Medline: 21262990]
5. Mills KT, Stefanescu A, He J. The global epidemiology of hypertension. Nat Rev Nephrol 2020 Apr;16(4):223-237 [FREE Full text] [doi: 10.1038/s41581-019-0244-2] [Medline: 32024986]
6. Hedayatnia M, Asadi Z, Zare-Feyzabadi R, Yaghooti-Khorasani M, Ghazizadeh H, Ghaffarian-Zirak R, et al. Dyslipidemia and cardiovascular disease risk among the MASHAD study population. Lipids Health Dis 2020 Mar 16;19(1):42 [FREE Full text] [doi: 10.1186/s12944-020-01204-y] [Medline: 32178672]
7. Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, IDF Diabetes Atlas Committee. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9 edition. Diabetes Res Clin Pract 2019 Nov;157:107843 [FREE Full text] [doi: 10.1016/j.diabres.2019.107843] [Medline: 31518657]
8. Virani SS, Alonso A, Benjamin EJ, Bittencourt MS, Callaway CW, Carson AP, American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics-2020 update: A report from the American Heart Association. Circulation 2020 Mar 03;141(9):e139-e596 [FREE Full text] [doi: 10.1161/CIR.0000000000000757] [Medline: 31992061]

9. D'Agostino RB, Vasan RS, Pencina MJ, Wolf PA, Cobain M, Massaro JM, et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. Circulation 2008 Feb 12;117(6):743-753 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.107.699579] [Medline: 18212285]
10. Gaziano TA, Bitton A, Anand S, Weinstein MC, International Society of Hypertension. The global cost of nonoptimal blood pressure. J Hypertens 2009 Jul;27(7):1472-1477. [doi: 10.1097/HJH.0b013e32832a9ba3] [Medline: 19474763]
11. Wierzejska E, Giernaś B, Lipiak A, Karasiewicz M, Cofta M, Staszewski R. A global perspective on the costs of hypertension: a systematic review. Arch Med Sci 2020;16(5):1078-1091 [FREE Full text] [doi: 10.5114/aoms.2020.92689] [Medline: 32863997]
12. NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants. Lancet 2016 Apr 09;387(10027):1513-1530 [FREE Full text] [doi: 10.1016/S0140-6736(16)00618-8] [Medline: 27061677]
13. The Economic Burden of Hypercholesterolaemia: Economic Report into High Cholesterol. National Heart Foundation of Australia. 2018. URL: https://www.heartfoundation.org.au/getmedia/dc7b68ad-f49d-4c93-9583-68bdfb854449/Hyperchol_20page_HF_report_WEB.pdf [accessed 2021-11-08]
14. Lawes CMM, Vander Hoorn S, Law MR, Elliott P, MacMahon S, Rodgers A. Blood pressure and the global burden of disease 2000. Part II: estimates of attributable burden. J Hypertens 2006 Mar;24(3):423-430. [doi: 10.1097/01.hjh.0000209973.67746.f0] [Medline: 16467640]
15. Müller-Riemenschneider F, Meinhard C, Damm K, Vauth C, Bockelbrink A, Greiner W, et al. Effectiveness of nonpharmacological secondary prevention of coronary heart disease. Eur J Cardiovasc Prev Rehabil 2010 Dec;17(6):688-700. [doi: 10.1097/HJR.0b013e32833a1c95] [Medline: 20458247]
16. Riegel B, Moser DK, Buck HG, Dickson VV, Dunbar SB, Lee CS, American Heart Association Council on CardiovascularStroke Nursing; Council on Peripheral Vascular Disease;Council on Quality of CareOutcomes Research. Self-care for the prevention and management of cardiovascular disease and stroke: A scientific statement for healthcare professionals from the American Heart Association. J Am Heart Assoc 2017 Aug 31;6(9):e006997 [FREE Full text] [doi: 10.1161/JAHA.117.006997] [Medline: 28860232]
17. Levine GN, Cohen BE, Commodore-Mensah Y, Fleury J, Huffman JC, Khalid U, et al. Psychological health, well-being, and the mind-heart-body connection: A scientific statement from the American Heart Association. Circulation 2021 Mar 09;143(10):e763-e783. [doi: 10.1161/cir.0000000000000947]
18. Kubzansky LD, Huffman JC, Boehm JK, Hernandez R, Kim ES, Koga HK, et al. Positive psychological well-being and cardiovascular disease: JACC Health Promotion Series. J Am Coll Cardiol 2018 Sep 18;72(12):1382-1396 [FREE Full text] [doi: 10.1016/j.jacc.2018.07.042] [Medline: 30213332]
19. Lloyd-Jones DM, Hong Y, Labarthe D, Mozaffarian D, Appel LJ, Van Horn L, American Heart Association Strategic Planning Task Force and Statistics Committee. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's strategic Impact Goal through 2020 and beyond. Circulation 2010 Feb 02;121(4):586-613. [doi: 10.1161/CIRCULATIONAHA.109.192703] [Medline: 20089546]
20. Freeborne N, Simmens SJ, Manson JE, Howard BV, Cené CW, Allison MA, et al. Perceived social support and the risk of cardiovascular disease and all-cause mortality in the Women's Health Initiative Observational Study. Menopause 2019 Jul;26(7):698-707. [doi: 10.1097/GME.0000000000001297] [Medline: 30789457]
21. Mookadam F, Arthur HM. Social support and its relationship to morbidity and mortality after acute myocardial infarction: systematic overview. Arch Intern Med 2004 Jul 26;164(14):1514-1518. [doi: 10.1001/archinte.164.14.1514] [Medline: 15277281]
22. Compare A, Zarbo C, Manzoni GM, Castelnuovo G, Baldassari E, Bonardi A, et al. Social support, depression, and heart disease: a ten year literature review. Front Psychol 2013;4:384 [FREE Full text] [doi: 10.3389/fpsyg.2013.00384] [Medline: 23847561]
23. Ferdinand KC, Senatore FF, Clayton-Jeter H, Cryer DR, Lewin JC, Nasser SA, et al. Improving medication adherence in cardiometabolic disease: Practical and regulatory implications. J Am Coll Cardiol 2017 Jan 31;69(4):437-451 [FREE Full text] [doi: 10.1016/j.jacc.2016.11.034] [Medline: 28126162]
24. Mead H, Andres E, Ramos C, Siegel B, Regenstein M. Barriers to effective self-management in cardiac patients: the patient's experience. Patient Educ Couns 2010 Apr;79(1):69-76. [doi: 10.1016/j.pec.2009.08.003] [Medline: 19748205]
25. Jerant AF, von Friederichs-Fitzwater MM, Moore M. Patients' perceived barriers to active self-management of chronic conditions. Patient Educ Couns 2005 Jun;57(3):300-307. [doi: 10.1016/j.pec.2004.08.004] [Medline: 15893212]
26. Kulkarni SP, Alexander KP, Lytle B, Heiss G, Peterson ED. Long-term adherence with cardiovascular drug regimens. Am Heart J 2006 Jan;151(1):185-191. [doi: 10.1016/j.ahj.2005.02.038] [Medline: 16368315]
27. DiMatteo MR, Lepper HS, Croghan TW. Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. Arch Intern Med 2000 Jul 24;160(14):2101-2107. [doi: 10.1001/archinte.160.14.2101] [Medline: 10904452]
28. Kronish IM, Rieckmann N, Halm EA, Shimbo D, Vorchheimer D, Haas DC, et al. Persistent depression affects adherence to secondary prevention behaviors after acute coronary syndromes. J Gen Intern Med 2006 Nov;21(11):1178-1183 [FREE Full text] [doi: 10.1111/j.1525-1497.2006.00586.x] [Medline: 16899061]

29. Katch H. The role of self-efficacy in cardiovascular disease self-management: a review of effective programs. PI 2010 Oct:33. [doi: 10.2147/pi.s12624]
30. Sharma Dhital P, Sharma K, Poudel P, Dhital PR. Anxiety and depression among patients with coronary artery disease attending at a cardiac center, Kathmandu, Nepal. Nurs Res Pract 2018;2018:4181952 [FREE Full text] [doi: 10.1155/2018/4181952] [Medline: 30595917]
31. Keyes CLM. Promoting and protecting mental health as flourishing: a complementary strategy for improving national mental health. Am Psychol 2007;62(2):95-108. [doi: 10.1037/0003-066X.62.2.95] [Medline: 17324035]
32. Keyes CLM. Mental illness and/or mental health? Investigating axioms of the complete state model of health. J Consult Clin Psychol 2005 Jun;73(3):539-548. [doi: 10.1037/0022-006X.73.3.539] [Medline: 15982151]
33. Manwell LA, Barbic SP, Roberts K, Durisko Z, Lee C, Ware E, et al. What is mental health? Evidence towards a new definition from a mixed methods multidisciplinary international survey. BMJ Open 2015 Jun 02;5(6):e007079-e007079 [FREE Full text] [doi: 10.1136/bmjopen-2014-007079] [Medline: 26038353]
34. Payton AR. Mental health, mental illness, and psychological distress: same continuum or distinct phenomena? J Health Soc Behav 2009 Jun;50(2):213-227. [doi: 10.1177/002214650905000207] [Medline: 19537461]
35. Vaingankar JA, Chong SA, Abdin E, Siva Kumar FD, Chua BY, Sambasivam R, et al. Understanding the relationships between mental disorders, self-reported health outcomes and positive mental health: findings from a national survey. Health Qual Life Outcomes 2020 Mar 04;18(1):55 [FREE Full text] [doi: 10.1186/s12955-020-01308-0] [Medline: 32131837]
36. Mensah GA, Collins PY. Understanding mental health for the prevention and control of cardiovascular diseases. Glob Heart 2015 Sep 01;10(3):221-224 [FREE Full text] [doi: 10.1016/j.gheart.2015.08.003] [Medline: 26407518]
37. Papousek I, Schulter G. Effects of a mood-enhancing intervention on subjective well-being and cardiovascular parameters. Int J Behav Med 2008 Dec;15(4):293-302. [doi: 10.1080/10705500802365508] [Medline: 19005929]
38. De Hert J, Vancampfort D. The intriguing relationship between coronary heart disease and mental disorders. Dialogues Clin Neurosci 2018 Mar;20(1):31-40. [doi: 10.31887/dcns.2018.20.1/mdehert]
39. McPhillips R, Salmon P, Wells A, Fisher P. Cardiac rehabilitation patients' accounts of their emotional distress and psychological needs: A qualitative study. JAHA 2019 Jun 04;8(11):1. [doi: 10.1161/jaha.118.011117]
40. Lespérance F, Frasure-Smith N. Depression in patients with cardiac disease: a practical review. J Psychosom Res 2000;48(4-5):379-391. [doi: 10.1016/s0022-3999(99)00102-6] [Medline: 10880660]
41. Scott KM. Depression, anxiety and incident cardiometabolic diseases. Curr Opin Psychiatry 2014 Jul;27(4):289-293. [doi: 10.1097/YCO.0000000000000067] [Medline: 24840158]
42. Pan A, Keum N, Okereke OI, Sun Q, Kivimaki M, Rubin RR, et al. Bidirectional association between depression and metabolic syndrome: a systematic review and meta-analysis of epidemiological studies. Diabetes Care 2012 May 19;35(5):1171-1180 [FREE Full text] [doi: 10.2337/dc11-2055] [Medline: 22517938]
43. Xiang X, An R. Depression and onset of cardiovascular disease in the US middle-aged and older adults. Aging Ment Health 2015;19(12):1084-1092. [doi: 10.1080/13607863.2014.1003281] [Medline: 25616725]
44. O'Neil A, Williams ED, Stevenson CE, Oldenburg B, Berk M, Sanderson K. Co-morbid cardiovascular disease and depression: sequence of disease onset is linked to mental but not physical self-rated health. Results from a cross-sectional, population-based study. Soc Psychiatry Psychiatr Epidemiol 2012 Jul 10;47(7):1145-1151. [doi: 10.1007/s00127-011-0421-5] [Medline: 21830082]
45. Goodwin RD, Davidson KW, Keyes K. Mental disorders and cardiovascular disease among adults in the United States. J Psychiatr Res 2009 Jan;43(3):239-246 [FREE Full text] [doi: 10.1016/j.jpsychires.2008.05.006] [Medline: 18614179]
46. Chaddha A, Robinson EA, Kline-Rogers E, Alexandris-Souphis T, Rubenfire M. Mental health and cardiovascular disease. Am J Med 2016 Nov;129(11):1145-1148. [doi: 10.1016/j.amjmed.2016.05.018] [Medline: 27288855]
47. Headrick JP, Peart JN, Budiono BP, Shum DHK, Neumann DL, Stapelberg NJC. The heartbreak of depression: 'Psycho-cardiac' coupling in myocardial infarction. J Mol Cell Cardiol 2017 May;106:14-28. [doi: 10.1016/j.yjmcc.2017.03.007] [Medline: 28366738]
48. Pai JK, Pischon T, Ma J, Manson JE, Hankinson SE, Joshipura K, et al. Inflammatory markers and the risk of coronary heart disease in men and women. N Engl J Med 2004 Dec 16;351(25):2599-2610. [doi: 10.1056/nejmoa040967]
49. Pradhan AD, Manson JE, Rifai N, Buring JE, Ridker PM. C-reactive protein, interleukin 6, and risk of developing type 2 diabetes mellitus. JAMA 2001 Jul 18;286(3):327-334. [doi: 10.1001/jama.286.3.327] [Medline: 11466099]
50. Ridker PM, Rifai N, Rose L, Buring JE, Cook NR. Comparison of C-reactive protein and low-density lipoprotein cholesterol levels in the prediction of first cardiovascular events. N Engl J Med 2002 Nov 14;347(20):1557-1565. [doi: 10.1056/nejmoa021993]
51. Sesso HD, Buring JE, Rifai N, Blake GJ, Gaziano JM, Ridker PM. C-reactive protein and the risk of developing hypertension. JAMA 2003 Dec 10;290(22):2945-2951. [doi: 10.1001/jama.290.22.2945] [Medline: 14665655]
52. Knight EL, Jiang Y, Rodriguez-Stanley J, Almeida DM, Engeland CG, Zilioli S. Perceived stress is linked to heightened biomarkers of inflammation via diurnal cortisol in a national sample of adults. Brain Behav Immun 2021 Mar;93:206-213. [doi: 10.1016/j.bbi.2021.01.015] [Medline: 33515741]
53. Boehm JK, Kubzansky LD. The heart's content: the association between positive psychological well-being and cardiovascular health. Psychol Bull 2012 Jul;138(4):655-691. [doi: 10.1037/a0027448] [Medline: 22506752]

54. Boehm JK, Chen Y, Williams DR, Ryff CD, Kubzansky LD. Subjective well-being and cardiometabolic health: An 8-11year study of midlife adults. J Psychosom Res 2016 Jun;85:1-8 [FREE Full text] [doi: 10.1016/j.jpsychores.2016.03.018] [Medline: 27212662]
55. de Ridder D, Geenen R, Kuijer R, van Middendorp H. Psychological adjustment to chronic disease. Lancet 2008 Jul 19;372(9634):246-255. [doi: 10.1016/S0140-6736(08)61078-8] [Medline: 18640461]
56. Rozanski A. Integrating psychologic approaches into the behavioral management of cardiac patients. Psychosom Med 2005;67 Suppl 1:S67-S73. [doi: 10.1097/01.psy.0000164252.07368.81] [Medline: 15953806]
57. Beck AT, Dozois DJA. Cognitive therapy: current status and future directions. Annu Rev Med 2011;62:397-409. [doi: 10.1146/annurev-med-052209-100032] [Medline: 20690827]
58. Carpenter JK, Andrews LA, Witcraft SM, Powers MB, Smits JAJ, Hofmann SG. Cognitive behavioral therapy for anxiety and related disorders: A meta-analysis of randomized placebo-controlled trials. Depress Anxiety 2018 Jun;35(6):502-514 [FREE Full text] [doi: 10.1002/da.22728] [Medline: 29451967]
59. Hofmann SG, Asnaani A, Vonk IJJ, Sawyer AT, Fang A. The efficacy of cognitive behavioral therapy: A review of meta-analyses. Cognit Ther Res 2012 Oct 01;36(5):427-440 [FREE Full text] [doi: 10.1007/s10608-012-9476-1] [Medline: 23459093]
60. Berkman LF, Blumenthal J, Burg M, Carney RM, Catellier D, Cowan MJ, Enhancing Recovery in Coronary Heart Disease Patients Investigators (ENRICHD). Effects of treating depression and low perceived social support on clinical events after myocardial infarction: the Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) Randomized Trial. JAMA 2003 Jun 18;289(23):3106-3116. [doi: 10.1001/jama.289.23.3106] [Medline: 12813116]
61. Gooding HC, Gidding SS, Moran AE, Redmond N, Allen NB, Bacha F, et al. Challenges and opportunities for the prevention and treatment of cardiovascular disease among young adults: Report from a National Heart, Lung, and Blood Institute Working Group. JAHA 2020 Oct 06;9(19):1. [doi: 10.1161/jaha.120.016115]
62. Dickens C, Cherrington A, Adeyemi I, Roughley K, Bower P, Garrett C, et al. Characteristics of psychological interventions that improve depression in people with coronary heart disease: a systematic review and meta-regression. Psychosom Med 2013 Feb;75(2):211-221. [doi: 10.1097/PSY.0b013e31827ac009] [Medline: 23324874]
63. Lett HS, Davidson J, Blumenthal JA. Nonpharmacologic treatments for depression in patients with coronary heart disease. Psychosom Med 2005;67 Suppl 1:S58-S62. [doi: 10.1097/01.psy.0000163453.24417.97] [Medline: 15953803]
64. Richards SH, Anderson L, Jenkinson CE, Whalley B, Rees K, Davies P, et al. Psychological interventions for coronary heart disease: Cochrane systematic review and meta-analysis. Eur J Prev Cardiol 2018 Feb;25(3):247-259. [doi: 10.1177/2047487317739978] [Medline: 29212370]
65. Abbott RA, Whear R, Rodgers LR, Bethel A, Thompson Coon J, Kuyken W, et al. Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. J Psychosom Res 2014 May;76(5):341-351 [FREE Full text] [doi: 10.1016/j.jpsychores.2014.02.012] [Medline: 24745774]
66. Diener E, Chan MY. Happy people live longer: Subjective well-being contributes to health and longevity. Applied Psychology: Health and Well-Being 2011;3(1):1-43 [FREE Full text] [doi: 10.1111/j.1758-0854.2010.01045.x] [Medline: 24745774]
67. Diener E, Pressman SD, Hunter J, Delgadillo-Chase D. If, why, and when subjective well-being influences health, and future needed research. Appl Psychol Health Well Being 2017 Jul 14;9(2):133-167. [doi: 10.1111/aphw.12090] [Medline: 28707767]
68. Liu B, Floud S, Pirie K, Green J, Peto R, Beral V. Does happiness itself directly affect mortality? The prospective UK Million Women Study. The Lancet 2016 Feb;387(10021):874-881. [doi: 10.1016/s0140-6736(15)01087-9]
69. Andrade LH, Alonso J, Mneimneh Z, Wells JE, Al-Hamzawi A, Borges G, et al. Barriers to mental health treatment: results from the WHO World Mental Health surveys. Psychol Med 2014 Apr;44(6):1303-1317 [FREE Full text] [doi: 10.1017/S0033291713001943] [Medline: 23931656]
70. Adler AJ, Martin N, Mariani J, Tajer CD, Owolabi OO, Free C, et al. Mobile phone text messaging to improve medication adherence in secondary prevention of cardiovascular disease. Cochrane Database Syst Rev 2017 Apr 29;4:CD011851 [FREE Full text] [doi: 10.1002/14651858.CD011851.pub2] [Medline: 28455948]
71. Lundgren JG, Dahlström Ö, Andersson G, Jaarsma T, Kärner Köhler A, Johansson P. The effect of guided web-based cognitive behavioral therapy on patients with depressive symptoms and heart failure: A pilot randomized controlled trial. J Med Internet Res 2016 Aug 03;18(8):e194 [FREE Full text] [doi: 10.2196/jmir.5556] [Medline: 27489077]
72. Palmer MJ, Barnard S, Perel P, Free C. Mobile phone-based interventions for improving adherence to medication prescribed for the primary prevention of cardiovascular disease in adults. Cochrane Database Syst Rev 2018 Jun 22;6:CD012675 [FREE Full text] [doi: 10.1002/14651858.CD012675.pub2] [Medline: 29932455]
73. Coorey G, Peiris D, Usherwood T, Neubeck L, Mulley J, Redfern J. Persuasive design features within a consumer-focused eHealth intervention integrated with the electronic health record: A mixed methods study of effectiveness and acceptability. PLoS One 2019;14(6):e0218447 [FREE Full text] [doi: 10.1371/journal.pone.0218447] [Medline: 31220127]
74. Chow CK, Redfern J, Hillis GS, Thakkar J, Santo K, Hackett ML, et al. Effect of lifestyle-focused text messaging on risk factor modification in patients with coronary heart disease: A randomized clinical trial. JAMA 2015;314(12):1255-1263. [doi: 10.1001/jama.2015.10945] [Medline: 26393848]

75. Santo K, Redfern J. Digital health innovations to improve cardiovascular disease care. Curr Atheroscler Rep 2020 Oct 03;22(12):71 [FREE Full text] [doi: 10.1007/s11883-020-00889-x] [Medline: 33009975]
76. Luberto CM, Huberty J, Puzia M, Vranceanu A. Usage patterns of the Calm meditation app among people with cardiovascular disease. Mindfulness 2021 Jan 07;12(4):983-993. [doi: 10.1007/s12671-020-01567-4]
77. Barton K, Mikan V. Meditation education for cardiac rehabilitation patients. International Journal of Exercise Science: Conference Proceedings 2020;2(12):135 [FREE Full text] [doi: 10.1007/978-1-4471-2888-5_10]
78. 2021 State Of Mental Health In America. Mental Health America. 2021 Oct 20. URL: https://www.mhanational.org/research-reports/2021-state-mental-health-america [accessed 2021-11-08]
79. Mohr DC, Burns MN, Schueller SM, Clarke G, Klinkman M. Behavioral intervention technologies: evidence review and recommendations for future research in mental health. Gen Hosp Psychiatry 2013;35(4):332-338 [FREE Full text] [doi: 10.1016/j.genhosppsych.2013.03.008] [Medline: 23664503]
80. Mohr DC, Weingardt KR, Reddy M, Schueller SM. Three Problems With Current Digital Mental Health Research . . . and Three Things We Can Do About Them. Psychiatr Serv 2017 May 01;68(5):427-429 [FREE Full text] [doi: 10.1176/appi.ps.201600541] [Medline: 28412890]
81. Andrews G, Basu A, Cuijpers P, Craske MG, McEvoy P, English CL, et al. Computer therapy for the anxiety and depression disorders is effective, acceptable and practical health care: An updated meta-analysis. J Anxiety Disord 2018 Apr;55:70-78 [FREE Full text] [doi: 10.1016/j.janxdis.2018.01.001] [Medline: 29422409]
82. Sasseville M, LeBlanc A, Boucher M, Dugas M, Mbemba G, Tchuente J, et al. Digital health interventions for the management of mental health in people with chronic diseases: a rapid review. BMJ Open 2021 Apr 05;11(4):e044437 [FREE Full text] [doi: 10.1136/bmjopen-2020-044437] [Medline: 33820786]
83. Wilhelm S, Weingarden H, Ladis I, Braddick V, Shin J, Jacobson NC. Cognitive-behavioral therapy in the digital age: Presidential address. Behav Ther 2020 Jan;51(1):1-14 [FREE Full text] [doi: 10.1016/j.beth.2019.08.001] [Medline: 32005328]
84. Messerli-Bürgy N, Barth J, Berger T. The InterHerz project--a web-based psychological treatment for cardiac patients with depression: study protocol of a randomized controlled trial. Trials 2012 Dec 28;13:245 [FREE Full text] [doi: 10.1186/1745-6215-13-245] [Medline: 23273042]
85. Akinosun AS, Polson R, Diaz-Skeete Y, De Kock JH, Carragher L, Leslie S, et al. Digital technology interventions for risk factor modification in patients with cardiovascular disease: Systematic review and meta-analysis. JMIR Mhealth Uhealth 2021 Mar 03;9(3):e21061 [FREE Full text] [doi: 10.2196/21061] [Medline: 33656444]
86. Johansson P, Westas M, Andersson G, Alehagen U, Broström A, Jaarsma T, et al. An internet-based cognitive behavioral therapy program adapted to patients with cardiovascular disease and depression: Randomized controlled trial. JMIR Ment Health 2019 Oct 03;6(10):e14648 [FREE Full text] [doi: 10.2196/14648] [Medline: 31584000]
87. Barley EA, Clifton A, Lee G, Norman IJ, O'Callaghan D, Tierney K, et al. The space from heart disease intervention for people with cardiovascular disease and distress: A mixed-methods study. JMIR Res Protoc 2015 Jul 01;4(3):e81 [FREE Full text] [doi: 10.2196/resprot.4280] [Medline: 26133739]
88. Marshall JM, Dunstan DA, Bartik W. Apps with maps-anxiety and depression mobile apps with evidence-based frameworks: Systematic search of major app stores. JMIR Ment Health 2020 Jun 24;7(6):e16525 [FREE Full text] [doi: 10.2196/16525] [Medline: 32579127]
89. Wykes T, Schueller S. Why reviewing apps is not enough: Transparency for Trust (T4T) principles of responsible health app marketplaces. J Med Internet Res 2019 May 02;21(5):e12390 [FREE Full text] [doi: 10.2196/12390] [Medline: 31045497]
90. Parks AC, Williams AL, Tugade MM, Hokes KE, Honomichl RD, Zilca RD. Testing a scalable web and smartphone based intervention to improve depression, anxiety, and resilience: A randomized controlled trial. Intnl. J. Wellbeing 2018 Dec 08;8(2):22-67. [doi: 10.5502/ijw.v8i2.745]
91. Parks AC, Williams AL, Kackloudis GM, Stafford JL, Boucher EM, Honomichl RD. The effects of a digital well-being intervention on patients with chronic conditions: Observational study. J Med Internet Res 2020 Jan 10;22(1):e16211 [FREE Full text] [doi: 10.2196/16211] [Medline: 31922491]
92. Verster JC, van de Loo AJAE, Adams S, Stock A, Benson S, Scholey A, et al. Advantages and limitations of naturalistic study designs and their implementation in alcohol hangover research. J Clin Med 2019 Dec 06;8(12):2160 [FREE Full text] [doi: 10.3390/jcm8122160] [Medline: 31817752]
93. Schueller SM, Kashdan TB, Parks AC. Synthesizing positive psychological interventions: Suggestions for conducting and interpreting meta-analyses. Intnl. J. Wellbeing 2014 Jun 04;4(1):91-98. [doi: 10.5502/ijw.v4i1.5]
94. Kabat-Zinn J. Mindfulness-based interventions in context: Past, present, and future. Clinical Psychologycience and Practice 2003;10(2):144-156 [FREE Full text] [doi: 10.1093/clipsy.bpg016]
95. Williams A, Parks A, Cormier G, Stafford J, Whillans A. Improving resilience among employees high in depression, anxiety, and workplace distress. International Journal of Management Research 2018 Dec;09(1-2):04-22 [FREE Full text]
96. Kroenke K, Spitzer RL, Williams JBW, Monahan PO, Löwe B. Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. Ann Intern Med 2007 Mar 06;146(5):317-325 [FREE Full text] [doi: 10.7326/0003-4819-146-5-200703060-00004] [Medline: 17339617]

97. Carpenter J, Crutchley P, Zilca RD, Schwartz HA, Smith LK, Cobb AM, et al. Correction: Seeing the "big" picture: Big data methods for exploring relationships between usage, language, and outcome in internet intervention data. J Med Internet Res 2017 Dec 19;19(12):e347 [FREE Full text] [doi: 10.2196/jmir.8099] [Medline: 29258059]
98. Lyubomirsky S, Lepper H. A measure of subjective happiness: Preliminary reliability and construct validation. Social Indicators Research 1999;46(2):137-155 [FREE Full text] [doi: 10.1023/a:1006824100041]
99. Radloff LS. The CES-D Scale: A self-report depression scale for research in the general population. Applied Psychological Measurement 1977 Jun 01;1(3):385-401. [doi: 10.1177/014662167700100306]
100. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006 May 22;166(10):1092-1097 [FREE Full text] [doi: 10.1001/archinte.166.10.1092] [Medline: 16717171]
101. Sapra A, Bhandari P, Sharma S, Chanpura T, Lopp L. Using Generalized Anxiety Disorder-2 (GAD-2) and GAD-7 in a primary care setting. Cureus 2020 May 21;12(5):e8224 [FREE Full text] [doi: 10.7759/cureus.8224] [Medline: 32582485]
102. Staples LG, Dear BF, Gandy M, Fogliati V, Fogliati R, Karin E, et al. Psychometric properties and clinical utility of brief measures of depression, anxiety, and general distress: The PHQ-2, GAD-2, and K-6. General Hospital Psychiatry 2019 Jan;56:13-18 [FREE Full text] [doi: 10.1016/j.genhosppsych.2018.11.003]
103. Cnaan A, Laird NM, Slasor P. Using the general linear mixed model to analyse unbalanced repeated measures and longitudinal data. Statist. Med 1997 Oct 30;16(20):2349-2380. [doi: 10.1002/(sici)1097-0258(19971030)16:20<2349::aid-sim667>3.0.co;2-e] [Medline: 9351170]
104. Janmaat CJ, van Diepen M, Tsonaka R, Jager KJ, Zoccali C, Dekker FW. Pitfalls of linear regression for estimating slopes over time and how to avoid them by using linear mixed-effects models. Nephrol Dial Transplant 2019 Apr;34(4):561-566 [FREE Full text] [doi: 10.1093/ndt/gfy128] [Medline: 29796633]
105. R Core Team. R: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing; 2021. URL: https://www.R-project.org [accessed 2021-11-08]
106. Pinheiro J, Bates D, DebRoy S, Sarkar D, R Core Team. nlme: Linear and Nonlinear Mixed Effects Models. 2021 Sep 07. URL: https://CRAN.R-project.org/package=nlme [accessed 2021-11-08]
107. Monti S, Grosso V, Todoerti M, Caporali R. Randomized controlled trials and real-world data: differences and similarities to untangle literature data. Rheumatology (Oxford) 2018 Dec 01;57(57 Suppl 7):vii54-vii58 [FREE Full text] [doi: 10.1093/rheumatology/key109] [Medline: 30289534]
108. Blonde L, Khunti K, Harris SB, Meizinger C, Skolnik NS. Interpretation and impact of real-world clinical data for the practicing clinician. Adv Ther 2018 Nov;35(11):1763-1774 [FREE Full text] [doi: 10.1007/s12325-018-0805-y] [Medline: 30357570]
109. Notice. Developing a framework for regulatory use of real-world evidence. Washington, DC: Food and Drug Administration; 2017 Jul 31. URL: https://www.regulations.gov/document/FDA-2017-N-0001-0028 [accessed 2021-11-07]
110. Baumel A, Muench F, Edan S, Kane JM. Objective user engagement with mental health apps: Systematic search and panel-based usage analysis. J Med Internet Res 2019 Sep 25;21(9):e14567 [FREE Full text] [doi: 10.2196/14567] [Medline: 31573916]
111. Meyerowitz-Katz G, Ravi S, Arnolda L, Feng X, Maberly G, Astell-Burt T. Rates of attrition and dropout in app-based interventions for chronic disease: Systematic review and meta-analysis. J Med Internet Res 2020 Sep 29;22(9):e20283 [FREE Full text] [doi: 10.2196/20283] [Medline: 32990635]
112. Weisel KK, Fuhrmann LM, Berking M, Baumeister H, Cuijpers P, Ebert DD. Standalone smartphone apps for mental health-a systematic review and meta-analysis. NPJ Digit Med 2019 Dec 02;2(118):1-10 [FREE Full text] [doi: 10.1038/s41746-019-0188-8] [Medline: 31815193]
113. Zender R, Olshansky E. Women's mental health: depression and anxiety. Nurs Clin North Am 2009 Sep;44(3):355-364. [doi: 10.1016/j.cnur.2009.06.002] [Medline: 19683096]
114. Kim DJ, Choo EK, Ranney ML. Impact of gender on patient preferences for technology-based behavioral interventions. West J Emerg Med 2014 Aug;15(5):593-599 [FREE Full text] [doi: 10.5811/westjem.2014.4.21448] [Medline: 25157307]
115. Gao Z, Chen Z, Sun A, Deng X. Gender differences in cardiovascular disease. Medicine in Novel Technology and Devices 2019 Dec;4:100025 [FREE Full text] [doi: 10.1016/j.medntd.2019.100025] [Medline: 34237259]
116. Möller-Leimkühler AM. Gender differences in cardiovascular disease and comorbid depression. Dialogues Clin Neurosci 2007 Mar;9(1):71-83 [FREE Full text] [Medline: 17506227]
117. Steptoe A, Kivimäki M. Stress and cardiovascular disease. Nat Rev Cardiol 2012 Apr 03;9(6):360-370 [FREE Full text] [doi: 10.1038/nrcardio.2012.45] [Medline: 22473079]
118. Brinkley TE, Leng X, Miller ME, Kitzman DW, Pahor M, Berry MJ, et al. Chronic inflammation is associated with low physical function in older adults across multiple comorbidities. J Gerontol A Biol Sci Med Sci 2009 Apr;64(4):455-461 [FREE Full text] [doi: 10.1093/gerona/gln038] [Medline: 19196644]
119. Hughes AJ, Dunn KM, Chaffee T, Bhattarai JJ, Beier M. Diagnostic and clinical utility of the GAD-2 for screening anxiety symptoms in individuals with multiple sclerosis. Arch Phys Med Rehabil 2018 Oct;99(10):2045-2049 [FREE Full text] [doi: 10.1016/j.apmr.2018.05.029] [Medline: 29964000]

120. Lustria MLA, Noar SM, Cortese J, Van Stee SK, Glueckauf RL, Lee J. A meta-analysis of web-delivered tailored health behavior change interventions. J Health Commun 2013;18(9):1039-1069. [doi: 10.1080/10810730.2013.768727] [Medline: 23750972]
121. Mizuno A, Changolkar S, Patel MS. Wearable devices to monitor and reduce the risk of cardiovascular disease: Evidence and opportunities. Annu Rev Med 2021 Jan 27;72(1):459-471. [doi: 10.1146/annurev-med-050919-031534] [Medline: 32886543]
122. Cohen BE, Edmondson D, Kronish IM. State of the art review: Depression, stress, anxiety, and cardiovascular disease. Am J Hypertens 2015 Nov;28(11):1295-1302 [FREE Full text] [doi: 10.1093/ajh/hpv047] [Medline: 25911639]
123. Carpenter J, Crutchley P, Zilca RD, Schwartz HA, Smith LK, Cobb AM, et al. Seeing the "big" picture: Big data methods for exploring relationships between usage, language, and outcome in internet intervention data. J Med Internet Res 2016 Aug 31;18(8):e241 [FREE Full text] [doi: 10.2196/jmir.5725] [Medline: 27580524]
124. AHA Center for Health Innovation. Behavioral health integration: treating the whole person. Washington, D. C: American Health Association; 2019. URL: https://www.aha.org/system/files/media/file/2019/06/Market_Insights-Behavioral_Health_Report.pdf [accessed 2021-11-07]
125. Boumparis N, Karyotaki E, Kleiboer A, Hofmann SG, Cuijpers P. The effect of psychotherapeutic interventions on positive and negative affect in depression: A systematic review and meta-analysis. J Affect Disord 2016 Sep 15;202:153-162. [doi: 10.1016/j.jad.2016.05.019] [Medline: 27262637]

Abbreviations

CBT: cognitive behavioral therapy
CVD: cardiovascular disease
GAD-2: Generalized Anxiety Disorder-2
LME: linear mixed effects
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 29.07.21; peer-reviewed by S Bhattacharjee, L Balcombe; comments to author 15.09.21; revised version received 05.10.21; accepted 06.10.21; published 19.11.21.

Please cite as:
Montgomery RM, Boucher EM, Honomichl RD, Powell TA, Guyton SL, Bernecker SL, Stoeckl SE, Parks AC
The Effects of a Digital Mental Health Intervention in Adults With Cardiovascular Disease Risk Factors: Analysis of Real-World User Data
JMIR Cardio 2021;5(2):e32351
URL: https://cardio.jmir.org/2021/2/e32351
doi:10.2196/32351
PMID:34806986

Original Paper

Patient-Reported Outcomes From Patients With Heart Failure Participating in the Future Patient Telerehabilitation Program: Data From the Intervention Arm of a Randomized Controlled Trial

Cathrine Skov Schacksen[1], MSc; Anne-Kirstine Dyrvig[2], MSc, PhD; Nanna Celina Henneberg[1], BSc; Josefine Dam Gade[1], MSc; Helle Spindler[3], MSc, PhD; Jens Refsgaard[4], MD, PhD; Malene Hollingdal[4], MD, PhD; Lars Dittman[5], MSc, PhD; Kim Dremstrup[6], MSc, PhD; Birthe Dinesen[1], MSc, PhD

[1]Laboratory for Welfare Technology - Telehealth & Telerehabilitation, Sport Sciences - Performance and Technology, Department of Health Science and Technology, Aalborg University, Aalborg East, Denmark

[2]The Danish Clinical Quality Program– National Clinical Registries (RKKP), Odense, Denmark

[3]Department of Psychology and Behavioral Sciences, Aarhus University, Aarhus, Denmark

[4]Cardiology Ward, Regional Hospital Viborg, Viborg, Denmark

[5]Networks Technology and Service Platforms, DTU Fotonik, Department of Photonics Engineering, Technical University of Denmark, Kgs Lyngby, Denmark

[6]Department of Health Science and Technology, Aalborg University, Aalborg, Denmark

Corresponding Author:
Cathrine Skov Schacksen, MSc
Laboratory for Welfare Technology - Telehealth & Telerehabilitation, Sport Sciences - Performance and Technology, Department of Health Science and Technology
Aalborg University
Fredrik Bajers Vej 7, Bld A1
Aalborg East, 9220
Denmark
Phone: 45 61285904
Email: cass@hst.aau.dk

Abstract

Background: More than 37 million people worldwide have been diagnosed with heart failure, which is a growing burden on the health sector. Cardiac rehabilitation aims to improve patients' recovery, functional capacity, psychosocial well-being, and health-related quality of life. However, cardiac rehabilitation programs have poor compliance and adherence. Telerehabilitation may be a solution to overcome some of these challenges to cardiac rehabilitation by making it more individualized. As part of the Future Patient Telerehabilitation program, a digital toolbox aimed at enabling patients with heart failure to monitor and evaluate their own current status has been developed and tested using data from a patient-reported outcome questionnaire that the patient filled in every alternate week for 1 year.

Objective: The aim of this study is to evaluate the changes in quality of life and well-being among patients with heart failure, who are participants in the Future Patient Telerehabilitation program over the course of 1 year.

Methods: In total, 140 patients were enrolled in the Future Patient Telerehabilitation program and randomized into either the telerehabilitation group (n=70) or the control group (n=70). Of the 70 patients in the telerehabilitation group, 56 (80.0%) answered the patient-reported outcome questionnaire and completed the program, and these 56 patients comprised the study population. The patient-reported outcomes consisted of three components: (1) questions regarding the patients' sleep patterns assessed using the Spiegel Sleep Questionnaire; (2) measurements of physical limitations, symptoms, self-efficacy, social interaction, and quality of life assessed using the Kansas City Cardiomyopathy Questionnaire in 10 dimensions; and (3) 5 additional questions regarding psychological well-being that were developed by the research group.

Results: The changes in scores during 1 year of the study were examined using 1-sample Wilcoxon signed-rank tests. There were significant differences in the scores for most of the slopes of the scores from the dimensions of the Kansas City Cardiomyopathy Questionnaire (P<.05).

Conclusions: There was a significant increase in clinical and social well-being and quality of life during the 1-year period of participating in a telerehabilitation program. These results suggest that patient-reported outcome questionnaires may be used as a tool for patients in a telerehabilitation program that can both monitor and guide patients in mastering their own symptoms.

Trial Registration: ClinicalTrials.gov NCT03388918; https://clinicaltrials.gov/ct2/show/NCT03388918

(JMIR Cardio 2021;5(2):e26544) doi:10.2196/26544

KEYWORDS

adherence; cardiology; cardiomyopathy; compliance; heart failure; heart; Kansas City Cardiomyopathy Questionnaire; monitoring; patient-reported outcome; patients; quality of life; rehabilitation; self-reporting; telehealth; telemonitoring

Introduction

Cardiovascular diseases are the leading cause of death worldwide [1]. In 2016, cardiovascular diseases were the cause of 31% of all deaths, which corresponded to 17.9 million people [1]. More than 37 million people worldwide have been diagnosed with heart failure (HF). Because of a poor prognosis, a high risk of disadvantageous outcomes, and increasing prevalence, HF is a growing burden on the health sector [2-4]. Cardiac rehabilitation aims to improve patients' recovery, functional capacity, psychosocial well-being, and health-related quality of life. The rehabilitation process combines activities such as physical activity, improved diet, weight control, psychosocial coping, and disease management [5]. However, cardiac rehabilitation programs have poor compliance and adherence. Patients may have poor means of transport to the rehabilitation facility, lack motivation, and feel that rehabilitation activities are not sufficiently individualized; all of these barriers negatively impact adherence to rehabilitation programs, which may in turn exacerbate symptoms including edema, fatigue, and shortness of breath, thus leading to readmissions [5,6]. Telerehabilitation (TR) may be a solution to overcome some of these challenges to cardiac rehabilitation [7,8]. TR is defined as the delivery of rehabilitation services through information and communication technologies [9].

TR may also be clinically relevant in obtaining health status measures from the patients. In turn, these measures add information regarding the severity of HF and may be used as an aid for clinical management [10]. Patient-reported outcomes (PROs) are clinical outcomes that increasingly focus on reducing the disease burden and improving general well-being and lifespan [11]. PRO can be used as a tool for screening and monitoring symptoms and assessing the course of the disease over time for clinicians to evaluate patient symptoms [12]. In a PRO regime, the outcome of a treatment is directly self-reported by the patient without registration or interpretation by a clinician [11]. Some of the outcomes are measurements of the patient's symptoms and health-related quality of life, which enable PROs to enhance targeted care and contribute to the optimal use of health care resources [11]. In this study, PRO from the Future Patient Telerehabilitation (FPT) program will be made available to patients as a tool for empowering them and increasing their knowledge of their own disease.

Through a user-driven innovation process, we have developed the FPT program for patients with HF. The overall purpose of the FPT program has been to increase the quality of life for patients with HF and to educate the patients to perform individualized monitoring to detect worsening of their own symptoms, thereby avoiding rehospitalization [13]. As part of the FPT program, a digital toolbox containing a PRO questionnaire was created. The purpose of the digital toolbox was to enable HF patients to monitor and evaluate their own current status over the 1-year duration of the TR program, thus enabling them to facilitate their contact with the hospital or their consulting general practitioners. To our knowledge, no previous studies that have investigated the clinical and psychological value of PROs in TR for patients with HF. A review from 2016 [14] on the use of PRO instruments in HF management concluded that the Minnesota Living with Heart Failure and Kansas City Cardiomyopathy Questionnaire (KCCQ) were useful PRO instruments in clinical care. However, more studies are needed on the value and interpretability of PRO instruments in clinical settings. The aim of this study is to evaluate the changes in quality of life and well-being among patients with HF, who are participants in the FPT program over the course of 1 year [13].

Methods

Ethical Considerations

This study utilized data from an intervention group that received TR (the TR group) in the FPT study, which was approved by the North Denmark Region Committee on Health Research Ethics (N-20160055) and the Danish Data Protection Agency. The study is registered on ClinicalTrials.gov (NCT03388918). The study was conducted in accordance with the tenets of the Helsinki declaration, and all participants signed an informed consent form prior to enrollment in the study.

Context and Intervention of the Study

The overall aim of the FPT study was to increase the quality of life of patients with HF by training them to perform individualized monitoring, which would enable to detect worsening of their symptoms in a timely manner, thereby avoiding rehospitalization [13]. The intervention of the FPT was divided into three phases (Figure 1): (1) TR and titration of medicine; as the adjustment of medication is specific to each patient, this phase will last 0-3 months; (2) TR at home and at a health care center or call center (3 months); and (3) follow-up with TR in everyday life (6 months). The TR program was based on a webpage called the HeartPortal [15], which is a digital toolbox that functions as an interactive learning module. The HeartPortal consists of (1) an information page containing text and short videos, (2) a communication platform that helps patients design their own TR plan and communicate directly

with health care professionals, (3) visualization of measured values, and (4) a PRO questionnaire to be answered every second week. The measured values in HeartPortal included the patients' vital signs such as blood pressure, daytime and nighttime pulse rates, weight, step count, respiration, and hours of sleep. All data measured from the technologies were transmitted by the patient to HeartPortal. The data are illustrated as graphs and can be visualized and shared among patients, their relatives, and health care professionals. Upon enrollment in the study, the patients were instructed on how to use the PRO data to monitor their own disease and how to take necessary action if their symptoms worsened. The patients had the opportunity to contact the TR coordinator of the FPT program regarding any necessary action to be taken. Figure 2 shows the patients' PRO data in graphical format over a period of 2 months. The control group participated in the same 3 phases but without participating in the TR program; that is, they had no access to HeartPortal.

Figure 1. The 3 phases of the Future Patient Telerehabilitation study. PRO: patient-reported outcome.

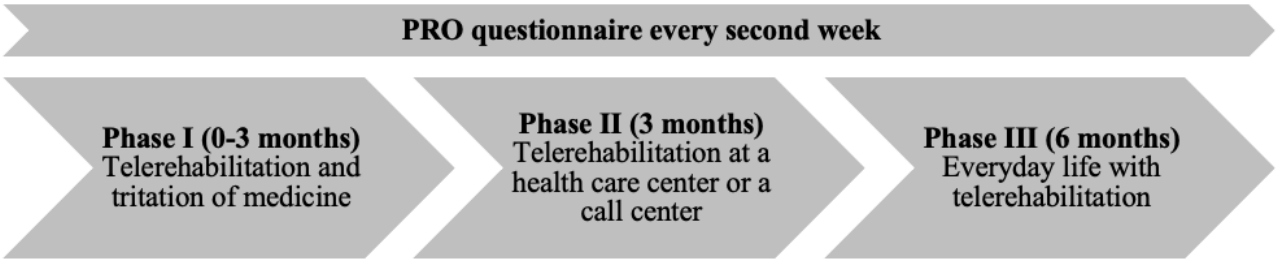
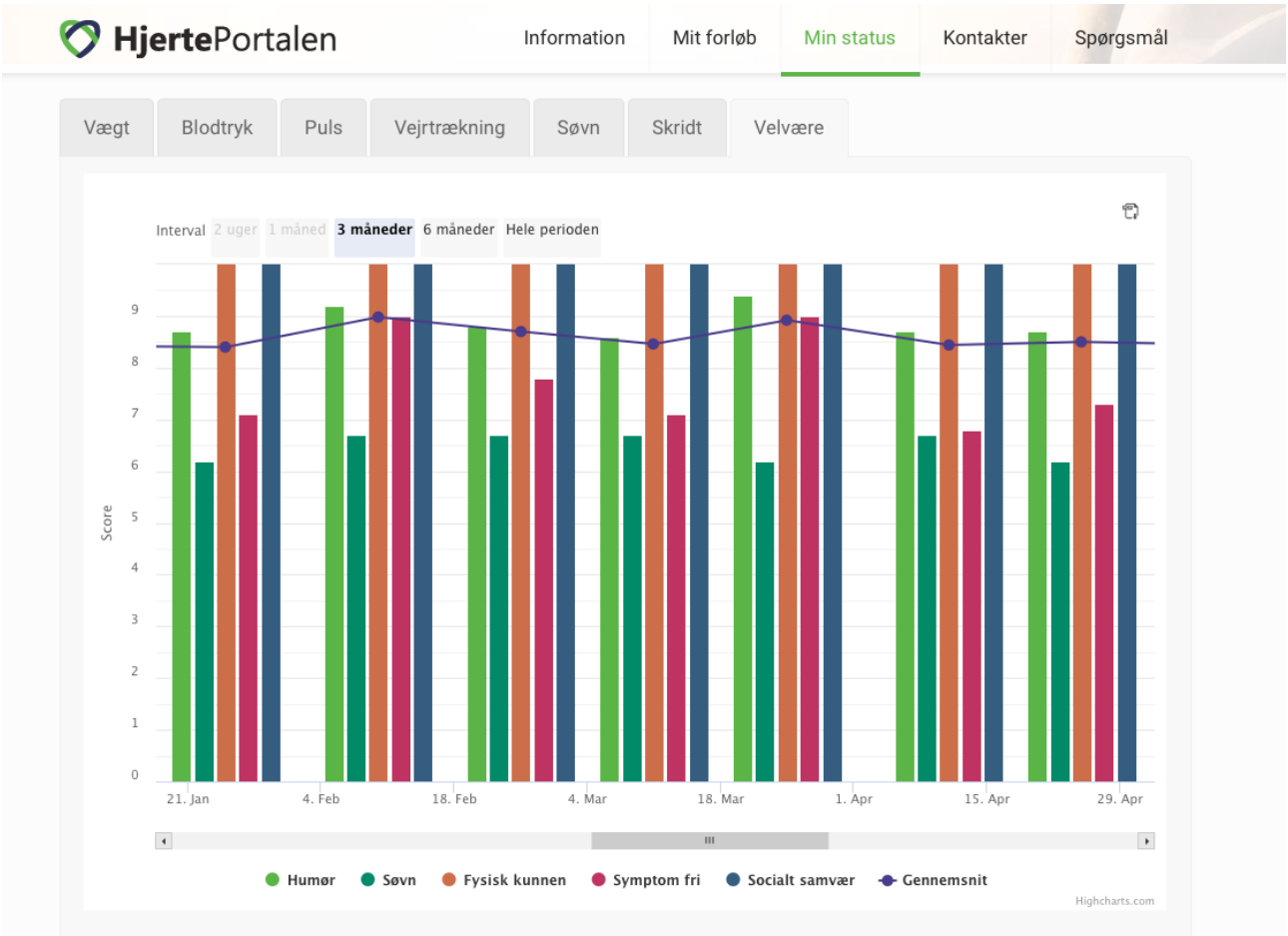


Figure 2. A screen capture of HeartPortal. An illustration of the patient-reported outcome. Row 1: Information, My Treatment, My Status, Contacts, and Questions; Row 2: Weight, Blood Pressure, Pulse, Breathing, Sleep, Steps, and Well-being; Row 3: Time Intervals (3 months, 6 months, and Entire period); and Row 4 (bottom): Mood (light-green dot), Sleep (dark-green dot), Physical condition (orange dot), Symptom-free (red dot), Social contact (blue dot), and Mean (blue line).



Participants

Participants were recruited from the cardiology wards at hospitals in Skive, Viborg, Silkeborg, and Randers in Denmark. Participants were recruited by a project nurse. The inclusion criteria for the FPT were the following: patients with HF with a New York Heart Association (NYHA) functional class of I-IV, of whom a maximum of 20% of the patients were of NYHA class I, ≥18 years of age, able to care for themselves, and had basic computer skills.

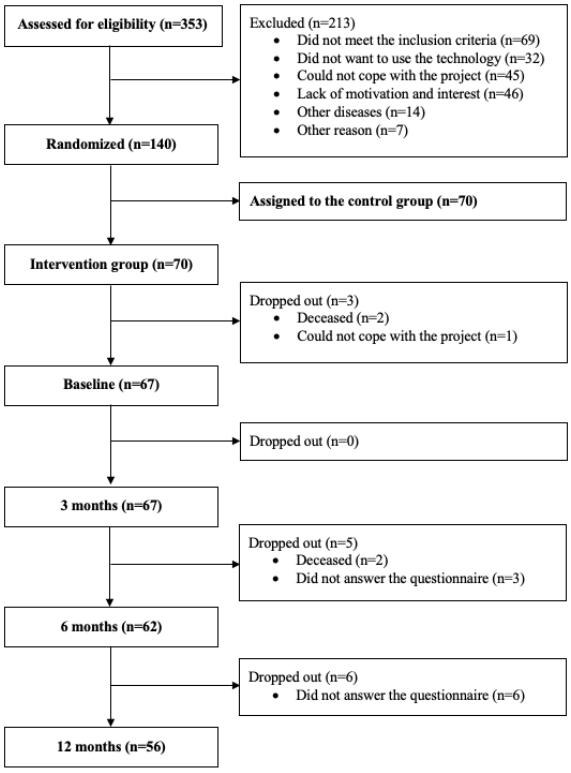
Sample Size

The sample size of the FPT study was determined to be 70 patients in each group (assuming a normal distribution), a power of 80%, and a potential 10% dropout. This calculation was based on the KCCQ guidelines, which state that a "moderate" level of improvement is equal to a 10-point increase in the KCCQ score [13,16]. In this study of the FPT program, only the KCCQ outcomes from the intervention are reported. A comparison of the KCCQ results from both the intervention and control groups will be reported in a subsequent study on the evaluation of health utilizations.

One Arm of a Randomized Controlled Trial

In total, 140 patients were enrolled in the FPT and randomized into either the TR group (n=70) or the control group (n=70) [13]. This study only reports the findings of the TR group. Of the 70 patients in the TR group, 56 (80.0%) answered the PRO questionnaire and completed the program, and these 56 patients constituted the study population. The randomization and follow-up procedure for the patients in the TR group are shown in the CONSORT (Consolidated Standards of Reporting Trials) diagram in Figure 3.

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) diagram for the intervention group of the Future Patient Telerehabilitation trial.



Sociodemographic and Clinical Data

Sociodemographic data (age, gender, education, employment status, and civil status) and clinical data (etiology of heart failure, NYHA class, ejection fraction, weight, blood pressure, and heart rate) were collected through self-reports or from the electronic patient record.

PRO Measures

The PRO questionnaire consisted of components from three questionnaires: (1) patients' sleep quality was evaluated using the Spiegel Sleep Questionnaire [17]; (2) physical limitations, symptoms, self-efficacy, social interactions, and quality of life were assessed using the validated KCCQ [16,18]; and (3) psychological well-being was evaluated using 5 additional questions developed by the research group.

Spiegel Sleep Questionnaire

Sleep quality was measured using the Spiegel Sleep Questionnaire [17]. The questionnaire consists of 6 questions regarding the patients' sleep patterns and sleep quality, with all items scored using a 5-point Likert scale. This is a validated sleep questionnaire and has been used in clinical studies [17,19].

KCCQ

Measures of physical limitations, symptoms, self-efficacy, social interaction, and quality of life were self-assessed using the validated KCCQ. The KCCQ is a 23-item self-administered questionnaire with 15 questions. All items are scored on a 5-7–point Likert scale. There are 5 individual subscales, all of which, except for the self-efficacy subscale, are aggregated into the clinical and overall summary scores. The total score of the questionnaire is calculated by assigning an ordinal value to each response, with 1 as the lowest value, and then adding the values to obtain a scaled score for each domain. Accordingly, the scaled scores range from 0 to 100, with a higher score indicating a better health status, fewer symptoms, and increased quality of life. Missing responses are assigned a value that corresponds to an average of the answered items within the domain [16,20].

Psychological Well-being

The psychological well-being of the participants was measured using 5 questions developed by the research group. The

questions were validated for clarity and understanding among patients with HF before use, in an iterative process. The questions were answered using a visual analogue scale, with 0 being the lowest value and 9 being the highest value. The 5-item psychological well-being scale was constructed on the basis of 5 different psychological aspects known to be of importance in HF (depression, anxiety, positive affect, hopelessness, and social support). We chose this approach, as it was not feasible to measure these factors using 5 psychological questionnaires in their entirety to measure these aspects. In addition, it has previously been shown that it may be possible to assess some of these factors through very brief questionnaires [21]. Furthermore, these questions were not intended as a means of diagnosis, but rather as indications of the patients' psychological status at the time of measurement.

Data Collection

All PRO questionnaire data were collected using Research Electronic Data Capture platform (Vanderbilt University). The questionnaires were made available on the internet to the patients on HeartPortal twice a month (between days 10-14 and 24-28 of the month). If the patients did not answer the questionnaire, the TR coordinator sent them a reminder.

Data Preprocessing

Data quality was ensured through data preprocessing. The time points for the data were converted from dates to a numeric variable—the questionnaire number. The PRO questionnaires were available to the patients twice a month at the aforementioned timepoints. Consequently, the questionnaires were still available for responses during the entire period and were not withdrawn after being completed by the patient. To correct for multiple responses to the same timepoint, the first responses within each time period were used in further analysis.

Statistical Analysis

Missing data were imputed by matching the responses from the questionnaires answered to those closest to the timepoint of the missing value [22]. Furthermore, our analyses showed that the imputation strategy did not significantly alter the results (these analyses are not included in this study). Nevertheless, missing data constitute a noteworthy problem. Furthermore, to account for missing data and varying durations of the 3 phases for the individual subjects in the study, the differences in scores in the 3 phases have been compared with trends for the subjects individually, in terms of slopes from linear regression analysis. In addition, when calculating the results for each dimension of the questionnaire, a minimum of half of the questions in each dimension was required. If less than half of the questions were answered, the results from that particular dimension would be excluded from the analysis [22].

All preprocessing steps and data analysis were performed using MATLAB (version R2019a, The MathWorks Inc). All statistical analyses were performed using IBM SPSS Statistics (version 26, IBM Corp).

Prior to analysis, the data were examined for normality of their distribution, using a Shapiro–Wilk test and by visual inspection of scatter plots. The 3 different questionnaires, as well as the subscales, comprising the PRO questionnaire in the FPT program were analyzed individually. To enable comparisons across subscales, scores were standardized by transforming each subscale to a range of 0-100 with higher scores indicating better health.

To evaluate changes in PROs during the 1-year duration of the intervention, Friedman tests were used. In case of significance, Wilcoxon sign-rank post hoc tests were used to determine in which phase the differences occurred during the 1-year duration.

Results

Patient Characteristics

Table 1 shows the baseline sociodemographic and clinical characteristics of patients in the TR group. These characteristics are depicted as either the number of patients or as mean (SD) values and ranges for the different parameters.

Table 1. Clinical and sociodemographic data of the patients enrolled in the intervention group of the Future Patient Telerehabilitation program (N=67).

Variables	Values
Age (years), mean (SD); range	
Men (n=51)	62.18 (10.64); 35-81
Women (n=16)	60.31 (11.31); 43-81
Men and women (n=67)	61.73 (10.75); 35-81
Clinical parameters, mean (SD); range	
Weight (kg)	85.34 (20.35); 56-166
Systolic blood pressure (mmHg)	124.42 (17.67); 84-172
Diastolic blood pressure (mmHg)	78.97 (10.99); 48-122
Heart rate (beats/minute)	78.70 (17.76); 46-119
Ejection fraction (%)	31.80 (8.49); 10-45
Number of patients by New York Heart Association class, n (%)	
I	10 (14.9)
II	42 (62.7)
III	13 (19.4)
IV	2 (2.9)
Number of patients by the etiology[a] of heart failure, n (%)	
Ischemia	32 (47.8)
Idiopathy	17 (25.4)
Hypertension	6 (8.9)
Valvular heart disease	8 (11.4)
Alcoholism	0 (0.0)
Postpartum heart failure	0 (0.0)
Chemotherapy	0 (0.0)
Others	18 (26.9)
Marital status, n (%)	
Single or living alone	24 (35.8)
Married or living with a partner	43 (64.2)
Education level, n (%)	
Primary school	4 (5.9)
Unskilled	16 (23.9)
Skilled worker	30 (44.8)
High school	5 (7.5)
Bachelor’s degree	9 (13.4)
Master’s degree	2 (2.9)
Doctoral degree	1 (0.7)
Employment status, n (%)	
Unemployed	0 (0.0)
Sick leave	19 (28.4)
Working for <20 hours/week	5 (7.5)
Working for 20-36 hours/week	2 (2.9)
Working full-time for 37 h/week	9 (13.4)
Retired	32 (47.8)

[a]Some patients have more causes of etiology of heart failure.

Well-being in the 3 Phases of the Study

The intervention in the FPT program was divided into 3 phases. The mean participation times for the TR patients in each phase were as follows: (1) TR and titration of medicine (2.37 months, SD 1.72 months), (2) TR at home and at a health care center or call center (3.43 months, SD 0.89 months), and (3) follow-up with TR in everyday life (5.77 months, SD 1.00 month). The patients completed 74.93% (SD 23.31%) of the total number of questionnaires, with a minimum compliance of 14.81% and a maximum compliance of 100%.

The Shapiro–Wilk test revealed that the data in the 13 different dimensions of the questionnaire were not normally distributed. Therefore, descriptive statistics for the data in 13 dimensions are presented in Table 2 as median (IQR) scores.

Changes in the median scores from each dimension for the 3 phases are illustrated in Figure 4. The dotted lines in Figure 4 demarcate the 3 phases. Each line in Figure 4, within each phase, represents 1 of the 13 dimensions of the questionnaires. As such, Figure 4 illustrates the trend within each of the 3 phases and serves as a visual presentation of the data, showing that all 3 phases have an increasing slope. Based on the changes in the median scores shown in Figure 4, we observed a trend that indicates that the scores increased for most of the dimensions during the 3 phases, most notably in phase 1.

Changes in PRO scores across the 3 phases of the study were examined using Friedman tests. As shown in Table 3, there were significant differences in scores on most of the dimensions in the KCCQ ($P<.05$) during the 1-year intervention. Wilcoxon signed-rank post hoc tests were performed to examine the differences identified by the Friedman tests. These results are presented in Table 4 as *z* scores, which are standardized scores that indicate the difference between preintervention and postintervention scores of the measure in question. As such, a negative *z* score indicates a positive change over time (median scores for each phase are provided in Table 2). However, since no significant differences were observed across phases 2 and 3, these results are not shown.

Table 2. Median (IQR) scores for all patient-reported outcome measures.

Questionnaire	Dimension	Median (IQR) score in phase 1 (n=67)	Median (IQR) score in phase 2 (n=62)	Median (IQR) score in phase 3 (n=56)	Median (IQR) score in all phases (n=56)
Spiegel Sleep Questionnaire	Sleep	58.33 (12.50)	58.33 (12.50)	57.20 (12.50)	58.33 (12.50)
Psychological well-being	Psychological well-being	28.89 (8.89)	28.89 (6.67)	28.89 (6.67)	28.89 (5.28)
Kansas City Cardiomyopathy Questionnaire					
	Physical limitations	79.17 (31.25)	87.50 (26.56)	91.67 (29.17)	88.75 (29.17)
	Symptom stability	50.00 (0.00)	50.00 (0.00)	50.00 (0.00)	50.00 (0.00)
	Symptom frequency	79.17 (37.50)	77.60 (35.94)	83.33 (37.76)	82.81 (36.98)
	Symptom burden	75.00 (3.50)	75.00 (25.00)	83.33 (35.42)	83.33 (31.25)
	Total symptom score	76.04 (34.37)	78.39 (30.99)	83.33 (34.90)	82.81 (33.20)
	Self-efficacy	75.00 (25.00)	75.00 (25.00)	75.00 (25.00)	75.00 (25.00)
	Quality of life	66.67 (3.33)	75.00 (35.42)	83.33 (32.29)	83.33 (33.33)
	Social limitation	66.67 (46.88)	80.21 (32.29)	83.85 (33.33)	81.25 (37.50)
	Overall summary score	72.14 (32.42)	77.34 (33.28)	82.58 (31.48)	79.75 (30.21)
	Clinical summary score	76.04 (27.08)	79.82 (24.90)	86.98 (32.03)	85.02 (30.14)

Figure 4. Changes in median scores from the 13 dimensions of the questionnaires. Dotted lines indicate a change in phase in the Future Patient Telerehabilitation program.

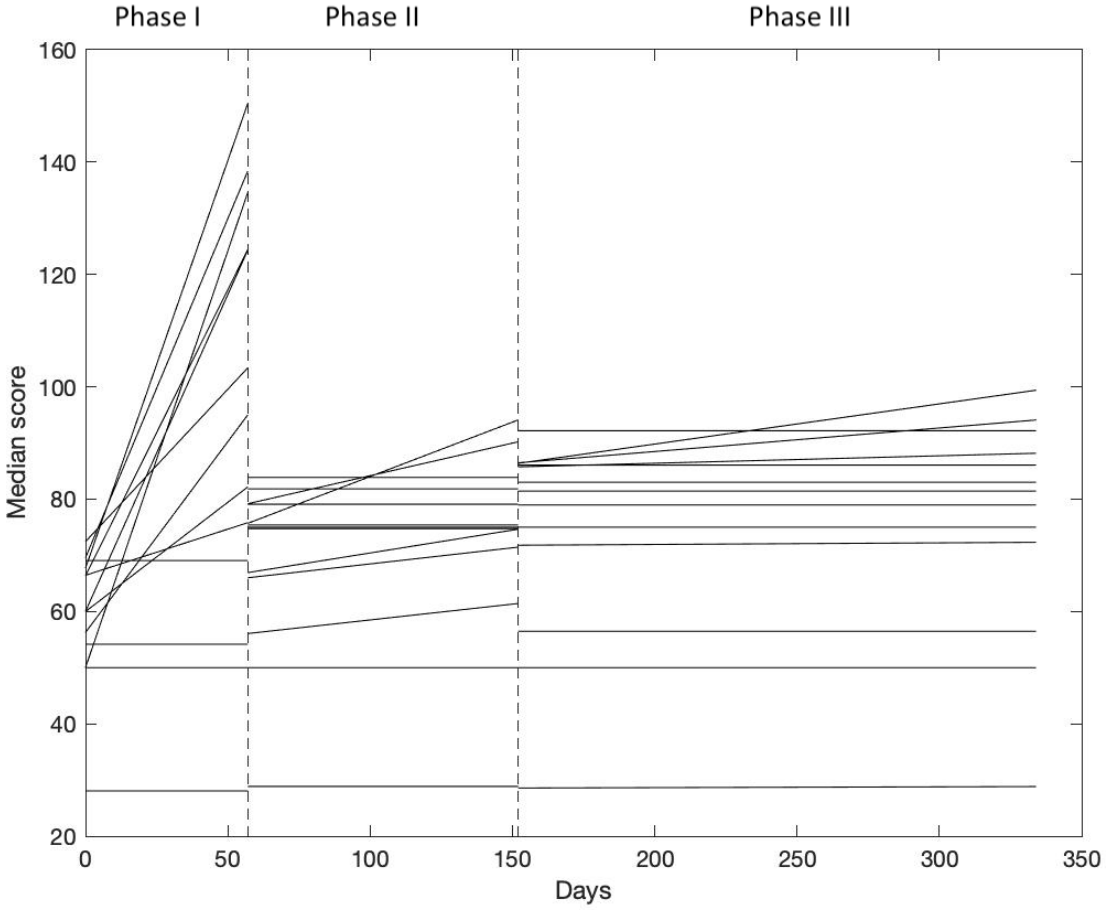


Table 3. Results of the Friedman test of the individual dimensions during 1 year.

Questionnaire	Dimension	Changes in score over time	
		χ^2 (*df*)	*P* value
Spiegel Sleep Questionnaire	Sleep quality	0.14 (2)	.93
Psychological well-being	Psychological well-being	0.04 (2)	.98
Kansas City Cardiomyopathy Questionnaire			
	Physical limitations	9.25 (2)	.01[a]
	Symptom stability	0.75 (2)	.69
	Symptom frequency	16.75 (2)	<.001[a]
	Symptom burden	11.61 (2)	.001[a]
	Total symptom score	17.18 (2)	<.001[a]
	Self-efficacy	4.32 (2)	.12
	Quality of life	7.54 (2)	.02[a]
	Social limitation	19.75 (2)	<.001[a]
	Overall summary score	14.71 (2)	.001[a]
	Clinical summary score	19.54 (2)	<.001[a]

[a]Statistically significant at $P<.05$ (2-tailed).

Table 4. *z* scores and significance levels from the Wilcoxon signed-rank post hoc tests when testing for differences in trends on the Kansas City Cardiomyopathy Questionnaire in terms of slopes between the phases.

Dimension	Slopes			
	Phase I vs phase II		Phase I vs phase III	
	z score	*P* value	*z* score	*P* value
Physical limitations	–2.41	.02[a,b]	–2.62	.009[a,b]
Symptom frequency	–3.30	.001[a,b]	–3.58	<.001[a,b]
Symptom burden	–1.74	.08[a]	–2.73	.006[a,b]
Total symptom score	–2.77	.006[a,b]	–3.30	.001[a,b]
Quality of life	–1.69	.09[a]	–3.15	.002[a,b]
Social limitation	–2.85	.004[a,b]	–3.33	.001[a,b]
Overall summary score	–2.27	.006[a,b]	–3.83	<.001[a,b]
Clinical summary score	–3.76	<.001[a,b]	–3.90	<.001[a,b]

[a]Statistically significant at $P<.05$.

[b]Higher slopes in phase I.

Discussion

Principal Findings

In the FPT program, the PRO questionnaire has served as a tool for patients on HeartPortal to help themselves monitor their well-being. The aim of this study was to evaluate the changes in quality of life and well-being for patients with HF who are participants in the FPT program over a 1-year period. We found that during the 1-year intervention, the following dimensions showed an increase in their median scores: physical limitation, symptom frequency, total symptom score, quality of life, social limitation, overall summary score, and clinical summary score. These changes were significantly different for most of the change in scores over time from the dimensions from the KCCQ.

In Figure 4, the increase in scores appeared more pronounced in the first phase, where patients start their TR and have their medication adjusted, compared to phases II (TR at home and rehabilitation at a health care center) and III (TR at home and follow-up in everyday life). However, patient scores increased continuously throughout all phases. This suggests that the intervention is most effective in phase I, as patients in this initial phase will tend to be more open-minded and motivated for changing their lifestyle and using the digital toolbox to empower themselves. As such, our results support the notion that rehabilitation should be initiated as soon as possible, preferably as part of the initial treatment phase, when patients are most motivated to initiate such changes. An analysis of the changes in scores during a year of TR showed significant differences in the scores on all dimensions of the KCCQ, except for self-efficacy. In general, these findings indicate that almost all scores from the different dimensions showed an increase and a significant difference for the overall change during 1 year of the intervention, thus indicating an improvement in the patients' health. We have not identified other studies reporting this type of improvement by using PRO questionnaires.

PRO questionnaires are normally used as a tool for research. They enable clinicians to obtain a better understanding of the patients' health status and serve as a clinical management tool [10]. In the FPT program, we deployed PRO as a tool for patients to monitor their own disease during their rehabilitation process. The patients answered almost 75% of all questionnaires for a period of 1 year, thus indicating a high degree of compliance with the PRO tool on HeartPortal. A study in Denmark [23] on HF and PRO has reported a compliance rate of approximately 50%. In this study, however, the PRO questionnaire was used by patients to document their symptoms prior to visiting the HF outpatient clinic at the hospital. Thus, PRO served as a tool for clinicians as well [23]. This active use of PRO data by patients may help explain the high compliance rate in our FPT program. To our knowledge, no other TR studies have allowed for the possibility of evaluating the current status of patients with HF during 1 year with the use of PRO measures. Our data analysis has thus demonstrated that the PRO questionnaire can provide a cross-sectional view of the development of the patients' well-being and quality of life. The increase in the scores over time may indicate that the patients have used the PRO questionnaire to become more aware of their own symptoms and, therefore, be better equipped to navigate and cope with HF in their everyday lives. We have explored how patients have used the PRO questionnaire in the digital toolbox during their participation in the FPT program. This will be further documented in a subsequent study that describes patients' qualitative perspectives of using PRO as a part of TR.

A new study by Butler et al [24] in 2020 suggests that changes even smaller than 5-point improvements in KCCQ scores may be clinically significant. In the FPT study, the median (IQR) of the KCCQ clinical summary score increased from 76.04 (IQR 27.08) in phase I to 86.98 (IQR 32.03) in phase III, yielding a total median increase of more than 10 points. This indicates that the change in scores has clinical relevance, thereby indicating improvements in health based on the KCCQ results. However, no change was observed in the median scores of the Spiegel

Sleep Questionnaire or the psychological well-being questionnaire. However, the FPT program was not designed to provide a specialized psychological intervention for psychological distress, such as anxiety and depression, but followed general guidelines for identifying and treating psychological distress in patients with HF.

Limitations

This study has limitations that should be considered. First, the timing of the PRO questionnaires may have been too frequent. In this study, it was collected every second week during 1 year, and this may have resulted in some patients skipping some of the questionnaires, thereby resulting in missing data. However, as some of the questionnaires referred to the patients' perceived symptoms over the previous 2 weeks, we considered this a relevant timeframe to detect changes in symptoms. Moreover, the responses from the PRO questionnaire provide subjective cross-sectional insights into the patients' well-being, which should be taken into consideration when evaluating their general well-being and when used in a clinical setting. In future studies, technological opportunities for mandatory responses may be used to generate more complete data from all participants.

It would have been valuable to include data from the control group for comparison. This study compared individual data over time, which is a valuable approach in identifying a trend. Nevertheless, on the basis of the available data, it was not possible to assess the development in quality of life and clinical aspects within the control group.

Conclusions

There was a significant increase in clinical and social well-being and quality of life during 1 year of participating in the TR program. These results suggest that PRO questionnaires may be used as a tool for patients in a TR program that can both monitor and guide the patients in mastering their own symptoms, improving their own well-being in a TR program, and enhancing their recovery.

Acknowledgments

We wish to thank the patients and all partners who participated in the study, including the health care centers and cardiology wards of regional hospitals in Viborg, Skive, Randers, and Silkeborg; the Danish Heart Association; Technical University of Denmark; Department of Psychology and Behavioral Sciences, Aarhus University; Department of Computer Science, Aalborg University; Centre for Innovative Medical Technology, Odense University Hospital; and the Laboratory for Welfare Technologies, Aalborg University. Furthermore, the authors wish to thank Aage and Johanne-Louis Hansen's Foundation for their financial support for this study. The Future Patient project was financed by Aage and Johanne-Louis Hansen's Foundation, Aalborg University, Viewcare, and partners in the study.

Authors' Contributions

BD, HS, MH, and JR designed the study. CS, NH, JG, AD, and BD drafted the manuscript. All authors provided feedback on the manuscript and approved the final manuscript before submission.

Conflicts of Interest

None declared.

References

1. Cardiovascular diseases (CVDs). World Health Organization. 2021 Jun 11. URL: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds) [accessed 2021-06-22]
2. Ziaeian B, Fonarow GC. Epidemiology and aetiology of heart failure. Nat Rev Cardiol 2016 Jun;13(6):368-378 [FREE Full text] [doi: 10.1038/nrcardio.2016.25] [Medline: 26935038]
3. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, Coats AJS, ESC Scientific Document Group. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J 2016 Jul 14;37(27):2129-2200. [doi: 10.1093/eurheartj/ehw128] [Medline: 27206819]
4. Ambrosy AP, Hernandez AF, Armstrong PW, Butler J, Dunning A, Ezekowitz JA, et al. The clinical course of health status and association with outcomes in patients hospitalized for heart failure: insights from ASCEND-HF. Eur J Heart Fail 2016 Mar;18(3):306-313 [FREE Full text] [doi: 10.1002/ejhf.420] [Medline: 26467269]
5. Anderson L, Taylor RS. Cardiac rehabilitation for people with heart disease: an overview of Cochrane systematic reviews. Cochrane Database Syst Rev 2014 Dec 12(12):CD011273 [FREE Full text] [doi: 10.1002/14651858.CD011273.pub2] [Medline: 25503364]
6. Tian J, Xue J, Hu X, Han Q, Zhang Y. CHF-PROM: validation of a patient-reported outcome measure for patients with chronic heart failure. Health Qual Life Outcomes 2018 Mar 20;16(1):51 [FREE Full text] [doi: 10.1186/s12955-018-0874-2] [Medline: 29554963]
7. Mampuya WM. Cardiac rehabilitation past, present and future: an overview. Cardiovasc Diagn Ther 2012 Mar;2(1):38-49 [FREE Full text] [doi: 10.3978/j.issn.2223-3652.2012.01.02] [Medline: 24282695]

8. Dinesen B, Nielsen G, Andreasen JJ, Spindler H. Integration of Rehabilitation Activities Into Everyday Life Through Telerehabilitation: Qualitative Study of Cardiac Patients and Their Partners. J Med Internet Res 2019 Apr 15;21(4):e13281 [FREE Full text] [doi: 10.2196/13281] [Medline: 30985284]
9. Brennan D, Tindall L, Theodoros D, Brown J, Campbell M, Christiana D, et al. A blueprint for telerehabilitation guidelines. Int J Telerehabil 2010;2(2):31-34 [FREE Full text] [doi: 10.5195/ijt.2010.6063] [Medline: 25945175]
10. Heidenreich PA, Spertus JA, Jones PG, Weintraub WS, Rumsfeld JS, Rathore SS, Cardiovascular Outcomes Research Consortium. Health status identifies heart failure outpatients at risk for hospitalization or death. J Am Coll Cardiol 2006 Feb 21;47(4):752-756 [FREE Full text] [doi: 10.1016/j.jacc.2005.11.021] [Medline: 16487840]
11. Anker SD, Agewall S, Borggrefe M, Calvert M, Jaime Caro J, Cowie MR, et al. The importance of patient-reported outcomes: a call for their comprehensive integration in cardiovascular clinical trials. Eur Heart J 2014 Aug 07;35(30):2001-2009. [doi: 10.1093/eurheartj/ehu205] [Medline: 24904027]
12. Snyder CF, Aaronson NK. Use of patient-reported outcomes in clinical practice. Lancet 2009 Aug 01;374(9687):369-370. [doi: 10.1016/S0140-6736(09)61400-8] [Medline: 19647598]
13. Dinesen B, Dittmann L, Gade JD, Jørgensen CK, Hollingdal M, Leth S, et al. "Future Patient" Telerehabilitation for Patients With Heart Failure: Protocol for a Randomized Controlled Trial. JMIR Res Protoc 2019 Sep 19;8(9):e14517 [FREE Full text] [doi: 10.2196/14517] [Medline: 31538944]
14. Kelkar AA, Spertus J, Pang P, Pierson RF, Cody RJ, Pina IL, et al. Utility of Patient-Reported Outcome Instruments in Heart Failure. JACC Heart Fail 2016 Mar;4(3):165-175 [FREE Full text] [doi: 10.1016/j.jchf.2015.10.015] [Medline: 26874386]
15. Joensson K, Melholt C, Hansen J, Leth S, Spindler H, Olsen MV, et al. Listening to the patients: using participatory design in the development of a cardiac telerehabilitation web portal. Mhealth 2019;5:33 [FREE Full text] [doi: 10.21037/mhealth.2019.08.06] [Medline: 31620460]
16. Green CP, Porter CB, Bresnahan DR, Spertus JA. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. J Am Coll Cardiol 2000 Apr;35(5):1245-1255 [FREE Full text] [doi: 10.1016/s0735-1097(00)00531-3] [Medline: 10758967]
17. Spiegel R. Sleep and Sleeplessness in Advanced Age (Advances in Sleep Research, volume 5). New York, NY: SP Medical and Scientific Books; 1981.
18. Spertus JA, Conard MW, Rinaldi J, Tsuyuki R, Krumholz H, Pina I, et al. The kansas city cardiomyopathy questionnaire is sensitive to clinical change in congestive heart failure. J Am Coll Cardiol 2002 Mar;39:460. [doi: 10.1016/S0735-1097(02)82069-1]
19. Drewes AM, Bjerregård K, Taagholt SJ, Svendsen L, Nielsen KD. Zopiclone as night medication in rheumatoid arthritis. Scand J Rheumatol 1998;27(3):180-187. [doi: 10.1080/030097498440787] [Medline: 9645412]
20. Spertus JA, Jones PG, Sandhu AT, Arnold SV. Interpreting the Kansas City Cardiomyopathy Questionnaire in Clinical Trials and Clinical Care: JACC State-of-the-Art Review. J Am Coll Cardiol 2020 Nov 17;76(20):2379-2390 [FREE Full text] [doi: 10.1016/j.jacc.2020.09.542] [Medline: 33183512]
21. Everson SA, Goldberg DE, Kaplan GA, Cohen RD, Pukkala E, Tuomilehto J, et al. Hopelessness and risk of mortality and incidence of myocardial infarction and cancer. Psychosom Med 1996;58(2):113-121. [doi: 10.1097/00006842-199603000-00003] [Medline: 8849626]
22. Schafer JL, Graham JW. Missing data: our view of the state of the art. Psychol Methods 2002 Jun;7(2):147-177. [Medline: 12090408]
23. Rasmussen AA, Larsen SH, Jensen M, Berg SK, Rasmussen TB, Borregaard B, et al. Prognostic Impact of Self-Reported Health on Clinical Outcomes in Patients with Heart Failure. Eur Heart J Qual Care Clin Outcomes 2020 Mar 31:qcaa026. [doi: 10.1093/ehjqcco/qcaa026] [Medline: 32232437]
24. Butler J, Khan MS, Mori C, Filippatos GS, Ponikowski P, Comin-Colet J, et al. Minimal clinically important difference in quality of life scores for patients with heart failure and reduced ejection fraction. Eur J Heart Fail 2020 Jun;22(6):999-1005 [FREE Full text] [doi: 10.1002/ejhf.1810] [Medline: 32239794]

Abbreviations

FPT: Future Patient Telerehabilitation
HF: heart failure
KCCQ: Kansas City Cardiomyopathy Questionnaire
NYHA: New York Heart Association
PRO: patient-reported outcome
TR: Telerehabilitation

Edited by G Eysenbach; submitted 16.12.20; peer-reviewed by K Kastelic, T Wieringa, M Ferrer, J Knitza; comments to author 15.03.21; revised version received 13.04.21; accepted 19.05.21; published 02.07.21.

Please cite as:
Skov Schacksen C, Dyrvig AK, Henneberg NC, Dam Gade J, Spindler H, Refsgaard J, Hollingdal M, Dittman L, Dremstrup K, Dinesen B
Patient-Reported Outcomes From Patients With Heart Failure Participating in the Future Patient Telerehabilitation Program: Data From the Intervention Arm of a Randomized Controlled Trial
JMIR Cardio 2021;5(2):e26544
URL: https://cardio.jmir.org/2021/2/e26544
doi:10.2196/26544
PMID:34255642

Original Paper

Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation

Amber Seiler[1], NP, MSN, FHRS, CEPS, CCDS; Eliana Biundo[2], MSc; Marco Di Bacco[3], PharmD, MS; Sarah Rosemas[3], MPH; Emmanuelle Nicolle[3], MSc, MD; David Lanctin[3], MPH; Juliette Hennion[2], MSc; Mirko de Melis[3], PhD; Laura Van Heel[4], BSN

[1]Cone Health Medical Group, Greensboro, NC, United States

[2]Deloitte, Brussels, Belgium

[3]Medtronic, Mounds View, MN, United States

[4]Centracare, St. Cloud, MN, United States

Corresponding Author:
David Lanctin, MPH
Medtronic
8200 Coral Sea Ct NE
Mounds View, MN, 55112
United States
Phone: 1 800 633 8766
Email: david.lanctin@medtronic.com

Abstract

Background: The number of patients with cardiac implantable electronic device (CIED) is increasing, creating a substantial workload for device clinics.

Objective: This study aims to characterize the workflow and quantify clinic staff time requirements for managing patients with CIEDs.

Methods: A time and motion workflow evaluation was performed in 11 US and European CIEDs clinics. Workflow tasks were repeatedly timed during 1 business week of observation at each clinic; these observations included all device models and manufacturers. The mean cumulative staff time required to review a remote device transmission and an in-person clinic visit were calculated, including all necessary clinical and administrative tasks. The annual staff time to manage a patient with a CIED was modeled using CIED transmission volumes, clinical guidelines, and the published literature.

Results: A total of 276 in-person clinic visits and 2173 remote monitoring activities were observed. Mean staff time required per remote transmission ranged from 9.4 to 13.5 minutes for therapeutic devices (pacemaker, implantable cardioverter-defibrillator, and cardiac resynchronization therapy) and from 11.3 to 12.9 minutes for diagnostic devices such as insertable cardiac monitors (ICMs). Mean staff time per in-person visit ranged from 37.8 to 51.0 and from 39.9 to 45.8 minutes for therapeutic devices and ICMs, respectively. Including all remote and in-person follow-ups, the estimated annual time to manage a patient with a CIED ranged from 1.6 to 2.4 hours for therapeutic devices and from 7.7 to 9.3 hours for ICMs.

Conclusions: The CIED patient management workflow is complex and requires significant staff time. Understanding process steps and time requirements informs the implementation of efficiency improvements, including remote solutions. Future research should examine heterogeneity in patient management processes to identify the most efficient workflow.

(JMIR Cardio 2021;5(2):e27720) doi:10.2196/27720

KEYWORDS

cardiac implantable electronic devices; remote monitoring; patient management; clinic efficiency; digital health; mobile phone

Introduction

Background

The number of patients receiving and living with cardiac implantable electronic devices (CIEDs), including permanent pacemakers, implantable cardioverter-defibrillators (ICD), cardiac resynchronization therapy (CRT) devices, and insertable cardiac monitors (ICMs), has increased significantly in the past several years [1-3]. Accordingly, the burden for device clinics to manage follow-up visits has increased. Such follow-up visits, consisting of device interrogation and subsequent care changes (ie, reprogramming device settings and acting upon clinical findings), have traditionally been performed in person. Their frequency, essentially based on clinical guidelines, may vary depending on the facility, physician and patient preferences, and available resources [4]. As an alternative or complement to in-person visits, remote monitoring (RM) has become a guideline-recommended method for managing patients with CIEDs [5,6]. RM capabilities are a standard feature of modern CIEDs, and data are continuously transmitted through landlines or mobile networks, which supplies health care providers with critical clinical (eg, arrhythmias) and device-related (eg, battery longevity) information that allows them to adjust and optimize patient treatment accordingly. In the 2015 Heart Rhythm Society (HRS) Consensus Statement on remote interrogation and monitoring for CIEDs, endorsed by European Heart Rhythm Association and other international societies, RM combined with an annual in-person visit is recommended rather than in-person evaluation alone, with the strongest (class I) recommendation and the highest level of evidence (A) [5]. This recommendation is primarily because of earlier detection of clinical events, including atrial fibrillation, ventricular arrhythmias, and pause arrhythmias, to which RM enables faster clinical response and appropriate medical action [7-9]. Several studies have confirmed the clinical and economic benefits of RM, including improved patient outcomes and reduced health care use [5,9-13].

Furthermore, the literature has shown that the review of an RM transmission requires less staff time than an in-office interrogation, and RM is associated with greater patient adherence to device follow-up checks and a reduction in scheduled, often nonactionable in-office visits [10,14,15]. However, implementation in clinical practice of an overall management process for patients with CIEDs, incorporating both RM and in-person visits, can be challenging because of the scarcity of information on organizational models and requirements. The specific steps involved and the health care professional time required for these activities are poorly understood, which may hinder the implementation of optimal follow-up strategies, including remote solutions.

Objective

This study aims to characterize the workflow processes and clinic staff time required for remote and in-person device follow-up of patients with CIEDs.

Methods

Data Collection

A time and motion workflow evaluation was performed in 11 CIED clinics internationally to characterize the discrete activities and associated time required for all tasks related to managing patients with CIEDs. Among the participating clinics, 6 were located in the United States, and 5 were located in Europe (3 in the United Kingdom, 1 in France, and 1 in Germany). Participating clinics were actively managing an average of 5758 (range: 870-22,000) patients with CIEDs, an average of 4217 patients in the United States and 7606 in Europe. All 11 clinics used guideline-recommended RM in combination with in-person device follow-up. Half (3) of the US clinics were located within academic institutions, and 3 of the 5 European clinics were academic.

A third-party observer prospectively collected data for one business week (5 days) at each clinic, recorded the tasks performed by the staff, and measured each task's duration with a stopwatch. Workflow measurements included all CIED types (permanent pacemaker, ICD, CRT, ICM) across any device manufacturer found within the clinic during the study week (Abbott, Biotronik, Boston Scientific, Medtronic, and Microport).

The observations included all activities related to managing patients with CIEDs and were categorized into 3 groups of activities: in-person clinic visits, remote transmission review, and other patient management activities not attributable to a specific patient device check (eg, patient triage and scheduling, identifying patients lost to follow-up, and telephone communication with patients). Owing to insufficient data collection on remote transmission review workflow activities at the German site, these observations were excluded from the analysis.

Statistical Analysis

Staff Time Per Device Check for Remote and In-Person Device Follow-ups

Multimedia Appendix 1 lists all observed workflow steps occurring within each activity category (in-person clinic visit, remote transmission review, and other patient management activities). The differences in observed steps between categories are because of differences in device check scope; for example, assessing patient vitals or reprogramming device therapy are specific to in-person clinic visits. These lists are comprehensive of all possible steps observed, but all steps may not have occurred during each device check or in sequence as listed, as practices and workflow vary widely. Thus, to quantify the workload associated with an *average* patient device check (remote or in-person), the unit steps were weighted based on each step's likelihood of occurring in a given device check. The weighting factors are listed in Multimedia Appendix 2 [5,14,16-21] and were based on study observations where possible, supplemented by data from the literature. The mean time per remote and in-person device checks was calculated, including all clinical tasks and any administrative tasks related

to that device check (eg, software access, documentation, scheduling follow-up, and sending information for billing).

For remote transmission review tasks, consideration of the transmission type and review process enabled further analyses. Transmissions were classified as nonactionable versus actionable (ie, requiring clinical follow-up because of either abnormal device functioning or a clinical patient event, such as an arrhythmia). It was assumed that 27% of transmissions would be actionable, based on a previously published time and motion evaluation [14]. Scenario analyses were performed to test the sensitivity of this parameter using additional literature-derived estimates [14,22,23]. We also estimated staff time spent on first- and second-line review of remote transmission data, considering that transmissions sometimes require escalation to more experienced staff for review and clinical decision-making. We assumed that 8.2% of transmissions would be sent for second-line review based on the aforementioned time and motion study [14]. For in-person clinic visits, 21.8% (27/124) of the visits were actionable based on study observations.

Annual Staff Time Per Patient for Remote and In-Person Device Follow-ups

On the basis of the calculated mean time per activity category, the annual staff time required to manage each patient with a CIED was modeled. The volume of remote transmissions per patient per year was based on real-world device transmissions from the calendar year 2016-2017 and included routine and alert-driven transmissions (Multimedia Appendix 2). For in-person clinical visits, it was assumed that each patient would have a routine visit per year according to clinical guidelines [6] and a number of unscheduled visits (ie, device alert or symptom-driven) based on the frequencies reported in the remotely monitored arm of published RM trials for each CIED type [16-20].

Annual Staff Time for Other Patient Management Activities

The annual time spent on other patient management activities not attributable to a specific patient device check was calculated based on observed clinic norms for performing tasks (eg, weekly identification of patients with disconnected monitors), whereas the frequency of telephone calls between the clinic and patient was based on a previous workflow study [21]. The per-patient workflow for in-person clinic visits, remote transmission review, and other patient management activities were extrapolated to the clinic level based on the average size of the clinics participating in the study (5758 patients).

Predictors of Clinic Efficiency

Prespecified subanalyses were performed to identify efficient clinical practices. Leveraging the same approach described above for modeling staff time per remote and in-person device check, the staff time per device check was modeled separately for the 3 US clinics in which vendor-neutral CIED management software (Medtronic Paceart Optima) was used during on-site observations, in comparison with 3 US clinics without management software. Similarly, the staff time per in-person visit was modeled separately for observations in which a tablet programmer was used versus visits in which a tablet programmer was not used.

Ethical Considerations

As this study was a workflow process evaluation that collected no patient or clinical data and only collected staff time measurements, the study protocol did not require approval from a local ethics committee or institutional review board. This study adhered to the General Data Protection Regulation and Health Insurance Portability and Accountability Act data privacy guidelines in Europe and the United States, respectively. The included sites consented to participate in the data collection process in accordance with their privacy requirements. Participating sites were required to have more than one employee of any given type (eg, nurse, physiologist, and physician) to preserve employee privacy, with all workflow data pooled across a staff of the same type.

Results

Data Collection

A total of 54 distinct workflow steps were observed and timed during the management of patients with CIEDs: 31% (17/54) for remote transmission review, 39% (21/54) for in-person clinic visits, and 30% (16/54) for other patient management activities such as patient phone calls and patient triage. The average time associated with each step is reported in Multimedia Appendices 3-5. During 11 total business weeks of data collection, observations included 276 in-person clinic visits (124/276, 44.9% the United States and 152/276, 55.1%, Europe), 1948 (1269/1948, 65.14% the United States and 679/1948, 34.86% Europe) individual remote transmission review tasks (not every step could be observed for each given transmission, as they often did not occur sequentially), and 440 other patient management tasks (the United States only). Considering all individual time recordings, approximately 50.21% (2424/4828) of the observations were in patients using pacemakers, 17.13% (827/4828) were in patients using ICD, 20.89% (1009/4828) were in patients using CRT, and 11.76% (568/4828) were in patients using ICM.

Staff Time per Device Check for Remote and In-Person Device Follow-ups

Mean cumulative staff time required to review a remote device transmission ranged from 9.4 to 13.5 minutes (16.1-21.7 minutes for actionable and 6.1-11.2 minutes for nonactionable transmissions) for therapeutic devices (pacemaker, ICD, or CRT) and 11.3 to 12.9 minutes (17.3-20.3 minutes for actionable and 8.0-11.3 minutes for nonactionable transmissions) for ICMs.

Participating clinics generally used a two-level transmission-review process. A nurse or device technician performed a preliminary review (first-line review) to determine if the transmission requires the intervention of an advanced practitioner (second-line review performed by a nurse practitioner, physician assistant, or medical doctor). The staff time for a first-line review ranged from 11.9 to 13.0 minutes in the United States and 9.63 to 11.1 minutes in Europe, depending on device type. A second-line review ranged from 7.2 to 7.9

minutes in US clinics and 6.72 to 9.23 minutes in European clinics (Table 1).

Cumulative staff time per in-person clinic visit ranged from 37.8 to 51.0 minutes and 39.9 to 45.8 minutes for therapeutic devices and ICM, respectively (Table 1). For both remote transmission review and in-person clinic visits, the overall percentage of labor performed by each staff type (nurses, technician or medical assistants, medical doctors, physician assistants, or nurse practitioners, administrative assistants, and physiologists) is characterized by country in Table 2. Furthermore, the staff performing administrative tasks differed by site and region. In the United States, 46.3% (348/751) of all administrative workflow observations were performed by medical and administrative assistants, whereas 53.7% (403/751) of administrative tasks were performed by clinical practitioners. In the United Kingdom, all administrative workflow observations (n=165) were performed by clinical staff, including nurses, physiologists, and other advanced practitioners (Table 2).

Given that the estimated time to review an average remote transmission was dependent on the likelihood of a transmission being actionable, a series of scenario analyses were performed to test the sensitivity of this parameter. On the basis of the range of available literature-derived estimates (ranging from 8% to 27%), the time to review a transmission in the United States ranged from 11.9 to 13.5 minutes for patients with pacemakers, 10.8 to 12.7 minutes for patients with ICDs, 10.8 to 11.9 minutes for patients with CRTs, and 11.7 to 12.9 minutes for patients with ICMs. In Europe, the time ranged from 7.7 to 9.4 minutes for patients with pacemakers, 9.8 to 11.6 minutes for patients with ICDs, 10.7 to 12.4 minutes for patients with CRTs, and 9.6 to 11.3 minutes for patients with ICM.

Table 1. Mean cumulative staff time required per remote transmission review and in-person clinic visit.

Workflow activity	United States				Europe			
	PM[a]	ICD[b]	CRT[c]	ICM[d]	PM	ICD	CRT	ICM
Remote device transmission review								
Staff time per average transmission[e], minutes	13.5	12.7	11.9	12.9	9.4	11.6	12.4	11.3
Number of transmissions per year (both scheduled and unscheduled transmissions)[f]	3.7	4.6	5.1	38.9	3.6	5.1	5.9	35.6
Annual staff time for remote transmissions per patient, hours	0.8	1.0	1.2	8.4	0.6	1.0	1.2	6.7
In-person clinic visits								
Staff time per visit, minutes	50.1	51.0	43.4	45.8	41.2	37.8	40.9	39.9
Number of visits per year (both routine and event-driven visits)	1.5	1.7	1.7	1.3	1.5	1.7	1.7	1.3
Annual staff time for clinic visits per patient, hours	1.3	1.4	1.2	1.0	1.0	1.1	1.1	1.0
Total annual per patient staff time, hours	2.1	2.4	2.4	9.3	1.6	2.0	2.4	7.7
Type of remote device transmission								
Staff time required to review actionable versus nonactionable transmissions, minutes								
Staff time per actionable transmission	19.8	20.1	16.1	17.3	18.3	20.6	21.7	20.3
Staff time per nonactionable transmission	11.2	9.9	10.3	11.3	6.1	8.3	9.0	8.0
Distribution of staff time for first-line versus second-line review of remote transmissions, minutes								
Staff time for first-line transmission review (relevant for all transmissions)	13.0	12.2	11.9	12.5	9.6	10.4	11.1	10.7
Staff time for second-line transmission review (required for only 8.2% of transmissions)	7.8	7.9	7.2	7.8	8.0	6.7	9.2	8.0

[a]PM: permanent pacemaker.

[b]ICD: implantable cardioverter-defibrillator.

[c]CRT: cardiac resynchronization therapy.

[d]ICM: insertable cardiac monitors.

[e]The time required for an average transmission was modeled based on the assumption that 27% of transmissions are actionable and 73% of transmissions are nonactionable [14].

[f]The transmission volume is based on real-world data, and generalizability to other clinics will vary significantly depending on device programming practices, patient indications, and patient education.

Table 2. Percentage of cardiac implantable electronic devices management workload by staff type and region.[a]

Staff type and region	Nurse, n	Technician or medical assistant, n	Medical doctor, physician assistant, or nurse practitioner, n	Administrative assistant, n	Physiologist[b], n
In-person clinic visits					
United States	24	29	45	2	0
United Kingdom	2	0	46	0	52
Remote transmission review					
United States	53	10	35	3	0
United Kingdom	0	0	0	0	100
Other patient management (eg, calls and connectivity troubleshooting)[c]					
United States	48	51	0	1	0
Time contribution by staff type: overall					
United States	44	20	34	2	0
United Kingdom	1	0	19	0	80

[a]Labor share was calculated in the United States and the United Kingdom due to having multiple clinics observed in each country (6 and 3, respectively). As only one clinic was observed in Germany and France, there were insufficient data to perform this analysis in these countries.

[b]Clinical cardiac physiologists in the United Kingdom carry out procedures and investigations on patients related to diagnosis, monitoring, and treatment.

[c]The Other Patient Management data were only collected in the United States.

Annual Staff Time Per Patient for Remote and In-Person Device Follow-ups

The mean number of transmissions per year per patient (including scheduled and unscheduled transmissions) ranged from 3.6 to 5.9 for therapeutic devices and 35.6 to 38.9 for ICMs (Table 1). In contrast, the number of expected in-person clinic visits per year ranged from 1.3 to 1.7 per patient. Although we seek to model time for an average clinic, the frequency of in-person and remote device checks will vary significantly between clinics depending on device programming practices, patient indications, and patient education.

Multiplying the staff time for each expected remote and in-person device check by the annual frequencies of device checks per year yielded an estimated total annual staff time of 1.6 to 2.4 hours to manage a patient with a therapeutic device and 7.7 to 9.3 hours for a patient with an ICM (Table 1). The higher staff time to manage a patient with an ICM was attributed to the increased transmission volume observed.

Annual Staff Time for Other Patient Management Activities

The staff time required for other patient management tasks such as calling patients, troubleshooting device connectivity issues, identifying loss to follow-up, and triaging patients or transmissions (full task list provided in Multimedia Appendix 5) was estimated to be 17.3 minutes per patient annually. At the clinic level (based on the average 5758-patient clinic size of participating clinics), this translates to 1659.2 hours of staff time per year (31.9 hours per week).

Predictors of Clinic Efficiency

A series of prespecified subanalyses were conducted to identify the predictors of clinic efficiency.

Vendor-Neutral Patient Management Software

The staff time required per remote and in-person device check was modeled separately for the 3 US clinics in which vendor-neutral CIED management software (Medtronic Paceart Optima) was used during on-site observations in comparison with the 3 US clinics without management software. On average, the total staff time to review a remote transmission was 2.1 minutes lower at sites with management software (11.5 vs 13.6 minutes). The staff time associated with an in-clinic visit was 2.2 minutes lower at clinics with management software (50.4 vs 52.6 minutes). For both remote transmission review and in-person clinic visits, the time savings were driven by the steps involved in electronic health record documentation. When extrapolated to an average clinic size of 5758 patients, the use of such software was associated with an estimated 10.1 cumulative staff hours saved during a clinic day (50.7 hours per week) based on 171 weekly clinic visits and 1335 weekly remote transmissions. Annually, this translates to 2639 hours of staff time saved, equivalent to 1.4 annual full-time equivalents.

Tablet-Based Programmers

In-person clinic visit staff time was modeled separately for visits in which a tablet-based CIED programmer was used (n=599 total observations) compared with visits in which a legacy programmer—which is large and cumbersome—was used (n=794). A tablet-based programmer was associated with an average of 5.2 minutes lower staff time (54 vs 49 minutes; 9.6% reduction) for a clinic visit, driven by reduced time for programmer device transport to a patient room and improved data connectivity with the electronic health record.

Discussion

Principal Findings

This study characterized the staffing resources necessary for cardiac device clinics to manage patients with CIEDs, including detailed time associated with each workflow step and breakdowns by device, geographic region, and staffing types. Although differences were observed across device types and geographic regions, the overall workload was found to be consistently substantial, regardless of CIED type and region.

As CIED technology advances, so do device data capabilities to inform and optimize patient care. The benefits of RM have been illustrated in several clinical studies, including faster event detection, improved patient outcomes, and reduced health care use. However, data alone will not result in clinical and economic benefits unless timely clinical action is taken. Clinical workflows must be optimized to capture the value of the device data.

The HRS consensus statement on RM outlined the importance of implementing a streamlined organization with clear roles and responsibilities to manage RM data in parallel with in-person follow-ups [5]. However, there is limited literature on how patients with CIEDs are managed in practice, including the workflow steps and the staffing requirements associated with each task, creating implementation challenges for new RM users. Protocols for remote management of patients with CIEDs have been developed, including the HomeGuide registry study [24], which implemented a dedicated nurse-physician team strategy. Similar to most sites in this study, a two-tiered remote transmission review structure was leveraged, in which nurses (or other similar practitioners) performed the initial transmission review and escalated critical events to a physician. However, this model may not apply to all device clinics, depending on the size, RM infrastructure, and staff resources available.

Although different organizational models, staff types, and workflows may exist in practice depending on the setting and available resources, the essential tasks required to manage patients with CIEDs remain similar. This evaluation sets a baseline by describing the essential activities performed by clinical staff to manage a population of patients with CIEDs and the time required to execute it. It also underscores the complexity of the current management of patients with CIEDs, identifying 54 distinct workflow tasks across three categories (remote transmission review, in-person clinic visits, and other patient management activities, such as patient phone calls and triaging).

Mean staff time required per remote transmission review and in-person clinic visit ranged from 9.4 to 13.5 minutes and 37.8 to 51.0 minutes, respectively, depending on device type. This validates previous research demonstrating the efficiency opportunities for RM [14]. The annual time per patient required for in-person device checks was relatively consistent across device types (1.0-1.4 hours), perhaps because of the low frequency of office visits required for patients being continuously monitored with RM. The annual time per patient for RM was higher in patients with diagnostic devices (ICMs: 6.7-8.4 hours per year vs only 0.6-1.2 hours for therapeutic devices) because of increased device transmissions both for routine data review and programmable automatic device alerts. However, it should be noted that the magnitude of the device transmission frequency with ICMs is highly dependent on the alert programming settings, patient indications, and patient education. The overall annual time required to follow and manage a patient with a CIED is lower for a patient with a therapeutic device (1.6-2.4 hours) than a patient with a diagnostic device (ICM: 7.7-9.3 hours).

As revealed by the predictors of efficiency analysis described above, even small improvements in the efficiency of CIED clinics can have a significant positive impact on time savings. Although our study observed meaningful time savings associated with the use of patient management software and tablet-based programmers, further research is needed to identify other strategies for optimal patient follow-up. For instance, the growing number of technologies capable of transmitting patient data to CIED clinics represents a challenge for data management [25,26]. Further innovation on solutions for integrating and storing data from this multitude of sources could enhance the efficient management of patients with CIEDs. This software also presents an opportunity for closer clinical care and patient safety; previous studies using the triaging and analytic capabilities of the PaceArt Optima system showed an improved enrollment of patients in RM [27] and identification and successful interventions for patients with suboptimal ICD programming [28] and low CRT pacing [29,30].

Our study observed a significant workload associated with fielding patient calls and troubleshooting connectivity, which is consistent with a recent study that found that more than 40% of patient calls received by CIED clinics pertain to troubleshooting RM equipment and transmission status [21]. Strategies to improve device connectivity—for instance, Bluetooth-enabled, smartphone-paired, or widespread use of other wireless monitors—could alleviate this significant workload burden on CIED clinics. Furthermore, optimizing the appropriate staffing types for each activity (eg, administrative tasks performed by administrative staff) could help clinics balance operational costs and resource availability.

A number of studies have previously estimated the time to perform remote and in-person device checks, yielding a wide range of time estimates, suggesting that there may be significant clinic-to-clinic variability [14,31-33]. To our knowledge, this study is the first multicenter, multinational study to describe comprehensive work requirements for managing patients with CIEDs. Considering the significant time-consuming activities related to follow up patients with CIEDs, appropriate funding needs to be in place to ensure that this crucial part of the patient care pathway is not overlooked. As RM is considered a guideline-recommended standard of care for all patients with CIEDs, hospital or clinic budget holders, payers, and reimbursement authorities should financially support its implementation and day-to-day practice. Funding and reimbursement of RM are variable and remain a challenge in many geographies today, as all stakeholders involved in this continuous service provision are often not remunerated or insufficient. Such a barrier affects RM adoption and its implementation as a standard of care. For this time and motion

evaluation, countries where RM reimbursement is available were selected to avoid the influence of this lack of financial incentives on patient management organizations, which could be reflected in time measures. However, local reimbursement challenges persist, including limitations on specific cardiac devices, settings, and health care professionals in France and Germany. RM may not be suitable for every patient for different reasons (technical, clinical, or patient preference) but should be proposed to all eligible patients, in line with the medical recommendations and considering the current environment [34,35]. With the COVID-19 pandemic, RM benefits have been reinforced, also underlining the need to establish an appropriate infrastructure to manage patients remotely, which requires human, time, and financial investment.

Although it is widely acknowledged today that RM is a valuable tool for optimal follow-up of patients with CIEDs, to achieve this objective, infrastructure investments are required, including equipment (eg, additional computer or monitors) and setting up a specific clinic workflow organization involving sufficient human resources. As this infrastructural investment might not be an option in all settings, outsourcing remote patient management to other clinics or third-party arrhythmia review services could be an alternative to in-house implementation, as has been shown previously [36].

Limitations

This study had several limitations. Owing to the real-world observational nature of this analysis, study measurements were reliant on the workflow taking place during the data collection week and were not systematically controlled for patient or center characteristics. This study describes the workflow observed at 11 centers in the United States and Europe, but the generalizability of these observations to other centers with different device populations and staffing resources is unknown. However, this is the first attempt at characterizing cardiac device clinic workflow in full and provides a first step in filling the knowledge gap around patient management practices and resource requirements.

In addition, as the time and motion methodology was designed as a clinic-perspective workflow characterization and did not follow patients longitudinally, we were unable to measure patient clinical metrics, such as device connectivity success and patient adherence to follow-ups. Finally, extrapolations were made using externally published data (eg, proportion of device checks requiring second-line assessment) and HRS guidelines for patient follow-up, and these assumptions may not be generalizable to all clinics. A series of sensitivity analyses were performed to test the impact of our assumption on transmission actionability. Although device check-level and annual resource use will be dependent on individual workflow practices, individual workflow step measurements can readily be used to create a workflow framework that is highly customizable to individual centers and circumstances.

Conclusions

This observational study confirmed the complexity of the management of patients with CIEDs. The associated workflows require significant clinical and administrative staff time across in-person clinic visits, remote transmission review, and other patient management tasks. RM is an efficient component of managing patients with CIEDs, allowing for continuous follow-up of patients with reduced staff time required per device check. Detailed recommendations on organizational models for managing patients with CIEDs are warranted to ensure homogeneous follow-up, support RM implementation, and enable optimal patient care.

Acknowledgments

The authors would like to thank each of the 11 participating clinics for permitting observation of their workflow. Data collection and analysis were funded by Medtronic.

Conflicts of Interest

MDB, SR, EN, DL, and MM are Medtronic employees and shareholders. Data collection for this study, performed by Deloitte, was funded by Medtronic.

Multimedia Appendix 1
Workflow steps observed during the management of cardiac implantable electronic devices patients.
[DOCX File , 46 KB - cardio_v5i2e27720_app1.docx]

Multimedia Appendix 2
Modeling inputs.
[DOCX File , 17 KB - cardio_v5i2e27720_app2.docx]

Multimedia Appendix 3
Mean staff time required per instance for remote transmission review steps.
[DOCX File , 38 KB - cardio_v5i2e27720_app3.docx]

Multimedia Appendix 4

Mean staff time required per instance for in-person clinic visit steps.
[DOCX File , 42 KB - cardio_v5i2e27720_app4.docx]

Multimedia Appendix 5
Mean staff time required per instance for other patient management activities.
[DOCX File , 37 KB - cardio_v5i2e27720_app5.docx]

References

1. Mond HG, Irwin M, Ector H, Proclemer A. The world survey of cardiac pacing and cardioverter-defibrillators: calendar year 2005 an International Cardiac Pacing and Electrophysiology Society (ICPES) project. Pacing Clin Electrophysiol 2008 Sep;31(9):1202-1212. [doi: 10.1111/j.1540-8159.2008.01164.x] [Medline: 18834475]
2. Uslan DZ, Tleyjeh IM, Baddour LM, Friedman PA, Jenkins SM, St Sauver JL, et al. Temporal trends in permanent pacemaker implantation: a population-based study. Am Heart J 2008 May;155(5):896-903 [FREE Full text] [doi: 10.1016/j.ahj.2007.12.022] [Medline: 18440339]
3. Kurtz SM, Ochoa JA, Lau E, Shkolnikov Y, Pavri BB, Frisch D, et al. Implantation trends and patient profiles for pacemakers and implantable cardioverter defibrillators in the United States: 1993-2006. Pacing Clin Electrophysiol 2010 Jun 01;33(6):705-711. [doi: 10.1111/j.1540-8159.2009.02670.x] [Medline: 20059714]
4. Nishii N. Remote monitoring of cardiac implantable electronic devices. Journal of Arrhythmia 2014 Dec;30(6):395-412 [FREE Full text] [doi: 10.1016/j.joa.2014.03.009]
5. Slotwiner D, Varma N, Akar JG, Annas G, Beardsall M, Fogel RI, et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm 2015 Jul;12(7):69-100. [doi: 10.1016/j.hrthm.2015.05.008] [Medline: 25981148]
6. Brignole M, Auricchio A, Baron-Esquivias G, Bordachar P, Boriani G, Breithardt O, ESC Committee for Practice Guidelines (CPG), Document Reviewers, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Eur Heart J 2013 Aug;34(29):2281-2329. [doi: 10.1093/eurheartj/eht150] [Medline: 23801822]
7. Crossley GH, Boyle A, Vitense H, Chang Y, Mead RH. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. J Am Coll Cardiol 2011 Mar 8;57(10):1181-1189 [FREE Full text] [doi: 10.1016/j.jacc.2010.12.012] [Medline: 21255955]
8. Sanna T, Diener H, Passman RS, Di LV, Bernstein RA, Morillo CA, et al. Cryptogenic stroke and underlying atrial fibrillation. N Engl J Med 2014 Jun 26;370(26):2478-2486. [doi: 10.1056/NEJMoa1313600] [Medline: 24963567]
9. Landolina M, Perego GB, Lunati M, Curnis A, Guenzati G, Vicentini A, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. Circulation 2012 Jun 19;125(24):2985-2992 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.111.088971] [Medline: 22626743]
10. Varma N, Epstein AE, Irimpen A, Schweikert R, Love C. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial. Circulation 2010 Jul 27;122(4):325-332 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.110.937409] [Medline: 20625110]
11. Raatikainen MJ, Uusimaa P, van Ginneken MM, Janssen JP, Linnaluoto M. Remote monitoring of implantable cardioverter defibrillator patients: a safe, time-saving, and cost-effective means for follow-up. Europace 2008 Oct;10(10):1145-1151 [FREE Full text] [doi: 10.1093/europace/eun203] [Medline: 18703585]
12. Bogyi P, Vamos M, Bari Z, Polgar B, Muk B, Nyolczas N, et al. Association of remote monitoring with survival in heart failure patients undergoing cardiac resynchronization therapy: retrospective observational study. J Med Internet Res 2019 Jul 26;21(7):e14142 [FREE Full text] [doi: 10.2196/14142] [Medline: 31350836]
13. Dario C, Delise P, Gubian L, Saccavini C, Brandolino G, Mancin S. Large controlled observational study on remote monitoring of pacemakers and implantable cardiac defibrillators: a clinical, economic, and organizational evaluation. Interact J Med Res 2016 Jan 13;5(1):e4 [FREE Full text] [doi: 10.2196/ijmr.4270] [Medline: 26764170]
14. Cronin EM, Ching EA, Varma N, Martin DO, Wilkoff BL, Lindsay BD. Remote monitoring of cardiovascular devices: a time and activity analysis. Heart Rhythm 2012 Dec;9(12):1947-1951. [doi: 10.1016/j.hrthm.2012.08.002] [Medline: 22864266]
15. Varma N, Michalski J, Stambler B, Pavri BB, TRUST Investigators. Superiority of automatic remote monitoring compared with in-person evaluation for scheduled ICD follow-up in the TRUST trial - testing execution of the recommendations. Eur Heart J 2014 May 21;35(20):1345-1352 [FREE Full text] [doi: 10.1093/eurheartj/ehu066] [Medline: 24595864]
16. Mabo P, Victor F, Bazin P, Ahres S, Babuty D, Da CA, et al. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial). Eur Heart J 2012 May;33(9):1105-1111 [FREE Full text] [doi: 10.1093/eurheartj/ehr419] [Medline: 22127418]

17. Calò L, Gargaro A, De RE, Palozzi G, Sciarra L, Rebecchi M, et al. Economic impact of remote monitoring on ordinary follow-up of implantable cardioverter defibrillators as compared with conventional in-hospital visits. A single-center prospective and randomized study. J Interv Card Electrophysiol 2013 Jun;37(1):69-78. [doi: 10.1007/s10840-013-9783-9] [Medline: 23515883]
18. Guédon-Moreau L, Lacroix D, Sadoul N, Clémenty J, Kouakam C, Hermida J, ECOST Trial Investigators. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. Eur Heart J 2013 Feb;34(8):605-614 [FREE Full text] [doi: 10.1093/eurheartj/ehs425] [Medline: 23242192]
19. Heidbuchel H, Hindricks G, Broadhurst P, Van Erven L, Fernandez-Lozano I, Rivero-Ayerza M, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net financial impact of follow-up with or without remote monitoring. Eur Heart J 2015 Jan 14;36(3):158-169 [FREE Full text] [doi: 10.1093/eurheartj/ehu339] [Medline: 25179766]
20. Boriani G, Da CA, Quesada A, Ricci RP, Favale S, Boscolo G, MORE-CARE Study Investigators. Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial. Eur J Heart Fail 2017 Mar;19(3):416-425. [doi: 10.1002/ejhf.626] [Medline: 27568392]
21. Van Heel L, Seiler A, Cirocco T, Bayer J, Epstein LM, Kalenderian D, et al. Characterization of patient calls at cardiac device clinic: Economic implications and opportunities for improved efficiency. Circulation 2019;140:A11847 [FREE Full text]
22. Facchin D, Baccillieri MS, Gasparini G, Zoppo F, Allocca G, Brieda M, et al. Findings of an observational investigation of pure remote follow-up of pacemaker patients: is the in-clinic device check still needed? Int J Cardiol 2016 Oct 01;220:781-786. [doi: 10.1016/j.ijcard.2016.06.162] [Medline: 27394974]
23. Ricci RP, Morichelli L, Santini M. Home monitoring remote control of pacemaker and implantable cardioverter defibrillator patients in clinical practice: impact on medical management and health-care resource utilization. Europace 2008 Feb;10(2):164-170 [FREE Full text] [doi: 10.1093/europace/eum289] [Medline: 18199570]
24. Ricci RP, Morichelli L, D'Onofrio A, Calò L, Vaccari D, Zanotto G, et al. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry. Europace 2013 Jul;15(7):970-977 [FREE Full text] [doi: 10.1093/europace/eus440] [Medline: 23362021]
25. Bashi N, Karunanithi M, Fatehi F, Ding H, Walters D. Remote monitoring of patients with heart failure: an overview of systematic reviews. J Med Internet Res 2017 Jan 20;19(1):e18 [FREE Full text] [doi: 10.2196/jmir.6571] [Medline: 28108430]
26. Albahri OS, Albahri AS, Mohammed KI, Zaidan AA, Zaidan BB, Hashim M, et al. Systematic review of real-time remote health monitoring system in triage and priority-based sensor technology: taxonomy, open challenges, motivation and recommendations. J Med Syst 2018 Mar 22;42(5):80. [doi: 10.1007/s10916-018-0943-4] [Medline: 29564649]
27. Allen M, Kaplon R, Rosemas S. Use of vendor neutral clinic management software to improve cardiac device patient enrollment in remote monitoring. Heart Rhythm 2020;17(5 Suppl):S210 [FREE Full text]
28. Seiler A, Kaplon R, Rosemas S, Allred J. Use of analytics to optimize tachycardia therapy programming. Heart Rhythm 2020;16(5 Suppl):S236 [FREE Full text]
29. Davenport E, Cooper T, Leahy R, Gupta S, Kaplon R, Emig M, et al. Percent biventricular pacing in cardiac resynchronization therapy: is more always better? Heart Rhythm 2011 Sep;8(9):1476-1477 [FREE Full text]
30. Seiler A, Clegg A, Kaplon R, Rosemas S, Allred J. Use of analytics to identify patients with sub-optimal cardiac resynchronization therapy pacing. J Card Fail 2019 Aug;25(8):S5. [doi: 10.1016/j.cardfail.2019.07.542]
31. Ricci RP, Morichelli L. Workflow, time and patient satisfaction from the perspectives of home monitoring. Europace 2013 Jun 04;15 Suppl 1(suppl 1):i49-i53. [doi: 10.1093/europace/eut113] [Medline: 23737231]
32. Guédon-Moreau L, Finat L, Boulé S, Wissocque L, Marquié C, Brigadeau F, et al. Validation of an organizational management model of remote implantable cardioverter-defibrillator monitoring alerts. Circ Cardiovasc Qual Outcomes 2015 Jul;8(4):403-412. [doi: 10.1161/CIRCOUTCOMES.114.001433] [Medline: 26105725]
33. Massey A, May P, Murphy C, Norman A, Reid C, Robinson A, et al. Clinician time required to complete in-person and remote cardiac device evaluations. Heart Rhythm 2019:A [FREE Full text]
34. Cleland JG, Clark RA, Pellicori P, Inglis SC. Caring for people with heart failure and many other medical problems through and beyond the COVID-19 pandemic: the advantages of universal access to home telemonitoring. Eur J Heart Fail 2020 Jun;22(6):995-998 [FREE Full text] [doi: 10.1002/ejhf.1864] [Medline: 32385954]
35. Gorodeski EZ, Goyal P, Cox ZL, Thibodeau JT, Reay RE, Rasmusson K, et al. Virtual visits for care of patients with heart failure in the era of COVID-19: a statement from the Heart Failure Society of America. J Card Fail 2020 Jul;26(6):448-456 [FREE Full text] [doi: 10.1016/j.cardfail.2020.04.008] [Medline: 32315732]
36. Giannola G, Torcivia R, Airò Farulla R, Cipolla T. Outsourcing the remote management of cardiac implantable electronic devices: medical care quality improvement project. JMIR Cardio 2019 Dec 18;3(2):e9815 [FREE Full text] [doi: 10.2196/cardio.9815] [Medline: 31845898]

Abbreviations

CIED: cardiac implantable electronic device
CRT: cardiac resynchronization therapy
HRS: Heart Rhythm Society
ICD: implantable cardioverter-defibrillator
ICM: insertable cardiac monitor
RM: remote monitoring

Edited by G Eysenbach; submitted 04.02.21; peer-reviewed by G Boriani, M von Wagner; comments to author 09.03.21; revised version received 02.04.21; accepted 31.05.21; published 15.10.21.

Please cite as:
Seiler A, Biundo E, Di Bacco M, Rosemas S, Nicolle E, Lanctin D, Hennion J, de Melis M, Van Heel L
Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation
JMIR Cardio 2021;5(2):e27720
URL: https://cardio.jmir.org/2021/2/e27720
doi:10.2196/27720
PMID:34156344

Short Paper

Initial Outcomes of CardioClick, a Telehealth Program for Preventive Cardiac Care: Observational Study

Neil M Kalwani[1,2,3*], MD, MPP; Austin N Johnson[4*], BS; Vijaya Parameswaran[1], MS; Rajesh Dash[1,2], MD, PhD; Fatima Rodriguez[1,2], MD, MPH

[1]Division of Cardiovascular Medicine, Department of Medicine, Stanford University School of Medicine, Stanford, CA, United States

[2]Cardiovascular Institute, Stanford University School of Medicine, Stanford, CA, United States

[3]Department of Health Policy, Stanford University School of Medicine, Stanford, CA, United States

[4]Stanford University School of Medicine, Stanford, CA, United States

[*]these authors contributed equally

Corresponding Author:
Neil M Kalwani, MD, MPP
Division of Cardiovascular Medicine
Department of Medicine
Stanford University School of Medicine
Encina Commons, MC 6019
615 Crothers Way, #203
Stanford, CA, 94305-6006
United States
Phone: 1 650 723 6661
Email: nkalwani@stanford.edu

Abstract

Background: Telehealth use has increased in specialty clinics, but there is limited evidence on the outcomes of telehealth in primary cardiovascular disease (CVD) prevention.

Objective: The objective of this study was to evaluate the initial outcomes of CardioClick, a telehealth primary CVD prevention program.

Methods: In 2017, the Stanford South Asian Translational Heart Initiative (a preventive cardiology clinic focused on high-risk South Asian patients) introduced CardioClick, which is a clinical pathway replacing in-person follow-up visits with video visits. We assessed patient engagement and changes in CVD risk factors in CardioClick patients and in a historical in-person cohort from the same clinic.

Results: In this study, 118 CardioClick patients and 441 patients who received in-person care were included. CardioClick patients were more likely to complete the clinic's CVD prevention program (76/118, 64.4% vs 173/441, 39.2%, respectively; $P<.001$) and they did so in lesser time (mean, 250 days vs 307 days, respectively; $P<.001$) than the patients in the historical in-person cohort. Patients who completed the CardioClick program achieved reductions in CVD risk factors, including blood pressure, lipid concentrations, and BMI, which matched or exceeded those observed in the historical in-person cohort.

Conclusions: Telehealth can be used to deliver care effectively in a preventive cardiology clinic setting and may result in increased patient engagement. Further studies on telehealth outcomes are needed to determine the optimal role of virtual care models across diverse preventive medicine clinics.

(JMIR Cardio 2021;5(2):e28246) doi:10.2196/28246

KEYWORDS

telehealth; telemedicine; digital health; eHealth; preventive medicine; prevention; outpatient care; cardiovascular disease; cardiology; South Asian

Introduction

The COVID-19 pandemic has accelerated the adoption of telehealth and will likely lead to the permanent inclusion of virtual care delivery models in health care systems [1-3]. Cardiovascular disease (CVD) is the leading cause of death in the United States, and as such, it is critical to understand the impact of telehealth on CVD prevention [4]. There are many barriers to in-person care in preventive cardiology clinics, including travel time and the economic costs of time taken off from work for appointments [5,6]. These barriers along with limited engagement among asymptomatic patients with high CVD risk often lead to forgoing of preventive care [7]. Telehealth offers a mechanism to address these barriers [8,9].

Previous studies have suggested that telehealth is as effective as traditional in-office visits in improving the control of chronic diseases such as diabetes [10]. Telehealth adaptation for CVD prevention has been limited but has yielded promising results [11]. Telehealth programs for *secondary* prevention of CVD have achieved equal or superior reductions in risk factors when compared to those achieved in traditional in-person clinics and cardiac rehabilitation [12-14]. Evidence supporting the efficacy of telehealth in *primary* CVD prevention, however, is less conclusive. A randomized controlled trial of a web-based lifestyle intervention for patients with familial hypercholesterolemia did not find significant improvements in CVD risk factors, and a meta-analysis evaluating telehealth in primary CVD prevention concluded that there was insufficient evidence to determine its effectiveness [15,16].

There is some evidence that substituting telehealth visits for in-person visits in preventive cardiology clinics may be effective. An observational evaluation of clinic-based telehealth follow-up visits for CVD risk reduction in remote Saskatchewan, Canada found increased visit completions and similar risk reductions with telehealth as compared to that with usual care, but this study included only 9 patients in the intervention arm [17]. Further research is needed to evaluate telehealth care models in primary CVD prevention. In this study, we describe the early results of CardioClick, a novel telehealth CVD prevention program launched in 2017 in the Stanford South Asian Translational Heart Initiative (SSATHI), a preventive cardiology clinic focused on high-risk South Asian patients based at Stanford Health Care in Northern California.

Methods

The SSATHI clinic consists of a multidisciplinary care team of cardiologists, an insulin resistance specialist, and registered dieticians. Patients enrolled in the SSATHI prevention program complete initial visits and 2 follow-up visits with a physician and a dietician. Patients undergo a comprehensive risk assessment, including an advanced cardiometabolic panel comprising lipid subfraction, inflammatory markers, lipoprotein(a), and apolipoprotein B/A1 ratio tests. Patients then receive personalized treatment focused on intensive risk reduction through lifestyle interventions and pharmacotherapy, including treatment of hypertension and hyperlipidemia as per the American College of Cardiology and American Heart Association guidelines. Dieticians act as lifestyle intervention specialists in the areas of Nutrition and metabolism, Exercise, Sleep, Transcend stress management (NEST) and medication adherence. A lifestyle questionnaire is administered at the beginning and the end of the program. Based on questionnaire responses, cardiometabolic risk factors, and patient engagement, culturally tailored lifestyle recommendations are provided at each visit. Program completion is defined as completion of baseline and follow-up laboratory tests and at least 2 physician and dietician visits.

In 2017, CardioClick, a novel telehealth clinical pathway, was implemented in SSATHI. Patients enrolled in CardioClick participated in the same prevention program as traditional SSATHI patients, but all follow-up visits with physicians and dieticians were provided as video visits rather than in-person visits (Figure S1 in Multimedia Appendix 1). Patients aged 18-63 years were eligible, limiting enrollees to those with private insurance, as Medicare did not reimburse for video visits at the time. All eligible SSATHI patients were consented for enrollment in CardioClick by default. If they did not wish to enroll, they were offered traditional in-person care. Health care providers were trained to use the video visit platform. Patient access to video visits was enabled through the Stanford Health Care MyHealth mobile app. Patients could complete video visits from a smartphone, tablet, or computer workstation.

The demographic and clinical data for the cohort of CardioClick patients and a historical cohort of patients enrolled in the in-person SSATHI prevention program were manually extracted from the electronic medical records. Patients included in the historical in-person cohort were limited to those aged 18-63 years. Both cohorts included all patients enrolled sequentially between May 2017 and February 2019 for CardioClick and between January 2014 and July 2019 for the historical in-person cohort. Video and in-person physician and dietician follow-up visits were scheduled by the same clinic coordinator at the time of the initial visit or subsequently by phone. All follow-up visits were scheduled for 30-minute slots and were delivered by the same group of physicians and dieticians for both cohorts.

Statistical analyses were completed using SPSS Statistics package (IBM Corp). Unpaired two-tailed *t* tests were used to compare the baseline continuous variables, and chi-square tests were used to compare the categorical variables. Paired two-tailed *t* tests were used to assess within cohort changes in CVD risk factors at follow-up, and unpaired two-tailed *t* tests were used to compare changes between cohorts. *P* values less than .05 were deemed statistically significant. This study was approved by the Stanford Institutional Review Board.

Results

The CardioClick cohort consisted of 118 patients and the historical in-person cohort consisted of 441 patients. CardioClick patients were older (43 years vs 41 years, respectively; *P*=.009) and had lower baseline triglyceride levels (113 mg/dL vs 134 mg/dL, respectively; *P*=.01) than the in-person cohort patients. The cohorts were otherwise similar in terms of demographics, comorbidities, and baseline CVD risk factors (Table 1).

Table 1. Baseline characteristics and completion rates of the preventive cardiac care program.

Characteristics	CardioClick cohort (n=118)	Historical in-person cohort (n=441)	*P* value[a]
Age (years), mean (SD)	43 (9)	41 (9)	.009
Gender (male), n (%)	94 (79.7)	375 (85.0)	.66
Diabetes, n (%)	9 (7.6)	43 (9.8)	.48
Hypertension, n (%)	31 (26.3)	101 (22.9)	.47
Smoker, n (%)	24 (20.3)	93 (21.1)	.86
Systolic blood pressure (mm Hg), mean (SD)	124 (13)	124 (15)	.79
Diastolic blood pressure (mm Hg), mean (SD)	78 (10)	80 (9)	.30
Total cholesterol (mg/dL), mean (SD)	185 (43)	193 (46)	.09
Low-density lipoprotein cholesterol (mg/dL), mean (SD)[b]	119 (40)	124 (40)	.18
High-density lipoprotein cholesterol (mg/dL), mean (SD)	48 (14)	48 (13)	.84
Triglycerides (mg/dL), mean (SD)	113 (61)	134 (78)	.01
Hemoglobin A_{1c} (%), mean (SD)[b]	5.7 (0.7)	5.7 (0.9)	.61
BMI (kg/m^2), mean (SD)	27 (4)	27 (4)	.27
Completed program, n (%)	76 (64.4)	173 (39.2)	<.001

[a]*P* values are for between-group comparisons.

[b]Reported for only those patients for whom data were available.

With the introduction of CardioClick, patients were significantly more likely to complete the clinic's prevention program (76/118, 64.4% vs 173/441, 39.2%, respectively; *P*<.001) and they did so in lesser time (mean 250 days vs 307 days, respectively; *P*<.001) than the in-person cohort patients. CardioClick patients were also more likely to utilize clinic services. Of the 3 dietician visits offered, the typical CardioClick patient completed all 3 visits, while the typical patient in the historical in-person cohort only completed 1 visit. Patients who completed CardioClick experienced significant reductions in CVD risk factors, including systolic and diastolic blood pressure, total cholesterol levels, low-density lipoprotein cholesterol levels, triglyceride levels, and BMI (*P*<.001 for all) (Figure 1). In contrast, there was no reduction in BMI observed among patients who completed the prevention program in the historical in-person cohort, and the observed reduction in total cholesterol levels for these patients was lower than that observed in CardioClick patients (–19 mg/dL vs –33 mg/dL, respectively; *P*=.02). Reductions in other risk factors were not significantly different between patients completing the prevention program in the 2 cohorts (Table 2).

Figure 1. Percentage change in the cardiovascular disease risk factors in CardioClick patients at the completion of the preventive cardiac care program. The changes in all the cardiovascular disease risk factors, except HbA_{1c}, were statistically significant at $P<.05$. BP: blood pressure; HbA_{1c}: hemoglobin A_{1c}; LDL-C: low-density lipoprotein cholesterol.

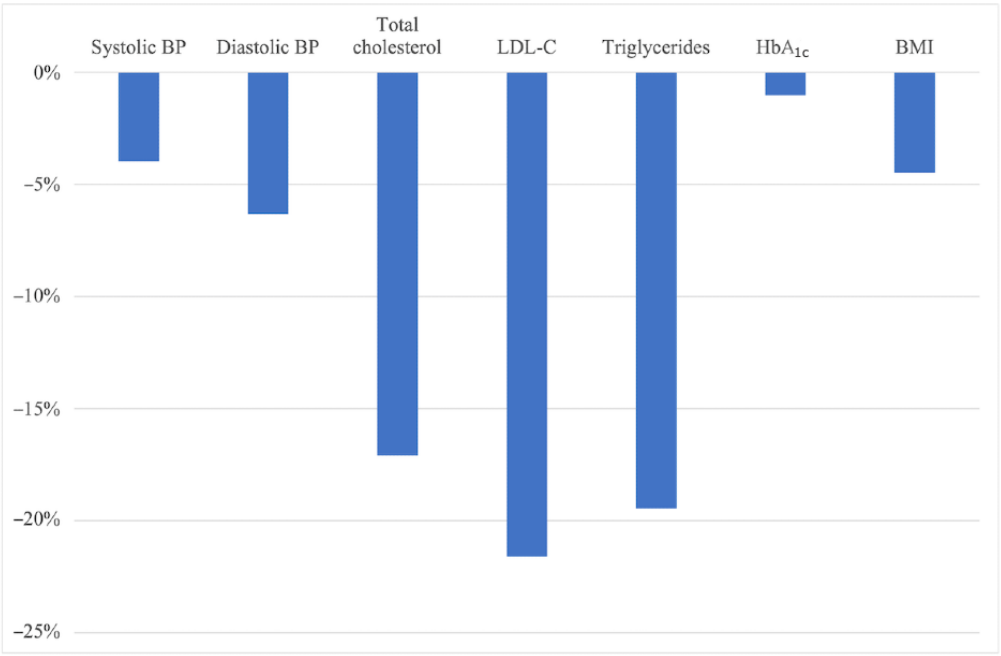


Table 2. Changes in the cardiovascular disease risk factors at the completion of the preventive cardiac care program.

Risk factors	CardioClick cohort (n=76)				Historical in-person cohort (n=173)				Comparison of change between cohorts, *P* value
	Baseline	Follow-up	Change	Within cohort, *P* value	Baseline	Follow-up	Change	Within cohort, *P* value	
Systolic blood pressure (mm Hg), mean (SD)	126 (17)	121 (13)	–5 (11)	<.001	128 (15)	125 (13)	–3 (13)	.005	.24
Diastolic blood pressure (mm Hg), mean (SD)	79 (10)	74 (9)	–5 (11)	<.001	81 (10)	79 (8)	–2 (10)	.009	.05
Total cholesterol (mg/dL), mean (SD)	193 (41)	160 (38)	–33 (45)	<.001	190 (47)	171 (43)	–19 (44)	<.001	.02
Low-density lipoprotein cholesterol (mg/dL), mean (SD)[a]	125 (36)	98 (33)	–27 (40)	<.001	121 (39)	104 (37)	–17 (38)	<.001	.06
High-density lipoprotein cholesterol (mg/dL), mean (SD)	50 (14)	49 (11)	–1 (8)	.22	48 (14)	49 (14)	0.8 (7)	.11	.08
Triglycerides (mg/dL), mean (SD)	113 (55)	91 (40)	–22 (44)	<.001	135 (83)	112 (67)	–23 (82)	<.001	.92
Hemoglobin A_{1c} (%), mean (SD)[a]	5.8 (0.6)	5.8 (0.5)	–0.1 (0.5)	.52	6.0 (1.0)	5.9 (0.1)	–0.1 (0.5)	.23	.86
BMI (kg/m^2), mean (SD)	26.8 (4)	25.6 (3)	–1.2 (1.2)	<.001	26.7 (3.7)	26.7 (4.7)	0.01 (3.5)	.96	.004

[a]Reported only for those patients for whom data were available.

Discussion

Principal Findings

The use of telehealth has rapidly expanded as a result of the COVID-19 pandemic; however, there has been limited and inconclusive evidence on the effectiveness of telehealth in primary CVD prevention [11,15]. The initial results of CardioClick presented here precede the COVID-19 pandemic and suggest that telehealth is an effective way for delivering preventive cardiac care and may enhance patient engagement. Following implementation, CardioClick became the default

care pathway in the SSATHI clinic. We found that CardioClick patients were similar demographically and clinically to a historical cohort of SSATHI patients who received in-person care, suggesting against significant selection bias in enrollment. Importantly, patients in both cohorts were treated by the same group of health care providers using the same prevention program framework.

CardioClick patients completed the prevention program at a higher rate and in a shorter amount of time on average, suggesting that telehealth may decrease barriers to care in settings with readily available in-person specialty care and not just in low-access settings, as has been demonstrated previously [18]. We found that CardioClick participants who completed the prevention program achieved reductions in CVD risk factors, including blood pressure, lipid concentrations, and BMI, which matched or exceeded the reductions observed in the historical in-person cohort. Notably, the reductions in blood pressure achieved exceed those previously reported in the literature for several telehealth primary prevention lifestyle interventions [11,15,16].

To our knowledge, this study represents the first evaluation of a telehealth care model for primary CVD prevention in a clinic setting with patients completing visits from home. The risk factor reductions observed support the continued use of telehealth in preventive medicine clinics and motivate further study of its impact on care delivery and outcomes.

Limitations

This study should be interpreted in the context of several limitations. The intervention was implemented at a single center with a patient population that was majority male, middle-aged, and of South Asian origin. It is unclear whether the observed reductions in CVD risk factors would be generalizable to diverse patient populations. Although patients were enrolled in CardioClick by default, there may exist unobserved differences between the cohorts, which accounted for the observed differences in the outcomes. Finally, it is unknown whether the risk factor reductions achieved will be sustained in long-term follow-up.

Conclusions

Implementation of CardioClick, a clinic-based telehealth primary CVD prevention program, was associated with increased patient engagement and significant reductions in risk factors among those completing the program. The success of this initiative suggests that telehealth can be utilized to deliver care effectively in the preventive cardiology clinic setting. Further research is needed assessing telehealth outcomes with randomized evaluations across diverse patient populations.

Acknowledgments

NMK is funded by a grant from the Agency for Healthcare Research and Quality (Rockville, MD; T32HS026128). FR is funded by a career development award from the National Heart, Lung, and Blood Institute (K01 HL144607 01) and the American Heart Association/Robert Wood Johnson Harold Amos Medical Faculty Development Program. RD is funded by a Stanford Cardiovascular Institute seed grant and the Kothari Family Fund. These sponsors played no role in the study design, data analysis, manuscript preparation, or the decision to submit for publication.

Conflicts of Interest

VP, RD, and FR were involved in the development of CardioClick.

Multimedia Appendix 1
CardioClick prevention program overview.
[PNG File , 48 KB - cardio_v5i2e28246_app1.png]

References

1. Bokolo Anthony Jnr. Use of Telemedicine and Virtual Care for Remote Treatment in Response to COVID-19 Pandemic. J Med Syst 2020 Jun 15;44(7):132 [FREE Full text] [doi: 10.1007/s10916-020-01596-5] [Medline: 32542571]
2. Mills EC, Savage E, Lieder J, Chiu ES. Telemedicine and the COVID-19 Pandemic: Are We Ready to Go Live? Adv Skin Wound Care 2020 Aug;33(8):410-417 [FREE Full text] [doi: 10.1097/01.ASW.0000669916.01793.93] [Medline: 32701252]
3. Ben-Pazi H, Beni-Adani L, Lamdan R. Accelerating Telemedicine for Cerebral Palsy During the COVID-19 Pandemic and Beyond. Front Neurol 2020;11:746 [FREE Full text] [doi: 10.3389/fneur.2020.00746] [Medline: 32670193]
4. Benjamin EJ, Virani SS, Callaway CW, Chamberlain AM, Chang AR, Cheng S, American Heart Association Council on Epidemiology Prevention Statistics Committee Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2018 Update: A Report From the American Heart Association. Circulation 2018 Mar 20;137(12):e67-e492. [doi: 10.1161/CIR.0000000000000558] [Medline: 29386200]
5. Gaziano TA. Lifestyle and Cardiovascular Disease: More Work to Do. J Am Coll Cardiol 2017 Mar 07;69(9):1126-1128 [FREE Full text] [doi: 10.1016/j.jacc.2016.12.019] [Medline: 28254174]
6. Eckel RH. Preventive Cardiology by Lifestyle Intervention: Opportunity and/or Challenge. Circulation 2006 Jun 06;113(22):2657-2661. [doi: 10.1161/circulationaha.106.175744]

7. de Waard AM, Wändell PE, Holzmann MJ, Korevaar JC, Hollander M, Gornitzki C, SPIMEU Research Group. Barriers and facilitators to participation in a health check for cardiometabolic diseases in primary care: A systematic review. Eur J Prev Cardiol 2018 Aug;25(12):1326-1340 [FREE Full text] [doi: 10.1177/2047487318780751] [Medline: 29916723]
8. Schwamm LH, Chumbler N, Brown E, Fonarow GC, Berube D, Nystrom K, American Heart Association Advocacy Coordinating Committee. Recommendations for the Implementation of Telehealth in Cardiovascular and Stroke Care: A Policy Statement From the American Heart Association. Circulation 2017 Feb 14;135(7):e24-e44. [doi: 10.1161/CIR.0000000000000475] [Medline: 27998940]
9. Pearl R. Kaiser Permanente Northern California: current experiences with internet, mobile, and video technologies. Health Aff (Millwood) 2014 Feb;33(2):251-257. [doi: 10.1377/hlthaff.2013.1005] [Medline: 24493768]
10. Levin K, Madsen JR, Petersen I, Wanscher CE, Hangaard J. Telemedicine diabetes consultations are cost-effective, and effects on essential diabetes treatment parameters are similar to conventional treatment: 7-year results from the Svendborg Telemedicine Diabetes Project. J Diabetes Sci Technol 2013 May 01;7(3):587-595 [FREE Full text] [doi: 10.1177/193229681300700302] [Medline: 23759390]
11. Widmer RJ, Collins NM, Collins CS, West CP, Lerman LO, Lerman A. Digital health interventions for the prevention of cardiovascular disease: a systematic review and meta-analysis. Mayo Clin Proc 2015 Apr;90(4):469-480 [FREE Full text] [doi: 10.1016/j.mayocp.2014.12.026] [Medline: 25841251]
12. Neubeck L, Redfern J, Fernandez R, Briffa T, Bauman A, Freedman SB. Telehealth interventions for the secondary prevention of coronary heart disease: a systematic review. Eur J Cardiovasc Prev Rehabil 2009 Jun;16(3):281-289. [doi: 10.1097/HJR.0b013e32832a4e7a] [Medline: 19407659]
13. Frederix I, Hansen D, Coninx K, Vandervoort P, Vandijck D, Hens N, et al. Medium-Term Effectiveness of a Comprehensive Internet-Based and Patient-Specific Telerehabilitation Program With Text Messaging Support for Cardiac Patients: Randomized Controlled Trial. J Med Internet Res 2015 Jul 23;17(7):e185 [FREE Full text] [doi: 10.2196/jmir.4799] [Medline: 26206311]
14. Hanlon P, Daines L, Campbell C, McKinstry B, Weller D, Pinnock H. Telehealth Interventions to Support Self-Management of Long-Term Conditions: A Systematic Metareview of Diabetes, Heart Failure, Asthma, Chronic Obstructive Pulmonary Disease, and Cancer. J Med Internet Res 2017 May 17;19(5):e172 [FREE Full text] [doi: 10.2196/jmir.6688] [Medline: 28526671]
15. Merriel SWD, Andrews V, Salisbury C. Telehealth interventions for primary prevention of cardiovascular disease: a systematic review and meta-analysis. Prev Med 2014 Jul;64:88-95 Erratum in: Prev Med. [doi: 10.1016/j.ypmed.2014.04.001] [Medline: 24726502]
16. Broekhuizen K, van Poppel MN, Koppes LL, Kindt I, Brug J, van Mechelen W. No significant improvement of cardiovascular disease risk indicators by a lifestyle intervention in people with familial hypercholesterolemia compared to usual care: results of a randomised controlled trial. BMC Res Notes 2012 Jul 04;5:181 [FREE Full text] [doi: 10.1186/1756-0500-5-181] [Medline: 22490761]
17. PausJenssen AM, Spooner BA, Wilson MP, Wilson TW. Cardiovascular risk reduction via telehealth: A feasibility study. Canadian Journal of Cardiology 2008 Jan;24(1):57-60. [doi: 10.1016/s0828-282x(08)70550-6]
18. Vilme H, Duke NN, Muiruri C, Wordlaw L, Skinner AC. Using Telehealth to Disseminate Primary, Secondary, and Tertiary CVD Interventions to Rural Populations. Curr Hypertens Rep 2019 Nov 07;21(12):92. [doi: 10.1007/s11906-019-0998-8] [Medline: 31701257]

Abbreviations

CVD: cardiovascular disease
NEST: Nutrition and metabolism, Exercise, Sleep, Transcend stress management
SSATHI: Stanford South Asian Translational Heart Initiative

Edited by G Eysenbach; submitted 27.02.21; peer-reviewed by E van der Velde, O Joel, J Vilaplana; comments to author 31.05.21; revised version received 26.07.21; accepted 03.08.21; published 09.09.21.

Please cite as:
Kalwani NM, Johnson AN, Parameswaran V, Dash R, Rodriguez F
Initial Outcomes of CardioClick, a Telehealth Program for Preventive Cardiac Care: Observational Study
JMIR Cardio 2021;5(2):e28246
URL: https://cardio.jmir.org/2021/2/e28246
doi:10.2196/28246
PMID:34499037

Original Paper

Experiences and Perceptions of Patients and Providers Participating in Remote Titration of Heart Failure Medication Facilitated by Telemonitoring: Qualitative Study

Veronica Artanian[1], MSc; Patrick Ware[2], MPH, PhD; Valeria E Rac[1,3,4], MD, PhD; Heather J Ross[4,5,6], MHSc, MD; Emily Seto[1,2], PhD, PEng

[1]Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

[2]Centre for Global eHealth Innovation, Techna Institute, University Health Network, Toronto, ON, Canada

[3]Program for Health System and Technology Evaluation, Toronto General Hospital Research Institute, University Health Network, Toronto, ON, Canada

[4]Ted Rogers Centre for Heart Research, Peter Munk Cardiac Centre, University Health Network, Toronto, ON, Canada

[5]Toronto General Hospital Research Institute, University Health Network, Toronto, ON, Canada

[6]Department of Medicine, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Veronica Artanian, MSc
Institute of Health Policy, Management and Evaluation
Dalla Lana School of Public Health
University of Toronto
155 College St
Toronto, ON, M5T 3M6
Canada
Phone: 1 6 978 4326
Email: art.vt@outlook.com

Abstract

Background: Guideline-directed medical therapy (GDMT), optimized to target doses, improves health outcomes in patients with heart failure. However, GDMT remains underused, with <25% of patients receiving target doses in clinical practice. A randomized controlled trial was conducted at the Peter Munk Cardiac Centre in Toronto to compare a remote GDMT titration intervention with standard in-office titration. This randomized controlled trial found that remote titration increased the proportion of patients who achieved optimal GDMT doses, decreased the time to dose optimization, and reduced the number of essential clinic visits. This paper presents findings from the qualitative component of the mixed methods study, which evaluated the implementation of the remote titration intervention.

Objective: The objective of the qualitative component is to assess the perceptions and experiences of clinicians and patients with heart failure who participated in the remote titration intervention to identify factors that affected the implementation of the intervention.

Methods: We conducted semistructured interviews with clinicians (n=5) and patients (n=11) who participated in the remote titration intervention. Questions probed the experiences of the participants to identify factors that can serve as barriers and facilitators to its implementation. Conventional content analysis was first used to analyze the interviews and gain direct information based on the participants' unique perspectives. Subsequently, the generated themes were delineated and mapped following a multilevel framework.

Results: Patients and clinicians indicated that the intervention was easy to use, integrated well into their routines, and removed practical barriers to titration. Key implementation facilitators from the patients' perspective included the reduction in clinic visits and daily monitoring of their condition, whereas clinicians emphasized the benefits of rapid drug titration and efficient patient management. Key implementation barriers included the resources necessary to support the intervention and lack of physician remuneration.

Conclusions: This study presents results from a real-world implementation assessment of remote titration facilitated by telemonitoring. It is among the first to provide insight into the perception of the remote titration process by clinicians and patients. Our findings indicate that the relative advantages that remote titration presents over standard care strongly appeal to both clinicians

and patients. However, to ensure uptake and adherence, it is important to ensure that suitable patients are enrolled and the impact on the physicians' workload is minimized. The implementation of remote titration is now more critical than ever, as it can help provide access to care for patients during times when physical distancing is required.

Trial Registration: ClinicalTrials.gov NCT04205513; https://clinicaltrials.gov/ct2/show/NCT04205513

International Registered Report Identifier (IRRID): RR2-10.2196/19705

(JMIR Cardio 2021;5(2):e28259) doi:10.2196/28259

KEYWORDS

telemonitoring; remote; titration; monitoring; mHealth; heart failure; qualitative; mobile phone

Introduction

Heart failure (HF) is a common diagnosis affecting at least 26 million people worldwide [1]. It is associated with poor clinical outcomes and high use of health care resources. Large-scale randomized controlled trials (RCTs) have demonstrated that guideline-directed medical therapy (GDMT), optimized to maximal tolerated doses, improves clinical outcomes in patients with HF [2]. However, in clinical practice, large registries confirm that GDMTs are underused, and management of HF tends to fall short when it comes to dose optimization [3,4].

Patient-related factors such as time constraints and financial limitations, physician-related issues such as knowledge of drug therapy optimization, or institution-related logistical issues surrounding clinic visits often complicate the titration process [2,5]. These factors present barriers to timely optimization of vital therapy for patients with HF, which are particularly detrimental, as delays in therapy can lead to significant disease progression that may have been preventable [6].

Telemonitoring is a potential component in the management of HF that allows patients to remotely provide reliable and real-time physiological data for clinical decision support. As such, telemonitoring could be used to facilitate remote titration of HF medications by health care providers. Meta-analyses of telemonitoring studies indicate that telemonitoring has a positive impact on HF outcomes, such as mortality and hospitalizations [7-9], while qualitative assessments of telemonitoring interventions and their acceptance reveal that both patients and clinicians view telemonitoring as efficacious and useful [10-12]. Research on remote titration of HF medications is somewhat limited; however, the results of previous studies indicate that remote titration could be leveraged to garner improvements in GDMT optimization [13-17].

A pilot RCT was conducted at the Peter Munk Cardiac Centre (PMCC), University Health Network (UHN), in Toronto, between January and December 2019. The trial enrolled 42 patients and compared a remote titration intervention, facilitated by telemonitoring data, with standard in-office titration. Within 6 months of enrollment, 86% (18/21) of patients in the intervention group achieved optimal doses versus only 48% (10/21) of patients in the control group. The median time to dose optimization was 7.8 weeks lower in the intervention group, and the number of in-person visits was reduced by 54.5% [18]. The purpose of this paper is to describe a qualitative study that assessed the perceptions and experiences of clinicians and patients with HF participating in the remote titration intervention to identify barriers and facilitators that impact its implementation. The full study protocol and the results of the pilot have been published separately [18,19].

Methods

Study Overview

This paper discusses the qualitative component of a mixed methods study aiming to evaluate the effectiveness and implementation of remote titration facilitated by telemonitoring. The study consisted of a pilot RCT and a qualitative study with a purposive sample of participants.

The study was registered on ClinicalTrials.gov (NCT04205513) and received approval from the research ethics boards (REBs) of the University of Toronto (REB number 00036655) and the UHN (REB number 18-5351), where patients were recruited and patient data were stored.

Study Design

The study was conducted in a Heart Function Clinic (HFC) at PMCC. The RCT compared a remote titration strategy, which used data from a smartphone-based telemonitoring system versus a standard titration program consisting of in-office visits. The qualitative study consisted of semistructured interviews conducted with clinicians and patients allocated to the intervention arm during the RCT.

Medly Telemonitoring Program

Medly, a telemonitoring program for patients with HF launched at UHN in 2016, was chosen to facilitate remote medication titration in this study. Medly enables patients to take daily clinically relevant physiological measurements with wireless home medical devices in addition to answering symptom questions through a mobile app. The measurements are transmitted to the mobile phone and then to a data server. If there are signs of their status deteriorating, an individualized alert generated through a rule-based algorithm is sent to a clinician at the HFC through an email. Clinicians are also able to view alerts and their patients' telemonitoring data through a secure web portal. Studies performed to evaluate Medly found improvements in patient health outcomes, as well as high patient and clinician satisfaction [20-22].

Remote Titration Intervention

Data reported via Medly were used to perform medication changes every 2 weeks through communication between the nurse coordinator and patients over the phone. Details regarding

the remote titration process can be found in the papers outlining the study protocol and the results of the pilot RCT [18,19].

Study Population

A subset of patients randomized into the intervention group and all the clinicians participating in the remote titration program were invited to participate in individual interviews intended to assess their experiences and perceptions of the program on titration completion. Maximum variation sampling [23] was used to select patients representing a range of experiences with the intervention. The patient participants included men and women varying in age, patients who resided at different distances from the clinic, and a patient who chose to withdraw from the intervention.

Data Collection

Semistructured one-on-one interviews were conducted with patients and clinicians. Interview guides were designed to explore participants' views on various aspects of the remote titration program. The Chaudoir et al [24] multilevel framework that outlines factors that predict implementation outcomes was broadly used to conceptualize the interview to touch upon the various factors. However, to ensure that generated information was based on the participants' unique perspectives, questions did not follow specific constructs. Instead, participants were asked open-ended questions to obtain a sense of their comfort with the intervention and its delivery, any concerns or difficulties they may have had regarding the intervention, and whether it met their goals and expectations.

Interviews lasted 20-45 minutes and were conducted in a quiet and private space within the clinic or over the telephone, depending on the preference of the participant. Before the interview, participants were informed that notes will be taken and that the interviews will be audiotaped for data analysis. Interviews were transcribed verbatim.

Data Analysis

Conventional content analysis [25] was used to analyze the transcribed interviews and coding was performed via the software NVivo version 12 (QSR International). A conventional approach was selected to gain direct information from study participants, without imposing preconceived categories or theoretical perspectives, and to ensure that knowledge generated from the content analysis is based on the participants' unique perspectives [26].

Specifically, following familiarization with the data, initial codes were generated by 2 researchers (PW and VA) independently, via standard inductive thematic analysis, allowing the categories and codes to flow directly from the collected data [25]. After the initial round of coding, the researchers discussed emerging codes until consensus was reached. The results were reviewed and refined to identify themes reflecting the issues arising from the data set.

Finally, deductive content analysis was used as the final step to frame the analysis. The deductive analysis used existing theory or predetermined categories to guide the content analysis [25]. Specifically, the themes generated through the content analysis were delineated and mapped following the theoretical framework by Chaudoir et al described below [24]. The mapping to the framework was reserved for the last stage to ensure that the full range of themes emerging from the data was captured under the broader constructs.

Theoretical Framework

Technology acceptance frameworks often heavily focus on the technology itself and its users. However, even though some of them have a sociotechnical lens, they tend to omit other levels of complexities brought in when technology is nested within the complex context of an organization and the broader system itself. As our intervention was embedded within the HFC at PMCC, the intent was to explore the full range of factors that impacted its implementation. Furthermore, while many different frameworks address the implementation process and implementation outcomes, there is considerable heterogeneity in the constructs that are included and the operationalization of constructs with the measures available to assess them. Some frameworks examine the impact of a single type of factor, such as constructs related to the individual provider (eg, Transtheoretical Model [27,28]) or constructs related to the organization (eg, Implementation Effectiveness Model [29]), whereas the more recent frameworks include a set of multilevel factors or constructs at micro-, meso-, and macrolevels [30-34].

The Chaudoir et al framework [24] was ultimately selected to guide this research, as in addition to innovation-, provider-, organization- and structural-level factors, it includes the patient-level factor and its related constructs. Patient-level associated constructs, such as patient health literacy, health-relevant beliefs, motivation, and personality traits, impact patients' perceptions of and experiences with the innovation. Thus, this framework, which has been successfully used to guide the evaluation of the largest Canadian heart failure and chronic obstructive pulmonary disease telemonitoring program [12], brings a holistic lens to implementation research, especially for complex interventions.

Results

Participants

Interviews were conducted with 16 participants (N=16), as outlined in Table 1. Of the 8 (n=8) clinicians invited to participate in the interviews, 63% (5/8 clinicians) agreed to participate and 38% (3/8 clinicians) were unavailable owing to scheduling conflicts. The clinicians (5/8, 63%) consisted of the dedicated program nurse, who participated in the project from the planning stages, 2 cardiologists who were early adopters of the intervention, and 2 cardiologists who were late adopters of the intervention, as outlined in Table 1. The patient interviewees (n=11) included 91% (10/11) of patients who completed the remote titration program and 9% (1/11) who requested to discontinue remote medication titration and exit the study; this 1 patient requested to exit the study, as he was not comfortable with performing medication changes over the phone.

Table 1. Overview of clinicians and patients that participated in the semistructured interviews.

Study identifier	Role	Sex	Age (years)	Description
Clinicians				
Clinician 1	Nurse coordinator	Female	N/A[a]	Dedicated program nurse
Clinician 2	Cardiologist	Female	N/A[a]	Early adopter (month 1), under 5 years in practice
Clinician 3	Cardiologist	Female	N/A[a]	Late adopter (month 3), over 10 years in practice
Clinician 4	Cardiologist	Male	N/A[a]	Late adopter (month 4), over 10 years in practice
Clinician 5	Cardiologist	Female	N/A[a]	Early adopter (month 1), under 5 years in practice
Patients				
Patient 1	Patient	Male	59	Greater Toronto Area
Patient 2	Patient	Male	62	Greater Toronto Area
Patient 3	Patient	Female	60	Remote location
Patient 4	Patient	Male	50	Remote location
Patient 5	Patient	Male	46	Remote location
Patient 6	Patient	Male	57	Greater Toronto Area
Patient 7	Patient	Female	37	Greater Toronto Area
Patient 8	Patient	Female	49	Greater Toronto Area
Patient 9	Patient	Male	54	Greater Toronto Area
Patient 10	Patient	Female	55	Remote location
Patient 11	Patient	Female	57	Remote location

[a]N/A: not applicable.

More men (9/16, 55%) than women (7/16, 45%) participated in the interviews. This distribution is in line with the overall population of the RCT. The age range of the patient interviewees was 37 to 62 years, with a higher proportion of patients in their 50s (9/16, 55%). Of 11 patients, 6 (55%) resided in or near the Greater Toronto Area, requiring a commute of 1.5 hours or less to reach the clinic, while the remaining 5 (45%) lived farther away from the clinic requiring a commute of more than 1.5 hours. This sample was representative of the patients attending the UHN HFC. Patients are frequently referred to this particular clinic for a heart transplant or mechanical circulatory support device therapy. Therefore, the clinic treats patients from across the province of Ontario and has a higher-than-average proportion of severely ill patients, including very young patients with HF.

Findings

Overview

Interviews revealed that most participants viewed the program positively and thought that the intervention was successfully implemented. However, some factors that can hinder implementation success were identified as well. Results are summarized in accordance with the 5 levels of the Chaudoir multilevel framework [24]: innovation-, patient-, provider-, organizational-, and structural-level factors.

Innovation-Level Factors

A key aspect of the intervention, which differentiated it from standard care, was that it largely relied on communication via technology. Both patients and clinicians were satisfied with the use of the telephone as the mode of communication for medication titration purposes:

> *[I] have a number for the nurse, and anytime if I want to talk, I can contact her. Like in case we make an increase, and it is not agreeing with me, I can let her know... I can always contact her.* [Patient #11]

The intervention also relied on data that were reported daily by patients, and clinicians found this suitable owing to the comprehensive monitoring that this approach facilitated. All the clinicians believed that the daily measurements provided a reliable and timely reflection of the patients' conditions. Some stated that the intervention made it possible to obtain more comprehensive and accurate data about the patient's well-being than standard care and found that daily data provided the clinicians with a reassurance that their patients were safe:

> *In fact, you can make an argument that it's a more reliable way to know what the effects of your changes are, because, for example, traditionally when you make an adjustment in one of their medications, you get a vital sign assessment in the clinic, you may get the patient to check sometime between now and the next time you see them, or you may not, so I actually found that making adjustments through [the remote titration intervention] and having patients assessed on a daily basis, in their own environment, in many ways was reassuring, as opposed to concerning for the safety components.* [Clinician #2]

The ease of use of the intervention was another topic commented on by both clinicians and patients, encompassing the smooth integration of the intervention into clinical practice and the patient's daily routine. The clinicians who participated in our intervention expressed satisfaction with the intervention process and indicated that it provided a plan that was easy to follow, integrated well with clinic practices, and was not onerous. Patients also found the app straightforward and convenient:

> *It was very well organized. I like the term "slick," so it flows well with your clinic interactions.* [Clinician #3]

> *The app is very straightforward, usually it's very fast. Once you go through it once or twice, it seems quite easy.* [Patient #1]

The intervention also presented a relative advantage over standard care, which served as a significant facilitator. The intervention provided a way to overcome the limitation of clinic space. Several clinicians touched upon the fact that the clinic had to cope with a large volume of patients, which sometimes imposed a limitation on how frequently patients could be seen:

> *I know from my experience that when starting a patient on brand new medication for their heart failure and you bring them into the clinic, no matter how good you are, clinic visits are based on space. It may take you three months to get them anywhere, it just takes longer because of the feasibility of bringing them back, etc.* [Clinician #2]

Perhaps the strongest implementation facilitators from the clinicians' perspective were highlighted by 3 themes associated with the usefulness of the intervention: the ability to perform more titrations, rapid achievement of target doses, and optimization of clinic resources:

> *They have to wait around...that time and that process is of no benefit to them, and the outcome is the same as what Medly Titrate does. And not only that, but you're also potentially not triaging a patient who does require that, so I think...it's like balancing the resources, which is a finite amount of space and time in the clinic, to see the patients who need to be seen and optimize the patients who can be optimized remotely.* [Clinician #5]

Patient-Level Factors

The benefits that patients derived from the intervention played an important role in the uptake of the intervention, while certain individual patient preferences acted as barriers. Primarily, all the patients indicated that they favored the intervention, as it allowed them to avoid clinic visits. Most patients noted that it was preferable, as it eliminated the expenses associated with visits to the hospital. Importantly, 5 patients indicated that they resided too far away from Toronto and would not have been able to attend visits at the required frequency. They were only able to undergo guideline recommended biweekly titrations through the remote titration program:

> *I am about 3 hours away from [the HFC] so the drive down takes a long time, and there's a lot of waiting involved...That was the main reason I wanted to be in the study, so I wouldn't have to come in.* [Patient 4]

Conversely, individual preferences, such as a preference for face-to-face contact, or the lack of desire to perform daily measurements over a prolonged period, highlighted potential barriers to implementation. Notably, 1 patient requested to discontinue remote medication titration and transfer to standard care, as he was not comfortable with performing medication changes over the phone:

> *[I] wait until I see the cardiologist in person and then I start switching the medication. I just don't go ahead and do what they tell me to...the recommendation is made and then I do my research and then I see the doctor in-person, and we talk about it and then we make the decision.* [Patient #9]

In fact, all clinicians noted that the success of the intervention depended on the enrollment of suitable patients. The suitability of the patients depended not only on their medical characteristics and their conformity with the inclusion criteria but also on certain personal traits such as the ability to properly understand the information and instructions that they were receiving and act on them:

> *I think that it's always about the right patient. So, they have to be a patient who has a degree of understanding and being able to follow directions...you can generally tell which patient won't.* [Clinician #2]

Provider-Level Factors

Interviews revealed that the workload associated with the intervention served as a potential barrier to implementation. In our study, the nurse coordinator was responsible for the preparation of reports summarizing the patients' data and condition since the last checkpoint, as well as the implementation of medication changes prescribed by the physicians, and their communication to the patients. This streamlined the physicians' involvement in the intervention. However, several physicians noted that if the nurse coordinator were absent, the intervention became quite time consuming for them, which would present a significant barrier to implementation:

> *I think that on the week that [Medly nurse coordinator] was gone there was quite a bit of extra work, so I think it's super important to have [Medly nurse coordinator], or someone like [Medly nurse coordinator], all the time...it's very time-consuming for us physicians if we don't have somebody to take care of it.* [Clinician #4]

Another provider-level factor impacting implementation was the clinicians' preparedness to implement the intervention. Of the 5 physicians, 2 (40%) indicated that the information that they received in the beginning to help them decide if they wanted to conduct remote titration facilitated by Medly, was sufficiently comprehensive and motivated them to try the intervention:

> *I read the email that was sent, circulated in the beginning about to study...everything that I needed was there, to figure out whether I want to participate and enroll patients, and it had what it was doing, so I was committed to enrolling patients that I thought would benefit from it.* [Clinician #5]

However, 2 physicians pointed to initial uncertainty regarding the way that the intervention would work. This uncertainty impacted their intent to try the intervention in the early stages of the program:

> *I think my initial concern was trying to figure out how it all works. How am I going to remember what the patients are on? ...and how am I going to be prompted to make any changes? …and the format where I get a prompt from the [nurse] coordinator seems to work well.* [Clinician #3]

Organizational- and Structural-Level Factors

The availability of institutional resources in the form of dedicated nursing staff support served as a substantial implementation facilitator. However, the costs associated with securing such staff, as well as physician remuneration, were perceived as significant barriers for sustaining the intervention beyond the trial period. It is important to note that the physicians participating in this study did not receive any remuneration and performed all the work voluntarily. It was noted that in the long run, the lack of compensation for services performed by clinicians remotely could serve as a deterrent and could impede the extent to which the intervention would be used. The arrangement of remuneration was thought to be necessary to ensure extensive physician buy-in:

> *I think technology implementation is feasible, I think buy-in from the physicians and the right patients is definitely feasible, and I think that that is the one barrier that could perhaps irk some people about its widespread implementation, which is "how do I get compensation for the work that I'm doing?," and if that's addressed, I don't see why anyone would not think that this is a great thing.* [Clinician #2]

Discussion

Principal Findings

This study aimed to obtain a deeper understanding of the experiences of clinicians and patients with HF taking part in a remote titration program to identify factors that can promote successful implementation of the intervention or hinder it. Most participants expressed favorable views of the intervention. Our multilevel analysis revealed the presence of several facilitators and relatively few barriers. Innovation-, patient- and organizational-level factors predominantly highlighted facilitators, while provider- and structural-level factors shed light on some barriers.

Innovation-Level Factors

Telephone-administered therapies have recently emerged as an alternative method of treatment delivery. Therefore, it is important to ensure that both patients and clinicians are comfortable with this treatment modality and that it does not have a deleterious effect on the therapeutic alliance. The patients and clinicians participating in our study had a predominantly positive opinion of telephone communication and indicated that their rapport was maintained. This finding is supported by previous studies, which also noted that patients did not find telephone communication discomfiting [35,36]. Active daily monitoring further enhanced the perceived fit of the intervention. Studies have indicated that the success of telemedicine may rely on the capacity of the technology to facilitate prompt detection of clinical deterioration signs, enabling counteractive interventions [37-39]. The findings of our study echo these sentiments. Clinicians believed that the daily measurements provided a reliable and timely reflection of the patients' condition and allowed for rapid action in the event of any alerts. This management was facilitated by the integration of the intervention within the clinic. The remote titration protocol was implemented by members of the patients' existing care team. This approach enabled clinicians to rapidly respond to changes in the patients' condition, potentially contributing to a more effective model of care versus a centralized approach, where a separate team of specialists conducts the telemonitoring and provides treatment recommendations to the patient's care team [40].

The intervention was found to be easy to use, integrated well into both patients' and clinicians' routines, and removed practical barriers to titration. These factors resulted in a favorable user experience for both clinicians and patients and served to facilitate successful implementation. Owing to patient characteristics, such as decreased concentration, memory or vision impairments, and their unfamiliarity with telemonitoring, usability of systems must be clear and simple, as complex systems may cause stress and anxiety [41]. In addition, studies have found that the intensity, complexity, and integration of telemedicine programs into clinical practice are crucial factors that are highly relevant to predetermining the outcomes of interventions [32,42]. All of these factors received predominantly positive feedback in our study.

Perhaps most importantly, the usefulness of the intervention had a crucial impact on its acceptability. Health care professionals and organizations often expect telemonitoring to be one of the solutions for shortages in health care resources, as well as for maintaining or even increasing productivity [41]. Eurlings et al [43] noted that telemonitoring serves 2 important purposes: improving care and reducing costs. These notions were reflected in our findings as well. The ability to perform more titrations and reach target doses faster significantly enhanced the appeal of the intervention to clinicians. On the patients' end, the intervention eliminated the need to attend clinic visits, which saved them time and money, and in some cases, gave them access to care that they would have otherwise been unable to obtain as frequently.

Patient-Level Factors

As key stakeholders in all implementation efforts, patients are active agents and consumers of health care from whom buy-in is necessary [24]. The patient-level constructs identified in our analysis highlighted the important role that perceived benefits

play in this buy-in. However, these perceived benefits are not universal to all patients, and certain individual preferences, such as a preference for face-to-face contact, highlight potential barriers to implementation.

Other studies have also noted that telehealth should not be viewed as a panacea; there will be groups of patients where telehealth is not in their best interests, and others where its use is unlikely to improve outcomes compared with usual care [38,41,44]. Therefore, alignment between the nature of the program and the patients' preferences, characteristics, and abilities is paramount [12]. This highlighted a potential change that should be made in our intervention to facilitate more successful implementation. User-related factors are important to note, and it is essential to clearly define the patient population that should be enrolled in the program, beyond clinical inclusion and exclusion criteria. Patient profiles consisting of illness characteristics, comorbidities, cognition, and literacy can serve as a potential helpful tool in matching individual patients with telemonitoring interventions [41]. This will ensure that suitable patients are enrolled in the intervention and could enhance the results of telemonitoring, which in turn will influence the motivation of patients and health care professionals to implement it in daily life.

Provider-Level Factors

Provider-level factors, namely the intervention's impact on the clinicians' workload, highlighted a potential barrier to implementation. Clinicians noted that while the intervention was usually very quick and easy to execute, it became time-consuming in the absence of the nurse coordinator. Owing to the limited time available to physicians, a time-consuming intervention is not likely to be used, and it is important to maintain minimal impact on the physicians' workload to ensure uptake. This finding is supported by previous research indicating that clinicians expect systems to integrate well into their practice and not impact their workload [38].

The extent of the information provided to physicians at the beginning of the program was another potential factor affecting implementation. In our study, physicians who believed they were prepared to implement the intervention were among the earlier adopters with a larger number of patients enrolled, whereas those who were uncertain of their preparedness came onboard later and subsequently had fewer patients enrolled. This highlighted another potential change that should be made in our intervention to facilitate more successful implementation. The tasks of clinicians involved in the intervention should be clearly delineated and communicated from the start, along with a complete training plan. This would provide a better assessment of the time burden of the intervention and outline its potential impact on the workload of all team members. In addition, this will help establish confidence in the intervention and enable providers to feel more prepared to implement it.

Organizational- and Structural-Level Factors

Finally, structural- and organizational-level factors included several interrelated findings. Dedicated nursing staff support was a strong organizational facilitator, as it provided a consistent point of contact for the patients and streamlined the physician's involvement in the intervention. Other studies have also noted that dedicated nursing resources significantly contribute to telehealth work [45]. Furthermore, a recent Cochrane review encompassing 7 RCTs, which included a total of 1684 patients with HF with reduced ejection fraction reported that nurse-led medication titration resulted in a 2-fold increase in the number of participants achieving target doses of β-blockers, a 20% relative risk reduction in all-cause hospitalization, and a 34% relative risk reduction in all-cause mortality [2], highlighting the significant role that nurses can play in such interventions. More extensive integration of nursing staff support could facilitate effective implementation and promote sustainability while potentially reducing operational cost.

However, on a structural level, the financial resources necessary to acquire any required additional nursing staff, as well as arrange physician remuneration, serve as potential implementation barriers. Reimbursement remains one of the most considerable barriers to telemonitoring services, and the need to improve reimbursement models has been noted in many studies as a prerequisite for widespread adoption of such interventions [46]. This challenge is a system issue as reimbursement for clinicians providing various telemedicine services is not sufficiently addressed in the current regulatory framework for health care services. Both in the United States and in Canada, regulatory agencies place constraints on the types of providers that can deliver telehealth services (eg, licensure and credentialing requirements), the allowable originating sites, and the eligible services. However, historically, providers do not receive reimbursement for the specific tools they use to deliver care; rather, providers are paid for the care they deliver. Therefore, it may be beneficial to view telemedicine as a modality for delivering health care. As noted by LeRouge and Garfield [47], the key to telehealth success in the future is to view it as an integral part of health care services and not as a stand-alone project. The establishment of reimbursement models can help promote telemedicine from an experimental modality to a standard health service within health care organizations, and the implementation of telemedicine would enable providers to deliver timelier, patient-centered, high-quality care.

Study Limitations

The results of this study should be interpreted while taking some limitations into account. The patient population enrolled in this study was recruited from a single specialized HFC that had launched the Medly Program in 2016. On the clinicians' end, their familiarity with telemonitoring, as well as the existing processes for communication of information obtained through Medly, may have mitigated challenges that could have otherwise been encountered and may have contributed to a more favorable perception of telemonitoring. On the patients' end, the average age of the participants was notably lower than the general HF patient population. As younger patients may be more comfortable with technology, the younger age of our patient participants may have led to higher preference for telemonitoring and remote care compared with the general HF patient population. However, a previous study conducted with Medly found that its ease of use and the availability of supporting

services led to higher and more consistent adherence rates in older patients (70 years or older) [48].

It should also be noted that despite the central role of the nurse coordinator, there was only 1 nurse in this study. This represents a limitation, as this qualitative inquiry included 4 physicians and only 1 nurse. As such, thematic analysis may have highlighted the physicians' perspective and not revealed important themes from the nurse's point of view. Similarly, there was only 1 patient in the RCT who requested to discontinue remote medication titration. As there were 10 other interviewed patients who favored remote titration, the emerging themes may have predominantly reflected their experiences and perceptions. Overall, it is important to note that the small number of patients and clinicians involved in this study represents a strong limitation of this qualitative inquiry. Although the gathered data are promising, the single-center nature and limited number of participants, preclude us from drawing definitive conclusions. A study with a much larger number of participants is currently underway, which will allow us to collect more data and provide a more comprehensive assessment of the intervention, its implementation, and its acceptance.

Conclusions

To realize the potential benefits of remote medication titration, complex challenges of integration in real clinical settings must be faced. This study presents results from the real-world implementation assessment of remote titration facilitated by telemonitoring. It is among the first to provide insights into the perception of the remote titration process by patients and clinicians. Although the intervention was predominantly positively received, our study illuminated both facilitators and barriers, and we proposed several improvements, which can lead to more effective implementation in the future. Our findings indicate that the relative advantages that remote titration presents over standard care, such as rapid GDMT optimization and reduction in clinic visits, strongly appeal to both clinicians and patients. However, to ensure uptake and adherence, it is important to ensure that the characteristics and preferences of enrolled patients align with the program and minimize the impact of the intervention on the physicians' workload. More extensive reliance on nursing staff support, or perhaps even the incorporation of nurse practitioners who are authorized to interpret diagnostic tests and prescribe medications, could mitigate this issue and facilitate effective implementation, while potentially reducing operational cost.

This qualitative inquiry is particularly timely, as the COVID-19 pandemic has highlighted the need to provide safe care for patients at a distance whenever possible. Remote virtual care can play an important role in maintaining the safety of both patients and clinicians, while ensuring continuity of care. This qualitative assessment of the barriers and facilitators, along with the evaluation of the effectiveness of the remote titration program, represent the first steps in research that can lead to wider implementation and adoption of remote titration in a population that can greatly benefit from it, both under regular circumstances and particularly during challenging times such as the COVID-19 pandemic.

Acknowledgments

Funding for this study was provided by the Ted Rogers Centre for Heart Research and Peter Munk Cardiac Centre Site and through a National Sciences and Engineering Research Council of Canada Discovery Grant.

Conflicts of Interest

Members of the research team (ES and HJR) have intellectual property rights of the Medly system.

References

1. Roger VL. Epidemiology of heart failure. Circ Res 2013 Aug 30;113(6):646-659. [doi: 10.1161/circresaha.113.300268]
2. Atherton JJ, Hickey A. Expert comment: is medication titration in heart failure too complex? Card Fail Rev 2017;3(1):25-32. [doi: 10.15420/cfr.2017:1:2]
3. Maggioni AP, Anker SD, Dahlström U, Filippatos G, Ponikowski P, Zannad F, Heart Failure Association of the ESC. Are hospitalized or ambulatory patients with heart failure treated in accordance with European Society of Cardiology guidelines? Evidence from 12,440 patients of the ESC Heart Failure Long-Term Registry. Eur J Heart Fail 2013 Oct 27;15(10):1173-1184 [FREE Full text] [doi: 10.1093/eurjhf/hft134] [Medline: 23978433]
4. Greene SJ, Butler J, Albert NM, DeVore AD, Sharma PP, Duffy CI, et al. Medical therapy for heart failure with reduced ejection fraction: the CHAMP-HF Registry. J Am Coll Cardiol 2018 Jul 24;72(4):351-366. [doi: 10.1016/j.jacc.2018.04.070] [Medline: 30025570]
5. Gracia E, Hamid A, Butler J. Timely management of new-onset heart failure. Circulation 2019 Aug 20;140(8):621-623. [doi: 10.1161/circulationaha.118.035452]
6. Zaman S, Zaman SS, Scholtes T, Shun-Shin MJ, Plymen CM, Francis DP, et al. The mortality risk of deferring optimal medical therapy in heart failure: a systematic comparison against norms for surgical consent and patient information leaflets. Eur J Heart Fail 2017 Nov 08;19(11):1401-1409 [FREE Full text] [doi: 10.1002/ejhf.838] [Medline: 28597606]
7. Clark RA, Inglis SC, McAlister FA, Cleland JG, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. Br Med J 2007 May 05;334(7600):942 [FREE Full text] [doi: 10.1136/bmj.39156.536968.55] [Medline: 17426062]

8. Kotb A, Cameron C, Hsieh S, Wells G. Comparative effectiveness of different forms of telemedicine for individuals with heart failure (HF): a systematic review and network meta-analysis. PLoS One 2015 Feb 25;10(2):e0118681 [FREE Full text] [doi: 10.1371/journal.pone.0118681] [Medline: 25714962]
9. Zhu Y, Gu X, Xu C. Effectiveness of telemedicine systems for adults with heart failure: a meta-analysis of randomized controlled trials. Heart Fail Rev 2020 Mar 24;25(2):231-243 [FREE Full text] [doi: 10.1007/s10741-019-09801-5] [Medline: 31197564]
10. Seto E, Leonard KJ, Masino C, Cafazzo JA, Barnsley J, Ross HJ. Attitudes of heart failure patients and health care providers towards mobile phone-based remote monitoring. J Med Internet Res 2010 Nov 29;12(4):e55 [FREE Full text] [doi: 10.2196/jmir.1627] [Medline: 21115435]
11. Fairbrother P, Ure J, Hanley J, McCloughan L, Denvir M, Sheikh A, Telescot Programme Team. Telemonitoring for chronic heart failure: the views of patients and healthcare professionals - a qualitative study. J Clin Nurs 2014 Jan 04;23(1-2):132-144. [doi: 10.1111/jocn.12137] [Medline: 23451899]
12. Hunting G, Shahid N, Sahakyan Y, Fan I, Moneypenny CR, Stanimirovic A, et al. A multi-level qualitative analysis of Telehomecare in Ontario: challenges and opportunities. BMC Health Serv Res 2015 Dec 09;15(1):544 [FREE Full text] [doi: 10.1186/s12913-015-1196-2] [Medline: 26645639]
13. D'Onofrio A, Palmisano P, Rapacciuolo A, Ammendola E, Calò L, Ruocco A, et al. Effectiveness of a management program for outpatient clinic or remote titration of beta-blockers in CRT patients: the RESTORE study. Int J Cardiol 2017 Jun 01;236:290-295. [doi: 10.1016/j.ijcard.2017.02.015] [Medline: 28188000]
14. Smeets CJ, Storms V, Vandervoort PM, Dreesen P, Vranken J, Houbrechts M, et al. A novel intelligent two-way communication system for remote heart failure medication uptitration (the CardioCoach study): randomized controlled feasibility trial. JMIR Cardio 2018 Apr 04;2(1):e8 [FREE Full text] [doi: 10.2196/cardio.9153] [Medline: 31758773]
15. Steckler A, Bishu K, Wassif H, Sigurdsson G, Wagner J, Jaenicke C, et al. Telephone titration of heart failure medications. J Cardiovasc Nurs 2011;26(1):29-36. [doi: 10.1097/JCN.0b013e3181ec1223] [Medline: 21127425]
16. Moyer-Knox D, Mueller TM, Vuckovic K, Mischke L, Williams RE. Remote titration of carvedilol for heart failure patients by advanced practice nurses. J Card Fail 2004 Jun;10(3):219-224. [doi: 10.1016/j.cardfail.2003.09.009] [Medline: 15190531]
17. Spaeder J, Najjar SS, Gerstenblith G, Hefter G, Kern L, Palmer JG, et al. Rapid titration of carvedilol in patients with congestive heart failure: a randomized trial of automated telemedicine versus frequent outpatient clinic visits. Am Heart J 2006 Apr;151(4):1-10. [doi: 10.1016/j.ahj.2005.06.044] [Medline: 16569544]
18. Artanian V, Ross HJ, Rac VE, O'Sullivan M, Brahmbhatt DH, Seto E. Impact of remote titration combined with telemonitoring on the optimization of guideline-directed medical therapy for patients with heart failure: internal pilot of a randomized controlled trial. JMIR Cardio 2020 Nov 03;4(1):e21962 [FREE Full text] [doi: 10.2196/21962] [Medline: 33141094]
19. Artanian V, Rac VE, Ross HJ, Seto E. Impact of remote titration combined with telemonitoring on the optimization of guideline-directed medical therapy for patients with heart failure: protocol for a randomized controlled trial. JMIR Res Protoc 2020 Oct 13;9(10):e19705 [FREE Full text] [doi: 10.2196/19705] [Medline: 33048057]
20. Seto E, Leonard KJ, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Mobile phone-based telemonitoring for heart failure management: a randomized controlled trial. J Med Internet Res 2012 Feb 16;14(1):e31 [FREE Full text] [doi: 10.2196/jmir.1909] [Medline: 22356799]
21. Ware P, Ross HJ, Cafazzo JA, Laporte A, Gordon K, Seto E. Evaluating the implementation of a mobile phone-based telemonitoring program: longitudinal study guided by the consolidated framework for implementation research. JMIR Mhealth Uhealth 2018 Jul 31;6(7):e10768 [FREE Full text] [doi: 10.2196/10768] [Medline: 30064970]
22. Ware P, Ross HJ, Cafazzo JA, Boodoo C, Munnery M, Seto E. Outcomes of a heart failure telemonitoring program implemented as the standard of care in an outpatient heart function clinic: pretest-posttest pragmatic study. J Med Internet Res 2020 Feb 08;22(2):e16538 [FREE Full text] [doi: 10.2196/16538] [Medline: 32027309]
23. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. Adm Policy Ment Health 2015 Sep 6;42(5):533-544 [FREE Full text] [doi: 10.1007/s10488-013-0528-y] [Medline: 24193818]
24. Chaudoir SR, Dugan AG, Barr CH. Measuring factors affecting implementation of health innovations: a systematic review of structural, organizational, provider, patient, and innovation level measures. Implement Sci 2013 Feb 17;8(6):22 [FREE Full text] [doi: 10.1186/1748-5908-8-22] [Medline: 23414420]
25. Hsieh H, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005 Nov 01;15(9):1277-1288. [doi: 10.1177/1049732305276687] [Medline: 16204405]
26. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011 Mar 19;38(2):65-76 [FREE Full text] [doi: 10.1007/s10488-010-0319-7] [Medline: 20957426]
27. Cohen S, Halvorson H, Gosselink C. Changing physician behavior to improve disease prevention. Prev Med 1994 May;23(3):284-291. [doi: 10.1006/pmed.1994.1040] [Medline: 8078848]
28. Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. J Consult Clin Psychol 1983;51(3):390-395. [doi: 10.1037/0022-006x.51.3.390]

29. Klein KJ, Sorra JS. The challenge of innovation implementation. Acad Manag Rev 1996 Oct;21(4):1055-1080. [doi: 10.5465/amr.1996.9704071863]
30. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health 1999 Sep;89(9):1322-1327. [doi: 10.2105/ajph.89.9.1322] [Medline: 10474547]
31. Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. Adm Policy Ment Health 2009 Jan 23;36(1):24-34 [FREE Full text] [doi: 10.1007/s10488-008-0197-4] [Medline: 19104929]
32. Rogers EM. Diffusion of Innovations, 5th Ed. New York: Free Press; 2003.
33. Durlak J, DuPre E. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. Am J Community Psychol 2008 Jun;41(3-4):327-350. [doi: 10.1007/s10464-008-9165-0] [Medline: 18322790]
34. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009 Aug 07;4(1):50 [FREE Full text] [doi: 10.1186/1748-5908-4-50] [Medline: 19664226]
35. Turner J, Brown JC, Carpenter DT. Telephone-based CBT and the therapeutic relationship: the views and experiences of IAPT practitioners in a low-intensity service. J Psychiatr Ment Health Nurs 2018 Jun 30;25(5-6):285-296. [doi: 10.1111/jpm.12440] [Medline: 29117458]
36. Turgoose D, Ashwick R, Murphy D. Systematic review of lessons learned from delivering tele-therapy to veterans with post-traumatic stress disorder. J Telemed Telecare 2017 Sep 29;24(9):575-585. [doi: 10.1177/1357633x17730443]
37. Desai AS, Stevenson LW. Connecting the circle from home to heart-failure disease management. N Engl J Med 2010 Dec 09;363(24):2364-2367. [doi: 10.1056/nejme1011769]
38. de Vries AE, van der Wal MH, Nieuwenhuis MM, de Jong RM, van Dijk RB, Jaarsma T, et al. Health professionals' expectations versus experiences of internet-based telemonitoring: survey among heart failure clinics. J Med Internet Res 2013 Jan 10;15(1):e4 [FREE Full text] [doi: 10.2196/jmir.2161] [Medline: 23305645]
39. Kato NP, Johansson P, Okada I, de Vries AE, Kinugawa K, Strömberg A, et al. Heart failure telemonitoring in Japan and Sweden: a cross-sectional survey. J Med Internet Res 2015 Nov 13;17(11):e258 [FREE Full text] [doi: 10.2196/jmir.4825] [Medline: 26567061]
40. Papoutsi C, A'Court C, Wherton J, Shaw S, Greenhalgh T. Explaining the mixed findings of a randomised controlled trial of telehealth with centralised remote support for heart failure: multi-site qualitative study using the NASSS framework. Trials 2020 Oct 27;21(1):891 [FREE Full text] [doi: 10.1186/s13063-020-04817-x] [Medline: 33109254]
41. Boyne JJ, Vrijhoef HJ. Implementing telemonitoring in heart failure care: barriers from the perspectives of patients, healthcare professionals and healthcare organizations. Curr Heart Fail Rep 2013 Sep 12;10(3):254-261. [doi: 10.1007/s11897-013-0140-1] [Medline: 23666901]
42. Crundall-Goode A, Goode KM, Clark AL. What impact do anxiety, depression, perceived control and technology capability have on whether patients with chronic heart failure take-up or continue to use home tele-monitoring services? Study design of ADaPT-HF. Eur J Cardiovasc Nurs 2017 Apr 07;16(4):283-289. [doi: 10.1177/1474515116657465] [Medline: 27352948]
43. Eurlings CG, Boyne JJ, de Boer RA, Brunner-La Rocca HP. Telemedicine in heart failure-more than nice to have? Neth Heart J 2019 Jan 10;27(1):5-15 [FREE Full text] [doi: 10.1007/s12471-018-1202-5] [Medline: 30536146]
44. Crundall-Goode A, Goode KM. Using telehealth for heart failure: barriers, pitfalls and nursing service models. Br J Card Nurs 2014 Aug 02;9(8):396-406. [doi: 10.12968/bjca.2014.9.8.396]
45. Taylor J, Coates E, Brewster L, Mountain G, Wessels B, Hawley MS. Examining the use of telehealth in community nursing: identifying the factors affecting frontline staff acceptance and telehealth adoption. J Adv Nurs 2015 Feb 29;71(2):326-337. [doi: 10.1111/jan.12480] [Medline: 25069605]
46. Mechanic O, Persaud Y, Kimball A. Telehealth systems. StatPearls. 2019. URL: https://www.statpearls.com/ArticleLibrary/viewarticle/35190 [accessed 2021-10-08]
47. LeRouge C, Garfield M. Crossing the telemedicine chasm: have the U.S. barriers to widespread adoption of telemedicine been significantly reduced? Int J Environ Res Public Health 2013 Nov 28;10(12):6472-6484 [FREE Full text] [doi: 10.3390/ijerph10126472] [Medline: 24287864]
48. Ware P, Dorai M, Ross HJ, Cafazzo JA, Laporte A, Boodoo C, et al. Patient adherence to a mobile phone-based heart failure telemonitoring program: a longitudinal mixed-methods study. JMIR Mhealth Uhealth 2019 Feb 26;7(2):e13259 [FREE Full text] [doi: 10.2196/13259] [Medline: 30806625]

Abbreviations

GDMT: guideline-directed medical therapy
HF: heart failure
HFC: Heart Function Clinic
PMCC: Peter Munk Cardiac Centre
RCT: randomized controlled trial

REB: research ethics board
UHN: University Health Network

Edited by G Eysenbach; submitted 26.02.21; peer-reviewed by C Jacob, L Zhou, S Winkler; comments to author 19.04.21; revised version received 29.08.21; accepted 18.09.21; published 25.11.21.

Please cite as:
Artanian V, Ware P, Rac VE, Ross HJ, Seto E
Experiences and Perceptions of Patients and Providers Participating in Remote Titration of Heart Failure Medication Facilitated by Telemonitoring: Qualitative Study
JMIR Cardio 2021;5(2):e28259
URL: https://cardio.jmir.org/2021/2/e28259
doi:10.2196/28259
PMID:34842546

Original Paper

Real-World Experience of mHealth Implementation in Clinical Practice (the Box): Design and Usability Study

Tom Biersteker[1], MD; Alexander Hilt[1], MD; Enno van der Velde[1], PhD; Martin Jan Schalij[1], MD, PhD; Roderick Willem Treskes[1], MD, PhD

Department of Cardiology, Leiden University Medical Center, Leiden, Netherlands

Corresponding Author:
Martin Jan Schalij, MD, PhD
Department of Cardiology
Leiden University Medical Center
Albinusdreef 2
Leiden, 2333 ZA
Netherlands
Phone: 31 715262020
Email: m.j.schalij@lumc.nl

Abstract

Background: Mobile health (mHealth) is an emerging field of scientific interest worldwide. Potential benefits include increased patient engagement, improved clinical outcomes, and reduced health care costs. However, mHealth is often studied in projects or trials, and structural implantation in clinical practice is less common.

Objective: The purpose of this paper is to outline the design of *the Box* and its implementation and use in an outpatient clinic setting. The impact on logistical outcomes and patient and provider satisfaction is discussed.

Methods: In 2016, an mHealth care track including smartphone-compatible devices, named *the Box*, was implemented in the cardiology department of a tertiary medical center in the Netherlands. Patients with myocardial infarction, rhythm disorders, cardiac surgery, heart failure, and congenital heart disease received devices to measure daily weight, blood pressure, heart rate, temperature, and oxygen saturation. In addition, professional and patient user comments on the experience with the care track were obtained via structured interviews.

Results: From 2016 to April 2020, a total of 1140 patients were connected to the mHealth care track. On average, a Box cost €350 (US $375), not including extra staff costs. The median patient age was 60.8 (IQR 52.9-69.3) years, and 73.59% (839/1140) were male. A median of 260 (IQR 105-641) measurements was taken on a median of 189 (IQR 98-372) days. Patients praised the ease of use of the devices and felt more involved with their illness and care. Professionals reported more productive outpatient consultations as well as improved insight into health parameters such as blood pressure and weight. A feedback loop from the hospital to patient to focus on measurements was commented as an important improvement by both patients and professionals.

Conclusions: In this study, the design and implementation of an mHealth care track for outpatient follow-up of patients with various cardiovascular diseases is described. Data from these 4 years indicate that mHealth is feasible to incorporate in outpatient management and is generally well-accepted by patients and providers. Limitations include the need for manual measurement data checks and the risk of data overload. Moreover, the tertiary care setting in which *the Box* was introduced may limit the external validity of logistical and financial end points to other medical centers. More evidence is needed to show the effects of mHealth on clinical outcomes and on cost-effectiveness.

(JMIR Cardio 2021;5(2):e26072) doi:10.2196/26072

KEYWORDS

eHealth; mHealth; remote patient monitoring; cardiology; patient satisfaction; patient empowerment; mobile phone

Introduction

Background

The World Health Organization defines mobile health (mHealth) as "a component of electronic health (eHealth), which involves the use of a mobile phone, patient monitoring devices, and other wireless devices to support medical and public health practise" [1]. It is a growing industry and field of research interest, with over 300,000 health apps now being available in major app stores and 1697 hits on PubMed being available in 2019 versus 319 in 2013 [2].

In 2019, 97% of all Dutch inhabitants had access to broadband internet, and 84% used a smartphone to browse the internet [3,4]. This is consistent with other Western countries [4,5]. With most of the Western population using smartphones and health care models becoming increasingly patient-centered, there is a promise for mHealth to change the future of health care [6]. Although sometimes described as a hype with scarce concise scientific projects or evidence [7], mHealth presents opportunities to increase patient engagement, improve clinical outcomes, and reduce health care costs [8,9]. In cardiovascular outpatient care, health care providers and patients are positive toward the potential that mHealth holds [10-12].

In 2016, mHealth was introduced in outpatient care in the department of cardiology at a large tertiary medical center in the Netherlands. This project, named *the Box*, equipped patients with mHealth devices that were handed out at discharge and came in a box for easier transportation. It has been the main focus to make this type of care accessible to every patient with a low threshold for participation [13].

Objectives

The purpose of this paper is to outline the design of *the Box* and its implementation and use in the outpatient clinic setting. It presents the results of 4 years of structural implementation; logistical and clinical processes as well as reported patient and physician satisfaction are discussed.

Methods

Project Design and Evolvement

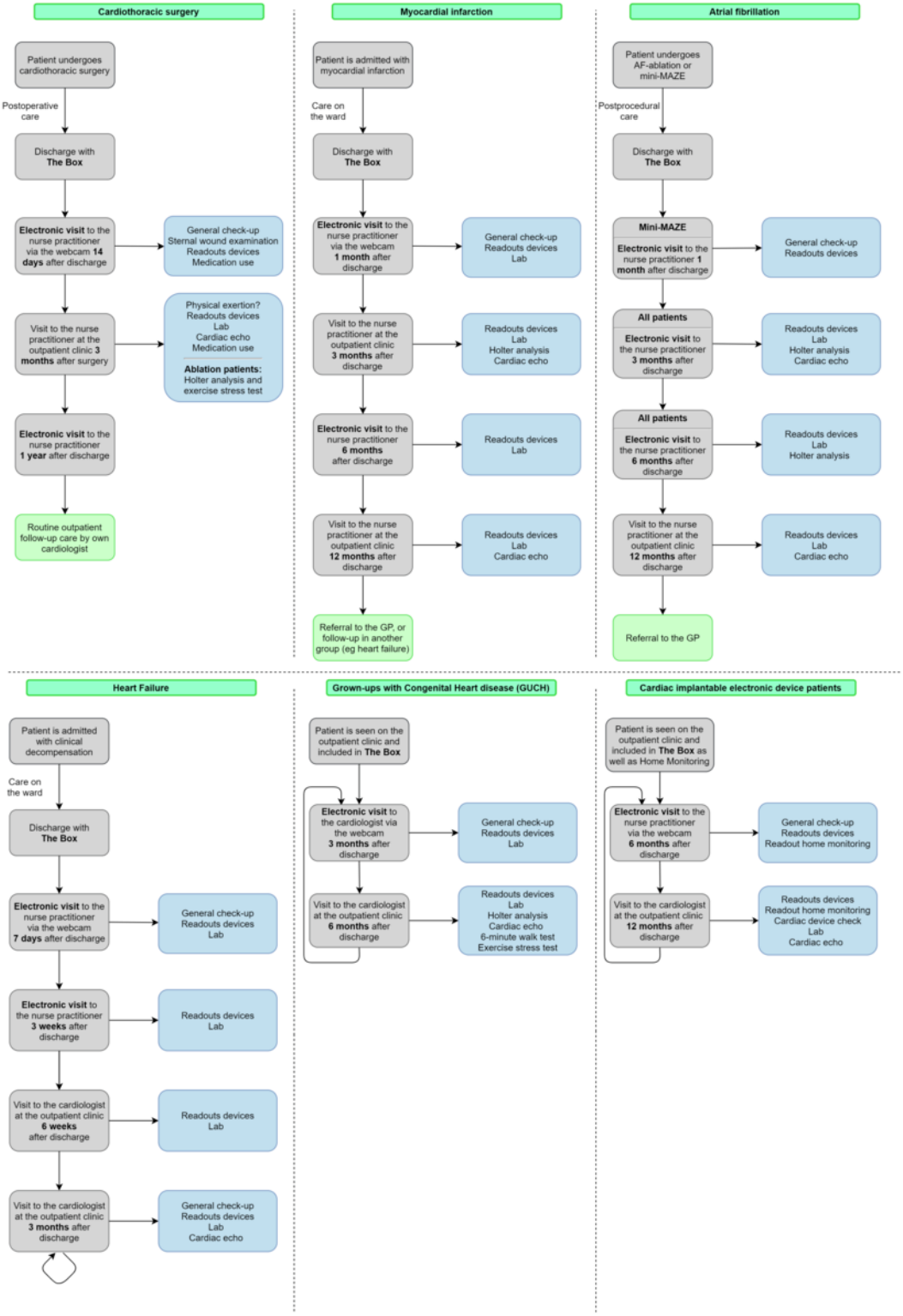
The Leiden University Medical Center (LUMC) delivers tertiary care for cardiovascular patients, such as primary percutaneous coronary interventions and advanced cardiac surgery as well as atrial and ventricular ablation procedures. Outpatient care of specific patient populations, such as patients who had a myocardial infarction (MI), patients who underwent pulmonary vein isolation for atrial fibrillation (AF), patients with a diagnosis of advanced heart failure (HF), and patients after implantable cardioverter-defibrillator implantation, has been standardized into care tracks. Patients were seen at the outpatient clinic by a nurse practitioner (NP) who was supervised by a consultant cardiologist. This has been described in detail in a previous study [14]. In 2015, it was hypothesized that some of these protocols could be executed via mHealth, as follows:

1. Replacing physical outpatient clinic visits by digital visits via the webcam, as this was hypothesized to be more patient-friendly by saving the patient time and money.
2. Introducing patient home monitoring. As such, patients could review measurements such as blood pressure or heart rate, involving them more in the treatment of their condition. It was hypothesized that by increasing the number of data points, abnormal trends such as high blood pressure could be detected earlier.

As such, an mHealth initiative called *the Box* was launched. For this initiative, smartphone-connectible, consumer-grade health monitoring devices were used, and outpatient contact moments were replaced with video consultations. *The Box* was started at the cardiology department of the LUMC in April 2016, at first as a part of a randomized controlled trial (RCT), registered at ClinicalTrials.gov (NCT02976376). The methods and results of this specific RCT have been described previously [13,15]. In 2018, it was decided to start another study on patients who underwent cardiac surgery, which hypothesized an increased detection of postoperative AF with the use of mHealth devices as well as increased patient satisfaction and empowerment [16]. This study began recruitment in November 2018 and is still ongoing. It has been registered at ClinicalTrials.gov (NCT03690492).

Simultaneously, positive first results regarding the RCT led to the introduction of *the Box* as standard care to additional patient groups other than those who had an MI or underwent cardiac surgery; *the Box* was introduced to patients who underwent catheter pulmonary vein isolation and patients with HF, to those after implantation of an implantable cardiac defibrillator or cardiac resynchronization therapy device for any reason, and to grown-ups with congenital heart (GUCH) disease. All currently used outpatient follow-up protocols are listed in Figure 1. Follow-up of the patients was primarily the responsibility of the NPs who handled one patient group each. Measurement results were checked by NPs, and video consultations were also carried out. The video consultations are with regard to discussion topics (symptoms, side effects of medication, etc) comparable with physical outpatient clinic visits.

Figure 1. Protocols for follow-up with *the Box*. AF: atrial fibrillation; GP: general practitioner.



Contents of the Box

Figure 2 shows a Box with all mHealth devices that are currently being used, as described in an earlier study [16]. Patients received mHealth devices depending on their specific disease. Table 1 summarizes the requested measurement frequency, intended follow-up duration, and number of devices per Box type.

Figure 2. *The Box* with all mobile health devices.

Table 1. The measuring frequency and devices provided per patient group (N=1140).

Devices	Measuring frequency and follow-up duration					
	Myocardial infarction (n=449); thrice per week; 12-month follow-up	Cardiac surgery (n=290); thrice per week[a]; 3-month follow-up	Atrial fibrillation (n=260); once per week; 12-month follow-up	Device patients (n=71); thrice per week; follow-up differs per user	Heart failure (n=65); thrice per week; indefinite follow-up	Grown-ups with congenital heart (n=29); twice per week; indefinite follow-up
Blood pressure monitor	✓[b]	✓	✓	✓	✓	✓
Weight scale	✓	✓	✓	✓	✓	✓
Pedometer	✓	✓	✓	✓	✓	✓
Thermometer		✓				
AliveCor Kardia	✓	✓		✓	✓	✓
CardioSecur[c]		✓	✓			
Pulse oximeter		✓				

[a]Daily measurements during the first 2 weeks after discharge.

[b]Device used.

[c]CardioSecur measurements: once every week, plus an extra registration when there are complaints of palpitations, or when the AliveCor Kardia detects possible atrial fibrillation.

A blood pressure monitor, weight scale, thermometer, and activity tracker (pedometer) were provided by Withings. Since 2019, multiple versions of the Withings pedometer, a wristwatch, have been used; some versions (Withings Move ECG and Scanwatch) allow lead-I electrocardiogram (ECG) devices to be made. *The Box* could furthermore contain a pulse oximeter by Masimo, an AliveCor Kardia single lead ECG device (AliveCor Inc) or a CardioSecur, which is a 4-electrode EASI-derived ECG device (Personal MedSystems GmbH). These devices are all consumer-grade, Conformité Européenne–marked, and available in the public market. All devices are smartphone-connectible via Bluetooth or through a wire in the case of CardioSecur and managed in the device-dedicated smartphone apps. Apart from the CardioSecur ECG device and pulse oximeter, all devices were gifted to the patient. On average, one Box with its contents costs the

cardiology department of the LUMC a total amount of €350 (US $375), not including extra staff costs. *The Box* is not sponsored by the manufacturers of the devices.

Installation Process and Support

Patients individually received installation instructions from technical assistants who had no medical background but received specific training. All relevant apps were installed, and all devices were connected to the patient's smartphone via Bluetooth upon discharge. If a patient did not own a smartphone, a loan device was provided, which was returned after the patient's follow-up was complete. Furthermore, patients received ample instructions on device operation as well as detailed manuals on the use of all individual devices and video consultation. Moreover, technical assistants ran a helpdesk which could be called by patients in case of technical issues with the devices of *the Box*. Patients were visited at home whenever the technical assistants were unable to resolve a technical issue by telephone.

Connectibility

The data from the Withings devices were connected to the patient's electronic medical record (EMR) via the Withings application programming interface via a specific authorization protocol (OAUTH2). CardioSecur ECG registrations were saved to the servers of the manufacturer located in Germany and could be checked by the NP on a web-based dashboard. The patient emailed the single lead ECG registrations and pulse oximeter data to the LUMC. When a rhythm disturbance was diagnosed by the NP, the ECG was manually added to the EMR.

Measurements and Feedback

Patients received automated feedback from the manufacturer's apps based on the readouts of the devices. Measurement results were checked by NPs 2 to 3 times per week after passing through an algorithm. This algorithm, programmed by software developers of the cardiology department of the LUMC, flagged abnormal results if the measurements exceeded a certain limit. As such, the upper and lower limits of measurement results, such as blood pressure and weight, could be set per patient individually. The limits were determined at the start of the use period of *the Box* by the responsible NP.

Manual feedback by the NP was provided only in the case of anomalies. As all used devices are consumer grade rather than medical grade, therefore lacking scientifically proven accuracy, this feedback was based on trends rather than individual measurements. Patients were instructed of this *no news is good news* method as well as NPs looking at trends, which was also clearly stated in the provided manuals. However, patients could contact the NP with their measurement results when they felt uncomfortable. Most importantly, though, all patients were instructed to use *the Box* in the outpatient setting but not to use it in case of emergencies. This was communicated during face-to-face instructions by the technical assistants and in all manuals provided with *the Box*.

Video Consultation

As shown in Figure 1, several protocolled outpatient clinic visits were replaced by video consultations. The patient communicated with their NP via a secured webcam (Webcamconsult) connection. The contents of video consultations and in-office outpatient clinic visits were comparable.

Patient Privacy

To use mHealth devices, patients must register for the smartphone app. This app is developed and owned by the device manufacturer. As data safety and patient privacy are a big concern in eHealth [17], this raises privacy concerns as patient data are stored on the manufacturer's servers. To protect patient privacy, patients were provided with an email address containing no personal or any other relatable information. The domain of these email addresses was owned by the LUMC. The account details were exclusively known to the patient and the LUMC, the passwords were randomly generated, and, in every case, the date of birth was January 1, 1950. With this alias, the patient did not have to share personal information such as their name, gender, or date of birth with the manufacturers of the mHealth devices. Moreover, device manufacturers could not contact the patients directly. Importantly, because of working with anonymized accounts, no patient information could be obtained by a third party in case of a data breach concerning the mHealth device accounts.

At the end of the use period of *the Box*, the randomly generated accounts were disconnected from the EMR. This was also discussed with patients at the start of their Box period. This prevented patients from indefinitely sending in their data when their care may have been transferred to another institution or a general practitioner.

Outcome Measure: Patient and Professional Experiences With the Box

Patient Satisfaction

To understand and measure patient satisfaction on the usability and experience of *the Box*, 14 qualitative interviews have been conducted over the course of 2017 until 2019. For these interviews, 14 patients were randomly selected from the RCT. Moreover, to understand patient satisfaction in patients with a low socioeconomic status (SES), 10 in-depth interviews were conducted, mainly focusing on the provision of information and communication by the care team. These patients were selected from the Box 2.0 study.

All qualitative data could be summarized into 5 themes regarding the use of *the Box*, namely, general instructions and information provision, the distribution of *the Box* by the hospital, taking home measurements, the video consultation, and finally the quality of provided support. Patients with a low SES completed additional questions on information provision and communication.

Professional Experience

Finally, the NPs and their supervisors were asked to share their experiences, thoughts, and comments. This team has worked with *the Box* and its patients daily since 2016, checking the measurement results and conducting video consultations.

Data Analysis

Content analysis was used for all qualitative data to structure the output provided by patients and professionals. Authors TEB

and ADH structured outcomes into different themes related to the process of using *the Box*.

Results

Demographics of All Box Patients

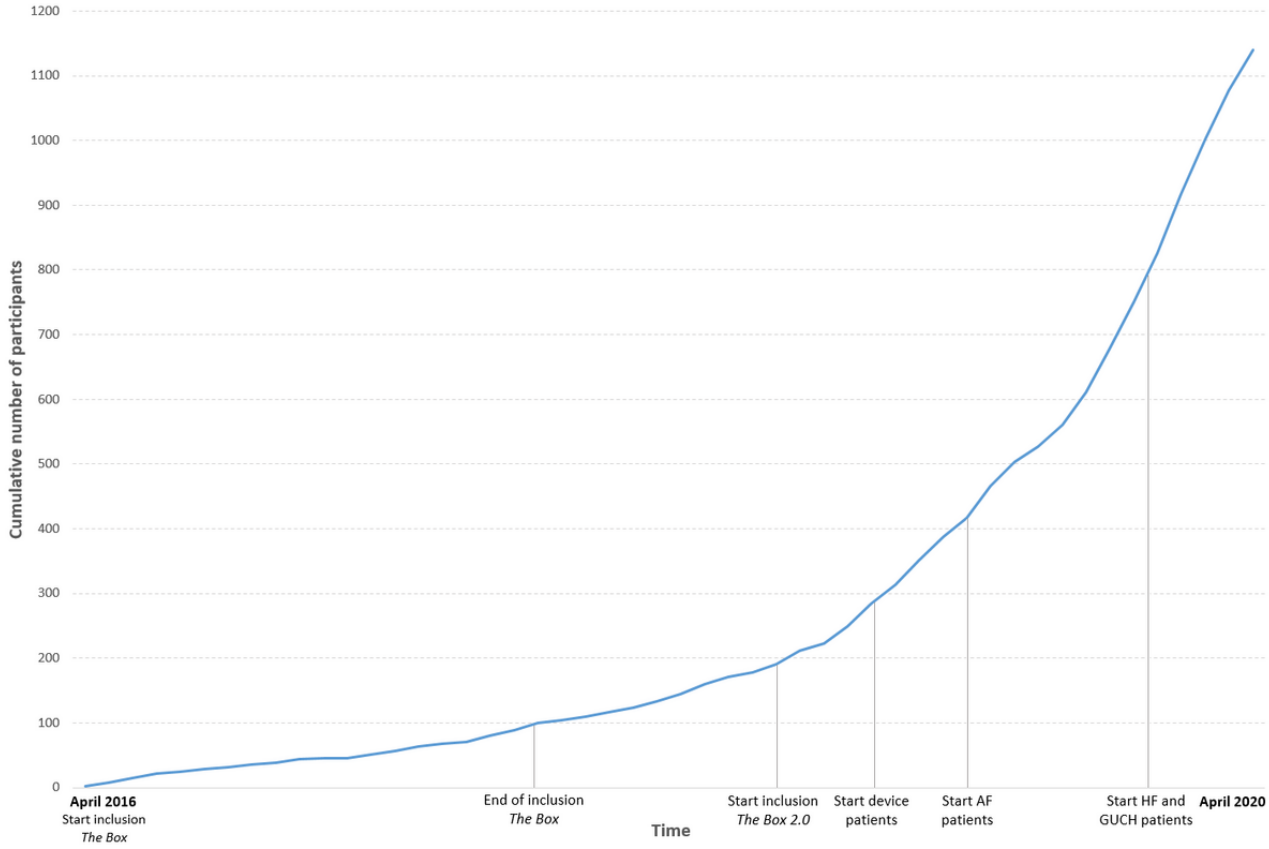
Patient demographics are shown in Table 2. From April 2016 to April 2020, a total of 1164 boxes were handed out to 1140 patients. A total of 24 patients were included in 2 protocols. Of the 24 patients, 20 (83%) used *the Box* after an MI, who were then switched to a postsurgery Box after they underwent coronary artery bypass grafting. The other 17% (4/24) of patients with 2 boxes used a Box after cardiac surgery, after which they were diagnosed with AF, who eventually needed to be treated with pulmonary vein isolation. As such, they used *the Box* for follow-up after AF ablation.

Table 2. Group characteristics of Box patients (N=1140).

Group characteristics	Total (n=1140)	Myocardial infarction (n=449)	Cardiac surgery (n=290)	Atrial fibrillation (n=260)	Device patients (n=71)	Heart failure (n=65)	Grown-ups with congenital heart (n=29)
Sex (male), n (%)	839 (73.6)	336 (75.5)	221 (76.2)	185 (71.2)	55 (77.5)	40 (60.1)	16 (55.2)
Age (years), median (IQR; range)	60.8 (52.9-69.3; 21.2-83.0)	59.9 (52.0-67.8; 32.7-83.0)	61.2 (53.9-69.5; 21.6-80.9)	62.0 (56.9-69.5; 34.8-78.9)	66.3 (59.7-72.6; 44.3-79.1)	67.4 (52.2-72.9; 32.8-80.0)	46.4 (43.9-49.6; 21.2-57.7)
Number of measurements, median (IQR; range)	260 (105-641; 1-3159)	336 (133-790; 2-3159)	295 (159-504; 2-2537)	54 (16-128; 2-993)	867 (503-1177; 1-2010)	337 (145-492; 6-1882)	169 (62-368; 11-1675)
Number of days of measurements taken, median (IQR; range)	189 (98-372; 1-1216)	296 (120-466; 1-1216)	165 (87-338; 1-846)	137 (43-232; 1-519)	303 (230-376; 1-468)	142 (99-177; 3-246)	144 (104-179; 2-230)
Travel distance (kilometers), median (IQR; range)	14.8 (7.0-24.3; 1.0-2075.0)	10.5 (5.1-21.2; 1.0-571.0)	14.8 (7.0-23.0; 1.0-2075.0)	16.6 (10.1-28.7; 1.0-193.6)	17.3 (7.0-28.0; 3.1-121.1)	14.3 (7.0-20.9; 2.6-105.8)	50.1 (22.9-119.6; 5.1-230.9)

The median age of all patients of *the Box* was 60.8 (IQR 52.9-69.3) years, with GUCH disease being the youngest (median 46.4, IQR 43.9-69.6 years) and patients with HF being the oldest (median 67.4, IQR 52.2-72.9 years). In total, 73.59% (839/1140) of patients were male. The median number of measurements taken was 260 (IQR 105-641). There was a large between-group variation, which could be explained by the difference in the number of devices used and the difference in follow-up time. The median number of days on which patients conducted at least one measurement was 189 (IQR 98-372). This might be explained by the difference when each group has started using *the Box*, as shown in Figure 3.

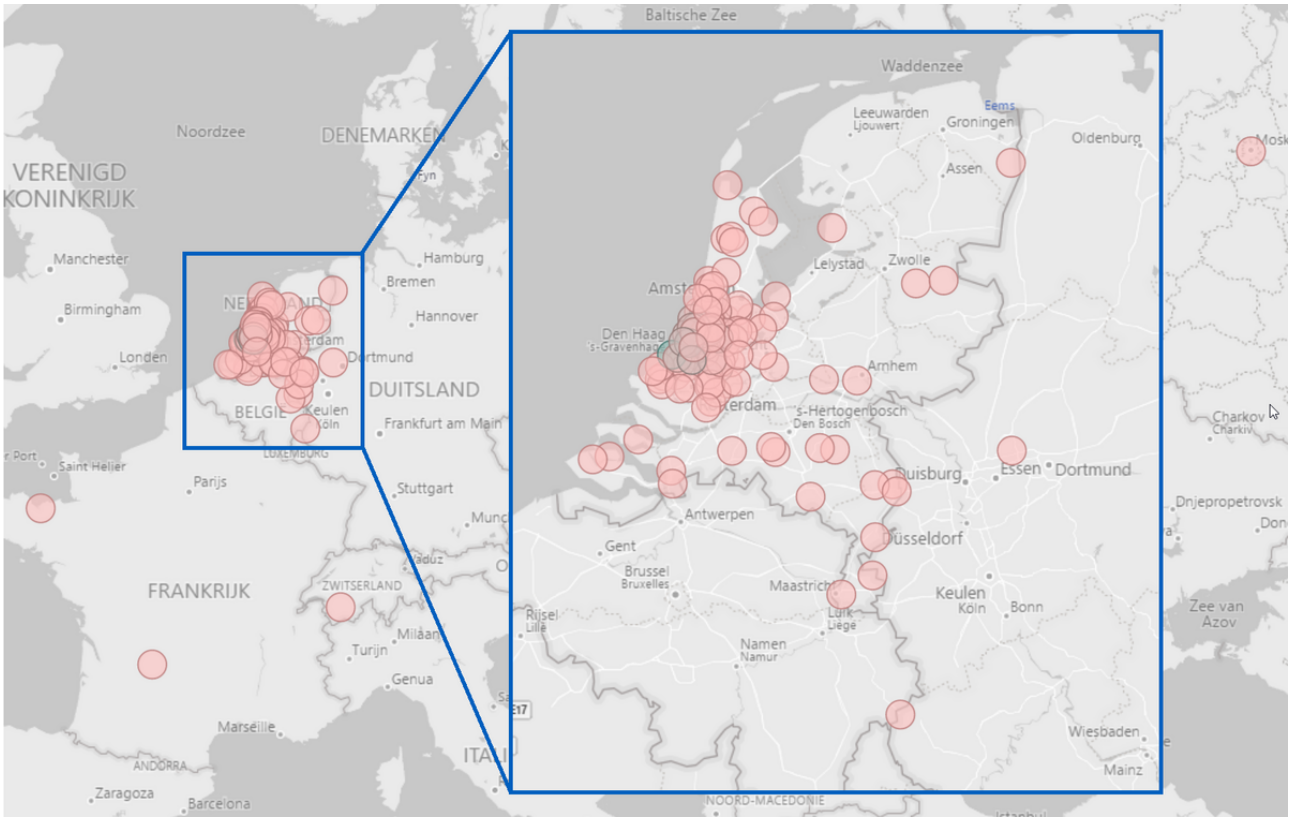
Figure 3. The cumulative number of Box patients over time. *The Box*: randomized controlled trial randomizing 200 patients after myocardial infarction to either the Box or regular follow-up. *The Box 2.0*: trial including 350 post–cardiac surgery patients comparing them with 350 historic control patients. Device patients: patients with an implantable cardioverter-defibrillator or cardiac resynchronization therapy device (patients with AF: patients who underwent atrial fibrillation ablation). AF: atrial fibrillation; GUCH: grown-ups with congenital heart; HF: heart failure.



The mean travel distance to the hospital was 14.8 (IQR 7.0-24.3) km. Most Box patients live relatively close to the LUMC. Some, however, live outside the Netherlands, with the furthest patients living in Thailand. Figure 4 shows the locations of all 1140 Box patients throughout the Netherlands and Europe.

A total of 19,450 single lead Kardia ECGs were sent in (patient's mean 39; IQR 21-67) by 449 patients. The number of CardioSecur ECGs was 2125 (patient's mean 8; IQR 6-13) in 290 cardiac surgery patients. The AF cohort of 260 patients made 2910 CardioSecur ECGs (patient's mean 11; IQR 7-17). The large difference between the MI group and the other 2 groups regarding ECG measurements is because the follow-up of the MI population is longer than any other group and because they were requested to send in a registration 3 times per week. The other groups only did so once every week but also when the Kardia indicated a possible rhythm disturbance and when patients experienced palpitations.

Figure 4. Patient spread throughout the Netherlands and Europe. The red dots represent patient locations, and the green dot represents the location of the Leiden University Medical Center.



Box Distribution

The Box started with 200 patients who were included in the RCT in a 1:1, randomized fashion between receiving mHealth follow-up with a Box or regular outpatient follow-up. In November 2017, the last patient was included in this RCT, and as such, 100 boxes were distributed. Thereafter, *the Box* was continued as a standard of care for patients who had MI. In November 2018, *the Box 2.0* started including patients who underwent cardiac surgery. In February 2019, *the Box* became the standard outpatient care for patients with a cardiac device, and in May 2019, *the Box* became the standard outpatient care for patients after AF ablation. Finally, from November 2019 onward, the GUCH disease and patients with HF received *the Box*. Figure 3 shows the cumulative number of patients over time. From 2016 to 2019, 44, 65, 175, and 542 boxes were distributed annually. In 2020, a distribution of 1100 boxes was expected.

Patient Interviews

Overview

The 24 patients who were interviewed had a median age of 61.3 (IQR 48.4-69.7) years. In total, 14 of them participated in *the Box* in 2017, 7 in 2018, and 3 in 2019. Generally, the patients stated *the Box* to be a useful tool for longer use than the intended period of 1 year in patients with MI. Most (21/24, 88%) patients felt *looked after* with the use of *the Box*; however, 33% (8/24) of patients would have preferred an improved feedback system. Textboxes 1 and 2 show the most often heard positive and negative statements regarding the use of *the Box*.

Textbox 1. Most frequent positive comments.

Positive comments about *the Box*

- "*The Box* is easy to use."
- "*The Box* stimulates me to go out: my physical condition has improved and I feel less tired."
- "I know more about my illness now that I'm learning normal blood pressure values and ECG readings from taking daily measurements."
- "It is reassuring to know that professionals look after me, also in my own environment."
- "I feel more confident in my body since the use of the mHealth devices."
- "I, but also my family, are more aware of potential lifestyle improvements."
- "I better understand now that patients have a responsibility in their rehabilitation, and *The Box* is a tool that helps me do so."

Textbox 2. Most frequent negative comments.

Negative comments about *the Box*

- "I would have preferred a feedback system, which reassures patients that the measurements are looked at."
- "*The Box* confronts me with my illness on a daily basis."
- "*The Box* is too big."
- "It does not yet feel like the Box connects seamlessly with other rehabilitation programs."

General Instructions and Provision of Information

Most patients (22/24, 92%) reported the installation process to be successful before they left the hospital, although at the same time, an equally large group of patients (22/24, 92%) recalled that the amount of information was too much to remember. In total, 21% (5/24) of patients had questions within a day after *the Box* was installed, of whom, 60% (3/5) were able to solve their questions with the manuals of *the Box*. However, no patients stated that *the Box* was too complicated for them to be able to start with.

Distribution Phase

All the patients valued the personal instructions, and no remarks were made on how this process took place. Out of the 24 patients, 8 (33%) patients would have preferred to install *the Box* on their own. A total of 79% (19/24) of patients were satisfied with receiving instructions in the hospital, and 21% (4/24) of patients preferred it to take place after discharge from the hospital.

Home Measurements

Patients took a median of 10 (IQR 5-15) minutes daily to take their measurements. A total of 71% (17/24) of patients trusted the validity of the measurements, whereas 4% (1/24) did not. The other 25% (6/24) of patients had no opinion on this subject. A total of 71% (17/24) of patients reported improved patient empowerment and a feeling of control over their illness, with the use of *the Box*, but 21% (5/24) of patients noticed no difference. A total of 8% (2/24) of patients did not answer this question. The reported issues were loss of Bluetooth connection with the devices (7/24, 29%), mainly the blood pressure monitor and signal noise when taking an ECG with the AliveCor Kardia (6/24, 25%). In addition, patients reported the use of all different mobile apps as time consuming (19/24, 79%).

Video Consultation

A total of 71% (17/24) of patients completed a video consultation. A total of 29% (7/24) of patients were unable to do so, with technical issues being the major reason (5/7, 71%). Some patients (3/24, 13%) experienced problems with either sound or video connection. Patients praised the fact that it was not necessary to come to the hospital, especially for people with mobility issues. One patient stated that the video consultation was effective but preferred a physical consultation, nonetheless.

Quality of Provided Support

Most patients (18/24, 75%) did not contact the helpdesk during the time they used *the Box*. Of the remaining 6 patients, 5 (21%) reported being happy with the service provided by the helpdesk, whereas 4% (1/24) of patients reported that issues were not resolved.

Most patients (18/24, 75%) stated that they preferred feedback on the measurements sent. A total of 17% (4/24) of patients recalled having noticed abnormal measurements, but only 4% (1/24) acted upon this. Of the other 3 patients, 2 (67%) expected to be contacted by *the Box* care team, and 1 (33%) patient did not want to bother the care providers.

Extra Items for Patients With a Low SES

A total of 90% (9/10) of patients with a low SES reported having issues with using the Health Mate and AliveCor Kardia apps because of the English instructions. A total of 50% (5/10) of patients stated that the terminology used in the manuals provided was too complicated to comprehend. A total of 30% (3/10) of patients stated that the use of more pictures would increase the functionality of the manuals and apps. Finally, 20% (2/10) of patients spontaneously mentioned that a reward system may be beneficial for their physical rehabilitation.

Professional Experience

All NPs stated that when patients used *the Box*, fewer questions were asked, and the questions they had were more related to the illness, compared with non-Box patients. The NPs reported that the number of telephone consultations based on device readouts was low and did not interfere with their daily patient care. In addition, the possibility of looking up historical measurements and following a blood pressure trend were regarded as positive.

Video consultations provided a lower threshold to discuss topics such as sexuality and lifestyle without an increase in consultation time. However, professionals stated that difficulties with the internet connection at the patients' homes interfered with the quality of the consultations done via the web. Equally, the necessity of a well-equipped and staffed technical support service was stressed as an important improvement for professionals.

Discussion

Principal Findings

Overview

The Box shows that a structural implementation of an mHealth initiative in daily outpatient clinic care is feasible in patients with cardiovascular disease (CVD). *The Box* has served 1140 patients within 4 years since its implementation, with a median participant's age of 60.8 years. Most patients (839/1140, 73.59%) were male, which is most likely not explained by a

higher mHealth engagement in men but rather by known sex differences in CVD leading to an overrepresentation of male patients [18-20]. *The Box* was well-received: patients described *the Box* as easy to use and reported an increased empowerment, providing them with more insight on their illness. NPs noticed this empowerment as well, as they described receiving fewer questions from patients and the questions being more on-topic compared with patients without a Box.

Trends in Box Distribution

As shown in Figure 3, it has been noticed that the number of patients receiving a Box is somewhat less during summer compared with the rest of the year. It is hypothesized that this is mainly because of fewer interventions (eg, AF ablations, cardiac surgery, and implantable cardioverter-defibrillator implantations) being carried out. After the outbreak of COVID-19 in the Netherlands in March 2020 [21], the initial rate at which boxes were handed out to patients with CVD has slowed down slightly because of a decline in the number of elective interventions. However, because of lockdown measures, physical outpatient clinic visits were cancelled and replaced by video consultations. To support this, more patients chose follow-up with *the Box* and concordantly, by video consultations instead of physical outpatient clinic visits without a Box. Moreover, a tailored Box was designed for patients with COVID-19. The timing of these adjustments correlates with the timing of the increase in the number of boxes. Thus, causality was assumed.

Patient Experiences and Perspectives

Overview

Box users were overall satisfied with the care delivered via the mHealth care track. Distribution, installation, technical support, and ease of use were praised; however, internet and Bluetooth connection issues were frequently reported by users as troublesome. Identically, a feedback mechanism for sent measurements was noted by the majority of the interviewees as an important missing feature. These findings are in line with other studies that implemented eHealth care tracks in different health care domains [22-25]. eHealth satisfaction is generally high, as suggested by other sample studies [26,27]. Although evidence is scarce, internet connection and video quality issues are often mentioned to reduce satisfaction. These issues were also mentioned by the interviewees. This stresses the need for a strong digital infrastructure to support patients and professionals alike.

In the qualitative interviews, it was found that although satisfaction is high, patients find taking their own measurements time-consuming. This is possibly reflected in the relatively low median number of measurements taken, as shown in Table 2. However, there is no consensus on how to increase patient empowerment and participation; the concept of *gamification* could help to increase the number of measurements taken per patient [28,29]. This method has been proposed to improve patient behavior such as self-monitoring and could be investigated further for future improvements of *the Box* [30].

Feasibility of mHealth From the Patient's Perspective

The findings of 4 years of clinical experience have indicated that eHealth is accepted by patients and that implementation is feasible. The results of our qualitative interviews indicate that patients become more active participants as they are asked to measure their own vitals daily. These findings were supported by the findings of an RCT in patients who had an MI [15]. These findings should be considered as hypothesis-generating and should be corroborated in future studies. A small minority of patients stopped using *the Box*. Of this group, the majority stated that taking daily measurements caused anxiety or distress rather than providing control over their disease. To some, it feels that they are continuously confronted with their illness, stigmatizing them. This effect has not yet been described in the literature; however, the negative effects of smartphone use on anxiety and stress levels have been described [31,32]. It is questionable how much an mHealth care track contributes to health care in patients who experience anxiety or another form of distress because of the service. Therefore, the extent and implications are being investigated as part of *the Box 2.0* [16].

Comparison With the Literature

Often, mHealth studies use apps or other forms of guidance via participants' mobile phones as an intervention rather than using mHealth devices such as a blood pressure monitor. For example, mHealth interventions in patients with chronic pain, diabetes mellitus, and mental health issues focus on improved information provision and strive for accessible ways to do so [33-35]. As these studies differ vastly from device studies, it was decided to only compare studies in which mHealth devices were used.

Lu et al [36] recently performed a meta-analysis of 11 RCTs to synthesize the effects of mHealth on blood pressure control, 9 of which used a self-monitoring blood pressure intervention. Participants were asked to measure their blood pressure up to 4 times a week and were followed up by telephone calls, SMS text messages, and emails. The mean participant age of these 9 studies varied from 57.0 to 67.4 years, with a median of 60.7 years. This is in line with the median age of 60.8 years of Box participants. One trial did not report the gender of the participants. Of the 3144 participants in the 8 remaining trials, 1752 (55.72%) were male. However, these studies were not carried out in patients with CVD but in patients with hypertension. The same is true for one of the largest mHealth trials, Assessment of Remote Heart Rhythm Sampling using the AliveCor heart monitor to screen for AF, which recruited 1001 participants >65 years via general practitioner records [37]. The mean age was 72.6 years (SD 5.4 years), and 46.55% (466/1001) of participants were males. A total of 50.05% (501/1001) of participants underwent an mHealth intervention, which consisted of acquiring a single lead ECG using an AliveCor Kardia twice weekly over 12 months. Although the mean age was high, most participants found it easy to use the device.

Few mHealth studies, focusing on those with CVD, can be compared with *the Box*. Oftentimes, studies only use 1 device, compared with up to 7 devices of *the Box* or a patch is studied for its diagnostic capabilities of rhythm disturbances [38-40].

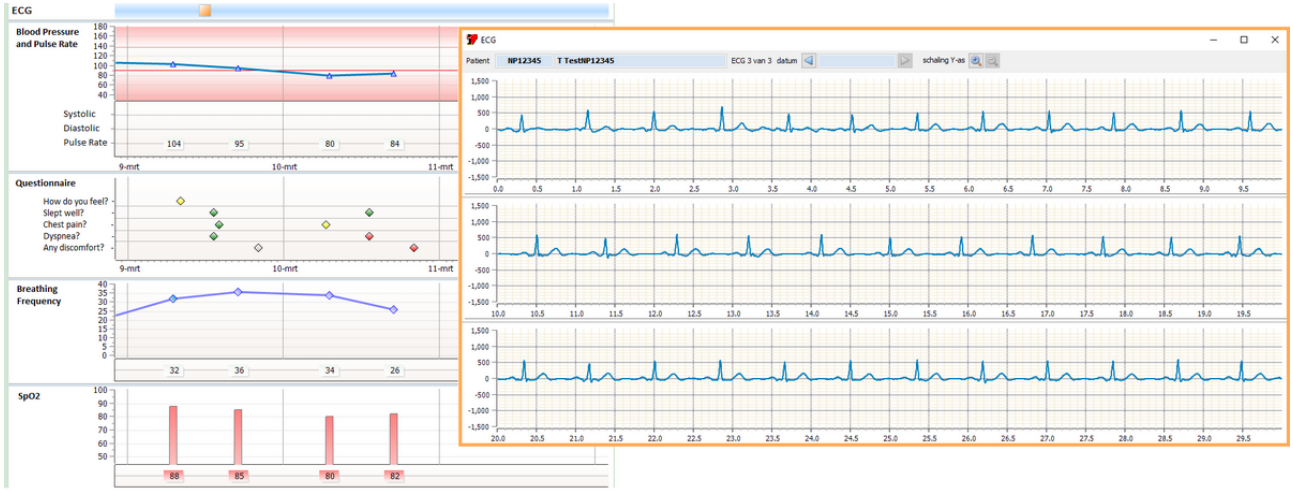
One study carried out by McElroy et al [41] included 443 patients who underwent cardiac surgery. These patients underwent an intervention to reduce readmissions by offering improved education, including daily face-to-face sessions. Simultaneously, 27 patients who enrolled in a pilot project also received an mHealth intervention in the form of a so-called digital health kit, consisting of a blood pressure and heart rate monitor, a pulse oximeter, and a weight scale. However, it is unclear how these 27 patients were selected. The mean age of the 416 patients who received the improved education was 65.9 years (SD 14.1 years), with 65.8% (274/416) being male. The mean age of the 27 patients who received the mHealth intervention was 62.9 years (SD 9.8 years), with 85% (23/27) being male. However, the mHealth intervention did not significantly reduce the readmission rate; both patients and health care providers were satisfied with the intervention.

Strengths and Limitations of the Box

The Box has strengths on both the patient and care provider level: it provides patients with more insight on their illness and engages them in their own care. Simultaneously, the NPs reported receiving fewer but more to-the-point questions from these patients. *The Box* has resulted in more outpatient clinic visits being replaced by webcam consultations. These consultations have been reported by both patients and health care professionals as accessible, more homelike, and productive. Therefore, *the Box* has become a major asset to the cardiology department of the LUMC.

A limitation of *the Box* is the need for manual measurement checks. Although time is saved because of the replacement of outpatient contact moments with video consultations, NPs manually go through the list of measurements multiple times a week, creating a risk of data overload. Artificial intelligence may provide a solution to this problem. This is currently being investigated, together with engineers at the Delft University of Technology. However, as the project developed, EMR updates have provided NPs with a user interface for an easier overview of patients' measurements, saving time compared with the start of the project. The most recent version of the EMR is shown in Figure 5.

Figure 5. The user interface of the electronic medical record as of 2020, with incorporation of device and electrocardiogram data from the Withings Move electrocardiogram. ECG: electrocardiogram.



Another limitation of our satisfaction analysis was the qualitative approach via interviews with a smaller sample. For a validated approach, satisfaction could have been measured more quantitatively with, for instance, the Telemedicine Usability Questionnaire [42].

Finally, it has to be noted that *the Box* was implemented in a tertiary care center, connected to a university. As *the Box* started with an RCT, part of the infrastructure was built for research purposes and funded via research grants. It is acknowledged that the setting might limit the external validity of the claim that *the Box* can be implemented in regular clinical care.

Conclusions

In this study, the design and implementation of an mHealth care track in the outpatient clinic follow-up of patients with various CVDs was described. Data from these 4 years indicate that mHealth is feasible to incorporate in outpatient management and is generally well-accepted by patients and providers. Patient satisfaction is generally high, with patients praising its ease of use and educational capabilities. Providers commend on its ability to enhance patient engagement and medical literacy. Limitations include the need for manual measurement data checks and the risk of data overload. Moreover, the tertiary care setting in which *the Box* was introduced may limit the external validity of logistical and financial end points to other medical centers. More evidence is needed to show the effects of mHealth on clinical outcomes and cost-effectiveness.

Conflicts of Interest

RWT receives speaker fees from Boston Scientific, Pfizer, and Sanofi.

References

1. World Health Organization. MHealth: New Horizons for Health Through Mobile Technologies. Geneva, Switzerland: World Health Organization; 2011.
2. PubMed. (ehealth or mhealth) not telemedicine. 2020. URL: https://pubmed.ncbi.nlm.nih.gov/?term=%28ehealth+or+mhealth%29+not+telemedicine; [accessed 2020-10-18]
3. CBS. Internet; toegang, gebruik en faciliteiten; 2012-2019. 2020. URL: https://opendata.cbs.nl/statline/#/CBS/nl/dataset/83429NED/table?fromstatweb; [accessed 2020-10-18]
4. Internet; toegang, gebruik en faciliteiten; 2012-2019. Statline. 2019. URL: https://longreads.cbs.nl/europese-meetlat-2019/internet/ [accessed 2020-10-18]
5. O'Dea S. Smartphone user penetration as share of population in the United States from 2018 to 2025. Available via https://www.statista.com/statistics/201184/percentage-of-mobile-phone-users-who-use-a-smartphone-in-the-us/: Statista; Oct 2020.
6. Topol EJ. Transforming medicine via digital innovation. Sci Transl Med 2010 Jan 27;2(16):16cm4 [FREE Full text] [doi: 10.1126/scitranslmed.3000484] [Medline: 20371472]
7. Dorn SD. Digital health: hope, hype, and Amara's law. Gastroenterology 2015 Sep;149(3):516-520. [doi: 10.1053/j.gastro.2015.07.024] [Medline: 26226565]
8. Silva BM, Rodrigues JJ, de la Torre Díez I, López-Coronado M, Saleem K. Mobile-health: a review of current state in 2015. J Biomed Inform 2015 Aug;56:265-272 [FREE Full text] [doi: 10.1016/j.jbi.2015.06.003] [Medline: 26071682]
9. Dorsey ER, Topol EJ. Telemedicine 2020 and the next decade. Lancet 2020 Mar 14;395(10227):859. [doi: 10.1016/S0140-6736(20)30424-4] [Medline: 32171399]
10. Treskes RW, Koole M, Kauw D, Winter MM, Monteiro M, Dohmen D, et al. Adults with congenital heart disease: ready for mobile health? Neth Heart J 2019 Mar 13;27(3):152-160 [FREE Full text] [doi: 10.1007/s12471-019-1237-2] [Medline: 30758718]
11. Treskes RW, Wildbergh TX, Schalij MJ, Scherptong RW. Expectations and perceived barriers to widespread implementation of e-Health in cardiology practice: results from a national survey in the Netherlands. Neth Heart J 2019 Jan 28;27(1):18-23 [FREE Full text] [doi: 10.1007/s12471-018-1199-9] [Medline: 30488379]
12. Kauw D, Koole MA, Winter MM, Dohmen DA, Tulevski II, Blok S, et al. Advantages of mobile health in the management of adult patients with congenital heart disease. Int J Med Inform 2019 Dec;132:104011 [FREE Full text] [doi: 10.1016/j.ijmedinf.2019.104011] [Medline: 31654966]
13. Treskes RW, van Winden LA, van Keulen N, Atsma DE, van der Velde ET, van den Akker-van Marle E, et al. Using smart technology to improve outcomes in myocardial infarction patients: rationale and design of a protocol for a randomized controlled trial, The Box. JMIR Res Protoc 2017 Sep 22;6(9):e186. [doi: 10.2196/resprot.8038] [Medline: 28939546]
14. Liem S, van der Hoeven BL, Oemrawsingh PV, Bax JJ, van der Bom JG, Bosch J, et al. MISSION!: optimization of acute and chronic care for patients with acute myocardial infarction. Am Heart J 2007 Jan;153(1):14.e1-14e11. [doi: 10.1016/j.ahj.2006.10.002] [Medline: 17174628]
15. Treskes RW, van Winden LA, van Keulen N, van der Velde ET, Beeres SL, Atsma DE, et al. Effect of smartphone-enabled health monitoring devices vs regular follow-up on blood pressure control among patients after myocardial infarction: a randomized clinical trial. JAMA Netw Open 2020 Apr 01;3(4):e202165 [FREE Full text] [doi: 10.1001/jamanetworkopen.2020.2165] [Medline: 32297946]
16. Biersteker TE, Boogers MJ, de Lind van Wijngaarden RA, Groenwold RH, Trines SA, van Alem AP, et al. Use of smart technology for the early diagnosis of complications after cardiac surgery: The Box 2.0 study protocol. JMIR Res Protoc 2020 Apr 21;9(4):e16326 [FREE Full text] [doi: 10.2196/16326] [Medline: 32314974]
17. Clark PA, Capuzzi K, Harrison J. Telemedicine: medical, legal and ethical perspectives. Med Sci Monit 2010;16(12):RA261-RA272. [Medline: 21119593]
18. Möller-Leimkühler AM. Gender differences in cardiovascular disease and comorbid depression. Dialogues Clin Neurosci 2007;9(1):71-83 [FREE Full text] [doi: 10.31887/DCNS.2007.9.1/ammoeller] [Medline: 17506227]
19. Regitz-Zagrosek V, Kararigas G. Mechanistic pathways of sex differences in cardiovascular disease. Physiol Rev 2017 Jan;97(1):1-37 [FREE Full text] [doi: 10.1152/physrev.00021.2015] [Medline: 27807199]
20. Jackson R, Chambless L, Higgins M. Sex difference in ischemic heart disease mortality and risk factors in 46 communities: an écologie analysis. WHO MONICA project, and ARIC study. Cardiovasc Risk Factors 1997;7:43-54 [FREE Full text]
21. Actuele Informatie Over Het Nieuwe Coronavirus (COVID-19). RIVM. 2020. URL: https://www.rivm.nl/coronavirus-covid-19/actueel [accessed 2020-10-18]
22. Khairat S, Liu S, Zaman T, Edson B, Gianforcaro R. Factors determining patients' choice between mobile health and telemedicine: predictive analytics assessment. JMIR Mhealth Uhealth 2019 Jun 08;7(6):e13772 [FREE Full text] [doi: 10.2196/13772] [Medline: 31199332]
23. Alessi SM, Rash CJ. Treatment satisfaction in a randomized clinical trial of mHealth smoking abstinence reinforcement. J Subst Abuse Treat 2017 Jan;72:103-110 [FREE Full text] [doi: 10.1016/j.jsat.2016.06.013] [Medline: 27449226]
24. Hsiao JL, Chen RF. Understanding determinants of health care professionals' perspectives on mobile health continuance and performance. JMIR Med Inform 2019 Mar 18;7(1):e12350 [FREE Full text] [doi: 10.2196/12350] [Medline: 30882353]

25. Layfield E, Triantafillou V, Prasad A, Deng J, Shanti RM, Newman JG, et al. Telemedicine for head and neck ambulatory visits during COVID-19: evaluating usability and patient satisfaction. Head Neck 2020 Jul;42(7):1681-1689 [FREE Full text] [doi: 10.1002/hed.26285] [Medline: 32476228]
26. Forbes RC, Solorzano CC, Concepcion BP. Surgical telemedicine here to stay: more support from a randomized controlled trial on postoperative surgery visits. Am J Surg 2020 Jun;219(6):880-881 [FREE Full text] [doi: 10.1016/j.amjsurg.2020.03.033] [Medline: 32265012]
27. Serwe KM, Hersch GI, Pancheri K. Feasibility of using telehealth to deliver the "powerful tools for caregivers" program. Int J Telerehabil 2017;9(1):15-22 [FREE Full text] [doi: 10.5195/ijt.2017.6214] [Medline: 28814991]
28. Risling T, Martinez J, Young J, Thorp-Froslie N. Evaluating patient empowerment in association with eHealth technology: scoping review. J Med Internet Res 2017 Sep 29;19(9):e329 [FREE Full text] [doi: 10.2196/jmir.7809] [Medline: 28963090]
29. Deterding S, Dixon D, Khaled R, Nacke L. From game design elements to gamefulness. In: Proceedings of the 15th International Academic MindTrek Conference: Envisioning Future Media Environments. 2011 Presented at: The 15th International Academic MindTrek Conference on Evisioning Future Media Environments; Sep 28 - 30, 2011; Tampere Finland. [doi: 10.1145/2181037.2181040]
30. Turner-McGrievy GM, Beets MW, Moore JB, Kaczynski AT, Barr-Anderson DJ, Tate DF. Comparison of traditional versus mobile app self-monitoring of physical activity and dietary intake among overweight adults participating in an mHealth weight loss program. J Am Med Inform Assoc 2013 May 01;20(3):513-518 [FREE Full text] [doi: 10.1136/amiajnl-2012-001510] [Medline: 23429637]
31. Vahedi Z, Saiphoo A. The association between smartphone use, stress, and anxiety: a meta-analytic review. Stress Health 2018 Aug 19;34(3):347-358. [doi: 10.1002/smi.2805] [Medline: 29673047]
32. Tangmunkongvorakul A, Musumari PM, Thongpibul K, Srithanaviboonchai K, Techasrivichien T, Suguimoto SP, et al. Association of excessive smartphone use with psychological well-being among university students in Chiang Mai, Thailand. PLoS One 2019 Jan 7;14(1):e0210294 [FREE Full text] [doi: 10.1371/journal.pone.0210294] [Medline: 30615675]
33. Moman R, Dvorkin J, Pollard EM, Wanderman R, Murad MH, Warner DO, et al. A systematic review and meta-analysis of unguided electronic and mobile health technologies for chronic pain-is it time to start prescribing electronic health applications? Pain Med 2019 Nov 01;20(11):2238-2255. [doi: 10.1093/pm/pnz164] [Medline: 31386151]
34. Nkhom D, Soko C, Bowrin P, Iqbal U. Stud Health Technol Inform 2020 Jun 16;270:1263-1264. [doi: 10.3233/SHTI200393] [Medline: 32570610]
35. Inal Y, Wake JD, Guribye F, Nordgreen T. Usability evaluations of mobile mental health technologies: systematic review. J Med Internet Res 2020 Jan 06;22(1):e15337 [FREE Full text] [doi: 10.2196/15337] [Medline: 31904579]
36. Lu X, Yang H, Xia X, Lu X, Lin J, Liu F, et al. Interactive mobile health intervention and blood pressure management in adults. Hypertension 2019 Sep;74(3):697-704. [doi: 10.1161/HYPERTENSIONAHA.119.13273] [Medline: 31327259]
37. Halcox JP, Wareham K, Cardew A, Gilmore M, Barry JP, Phillips C, et al. Assessment of Remote heart rhythm sampling using the AliveCor heart monitor to screen for atrial fibrillation: the REHEARSE-AF study. Circulation 2017 Nov 07;136(19):1784-1794. [doi: 10.1161/CIRCULATIONAHA.117.030583] [Medline: 28851729]
38. Barrett PM, Komatireddy R, Haaser S, Topol S, Sheard J, Encinas J, et al. Comparison of 24-hour Holter monitoring with 14-day novel adhesive patch electrocardiographic monitoring. Am J Med 2014 Jan;127(1):95.e11-95.e17 [FREE Full text] [doi: 10.1016/j.amjmed.2013.10.003] [Medline: 24384108]
39. Reed MJ, Grubb NR, Lang CC, Gray AJ, Simpson K, MacRaild A, et al. Diagnostic yield of an ambulatory patch monitor in patients with unexplained syncope after initial evaluation in the emergency department: the PATCH-ED study. Emerg Med J 2018 Aug 19;35(8):477-485. [doi: 10.1136/emermed-2018-207570] [Medline: 29921622]
40. Kaura A, Sztriha L, Chan FK, Aeron-Thomas J, Gall N, Piechowski-Jozwiak B, et al. Early prolonged ambulatory cardiac monitoring in stroke (EPACS): an open-label randomised controlled trial. Eur J Med Res 2019 Jul 26;24(1):25 [FREE Full text] [doi: 10.1186/s40001-019-0383-8] [Medline: 31349792]
41. McElroy I, Sareh S, Zhu A, Miranda G, Wu H, Nguyen M, et al. Use of digital health kits to reduce readmission after cardiac surgery. J Surg Res 2016 Jul;204(1):1-7. [doi: 10.1016/j.jss.2016.04.028] [Medline: 27451860]
42. Parmanto B, Lewis Jr AN, Graham KM, Bertolet MH. Development of the Telehealth Usability Questionnaire (TUQ). Int J Telerehabil 2016;8(1):3-10 [FREE Full text] [doi: 10.5195/ijt.2016.6196] [Medline: 27563386]

Abbreviations

AF: atrial fibrillation
CVD: cardiovascular disease
ECG: electrocardiogram
EMR: electronic medical record
GUCH: grown-ups with congenital heart
HF: heart failure
LUMC: Leiden University Medical Center
mHealth: mobile health

MI: myocardial infarction
NP: nurse practitioner
RCT: randomized controlled trial
SES: socioeconomic status

Edited by R Kukafka, G Eysenbach; submitted 26.11.20; peer-reviewed by H Saner, M Mars; comments to author 27.01.21; revised version received 15.02.21; accepted 03.10.21; published 16.12.21.

Please cite as:
Biersteker T, Hilt A, van der Velde E, Schalij MJ, Treskes RW
Real-World Experience of mHealth Implementation in Clinical Practice (the Box): Design and Usability Study
JMIR Cardio 2021;5(2):e26072
URL: https://cardio.jmir.org/2021/2/e26072
doi:10.2196/26072
PMID:34642159

Original Paper

Financial Incentives for Healthy Living for Patients With Cardiac Disease From the Perspective of Health Care Professionals: Interview Study

David de Buisonjé[1], MSc; Jessica Van der Geer[1], MSc; Mike Keesman[1], PhD; Roos Van der Vaart[1], PhD; Thomas Reijnders[1], PhD; Jobke Wentzel[2], PhD; Hareld Kemps[3], MD, PhD; Roderik Kraaijenhagen[4], MD, PhD; Veronica Janssen[1,5], PhD; Andrea Evers[1,5,6], Prof Dr

[1]Health, Medical and Neuropsychology Unit, Leiden University, Leiden, Netherlands

[2]Department of Psychology, Health and Technology, University of Twente, Enschede, Netherlands

[3]Department of Cardiology, Máxima Medical Center, Veldhoven, Netherlands

[4]Hearts4people Foundation, Amsterdam, Netherlands

[5]Leiden University Medical Center, Leiden University, Leiden, Netherlands

[6]Medical Delta, Leiden-Delft-Erasmus Universities, Delft, Netherlands

Corresponding Author:
David de Buisonjé, MSc
Health, Medical and Neuropsychology Unit
Leiden University
Faculty of Social Sciences, Room 2A22
Wassenaarseweg 52
Leiden, 2333 AK
Netherlands
Phone: 31 630665252
Email: d.r.de.buisonje@fsw.leidenuniv.nl

Abstract

Background: A promising new approach to support lifestyle changes in patients with cardiovascular disease (CVD) is the use of financial incentives. Although financial incentives have proven to be effective, their implementation remains controversial, and ethical objections have been raised. It is unknown whether health care professionals (HCPs) involved in CVD care find it acceptable to provide financial incentives to patients with CVD as support for lifestyle change.

Objective: This study aims to investigate HCPs' perspectives on using financial incentives to support healthy living for patients with CVD. More specifically, we aim to provide insight into attitudes toward using financial incentives as well as obstacles and facilitators of implementing financial incentives in current CVD care.

Methods: A total of 16 semistructured, in-depth, face-to-face interviews were conducted with Dutch HCPs involved in supporting patients with CVD with lifestyle changes. The topics discussed were attitudes toward an incentive system, obstacles to using an incentive system, and possible solutions to facilitate the use of an incentive system.

Results: HCPs perceived an incentive system for healthy living for patients with CVD as possibly effective and showed generally high acceptance. However, there were concerns related to focusing too much on the extrinsic aspects of lifestyle change, disengagement when rewards are insignificant, paternalization and threatening autonomy, and low digital literacy in the target group. According to HCPs, solutions to mitigate these concerns included emphasizing intrinsic aspects of healthy living while giving extrinsic rewards, integrating social aspects to increase engagement, supporting autonomy by allowing freedom of choice in rewards, and aiming for a target group that can work with the necessary technology.

Conclusions: This study mapped perspectives of Dutch HCPs and showed that attitudes are predominantly positive, provided that contextual factors, design, and target groups are accurately considered. Concerns about digital literacy in the target group are novel findings that warrant further investigation. Follow-up research is needed to validate these insights among patients with CVD.

(JMIR Cardio 2021;5(2):e27867) doi:10.2196/27867

KEYWORDS

financial incentives; material rewards; healthy lifestyle; cardiovascular disease; cardiac rehabilitation; CVD

Introduction

Background

Despite the proven effectiveness of cardiac rehabilitation in initiating lifestyle change, many people with cardiovascular disease (CVD) fail to maintain a healthy lifestyle in the long term and relapse into unhealthy habits when they return to everyday life [1]. Therefore, there is an urgent need to find new approaches that increase the uptake of and long-term adherence to lifestyle interventions for patients with CVD [2]. A promising new approach is the use of financial incentives as a supplement to existing lifestyle interventions in CVD care. Financial incentives have not been applied often in the context of CVD care but have proven to be effective for a wide range of lifestyle behaviors that are relevant to CVD, including medication adherence, weight loss, smoking cessation, and physical activity [3-6]. However, implementing financial incentives for a healthy lifestyle remains controversial, and ethical objections have been raised [7]. For example, financial incentives can be perceived as paternalistic, coercive, involve bribery, or undermine the agency of the person [7]. Indeed, a recent systematic review on the acceptance of financial incentives for a healthy lifestyle has shown that acceptability is polarized and context dependent [8].

The acceptability of financial incentives has been studied often, among different populations, and with mixed results [8,9]. The most recently available systematic review on financial incentive acceptability concluded that “acceptability remains polarized, and [...] is shaped in complex and unpredictable ways” [8]. As an illustration of this polarization, incentives that specifically target deprived or vulnerable subgroups are found fair by some studies because they are a tool to redistribute resources to improve health among the disadvantaged [10]. In contrast, other research found a preference for generic incentives because targeted incentives were perceived as unfair to individuals who had already maintained a healthy lifestyle [11]. Although polarized, the available research has identified factors that consistently moderate the acceptability of financial incentives. Financial incentives appear to be more acceptable when they are privately funded, perceived as fair, (cost) effective, and when offered in the form of vouchers instead of cash [8,9,12,13].

Despite the variability found in acceptability, when we look specifically at the acceptability of financial incentives among health care professionals (HCPs), Hoskins et al [8] reported consistently high levels of acceptability. However, the authors point out that the reviewed studies were performed only in the United States, the United Kingdom, Australia, Canada, and France, which limits the generalizability of these findings. To the best of our knowledge, one study has specifically investigated the acceptability among HCPs working in CVD care in the United States [14]. This study showed that primary care physicians show a *broad and deep* acceptance of financial incentives. More importantly, this study showed that physicians’ perceptions of financial incentives were related to their patients’ clinical outcomes, thus emphasizing the importance of studying acceptability among HCPs involved in delivering the incentives.

To summarize, the acceptability of financial incentives is polarized, but reviews show indications of high acceptance among HCPs. At the same time, acceptability also appears highly dependent on the specific form and context in which financial incentives are offered and implemented.

Objectives

To our knowledge, this study is the first to investigate the perspectives of Dutch HCPs on financial incentives as a supplement to CVD care in the Netherlands. We study the perspectives of HCPs because they are expected to deliver the intervention, promote its uptake among patients, and guide implementation in current health care in the Netherlands. This study addresses two research questions. First, what are HCPs’ attitudes toward using a financial incentive system for healthy living for patients with CVD? Second, what are the barriers and facilitators for implementing a financial incentive system as a supplement to existing CVD care?

Methods

Sample

A total of 16 semistructured, in-depth, face-to-face interviews were conducted between December 2017 and March 2018 with Dutch HCPs who support patients with CVD with living more healthily. In the Netherlands, the responsibility for supporting lifestyle changes in patients with CVD lies primarily with specialized nurse practitioners in hospitals, multidisciplinary professionals working in cardiac rehabilitation centers, and general practitioners and their assistants working in primary care. Therefore, we aimed to obtain diverse perspectives by including professionals with varying backgrounds from different institutions that are widely spread across the Netherlands (Table 1). After 16 interviews, no new information emerged, and data saturation was reached.

Table 1. Organization and professional background of respondents (N=16).

Organization and professional background	Respondents, n (%)
Academic hospital A	
Nurse practitioner working in cardiac rehabilitation	2 (13)
Academic hospital B	
Neurovascular nurse practitioner	1 (6)
Physician assistant specialized in cardiovascular risk factor management	1 (6)
Hospital A	
Physiotherapist working in cardiac rehabilitation	1 (6)
Nurse practitioner working in cardiac rehabilitation	1 (6)
Hospital B	
Physician-researcher working in cardiac rehabilitation	1 (6)
Nurse practitioner working in cardiac rehabilitation	1 (6)
Hospital C	
Neurologist specialized in cardiac rehabilitation	1 (6)
Nurse practitioner working in cardiac rehabilitation	1 (6)
Cardiac rehabilitation center A	
Cardiologist in residence	1 (6)
Lifestyle coach working in cardiac rehabilitation	1 (6)
Cardiac rehabilitation center B	
Physiotherapist working in cardiac rehabilitation	1 (6)
Cardiac rehabilitation center C	
Psychologist specialized in cardiac rehabilitation	1 (6)
General practice center A	
General practitioner specialized in cardiovascular disease care	1 (6)
Nurse practitioner working in cardiac rehabilitation	1 (6)

Procedure

We used convenience sampling and contacted individuals and organizations that were associated with the BENEFIT consortium. The BENEFIT consortium integrates care and noncare settings and connects public and private partners with the aim of scientifically evaluating the implementation of a reward system for healthy living for patients with CVD. Interviewees were contacted based on three criteria: (1) the interviewee had to be involved in lifestyle changes in patients with CVD, (2) we aimed to recruit HCPs from diverse professional backgrounds, and (3) we aimed to recruit HCPs from different organizations geographically spread across the Netherlands. We did not receive any explicit rejection to participate. Interview appointments were made by phone, after which the interviews were planned based on the location of the interviewee. Before the start of the interview, the interviewee was given a brief introduction about the project of which this interview was a part of, the goal of the interview, the procedure that would be followed and how the data would be processed. If the interviewee agreed and had no further questions, they signed an informed consent form, and the interview started. The interviews were conducted by 2 researchers (JVDG and DDB). One of the researchers led the interview, whereas the other was responsible for managing the audio recording and taking notes (these roles were alternated each time). The conversations were held in Dutch, audio recorded, fully transcribed, and finally pseudonymized to secure the privacy of the interviewees and possible relevant other people or organizations that were mentioned during the interviews. At the end of the interviews, the researcher summarized the key points covered and offered participants the chance to add to, revise, or clarify their views. Ethical approval for this study was obtained through a larger ethical approval process, which was required for the project at large. The main ethical concerns revolved around protecting the identity of individuals and the name of the organizations that were mentioned during the interviews, and we dealt with this by pseudonymizing the transcripts as described earlier.

A semistructured topic guide shaped the structure of the interviews, while allowing the interviewers to elaborate on the answers of the HCPs when relevant. This study reports on a subset of data related to the perceptions of HCPs on using a financial incentive system for lifestyle change in patients with CVD. This was one of the six themes discussed during the interviews. The other themes that were discussed, but not addressed in this study, were adherence of patients with CVD

to a healthy lifestyle, supporting a healthy lifestyle, which stakeholders are involved in supporting a healthy lifestyle, using eHealth to support a healthy lifestyle, and using wearables and sensors to support a healthy lifestyle. Multimedia Appendix 1 contains the entire topic guide of the interviews. The interviews took an average of 60 minutes, of which approximately 15 minutes were spent on talking about an incentive system.

The interviewer first explained what the financial incentive system might look like. This explanation was based on the conceptual ideas developed within the BENEFIT consortium [15]:

> *With the BENEFIT program, patients can earn reward points for behaving healthily. For example, by going to their scheduled GP visits, but also by being physically active or self-monitoring their blood pressure. These reward points can then be exchanged for discounts on grocery items in the supermarket or to get a free healthy activity.*

Then, the interviewer asked three questions: (1) What is your *opinion* on using an incentive system? (2) What could be *obstacles* for using an incentive system? and (3) What could be *solutions* to facilitate the use of an incentive system?

Analysis

Transcripts were analyzed using a bottom-up inductive approach. This means that we made meaning out of the data itself instead of using a top-down theoretical approach with a framework or theory to which data were fitted. To structure the data analysis process, we followed the six steps of thematic analysis [16], which included (1) data familiarization, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report.

In each of the pseudonymized transcripts, 2 researchers (JVDG and DDB) independently marked quotations containing pieces of data that were relevant for analysis. These quotations were compared, and a consensus document that contained all relevant pieces of data for each transcript was created. Each quotation was then classified as containing information about negative opinions, positive opinions, facilitating factors, barriers, or solutions. After this first rough classification into categories, the quotations were further interpreted by a single researcher who identified specific codes (eg, "people are naturally inclined to respond to rewards"). These specific codes were then again reviewed by an independent second coder who agreed or disagreed with the identified codes. Through discussion, all disagreements were eventually solved, resulting in a list of 33 codes. These specific codes were first categorized into broader categories and finally assigned to one of four overarching themes that emerged (eg, "positive attitude toward rewards"). This process involved sorting and categorizing similar codes and retracting each step multiple times until each of the 33 codes was assigned to one of the four overarching themes. Although data were analyzed and themes were identified using thematic analysis, we additionally used a technique taken from content analysis and counted how often a piece of code was encountered. This helped us quantify how often a specific code was mentioned. For publication purposes, quotation examples were translated into English by 2 researchers (JVDG and DDB).

Results

The following themes emerged: (1) positive attitude toward rewards, (2) too much focus on extrinsic aspects, (3) structure and form of the reward, and (4) characteristics of the target group.

Positive Attitude Toward Rewards

The first important finding is that HCPs generally show high acceptance of and hold positive attitudes toward a financial incentive system. Although one respondent explicitly rejected the idea of rewarding people and 2 others were doubtful whether it would be a good idea, the majority of respondents (13/16, 81%) expressed positive attitudes. Often mentioned was that a healthy lifestyle is challenging for patients with CVD and HCPs believe that a reward might help to provide a necessary nudge (7/16, 44%). HCPs believe that external commitment from a reward system would be effective in supporting sustained healthy living (7/16, 44%). One respondent explained this by emphasizing the affirmation that the delivery of a reward might provide:

> *I certainly think that receiving a reward provides patients with a sort of feedback. That feedback gives them the recognition that they are doing something right. I certainly believe that it has potential.* [HCP1]

Furthermore, respondents believed rewards to be effective because people are naturally inclined to respond to rewards (4/16, 25%): "A reward system always works because that is how people are wired" [HCP2].

Too Much Focus on Extrinsic Aspects

The second important finding is that half of the HCPs (8/16, 50%) believe that a financial reward system might put too much emphasis on extrinsic motivational aspects of lifestyle change. This could draw attention away from the intrinsically rewarding aspects of healthy living, such as feeling more fit (3/16, 19%). A proposed solution would be to always emphasize the intrinsic aspects and health benefits in addition to providing extrinsic rewards (2/16, 13%). Furthermore, providers of a reward system risk paternalizing patients by communicating to them what they should be doing and thus threatening patients' autonomy (2/16, 13%): "I would have objections when a reward system moves in the direction of conditioning people to act like circus animals" [HCP3]. According to the respondents, this focus on rewards could then also lead patients to overstrain themselves or even manipulate to get rewards (3/16, 19%). A possible solution would be to support autonomy by allowing freedom of choice in rewards (3/16, 19%). In addition, a sentiment strongly felt by some was that patients should find motivation from within, instead of needing a reward system (3/16, 19%):

> *Patients should know better, especially patients that get acute hospitalizations [...] they should investigate their own behavior and change that* [HCP4]

Finally, almost half of the HCPs expected the motivating effect of rewards to fade out over time (7/16, 44%).

Structure and Form of the Reward

The structure and form of the reward itself were deemed relevant for the success of implementing a reward system by 6 respondents. Related to the form of the reward, HCPs were worried that when rewards were not large enough, they would not have the intended motivating effect (2/16, 13%). Although one respondent argued for allowing as much freedom of choice as possible (eg, by letting participants choose how to be rewarded; 1/16, 6%), another emphasized that to avoid supporting unhealthy behavior, only rewards should be provided that are in line with the behavior needed to attain them (eg, running for a discount on running shoes; 1/16, 6%). Another concern was that the rules for how rewards could be earned would be made too complex or nontransparent (2/16, 13%). Finally, two respondents suggested to stimulate engagement with a reward system by using social interaction (2/16, 13%):

> *I do think that a reward system would work best when you make it social [...] You are not going to celebrate when nobody is watching. While if there are many people watching—suppose I won a trophy at the Australian Open and 20.000 people are watching—I am going to scream from the top of my lungs to celebrate!* [HCP1]

Characteristics of the Target Group

The respondents mentioned several concerns regarding the characteristics of subgroups of the population with CVD that could interfere with the successful implementation of a reward system. As patients with CVD are generally older, respondents are worried that some will have trouble using the technology necessary to measure their lifestyle behavior and receive the rewards (4/16, 25%): “A problem will be a lack of digital know-how, so logging into the system will be an issue, especially for the elderly” [HCP5]. This issue might be diminished by targeting a younger, more digitally literate population (2/16, 13%). Another issue is that respondents see 2 subgroups of patients who might not benefit from receiving rewards: (1) the already highly motivated individuals who will not receive additional motivation from being offered a reward system (1/16, 6%) and (2) the not-at-all motivated who will not respond to anything that is offered (1/16, 6%). Finally, respondents argued that a reward system risks rewarding the already successful (who do not need extra motivation) while punishing (and thus demotivating) nonachievers (4/16, 25%):

> *[...] how do you deal with situations where people do not achieve their goal? This could of course have multiple different reasons and in that situation, people are in fact being punished.* [HCP6]

Key Concerns and Related Solutions

Whenever concerns were mentioned, we also asked for possible solutions. Therefore, in Textbox 1, we summarize the main concerns and related solutions suggested by the HCPs during the interviews.

Textbox 1. Key concerns and suggested solutions for implementing a financial incentive system.

Concerns

- Focusing too much on extrinsic rewards
- Disengagement when rewards are insignificant, nontailored, or longitudinally provided
- Paternalization and threatening autonomy
- Lack of digital literacy in target group

Suggested Solutions

- Emphasize intrinsic aspects of healthy living while giving extrinsic rewards
- Integrate social aspects to increase engagement with rewards
- Support autonomy by allowing freedom of choice in rewards
- Focus on a target group that can work with the necessary technology

Discussion

Principal Findings

This is the first study to investigate the acceptability of a financial incentive system among Dutch CVD HCPs. Furthermore, we explored the barriers and facilitators of its implementation. The HCPs in our sample generally showed high acceptance of a reward system for healthy living for patients with CVD. This finding is consistent with the existing literature that also showed, among HCPs in the United States, high acceptance of a reward system for healthy living in CVD management [10]. The level of acceptability we found is also in line with the idea that attitudes are not necessarily negative but depend on contextual factors such as how the incentive is designed and whom it targets [9,12,17]. With regard to these contextual factors, Giles et al [9] and Promberger et al [17] found that acceptability was higher when incentives were perceived as more effective (“pay them if it works”). In line with these findings, this study indeed found that many respondents perceived financial incentives as an effective intervention, which might have been related to the relatively high acceptance that was found. Furthermore, Giles et al [11] showed that policy makers perceive financial incentives as more acceptable when they target vulnerable subgroups. People with CVD might be considered a vulnerable group, which might explain why it is more acceptable to reward them for healthy living [11]. Similarly, the high acceptability we found could be

explained by previous research, suggesting that voucher-based incentives—as presented to HCPs in this research—are more acceptable than cash incentives [12,18]. Finally, previous research has shown that privately funded incentives are considered more acceptable than publicly funded incentives [12,13]. The way the reward system for this study was explained to participants might have implied private funding, and thus high acceptance, because we mentioned the use of reward points that could be exchanged for discounts at commercial product and service suppliers.

Notwithstanding the generally positive evaluations we found, several important concerns emerged within the themes that were discussed. HCPs were concerned that rewards could lead to focusing too much on the extrinsic aspects of lifestyle change and could threaten autonomy. This might have negative effects, such as increasing pressure on patients with CVD and possibly leading to manipulation for rewards. These concerns can be interpreted as a reflection of ethical objections among HCPs in our sample. This finding is in line with the ethical reflection by Ashcroft, which states that financial incentives can be perceived as paternalistic, coercive, involve bribery, or undermine the agency of the person [7]. At a more practical level, concerns emerged around disengagement with rewards in the long term. For those looking to implement a financial incentive system that aims to be in place long term, it is important to take these practical concerns into account. For example, as mentioned by the respondents, through integrating social aspects in the incentive system.

An important new finding that emerged from this work is that digital literacy in the target population might be an obstacle to implementing a reward system for healthy living in CVD management. The use of digital technology is necessary to objectively measure goal progress and provide associated rewards. As the onset of CVD generally occurs at an older age, patients with CVD are expected to have lower digital literacy. For those looking to implement a financial incentive system that targets a less digitally literate group (eg, patients with CVD) and aims to be in place long term, it appears important to take these practical concerns into account. This obstacle could be overcome by either focusing on a subsection of younger, more technologically savvy participants or by simplifying the technological solutions to accommodate a larger group of patients with CVD. Future research should investigate whether patients with CVD recognize this obstacle and what they see as viable solutions. Developing a reward system in cocreation with patients with CVD can help simplify the technological solution and match its complexity to the digital literacy of the intended users. On the basis of the answers of the HCPs in this study, and in line with what other authors found [12], we propose that both ethical and practical concerns should be mitigated through thoughtful incentive design in cocreation with patients with CVD.

A limitation of this study is the possibility that HCPs opinions on using a financial incentive system were influenced by preceding discussions (as described in the *Method*s section) about other themes related to lifestyle change. More specifically, having thought about obstacles in providing support for lifestyle changes in patients with CVD might have primed HCPs to the necessity of accepting alternative intervention supplements such as financial incentives. This could have led to an overestimation of acceptability to levels that would not be found when the financial incentive system would have been discussed in isolation. In addition, because we used convenience sampling and contacted individuals and organizations that were associated with the BENEFIT consortium, opinions on a reward system could be more positive than would otherwise be the case. Although the high acceptability that we found is consistent with existing research, some caution in drawing firm conclusions with regard to acceptability is warranted. Another consideration is that before asking HCPs about their opinions, we provided a concrete example of what a financial incentive system might look like. Therefore, the findings of this study should be interpreted in relation to a voucher-based financial incentive system (points to be exchanged for goods and services), and generalizing these insights to other forms of financial incentive systems should be done with caution. Finally, the sample used in this study was heterogeneous and relatively small. Integrating the perspectives of HCPs from various disciplines and institutes across the Netherlands ensures a broad view of opinions but makes in-depth discussions about discipline-specific or institute-specific insights impossible. Future research that aims to support local implementation could use a more homogenous sample and a fine-grained approach to overcome this.

Conclusions

This study mapped the opinions of Dutch HCPs working in CVD care. In line with existing studies on different populations outside the Netherlands, Dutch HCPs in general showed high acceptance of a financial incentive system for healthy living for patients with CVD. However, there are important concerns that should be considered when designing a financial incentive system. In particular, the concern about digital literacy in the target group is a novel finding and warrants further investigation. According to the HCPs interviewed in this study, suggested solutions to overcome concerns around a financial incentive system for patients with CVD are (1) emphasizing intrinsic aspects of healthy living while giving extrinsic rewards, (2) integrating social aspects to increase engagement with rewards, (3) supporting autonomy by allowing freedom of choice in rewards, and (4) aiming for a target group that can work with the necessary technology.

The high level of acceptability we found among Dutch HCPs provides support for further investigation and development of a reward system for CVD, as will be pursued in the BENEFIT consortium. Finally, although investigating HCPs' opinions is an important first step, it is also important to know the opinions of the patients that would be targeted by financial incentives. Therefore, in the next step, we will validate the current insights among Dutch patients with CVD. The aim of these cocreation efforts is to contribute to the design of financial incentive interventions to better fit the needs of both clinicians and patients in CVD care.

Acknowledgments

The authors would like to thank Floor Sieverink for helping with designing the interview questions. Furthermore, the authors would like to thank Brecht Otto (Bachelor student applied Psychology, University of Applied Sciences Leiden) and Pauline van Wolferen (Master Student Health Science, University Twente) for their help with transcribing the interviews. This work was supported by the Netherlands Cardiovascular Research Initiative, an initiative with support from the Dutch Heart Foundation, CVON2016-12 BENEFIT, ZonMw (the Netherlands Organization for Health Research and Development), and the members of the BENEFIT consortium.

Authors' Contributions

DDB, MK, JVDG, VJ, and AE contributed to the conception and design of the work. JW contributed to the design of the work. HK and RK contributed to the conception of the work. DDB, MK, JVDG, RVDV, HK, VJ, and AE contributed to the acquisition, analysis, or interpretation. DDB and TR drafted the manuscript, and all authors critically revised the manuscript, gave final approval, and agreed to be accountable for all aspects of work, ensuring integrity and accuracy.

Conflicts of Interest

DDB, JVDG, MK, RVDV, TR, JW, HK, VJ, and RK reports grants from the Dutch Heart Foundation during the study. AE reports grants from the Dutch Heart Foundation, grants from ZonMW, and grants from NWO (Nederlandse Organisatie voor Wetenschappelijk Onderzoek) Vici during the study.

Multimedia Appendix 1
Overview of the interview guide.
[DOCX File , 15 KB - cardio_v5i2e27867_app1.docx]

References

1. Kotseva K, De Backer G, De Bacquer D, Rydén L, Hoes A, Grobbee D, EUROASPIRE Investigators. Lifestyle and impact on cardiovascular risk factor control in coronary patients across 27 countries: Results from the European Society of Cardiology ESC-EORP EUROASPIRE V registry. Eur J Prev Cardiol 2019 May;26(8):824-835. [doi: 10.1177/2047487318825350] [Medline: 30739508]
2. Peters RJG. Lifestyle changes in secondary prevention of coronary heart disease: breaking the chains of unhealthy habits. Neth Heart J 2013 Jul;21(7-8):322-323 [FREE Full text] [doi: 10.1007/s12471-013-0437-4] [Medline: 23835936]
3. Giles EL, Robalino S, McColl E, Sniehotta FF, Adams J. The effectiveness of financial incentives for health behaviour change: systematic review and meta-analysis. PLoS One 2014;9(3):e90347 [FREE Full text] [doi: 10.1371/journal.pone.0090347] [Medline: 24618584]
4. Mantzari E, Vogt F, Shemilt I, Wei Y, Higgins JPT, Marteau TM. Personal financial incentives for changing habitual health-related behaviors: A systematic review and meta-analysis. Prev Med 2015 Jun;75:75-85 [FREE Full text] [doi: 10.1016/j.ypmed.2015.03.001] [Medline: 25843244]
5. Kurti AN, Davis DR, Redner R, Jarvis BP, Zvorsky I, Keith DR, et al. A Review of the Literature on Remote Monitoring Technology in Incentive-Based Interventions for Health-Related Behavior Change. Transl Issues Psychol Sci 2016 Jun;2(2):128-152 [FREE Full text] [doi: 10.1037/tps0000067] [Medline: 27777964]
6. Volpp KG, John LK, Troxel AB, Norton L, Fassbender J, Loewenstein G. Financial incentive-based approaches for weight loss: a randomized trial. JAMA 2008 Dec 10;300(22):2631-2637 [FREE Full text] [doi: 10.1001/jama.2008.804] [Medline: 19066383]
7. Ashcroft RE. Personal financial incentives in health promotion: where do they fit in an ethic of autonomy? Health Expect 2011 Jun;14(2):191-200 [FREE Full text] [doi: 10.1111/j.1369-7625.2011.00664.x] [Medline: 21348904]
8. Hoskins K, Ulrich CM, Shinnick J, Buttenheim AM. Acceptability of financial incentives for health-related behavior change: An updated systematic review. Prev Med 2019 Sep;126:105762. [doi: 10.1016/j.ypmed.2019.105762] [Medline: 31271816]
9. Giles EL, Robalino S, Sniehotta FF, Adams J, McColl E. Acceptability of financial incentives for encouraging uptake of healthy behaviours: A critical review using systematic methods. Prev Med 2015 Apr;73:145-158. [doi: 10.1016/j.ypmed.2014.12.029] [Medline: 25600881]
10. Hoddinott P, Morgan H, MacLennan G, Sewel K, Thomson G, Bauld L, et al. Public acceptability of financial incentives for smoking cessation in pregnancy and breast feeding: a survey of the British public. BMJ Open 2014 Jul 18;4(7):e005524 [FREE Full text] [doi: 10.1136/bmjopen-2014-005524] [Medline: 25037645]
11. Giles EL, Sniehotta FF, McColl E, Adams J. Acceptability of financial incentives for health behaviour change to public health policymakers: a qualitative study. BMC Public Health 2016 Sep 15;16:989 [FREE Full text] [doi: 10.1186/s12889-016-3646-0] [Medline: 27633661]

12. Mitchell MS, Goodman JM, Alter DA, Oh PI, Faulkner GEJ. 'Will walk for groceries': Acceptability of financial health incentives among Canadian cardiac rehabilitation patients. Psychol Health 2014;29(9):1032-1043. [doi: 10.1080/08870446.2014.904863] [Medline: 24731024]
13. Bigsby E, Seitz HH, Halpern SD, Volpp K, Cappella JN. Estimating Acceptability of Financial Health Incentives. Health Educ Behav 2017 Aug;44(4):513-518. [doi: 10.1177/1090198116664072] [Medline: 27535320]
14. Liu T, Asch DA, Volpp KG, Zhu J, Wang W, Troxel AB, et al. Physician attitudes toward participating in a financial incentive program for LDL reduction are associated with patient outcomes. Healthc (Amst) 2017 Sep;5(3):119-124 [FREE Full text] [doi: 10.1016/j.hjdsi.2016.09.002] [Medline: 27932264]
15. Keesman M, Janssen V, Kemps H, Hollander M, Reimer WSO, Gemert-Pijnen LV, BENEFIT consortium. BENEFIT for all: An ecosystem to facilitate sustained healthy living and reduce the burden of cardiovascular disease. Eur J Prev Cardiol 2019 Apr;26(6):606-608 [FREE Full text] [doi: 10.1177/2047487318816388] [Medline: 30486650]
16. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa] [Medline: 22142324]
17. Promberger M, Dolan P, Marteau TM. "Pay them if it works": discrete choice experiments on the acceptability of financial incentives to change health related behaviour. Soc Sci Med 2012 Dec;75(12):2509-2514 [FREE Full text] [doi: 10.1016/j.socscimed.2012.09.033] [Medline: 23102753]
18. McGill B, O'Hara BJ, Grunseit AC, Bauman A, Osborne D, Lawler L, et al. Acceptability of financial incentives for maintenance of weight loss in mid-older adults: a mixed methods study. BMC Public Health 2018 Feb 13;18(1):244 [FREE Full text] [doi: 10.1186/s12889-018-5136-z] [Medline: 29439689]

Abbreviations

CVD: cardiovascular disease
HCP: health care professional
NWO: Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Edited by G Eysenbach; submitted 10.02.21; peer-reviewed by E Giles, J Bruthans; comments to author 13.04.21; revised version received 01.06.21; accepted 05.07.21; published 30.08.21.

Please cite as:
de Buisonjé D, Van der Geer J, Keesman M, Van der Vaart R, Reijnders T, Wentzel J, Kemps H, Kraaijenhagen R, Janssen V, Evers A
Financial Incentives for Healthy Living for Patients With Cardiac Disease From the Perspective of Health Care Professionals: Interview Study
JMIR Cardio 2021;5(2):e27867
URL: https://cardio.jmir.org/2021/2/e27867
doi:10.2196/27867
PMID:34459748

Original Paper

Transitions in Technology-Mediated Cardiac Rehabilitation and Self-management: Qualitative Study Using the Theoretical Domains Framework

Shreya Tadas[1], MSc; Claudette Pretorius[1], PhD; Emma J Foster[2], BSc, BMedSci, MBChB; Trish Gorely[3], PhD; Stephen J Leslie[4], PhD; David Coyle[1], PhD

[1]School of Computer Science, University College Dublin, Dublin, Ireland

[2]Cardiac Unit, NHS Highland, Inverness, United Kingdom

[3]Department of Nursing and Midwifery, University of the Highlands and Islands, Inverness, United Kingdom

[4]School of Health, Social Care and Life Sciences, University of the Highlands and Islands, Inverness, United Kingdom

Corresponding Author:
Shreya Tadas, MSc
School of Computer Science, University College Dublin
Belfield
Dublin, 4
Ireland
Phone: 353 899882380
Email: shreya.tadas@ucdconnect.ie

Abstract

Background: An acute cardiac incident is a life-changing event that often necessitates surgery. Although surgery has high success rates, rehabilitation, behavioral changes, and self-care are critical to long-term health. Recent systematic reviews have highlighted the potential of technology in this area; however, significant shortcomings have also been identified, particularly with regard to patient experience.

Objective: This study aims to improve future systems and to explore the experiences of cardiac patients during key phases after hospitalization: recuperation, initial rehabilitation, and long-term self-management. The key objective is to provide a holistic understanding of behavioral factors that impact people across these phases, understand how experiences evolve over time, and provide user-centered recommendations to improve the design of cardiac rehabilitation and self-management technologies.

Methods: Semistructured interviews were conducted with people who attended rehabilitation programs following hospitalization for acute cardiac events. Interviews were developed and data were analyzed via the Theoretical Domains Framework, a pragmatic framework that synthesizes prior theories of behavioral change.

Results: Three phases that arise posthospitalization were examined, namely, recuperation, rehabilitation, and long-term self-management. Through these phases, we describe the impact of key factors and important changes that occur in patients' experiences over time, including the desire for and redefinition of normal life, the need for different types of formal and informal knowledge, the benefits of safe zoning and connectedness, and the need to recognize capability. The use of the Theoretical Domains Framework allows us to show how factors that influence behavior evolve over time and to identify potential sources of tension.

Conclusions: This study provides empirically grounded recommendations for the design of technology-mediated cardiac rehabilitation and self-management systems. Key recommendations include the use of technology to support a normal life, leveraging social influences to extend participants' sense of normality, the use of technology to provide a safe zone, the need to support both emotional and physical well-being, and a focus on recognizing capability and providing recommendations that are positive and reinforce this capability.

(JMIR Cardio 2021;5(2):e30428) doi:10.2196/30428

KEYWORDS

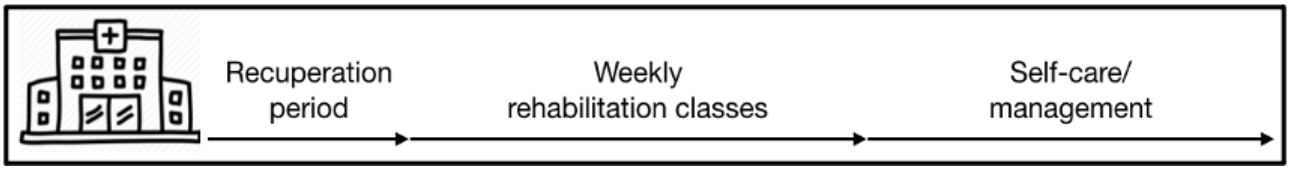
cardiac rehabilitation; self-management; self-care; behavioral change; Theoretical Domains Framework; qualitative methods; mobile phone

Introduction

Background

Cardiovascular disease (CVD) is a leading cause of morbidity and mortality worldwide, with an estimated 17.9 million deaths each year [1]. CVDs are a group of disorders of the heart and blood vessels, usually associated with a buildup of fatty deposits inside the arteries that occur when the flow of oxygen-rich blood to the heart is blocked, leading to increased strain on the heart [2]. Four out of five cardiac-related deaths are due to acute events, such as heart attacks and strokes. One-third of these deaths occur prematurely in people under 70 years of age [1]. Fortunately, the success rate of modern cardiac surgery and nonsurgical interventions, such as percutaneous coronary intervention (stent insertion), is high. As a result, an increasing number of people live with CVD as a long-term chronic condition. Following acute events, which are often sudden, ongoing treatment for CVD involves lifestyle changes and medicines. Cardiac rehabilitation is considered a vital part of long-term recovery and a key component of patient management. It may include clinical assessment, medication review, risk factor modification, psychological support, and supervised exercise [3]. After a person is hospitalized and after discharge, they go through a recuperation period (Figure 1). Many patients attend rehabilitation programs. Individualized cardiac rehabilitation programs are usually for a duration of 6-8 weeks and comprise a mix of monitored exercises and educational sessions. Following these initial stages, people must continue self-management. According to Barlow et al [4], "self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychological consequences and lifestyle changes." Many people face emotional and physical challenges during the transition from hospitalization to self-management [5]. For successful and long-term self-management, behavior and behavioral change play a central role [6]. Evidence suggests that rehabilitation programs can play a vital role in the transition from hospitalization to self-care [7]. Despite the proven benefits, uptake and adherence in traditional face-to-face programs are often low due to barriers such as lack of awareness, transport, motivation, cost, and poor social support [8].

Figure 1. Participants' journey after their cardiac event.



Recent systematic reviews have highlighted the potential of digital health interventions to support rehabilitation and subsequent self-management of cardiovascular conditions [9-11]. However, significant shortcomings were identified. Evidence suggests that tightly supervised intervention programs are most successful and that self-directed management is less successful due to problems with engagement and adherence. Piette et al [10] highlighted the need for future interventions to incorporate advances in behavioral theories and artificial intelligence in order to be more effective and adaptive to the changing needs of patients. Despite recent calls for technology that supports personalization and focuses on user needs, Tadas et al [11] found that, with notable exceptions, prior research in the cardiovascular domain has made limited use of user-centered approaches. This is consistent with the findings of Siegers et al [12], who also reported that most developers of digital interventions for cardiac self-management did not engage with the direct experiences of patients, such as those who have attended rehabilitation programs. Prior studies have also tended to focus on specific aspects of self-management, such as physical activity [13] and medication management [9,14]. They do not provide a holistic understanding of the behavioral factors that impact people throughout recuperation, rehabilitation, and self-management.

This paper builds on recent research on posthospital transitions [5,15] and on rehabilitation and self-management in chronic conditions [16,17]. It responds directly to calls for research in the cardiovascular domain to engage more deeply with both behavioral change theories and with patient experience. The contributions of this paper include a comprehensive assessment of people's experiences of recuperation, rehabilitation, and self-management, their attitude toward technology, and the ways in which it could better support rehabilitation and self-care. The analysis is framed via the Theoretical Domains Framework (TDF), an integrated theoretical framework synthesized from 33 prior theories of behavioral change. The key strength of the TDF is that it provides a rigorous and comprehensive framework to identify factors that impact behavior and behavioral change. Our analysis was grounded in a semistructured interview study with 19 participants who were hospitalized following an acute cardiac incident and subsequently attended a cardiac rehabilitation program.

Our research questions include:

1. What were the key experiences of patients after cardiac surgery and how did these experiences support or hinder rehabilitation and ongoing self-management?
2. How did the experiences of patients change over different phases of recuperation, rehabilitation, and self-management?
3. What strategies can be applied in design to better support technology-mediated cardiac rehabilitation and self-management?

Related Work

Overview

The work presented in this paper builds on existing research in a number of key areas, including literature on posthospitalization transitions and support, rehabilitation, and self-management in chronic conditions, and theories and frameworks for behavioral change. We begin with an overview of key recent work specific

to cardiovascular care and then consider related work outside of the cardiovascular domain. In addition to research in the health domain and reflecting the emphasis in the paper on understanding user experience, we consider relevant literature in the field of human-computer interaction (HCI).

Technology in Cardiovascular Care

Technology-mediated cardiovascular rehabilitation and self-management has generally been provided through mobile apps, web apps, sensors, or an integration of these [11]. These systems aim to increase adherence, motivation, and engagement through different means, including gamification, guidance, and education about the condition, reminders, and data tracking through sensors. Most of these studies have focused on interventions to increase physical activity and exercise. Some aim to provide a medium for better communication and data sharing between patients and care providers, nurses, or health professionals. A small number facilitate remote cardiac rehabilitation. A recent systematic review [9] concluded that mobile apps in particular offer an important opportunity to improve access to secondary prevention for cardiac patients, but also concluded that this potential has not been achieved to date. The authors stress the need for personalized and user-friendly apps that can cater to the needs of individual patients from different age groups. A systematic review of mobile health apps for CVD, including commercially available apps, by Athilingam et al [18] identified a trend toward cost-effectiveness and potential solutions for symptom monitoring and promoting patient engagement in their own homes. However, evidence of impact on heart failure–related outcomes is inconclusive. The review also found that most apps focused on monitoring patients' symptoms and activity but provided limited feedback on unusual or irregular events. Andersen et al [19] emphasized the importance of aligning concerns of patients and clinicians and proposed three key concepts to consider while designing eHealth systems: the system should be meaningful and actionable to both clinicians and patients and feasible within the organizational and social context. Another study by Andersen et al [20] demonstrated the use of user-centered design methods for reintroducing patients as active diagnostic agents to design a collaborative digital tool for monitoring heart patients after hospitalization. This study emphasizes the importance of increasing patient participation in the design of eHealth systems and telemonitoring practices. Similar studies on posthospital transitions in chronic patients describe how discharged patients are often unprepared to self-manage their condition at home [5]. Being discharged from hospital meant a transition from a safe environment at the hospital to an unknown environment at home [15,21]. The transition of people with cardiac conditions from hospital after surgery to their homes is equally likely to create challenges and design opportunities, which this paper seeks to address; there is a need for more participatory and iterative approaches to design patient-centered eHealth systems [19,22]. A qualitative systematic review by Tadas et al [11] identified the limited use of user-centered design methods and theoretical models to guide the design of technology for cardiovascular care.

Digital apps for cardiac-specific rehabilitation and self-management are focused on physical activity monitoring [23], virtual rehabilitation programs [24], medication management [14], and heart rate and blood pressure monitoring [25-27]. Although recent digital apps show effective results, self-management and rehabilitation using digital apps generally show a gradual decline in use over time due to resistance to behavioral change and lack of motivation [14]. Investigations by Maitland et al [28] on the role of self-monitoring found an overall reluctance toward unnecessary self-monitoring and suggested that technology should focus on self-awareness and self-determination. Overall, there is a need for more research directly examining the experiences of people after cardiac events in relation to digital tools to support cardiac rehabilitation and self-management.

The HCI community, which promotes and practices user-centered design methods, has relatively less research on technologies for cardiac conditions, an observation also noted by Nunes et al [17] in their comprehensive review of HCI research on self-care technologies. Of the 30 studies included in their review, only 3 addressed cardiac conditions. Diabetes was found to be the most common condition addressed by the HCI research on self-care technologies. Examples of self-care technology used for diabetes management include the AssistingInsulin smartphone app by Preuveneers et al [29], which recommends insulin dosages based on predictions of the user's activity, and exploration of contextual frames by Raj et al [30] that demonstrates the relationship between context and behavior and the importance of context-aware apps for self-management. Furthermore, recent research shows an increasing demand for self-management technology that supports people's mundane activities and informal ways of exercise [31]. Significant research also exists in the space of self-management technologies aimed at addressing chronic disease management in older adults [16,32,33]. For example, the study on managing multimorbidity in older adults by Doyle et al [16], suggests the need for self-management apps to primarily focus on information support and teaching how to self-manage. There is also a growing body of work targeted at supporting chronic obstructive pulmonary disease therapy and training at home with the use of sensors, smartphones, television, and webcams [34,35]. Research in this area demonstrates the increasing accuracy of smartphone-based training apps and their acceptance. Existing research on other chronic conditions has clear relevance for the cardiovascular domain. However, to be most effective, we require a detailed understanding of the specific requirements of the people experiencing CVD.

Theoretical Domains Framework

Behavioral change theories and methodologies have been widely applied to guide the design of technical systems and evaluation strategies [36-38]. A systematic review exploring the potential of web-based self-management programs found that systems that incorporated behavioral change techniques were more effective than those that did not, and that web-based systems were more effective than no intervention [39]. There are many theoretical models of behavior, including the Health Belief Model [40], the theory of reasoned action [41], the theory of planned behavior [41], and the social cognitive theory [42]. Although a large number of theoretical models present opportunities, they also create challenges. Many theories either

include a small number of constructs or share common or overlapping constructs, such as intention, social norms, beliefs, or control or self-efficacy. Therefore, in some cases, it is difficult to decipher which the most appropriate factors to target are in behavioral change interventions. In other cases, it is also possible that the key determinants of the target behavior are not represented. TDF [10,43] was developed in response to these challenges, in an effort to assimilate overlapping constructs in a pragmatic framework and to improve researchers' access to and application of psychological theory.

TDF is an integrated theoretical framework composed of domains synthesized from 33 prior theories and 128 theoretical constructs relevant to behavioral change [43]. It was developed in collaboration with behavioral scientists and implementation researchers to provide a comprehensive and holistic approach to identify determinants of behavior and potential targets for behavioral change. The TDF contains 14 domains covering 84 constructs, examples of which include *environmental context and resources*, *emotion*, *goals and intentions*, *beliefs about capabilities*, *knowledge and skills*, and *social influences*. A complete listing of the domains and the constructs related to each is available in Lou Atkins et al [43]. TDF was initially developed to identify influences on health professional behavior, but has been extended to many areas in which changing behavior is important, including changing patient behavior [43]. It supports the assessment of problems and identification of potential solutions by providing a lens to view the cognitive, affective, social, and environmental influences on behavior. As a pragmatic framework, it signals opportunities and methods for intervention by first identifying key domains and constructs and subsequently providing a guide to relevant explanations of current behaviors [10].

TDF has been widely used in health research, particularly for qualitative approaches [44]. Examples of qualitative studies include using TDF to formulate interview questionnaires to address target behavior [45,46], to analyze interview responses to identify barriers and facilitators in implementing interventions for families of people with schizophrenia [47], and increasing physical activity in stroke survivors [48]. In applying TDF, we aimed to identify key determinants of behavior in cardiac rehabilitation and self-management at the individual level. We also aimed to explore the key barriers and facilitators to implementing technology-mediated cardiac rehabilitation and self-management solutions. In this paper, we use TDF in the following ways: (1) as a basis for the interview questionnaire to explore individual motivation and capability factors while also covering the physical and environmental influences; (2) to identify the relevant domains that are most likely to influence technology-mediated cardiac rehabilitation and self-management and associated behaviors; and (3) to identify the key points during recuperation, rehabilitation, and self-management journey when different domains exert a strong influence on peoples' experiences and behaviors. The key advantage of TDF is that it provides a pragmatic, yet rigorous, and holistic framework to address these issues.

Methods

Overview

We conducted semistructured interviews with people who had been hospitalized due to a cardiac event and subsequently attended supervised rehabilitation programs. Interviews were framed using TDF and explored participants' journeys and experiences after hospitalization, their cardiac rehabilitation experiences, and their attitudes toward technology. Thereafter, as supported by the TDF guidelines, we performed an inductive analysis of the interview responses following the Braun and Clarke thematic approach [49].

Recruitment

This study was conducted in collaboration with the cardiac unit at Raigmore Hospital, a National Health Service (NHS) Trust in the United Kingdom. A total of 19 participants (11 women) were recruited. All participants had had either a cardiac incident or a cardiac disease in the past. All participants were offered a postsurgery cardiac rehabilitation program at the Raigmore Hospital [50]. The program consisted of a mix of education sessions and monitored exercises. To represent a range of views, we recruited patients who had attended some, but not all, rehabilitation classes and others who had attended all classes (Multimedia Appendix 1). The exclusion criteria were adolescents and people with severe cognitive impairment or terminal illness, as it was outside the scope of this study. Participants' ages ranged between 50 and 86 years, mean 70 (SD 9).

Procedure

This study was approved by the Health Research Authority, NHS Research Scotland, and the Human Research Ethics Committee, University College Dublin. A total of 52 patients were sent interview requests over post. Nineteen patients agreed to participate in the study. The interviews were conducted separately over telephone calls and audio recorded. Each interview took approximately 45 minutes.

The interview questions were based on TDF and inquired about patients' experiences after cardiac surgery, focusing on domains of TDF related to knowledge and skills, individual goals and intentions, social and environmental influences, and emotional influence [43]. All TDF domains were examined, and only those relevant to the aims of this study were considered. This is consistent with the guidelines for the use of TDF. Questions about knowledge and skills inquired about their help seeking, new skills or techniques considered after cardiac events, sources of information, and awareness of their cardiac condition. This included, but was not limited to, awareness of support resources such as mainstream self-care technologies and rehabilitation programs. Individual goals and intentions questions were about their experience of the rehabilitation program and its barriers and facilitators, posthospitalization life goals and changes, and progress tracking. Questions about social and environmental factors probed environmental and social sources of influence and motivation, including the role of health experts and technology on self-management postcardiac events. Questions

about emotional influences focused on emotional reactions and feelings of after cardiac events.

The interview questions were structured according to each phase the participant went through after hospitalization (Figure 1). The interview protocol was designed in collaboration with all the authors and is available in Multimedia Appendix 2. The interviews were conducted by the first author (ST), who has a background in HCI and is an experienced qualitative researcher. The semistructured interview started with questions about the participants' first cardiac incident, including hospitalization, initial awareness about the cardiac condition, and support resources. This was followed by questions related to the rehabilitation program experience, and then the self-management experience.

Analysis

Audio recordings of the interviews were transcribed verbatim. The transcripts were analyzed using the NVivo 12 (QSR International) software and inductively coded using a thematic approach following the Braun and Clarke methodology [49]. A codebook was created through an iterative process of coding and clean coding. This was performed by dividing 30% of the total interviews between the two authors. Coding was performed using an inductive approach. Conflicts were discussed and resolved through discussions with a third researcher. After reaching a consensus on the codebook, three randomly selected interviews from the entire data set were coded. The Cohen κ coefficient was computed to assess the interrater reliability at this point, with a score across all codes of 0.53. Further discussion and refinement of codes took place to clarify and agree with the final set of codes. On the basis of this final codebook, the remaining transcripts were coded by the first author (ST). Following coding, themes were identified and again reviewed and defined through an iterative process of independent and group analysis involving all 3 authors.

Results

Overview

An analysis of interviews with participants about their posthospitalization experiences identified a number of key themes. In Table 1, these themes are categorized into the three key phases the patients went through after hospitalization, namely, recuperation, rehabilitation, and self-management. As shown in Table 1, the findings are also classified in the context of the TDF domains. It is important to note that there is some overlap in the themes identified in Table 1, with issues present in more than 1 phase. Our analysis deliberately placed emphasis on identifying the themes in each phase. This has resulted in more overall themes than might typically be the case in thematic analysis. However, structuring our findings in this way has the benefit of allowing us to identify the point when particular experiences first emerged, and when they were felt most strongly. In the Discussion section, we will reflect on how specific needs (eg, a desire for normality) change over time and the implications these changes have on the design of technology.

Table 1. Mapping of posthospitalization transition phases, relevant Theoretical Domains Framework (TDF) domains, and themes from findings.

Transition and TDF domains	Themes	Codes
Recuperation phase		
• Goals	A desire for normality	• Feeling better after cardiac event • Rebuilding strength • Desire for a normal life
• Knowledge	Sources of information and role of official or expert resources	• Initial help seeking • Need for information • Contact with health care professionals • Resources recommended by experts
• Emotion	Shock and gratitude	• Gratitude or appreciation • Emotional response or reaction
Rehabilitation classes phase		
• Emotion • Optimism	Mindset and emotion	• Stress or anxiety and relaxation • Positivity or negativity • Fear
• Environmental context and resources	Rehabilitation classes provide a safe space	• Preference for local or in-person rehab • Rehabilitation classes as a training place • Classes as a safe zone • Tailoring • Barriers to local attendance
• Social influences	Rehabilitation classes provide a social space	• Rehabilitation classes as a social place
Self-management phase		
• Environmental context and resources • Social influences	The importance of family and social support	• Environmental or contextual support • Social support and types of social support • Self-reliance
• Behavioral regulation	Monitoring	• Bodily awareness • Monitoring • Motivation or demotivation
• Beliefs about capability	Capability	• Emphasize what can be done • Physical activity found in daily activity

Recuperation Phase

Recuperation phase is the period immediately after discharge from hospital following cardiac surgery.

Desire for Normality

The desire for a normal life (defined as the life patients had before cardiac surgery) was identified across each of the three phases described in our results. However, this desire first emerged and was expressed most strongly during the recuperation phase. While some patients experienced significant physical and mental effects, other patients described feeling better and healthier after surgery. Some went so far as to say procedures such as the insertion of stents had *fixed them* (ie, cured the cardiac problem) and given them confidence to return to normal life:

> *Once the stents had been fitted, the pain had disappeared, and I felt that the care that I was getting in hospital gave me the confidence to go ahead.* [P19]

> *I don't have a condition as far as I am concerned. I had the operation repaired and I've never looked back.* [P8]

Others spoke positively about their posthospitalization recuperation but described a more step-by-step, gradual process of rebuilding strength. Every day, they would push themselves to do more, but in small increments:

> *Right enough, the next day I went out, I got a bit further. The day after that, a bit further. That was fine. So, I didn't actually have any low points. I didn't regress much at all. It was a fairly gradual and continuous improvement.* [P13]

Overall, participants expressed a strong desire to lead a *normal life* after the cardiac event, without the need to be reminded of their condition. Although hospitals provide a lot of information during discharge on potential risks and the importance of aftercare, many were more interested in knowing how and when they could return to their normal way of living:

> *They had a lot of information on the aftercare definitely, what we should do, but I was more interested in would I return to my normal things 'cause I'm a physical person. I'm a walker and I'm always very active and they encouraged me to carry on just like that.* [P3]

> *I think we all change a wee bit but the whole point is, is not to make a fuss about it, you have to try and get back in your routine again with your family as much as possible and keep it as normal as possible.* [P17]

This desire was also expressed with regard to relationships. People wanted to be treated as normal by their friends and family, that is, not being overcared for. They wanted *to get on their feet* and participate in family life in the same way they had normally done before the incident:

> *Just treating you I suppose how you were before the incident, if you know what I mean. You're not any different. Maybe my family is just like that. Once I was up on my feet, that was it. Mum's back, sort of thing. I got away with making the Christmas dinner the first year 'cause I was away at the hospital, but I was back to it the next year. That did help because it makes things seem normal. I've had this incident and I can just go on with the rest of the life. So that helped me in that way.* [P15]

Viewed through TDF, returning to normal life can be seen as a goal of our participants. It is likely to have a strong influence on the participants' behavior. The fact that this goal is strongly linked to participants' sense of role and identity (eg, the family role) is likely to act as further reinforcement. However, the goal of returning to their life before surgery creates a potential tension, as it may come into conflict with the lifestyle change goals recommended for rehabilitation and long-term health management. Resolving this tension is therefore important for technology designs in this space.

Sources of Information and Role of Official or Expert Resources

The patients stressed the need for information about their condition. Increasing awareness and information is important for building confidence, "Having a heart attack was quite a shock to me and as I said I read as much as I could about it" [P18].

There is a need for reliable information and a need to help people retain this information. Those who had a family history or earlier awareness of cardiac symptoms were better prepared to handle the repercussions. When asked about how they sought information initially, the most common response was from the internet and booklets given by their hospital. However, patients also expressed concerns about the credibility and possibility of harm in seeking information on the internet:

> *If I had a problem or if I wanted to find out anything about health I will look it up on the computer.* [P10]

> *Googling too much messes with the head - panic due to sharp info content.* [P4]

In the initial stages of recuperation, the resources recommended by experts were highly valued, as patients trusted these resources. Participants were strongly of the view that there was a need for access to and contact with experts and health professionals after discharge. Any type of contact with health professionals was found to be reassuring during the transition from hospital to self-care and recovery. Talks from experts in rehabilitation programs were considered valuable. However, this contact was sometimes restrained because of time restrictions on health professionals. However, it is also due to concerns on the part of patients that they might burden health professionals:

> *Maybe just more contact or freer to contact the cardiac advice line because, me personally, you tend not to want to be contacting them unnecessarily but sometimes just after in the first two or three months...It's just that you feel that you weren't encouraged to do it. No one said, "Just contact us if you're concerned about anything."* [P3]

Participants' desire for information is consistent with the TDF *Knowledge* domain. During the recuperation phase, participants had a need for general knowledge about cardiac conditions and rehabilitation procedures. They placed a strong emphasis on official knowledge sources. As will be seen in later sections, the types of knowledge participants prioritized evolved during subsequent phases, with a greater emphasis on detailed personalized understanding and informal information sources.

Shock and Gratitude

Acute cardiac events are typically sudden, and unsurprisingly, trigger strong emotional responses. Some participants were physically fit, had no other earlier health issues, no symptoms, and no one in their family had had heart problems earlier. However, suddenly, they experienced a life-threatening event, were hospitalized, and underwent surgery. This was a significant shock. One participant described being so surprised that it took him a few months to come to terms with the fact that he had had a heart attack. Recovering from such incidents requires both emotional and physical healing,

> *It was a huge shock to have a heart attack, a real shock to the system, and it just shows you how vulnerable we are and I think that in itself was an incentive.* [P18]

Following this initial shock, many patients described a newfound appreciation of life and did not want to take their health for granted. They also expressed immense gratitude to and appreciation of health care providers:

> *I was aware that this is real, what happened to me, and you know, I used to think I was invincible. Well, I never really thought I was anything other than fit and nothing would go wrong, but now I'm aware, much more aware, that something could go wrong, and I'm very grateful for what they did to me.* [P16]

TDF emphasizes the important role that emotion plays in driving behavior. Participants' sense of shock clearly shows how the emotions experienced have the potential to drive emotional and physical tension. Interestingly, while shock delayed some

patients' ability to move forward, in others, it helped raise awareness and acted as an incentive. In contrast, gratitude always triggered strongly positive responses during the recuperation phase.

Rehabilitation Phase

All participants were offered a cardiac rehabilitation program after surgery at a hospital in the NHS Trust [50]. This section discusses the participants' experiences of rehabilitation classes and this phase more broadly.

Mindset and Emotions

The patients' emotional responses developed and evolved during the rehabilitation phase. Although cardiac events brought out both positive and negative emotions, many described how their mindset or outlook played a major role in recovery and rehabilitation. Participants pointed out that their confidence, determination, and acceptance of their condition helped to reduce the impact of the event on their life:

> *I'm generally quite a positive person and reasonably confident. I think not unnaturally confident, but if I understand a situation and I know about it and I know what to expect, then I'm fine with it.* [P13]

Participants realized the importance of reducing stress or anxiety and noted the benefits of relaxation exercises, which were introduced in the rehabilitation classes and were new to many, "I really liked the relaxation type of stuff, I had never done that in my life, never knew anything about that" [P13].

On the contrary, some participants emphasized that a lack of attention to mental health support, after discharge from hospital and in the rehabilitation program had an impact on their recovery. One patient was moved to look for private psychological support outside the public NHS system,

> *Half of the problem's with my head to be quite honest with you and if anything I feel that you get let down a wee bit on the recovery part or the mental side of the trauma and I don't feel there's enough done in cardio rehab.* [P4]

Fear was a common emotion during rehabilitation. Some, for example, were apprehensive about pushing themselves to perform exercises as they were constantly afraid of harming themselves. Others expressed a general concern about an uncertain future. Participants felt that this buildup of fear in their minds hindered their progressive recovery and potential for self-management:

> *I didn't sleep very well. In fact, I slept in a chair most of the time. It was just apprehension, I suppose, wondering if your life was going – I just thought it was going to drastically change and I wasn't going to be able to do anything, if you know what I mean. I got over that, but it was always at the back of my mind how much will I be able to do because I didn't want to be having to just sit about all the time, but that wore off the better that I got. I did pick up quite quickly.* [P15]

The TDF domain *Emotion* includes the constructs *fear*, *anxiety*, *positive/negative affect*, and *stress*. Helping people address these emotions is clearly an important priority in enabling effective rehabilitation and self-management, but one that may be overlooked in some traditional rehabilitation programs. This emphasizes the importance of supporting both physical and mental health during rehabilitation. Technologies that can provide emotional and mental support, along with reinforcement of a positive mindset and self-reliance, have significant potential in this space.

Rehabilitation Classes Provide a Safe Space

Although participants identified barriers, they generally expressed a strong preference for local and in-person rehabilitation. Common barriers reported included transportation, distance, schedule delays, low attendance, limited expert availability, and logistic difficulties. Although the preference for in-person rehabilitation is perhaps unsurprising given the participants recruited, the reasons behind this preference point to important factors for technology design.

Rehabilitation classes provided support for training, giving people the opportunity to gain information and practice physical exercises that they could continue during self-management. They liked the personal interaction with health professionals as it gave them confidence and reassurance that they were doing things properly and progressing. Critically, rehabilitation classes provided a controlled environment—a *safe zone*—while exercising and people felt that they could push themselves without the risk of overburdening their body. This safe zoning was important in helping participants overcome emotions such as fear:

> *I benefitted greatly from the program – the exercise program. Principally because it was monitored because if I get breathless now doing things, I don't want to push it because I don't know how serious that would be, but in the classes when I got nearly breathless, the physio really checked carefully and I felt perfectly relaxed. I knew that nothing untoward would happen while I was in their care.* [P9]

The patients found that the tailored support focusing on individual needs was encouraging. The rehabilitation program was appreciated for treating every patient individually and helping set appropriate individual goals and where everybody felt they were achieving something. This encouraged them to continue their progress. However, some patients found the rehabilitation classes a bit slow and pointed out that the official self-management information resources received from the hospital were generic. Patients wanted the rate of exercise, type of exercise, and information they received to be determined by their particular needs and how they progressed individually,

> *My feeling is slightly that each person's recovery is very individual and not everybody would want to read through the British Heart Foundation.* [P1]

Importantly, rehabilitation classes also provided a structured approach, compartmentalized physical activity, and monitored to set time, separated from regular day-to-day activities. This was key for some participants, as it supported a sense of normality outside of classes, by allowing for time-bound

engagement in physical activity and reserving a set time and place to completely focus on recovery.

TDF emphasizes the behavioral impact of the environmental context and resources. Our findings show that individual and tailored support, safe zoning, and structure or compartmentalization are important elements in the environment provided by rehabilitation classes. Therefore, designs that leverage or recreate these environmental factors have significant potential.

Rehabilitation Classes Provide a Social Space

Together with the environmental benefits, rehabilitation classes were also a social place. This provided several clear benefits, consistent with the TDF social influence domain. In particular, it provided a sense of community and gave people the opportunity to talk to others in similar positions,

> *I think when you are face-to-face with a group of people who are recovering, the same way as you are, I think you encourage each other and I think also the information that you receive collectively adds force to the information that you are given.* [P18]

In contrast to formal information provided by health professionals during the recuperation phase, information at this point also came in the form of shared experiences. Although this information is less formal, it is also more personal and has collective power. Patients discussed their direct experiences of dealing with various aspects of the recovery process and reassured each other:

> *One other big advantage was being able to talk to other people who were in a similar position. That was really useful, and I think we could reassure each other, and we could talk to each other about how we dealt with various aspects of the recovery process. That was a very valuable part of it.* [P13]

A contrast was observed in the case of normality. In the recuperation phase, normality was associated with life before cardiac surgery. The social aspect of rehabilitation classes had the potential to help participants normalize their new experiences, which in turn helped them adjust to a changing life after hospitalization,

> *The classes were good, mainly the fact that we were talking to people who had gone through the same problem, and come out the other end, and we were getting the feedback from them, making us feel, well, they've been through it, they're looking well, so maybe we can do the same.* [P11]

Finally, the social nature of the rehabilitation classes was a clear source of motivation. Many participants had experienced technology as *solitary* and not something that was shared with other people. Many were reluctant to replace human contact with technology. *Human touch* was considered very important, whereas technology was considered optional or supplementary,

> *The motivation is to meet with people and you all join in and that's the motivation I think and you would find time to go to a class, whereas if you were busy during the day doing other things, you sort of put it off and maybe the grandchildren will come and you want to spend time with them and you think I will do that later, the motivation isn't there.* [P19]

Self-management Phase

Following the recuperation and rehabilitation class phase, participants moved to the self-management phase, requiring them to take greater responsibility to manage their own condition, without regular professional support.

Importance of Family and Social Support

Social influence was again a key factor in the self-management phase, but here the focus shifted toward preestablished and longer-term relationships. Family was a key enforcer in every phase, but became particularly important in the self-management phase, with close partners particularly important. Family or partners influenced patients' physical state by accompanying them for fitness activities or caring for their diet. They influenced their mental state by encouraging and caring, or just being normal:

> *My wife is very encouraging of me to do healthy things. She leaves it to me, but she's very positive about it, very helpful. She doesn't badger me at all, but she encourages me. I think that's important. If there is someone close to you who cheers your goals and wants you to do well in those goals. I think that makes a huge difference.* [P13]

Other social support included friends, common interest groups, or web-based support groups. Web-based support groups, although not described favorably by many participants, enabled continuity of communication and mutual support for people who may be living in remote areas or are unable to get together with others:

> *Interacting with people is much more important because it's social. It prevents depression. I could quite see how you come home from hospital, you're living on your own, I'm frightened.* [P2]

Participants also described the influence of environmental or contextual factors, such as the home, workplace, and surroundings on recovery and self-management. Stress at home and workplace causes anxiety, which could have detrimental effects. Most patients found scenic surroundings and nature walks beneficial:

> *I'm very lucky. We live in the country, we own our own house, I have a most amazing view from where I'm sitting talking to you just now, and I don't have pressures that a lot of people will have.* [P2]

Although many participants valued social support, some patients preferred to be self-reliant, not liking to be told what to do, and wanting to be in control of their lives. Some did not want to be a burden on their family and would not bother their general practitioners unless absolutely necessary. However, 2 patients stressed that they did not need any type of help or support, as they considered themselves to be self-sufficient:

> *I'm fortunate that I've not got people around at all to assist me or help me in any way and that I maintain is a great, because I strive to do these things.* [P9]

> *I've lived on my own for most of my life and I'm very sort of self-sufficient I suppose, in a way.* [P7]

In the self-management phase, there is a clear overlap between the TDF domains, social influences, and environmental context and resources. This is unsurprising given the interconnected nature of home, work, and social or family lives in the day-to-day lives of many people. Leveraging technology to provide increased opportunities for family involvement has clear potential and has been widely explored in other areas of health-focused research. Maintaining a balance between people's desire to be self-reliant and their desire to be connected is also critical in designing such technology.

Monitoring

Many participants described becoming more aware of their body, the link between their mind and body, and *listened to their body* more after cardiac events. As described above, rehabilitation classes provided a safe zone. Monitoring was a key part of this, with close overall monitoring by health professionals and regular pulse and blood pressure monitoring. During the self-management phase, self-monitoring in daily life was common and again gave many patients confidence to continue with physical activities and push themselves. The most commonly monitored measurements reported by participants were heart rate, blood pressure, steps, sleep, and medication. Among these steps was the most frequently monitored unit. Fitbit (FitBit Inc) is the most widely used and well-known monitoring technology among participants. All patients who owned a Fitbit started using it after hospitalization. This was mainly for self-motivation and safety, and to obtain other useful insights about their body. Monitoring was also done to share information with the general practitioners,

> *I probably wouldn't push myself to do things, whereas now, with the Fitbit, I try where possible to be able to fulfil my steps every day.* [P18]

TDF describes the behavioral regulation domain as anything aimed at managing or changing objectively observed or measured actions. Self-monitoring is an important component of this domain. This quote shows how some participants used monitoring technologies for behavioral regulation during the self-management phase. Monitoring also helped to provide ongoing insight and more personalized knowledge about their own body. However, continuous monitoring could also cause stress, and some patients liked monitoring only when they were performing physical activity. Warnings were seen as valuable, but only where something specific and unusual was detected, and not in a more routine or general way that highlights limitations:

> *That could actually cause more of a kind of worrying aspect to people, it could lead to more stress, having to do that and to also find if their heart rate wasn't good, it would be more of a worry to them.* [P19]

> *It would be useful if...it could issue a warning if something irregular began to happen.* [P13]

This perspective suggests that for some people, long-term monitoring will work best when it is structured or compartmentalized. By combining this approach with warnings that are largely focused on irregular events, it may be possible to develop systems that provide a safe zoning effect similar to that identified in face-to-face classes in the rehabilitation phase. To achieve this monitored safe zone, it is critical that people trust the privacy of monitoring technologies. Some participants questioned the integrity and transparency of technologies and were unsure if web-based resources could be trusted. Surprisingly, others also questioned their own potential honesty when entering their own information to seek help through digital apps:

> *You can put into a computer whatever you like. You can say I'm a 6-foot leggy blonde, how do you advise me to get better, but you can type anything in. You're not going to have to be honest into a computer but face-to-face...* [P2]

Capability

One of the most interesting recommendations made by the participants was that technology should act as an empowering agent. In particular, it should focus on what can be done, rather than identifying or tracking limitations. Patients believed that technology should guide them by allowing them to see what kind and how much exercise they could perform. In this way, technology would more closely mirror the guidance provided by health professionals in rehabilitation classes,

> *If there was any kind of technology or anything that would say to them you could actually do this after so many weeks, with care, I think so because all you get told, 'Don't do this', and then you're sitting there and you think, oh, and everything just seizes up and your confidence does go, to be honest with you.* [P15]

Respect for people's autonomy was also important, with 1 participant negatively describing technology as *assertive*. To be successful, it was essential that technology respected peoples' autonomy:

> *That you're always in control of them. What they're providing you with is information and suggestions rather than commands.* [P13]

It was found that patients accomplished physical activity through activities in daily life. The preferred type of physical activity for most patients was walking and gardening. Their occupation and where they lived reflected on the type of physical activity they preferred:

> *My husband's a farmer. We live on a farm. We have no problem with exercise at all.* [P2]

As discussed above, self-monitoring is an important construct within the TDF *behavioral regulation* domain. Habit is an important construct in this domain. Alongside encouraging targeted lifestyle changes, our data suggest that long-term rehabilitation technology will be most effective if it draws on previously established healthy habits and activities of daily life. This can be combined with recommendations that emphasize capability and reinforce positive opportunities, allowing designers to build on the empowerment construct, which is emphasized in the TDF's *Belief about Capability* domain. This

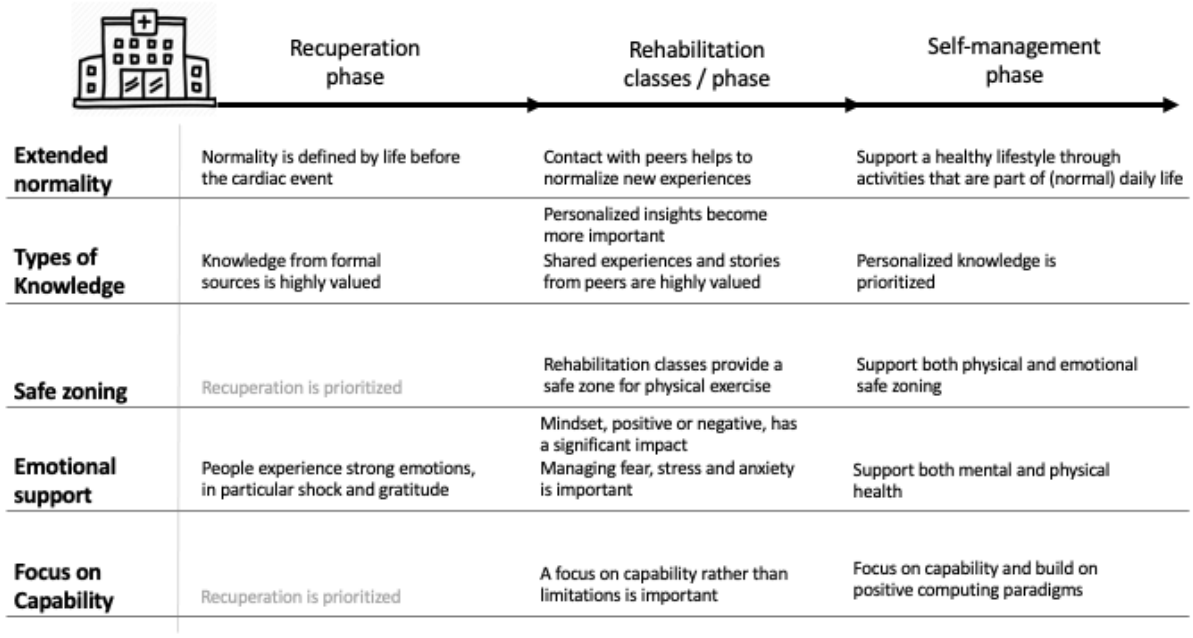
overall approach is complementary to participants' desire for a normal life and should thus be a key focus for designers.

Discussion

Principal Findings

As described in the Related Work section, TDF is a synthesis of previous theories of behavioral change. Mapping the themes to the TDF domains provided us with key domains and behavioral constructs to consider in each phase after the cardiac event. The key strength of TDF is that it provides a rigorous and holistic framework for identifying a wide range of factors that impact behavior. Unsurprisingly, this has resulted in individual findings that are consistent with earlier research on health behavioral change, both in the cardiac domain and beyond. Critically, however, the use of TDF has also allowed us to see how factors that influence behavior evolve over time and identify potential sources of tension. For example, participants experienced a strong initial need for formal knowledge and access to health experts. This subsequently shifted to a desire for detailed personal insight and shared peer knowledge. We also see how participants experienced a strong desire for a normal life after surgery and how a redefinition of normality is important in long-term recovery. In this section, we discuss our findings, focusing on five key issues, namely, extended normality, safe zoning, focus on capability, different types of knowledge, and emotional support. Figure 2 provides an overview of the key points and recommendations addressed in the *Discussion*.

Figure 2. Key patient experiences and areas where technology can provide support during recuperation, rehabilitation, and self-management.



Extended Normality

Existing literature has described the mundane nature of day-to-day self-care [17] and the degree to which people prefer not to be reminded of chronic health conditions [28]. We also find that a desire for normality is a strong motivating factor; indeed, it is a stated goal for many people after cardiac surgery. This creates an obvious source of tension, as lifestyle change is an important part of cardiac rehabilitation and is critical to long-term health. Given participants' strength of feelings, it is unlikely that behavioral change strategies that run counter to the goal of normality will be successful. Interestingly, our findings show how some participants' conceptions of normality evolved over time and suggest ways to address this challenge. We call this *extended normality*.

During the recuperation phase, normality is defined as a return to the life participants lived before their acute cardiac event. Official knowledge sources and contact with experts provided information on the recommended changes. However, in rehabilitation classes, participants also began to normalize their new experiences through social interaction and by sharing experiences with other cardiac patients. In the self-management phase, the participants who were most successful in sustaining healthy behavior were those who integrated their health management with their preferred activities of daily life, such as walking or gardening. This helped them reclaim a sense of their old routine, independence, and *normal life*. Viewed through TDF, this also engages with the importance of self-identification in either hindering or supporting healthy behavior. The study of stroke survivors by Ploderer et al [15] also highlighted the people's efforts to manage the illness as well as everyday life activities and to reconstruct their identities.

This has led to several recommendations for technology. Critically, technologies should recognize that exceptional goals and external incentives may not be necessary. Normal life is a goal and incentive in and of itself. Care should also be taken to resolve the potential conflict that might arise between participants' goal for normality and the lifestyle change goals recommended by professionals for rehabilitation and long-term health management. Personalized rehabilitation programs that respect personal autonomy and provide tailored recommendations linked to daily life can help address this

tension. As people transition to life after surgery, technology that supports enhanced contact with peers and shared stories can also help develop a new sense of normality.

Types of Knowledge

A previous study by Pollack et al [5] provided a detailed exploration of the experience of patients discharged from the hospital. They describe how people are often unprepared for a transition from the hospital and identified three important challenges for patients recovering from illness and needed to engage in successful self-management: (1) lack of support for health knowledge, (2) no opportunity to access resources, and (3) no opportunities to promote self-efficacy. We discuss self-efficacy in greater detail in the section focusing on capability below. Here, we consider knowledge and access. Our findings again show that people's knowledge needs changed over time.

During the recuperation phase, people place a high value on formal knowledge, by which we mean information provided by health professionals and official sources. Much of this was standardized information about cardiac rehabilitation and lifestyle management, including standardized official booklets. Participants also sought web-based information but were often mistrusting of such sources. During the rehabilitation phase, a change occurred in the information that participants valued. Formal knowledge remained important, but participants no longer wanted generic information. They placed a high value on both shared experiential knowledge and detailed personal insight. Shared experience was facilitated through contact with peers in rehabilitation classes and occasionally through web-based support groups. As noted above, it played an important role in normalizing people's new experiences. Personal knowledge was initially facilitated through the tailored support provided by health professionals in classes and later, although typically to a lesser degree, through self-monitoring technology.

Our findings regarding types of knowledge are consistent with a recent systematic review of barriers and facilitators of technology for cardiac rehabilitation and self-management. It also emphasized the need for technology designers to support background knowledge as well as personal and in-the-moment knowledge, where background knowledge is awareness of their medical conditions, medication, posthospital care measures, and available support systems; and in-the-moment knowledge is awareness of current body condition and changes in their body [11].

Moving forward, technologies that support different types of knowledge have significant potential. However, it was striking that many of our participants expressed the view that technology is a *solitary* thing. Within the HCI field, significant research has been conducted on the design of technologies that support social connectedness in health [51], and in personal and lived informatics [52] and the use of technology to support informal caregiving [53]. We do not have the scope to elaborate on this work at this point, except to state that the development of effective social networks in self-monitoring technologies in the health domain is clearly not a trivial task. However, research in the cardiac space will benefit from building on this earlier work.

Safe Zoning

During the rehabilitation phase, participants liked the controlled environment, intensive monitoring, and detailed personalized support provided by health professionals. It provided insight about their current health status and increased confidence by assuring them that they were within a safe zone of physical activity. This *safe zoning* helped participants overcome emotions such as fear. Critically, it did not provide safety by reducing the activity. Rather, it provided a space where people could push themselves without the fear of overburdening their body.

Technology that supports this safe zoning on an ongoing basis is likely to be highly valuable. Importantly, safe zoning should consider not only physical, but also emotional safe zones. During the self-management phase, self-monitoring gave some patients confidence to continue physical activities and push themselves. However, many patients also did not want to be monitored continuously, as this could cause anxiety and interfere with their desire for normality. This finding is consistent with previous findings of Maitland et al [28] that cardiovascular patients were reluctant to accept unnecessary monitoring. Warnings were also considered valuable only when something unusual was detected and not in a more routine or general way. A structured or compartmentalized monitoring approach with warnings largely focused on irregular events may help to provide a *safe zone* effect similar to face-to-face rehabilitation classes. Transparency and trust in the privacy of monitoring technologies are critical for achieving this goal.

Emotional Support

Acute cardiac events affect people both physically and mentally. In recent decades, health research has increasingly recognized and addressed the interrelated nature of physical and mental health. For example, the recognition of psycho-oncology is a key element in rehabilitation for cancer survivors [54,55].

As participants transitioned from recuperation to the rehabilitation phase, their emotions transitioned from shock and gratitude to long-term emotions. Multiple emotions built up and left unchecked can affect a person's mental health, inducing fear, anxiety, negativity, and loss of confidence. Many patients have stressed the importance of emotional support. Family and close friends are often vital sources of emotional support. Participants pointed out that although a lot was done to educate and motivate them on physical exercise and diet, less attention was given to emotional strength. Although in-person emotional or mental support is preferred, there is increasing evidence in recent years that technology can play a significant role in providing support for mental health [56]. Examples range from systems specifically designed to integrate with traditional care [57] to the more exploratory use of voice interfaces and chatbots using artificial intelligence to provide emotional support [58]. Importantly, alongside negative emotional experiences, participants also expressed positive emotions such as gratitude and renewed appreciation of the natural world. Many also described the beneficial impact of a positive mindset and an increased sense of the link between mind and body, including

an appreciation of the stress reduction in rehabilitation classes. This suggests significant potential in the application of positive computing approaches [59] that emphasize human potential and reinforce emotions such as kindness and gratitude. Approaches such as computer-supported mindfulness also have significant potential to support stress reduction and enhance the sense of a positive mind-body link [60].

Focus on Capability

Building on the value of positive computing approaches, this study strongly suggests that designers should focus on capability rather than limitations. Particularly in the self-management phase, our participants expressed a strong desire for technology that could recognize renewed strength and make positive recommendations. They wanted technology to show what is possible by tailoring to their capabilities rather than focusing on limitations. They also wanted technology that respected their autonomy, placed them in control, and offered suggestions rather than being directive. Interestingly, some participants placed a significant value on self-sufficiency. They did not like to be helped by their families or friends. It is possible that people in this group would also consider technology as encroaching on their preference for self-sufficiency. However, we consider it more likely that autonomy-respecting and capability-focused systems will have a significant potential with this group. This analysis resonates with the conclusions of Andersen et al [20], where reintroducing patients as active diagnostic agents in the telemonitoring system showed patient willingness to take on the added workload and become actively engaged in their monitoring and diagnosis.

Through the growing capabilities of recommendation system techniques, we envision technology to be key in enabling personalized rehabilitation and self-care by focusing on individual capabilities. Tailoring recommendations for daily activities will be important in achieving this. Apps should also take into account the effect of progress awareness, wherein tailored programs based on step-by-step progress and presentation of the progress would contribute toward motivation. Previous HCI literature on person-centered recommender systems by researchers such as Konrad et al [61] and Hollis et al [62] offers valuable guidance in this area.

Limitations

Although we interviewed a relatively diverse group of people with cardiac problems, including people who both withdrew from and attended a full rehabilitation program, it will be beneficial if future studies include more people aged less than 55 years and more people from urban areas. Although our findings are directed toward supporting patients, we understand that the opinions of caregivers are crucial and involving them will provide a broader view of the impact technology in support rehabilitation and self-care. Similarly, including health care professionals in the design process will also be crucial to the development of technologies that are acceptable and effective in improving the rehabilitation and self-management practices of patients. This work is beyond the scope of this study. Our future studies will involve both patients and health professionals and will apply co-design methods to implement systems that operationalize and evaluate the recommendations provided in this paper.

Future Work

The *Discussion* section has identified a number of important avenues for research on the design of technology to support cardiovascular rehabilitation and self-management. Continuing to address the theoretical basis for this research will be a key focus of our work. As described in the related work section, TDF is an integrated theoretical framework composed of domains synthesized from theories and theoretical constructs relevant to behavioral change. Building on TDF, researchers in behavior change have also developed the behavior change wheel (BCW) [43,44]. This supports intervention designers in selecting intervention and behavioral change techniques by mapping the TDF domains to the BCW. BCW is based on three components, namely, capability, opportunity, and motivation (the COM-B model). It presents human behavior (B) as resulting from the interaction between physical and psychological capabilities (C), opportunities provided by the physical and social environment (O), and reflective and automatic motivation (M) [63,64]. For example, TDF domains linked to capability (C) are knowledge, skills, memory, and behavioral regulation. BCW proposes the following interventions to address factors related to capability: education, training, and enablement. In this way, BCW proposes interventions and policies for each of the three components. Building on the identification of important TDF domains and constructs in this study, application of BCW is a key priority in our future research.

Conclusions

This paper has applied the TDF to explore the experiences of people with CVD, focusing specifically on recuperation, rehabilitation, and self-management phases after an acute cardiac event. Through these three phases, we have described how factors such as desire for normality, types of knowledge, safe zoning, connectedness, and capability impact patients. We then highlight the TDF domains that are linked to the factors arising in the three phases. Building on our findings, we have provided implications of these factors and the TDF domains in the design of technology-mediated cardiac rehabilitation and self-management.

Acknowledgments

This project is supported by the European Union's INTERREG VA Program, managed by the Special European Union Programmes Body.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Demographic information about the participants.
[DOCX File , 15 KB - cardio_v5i2e30428_app1.docx]

Multimedia Appendix 2
Interview guide.
[DOCX File , 20 KB - cardio_v5i2e30428_app2.docx]

References

1. Cardiovascular diseases (CVDs). World Health Organization. URL: https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds) [accessed 2021-09-17]
2. Cardiovascular disease. National Health Service. URL: https://www.nhs.uk/conditions/cardiovascular-disease/ [accessed 2020-05-11]
3. Cardiac rehabilitation. British Heart Foundation. URL: https://www.bhf.org.uk/informationsupport/support/practical-support/cardiac-rehabilitation [accessed 2020-05-11]
4. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns 2002;48(2):177-187. [doi: 10.1016/s0738-3991(02)00032-0] [Medline: 12401421]
5. Pollack AH, Backonja U, Miller AD, Mishra SR, Khelifi M, Kendall L, et al. Closing the gap: supporting patients' transition to self-management after hospitalization. In: Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems. 2016 Presented at: CHI'16: CHI Conference on Human Factors in Computing Systems; May 7 - 12, 2016; San Jose California USA p. 5324-5336. [doi: 10.1145/2858036.2858240]
6. Serlachius A, Sutton S. Self-management and behaviour change: theoretical models. In: Newman S, Steed E, Mulligan K, editors. Chronic Physical Illness: Self-management and Behavioural Interventions. Maidenhead, Berkshire, United Kingdom: Open University Press - McGraw-Hill; 2009:47-63.
7. Yohannes AM, Doherty P, Bundy C, Yalfani A. The long-term benefits of cardiac rehabilitation on depression, anxiety, physical activity and quality of life. J Clin Nurs 2010 Oct;19(19-20):2806-2813. [doi: 10.1111/j.1365-2702.2010.03313.x] [Medline: 20738450]
8. Daly J, Sindone AP, Thompson DR, Hancock K, Chang E, Davidson P. Barriers to participation in and adherence to cardiac rehabilitation programs: a critical literature review. Prog Cardiovasc Nurs 2002;17(1):8-17. [doi: 10.1111/j.0889-7204.2002.00614.x] [Medline: 11872976]
9. Gallagher R, Roach K, Sadler L, Glinatsis H, Belshaw J, Kirkness A, et al. Mobile technology use across age groups in patients eligible for cardiac rehabilitation: survey study. JMIR Mhealth Uhealth 2017 Oct 24;5(10):e161 [FREE Full text] [doi: 10.2196/mhealth.8352] [Medline: 29066425]
10. Susan M, Marie J, Jill F, Wendy H, Martin E. From theory to intervention: mapping theoretically derived behavioural determinants to behaviour change techniques. Appl Psychol 2008 Jul 08;57(4):660-680 [FREE Full text] [doi: 10.1111/j.1464-0597.2008.00341.x]
11. Tadas S, Coyle D. Barriers to and facilitators of technology in cardiac rehabilitation and self-management: systematic qualitative grounded theory review. J Med Internet Res 2020 Nov 11;22(11):e18025 [FREE Full text] [doi: 10.2196/18025] [Medline: 33174847]
12. Siegers K, Van Mechelen M, Vanattenhoven J. Mapping the health technology needs of congestive heart failure patients: user needs vs. feasibility. In: Proceedings of the 11th EAI International Conference on Pervasive Computing Technologies for Healthcare. 2017 Presented at: PervasiveHealth '17: 11th EAI International Conference on Pervasive Computing Technologies for Healthcare; May 23 - 26, 2017; Barcelona Spain p. 266-271. [doi: 10.1145/3154862.3154916]
13. Antypas K, Wangberg SC. Combining users' needs with health behavior models in designing an internet- and mobile-based intervention for physical activity in cardiac rehabilitation. JMIR Res Protoc 2014 Jan 10;3(1):e4 [FREE Full text] [doi: 10.2196/resprot.2725] [Medline: 24413185]
14. Sankaran S, Frederix I, Haesen M, Dendale P, Luyten K, Coninx K. A grounded approach for applying behavior change techniques in mobile cardiac tele-rehabilitation. In: Proceedings of the 9th ACM International Conference on PErvasive Technologies Related to Assistive Environments. 2016 Presented at: PETRA '16: 9th ACM International Conference on PErvasive Technologies Related to Assistive Environments; June 29 - July 1, 2016; Corfu Island Greece p. 1-8. [doi: 10.1145/2910674.2910680]
15. Ploderer B, Stuart J, Tran V, Green T, Muller J. The transition of stroke survivors from hospital to home: understanding work and design opportunities. In: Proceedings of the 29th Australian Conference on Computer-Human Interaction. 2017 Presented at: OzCHI '17: 29th Australian Conference on Human-Computer Interaction; November 28 - December 1, 2017; Brisbane Queensland Australia p. 1-9. [doi: 10.1145/3152771.3152772]
16. Doyle J, Murphy E, Kuiper J, Smith S, Hannigan C, Jacobs A, et al. Managing multimorbidity: identifying design requirements for a digital self-management tool to support older adults with multiple chronic conditions. In: Proceedings of the 2019

CHI Conference on Human Factors in Computing Systems. 2019 Presented at: CHI '19: CHI Conference on Human Factors in Computing Systems; May 4 - 9, 2019; Glasgow Scotland UK p. 1-14. [doi: 10.1145/3290605.3300629]
17. Nunes F, Verdezoto N, Fitzpatrick G, Kyng M, Grönvall E, Storni C. Self-care technologies in HCI. ACM Trans Comput Hum Interact 2015 Dec 14;22(6):1-45 [FREE Full text] [doi: 10.1145/2803173]
18. Athilingam P, Jenkins B. Mobile phone apps to support heart failure self-care management: integrative review. JMIR Cardio 2018 May 02;2(1):e10057 [FREE Full text] [doi: 10.2196/10057] [Medline: 31758762]
19. Andersen TO, Bansler JP, Kensing F, Moll J, Mønsted T, Nielsen KD, et al. Aligning concerns in telecare: three concepts to guide the design of patient-centred e-health. Comput Supported Coop Work 2018 May 19;27(3-6):1039-1079 [FREE Full text] [doi: 10.1007/s10606-018-9309-1]
20. Andersen T, Bjørn P, Kensing F, Moll J. Designing for collaborative interpretation in telemonitoring: re-introducing patients as diagnostic agents. Int J Med Inform 2011 Aug;80(8):112-126. [doi: 10.1016/j.ijmedinf.2010.09.010] [Medline: 21067968]
21. Wottrich AW, Aström K, Löfgren M. On parallel tracks: newly home from hospital--people with stroke describe their expectations. Disabil Rehabil 2012;34(14):1218-1224. [doi: 10.3109/09638288.2011.640381] [Medline: 22200192]
22. O'Shea O, Woods C, McDermott L, Buys R, Cornelis N, Claes J, et al. A qualitative exploration of cardiovascular disease patients' views and experiences with an eHealth cardiac rehabilitation intervention: The PATHway Project. PLoS One 2020 Jul 06;15(7):e0235274 [FREE Full text] [doi: 10.1371/journal.pone.0235274] [Medline: 32628688]
23. Geurts E, Hansen D, Dendale P, Coninx K. Impact of a mobile cycling application on cardiac patients' cycling behavior and enjoyment. In: Proceedings of the 11th PErvasive Technologies Related to Assistive Environments Conference. 2018 Presented at: PETRA '18: The 11th PErvasive Technologies Related to Assistive Environments Conference; June 26 - 29, 2018; Corfu Greece p. 257-264. [doi: 10.1145/3197768.3197783]
24. Beatty AL, Magnusson SL, Fortney JC, Sayre GG, Whooley MA. VA fitheart, a mobile app for cardiac rehabilitation: usability study. JMIR Hum Factors 2018 Jan 15;5(1):e3 [FREE Full text] [doi: 10.2196/humanfactors.8017] [Medline: 29335235]
25. Aarhus R, Ballegaard SA. Negotiating boundaries: managing disease at home. In: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems. 2010 Presented at: CHI '10: CHI Conference on Human Factors in Computing Systems; April 10 - 15, 2010; Atlanta Georgia USA p. 1223-1232. [doi: 10.1145/1753326.1753509]
26. Geurts E, Haesen M, Dendale P, Luyten K, Coninx K. Back on bike: the BoB mobile cycling app for secondary prevention in cardiac patients. In: Proceedings of the 18th International Conference on Human-Computer Interaction with Mobile Devices and Services. 2016 Presented at: MobileHCI '16: 18th International Conference on Human-Computer Interaction with Mobile Devices and Services; September 6 - 9, 2016; Florence Italy p. 135-146. [doi: 10.1145/2935334.2935377]
27. Grönvall E, Verdezoto N. Beyond self-monitoring: understanding non-functional aspects of home-based healthcare technology. In: Proceedings of the 2013 ACM international joint conference on Pervasive and ubiquitous computing. 2013 Presented at: UbiComp '13: The 2013 ACM International Joint Conference on Pervasive and Ubiquitous Computing; September 8 - 12, 2013; Zurich Switzerland p. 587-596. [doi: 10.1145/2493432.2493495]
28. Maitland J, Chalmers M. Self-monitoring, self-awareness, and self-determination in cardiac rehabilitation. In: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems. 2010 Presented at: CHI '10: CHI Conference on Human Factors in Computing Systems; April 10 - 15, 2010; Atlanta Georgia USA p. 1213-1222. [doi: 10.1145/1753326.1753508]
29. Preuveneers D, Berbers Y. Mobile phones assisting with health self-care: a diabetes case study. In: Proceedings of the 10th international conference on Human computer interaction with mobile devices and services. 2008 Presented at: MobileHCI08: 10th International Conference on Human Computer Interaction with Mobile Devices and Services; September 2 - 5, 2008; Amsterdam The Netherlands p. 177-186. [doi: 10.1145/1409240.1409260]
30. Raj S, Toporski K, Garrity A, Lee JM, Newman MW. "My blood sugar is higher on the weekends": finding a role for context and context-awareness in the design of health self-management technology. In: Proceedings of the 2019 CHI Conference on Human Factors in Computing Systems. 2019 Presented at: CHI '19: CHI Conference on Human Factors in Computing Systems; May 4 - 9, 2019; Glasgow Scotland UK p. 1-13. [doi: 10.1145/3290605.3300349]
31. Nunes F. From medicalized to mundane self-care technologies. interactions 2019 Apr 23;26(3):67-69. [doi: 10.1145/3319374]
32. Banerjee S. Multimorbidity--older adults need health care that can count past one. Lancet 2015 Feb 14;385(9968):587-589. [doi: 10.1016/S0140-6736(14)61596-8] [Medline: 25468155]
33. Emma M, Julie D, Caoimhe H, Suzanne S, Janneke K, An J, et al. Perceptions and use of technology to support older adults with multimorbidity. Stud Health Technol Inform 2017;242:160-167 [FREE Full text] [doi: 10.5334/ijic.3521] [Medline: 28873794]
34. Spina G, Huang G, Vaes A, Spruit M, Amft O. COPDTrainer: a smartphone-based motion rehabilitation training system with real-time acoustic feedback. In: Proceedings of the 2013 ACM international joint conference on Pervasive and ubiquitous computing. 2013 Presented at: UbiComp '13: The 2013 ACM International Joint Conference on Pervasive and Ubiquitous Computing; September 8 - 12, 2013; Zurich Switzerland p. 597-606. [doi: 10.1145/2493432.2493454]
35. Taylor A, Godden D, Aitken A, Colligan J, Wilson R. Delivering group-based services to the home via the internet: maximising clinical and social benefits. In: Proceedings of the 5th International Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth) and Workshops.: IEEE; 2011 Presented at: 5th International Conference

on Pervasive Computing Technologies for Healthcare (PervasiveHealth) and Workshops; May23-26, 2011; Dublin, Ireland. [doi: 10.4108/icst.pervasivehealth.2011.246004]
36. Hekler EB, Klasnja P, Froehlich JE, Buman MP. Mind the theoretical gap: interpreting, using, and developing behavioral theory in HCI research. In: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems. 2013 Presented at: CHI '13: CHI Conference on Human Factors in Computing Systems; April 27 - May 2, 2013; Paris France p. 3307-3316. [doi: 10.1145/2470654.2466452]
37. Klasnja P, Consolvo S, Pratt W. How to evaluate technologies for health behavior change in HCI research. In: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems. 2011 Presented at: CHI '11: CHI Conference on Human Factors in Computing Systems; May 7 - 12, 2011; Vancouver BC Canada p. 3063-3072. [doi: 10.1145/1978942.1979396]
38. O'Leary K, Eschler J, Kendall L, Vizer L, Ralston J, Pratt W. Understanding design tradeoffs for health technologies: a mixed-methods approach. In: Proceedings of the 33rd Annual ACM Conference on Human Factors in Computing Systems. 2015 Presented at: CHI '15: CHI Conference on Human Factors in Computing Systems; April 18 - 23, 2015; Seoul Republic of Korea p. 4151-4160. [doi: 10.1145/2702123.2702576]
39. McDermott MS, While AE. Maximizing the healthcare environment: a systematic review exploring the potential of computer technology to promote self-management of chronic illness in healthcare settings. Patient Educ Couns 2013 Jul;92(1):13-22. [doi: 10.1016/j.pec.2013.02.014] [Medline: 23566427]
40. Charles AS. The health belief model. In: Cambridge Handbook of Psychology, Health and Medicine, Second Edition. Cambridge, United Kingdom: Cambridge University Press; 2014:97-102.
41. Madden TJ, Ellen PS, Ajzen I. A comparison of the theory of planned behavior and the theory of reasoned action. Pers Soc Psychol Bull 2016 Jul 02;18(1):3-9 [FREE Full text] [doi: 10.1177/0146167292181001]
42. Bandura A. Social cognitive theory of self-regulation. Organ Behav Hum Decis Process 1991 Dec;50(2):248-287 [FREE Full text] [doi: 10.1016/0749-5978(91)90022-l]
43. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the theoretical domains framework of behaviour change to investigate implementation problems. Implement Sci 2017 Jun 21;12(1):77 [FREE Full text] [doi: 10.1186/s13012-017-0605-9] [Medline: 28637486]
44. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci 2012 Apr 24;7:37 [FREE Full text] [doi: 10.1186/1748-5908-7-37] [Medline: 22530986]
45. Taylor N, Lawton R, Conner M. Development and initial validation of the determinants of physical activity questionnaire. Int J Behav Nutr Phys Act 2013 Jun 11;10:74 [FREE Full text] [doi: 10.1186/1479-5868-10-74] [Medline: 23758912]
46. Taylor N, Parveen S, Robins V, Slater B, Lawton R. Development and initial validation of the influences on patient safety behaviours questionnaire. Implement Sci 2013 Jul 29;8:81 [FREE Full text] [doi: 10.1186/1748-5908-8-81] [Medline: 23895628]
47. Michie S, Pilling S, Garety P, Whitty P, Eccles MP, Johnston MA, et al. Difficulties implementing a mental health guideline: an exploratory investigation using psychological theory. Implement Sci 2007 Mar 26;2:8 [FREE Full text] [doi: 10.1186/1748-5908-2-8] [Medline: 17386102]
48. Nicholson SL, Donaghy M, Johnston M, Sniehotta FF, van Wijck F, Johnston D, et al. A qualitative theory guided analysis of stroke survivors' perceived barriers and facilitators to physical activity. Disabil Rehabil 2014;36(22):1857-1868. [doi: 10.3109/09638288.2013.874506] [Medline: 24377329]
49. Braun V, Clarke V. Successful Qualitative Research: A Practical Guide for Beginners. UK: SAGE Publications; 2013.
50. Foster EJ, Munoz SA, Crabtree D, Leslie SJ, Gorely T. Barriers and facilitators to participating in cardiac rehabilitation and physical activity in a remote and rural population: a cross-sectional survey. Cardiol J 2021;28(5):697-706 [FREE Full text] [doi: 10.5603/CJ.a2019.0091] [Medline: 31565795]
51. Peters D, Calvo RA, Ryan RM. Designing for motivation, engagement and wellbeing in digital experience. Front Psychol 2018 May 28;9:797 [FREE Full text] [doi: 10.3389/fpsyg.2018.00797] [Medline: 29892246]
52. Rooksby J, Rost M, Morrison A, Chalmers M. Personal tracking as lived informatics. In: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems. 2014 Presented at: CHI '14: CHI Conference on Human Factors in Computing Systems; April 26 - May 1, 2014; Toronto Ontario Canada p. 1163-1172. [doi: 10.1145/2556288.2557039]
53. Güldenpfennig F, Nunes F, Fitzpatrick G. Proxycare: integrating informal care into formal settings. In: Proceedings of the 9th International Conference on Pervasive Computing Technologies for Healthcare.: IEEE; 2015 Aug 03 Presented at: 9th International Conference on Pervasive Computing Technologies for Healthcare; May 20–23, 2015; Istanbul, Turkey. [doi: 10.4108/icst.pervasivehealth.2015.259109]
54. Andrykowski MA, Lykins E, Floyd A. Psychological health in cancer survivors. Semin Oncol Nurs 2008 Aug;24(3):193-201 [FREE Full text] [doi: 10.1016/j.soncn.2008.05.007] [Medline: 18687265]
55. Dale HL, Adair PM, Humphris GM. Systematic review of post-treatment psychosocial and behaviour change interventions for men with cancer. Psychooncology 2010 Mar;19(3):227-237. [doi: 10.1002/pon.1598] [Medline: 19588538]
56. Sanches P, Janson A, Karpashevich P, Nadal C, Qu C, Roquet CD, et al. HCI and affective health: taking stock of a decade of studies and charting future research directions. In: Proceedings of the 2019 CHI Conference on Human Factors in

Computing Systems. 2019 Presented at: CHI '19: CHI Conference on Human Factors in Computing Systems; May 4 - 9, 2019; Glasgow Scotland UK p. 1-17. [doi: 10.1145/3290605.3300475]
57. Stawarz K, Preist C, Tallon D, Thomas L, Turner K, Wiles N, et al. Integrating the Digital and the Traditional to Deliver Therapy for Depression: Lessons From a Pragmatic Study. 2020. URL: https://usabilitypanda.com/publications/Stawarz2020_integrated_platform_evaluation.pdf [accessed 2021-09-17]
58. Beaudry J, Consigli A, Clark C, Robinson KJ. Getting ready for adult healthcare: designing a chatbot to coach adolescents with special health needs through the transitions of care. J Pediatr Nurs 2019;49:85-91. [doi: 10.1016/j.pedn.2019.09.004] [Medline: 31644960]
59. Calvo RA, Peters D. Positive Computing – Technology for Wellbeing and Human Potential. Cambridge, Massachusetts, United States: MIT Press; 2017:1-298.
60. Terzimehić N, Häuslschmid R, Hussmann H, Schraefel MC. A review and analysis of mindfulness research in HCI: framing current lines of research and future opportunities. In: Proceedings of the 2019 CHI Conference on Human Factors in Computing Systems. 2019 Presented at: CHI '19: CHI Conference on Human Factors in Computing Systems; May 4 - 9, 2019; Glasgow Scotland UK p. 1-13. [doi: 10.1145/3290605.3300687]
61. Konrad A, Bellotti V, Crenshaw N, Tucker S, Nelson L, Du H, et al. Finding the adaptive sweet spot: balancing compliance and achievement in automated stress reduction. In: Proceedings of the 33rd Annual ACM Conference on Human Factors in Computing Systems. 2015 Presented at: CHI '15: CHI Conference on Human Factors in Computing Systems; April 18 - 23, 2015; Seoul Republic of Korea p. 3829-3838. [doi: 10.1145/2702123.2702512]
62. Hollis V, Konrad A, Springer A, Antoun M, Antoun C, Martin R, et al. What does all this data mean for my future mood? Actionable analytics and targeted reflection for emotional well-being. Hum Comput Interact 2017 Mar 16;32(5-6):208-267 [FREE Full text] [doi: 10.1080/07370024.2016.1277724]
63. Susan M, Lou A, Robert W. The Behaviour Change Wheel : A Guide to Designing Interventions. Sutton, United Kingdom: Silverback; 2014.
64. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011 Apr 23;6:42 [FREE Full text] [doi: 10.1186/1748-5908-6-42] [Medline: 21513547]

Abbreviations

BCW: behavior change wheel
CVD: cardiovascular disease
HCI: human-computer interaction
NHS: National Health Service
TDF: Theoretical Domains Framework

Edited by G Eysenbach; submitted 13.05.21; peer-reviewed by L Russell, Z Xie; comments to author 04.06.21; revised version received 17.06.21; accepted 30.07.21; published 14.10.21.

Please cite as:
Tadas S, Pretorius C, Foster EJ, Gorely T, Leslie SJ, Coyle D
Transitions in Technology-Mediated Cardiac Rehabilitation and Self-management: Qualitative Study Using the Theoretical Domains Framework
JMIR Cardio 2021;5(2):e30428
URL: https://cardio.jmir.org/2021/2/e30428
doi:10.2196/30428
PMID:34647892

Review

Interventions Using Heart Age for Cardiovascular Disease Risk Communication: Systematic Review of Psychological, Behavioral, and Clinical Effects

Carissa Bonner[1], MPH, PhD; Carys Batcup[1], MSc; Samuel Cornell[1], MSc; Michael Anthony Fajardo[1], PhD; Anna L Hawkes[2], PhD; Lyndal Trevena[1], MBBS, MPhilPH, PhD; Jenny Doust[3], MBBS, PhD

[1]School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia

[2]National Heart Foundation of Australia, Brisbane, Australia

[3]School of Public Health, Faculty of Medicine, University of Queensland, Brisbane, Australia

Corresponding Author:
Carissa Bonner, MPH, PhD
School of Public Health
Faculty of Medicine and Health
University of Sydney
Edward Ford Building A27
Sydney, 2006
Australia
Phone: 61 29351 7125
Email: carissa.bonner@sydney.edu.au

Abstract

Background: Cardiovascular disease (CVD) risk communication is a challenge for clinical practice, where physicians find it difficult to explain the absolute risk of a CVD event to patients with varying health literacy. Converting the probability to *heart age* is increasingly used to promote lifestyle change, but a rapid review of biological age interventions found no clear evidence that they motivate behavior change.

Objective: In this review, we aim to identify the content and effects of heart age interventions.

Methods: We conducted a systematic review of studies presenting heart age interventions to adults for CVD risk communication in April 2020 (later updated in March 2021). The Johanna Briggs risk of bias assessment tool was applied to randomized studies. Behavior change techniques described in the intervention methods were coded.

Results: From a total of 7926 results, 16 eligible studies were identified; these included 5 randomized web-based experiments, 5 randomized clinical trials, 2 mixed methods studies with quantitative outcomes, and 4 studies with qualitative analysis. Direct comparisons between heart age and absolute risk in the 5 web-based experiments, comprising 5514 consumers, found that heart age increased positive or negative emotional responses (4/5 studies), increased risk perception (4/5 studies; but not necessarily more accurate) and recall (4/4 studies), reduced credibility (2/3 studies), and generally had no effect on lifestyle intentions (4/5 studies). One study compared heart age and absolute risk to fitness age and found reduced lifestyle intentions for fitness age. Heart age combined with additional strategies (eg, in-person or phone counseling) in applied settings for 9582 patients improved risk control (eg, reduced cholesterol levels and absolute risk) compared with usual care in most trials (4/5 studies) up to 1 year. However, clinical outcomes were no different when directly compared with absolute risk (1/1 study). Mixed methods studies identified consultation time and content as important outcomes in actual consultations using heart age tools. There were differences between people receiving an older heart age result and those receiving a younger or equal to current heart age result. The heart age interventions included a wide range of behavior change techniques, and conclusions were sometimes biased in favor of heart age with insufficient supporting evidence. The risk of bias assessment indicated issues with all randomized clinical trials.

Conclusions: The findings of this review provide little evidence that heart age motivates lifestyle behavior change more than absolute risk, but either format can improve clinical outcomes when combined with other behavior change strategies. The label for the *heart age* concept can affect outcomes and should be pretested with the intended audience. Future research should consider consultation time and differentiate between results of older and younger heart age.

International Registered Report Identifier (IRRID): NPRR2-10.1101/2020.05.03.20089938

(JMIR Cardio 2021;5(2):e31056) doi:10.2196/31056

KEYWORDS

heart age; cardiovascular disease; risk assessment; risk communication; prevention

Introduction

Background

Cardiovascular disease (CVD) risk communication is a challenge for clinical practice, where physicians find it difficult to explain the absolute percentage risk of a CVD event to patients with varying health literacy [1,2]. Absolute risk calculators are recommended in clinical guidelines around the world as the best way to predict the risk of a CVD event over a relatively short period, by incorporating both modifiable (eg, smoking, blood pressure, and cholesterol levels) and nonmodifiable (eg, age and gender) risk factors [3-6]. These calculators are designed to determine whether preventive medication should commence, which is generally recommended for high risk and low risk categories. They are not designed to motivate or determine when to commence lifestyle changes, as this is recommended for all risk categories. For example, smoking cessation should always be recommended for a person who smokes, regardless of the calculated absolute risk. However, the implementation of absolute risk calculators has been poor, and communication barriers have been identified as one reason for this [2,7-10]. One proposed solution is to use more intuitive and motivating risk communication concepts rather than abstract probabilities [11,12]. *Heart age* has been suggested as an alternative to absolute percentage risk of a CVD event and can be calculated by comparing an individual's absolute risk over 5 or 10 years with ideal risk factors (eg, blood pressure of 120/80 mm Hg) or the average for their age or gender category [11].

Heart age tools are increasingly used to promote behavior change around the world, including clinical contexts and web-based consumer resources. They have not generally been used to guide decisions to commence medication in the same way that absolute risk calculators have, although the Joint British Societies (JBS)-3 guidelines in the United Kingdom do suggest that older heart age may be considered as a reason to initiate medication [3]. Following clinical trials of the lung age and heart age concepts, the World Heart Federation collaborated with Unilever for an international promotion to at least 2.7 million consumers in 2009 [13]. Since then, heart age tools have also been promoted to support clinical guidelines in the United Kingdom, New Zealand, and Australia, reaching millions more through nonprofits and health services [14,15]. However, despite this mass appeal, there is no clear evidence that such tools actually motivate behavior change. A review of CVD risk communication in 2011 identified heart age as a potentially useful concept that requires further research [12]. A 2016 review of vascular age concepts in clinical applications found limited trials testing the effects of communicating this concept [16], but a recent rapid review in 2020 highlighted the increasing number of studies on age-based risk formats, suggesting there may now be more evidence available [17].

Heart age tools vary widely in terms of their underlying risk models and results, with the possibility of receiving an older heart age on one calculator but a younger result on another [18]. This is because the tools have different underlying algorithms to assess CVD event risk (eg, Framingham vs QRISK), and different thresholds for comparing an individual's result with ideal or average risk factors (eg, systolic blood pressure may be compared with 120 for ideal vs 125 for average). Another factor is that many people do not know their blood pressure or cholesterol levels, and different techniques are used to estimate this (eg, BMI or population average) [13].

In addition to the underlying algorithms, the way heart age results are explained can come in many forms. The Australian heart age calculator is relatively simple with a single heart age result and prompts an individual to see a physician for a more accurate risk assessment [14]. UK-based heart age calculators include numerous risk communication formats, including the percentage chance of a heart attack or stroke over 10 years or a lifetime, estimated life expectancy, and graphical displays [15]. Heart age tools are often linked to further lifestyle change messages [14], but research on heart age interventions has not differentiated well between these components, despite the fact that they represent different behavior change techniques—the *active ingredients* of behavioral interventions [19]. Heart age interventions may range from a simple one-off message frame (eg, communicating risk as *older heart age* without any further information) to complex programs involving health professional counseling and goal-setting or monitoring of heart age over time.

Objectives

Previous reviews relating to the heart age concept have been descriptive about the models [16,20] or concepts but have not made a distinction between the comparison groups involved in trials (eg, heart age vs standard care or absolute risk [12,17]), have not clearly identified the behavior change techniques included within heart age interventions [12,17,20], or have not included qualitative studies that may provide additional insights into why these tools are so widely used in spite of limited evidence for their effectiveness [16,17,20]. The aim of this systematic review is to identify the content and effects of heart age interventions presented to patients or consumers for the purpose of CVD risk communication in detail, in order to shed light on mixed evidence of their effectiveness.

Methods

Our methods protocol was prepublished on the preprint server medRxiv [21] (not peer-reviewed).

Eligibility Criteria

Studies were considered eligible if they met the following criteria:

1. Published from the inception of the database to April 2020 (this was later updated to March 2021) in peer-reviewed journals.

2. Population: used an adult population (over 18 years of age) or, if not explicit regarding age, are clear that participants were not children.
3. Intervention: present the concept of *heart age* to patients or consumers for the purpose of CVD risk communication, in any setting, including general practices, hospitals, health clinics or community centers, workplaces, or on the web. This included both simple message frame experiments and complex programs in applied settings.
4. Comparators: we placed no restrictions on whether a comparison or control group was used.
5. Outcomes: report qualitative themes or quantitative outcomes related to psychological or behavioral responses to heart age, including clinical outcomes.

Studies that were not peer-reviewed journal articles, such as conference proceedings, dissertations, or government reports, were excluded. Protocol papers, opinion papers, reviews, web-based user descriptions, and heart age algorithm development or validation were excluded. Some studies applied a heart age algorithm to population data or individual patients as an outcome, but the results were not conveyed to individuals, so these were excluded. Studies that presented heart age to adults but did not measure outcomes or collect qualitative data were also excluded.

Information Sources

The following databases were searched: the Cochrane Central Register of Controlled Trials (via OvidSP), MEDLINE (via OvidSP), Embase (via OvidSP), and PsycINFO (via OvidSP) up to March 2021. The search terms are based on an earlier vascular age review in 2016, with additional free text terms based on known relevant papers. The full list of terms is based on a previous review and includes (*vascular*, *vessel*, *arterial*, *heart*, *cardiovascular*, *coronary*, *risk* AND *age*, *ages*, *ageing*, or *aging*), OR *heart forecast*, and limited to human studies. We then searched the citations and references of the final included studies and 2 previous reviews of vascular age models and more general age-related risk concepts. We also included any papers mentioned on publicly accessible heart age websites.

Data Management

We downloaded the references identified in the searches (electronic databases and additional searches) into Microsoft Excel. Duplicates were then removed, and 2 reviewers (SC and C Batcup) screened the titles and abstracts of each study to determine whether they should be included. Discrepancies were resolved by discussion with C Bonner.

Selection Process

The screening process was undertaken by 2 review authors (C Batcup and SC). Each reviewer independently assessed a study's suitability to be included in the review by marking against each study on an Excel spreadsheet, which contained the title and abstract. Studies that did not meet the inclusion criteria were excluded. We obtained the full text of the remaining papers and then assessed the remaining papers against the full inclusion terms for the review to determine their eligibility for inclusion. Non–English language papers were translated into English using Google Translate and verified for inclusion or exclusion by speakers of the relevant language. The review authors resolved disagreements through a consensus-based decision-making process or, when necessary, discussion with a third review author (C Bonner). Two Japanese language studies were considered for inclusion but deemed ineligible by an author who could read Japanese (JD).

Data Extraction

Two review authors (C Batcup and SC) completed web-based training to apply the behavior change technique taxonomy to published methods and used a predefined data extraction form to collect data from the included studies. Reviewers piloted the data extraction form with a sample of included papers; however, no amendments were made. An Excel database was used to extract quantitative and qualitative data from the included studies.

Quantitative data extracted included year, country, study design, study population (age, education, socioeconomic status, health literacy, race or culture or ethnicity), number of participants, intervention format (web or paper based), comparison groups (standard care or absolute risk alone), clinical measures (blood pressure, cholesterol levels, weight, BMI, waist circumference, and prescribed medications), behavioral measures (medication adherence, lifestyle intentions or self-report), psychological measures (probabilistic or evaluative risk perceptions, positive or negative emotional responses, credibility, and recall), and a summary of significant effects of heart age communication.

Qualitative data extracted included behavioral themes (eg, lifestyle change), psychological themes (eg, emotional reaction), stated benefits of heart age (eg, motivates people to take action), and stated problems with heart age (eg, reduced credibility).

Intervention content data included additional risk communication formats (eg, absolute risk, risk level, graphs), underlying model (eg, 5-year or 10-year CVD risk model), and behavior change techniques (eg, email prompts or action plans) coded based on the taxonomy of 93 techniques by Michie et al [19]. This was done based on the methods published in the results paper and any referenced protocol papers.

Risk of bias assessment included randomized studies that were critically appraised independently by 2 review authors (MF, C Bonner, or C Batcup if C Bonner was an author) using the relevant Johanna Briggs Institute tools for the study design [22]. Disagreement was resolved by discussion, with decisions applied consistently where there was a common methodology, for example, if the participants were randomized on a computer, *was allocation to groups concealed* was marked as not applicable (N/A). Similarly, as all participants in all the papers could see the risk communication format they were allocated to, all were marked as *No* for being *blind to treatment assignment*.

Results

Overview

Figure 1 shows the search process and results. In April 2020, 5839 database results and 159 references from previous reviews were assessed for eligibility, and in March 2021, an additional

543 database results and 1385 citations and references were reviewed. From 7626 total results, 16 eligible studies were identified with heterogeneous study designs and outcomes, and the results are reported below by study type: 5 randomized web-based experiments comparing heart age with percentage risk, 5 randomized clinical trials with mixed interventions, 2 mixed methods studies with quantitative outcomes, and 4 qualitative studies. Study details and outcomes are summarized by study category in Tables 1-3. Multimedia Appendix 1 [23-32] provides details about the measures used in each study, and Multimedia Appendix 2 [14,23-37] provides details of behavior change techniques included in the control versus intervention groups.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram.

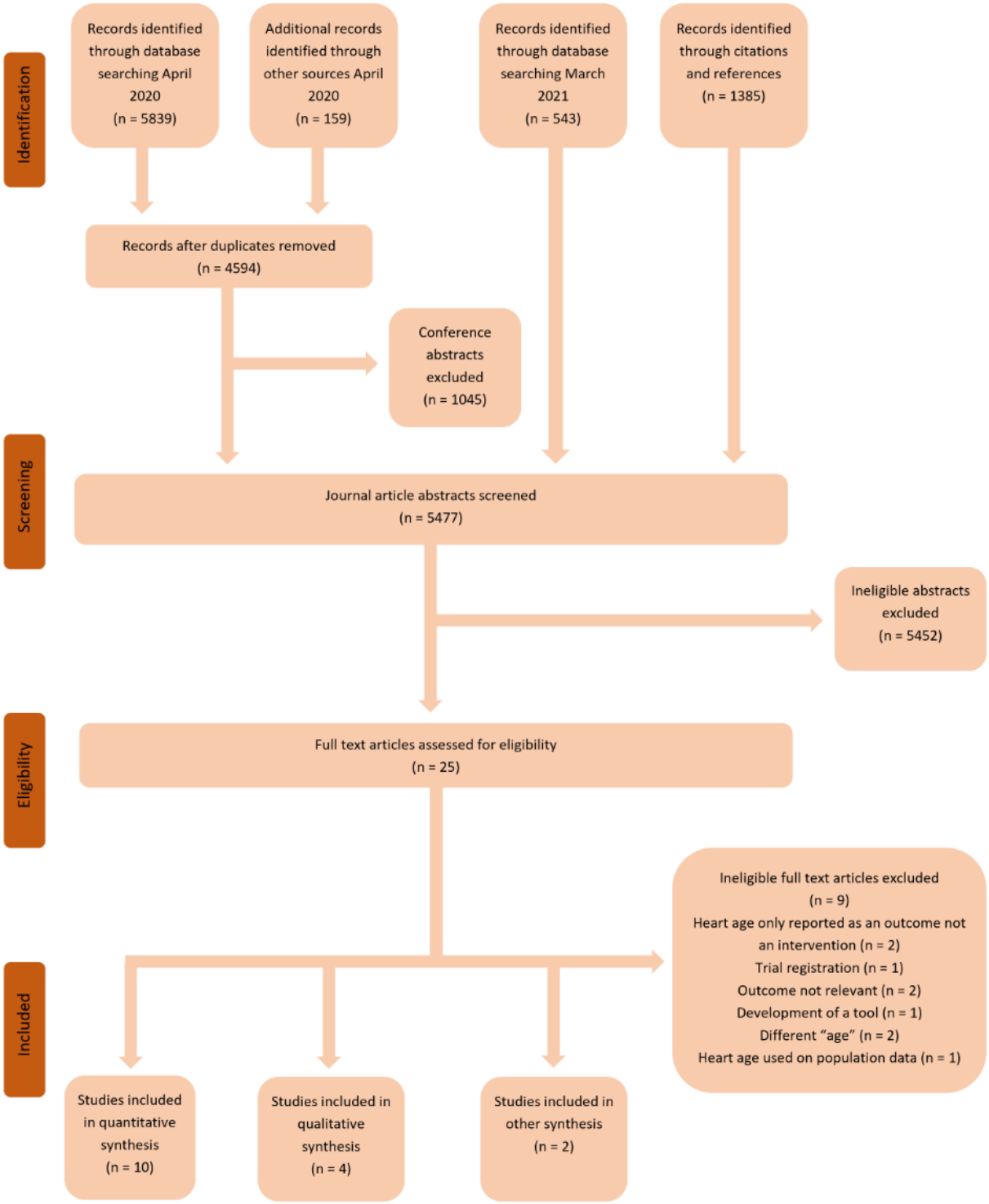


Table 1. Randomized web-based experiments directly comparing heart age with absolute risk.

Study details	Intervention format	Comparison groups	CVD[a] risk algorithm	Participants	Principal findings
Soureti et al (2010) [23]; 2-arm RCT[b] in the United Kingdom	Web-based questionnaire, postintervention outcomes	1. 10-year percentage risk 2. Heart age	Framingham	413; 209 in percentage risk, 204 in heart age; aged 30-60 years	• Intentions to change behavior: no significant differences in intention to stop smoking, improve diet, or increase physical activity between heart age and percentage risk groups. Higher worry and identifying the information as a wake-up call were significantly correlated with overall intention to change behavior. • Risk perceptions: no difference in average risk perception between heart age and percentage risk groups. Higher worry and identifying the information as a wake-up call were significantly correlated with risk perceptions. • Emotional response: no difference in terms of levels of worry or perceiving the information as a wake-up call between heart age and percentage risk groups. For younger participants with higher levels of risk, the heart age group was more likely to have a worried response and perceive the message to be a wake-up call than the percentage risk group. The 2 items were also highly correlated. • Credibility: no difference in credibility between heart age and percentage risk groups.
Witteman et al (2014) [24]; 2-arm RCT in the United States	Web-based questionnaire, postintervention outcomes	1. 10-year percentage risk 2. 10-year percentage risk and heart age	Framingham	3630, numbers in each group not given; aged 35-74 years; mean 53 (SD 10) years	• Intentions to change behavior: no difference between heart age and no heart age on quitting smoking, exercising, eating a DASH[c] diet, losing weight, and seeing a physician in the next 30 days.
Bonner et al (2015) [25]; 2 × 3 factorial design RCT in Australia	Web-based questionnaire. Participants shown either 5-year absolute risk or heart age, and within that different text and visual formats. Postintervention outcomes and followed up on the web 2 weeks later	1. 5-year percentage risk: (a) text only; (b) text + bar graph; (c) text + line graph 2. Heart age: (a) text only; (b) text + bar graph; (c) text + line graph	Framingham	570; 281 in percentage risk and 289 in heart age; aged 45-64 years; mean 54 (SD 6) years	• Intentions to change behavior: for intention to change lifestyle (diet, physical activity, smoking, and the average of these), there were no significant differences between the heart age and percentage risk groups. • Self-reported behavior change: at 2-week follow-up, no differences were found between heart age and percentage risk groups (adequate diet, adequate physical activity, smokers, or making a GPd appointment for CVD risk assessment). • Risk perceptions: heart age was more likely to be perceived as indicating moderate or high risk compared with percentage risk, even though the sample was predominantly low risk (P<.001). • Emotional response: the heart age group had a less positive emotional response to the risk result compared with the percentage risk group (P<.001). No difference in negative emotional response. • Credibility: lower perceived credibility for the heart age group vs the percentage risk group (P<.001). • Recall: there was no difference in recall immediately postintervention. However, those in the heart age group are significantly more likely to correctly recall their exact result after 2 weeks (32%) vs percentage risk group (16%; P<.001).

Study details	Intervention format	Comparison groups	CVD[a] risk algorithm	Participants	Principal findings
Damman et al (2018) [26]; 2×2 factorial design RCT in the Netherlands	Web-based questionnaire (hypothetical results). Postintervention outcomes	1. Infographics of 10-year risk information (a) alone or (b) with a risk percentage and icon array 2. Text of risk information (a) alone or (b) with a risk percentage and icon array 3. Heart age with infographics	Framingham	727; 151 in infographics alone, 145 in infographics plus risk percentage, 133 in risk text alone, 168 in risk text plus risk percentage, 130 in heart age; aged 45-65 years	• Intentions to change behavior: mixed results: intention to visit GP (*P*=.02) and to become more physically active (*P*=.01) were significantly different between percentage risk and heart age (more likely to if seeing heart age) but no difference for eating more healthily and using medication. • Risk perceptions: heart age perceived risk as higher: more likely to experience a CVD event (*P*=.003), saw their risk as higher chance (*P*=.004), and overall comprehended their risk as higher (eg, serious consequences, means something is going on with my health; *P*=.02). • Credibility: in terms of thinking the information is clear, relevant, useable, realistic, etc, no difference between percentage risk and heart age, apart from the fact that the information is helpful (*P*=.03). • Emotional response: worry was significantly higher in the heart age group (*P*=.02), positive affect was no different, and negative affect was significantly higher in the heart age group (*P*=.002). • Recall: those with heart age were correct in recalling their heart age 60.8% of the time vs 55.2% of the time for percentage risk (not a significant difference). However, the heart age group was significantly (*P*=.008) more likely to recall the verbal label (increased risk—66.2% vs 50.3%). There were no significant differences in recall of the causes, timeline, or consequences of their risk result.
Van Der Pol-Harney et al (2021) [27]; 2 × 3 factorial design RCT in Australia	Web-based questionnaire. Participants randomized to one of 3 risk communication formats and received low or high risk based on self-report lifestyle risk factors. Postintervention outcomes	1. Lifetime percentage risk 2. Heart age 3. Fitness age	Provided with either low (5%, 16 years) or high (69%, 35 years) lifetime risk. High risk=smoke or eat 1 or no servings of fruit per day	174; 53 in percentage risk, 50 in heart age, 71 in fitness age; mean age 19 (SD 2.3) years	• Intentions to change behavior: fitness age group had lower intentions to change diet and exercise than the heart age group (*P*=.048), percentage risk group (*P*=.02), and these 2 groups combined (*P*=.02). • Risk perceptions: receiving a high-risk result was associated with higher perceived numerical, verbal, and comparative risk (across all formats). Perceived numerical and comparative risk did not vary greatly with actual risk for those given a fitness age; however, those given either a heart age or percentage risk format expressed higher perceived risk after being categorized as high risk. • Emotional response: receiving a high-risk result was associated with greater postintervention worry (for all formats), more so for smokers. • Credibility: receiving a high-risk result was associated with lower credibility, across all risk formats. This difference was greatest in the heart age group. Results were more likely to be seen as credible for participants who received results better than expected.

[a]CVD: cardiovascular disease.

[b]RCT: randomized clinical trial.

[c]DASH: Dietary Approaches to Stop Hypertension.

[d]GP: general practitioner.

Table 2. Randomized clinical trials in applied settings comparing mixed interventions.

Study details	Intervention format	Comparison groups	CVD[a] risk model	Participants	Principal findings
Lowensteyn et al (1998) [28]; RCT[b] in Canada	Physicians enrolled their own patients who they thought would benefit from a risk profile. Followed up 3 months later	1. Control: usual care 2. Intervention: paper-based risk profile, including their 8-year risk of developing coronary disease, and how this risk would reduce if they changed one or more risk factors. Cardiovascular age also shown.	Framingham	958; 176 in control, 782 in risk profile; aged 30-74 years; mean age 51 (SD 11) years	• Blood pressure: no difference between change in blood pressure in profile group vs control group (–2 systolic in profile group vs –1.2; –0.9 for diastolic in profile group vs 0.1). • Cholesterol: at the 3-month follow-up, patients who were shown their risk profile had significantly greater reductions (P<.05) in total cholesterol, LDLc, and total or HDLd cholesterol ratio (after adjusting for group differences at baseline and clustering for same physician). • Absolute risk: Significantly greater improvement in cardiovascular age (P<.01) and 8-year coronary risk (P<.01) compared with the control group (because of cholesterol change). • Weight: no difference in BMI between groups.
Grover et al (2007) [29]; RCT in Canada	Physicians enrolled their patients. Baseline visit, and followed up at 3, 6, 9, and 12 months	1. Control: usual care 2. Intervention: paper-based risk profile including cardiovascular age, ongoing feedback on risk after lifestyle changes or medication	Framingham (or Cardiovascular Life Expectancy Model for patients with CVD)	3053 received initial intervention: 1510 in risk profile group and 1543 in control; mean age 64 (SD 8) years	• Blood pressure: after 12 months, both systolic (P=.005) and diastolic (P=.01) blood pressure decreased significantly more in the intervention group vs usual care. • Cholesterol: patients who were shown their risk profile reduced their LDL cholesterol by 51.2 mg/dL whereas in usual care it reduced by 48.0 mg/dL (P=.02). Similarly, total cholesterol (P=.02) and cholesterol ratio (P=.002) was significantly more reduced in the intervention group at 1 year. HDL cholesterol was no more improved in the risk profile group than in the control group. • Absolute risk: significantly greater improvement in 10-year risk of CVD in the risk profile group 12 months later (P<.001).
Lopez-Gonzalez et al (2013) [30]; RCT in Spain	Participants interviewed by researchers and clinical assistants; measurements taken. Follow-up measurements taken 12 months later	1. Usual care 2. Percentage risk 3. Heart age	Framingham	2844: 975 in usual care, 955 in percentage risk, and 914 in heart age; mean age 46 (SD 7) years	• Self-reported behavior change: physical activity sessions per week decreased in control (0.35) but increased to a similar extent in both risk (0.68) and heart age groups (0.88; all P<.001). Number of people currently smoking increased in control by 0.9%, decreased in risk by 0.4%, and decreased in heart age by 1.8% (P<.001). • Blood pressure: systolic blood pressure reduced by 2.31 mm Hg in risk vs 4.37 mm Hg in heart age, diastolic reduced by 1.77 mm Hg in risk and 2.88 mm Hg in heart age. Control increased in both (1.02 systolic and 1.21 diastolic; P<.001). • Cholesterol: total reduced by 3.36 mg/dL in percentage risk, 6.54 mg/dL in heart age. HDL increased by 0.47 mg/dL in risk and 1.27 mg/dL in heart age. Triglycerides reduced by 2.65 mg/dL in risk and 5.14 mg/dL in heart age. Control increased in both total (5.36) and triglycerides (4.38) and decreased in HDL (0.92; all P<.001). • Weight: weight decreased by 0.22 kg in risk, 0.77 kg in heart age. Control increased by 0.72 kg (P<.001). BMI reduced by 0.11 in risk, 0.27 in heart age. Control increased by 0.25. Overall difference between 3 groups (P<.001). Waist circumference reduced by 0.05 cm in risk, 0.15 cm in heart age. Control increased by 0.13 cm (P<.001).

Study details	Intervention format	Comparison groups	CVD[a] risk model	Participants	Principal findings
Näslund et al (2019) [31]; RCT in Sweden	Participants meeting with their primary care physician, measurements taken. Follow-up measurements taken 12 months later	1. Control: completing a primary care health survey including CVD risk factor screening, pharmacological CVD prevention if required, and advice on healthy lifestyle, and an ultrasound 2. Intervention: the above plus a pictorial representation of carotid ultrasound (including vascular age) plus a nurse phone call to confirm understanding 2-4 weeks later and information repeated after 6 months	Framingham	3532; 1783 in control, 1749 in intervention; aged 40-60 years	• Self-reported behavior change: significant increase in use of lipid-lowering medication in the intervention group compared with control group (P<.05). • Blood pressure: systolic increased by 1.6 mm Hg in control and was stable (–0.2 mm Hg) in the intervention group—not significant. • Cholesterol: total and LDL decreased in both groups, but the reduction was greater in the intervention group than in the control group at the 1-year follow-up (P<.05). • Weight: slight increase in control group and slight decrease in intervention group—not significant. • Absolute risk: at the 1-year follow-up, those in the intervention group had a decreased Framingham risk score, whereas in the control group this was increased (P<.05). Systematic coronary risk evaluation measure increased to a lesser extent in the intervention group (P<.05).
Svendsen et al (2020) [32]; cluster RCT in Norway	Participants discussed risk with pharmacy staff. Follow-up after 4 weeks	1. Control: conventional risk communication, each risk factor categorized in 4 groups from good (green) to poor (red), and diet and lifestyle advice given verbally and in written form 2. Intervention: the above plus heart age	JBS[e]-3	257; 120 in control, 137 in intervention; mean age 60 (SD 13) years	• Self-reported behavior change: physical activity levels did not change after 4 weeks in either of the groups. • Blood pressure: no differences in blood pressure levels. • Cholesterol: no differences in cholesterol levels between the groups. • Consultation communication: the heart age tool was considered a convenient and motivating communication tool by pharmacy staff.

[a]CVD: cardiovascular disease.

[b]RCT: randomized clinical trial.

[c]LDL: low-density lipoprotein.

[d]HDL: high-density lipoprotein.

[e]JBS: Joint British Societies.

Table 3. Mixed methods studies with no randomization.

Study details	Intervention format	Comparison groups	CVD[a] risk model	Participants	Principal findings
Goldman et al (2006) [34]; focus groups in the United States (qualitative)	Responded to 3 visual representations of risk (all of a hypothetical man aged 42 years)	1. Icon chart risk vs ideal 2. Bar chart risk vs ideal 3. Bar chart heart age vs ideal vs age	Hypothetical person but based on Framingham	50 adults in 7 focus groups; aged 27-84 years	• Emotional response: bar graph lacked impact: it was "too statistical," "scientific," "too dry." But heart age was "catchy," memorable, and engaging. Some participants said patients may be alarmed by heart age. Debate as to whether it is motivating or just frightening. Still thought heart age was better though as more engaging and memorable • Credibility: some skepticism about the validity of age calculation
Bonner et al (2014) [36]; think-aloud process and interviews in Australia (qualitative)	Participants viewed 2 different heart age calculators	1. Heart age 2. 10-year percentage risk and heart age	Framingham	26 patients recruited from general practice; aged 39-67 years	• Intentions to change behavior: heart age calculators led participants to consider lifestyle changes • Emotional response: heart age elicited emotional responses; for example, younger heart age seen as positive and older heart age was confronting • Credibility: process of using the calculators results in different credibility perception • Understanding: not understanding percentage risk information, but heart age much easier to understand and more meaningful • Other: modifying risk factors had mixed response; for example, some not interested or did not understand and some spent time changing things
Shefer et al (2016) [35]; interviews and focus groups in the United Kingdom (qualitative)	Patients randomized to different web-based questionnaires. Then either interviewed or took part in a focus group	1. Control 2. Lifestyle advice only 3. Lifestyle advice plus 10-year percentage risk (phenotype) 4. Lifestyle advice plus 10-year percentage risk (phenotype + genetic) *includes heart age and ideal risk*	Framingham	41 adults in interviews (22 in group 4, 15 in group 3, and 4 in group 2) and 13 adults in 2 focus groups (one with 6 patients and one with 7; 8 in group 4, 5 in group 3); aged 40-80 years	• Intentions to change behavior: for some, heart age was a "wake-up call" to make changes. • Self-reported behavior change: more than two-thirds, including those with low or medium risk, maintained lifestyle changes (gap between seeing the intervention and interview was between 1 and 134 days)—although modest. Intervention added as a "reminder," "trigger"—already aware they needed to do something beforehand. • Risk perceptions: despite two-thirds having an older heart age, only a minority were concerned about their risk. Could be because of not recollecting their risk score, or not remembering context of whether the percentage risk was low or high even if they did remember the number. Or that they overestimated their risk before the intervention (eg, female mean risk of 3.5% but mean predicted risk of 29.5%). Or that many patients thought a high risk was above 50%, so lower than that did not seem that high; one-fourth concerned about risk, all of them concerned primarily with heart age, despite having a risk above 20%. • Emotional response: heart age stood out as a powerful message about patients' lifestyle: "it was the heart age that really shook me." Link to age; for example, "risk is that of somebody who's retired."

Study details	Intervention format	Comparison groups	CVD[a] risk model	Participants	Principal findings
Riley et al (2020) [37]. Recorded GP[b] consultations in the United Kingdom (qualitative)	GP consultations using either JBS[c]-3 or QRISK calculators were recorded and analyzed qualitatively	1. JBS-3 calculator 2. QRISK calculator	JBS-3 or QRISK	128 consultations analyzed; 64 in QRISK group and 64 in JBS-3; aged 40-74 years	• Intentions to change behavior: coping appraisal more common in JBS than QRISK. Not much discussion around costs for changing behavior. Some maladaptive coping; for example, dismissive of suggestions. Sometimes maladaptive responses to the percentage risk score could be prompted into a more positive response through communication of heart age. Adaptive coping shown by a number of patients showed intentions to change behavior as a result of seeing their risk • Risk perceptions: threat appraisal observed in all consultations (although less frequently in JBS-3 consultations vs QRISK). Patients acknowledged their risk level but understanding of percentage risk was unclear. Heart age aided understanding and intention to change risk • Credibility: surprised at their risk leading to questioning how the risk was calculated • Consultation communication: misunderstanding of risk, which was not helped by the GP, although more evidence of active practitioner-patient engagement in the JBS-3 group following risk score manipulation. GPs seemed less confident in discussing percentage risk than heart age. GPs consistently did not ask questions to check understanding. • Understanding: understanding of 10-year percentage risk was unclear. Heart age aided patient understanding of CVD risk.
Gidlow et al (2020) [33]. Recorded GP consultations in the United Kingdom (quantitative)	GP consultations using either JBS-3 or QRISK calculators were recorded	1. JBS-3 calculator 2. QRISK calculator	JBS-3 or QRISK	173 general practice consultations; 73 QRISK and 100 JBS-3; aged 40-74 years	• Consultation time: 10% of time discussing CVD risk in JBS-3 vs 7% in QRISK. 35% (JBS-3) vs 41% (QRISK) of time spent discussing CVD risk factors. Risk management interventions discussed in 19% of JBS-3 vs 21% of QRISK. Lifestyle interventions discussed in 16% of JBS-3 and 18% of QRISK. Medication in 58% of JBS-3 and 70% of QRISK • Consultation communication: 94% vs 95% of consultations referenced the percentage risk score. Proportion of patients asking questions on risk was higher in JBS-3 than QRISK (32% vs 12%). All physicians discussed heart age in JBS-3 vs 52% in QRISK. Risk manipulation shown in 92% of JBS-3 and 22% of QRISK. Physicians spoke for 47% of time in JBS-3 and 55% in QRISK. Verbal dominance ratio of 2.35 in JBS-3 and 3.21 in QRISK
Bonner et al (2020) [14]; survey in Australia (quantitative outcomes and content analysis of open responses)	Web-based heart age calculator open to the public. Some participants elected to receive their results via email. A subgroup completed a survey about their results, 10 weeks after seeing them	1. Heart age	Framingham	361,044 heart age calculator users; 30,279 provided email to receive heart age report; 1303 survey respondents; Mean age of users 49; of those who requested a report 56; survey respondents 60	• Intentions to change behavior: Content analysis—either no motivation to change or it is a wake-up call to change lifestyle to reduce the heart age. • Self-reported behavior change: 63% improved diet and 62% physical activity, 32% reduced stress, 31% reduced alcohol, 48% of smokers reduced. 48% saw GP and 28% had heart health check. Diet and seeing physician were more likely for older heart age than younger or equal heart age. • Risk perceptions: Content analysis—whether heart age was higher or lower affects perception of risk. • Emotional response: 39% very motivated, 25% very optimistic, 13% very anxious, 12% very worried. Older heart age associated with more anxiety or worry and less optimism, but similar motivation versus younger or equal heart age. Reflected in content analysis. • Credibility: Content analysis—expectations affected credibility; for example, “I’m a bit unsure why as I exercise regularly,” “my cardiologist...said my heart is very good,” “questions were quite limited and did not take account lifestyle.” • Recall: Most were able to recall their heart age category 10 weeks later (69%; although unclear if they accessed report again), especially for those with younger (67%) and older (70%) heart ages. It was lower for equal heart age results (57%). • Cholesterol: 57% checked their cholesterol in the 10 weeks after seeing their heart age. More likely for those with older heart age. • Weight: 49% reported weight loss 10 weeks after getting heart age. This was more significant for those with a higher heart age vs younger or equal heart age.

[a]CVD: cardiovascular disease.

[b]GP: general practitioner.

[c]JBS: Joint British Societies.

Randomized Web-Based Experiments

Direct comparisons between heart age and absolute risk in 5 web-based experiments [23-27], with no in-person computer lab experiments identified. The studies included 5514 consumers and found that heart age leads to more negative emotional responses (3/4, 75% of relevant studies show higher negative emotions or lower positive emotions); higher perceptions of CVD risk being higher probability, more serious or in a higher risk category (2/4, 50% of relevant studies); higher exact or verbal recall (2/2, 100% of relevant studies); lower perceived credibility (2/3, 67% of relevant studies); and generally had no effect on lifestyle intentions (1/5, 20% of relevant studies) or self-reported behavior (no study). One study compared heart age and absolute risk to fitness age among young adults and found that fitness age led to lower lifestyle change intentions compared with the other formats [27]. All trials used the US Framingham model for risk except Van der Pol-Harney et al [27], which used lifetime CVD risk estimates and hypothetical ages to indicate low risk (younger age) and high risk (older age). All trials measured self-reported outcomes immediately postintervention, and 1 study conducted a follow-up survey after 2 weeks [25]. Soureti et al [23] compared the calculated 10-year risk to heart age among 413 people and found no significant differences for smoking, diet or exercise intentions, risk perception, emotional response, or credibility. They found that younger people with higher risk were more likely to be worried and perceive the result as a *wake-up call* when receiving heart age. Witteman et al [24] compared personalized 10-year risk to 10-year risk + heart age among 3630 people and found no significant differences in smoking, exercise, diet, weight, or physician visit intentions. Bonner et al [25] compared personalized 5-year risk to heart age with varying graphical formats in a 2 × 3 design among 570 people and found no significant difference in diet, exercise, smoking, or physician visit intentions or behavior after 2 weeks, or information seeking. They found that heart age led to lower positive emotions and credibility, and higher risk perception (such that low-risk people thought they were high risk) and recall after 2 weeks. Damman et al [26] compared hypothetical 10 year risk in various formats to heart age in a 2×2 design among 727 people and found mixed effects of heart age on intentions (higher intentions to visit a physician and exercise; no effect for diet or medication), higher risk perception, no difference in information perceptions relating to credibility (but heart age was perceived as more helpful), and higher recall for the verbal *increased risk* evaluative label. Van der Pol-Harney et al [27] compared the hypothetical lifetime risk to heart age or fitness age among 174 younger adults with different low- versus high-risk values for those with and without lifestyle risk factors in a 2 × 3 design. They found that heart age and percentage risk were generally equivalent, but there was a detrimental effect of fitness age, including lower exercise and diet intentions, lower credibility when given a high-risk result, and lower risk perception for high-risk results. Receiving a high-risk result was associated with higher risk perception, higher worry especially for smokers, and lower credibility, especially if the results were worse than expected (Table 1).

Randomized Clinical Trials

When heart age was combined with additional strategies (eg, in person or phone counseling) in 5 applied trials [28-32] for 9582 patients, it improved risk control (eg, reduced cholesterol and absolute risk) compared with usual care in most trials (4/5, 80% of relevant studies) up to 1 year. However, the direction of outcomes (lifestyle, blood pressure, cholesterol, and weight) was the same for absolute risk and heart age groups in one trial that compared each group to usual care (1/1, 100% of relevant studies). Follow-up periods ranged from 4 weeks to 12 months, and all trials used the US Framingham model for risk except Svendsen et al [32], which used the UK JBS-3 model. Lowensteyn et al [28] compared a paper-based risk profile intervention (8-year risk, cardiovascular age, effect of reducing risk factors) to usual care among 958 patients over 3 months and found no difference in blood pressure but lower cholesterol, leading to lower absolute risk. Grover et al [29] compared a paper-based risk profile including cardiovascular age plus 3-monthly feedback to usual care among 2687 patients over 1 year and found lower blood pressure and cholesterol, leading to lower absolute risk. Lopez-Gonzalez et al [30] compared a web-based interactive heart age tool to verbal communication of percentage risk or usual care among 2844 employees over 1 year and found higher physical activity and lower smoking, blood pressure, cholesterol, weight, and waist circumference in intervention groups versus control, with greater benefits in the heart age group; however, analyses of the difference between heart age and risk groups were not reported. Näslund et al [31] compared 2 complex interventions, including one with heart age (heart age intervention: risk assessment and advice plus a carotid ultrasound image including vascular age and a nurse phone call, with information repeated after 6 months; control: risk assessment and advice only) among 3532 patients. They found higher use of cholesterol medication, lower cholesterol levels, and lower absolute risk in the heart age intervention group than in the control group; however, there was no difference in blood pressure or weight. Svendsen et al [32] compared conventional risk communication (risk categories, colors, evaluative labels, verbal and written advice) to the same information plus heart age among 257 patients visiting a pharmacy, and they found that although using heart age was popular among pharmacy staff, adding heart age was no more effective than conventional risk communication alone in changing physical activity or reducing cholesterol and blood pressure levels (Table 2).

Mixed Methods Studies With Quantitative Outcomes

Two studies used a mixed methods design to investigate heart age: a survey of 1303 users of the Australian heart age calculator included quantitative outcomes and thematic content analysis of open responses [14]; and a UK study of video consultations using QRISK2 and JBS-3 risk calculators coded the content for

quantitative outcomes in 12 general practices [33]. Because of their study design, it is not possible to attribute outcomes to heart age from these studies, but they do suggest additional possible outcomes of heart age tools: different effects for older versus younger or equal heart age results, and risk communication content and time within consultations. An Australian survey found that a subsample of heart age users who completed a 10-week email journey had high recall and varied emotional responses to heart age, including motivation, optimism, anxiety, and worry [14]. Recall was lower for equal heart age, and anxious or worried responses were higher for older heart age. Most of the respondents reported improved diet and exercise, with many reporting weight loss, reduced stress, and reduced smoking. People with older or equal heart age reported higher rates of diet and weight loss than those with younger heart age. People with older heart age were more likely to visit a physician or have a heart health check compared with those with younger or equal heart age. Credibility issues were identified in open responses. A UK study of consultations using 2 different risk communication tools found that 10% of consultation time (<2 minutes) was devoted to CVD risk [33]. Using JBS-3 increased the time spent discussing CVD risk, the proportion of patients asking questions about CVD risk, discussion of heart age, and medication, whereas using QRISK2 increased the time spent talking about risk factors. One-fifth of consultation time was spent on interventions, mostly lifestyle (Table 3).

Mixed Methods Studies With Qualitative Analysis

Four studies used qualitative methods, including focus groups [34,35], interviews [35-37], think-aloud [36] and video prompt [37] methods. In general, the findings reflected trial outcomes in relation to recall, risk perception, emotional response, motivation, and credibility. Heart age was noted by participants across the studies as being more memorable and easier to understand than other risk formats. In a UK study where recorded consultation videos were used as a prompt for interviews, some practitioners did not fully understand risk percentages and preferred to use heart age or seemed more confident in discussing heart age as opposed to percentage risk [37]. This study also indicated that additional behavior change techniques may be added by the health provider depending on how they use the heart age tool. As reflected in the quantitative data, heart age also resulted in stronger emotional reactions from participants, for example, “it was the heart age that really shook me” [35]; however, it was noted that this could be either motivating or frightening [34]. Heart age prompted some participants to consider changing their lifestyle (eg, losing 9 kg [35]; “my weight is something I need to work on” [36]), which was also reflected in those who saw their risk percentage, and many with low or moderate risk scores discussed lifestyle changes. There was a suggestion that any intervention discussing risk with participants acts as a “reminder” or ”trigger,” “the kick that [they] needed” [35] to change behavior. Similarly, discussing risk with a practitioner resulted in the intention to change behavior [37]. Some participants were skeptical of the calculations for heart age and questioned their credibility (Table 3) [34,36,37].

Behavior Change Techniques

The interventions included in the heart age studies varied in terms of behavior change techniques. From the Michie et al taxonomy of 93 techniques [19], we identified 14 from methods section descriptions or published protocols. All studies included salience of consequences by definition (as we interpreted heart age as increasing the salience of the risk assessment) and information about health consequences (ie, CVD outcomes). Instructions on how to perform a behavior, credible source, and comparative imagining of future outcomes were common for both the intervention and control groups. It should be noted that the results sections of the qualitative studies indicated that additional behavior change techniques may be used by health providers using these tools in a consultation, and this may influence how effective they are in clinical practice (Figure 2 [14,23-37]; Multimedia Appendix 2).

Figure 2. Behavior change techniques mentioned in methods for heart age interventions [14,23-37].

Author (year)	Behaviour Change Techniques[a]													
	1.1	1.2	2.5	2.6	2.7	3.1	4.1	5.1	5.2	6.2	7.1	9.1	9.3	10.3
	Goal setting (behaviour)	Problem solving	Monitoring outcome(s) by others without feedback	Biofeedback	Feedback on outcome(s) of behaviour	Social support (unspecified)	Instruction on how to perform a behaviour	Information about health consequences	Salience of consequences	Social comparison	Prompts/cues	Credible source	Comparative imagining of future outcomes	Non-specific reward
Soureti et al (2010) [23]							■	■	■					
Witteman et al (2014) [24]							■	■	■					
Bonner et al (2015) [25]							■	■	■			■	■	
Damman et al (2018) [26]								■	■					
Van Der Pol-Harney et al (2021) [27]							■	■	■				■	
Lowensteyn et al (1998) [28]								■	■			■	■	
Grover et al (2007) [29]					■			■	■	■		■		
Lopez-Gonzalez et al (2013) [30]			■				■	■	■			■		
Näslund et al (2019) [31]				■	■	■	■	■	■			■		
Svendsen et al (2020) [32]							■	■	■			■	■	
Goldman et al (2006) [34]								■	■	■				
Bonner et al (2014) [36]								■	■			■	■	
Shefer et al (2016) [35]	■	■					■	■	■	■				
Riley et al (2020) [37]								■	■			■	■	
Gidlow et al (2020) [33]								■	■			■	■	
Bonner et al (2020) [14]						■	■	■	■		■	■		■

[a]The control groups often had overlapping behavior change techniques; heart age as a risk communication format was defined as "increasing salience of consequences".

Risk of Bias Assessment

Risk of bias was noted for all randomized studies, with some applied clinical trials being particularly concerning in terms of unclear or questionable methods for randomization and analyses, including contamination between groups and analysis not per original randomized group. All experimental trials used self-reported outcomes rather than objective methods (Figure 3, [23-32]).

Figure 3. Risk of bias assessment for quantitative studies. RCT: randomized clinical trial [23-32].

	Was true randomisation used for assignment of participants to treatment groups?	Was allocation to groups concealed?	Were treatment groups similar at the baseline?	Were participants blind to treatment assignment?	Were those delivering treatment blind to treatment assignment?	Were outcomes assessors blind to treatment assignment?	Were treatment groups treated identically other than the intervention of interest?	Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	Were participants analysed in the groups to which they were randomised?	Were outcomes measured in the same way for treatment groups?	Were outcomes measured in a reliable way?	Was appropriate statistical analysis used?	Was the trial design appropriate for the topic, and any deviations from the standard RCT design accounted for in the conduct and analysis?
Soureti et al (2010) [23]	?	/	+	-	/	/	+	/	+	+	+	+	+
Witteman et al (2014) [24]	?	/	?	-	/	/	+	/	+	+	+	+	+
Bonner et al (2015) [25]	?	/	+	-	/	/	+	-	+	+	?	+	+
Damman et al (2018) [26]	?	/	+	-	/	/	+	/	+	+	?	+	+
Van Der Pol-Harney et al (2021) [27]	?	/	+	-	/	?	+	/	+	+	+	+	+
Lowensteyn et al (1998) [28]	?	-	-	-	-	?	-	-	+	+	?	+	-
Grover et al (2007) [29]	?	-	+	-	-	?	+	+	+	+	+	+	+
Lopez-Gonzalez et al (2013) [30]	?	?	-	-	-	+	+	-	+	+	?	-	-
Näslund et al (2019) [31]	?	-	+	-	-	+	+	+	+	+	?	+	+
Svendsen et al (2020) [32]	?	-	-	-	-	?	?	-	-	+	?	+	+

Blue / = N/A; Yellow ? = Unsure; Red - = No; Green + = Yes; Grey = online experiment directly comparing heart age to % risk

Discussion

Principal Findings

When randomized trials are separated into direct comparisons between heart age and absolute risk versus complex interventions, there is limited evidence for the effectiveness of heart age over absolute risk expressed as a percentage risk over time in terms of lifestyle change. Heart age does appear to evoke a greater emotional response (both positive and negative), increases risk perception (although low-risk people may think they are high risk), and reduces credibility [23-27]. Both

percentage risk and heart age can be effective as risk communication formats when combined with other various behavior change techniques in applied settings, and have the potential to reduce blood pressure, cholesterol levels, and weight, which in turn can reduce absolute risk [28-32]. Only one study [27] compared different labels for the heart age concept and found different psychological effects, indicating the importance of testing evaluative labels with the intended target audience. Qualitative and mixed methods studies generally reflected the outcomes measured in the randomized studies but tended to conclude that heart age was more motivating than percentage risk for lifestyle change, whereas randomized trial data did not support this assertion [14,33-37].

Limitations

Owing to the heterogeneity of both the intervention components and the outcomes, we were unable to synthesize the results as a meta-analysis. Therefore, our findings are descriptive across a range of outcomes and measurement methods. All randomized studies had some risk of bias, particularly some of the complex intervention studies in applied settings where randomization and analysis processes did not follow best practices, including contamination between groups and analyses not reflecting the initial randomization to groups. Outcomes in experimental studies were based on self-report rather than objective measurements.

Comparison With Previous Work

This is the first systematic review of the effects of heart age interventions. Previous reviews of CVD risk communication formats or biological age concepts have either been descriptive in relation to the models themselves [16,20] or have not differentiated between the behavior change techniques used in intervention versus control groups, leading to mixed results overall [17,38]. This study shows the importance of identifying active ingredients in behavioral interventions to identify meaningful comparisons for future reviews [19]. The design of applied clinical trials of heart age interventions did not differentiate between heart age as a risk communication format and supplementary behavior change techniques, with an insufficient description of the meaningful differences between the intervention and control groups. The finding in one study that the label for the heart age concept (heart age vs fitness age) affected outcomes echoes recent findings on different terms for elevated blood pressure [27,39].

Future Research

The risk of bias could be improved in future heart age trials, but we note that blinding is not generally possible in a risk communication intervention. The mixed methods studies suggest additional outcomes should be included, such as overall consultation time, clinical communication content, and time spent on different aspects (eg, risk factors, risk communication formats, risk manipulation, lifestyle change, and medication [33,37]). Several studies highlight the importance of differentiating among older, younger, and equal heart age results in analyses and considering expectations in relation to this [14,25,27]. Authors of heart age studies need to take care to specify the components of their interventions, including the risk communication tool itself and the way that health care providers use and explain this in a consultation. Our findings suggest that the most appropriate outcomes to measure for heart age as a standalone risk communication format are emotional response, perceived credibility, and risk perception. Combining heart age with other behavior change techniques may be effective for behavior change if they are selected for a specific outcome in mind based on other evidence. Authors should avoid overstating the benefits of heart age as a standalone risk communication or behavior change tool by ensuring that all conclusions are supported by the data.

Practical Implications

The appeal of heart age to consumers is suggested by its widespread use among millions of people worldwide [13-15]. However, if lifestyle change is the intended outcome, additional support is needed using evidence-based behavior change techniques, such as action plans and goal-setting. This is in line with the behavior change literature, where many different health models that show risk communication is necessary but not sufficient for behavior change. Heart age is a risk communication format that can capture attention and provoke an emotional response, but it is not enough as a standalone intervention for behavior change [40]. For example, in the Australian survey identified in this review, the initial heart age assessment was followed by a 10-week email journey where behavior change could be reinforced with prompts, activities and planning tools [14]. In a recent review on how to present probabilities in patient decision aids, biological age was not recommended because it may undermine understanding of absolute risk, which is required for making informed, shared decisions about medication [41]. General practitioners, nurses, and cardiologists engaged in CVD risk assessment need to consider what their communication aim is to determine whether heart age or absolute risk is most appropriate. If heart age is communicated with the aim of motivating lifestyle change, it needs to be supported by other behavior change techniques such as action plans.

Conclusions

This review found little evidence that heart age motivates lifestyle behavior change more than percentage risk, but either format can improve clinical outcomes when combined with other behavior change strategies. The label for the *heart age* concept can affect outcomes and should be pretested with the intended audience. Future research should more carefully specify the components of the intervention, avoid overstating the benefits of heart age as a standalone risk communication format, consider effects on physician-patient consultations, and differentiate between older and younger heart age results.

Authors' Contributions

C Bonner, C Batcup, LT, and JD have been involved in developing and evaluating heart age tools for research projects, including papers cited in this review. AH works for the Heart Foundation, which developed a heart age tool in Australia.

Conflicts of Interest

C Bonner is supported by the National Health and Medical Research Council/Heart Foundation fellowship, and C Batcup is supported by the Heart Foundation grant. C Bonner had authored some papers included this study.

Multimedia Appendix 1
Measures used in each study, and whether significant outcomes were found.
[XLSX File (Microsoft Excel File), 37 KB - cardio_v5i2e31056_app1.xlsx]

Multimedia Appendix 2
Behavior change techniques by intervention group.
[XLSX File (Microsoft Excel File), 13 KB - cardio_v5i2e31056_app2.xlsx]

References

1. Bonner C, McKinn S, Lau A, Jansen J, Doust J, Trevena L, et al. Heuristics and biases in cardiovascular disease prevention: how can we improve communication about risk, benefits and harms? Patient Educ Couns 2018;101(5):843-853. [doi: 10.1016/j.pec.2017.12.003] [Medline: 29269097]
2. Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, et al. Communicating cardiovascular disease risk: an interview study of general practitioners' use of absolute risk within tailored communication strategies. BMC Fam Pract 2014;15(1):106 [FREE Full text] [doi: 10.1186/1471-2296-15-106] [Medline: 24885409]
3. JBS3 Board. Joint British Societies' consensus recommendations for the prevention of cardiovascular disease (JBS3). Heart 2014;100 Suppl 2(5):1-67. [doi: 10.1136/heartjnl-2014-305693] [Medline: 24667225]
4. Guidelines for the assessment of absolute cardiovascular disease risk: approved by the National Health and Medical Research Council. National Vascular Disease Prevention Alliance (NVDPA). 2009. URL: https://www.diabetesaustralia.com.au/for-health-professionals/best-practice-guidelines/absolute-cardiovascular-risk/ [accessed 2021-10-07]
5. Hippisley-Cox J, Coupland C, Brindle P. Development and validation of qrisk3 risk prediction algorithms to estimate future risk of cardiovascular disease: prospective cohort study. Br Med J 2017;357:j2099 [FREE Full text] [doi: 10.1136/bmj.j2099] [Medline: 28536104]
6. Whelton PK, Carey RM, Aronow WS, Casey DE, Collins KJ, Himmelfarb CD, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. J Am Coll Cardiol 2018;71(19):127-248 [FREE Full text] [doi: 10.1016/j.jacc.2017.11.006] [Medline: 29146535]
7. Sposito AC, Ramires JA, Jukema JW, Molina JC, da Silva PM, Ghadanfar MM, et al. Physicians' attitudes and adherence to use of risk scores for primary prevention of cardiovascular disease: cross-sectional survey in three world regions. Curr Med Res Opin 2009;25(5):1171-1178. [doi: 10.1185/03007990902846423] [Medline: 19323611]
8. Hobbs FD, Jukema JW, Da Silva PM, McCormack T, Catapano AL. Barriers to cardiovascular disease risk scoring and primary prevention in Europe. QJM 2010;103(10):727-739. [doi: 10.1093/qjmed/hcq122] [Medline: 20685842]
9. Gupta M, Singh N, Tsigoulis M, Kajil M, Hirjikaka S, Quan A, et al. Perceptions of Canadian primary care physicians towards cardiovascular risk assessment and lipid management. Can J Cardiol 2012;28(1):14-19. [doi: 10.1016/j.cjca.2011.09.014] [Medline: 22264843]
10. Gupta R, Stocks N, Broadbent J. Cardiovascular risk assessment in Australian general practice. Aust Fam Physician 2009;38(5):364-368 [FREE Full text] [Medline: 19458809]
11. Wells S, Kerr A, Eadie S, Wiltshire C, Jackson R. Your heart forecast': a new approach for describing and communicating cardiovascular risk? Heart 2010;96(9):708-713. [doi: 10.1136/hrt.2009.191320] [Medline: 20424153]
12. Waldron C, van der Weijden T, Ludt S, Gallacher J, Elwyn G. What are effective strategies to communicate cardiovascular risk information to patients? A systematic review. Patient Educ Couns 2011;82(2):169-181. [doi: 10.1016/j.pec.2010.04.014] [Medline: 20471766]
13. Neufingerl N, Cobain MR, Newson RS. Web-based self-assessment health tools: who are the users and what is the impact of missing input information? J Med Internet Res 2014;16(9):e215 [FREE Full text] [doi: 10.2196/jmir.3146] [Medline: 25261155]
14. Bonner C, Raffoul N, Battaglia T, Mitchell JA, Batcup C, Stavreski B. Experiences of a national web-based heart age calculator for cardiovascular disease prevention: user characteristics, heart age results, and behavior change survey. J Med Internet Res 2020;22(8):e19028 [FREE Full text] [doi: 10.2196/19028] [Medline: 32763875]

15. Patel RS, Lagord C, Waterall J, Moth M, Knapton M, Deanfield JE. Online self-assessment of cardiovascular risk using the Joint British Societies (JBS3)-derived heart age tool: a descriptive study. BMJ Open 2016;6(9):e011511 [FREE Full text] [doi: 10.1136/bmjopen-2016-011511] [Medline: 27683512]
16. Groenewegen K, den Ruijter H, Pasterkamp G, Polak J, Bots M, Peters SA. Vascular age to determine cardiovascular disease risk: a systematic review of its concepts, definitions, and clinical applications. Eur J Prev Cardiol 2016;23(3):264-274. [doi: 10.1177/2047487314566999] [Medline: 25609227]
17. Kulendrarajah B, Grey A, Nunan D. How effective are 'age' tools at changing patient behaviour? A rapid review. BMJ Evid Based Med 2020;25(2):1-2. [doi: 10.1136/bmjebm-2019-111244] [Medline: 31558486]
18. Bonner C, Bell K, Jansen J, Glasziou P, Irwig L, Doust J, et al. Should heart age calculators be used alongside absolute cardiovascular disease risk assessment? BMC Cardiovasc Disord 2018;18(1):19 [FREE Full text] [doi: 10.1186/s12872-018-0760-1] [Medline: 29409444]
19. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013;46(1):81-95. [doi: 10.1007/s12160-013-9486-6] [Medline: 23512568]
20. Spiegelhalter D. How old are you, really? Communicating chronic risk through 'effective age' of your body and organs. BMC Med Inform Decis Mak 2016;16(1):104 [FREE Full text] [doi: 10.1186/s12911-016-0342-z] [Medline: 27496144]
21. Bonner C, Batcup C, Cornell S. Protocol for a systematic review of qualitative and quantitative effects of cardiovascular disease risk communication using heart age concepts: Preprint. medRxiv 2020:20089938. [doi: 10.1101/2020.05.03.20089938]
22. Critical appraisal tools. Joanna Briggs Institute. URL: https://jbi.global/critical-appraisal-tools [accessed 2021-06-08]
23. Soureti A, Hurling R, Murray P, van Mechelen W, Cobain M. Evaluation of a cardiovascular disease risk assessment tool for the promotion of healthier lifestyles. Eur J Prev Cardiol 2010;17(5):519-523. [doi: 10.1097/hjr.0b013e328337ccd3]
24. Witteman HO, Fuhrel-Forbis A, Wijeysundera HC, Exe N, Dickson M, Holtzman L, et al. Animated randomness, avatars, movement, and personalization in risk graphics. J Med Internet Res 2014;16(3):e80 [FREE Full text] [doi: 10.2196/jmir.2895] [Medline: 24642037]
25. Bonner C, Jansen J, Newell BR, Irwig L, Teixeira-Pinto A, Glasziou P, et al. Is the “heart age” concept helpful or harmful compared to absolute cardiovascular disease risk? An experimental study. Med Decis Making 2015;35(8):967-978. [doi: 10.1177/0272989x15597224]
26. Damman OC, Vonk SI, van den Haak MJ, van Hooijdonk CM, Timmermans DR. The effects of infographics and several quantitative versus qualitative formats for cardiovascular disease risk, including heart age, on people's risk understanding. Patient Educ Couns 2018;101(8):1410-1418. [doi: 10.1016/j.pec.2018.03.015] [Medline: 29559200]
27. Van Der Pol-Harney E, Turner R, McCaffery K, Bonner C. The effects of communicating cardiovascular disease risk as 'fitness age' on behavioral intentions and psychological outcomes. Patient Educ Couns 2021;104(7):1704-1711. [doi: 10.1016/j.pec.2020.12.030] [Medline: 33485734]
28. Lowensteyn I, Joseph L, Levinton C, Abrahamowicz M, Steinert Y, Grover S. Can computerized risk profiles help patients improve their coronary risk? The results of the coronary health assessment study (CHAS). Prev Med 1998;27(5 Pt 1):730-737. [doi: 10.1006/pmed.1998.0351] [Medline: 9808805]
29. Grover SA, Lowensteyn I, Joseph L, Kaouache M, Marchand S, Coupal L, et al. Patient knowledge of coronary risk profile improves the effectiveness of dyslipidemia therapy: the CHECK-UP study: a randomized controlled trial. Arch Intern Med 2007;167(21):2296-2303. [doi: 10.1001/archinte.167.21.2296] [Medline: 18039987]
30. Lopez-Gonzalez AA, Aguilo A, Frontera M, Bennasar-Veny M, Campos I, Vicente-Herrero T, et al. Effectiveness of the heart age tool for improving modifiable cardiovascular risk factors in a Southern European population: a randomized trial. Eur J Prev Cardiol 2015;22(3):389-396. [doi: 10.1177/2047487313518479] [Medline: 24491403]
31. Näslund U, Ng N, Lundgren A, Fhärm E, Grönlund C, Johansson H, et al. Visualization of asymptomatic atherosclerotic disease for optimum cardiovascular prevention (VIPVIZA): a pragmatic, open-label, randomised controlled trial. Lancet 2019;393(10167):133-142. [doi: 10.1016/s0140-6736(18)32818-6]
32. Svendsen K, Jacobs D, Mørch-Reiersen LT, Garstad KW, Henriksen HB, Telle-Hansen VH, et al. Evaluating the use of the heart age tool in community pharmacies: a 4-week cluster-randomized controlled trial. Eur J Public Health 2020;30(6):1139-1145. [doi: 10.1093/eurpub/ckaa048] [Medline: 32206810]
33. Gidlow CJ, Ellis NJ, Cowap L, Riley VA, Crone D, Cottrell E, et al. Quantitative examination of video-recorded NHS health checks: comparison of the use of QRISK2 versus JBS3 cardiovascular risk calculators. BMJ Open 2020;10(9):e037790 [FREE Full text] [doi: 10.1136/bmjopen-2020-037790] [Medline: 32978197]
34. Goldman RE, Parker DR, Eaton CB, Borkan JM, Gramling R, Cover RT, et al. Patients' perceptions of cholesterol, cardiovascular disease risk, and risk communication strategies. Ann Fam Med 2006;4(3):205-212 [FREE Full text] [doi: 10.1370/afm.534] [Medline: 16735521]
35. Shefer G, Silarova B, Usher-Smith J, Griffin S. The response to receiving phenotypic and genetic coronary heart disease risk scores and lifestyle advice - a qualitative study. BMC Public Health 2016;16(1):1221 [FREE Full text] [doi: 10.1186/s12889-016-3867-2] [Medline: 27914472]

36. Bonner C, Jansen J, Newell BR, Irwig L, Glasziou P, Doust J, et al. I don't believe it, but I'd better do something about it: patient experiences of online heart age risk calculators. J Med Internet Res 2014;16(5):e120 [FREE Full text] [doi: 10.2196/jmir.3190] [Medline: 24797339]
37. Riley V, Ellis NJ, Cowap L, Grogan S, Cottrell E, Crone D, et al. A qualitative exploration of two risk calculators using video-recorded NHS health check consultations. BMC Fam Pract 2020;21(1):250 [FREE Full text] [doi: 10.1186/s12875-020-01315-6] [Medline: 33272217]
38. Sheridan SL, Crespo E. Does the routine use of global coronary heart disease risk scores translate into clinical benefits or harms? A systematic review of the literature. BMC Health Serv Res 2008;8(1):60 [FREE Full text] [doi: 10.1186/1472-6963-8-60] [Medline: 18366711]
39. Muscat DM, Morris GM, Bell K, Cvejic E, Smith J, Jansen J, et al. Benefits and harms of hypertension and high-normal labels: a randomized experiment. Circ Cardiovasc Qual Outcomes 2021;14(4):e007160. [doi: 10.1161/CIRCOUTCOMES.120.007160] [Medline: 33813855]
40. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011;6:42 [FREE Full text] [doi: 10.1186/1748-5908-6-42] [Medline: 21513547]
41. Bonner C, Trevena LJ, Gaissmaier W, Han PK, Okan Y, Ozanne E, et al. Current best practice for presenting probabilities in patient decision aids: fundamental principles. Med Decis Making 2021;41(7):821-833. [doi: 10.1177/0272989x21996328]

Abbreviations

CVD: cardiovascular disease
JBS: Joint British Societies

Edited by G Eysenbach; submitted 08.06.21; peer-reviewed by A Pfammatter, N Reynoso-Noverón, M Salimi; comments to author 17.07.21; revised version received 23.08.21; accepted 13.09.21; published 05.11.21.

Please cite as:
Bonner C, Batcup C, Cornell S, Fajardo MA, Hawkes AL, Trevena L, Doust J
Interventions Using Heart Age for Cardiovascular Disease Risk Communication: Systematic Review of Psychological, Behavioral, and Clinical Effects
JMIR Cardio 2021;5(2):e31056
URL: https://cardio.jmir.org/2021/2/e31056
doi:10.2196/31056
PMID:34738908

Original Paper

Toward the Value Sensitive Design of eHealth Technologies to Support Self-management of Cardiovascular Diseases: Content Analysis

Roberto Rafael Cruz-Martínez[1], MSc; Jobke Wentzel[1,2], PhD; Britt Elise Bente[1], MSc; Robbert Sanderman[1,3], PhD; Julia EWC van Gemert-Pijnen[1], PhD

[1]Department of Psychology, Health and Technology, Faculty of Behavioural, Management and Social Sciences, Technical Medical Centre, University of Twente, Enschede, Netherlands

[2]Department of Health and Social Studies, Windesheim University of Applied Sciences, Zwolle, Netherlands

[3]General Health Psychology, University Medical Center Groningen, University of Groningen, Groningen, Netherlands

Corresponding Author:
Roberto Rafael Cruz-Martínez, MSc
Department of Psychology, Health and Technology
Faculty of Behavioural, Management and Social Sciences, Technical Medical Centre
University of Twente
Cubicus Bldg
10, De Zul
Enschede, 7522 NJ
Netherlands
Phone: 31 683186149
Fax: 31 534892895
Email: r.cruzmartinez@utwente.nl

Abstract

Background: eHealth can revolutionize the way self-management support is offered to chronically ill individuals such as those with a cardiovascular disease (CVD). However, patients' fluctuating motivation to actually perform self-management is an important factor for which to account. Tailoring and personalizing eHealth to fit with the values of individuals promises to be an effective motivational strategy. Nevertheless, how specific eHealth technologies and design features could potentially contribute to values of individuals with a CVD has not been explicitly studied before.

Objective: This study sought to connect a set of empirically validated, health-related values of individuals with a CVD with existing eHealth technologies and their design features. The study searched for potential connections between design features and values with the goal to advance knowledge about how eHealth technologies can actually be more meaningful and motivating for end users.

Methods: Undertaking a technical investigation that fits with the value sensitive design framework, a content analysis of existing eHealth technologies was conducted. We matched 11 empirically validated values of CVD patients with 70 design features from 10 eHealth technologies that were previously identified in a systematic review. The analysis consisted mainly of a deductive coding stage performed independently by 3 members of the study team. In addition, researchers and developers of 6 of the 10 reviewed technologies provided input about potential feature-value connections.

Results: In total, 98 connections were made between eHealth design features and patient values. This meant that some design features could contribute to multiple values. Importantly, some values were more often addressed than others. CVD patients' values most often addressed were related to (1) having or maintaining a healthy lifestyle, (2) having an overview of personal health data, (3) having reliable information and advice, (4) having extrinsic motivators to accomplish goals or health-related activities, and (5) receiving personalized care. In contrast, values less often addressed concerned (6) perceiving low thresholds to access health care, (7) receiving social support, (8) preserving a sense of autonomy over life, and (9) not feeling fear, anxiety, or insecurity about health. Last, 2 largely unaddressed values were related to (10) having confidence and self-efficacy in the treatment or ability to achieve goals and (11) desiring to be seen as a person rather than a patient.

Conclusions: Positively, existing eHealth technologies could be connected with CVD patients' values, largely through design features that relate to educational support, self-monitoring support, behavior change support, feedback, and motivational incentives.

Other design features such as reminders, prompts or cues, peer-based or expert-based human support, and general system personalization were also connected with values but in narrower ways. In future studies, the inferred feature-value connections must be validated with empirical data from individuals with a CVD or similar chronic conditions.

(JMIR Cardio 2021;5(2):e31985) doi:10.2196/31985

KEYWORDS

eHealth; self-management; self-care; cardiovascular diseases; value sensitive design; values; content analysis

Introduction

The Promise of eHealth for Self-management Support

Self-management can be broadly defined as an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic illness [1]. In 2005, the influential psychologist Albert Bandura [2] characterized self-management as "good medicine" and went even further, stating that "if the huge benefits of these few habits were put into a pill, it would be declared a scientific milestone in the field of medicine." Such a milestone would certainly lead to a much-needed reduction of the alarming burden on health care systems worldwide caused by the increasing amount of chronically ill individuals, many of them with a cardiovascular disease (CVD) [3].

Obviously, there is not yet—and perhaps there will never be—a "pill" that prompts individuals to actively engage in the maintenance, monitoring, and management of their own health. The reality is much more challenging, as performing self-management entails the enactment of multiple behaviors and a continuous confrontation with barriers and competing interests [4]. For example, stroke survivors can be overwhelmed by the physical and cognitive efforts required by rehabilitation programs and by other sudden changes to their lifestyles, leading them to feel as if they have "lost control" over their life.

Although not a "pill," the use of digital technologies to support health, well-being, and health care holds high promise. Such an approach is better known by the term of electronic health or eHealth [5]. Specifically, technologies such as smartphone applications and internet-enabled monitoring devices have been proposed as tools that can support self-management [6,7]. Among other things, eHealth promises to facilitate tasks and provide personalized information, feedback, or cues to action. eHealth technologies have, in fact, already shown positive results in terms of supporting patients in the management of chronic conditions, including CVD [6-13].

Realizing the Promise of eHealth Through Value Sensitive Design

Despite their promising results and recognized potential, eHealth technologies that aim to support self-management have come across multiple challenges. One of the most important obstacles is the fluctuating motivation of individuals to actually perform self-management [9,10]. As a result, when motivation is low, eHealth technologies can become an added burden [14]. To overcome that barrier, multiple calls have been made to design eHealth in a way that better aligns with the underlying needs of individuals [6,7,10,15]. One key proposal is that eHealth technologies should be personalized in a way that taps into a more powerful source of motivation: values. To realize this, eHealth technologies should be designed in a way that strengthens patients' values and fulfills their needs. For instance, patients who highly value social interactions could be motivated through eHealth features that facilitate communication with peers, friends, or the health care team.

In fact, the need to meet patient values through the design of technologies has led to the development of novel methodologies and theoretical approaches. One of these approaches is value sensitive design, which serves as both a theoretical and methodological framework that seeks to integrate values into design work [16]. Value sensitive design ensures that the design of technologies accounts for values in a principled and comprehensive manner, through integrative and iterative methodologies that include conceptual, empirical, and technical investigations [16]. Conceptual investigations can focus on the philosophical analysis and specification of value constructs (eg, the value of "feeling in control" or the value of "feeling supported by others"). Meanwhile, technical investigations can take the analysis further and design technologies using the identified values as assessment criteria (eg, how do wearable technologies meet the value of "feeling in control over life?"). Finally, empirical investigations can evaluate the process of a particular design or context use (eg, a formative evaluation of technologies to assess if and how they contribute to patient values).

Conceptualizing Values for eHealth Design

In the value sensitive design framework, a value refers to "what a person or group of people considers important in life" [16]. In eHealth, this could translate to a life ideal or important interest, related to health or well-being, that individuals could pursue or meet with the help of technologies [15]. This paper uses the terms "values" and "patient values" interchangeably. Moreover, this paper uses the term "connection" to refer to a potentially positive relationship between a specific technology—or one of its design features—and a patient's value that leads to an increase or maintenance of motivation (eg, a self-monitoring feature might be "connected" to the value of "feeling safe and stable"). Other terms used in scientific works talk about how technologies or design can "contribute," "meet," "support," or "honor" values. These verbs are all understood to refer to the same relationship.

As mentioned before, incorporating values into technologies can entail multiple integrative and iterative steps. For instance, value specification precedes value sensitive design. Value specification is the identification of the most important values for stakeholders of eHealth (eg, end users such as individuals with a CVD) [17]. Holistic approaches to eHealth development

and design, such as the one promoted by the Center for eHealth Research (CeHRes) Roadmap [18], stress the importance of identifying the diverse and often conflicting values and concerns that different stakeholders have (eg, what does a patient value in health and life and thus expect to be helped with through eHealth?). This raises a fundamental question: What values must be considered to design effective support for the values of individuals with a CVD? A previous investigation by authors of this study directly addressed this question [19]. Concretely, an interview study integrated a list of 11 values of patients with a CVD [19]. Then, as a follow-up study, the list of values was revised and empirically validated through a survey with members of a patient association in the Netherlands, constituted by individuals who have attended or are still attending a cardiac rehabilitation program [19]. Therefore, there are already available data establishing a set of potential values of importance for individuals diagnosed with a CVD.

Connecting Values With eHealth Technologies and Design Features

Importantly, the value sensitive design framework also presupposes that a given technology is more suitable for certain activities and more readily supports certain values, while rendering others more difficult to realize [16]. Therefore, it suggests that it all depends on the "features" or "properties" that people design into technologies. In this study, the term "design feature" is used to define any clearly identifiable property of a technology that serves a specific function and is proposed to help achieve an overarching aim. Given such a definition, design features could be functional or visual properties, underlying technical mechanisms, as well as recognizable "building blocks" such as behavior change techniques [20] and persuasive design strategies [21]. Furthermore, this study defines an eHealth technology as a (set of) technological instrument(s), such as a mobile app, that is specifically developed to support well-being, health, or health care [5]. In contrast, an eHealth intervention is defined as the full package and procedures that describe how a specific eHealth technology intervenes to support well-being, health, or health care [5]. The former concept is favored because the focus of this study is design features of technologies that are at different stages of development (eg, from high-fidelity prototypes to systems that have already been implemented and evaluated).

In light of the aforementioned information and given the numerous examples of eHealth technologies that exist, it is plausible that several values have already been met by their design features. However, to the best of our knowledge, the connection between specific design features and patient values has not been directly investigated in previous studies. Therefore, it is necessary to advance the understanding about how technologies can best support the values of individuals. This knowledge can be uncovered through what the value sensitive design framework calls "technical investigations," which are studies that focus on how existing technological properties and underlying mechanisms support or hinder values [16]. In this way, technical investigations could help advance knowledge about what works, for whom, and why in terms of CVD self-management [22]. Consequently, evidence on the most effective technological properties and mechanisms could be translated into practical guidelines for the development and design of future eHealth technologies.

As empirical knowledge about the values of individuals with a CVD already exists, what is needed is a set of technologies that can be investigated with the aforementioned aim in mind. To that end, the outcomes of a recent systematic review that identified and analyzed multiple eHealth technologies for CVD self-management could be used [23,24]. The review analyzed technologies with sufficient and substantial information about their objectives and design (ie, their design features). Thus, information about the design features of existing eHealth technologies is also readily available for the purposes of this investigation.

Aim

This study sought to connect a set of empirically validated values of patients diagnosed with a CVD with existing eHealth technologies and their design features. By doing so, the findings of the study aimed to be a foundation for new hypothetical assumptions that contribute to value sensitive eHealth design and that could be validated in future empirical studies.

Content analysis is proposed as a suitable method to meet this aim because it allows making replicable and valid inferences from texts or other meaningful matter to the contexts of their use [25]. As a scientific tool, content analysis can provide new insights, increase the understanding of particular phenomena, or inform practical actions [25]. In short, content analysis offers a sound and verifiable method that can connect patient values with multiple and distinguishable eHealth design features. Following what has been issued in the previous sections, this research follows a patient-centered design approach to focus on the main drivers of patients' needs and concerns: their values. The research question is: *What eHealth design features can be connected with the values of patients with a CVD?*

Methods

Overview

To meet the study aims, the research team conducted a content analysis [25]. The content analysis consisted of 3 stages: preparation, organization, and analysis and reporting [26]. The main researcher (RRCM) conducted the preparation stage by collecting and setting up the data to analyze the eHealth design features [26]. Next, 3 researchers (RRCM, JW, and BEB) performed the organization stage independently by deductively coding the data [26]. Finally, all researchers contributed to the reporting stage, consisting of displaying the results according to the selected approach and categorization scheme [26].

Preparation

The preparation stage aimed to identify design features of existing eHealth technologies and to describe them in a format that facilitated their analysis. To identify eHealth design features for the study, RRCM revised and expanded the data extracted about 10 eHealth technologies during a previous literature systematic review [23,24]. Additionally, RRCM searched for newer publications of all technologies through reference tracking of the included papers. Importantly, RRCM extracted both

descriptive and contextual information about each eHealth design feature. Descriptive information could be a clear textual description of the design feature (eg, what it does or intends to do according to the publication) and a figure or picture of it (when available). In contrast, contextual information could be the name of technologies, their main characteristics, their target group, and any specific objectives. RRCM integrated all descriptive and contextual information about each eHealth design feature in separate Microsoft PowerPoint slides. For example, the Engage mobile application included 5 design features [27]: log, hint/facts, goal, progress report, and deck of cards.

At this stage, RRCM noticed and began to group the design features of different technologies according to their similar characteristics or functions. For example, the "log" feature of the Engage technology [27] is similar to the "assessment" feature of the HeartMapp [28] technology, in the sense that they both facilitate self-reporting of symptoms and other self-management behaviors. The researchers finally agreed on the final grouping of design features at the analysis and reporting stages (as described in the following sections). In this way, both descriptive and contextual information facilitated a better comprehension of eHealth design and its features. In total, the study analyzed 70 design features from 10 different CVD eHealth technologies. Multimedia Appendix 1 presents a detailed overview of the included technologies and their design features.

Organization

The organization stage aimed to connect a list of 11 empirically validated patient values to the eHealth design features by means of deductive coding. A usability study and a follow-up survey study generated and validated the list of values [19]. The first study consisted of 10 interviews within the context of patients' usability tests with the online BENEFIT Personal Health Platform, which aims to support the adoption and maintenance of healthy lifestyles [19]. The second study distributed an online survey to panel members of Harteraad, a Dutch patient association for cardiac diseases (in total, the survey had 710 respondents) [19]. In this survey, the respondents rated the values identified in the first study according to their importance for themselves, which aimed to estimate relevance and generalizability of the values in a larger population. To prepare the codebook for this study, BEB and JW translated the list of values from the Dutch language into English. Table 1 presents the list of values in their final form as the codebook for this study.

Table 1. Codebook with list of patient values and their definitions.

Number	Value label	Value definition
1	To have confidence and self-efficacy in treatment and ability to achieve goals	Having confidence in the doctors and the treatment they prescribe or having the feeling that patients are capable of following the treatment plan or have the ability to achieve their goals
2	To be seen as a person rather than a patient	Not constantly feeling that they are a patient with a disease but also still being able to be a human without their illness
3	To not feel fear, anxiousness, or insecurity about their health	Not having to worry about their physical condition, being provided coping strategies or information that helps them feel safe or less anxious
4	To preserve a sense of autonomy over their life	Having a feeling of being in control of their life (eg, being able to make their own decisions)
5	To receive social support	Feeling heard, supported, and understood by the people that surround them (eg, family and friends) and having the feeling that they have somewhere or someone to go to when they need a sympathetic ear (eg, via a virtual coach or a chat)
6	To have or maintain a healthy lifestyle	Maintaining or changing their lifestyle in such a way that new incidents are prevented and they (re)gain health
7	To have an overview of personal health data	Having a central source where they have insight into their personal health data or condition (eg, measured values or any insights into physical and mental well-being and health)
8	To perceive low thresholds to access health care	Being helped or treated quickly and easily, at a health care organization or at home; being facilitated to manage their own disease and take action
9	To be extrinsically motivated to accomplish goals or activities (related to health/lifestyle)	Being extrinsically motivated to do or accomplish things, such as their treatment or activities for a healthy lifestyle (eg, via social pressure)
10	To have reliable information and advice	Having understandable, relevant information and advice that is scientifically proven and recommended by the clinical team (ie, evidence-based information)
11	To receive personalized care	Receiving a personal approach in which their opinion and preferences are taken into account (eg, personalization or tailoring of treatment choices or features)

RRCM, BEB, and JW independently performed the coding of the eHealth design features. All coders are experts in eHealth research and development, having overall conducted various studies focused on eHealth design and evaluation involving multiple stakeholders' perspectives (eg, end users such as patients or expert stakeholders such as health care providers). The researchers first conducted a pilot of the coding using design features of a technology that was not included in the systematic review (the Care4myHeart app [29,30]). Minor adjustments were made to the codebook based on the resulting discrepancies.

During coding, each researcher could characterize the connection between a specific design feature and a patient value as follows: (1) "Yes," if the design feature directly and clearly accomplishes or contributes to a value; (2) "Maybe," if the design feature accomplishes or contributes to a value only indirectly or if the information is unclear; and (3) "No," if the design feature clearly does not accomplish or contribute to a value.

In addition to the deductive coding stage, RRCM invited authors of publications related to the included technologies via email to fill in a self-assessment form that asked about the relationship between their technology and the list of patient values. The self-assessment form posed 2 questions: (1) "Do you consider that your intervention accomplishes or contributes to any of the patient values listed below?" and (2) "When applicable, can you specify which feature or part of the intervention you consider seeks to accomplish or contribute to the corresponding patient value?" Finally, respondents could also freely state if other patient values outside the list provided were considered targets of the technology. In this way, it was expected that authors could link their technology and one or multiple design features to one of the values in the codebook. Multimedia Appendix 2 presents the self-assessment form that authors were invited to fill in. During the coding stage, the research team was blinded to any self-assessment sent by the researchers or developers of technologies.

Analysis and Reporting

To analyze the results, simple agreements (percent agreements) and the interrater reliability resulting from the deductive coding were calculated. Krippendorff alpha (KALPHA) was used as the measure of interrater reliability because, among other things, it takes into account the expected disagreement and not only the observed disagreement [25,31]. Values of KALPHA range from 0 to 1, where 0 is perfect disagreement and 1 is perfect agreement. Although it depends on the context, an alpha >0.80 is usually ideal, and a minimum level of acceptance is typically 0.667 [25].

Although independent coding performed by the research team led the search for potential connections, the input received from researchers and developers of technologies could support the identification when full agreement was not achieved. Therefore, the positive identification of a potential connection had to meet 1 of 2 criteria. The first and main criterion was to have full agreement on a connection among the 3 coders (ie, 3 out of 3 agreed on a feature-value connection). However, a potential connection was also recorded when the input by researchers and developers of technologies suggested it, as long as there was also partial agreement between coders (ie, 2 out of 3 agreed independently on a feature-value connection).

To report the results, the connections were first summarized at the level of the technologies. This first summary is reported because it is important to understand—and later to discuss—the surrounding context of the design features, which could have a relationship with their potential connections with patient values (eg, the intended goals of technologies that led design choices). Next, the design features that were connected with values were grouped according to their objectives and functionalities (eg, grouping different design features that relate to "self-monitoring" support, as with the previously mentioned "log" and "assessment" design features). By grouping specific design features according to their common characteristics, it was easier to identify potential differences in their design and their potential connections to values. For example, 2 different self-monitoring support design features could still be distinct enough that one could potentially contribute directly and clearly to a value while another one does so indirectly. This meant that some types of design features could entail both direct and indirect pathways toward a value. When relevant, some outstanding design features were textually described (eg, features that contributed to largely unaddressed values).

Results

Deductive Coding

In total, 70 design features from 10 different eHealth technologies were used for the content analysis (see Multimedia Appendix 1 for the full overview). To recall, each design feature was coded according to its potential connection with 11 different values (as "Yes," "Maybe," or "No"). Table 2 presents a summary of the percent agreements that resulted from the independent deductive coding. As can be observed in Table 2, 41 direct and clear connections between design features and patient values were identified in this way (ie, the ones with full agreement on "Yes"). In addition, 4 pairings were characterized as indirect or unclear (ie, the ones with full agreement on "Maybe").

The KALPHA coefficient for all data was 0.4536 (95% CI 0.4087-0.4978), which is low (0.667 is typically the minimum acceptable level [25]). KALPHA was computed using an ordinal measurement level that treated the potential connection between a design feature and a patient value as increasing from "No" (0) to "Maybe" (1) and "Yes" (2).

At the start, as can be seen in Table 2, 44 connections (41 "Yes" and 4 "Maybe") were identified through deductive coding. However, after integrating the input of researchers and designers of the reviewed technologies, the inferred connections between eHealth design features and patient values increased up to a total of 98 connections. Of the 45 researchers invited to complete the form, 6 individuals returned it (6 more also responded but redirected the request to a co-author who ultimately responded). Each form received related to a different technology; therefore, input was received for 6 of the 10 reviewed technologies: Engage [27], HeartMapp [28,32,33], HOME BP [34-38], PATHway [39,40], SMART-PSMS [41-46], and SUPPORT-HF [47-50]. For the remaining technologies, the authors either declined the invitation or did not respond after several reminders: MedFit [51-53], MyHeart [54-56], SMASH [57-62], and Mock-Up by Baek et al [63].

Table 2. Summary of percent agreements from deductive coding of 70 eHealth design features according to the potential connection with 11 different patient values, resulting in 770 possible connections between a design feature and a patient value.

Level of agreement	Results, n (%)
Connections with *full* agreement (ie, 3 out of 3)	502 (65.2)
Responses for connections with *full* agreement (ie, 3 out of 3)	
Yes	41 (8.2)
Maybe	4 (0.8)
No	457 (91.0)
Connections with *partial* agreements (ie, 2 out of 3)	209 (27.1)
Responses for connections with *partial* agreements (ie, 2 out of 3)	
Yes	48 (23.0)
Maybe	10 (4.8)
No	151 (72.2)
Null agreement (ie, 0 out of 3)	59 (7.7)

Contributions of Existing eHealth Technologies to Patient Values

The design features reviewed in this study were not created in isolation. Their surrounding context was an overarching eHealth technology with specific goals that led design choices. Because such context is important, it is also relevant—although not the focus of the study—to report the identified connections between eHealth technologies and patient values. The 98 connections suggest that some of the values are addressed by a majority of the 10 eHealth technologies. For instance, all of the technologies were connected with the patient value of "having or maintaining a healthy lifestyle." Similarly, the following values were connected with 8 different technologies: "having an overview of personal health data," "having reliable information and advice," "being extrinsically motivated," and "receiving personalized care." Less frequently, the "perceiving low thresholds to access health care" value was connected with 6 different technologies.

In contrast, other values connected with only a minority of the reviewed eHealth technologies. For instance, only 3 of 10 technologies were connected with the patient value of "receiving social support": PATHway [40], MedFit [51-53], and HOME BP [34-38]. Likewise, only 3 different technologies were connected with the patient value of "not feeling fear, anxiousness, or insecurity about health": SMASH [57,61], HOME BP [34-38], and SUPPORT-HF [47,49]. Only 2 technologies were connected with the patient value of "preserving a sense of autonomy": Engage [27] and the SMART PSMS [43,44]. Only the "On-screen positive reinforcement" design feature of the PATHway technology was connected with the patient value of "having confidence and self-efficacy in the treatment and the ability to achieve goals" [39,40]. Similarly, only the "culturally-attuned motivational and reinforcement SMS messages" design feature of the SMASH technology was connected with the patient value of "being seen as a person rather than a patient" [58,61,62].

Contributions of eHealth Design Features to Patient Values

The eHealth design features could be grouped according to their similar objectives and functionalities (ie, what they aim to do and how they try to do it). In total, the analysis identified 13 distinguishable "types" of design features: educational support, self-monitoring support, behavioral assessment support, behavioral planning support, behavioral performance support, feedback on monitored data, feedback during behavior performance, motivational incentives, prompts or cues, reminders, peer-based support, expert-based support, and the personalization of the system's design features. Textbox 1 presents descriptions and examples of the types of eHealth design features.

Textbox 1. Types of design features of eHealth technologies that support self-management of cardiovascular disease (CVD).

- Educational support: Features that enable the patients to access educational materials on various topics (eg, the "Heart Failure (HF) Info" feature of HeartMapp [28,32,33]); educational information could be presented with text, audio, or videos.
- Self-monitoring support: Features that facilitate the patient's monitoring of various types of data (eg, the "log" feature of Engage [27]), for instance, monitoring symptoms, weight, or self-management behaviors.
- Behavioral planning support: Features that facilitate selection and action-planning of health maintenance behaviors (eg, the "goal" feature of Engage [27]), for instance, to decide when and how to exercise based on long-term goals that were either self-set or agreed upon with health care providers.
- Behavioral performance support: Features that provide information, guidance, or support for the actual performance of health maintenance behaviors (eg, the "exercise" feature of MedFit [51-53]), for instance, an animated deep breathing practice or a list of guided exercise classes; the features can include real-time feedback or self-evaluation options (eg, rating performance or intensity).
- Behavioral assessment support: Features that assess a patient's readiness to change a selected behavior (eg, PATHway's "behavioral change assessment" and "good habits visualization" [40]); they can lead to a visual display of risk factors or recommended priorities for behavior change.
- Feedback on monitored data: Features that present graphs, charts, or written reports of a patient's data over time (eg, "statistics/stats" feature of HeartMapp [28,32,33]); the data can be about symptoms, behaviors, or the progress toward a desired performance.
- Feedback during behavior performance: Features that provide real-time feedback during the performance of health maintenance behaviors (eg, the "on-screen positive reinforcement" feature of PATHway [39,40]), for instance, to incentivize the correct execution of physical rehabilitation exercises.
- Motivational incentives: Features that incentivize engagement with the technology by using metaphors such as "missions," "medals," or "cards" (eg, the "deck of cards" feature of Engage [27]); they can be personalized according to a prescribed treatment, self-set goals, or automatic analyses of data collected.
- Cues: Features that provide prompts or cue to actions (eg, the "behavior change notifications" feature of PATHway [40]); they are directed to specific behaviors and can be personalized to a patient's preferences.
- Reminders: Features that provide reminders to facilitate adherence to medication (eg, the "medication tray reminder signals" of SMASH [59-61]); they can include the demand of an action or a request for additional input such as a reason for not conducting the behavior (eg, report the intake of medication as prescribed or a reason for skipping it).
- Peer-based human support: Features that facilitate interaction with peers (eg, the "multiplayer class" feature of PATHway [40]), for instance, through online platforms that allow data comparison between individuals or make it possible to plan activities with others.
- Expert-based human support: Features that focus on the interaction or involvement of health care providers (eg, the "contact" feature of SUPPORT-HF [47-49]); they can include a communication channel with an expert or support team and be linked to a clinical team module or a back-end alarm system that prompts interaction.
- System personalization features: Features that aim to (de-)activate the system's modules based on individual needs (eg, the "remote system refinements and features activation" feature of SUPPORT-HF [48,49]); personalization can occur at the initial introduction of the technology or as a response to the evolving situation of the individual.

The results of the content analysis revealed that different (types of) design features from existing eHealth technologies could be connected with values of patients with a CVD. Figures 1 and 2 present overviews of how the different types of eHealth design features connected with one or more patient values. Both figures summarize the cases where at least one specific design feature connected with a value and mark whether that connection was inferred to be direct or indirect. To recall, a direct connection referred to a clear and potentially positive relationship between a design feature and a patient value, leading to an increase or maintenance of motivation for self-management. In contrast, an indirect connection referred to an instance where the positive relationship required some assumptions to be made on behalf of the research team (eg, because information about a design feature's functionality was unclear or unavailable). Moreover, both figures also show that, in some cases, design features within the same category could have different connections (ie, one direct and another indirect).

Figure 1. Overview of the types of eHealth design features that were most frequently connected with values of patients with a cardiovascular disease.

Types of eHealth design features	Patient values: To have or maintain a healthy lifestyle	To have an overview of personal health data	To have reliable information and advice	To be extrinsically motivated to accomplish goals or activities (related to health/lifestyle)	To receive personalized care
Educational support	Indirect (1)/Direct (2)		Direct (9)		Direct (1)
Self-monitoring support	Indirect (1)/Direct (5)	Indirect (1)/Direct (1)	Direct (3)		
Behavioral planning support	Direct (4)			Indirect (1)	Indirect (1)/Direct (3)
Behavioral performance support	Direct (5)				Direct (1)
Behavioral assessment support	Indirect (1)	Direct (1)			
Feedback on monitored data	Indirect (2)/Direct (1)	Direct (8)	Direct (1)		
Feedback during behavior performance	Direct (2)	Direct (3)			
Motivational incentives	Indirect (4)	Direct (1)		Indirect (1)/Direct (2)	Direct (1)
Cues				Direct (4)	Direct (1)
Reminders	Indirect (1)/Direct (1)			Direct (2)	Direct (1)
Human peer-based support				Direct (1)	
Human expert-based support					
System personalization					Indirect (1)/Direct (1)
Total amount of connected features:	30	15	13	11	11

Legend:	
Direct	eHealth design feature(s) could directly and clearly contribute to the patient value.
Indirect	eHealth design feature(s) could contribute to the patient value but only indirectly.
Indirect/Direct	eHealth design feature(s) could contribute to the patient value both directly and indirectly.

Figure 2. Overview of the types of eHealth design features that were least frequently connected with values of patients with a cardiovascular disease.

Types of eHealth design features	Patient values: To perceive low thresholds to access health care	To receive social support	To preserve a sense of autonomy over their life	To not feel fear, anxiousness, or insecurity about their health	To have confidence and self-efficacy in treatment and the ability to achieve goals	To be seen as a person rather than a patient
Educational support				Indirect (1)/Direct (1)		
Self-monitoring support	Indirect (1)		Indirect (1)			
Behavioral planning support			Direct (2)			
Behavioral performance support						
Behavioral assessment support						
Feedback on monitored data						
Feedback during behavior performance					Direct (1)	
Motivational incentives						Direct (1)
Cues						
Reminders						
Human peer-based support		Direct (3)				
Human expert-based support	Indirect (2)/Direct (3)	Direct (1)		Indirect (1)		
System personalization						
Total amount of connected features:	6	4	3	3	1	1

Legend:	
Direct	eHealth design feature(s) could directly and clearly contribute to the patient value.
Indirect	eHealth design feature(s) could contribute to the patient value but only indirectly.
Indirect/Direct	eHealth design feature(s) could contribute to the patient value both directly and indirectly.

Figure 1 summarizes the patient values most frequently connected with the eHealth design features analyzed in this study. As can be seen in Figure 1, 5 of the 11 patient values were extensively connected with multiple design features with distinct characteristics and objectives. An apparent exception is the "to have reliable information and advice" value, which was connected with 3 types of design features (educational support, self-monitoring support, and feedback on monitored data). However, even in that case, the total amount of specific design features was relatively high (13 in total). Beyond

frequencies, Figure 1 also visualizes potential clusters of design feature types in relation to patient values. For instance, several features providing feedback on monitored data connected with the value of "having an overview of personal health data." Likewise, motivational incentives, cues, and reminders most frequently connected with the value of "being extrinsically motivated."

In contrast to the aforementioned results, Figure 2 summarizes the patient values least frequently connected with the eHealth design features analyzed in this study. Figure 2 shows that, for the remaining 6 patient values, the amount of connected design features is fewer, also varying less in their functionalities or objectives. In comparison with Figure 1, the values presented in Figure 2 connected only, at most, with 2 different types of eHealth design features. Beyond mere frequencies, Figure 2 shows that both human peer–based and expert-based support clustered toward a couple of the values in Figure 2. Namely, the values of "perceiving low thresholds to access health care" (5 specific features) and "receiving social support" (4 specific features). The rest of the values in Figure 2, however, connected only to a maximum of 2 specific features. Finally, the values of "having confidence and self-efficacy" and "being seen as a person rather than a patient" connected only with a single feature each.

Discussion

Principal Findings

This study sought an answer to the research question "what eHealth design features can be connected with the values of patients with a CVD?" To approach an answer, the study explored potential connections between 11 empirically validated values of patients diagnosed with a CVD and 70 design features of 10 existing eHealth technologies that aim to support this population. In total, 98 connections—both direct and indirect—were inferred between the design features and the values included in the analysis. On the one hand, some design features connected with multiple values. On the other hand, some values were less frequently connected, with a couple remaining largely unaddressed.

Principally, the results of the study show that design features of existing eHealth technologies could already be connected with values of individuals with a CVD (see Figures 1 and 2). The findings add up to the general literature about value sensitive studies of chronically ill populations and the design of self-management eHealth solutions. The connections between design features and values inferred by this study are still hypothetical, but the knowledge generated can be used to suggest new approaches for the development of personalized and tailored eHealth. The following discussion centers on the arguments that underlie outstanding cases among the 98 inferred connections, as well as some of their potential applications to the design of eHealth for self-management support.

Inferred Connections Between eHealth Design Features and Patient Values

Supporting Patients Who Value "a Healthy Lifestyle"

It comes arguably without surprise that the most frequently connected patient value was "to have or maintain a healthy lifestyle" (see Figure 1). Design features such as goal setting, suggestions, or reminders have been identified as key components of eHealth technologies that aim to promote healthy lifestyles [64]. Figure 1 reflects a similar variety in the types of eHealth design features connected with this value (eg, all forms of behavioral support). Outstandingly, design features related to behavioral planning support, behavioral performance support, and the provision of feedback during behavior performance directly connected with this value. However, the analysis identified only 2 examples of real-time feedback features during performance. Specifically, the "on-screen positive reinforcement" feature of PATHway [38,39] and the "upper-limb rehabilitation" feature of the SMART PSMS stroke module [46]. Similarly, the PATHway "behavioral change assessment" feature stood out as a way to potentially and indirectly honor this value [40]. The aforementioned features could represent untapped design opportunities to support individuals who highly value the maintenance of a healthy lifestyle (full details and references to specific features can be found in Multimedia Appendix 1).

Supporting Patients Who Value "an Overview of Personal Health Data"

The study also connected several eHealth design features with the value of "having an overview of personal health data" (Figure 1). These included all types of feedback provision but also self-monitoring support, behavioral assessment support, and even motivational incentives. That the agreed connections went beyond the "typical" feedback features (eg, statistics charts) could arguably hint toward ways to resolve the challenges reported by patients for the *sensemaking* of their health data [65,66]. Sensemaking is considered the explicit and effortful approach of individuals to analytically engage with a situation, in order to construct explanations that allow them to select appropriate actions [65]. For example, the "good habits visualization" feature of PATHway [40] is a behavioral assessment feature that not only delivers an overview of data but also suggests areas that need to be improved. Similarly, the self-monitoring features connected with this value included a follow-up overview of monitored data. Specifically, the "self-management" feature of mock-up by Baek et al [63] directly provides an overview of data, while the "log" feature of Engage [27] indirectly does so by requiring a few actions to access one. The "walking re-education and foot placement" feature of the SMART PSMS stroke module is the single motivational incentive feature connected with this value [44,45]. The overview provided by this feature emphasizes a feeling of progress and reward [45]. Studies from the sensemaking perspective support the notion that data-driven features can engage patients in different ways, by providing external motivational incentives, facilitating goal setting, or, in a lesser degree, allowing open exploration of their health data (ideally triggering sensemaking) [67,68].

Supporting Patients Who Value "Reliable Information and Advice"

Unsurprisingly, multiple educational support features connected with the value of "having reliable information and advice" (Figure 1). Additionally, self-monitoring and monitored data feedback features connected with this value by guiding correct monitoring procedures and providing quick practical advice. For example, the "assessment" feature of HeartMapp goes beyond just self-monitoring support by classifying patients according to safety levels and delivering behavioral actions [28]. Importantly, some features connected also with other less frequently addressed values, such as "not feeling fear, anxiety, or insecurity" or "having confidence and self-efficacy." The struggles of patients in their transition from hospital-based care to self-managing at home are widely acknowledged [69]. The ability to access reliable information and advice during and after this transition could underlie the aforementioned feature-value connections but also a relation between patient values.

Supporting Patients Who Value "Extrinsic Motivation"

The study also connected multiple eHealth design features with the value of "being extrinsically motivated to accomplish goals or activities related to healthy lifestyles" (Figure 1). Cues, reminders, peer-based support, and motivational incentives directly connected with this value. These connections could be supported by the available evidence on the positive effects of social support [70] and of features that prompt immediate behavioral action [71], remind patients about key activities [29], or aim to motivate self-management in general [57,72]. In this regard, the "culturally-attuned motivational and reinforcement SMS messages" of the SMASH technology stood out because it also directly connected with other values, including the least frequently addressed value of "being perceived as a person rather than a patient" [57,58,61]. Finally, the "goal" feature of Engage was the only behavioral planning feature indirectly connected with the "extrinsic motivation" value [27]. The argument for the indirect connection is its integration with the "deck of cards" motivational feature [27].

Supporting Patients Who Value "Personalized Care"

As with the previous cases, the study connected several eHealth features with the value of "receiving personalized care" (Figure 1). These included educational support features; behavioral planning and performance support; and motivational incentives, cues, and reminders. As an example, the "optional lifestyle changes" educational feature of HOME BP allows patients to personally request additional content [34-38]. Alternatively, the "exercise" feature of MedFit automatically updates the list of guided exercise classes based on the evaluation of classes performed earlier [51-53]. Outstandingly, 2 overarching system personalization features connected with this value. On the one hand, the "my stroke" feature of the SMART PSMS permitted the customization of the system during its deployment, with the involvement of both the patient and health care provider [43,44]. On the other hand, the "remote system refinements and features activation" of SUPPORT-HF connected indirectly because the personalization seemed to be exclusively controlled by clinicians [48,49]. Both features exemplify what appear to be still untapped opportunities in terms of modular customization of eHealth technologies for individual cases.

Supporting Patients Who Value "Low Thresholds to Health Care"

In contrast to the previous values, only 5 human expert–based support features and a single self-monitoring support feature connected with the value of "perceiving low thresholds to access health care" (Figure 2). The connections with expert-based support features align with literature highlighting the irreplaceable role of health care providers, especially when it comes to remote support [66,73]. In this regard, front-end support features permitting the patients to trigger, request, or receive advice from professionals connected directly with this value. For example, the "contact" feature of SUPPORT-HF allows patients to contact the support team [47,48,50]. In comparison, back-end features exclusively available to health care providers connected only indirectly, for example, the "clinical team module" of the HeartMapp application [33]. Standing on its own, the "today's exercise" self-monitoring feature of the SMART PSMS stroke module also connected indirectly with this value [43,45]. This specific connection was argued on the integration of a preliminary check of symptoms and mood, which, if necessary, prompts patients to call the hospital for assistance before initiating exercises [43,45].

Supporting Patients Who Value "Social Support"

Expectedly, 3 peer-based support features connected with the value of "receiving social support" (Figure 2). PATHway's "multiplayer class" and "calendar for events/exercise" features [40] as well as MedFit's "social interaction" feature connected directly with this value [51-53]. Perhaps more surprising in this case is that the expert-based "behavioral support (via health care provider)" feature of HOME BP connected with this value [34-38]. This feature gives patients the option to request face-to-face or telephone-based behavioral support for self-monitoring and lifestyle modifications [34-38]. The underlying argument for this connection was the implementation of a training protocol for caregivers called "congratulate, ask, reassure, encourage" or CARE [34-38]. Although patients' families and peers are typically the expected sources of social support, a recent study acknowledged that health care providers can also play significant roles in this regard [74].

Supporting Patients Who Value "a Sense of Autonomy"

This study only connected 3 eHealth design features with the value of "preserving a sense of autonomy" (Figure 2). The "goal" feature of Engage [27] and the "my exercises" feature of the SMART PSMS stroke module [43,44] connected directly by allowing patients to create their own self-management action plans. Indirectly connected, Engage's "log" self-monitoring feature allows patients to select and record the performance of activities based on a predetermined set of recommended actions [27]. Supporting this connection, recent works ascertained how the support for autonomy can also promote the patients' individual responsibility for their own care [71,73]. The aforementioned features exemplify how eHealth might be able to promote autonomy, that is, by providing options and thus

avoiding fixed or generic recommendations for self-management.

Supporting Patients Who Value "Not Feeling Fear, Anxiety, or Insecurity"

The study directly connected only 1 eHealth design feature with the value of "not feeling fear, anxiousness, or insecurity about health" and 2 more indirectly (Figure 2). The "education about medication titration" feature of HOME BP connected directly because it addressed potential concerns about the side effects of medication [34-38]. The "how to keep healthy" educational feature of SUPPORT-HF connected indirectly by its presentation of videos depicting other patients' stories [47,49]. The "clinical inertia alarms (to health care providers)" feature of SMASH [57,61] also connected indirectly. In this regard, a study has reported how awareness of such links with health professionals can generate feelings of safety in patients [75]. The small amount of features connected with this value is worrying in consideration of the feelings of fear, anxiety, and hopelessness that are commonly reported by patients with a CVD [69,76]. Therefore, it seems important that future eHealth technologies aim to assist the patient's control over these emotions. Although not reviewed by this study, there are some design examples that go beyond those already mentioned, such as feedback during behavior performance based on optimal training zones identified through heart rate monitoring (eg, during cycling [77]).

Supporting Patients Who Value "Confidence in Treatment and for Goal Achievement"

The "on-screen positive reinforcement" of PATHway is the only feature connected with the value of "having confidence and self-efficacy in the treatment and the ability to achieve goals" [39,40] (Figure 2). This specific finding could represent an important gap in eHealth design, as self-efficacy is known to be a key influencing factor for self-management behaviors [78,79]. Future eHealth technologies could attempt to integrate principles of evidence-based approaches such as motivational interviewing [80]. Alternatively, it could be explored why previous design approaches seem to fall short in boosting self-efficacy, that is, because a recent scoping review of digital games aiming to support CVD self-management concluded that they failed to improve the self-efficacy of patients [81].

Supporting Patients Who Value "Being Seen as a Person Rather Than a Patient"

Finally, this study connected only the "culturally-attuned motivational and reinforcement SMS messages" feature of SMASH with the value of "being seen as a person rather than a patient" [58,61] (Figure 2). This feature delivers motivational and reinforcement messages tailored to the patient's values, beliefs, and short- or long-term life goals [62]. This is arguably an important yet challenging objective for value sensitive design. The shift from hospital- to home-based care could be accompanied by a change in perspective about how individuals are treated. Novel eHealth design approaches could take into consideration recent studies that explored ways to identify, elicit, and communicate about the values of individuals with multiple chronic conditions [82-85].

Applications and Challenges of Value Sensitive eHealth Design for Self-management

The potential connections described in the previous sections represent only a first step toward a value sensitive approach to the design of eHealth for CVD self-management support. Operationalizing value sensitive design will certainly require more than making one-to-one connections between features and values, mainly because self-management is a naturalistic, dynamic, and complex decision-making process [4,86]. Self-management entails distinct and often conflicting goals [86] (eg, health goals vs personal life goals [87,88]), intricate interactions between different actors (eg, patients, families, caregivers [88,89]), and many influencing factors (eg, skill, motivation, confidence [86]). eHealth must aim to facilitate self-management processes, whether it is by delivering only key information, allowing care customization, or addressing person-specific barriers [88].

Moreover, studies involving patients with multiple chronic conditions have also shown the challenges in the identification and conceptualization of their values [90,91]. For example, a study has shown that values can be explicitly or implicitly stated by patients, be also in conflict in with each other, and extend across several conceptual domains [91]. Therefore, value sensitive design is in itself a complex approach and cannot be expected to account for all the challenges ascribed to eHealth self-management solutions. However, its importance lies in the premise that it aims to maximize the patients' motivation to engage in their own care. Some of its methodological challenges are worth discussing: first, the required methods for the elicitation and translation of values to eHealth design; second, the strategies to simultaneously personalize eHealth to both self-management needs and patient values; third, the underlying research and development approaches through which the aforementioned challenges can be tackled.

Elicitation and Translation of Values to Design as a Collaborative Task

The elicitation and translation of values to eHealth design is a task that demands the involvement of multiple stakeholders, including health care providers, patients, and their families [82,83]. The findings of this study represent only hypothetical connections that must be validated in consideration of the key elements of a patient's work system (ie, the persons, tasks, tools, and surrounding contexts) [89]. For example, studies involving informal (family) caregivers report the feelings of stress and anxiety caused by a patient's discharge from a hospital [92]. Both patients and caregivers alike expressed the need for more involvement of health care providers in this follow-up process [92]. Although this study identified features that connect with similar values such as "having reliable information and advice," it is unclear if the conceptualization accurately expresses the interests and needs of informal caregivers. It is necessary to validate all observed connections with the actors that become implicit participants by eHealth design (eg, expert-based support features imply the involvement of clinicians and nurses). At early stages of eHealth development, human-centered [93] or holistic approaches to eHealth [18] could be instrumental for the elicitation and translation of patient values (ie, a

consideration of perspectives from diverse stakeholders and scientific disciplines).

Personalizing eHealth Design to Self-management Needs and Patient Values

The 98 connections suggest different ways in which eHealth design could be personalized to keep patients motivated and engaged in self-management. However, in naturalistic settings, it is necessary to consider many more influencing factors before settling for a personalization strategy. For example, older adult patients, a majority in chronically ill populations, often experience cognitive decline [94], have to deal with comorbidities [95], and might require training in the use of technologies [10]. For these patients, traditional educational strategies tend to be ineffective [94] while high levels of comorbidity decrease their self-efficacy. This study suggests design choices such as providing feedback during self-management performance or those argued before as capable to support sense-making. In short, it could be hypothesized that older adult patients who highly value "feeling confident" will benefit more from features sensitized to such value. This requirement also makes apparent that overarching remote system personalization features are vital for proper and on-the-go personalization to individual cases (eg, as done by the SMART PSMS [43,44] or the SUPPORT-HF intervention [48,49]).

Research and Development Approaches to Aid Value Sensitive Design

To ensure its successful operationalization, value sensitive design must be integrated with both existing and novel approaches of eHealth research and development. On the one hand, value sensitive design aims to sensitize researchers and developers to value-centered work, from theory to practice and vice versa [96]. On the other hand, what is also needed are underlying approaches that guide the actual design processes of value sensitive technologies. In eHealth, user- or human-centered frameworks stand out as widely accepted practices for development [93]. However, the practical challenges and pitfalls of these approaches are seldomly reported in published literature [97]. Challenges can come in formative, design, and evaluation stages or as recurrent processes [97]. On top of that, to validate value sensitive eHealth, it will be necessary to test the differences in actual effectiveness trials. Methodologies such as the Multiphase Optimization Strategy (MOST) could be most suitable [98]. MOST's fundamental idea is that interventions should be optimized to meet specific criteria before conducting a large-scale randomized control trial [98]. Given the motivational aim of value sensitive design, eHealth technologies could be optimized based on multiple criteria of self-management engagement or its health-related outcomes.

Future Work

Future studies in the area of value sensitive eHealth design should seek to explore and confirm the connections made by this study. Primarily, studies could pursue further validation of the value conceptualizations in CVD populations. If validated, future studies could then seek the integration of other values identified in similar populations (eg, other chronic conditions such as diabetes or chronic obstructive pulmonary disease). Similarly, future studies could revise or expand the categorization of eHealth design features proposed by this study (ie, according to what they aim to do or how they try to do it) [23]. Certainly, design work is and should always be context-specific, and so the operationalization of design features even for similar objectives might never be exactly the same. However, by refining value conceptualizations and by clustering specific design features within identifiable categories, new hypotheses and guidelines could be tested in order to advance value sensitive design across different eHealth applications and contexts.

Strengths and Limitations

The hypothetical connections identified by this study can be debated from multiple perspectives. For instance, there is a number of caveats that concern the clarity and reliability of the inferred connections. To recall, the connections are the result of combining a content analysis performed by the authors of this study with the input received from researchers and designers of 6 of the 10 reviewed technologies. On the one hand, the deductive coding of the content analysis shows that all 3 raters agreed most of the time (65.2%, see Table 2). Additionally, one-third of the time, 2 of 3 raters agreed (27.1%), and for 7.7% of the total pairings, there was no agreement at all. On the other hand, the KALPHA coefficient for all data was low (0.4536; 95% CI 0.4087-0.4978). However, it must be considered that KALPHA is a strict coefficient that accounts for the expected disagreement and not only the observed disagreement [25,31]. Therefore, the measure punishes when agreements were not achieved by the challenging, interpretative task of linking design features—described as best as possible with the available information—and a set of values, which are, by definition, subjective. Despite this, the hypothetical connections brought forward by the study must also be valued in light of the aims of the study, namely that it was not the objective to immediately agree on a characterization of values and their potential contributions. In fact, the reliability and lack of agreement were deemed relatively negligible given that the next objective of the project is to validate the presumed connections with individuals in the target group. Thus, the most obvious limitation that the study confronts is that all inferences are still hypothetical and expert-based. In other words, the connections between design features and values must continue to be tested, refined, and generalized.

Conclusions

This study identified 98 connections between design features of existing eHealth technologies and a set of empirically validated values of individuals living with a CVD. Although existing eHealth technologies were already found to have design features that could align well with patient values, some values were not frequently addressed. These results shed light on the importance of value sensitive design for future eHealth technologies. By and large, what this study adds are explicit and specific design hypotheses for future study that still require validation but, nevertheless, promise to advance the uptake and effectiveness of eHealth self-management support for individuals with a CVD.

Acknowledgments

This study was funded by the Mexican National Council for Science and Technology (CONACYT in Spanish).

Authors' Contributions

RRCM led and was involved throughout all stages of the study. JW and BEB participated in the coding and analysis of results. RS and JEWCGP provided feedback for the analysis, results, and discussion. All authors critically evaluated the manuscript multiple times and gave their final approval before submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
eHealth technologies and design features included in the content analysis.
[DOCX File , 57 KB - cardio_v5i2e31985_app1.docx]

Multimedia Appendix 2
Self-assessment form.
[DOCX File , 36 KB - cardio_v5i2e31985_app2.docx]

References

1. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns 2002;48(2):177-187. [doi: 10.1016/s0738-3991(02)00032-0] [Medline: 12401421]
2. Bandura A. The primacy of self-regulation in health promotion. Applied Psychology 2005 Apr;54(2):245. [doi: 10.1111/j.1464-0597.2005.00208.x]
3. Roth GA, Johnson C, Abajobir A, Abd-Allah F, Abera SF, Abyu G, et al. Global, regional, and national burden of cardiovascular diseases for 10 causes, 1990 to 2015. J Am Coll Cardiol 2017 Jul 04;70(1):1-25 [FREE Full text] [doi: 10.1016/j.jacc.2017.04.052] [Medline: 28527533]
4. Riegel B, Moser DK, Buck HG, Dickson VV, Dunbar SB, Lee CS, American Heart Association Council on Cardiovascular and Stroke Nursing, Council on Peripheral Vascular Disease, Council on Quality of Care and Outcomes Research. Self-care for the prevention and management of cardiovascular disease and stroke: A scientific statement for healthcare professionals from the American Heart Association. J Am Heart Assoc 2017 Aug 31;6(9):1 [FREE Full text] [doi: 10.1161/JAHA.117.006997] [Medline: 28860232]
5. van Gemert-Pijnen L, Kip H, Kelders SM, Sanderman R. Introducing eHealth. In: van Gemert-Pijnen L, Kelders SM, Kip H, Sanderman R, editors. eHealth Research, Theory and Development. Oxfordshire, England: Routledge; 2018:23-46.
6. Greenwood DA, Gee PM, Fatkin KJ, Peeples M. A systematic review of reviews evaluating technology-enabled diabetes self-management education and support. J Diabetes Sci Technol 2017 Sep;11(5):1015-1027 [FREE Full text] [doi: 10.1177/1932296817713506] [Medline: 28560898]
7. Hanlon P, Daines L, Campbell C, McKinstry B, Weller D, Pinnock H. Telehealth interventions to support self-management of long-term conditions: A systematic metareview of diabetes, heart failure, asthma, chronic obstructive pulmonary disease, and cancer. J Med Internet Res 2017 May 17;19(5):e172 [FREE Full text] [doi: 10.2196/jmir.6688] [Medline: 28526671]
8. Jonkman NH, Groenwold RHH, Trappenburg JCA, Hoes AW, Schuurmans MJ. Complex self-management interventions in chronic disease unravelled: a review of lessons learned from an individual patient data meta-analysis. J Clin Epidemiol 2017 Mar;83:48-56. [doi: 10.1016/j.jclinepi.2017.01.004] [Medline: 28126599]
9. Kebapci A, Ozkaynak M, Lareau SC. Effects of eHealth-based interventions on adherence to components of cardiac rehabilitation: A systematic review. J Cardiovasc Nurs 2020;35(1):74-85. [doi: 10.1097/JCN.0000000000000619] [Medline: 31738217]
10. Kim BY, Lee J. Smart devices for older adults managing chronic disease: A scoping review. JMIR Mhealth Uhealth 2017 May 23;5(5):e69 [FREE Full text] [doi: 10.2196/mhealth.7141] [Medline: 28536089]
11. Pfaeffli Dale L, Dobson R, Whittaker R, Maddison R. The effectiveness of mobile-health behaviour change interventions for cardiovascular disease self-management: A systematic review. Eur J Prev Cardiol 2016 May;23(8):801-817. [doi: 10.1177/2047487315613462] [Medline: 26490093]
12. Triantafyllidis A, Kondylakis H, Votis K, Tzovaras D, Maglaveras N, Rahimi K. Features, outcomes, and challenges in mobile health interventions for patients living with chronic diseases: A review of systematic reviews. Int J Med Inform 2019 Dec;132:103984. [doi: 10.1016/j.ijmedinf.2019.103984] [Medline: 31605884]

13. Villarreal V, Berbey-Alvarez A. Evaluation of mHealth applications related to cardiovascular diseases: a systematic review. Acta Inform Med 2020 Jun;28(2):130-137 [FREE Full text] [doi: 10.5455/aim.2020.28.130-137] [Medline: 32742066]
14. Harvey J, Dopson S, McManus RJ, Powell J. Factors influencing the adoption of self-management solutions: an interpretive synthesis of the literature on stakeholder experiences. Implement Sci 2015 Nov 13;10:159 [FREE Full text] [doi: 10.1186/s13012-015-0350-x] [Medline: 26566623]
15. Van Velsen L, Wentzel J, Van Gemert-Pijnen JE. Designing eHealth that matters via a multidisciplinary requirements development approach. JMIR Res Protoc 2013 Jun 24;2(1):e21 [FREE Full text] [doi: 10.2196/resprot.2547] [Medline: 23796508]
16. Friedman B, Kahn P, Borning A, Huldtgren A. Value Sensitive Design and Information Systems. In: Doorn N, Schuurbiers D, van de Poel I, Gorman M, editors. Early engagement and new technologies: Opening up the laboratory. Philosophy of Engineering and Technology, vol 16. Dordrecht, Netherlands: Springer Netherlands; 2013:55-95.
17. Kip H, van Gemert-Pijnen L. Holistic development of eHealth technology. In: van Gemert-Pijnen L, Kelders SM, Kip H, Sanderman R, editors. eHealth Research, Theory and Development. Oxfordshire, England: Routledge; 2018:151-186.
18. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res 2011 Dec 05;13(4):e111 [FREE Full text] [doi: 10.2196/jmir.1672] [Medline: 22155738]
19. Bente BE, Wentzel J, Groeneveld RG, IJzerman RV, de Buisonjé DR, Breeman LD, et al. Values of importance to patients with cardiovascular disease as a foundation for eHealth design and evaluation: Mixed methods study. JMIR Cardio 2021 Oct 22;5(2):e33252 [FREE Full text] [doi: 10.2196/33252] [Medline: 34677130]
20. Michie S, Wood CE, Johnston M, Abraham C, Francis JJ, Hardeman W. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). Health Technol Assess 2015 Nov;19(99):1-188 [FREE Full text] [doi: 10.3310/hta19990] [Medline: 26616119]
21. Oinas-Kukkonen H, Harjumaa M. Persuasive systems design: Key issues, process model, and system features. CAIS 2009;24:1. [doi: 10.17705/1cais.02428]
22. Michie S, Yardley L, West R, Patrick K, Greaves F. Developing and evaluating digital interventions to promote behavior change in health and health care: Recommendations resulting from an international workshop. J Med Internet Res 2017 Jun 29;19(6):e232 [FREE Full text] [doi: 10.2196/jmir.7126] [Medline: 28663162]
23. Cruz-Martínez RR, Wentzel J, Asbjørnsen RA, Noort PD, van Niekerk JM, Sanderman R, et al. Supporting self-management of cardiovascular diseases through remote monitoring technologies: Metaethnography review of frameworks, models, and theories used in research and development. J Med Internet Res 2020 May 21;22(5):e16157 [FREE Full text] [doi: 10.2196/16157] [Medline: 32436852]
24. Cruz-Martínez RR, Noort PD, Asbjørnsen RA, van Niekerk JM, Wentzel J, Sanderman R, et al. Frameworks, models, and theories used in electronic health research and development to support self-management of cardiovascular diseases through remote monitoring technologies: Protocol for a metaethnography review. JMIR Res Protoc 2019 Jul 16;8(7):e13334. [doi: 10.2196/13334]
25. Krippendorff K. Content Analysis: An Introduction to Its Methodology. Thousand Oaks, CA: Sage Publications, Inc; 2004:18-241.
26. Elo S, Kääriäinen M, Kanste O, Pölkki T, Utriainen K, Kyngäs H. Qualitative content analysis. SAGE Open 2014 Feb 11;4(1):2158244014522633. [doi: 10.1177/2158244014522633]
27. Srinivas P, Cornet V, Holden R. Human factors analysis, design, and evaluation of Engage, a consumer health IT application for geriatric heart failure self-care. Int J Hum Comput Interact 2017 Sep;33(4):298-312 [FREE Full text] [doi: 10.1080/10447318.2016.1265784] [Medline: 30429638]
28. Athilingam P, Clochesy JM, Labrador MA. Intervention mapping approach in the design of an interactive mobile health application to improve self-care in heart failure. Comput Inform Nurs 2018 Feb;36(2):90-97. [doi: 10.1097/CIN.0000000000000383] [Medline: 28901967]
29. Woods LS, Duff J, Roehrer E, Walker K, Cummings E. Patients' experiences of using a consumer mHealth app for self-management of heart failure: Mixed-methods study. JMIR Hum Factors 2019 May 02;6(2):e13009 [FREE Full text] [doi: 10.2196/13009] [Medline: 31045504]
30. Woods L, Duff J, Roehrer E, Walker K, Cummings E. Design of a consumer mobile health app for heart failure: Findings from the nurse-led co-design of Care4myHeart. JMIR Nurs 2019 Sep 23;2(1):e14633 [FREE Full text] [doi: 10.2196/14633] [Medline: 34345774]
31. Krippendorff K. Agreement and information in the reliability of coding. Communication Methods and Measures 2011 Apr;5(2):93-112. [doi: 10.1080/19312458.2011.568376]
32. Athilingam P, Labrador MA, Remo EFJ, Mack L, San Juan AB, Elliott AF. Features and usability assessment of a patient-centered mobile application (HeartMapp) for self-management of heart failure. Appl Nurs Res 2016 Nov;32:156-163. [doi: 10.1016/j.apnr.2016.07.001] [Medline: 27969021]
33. Di Sano S, Perez A, Labrador MA, Athilingam P, Giovannetti F. HeartMapp: a mobile application to improve CHF outcomes and reduce hospital readmissions. Demonstration paper: HeartMapp; 2015 Presented at: WH '15: Proceedings of the

conference on Wireless Health; October 14-16, 2015; Bethesda, MD URL: https://dl.acm.org/doi/10.1145/2811780.2811914 [doi: 10.1145/2811780.2811914]
34. Band R, Bradbury K, Morton K, May C, Michie S, Mair FS, et al. Intervention planning for a digital intervention for self-management of hypertension: a theory-, evidence- and person-based approach. Implement Sci 2017 Feb 23;12(1):25 [FREE Full text] [doi: 10.1186/s13012-017-0553-4] [Medline: 28231840]
35. Band R, Morton K, Stuart B, Raftery J, Bradbury K, Yao GL, et al. Home and Online Management and Evaluation of Blood Pressure (HOME BP) digital intervention for self-management of uncontrolled, essential hypertension: a protocol for the randomised controlled HOME BP trial. BMJ Open 2016 Nov 07;6(11):e012684 [FREE Full text] [doi: 10.1136/bmjopen-2016-012684] [Medline: 27821598]
36. Bradbury K, Morton K, Band R, May C, McManus R, Little P, et al. Understanding how primary care practitioners perceive an online intervention for the management of hypertension. BMC Med Inform Decis Mak 2017 Jan 09;17(1):5 [FREE Full text] [doi: 10.1186/s12911-016-0397-x] [Medline: 28069041]
37. Bradbury K, Morton K, Band R, van Woezik A, Grist R, McManus RJ, et al. Using the Person-Based Approach to optimise a digital intervention for the management of hypertension. PLoS One 2018;13(5):e0196868 [FREE Full text] [doi: 10.1371/journal.pone.0196868] [Medline: 29723262]
38. Morton K, Dennison L, Bradbury K, Band R, May C, Raftery J, et al. Qualitative process study to explore the perceived burdens and benefits of a digital intervention for self-managing high blood pressure in Primary Care in the UK. BMJ Open 2018 May 08;8(5):e020843 [FREE Full text] [doi: 10.1136/bmjopen-2017-020843] [Medline: 29739782]
39. Triantafyllidis A, Filos D, Buys R, Claes J, Cornelissen V, Kouidi E, et al. Computerized decision support for beneficial home-based exercise rehabilitation in patients with cardiovascular disease. Comput Methods Programs Biomed 2018 Aug;162:1-10. [doi: 10.1016/j.cmpb.2018.04.030] [Medline: 29903475]
40. Walsh D, Moran K, Cornelissen V, Buys R, Claes J, Zampognaro P, et al. The development and codesign of the PATHway intervention: a theory-driven eHealth platform for the self-management of cardiovascular disease. Transl Behav Med 2019 Jan 01;9(1):76-98. [doi: 10.1093/tbm/iby017] [Medline: 29554380]
41. Bartlett YK, Haywood A, Bentley CL, Parker J, Hawley MS, Mountain GA, et al. The SMART personalised self-management system for congestive heart failure: results of a realist evaluation. BMC Med Inform Decis Mak 2014 Nov 25;14:109 [FREE Full text] [doi: 10.1186/s12911-014-0109-3] [Medline: 25421307]
42. Burns WP, Davies RJ, Nugent CD, McCullagh PJ, Zheng H, Black ND, et al. A Personalised Self-Management System for Chronic Heart Failure. 2010 Presented at: 2010 Computing in Cardiology; September 26-29, 2010; Belfast, UK.
43. Mawson S, Nasr N, Parker J, Davies R, Zheng H, Mountain G. A personalized self-management rehabilitation system with an intelligent shoe for stroke survivors: A realist evaluation. JMIR Rehabil Assist Technol 2016 Jan 07;3(1):e1 [FREE Full text] [doi: 10.2196/rehab.5079] [Medline: 28582250]
44. Mawson S, Nasr N, Parker J, Zheng H, Davies R, Mountain G. Developing a personalised self-management system for post stroke rehabilitation; utilising a user-centred design methodology. Disabil Rehabil Assist Technol 2014 Nov;9(6):521-528. [doi: 10.3109/17483107.2013.840863] [Medline: 24131371]
45. Parker J, Mawson S, Mountain G, Nasr N, Davies R, Zheng H. The provision of feedback through computer-based technology to promote self-managed post-stroke rehabilitation in the home. Disabil Rehabil Assist Technol 2014 Nov;9(6):529-538. [doi: 10.3109/17483107.2013.845611] [Medline: 24131369]
46. Parker J, Mawson S, Mountain G, Nasr N, Zheng H. Stroke patients' utilisation of extrinsic feedback from computer-based technology in the home: a multiple case study realistic evaluation. BMC Med Inform Decis Mak 2014 Jun 05;14(1):46 [FREE Full text] [doi: 10.1186/1472-6947-14-46] [Medline: 24903401]
47. Chantler T, Paton C, Velardo C, Triantafyllidis A, Shah SA, Stoppani E, et al. Creating connections - the development of a mobile-health monitoring system for heart failure: Qualitative findings from a usability cohort study. Digit Health 2016 Oct 10;2:2055207616671461 [FREE Full text] [doi: 10.1177/2055207616671461] [Medline: 29942568]
48. Rahimi K, Velardo C, Triantafyllidis A, Conrad N, Shah SA, Chantler T, SUPPORT-HF Investigators, et al. A user-centred home monitoring and self-management system for patients with heart failure: a multicentre cohort study. Eur Heart J Qual Care Clin Outcomes 2015 Nov 01;1(2):66-71 [FREE Full text] [doi: 10.1093/ehjqcco/qcv013] [Medline: 29474596]
49. Triantafyllidis A, Velardo C, Chantler T, Shah SA, Paton C, Khorshidi R, SUPPORT-HF Investigators. A personalised mobile-based home monitoring system for heart failure: The SUPPORT-HF Study. Int J Med Inform 2015 Oct;84(10):743-753. [doi: 10.1016/j.ijmedinf.2015.05.003] [Medline: 26037921]
50. Triantafyllidis A, Velardo C, Shah SA, Tarassenko L, Chantler T, Paton C, et al. Supporting heart failure patients through personalized mobile health monitoring. 2015 Presented at: 4th International Conference on Wireless Mobile Communication and Healthcare - Transforming Healthcare Through Innovations in Mobile and Wireless Technologies (MOBIHEALTH); November 3-5, 2014; Athens, Greece. [doi: 10.4108/icst.mobihealth.2014.257217]
51. Duff O, Walsh D, Malone S, McDermott L, Furlong B, O'Connor N, et al. MedFit app, a behavior-changing, theoretically informed mobile app for patient self-management of cardiovascular disease: user-centered development. JMIR Form Res 2018 Apr 27;2(1):e8 [FREE Full text] [doi: 10.2196/formative.9550] [Medline: 30684426]

52. Kuklyte J, Gualano L, Prabhu G, Venkataraman K, Walsh D, Woods C, et al. MedFit: A Mobile Application for Patients in CVD Recovery. 2017 Presented at: 2nd International Workshop on Multimedia for Personal Health and Health Care; Mountain View, CA; October 23, 2017. [doi: 10.1145/3132635.3132651]
53. Prabhu G, Kuklyte J, Gualano L, Venkataraman K, Ahmadi A, Duff O, et al. Design and development of the medFit app: A mobile application for cardiovascular disease rehabilitation. 2017 Presented at: 7th International Conference on Wireless Mobile Communication and Healthcare; November 14-15, 2017; Vienna, Austria. [doi: 10.1007/978-3-319-98551-0_3]
54. Villalba E, Salvi D, Peinado I, Ottaviano M, Arredondo MT. Validation Results of the User Interaction in a Heart Failure Management System. 2009 Presented at: International Conference on eHealth, Telemedicine, and Social Medicine; February 1-7, 2009; Cancun, Mexico. [doi: 10.1109/etelemed.2009.41]
55. Villalba E, Arredondo M, Ottaviano M, Salvi D, Hoyo-Barbolla E, Guillen S. Heart failure monitoring system based on wearable and information technologies. JCM 2007 Mar 01;2(2):1. [doi: 10.4304/jcm.2.2.10-21]
56. Villalba Mora E, Salvi D, Ottaviano M, Peinado I, Waldmeyer MTA. Iterative user interaction design for wearable and mobile solutions to assess cardiovascular chronic diseases. In: Pavlidis I, editor. Human Computer Interaction. London, England: IntechOpen; 2008:335-354.
57. Chandler J, Sox L, Kellam K, Feder L, Nemeth L, Treiber F. Impact of a culturally tailored mHealth medication regimen self-management program upon blood pressure among hypertensive Hispanic adults. Int J Environ Res Public Health 2019 Apr 06;16(7):1 [FREE Full text] [doi: 10.3390/ijerph16071226] [Medline: 30959858]
58. Davidson TM, McGillicuddy J, Mueller M, Brunner-Jackson B, Favella A, Anderson A, et al. Evaluation of an mHealth medication regimen self-management program for African American and Hispanic uncontrolled hypertensives. J Pers Med 2015 Nov 17;5(4):389-405 [FREE Full text] [doi: 10.3390/jpm5040389] [Medline: 26593951]
59. McGillicuddy JW, Gregoski MJ, Weiland AK, Rock RA, Brunner-Jackson BM, Patel SK, et al. Mobile health medication adherence and blood pressure control in renal transplant recipients: A proof-of-concept randomized controlled trial. JMIR Res Protoc 2013 Sep 04;2(2):e32 [FREE Full text] [doi: 10.2196/resprot.2633] [Medline: 24004517]
60. McGillicuddy JW, Weiland AK, Frenzel RM, Mueller M, Brunner-Jackson BM, Taber DJ, et al. Patient attitudes toward mobile phone-based health monitoring: questionnaire study among kidney transplant recipients. J Med Internet Res 2013 Jan 08;15(1):e6 [FREE Full text] [doi: 10.2196/jmir.2284] [Medline: 23305649]
61. McGillicuddy JW, Gregoski M, Brunner-Jackson BM, Weiland AK, Patel SK, Rock RA, et al. Facilitating medication adherence and eliminating therapeutic inertia using wireless technology: proof of concept findings with uncontrolled hypertensives and kidney transplant recipients. 2012 Presented at: Conference on Wireless Health; October 23-25, 2012; San Diego, CA. [doi: 10.1145/2448096.2448108]
62. Sieverdes J, Gregoski M, Patel S, Williamson D, Brunner-Jackson B, Rundbaken J, et al. mHealth medication and blood pressure self-management program in Hispanic hypertensives: a proof of concept trial. Smart Homecare Technology and TeleHealth 2013 Oct;1:1-10. [doi: 10.2147/SHTT.S49633]
63. Baek H, Suh J, Kang S, Kang S, Lim TH, Hwang H, et al. Enhancing user experience through user study: Design of an mHealth tool for self-management and care engagement of cardiovascular disease patients. JMIR Cardio 2018 Feb 09;2(1):e3 [FREE Full text] [doi: 10.2196/cardio.9000] [Medline: 31758783]
64. Lentferink AJ, Oldenhuis HK, de Groot M, Polstra L, Velthuijsen H, van Gemert-Pijnen JEWC. Key components in eHealth interventions combining self-tracking and persuasive eCoaching to promote a healthier lifestyle: A scoping review. J Med Internet Res 2017 Aug 01;19(8):e277 [FREE Full text] [doi: 10.2196/jmir.7288] [Medline: 28765103]
65. Mamykina L, Smaldone AM, Bakken SR. Adopting the sensemaking perspective for chronic disease self-management. J Biomed Inform 2015 Aug;56:406-417 [FREE Full text] [doi: 10.1016/j.jbi.2015.06.006] [Medline: 26071681]
66. Morton K, Dennison L, May C, Murray E, Little P, McManus R, et al. Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies. Patient Educ Couns 2017 Apr;100(4):616-635 [FREE Full text] [doi: 10.1016/j.pec.2016.10.019] [Medline: 28029572]
67. Mamykina L, Heitkemper EM, Smaldone AM, Kukafka R, Cole-Lewis HJ, Davidson PG, et al. Personal discovery in diabetes self-management: Discovering cause and effect using self-monitoring data. J Biomed Inform 2017 Dec;76:1-8 [FREE Full text] [doi: 10.1016/j.jbi.2017.09.013] [Medline: 28974460]
68. Turchioe M, Heitkemper E, Lor M, Burgermaster M, Mamykina L. Designing for engagement with self-monitoring: A user-centered approach with low-income, Latino adults with Type 2 Diabetes. Int J Med Inform 2019 Oct;130:103941 [FREE Full text] [doi: 10.1016/j.ijmedinf.2019.08.001] [Medline: 31437618]
69. Nordfonn OK, Morken IM, Bru LE, Husebø AML. Patients' experience with heart failure treatment and self-care-A qualitative study exploring the burden of treatment. J Clin Nurs 2019 May;28(9-10):1782-1793. [doi: 10.1111/jocn.14799] [Medline: 30667120]
70. Fivecoat HC, Sayers SL, Riegel B. Social support predicts self-care confidence in patients with heart failure. Eur J Cardiovasc Nurs 2018 Oct;17(7):598-604 [FREE Full text] [doi: 10.1177/1474515118762800] [Medline: 29533083]
71. Vo V, Auroy L, Sarradon-Eck A. Patients' perceptions of mHealth apps: Meta-ethnographic review of qualitative studies. JMIR Mhealth Uhealth 2019 Jul 10;7(7):e13817 [FREE Full text] [doi: 10.2196/13817] [Medline: 31293246]

72. van Velsen L, Broekhuis M, Jansen-Kosterink S, Op den Akker H. Tailoring persuasive electronic health strategies for older adults on the basis of personal motivation: Web-based survey study. J Med Internet Res 2019 Sep 06;21(9):11759 [FREE Full text] [doi: 10.2196/11759] [Medline: 31493323]
73. Tadas S, Coyle D. Barriers to and facilitators of technology in cardiac rehabilitation and self-management: Systematic qualitative grounded theory review. J Med Internet Res 2020 Nov 11;22(11):e18025. [doi: 10.2196/18025] [Medline: 33174847]
74. Won MH, Son Y. Perceived social support and physical activity among patients with coronary artery disease. West J Nurs Res 2017 Dec 23;39(12):1606-1623. [doi: 10.1177/0193945916678374] [Medline: 27881811]
75. Middlemass JB, Vos J, Siriwardena AN. Perceptions on use of home telemonitoring in patients with long term conditions - concordance with the Health Information Technology Acceptance Model: a qualitative collective case study. BMC Med Inform Decis Mak 2017 Jun 26;17(1):89 [FREE Full text] [doi: 10.1186/s12911-017-0486-5] [Medline: 28651588]
76. Greenhalgh T, A'Court C, Shaw S. Understanding heart failure; explaining telehealth - a hermeneutic systematic review. BMC Cardiovasc Disord 2017 Jun 14;17(1):156 [FREE Full text] [doi: 10.1186/s12872-017-0594-2] [Medline: 28615004]
77. Geurts E, Haesen M, Dendale P, Luyten K, Coninx K. Back on bike: the BoB mobile cycling app for secondary prevention in cardiac patients. 2016 Presented at: 18th International Conference on Human-Computer Interaction with Mobile Devices and Services; September 6-9, 2016; Florence, Italy. [doi: 10.1145/2935334.2935377]
78. Huygens MWJ, Swinkels ICS, de Jong JD, Heijmans MJWM, Friele RD, van Schayck OCP, et al. Self-monitoring of health data by patients with a chronic disease: does disease controllability matter? BMC Fam Pract 2017 Mar 20;18(1):40 [FREE Full text] [doi: 10.1186/s12875-017-0615-3] [Medline: 28320330]
79. Riegel B, Dickson VV, Garcia LE, Masterson Creber R, Streur M. Mechanisms of change in self-care in adults with heart failure receiving a tailored, motivational interviewing intervention. Patient Educ Couns 2017 Feb;100(2):283-288 [FREE Full text] [doi: 10.1016/j.pec.2016.08.030] [Medline: 27599712]
80. Vellone E, Paturzo M, D'Agostino F, Petruzzo A, Masci S, Ausili D, et al. MOTIVATional intErviewing to improve self-care in Heart Failure patients (MOTIVATE-HF): Study protocol of a three-arm multicenter randomized controlled trial. Contemp Clin Trials 2017 Apr;55:34-38. [doi: 10.1016/j.cct.2017.02.003] [Medline: 28185994]
81. Radhakrishnan K, Baranowski T, Julien C, Thomaz E, Kim M. Role of digital games in self-management of cardiovascular diseases: A scoping review. Games Health J 2019 Apr;8(2):65-73 [FREE Full text] [doi: 10.1089/g4h.2018.0011] [Medline: 30199275]
82. Berry ABL, Lim C, Hartzler AL, Hirsch T, Ludman E, Wagner EH, et al. Eliciting values of patients with multiple chronic conditions: Evaluation of a patient-centered framework. AMIA Annu Symp Proc 2017;2017:430-439 [FREE Full text] [Medline: 29854107]
83. Berry ABL, Lim C, Hartzler AL, Hirsch T, Ludman E, Wagner EH, et al. Creating Conditions for Patients' Values to Emerge in Clinical Conversations: Perspectives of Health Care Team Members. 2017 Presented at: Conference on Designing Interactive Systems; June 10-14, 2017; Edinburgh, UK. [doi: 10.1145/3064663.3064669]
84. Berry ABL, Lim C, Hartzler AL, Hirsch T, Wagner EH, Ludman E, et al. How Values Shape Collaboration Between Patients with Multiple Chronic Conditions and Spousal Caregivers Share on. 2017 Presented at: CHI Conference on Human Factors in Computing Systems; May 6-11, 2017; Denver, CO. [doi: 10.1145/3025453.3025923]
85. Berry ABL, Lim CY, Hirsch T, Hartzler AL, Kiel LM, Bermet ZA, et al. Supporting Communication About Values Between People with Multiple Chronic Conditions and their Providers. 2019 Presented at: CHI Conference on Human Factors in Computing Systems; May 4-9, 2019; Glasgow, UK. [doi: 10.1145/3290605.3300700]
86. Riegel B, Jaarsma T, Strömberg A. A middle-range theory of self-care of chronic illness. ANS Adv Nurs Sci 2012;35(3):194-204. [doi: 10.1097/ANS.0b013e318261b1ba] [Medline: 22739426]
87. Cornet V, Voida S, Holden RJ. Activity theory analysis of heart failure self-care. Mind Cult Act 2018 Sep 21;25(1):22-39 [FREE Full text] [doi: 10.1080/10749039.2017.1372785] [Medline: 31105419]
88. Cornet VP, Daley C, Cavalcanti LH, Parulekar A, Holden RJ. Chapter 14 - Design for self-care. In: Sethumadhavan A, Sasangohar F, editors. Design for Health: Applications of Human Factors. Cambridge, MA: Academic Press; 2020:277-302.
89. Holden R, Schubert C, Mickelson R. The patient work system: an analysis of self-care performance barriers among elderly heart failure patients and their informal caregivers. Appl Ergon 2015 Mar;47:133-150 [FREE Full text] [doi: 10.1016/j.apergo.2014.09.009] [Medline: 25479983]
90. Lim CY, Berry ABL, Hartzler AL, Hirsch T, Carrell DS, Bermet ZA, et al. Facilitating Self-reflection about Values and Self-care Among Individuals with Chronic Conditions. 2019 Presented at: CHI Conference on Human Factors in Computing Systems; May 4-9, 2019; Glasgow, UK. [doi: 10.1145/3290605.3300885]
91. Lim CY, Berry ABL, Hirsch T, Hartzler AL, Wagner EH, Ludman EJ, et al. Understanding what is most important to individuals with multiple chronic conditions: A qualitative study of patients' perspectives. J Gen Intern Med 2017 Dec 28;32(12):1278-1284 [FREE Full text] [doi: 10.1007/s11606-017-4154-3] [Medline: 28849368]
92. Blair J, Volpe M, Aggarwal B. Challenges, needs, and experiences of recently hospitalized cardiac patients and their informal caregivers. J Cardiovasc Nurs 2014 Mar 22;29(1):29-37 [FREE Full text] [doi: 10.1097/JCN.0b013e3182784123] [Medline: 23416934]

93. Burns C. Human centred design. In: van Gemert-Pijnen L, Kelders SM, Kip H, Sanderman R, editors. eHealth Research, Theory and Development. Oxfordshire, England: Routledge; 2018:207-227.
94. Vaughan Dickson V, Lee CS, Riegel B. How do cognitive function and knowledge affect heart failure self-care? Journal of Mixed Methods Research 2011 Mar 23;5(2):167-189. [doi: 10.1177/1558689811402355]
95. Dickson VV, Buck H, Riegel B. Multiple comorbid conditions challenge heart failure self-care by decreasing self-efficacy. Nurs Res 2013;62(1):2-9. [doi: 10.1097/NNR.0b013e31827337b3] [Medline: 23052421]
96. Hendry DG, Friedman B, Ballard S. Value sensitive design as a formative framework. Ethics Inf Technol 2021 Feb 26;23(1):39-44. [doi: 10.1007/s10676-021-09579-x]
97. Cornet VP, Toscos T, Bolchini D, Rohani Ghahari R, Ahmed R, Daley C, et al. Untold stories in user-centered design of mobile health: Practical challenges and strategies learned from the design and evaluation of an app for older adults with heart failure. JMIR Mhealth Uhealth 2020 Jul 21;8(7):e17703 [FREE Full text] [doi: 10.2196/17703] [Medline: 32706745]
98. Collins LM. Optimization of Behavioral, Biobehavioral, and Biomedical Interventions: The Multiphase Optimization Strategy (MOST). Cham, Switzerland: Springer; 2018:55-56.

Abbreviations

CeHRes: Center for eHealth Research
CVD: cardiovascular diseases
KALPHA: Krippendorf alpha
MOST: Multiphase Optimization Strategy

Edited by G Eysenbach; submitted 12.07.21; peer-reviewed by V Cornet, K Blondon; comments to author 03.08.21; revised version received 16.08.21; accepted 03.10.21; published 01.12.21.

Please cite as:
Cruz-Martínez RR, Wentzel J, Bente BE, Sanderman R, van Gemert-Pijnen JEWC
Toward the Value Sensitive Design of eHealth Technologies to Support Self-management of Cardiovascular Diseases: Content Analysis
JMIR Cardio 2021;5(2):e31985
URL: https://cardio.jmir.org/2021/2/e31985
doi:10.2196/31985
PMID:34855608

Original Paper

Efficacy of Telemedicine in Hypertension Care Through Home Blood Pressure Monitoring and Videoconferencing: Randomized Controlled Trial

Junichi Yatabe[1], MD, PhD; Midori Sasaki Yatabe[1], MD, PhD; Rika Okada[2], MD; Atsuhiro Ichihara[3], MD, PhD

[1]General Incorporated Association TelemedEASE, Shinjuku-ku, Tokyo, Japan

[2]TM Clinic Nishishinjuku, Shinjuku-ku, Tokyo, Japan

[3]Department of Endocrinology and Hypertension, Tokyo Women's Medical University, Shinjuku-ku, Tokyo, Japan

Corresponding Author:
Junichi Yatabe, MD, PhD
General Incorporated Association TelemedEASE
201 FARO Kagurazaka, 5-1 Fukuromachi
Shinjuku-ku, Tokyo, 162-0828
Japan
Phone: 81 3 6869 6938
Fax: 81 3 6478 8301
Email: jyatabe@telemedease.org

Abstract

Background: The burden of time is often the primary reason why patients discontinue their treatment. Telemedicine may help patients adhere to treatment by offering convenience.

Objective: This study examined the efficacy and safety of telemedicine for the management of hypertension in Japan.

Methods: Patients with uncomplicated hypertension were recruited through web advertising between November 2015 and February 2017. They were then screened, stratified by office systolic blood pressure (SBP), and randomized into two groups: usual care (UC) and telemedicine. The telemedicine group used a 3G network–attached home blood pressure (BP) monitoring device, consulted hypertension specialists from an academic hospital through web-based video visits, and received prescription medication by mail for 1 year. The UC group used the same BP monitoring device but was managed using self-recorded BP readings, which included their diary entries and office BP taken in a community practice setting.

Results: Initial screening was completed by 99 patients, 54% of whom had untreated hypertension. Baseline BP was similar between the groups, but the weekly average SBP at the end of the 1-year study period was significantly lower in the telemedicine group (125, SD 9 mmHg vs 131, SD 12 mmHg, respectively; *P*=.02). SBP in the telemedicine group was 3.4 mmHg lower in the morning and 5.8 mmHg lower in the evening. The rate of SBP control (135 mmHg) was better in the telemedicine group (85.3% vs 70.0%; *P*=.01), and significant adverse events were not observed.

Conclusions: We present evidence suggesting that antihypertensive therapy via home BP telemonitoring and web-based video visits achieve better BP control than conventional care and is a safe treatment alternative that warrants further investigation.

Trial Registration: UMIN-CTR UMIN000025372; https://tinyurl.com/47ejkn4b

(JMIR Cardio 2021;5(2):e27347) doi:10.2196/27347

KEYWORDS

blood pressure management; digital health; web-based medicine; prospective study; telemonitoring; blood pressure; monitoring; telemedicine; telehealth; efficacy; hypertension; video conference; safety; Japan

Introduction

Antihypertensive therapy has advanced over the years to enable lowering of blood pressure (BP) in most patients with hypertension if they receive proper treatment. Nevertheless, in Japan, only 12 million of 43 million individuals with hypertension receive treatment and have their BP controlled [1]. This phenomenon, termed the "hypertension paradox," must be resolved to improve public health [2]. Among the reasons why individuals do not take action to control their hypertension,

the burden of time takes precedence for discontinuation or noninitiation of antihypertensive treatment. Telemedicine using internet-based communication may lower the hurdle for starting and adhering to hypertension treatment, eventually leading to the prevention of cardiovascular disease. This approach may also result in higher satisfaction among patients by allowing better use of their time rather than having them spend much of it waiting at clinics or hospitals. Technical difficulty and anxiety associated with telemedicine hence need to be managed sufficiently.

Achieving target BP levels in the treatment of hypertension requires patients' adherence to and persistence in taking their medication. Self-measurement of home BP (SMBP) helps improve adherence to treatment and aids in BP control [3,4]. Adjusting antihypertensive medication based on self-measured home BP (HBP) for long periods is feasible, and HBP self-monitoring with self-titration of antihypertensive medication in accordance with an individualized predetermined protocol has been reported to result in better BP control than that with usual care (UC) [5].

In Japan, telemedicine without face-to-face communication has been permitted since early 2015. We developed an integrated web-based telemedicine platform to manage appointments, medical care, and payment without patients visiting a clinic. However, clinical evidence concerning the efficacy and safety of telemedicine remains scarce. In this study, we attempted to demonstrate the advantages of telemedicine over traditional care in the management of hypertension. The Paradigm of Antihypertensive Therapy along with Telemedicine Randomized (POATRAND) trial was designed and performed as a prospective, randomized, open-label, 2-arm study of patients with uncontrolled, uncomplicated hypertension to test the effectiveness and safety of BP telemonitoring as well as hypertension telemedicine.

Methods

Study Design and Participant Recruitment

The POATRAND trial was a multicenter, open-label randomized controlled trial performed at Tokyo Women's Medical University Clinic and private clinics in Japan. Potentially eligible participants with hypertension were recruited through web advertising. The inclusion criteria were age over 20 years, elevated systolic BP (SBP) or diastolic BP (DBP), ability to visit the Tokyo Women's Medical University Clinic for the initial screening, willingness to receive hypertension care through telemedicine, and ability to self-measure HBP. The exclusion criteria were inability to use a smartphone, pregnancy, presence of major cardiovascular events and diabetes mellitus, an estimated glomerular filtration rate lower than 30 mL/min/1.73 m^2 determined using the modified Modification of Diet in Renal Disease formula for Japanese patients [6], and presence of secondary hypertension excluding primary aldosteronism without surgical indication. The study protocol was approved by the Tokyo Women's Medical University Research Ethics Committee (approval 160603) and registered in the UMIN Clinical Trials Registry under accession number UMIN000025372. All patients provided their written informed consent to participate in the study.

Randomization

Potentially eligible patients were invited to Tokyo Women's Medical University Clinic between November 2015 and February 2017 for screening. After eligibility screening and provision of informed consent, each patient's office BP was measured with the patient sitting quietly alone in a room. Before measurement, an experienced staff member instructed the patient on the procedure, placed a cuff with an appropriately sized bladder on the patient's upper left arm, and left the room. BP was measured 3 times at 3-min intervals. Office BP was measured using the same validated BP monitor as the one used for home BP measurements (HEM-7252G-HP; Omron) [7], and the values were not concealed from the participants. At the second baseline visit, screening results were communicated to the participants, and the participants were stratified by the average of the second and third office SBP readings at the first visit and randomly assigned at a 1:1 ratio into the UC or telemedicine group, using an Excel-based random sampling number system.

Procedures

HBP was measured using a 3G network–equipped automatic sphygmomanometer (HEM-7252G-HP; Omron) [7]. The device was based on the cuff–oscillometric principle and validated to meet the criteria of the Association for the Advancement of Medical Instrumentation. The device recorded and transmitted SBP and DBP values, heart rate, and the date and time of each measurement. Registered patients were instructed on how to use the device and asked to take their HBP reading in a sitting position twice every morning within 1 h of waking before taking a meal or medication and after more than 2 minutes of rest. Participants were also asked to measure their HBP twice every evening before going to bed. The telemedicine group used this device, consulted a physician through web-based visits in consideration of their transmitted BP values, and received prescription medication by mail for 1 year. The UC group used the same BP monitoring device but was managed with actual office visits using self-recorded BP readings, such as their diary entries. After randomization, baseline HBP was measured in both groups without changes in treatment. The standard visit-to-visit interval was set at 6 weeks for the telemedicine group and was unspecified for the UC group, leaving it to the physician's discretion.

Primary and Secondary Outcomes

The primary outcome was the average home SBP during the last week of the 12-month study period. Secondary outcomes included other measures of office BP and HBP including morning and evening SBP, DBP, and BP control rates, adverse events (eg, side effects and cardiovascular events), medication prescription (ie, number and defined daily dose), body weight, and laboratory measures.

Statistical Analysis

We initially estimated that 260 patients were required for screening per group to detect a 4-mmHg difference in home SBP values between the 2 groups, with a 2-sided *P* value of .05

and 80% power. However, the study was prematurely terminated at the end of March 2018 because the health insurance policy in Japan changed, requiring a face-to-face visit at least every 3 months. SPSS (version 21, IBM Corp) was used for statistical analyses. All *P* values were 2-sided, and $P \leq .05$ was considered statistically significant. Data are presented as mean (SD) values unless otherwise indicated.

Results

Baseline Participant Characteristics

In total, 159 patients were screened for the study (Figure 1). Their baseline characteristics are shown in Table 1. The groups did not show significant differences in age, female-to-male ratio, BMI, home SBP, home DBP, pulse rate, plasma aldosterone concentration, plasma renin activity, estimated glomerular filtration rate, hemoglobin A_{1c} level, and low-density-lipoprotein cholesterol (LDL-C) level. At the end of the study, we assessed 46 individuals from the UC group and 48 from the telemedicine group. Dropout rates and adverse events are discussed subsequently.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flowchart for the study. TM: telemedicine, UC: usual care.

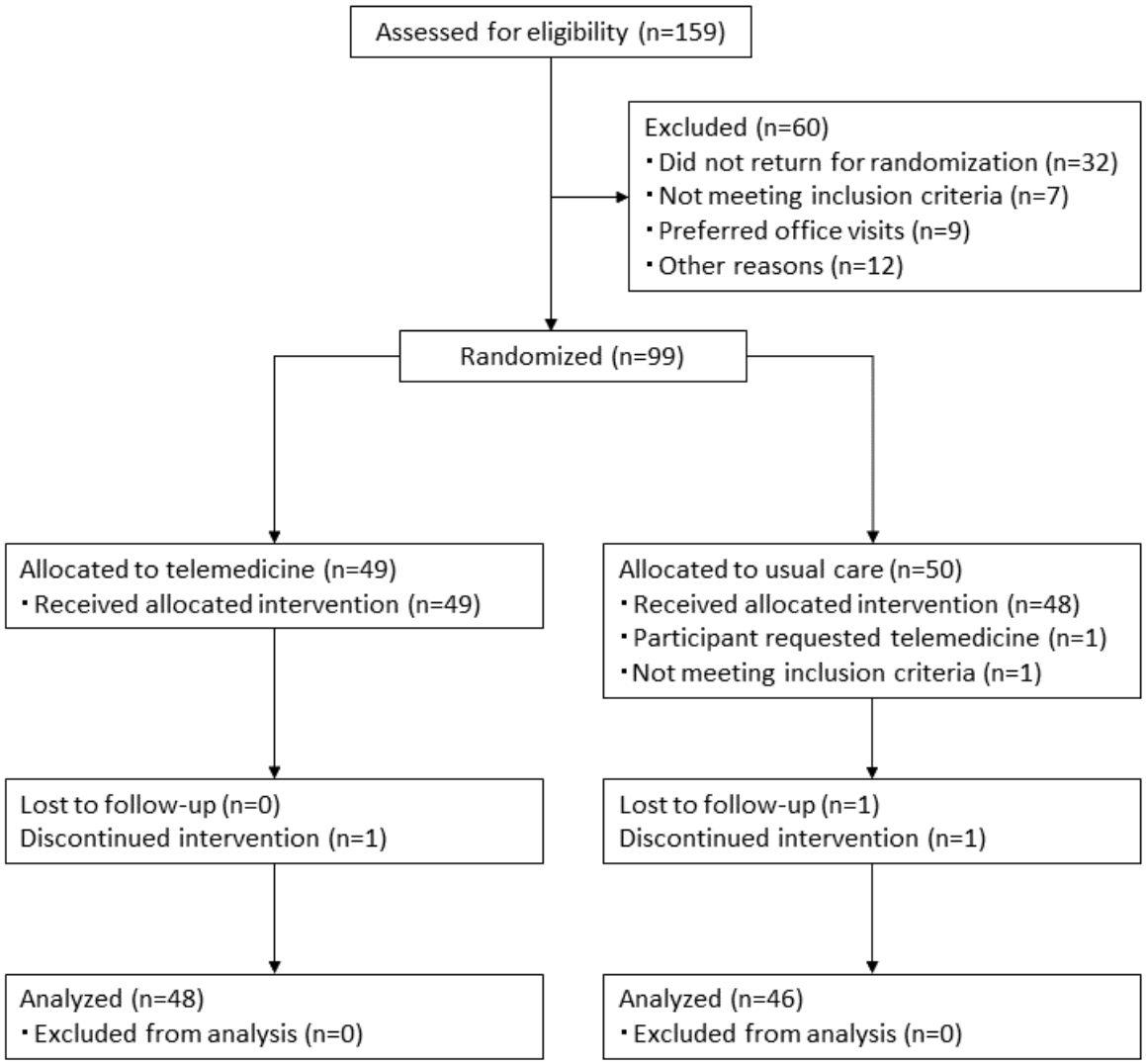


Table 1. Baseline characteristics of the study participants (N=97).

Parameters	All participants	Usual care group (n=48)	Telemedicine group (n=49)
Female, n (%)	58 (60%)	30 (63%)	28 (57%)
Age (years), mean (SD)	53 (9)	53 (9)	53 (9)
BMI (kg/m^2), mean (SD)	24.2 (3.9)	24.3 (4.3)	24.2 (3.4)
Home systolic blood pressure (mmHg), mean (SD)	136 (13)	136 (11)	136 (15)
Home diastolic blood pressure (mmHg), mean (SD)	91 (9)	91 (8)	90 (10)
Home pulse rate (bpm), mean (SD)	73 (9)	74 (9)	73 (9)
Antihypertensive treatment, n (%)	55 (57)	29 (60)	26 (53)
Estimated glomerular filtration rate (mL/min/1.73 m^2), mean (SD)	75.9 (14.0)	77.3 (13.3)	74.4 (14.4)
Low-density-lipoprotein cholesterol (mg/dL), mean (SD)	121.1 (28.8)	119.2 (28.9)	123.0 (28.3)
Hemoglobin A_{1c} (%), mean (SD)	5.7 (0.3)	5.6 (0.3)	5.7 (0.3)
Plasma aldosterone (pg/mL), median (IQR)	155 (119-216)	150 (112-199)	167 (136-232)
Plasma renin activity (ng/mL/h), median (IQR)	1.1 (0.6-1.9)	0.9 (0.5-1.8)	1.2 (0.9-2.0)

Changes in HBP and Laboratory Data Before and After the Study

Home SBP and DBP significantly decreased after 1 year in both groups (Tables 2 and 3). Plasma renin activity was significantly increased in the UC group (*P*=.02) but not in the telemedicine group.

Table 2. Outcomes.

	Usual care group			Telemedicine group			*P* value
	Preintervention (n=48)	Postintervention (n=46)	*P* value	Preintervention (n=49)	Postintervention (n=48)	*P* value	
BMI (kg/m^2), mean (SD)	24.2 (4.3)	3.9 (4.1)	.86	24.2 (3.4)	23.9 (3.3)	.29	.10
Home systolic blood pressure (mmHg), median (95% CI)	136 (133-139)	131 (128-134)	.01	136 (132-140)	125 (122-128)	<.001	.02
Home diastolic blood pressure (mmHg), median (95% CI)	91 (89-93)	87 (85-89)	.02	90 (87-93)	83 (81-85)	<.001	.07
Home pulse rate (bpm), mean (SD)	74 (9)	71 (7)	.46	73 (9)	71 (8)	.08	.08
Systolic blood pressure control rate (%)	41.3	70.0	<.001	47.7	85.4	<.001	.01
Estimated glomerular filtration rate (mL/min/1.73 m^2), mean (SD)	77.3 (13.3)	76.8 (11.9)	.16	74.4 (14.4)	72.4 (14.4)	.30	.05
Potassium (mEq/L), mean (SD)	4.1 (0.3)	4.1 (0.3)	.81	4.1 (0.3)	4.1 (0.3)	.65	.93
Low-density-lipoprotein cholesterol (mg/dL), mean (SD)	119.2 (28.9)	110.3 (22.7)	.53	123.0 (28.3)	123.8 (28.6)	.11	.04
Hemoglobin A_{1c} (%), mean (SD)	5.6 (0.3)	5.7 (0.3)	.74	5.7 (0.3)	5.7 (0.4)	.60	.53
Plasma aldosterone (pg/mL), median (IQR)	150 (112-199)	151 (115-226)	.07	167 (136-232)	171 (139-229)	.54	.49
Plasma renin activity (ng/mL/h), median (IQR)	0.9 (0.5-1.8)	1.1 (0.6-3.6)	.02	1.2 (0.9-2.0)	1.9 (1.1-4.8)	.07	.57

Table 3. Home blood pressure change from baseline till the end of the 1-year study period.

	Usual care group	Telemedicine group	*P* value
Change in systolic blood pressure (mmHg), mean (SD)	–5.4 (11.3)	–9.2 (14.3)	.23
Change in diastolic blood pressure (mmHg), mean (SD)	–3.5 (8.1)	–5.5 (8.7)	.33

Differences in HBP Between the Participant Groups

The average home SBP during the last week of the study was significantly lower (by 6 mmHg) in the telemedicine group than in the UC group (Table 2). Home DBP after the 1-year study period tended to be lower in the telemedicine group, but the difference was not significant. The average SBP and DBP reached the therapeutic targets of less than 135 mmHg and 85 mmHg, respectively, at the time of measurement in the telemedicine group only.

When morning (4-10:59 AM) and evening (6 PM to 3:59 AM) BPs were analyzed separately (Table 4), the telemedicine group showed significantly lower evening SBP and DBP readings. The average morning SBP and DBP readings were also lower in the telemedicine group, but the difference was not significant.

The number of BP measurements per week for the whole study period was significantly higher in the telemedicine group (17.8, SD 11.5) than in the UC group (12.1, SD 11.0) (P=.02).

Table 4. Average morning and evening home blood pressure readings during the last week of the 1-year study period.

	Usual care group (n=46), mean (SD)	Telemedicine group (n=48), mean (SD)	*P* value
Morning			
Home systolic blood pressure (mmHg)	134.0 (8.6)	130.6 (10.3)	.09
Home diastolic blood pressure (mmHg)	90.6 (7.2)	88.3 (7.7)	.14
Home pulse rate (bpm)	71.6 (8.0)	69.7 (7.5)	.25
Evening			
Home systolic blood pressure (mmHg)	131.6 (8.7)	125.8 (11.5)	.007
Home diastolic blood pressure (mmHg)	87.2 (7.5)	82.5 (7.5)	.003
Home pulse rate (bpm)	76.3 (9.4)	74.2 (8.5)	.27

Clinical Parameters at the End of the Study

At the end of the study, LDL-C was significantly lower in the UC group than in the telemedicine group. Plasma renin activity was not significantly different between the 2 groups at baseline, but significantly increased at the endpoint only in the UC group. The endpoint plasma renin activity was not significantly different between the 2 groups. Other laboratory data were not significantly different between the 2 groups.

Prescription Data for Antihypertensive Medications

Percentages of antihypertensive treatment are shown in Table 5.

Table 5. Prescription data.

	Usual care group	Telemedicine group	
	Preintervention (n=48), n (%)	Preintervention (n=49), n (%)	Postintervention (n=48), n (%)
No medication	29 (60.0)	26 (54.2)	7 (14.6)
Calcium channel blocker only	11 (23.0)	13 (27.1)	8 (16.7)
Angiotensin II receptor blocker only	0 (0)	2 (4.2)	3 (6.3)
Mineralocorticoid receptor blocker only	2 (4.0)	0 (0)	3 (6.3)
Angiotensin II receptor blocker/angiotensin converting enzyme inhibitor + calcium channel blocker	5 (10.0)	7 (14.6)	22 (45.8)
Mineralocorticoid receptor blocker + calcium channel blocker	1 (2.0)	1 (2.1)	3 (6.3)
Angiotensin II receptor blocker + diuretic	0 (0)	0 (0)	0 (0)
Angiotensin II receptor blocker/angiotensin converting enzyme inhibitor + calcium channel blocker + diuretic	0 (0)	0 (0)	2 (4.2)

Dropout Rates and Adverse Events

Of the 50 and 49 participants allocated to the UC and telemedicine groups, respectively, we assessed 46 from the UC group and 48 from the telemedicine group. In the UC group, a participant requested telemedicine, another did not meet the inclusion criteria, and another was lost to follow-up; hence, all 3 were excluded from the study. One participant from the UC group experienced a mild subarachnoid hemorrhage with no neurological deficits or hospitalization and dropped out of the study. In the telemedicine group, 1 participant experienced angina pectoris and discontinued the intervention. Medication-related complaints upon initiation or change of antihypertensive drugs included urticaria (n=1) and concerns of having considerably low BP (n=3). No discontinuation owing

to drug side effects or difficulty using the telemedicine interface was recorded.

Discussion

Principal Findings

This study, for the first time in Japan, conducted hypertension treatment using telemonitoring and telemedicine without face-to-face visits for 1 year and revealed 2 major findings. First, telemedicine without actual office visits was determined to be relatively safe in managing hypertension for 1 year. Second, the telemedicine group achieved a lower BP than the UC group. Although the BP difference from baseline was not significantly different between the groups, the telemedicine group demonstrated a reduction in SBP of 9.2 mmHg, whereas the reduction in the UC group was 5.4 mmHg.

In a previous study that investigated the safety of telemedicine without office visits, the number of adverse events was not significantly different from that of UC. In the Telemonitoring and Self-management of Hypertension (TASMINH2) Trial, the frequency of side effects, such as swelling of legs, stiff joints, fatigue, and cough, was similar between the telemedicine and UC groups [5]. In our study, 2 patients dropped out owing to cardiovascular events during the study: 1 from the telemedicine group for new-onset angina pectoris and 1 from the UC group for subarachnoid hemorrhage. No significant difference in the laboratory findings was observed between the 2 groups at the end of the study, except for lower LDL-C in the UC group. Medication-related complaints were successfully managed through web-based consultations. The results of this and previous studies suggest that telemedicine is reasonably safe for use in controlling BP in uncomplicated hypertension.

Superior BP control in the telemedicine group than that in the UC group could be attributed to several factors, one being the intensity of the intervention. Sheppard et al [8] demonstrated that intense interventions, such as pharmacotherapeutic intervention managed by a pharmacist, with frequent telemonitoring, were more effective than low-intensity interventions, such as telemonitoring only, in patients with obesity. In this study, the telemedicine group received team-based care from physicians specializing in hypertension, and the participants were able to ask questions using the app. Therefore, the effects of antihypertensive intervention could have been enhanced by the more intensive interventions and greater expertise that the telemedicine group received. Several studies found that telemonitoring of BP improves BP control [3,4]. On the other hand, other studies showed that telemonitoring by itself does not significantly improve it [9]. Pellegrini et al [10] recently reported that self-monitoring of BP at home with co-interventions, such as telecounseling, favorably controlled BP more than self-monitoring of BP alone did. Nevertheless, regardless of their effects on BP control, advances in internet technology and data technology should accelerate the dissemination of BP telemonitoring and telemedicine, which would make retrospective analysis of BP management interventions in the future much easier than those in the past, when such analysis depended on a paper-based approach. In our previous study, an electronic sphygmomanometer with an automated 3G data transfer and room temperature monitor was used for daily SMBP [11]. BP variability based on SMBP can predict cardiovascular outcome in patients with hypertension [12,13]. Room temperature at the time of SMBP significantly correlates with variability of SBP [14,15]. Therefore, an HBP monitor equipped with various sensors, serving as the “Internet of Things,” may be used to monitor environmental conditions to maintain the optimal BP in future studies.

Regarding adherence, the frequency of HBP measurements was much higher in the telemedicine group than in the UC group. We do not have data on medication adherence, but Ogedegbe and Schoenthaler [16] demonstrated that HBP self-monitoring significantly improved medication adherence and reported that the telemedicine group self-monitored their BP more frequently.

Limitations

This study has several limitations. First, this study was limited by its design in that the physicians’ level of expertise differed for the telemedicine and UC groups. Second, although the rate of treated hypertension at baseline was not different between the groups, changes in prescription were precisely tracked only in the telemedicine group. Third, the number of visits for the UC group was not determined, and the average number of visits could not be compared. In Japan, regular face-to-face visits for hypertension management in clinics generally occur at 2- to 8-week intervals. Fourth, because the study was terminated prematurely, it did not reach its intended sample size, making the power of the study insufficient for some analyses. Nevertheless, our finding of a significantly lower HBP at the end of the study period in the telemedicine group despite a smaller-than-intended sample size is promising for the improvement of BP control through telemedicine. Fifth (related to the first limitation), although the participants in the UC group were referred to primary care physicians with a letter asking them to target an HBP of less than 135/85 mmHg, it is not clear whether the physicians actually adhered to this request [17]. Although this study cannot delineate the effects of telemonitoring, telemedicine, and specialist intervention compared with UC, ours is a real-world study providing pilot data on hypertension telemedicine in Japan, which can be used to design future studies.

Conclusions

Our results suggest that antihypertensive telemedicine using HBP telemonitoring and web-based video visits is safe. The telemedicine group of patients with uncomplicated hypertension achieved better BP control than the group assigned to conventional care. Further investigations are required to elucidate the benefits of telemedicine in treating hypertension on a larger scale.

Acknowledgments

This study was conducted at Tokyo Women's Medical University. This study was supported in part by the PORT Corporation. We gratefully acknowledge the excellent technical assistance of Erina Yamaguchi, who participated in data collection and analysis.

Authors' Contributions

JY and MSY contributed to the design of the study and performed data collection and analysis. JY, MSY, RO, and AI drafted, critically revised, and approved the final version of the paper for submission.

Conflicts of Interest

JY and MSY are directors of General Incorporated Association TelemedEASE, which aims to facilitate safe and effective telemedicine.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 729 KB - cardio_v5i2e27347_app1.pdf]

References

1. Umemura S, Arima H, Arima S, Asayama K, Dohi Y, Hirooka Y, et al. The Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2019). Hypertens Res 2019 Sep;42(9):1235-1481. [doi: 10.1038/s41440-019-0284-9] [Medline: 31375757]
2. Chobanian AV. Shattuck Lecture. The hypertension paradox--more uncontrolled disease despite improved therapy. N Engl J Med 2009 Aug 27;361(9):878-887. [doi: 10.1056/NEJMsa0903829] [Medline: 19710486]
3. Duan Y, Xie Z, Dong F, Wu Z, Lin Z, Sun N, et al. Effectiveness of home blood pressure telemonitoring: a systematic review and meta-analysis of randomised controlled studies. J Hum Hypertens 2017 Jul;31(7):427-437. [doi: 10.1038/jhh.2016.99] [Medline: 28332506]
4. Omboni S, Gazzola T, Carabelli G, Parati G. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomized controlled studies. J Hypertens 2013 Mar;31(3):455-467. [doi: 10.1097/HJH.0b013e32835ca8dd] [Medline: 23299557]
5. McManus R, Mant J, Bray E, Holder R, Jones MI, Greenfield S, et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. Lancet 2010 Jul 17;376(9736):163-172. [doi: 10.1016/S0140-6736(10)60964-6] [Medline: 20619448]
6. Horio M, Imai E, Yasuda Y, Watanabe T, Matsuo S. Modification of the CKD epidemiology collaboration (CKD-EPI) equation for Japanese: accuracy and use for population estimates. Am J Kidney Dis 2010 Jul;56(1):32-38. [doi: 10.1053/j.ajkd.2010.02.344] [Medline: 20416999]
7. Takahashi H, Yoshika M, Yokoi T. Validation of two automatic devices: Omron HEM-7252G-HP and Omron HEM-7251G for self-measurement of blood pressure according to the European Society of Hypertension International Protocol revision 2010. Blood Press Monit 2015 Oct;20(5):286-290. [doi: 10.1097/MBP.0000000000000127] [Medline: 25932887]
8. Sheppard J, Tucker K, Davison W, Stevens R, Aekplakorn W, Bosworth HB, et al. Self-monitoring of Blood Pressure in Patients With Hypertension-Related Multi-morbidity: Systematic Review and Individual Patient Data Meta-analysis. Am J Hypertens 2020 Mar 13;33(3):243-251 [FREE Full text] [doi: 10.1093/ajh/hpz182] [Medline: 31730171]
9. Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP, et al. Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. PLoS Med 2017 Sep;14(9):e1002389 [FREE Full text] [doi: 10.1371/journal.pmed.1002389] [Medline: 28926573]
10. Pellegrini D, Torlasco C, Ochoa JE, Parati G. Contribution of telemedicine and information technology to hypertension control. Hypertens Res 2020 Jul;43(7):621-628. [doi: 10.1038/s41440-020-0422-4] [Medline: 32203451]
11. Yatabe J, Yatabe MS, Morimoto S, Watanabe T, Ichihara A. Effects of room temperature on home blood pressure variations: findings from a long-term observational study in Aizumisato Town. Hypertens Res 2017 Aug;40(8):785-787. [doi: 10.1038/hr.2017.18] [Medline: 28230196]
12. Stevens SL, Wood S, Koshiaris C, Law K, Glasziou P, Stevens RJ, et al. Blood pressure variability and cardiovascular disease: systematic review and meta-analysis. BMJ 2016 Aug 09;354:i4098 [FREE Full text] [doi: 10.1136/bmj.i4098] [Medline: 27511067]
13. Juhanoja EP, Niiranen TJ, Johansson JK, Puukka PJ, Thijs L, Asayama K, International Database on Home Blood Pressure in Relation to Cardiovascular Outcome (IDHOCO) Investigators. Outcome-Driven Thresholds for Increased Home Blood Pressure Variability. Hypertension 2017 Apr;69(4):599-607. [doi: 10.1161/HYPERTENSIONAHA.116.08603] [Medline: 28193705]

14. Iwahori T, Miura K, Obayashi K, Ohkubo T, Nakajima H, Shiga T, et al. Seasonal variation in home blood pressure: findings from nationwide web-based monitoring in Japan. BMJ Open 2018 Jan 05;8(1):e017351 [FREE Full text] [doi: 10.1136/bmjopen-2017-017351] [Medline: 29306878]
15. Hanazawa T, Asayama K, Watabe D, Tanabe A, Satoh M, Inoue R, HOMED‐BP (Hypertension Objective Treatment Based on Measurement by Electrical Devices of Blood Pressure) Investigators. Association Between Amplitude of Seasonal Variation in Self-Measured Home Blood Pressure and Cardiovascular Outcomes: HOMED-BP (Hypertension Objective Treatment Based on Measurement By Electrical Devices of Blood Pressure) Study. J Am Heart Assoc 2018 May 04;7(10):e008509 [FREE Full text] [doi: 10.1161/JAHA.117.008509] [Medline: 29728372]
16. Ogedegbe G, Schoenthaler A. A systematic review of the effects of home blood pressure monitoring on medication adherence. J Clin Hypertens (Greenwich) 2006 Mar;8(3):174-180 [FREE Full text] [doi: 10.1111/j.1524-6175.2006.04872.x] [Medline: 16522994]
17. Nishigaki N, Shimasaki Y, Yoshida T, Hasebe N. Physician and patient perspectives on hypertension management and factors associated with lifestyle modifications in Japan: results from an online survey. Hypertens Res 2020 May;43(5):450-462 [FREE Full text] [doi: 10.1038/s41440-020-0398-0] [Medline: 31996815]

Abbreviations

BP: blood pressure
DBP: diastolic blood pressure
HBP: home blood pressure
LDL-C: low-density-lipoprotein cholesterol
POATRAND: Paradigm of Antihypertensive Therapy Along With Telemedicine Randomized Trial
SBP: systolic blood pressure
SMBP: self-measurement of home blood pressure
UC: usual care

Edited by G Eysenbach; submitted 31.01.21; peer-reviewed by B Green, S Omboni; comments to author 22.02.21; revised version received 20.07.21; accepted 28.07.21; published 31.08.21.

Please cite as:
Yatabe J, Yatabe MS, Okada R, Ichihara A
Efficacy of Telemedicine in Hypertension Care Through Home Blood Pressure Monitoring and Videoconferencing: Randomized Controlled Trial
JMIR Cardio 2021;5(2):e27347
URL: https://cardio.jmir.org/2021/2/e27347
doi:10.2196/27347
PMID:34321194

Original Paper

The Effects of Lifestyle Intervention Using the Modified Beliefs, Attitude, Subjective Norms, Enabling Factors Model in Hypertension Management: Quasi-Experimental Study

Resti Tito Villarino[1,2*], MA, LPT, RN; Christopher Asuncion Arcay[3*], MSc; Maria Concepcion Temblor[1*], MA; Maureen Lorence Villarino[4*], LPT, RN; Rosita Bagsit[1*], EdD; Lanndon Ocampo[5*], PhD; Paquito Bernard[6,7*], PhD

[1]Cebu Technological University, Moalboal Campus, Cebu, Philippines
[2]National Research Council of the Philippines, Manila, Philippines
[3]Mater Dei College, Tubigon, Bohol, Philippines
[4]University of San Agustin, Iloilo City, Philippines
[5]Cebu Technological University, Main Campus, Cebu City, Philippines
[6]Université du Québec à Montréal, Montréal, QC, Canada
[7]Research Center of the University Institute in Mental Health of Montreal, Montréal, QC, Canada
[*]all authors contributed equally

Corresponding Author:
Resti Tito Villarino, MA, LPT, RN
Cebu Technological University, Moalboal Campus
Moalboal
Cebu, 6032
Philippines
Phone: 63 9222212373
Email: villarino.resti_tito@courrier.uqam.ca

Abstract

Background: Hypertension is a serious health issue and a significant risk factor for cardiovascular disease and stroke. Although various health education models have been used to improve lifestyle in patients with hypertension, the findings have been inconsistent.

Objective: This study aims to assess the effects of a lifestyle intervention program using a modified Beliefs, Attitude, Subjective Norms, Enabling Factors (BASNEF) model among nonadherent participants with hypertension in managing elevated blood pressure (BP) levels.

Methods: This study reports a quantitative quasi-experimental research work, particularly using a repeated-measures design of the within-subjects approach on the 50 nonadherent patients who received a diagnosis of essential hypertension in Cebu, Philippines. The research participants received 5 sessions of training based on a modified BASNEF model. An adherence instrument was used as an evaluation platform. The first phase gathers participants' relevant profiles and background, and the final phase gathers participants' systolic BP, diastolic BP, heart rate, and adherence scores.

Results: The results indicate that the phase 1 mean systolic readings (146.50, SD 19.59) differ significantly from the phase 4 mean systolic readings (134.92, SD 15.24). They also suggest that the lifestyle intervention based on session III or phase IV behavioral intention in the BASNEF model microgroup sessions positively affects BP readings among the research participants.

Conclusions: This study has established that the BASNEF model approach can be a good BP management technique.

(JMIR Cardio 2021;5(2):e20297) doi:10.2196/20297

KEYWORDS

hypertension; BASNEF; blood pressure; medication adherence

Introduction

Background

The third goal (ie, goal 3, to ensure healthy lives and promote well-being for all ages) of the United Nations Sustainable Development Goals targets reducing premature deaths from noncommunicable diseases by one-third through prevention and treatment by the year 2030 [1]. One crucial health dilemma worldwide is the prevalence of hypertension. Hypertension is defined as systolic blood pressure (BP) elevated to more than 140 mm Hg or diastolic BP less than 90 mm Hg [2] and is one of the factors that increase mortality in both high-income and low-to-middle–income countries. According to the World Health Organization, hypertension accounted for 12% of global deaths in 2013 [3]. The prevalence of hypertension in adults (>18 years) is 22% [4].

Hypertension is the most common cardiovascular disease, often resulting in stroke, heart attack, kidney disease, and aneurysm [5]. Patients with hypertension do not meet the existing BP goal set in international guidelines [6]. Target levels were set to measure the BP and to determine whether readings belong to the standard category. In addition to the BP readings, the heart rates (HRs) were also measured. Another set of categories was also established to determine whether HR readings belong to the standard category [7]. The etiology of hypertension is unknown in the current literature. Some potential factors have been identified, including obesity, diet, and physical activity [8]. Hypertension cannot be treated under normal conditions, but it can be managed through medication as the primary management scheme. More than 100 different medicines with proven efficacy are available; most have untoward side effects, and many are formulated for maintenance [9].

The traditional approach in managing hypertension involves following health guidelines to prevent adverse health issues. Despite these guidelines, encouraging patients to modify their lifestyle over time remains a considerable challenge in hypertension management. How health education is implemented is crucial in helping patients change their lifestyle over the long term [10]. The World Health Organization considers lifestyle as the regular patterns of behaviors resulting from interactions among characteristics, relationships, milieu, and economic circumstances [11]. Lifestyle plays an essential role in hypertension development [12]. The current literature has reported particularly critical lifestyle factors, including nutrition, exercise, stress, smoking, weight management, sleep, and rest. The Seventh Report of the Joint National Committee on Prevention, Diagnosis, Evaluation, and Treatment of hypertension considers inadequate attention to a lack of social coverage of health education as the most significant obstacle to health education [13].

Various literature models were offered as supportive behavioral change tools and current sociocultural contexts [14,15]. Among them is the Beliefs, Attitude, Subjective Norms, Enabling Factors (BASNEF) model, which is a systematic and comprehensive tool “to study behaviors and plans to change them and to define the factors effective on individuals’ decision-making” [16]. The underlying concept behind the BASNEF model is that individuals develop a new behavior when they feel that the behavior is helpful to them [16]. The assessment process individuals implement to understand the efficacy of behavior contributes to their attitudes about their behavior. The direct implication of this concept is that key individuals in one’s life can influence one’s decision for new behavior, which in turn acts as either a facilitator or an inhibitor. Because beliefs dictate the subjective norms of individuals, the convergence of social expectations contributes in the development of decision-making associated with achieving new behavior. On the contrary, factors such as ability, resources, and expense, among others, can help turn a purpose into efficient action. These conditions usually exist before a behavior occurs [14].

As a healthy lifestyle is widely believed to be a critical factor in reducing disease incidence, severity, and complications, particularly in hypertension, the BASNEF model addresses a significant gap. As a framework, the BASNEF model considers environmental and social norms in changing behavior, in addition to the knowledge and attitude of patients. A prerequisite for an effective health education model is an understanding of the factors underlying the behavior of a person. Conceptually, the BASNEF model is a simplified behavioral understanding approach based on the Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation model and value expectation theory. Applying the BASNEF strategy involves assessing the group outlook for behavior with adequately defined actions. In addition to adequately defined actions, it is also essential to pay attention to the facilities and knowledge that a motivated person needs to ensure that all enabling factors are available for a motivated person. With these factors in place and a good understanding of the immediate community, it is possible to use the BASNEF model to design health education interventions.

Few studies have explored the BASNEF model to improve the lifestyle of patients with hypertension. The model has been used to develop lifestyle changes in different domains, including investigations for several interventions [13,17], self-monitoring [18], and lower BP [19], and cesarean section rates among pregnant women. Various studies have demonstrated that enhancing variables such as family and support [20], attitude, and subjective norms [21], which are elements of the BASNEF model, can substantially anticipate health habits and long-term adherence treatments. Clinical findings have shown that health education and fitness programs [22] and a holistic lifestyle change [23] in patients with hypertension may significantly improve hypertension, diet, weight, and physical activity. In comparison, several studies have indicated that health education [24] and lifestyle education [25] can improve the understanding of patients with hypertension. However, BP cannot be reduced [24]. A study revealed that nurse-led therapy (ie, trying to affect patient subjective norms) did not affect outpatient BP and antihypertensive drug treatments in patients at elevated cardiovascular disease risk [26].

In patients with hypertension, health education has been shown to have a significant impact on self-care behaviors. The prevalence of precautionary measures via health education is a robust tool for healthier lifestyles while safeguarding from

complications of hypertension. It was also found that the use of these preventive procedures in educating self-care behaviors in patients with hypertension without a holistic educational structure is less vital than conventional teaching, considering the long history of design and educational structures in global health systems and given that these approaches are preferred educational instruments [13]. The training provided is not successful without the use of educational models or rational processes to transform behavior. Although parameters in awareness and attitude and their influence on behavior are significant, during care and compliance with patients receiving nutritional therapy, other significant factors, such as personal abilities and milieu, affect the conduct and behavior of patients. Thus, it can be inferred that using important constructs and health education models to produce better outcomes would yield outputs that are more successful. Although the BASNEF model has been implemented in hypertension management, to the best of our knowledge, no work has been reported on measuring the effectiveness of health education programs in managing hypertension in the context of the BASNEF. Consequently, this study was conducted to examine the effects of a lifestyle intervention program using the BASNEF model among nonadherent hypertensive respondents.

Objectives

This study aims to determine if there is significant evidence to support the following research hypotheses (RH):

1. The different phases of medication significantly differ in systolic BP readings (RH1), diastolic BP readings (RH2), and HR readings (RH3).
2. Sex classifications of the participants differ significantly in systolic BP readings (RH4), diastolic BP readings (RH5), HR readings (RH6), and Morisky Scale (MS) scores (RH7).
3. Age classifications of the participants differ significantly in systolic BP readings (RH8), diastolic BP readings (RH9), HR readings (RH10), and MS scores (RH11).
4. Medication adherence (ie, MS scores) of the participants differs significantly in systolic BP readings (RH12), diastolic BP readings (RH13), and HR readings (RH14).
5. The age of the participants significantly relates to systolic BP readings (RH15), diastolic BP readings (RH16), HR readings (RH17), and MS scores (RH18).
6. Medication adherence (ie, MS scores) of the participants significantly relates to systolic BP readings (RH19), diastolic BP readings (RH20), and HR readings (RH21).

Methods

Methods and Materials

This study is a quantitative quasi-experimental research work, particularly using a repeated-measures design of the within-subjects approach [27-29]. A study in the Philippines on 50 nonadherent patients diagnosed with essential hypertension was reported. The research participants received 5 sessions by phase in the context of a modified BASNEF model. A Morisky Medication Adherence instrument was used. The first phase of the program involved distributing the demographic questionnaire, including the age and sex of the participants. The final phase focused on the evaluation of the program. Self-BP and HR monitoring were performed daily in the morning and recorded by the patient or significant other using a standard digital sphygmomanometer (ie, Docteurs Choice Arm-cuff Digital Blood Pressure Monitor) that was provided to them for the duration of the program. Monitoring was performed after breakfast, before taking antihypertensive maintenance medications. BP and HR readings were collected every Friday, and the average readings were reported. The time frame of the program was 10 months. The University Research Ethics Committee of Cebu Technological University approved the design of the research, protocols, and informed consent process.

Study Population

This study was conducted on 120 nonadherent patients diagnosed with stage 1 or stage 2 hypertension listed in the Rural Health Unit-Hypertension Club. The participants are currently living in a mountain village in the municipality of Moalboal, Cebu (Philippines). The sampling design followed the approach in Arani et al [12]. A set of inclusion criteria was established to determine the participants of the study from the 120 listed patients. Of the initial 120 patients, 20 failed to meet the inclusion criteria, and 50 did not agree to participate. A total of 50 nonadherent patients provided their consent to participate in the study. No participant was excluded owing to withdrawal from the study, absence at >1 session, or hospitalization.

Instrument

In this study, the MS determines the level of medication adherence of the participants with hypertension. MS is a standardized measure intended to measure the risk of nonadherence to medication [20,30]. This method is widely used in domain literature. It is used for various illnesses, such as high BP, hyperlipidemia, asthma, and HIV. The results are based on answers of patients to 4 questions, which are answered by a yes or a no.

The Lifestyle Intervention Program

The intervention was given every Friday afternoon in 5 sessions after collecting their BP and HR readings. Every session had a design that integrated various aspects of a lifestyle change program. Participants received printed materials containing Microsoft PowerPoint slides included in the sessions expressed in the local dialect (ie, Cebuano) for reference. The relevance and internal validity of the educational materials draw parallel to the work of Arani et al [12] and Villarino et al [31]:

1. Phase 1 (month 1): This phase covers activities such as orientation to the session design, signing of the informed consent document, finishing the research tool (ie, MS), and carrying out the baseline measurements (ie, BP and HR readings).
2. Session I, phase 2 (month 2): This phase aims to enhance the knowledge and transform the behavior, attitudes, and beliefs of the participants based on the BASNEF model. It also provides 45-60 min/week lecture on hypertension (eg, the definition of hypertension, its causes, and several contributing factors).
3. Session II, phase 3 (month 3): This phase discusses the cumulative and salient effects of high BP and the

consequences of smoking, alcohol, and caffeine. It also elucidates the side effects of antihypertensive drugs.

4. Session III, phase 4 (month 4): This phase highlights the behavioral intention of the BASNEF model (ie, via microgroups). It aims to educate the participants on what action is anticipated and how to do it (eg, practical tips on keeping the ideal weight considering the BMI, methods for reducing salt consumption, and practical stress management methods).
5. Session IV, phase 5 (month 5): This phase elucidates subjective norms. It includes a session for individuals who would help improve the lifestyle of the participant and thus help reduce hypertension, such as their partner and children, in a way that explains their role in behavioral modification and hypertension management.
6. Session V, phase 6 (month 6): This phase emphasizes the enabling factors. At meetings, all participants were provided with a pamphlet to keep the training fluid. The participants were informed of how to use health care center services and access the necessary treatment.
7. Phase 7 (month 7): This phase includes the necessary evaluation activities, such as reviewing the previous education sessions, conducting the posttest and BP readings, and taking a post–lifestyle intervention program for the participants.

Statistical Analysis

Categorical variables, particularly the sex and age of participants, were expressed as frequencies and percentages. Continuous variables, such as systolic BP, diastolic BP, HR readings, and MS scores, were defined as mean (SD). Repeated-measures one-way analysis of variance (ANOVA) was used for testing RH1 to RH14, except for RH4 to RH7, in which a 2-tailed independent *t* test was used. When an RH was rejected (eg, RH4, RH5, and RH8), a Tukey post hoc test was used to identify the source of the significant differences. To test the association of age and BP and HR readings, and MS scores and MS scores and BP and HR readings (ie, RH15 to RH21), the Pearson product-moment correlation test was used. Correlation coefficients (*r*) and *P* values were reported. Finally, the 1-way ANOVA test was used to test the differences in systolic BP, diastolic BP, and HR readings according to MS scores. The significance level of all tests was set at α=.05. All analyses were performed using R (programming language; R Foundation for Statistical Computing).

Results

Profiles of the Participants

The distribution of research participants in terms of sex and age are presented in Table 1. More than three-fourths of the participants were female (39/50, 78%). The ages of these participants also show a relatively bimodal distribution, with those in the age groups of 40-49 and 70-79 years having the highest frequencies.

Table 1. Profile of the participants (N=50).

Profile	Frequency, n (%)
Sex	
Female	39 (78)
Male	11 (22)
Age (years)	
80-89	4 (8)
70-79	13 (26)
60-69	8 (16)
50-59	7 (14)
40-49	12 (24)
30-39	6 (12)

BP and HR Readings

Table 2 shows the highest BP readings of the participants, with a mean of 146.50/84.6 in phase 1 of the study. Note that phase 1 denotes the baseline BP readings of participants with hypertension before they received interventions via health education. The lowest BP readings of the participants with a mean of approximately 135/80 were recorded in phase 4 of the study.

Table 2. Blood pressure and heart rate readings of the participants.

Phases	Blood pressure readings[a]			Heart rate readings[b]	
	Systolic, mean (SD)	Diastolic, mean (SD)	Interpretation	Heart rate, mean (SD)	Interpretation
1	146.50 (19.59)	84.60 (12.59)	Hypertension stage 2	77.76 (11.65)	Normal
2	136.64 (18.42)	80.36 (11.83)	Hypertension stage 1	76.92 (10.71)	Normal
3	136.80 (16.37)	79.26 (9.90)	Hypertension stage 1	76.08 (9.93)	Normal
4	134.92 (15.24)	78.76 (10.81)	Hypertension stage 1	77.94 (12.43)	Normal
5	137.88 (19.18)	79.96 (11.24)	Hypertension stage 1	79.16 (12.01)	Normal
6	136.86 (15.14)	79.58 (10.76)	Hypertension stage 1	77.06 (11.32)	Normal

[a]Mean systolic blood pressure, 138.27 (SD13.31); mean diastolic blood pressure, 80.42 (SD 7.97).

[b]Mean heart rate, 77.49 (SD 7.70); interpretation: normal.

As presented in Table 2, the HR readings of the participants were highest in phase 5, with a mean of 79.16, and the lowest mean readings of 76.08 were recorded in phase 3. Increased HR is associated with high BP, increased risk of hypertension, and increased cardiovascular disease risk in patients with hypertension [32].

Differences in Systolic BP, Diastolic BP, and HR Readings, and MS Scores

A summary of the results of the tests for RH1 to RH14 (numerical values and descriptive entries on the differences in systolic BP, diastolic BP, and HR readings based on the phases of medication, sex, age, and MS scores) is presented in Table 3.

Using repeated-measures ANOVA, all *P* values of the systolic BP (*P*=.80), diastolic BP (*P*=.90), and HR (*P*=.46) readings exceeded the level of significance of .05, based on the stages of medication. These results lead to the nonrejection of the null hypotheses of no significant differences in the systolic BP, diastolic BP, and HR readings of the participants based on all medication phases. The *P* values of the systolic readings (*P*=.02) and the diastolic readings (*P*<.001) were less than the significance level of .05, based on sex, after using an independent *t* test. This implies rejecting the null hypothesis of no significant difference in systolic and diastolic BP readings. However, because the *P* values of the HR readings (*P*=.56) and MS scores (*P*=.25) of the male and female participants exceeded the level of significance of .05, the null hypotheses of no significant differences were not rejected.

The *P* value of the systolic BP readings (*P*<.001) was less than the significance level of .05, after using 1-way ANOVA. The null hypothesis of no significant difference was rejected, which led to the RH's support (RH8). In this study, the systolic BP readings of the participants differed significantly when grouped according to their age classifications. After using the Tukey post hoc test to determine which age classifications differ from others, it was found out that those in the age group 30-39 years had significantly lower average systolic BP readings of 121.72 compared with the rest of the age groups that did not differ. In contrast, after the 1-way ANOVA test, as the diastolic BP readings (*P*=.28), HR (*P*=.24) readings, and MS scores (*P*=.29) had *P* values greater than the level of significance of .05, the null hypotheses of no significant differences were not rejected. The *P* values of the systolic BP (*P*=.08), diastolic BP (*P*=.11), and HR (*P*=.59) readings were higher than the significance level of .05, after a 1-way ANOVA test. This leads to the null hypothesis that there is no significant difference (ie, RH12, RH13, RH14). In Table 3, the evidence was not enough to support the RHs that the systolic BP (RH1), diastolic BP (RH2), and HR (RH3) readings significantly differ based on the phases of medication adherence. This finding suggests that the participants had statistically the same systolic BP, diastolic BP, and HR readings in the phases of medication adherence. Reductions or increases that were observed in all the BP and HR readings from 1 phase to the next were insignificant. Sufficient evidence supports the RHs that both systolic BP (RH4) and diastolic BP (RH5) readings differ based on sex. This result implies, more specifically, that the male participants had a significantly higher mean systolic BP of 146.61 and mean diastolic BP of 88.62 compared with the systolic mean of 135.92 and diastolic mean of 78.11 of the female participants. The evidence did not support the RHs that the HR readings (RH6) and MS scores (RH7) differ according to sex. Thus, the male and female participants had the same HR readings and medication adherence as indicated by the MS scores. The results did not support the RHs that diastolic BP readings (RH9) and HR readings (RH10), together with MS scores (RH11), differ according to age. These results imply that diastolic BP and HR readings and MS scores were statistically the same according to age.

Table 3. Summary of inferences on systolic BP[a], diastolic BP, and HR[b] readings, and MS[c] scores based on the phases of medication, sex, age, and MS scores.

Comparison bases	RH[d]	Critical value[e]	Test value	*P* value	Decision on H0	Difference
Phases of medication						
Systolic BP readings	RH1	2.42	0.41	.80	Not rejected	Not significant
Diastolic BP readings	RH2	2.42	0.27	.90	Not rejected	Not significant
HR readings	RH3	2.42	0.90	.46	Not rejected	Not significant
Sex						
Systolic BP readings	RH4	2.11	2.59	.02	Rejected	Significant
Diastolic BP readings	RH5	2.10	4.85	<.001	Rejected	Significant
HR readings	RH6	2.13	0.59	.56	Not rejected	Not significant
MS scores	RH7	2.08	1.18	.25	Not rejected	Not significant
Age (years)						
Systolic BP readings	RH8	2.43	5.10	<.001	Rejected	Significant
Diastolic BP readings	RH9	2.43	1.30	.28	Not rejected	Not significant
HR readings	RH10	2.43	1.40	.24	Not rejected	Not significant
MS scores	RH11	2.43	1.28	.29	Not rejected	Not significant
MS scores						
Systolic readings	RH12	2.58	2.21	.08	Not rejected	Not significant
Diastolic readings	RH13	2.58	2.02	.11	Not rejected	Not significant
HR readings	RH14	2.58	0.71	.59	Not rejected	Not significant

[a]BP: blood pressure.

[b]HR: heart rate.

[c]MS: Morisky Scale.

[d]RH: research hypothesis.

[e]The critical values used were *F* values except those of sex, which used *t* values. The significance level was set at *P*=.05.

Differences in Systolic BP, Diastolic BP, and HR Readings Per MS Scores

The *P* values of the systolic BP, diastolic BP, and HR readings are provided in Table 4.

The *P* values of the systolic BP (*P*=.08), diastolic BP (*P*=.11), and HR (*P*=.59) readings shown in Table 4 were higher than the significance level of .05 after the one-way ANOVA test. This leads to the nonrejection of the null hypothesis of no difference. The findings presented in Table 4 do not support the RHs advanced in this study that the systolic BP (RH12), diastolic BP (RH13), and HR (RH14) readings of the participants significantly differed based on MS scores. Hence, all BP and HR readings were statistically the same when grouped on the basis of medication adherence through MS scores. This result suggests that they had the same systolic BP, diastolic BP, and HR readings regardless of the medication adherence of the participants.

Table 4. Significance of differences in systolic BP[a], diastolic BP, and heart rate readings based on Morisky Scale scores.

	Critical *F* value (*df*)	Computed *F* value (*df*)	*P* value[b]	Decision on H0	Difference
Systolic BP readings	2.58 (4)	2.21 (45)	.08	Not rejected	Not significant
Diastolic BP readings	2.58 (4)	2.02 (45)	.11	Not rejected	Not significant
Heart rate readings	2.58 (4)	0.71 (45)	.59	Not rejected	Not significant

[a]BP: blood pressure.

[b]Significance level *P*=.05.

Relationships in Systolic BP, Diastolic BP, HR Readings Per Age, and MS Scores

Table 5 presents the numerical values and descriptive entries on the significance of relationships between the age of the participants and the BP and HR readings and the MS scores, and between the MS scores and BP and HR readings after using the Pearson product-moment correlation test. The systolic BP readings had a *P* value of .002, which was lower than the level of significance of .05. This leads to the rejection of the null hypothesis and sufficient evidence to support a significant relationship claimed in RH15.

Table 5. Significance of relationships between the readings with MS[a] scores and age and between the readings and MS scores.

Relationship bases	Correlation coefficient (*r*)	*P* value	Decision on H0	Relationship
Age				
Systolic	0.42	.002	Rejected	Significant
Diastolic	0.10	.49	Not rejected	Not significant
Heart rate	0.11	.43	Not rejected	Not significant
MS scores	0.25	.08	Not rejected	Not significant
MS scores				
Systolic	0.26	.07	Not rejected	Not significant
Diastolic	0.21	.14	Not rejected	Not significant
Heart rate	0.10	.51	Not rejected	Not significant

[a]MS: Morisky Scale.

In contrast, because the *P* values of diastolic BP (*P*=.49) and HR (*P*=.43) readings and MS scores (*P*=.08) were more than the level of significance of .05, the null hypotheses of no relationship were not rejected. In addition, the *P* values of systolic BP (*P*=.07), diastolic BP (*P*=.14), and HR (*P*=.51) readings exceeded the level of significance of .05; therefore, the null hypotheses of no significant relationship were not rejected. Thus, the evidence failed to support the RHs that MS scores were significantly related to systolic BP (RH19), diastolic BP (RH20), and HR (RH21) readings. Hence, though this study found a significant relationship between systolic BP and age, it failed to find any effect of medication adherence through the MS scores on the systolic and diastolic BP readings and HR readings of the participants. However, low compliance to antihypertensive drugs is standard and contributes to poor BP control and adverse effects [32]. There is a lack of understanding of how patient-specific challenges affect poor adherence to medication and how successful approaches can be aimed at overcoming obstacles and enhancing adherence behavior in hypertensive adults.

Discussion

Principal Findings

This study assessed the effects of a lifestyle intervention program on nonadherent patients with hypertension using a modified BASNEF model. The results suggest that the lifestyle intervention based on session III or phase IV behavioral intention in the BASNEF model microgroup sessions positively affects BP readings among the research participants. The descriptive results indicate that the BP readings of the population under consideration were not significantly different from their MS scores.

In the last 3 months of the implementation of the program, our study found significant modifications in systolic and diastolic BP and improvements in all behavioral factors. Participants had reduced dietary sodium intake, had taken their maintenance antihypertensive medications if available, and if budget warranted, and had limited their alcohol and cigarette consumption. Our findings indicate that lifestyle change interventions have effectively decreased BP levels by having participants take steps such as reducing salt consumption, taking prescribed medicines, and limiting alcohol and cigarette consumption [33,34]. This agrees with some findings in the literature, such as the study conducted by Englert et al [35], which found substantial decreases in cholesterol, low-density lipoprotein, triglycerides, blood glucose, and BP levels, and weight loss in a group-based risk prevention plan. Repeated measures revealed that the program substantially decreased systolic and diastolic BP during the 10-month program implementation and a follow-up visit 3 months later. Previous studies found that lifestyle modifications could enhance BP regulation and reduce the risk of chronic illnesses [13,36].

Our results are also consistent with studies that used the BASNEF model to manage anxiety disorders in patients with hypertension [37]. Our study finds that a BASNEF-based program may improve all aspects of patient lifestyle by increasing awareness, enhancing patient beliefs and attitudes, and altering social norms through the participation of family members of patients. In addition, Baghianimoghadam et al [5] and Arani et al [12] argued that the lifestyle intervention program anchored on the BASNEF model has considerable advantages and significantly increases medication adherence in patients with hypertension. However, a few studies have indicated that behavioral approaches in patients with unstable angina [23] could not modify their lifestyle (ie, the prevalence of smoking, drug abuse, and mental health). Khavoshi et al [2] pointed out that lifestyle, social, and psychological well-being in older adults could not be influenced by educational interference using a self-belief model. Many habits, such as

avoiding smoking, have a complicated structure, and many social and personality variables are affected. Therefore, improving knowledge and understanding of the population cannot influence these habits. However, the BASNEF model recognizes several factors, including intelligence and understanding, attitudes, cultural values, and milieu and social influences [13,23,38]. A wide range of people, such as families, friends, and other essential persons, can affect the understanding of social and psychological well-being of the patients. Thus, the BASNEF model would affect habits and activities of individuals and affect their psychosocial well-being, which family and other significant people influence [12]. This study found that designing and implementing theme-driven programs that merit milieu is more effective than the current health promotion programs that acknowledge the knowledge of patients, attitudes, and beliefs without regard to the factors that influence their behavior. This research also found that lifestyle interventions for managing hypertension that need consistent attention to medication adherence, diet, and behavioral management of the individual must involve the patients and health care workers, family, and the people who have impact on the behavior of patients.

Conclusions

This study established that the BASNEF model approach can be an effective BP management technique. A significant change in BP was observed in sessions III or phase IV of the program, where behavioral intention in the BASNEF model (ie, microgroups) was implemented. The results of this study are relevant for patients with hypertension without comorbidities such as diabetes mellitus and physical or mental disorders. For future work, a longitudinal study may be conducted to determine the significant difference between the BP and HR readings among the respondents and emphasize the essentiality of medical adherence in managing hypertension using health education models.

Acknowledgments

The General Appropriations Act of the Cebu Technological University funded this research project. The authors would like to thank Cebu Technological University President, Dr Rosein A Ancheta Jr, the late Cebu Technological University Director for Internationalization and ASEAN Integration, Dr Doris O Gascon, and Cebu Technological University-Moalboal Campus, and Dr Eldie V Abenido for their inspiration and generosity. The authors are grateful to Dr Raymond R Tan and Dr Kathleen B Aviso of De La Salle University for their profound wisdom and insights that polished the manuscript into fruition. The final stages of manuscript preparation were supported by the United States Agency for International Development via the Science, Technology, Research and Innovation for Development program's skills in technical and advanced research training courses.

Authors' Contributions

RTV, CAA, MCT, and MLV conceived the idea. RTV, CAA, MLV, RB, LO, and PB developed the theory and performed the computations. RB, LO, and PB verified the analytical methods. RTV, CAA, MCT, MLV, RB, LO, and PB supervised the findings of this study. All authors have discussed the results and contributed to the final manuscript.

Conflicts of Interest

None declared.

References

1. Sustainable development knowledge platform. United Nations. URL: https://sustainabledevelopment.un.org/index.html [accessed 2021-04-19]
2. Khavoshi A, Tol A, Shojaeizade D, Shamshiri A. Effect of educational intervention on the lifestyle of elderly people referred to clinical centers of Eslamshahr, Iran: application of health belief model. J Nurs Educ 2015;3(4):19-28 [FREE Full text]
3. World health day 2013. World Health Organization. URL: http://www.emro.who.int/world-health-days/2013/ [accessed 2021-04-19]
4. Cardiovascular diseases (CVDs). World Health Organization. 2014. URL: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds) [accessed 2021-04-19]
5. Baghianimoghadam M, Rahaee Z, Morowatisharifabad MA, Sharifirad G, Andishmand A, Azadbakht L. Effects of education on self-monitoring of blood pressure based on BASNEF model in hypertensive patients. J Res Med Sci 2010 Mar;15(2):70-77 [FREE Full text] [Medline: 21526062]
6. Katigbak C, Fontenot HB. A primer on the new guideline for the prevention, detection, evaluation, and management of hypertension. Nurs Womens Health 2018 Aug;22(4):346-354. [doi: 10.1016/j.nwh.2018.06.003] [Medline: 30077241]
7. Dzudie A, Rayner B, Ojji D, Schutte AE, Twagirumukiza M, Damasceno A, PASCAR task force on hypertension. Roadmap to achieve 25% hypertension control in Africa by 2025. Cardiovasc J Afr 2017;28(4):262-272 [FREE Full text] [doi: 10.5830/CVJA-2017-040] [Medline: 28906541]
8. Okwuonu C, Ngoka S, Chimezie O, Eze TH, Uwanurochi K, Mbanaso AU. Towards prevention of hypertension in Nigeria: a study of prehypertension and its associations among apparently healthy adults in Umuahia, South-East Nigeria. Int J Prev Med 2015 Jul 13;6:61 [FREE Full text] [doi: 10.4103/2008-7802.160968] [Medline: 26288705]

9. Bezalel T, Carmeli E, Katz-Leurer M. The effect of a group education programme on pain and function through knowledge acquisition and home-based exercise among patients with knee osteoarthritis: a parallel randomised single-blind clinical trial. Physiotherapy 2010 Jun;96(2):137-143. [doi: 10.1016/j.physio.2009.09.009] [Medline: 20420960]
10. Lee GK, Wang HH, Liu KQ, Cheung Y, Morisky DE, Wong MC. Determinants of medication adherence to antihypertensive medications among a Chinese population using Morisky Medication Adherence Scale. PLoS One 2013 Apr 25;8(4):e62775 [FREE Full text] [doi: 10.1371/journal.pone.0062775] [Medline: 23638143]
11. Shayesteh H, Mirzaei A, Sayehmiri K, Qorbani M, Mansourian M. Effect of education intervention on lifestyle of patients with hypertension among the rural population of lorestan province. J Lifestyle Med 2016 Sep;6(2):58-63 [FREE Full text] [doi: 10.15280/jlm.2016.6.2.58] [Medline: 27924284]
12. Arani MD, Taghadosi M, Gilasi HR. The effect of education based on BASNEF model on lifestyle in patients with hypertension. Iran Red Crescent Med J 2016 Oct;19(11):A [FREE Full text] [doi: 10.5812/ircmj.40731]
13. Tam HL, Wong EM, Cheung K. Effectiveness of educational interventions on adherence to lifestyle modifications among hypertensive patients: an integrative review. Int J Environ Res Public Health 2020 Apr 07;17(7):2513 [FREE Full text] [doi: 10.3390/ijerph17072513] [Medline: 32272601]
14. Jeihooni A, Barati M, Kouhpayeh A, Kashfi S, Harsini P, Rahbar M. The effect of educational intervention based on BASNEF model on self-medication behavior of type 2 diabetic patients. Indian J Endocrinol Metab 2019;23(6):616-622 [FREE Full text] [doi: 10.4103/ijem.IJEM_436_19] [Medline: 32042697]
15. Villarino RT. Convergence model of motivational attributes and academic performance among college students. Int J Adv Res Pub 2020 Mar;4(3):A [FREE Full text]
16. Sarayloo K, Moghadam ZB, Mansoure JM, Mostafa H, Mohsen S. The impact of an educational program based on BASNEF model on the selection of a contraceptive method in women. Iran J Nurs Midwifery Res 2015;20(2):171-178 [FREE Full text] [Medline: 25878691]
17. Villarino R. Modified BASNEF Model For Hypertension Management Manual. Seattle, Washington: Kindle Direct Publishing; Feb 2019.
18. Charkazi A, Miraeiz S, Razzaghnejad A, Shahnazi H, Hasanzadeh A, Badleh M. Breastfeeding status during the first two years of infants' life and its risk factors based on BASNEF model structures in Isfahan. J Educ Health Promot 2013 Feb 28;2:9 [FREE Full text] [doi: 10.4103/2277-9531.107938] [Medline: 24083259]
19. Ornish D, Scherwitz LW, Billings JH, Brown SE, Gould KL, Merritt TA, et al. Intensive lifestyle changes for reversal of coronary heart disease. J Am Med Assoc 1998 Dec 16;280(23):2001-2007. [doi: 10.1001/jama.280.23.2001] [Medline: 9863851]
20. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. J Clin Hypertens (Greenwich) 2008 May;10(5):348-354 [FREE Full text] [doi: 10.1111/j.1751-7176.2008.07572.x] [Medline: 18453793]
21. Park Y, Song M, Cho B, Lim J, Song W, Kim S. The effects of an integrated health education and exercise program in community-dwelling older adults with hypertension: a randomized controlled trial. Patient Educ Couns 2011 Jan;82(1):133-137. [doi: 10.1016/j.pec.2010.04.002] [Medline: 20434864]
22. Bane C, Hughe C, McElney J. Determinants of medication adherence in hypertensive patients: an application of self-efficacy and the Theory of Planned Behaviour. Int J Pharm Pract 2006 Sep;14(3):197-204. [doi: 10.1211/ijpp.14.3.0006]
23. Elmer PJ, Obarzanek E, Vollmer WM, Simons-Morton D, Stevens VJ, Young DR, PREMIER Collaborative Research Group. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. Ann Intern Med 2006 Apr 04;144(7):485-495. [doi: 10.7326/0003-4819-144-7-200604040-00007] [Medline: 16585662]
24. Pandit AU, Tang JW, Bailey SC, Davis TC, Bocchini MV, Persell SD, et al. Education, literacy, and health: mediating effects on hypertension knowledge and control. Patient Educ Couns 2009 Jun;75(3):381-385. [doi: 10.1016/j.pec.2009.04.006] [Medline: 19442477]
25. Stewart S, Carrington MJ, Swemmer C, Kurstjens N, Jennings GL. Optimising management of hypertension in primary care: the Valsartan Intensified Primary Care Reduction of Blood Pressure (Viper-Bp) study. Int J Cardiol 2011 Dec 15;153(3):317-322. [doi: 10.1016/j.ijcard.2010.12.055] [Medline: 21215482]
26. Woollard J, Burke V, Beilin L. Effects of general practice-based nurse-counselling on ambulatory blood pressure and antihypertensive drug prescription in patients at increased risk of cardiovascular disease. J Hum Hypertens 2003 Oct;17(10):689-695. [doi: 10.1038/sj.jhh.1001593] [Medline: 14504627]
27. Cannon MJ, Stowell JD, Clark R, Dollard PR, Johnson D, Mask K, et al. Repeated measures study of weekly and daily cytomegalovirus shedding patterns in saliva and urine of healthy cytomegalovirus-seropositive children. BMC Infect Dis 2014 Nov 13;14:569 [FREE Full text] [doi: 10.1186/s12879-014-0569-1] [Medline: 25391640]
28. Edmonds W, Kennedy T. An Applied Reference Guide to Research Designs: Quantitative, Qualitative, and Mixed Methods. Thousand Oaks, CA: Sage Publication; 2012.
29. Villarino R. Fundamentals of Research: A Practical Guide for College Students. The Philippines: Independently published; Dec 25, 2020.

30. Villarino R. Fundamentals of Academic Publishing: A Handbook in Writing a Scientific Paper for Publication. The Philippines: Independently published; 2021.
31. Villarino R. Health and Well-being Program for College Students. Seattle, Washington: Kindle Direct Publishing; Nov 2020.
32. Palatini P, Julius S. Elevated heart rate: a major risk factor for cardiovascular disease. Clin Exp Hypertens 2004;26(7-8):637-644. [doi: 10.1081/ceh-200031959] [Medline: 15702618]
33. Appel LJ. Lifestyle modification as a means to prevent and treat high blood pressure. J Am Soc Nephrol 2003 Jul;14(7 Suppl 2):99-102 [FREE Full text] [doi: 10.1097/01.asn.0000070141.69483.5a] [Medline: 12819311]
34. Krousel-Wood MA, Muntner P, Islam T, Morisky DE, Webber LS. Barriers to and determinants of medication adherence in hypertension management: perspective of the cohort study of medication adherence among older adults. Med Clin North Am 2009 May;93(3):753-769 [FREE Full text] [doi: 10.1016/j.mcna.2009.02.007] [Medline: 19427503]
35. Englert HS, Diehl HA, Greenlaw RL. Rationale and design of the Rockford CHIP, a community-based coronary risk reduction program: results of a pilot phase. Prev Med 2004 Apr;38(4):432-441. [doi: 10.1016/j.ypmed.2003.11.007] [Medline: 15020176]
36. Weintraub WS, Daniels SR, Burke LE, Franklin BA, Goff DC, Hayman LL, American Heart Association Advocacy Coordinating Committee, Council on Cardiovascular Disease in the Young, Council on the Kidney in Cardiovascular Disease, Council on EpidemiologyPrevention, Council on Cardiovascular Nursing, Council on Arteriosclerosis, ThrombosisVascular Biology, Council on Clinical Cardiology, Stroke Council. Value of primordial and primary prevention for cardiovascular disease: a policy statement from the American Heart Association. Circulation 2011 Aug 23;124(8):967-990. [doi: 10.1161/CIR.0b013e3182285a81] [Medline: 21788592]
37. Blom EH, Olsson EM, Serlachius E, Ericson M, Ingvar M. Heart rate variability (HRV) in adolescent females with anxiety disorders and major depressive disorder. Acta Paediatr 2010 Apr;99(4):604-611 [FREE Full text] [doi: 10.1111/j.1651-2227.2009.01657.x] [Medline: 20121706]
38. Goyer L, Dufour R, Janelle C, Blais C, L'Abbé C, Raymond E, et al. Randomized controlled trial on the long-term efficacy of a multifaceted, interdisciplinary lifestyle intervention in reducing cardiovascular risk and improving lifestyle in patients at risk of cardiovascular disease. J Behav Med 2013 Apr;36(2):212-224. [doi: 10.1007/s10865-012-9407-3] [Medline: 22402823]

Abbreviations

ANOVA: analysis of variance
BASNEF: Beliefs, Attitude, Subjective Norms, Enabling Factors
BP: blood pressure
HR: heart rate
MS: Morisky Scale
RH: research hypothesis

Edited by G Eysenbach; submitted 15.05.20; peer-reviewed by RJ Katz, A Khoja; comments to author 27.10.20; revised version received 24.07.21; accepted 27.07.21; published 24.09.21.

Please cite as:
Villarino RT, Arcay CA, Temblor MC, Villarino ML, Bagsit R, Ocampo L, Bernard P
The Effects of Lifestyle Intervention Using the Modified Beliefs, Attitude, Subjective Norms, Enabling Factors Model in Hypertension Management: Quasi-Experimental Study
JMIR Cardio 2021;5(2):e20297
URL: https://cardio.jmir.org/2021/2/e20297
doi:10.2196/20297
PMID:34559063

Original Paper

Patient Perspectives on Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure (ITEC-CHF): Usability Study

Sheau Huey Chen[1*], BSc, PGCert; Iain Edwards[2], MBA; Rajiv Jayasena[3], PhD; Hang Ding[4,5,6*], PhD; Mohanraj Karunanithi[5], PhD; Alison Dowling[2], MPH; Jamie Layland[7,8], MBChB, MD, PhD; Andrew Maiorana[1,9], PhD

[1]School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

[2]Department of Community Health, Peninsula Health, Melbourne, Australia

[3]The Australian e-Health Research Centre, Health and Biosecurity Unit, Commonwealth Scientific & Industrial Research Organisation, Melbourne, Australia

[4]RECOVER Injury Research Centre, Faculty of Health and Behavioural Sciences, The University of Queensland, Brisbane, Australia

[5]The Australian e-Health Research Centre, Health and Biosecurity Unit, Commonwealth Scientific & Industrial Research Organisation, Brisbane, Australia

[6]PCH-Northside Clinical Unit School, Faculty of Medicine, The University of Queensland, Brisbane, Australia

[7]Department of Cardiology, Peninsula Health, Melbourne, Australia

[8]Peninsula Clinical School, Monash University, Melbourne, Australia

[9]Allied Health Department and Advanced Heart Failure and Cardiac Transplant Service, Fiona Stanley Hospital, Perth, Australia

[*]these authors contributed equally

Corresponding Author:
Andrew Maiorana, PhD
School of Physiotherapy and Exercise Science
Curtin University
GPO Box U1987
Perth, 6845
Australia
Phone: 61 8 9266 9225
Email: A.Maiorana@curtin.edu.au

Abstract

Background: Telemonitoring enables care providers to remotely support outpatients in self-managing chronic heart failure (CHF), but little is known about the usability and patients' willingness to engage with this technology.

Objective: This study aims to evaluate feedback from patients with CHF following participation in the Innovative Telemonitoring Enhanced Care program for CHF (ITEC-CHF) study.

Methods: The telemonitoring intervention consisted of three components: remote weight monitoring, structured telephone support, and nurse-led collaborative care. Participants were provided with electronic weighing scales (W550; ForaCare), and a computer tablet (Galaxy Tab A; Samsung). They were asked to weigh themselves on the provided scales daily. Telemonitoring was integrated with a personal assistance call service and a nurse care service according to their workflows in usual care. Feedback on the usability of ITEC-CHF was collected via survey from study participants following 6 months of receiving telemonitoring care for their body weight. Survey responses were provided on a 5-point Likert scale and through open-ended questions to determine participants' perceived benefits and barriers to using ITEC-CHF.

Results: A total of 67 participants (49/67, 73% male), with a mean age of 69.8 (SD 12.4) years completed the survey. The majority of participants agreed or strongly agreed that the ITEC-CHF program was easy to use (61/67, 91%), easy to navigate (51/65, 78%), useful (59/65, 91%), and made them feel more confident in managing their weight (57/67, 85%). Themes related to participants' perceptions of telemonitoring included increased support for early intervention of clinical deterioration, improved compliance to daily weighing, a sense of reassurance, and improved self-care and accountability, among others.

Conclusions: ITEC-CHF was rated highly on usability and was well accepted by users as part of their routine self-management activities. Participants were willing to use telemonitoring because they perceived a broad spectrum of benefits for CHF management.

Trial Registration: Australian New Zealand Clinical Trial Registry ID ACTRN 12614000916640; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=366691.

(JMIR Cardio 2021;5(2):e24611) doi:10.2196/24611

KEYWORDS

chronic heart failure; telemonitoring; usability; acceptance; patient perspectives

Introduction

Chronic heart failure (CHF) is a complex disease that is expensive to manage and affects approximately 2%-3% of the adult population [1], with a prevalence that continues to increase [2]. Daily weight monitoring and symptom control are cornerstones of CHF management [3]; hence, innovative strategies that are both effective and acceptable to patients are required to support traditional approaches to manage these aspects of care. Recent studies have reported that remote monitoring can improve health outcomes and reduce costs associated with CHF care by providing real-time physiological information to health care providers that can be acted on quickly, reducing the potential for progressive clinical deterioration and more complex care requirements [4,5]. These contemporary telemonitoring systems have the advantage of being delivered by portable devices, enabling patients to be monitored in real time from anywhere with access to the internet [6]. However, positive findings of the efficacy of telemonitoring in CHF management are not ubiquitous, with several studies identifying patients who are resistant to change [7-9].

The mixed results from telemonitoring studies may, in part, reflect the willingness or readiness of patients with CHF to engage with telemonitoring technology and to adhere to its use [10-12]. Because the prevalence of CHF increases with age, a high proportion of patients with CHF are over 75 years of age. This is a subset of the population in whom digital literacy has historically been low. However, the characteristics of the "over 75 years" demographic in modern times is different than that in prior generations, with increased life expectancy [13] and rapidly improving digital literacy [12] highlighting the need for new research in this area.

Although several recent studies have investigated the perceptions of telemonitoring in other clinical cohorts, such as patients with chronic kidney disease, chronic obstructive pulmonary disease, or hypertension [10,11,14,15], there are few contemporary studies describing the perceptions of telemonitoring in patients with CHF. Remote monitoring in patients with CHF has specific objectives and unique challenges. For example, rapid fluctuations in body weight (>2 kg in 48 hours) may be the result of a variety of precipitating factors such as poor adherence to fluid and salt restrictions or noncompliance with medication, which can be rectified through modification of self-care behaviors, or it may be attributed to cardiac deterioration warranting urgent medical support [16]. This increases the complexity of telemonitoring and emphasizes the importance of integrated clinical support in telemonitoring ecosystems [16,17], highlighting the importance of user-friendly technology [18-20].

The Innovative Telemonitoring Enhanced Care program for CHF (ITEC-CHF) was the first such program to incorporate telemonitoring supported by a 24-hour call center and first-line nurse-led CHF intervention in community care settings in Australia [21,22]. To minimize weight monitoring burdens and technical difficulties, the program introduced a novel "zero-touch" design, meaning that the participants were not required to interact with the technology other than stepping onto a scale for weight measurement as in usual care, and they did not need to have extra knowledge or skills to receive the telemonitoring intervention [21,22]. The objective of this study was to assess perceptions of telemonitoring among patients with CHF who participated in the ITEC-CHF study and to evaluate the usability of this model of care.

Figure 1. ITEC-CHF Telemonitoring System. ITEC-CHF: Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure.

Methods

Study Setting and Design

A detailed description of the protocol for the ITEC-CHF study has been previously published [23]. Participants were recruited from the Frankston Hospital and Rosebud Hospital in Victoria, Australia, and Royal Perth Hospital and Fiona Stanley Hospital in Western Australia. Between January 2016 and December 2017, a total of 91 participants enrolled in the ITEC-CHF trial were mailed a survey and provided with a self-addressed and stamped envelope to return the survey at the end of the 6-month intervention. The survey consisted of two parts (see Multimedia Appendix 1). Part 1 was designed to evaluate the usability of the ITEC-CHF telemonitoring system and consisted of 9 questions, which were scored on a 5-point Likert scale (1=strongly disagree; 2=disagree; 3=neither agree nor disagree; 4=agree; and 5=strongly agree). The 9 Likert scale questions addressed the following concepts adapted from the technology acceptance model (TAM) and attitude toward technology use: (1) ease of use, (2) participants' confidence with managing CHF, (3) participants' ability to navigate the technology, and (4) perceived usefulness [23-26]. These questions assessed the participants' perceptions of telemonitoring and their comfort with using the technology involved. The TAM is an information technology framework for understanding users' adoption and use of emerging health care technologies [25,26]. The model states that usefulness and ease of use are two essential elements in describing participants' attitudes when using a new technology [26]. A number of studies support the validity of the TAM and its satisfactory explanation of end-user system usage [23,24,27]. Part 2 of the survey involved 3 open-ended questions to provide the participants an opportunity to express more detailed opinions about the ITEC-CHF telemonitoring system. The open-ended questions addressed perceived benefits and perceived barriers, as well as sought participants' suggestions about improving the system. The estimated time to complete all questions was approximately 15 minutes.

ITEC-CHF Telemonitoring System

Eligible participants for the survey were required to have completed the ITEC-CHF intervention. The detailed protocol for this study has been published [22], but it is summarized as follows:

Participants were provided with electronic weighing scales (W550; ForaCare), and a computer tablet (Galaxy Tab A; Samsung). They were asked to weigh themselves on the provided scales daily. The measured weight entry was recorded in the weighing scale and then automatically transmitted to the tablet via a wireless Bluetooth function embedded in the scales. The tablet was preloaded with an Android application (MedTech Global) that received the weight entry and uploaded it to a proprietary software package, ManageMyHealth (MedTech Global). A web application in MMH automatically monitored the uploaded weight entries in real time to generate alerts and triage those alerts to project nurses and the call center. The alerts were designed in accordance with the National Heart Foundation of Australia's *Guidelines for the Prevention, Detection, and Management of Chronic Heart* [17].

The telemonitoring intervention consisted of three components: remote weight monitoring, structured telephone support, and nurse-led collaborative care. Telemonitoring was integrated with a personal assistance call service (MePACS) and a nurse care service according to their workflows in usual care.

Operators at the call center responded to the alerts in real time (24 hours, 7 days a week). In cases where the participant required clinical support, such as advice for assessing CHF symptoms or managing fluid and salt restriction, the call operator arranged a nurse follow-up.

The project nurses provided structured interventions according to three types of alerts: rapid weight fluctuation (±2 kg in 2 days), slow weight fluctuation (±5 kg in 28 days), and low-risk weight fluctuation (±1 kg over 24 hours). If a participant's body weight fluctuation exceeded ±1 kg (but less than ±2 kg) over 24 hours, a questionnaire was automatically triggered and sent to the participant's computer tablet. If the participant reported

any of the clinical conditions in the questionnaire or did not respond to the questionnaire, the project nurses contacted the participant for a clinical assessment. However, if the response to the questionnaire determined the participant was asymptomatic, the alert was cancelled automatically to minimize unnecessary alerts to the project nurses.

Inclusion and Exclusion Criteria

The study's inclusion criteria were as follows: patients (1) with CHF diagnosed by a clinician with an ejection fraction ≤40%, (2) who were able to weigh oneself safely, (3) who were at least 18 years of age, (4) who have a regular personal general practitioner (GP) or agree to use a designated GP, (5) who have a permanent residential address, and (6) without significant cognitive impairment. The exclusion criteria were as follows: (1) patients with expected survival <12 months, (2) patients with end-stage renal failure on dialysis, (3) long-term nursing home residents, or (4) patients participating in any other clinical trial. All participants provided written informed consent.

Statistical Methods

Statistical analyses were performed using SPSS software (version 26.0; SPSS Inc.). Descriptive statistics (mean and SD, frequencies, and percentages) were used to characterize the study population and described participants' perceptions of usability of ITEC-CHF.

Open-ended questions were transcribed and imported into NVivo version 12 (QSR International) to facilitate the coding and to maximize the effectiveness and efficiency in sorting and merging the data according to themes reflecting common views and experiences. These were collated and supported by deidentified quotes from participants. Thematic analysis was performed to identify themes related to participants' perceptions of the perceived benefits and perceived barriers, as well as their suggestions about improving the system, thus capturing participants' understandings and allowing an in-depth analysis of the data [24]. Data were described, summarized, and then interpreted in relation to broader implications. The first author (SC), who is a nurse researcher with experience of research on CHF telemonitoring, familiarized herself with the data by reading the participants' responses several times, while taking notes. Points of interest were noted while reading and re-reading the transcripts. Following production of an initial set of codes, a thematic map was developed, which presented themes and subthemes. Accounts were then re-read to ensure that coding was checked and that nothing had been overlooked. Themes and subthemes were then allocated. The last author (AM), who is an experienced researcher in the fields of cardiac rehabilitation and heart failure management, cross-checked the set of themes and was fully involved in the data interpretation and write-up for dissemination.

Ethics Approval

The ethics application for the trial site in Victoria has been approved by Peninsula Health Human Research Ethics Committee (HREC Reference: HREC/14/PH/27), and the ethics applications for trial sites in Western Australia have been approved by Royal Perth Hospital Human Research Ethics Committee (Reference: 15-081) and the Curtin University Human Research Ethics Committee (Reference: HR 181/2014). This study complies with the Declaration of Helsinki. The trial has been registered in the Australian New Zealand Clinical Trials Registry, Trial ID: ACTRN12614000916640.

Results

Overview

The survey response rate was 77% (67/91 surveys; Table 1). There were no significant differences between the demographics or clinical characteristics of the participants who completed the survey and the overall cohort who completed the ITEC-CHF study.

For the broad concepts of *ease of use*, *confidence*, *navigability*, and *usefulness* described in the TAM, 91% (61/67) of participants "agreed" or "strongly agreed" that the telemonitoring system was easy to use, 85% (57/67) "agreed" or "strongly agreed" that the technology improved their confidence in managing their CHF condition, 78% (51/65) "agreed" or "strongly agreed" that the technology was easy to navigate, and 91% (59/65) "agreed" or "strongly agreed" that the telemonitoring was useful. A few participants indicated that they "disagreed" or "strongly disagreed that the telemonitoring system was easy to use (3%), that the technology improved their confidence in managing their CHF condition (2%), that the technology was easy to navigate (2%), and that the telemonitoring was useful (2%).

Table 2 presents the information related to the 9 questions that were rated on a 5-point Likert scale. Each indicator was evaluated across multiple questions.

Table 1. Demographics and clinical characteristics of study participants.

Characteristic	Value		*P* value
	Completed survey (n=67)	Completed ITEC-CHF[a] (N=91)	
Age in years, mean (SD)	69.8 (12.4)	69.5 (12.3)	.89
Gender, n (%)			
Male	49 (73)	66 (73)	.94
Female	18 (27)	25 (27)	.95
Highest education achieved, n (%)			
Less than high school	9 (13)	10 (11)	.64
High school	28 (42)	41 (45)	.68
Trade or technical training	8 (12)	12 (13)	.81
College or university undergraduate	19 (28)	23 (25)	.67
Postgraduate	3 (4)	5 (5)	.78
BMI, mean (SD)	32.1 (10.6)	31.4 (9.6)	.86
NYHA[b], n (%)			
I	5 (7)	8 (9)	.77
II	50 (75)	68 (75)	.99
III	11 (16)	14 (15)	.86
IV	1 (1)	1 (1)	.83
LVEF[c] (%), mean (SD)	28.7 (7.7)	29.1 (7.1)	.97
Other medical conditions, n (%)			
CHD[d]	46 (68)	58 (64)	.52
COPD[e] or asthma	16 (24)	23 (25)	.74
CKD[f]	7 (10)	10 (11)	.75
T2DM[g]	22 (33)	28 (31)	.87

[a]ITEC-CHF: Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure

[b]NYHA: New York Heart Association Functional Classifcation.

[c]LVEF: left ventricular ejection fraction.

[d]CHD: coronary heart disease.

[e]COPD: chronic obstructive pulmonary disease.

[f]CKD: chronic kidney disease.

[g]T2DM: type 2 diabetes mellitus

Table 2. Respondents' grading based on usability survey questions.

Survey item	Value, n (%)					Score, mean (SD)
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	
Ease of use (n=67)						
The weighing scale was easy to use	1 (1.5)	1 (1.5)	3 (4.5)	9 (13.4)	53 (79.1)	4.7 (0.8)
The touch screen tablet was easy to use	0 (0)	3 (4.5)	8 (11.9)	17 (25.3)	39 (58.2)	4.4 (0.9)
The information given to me in how to weigh myself using the device was easy to understand	0 (0)	0 (0)	2 (3)	25 (37.3)	40 (59.7)	4.6 (0.6)
Confidence (n=67)						
The technology helped me to manage my chronic heart condition	0 (0)	2 (3)	2 (3)	33 (49.3)	30 (34.3)	4.1 (0.8)
I feel more confident about managing my chronic heart failure after taking part in this research project	0 (0)	0 (0)	2 (3)	34 (50.8)	13 (35.8)	4.2 (0.7)
Navigability						
I found the weight reminders helpful on the touch screen tablet (n=56)	0 (0)	0 (0)	11 (19.6)	22 (39.3)	23 (41.1)	4.2 (0.8)
I found the symptom questions easy to respond to on the touch screen tablet (n=65)	0 (0)	3 (4.6)	13 (20)	20 (30.8)	29 (44.6)	4.2 (0.9)
Usefulness						
When I forgot to weigh myself, I found the reminder calls helpful (n=63)	1 (1.6)	1 (1.6)	6 (9.5)	17 (27)	38 (60.3)	4.4 (0.9)
When my weight changed, I found the call from the Chronic Heart Failure nurse helpful (n=65)	1 (1.5)	0 (0)	3 (4.6)	23 (35.4)	38 (58.5)	4.5 (0.7)

Themes and Subthemes Analyzed

Participants provided feedback, including a range of benefits and barriers to using telemonitoring. Eight key themes related to the ITEC-CHF program emerged from responses to the open-ended questions. Quotes from participants are provided to support each theme.

Increased Support for Early Intervention of Clinical Deterioration

Clinicians were able to view patient health data easily and quickly, which enabled early detection of clinical deterioration. This meant that problems were detected quickly, and participants were able to receive an early intervention.

> *Weight fluctuation detected early and see GP same day.*

Improved Compliance to Daily Weighing

The telemonitoring system helped participants get into a routine and inform them when a change occurred in their weight that was outside the predetermined limits.

> *Information exchange. Motivation to try and be healthy.*
>
> *Learning about weight changes and fluid balance.*

A Sense of Reassurance

Participants indicated they felt reassured that a clinician was behind the scenes reviewing their data.

> *Staff are competent.*
>
> *Safety net that someone is watching.*

Improved Self-care and Accountability

Participants felt accountable for their self-management because they were being monitored and would receive a reminder if they missed weighing themselves. This was reported as having had a positive effect on compliance to their self-management regime.

> *Weight measurement helped me with trying to maintain my health status.*
>
> *Made me personally more accountable of fluid management.*
>
> *Encouraging to weigh regularly. Help keep an eye on my diet.*

Supportive of Self-Management

The ITEC-CHF environment helped participants feel supported in self-managing their condition while reflecting on the telemonitoring system in self-care.

> *Weighing reminders from MEPACS.*
>
> *Don't feel alone. Familiar with nurses.*
>
> *Reassuring that help is on hand.*

Technical Difficulties

Some concerns expressed by participants were related to the technology, mainly due to Bluetooth connectivity issues in the early stages of the trial.

> *When machine doesn't register (scales).*
>
> *Computer tablet not registering weight measured from scales.*

Flexibility of Telemonitoring System

Some participants suggested they would have liked greater flexibility to be able to weigh themselves later than 10 AM to suit their lifestyle. This feedback was provided by participants who are employed, including those who work a night shift, to have the flexibility of the cutoff time to weigh in extended.

> *Sunday mornings when woken by MEPACS.*
>
> *Extend time to midday.*
>
> *Extend time limit.*

System Not Suitable for All Patients

Participants who had lifestyles involving frequent traveling found the continuous telemonitoring unsuitable. In addition, some participants reported difficulty in answering the questions on the computer tablet in a timely manner.

> *Not suitable when going away on holiday.*
>
> *Not enough time to answer symptoms questions.*

Discussion

Principal Findings

In this evaluation of the perceptions of telemonitoring among patients with CHF, the majority of participants "agreed" or "strongly agreed" that the intervention was feasible and helpful in their care. This included being easy to use (91% agreement) and helpful in improving their confidence in self-management (85% agreement). These findings are consistent with those reported from studies in other cohorts of people with chronic diseases that have evaluated perceptions of telemonitoring [10,11,14,15], but these results also provide new insights into the perceptions of patients with CHF.

Feedback from participants in this study highlights the importance of minimal user burden and ensuring user-friendly technology for telemonitoring to be acceptable to patients. High rates of satisfaction were observed with all the aspects of usability surveyed. Participants reported that the ITEC-CHF program was easy to use, easy to navigate, useful, and increased their confidence in managing their weight. Similarly, patients with chronic kidney disease were found to be highly accepting of using telemonitoring because they perceived it as being interactive and applicable in managing their condition [10]. In patients with hypertension, high levels of acceptability in using telemonitoring that relates to user-friendly technology has been previously reported [11]. User acceptance is especially important if telemonitoring is to be widely adopted; this is an important objective in the COVID-19 era when remotely delivered health care is increasingly being utilized to avoid subjecting patients to the risk of infection.

Compliance with care provider instructions and being self-disciplined in health management activities and self-care were two themes that were expressed by a high proportion of participants using the ITEC-CHF system. Compliance with self-care activities, such as diet, exercise, and medication adherence, are important factors in managing chronic conditions such as CHF given that successful disease management is, in part, dependent on patients' ability and willingness to carry out self-care activities [17]. Moreover, confidence in undertaking self-management activities, particularly the ability to reliably self-identify symptoms associated with clinical deterioration and take appropriate action in a timely manner is an important component of chronic disease management [28]. The observation that telemonitoring is beneficial for weight surveillance represents an important clinical outcome given that fluctuations in body weight are a reliable way of detecting fluid imbalance, which can be associated with poor self-care compliance or disease exacerbation [29-31].

However, the acceptance of telemonitoring was not ubiquitous for participants in the current study. For example, the technology in its current form may not suit patients who travel frequently. Several participants also indicated that greater flexibility in the telemonitoring system would reduce disruption to their lives, especially during holidays and on weekends. It was suggested by some participants that having the ability to alter the time before an alert was sent (ie, changing it to after 10 AM) would reduce the psychological burden of the alert system during these periods. This is an important consideration because previous studies have found that insufficient flexibility in telemonitoring models may hinder the ongoing use of the system [32-36].

Participant feedback also highlighted the importance of engaging consumers with a lived experience of CHF in the co-design of telemonitoring to ensure that it is simple and easy to engage with by the end user. Participants stressed the importance of a system that is robust, with easily accessible technical support—a finding consistent with observations in other clinical groups [37,38]. This is critical because technical problems are known to be a significant impediment to the uptake and adherence to telemonitoring [30-32]. From the ITEC-CHF trial, it was evident that technical issues led to disengagement from the system when encountered by some participants [22]. Patients with CHF often have multiple competing comorbid health issues to manage in their lives, so a seamless system of telemonitoring takes on additional importance.

Limitations

There are several limitations to the study that warrant highlighting. First, the results from the usability of the ITEC-CHF program were based on a relatively small sample size, so larger studies are required to confirm these findings. Second, there was no baseline data of participants' perceptions of the usability of the system to provide a comparison for user satisfaction measured at the end of the study. However, this design would have its own limitations because participants would lack the experiential insight derived from being involved in the trial to answer some of the questions at baseline. Third, the findings are based on the experiences of participants who completed the trial and who are, therefore, likely to have a more

favorable view of the telemonitoring system than those who dropped out. Finally, the single-group ITEC-CHF usability design precluded the assessment of the feasibility of randomization procedures, attrition, outcome measures, and acceptability in a control arm.

Conclusions

In this study evaluating the usability of a telemonitoring program in patients with CHF, a high overall usability rating was achieved, and the telemonitoring system was generally well accepted by users as an adjunct to their routine self-management activities. Participants in the study expressed that they were confident in using the ITEC-CHF system and reported many perceived benefits, including quick identification of early signs of clinical deterioration, which allows for faster response to manage the symptoms of CHF. Future trials that are powered to assess whether telemonitoring effects rehospitalization and mortality rates are required to determine whether these characteristics of telemonitoring translate to an improvement in clinical outcomes for patients with CHF.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure (ITEC-CHF) participant evaluation form.
[DOCX File , 16 KB - cardio_v5i2e24611_app1.docx]

References

1. Cook C, Cole G, Asaria P, Jabbour R, Francis DP. The annual global economic burden of heart failure. Int J Cardiol 2014 Feb 15;171(3):368-376. [doi: 10.1016/j.ijcard.2013.12.028] [Medline: 24398230]
2. Cowie MR, Anker SD, Cleland JGF, Felker GM, Filippatos G, Jaarsma T, et al. Improving care for patients with acute heart failure: before, during and after hospitalization. ESC Heart Fail 2014 Dec 21;1(2):110-145 [FREE Full text] [doi: 10.1002/ehf2.12021] [Medline: 28834628]
3. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, Coats AJS, ESC Scientific Document Group. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J 2016 Jul 14;37(27):2129-2200. [doi: 10.1093/eurheartj/ehw128] [Medline: 27206819]
4. Bashi N, Karunanithi M, Fatehi F, Ding H, Walters D. Remote monitoring of patients with heart failure: an overview of systematic reviews. J Med Internet Res 2017 Jan 20;19(1):e18 [FREE Full text] [doi: 10.2196/jmir.6571] [Medline: 28108430]
5. Queenan C, Cameron K, Snell A, Smalley J, Joglekar N. Patient heal thyself: reducing hospital readmissions with technology‐enabled continuity of care and patient activation. Prod Oper Manag 2019 Aug 11;28(11):2841-2853. [doi: 10.1111/poms.13080]
6. Wongvibulsin S, Martin SS, Steinhubl SR, Muse ED. Connected health technology for cardiovascular disease prevention and management. Curr Treat Options Cardiovasc Med 2019 May 18;21(6):29-29 [FREE Full text] [doi: 10.1007/s11936-019-0729-0] [Medline: 31104157]
7. Tsai C, Kuo Y, Uei S. Influences of satisfaction with telecare and family trust in older Taiwanese people. Int J Environ Res Public Health 2014 Jan 27;11(2):1359-1368 [FREE Full text] [doi: 10.3390/ijerph110201359] [Medline: 24473111]
8. Bishop TF, Press MJ, Mendelsohn JL, Casalino LP. Electronic communication improves access, but barriers to its widespread adoption remain. Health Aff (Millwood) 2013 Aug;32(8):1361-1367 [FREE Full text] [doi: 10.1377/hlthaff.2012.1151] [Medline: 23918479]
9. Alnosayan N, Chatterjee S, Alluhaidan A, Lee E, Houston Feenstra L. Design and usability of a heart failure mHealth system: a pilot study. JMIR Hum Factors 2017 Mar 24;4(1):e9 [FREE Full text] [doi: 10.2196/humanfactors.6481] [Medline: 28341615]
10. Martínez García MA, Fernández Rosales MS, López Domínguez E, Hernández Velázquez Y, Domínguez Isidro S. Telemonitoring system for patients with chronic kidney disease undergoing peritoneal dialysis: Usability assessment based on a case study. PLoS One 2018;13(11):e0206600 [FREE Full text] [doi: 10.1371/journal.pone.0206600] [Medline: 30399164]
11. Albrecht L, Wood PW, Fradette M, McAlister FA, Rabi D, Boulanger P, et al. Usability and acceptability of a home blood pressure telemonitoring device among community-dwelling senior citizens with hypertension: qualitative study. JMIR Aging 2018 Jul 24;1(2):e10975 [FREE Full text] [doi: 10.2196/10975] [Medline: 31518242]
12. Nancarrow S, Banbury A, Buckley J. Evaluation of a National Broadband Network-enabled Telehealth trial for older people with chronic disease. Aust Health Review 2016;40(6):641. [doi: 10.1071/ah15201]
13. World Population Prospects 2019: Highlights. United Nations - Department of Economic and Social Affairs Population Dynamics. 2019. URL: https://population.un.org/wpp/Publications/ [accessed 2021-09-01]

14. Alghamdi SM, Janaudis-Ferreira T, Alhasani R, Ahmed S. Acceptance, adherence and dropout rates of individuals with COPD approached in telehealth interventions: a protocol for systematic review and meta-analysis. BMJ Open 2019 Apr 25;9(4):e026794 [FREE Full text] [doi: 10.1136/bmjopen-2018-026794] [Medline: 31028042]
15. Anglada-Martínez H, Martin-Conde M, Rovira-Illamola M, Sotoca-Momblona JM, Sequeira E, Aragunde V, et al. Feasibility and preliminary outcomes of a web and smartphone-based medication self-management platform for chronically ill patients. J Med Syst 2016 Apr 12;40(4):99-99. [doi: 10.1007/s10916-016-0456-y] [Medline: 26872781]
16. National Heart Foundation of Australia. Living Well With Chronic Heart Failure. Melbourne: National Heart Foundation of Australia; 2018.
17. NHFA CSANZ Heart Failure Guidelines Working Group, Atherton JJ, Sindone A, De Pasquale CG, Driscoll A, MacDonald PS, et al. National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand: Guidelines for the Prevention, Detection, and Management of Heart Failure in Australia 2018. Heart Lung Circ 2018 Oct;27(10):1123-1208 [FREE Full text] [doi: 10.1016/j.hlc.2018.06.1042] [Medline: 30077227]
18. Walker RC, Tong A, Howard K, Palmer SC. Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies. Int J Med Inform 2019 Apr;124:78-85 [FREE Full text] [doi: 10.1016/j.ijmedinf.2019.01.013] [Medline: 30784430]
19. Nymberg VM, Bolmsjö BB, Wolff M, Calling S, Gerward S, Sandberg M. 'Having to learn this so late in our lives…' Swedish elderly patients' beliefs, experiences, attitudes and expectations of e-health in primary health care. Scand J Prim Health Care 2019 Mar;37(1):41-52 [FREE Full text] [doi: 10.1080/02813432.2019.1570612] [Medline: 30732519]
20. Heiney SP, Donevant SB, Arp Adams S, Parker PD, Chen H, Levkoff S. A smartphone app for self-management of heart failure in older African Americans: feasibility and usability study. JMIR Aging 2020 Apr 03;3(1):e17142 [FREE Full text] [doi: 10.2196/17142] [Medline: 32242822]
21. Ding H, Jayasena R, Chen SH, Maiorana A, Dowling A, Layland J, et al. The effects of telemonitoring on patient compliance with self-management recommendations and outcomes of the innovative telemonitoring enhanced care program for chronic heart failure: randomized controlled trial. J Med Internet Res 2020 Jul 08;22(7):e17559 [FREE Full text] [doi: 10.2196/17559] [Medline: 32673222]
22. Ding H, Jayasena R, Maiorana A, Dowling A, Chen S, Karunanithi M, et al. Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure (ITEC-CHF) to improve guideline compliance and collaborative care: protocol of a multicentre randomised controlled trial. BMJ Open 2017 Oct 08;7(10):e017550 [FREE Full text] [doi: 10.1136/bmjopen-2017-017550] [Medline: 28993389]
23. Wu J, Chen Y, Lin L. Empirical evaluation of the revised end user computing acceptance model. Comput Human Behav 2007 Jan;23(1):162-174. [doi: 10.1016/j.chb.2004.04.003]
24. Holden RJ, Karsh B. The technology acceptance model: its past and its future in health care. J Biomed Inform 2010 Feb;43(1):159-172 [FREE Full text] [doi: 10.1016/j.jbi.2009.07.002] [Medline: 19615467]
25. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Quarterly 1989 Sep;13(3):319. [doi: 10.2307/249008]
26. Taherdoost H. A review of technology acceptance and adoption models and theories. Procedia Manuf 2018;22:960-967. [doi: 10.1016/j.promfg.2018.03.137]
27. Giger J, Pope N, Vogt H, Gutierrez C, Newland L, Lemke J, et al. Remote patient monitoring acceptance trends among older adults residing in a frontier state. Comput Human Behav 2015 Mar;44:174-182 [FREE Full text] [doi: 10.1016/j.chb.2014.11.044]
28. Massouh A, Skouri H, Cook P, Huijer HAS, Khoury M, Meek P. Self-care confidence mediates self-care maintenance and management in patients with heart failure. Heart Lung 2020 Jan;49(1):30-35. [doi: 10.1016/j.hrtlng.2019.07.008] [Medline: 31371031]
29. Dendale P, De Keulenaer G, Troisfontaines P, Weytjens C, Mullens W, Elegeert I, et al. Effect of a telemonitoring-facilitated collaboration between general practitioner and heart failure clinic on mortality and rehospitalization rates in severe heart failure: the TEMA-HF 1 (TElemonitoring in the MAnagement of Heart Failure) study. Eur J Heart Fail 2012 Mar 18;14(3):333-340 [FREE Full text] [doi: 10.1093/eurjhf/hfr144] [Medline: 22045925]
30. Koehler F, Koehler K, Deckwart O, Prescher S, Wegscheider K, Kirwan B, et al. Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial. The Lancet 2018 Sep;392(10152):1047-1057. [doi: 10.1016/s0140-6736(18)31880-4]
31. Melin M, Hägglund E, Ullman B, Persson H, Hagerman I. Effects of a tablet computer on self-care, quality of life, and knowledge. J Cardiovasc Nurs 2018;33(4):336-343. [doi: 10.1097/jcn.0000000000000462]
32. May CR, Finch TL, Cornford J, Exley C, Gately C, Kirk S, et al. Integrating telecare for chronic disease management in the community: what needs to be done? BMC Health Serv Res 2011 May 27;11(1):131-131 [FREE Full text] [doi: 10.1186/1472-6963-11-131] [Medline: 21619596]
33. Hanley J, Pinnock H, Paterson M, McKinstry B. Implementing telemonitoring in primary care: learning from a large qualitative dataset gathered during a series of studies. BMC Fam Pract 2018 Jul 18;19(1):118-118 [FREE Full text] [doi: 10.1186/s12875-018-0814-6] [Medline: 30021535]

34. Ammenwerth E, Modre-Osprian R, Fetz B, Gstrein S, Krestan S, Dörler J, et al. HerzMobil, an integrated and collaborative telemonitoring-based disease management program for patients with heart failure: a feasibility study paving the way to routine care. JMIR Cardio 2018 Apr 30;2(1):e11 [FREE Full text] [doi: 10.2196/cardio.9936] [Medline: 31758765]
35. Ware P, Ross HJ, Cafazzo JA, Laporte A, Gordon K, Seto E. User-centered adaptation of an existing heart failure telemonitoring program to ensure sustainability and scalability: qualitative study. JMIR Cardio 2018 Dec 06;2(2):e11466 [FREE Full text] [doi: 10.2196/11466] [Medline: 31758774]
36. Ware P, Ross HJ, Cafazzo JA, Laporte A, Gordon K, Seto E. Evaluating the implementation of a mobile phone-based telemonitoring program: longitudinal study guided by the consolidated framework for implementation research. JMIR Mhealth Uhealth 2018 Jul 31;6(7):e10768 [FREE Full text] [doi: 10.2196/10768] [Medline: 30064970]
37. Vermeulen J, Verwey R, Hochstenbach LMJ, van der Weegen S, Man YP, de Witte LP. Experiences of multidisciplinary development team members during user-centered design of telecare products and services: a qualitative study. J Med Internet Res 2014 May 19;16(5):e124 [FREE Full text] [doi: 10.2196/jmir.3195] [Medline: 24840245]
38. Fischer B, Peine A, Östlund B. The importance of user involvement: a systematic review of involving older users in technology design. Gerontologist 2020 Sep 15;60(7):e513-e523 [FREE Full text] [doi: 10.1093/geront/gnz163] [Medline: 31773145]

Abbreviations

CHF: chronic heart failure
HREC: Human Research Ethics Committee
ITEC-CHF: Innovative Telemonitoring Enhanced Care program for CHF
TAM: technology acceptance model

Edited by G Eysenbach; submitted 27.09.20; peer-reviewed by D Tao, V Stara, S Bhattacharjya; comments to author 18.11.20; revised version received 07.03.21; accepted 31.05.21; published 14.09.21.

Please cite as:
Chen SH, Edwards I, Jayasena R, Ding H, Karunanithi M, Dowling A, Layland J, Maiorana A
Patient Perspectives on Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure (ITEC-CHF): Usability Study
JMIR Cardio 2021;5(2):e24611
URL: https://cardio.jmir.org/2021/2/e24611
doi:10.2196/24611
PMID:34519663

Original Paper

The Effect of Cardiovascular Comorbidities on Women Compared to Men: Longitudinal Retrospective Analysis

Elma Dervic[1,2*], MSc; Carola Deischinger[3*], BA, MD; Nils Haug[1,2], PhD; Michael Leutner[3], MD, PhD; Alexandra Kautzky-Willer[3,4], MD, PhD; Peter Klimek[1,2], PhD

[1]Section for Science of Complex Systems, Center for Medical Statistics, Informatics and Intelligent Systems, Medical University of Vienna, Vienna, Austria

[2]Complexity Science Hub Vienna, Vienna, Austria

[3]Department of Internal Medicine III, Clinical Division of Endocrinology and Metabolism, Gender Medicine Unit, Medical University of Vienna, Vienna, Austria

[4]Gender Institute, Gars am Kamp, Austria

[*]these authors contributed equally

Corresponding Author:
Peter Klimek, PhD
Section for Science of Complex Systems
Center for Medical Statistics, Informatics and Intelligent Systems
Medical University of Vienna
Spitalgasse 23
Vienna, 1090
Austria
Phone: 43 1 40160 36252
Email: Peter.Klimek@meduniwien.ac.at

Related Articles:

Comment in: https://cardio.jmir.org/2022/1/e34647

Comment in: https://cardio.jmir.org/2022/1/e36801

Abstract

Background: Although men are more prone to developing cardiovascular disease (CVD) than women, risk factors for CVD, such as nicotine abuse and diabetes mellitus, have been shown to be more detrimental in women than in men.

Objective: We developed a method to systematically investigate population-wide electronic health records for all possible associations between risk factors for CVD and other diagnoses. The developed structured approach allows an exploratory and comprehensive screening of all possible comorbidities of CVD, which are more connected to CVD in either men or women.

Methods: Based on a population-wide medical claims dataset comprising 44 million records of inpatient stays in Austria from 2003 to 2014, we determined comorbidities of acute myocardial infarction (AMI; International Classification of Diseases, Tenth Revision [ICD-10] code I21) and chronic ischemic heart disease (CHD; ICD-10 code I25) with a significantly different prevalence in men and women. We introduced a measure of sex difference as a measure of differences in logarithmic odds ratios (ORs) between male and female patients in units of pooled standard errors.

Results: Except for lipid metabolism disorders (OR for females [ORf]=6.68, 95% confidence interval [CI]=6.57-6.79, OR for males [ORm]=8.31, 95% CI=8.21-8.41), all identified comorbidities were more likely to be associated with AMI and CHD in females than in males: nicotine dependence (ORf=6.16, 95% CI=5.96-6.36, ORm=4.43, 95% CI=4.35-4.5), diabetes mellitus (ORf=3.52, 95% CI=3.45-3.59, ORm=3.13, 95% CI=3.07-3.19), obesity (ORf=3.64, 95% CI=3.56-3.72, ORm=3.33, 95% CI=3.27-3.39), renal disorders (ORf=4.27, 95% CI=4.11-4.44, ORm=3.74, 95% CI=3.67-3.81), asthma (ORf=2.09, 95% CI=1.96-2.23, ORm=1.59, 95% CI=1.5-1.68), and COPD (ORf=2.09, 95% CI 1.96-2.23, ORm=1.59, 95% CI 1.5-1.68). Similar results could be observed for AMI.

Conclusions: Although AMI and CHD are more prevalent in men, women appear to be more affected by certain comorbidities of AMI and CHD in their risk for developing CVD.

(JMIR Cardio 2021;5(2):e28015) doi:10.2196/28015

KEYWORDS

gender gap; sex differences; cardiovascular diseases; acute myocardial infarction; chronic ischemic heart disease; gender; diabetes; smoking; risk factors; comorbidities

Introduction

Despite the overall higher prevalence of cardiovascular disease (CVD) in men, the gender gap in CVD narrows with age, especially postmenopause [1]. Potential explanations are plentiful and range from a menopausal drop in protective estrogen to certain comorbidities affecting women in a more impactful way [2-5]. However, whether these findings just represent anecdotal evidence or whether they hint at a systematic development in which, given certain risk factors, women are getting an increasingly higher risk for CVD than men is currently unclear. To clarify the role of comorbidities in the CVD gender gap, we aimed at developing a structured approach to screening and identifying sex-specific differences in comorbidities associated with CVD in this analysis.

Some risk factors for CVD are associated with excess risk in 1 sex but not the other. A series of meta-analyses identified smoking [3] and diabetes [2,4] to have a stronger relative effect on CVD risk in women than in men, which, in the case of diabetes mellitus, has been extensively studied. Diabetes mellitus not only doubles the CVD risk but increases the risk by 44% more in females compared to males [6,7]. In the case of chronic kidney disease (CKD) and CVD, dialysis patients have a 50-fold increased CVD mortality rate in comparison to the general population; females, specifically, lose their survival advantage [8]. The female sex has independently been associated with CKD among ST-elevation myocardial infarction (STEMI) patients, which then resulted in a 2-fold relative increase of in-hospital mortality for women in the same study [9]. Sex differences (SDs) in CVD risk amongst patients with respiratory diseases have not been sufficiently investigated so far. In respiratory diseases, both sexes with active asthma were at a 29% higher risk of suffering from an acute myocardial infarction (AMI) compared with adults without asthma in a 2019 study [10]. Although chronic obstructive pulmonary disease (COPD) is more prevalent in men, prevalence and mortality among women have been rising and there are indications that COPD and risk factors for COPD are more detrimental in women than in men. In a study on women and COPD, women were significantly younger and had smoked less than men [11]. Furthermore, although the prevalence of CVD in COPD is higher in men, the impact of CVD on mortality in women with COPD increased in the Obstructive Lung Disease in Northern Sweden (OLIN) COPD study [12].

A more comprehensive quantification of SDs in AMI or chronic ischemic heart disease (CHD) risk in association with other comorbidities, such as respiratory and renal diseases, is still needed. This analysis aimed to fill this knowledge gap by identifying potential gender gaps in comorbidities associated with AMI or CHD and by determining the extent of age-/menopause-related differences in the gender gaps.

Methods

Both the terms “woman/man” and “female/male” are used in this paper as we investigate SDs. However, through our study design, we cannot rule out an influence of gender aspects (in addition to sex-specific aspects) on disease risk. For the purpose of this study and in line with the previous literature [5,13], “gender gap” is used to describe sex and gender differences in disease risk between men and women.

Data

Medical claims data of the entire Austrian population were examined with a structured approach to analyze comorbidity networks for female and male patients. This database contains approximately 44 million records, containing for each in-hospital stay in Austria from 1997 until 2014 the patient’s ID, age, date of admission, date of discharge, primary diagnosis, secondary diagnoses, and type of release. The age of patients is given at a resolution of 5 years. The reason for the hospital admission is given by the primary diagnosis. Conditions that coexist at the time of admission are secondary diagnoses. In this study, we considered primary and secondary diagnoses as equally relevant. All diagnoses are recorded in the form of level 3 International Classification of Diseases, Tenth Revision (ICD-10) codes, a medical classification system by the World Health Organization (WHO). This study concentrated on 1080 different ICD-10 codes ranging from A00 to N99. We only extracted the subset of patients who did not have any hospital stays during the 6 years from 1997 to 2002.

The total number of patients in the database is 8,996,916. After extracting the described subset of patients, the total number of patients for this analysis was 3,758,634 (51% women, 49% men). To compare changes that might occur before and after (peri-)menopause, we conducted additional analyses comparing patient groups with ages being above or below the cutoff age of 50 years. The total number of all diagnoses recorded in the selected dataset was 36,358,201 (50.14% diagnoses of female patients, 49.86% diagnoses of male patients). The 5 most frequent diagnoses were hypertension (I10), CHD (I25), type 2 diabetes mellitus (E11), atrial fibrillation and flutter (I48), lipid metabolism disorder (E78) (female: I10, malignant neoplasm of breast [C50], other disorders of urinary system [N39], I25, E11; male: I10, I25, E11, E78, COPD [J44]).

Co-occurrence Analysis/Relative Risks for Comorbidities

Comorbidities indicate the presence of more than 1 disease in the same person. In our analysis, we investigated all statistically significant co-occurring diseases.

Stratified analysis was performed to adjust for confounding variables (age, time period). The analyzed dataset was stratified by age (10-year age groups) and 6 time windows of 2 years each from 2003 to 2014 (2003-2004, 2005-2006, and so on), resulting in 48 strata for women and men. For each pair of diagnoses for each stratum, a contingency table was built. Contingency tables that contained a sufficient number of patients in each subgroup (>4) were used for computing relative risks (RRs) and the *P*-value for rejecting the null hypothesis that the co-occurrence of 2 analyzed diagnoses is statistically independent.

By using the Cochran–Mantel–Haenszel method [14], we calculated a weighted average of the estimates of the risk ratios and odds ratios (ORs) across the stratified data. To identify sex-specific differences in comorbidities, we identified all comorbidities with an RR higher than 1.5 and a *P*-value smaller than 0.01. Comorbidities with less than 1000 occurrences in female or male patients were excluded.

Sex Differences

As a test statistic for SDs, we measured the differences of logarithmic ORs between male and female patients in units of pooled standard errors:

$$SD = [\log(ORm) - \log(ORf)]/\sqrt{(SEm^2 + SEf^2)}$$

where ORm is the OR for males, ORf is the OR for females, SEm is the standard error of ORm, and SEf is the standard error of ORf.

To test for significant SDs, we tested the null hypothesis that an SD is measured from a normal distribution with zero mean to obtain the SD *P*-value *P*_SD.

We defined 5 significance levels of SDs:

- Not significant (SD<=2<==>*P*_SD>=.045)
- Weak (2<SD<=3<==>.003<=*P*_SD<.045)
- Substantial (3<SD<=4<==>.00006<=*P*_SD<.003)
- Strong (4<SD<=5<==>.0001<=*P*_SD<.00006)
- Very strong (5<SD<==>*P*_SD<.00001)

Time Directionality

We calculated the time difference for each pair of diagnoses (A and B) for every patient in the period 2003-2014. The time difference was defined as the difference between the time of the first diagnosis of A and the time of the first diagnosis of B. Patients were separated into 4 groups based on the time interval for each pair: (1) A and B were diagnosed during the same hospital stay and the time difference between A and B was (2) less than 3 months, (3) greater than 3 months and less than approximately 1 year (360 days), or, finally, (4) greater than approximately 1 year.

In each group and for each pair, we counted the number of patients who were first diagnosed with disease A and then disease B, $N(A \rightarrow B)$, and vice versa, $N(B \rightarrow A)$.

For all 4 above-defined time intervals, we calculated the ratio between the number of patients with the direction of "first A then B" relative to "first B then A" and the time order ratio $TOR(A \rightarrow B) = N(A \rightarrow B)/N(B \rightarrow A)$ to identify the "direction" of each pair.

A $TOR(A \rightarrow B)$ of <1 (>1) indicates that B (A) tends to occur before A (B). To see whether $TOR(A \rightarrow B)$ is significantly different from 1, we tested the null hypothesis that $N(A \rightarrow B) = N(B \rightarrow A)$, assuming that both counts stem from a binomial distribution with equal success probability.

Results

Baseline Characteristics

We focused on the age group of 20-79 years, with a total of 2,716,967 patients (50.12% women, 49.88% men). As shown in Table 1, 2.02% of all patients were diagnosed with AMI (1.42% women, 2.64% men) and 6.22% of all patients were diagnosed with CHD (4.9% women, 7.58% men).

Table 1. Baseline characteristics and prevalence (%) among all patients aged 20-79 years in Austria from 2003 to 2014.

Parameters and diagnoses	All	Female patients	Male patients
All patients	2,716,967	1,361,704	1,355,263
Age (years, mean±SE[a])	48.53±15.99	47.99±16.2	49.07±15.77
Number of hospital stays (mean±SE)	3.04±4.92	3±4.82	3.08±5.01
Hospital days (mean±SE)	17.52±45.83	16.65±44.38	18.38±47.3
Number of hospital diagnoses (mean±SE)	4.28±4.83	4.12±4.66	4.44±4.99
Obesity and overweight (%)	4.37	4.47	4.26
Disorders of lipoprotein metabolism and other lipidemias (%)	8.46	7.33	9.62
Nicotine dependence (%)	3.16	2.01	4.33
AMI[b] (%)	2.02	1.42	2.64
CHD[c] (%)	6.22	4.9	7.58
Asthma (%)	1.3	1.28	1.31
COPD[d] (%)	3.41	2.69	4.15
Respiratory failure (%)	0.91	0.76	1.06
Diabetes mellitus (%)	6.49	5.93	7.07
Acute kidney failure and CKD[e] (%)	3.77	3.66	3.88

[a]SE: standard error.

[b]AMI: acute myocardial infarction.

[c]CHD: chronic ischemic heart disease.

[d]COPD: chronic obstructive pulmonary disease.

[e]CKD: chronic kidney disease.

Overweight and Obesity

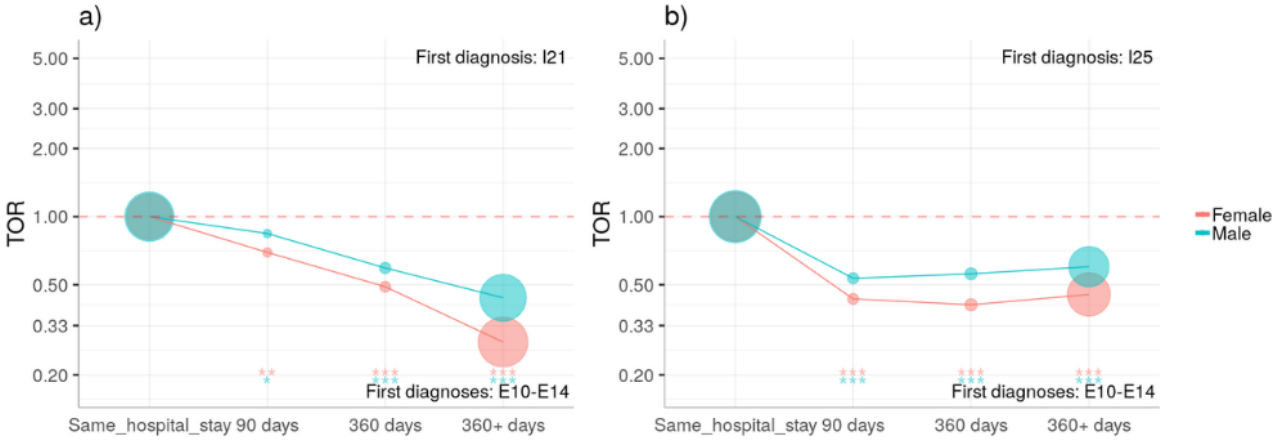
In the analysis at hand, the diagnosis of overweight and obesity was more prominently associated with AMI (ORf=3.36, 95% confidence interval [CI]=3.22-3.51 vs ORm=2.8, 95% CI=2.72-2.88, *P*_SD<.0001) and CHD (ORf=3.64, 95% CI=3.56-3.72, ORm=3.33, 95% CI=3.27-3.39, *P*_SD<.0001) in females than in males. To account for potential differences before and after an age considered likely (peri-)menopausal, we investigated the association of overweight and obesity with AMI and CHD in the age group under 50 and over 50 years. The results were similar in both groups; however, the effect of sex on the association between overweight/obesity and AMI and CHD risk was more prominent in the age group of 50 years and above.

Diabetes Mellitus

Females showed a stronger association of diabetes mellitus with AMI and CHD compared to males (AMI: ORf=2.94, 95% CI=2.77-3.12 vs ORm=2.17, 95% CI=2.09-2.26, *P*_SD<.0001; CHD: ORf=3.52, 95% CI=3.45-3.59, 0.01, ORm=3.13, 95% CI=3.07-3.19, *P*_SD<.0001). The effect was greater in the age group of 50-79 years than in younger patients.

There is a tendency that diabetes mellitus is diagnosed before AMI and CHD; see Figure 1, where we show the corresponding TORs as a function of time.

Figure 1. Diabetes mellitus is typically diagnosed before AMI and CHD. We show the time directionality (see Methods) for patients with a diagnosis of diabetes (E10-E14) and (a) AMI (I21) and (b) CHD (I25). The larger the time difference between these two diagnoses, the stronger the dominance of patients first having a diabetes mellitus diagnosis (TOR<1). Significance levels of the TOR are indicated by asterisks (*P<.05, **P<.01, ***P<.0001). AMI: acute myocardial infarction; CHD: chronic ischemic heart disease; TOR: time order ratio.

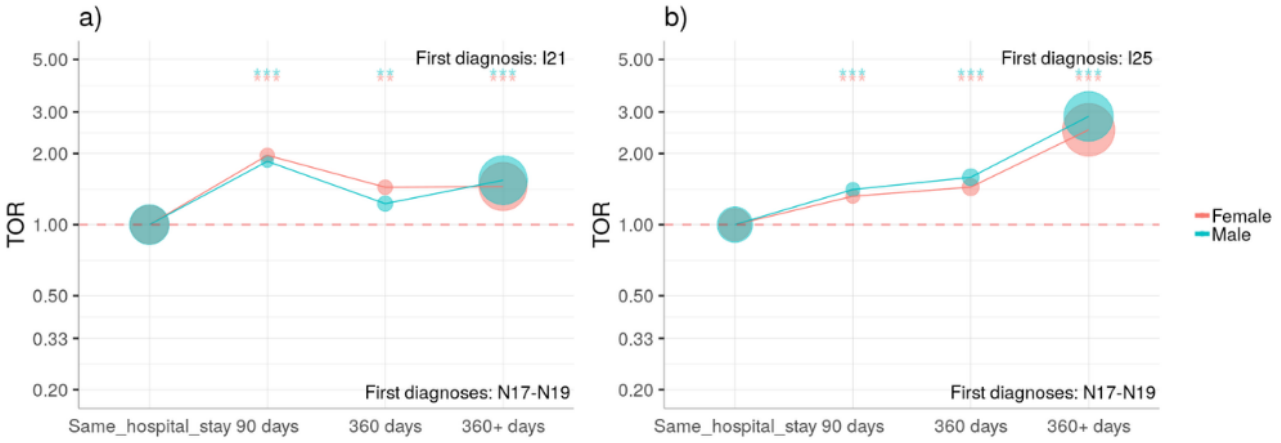


The increased risk for female patients with diabetes mellitus to develop AMI or CHD is a well-researched finding. Diabetes mellitus not only doubles the CVD risk but rather adds an additional 44% risk to females compared to males [6,7].

Acute and Chronic Kidney Disease

Female patients with acute kidney disease and CKD were more likely to be diagnosed with AMI and CHD, respectively, than male patients in our cohort (AMI: ORf=3.96, 95% CI=3.73-4.2 vs ORm=2.8, 95% CI=2.69-2.91, P_SD<.0001; CHD: ORf=4.27, 95% CI=4.11-4.44 vs ORm=3.74, 95% CI=3.67-3.81, P_SD<.0001). This effect was especially prominent in the age group of 50-79 years compared to younger patients. There is a tendency that acute kidney disease and CKD are diagnosed after AMI and CHD; see Figure 2.

Figure 2. Time directionality analysis for CKD. There is a tendency that patients are first diagnosed with (a) AMI and (b) CHD and then with CKD. Results are shown as in Figure 1 for diabetes. AMI: acute myocardial infarction; CHD: chronic ischemic heart disease; CKD: chronic kidney disease; TOR: time order ratio.



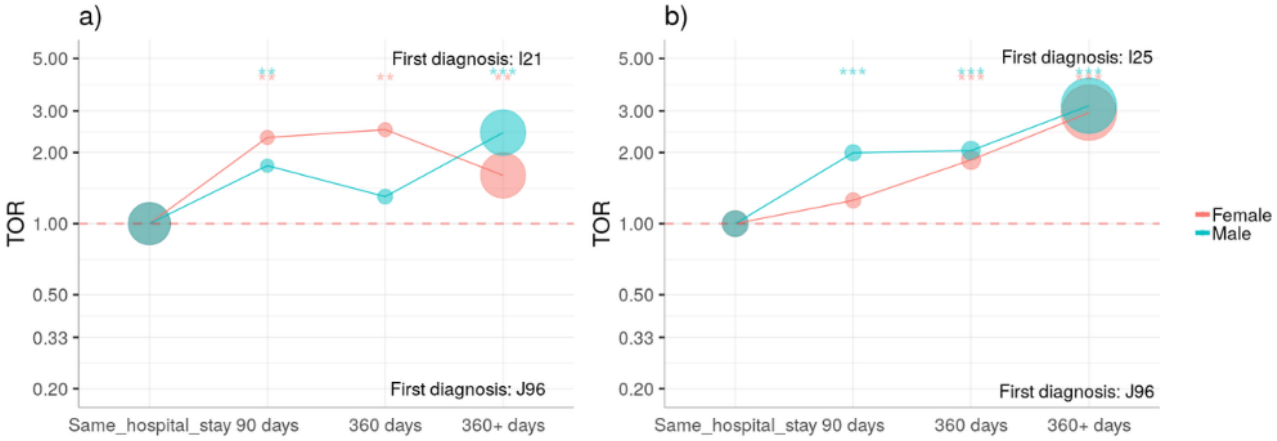
Nicotine Dependence

Nicotine abuse had a significantly higher associated AMI and CHD risk for female patients than male patients (AMI: ORf=10.14, 95% CI=9.66-10.64 vs ORm=6.68, 95% CI=6.51-6.84, P_SD<.0001; CHD: ORf=6.16, 95% CI=5.96-6.36 vs ORm=4.43, 95% CI=4.35-4.5, P_SD<.0001).

Respiratory Failure

Female patients showed a stronger association of respiratory failure with AMI and CHD compared to male patients (AMI: ORf=3.11, 95% CI=2.78-3.48 vs ORm=2.24, 95% CI=2.09-2.4, P_SD<.0001; CHD: ORf=2.92, 95% CI=2.75-3.1 vs ORm=2.18, 95% CI=2.1-2.27, P_SD<.0001). When splitting the patients in 2 age groups (20-49 years, 50-79 years) to account for potential changes likely related to (peri-)menopause status, respiratory failure was associated with AMI and CHD in the age group of 50-79 years (AMI: ORf=3.11, 95% CI=2.76-3.5 vs ORm=2.23, 95% CI=2.06-2.41, P_SD<.0001; CHD: ORf=2.89, 95% CI=2.72-3.07 vs ORm=2.16, 95% CI=2.08-2.25, P_SD<.0001) but only with CHD (ORf=6.68, 95% CI=4.34-10.28 vs ORm=2.76, 95% CI=2.27-3.36, P_SD<.0001) and not AMI in younger patients. Based on time directionality analysis, we concluded that there is a tendency that respiratory failure is diagnosed after AMI; the same effect can be observed for respiratory failure and CHD (see Figure 3).

Figure 3. Time directionality analysis for respiratory failure. There is a tendency that patients are first diagnosed with (a) AMI and (b) CHD and then with respiratory failure. Results are shown in Figure 1 for diabetes mellitus. AMI: acute myocardial infarction; CHD: chronic ischemic heart disease; TOR: time order ratio.



Asthma

Female patients had a significantly higher risk of having asthma and CHD (ORf=2.09, 95% CI=1.96-2.23 vs ORm=1.59, 95% CI=1.5-1.68, *P*_SD<.0001) but not asthma and AMI.

When splitting patients into 2 age groups (20-49 years, 50-79 years) to account for potential differences before and after an age considered likely (peri-)menopausal, asthma and AMI and CHD were significantly more often connected in females in the age group of 50-79 years than in younger patients.

COPD

COPD and AMI or CHD were more likely to co-occur in female patients than in male patients (AMI: ORf=2.49, 95% CI=2.35-2.63 vs ORm=1.62, 95% CI=1.56-1.68, *P*_SD<.0001; CHD: ORf=2.09, 95% CI=1.96-2.23 vs ORm=1.59, 95% CI=1.5-1.68, *P*_SD<.0001). COPD was more prominently associated with AMI or CHD in the age group of 50-79 years than in younger patients.

Lipid Metabolism Disorders

Lipid metabolism disorders were associated with an excess risk for AMI and CHD in male than in female patients in our analysis (AMI: ORf=6.3, 95% CI=6.1-6.5 vs ORm=7.21, 95% CI=7.07-7.35, *P*_SD<.0001; CHD: ORf=6.68, 95% CI=6.57-6.79, ORm=8.31, 95% CI=8.21-8.41, *P*_SD<.0001).

Discussion

Principal Findings

The results of this analysis demonstrated that except for lipid metabolism disorders, the risk factors overweight and obesity, diabetes mellitus, acute kidney disease and CKD, nicotine dependence, respiratory failure, asthma, and COPD display a stronger connection to CHD and AMI in women than in men.

Obesity predisposes to a multitude of comorbidities, many of which have a negative impact on CVD risk. As women are more likely to be obese [15], these results might be useful to improve screening practices. However, these data contrast a 2015 meta-analysis that concluded that there was no evidence of an SD in CVD risk associated with the body mass index (BMI) [16]. The discrepancy between the meta-analysis and our calculations might stem from coding practices with the ICD-10 code E66 (“overweight and obesity”) preferably being used in patients with a high BMI, whereas the meta-analysis by Mongraw-Chaffin et al related a continuous BMI to CVD risk and, thus, included lower BMI categories as well [16]. An important consideration in overweight and obesity is body fat distribution, often measured in waist-to-hip distribution, as it can predict CVD risk [17].

Before menopause, the more favorable body fat distribution in the lower-body subcutaneous areas might mitigate CVD risk in females. The menopausal loss of ovarian hormones induces a redistribution of body fat to a more visceral, less favorable distribution [18]. In this analysis, the effect of sex on the association between overweight and obesity and AMI and CHD risk was more prominent in the age group of 50 years and above, which potentially corroborates research stating a less favorable distribution after menopause.

Similar to overweight and obesity, females showed a stronger association of diabetes mellitus with AMI or CHD compared to males. The increased risk for female patients with diabetes mellitus to develop AMI or CHD in this study is a well-researched finding, as females with diabetes mellitus lose their “female protection” against CVD [19]. Diabetes mellitus does not only double CVD risk but rather adds an additional 44% risk to females compared to males [6,7].

We found similar increased ORs in female patients with acute kidney disease and CKD who were also more likely to be diagnosed with AMI or CHD than in male patients in our cohort. The complex relationship between CKD and CVD probably results from overlapping risk factors and clustering of unspecific CVD risk factors, such as hypertension, diabetes mellitus, dyslipidemia, and CKD-specific factors (eg, anemia, volume overload) [20]. In general, women have a slightly higher prevalence of CKD, which can most likely be explained by the longer life expectancy of women paired with the age-related decline in kidney function [21]. However, studies show a gender gap in CVD among CKD patients, which emerges in the early nondialysis stages of CKD, with a CVD prevalence of 17.9% in men and 20.4% in women [22]. In studies involving STEMI

patients, females had a 5 times greater OR to be diagnosed with renal failure (defined as estimated glomerular filtration rate<60 mL/min), which cannot be fully explained by the marginally higher prevalence of CKD in women [23,24].

Concerning respiratory diseases, females had a 39% or 34% (54% or 31%) increased OR to be diagnosed with AMI or CHD, respectively, than males when they had respiratory failure (COPD). Respiratory failure was significantly more associated with AMI or CHD in women than in men in the age group of 50-79 years compared to younger patients. In younger patients, the effect was only visible in patients with CHD but not AMI. Furthermore, women had a significantly higher risk of having asthma and CHD but not asthma and AMI than men. Accordingly, asthma has been associated with a modest increase in CHD risk in females in a previous study [25]. A possible explanation lies in differences in sex hormones. Estrogen increases and testosterone decreases airway inflammation in asthma. Correspondingly, females begin to display increased asthma symptoms after puberty. The impact of changes in sex hormones levels during menstruation, pregnancy, and menopause are less clear [26]. The higher levels of obesity in females could impact levels of systemic inflammation as well and lead to a relatively increased asthma risk [27]. Moreover, women are more prone to adult asthma and more likely to have severe asthma [26], and an impaired forced expiratory pressure in 1 s (FEV_1) is associated with a slightly higher hazard ratio (HR) for ischemic heart disease in women than in men [28]. To some extent, we cannot entirely rule out a systematic bias, as smokers with respiratory symptoms tend to be diagnosed with asthma if they are female and with COPD if male. However, even a small increase in the relative incidence of CHD associated with a diagnosis of asthma would have a significant impact due to the commonality of asthma. Further cohort studies are, thus, needed to fully understand the relationship between asthma, FEV_1, and CHD and be able to take preventative measures [29].

Like in patients with asthma, COPD and AMI or CHD were more likely to co-occur in women than in men. A Finnish national health examination concluded that signs of obstruction in a spirometer at age 30–49 years appears to predict a major coronary event (adjusted HR=4.21) in women only. COPD is the fourth-leading cause of death globally; approximately 50% of those deaths can be attributed to a cardiovascular event (eg, myocardial infarction). With 9.23%, COPD is more prevalent in males than in females (6.95%) [30]; however, the relative prevalence of COPD is rising in women, which is usually explained by the delayed rise of nicotine abuse prevalence among women. Another potential explanation is the susceptibility to COPD risk factors, most importantly nicotine abuse, which appears to be higher in women. Women with COPD are younger and have smoked considerably less than their male counterparts [11]. As nicotine abuse is more detrimental for women in terms of CVD risk as well, it is a crucial shared risk factor for COPD and CVD [30]. Nicotine abuse alone has a significantly higher associated AMI and CHD risk for females than males, which supports the conclusion of a meta-analysis by Huxley and Woodward [3]. Although smoking prevalence is declining worldwide [31], these results are still critical, for instance, considering the high smoking rates among women in high-income countries (16.4%) [31].

Lipid metabolism disorders were the only risk factor with an extensive gender gap in relative AMI and CHD risk associated with an excess risk for males in our analysis. Correspondingly, total cholesterol displayed a higher RR for CVD for men in a meta-analysis as well [32]. At least some of the risk mitigation can be attributed to the less proatherogenic lipid profile of premenopausal women. Specifically, women have relatively more high-density lipoprotein (HDL), less low-density lipoprotein (LDL), but on average larger LDL particles, lower total triglycerides, and circulating very low-density lipoprotein (VLDL) in both smaller concentration and size [33].

Limitations and Strengths

The analysis is based on a large dataset containing over 45,000,000 hospital diagnoses of the whole Austrian population from 1997 to 2014. The size of the hospital dataset is a clear strength; however, outpatient visits were not recorded. Patients had to have been admitted to a hospital at least once to be included in the analysis. As it is usually the case with medical claims data, our results are likely to be affected by missing diagnoses (in particular, diseases typically not treated in an inpatient setting) and wrong disease classifications. However, nonsystematic errors, for instance, randomly missing diagnoses, do not play a major role, as even if many data points would be missing, the larger the sample size, the more likely one is to still be able to statistically identify an existing correlation. This, of course, does not necessarily apply in the case of systematic errors in the data. Due to the character of this analysis, which is solely based on disease codes, we cannot rule out unobserved confounding factors related to gender aspects. Furthermore, repeated observations of patients over 12 years allowed us to perform a time directionality analysis to identify whether it is more likely that disease A increases the risk for diseases B or whether B is a risk factor for A. However, given the purely observational nature of our dataset, no statements on causality can be made based on this analysis. We chose age 50 as a cutoff for before and after (peri-)menopause as we did not have access to hormone levels or gynecological history; the unreliability of this strict cutoff is a limitation of this analysis.

Conclusion

Although all the discussed factors increase the risk for CVD in both sexes, nicotine abuse, diabetes mellitus, renal failure, obesity and overweight, and respiratory diseases were relatively more associated with AMI and CHD risk in women in this analysis. Only lipid metabolism disorders displayed the opposite relationship with AMI and CHD. As the inflammatory effect of sex hormones is believed to be a strong influencing factor for SDs in respiratory diseases, we hypothesized that these differences might be age related and change during menopause. Accordingly, SDs in the age group of over 50 years were more prominent than in under 50-year-olds. Further analyses, especially prospective studies, are needed to investigate this topic in detail. However, taken together, these results underline the importance of CVD-screening practices, specifically in women with the above-mentioned risk factors, and emphasize that physicians should be aware of the sex-specific excess risk

for AMI and CHD associated with some but not all of their comorbidities.

Data Availability

The data that support the findings of this study are available from the Austrian Ministry of Health, but restrictions apply to the availability of these data, which were used under license for the current study and so are not publicly available. Data are, however, available from the authors upon reasonable request and with permission of the Austrian Ministry of Health.

Acknowledgments

Funding was received from the Vienna Science and Technology Fund (WWTF; MA16-045).

Authors' Contributions

ED and CD wrote the manuscript and researched data. ED analyzed the data. AK-W, ML, and NH contributed to the discussion and reviewed/edited the manuscript. PK researched data, contributed to the methods, and reviewed/edited the manuscript. PK is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

All authors have no relevant conflicts of interest to disclose.

References

1. Merz AA, Cheng S. Sex differences in cardiovascular ageing. Heart 2016 Jun 01;102(11):825-831 [FREE Full text] [doi: 10.1136/heartjnl-2015-308769] [Medline: 26917537]
2. Wang Y, O'Neil A, Jiao Y, Wang L, Huang J, Lan Y, et al. Sex differences in the association between diabetes and risk of cardiovascular disease, cancer, and all-cause and cause-specific mortality: a systematic review and meta-analysis of 5,162,654 participants. BMC Med 2019 Jul 12;17(1):136 [FREE Full text] [doi: 10.1186/s12916-019-1355-0] [Medline: 31296205]
3. Huxley R, Woodward M. Cigarette smoking as a risk factor for coronary heart disease in women compared with men: a systematic review and meta-analysis of prospective cohort studies. Lancet 2011 Oct;378(9799):1297-1305 [FREE Full text] [doi: 10.1016/s0140-6736(11)60781-2]
4. Peters S, Huxley RR, Woodward M. Diabetes as risk factor for incident coronary heart disease in women compared with men: a systematic review and meta-analysis of 64 cohorts including 858,507 individuals and 28,203 coronary events. Diabetologia 2014 Aug;57(8):1542-1551 [FREE Full text] [doi: 10.1007/s00125-014-3260-6] [Medline: 24859435]
5. Deischinger C, Dervic E, Leutner M, Kosi-Trebotic L, Klimek P, Kautzky A, et al. Diabetes mellitus is associated with a higher risk for major depressive disorder in women than in men. BMJ Open Diabetes Res Care 2020 Sep;8(1) [FREE Full text] [doi: 10.1136/bmjdrc-2020-001430] [Medline: 32973072]
6. Woodward M, Peters SAE, Huxley RR. Diabetes and the female disadvantage. Womens Health (Lond) 2015 Nov;11(6):833-839 [FREE Full text] [doi: 10.2217/whe.15.67] [Medline: 26368038]
7. Kautzky-Willer A, Harreiter J, Pacini G. Sex and gender differences in risk, pathophysiology and complications of type 2 diabetes mellitus. Endocr Rev 2016 Jun;37(3):278-316 [FREE Full text] [doi: 10.1210/er.2015-1137] [Medline: 27159875]
8. Villar E, Remontet L, Labeeuw M, Ecochard R. Effect of age, gender, and diabetes on excess death in end-stage renal failure. JASN 2007 Jun 20;18(7):2125-2134 [FREE Full text] [doi: 10.1681/asn.2006091048]
9. Gevaert S, De Bacquer D, Evrard P, Renard M, Beauloye C, Coussement P, et al. Renal dysfunction in STEMI-patients undergoing primary angioplasty: higher prevalence but equal prognostic impact in female patients; an observational cohort study from the Belgian STEMI registry. BMC Nephrol 2013 Mar 18;14:62 [FREE Full text] [doi: 10.1186/1471-2369-14-62] [Medline: 23506004]
10. Cepelis A, Brumpton BM, Laugsand LE, Dalen H, Langhammer A, Janszky I, et al. Asthma, asthma control and risk of acute myocardial infarction: HUNT study. Eur J Epidemiol 2019 Oct;34(10):967-977 [FREE Full text] [doi: 10.1007/s10654-019-00562-x] [Medline: 31512117]
11. Alonso T, Sobradillo P, de Torres J. Chronic obstructive pulmonary disease in women. Is it different? Archivos de Bronconeumología (English Edition) 2017 Apr;53(4):222-227 [FREE Full text] [doi: 10.1016/j.arbr.2017.02.012]
12. Sawalha S, Hedman L, Backman H, Stenfors N, Rönmark E, Lundbäck B, et al. The impact of comorbidities on mortality among men and women with COPD: report from the OLIN COPD study. Ther Adv Respir Dis 2019;13:1753466619860058 [FREE Full text] [doi: 10.1177/1753466619860058] [Medline: 31291820]
13. Deischinger C, Dervic E, Kaleta M, Klimek P, Kautzky-Willer A. Diabetes mellitus is associated with a higher relative risk for Parkinson's disease in women than in men. JPD 2021 Apr 13;11(2):793-800 [FREE Full text] [doi: 10.3233/jpd-202486]
14. Kuritz S, Landis JR, Koch GG. A general overview of Mantel-Haenszel methods: applications and recent developments. Annu Rev Public Health 1988;9:123-160 [FREE Full text] [doi: 10.1146/annurev.pu.09.050188.001011] [Medline: 3288229]

15. Garawi F, Devries K, Thorogood N, Uauy R. Global differences between women and men in the prevalence of obesity: is there an association with gender inequality? Eur J Clin Nutr 2014 Oct;68(10):1101-1106 [FREE Full text] [doi: 10.1038/ejcn.2014.86] [Medline: 24918120]
16. Mongraw-Chaffin M, Peters S, Huxley R, Woodward M. The sex-specific association between BMI and coronary heart disease: a systematic review and meta-analysis of 95 cohorts with 1·2 million participants. Lancet Diabetes Endocrinol 2015 Jun;3(6):437-449 [FREE Full text] [doi: 10.1016/s2213-8587(15)00086-8]
17. Canoy D, Boekholdt S, Wareham N, Luben R, Welch A, Bingham S, et al. Bodyfat distribution and risk of coronary heart disease in men and women in the European prospective investigation into cancer and nutrition in Norfolk cohort. Circulation 2007 Dec 18;116(25):2933-2943 [FREE Full text] [doi: 10.1161/circulationaha.106.673756]
18. Svendsen O, Hassager C, Christiansen C. Age- and menopause-associated variations in body composition and fat distribution in healthy women as measured by dual-energy x-ray absorptiometry. Metabolism 1995 Mar;44(3):369-373 [FREE Full text] [doi: 10.1016/0026-0495(95)90168-x]
19. Norhammar A, Schenck-Gustafsson K. Type 2 diabetes and cardiovascular disease in women. Diabetologia 2013 Jan;56(1):1-9 [FREE Full text] [doi: 10.1007/s00125-012-2694-y] [Medline: 22945305]
20. Liu M, Li XC, Lu L, Cao Y, Sun RR, Chen S, et al. Cardiovascular disease and its relationship with chronic kidney disease. Eur Rev Med Pharmacol Sci 2014 Oct;18(19):2918-2926 [FREE Full text] [Medline: 25339487]
21. Carrero J, Hecking M, Chesnaye NC, Jager KJ. Sex and gender disparities in the epidemiology and outcomes of chronic kidney disease. Nat Rev Nephrol 2018 Mar;14(3):151-164 [FREE Full text] [doi: 10.1038/nrneph.2017.181] [Medline: 29355169]
22. KDOQI. KDOQI clinical practice guidelines and clinical practice recommendations for diabetes and chronic kidney disease. Am J Kidney Dis 2007 Feb;49(2 Suppl 2):S12-154. [doi: 10.1053/j.ajkd.2006.12.005] [Medline: 17276798]
23. Sederholm Lawesson S, Tödt T, Alfredsson J, Janzon M, Stenestrand U, Swahn E. Gender difference in prevalence and prognostic impact of renal insufficiency in patients with ST-elevation myocardial infarction treated with primary percutaneous coronary intervention. Heart 2011 Feb;97(4):308-314 [FREE Full text] [doi: 10.1136/hrt.2010.194282] [Medline: 21212134]
24. Sederholm Lawesson S, Alfredsson J, Szummer K, Fredrikson M, Swahn E. Prevalence and prognostic impact of chronic kidney disease in STEMI from a gender perspective: data from the SWEDEHEART register, a large Swedish prospective cohort. BMJ Open 2015 Jun 23;5(6):e008188 [FREE Full text] [doi: 10.1136/bmjopen-2015-008188] [Medline: 26105033]
25. Iribarren C, Tolstykh IV, Eisner MD. Are patients with asthma at increased risk of coronary heart disease? Int J Epidemiol 2004 Aug;33(4):743-748 [FREE Full text] [doi: 10.1093/ije/dyh081] [Medline: 15131088]
26. Fuseini H, Newcomb DC. Mechanisms driving gender differences in asthma. Curr Allergy Asthma Rep 2017 Mar;17(3):19 [FREE Full text] [doi: 10.1007/s11882-017-0686-1] [Medline: 28332107]
27. Zhang P, Zein J. Novel insights on sex-related differences in asthma. Curr Allergy Asthma Rep 2019 Sep 05;19(10):44 [FREE Full text] [doi: 10.1007/s11882-019-0878-y] [Medline: 31486898]
28. Hole D, Watt GC, Davey-Smith G, Hart CL, Gillis CR, Hawthorne VM. Impaired lung function and mortality risk in men and women: findings from the Renfrew and Paisley prospective population study. BMJ 1996 Sep 21;313(7059):711-5; discussion 715 [FREE Full text] [doi: 10.1136/bmj.313.7059.711] [Medline: 8819439]
29. Hubbard R, West J. Commentary: does the presence of asthma increase the incidence of coronary heart disease? Int J Epidemiol 2004 Aug;33(4):749-750 [FREE Full text] [doi: 10.1093/ije/dyh166] [Medline: 15131092]
30. Ntritsos G, Franek J, Belbasis L, Christou M, Markozannes G, Altman P, et al. Gender-specific estimates of COPD prevalence: a systematic review and meta-analysis. COPD 2018 May;Volume 13:1507-1514 [FREE Full text] [doi: 10.2147/copd.s146390]
31. World Health Organization. Report on Global Tobacco Epidemic. Washington, D.C: WHO; 2019.
32. Peters S, Singhateh Y, Mackay D, Huxley RR, Woodward M. Total cholesterol as a risk factor for coronary heart disease and stroke in women compared with men: a systematic review and meta-analysis. Atherosclerosis 2016 May;248:123-131 [FREE Full text] [doi: 10.1016/j.atherosclerosis.2016.03.016] [Medline: 27016614]
33. Wang X, Magkos F, Mittendorfer B. Sex differences in lipid and lipoprotein metabolism: it's not just about sex hormones. J Clin Endocrinol Metab 2011 Apr;96(4):885-893 [FREE Full text] [doi: 10.1210/jc.2010-2061] [Medline: 21474685]

Abbreviations

AMI: acute myocardial infarction
BMI: body mass index
CHD: chronic ischemic heart disease
CI: confidence interval
CKD: chronic kidney disease
COPD: chronic obstructive pulmonary disease
CVD: cardiovascular disease
FEV1: forced expiratory pressure in 1 s
HDL: high-density lipoprotein

HR: hazard ratio
ICD-10: International Classification of Diseases, Tenth edition
LDL: low-density lipoprotein
ORm: odds ratio males
ORf: odds ratio females
P_SD: sex difference P-value
RR: relative risk
SD: sex difference
SE: standard error
STEMI: ST-elevation myocardial infarction
TOR: time order ratio
VLDL: very low-density lipoprotein
WHO: World Health Organization

Edited by G Eysenbach; submitted 20.02.21; peer-reviewed by K Schenck-Gustafsson, D Arigo, B Bock; comments to author 31.05.21; revised version received 07.07.21; accepted 27.07.21; published 04.10.21.

Please cite as:
Dervic E, Deischinger C, Haug N, Leutner M, Kautzky-Willer A, Klimek P
The Effect of Cardiovascular Comorbidities on Women Compared to Men: Longitudinal Retrospective Analysis
JMIR Cardio 2021;5(2):e28015
URL: https://cardio.jmir.org/2021/2/e28015
doi:10.2196/28015
PMID:34605767

Original Paper

Values of Importance to Patients With Cardiovascular Disease as a Foundation for eHealth Design and Evaluation: Mixed Methods Study

Britt E Bente[1], MSc; Jobke Wentzel[1,2], PhD; Rik GH Groeneveld[1], MSc; Renée VH IJzerman[3,4], MSc; David R de Buisonjé[3], MSc; Linda D Breeman[3], PhD; Veronica R Janssen[3,5], PhD; Roderik Kraaijenhagen[6,7], MD; Marcel E Pieterse[1], PhD; Andrea WM Evers[7,8*], PhD; Julia EWC van Gemert-Pijnen[1*], PhD

[1]Department of Psychology, Health and Technology, Centre for eHealth and Wellbeing Research, University of Twente, Enschede, Netherlands
[2]Research Group IT Innovations in Health Care, Windesheim University of Applied Sciences, Zwolle, Netherlands
[3]Unit of Health, Medical, and Neuropsychology, Faculty of Social and Behavioural Sciences, Leiden University, Leiden, Netherlands
[4]Department of Cardiology, Amsterdam University Medical Center, Academic Medical Center, Amsterdam, Netherlands
[5]Department of Cardiology, Leiden University Medical Center, Leiden, Netherlands
[6]Vital10, Amsterdam, Netherlands
[7]NDDO Institute for Prevention and Early Diagnostics (NIPED), Amsterdam, Netherlands
[8]Department of Psychiatry, Leiden University Medical Center, Leiden, Netherlands
[*]these authors contributed equally

Corresponding Author:
Britt E Bente, MSc
Department of Psychology, Health and Technology
Centre for eHealth and Wellbeing Research
University of Twente
Drienerlolaan 5
Enschede, 7522 NB
Netherlands
Phone: 31 53 489 9660
Email: b.e.bente@utwente.nl

Abstract

Background: eHealth interventions are developed to support and facilitate patients with lifestyle changes and self-care tasks after being diagnosed with a cardiovascular disease (CVD). Creating long-lasting effects on lifestyle change and health outcomes with eHealth interventions is challenging and requires good understanding of patient values.

Objective: The aim of the study was to identify values of importance to patients with CVD to aid in designing a technological lifestyle platform.

Methods: A mixed method design was applied, combining data from usability testing with an additional online survey study, to validate the outcomes of the usability tests.

Results: A total of 11 relevant patient values were identified, including the need for security, support, not wanting to feel anxious, tailoring of treatment, and personalized, accessible care. The validation survey shows that all values but one (value 9: To have extrinsic motivation to accomplish goals or activities [related to health/lifestyle]) were regarded as important/very important. A rating of very unimportant or unimportant was given by less than 2% of the respondents (value 1: 4/641, 0.6%; value 2: 10/641, 1.6%; value 3: 9/641, 1.4%; value 4: 5/641, 0.8%; value 5: 10/641, 1.6%; value 6: 4/641, 0.6%; value 7: 10/639, 1.6%; value 8: 4/639, 0.6%; value 10: 3/636, 0.5%; value 11: 4/636, 0.6%) to all values except but one (value 9: 56/636, 8.8%).

Conclusions: There is a high consensus among patients regarding the identified values reflecting goals and themes central to their lives, while living with or managing their CVD. The identified values can serve as a foundation for future research to translate and integrate these values into the design of the eHealth technology. This may call for prioritization of values, as not all values can be met equally.

(JMIR Cardio 2021;5(2):e33252) doi:10.2196/33252

KEYWORDS

patient values; health behavior; lifestyle; mobile app; user-centered design; eHealth; cardiovascular disease; behavior; app; design; cardiovascular; evaluation; platform; support; intervention

Introduction

On being diagnosed with a cardiovascular disease (CVD), patients must learn to manage changes in their everyday life due to their disease and its treatment. This new behavior to improve patients' lifestyle includes following a strict medication regime and learning to self-monitor their health [1]. The aimed health behaviors include, for example, eating a healthy diet; taking regular physical activity; reducing or quitting smoking and alcohol intake; and reducing the body weight, blood pressure, and blood cholesterol [1]. Patients often need support during the period of acquiring new self-management skills and lifelong health maintenance behaviors.

eHealth interventions can support patients in the self-care tasks and the required lifestyle changes. Technology-facilitated health care may offer ubiquitous, ongoing, and personal guidance that supports changes in patient behavior. A recent review showed that eHealth interventions, aimed at CVD self-management, help patients to monitor symptoms, provide information, and provide contact with a care provider in case of questions [2]. In chronic care, one of the challenges is how patients can reach a realistic balance between treatment goals and optimal lifestyle changes, while considering their capability, needs, and wishes [3,4]. To do this, eHealth technology that supports patients with these tasks should be designed via a user- or patient-centered approach. This contributes to better uptake and adherence to lifestyle change, and improve health outcomes [5]. However, achieving long-lasting effects is a challenge [6], and therefore, critical reflection on the development and evaluation of eHealth technology is needed in practice [6]. Patients should be involved in the development of interventions, so that their goals, wishes, and needs lie at the core of development processes. Then the intervention will be appealing to patients and result in the desired uptake and health outcomes.

Consequently, patient (user) values should be considered at the earliest stages of eHealth technology development [1]. Values capture specific needs and desires of patients, such as desired future state, and the motivations and drivers of their behavior [7]. These values should form the basis for the development and evaluation of eHealth technologies in practice, enabling developers to evaluate and attune design choices, for example, persuasive features [8] and personas [9]. Furthermore, patient values (and other stakeholders' values) should form the basis for a business model that underpins the implementation of eHealth [2].

This study focuses on identifying values of importance for patients with CVD, within the context of the online "BENEFIT" personal health platform (PHP). This online platform aims to support patients with CVD to adopt and maintain a healthy lifestyle [10]. Users can, for example, self-log their data (eg, body weight or blood pressure), view their progress, receive advices based on their health data, and can contact coaches via a chat when they need support or help. We explore how patients with CVD want to be supported to accomplish the many goals they must set. We aim to answer the following research question: *What values are proposed by patients with CVD to achievepermanent lifestyle changes, and which should be considered when designing an eHealth platform to promote a healthy lifestyle*? The identified values will provide a relevant foundation for the development and implementation of new eHealth technologies.

Methods

Study Design

In this study, a mixed method design was used, combining secondary analyses of usability tests conducted in 2018 (study 1) with an online survey study carried out in 2020 (study 2). The aim of study 1 was to identify relevant patient values, while the aim of study 2 was to validate and bring a hierarchy in weighted values at the population level. This created a foundation to draw conclusions about values of patients with CVD [10]. The qualitative data (study 1) were from 10 interviews conducted in the context of patients' usability tests with the online "BENEFIT" PHP. Study 2 was a survey distributed to panel members of Harteraad, a Dutch patient association for CVDs.

Ethical Approval and Consent to Participate

Study 1 was approved by the University's Ethical Committee (BCE18142). Participants were informed of the voluntary nature of their participation and confidentially was guaranteed. All participants signed an informed consent. Study 2 was approved by the Psychology Research Ethics Committee (2020-06-05-A.W.M. Evers-V1-2474). Informed consent was provided digitally by signing the consent page before starting the online survey.

Study 1: Secondary Analysis of Usability Tests and Interviews

Data Set

The secondary data set included transcripts of usability tests conducted with 10 patients with CVD. These 10 patients were included in an earlier usability study by convenience sampling. The aim of that study was to evaluate the usability of the BENEFIT PHP. These usability sessions (see Multimedia Appendix 1) were guided with a script of assignments based on the BENEFIT PHP's main functionalities and goals. Interview questions were structured to include 6 main subjects: background information, experiences with their illness, adjustments in life, support, self-management, and drivers in the self-rehabilitation of patients [11].

Data Analysis

First, all verbatim transcripts of the data set were revised by one researcher (BB) to identify quotations about what patients with CVD indicated they needed to maintain a healthy lifestyle. All usable quotes were inductively linked to individual codes

among the theme "Needs." A second researcher (JW) checked 10% of the quotations, and disagreements in coding were discussed. Second, these needs were translated to values (BB). We defined values as "Ideals or interests respondents have, the underlying reason why someone wants or needs what they want or need" [7]. While needs reflected a concrete desire, the values are the (underlying) drivers of such needs, and are usually of a more generic nature. By applying this definition, initial codes were grouped on the value level by determining what underlying value could be the driver of these codes. The second researcher (JW) checked whether all codes identified in the first part fitted with the determined values. All resulting values were discussed within a BENEFIT research team meeting consisting of 8 researchers. All participants were informed about the results.

Study 2: Online Survey Study

Sample and Procedure

The survey was created and distributed via Qualtrics software [12] and formed part of a larger survey study in the BENEFIT project (R. V. H. IJzerman et al, MSc, unpublished data, 2020). Respondents received information and an invitation to participate via email from Harteraad, including a link to the survey. Survey data were collected between June 29 and July 14, 2020.

Materials

The 11 identified values were framed as closed question statements. Respondents were asked to rate these values on a 7-point Likert scale (ranging from 1=not important at all to 7=very important).

Data Analysis

Descriptive statistics were generated for the questionnaire data using SPSS version 26 (IBM) [13]. Friedman nonparametric test for related samples was applied to test for possible differences in importance ratings between the values. After an initial overall test, post hoc pairwise comparisons were performed. To compensate for multiple testing, the level of significance was set to .005.

Availability of Data and Materials

The transcribed data are not publicly available due to privacy restrictions but are available from the corresponding author on reasonable request.

Results

Study 1: Usability Tests

Participant Characteristics

This study included data of 10 participants at 4 different health care facilities (eg, rehabilitation centers and hospital cardiac departments) in the Netherlands. Participant age range was between 35 and 79 years, with 8 female participants (Table 1). Most of the participants assessed their own digital skills as medium to good. Inclusion criteria were kept wide regarding CVD diagnosis, to obtain a representative input from all types of patients with CVD.

A total of 11 patient values were determined based on the indicated needs from the data (Textbox 1) of patients with CVD.

Table 1. Demographic characteristics of patient sample group 1.

Participant number	Gender	Age (years)	Digital skills (self-assessed by participants)	Diagnosis	Time since diagnosis
1	Female	79	Low	Cardiovascular disease	2 days
2	Female	72	Low	Cardiovascular disease	2 days
3	Female	Did not state	Good	Heart disease	2 years
4	Female	64	Good	Cardiovascular disease	20 years
5	Male	62	Good	Cardiovascular disease	20 years
6	Male	64	Medium	Vascular disease	2.5 years
7	Female	35	Good	Did not state	Entire lifetime
8	Female	71	Medium	Heart disease	Entire lifetime
9	Female	Did not state	Medium	Cardiovascular disease	Did not state
10	Female	36	Good	Heart disease	Entire lifetime

Textbox 1. Overview of perceived needs and assessed values (bold) of patients with cardiovascular disease.

1. To have confidence and self-efficacy in the treatment and ability to achieve goals

- Need to receive health-related feedback from the health care provider
- Desire to receive knowledge of treatment methods

2. To be seen as a person rather than as a patient

- Need to not continuously be treated as a patient by social environment

3. To not feel fear, anxiety, or insecurity about their health

- Need to have a feeling of health-related safety
- Need to have taken away fears regarding their health status
- Desire to trust their own knowledge

4. To preserve a sense of autonomy over their life

- Desire to have some autonomy during their rehabilitation
- Need to stay in charge
- Need to keep their freedom
- Need to have control over own situation
- Need to feel heard by the health care provider

5. To receive social support

- Need to have contact with fellow sufferers
- Need to feel support from social circle
- Need to feel acknowledged and understood by their social circle

6. To have or maintain a healthy lifestyle

- Desire to prevent new incidents
- Need to stay healthy
- Desire to use less medication by implementing alternatives (such as a healthy lifestyle)
- Need to receive help with physical activity, staying healthy

7. To have an overview of personal health data

- Need to have a clear overview of own health data
- Desire to have all health data in one place
- Need to see relations between medical, lifestyle, and mental health status
- Desire to have a (quantified) display of how they feel at that moment

8. To perceive low thresholds to access health care

- Need to be treated or helped quickly
- Desire to receive care/treatment at home
- Need to have personal contact with health care providers
- Need for health care professionals to be easily approachable

9. To be extrinsically motivated to accomplish goals or activities (related to health/lifestyle)

- Desire to have a new (health) purpose in life
- Need to be motivated
- Need to be guided and supported through the lifestyle change process

10. To receive reliable information and advice

- Need to receive reliable information
- Desire to be advised about validated apps, applicable in their own situation
- Desire to receive help by use of interventions/technology
- Need to receive concrete and easily applicable advice to improve their health
- Need to have a guideline in dealing with their illness (also for patients' environment)

11. To receive personalized care

- Need to be the central focus of the therapy
- Need to have own priorities being recognized
- Need to have a personal approach (no one is the average patient as described in protocols)

To Have Confidence and Self-Efficacy in the Treatment and Ability to Achieve Goals

Patients valued having confidence in their health care professionals and the treatment they prescribe. Patients also valued that they could follow the treatment plan or were able to achieve their goals. Patients indicated that, for this, they needed sufficient knowledge about the treatment methods they received. Maintaining close contact with their caregiver was also reported as important; patients needed to be updated about their health progress by the involved caregiver, to feel confident about their health status.

> *When you have breathing problems, that carries a whole other mental load […] it affects your mental wellbeing. […] In those cases, it is pleasant if you don't have to wait for an appointment with your general practitioner. […] I have a very nice cardiologist here in the Netherlands, I have his email and I can always call him* [Participant 7]

To Be Seen as a Person Rather Than a Patient

Patients valued not constantly feeling that they were a patient with a disease. Patients appreciated that their health complaints were acknowledged by their family and friends, but they also wanted to feel like the person they were before they were diagnosed with chronic heart disease, without bystanders worrying about them.

> *Until my death I need top medical care, I'm just trying to be 'friends' with my health care provider, or at least communicate on an equal level with him […] because in the end, we are both humans* [Participant 10]

To Not Feel Fear, Anxiety, or Insecurity About Their Health

Patients valued not worrying about their physical condition. They liked to be provided with coping strategies or information that helped them feel safe or less anxious. Many patients reported the need for overcoming their fears of having a new incident or worsening condition, and for this they needed reassurance. Patients had lost trust in their body and wanted to be confident about their new capabilities after CVD diagnosis.

> *Physically, I actually did have confidence, because I'm still young and the rest of my body works properly […] but to go exercise… that was really in my head. I was really afraid to burden myself again.* [Participant 7]

To Preserve a Sense of Autonomy Over Their Life

Patients valued being in control of their life (eg, being able to make their own decisions). Patients indicated their need to oversee their own health and treatment. They wanted to be involved in shared treatment-related decision making.

> *I like that [participant referring to a situation in which her doctor asked her about her opinion about prescribed medication] kind of interaction, I'm not the type of patient that accepts a mentality like 'I am the doctor, and you have to do what we tell you'. No, it's my life. I do come to the doctors for help if I feel like I need them to stay alive, but only in such a way that it feels right for me.* [Participant 10]

To Receive Social Support

Patients valued being heard, supported, and understood by the people that surround them (eg, family and friends) and that they had an empathetic person to talk to. Patients needed to feel acknowledged and understood, as well as supported by their friends and family. However, not only did they need support from family and friends, but also some indicated the need to share experiences with patients with similar experience.

> *[Researcher: And what about contact with peers? Do you like that?] Yes, if you search on the internet, you'll find user forums. In there, you can find information about what others did in similar situations or give recommendations for specific problems.*" [Participant 8]

To Have or Maintain a Healthy Lifestyle

Patients valued maintaining or changing their lifestyle in such a way that new incidents were prevented, and they regained their health. They wanted to use less medication, for example, by becoming more physically active or adjusting their eating patterns. However, patients reported that they needed help and guidance for improving their lifestyle.

> *I've always been very active, and I try to maintain that until I'm very old. And I hope that that [points to heart] will cooperate because it's important to me.*

It will be great if I can just save myself… [Participant 3]

To Have an Overview of Personal Health Data

Patients valued having a central source where they could look up all their health data (eg, measured values of physical and mental well-being and health). They needed a place where all collected information was presented and which provided new insights into their condition (eg, because it gives the opportunity to compare data).

I can imagine that there are many people, especially if their medication changes a lot, who at some point lose the overview. I also had a period in which it became difficult to remember what was prescribed. If you can see all that information at a glance, it would be very useful. [Participant 5]

To Perceive Low Thresholds to Access Health Care

Patients valued receiving help and being treated quickly and easily, at a health care organization or at home. They wanted to be facilitated to manage their own disease and take action. Patients indicated that they sometimes had questions which were, in their opinion, not important enough to make an appointment with their caregiver. They desired easily accessible contact with caregivers and preferred to have access to health care from home.

Well, most of the questions I have are not that urgent that you need an answer right away; these are often practical things. Look, if there is really something wrong, you should contact the general practitioner or the cardiology department quickly. But if you have practical questions, it is easy to ask them this way, then it is not necessary to ask for a consultation. I think that is useful. [Participant 5]

To Be Extrinsically Motivated to Accomplish Goals or Activities (Related to Health/Lifestyle)

Patients valued being extrinsically motivated or pushed to do or accomplish things, such as following their treatment or performing activities to achieve a healthy lifestyle (eg, via social pressure). They needed a driving force as guidance through the process. They desired to be led through their rehabilitation, to be motivated to achieve their goals.

[Regarding the participation in an online module] Do I get an email that there is a new module available for me? And what if I decline? Could it be that during my next consult, my physician says something like 'hey you didn't participate, why not?' [Yes, that is possible]. Okay, I like that there is some sort of motivational force behind it." [Participant 10]]

To Receive Reliable Information and Advice

Patients valued having understandable, relevant information and advice that is scientifically proven and recommended by physicians (ie, evidence-based information). They needed information on which they could rely on and on which they could repeatedly consult (eg, an information flyer about their treatment). There is also much information on the internet, but patients were not sure which information was trustworthy. Patients needed simple, concrete advice about improving their lifestyle, and a guideline for dealing with their disease.

Well, sometimes there is the problem, that when you visit the doctor for an appointment, you get so much information that you do not remember it at all. For that reason, it is also useful to bring someone else in there, but it would be helpful if you can also look up the information here, that's very easy. [Participant 5]

To Receive Personalized Care

Patients valued receiving a personal approach in which their opinion and preferences were considered (eg, personalization or tailoring of treatment choices or technical platform features). They needed to be heard by the caregiver and wanted their priorities to be recognized. Patients needed a personal, relevant approach, because there is no "one size fits all" solution for patients. Not all patients react the same on a treatment prescribed in protocols.

My doctor sometimes says, 'it is your body, it is your life, if you want to try this medication, we will do that, and if you want to quit them, we will quit'. I am in a clinic where doctors and nurses think along with you about everything. That is very pleasant." [Participant 10]

Study 2: Online Survey

Participant Characteristics

The survey sample consisted of Dutch patients with CVD, who were representatives from the panel of Harteraad. In total, the panel included 2600 members [14], of whom 739 responded and 710 completed the survey (response rate of 28.42%). Respondents' mean age was 67 years, 57.6% (426/739) of them were male, and 43.4% (321/739) attended a form of higher vocational education or university (Table 2).

Table 2. Participants' characteristics in study 2 (N=739).

Characteristics	Value
Age (years), mean (range)	67 (23-90)
Gender, n (%)	
Men	426 (57.6)
Women	284 (38.4)
Did not state	29 (3.9)
Last treated vascular condition, n (%)	
Heart disease	285 (38.6)
Vascular disease	86 (11.6)
Cardiovascular disease	176 (23.8)
Other	152 (20.6)
Did not state	40 (5.4)
Highest completed education, n (%)	
Primary education or less	8 (1.1)
Lower vocational education	163 (22.1)
Intermediate vocational education	151 (20.4)
Senior general or preuniversity secondary school	58 (7.8)
Higher vocational education	235 (31.8)
University education (bachelor's, master's, [post]doctoral)	86 (11.6)
Other	9 (1.2)
Did not state	29 (3.9)
Relationship status, n (%)	
No partner	158 (21.4)
A partner with whom I do not live	31 (4.2)
A partner with whom I live	522 (70.6)
Did not state	28 (3.8)

Perceived Importance of Values

Respondents were asked to rate the 11 values found in study 1 on how important each value was to them. Some respondents failed to provide a rating for every value; nonresponse ranged between 98 and 103 missing responses per value. On a scale of importance from 1 to 7, the mean scores ranged between 5.13 (value 9) and 6.32 (value 4), as Table 3 shows. For all values, the median was 6 (important), except for value 9. For this value the median was 5 (slightly important). The mode for every value was 6 (important). Table 3 shows the perceived importance ratings per value.

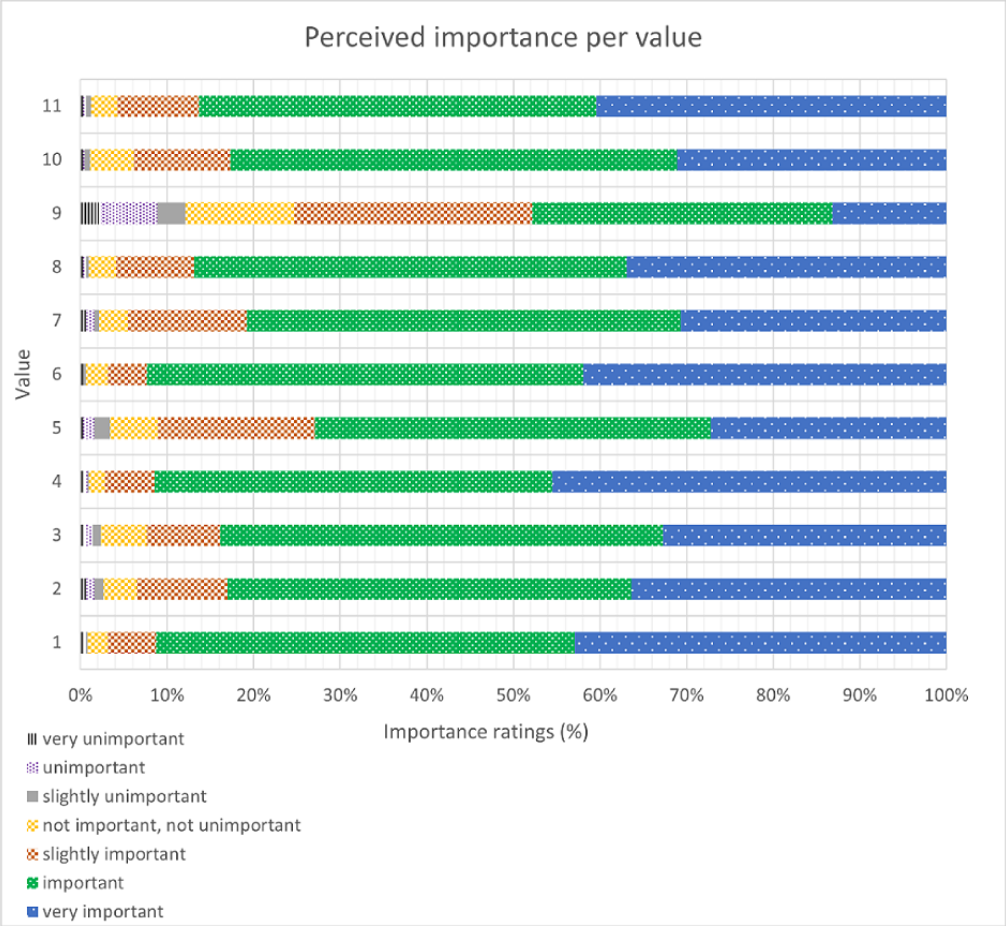
The distribution of the rated perceived importance per value is shown in Figure 1. Value 1 (585/641, 91.3%; To have confidence and self-efficacy in their treatment or therapy and their ability to achieve goals), value 4 (586/641, 91.4%; To feel a sense of autonomy of their life), value 6 (590/641, 92.0%; To have or maintain a healthy lifestyle), value 8 (555/639, 86.9%; To have a low threshold to access health care), and value 11 (549/636, 86.3%; To receive personalized care) were considered important or very important by many of the respondents (>85%). For values 1, 4, and 6 this translates to over 90% of the respondents. All other values received ratings of important or very important by most respondents (with ratings for values 2, 3, 5, 7, and 10 ranging between 72.9% and 83.9; ie, value 2: 532/641, 83.0%; value 3: 538/641, 83.9%; value 5: 466/639, 72.9%; value 7: 516/639, 80.8%; value 10: 526/636, 82.7%), except value 9 (To be motivated to accomplish goals or activities [related to health/lifestyle]). This value was rated important or very important by 304/636 (47.8%) respondents. The rating "very unimportant" or "unimportant" was given by less than 2% of the respondents (value 1: 4/641, 0.6%; value 2: 10/641, 1.6%; value 3: 9/641, 1.4%; value 4: 5/641, 0.8%; value 5: 10/641, 1.6%; value 6: 4/641, 0.6%; value 7: 10/639, 1.6%; value 8: 4/639, 0.6%; value 10: 3/636, 0.5%; value 11: 4/636, 0.6%) to all values, except for value 9 (To be extrinsically motivated to accomplish goals or activities [related to health/lifestyle]). This value more often received a rating of "very unimportant" or "unimportant" by 8.8% (56/636) of the respondents.

Table 3. Perceived importance ratings per value, ranged from high to low.

Values	Descriptives				
	n	Missing, n (%)	Median[a]	Q1-Q3	Mode[a]
1. To have confidence and self-efficacy in the treatment and ability to achieve goals	641	98 (15.3)	6 (important)	6-7	6 (important)
2. To be seen as a person rather than a patient	641	98 (15.3)	6 (important)	6-7	6 (important)
3. To not feel fear, anxiety, or insecurity about their health	641	98 (15.3)	6 (important)	6-7	6 (important)
4. To preserve a sense of autonomy over their life	641	98 (15.3)	6 (important)	6-7	6 (important)
5. To receive social support	639	100 (15.6)	6 (important)	5-7	6 (important)
6. To have or maintain a healthy lifestyle	639	100 (15.6)	6 (important)	6-7	6 (important)
7. To have an overview of personal health data	639	100 (15.6)	6 (important)	6-7	6 (important)
8. To perceive low thresholds to access health care	639	100 (15.6)	6 (important)	6-7	6 (important)
9. To be extrinsically motivated to accomplish goals or activities (related to health/lifestyle)	636	103 (16.2)	5 (slightly important)	5-6	6 (important)
10. To receive reliable information and advice	636	103 (16.2)	6 (important)	6-7	6 (important)
11. To receive personalized care	636	103 (16.2)	6 (important)	6-7	6 (important)

[a]Likert scales were applied, ranging from 1 (not important at all) to 7 (very important).

Figure 1. Distribution of perceived importance per value.



As value 9's ratings resulted in a lower mean, median, and score distribution, a nonparametric test was carried out to investigate if the pattern in ratings differs between the values. The results of Friedman nonparametric test for related samples show that an overall difference in ratings (n=636) was found when comparing all value ratings ($F_{10,625}$=856.56, P<.001).

Discussion

Principal Findings

This study aimed to reveal health-related values of patients with CVD which should be considered when designing an eHealth platform that supports patients to achieve and maintain a healthy lifestyle. These values could provide a relevant foundation for the development and implementation of new eHealth technologies. A total of 11 relevant patient values were identified, ranging from the need for security, support, and reduction in anxiety, to tailoring of treatment, and personalized and accessible care. We also showed a high consensus regarding the perceived importance of these values among patients with CVD.

The highest importance ratings were related to preserve a sense of autonomy, have or maintain a healthy lifestyle, and to have confidence and self-efficacy in the treatment and ability to achieve goals. According to a study by Zhang and colleagues [15] on health-related goals of patients with heart failure and self-care management, maintaining autonomy is the major patient goal [15]. This was evidenced by patient's need to control their own lives and be physically independent [15]. The results of study 1 also showed that patients value security and support in reaching their health-related behavior goals: they need to know that they have the capacity (self-efficacy) to succeed or will be helped and guided. This feeling of security and perceived support has been highlighted in other studies on patients with CVD [16]. It is shown that patients with lower levels of self-efficacy in exercising are less physically active, regardless of their motivation to exercise [17]. Self-efficacy is also associated with better self-care [17] and adherence to healthy habits [15]. For patients with other chronic diseases, such as chronic obstructive pulmonary disease, values similar to ours have been identified, such as the value to receive empathy and be heard [18], to receive encouragement to be active [19] and to be reassured that exercising is safe [18,19]. In addition, it was reported in a study focusing on patients with heart failure that experiencing social support contributes to healthy self-care behavior [20], although the social environment can also affect the patients' behavior in an unhealthy way [21]. Additionally, easy access to care (value 8) was highlighted as very important to support self-care of patients with CVD [22].

Of significance is the rating of value 9 (To be extrinsically motivated to accomplish goals or activities [related to health/lifestyle]), which differed from the ratings of the other values, with a rating distribution displaying less perceived importance than the distribution of the other values. Other studies show the complexity of motivation and rewards. Patients could be motivated by extrinsic motivations. However, other values could also indirectly act as a driving force to motivate patients to perform certain behaviors [23]. The Self-Determination Theory describes that needs such as competence, relatedness, and autonomy form the basis for self-motivation [24]. Thus, motivating patients using an extrinsic route may contribute to achieving a healthy lifestyle, but it may hamper the fulfillment of autonomy, which is a value that scored highly on importance in this study. Having a sense of autonomy can indirectly motivate patients to engage with the eHealth platform and self-manage their condition. The relation between values and outcomes is complex and fulfilling one value may not always mean that other values are reinforced too, even when target behaviors are the same.

Recommendations

The patient values that were identified in this study can be used as input for the development or improvement of eHealth technologies aimed at patients with CVD. Even though the values were recognized and validated by a large patient group, the technical features that can be created based on these values may not be accepted by all patients. We recommend that the identified values are used as a starting point when setting requirements and designing technical features. When translating values into technology features and personalization of interventions, developers will still need to consider variation in preferences and personal circumstances. Overall goals and desires may be similar, but the exact approach will differ for each patient. Finding a workable level of personalization needs further study [25]. How values as a design basis can be integrated into technology is shown in a recent study by Asbjørnsen et al [26]. The authors combined different development and design approaches [8,27] with persuasive features [28] and behavior change techniques [29] to organize the development and design process of a weight loss maintenance interventions. The study shows how values can aid in operationalization of intervention components, to create focus and prioritize features and evaluate them based on stakeholder perspectives [26].

Additionally, patients' values and behavior may change over time. Developers must consider that acceleration and dosage per value ingredient can both differ between patients and change over time for individuals. Therefore, one strategy is to let patients prioritize preset values or options to identify what appeals to them in treatment. One benefit of eHealth technology is that it can be tailored to patient's wishes and needs and be sensitive to their underlying needs. Thus, patient data registered via the technology (eg, log data) may be used to further tailor the technology using predictive analyses or artificial intelligence. This way, certain behaviors or behavior changes can be predicted, and eHealth technologies could be adapted to them by providing the patient with information, support, or tasks [30].

In addition, when prioritizing the identified 11 values, patients were inclined to assess all values as important. Actually, some of these are quite basic human needs, and should be considered in any eHealth intervention. For example, catering to the value of staying healthy or being autonomous is interwoven with most eHealth designs. Thus, such important values should be considered in the design and researchers should aim to translate them into specific technology requirements [10]. Possibly, the more basic needs values leave more room for creative translations and more diverse requirements than more concrete specified values. There are many ways to operationalize an eHealth technology design that aims to keep users healthy, whereas the value of receiving information/being informed is already more specific. This is beyond the scope of this research, but we recommend evaluating eHealth interventions regarding

how patient values are integrated into the technology. Future research should focus on whether and to what extent the integrated features/attributes within eHealth interventions contribute to patient (user) values, and determine which features are suitable for fulfilling specific patient values.

Strengths and Limitations

A strength of the study is that by conducting usability tests, the study was not only able to identify patient perspectives, but also user perspectives (from patients using the BENEFIT PHP). Although usability tests have the purpose of recommending specific improvements for the design of eHealth interventions, this method is also useful to discover the drive of the users, their response to the technology, and the associated care tasks. Applying a think-aloud protocol during usability testing is useful for developing the design of the technology [31].

This study also had limitations. In the translation of needs and wishes into values, an interpretation bias may have occurred due to the qualitative nature of the data. To overcome this, a coding scheme was created based on a preliminary analysis and tested by 2 coders applying it and discussing disagreements. Another possible bias lies in the representativeness of the interview sample. The relatively low number of participants in study 1, with an overrepresentation of women may not generate results applicable to all patients with CVD. We have accounted for this bias and heterogeneity to some extent by validating the qualitative interview data among a large sample of patients with CVD. Even though they could not propose new values, the presented values were recognized by this group and except one—to be extrinsically motivated to accomplish goals or activities (related to health/lifestyle)—all values were perceived as important.

Conclusion

When making design choices during the development of an eHealth technology, knowing how values are prioritized by patients may help in deciding if and how to implement features. Health care providers and patients can discuss which features match their needs and receive a more personalized approach from the technology. In addition, establishing a business model is very relevant for developers in making design choices. Next to considering which values contribute to the intended aim of the technology, another consideration is whether all proposed design choices based on values are feasible, affordable, and relevant for all key stakeholders.

Acknowledgments

We acknowledge the help of Pauline van Wolferen in preparing data, Floor Sieverink in collecting and analyzing the data as an independent researcher, and Mike Keesman and Jessica van der Geer for their input in the brainstorming sessions about the values. This work was supported by the Netherlands Cardiovascular Research Initiative: an initiative with support of the Dutch Heart Foundation, CVON2016-12 BENEFIT, ZonMw (the Netherlands Organization for Health Research and Development), and the members of the BENEFIT for All consortium.

Authors' Contributions

JW, AE, VJ, RK, and LG devised the study as part of the development process of the BENEFIT platform. RG, AE, and VJ were involved in the creation of the usability tests and interviews, which were conducted by RG. BB analyzed the qualitative data. JW was the second coder. BB and RI created the online questionnaire. Analyses were performed by BB and JW. BB and JW drafted the manuscript, and all authors revised the manuscript, gave final approval, and agree to be accountable for all aspects of work ensuring integrity and accuracy.

Conflicts of Interest

RK is the founder and a shareholder of NIPED, CardioVitaal, and Vital10.

Multimedia Appendix 1
Interview Script.
[DOCX File , 16 KB - cardio_v5i2e33252_app1.docx]

References

1. F Piepoli M. 2016 European Guidelines on cardiovascular disease prevention in clinical practice : The Sixth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of 10 societies and by invited experts). Int J Behav Med 2017 Jun;24(3):321-419. [doi: 10.1007/s12529-016-9583-6] [Medline: 28290077]
2. Cruz-Martínez RR, Wentzel J, Asbjørnsen RA, Noort PD, van Niekerk JM, Sanderman R, et al. Supporting Self-Management of Cardiovascular Diseases Through Remote Monitoring Technologies: Metaethnography Review of Frameworks, Models, and Theories Used in Research and Development. J Med Internet Res 2020 May 21;22(5):e16157 [FREE Full text] [doi: 10.2196/16157] [Medline: 32436852]

3. de Silva D. Helping People Help Themselves: A Review of the Evidence Considering Whether It Is Worthwhile to Support Self-Management. 2011. URL: https://www.health.org.uk/sites/default/files/HelpingPeopleHelpThemselves.pdf [accessed 2021-10-05]
4. Vervloet M, Korevaar JC, Leemrijse CJ, Paget J, Zullig LL, van Dijk L. Interventions to Improve Adherence to Cardiovascular Medication: What About Gender Differences? A Systematic Literature Review. Patient Prefer Adherence 2020;14:2055-2070 [FREE Full text] [doi: 10.2147/PPA.S260562] [Medline: 33154630]
5. Michie S, Yardley L, West R, Patrick K, Greaves F. Developing and Evaluating Digital Interventions to Promote Behavior Change in Health and Health Care: Recommendations Resulting From an International Workshop. J Med Internet Res 2017 Jun 29;19(6):e232 [FREE Full text] [doi: 10.2196/jmir.7126] [Medline: 28663162]
6. Engelen MM, van Dulmen S, Puijk-Hekman S, Vermeulen H, Nijhuis-van der Sanden MW, Bredie SJ, et al. Evaluation of a Web-Based Self-Management Program for Patients With Cardiovascular Disease: Explorative Randomized Controlled Trial. J Med Internet Res 2020 Jul 24;22(7):e17422 [FREE Full text] [doi: 10.2196/17422] [Medline: 32706708]
7. Van Velsen L, Wentzel J, Van Gemert-Pijnen JEWC. Designing eHealth that Matters via a Multidisciplinary Requirements Development Approach. JMIR Res Protoc 2013 Jun 24;2(1):e21 [FREE Full text] [doi: 10.2196/resprot.2547] [Medline: 23796508]
8. Oinas-Kukkonen H, Harjumaa M. Persuasive Systems Design: Key Issues, Process Model, and System Features. Communications of the Association for Information Systems 2009;24:485-500 [FREE Full text] [doi: 10.17705/1CAIS.02428]
9. ten Klooster I, Wentzel J, Sieverink F, Linssen G, Wesselink R, van Gemert-Pijnen L. Personas for Perfectly Tailored eHealth Technologies: A Multi-Method Study. JMIR Preprints 2021;1:1 [FREE Full text]
10. Keesman M, Janssen V, Kemps H, Hollander M, Reimer WSO, Gemert-Pijnen LV, BENEFIT consortium. BENEFIT for all: An ecosystem to facilitate sustained healthy living and reduce the burden of cardiovascular disease. Eur J Prev Cardiol 2019 Apr 28;26(6):606-608 [FREE Full text] [doi: 10.1177/2047487318816388] [Medline: 30486650]
11. Cruz-Martínez RR, Sieverink F, Wesselink R, van Gemert-Pijnen JEWC. Towards Data-Driven Persuasive Coaching in a Heart Failure Telemonitoring Technology. 2018. URL: http://ceur-ws.org/Vol-2102/paper_5_Cruz-Martinez.pdf [accessed 2021-10-05]
12. Liederman EM, Morefield CS. Web messaging: a new tool for patient-physician communication. J Am Med Inform Assoc 2003;10(3):260-270 [FREE Full text] [doi: 10.1197/jamia.M1259] [Medline: 12626378]
13. IBM Corporation. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corporation; 2019. URL: https://www.ibm.com/support/pages/downloading-ibm-spss-statistics-26 [accessed 2021-10-05]
14. Bolijn R, Schalkers I, Tan HL, Kunst AE, van Valkengoed IGM. Patient perspectives on priorities for research on conventional and sex- and gender-related cardiovascular risk factors. Neth Heart J 2020 Dec 06;28(12):656-661 [FREE Full text] [doi: 10.1007/s12471-020-01497-9] [Medline: 33025404]
15. Zhang KM, Dindoff K, Arnold JMO, Lane J, Swartzman LC. What matters to patients with heart failure? The influence of non-health-related goals on patient adherence to self-care management. Patient Educ Couns 2015 Aug;98(8):927-934. [doi: 10.1016/j.pec.2015.04.011] [Medline: 25979423]
16. Klompstra L, Jaarsma T, Strömberg A. Self-efficacy Mediates the Relationship Between Motivation and Physical Activity in Patients With Heart Failure. J Cardiovasc Nurs 2018;33(3):211-216. [doi: 10.1097/jcn.0000000000000456]
17. Kessing D, Denollet J, Widdershoven J, Kupper N. Psychological Determinants of Heart Failure Self-Care: Systematic Review and Meta-Analysis. Psychosom Med 2016 May;78(4):412-431. [doi: 10.1097/PSY.0000000000000270] [Medline: 27082055]
18. Papandony M, Chou L, Seneviwickrama M, Cicuttini F, Lasserre K, Teichtahl A, et al. Patients' perceived health service needs for osteoarthritis (OA) care: a scoping systematic review. Osteoarthritis Cartilage 2017 Jul;25(7):1010-1025 [FREE Full text] [doi: 10.1016/j.joca.2017.02.799] [Medline: 28232144]
19. Rodgers S, Dyas J, Molyneux A, Ward M, Revill S. Evaluation of the information needs of patients with chronic obstructive pulmonary disease following pulmonary rehabilitation: a focus group study. Chron Respir Dis 2007 Jun 29;4(4):195-203 [FREE Full text] [doi: 10.1177/1479972307080698] [Medline: 18029432]
20. Graven LJ, Grant JS, Vance DE, Pryor ER, Grubbs L, Karioth S. Predicting Depressive Symptoms and Self-care in Patients with Heart Failure. Am J Hlth Behav 2015 Jan 01;39(1):77-87. [doi: 10.5993/ajhb.39.1.9]
21. Buck HG, Mogle J, Riegel B, McMillan S, Bakitas M. Exploring the Relationship of Patient and Informal Caregiver Characteristics with Heart Failure Self-Care Using the Actor-Partner Interdependence Model: Implications for Outpatient Palliative Care. J Palliat Med 2015 Dec;18(12):1026-1032. [doi: 10.1089/jpm.2015.0086] [Medline: 26540092]
22. Liljeroos M, Agren S, Jaarsma T, Strömberg A. Perceived caring needs in patient-partner dyads affected by heart failure: a qualitative study. J Clin Nurs 2014 Oct 03;23(19-20):2928-2938. [doi: 10.1111/jocn.12588] [Medline: 24698101]
23. Jaarsma T, Cameron J, Riegel B, Stromberg A. Factors Related to Self-Care in Heart Failure Patients According to the Middle-Range Theory of Self-Care of Chronic Illness: a Literature Update. Curr Heart Fail Rep 2017 Apr 17;14(2):71-77 [FREE Full text] [doi: 10.1007/s11897-017-0324-1] [Medline: 28213768]
24. Deci EL, Ryan RM. Self-determination theory. In: Van Lange PAM, Kruglanski AW, Higgins ET, editors. Handbook of Theories of Social Psychology. Thousand Oaks, CA: Sage Publications; 2012:416-436.

25. van Velsen L, Broekhuis M, Jansen-Kosterink S, Op den Akker H. Tailoring Persuasive Electronic Health Strategies for Older Adults on the Basis of Personal Motivation: Web-Based Survey Study. J Med Internet Res 2019 Sep 06;21(9):11759 [FREE Full text] [doi: 10.2196/11759] [Medline: 31493323]
26. Asbjørnsen RA, Wentzel J, Smedsrød ML, Hjelmesæth J, Clark MM, Solberg Nes L, et al. Identifying Persuasive Design Principles and Behavior Change Techniques Supporting End User Values and Needs in eHealth Interventions for Long-Term Weight Loss Maintenance: Qualitative Study. J Med Internet Res 2020 Nov 30;22(11):e22598 [FREE Full text] [doi: 10.2196/22598] [Medline: 33252347]
27. British Design Council. The Double Diamond: A Universally Accepted Depiction of the Design Process. 2005. URL: http://www.designcouncil.org.uk/news-opinion/double-diamond-universally-accepted-depiction-design-process [accessed 2021-10-05]
28. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res 2011 Dec 05;13(4):e111 [FREE Full text] [doi: 10.2196/jmir.1672] [Medline: 22155738]
29. Michie S, Johnston M. Theories and techniques of behaviour change: Developing a cumulative science of behaviour change. Health Psychology Review 2012 Mar;6(1):1-6. [doi: 10.1080/17437199.2012.654964]
30. Michie S, Thomas J, Johnston M, Aonghusa PM, Shawe-Taylor J, Kelly MP, et al. The Human Behaviour-Change Project: harnessing the power of artificial intelligence and machine learning for evidence synthesis and interpretation. Implement Sci 2017 Oct 18;12(1):121 [FREE Full text] [doi: 10.1186/s13012-017-0641-5] [Medline: 29047393]
31. Kilsdonk E, Peute L, Riezebos R, Kremer L, Jaspers M. Uncovering healthcare practitioners' information processing using the think-aloud method: From paper-based guideline to clinical decision support system. Int J Med Inform 2016 Feb;86:10-19 [FREE Full text] [doi: 10.1016/j.ijmedinf.2015.11.011] [Medline: 26725690]

Abbreviations

CVD: cardiovascular disease
PHP: personal health platform

Edited by G Eysenbach; submitted 30.08.21; peer-reviewed by H Ögmundsdóttir Michelsen, T Hirosawa; comments to author 07.09.21; revised version received 10.09.21; accepted 17.09.21; published 22.10.21.

Please cite as:
Bente BE, Wentzel J, Groeneveld RGH, IJzerman RVH, de Buisonjé DR, Breeman LD, Janssen VR, Kraaijenhagen R, Pieterse ME, Evers AWM, van Gemert-Pijnen JEWC
Values of Importance to Patients With Cardiovascular Disease as a Foundation for eHealth Design and Evaluation: Mixed Methods Study
JMIR Cardio 2021;5(2):e33252
URL: https://cardio.jmir.org/2021/2/e33252
doi:10.2196/33252
PMID:34677130

Original Paper

The Danish Future Patient Telerehabilitation Program for Patients With Atrial Fibrillation: Design and Pilot Study in Collaboration With Patients and Their Spouses

Birthe Dinesen[1], MSc, PhD; Josefine Dam Gade[1], MSc; Cathrine Skov Schacksen[1], MSc; Helle Spindler[2], MSc, PhD; Andi Eie Albertsen[3], MD, PhD; Lars Dittmann[4], MSc, PhD; Mads Jochumsen[1], MSc, PhD; Dorthe Svenstrup Møller[3], MD, PhD

[1]Department of Health Science and Technology, Laboratory for Welfare Technology - Telehealth & Telerehabilitation, Sport Sciences - Performance and Technology, Aalborg University, Aalborg East Denmark, Denmark

[2]Department of Psychology and Behavioral Sciences, Aarhus University, Aarhus, Denmark

[3]Department of Cardiology, Viborg and Skive Regional Hospital, Viborg, Denmark

[4]Department of Photonics Engineering, Danish Technical University, Copenhagen, Denmark

Corresponding Author:
Cathrine Skov Schacksen, MSc
Department of Health Science and Technology
Laboratory for Welfare Technology - Telehealth & Telerehabilitation, Sport Sciences - Performance and Technology
Aalborg University
Fredrik Bajers Vej 7, Bld A1
Aalborg East Denmark, 9220
Denmark
Phone: 45 61285904
Email: cass@hst.aau.dk

Abstract

Background: Atrial fibrillation (AF) is the most common cardiac arrhythmia and is predicted to more than double in prevalence over the next 20 years. Tailored patient education is recommended as an important aspect of AF care. Current guidelines emphasize that patients become more active participants in the management of their own disease, yet there are no rehabilitation programs for patients with AF in the Danish health care system. Through participatory design, we developed the Future Patient Telerehabilitation (TR) Programs, A and B, for patients with AF. The 2 programs are based on HeartPortal and remote monitoring, together with educational modules.

Objective: The aim of this pilot study is to evaluate and compare the feasibility of the 2 programs of TR for patients with AF.

Methods: This pilot study was conducted between December 2019 and March 2020. The pilot study consisted of testing the 2 TR programs, A and B, in two phases: (1) treatment at the AF clinic and (2) TR at home. The primary outcome of the study was the usability of technologies for self-monitoring and the context of the TR programs as seen from patients' perspectives. Secondary outcomes were the development of patients' knowledge of AF, development of clinical data, and understanding the expectations and experiences of patients and spouses. Data were collected through interviews, questionnaires, and clinical measurements from home monitoring devices. Statistical analyses were performed using the IBM SPSS Statistics version 26. Qualitative data were analyzed using NVivo 12.0.

Results: Through interviews, patients articulated the following themes about participating in a TR program: usefulness of the HeartPortal, feeling more secure living with AF, community of practice living with AF, and measuring heart rhythm makes good sense. Through interviews, the spouses of patients with AF expressed that they had gained increased knowledge about AF and how to support their spouses living with AF in everyday life. Results from the responses to the Jessa AF Knowledge Questionnaire support the qualitative data, as they showed that patients in program B acquired increased knowledge about AF at follow-up compared with baseline. No significant differences were found in the number of electrocardiography recordings between the 2 groups.

Conclusions: Patients with AF and their spouses were positive about the TR program and they found the TR program useful, especially because it created an increased sense of security, knowledge about mastering their symptoms, and a community of

practice linking patients with AF and their spouses and health care personnel. To assess all the benefits of the Future Patient–TR Program for patients with AF, it needs to be tested in a comprehensive randomized controlled trial.

Trial Registration: ClinicalTrials.gov NCT04493437; https://clinicaltrials.gov/ct2/show/NCT04493437.

(JMIR Cardio 2021;5(2):e27321) doi:10.2196/27321

KEYWORDS

atrial fibrillation; cardiac rehabilitation; telerehabilitation; patient education

Introduction

Background

Atrial fibrillation (AF) is the most common cardiac arrhythmia, occurring in 3% of the adult population worldwide and is predicted to be more than double in prevalence over the next 20 years [1]. The increase in AF prevalence can be attributed to aging of the population, better screening for silent AF, and to an increase in conditions predisposing individuals to AF, such as obesity, hypertension, diabetes, obstructive sleep apnea, and physical inactivity [2]. AF is a chronic disease and a major cause of cardiovascular morbidity and mortality. If untreated, AF is associated with a five-fold increased risk of stroke, and 20%-30% of all strokes are attributable to arrhythmia [1].

Patients with AF experience a variety of symptoms, such as palpitations, fatigue, dyspnea, chest pain, sleeping difficulties, fear, and anxiety. The severity of symptoms varies from individual to individual. Although up to 40% of patients with AF are asymptomatic, others report severe or disabling symptoms [1]. In addition, patients with AF have significantly lower health-related quality of life (QoL) compared with healthy controls [3], and they experience more anxiety compared with patients with other heart diseases [4]. In turn, anxiety may lead to avoidance behaviors and a sedentary lifestyle. Both anxiety and depression in patients with AF have been linked to impaired QoL [3].

Apart from anticoagulation to prevent strokes, the management of patients with AF includes risk factor modification and reduction of symptoms and measures to improve their QoL [5,6]. Hence, the evaluation of QoL is an important part of disease management in patients with AF.

Tailored patient education is recommended as an important aspect of AF care. Current guidelines for patients with AF emphasize measures enabling these patients to become more active participants in the management of their own disease [1,3]. In addition, patient knowledge about AF, risk factors, treatment, and self-management strategies are key factors enabling patients to feel more informed, involved, and empowered in relation to self-care and disease management. Patient acceptance of their AF treatment plan will affect their coping abilities and increase their adherence to the recommended therapy. Education of patients and their spouses is therefore essential not only for their understanding of the disease but also for empowering patients to participate in shared decision making and for encouraging their self-management role in relation to recurrent symptomatic AF [7].

Patients with AF report that they do not receive sufficient education or assistance from health care professionals regarding how to live with their AF [7,8]. Moreover, various studies have demonstrated that patients with AF often have poor knowledge of the arrhythmia, how it can be treated, and how to self-manage their disease [7,9,10]. Conventional cardiac rehabilitation has shown benefits in other chronic cardiovascular conditions, demonstrating significant reductions in cardiovascular mortality and rehospitalizations as well as improvements in health-related QoL [11]. In 2019, Denmark launched the first national strategy for the rehabilitation of patients with AF. However, the Danish health care system does not yet offer rehabilitation programs for patients with AF [12]. Standardized care for patients with AF in the Danish health care system consists of visits to doctors and nurses in outpatient AF clinics. During these visits, the patients received advice and education on living with AF and anticoagulation therapy. After the patients with AF have completed their orientation at the AF clinic, they can contact their own general practitioner if needed. With this gap in rehabilitation offerings, there is an urgent need to develop and test new rehabilitation programs for patients with AF. To address this shortcoming, telerehabilitation (TR) may be a new innovative strategy that may be useful in the COVID-19 context.

TR is defined as rehabilitation using information and communication technologies for delivery of rehabilitation activities [13]. Reviews describing TR in cardiac patients highlight the findings that TR has been shown to be as effective as conventional rehabilitation [14,15]. A review of the literature showed no studies of TR programs for AF patients that included monitoring parameters such as electrocardiography (ECG), steps, sleep, blood pressure, pulse, and weight. Moreover, no studies were found on TR programs that included patient education for patients with AF.

Objective

Between 2016 and 2019, our research group developed and tested the Future Patient (FP) program for patients with heart failure (HF) in a participatory design process [16-18]. The outcome of this process was the development of a TR program using a web-based digital toolbox and communication platform the *HeartPortal*, reported in Joensson et al [19]. The design of HeartPortal is based on a self-determination theory, which conceptualizes how patients experience feelings of autonomy, competency, and relatedness in relation to their disease management. A high level of self-determination is essential for sustained patient motivation [20].

The aim of this pilot study is to evaluate and compare the feasibility of the 2 TR programs for patients with AF.

Methods

FP-TR Program

Two FP programs for patients with AF (FP-AF), A and B, have been developed based on a review of the literature, clinical guidelines [1,12], and a participatory design process [16,17,21]. The pilot phase was conducted between December 2019 and March 2020. The AF clinic at Viborg and Skive Regional Hospital in Denmark and the health care centers in Viborg and Skive Municipalities participated in the pilot study. On the basis of the participatory design process, 2 TR programs, A and B, were developed and are described in the section below.

Presentation of Programs for TR of AF

The pilot study consisted of testing programs A and B in two phases: (1) initial treatment at the AF clinic and (2) TR at home. The elements of the 2 TR programs are presented in Textbox 1. Programs A and B differed primarily in relation to patient education, as patients in program B participated in rehabilitation at the health care center during phase 2 in the form of four closed sessions focusing on patient education, whereas patients in program A received brief individual instruction by a nurse. Each educational session lasted 2 hours. The topics covered during these sessions included knowledge of AF, AF medication, AF attacks, mental health, lifestyle changes, and body awareness. These topics were chosen based on the recommendations from national guidelines [7,12] regarding patient education aimed at AF disease management. The two phases and their contexts are illustrated in Figure 1.

Both groups received a blood pressure device (iHealth Neo), weight scale (iHealth Lina), sleep sensor (Emfit QS), step counter (Fitbit Inspire or Charge 3), an iPad (Apple iPad Air 2), and an ECG monitor (AliveCor KardiaMobile). Furthermore, the 2 groups obtained access to the HeartPortal web portal, which is a digital toolbox that functions as an interactive learning module. Screenshots of selected information sites of the HeartPortal are shown in Figure 2. The module consists of an interactive information site for patient education, a communication platform enabling patients to communicate directly with health care professionals through chat or video consultations with health care professionals, a self-tracking module with visualization of measured data, and questionnaires. These devices were chosen based on the FP-TR program for patients with HF [22].

Textbox 1. Presentation of telerehabilitation programs A and B.

Telerehabilitation Program A

- Content of the program and education of patients and spouses
  - At enrollment, the project nurse orients the patients and spouses briefly on the following topics knowledge of atrial fibrillation (AF), AF medication, AF attacks, mental health, lifestyle changes, and body awareness. The project nurse encourages the patients and spouses to study the information module at the HeartPortal, where they can read more about the topics.
- Technologies
  - Blood pressure device
  - Weight scale
  - Sleep sensor
  - Step counter
  - iPad
  - Electrocardiography monitor
- Communication platform
  - Dialogue and video module at the HeartPortal among patients, the AF clinic at the hospital, and health care centers.
  - Patients, spouses, health care professionals from the AF clinic at the hospital and health care professionals from the health care centers had access to the HeartPortal.
- Overview of monitored data and rehabilitation plan
  - Graphic module with overview of measured data at the HeartPortal.
  - Patient can design their own rehabilitation plan.

Telerehabilitation Program B

- Content of the program and education of patients and spouses
  - Patients and spouses were offered to participate in rehabilitation at the health care center in the form of four closed sessions focusing on patient education. The topics during these sessions included knowledge of AF, AF medication, AF attacks, mental health, lifestyle changes, and body awareness. Each session lasted 2 hours, and the teaching was carried out by a nurse from the AF clinic at the hospital and by physiotherapists and a psychologist from the health care center. The patients and spouses were encouraged to study the information module at the HeartPortal, where they can read more about the topics.
- Technologies
  - Blood pressure device
  - Weight scale
  - Sleep sensor
  - Step counter
  - iPad
  - Electrocardiography monitor
- Communication platform
  - Dialogue and video module at the HeartPortal among patients, the AF clinic at the hospital, and health care centers.
  - Patients, spouses, health care professionals from the AF clinic at the hospital, and health care professionals from the health care centers had access to the HeartPortal.
- Overview of monitored data and rehabilitation plan
  - Graphic module with overview of measured data at the HeartPortal.
  - Patient can design their own rehabilitation plan.

Figure 1. Telerehabilitation in two phases.

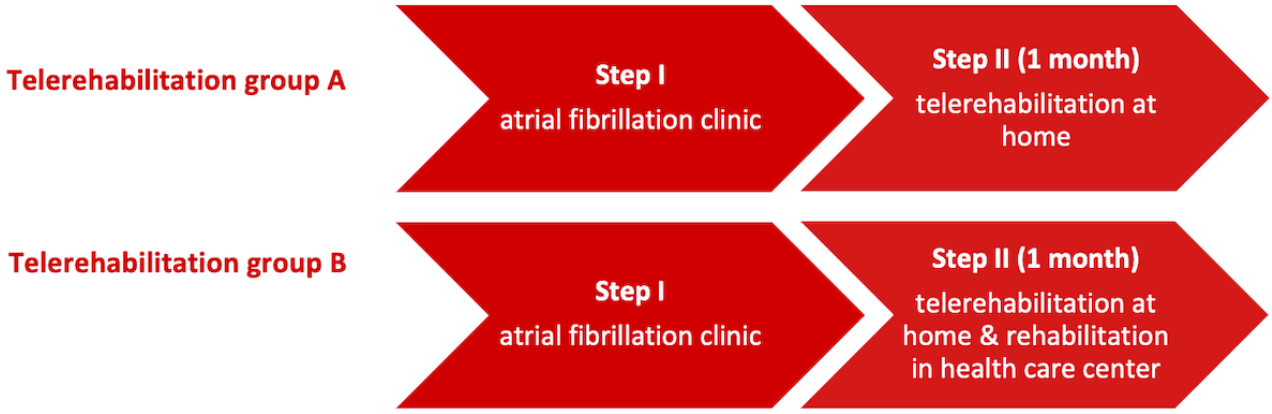
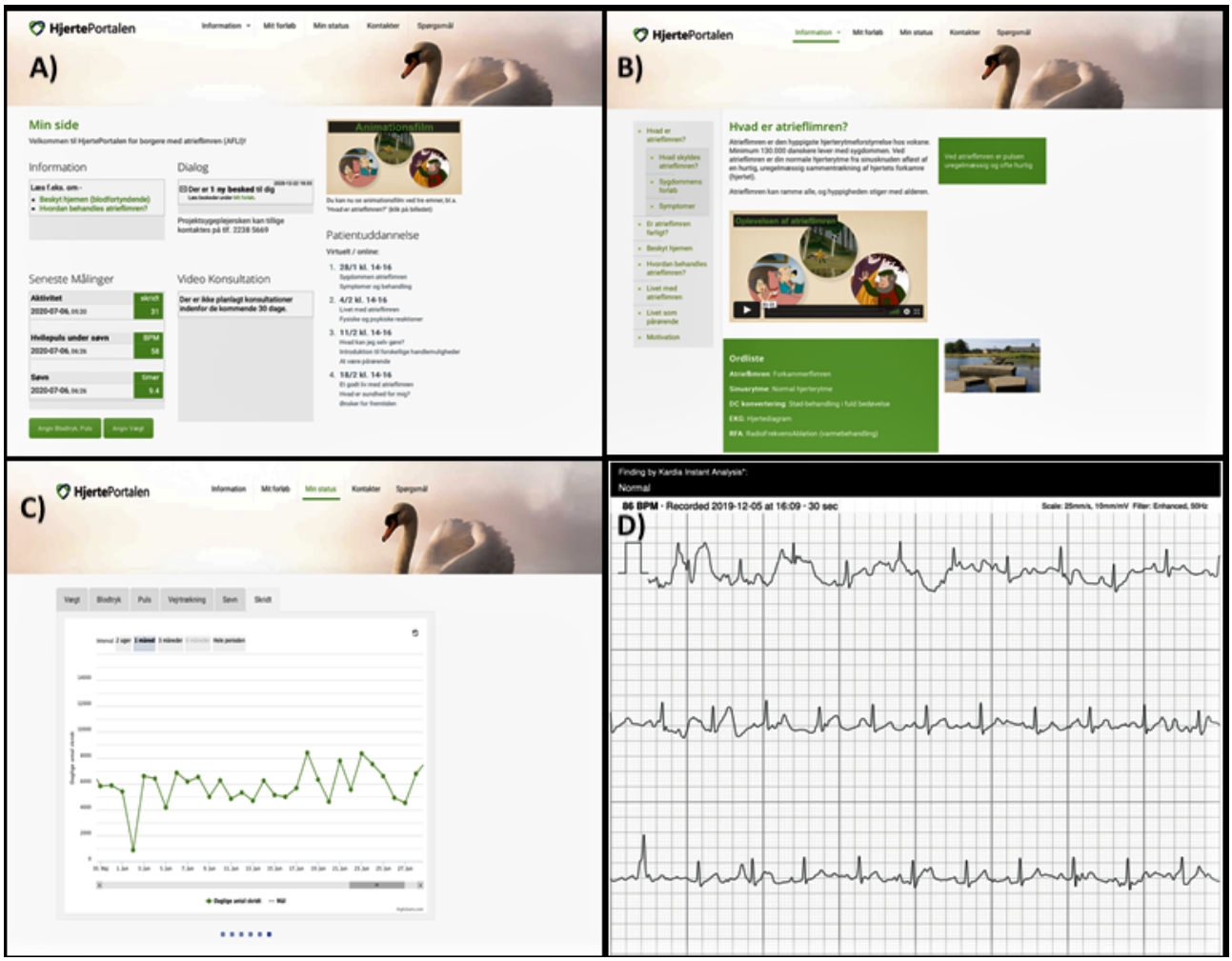


Figure 2. Screen captures of selected information pages from the HeartPortal (Danish: Hjerteportalen.dk). (A) My page (Danish: Min side) with the latest measurement and access to dialogue and video consultation; (B) information module with information about what is AF? (Danish: Hvad er atrieflimren?); (C) overview of steps taken; and (D) overview of heart rhythm from the electrocardiography monitor.



Outcomes

The following primary and secondary outcomes have been defined in the pilot study:

1. Primary outcome:
   - Usability of technologies and content of the TR program seen from patients' perspectives.
2. Secondary outcomes:
   - Patients' knowledge of AF at baseline and at the end of the study.
   - Development of clinical data over 4 weeks.
   - Patients' and spouses' expectations and experiences of participating in the TR program.

Ethical Considerations

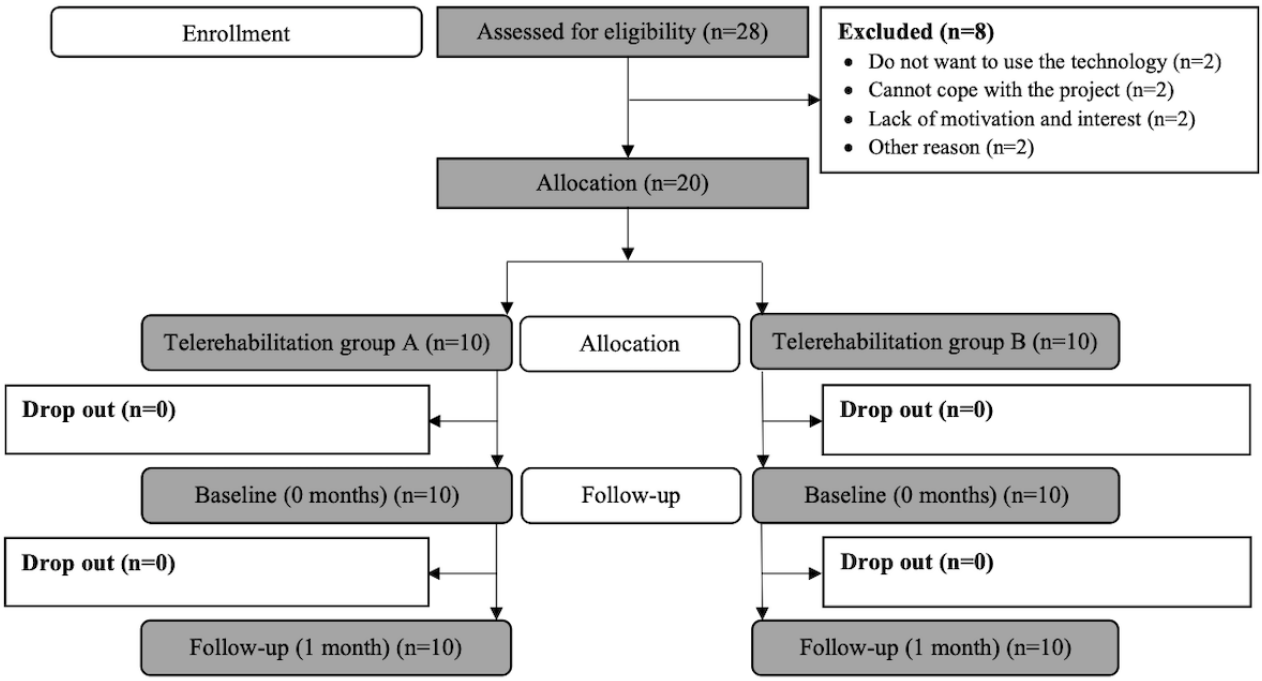
This pilot study was approved by the North Denmark Region Committee on Health Research Ethics (N-20190059) and is listed on ClinicalTrials.gov (NCT04493437). The study was conducted in accordance with the Declaration of Helsinki. All participants signed an informed consent form before enrollment in the study.

Participants and Recruitment

The target group of the FP-AF pilot study included patients diagnosed with AF. The patients were recruited from AF clinics at the Viborg and Skive Regional Hospital, Denmark. Patients were eligible for the study if they were diagnosed with AF, were adults above 18 years of age, were living in Viborg or Skive Municipality, were living at home and capable of caring for themselves, and had basic computer skills or a spouse with basic computer skills. Patients were excluded if they were pregnant, lacked the ability to cooperate, or had insufficient basic Danish language skills.

In total, 20 patients with AF were included in the FP-AF pilot study, of which the first 10 patients were allocated to participate in program A, and the next 10 patients were allocated to participate in program B. The allocation and follow-up of the patients are shown in the CONSORT (Consolidated Standards of Reporting Trials) diagram illustrated in Figure 3.

Figure 3. Consolidated Standards of Reporting Trials (CONSORT) diagram of the pilot study.



Data Collection

Sociodemographic and clinical data were acquired from the patients' medical journal or through self-reporting.

Interviews

Semistructured qualitative interviews, inspired by Brinkmann and Kvale [23], were conducted at the end of the study with patients and spouses in programs A and B at the patients' homes by the first (BD) and second author (JDG). The aim of the interviews was to collect data on how patients viewed the usability of the technologies, the content of the TR programs, and the experiences of the patients and spouses participating in the FP-AF. All 10 patients in program A but only 9 patients in program B participated in the interviews, as did 11 of their spouses. Each interview lasted 30-40 minutes and was tape-recorded. The interviews were transcribed and documented in word files.

Questionnaires

All questionnaire data were collected using the Research Electronic Data Capture (Vanderbilt). To evaluate the usability of HeartPortal, a 5-point Likert scale questionnaire was used, covering both the usability and design aspects of HeartPortal [24]. The questionnaire was validated in a previous study [19]. All patients in programs A and B completed the questionnaire.

Data regarding patients' AF knowledge were collected using the Jessa AF Knowledge Questionnaire (JAKQ) [10,25]. These questionnaires were web-based and answered by patients in both groups, both at baseline and at the end of the study. The answers from the JAKQ were scored on a 4-point Likert scale. The questionnaire responses were extracted from REDCap (Research Electronic Data Capture).

Clinical Measures

The self-monitored data from the devices that the patients had used at home were acquired from Fitbit, iHealth, and Emfit using an application programming interface, whereas the self-monitored ECG data were acquired from KardiaPro. After an ECG measurement, the Alivecor Kardia software displayed feedback to the patient showing whether the measurement had been classified as *Normal ECG*,*Possible AF*, or *Unclassified*.

Statistical Analysis

Before the statistical analyses, data were examined for normality of distribution using the Shapiro-Wilk test.

The sociodemographic and clinical data at baseline and the number of ECG measurements were compared between the 2 groups using an independent samples *t* test (two-tailed) for normally distributed variables and a Mann-Whitney test for nonnormally distributed variables.

The JAKQ answers were recalculated into a percentage score, such that a higher percentage indicated higher AF knowledge. The questionnaire data from JAKQ were compared between the 2 groups at baseline and at follow-up using a Mann-Whitney test, and within the 2 groups from baseline to follow-up using a Wilcoxon signed-rank test.

Data preprocessing was performed using MATLAB version R2019a, and statistical analyses were performed using IBM SPSS Statistics version 26. A significance level of α=.05 was adopted for all analyses.

Analysis of Qualitative Data

The transcribed interviews were coded and analyzed using NVivo 12.0, inspired by Brinkmann and Kvale [23]. The findings are reported in themes, subthemes, and citations.

Results

Patient Characteristics

The sociodemographic and clinical patient characteristics of both groups at baseline are depicted in Table 1 either as the number of patients or as the means and SDs for the different parameters. The test statistics from the comparison between the characteristics of the 2 groups are shown in Table 1. At baseline, there were no significant differences among patients in programs A and B, except for the resting pulse, which was significantly higher in patients in program A (*P*=.01; Table 1).

Table 1. Sociodemographic and clinical patient characteristics at baseline for the patients in program A and B (N=20).

Variable	Program A (N=10)	Program B (N=10)	*P* value
Age (years) by gender, mean (SD); n			
Men	68.4 (3.29); n=5	70.88 (5.69); n=8	.40
Women	74 (4.3); n=5	66.50 (7.78); n=2	.14
Men and women	71.2 (4.66); n=10	70 (5.94); n=10	.62
Clinical parameters, mean (SD)			
Height (cm)	174.40 (7.66)	180 (6.82)	.10
Weight (kg)	86.80 (15.58)	90.2 (20.25)	.68
Systolic blood pressure (mm Hg)	134.70 (16.39)	143.3 (20.51)	.33
Diastolic blood pressure (mm Hg)	83 (14.95)	81.4 (16.47)	.82
Resting pulse (beats/min)	84 (21.88)	61.4 (14.37)	.01[a]
Ejection fraction (%)	58.50 (4.74)	58.5 (3.38)	.63
CHA_2DS_2-VASc-score[b]	2.50 (1.08)	1.9 (1.29)	.34
HADS-BLED-score[c]	1.80 (0.63)	1.2 (0.79)	.10
EHRA[d]-score	2.10 (0.74)	2.2 (0.63)	.77
Former DC[e] (quantity)	0.5 (1.08)	1.3 (1.77)	.12
Former RFA[f] (quantity)	0.80 (1.48)	0.4 (0.7)	.82
P-creatinine (µmol/L)	69.40 (17.13)	92.1 (33.45)	.11
B-hemoglobin (mmol/L)	8.88 (0.81)	9.2 (0.75)	.68
TSH[g] ($\times 10^{-3}$ IU/L)	1.70 (0.7)	1.72 (1.23)	.60
Years with AF[h]	4 (5.831)	5.8 (6.27)	.18
Primary diagnoses, n (%)			.99
Paroxysmal AF	8 (80)	8 (80)	
Persistent AF	1 (10)	1 (10)	
Permanent AF	1 (10)	1 (10)	
Secondary diagnosis, n (%)			.79
Hypertension	3 (30)	5 (50)	
Diabetes mellitus	0 (0)	0 (0)	
Former stroke or TIA[i] peripheral embolism	2 (20)	0 (0)	
Ischemic heart disease	0 (0)	0 (0)	
Claudication	0 (0)	0 (0)	
Civil status, n (%)			.07
Single or living alone	2 (20)	0 (0)	
Married or living with a partner	8 (80)	10 (100)	
Education, n (%)			.59
Primary school	0 (0)	1 (10)	
Unskilled	0 (0)	0 (0)	
Skilled worker	4 (40)	4 (40)	
High school	0 (0)	0 (0)	
Bachelor’s degree	5 (50)	4 (40)	
Master’s degree	1 (10)	1 (10)	

Variable	Program A (N=10)	Program B (N=10)	*P* value
At least PhD	0 (0)	0 (0)	
Work status, n (%)			.65
Unemployed	0 (0)	0 (0)	
Sick leave	0 (0)	0 (0)	
Works under 20 hours/week	0 (0)	0 (0)	
Works 20-36 hours/week	1 (10)	1 (10)	
Works full-time 37 hours/week	1 (10)	2 (20)	
Retired	8 (80)	7 (70)	

[a]Indicates significant test statistics (*P*=.05).

[b]CHA_2DS_2-VASc-score.

[c]HADS-BLED-score.

[d]EHRA: European Heart Rhythm Association.

[e]DC: direct current cardioversion.

[f]RFA: radiofrequency ablation.

[g]TSH: thyroid-stimulating hormone.

[h]AF: atrial fibrillation.

[i]TIA: transient ischemic attack.

Patients' Experiences

Patients' experiences were evaluated based on qualitative data from their interviews. The interview data were categorized into the following themes: user-friendliness of the technologies, usage of the HeartPortal and preferences in acquiring information (Textbox 2).

In Tables 2 and 3, most of the patients in programs A and B responded that HeartPortal has a high degree of usability in relation to navigation, easy information, and logical structure.

Tables 4 and 5 demonstrate that patients in program B highlight the importance of education at the health care center for them and their spouses. They found education to be useful and relevant.

Textbox 2. Findings from interviews with patients with atrial fibrillation and their spouses.

Patients' Perspectives in Themes

The portal is a useful digital tool when you need to learn to live with atrial fibrillation.

- Usefulness of the HeartPortal.dk
  - Information is easy to understand
  - Animation video communicating knowledge about life with atrial fibrillation (AF) in a simple way
  - Data give me an overview of the progress of my rehabilitation
  - The portal is a good tool for AF rehabilitation

When I learn about my disease and symptoms, I feel secure living with atrial fibrillation.

- Feeling more secure living with AF
  - Learning about my disease creates a sense of security

Meeting other patients and spouses gives me a feeling of not being alone; my wife and I learn from the other participants.

- Community of practice between patients living with AF
  - Teaching at the health care center creates a feeling of cohesion
  - Mutual interest and learning among patients and spouses

I feel secure when I can see how my heart is beating.

- Measuring heart rhythm makes good sense
  - Feeling of security
  - Need more knowledge about how to read the electrocardiography

Spouses Perspectives in Themes

There is useful information in the HeartPortal on how to live with atrial fibrillation as a patient and for me as a spouse. I like that it is also communicated in animation videos.

- Increased knowledge about AF and how to support spouse living with AF
  - HeartPortal is a useful toolbox
  - Feeling of security

During the education at the health care center, I met other spouses and we formed relationships and felt confident sharing experiences.

- Community of practice between spouses
  - Knowledge sharing with other spouses is useful
  - Exchange of ideas on how to support spouse living with AF

Table 2. Patients' responses to usability of the HeartPortal.

Variable: usability of the HeartPortal	Strongly agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly disagree, n (%)
It is easy to navigate on the HeartPortal	8 (42.11)	6 (31.58)	4 (21.05)	1 (5.26)	0 (0)
The information is understandable	13 (68.42)	6 (31.58)	0 (0)	0 (0)	0 (0)
I gain new knowledge about AF[a] from the videos	6 (31.58)	4 (21.05)	4 (21.05)	5 (26.32)	0 (0)
The HeartPortal is logically structured	12 (63.16)	5 (26.32)	0 (0)	2 (10.52)	0 (0)
The buttons have a suitable size	12 (63.16)	7 (36.84)	0 (0)	0 (0)	0 (0)

[a]AF: atrial fibrillation.

Table 3. Patients' responses to the design of the HeartPortal.

Variable: design of the HeartPortal	Excellent, n (%)	Very good, n (%)	Good, n (%)	Bad, n (%)	Very bad, n (%)
Text size	13 (68.42)	4 (21.06)	2 (10.52)	0 (0)	0 (0)
Amount of text	7 (36.84)	7 (36.84)	5 (26.32)	0 (0)	0 (0)
Color scheme	12 (63.16)	4 (21.05)	3 (15.79)	0 (0)	0 (0)
Length of the videos	13 (68.42)	1 (5.26)	4 (21.05)	1 (5.26)	0 (0)
Structure of the HeartPortal	12 (63.16)	2 (10.52)	5 (26.32)	0 (0)	0 (0)

Table 4. Response of patients in program B to patient education at the health care center[a].

Variable	Strongly agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly disagree, n (%)
I have gained more knowledge on living with AF[b]	5 (55.56)	4 (44.44)	0 (0)	0 (0)	0 (0)
The education has helped me feel more comfortable living with AF	6 (66.67)	3 (33.33)	0 (0)	0 (0)	0 (0)
The education complements the HeartPortal	5 (55.56)	4 (44.44)	0 (0)	0 (0)	0 (0)
It has been important for me to have my spouses with me at the health care center	4 (44.44)	1 (11.11)	3 (33.33)	0 (0)	1 (11.11)
The topics have been relevant for me	7 (77.78)	1 (11.11)	1 (11.11)	0 (0)	0 (0)

[a]One person did not participate in the interview.

[b]AF: atrial fibrillation.

Table 5. Response of patients in program B to patient education at the health care center[a].

Variable	Excellent, n (%)	Very good, n (%)	Good, n (%)	Bad, n (%)	Very bad, n (%)
How have you experienced the education at the health care center?	7 (77.78)	1 (11.11)	1 (11.11)	0 (0)	0 (0)
What do you think about the form of the education?	5 (55.56)	3 (33.33)	1 (11.11)	0 (0)	0 (0)

[a]One person did not participate in the interview.

AF Knowledge

A Wilcoxon signed-rank test was used to test whether a statistically significant difference was present when comparing the median scores (%) and IQR of the JAKQ scores at baseline and follow-up individually in the 2 groups, and on this basis. Patients in program B showed statistically significantly higher AF knowledge (P=.02) at follow-up (median 86.06, IQR 22.36) compared with baseline (median 69.23, IQR 21.88), whereas no difference was found for patients in program A (baseline: median 78.13, IQR 31.25; follow-up: median 81.25, IQR 25; P=.13).

Clinical Measures

During the intervention, both groups performed self-monitoring of the clinical measurements. The mean and SD of these measurements were evaluated for each week of the intervention for both patients in program A and those in program B. The results are shown in Table 6.

Table 6. Clinical measures as monitored by the patients for program A and program B.

Variable	Week 1, mean (SD)	Week 2, mean (SD)	Week 3, mean (SD)	Week 4, mean (SD)
Program A				
Systolic blood pressure (mm Hg)	138.5 (11.15)	142.85 (19.62)	137.28 (11.24)	134.67 (13.03)
Diastolic blood pressure (mm Hg)	82.8 (11.13)	84.95 (8.89)	81.11 (10.31)	82.28 (10.85)
Pulse (beats per min)	76.3 (14.18)	73.95 (17.11)	68.61 (13.37)	71.78 (14.27)
Weight (kg)	88.38 (15.69)	90.6 (16.39)	89.25 (16.95)	90.06 (18.32)
Daily steps (n)	7150.5 (5370.17)	8443.4 (6069.01)	5993.55 (4172.97)	7236.50 (5110.75)
Distance (km)	5.33 (4.01)	6.29 (4.51)	4.45 (3.08)	5.39 (3.82)
Pulse during sleep (beats per min)	63.86 (8.59)	63.73 (8.6)	63.75 (8.64)	63.9 (7.76)
Respiration during sleep (breaths per min)	15.41 (1.9)	15.12 (1.98)	15.02 (2.1)	15.05 (1.85)
Sleep score (%)	70.5 (12.41)	82.25 (16.13)	84.05 (15.3)	78.59 (20.62)
Sleep time (hours)	7.09 (1.6)	7.56 (1.43)	7.68 (1.21)	8.02 (1.75)
Program B				
Systolic or diastolic blood pressure (mm Hg)	139.25 (18.04)/82.3 (12.93)	135.22 (14.69)/79.94 (10.13)	129.28 (12.92)/78.11 (6.16)	127.33 (16.3)/77.72 (10.99)
Pulse (beats per min)	66.35 (11.08)	66.39 (10.72)	66.56 (11.9)	64.78 (7.6)
Weight (kg)	88.42 (20.44)	90.15 (20.04)	89.38 (21.27)	90.68 (22.69)
Steps	8638.35 (4783.43)	8683.00 (5003.07)	7585.85 (4959.23)	7565.25 (3982.92)
Distance (km)	6.41 (3.55)	6.44 (3.76)	5.64 (3.69)	5.64 (2.98)
Pulse during sleep (beats per min)	57.98 (4.58)	58.61 (4.91)	59.17 (4.55)	60.74 (4.66)
Respiration during sleep (breaths per min)	14.44 (1.27)	14.57 (1.3)	14.24 (1.32)	14.29 (1.29)
Sleep score (%)	75.16 (18.81)	83.52 (8.87)	78.81 (17.27)	78.68 (13.16)
Sleep time (hours)	7.59 (1.5)	7.74 (0.68)	7.83 (0.8)	7.76 (0.9)

The median number of ECG recordings and classifications and the IQR are shown in Table 7. In addition, the difference between the 2 groups was statistically analyzed using the Mann-Whitney test, the results of which are also shown in Table 7. The results showed that there were no statistical differences in the number of ECG recordings or classifications between the patients in programs A and B.

Table 7. Median number of electrocardiography recordings for groups A and B and IQR and results of the Mann-Whitney tests.

Variable	Program A, median (IQR)	Program B, median (IQR)	*P* value
Total number of recordings	19 (20)	19 (19)	.85
Normal ECG[a]	7 (16)	7.5 (14)	.70
Possible AF[b]	10 (13)	5.5 (23)	.82
Unclassified	3 (6)	4 (6)	.94

[a]ECG: electrocardiography.

[b]AF: atrial fibrillation.

Discussion

Principal Findings

The aim of this pilot study was to evaluate and compare the feasibility of the 2 TR programs for patients with AF. The sociodemographic and clinical patient characteristics showed that the 2 groups in the study were comparable at baseline (Table 1). Through interviews, patients articulated the following themes (Textbox 2) about their participation in a TR program: the HeartPortal is a useful tool, increased feeling of security while living with AF, being part of a community of practice living with AF, and measuring one's heart rhythm makes good sense in AF disease management. The findings from the FP-AF study are in line with the findings from a qualitative study by Dinesen et al [22] on TR in patients with HF. These patients stated that TR technologies and access to their own data provided a relevant overview for the patients in relation to their rehabilitation

processes. Furthermore, the patients stated that TR encouraged them to carry out activities on their own, and that they felt more at ease in performing their rehabilitation activities outside the hospital and the health care centers [26]. Other data from the same study comparing psychological aspects across conventional rehabilitation and rehabilitation were reported by Spindler et al [27], where conventional rehabilitation therapy versus TR in patients with HF was compared [27]. They showed that patients in both groups were equally motivated for lifestyle changes and self-care, and that they experienced similar levels of psychological distress and QoL. Spindler et al [27] concluded that based on psychological measures, TR may be a feasible alternative to conventional rehabilitation. The previous study can help us take the next step in testing FP-AF [27].

Through interviews, the spouses of patients with AF expressed that they had gained increased knowledge about AF and on how to support their spouses to cope with their AF in everyday life. The spouses (Textbox 2) also expressed that they felt more like part of a community of practice with the other spouses participating in education at the health care center. The qualitative study by Dinesen et al [22] on TR in patients with HF also explored how their spouses participated in a TR program. They found that the spouses had an increased sense of security, they took too much responsibility on behalf of their partner, and that they tended to push their partner too hard at times. As such, Dinesen et al [22] suggested that it is important to identify the most effective ways of involving spouses when designing a new cardiac TR program. The spouses certainly need to acquire sufficient knowledge and education about the disease of their partner, and they need to find the best way to help their partner prevent worsening of their symptoms [26].

On the basis of questionnaire responses, the patients reported that they found the HeartPortal easy to navigate, that the information provided was understandable, that the animation videos helped them gain new knowledge about AF, that the HeartPortal was logically structured, and that the design of the HeartPortal was assessed as very good or excellent (Tables 2 and 3). In addition, patients in program B expressed the view that the education at the health care center helped them gain more knowledge about living with AF, and they valued having their spouses participating in the sessions at the health care center (Tables 4 and 5). These results are supported by findings based on the AF knowledge questionnaire, JAKQ, showing that patients in program B acquired increased knowledge about AF at follow-up compared with baseline. These results are comparable with findings from another study using the JAKQ to evaluate the effectiveness and usability of an online tailored education platform to inform patients with AF undergoing direct current cardioversion or pulmonary vein isolation [25]. This study found that AF-related knowledge in patients who received online education was significantly better after 6 weeks, whereas no significant differences over time were found in the group that received online standard care. A review of digitalized patient education for patients with HF, coronary artery disease, and AF concluded that digital education increased QoL, increased knowledge, and decreased depression and anxiety [28]. In addition, the review by Oudkerk Pool et al [28] highlighted that patients are satisfied with digital platforms. However, the review only included 1 pilot study with 100 patients with AF; therefore, there is an urgent need for more knowledge of digitalized patient education for patients with AF in TR programs.

Kayser et al [29] stressed that in a matrix framework for designing digital technologies and services for patients with chronic conditions, they needed to view the patients' role more broadly, in terms of engagement, empowerment, and emancipation. In programs A and B of the FP-AF, we attempted to design the HeartPortal, remote monitoring, and educational modules to be interactive and motivating. In addition, we educate health care professionals to help facilitate empowerment and emancipation. These issues will be addressed in a future larger study of the FP-AF program.

Clinical data are shown in Table 6 for groups A and B at both the baseline and follow-up stages. The same number of ECG recordings was carried out for patients in programs A and B, and there was an equal number of normal ECGs in the 2 groups (Table 7). In program A, a median of 10 cases of possible AF were identified, and in program B, the median of possible cases of AF was 5.5. However, no significant differences were found in the ECG recordings of the 2 groups. When designing a TR program, the burden of tracking arises as a question. For patients with AF, we questioned whether patients would benefit from measuring their ECG at home and whether this measurement activity would be a burden for the patient. In our qualitative interviews with patients with AF, they expressed the view that they felt secure measuring their own ECG; however, they needed more knowledge about how to read the ECGs. We identified a new European TeleCheck-AF mobile health study that began as a response to the COVID-19 pandemic [30]. The focus of the TeleCheck-AF study was on remote AF and risk factor management through teleconsultation. In that study, patients with AF were asked to measure their heart rhythm and heart rate for 7 days before a scheduled teleconsultation with a doctor at the hospital. The TeleCheck-AF study is ongoing in several European countries, but the results are not yet available. We have not identified other studies with a focus on TR for patients with AF using components such as remote monitoring, a web-based interactive platform, or education at a health care center.

On the basis of our experiences with using participatory design for TR programs, we also used this approach as an overall method for developing the FP program and the HeartPortal in collaboration among patients, spouses, and health care professionals [19,22]. Program B (Textbox 2) of the TR program was chosen by the patients as the best program in terms of content and structure, as they value having education at the health care center with their spouses as a part of the TR program.

Limitations

One limitation of this study is that the pilot phase lasted for only 1 month. Program B of the FP-AF will have to be tested for a longer period by both patients with AF and spouses, and further, in a randomized controlled trial to generate sufficient evidence about the effects of the program. The pilot study has been tested only on Danish patients, which is a limitation, as the results

may not readily be generalized to other cultural contexts at this stage.

Conclusions

Overall, patients with AF and their spouses were positive about participating in a TR program consisting of remote monitoring, an interactive web-based HeartPortal, and education at a local health care center. Patients with AF and their spouses found the TR program useful, especially because it created an increased sense of security, enhanced their knowledge about mastering their symptoms, and a feeling of belonging to a community of practice linking patients with AF and their spouses and health care personnel. To assess the full benefits of FP-AF, this TR program needs to be tested in a comprehensive randomized controlled trial.

Acknowledgments

The authors wish to thank the patients with AF, their spouses, and health care professionals for participating in this study. The authors also wish to thank the staff at the 2 health care centers in Viborg and Skive and the Department of Cardiology at Viborg and Skive Regional Hospital for their cooperation. Thank you for the project nurse, Helle Mark Mogensen. The project partners are health care centers in Viborg and Skive, Department of Cardiology, Viborg and Skive Regional Hospital; Danish Heart Association; Department of Photonics Engineering, Technical University of Denmark; Department of Psychology and Behavioral Sciences, Aarhus University; Laboratory of Welfare Technologies-Telehealth & Telerehabilitation, Sport Sciences -Performance and Technology, Department of Health Science and Technologies, Aalborg University, Denmark. The FP project is financed by the Aage and Johanne-Louis Hansen's Foundation, Aalborg University, and with cofinancing from all partners in the project.

Conflicts of Interest

None declared.

References

1. Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B, ESC Scientific Document Group. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J 2016 Oct 7;37(38):2893-2962. [doi: 10.1093/eurheartj/ehw210] [Medline: 27567408]
2. Schnabel R, Yin X, Gona P, Larson M, Beiser A, McManus D, et al. 50 year trends in atrial fibrillation prevalence, incidence, risk factors, and mortality in the Framingham Heart Study: a cohort study. Lancet 2015 Jul;386(9989):154-162. [doi: 10.1016/s0140-6736(14)61774-8]
3. Thrall G, Lane D, Carroll D, Lip GY. Quality of life in patients with atrial fibrillation: a systematic review. Am J Med 2006 May;119(5):448.e1-448.19. [doi: 10.1016/j.amjmed.2005.10.057] [Medline: 16651058]
4. Christiansen N, Zinckernagel L, Zwisler A, Rod M, Holmberg T. Livet Med en Hjertesygdom. Hjertesygdom. 2015. URL: https://www.sdu.dk/sif/-/media/images/sif/sidste_chance/sif/udgivelser/2015/livet_med_en_hjertesygdom.pdf [accessed 2021-06-17]
5. Gallagher C, Hendriks JM, Mahajan R, Middeldorp ME, Elliott AD, Pathak RK, et al. Lifestyle management to prevent and treat atrial fibrillation. Expert Rev Cardiovasc Ther 2016 Jul;14(7):799-809. [doi: 10.1080/14779072.2016.1179581] [Medline: 27112903]
6. Pathak RK, Middeldorp ME, Meredith M, Mehta AB, Mahajan R, Wong CX, et al. Long-term effect of goal-directed weight management in an atrial fibrillation cohort: a long-term follow-up study (legacy). J Am Coll Cardiol 2015 May 26;65(20):2159-2169 [FREE Full text] [doi: 10.1016/j.jacc.2015.03.002] [Medline: 25792361]
7. Salmasi S, De Vera MA, Barry A, Bansback N, Harrison M, Lynd LD, et al. Assessment of condition and medication knowledge gaps among atrial fibrillation patients: a systematic review and meta-analysis. Ann Pharmacother 2019 Aug 2;53(8):773-785. [doi: 10.1177/1060028019835845] [Medline: 30829052]
8. Lane DA, Aguinaga L, Blomström-Lundqvist C, Boriani G, Dan G, Hills MT, et al. Cardiac tachyarrhythmias and patient values and preferences for their management: the European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLEACE). Europace 2015 Dec;17(12):1747-1769. [doi: 10.1093/europace/euv233] [Medline: 26108807]
9. McCabe P, Barnason S, Houfek J. Illness beliefs in patients with recurrent symptomatic atrial fibrillation. Pacing Clin Electrophysiol 2011 Jul;34(7):810-820. [doi: 10.1111/j.1540-8159.2011.03105.x] [Medline: 21507022]
10. Desteghe L, Engelhard L, Raymaekers Z, Kluts K, Vijgen J, Dilling-Boer D, et al. Knowledge gaps in patients with atrial fibrillation revealed by a new validated knowledge questionnaire. Int J Cardiol 2016 Nov 15;223:906-914. [doi: 10.1016/j.ijcard.2016.08.303] [Medline: 27589038]
11. Anderson L, Oldridge N, Thompson DR, Zwisler A, Rees K, Martin N, et al. Exercise-based cardiac rehabilitation for coronary heart disease: cochrane systematic review and meta-analysis. J Am Coll Cardiol 2016 Jan 5;67(1):1-12 [FREE Full text] [doi: 10.1016/j.jacc.2015.10.044] [Medline: 26764059]

12. Risom SS. National Klinisk Retningslinje for Rehabilitering Til Patienter Med Atrieflimren, Atrieflagren, Patienter Med Endokarditis Og Patienter Behandlet Med en Implanterbar Cardioverter Defibrillator (ICD). Rigshospitalet. 2019. URL: https://www.fysio.dk/globalassets/documents/fafo/kliniske-retningslinjer/hjerte-lunge/nkr_rehabilitering_arterieflimren_endokarditis_icd.pdf [accessed 2021-06-17]
13. Brennan D, Tindall L, Theodoros D, Brown J, Campbell M, Christiana D, et al. A blueprint for telerehabilitation guidelines. Int J Telerehabil 2010;2(2):31-34 [FREE Full text] [doi: 10.5195/ijt.2010.6063] [Medline: 25945175]
14. Rawstorn JC, Gant N, Direito A, Beckmann C, Maddison R. Telehealth exercise-based cardiac rehabilitation: a systematic review and meta-analysis. Heart 2016 Aug 1;102(15):1183-1192. [doi: 10.1136/heartjnl-2015-308966] [Medline: 26936337]
15. Brouwers RW, van Exel HJ, van Hal JM, Jorstad HT, de Kluiver EP, Kraaijenhagen RA, Committee for Cardiovascular Prevention and Cardiac Rehabilitation of the Netherlands Society of Cardiology. Cardiac telerehabilitation as an alternative to centre-based cardiac rehabilitation. Neth Heart J 2020 Sep;28(9):443-451 [FREE Full text] [doi: 10.1007/s12471-020-01432-y] [Medline: 32495296]
16. Kushniruk A, Nøhr C. Participatory design, user involvement and health IT evaluation. Stud Health Technol Inform 2016;222:139-151. [Medline: 27198099]
17. Kanstrup A, Madsen J, Nøhr C, Bygholm A, Bertelsen P. Developments in participatory design of health information technology - a review of PDC publications from 1990 - 2016. Stud Health Technol Info 2017;233:1-13. [doi: 10.3233/978-1-61499-740-5-1]
18. Clemensen J, Rothmann MJ, Smith AC, Caffery LJ, Danbjorg DB. Participatory design methods in telemedicine research. J Telemed Telecare 2017 Oct;23(9):780-785. [doi: 10.1177/1357633X16686747] [Medline: 28027678]
19. Joensson K, Melholt C, Hansen J, Leth S, Spindler H, Olsen MV, et al. Listening to the patients: using participatory design in the development of a cardiac telerehabilitation web portal. Mhealth 2019;5:33 [FREE Full text] [doi: 10.21037/mhealth.2019.08.06] [Medline: 31620460]
20. Ryan R, Patrick H, Deci E, Williams G. Facilitating health behaviour change and its maintenance: interventions based on self-determination theory. Eur Heal Psychol 2008;10:2-5.
21. Hippel VE. Democratizing Innovation. Cambridge, Mass: MIT Press; 2005.
22. Dinesen B, Dittmann L, Gade JD, Jørgensen CK, Hollingdal M, Leth S, et al. 'Future patient' telerehabilitation for patients with heart failure: protocol for a randomized controlled trial. JMIR Res Protoc 2019 Sep 19;8(9):e14517 [FREE Full text] [doi: 10.2196/14517] [Medline: 31538944]
23. Brinkmann S, Kvale S. Interviews?: Learning the Craft of Qualitative Research Interviewing. Los Angeles, California: Sage Publications; 2015.
24. Maramba I, Chatterjee A, Newman C. Methods of usability testing in the development of eHealth applications: a scoping review. Int J Med Inform 2019 Jun;126:95-104. [doi: 10.1016/j.ijmedinf.2019.03.018] [Medline: 31029270]
25. Desteghe L, Germeys J, Vijgen J, Koopman P, Dilling-Boer D, Schurmans J, et al. Effectiveness and usability of an online tailored education platform for atrial fibrillation patients undergoing a direct current cardioversion or pulmonary vein isolation. Int J Cardiol 2018 Dec 1;272:123-129. [doi: 10.1016/j.ijcard.2018.07.065] [Medline: 30049498]
26. Dinesen B, Nielsen G, Andreasen JJ, Spindler H. Integration of rehabilitation activities into everyday life through telerehabilitation: qualitative study of cardiac patients and their partners. J Med Internet Res 2019 Apr 15;21(4):e13281 [FREE Full text] [doi: 10.2196/13281] [Medline: 30985284]
27. Spindler H, Leerskov K, Joensson K, Nielsen G, Andreasen JJ, Dinesen B. Conventional rehabilitation therapy versus telerehabilitation in cardiac patients: a comparison of motivation, psychological distress, and quality of life. Int J Environ Res Public Health 2019 Feb 12;16(3):- [FREE Full text] [doi: 10.3390/ijerph16030512] [Medline: 30759761]
28. Oudkerk Pool MD, Hooglugt JQ, Schijven MP, Mulder BJ, Bouma BJ, de Winter RJ, et al. Review of digitalized patient education in cardiology: a future ahead? Cardiology 2021;146(2):263-271 [FREE Full text] [doi: 10.1159/000512778] [Medline: 33550295]
29. Kayser L, Nøhr C, Bertelsen P, Botin L, Villumsen S, Showell C, et al. Theory and practice in digital behaviour change: a matrix framework for the co-production of digital services that engage, empower and emancipate marginalised people living with complex and chronic conditions. Informatics 2018 Nov 9;5(4):41. [doi: 10.3390/informatics5040041]
30. Hermans AN, van der Velden RM, Gawalko M, Verhaert DV, Desteghe L, Duncker D, TeleCheck-AF investigators. On-demand mobile health infrastructures to allow comprehensive remote atrial fibrillation and risk factor management through teleconsultation. Clin Cardiol 2020 Nov;43(11):1232-1239 [FREE Full text] [doi: 10.1002/clc.23469] [Medline: 33030259]

Abbreviations

AF: atrial fibrillation
CONSORT: Consolidated Standards of Reporting Trials
ECG: electrocardiography
FP: future patient
FP-AF: FP telerehabilitation program for patients with AF

HF: heart failure
JAKQ: Jessa AF Knowledge Questionnaire
QoL: quality of life
REDCap: Research Electronic Data Capture
TR: telerehabilitation

Edited by G Eysenbach; submitted 21.01.21; peer-reviewed by C Gallagher, S Riggare; comments to author 23.02.21; revised version received 15.04.21; accepted 16.05.21; published 19.07.21.

Please cite as:
Dinesen B, Dam Gade J, Skov Schacksen C, Spindler H, Eie Albertsen A, Dittmann L, Jochumsen M, Svenstrup Møller D
The Danish Future Patient Telerehabilitation Program for Patients With Atrial Fibrillation: Design and Pilot Study in Collaboration With Patients and Their Spouses
JMIR Cardio 2021;5(2):e27321
URL: https://cardio.jmir.org/2021/2/e27321
doi:10.2196/27321
PMID:34279239

Original Paper

Usability and Perceived Usefulness of the AFib 2gether Mobile App in a Clinical Setting: Single-Arm Intervention Study

Alok Kapoor[1], MSc, MD; Anna Hayes[1], BSc; Jay Patel[1], BSc; Harshal Patel[1], BA; Andreza Andrade[1], BA; Kathleen Mazor[1], EdD; Carl Possidente[2], PharmD; Kimberly Nolen[2], BSc, PharmD; Rozelle Hegeman-Dingle[2], PharmD; David McManus[1], MSc, MD

[1]Department of Medicine, University of Massachusetts Chan Medical School, Worcester, MA, United States

[2]Division of Medical Affairs, Pfizer Inc, New York, NY, United States

Corresponding Author:
Alok Kapoor, MSc, MD
Department of Medicine
University of Massachusetts Chan Medical School
55 North Lake Ave
Worcester, MA, 01655
United States
Phone: 1 9178564538
Email: alok.kapoor@umassmemorial.org

Abstract

Background: Although the American Heart Association and other professional societies have recommended shared decision-making as a way for patients with atrial fibrillation (AF) or atrial flutter to make informed decisions about using anticoagulation (AC), the best method for facilitating shared decision-making remains uncertain.

Objective: The aim of this study is to assess the AFib 2gether mobile app for usability, perceived usefulness, and the extent and nature of shared decision-making that occurred for clinical encounters between patients with AF and their cardiology providers in which the app was used.

Methods: We identified patients visiting a cardiology provider between October 2019 and May 2020. We measured usability from patients and providers using the Mobile App Rating Scale. From the 8 items of the Mobile App Rating Scale, we reported the average score (out of 5) for domains of functionality, esthetics, and overall quality. We administered a 3-item questionnaire to patients relating to their perceived usefulness of the app and a separate 3-item questionnaire to providers to measure their perceived usefulness of the app. We performed a chart review to track the occurrence of AC within 6 months of the index visit. We also audio recorded a subset of the encounters to identify evidence of shared decision-making.

Results: We facilitated shared decision-making visits for 37 patients visiting 13 providers. In terms of usability, patients' average ratings of functionality, esthetics, and overall quality were 4.51 (SD 0.61), 4.26 (SD 0.51), and 4.24 (SD 0.89), respectively. In terms of usefulness, 41% (15/37) of patients agreed that the app improved their knowledge regarding AC, and 62% (23/37) agreed that the app helped clarify to their provider their preferences regarding AC. Among providers, 79% (27/34) agreed that the app helped clarify their patients' preferences, 82% (28/34) agreed that the app saved them time, and 59% (20/34) agreed that the app helped their patients make decisions about AC. In addition, 32% (12/37) of patients started AC after their shared decision-making visits. We audio recorded 25 encounters. Of these, 84% (21/25) included the mention of AC for AF, 44% (11/25) included the discussion of multiple options for AC, 72% (18/25) included a provider recommendation for AC, and 48% (12/25) included the evidence of patient involvement in the discussion.

Conclusions: Patients and providers rated the app with high usability and perceived usefulness. Moreover, one-third of the patients began AC, and approximately 50% (12/25) of the encounters showed evidence of patient involvement in decision-making. In the future, we plan to study the effect of the app on a larger sample and with a controlled study design.

Trial Registration: ClinicalTrials.gov NCT04118270; https://clinicaltrials.gov/ct2/show/NCT04118270

International Registered Report Identifier (IRRID): RR2-21986

(JMIR Cardio 2021;5(2):e27016) doi:10.2196/27016

KEYWORDS

shared decision-making; mobile health; stroke risk; anticoagulation risk; anticoagulation; atrial fibrillation; anticoagulation therapy; atrial flutter; mobile phone

Introduction

Significance

Atrial fibrillation (AF) and atrial flutter occur in epidemic proportions in the United States, affecting approximately 5 million people [1-5]. As AF is a major risk factor for stroke, professional societies recommend anticoagulation (AC) in most patients; however, some patients are reluctant to start taking it. Limited health literacy, inaccurate perception of the risk of AF, and lack of trust in physicians contribute to patient refusal, with up to 39.3% (257,415/655,000) of patients remaining off AC across the country [6-8]. Among the patients who start AC, many discontinue treatment, especially after the onset of bleeding or other setbacks. Providers struggle to evaluate the risks and benefits of AC [8]. The American Heart Association and other professional societies recommend shared decision-making as a way of arriving at the optimal decision about AC for each patient; however, the feasibility of integrating shared decision-making into routine clinical care is unclear [9-11].

Approach

The AFib 2gether mobile app [12] was developed by Pfizer Inc in consultation with a cardiologist (DM) as a potential approach for operationalizing shared decision-making around AC for AF. Specifically, Pfizer Inc convened a hackathon over a 2-day period that included physicians, pharmacists, app developers, and legal and patient education professionals at its headquarters. During this meeting, analysts programmed and improved the app using an iterative design methodology. Using the app, we aim to promote collaboration between patients and providers. Specifically, by using the app, patients first identify their stroke risk factors and later receive a stroke risk score with the projected yearly stroke risk. Patients may then select (from a list of commonly asked examples developed during the hackathon) the questions that they would like their provider to answer at their next visit. The provider can review patient entries on the same app (but with different landing pages based on their role as provider) at the time of each visit to help the patient make an informed decision about AC. The app has not been previously tested with patients and providers for usability, perceived usefulness, frequency of AC starts occurring after visits in which providers and patients use the app, or evidence of shared decision-making. We recently published a protocol to evaluate the usability, perceived usefulness, and feasibility of the app for actual clinical encounters between patients with AF and their cardiology providers [13]. This paper reports the results from the completed study and their interpretation.

Methods

Overview

We previously published a protocol for integrating the AFib 2gether app in encounters between patients and their cardiology providers [13]. We briefly summarize the methods below. The sponsor of this work, Pfizer Inc, reviewed and edited the drafts of our study design and manuscript interpreting the results.

Population

The study included patients with AF and with a CHA_2DS_2-VASc score ≥2 who were not currently on AC and were visiting cardiology providers at the University of Massachusetts Memorial Medical Center. The CHA_2DS_2-VASc score assigns 1 point for congestive heart failure, hypertension, age 65-74 years, diabetes, vascular disease history such as myocardial infarction, and female sex and 2 points for age ≥75 years or prior stroke or transient ischemic attack.

Procedures

We obtained consent from the cardiology providers. After enrollment, each cardiology provider completed questionnaires regarding their knowledge and confidence in AF management. Specifically, we asked providers to report their confidence in using information about stroke risk and bleeding risk to determine appropriate antithrombotic therapy and familiarity with the American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) guidelines for AF management. We also asked 2 questions requiring providers to accurately calculate the CHA_2DS_2-VASc score and make a decision to prescribe AC based on it for a patient presented in a clinical vignette. Next, we moved to recruit the patients of these providers by mailing introductory letters with a fact sheet to facilitate verbal consent. We then telephoned the patients to obtain their consent and enroll them. During the enrollment telephone call, we asked patients to download the app if they had a smartphone and provided a brief orientation (lasting 2-3 minutes, although we did not record the exact duration). For those without a smartphone, we provided a study smartphone when the patient arrived for their in-person visit with their cardiology provider.

After the app orientation, patients answered questions in the app to determine their stroke risk score based on the CHA_2DS_2-VASc risk score. Once the participants answered the questions, the app displayed their stroke risk factors and allowed them to select questions from a list of commonly asked questions that they wanted to ask their providers during their visits based on this score. The app then sent the patients' completed inventory of stroke risk factors and questions for discussion to their providers to review. The participants then completed the Mobile App Rating Scale (MARS) questionnaire [14]. The providers then reviewed their patients' stroke risk answers and compared them to what they knew about the patients' risk. After the providers made any corrections to the stroke risk factors, the patient scores were made available to the patients and providers to review and discuss.

At the visit, we reminded the providers to review the app information completed by the patients (if they had not done so before the start of the visit). We then audio recorded the

conversation for those who had in-person visits (ie, those who were seen before restrictions were put in place during the COVID-19 pandemic of 2019-2020). At the conclusion of the visit, both the patients and providers completed a 3-question survey on the perceived usefulness of the app.

We transcribed the audio recordings and reviewed them for evidence of shared decision-making using a prespecified list of items modified from an established instrument for measuring shared decision-making (ie, Observing Patient Involvement in Decision Making Scale) [15] as well as novel items specifically related to AF management (Table 1).

Table 1. Providers' perceived usefulness of the AFib 2gether app (N=34).

Usefulness item	Frequency (encounters),[a] n (%)
The app improved my understanding of the patient's preferences regarding AC[b]	
Strongly agree or agree	27 (79)
Neutral	7 (21)
Disagree or strongly disagree	0 (0)
The app will save me time in focusing on those items which are most important to patients	
Strongly agree or agree	28 (82)
Neutral	5 (15)
Disagree or strongly disagree	1 (3)
The app will help me decide if my patient needs to be on AC	
Strongly agree or agree	20 (59)
Neutral	12 (35)
Disagree or strongly disagree	2 (6)

[a]Providers contributed multiple times to the frequency statistics, as they answered our survey after each shared decision-making visit. In 3 cases, we were not able to collect responses from providers.

[b]AC: anticoagulation.

Descriptive Statistics

We collected demographic information and information on comorbid conditions from electronic capture of patient information from our institution's electronic health record (EHR). Specifically, we worked with an experienced EHR analyst who interrogated the Clarity database associated with Epic Systems EHR to identify demographic information. Through the use of ICD codes that we previously validated, the analyst was also able to identify the presence of comorbid conditions [3,16]. From chart reviews, we also captured the reason why a patient was not on AC. In this review, we grouped patients into the following categories: low AF burden, refused AC, fall risk, gastrointestinal bleeding, other bleedings, or unspecified reasons. During our review, we also captured the number of years elapsed since AF onset. For providers, we administered a provider knowledge survey, as described in the protocol.

Outcomes

Primary Outcomes

We grouped items in the MARS into the 3 domains of functionality, esthetics, and overall quality or the number of stars out of 5, following a validated protocol [17]. The perceived usefulness questions for patients spanned 3 usefulness domains: improving knowledge, clarifying preferences, and making a decision about AC. Similarly, the provider usefulness questions spanned 3 items: clarifying patient preferences, saving time, and helping to make a decision for the patient. The response format for each set of questions was on a 5-point Likert scale, ranging from strongly agree to strongly disagree. Given the small numbers, we consolidated *strongly agree* with *agree* and *strongly disagree* with *disagree*.

Secondary Outcomes

We tracked the start of (although not the adherence to) AC in the 6 months after the shared decision-making visit. From the audio recordings, we counted the number of turns of conversations dedicated to discussions about AC. Each turn represented a dialog from 1 speaker before turning to the other. In terms of the evidence of shared decision-making, we captured how often a provider presented medication options and discussed the benefits and risks of AC and how often patients participated in the discussions, following an established instrument from which we adapted our review process. [18]. We also collected some app-specific information on whether the provider checked the risk score on the app and whether the patients' self-identified risk factors were correct.

Analysis

For each domain of the usability of the app or the MARS items, we calculated the mean and SD. By contrast, for perceived usefulness, we grouped patients into 3 categories, combining *strongly agree* with *agree* and *strongly disagree* with *disagree*. For the start of AC, we tabulated the frequency and calculated the simple percentage of the number of starts divided by the total number of patients.

We received approval for our study from the University of Massachusetts Chan Medical School Institutional Review Board. We conducted our study ethically by obtaining informed consent, with no change in treatment for patients who declined to participate.

Results

Descriptive Statistics

We sent letters to or approached in person a total of 165 eligible patients. From this pool of 165 patients, we conducted visits using our app with 37 (22.4%) patients who were seeing 13 cardiology providers. Of the 128 patients who were not included, we were unable to reach 10 (7.8%). Another 23.4% (30/128) declined, with not being interested as the most common reason, followed by not feeling well enough to participate as the next most common reason. For the remaining 68.8% (88/128) of patients, no attempt was made, as the study staff were not available or did not need to recruit additional patients at the time of the patient's visit. Nearly all patients (36/37, 97%) were White, and approximately half of the enrolled participants were aged ≥75 years. This age distribution followed the typical epidemiology of AF, including those in our previous studies [3,16,19]. Most patients were men (26/37, 70%) and had a CHA_2DS_2-VASc score between 2 and 4 (28/37, 76%). A chart review of the reasons why patients were not on AC before their appointment revealed that, of the 37 patients, 16 (43%) patients had a low AF burden, whereas 10 (27%) patients refused without further explanation clearly documented. In terms of the length of AF diagnosis, 41% (15/37) of patients had a history of AF in the past 1 to 5 years (Table 2). All patients entered enough information in the app to compute their CHA_2DS_2-VASc scores. Of the 37 patients, 21 (57%) asked at least one question. Of the 37 patients, 21 (57%) did not have their own smartphone and therefore required the use of our study phone.

Table 2. Comparison of key patient characteristics (N=37).

Characteristics	Frequency, n (%)
Age (years)	
>75	17 (46)
65-74	14 (38)
<65	6 (16)
Sex	
Female	11 (30)
Male	26 (70)
Race	
Non-White	1 (3)
White	36 (97)
Ethnicity	
Hispanic	1 (3)
Non-Hispanic	36 (97)
Individual predictors of CHA_2DS_2-VASc score[a]	
Congestive heart failure	14 (38)
Hypertension	33 (89)
Diabetes	7 (19)
Stroke or transient ischemic attack	5 (14)
Vascular disease	14 (38)
CHA_2DS_2-VASc score	
2	9 (24)
3	10 (27)
4	9 (24)
5	6 (16)
6	2 (5)
7	0 (0)
8	0 (0)
9	1 (3)
Reason for not being on anticoagulation before index appointment with cardiology provider[b]	
Low AF[c] burden	16 (43)
Refused	10 (27)
Not listed	5 (14)
Fall risk	1 (3)
Gastrointestinal bleeding	2 (5)
Other bleeding	3 (8)
Years since AF onset	
1-5	15 (41)
5-10	12 (32)
>10	10 (27)
Had another AF episode in the past year	
Yes	26 (70)

[a]The CHA_2DS_2−VASc score assigns 1 point for congestive heart failure, hypertension, age 65-74 years, diabetes mellitus, vascular disease history, such as myocardial infarction, and female sex and 2 points for age >75 years, previous stroke, or transient ischemic attack.

[b]Index appointment is the encounter in which we used the AFib 2gether app.

[c]AF: atrial fibrillation.

Most enrolled providers had been in practice for ≥10 years. Of the 13 providers, 9 (69%) were physicians, 2 (15%) were physician assistants, and 2 (15%) were nurse practitioners. The providers' self-rated confidence was high in our sample. More specifically, 85% (11/13) of providers were very confident in assessing antithrombotic therapy for patients who had stroke and selecting the appropriate AC, and 77% (10/13) felt very confident in using oral AC therapies for reducing stroke risk. The HAS-BLED bleeding risk score assigns 1 point for hypertension, abnormal renal function, abnormal liver function, tendency for bleeding, labile international normalized ratio, age >65 years, history of alcohol or drug usage, and medication usage predisposing to bleeding. Confidence in using the HAS-BLED bleeding risk calculator was more variable. Only 31% (4/13) of providers felt very confident in this skill. For a 2-part knowledge inquiry based on a clinical vignette presented, 77% (10/13) of providers accurately calculated a CHA_2DS_2-VASc score and based anticoagulant decision-making on it. Of the 13 providers, 7 (54%) providers reported that <25% of their patients had a diagnosis of AF, whereas 6 (46%) reported that >25% had a diagnosis of AF (Table 3).

Table 3. Provider characteristics, knowledge, and confidence in managing patients with AF[a] (N=13).

Demographics	Frequency, n (%)
Years in practice	
<10	3 (23)
10-20	4 (31)
>20	6 (46)
Type of provider	
Nurse practitioner	2 (15)
Physician assistant	2 (15)
MD[b]	9 (70)
How confident are you in assessing antithrombotic therapy for stroke risk patients?	
Somewhat confident	0 (0)
Moderately confident	2 (15)
Very confident	11 (85)
How confident are you in selecting appropriate anticoagulant therapy?	
Somewhat confident	0 (0)
Moderately confident	2 (15)
Very confident	11 (85)
How confident are you in using oral - anticoagulant therapies for reducing stroke risk?	
Somewhat confident	0 (0)
Moderately confident	3 (23)
Very confident	10 (77)
How confident or familiar are you in using CHA_2DS_2-VASc scores[c] to assess stroke risk?[d]	
Somewhat confident	0 (0)
Moderately confident	2 (17)
Very confident	10 (83)
How confident are you in applying ACC/AHA/HRS[e] guidelines to the management of AF?[f]	
Somewhat confident	0 (0)
Moderately confident	3 (23)
Very confident	10 (77)
How confident or familiar are you in using HAS-BLED[g] score to assess bleeding risk?	
Somewhat confident	2 (15)
Moderately confident	7 (54)
Very confident	4 (31)
Correctly identified CHA_2DS_2-VASc score=3 for a clinical vignette of a 73-year-old male patient with hypertension and CHF[h]	
Correct	10 (77)
Incorrect	3 (23)
Correctly identifying that aspirin would not be an appropriate antithrombotic for the above patient	
Correct	13 (100)
Incorrect	0 (0)
Approximately what percentage of your adult patients have a diagnosis of AF?	
<25%	7 (54)
>25%	6 (46)

[a]AF: atrial fibrillation.

[b]MD: doctor of medicine.

[c]The CHA_2DS_2 - VASc score assigns 1 point for congestive heart failure, hypertension, age 65-74 years, diabetes mellitus, vascular disease history such as myocardial infarction, and female sex and 2 points for age >75 or previous stroke or transient ischemic attack.

[d]For this item, N=12, given nonresponse from 1 provider.

[e]ACC/AHA/HRS: American College of Cardiology/American Heart Association/Heart Rhythm Society.

[f]Refers to the 2014 jointly issued guidelines from the American College of Cardiology, American Heart Association, and Heart Rhythm Society that provide guidance on the use of anticoagulation for patients with AF.

[g]HAS-BLED score is a bleeding risk score that includes predictors for hypertension, abnormal renal or liver function, stroke, bleeding history or predisposition, labile international normalized ratio, older adults, and drugs or alcohol concomitantly.

[h]CHF: congestive heart failure.

Primary Outcomes

Patients rated the AFib 2gether app highly on all domains of usability. The MARS combined average functionality score for patients was 4.51 (SD 0.61) out of a possible score of 5. Patients also rated the app highly in the MARS esthetics category with a score of 4.26 (SD 0.51) out of 5. Patients rated the app usability highly; the mean MARS star usability rating was 4.24 (SD 0.89) out of a possible 5. There was no sizable difference in the rating of patients who asked questions and those who did not (overall rating 4.30 vs 4.17).

Patients also gave high perceived usefulness ratings. Specifically, 40% (15/37) of patients agreed with the statement "the app improved my knowledge regarding anticoagulation." Similarly, 62% (23/37) of patients agreed with the statement "the app helped me clarify my provider preferences regarding anticoagulation" (Table 4).

Table 4. Patients' perceived usefulness of the app (N=37).

Usefulness item	Frequency, n (%)
The app improved my knowledge regarding AC[a]	
Strongly agree or agree	15 (40)
Neutral	18 (49)
Disagree or strongly disagree	4 (11)
The app clarified my AC preferences to my provider	
Strongly agree or agree	23 (62)
Neutral	11 (30)
Disagree or strongly disagree	3 (8)
The app helped me decide if I should go on AC	
Strongly agree or agree	20 (54)
Neutral	12 (32)
Disagree or strongly disagree	5 (14)

[a]AC: anticoagulation.

Provider ratings for usability were also high. Out of a maximum of 5, the mean of providers' ratings for functionality was 4.19 (SD 0.50), for esthetics was 4.04 (SD 0.50), and for overall star-based quality was 3.76 (SD 0.44).

Providers also reported high perceived usefulness. Specifically, 79% (27/34) somewhat or strongly agreed that the app helped clarify the preferences of their patients, and 82% (28/34) agreed that the app saved them time. Slightly fewer providers (20/34, 59%) agreed that the app helped their patients make a decision about AC (Table 1).

Secondary Outcomes

Approximately 32% (12/37) of patients started AC after their appointment. This included 56% (9/16) of patients who were previously not on AC because of the low AF burden. Of the 10 patients who had previously refused to be on AC, 2 (20%) started AC after the visit. Of the 5 patients without a specified reason for not being on AC before the visit, 1 (20%) started AC after it.

We were able to collect audio recordings from the first 68% (25/37) of patients we recruited. After that point, our institution restricted in-person recruitment to limit the spread of COVID-19 in 2019. From the available encounters, we noted that AC for AF was mentioned 84% (21/25) of the time. We also noted the discussion of multiple options of AC in 44% (11/25) of patient encounters. In 72% (18/25) of the encounters, the provider made a recommendation regarding AC for the patient. The recommendations included whether the provider believed that the patient should be anticoagulated, as well as which anticoagulant the provider believed would be best for the patient. We identified that in 48% (12/25) of the patient encounters,

there was evidence of patient involvement in the discussion (Table 5).

Table 5. Frequency of shared decision-making or AF[a] management items observed in audio recordings of patient encounters (N=25).

General theme and specific item or shared decision-making element	Frequency, n (%)
Background	
AF mentioned	24 (96)
Mention of AC[b] for AF in the conversation	21 (84)
Medication options	
Multiple options for AC mentioned	11 (44)
Provider makes a recommendation regarding AC	18 (72)
Stroke and bleeding risk and risk factors	
CHA_2DS_2-VASc stroke risk score[c] mentioned by physician	6 (24)
Evidence that the provider shared the stroke risk with the patient	14 (56)
Bleeding risk addressed by provider (patient can bring up the issue so long as the provider tries to give an answer)	12 (48)
Bleeding risk used for the purpose of deciding whether to prescribe AC	7 (28)
Bleeding risk factors addressed in terms of identifying factors that are modifiable—alcohol, previous labile INR,[d] hypertension, and aspirin or NSAID[e] use	11 (44)
AC benefits	
Discussion included benefits of AC	2 (8)
AC resumption	
Discussion of AC resumption after bleeding	13 (52)
Patient involvement	
Evidence of patient involvement in the discussion (eg, patient declined AC and patient wanted to discuss with [another person])	12 (48)
Patient asked a question or multiple questions	10 (40)
Provider checked that the patient understood all the information they told them (eg, information about AC and AF status)	4 (16)
Provider offered patient explicit opportunities to ask questions during the decision-making process	5 (20)
App-specific items	
Provider checked the risk score on the app	12 (48)
Patient's self-identified risk factors were correct according to provider and it was mentioned during the encounter	12 (48)
Patient selected questions in the app	11 (44)

[a]AF: atrial fibrillation.

[b]AC: anticoagulation.

[c]The CHA_2DS_2−VASc score assigns 1 point for congestive heart failure, hypertension, age 65-74 years, diabetes mellitus, vascular disease history such as myocardial infarction, and female sex and 2 points for age >75 years or previous stroke or transient ischemic attack.

[d]INR: international normalized ratio.

[e]NSAID: nonsteroidal anti-inflammatory drug.

Discussion

Principal Findings

Most patients in this study gave high usability ratings to our shared decision-making app across 3 separate domains. They also reported that the app helped clarify their preferences to their providers and improved their knowledge of AC. One-third of these patients started AC after their appointment with their providers. Approximately half of the patients demonstrated involvement in AC decision-making.

To understand the importance of our findings, we compared them with findings of other intervention studies in the AC management of AF. Man-Son-Hing et al [20] developed a decision aid based on a risk stratification scheme that helped patients with AF and their providers make informed decisions about whether to use warfarin or aspirin. They then tested this in a randomized trial. They found that patients in the group assigned to the decision aid were more able to make definite choices regarding antithrombotic therapy (99% vs 94%; *P*=.02). More recently, Kunneman et al [21] tested a shared decision-making tool that provided individualized risk estimates of stroke in various anticoagulant treatment options. Although

they did not find a significant effect on treatment decisions, more clinicians were satisfied with the encounter in the intervention arm compared with the standard arm. Neither of the 2 studies specifically studied the usability or perceived usefulness of their shared decision-making tool.

Our app compared favorably with the ratings published for other health mobile technology tools evaluated using MARS. In particular, authors of a systematic review documented an average score (averaged across the same 3 domains of usability that we analyzed) ranging from 2.40 to 2.63 for blood pressure apps deployed on smartphone platforms [22]. We found that our app performed significantly better than those included in the review of blood pressure apps, although our particular cohort of patients did not evaluate other apps' limiting comparisons.

Our findings have several implications. Our app appears to be usable by both patients and providers. Moreover, 32% (12/37) of patients started AC after having used the app for their clinical visit. To better understand the effectiveness of the app, we will require a controlled study, given that the participants who agreed to participate in our study may have been more educated or *activated* than typical patients in routine clinical practice. In terms of other implications, we also found that there was a moderately high level of patient involvement as measured through audio recordings. However, some elements of shared decision-making occurred infrequently. Further enhancements of the app, for example, prompts to encourage the use of more shared decision-making elements, may stimulate even greater encouragement for patient involvement. Other enhancements to the app may also better prepare patients to participate in AC discussions. Of the 37 patients, 16 (43%) were not on AC because of the isolated and low burden of AF. However, the current ACC/AHA/HRS guidelines for AC do not take the AF burden into account when recommending treatment [10]. Further clarification of guidelines by its authors for prescribing AC in the setting of isolated and low burden of AF and education of providers may help overcome some of the gaps in AC use beyond patient hesitancy or refusal.

Limitations

There are a number of limitations to this study. One limitation is the absence of a control group. Nevertheless, we are not aware of other single-arm studies that demonstrated a 32% increase in AC with a single-encounter intervention. Expanding our testing to other centers and including a control group would provide better information on the potential benefits of the app. Another limitation of our work is that we were only able to record encounters for 68% (25/37) of patients, given the interruption in our study caused by the restrictions against in-person recruitment at the time of the COVID-19 pandemic. Despite this limitation, we demonstrated a moderately high level of patient involvement in the visits that we recorded. Another limitation was the absence of custom information for patients with discrete reasons, such as bleeding, for not being on AC at the time of the visit. Future iterations of the app may want to include custom information. Finally, our population was heterogeneous in terms of the reason for not being on AC, potentially introducing bias into the measurements we recorded.

Conclusions

In conclusion, patients and providers found the AFib 2gether app usable, and there was a high level of perceived usefulness that facilitated an informed discussion with the provider, leading to increased guideline-based AC management. We await further testing at other centers and in a controlled study design to assess the potential benefit of the app and its ability to increase AC use, consistent with prevailing professional society guidelines designed to prevent stroke in patients with AF.

Acknowledgments

The authors would like to extend their gratitude to all those who participated in this study and the staff who contributed to this research. This study was sponsored by Pfizer Inc.

Conflicts of Interest

AK received sponsored research support from Pfizer Inc for this project and has received similar support in the past from both Bristol-Myers Squibb and Pfizer Inc. DM received sponsored research support from Bristol Myers Squibb, Boehringer Ingelheim, Pfizer Inc, Biotronik, Philips Healthcare, and Flexcon and has consulted for Bristol-Myers Squibb, FlexCon, Samsung, Philips, Fitbit, and Pfizer Inc. AH, JP, HP, AA, DM, KM, and AK are employees of the Department of Medicine, University of Massachusetts Chan Medical School, Worcester, Massachusetts, which received financial support from Pfizer Inc in connection with this research. CP, KN, and RHD are full-time employees of Pfizer Inc.

References

1. Atrial filbrillation. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/heartdisease/atrial_fibrillation.htm [accessed 2021-10-29]
2. Colilla S, Crow A, Petkun W, Singer DE, Simon T, Liu X. Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. Am J Cardiol 2013 Oct 15;112(8):1142-1147. [doi: 10.1016/j.amjcard.2013.05.063] [Medline: 23831166]
3. Kapoor A, Amroze A, Golden J, Crawford S, O'Day K, Elhag R, et al. SUPPORT-AF: piloting a multi-faceted, electronic medical record-based intervention to improve prescription of anticoagulation. J Am Heart Assoc 2018 Sep 04;7(17):e009946 [FREE Full text] [doi: 10.1161/JAHA.118.009946] [Medline: 30371161]

4. Miyasaka Y, Barnes ME, Bailey KR, Cha SS, Gersh BJ, Seward JB, et al. Mortality trends in patients diagnosed with first atrial fibrillation: a 21-year community-based study. J Am Coll Cardiol 2007 Mar 06;49(9):986-992 [FREE Full text] [doi: 10.1016/j.jacc.2006.10.062] [Medline: 17336723]
5. Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, American Heart Association Statistics CommitteeStroke Statistics Subcommittee. Heart disease and stroke statistics--2015 update: a report from the American Heart Association. Circulation 2015 Jan 27;131(4):e29-322. [doi: 10.1161/CIR.0000000000000152] [Medline: 25520374]
6. Cullen MW, Kim S, Piccini JP, Ansell JE, Fonarow GC, Hylek EM, ORBIT-AF Investigators. Risks and benefits of anticoagulation in atrial fibrillation: insights from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF) registry. Circ Cardiovasc Qual Outcomes 2013 Jul;6(4):461-469. [doi: 10.1161/CIRCOUTCOMES.113.000127] [Medline: 23759473]
7. Gladstone DJ, Bui E, Fang J, Laupacis A, Lindsay MP, Tu JV, et al. Potentially preventable strokes in high-risk patients with atrial fibrillation who are not adequately anticoagulated. Stroke 2009 Jan;40(1):235-240. [doi: 10.1161/STROKEAHA.108.516344] [Medline: 18757287]
8. Marzec LN, Wang J, Shah ND, Chan PS, Ting HH, Gosch KL, et al. Influence of direct oral anticoagulants on rates of oral anticoagulation for atrial fibrillation. J Am Coll Cardiol 2017 May 23;69(20):2475-2484 [FREE Full text] [doi: 10.1016/j.jacc.2017.03.540] [Medline: 28521884]
9. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland Jr JC, American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2014 Dec 02;64(21):e1-76 [FREE Full text] [doi: 10.1016/j.jacc.2014.03.022] [Medline: 24685669]
10. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines and the heart rhythm society in collaboration with the society of thoracic surgeons. J Am Coll Cardiol 2019 Jul 09;74(1):104-132 [FREE Full text] [doi: 10.1016/j.jacc.2019.01.011] [Medline: 30703431]
11. Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Europace 2016 Nov;18(11):1609-1678. [doi: 10.1093/europace/euw295] [Medline: 27567465]
12. AFib 2gether. Pfizer Inc. 2021. URL: https://play.google.com/store/apps/details?id=com.pfizer.us.AfibTogether&hl=en_US&gl=US [accessed 2021-10-26]
13. Kapoor A, Andrade A, Hayes A, Mazor K, Possidente C, Nolen K, et al. Usability, perceived usefulness, and shared decision-making features of the AFib 2gether mobile app: protocol for a single-arm intervention study. JMIR Res Protoc 2021 Mar 24;10(2):e21986 [FREE Full text] [doi: 10.2196/21986] [Medline: 33625361]
14. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Mar 11;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]
15. Elwyn G, Hutchings H, Edwards A, Rapport F, Wensing M, Cheung WY, et al. The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. Health Expect 2005 Mar;8(1):34-42 [FREE Full text] [doi: 10.1111/j.1369-7625.2004.00311.x] [Medline: 15713169]
16. Kapoor A, Amroze A, Vakil F, Crawford S, Der J, Mathew J, et al. SUPPORT-AF II: supporting use of anticoagulants through provider profiling of oral anticoagulant therapy for atrial fibrillation: a cluster-randomized study of electronic profiling and messaging combined with academic detailing for providers making decisions about anticoagulation in patients with atrial fibrillation. Circ Cardiovasc Qual Outcomes 2020 Feb;13(2):e005871 [FREE Full text] [doi: 10.1161/CIRCOUTCOMES.119.005871] [Medline: 32063041]
17. Terhorst Y, Philippi P, Sander LB, Schultchen D, Paganini S, Bardus M, et al. Validation of the Mobile Application Rating Scale (MARS). PLoS One 2020;15(11):e0241480 [FREE Full text] [doi: 10.1371/journal.pone.0241480] [Medline: 33137123]
18. Elwyn G, Edwards A, Wensing M, Hood K, Atwell C, Grol R. Shared decision making: developing the OPTION scale for measuring patient involvement. Qual Saf Health Care 2003 Apr;12(2):93-99 [FREE Full text] [doi: 10.1136/qhc.12.2.93] [Medline: 12679504]
19. Feinberg WM, Blackshear JL, Laupacis A, Kronmal R, Hart RG. Prevalence, age distribution, and gender of patients with atrial fibrillation. Analysis and implications. Arch Intern Med 1995 Mar 13;155(5):469-473. [Medline: 7864703]
20. Man-Son-Hing M, Laupacis A, O'Connor AM, Biggs J, Drake E, Yetisir E, et al. A patient decision aid regarding antithrombotic therapy for stroke prevention in atrial fibrillation: a randomized controlled trial. JAMA 1999 Aug 25;282(8):737-743. [doi: 10.1001/jama.282.8.737] [Medline: 10463708]
21. Kunneman M, Branda ME, Hargraves IG, Sivly AL, Lee AT, Gorr H, Shared Decision Making for Atrial Fibrillation (SDM4AFib) Trial Investigators. Assessment of shared decision-making for stroke prevention in patients with atrial fibrillation: a randomized clinical trial. JAMA Intern Med 2020 Sep 01;180(9):1215-1224 [FREE Full text] [doi: 10.1001/jamainternmed.2020.2908] [Medline: 32897386]

22. Jamaladin H, van de Belt TH, Luijpers LC, de Graaff FR, Bredie SJ, Roeleveld N, et al. Mobile apps for blood pressure monitoring: systematic search in app stores and content analysis. JMIR Mhealth Uhealth 2018 Nov 14;6(11):e187 [FREE Full text] [doi: 10.2196/mhealth.9888] [Medline: 30429116]

Abbreviations

AC: anticoagulation
ACC/AHA/HRS: American College of Cardiology/American Heart Association/Heart Rhythm Society
AF: atrial fibrillation
EHR: electronic health record
MARS: Mobile App Rating Scale

Edited by G Eysenbach; submitted 20.01.21; peer-reviewed by M Puts, E Ding, HL Tam; comments to author 04.04.21; revised version received 21.04.21; accepted 03.10.21; published 19.11.21.

Please cite as:
Kapoor A, Hayes A, Patel J, Patel H, Andrade A, Mazor K, Possidente C, Nolen K, Hegeman-Dingle R, McManus D
Usability and Perceived Usefulness of the AFib 2gether Mobile App in a Clinical Setting: Single-Arm Intervention Study
JMIR Cardio 2021;5(2):e27016
URL: https://cardio.jmir.org/2021/2/e27016
doi:10.2196/27016
PMID:34806997

Original Paper

A Patient Decision Aid for Anticoagulation Therapy in Patients With Nonvalvular Atrial Fibrillation: Development and Pilot Study

Kim Paul de Castro[1], MD, MBA; Harold Henrison Chiu[1], MD; Ronna Cheska De Leon-Yao[1], MD; Lorraine Almelor-Sembrana[2], MD; Antonio Miguel Dans[3], MSc, MD

[1]Department of Medicine, Philippine General Hospital, University of the Philippines, Manila, Philippines

[2]Department of Adult Cardiology, Philippine Heart Center, Quezon City, Philippines

[3]Division of Adult Medicine, Department of Medicine, Philippine General Hospital, University of the Philippines, Manila, Philippines

Corresponding Author:
Kim Paul de Castro, MD, MBA
Department of Medicine
Philippine General Hospital
University of the Philippines
Taft Avenue
Manila
Philippines
Phone: 63 9989563472
Email: kimpauldecastro@gmail.com

Abstract

Background: Atrial fibrillation (AF) is one of the most common predisposing factors for ischemic stroke worldwide. Because of this, patients with AF are prescribed anticoagulant medications to decrease the risk. The availability of different options for oral anticoagulation makes it difficult for some patients to decide a preferred choice of medication. Clinical guidelines often recommend enhancing the decision-making process of patients by increasing their involvement in health decisions. In particular, the use of patient decision aids (PDAs) in patients with AF was associated with increased knowledge and increased likelihood of making a choice. However, the majority of available PDAs are from Western countries.

Objective: We aimed to develop and pilot test a PDA to help patients with nonvalvular AF choose an oral anticoagulant for stroke prevention in the local setting. Outcomes were (1) reduction in patient decisional conflict, (2) improvement in patient knowledge, and (3) patient and physician acceptability.

Methods: We followed the International Patient Decision Aid Standards (IPDAS) to develop a mobile app–based PDA for anticoagulation therapy in patients with nonvalvular AF. Focus group discussions identified decisional needs, which were subsequently incorporated into the PDA to compare choices for anticoagulation. Based on recommendations, the prototype PDA was rendered by at least 30 patients and 30 physicians. Decisional conflict and patient knowledge were tested before and after the PDA was implemented. Patient acceptability and physician acceptability were measured after each encounter.

Results: Anticoagulant options were compared by the PDA using three factors that were identified (impact on stroke and bleeding risk, and price). The comparisons were presented as tables and graphs. The prototype PDA was rendered by 30 doctors and 37 patients for pilot testing. The mean duration of the encounters was 15 minutes. The decisional conflict score reduced by 35 points (100-point scale; $P<.001$). The AF knowledge score improved from 10 to 15 ($P<.001$). The PDA was acceptable for both patients and doctors.

Conclusions: Our study showed that an app-based PDA for anticoagulation therapy in patients with nonvalvular AF (1) reduced patient decisional conflict, (2) improved patient knowledge, and (3) was acceptable to patients and physicians. A PDA is potentially acceptable and useful in our setting. A randomized controlled trial is warranted to test its effectiveness compared to usual care. PDAs for other conditions should also be developed.

(JMIR Cardio 2021;5(2):e23464) doi:10.2196/23464

KEYWORDS

shared decision-making; patient decision aid; atrial fibrillation; anticoagulation; stroke prevention; mHealth; mobile health

Introduction

Atrial fibrillation (AF) is the most common sustained cardiac dysrhythmia [1] and has been recognized as one of the most common causes of ischemic stroke. In a global survey published in 2016, it was found that the frequency of AF-associated stroke was 28% [2]. The risk of developing a stroke from AF can be decreased with the use of anticoagulation therapy. However, almost half of all patients with AF were shown to never start or continue their anticoagulant medications to prevent the occurrence of a stroke [3-5]. Currently, multiple drug options with different efficacy and safety profiles exist in the market. Therefore, it is imperative for health care providers to consider their patients' individual preferences and involve them in the decision-making process.

Shared decision-making (SDM) has been promoted as a helpful adjunct in health care delivery, especially when multiple treatment options with varied outcomes exist. This point in the decision-making process creates a state of uncertainty known as decisional conflict [6]. In order to facilitate SDM, patient decision aids (PDAs) that take into consideration the patient's values and needs have been advocated to encourage a two-way exchange of information between the health care provider and the patient [7-9]. Among patients with AF, the use of PDAs was associated with increased patient knowledge, increased likelihood of making a choice, and low decisional conflict [10]. This is particularly important because patients whose values and preferences were not taken into consideration in the decision-making process were shown to be more dissatisfied and nonadherent to therapy, hence increasing the risk for ischemic stroke [4,11,12]. The latest cardiovascular clinical guidelines already recommend the use of SDM to facilitate an individualized approach to anticoagulation therapy in patients with nonvalvular AF [13].

While the benefits of using PDAs have been validated in Western countries, SDM still remains a novel concept in Asia where paternalism is still the norm [14]. Nevertheless, it has been found that patients in Asia want to be involved in SDM [15,16]. In the Philippines, there has only been one published study on a PDA that was developed for diabetic patients choosing an oral hypoglycemic agent [17]. This study found that PDAs are feasible to use in a lower middle–income country without significantly increasing consult time. To date, no PDA for anticoagulation therapy in AF has been developed and published in our setting. We developed a PDA to address this gap.

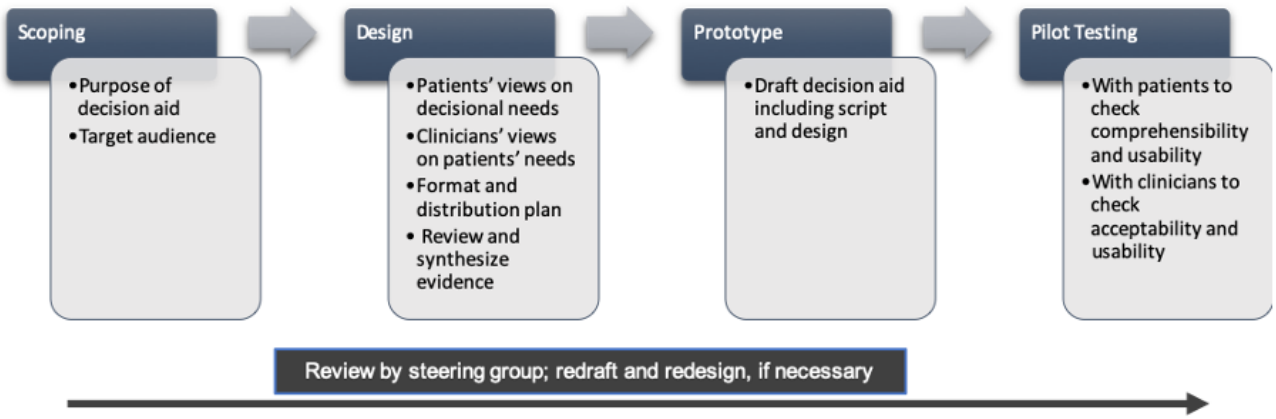
Specifically, we aimed to develop and pilot test a mobile app–based decision aid that focuses on supporting the decision-making process of patients with nonvalvular AF regarding their choice of oral anticoagulation therapy in our setting. As a pilot test, our study sought to determine the level of decisional conflict and knowledge among patients at baseline and after administration of the decision aid, and to assess the acceptability of our decision aid among doctors and patients in the local setting.

Methods

Overview

This study encompasses the first two parts of the PDA development process, as outlined by The International Patient Decision Aid Standards (IPDAS) [8]. It was executed in two phases. Phase I involved literature review and focus group discussions (FGDs) among patients and doctors, which assessed their values and decisional needs. The product of phase I was a prototype application-based PDA that was used in the implementation of phase II. In phase II, pilot testing was done to assess the PDA's acceptability for doctors and patients and its effect on patients' knowledge and decisional conflicts. This pilot testing employed a before-and-after study with the aid of validated outcome assessment tools from the Ottawa Decision Support Framework [6,18,19]. The University of the Philippines – Philippine General Hospital (UP-PGH) Expanded Hospital Research Office approved this study. Figure 1 shows the general flow of the development process.

Figure 1. Decision aid development process.



Phase I: Creation of a PDA Prototype

Decisional Needs Assessment

Patients were selected through convenience sampling from the UP-PGH General Medicine, Cardiology, and Neurology Outpatient Clinics. Recruitment was done in the following two ways: (1) through physicians from the abovementioned outpatient clinics who identified patients with nonvalvular AF, and (2) research assistants who were stationed outside the said clinics who actively asked patients if they have "irregular beating of the heart" or are taking anticoagulants. Once assessed by the investigators as qualified, a trained research assistant explained the informed consent, and those who consented were included in the FGDs.

Physicians who were included for the needs assessment were doctors from different specialties who were direct health care providers for patients with AF. They were mainly recruited from the residents and fellows in training under Internal Medicine, Cardiology, and Neurology.

FGDs were conducted with both patients and physicians to identify the decision-making issues when dealing with patients with AF. The discussions were centered on the overall theme of SDM, its applicability to the local setting, and factors that patients and doctors consider important when faced with the different options of anticoagulation for stroke prevention.

Two FGDs with six to eight participants were conducted to identify the decisional needs. After informed consent was obtained from each participant, a moderator facilitated the discussion using a set of guide questions. Both sessions were recorded and transcribed verbatim by a research assistant, and the data were processed for analysis.

Drafting of the PDA Prototype

The authors served as the steering group of clinicians who guided the drafting of the PDA prototype in all its stages of development. Information gathered from the aforementioned FGDs that identified decisional needs were incorporated in the prototype PDA. A systematic literature search was done for evidence on the effectiveness, bleeding risk, adverse effects, and dosing of the different medications available in the Philippines. The available literature that was used in the study was appraised for directness, validity, and applicability prior to inclusion into the evidence base of the PDA [20-22]. The cost of the included medications was surveyed from the largest chain of pharmacies in the country. A modified version of a validated image [23] for patient education was also incorporated into the PDA prototype. These plans were communicated through a series of meetings with an independent third-party contractor that was commissioned to program the PDA into a mobile-based app.

Phase II: Pilot Testing

A prospective before-and-after observational design was used to pilot test the PDA. Doctors and patients from the UP-PGH General Internal Medicine, Neurology, Cardiology, and Faculty Clinics were invited to participate in pilot testing through convenience sampling. Eligible patients included adults who were at least 19 years old, were able to speak and understand Filipino and English, and had a diagnosis of nonvalvular AF. Patients with major cognitive or psychiatric symptoms were excluded. Similar to phase I, recruitment was done in the following two ways: (1) through physicians who referred their patients with nonvalvular AF, and (2) through research assistants who were stationed outside the said clinics who actively asked patients if they have "irregular beating of the heart" or are taking anticoagulants. Once deemed eligible, written informed consent was obtained prior to enrollment. A convenience sample of 30 doctors and 37 patients participated. Prior to the actual patient-doctor encounter, a special training session was held to give the physicians a trial copy of the PDA, introduce them to the interface, and allow them to practice using the mobile app. On the day of the patient-doctor encounter, the physicians were instructed to use the PDA to facilitate patient education and decision-making regarding anticoagulation therapy.

Before the encounter, data collected from patients included demographics, baseline knowledge about AF using the Ottawa PDA Knowledge Tool, and baseline level of decisional conflict measured using the Ottawa PDA Decisional Conflict Scale (DCS). After the encounter, patients were again asked to answer the Ottawa Knowledge Tool and Ottawa PDA DCS [6,18]. Both patients and doctors were also asked to answer the Ottawa Acceptability Tool–Patient and Practitioner Versions [19]. These validated outcome assessment tools were administered via an interviewer-assisted questionnaire. In order to protect the participants' information, names were anonymized and the data collection forms were coded and kept in a locked cabinet.

The outcomes for this pilot study were the developed PDA's effects on patient knowledge, the level of decisional conflict, and patient and physician acceptability. Descriptive statistics using means and SDs were used for continuous variables, and proportions were used for categorical variables. Bivariate analysis included paired *t* tests for comparing pre-PDA and post-PDA knowledge and decisional conflict scores.

Results

Decisional Needs Assessment: Patients

A FGD was conducted wherein eight patients (five female and three male patients) participated. They were all diagnosed with nonvalvular AF and were taking anticoagulant medications (five were on warfarin and three were on rivaroxaban). Important points that emerged during the discussion were as follows:

1. Participants knew that AF is the irregular beating of the heart, but they were unsure what causes the condition.
2. The bad outcomes of AF that patients knew were ischemia (ie, stroke and transient ischemic attacks) and symptoms of heart failure (ie, easy fatigability, dyspnea, and orthopnea). Awareness of these conditions causes anxiety.
3. The prevention of bad outcomes entails intake of anticoagulants and regular follow-up with health care providers.
4. Factors taken into consideration when choosing anticoagulant medications are efficacy, side effects (ie, risk of bleeding and gastrointestinal upset), cost, frequency of laboratory testing, and doctor's preference.

5. Benefits associated with the intake of drugs include anticoagulation, stroke prevention, and better sense of well-being (ie, tolerate exercise). Unwanted consequences of taking medications include bleeding, frequent laboratory testing, and diet modifications.
6. The participants had different opinions on SDM. A majority would like to be involved in health care decisions, while some still subscribed to the paternalistic doctor-patient relationship.

Decisional Needs Assessment: Doctors

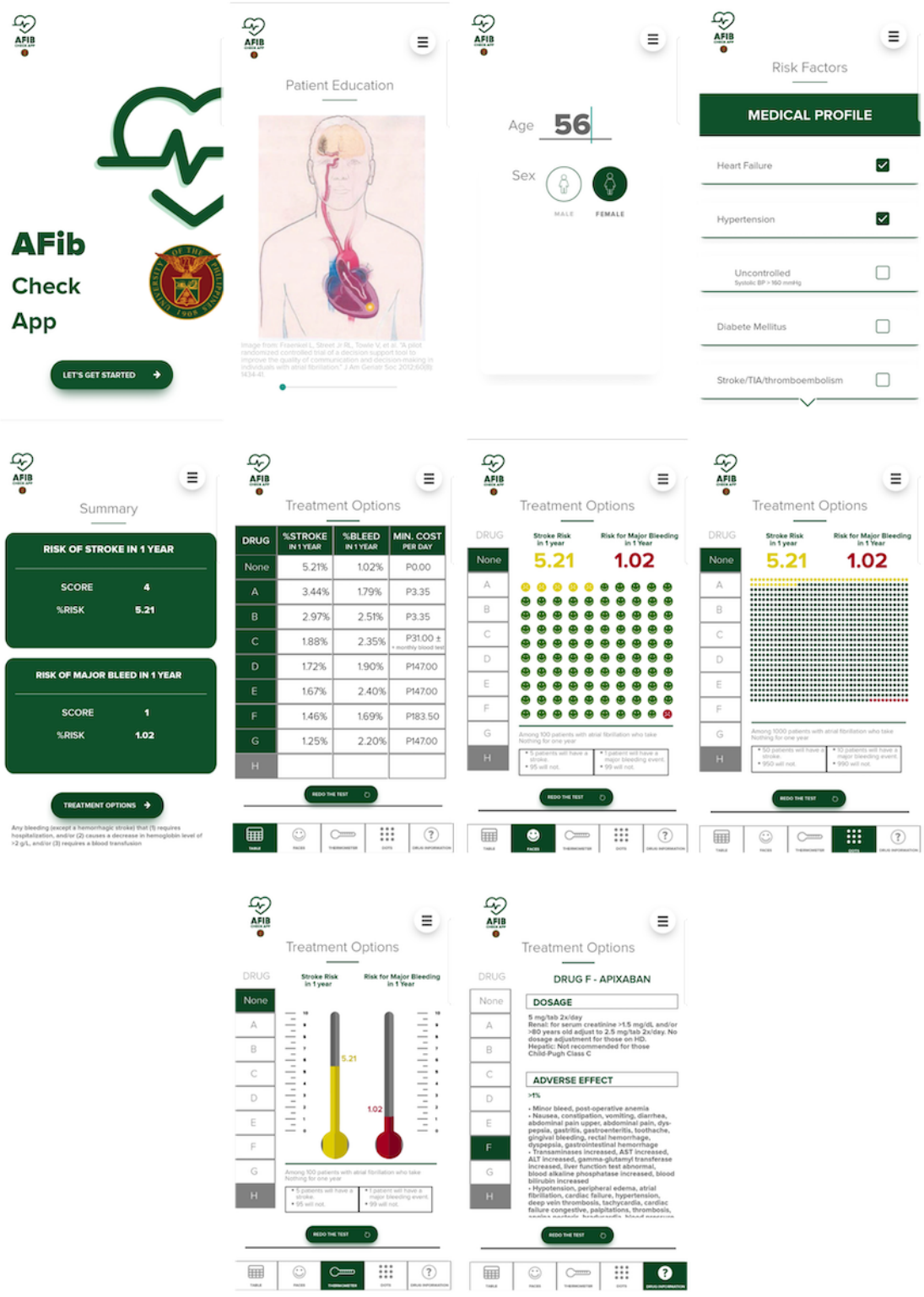
Six physicians (three internists, two neurologists, and one cardiologist) participated. Salient points that surfaced during the discussion were as follows:

1. The doctor-patient relationship is a partnership. Providing patients with enough knowledge is important for them to make an informed choice when it comes to their health. Once a decision has been made, patient autonomy should always be respected.
2. Patients are uncomfortable with initiating anticoagulants due to frequent blood tests, adverse effects of the drugs, and associated costs. A better understanding of AF and the need for anticoagulation makes it easier to convince them to start anticoagulants.
3. In helping patients choose their medications, it is crucial to tell them about the risks, benefits, frequency of laboratory tests, ease of compliance, and cost of the drugs. The availability of a reversal agent should also be mentioned.
4. Support from family and the health care provider helps patients make decisions regarding their health.
5. Different strategies, such as using visual aids, modeling, presenting real-world data, and enlisting the help of patient education advocates, can help patients in choosing an anticoagulant.

PDA Prototype

Based on literature review, scoping, and inputs from the focus groups of patients and clinicians, a mobile app was developed as a point-of-care PDA to support the decision-making process of patients with nonvalvular AF regarding their choice of oral anticoagulation. It contains basic information about AF and the different choices for oral anticoagulation among nonvalvular AF for stroke prevention. This can be accessed offline and is intended to be used in the setting of a clinical consultation in order to facilitate communication and discussion of treatment options between patients and clinicians. A modified version of a validated image [23] for patient education was incorporated into the PDA prototype in order to aid clinicians to explain to patients how their condition can predispose them to the development of an ischemic stroke. It also includes a risk calculator that computes for individualized baseline stroke and bleeding risk using mCHA2DS2VASc (modified congestive heart failure, hypertension, age ≥75, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 50 to 74, sex) and HASBLED (hypertension, abnormal renal and liver function, stroke, bleeding predisposition, labile INRs, elderly, drugs or alcohol) scores. The current locally available oral anticoagulant choices include aspirin, warfarin, apixaban, rivaroxaban, and dabigatran. Individual data of the drugs' stroke risk reduction and bleeding risk were compared using the data from a 2017 network meta-analysis [20]. The latest market price has also been presented. Medications have been anonymized using letters to facilitate unbiased decision-making based on the factors identified in the early phase of the study. These factors are the drug's stroke risk reduction, bleeding risk, and cost. Individualized stroke risks and bleeding risks were presented as three pictographs as follows: (1) number of events among 100 people in 1 year, (2) the number of events among 1000 people in 1 year, and (3) a thermometer scale with percentages of stroke risk and major bleeding episodes in 1 year. Once a decision is made, the name of the chosen drug, together with relevant information on dosing and diet advise, can be revealed by tapping on the letter that corresponds to the drug of choice. Screenshots of the app can be seen in Figure 2.

Figure 2. Screenshots of the patient decision aid prototype.



Pilot Test

We performed pilot testing of the decision aid on a sample of 30 physicians and 37 patients. The demographic characteristics of both patients and physicians are summarized in Tables 1 and 2.

As seen in Table 3, the use of the PDA resulted in a significant decrease in the total DCS score and all its subscale scores. The total DCS score showed a decrease by 35 points (100-point scale) (P<.001). Only 8% of the patients had a total DCS score <25 (associated with implementing decisions) before PDA implementation compared with 73% after its implementation. Similarly, 68% of patients had a total DCS score >37.5 (associated with decision delay or feeling unsure about implementation) before PDA implementation compared with 3% after its implementation.

Table 1. Patient characteristics.

Characteristic	Value (N=37)
Age (years), mean (SD)	61 (11)
Sex, n (%)	
Male	27 (73%)
Female	10 (27%)
Highest educational attainment, n (%)	
Elementary	12 (32%)
High school	13 (35%)
College	4 (11%)
Vocational	3 (8%)
Postgraduate	5 (14%)
Annual household income (PHP[a]), n (%)	
Less than 80,000	35 (94%)
80,000-160,000	1 (3%)
320,000-400,000	1 (3%)

[a]PHP: Philippine peso.

Table 2. Physician characteristics.

Characteristic	Value (N=30)
Age (years), mean (SD)	29 (2)
Sex, n (%)	
Male	19 (63%)
Female	11 (37%)
Specialization, n (%)	
Internal medicine	20 (67%)
Cardiology	8 (27%)
Neurology	2 (7%)

Table 3. Decisional conflict scores (N=37).

Variable	Pre-PDA[a] score, mean (SD)	Post-PDA score, mean (SD)	*P* value (two-tailed, paired)
Total DCS[b] score[c]	48.73 (18.49)	13.97 (12.09)	<.001
Uncertainty subscore[d]	43.91 (21.57)	13.73 (15.49)	<.001
Informed subscore[e]	57.20 (22.66)	12.83 (15.66)	<.001
Values clarity subscore[f]	57.88 (45.51)	13.47 (21.17)	<.001
Support subscore[g]	43.46 (20.13)	21.17 (16.26)	<.001

[a]PDA: patient decision aid.

[b]DCS: Decisional Conflict Scale.

[c]Scores range from 0 (no decisional conflict) to 100 (extremely high decisional conflict).

[d]Scores range from 0 (feels extremely certain about the best choice) to 100 (feels extremely uncertain about the best choice).

[e]Scores range from 0 (feels extremely informed) to 100 (feels extremely uninformed).

[f]Scores range from 0 (feels extremely clear about personal values for benefits & risks/side effects) to 100 (feels extremely unclear about personal values).

[g]Scores range from 0 (feels extremely supported in decision-making) to 100 (feels extremely unsupported in decision-making).

Patients also exhibited an increase in the AF knowledge score after the use of the decision aid by 5 points, using a 24-point knowledge tool (mean 10.35, SD 2.43 vs mean 15.4, SD 4.4; *P*<.001). The mean duration of the consults was 15 (SD 6) minutes.

Lastly, we examined the acceptability of the decision aid for both patients and doctors by checking the responses to the Ottawa Acceptability questionnaire (Tables 4 and 5). Acceptability for both patients and doctors was generally high. The percentages of patients who found that the way information was presented was satisfactory were as follows: (1) impact of AF: 98% (36/37), (2) information on risk factors: 95% (35/37), (3) medication options: 98% (36/37), (4) treatment benefits: 98% (36/37), and (5) treatment risks: 95% (35/37). In addition, 92% (34/37) of patients found the length of material to be just right, 92% (34/37) found the calculated values easy to understand, all patients found the amount of information to be just right, and all agreed that the material was balanced, helpful, and with enough information to decide.

Table 4. Patient acceptability (presentation of information) (N=37).

Presentation of information	Value, n (%)[a]			
	Poor	Fair	Good	Excellent
Impact of atrial fibrillation	0 (0%)	1 (3%)	11 (30%)	25 (68%)
Risk factors	0 (0%)	2 (5%)	10 (27%)	25 (68%)
Medication options	0 (0%)	1 (3%)	9 (24%)	27 (73%)
Treatment benefits	0 (0%)	1 (3%)	9 (24%)	27 (73%)
Treatment risks	0 (0%)	2 (5%)	11 (30%)	24 (65%)

[a]The percentages do not add up to 100% because of rounding error.

Table 5. Patient acceptability (other measures) (N=37).

Other measures	Value, n (%)
Length of material	
Too long	2 (5%)
Too short	1 (3%)
Just right	34 (92%)
Amount of information	
Too much	0 (0%)
Too little	0 (0%)
Just right	37 (100%)
Balanced presentation	
Slanted	0 (0%)
Balanced	37 (100%)
Use in decision-making	
Useful	37 (100%)
Not useful	0 (0%)
Understandability	
Easy	34 (92%)
Difficult	3 (8%)
Information e nough to d ecide	
Yes	37 (100%)
No	0 (0%)

Thirty doctors pilot tested the mobile app. They found that the decision aid was easy to use (87%), easy to understand (90%), and easy to experiment with (80%). Moreover, they agreed that this strategy is reliable (90%), is better than their usual way of helping patients decide (90%), is compatible with how they think things should be done (97%), is cost-effective compared with their usual approach (80%), will save them time (67%), has results that are easy to see (90%), and will result in patients making more informed decisions (93%). Moreover, most (90%) doctors thought that the components of the aid can be used by

themselves. The majority (90%) of the doctors who used the aid found that it complements their usual approach, which means that they do not need to make major changes to the way they do things (73%). Lastly, most of them thought that the use of the aid will cause more benefit than harm (93%) and that it is suitable for helping patients make value-laden choices (94%).

Discussion

Principal Findings

In this paper, we describe the development process of a decision aid to help patients with nonvalvular AF choose among the available options for anticoagulation for stroke prevention. Our PDA was effective in reducing patient decisional conflict and increasing patient knowledge, and was acceptable to doctors and patients alike. It is meant to facilitate a two-way communication between the doctor and patient, thus involving both parties in decision-making. Currently, this is the only PDA developed for patients with nonvalvular AF in our setting.

Our PDA development was guided by the IPDAS systematic process to ensure that it adheres to international standards [8]. Since the population in which we tested our decision aid mostly included patients with a low socioeconomic status, who were also more likely to have a lower health literacy [24], special attention was paid to make the PDA easily comprehensible. In addition, our PDA is meant to be downloaded to the clinician's device and used in the clinic during consultation as an adjunct tool to facilitate communication and discussion of the different treatment options. As suggested by current available evidence [24], successful health literacy interventions should be delivered by a health professional and must be designed using plain language, simple numbers, and visual techniques. These features were incorporated in the design of our decision aid.

Our pilot study demonstrated that this decision aid was generally acceptable in the Philippine setting. In the FGDs, both doctors and patients expressed interest in participating in SDM when presented with the opportunity. This was also reflected by the predominantly positive responses when we assessed for the acceptability of the PDA on pilot testing. This finding is of great importance to the evidence base for SDM and decision aids in general since most studies on the subject are conducted in Western countries. This finding is also consistent with the finding of a previously published study on the use of a decision aid in the Filipino population [17].

The noted reduction in patient decisional conflict is particularly significant since it provides preliminary evidence regarding the effectiveness of our decision aid as a decision support intervention, as previously documented by a systematic review [10]. Participants showed a change from a score that is associated with decision delay and uncertainty prior to the use of the decision aid to a score that is associated with implementing decisions after its use. This is indicative of effective decision-making where patients are likely to make an informed choice that is consistent with their personal values [25]. Often, it is seen to be translatable to more patient satisfaction and adherence to the choice made. In contrast, a higher decisional conflict is seen as an independent predictor of blame for bad outcomes [26,27]. It has been found that for every unit increase in the DCS score, patients are 19% more likely to blame their doctor for bad outcomes [26].

Several limitations must be acknowledged. As this was a pilot study that used a before-and-after study design, our findings and analyses are derived from a relatively small convenience sample of resident doctors and patients from a single center, which may have generalizability issues. Moreover, we only explored the effectiveness of the decision aid in terms of immediately observable outcomes, that is, decisional conflict, knowledge, and applicability. A randomized controlled trial, therefore, is warranted to explore other outcomes, such as choice adherence, in a larger sample while comparing the use of PDAs to usual care.

Conclusions

The developed app-based PDA, which was designed to help patients with nonvalvular AF choose among different anticoagulation options for stroke prevention, (1) reduced patient decisional conflict, (2) improved patient knowledge, and (3) was acceptable to patients and physicians in the local setting. Future research should focus on further testing its effectiveness compared to usual care using a randomized controlled trial. Decision aids for other conditions should also be developed.

Acknowledgments

We thank Josephine Sanchez for her indispensable technical and logistical support especially in the earlier stages of this work. We also thank Princess Marie Sulit for her valuable assistance in data collection. The programming of the app was done by an independent contractor and was supported by an unrestricted grant from Pfizer, Inc. The funding agency was not involved in the planning, conduct, and writing of this research.

Conflicts of Interest

None declared.

References

1. Iwasaki Y, Nishida K, Kato T, Nattel S. Atrial Fibrillation Pathophysiology. Circulation 2011 Nov 15;124(20):2264-2274. [doi: 10.1161/circulationaha.111.019893]

2. Perera KS, Vanassche T, Bosch J, Swaminathan B, Mundl H, Giruparajah M, ESUS Global Registry Investigators. Global Survey of the Frequency of Atrial Fibrillation-Associated Stroke: Embolic Stroke of Undetermined Source Global Registry. Stroke 2016 Sep;47(9):2197-2202. [doi: 10.1161/STROKEAHA.116.013378] [Medline: 27507860]
3. Ogilvie IM, Newton N, Welner SA, Cowell W, Lip GY. Underuse of oral anticoagulants in atrial fibrillation: a systematic review. Am J Med 2010 Jul;123(7):638-645.e4. [doi: 10.1016/j.amjmed.2009.11.025] [Medline: 20609686]
4. Yao X, Abraham NS, Alexander GC, Crown W, Montori VM, Sangaralingham LR, et al. Effect of Adherence to Oral Anticoagulants on Risk of Stroke and Major Bleeding Among Patients With Atrial Fibrillation. JAHA 2016 Feb 23;5(2). [doi: 10.1161/jaha.115.003074]
5. Hernandez I, He M, Chen N, Brooks MM, Saba S, Gellad WF. Trajectories of Oral Anticoagulation Adherence Among Medicare Beneficiaries Newly Diagnosed With Atrial Fibrillation. JAHA 2019 Jun 18;8(12). [doi: 10.1161/jaha.118.011427]
6. O'Connor AM. User Manual - Decisional Conflict Scale. Ottawa Hospital Research Institute. 1993. URL: https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf [accessed 2018-05-01]
7. Lin GA, Fagerlin A. Shared Decision Making. Circ: Cardiovascular Quality and Outcomes 2014 Mar;7(2):328-334. [doi: 10.1161/circoutcomes.113.000322]
8. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. BMC Med Inform Decis Mak 2013 Nov 29;13(S2). [doi: 10.1186/1472-6947-13-s2-s2]
9. O'Connor AM, Jacobsen MJ. Workbook on developing and evaluating patient decision aids. Ottawa Health Research Institute. 2003. URL: https://decisionaid.ohri.ca/docs/develop/develop_da.pdf [accessed 2018-05-01]
10. O'Neill ES, Grande SW, Sherman A, Elwyn G, Coylewright M. Availability of patient decision aids for stroke prevention in atrial fibrillation: A systematic review. Am Heart J 2017 Oct;191:1-11. [doi: 10.1016/j.ahj.2017.05.014] [Medline: 28888264]
11. Gorst-Rasmussen A, Skjøth F, Larsen TB, Rasmussen LH, Lip GYH, Lane DA. Dabigatran adherence in atrial fibrillation patients during the first year after diagnosis: a nationwide cohort study. J Thromb Haemost 2015 May 12;13(4):495-504 [FREE Full text] [doi: 10.1111/jth.12845] [Medline: 25594442]
12. Abdou JK, Auyeung V, Patel JP, Arya R. Adherence to long-term anticoagulation treatment, what is known and what the future might hold. Br J Haematol 2016 Jul 12;174(1):30-42. [doi: 10.1111/bjh.14134] [Medline: 27173746]
13. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC, ACC/AHA Task Force Members. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. Circulation 2014 Dec 02;130(23):2071-2104. [doi: 10.1161/CIR.0000000000000040] [Medline: 24682348]
14. Tong WT, Lee YK, Ng CJ, Lee PY. Factors influencing implementation of a patient decision aid in a developing country: an exploratory study. Implement Sci 2017 Mar 21;12(1):40 [FREE Full text] [doi: 10.1186/s13012-017-0569-9] [Medline: 28327157]
15. Sekimoto M, Asai A, Ohnishi M, Nishigaki E, Fukui T, Shimbo T, et al. Patients' preferences for involvement in treatment decision making in Japan. BMC Fam Pract 2004 Mar 01;5(1):1 [FREE Full text] [doi: 10.1186/1471-2296-5-1] [Medline: 15053839]
16. Wong IO, Lam WW, Wong CN, Cowling BJ, Leung GM, Fielding R. Towards informed decisions on breast cancer screening: Development and pilot testing of a decision aid for Chinese women. Patient Educ Couns 2015 Aug;98(8):961-969. [doi: 10.1016/j.pec.2015.04.014] [Medline: 25959986]
17. Macalalad-Josue AA, Palileo-Villanueva LA, Sandoval MA, Panuda JP. Development of a Patient Decision Aid on the Choice of Diabetes Medication for Filipino Patients with Type 2 Diabetes Mellitus. J ASEAN Fed Endocr Soc 2019 Apr 04;34(1):44-55 [FREE Full text] [doi: 10.15605/jafes.034.01.08] [Medline: 33442136]
18. O'Connor AM. User Manual - Knowledge. Ottawa Hospital Research Institute. 2000. URL: https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Knowledge.pdf [accessed 2018-05-01]
19. O'Connor AM, Cranney A. User Manual - Acceptability. Ottawa Hospital Research Institute. 1996. URL: https://decisionaid.ohri.ca/docs/develop/user_manuals/um_acceptability.pdf [accessed 2018-05-01]
20. Sterne JA, Bodalia PN, Bryden PA, Davies PA, López-López JA, Okoli GN, et al. Oral anticoagulants for primary prevention, treatment and secondary prevention of venous thromboembolic disease, and for prevention of stroke in atrial fibrillation: systematic review, network meta-analysis and cost-effectiveness analysis. Health Technol Assess 2017 Mar;21(9):1-386 [FREE Full text] [doi: 10.3310/hta21090] [Medline: 28279251]
21. Chao T, Lip GY, Liu C, Tuan T, Chen S, Wang K, et al. Validation of a modified CHA2DS2-VASc score for stroke risk stratification in Asian patients with atrial fibrillation: a nationwide cohort study. Stroke 2016 Oct;47(10):2462-2469. [doi: 10.1161/strokeaha.116.013880]
22. Pisters R, Lane DA, Nieuwlaat R, de Vos CB, Crijns HJ, Lip GY. A novel user-friendly score (HAS-BLED) to assess 1-year risk of major bleeding in patients with atrial fibrillation: the Euro Heart Survey. Chest 2010 Dec;138(5):1093-1100. [doi: 10.1378/chest.10-0134] [Medline: 20299623]
23. Fraenkel L, Street RL, Towle V, O'Leary JR, Iannone L, Van Ness PH, et al. A pilot randomized controlled trial of a decision support tool to improve the quality of communication and decision-making in individuals with atrial fibrillation. J Am Geriatr Soc 2012 Aug 02;60(8):1434-1441 [FREE Full text] [doi: 10.1111/j.1532-5415.2012.04080.x] [Medline: 22861171]

24. McCaffery KJ, Holmes-Rovner M, Smith SK, Rovner D, Nutbeam D, Clayman ML, et al. Addressing health literacy in patient decision aids. BMC Med Inform Decis Mak 2013 Nov 29;13(S2). [doi: 10.1186/1472-6947-13-s2-s10]
25. O'Connor AM. Validation of a Decisional Conflict Scale. Med Decis Making 2016 Jul 02;15(1):25-30. [doi: 10.1177/0272989x9501500105]
26. Gattellari M, Ward JE. Will men attribute fault to their GP for adverse effects arising from controversial screening tests? An Australian study using scenarios about PSA screening. J Med Screen 2004 Jun 22;11(4):165-169. [doi: 10.1258/0969141042467386] [Medline: 15563771]
27. Sun Q. Predicting downstream effects of high decisional conflict: meta-analyses of the decisional conflict scale. University of Ottawa. 2005. URL: https://ruor.uottawa.ca/bitstream/10393/27050/1/MR11422.PDF [accessed 2018-05-01]

Abbreviations

AF: atrial fibrillation
DCS: Decisional Conflict Scale
FGD: focus group discussion
IPDAS: International Patient Decision Aid Standards
PDA: patient decision aid
SDM: shared decision-making
UP-PGH: University of the Philippines – Philippine General Hospital

Edited by G Eysenbach; submitted 13.08.20; peer-reviewed by K Usop, J Ansell, C Hoving; comments to author 18.11.20; revised version received 06.04.21; accepted 02.06.21; published 12.08.21.

Please cite as:
de Castro KP, Chiu HH, De Leon-Yao RC, Almelor-Sembrana L, Dans AM
A Patient Decision Aid for Anticoagulation Therapy in Patients With Nonvalvular Atrial Fibrillation: Development and Pilot Study
JMIR Cardio 2021;5(2):e23464
URL: https://cardio.jmir.org/2021/2/e23464
doi:10.2196/23464
PMID:34385138

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org