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## Contents

### Original Papers

- Cardiorespiratory Fitness Estimation Based on Heart Rate and Body Acceleration in Adults With Cardiovascular Risk Factors: Validation Study ([e35796](#))  
Antti-Pekka Rissanen, Mirva Rottensteiner, Urho Kujala, Jari Kurkela, Jan Wikgren, Jari Laukkanen. . . . . 3
- Prediction of VO<sub>2</sub>max From Submaximal Exercise Using the Smartphone Application Myworkout GO: Validation Study of a Digital Health Method ([e38570](#))  
Jan Helgerud, Håvard Haglo, Jan Hoff. . . . . 17
- Home Telemonitoring and a Diagnostic Algorithm in the Management of Heart Failure in the Netherlands: Cost-effectiveness Analysis ([e31302](#))  
Fernando Albuquerque de Almeida, Isaac Corro Ramos, Maiwenn Al, Maureen Rutten-van Mölken. . . . . 27
- The Association Between Telemedicine Use and Changes in Health Care Usage and Outcomes in Patients With Congestive Heart Failure: Retrospective Cohort Study ([e36442](#))  
Cherry Chu, Vess Stamenova, Jiming Fang, Ahmad Shakeri, Mina Tadrous, R Bhatia. . . . . 48
- The First National Program of Remote Cardiac Rehabilitation in Israel—Goal Achievements, Adherence, and Responsiveness in Older Adult Patients: Retrospective Analysis ([e36947](#))  
Irene Nabutovsky, Daniel Breitner, Alexis Heller, Mickey Scheinowitz, Yarin Klempfner, Robert Klempfner. . . . . 59
- Analyzing Public Conversations About Heart Disease and Heart Health on Facebook From 2016 to 2021: Retrospective Observational Study Applying Latent Dirichlet Allocation Topic Modeling ([e40764](#))  
Haoning Xue, Jingwen Zhang, Kenji Sagae, Brian Nishimine, Yoshimi Fukuoka. . . . . 126
- Racial and Socioeconomic Differences in Heart Failure Hospitalizations and Telemedicine Follow-up During the COVID-19 Pandemic: Retrospective Cohort Study ([e39566](#))  
Zachary Hughes, Julia Simkowski, Parry Mendapara, Nicolas Fink, Sparsh Gupta, Quentin Youmans, Sadiya Khan, Jane Wilcox, R Mutharasan. . . . . 1
- Evaluating Health Care Provider Perspectives on the Use of Mobile Apps to Support Patients With Heart Failure Management: Qualitative Descriptive Study ([e40546](#))  
Bride Sivakumar, Manon LEMONDE, Matthew Stein, Sarah Goldstein, Susanna Mak, JoAnne Arcand. . . . . 154
- Attitudes of Patients With Chronic Heart Failure Toward Digital Device Data for Self-documentation and Research in Germany: Cross-sectional Survey Study ([e34959](#))  
Lorina Buhr, Pauline Kaufmann, Katharina Jörß. . . . . 167

Use of Digital Technology Tools to Characterize Adherence to Prescription-Grade Omega-3 Polyunsaturated Fatty Acid Therapy in Postmyocardial or Hypertriglyceridemic Patients in the DIAPAsOn Study: Prospective Observational Study ([e37490](#))  
 Gregory Arutyunov, Alexander Arutyunov, Fail Ageev, Tatiana Fofanova. . . . . 181

The Impact of Time Horizon on Classification Accuracy: Application of Machine Learning to Prediction of Incident Coronary Heart Disease ([e38040](#))  
 Steven Simon, Divneet Mandair, Abdel Albakri, Alison Fohner, Noah Simon, Leslie Lange, Mary Biggs, Kenneth Mukamal, Bruce Psaty, Michael Rosenberg. . . . . 195

**Viewpoint**

Digital Health Solutions to Reduce the Burden of Atherosclerotic Cardiovascular Disease Proposed by the CARRIER Consortium ([e37437](#))  
 Bart Scheenstra, Anke Bruninx, Florian van Daalen, Nina Stahl, Elizabeth Latuapon, Maïke Imkamp, Lianne Ippel, Sulaïka Duijsings-Mahangi, Djura Smits, David Townend, Inigo Bermejo, Andre Dekker, Laura Hochstenbach, Marieke Spreeuwenberg, Jos Maessen, Arnoud van 't Hof, Bas Kietselaer. . . . . 67

**Reviews**

The Use of Dietary Approaches to Stop Hypertension (DASH) Mobile Apps for Supporting a Healthy Diet and Controlling Hypertension in Adults: Systematic Review ([e35876](#))  
 Ghadah Alnooh, Tourkiah Alessa, Mark Hawley, Luc de Witte. . . . . 78

Frameworks for Implementation, Uptake, and Use of Cardiometabolic Disease–Related Digital Health Interventions in Ethnic Minority Populations: Scoping Review ([e37360](#))  
 Mel Ramasawmy, Lydia Poole, Zareen Thorlu-Bangura, Aneesha Chauhan, Mayur Murali, Parbir Jagpal, Mehar Bijral, Jai Prashar, Abigail G-Medhin, Elizabeth Murray, Fiona Stevenson, Ann Blandford, Henry Potts, Kamlesh Khunti, Wasim Hanif, Paramjit Gill, Madiha Sajid, Kiran Patel, Harpreet Sood, Neeraj Bhala, Shivali Modha, Manoj Mistry, Vinod Patel, Sarah Ali, Aftab Ala, Amitava Banerjee. . . . . 91

Characteristics of Smart Health Ecosystems That Support Self-care Among People With Heart Failure: Scoping Review ([e36773](#))  
 Rebecca Nourse, Elton Lobo, Jenna McVicar, Finn Kensing, Sheikh Islam, Lars Kayser, Ralph Maddison. . . . . 108

Original Paper

# Cardiorespiratory Fitness Estimation Based on Heart Rate and Body Acceleration in Adults With Cardiovascular Risk Factors: Validation Study

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## Abstract

**Background:** Cardiorespiratory fitness (CRF) is an independent risk factor for cardiovascular morbidity and mortality. Adding CRF to conventional risk factors (eg, smoking, hypertension, impaired glucose metabolism, and dyslipidemia) improves the prediction of an individual's risk for adverse health outcomes such as those related to cardiovascular disease. Consequently, it is recommended to determine CRF as part of individualized risk prediction. However, CRF is not determined routinely in everyday clinical practice. Wearable technologies provide a potential strategy to estimate CRF on a daily basis, and such technologies, which provide CRF estimates based on heart rate and body acceleration, have been developed. However, the validity of such technologies in estimating individual CRF in clinically relevant populations is poorly known.

**Objective:** The objective of this study is to evaluate the validity of a wearable technology, which provides estimated CRF based on heart rate and body acceleration, in working-aged adults with cardiovascular risk factors.

**Methods:** In total, 74 adults (age range 35-64 years; n=56, 76% were women; mean BMI 28.7, SD 4.6 kg/m<sup>2</sup>) with frequent cardiovascular risk factors (eg, n=64, 86% hypertension; n=18, 24% prediabetes; n=14, 19% type 2 diabetes; and n=51, 69% metabolic syndrome) performed a 30-minute self-paced walk on an indoor track and a cardiopulmonary exercise test on a treadmill. CRF, quantified as peak O<sub>2</sub> uptake, was both estimated (self-paced walk: a wearable single-lead electrocardiogram device worn to record continuous beat-to-beat R-R intervals and triaxial body acceleration) and measured (cardiopulmonary exercise test: ventilatory gas analysis). The accuracy of the estimated CRF was evaluated against that of the measured CRF.

**Results:** Measured CRF averaged 30.6 (SD 6.3; range 20.1-49.6) mL/kg/min. In all participants (74/74, 100%), mean difference between estimated and measured CRF was -0.1 mL/kg/min (*P*=.90), mean absolute error was 3.1 mL/kg/min (95% CI 2.6-3.7), mean absolute percentage error was 10.4% (95% CI 8.5-12.5), and intraclass correlation coefficient was 0.88 (95% CI 0.80-0.92). Similar accuracy was observed in various subgroups (sexes, age, BMI categories, hypertension, prediabetes, and metabolic syndrome). However, mean absolute error was 4.2 mL/kg/min (95% CI 2.6-6.1) and mean absolute percentage error was 16.5% (95% CI 8.6-24.4) in the subgroup of patients with type 2 diabetes (14/74, 19%).

**Conclusions:** The error of the CRF estimate, provided by the wearable technology, was likely below or at least very close to the clinically significant level of 3.5 mL/kg/min in working-aged adults with cardiovascular risk factors, but not in the relatively small subgroup of patients with type 2 diabetes. From a large-scale clinical perspective, the findings suggest that wearable technologies have the potential to estimate individual CRF with acceptable accuracy in clinically relevant populations.

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## KEYWORDS

cardiopulmonary exercise test; cardiorespiratory fitness; heart rate variability; hypertension; type 2 diabetes; wearable technology

## Introduction

Cardiovascular diseases (CVDs) are a major cause of morbidity, mortality, and economic burden worldwide [1]. In addition to conventional modifiable risk factors for CVD, such as smoking, high blood pressure, impaired glucose metabolism, and dyslipidemia, unambiguous epidemiological evidence shows that cardiorespiratory fitness (CRF) also is an independent and modifiable risk factor for nonfatal CVD events and for cardiovascular and all-cause mortality [2-4]. This is physiologically plausible, as while CRF reflects the integrated capacity of respiratory, cardiovascular, and skeletal muscle systems to take up, transport, and use O<sub>2</sub> [5], reduced CRF reflects insufficiencies in one or several of these systems. Nonetheless, although adding CRF to conventional risk factors improves the prediction of risk for adverse CVD outcomes [4] and thus provides an opportunity to optimize patient management, it is still the only major CVD risk factor that is not routinely determined in everyday clinical practice [6].

CRF is quantified as an individual's maximal O<sub>2</sub> uptake or peak O<sub>2</sub> uptake (VO<sub>2peak</sub>) and typically measured by ventilatory gas analysis during a cardiopulmonary exercise test (CPET) in clinical practice [7]. CPET requires access of a clinician; equipment; proficiency of clinical personnel conducting and interpreting the test; and to determine CRF, maximal effort of an individual performing the test [7]. As such factors may limit the use of CPET for CRF determination in clinical practice, particularly for large-scale risk prediction in asymptomatic individuals, alternative strategies to estimate CRF as part of routine clinical visits have been developed [6]. For example, several nonexercise CRF prediction equations exist; however, their limited accuracy in estimating CRF at an individual level limits their clinical utility [8]. Submaximal exercise tests, based on linear relationships between O<sub>2</sub> uptake (VO<sub>2</sub>) and either heart rate (HR) or mechanical workload, are another alternative to estimate CRF [9]. However, their weakness is related to accuracy, confounding factors (eg, medications), interindividual personalization, ceiling effect of the predictive parameter such as HR, and learning effect [9]. To highlight the limitations related to nonexercise and exercise equations, a recent comprehensive analysis of 15 different equations revealed that the accuracy of such equations in estimating CRF is limited from the perspective of individualized clinical decision-making [10]. Consequently, further strategies to estimate CRF with clinically acceptable accuracy are welcome.

Easily available technology provides a strategy to estimate CRF as recent technological advances in wearable devices, such as

patches, clothing, and wristband monitors, enable the measurement of HR and multiple other health-related physiological signals in free-living conditions [11]. The validity of several wearable technologies in estimating CRF has been evaluated in healthy young individuals [12-15]. However, although one such study has also included a small number of individuals who are middle-aged and obese [16], the validity of wearable technologies to estimate CRF in clinically relevant populations with CVD risk factors, chronic diseases and medications, and heterogeneous fitness levels is poorly known [15].

In this study, we estimated CRF using a wearable single-lead electrocardiogram (ECG) device. The device can detect atrial fibrillation accurately [17], suggesting that it has clinical applicability within phenomena related to HR and HR variability (HRV). For estimating CRF, the technology of the device relies on HR, HRV, and triaxial body acceleration signals and does not require data from any predetermined protocol, but enables the estimation during self-paced walking performed in free-living conditions [18]. Our aim was to examine the validity of the CRF estimate by comparing it with VO<sub>2peak</sub> measured directly by CPET in a clinically relevant cohort of working-aged adults with heterogeneous CVD risk factor profiles.

## Methods

### Participants

This validation study was a part of a research collaboration entitled *Heart rate variability analytics to support behavioral interventions for chronic disease prevention and management* (HealthBeat) and conducted between Central Finland Health Care District, University of Jyväskylä, and Firstbeat Technologies Oy in Jyväskylä, Finland. The participants in the HealthBeat study were primarily recruited via web-based advertisements, public advertisements delivered to local noticeboards, and asking the personnel of local health care providers to inform their patients about the study. The inclusion criteria of the study were (1) age between 18 and 64 years, (2) BMI <40 kg/m<sup>2</sup>, (3) either previous evidence of prediabetes (ie, impaired fasting glucose and/or impaired glucose tolerance) or type 2 diabetes diagnosed no more than 5 years ago and/or diagnosed arterial hypertension, and (4) overall physical function not preventing the participant from safely performing the experiments including CPET. The exclusion criteria of the study were anemia, cancer, chronic obstructive pulmonary disease, cerebrovascular disease, chronic atrial fibrillation, clinically significant hypertension-mediated organ damage, diagnosed diabetes-related microvascular disease (ie, nephropathy,

neuropathy, and retinopathy), heart failure, insulin use, ischemic heart disease, left bundle branch block, obstructive sleep apnea requiring continuous positive airway pressure treatment, pregnancy or breastfeeding, psychotic disorder or some other unstable psychiatric disorder, secondary hypertension, significant deficit in overall physical function, significant or nonspecified valvular disease, specific medications affecting HR and HRV ( $\beta$ -blockers, serotonin and noradrenaline reuptake inhibitors, and tricyclic antidepressants), substance abuse, symptomatic or unstable asthma, and symptomatic or unstable disorder of the thyroid gland.

For those who were interested in participating in the study, preliminary health screening was conducted by telephone. Then, potentially eligible participants were invited to a preparticipation health screening conducted by a physician with the assistance of a nurse. The preparticipation health screening consisted of a thorough interpretation of an individual's medical history, clinical status, resting blood pressure, resting ECG, and body mass and height measurements. The antecubital venous blood samples drawn after overnight fasting in an accredited laboratory (FimLab Laboratoriot Oy Ltd, Jyväskylä, Finland) complemented the health screening. The blood sampling included the assessment of blood count, lipid profile, glycemic control, electrolyte balance, and renal function. Frequency, intensity, and duration of both commuting and leisure-time physical activity were obtained as a part of the screening, and total physical activity volume was subsequently expressed as the sum score of metabolic equivalent (MET) hours per day [19] by using the latest available MET values [20]. Overall, the screening focused on evaluating the individual's signs or symptoms; known cardiovascular, metabolic, or renal disease; current level of physical activity; and desired exercise intensity, as recommended [21].

Altogether, 87 individuals were eligible to participate in the HealthBeat study according to the preparticipation health screening. Of these 87 individuals, planned CPET of 4 (5%) participants was canceled owing to logistic or regulatory circumstances related to the COVID-19 pandemic; 4 (5%) participants withdrew before the planned CPET owing to individual reasons (back pain, lack of time, lower limb pain, and plantar fasciitis); and 1 (1%) participant was excluded after CPET, which unmasked clinical evidence of obstructive coronary artery disease. Therefore, 78 participants who performed CPET for CRF measurement also performed a self-paced walk for CRF estimation. Among the 78 participants, as HR and body acceleration measurements during the self-paced walk were technically unsuccessful in the case of 4 (5%) participants, 74 (95%) participants were eventually included in the final analyses of this study.

### CPET Procedure

To complete CPET, the participants reported to a laboratory for a visit comprising pre-exercise measurements and a graded treadmill walking test. Before the visit, the participants were advised to avoid strenuous physical activity and alcohol use for at least 36 hours and any eating and consumption of coffee, tea, cola, or other stimulative drinks for at least two hours. Body mass and composition were measured using a bioimpedance

device (InBody770; InBody Co. Ltd) with the participant in bare feet and light clothing. Body mass and height were used for the calculation of BMI. Waist circumference was measured using stretch-resistant tape at the midpoint between the superior iliac spine and the margin of the lower rib. The circumference was measured to the nearest 0.5 cm and the mean of 2 measurements was calculated. Resting blood pressure was measured with an automated sphygmomanometer device (SunTech Tango M2; SunTech Medical, Inc), and 12-lead ECG (CardioSoft V5.02; GE Medical Systems Information Technologies GmbH) was recorded in the supine position after 5-minute supine rest. Fingertip capillary blood was drawn to measure blood glucose concentration (evercare genius; TaiDoc Technology Corporation) from participants with diabetes to confirm their pre-exercise glucose level being between 5 and 13.9 mmol/L as recommended [22].

The participants performed CPET on a treadmill (JUOKSUMATTO OJK-1; Telineyhtymä) under the supervision of a physician and a nurse. The USAFSAM protocol [23] was used: the test began with 5 minutes of standing at rest, which was followed by 3 minutes of walking at 3.2 km/h (incline 0%), after which the walking speed was set at 5.3 km/h, and the incline of the treadmill was then increased by 5% every 3 minutes until the participant's volitional task failure. Exercise cessation was followed by 5 minutes of recovery, comprising 1 minute in standing position and subsequent 4 minutes in supine position. During CPET, breath-by-breath inspiratory and expiratory volumes and flows were measured using a low-resistance volume turbine (Triple V, Erich Jaeger), and breath-by-breath inspired and expired gases were sampled continuously at the mouth for the analysis of O<sub>2</sub> and CO<sub>2</sub> concentrations (Oxycon Pro Version 5.0; VIASYS Healthcare GmbH). Before each CPET, automatic calibration of the turbine volume transducer and gas analyzer was performed according to the manufacturer's guidelines. The 12-lead ECG and arterial O<sub>2</sub> saturation obtained using fingertip pulse oximetry (Nellcor PM10N; Covidien Inc) were monitored throughout CPET. Systemic arterial blood pressure was measured with the automated sphygmomanometer device during the last 30 seconds of each exercise stage and before anticipated task failure near peak exercise. The rating of perceived exertion at the end of each exercise stage and at peak exercise was obtained (the Borg 6-20 category scale).

VO<sub>2peak</sub>, representing each participant's directly measured CRF, was determined as the highest value of a 30-second moving averaging VO<sub>2</sub> interval [24]. The participants' measured CRF was also characterized as the percentage of predicted VO<sub>2peak</sub> in relation to Norwegian reference data on VO<sub>2peak</sub> (mL/kg/min) [25]. As no Finnish reference values exist for treadmill CPET data, the particular data set was used owing to the geographical proximity of Norway to Finland; importantly, considerable differences exist between different reference data sets, and this is partly because of geographical variation [26]. To determine whether the participants achieved VO<sub>2</sub> plateau, a previously described method to detect each participant's possible VO<sub>2</sub> plateau was used [27]: A scatter plot of VO<sub>2</sub> versus CPET time was first inspected for detecting deviation from linearity, and

if evidence of such deviation was observed, a regression line was fitted to the 4 minutes of  $\text{VO}_2$  data preceding the starting point of the deviation. Then, the regression line was extrapolated to the last completed 30 seconds of CPET, and if the difference between this extrapolated  $\text{VO}_2$  value and the participant's  $\text{VO}_{2\text{peak}}$  was  $>50\%$  of the slope of the regression line, the participant was concluded to demonstrate  $\text{VO}_2$  plateau.

### Self-paced Walk

To complete a self-paced walk for CRF estimation, the participants reported to an indoor hall for a beforehand scheduled walk after CPET; the median of the gap between CPET and the self-paced walk was 3 days with an IQR of 2 to 7 days. The participants performed a 30-minute self-paced walk on a 200-meter indoor track under the supervision of a physician or nurse. The distance walked in 30 minutes was documented. During the walk, the participants wore a lightweight device (Bodyguard 2; Firstbeat Technologies Oy) attached with 2 skin electrodes on the chest [17] to obtain each participant's estimated CRF.

### Wearable Device

The wearable device (Bodyguard 2; Firstbeat Technologies Oy) worn during the 30-minute self-paced walk recorded continuous beat-to-beat R-R intervals (ECG sampling frequency: 1000 Hz; R-R interval accuracy: 1 ms) and triaxial body acceleration (movement sampling frequency: 12.5 Hz), and thus provided each participant's estimated CRF (ie, estimated  $\text{VO}_{2\text{peak}}$  in mL/kg/min). The technology of the device to provide estimated CRF has been developed by Firstbeat Technologies Oy and relies on HR, HRV, and body acceleration signals; the method has been described elsewhere [18]. Although the technology is built on the known, relatively linear relationship between HR and external workload during exercise, it does not require data from any predetermined protocol, but allows CRF estimation from self-paced walking periods performed in free-living conditions. Walking periods providing the most reliable data points and segments for CRF estimation are automatically identified during recording, after which the reliability of the data is automatically evaluated and then used for CRF estimation together with individual background information including at least age, sex, body mass, height, and either age-predicted or known maximal HR. In this study, the background information acquired during the CPET visit was used to obtain estimated CRF, and thus included age, sex, body mass, height, and known maximal HR. The exact algorithm behind the CRF estimation technology is proprietary; thus, it is inaccessible and not presented here.

### Statistical Analysis

Descriptive statistics were used to characterize the participants. Mean difference between the estimated and measured CRF was quantified (difference = estimated CRF – measured CRF) and evaluated using paired-samples 2-tailed *t* test. Mean absolute error (MAE; absolute error = |estimated CRF – measured CRF|) and mean absolute percentage error (MAPE; absolute percentage error = [|estimated CRF – measured CRF|] / measured CRF  $\times$  100%) of the estimated CRF were calculated to describe the magnitude of error for individual-level estimation [28]. Intraclass correlation coefficients (ICCs) were determined to test the overall concordance between estimated and measured CRF [29]. Bland-Altman plot complemented the validity analyses to visually demonstrate the level of agreement between estimated and measured CRF with 95% limits of agreement across the whole range of CRF levels [30]. Shapiro-Wilk test (in case of a sample size  $<50$  participants) and Kolmogorov-Smirnov (in case of a sample size  $\geq 50$  participants) test were used to test the normality of the data. In case of absolute and absolute percentage errors, nonnormally distributed subgroup-specific data were bootstrapped ( $\times 10,000$ ) to present the data with 95% CIs. Data are presented as mean (SD) or mean (95% CI) for normally distributed continuous variables, median (IQR) for nonnormally distributed continuous variables, and *n* (%) for categorical variables. Statistical analyses were performed using IBM SPSS Statistics 26.0 (IBM), and the statistical significance was set at  $P < .05$ .

### Ethics Approval

The HealthBeat study was conducted according to the guidelines of the Declaration of Helsinki and approved by the ethics committee of the Central Finland Hospital District, Jyväskylä, Finland (Dnro 23U/2018). All participants provided their oral and written informed consent before their participation.

## Results

### Participants

The participants were Finns. Table 1 presents the participants' descriptive characteristics. To complement the data in Table 1, 5% (4/74) of the participants had first-degree atrioventricular block, but resting 12-lead ECG did not reveal any significant rhythm or conduction abnormalities. Table 2 presents the relevant cardiometabolic risk factors and medications used by the participants. Overall, the participants' CVD risk factor profiles were heterogeneous, as shown in Tables 1 and 2.

**Table 1.** Descriptive characteristics (N=74)<sup>a</sup>.

Characteristics	Data	Range
<b>Sex, n (%)</b>		
Female	56 (76)	N/A <sup>b</sup>
Male	18 (24)	N/A
Age (years), median (IQR)	55.8 (49.9-59.5)	34.8-64.5
Physical activity (MET <sup>c</sup> hours per day), median (IQR)	2.6 (1.3-4.9)	0.04-15.4
<b>Body size and composition</b>		
Body mass (kg), mean (SD)	82 (16.7)	53.6-135.8
Height (cm), median (IQR)	165 (162-175)	152-191
BMI (kg/m <sup>2</sup> )	28.7 (4.6)	21.9-39.9
Fat-free mass (kg), median (IQR)	50.8 (46.7-61.1)	35.9-84.7
Fat percentage (%), mean (SD)	33 (9)	12-51
Fat mass (kg), mean (SD)	27.6 (10.5)	9.5-54.7
Waist circumference (cm), mean (SD)	98 (13)	74-132
<b>Blood samples</b>		
Hemoglobin (g/L), mean (SD)	143 (10)	123-167
Total cholesterol (mmol/L), mean (SD)	4.9 (0.9)	2.8-7
LDL <sup>d</sup> cholesterol (mmol/L), mean (SD)	3.1 (0.9)	1.4-5.1
HDL <sup>e</sup> cholesterol (mmol/L), mean (SD)	1.5 (0.4)	0.9-2.4
Triglycerides (mmol/L), median (IQR)	1.1 (0.8-1.8)	0.4-4
Fasting glucose (mmol/L), median (IQR)	5.7 (5.2-6.2)	4.6-7.8
HbA <sub>1c</sub> <sup>f</sup> (mmol/mol), median (IQR)	38 (35-40)	31-50
Estimated GFR <sup>g</sup> (mL/min/1.73 m <sup>2</sup> ), mean (SD)	84 (13)	56-125
<b>Resting hemodynamics</b>		
Sinus rhythm, n (%)	74 (100)	N/A
Heart rate (bpm <sup>h</sup> ), median (IQR)	67 (61-76)	48-105
Systolic blood pressure (mm Hg), mean (SD)	135 (13)	106-178
Diastolic blood pressure (mm Hg), mean (SD)	83 (7)	64-98

<sup>a</sup>Data are presented as mean (SD) for normally distributed continuous variables, median (IQR) for nonnormally distributed continuous variables, and n (%) for categorical variables.

<sup>b</sup>N/A: not applicable.

<sup>c</sup>MET: metabolic equivalent.

<sup>d</sup>LDL: low-density lipoprotein.

<sup>e</sup>HDL: high-density lipoprotein.

<sup>f</sup>HbA<sub>1c</sub>: glycosylated hemoglobin A<sub>1c</sub>.

<sup>g</sup>GFR: glomerular filtration ratio.

<sup>h</sup>bpm: beats per minute.

**Table 2.** Cardiometabolic risk factors and medications (N=74).

	Data, n (%)
Arterial hypertension	64 (86)
Prediabetes <sup>a</sup>	18 (24)
Type 2 diabetes	14 (19)
Metabolic syndrome <sup>b</sup>	51 (69)
<b>Smoking</b>	
Yes	4 (5)
No	70 (95)
<b>Family history of premature heart disease<sup>c</sup></b>	
Yes	21 (28)
No	47 (64)
Do not know	6 (8)
<b>Medication</b>	
ACE <sup>d</sup> or ARB <sup>e</sup>	55 (74)
Calcium channel blockers	18 (24)
Diuretics	11 (15)
Statins	14 (19)
Tablet treatment for diabetes	12 (16)

<sup>a</sup>Evidence of impaired fasting glucose (6.1-6.9 mmol/L) previously or during this study and previous evidence of impaired glucose tolerance, but no type 2 diabetes.

<sup>b</sup>As defined by the International Diabetes Federation [31].

<sup>c</sup>Sudden cardiac death, angina pectoris, or coronary artery disease at young age (ie, men aged <55 years and women aged <65 years) in first-degree relatives.

<sup>d</sup>ACE: angiotensin-converting enzyme inhibitor.

<sup>e</sup>ARB: angiotensin receptor blocker.

### CPET and Self-paced Walk

Table 3 presents CPET and self-paced walk data. On the basis of respiratory exchange ratio, rating of perceived exertion, and percentage of age-predicted maximal HR, the participants

performed their maximal effort during CPET, whereas only 36% (27/74) of the participants achieved VO<sub>2</sub> plateau along with previous observations [25]. Measured VO<sub>2peak</sub> ranged from 20.1 to 49.6 mL/kg/min, and the participants represented different CRF categories as shown in Table 3.



**Table 3.** Cardiopulmonary exercise test and self-paced walk (N=74)<sup>a</sup>.

Methods	Data
<b>Cardiopulmonary exercise test</b>	
Exercise time (minutes), mean (95% CI)	15.6 (15-16.2)
Measured VO <sub>2peak</sub> <sup>b</sup> (L/min), median (IQR)	2.3 (2-2.8)
Measured VO <sub>2peak</sub> (mL/kg/min), mean (95% CI)	30.6 (29.2-32.1)
Measured VO <sub>2peak</sub> (mL/kg FFM <sup>c</sup> /min), mean (95% CI)	45.6 (44.3-46.9)
Measured VO <sub>2peak</sub> (percentage of predicted VO <sub>2peak</sub> ) <sup>d</sup> , mean (95% CI)	94 (90-98)
Achieved VO <sub>2</sub> <sup>e</sup> plateau, n (%)	27 (36)
Maximal V <sub>E</sub> <sup>f</sup> (L/min), median (IQR)	88 (75-110)
Maximal RER <sup>g</sup> , mean (95% CI)	1.16 (1.15-1.18)
Maximal RPE <sup>h</sup> , median (IQR)	19 (17-19)
SpO <sub>2</sub> <sup>i</sup> at peak exercise (%), mean (95% CI)	95 (95-96)
Maximal HR <sup>j</sup> (bpm <sup>k</sup> ), mean (95% CI)	172 (169-175)
Maximal HR (percentage of age-predicted maximal HR) <sup>l</sup> , mean (95% CI)	103 (102-105)
Maximal systolic blood pressure (mm Hg), mean (95% CI)	216 (210-221)
Maximal diastolic blood pressure (mm Hg), mean (95% CI)	94 (91-96)
<b>CRF<sup>m</sup> category (percentage of predicted VO<sub>2peak</sub>)<sup>d</sup>, n (%)</b>	
<80	15 (20)
80-99	38 (51)
100-120	16 (22)
>120	5 (7)
<b>Self-paced walk, mean (95% CI)</b>	
Walking distance (m)	3174 (3114-3235)
Estimated VO <sub>2peak</sub> (mL/kg/min)	30.6 (29.2-32)

<sup>a</sup>Data are presented as mean (95% CI) for normally distributed continuous variables, median (IQR) for nonnormally distributed continuous variables, and n (%) for categorical variables.

<sup>b</sup>VO<sub>2peak</sub>: peak O<sub>2</sub> uptake.

<sup>c</sup>FFM: fat-free mass.

<sup>d</sup>Predicted VO<sub>2peak</sub> based on Edvardsen et al [25].

<sup>e</sup>VO<sub>2</sub>: O<sub>2</sub> uptake.

<sup>f</sup>V<sub>E</sub>: minute ventilation.

<sup>g</sup>RER: respiratory exchange ratio.

<sup>h</sup>RPE: rating of perceived exertion.

<sup>i</sup>SpO<sub>2</sub>: arterial O<sub>2</sub> saturation.

<sup>j</sup>HR: heart rate.

<sup>k</sup>bpm: beats per minute.

<sup>l</sup>Age-predicted maximal HR=220–age.

<sup>m</sup>CRF: cardiorespiratory fitness.

### Validity of Estimated CRF in All Participants

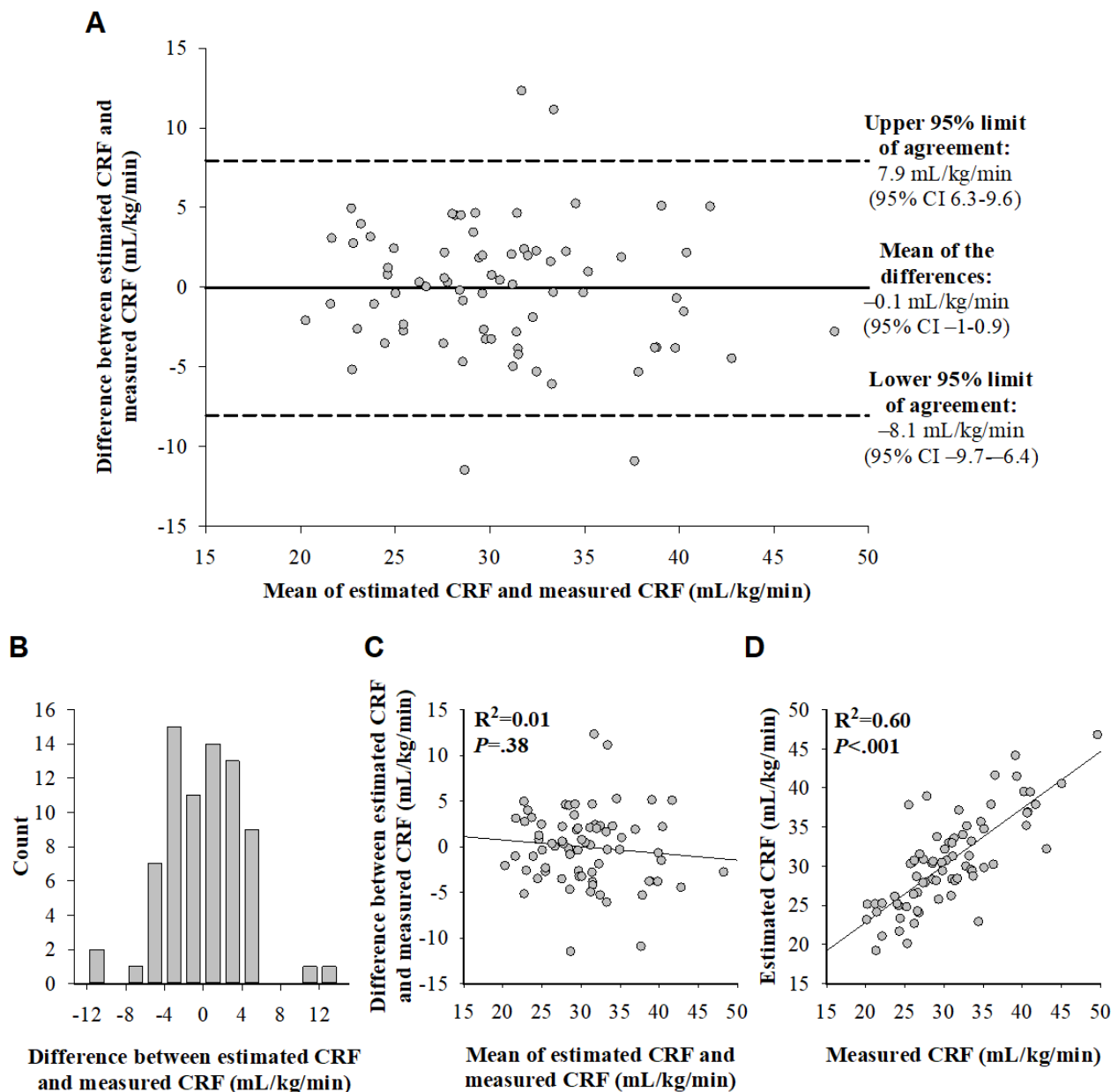
The pooled analysis of all 74 participants revealed that the mean difference between estimated and measured CRF was minimal (–0.1 mL/kg/min; *P*=.90; Figure 1; Table 4). MAE was 3.1

mL/kg/min and MAPE was 10.4% (Table 4). In addition, ICC (*r*=0.88; 95% CI 0.80-0.92) demonstrated good concordance between the 2 methods (Table 4). According to the Bland-Altman plot and its complementary graphs (Figure 1), the level of agreement between estimated and measured CRF

was similar across the whole range of CRF levels; however, 5% (4/74) of the participants had their between-method difference beyond the 95% limits of agreement. A detailed

inspection of the characteristics of that 5% (4/74) of the participants did not reveal any specific explanation for such exaggerated differences (Multimedia Appendix 1 [25,31]).

**Figure 1.** (A) Bland-Altman plot for agreement between estimated cardiorespiratory fitness (CRF; ie, peak O<sub>2</sub> uptake in mL/kg/min, estimated based on a 30-minute self-paced walk) and measured CRF (ie, peak O<sub>2</sub> uptake in mL/kg/min, measured using a cardiopulmonary exercise test) in all participants (74/74, 100%). The solid horizontal line represents the mean of the differences between the methods, and the dashed lines represent the upper and lower 95% limits of agreement. (B) Distribution histogram of the differences between estimated and measured CRF, which are normally distributed (Kolmogorov-Smirnov test,  $P=.20$ ; Shapiro-Wilk test,  $P=.07$ ). (C) Scatter plot with regression fit of the differences between estimated and measured CRF versus the means of the estimated and measured CRF. (D) Scatter plot with regression fit of estimated CRF versus measured CRF. CRF: cardiorespiratory fitness.



**Table 4.** Mean differences between estimated CRF<sup>a</sup> (ie, peak O<sub>2</sub> uptake in mL/kg/min, estimated based on a 30-minute self-paced walk) and measured CRF (ie, peak O<sub>2</sub> uptake in mL/kg/min, measured through a cardiopulmonary exercise test), mean absolute and mean absolute percentage errors of estimated CRF, and ICCs<sup>b</sup> between estimated and measured CRF for all participants and subgroups (N=74)<sup>c</sup>.

	Participants, n (%)	Paired-samples <i>t</i> test <sup>d</sup>		Errors, mean (95% CI)		ICC, <i>r</i> (95% CI)
		Difference (mL/kg/min), mean (95% CI)	<i>P</i> value	Absolute error (mL/kg/min)	Absolute percentage error (%)	
All	74 (100)	-0.1 (-1 to 0.9)	.90	3.1 (2.6 to 3.7) <sup>e</sup>	10.4 (8.5 to 12.5) <sup>e</sup>	0.88 (0.80 to 0.92)
<b>Sex</b>						
Female	56 (76)	-0.03 (-1.1 to 1.1)	.96	3 (2.3 to 3.8)	10.5 (8 to 13.1)	0.85 (0.75 to 0.91)
Male	18 (24)	-0.2 (-2.2 to 1.8)	.87	3.4 (2.5 to 4.4)	10.1 (7.2 to 13)	0.87 (0.66 to 0.95)
<b>Age</b>						
Below median (<55.8 years)	37 (50)	-0.7 (-2.2 to 0.7)	.30	3.4 (2.6 to 4.3) <sup>e</sup>	10.5 (8 to 13.5) <sup>e</sup>	0.85 (0.71 to 0.92)
Above median (>55.8 years)	37 (50)	0.6 (-0.7 to 1.9)	.33	2.9 (2.1 to 3.8) <sup>e</sup>	10.4 (7.7 to 13.3) <sup>e</sup>	0.88 (0.76 to 0.94)
<b>BMI (kg/m<sup>2</sup>)</b>						
<25	18 (24)	-1.4 (-3.7 to 1)	.23	3.7 (2.4 to 5.2) <sup>e</sup>	10.5 (6.9 to 14.6) <sup>e</sup>	0.79 (0.44 to 0.92)
25-29.99	30 (41)	0.5 (-1.1 to 2.1)	.53	3.2 (2.3 to 4.3) <sup>e</sup>	10.4 (7.1 to 14.4) <sup>e</sup>	0.82 (0.62 to 0.91)
≥30	26 (35)	0.2 (-1.1 to 1.5)	.74	2.6 (1.9 to 3.3)	10.4 (7.6 to 13.2)	0.81 (0.57 to 0.91)
Arterial hypertension	64 (86)	-0.6 (-1.5 to 0.4)	.24	3 (2.4 to 3.6) <sup>e</sup>	9.7 (8 to 11.6) <sup>e</sup>	0.88 (0.80 to 0.93)
<b>Glucose metabolism</b>						
Normal	42 (57)	-0.7 (-1.7 to 0.4)	.21	2.8 (2.1 to 3.4) <sup>e</sup>	8.5 (6.7 to 10.3)	0.91 (0.84 to 0.95)
Prediabetes <sup>f</sup>	18 (24)	-0.4 (-2.5 to 1.6)	.66	3.2 (2.1 to 4.5) <sup>e</sup>	10.2 (7.1 to 14) <sup>e</sup>	0.88 (0.66 to 0.95)
Type 2 diabetes	14 (19)	2.3 (-0.7 to 5.2)	.12	4.2 (2.6 to 6.1) <sup>e</sup>	16.5 (8.6 to 24.4)	0.66 (0.03 to 0.89)
Metabolic syndrome <sup>g</sup>	51 (69)	0.7 (-0.4 to 1.7)	.22	3.0 (2.3 to 3.7)	10.8 (8.2 to 13.3)	0.82 (0.69 to 0.90)

<sup>a</sup>CRF: cardiorespiratory fitness.

<sup>b</sup>ICC: intraclass correlation coefficient.

<sup>c</sup>Data are presented as mean (95% CI) for the differences and errors and *r* (95% CI) for ICC.

<sup>d</sup>2-tailed.

<sup>e</sup>Bootstrapped (×10,000) owing to originally nonnormally distributed data.

<sup>f</sup>Evidence of impaired fasting glucose (6.1-6.9 mmol/L) previously or during this study and previous evidence of impaired glucose tolerance, but no type 2 diabetes.

<sup>g</sup>As defined by the International Diabetes Federation [31].

### Validity of Estimated CRF in Subgroups

Data related to the validity of estimated CRF in different subgroups are presented in Table 4. The data show that the CRF estimation method was likely to provide similar accuracy in women and men and across age and BMI categories, when comparing with the data on all participants (Table 4). This was also evident in the participants with hypertension, normal glucose metabolism, prediabetes, and metabolic syndrome (Table 4). In contrast, the participants with type 2 diabetes demonstrated lower estimation accuracy than other subgroups; for example, MAPE was 16.5% in those with type 2 diabetes (Table 4). The accuracy of the CRF estimation method was equally good in 36% (27/74) of the participants who achieved VO<sub>2</sub> plateau at the end of CPET and in 64% (47/74) of the

participants who did not achieve it (eg, MAE was 3.3 mL/kg/min, 95% CI 2.3-4.4 and 3 mL/kg/min, 95% CI 2.4-3.8, respectively; MAPE was 10.4%, 95% CI 7.2-13.9 and 10.4%, 95% CI 8.2-13, respectively).

## Discussion

### Principal Findings

Wearable technology provides a strategy to estimate CRF as part of routine clinical practice. In this study, we estimated the CRF of working-aged adults with heterogeneous CVD risk factor profiles with a technology that uses wearable device data on HR, HRV, and body acceleration monitored during self-paced walking. We tested the validity of the technology by comparing the participants' estimated CRF with their CRF measured

directly by ventilatory gas analysis during CPET. For all participants (74/74, 100%), the mean difference between estimated and measured CRF was  $-0.1$  mL/kg/min, MAE was 3.1 mL/kg/min, MAPE was 10.4%, and average ICC was 0.88, reflecting high accuracy of the examined method to estimate CRF. In subgroup analyses, similar accuracy of the CRF estimation method was observed in both sexes, different age and BMI categories, patients with hypertension, patients with prediabetes, and patients with metabolic syndrome. However, the technology did not provide equally accurate CRF estimation in the small subgroup of patients with type 2 diabetes (14/74, 19%), in whom MAE and MAPE were 4.2 mL/kg/min and 16.5%, respectively.

### Comparison With Previous Studies

CRF, quantified as an individual's maximal  $VO_2$  or  $VO_{2peak}$ , reflects the integrated capacity of the respiratory, cardiovascular, and skeletal muscle systems to take up, transport, and use  $O_2$  [5], and thus it has normal physiological variation. Studies that have examined the test-retest repeatability of CPET parameters in healthy populations have observed the coefficient of variation of directly measured  $VO_{2peak}$  to be approximately 5% [32,33]. Such a level of test-retest repeatability is not attained in patient populations. The coefficient of variation of directly measured  $VO_{2peak}$  has varied between 6% and 9% in various patient populations such as patients with chronic obstructive pulmonary disease [34], heart failure [34,35], peripheral arterial disease [36], pulmonary arterial hypertension [37], or severe mitral valve disease [34]. In light of these findings, it may be postulated that the MAPE of the CRF estimation method could have ideally been between 5% and 9% in this study, which included a patient cohort with frequent cardiovascular risk factors and medications. Thus, as the MAPE of estimated CRF varied between 8.5% and 10.8% in both the pooled cohort and all subgroups in this study, except for the patients with type 2 diabetes, the accuracy of the method to estimate CRF can be considered to be acceptable in terms of the inevitable physiological variation of CRF.

Wearable technology provides an approach to estimate CRF for routine individualized risk prediction in everyday clinical practice. The validity of several wearable technologies that provide CRF estimations has been studied [12-16]. Similar to the CRF estimation method examined in this study, most of the technologies have used HR and body acceleration data [12,14-16], whereas some technologies combine HR and body acceleration data with data from respiratory bands [13]. MAPE of such estimates has ranged from 8% to 10.2% [14,15]. From the clinical perspective, it is important to note that the participants in most of those studies were healthy and relatively young and fit [12-15]; however, one such study has also included 9 individuals aged  $>50$  years and 7 individuals who were obese [16]. In consequence, the need for validation studies including clinically relevant populations (eg, older people, individuals who are obese, and individuals with chronic diseases) has been highlighted [12,14,15]. In this regard, it is noteworthy that, when compared with the previously reported accuracies of the other technologies, the accuracy of the CRF estimation method examined in this study was similar and particularly did so in

the clinically relevant cohort with heterogeneous and comprehensively reported CVD risk profiles.

The accuracy of the CRF estimation method was lower for the participants with type 2 diabetes (14/74, 19%) than for the pooled study cohort or other subgroups. For instance, MAE was 4.2 mL/kg/min and MAPE was 16.5% for the participants with diabetes. Patients with diabetes are prone to cardiac autonomic neuropathy, the signs and symptoms of which include reduced HRV, resting tachycardia, abnormal blood pressure regulation, orthostatic hypotension, orthostatic tachycardia or bradycardia, chronotropic incompetence, and exercise intolerance [38]. In addition, exaggerated HRV complexity during CPET has been observed in working-aged adults with well-controlled type 1 diabetes [39]. Although the prevalence of diabetes-related cardiac autonomic neuropathy increases with diabetes duration and may be evident in 60% of patients with type 2 diabetes after 15 years, cardiac autonomic neuropathy may also be asymptomatic and manifest only as reduced HRV [38]. Thus, it may be that the reduced accuracy of the CRF estimation method in the type 2 diabetes subgroup was owing to early diabetes-related disturbances in cardiac autonomic modulation, although the participants with type 2 diabetes had good glycemic control in terms of glycosylated hemoglobin  $A_{1c}$ , short diabetes duration (from 0.5 to 4.4 years), and no previous evidence of autonomic neuropathy. Importantly, the accuracy of the CRF estimation method was not reduced in the subgroups with prediabetes or metabolic syndrome. This suggests that the method provides an accurate estimation of CRF in the 2 clinically relevant patient groups; however, this may not be the case for patients with both metabolic syndrome and type 2 diabetes. Overall, as the subgroup with type 2 diabetes included only 19% (14/74) of the participants, future validation studies including large number of patients with diabetes are warranted.

The findings of this study have relevant clinical applicability. As epidemiological evidence shows that CRF independently predicts incidence and mortality of not only CVD but also respiratory diseases and cancer and all-cause mortality [2-4], determining CRF as a vital sign in routine clinical practice as recommended may lead to several health benefits [6]. For example, identifying individuals with low CRF and thus increased risk for adverse health outcomes may guide health care providers to target more intensive preventive interventions at such individuals. CRF can be used as a medium for facilitating discussions about individual health concerns and lifestyle modification, and determined CRF can also be added to classic risk algorithms to improve the accuracy of individual risk prediction [6,40]. For such daily clinical purposes, the feasibility to use CPET may be limited by requirements related to costs, expertise, resources, and effort dependency [7]. In addition, the feasibility to use exercise-based prediction equations for individualized clinical decision-making is limited by the accuracy of such equations. This was recently demonstrated by Peterman et al [10], who reported limited accuracy levels of 2 nonexercise (SE of estimate [SEE] 4.9 mL/kg/min), 3 submaximal exercise (SEE 7-9.1 mL/kg/min), and 10 maximal exercise equations (SEE 3.6-5.6 mL/kg/min; except for 1 equation with SEE of 2.5 mL/kg/min). Regarding the CRF estimation method examined in this study, MAE was 3.1

mL/kg/min in the pooled study cohort and 2.6 to 3.7 mL/kg/min in each subgroup, except for the participants with type 2 diabetes. Thus, the overall level of accuracy was higher than the recently reported levels of the prediction equations [10]. In addition, although approximately one-third (27/74, 36%) of participants had their absolute error >1 MET (ie, >3.5 mL/kg/min), MAE of 3.1 mL/kg/min was <1 MET, which is noteworthy because even +1 or -1 MET translates into prognostically significant CRF deviation [6]. Furthermore, the Bland-Altman plot and its complementary analyses (Figure 1) demonstrate that the level of accuracy was similar across the whole range of CRF levels. In summary, the accuracy of the CRF estimation method may be considered as likely sufficient for individualized clinical decision-making, irrespective of the individual's CRF level.

### Strengths and Limitations

The main strength and the main novelty of this study reside in the characteristics of the participants: The working-aged adults comprised a clinically relevant cohort with frequent cardiovascular risk factors (eg, hypertension and impaired glucose metabolism) and common medications (eg, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, statins, and metformin). The need for strategies to estimate CRF with clinically acceptable accuracy in such individuals has been highlighted [6,12,14,15]. The cohort size was also relatively large compared with previous similar validation studies examining healthy individuals [12-16]; however, the sex distribution was not optimally balanced (women: 56/74, 76% and men: 18/74, 24%). An important limitation of this study is that CRF was estimated based on a standard 30-minute self-paced walk. Thus, the validity of the CRF estimation method remains to be tested under completely free-living conditions. In addition, the risk of recruitment bias may not be optimally avoided, as the median volume of total physical activity of the participants was 2.6 MET hours per day, which approximately corresponds, for example, to 30 minutes of moderate-intensity aerobic activity per day [41]. This may

reflect the tendency for physically active individuals to volunteer for this type of study that includes exercise provocations. However, the average CRF of the participants was 94% of predicted, the participants represented a wide spectrum of different CRF categories, and importantly, the accuracy level of the CRF estimation method was similar across the measured  $VO_{2peak}$  range of 20.1 to 49.6 mL/kg/min. Thus, the findings and conclusions of this study can be generalized to working-aged adults with frequent cardiovascular risk factors and  $VO_{2peak} >20$  mL/kg/min but without the exclusion criteria of this study.

### Conclusions

We estimated the CRF of 74 working-aged adults with heterogeneous CVD risk factor profiles with a technology that uses wearable device data on HR, HRV, and body acceleration monitored during self-paced walking. After comparing the participants' estimated CRF with their directly measured CRF, we conclude that, in populations comparable with the cohort examined in this study, the error of the CRF estimate is likely below or at least very close to 1 MET. This is relevant because even +1 or -1 MET translates into prognostically significant CRF deviation [6]. Such accuracy was observed in the pooled study cohort and various subgroups including both sexes, different age and BMI categories, patients with hypertension, patients with prediabetes, and patients with metabolic syndrome, but not in a small subgroup of patients with type 2 diabetes (14/74, 19%). Future studies are warranted to examine the validity of the method in large type 2 diabetes cohorts, under completely uncontrolled free-living conditions, and in test-retest and longitudinal settings to evaluate whether the method can be used for clinical follow-up purposes.

From a large-scale clinical perspective, this study suggests that wearable technologies may have the potential to estimate individual CRF with acceptable accuracy in clinically relevant populations and thus aid in improving the prediction of individual risk for adverse health outcomes such as adverse CVD events.

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### Data Availability

The data underlying the reported conclusions will be shared upon request to the corresponding author.

### Authors' Contributions

APER and MR contributed equally to the study. All authors made important contributions to the conception and design of the study. APER and MR made important contributions to the acquisition, analysis, and interpretation of data. APER and MR drafted the manuscript. UMK, JLOK, JW, and JAL revised the manuscript critically for intellectual content. All authors approved the final version of the submitted manuscript.

### Conflicts of Interest

A family member of MR is an employee and stockowner of Firstbeat Technologies Oy (Jyväskylä, Finland).

## Multimedia Appendix 1

Characteristics of the 5% (4/74) of the participants (1-4), in whom the difference between estimated and measured cardiorespiratory fitness fell beyond the 95% limits of agreement, as shown in [Figure 1](#).

[[DOCX File, 24 KB - cardio\\_v6i2e35796\\_app1.docx](#)]

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## Abbreviations

**CPET:** cardiopulmonary exercise test

**CRF:** cardiorespiratory fitness

**CVD:** cardiovascular disease

**ECG:** electrocardiogram

**HealthBeat:** Heart rate variability analytics to support behavioral interventions for chronic disease prevention and management

**HR:** heart rate

**HRV:** heart rate variability

**ICC:** intraclass correlation coefficient

**MAE:** mean absolute error

**MAPE:** mean absolute percentage error

**MET:** metabolic equivalent

**SEE:** SE of estimate

**VO<sub>2</sub>:** O<sub>2</sub> uptake

**VO<sub>2peak</sub>:** peak O<sub>2</sub> uptake

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Original Paper

# Prediction of VO<sub>2</sub>max From Submaximal Exercise Using the Smartphone Application Myworkout GO: Validation Study of a Digital Health Method

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## Abstract

**Background:** Physical inactivity remains the largest risk factor for the development of cardiovascular disease worldwide. Wearable devices have become a popular method of measuring activity-based outcomes and facilitating behavior change to increase cardiorespiratory fitness (CRF) or maximal oxygen consumption (VO<sub>2max</sub>) and reduce weight. However, it is critical to determine their accuracy in measuring these variables.

**Objective:** This study aimed to determine the accuracy of using a smartphone and the application Myworkout GO for submaximal prediction of VO<sub>2max</sub>.

**Methods:** Participants included 162 healthy volunteers: 58 women and 104 men (17-73 years old). The study consisted of 3 experimental tests randomized to 3 separate days. One-day VO<sub>2max</sub> was assessed with Metamax II, with the participant walking or running on the treadmill. On the 2 other days, the application Myworkout GO used standardized high aerobic intensity interval training (HIIT) on the treadmill to predict VO<sub>2max</sub>.

**Results:** There were no significant differences between directly measured VO<sub>2max</sub> (mean 49, SD 14 mL/kg/min) compared with the VO<sub>2max</sub> predicted by Myworkout GO (mean 50, SD 14 mL/kg/min). The direct and predicted VO<sub>2max</sub> values were highly correlated, with an R<sup>2</sup> of 0.97 ( $P < .001$ ) and standard error of the estimate (SEE) of 2.2 mL/kg/min, with no sex differences.

**Conclusions:** Myworkout GO accurately calculated VO<sub>2max</sub>, with an SEE of 4.5% in the total group. The submaximal HIIT session (4 x 4 minutes) incorporated in the application was tolerated well by the participants. We present health care providers and their patients with a more accurate and practical version of health risk estimation. This might increase physical activity and improve exercise habits in the general population.

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## KEYWORDS

high-intensity interval training; cardiovascular health; physical inactivity; endurance training; measurement accuracy

## Introduction

Physical inactivity is one of the leading health problems in the world. Exercise is important for rehabilitation, to enhance health,

and for health maintenance, in addition to its role in conditioning for competitive sports [1-3]. Robust evidence shows that low levels of cardiorespiratory fitness (CRF) are associated with a high risk of cardiovascular disease and all-cause mortality. CRF, typically assessed by directly measuring maximal oxygen

consumption ( $VO_{2max}$ ), is a potentially stronger predictor of mortality than established risk factors such as smoking [4]. The addition of CRF to traditional risk factors could lead to improved clinical practice and public health.

Indirect estimates of CRF have been associated with health outcomes for more than 50 years. There is a high correlation between cardiac output during exercise and  $VO_2$  [5]. A low heart rate (HR) at a given  $VO_2$  is thus associated with a large stroke volume. This physiological fact forms an important basis for submaximal exercise tests. Most modern circulatory exercise tests are based on the linear increase in HR with increasing  $VO_2$ . However, only a few studies have established these prediction equations [4,6].

CRF has usually been estimated using maximal treadmill and bike testing [7-9]. However, a submaximal exercise test can be chosen when the apparatus and trained personnel to perform direct  $VO_{2max}$  measurements are either not available or considered inappropriate [5]. In addition, many researchers and clinicians are not willing to accept the definite risk involved in an incremental test to exhaustion. Submaximal exercise tests based on the HR response to work rate can be performed with little risk to the participant. However, the usefulness of CRF prediction must be considered with regard to the relatively large standard error of the estimate (SEE), which is typically in the range of more than 10% to 15% [4,6].

Wearable devices have become a popular method in health care and clinical research for measuring both activity-based outcomes and CRF. In a randomized controlled trial with patients with an inflammatory rheumatic disease, we recently documented the effect of a smartphone-assisted high aerobic intensity interval training (HIIT) with the app Myworkout GO [10]. Similar improvements in  $VO_{2max}$  and health-related quality of life were observed following HIIT when patients with an inflammatory rheumatic disease were guided by health care professionals or the training was self-administered and app-guided with CRF

exercise feedback. Digital rehabilitation appears to be an excellent, cost-effective treatment strategy and should be considered in clinical practice in the future. It is thus critical to understand the accuracy when measuring these variables because it may affect research conclusions and impact health care decision-making. Since wearable technology companies are solely responsible for reporting the accuracy of their products, little information about the evaluation method is made publicly available [11-13].

Although a number of risk scores combining multiple variables have been developed and validated as prognostic tools, we sought to predict  $VO_{2max}$  and thus “biological age” based on submaximal exercise performance with the application Myworkout GO. “Biological age” in the present study was defined as the average  $VO_{2max}$  for each sex and age in the general population [14]. The goal was to present both the general population and health care providers with a more accurate, easy to understand, and practical version of risk estimate. This might initially increase physical activity and improve exercise habits in the population. The aim of the present study was to evaluate the accuracy of predicting  $VO_{2max}$  from submaximal exercise using the application Myworkout GO. The hypothesis was that  $VO_{2max}$  predicted by the commercial smartphone application Myworkout GO would be significantly similar to direct  $VO_{2max}$  assessments.

## Methods

### Study Design and Participants

In this criterion-related validity design, study participants were recruited from universities, workplaces, athletic clubs, and senior organizations. Participants with previously diagnosed cardiovascular disease were excluded from this study. The intention was to recruit healthy people at different levels of CRF. Table 1 shows the main characteristics of the participants.

**Table 1.** Descriptive characteristics.

Characteristics	Total (n=162)		Men (n=104)		Women (n=58)		P value <sup>a</sup>
	Mean (SD)	Minimum-maximum	Mean (SD)	Minimum-maximum	Mean (SD)	Minimum-maximum	
Age (years)	38 (16)	17-73	30 (14)	17-71	50 (11)	30-73	<.001
Body mass (kg)	79 (12)	51-128	81 (12)	60-128	76 (12)	51-102	.01
Height (cm)	176 (8)	158-197	180 (7)	160-197	168 (4)	158-176	<.001
<b><math>VO_{2max}</math><sup>b</sup> (mL/kg/min)</b>							
Direct	49 (14)	19-79	57 (11)	31-79	36 (8)	19-54	<.001
Indirect <sup>c</sup>	50 (14)	17-77	57 (11)	30-77	36 (7)	17-53	<.001

<sup>a</sup>Difference between men and women.

<sup>b</sup> $VO_{2max}$ : maximal oxygen consumption.

<sup>c</sup> $VO_{2max}$  calculated by the application Myworkout GO.

### Ethics Approval

Review of the study design was undertaken by the Committee for Medical and Health Research Ethics in Norway who

determined that a full committee review was not required given the healthy population. According to university policy, the study was submitted and approved by the institutional research board at the Norwegian University of Science and Technology and

was performed in accordance with the Declaration of Helsinki (review number: NTNU/MH/ISB/JH/010919). All participants gave their written informed consent to participate after having reviewed oral and written information about the study and the procedures.

### Instruments

A calibrated motorized treadmill (TX200 GymSport, Trondheim, Norway) was used for both the  $VO_{2max}$  tests and Myworkout GO application assessments in this study. All measurements of pulmonary gas exchange were obtained using a Cortex Metamax II portable metabolic test system (Cortex, Leipzig, Germany). The participants used a face mask with a head cap assembly. The volume transducer for the Metamax system was connected to the face mask, together with a tube that collected samples of the gas concentration in the mask. This system was connected to a personal computer. The measurements were recorded every 10 seconds. The portable Metamax II metabolic test system offers an opportunity to measure all ventilatory parameters,  $VO_2$  and carbon dioxide output, and ambient air temperature and pressure. The ventilation volume transducer is a digital Triple-V turbine that measures a volume range of 0.0 L/s to 14.0 L/s, with an accuracy of 1.5%. To analyze the oxygen concentration, a Zirconium sensor was used. The oxygen concentration range for the sensor is between 0 vol % and 25 vol %, with an accuracy of <0.1 vol %. Carbon dioxide was analyzed by an infrared sensor with a range from 0 vol % to 10 vol % and an accuracy of <0.1 vol %. Prior to the tests, the volume transducer was calibrated with a 3-L standardized calibration syringe (Hans Rudolph Jäger GmbH, Hoechberg, Germany). The gas concentration sensor was calibrated with ambient air and a chemically standardized calibration gas with 16%  $O_2$ , 4%  $CO_2$ , and 80% nitrogen (SensorMedics Corporation, Yorba Linda, CA).

Myworkout GO is an application accessible for both Android and iOS smartphones and gives timing information for performing a 4x4-minute workout. Myworkout GO has a specific algorithm for the prediction of  $VO_{2max}$  that will not be disclosed. The algorithm is based on completed amount of work (speed and inclination) during the 16-minute high aerobic intensity training that is manually registered in the app after completion of the HIIT session. Based upon the linear relationship between work and  $VO_{2max}$  [5], the application is able to evaluate the relative training intensity without wearing a HR monitor.

### Test Protocols

The study consisted of 3 experimental tests in randomized order on nonconsecutive days. The tests were performed within a maximum period of 2 weeks. One test was a direct  $VO_{2max}$  test on the treadmill, while Myworkout GO used a standardized HIIT protocol on the other 2 days. The highest predicted  $VO_{2max}$  value was used, blinded for directly measured results. Participants' preparations consisted of not carrying out extreme exercise the day before the tests, not eating or drinking in the 2.5 hours before the tests, and not using tobacco in the 2 hours before the tests.

The  $VO_{2max}$  protocol on the treadmill involved a 10-minute warm-up period at about 70% of estimated maximum HR ( $HR_{max}$ ) based on the standard formula from the American College of Sports Medicine [15]. The test started after mounting the face mask and connecting it to the Metamax system. The workload was adjusted based on information about each participant's weekly physical exercise level and treadmill practice. The participants typically started at the speed at which they finished their warm-up period.  $VO_2$  was measured constantly as the speed of the treadmill was increased every minute. This continued until the participant reached exhaustion after about 5 minutes to 8 minutes. To ensure that  $VO_{2max}$  was reached, the participants were encouraged to continue as long as possible so that a leveling off of  $VO_2$  occurred [1]. A plateau was displayed by all participants at the end of the test, confirming  $VO_{2max}$ .

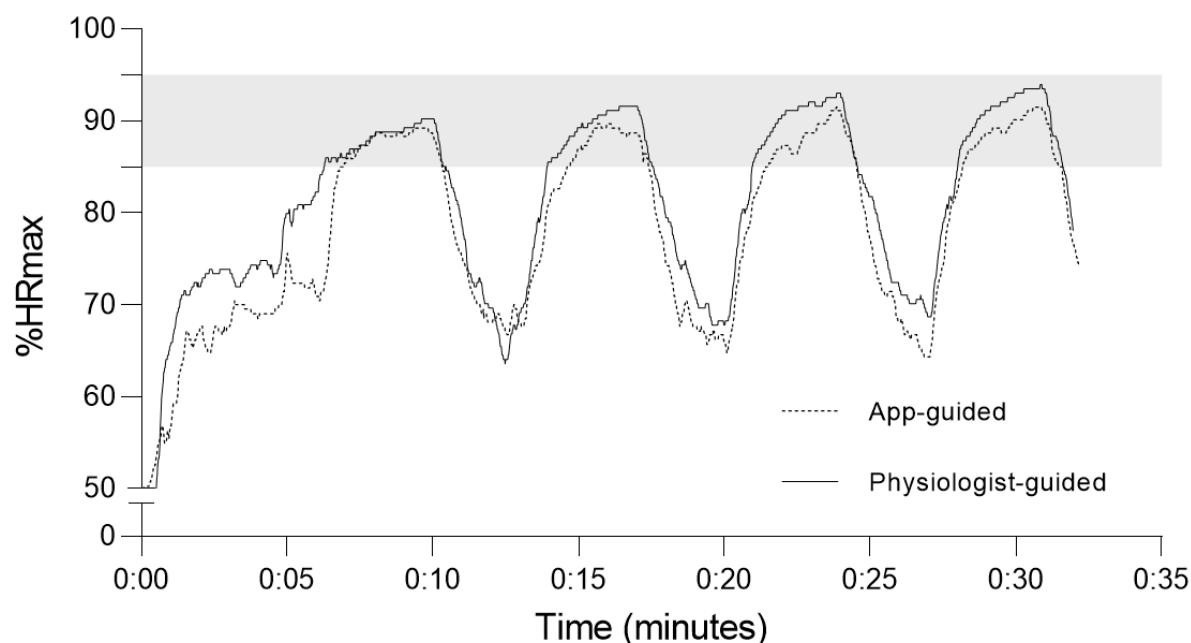
The HIIT protocol used in Myworkout GO was performed individually on the treadmill, walking or running, and consisted of a 6-minute warm-up at "talking speed." Then, the participants underwent a 4x4-minute interval training (breathing heavy but with no obvious feeling of lactic acid accumulation), interrupted by 3 minutes of active rest periods at "talking speed" between each interval [1]. The 2 HIIT sessions were performed in a supervised setting by an exercise physiologist; however, the exercise itself was guided by the app, with the following instructions:

1. Walk or run uphill for the 6-minute warm-up at moderate intensity (talking pace).
2. Perform 4x4-minute intervals at an intensity at which you are breathing heavily after 2 minutes but do not feel any discomfort or stiff legs.
3. After the 4 minutes of high intensity, you should be able to do 1 more minute, and when you have completed the 4x4 minutes, given an active break, you should be able to do 1 more 4-minute interval.
4. Take 3-minute active breaks at talking pace between each interval.
5. Perform a 3-minute cooldown.

Since HR was not measured during the HIIT sessions, a randomized controlled pilot study was conducted prior to this study. The aim was to verify whether individuals can achieve the target intensity zone during HIIT when they either receive guidance by an exercise physiologist based on subjective feeling and observed level of exertion or simply follow the guidelines provided by the application Myworkout GO. For this purpose, 6 healthy, young individuals (4 men, 2 women; 20-30 years old) were recruited and randomized to a physiologist-guided (n=3) or an app-guided group (n=3). Every individual was advised to perform 3 HIIT sessions within 3 weeks on nonconsecutive days. HR was measured at the upper arm using a Polar OH1 monitor (Polar Electro Oy, Kempele, Finland). The Polar OH1 was recently validated with the gold standard for HR measurement, electrocardiography [16]. Both researchers and participants were blinded for HR during the pilot study. An example of the HR response for each group is presented in Figure 1. For statistical analysis, 4 data points per HIIT session

were extracted, 1 average data point (in % of the individuals'  $HR_{max}$ ) from the third minute of every interval.

**Figure 1.** Examples of heart rate response to 4x4 high aerobic intensity interval training (HIIT) in healthy, young participants guided either by a physiologist or mobile application. The shaded area represents target intensity during the high-intensity intervals (85%-95% of maximum heart rate [ $HR_{max}$ ]).



### Statistical Analysis

Statistical analyses were performed using SPSS version 26 (IBM Corp, Armonk, NY). Means and standard deviations were computed for all the participants, and the measured variables are reported using descriptive statistics. Student *t* tests and linear regressions were used to calculate comparisons between the different means and variables in the tables and figures. Pearson correlation was performed to find the relationship between direct  $VO_{2max}$  and  $VO_{2max}$  estimated from Myworkout GO. Further, a Bland-Altman plot was used to describe the agreement of the 2 methods. In all statistical analyses, significance was accepted at  $P < .05$ . The figures were constructed using GraphPad Prism 8 (GraphPad Software, San Diego, CA).

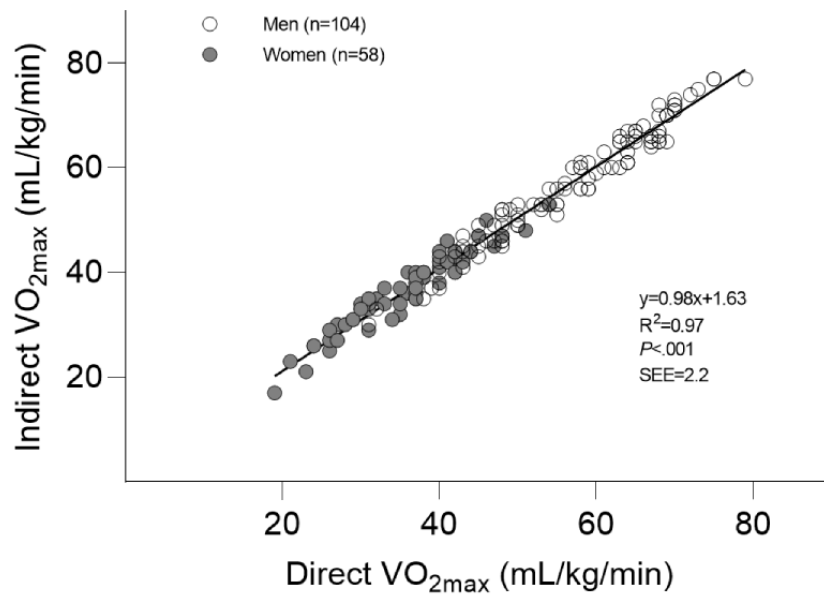
### Results

Participants included 162 healthy volunteers, 58 women and 104 men, between 17 years and 73 years of age. There were no significant differences between direct measurements of  $VO_{2max}$  and indirect calculations by Myworkout GO in all participants (Table 1) nor were there significant differences when the

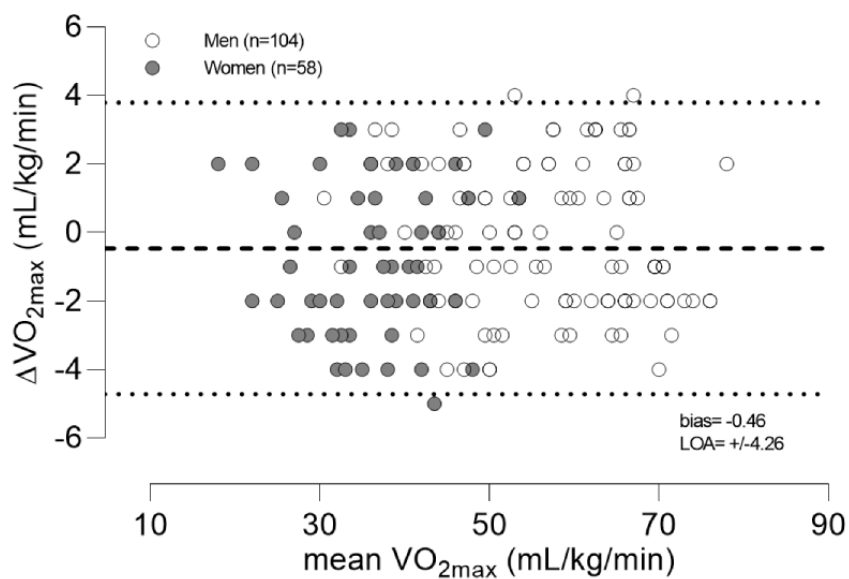
participants were divided into men and women. The direct and predicted  $VO_{2max}$  values were highly correlated, with an  $R^2$  of 0.97 ( $P < .001$ ) and SEE of 2.2 mL/kg/min (4.5%; Figure 2), with no sex differences. The Bland-Altman plot for the direct and predicted  $VO_{2max}$  values is presented in Figure 3. The group of women were significantly older, had lower body mass and height, and had a significantly lower  $VO_{2max}$  than men (Table 1). Table 2 shows the age distribution among all the participants.

Results from the pilot study ( $n=6$ ) revealed no significant difference between physiologist-guided and app-guided  $\%HR_{max}$  in the first (mean 90.9, SD 2.4% vs mean 87.8, SD 3.8%;  $P=.05$ ), second (mean 93.1, SD 2.6% vs mean 90.3, SD 4.2%;  $P=.11$ ), third (mean 93.8, SD 2.1% vs mean 91.4, SD 4.5%;  $P=.18$ ), and fourth (mean 94.4, SD 1.6% vs mean 92.3, SD 4.5%;  $P=.23$ ) intervals. A typical example of the HR response for 1 participant in each group is presented in Figure 1. These findings were supported by the Bland-Altman plots, with all data points being within the 95% levels of agreement (Figure 4).

**Figure 2.** For all participants (n=162), the linear relationship between direct maximal oxygen consumption (VO<sub>2max</sub>) and predicted VO<sub>2max</sub> calculated with the application Myworkout GO. SEE: standard error of the mean.



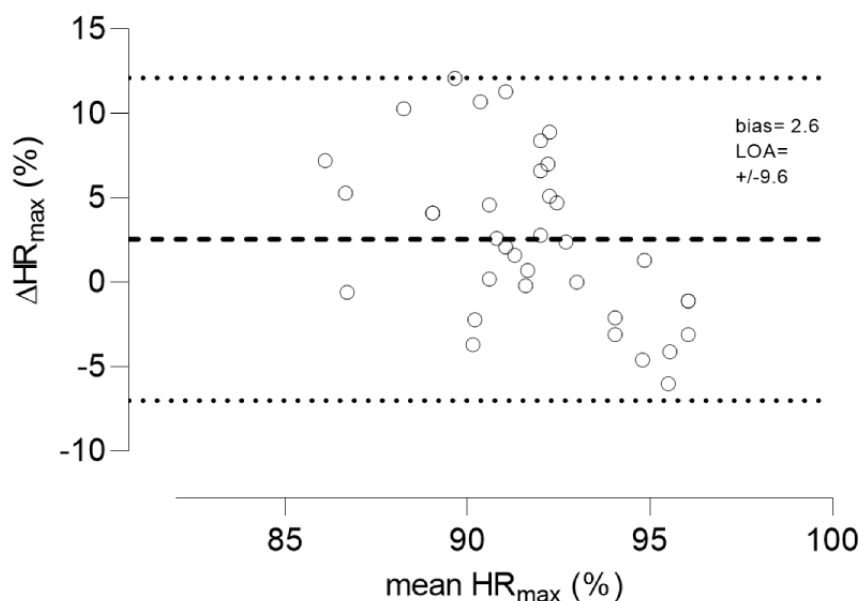
**Figure 3.** Bland-Altman plot showing the mean direct and predicted maximal oxygen consumption (VO<sub>2max</sub>) assessments plotted against the difference (Δ, direct - predicted) of the assessments (n=162). Bias is shown by the dashed line, and the 95% limits of agreement (LOA) are indicated by the dotted lines.



**Table 2.** Age distribution (n=162).

Age (years)	n
17-30	70
30-40	18
40-50	28
50-60	32
60-70	10
>70	4

**Figure 4.** Bland-Altman plot of mean heart rate (HR) response for physiologist-guided and app-guided groups (n=6) for all intervals plotted against the difference ( $\Delta$ , physiologist-guided – app-guided) in HR between groups. Data are presented as percentage (%) of the individual's maximum HR (HR<sub>max</sub>). Bias is shown by the dashed line, and the 95% limits of agreement (LOA) are indicated by the dotted lines.



## Discussion

### Principal Findings

The major novel finding of this study was no significant difference between direct  $VO_{2max}$  measurement (“gold standard”) and the predicted  $VO_{2max}$  measurement using the application Myworkout GO. The 2 methods were highly correlated ( $R^2=0.97$ ,  $P<.001$ ), with an SEE of 2.2 mL/kg/min, which is equal to 4.5% of the average  $VO_{2max}$  in the total sample (mean 49, SD 14 mL/kg/min). The HIIT exercise in the app was tolerated well by the participants, and no adverse events were reported. Additionally, the pilot study demonstrated that the target intensity zone was reached. The calculated means and SEs for the physiologist-guided %HR<sub>max</sub> (mean 93.0, SE 0.4%) and app-guided %HR<sub>max</sub> (mean 90.5, SE 0.7%) exercise for all participants were not significantly different. Based on these results, we concluded that both methods guided individuals to the correct intensity zone (85%-95% HR<sub>max</sub>).

### Comparison With Prior Work

Compared with  $VO_{2max}$  reference data on a treadmill from 3816 healthy men and women aged 20 years to 90 years from the Norwegian population, our data were similar [17]. The baseline  $VO_{2max}$  of the male group (mean age 30, SD 13 years) was similar to the reference data in the age group of 20-30 years (mean 57, SD 10 mL/kg/min vs mean 54, SD 8 mL/kg/min) [17]. The female group (mean age 50, SD 13 years) was also similar to the reference data in the age group of 40-50 years (mean 35, SD 7 mL/kg/min vs mean 38, SD 8 mL/kg/min) [17]. In comparison, Edvardsen et al [14] presented normative  $VO_{2max}$  data from 759 male and female participants in Norway and reported lower numbers for both men in the age group of 20-30

years (mean 49, SD 10 mL/kg/min) and women in the age group of 40-50 years (mean 33, SD 6 mL/kg/min).

More recently, the Fitness Registry and the Importance of Exercise National Database published  $VO_{2max}$  reference standards for 4611 adult men and 3172 women (20-79 years old) obtained from direct  $VO_{2max}$  measurements [18]. Compared with the results from Edvardsen et al [14], these average numbers from the US population are similar for men (mean 48, SD 11 mL/kg/min) but slightly lower for women (mean 28, SD 8 mL/kg/min).

The exercise testing modality has a significant impact on results; the values were 10% to 20% lower when using a cycle ergometer compared with a treadmill in untrained individuals [5]. Moreover, study population, test protocol, exclusion criteria prior to testing, and type of equipment used are some reasons why differences occur across studies. Physical activity level and a smaller sample size may well explain differences in  $VO_{2max}$ , both between the reference data and this study.

### Physical Activity, CRF, and Health

Physical activity can act as primary prevention against more than 35 chronic diseases and should thus be prescribed as medicine [19]. There is, however, a need to translate basic research to clinical practice to make more people move. It is crucial to note that “Nonexercise estimated CRF should not be viewed as a replacement for objective assessment of CRF, especially in some at-risk patient populations” [4]. This is illustrated by the SEE for their equations ranging from an SEE of 3.0 mL/kg/min (9.7%;  $R^2=0.74$ ) reported by Cao et al [20] to an SEE of 5.7 mL/kg/min (12.8%;  $R^2=0.61$ ) reported by Nes et al [21]. Ross and collaborators [4] also concluded that CRF should be measured in clinical practice since it can provide additional information that influences patient management.

After adjustment for age and other risk factors, CRF has been documented to be a strong independent marker of risk for cardiovascular and all-cause mortality. A meta-analysis by Kodama et al [22] extracted 33 studies including nearly 103,000 participants. For every metabolic equivalent (resting metabolic rate or oxygen consumption of 3.5 mL/kg/min) increase in CRF, 13% and 15% reductions in cardiovascular and all-cause mortality, respectively, were observed.

Harb and colleagues [9] calculated the risk of death in their study of 126,356 participants (1991-2015), adjusted for sex, cardiovascular disease, type 2 diabetes, statin use, hypertension, smoking, and body mass index. They concluded that “biological age” based on CRF better predicts all-cause mortality compared with chronological age. Every effort should be undertaken to improve CRF in sedentary adults, since half the reduction in all-cause mortality occurs between the least-fit group and the next least-fit group. However, higher CRF is associated with reduced risk even among participants within the low-fit [23] or low-risk group [24].

CRF is often neglected as a risk marker compared with conditions treatable with drugs or invasive procedures [18]. Wearable technologies claim to provide accurate measurements of HR, energy expenditure, and  $VO_{2max}$ . However, Wallen et al [25] demonstrated that all tested devices measuring HR via photoplethysmography underestimated HR and especially energy expenditure. Thus, it would limit their use for evaluating CRF and training intensity and acting as a weight loss aid. Bent et al [11] documented that wearable optical HR sensors had, on average, an absolute error during activity 30% higher than during rest. Digital biomarker interpretation must take the data quality into account when making health-related decisions.

### Clinical Perspectives

Considering the strong independent value of CRF as a risk marker for cardiovascular and all-cause mortality [22], evaluation of CRF is of utmost importance in a vast number of clinical populations. Patients may encounter different central or peripheral pathologies that cause limitations set by metabolic demands or by one or more of the components of the integrated  $O_2$  transport pathway [26], limitations that may inhibit these individuals' maximal exercise capacity and ability to reach a plateau of  $VO_2$ , consequently attaining  $VO_{2peak}$  instead of  $VO_{2max}$ . Whether Myworkout GO's algorithm will be able to predict symptom-limited  $VO_{2peak}$  as it relates to different patient populations, with similar accuracy as presented in this study with healthy participants, is yet to be determined. However, the submaximal HIIT exercise utilized by the application has high clinical value, as it indeed represents the current state of symptom-limiting exercise capacity. It presents a unique evaluation of exercise tolerance while under controlled conditions and assesses the response from all elements involved in the  $O_2$  pathway, from the atmosphere to the working mitochondria. These results may provide valuable information for clinical practice, both diagnostically and in terms of exercise treatment.

### Practical Applications and Future Directions

Cars, elevators, remote controls, and other modern devices all help to engineer physical activity out of people's lives. Engineering physical activity back into their lives and informing them of the health benefits are paramount. It has also been documented that people will miss less work and be more productive [27]. We sought to close the gap between knowledge and practice. It is well established that exercise is medicine and utilizing smartphone applications, such as Myworkout GO, creates an accessible solution to administer exercise worldwide. The application provides an opportunity to revolutionize health care, particularly in communities with traditionally limited health care access. Consequently, investigations targeting the accuracy of exercise-based CRF prediction in patient populations are warranted. Outside the clinical setting, smartphone applications can in fact utilize available technology such as GPS, barometric pressure, and high-quality map data to automatically track and generate the required information from a free living situation to predict CRF from outdoor workouts. This opens up the possibilities for future research and, more importantly, the population to health-enhancing activity while simultaneously receiving evaluation of relevant health information.

### Strengths and Limitations

There are both strength and limitations to this study. One limitation is the possibility that people who volunteer for participation in an exercise research study are experienced with physical exercise and subsequently have high internal motivation to adhere to the research protocol, causing a selection bias. However, comparison of CRF with reference data [17] revealed that the results for both men and women in this study were similar to those of the general Norwegian population, indicating comparable populations.

The controlled laboratory setting utilized in this study is a strength, as this type of investigation gives great insight into the genuine accuracy of the algorithm when there is compliance with the protocol. However, caution must be taken as to not indiscriminately extrapolate the results from this study to a free-living situation where sincere adherence to the protocol may be muddled with the intention to comply. Correct execution of both the HIIT exercise and in-app registration is crucial for CRF prediction accuracy. Consideration of not only human error but also potential technical complications such as uncalibrated exercise equipment as factors influencing the accuracy of the CRF prediction must occur. Ultimately, the algorithm simply works with what it is given.

Although outside the scope of this study, low-threshold, easily available, outdoor exercise is appealing for many. Speed and inclination from outdoor walking or running can be attained and automatically registered by Myworkout GO and utilized to predict CRF. However, it is prudent to remember that potential limitations to such measurements may exist. For instance, GPS data accuracy and type of surface will influence the input to the CRF prediction, even though the exercise effect of the HIIT sessions may be similar. Thus, to increase the extrapolatory value to free-living situations, compliance with the HIIT

guidance and standardization of the test setting should be emphasized.

### Conclusion

There was no significant difference between direct  $VO_{2max}$  measurement and predicted  $VO_{2max}$  measurement using the application Myworkout GO in the total sample. The 2 methods were highly correlated, with an SEE of 2.2 mL/kg/min, which

is equal to 4.5% of the average  $VO_{2max}$ , in healthy participants who comply with the protocol. The HIIT session (4x4 minutes) incorporated in the application Myworkout GO was tolerated well by the participants. Another goal with Myworkout GO is to give the most time-efficient recommendations to improve CRF for both the healthy population and patients. Precise and effective digital health applications have the potential to transform health care through inexpensive and convenient monitoring outside the clinic.

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### Data Availability

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

### Authors' Contributions

J Helgerud, HH, and J Hoff conceived and designed the experiment. J Helgerud conducted the experiment. J Helgerud and HH analyzed the data and interpreted the results. J Helgerud wrote the manuscript. J Hoff and HH provided critical input and contributed to writing the manuscript.

### Conflicts of Interest

HH is employed by the Medical Rehabilitation Clinic, Myworkout, a section of Myworkout AS. Myworkout AS is the developer of the smartphone application Myworkout GO. J Helgerud and J Hoff are board members and shareholders of Myworkout AS. There are no further disclosures or potential conflicts of interest to report.

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## Abbreviations

- CRF:** cardiorespiratory fitness
- HIIT:** high aerobic intensity interval training
- HR:** heart rate
- HRmax:** maximum HR
- SEE:** standard error of the estimate
- VO<sub>2</sub>max:** maximal oxygen consumption

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Original Paper

# Home Telemonitoring and a Diagnostic Algorithm in the Management of Heart Failure in the Netherlands: Cost-effectiveness Analysis

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## Abstract

**Background:** Heart failure is a major health concern associated with significant morbidity, mortality, and reduced quality of life in patients. Home telemonitoring (HTM) facilitates frequent or continuous assessment of disease signs and symptoms, and it has shown to improve compliance by involving patients in their own care and prevent emergency admissions by facilitating early detection of clinically significant changes. Diagnostic algorithms (DAs) are predictive mathematical relationships that make use of a wide range of collected data for calculating the likelihood of a particular event and use this output for prioritizing patients with regard to their treatment.

**Objective:** This study aims to assess the cost-effectiveness of HTM and a DA in the management of heart failure in the Netherlands. Three interventions were analyzed: usual care, HTM, and HTM plus a DA.

**Methods:** A previously published discrete event simulation model was used. The base-case analysis was performed according to the Dutch guidelines for economic evaluation. Sensitivity, scenario, and value of information analyses were performed. Particular attention was given to the cost-effectiveness of the DA at various levels of diagnostic accuracy of event prediction and to different patient subgroups.

**Results:** HTM plus the DA extendedly dominates HTM alone, and it has a deterministic incremental cost-effectiveness ratio compared with usual care of €27,712 (currency conversion rate in purchasing power parity at the time of study: €1=US \$1.29; further conversions are not applicable in cost-effectiveness terms) per quality-adjusted life year. The model showed robustness in the sensitivity and scenario analyses. HTM plus the DA had a 96.0% probability of being cost-effective at the appropriate €80,000 per quality-adjusted life year threshold. An optimal point for the threshold value for the alarm of the DA in terms of its cost-effectiveness was estimated. New York Heart Association class IV patients were the subgroup with the worst cost-effectiveness results versus usual care, while HTM plus the DA was found to be the most cost-effective for patients aged <65 years and for patients in New York Heart Association class I.

**Conclusions:** Although the increased costs of adopting HTM plus the DA in the management of heart failure may seemingly be an additional strain on scarce health care resources, the results of this study demonstrate that, by increasing patient life expectancy by 1.28 years and reducing their hospitalization rate by 23% when compared with usual care, the use of this technology may be seen as an investment, as HTM plus the DA in its current form extendedly dominates HTM alone and is cost-effective compared with usual care at normally accepted thresholds in the Netherlands.

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**KEYWORDS**

discrete event simulation; cost-effectiveness; early warning systems; home telemonitoring; diagnostic algorithm; heart failure

## Introduction

### Background

Heart failure is a major health concern associated with significant morbidity, mortality, and reduced quality of life in patients. An estimated 64.3 million people worldwide live with heart failure [1]. A meta-analysis based on echocardiographic screening studies in the general population in high-income countries revealed that the prevalence of heart failure is approximately 11.8% in those aged  $\geq 65$  years [2]. In 2019, the Dutch prevalence of heart failure was estimated to be 238,700, with an incidence of 37,400 new cases and 7264 deaths due to heart failure [3]. Accordingly, heart failure is responsible for elevated health care costs in the Netherlands: €17 million (currency conversion rate in purchasing power parity at the time of study: €=US \$1.29; further conversions are not applicable in cost-effectiveness terms) in 2017, corresponding to 8% of the costs for cardiovascular diseases and approximately 1% of the total health care expenditure for that year [4]. Of the total heart failure costs, 45% are attributable to care provided in the hospital and 43% are spent on care for older adults (long-term institutional older adult care, assisted-living facilities for older adults, and home care) [4].

Remote patient monitoring is a patient management approach that uses information and communication technologies to monitor and transmit physiological data related to patient health status between geographically separated individuals [5]. Home telemonitoring (HTM) is the particular case in which the monitoring and transmission of data are performed from the patient's home. HTM facilitates frequent or continuous assessment of disease signs and symptoms, and it has shown to improve compliance by involving patients in their own care and prevent emergency admissions by facilitating early detection of clinically significant changes [6]. The use of information and communication technologies in the management of chronic diseases has become increasingly important, especially since the COVID-19 pandemic when routine care had to be postponed or replaced by remote alternatives. Evidence shows that HTM can have a positive impact on both mortality and hospital admissions [7-9], whereas other studies question the effectiveness [10] and cost-effectiveness [11] of home-based monitoring systems.

Diagnostic algorithms (DAs) can be defined as predictive mathematical relationships that make use of a wide range of collected data for calculating the likelihood of a particular event (eg, death or hospitalization). These algorithms use this output for prioritizing patients with regard to their treatment by raising alarms that trigger follow-up actions if the probability of the event exceeds a predefined threshold. Evidence shows that data-driven approaches looking at trends and patterns of change in recorded parameters improve the accuracy of detecting disease deterioration when compared with clinical decision rules [12-15]. Coupled with the fact that a large number of parameters associated with heart failure events can be measured with HTM,

it is expected that advanced algorithms with better diagnostic performance will result in time efficiency when analyzing the data generated with HTM systems. Therefore, they may improve clinical decision-making by raising alerts in a manner that can be intuitively used by clinicians with a high degree of confidence [16]. However, health care funds are limited, and scarce resources must be allocated to patient subgroups for which new interventions are most beneficial.

### Objectives

The objective of this study was to assess the cost-effectiveness of HTM and a DA for the management of heart failure in the Netherlands. A base-case analysis was performed, and structural and parametric uncertainty was assessed through scenario, sensitivity, and value of information analyses. Furthermore, we focused particularly on the assessment of the cost-effectiveness of the DA at different levels of diagnostic accuracy of event prediction, that is, different points of its receiver operating characteristic (ROC) curve, and on the cost-effectiveness of the interventions under analysis for a wide range of patient subgroups.

## Methods

### Interventions

Three interventions were included in the cost-effectiveness analysis: (1) usual care; (2) HTM, as described in the Trans-European Network—Home-Care Management System (TEN-HMS) original publication [17] (HTM); and (3) HTM with the addition of a DA (HTM+DA).

Usual care consisted of an individualized written management plan by the investigator that described what pharmacological treatment patients should receive, in what order, and how it should be monitored. All patients required a loop diuretic according to the inclusion criteria. The management plan focused on the treatment of left ventricular systolic dysfunction with appropriate doses of angiotensin-converting enzyme inhibitors and  $\beta$ -blockers. If severe symptoms persisted, spironolactone was added to the therapeutic plan according to regional guidelines. Digoxin and anticoagulants were recommended for patients in atrial fibrillation. The patient management plan was sent to and implemented by the patient's primary care physician [17].

HTM, as described in the original publication of the TEN-HMS [17], consisted of monitoring the patient's weight, blood pressure, heart rate, and rhythm twice daily. Values greater than or less than the preset limits were notified automatically to the study nurses, who reviewed the information and took action either directly, for any short-term advice, or through the primary care physician, if long-term changes in therapy were required. Nurses could also manually scan patient data to identify any trends that they considered as requiring action. The study personnel were primarily responsible for the implementation of the management plan in patients assigned to HTM, whereas

the primary care physician and the investigator were kept informed of all contacts.

HTM+DA consisted of a previously described HTM intervention with the addition of a DA published elsewhere [18]. The algorithm used data collected from patients with heart failure who adopted HTM as part of their daily health care. Their hospital records were retrospectively reviewed, and heart failure-related admissions data were collected. The DA used collected data (eg, blood pressure, heart rate, and weight) to predict patient hospitalization. The prediction or classification performance of the algorithm was assessed using an ROC analysis (curve shown in Figure S1 in [Multimedia Appendix 1](#) [17-28]).

### Model Structure

The patient-level discrete event simulation model used for the analysis was developed and described in detail elsewhere [29]. Unlike other published health economic models for heart failure, this is a singular model that includes a wide range of patient characteristics and outcomes. The model consists of a series of regression equations describing the statistical associations between patient characteristics and changes in intermediate and

final outcomes over time. The time-to-event regression equations were estimated using the patient-level data from the TEN-HMS study [17]. The model simulates the time to an outpatient visit, hospitalization, and death. Intermediate outcomes generated from the model are the number of outpatient visits, hospitalizations, and avoided hospitalizations. Final outcomes are the total life years, quality-adjusted life years (QALYs), and costs.

### Model Population

In the base-case analysis, patients were randomly sampled (with replacement) from the entire population included in the TEN-HMS study [17]. The baseline patient and disease characteristics of the study population are shown in [Table 1](#). The presented patient and disease characteristics are a subset of the entire range of patient-level data available in the TEN-HMS study, and they represent the inputs used in the simulation. The patient population was assumed to be representative of the Dutch heart failure patient population.

Each patient was simulated for the three interventions included in the cost-effectiveness analysis: (1) usual care, (2) HTM, and (3) HTM + DA.

**Table 1.** Baseline patient and disease characteristics of the model population.

Baseline characteristics	Value
Sample size, n	426
EF <sup>a</sup> (%), mean (SD)	25.06 (7.58)
Age (years), mean (SD)	67.56 (11.64)
SBP <sup>b</sup> (mm Hg), mean (SD)	114.24 (19.25)
BMI (kg/m <sup>2</sup> ), mean (SD)	26.17 (4.73)
Creatinine (µmol/L), mean (SD)	135.71 (51.98)
<b>NYHA<sup>c</sup> class (%)</b>	
1	79 (18.5)
2	185 (43.4)
3	132 (31)
4	30 (7.1)
Sex (male), n (%)	330 (77.5)
Smoker, n (%)	52 (12.2)
Diabetes, n (%)	149 (35)
COPD <sup>d</sup> , n (%)	104 (24.4)
Recent diagnosis, n (%)	187 (43.9)
No β-blocker medication, n (%)	159 (37.3)
No ACE <sup>e</sup> inhibitor medication, n (%)	79 (18.5)
Myocardial infarction, n (%)	242 (56.8)
Chronic atrial fibrillation, n (%)	112 (26.3)

<sup>a</sup>EF: ejection fraction.

<sup>b</sup>SBP: systolic blood pressure.

<sup>c</sup>NYHA: New York Heart Association.

<sup>d</sup>COPD: chronic obstructive pulmonary disease.

<sup>e</sup>ACE: angiotensin-converting enzyme.

### Base-Case Analysis

The base-case analysis was conducted in accordance with Dutch guidelines for economic evaluations in health care [30]. A societal perspective was adopted, which considered all costs inside the health care sector, patient and family sector, and other sectors, regardless of who is paying for those costs, as well as productivity losses assessed using the friction cost method [31], and future unrelated medical costs. All costs were reported in

2020 euros, where 2020 figures were not available, and older costs were inflated using the general price index from the Dutch Central Bureau of Statistics [32]. Health outcomes (effects) were presented in life years and QALYs and discounted at 4%, whereas costs were discounted at 1.5%. The analysis adopted a lifetime horizon, and the model was run for 1000 patients. An overview of the model input parameters is presented in Table 2 and is explained in detail in the following sections.

**Table 2.** Model input parameters.

Parameter (source)	Mean value	Probabilistic sensitivity analysis		Deterministic sensitivity analysis (95% CI)	Observations
		SE	Distribution		
<b>Model settings</b>					
Discount rate (costs, %) [30]	4	N/A <sup>a</sup>	N/A	0-8	Dutch EE <sup>b</sup> guidelines
Discount rate (effects, %) [30]	1.5	N/A	N/A	0-3	Dutch EE guideline
Time horizon [30]	Lifetime	N/A	N/A	N/A	Dutch EE guidelines
<b>Treatment effect</b>					
Time-to-death (distribution) [29]	Weibull	N/A	N/A	N/A	Uncertainty assessed in the scenario analyses
Time-to-hospitalization (distribution) [29]	Log-normal	N/A	N/A	N/A	Uncertainty assessed in the scenario analyses
Time-to-outpatient visit (UC <sup>c</sup> , months) [17]	2.81	10% of the mean	Normal	2.46-3.13	None
Time-to-outpatient visit (HTM <sup>d</sup> , months) [17]	1.69	10% of the mean	Normal	1.59-1.79	None
<b>Diagnostic algorithm</b>					
Sensitivity [18]	0.52	N/A	N/A	N/A	Uncertainty assessed in the scenario analyses for the DA <sup>e</sup>
False-positive rate [18]	0.03	N/A	N/A	N/A	Uncertainty assessed in the scenario analyses for the DA
Proportion avoidable hospitalizations (%) [33]	50	20% of the mean	Normal	33.6-66.4	None
<b>Costs (€)</b>					
Outpatient visit (UC) [17,19]	44.50	20% of the mean	Gamma	30.94-60.08	None
Outpatient visit (HTM) [17,19]	43.30	20% of the mean	Gamma	30.11-58.46	None
Other HF <sup>f</sup> -related care provider contacts (UC) [17,19]	188.38	20% of the mean	Gamma	130.98-254.33	None
Other HF-related care provider contacts (HTM) [17,19]	623.61	20% of the mean	Gamma	433.59-841.93	None
Hospitalization [17,19,20]	4404.46	20% of the mean	Gamma	3062.36-5946.44	None
HTM device (per year) [21]	1257.75	20% of the mean	Gamma	1059.87-1469.69	None
Managing alarm [19]	18.38	20% of the mean	Gamma	12.78-24.81	None
Drug costs (per year) [17,22]	286.44	20% of the mean	Gamma	199.16-386.72	None
Traveling expenses (outpatient visit) [17,19,23]	3.75	20% of the mean	Gamma	2.61-5.06	None
Traveling expenses (hospitalization) [19,23]	4.68	20% of the mean	Gamma	3.25-6.32	None

Parameter (source)	Mean value	Probabilistic sensitivity analysis		Deterministic sensitivity analysis (95% CI)	Observations
		SE	Distribution		
Informal care (per year) [17,19,24,34]	2098.28	20% of the mean	Gamma	1458.90-2832.88	None
<b>Utilities</b>					
NYHA <sup>§</sup> class I [21]	0.87976	0.00827	Beta	0.86588-0.89308	None
NYHA class II [21]	0.71178	0.00944	Beta	0.69615-0.72720	None
NYHA class III [21]	0.61405	0.01349	Beta	0.59176-0.63614	None
NYHA class IV [21]	0.49228	0.03032	Beta	0.44243-0.54220	None
Utility multiplier (outpatient visit)	1	N/A	N/A	N/A	Assumption; excluded from uncertainty analyses <sup>h</sup>
Utility multiplier (hospitalization) [35]	0.82	10% of the mean	Normal	0.69-0.95	None

<sup>a</sup>N/A: not applicable.

<sup>b</sup>EE: economic evaluation.

<sup>c</sup>UC: usual care.

<sup>d</sup>HTM: home telemonitoring.

<sup>e</sup>DA: diagnostic algorithm.

<sup>f</sup>HF: heart failure.

<sup>§</sup>NYHA: New York Heart Association.

<sup>h</sup>Depending on the rate of outpatient visits, positive values may generate higher quality-adjusted life years when compared with life years.

### Treatment Effect of HTM (Compared With Usual Care)

When compared with usual care, HTM is modeled to increase time-to-hospitalization and time-to-death while decreasing time-to-outpatient visits.

The treatment effect of HTM on time-to-hospitalization and time-to-death was modeled using parametric models (exponential, Weibull, log-normal, log-logistic, Gompertz, and generalized gamma) fitted to empirical time-to-hospitalization and time-to-death data (Kaplan-Meier curves) for HTM and usual care from the TEN-HMS trial [17]. The models assumed proportional hazards between HTM and usual care. In the base-case analysis, a Weibull distribution was used to extrapolate time-to-death and a log-normal distribution to extrapolate time-to-hospitalization. The distributions were chosen according to the recommendations issued by the Decision Support Unit commissioned by the National Institute for Health and Clinical Excellence [36]. Details of the survival analysis can be found in the original publication of the model [29].

To predict in-hospital patient mortality, we ran a logistic regression where the probability of dying in the hospital was explained by age, sex, previous history of myocardial infarction or chronic atrial fibrillation, comorbidities (diabetes or chronic obstructive pulmonary disease), and the number of previous hospitalizations.

The time-to-outpatient visit was a parameter set by the user in the model. There is no periodic outpatient visit suggested in Dutch or international guidelines, as it is recommended that the time to the next consultation be scheduled by the accompanying

physician and based on the clinical status of the patient [37,38]. Therefore, we assumed that the time-to-outpatient visit for the population under analysis is properly represented by the observations in the TEN-HMS study [17]: 2.81 months for usual care and 1.69 months for HTM-based interventions. This assumption is strengthened by the fact that 37.8% (161/426) of patients included in the TEN-HMS trial were treated in Dutch hospitals [17].

### Treatment Effect of the DA (When Added to HTM)

To model the treatment effect of adding the DA to the HTM, we considered the algorithm as a binary test for predicting hospitalization. Depending on the threshold value for the alarm of the DA, it has a certain sensitivity and specificity. The treatment effect of the DA is included in the model through its sensitivity and false-positive rate (same as  $1 - \text{specificity}$ ).

Sensitivity corresponds to the probability of correctly predicting a hospitalization when that would be the next event to be processed in the model. Hospitalization is avoided in the simulation when it is correctly detected and clinically avoidable; the latter is approximated by the average for potentially preventable hospitalizations in heart failure reported in the literature, which is 50% [33]. Thus, assuming the sensitivity of the alarm is 0.52 and that 50% of hospitalizations are clinically avoidable,  $0.52 \times 50\% = 26\%$  would be the overall probability of avoiding hospitalization.

The false-positive rate represents the proportion of false-positive alarms. Hence, if the false-positive rate of the DA (with daily alarms) was 0.03 and there were 100 days between the previous and current events simulated in the model, there would be 3



false-positive alarms during the period between both events. The false-positive alarms are included in the model through the cost of managing those alarms, and they are assumed to have no consequences for health outcomes.

In our study, we used the DA developed using multiresolution analysis signals for diastolic blood pressure and weight collected daily by a noninvasive HTM for predicting hospitalization published elsewhere [18]. The sensitivity and false-positive rate in the base-case analysis were set to the figures reported in that study: 0.52 and 0.03, respectively.

### Outpatient Visit Costs

The office visits reported in the TEN-HMS trial discriminated among general practitioner, nurse, and specialist visits for both usual care and HTM [17]. We assumed that this partition was representative of Dutch clinical practices for the population under analysis. Through calculating the weighted average between the product of the visit type and its reference price in the Dutch Costing Manual [19], we estimated the costs of an outpatient visit to be €44.50 for usual care and €43.30 for HTM (Table S1 in [Multimedia Appendix 1](#)).

### Costs of Other Heart Failure–Related Care Provider Contacts

The number and type of health care resources used (emergency room visits, office visits, home visits, and telephone calls) during the TEN-HMS trial were reported for usual care and HTM for 240 follow-up days [17]. The TEN-HMS data were also assumed to represent Dutch clinical practices for heart failure management. To estimate the costs of other heart failure–related care provider contacts, we excluded office visits, as they were used separately for estimating the cost per outpatient visit (see *Outpatient Visit Costs* section). We converted the resources used during the follow-up period in the TEN-HMS trial (240 days) to yearly rates per patient and multiplied these figures by the cost of the resources included in the Dutch Costing Manual [19]. The estimated costs of contact with other heart failure–related care providers per year were €188.38 for usual care and €623.61 for HTM (Table S2 in [Multimedia Appendix 1](#)).

### Hospitalization Costs

The average hospital stay in the Netherlands for heart failure was 8.6 days for men and 8.4 days for women [20]. The sex partition of the population included in the TEN-HMS trial was 77.5% (330/426) men and 22.5% (96/426) women [17]. Using the average cost of a hospital day from the Dutch Costing Manual [19] and the weighted average of hospital days according to sex, we estimated the average costs per hospitalization at €404.46 (Table S3 in [Multimedia Appendix 1](#)).

### HTM Costs

We used the midpoint of the telemonitoring costs from the range of yearly equipment and service fees and the installment fee (every 5 years) reported elsewhere [21] to obtain a yearly cost estimate of €1257.75 for HTM. In addition, we used the cost for a general practitioner teleconsultation reported in the Dutch

Costing Manual [19] (€18.38) to manage false-positive alarms raised by the DA (Table S4 in [Multimedia Appendix 1](#)).

### Drug Costs

The TEN-HMS database contains information about the drugs used by each patient. Every drug reported to have been used in >5% of the total patients was included in the cost analysis. The daily dose assumptions for each drug were obtained from figures reported elsewhere [25] and confirmed by expert opinion. The representativeness of the TEN-HMS trial for Dutch clinical practices for the considered population is discussed earlier in the text and assumed for drug use.

The daily drug costs were based on the cheapest option available in the Z-index [22] and calculated using the following formula from the Dutch Costing Manual [19]: Drug costs=pharmacists purchase price (Z-index)–clawback (8.3%)+value added tax (6%)+pharmacy dispensing fee. The pharmacy dispensing fee was calculated by dividing the total fee by the number of units in the considered presentation and multiplying it by the number of units taken daily. The costs of insulin therapy were not available in the Z-index database and were extracted from the literature [26].

The total average drug cost per patient per year was estimated at €286.44 (Table S5 in [Multimedia Appendix 1](#) shows the breakdown of drug costs included in the model).

### Informal Care Costs

The TEN-HMS database contained information on the burden to others reported at baseline for 98.6% (420/426) of the patients. Possible answers were *no*, *very little*, *a little*, *some*, *a lot*, and *very much*. These were modeled to correspond to 0%, 2%, 4%, 6%, 8%, and 10% of the time spent on informal care during a 16-hour day, respectively. After analyzing these data based on the New York Heart Association (NYHA) classification, we determined that there were no significant differences between classes (Table S6 in [Multimedia Appendix 1](#)), and we used the average of the whole population to obtain informal care costs. The total average cost of informal care per patient per year (€2098.28) was obtained by multiplying the average hours of informal care per 16-hour day by 365.25 days and by the hourly cost of informal care from the Dutch Costing Manual [19] (Table S7 in [Multimedia Appendix 1](#)).

### Traveling Expenses

Traveling expenses were calculated based on Kanters et al [23] and added to the costs of outpatient visits and hospitalizations (Table S8 in [Multimedia Appendix 1](#)).

### Costs Related to Productivity Losses

Because we used a patient-level simulation model, we could include age- and sex-specific productivity costs for each individual patient until 65 years of age, after which we assumed that patients did not incur further productivity costs.

Productivity losses were assigned to hospitalizations of patients who were considered working at baseline. We assumed that a hospitalized patient incurs productivity costs for 1 whole month, as it seems unlikely that the patient will be able to return to work immediately after being hospitalized. We further assumed

that the working status did not change during the model, which led to the exclusion of long-term productivity costs from the model. We used the proportion of patients assumed to be working per NYHA class based on expert opinions reported elsewhere [25]. The working probability of each patient was adjusted using an age- and sex-specific net labor participation rate for the general population [34]. The total cost per day was calculated using age- and sex-specific data on working hours per week and hourly labor cost [24] (Table S9 in [Multimedia Appendix 1](#) shows the inputs for the calculation of productivity costs, and Table S10 in [Multimedia Appendix 1](#) shows an example of the costs incurred by a hypothetical patient).

### Future Unrelated Medical Costs

Dutch guidelines require the inclusion of additional costs from unrelated diseases during the life years gained with interventions that extend life expectancy [30]. We extracted the estimates of per capita health care expenditures based on age and sex from the Practical Application to Include Disease Costs 3.0 tool and included those costs for each patient individually during the simulation [27,39] (Table S11 in [Multimedia Appendix 1](#)).

### Health Outcomes and Utilities

QALYs were obtained by weighing life years with patient utility over time. Utilities were attributed to each patient at the start of the simulation according to their NYHA class at baseline and to NYHA class-specific utility values reported elsewhere [21] (Table S12 in [Multimedia Appendix 1](#)). The utilities change over time with events occurring in the simulation. It was assumed that there were no utility changes resulting from outpatient visits and that hospitalizations resulted in a decrease in utility by a factor of 0.82, following the change in utility observed between NYHA classes reported in another study published for a similar heart failure population [35]. We assumed that the disutility factor from hospitalization should be limited to 3 events.

On the basis of the equation estimated by Ara and Brazier for the utilities for the general UK population (equation S1 in [Multimedia Appendix 1](#)), age-sex-specific utilities attributed at baseline were capped, and a decrement factor for aging was implemented [28].

### Cost-effectiveness

The average outcome per patient is presented for each intervention. The incremental cost-effectiveness ratio (ICER) was calculated as the difference in the average total cost per patient divided by the difference in the average number of QALYs per patient (€/QALY). The calculated ICER was then compared with the Dutch cost-effectiveness threshold. The intervention can be considered cost-effective if the calculated ICER is lower than the appropriate cost-effectiveness threshold for the population and the situation under analysis.

The cost-effectiveness threshold in the Netherlands depends on the burden of disease as measured by the fraction of QALYs that people lose relative to the situation in which the disease had been absent (proportional shortfall) [40-42]. The appropriate cost-effectiveness threshold, which represents the societal willingness to pay for an additional QALY for that specific

patient population, can be calculated using the Institute for Medical Technology Assessment Disease Burden Calculator [43].

### Sensitivity and Scenario Analyses

Parameter uncertainty was assessed using deterministic sensitivity analyses [44]. The joint parameter uncertainty was explored through probabilistic sensitivity analysis, including the parameter distributions specified in [Table 2](#) [45,46]. Following the methodology for addressing uncertainty in discrete event simulation models published elsewhere [47], probabilistic sensitivity analysis was implemented as a double loop: an inner loop, in which a predetermined number of patients were sampled with replacement from the baseline population, and an outer loop, in which the values of the input parameters of the model were randomly drawn. The results of a probabilistic sensitivity analysis with an inner loop of 100 patients and an outer loop of 500 iterations were plotted on the cost-effectiveness plane [46,48,49]. Cost-effectiveness acceptability curves were drawn [50,51].

Scenario analyses were run, in which key structural assumptions regarding time-to-death and time-to-hospitalization parametric survival models, time-to-outpatient visits, utilities, and costs were varied to estimate the impact of these assumptions on the outcomes.

### Value of Information Analysis

The guidelines for economic evaluations in the Netherlands require calculation of the expected value of perfect information (EVPI) when the probability that the intervention is cost-effective at the appropriate cost-effectiveness threshold is <100% [30]. EVPI per patient is calculated as the average of the maximum net benefits in each probabilistic sensitivity analysis iteration minus the maximum average net benefit for the interventions considered in the analysis [52-54]. The population EVPI is calculated by multiplying EVPI per patient by the size of the potential population benefiting from the new intervention across the time span for which the recommendation resulting from the value of information analysis is applicable. We assumed 5 years for the expected applicability of the recommendation, and we estimated the number of patients eligible for HTM-based interventions in the Netherlands from 2020 to 2024 to be 53,140, 55,009, 56,943, 58,946, and 61,019 [55-57]. We discounted EVPI at 4% per year.

### Cost-effectiveness of the DA

In the context of the predictive performance of binary diagnostic tests, an ROC curve is a graph that illustrates the diagnostic ability of a binary classifier system by plotting the sensitivity values against the false-positive rates (1-specificity) at various threshold settings.

To properly assess the cost-effectiveness of the DA when added to the HTM intervention, we ran the model at different points of the ROC curve of the DA other than the base-case scenario, thus inferring at which combinations of sensitivity and specificity the DA would be the most cost-effective. In other words, this analysis aimed to determine the operating point at which the threshold of the DA should be set to achieve the best

balance between costs and health outcomes for the HTM+DA intervention. The values of sensitivity and false-positive rate were measured using Graphreader [58].

### Subgroup Analyses

We analyzed a wide range of subgroups by varying patient and disease characteristics, as presented in Table 1. We created 2 subgroups based on age (<65 and ≥65 years) and 2 subgroups based on the ejection fraction (<25% and >25%). We further analyzed patients belonging to each NYHA class separately, creating 4 subgroups. Finally, each dichotomous variable generated 2 subgroups (characteristic present or not present). In total, we analyzed 26 patient subgroups.

### Ethics Approval

As this is a mathematical simulation study, ethics approval was not applicable.

## Results

### Base-Case Analysis

The main results of the base-case analysis are summarized in Table 3 (average outcomes per patient) and Table 4 (incremental cost-effectiveness ratios).

Usual care patients experienced approximately 3 outpatient visits per year less than HTM-based interventions. Conversely,

HTM results in a decrease in the yearly rate of hospitalizations compared with usual care (1.64 vs 1.70). This decrease is even more pronounced when the DA is added to HTM, as 0.45 (95% CI 0-2.12) hospitalizations per year are avoided owing to the DA.

Usual care was the intervention with the lowest total discounted costs (€46,879), followed by HTM (€60,343), and HTM+DA (€65,008). On average, patients were expected to survive 2.18 discounted years with usual care, 2.96 with HTM, and 3.44 with HTM+DA, corresponding to 1.12, 1.51, and 1.78 discounted QALYs, respectively. The hierarchical analysis of the costs and QALYs of the 3 interventions showed that HTM is extendedly dominated by HTM+DA, as the ICER of HTM compared with usual care (€34,449/QALY) is higher than that of HTM+DA (the next, more effective, alternative) compared with usual care (€27,712/QALY).

The standardized quality-adjusted life expectancy for the population included in the analysis (approximately 67 years of age and 78% of male patients) was 14.7 QALYs. The total expected undiscounted QALYs accrued with the current standard of care (usual care) in the model being 1.16, which indicates that 92.1% of normal quality-adjusted life expectancy is lost owing to the disease. In this situation, the appropriate cost-effectiveness threshold using the proportional shortfall approach was €80,000 per QALY.

**Table 3.** Average outcomes per patient in the base-case analysis (n=1000).

Average outcomes per patient	UC <sup>a</sup>	HTM <sup>b</sup>	HTM+DA <sup>c</sup>
<b>Intermediate outcomes (events per year)</b>			
Outpatient visits	3.60	6.62	6.63
Hospitalizations	1.70	1.64	1.31
Avoided hospitalizations	— <sup>d</sup>	—	0.45 <sup>e</sup>
<b>Death type</b>			
Death in hospital, n (%)	472 (47.2)	642 (64.2)	585 (58.5)
Death (other), n (%)	528 (52.8)	358 (35.8)	415 (41.5)
<b>Final outcomes (discounted)</b>			
Total costs (€)	46,879	60,343	65,008
Total life years	2.18	2.96	3.44
Total QALYs <sup>f</sup>	1.12	1.51	1.78

<sup>a</sup>UC: usual care.

<sup>b</sup>HTM: home telemonitoring.

<sup>c</sup>DA: diagnostic algorithm.

<sup>d</sup>Not available.

<sup>e</sup>Avoided hospitalizations within the HTM+DA intervention group.

<sup>f</sup>QALY: quality-adjusted life year.

**Table 4.** Incremental cost-effectiveness ratios.

Incremental cost-effectiveness analysis	HTM <sup>a</sup> vs UC <sup>b</sup>	HTM+DA <sup>c</sup> vs HTM <sup>d</sup>	HTM+DA vs UC
Δ€	13,465	4665	18,129
ΔQALY <sup>e</sup>	0.39	0.26	0.65
Δ€ΔQALY	€34,449 <sup>f</sup>	€17,713	€27,712

<sup>a</sup>HTM: home telemonitoring.

<sup>b</sup>UC: usual care.

<sup>c</sup>DA: diagnostic algorithm.

<sup>d</sup>Extendedly dominated by HTM+DA. Extended dominance was investigated by ranking the 3 interventions (HTM+DA, HTM, and UC) according to their effectiveness and calculating the ICER to the next best alternative (ie, HTM+DA vs HTM and HTM vs UC). When the cost-effectiveness of HTM versus UC is worse, that is, the ICER is higher than that of HTM+DA vs HTM, HTM is extendedly dominated by HTM+DA. HTM should not be adopted because a combination of the standard of care (UC) and the most effective treatment alternative (HTM+DA) generates better outcomes than the extendedly dominated treatment alternative (HTM).

<sup>e</sup>QALY: quality-adjusted life year.

### Sensitivity and Scenario Analyses

Considering the extended dominance of HTM+DA over HTM, univariate sensitivity analyses were performed only for the HTM+DA versus usual care comparison. The results of the 5 input parameters with the largest effects on the ICER are presented in the tornado diagram in [Figure 1](#). All ICERs remained below the threshold of €80,000/QALY.

The probabilistic sensitivity analysis outcomes plotted in the cost-effectiveness plane for each pairwise comparison show that the great majority of simulations fall in the northeast quadrant; that is, interventions have higher costs and accrue more QALYs than their comparators ([Figure 2](#)). The probabilistic ICER between HTM+DA and usual care was similar to that found in the base-case analysis: €25,864/QALY (95% CI 15,527-54,151). The cost-effectiveness acceptability curves for the 3 interventions show that usual care is expected

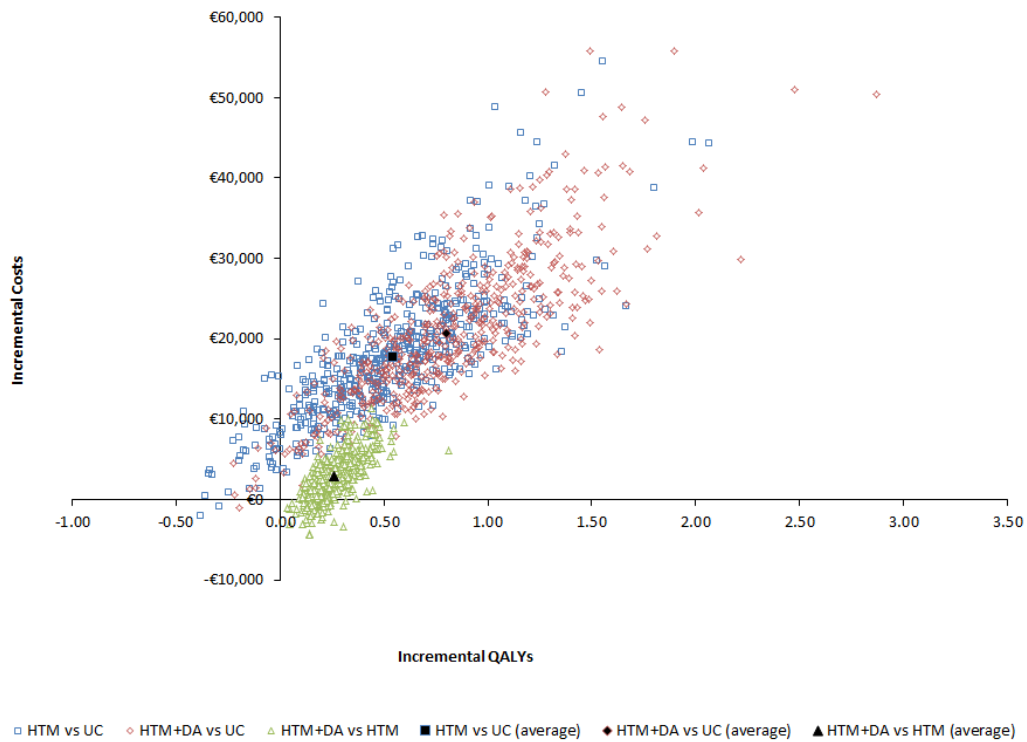
to be the most cost-effective at low willingness-to-pay thresholds, HTM is never the most cost-effective intervention, and HTM+DA becomes the intervention most likely to be cost-effective from €25,864 per QALY upward, reaching a 96.0% probability at the appropriate cost-effectiveness threshold of €80,000 per QALY ([Figure 3](#)).

The results of the scenario analyses assessing the structural assumptions of the model are summarized in Table S13 in [Multimedia Appendix 1](#). The scenario with the highest impact on the ICER was the one where a health care perspective was taken, which resulted in an ICER between HTM+DA and usual care of €14,408/QALY (-48.0% when compared with the base-case analysis). In contrast, the scenario taking all costs from the upper bound of the 95% CIs was the one with the highest ICER (€31,829/QALY). All ICERs from the scenario analyses remained below the threshold of €80,000 per QALY.

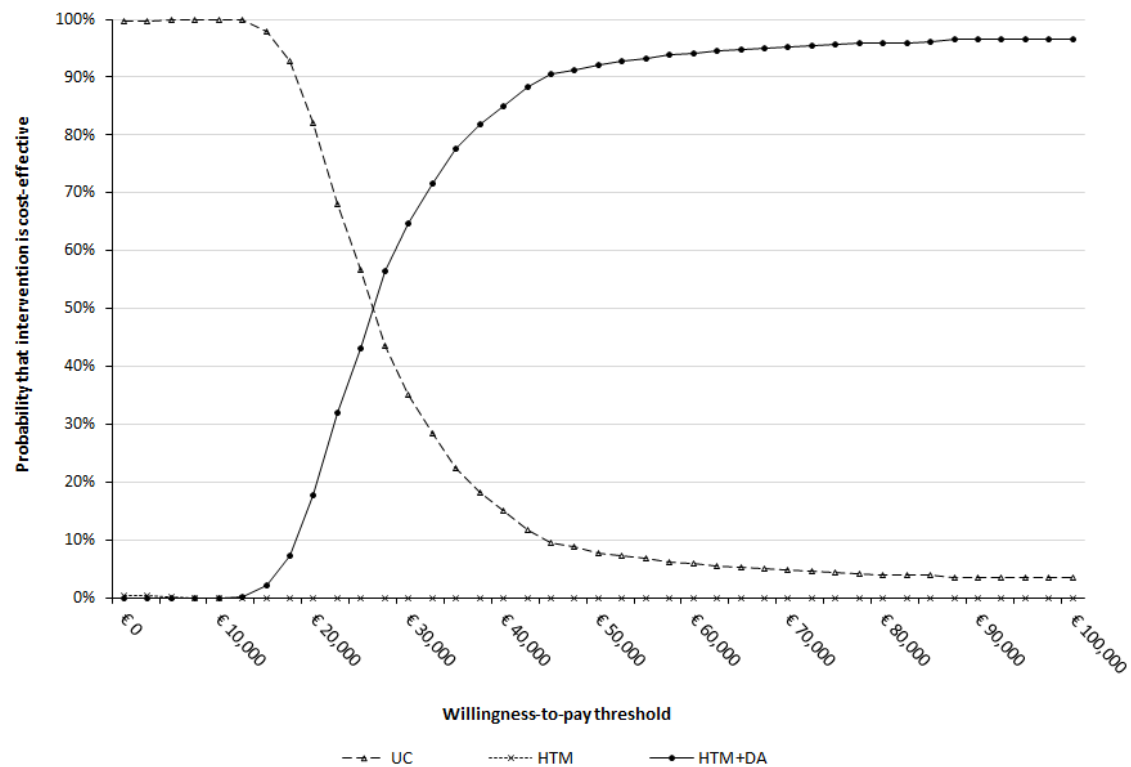
**Figure 1.** Tornado diagram for the home telemonitoring plus diagnostic algorithms vs usual care comparison. ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life year.



**Figure 2.** Incremental cost-effectiveness plane. DA: diagnostic algorithm; HTM: home telemonitoring; QALY: quality-adjusted life year; UC: usual care.



**Figure 3.** Cost-effectiveness acceptability curve. DA: diagnostic algorithm; HTM: home telemonitoring; UC: usual care.



### Value of Information Analysis

In the base-case analysis, at the appropriate threshold of €80,000 per QALY, the probability of HTM+DA being cost-effective was 96.0%. The calculated EVPI per patient was €341. With an estimated number of patients eligible for the HTM-based interventions in the Netherlands being 253,118 (after discounting) from 2020 to 2024, the population EVPI was estimated at €6,383,575.

### Cost-effectiveness of the DA

The results for the treatment scenarios, assuming different characteristics of the DA, are presented for the comparison of

HTM+DA with usual care in Table 5. Increasing the sensitivity of the DA by setting a lower threshold for the alarm to go off, which entails an increase in the false-positive rate (decreased specificity), resulted in a higher number of avoided hospitalizations, life years, and QALYs, but with higher costs. Alternatively, decreasing sensitivity (ie, setting a higher threshold for the alarm) resulted in lower costs but worse health outcomes. From the scenarios tested, the most cost-effective was scenario 3, where the sensitivity was set to 0.600 and the false-positive rate to 0.068. In the scenario tests, moving away from that point in either direction of the ROC curve resulted in higher ICERs (ICER range: €25,734/QALY-€35,560/QALY).

**Table 5.** Results of the scenario analyses for the diagnostic algorithm (DA).

Average outcomes per patient (HTM <sup>a</sup> +DA)	DA scenarios					
	1 (sens <sup>b</sup> : 0.200; FPR <sup>c</sup> : 0.007)	2 (sens: 0.400; FPR: 0.024)	BC <sup>d</sup> (sens: 0.520; FPR: 0.030)	3 (sens: 0.600 FPR: 0.068)	4 (sens: 0.800; FPR: 0.194)	5 (sens: 0.950; FPR: 0.562)
<b>Intermediate outcomes (events per year)</b>						
Outpatient visits	6.63	6.64	6.63	6.62	6.62	6.63
Hospitalizations	1.52	1.36	1.31	1.23	1.10	1.00
Avoided hospitalizations	0.18	0.33	0.45	0.56	0.76	0.92
<b>Final outcomes</b>						
Total costs, €	62,085	63,394	65,008	64,163	71,016	82,108
Total life years	3.14	3.29	3.44	3.43	3.73	3.99
Total QALYs <sup>e</sup>	1.61	1.70	1.78	1.80	1.96	2.11
<b>ICER<sup>f</sup></b>						
Versus UC <sup>g</sup> (€/QALY)	30,984	28,881	27,712	25,734	29,004	35,560
Change vs base case (%)	+11.8	+4.2	0	-7.1	+4.7	+28.3

<sup>a</sup>HTM: home telemonitoring.

<sup>b</sup>sens: sensitivity.

<sup>c</sup>FPR: false-positive rate.

<sup>d</sup>BC: base case.

<sup>e</sup>QALY: quality-adjusted life year.

<sup>f</sup>ICER: incremental cost-effectiveness ratio.

<sup>g</sup>UC: usual care.

### Subgroup Analyses

A summary of the cost-effectiveness results of subgroup analyses is presented in [Table 6](#). Because each subgroup was created from a subset of the population in the TEN-HMS database [17], the characteristics of the baseline population for each subgroup may differ. The baseline patient and disease characteristics of the model population for each of the analyzed subgroups are presented in Tables S1-S26 in [Multimedia Appendix 2](#). All ICER changes versus the base-case concern the comparison between HTM+DA and usual care.

Although many other subgroups did not show such a high variation in the ICER, as this is a ratio that depends on the simultaneous variation of costs and QALYs for each of the interventions being compared, large differences in the final outcomes were observed for some subgroups. Male patients (especially when compared with female patients) and patients from NYHA class III, with diabetes, with chronic obstructive

pulmonary disease, not on  $\beta$ -blocker medication, not on angiotensin-converting enzyme medication, with a history of myocardial infarction, and with a history of chronic atrial fibrillation showed a considerable decrease in QALYs for both HTM+DA and usual care. For those subgroups, given that we were dealing with dichotomous variables, the complementary subgroups resulted in higher QALYs (ie, better health outcomes), with the exception of smokers versus nonsmokers, where the comparison showed small differences in QALYs and costs.

For all subgroups that showed a decrease in QALYs, a decrease in costs was also observed. This corroborates the positive correlation between costs and effects that were noticeable in the incremental cost-effectiveness plane shown in [Figure 2](#). Hence, a decrease in life expectancy, and therefore QALYs, is associated with increased ICERs when compared with the base-case analysis.

**Table 6.** Subgroup analyses: summary of cost-effectiveness results.

Number	Subgroup <sup>a</sup>	Costs (€)			QALYs <sup>b</sup>			ICER <sup>c</sup> (€/QALY)	
		UC <sup>d</sup>	HTM <sup>e</sup>	HTM+DA <sup>f</sup>	UC	HTM <sup>g</sup>	HTM+DA	HTM+DA vs UC	Percentage vs base case
—	Baseline population	46,879	60,343	65,008	1.12	1.51	1.78	27,712	0.0
1	Age <65 years	59,543	75,311	79,144	1.78	2.25	2.64	22,830	-17.6
2	Age ≥65 years	39,380	52,035	56,483	0.82	1.14	1.32	34,368	+24.0
3	Ejection fraction <25%	45,516	60,745	64,906	1.22	1.67	1.94	26,813	-3.2
4	Ejection fraction ≥25%	46,843	61,279	65,606	1.06	1.39	1.65	31,372	+13.2
5	NYHA <sup>h</sup> class I <sup>i</sup>	53,679	72,656	77,377	1.84	2.51	2.88	22,870	-17.5
6	NYHA class II	48,659	64,094	67,515	1.24	1.63	1.90	28,827	+4.0
7	NYHA class III	43,142	51,046	54,454	0.80	1.00	1.18	29,759	+7.4
8	NYHA class IV	36,821	45,218	48,957	0.38	0.50	0.61	52,727	+90.3
9	Sex: male	45,762	57,518	61,122	1.08	1.36	1.60	29,777	+7.5
10	Sex: female	51,148	68,937	75,954	1.53	2.05	2.38	29,038	+4.8
11	Smoker: yes	49,819	62,956	64,973	1.18	1.48	1.73	27,765	+0.2
12	Smoker: no	45,741	60,614	64,392	1.13	1.49	1.74	30,208	+9.0
13	Diabetes: yes	43,213	55,144	59,211	0.96	1.26	1.48	30,624	+10.5
14	Diabetes: no	48,611	60,287	65,193	1.27	1.59	1.86	27,980	+1.0
15	COPD <sup>j</sup> : yes	39,386	47,599	52,293	0.80	1.02	1.24	29,560	+6.7
16	COPD: no	49,180	67,014	70,128	1.23	1.67	1.92	30,105	+8.6
17	Recent diagnosis: yes	54,103	69,207	74,122	1.53	1.90	2.20	29,748	+7.3
18	Recent diagnosis: no	42,619	53,123	56,272	0.91	1.18	1.39	28,567	+3.1
19	No β-blocker medication: yes	38,967	48,709	50,661	0.70	0.92	1.09	29,830	+7.6
20	No β-blocker medication: no	51,211	67,252	71,213	1.41	1.85	2.15	27,127	-2.1
21	No ACE <sup>k</sup> inhibitor medication: yes	39,967	52,165	54,888	0.76	1.04	1.21	32,921	+18.8
22	No ACE inhibitor medication: no	47,208	61,294	65,897	1.20	1.57	1.84	29,424	+6.2
23	Myocardial infarction: yes	43,366	57,360	61,261	0.99	1.33	1.56	30,958	+11.7
24	Myocardial infarction: no	51,222	64,252	69,338	1.41	1.79	2.10	26,195	-5.5
25	Chronic atrial fibrillation: yes	38,205	49,469	53,452	0.72	1.02	1.19	32,415	+17.0
26	Chronic atrial fibrillation: no	50,164	64,086	68,856	1.31	1.71	2.01	26,812	-3.2

<sup>a</sup>Because each subgroup was created from a subset of the population in the TEN-HMS database [17], the characteristics of the baseline population for each subgroup may differ. The baseline patient and disease characteristics of the model population for each of the analyzed subgroups are presented in Tables S1-S26 in [Multimedia Appendix 2](#).

<sup>b</sup>QALY: quality-adjusted life year.



<sup>c</sup>ICER: incremental cost-effectiveness ratio.

<sup>d</sup>UC: usual care.

<sup>e</sup>HTM: home telemonitoring.

<sup>f</sup>DA: diagnostic algorithm.

<sup>g</sup>HTM is extendedly dominated by HTM+DA in all analyzed subgroups. The ICER comparison against the base case is shown only for HTM+DA versus UC.

<sup>h</sup>NYHA: New York Heart Association.

<sup>i</sup>The subgroup of patients with NYHA class IV registered the highest deviation from the base-case analysis results, with an ICER of €52,727/QALY (+90.3%). By contrast, the subgroups with better cost-effectiveness ratios were patients <65 years of age and patients belonging to NYHA class I (22,830/QALY [-17.6%] and €22,870/QALY [-17.5%], respectively).

<sup>j</sup>COPD: chronic obstructive pulmonary disease.

<sup>k</sup>ACE: angiotensin-converting enzyme.

## Discussion

### Principal Findings

This study aimed to assess the cost-effectiveness of HTM and a DA in the management of heart failure in the Netherlands. It used a previously validated patient-level discrete event simulation model [29] for analyzing 3 separate interventions: usual care, HTM, and HTM+DA. The base-case analysis determined that HTM is extendedly dominated by HTM+DA, with the latter intervention being cost-effective versus usual care at a deterministic ICER of €27,712 per QALY gained (Table 4).

The cost-effectiveness of the DA was carefully examined through creating various scenarios with different values for sensitivity and false-positive rate from the ROC curve published by Koulaouzidis et al [18]. These scenarios generated model outcomes that allowed for the comparison of the ICER of HTM+DA versus usual care at various thresholds of the DA (Table 5), thereby assessing the inherent trade-off between false positives and false negatives in cost-effectiveness terms. In this study, false positives corresponded to alarms that were incorrectly raised, as the patient would not have been hospitalized, whereas false negatives represented alarms that were correctly raised and thus did not possibly avoid hospitalization. In the DA scenarios tested, scenario 5 minimized false negatives at the expense of increasing the number of false positives. Conversely, scenario 1 minimizes false positives at the expense of increasing false negatives. Although both false positives and false negatives are undesirable, there is an optimal point in terms of cost-effectiveness, which represents the balance between sensitivity and false-positive rate within the ROC curve in terms of generated QALYs and associated costs. In our analysis, scenario 3 is closer to this optimal point, as it leads to the lowest ICER of HTM+DA compared with usual care.

Subgroup analyses showed considerable variation in the ICERs of HTM+DA versus usual care (Table 6), with the highest ratios recorded for the subgroups of patients ≥65 years of age and those in NYHA class IV. A large variation in costs and QALYs was also observed, even when the resulting ICER did not change significantly from the base-case analysis for the HTM+DA versus usual care comparison, which may be attributed to the positive correlation between costs and effects observed in the subgroup analyses. It was also observed that complementary subgroups (with the exception of smokers or nonsmokers) went in opposite directions in relation to final outcomes (eg, lower

QALYs and costs for patients with a history of myocardial infarction contrasted with higher QALYs and costs for patients without any history of myocardial infarction).

Deterministic sensitivity analyses and scenario analyses showed that the model results were robust to the variation of most parameters (Figure 1) and to most changes in structural assumptions, with the highest change in the ICER resulting from taking a health care perspective in the analysis. Probabilistic sensitivity analysis revealed a 96.0% chance of HTM with the addition of the DA being cost-effective at the appropriate threshold of €80,000/QALY (as determined by the proportional shortfall method).

### Practical Implication of Study Findings

From the point of view of clinicians, the findings of this study suggest an improvement in health outcomes when using the HTM system in the management of heart failure, especially when the DA is added. Thus, the results of this study support a change in the clinical practice for managing patients with heart failure, namely through the inclusion of the aforementioned health technologies.

The cost-effectiveness analysis presented in this paper relies on several distinguishing features of the Dutch economic evaluation guidelines: the adoption of a societal perspective, the calculation of productivity losses by using the friction cost method, differential discounting, the inclusion of caregiver burden on the cost side of the economic evaluation, the incorporation of indirect medical costs of life years gained, and the value of information analysis. Considering that the study followed all the methodological requirements for informing decision-making in the Netherlands, the financing of HTM and the DA in the Dutch health care system should be ensured.

Although this study only analyzed the cost-effectiveness of a particular HTM intervention and a DA, it serves to raise awareness that the arsenal for providing care is becoming more diverse and that the methodology for properly assessing new health technologies should follow that trend. The Federal Institute for Drugs and Medical Devices in Germany assesses digital health applications for reimbursement [59]. Other countries' policy makers ought to learn from this experience and collaboratively work on solutions for the assessment of health care interventions supported by digital technologies, eHealth, and mHealth, particularly with regard to their cost-effectiveness. Only a correct assessment of their cost-effectiveness, which is a key criterion for deciding on the

reimbursement of a new health technology in most developed health care systems, can result in an appropriate resource allocation within the present health care panorama.

### Comparison With Prior Work

To our knowledge, this is the first study to use a health economic patient-level simulation model to assess the cost-effectiveness of heart failure intervention in the Netherlands. Concerning the intervention, 2 studies have also assessed the cost-effectiveness of HTM in the Netherlands (Boyne et al [60] and Grustam et al [3,21]). Boyne et al [61,62] performed a trial-based economic evaluation of the Telemonitoring in Heart Failure (TEHAF) study, a prospective open-label, multicenter, randomized controlled trial with blinded endpoint evaluation, conducted at 3 hospitals in the Netherlands. The results of this study cannot be compared with those of our study. First, because the population in the TEHAF study was in a better health state than that in the TEN-HMS study (eg, mean ejection fraction of 36% vs 25%), and second, because the time horizon of their study was only 1 year, which cannot properly capture the lifetime change in costs and effects between the interventions because patients are expected to survive for >1 year. Grustam et al [21] used a Markov cohort model with most of the data from the TEN-HMS study to assess the cost-effectiveness of HTM compared with usual care. They took a third-party payer's perspective, and a direct comparison of results with that study would be unwise and uninformative. However, in the scenario analysis where we took a health care perspective (scenario 23 in Table S13 in [Multimedia Appendix 1](#)), we estimated similar costs: €6,034 for usual care and €25,433 for HTM versus €4,414 and €7,186, respectively, as found by Grustam et al [21]. However, the ICERs were different because we estimated fewer QALYs. One possible explanation is the assumption by Grustam et al [21] that the transition probabilities measured in the time frame of 240 to 450 days in the TEN-HMS study continued unaltered for 20 years, which, given the mean age of 67 years of the patients included in the model and their very poor health state, seems unlikely. This assumption may have overestimated the survival in their study. Another possible explanation for the aforementioned difference is the potential underestimation of survival in our study owing to the regression equation for in-hospital mortality. The regression equation that calculates time-to-death predicts all-cause mortality. Thus, patients dying in hospitals may result in some type of double counting of mortality owing to the inherent imprecision of data-driven estimates. If the predictions were 100% accurate, the model would predict the time of death flawlessly, which never happens in practice. However, given the higher number of hospitalizations experienced by patients in the intervention arms owing to their increased survival, the cost-effectiveness estimates, if anything, are conservative.

The findings in our study of lower mortality and hospitalizations with HTM-based intervention when compared with usual care are consistent with the results previously published in 2 network meta-analyses [63,64]. Regarding costs, we found an increase in total costs with HTM when compared with usual care. In a review by Inglis et al [64], the authors identified 3 studies reporting costs for *HTM versus usual care*; one reported a decrease in costs and 2 reported increases in costs due both to

the cost of the intervention and to increased medical management [64].

It is worth mentioning that the structure of the model used in our study allowed us to explore the impact of adding a DA to HTM intervention. This is a critical aspect of our study as it is the first to assess the cost-effectiveness of a DA in the context of chronic disease management. Although we have used this concept in the context of heart failure intervention, it can be adapted for other disease areas. This subject has been discussed in a publication on the validation of the model used in this study [29].

### Limitations

The first limitation stems from the TEN-HMS study dating from 2005, which resulted in a large enough period for medical practice to have changed, especially because we are discussing technologies that are developed at a fast pace. The experience that results from the continuous use of these technologies can ultimately have an impact on their effectiveness and cost-effectiveness. Also related to the TEN-HMS study, it should be noted that drug use patterns and their costs pertain to the standards existing at the time of the trial. Even if standards in terms of therapeutic classes are not necessarily different, the drugs used are older and are likely cheaper than the more recent alternatives (this impact was assessed via scenario analysis). In addition, some inputs used in the model, namely the proportion of avoidable hospitalizations and the utility decrement resulting from a hospitalization, were already older in age and were used due to the lack of more recent estimates. Finally, there could be some variation in health care systems between patients included in the TEN-HMS study (United Kingdom, the Netherlands, and Germany), which was not accounted for in the model.

The second limitation relates to the DA ROC curve used for the analysis. Because the ROC curve was not obtained using the same population or HTM system, we assumed that the different levels of diagnostic accuracy of the DA, that is, the different points of the ROC curve, would also be applicable to the population in our model. The population used in the study by Koulaouzidis et al [18] seemed to be in a better health state than that in the TEN-HMS study [17] (eg, ejection fraction of 36.6% vs 25.1%). Ideally, we would have a DA constructed with TEN-HMS data, as we would want to optimize the threshold of a DA that would have been designed with the same HTM system. Thus, we could use the data generated by this system to continuously improve predictions of hospitalization and, consequently, improve the cost-effectiveness of the HTM+DA intervention.

Concerning subgroup analyses, it is critical to emphasize that their interpretation is a sensitive matter, as every subgroup is created from the baseline population by restricting the variables of interest to values compatible with the subgroup being analyzed. Thus, subgroups are likely to have different patient and disease characteristics when compared with the model population used in the base-case analysis (Tables S1-S26 in [Multimedia Appendix 2](#)). For instance, NYHA class IV patients were also older, on average, than the baseline model population. Hence, the outcomes from the model and their variation from

the base-case analysis in that situation are not only dependent on the impact of NYHA IV but also on all other patient and disease characteristics that change in the subgroup population when compared with the base-case population. Thus, the correct interpretation of subgroup analyses requires a link with the patient and disease characteristics than can be correlated with the particular characteristic changes in any given subgroup.

There is a dimension of patient preferences that has not been assessed in this study. Moving from a face-to-face type of care to a remote environment implies a change in the behavior of patients and their interaction with the health care system, which should be assessed more carefully.

Finally, strictly speaking, the results presented in this study concern only the specific HTM intervention used in the TEN-HMS study and the DA presented by Koulaouzidis et al [18] (see the *Interventions* section). Although some qualitative extrapolation to similar technologies could be made, the quantitative results presented in this study are specific to the data generated in the TEN-HMS study and the study by Koulaouzidis et al [17,18]. It should also be noted that the outcomes of HTM systems depend on patient use of the system. Therefore, the effectiveness in the real world could vary from the efficacy found in a controlled clinical environment. As such, generalization of the results of this study to other HTM systems and patient populations should be performed carefully and informedly.

### Future Directions

The model could include individual drug costs and optimize the medication used at each processed event. To achieve this, patient characteristics should be updated at these events to define the correct medication for each patient. In doing so, the model would also capture the drug costs more accurately.

Further research must be conducted to better describe the DAs and follow-up actions they entail in clinical practice and disease pathways. Although the discrete event simulation framework allowed for the assessment of the cost-effectiveness of the DA, the potential of these models opens enormous possibilities for designing a model with highly detailed disease pathways for clinicians and decision makers who are less familiar with decision modeling in the context of the economic evaluation of health technologies. However, the increased complexity of models comes at the expense of the need for patient-level data to build and validate the model. Theoretically, all patient pathways after an alarm can be included in a discrete event simulation framework. The question is whether there would be reliable data on the outcomes for each of the pathways that could be conceived for reacting to an alarm. As is widely described in the health economics literature, models should abide by the principle of parsimony; that is, they should be as simple as possible to accurately reflect the problem under analysis and allow for making an informed decision.

### Conclusions

Although increased costs of adopting HTM and a DA in the management of heart failure may seemingly be an additional strain on scarce health care resources, the results of this study demonstrate that, by increasing patient life expectancy by 1.28 years and reducing their hospitalization rate by 23% when compared with usual care, the use of this technology may be seen as an investment, as HTM+DA in its current form extendedly dominates HTM and generates an extra QALY for a €27,712 investment. At the appropriate cost-effectiveness threshold of €80,000/QALY resulting from the proportional shortfall methodology used in the Dutch economic evaluation guidelines, HTM+DA had a 96.0% probability of being cost-effective.

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### Conflicts of Interest

None declared.

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#### Multimedia Appendix 1

Additional tables and figures.

[\[DOCX File , 116 KB - cardio\\_v6i2e31302\\_app1.docx \]](#)

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#### Multimedia Appendix 2

Baseline patient and disease characteristics of the model populations used in subgroup analyses.

[\[DOCX File , 37 KB - cardio\\_v6i2e31302\\_app2.docx \]](#)

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## Abbreviations

- DA:** diagnostic algorithm
- EVPI:** expected value of perfect information
- HTM:** home telemonitoring
- ICER:** incremental cost-effectiveness ratio
- NYHA:** New York Heart Association
- QALY:** quality-adjusted life year
- ROC:** receiver operating characteristic
- TEN-HMS:** Trans-European Network—Home-Care Management System

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Original Paper

# The Association Between Telemedicine Use and Changes in Health Care Usage and Outcomes in Patients With Congestive Heart Failure: Retrospective Cohort Study

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## Abstract

**Background:** Telemedicine use has become widespread owing to the COVID-19 pandemic, but its impact on patient outcomes remains unclear.

**Objective:** We sought to investigate the effect of telemedicine use on changes in health care usage and clinical outcomes in patients diagnosed with congestive heart failure (CHF).

**Methods:** We conducted a population-based retrospective cohort study using administrative data in Ontario, Canada. Patients were included if they had at least one ambulatory visit between March 14 and September 30, 2020, and a heart failure diagnosis any time prior to March 14, 2020. Telemedicine users were propensity score-matched with unexposed users based on several baseline characteristics. Monthly use of various health care services was compared between the 2 groups during 12 months before to 3 months after their index in-person or telemedicine ambulatory visit after March 14, 2020, using generalized estimating equations.

**Results:** A total of 11,131 pairs of telemedicine and unexposed patients were identified after matching (49% male; mean age 78.9, SD 12.0 years). All patients showed significant reductions in health service usage from pre- to postindex visit. There was a greater decline across time in the unexposed group than in the telemedicine group for CHF admissions (ratio of slopes for high- vs low-frequency users 1.02, 95% CI 1.02-1.03), cardiovascular admissions (1.03, 95% CI 1.02-1.04), any-cause admissions (1.03, 95% CI 1.02-1.04), any-cause ED visits (1.03, 95% CI 1.03-1.04), visits with any cardiologist (1.01, 95% CI 1.01-1.02), laboratory tests (1.02, 95% CI 1.02-1.03), diagnostic tests (1.04, 95% CI 1.03-1.05), and new prescriptions (1.02, 95% CI 1.01-1.03). However, the decline in primary care visit rates was steeper among telemedicine patients than among unexposed patients (ratio of slopes 0.99, 95% CI 0.99-1.00).

**Conclusions:** Overall health care usage over time appeared higher among telemedicine users than among low-frequency users or nonusers, suggesting that telemedicine was used by patients with the greatest need or that it allowed patients to have better access or continuity of care among those who received it.

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**KEYWORDS**

telemedicine; telehealth; eHealth; digital health; population; outcomes; health service; health system; utilization; congestive heart failure; cardiology; health outcome; clinical outcome; patient outcome; heart; cardiac; cardiology; ambulatory; COVID-19



## Introduction

The COVID-19 pandemic has significantly increased the adoption of telemedicine globally, with governments reducing regulatory restrictions on telemedicine platforms and funding telemedicine visits with new billing codes [1]. Telemedicine was seen as an effective pandemic response strategy to allow physicians to manage ambulatory patients with chronic disease while reducing the risks of viral transmission to health care providers and other patients and conserve personal protective equipment (PPE) [2]. The uptake of telemedicine during the first wave of the pandemic was between 38%-77% across different countries with no signs of a return to prepandemic levels [1,3]. With increasing rates of vaccination and a consistent supply of PPE, the long-term sustainability and impact of telemedicine beyond the pandemic is uncertain.

Congestive heart failure (CHF) is an example of an ambulatory sensitive chronic disease where it is presumed that an in-person clinical assessment, including a physical examination, is necessary to provide high-quality care [4]. There have been numerous studies that have demonstrated remote monitoring for patients with CHF, which have led to improved outcomes, including reduced hospitalizations and deaths as an adjunctive strategy; however, to date, no studies have compared telemedicine visits as a substitute to in-person care [5-7]. While telemedicine is generally thought to improve patient experience as it is more convenient with reduced travel time to appointments, there is a worry that telemedicine and the inability to examine the patient physically will lead to increased usage of health services, including more frequent visits, diagnostic testing, and potentially worse clinical outcomes [8-10]. To date, there are limited large-scale studies assessing the impact of telemedicine visits on quality of care on patients with CHF.

The purpose of this study was to investigate the association between telemedicine use and changes in other forms of health care usage and clinical outcomes among patients with CHF from before the COVID-19 pandemic to the early stages of the pandemic, when telemedicine usage became widespread.

## Methods

### Study Design and Data Sources

We conducted a population-based, retrospective cohort study of patients with CHF, using administrative claims data from Ontario, Canada. The following databases were used: (1) Ontario Health Insurance Plan (OHIP), which includes information on all health services delivered by physicians to Ontario patients who are eligible for coverage; (2) the Discharge Abstract Database, which records all inpatient hospital admissions; (3) the National Ambulatory Care Reporting System, which contains data on all hospital- and community-based ambulatory care (including emergency department [ED] visits); (4) Ontario Drug Benefit, which includes data on prescription claims for patients aged >65 years; (5) the Registered Persons Database, which contains demographic information of all patients covered under OHIP; and (6) the CHF database, an Institute for Clinical Evaluative Sciences (ICES) database that uses validated algorithms to identify patients ever diagnosed with CHF, and

other ICES-validated disease-specific registries [11]. The Postal Code Conversion File was used to convert all patient postal codes to neighborhood income quintiles. ICES is an independent nonprofit research institute whose legal status under Ontario's health information privacy law allows it to collect and analyze health care and demographic data without consent for health system evaluation and improvement. Databases were linked using unique encoded identifiers and analyzed at ICES.

### Population

We identified patients diagnosed with heart failure by using a validated algorithm with high sensitivity and specificity [12], who were included if they met all of the following criteria: (1) having a record in the ICES CHF database any time prior to March 14, 2020; (2) having at least one ambulatory visit between March 14 and September 30, 2020; and (3) having at least one hospital admission or ED visit with International Classification of Disease–10th Revision code I50 listed as the most responsible diagnosis in the 3 years prior to their ambulatory visit (Table S1 in [Multimedia Appendix 1](#)). We selected March 14, 2020, as the start date of the observation window because it was the day that new temporary billing codes were introduced by the Ontario government, which expanded physician reimbursement of telemedicine services in response to the COVID-19 pandemic [13].

We then stratified the cohort of patients with CHF into 2 groups: a telemedicine group, comprising patients who had at least 2 telemedicine visits, which includes both telephone and video visits, within the observation window (March 14 to September 30, 2020); and an unexposed group, comprising patients who had no more than one telemedicine visit but did have at least one ambulatory visit (in-person or telemedicine) within the observation window. The index visit for each patient was their first telemedicine visit (or first in-person visit for those with zero telemedicine visits during the window). Table S2 in [Multimedia Appendix 1](#) provides the codes used to define telemedicine claims. We excluded patients who were not Ontario residents or had an invalid or missing health card number.

### Propensity Score Matching

To ensure comparability between the telemedicine group and unexposed group, we calculated a propensity score for each patient to represent their probability of receiving telemedicine. Individuals from the telemedicine group and the unexposed group were then matched 1:1 based on their propensity scores using greedy matching algorithms within 0.2 SD. We randomly assigned each individual in the unexposed group an index date to match the distribution of the exposure group index dates. Furthermore, we exact-matched on several key variables: age, sex, and number of hospitalizations owing to CHF in the 3 months prior to the index date. To ensure that matching was successful, the distribution of characteristics in both groups was then compared, and standardized differences greater than 0.1 were considered imbalanced. The following covariates were incorporated into the model that was used to generate individual propensity scores: income quintile, rural residence, number of ED visits owing to heart failure in 12 months prior to the index date, prescription claims for select medication classes in 100 days prior to the index date (angiotensin-converting enzyme

inhibitors or angiotensin II receptor blockers, antiplatelets, beta-blockers, aldosterone receptor antagonists, statins, diuretics, nitrates, and digoxin), Charlson comorbidity index in 3 years prior, number of outpatient primary care and cardiology visits in the year prior, diabetes diagnosis any time prior, hypertension diagnosis any time prior, hospitalization for acute myocardial infarction in 3 years prior, peripheral vascular disease within 3 years prior, history of coronary artery disease in 3 years prior, and atrial fibrillation diagnosis in 3 years prior (Table S3 in [Multimedia Appendix 1](#)).

### Outcomes

We enumerated the following health care usage outcomes monthly, 12 months before the index date, and over the 90-day period post the index date: number of hospitalizations owing to CHF, hospitalizations owing to cardiovascular disease, all-cause hospitalizations, all-cause ED visits, outpatient primary care visits, repeat outpatient cardiology visits, outpatient cardiology visits with any cardiologist, laboratory claims (ie, hemoglobin A<sub>1c</sub>, lipid profile, complete blood count, and creatinine), cardiac diagnostic tests (transthoracic echocardiogram, cardiac stress test, cardiac catheterization, and Holter monitoring), and new prescription claims.

### Statistical Analysis

We developed a generalized estimating equation (GEE) model for each outcome based on the independent variables time, exposure group, and the time×group interaction. We accounted for correlation due to matching as the GEE could only incorporate one level of clustering. An exchangeable correlation structure was used. Rate ratios, also known as the slope of change over the 15-month period, were calculated for both unexposed and telemedicine groups for each outcome. A rate ratio, or slope, greater than 1 implies that there was a general increase in usage over time for that group. A ratio of the slopes,

defined as the slope for the telemedicine group divided by the slope for the unexposed group, was also calculated to compare whether the rate of change over time significantly differed between groups. A ratio of slopes greater than 1 implies that there was higher usage over time in the telemedicine group than in the unexposed group. Absolute rates of usage per 100 person-months over the 15-month period were also calculated for each outcome, along with rate differences to compare between groups. The rate of the unexposed group was subtracted from that of the telemedicine group; therefore, a positive rate difference indicates a higher rate in the telemedicine group. All analyses were performed in SAS (version 9.4; SAS Institute).

### Ethics Approval

Use of these databases for the purposes of this study was authorized under §45 of Ontario's Personal Health Information Protection Act, which does not require review by a research ethics board. An exemption was also received from the Women's College Hospital Research Ethics Board (reference number: (REB # 2020-0106-E).

## Results

### Patient Characteristics

Prior to matching, we identified 12,741 eligible patients with CHF in the unexposed group and 33,250 patients with CHF in the telemedicine group ([Table 1](#)), and after propensity score matching, 11,131 pairs were identified. [Table 1](#) shows the distribution of baseline patient characteristics in the unexposed versus telemedicine group before and after matching (49% were male; mean age 78.9, SD 12.0 years). Matching successfully balanced characteristics between the 2 groups, as demonstrated by standardized differences of <0.10 for all measured baseline characteristics.

**Table 1.** Baseline characteristics of patients before and after propensity score matching (with standardized differences).

Variables	Before propensity score matching			After propensity score matching		
	Unexposed group (n=12,741)	Telemedicine group (n=33,250)	Standardized difference	Unexposed group (n=11,131)	Telemedicine group (n=11,131)	Standardized difference
<b>Sex, n (%)</b>						
Female	6703 (52.6)	16,111 (48.5)	0.08	5677 (51.0)	5677 (51.0)	0
Male	6038 (47.4)	17,139 (51.5)	0.08	5454 (49.0)	5454 (49.0)	0
Age (years), mean (SD)	79.7 (12.3)	76.9 (11.6)	0.23 <sup>a</sup>	78.9 (12.0)	78.9 (12.0)	0
<b>Charlson comorbidity index, n (%)</b>						
0	1469 (11.5)	3828 (11.5)	0	1325 (11.9)	1297 (11.7)	0.01
1	2959 (23.2)	7007 (21.1)	0.05	2550 (22.9)	2619 (23.5)	0.01
≥2	8313 (65.2)	22,415 (67.4)	0.05	7256 (65.2)	7215 (64.8)	0.01
Congestive heart failure admission in 3 months prior, n (%)	964 (7.6)	3224 (9.7)	0.08	706 (6.3)	706 (6.3)	0
Congestive heart failure admission in 1 year prior, n (%)	3595 (28.2)	10,513 (31.6)	0.07	3128 (28.1)	2919 (26.2)	0.04
Emergency department visit for congestive heart failure in 1 year prior, n (%)	4228 (33.2)	12,901 (38.8)	0.12 <sup>a</sup>	3745 (33.6)	3708 (33.3)	0.01
<b>Neighborhood income quintile, n (%)</b>						
1	3585 (28.1)	8231 (24.8)	0.08	3027 (27.2)	3041 (27.3)	0
2	2860 (22.4)	7464 (22.4)	0	2527 (22.7)	2545 (22.9)	0
3	2365 (18.6)	6703 (20.2)	0.04	2109 (18.9)	2066 (18.6)	0.01
4	2031 (15.9)	5632 (16.9)	0.03	1780 (16.0)	1812 (16.3)	0.01
5	1812 (14.2)	5085 (15.3)	0.03	1626 (14.6)	1595 (14.3)	0.01
<b>Rurality, n (%)</b>						
Rural	1550 (12.2)	2691 (8.1)	0.14 <sup>a</sup>	1231 (11.1)	1253 (11.3)	0.01
Urban	10,895 (85.5)	30,195 (90.8)	0.16 <sup>a</sup>	9696 (87.1)	9682 (87.0)	0
Prior diabetes, n (%)	6585 (51.7)	19,122 (57.5)	0.12 <sup>a</sup>	5941 (53.4)	5863 (52.7)	0.01
Prior hypertension, n (%)	11,620 (91.2)	30,759 (92.5)	0.05	10,188 (91.5)	10,194 (91.6)	0
Acute myocardial infarction admission in 3 years prior, n (%)	954 (7.5)	2551 (7.7)	0.01	859 (7.7)	849 (7.6)	0
Peripheral vascular disease in 3 years prior, n (%)	936 (7.3)	2722 (8.2)	0.03	843 (7.6)	854 (7.7)	0
Coronary artery disease in 3 years prior, n (%)	1694 (13.3)	5366 (16.1)	0.08	1576 (14.2)	1568 (14.1)	0
Atrial fibrillation in 3 years prior	6790 (53.3)	18,330 (55.1)	0.04	5967 (53.6)	5934 (53.3)	0.01
Outpatient primary care visits in 1 year prior, mean (SD)	3.5 (4.5)	5.9 (5.6)	0.47 <sup>a</sup>	3.9 (4.6)	3.9 (4.5)	0
Outpatient visits with same cardiologist in 1 year prior, mean (SD)	0.5 (1.2)	1.0 (1.7)	0.34 <sup>a</sup>	0.5 (1.2)	0.6 (1.3)	0.02
Outpatient visits with any cardiologist in 1 year prior, mean (SD)	0.9 (1.5)	1.6 (2.0)	0.41 <sup>a</sup>	1.0 (1.5)	1.0 (1.5)	0.02
<b>Prescriptions in 100 days prior, n (%)</b>						

Variables	Before propensity score matching			After propensity score matching		
	Unexposed group (n=12,741)	Telemedicine group (n=33,250)	Standardized difference	Unexposed group (n=11,131)	Telemedicine group (n=11,131)	Standardized difference
Angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker	3703 (29.1)	10,919 (32.8)	0.08	3362 (30.2)	3339 (30.0)	0
Antithrombotic	2419 (19.0)	6754 (20.3)	0.03	2119 (19.0)	2179 (19.6)	0.01
Beta-blocker	6504 (51.0)	17,944 (54.0)	0.06	5760 (51.7)	5824 (52.3)	0.01
Diuretic	5837 (45.8)	15,515 (46.7)	0.02	5137 (46.2)	5180 (46.5)	0.01
Calcium channel blocker or statin	7524 (59.1)	21,934 (66.0)	0.14 <sup>a</sup>	6855 (61.6)	6951 (62.4)	0.02
Nitrate	1142 (9.0)	2687 (8.1)	0.03	967 (8.7)	969 (8.7)	0
Aldosterone receptor antagonist	8473 (66.5)	22,416 (67.4)	0.02	7385 (66.3)	7450 (66.9)	0.01
Digoxin	1718 (13.5)	4559 (13.7)	0.01	1473 (13.2)	1493 (13.4)	0.01

<sup>a</sup>Standardized difference>0.1.

### Hospitalizations and ED Visits

Figure 1 illustrates the adjusted rates of hospitalizations and ED visits across time in both the unexposed and telemedicine groups. During the 15-month period starting 12 months before their index visit, which was defined as their first in-person or telemedicine visit during the pandemic, to 3 months post the index date, both groups had a significant reduction in CHF and cardiovascular admissions, though the decrease was greater in

the unexposed group. The average monthly decrease in CHF admissions over the 15-month observation period was -5.2% in the unexposed group versus -1.7% in the telemedicine group and -4.7% in the unexposed group versus -2.2% in the telemedicine group for cardiovascular admissions. Similarly, both groups saw declines in monthly all-cause ED visits over the observation period (-3.6% for the unexposed group vs -0.6% for the telemedicine group).

Figure 1. Rate of hospitalizations and emergency department visits by exposure group. CHF: congestive heart failure; ED: emergency department.

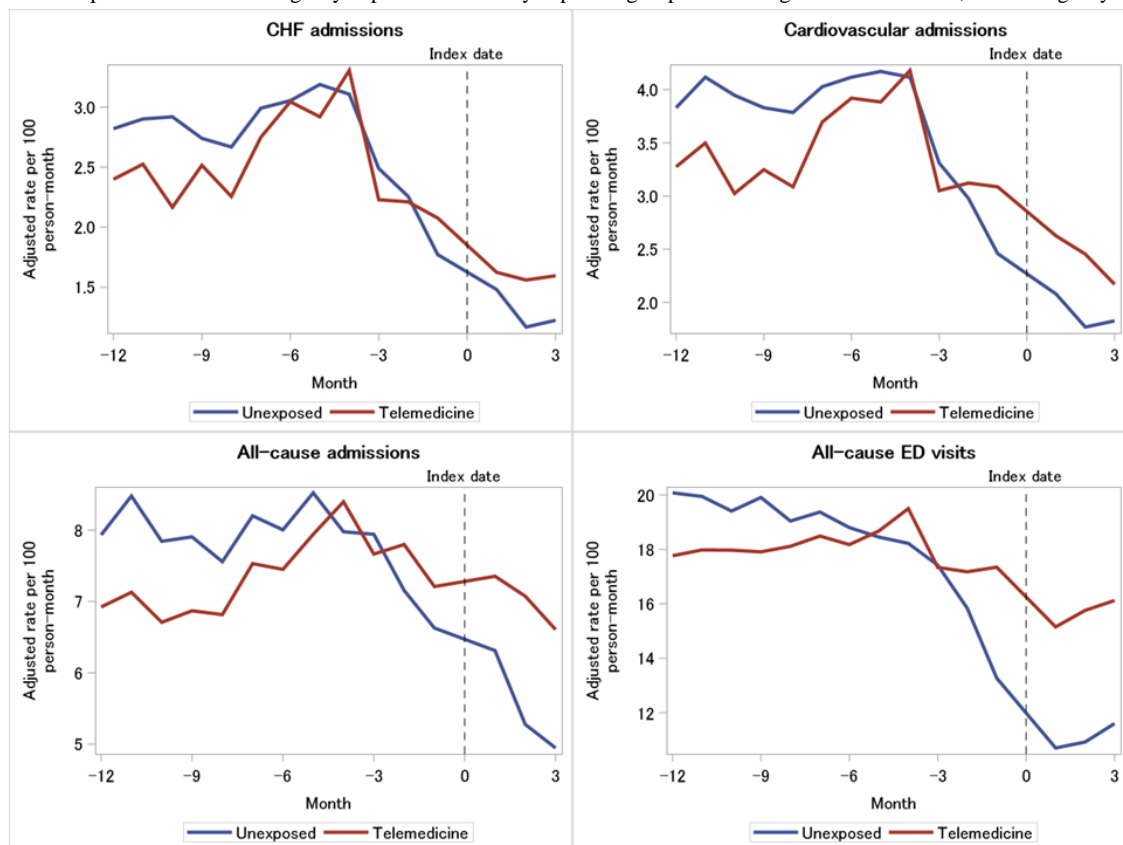


Table 2 reports the rate ratio (slope) and ratio of slope estimates from the GEE model, as well as the absolute rates and accompanying rate differences. The ratio of the slopes indicates a steeper decline in the unexposed group in CHF admissions (ratio of rate ratio [RRR] 1.02, 95% CI 1.02-1.03),

cardiovascular admissions (RRR 1.03, 95% CI 1.02-1.04), all-cause admissions (RRR 1.03, 95% CI 1.02-1.04), and any-cause ED visits (RRR 1.03, 95% CI 1.03-1.04). The absolute rate differences were  $-0.12$ ,  $-0.15$ ,  $-0.08$ , and  $0.67$  admissions per 100 person-months, respectively.

**Table 2.** Absolute and relative rates by virtual care user group.

Outcomes	Rate ratio or slope <sup>a</sup> (95% CI)		Ratio of slopes <sup>b</sup> (95% CI)	Absolute rate per 100 person-month		Rate difference
	Unexposed group	Telemedicine group		Unexposed group	Telemedicine group	
<b>Hospitalizations and emergency department visits</b>						
Congestive heart failure admission	0.95 (0.94-0.96) <sup>c</sup>	0.98 (0.97-0.98) <sup>c</sup>	1.02 (1.02-1.03) <sup>c</sup>	2.47	2.36	-0.12
Cardiovascular admission	0.95 (0.95-0.96) <sup>c</sup>	0.98 (0.97-0.99) <sup>c</sup>	1.03 (1.02-1.04) <sup>c</sup>	3.39	3.24	-0.15
Any-cause admission	0.98 (0.97-0.98) <sup>c</sup>	1.00 (1.00-1.01)	1.03 (1.02-1.04) <sup>c</sup>	7.46	7.38	-0.08
Any-cause emergency department visits	0.96 (0.96-0.96) <sup>c</sup>	0.99 (0.99-0.99) <sup>c</sup>	1.03 (1.03-1.04) <sup>c</sup>	17.17	17.84	0.67
<b>Physician visits</b>						
Primary care visits	0.93 (0.92-0.93) <sup>c</sup>	0.92 (0.92-0.92) <sup>c</sup>	0.99 (0.99-1.00) <sup>c</sup>	28.07	27.49	-0.58
Visits with the same cardiologist	0.93 (0.92-0.93) <sup>c</sup>	0.93 (0.93-0.94) <sup>c</sup>	1.01 (1.00-1.02)	3.92	4.13	0.22
Visits with any cardiologist	0.92 (0.92-0.93) <sup>c</sup>	0.93 (0.93-0.94) <sup>c</sup>	1.01 (1.01-1.02) <sup>c</sup>	6.74	7.06	0.32
<b>Other health care usage</b>						
Total laboratory tests	0.97 (0.96-0.97) <sup>c</sup>	0.99 (0.99-0.99) <sup>c</sup>	1.02 (1.02-1.03) <sup>c</sup>	58.48	71.32	12.84
Total diagnostic tests	0.94 (0.94-0.95) <sup>c</sup>	0.98 (0.98-0.99) <sup>c</sup>	1.04 (1.03-1.05) <sup>c</sup>	10.67	12.10	1.43
New prescriptions (age>65 years)	0.94 (0.93-0.94) <sup>c</sup>	0.96 (0.95-0.96) <sup>c</sup>	1.02 (1.01-1.03) <sup>c</sup>	22.53	21.59	-0.94

<sup>a</sup>A rate ratio or slope of greater than 1 implies a general increase in health care usage over time, and vice versa.

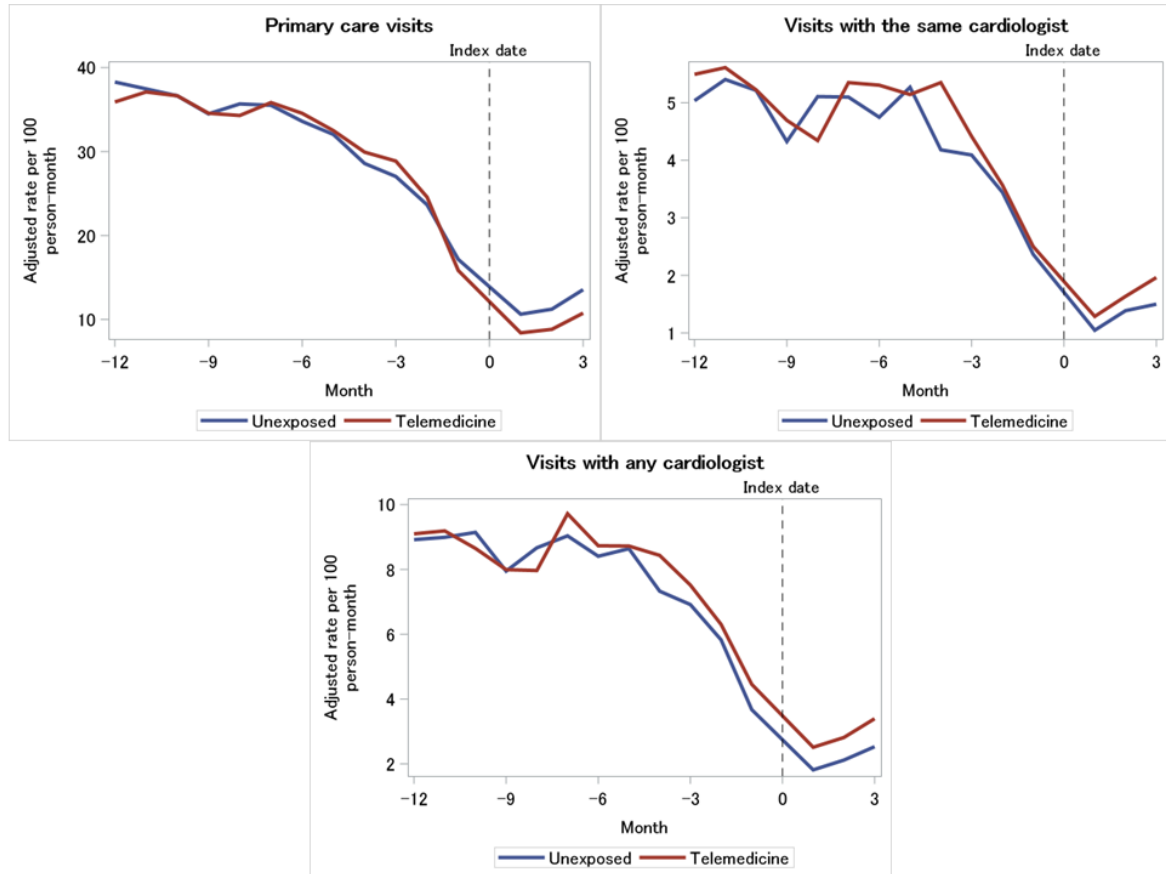
<sup>b</sup>Ratio of the slopes is defined as the slope for the telemedicine group divided by the slope for the unexposed group. A value greater than 1 implies that there was higher usage over time in the telemedicine group than in the unexposed group.

<sup>c</sup>Statistically significant (95% CI does not include 1, or  $P < .05$ ).

## Physician Visits

Figure 2 shows the trends in physician visit rates for the unexposed and telemedicine groups. Over the 15-month study period, both groups had a significant monthly decline in primary care visits ( $-6.1\%$  for the unexposed group vs  $-6.5\%$  for the telemedicine group), visits with the same cardiologist as the index visit ( $-5.4\%$  for the unexposed group vs  $-4.8\%$  for the telemedicine group), and visits with any cardiologist ( $-6.4\%$  for the unexposed group vs  $-5.1\%$  in the telemedicine group).

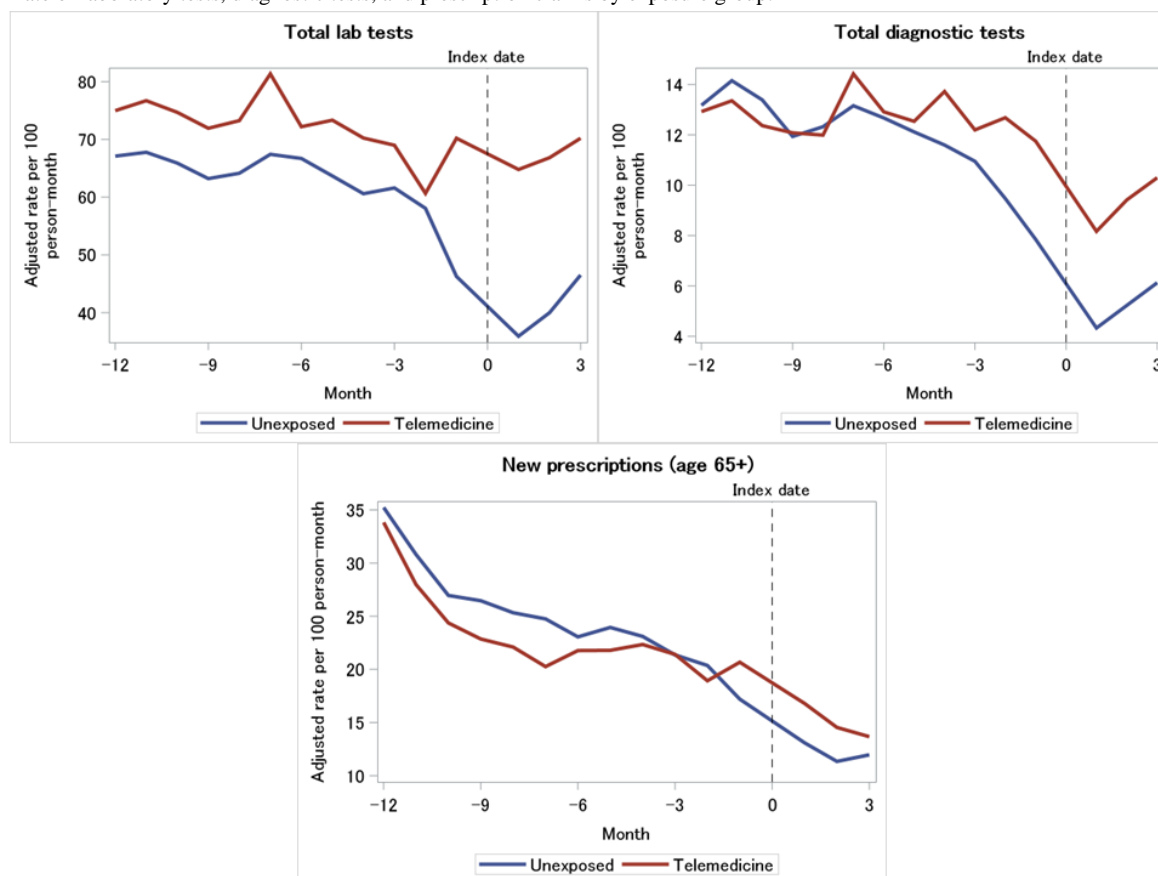
When comparing the 2 groups, the decline in the rate of visits with any cardiologist was steeper in the unexposed group than in the telemedicine group (RRR 1.01, 95% CI 1.01-1.02) with an absolute difference of 0.32 visits per 100 person-months; however, the decline in primary care visit rates was steeper in the telemedicine group (RRR 0.99, 95% CI 0.99-1.00) with an absolute difference of  $-0.58$  visits per 100 person-months. There was no significant difference between low and high users in their slopes for visits with the same cardiologist.

**Figure 2.** Rate of physician visits by exposure group.

### Laboratory Testing, Diagnostic Imaging, and Medication Usage

Figure 3 displays the monthly ordering rates of laboratory testing, imaging, and medication prescriptions over time. Both the unexposed and telemedicine groups reported a significant decrease across the 15-month observation period in the monthly rates of total laboratory tests ( $-2.1\%$  for the unexposed group vs  $-0.2\%$  for the telemedicine group), total diagnostic tests ( $-3.9\%$  for the unexposed group vs  $-0.8\%$  for the telemedicine

group), and new prescriptions among those aged 65 years and older ( $-7.1\%$  for the unexposed group vs  $-5.9\%$  for the telemedicine group). The unexposed group showed a steeper decline in laboratory testing (RRR 1.02, 95% CI 1.02-1.03), diagnostic testing (RRR 1.04, 95% CI 1.03-1.05), and new prescriptions (RRR 1.02, 95% CI 1.01-1.03) than the telemedicine group. The corresponding absolute differences were 12.84, 1.43, and  $-0.94$  tests or claims per 100 person-months, respectively.

**Figure 3.** Rate of laboratory tests, diagnostic tests, and prescription claims by exposure group.

## Discussion

### Principal Findings

In this large, population-based study, we aimed to evaluate the impact of telemedicine use on changes in health care usage and outcomes on patients with CHF during the first wave of the COVID-19 pandemic. Both the telemedicine and unexposed groups showed significant reductions in health service use in the months leading up to and during the pandemic. Patients with CHF in the unexposed group saw steeper reductions in hospitalization and ED usage rates than those in the telemedicine group. In addition, patients in the unexposed group had steeper reductions in testing and medication prescriptions. In contrast, the rate of decrease in primary care physician visits was higher in the telemedicine group. To further supplement our findings, we also report difference-in-difference ratios comparing the pre- and postindex rates between exposure groups (Table S4 in [Multimedia Appendix 1](#)). These results show that the rate comparisons before and during the pandemic between groups are consistent with our main findings. While the differences we found were significant, the absolute differences between the 2 groups were mostly small, and the clinical significance of these findings are uncertain. However, these results highlight the fact that patients with higher telemedicine usage also seem to have higher usage of many other health care services.

### Comparison to Prior Work

The COVID-19 pandemic led to widespread telemedicine adoption in a very short time frame, with rates of telemedicine usage ranging from 1% before the pandemic to over 70% within

weeks of the first wave of the pandemic [3], with over 90% of the visits being facilitated by telephone. Telemedicine was widely seen as a temporary emergency measure designed to quickly provide care to patients with chronic disease while reducing infection risk [2]. Despite initial concerns that telemedicine would compromise the quality of care, our findings demonstrate small, albeit significant differences in hospitalization and ED visit rates, which were generally higher over time within telemedicine compared to in-person care. Prior studies of telemedicine and CHF have reported mixed results, with Klersy et al [14] and Chaudhry et al [15] having failed to demonstrate improvements in CHF outcomes in a large, randomized controlled trial of a telemonitoring solution; however, the more recent Telemedical Interventional Management in Heart Failure II study [5] demonstrated significant reductions in hospitalizations and mortality. These studies, however, were mostly conducted before the pandemic and assessed telemonitoring systems that are adjunctive to physician visits, of which the majority of visits in these studies were conducted in person. This study assessed telemedicine visits as a substitute to in-person physician visits. It is possible that frequent telemedicine visits, which are more easily accessible for frail patients with CHF, may have brought patients to medical attention and facilitated hospitalization. It is also possible that patients who had more frequent telemedicine visits were likely to be acutely decompensating, requiring an ED visit for assessment, particularly when access to in-person care was limited. In contrast to our findings, a few international studies have evaluated telemedicine use in the population of patients with heart failure during the COVID-19 pandemic and found

that those accessing telemedicine saw a decrease or no difference in hospitalizations during this time [16,17].

The American College of Cardiology's CHF guidelines recommend recording volume status and vital signs as part of every clinical assessment [4]. Telemedicine visits limit the ability to conduct a physical examination; hence, some suspected that telemedicine visits would lead to higher use of diagnostic testing in lieu of a clinical examination. Our results suggest higher usage of laboratory and diagnostic testing in the telemedicine group, though the reason for that difference is not easy to ascertain from the data. One possible explanation is that, as stated previously, more diagnostic testing was ordered to augment clinical assessment. Another possible explanation, similar to the explanation around ED visits, is that patients with CHF who were more acute received telemedicine visits and consequently received more diagnostic tests and medication prescriptions. It is interesting that there were only marginal differences in physician visit trends between the 2 groups, however, suggesting that differences in testing and medication ordering were beyond merely increased access to physicians. It is possible that because these patients were more unstable, physicians ordered more testing in advance but only scheduled a visit if the test results indicated an issue for follow-up.

The findings of this study have important implications for the long-term sustainability of telemedicine in a postpandemic era. While telemedicine during the pandemic was mainly used to reduce infection risk and conserve PPE [18], the long-term sustainable PPE supply and readily available COVID-19 vaccines necessitate telemedicine use to align with the quadruple aim of improved patient and provider experience, improved health outcomes, and value for money. Prior studies on telemedicine in CHF seem to demonstrate improved patient satisfaction and potentially improved health outcomes; however, these studies were not population-based [19]. Importantly, CHF telemedicine programs need to integrate fully into the normal delivery of CHF care, including in-person visits, to be effective [18].

## Limitations

The results of this study should be contextualized by some significant limitations. First, although we propensity score-matched high-frequency and low-frequency users or nonusers of telemedicine based on a number of important baseline characteristics, there still exists the potential for unmeasured confounders as administrative data do not account for vital signs, laboratory values, or other markers of disease acuity. Second, these user definitions may not be as applicable as we enter a postpandemic era and away from a "virtual-first" model of care. The study took place within the first wave of the COVID-19 pandemic, when in-person services were being significantly curtailed, which limits the generalizability of the study. Third, we are unable to determine the type of telemedicine platform used—telephone or video—in these encounters, although anecdotal evidence from patients and providers suggests that the majority of visits based in Ontario were conducted over the telephone. Finally, we are also unable to ascertain whether other adjunctive devices, such as wearable devices, were used as part of the telemedicine visit, although those devices were not part of common practice. Despite these limitations, our results provide important observations regarding the use of telemedicine and subsequent health care system usage and patient outcomes.

## Conclusions

In this population-based retrospective cohort study of patients with CHF in Ontario, Canada, we found that telemedicine patients had significantly higher use of health care services over time than low-frequency users or nonusers of telemedicine, although clinically significant differences were minimal for most outcomes. As telemedicine becomes a more widespread and permanent form of care delivery, future research is needed to rigorously assess the optimal use of telemedicine—such as which clinical situations would telemedicine derive the most benefit—and quality of care provided during these interactions in order to determine the sustainability of telemedicine as it is integrated into the health system in a post-COVID-19 era.

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## Acknowledgments

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## Data Availability

The data sets generated during or analyzed in this study are not publicly available owing to restricted data sharing agreements with Institute for Clinical Evaluative Sciences (ICES) and the Canadian Institute for Health Information (CIHI), but access to the data may be granted by contacting ICES.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Tables S1-S4.

[\[DOCX File , 22 KB - cardio\\_v6i2e36442\\_app1.docx \]](#)**References**

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**Abbreviations**

**CHF:** congestive heart failure  
**CIHI:** Canadian Institute for Health Information  
**ED:** emergency department  
**GEE:** generalized estimating equation  
**ICES:** Institute for Clinical Evaluative Sciences  
**MOH:** Ministry of Health  
**OHIP:** Ontario Health Insurance Plan  
**PPE:** personal protective equipment  
**RRR:** ratio of rate ratio

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Original Paper

# The First National Program of Remote Cardiac Rehabilitation in Israel—Goal Achievements, Adherence, and Responsiveness in Older Adult Patients: Retrospective Analysis

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## Abstract

**Background:** Remote cardiac rehabilitation (RCR) after myocardial infarction is an innovative Israeli national program in the field of telecardiology. RCR is included in the Israeli health coverage for all citizens. It is generally accepted that telemedicine programs better apply to younger patients because it is thought that they are more technologically literate than are older patients. It has also previously been thought that older patients have difficulty using technology-based programs and attaining program goals.

**Objective:** The objectives of this study were as follows: to study patterns of physical activity, goal achievement, and improvement in functional capacity among patients undergoing RCR over 65 years old compared to those of younger patients; and to identify predictors of better adherence with the RCR program.

**Methods:** A retrospective study of patients post-myocardial infarction were enrolled in a 6-month RCR program. The activity of the patients was monitored using a smartwatch. The data were collected and analyzed by a special telemedicine platform. RCR program goals were as follows: 150 minutes of aerobic activity per week, 120 minutes of the activity in the target heart rate recommended by the exercise physiologist, and 8000 steps per day. Models were created to evaluate variables predicting adherence with the program.

**Results:** Out of 306 patients, 80 were older adults (mean age 70 years, SD 3.4 years). At the end of the program, there was a significant improvement in the functional capacity of all patients ( $P=.002$ ). Specifically, the older adult group improved from a mean 8.1 (SD 2.8) to 11.2 (SD 12.6). The metabolic equivalents of task (METs) and final MET results were similar among older and younger patients. During the entire program period, the older adult group showed better achievement of program goals compared to younger patients ( $P=.03$ ). Additionally, we found that younger patient age is an independent predictor of early dropout from the program and completion of program goals ( $P=.045$ ); younger patients were more likely to experience early program dropout and to complete fewer program goals.

**Conclusions:** Older adult patients demonstrated better compliance and achievement of the goals of the remote rehabilitation program in comparison with younger patients. We found that older age is not a limitation but rather a predictor of better RCR program compliance and program goal achievement.

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**KEYWORDS**

remote cardiac rehabilitation; mobile application; adherence; elderly patients; telehealth; telemedicine; cardiology; smartwatch; wearable; patient monitoring

## Introduction

### Background

Cardiac rehabilitation (CR) is essential for comprehensive cardiac care, as it prevents future heart-related complications which often result in hospital readmissions and death [1,2]. Despite this strong evidence, patients often do not participate in traditional CR for several reasons, such as the location of the medical center, lack of transportation, and travel cost. Other factors include socioeconomic status, as well as behavioral and psychosocial reasons [3-5]. In contrast, remote CR (RCR) programs are individualized to each patient through telemedicine, regardless of where they are. This permits RCR to achieve all of the clinical goals set by CR while at the same time overcoming the many well-known barriers of CR. RCR has been shown to improve exercise adherence, increase physical activity level, and reduce the relative cost of treatment [6,7]. With this in mind, RCR has been introduced in Israel and is subsidized under its national health care coverage. As a result, Israel became one of the first countries where RCR began to play an important clinical role and is free of charge for all low risk patients with an indication for CR.

It is generally believed that older adults (>65 years old) struggle to use newer technologies. Various factors such as age-related cognitive impairment, vision or hearing difficulties, short-term memory loss, and physical limitations contribute to this assumption. Additionally, older adult patients have a preference for in-person communication with their physicians, resulting in a lower rate of acceptance of new technological applications [8,9]. Furthermore, a majority of older adult adults need assistance in using new digital devices, claiming they do not feel comfortable learning to use new technological devices such as smartphones or tablets on their own [9]. Some physicians are also less likely to send an older adult patient to a program that requires significant use of technology because they think that the patient is not likely to cope [10]. This is partly due to the current understanding that older adult patients have more difficulties absorbing new content and adapting to a changing environment, which poses another barrier to telemedicine [8] and digital health in general.

However, in recent years, there has been an understanding that older people are also willing and able to manage their health using the newest technologies [11]. Although the rates of mobile app usage among people aged 65 years or older is relatively small, holding steady with 20% usage [12], the introduction of telemedicine programs for older adults is increasing, ignoring the preconceived biases related to the ability of older adults in using technology [13]. These trends both emphasize the growing usage of technological devices by the older adult population and show the desire of older adult patients to control their health through digital devices.

It is well known that CR is essential for older adult patients due to this population having a higher risk of complications from

cardiac-related causes compared to younger patients. However, there are contrasting results in this field of research. Previous studies have shown that older age is associated with a lower likelihood of participation in remote CR [14], while other studies have shown that patients over the age of 65 years are significantly more adherent to hospital-based CR [15]. However, the relationship between older adult patient adherence with remote CR has not been studied in detail.

Our goal is to further expand this area of research by comparing the adherence and program goals achievements between older and younger patients. The objectives of this study were as follows: to study patterns of physical activity, goal achievement, and improvement in functional level among patients over 65 years old undergoing RCR and compare them to those of younger patients; and to identify predictors of better adherence with the RCR program.

### RCR Program Description

The CR program is based on national guidelines provided by the Israeli Heart Society, specifically for comprehensive CR and the specific goals. A detailed description of the program and the Datos Health platform powering our RCR program was published previously [16]. In short, the main component of the program is structured exercise, monitored by a smartwatch capturing the essential data which are then transferred to a mobile app and presented to the patient and securely transferred to the medical operations center at our hospital ([Multimedia Appendix 1](#) and [2](#)). The remote care platform receives all the data generated by the smartwatch and the patient's mobile app and presents the information to the relevant care team member. The platform also includes care coordination tools scheduling follow-up remote visits with the multidisciplinary care team and provides easily accessible educational content that is pushed to the patients according to a prespecified plan. The platform allows the tracking of various measurements trends, interaction with the patient using asynchronous messaging and video chat, and collection of patients reported outcomes and questionnaires. The integrated information makes it possible to monitor, make decisions, and give recommendations regarding patient physical activity.

## Methods

### Study Cohort

Over the 18 months of the program's existence, we collected data on behavior patterns, training, and goal achievements from the first low-risk group of 306 patients rehabilitating under the RCR program at Sheba Medical Center in Israel. The participants of the group were both young and older adult patients. The collection of information and analysis were carried out retrospectively. The program goals were the same for all individuals regarding monthly exercise minutes (total exercise minutes and exercise in the target heart zone), and the exercise intensity was derived from the results of the exercise test

reflecting the age-dependent maximal heart rate. Resistance training sessions and repetitions were similar but with individualized resistance. Basic characteristics, including a complete medical history, risk factors, and laboratory tests were collected. Training patterns were obtained by the smartwatch and then analyzed prospectively by the platform for 24 weeks. Improvement of an individual's functional capacity was assessed as the change between the first (prerehabilitation) and the second (following 3 months of rehabilitation) exercise stress test (ergometry)—estimated metabolic equivalents of task (METs). Satisfaction with the program and the care received were assessed using a digital questionnaire.

### Study End Points

The primary end point of the study was to determine the difference in adherence to the RCR program goals among patients over 65 years of age compared with younger patients. The following variables were evaluated longitudinally in each month of the exercise program: the number of minutes of aerobic exercise (aerobic minutes), the number of aerobic minutes in the target heart rate, the assessment of perceived Borg scale, the number of daily steps, and the use of the RCR mobile app (number of weekly entries). Secondary end points included the improvement in functional capacity, the number of training sessions, and the satisfaction with the RCR program overall.

### Ethics Approval

All required ethics board approvals for this study have been given by the Sheba Medical Center committee (Sheba institutional review board approval #SMC-14-1553).

### Statistical Analysis

Descriptive statistics are presented according to variable characteristics and normality assumption evaluation. Baseline characteristics are presented as median, mean and SD, or percentages as appropriate. Group comparisons were performed according to data type and its respective distribution. A paired sample *t* test or Wilcoxon signed-rank test was used according to the data distribution to assess the differences between baseline and program completion values for the entire group and for age-stratified subgroups. A logistic regression model was constructed using the best subset method in order to determine independent predictors of selected program goals. The following covariables were introduced: age, sex, prerehabilitation METs, and indication for CR.

A *P* value <.05 was considered statistically significant. Tests were 2-sided. Statistical analyses were performed using R statistical software version 4.1.2 (The R Foundation for Statistical Computing).

## Results

The study included 306 patients, 26.1% (80/306) of whom were over 65 years old. Detailed characteristics of the group are

summarized in [Table 1](#). The main indications for CR were percutaneous coronary intervention (137/28, 148.8%) and myocardial infarction (138/281, 49.1%). Participants had a preserved or normal systolic function and no high-risk criteria, such as significant ischemia, angina, clinically significant ventricular arrhythmia, or signs of clinical instability. Older patients had significantly more individuals after coronary artery bypass graft (16/80, 21.6%) compared to younger patients (19/203, 9.3%; *P*=.01). The median number of total minutes of aerobic training for 6 months was 183 minutes per week in the entire population. The older adult group achieved 222 minutes, whereas the younger group achieved 168 minutes (*P*=.003). [Table 2](#) presents the total aerobic activity by program month. Additionally, the number of mobile app entries per week was significantly higher among older adult individuals during the entire duration of the program. Older adult patients had a median of 5.7 mobile app entries per week, whereas younger patients had 3.7 entries per week (*P*=.007).

[Table 3](#) shows that the objective improvement in aerobic functional capacity after 3 months of RCR when compared to baseline was significant in the entire group (*P*=.001). Interestingly, prior to RCR initiation, there was a significant difference between the older adult group and the younger group in the baseline exercise capacity as expressed by METs (*P*=.002). However, this difference disappeared after 3 months of RCR.

[Table 4](#) shows the percentage of those who achieved the main goals of RCR in the first 3 months of rehabilitation. These goals involved achieving 150 aerobic training minutes weekly and achieving 120 aerobic minutes in target heart rate per week. Among those who achieved these goals, the percentage of older adult patients was significantly higher when compared to younger patients (*P*=.03). The basic characteristics of patients who achieved the main goals versus those who did not during the third month of the program were also evaluated. Other than age, there was no significant difference between the groups of those who achieved versus those who did not achieve these goals. Older patients had significantly better completion rates of the three program goals: (1) completion of the full 3 months of RCR—the average age in the group of those who completed the program was 58.5 years while the average age of those in the group who dropped out was 55.5 years (*P*=.044); (2) achieving at least 600 aerobic minutes per month—the age of those who achieved this goal was 60 years while the average age of those who did not achieve this goal was 55 years (*P*=.001); (3) achieving at least 400 minutes per month of training in the target heart rate—the average age of those who achieved this goal was 63.7 years while the average age of those who did not achieve this goal was 56.9 years (*P*=.001).

**Table 1.** Baseline demographic and clinical characteristics of the study population.

Variables	Total population (N=306)	<65 years old (n=222)	>65 years old (n=80)	P value
Age (years), mean (SD)	57.59 (10.62)	53.01 (8.48)	70.16 (3.38)	<.001
Male sex, n (%)	229 (81.5)	171 (83.4)	56 (75.7)	.2
<b>Comorbidities, n (%)</b>				
<b>Metabolic</b>				
Dyslipidemia	85 (30.2)	57 (27.8)	27 (36.5)	.21
Hypertension	72 (25.6)	44 (21.5)	28 (37.8)	.009
Diabetes mellitus	17 (6)	11 (5.4)	6 (8.1)	.57
<b>Cardiovascular</b>				
Myocardial infarction	138 (49.1)	101 (49.3)	35 (47.3)	.88
Atrial fibrillation	29 (10.3)	15 (7.3)	14 (18.9)	.01
Atrial flutter	4 (1.4)	3 (1.5)	1 (1.4)	>.99
Status post–coronary artery bypass graft	35 (12.5)	19 (9.3)	16 (21.6)	.01
Status post–percutaneous coronary intervention	137 (48.8)	103 (5.2)	33 (44.6)	.49
<b>Physical and functional status, mean (SD)</b>				
BMI (kg/m <sup>2</sup> )	27.76 (11.77)	28.15 (13.57)	26.91 (4.20)	.42
Systolic blood pressure (mmHg)	131.18 (20.13)	128.35 (19.78)	139.79 (18.74)	.002
Diastolic blood pressure (mmHg)	75.71 (12.12)	75.21 (12.18)	77.46 (11.90)	.32
Pre–heart rate at maximum effort	140.01 (19.66)	144.98 (18.11)	125.99 (17.09)	<.001
Post–heart rate at maximum effort	145.35 (18.87)	148.77 (18.44)	136.24 (17.09)	<.001
Pre-METs <sup>a</sup> (kcal/kg/min)	9.49 (2.88)	9.98 (2.76)	8.11 (2.80)	<.001
Post-METs (kcal/kg/min)	11.38 (7.00)	11.42 (3.13)	11.25 (12.62)	.88

<sup>a</sup>MET: metabolic equivalent task.

**Table 2.** Total aerobic minutes per month.

Month	<65 years old (min), median (n=222)	>65 years old (min), median (n=80)	P value
1	167	215	.002
2	166	230	.001
3	158	212	.002
4	150	213	.002
5	165	213	.004
6	142	168	.004

**Table 3.** Exercise capacity before and after RCR.

Max METs <sup>a</sup>	<65 years old (n=222)	>65 years old (n=80)	P value
Pre-RCR <sup>b</sup>	9.98	8.11	.001
Post-RCR	11.42	11.25	.33

<sup>a</sup>MET: metabolic equivalent of task

<sup>b</sup>RCR: remote cardiac rehabilitation.

**Table 4.** RCR outcomes by age group.

RCR <sup>a</sup> outcomes	<65 years old, n (%) (n=222)	>65 years old, n (%) (n=80)	P value
Reached target heart rate minutes 1st month	31 (14.1)	24 (29.8)	.04
Reached target heart rate minutes 2nd month	38 (17.3)	31 (38.6)	.01
Reached target heart rate minutes 3rd month	102 (45.8)	42 (52.9)	.21
Reached total aerobic minutes 1st month	150 (67.6)	66 (82.5)	.04
Reached total aerobic minutes 2nd month	147 (66.2)	69 (86.2)	.03
Reached total aerobic minutes 3rd month	141 (63.4)	67 (84.3)	.02

<sup>a</sup>RCR: remote cardiac rehabilitation.

## Independent Predictors of Goal Completion

A logistic regression model was constructed to predict each of the 3 main program goals. Higher age was consistently an independent predictor of achieving the RCR aerobic exercise goals of completing at least 600 aerobic minutes per month (odds ratio 1.07, 95% CI 1.03-1.13;  $P=.007$ ) and completing at least 400 minutes per month of training in the target heart rate (odds ratio 1.09, 95% CI 1.03-1.15;  $P=.008$ ).

There was no significant difference between older adult and younger patients in the number of daily steps or in the amount of weekly use of the mobile app. However, a significant difference was observed in the number of aerobic workouts per week: the median number of workouts per week in the older adult group was 6.7 versus 3.7 in the younger group ( $P=.002$ ).

Over 85.9% (263/306) of patients reported feeling safe and satisfied with RCR, and 83.9% (257/306) of patients answered that the program helped them maintain a healthy lifestyle.

## Discussion

### Principal Findings

The principal findings of our study are the following: participants of the RCR adhered to the program and most attained the prespecified goals, older adult patients had higher compliance and were more likely to reach RCR goals compared to younger participants, and older adult patients had a significant absolute improvement in functional capacity assessed objectively by the stress test.

### Comparison With Prior Work

Previous studies have mentioned factors such as preexisting health conditions and lower physical functioning as additional barriers which make older adult patients unable to benefit from CR compared to younger patients [17]. However, our results did not find that these factors were significant barriers to older adult patients' remote CR adherence. Our study demonstrated that older adult patients were able to effectively adhere to and use modern technology during the program. Our results found that older adult patients had greater program compliance than that originally thought. This could be due to several factors. First, patients with previous cardiovascular events (ie, acute coronary syndrome or revascularization procedures) who are older are usually at a higher risk compared to younger patients

[18]. Their higher risk status could have motivated them to participate more actively when compared to younger patients. Other studies have also shown that older adult patients seem to be more attentive to their health conditions, whereas younger patients might be less attentive because they often consider themselves to have a strong recovery ability [19]. Second, other studies have shown that higher risk patients in CR participate in more CR sessions than do lower risk patients [15]. Although we did not stratify patients into these same categories, we showed that older adult patients attended more remote CR sessions than did their younger counterparts. This was found to lead to better program goal achievements. One explanation for this could be that older adult patients are generally retired and have more free time compared to younger patients. This concept has been previously studied, showing that employment status can be a negative predictor of CR adherence, as older patients tend to be retired and have more free time for training [20]. Program goal achievement was correlated with the significant improvement in functional capacity where the older adult group reached similar levels of exercise capacity (assessed in METs) as did young patients despite the difference in functional capacity at the beginning of the program. Improvements in performance have been shown to be associated with improved survival and overall well-being [21,22].

A common misperception is that older adult people (>65 years old) are hesitant to accept new technologies. Several studies state barriers such as lack of knowledge or fear of misusing remote CR technology [23]. However, other studies also report that older adult patients were eager to adopt new technologies and had no difficulty using remote CR devices [23,24]. The second group of studies above aligns well with the findings of our study. Older adult patients were effectively able to use remote CR technology. Moreover, we found that these older adult patients were more consistent in achieving the goals of the program when compared with younger patients.

### Strengths and Limitations

The strength of this study is that it is the first and exclusive study of a new national telerehabilitation program fully subsidized by the Ministry of Health. Moreover, the analysis carried out in this study covered a relatively large cohort of patients and carefully analyzed multiple aspects of their performance over a 6-month period. Nevertheless, our study has a number of limitations. First, it used a retrospective design and included a relatively low risk population, with most of the

participants being men. This is unsurprising, as secondary prevention treatments are underused in women with coronary heart disease [25]. Second, we present the experience of a single center following a specific RCR protocol using a dedicated digital health platform. At the time of the study, there were no other cardiology centers in our country offering a similar program to patients, so it was impossible to create a multicenter study. In the future, it is essential to collect data from multiple sites to increase the generalizability of the results and to allow for the comparison among different programs.

### Future Directions

Multicenter prospective research is necessary in order to assess the generalizability of these findings. Furthermore, now having an understanding of the successful implementation of the program even among low-tech older adult people, we further seek to expand the implementation of telerehabilitation usage

among patients at medium and high risk, for example, patients with heart failure. The recent experience of the COVID-19 pandemic has further emphasized the importance of implementing telecare for all types of patients without exception.

### Conclusions

Our study showed that older adult patients demonstrated better compliance with the remote CR program in most aspects. Higher age was an independent predictor of better compliance with program goals. Given these results, we suggest that CR programs are more suitable for older adult patients than initially thought. However, due to the misconceptions about their ability to use technology, older adult patients remain underrepresented in current remote digital health studies. Future studies need to be conducted to understand this relationship and explore the potential benefit of remote rehabilitation in other fields of medicine among older adult patients.

### Data Availability

The data set used for this study contains a great number of details per patient each and cannot, per institutional review board approval, be shared even in anonymized form. Requests for partial anonymized data for specific projects can be discussed with the corresponding author (RK).

### Conflicts of Interest

None declared.

#### Multimedia Appendix 1

Care management screens of the remote cardiac rehabilitation.

[PNG File , 457 KB - [cardio\\_v6i2e36947\\_app1.png](#) ]

#### Multimedia Appendix 2

The remote cardiac rehabilitation patient mobile app (iOS and Android).

[PNG File , 393 KB - [cardio\\_v6i2e36947\\_app2.png](#) ]

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## Abbreviations

- CR:** cardiac rehabilitation  
**MET:** metabolic equivalent of task  
**RCR:** remote cardiac rehabilitation

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Viewpoint

# Digital Health Solutions to Reduce the Burden of Atherosclerotic Cardiovascular Disease Proposed by the CARRIER Consortium

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## Abstract

Digital health is a promising tool to support people with an elevated risk for atherosclerotic cardiovascular disease (ASCVD) and patients with an established disease to improve cardiovascular outcomes. Many digital health initiatives have been developed and employed. However, barriers to their large-scale implementation have remained. This paper focuses on these barriers and presents solutions as proposed by the Dutch CARRIER (ie, Coronary ARtery disease: Risk estimations and Interventions for prevention and EaRly detection) consortium. We will focus in 4 sections on the following: (1) the development process of an eHealth solution that will include design thinking and cocreation with relevant stakeholders; (2) the modeling approach for two clinical prediction models (CPMs) to identify people at risk of developing ASCVD and to guide interventions; (3) description of a federated data infrastructure to train the CPMs and to provide the eHealth solution with relevant data; and (4) discussion of an ethical and legal framework for responsible data handling in health care. The Dutch CARRIER consortium consists of a collaboration between experts in the fields of eHealth development, ASCVD, public health, big data, as well as ethics and law. The consortium focuses on reducing the burden of ASCVD. We believe the future of health care is data driven and supported by digital health. Therefore, we hope that our research will not only facilitate CARRIER consortium but may also facilitate other future health care initiatives.

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**KEYWORDS**

atherosclerotic cardiovascular disease; ASCVD; cardiovascular risk management; CVRM; eHealth; digital Health; personalized e-coach; big data; clinical prediction models; federated data infrastructure

## Introduction

Atherosclerotic cardiovascular disease (ASCVD) remains one of the leading causes of death worldwide [1] and is a burden to medical expenses in Europe [2]. The occurrence of ASCVD is highly correlated with conventional risk factors such as high blood pressure and smoking. Therefore, prevention and treatment of risk factors is of importance in reducing this burden. ASCVD can be prevented to a great extent by a healthy lifestyle [3].

However, a recent survey from EUROASPIRE V investigators showed that “a large majority of patients at high [AS]CVD risk fail to achieve lifestyle, blood pressure, lipid, and glycemic targets” [4]. The limited adherence to these targets is one of the causes of the remaining burden of ASCVD. Therefore, there is an unmet clinical need for innovative solutions to support people at risk, patients with an established disease, and their health care professionals to improve cardiovascular outcomes.

eHealth has the potential to reach a wide audience of people at risk and support patients to adopt a healthy lifestyle and reduce their cardiovascular risk [5-7]. Nevertheless, there are barriers to large-scale implementation of digital health as stated by the Society of Cardiology e-Cardiology working group in their recent position paper [8].

One of the barriers to eHealth implementation is a mismatch between the end product and the needs of its end users [8-10]. It is known that specific groups have a low adherence to eHealth (eg, people in older age and those with low health literacy). Involvement of relevant stakeholders (eg, physicians and patients) during development (or so-called cocreation) enhances the adoption of the end product by its end users [11].

In addition to cocreation with relevant stakeholders, implementation also depends on availability and communicability of data between stakeholders involved in the prevention of ASCVD. The availability of data is essential for innovative clinical prediction models (CPMs) for the early

identification of people at risk, accurate risk estimation, and guiding interventions [12].

Unfortunately, data are scattered among the stakeholders, and thus, not readily available. Therefore, a mature data infrastructure connecting the stakeholders needs to be developed. A federated data infrastructure using the Personal Health Train [13] is a promising technology to connect stakeholders.

Finally, successful implementation of digital health interventions requires consideration of ethical and legal demands for the aforementioned data infrastructure. Therefore, an ethical and legal framework for responsible data handling in health care needs to be instigated.

The Dutch CARRIER (ie, Coronary ARtery disease: Risk estimations and Interventions for prevention and EaRly detection) consortium (Table 1) consists of a collaboration between experts in the fields of eHealth development, ASCVD, public health, big data, and ethics and law. The consortium was established in 2020 and is funded by the Dutch Research Council. CARRIER targets early identification, prevention, and treatment of ASCVD, with a regional alliance in the south of the Netherlands. We believe the future of health care is data driven and supported by digital health. Therefore, we collaborate on research of big data-driven, participative self-care interventions to reduce the burden of ASCVD.

In this paper, we will discuss the aforementioned barriers and propose the following practical solutions for the implementation of digital health to reduce the burden of ASCVD: (1) description of the development process of an eHealth application using cocreation with relevant stakeholders, which enhances the adoption of the end product by its end users; (2) presentation of the modeling approach for two innovative CPMs for the early identification of people at risk of developing ASCVD, accurate risk estimation, and guiding interventions; (3) description of a federated data infrastructure using the Personal Health Train to connect relevant stakeholders; and (4) discussion of an ethical and legal framework for responsible data handling in health care.

**Table 1.** Terms and abbreviations used within CARRIER consortium and their definitions.

Term or abbreviation	Definition
Digital health	A broad umbrella term encompassing the whole technical solution CARRIER proposes
eHealth	The product that is used by the end users
ASCVD	Atherosclerotic cardiovascular disease
Design thinking	A cyclic process to develop products
Cocreation	Involvement of relevant stakeholders during the development of products
CPM	Clinical prediction model
Implementation	The process that ensures the end product is used in daily practice
Federated learning	A technique that trains algorithms using data from decentralized organizations
Federated data infrastructure	A set of tools and processes that allows federated learning
Ethical and legal framework	The framework that needs to be created to ensure responsible data handling
SN	Statistics Netherlands—the national office for statistics
EHR	Electronic health record
NLP	Natural language processing, or text mining—a technique to analyze human language
FAIR data	Findable, Accessible, Interoperable, and Reusable data
Vertically partitioned	Data from the same individual that is distributed among different organizations
Record linkage	Linking records that correspond to the same individual across different data sets
SMC	Secure multiparty computation, which allows organizations to perform calculations with private data without revealing the data
$\epsilon$ -Differential privacy	The degree of privacy sensitivity of an analysis
GDPR	General Data Protection Regulation

## The Development Process of a Digital Health Solution

To increase the likelihood of successful adoption of the end product by its end users, the user-centered design approach—“design thinking”—will be applied [14,15]. Design thinking is an iterative process to create and evaluate innovative solutions; this means that end users and relevant stakeholders will be involved throughout the development process to ensure the final product meets the needs and vision of all relevant parties. Design thinking consists of 5 iterative phases (Figure 1).

Within the first 2 phases (ie, empathize and define), we used cocreation to describe our ideal digital health solution for ASCVD. Essential elements of this solution are as follows: a CPM for risk estimation, personalized risk communication, personalized treatment goals, individualized eHealth modules to guide and monitor treatment and outcomes, and the use of a federated data infrastructure to connect different organizations involved (Figure 2). These elements are explained in more detail in the next sections.

Integration of CPMs in a digital health solution enables the use of relevant and readily available data from different organizations to identify people at risk. After calculating the risk, this will be visualized and communicated according to the preferences and level of understanding of the individual. This information supports the patient and health care professional to

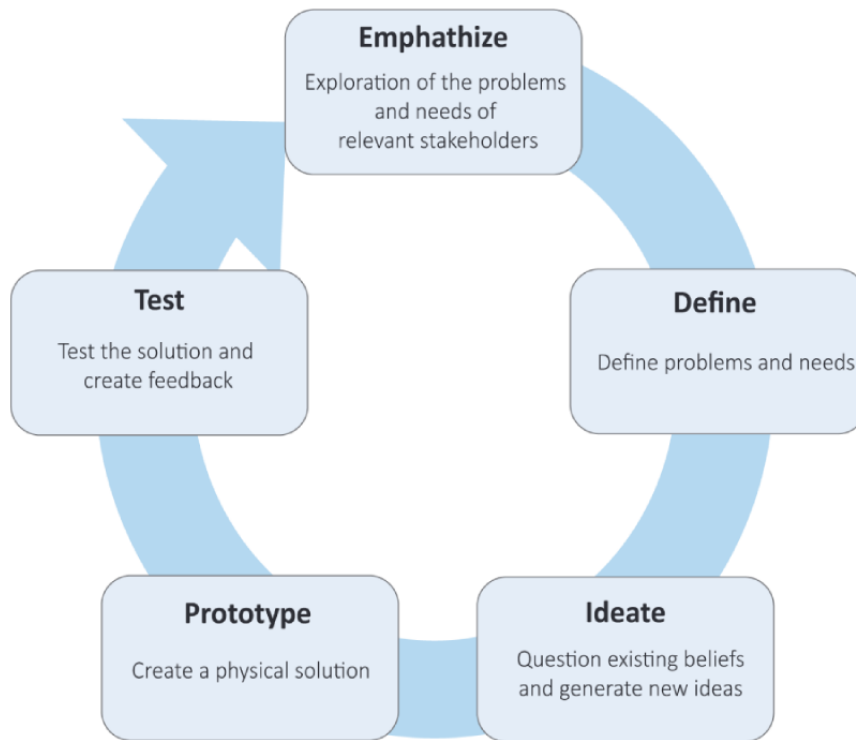
set tailored goals using shared decision-making. The optimal format and visualization for risk communication is further examined and is therefore part of the objectives of CARRIER.

As different subgroups of people have a different adherence to lifestyle interventions, eHealth modules need to be adapted toward a personalized approach [16]. When interventions are personalized, the content becomes more relevant to the individual. This will result in an increased adherence to the intervention and a greater improvement in health outcomes [17].

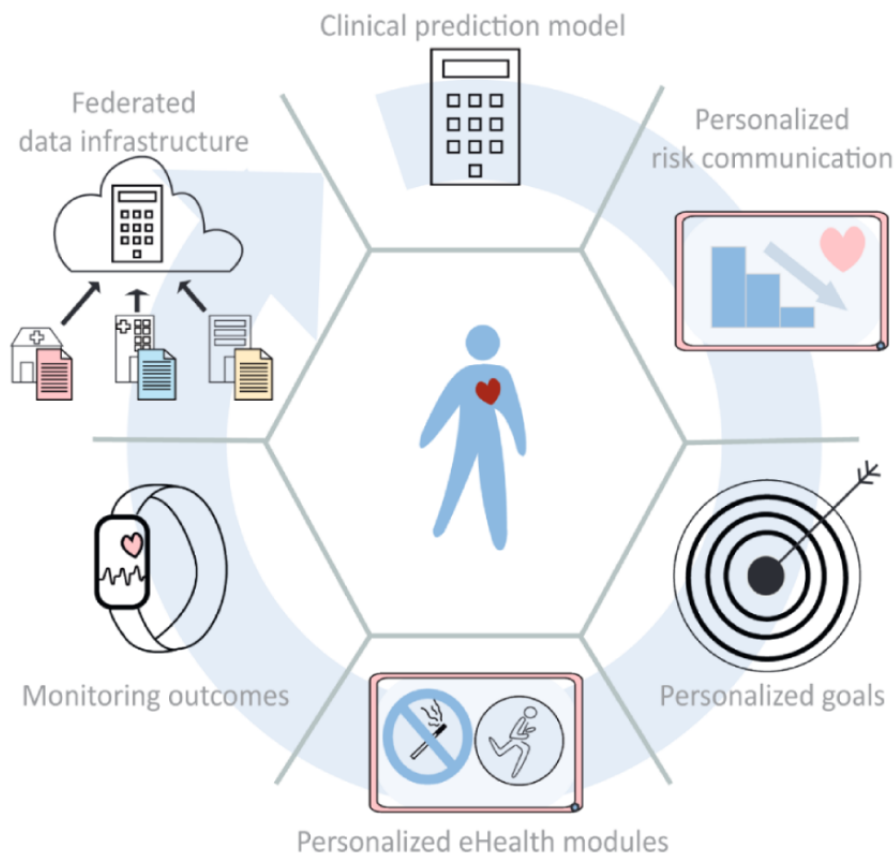
eHealth modules that support patients in achieving their goals will be available within the eHealth solution for cardiovascular risk factors, such as smoking, hypertension, diabetes, and hypercholesterolemia, and additionally, for medication adherence, a healthy diet, physical activity, and stress reduction. The modules should also provide the possibility to monitor the effect of the interventions by (automatic) collection of relevant data. Activity trackers, for example, can be used to obtain insight into the physical activity of the patient. The modules should provide personalized feedback to the patients and their health care professionals. Monitoring of the goals can assist the patient and health care professional to guide the timing and frequency of medical follow-up. Relevant outcomes should be collected and used to improve the content of the eHealth modules and the risk estimation of the CPMs. Besides the first 2 steps (ie, empathize and define) of the design thinking process, the other 3 steps include the following: ideate, prototype, and testing. The testing phase will include an evaluation with the involvement of end users. Thereby, the testing phase provides

feedback and may lead to reevaluation of the proposed solution. To ensure maximal implementation, the eHealth solution needs to be integrated into the workflow of care pathways [8].

**Figure 1.** The 5 iterative phases of design thinking.



**Figure 2.** Proposed digital health solution.



## *The Modeling Approach for a Screening and Interventional Model*

The early identification of people at risk for ASCVD can be supported by CPMs. However, current CPMs, such as Framingham or SCORE, only use conventional patient characteristics for their risk estimation [18]. To improve the accuracy of CPMs, nonconventional risk factors, such as ethnicity, socioeconomic status, obesity, and physical inactivity, can be added [12,19,20]. Adding nonconventional risk factors can identify people at increased risk without the need for prior medical testing (unlike measurement of high blood pressure and hypercholesterolemia) and can inform lifestyle interventions (eg, losing weight and increasing physical activity).

Two CPMs will be constructed in CARRIER. The first model aims to identify people at risk to develop ASCVD. The second model aims to guide interventions for those at a high risk or with an established ASCVD. We will refer to the first model as the screening model and to the second model as the intervention model.

Consensus on which conventional and nonconventional risk factors should be included in the models will be reached through a Delphi study [21] by experts in the field of ASCVD. The relationships among these factors and ASCVD will be depicted using a causal graph [22]. This is a graphical representation of the causal structure among the factors, in which arrows indicate the direction of the causal effects.

The screening model will be based on federated learning (explained in the next section) using data from three different organizations: hospitals, general practices, and the national office for statistics (in our case, Statistics Netherlands [SN]). Data from the hospitals and general practices include electronic health record (EHR) data from individual patients. EHR data are not systematically gathered, resulting in many possible sources of bias (eg, nonrandom missingness) [23], which we will adjust by applying a range of techniques [24]. Furthermore, EHR data sets contain much information in free-text form. We will explore to which extent natural language processing (or text mining) techniques aid to supplement the structured EHR data with data extracted from free text [25].

Regarding the intervention model, we plan to make use of data of a regional observational cohort study in which clinical and lifestyle data are being collected [26]. These data are required to construct a causal model that can estimate the effect of lifestyle interventions. The following two main strategies were identified to incorporate hypothetical interventions in CPMs [27]: combining a CPM with causal effects estimated in randomized controlled trials and estimating causal effects based on observational data alone. We will use both these strategies during the development of CPMs within CARRIER.

In terms of statistical modelling techniques, we plan to use (1) regression models; (2) Bayesian networks, which suit well to causal graphs and provide an intuitive and explainable framework where data can be combined with expert knowledge [28]; and (3) neural networks or deep learning, which have

gained popularity in recent years due to model complex functions [29]. Established models such as SCORE2 [30] will be used to compare the models' performance. After model development, we envision external validations in order to research the models' transportability to different settings and related populations. Reporting of the development and validations of the CPMs will adhere to the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) guidelines [31].

When implementing the screening and intervention model, we anticipate a deterioration of the models' performance over time due to shifting data distributions [32]. Therefore, we aspire to schedule temporal validations and updates of the models. In addition, we aim to monitor predictors continuously to detect changes in their univariable distribution, which may trigger an earlier than planned check.

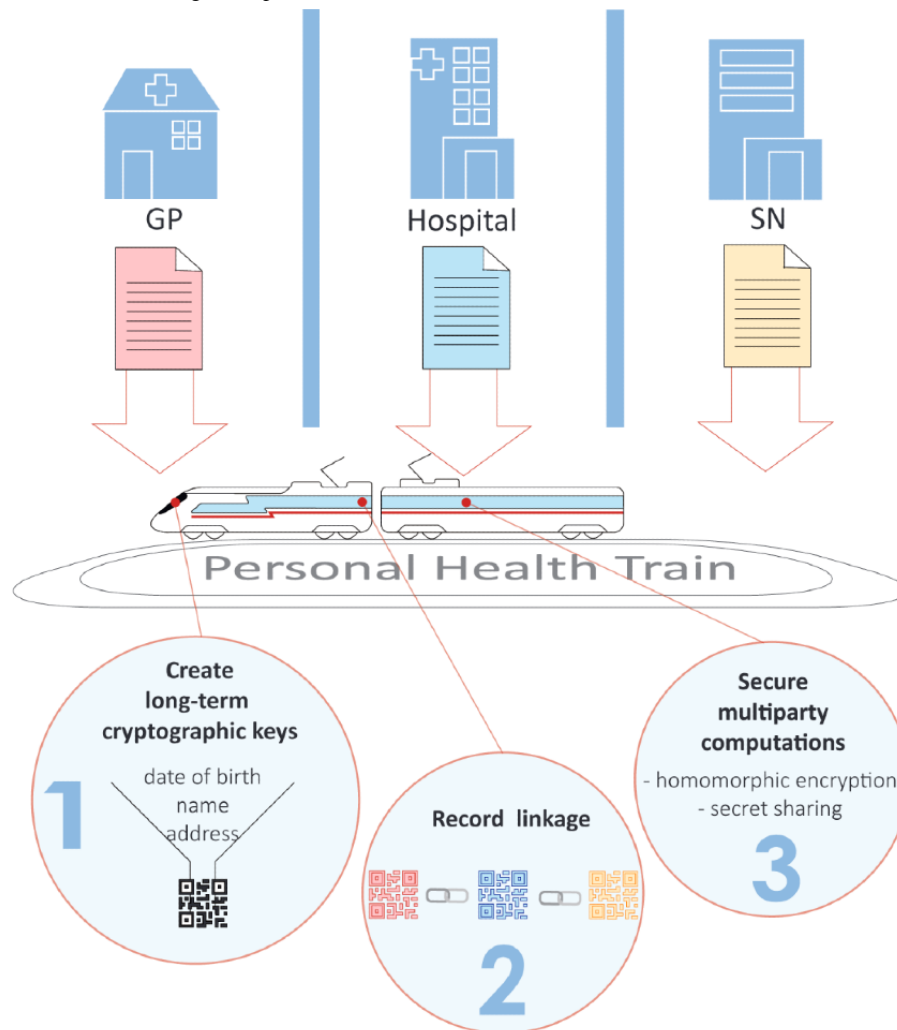
## *The Federated Data Infrastructure to Support Our Digital Health Solution*

The two main issues of using medical data for prediction modelling are poor quality and scattering across different organizations. CARRIER aims to tackle these problems by following the Findable, Accessible, Interoperable, and Reusable (FAIR) data principles [33] and by developing a federated data infrastructure. FAIR data principles establish a set of guidelines that lead to the improvement of data quality, such as the use of metadata and standard vocabularies and ontologies. The use of standards also allows for data from different organizations to be combined [34] and increases the chances of data being reusable for secondary purposes [35].

To develop our screening model, we need to combine data from different organizations. Currently, relevant and potentially privacy-sensitive data from different organizations need to be shared to a central database before they can be analyzed. However, growing awareness of privacy and data ownership-related ethical issues have led to growing legal restrictions on data sharing. This is noticeable under the current legal regimens (more details are provided in the next section).

In the last few years, federated learning has risen to prominence to analyze distributed data, for example, to train machine learning models [36,37]. Although the term federated learning seems to denote the algorithm, we will use the term 'federated data infrastructure' to denote the collection of tools and processes necessary to allow federated learning to work safely and reliably. As such, federated data infrastructures allow for decentralized data to be analyzed without subject-level data leaving the organization. This has implications on privacy preservation and on retaining control of data by its owner, which will allow for safer reuse of data [38]. In CARRIER, we will use the Personal Health Train [13], a federated learning platform that encompasses technical and legal aspects. This is implemented with an open-source software that handles the communication and authentication and provides an environment to implement federated algorithms [39]. The federated data infrastructure is visualized in Figure 3.

**Figure 3.** Federated data infrastructure. GP: general practices; SN: Statistics Netherlands.



Data from hospitals, general practices, and SN will be used to develop the screening model for ASCVD. Hence, data on each individual are distributed across different organizations. This is termed ‘vertically partitioned’ (or ‘heterogeneous’). Federated learning on vertically partitioned data presents a unique set of challenges. The first is privacy-preserving record linkage, that is, linking records that correspond to the same individual across different data sets, without revealing any sensitive information [40]. Given that readily available identifiers, such as the citizens’ service number, are illegal to be used due to privacy concerns, we will use alternatives such as long-term cryptographic keys [41]. This technique uses personal characteristics, such as name, date of birth, and address, to create a unique encrypted code, which is used for record linkage.

After matching the individual records, the main challenge is to perform data analysis on different sources without each party revealing their data to the other parties. Secure multiparty computation (SMC) is a subfield of cryptography that allows a set of parties (or organizations) to perform calculations with their private data without revealing these data to the other parties [42]. A technique used in SMC is homomorphic encryption [43] (Figure 4), which is a form of encryption that allows

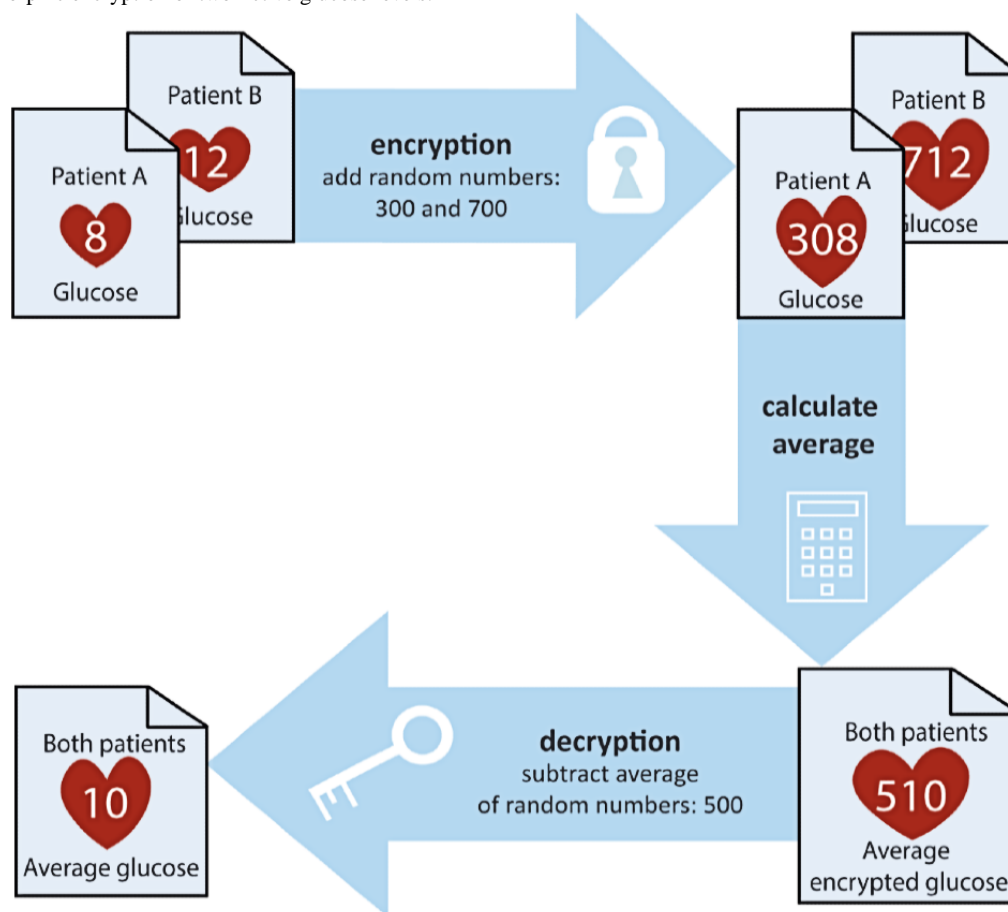
computations on encrypted data. Another technique used in SMC is secret sharing [44], where numbers are ‘split’ across multiple organizations and can only be reconstructed after being combined. As such, SMC can be used to analyze data and even train models from different organizations without the data being revealed.

After requested analyses are performed within the federated data infrastructure, the degree of privacy sensitivity of an analysis can be represented by  $\epsilon$ -differential privacy [45]. This can be used as a criterion before sharing an analysis from one source to the other. An analysis is  $\epsilon$ -differentially private when its results do not change significantly with slight changes in the population. This guarantees that the results do not depend on the values of any given individual in the data set, and therefore, it is not possible to trace back information to an individual patient.

In summary, in CARRIER, we are developing a federated, FAIR data infrastructure. This infrastructure allows us to train models on vertically partitioned data and ensures that our analyses preserve privacy by means of SMC techniques and  $\epsilon$ -differential privacy.



**Figure 4.** Homomorphic encryption of two fictive glucose levels.



## *The Development of an Ethical and Legal Framework for Responsible Data Handling in Health Care*

CARRIER concerns the processing of different medical, lifestyle, and other personal data, held by different organizations, that relate to citizens. These data are collected for a range of different purposes, but the processing for CARRIER involves the processing of newly gathered data as well as the processing of already gathered data for the prevention and treatment of ASCVD. This means that the processing relies on the manner in which the data have been gathered in the first place and how the different applicable legal regimes impact upon that processing.

CARRIER is a project primarily taking place in the Netherlands. Therefore, it is subject to the European Union General Data Protection Regulation (GDPR), which has direct effect in European Union Member States' law and the national law implementing the GDPR. The implementing law enables the Netherlands to make choices in relation to discretions contained in the GDPR. Alongside the personal data protection laws, the law relating to medical devices must be taken into consideration, as CARRIER seeks to create a digital health solution. SN is a partner in the project and holds one of the data sets that is key to the development of the project. The rules under which personal data held by SN can be accessed or processed by third party partners is strictly governed under the SN act. Finally,

besides legal considerations, there are ethical considerations, particularly in relation to 'nudging' people to adopt particular behaviors (ie, using an eHealth solution to adopt a healthy lifestyle), and more broadly, about the ethics of individuality and solidarity in relation to the use of personal data for developing novel CPMs for ASCVD.

Federated learning, as is explained previously, enables communication of pseudonymized data from different organizations. Federated learning might therefore provide safeguards and techniques that enable the sharing of nonidentifiable answers to questions asked of the data between the stakeholders, thereby contributing to public health while respecting individuals' privacy. However, how this federated data infrastructure can be organized and accepted within the requirements of law and ethics is one of the goals of CARRIER.

In order to make this assessment, CARRIER follows 3 broad phases. First, it ensures that the research undertaken—particularly in relation to the development of CPMs using already gathered data—conforms to the law as it is currently understood. Second, it identifies alternative interpretations sustainable in the law to ensure the future operation of the digital health solution and the continuing research. This part acknowledges that GDPR (and local implementing law) presents a number of options for, for example, processing data in the public interest. Further, the operation of informed consent is far from clear in GDPR. Given that there are legitimate options available for the interpretation of GDPR, CARRIER is exploring how those interpretations of

the law can work in relation to the work of the project. One aspect of this exploration is to present to different publics (eg, patients, citizens, and policymakers) the dilemma that citizens want both new and effective treatments that are dependent upon big data processing techniques, and at the same time, they want control of their privacy. This public engagement produces a set of answers that feeds into the last phase. Last, it engages with regulatory authorities, whereby CARRIER will present to the European Data Protection Board and the Dutch Supervisory Authority the findings of the second phase of the work. The aim is to produce a dialogue around the interpretation of GDPR that is open to different understandings of the central dilemma (as explained above), and the interpretation of autonomy and solidarity in the use of personal data in (big data) research.

## Conclusion

Digital health is a promising tool for the prevention and treatment of ASCVD. In recent years, many digital health solutions have been developed, but barriers, as described by the Society of Cardiology e-Cardiology working group, exist for a successful large-scale implementation. In this paper, we presented solutions as proposed by the CARRIER consortium.

We described the development process of a digital health solution, employing design thinking and cocreation with relevant stakeholders. Using cocreation, we ensure that the digital health

solution meets the needs and vision of future end users. Personalization of the eHealth solution can improve adherence to the intervention. This enhances the eHealth implementation in care pathways for ASCVD.

We also described the modeling approach for a screening model to identify people at high risk for ASCVD. CPMs that can make use of conventional and nonconventional risk factors from different organization create the opportunity for early identification and guiding interventions, even without the need for medical testing.

However, a data infrastructure connecting these different organizations is currently not available. We described the possibilities and characteristics of a federated data infrastructure that enables the connection of these organizations. The Personal Health Train allows for federated data analysis while keeping data owners in control of their data. As this federated data infrastructure raises ethical and legal questions, we also described the development of a framework that ensures responsible data handling in health care.

We believe the future of health care is data driven and supported by eHealth. Therefore, our research on a mature and sustainable federated data infrastructure and ethical and legal aspects will not only facilitate CARRIER but may also facilitate other future health care initiatives.

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## Conflicts of Interest

None declared.

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## Abbreviations

**ASCVD:** atherosclerotic cardiovascular disease

**CARRIER:** Coronary ARtery disease: Risk estimations and Interventions for prevention and EaRly detection

**CPM:** clinical prediction model

**EHR:** electronic health record

**ESC:** Society of Cardiology

**GDPR:** General Data Protection Regulation

**SMC:** secure multiparty computation

**SN:** Statistics Netherlands

**TRIPOD:** Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis

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Review

# The Use of Dietary Approaches to Stop Hypertension (DASH) Mobile Apps for Supporting a Healthy Diet and Controlling Hypertension in Adults: Systematic Review

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## Abstract

**Background:** Uncontrolled hypertension is a public health issue, with increasing prevalence worldwide. The Dietary Approaches to Stop Hypertension (DASH) diet is one of the most effective dietary approaches for lowering blood pressure (BP). Dietary mobile apps have gained popularity and are being used to support DASH diet self-management, aiming to improve DASH diet adherence and thus lower BP.

**Objective:** This systematic review aimed to assess the effectiveness of smartphone apps that support self-management to improve DASH diet adherence and consequently reduce BP. A secondary aim was to assess engagement, satisfaction, acceptance, and usability related to DASH mobile app use.

**Methods:** The Embase (OVID), Cochrane Library, CINAHL, Web of Science, Scopus, and Google Scholar electronic databases were used to conduct systematic searches for studies conducted between 2008 and 2021 that used DASH smartphone apps to support self-management. The reference lists of the included articles were also checked. Studies were eligible if they (1) were randomized controlled trials (RCTs) or pre-post studies of app-based interventions for adults (aged 18 years or above) with prehypertension or hypertension, without consideration of gender or sociodemographic characteristics; (2) used mobile phone apps alone or combined with another component, such as communication with others; (3) used or did not use any comparator; and (4) had the primary outcome measures of BP level and adherence to the DASH diet. For eligible studies, data were extracted and outcomes were organized into logical categories, including clinical outcomes (eg, systolic BP, diastolic BP, and weight loss), DASH diet adherence, app usability and acceptability, and user engagement and satisfaction. The quality of the studies was evaluated using the Cochrane Collaboration's Risk of Bias tool for RCTs, and nonrandomized quantitative studies were evaluated using a tool provided by the US National Institutes of Health.

**Results:** A total of 5 studies (3 RCTs and 2 pre-post studies) including 334 participants examined DASH mobile apps. All studies found a positive trend related to the use of DASH smartphone apps, but the 3 RCTs had a high risk of bias. One pre-post study had a high risk of bias, while the other had a low risk. As a consequence, no firm conclusions could be drawn regarding the effectiveness of DASH smartphone apps for increasing DASH diet adherence and lowering BP. All the apps appeared to be acceptable and easy to use.

**Conclusions:** There is weak emerging evidence of a positive effect of using DASH smartphone apps for supporting self-management to improve DASH diet adherence and consequently lower BP. Further research is needed to provide high-quality evidence that can determine the effectiveness of DASH smartphone apps.

**KEYWORDS**

DASH diet; Dietary Approaches to Stop Hypertension; smartphone app; mobile app; blood pressure

## Introduction

### Background

Hypertension is a serious medical condition that has become a public health problem. Globally, in 2015, 1.13 billion people (1 out of 4 men and 1 out of 5 women) had hypertension, and most of them were living in low- and middle-income countries [1]. Hypertension is attributed to the following 2 kinds of risk factors: (1) modifiable risk factors, which include unhealthy diet, physical inactivity, obesity, and consumption of tobacco and alcohol; and (2) nonmodifiable risk factors, which include family history of hypertension, age over 65 years, and chronic diseases, such as diabetes and kidney disease [1]. Uncontrolled hypertension might lead to significant complications, such as heart failure, stroke, kidney failure, and economic difficulties stemming from both treatment costs and human capital loss [2-6]. Several studies have shown that hypertension is often poorly controlled and that treatment measures include preventive behaviors and risk factor management [2,5,7]. The World Health Organization recommends the participation of patients through self-monitoring of weight, consumption of diets that are low in sodium and fat, physical activity, smoking cessation, stress reduction, and regular hospital visits to better control hypertension [6].

Self-management is one of the most effective approaches for dealing with hypertension, allowing people with hypertension to feel more responsible for their own health [8]. The Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure has given 6 self-management recommendations that are considered essential for high blood pressure (BP) control: (1) adhering to medication protocols, (2) following the Dietary Approaches to Stop Hypertension (DASH) diet, (3) engaging in physical activities, (4) limiting alcohol consumption, (5) avoiding tobacco, and (6) maintaining a healthy weight [9].

The DASH diet was established by the National Heart, Lung, and Blood Institute (NHLBI) [10]. It provides basic recommendations for a balanced healthy diet that includes various foods [11]. Specifically, the DASH diet comprises vegetables, fruits, whole grains, fish, poultry, beans, nuts, and healthy oils [12]. The DASH diet also recommends a sodium intake of 2300 mg/day or 1500 mg/day for high-risk individuals (eg, those with hypertension or type 2 diabetes) [12]. The diet is also focused on consuming foods that are rich in potassium, calcium, magnesium, protein, and fiber [12].

Consumption of the DASH diet is correlated with a reduction in BP [12]. Recently, an umbrella review was conducted to summarize the available systematic reviews and meta-analyses of randomized controlled trials (RCTs) on different dietary patterns that reduce BP [13]. The review found that a decline in BP correlated with the DASH diet, with the mean differences ranging from  $-3.20$  mmHg to  $-7.62$  mmHg for systolic blood

pressure (SBP) and from  $-2.50$  mmHg to  $-4.22$  mmHg for diastolic blood pressure (DBP) [13]. In addition, for 8 years in a row, *US News and World Report* ranked the DASH diet developed by the National Institutes of Health as the “best overall” diet among almost 40 diets that were reviewed [14].

Additionally, systematic reviews have concluded that the DASH diet is beneficial for not only reducing BP, which was its original intended purpose, but also decreasing the risk of cardiovascular diseases, including that of the main subclasses “coronary heart disease,” “heart failure,” and “stroke” [15,16]. Furthermore, several systematic reviews investigating the DASH diet’s effects on insulin resistance and obesity have found that it may play an important role in controlling hyperglycemia and reducing weight [17,18]. Based on these results, the DASH diet has been promoted as a first-line nonpharmacological therapy along with lifestyle modifications for the treatment of many chronic diseases [15-18].

According to the NHLBI, adherence to the DASH diet in the United States is low [19]. Understanding the determinants of adherence is crucial for improving adherence [19]. At the clinical level, primary care physicians can offer guidance on proper nutritional habits for the treatment of hypertension [19]; however, physicians often state that they have insufficient time, resources, and knowledge for dietary counseling [19]. Additionally, commitment to several consulting sessions is challenging for patients [20].

Over the past decades, there has been a rapid increase in the use of smartphones, and by 2022, it is projected that there will be 6.8 billion smartphone users [21]. In parallel, there has been a rapid increase in mobile apps providing information and health services [21]. Smartphones running health apps are of particular interest because they can promote patient engagement and self-management, and allow for remote follow-up without the need for in-person physician visits [20,22,23].

### Aim

This review aimed at synthesizing existing evidence on the effectiveness of smartphone apps that support self-management to improve DASH diet adherence and accordingly reduce BP, as well as assessing app usability and acceptability, and user engagement and satisfaction. To the best of our knowledge, no studies have summarized the effects of DASH smartphone apps on DASH diet adherence.

## Methods

### Guideline

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline for systematic reviews was used to conduct and report this systematic review [24].

## Data Sources and Search Methods

The following electronic databases were searched: Embase (OVID), Cochrane Library, CINAHL, Web of Science, Scopus, and Google Scholar. The databases were searched using keywords related to dietary approaches to stop hypertension, the DASH diet, and smartphone apps, and using MeSH terms, as well as appropriate synonyms (see [Multimedia Appendix 1](#) for the search strategy). The terms were combined using Boolean operators OR and AND. The search was restricted to English language research published from 2008, when the first app store was introduced [25], to February 22, 2021. Google Scholar was used to search for any additional grey literature using a collection of text words chosen from the papers found in the electronic databases, such as “DASH diet mobile phone apps” and “DASH diet smartphone apps.” Reference lists of the included studies were checked by hand searching to find additional potentially relevant research.

## Inclusion Criteria

The population, intervention, comparison, outcome, and study design (PICOS) framework was used to create the inclusion criteria [24].

### Population

The review included studies that involved people with prehypertension and hypertension who were aged 18 years or over, without consideration of gender or sociodemographic characteristics. Overweight and obese people, including those with hypertension, were included because a higher BMI is associated with a higher risk of eventually developing hypertension [26].

### Intervention

The intervention target was mobile phone apps for dietary behavioral change. To be included, a study had to focus mainly on evaluating a mobile app that assists users in adopting, improving, or maintaining the DASH diet to reduce BP. Studies that combined the mobile phone app with another component, such as communication with others (eg, a coach or research team) by phone, text message, or email, were also included.

### Comparator

The review included studies that used any comparator, for example, studies comparing usual care with the DASH mobile phone app or any other control intervention. Studies without a comparator, such as pre-post pilot studies, were also included.

### Outcome

The primary outcome measures of the included studies were BP level and adherence to the DASH diet.

### Study Design

This review included RCTs and pre-post studies. To minimize the probability of missing important articles both peer-reviewed articles and under-review articles were included.

## Exclusion Criteria

The following criteria were used to exclude studies: (1) Studies that focused on a healthy population, adolescents and children, or pregnant women; (2) Studies that only used messaging, which

included text messaging, SMS text messaging, and emails, or only used websites; (3) Studies solely describing the development of a mobile system's technology; (4) Studies that did not focus on the DASH diet; and (5) Conference abstracts, conference papers, protocols, and studies not published in English.

## Selection of Studies

Reference management software (Endnote X9.0, Clarivate Analytics) was used to import and collect study citations for selection and to deduplicate articles. The screening and selection of titles of studies were conducted by 2 researchers (GA and TA) independently based on eligible criteria. In the second phase, GA and TA checked the abstracts of selected titles. Titles and abstracts received 2 points if they matched the criteria, 0 points if they did not, and 1 point if there was doubt. A study was included in the next phase if the sum of reviewer scores for the title was 2 or more. Studies that received less than 2 points were excluded. Cohen kappa was used to evaluate the agreement of reviewers in each phase of the title and abstract selection process. Controversial studies and disagreements between reviewers were discussed with other researchers (LdW and MH).

## Data Extraction

Two reviewers (GA and TA) independently extracted data and cross-checked the data. The reviewers piloted a standardized form that was used to extract data. Any disagreements were resolved through discussion with the other researchers (LdW and MH) until consensus was obtained. The data included study characteristics (authors, year of publication, follow-up duration, and country); information on participants (sample size, age, gender, and diseases they had); information on apps (name, type, and functionalities); app input (information obtained from users and mode of entering user data); intervention characteristics; mode of intervention delivery (eg, stand-alone app or combined with another component such as phone or text message); and intervention content (information that the intervention gives to users). In addition, the theoretical framework used to develop or guide the intervention was extracted. For health outcomes, the primary and secondary health outcomes were extracted. We extracted the outcome data from the last follow-up and from both control and intervention groups.

## Data Analysis and Synthesis

A narrative summary of the studies was conducted. The data from each study were extracted, and the outcomes were organized into logical categories, including clinical outcomes (eg, SBP, DBP, and weight loss), DASH diet adherence, app usability and acceptability, and user engagement and satisfaction. The variety of study methods and reported outcomes meant that a meta-analysis was not possible. This review followed the PRISMA 2020 statement ([Multimedia Appendix 2](#)) [27].

## Assessment of the Risk of Bias

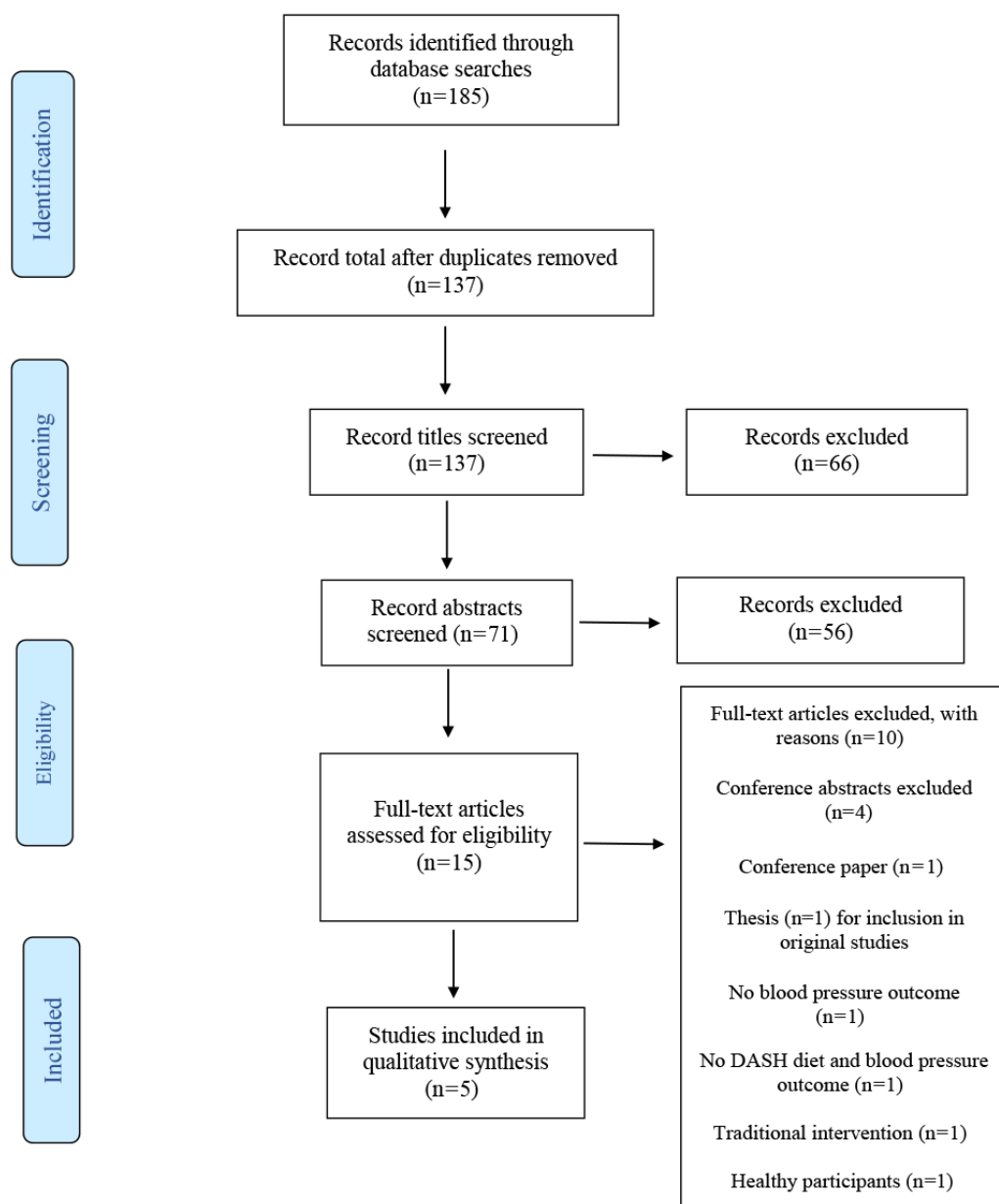
Two reviewers (GA and TA) independently assessed the risk of bias of the included studies. Any disagreements were addressed through discussion with the other researchers (LdW



and MH). The risk of bias was assessed using the Cochrane Collaboration's Risk of Bias Tool for RCTs, 2018 [28]. Risk ratings of "low," "high," and "some concerns" were assigned to the RCTs based on the presence of the following items: performance bias, selection bias, detection bias, attrition bias, reporting bias, and other bias. The overall risk of bias was high if any element was classified as high risk [28]. Robvis software, a visualization tool for risk of bias assessments in systematic reviews, was used [29].

Nonrandomized quantitative studies were evaluated using a tool for pre-post studies without a control group, which was provided by the US National Institute of Health (NIH) [30]. The quality ratings were "good," "fair," and "poor." If the rating was poor, reasons were noted.

**Figure 1.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. DASH: Dietary Approaches to Stop Hypertension.



## Results

### Summary of the Search Results

A total of 185 publications were identified from the searches, all of which came from electronic databases, as follows: 30 publications from Embase, 84 from Cochrane Library, 15 from CINAHL, 19 from Web of Science, 35 from Scopus, and 2 from Google Scholar. After duplicates were removed, 137 publications were screened for eligibility. From these, 122 were excluded after screening the titles and abstracts, and 15 full texts were retrieved. Examining the latter led to the exclusion of 10 publications that did not meet the inclusion criteria. In total, 5 publications were included in the analysis (Figure 1).

## Characteristics of the Studies

Of the 5 included studies, 3 were conducted in the United States [31-33] and 2 in Iran [34,35]. All were published between 2017 and 2021 (Multimedia Appendix 3). The included studies had sample sizes ranging from 17 to 120 participants, with a total of 334 participants. Four studies included both males and females [31,32,34,35], whereas 1 study included only females [33]. Participants from all the studies ranged in age from 18 to 75 years. Three studies [31,33,35] included participants with either hypertension or prehypertension alone, or participants with hypertension who were overweight or obese [32,34].

Of the 5 studies, 3 were RCTs [33-35] and 2 were pre-post pilot studies [31,32]. In terms of duration, the interventions were commonly conducted for 3 to 6 months [31-35].

All studies supported self-management of the DASH diet and hypertension. They all aimed to enhance self-management with increased patient awareness through educational information [31-35]. One study enhanced self-management without involving a human coach to monitor patients remotely [35], whereas the remaining 4 studies aimed to enhance self-management by involving a human coach [31,32] or research team to monitor patient data and health status remotely [33,34]. All studies

reported the effectiveness of the apps in terms of dietary behavioral changes and controlling BP [31-35]. Four studies evaluated user engagement [31-33,35]; 2 assessed user satisfaction [33,35]; 1 evaluated acceptance [31]; 1 assessed usability, user knowledge, and user attitudes [35]; and 1 evaluated user self-efficacy [34].

One study [34] reported having applied behavioral theories (self-efficacy theory was applied). The 4 remaining studies did not report using behavioral theories. However, the functionalities of the apps were investigated, and identifiable components of behavioral change strategies were discovered in every study, for example, self-monitoring, feedback, setting goals, and messages.

## Intervention Characteristics

The app characteristics are shown in Table 1. Each of the reviewed studies used a different app [31-35], with 2 apps commercially available (apps available to the public on an app store) [32,33] and 3 developed specifically for the study [31,34,35]. Among the 3 reviewed RCTs, the control groups in 2 RCTs received usual care [34,35], while the other control group received a mobile phone app to track food, without receiving feedback and motivational messages [33].

**Table 1.** App intervention characteristics.

App intervention type	App name (purpose)	App type	App functionalities
App + 1 other approach (communication with a coach by phone call to establish personalized DASH <sup>a</sup> diet plans and feedback)	Noom (healthy weight loss and more)	Commercial <sup>b</sup>	Self-monitoring (BP <sup>c</sup> , weight, and PA <sup>d</sup> ) Diet self-monitoring with a comprehensive and easily accessible nutrient database Educational information, goal setting, feedback, motivational messages, and reminder
App + 2 other approaches (motivation and feedback text message + DASH video and booklet)	Nutritionix (diet tracking)	Commercial	Diet self-monitoring with a comprehensive and easily accessible nutrient database
App + 1 other approach (communication with a coach by text message or email)	DASH mobile	Noncommercial <sup>e</sup>	Self-monitoring (BP, weight, daily diet, and PA). Educational information, feedback, motivational messages, goal setting, and communication with a coach by chat
App + 2 other approaches (phone call + text message)	DASH-related recommendations	Noncommercial	Educational information
App stand-alone	Blood Pressure Management Application (BPMAP)	Noncommercial	Self-monitoring (BP) Educational information, feedback, motivational messages, reminder, and DASH diet plan

<sup>a</sup>DASH: Dietary Approaches to Stop Hypertension.

<sup>b</sup>Smartphone app that is available on app stores.

<sup>c</sup>BP: blood pressure.

<sup>d</sup>PA: physical activity.

<sup>e</sup>Smartphone app that is not available on app stores.

## Outcomes

### Effect on BP and Weight

All studies [31-35] examined the direct impact of DASH mobile app interventions on health outcomes in terms of BP, and 4 studies assessed weight loss [31,32,34,35].

Four studies reported a positive effect of the DASH diet app on both SBP and DBP [32-35], and 3 studies reported significant results [32,34,35]. In total, 3 studies reported significantly reduced weight loss (Tables 2 and 3) [32,34,35].

**Table 2.** Blood pressure and weight loss effects in randomized controlled trials.

Study and variable	Total length of the intervention	Blood pressure			Effect (blood pressure)	BMI (kg/m <sup>2</sup> )	Effect (BMI)
		SBP <sup>a</sup> (mmHg)	DBP <sup>b</sup> (mmHg)	Change in arterial pressure (mmHg)			
<b>Darabi et al [34]</b>	12 weeks			NR <sup>c</sup>	Positive <sup>d</sup>		Positive <sup>d</sup>
<b>Intervention (n=44), mean (SD)</b>							
Baseline		150.43 (10.19)	94.15 (7.69)			29.51 (2.89)	
12 weeks		144.65 (10.36)	88.59 (8.34)			29.40 (2.91)	
<b>Control (n=44), mean (SD)</b>							
Baseline		155.88 (16.81)	96.13 (8.41)			28.53 (2.57)	
12 weeks		161.09 (17.46)	97.61 (7.27)			28.64 (2.62)	
<b>Bozorgi et al [35]</b>	24 weeks	NR	NR		Positive <sup>d</sup>		Positive <sup>d</sup>
<b>Intervention (n=60), mean (SD)</b>							
Baseline				108.9 (13.5)		29.7 (3.4)	
24 weeks				94.8 (3.42)		28.6 (3.2)	
<b>Control (n=60), mean (SD)</b>							
Baseline				114.9 (14.30)		28.5 (3.6)	
24 weeks				100.1 (7.20)		28.4 (3.7)	
<b>Steinberg et al [33] (N=59)</b>	3 months			NR	Neutral <sup>e</sup>	NR	NR
Baseline for both groups, mean (SD)		122.9 (14.2)	80.2 (8.8)				
Between group difference, mean (95% CI)		-2.8 (-1.8 to 7.4)	-3.6 (-0.2 to 7.3)				

<sup>a</sup>SBP: systolic blood pressure.

<sup>b</sup>DBP: diastolic blood pressure.

<sup>c</sup>NR: not reported.

<sup>d</sup>Blood pressure was significantly reduced by the app.

<sup>e</sup>Blood pressure was neutrally affected by the app.

**Table 3.** Blood pressure and weight loss effects in pre-post studies.

Study and variable	Total length of the intervention	Blood pressure		Effect (blood pressure)	BMI (kg/m <sup>2</sup> )	Effect (BMI)
		SBP <sup>a</sup> (mmHg)	DBP <sup>b</sup> (mmHg)			
<b>Weerahandi et al [31] (N=17)</b>	120 days			Neutral <sup>c</sup>		Neutral <sup>c</sup>
Baseline, mean (SD)		138.6 (21.47)	86.9 (16.10)		33.6 (7.46)	
120 days, mean (SD)		139.75 (15.85)	89.50 (13.85)		33.83 (7.64)	
<b>Toro-Ramos et al [32] (N=50)</b>	24 weeks			Positive <sup>d</sup>		Positive <sup>d</sup>
Baseline, mean (SD)		130.93 (12.81)	83.03 (11.32)		33.60 (8.29)	
Change from baseline to 24 weeks, mean (SD)		-5.98 (17.60)	-5.06 (11.89)		-1.21 (1.38)	

<sup>a</sup>SBP: systolic blood pressure.

<sup>b</sup>DBP: diastolic blood pressure.

<sup>c</sup>Blood pressure was neutrally affected by the app.

<sup>d</sup>Blood pressure was significantly reduced by the app.

### DASH Diet Adherence

The 3 randomized studies [33,34,35] evaluated the effects of apps on dietary behavioral changes. The DASH score was used to evaluate adherence to DASH and was calculated using 9 [33,34] target nutrients. The sum of all nutrient goal values, with a maximum of 9, was used to calculate the DASH score. A value of 1 was assigned if the DASH target for a nutrient was met, 0.5 if the intermediate target was met, and 0 if no target was met [36]. Bozorgi et al [35] used a food frequency questionnaire to assess dietary change.

Three studies demonstrated that using a DASH app resulted in better adherence to the DASH diet and consequently lower BP (Table 4). Darabi et al [34] demonstrated that using a smartphone app to educate patients about the DASH diet and improve self-efficacy resulted in better adherence to the DASH diet, with significant differences between groups at the end of

the trial. Bozorgi et al [35] evaluated the app's impact on patient adherence to the DASH diet. They observed increased consumption of fruits, vegetables, and dairy in the intervention group compared with the control group. Moreover, the consumption of low-fat and low-salt diet plans increased by 1.7 and 1.5 points, respectively. Steinberg et al [33] compared dietary changes between women who used app-based diet tracking (control group) and those who used app-based diet tracking with feedback on DASH adherence through text messages (intervention group) over 3 months. They found that both groups' DASH scores improved significantly after 3 months. A single-unit increase in the DASH score in the intervention group was linked to a 2.7 (95% CI 0.4-5) mmHg drop in SBP ( $P=.03$ ) and a 1.3 (95% CI 1.0-3.6) mmHg drop in DBP ( $P=.26$ ). In the control group, the association was a little weaker, with a single-unit increase in the DASH score linked to a 1.7 (95% CI 2.1-5.4) mmHg drop in SBP ( $P=.37$ ) and a 1.8 (95% CI 0.8-4.4) mmHg drop in DBP ( $P=.26$ ).

**Table 4.** Change in the Dietary Approaches to Stop Hypertension (DASH) adherence score.

Study (follow-up) and DASH <sup>a</sup> score	Change in the DASH adherence score		Effect
	Intervention group, mean (SD)	Control group, mean (SD)	
<b>Darabi et al [34] (12 weeks)</b>			Positive <sup>b</sup>
Baseline score	2.895 (0.457)	2.931 (0.534)	
End of trial score	3.837 (0.761)	3.875 (0.699)	
<b>Bozorgi et al [35] (24 weeks)</b>			
No assessment reported	NR <sup>c</sup>	NR	NR
<b>Steinberg et al [33] (12 weeks)</b>			Positive <sup>b</sup>
Baseline score	2.2 (1.3)	2.3 (1.3)	
End of trial score	3.1 (1.4)	3.1 (1.3)	

<sup>a</sup>DASH: Dietary Approaches to Stop Hypertension.

<sup>b</sup>DASH adherence was significantly increased by the app.

<sup>c</sup>NR: not reported.

**App Usability and Acceptability, and User Engagement and Satisfaction**

Four studies assessed user engagement [31-33,35], 2 evaluated user satisfaction [33,35], and 1 evaluated acceptance [31]. All focused on the patients’ perspectives, and 1 study also assessed patients’ knowledge and app usability [35].

User engagement was assessed by logging food intake, BP, weight, and step count. Chats, phone calls, and text messages were also incorporated [31-33,35]. Generally, participants’ use of the apps to record food, BP, and weight was high.

In the 2 studies that evaluated user satisfaction, participants were very accepting of the use of apps [33,35]. In the study by Steinberg et al [33], participants reported that the app was easy to use, and that they used it frequently and would recommend it to friends [33]. They also reported that the DASH score was helpful and motivational, and that the timing of the text messages was convenient and helped them achieve their goals [33].

In the study conducted by Bozorgi et al [35], the results suggested that usability was good.

**Quality Appraisal of Studies**

All included RCTs used an appropriate random allocation sequence for randomization. The allocation sequences were concealed by all studies until the participants were enrolled. Therefore, all studies had low bias risk due to randomization (Figure 2).

The staff in studies testing the DASH diet smartphone app and the participants were aware of the assigned interventions in 3

and 2 studies, respectively. In all studies, a suitable analysis was used to estimate the effect of the assigned intervention (intention-to-treat or modified intention-to-treat analysis). Accordingly, the risk of bias due to deviations from intended interventions had “some concerns” in all studies.

In all studies, outcome data were available for most or all participants. The “missing outcome data” domain was deemed to have low risk of bias in all studies (Figure 2).

All included studies evaluated the outcome of interest (ie, BP level and DASH diet adherence) using appropriate measures and used methods that were comparable between intervention groups. However, in all studies, the assessor of the outcome was not blinded. For this reason, all studies were rated as having high risk of bias in the “measuring the outcome” domain (Figure 2).

The prespecified analysis plan (eg, protocol) was published in 2 studies. Therefore, 2 studies were considered to have low risk of bias due to selection of reported results (Figure 2).

All studies were judged to have high risk of bias in the last domain, “overall bias,” because they had a high risk in at least one domain.

Of the 2 pre-post studies, 1 was of poor quality [31] due to the study’s design (pilot study, small sample size, and lack of power analysis). Moreover, there was some missing information that affected study validity. The other study [32] was deemed to be of fair quality because it had a good sample size, and a clear method was used. Quality assessment results are reported in Multimedia Appendix 4.

**Figure 2.** Summary of the risk of bias assessment using the Cochrane Collaboration’s Risk of Bias tool.

		Risk of bias domains					
		D1	D2	D3	D4	D5	Overall
Study	Darabi et al [34]						
	Bozorgi et al [35]						
	Steinberg et al [33]						

Domains:

D1: Bias arising from the randomization process.

D2: Bias due to deviations from intended intervention.

D3: Bias due to missing outcome data.

D4: Bias in measurement of the outcome.

D5: Bias in selection of the reported result.

Judgement

High

Some concerns

Low

**Discussion**

**Principal Findings**

This systematic review aimed to synthesize evidence on the effectiveness of DASH smartphone apps that support self-management in order to improve DASH diet adherence and consequently reduce BP. It also aimed to examine satisfaction,

acceptability, engagement, and usability of DASH smartphone apps. Our review highlighted weak emerging evidence of a positive effect of using DASH smartphone apps. However, the evidence is inconclusive because some studies on the topic were of low quality due to the fact that blinding of participants and assessors was not implemented, and the study protocol was not published. Furthermore, 1 of the 3 studied RCTs was

unpublished, that is, the manuscript is under review. Therefore, the data do not allow firm conclusions about the effectiveness of DASH smartphone apps to increase DASH diet adherence and lower BP.

This review indicates that a DASH mobile app that engages patients and encourages self-management of the DASH diet may be helpful in improving adherence to the DASH diet. The findings are in line with the findings of other systematic reviews that involved chronic kidney disease dietary mobile app interventions for changing user dietary behavior, which illustrated that the use of nutritional apps enhanced adherence to sodium reduction, protein intake, caloric intake, and fluid dietary limitations [37,38]. Our results showed that using a DASH smartphone app may improve DASH diet adherence and consequently reduce BP and body weight [32,34,35]. This is consistent with systematic reviews that have focused on traditional interventions, which showed that adherence to the DASH diet significantly reduces SBP, DBP, and body weight [18,39].

In this review, all apps had some similar functionalities; 3 out of the 5 apps combined 3 functionalities, including educational information, feedback, and messages (reminder or motivation), with other functions. We could not determine the most effective functionalities because there was no clear difference in the results between apps with different functionalities [23,40]. In this review, we found no difference between commercial and noncommercial apps in terms of their characteristics.

Interventions involved the mobile app alone or in combination with other communication tools, such as phone calls, chats through the app itself, or text messaging. It was not possible to determine from the results whether combining the app with other modalities increased effectiveness. However, Schoeppe et al [41] found that apps were most successful when combined with other tools rather than used as a stand-alone intervention.

The findings with regard to usability and feasibility are in line with studies assessing dietary smartphone apps for changing the behavior of chronic kidney disease patients [37], which also found that the apps were useable and feasible. Studies assessing the acceptance and usability of mobile apps for chronic disease management support our results regarding acceptance [40,42].

After examining the risk of bias of the included studies, the findings of this review should be treated with caution because several studies had high risk of bias. Three RCTs and 2 pre-post pilot studies were included. Four out of the 5 studies had methodological issues. These difficulties arose from potential biases in all RCTs because blinding of participants and assessors was not implemented, the study protocol was not published [33], or the study duration was short [31-35]. Due to the nature of using apps, blinding of subjects was not possible across interventions. One of the 3 RCTs is still under review [34]. All RCTs used an appropriate random allocation sequence for randomization and concealed the allocation sequence [33-35]. The outcome data were available for most or all participants [33-35]. One pre-post pilot study had limitations that included small sample size, short duration, and missing information [31].

## Strengths and Limitations of This Review

The studies included in this review have some limitations. First, 4 included studies were evaluated as “low quality,” implying that unreliable outcomes were possible. These factors, together with heterogeneous outcomes and the methods used to quantify them, make drawing generalizable conclusions difficult. Owing to the variability in study design, a meta-analysis was not possible. Second, 1 study was under review, and low-quality studies were considered because more recent findings are often helpful. Finally, in the included studies, the socioeconomic characteristics of participants were rarely reported; nevertheless, when they were reported, they revealed a high educational level, thus further limiting the generalizability of the results.

Additionally, this review has certain limitations. First, few studies exploring the use of smartphone apps to enhance DASH diet adherence could be found, even though the authors established a comprehensive search strategy for the 5 main databases and manually reviewed the reference lists of each full-text article to identify potentially relevant research for inclusion in this systematic review. Second, due to the low number of RCTs, we were unable to evaluate the effectiveness of DASH smartphone apps. Third, studies written in languages other than English were excluded, increasing the chance of relevant research being missed.

Despite these limitations, to our knowledge, this is the first systematic review investigating the effectiveness of using smartphone apps for patient adherence to the DASH diet, which is known to lower BP, and assessing user satisfaction and app acceptance. This review also highlights the crucial issue of the lack of high-quality research in this field, and thus, this review could help improve future research on the use of DASH smartphone apps by people with hypertension.

## Future Directions

In general, the methodological quality of the research included in this study was poor. This suggests that future studies should include a sufficient number of participants and a sufficiently long duration, and should ensure blinding of assessors and low attrition rates. It would also be beneficial to conduct a well-designed RCT with multiple arms using apps with different combinations of functionalities to identify the most effective combinations. The results of this review are applicable to short-term app use because most interventions lasted between 3 and 6 months. Longer-term studies are needed to integrate smartphone apps into people’s daily routines and assess their usefulness for long-term DASH diet adherence. It is also essential to evaluate and understand users’ acceptance of and satisfaction with these apps. Most studies included in this review evaluated DASH diet adherence by calculating the DASH score based on a food recall questionnaire that may be impacted by inaccurate reporting by participants [33-35]. Future studies should incorporate objective measures, such as urinary excretion, to measure dietary adherence to DASH [43].

## Conclusion

This review identified 5 studies including a total of 334 participants. Use of smartphone apps to increase DASH diet adherence and reduce BP in hypertensive patients is clearly in

the early stages of development. However, the fact that studies were found in 2 different countries (using 5 smartphone apps with similar functionalities) and that all of them were published in the last 4 years indicates that the research community is now taking interest in the DASH diet. All the apps seemed to be accepted and easy to use. Although it is impossible to draw firm conclusions from the current evidence, the studies indicated

positive trends, suggesting that DASH smartphone apps could be useful tools to increase DASH diet adherence and reduce BP. Further research is needed that can provide higher-quality evidence to determine the effectiveness of DASH smartphone apps to improve adherence to the DASH diet and correspondingly lower BP.

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## Authors' Contributions

The review protocol was developed by GA, and LdW and MH made substantial contributions to its development. GA and TA screened the relevant studies identified in the databases and performed data extraction. The manuscript was written by GA, and LdW and MH read the manuscript and provided feedback on further iterations. The final review was read and approved by GA, MH, and LdW.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Search strategy.

[[DOCX File , 23 KB - cardio\\_v6i2e35876\\_app1.docx](#) ]

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### Multimedia Appendix 2

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.

[[DOCX File , 25 KB - cardio\\_v6i2e35876\\_app2.docx](#) ]

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### Multimedia Appendix 3

Summary of study characteristics.

[[DOCX File , 19 KB - cardio\\_v6i2e35876\\_app3.docx](#) ]

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### Multimedia Appendix 4

Quality criteria checklist of articles included in the systematic review.

[[DOCX File , 16 KB - cardio\\_v6i2e35876\\_app4.docx](#) ]

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## Abbreviations

- BP:** blood pressure
- DASH:** Dietary Approaches to Stop Hypertension
- DBP:** diastolic blood pressure
- NHLBI:** National Heart, Lung, and Blood Institute
- RCT:** randomized controlled trial
- SBP:** systolic blood pressure

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Review

# Frameworks for Implementation, Uptake, and Use of Cardiometabolic Disease–Related Digital Health Interventions in Ethnic Minority Populations: Scoping Review

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**Abstract**

**Background:** Digital health interventions have become increasingly common across health care, both before and during the COVID-19 pandemic. Health inequalities, particularly with respect to ethnicity, may not be considered in frameworks that address the implementation of digital health interventions. We considered frameworks to include any models, theories, or taxonomies that describe or predict implementation, uptake, and use of digital health interventions.

**Objective:** We aimed to assess how health inequalities are addressed in frameworks relevant to the implementation, uptake, and use of digital health interventions; health and ethnic inequalities; and interventions for cardiometabolic disease.

**Methods:** SCOPUS, PubMed, EMBASE, Google Scholar, and gray literature were searched to identify papers on frameworks relevant to the implementation, uptake, and use of digital health interventions; ethnically or culturally diverse populations and health inequalities; and interventions for cardiometabolic disease. We assessed the extent to which frameworks address health inequalities, specifically ethnic inequalities; explored how they were addressed; and developed recommendations for good practice.

**Results:** Of 58 relevant papers, 22 (38%) included frameworks that referred to health inequalities. Inequalities were conceptualized as society-level, system-level, intervention-level, and individual. Only 5 frameworks considered all levels. Three frameworks considered how digital health interventions might interact with or exacerbate existing health inequalities, and 3 considered the process of health technology implementation, uptake, and use and suggested opportunities to improve equity in digital health. When ethnicity was considered, it was often within the broader concepts of social determinants of health. Only 3 frameworks explicitly addressed ethnicity: one focused on culturally tailoring digital health interventions, and 2 were applied to management of cardiometabolic disease.

**Conclusions:** Existing frameworks evaluate implementation, uptake, and use of digital health interventions, but to consider factors related to ethnicity, it is necessary to look across frameworks. We have developed a visual guide of the key constructs across the 4 potential levels of action for digital health inequalities, which can be used to support future research and inform digital health policies.

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## KEYWORDS

eHealth; framework; cardiometabolic; health inequalities; health inequality; health technology; ethnicity; minority; digital health; review; cultural; diverse; diversity; cardiology; metabolism; metabolic

## Introduction

Individuals of an ethnic minority background constitute at least 14% of the UK population [1] and have an increased risk of type 2 diabetes [2] and cardiovascular disease [3] (together, also known as cardiometabolic disease), particularly South Asian and Black individuals. Even before, but particularly during, the COVID-19 pandemic, digital health interventions became important in the education, prevention, diagnosis, treatment, and rehabilitation [4,5] of diseases such as cardiometabolic disease [6,7].

Whether via smartphones, websites, or text messaging, digital health interventions need to be culturally competent (ie, able to meet the needs of users with diverse values, beliefs, and behaviors) to be accessible to all [8,9], but the effectiveness of digital health interventions may vary across different groups (by age, clinical need, socioeconomic, or other factors) [7]. Moreover, unequal access to hardware, software, and the internet, as well as variations in digital literacy, create a digital divide through which digital health interventions could exacerbate existing socioeconomic, educational, and health inequalities [10,11]. Therefore, digital health interventions, similar to other health interventions, require robust evaluation before and after implementation, by using frameworks that take into account society-level (eg, political context, interorganizational networks), system- or organization-level (eg, organizational capacity and engagement), and individual (eg, literacy, financial resources) factors. Existing frameworks

include those adapted from other fields [12,13], as well as those developed specifically for health and health care technology [14]. Despite multiple ways of analyzing health inequalities [15], frameworks have often overlooked the experiences of ethnic minority populations. Given the excess cardiometabolic burden faced by ethnic minority groups, digital health interventions designed for cardiometabolic disease are an important area of study.

This scoping review aims to identify existing frameworks, models, or theories that address (1) implementation, uptake, and use of digital health interventions by end users; (2) health interventions in ethnically or culturally diverse populations; or (3) interventions for cardiometabolic disease. For identified frameworks, we examine the extent to which they include and how they address health inequalities, specifically regarding ethnicity and relevance to ethnic inequalities in cardiometabolic disease.

## Methods

### Search Strategy and Selection Criteria

We conducted this review in accordance with PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews) guidelines ([Multimedia Appendix 1](#)). We included papers that presented a new, revised, or adapted framework that could be used to understand either factors in: the adoption and acceptance of digital health; or cardiometabolic interventions; or sociodemographic inequalities in health ([Multimedia Appendix 2](#)). We considered frameworks

to be any models, theories, or taxonomies. There are multiple definitions of implementation and the technology acceptance lifecycle [16,17]. We focused on 3 stages: implementation (putting interventions to use within a setting) [17], uptake (adoption by end users), and use (sustained use and acceptance) [16]. We excluded frameworks aimed at delivery processes, technology development processes, or economic assessments. Given the extensive literature on frameworks for technology adoption, only papers that presented frameworks that have been designed or adapted to health and care settings were included. There was no limit on publication date.

### Information Sources

SCOPUS, PubMed, EMBASE, and Google Scholar were searched electronically in April 2021 (by MR). Gray literature was identified via OpenGrey [18] and the New York Academy of Medicine Grey Literature Report [19].

### Search

An initial keyword search (“digital” AND “health” AND “ethnicity” AND “cardiometabolic” AND “framework”) demonstrated that there was no existing systematic or scoping review that addressed ethnic digital health inequalities. The 3 areas of interest for review were used to define relevant keywords for the search strategy (Multimedia Appendix 3).

### Study Selection

Search result records were imported into Rayyan (Qatar Computing Research Institute) after removing duplicate records. Title and abstract screening against inclusion and exclusion criteria were conducted by a team (AC, AGM, JP, LP, MB, MM, MR, PJ, ZTB), with 2 rounds of testing in which any queries were discussed. The guide for interpretation of the inclusion criteria that was developed via this iterative approach can be found in Multimedia Appendix 4. Additional frameworks identified at the abstract screening stage were searched for and added to the full-text review (Multimedia Appendix 5). Full texts were reviewed (by MR) if abstracts lacked sufficient information. The final selection was made by 2 authors (MR and LP); disagreements in study selection were resolved by discussion until consensus was reached, or with a third reviewer (ZTB) when it was not reached.

### Data Analysis

Data charting was piloted on 10 randomly selected papers and refined to ensure consistency across researchers (categories of information are set out in Multimedia Appendix 6). Data charting was repiloted on 10 additional studies and after a final review to ensure agreement in information extracted and

summarized, the remainder of the papers were charted. Citation details, evidence type, framework context, framework focus, and framework beneficiary were charted. Qualitative analysis was conducted. Data are reported according to PRISMA-ScR [20]. Papers were assessed for the degree to which they considered factors related to inequalities: this was defined broadly to include racial, ethnic, or cultural diversity; health inequalities; digital inequalities; or social determinants of health.

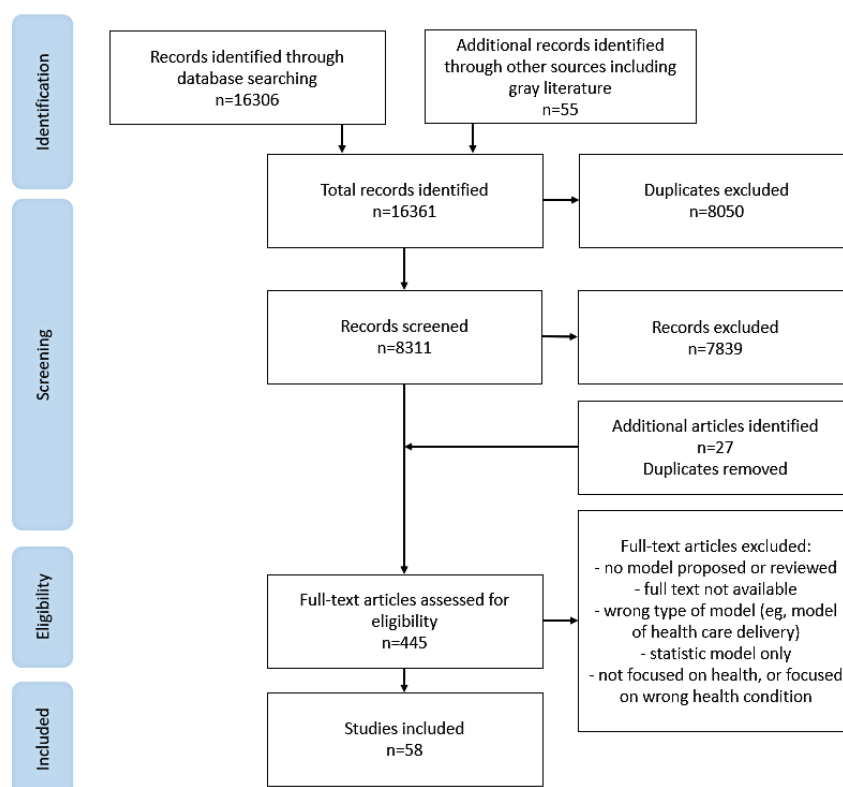
## Results

### Scoping Review

A total of 7830 unique records were identified. A total of 58 papers were included (Figure 1; Multimedia Appendix 7), of which 32 papers included adapted or extended existing frameworks. A majority included the Technology Acceptance Model [21-37] or the Unified Theory of Acceptance and Use of Technology [26,27,38-43]. New frameworks, developed from the review and synthesis of existing frameworks or from empirical research, were proposed by 26 papers [14,15,44-67]. First author institution was listed in Europe, North America, or Australia for the majority of papers (n=39) [14,23,24,31-33,35,37,39,43,44,46-48,51-55,58-77]; Asia or the Middle East (n=13); and South Africa (n=2) [50,57]. The remaining had first authors with affiliations in more than one country [15,26,27,36,56]. Many papers did not specify the geographic location in which the framework was designed for use or testing [14,15,24,27,31,35,44-46,49-55,58-61,68,69,71,74,75] (n=25); of those that did, the majority (n=14) were developed or tested in Europe, North America, or Australia [37,39,43,47,62-67,70,72,76,77].

The majority of frameworks had digital health interventions or health technology (such as electronic health records, or remote monitoring) as the only or key focus (n=39). Fifteen of the remaining frameworks considered at least two of digital health interventions, health inequalities and ethnicity, or cardiometabolic disease. The purpose of most frameworks was to understand factors related to the adoption, acceptance, and use of digital health technology (n=43), with the remaining frameworks (n=15) considering health inequalities, chronic disease management, and evaluation of interventions. In the majority of papers, the end user who was likely to benefit from the application of the framework was either a patient or member of the public (eg, as targets for interventions for disease prevention or management) (n=33) or a clinician (n=5). Seven frameworks focused on the intervention or technology itself. The remaining frameworks had no specific end user or covered a combination of benefits.

Figure 1. Paper selection flowchart.



### Extent of Inclusion of Health Inequalities in Existing Frameworks

Over half of the papers that showed no or limited inclusion of inequalities (26/36) did not address inequalities in either the body text or the framework themselves. A few papers (n=7) acknowledged the wider socioeconomic context in the paper or included a high-level reference to social or contextual factors that might influence uptake and use of health technology, for example, by including the factor *broad context* [44]. Another group of frameworks took digital access into account within the *facilitating conditions* construct, based on either the Technology Acceptance Model [28] or the Unified Theory of Acceptance and Use of Technology [41,43]. Many were focused on the factors affecting adoption and use in specific populations, such as older adults (n=6), the workforce (n=8), or in Asian or low- and middle-income contexts (n=5) (Table 1).

A few frameworks took the specific challenges of mobile health (mHealth) readiness [56], adoption [26,57], acceptance [23],

and impact on access to care [32] in low- or middle-income countries into account; these frameworks were assessed as having limited applicability to the specific challenges of multiethnic populations in Western countries. Some frameworks that focused on understanding patient or public acceptance of and engagement with digital health interventions considered how these may be affected by factors related to health or digital inequalities, for example, tech generation (experience of individuals of different age groups of different technologies), health literacy, and education [58]; demographic, psychological, physical, and social factors [59]; or personal lifestyle factors [60] (Table 2). Many papers that looked specifically at ethnic inequalities in health frameworks included ethnicity in the *demographic factors* element of the framework itself [15,25,59,61,62,74-76] or discussed ethnicity in the accompanying text [63-65]. Notably, Schillinger [65] discussed the limitations of current research on health literacy and known racial and ethnic health disparities [65]. Only 3 frameworks (Table 2) focused on the mechanisms through which ethnicity impacts health and engagement with interventions [25,66,76].

**Table 1.** Frameworks with no or limited consideration of ethnic and social inequalities in health.

Reason for which papers were deemed to have no or limited consideration and the key focus of the framework	Papers (n=36)	
	Reference	n
<b>Does not address health or digital inequalities (population)</b>		
Older adults or elderly populations	[21,31,36,45,68]	5
Health care professionals	[27,40,46-48,69]	6
Workplace or workforce	[34,42]	2
South Asian and low- and middle-income contexts	[21,29,30,33]	4
Other	[24,39,49-52,70,71]	8
Review paper	[35]	1
<b>Acknowledgment of contextual factors in the paper only</b>		
Digital cardiovascular prevention	[37]	1
Implementation effectiveness	[53]	1
<b>High-level factoring of the wider context in the framework figure</b>		
Engagement with health apps	[72]	1
Integration of health interventions into health systems	[44]	1
<b>High-level factoring of social factors or access into the framework</b>		
<b>Digital access considered within the facilitating conditions construct of the Technology Acceptance Model or the Unified Theory of Acceptance and Use of Technology variant</b>		3
Electronic health record adoption	[43]	
Older adults	[41]	
Tested in Pakistan	[28]	
<b>Model includes broadly defined factors such as sociodemographic factors</b>		3
National culture differences in acceptance	[73]	
Telehealth in chronic disease intervention design and evaluation	[54]	
Implementation planning and evaluation	[55]	

**Table 2.** Frameworks that show some or detailed consideration of ethnic and social inequalities in health.

Reason for which papers were deemed to show some or detailed consideration and the key focus of the framework	Papers (n=22)	
	Reference	n
<b>Model aimed at global health inequalities or developed in low- or middle-income countries</b>		
mHealth <sup>a</sup> adoption in developing world	[26,57]	2
mHealth readiness, developed in rural Bangladesh	[56]	1
mHealth contributions to care access, sub-Saharan Africa	[32]	1
mHealth interventions targeted at low-literacy end users in resource-limited settings	[23]	1
<b>Includes factors related to health or digital inequalities</b>		
Acceptance of remote patient management	[58]	1
Engagement and recruitment to digital health intervention	[59,60]	2
Nonadoption, Abandonment, Scale-up, Spread, and Sustainability framework	[14]	1
<b>Framework aims to address health inequalities or to be used in populations facing health inequalities</b>		
<b>Health inequalities</b>		3
A Conceptual Framework for Action on the Social Determinants of Health	[15]	
Community Chronic Care Model	[77]	
Conceptual Framework for the Pathways that Connect Social Determinants of Health, Health Literacy and Health Disparities	[65]	
<b>Digital health and access or inequalities</b>		6
eHealth Equity Framework	[74]	
Digital Health Equity Framework	[75]	
The Updated Integrative Model of eHealth Use	[63]	
Modeling the process of using an eHealth tool by people vulnerable to social health inequalities	[61]	
Culture-centered Technology Acceptance Model	[25]	
Pathways of access, use, and benefit from digital health services	[64]	
<b>Cardiometabolic disease and inequalities</b>		4
Conceptual framework for understanding the development and role of financial barriers for patients with cardiovascular-related chronic diseases	[67]	
A Gender-Centered Diabetes Management Education Ecological Framework	[76]	
Diabetes in Ageing and Diverse Populations	[66]	
Workforce Evidence-Based model for diabetes	[62]	

<sup>a</sup>mHealth: mobile health.

## How Frameworks Address Health Inequalities

We identified 13 frameworks that explicitly aimed to understand or address general health inequalities [15,65,77], health inequalities in relation to the management of cardiometabolic disease [62,66,67,76], digital health equity [61,63,64,74,75], or recommendations on how to culturally tailor digital health approaches [25] (Table 3). Key factors or constructs in these frameworks [15,25,61-67,74-77] could be mapped to the 4 levels of action in which digital health care is seen to operate—society or population, health care system, intervention, and individual (Figure 2)—and 5 frameworks included factors in all 4 levels, for example, individual health status and beliefs, support for digital health use, social policy and action, and cultural adaptations of the intervention [25,66,74-76]. The wide scope of factors included in these frameworks reflects the diversity

of theoretical approaches used, for example, adaptation of an existing model of social determinants of health to digital health [74,75], adaptation of existing models such as the Technology Acceptance Model for interventions or innovation [25,63,77], and the development of novel frameworks through methods such as grounded theory or thematic analysis [61,62,66,67] (Table 3).

Some frameworks delineated the interaction between these levels to account for how health inequalities occur [15,65,77]. Such frameworks tended to focus on the top-down processes by which societal and system factors filter down to affect health outcomes [15,65,77]. For example, the Community Chronic Care Model [77] was used to demonstrate how community resources and health care provider systems contribute to improved community-wide health outcomes. Schillinger [65] brought together research from multiple disciplines, such as



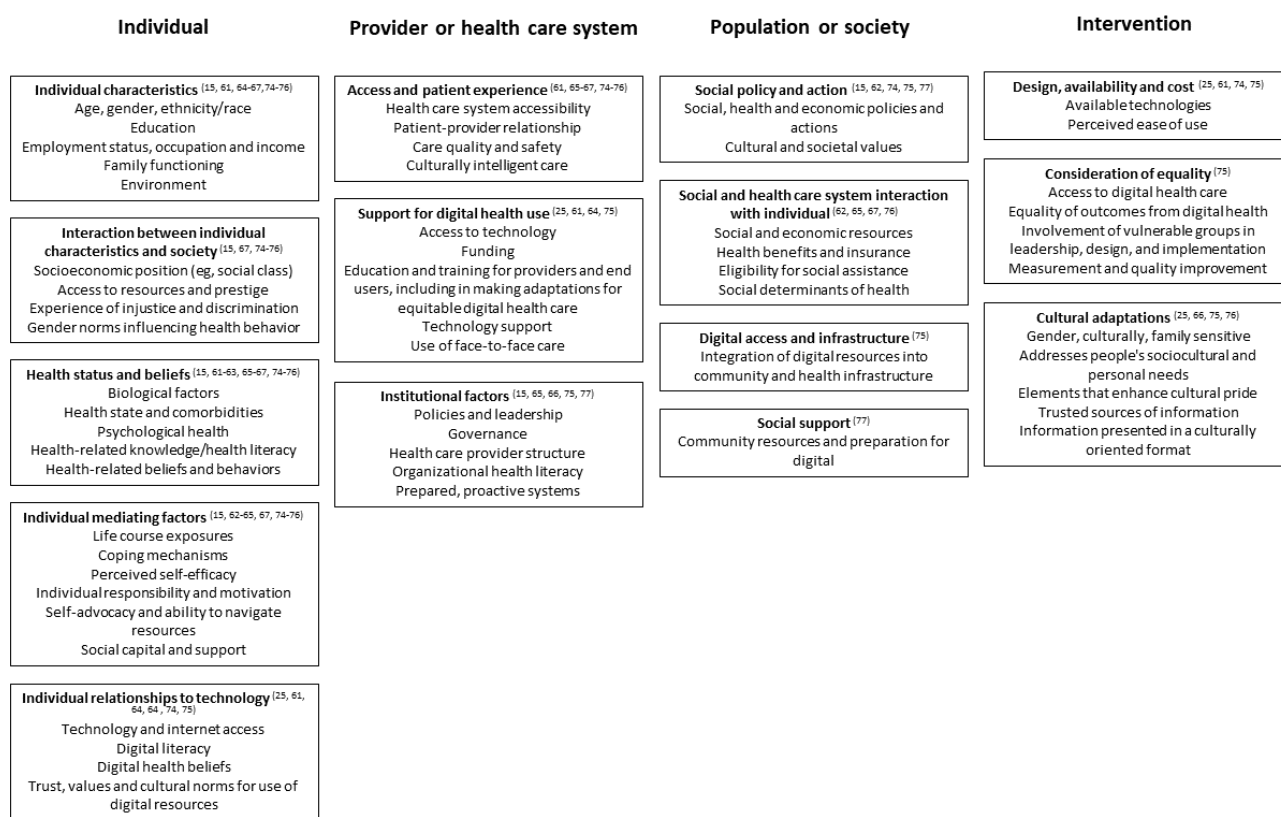
epidemiology, anthropology, and public health, to describe two routes through which social determinants of health act on health outcomes and health disparities: unequal distribution of resources and the health care systems themselves.

We identified 3 frameworks [63,74,75] that were developed as tools to understand and address the potential role of digital health interventions in exacerbating existing health inequalities. The eHealth Equity Framework [74], based on the World Health Organization’s Commission on Social Determinants of Health conceptual framework [15], incorporates technology into the macro socio-techno-economic-political context with intermediary determinants of health care access and use, such as material circumstances, social capital, and literacy. Similarly, the Digital Health Equity Framework [75] integrated digital determinants of health and digital health equity into known health equity factors based on previous work [78]. The Updated Integrated Model of eHealth Use describes how social determinants of health impact user interactions with health technologies and health outcomes [63].

Three frameworks targeted the design and implementation of digital health interventions. In 2 papers [61,64], the use of digital health tools by people vulnerable to social inequalities and opportunities to identify and address barriers were discussed. In another paper [25], the extension of the Technology Acceptance Model, by integrating Community Infrastructure Theory, was described and approaches to engage with marginalized populations were tested.

We found 4 frameworks relevant to cardiometabolic disease. Two frameworks looked at socioeconomic factors affecting health inequalities: one focused on supporting health care professionals to identify and support at-risk groups [62], and the other considered the role of financial barriers on outcomes for patients with cardiovascular-related chronic diseases [67]. Two frameworks aimed to improve outcomes for diabetes in specific ethnic minority groups: older South Asian adults in the United Kingdom [66] and Black men in the United States [76].

Figure 2. Guide showing how framework constructs that consider inequalities map onto the 4 levels of action.



**Table 3.** Frameworks that consider equity in digital health or cardiometabolic disease intervention.

Framework or key focus	Reference	Purpose	Theoretical basis	Intended audience
<b>Digital health equity (conceptual)</b>				
eHealth Equity Framework	[74]	Apply a health equity approach within eHealth	World Health Organization Conceptual Framework for Action on the Social Determinants of Health [15]	Public health, research, policy, health technology development
Digital Health Equity Framework	[75]	Identify the digital determinants of health and their links to digital health equity	Health equity measurement framework [78]	Research, health (service) implementation
Updated Integrative Model of eHealth Use	[63]	Understand how (digital and health) literacy contributes to health and well-being	Integrative Model of eHealth Use [79]	Health communication, public health
<b>Equitable digital health services</b>				
Pathways of access, use, and benefit from digital health services	[64]	Map key factors influencing digital health service outcomes	Frameworks of access to health services	Research, policy, health services, and public health
<b>Equitable digital health intervention design</b>				
Modeling the process of using an eHealth tool by people vulnerable to social health inequalities	[61]	Identify stages of the process of using an eHealth tool that can account for reducing barriers for those at risk of social health inequalities	Structural Influence Model	Research, health technology development
Culture-centered Technology Acceptance Model	[25]	Describe factors that account for people's social and cultural needs when considering technology acceptance	Technology Acceptance Model [80]	Policy, health technology, or intervention development
<b>Reducing impact of inequalities in patients with cardiometabolic disease</b>				
Conceptual framework for understanding the development and role of financial barriers for patients with cardiovascular-related chronic diseases	[67]	Understand the patient experience of financial barriers and impact on behavior and clinical outcomes (in relation to chronic disease)	None specified	Research, clinical, policy
Workforce Evidence-Based model for diabetes	[62]	Recognize and manage the complex needs of individual patients with chronic disease	None specified	Clinical, research, health education, health service, and workforce planning
Diabetes in Ageing and Diverse Populations	[66]	Map how links between cultural competency, comorbidity and stratification, and access can contribute to effective diabetes care for aging and diverse populations	Realist review approach, underpinned by the theme of individualized care	Research
A Gender-Centered Diabetes Management Education Ecological Framework	[76]	Incorporate gender into an understanding of variables that affect diabetes health outcomes	Key focus is theories of gender	Research (diabetes education)
Community Chronic Care Model	[77]	Map how community and health care provider systems interact with other influences to improve community-wide health outcomes and eliminate health disparities	Chronic Care Model, concepts of community	Community and health care provider organizations, research, clinical

### Ethnic Inequalities in Cardiometabolic Disease

Nine papers recommended solutions to increase the adoption and acceptance of interventions in ethnically or culturally diverse populations, with some focusing on cardiometabolic disease. The Workforce Evidence-Based model for diabetes [62] was developed to meet the need for tailored management for a diverse patient population, by guiding health professionals in determining which patients may require additional support. In the culture-centered Technology Acceptance Model [25], a range of individual and intervention attributes that can impact

acceptance, such as enhancing cultural pride or using presenters from the community to increase trust, are identified.

The Community Chronic Care Conceptual Model was used to show how community resources and health care provider systems can interact with other factors to impact community-wide health outcomes, with examples of direct action, such as increasing community health professional training targeted at reducing amputations in African-American men with diabetes [77]. Other recommendations for action included video-based information for the public [63,77], internet

training, and meaningful involvement in patient groups from co-design to implementation [63,75]. However, working with South Asian people with diabetes in the United Kingdom, Wilkinson et al [66] noted the need for further data to understand the effectiveness of cultural adaptations and approaches to culturally competent care, such as peer support. Crawford and Serhal [75] also reiterated the need for additional data collection around health inequalities to implement and evaluate digital health through an equitable lens.

## Discussion

### Principal Findings

We identified 58 frameworks relevant to digital health adoption that address health inequalities and cardiometabolic interventions. Several frameworks were found to consider health inequalities in digital health interventions and inequalities in cardiometabolic disease, but none covered all 3 areas of interest. Less than half (n=22) addressed health inequalities in detail; the remainder did not address health or digital inequalities at all or included only a high-level factor in the body text of the paper or as a framework construct (such as “differentiated by national culture” [73] or “wider social and health system” [54]). We identified 3 models for understanding the digital determinants of health equity [74,75] and 3 frameworks that describe factors related to implementation, uptake, and use of health technologies [25,61,64].

Where health inequalities were considered, they were broadly related to social theory, and more specifically, the social determinants of health, which is described as “the causes of the causes” [81] of health inequality. For example, in the papers [15,75] describing the Digital Health Equity Framework and the Commission on Social Determinants of Health Conceptual Framework, it is highlighted that the health system itself acts as a social determinant of health. In the paper [74] that presented the eHealth Equity Framework, it is argued that technology should be integrated into models of health, in much the same way that the role of social structures is integrated in models of health and well-being outcomes.

In the majority of frameworks, ethnicity was considered under this broad banner of social determinants of health, rather than as a separate construct [15,25,59,61,62,74-76]. While this approach is a useful starting point when considering the factors related to implementation, uptake, and use, a more detailed approach is necessary when considering complex social, educational, and cultural factors relevant in ethnic minority groups for the design, implementation, and evaluation of digital health interventions. For example, a recent report highlighted the specific experiences of people from an ethnic minority background using the National Health Service (NHS) in England, including lack of trust, fear of discrimination, experiences of culturally insensitive behavior, communication barriers, and racism [82]. There is also evidence of worse outcomes for ethnic minority populations with specific digital health approaches, for example, differences in referrals to urgency and emergency care services by the NHS Direct telephone service [82]. We found only 3 frameworks that explicitly considered these factors [25,66,76]. In producing the

culture-centered Technology Acceptance Model, Guttman and colleagues [25] describe the experiences of Ethiopian immigrants in the health care system in Israel and set out an iterative design process for a health website that took into account views from community groups and individuals. Culture-centered constructs, such as “elements that enhance cultural pride” and “addresses people’s sociocultural and personal needs” emerged from this research [25]. These constructs represent motivations to use the website beyond health information, for example, pride in traditional, cultural, and language identity, and benefits such as improving intergenerational communication [25]. Culturally tailored designs have been found to be important in digital health interventions for ethnic minority and other underserved populations [83].

Two frameworks were specifically designed in the context of ethnic differences in diabetes care and outcomes. Knowledge gained from these can be applied to other chronic health conditions and to the design and implementation of digital health services. Wilkinson and colleagues [66] did not identify any studies that focused on older people from a South Asian background in a review of literature on diabetes care. Their theoretical framework draws relationships between key concepts emerging from the literature: cultural stratification and comorbidities, cultural competency, and access [66]. The Gender-Centered Diabetes Management Education Ecological Framework takes a more detailed approach to address disparities in diabetes outcomes for Black men in the United States by placing diabetes management education into a broad context that includes demographic characteristics, gender roles, and family situation. While developed in one particular group, these constructs are applicable to understanding health management in other ethnic minority groups; for example, specific barriers to exercise have been identified in South Asian women with diabetes and cardiovascular disease, including family obligations, fears about women going out alone, lack of single-sex exercise facilities [84], and perceptions of taking time to exercise as being “selfish” and taking women away from their “daily work [85].”

### Comparison With Prior Work

It is necessary to consider health disparities in research on health technology, particularly in understanding the role of technology in exacerbating or addressing inequalities, and in the design and evaluation of interventions [86]. Approaches including defining common terms and proposing standardized language and measurement tools [16], mapping concepts of engagement with digital behavior change interventions [59], and describing commonly used frameworks in clinicians’ adoption of mHealth [27] have been used to review frameworks for the uptake and use of digital health interventions. Recently, reviews on equitable approaches to research [87] and use [88] of health portals have examined digital health equity at the intervention level. Researchers have also responded to the need for equitable approaches to virtual care provision (eg, access to phone or video consultations) highlighted during the COVID-19 pandemic [89,90], including adaptation of the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability framework [14] to include

digital inclusion as a concept that contributes to the *patient* domain [90].

As digital health approaches become embedded in national health strategies, there is also a need for the application of frameworks to ensure equitable digital health implementation in ethnically and culturally diverse populations. The NHS is promoting digital services and tools in England [91], including for cardiometabolic disease, such as a digital pilot of the NHS Diabetes Prevention Programme [92] and a cardiology digital playbook that promotes digital tools to support patients remotely [93]. Furthermore, the adoption of digital health interventions was actively encouraged to mitigate the risk of face-to-face interaction during the pandemic [94], and going forward, digital health interventions are seen as adoption of innovation to provide cost-effective outcomes in health [95]. However, digital exclusion has the potential to exacerbate health inequalities, both directly (reduced access to services and resources) and indirectly (access to wider determinants of health, such as housing or occupation opportunities) [96]. The frameworks identified in this scoping review and the guide to the key constructs they contain (Figure 2) can be used as tools to identify the individual, technological, and contextual factors that influence the direct routes between digital and health inequalities.

### Strengths and Limitations

We aimed to explore the breadth of potential frameworks that were applicable to understanding inequalities in digital health uptake and use. The configurative approach to a scoping review generates or explores theories, rather than aggregating data to test theories [97]. Taking an iterative approach also allows inclusion and exclusion criteria to be refined through the course of the review [98]. In this case, with an unknown literature base regarding digital health inequalities, we were able to further refine inclusion criteria during the full-text review to exclude a number of papers that focused on statistically testing minor variations of the Technology Acceptance Model. However, scoping reviews do not usually undertake formal quality appraisal [98]; therefore, synthesizing the results was difficult because of the range of frameworks identified. In a review of Technology Acceptance Model adaptations alone, a high degree of study heterogeneity was identified [12]. Additionally, there was a lack of standardization of terms, with the terms *acceptance*, *adoption*, and *acceptability* being used interchangeably. We took an inclusive approach when considering the use of such terminology [12,16].

### Acknowledgments

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### Future Directions

Beyond the scope of the review, other papers were identified during the screening process, which could have some relevance for the process of design and implementation of digital health interventions, for example, the RESET (relevance, evidence base, stages of intervention, ethnicity and trends) tool to adapt health promotions to meet the needs of ethnic minority groups [99] and a framework for coproduction of digital services for marginalized people living with complex and chronic conditions [100]. A number of papers have put forward design and assessment tools for equity in digital health [61,64,101-103]. A review of tools for inclusivity and cultural sensitivity, coproduction approaches, and equitable design processes could identify practical steps that could be taken by developers to promote equity in digital health.

Future research should assess how the frameworks identified in this scoping review can be used and applied to different ethnic minority groups and in the management of other health conditions. The complex intersections of factors associated with health and other inequalities should also be considered. For example, in England, some ethnic groups are more likely to live in deprived areas [104], and deprivation is associated with increased mortality across all ethnic groups, including White ethnicity [105]. Application of appropriate frameworks for engagement, implementation, and evaluation can improve the reach of measures to address broader health inequalities and target all underserved groups.

### Conclusions

Health inequalities continue to be a major focus in health policy and research globally. A number of frameworks have been put forward to address social determinants of health [15] or to improve inequalities in particular major chronic health conditions, such as cardiometabolic diseases [106]. As digital health approaches are encouraged and become more commonplace, we should use our existing theoretical understanding of the interaction between digital health approaches and health inequalities to improve equitable distribution of benefits, including to ethnic minority populations. We have produced a visual guide (Figure 2) to shape action when considering preventable or manageable chronic disease in the community that shows ethnic inequalities in outcomes, such as cardiometabolic disease.

## Authors' Contributions

The review concept was designed by MR, LP, A Banerjee, EM, and A Blandford. Literature searches were conducted by MR. Screening was led by MR and conducted by LP, ZTB, AC, M Murali, PJ, MB, JP, and AG-M. Data charting was carried out by MR, LP, and ZTB, and further analysis was done by MR. Figures were designed by MR, and LP wrote the original draft, with review and edits from A Banerjee, A Blandford, FS, and HWWP. Additional review was carried out by KK, WH, PG, MS, KP, HS, NB, AU, SM, M Mistry, VP, SNA, and AA for the DISC Study consortium.

## Conflicts of Interest

KK is director of the University of Leicester Centre for Ethnic Health Research and trustee of the South Asian Health Foundation. HWWP receives consultancy fees, through his employer, from Ipsos MORI and has PhD students who work at and have fees paid by AstraZeneca and BetterPoints. A Banerjee has received research grants from National Institute for Health and Care Research (NIHR), British Medical Association, UK Research and Innovation, European Union, and Astra Zeneca.

### Multimedia Appendix 1

PRISMA-ScR checklist.

[[DOCX File , 55 KB - cardio\\_v6i2e37360\\_app1.docx](#) ]

### Multimedia Appendix 2

Inclusion and exclusion criteria for literature searches.

[[DOCX File , 50 KB - cardio\\_v6i2e37360\\_app2.docx](#) ]

### Multimedia Appendix 3

Search strategy as used for SCOPUS.

[[DOCX File , 55 KB - cardio\\_v6i2e37360\\_app3.docx](#) ]

### Multimedia Appendix 4

Inclusion and exclusion guide for title and abstract screening.

[[DOCX File , 53 KB - cardio\\_v6i2e37360\\_app4.docx](#) ]

### Multimedia Appendix 5

Additional frameworks identified through abstract screening.

[[DOCX File , 51 KB - cardio\\_v6i2e37360\\_app5.docx](#) ]

### Multimedia Appendix 6

Data-charting form.

[[DOCX File , 50 KB - cardio\\_v6i2e37360\\_app6.docx](#) ]

### Multimedia Appendix 7

Summary of papers included in the data charting.

[[DOCX File , 73 KB - cardio\\_v6i2e37360\\_app7.docx](#) ]

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## Abbreviations

**mHealth:** mobile health

**NHS:** National Health Service

**NIHR:** National Institute for Health Research

**PRISMA-ScR:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews

**RESET:** relevance, evidence base, stages of intervention, ethnicity and trends

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Review

# Characteristics of Smart Health Ecosystems That Support Self-care Among People With Heart Failure: Scoping Review

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## Abstract

**Background:** The management of heart failure is complex. Innovative solutions are required to support health care providers and people with heart failure with decision-making and self-care behaviors. In recent years, more sophisticated technologies have enabled new health care models, such as smart health ecosystems. Smart health ecosystems use data collection, intelligent data processing, and communication to support the diagnosis, management, and primary and secondary prevention of chronic conditions. Currently, there is little information on the characteristics of smart health ecosystems for people with heart failure.

**Objective:** We aimed to identify and describe the characteristics of smart health ecosystems that support heart failure self-care.

**Methods:** We conducted a scoping review using the Joanna Briggs Institute methodology. The MEDLINE, Embase, CINAHL, PsycINFO, IEEE Xplore, and ACM Digital Library databases were searched from January 2008 to September 2021. The search strategy focused on identifying articles describing smart health ecosystems that support heart failure self-care. A total of 2 reviewers screened the articles and extracted relevant data from the included full texts.

**Results:** After removing duplicates, 1543 articles were screened, and 34 articles representing 13 interventions were included in this review. To support self-care, the interventions used sensors and questionnaires to collect data and used tailoring methods to provide personalized support. The interventions used a total of 34 behavior change techniques, which were facilitated by a combination of 8 features for people with heart failure: automated feedback, monitoring (integrated and manual input), presentation of data, education, reminders, communication with a health care provider, and psychological support. Furthermore, features to support health care providers included data presentation, alarms, alerts, communication tools, remote care plan modification, and health record integration.

**Conclusions:** This scoping review identified that there are few reports of smart health ecosystems that support heart failure self-care, and those that have been reported do not provide comprehensive support across all domains of self-care. This review describes the technical and behavioral components of the identified interventions, providing information that can be used as a starting point for designing and testing future smart health ecosystems.

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**KEYWORDS**

digital health; review; chronic diseases; cardiovascular disease; information technology; digital technology; mobile phone; self-management

## Introduction

Heart failure is associated with a decreased quality of life and increased health care system costs, predominantly because of hospital admissions [1,2]. To prevent deterioration and readmission to hospital, primary and secondary health care providers such as physicians, nurses, and allied health professionals use the practices described in clinical guidelines [3,4]. However, these guidelines are typically long, complex, and subject to changes [5], making them difficult to follow. People with heart failure are also encouraged to practice self-care behaviors to improve their symptoms and manage their health [6,7]. Self-care behaviors include taking medication as prescribed, regular exercise, monitoring symptoms, and titrating medication based on the detection and interpretation of symptoms [6,7]. However, there are numerous barriers to self-care among people with heart failure, including difficulties in recognizing and interpreting symptoms and deciding what course of action to take [8,9].

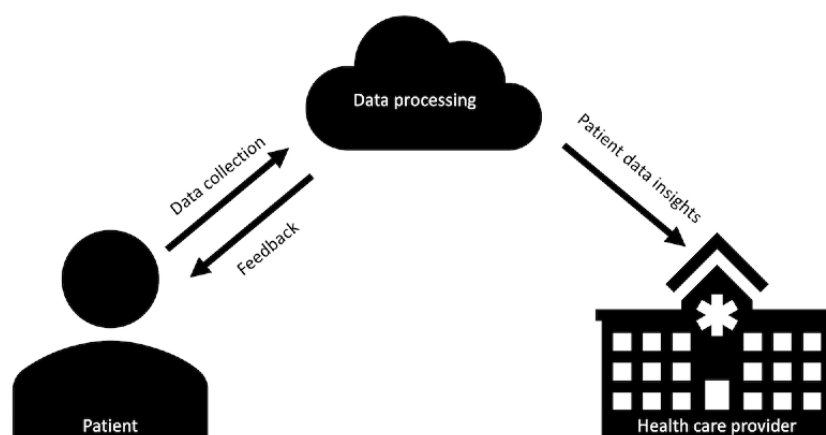
Innovative solutions are required to support health care providers' decision-making and support people with heart failure to initiate and sustain appropriate self-care behaviors. A recent systematic review of interventions to support self-care among people with heart failure described that effective interventions may have capitalized on interactive telemonitoring devices [10-12], automated and timely responses to participants based on their data [13], and the involvement of health care providers [13,14]. In recent years, improvements in interoperability have driven the integration of more sophisticated technologies (eg, Internet of Things, data storage systems, and artificial intelligence) within health care practice [15,16]. These technologies enable new models of health care that are increasingly being used to assist in the diagnosis, treatment, monitoring and management, including self-care, of people with

chronic conditions [17-19]. We refer to this as a smart health ecosystem (Figure 1).

Despite these potential advantages, we do not fully understand the characteristics of smart health ecosystems that support heart failure self-care. In particular, understanding the technical and behavioral components could inform the future design, evaluation, and hypotheses about the mechanisms of action of such interventions. Technical components include the devices used for interaction with the system and data collection and how data are processed and communicated back to people with heart failure and health care professionals. Behavioral components include the active ingredients that change behavior [20]. The behavior change technique taxonomy, version 1 (BCTTv1), provides a list of 93 behavior change techniques (BCTs), which are the smallest components capable of changing behavior [20]. The BCTTv1 can be used to code behavioral components in interventions; for example, setting a target to self-weigh each day would be coded as "goal setting," receiving information about weekly medication adherence would be coded as "feedback on behavior" and an alarm to remind about taking medication would be coded as "prompts or cues."

A scoping review can be used to understand a body of literature, identify gaps, and clarify concepts [21]. A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews, and Joanna Briggs Institute Evidence Synthesis was conducted, and no current or ongoing systematic reviews or scoping reviews on this topic were identified. This scoping review aimed to answer the following questions: (1) What smart health ecosystems to support self-care among people with heart failure are reported in the literature? (2) What self-care behaviors do smart health ecosystems for people with heart failure support? (3) How do smart health ecosystems aim to change or support self-care behaviors?

**Figure 1.** Concept of a smart health ecosystem.



## Methods

### Study Design

This review was conducted following the Joanna Briggs Institute (JBI) methodology for scoping reviews [22] and adheres to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews)

[23]. We did not appraise the methodological quality or risk of bias of the included articles as this is not required for a scoping review.

### Eligibility Criteria

This review was guided by the "population, concept, context" framework suggested by the JBI methodology [22].

## Population

We considered studies that involved adults (aged  $\geq 18$  years) with heart failure living in the community, health care providers (people delivering health care services for people with heart failure), caregivers, and families of people with heart failure, and studies without a population, such as methodological articles, if they addressed the relevant interventions (see concept).

## Concept and Context

This review considered articles that described, reported the design, or investigated the use of smart health ecosystems (the intervention) that support self-care behaviors in adults (aged  $\geq 18$  years) with heart failure living in the community. Although there is no existing definition of such interventions, we considered those with the following elements: (1) data collection using a digital device; (2) automatic processing of data to provide personalized, actionable insights on health and well-being, for example, a recommendation to adjust medication; and (3) health care provider access to data. Interventions that did not explicitly prompt self-care behaviors were excluded, such as those that used an implantable cardiac device or presented data without providing behavioral support or actionable advice. [Figure 1](#) provides a visual representation of this concept.

## Types of Sources

The following peer-reviewed study designs were considered for this review: experimental and quasi-experimental studies, analytical and descriptive observational studies, and qualitative studies, including intervention design studies. Conference proceedings that reported the listed study designs were considered if they were peer-reviewed, as is the case in many information technology journals. To this end, we excluded conference proceedings that were not peer-reviewed or did not contain a full description of the intervention, such as conference abstracts and posters. Review studies and opinion articles were excluded to limit the studies to technologically feasible interventions.

## Search Strategy

The search strategy was aimed at locating published articles. An initial limited search of MEDLINE and SCOPUS was performed to identify articles on the topic. Text words contained in the titles and abstracts of relevant articles and article index terms were used to develop a complete search strategy for MEDLINE. The search strategy, including all the identified keywords and index terms, was adapted for each included database ([Multimedia Appendix 1](#) contains the search strategies for each database). A research librarian was consulted while developing the search terms and translating the strategy across the databases. The databases searched were MEDLINE (via EBSCO), Embase, CINAHL (via EBSCO), PsycINFO (via EBSCO), IEEE Xplore, and the ACM Digital Library. The searches were conducted in September 2021. The reference lists of included articles were screened for additional papers. For feasibility reasons, only articles published in English were

considered. In addition, only articles published between January 2008 and September 2021 (inclusive) were considered. This date range was selected as it accounts for when the Internet of Things was “born” [24].

## Study Selection

Following the searches, all identified articles were collated and uploaded into EndNote X9 (Clarivate Analytics), and duplicates were removed. The citation details of potentially relevant articles were imported into Covidence (Veritas Health Innovation). A total of 2 independent reviewers (RN and JM) screened the titles and abstracts to assess the inclusion criteria. The full texts of the selected articles were assessed in detail against the inclusion criteria by 3 reviewers (RN with EL or JM). During the selection process, disagreements between the reviewers were resolved through discussion or with a third reviewer (EL, JM, or LK).

## Data Extraction

Data from the included articles were extracted by 2 independent reviewers (EL and RN). RN and LK developed the data extraction tool for this review (provided in [Multimedia Appendix 2](#)) by adding items relevant to the population, concept and context and research questions to an example form provided by the JBI. Data extracted from all articles included the year of publication, author names, journals, and descriptions of the interventions. For articles that implemented an intervention, details about the participants were extracted. Where multiple articles reported the same intervention, data pertaining to the intervention characteristics were extracted into a single form.

## Data Analysis and Presentation

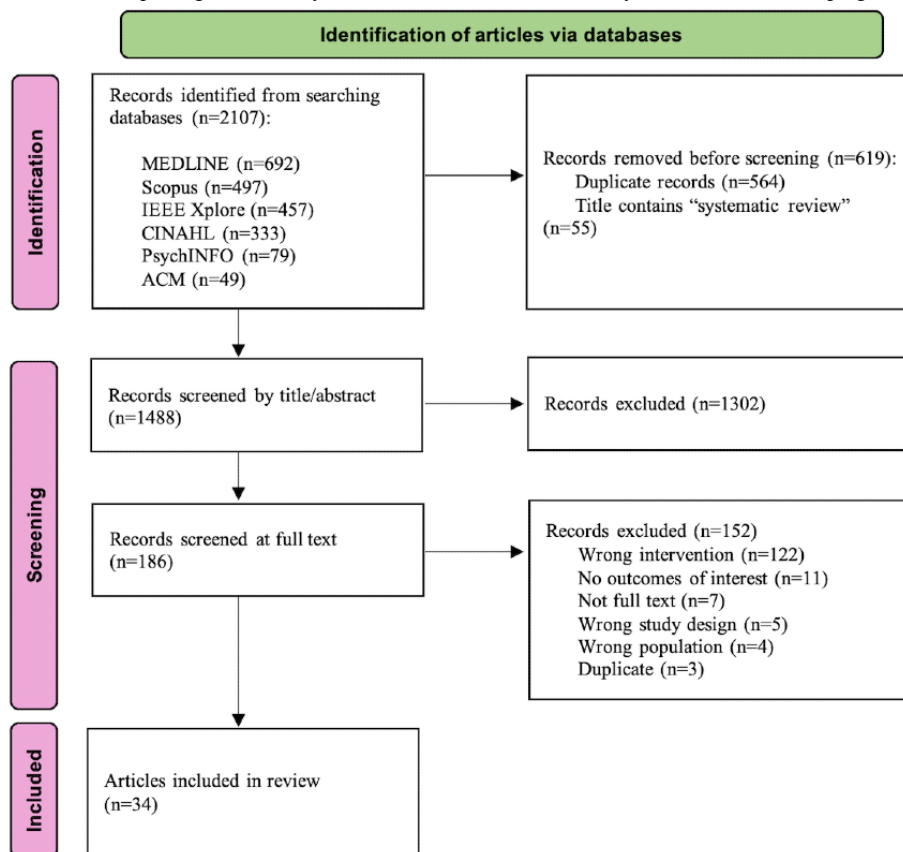
An inductive content analysis of the intervention descriptions was used to identify and categorize the intervention characteristics. We also deductively coded the intervention descriptions using BCTTv1, a list of 93 techniques categorized into 16 categories [20], to identify the BCTs used in the interventions. RN led the analysis and was supported by EL, LK, and RM, who each had expertise in relevant subject areas (technical, clinical, and behavioral). The results of this review are presented in 2 parts. First, a brief description of the included articles is presented. Next, the characteristics of the interventions are presented.

## Results

### Article Inclusion

A total of 2107 articles were identified from the database searches. After manually removing duplicates ( $n=564$ ) and using EndNote to remove articles with the words “systematic review” in the title ( $n=55$ ), 1488 articles remained. The title and abstract screening process left 170 articles for full-text review. A total of 34 articles [13,25-57] representing 13 unique interventions were included in this review. The PRISMA-ScR [58] flowchart in [Figure 2](#) illustrates the selection process. The main reason for excluding articles during full-text review was that they reported an intervention that did not meet our description of a smart health ecosystem.

**Figure 2.** PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) flowchart.



### Characteristics of the Included Articles

The 34 articles were published between 2009 and 2021, most of which were published during or after 2017 (18/34, 53%). Most of the included articles were published in journals (22/34, 64%), and the remainder were conference proceedings (12/34, 35%). Characteristics of the included articles are provided in [Multimedia Appendix 3](#).

### Intervention Characteristics

#### Overview

As the purpose of this review is to report the characteristics of the 13 included interventions, for the remainder of this review, we will use the metric of the intervention rather than the 34 articles. As such, for interventions reported in multiple articles, only the main article reporting the contents of the intervention (see column 1 in [Table 1](#)) is referenced in the subsequent text and tables.

**Table 1.** Intervention mode of delivery.

Intervention name (primary reference)	Mode of delivery for people with heart failure	Mode of delivery for health care provider
CONNECARE [25]	Mobile phone (app)	Web-based platform—accessed by portable tablet
Do Cardiac Health Advanced New Generated Ecosystem (Do CHANGE 2) [27]	Mobile phone (apps, phone call, SMS text messaging), CarePortal, Docobo Ltd.	Web-based portal
HeartCycle Heart Failure Management system [30]	Device connected to television (Philips Motiva)	Web-based platform
HeartMan [35]	Mobile phone (app, phone call), wristband display (custom wristband), pill organizer (PuTwo, 7-Day AM or PM Night Reminder Medi-Planner)	Web application
HeartMapp [40]	Mobile phone (app)	Not reported
Home Automated Telemanagement system [42]	Home unit (notebook computer, PlayStation, Xbox, or Wii)	Clinician unit, email
Medly [48]	Mobile phone (app, automated phone call)	Web dashboard, email
N/A <sup>a</sup> —voice interface technology [52]	Conversational agent (Alexa)	Email and text (alerts)
CardioConsult HF [53]	Health monitor (Turnstall)	SMS text messaging, email, decision support management system (computer)
N/A—a home-based self-management program [54]	Mobile phone (app)	Not reported
N/A—an eHealth self-management intervention [55]	Tablet (app), Respiro, Amiko Digital Health add-on inhaler sensor, face-to-face (individual and group training sessions), phone call	Website
Veta Health [56]	Mobile phone (app)	Veta Health platform (computer)
N/A—an integrated, automatic home-monitoring and assist system [57]	Interactive display wall (video call)	Not reported

<sup>a</sup>N/A: not applicable.

### **Intervention Context**

A summary of the contextual characteristics of all 13 interventions is presented in [Table 2](#). Most interventions were designed to address heart failure alone (9/13, 69%) [30,35,40,42,48,52-54,56]. Only 1 intervention was designed for people with both chronic obstructive pulmonary disease and heart failure [55]. In addition, 3 interventions were designed for people with at least one of multiple conditions; people with heart disease (including heart failure) who had received a mechanical circulatory support device [57]; people with

coronary artery disease, hypertension, or heart failure [27]; and those with chronic obstructive pulmonary disease or heart failure with a history of hospitalization or who were undergoing major surgery (hip or knee replacement) [25].

Of the 13 interventions, 11 (85%) were tested among participants or involved participants in the intervention development process: 5 in European countries, 4 in the United States, 1 in Canada, and 1 intervention was deployed in a multicenter study in the Netherlands, Spain, and Taiwan ([Table 2](#)).



**Table 2.** Characteristics of included interventions.

Name and description (primary reference)	Target condition	Country
CONNECARE—a mobile health-enabled integrated care model [25]	COPD <sup>a</sup> , HF <sup>b</sup>	Spain
Do Cardiac Health Advanced New Generated Ecosystem (Do CHANGE 2)—a personalized digital behavioral intervention program [27]	CAD <sup>c</sup> , HF, HT <sup>d</sup>	Netherlands, Spain, Taiwan
HeartCycle Heart Failure Management System—a personalized disease management care system [30]	HF	N/A <sup>e</sup>
HeartMan—a personal health system [35]	HF	Belgium, Italy
HeartMapp—a theory-based mobile app [40]	HF	United States
Home Automated Telemanagement system—a pervasive telemedicine application [42]	HF	United States
Medly—a mobile phone-based heart failure telemonitoring program [48]	HF	Canada
N/A—voice interface technology [52]	HF	United States
CardioConsult HF—a computerized decision support system [53]	HF	Netherlands
N/A—a home-based self-management program [54]	HF	N/A
N/A—an eHealth self-management intervention [55]	COPD, HF	Netherlands
Veta Health—a hybrid mHealth model [56]	HF	United States
N/A—an integrated, automatic home-monitoring and assist system [57]	Heart disease (including HF) with mechanical circulatory support devices	Germany

<sup>a</sup>COPD: chronic obstructive pulmonary disease.

<sup>b</sup>HF: heart failure.

<sup>c</sup>CAD: coronary artery disease.

<sup>d</sup>HT: hypertension.

<sup>e</sup>N/A: not applicable.

### Mode of Delivery

Most interventions were delivered entirely digitally (12/13, 92%), and 1 (8%) intervention included a face-to-face component (we did not consider study or trial enrollment sessions), which included individual and group training sessions [55]. Digital modes of delivery included applications or programs available on mobile phones (7/13, 54%) [25,27,35,40,48,54,56], tablets (1/13, 8%) [55], conversational agents (1/13, 8%) [52], notebook computers (1/13, 8%) [42], televisions (1/13, 8%) [30], interactive walls (1/13, 8%) [57], and gaming systems (Microsoft Xbox, Sony PlayStation, and Nintendo Wii; 1/13, 8%) [42]. In addition, existing medical platforms (CarePortal by Docobo, Motiva by Philips, a Tunstall health monitor, and Veta Health) were used in 4 interventions [27,30,53,56], with the Motiva system being adapted by the study group [30]. Furthermore, the interventions used text messages, emails, automated phone calls, and wristband displays as communication tools. More recent interventions used portable devices, such as mobile phones, whereas older interventions used devices placed in the home (eg, gaming systems). Most

interventions used a single device as the mode of delivery (10/13, 77%) [25,30,35,42,48,52-54,56,57], whereas 23% (3/13) of interventions [27,35,55] leveraged more than one. Health care providers interacted with the interventions through websites and apps hosted on various devices and received alerts by text messages and emails, but this was less clearly reported in the intervention descriptions.

### Features for People With Heart Failure

All interventions included 2 features: provision of automated feedback (13/13, 100%) [25,27,30,35,40,42,48,52-57] and monitoring that required manual input (13/13, 100%) [25,27,30,35,40,42,48,52-57]. Additional features were integrated monitoring (11/13, 85%) [25,27,30,35,40,48,53-57], presentation of data (11/13, 85%) [25,27,30,35,40,42,48,54-57], education (10/13, 77%) [25,27,30,35,40,42,53-56], reminders (7/13, 54%) [35,40,48,52,54-56], integrated communication with health care providers (5/13, 38%) [25,42,54,56,57], and psychological support (3/13, 23%) [27,35,55]. None of the interventions delivered all features (range 3-7). Table 3 provides a summary and examples.

**Table 3.** Features for people with heart failure (N=13).

Feature	Value, n (%)	Primary reference for intervention	Examples (not a comprehensive list)
Automated feedback	13 (100)	[25,27,30,35,40,42,48,52-57]	Virtual coach with automated feedback [25]; receive “To-Do” messages based on psychological profile and current functioning [27]; actionable feedback about vital signs measurements to help track progress toward personal goals [30]; warnings if measurements are outside certain ranges [35,57]; automated feedback on walking performance [40]; instant feedback based on action plan zone and measurements [42,52]; automatically generated advice to act (eg, sodium and fluid restriction, contact nurse, monitor blood pressure) [53]; feedback on fluid intake [54]; automated messages with action to take (eg, initiate self-treatment, call case manager) [55]; automated responses to data to promote understanding of self-monitoring data [56]
Monitoring (manual input)	13 (100)	[25,27,30,35,40,42,48,52-57]	Symptom reporting questionnaires [25,27,40,52-56]; health surveys [30]; rating intensity of exercise [35]; disease diary [42]; option to record user-specified data [57]
Monitoring (integrated)	11 (85)	[25,27,30,35,40,48,53-57]	Physiological monitoring with devices (eg, Bluetooth-connected blood pressure monitor, weight scales) [25,27,30,35,40,48,53-57]; take photographs of food (monitored by health care professional) [27]
Presentation of data	11 (85)	[25,27,30,35,40,42,48,54-57]	Overview of data collected by sensors and questionnaires [25,27,30,40,42,48,54-57]; dashboards show the percentage of monthly or weekly activities performed [35]
Education	10 (77)	[25,27,30,35,40,42,53-56]	Health education videos (eg, what is heart failure, symptoms to look out for, physical activity video) [25,30]; guidance on how to take electrocardiogram measurement [27]; educational statements and advice on how to modify the diet to make it healthier [35]; randomly generated questions used to test knowledge (learning by teaching) [40]; interactive questions for disease-specific education [51]; education about heart failure [53]; mini educational game and text-based information [54]; in-person training sessions (group and individual) [55]; view educational content [56]
Reminders	7 (54)	[35,40,48,52,54-56]	Reminders to take measurements (eg, weight, blood pressure) [35,40,48,54]; reminders to answer questionnaire [52]; reminders to take medication [35,40,54]; on sensor audio-visual signs to remind about scheduled medication dose [55]; pop-up notifications for measurements and surveys [56]
Integrated communication with health care provider	5 (38)	[25,42,54,56,57]	Messaging with health care team (including the ability to send images and videos) [25,54]; ability to send messages to health care team (stock messages or can type their own) [42]; direct link to health care provider [56]; direct video link to health care provider [57]
Psychological support	3 (23)	[27,35,55]	Receive “ToDo” messages based on psychological profile and current functioning [27]; cognitive behavioral therapy messages based on psychological profile and games to deal with intrusive thoughts [35]; instruction videos with exercises for relaxation [55]

### Features for Health Care Providers

Health care providers involved in the interventions were case managers, nurses, specialists, nutritionists, psychologists, and general practitioners. Features for these health care providers included support for decision-making and prioritization through providing visualization of information and data that had been collected using sensors and questionnaires (13/13, 100%) [25,27,30,35,40,42,48,52-57], alerts and alarms (eg, for

measurements that fell out of range or symptom deterioration (9/13, 69%) [25,30,42,48,52-54,56,57], and by facilitating remote treatment plan changes (5/13, 38%) [25,30,35,42,53]. Although only 38% (5/13) of interventions facilitated in-system communication with people with heart failure (eg, through in-app messaging or a video consultation) [25,42,54,56,57], many intervention descriptions inferred that health care providers would provide direct contact if required. Only one

intervention alerted health care providers to any technical problems—a low battery on a weight scale [53].

### **Data Collection**

Data collection fell under 4 categories: physiological, symptom, behavioral, and others (Table 4). Only 1 intervention did not collect any physiological data [52], 3 did not collect any information about symptoms [35,54,57], and 3 did not collect data on behaviors [30,48,53]. Data on physiological parameters were collected using commercially available devices. Although most interventions were intended to supply the devices required to collect relevant data, others used devices owned or supplied by people with heart failure [40,48,54,56]. Overall, the content of questionnaires was not clearly reported in the intervention descriptions. Where reported, symptoms included shortness of breath, edema, chest pain, fatigue, palpitations, dizziness, medication side effects, fainting, implantable cardiac device activation, nighttime breathing, and cough. Questionnaires included rating symptoms from absent to severe [30], comparing symptoms to “usual” symptoms [55], and simply reporting the absence or presence of a symptom [25,27,40,42,48,52,53,56]. A conversational agent was used to ask a series of questions that required a yes or no response by 1 intervention [52]; this

questionnaire was based on 3 literature sources [59-61]. Although physiological data collection relied on sensors and symptom data on self-reports, behavioral data were collected by both sensors and self-reports. Behaviors monitored by the interventions included physical activity, medication adherence and techniques, sleep, adherence to self-weighing, fluid intake, food consumption, and cooking behavior. Some devices were used to collect more than one parameter; for example, a Fitbit could collect both heart rate and sleep data. Custom-built devices were used in 3 interventions; these devices included a wristband with a photoplethysmography sensor, triaxial accelerometer, and a temperature sensor [35]; a shirt to measure vitals during exercise [30]; a smart spatula to measure cooking behavior and salinity of food being cooked; and a fluid monitor that could be attached to a glass or bottle to gauge the amount of fluid contained [27]. Other data collected were mostly used to further personalize interventions (see the section Tailoring and Personalization). Questionnaires were used to determine personality profiles, comprehension and motivation, depression, and anxiety scores. These devices were used to collect GPS location data, voice recordings, and environmental and humidity data.

**Table 4.** Physiological and behavioral data collection: parameters and measurement tools (N=13).

Parameter	Value, n (%)	Measurement tools in each intervention (primary reference)
<b>Physiological</b>		
Weight	11 (85)	Weight scale, Withings (unspecified model) [25]; Aura 807 scale, Seca [27] <sup>a</sup> ; Silje BE 1303 [35]; Self-owned scale [40,48,54,56] <sup>a</sup> ; 321P, Lifesource [42] <sup>a</sup> ; Bluetooth-enabled weight scales [48,55]; Weight scale, A&D instruments (unspecified model) [53]; Weight scale, Kern (placed under a floor tile) [57]; Network of piezoelectric sensors under floor tiles [57]
Blood pressure	8 (61)	Monitor, Withings (unspecified model) [25]; UA-737 Plus, A&D Medical [27] <sup>a</sup> ; UA-611, A&D Medical [35]; Bluetooth-enabled blood pressure cuff [48,56]; Monitor, A&D instruments (unspecified model) [53]; Boso sensor integrated into furniture [57]; Unspecified [54] <sup>a</sup>
Heart rate	7 (54)	Fitbit Alta HR, Fitbit [27]; Wristband sensor, BITTIUM, Oulo (custom developed for study) [35]; BioHarness-3 chest strap [40]; Boso sensor integrated into furniture [57]; Unspecified [48,54,56] <sup>a</sup>
Temperature	3 (23)	Monitor, Withings (unspecified model) [25]; wristband sensor, BITTIUM, Oulo (custom developed for study) [35]; High precision infrared camera, Flir Systems (placed on wall) [57]
Blood oxygen saturation	2 (15)	Monitor, Withings (unspecified model) [25]; Bluetooth-enabled pulse oximeter [56]
Heart rate variability	1 (8)	Wristband sensor, BITTIUM, Oulo (custom developed for study) [35]; BioHarness-3 chest strap [40]
Electrocardiogram	1 (8)	CarePortal, Docobo [27]
Heart rate (sleep)	1 (8)	Beddit 3 [27]
Breathing rate (sleep)	1 (8)	Beddit 3 [27]
Galvanic skin response	1 (8)	Wristband sensor, BITTIUM, Oulo (custom developed for study) [35]
Coagulation	1 (8)	CoaguChek, Roche Diagnostics integrated into furniture [57]
Unspecified	1 (8)	Unspecified devices to measure vital parameters [30]
<b>Behavioral</b>		
Physical activity (eg, step count, accelerometry)	5 (38)	Fitbit Alta HR, Fitbit [27]; Fitbit (unspecified model) [25,55]; Wristband sensor, BITTIUM, Oulo (custom developed for study) [35]; BioHarness-3 chest strap [40]
Medication adherence	4 (31)	Question on number of pills remaining, adherence calculated based on deviation from expected number [35]; voice response questionnaire [52]; Respiro, Amiko Digital Health (add-on sensor for inhaler) [55]; unspecified questionnaire [56]
Salt intake	2 (15)	CooKiT, study developed device (sodium and potassium sensor) [27]; voice response questionnaire [52]
Fluid intake	2 (15)	FLUiT study developed device [27]; self-report intake [54]
Medication technique	1 (8)	Respiro, Amiko Digital Health (add-on sensor for inhaler) [55]
Eating behavior	1 (8)	Take photographs of food 3 times a day in mobile app [27]
Self-weighing	1 (8)	Voice response questionnaire [52]
Cooking behavior	1 (8)	CooKiT, study developed device (motion sensor spatula) [27]
Sleep	1 (8)	Beddit 3 [27]
Adherence (unspecified)	1 (8)	Questionnaire [42]

<sup>a</sup>Denotes manual input required.

### Tailoring and Personalization

Tailoring and personalization were driven by human input or by algorithms and machine learning techniques (Table 5 provides a summary and examples). All interventions provided tailored advice based on the data collected. Interventions leveraged multiple processing techniques such as rule-based reasoning, machine learning, and comparing data to parameters

set by clinical guidelines, historical trends, or expert data from health care providers (3/13, 23%) [42,48,57]. In addition, 10 interventions [25,27,30,35,40,42,48,52,54,55,57] demonstrated enhanced personalization, including tailoring intervention content (5/13, 38%) [25,35,40,54,62], timing of delivery (3/13, 23%) [27,35,52], monitoring devices (3/13, 23%) [25,27,55], and the mode of delivery (1/13, 8%) [27].

**Table 5.** Tailoring and personalization (N=13).

Features	Value, n (%)	Primary reference for intervention	Examples (not a comprehensive list)
Advice	13 (100)	[25,27,30,35,40,42,48,52-57]	Advice based on risk stratification (calculated by assessing personal characteristics and environment) [25]; messages personalized based on personality profile, social opportunity, variety and activity, and physical activity status [27]; predictive models recommended actions related to temperature and humidity [35]; built-in algorithm analyzed weight and symptom data and gave feedback depending on status [40]; in case of deviation from predefined values, system asked about symptoms and then provides advice based on heart failure guidelines [53]
Intervention content	5 (38)	[25,30,35,40,54]	Cycloergometry or 6-minute walk test used to assess fitness, appropriate exercises given based on test results [35]; questions on current lifestyle and behavior determined which education topics are presented [30]
Alert parameters	3 (23)	[42,48,57]	Adaptive feature extraction—can be updated with current user or expert data [57]
Timing of delivery	3 (23)	[27,35,52]	Physical activity recognition from accelerometer in wristband allowed for psychological interventions to be delivered at an appropriate moment [35]; reminder alarm time could be scheduled at a preferred time [52]
Monitoring devices	3 (23)	[25,27,55]	Devices determined by health care team [25,27,55]
Mode of delivery	1 (8)	[27]	Options for mode of delivery of messages [27]

### Theoretical Grounding

Of the 13 interventions, 7 (54%) were developed with guidance from one or more theories: self-regulation theory [30], cognitive behavioral therapy [35], theory of cognitive dissonance [35], Do Something Different behavior change program [27], the multidimensional framework of patient engagement [40], intervention motivation-behavior model [40], chronic disease care model [42], the framework for Self-Care in Chronic Illness [48], activity theory [54], and multiple theories used to promote engagement with educational content [40]. The details of the theories corresponding to each intervention are available in [Multimedia Appendix 4](#). Finally, 4 interventions included educational content or advice based on clinical guidelines and recommendations [30,40,53,54].

### Behavior Change Techniques

A total of 34 unique BCTs from BCTTv1 were identified in the 13 interventions, with an average of 12 BCTs per intervention (range 7-26). [Table 6](#) provides a summary of the BCTs and their corresponding categories from the BCTTv1 that we identified for each intervention. A total of 8 BCTs were identified in at least 75% of the interventions: adding objects to the environment (13/13, 100%), self-monitoring of outcome(s) of behavior (12/13, 92%), biofeedback (12/13, 92%), pharmacological support (12/13, 92%), feedback on behavior (11/13, 85%), prompts and cues (11/13, 85%), self-monitoring of behavior (10/13, 77%), and social support (10/13, 77%).

**Table 6.** Summary of behavior change techniques used in the interventions according to behavior change technique taxonomy, version 1 (BCTTv1) (N=13).

Behavior change technique (numbering according to BCTTv1)	Value, n (%)	Primary reference for intervention
<b>1. Goals and planning</b>		
1.1. Goal setting (behavior)	4 (31)	[25,30,35,54]
1.2. Problem solving	2 (15)	[35,55]
1.4. Action planning	7 (54)	[30,35,42,48,53,55,56]
1.5. Review behavior goal(s)	1 (8)	[35]
1.6. Discrepancy between current behavior and goal	5 (38)	[25,35,54-56]
<b>2. Feedback and monitoring</b>		
2.1 Monitoring of behavior without feedback	1 (8)	[27]
2.2. Feedback on behavior	11 (85)	[25,27,30,35,40,42,52,54-57]
2.3. Self-monitoring of behavior	10 (77)	[25,30,35,40,42,52,54-57]
2.4. Self-monitoring of outcome(s) of behavior	12 (92)	[27,30,35,40,42,48,52-57]
2.6. Biofeedback	12 (92)	[25,27,30,35,40,42,48,53-57]
2.7. Feedback on outcome(s) of behavior	9 (69)	[25,27,30,40,42,48,52,53,57]
<b>3. Social support</b>		
3.1. Social support (unspecified)	10 (77)	[25,27,30,35,40,52,54-57]
<b>4. Shaping knowledge</b>		
4.1. Instruction on how to perform the behavior	5 (38)	[25,27,35,42,55]
<b>5. Natural consequences</b>		
5.1. Information about health consequences	3 (23)	[35,40,55]
5.4. Monitoring of emotional consequences	1 (8)	[35]
5.5. Anticipated regret	1 (8)	[35]
5.6. Information about emotional consequences	1 (8)	[40]
<b>6. Comparison of behavior</b>		
6.1. Demonstration of the behavior	2 (15)	[25,55]
<b>7. Associations</b>		
7.1. Prompts or cues	11 (85)	[27,30,35,40,48,52-57]
<b>8. Repetition and substitution</b>		
8.1. Behavioral practice or rehearsal	3 (23)	[35,54,55]
8.2. Behavior substitution	2 (15)	[27,35]
8.3. Habit formation	2 (15)	[35,54]
8.4. Habit reversal	2 (15)	[27,35]
8.7. Graded tasks	2 (15)	[30,35]
<b>9. Comparison of outcomes</b>		
9.1. Credible source	5 (38)	[25,40,42,54,55]
<b>10. Reward and threat</b>		
10.2. Material reward (behavior)	1 (8)	[54]
10.3. Nonspecific reward	1 (8)	[25]
10.4. Social reward	4 (31)	[30,35,54,56]
<b>11. Regulation</b>		
11.1. Pharmacological support	12 (92)	[25,30,35,40,42,48,52-57]
11.2. Reduce negative emotions	3 (23)	[35,40,55]

Behavior change technique (numbering according to BCTTv1)	Value, n (%)	Primary reference for intervention
<b>12. Antecedents</b>		
12.1. Restructuring the physical environment	1 (8)	[35]
12.3. Avoidance or reducing exposure to cues for the behavior	2 (15)	[35,55]
12.4. Distraction	1 (8)	[35]
12.5. Adding objects to the environment	13 (100)	[25,27,30,35,40,42,48,52-57]

## Discussion

### Principal Findings

This scoping review aimed to understand the extent of the literature on, and the characteristics of, smart health ecosystems that support self-care behaviors among people with heart failure. We identified 34 articles describing 13 interventions. Most of the articles were published during or since 2017. Only 61% (8/13) of interventions in this review had undergone effectiveness testing or implementation at the point of the search, highlighting the novelty of this research area. We expect that the literature published in this area will increase as technologies are developed, tested, and integrated into health care delivery.

Heart failure self-care requires a person to recognize their symptoms [7]. Several devices and questionnaires were used to monitor signs and symptoms but still required a degree of manual input. As these interventions require daily use, future designs may consider using more sophisticated data processing techniques to reduce the workload of people with heart failure. For example, 1 intervention used machine learning techniques to infer physiological and psychological status, which potentially reduced the need to use monitoring tools multiple times a day [35]. With more advanced data collection and processing, privacy and security issues may concern stakeholders. Hence, as with any intervention embedded in a health care system, rigorous data management and storage protocols must be implemented.

We found that interventions leveraged commercially available or hidden devices (embedded within furniture [57]) which may reduce condition-related stigmatization and a feeling of disease being in the home compared with medical devices [63-65]. However, devices that are not portable could lead people with heart failure to feel as though they are confined to the home, or a spot within the home, because the device cannot travel with them. Some interventions have used portable devices that will allow for mobility. Commercially available devices may have limited validity in people with chronic conditions. For instance, Fitbits were used to track steps; however, a study testing the use of Fitbits to measure steps in free-living conditions concluded that although clinicians may use the data to motivate people with heart failure to walk more, the device did not meet a threshold for validity [66]. This may present a safety concern if automated advice is based on invalid data, especially without review by a health care provider. A recently developed framework for choosing devices for mHealth interventions might provide a starting point for future intervention designs [67]. Moreover, despite more people developing competence in interacting with digital technology, there are still groups of

people who are not confident, have poor digital literacy or do not have access to the internet. Smart health ecosystems risk exacerbating health inequalities without careful consideration by intervention developers and policy makers [68,69].

In addition to monitoring, many interventions included features that may aid people with heart failure in recognizing and interpreting their symptoms. These features included the provision of education and coaching; for example, by providing videos demonstrating what a particular symptom looks like before filling out a symptom questionnaire. Finally, by providing personalized automated feedback, interventions may help people with heart failure to take evidence-based actions to promote health and prevent further deterioration.

Compared with clinical guidelines [3,4] and a list of practical self-care behaviors developed by the European Society of Cardiology [6], the interventions reported in this review covered a broad range of self-care behaviors. However, no single intervention has provided comprehensive support across all recommendations. As self-care can be practiced in both healthy and ill states [7], there is an opportunity for future interventions to support people before their symptoms deteriorate by providing features that promote health maintenance and adherence. The interventions in this review included BCTs that fall under the categories of “goals and planning,” “feedback and monitoring,” and “antecedents.” A study analyzing digital health behavior change technologies from 2000 to 2018 also reported that the most common BCTs identified in such interventions were related to goal setting and self-monitoring [70]. However, a study that identified BCTs to overcome barriers to self-care among people with heart failure included those in the categories of “social support,” “shaping knowledge,” “natural consequences,” and “repetition and substitution” [9]. The adaptability and flexibility of smart health ecosystems can allow for innovative functions and features, including the delivery of additional BCTs.

The articles reported limited information on how the interventions supported the health care providers. From the evidence provided, interventions presented health care providers with clear and timely information about health status, prompting clinical intervention when required. The interventions were designed to identify early signs of deterioration and to enhance existing services rather than replace them. One limitation to using automated decision support in health care is automation bias and complacency, where health care providers rely on the technology and do not perform as diligently as they would without it [71]. Future interventions should consider ways to avoid this potential problem. Nevertheless, we hypothesize that well-designed interventions may streamline health care providers' work as the number of people with heart failure

increases. In addition, by providing automated advice to people with heart failure, less frequent support from health care providers may be required. The normalization process theory framework [72] may inform the design and evaluation of future interventions to understand and enhance how they are integrated into users' daily habits and routines [73-75]. Finally, to prevent siloed care, interventions should combine data with electronic health records and facilitate communication with other members of the care team.

### Implications for Research

Gaps in the literature related to smart health ecosystems for people with heart failure were identified. Few interventions provided comprehensive self-care support across all self-care behaviors or considered the presence of comorbidities that may interact with signs, symptoms, and self-care behavior among people with heart failure. A recent review of self-care interventions for chronic conditions also reported this finding [76]. Future interventions should incorporate support for a wide range of behaviors that can be tailored to individual needs. Technologies and data analyses are now advanced enough to consider the interaction of comorbidities with heart failure, and as the number of people with more than one condition increases, interventions could target people with multiple conditions. Moreover, most studies were conducted in the United States and Europe. Research should be conducted in additional regions of the world and, thus, different health care settings to provide deeper insights. Further research should include a systematic review to investigate the effects of smart health ecosystems on people with heart failure.

### Strengths and Limitations

To our knowledge, this scoping review is the first to examine the characteristics of smart health ecosystems to support self-care in people with heart failure. We conducted an extensive literature search using 5 health science and information technology databases and considered a broad range of study designs. On the basis of the number of published articles identified in our original search, we chose not to extend the search to include gray literature or patent databases; however, this may have uncovered upcoming, promising interventions. Searching the literature for "smart health ecosystems" was difficult because of the diversity in the language used to describe such interventions. Consequently, some articles may have been missed. Two reviewers extracted data from the included articles and coded the intervention characteristics, but only one reviewer coded the intervention descriptions against BCTTv1. In this instance, coding was kept close to the manifest meaning of the text, and other reviewers with expertise in this area were consulted throughout the process. Finally, our analysis was based on information in the articles and their published protocols, but we may have missed intervention characteristics due to unclear descriptions.

### Conclusions

This scoping review identified and described the characteristics of 13 smart health ecosystems that support self-care among people with heart failure. We have outlined the behavioral and technical components of the interventions and have highlighted gaps in the provision of support and the literature. We discuss opportunities to augment smart health ecosystems and suggest further research to assess their effectiveness. Alongside other literature, this information can be used to assist in the development and evaluation of future interventions.

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### Authors' Contributions

RN, LK, RM, FK, and SMSI contributed to the conceptualization of the study. RN, EL, and JM were involved in screening for studies. RN and EL were responsible for data extraction. RN was responsible for data analysis and was supported by EL, LK, and RM. RN prepared the first draft of the manuscript, and all authors contributed to further drafts.

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### Conflicts of Interest

None declared.

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#### Multimedia Appendix 1

Search strategies for the MEDLINE, Embase, CINAHL, PsycINFO, IEEE Xplore, and ACM Digital Library databases.  
[DOCX File, 25 KB - [cardio\\_v6i2e36773\\_app1.docx](#) ]

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#### Multimedia Appendix 2

Data extraction form.  
[DOCX File, 14 KB - [cardio\\_v6i2e36773\\_app2.docx](#) ]

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#### Multimedia Appendix 3

Summary characteristics of included articles.



[PDF File (Adobe PDF File), 148 KB - [cardio\\_v6i2e36773\\_app3.pdf](#) ]

#### Multimedia Appendix 4

Intervention characteristics.

[PDF File (Adobe PDF File), 146 KB - [cardio\\_v6i2e36773\\_app4.pdf](#) ]

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## Abbreviations

**BCT:** behavior change technique

**BCTTv1:** behavior change technique taxonomy, version 1

**JI:** Joanna Briggs Institute

**PRISMA-ScR:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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Original Paper

# Analyzing Public Conversations About Heart Disease and Heart Health on Facebook From 2016 to 2021: Retrospective Observational Study Applying Latent Dirichlet Allocation Topic Modeling

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## Abstract

**Background:** Heart disease continues to be the leading cause of death in men and women in the United States. The COVID-19 pandemic has further led to increases in various long-term cardiovascular complications.

**Objective:** This study analyzed public conversations related to heart disease and heart health on Facebook in terms of their thematic topics and sentiments. In addition, it provided in-depth analyses of 2 subtopics with important practical implications: heart health for women and heart health during the COVID-19 pandemic.

**Methods:** We collected 34,885 posts and 51,835 comments spanning from June 2016 to June 2021 that were related to heart disease and health from public Facebook pages and groups. We used latent Dirichlet allocation topic modeling to extract discussion topics illuminating the public's interests and concerns regarding heart disease and heart health. We also used Linguistic Inquiry and Word Count (Pennebaker Conglomerates, Inc) to identify public sentiments regarding heart health.

**Results:** We observed an increase in discussions related to heart health on Facebook. Posts and comments increased from 3102 and 3632 in 2016 to 8550 (176% increase) and 14,617 (302% increase) in 2021, respectively. Overall, 35.37% (12,340/34,885) of the posts were created after January 2020, the start of the COVID-19 pandemic. In total, 39.21% (13,677/34,885) of the posts were by nonprofit health organizations. We identified 6 topics in the posts (heart health promotion, personal experiences, risk-reduction education, heart health promotion for women, educational information, and physicians' live discussion sessions). We identified 6 topics in the comments (personal experiences, survivor stories, risk reduction, religion, medical questions, and appreciation of physicians and information on heart health). During the pandemic (from January 2020 to June 2021), risk reduction was a major topic in both posts and comments. Unverified information on alternative treatments and promotional content was also prevalent. Among all posts, 14.91% (5200/34,885) were specifically about heart health for women centering on local event promotion and distinctive symptoms of heart diseases for women.

**Conclusions:** Our results tracked the public's ongoing discussions on heart disease and heart health on one prominent social media platform, Facebook. The public's discussions and information sharing on heart health increased over time, especially since the start of the COVID-19 pandemic. Various levels of health organizations on Facebook actively promoted heart health information and engaged a large number of users. Facebook presents opportunities for more targeted heart health interventions that can reach and engage diverse populations.

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**KEYWORDS**

heart health; heart disease; topic modeling; sentiment analysis; social media; Facebook; COVID-19; women's heart health

## Introduction

### Background

Heart disease continues to be the leading cause of death in men and women in the United States [1]. In 2020, approximately 690,000 individuals died of heart disease, and heart disease deaths increased by 4.8%, the greatest increase since 2012 [2]. The COVID-19 pandemic may be associated with this significant increase in heart disease mortality because of the disruption of access to health care and treatment [3]. In addition, recent research has documented a variety of long-term cardiovascular complications resulting from COVID-19 [4]. Given the increasing burden of heart diseases, understanding public knowledge and interests in heart disease and heart health is urgently needed to develop public and targeted interventions and communication programs to improve preventive measures and health care access and use for heart diseases in the United States.

### Theoretical Background

Researchers and health care providers have increasingly embraced social media data to understand and engage in public conversations regarding various public health issues, including cardiovascular diseases and heart health. Social media provides a great opportunity to observe and understand the information environment related to heart diseases and health. We based our research inquiries on 2 theoretical backgrounds.

First, we drew on the Health Belief Model, which theorizes how perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy work together to influence health behaviors and decisions [5]. Using this theoretical lens, we expect to uncover how social media discussions about heart health reveal the public's risk perceptions and related theoretical constructs, suggesting important factors to be considered in health communication messages and programs for promoting heart health. Previous research has mostly studied people's perceptions using self-reported measures [6]. Given the data from social media, we aimed to investigate the presence of the public's risk perceptions and other related perceptions in this retrospective observational study of social media information exchange.

Second, health-related conversations on social media can affect one's perceived susceptibility to and severity of heart diseases [7]. Social media discussions can also influence one's health-related knowledge, with which one may develop a stronger belief in the benefits and effectiveness of preventive behaviors and self-efficacy [8]. It is crucial to construct a high-level overview of heart health-related information on social media to understand the web-based information environment that influences the public's health beliefs and behaviors [9].

Finally, social media provides a platform for the public to not only obtain access to health information but also connect with each other [10]. The review by Zhang and Centola [11] theorizes social media as a web-based structure that can facilitate various

social processes (eg, social support, social comparison, and social influence) for information diffusion and behavior change. Especially relevant to web-based health discussions, social support and collective information exchange can increase efficacy and motivate preventive actions and health behaviors [12]. Understanding web-based exchanges among the public can provide us with more insights into the public's support dynamics, which can contribute to improved health beliefs and behaviors.

### Study Context and Aims

Facebook is the most popular social media platform worldwide [13]. In 2021, a total of 7 in 10 American adults used Facebook; Facebook had more users than Twitter and Instagram [14]. However, existing studies have only examined Twitter posts and comments regarding cardiovascular disease and its risk factors [15,16]. For instance, Musaev et al [16] studied Twitter conversations related to cardiovascular diseases. They found that only a few state health departments have played a central role in these public conversations, although the topics of these conversations were not specified. Although topic modeling methods have been increasingly used to categorize public opinions on and concerns about certain health topics, there is no comprehensive analysis of the public's heart health discussions on Facebook, a frequently used social media platform for health concerns. Topic analyses of longitudinal Facebook data can point out gaps in education and intervention efforts and also reveal significant insights into social media use in public engagement with heart health and the population's knowledge deficit or misbeliefs.

The primary aim of this study was to analyze public Facebook posts and comments related to heart disease and heart health over the past 5 years in the United States. We used Linguistic Inquiry and Word Count (LIWC; Pennebaker Conglomerates, Inc) [17] to analyze the public's sentiments regarding heart disease and health. We used the latent Dirichlet allocation (LDA) method to extract discussion topics illuminating the public's interests and concerns regarding heart disease and heart health [18]. Furthermore, we conducted two subgroup analyses by (1) stratifying the data by gender and zooming in on conversations on heart health for women and (2) comparing the conversations before and during the COVID-19 pandemic. The rationale for delving into these 2 issues is as follows. First, cardiovascular disease is a leading cause of death in women, and the number of deaths in women has been exceeding that in men [19]. However, public awareness of women-specific risks, symptoms, and prevention remains low [20]. Identifying the concerns and discussions specifically related to heart health for women can inform better public communication and interventions for women. Second, COVID-19 has exposed people with preexisting cardiovascular conditions to greater risks, coupled with negative health outcomes because of social isolation and decreased physical activity [21,22]. Understanding conversations during the pandemic provides us with valuable information about the real impact of COVID-19 on people with cardiovascular conditions and their concerns, which will help

us cope with similar public health emergencies in the future. With this study that aimed to analyze public discussions and communication patterns on heart health and heart disease on Facebook, the findings can provide new insights into the design of effective health communication and intervention programs to reduce the burden of heart disease in the United States.

## Methods

### Retrospective Study Design

In this retrospective observational study, we collected US posts and comments in English related to heart disease and heart health from Facebook using the *CrowdTangle* (Meta Platforms) data monitoring platform [23]. *CrowdTangle* is a tool from Meta (Facebook's parent company) that tracks social media conversations and related data. We extracted the data from June 2016 to June 2021 for the cohort of social media users in the United States, tracing the first available heart disease and health-related Facebook data available on *CrowdTangle* until the end date of data collection.

### Ethics Approval

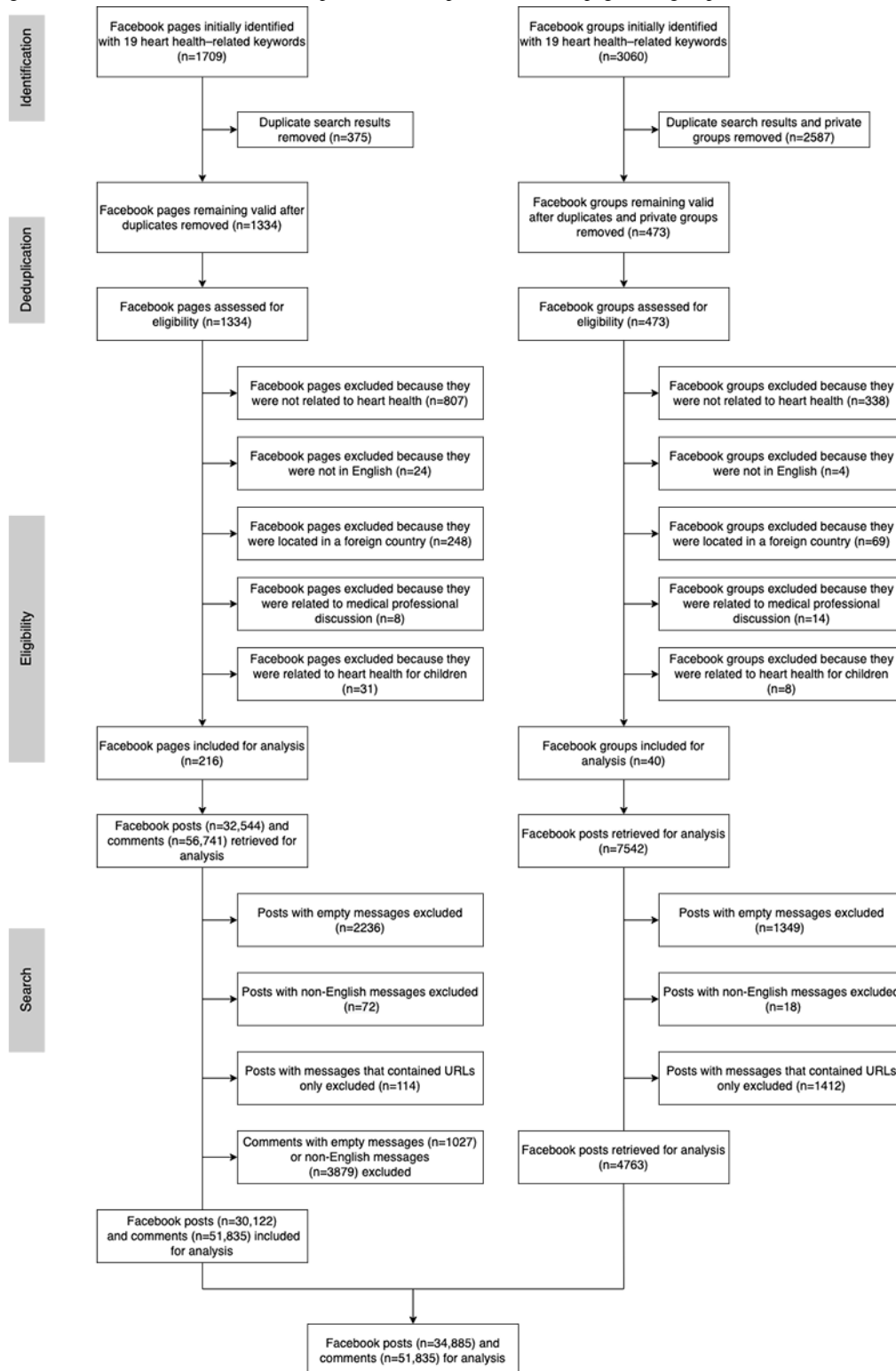
This study was approved by the University of California, San Francisco Institutional Review Board (21-34235).

### Facebook Data Extraction

#### *Identification and Deduplication*

Figure 1 shows the data extraction process covering public Facebook pages, groups, posts, and comments. We compiled a set of 19 search keywords related to heart disease (eg, *heart attack*), heart health (eg, *heart health symptoms*), social support (eg, *heart attack support*), and campaigns related to heart health and heart disease (eg, *Go Red for Women*; see Table S1 in [Multimedia Appendix 1](#) for the complete search term list). We searched Facebook pages and groups using the keywords and a web scraping tool, *Selenium Python* [24]. We searched each keyword on Facebook for both public pages and public groups and retrieved all results for each search task. In total, we conducted 38 searches. After retrieving all pages and groups, we removed duplicates and private groups because of no data access, resulting in 1334 pages and 473 groups.



**Figure 1.** Flow diagram of data extraction and collection processes from public Facebook pages and groups.

### Eligibility

As a robustness check, 2 trained research assistants screened for the relevance of the resulting pages and groups. Pages and groups were excluded if they were (1) private or closed (ie, not public), (2) not related to heart disease or heart health, (3) not in English, (4) about pets or animals (eg, animal vaccination), or (5) in a specified foreign location. The 2 research assistants coded a random 10% (100/1334, 7.5% of pages and 48/473,

10.1% of groups) sample of the list. They achieved a 94% agreement rate for page coding and 89% for group coding. Finally, we included 216 public pages and 40 public groups for data collection and analysis.

### Search

Next, we searched within the Facebook pages and groups and collected posts related to heart health and heart disease using CrowdTangle [23]. We then retrieved public comments attached

to all the posts from Facebook pages using Facepacer [25] as CrowdTangle does not track comments and Facepacer provides access to comments on Facebook pages only. Owing to the restriction of the Facebook Graph application programming interface, we could not access comments to posts from Facebook groups. In addition, we collected data on post metrics such as the number of comments, likes, and shares, as provided by CrowdTangle. After collecting all posts and comments, we conducted additional human checking to ensure that the data were relevant and useful for textual analysis. We excluded posts and comments that (1) contained no text (ie, posts with images, videos, or URLs only) or (2) were not in English. Finally, we obtained 34,885 posts and 51,835 comments for analysis.

### Analytical Strategy

We first used LIWC [17] to obtain the sentiments of the posts and comments and explore public sentiments on heart health. LIWC is a software program that captures linguistic features and sentiments in texts using dictionary-based methods. For example, LIWC calculates positive emotions in a given document by counting the percentage of words that appear in the dictionary indicating positive emotions. It has been widely used to analyze health-related conversations on social media and identify the public's emotions and attitudes [26].

We then performed topic modeling on the data using LDA [18], a widely used computational approach that discovers thematic topics by identifying the co-occurrence of words in different documents. We ran LDA topic modeling with *Gensim* (RARE Technologies Ltd) in Python for the data set of posts and the data set of comments separately [27]. Each LDA model reported the number of topics identified for a given data set, the top 10 words that contributed to a topic, and their relative weights. The optimal number of topics was determined based on the perplexity score of the LDA model [27]. We also extracted the relative weight of each topic for each post or comment, which was used to identify the most relevant topic a post or comment was associated with. One author and a trained research assistant qualitatively analyzed the prominent keywords and associated texts to develop meaningful topic interpretations.

### Heart Disease and Heart Health for Women

To examine the discussion of heart disease and heart health for women specifically, we delved into posts and comments that were analyzed as belonging to the one special topic on heart

health for women from the topic analysis results. This included posts (5200/34,885, 14.91%) and their attached comments (9501/51,835, 18.33%) that received a higher topic weight for the one topic on heart health for women than for all other topics.

### Heart Health Before and During the COVID-19 Pandemic

To discern differences in the discussions before and during the COVID-19 pandemic, we separated the data set into pre-COVID-19 posts and comments (before January 1, 2020; 22,545/34,885, 64.63% of posts and 32,774/51,835, 63.23% of comments) and post-COVID-19 posts and comments (after January 1, 2020; 12,340/34,885, 35.37% of posts and 19,061/51,835, 36.77% of comments). Although the first case of COVID-19 in the United States was confirmed on January 21, 2020 [28], we selected January 1, 2020, as the cutoff date as COVID-19 had already received public attention since December 2019 when it started.

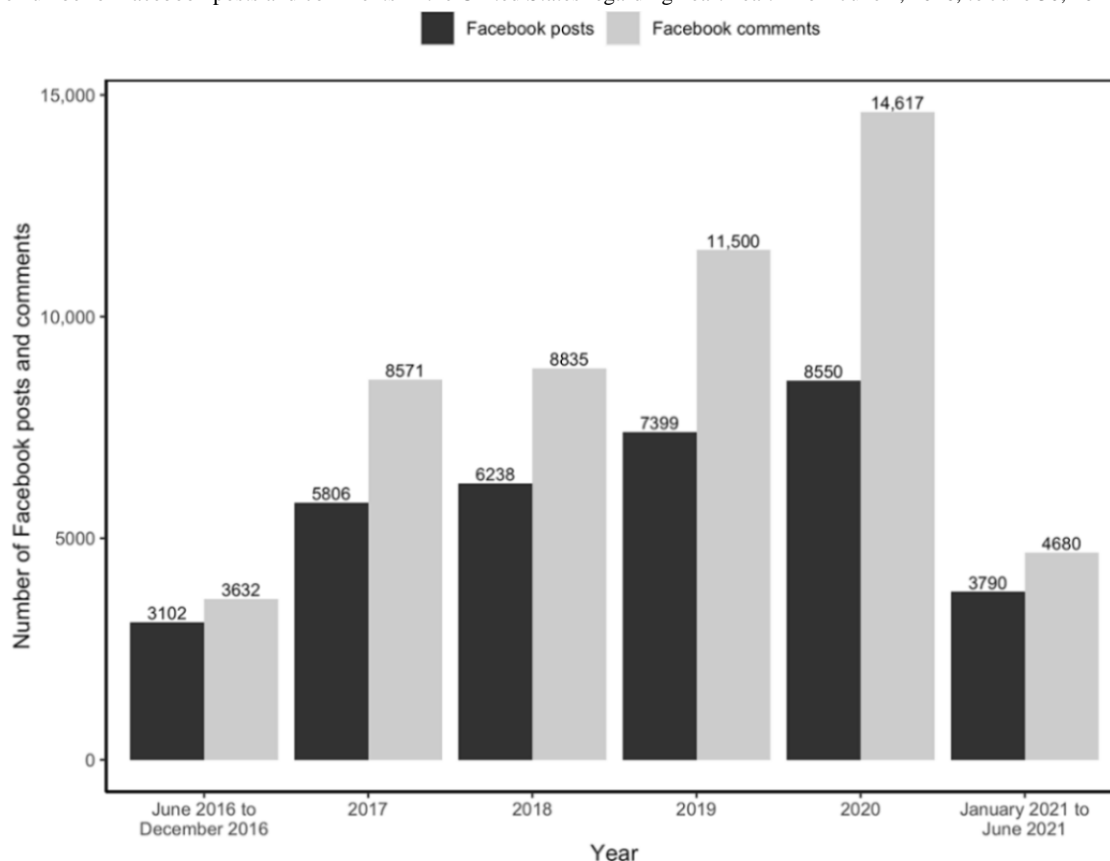
### Statistical Analysis

To analyze and compare the level of emotions in posts and comments, we used 2-tailed 2-sample *t* tests to compare the levels of different emotions within posts and comments [29]. Similarly, we used 2-sample *t* tests to compare the same emotion between posts and comments. Finally, we used 2-sample *t* tests to compare the level of emotions in posts and comments before and during the COVID-19 pandemic. Although the sentiments in posts and comments were nonnormal and left-skewed, it is still robust to use *t* tests given the large sample size in this study [30]. In addition, we performed nonparametric tests (ie, Wilcoxon signed-rank tests) and found consistent results.

## Results

### Descriptive Statistics

We obtained 34,885 Facebook posts and 51,835 comments (attached to 8885 unique posts) for analysis. Figure 2 shows the distribution of the number of posts and comments from June 2016 to June 2021. Both posts and comments increased steadily over the past 5 years. A post on average contained 51.84 (SD 58.93; median 35) words and generated 49.15 (SD 236.31) likes, 4.79 (SD 20.92) comments, and 16.44 (SD 104.59) shares. Comments were significantly shorter than posts, with 17.88 (SD 30.08; median 9) words on average.

**Figure 2.** The number of Facebook posts and comments in the United States regarding heart health from June 1, 2016, to June 30, 2021.

### Sentiment in Posts and Comments

We obtained the level of positive and negative emotions with LIWC for posts and comments and used 2-sample *t* tests to compare the level of emotions (Table S2 in [Multimedia Appendix 1](#)). In the posts, there were significantly more positive emotions than negative emotions ( $P < .001$ ). Comments also had more positive emotions than negative emotions ( $P < .001$ ). In addition, comments showed significantly more positive emotions and significantly more negative emotions than posts.

Regarding specific negative emotions, LIWC only reported scores for anxiety, anger, and sadness. Posts contained more anxiety ( $P < .001$ ) and anger ( $P < .001$ ) than sadness, whereas comments contained significantly more anger than anxiety ( $P < .001$ ) and sadness ( $P < .001$ ). Overall, both posts and comments contained more positive than negative emotions. Compared with posts, comments were more emotional than posts, with more positive emotions and anger.

### Thematic Topics of All Posts

For the post data set, we extracted 6 thematic topics. [Table 1](#) summarizes the topic keywords and weights, topic interpretations, and example posts for each topic. The topic sequence was determined by the number of posts associated with each topic. Topic 1, heart health promotion, had the greatest number of posts and was about promoting heart health and local events for heart disease and stroke prevention and support provided by national and local organizations. For instance, the American Heart Association has been promoting national campaigns such as Go Red for Women, and state-level organizations of the American Heart Association have promoted

localized events such as hiking on their own Facebook pages. Topic 2, sharing personal experiences, included posts that encouraged people to share personal experiences related to heart disease and heart health or posts sharing personal experiences to increase public awareness. Topic 3, risk-reduction education, centered on information related to risk reduction and lifestyle modifications for heart health. Topic 4, heart disease and health promotion for women, contained posts that specifically aimed at promoting heart health for women and emphasized the distinctions in symptoms and warning signs of heart diseases between women and men. Topics 5 and 6 revolved around sharing resources related to heart health. The major difference is that topic 5, educational information sharing, was about heart health-related articles and videos shared by health care professionals in the web-based space, as indicated by the extremely high word counts. In contrast, posts on topic 6, physicians live discussion sessions, promoted live Facebook sessions of physicians and cardiologists sharing heart health-related information.

[Table 2](#) shows the average social media metrics (ie, the number of likes, comments, and shares) from Facebook as well as word count and sentiments from LIWC. Women-specific information on heart health was well liked and considered valuable as posts on topic 4 on average received the most likes and shares of all 6 topics. The public participated and commented the most on posts sharing information and relevant resources (topic 5) and physicians' live sessions (topic 6). Results from LIWC showed that heart health promotional posts on topic 1 were the most positive, whereas posts concerning risk reduction on topic 3 were mostly negative.

**Table 1.** Latent Dirichlet allocation topic modeling for all Facebook posts, showing topic keywords and weights, topic interpretation, and example posts (N=34,885).

Topic number	Topic name	Top 10 keywords and weights <sup>a</sup>	Interpretation by authors	Example of Facebook posts (paraphrased)
1	Heart health promotion	<ul style="list-style-type: none"> <li>• 0.052*heart</li> <li>• 0.022*health</li> <li>• 0.018*disease</li> <li>• 0.013*american</li> <li>• 0.012*stroke</li> <li>• 0.011*association</li> <li>• 0.011*thank</li> <li>• 0.011*join</li> <li>• 0.010*live</li> <li>• 0.009*support</li> </ul>	Heart health–, heart disease–, and stroke-related events and support by organizations (eg, the American Heart Association)	The Heart Walk is how the American Heart Association mainly raises funds to prevent heart disease and stroke. It promotes physical activity and healthy heart living, and creates a family-friendly environment. On April 1st, a Saturday, the AHA is holding their annual Franklin County Heart Walk at the Washington City Fairgrounds Swine Pavilion at 9 a.m., with the walking starting at 10.
2	Sharing personal experiences	<ul style="list-style-type: none"> <li>• 0.043*heart</li> <li>• 0.018*attack</li> <li>• 0.009*know</li> <li>• 0.009*life</li> <li>• 0.008*time</li> <li>• 0.008*day</li> <li>• 0.008*go</li> <li>• 0.007*years</li> <li>• 0.007*feel</li> <li>• 0.007*family</li> </ul>	Sharing personal and family stories related to heart disease and encouraging people to share their stories to increase public awareness	It's been 5 years since I had my heart attack. I waited for about 15 hours with symptoms coming and going before I decided to drive myself to the hospital. After my heart attack, I was traumatized by the fear of death, and I started to exercise and eat healthier. It's important it is to know the symptoms and listen to your body because one day it could save your life.
3	Risk-reduction education	<ul style="list-style-type: none"> <li>• 0.052*heart</li> <li>• 0.027*disease</li> <li>• 0.024*risk</li> <li>• 0.023*blood</li> <li>• 0.015*health</li> <li>• 0.013*pressure</li> <li>• 0.011*high</li> <li>• 0.010*stroke</li> <li>• 0.009*cholesterol</li> <li>• 0.008*study</li> </ul>	Risk reduction (eg, blood pressure and cholesterol) and lifestyle modification for heart health and disease and stroke	Eat something healthy and delicious in Barbued salmon, sauteed zucchini, sweet potatoes, and asparagus. Control your heart health by lowering cholesterol and salt intake.
4	Heart disease and heart health promotion for women	<ul style="list-style-type: none"> <li>• 0.053*women</li> <li>• 0.048*heart</li> <li>• 0.040*red</li> <li>• 0.028*disease</li> <li>• 0.012*attack</li> <li>• 0.010*wear</li> <li>• 0.008*available</li> <li>• 0.008*symptoms</li> <li>• 0.008*awareness</li> <li>• 0.007*abstract</li> </ul>	Promoting awareness of myocardial infarction symptoms for women and emphasizing characteristics of women's myocardial infarction by the Go Red for Women Campaign	#GoRedForWomen today. We're bringing attention to women's heart disease. Women have different warning signs for heart attacks.
5	Educational information sharing	<ul style="list-style-type: none"> <li>• 0.050*article</li> <li>• 0.047*video</li> <li>• 0.042*content</li> <li>• 0.035*presentation</li> <li>• 0.023*information</li> <li>• 0.021*health</li> <li>• 0.013*heart</li> <li>• 0.012*purpose</li> <li>• 0.012*attack</li> <li>• 0.012*general</li> </ul>	Presenting articles and videos related to heart health and myocardial infarction information	Dr. A, Consulting Physical, discusses heart attack prevention.

Topic number	Topic name	Top 10 keywords and weights <sup>a</sup>	Interpretation by authors	Example of Facebook posts (paraphrased)
6	Physicians' live discussion sessions	<ul style="list-style-type: none"> <li>• 0.065*dr</li> <li>• 0.036*heart</li> <li>• 0.027*cardiology</li> <li>• 0.026*attack</li> <li>• 0.023*discuss</li> <li>• 0.020*page</li> <li>• 0.018*cardiologist</li> <li>• 0.018*facebook</li> <li>• 0.016*pm</li> <li>• 0.014*live</li> </ul>	Live Facebook sessions by physicians to discuss myocardial infarctions	Dr. B discussed how to reduce cardiovascular events in a Facebook LIVE session.

<sup>a</sup>The asterisk (\*) shows the weight of each keyword.

**Table 2.** Latent Dirichlet allocation topic modeling for all posts, showing the topics' post distribution, Facebook metrics, and sentiments from Linguistic Inquiry and Word Count (LIWC; N=34,885).

Topic number	Topic name	Posts, n (%)	Facebook metrics <sup>a</sup>			Sentiments from LIWC <sup>b</sup>		
			Number of likes, mean (SD)	Number of comments, mean (SD)	Number of shares, mean (SD)	Word count, mean (SD)	Positive emotion percentage, mean (SD)	Negative emotion percentage, mean (SD)
1	Heart health promotion	10,912 (31.3)	37.67 (264.95)	2.31 (14.51)	8.81 (50.78)	47.64 (36.70)	5.26 (5.16)	1.12 (2.05)
2	Sharing personal experiences	8094 (23.2)	48.37 (205.55)	8.04 (26.47)	15.14 (113.92)	59.02 (77.90)	4.84 (5.58)	3.02 (4.12)
3	Risk-reduction education	8557 (24.5)	49.63 (217.25)	2.82 (17.36)	18.85 (108.32)	43.04 (57.96)	4.87 (8.56)	4.14 (4.54)
4	Heart disease and heart health promotion for women	5200 (14.9)	68.65 (276.00)	5.56 (24.39)	33.36 (166.07)	44.41 (53.66)	2.53 (3.57)	2.62 (4.03)
5	Educational information sharing	1208 (3.5)	63.65 (114.14)	10.43 (18.39)	5.77 (18.25)	137.98 (40.63)	3.02 (7.25)	2.78 (1.37)
6	Physicians' live discussion sessions	924 (2.6)	58.21 (152.55)	11.97 (32.09)	14.03 (46.10)	49.2 (34.61)	1.38 (2.10)	3.19 (3.00)

<sup>a</sup>Data collected in November 2021.

<sup>b</sup>Positive and negative emotions represent the percentage of words in a post that appear in the dictionary indicating positive and negative emotions.

### Thematic Topics of All Comments

We extracted 6 topics from the comments. These topics centered on personal experience sharing and social interactions. [Table 3](#) lists all topics with keywords and examples. Topic 1, sharing personal experiences, was about sharing one's experience with heart diseases, physicians, and health insurance. Topic 2, survivor stories, centered on individuals with a history of congenital heart disease sharing their stories when they were young. Social interactions in the comments took the form of discussions, social support, and information sharing. Topic 3, risk-reduction discussion, included comments where people discussed daily risk reduction related to diets, exercise, and smoking for better heart health. Topic 4, religious content, included comments with religious content such as prayers and

expressing thanks to God. Topic 5, asking medical questions, revolved around interactions with physicians by asking questions related to heart diseases and risk reduction. Topic 6, sharing appreciation and information, was about people providing social support for each other, appreciating useful information shared by others, and interacting with their social network by tagging their friends in the comments.

[Table 4](#) summarizes the distribution of the 6 topics in the heart health-related comments. Comments to heart health-related posts showed various levels of emotions. Comments on topic 4 had an extremely high level of positive emotions and a low level of negative emotions, suggesting a community with positive and prosocial interactions. In contrast, posts and comments about risk reduction (topic 5) had the most negative emotions.

**Table 3.** Latent Dirichlet allocation topic modeling for all Facebook comments, showing topic keywords and weights, topic interpretation, and example comments (N=51,835).

Topic number	Topic name	Top 10 keywords and weights <sup>a</sup>	Interpretation by authors	Example of Facebook comments (paraphrased)
1	Sharing personal experiences	<ul style="list-style-type: none"> <li>• 0.013*go</li> <li>• 0.011*heart</li> <li>• 0.010*time</li> <li>• 0.010*like</li> <li>• 0.009*think</li> <li>• 0.009*tell</li> <li>• 0.009*doctor</li> <li>• 0.009*know</li> <li>• 0.009*pain</li> <li>• 0.009*get</li> </ul>	People shared personal stories related to heart disease, physicians, and insurance.	The cardiologist never explained what was going on, and the ER doctors also never said except they needed more tests to make money from you. [I] am afflicted with cardiomyopathy and afib, making my hands and feet cold from poor circulation.
2	Survivor stories	<ul style="list-style-type: none"> <li>• 0.065*heart</li> <li>• 0.031*years</li> <li>• 0.026*surgery</li> <li>• 0.022*valve</li> <li>• 0.017*ago</li> <li>• 0.017*old</li> <li>• 0.016*attack</li> <li>• 0.014*year</li> <li>• 0.013*open</li> <li>• 0.012*dr</li> </ul>	Survivors shared personal experiences with congenital heart disease when they were young.	Heart Warrior! Had pulmonary valve stenosis, subvalvular stenosis, and artery stenoses all surgically helped in 1993. Another surgery down the line. Fundraised and walked for CHD, grateful for those who also support current and future heart warriors!
3	Risk-reduction discussion	<ul style="list-style-type: none"> <li>• 0.042*heart</li> <li>• 0.026*disease</li> <li>• 0.016*eat</li> <li>• 0.016*healthy</li> <li>• 0.014*red</li> <li>• 0.012*diet</li> <li>• 0.012*health</li> <li>• 0.011*smoke</li> <li>• 0.010*exercise</li> <li>• 0.010*risk</li> </ul>	Discussion on risk factors and risk reduction to prevent heart disease and improve health (eg, diet, exercise, and smoking cessation)	A healthy lifestyle helps! Water over sweetened beverages and being active keeps the heart healthy! My family has a high BP history, and I need to reduce the sodium in eating, as well as walk more.
4	Religious content	<ul style="list-style-type: none"> <li>• 0.061*thank</li> <li>• 0.031*god</li> <li>• 0.029*good</li> <li>• 0.020*bless</li> <li>• 0.018*love</li> <li>• 0.017*share</li> <li>• 0.013*great</li> <li>• 0.011*family</li> <li>• 0.010*happy</li> <li>• 0.010*amaze</li> </ul>	Religious content—thanks to God and others	H is beautiful in the pictures, I wish [H] luck. [H] is amazing and kind, Peace with God. It calmed me, and I prayed. I'm doing well after 5 hospital visits, thank you Jesus. Blessed and at home with family.
5	Asking medical questions	<ul style="list-style-type: none"> <li>• 0.121*heart</li> <li>• 0.097*attack</li> <li>• 0.017*congratulations</li> <li>• 0.017*women</li> <li>• 0.013*symptoms</li> <li>• 0.012*sir</li> <li>• 0.012*sign</li> <li>• 0.008*cause</li> <li>• 0.007*patient</li> <li>• 0.006*patients</li> </ul>	People ask physicians about heart diseases and risk reduction.	What are the precautions for a silent heart attack? Can it be removed? Women's symptoms are different from mens (not as widely known)

Topic number	Topic name	Top 10 keywords and weights <sup>a</sup>	Interpretation by authors	Example of Facebook comments (paraphrased)
6	Sharing appreciation and information	<ul style="list-style-type: none"> <li>• 0.031*great</li> <li>• 0.031*love</li> <li>• 0.028*information</li> <li>• 0.024*nice</li> <li>• 0.023*awesome</li> <li>• 0.019*sir</li> <li>• 0.018*good</li> <li>• 0.017*dr</li> <li>• 0.011*job</li> <li>• 0.011*pressure</li> </ul>	People appreciate good information shared by others and organizations and share with their Facebook friends by tagging their names in the comments.	Dr. W, Dr. M; they listened and respected me. Good information in understandable language.

<sup>a</sup>The asterisk (\*) shows the weight of each keyword.

**Table 4.** Latent Dirichlet allocation topic modeling for all comments, showing comment distribution, Facebook metrics, and sentiments from Linguistic Inquiry and Word Count (LIWC; N=51,835).

Topic number	Topic name	Facebook metrics <sup>a</sup> —comments, n (%)	Sentiments from LIWC <sup>b</sup>		
			Word count, mean (SD)	Positive emotion percentage, mean (SD)	Negative emotion percentage, mean (SD)
1	Sharing personal experiences	14,000 (27)	33.72 (46.15)	4.29 (11.34)	3.41 (7.40)
2	Survivor stories	7026 (13.6)	18.95 (22.61)	5.93 (13.98)	2.18 (4.49)
3	Risk-reduction discussion	7080 (13.7)	16.39 (25.26)	4.94 (10.93)	3.39 (6.24)
4	Religious content	11,254 (21.7)	10.03 (13.90)	23.44 (22.05)	0.91 (5.12)
5	Asking medical questions	5964 (11.5)	9.33 (9.21)	4.87 (15.11)	6.93 (9.37)
6	Sharing appreciation and information	6511 (12.6)	5.71 (10.08)	23.87 (26.99)	0.89 (4.11)

<sup>a</sup>Data collected in November 2021.

<sup>b</sup>Positive and negative emotions represent the percentage of words in a post that appear in the dictionary indicating positive and negative emotions.

## Thematic Topics of Pre-COVID-19 Posts and Comments

We identified 5 topics for pre-COVID-19 posts and comments (Table S3 in [Multimedia Appendix 1](#) shows topic summaries and examples). The topics identified for pre-COVID-19 posts were similar to the topics identified for all posts: topic 1, promoting experience sharing, was about heart health organizations encouraging the public to share personal experiences; topic 2, sharing local events, centered on the promotion of local events related to heart health; topic 3, risk-reduction discussion, was about risk reduction and lifestyle modification; topic 4, sharing warning signs, was about information related to warning signs and symptoms of specific heart diseases such as hypertrophic cardiomyopathy and cardiac arrest; and topic 5 was about Facebook live sessions of physicians and cardiologists.

Of all topics, topic 4 was the most popular, with the highest number of shares (mean 70.99, SD 264.09) and likes (mean 36.73, SD 174.07), which indicated that people with heart health concerns cared about the warning signs and symptoms of myocardial infarctions (see Table S4 in [Multimedia Appendix 1](#) for summary statistics). Consistently, most negative emotions

(mean 4.28, SD 4.59) were expressed when discussing life modifications and risk-reduction methods in topic 3.

In the comments (see Table S5 in [Multimedia Appendix 1](#) for topic summaries and examples), topic 1, sharing warning signs, revolved around people sharing personal experiences related to heart health, including their symptoms and warning signs and diagnoses by different physicians. Topic 2, sharing risk reduction, involved discussions on social relationships that were influenced by heart diseases and their daily risk-reduction practices. Similarly, in topic 3, providing emotional support, people interacted with physicians by expressing appreciation and with others by providing social support and encouragement. Topic 4, religious content, was about religious discussions and appreciation. Topic 5, general health discussions, involved health-related topics other than heart health, such as using e-cigarettes for smoking cessation.

The public expressed the least positive emotions (mean 2.37, SD 4.74) and the most negative emotions (mean 4.01, SD 6.35) in comments on topic 1, where people shared negative emotions, symptoms, and experiences (Table S6 in [Multimedia Appendix 1](#)). In contrast, the most positive emotions were expressed on topics 3 (mean 16.64, SD 22.77) and 4 (mean 23.17, SD 27.18), where people were particularly positive in providing emotional support.

## Thematic Topics of Post–COVID-19 Posts and Comments

We discovered 5 topics in post–COVID-19 posts (see Table S7 in [Multimedia Appendix 1](#) for topic summaries and examples). During the pandemic, topic 1 was about physicians' live discussion sessions. Topic 2 was about general risk-reduction discussions and tips. Topic 3 centered on risk-reduction discussions and awareness promotion specifically for women. Topic 4, risk-reduction discussions for the pandemic, specifically focused on health tips on daily risk reduction during the pandemic. It was more important for people with heart health risks to pay attention to their diet and exercise with stay-at-home orders and social isolation. These posts encouraged people to eat healthily and exercise more at home to maintain a good heart health during the pandemic, which is important for the control and prevention of cardiovascular disease. Topic 5 was about resource sharing related to heart health.

Furthermore, during the pandemic, the public liked (mean 61.55, SD 112.25) and commented (mean 10.08, SD 18.12) on posts related to topic 1 the most (see Table S8 in [Multimedia Appendix 1](#) for detailed statistics). This suggests that the public had a heightened need to seek information and interact with physicians on the web during the pandemic. Live Facebook discussion sessions drew a lot of attention and engagement. Posts on topic 2 were mostly shared by others (mean 17.83, SD 108.32), suggesting that information on risk reduction and other related health topics was perceived as useful and valuable for sharing with others on their social networks. Topic 2 contained the most negative emotions (mean 4.01, SD 4.25), whereas topics 4 (mean 6.07, SD 5.63) and 5 (mean 6.65, SD 10.00) related to health tips and resource sharing contained the most positive emotions.

A total of 4 topics were identified in the post–COVID-19 comments (Table S9 in [Multimedia Appendix 1](#) shows the topic summaries and examples). Topic 1, unverified information, included advertisements and potential misinformation that promoted unverified physicians and alternative treatments such as herbs. These promotional contents were lengthier than other comments. Topic 2, asking medical questions, was related to inquiries to physicians and cardiologists. Topic 3 was about sharing personal experiences with heart diseases. Topic 4, providing social support, was about people providing social support to each other and discussing risk reduction. Regarding sentiments (Table S10 in [Multimedia Appendix 1](#) shows summary statistics), topic 2 (mean 7.85, SD 9.05) about risk reduction contained the most negative emotions, and topics 3 (mean 28.32, SD 23.99) and 4 (mean 11.03, SD 20.89) related to social support and sharing had the most positive emotions.

In addition, sentiments in posts and comments also changed during the COVID-19 pandemic. Compared with positive (mean 4.55, SD 6.43) and negative (mean 2.70, SD 3.98) emotions before the COVID-19 pandemic, posts became less emotional during the pandemic, with significantly less positive (mean 4.34, SD 5.78;  $P=.002$ ) and negative (mean 2.52, SD 3.41;  $P<.001$ ) emotions. However, in the comments, compared with positive (mean 10.72, SD 19.38) and negative (mean 2.27, SD 6.06) emotions before the COVID-19 pandemic, there were

significantly more positive (mean 12.27, SD 19.67;  $P<.001$ ) and negative (mean 3.67, SD 7.46;  $P<.001$ ) emotions during the pandemic.

To summarize, there were specific discussions related to COVID-19, pandemic situations, and risks of heart disease in posts and comments published during the pandemic. The post–COVID-19 topics and comments highlighted the urgency for people to seek web-based information, connect with physicians, and share risk-reduction tips while people were enduring lockdowns, limited health care access, and restricted physical movements and social connection.

## Thematic Topics of Posts on Heart Health for Women

A total of 4 topics were identified in posts about heart health for women (Table S11 in [Multimedia Appendix 1](#) shows the topic summaries and examples). Topic 1, local events for women, was about heart health organizations sharing local events to promote heart health for women and the awareness of women-specific symptoms and prevention. Topic 2, gender-specific symptoms, was information on the differences in heart disease symptoms and warning signs between men and women. Topic 3, sharing information, was about sharing information on specific heart diseases, organs, and surgical procedures. Topic 4, sharing resources, centered on sharing heart health–related resources, including identified misinformation. Table S12 in [Multimedia Appendix 1](#) shows the engagement and sentiment information for the different topics. Posts on topic 3 received the highest number of likes (mean 137.18, SD 322.73), comments (mean 13.15, SD 32.71), and shares (mean 44.63, SD 93.86). This suggests that the public was concerned with the details of cardiovascular diseases and surgical procedures by asking and sharing relevant information and experiences. Posts on topic 1 were the most positive (mean 3.85, SD 4.16), and posts on topic 2 were the most negative (mean 4.87, SD 5.33).

## Thematic Topics of Comments on Heart Health for Women

We extracted 4 topics from comments related to heart health for women (Table S13 in [Multimedia Appendix 1](#) provides topic summaries and examples). Topic 1, sharing symptoms, was about people sharing their own experiences with heart diseases, especially their distinctive warning signs and symptoms that differentiated them from those of men. Topic 2, sharing personal experiences, revolved around survivors of heart diseases sharing experiences after their surgeries and expressing appreciation for their physicians and surgical teams. Topic 3, providing emotional support, was about people providing informational and emotional support for each other by sharing heart health– and heart disease–related information. Topic 4, religious content and support, was about people providing encouragement and thanks and sharing Facebook posts by tagging their Facebook friends in the comments. Table S14 in [Multimedia Appendix 1](#) shows topic engagement and sentiment statistics. Supportive comments on topics 3 (mean 13.49, SD 19.03) and 4 (mean 19.08, SD 29.26) were extremely positive, whereas comments on topic 1 were the most negative (mean 3.85, SD 4.16).



## Discussion

### Principal Findings

This study analyzed heart health- and heart disease-related conversations on Facebook from 2016 to 2021. First, we observed an increase in heart health-related discussions on Facebook from 2016 to 2021. Second, health organizations were major contributors to heart disease and health-related discussions, especially in terms of information dissemination and heart health promotion. Third, the public was concerned about heart health during the COVID-19 pandemic, which was addressed by organizations and physicians. Fourth, we observed an extensive discussion on heart health for women. Finally, we observed some promotional or misleading content on alternative treatments that need to be effectively addressed by health care professionals in the web-based space or the platform. In the following sections, we discuss these findings in more detail.

### Comparison With Prior Work

Social media has become a popular platform for health information exchange, especially for organizations to communicate information related to heart health, promote events, and address the public's concerns directly on social media [31,32]. From 2016 to 2021, the public's discussions on heart disease prevention and treatment and the perceived risk of cardiovascular disease increased, indicating a general trend of increased awareness of heart health [33]. Through the theoretical lens of the Health Belief Model, we found that web-based Facebook discussions primarily covered constructs of perceived risks (ie, discussing personal experiences with and opinions on heart diseases), perceived benefits of preventative actions (ie, discussing risk-reduction behaviors), and self-efficacy (ie, discussing prevention and treatment). The fact that organizations and physicians are major contributors to heart health content suggests that Facebook is becoming a useful channel that connects health care professionals and the public and enables health care professionals to deliver useful educational and behavior change messages to the public. The public also leverages the platform to share their own experiences, ask questions, exchange resources, and provide social support, which can potentially contribute to higher collective and individual efficacy in preventing or managing heart diseases [34].

The discussions related to heart health and heart disease on Facebook are mostly contributed to by health organizations such as the American Heart Association. These organizations have used social media to educate the public on heart disease prevention, risk reduction, and treatment [35]. The posts created by health organizations had a positive tone overall, although the posts related to risk reduction were more negative, with warnings of symptoms and negative consequences. In addition, health organizations engaged and interacted with the audience in different ways. Local organizations (eg, state-level organizations) engaged the communities in local events such as hiking to enhance the community's physical activity, promote heart health knowledge, and build connections with the local community. For example, both topic 1 for all posts (Table 1) and topic 1 for posts on heart health for women (Table S11 in

Multimedia Appendix 1) showed the promotion of heart health knowledge and local activities. Health organizations encouraged the audience to share personal experiences with cardiovascular diseases, such as symptoms, treatment, and diagnosis. The audience was responsive by discussing topics in comments similar to topics in posts, such as sharing personal stories and discussing risk-reduction methods. This maintained a healthy community through social interactions and discussions. We want to highlight that health care professionals and physicians directly leverage Facebook to deliver live discussion sessions. This synchronous communication directly connects the public with informational sources where people can exchange questions and concerns in real time [34]. Overall, health organizations contribute significantly to heart health-related discussions on Facebook and promote an interactive and supportive community.

The comparison of the conversations before and during the COVID-19 pandemic informed us of the impact of COVID-19 on individuals with preexisting cardiovascular conditions. Posts during the pandemic specifically focused on risk-reduction practices in diet and exercise as social isolation forced people to live with a different daily routine where securing healthy foods and engaging with sufficient physical activity became very challenging, which posed elevated risks to already vulnerable individuals. Health organizations promptly provided information on COVID-19 and heart health and engaged them in preventive care for heart health during the pandemic [36]. Organizations also addressed the public's concerns regarding the influence of COVID-19 on heart conditions [36]. The public was responsive to these resources, with high levels of likes, shares, and comments. They also responded to physicians' live sessions with questions and appreciation. This finding is consistent with previous research showing that people actively seek health information on social media, especially during the COVID-19 pandemic [32].

A prominent conversation was related to heart disease and heart health in women. Women-specific posts accounted for 14.91% (5200/34,885) of all posts. These contents centered on (1) women-specific promotional events as a part of the Go Red for Women campaign to promote the awareness of heart health and heart disease for women and (2) information related to the differences between women and men in warning signs, symptoms, treatments, and prevention. As an old myth goes, heart disease is a "man's disease" [21]. With the growing promotion of and discussion on heart health for women, such myths have been actively debunked via social media. As social media platforms are preferred channels for women to become informed [37], the public, especially women, may have become more aware of and educated on women-specific symptoms and treatments. In addition to social media content, a study on search queries also supported the increasing awareness of heart health for women [38]. Increasing awareness can help improve the well-being of women and decrease the number of women with cardiovascular diseases.

Finally, we observed a few promotional comments during the pandemic and women-related posts, such as the promotion of alternative treatments for heart disease, cancer, and other major diseases and the specific promotion of physicians with unverified patient narratives and contact information. Although

this kind of unverified information accounted for a small portion of the heart health community on Facebook, some individuals may still fall for it. Although our findings generally support the positive role that Facebook has played in promoting public awareness and education on heart health, we still acknowledge that identifying and managing unverified information on the platform is urgently needed as unverified misinformation can affect the public's health-related attitudes and behaviors. So far, Facebook has not published rules or policies for general or heart health-specific information. A practical route may be for health organizations to maintain their pages or groups to actively monitor and address shared unverified information.

### Limitations

There are a few limitations noted in this research. First, this study focused on Facebook conversations related to heart health. Although it filled a research gap in examining Facebook data, we acknowledge that other social media platforms also support and engage the public on heart health. Data from platforms such as Instagram and Reddit are worth investigating. Second, within the scope of Facebook data, because of platform policies and ethical considerations, we did not obtain data from private groups or comments from public groups. Such data may add more insights into how individual users discuss, relate to, and understand heart diseases in more private web-based interaction settings. Third, we were unable to eliminate the factor of time in the comparison between before and during the COVID-19 pandemic. Although we observed differences in sentiments and thematic topics before and during the COVID-19 pandemic, these differences might not be fully attributable to the COVID-19 pandemic. Finally, this study was observational in nature, and we cannot draw any causal conclusions from this study. Although this study presented public discussions on heart health, we cannot draw any conclusions on how heart health information from organizations may have affected public discussions on heart health.

### Conclusions, Implications, and Future Directions

On the basis of a 5-year data set of public Facebook groups and pages, we observed informative and interactive conversations on Facebook related to heart health and heart disease for the

general public, specifically women and individuals with preexisting cardiovascular conditions. The active participation by health organizations, physicians, and the public at both the national and local levels contributed to a diverse discussion with information, resources, experience sharing, and social support.

This study has implications for heart health organizations to engage in two-way communication with the public given the interactive nature of social media platforms [39]. Although posts from organizations are mainly about information and resource sharing, the public still has specific questions regarding heart health and diseases. Posts about physicians' live sessions received a high volume of attention in terms of the number of likes, comments, and shares. This provides an opportunity for heart health organizations to listen to the audience and address the public's concerns for more effective health education and promotion [25]. Although we observed an increasing discussion on heart health for women, heart health organizations should provide more gender-specific information for women. Such posts are likely to be further shared among the users' social networks to benefit other family members and friends who are women [29].

This study provides an overview of heart health discussions on social media, especially in terms of thematic topics and public sentiments. Future studies are needed to analyze heart health discussions on other social media platforms, public forums, and discussion boards to provide a more comprehensive examination of the public discourse on social media. In addition, future studies may investigate how demographic differences play a role in shaping the public discourse on heart health. Disparities in heart health knowledge and health behaviors among different racial and ethnic groups can be examined. We only investigated the distinctive discussions on heart health for women; other demographic characteristics such as age and ethnicity should be further explored. Finally, given the increasing public communication on heart health, studies should be conducted to develop effective communication strategies leveraging social media such as Facebook for more effective health promotion and education.

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### Data Availability

Data sharing was not applicable to this study as we used Facebook data that were available to the public and did not generate new data.

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### Authors' Contributions

YF, JZ, and KS contributed to the conception and design of the study. HX conducted data extraction and analyses; BN assisted in data extraction and cleaning; and KS supervised the data analyses. HX, YF, JZ, and KS wrote the first manuscript, and all authors contributed to the manuscript revision and read and approved the submitted version.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Supplementary information for study procedure and results.

[DOCX File, 54 KB - [cardio\\_v6i2e40764\\_app1.docx](#)]

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## Abbreviations

**LDA:** latent Dirichlet allocation

**LIWC:** Linguistic Inquiry and Word Count

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Original Paper

# Racial and Socioeconomic Differences in Heart Failure Hospitalizations and Telemedicine Follow-up During the COVID-19 Pandemic: Retrospective Cohort Study

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## Abstract

**Background:** Low rates of heart failure (HF) hospitalizations were observed during the 2020 peak of the COVID-19 pandemic. Additionally, posthospitalization follow-up transitioned to a predominantly telemedicine model. It is unknown whether the shift to telemedicine impacted disparities in posthospitalization follow-up or HF readmissions.

**Objective:** The aim of this paper is to determine whether the shift to telemedicine impacted racial and ethnic as well as socioeconomic disparities in acute decompensated heart failure (ADHF) follow-up and HF readmissions. We additionally sought to investigate the impact of the COVID-19 pandemic on the severity of ADHF hospitalizations.

**Methods:** This was a retrospective cohort study of HF admissions across 8 participating hospitals during the initial peak of the COVID-19 pandemic (March 15 to June 1, 2020), compared to the same time frame in 2019. Patients were stratified by race, ethnicity, and median neighborhood income. Hospital and intensive care unit (ICU) admission rates, inpatient mortality, 7-day follow-up, and 30-day readmissions were assessed.

**Results:** From March 15, 2019, to June 1, 2020, there were 1162 hospitalizations for ADHF included in the study. There were significantly fewer admissions for ADHF in 2020, compared with 2019 (442 vs 720;  $P<.001$ ). Patients in 2020 had higher rates of ICU admission, compared with 2019 (15.8% vs 11.1%;  $P=.02$ ). This trend was seen across all subgroups and was significant for patients from the highest income quartile (17.89% vs 10.99%;  $P=.02$ ). While there was a trend toward higher inpatient mortality in 2020 versus 2019 (4.3% vs 2.8%;  $P=.17$ ), no difference was seen among different racial and socioeconomic groups. Telemedicine comprised 81.6% of 7-day follow-up in 2020, with improvement in 7-day follow-up rates (40.5% vs 29.6%;  $P<.001$ ). Inequities in 7-day follow-up for patients from non-Hispanic Black racial backgrounds compared to those from non-Hispanic White backgrounds decreased during the pandemic. Additionally, those with telemedicine follow-up were less likely to be readmitted in 30 days when compared to no follow-up (13.8% vs 22.4%;  $P=.03$ ).

**Conclusions:** There were no major differences in HF ICU admissions or inpatient mortality for different racial and socioeconomic groups during the COVID-19 pandemic. Inequalities in 7-day follow-up were reduced with the advent of telemedicine and decreased 30-day readmission rates for those who had telemedicine follow-up.

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**KEYWORDS**

heart failure; disparities; disparity; SARS-CoV-2; Coronavirus; pandemic; COVID-19; hospitalization; telemedicine; heart disease; heart; socioeconomic; cardiology; cardiac; hospital admission; intensive care unit; ICU admission; mortality; inequality; inequalities; minority; socioeconomic; health disparity; racial; ethnic

## Introduction

Acute decompensated heart failure (ADHF) is the leading hospital discharge diagnosis in the United States [1]. However, during the initial peak of the global COVID-19 pandemic, there was an unprecedented decrease in ADHF hospitalizations. In Europe, reports from individual hospitals as well as national data registries have shown reductions in heart failure (HF) admissions ranging from 30% to 50% [2,3]. Several institutions in the United States have shown similar decreases in HF admissions [4,5]. Despite lower admission rates, when patients do present, they are more ill with higher New York Heart Association class and more severe peripheral edema [6]. The global COVID-19 pandemic has not only affected the rates and severity of ADHF hospitalizations, but also postdischarge follow-up. Early follow-up, especially within 7 days after discharge, has been associated with better outcomes and reduced 30-day readmissions for patients with ADHF [7,8]. With wide-ranging stay-at-home orders to prevent the spread of infection, many US health care systems reduced in-person clinic visits in favor of telemedicine phone and video interactions. Several professional societies, including the Heart Failure Society of America, have released statements in support of telemedicine visits, though it has yet to be seen as an effective tool in reducing 30-day readmission rates [9].

While the COVID-19 pandemic has had many different effects on the health care system, one constant thread has been the disproportionate toll the virus has had on patients who self-identify with racial and ethnic minority groups, as well as patients who live in lower-income neighborhoods [10]. In Chicago, Black individuals were burdened with more than 50% of the COVID-19 cases and 70% of COVID-19 deaths despite representing only 30% of the city's population [11]. Parallel disparities in HF outcomes associated with race, ethnicity, and socioeconomic status have been seen. Patients with HF who self-identify as Black or are residents of lower-income neighborhoods have worse health status and higher rates of mortality when compared to the general population [12]. These at-risk groups already struggle with access to care, and the COVID-19 pandemic may further exacerbate these disparities. Currently, there are no studies investigating the impact of the transition to telemedicine on the incidence of HF readmissions and early posthospitalization follow-up for patients of different racial, ethnic, and socioeconomic backgrounds. It is also unknown whether the COVID-19 pandemic affected the

incidence or severity of ADHF admissions for patients of varying minority groups. Therefore, the objective of this study is twofold: (1) determine whether the shift to telemedicine impacted racial and ethnic as well as socioeconomic disparities in ADHF follow-up and HF readmissions, and (2) determine the impact of the COVID-19 pandemic on the severity of ADHF hospitalizations.

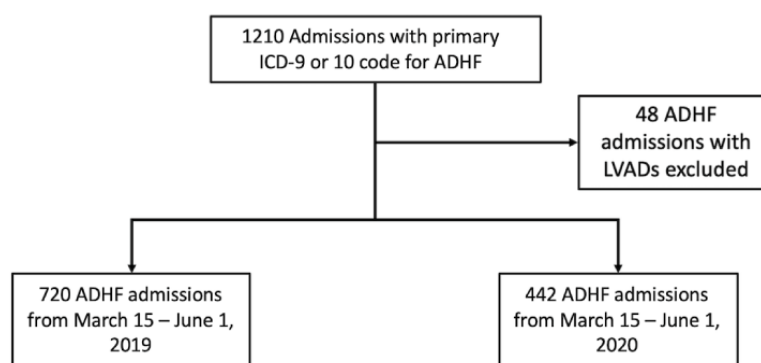
## Methods

### Patient Selection

This was a retrospective cohort study derived from patients who were hospitalized for ADHF within the Northwestern Memorial Healthcare (NMHC) system. The NMHC system comprises over 200 sites and 10 hospitals that provide health care to a varying and diverse population throughout the city of Chicago and the surrounding metropolitan area. Overall, 8 hospitals were included that collected data on patients who were hospitalized in 2019 and 2020. Two hospitals that did not collect data in 2019 were excluded.

Patient data were obtained via the Northwestern Medicine Enterprise Data Warehouse. The latter provides a single comprehensive repository of all clinical and research data across all NMHC facilities. Included in this retrospective cohort study were adults aged 18 years and older who were hospitalized with the International Classification of Diseases (ICD), ninth revision (ICD-9: 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, and 428.0-428.9) or tenth revision, ICD-10 (I11.0, I13.0, I13.2, and I50.0-I50.9) primary diagnosis of ADHF (Figure 1). Patients with left ventricular assist devices were excluded. For those who were hospitalized with a primary ICD diagnosis of ADHF, patient characteristics including age, race, ethnicity, zip code, BMI, weight, most recent left ventricular ejection fraction determined by echocardiography, as well as the comorbidities hypertension, chronic obstructive pulmonary disease, and type 1 or type 2 diabetes mellitus were obtained via chart review. During the peak of the COVID-19 pandemic, a stay-at-home order was placed for the city of Chicago and the state of Illinois from March 19, 2020, to June 3, 2020. This order required citizens to self-isolate at home except for essential needs, such as grocery shopping or seeking medical care. Therefore, we selected patients hospitalized for ADHF from March 15, 2020, to June 1, 2020, and compared these patients to those who were admitted from March 15, 2019, to June 1, 2019.

**Figure 1.** Patient selection. ADHF: acute decompensated heart failure; ICD: International Classification of Diseases; LVAD: left ventricular assist device.



## Statistical Analysis

The primary objective of this study was to investigate the effect of the COVID-19 pandemic on both acuity of ADHF hospitalizations as well as changes in posthospitalization follow-up after the implementation of telemedicine. The endpoints assessed included the rate of inpatient mortality, predicted inpatient mortality calculated by validated risk scores, incidence of intensive care unit (ICU) admission, posthospitalization follow-up within 7 days, and 30-day readmission rates. Predicted in-hospital mortality was determined using Get With the Guidelines—Heart Failure (GWTG-HF) as well as the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF) risk scores. Both the GWTG-HF score and the OPTIMIZE-HF score are successful predictors of in-hospital mortality for both patients with reduced HF and preserved left ventricular ejection fraction [13,14]. GWTG-HF and OPTIMIZE-HF risk scores were calculated using the variables as previously reported [13,14]. For both risk scores, a patient's score is obtained by summing points assigned to the value of each predictor. The values of the score are between 0 and 100, with higher scores correlating to a higher-percent predicted inpatient mortality [13,14]. Follow-up was codified as either in-person or telemedicine as documented in the electronic medical record. Telemedicine follow-up included both phone as well as video encounters as documented by the outpatient primary provider in the electronic medical record.

Results were stratified by race and ethnicity as well as median neighborhood income quartile. Patients were divided into income quartiles based on their zip code's median household income using data from the US Census Bureau American Community Survey 2010-2014. Income quartile 1 represents the lowest median household income while income quartile 4 represents the highest.

Data are presented as mean values with SD if normally distributed and median with interquartile range if skewed. Categorical data are presented as frequencies and percentages. Baseline characteristics and outcomes were compared between the 2019 historical control cohort and the 2020 peak COVID-19 pandemic cohort, using Student *t* tests and  $\chi^2$  tests where appropriate.  $P < .05$  (2 - sided test) was considered significant. All statistical tests and analyses were performed with Stata, version 16 (StataCorp).

## Ethics Approval

This study was approved by the institutional review board at Northwestern University (IRB approval number: STU00213213), and the procedures followed were in accordance with the with the Helsinki Declaration of 1975, as revised in 2000. All patient data included within the study have been deidentified.

## Results

Overall, there were 1162 hospitalizations for ADHF between the 2 cohorts. There were significantly fewer admissions for ADHF in 2020 compared with 2019 (442 vs 720;  $P < .001$ ). Baseline patient characteristics are presented in [Table 1](#).

Patients admitted in 2020 were more likely to have chronic obstructive pulmonary disease (26.2% vs 19.8%;  $P = .01$ ) and had a higher percentage admitted from income quartile 3 (20.1% vs 10.6%;  $P < .001$ ) as well as fewer from income quartile 2 (4.5% vs 7.9%;  $P = .02$ ). There were significantly more patients with non-Hispanic White racial backgrounds (59.7% vs 70.6%;  $P < .001$ ) admitted in 2020 with a coinciding decrease in non-Hispanic Black admissions (27.8% vs 19.4%;  $P = .001$ ).

Inpatient outcomes for those hospitalized with ADHF are reported in [Table 2](#) as well as [Figure 2](#).

A greater proportion of patients were admitted to the ICU in 2020 compared to 2019 (15.8% vs 11.1%;  $P = .02$ ). Patients from income quartile 4 (15.8% vs 10.7%;  $P = .05$ ) had greater rates of ICU admissions in 2020 compared to 2019. Though not statistically significant, there was a trend toward higher mortality for those admitted in 2020 compared to 2019 (4.3% vs 2.8%;  $P = .17$ ). There was no difference in predicted inpatient mortality between the 2019 and 2020 cohorts or any of the racial or socioeconomic subgroups.

Follow-up and readmission data are reported in [Tables 3](#) and [4](#), as well as [Figures 3](#) and [4](#).

In 2020, 81.6% of 7-day follow up was conducted via telemedicine as compared to 0% in 2019 ( $P < .001$ ). Moreover, 142 (97.2%) of the telemedicine follow-up encounters were conducted via phone while only 4 (2.8%) were conducted by video. A greater proportion of patients had successful 7-day follow-up in 2020 compared to 2019 (40.5% vs 29.6%;  $P < .001$ ). All racial, ethnic, and socioeconomic groups saw a trend toward



improved 7-day follow-up with patients who had non-Hispanic Black racial backgrounds (33% vs 17%;  $P=.003$ ) meeting statistical significance as well as those from income quartiles 3 (37% vs 23%;  $P=.05$ ) and 4 (47.1% vs 36.0%;  $P=.004$ ). Female patients also saw significant improvements in follow-up with the implementation of telemedicine as compared to 2019 (41.9% vs 24.7%;  $P<.001$ ). In 2020, patients who received

follow-up within 7 days of hospital discharge were significantly less likely to be readmitted in 30 days when compared to those who had no follow-up (14.5% vs 22.4%;  $P=.04$ ). Patients who received 7-day follow-up via telemedicine (13.8% vs 22.4%;  $P=.03$ ) were also less likely to be readmitted in 30 days when compared to no follow-up.

**Table 1.** Baseline characteristics.

Characteristics	2019 (n=720)	2020 (n=442)	P value
Age (years), mean (SD)	73.1 (0.9)	72.4 (0.7)	.44
Gender (male), n (%)	378 (52.5)	232 (52.4)	.48
<b>Race or ethnicity, n (%)</b>			
NHW <sup>a</sup>	429 (59.7)	312 (70.6)	<.001
NHB <sup>b</sup>	200 (27.8)	86 (19.4)	.001
Hispanic	45 (6.2)	27 (6.1)	.94
NHAPI <sup>c</sup>	26 (3.6)	11 (2.5)	.30
Other	19 (2.7)	6 (1.4)	.87
BMI (kg/m <sup>2</sup> ), mean (SD)	32.49 (0.8)	32.60 (0.6)	.89
Weight (lbs), mean (SD)	200.5 (3.9)	203.1 (3.2)	.38
COPD <sup>d</sup> , n (%)	142 (19.8)	100 (26.2)	.01
DM2 <sup>e</sup> , n (%)	326 (45.4)	205 (45.7)	.89
HTN <sup>f</sup> , n (%)	626 (87.1)	349 (85.7)	.47
<b>Income quartile, n (%)</b>			
IQ1 <sup>g</sup>	139 (19.3)	73 (16.5)	.23
Q2	57 (7.9)	20 (4.5)	.02
Q3	77 (10.6)	89 (20.1)	<.001
Q4	447 (62.1)	259 (58.6)	.24
LVEF <sup>h</sup> (<40%), n (%)	249 (34.6)	159 (35.9)	.68
Average percentage of LVEF, mean (SD)	47.5 (0.68)	47.1 (1.23)	.76

<sup>a</sup>NHW: non-Hispanic White.

<sup>b</sup>NHB: non-Hispanic Black.

<sup>c</sup>NHAPI: non-Hispanic Asian or Pacific Islander.

<sup>d</sup>COPD: chronic obstructive pulmonary disease.

<sup>e</sup>DM2: type 2 diabetes mellitus.

<sup>f</sup>HTN: hypertension.

<sup>g</sup>IQ: income quartile.

<sup>h</sup>LVEF: left ventricular ejection fraction.

**Table 2.** Inpatient outcomes.

Variable	Value		P value
	2019	2020	
<b>ICU<sup>a</sup> admissions, n (%)</b>			
Total	80 (11.1)	70 (15.8)	.02
<b>Sex</b>			.10
Male	44 (11.6)	38 (16.3)	
Female	36 (10.6)	32 (15.2)	
<b>Race or ethnicity</b>			
NHW <sup>b</sup>	41 (9.6)	30 (9.6)	.98
NHB <sup>c</sup>	26 (13)	15 (17)	.33
Hispanic	3 (5)	4 (14)	.21
NHAPI <sup>d</sup>	4 (15)	3 (27)	.62
<b>Income quartile</b>			
IQ1 <sup>e</sup>	16 (11.6)	10 (14)	.61
IQ2	7 (13)	5 (25)	.21
IQ3	7 (9)	14 (16)	.18
IQ4	49 (10.7)	41 (15.8)	.05
<b>Mortality, n (%)</b>			
Total	20 (2.8)	19 (4.3)	.17
<b>Sex</b>			
Male	10 (2.8)	10 (4.3)	.22
Female	10 (2.8)	9 (4.3)	.23
<b>Race or ethnicity</b>			
NHW	14 (1.9)	16 (5.1)	.20
NHB	3 (1.5)	1 (1)	.83
Hispanic	2 (4)	1 (4)	.93
NHAPI	0 (0)	1 (11)	.08
<b>Income quartile</b>			
IQ1	3 (2.2)	2 (3)	.79
IQ2	2 (4)	1 (5)	.64
IQ3	2 (3)	4 (4)	.77
IQ4	12 (2.7)	13 (5.0)	.11
<b>GWTC-HF<sup>f</sup> score</b>			
Total	40.86	40.74	.82
<b>Sex</b>			
Male	41.67	41.78	.89
Female	39.95	39.68	.72
<b>Race or ethnicity</b>			
NHW	42.99	42.24	.22
NHB	35.17	34.59	.60
Hispanic	40.81	36.25	.051
NHAPI	44.50	42.82	.51

Variable	Value		P value
	2019	2020	
<b>Income quartile</b>			
IQ1	36.68	38.27	.26
IQ2	40.86	38.15	.33
IQ3	40.51	39.59	.47
IQ4	42.18	42.00	.79
<b>OPTIMIZE-HF<sup>g</sup> score</b>			
Total	34.49	34.05	.39
<b>Sex</b>			
Male	35.35	35.05	.68
Female	33.53	33.06	.49
<b>Race or ethnicity</b>			
NHW	35.49	35.00	.43
NHB	32.17	31.35	.43
Hispanic	32.71	30.52	.26
NHAPI	37.88	36.63	.20
<b>Income quartile</b>			
IQ1	32.69	33.57	.57
IQ2	34.12	33.10	.70
IQ3	34.12	33.26	.49
IQ4	35.08	34.54	.39

<sup>a</sup>ICU: intensive care unit.

<sup>b</sup>NHW: non-Hispanic White.

<sup>c</sup>NHB: non-Hispanic Black.

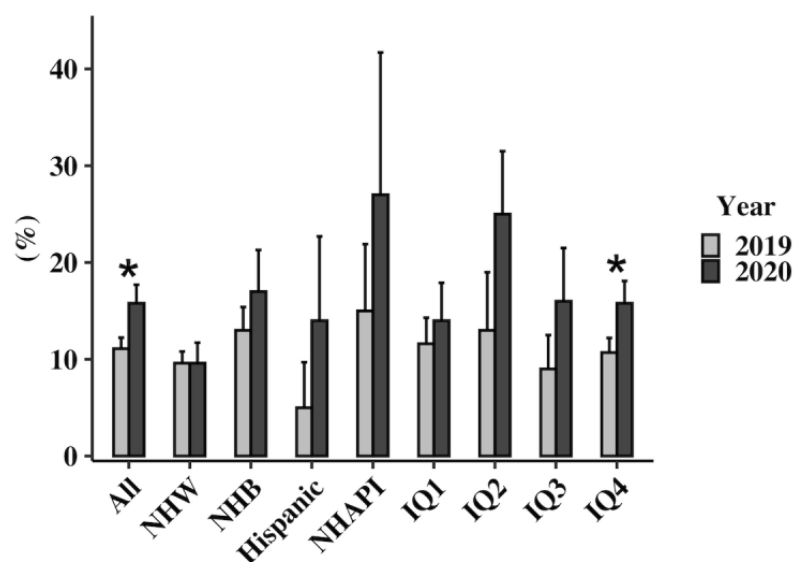
<sup>d</sup>NHAPI: non-Hispanic Asian or Pacific Islander.

<sup>e</sup>IQ: income quartile.

<sup>f</sup>GWG-HF: Get With the Guidelines—Heart Failure.

<sup>g</sup>OPTIMIZE-HF: Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure.

**Figure 2.** Intensive care unit admission rates 2019 vs 2020. IQ: income quartile; NHAPI: non-Hispanic Asian or Pacific Islander; NHB: non-Hispanic Black; NHW: non-Hispanic White.



**Table 3.** Posthospitalization follow-up.

Variable	Value		P value
	2019, n (%)	2020, n (%)	
Total	213 (29.6)	179 (40.5)	<.001
<b>Sex</b>			
Male	129 (33.9)	87 (39.2)	.19
Female	84 (24.7)	92 (41.8)	<.001
<b>Race or ethnicity</b>			
NHW <sup>a</sup>	157 (36.6)	136 (43.6)	.05
NHB <sup>b</sup>	34 (17)	28 (33)	.003
Hispanic	11 (24)	9 (33)	.41
NHAPI <sup>c</sup>	8 (31)	5 (45)	.39
<b>Income quartile</b>			
IQ1 <sup>d</sup>	24 (17.4)	18 (25)	.19
IQ2	10 (18)	6 (30)	.26
IQ3	18 (23)	33 (37)	.05
IQ4	161 (36)	122 (47.1)	.004
Telemedicine	0 (0)	146 (81.6)	<.001
Cardiologist	131 (61.5)	125 (69.8)	.09
Primary care provider	82 (38.5)	54 (30.2)	.09

<sup>a</sup>NHW: non-Hispanic White.

<sup>b</sup>NHB: non-Hispanic Black.

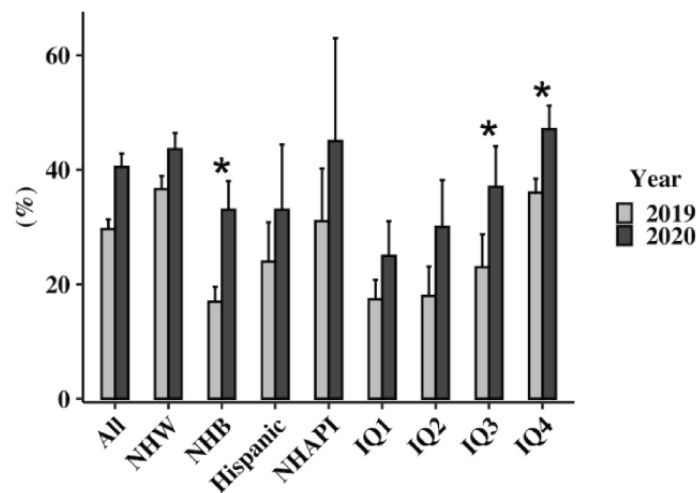
<sup>c</sup>NHAPI: non-Hispanic Asian or Pacific Islander.

<sup>d</sup>IQ: income quartile.

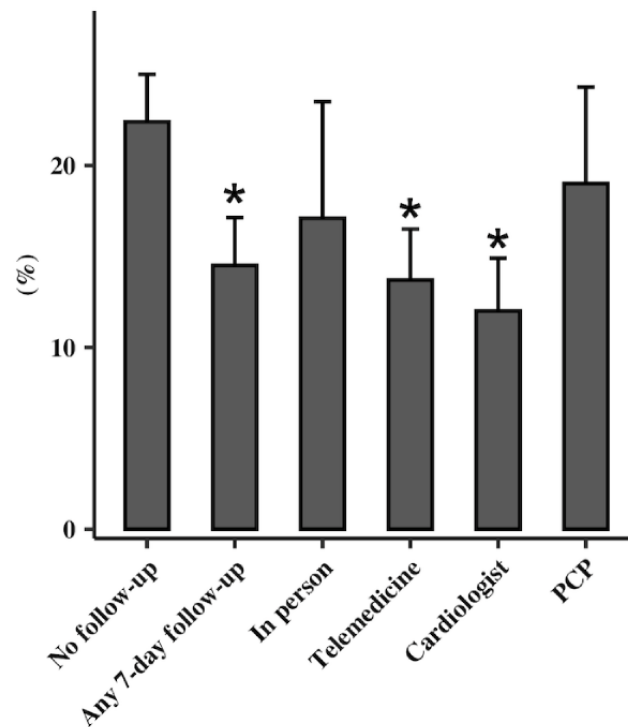
**Table 4.** Thirty-day readmission rates by follow-up type.

Year and follow-up type	Value		P value
	N (%)		
<b>2019</b>			
No follow-up	127 (25)		Reference
Any 7-day follow-up	46 (21.6)		.29
Cardiologist	30 (22.9)		.61
Primary care provider	15 (19)		.22
<b>2020</b>			
No follow-up	59 (22.4)		Reference
Any 7-day follow-up	26 (14.5)		.04
Cardiologist	15 (12)		.03
Primary care provider	10 (19)		.53
Telemedicine	20 (13.7)		.03
In person	6 (17.1)		.47

**Figure 3.** Seven-day follow-up rates, 2019 versus 2020. IQ: income quartile; NHAPI: non-Hispanic Asian or Pacific Islander; NHB: non-Hispanic Black; NHW: non-Hispanic White.



**Figure 4.** Thirty-day readmission rates in 2020. PCP: primary care physician.



## Discussion

### Principal Findings

This study investigated differences in ADHF hospitalizations, inpatient outcomes, posthospitalization follow-up, and 30-day readmissions for patients of varying racial, ethnic, and socioeconomic backgrounds during the COVID-19 pandemic. The principal findings of our study are that patients with ADHF, admitted during the COVID-19 pandemic, (1) were more likely to be admitted to the ICU, though there were no major differences in ICU admission rates among different racial and ethnic minorities or neighborhood income levels; (2) had lower rates of 30-day readmissions with telemedicine follow-up within 7 days of discharge; and (3), perhaps most importantly, had a reduction in follow-up rate disparities and increased rates of

7-day follow-up with the advent of telemedicine. Though previous studies have reported on ADHF admissions and outcomes during the COVID-19 pandemic, to our knowledge, our study is the first to investigate racial, ethnic, and socioeconomic differences for patients with HF during the acute hospitalization. It is also the first study to assess the impact of telemedicine on disparities in ADHF posthospitalization follow-up and 30-day readmission rates.

### Comparison With Prior Work

Our study supports prior findings of reduced admissions for ADHF seen throughout the United States and Europe with the onset of the COVID-19 pandemic [2-6]. This phenomenon is likely secondary to a complex interplay of multiple public health and social factors. It is possible that fear of acquisition of COVID-19 associated with the medical environment and strict

social isolation precautions placed by local and national authorities may have prejudiced patients to defer pursuit of medical care or attempt to self-manage care at home. The decreased overall admissions and concurrent increase in ICU admission rates seen in 2020 compared to 2019 supports the notion that patients may have delayed care until their disease status was more progressed.

The COVID-19 pandemic has had an unequal toll on patients from racial and ethnic minorities and those from lower income neighborhoods. Self-identified Black patients and those from poorer neighborhoods who contracted SARS-CoV-2 were more likely to be hospitalized and have worse inpatient outcomes when compared to White patients and those from more affluent areas [15,16]. Regarding cardiovascular disease specifically, Black patients have had higher rates of hospitalization from myocardial infarction and greater event rates of sudden cardiac death during the COVID-19 pandemic when compared to prior studies [17,18]. Interestingly though, our study showed a decrease in admissions for non-Hispanic Black patients and no difference in rates of hospitalization for ADHF for other racial and ethnic minority groups. Non-Hispanic Black and Hispanic patients made up the majority of those admitted from neighborhoods below the average median income. The peak pandemic cohort had more patients admitted from income quartile 3, those whose median household income was average to above average when compared to the rest of the cohort. Patients from income quartile 3 tended to be White, male, and on average 2 years younger than the rest of the patients admitted in 2020. Overall, there were no major differences in comorbidities or baseline characteristics for income quartile 3 when compared to the other quartiles. It is unclear what social factors, if any, were at play that led to a higher admission rate for this income quartile.

Previous reports have differed on whether there have been higher rates of ICU admission or inpatient mortality during the COVID-19 pandemic for ADHF [3,6,19,20]. In Germany, in the largest sample, to date, of ADHF hospitalizations during the COVID-19 pandemic (N=1972), there was an increase in ICU admission rates as well as inpatient mortality [20]. In our cohort, there was also an increase in ICU admission rates for all patients admitted for ADHF. Patients from all racial and ethnic minorities as well as all neighborhood income levels saw an increase in ICU admission rates, though statistical significance of the increase in these rates was seen only in patients from income quartile 4. This income quartile made up almost 60% of the entire cohort. It is likely that our study was underpowered to find significant increases in ICU admissions among patients from lower income neighborhoods as well as those from different racial and ethnic minorities. Overall, both the prepandemic and COVID-19 pandemic cohorts had lower inpatient mortality rates than the reported national rate of 5.8% [21]. Though not reaching significance, a trend was seen for patients having higher inpatient mortality during the COVID-19 pandemic. Again, our sample size may have been too small to reach statistical significance.

Lack of follow-up after hospitalization for ADHF is associated with an increased risk of rehospitalization for patients of racial and ethnic minorities, and those from lower socioeconomic

backgrounds [7,22-24]. In a face-to-face survey of patients who were recently hospitalized for ADHF, over half had a major barrier to follow-up such as no form of personal transportation [25]. Additionally, prior meta-analysis of 41 randomized controlled trials has shown that a combination of home visits, phone calls, and clinic visits were the most effective way to reduce rehospitalizations for ADHF [26]. Telemedicine may be able to circumvent some of the larger barriers to care while also supplying more effective tools for preventing rehospitalization. In our study, 7-day follow-up improved most for non-Hispanic Black patients during the pandemic. These follow-up visits were 81.6% by telemedicine. A similar trend was seen across income quartiles, with all median household income quartiles seeing improvement in 7-day follow-up. Importantly, inequities in 7-day follow-up rate in patients from non-Hispanic Black racial backgrounds as compared to those from non-Hispanic White backgrounds *decreased* during the pandemic period. Whereas in 2019, the gap was 36.6% of non-Hispanic White patients getting 7-day follow-up visits compared to 17.0% of non-Hispanic Black patients, in 2020, this gap *narrowed* to 43.6% of non-Hispanic White patients, as compared to 33% of non-Hispanic Black patients getting follow-up care. This disparity has been well reported, with Black race being associated with lower odds of early physician follow-up for not only HF but other chronic conditions as well [27-29]. It is expected that telemedicine may not only improve early physician follow-up for all patients but help reduce disparities that have long been present.

We found a striking reduction in readmission rates for patients with telemedicine follow-up compared to no follow-up. The reason for this association is not clear. It is possible that this association is confounded by an omitted variable, and that patients who can conduct a telemedicine appointment have other factors that also mitigate risk of readmission. It is also possible that during a period with limited in-person appointments, patients selected for in-person follow-up were sicker and were more likely to need readmission. However, this finding is promising, and further prospective studies should be pursued to assess if telemedicine may be a feasible option in reducing 30-day HF readmissions.

## Limitations

Our study has important limitations. While median neighborhood household income can help estimate a patient's financial and social situation, it does not fully capture each patient's individual socioeconomic status. Additionally, our cohort consisted of patients admitted with a primary diagnosis of ADHF, but we cannot rule out that some patients may have contracted the SARS-CoV-2 virus as an additional contributor to the higher morbidity and mortality seen during the pandemic. We did not exclude patients with SARS-CoV-2 infection because this would inaccurately reflect the true burden of HF admissions during the pandemic. Additionally, the inclusion of these patients allowed greater accuracy in assessing 7-day follow-up and 30-day readmission rates. Finally, while our hospital system has locations throughout the Chicago metropolitan area, we were unable to capture 30-day readmissions for patients who were admitted to medical centers outside of the NMHC system.

## Conclusions

Patients admitted for ADHF during the COVID-19 pandemic had higher rates of ICU admissions and a trend toward higher inpatient mortality; however, there were no major differences seen in rates between different racial, ethnic, and socioeconomic groups. Additionally, as the use of telemedicine became more ubiquitous, 7-day follow-up after hospital discharge increased for all patients and decreased disparities in follow-up. Patients who had 7-day follow-up, including telemedicine follow-up, were also less likely to be readmitted in 30 days. These findings

suggest that telemedicine acts as a digital bridge rather than a digital divide in improving early follow-up, decreasing disparities in follow-up, and reducing 30-day readmissions. Future prospective randomized trials are needed to assess whether telemedicine may be a feasible tool in reducing HF readmission rates and improving access to follow-up, especially for those from marginalized communities. Further work is needed to assess whether telemedicine should remain as a viable option for the delivery of care to patients with HF during and beyond the pandemic.

## Data Availability

All data generated or analyzed during this study are included in this published article or in [Multimedia Appendix 1](#).

## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Racial and socioeconomic differences in heart failure hospitalizations and telemedicine follow-up data set.

[[XLSX File \(Microsoft Excel File\), 379 KB - cardio\\_v6i2e39566\\_app1.xlsx](#) ]

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## Abbreviations

- ADHF:** acute decompensated heart failure
- GWTG-HF:** Get With the Guidelines—Heart Failure
- HF:** heart failure
- ICD:** International Classification of Diseases



**ICU:** intensive care unit

**NMHC:** Northwestern Memorial Healthcare

**OPTIMIZE-HF:** Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure

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Original Paper

# Evaluating Health Care Provider Perspectives on the Use of Mobile Apps to Support Patients With Heart Failure Management: Qualitative Descriptive Study

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## Abstract

**Background:** Nonadherence to diet and medical therapies in heart failure (HF) contributes to poor HF outcomes. Mobile apps may be a promising way to improve adherence because they increase knowledge and behavior change via education and monitoring. Well-designed apps with input from health care providers (HCPs) can lead to successful adoption of such apps in practice. However, little is known about HCPs' perspectives on the use of mobile apps to support HF management.

**Objective:** The aim of this study is to determine HCPs' perspectives (needs, motivations, and challenges) on the use of mobile apps to support patients with HF management.

**Methods:** A qualitative descriptive study using one-on-one semistructured interviews, informed by the diffusion of innovation theory, was conducted among HF HCPs, including cardiologists, nurses, and nurse practitioners. Transcripts were independently coded by 2 researchers and analyzed using content analysis.

**Results:** The 21 HCPs (cardiologists: n=8, 38%; nurses: n=6, 29%; and nurse practitioners: n=7, 33%) identified challenges and opportunities for app adoption across 5 themes: *participant-perceived factors that affect app adoption*—these include patient age, technology savviness, technology access, and ease of use; *improved delivery of care*—apps can support remote care; collect, share, and assess health information; identify adverse events; prevent hospitalizations; and limit clinic visits; *facilitating patient engagement in care*—apps can provide feedback and reinforcement, facilitate connection and communication between patients and their HCPs, support monitoring, and track self-care; *providing patient support through education*—apps can provide HF-related information (ie, diet and medications); and *participant views on app features for their patients*—HCPs felt that useful apps would have reminders and alarms and participative elements (gamification, food scanner, and quizzes).

**Conclusions:** HCPs had positive views on the use of mobile apps to support patients with HF management. These findings can inform effective development and implementation strategies of HF management apps in clinical practice.

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**KEYWORDS**

heart failure; mobile health; mHealth; eHealth; mobile apps; adherence; self-management; mobile phone

## Introduction

### Background

Heart failure (HF) is a progressive clinical syndrome in which abnormalities in heart function, marked by reduced cardiac output and congestion [1], often result in periods of acute decompensation. HF is managed through pharmacological therapies, accompanied by self-care recommendations that emphasize dietary modification and daily weight and symptom monitoring [1,2]. However, patient adherence to these treatments can be challenging, with medication and dietary nonadherence rates being 50% and 22% to 50%, respectively [3-7]. Nonadherence is associated with increased risk of HF hospitalizations and mortality, which contribute to the growing economic burden of HF [8].

Currently, a significant amount of behavioral and nutritional counseling occurs in the clinical setting, with the counseling provided by health care providers (HCPs), including physicians and nurses, with consultation from pharmacists and registered dietitians as needed, to support patients with HF management and adherence [9-12]. The delivery of this education can be limited by HCPs' lack of knowledge, time, and compensation [13]. In addition, patients with HF, especially those living in rural and remote regions, may not have access to these professionals, and even if they do, HCPs are unable to monitor the patients and provide feedback in real time and on day-to-day progress. Given the clinical relevance of treatment adherence to HF outcomes and the real-life challenges that patients may experience, it is not surprising that initiatives to support adherence are highlighted as a priority action area by the American Heart Association [14].

Mobile health (mHealth) technologies present opportunities to improve adherence and support HF management. Several randomized controlled trials examining the impact of mHealth-based interventions in HF have reported significant improvements in cardiovascular and all-cause mortality, New York Heart Association class, left ventricular ejection fraction, quality of life, and physical functioning [15-18]. mHealth-based interventions improve outcomes by supporting the delivery and continuity of care in HF by relaying health information, monitoring patient symptoms outside of clinical setting, and supporting patient education [19,20]. Modern mHealth tools such as mobile apps are also able to provide real-time feedback in a way that is less resource intensive than other eHealth interventions (eg, telemonitoring) [19,20]. Multiple systematic reviews have reported that mHealth apps for HF improve engagement in self-care behaviors as well as patient self-efficacy, self-confidence, and communication with HCPs, offering a potential cost-effective solution to support patients with HF treatment adherence and self-management [21-24].

### Objectives

Among existing apps available to support HF management, few are considered high quality based on content, features, and functionality when assessed against established rating scales [24,25]. In fact, it has been suggested that many apps require redesign because of a lack of appropriate features to engage patients in self-care and failure to meet the needs and

motivations of the population with HF [24]. In contrast, well-designed mHealth apps that integrate input from both patients and HCPs are more likely to also meet HCPs' needs, leading to overall better acceptability and HCPs' willingness to adopt and recommend such tools to their patients [26]. Moreover, HCPs have a unique understanding of what is required to support patients in HF management [27]. A few studies have explored HCPs' perceptions on the use of technology-based interventions for HF management [28-30]. However, these studies have only focused on mobile phone-based interventions for wireless Bluetooth-enabled remote monitoring of patient symptoms, SMS text messaging, and sensor-focused mHealth apps and do not capture HCPs' perceptions on mHealth interventions using more advanced applications, which have unique opportunities and challenges of their own. Determining HCPs' perspectives and attitudes on the use of mobile apps for HF management can inform the effective design of such apps, including their features and content, increasing the likelihood of app adoption in this population. Therefore, the objective of this qualitative descriptive study was to determine HCPs' perspectives (needs, motivations, and challenges) on the use of mHealth apps to support patients with HF management. For the purposes of this study, HCPs included cardiologists, nurses, and nurse practitioners.

## Methods

### Study Design and Research Team

This study followed a qualitative descriptive design. Rooted in naturalist inquiry, this design allows for meaningful summarization of the data in everyday terms and has been used to inform development of health interventions [31]. The study followed the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines for qualitative research [32]. The research team included a PhD graduate student (BS); 2 faculty members with expertise in HF, digital intervention research, and qualitative methods (JA and ML); an HF cardiologist (SM); and a social scientist with qualitative expertise (MS). There was no prior relationship between the interviewer and the participants.

### Ethics Approval

The study was approved by the research ethics board of Ontario Tech University (14882), and informed consent was obtained from all participants.

### Study Participants and Recruitment

Purposive sampling was used to recruit cardiologists, nurses, and nurse practitioners who work in outpatient HF programs in Canada. Registered dietitians and pharmacists were excluded because they are not the primary point of care for patients with HF. Recruitment was conducted with advertisements and emails circulated by the Canadian Heart Failure Society as well as with a snowball sampling approach. Eligible participants were invited to participate via an email invitation. Participants completed a web-based consent form. Participants were compensated CAD \$20 (US \$15) in the form of a gift card for their participation in the study.

## Data Collection

One-on-one 15-minute telephone interviews were conducted in English with participants between February 4, 2019, and June 4, 2020. Telephone interviews allow for flexibility and convenience for both researchers and participants and is an acceptable method for qualitative data collection [33,34]. The interviewer (BS) recorded field notes during and after each interview, which included reflective memos on unique ideas and insights as well as their interview experience. Participants were sent the interview questions before the interview.

The interviews were directed by a semistructured interview guide (Multimedia Appendix 1) that consisted of 8 open-ended questions that reflected the aim of the study. These questions were supplemented with research probes and paraphrasing to generate further clarification of participant responses and promote discussion. The interview guide was developed by expert consensus and informed by the diffusion of innovation theory [35], which is widely used in guiding the development and evaluation of innovations. The interview questions reflected the five main factors that influence the adoption of an innovation: (1) relative advantage refers to the degree to which an innovation is seen as better than standard care, (2) compatibility refers to how consistent the innovation is with the needs and values of the adopter (eg, patients), (3) complexity refers to the difficulty of the innovation, (4) trialability refers to the extent to which the innovation can be tested before use by users, and (5) observability refers to the extent to which the innovation provides results. The interview guide was reviewed and approved by members of the research team to ensure clarity and appropriateness of questions and probes. The guide was pilot-tested with an HF cardiologist external to the research team.

The interviews were audio recorded using a voice recorder, and the recordings were manually transcribed verbatim (BS and SG). Pseudonyms were used in the transcripts to protect the identity and maintain anonymity of the participants. All identifiable information was removed from the transcripts. The verbatim transcripts were verified by a research assistant by comparing the transcripts with the audio recordings to ensure accuracy.

Before the telephone interview, participants completed a short web-based questionnaire that asked about their views on using technology for managing HF as well as barriers related to supporting patients' diet and medication adherence. The questions were informed by what is known in the literature about barriers and facilitators related to medication and dietary adherence. The questionnaire consisted of 10 Likert scale-style questions, with answer choices ranging from 0 to 3 (I don't know, agree, neutral, and disagree). Sociodemographic information, including age, sex, years of practice, and professional role, was also collected. The questionnaire was validated by the research team for face and content validity.

## Data Analysis

Preceding analyses, all participants received their transcript for *member checking*, as described by Lincoln and Guba [36], to approve the verbatim transcripts and verify accuracy. Only minor amendments were received and integrated into the final transcripts, ensuring credibility of data. To prepare for data analysis, the audio recording, transcript, and field notes of each interview were reviewed multiple times. The transcripts were imported into NVivo software (version 12.0; QSR International), which supported the content analysis. The transcripts were inductively coded by 2 independent researchers (BS and MS). This was followed by comparison of coding, collaborative discussion of codes (for intercoder agreement), expansion of codes to capture subcodes, and ultimately the grouping of codes into common themes. For the purpose of this study, a theme reflected participant accounts related to their views (needs, motivations, and challenges) regarding the use of mobile apps for HF management. Themes were reviewed and finalized in discussion with a qualitative expert on the research team (ML) as well as the principal investigator (JA).

The questionnaire data were summarized using descriptive statistics. Categorical variables were presented as frequencies and percentages, and continuous variables were described as means and SDs.

## Results

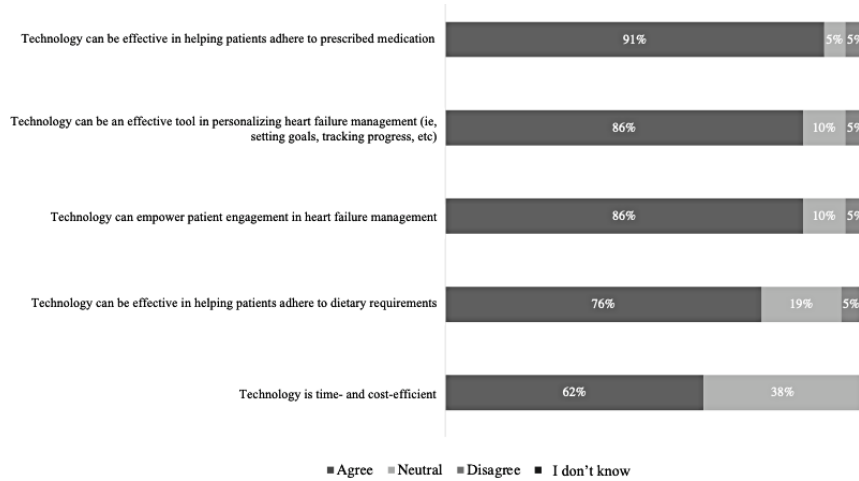
### Overview

A total of 21 HCPs (cardiologists: n=8, 38%; nurses: n=6, 29%; and nurse practitioners: n=7, 33%) participated. The mean age of the participants was 42.9 (SD 8.6) years, and 81% (17/21) were women. Participants' years of practice as HCPs included 1 to 5 years (1/21, 5%), 6 to 10 years (6/21, 29%), 11 to 15 years (5/21, 24%), 16 to 20 years (1/21, 5%), and >20 years (8/21, 38%).

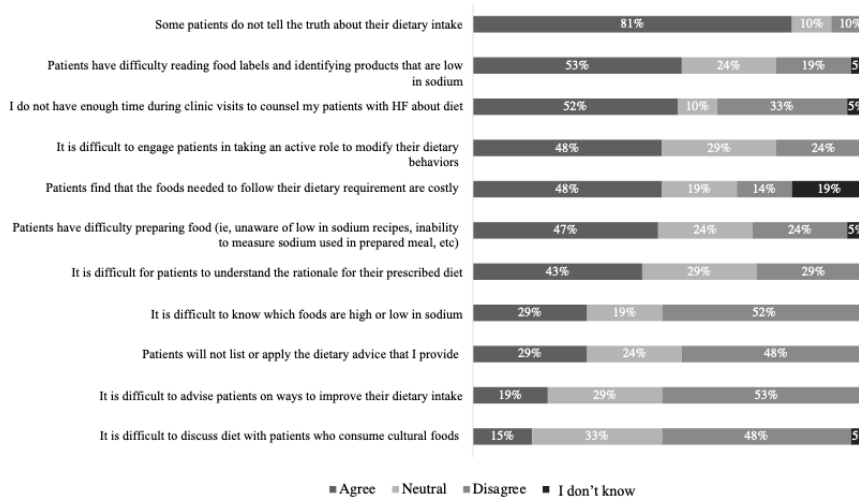
The questionnaire data indicated that the HCPs agreed that technology can be effective in helping patients to adhere to their prescribed medications (19/21, 90%) and dietary requirements (16/21, 76%; Figure 1). Barriers to supporting patients' diet and medication adherence included medication cost and financial burden (16/21, 76%), difficulties with reading food labels and identifying low-sodium products (11/21, 52%), and patients not being truthful about taking their medications (14/21, 67%) or their dietary intake (17/21, 81%; Figures 2 and 3).

Five themes were identified from the telephone interviews that reflect participant perspectives on the use of mobile apps for HF management. These included participant-perceived factors that affect app adoption, improved delivery of care, facilitating patient engagement in care, providing patient support through education, and participant views on app features for their patients.

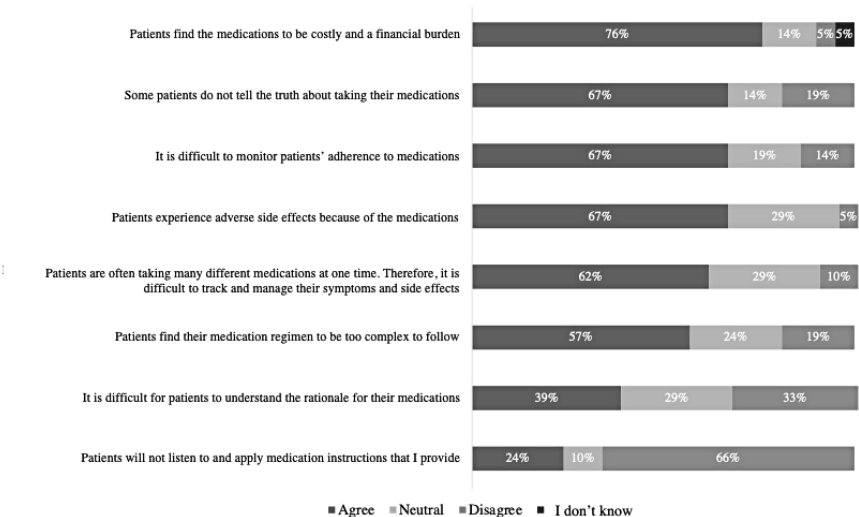
**Figure 1.** Health care providers' views on the use of technology to aid in managing heart failure (N=21).



**Figure 2.** Barriers faced by health care providers when supporting patients' dietary adherence (N=21).



**Figure 3.** Barriers faced by health care providers when supporting patients' medication adherence (N=21).



## Participant-Perceived Factors That Affect App Adoption

### Patient-Related Factors Affecting App Adoption

Participants described several factors that may affect the use of mobile apps by patients with HF, including *patient age, access*

*to mobile phones and internet, how technology savvy patients are, physical and cognitive function of patients, and their level of engagement in HF self-management.* Participants viewed apps as being more favorable among “younger” patients with HF, suggesting that the majority of patients with HF were older adults (aged >70 years), and thus they would be unfamiliar with using technology. One participant stated as follows:

*I don't like to peg people into categories, but certainly it seems like the younger crowd for which is like 50s, 60s, they might be the ones more interested in using [apps]. We certainly have a high number of elderly, or frail elderly in our clinic so a lot of them aren't, you know, on email or internet or things like that.* [Participant 9]

In addition, characteristics associated with aging, such as decline in physical and cognitive functioning, were considered barriers to app use. There was also concern that patients may lack access to mobile phones and internet needed to use apps, particularly in northern and rural communities. Participants expressed that some patients may lack motor function, have arthritis, be missing digits, have difficulty with their vision, or experience cognitive challenges, which would impede their ability to use apps. Participants also identified that adoption of apps required a certain level of motivation from patients and that those who are highly engaged in HF self-management would likely benefit from using such tools.

### **HCP-Related Factors Affecting App Adoption**

HCPs' buy-in and familiarity with HF apps as well as level of time, compensation, and workload burden for HCPs were perceived as factors that may affect their app use. Although some of the participants had experience using mobile apps in their clinical practice to monitor patient care, the majority were unaware of credible HF management apps to recommend to their patients. Moreover, buy-in from HCPs and clinical staff may be a challenge to app adoption in the clinical setting. A participant observed as follows:

*I don't know how we've gotten to this place but so many people are, they are negative nellys. They are not willing to try new things, because "oh, it's not going to work," "oh I've seen this, it's not going to work." How do we know unless we try? It's something new. Technology is where it's at, we all know that. So, I think the buy-in from staff is going to be part of the challenge.* [Participant 11]

Participants indicated that the time and workload required to teach patients how to use the app, interacting with patients through an app interface, and interpreting patient data from an app may interfere with app use. If app use was time consuming, it was felt that a lack of compensation for their time can prevent HCPs from using apps in their clinical practice. One participant stated as follows:

*If I need to spend hours in each clinic appointment educating the patient on how to use it [app], it's going to fall at the first hurdle. I don't have the time; I don't have the money.* [Participant 13]

### **App-Related Factors Affecting App Adoption**

The perceived app-related factors affecting adoption included information provided by apps, user-friendliness of apps, level of technical support and guidance provided for app use, app availability across multiple devices, level of privacy and protection for patient information, and integration into clinical practice and health care system as well as language and costs associated with app use. Participants felt that apps providing

personalized and tailored information to patients were valuable compared with apps presenting generalized information about HF. Apps also need to provide simple, practical, and meaningful information as well as be easy to use, simple, user-friendly, and compatible with different types of devices and platforms (smartphones, tablet devices, and web). Moreover, technical support and reasonable support and guidance on how to navigate the app should be provided. Participants felt that HF apps need to be encrypted, safe, and secure to ensure confidentiality of personal information. In addition, it would be beneficial to have apps be integrated into practice and the health care system, including the hospital, care team, and electronic medical records. A participant made the following observation:

*Now to use it [app], our whole team would have to adopt it. Meaning they would have to have a consensus on its use and then if we wanted to have data sent to us then obviously, that would be a whole system, how do you receive this information, how do you use this information, what's the protocol for receiving it and then acting on it, type of thing.* [Participant 6]

By contrast, some factors were identified as barriers to app use. Participants felt that language can be a barrier because not all patients with HF may be comfortable using apps that are primarily in English. Costs involved in downloading and using apps were also seen as a barrier. In addition, participants were concerned that the use of technologies such as apps may promote the use of appointments via telephone or videoconference, which they feel can be challenging because of the lack of in-person interaction.

### **Improved Delivery of Care**

Most participants felt that apps may positively affect their ability to provide remote and timely care, including remote monitoring, titration of medications, and check-ups, all of which may allow for timely delivery of care. It was also viewed that by providing opportunities for remote care, apps could limit clinic visits and save patient time and resources, including travel and parking costs associated with clinic visits. It was expressed that sometimes patients face difficulties with scheduling and clinic appointment travel; thus, apps may make care more accessible. One HCP provided an example of how an app supported remote care in their practice:

*Well for example I have a specific patient that is on [name of app]...cardiac failure that is related to myeloma, but [patient] is very sick and is on chemotherapy so by using the app I have been able to keep [patient] at home without coming to hospital. I don't know how much time they have, but the family is really happy that [patient] stays at home. And we have been asking for weight changes very quickly to try to keep them at home.* [Participant 1]

Apps may also provide additional benefits when compared with traditional telehealth services. A participant expressed the following view:

*The benefit is for sure we have maybe more information than the usual phone call. So, if you can*

*incorporate things that the patient can, let's say, send a picture or sharing how they look like. So, we have that visual, you know, presentation in front of you.* [Participant 7]

In addition, they can potentially *collect and assess real-time health information and prevent adverse events*. Participants felt that apps can collect real-time and day-to-day data on HF signs and symptoms that can be shared with HCPs, as needed. Specific data considered important by participants were weight, blood pressure, common HF symptoms (ie, swelling and shortness of breath), step count, and daily sodium and fluid intake. Apps could allow HCPs to gauge trends in these data to better assess the patient. An HCP stated as follows:

*It's also helpful to have the data when the patient comes to clinic because we can clearly sort of go back and say, "hey you know, this is what trend of this vital sign has been" and that's helpful information when you're seeing someone.* [Participant 3]

Participants felt that, ultimately, by being able to collect, share, and assess health information remotely, apps have the potential to identify worsening clinical signs and symptoms and precipitating factors for adverse clinical events, allowing for early intervention and the prevention of HF hospitalizations. A participant made the following observation:

*The device would let the attending physicians know when the patient was not doing that well...maybe some complications could be caught on time before they got really sick.* [Participant 17]

In addition, it was perceived that apps that use artificial intelligence could alert HCPs of patients who require immediate care. One HCP stated as follows:

*...patient-reported symptoms that are algorithmically determined at which point they create an alert...so you know worsening clinical symptoms create an alert that alert is then sent to a nurse or physician.* [Participant 15]

### Facilitating Patient Engagement in Care

Participants felt that apps can be used to *foster independence, awareness, and confidence* among patients because they can *support establishment of health goals and provide feedback and reinforcement*. Apps could encourage patients to take "ownership of their disease" and "empower" them to engage in self-care activities. In addition, they can allow patients to have awareness of their disease and health status. It was expressed that apps can support patients in goal setting and "guide them to make SMART goals" (ie, goals that are specific, measurable, achievable, relevant, and timely), as well as challenge patients in improving their health behaviors over time. A participant noted as follows:

*I think it's a great example that maybe you set a goal, okay so yesterday I can walk about a block before I'm getting shortness of breath maybe today let me try to walk one and a quarter block and see how I feel something like that.* [Participant 18]

Moreover, participants felt that apps present an opportunity for patients to "have ongoing reinforcement of the heart failure education of the diet and medication that are recommended for them." Apps can also generate automated feedback for patients based on their HF symptoms and specific medication and dietary intake behaviors that would otherwise be difficult to provide during clinic visits. Participants made the following observations:

*...so that way they would have feedback, you know, "this week you actually missed your medication three times." Perhaps prompting with a screen that says "you require a compliance of at least 90% to see effectiveness in this goal, this goal and this goal." So, kind of providing them with some research feedback.* [Participant 21]

*...you can say did you know that the choices, the ones you made are more higher in salt or you know you can give them more feedback, that structure is hard to do one on one in person visit.* [Participant 19]

Several participants thought that app adoption for HF management can *facilitate connection and communication between patients and their HCPs*. This could include the incorporation of a messaging feature for patients and HCPs, which can serve as a more efficient communication method than traditional telephone calls. An HCP commented as follows:

*...having the possibility of communicating with patients outside of phone call could be very helpful, a way to just send message that could be faster than having us to call back to answer questions or to confirm an information.* [Participant 4]

This type of communication may allow patients to write down questions in real time and engage in back-to-back communication with their HCPs, which can lead to more open conversations about their care. A participant observed as follows:

*Also, it may allow patients to kind of write down questions or they may be more open to discussing, what their intents are in the written form as opposed to face-to-face and they don't have to think about it. So, it's that extra time, it's not done by, for instance, where they have messages that go back and forth or what have you. It can allow them to kind of open up more, to think more about what they want to ask, and what kind of care do they want to have in the future.* [Participant 5]

One of the frequently mentioned opportunities for the use of HF mobile apps was that they can help patients *monitor and track self-care activities and indicators*. Participants felt that it may be beneficial if HF apps allowed patients to track their diet, including sodium and fluid intake, through manually entering food intake and scanning food labels. Participants stated as follows:

*I think what would be very valuable is a way to actually track, the way that um the way that weight loss apps track you sort of have an ongoing diary of how much you eat and then it spits out your calories*

*similarly, I think having um an ongoing tracking system of fluid intake would be particularly useful.* [Participant 15]

*So, I think putting in milligrams of sodium is a nice way in some kind of visual way where a lot of what looks like a battery and it's full at the beginning of the day and that represents your 2000 mg and then you have breakfast and you can sort of calculate it, depending on how good or bad you are at that, and then it's going to deplete some of that energy or sodium allowance per se.* [Participant 6]

In addition to tracking dietary intake, participants also saw opportunity for an app to track patients' physical activity (ie, step count) as well as patient symptoms (ie, daily weight, blood pressure, and pulse). It was suggested that an app for HF can be linked directly to other apps that track symptoms, diet, or exercise (eg, MyFitnessPal), allowing patients to have all information in "one spot."

### Providing Patient Support Through Education

Apps were viewed as a medium for patients to obtain *access to resources*. This included information about HF, HF guidelines and symptoms, and mental health support. Some of the participants felt that HF management resources available on the web (eg, the Heart and Stroke Foundation of Canada website) would be beneficial to patients in an app form because apps can present information in a more engaging way through visuals, interactions, and videos. One participant saw a unique opportunity for apps to tailor patient resources based on their geographical location:

*I was thinking about an app and how great it would be if that app you could plug in your geographic location and it would give you local access or national online access to information on any types of events, webinars, support groups.* [Participant 6]

A commonly perceived benefit to using an app for HF management was the potential for apps to facilitate *nutrition-related education*. As sodium restriction was a focal point of dietary education for HF management, it was felt that an app could teach patients about sodium intake recommendations, common dietary sources of sodium, and the sodium content in foods. Dietary potassium was also identified as an important part of education for patients with HF. Participants made the following observations:

*Salt restriction, giving them an idea of you know how much salt is recommended and then an example of what you know I always give this example to my patients the limitation is 2000 mg a day for the cardiac and a dill pickle is 550 so a quarter of the salt intake is in one dill pickle. So, it gives them real perspective.* [Participant 16]

*...kind of a dictionary where they could enter the name of food and see how much sodium...so they could see that oh well a bag of pretzel is 2 grams of salt and realize oh no I should not eat that because of the salt in it.* [Participant 4]

*...foods that would be high in potassium, so sometimes our patients have higher potassium that limits our ability to get them on guideline directed medical therapy or up-titrated and so knowing what foods were higher in potassium might be helpful because if we said to the patient "we want you to eat foods that are lower in potassium," they always want to know what those are.* [Participant 3]

Apps could also support food skills development such as reading food labels on packaged foods, food preparation, and "culinary literacy." It was also identified by several participants that apps can have information to guide patients about foods to consume versus foods to avoid, as well as provide dietary tips (eg, managing sodium intake on cheat days and managing dry mouth), acceptable low-sodium substitutions, and low-sodium recipes:

*But if there would be little tips and tricks on things, if you have to buy canned green beans just rinse them off. Get rid of a lot of that sodium. Have tips like that on there...I think would be very helpful for people.* [Participant 11]

Providing *access to medication-related information* was another perceived benefit of apps. Multiple participants identified that patients may be better adherent to their HF medications if they are aware of the purpose for which the medications are prescribed and the "risk of skipping a couple of doses":

*...you know, in a much more basic level, why you are taking these drugs and why you are not to stop your ramipril just because your systolic only 100, you feel fine and you're not dizzy and you keep taking it because it's not for blood pressure...so having a bit of content in the background of why these medications are helpful, I think would be a little bit important for content inclusion for an app.* [Participant 6]

*...benefits of the medication, like a little blurb on why it is important that you take this medication, and all the ACE [angiotensin-converting enzyme] inhibitors decrease the mortality of HF by 30%, those things help the patient to be compliant.* [Participant 4]

Other medication-related information considered beneficial included a personalized medication list with relevant information such as name (ie, brand and generic drug names) and dosage as well as information on medication interactions and side effects for prescribed and over-the-counter medications. Participants stated as follows:

*Common side effects that they may anticipate, from the different families. You know they can go into ACE [angiotensin-converting enzyme] inhibitors, beta blockers, MRAs [mineralocorticoid receptor antagonists], they can go with all those different categories and look at, and self-education about the medication they are on so they know about it and know what side effects could possibly come up.* [Participant 8]



*...interaction of medications is always a useful thing to have, especially over the counter and the normal medication. [Participant 5]*

### Participant Views on App Features for Their Patients

App features perceived by participants as useful for patients included *gamification, reminders and alarms, and food scanners*. Participants had mixed views on the gamification of apps. Some of them felt that gamifying an app for HF may appeal to certain patients and if designed well it can be “fun,” “enjoyable,” “engaging,” and “interactive,” which can promote learning. One such example was embedding quizzes into the app that test patient knowledge on disease management. Other participants questioned the benefits to incentivizing someone’s health and whether patients would want to play a game, viewing it as an added task. A participant stated that they had “never seen a successful cardiovascular gamification in an app.” It was noted that gamification can be an attractive feature, especially for “young” patients with HF; however, it may be “demeaning” or not suitable for patients with HF, who are on average older. The HCPs felt that if an app for HF were gamified, it needs to be designed in a “mature” way. Participants made the following observations:

*Obviously like, interaction helps to promote education at all ages. You might have a hard time getting buy in from the older population. Just because you get that “I’ve been alive for 80 years I know what I am doing” type of thing. But that’s okay it’s never perfect for everybody. But I think would help with engagement. [Participant 6]*

*I think it’s great. My kids use educational apps that are kind of in a game format. So, I think it has a purpose. The question is, how do you do it for a mature adult? You know, are they going to find it too childish or are they going to actually enjoy it? If it’s done well, I think it’s great to keep patients engaged potentially. [Participant 5]*

*You know our population is elderly, they are frail, English is another language of theirs, they are hard of hearing, they are visually challenged. So, yeah. I mean they are not playing cards on their phones. [Participant 20]*

Participants expressed that integrating reminders and alarms in an app to reinforce daily weighing, fluid intake, and exercise as well as prescription refills and physician’s appointments would be helpful. Nearly all participants agreed that reminders in an app for taking pills would be useful for patients, with some suggesting the option for patients to personalize the reminders and alarms (ie, turn them off). It was mentioned that patients are often prescribed multiple medications, to be taken multiple times a day, for their HF as well as other comorbidities; thus, they may have difficulties with medication adherence because of forgetfulness. One HCP commented as follows:

*I was thinking about the medications. Like trying to make it compliant for the patients with their medications. If there was some sort of alarm, you know, within the app that would automatically remind*

*them: “Okay it’s time to take your pills.” [Participant 11]*

Another feature that participants considered useful in an app was the integration of a food scanner, whereby patients can take a picture of their food plate or scan a food label (ie, nutritional facts table), which will then display nutritional information such as sodium content and calories:

*I think it’s important, you know, the scanning of labels and then that calculates your salt content based on serving size and that would be a visual reminder of how much salt is actually in that and I think that when people scan enough labels, they’ll realize what they can and cannot eat. [Participant 14]*

## Discussion

### Principal Findings

To our knowledge, this is one of the first studies to determine the perspectives of HF cardiologists, nurses, and nurse practitioners on the use of mobile apps for HF management. Overall, participants had positive views about using mobile apps to support their patients with managing HF. They identified factors affecting app adoption (eg, patient age and technology access) and opportunities for app use, such as improving delivery of care, providing patient support through education, and facilitating patient engagement in care. App features such as gamification and quizzes were also identified by participants as being useful for patients. Our findings support previous research reporting that mHealth apps have the potential to be cost-effective interventions that optimize provision of care and support patients in HF self-management [22,25].

Perceived factors affecting app adoption related to the patient, clinical practice setting, and the apps themselves are consistent with findings from past studies [37-39]. One of the most frequently mentioned factors that affect app adoption, as perceived by our participants, was patient age. Findings from several studies also cite age as an individual-level factor affecting acceptance and use of mHealth apps [37,40-42] because most individuals using such technologies are often younger (aged <35 years), with those aged >70 years using mobile apps at the lowest frequency [40]. These findings are explained by Cajita et al [43] who found that older adults (aged ≥65 years) tended to lack knowledge on how to use mobile technologies. Evidence also suggests that older adults’ self-efficacy is low when learning to use mHealth apps [44]. Despite such findings, smartphone ownership among people with HF is relatively high among all age groups (eg, 84% in those aged 50-64 years), with older patients with HF also showing willingness to use mHealth apps to support HF management [45]. As the use of mHealth technologies for health-related activities is an emerging field, it is expected that older adults may face some difficulty and require support when using apps for HF management. However, the capability of patients with HF to use mobile apps should not be based on age alone; rather, factors associated with aging, such as visual impairment and cognitive dysfunction, may be more influential in the use of apps to support HF management. Regardless, accessibility features to accommodate users with special needs

should be considered when designing and developing apps. It is imperative to keep this in mind to close the digital divide among older adults and promote more equitable use and distribution of mHealth technologies [43,45].

A lack of time and workload burden for HCPs as well as the ability of an app to be integrated into clinical workflows were identified as factors influencing app adoption for HF management, particularly for apps that have features for clinical monitoring and patient-clinician interaction. These data are supported by 2 recent reviews, where increased work and responsibilities as well as lack of integration with electronic medical records were among the most frequently identified clinician-level barriers to digital health adoption [38,39]. The majority of mHealth tools for HF management focus on telemonitoring, which HCPs consider to be time and resource intensive because these tools can produce more web-based data, additional administrative work, and increased communication and interactions with patients [29]. It is unknown whether mobile apps supporting various other functions such as education and behavior change have similar challenges within the context of HF management, although several of these workload concerns may be common when using technology for health care delivery in general. HCPs may also need to provide patients with training to support the use of mHealth tools, a concern identified by participants in our study. Evidence suggests that clinicians are less likely to adopt mHealth technologies if they believe that such tools do not reduce their workload [46,47]. This has direct impact on mHealth uptake among patients because patient adoption of these tools is often dependent on HCPs' recommendations [48]. To address HCPs' concerns regarding mHealth workload, it is imperative that they are recognized as stakeholders in mHealth technology development and implementation. In line with recommendations by Davis et al [49] and Radhakrishnan et al [50] for remote monitoring and telehealth technologies, we emphasize the importance of involving HCPs during the design, development, and implementation stages of mHealth apps to maximize the relevance and usability of such apps, which can result in overall better uptake and adoption. Moreover, practicing and in-training HCPs should receive adequate education on the use of digital health technologies [38] to increase their familiarity and comfort with such tools, which can increase their acceptance and uptake [51]. Proper integration with electronic medical records and clinical workflow can also facilitate mHealth app adoption [38,49].

Participants in this study saw several opportunities for using apps for HF management. Notably, participants felt that apps can support patients with HF by providing access to dietary and nutritional information as well as medication-related information. However, by contrast, most HF management apps are focused on daily monitoring of symptoms, with only a few addressing diet and medication [24,25,52]. Moreover, of the apps that include diet and medication, the focus is on tracking behaviors, and these apps fail to incorporate key diet- and treatment-related knowledge and skills, such as low-sodium diet and interpreting food labels as well as information on medication interactions and side effects, which are important features identified by participants in this study; for example,

according to our questionnaire data, 52% (11/21) of the participants agreed that patients have difficulty reading food labels and identifying low-sodium products. Although these are not patient-reported data, this is an indication that HCPs see opportunities for mHealth apps beyond symptom monitoring. Albeit, such objective measures related to diet and medication would be supportive in promoting adherence, facilitating targeted behavior change, and supporting patients in forming fundamental skills and habits for managing HF.

This study uniquely explored HCP perceptions on features that may be useful to incorporate in an HF mobile app. One such feature that was widely discussed was gamification. Gamification is the use of game design mechanics in real-life, nongame environments [53]. The use of game techniques is an effective way to engage, motivate, and sustain health behavior change in individuals [54-56], and such techniques (eg, goal setting, reinforcement, and social connectivity) are closely related to proven health behavior change techniques [53]. However, the use of gamification in mHealth is an emerging concept and is being explored in the context of nutrition, physical activity, diabetes, mental health, and cardiovascular disease, including HF. The perspectives related to gamification for patients with HF in our study were mixed, with some of the participants recognizing that it can be an engaging and participative app feature and others questioning its appropriateness for the older population with HF. Interestingly, Radhakrishnan et al [57] conducted prototype testing of an HF mobile app integrated with contemporary game technology among older adults with HF (aged  $\geq 55$  years) and reported that the HF digital game was easy to play, enjoyable, and helpful in learning about HF and resulted in significant improvements in HF self-management knowledge. This study [57] and others [58-60] suggest the potential of gamification to be an effective medium to increase disease-related knowledge and support self-management of HF, even among older adults [61,62].

## Limitations

Our study includes potential limitations that warrant discussion. Although telephone interviews produce data comparable with those produced in face-to-face interviews, a few limitations to this method of qualitative interviewing exist, including the inability to observe and respond to visual cues, lack of contextual data, and potential challenges to establishing participant-interviewer rapport [33]. Despite these limitations, the use of telephone interviews was favorable in our study because it allowed for geographical flexibility and an efficient cost- and time-saving method that accommodated participants' schedules. Moreover, a part of our data collection period coincided with the COVID-19 pandemic, which may have shifted HCPs' perspectives on the use of technology in clinical practice because of the necessary transition to remote care and telehealth use. In addition, many of our participants were women, albeit the perspectives of cardiologists, nurses, and nurse practitioners were equally represented. The perspectives of HCPs in this study are limited to those of cardiologists, nurses, and nurse practitioners. We acknowledge that other health care professionals such as family physicians, dietitians, and pharmacists may hold different views. Finally, we recognize that our own beliefs and assumptions could have biased study

findings; however, steps were taken to minimize these biases. These steps included expert review of the interview guide, use of multiple data sources (interview and questionnaire), field notes by the interviewer, and independent coding by 2 researchers. We have also presented participant quotes that substantiate our findings and interpretations.

### Conclusions

This study demonstrated that cardiologists, nurses, and nurse practitioners generally have positive views on the use of mHealth apps to support patients with HF management. Several challenges and opportunities for app adoption were also identified. HCPs are gatekeepers of health care delivery; thus,

they are an integral part of the successful adoption and implementation of mHealth technologies in practice. Although HCPs may not be the primary users of mHealth apps, their views on these apps' perceived advantages and their degree of compatibility with patient care and needs combined with the HCPs' unique understanding of what is required to support patients in HF management will influence patients' decision to use such apps for the management of their condition. Our findings support the importance of including the perspectives of HCPs, who are key stakeholders in integrating such technologies into routine clinical practice, in the development and implementation of mHealth apps.

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### Data Availability

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

### Authors' Contributions

BS, ML, and JAA conceptualized and designed the study. SM helped with participant recruitment. BS led the writing of this manuscript and completed data collection and analysis. BS and SG prepared the transcripts. BS and MS conducted independent coding of transcripts. BS, ML, and JAA contributed to the interpretation of data. MS, SM, SG, ML, and JAA provided critical review of the manuscript. All authors read and approved the final version of the manuscript.

### Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide.

[[PDF File \(Adobe PDF File\), 41 KB - cardio\\_v6i2e40546\\_app1.pdf](#)]

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## Abbreviations

**COREQ:** Consolidated Criteria for Reporting Qualitative Research

**HCP:** health care provider

**HF:** heart failure

**mHealth:** mobile health

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Original Paper

# Attitudes of Patients With Chronic Heart Failure Toward Digital Device Data for Self-documentation and Research in Germany: Cross-sectional Survey Study

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## Abstract

**Background:** In recent years, the use of digital mobile measurement devices (DMMDs) for self-documentation in cardiovascular care in Western industrialized health care systems has increased. For patients with chronic heart failure (CHF), digital self-documentation plays an increasingly important role in self-management. Data from DMMDs can also be integrated into telemonitoring programs or data-intensive medical research to collect and evaluate patient-reported outcome measures through data sharing. However, the implementation of data-intensive devices and data sharing poses several challenges for doctors and patients as well as for the ethical governance of data-driven medical research.

**Objective:** This study aims to explore the potential and challenges of digital device data in cardiology research from patients' perspectives. Leading research questions of the study concerned the attitudes of patients with CHF toward health-related data collected in the use of digital devices for self-documentation as well as sharing these data and consenting to data sharing for research purposes.

**Methods:** A cross-sectional survey of patients of a research in cardiology was conducted at a German university medical center (N=159) in 2020 (March to July). Eligible participants were German-speaking adult patients with CHF at that center. A pen-and-pencil questionnaire was sent by mail.

**Results:** Most participants (77/105, 73.3%) approved digital documentation, as they expected the device data to help them observe their body and its functions more objectively. Digital device data were believed to provide *cognitive support*, both for patients' self-assessment and doctors' evaluation of their patients' current health condition. Interestingly, positive attitudes toward DMMD data providing cognitive support were, in particular, voiced by older patients aged >65 years. However, approximately half of the participants (56/105, 53.3%) also reported difficulty in dealing with self-documented data that lay outside the optimal medical target range. Furthermore, our findings revealed preferences for the self-management of DMMD data disclosed for data-intensive medical research among German patients with CHF, which are best implemented with a dynamic consent model.

**Conclusions:** Our findings provide potentially valuable insights for introducing DMMD in cardiovascular research in the German context. They have several practical implications, such as a high divergence in attitudes among patients with CHF toward different data-receiving organizations as well as a large variance in preferences for the modes of receiving information included in the consenting procedure for data sharing for research. We suggest addressing patients' multiple views on consenting and data sharing in institutional normative governance frameworks for data-intensive medical research.

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**KEYWORDS**

mobile health; mHealth; digital devices; wearables; heart failure; data sharing; consent; mobile phone

## Introduction

### Background

This study focused on views and attitudes toward the use of digital device data among patients with chronic heart failure (cHF) in Germany. cHF is one of the most prevalent health conditions in Western industrial societies, where morbidity and mortality rates are high [1]. Patients with cHF are among the patient groups with cardiovascular findings for whom digital self-documentation plays an increasingly important role in self-management. In terms of chronic cardiovascular diseases, German society may be considered a typical Western industrialized country. A key area of research currently focuses on reducing rehospitalizations, which are often associated with worsening syndrome progression [2,3]. In addition to pharmacological interventions and lifestyle changes, patient self-care and self-management are key factors in the overall treatment of the noncurable cHF. As part of cHF self-care, patient self-documentation or self-monitoring plays an important role because it allows the close and continuous monitoring of changes in different vital parameters to prevent possible readmission and allow timely countermeasures [4-11]. Self-documentation consists not only of regular self-monitoring of vital parameters, such as heart rate, blood pressure, and temperature, but also of recording physical activity or body weight [8,11]. In recent years, the use of digital mobile measurement devices (DMMDs) for self-documentation in cardiovascular care and research has increased in Western industrialized health care systems. This includes a range of devices for self-documentation, such as body scales or blood pressure monitors, mobile electrocardiograms, sensor devices, commercially available or medical-grade wearable technologies, and smartphone or tablet apps [12-14]. Throughout the text, we refer to the deployment of DMMDs for self-documentation as *digital self-documentation*, which we use synonymously with *digital self-monitoring*.

The digital self-documentation data of patients with cHF can be shared within telemonitoring programs and in data-intensive studies that collect and evaluate patient-reported outcome measures [15]. To do this, various vital signs are collected and transmitted for data analyses to remote health services, doctors, cardiology clinics, and research institutes. Preliminary evidence suggests that certain telemonitoring approaches have the potential to reduce hospitalization rates and improve the overall quality of life [3,14,16-20]. However, the implementation of data-intensive devices and data sharing pose several challenges for doctors and patients as well as for the ethical governance of data-driven medical research.

The main ethical challenges determined with the use of digital device data are data literacy and consent to the sharing of data gathered from DMMDs for health care and medical research. As per Koltay [21] and Johnson [22], data literacy may be defined as the “ability to process, sort and filter vast quantities of information, which requires knowing how to search, how to

filter and process, to produce and synthesize it.” Concerning digital device data, the question that arises is to what extent patients have those abilities and how well they are able to analyze and handle their own digital health data. Regarding models and ways of consenting to participation in medical research, in recent years, a politically supported shift has emerged in Germany and other European countries contesting the standard model of *informed consent* [23-26] and propagating *broad consent* and *data donation* solutions [27-29]. Although *informed consent* aims to ensure that participants are enabled to make informed choices by disclosing all information about a study, that is, its specific purpose, research question, rationale, and risks, the *broad consent* model grounds on the reuse of patients’ data or biospecimens for various and rather unspecific research questions, aims, researchers, or studies [30-32]. We argue that the aforementioned challenges surrounding DMMD data require further ethical reflection on data-intensive medical research and cardiac care; for this in turn, a more patient-centered perspective is required [33-35].

### Previous Work

#### *Attitudes Toward Sharing Digital Health Data for Research*

In this paper, we present some work that has been carried out in Western industrialized countries, which also form—from a global perspective—the sociopolitical context for evaluating the German health care system and medical research. In the past decade, there has been an increasing number of qualitative, quantitative, and mixed methods studies in Western industrialized contexts that explored patients’ and users’ behaviors, attitudes, and perceptions regarding mobile phone-based health apps. These studies focused on wearable devices [36-39], health apps in general [40-42], and health apps for certain diseases, for example, mental health or chronic diseases [43,44]. Most of these studies aimed to identify facilitators and barriers to the uptake of wearables and apps, such as concerns regarding data security, privacy policies, and individual control over data [45-48]. There is, however, only limited literature concerning public and patients’ views on data practices and procedures within the scope of digital health self-documentation and data sharing for research purposes. The first systematic review of qualitative studies on these topics by Aitken et al [49] reported a general and widespread support for data sharing for research purposes among the public [50]. This depends, however, on the condition that respondents have trust in the individuals and research organizations that receive and analyze their data. These findings were strengthened by a systematic review study on the use of patient data for research in the United Kingdom and the Republic of Ireland carried out by Stockdale et al [51]. They found that the public “evaluates trustworthiness of research organizations by assessing their competence in data-handling and motivation for accessing the data.” A recent focus group study among patients with cardiac diseases in the Netherlands conducted by Wetzels et al [52] revealed that patients were not sufficiently informed about the



aspects of data storage, data use, and access issues; furthermore, they “would prefer to have control over health data and to decide who be granted access and when.” Beierle et al [53] in their observation study also presented a rather complex picture of German smartphone users’ willingness to share their data; in addition to privacy concerns, personality traits, sex, and age were also found to be significant factors for refusing data sharing (N=461). In addition, according to a web-based survey of German students (N=682) and an analysis of data from the US Health Information National Trend Survey (N=2972-3155) by Kriwy and Glöckner [54], factors of self-declared poor health condition and a high level of education increased the willingness of patients to disclose device data on the web to their physicians or medical staff.

### **Consent Models for Data Sharing for Medical Research in Germany**

Richter et al [55] conducted 4 seminal survey studies regarding consent models for sharing digital health data for research, in which they investigated attitudes toward broad consent and *no consent* policies in Germany (3 studies) and the Netherlands (1 study). The results of these studies are presented in 3 papers [29,55,56]. The first study was a delivery-and-collection questionnaire survey conducted between 2015 and 2016 in which 760 adult patients at an outpatient clinic for inflammatory conditions at the University Hospital Schleswig-Holstein, Campus Kiel were invited to participate. It focused on the comprehensibility of the provided broad consent form and informational brochure as well as motivations to agree to broad consent for health care–embedded biobanking [56]. This study design was repeated in 2018, inquiring into attitudes toward routine clinical care data for secondary use for scientific research without consent in line with the General Data Protection Regulation by the European Union (Regulation 2016/678G EU, EU-GDPR, §27; the final data set consisted of 503 patients) [29]. Both studies reported high willingness to provide a broad consent for hospital-based biobanking (661/760, 86.9%, and 468/503, 93%). In addition, the second study reported that three-fourths of the patients (381/503, 75.7%) supported a *no consent* regulation—sometimes called *data donation*—for medical data processing. This regulation is in accordance with the current German law under certain conditions [29]. Finally, a telephone-based population survey (N=1006) carried out by the Technology, Methods, and Infrastructure for Networked Medical Research and the German Forsa Institute in August 2019 in Germany largely confirmed these findings [55].

### **Objectives**

This study explored the potential and challenges of digital device data for cardiology research. Key questions concerned patients’ attitudes toward health-related data collected using DMMDs for self-documentation, sharing health data and consenting to data sharing. To address these questions, this study was conducted. The results can provide empirically based ethical recommendations for the future development and implementation of DMMD and consent solutions for data-intensive cardiology research. To our knowledge, no previous study has focused on the attitudes of patients with CHF toward sharing DMMD data for research.

## **Methods**

### **Study Design**

A cross-sectional survey of patients with CHF was conducted from March to July 2020 at the University Medical Center Göttingen (UMG). The survey was embedded in a wider comparative study that aimed to cover cardiovascular patients’ views and attitudes on DMMD data use. Considering the ongoing development of digital devices and mobile health apps in the domain of cardiovascular diseases, the questionnaire was neither device-specific nor app-specific and included diverse DMMDs in cardiovascular care and research. The survey study forms a substudy of the HiGHmed Use Case Cardiology (HiGHmed-UCC) project, an ongoing noninterventional, nonrandomized, multicenter registry study covering patients with CHF [57,58]. For HiGHmed-UCC, patients with CHF were recruited at the UMG. Patients were recruited either during routine visits to the heart failure outpatient department or during their hospitalization in the cardiology ward at the UMG. They provided informed consent to allow recall for further studies. This, in turn, was a condition for participating in the survey. The inclusion criteria for patients participating in our survey were those used for HiGHmed-UCC, that is, adults aged  $\geq 18$  years, German-speaking, diagnosed with CHF, capable of providing consent and expected to survive for  $>6$  months, and consented to inclusion in HiGHmed-UCC.

### **Ethics Approval**

The HiGHmed-UCC and survey study were approved by the local Human Research Review Committee at the UMG (reference 21/9/18 and 28/7/18). For the survey study, no ethical and legal concerns were identified.

### **Questionnaire and Survey Items**

The survey questionnaire consisted of 66 questions or items. As a literature search for suitable questionnaires proved fruitless, we decided to construct a largely new questionnaire for our research purposes. The lack of suitable items, especially regarding attitudes toward self-documentation, digital devices, and digital device data, required *de novo* construction of 53 of 66 items specifically for this survey. The remaining 13 items were drawn from preexisting questionnaires or publications and modified for our purposes. [Multimedia Appendix 1](#) [59,60] lists the items presented in this paper and the original versions of the modified items. Owing to the preponderance of nonvalidated, newly constructed items, we took the following measures to ensure the integrity of our questionnaire: during the questionnaire development process, survey items were repeatedly discussed within the HiGHmed ethics team in Göttingen and reviewed by Bioethics colleagues for comprehensibility and consistency. In addition, we conducted a pretest to improve the applicability of our questionnaire.

In the questionnaire, questions with one or multiple-choice options were included, and 6-point Likert scales for questions regarding patient attitudes were also included. This paper presents the results of items addressing the following topics: attitudes toward self-documentation and digital devices as well as self-documentation behavior and use of digital devices in

daily life, attitudes toward digital device data and data sharing for research purposes along with data sharing conditions (modes of consent), attitudes toward medical research in general, and sociodemographic characteristics (age, gender, education, occupation, number of chronic diseases, and impairment due to diseases; [Multimedia Appendix 1](#)).

### Pretest

We conducted a pretest (N=11) with laypersons to check the general comprehensibility and feasibility of our questionnaire and detect potential problems with the items or questions included [61]. The age of the pretest participants ranged from 28 to 75 years (mean 60, SD 13). We included older adults to mirror the reality of most patients with CHF and cardiovascular diseases in Germany. On average, it took the pretest participants 32 minutes to complete the questionnaire. Suggestions for improvement and participants' impressions regarding the comprehensibility and order of the items from the pretest were considered in the revision of the questionnaire.

### Recruitment and Sample

In the view of the ongoing global COVID-19 pandemic, eligible HiGHmed-UCC patients were contacted remotely by phone and informed regarding the survey and its purpose. We sent an information flyer and a questionnaire by mail to those who voiced their interest in participating. We tried to contact 190 patients, of whom 179 (94.2%) were finally approached. Of these 179 patients, 159 (88.8%) showed interest in our study and were sent the survey documents. Participants filled out the questionnaire at home. Overall, we received 108 completed questionnaires. Thus, a high level of participation was achieved (response rate: 67.9%). To participate in our survey, all participants had to provide a signed informed consent form containing a data protection declaration. [Multimedia Appendix 2](#) provides an overview of recruitment and inclusion procedures.

### Statistical Analysis

Before conducting the statistical analysis, the 108 questionnaires were examined for completeness, and questionnaires with >30% missing data were excluded, which is an accepted cut-off mark in the literature [62]. After completing this examination, 105 questionnaires were included in the statistical analyses. We conducted descriptive statistics for all the items. Furthermore, we tested for differences in the attitudes toward self-documentation between sociodemographic groups. For the statistical analysis, age and subjective state of illness were grouped into binary categories. The age range was grouped into

<65 and >65 years, drawing on the definition of a recent United Nations definition of *older persons* [63] and age for retirement in Germany. Subjective state of illness was grouped into mild (1-5 on a 10-point scale) and severe (6-10 on a 10-point scale). We carried out 2-tailed *t* tests to detect significant differences between the 2 groups. To detect inhomogeneity of variance, we conducted a Welch test. In cases lacking a normal distribution or in those where it could not be assumed owing to the size of the groups, we applied the nonparametric Mann-Whitney *U* test. To test for significant differences among >2 groups, we used the nonparametric Kruskal-Wallis test because the requirements for one-way ANOVA were not met. In this case, the Monte Carlo significance was reported. Post hoc testing was performed using the Dunn-Bonferroni test. Statistically significant differences between groups that showed no statistical significance after post hoc testing are not reported in this paper. Statistical significance was set at  $P < .05$ . All statistical analyses were performed using the SPSS software for Windows (version 26; IBM). Within the scope of this paper, we focused on descriptive analyses of the selected items dealing with the topics of DMMD data for self-documentation, research, and consent preferences.

## Results

### Sample Characteristics

The mean age of the participants was 65.12 (SD 10.952; range 35-85) years. Of the 104 patients, 76 (73.1%) were men and 28 (26.9%) were women. The largest number of respondents declared to have completed lower secondary school (41/105, 40%), followed by secondary school (24/105, 22.9%), higher secondary school examination (*Abitur*; 22/105, 20.9%), and advanced technical college entrance qualification (15/105, 14.3%). A small number (2/105, 1.9%) of participants dropped out of school. A total of 66.7% (70/105) of the participants had retired at the time of the study, 22.9% (24/105) were working, 6.7% (7/105) were homemakers, and 3.8% (4/105) declared an alternative occupation status. Regarding the number of chronic diseases, 38.5% (40/104) of the participants claimed to have 1 to 2 chronic diseases, 37.5% (39/104) reported 3 to 4, and 24% (24/104) reported  $\geq 5$ . Almost half of the sample (45/105, 42.9%) disclosed mild disability owing to their disease, whereas the other half (60/105, 57.1%) experienced severe impairment in daily life. [Table 1](#) provides an overview of the sociodemographic and health characteristics of the sample.

**Table 1.** Sociodemographic and health characteristics of the sample (n=104-105).<sup>a</sup>

Characteristic	Value, n (%)
<b>Gender (n=104)</b>	
Female	28 (26.9)
Male	76 (73.1)
<b>Age (years; n=105)</b>	
<65	51 (48.6)
>65	54 (51.4)
<b>Education (n=105)</b>	
No education or dropout	2 (1.9)
Lower secondary school examination (Hauptschulabschluss)	41 (40)
Secondary school examination (Realschulabschluss)	24 (22.9)
Advanced technical college entrance qualification (Fachhochschulreife)	15 (14.3)
Final secondary school examination (Abitur or Hochschulreife)	22 (20.9)
<b>Occupation (n=105)</b>	
Working	24 (22.9)
Retired	70 (66.7)
Homemaker	7 (6.7)
Other	4 (3.8)
<b>Chronic diseases (n=104)</b>	
1 to 2	40 (38.5)
3 to 4	39 (37.5)
>5	24 (24)
<b>Impairment from diseases (n=105)</b>	
Mild	45 (42.9)
Severe	60 (57.1)

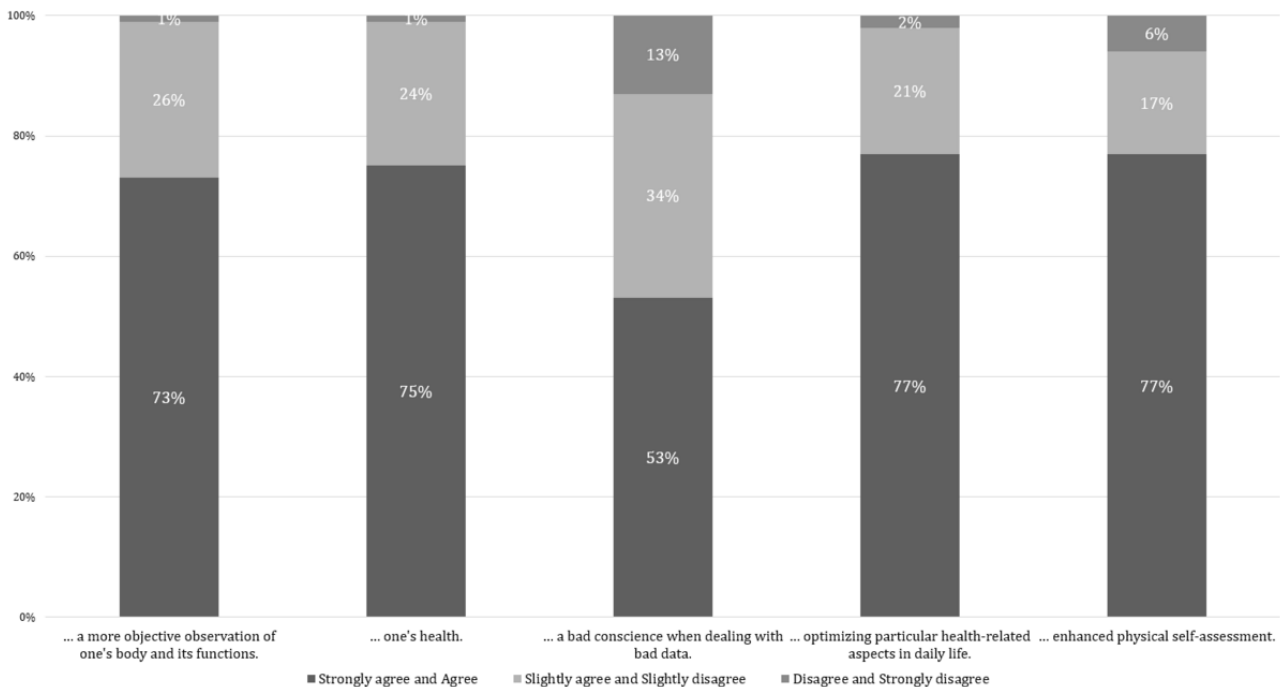
<sup>a</sup>Variance in the sample set was due to incomplete person-related data.

### Attitudes Toward Self-documentation and Device Data

Half of the participants reported performing self-documentation (53/105, 50.5%), and 55.2% (58/105) of the participants were using a digital device at the time of the survey. One-third (16/46, 35%) of the patients who did not use a digital device at the time of the survey had previously tried using a device.

In terms of general attitudes toward self-documentation, 73.3% (77/105) of the participants stated that self-documentation helps in observing the body and its functions more objectively. Moreover, 77.1% (81/105) of the participants felt that self-documentation enhanced their overall physical self-assessment. The vast majority (79/105, 75.2%) of the

participants found self-documented data to be health promoting, and 77.1% (81/105) of the participants stated that it helped to optimize health-related aspects of daily life. Approximately half of the participants (56/105, 53.3%) reported discomfort when confronted with self-reported data that lay outside the optimal medical target ranges. [Figure 1](#) provides an overview of the results. The main reasons for digital self-reporting by survey participants were as follows: 54% (31/58) wanted to improve their health, 45% (26/58) wished to provide health-related data for their doctors, 41% (24/58) required health-related data for themselves, and 40% (23/58) sought a better understanding of their body and its functions. In general, most participants (80/105, 76.2%) assumed that DMMD data would help doctors better understand their patients.

**Figure 1.** Attitudes toward self-documentation (n=105).

### Factors Influencing Attitudes Toward Self-documentation

Statistical analysis showed significant differences between younger and older participants regarding 4 of the 5 items that addressed general attitudes toward self-documentation. Older participants (aged >65 years) considered that self-documentation aided observing the body and its functions ( $P=.006$ ), enhancing overall physical self-assessment ( $P=.001$ ), promoting health ( $P=.008$ ), and optimizing certain health-related aspects in daily life ( $P=.03$ ; [Multimedia Appendix 3](#)). No statistical significance was found between younger and older participants regarding negative emotions when dealing with self-documented data that lay outside the optimal medical target ranges ( $P=.41$ ). Further statistical analysis revealed no statistically significant differences in terms of sociodemographic groups of gender, chronic diseases, and impairment.

### Attitudes Toward Sharing Device Data for Research

#### Characteristics of Data Sharing and Consenting

First, the overwhelming majority of participants (99/105, 94.3%) expressed a positive attitude toward medical research. When asked about concerns regarding personal DMMD data use in medical research, one-third of the participants feared data leakage (33/103, 32%) or its abuse (39/104, 37.5%). Most participants (65/104, 62.5%) believed that data protection regulations provided by the current German law were adequate. Nonetheless, the anonymization of personal digital device data was deemed important by the vast majority (87/104, 83.7%) of participants. In terms of consent, 83.7% (87/104) of the participants considered one-time information or education about sharing DMMD with medical research sufficient. By contrast, only 54.8% (57/104) of the participants considered receiving general information about the respective aims of medical research without detailed information about individual research

projects sufficient. Most participants wanted to access shared digital device data (79/105, 75.2%) as well as have the option to delete some or all of the shared data (71/104, 68.3%). More than half of the participants (62/104, 59.6%) could envisage nonprofit organizations assuming the management of their shared digital device data. Few participants (16/104, 15.4%) feared discrimination due to research findings to which they had contributed.

#### Strong Difference Between State-Funded and Private Organizations

Participants were asked whether they would agree to share their data with various organizations and actors. Almost all participants approved sharing data with their family doctors (99/105, 94.3%) and state-run research institutions (97/105, 92.4%), whereas only 33.3% (34/102) of the participants agreed to share data with private research institutions, and 33% (34/103) of the participants agreed to share data with collaborative projects involving private corporations and state-run research institutions. Only few participants (17/101, 16.8%) would share DMMD data with public authorities. Just over a third (36/102, 35.3%) of the participants would share their DMMD data with public health insurance companies, whereas only 23.1% (24/104) of the participants would share the same data with private health insurance companies. Remarkably, few participants (13/102, 12.8%) agreed to share their digital device data with smaller companies, and even fewer participants (9/103, 6.7%) agreed to share their digital device data with large international companies. [Multimedia Appendix 4](#) presents the summary statistic on attitudes toward data-receiving organizations and actors.

## Discussion

### Principal Findings and Comparison With Previous Work

This study examined the attitudes of a sample of patients with CHF in Göttingen, Germany, toward digital self-documentation and sharing of DMMD data with research institutes. Here, we focus on 3 key study findings. First, the results showed positive attitudes overall toward self-documentation among patients with CHF. Second, there were high expectations of DMMD data provision, which we propose to call *cognitive support* for the patients and for doctors to improve understanding of their patients' health conditions. Third, the findings indicated a range of preferences and needs in terms of features and requirements for consent in the context of sharing DMMD data for research.

### Affirmative Attitudes but Also Emotional Stress Toward Self-documentation in Case of Irregular Data

Notably, most participants (74/105, 70.5%) had experience of digital self-documentation, either formerly (16/105, 15.2%) or at the time of the survey (58/105, 55.2%). This indicates a widespread openness toward conducting digital self-documentation among the patients with CHF surveyed. In support of this finding, our study showed an overall positive attitude toward self-documentation, with three-fourths (79/105, 75.2%) of the participants stating that self-documentation would promote one's health and help to optimize health-related aspects of daily life (Figure 1).

As one-third of the patients (16/46, 35%) not performing digital self-documentation at the time of the survey had given up previous DMMD use, the potential of digital self-documentation turned out to be limited accordingly. Interestingly, for just over half of the participants yielding health data outside the normal range, this was accompanied by worries leading to mental and emotional stress. Statistical analysis showed no significant difference between younger and older participants in this respect. This finding suggests that negative feelings due to irregular data potentially affects all patients. Our result is consistent with those of other studies reporting that the negative mental impact of *abnormal data* can accompany device use [64,65]. Thus, digital self-documentation can potentially pose a significant burden for self-care [66]. Sjöklint et al [67] found that emotional tensions occurring due to reflecting on personal device data may promote neglect of device use and even induce its complete rejection. As approximately half of the patients with CHF experienced emotional stress, this poses a considerable challenge for DMMD use.

### Digital Self-documentation Data as Cognitive Support for Patients and Doctors

Our results reveal further interesting aspects. Many of our participants not only had high expectations of health promotion but also believed that self-documentation could enhance their knowledge base for understanding (77/105, 73.3%) and assessment of their own bodies and health conditions (81/105, 77.1%). Thus, data-intensive self-documentation was ascribed as *cognitive support*. As we had no items that asked for what we term *cognitive support*, it is a concept that we introduced

when we interpreted the collected data from our survey. The effect of cognitive support, as we understand it, was considered to serve patients by increasing self-understanding and improving self-assessment and the doctor-patient relationship owing to an enlarged database. It is also striking that almost half of the patients conducting digital self-documentation stated that they did so to provide health-related data for their attending doctors. A possible explanation for this might be that these patients consider DMMD data to provide doctors with more precise information about their physical condition, thus improving their quality of care. These results are consistent with those of Tran et al [39], who also found that many patients believed that the use of biometric monitoring devices would improve caregivers' work (21%) and communication (17%). Our statistical analysis showed that especially older and retired participants considered self-documentation and device data valuable for self-assessment and self-understanding and thus offered cognitive support. This is surprising because older people are often reported to need detailed training and intensified support when dealing with new digital technologies [68-70]. Against this backdrop, our findings indicate a gap between actual digital device use and public perceptions of device users. Thus, further research is needed to demonstrate how older people engage with and use personal DMMD data in their daily lives. Regarding cognitive support for patients' self-understanding and self-assessment, this is a remarkable finding, as relying on device data for self-assessment requires the ability to interpret and handle these data. Self-assessment via DMMD data needs, in other words, data literacy and, in the case of digital self-documentation, the advanced skill of eHealth literacy. Future research should investigate whether patients' eHealth literacy correlates with the expectation that self-documentation provides cognitive support. To measure eHealth literacy in the context of DMMD use for CHF treatment and prevention, the *eHealth Literacy Scale* developed by Norman and Skinner [71] seems to be a promising option (eg, the patient survey study by Knitza et al [72] in rheumatology by using the validated German version of eHealth Literacy Scale [73]).

### Heterogeneous Preferences for Data Sharing With Research

To identify attitudes toward sharing data from digital self-documentation for research, four aspects warrant consideration: (1) concerns about sharing data, (2) preferred modalities of data sharing and transmission, (3) informational conditions for consent, and (4) preferences for bodies receiving and mediating device data. The last 3 aspects present crucial dimensions for consenting to data sharing for research.

### Concerns About Data Sharing With Research

Our findings revealed a positive attitude toward medical research in general. However, there were some concerns about sharing data for research, as approximately one-third of the participants feared data leakage or abuse. Furthermore, some participants (16/104, 15.4%) feared discrimination when DMMD data are disclosed. By contrast, almost two-thirds of the participants (65/104, 62.5%) accepted the current legal data regulations as sufficient. Other studies showed that, generally, there seems to be widespread support for data sharing for research [55]. Trust

in research organizations and data protection regulations as well as possible public benefits from research mostly outweigh concerns regarding data security and privacy [49]. Our study confirms these findings. Although there were data security concerns, trust in medical research and data protection regulations was high. Therefore, it is necessary for research organizations to consolidate public trust by adequately addressing concerns such as data abuse, leakage, and potential discrimination [74]. This should be considered when engaging with potential participants in a data sharing research project.

### Preferred Modalities of Data Sharing and Management

Regarding the preferred modalities of data sharing for research, attitudes were less heterogeneous, as for the vast majority of participants anonymization, having access to disclosed data, and the option to delete DMMD data were priorities. In addition, the majority of participants (62/104, 59.6%) approved management of DMMD data via a nonprofit organization. Thus, although only some participants (4/105, 3.8%) disagreed to share their DMMD data for research, most participants (62/104, 59.6%) approved such an *intermediate mode* of institutional data disclosure with research institutions. This would allow retaining the control and management of device data, either by patients themselves or by a nonprofit organization. On the basis of these findings, we can infer that patients with CHF favor a controlled mode of data sharing with options to manage disclosed data continuously and confidentially. This interpretation is also consistent with the results of the focus group study by Wetzels et al [52].

### Informational Requirements of Consenting

Turning now to preferred solutions for providing information on research that would receive and use disclosed data, we again obtained a heterogeneous picture. On the one hand, for the vast majority of participants (87/104, 83.7%), one-time provision of information about sharing device data for research was considered sufficient. On the other hand, only half of the participants (57/104, 54.8%) considered receiving general information about the respective purposes of medical research sufficient. The apparent inconsistency of these results can be resolved if we interpret this finding as a widespread preference for a one-time instruction about the actual data sharing procedures for research combined with mixed attitudes toward the provision of detailed information on specific research projects and their aims. As the broad consent model for data sharing in medical contexts rests on the principle of general, not detailed, information provision on research aims, it is striking to note that almost half of the patients with CHF in this study tended to disagree with the broad consent model. This outcome conflicts with the results of Richter et al [29] who reported a very high willingness (436/468, 93%) to give broad consent for health care–embedded biobanking among outpatients in an inflammatory disease clinic in Germany. A possible explanation for this might be that patients with CHF are more wary of the management of large-scale health data than those with diseases not subject to data-intensive monitoring.

### Preferences on Data-Receiving Organizations

The fourth aspect of data sharing relates to attitudes toward organizations that receive data. One important finding was the extent to which attitudes toward state-funded and private research organizations vary among participants in this study: private research institutions and collaborative research projects combining publicly funded and private organizations (*public-private partnerships*) were considerably less endorsed for the sharing of device data. Here, we interpret a preference for an organization as an expression of trust. We found that trust in state-funded research institutes as well as in physicians is very high (>90% participants). This is an encouraging message for state-funded research intuitions despite ongoing public debate on privacy and data security. However, the large gap between state-funded and private research institutes, collaborative research projects, and private companies poses a challenge for mobile device development, which is mainly performed in public-private partnership consortia. Our findings corroborate those of Aitken et al [49], Stockdale et al [51], and Richter et al [55]. For example, a study of the population survey by Richter et al [55] reported a striking difference in willingness to share health data anonymously and free of charge with university and public research institutions on the one hand (96.7%) and with privately funded research institutes and industry for research purposes (16.6%) on the other hand.

### Limitations

Several limitations of this study should be acknowledged, notably those affecting sampling. There is always a chance of latent bias from the underrepresentation of certain subgroups when opting for convenience sampling, as we did [75]. We observed a higher percentage of male participants (76/105, 73.1%) as opposed to the more even gender distribution of patients with CHF in Germany [76]. Two-thirds of the participants (70/105, 66.7%) already had some experience with DMMDs. Studies have reported technical affinity and male gender as facilitators for the use of self-documentation devices [59,70]. This could explain the high rate of DMMD experiences among male participants, as technologically savvy males might have been more likely to respond to our survey. In addition, although this is not statistically significant, their experiences might have positively colored their views on self-documentation. Furthermore, our participants formed part of a uniform group consisting of patients with CHF treated at the UMG, and all the participants were already part of the HiGHmed-UCC. Those interested in digital devices and data sharing may have participated more readily. In addition, the homogeneity and limited size of our sample make it difficult to perform inferential statistical analysis, given the possible departures from a normal distribution. It is noteworthy that attitudes reported in our study do not necessarily translate into future patient behavior when dealing with self-documentation, digital devices, and opportunities for sharing digital device data. Concepts of health conditions, types of data sharing, and research modalities are notoriously difficult to convey to a lay population, leaving room for potential misunderstandings when answering our survey questionnaire. Finally, our survey was limited to fluent German speakers, which might have further reduced the sample diversity. Despite its limitations, our study provides new insights into our

understanding of attitudes of patients with CHF toward digital self-documentation and sharing device data for research as well as raises questions to be addressed in future studies in the German context. However, caution is required given the sample size limitations and any potential bias inherent in the study design; the findings might not be widely applicable to all patients with CHF or cardiovascular diseases.

## Conclusions

### Overview

The rapidly expanding field of digital devices in cardiac health care and research needs to engage with the attitudes and perceptions of patients and probands [33-35]. Current device development is accompanied by governance policies and research on ethical, legal, and social issues (ELSI). These frameworks consider the privacy and data safety perceptions of the broad population as key issues. Our survey study focused on the potential of digital self-documentation and sharing device data for data-intensive research among patients with CHF at a German university medical center. The results showed that self-documentation and device data play a major role in supporting self-care in patients with CHF. The survey study was conducted with a rather limited sample size; 190 patients were originally approached and 105 questionnaires were included in the statistical analysis. Recruitment was considerably limited owing to the pandemic situation in Germany in 2020. As we achieved a very high rate of survey participation (67.9%), the results, however, have good significance for the sample of patients with CHF at the university medical center. However, owing to sample size limitations and potential bias inherent in the study design, limitations in the general applicability of these results must be considered. Nevertheless, our findings provide valuable insights for introducing DMMD into cardiovascular research in the German context. Furthermore, although our findings result from a restricted sample of patients with CHF at a clinic in Germany, they might also contribute to a large-scale cross-cultural and cross-national comparative study on views of patients with cardiovascular diseases on data-driven methods and technology deployment, which is still a considerable research goal. In general, more research is needed on the specificities of data-intensive research methods and technology across Western industrialized countries and countries of the

global south. In any case, the results of our survey study among German patients with CHF have many practical implications for the German context, as detailed in the following sections.

### Practical Implications for Doctors

First, doctors should become aware that many patients with CHF endorse sharing DMMD data with their family doctors. For these patients, it might be disappointing should their doctors refuse to engage with DMMD data for cognitive support. Second, for older patients with CHF, self-documentation data played a crucial role in self-assessment. Accordingly, they might be more open-minded toward digital self-documentation than is commonly supposed. Third, our findings indicate that the handling of problematic data warrants special consideration in the introduction and use of the devices in cardiovascular treatment.

### Practical Implications for the Implementation of Data Sharing for Research

Our findings have significant implications for the implementation of technical solutions and governance models for data sharing and consent in cardiac research in Germany. First, our study documents at least two types of attitudes among patients with CHF regarding concerns raised by practices of data sharing in medical contexts: those who widely rely on current data protection regulations (this was the majority) and those who raise serious concerns about data security, misuse, and potential discriminatory effects when data are disclosed. From an ethical standpoint, these concerns should be addressed in communication and information procedures as well as in the technical and normative governance structures of data sharing in medical contexts. The same applies equally to, and this is the second implication, the preferred consent models in practice. The results of our study showed preferences for a dynamic rather than a broad consent approach among our survey participants with CHF. The dynamic consent model allows participants to handle permissions, education, and consent preferences in data-intensive medical research *dynamically* by selecting and modifying consent options temporally via digital consent tools [32,77-79]. Collectively, our findings provide key insights for the design of data sharing programs and data-intensive research projects in cardiovascular research and care at clinics and university medical centers in Germany.

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## Data Availability

The data sets generated and analyzed during this study can be obtained from the corresponding author upon reasonable request.

## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Topics and items of the questionnaire reported in this paper.

[[PDF File \(Adobe PDF File\), 156 KB - cardio\\_v6i2e34959\\_app1.pdf](#)]

### Multimedia Appendix 2

Flowchart of sample recruitment.

[[PDF File \(Adobe PDF File\), 130 KB - cardio\\_v6i2e34959\\_app2.pdf](#)]

### Multimedia Appendix 3

Correlations between age of the participants and attitudes toward self-documentation.

[[PDF File \(Adobe PDF File\), 152 KB - cardio\\_v6i2e34959\\_app3.pdf](#)]

### Multimedia Appendix 4

Preferences on data-receiving organizations (n=101-105).

[[PNG File , 26 KB - cardio\\_v6i2e34959\\_app4.png](#)]

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**Abbreviations**

**CHF:** chronic heart failure  
**DMMD:** digital mobile measurement device  
**ELSI:** ethical, legal, and social issues  
**HiGHmed-UCC:** HiGHmed Use Case Cardiology  
**UMG:** University Medical Center Göttingen

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Original Paper

# Use of Digital Technology Tools to Characterize Adherence to Prescription-Grade Omega-3 Polyunsaturated Fatty Acid Therapy in Postmyocardial or Hypertriglyceridemic Patients in the DIAPAsOn Study: Prospective Observational Study

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## Abstract

**Background:** Maintaining sustained adherence to medication for optimal management of chronic noninfectious diseases, such as atherosclerotic vascular disease, is a well-documented therapeutic challenge.

**Objective:** The DIAPAsOn study was a 6-month, multicenter prospective observational study in the Russian Federation that examined adherence to a preparation of highly purified omega-3 polyunsaturated fatty acids (Omacor) in 2167 adult patients with a history of recent myocardial infarction or endogenous hypertriglyceridemia.

**Methods:** A feature of DIAPAsOn was the use of a bespoke electronic patient engagement and data collection system to monitor adherence. Adherence was also monitored by enquiry at clinic visits. A full description of the study's aims and methods has appeared in JMIR Research Protocols.

**Results:** The net average reduction from baseline in both total and low-density lipoprotein cholesterol was approximately 1 mmol/L and the net average increase in high-density lipoprotein cholesterol was 0.2 (SD 0.53) mmol/L ( $P < .001$  for all outcomes vs baseline). The mean triglyceride level was 3.0 (SD 1.3) mmol/L at visit 1, 2.0 (SD 0.9) mmol/L at visit 2, and 1.7 (SD 0.7) mmol/L at visit 3 ( $P < .001$  for later visits vs visit 1). The percentage of patients with a triglyceride level  $< 1.7$  mmol/L rose from 13.1% (282/2151) at baseline to 54% (1028/1905) at the end of the study. Digital reporting of adherence was registered by 8.3% (180/2167) of patients; average scores indicted poor adherence. However, a clinic-based enquiry suggested high levels of adherence. Data on health-related quality of life accrued from digitally engaged patients identified improvements among patients reporting high adherence to study treatment, but patient numbers were small.

**Conclusions:** The lipid and lipoprotein findings indicate that Omacor had nominally favorable effects on the blood lipid profile. Less than 10% of patients enrolled in DIAPAsOn used the bespoke digital platform piloted in the study, and the level of self-reported adherence to medication by these patients was also low. Reasons for this low uptake and adherence are unclear. Better adherence was recorded in clinical reports.

**Trial Registration:** ClinicalTrials.gov NCT03415152; <https://clinicaltrials.gov/ct2/show/NCT03415152>

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**KEYWORDS**

primary care; research; myocardial infarction; cardiology; heart; cardiac; cardiac health; digital health; electronic patient engagement; eHealth; patient engagement; clinical report; treatment; treatment adherence

## Introduction

Non-high-density lipoprotein cholesterol (non-HDL-C) blood lipids are a source of residual cardiovascular risk in patients whose low-density lipoprotein cholesterol (LDL-C) levels are well controlled by medication, primarily statins [1-9].

Optimal risk reduction in cardiovascular disease, as in other forms of major noncommunicable disease, depends substantially on patients continuing to take their medications for extended periods of time. This can be a particular challenge in conditions such as hyperlipidemia, where the connection between symptomless elevations of blood lipid levels and major cardiovascular events can seem abstract or remote [10,11].

Recent comparative research in Russia and Norway has disclosed poor attainment of cholesterol targets in both countries, despite a notably higher prescription rate of these drugs in Norway [12]. Suboptimal patient adherence to prescribed treatments is likely to be a contributor to such findings, which illustrates that the challenges of promoting and sustaining adherence to therapy are not confined to any one country. It is nevertheless clear from the results of the CEPHEUS (Centralized Pan-Russian Survey of the Undertreatment of Hypercholesterolemia) II study that failure to reach targets for lipid-based risk reduction is widespread in Russia [13]. Patient-related factors associated with nonattainment of targets identified in that study included the consideration that it was acceptable to miss prescribed doses more than once per week. Poor adherence to medication for hypertension has likewise been documented in the Izhevsk Family Study II [14].

Those findings exemplify observations that the rates of both discontinuation and nonadherence to therapy are uniformly high in clinical trials of lipid-lowering drugs and even higher in unselected populations, with adherence deteriorating in proportion to the duration of follow up [15]. Analysis of a large Swiss health care claims database (N=4349) revealed that overall adherence to drug therapy for secondary cardiovascular prevention after myocardial infarction (MI) was only moderate, but that patients with high adherence to lipid-lowering therapy had a significantly reduced risk for all-cause mortality and major cardiovascular events, illustrating the potential for improvement of longer-term outcomes [16].

Omega-3-acid ethyl esters (OM3EE) are available as a prescription-only medication (Omacor, Abbott Laboratories GmbH) that is a preparation of highly purified long-chain omega-3 polyunsaturated fatty acids (n-3 PUFAs) (eicosapentaenoic acid/docosahexaenoic acid in a 1.2:1 ratio and 90% purity); this medication is widely approved for use at a daily dose of 1 g for the secondary prevention of major cardiovascular events in patients who have survived an MI, or at doses of 2 to 4 g/day for the regulation of triglyceride (TG) level. Prescription-only n-3 PUFAs such as OM3EE are qualitatively distinct from dietary n-3 PUFA supplements and have been evaluated in a range of clinical trials [17,18].

The emergence of widely available digital and internet technologies with the potential to provide immediate bidirectional communication between health care professionals (ie, doctors, nurses, and pharmacists) and patients may be an important new resource for promoting long-term adherence to therapies [19]. The DIAPAsOn study was devised to explore patient adherence to OM3EE therapy through the medium of digital technology tools [20].

## Methods

### Overview

A comprehensive description of the methodology of the DIAPAsOn study has previously been published, including baseline demographic data [20]. Briefly, DIAPAsOn was a prospective observational study conducted at >100 centers in the Russian Federation that was devised to examine adherence to a prescription of OM3EE as either a secondary preventive medical therapy (at a dose of 1 g/day) for patients with a history of recent MI or for blood lipid regulation (at a dose of 2-4 g/day) in patients with endogenous hypertriglyceridemia insufficiently responsive to dietary modification or drug therapy.

Participants were required to be adults (aged  $\geq 18$  years) with a history of MI for whom OM3EE was prescribed as part of a secondary prevention strategy; to have Fredrickson endogenous type IIb or III hypertriglyceridemia not satisfactorily controlled by statin therapy; or to have Fredrickson endogenous type IV hypertriglyceridemia not sufficiently controlled by a lipid-moderating diet. In addition, the included patients took OM3EE for less than 2 weeks prior to enrolment. DIAPAsOn is registered at ClinicalTrials.gov (NCT03415152).

### Schedule of Visits and Data Collection

The DIAPAsOn study had a scheduled duration of 6 months. Clinic visits were scheduled at the start of the study (visit 1), at approximately 3 months (visit 2), and at the end of the study (visit 3). At each of the 3 scheduled clinic visits, patients were questioned about their compliance with the OM3EE therapy using the Questionnaire of Treatment Compliance [21]. This instrument, which has been used in Russia to investigate compliance with other cardiovascular medications, produces a numerical indication of compliance, as follows: 12 to 15 points, very high; 8 to 11 points, high; 4 to 7, moderate; and 0 to 3, low.

A blood lipid profile was determined at each visit, and blood pressure and heart rate data were collected. Adverse events and hospitalization were recorded. Patients also received intervisit phone calls focused on adherence to therapy and safety.

A central aspect of DIAPAsOn was the use of remote digital technology that allowed patients to submit data and report on matters such as health-related quality of life (HRQoL) and product usability (rated as very good, good, moderate, or poor).

The electronic patient engagement and data collection system used in DIAPAsOn was developed in collaboration with the medical online platform Rosmed.info, which has wide-ranging experience in the development and operation of mobile health applications in the Russian Federation. A fuller description of the system used in DIAPAsOn is featured in a separate paper on the study's methodology [20].

### Ethics Approval

Ethical oversight of the DIAPAsOn study was exercised by the independent Interuniversity Ethics Committee Gagarinsky pereulok, 37, Moscow, Russian Federation (Protocol No. 09-17 of the Interuniversity Ethics Committee, dated 10/19/2017 and later amendments). All aspects of the DIAPAsOn study, including the associated mobile health app, conformed to relevant national and international legal and ethical regulations and requirements for the conduct of clinical research in human subjects, followed the provisions of the Declaration of Helsinki, and included patients' right to decline further participation in DIAPAsOn at any time and for any reason, whether stated or not, without prejudice to their subsequent treatment. A list of center investigators appears in [Multimedia Appendix 1](#).

### Statistical Methods

Methods were predominantly descriptive, conducted in accordance with the preapproved statistical analysis plan, and used the statistical programming language R (version 3.4.3).

The primary endpoint—adherence to therapy with OM3EE in post-MI patients or patients with hypertriglyceridemia—was

assessed in an analysis population, defined as those patients for whom data were obtained at least at visits 1 and 2.

Analysis of the primary endpoint included determination at the end of the study (ie, visit 3) of the mean adherence rate, which was defined as the number of days for which the patient took the full prescribed dose of OM3EE during the specified period divided by the total number of days in that period. The mean score on the National Questionnaire of Treatment Compliance was calculated at the same time.

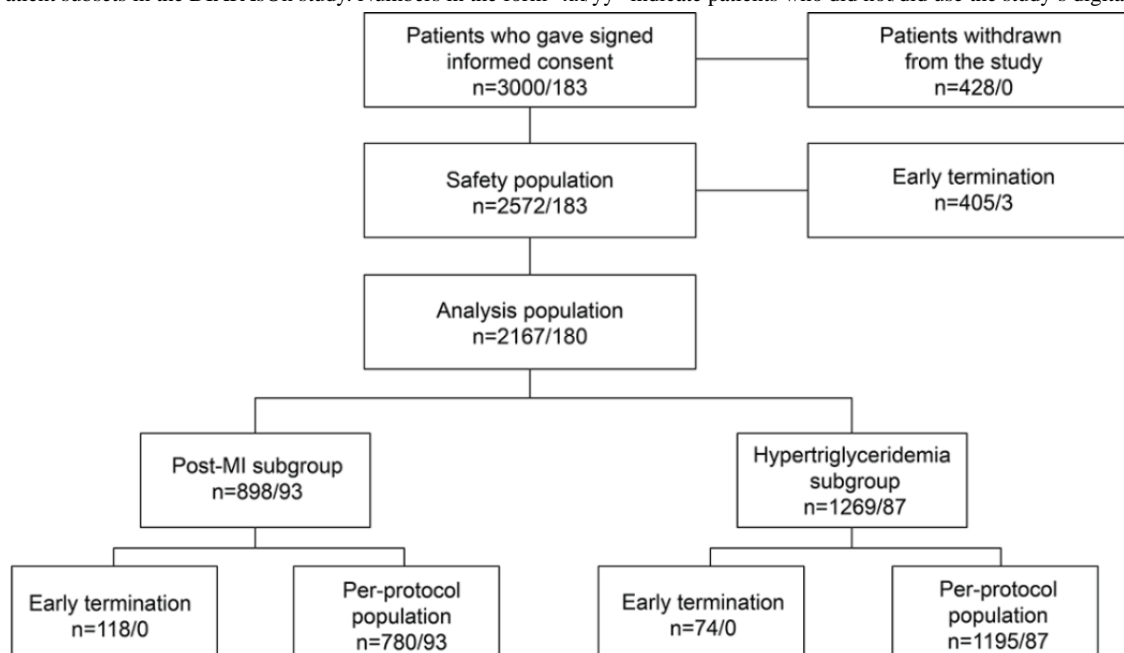
Comparison of individual patient data between visits was based on either a 2-tailed Student *t* test (for dependent variables) or the McNemar test (for qualitative data).

## Results

### Population Accounting

A total of 3000 patients were initially included in the program, but 428 (14.3%) were excluded because visit 1 data were incomplete. Valid and complete data from visit 1 were available for 2572 patients (85.7%), who constituted the safety population. After the exclusion of 405 patients lost before visit 3, an analysis population of 2167 patients remained, representing 72.2% of the total enrolled patients ([Figure 1](#)). Of these 2167 patients, 898 (41.4%) were taking OM3EE for secondary prevention after an MI and 1269 (58.6%) were taking OM3EE for hypertriglyceridemia.

**Figure 1.** Patient subsets in the DIAPAsOn study. Numbers in the form “xx/yy” indicate patients who did not/did use the study's digital tools.



DIAPAsOn was completed per protocol by 1975 patients (post-MI subgroup, 780/1975; hypertriglyceridemia subgroup, 1195/1975). This was an almost wholly White population (2118/2167, 97.7%) with a near-equal sex distribution (1145 men of 2167 patients, 52.8%; 1022 women of 2167 patients, 47.2%), an average age of 60 years, and an average body mass index of 30 kg/m<sup>2</sup>. There were more men than women in the

post-MI subgroup (608/898, 67.7%), whereas women outnumbered men in the hypertriglyceridemia subgroup (732/1269, 57.7%). Investigator-assessed clinically significant abnormalities in systolic and diastolic blood pressure were recorded in 21.4% (463/2167) and 12.8% (277/2167) of patients, respectively.

As illustrated in Figure 1, 180 of the 2167 patients in the analysis population (8.3%) submitted data via the mobile health platform, of whom 93 were enrolled in DIAPAsOn on the basis of a previous MI and 87 on the basis of a diagnosis of qualifying hyperlipidemia. From start to finish, 3 of the initial grouping of 183 patients who used the mobile health platform (1.6%) were withdrawn from the study or discontinued it, compared with 1025 of 2817 (36.4%) of those who did not submit data via the mobile platform. After establishment of the analysis population, early termination rates were 0% and 9.7% for those who did and did not use the mobile platform, respectively (Figure 1).

### Compliance With OM3EE

The mean duration of OM3EE administration was 166.5 (SD 70.6) days (median 199 days; range 14-268 days). Among the 2167 patients whose compliance was monitored at clinical visits but not self-reported via the mobile app, the mean score on the National Questionnaire of Treatment Compliance at visit 3 was 13 (SD 3) points, signifying high overall compliance with therapy. Mean scores >12 points were also recorded at visit 1 (12.5 points, SD 3.1) and visit 2 (13 points, SD 2.9). Relative to the mean score at visit 1, the mean scores at both visits 2 and 3 were statistically significantly higher ( $P<.001$ ) (Table 1). The distribution of adherence categories for the total study population and for the two subpopulations of DIAPAsOn is shown in Figure 2. Overall, high or very high compliance was recorded for 76/780 (87.9%) of respondents in the post-MI group and 1078/1195 (90.2%) of respondents in the hypertriglyceridemia group. Within the post-MI group, adherence fell significantly at age >75 years (61/81, 75%) compared to all younger age deciles (618/699, 88.4%;  $P=.007$ , chi-square test).

Very high adherence was reported significantly more often by men than women, especially in the hypertriglyceridemia subset (346/511, 67.7% vs 413/684, 60.4%, respectively;  $P=.007$ , chi-square test). Among patients with hypertriglyceridemia, very high adherence was also significantly more likely in those who were recorded as not working than those who were working (333/481, 69.2% vs 426/714, 59.7%, respectively;  $P<.001$ , chi-square test). Adherence was much higher among early school leavers than in any other category of education but, especially in the hypertriglyceridemia subset, this finding was based on small numbers ( $n=3$ ).

A total of 69/2572 patients (2.68%) discontinued OM3EE during the study. Of these 69 patients, the largest groups cited inconvenience of use ( $n=11$ ) and reported absence of stock at pharmacies ( $n=6$ ). A total of 50 patients discontinued use for a variety of other reasons, including the cost of the medication, reluctance to commit to long-term medication discontinued by another physician, normalization of blood lipid values, and change of residence. Inconvenience of use was more often recorded in hypertriglyceridemia patients than post-MI patients (10/52, 19% vs 1/17, 6%, respectively).

Among the 180 patients who registered data via the DIAPAsOn mobile platform, adherence to therapy, expressed as the ratio

of days when the full prescribed dose of OM3EE was taken to the total number of days in the treatment period, averaged 0.37 (SD 0.38) over the entire program, corresponding to a low level of adherence. Mean adherence between visits 1 and 2 was 0.48 (SD 0.4), while mean adherence between visits 2 and 3 was 0.24 (SD 0.4;  $P<.001$ ). Between visits 1 and 2, 50% (90/180) of patients had low adherence (<0.5), 15.6% (28/180) had moderate adherence (0.5-0.7) and 34.4% (62/180) had high adherence ( $\geq 0.8$ ). Between visits 2 and 3, the proportion of patients with low adherence increased to 75% (135/180), while the proportion with high adherence decreased to 20.6% (37/180). When the data were stratified by adherence level, there was an essentially binary split, with most patients reporting either low adherence (132/180, 74.4%) or high adherence (45/180, 25%).

In the subgroup of 93 patients taking OM3EE for secondary prevention after MI and self-reporting adherence via the study app, mean adherence between visits 1 and 3 was 0.47 (SD 0.39), with 67% (62/93) of patients recording low adherence and 32% (30/93) high adherence. Mean adherence in the post-MI subgroup reached 0.6 (SD 0.38) at visit 2, while at visit 3 it had decreased to 0.33 (SD 0.45;  $P<.001$ ). At visit 2, 32% (30/93) of patients had low adherence (<0.5) and 45% (42/93) had high adherence ( $\geq 0.8$ ). By visit 3, the proportion of patients with low adherence had increased to 68% (63/93), while the proportion with high adherence had declined to 30% (28/93).

Among the 87 app-using patients taking OM3EE for hypertriglyceridemia, mean adherence between visits 1 and 3 was 0.25 (SD 0.33), with most patients (83%, 72/87) self-reporting low adherence, and 17% (15/87) recording high adherence. In this subgroup, 69% of patients (60/87) had low adherence (<0.5) at visit 2 and 23% (20/87) had high adherence ( $\geq 0.8$ ). By visit 3, these percentages had changed to 83% (72/87) and 10% (9/87), respectively.

Cross-referencing of the results for the National Questionnaire of Treatment Compliance administered at the clinic visits with self-reported adherence, based on the ratio of administered and prescribed dose, established that among patients identified by their response to the National Questionnaire as having very high, high, or moderate adherence to therapy, app-reported mean adherence for the time period between visits 1 and 2 was 50.04%, 52.85% and 24.58%, respectively, while between visits 2 and 3 adherence was 28.67% for those assessed as having very high adherence, 19.11% for those with high adherence, and 5.57% for those with moderate adherence.

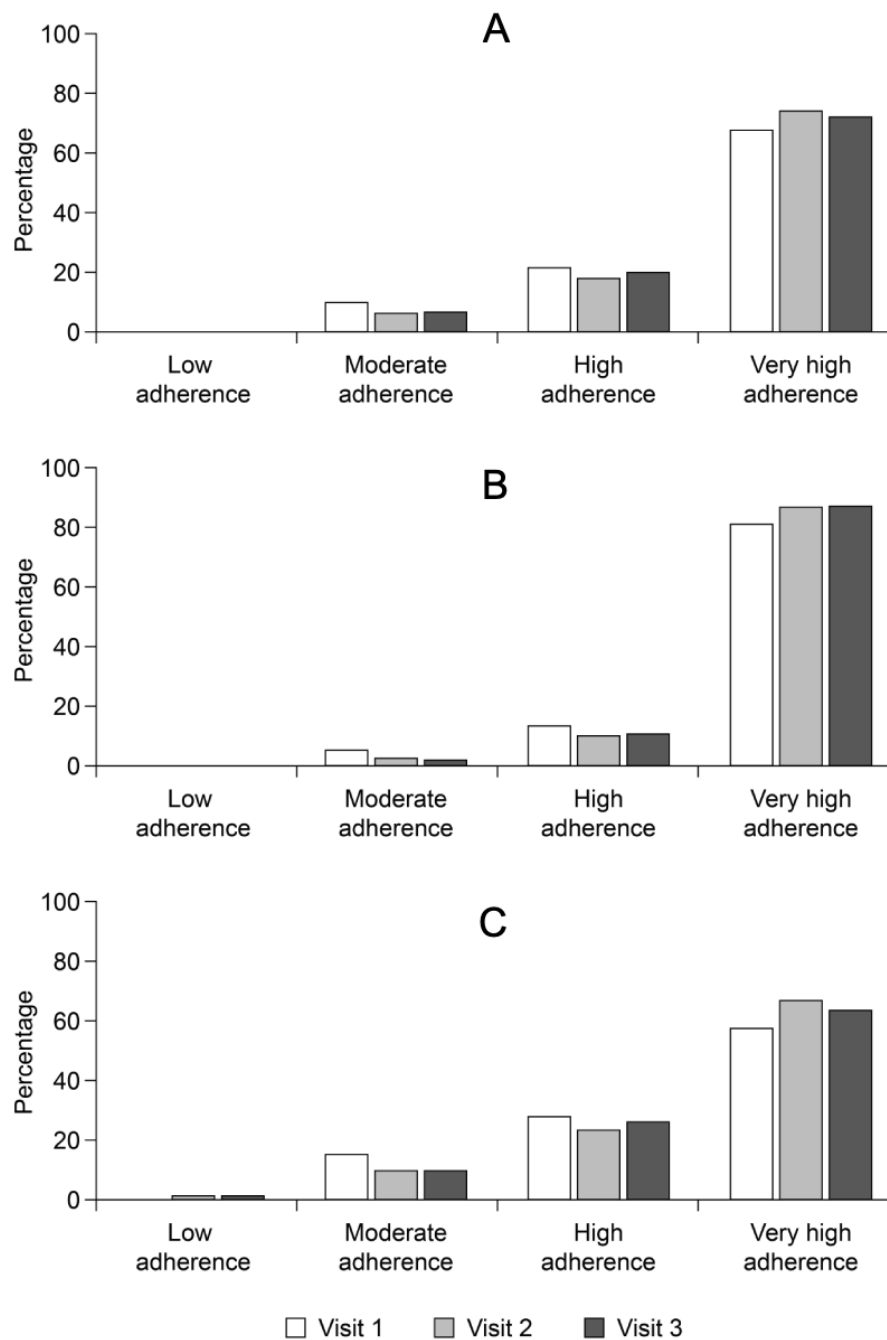
In the app-using analysis population as a whole, 64.5% of patients (69/107) rated the usability of OM3EE after 1 month of treatment as very good. A further 29.9% (32/107) and 5.6% (6/107), respectively, rated usability as good or moderate. No patient rated usability as poor. All the patients prescribed OM3EE for secondary prevention post-MI rated the usability as very good (41/58, 71%) or good (17/58, 29%), while among patients treated for hypertriglyceridemia, the usability of OM3EE was rated as very good by 57% of patients (28/49), good by 31% (15/49), and moderate by 12% (6/49).



**Table 1.** Changes in mean score on the National Questionnaire of Treatment Compliance between visit 1 (baseline) and visit 2 (at 3 months) or visit 3 (at study completion, after 6 months).

	Mean score (SD)	P value
Visit 1	12.5 (3.11)	N/A <sup>a</sup>
Visit 2	12.99 (2.88)	N/A
Visit 3	12.9 (2.99)	N/A
Visit 2 vs visit 1	0.47 (2.46)	<.001
Visit 3 vs visit 1	0.44 (2.52)	<.001

<sup>a</sup>N/A: not applicable.

**Figure 2.** Distribution of adherence categories for (A) the overall population (B), the post-myocardial infarction subgroup, and (C), the hypertriglyceridemia subgroup, based on responses to the National Questionnaire of Treatment Compliance.

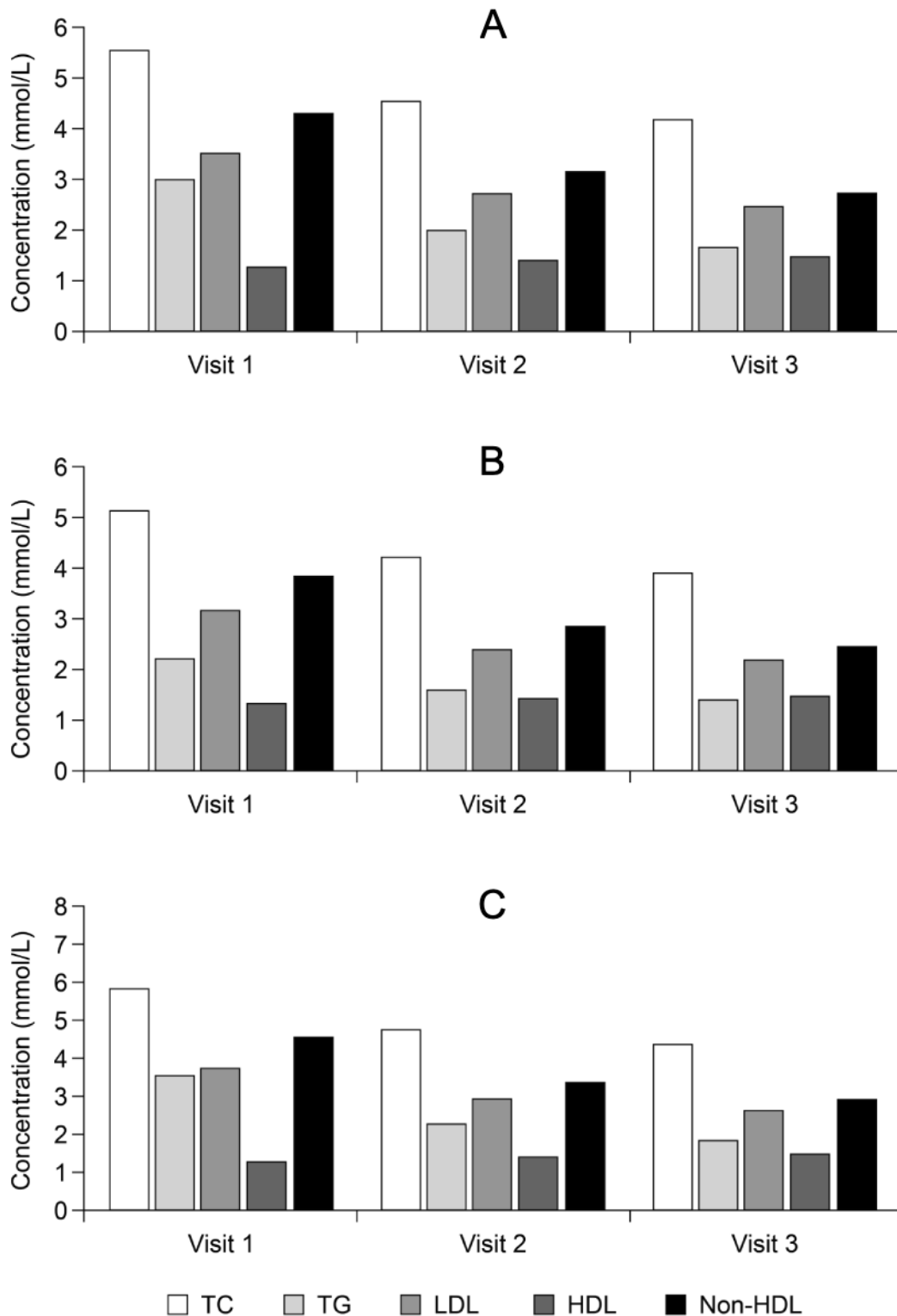
**Lipid Indices**

At baseline (N=2167), investigator-classified clinically significant deviations from normal for total cholesterol (TC), LDL-C, high-density lipoprotein cholesterol (HDL-C), and TG were recorded in 46.1% (999/2167), 40.9% (887/2167), 14.4% (312/2167) and 65% (1408/2167) of patients, respectively. Mean values for TC, TG, LDL-C, HDL-C and non-HDL-C were 5.55 (SD 1.39) mmol/L, 2.99 (SD 1.29) mmol/L, 3.5 (SD 1.25)

mmol/L, 1.27 (SD 0.46) mmol/L, and 4.29 (SD 1.47) mmol/L, respectively.

In-study changes in mean blood lipid levels are shown in Figure 3 for the overall DIAPASOn cohort and for the two subpopulations differentiated by indication. Analysis of lipid profiles stratified by baseline TG status revealed that an increasing TG level was associated with changes in TC that were potentially deleterious to cardiovascular health (Table 2).

**Figure 3.** In-study changes in blood lipids in (A) the overall population (B), the post-myocardial infarction subgroup, and (C), the hypertriglyceridemia subgroup. TC: total cholesterol; TG: triglyceride; LDL: low-density lipoprotein; HDL: high-density lipoprotein.



**Table 2.** Baseline lipid profile of the analysis population, stratified by triglyceride status, identified progressively more atherogenic patterns of total and lipoprotein cholesterol as triglyceride level increased.

TG <sup>a</sup> level	TC <sup>b</sup> (mmol/L)	TG (mmol/L)	LDL-C <sup>c</sup> (mmol/L)	HDL-C <sup>d</sup> (mmol/L)	Non-HDL-C (mmol/L)
<b>Low (&lt;1.7 mmol/L)</b>					
Patients, n	282	282	282	282	280
Mean (SD)	4.67 (1.33)	1.21 (0.31)	2.93 (1.14)	1.33 (0.5)	3.37 (1.4)
Median	4.5	1.2	2.7	1.2	3.25
<b>Moderate (1.7-2.3 mmol/L)</b>					
Patients, n	431	431	430	431	431
Mean (SD)	5.31 (1.24)	2.04 (0.19)	3.39 (1.3)	1.31 (0.51)	4 (1.4)
Median	5.5	2.01	3.1	1.2	4.01
<b>High (&gt;2.3 mmol/L)</b>					
Patients, n	1438	1438	1438	1438	1437
Mean (SD)	5.79 (1.37)	3.63 (1.08)	3.65 (1.22)	1.25 (0.44)	4.55 (1.42)
Median	5.9	3.4	3.5	1.1	4.6

<sup>a</sup>TG: triglyceride.

<sup>b</sup>TC: total cholesterol.

<sup>c</sup>LDL-C: low-density lipoprotein cholesterol.

<sup>d</sup>HDL-C: high-density lipoprotein cholesterol.

Lipid profile parameters were recorded at baseline (visit 1), as well as after 3 months (visit 2) and 6 months (visit 3) of follow up. Mean TC at visit 1 was 5.55 (SD 1.39) mmol/L. This had decreased to 4.54 (SD 1.04) mmol/L ( $P<.001$ ) by visit 2, and at visit 3 had been further reduced to 4.17 (SD 1.04) mmol/L ( $P<.001$ ). Across the period of observation, the net average change in mean TC was thus  $-1.32$  (SD 1.28) mmol/L.

At visit 2, mean LDL-C was 2.71 (SD 0.94) mmol/L, an average reduction from visit 1 of 0.77 (SD 0.92) mmol/L ( $P<.001$ ). Further reduction was observed at visit 3, when the mean LDL-C level was 2.46 (SD 0.76) mmol/L ( $P<.001$  vs visit 1). The average net decrease in LDL-C was thus 1.02 (SD 1.02) mmol/L.

Mean HDL-C levels at visits 1, 2, and 3 were, respectively, 1.27 (SD 0.46) mmol/L, 1.41 (SD 0.42) mmol/L ( $P<.001$  vs visit 1), and 1.44 (SD 0.42) mmol/L ( $P<.001$  vs visit 1), with an average increase of 0.2 (SD 0.53) mmol/L over the period of observation.

Non-HDL-C declined by an average of 1.6 (SD 1.54) mmol/L during the period of observation, falling from 4.27 (SD 1.47)

mmol/L at visit 1 to 3.14 (SD 1.12) mmol/L at visit 2 ( $P<.001$  vs visit 1) and to 2.71 (SD 1.0) mmol/L at visit 3 ( $P<.001$  vs visit 1).

Mean TG level was 3.0 (SD 1.3) mmol/L at visit 1, 2.0 (SD 0.9) mmol/L at visit 2, and 1.7 (SD 0.7) mmol/L at visit 3 ( $P<.001$  for both vs visit 1). The overall average reduction in the mean TG level was thus 1.32 (SD 1.15) mmol/L across the observation period.

Trends in overall TG levels during DIAPAsOn are displayed in more detail in [Table 3](#), with patients assigned to 1 of 3 baseline distribution categories. Statistically significant changes in the distribution toward lower levels of TG were apparent at both visits 2 and 3, with the percentage of patients recorded as having TG <1.7 mmol/L increasing from 13.1% (282/2151) at baseline to 54% (1028/1905) at the conclusion of the study period, while the percentage recorded as having TG >2.3 mmol/L fell from 66.9% (1438/2151) to 10.4% (198/1905).

**Table 3.** Trends in overall triglyceride levels during the DIAPAsOn study, stratified by baseline triglyceride category.

Baseline triglyceride level, n (%)	Visit 1 (N=2151)	Visit 2 (N=2037)	Visit 3 (N=1905)	P value (visit 2 vs 1)	P value (visit 3 vs 1)
Low (<1.7 mmol/l)	282 (13.1)	787 (38.6)	1028 (54)	<.001	<.001
Moderate (1.7-2.3 mmol/l)	431 (20)	670 (32.9)	679 (35.6)	<.001	<.001
High (>2.3 mmol/l)	1438 (66.9)	580 (28.5)	198 (10.4)	<.001	<.001

The average differences in TC, LDL-C, and non-HDL-C between baseline and visit 3 were a function of baseline TG. Thus, the reductions in patients with initial TG >2.3 mmol/L were  $-1.47$ ,  $-1.1$ , and  $-1.7$  mmol/L, respectively, while in patients with initial TG 1.7 to 2.3 mmol/L, the average intrastudy reductions from baseline to visit 3 were  $-1.16$ ,  $-0.99$ , and  $-1.32$

mmol/L, respectively. In patients with initial TG <1.7 mmol/L, the average reductions in TC, LDL-C, and non-HDL-C were  $-0.83$ ,  $-0.63$  and  $-0.94$  mmol/L, respectively. Nevertheless, the change in each parameter in each of these subgroups was statistically significant ( $P<.001$ ). The mean increase in HDL during observation versus baseline was 0.24 mmol/L in patients

with TG >2.3 mmol/L ( $P<.001$ ), 0.16 mmol/L in patients with TG 1.7 to 2.3 mmol/L ( $P<.001$ ), and 0.09 mmol/L in patients with TG <1.7 mmol/L ( $P=.002$ ). A statistically significant decrease in TG at visit 3 versus baseline was observed only in the subgroups of patients with baseline TG >2.3 or 1.7 to 2.3 mmol/L (–1.81 and –0.55 mmol/L, respectively;  $P<.001$  for both subgroups).

Subanalysis of the patients being treated for hypertriglyceridemia stratified according to the concomitant use or nonuse of statins or fibrates identified no substantial or significant intergroup differences in baseline levels of blood lipid components.

Subsequent in-study trends in blood lipid fractions in both these subgroups are summarized in [Table 4](#) and indicate significant longitudinal trends in both subgroups ( $P<.001$  for all indices in

both comparisons) with slightly more pronounced responses in patients who were taking additional lipid-regulating drugs in combination with OM3EE. Formal tests for differences between subgroups depending on the use or nonuse of statins or fibrates were not conducted.

Changes between baseline and visit 3 in the 180 patients who registered self-reported adherence in the study mobile app identified no correlations or associations between the level of adherence and absolute changes in levels of lipids or lipoproteins.

The results of investigations into the relationship between rates of adherence and patient demographic factors for the whole analysis population are summarized in [Multimedia Appendix 2](#).

**Table 4.** Trends in lipid and lipoprotein fractions in patients enrolled in the analysis population of DIAPAsOn for hypertriglyceridemia and receiving or not receiving concomitant statins or fibrates.

Change	TC <sup>a</sup> (mmol/l)	TG <sup>b</sup> (mmol/l)	LDL-C <sup>c</sup> (mmol/l)	HDL-C <sup>d</sup> (mmol/l)	Non-HDL-C (mmol/l)
<b>Patients receiving statins or fibrates</b>					
Visit 3 vs visit 1, mean (SD)	–1.5 (1.3)	–1.7 (1.2)	–1.2 (1.1)	0.2 (0.5)	–1.8 (1.5)
Visit 3 vs visit 1, median	–1.44	–1.7	–1.0	0.2	–1.9
<i>P</i> value (visit 3 vs visit 1)	<.001	<.001	<.001	<.001	<.001
<b>Patients not receiving statins or fibrates</b>					
Visit 3 vs visit 1, mean (SD)	–1.4 (1.3)	–1.5 (1.1)	–0.84 (0.9)	0.3 (0.6)	–1.7 (1.6)
Visit 3 vs visit 1, median	–1	–1.32	–0.7	0.2	–1.3
<i>P</i> value (visit 3 vs visit 1)	<.001	<.001	<.001	<.001	<.001

<sup>a</sup>TC: total cholesterol.

<sup>b</sup>TG: triglyceride.

<sup>c</sup>LDL-C: low-density lipoprotein cholesterol.

<sup>d</sup>HDL-C: high-density lipoprotein cholesterol.

## HRQoL Outcomes

HRQoL data accrued from patients who contributed to the digital data collection element of DIAPAsOn are summarized in [Table 5](#). These data represent mean (SD) scores from the the 36-item Short-Form Health Survey (SF-36), which has 8 domains: general health, physical functioning, role limitations due to physical health, role limitations due to emotional health, energy/fatigue, emotional well-being, social functioning, and

pain [22]. Data for the general health domain were excluded due to a technical error during data transfer. Statistically significant increases in the scores for all domains except the pain domain were recorded during the observation period. Further analysis, stratified by self-reported adherence to therapy (low, moderate, or high), indicated that these improvements in HRQoL were restricted to patients with high compliance (data not shown; the number of respondents ranged from 21 to 35 for each question).

**Table 5.** HRQoL data accrued from patients who contributed to the digital data-collection element of DIAPAsOn. Differences (visit 2 vs visit 1 and visit 3 vs visit 1) were paired and therefore estimated only for those patients who were scored on both relevant visits. Data for the general health domain were excluded due to a technical error during data transfer.

	PF <sup>a</sup>	RP <sup>b</sup>	RE <sup>c</sup>	E/F <sup>d</sup>	EW <sup>e</sup>	SF <sup>f</sup>	P <sup>g</sup>
<b>Visit 1</b>							
Respondents, n	82	82	82	82	82	82	82
Mean (SD) score	22.36 (16.18)	39.02 (44.11)	53.25 (41.2)	43.82 (21.62)	52.9 (16.1)	58.54 (26.34)	74.45 (31.16)
<b>Visit 2</b>							
Respondents, n	51	50	50	49	49	50	49
Mean (SD) score	34.56 (12.34)	87.5 (29.99)	93.33 (20.2)	72.28 (14.09)	76.01 (15.7)	89.25 (17.31)	94.23 (13.19)
<b>Visit 2 vs visit 1</b>							
Respondents, n	35	35	35	35	35	35	35
Mean (SD) score	7.63 (13.4)	32.86 (48.42)	25.71 (32.42)	20.81 (14.12)	22.66 (14.69)	26.43 (25.68)	8.43 (14.12)
P value	.002	<.001	<.001	<.001	<.001	<.001	.001
<b>Visit 3</b>							
Respondents, n	22	22	22	22	22	22	22
Mean (SD) score	40.1 (6.42)	98.86 (5.33)	100 (0)	80.23 (5.87)	86.73 (7.94)	98.3 (8)	98.52 (6.93)
<b>Visit 3 vs visit 1</b>							
Respondents, n	22	22	22	22	22	22	22
Mean (SD) score	6.69 (10.08)	29.55 (43.39)	18.18 (30.39)	18.18 (13.59)	25 (14.65)	16.48 (25.41)	-0.11 (0.53)
P value	.005	.004	.01	<.001	<.001	.006	.33

<sup>a</sup>PF: physical functioning.

<sup>b</sup>RP: role limitations due to physical health.

<sup>c</sup>RE: role limitations due to emotional health.

<sup>d</sup>E/F: energy/fatigue.

<sup>e</sup>EW: emotional well-being.

<sup>f</sup>SF: social functioning.

<sup>g</sup>P: pain.

## Safety and Adverse Events Data

The safety population included all patients who had completed at least visit 1 (2572).

A total of 4 adverse drug reactions (ADRs) were recorded in 3 patients (0.12%). Two patients had 1 ADR and 1 patient had 2 ADRs. No serious ADRs were recorded during DIAPAsOn.

Four deaths were recorded during the study, including 1 from cardiovascular disease. None of the deaths were causally related to the use of OM3EE.

There were 20 instances of hospitalization due to cardiovascular diseases, none of which were attributed to the use of OM3EE. Thirteen of these events affected participants who were being treated for hypertriglyceridemia, all of whom were also being medicated with statins, fibrates, or both.

OM3EE therapy was discontinued by 69 patients. Specified reasons for doing so included inconvenience of use (11/69), lack of availability in pharmacies (6/69) and lack of effect (2/69). Reasons for the remaining 50 discontinuations were recorded as “other.”

## Discussion

### OM3EE Effect on Lipid Profile

Considered overall, the data from DIAPAsOn suggest that the introduction of OM3EE had favorable effects on the blood lipid profile of our patients, consistent with experiences in previous controlled trials. As illustrated in [Table 3](#), the percentage of patients recorded as having TG <1.7 mmol/L quadrupled in response to OM3EE (from 282/2151, 13.1%, at baseline to 1028/1905, 54%, at the conclusion of the study); conversely, the percentage of patients recorded as having TG >2.3 mmol/L fell to 10.4% (198/1905) from 66.9% (1438/2151) at baseline. These changes were accompanied by alterations in other lipoprotein fractions compatible with an overall shift to a less atherogenic lipid profile, including a reduction in non-HDL-C, which declined by an average of 1.6 (SD 1.54) mmol/l. This pattern of response to OM3EE was substantially independent of the use or nonuse of statins by patients treated for hypertriglyceridemia ([Table 4](#)).

## Digital Versus Nondigital Adherence Findings

A central purpose of DIAPAsOn was to examine how the use of digital technologies might promote adherence to OM3EE therapy. This aspect of the study provided inconclusive and somewhat perplexing insights. The online facilities developed for DIAPAsOn were used by 180 of the 2167 patients (8.3%) in the analysis population.

Establishing why so many of our patients declined to use this option would require in-depth interviewing of several thousand people and is beyond the resources of the study as originally conceived. Similarly, we are not equipped to investigate whether or how physicians advocated for this aspect of the study during clinic visits or how patients might have responded to this encouragement. In retrospect, the lack of provision for detailed scrutiny of these matters is a limitation of our overall plan.

To a substantial (though unforeseen) extent, our study can be construed as an exploration of what may be called “spontaneous” adherence to a digital health initiative in response to an “open” invitation to a large and heterogeneous patient group. Our experience suggests that self-motivated engagement is exhibited by only a minority of patients. To the extent that this is a correct interpretation, it seems reasonable to conclude that plans to introduce such technologies need to place a much greater emphasis than we did on introducing and “selling” the concept and practice of eHealth to patients. The influences on engagement identified by Al-Naher et al [23] in their recent review of this field likely also applied to our study cohort; it must be acknowledged that limited emphasis was placed on these factors in our protocol. Many of the determinants of successful adoption of eHealth initiatives identified by Granja et al [24] will have been operative in the DIAPAsOn population (both patients and physicians). Notably, we may have made too little formal provision to anticipate and address patient concerns over privacy and security and physician concerns over workload.

Adherence to therapy for patients self-reporting via the DIAPAsOn digital platform was defined as the total number of days that a patient took the full prescribed dose of OM3EE during the specified period divided by the total number of days in that period. Calculating this way, adherence appeared to be low in these patients and declined during the period of observation. However, we have no means of ascertaining whether the data that the patients recorded accurately reflected their true adherence to study medication; actual adherence rates may therefore have been higher than the recorded findings suggest. This would be compatible with the finding that in-study trends in lipid and lipoprotein indices were favorable and numerically very similar in both digital adopters and the rest of the analysis population.

Comparison of the digital subset with the main analysis population identified no demographic differences between the two groups that might explain the adoption or nonadoption of the digital resources of DIAPAsOn. Wide-ranging technical obstacles seem unlikely given the high level of smartphone penetration in Russia [25], general access to the internet, and the requirement for digital proficiency as an inclusion criterion. The average age of the study population (approximately 58 years) is not, *prima facie*, a sufficient explanation for the low

level of digital uptake but may have exerted an influence that our study was not calibrated to identify.

Seemingly at odds with the low level of adoption of the mobile technology devised for DIAPAsOn—and the apparently low levels of medication adherence reported by those patients that used the technology—is the observation that the dropout rate among the digital adopters was zero. The impression of a subset of patients who are tenacious in their adherence to technology but inattentive in their reported adherence to medications is a paradox that we are at present unable to rationalize.

Another finding of note was that the HRQoL indices in the digitally engaged patients showed a striking and sustained improvement among those with self-reported high compliance. This study had small patient numbers and had an observational design that precluded a determination of cause and effect. Thus, ascertaining reasons for the improvement in HRQoL indices lies outside the scope of our research. This is, nevertheless, an intriguing finding that would merit attention in future investigations.

## Features and Limitations of This Study

Mobile- or internet-based health interventions to promote adherence to therapy are considered to have potential, but to need enhanced quality and range of research [26-28]. Four aspects of DIAPAsOn should be examined in this context. First, our original intention was to conduct a study that emphasized inclusivity and a wide geographical distribution in order to, as we saw it, gain as much real-world (and by implication generalizable) experience as was possible with both the n-3 PUFA preparation and the digital engagement instruments. To that end, we applied what might, with the benefit of hindsight, be seen as an excessively “open” approach to recruitment: access to and proficiency with digital technology was a prerequisite for participation, but we did not explore with individual patients their *a priori* willingness to use such technology and to sustain that use over a period of several months. Second, instruction in the use of the technology was essentially delegated to individual investigators; they, while fully competent as clinicians and clinical researchers, may not have been best qualified to instruct, monitor, or motivate patients in this aspect of the study. We do not know the extent (if any) to which patients’ misunderstanding of what was being asked of them contributed to the outcome. Third, the digital facilities used in DIAPAsOn were developed in conjunction with a professional technology provider that has substantial experience and success in providing such services to the medical community in Russia. Much of that experience is at registry level, however, with input from physicians or trained assistants. We sought to make the technology accessible and frictionless to “retail” users, but the facts of our experience suggest that this aspect of our program may not have been successful. Here again, however, we are unable to say with assurance if that really was the case and, if so, why. Fourth, our work might perhaps have benefited from a small-scale scoping study or a pilot phase before the technology was deployed in such a large patient population. The work of Chen et al [29] with the Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure system provides a model of how to explore patient engagement in such a preliminary phase.

Evaluation of our digital platform by means of the Mobile Application Rating Scale [30] might also have helped to refine the technology and enhance its acceptance by patients, and the failure to apply that test in advance may be considered a missed opportunity. One hazard of such an approach, however, is that by catering to the priorities of patients already well-disposed toward mobile health technology, the needs of “digital exiles” are overlooked. To that extent, DIAPASOn has provided useful insights into the sort of real-world populations that might be encountered (at least in Russia) and some of the challenges that these populations pose for proponents of mobile or eHealth services. Provision for a more rigorous, ongoing interrogation of patients’ lack of compliance with the electronic facilities devised for this study would, with hindsight, have been prudent, as well as possibly informative, and we would advocate for such provision in any similar future research.

An overarching conclusion from this experience has to be that active patient (and physician) engagement and participation in the development of an online or mobile adherence aid is critical for successful longer-term adoption. With hindsight, the omission of such a stage from our study may be seen as a missed opportunity and is something we would prioritize in any similar future study.

The duration of follow up in DIAPASOn was appropriate for a first assessment of a technical innovation in conjunction with an established therapy, but a substantially longer period of observation would be needed to demonstrate robust and meaningful improvements in long-term compliance and adherence, regardless of the technologies or medications used.

This is also a consideration that we would factor into any future similar research projects.

As with observational studies in general, the absence of a control group precludes any determination of cause and effect, and the potential for biases in any trial of this type must be acknowledged. A retrospective calculation of the Nichol score [31] for DIAPASOn confirmed that our study rated favorably in the subcategories “disease-related criteria” and “compliance definition and measurement criteria” but scored less strongly in the subcategory “study design criteria.”

## Conclusions

Uptake of digital methods for self-reporting adherence to therapy was low in this study and indicates a need for further research into the factors that motivate or discourage patients to take advantage of such services and how best to use these technologies to promote treatment compliance. Properly resourced attention to these considerations needs to be incorporated into study protocols.

Data collected through DIAPASOn confirm the clinical profile of OM3EE as an effective and well-tolerated lipid-modifying therapy and as an appropriate element of a medical regime for the management of hypertriglyceridemia or the secondary prevention of MI. Substantial (approximately 1 mmol/L) baseline-dependent reductions in TG were recorded, and other nominally advantageous alterations in the lipid profile were apparent, including reduction in levels of non-HDL-C, regardless of the concomitant use of statins or fibrates. Investigation into compliance with therapy produced conflicting results, depending on the method of reporting used.

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## Conflicts of Interest

GPA has not received any educational grants from any companies and has not received any fees or nonfinancial support from health care companies related to this study. GPA reports receiving honoraria for professional lectures at regional and national medical educational events from health care companies including Abbott, Bayer, Boehringer Ingelheim, and Servier. AGA has not received any educational grants from any companies and has not received any fees or nonfinancial support from health care companies related to this study. AGA reports receiving honoraria for professional lectures at regional and national medical educational events from health care companies including Abbott, Bayer, Boehringer Ingelheim, and Servier. FTA and TVF declare no conflicts of interest.

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### Multimedia Appendix 1

Listing of DIAPASOn center investigators.

[[DOCX File , 25 KB - cardio\\_v6i2e37490\\_app1.docx](#) ]

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### Multimedia Appendix 2

Supplementary tables.

[[DOCX File , 64 KB - cardio\\_v6i2e37490\\_app2.docx](#) ]

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## Abbreviations

**ADR:** adverse drug reaction

**CEPHEUS II:** Centralized Pan-Russian Survey of the Undertreatment of Hypercholesterolemia II

**HDL-C:** high-density lipoprotein cholesterol

**HRQoL:** health-related quality of life

**LDL-C:** low-density lipoprotein cholesterol

**MI:** myocardial infarction

**n-3 PUFA:** omega-3 polyunsaturated fatty acid

**OM3EE:** omega-3-acid ethyl esters

**TC:** total cholesterol

**TG:** triglyceride

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Original Paper

# The Impact of Time Horizon on Classification Accuracy: Application of Machine Learning to Prediction of Incident Coronary Heart Disease

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## Abstract

**Background:** Many machine learning approaches are limited to classification of outcomes rather than longitudinal prediction. One strategy to use machine learning in clinical risk prediction is to classify outcomes over a given time horizon. However, it is not well-known how to identify the optimal time horizon for risk prediction.

**Objective:** In this study, we aim to identify an optimal time horizon for classification of incident myocardial infarction (MI) using machine learning approaches looped over outcomes with increasing time horizons. Additionally, we sought to compare the performance of these models with the traditional Framingham Heart Study (FHS) coronary heart disease gender-specific Cox proportional hazards regression model.

**Methods:** We analyzed data from a single clinic visit of 5201 participants of a cardiovascular health study. We examined 61 variables collected from this baseline exam, including demographic and biologic data, medical history, medications, serum biomarkers, electrocardiographic, and echocardiographic data. We compared several machine learning methods (eg, random forest, L1 regression, gradient boosted decision tree, support vector machine, and k-nearest neighbor) trained to predict incident MI that occurred within time horizons ranging from 500-10,000 days of follow-up. Models were compared on a 20% held-out testing set using area under the receiver operating characteristic curve (AUROC). Variable importance was performed for random forest and L1 regression models across time points. We compared results with the FHS coronary heart disease gender-specific Cox proportional hazards regression functions.

**Results:** There were 4190 participants included in the analysis, with 2522 (60.2%) female participants and an average age of 72.6 years. Over 10,000 days of follow-up, there were 813 incident MI events. The machine learning models were most predictive over moderate follow-up time horizons (ie, 1500-2500 days). Overall, the L1 (Lasso) logistic regression demonstrated the strongest classification accuracy across all time horizons. This model was most predictive at 1500 days follow-up, with an AUROC of 0.71. The most influential variables differed by follow-up time and model, with gender being the most important feature for the

L1 regression and weight for the random forest model across all time frames. Compared with the Framingham Cox function, the L1 and random forest models performed better across all time frames beyond 1500 days.

**Conclusions:** In a population free of coronary heart disease, machine learning techniques can be used to predict incident MI at varying time horizons with reasonable accuracy, with the strongest prediction accuracy in moderate follow-up periods. Validation across additional populations is needed to confirm the validity of this approach in risk prediction.

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## KEYWORDS

coronary heart disease; risk prediction; machine learning; heart; heart disease; clinical; risk; myocardial; gender

## Introduction

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States and worldwide. The prevalence of CVD in adults within the United States has reached 48% and greater than 130 million adults in the United States are projected to have CVD by 2035, with total costs expected to reach US \$1.1 trillion [1]. The leading cause of deaths attributable to CVD are from coronary heart disease, followed by stroke, hypertension, and heart failure [1]. This year alone, roughly 605,000 Americans will have an incident myocardial infarction (MI) and greater than 110,000 will die from MI [1]. Given the high prevalence of MI, there is significant focus on identifying those most likely to develop incident coronary heart disease [2-5]. If properly identified, primary preventive pharmacologic and lifestyle strategies can be applied to those at the highest risk [6].

Historically, risk prediction models have been developed by applying traditional statistical models (ie, regression-based models and Cox) to cohort data [7-10]. These analyses have provided a breadth of information about the risk of CVD and have been very useful clinically, given their straightforward relationships between a small number of variables and the outcome of interest [11-16]. However, these risk scores often do not achieve high reliability when applied to novel data sets [10,17]. Currently, roughly half of MIs and strokes occur in people who are not predicted to be at an elevated risk for CVD [18].

Machine learning has been introduced as a novel method for processing large amounts of data, focused primarily on accurate prediction rather than understanding the relative effect of risk factors on disease. In some applications, machine learning methods have been found to improve upon traditional regression models for predicting various cardiovascular outcomes [19-22]. A key aspect of applying machine learning methods is the bias-variance trade-off or balancing how accurately a model fits the training data (bias) and how well it can be applied broadly (variance) in out-of-sample testing or validation data [23]. Machine learning models tend to excel when dealing with a large number of covariates and nonlinear or complex relationships of covariates, often at the expense of overfitting a particular training set [24]. However, with an increased ability to model complex interactions between covariables comes a decrease in understanding how risk factors relate to an outcome. Additionally, one key limitation of many machine learning methods is that they are often classification models that do not include well-developed methods to incorporate information

about time-to-event data. Investigators often select a single time horizon for classification, but how varying time horizons affect the relative prediction accuracy is a relatively unexplored aspect of machine learning methods. We hypothesize that there is a trade-off in the selection of the predictive time horizon, in which the use of shorter time horizons offers an increased relevance of predictors to outcomes and greater effect sizes. This is balanced against an increase in the number of events when the time horizon is of longer duration. Based on this trade-off, we would predict that moderate time horizons would have the highest predictive accuracy.

With this investigation, we examined the impact of varying time horizons on the prediction of incident MI. Using data from the Cardiovascular Health Study (CHS) [25], we examined the predictive accuracy of multiple machine learning algorithms over varying time frames of 500 days through 10,000 days of follow-up to identify incident MI. Additionally, we used the Framingham Heart Study (FHS) coronary heart disease gender-specific Cox proportional hazards regression model for comparison to the machine learning models. We aimed to find what time horizon would have the highest predictive accuracy and examine how this compared with the prediction accuracy of the FHS regression model.

## Methods

### Ethical Considerations

Data were approved for use by the Cardiovascular Health Study Policies and Procedures Committee with accompanying data and materials distribution agreement.

### Data Set Creation

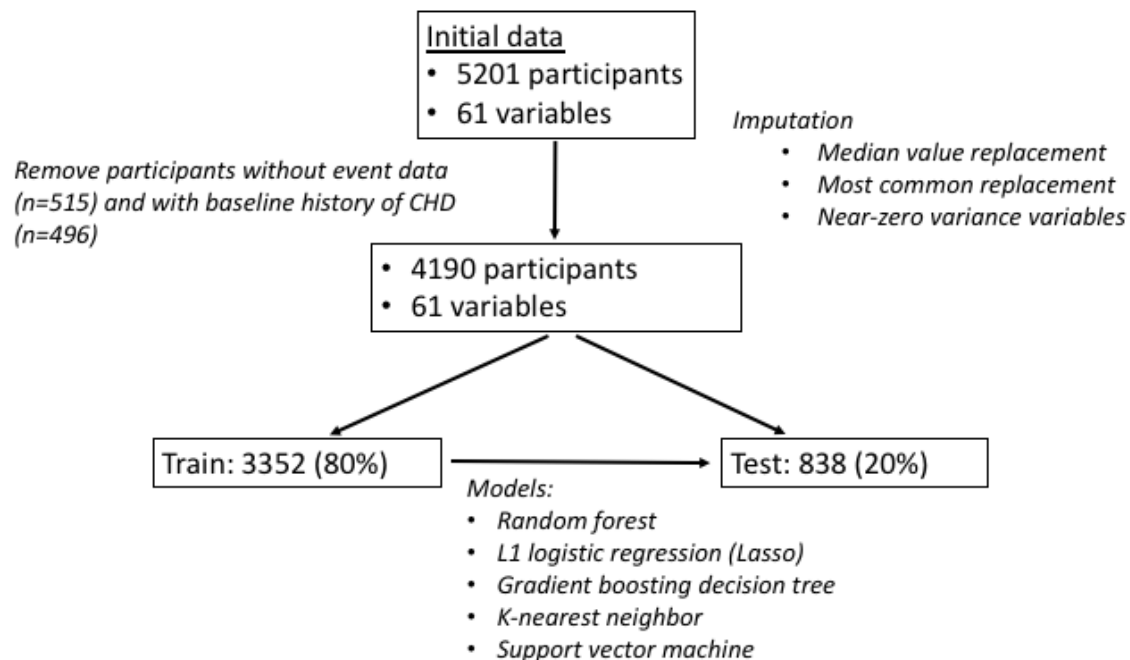
We used anonymized data from the CHS [25], the design and objectives of which have been previously described. Briefly, the CHS is a longitudinal study of men and women aged 65 years or older, recruited from a random sample of Medicare-eligible residents of Pittsburgh, PA, Forsyth County, NC, Sacramento, CA, and Hagerstown, MD. The original cohort of 5201 participants was enrolled in 1989-1990 and serves as the sample for this study. Baseline data were obtained in this cohort, and routine clinic visits and telephone interviews were conducted periodically going forward.

We excluded patients with a baseline history of prior MI from the cohort. We examined 61 variables collected from the baseline exam, including demographic and biologic data (Table S1 in [Multimedia Appendix 1](#)).

Using an end point of incident MI, we applied multiple machine learning methods across varying time horizons to define an optimal risk prediction. Missing variable data was quite uncommon for baseline demographic and laboratory data. Although overall infrequent, missing data was more common

for electrocardiogram variables. In these cases of missing data, imputation was performed on missing variables using median value replacement for continuous variables and most common replacement for categorical variables (Figure 1).

**Figure 1.** Analysis flowchart. CHD: Cardiovascular Health Study.



## Statistical Analysis

The data set was randomly split into a training set (80%) and a testing or validation set (20%). The training data set was used to construct 5 machine learning models: random forest, L1 (LASSO) regression, support vector machine, k-nearest neighbor, and gradient boosted decision tree. Hyperparameter tuning to identify the optimal values for parameters that are not learned during the training process was performed using the validation set. These models were then applied to the test set to examine model performance, which was assessed using an area under the receiver operating characteristic curve (AUROC). Additionally, we used the FHS coronary heart disease Cox proportional hazards regression model as a comparison to the machine learning models (Table S2 in [Multimedia Appendix 1](#)) [7,9,26].

Starting at 500 days, we looped each model over 500-day time horizons in order to identify the optimal predictive horizon up through 10,000 days of follow-up time. For each time horizon, variable importance algorithms were applied to the L1 regression and random forest models. In the L1 regression model, coefficients that are less helpful to the model were shrunk to zero, thereby removing unneeded variables altogether. The remaining coefficients are the variables selected. Because models use normalized inputs, direct comparison of coefficients can be performed based on the absolute value of the average coefficient for each input. In the random forest algorithm, we performed a “permutation” feature selection, which measures the prediction strength of each variable by measuring the

decrease in accuracy when a given variable is essentially voided within the model.

Preliminary analyses identified a high degree of bias related to the cases that were selected within the held-out split sample, and so we performed 50 analyses with different random seeds, with separate results stored for each model, time horizon, and seed number (a total of 1000 separate models for each type of model). Results were compiled based on the average AUROC, coefficient value (L1 regression), and impurity or accuracy (random forest) for each model. Model comparison was performed using linear mixed effects models, with seed number as the random effect and unstructured covariance matrix pattern.

All modeling was performed using publicly available packages on R software (version 1.1.463; The R Foundation for statistical computing). The code used for analysis is provided in [Multimedia Appendix 1](#). Model comparisons (mixed effects models) were performed using Stata IC (version 14; Stata, Inc).

## Results

Baseline characteristics of the study participants are presented in [Table 1](#). There were a total of 4190 participants included. The average age of the cohort was 72.6 years, and 2522 (60.2%) participants were female. At baseline, 2201 (53%) had a history of ever using tobacco, 2300 (55%) had a diagnosis of hypertension, and 389 (9.3%) had a diagnosis of diabetes. Over 30 years of follow-up, there were 813 incident MI events at a median follow-up time of 4725 days.

**Table 1.** Baseline Characteristics of the study participants.

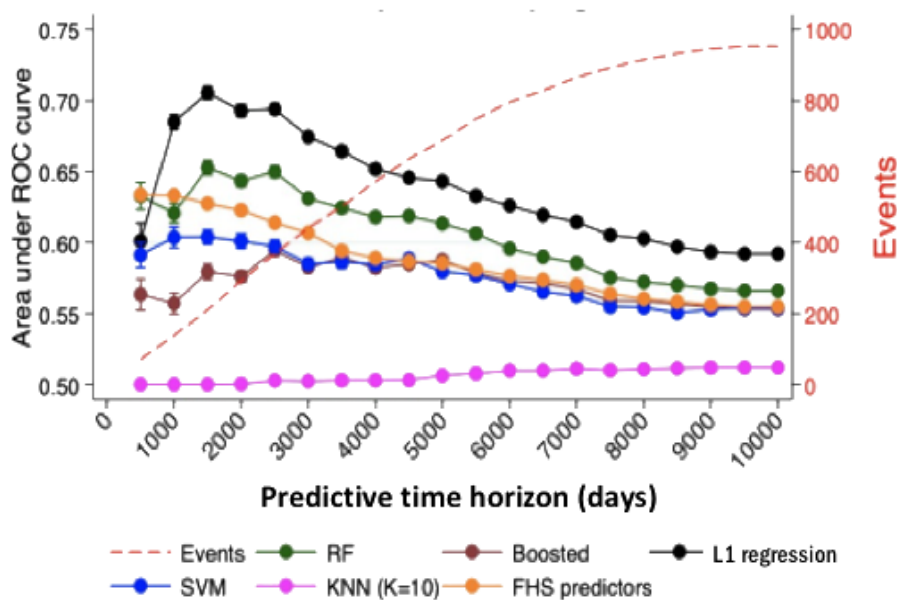
Characteristics	Values (N=4190)
Age (years), mean (SD)	72.6 (5.6)
Gender (male), n (%)	1668 (39.8)
Tobacco consumption, n (%)	2201 (53)
Hypertension, n (%)	2300 (55)
Diabetes, n (%)	389 (9.3)
Total Cholesterol (mg/dL), mean (SD)	211 (38)
BMI, mean (SD)	26.4 (1.9)

## Comparison of Prediction Models Across Time Horizons

Relative performance of the machine learning methods and FHS model is displayed in Figure 2 as the AUROC across cut points for the time horizon. The machine learning models were generally most predictive over moderate time horizons of 1500-2500 days of follow-up.

In addition to examining AUROC, we also examined the area under the precision-recall curve (Figure 3), which favored later time horizons, but with no change in the order of model performance. The L1 regression model still had the highest performance across time points.

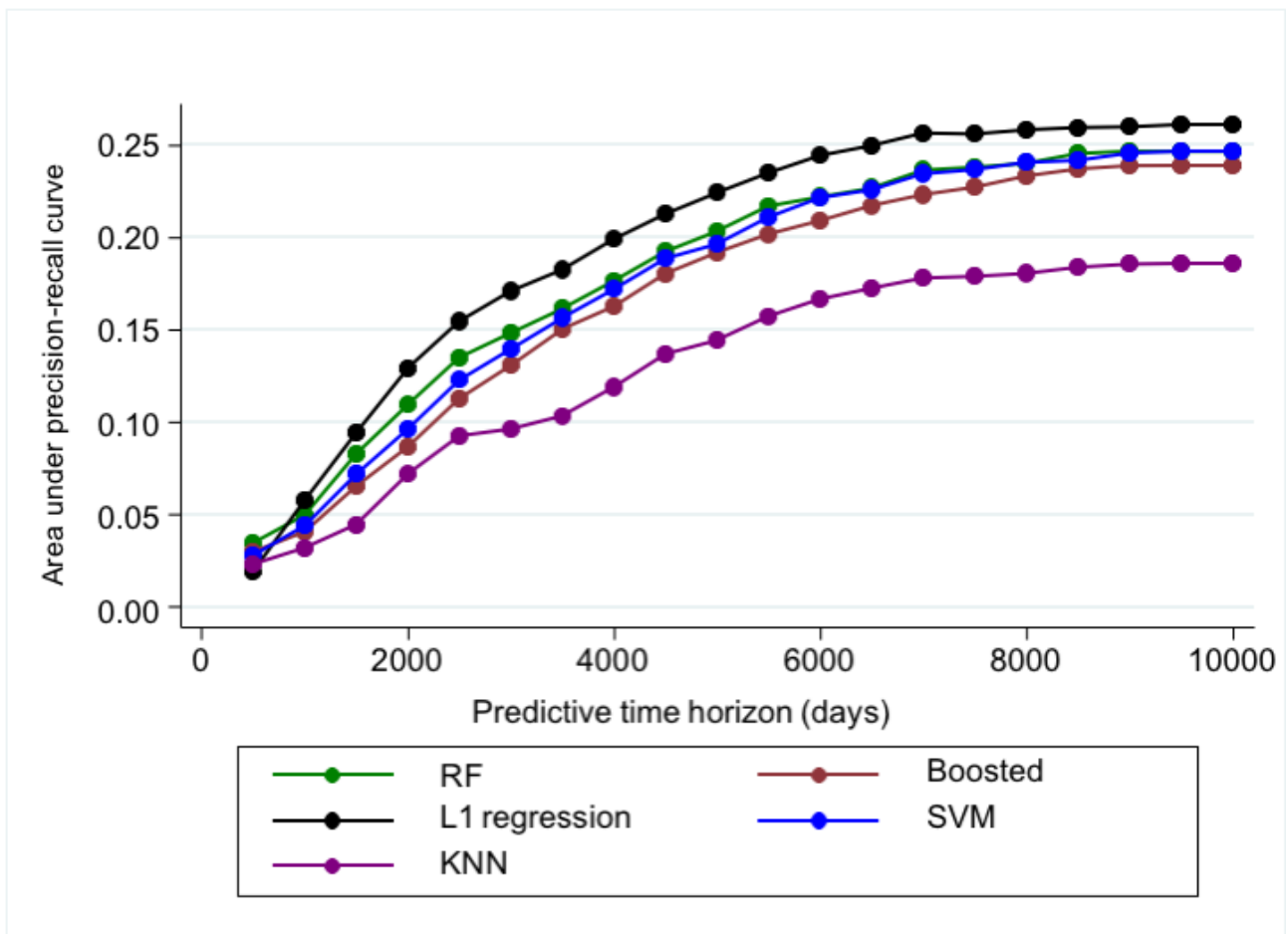
**Figure 2.** Predictive accuracy over varying time horizons. FHS: Framingham Heart Study; KNN: k-nearest neighbor; RF: random forest; ROC: receiver operating characteristics; SVM: support vector machine.



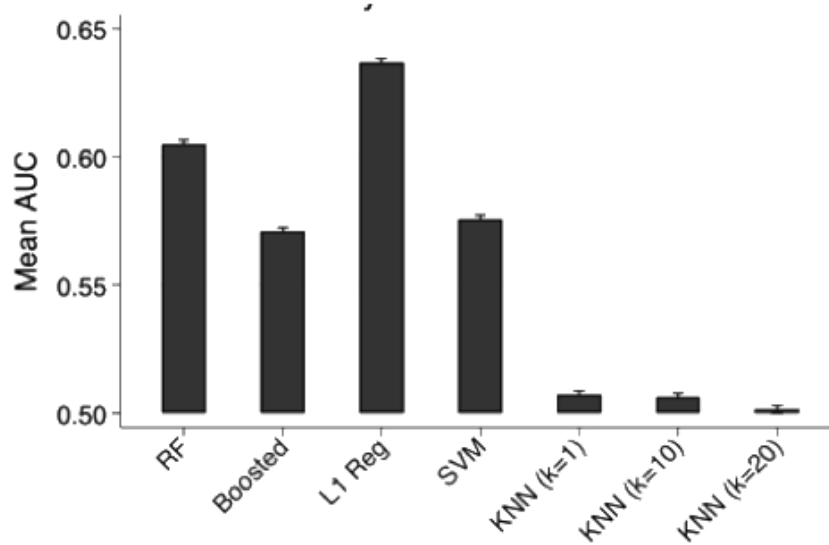
The L1 logistic regression was overall the most predictive across all time points (Figure 4) and displayed the highest prediction accuracy at 1500-day time horizon with an AUROC of 0.71. The k-nearest neighbor model performed relatively poorly across all time points.

When compared with the FHS model, the L1 model performed worse at 500 days of follow-up but had superior prediction accuracy at all subsequent follow-up times. The random forest model performed better than the FHS model starting at 1500 days of follow-up and longer. The remaining machine learning models were less predictive than the FHS model across all time frames (Figure 2).

**Figure 3.** Predictive Accuracy using area under precision-recall curve. KNN: k-nearest neighbor; PR: precision-recall; RF: random forest; SVM: support vector machine.



**Figure 4.** Prediction accuracy across all time horizons. AUC: area under the curve; KNN: k-nearest neighbor; RF: random forest; SVM: support vector machine.



## Feature Selection

Some machine learning algorithms allow for analysis of variable

contributions to the model. For this analysis, feature importance was performed across all time points for the L1 regression and random forest models (Table 2).

**Table 2.** Feature selection (top features).

Model	Short-term follow-up (500-1000 days)	Intermediate follow-up (1500-2500 days)	Long-term follow-up (>2500 days)
L1 regression	<ul style="list-style-type: none"> <li>Gender (0.90)</li> <li>Calcium channel blockers (0.47)</li> <li>IVCD<sup>a</sup> by ECG<sup>b</sup> (0.40)</li> <li>Diabetes mellitus (0.32)</li> <li>Smoking (0.22)</li> <li>Systolic blood pressure (0.21)</li> </ul>	<ul style="list-style-type: none"> <li>Gender (1.03)</li> <li>Diabetes mellitus (0.33)</li> <li>Calcium channel blockers (0.42)</li> <li>Hypertension (0.27)</li> <li>Alcohol (per week) (-0.21)</li> </ul>	<ul style="list-style-type: none"> <li>Gender (0.50)</li> <li>Calcium channel blockers (0.33)</li> <li>Diabetes mellitus (0.20)</li> </ul>
Random forest	<ul style="list-style-type: none"> <li>Weight</li> <li>FEV1<sup>c</sup></li> <li>BMI</li> <li>Height</li> <li>LDL-C<sup>d</sup></li> </ul>	<ul style="list-style-type: none"> <li>Weight</li> <li>FEV1</li> <li>BMI</li> <li>Height</li> <li>Gender</li> </ul>	<ul style="list-style-type: none"> <li>Weight</li> <li>Total cholesterol</li> <li>BMI</li> <li>Height</li> <li>LDL-C</li> </ul>

<sup>a</sup>IVCD: intraventricular conduction delay.

<sup>b</sup>ECG: electrocardiogram.

<sup>c</sup>FEV1: forced expiratory volume in one second.

<sup>d</sup>LDL-C: low-density lipoprotein cholesterol.

For the L1 regression, the most important variables (based on the absolute value of coefficients applied to normalized inputs) at short-term follow-up intervals (ie, <1000 days) were gender, history of diabetes, use of calcium channel blockers or  $\beta$ -blockers, and having a ventricular conduction defect by electrocardiogram. At intermediate follow-up interval (ie, 1500-2500 days), the most important variables were gender, use of calcium-channel blocker, history of diabetes, and history of hypertension. At longer follow-up times (ie, >2500 days), the most important variables were gender, use of calcium channel blocker, and history of diabetes.

For the random forest variable selection based on accuracy, the most important variables at short-term follow-up intervals (ie, <1000 days) were weight, forced expiratory volume (FEV) by pulmonary function testing, BMI, height, and low-density lipoprotein (LDL) cholesterol. At intermediate follow-up interval (1500-2500 days), the most important variables were weight, FEV, BMI, height, and gender. At longer follow-up times (ie, >2500 days), the most important variables were weight, height, BMI, LDL cholesterol, and total cholesterol.

## Discussion

### Principal Findings

This study demonstrates the ability to use machine learning methods for the prediction of incident MI over varying time horizons in cohort data. Using AUROC as the primary metric for model performance, prediction across all models was most accurate in the moderate (ie, 1500-2500 day) follow-up horizon. The L1 regularized regression provided the most accurate prediction across all time frames, followed by the random forest algorithms. These two models compared favorably to the FHS coronary heart disease prediction variables, especially at longer follow-up intervals. Applying ranked variable importance

algorithms demonstrated how the variables selected differed over time and in different models.

Prediction was most accurate in the moderate follow-up horizon. We suspect that this was due to the balance of accumulating enough events while still being close in time to the baseline data collected. A predictor that is measured closer in time to the outcome is more likely to be relevant in prediction, and as more events accumulate over time, the power to identify a predictive model increases. Prior studies have looked at machine learning prediction of coronary heart disease at short and intermediate follow-up times; however, to our knowledge, this is the first study to apply models to annual time horizons from short- to long-term follow-up [27].

The L1 regularized regression generally provided the most accurate prediction across all time frames. These regularized regression models expand upon traditional regression models by searching across all variables for the best subset of predictors prior to fitting a regression model. An L1 (Lasso) regression differs from other regularized regression models in that it can shrink the importance of many variables to zero, allowing for feature selection in addition to preventing overfitting. As such, it is very useful when using many variables, like in a cohort or electronic health record data. Prior studies have found these models to be comparable to more advanced machine learning methods for predicting clinical outcomes [28]. The random forest model also performed quite well. Random forest is a regularized form of classification and regression tree model that searches for the covariates that best split the data based on outcome, and then continues to split using additional covariates until many decision “trees” are formed. These models avoid overfitting and can also overcome nonlinearity and handle many variables. The accuracy of the L1 regression and random forest prediction models based on AUROC is reasonable in our study in comparison to prior work [29]. It is worthy of note that we did not include interaction or polynomial terms in the L1



regression, and as such, this model would not be able to identify nonlinear effects between predictors in the same manner as random forest. Our finding that L1 regression provided superior predictive accuracy despite this limitation suggests that nonlinear effects may be less important with these predictors for coronary artery disease or MI, although further work would be needed to support this claim.

With machine learning models, the relationship between any one variable and the outcome is not as clear as with standard regression models. However, some methods can provide the relative importance of each variable to the model creation. We performed ranked variable analysis for the L1 regression and random forest models. We found that, generally, the models found traditional risk factors to be the most important; however, these most important variables changed over time.

The random forest variable importance found weight, height, LDL-cholesterol, and BMI to be highly important across time frames. FEV was important in short- and medium-term follow-up but less important in longer-term follow-up. For the L1 regression, gender, history of diabetes, and the use of calcium channel blockers were important variables across all time horizons. Although these associations are interesting, causation cannot be applied to these analyses, and it can only suggest further study on the importance of these variables.

### Limitations

This study has some notable limitations. First, the CHS [25] data for incident MI are failure time data, and our model does

not allow for censored observations due to lack of follow-up. Second, both testing and validation were performed only within the CHS cohort. Although on the one hand, this is an important examination of a specific population, it limits the applicability of our findings to the global population. Machine learning models are very sensitive to the training population and have been found to be biased when created in one population and applied in another. Since the CHS cohort is composed of individuals over the age of 65 years, this analysis provides an opportunity to study machine learning models in this group. We used the original cohort of 5201 participants enrolled in the CHS, which leaves out a subsequent, predominantly African American cohort, making the results less applicable to the global population. Given these limitations, this analysis needs to be validated in novel cohorts. Additionally, this model cannot easily be directly applied to clinical practice; however, this study presents a model for performing similar analysis in more clinically applicable data sets, including electronic health record data. We aim to accomplish this with future studies.

### Conclusions

In a population free of coronary heart disease, machine learning techniques can be used to accurately predict development of incident MI at varying time horizons. Moderate follow-up time horizons appear to have the most accurate prediction given the balance between proximity to baseline data and allowing ample number of events to occur. Future studies are needed to validate this technique in additional populations.

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### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Tables and code used for model analysis.

[DOCX File, 43 KB - [cardio\\_v6i2e38040\\_app1.docx](#)]

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## Abbreviations

**AUROC:** area under the receiver operating characteristic curve

**CHS:** Cardiovascular Health Study

**CVD:** cardiovascular disease

**FEV:** forced expiratory volume

**FHS:** Framingham Heart Study

**MI:** myocardial infarction

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