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Original Paper

Consumer Wearable Devices for Activity Monitoring Among Individuals After a Stroke: A Prospective Comparison

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Abstract

Background: Activity monitoring is necessary to investigate sedentary behavior after a stroke. Consumer wearable devices are an attractive alternative to research-grade technology, but measurement properties have not been established.

Objective: The purpose of this study was to determine the accuracy of 2 wrist-worn fitness trackers: Fitbit Charge HR (FBT) and Garmin Vivosmart (GAR).

Methods: Adults attending in- or outpatient therapy for stroke (n=37) wore FBT and GAR each on 2 separate days, in addition to an X6 accelerometer and Actigraph chest strap monitor. Step counts and heart rate data were extracted, and the agreement between devices was determined using Pearson or Spearman correlation and paired *t* or Wilcoxon signed rank tests (one- and two-sided). Subgroup analyses were conducted.

Results: Step counts from FBT and GAR positively correlated with the X6 accelerometer ($\rho=.78$ and $\rho=.65$, $P<.001$, respectively) but were significantly lower ($P<.01$). For individuals using a rollator, there was no significant correlation between step counts from the X6 accelerometer and either FBT ($\rho=.42$, $P=.12$) or GAR ($\rho=.30$, $P=.27$). Heart rate from Actigraph, FBT, and GAR demonstrated responsiveness to changes in activity. Both FBT and GAR positively correlated with Actigraph for average heart rate ($r=.53$ and $.75$, $P<.01$, respectively) and time in target zone ($\rho=.49$ and $.74$, $P<.01$, respectively); these measures were not significantly different, but nonequivalence was found.

Conclusions: FBT and GAR had moderate to strong correlation with best available reference measures of walking activity in individuals with subacute stroke. Accuracy appears to be lower among rollator users and varies according to heart rhythm. Consumer wearables may be a viable option for large-scale studies of physical activity.

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KEYWORDS

physical activity; heart rate; accelerometry; stroke rehabilitation; walking

Introduction

Activity After Stroke

Physical activity and exercise are recommended for stroke survivors because of the wide range of benefits that support

recovery [1,2]. In addition to reducing disability, fitness interventions, particularly cardiorespiratory training, improve walking ability and aerobic capacity [3,4]. On the basis of strong evidence for a clear effect on cardiovascular health [5], physical activity is a key component of secondary prevention to lower

the risk of recurrent stroke [6]. Unfortunately, there is a gap between clinical guidelines and actual behavior. Studies have consistently found that persons with stroke are very sedentary [7-11], even when compared to older adults with other chronic health conditions [12,13]. Despite sufficient capability, many individuals are not active enough to support physical fitness [14], and cardiorespiratory health may decline over time [15].

Monitoring Activity

As an outcome measure for research trials, for example, testing the effectiveness of exercise training, self-report measures are frequently used to collect information on free-living physical activity but are prone to inaccuracy (eg, overestimation) from recall bias [16,17]. As several investigators have recommended [14,17-19], combining objective methods of quantifying movement (ie, accelerometry) with questionnaires and heart rate monitors will allow for better evaluation of interventions, both in and outside of clinical settings (eg, rehabilitation). Wearable technology provides a practical way to continuously record physiological responses as daily activity is tracked; however, challenges to implementation exist in certain contexts such as with patient populations.

Historically, accelerometer-based activity monitors developed for research settings have been expensive and relatively difficult to use. For example, the Accelerometry for Bilateral Lower Extremities system, which accurately measures walking activity after stroke, requires trained personnel and a custom algorithm that operates on proprietary software to process the data [20]. The commercially available Actigraph wGT3X+ can measure heart rate with a chest strap sensor; however, adherence to wearing the device in the community is extremely low [19]. Activity monitoring is now accessible to the public with recently developed “fitness trackers” (eg, Fitbit and Garmin) that are inexpensive and user-friendly. These popular consumer devices provide information on step counts and heart rate and are, therefore, attractive for large-scale studies of physical activity. As a health behavior change strategy, feedback to the wearer could also foster motivation and accountability in self-management programs [21,22].

Accelerometers can be reliable and valid for activity monitoring in persons with stroke [9], whereas the measurement properties of consumer “wearables” have not been established. The purpose of this study was to determine the accuracy of 2 fitness trackers—Fitbit Charge HR (FBT) and Garmin Vivosmart (GAR)—for measuring physical activity among individuals attending stroke rehabilitation. We hypothesized that step counts and heart rate data from the consumer devices would have “acceptable” agreement with previously validated sensors. Patient perceptions of device acceptability and usability were also investigated.

Methods

Participants

This study was approved by the institutional research ethics board. Sample size target was 40 to represent the range of physical function typical of the subacute stroke population. Between June 2016 and March 2017, 37 adults attending in- or outpatient therapy for stroke at the Toronto Rehabilitation Institute provided written informed consent following an invitation to participate. Individuals were excluded if they were unable to walk without physical assistance from another person or if they were unable to understand written or spoken English. Participant characteristics are presented in [Table 1](#).

Procedures

Participants wore 4 devices for 5.5-10 hours consecutively: (1) Actigraph chest strap heart rate monitor worn under clothing; (2) wGT3X+ sensor (Actigraph, Pensacola, Florida, USA); (3) Model X6-2mini (“X6”) accelerometer (Gulf Coast Data Concepts, LLC, Waveland, Mississippi, USA); and (4) consumer wearable device on the wrist of the less-affected arm: FBT (Fitbit Inc., San Francisco, California, USA) and GAR (Garmin Ltd., Schaffhausen, Switzerland), which were worn on 2 separate days within 1 week. The wGT3X+ sensor is also capable of accelerometry but was only used in this study to store the Actigraph heart rate data. Although body location differs between devices, the placements are consistent with previous validation methods and regular functionality such that results are applicable to use in “real-life.”

Study personnel visited inpatients on the stroke unit in the morning (typically between 8 am and 9 am) to don the devices and then retrieved them at the end of the workday (~4 pm). Outpatient participants were met during the day and sent home wearing the devices, along with instructions to remove them before bed and to return them at their next visit or therapy session. A piece of Fabrifoam was used to affix the wGT3X+ sensor and X6 accelerometer to the ankle of the less-affected leg. Participants were instructed to go about normal daily activities and not remove the devices unless required (eg, discomfort, personal hygiene, or risk of damage), or unless they became a burden. Upon retrieval or return, participants completed a feasibility questionnaire asking about their experience and thoughts on the device ([Multimedia Appendix 1](#)). Part A was completed after each time either the FBT or GAR was worn, and Part B, pertaining to the chest strap and ankle units, was administered on the second day. Both parts consisted of 6 questions, and responses were obtained through yes/no options, space for open explanations, as well as Likert and visual analog scales.

Table 1. Participant characteristics (n=37).

Descriptive variable	Mean (SD) ^a , median, or count	Range or percentage ^b
Age, years	64.4 (15.0)	41-90
Women	13	35
Height, cm	171.0 (9.3)	152-190.5
Weight, kg	77.1 (15.4)	45-113
Time post stroke, days	42.6 (33.2)	12-135
Affected side		
Left	20	54
Right	15	41
Bilateral	1	3
None	1	3
NIH-SS ^c score	2	0-11
COVS ^d score	85	65-91
BBS ^e score	53	4-56
CMSA ^f stage of leg	6	4-7
CMSA ^f stage of foot	6	3-7
Walking speed, m/s	0.92 (0.29)	0.28-1.5
Gait aid		
None	12	32
Rollator	17	46
Single point cane	8	22
Atrial fibrillation	6	16

^aSD: standard deviation.

^bPercentages may not sum to 100% due to rounding.

^cNIH-SS: National Institutes of Health-Stroke Scale.

^dCOVS: Clinical Outcome Variables Scale.

^eBBS: Berg Balance Scale.

^fCMSA: Chedoke-McMaster Stroke Assessment.

Within 2 days of activity monitoring, the following tests were conducted for each participant during a short data collection session or as part of routine clinical care (data then extracted from patient chart): the National Institutes of Health-Stroke Scale (NIH-SS) [23], Berg Balance Scale (BBS) [24], Clinical Outcome Variables Scale (COVS) [25], Chedoke-McMaster Stroke Assessment (CMSA) [26] stage of leg and foot, and self-selected walking pace obtained from a pressure-sensitive mat (GAITRite, CIR Systems Inc., Havertown, Pennsylvania, USA). Height and weight were also recorded. The following information was obtained from hospital charts or directly from participants: age, sex, time since stroke, lesion location, medical history, and list of medications.

Maximum heart rate was determined in 1 of the following 3 ways: cardiopulmonary exercise test as part of routine care (value recorded by electrocardiography when respiratory exchange ratio >1.1; n=3); estimation using published formulas (164–0.7×age for individuals taking beta-blockers [27] and 208–0.7×age for all others [28]; n=3 and 26, respectively); or

peak heart rate observed during the 2-day monitoring if higher than the age-predicted maximum (n=5).

Data Processing

Step counts were extracted from the X6 accelerometer data using a previously validated custom written algorithm implemented in MATLAB (MathWorks, Nantick, Massachusetts, USA) [29]. FBT and GAR were synchronized to the manufacturers' Web-based applications to extract step counts.

Heart rate data, transmitted from the Actigraph chest strap monitor to the wGT3X+ sensor via Bluetooth, were transferred to a computer, initially processed in 60-second epochs using the ActiLife software version 6 (Actigraph, Pensacola, Florida, USA), and exported to a text file. We noted that a number of Actigraph data points were physiologically improbable (<45 beats per minute); these were removed before further processing. To allow for comparison of heart rate measurement, we created time-aligned Actigraph and FBT/GAR data series. Actigraph

heart rate data were averaged over 5-min epochs to compare with FBT values, which were manually transcribed into a spreadsheet from the Web application due to manufacturer's restrictions in accessing raw data. GAR heart rate time series data were downloaded from the Web application as TCX files in 60-second epochs and converted into text files.

Because a large amount of heart rate data were missing, we first examined responsiveness of Actigraph, FBT, and GAR measures to changes in activity. Step counts from the X6 accelerometer were tallied over 5-min (for FBT) and 1-min (for GAR) epochs and aligned with the heart rate data. Heart rate, as recorded by each device, was averaged over all periods of rest (epochs with zero steps recorded) and at 3 intensities of walking activity: 50-79%, 80-99%, and $\geq 100\%$ of comfortable cadence (based on self-selected walking on the GAITRite mat). We then determined agreement between the Actigraph and FBT/GAR heart rate data. If epochs were missing for one device, the corresponding data were deleted for the other device. From these modified time series, average heart rate and time within a target zone (55-80% of maximum heart rate) were calculated for each device.

Data Analysis

Step counts from FBT and GAR were compared with the X6 accelerometer using Spearman correlation (ρ) and Wilcoxon signed rank tests. Both step count analyses were conducted for the whole group and separately by usual gait aid. To test the responsiveness of the devices to changes in physical activity, average heart rate at each intensity was compared with resting heart rate using paired t tests. Pearson or Spearman correlation and paired t tests or Wilcoxon signed rank tests, respectively, were used to compare average heart rate and time within the target heart rate zone from the Actigraph with those from the FBT and GAR. Analyses of heart rate data were conducted for

the group as a whole and separately for those with and without diagnosis of arrhythmia (ie, atrial fibrillation); only those participants with at least 60 min of valid heart rate data for both devices were included. For one-sided tests of equivalence, $\pm 5\%$ of the mean or median reference value was chosen as the upper/lower boundary limit; however, a clinically acceptable level of uncertainty is not clear from previous research. All statistical analyses were conducted in SAS version 9.2 (SAS Institute Inc., Cary, North Carolina, USA), and alpha was .05.

Bland-Altman plots were used to visualize interdevice agreement. The difference between the FBT or GAR data and the reference measurements for each participant were plotted against the average of the 2 values. The mean or median difference and its 95% CI or interquartile range were represented by lines on each graph.

Results

Missing Data

Out of all the participants, 5 chose not to complete the second day of the study; therefore, analysis of step count data was limited to 36 participants for FBT and 33 for GAR. Furthermore, 2 participants declined to wear the Actigraph chest strap, and there were less than 60 min of valid heart rate data on both devices for 4 (when wearing FBT) and 9 participants (when wearing GAR); therefore, comparison of Actigraph and wrist-device heart rate data was limited to 30 (for FBT) and 22 (for GAR) participants. Potential reasons for missing data are discussed below.

Step Counts

Results of the step count analyses are presented in Table 2, and Bland-Altman plots showing agreement of each wrist-worn device with the X6 accelerometer are in Figure 1.

Table 2. Agreement in step counts between X6 accelerometer and wrist-worn devices.

Group	FBT ^a				GAR ^b					
	n	ρ (P value)	Difference ^c (IQR) ^d	Error (IQR)	P ; $P_{U/L}$ ^e	n	ρ (P value)	Difference (IQR)	Error (IQR)	P ; $P_{U/L}$
All participants	36	.78 (<.001)	463 (-220 to 924)	32.9% (8.3-52.5)	.002; .99	33	.65 (<.001)	963 (59-1390)	40.9% (14.9-69.5)	.008; break>.99
No gait aid	13	.97 (<.001)	-203 (-288 to 339)	10.3% (5.5-30.4)	.85; .32	11	.56 (.07)	-561 (-1960 to 971)	23.1% (14.7-46.1)	.28; break>.077
Rollator	15	.42 (.12)	926 (386-1939)	52.3% (39.9-56.9)	.01; .99	15	.30 (.27)	1390 (283-2376)	67.2% (26.2-73.0)	.001; break>>.99
Single-point cane	8	.98 (<.001)	406 (-18 to 912)	12.6% (5.8-22.3)	.08; .90	7	.93 (.003)	963 (377-1330)	21.3% (15.0-41.1)	.02; break>.99

^aFBT: Fitbit Charge HR.

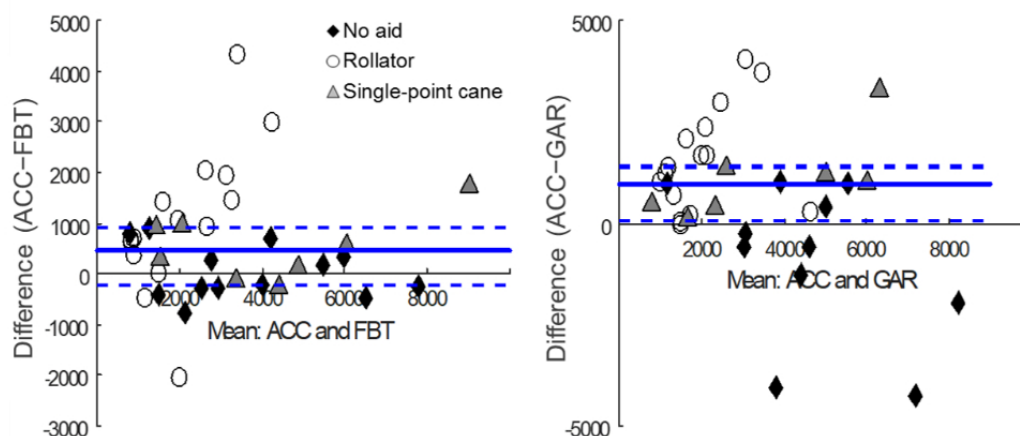
^bGAR: Garmin Vivosmart.

^cThe difference is calculated as the X6 accelerometer step count minus the wrist device step count; therefore, a positive value means the wrist-worn device undercounted, whereas a negative value means the wrist-worn device overcounted.

^dIQR: interquartile range

^e P values are for Wilcoxon signed rank tests: two-sided to compare median step counts of the devices and one-sided testing of whether the median difference is significantly different from a lower (P_L) and upper (P_U) limit (the greater of the 2 is reported).

Figure 1. Bland-Altman plots of step count agreement between X6 accelerometer (ACC) and wrist-worn devices: left, Fitbit Charge HR (FBT), and right, Garmin Vivosmart (GAR). Solid bold line is the median difference between step count measurements, averaged over all participants. Dashed lines are the interquartile range of the difference. Note that the scale on the y-axis is not the same between the graphs.



For step count measurement of all participants combined, there was a strong positive correlation between the X6 accelerometer and FBT ($\rho=.78$, $P<.001$) and a moderate positive correlation between the X6 accelerometer and GAR ($\rho=.65$, $P<.001$). However, the FBT ($S_{35}=191.5$, $P=.002$; 32.9% error) and GAR ($S_{32}=144.5$, $P=.008$; 40.9% error) significantly undercounted steps compared with the X6 accelerometer. According to the equivalence tests, the median step count differences were not significantly less than the respective upper boundary limits ($P_U=.99$).

For the gait aid subanalyses, there were strong positive correlations between X6 accelerometer and FBT step counts ($\rho>.97$, P values $<.001$) and no significant difference in step counts between devices in both the no gait aid ($S_{12}=-3$, $P=.85$; 10.3% error) and single-point cane ($S_7=13$, $P=.08$; 12.6% error) groups. However, nonequivalence from undercounting was revealed by one-tailed tests ($P_U=.32$ and $P_U=.90$, respectively). Conversely, for the rollator group, there was no significant correlation between X6 accelerometer and FBT step counts ($\rho=.42$, $P=.12$), and the FBT significantly undercounted steps

compared with the X6 accelerometer ($S_{14}=44$, $P=.01$; $P_U=.99$; 52.3% error). There was a moderate positive correlation ($\rho=.56$, $P=.07$) and no significant difference in step counts between the X6 accelerometer and GAR ($S_{10}=-13$, $P=.28$; 23.1% error) for participants not using a gait aid, but measurements were not equivalent ($P_L=.77$). Although there was a strong positive correlation between step counts from the X6 accelerometer and GAR in the single-point cane group ($\rho=.93$, $P=.003$), the GAR significantly undercounted steps for these individuals ($S_6=14$, $P=.02$; $P_U=.99$; 21.3% error). In the rollator group, there was no significant correlation between X6 accelerometer and GAR step counts ($\rho=.30$, $P=.27$), and the GAR significantly undercounted steps compared with the X6 accelerometer ($S_{14}=59$, $P=.001$; $P_U>.99$; 67.2% error).

Heart Rate

On average, valid Actigraph, FBT, and GAR heart rate data were available for 42.4% (95% CI 35.7-48.8), 95.3% (95% CI 93.3-97.2), and 75.1% (95% CI 63.8-86.5) of the time worn during monitoring, respectively. Data indicating responsiveness of heart rate to changes in activity are presented in Table 3.

Table 3. Responsiveness of heart rate devices to change in walking activity.

Cadence (%)	Five-min epochs				One-min epochs			
	FBT ^a		Actigraph		GAR ^b		Actigraph	
	Percentage change (95% CI) ^c	P (n) ^d	Percentage change (95% CI)	P (n)	Percentage change (95% CI)	P (n)	Percentage change (95% CI)	P (n)
50-79	6.3 (3.2-9.3)	<.001 (27)	4.7 (0.6-8.8)	.03 (20)	2.8 (0.9-4.7)	.006 (30)	3.5 (0.7-6.3)	.02 (28)
80-99	15.4 (10.0-20.7)	<.001 (13)	11.8 (-0.2 to 23.7)	.05 (7)	3.5 (0.5-6.5)	.02 (26)	6.6 (3.8-9.5)	<.001 (25)
≥ 100	16.8 (7.9-25.8)	.005 (6)	17.8 (-26.3 to 62.0)	.22 (3)	1.8 (-1.6 to 5.3)	.27 (14)	12.9 (5.7-20.2)	.003 (9)

^aFBT: Fitbit Charge HR.

^bGAR: Garmin Vivosmart.

^cValues presented are mean increase in heart rate from rest ("percentage change"), expressed as a percentage of estimated maximum heart rate, with 95% CI in parentheses.

^d P values correspond to t tests comparing heart rate at rest and different cadences. Note the sample sizes (n) differ between comparisons as not all participants walked at each cadence, or there were no valid heart rate data at that activity level.

Both Actigraph (for 1-min epochs) and FBT showed significant increases in heart rate when participants walked at greater than or equal to 50% of their self-paced cadence compared with rest (P values $\leq .017$). When Actigraph heart rate data were averaged over 5-min epochs, there was a trend toward higher heart rate with increasing activity, but the lack of significance for walking at 80-99% and greater than or equal to 100% of self-paced cadence was likely due to a large amount of missing data and consequent low sample size ($n=7$ and $n=3$, respectively; P values $\geq .052$). GAR showed a significant increase in heart rate at 50-79% ($P=.006$) and 80-99% ($P=.02$) but not greater than or equal to 100% of self-paced cadence ($P=.27$), compared with rest.

Results of the comparison in heart rate data between devices are presented in Table 4, and Bland-Altman plots showing agreement between the wrist-worn devices and Actigraph are in Figure 2. For average heart rate of all participants, there were moderate positive correlations and no significant difference between Actigraph and FBT ($r=.53$, $P=.003$; $t_{29}=1.11$, $P=.28$; 10.1% error) as well as between GAR and Actigraph ($r=.75$, $P<.001$; $t_{21}=-0.28$, $P=.78$; 7.4% error); however, nonequivalence

was revealed by one-tailed tests ($P_U=.30$ and $P_L=.16$, respectively). There was a significant positive correlation of Actigraph with GAR ($\rho=.74$, $P<.001$) and FBT ($\rho=.49$, $P=.006$) for time in target zone. Time in target zone was not significantly different between FBT and Actigraph ($S_{29}=-37.5$, $P=.43$; 42.9% error) or between GAR and Actigraph ($S_{21}=-42$, $P=.15$; 28.4% error), but measurements were not equivalent ($P_L=.67$ and $P_U=.82$, respectively).

When participants without arrhythmia were analyzed separately, the correlation between Actigraph and FBT for average heart rate ($r=.64$, $P<.001$) and time in target zone ($\rho=.57$, $P=.004$) improved slightly. Conversely, there were no significant correlations between Actigraph and FBT for average heart rate ($r=.16$, $P=.77$) or time in target zone ($\rho=-.03$, $P=.96$) among participants with atrial fibrillation. Average heart rate and time in target zone were not significantly different between FBT and Actigraph for participants without arrhythmia or those with atrial fibrillation (P values $>.31$; 9.9-66.7% error). According to the equivalence tests, none of the interdevice differences were significantly less than the upper or lower boundary limits (range of P values $=.20-.70$).

Table 4. Agreement in heart rate data between Actigraph and wrist-worn devices.

Group	FBT ^a					GAR ^b				
	n	Correlation coefficient (P value)	Difference ^c (95% CI) or (IQR) ^d	Error (95% CI) or (IQR)	P; P _{U/L} ^e	n	Correlation coefficient (P value)	Difference (95% CI) or (IQR)	Error (95% CI) or (IQR)	P; P _{U/L}
Average heart rate, beats per minute^f										
All participants	30	.53 (.003)	2.4 (-2.0 to 6.8)	10.1% (6.9-13.3)	.28; .30	22	.75 (<.001)	-0.5 (-4.1 to 3.1)	7.4% (4.7-10.2)	.78; .16
No arrhythmia	24	.64 (<.001)	1.1 (-3.2 to 5.5)	9.9% (6.8-13.1)	.61; .20	19	.74 (<.001)	-1.1 (-5.2 to 3.0)	7.7% (4.5-10.8)	.59; .23
Atrial fibrillation	6	.16 (.77)	7.6 (-9.8 to 24.9)	10.7% (-0.1 to 21.5)	.31; .67	3	.87 (.33)	3.1 (-11.6 to 17.8)	5.8% (1.2-10.4)	.46; .47
Time in target zone, minutes^g										
All participants	30	.49 (.006)	-15 (-30, 15)	42.9% (28.6-109.5)	.43; .67	22	.74 (<.001)	-5.5 (-22 to 8)	28.4% (15.7-49.5)	.15; .82
No arrhythmia	24	.57 (.004)	-15 (-28 to 12)	42.9% (28.6-100.0)	.45; .70	19	.73 (<.001)	-8 (-26 to 9)	29.4% (16.7-57.8)	.16; .85
Atrial fibrillation	6	-.03 (.96)	-5 (-50 to 20)	66.7% (38.1-145.2)	.88; .58	3	1.0 (<.001)	-1 (-11 to 8)	15.7% (8.8-18.6)	.75; .38

^aFBT: Fitbit Charge HR.

^bGAR: Garmin Vivosmart.

^cThe difference is calculated as the Actigraph value minus the value for the wrist device; therefore, a positive value means the wrist-worn device underestimated, whereas a negative value means the wrist-worn device overestimated.

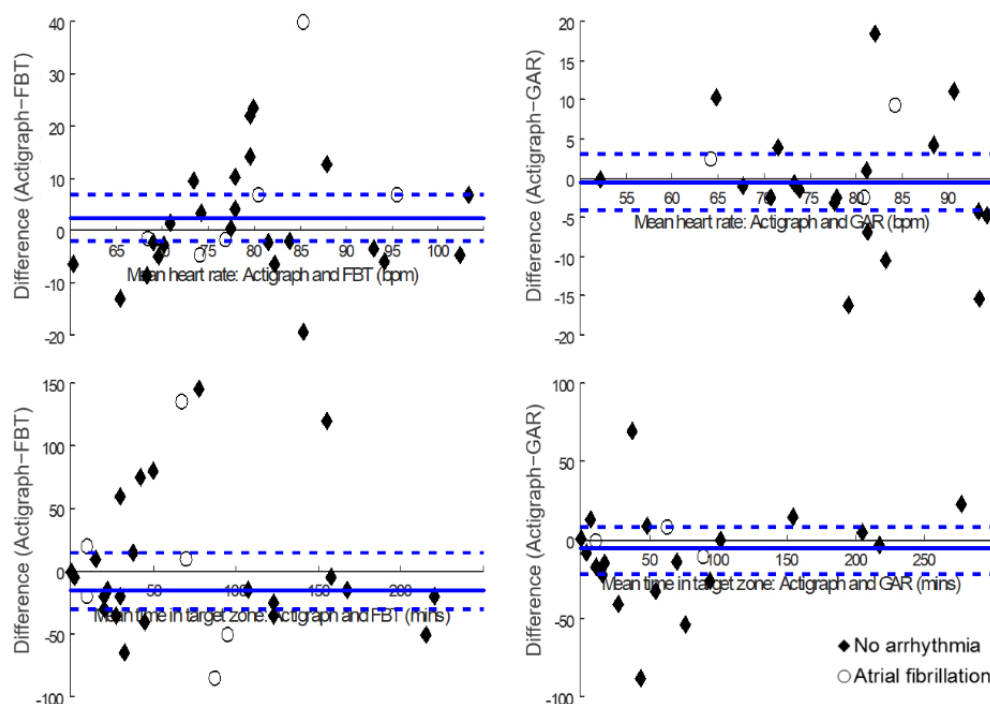
^dIQR: interquartile range.

^e P values are for paired t or Wilcoxon signed rank tests: two-sided to compare means or medians of the devices and one-sided testing of whether the mean or median difference is significantly different from a lower (P_L) and upper (P_U) limit (the greater of the 2 is reported).

^fPearson correlation coefficient.

^gSpearman correlation coefficient.

Figure 2. Bland-Altman plots of agreement between Actigraph and wrist-worn devices: left, Fitbit Charge HR (FBT), and right, Garmin Vivosmart (GAR) for mean heart rate (top) and median time in target zone (bottom). Solid bold line is the mean difference between measurements, averaged over all participants. Dashed lines are the 95% CI or interquartile range of the difference. Note that the scale on the y-axis is not the same between the graphs.



The positive correlations between Actigraph and GAR for average heart rate and time in zone remained high for both those without arrhythmia ($r=.74$, $P<.001$ and $\rho=.73$, $P<.001$, respectively) and those with atrial fibrillation ($r=.87$, $P=.33$ and $\rho=1.0$, $P<.001$, respectively). Average heart rate and time in target zone were not significantly different between GAR and Actigraph for participants without arrhythmia or those with atrial fibrillation (P values $\geq.16$; 5.8-29.4% error), yet there was no equivalence of measurements (range of P values=.16-.85).

Device Acceptability and Usability

All participants completed the feasibility questionnaire for at least 1 device; 27 individuals evaluated their experience with all 4 devices (both fitness trackers, X6 accelerometer, and chest strap). In terms of comfort, 94% (31/33) and 97% (32/33) of participants found FBT and GAR, respectively, to be somewhat or very comfortable, whereas 89% (33/37) and 91% (31/34) said the same for the X6 accelerometer and heart rate monitor, respectively. Overall, 7 individuals reported problems wearing the devices. Issues included general discomfort, trouble with doffing, and wrist strap feeling too tight. When asked about the level of confidence in their ability to don and doff independently, the average response, based on a visual analog scale from 0 (not confident at all) to 10 (extremely confident), was 8.8 for all devices except for the chest strap (7.7). A large majority of participants said they would be likely or very likely to participate in a study that involved wearing the FBT (28/33, 85%), GAR (29/33, 88%), X6 accelerometer (30/37, 81%), or heart rate monitor (24/34, 71%) every day for 1 week. Some concerns included sleeping with the device and remembering to put it on.

Discussion

Principal Findings

The main finding of this study is that FBT and GAR had a moderate to strong correlation with the best available reference devices for measuring walking activity in terms of step count and heart rate among individuals with subacute stroke. Accuracy varied widely according to mobility status and based on whether or not heart rhythm was normal. The consumer devices were well accepted by participants.

Counting Steps

In patients not using a gait aid, steps counted by the fitness trackers were not different from that of the X6 accelerometer; however, GAR was inaccurate (23.1% error) compared with FBT (10.3% error), and equivalence was not demonstrated. Neither device appears suitable for rollator users due to significant undercounting, and despite strong correlation of FBT with the X6 accelerometer for single-point cane users, accuracy was low ($>10\%$ error). Most studies on consumer wearables have been conducted with healthy adults, but, consistent with our results, overall validity of step counts with a tendency toward underestimation has been found [30]. A different Fitbit model worn at the waist also undercounted steps in people with chronic stroke tested over a short distance in a closed environment [31]. The lower accuracy in gait aid users seen herein may be attributed to a slower walking speed, which has been shown to affect accelerometer step count, especially when placed at the hip [32-34]. Limited arm swing during ambulation with a rollator could also limit accuracy of wrist-worn devices. Alternative placements of consumer devices for specific clinical subgroups should be explored in future studies.

Measuring Heart Rate

Although the high accuracy of chest strap monitors is well established, comparison of heart rate data was complicated by the low reliability of the Actigraph acquisition system. This may have been due to Bluetooth transmission problems, drying of electrode areas over time, or chest strap placement issues such as slippage through the day. Therefore, the positive correlations of the Actigraph with FBT and GAR could be over- or underestimated, and power to detect a difference in average heart rate or time in target zone was reduced. Considering data availability and responsiveness, FBT appeared superior, but heart rate measured by GAR was also sensitive to changes in walking intensity (ie, cadence). In general, intensity of physical activity appeared to be relatively low according to total time in target zone and the sample size of higher cadence levels, although data may not have been available when participants walked quickly, which could account for the relatively high error associated with this parameter. For individuals with atrial fibrillation, FBT had lower agreement with the Actigraph (10.7% average heart rate error) than did GAR; however, it is not clear to which device the inaccuracy for this clinical subgroup can be attributed as no criterion standard was performed for comparison (see below). Some wearable heart rate monitors based on photoplethysmography (optical detection of blood volume changes) have been evaluated with evidence of variable accuracy [35-38]. In 2 studies with healthy adults, the FBT was found to correlate well with electrocardiography but underestimated heart rate during more vigorous physical exertion [35,37]. The same device was significantly less accurate among hospital inpatients who were not in sinus rhythm [36]. Therefore, this technology may be more reliably applied in a clinical context when exercise intensity is limited and no arrhythmias are present.

Strengths and Limitations

It may have been possible to minimize the large amount of missing data by performing the study in a laboratory with

constant supervision of the participants, but, aside from being more resource-efficient, our design benefits from ecological validity. Devices were compared from different but typical and realistic body positions. The portability of the technology tested allowed for monitoring to take place under free-living conditions over many hours such that a range of activity levels could theoretically be captured. This precluded the use of “gold standard” measures such as electrocardiography and visual step counts to establish criterion validity. Clinically relevant variables were evaluated, and subanalyses revealed differences between groups to more precisely guide the interpretation of results. Although manual entry of some data was necessary for the purpose of this study, the commercially intended functions of consumer wearables provide information in a user-friendly format that could easily be applied in clinical or research settings.

Conclusions

Overall, the strength of correlations and measures of accuracy suggest that FBT is valid for step-counting in individuals who do not use a gait aid, whereas both devices are suitable for group analyses that tolerate greater measurement variability. The tendency to underestimate steps and general lack of equivalence with reference standards should be considered. FBT was reliable, responsive, and accurate for recording nonarrhythmic heart rate. Assessing validity in participants with atrial fibrillation was limited by low sample sizes. These results, along with the generally positive feedback from the feasibility questionnaire, imply that fitness trackers may be a viable alternative to “research grade” activity monitors for large clinical trials. As more commercial models and algorithms are developed, consumer wearables should continue to be investigated for accuracy. The selection of a device for research or health care purposes will ultimately depend on the context, including patient population and primary outcome.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Feasibility questionnaire.

[[PDF File \(Adobe PDF File\), 71KB - cardio_v2i1e1_app1.pdf](#)]

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Abbreviations

- BBS:** Berg Balance Scale
- CMSA:** Chedoke-McMaster Stroke Assessment
- COVS:** Clinical Outcome Variables Scale
- FBT:** Fitbit Charge HR
- GAR:** Garmin Vivosmart
- NIH-SS:** National Institutes of Health-Stroke Scale
- SD:** standard deviation

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Original Paper

Measuring Moderate-Intensity Exercise with the Apple Watch: Validation Study

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Abstract

Background: Moderate fitness levels and habitual exercise have a protective effect for cardiovascular disease, stroke, type 2 diabetes, and all-cause mortality. The Apple Watch displays exercise completed at an intensity of a brisk walk or above using a green “exercise” ring. However, it is unknown if the exercise ring accurately represents an exercise intensity comparable to that defined as moderate-intensity. In order for health professionals to prescribe exercise intensity with confidence, consumer wearable devices need to be accurate and precise if they are to be used as part of a personalized medicine approach to disease management.

Objective: The aim of this study was to examine the validity and reliability of the Apple Watch for measuring moderate-intensity exercise, as defined as 40-59% oxygen consumption reserve (VO₂R).

Methods: Twenty recreationally active participants completed resting oxygen consumption (VO₂rest) and maximal oxygen consumption (VO₂ max) tests prior to a series of 5-minute bouts of treadmill walking at increasing speed while wearing an Apple Watch on both wrists, and with oxygen consumption measured continuously. Five-minute exercise bouts were added until the Apple Watch advanced the green “exercise” ring by 5 minutes (defined as the treadmill inflection speed). Validity was examined using a one-sample t-test, with interdevice and intradevice reliability reported as the standardized typical error and intraclass correlation.

Results: The mean %VO₂R at the treadmill inflection speed was 30% (SD 7) for both Apple Watches. There was a large underestimation of moderate-intensity exercise (left hand: mean difference = -10% [95% CI -14 to -7], d=-1.4; right hand: mean difference = -10% [95% CI -13 to -7], d=-1.5) when compared to the criterion of 40% VO₂R. Standardized typical errors for %VO₂R at the treadmill inflection speed were small to moderate, with intraclass correlations higher within trials compared to between trials.

Conclusions: The Apple Watch threshold for moderate-intensity exercise was lower than the criterion, which would lead to an overestimation of moderate-intensity exercise minutes completed throughout the day.

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KEYWORDS

smartwatch; wearables; technology; physical activity; cardiovascular health, Apple Watch

Introduction

Background

Physical activity is well documented as a beneficial intervention for the prevention and treatment of chronic disease, while physical inactivity is an independent risk factor for the development of lifestyle-related chronic diseases, such as cardiovascular disease [1,2]. To be considered “physically active” it is recommended that adults accumulate >150 minutes of moderate or 75 minutes of vigorous-intensity physical activity (MVPA) over the course of a week to provide them with substantial health benefits [3]. Given that the average adult expends approximately four metabolic equivalents walking at a moderate pace [4], they would therefore need to walk at this pace for 125 minutes/week, or 30 minutes on most days of the week, to meet the minimum recommendations. Although these physical activity guidelines are strongly recommended by governments across the world [5-7], many people do not achieve them [8-11]. However, physical activity interventions that have incorporated technology-based support have shown promise in developing compliance to physical activity guidelines [12,13], possibly through reinforcement to develop habit-forming behaviors [14].

Although valid and reliable tools for measuring physical activity are available for researchers, such as the ActiGraph [15], it is the quantified-self movement [16] that has led to the increasing popularity of consumer wearable technology, with estimates indicating sales of over 200 million by 2021, including the Apple Watch [17]. Having contemporary instruments to integrate into exercise prescription and physical activity promotion that fit into people’s lifestyles is imperative. Although evidence on the validity and reliability of modern wearable devices with integrated screens to measure exercise and physical activity is increasing, no study has examined the accuracy of the Apple Watch for measuring MVPA.

Apple is one of the world’s most valuable companies (by market value) [18] and has changed a number of industries through disruptive devices (eg, iPod, iPhone). The Apple Watch, which was released in 2015, has reportedly become the highest selling wearable/smartwatch to date, with more than 12 million units reported to have been sold [19,20]. The widespread use of the Apple Watch would therefore allow physical activity interventions to reach a large proportion of the population. Additionally, the Apple Watch provides potential for data to be collected from, and returned to, the individual, to provide immediate individualized feedback via the wearable’s screen to promote behavior change and be shared with others, such as a clinician. However, Apple provides little detail on how the Apple Watch measures “exercise.” It appears that the built-in accelerometer is mostly used to measure physical activity throughout the day [21,22], although heart rate measurement is used periodically when walking [22]. Daily physical activity data is displayed within the “Activity” app, with a visual representation of the accumulated duration of “exercise” displayed as a green ring on the screen of the watch. Given that Apple refers to this as the “exercise” ring and that 30 minutes is the daily goal [23], it is reasonable to suggest that Apple

views this as representative of the daily goal of 30 minutes of MVPA for adults, as recommended by numerous guidelines [5-7]. Although Apple states that, “every full minute of movement that equals or exceeds the intensity of a brisk walk counts toward your daily exercise goal” [23], it is not clear how this measure of MVPA compares to the criterion measure of moderate-intensity exercise, oxygen consumption reserve (VO_{2R} : $[VO_{2max} - VO_{2rest}] \times \text{exercise intensity} + VO_{2rest}$).

Objective of This Study

Given the scale of smartwatch use around the world and the increasing attention on personalized medicine, the validity of the Apple Watch for measuring moderate-intensity exercise is important to examine. Establishing the validity of the Apple Watch would ensure that individuals are able to measure their own MVPA accurately and that health professionals have confidence in the data that their clients are sharing with them. Establishing the intradevice and interdevice reliability of the Apple Watch is also important so that daily measures can be compared, and that user preference for wearing the Watch on the left or right wrist does not introduce bias. Therefore, the aim of this study was to examine the validity and reliability of the Apple Watch for quantifying moderate-intensity exercise compared with directly measured VO_{2R} .

Methods

Study Design and Participants

The study used a repeated measures design with each participant completing two main trials. Prior to the main trials, maximal oxygen consumption (VO_{2max}) and resting oxygen consumption (VO_{2rest}) were measured in all participants. The study was approved by the Department of Sport, Health and Exercise Science Ethics Committee (approval number 1516076) at the University of Hull. Given the paucity of data on the Apple Watch at the time of study commencement, the sample size was estimated based on a previous study [24].

Recruitment

Participants were recruited from the University of Hull and local community via written promotional material or personal communication. Inclusion criteria stated that participants were aged between 18 and 50 years, and exclusion criteria were: (1) men and women classified as moderate or high-risk according to the American College of Sports Medicine (ACSM) risk classification criteria, (2) those unable to walk on a motorized treadmill, (3) current smokers, (4) BMI >30, and (5) those currently taking medication that alters the heart rate in response to exercise (eg, beta blockers). Inclusion and exclusion criteria were established with the aim of recruiting low-risk individuals, based on the ACSM risk classification criteria used at the commencement of the study.

Data Collection

Anthropometric

Participants were asked if they had voided before attending the session; if not, they were instructed to do so. Participants were then instructed to remove all clothing and nude body mass was

measured to the nearest 0.1 kg using digital scales (WB-100MA Mark 3, Tanita Corporation, Tokyo, Japan). The mean of two measurements was used for further analysis. Stretch stature was measured using a wall-mounted stadiometer (Holtain Ltd, Dyfed, Wales, UK) and according to the methods of the International Society for the Advancement of Kinanthropometry [25].

Familiarization

Following medical screening and admission to the study, participants were familiarized with the tasks required of them during the main trials. This familiarization session consisted of the participant practicing “hopping on” and “hopping off” the treadmill, as well as walking at a number of dedicated speeds. This familiarization procedure was repeated at three of the speeds used in the main trials (ie, 3, 4.5, 6 km/hour).

Resting Oxygen Consumption

VO_{2rest} was measured 30 minutes prior to, and in the same session, as VO_{2max} in a temperature-controlled laboratory. Participants lay supine on a bed with their head on a pillow for approximately 22 minutes. Oxygen consumption was measured continuously from expired air using a breath-by-breath online gas analysis system (Cortex Metalyzer 3B, GmbH, Germany). The analyzer was calibrated prior to each test using room air and known gas concentrations of oxygen and carbon dioxide. Volume was calibrated using a 3-liter syringe.

During the 22 minutes of measurement, the laboratory lights were turned off and all other laboratory activity was stopped. Prior to commencement of the measurement period, participants were instructed to relax as much as possible but to avoid going to sleep; they were not permitted to close their eyes. For analysis of the data, we discarded the first 10 minutes of data to allow for habituation and the last 2 minutes of data to allow for expectation effects. The mean of the remaining 10 minutes of data was taken as the VO_{2rest} . Although we are not aware of any standardized method for measuring VO_{2rest} for the purpose of calculating VO_{2R} , we developed our method based on that reported by Miller et al [26].

Maximal Oxygen Consumption

Maximal oxygen consumption was determined on a motorized treadmill (h/p/cosmos, Pulsar, Nussdorf-Traunstein, Germany) using an incremental protocol that commenced at 3 km/hour and a 1% gradient and increased 0.5 km/hour in speed every 30 seconds until volitional fatigue. Oxygen consumption was measured continuously from expired air using the same breath-by-breath system as described above for VO_{2rest} .

Exercise Protocol

For the 24 hours prior to each trial, participants were instructed to avoid exercise and maintain their normal diet, and for three hours prior to each trial avoid food and caffeinated drinks. On two separate occasions (mean 6 days apart, SD 3) participants completed a series of 5-minute bouts of walking on a treadmill at a gradient of 1%. Each bout was followed by 5-minutes of seated rest. On both occasions, the first 5-minute walking bout was conducted at 3 km/hour, with the treadmill speed increased for each successive 5-minute bout by 0.5 km/hour (ie, 3.5, 4).

Exercise bouts were continued until at least 6 km/hour was completed, and until the Apple Watch indicated that all 5-minutes of that bout was at a sufficient intensity to accumulate 5-minutes of the green “exercise” ring, as displayed within the Activity app. The treadmill speed at which this occurred was defined as the “treadmill inflection speed.” During each 5-minute period of exercise, oxygen consumption and heart rate were recorded by an online gas analysis system (as described previously), a Polar chest strap (Polar T31, Polar Electro, OY, Finland), and an Apple Watch (described below) worn on each wrist. During each 5-minute period of exercise, participants were instructed to maintain their normal gait and were not permitted to hold the treadmill handrails. Immediately at the cessation of each 5-minute exercise period, participants were instructed to grasp the treadmill handrails and straddle the treadmill belt. Once the treadmill belt was stationary, a chair was placed on the treadmill and the participant was instructed to sit. During the recovery period participants were required to sit motionless with each hand resting on the treadmill handrail. This was done to ensure that no activity during the recovery period contributed to the green “exercise” ring. Five minutes of seated rest was provided to enable each Apple Watch to update the green “exercise” ring. In pilot testing it was observed that the Apple Watch completed its update within a maximum of 5 minutes of rest following exercise. The mean oxygen consumption of the last three minutes at the treadmill inflection speed for each watch was used for later analysis.

Two first-generation (Series 0) Apple Watches running watchOS 2.0.1 were used to estimate moderate-intensity exercise. Each Apple Watch was paired to an iPhone 6 running iOS 9.1. Following each 5-minute rest period the number of “exercise” minutes, as measured by each of the Apple Watches, was manually recorded from the Activity app.

Moderate-intensity exercise is defined by the ACSM as that which elicits an oxygen consumption of between 40% and 59% of VO_{2R} . By rearranging the equation provided by the ACSM (see below) [3] and substituting target volume of oxygen (VO_2) for the measured oxygen consumption at the treadmill inflection speed, the percentage of VO_{2R} at the treadmill inflection speed (exercise intensity in the equation) can be calculated: Target $VO_2 = (VO_{2max} - VO_{2rest}) \times \text{exercise intensity} + VO_{2rest}$.

Statistical Analyses

Data were checked for normality using the Shapiro-Wilk test and graphical methods, and were found to be plausible. The VO_{2R} during Trial 2 was used to assess the validity of the Apple Watch for measuring moderate-intensity exercise, with VO_{2R} during both Trial 1 and 2 used to assess the interdevice and intradevice reliability. A one-sample t-test was used to test if the mean % VO_{2R} at the treadmill inflection speed for each Apple Watch was different from 40%, which is the lower limit of moderate-intensity exercise. A custom-designed Excel spreadsheet was used to examine differences between left and right Apple Watches for treadmill inflection speed and % VO_{2R} [27]. Pearson product-moment correlation was used to assess the association between VO_{2max} and the % VO_{2R} at the treadmill inflection speed. Based on the linear association

between VO_2max and $\% \text{VO}_2\text{R}$, linear regression was used to estimate the $\text{VO}_2\text{ max}$ and treadmill speed required for the Apple Watch to accurately measure moderate-intensity exercise. Interdevice and intradevice reliability is reported as the standardized typical error and intraclass correlation. Standardized typical error was doubled prior to assessing its magnitude [28]. Standardized effect size is reported as Cohen's d using the between-subject pooled SD as the denominator. The scale of magnitudes used to evaluate Cohen's d was: 0-0.19 *trivial*; 0.2-0.59 *small*; 0.6-1.19 *moderate*; 1.2-1.99 *large*; >2.0 *very large* [28]. Uncertainty in the population estimates are reported as 95% CIs.

Results

Twenty (10 male, 10 female) recreationally active participants (mean age 32 years [SD 10]; body mass 71.4 kg [SD 14.2]; stature 174.5 cm [SD 7.2]) provided written informed consent to undertake a maximal exercise test and the research exercise protocol. Participants had their cardiovascular risk assessed using the ACSM risk classification guidelines [3], with all participants classified as low risk.

The mean VO_2max and VO_2rest , as measured using the online gas analysis system, were 45 mL/kg/minute (SD 10) and 3.4 mL/kg/minute (SD 0.6), respectively. The mean treadmill "inflection" speeds that were required to advance the Apple Watch green exercise ring by 5 minutes were 5.6 km/hour (SD 0.5) and 5.6 km/hour (SD 0.5) for the left and right Apple Watches, respectively (mean difference: 0 km/hour [95% CI -0.1 to 0.2], $d=0.05$ [trivial]). The mean $\% \text{VO}_2\text{R}$ at the treadmill inflection speed for the left and right Apple Watches were 30%

(SD 7) and 30% (SD 7), respectively (mean difference: 0% [95% CI -1 to 2], $d=0.02$ [trivial]). When compared to the criterion threshold of 40% VO_2R , this represents a large underestimation in the ability of the Apple Watch to measure moderate-intensity exercise (left: mean difference = -10 [95% CI -14 to -7], $d=-1.4$ [large]; right: mean difference = -10 [95% CI -13 to -7], $d=-1.5$ [large]). The $\% \text{VO}_2\text{R}$ at the treadmill inflection speed for each participant and each watch is displayed, together with the mean and 95% CI for both watches, in Figure 1.

There was a very large negative correlation between $\% \text{VO}_2\text{R}$ at the treadmill inflection speed and VO_2max for the left Apple Watch (Figure 2), and a large negative correlation between $\% \text{VO}_2\text{R}$ at the treadmill inflection speed and VO_2max for the right Apple Watch (Figure 3). Participants with a higher VO_2max were exercising at a lower percentage of their VO_2R at the treadmill inflection speed (Figures 2 and 3). For the Apple Watch to accurately measure moderate-intensity exercise (40-59% VO_2R), based on the regression equation for the left Watch, the user would need a VO_2max between 16 (95% CI -3 to 36) and 35 (95% CI 19 to 50) mL/kg/minute. Based on within-participant linear regression analyses using the VO_2R at each speed, we estimate that to achieve 40% of VO_2R , participants would need to walk at a mean treadmill speed of 7.7 km/hour (95% CI 6.7 to 8.6) at 1% incline; which is 2.1 km/hour faster than that predicted by the Apple Watch. Only one participant had a comparable treadmill speed estimate for 40% VO_2R between the Apple Watch and the online gas analysis system. Interdevice and intradevice reliability statistics for both treadmill speed and VO_2R are displayed in Table 1.

Figure 1. The oxygen consumption reserve ($\% \text{VO}_2\text{R}$) at the treadmill inflection speed for each participant and each watch compared with the moderate-intensity zone.

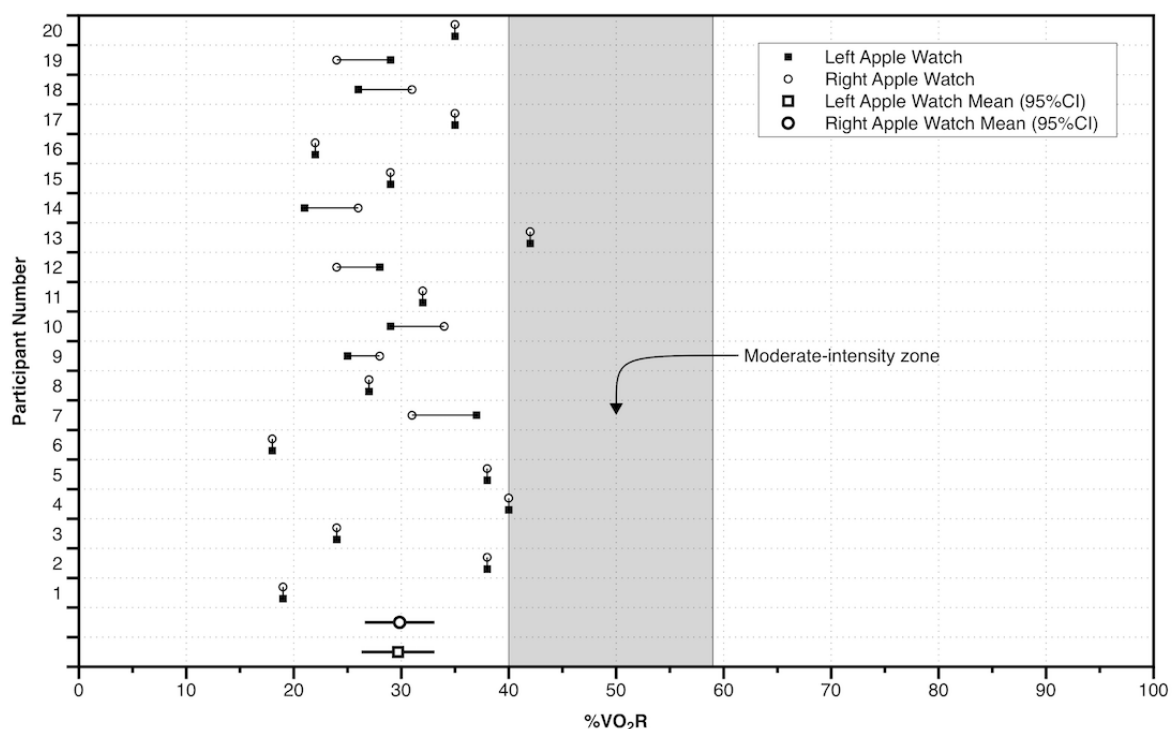


Figure 2. Pearson correlation between oxygen consumption reserve (%VO₂R) at the treadmill inflection speed and maximal oxygen consumption (VO₂max) for the left Apple Watch.

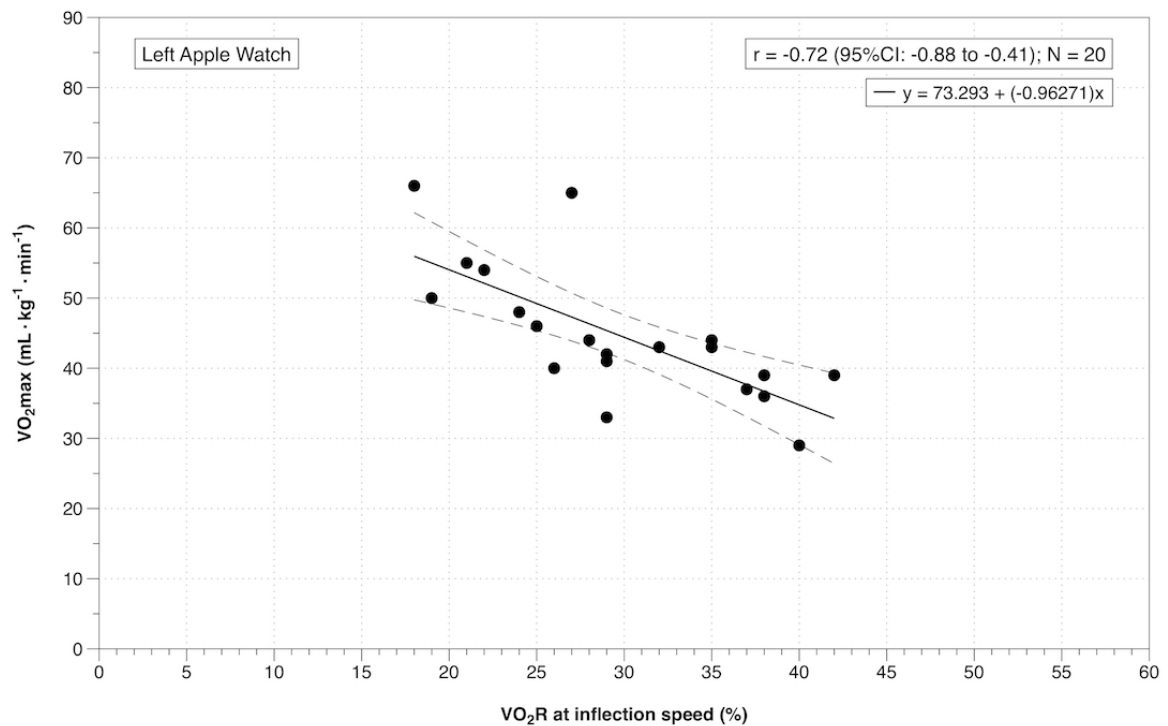


Figure 3. Pearson correlation between oxygen consumption reserve (%VO₂R) at the treadmill inflection speed and maximal oxygen consumption (VO₂max) for the right Apple Watch.

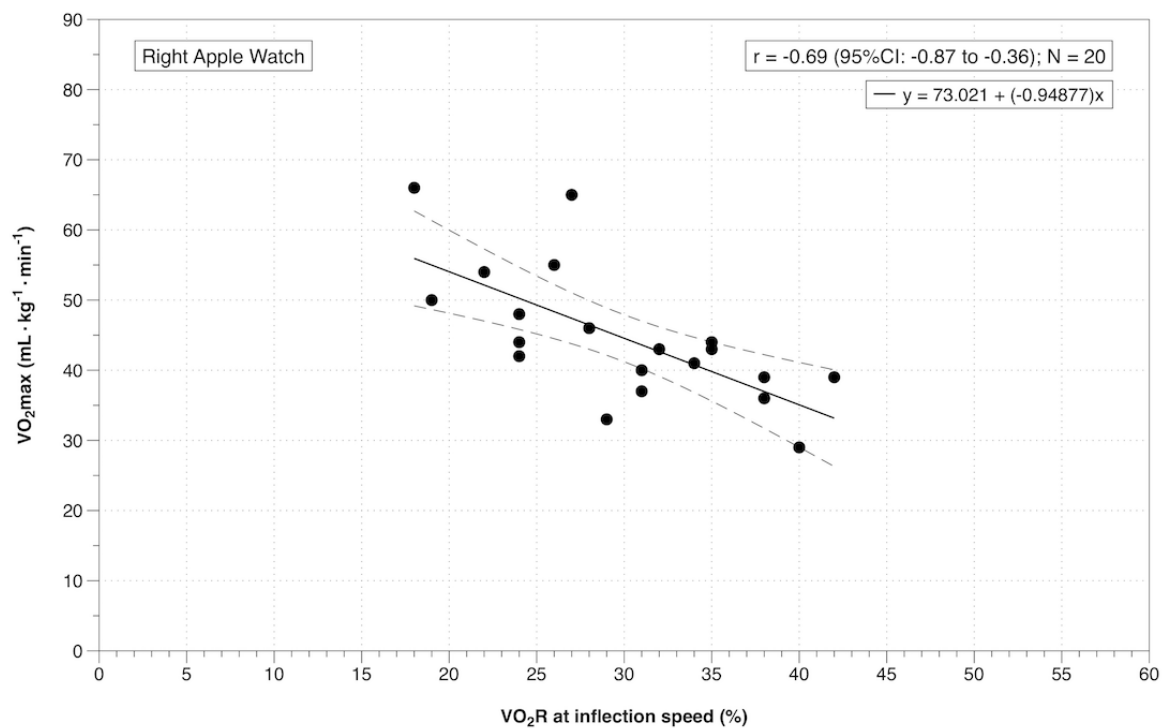


Table 1. Intradevice and interdevice reliability for both treadmill speed and oxygen consumption reserve (VO₂R) for left and right Apple Watches.

Parameter	Trial 1 Left vs Trial 1 Right	Trial 2 Left vs Trial 2 Right	Trial 1 Left vs Trial 2 Left	Trial 1 Right vs Trial 2 Right
Speed				
Standardized typical error (95% CI)	0.41 (0.31 to 0.60)	0.54 (0.41 to 0.79)	0.53 (0.40 to 0.79)	0.64 (0.49 to 0.92)
Qualitative interpretation	Moderate	Moderate	Moderate	Large
Intraclass correlation (95% CI)	0.87 (0.70 to 0.95)	0.79 (0.55 to 0.91)	0.80 (0.55 to 0.92)	0.73 (0.45 to 0.88)
VO₂R				
Standardized typical error (95% CI)	0.2 (0.15 to 0.29)	0.33 (0.25 to 0.50)	0.48 (0.36 to 0.71)	0.37 (0.28 to 0.54)
Qualitative interpretation	Small	Moderate	Moderate	Moderate
Intraclass correlation (95% CI)	0.97 (0.92 to 0.99)	0.91 (0.78 to 0.96)	0.83 (0.61 to 0.93)	0.89 (0.75 to 0.95)

Discussion

Principal Findings

This is the first study to investigate the validity and reliability of the Apple Watch for measuring moderate-intensity exercise (the green “exercise” ring) compared to the criterion measure of VO₂R. The Apple Watch largely underestimated the walking speed required to elicit the lower bound of moderate-intensity exercise (40% VO₂R), which is an important part of individualized [3] and population-based [29] exercise prescription guidelines. The standardized typical error, a measure of the “typical” test-retest variability presented in units of SD [28], was small to moderate with no mean difference between the left and right watches for the mean treadmill inflection speed or %VO₂R for the lower limit of moderate-intensity exercise [3].

For less fit individuals (<35 mL/kg/minute), using the Apple Watch to monitor moderate-intensity exercise is more likely to have the expected and desired improvements to fitness or clinical outcomes than for fitter individuals. However, for those that are fitter (>35 mL/kg/minute) it appears from our data that individuals would not meet the expectations of the lower end (40% VO₂R) of the moderate-intensity range [3], with the Apple Watch underestimating the threshold for moderate-intensity exercise, and therefore overestimating the number of minutes of moderate-intensity exercise an individual had completed. Thompson et al [30] recently came to a similar conclusion, reporting that commercially-available wearable devices for self-monitoring of physical activity overestimate MVPA by a factor of 5-to-7-fold because they capture all physical activity, including normal moderate-to-vigorous lifestyle activities. However, other recent studies have reported that Fitbit devices (Fitbit One and Fitbit Flex) underestimate MVPA [31,32], although in these studies the wearable device was compared against another wearable device (ActiGraph), not direct laboratory-measured moderate-intensity exercise as we have done in our study. In our study only two participants achieved a %VO₂R within the moderate-intensity exercise zone (Figure 1). Apart from the impact this may have on the expected physiological adaptations and fitness, it also has potential implications for morbidity and mortality risk, as moderate fitness levels and habitual exercise have a protective effect for

cardiovascular disease, stroke, type 2 diabetes, and all-cause mortality [33].

Measuring load in an individual is complicated with a variety of methods available to monitor internal and external load [34]. The Apple Watch does not substantially overestimate or underestimate heart rate [24] and has moderate interdevice variability of maximal heart rate when worn on each wrist [35]. Therefore, using a continuous combination of internal (heart rate) and external (accelerometer) training load measures [34,36] rather than using the accelerometer plus periodic use of heart rate as is currently used, may improve the accuracy of the green exercise ring and provide a greater personalization of the data available to an individual. Given the wide range of VO₂R responses observed at the treadmill speed that the Apple Watch determined to be “exercise” (<20% to >40%), and the variability between left and right Watches (Figure 1), it is clear that the Apple Watch needs to provide a more appropriate measure of the individualized response to exercise. This would not only enable more tailored feedback and exercise prescription, it would likely improve the physiological adaptations to any training and the associated cardiometabolic and musculoskeletal improvements for chronic disease prevention and treatment [33]. Better compliance to guidelines [13] and improved disease management and confidence [37] have been reported in healthy and chronic disease populations when technology-based support is incorporated. However, consumer and health professionals need to have confidence that any wearable device can both consistently and accurately measure the exercise intensity for individuals of all fitness levels.

The reliability data (Table 1) suggest that the reliability of VO₂R at the point where the Apple Watch determines that “exercise” has started (the treadmill inflection speed) is better within trials (interdevice) than between trials (intradevice). This finding would suggest that physical activity measurements are more reliable within the same training session or activity compared to between different training sessions or activities. The implication is that health professionals can be confident that the ability of the Apple Watch to measure physical activity (as used in the current study) is not adversely affected by the wrist (left or right) on which an individual wore the watch within a given training session or activity.

Strengths and Limitations

The main strength of our study is that this is the first investigation to examine the validity of the Apple Watch for measuring aspects of exercise related to the achievement of daily MVPA. The main limitation of this study is that we did not have direct access to the algorithms used by the Apple Watch for determining the exercise intensity at which the green “exercise” ring advances. Unfortunately, Apple does not publish these algorithms, probably due to commercial reasons. However, this is a limitation with most commercially-available wearable devices and is not restricted to the Apple Watch. A second limitation is that our data were derived from first generation Apple Watches. Although the method Apple uses to determine “exercise” using the Activity app has changed slightly with the periodic measurement of heart rate during walking [21,22], it is unclear how this would affect the validity of the Apple Watch for measuring MVPA. Further studies are required using the latest generation of Apple Watch for this to be determined. The exercise protocols used in our study were also constrained to linear walking on a treadmill. Movement patterns used by people outside of the laboratory while wearing an Apple Watch may

result in different physiological responses and different determinations of “exercise” by the Apple Watch. Fourth, although our primary measure was VO_2R , there are a number of factors that can influence the oxygen cost of exercise, such as economy [38,39]. For example, economy has been reported to be affected by age, such that older adults have less economy when walking compared to younger people [40]. The mean age of our participants was 32 years (SD 10), which places our participants midway between the young and old adults participating in the study of Martin et al [40]. Although factors such as economy and age should be taken into account when interpreting our results, the use of % VO_2R as a relative measure of oxygen cost means that between-individual comparisons should still be meaningful.

Conclusions

The Series 0 Apple Watch underestimates the threshold for moderate-intensity exercise compared to the criterion measure of VO_2R , which would result in an overestimation of the amount of MVPA undertaken throughout the day. This effect is more pronounced in fitter individuals.

Acknowledgments

GA, JB, and ACB designed the study. GA and JB collected the data. GA, JB, and ACB analyzed the data. GA, JB, and ACB prepared and revised the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ACSM: American College of Sports Medicine

MVPA: moderate-vigorous physical activity

VO₂: volume of oxygen

VO₂max: maximal oxygen consumption

VO₂R: oxygen consumption reserve

VO₂rest: resting oxygen consumption

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Original Paper

Handheld Ultrasound as a Novel Predictive Tool in Atrial Fibrillation: Prediction of Outcomes Following Electrical Cardioversion

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Abstract

Background: Atrial fibrillation (AF) recurrence after successful direct current cardioversion (CV) is common, and clinical predictors may be useful. We evaluated the risk of early AF recurrence according to inferior vena cava (IVC) measurements by handheld ultrasound (HHU) at the time of CV.

Objective: Assess HHU and objectively obtained measurements acquired at the point of care as potential clinical predictors of future clinical outcomes in patients with AF undergoing CV.

Methods: Maximum IVC diameter (IVCd) and collapsibility with inspiration were measured by the Vscan HHU (General Electric Healthcare Division) in 128 patients immediately before and after successful CV for AF. Patients were followed by chart review for recurrence of AF.

Results: Mean IVCd was 2.16 cm in AF pre-CV and 2.01 cm in sinus rhythm post-CV ($P<.001$). AF recurred within 30 days of CV in 34 of 128 patients (26.6%). Among patients with IVCd <2.1 cm pre-CV and decrease in IVCd post-CV, AF recurrence was 12.1%, compared to 31.6% in patients not meeting these parameters (odds ratio [OR] 0.299, $P=.04$). This association persisted after adjustment for age, ejection fraction $<50\%$, left atrial enlargement, and amiodarone use (adjusted OR 0.185, $P=.01$). Among patients with IVCd post-CV <1.7 cm, AF recurrence was 13.5%, compared to 31.9% in patients not meeting this parameter (OR 0.185, $P=.01$). IVC parameters did not predict AF recurrence at 180 or 365 days.

Conclusions: The presence of a normal IVCd pre-CV that becomes smaller post-CV and the presence of a small IVCd post-CV were each independently associated with reduced likelihood of early, but not late, AF recurrence. HHU assessment of IVCd at the time of CV may be useful to identify patients at low risk of early recurrence of AF after CV.

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KEYWORDS

atrial fibrillation; cardioversion; recurrence; inferior vena cava; hand held ultrasound; point of care

Introduction

Atrial fibrillation (AF), one of the most common abnormal rhythms of the heart, is associated with significant morbidity including heart failure and stroke [1]. In addition, up to 90% of patients may be symptomatic from AF [2]. Direct-current electrical cardioversion (CV) to restore sinus rhythm (SR) may be performed to improve symptoms, quality of life, and left ventricular function [3]. However, CV may be immediately unsuccessful in up to 20% of cases, and AF recurs in 60-80% of patients after one year [4]. Reliable prediction of SR maintenance after CV is important in order to weigh the benefits versus potential risks of CV including arrhythmias and thromboembolic complications. Several clinical, echocardiographic, and electrophysiological parameters have been identified to predict SR maintenance after CV, including age [5], left atrial size [4,6,7], right atrial size [8], prolonged duration of AF [9], low ejection fraction [4], mitral valve disease [4,5], or failure to correct the underlying physiologic trigger for AF. More recently, left atrial filling pressure and change in pressure after restoration of SR have been identified as predictors of AF recurrence [10,11]. Nevertheless, AF recurrence after CV remains common.

Assessment of the inferior vena cava (IVC) by ultrasound is a validated, noninvasive technique to assess central venous pressure and guide management in patients with dyspnea, critical illness, and heart failure. Current guidelines published by the American Society of Echocardiography in 2015 support the combined use of maximum IVC diameter (IVCd; $>$ or $<$ 2.1 cm) and inspiratory IVC collapsibility ($>$ or $<$ 50%) to estimate right atrial pressure (RAP) as low, intermediate, or high [12]. Handheld ultrasound (HHU) has emerged as an effective tool to obtain these measurements in a rapid and reproducible fashion at the point of care. This study had two primary objectives. The first was to assess the dynamic changes in IVC size as assessed by HHU according to the presence of AF, through measurements of the IVC immediately prior to and following CV. The second aim was to assess the relationship between IVC size at the time of CV and the risk of AF recurrence after CV.

Methods

Consecutive adult patients who were scheduled to undergo inpatient or outpatient direct current CV for AF or atrial flutter (AF/AF) at Cedars-Sinai Medical Center (Los Angeles, CA) were enrolled from January 2016 to May 2017. The longitudinal cardiovascular care for these patients also occurred at Cedars-Sinai Medical Center or affiliated outpatient offices. Patients both with and without a concomitant transesophageal echocardiogram at the time of CV were eligible for inclusion. Patients were excluded from analysis if direct current CV was not performed for any reason, or was unsuccessful in restoring SR. All subjects provided written informed consent. This was an investigator-initiated observational study, and the study protocol was reviewed and approved by the Cedars-Sinai Institutional Review Board.

Measurements of the IVC were obtained with the patient in a supine position using a HHU device (VScan, General Electric Healthcare Division; Figure 1), during periods of quiet spontaneous respiration. IVCd throughout the respiratory cycle was measured from the subcostal view 1-2 cm caudal to the right atrium/IVC junction with the IVC displayed along its long axis, in accordance with American Society of Echocardiography 2015 published guidelines [12]. Measurements were taken to the nearest one hundredth of a centimeter. A visual estimate of degree of collapsibility ($>$ or $<$ 50%) with passive inspiration was also recorded. HHU images used for measurement were saved and uploaded into the Epic-based electronic health record using the image screen capture tool on the Epic-based Haiku smartphone app [13]. Measurements of the IVC were obtained prior to CV (within 20 minutes) with the patient in AF/AF, and repeated within 20 minutes of successful CV with the patient in SR. All patients received deep sedation with propofol for the CV procedure. Sedation was not administered until after the baseline IVC measurement. Intravenous fluid was not added during sedation for any patients. All IVC measurements were obtained by study personnel with level II certification in adult echocardiography as well as special expertise in the use of HHU.

Blood pressure and heart rate were recorded at the time of ultrasound image acquisition both prior to and following CV. Baseline demographics, clinical history, and echocardiographic data were obtained by chart review. The categorization of unspecified, paroxysmal, and persistent AF was defined by chart documentation and was included even though all patients undergoing CV were determined to have persistent AF by study personnel. Echocardiographic data was only included if performed within 6 months prior to the date of CV, and was obtained from review of echocardiogram reports alone. Patients were followed by chart review for up to 365 days for the outcome of recurrence of AF/AF, which was determined by review of electrocardiograms, Holter monitors, and medical documentation.

Descriptive statistical analyses were performed. Data are reported as mean (standard deviation) or total number and percentage, as appropriate. Comparisons of characteristics between groups were made with the Fisher exact test for categorical variables and the Student t-test for continuous variables. All reported *P* values are two-sided. A Kaplan-Meier analysis was performed to compare the freedom from recurrence of AF/AF between groups with differing IVC parameters, and the log-rank test was used to compare groups. Bivariate and multivariate logistic regression analyses were performed for the association between several IVC parameters and recurrence of AF/AF at 30, 90, 180, and 365 days after CV. The multivariable model included adjustment for history of age, ejection fraction $<$ 50%, left atrial enlargement (none, mild, moderate, severe), and amiodarone use post-CV factors.

An IVC diameter of 2.1 cm was used as the cut-point in the analysis to remain consistent with published American Society of Echocardiography guidelines used to estimate RAP [12]. A 20% change in IVC diameter following CV was anticipated (1.7 cm) from our study pre-enrollment power calculation, and was thus used as a cut-point for analyses as well.

Figure 1. Handheld ultrasound.

Results

One hundred and fifty-nine patients consented for enrollment in the study. Of these, 11 patients were excluded from the analysis after CV was aborted due to the discovery of (or inability to) exclude left atrial appendage thrombus on a transesophageal echocardiogram performed prior to CV. An additional 15 patients were excluded due to unsuccessful CV. One patient was excluded due to inability to save the HHU measurements of the IVC. Four patients were excluded due to the spontaneous conversion to SR prior to CV. In total, 128 patients were included for analyses.

Baseline demographics of patients included for analyses are summarized in [Table 1](#). The mean age was 67.7 years, and 91 of the 128 patients (71.1%) were male. Thirty patients (30/128, 23.4%) had a history of heart failure with reduced ejection fraction, and 14 patients (14/128, 10.9%) had a history of heart failure with preserved ejection fraction. Twenty-three patients (23/128, 18.0%) had a chart-documented history of persistent AF, with 15 (15/128, 11.7%) having a prior history of ablation and 35 (35/128, 27.3%) having a prior history of CV. Fifty-two patients (52/128, 40.6%) were prescribed amiodarone following CV for maintenance of SR.

Thirty-day follow-up data were available for all 128 patients. One hundred and nineteen patients were followed for at least 90 days, 101 patients were followed for at least 180 days, and

80 patients were followed for 365 days. AF/AF recurrence was seen in 34 patients (34/128, 26.6%) within 30 days, 45 patients (45/128, 37.8%) within 90 days, 44 patients (44/128, 43.6%) within 180 days, and 42 patients (42/128, 52.5%) within 365 days (data not shown). Patients were excluded from the numerator of AF/AF patients and the analysis of study patients if they were not monitored for 90, 180, and 365 days.

Baseline characteristics were compared between patients with and without AF/AF recurrence within 30 days ([Table 1](#)). No significant difference was seen between groups with respect to age, gender, body mass index, inpatient status, coronary artery disease, hypertension, diabetes, chronic kidney disease, chronic lung disease, or heart failure. Chart-documented persistent AF was more common among patients with AF/AF recurrence (32.4% vs 12.8%, $P=.01$). Amiodarone use following CV was also more common among patients with recurrence (55.9% vs 35.1%, $P=.04$).

Baseline echocardiographic data were available for most, but not all, patients, and they are summarized in [Table 2](#). Mean ejection fraction was 52.6% overall, and was normal ($>55\%$) in 78 of 121 patients (64.5%). Fifteen patients (15/121, 12.4%) had an ejection fraction $<35\%$. Left atrial enlargement was seen in 97 of 117 patients (82.9%), but severe left atrial enlargement was seen in only 4 patients (4/117, 3.4%). Right atrial enlargement was seen in 54 of 113 patients (47.8%).

Moderate or greater mitral regurgitation was seen in 22 of 118 patients (18.6%). Moderate or greater tricuspid regurgitation was seen in 15 of 109 patients (13.8%). There were no significant differences seen between patients with and without 30-day AF/AF recurrence in ejection fraction, left atrial size, right atrial size, mitral regurgitation, or tricuspid regurgitation.

Example IVC measurements pre- and post-CV are shown in Figure 2, and all measurements are summarized in Table 2 and Figure 3. The mean pre-CV IVCd was 2.16 cm, compared to 2.01 cm in the same patients post-CV ($P<.001$). Inspiratory collapsibility $>50\%$ was seen in 63 patients (63/128, 49.2%) pre-CV, compared to 93 patients (93/128, 72.7%) post-CV ($P<.001$). RAP was estimated to be high (10-20 mmHg) in 51 patients (51/128, 39.8%), intermediate (5-10 mmHg) in 35 (35/128, 27.3%), and low (0-5 mmHg) in 42 (42/128, 32.8%) prior to CV, and after CV it was estimated to be high in 24 patients (24/128, 18.8%), intermediate in 40 (40/128, 31.3%), and low in 64 (64/128, 50.0%; $P<.001$). Thirty-six patients (36/128, 28.1%) were reclassified to a lower category of RAP following CV, and only 3 patients (3/128, 2.3%) were reclassified to a higher category of RAP following CV. When comparing patients with and without 30-day AF/AF recurrence, there was no significant difference in IVCd pre-CV (2.25 vs 2.12 cm, $P=.13$). However, patients with 30-day AF/AF recurrence were less likely to have inspiratory collapsibility $>50\%$ (35.5% vs 54.3%, $P=.07$) and more likely to have a larger IVCd post-CV (2.13 vs 1.97 cm, $P=.09$).

Systolic blood pressure, diastolic blood pressure, and heart rate were significantly higher in AF compared to SR (128.3 vs 105.8 mmHg, $P<.001$; 78.0 vs 65.5 mmHg, $P<.001$; 92.5 vs 67.0 beats per minute, $P<.001$; respectively). No significant correlation was seen between systolic blood pressure, diastolic blood pressure, or heart rate and either pre- or post-CV IVC size. Furthermore, no association was seen between the change in blood pressure or heart rate following CV and the change in IVC size following CV (data not shown).

The combined presence of IVCd <2.1 cm pre-CV and a change in IVCd <0 was associated with a lower rate of AF/AF recurrence at 30 days (12.1% vs 31.6%, unadjusted odds ratio [OR] 0.299, 95% CI 0.096-0.926, $P=.04$; Table 3). This association remained statistically significant (adjusted OR 0.178, 95% CI 0.046-0.682, $P=.01$) in the multivariate model. The combined parameter was similarly associated with a lower rate of AF/AF recurrence at 90 days (unadjusted OR 0.361, 95% CI 0.141-0.924, $P=.03$; adjusted OR 0.265, 95% CI 0.089-0.793, $P=.02$). No significant association was seen with AF/AF recurrence at 180 days or 365 days. Furthermore, the presence of IVCd <1.7 cm post-CV was associated with a lower rate of AF/AF recurrence at 30 days (13.5% vs 31.9%), corresponding to an unadjusted OR of 0.334 (95% CI 0.118-0.946, $P=.04$). This association remained statistically significant in the multivariate model (adjusted OR 0.185, 95% CI 0.050-0.691, $P=.01$).

Table 1. Baseline demographics.

Parameter	Total (N=128)	30-day AF/AF recurrence (n=34)	No 30-day AF/AF recurrence (n=94)	P value
Age, mean (SD)	67.7 (13.4)	66.9 (13.5)	68.0 (13.5)	.70
Male gender, n (%)	91 (71.1)	26 (76.5)	65 (69.1)	.51
Body mass index (kg/m ²), mean (SD)	28.4 (6.6)	28.7 (6.1)	28.3 (6.8)	.77
Inpatient, n (%)	47 (36.7)	11 (32.3)	36 (38.3)	.68
Coronary artery disease, n (%)	33 (25.8)	7 (20.6)	26 (27.7)	.49
Hypertension, n (%)	85 (66.4)	27 (79.4)	58 (61.7)	.09
Diabetes mellitus type II, n (%)	21 (16.4)	6 (17.6)	15 (16.0)	.79
Chronic kidney disease, n (%)	29 (22.7)	8 (23.5)	21 (22.3)	1.00
Chronic lung disease, n (%)	11 (8.6)	4 (11.8)	7 (7.4)	.48
Heart failure with reduced ejection fraction, n (%)	30 (23.4)	11 (32.4)	19 (20.2)	.16
Heart failure with preserved ejection fraction, n (%)	14 (10.9)	3 (8.8)	11 (11.7)	.76
Atrial fibrillation (n=117), n (%)				.01
Unspecified	18 (14.1)	1 (2.9)	17 (18.1)	
Paroxysmal	76 (59.4)	22 (64.7)	54 (57.4)	
Persistent	23 (18.0)	11 (32.4)	12 (12.8)	
Atrial flutter (any), n (%)	24 (18.8)	4 (11.8)	20 (21.3)	.31
Prior cardioversion, n (%)	35 (27.3)	8 (23.5)	27 (28.7)	.66
Prior ablation, n (%)	15 (11.7)	3 (8.8)	12 (12.8)	.76
Amiodarone (post-CV), n (%)	52 (40.6)	19 (55.9)	33 (35.1)	.04
Any anti-arrhythmic drug (post-CV), n (%)	69 (53.9)	21 (61.8)	48 (51.1)	.32

Table 2. Baseline echocardiographic data and IVC parameters pre-CV and post-CV.

Parameter	Total	30-day AF/AF recurrence (n=34)	No 30-day AF/AF recurrence (n=94)	P value
Ejection fraction (n=121)				
>55%, n (%)	78 (64.5)	21 (61.8)	57 (65.5)	
35-54%, n (%)	28 (23.1)	7 (20.6)	21 (24.1)	.34
<35%, n (%)	15 (12.4)	6 (17.6)	9 (10.3)	
Mean (SD)	52.6 (14.4)	50.9% (16.8%)	53.3% (13.4%)	.40
Left atrial enlargement (n=117), n (%)				
None	20 (17.1)	4 (13.3)	16 (18.4)	
Mild	64 (54.7)	20 (66.7)	44 (50.6)	
Moderate	29 (24.8)	5 (16.7)	24 (27.6)	
Severe	4 (3.4)	1 (3.3)	3 (3.4)	.48
Right atrial enlargement (n=113), n (%)				
None	59 (52.2)	12 (40.0)	47 (56.6)	
Mild	37 (32.7)	14 (46.7)	23 (27.7)	
Moderate	14 (12.4)	4 (13.3)	10 (12.0)	
Severe	3 (2.7)	0 (0)	3 (3.6)	.16
Mitral regurgitation (n=118), n (%)				
None/trace	33 (28.0)	11 (35.5)	22 (25.3)	
Mild	63 (53.4)	13 (41.9)	50 (57.5)	
Moderate	20 (16.9)	7 (22.6)	13 (14.9)	
Severe	2 (1.7)	0 (0)	2 (2.3)	.33
Tricuspid regurgitation (n=109), n (%)				
None/trace	47 (43.1)	13 (44.8)	34 (42.5)	
Mild	47 (43.1)	13 (44.8)	32 (40.0)	
Moderate	13 (11.9)	3 (10.3)	10 (12.5)	
Severe	2 (1.8)	0 (0)	2 (2.5)	.79
IVCd pre-CV (cm), mean (SD)	2.16 (0.44)	2.25 (0.34)	2.12 (0.47)	.13
IVC collapsibility >50% pre-CV, n (%)	63 (49.2)	12 (35.3)	51 (54.3)	.07
RAP estimate pre-CV, n (%)				
High (10-20 mmHg)	51 (39.8)	18 (52.9)	33 (35.1)	
Intermediate (5-10 mmHg)	35 (27.3)	9 (26.5)	26 (27.7)	.13
Low (0-5 mmHg)	42 (32.8)	7 (20.6)	35 (37.2)	
IVCd post-CV (cm), mean (SD)	2.01 (0.46)	2.13 (0.43)	1.97 (0.46)	.09
IVC collapsibility >50% post-CV, n (%)	93 (72.7)	22 (64.7)	71 (75.5)	.26
RAP estimate post-CV, n (%)				
High (10-20 mmHg)	24 (18.8)	7 (20.6)	17 (18.1)	
Intermediate (5-10 mmHg)	40 (31.3)	16 (47.1)	25 (26.6)	.10
Low (0-5 mmHg)	64 (50.0)	12 (35.3)	52 (55.3)	
Delta IVCd (cm), mean (SD)	-0.14 (0.27)	-0.13 (0.36)	-0.15 (0.24)	.71
Pre-CV IVCd <2.1 cm, mean (SD)	57 (44.5)	12 (35.3)	45 (47.9)	.23
Pre-CV IVCd <2.1 cm & Delta IVCd <0, mean (SD)	33 (25.8)	4 (11.8)	29 (30.9)	.04
Post-CV IVCd <1.7 cm, mean (SD)	37 (28.9)	5 (14.7)	32 (34.0)	.05

Figure 2. Example measurements of the inferior vena cava by handheld ultrasound.

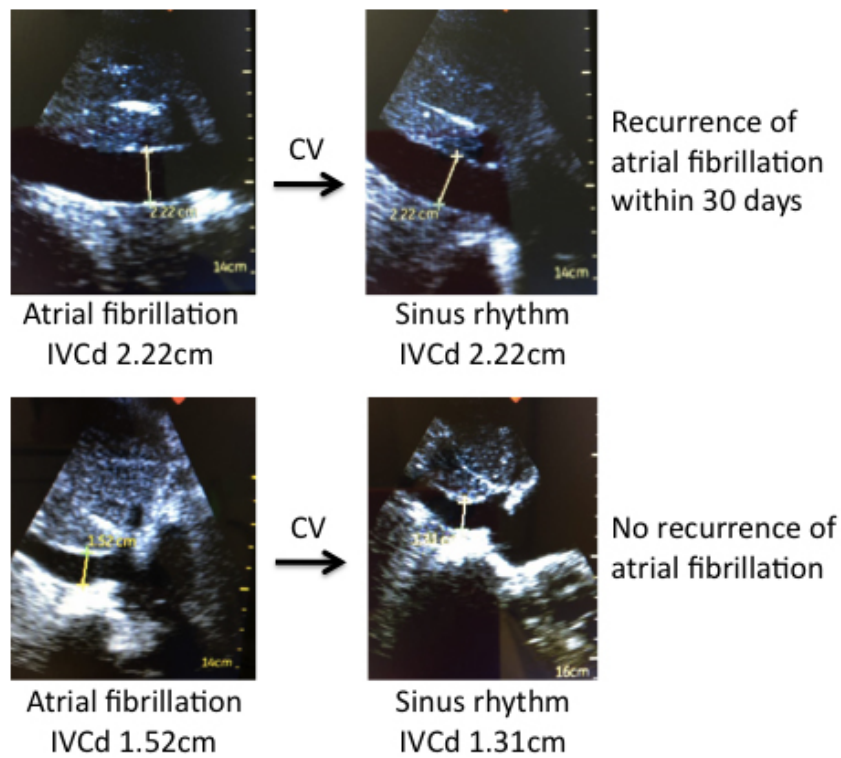


Figure 3. Mean inferior vena cava measurements.

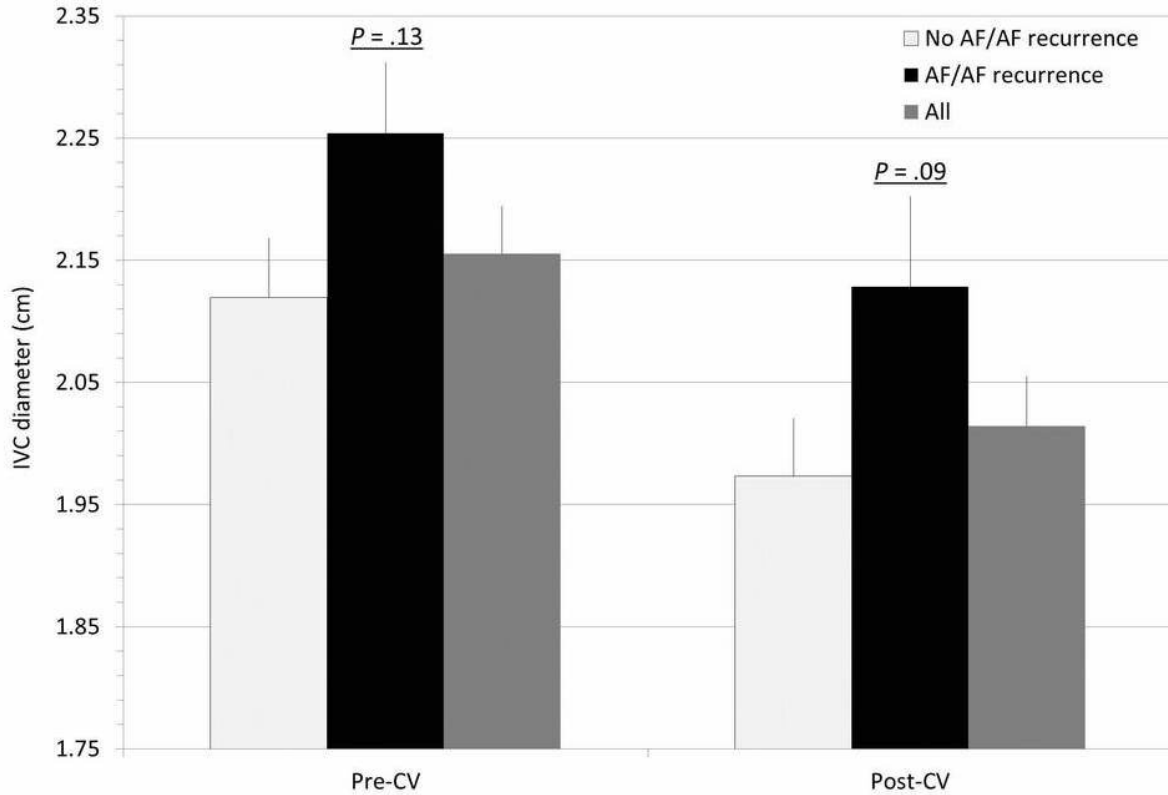
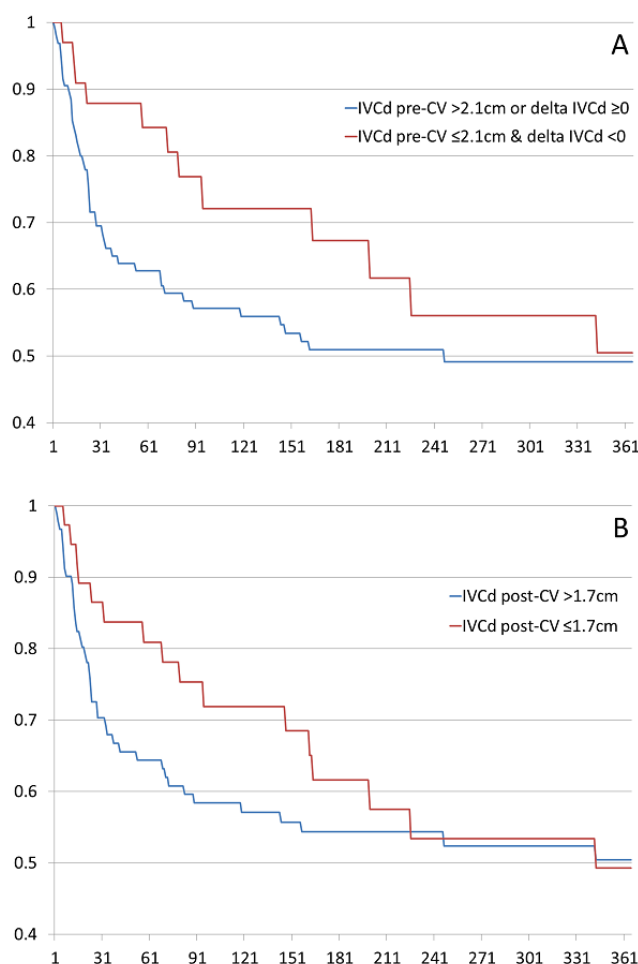


Table 3. Risk of AF recurrence by HHU-derived IVC parameters.

Parameter and follow-up (days)	AF/AF recurrence rate (%)		Odds Ratio (95% CI)			
	Parameter present	Parameter absent	Unadjusted	<i>P</i> value	Adjusted ^a	<i>P</i> value
IVCd pre-CV <2.1 cm & delta IVCd <0						
30	12.1	31.6	0.299 (0.096-0.926)	.04	0.178 (0.046-0.682)	.01
90	21.9	43.7	0.361 (0.141-0.924)	.03	0.265 (0.089-0.793)	.02
180	28.0	48.7	0.410 (0.154-1.095)	.08	0.459 (0.155-1.357)	.16
365	40.9	56.9	0.525 (0.194-1.420)	.20		
IVCd post-CV <1.7 cm						
30	13.5	31.9	0.334 (0.118-0.946)	.04	0.185 (0.050-0.691)	.01
90	25.0	43.4	0.435 (0.182-1.039)	.06	0.344 (0.124-0.958)	.04
180	34.5	47.2	0.588 (0.240-1.439)	.25		
365	44.0	56.4	0.608 (0.235-1.577)	.31		

^aAdjusted for age, ejection fraction <50%, left atrial enlargement, and amiodarone use post-CV

Figure 4. Handheld ultrasound.

At 90 days IVCd <1.7 cm post-CV was associated with a lower rate of AF/AF recurrence which was statistically significant after statistical adjustment, as noted above (unadjusted OR 0.435, 95% CI 0.182-1.039, *P*=.061; adjusted OR 0.344, 95% CI 0.124-0.958, *P*=.04). No significant association was seen with AF/AF recurrence at 180 days or 365 days.

Kaplan Meier curves were constructed to examine freedom from recurrence of AF/AF during follow-up (Figure 4). There were no significant differences overall in freedom from AF/AF after one year of follow-up between patients with the combination of IVCd pre-CV <2.1 cm and delta IVCd <0 compared to those without this combination of parameters (*P*=.10 by log-rank test), or between patients with IVCd post-CV <1.7 cm compared to

those with IVCd post CV >1.7 cm ($P=.21$ by log-rank test). However, the curves diverged in the initial 30-90 days, before converging with longer-term follow-up.

No significant associations were found between AF/AF recurrence at any time and low, medium, or high RAP estimates pre-CV, high RAP estimate post-CV, or delta IVCd <0 in either bivariate or multivariate models. A low estimated RAP post-CV was associated with a lower likelihood of AF/AF recurrence at 30 days (OR 0.441, 95% CI 0.196-0.993, $P=.05$), and the association remained significant after adjustment (OR 0.393, 95% CI 0.11600.966, $P=.04$) but was not significant at the 90, 180, or 365-day time points (data not shown).

Discussion

To our knowledge, this is the first study to evaluate measurements of IVC with HHU in the setting of AF/AF and CV. The key findings of this report are two-fold. First, we found that IVCd was larger and inspiratory collapsibility was less common in the presence of AF/AF compared to SR. These findings not only demonstrate that AF/AF influences the size and dynamics of the IVC, but also that HHU-derived measurements of the IVC (easily obtained anatomic measurements) are reflective of dynamic changes in physiology. These results suggest that changes in cardiovascular hemodynamics can be ascertained and quantified with a noninvasive handheld tool to potentially inform clinical decision support at the point of care.

Second, in our cohort, we found that a normal sized IVC (<2.1 cm) that becomes smaller following CV from AF/AF to SR, and a small IVC (<1.7 cm) following CV from AF/AF to SR are associated with decreased risk of early AF/AF recurrence at 30 or 90 days, even after adjustment for established clinical risk predictors of recurrence. In our study, these IVC parameters did not predict long-term risk of AF/AF recurrence beyond 90 days, suggesting that the factors mediating AF/AF recurrence evolve over time or that our cohort was insufficiently sized to make longer-term assessments of AF/AF recurrence. Further study may better differentiate potential subsets of patients in whom IVC parameters may be predictive of long-term outcomes.

Previously published data have demonstrated that atrial pressure is directly and immediately influenced by atrial rhythm. The first report of this phenomenon was published nearly half a century ago, when invasive measurements of RAP were shown to decrease immediately following CV from AF to SR [14]. A more contemporary study in an animal model also demonstrated higher atrial pressures in AF compared to SR [15]. Importantly, two recently published studies of patients undergoing catheter ablation of AF have demonstrated invasively measured correlates consistent with the findings from our study [10,11]. The first study showed a small but significant decrease in left atrial pressure following restoration of SR, with higher left atrial pressure in SR predicting risk of AF recurrence [10]. More recently, Kishima et al reported that an increase in left atrial pressure after CV was independently predictive of AF recurrence [11]. Our study represents the noninvasive corollary of these findings. We showed that noninvasive estimates of RAP decrease immediately following restoration of SR. We also

showed that in our cohort IVC parameters reflective of a low RAP in SR, and a decrease in RAP after CV, predict freedom from AF/AF recurrence at 30 and 90 days.

A growing body of evidence is accumulating in support of the use of HHU as an adjunctive tool for bedside diagnoses, with superior and additive diagnostic performance compared to a physical examination alone [16]. Increasing attention is now being placed on the use of HHU to improve clinical decision support and risk prediction at the point of care. Recently published data suggest that serial monitoring of IVC size predicts risk of hospitalization in stable outpatients with heart failure [17,18]. The findings of the present study expand the possible roles of HHU even further to possible risk prediction in AF and use of HHU at the point of care during CV.

It is noteworthy that amiodarone use was associated with increased risk of AF/AF recurrence. This unexpected finding likely reflects the observational design of this study and suggests that the prescribing physicians may have anticipated a higher rate of recurrence in these patients. Nevertheless, after adjustment for amiodarone use, as well as previously described predictors of AF/AF recurrence (age, ejection fraction $<50\%$, and left atrial enlargement) in our multivariate model, the HHU-derived measurements remained significant predictors of AF/AF recurrence in our cohort.

There are several important limitations to this study. First, because no intervention strategy was studied, these observational data can only be considered hypothesis-generating. An intervention trial would be needed to investigate whether a higher risk of recurrence indicated by IVC measurements at the time of CV might be mitigated by a change in treatment strategy. Second, AF and atrial flutter were grouped together for both patient enrollment and outcomes. The small number of patients with atrial flutter in this study precluded detailed assessment of whether the prognostic potential of IVC measurements applies equally to both AF and atrial flutter. In addition, the timing of IVC measurements (eg, pre- vs post-CV) was not blinded to the investigators acquiring them, introducing a potential for bias in measurement. Although the IVCd measurements were purely quantitative, in order to prioritize ease of acquisition, the assessment of IVC collapsibility was only performed as a visual estimate, which is a qualitative metric that is more vulnerable to the influence of bias. In addition, follow-up and ascertainment of echocardiographic information and past medical history were limited to review of the electronic medical record, and there was no requirement for concurrent echocardiogram at the time of enrollment in the study, nor any assessment of volume status at the time of CV. Therefore, although no significant associations were observed between echo-derived parameters and AF recurrence, the study was not designed to optimally compare the efficacy of established echo-derived or heart failure-based risk predictors of AF with HHU-derived IVC measurements. Another limitation of the study design is that invasive measurement of the RAP was not performed. However, ultrasound measurement of the IVC is well established as a correlate of invasive RAP measurement [19], and this study highlights the ability to gain potentially important prognostic information in a rapid, noninvasive fashion. Lastly, the

hemodynamic effects of the use of propofol on RAP and IVCd cannot be reliably determined as meaningful from our cohort.

The duration of AF/AF at the time of CV was not rigorously recorded in this study. One could hypothesize that atrial remodeling and fibrosis from longstanding AF/AF would be

associated with ineffective atrial contraction post-CV, and could influence IVC behavior in the early post-CV period. Atrial remodeling could mediate an association between larger IVCd post-CV and more frequent AF/AF recurrence. Further study inclusive of AF/AF duration and markers of atrial fibrosis could help to explore this potential connection.

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Conflicts of Interest

None declared.

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Abbreviations

AF: atrial fibrillation
AF/AF: atrial fibrillation or atrial flutter
CV: cardioversion
HHU: handheld ultrasound
IVC: inferior vena cava
IVCd: maximum inferior vena cava diameter
OR: odds ratio
RAP: right atrial pressure
SR: sinus rhythm

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Review

Smartphone Apps Using Photoplethysmography for Heart Rate Monitoring: Meta-Analysis

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Abstract

Background: Smartphone ownership is rising at a stunning rate. Moreover, smartphones prove to be suitable for use in health care due to their availability, portability, user-friendliness, relatively low price, wireless connectivity, far-reaching computing capabilities, and comprehensive memory. To measure vital signs, smartphones are often connected to a mobile sensor or a medical device. However, by using the white light-emitting diode as light source and the phone camera as photodetector, a smartphone could be used to perform photoplethysmography (PPG), enabling the assessment of vital signs.

Objective: The objective of this meta-analysis was to evaluate the available evidence on the use of smartphone apps to measure heart rate by performing PPG in comparison with a validated method.

Methods: PubMed and ISI Web of Knowledge were searched for relevant studies published between January 1, 2009 and December 7, 2016. The reference lists of included studies were hand-searched to find additional eligible studies. Critical Appraisal Skills Programme (CASP) Diagnostic Test Study checklist and some extra items were used for quality assessment. A fixed effects model of the mean difference and a random effects model of Pearson correlation coefficient were applied to pool the outcomes of the studies.

Results: In total, 14 studies were included. The pooled result showed no significant difference between heart rate measurements with a smartphone and a validated method (mean difference -0.32 ; 99% CI -1.24 to 0.60 ; $P=.37$). In adults, the Pearson correlation coefficient of the relation between heart rate measurement with a smartphone and a validated method was always $\geq .90$. In children, the results varied depending on measuring point and heart rate. The pooled result showed a strong correlation that was significant (correlation coefficient $.951$; 95% CI $0.906-0.975$; $P<.001$). The reported limits of agreement showed good agreement between a smartphone and a validated method. There was a moderately strong significant negative correlation between the year of publication of the included studies and the mean difference ($r=-.69$; $P<.001$).

Conclusions: Smartphone apps measuring heart rate by performing PPG appear to agree with a validated method in an adult population during resting sinus rhythm. In a pediatric population, the use of these apps is currently not validated.

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KEYWORDS

mobile applications; heart rate; photoplethysmography; electrocardiography; oximetry; meta-analysis

Introduction

Background

Smartphone ownership rises year by year. Advanced economies still have the highest smartphone ownership rates. Smartphone ownership in countries with an emerging and developing economy, however, is rising at a stunning rate [1].

Due to their availability, portability, user-friendliness, relatively low price, wireless connectivity, far-reaching computing capabilities, and comprehensive memory, smartphones prove to be suitable for use in health care [2-4]. A wide offer of health and medical applications exist from diagnostic tools over professional education to apps supporting patients and health consumers [3,5]. In the field of cardiological literature, there has been a growing interest in mobile apps since 2003 [6].

Measuring Vital Signs

Most of the studies focus on measuring vital signs using a smartphone. To this end, smartphones are mostly connected to a mobile sensor or medical device [6]. A majority of smartphones receive the information through built-in Bluetooth technology. They often process the information before transferring data to a server. At server level, the information can be further processed, organized, and analyzed to create a report for the user [2,4]. Hence, this type of monitoring requires several sensors or a separate device, which can be quite expensive [4]. Another way to measure heart rate is by utilizing a pulse oximeter using photoplethysmography (PPG). In total, 2 key components are essential to create a PPG waveform: a light source to illuminate the subcutaneous tissue and a photodetector to detect the changes in light intensity [7]. Jonathan en Leahy demonstrated that a smartphone could be used to perform PPG. The white light-emitting diode can be used as light source and the phone camera as photodetector. The 2 components should be positioned next to each other for reflection mode PPG; in comparison, in transmission mode PPG, the photodetector is placed opposite to the light source [8].

The PPG waveform is influenced by many factors enabling the assessment of vital signs, for example, oxygen saturation, blood pressure, respiratory rate, and heart rate. Promising results show the ability to screen for pathologies related to peripheral vascular disease [7-9]. The purpose of this review was to analyze the available evidence on measuring heart rate by performing PPG using smartphones in comparison with a validated method.

Methods

Literature Search and Selection Criteria

We conducted a systematic literature search of PubMed and ISI Web of Knowledge from January 1, 2009 to December 7, 2016, with the following search key: (smartphone* OR phone* OR ((Applic* OR App*) AND (mobile OR electronic OR software)) OR PPG OR Photoplethysmograph* OR Rheograph*) AND (Electrocardiogr* OR ECG OR EKG or Oximet*) AND ((rate* AND (heart OR pulse)) OR tachycardia* OR beat* OR complex* OR arrhythmia* OR fibrillation*). Only papers in

English, German, French, or Dutch were included. The reference lists of included studies were hand-searched to find additional eligible studies.

Studies were included if the measurement of heart rate was conducted with the photo camera of a smartphone by PPG; the measurements were made at a finger, toe, or earlobe; the measurements of the smartphone were compared with an electrocardiogram (ECG), a pulse oximeter, or another validated method to determine heart rate. Studies were excluded if the measurement was conducted with a mobile sensor or medical device connected to a smartphone; the paper did not have heart rate as one of the outcomes; no abstract or full text was available.

Data Extraction and Outcome Measures

Data were extracted by the first author and reviewed by all authors.

Following are study and intervention characteristics extracted from the included studies: first author, study country, study year, sample size, baseline characteristics of participants, age of the participants (mean or range), type of smartphone used, control instrument, duration and conditions of the measurement, and primary outcome measures. The primary outcome measures were the mean difference between heart rate measured by a smartphone and a validated method, the correlation coefficient of the relation between heart rate measurements made by both methods, and the 95% limits of agreement derived from a Bland-Altman plot.

Overall, 1 author was contacted to receive missing data about the heart rate measurements; 2 authors were contacted because of a lack of clarity about the data; and 7 authors were contacted to get access to the full text of the paper; but 2 authors failed to respond to that last request.

Study Quality

Study quality was appraised using the Critical Appraisal Skills Programme (CASP) Diagnostic Test Study checklist [10]. In addition, the included studies were evaluated by extra considerations described in the study of Hanneman [11]. The first was an appraisal tool developed for diagnostic studies. The checklist covered 3 sections: the validity of the results, the actual results, and the utility of the results. With the exception of the questions focusing on the actual results, the topics described were relevant for a method comparison study design. The 9 remaining questions were answered by “yes,” “can’t tell,” or “no.” One question was adapted so that “yes” always indicated a positive answer and “no” a negative answer. “Can’t tell” was answered when there was not enough information found in the study to answer the question. The checklist gave an indication of the quality per section and did not focus on a total score. The latter focused on specific considerations for a method comparison study design. The considerations were converted in 5 questions. These questions were also answered by “yes,” “can’t tell,” or “no.”

The quality assessment was performed by the first author and reviewed by the other authors.

Statistical Methods

In total, 3 different statistics were described, and 2 of them were used for estimation of the pooled result. The first was the mean difference between heart rate measured by a smartphone and a validated method. In case of absence of a mean value and standard deviation in the original paper, it was calculated manually where possible on the basis of the original data.

The second was the Pearson correlation coefficient calculated from the relation between heart rate measured by a smartphone and a validated method. The *P* value was calculated manually out of the correlation coefficient and sample size if not described in the original paper.

The third were the 95% limits of agreement. They were derived from a Bland-Altman plot. Lower and upper limits were calculated starting from the mean difference by respectively subtracting and adding up the standard deviation of the mean difference between both methods, multiplied by a factor of 1.96. In 2 studies, they were calculated manually starting from the mean difference and the described limit of agreement.

The pooled result was estimated using a fixed- or random-effects model. Statistical heterogeneity was tested using the chi-squared test where a significant result indicated statistical heterogeneity. To quantify inconsistency, the I^2 of Higgins was used. In case of statistical heterogeneity, a random-effects model was used for pooling the results. Due to the small number of included studies, it was not possible to explore heterogeneity by subgroup analysis or meta-regression [12].

Pearson correlation was used to analyze the relation between different variables (publication year, mean heart rate, and sample size) and the mean difference. The scatter plots of these correlations were drawn.

Statistical analyses were performed using Review Manager Version 5.3 (The Cochrane collaboration, Copenhagen: Denmark: The Nordic Cochrane Centre, 2014), MedCalc 17.4 (MedCalc Software, Ostend: Belgium, 2017), and Microsoft Office Excel 2007 (Microsoft, 2007). Statistical significance level was set at 5%, except for mean difference where statistical significance level was set at 1%.

Results

Study Identification and Selection

Figure 1 shows a diagram of the search and selection strategy. Initially, 1637 studies were found in 2 databases. First, 312 duplicates—identical studies found in both databases—were removed, followed by 1245 studies on the basis of an irrelevant title. The abstract of the remaining 80 studies was screened of which 55 were excluded for not fulfilling the selection criteria [4,13-66]. The 25 remaining studies were reviewed by reading the full text [8,67-90]. An additional 10 studies were excluded for not fulfilling the selection criteria [8,67,71,72,74,76,81,83,84,86]. For 2 studies, the full text could not be retrieved [69,77]. One paper was added after hand-searching the reference list of the included studies [91]. A total of 14 studies was used for this review and meta-analysis [68,70,73,75,78-80,82,85,87-91].

Study Characteristics

Table 1 presents the characteristics of the included studies. In total, 5 studies reported findings on North American participants [68,73,85,89,90], 6 on Western European participants [70,78-80,87,91], and 3 on East Asian participants [75,82,88]. The oldest studies dated from 2010 and the most recent from 2016. Sample sizes varied from 1 to 68, with a median of 24. In total, 8 studies studied an adult population [70,73,78,80,82,85,87,91] and 2 an infant population [75,90], and 4 studies did not mention the age of the participants [68,79,88,89]. In 9 studies, the reference instrument was an ECG [68,70,75,78,79,82,85,89,90]; in 4 studies, a pulse oximeter [80,87,88,91]; and in 1 study, both [73]. The duration of the measurement varied between 10 s and 5 min. Of the selected studies, 2 did not mention the duration of the measurement [89,90]. A total of 5 studies tried to evoke variations in heart rate [68,73,78,82,91], 2 studies controlled the breathing of the participants during measurement [85,89], 1 paper made measurements in different lighting conditions [87], and 1 paper made measurements during different heart rhythms [90]. Overall, 8 studies studied another outcome besides heart rate, namely heart rate variability parameters [68,78,79], other vital parameters [85,89], and other outcomes [70,82,88].

Study Quality

Table 2 presents the quality assessment of the included studies. The quality assessment questions are listed in Textbox 1. All studies had a clear study question and compared the measurements of the smartphone with an appropriate reference standard. Due to the type of test, it was not possible that the measurement of the reference standard influenced the measurement of the smartphone. Also, both methods did measure the same outcome simultaneously. Totally, 5 studies made a clear description of the disease status of the participants [70,73,80,82,90]. Just over half of the studies described the methods for performing the test in sufficient detail [68,70,73,75,78,80,82,85]. Half of the studies provided enough information about the participants to conclude that the results may be applicable to the population of interest [73,75,78,80,82,85,90]. All studies had the same relevant outcome and performed their measurements in a similar way. All but one [82] studies acknowledged that the sample size was small. In 6 studies, the authors made an effort to measure a wide range of the possible physiological values of heart rate [68,73,78,82,90,91]. Only 3 studies used a cutoff value for the clinical acceptable difference between the measurements made by the 2 methods [73,75,80].

Primary Outcome: Heart Rate

The mean difference between heart rate measured by a smartphone and a validated method was analyzed in a fixed-effects model (Figure 2). This statistic was reported in 7 studies [68,73,80,82,88,89,91]. For 2 studies, it was calculated manually out of the original data [85,87]. In 2 studies, the mean difference was consistently positive [82,89]; and in 5 studies, negative [73,80,85,87,88]. In 2 studies, the mean difference was negative, except for 1 condition where there was no difference [68] or the mean difference was positive [91]. The pooled estimate of the 9 included studies suggested that there is no

difference between both methods (mean difference -0.32 ; 99% CI -1.24 to 0.60 ; $P=.37$). No statistical heterogeneity was observed among the studies ($I^2=0\%$; $P>.99$).

Table 3 shows the correlation coefficient of the relation between heart rate measurement with a smartphone and a validated reference method. This statistic was reported in 9 studies [68,70,73,75,78-80,82,90]. Previous research stated that the correlation between 2 methods that measure heart rate should

be $\geq .90$ to be considered as valid [92]. In 7 studies, the correlation coefficient was always $\geq .90$ and the result was statistical significant [68,70,73,78-80,82]. The 2 studies that studied a pediatric population showed more variation in their results. In 1, the correlation coefficients were remarkably lower during periods of tachycardia, namely $.56$ and $-.43$ [90] and not statistical significant for the latter. In 1 paper, the correlation coefficient was only $\geq .90$ in 2 of the 4 apps. In 1 of these 2 apps, this was just the case for measurements at the earlobe [75].

Figure 1. Search and selection strategy.

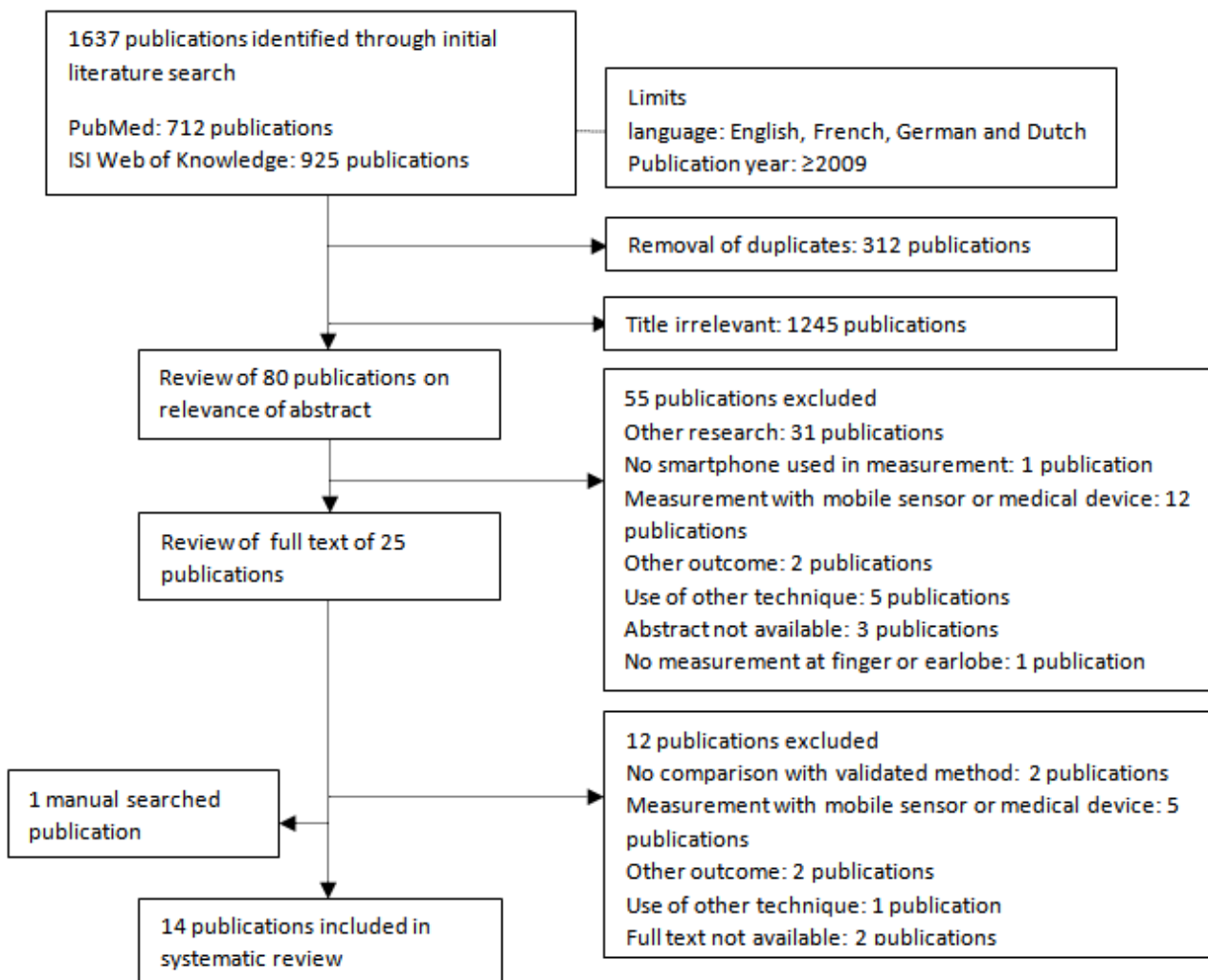


Table 1. Characteristics of included studies.

Author, year, and country	Sample size and age (range or mean [SD])	Smartphone	Control	Duration and conditions measurement	Outcome measure
Bolkhovskiy et al, 2012, United States [68]	22 subjects, age not specified	Motorola Droid, iPhone 4S	ECG ^a	2 × 2 min: supine and sitting up in tilt position (iPhone 4S, n=9); 2 × 5 min: supine and sitting up in tilt position (Motorola Droid, n=13)	Heart rate, heart rate variability
Drijkoningen et al, 2014, Belgium [70]	28 adults with sinus rhythm during electrophysiological examination, age not specified	Samsung Galaxy S4	ECG	60 s	Heart rate, premature atrial ectopic beats identification
Gregoski et al, 2012, United States [73]	14 adults, 18-59 years	Motorola Droid	ECG, pulse oximeter	3 × 5 min: sitting, at rest, reading, and playing a video game	Heart rate
Ho et al, 2014, Taiwan [75]	40 children undergoing ECG monitoring, 3 days to 15 years	iPhone 4S	ECG	3 × 20 s at finger (or toe) and earlobe	Heart rate
Koenig et al, 2016, Germany [78]	68 adults (45 patients from a cardiologic outpatient ambulance and 23 healthy controls), 51.7 (18.83) years	iPhone 4S	ECG	5 min: at rest 2 min: after 3 min of physical exercise (only controls)	Heart rate, heart rate variability
Kurylyak et al, 2012, Italy [91]	10 adults, 26-60 years	HTC HD2, iPhone 4, Nokia 5800, Samsung Galaxy S i9000	Pulse oximeter	2 × 60 s (per smartphone): at rest and after 60 s squatting	Heart rate
Lagido et al, 2014, Portugal [79]	43 heart failure patients, age not specified	Sony Xperia S	ECG	At rest	Heart rate, heart rate variability
Losa-Iglesias et al, 2016, Spain [80]	46 healthy adults, 39.3 (7.35) years	Samsung Galaxy Note	Radial pulse, pulse oximeter	3 × 10-30 s: at rest (resting 10 min before measurements)	Heart rate
Matsumara et al, 2013, Japan [82]	12 students, 21-24 years	iPhone 4S	ECG	3 × 3 min: at rest (resting 7 min before measurement), during mental arithmetic, and during mirror tracing	Heart rate, normalize pulse volume
Nam et al, 2016, United States [85]	11 healthy nonsmoking adults, 20-40 years	HTC One M8	ECG	3 × 2 min: breathing at frequencies from 0.1 to 0.5 Hz at increments of 0.1 Hz, breathing at 1 Hz and spontaneous breathing	Heart rate and breathing rate
Pelegris et al, 2010, UK [87]	50 adults, 21-55 years	HTC Tattoo	Pulse oximeter	2 × 9 s: well-lit room and average lit room	Heart rate
Po et al, 2015, China [88]	10 subjects, age not specified	Samsung Galaxy Nexus, LG Optimus P920, Samsung Galaxy S2, Samsung Galaxy Tablet 7.0, Motorola Atrix	Pulse oximeter	1 × 20 s	Heart rate and root mean square distortion of heart rate
Scully et al, 2012, United States [89]	1 subject, age not specified	Motorola Droid	ECG	1 × ?: spontaneous breathing 3 × 2 min: breathing at 0.2, 0.3, and 0.4 Hz	Heart rate, respiration rate, oxygen saturation
Wackel et al, 2014, United States [90]	26 children undergoing an electrophysiology study under general anesthesia, 5-17 years	iPhone 5	ECG	2 × ?: during baseline heart rate (34 measurements in 17 children) 2 × ?: during sustained supraventricular tachycardia (38 measurements during 21 supraventricular tachycardia in 18 children)	Heart rate

^aECG: electrocardiogram.

Table 2. Study quality according to Critical Appraisal Skills Programme Diagnostic Test study checklist and extra considerations. Y indicates yes; N indicates no; and C indicates can't tell.

Study	Validity of results						Utility of results			Extra considerations				
	Q1	Q2	Q3	Q4	Q5	Q6	Q9	Q10	Q11	E1	E2	E3	E4	E5
Bolkhovskiy et al	Y	Y	Y	Y	N	Y	C	Y	Y	Y	Y	N	Y	N
Drijkoningen et al	Y	Y	Y	Y	Y	Y	C	Y	Y	Y	Y	N	N	N
Gregoski et al	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y
Ho et al	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	N	Y
Koenig et al	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	N
Kurylyak et al	Y	Y	Y	Y	N	N	C	Y	Y	Y	Y	N	Y	N
Lagido et al	Y	Y	Y	Y	N	N	C	Y	Y	Y	Y	N	C	N
Losa-Iglesias et al	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	Y
Matsumara et al	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
Nam et al	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	N	N
Pelegris et al	Y	Y	Y	Y	N	N	C	Y	Y	Y	Y	N	N	N
Po et al	Y	Y	Y	Y	N	N	C	Y	Y	Y	Y	N	N	N
Scully et al	Y	Y	Y	Y	N	N	C	Y	Y	Y	Y	N	N	N
Wackel et al	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	N

Textbox 1. Quality assessment questions.

Critical Appraisal Skills Programme Diagnostic study checklist

- Validity of results
 - Was there a clear question for the study to address?
 - Was there a comparison with an appropriate reference standard?
 - Did all patients get the diagnostic test and reference standard?
 - Is there no possibility that the results of the test have been influenced by the results of the reference standard?
 - Is the disease status of the tested population clearly described?
 - Were the methods for performing the test described in sufficient detail?
- Utility of results
 - Can the results be applied to your patients/the population of interest?
 - Can the test be applied to your patient or population of interest?
 - Were all outcomes important to the individual or population considered?

Extra considerations

- Do both methods measure the same outcome?
- Do both methods measure the outcome simultaneous?
- Did the investigators motivate their choice for the sample size?
- Did the investigators test both methods in different conditions to simulate the possible physiological range of values?
- Did the investigators set up cutoff values for the clinical acceptable difference between both methods?

Figure 2. Forest plot for the meta-analysis of mean difference.

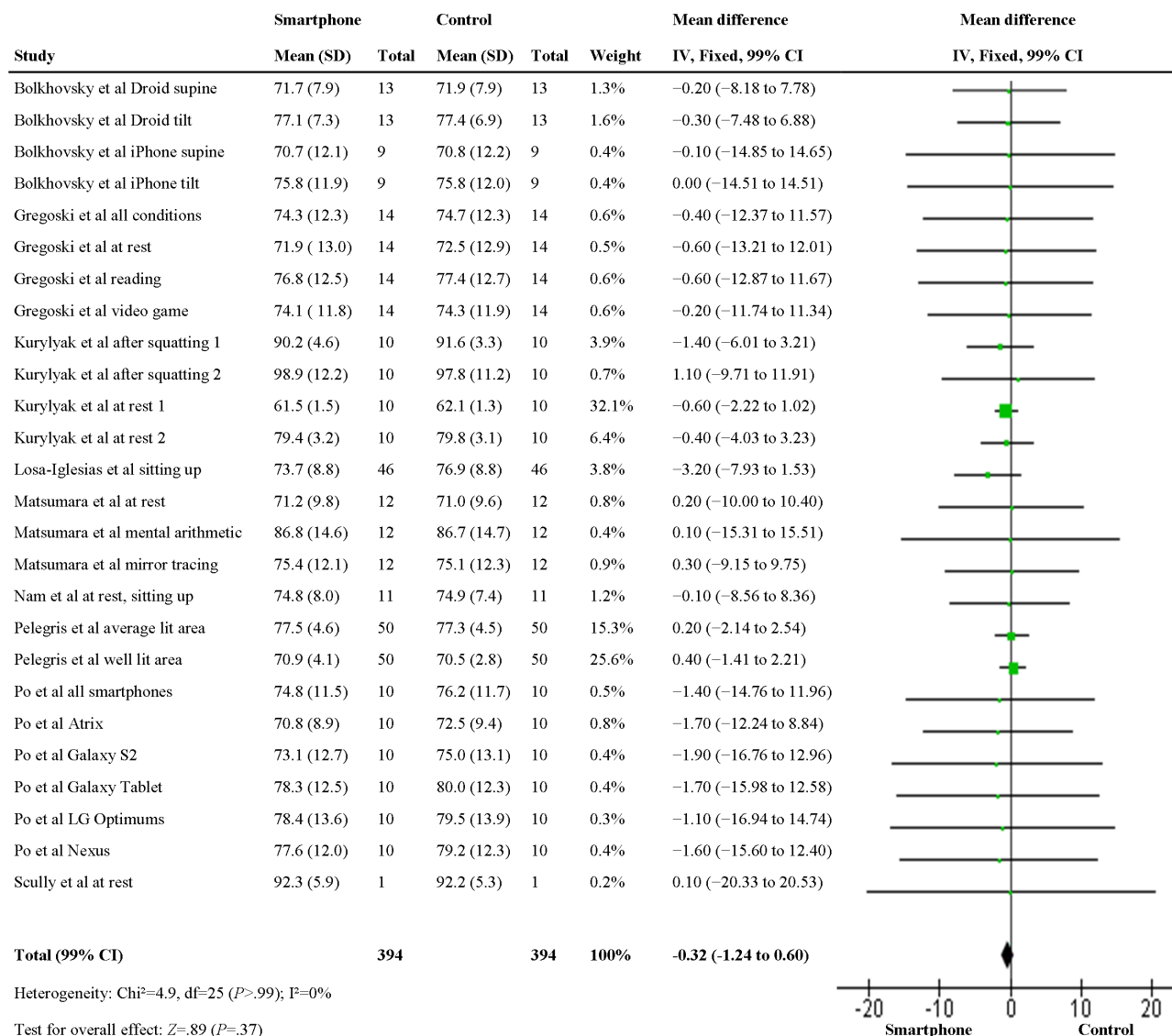


Table 3. Results for heart rate: Pearson correlation coefficient.

Study	Conditions (sample size)	r^a	$r \geq .90?$	P value ^b
Bolkhovskiy et al	iPhone supine (9)	>.99	Yes	<.001 ^c
	iPhone tilt (9)	>.99	Yes	<.001 ^c
	Droid supine (13)	.98	Yes	<.001 ^c
	Droid tilt (13)	>.99	Yes	<.001 ^c
Drijkoningen et al	Not specified (28)	.98	Yes	<.001
Gregoski et al	At rest (14)	.99	Yes	<.001 ^c
	Reading (14)	.99	Yes	<.001 ^c
	Video game (14)	.99	Yes	<.001
Ho et al	App A finger (40)	.81	No	<.001
	App A earlobe (40)	.91	Yes	<.001
	App B finger (40)	.75	No	<.001
	App B earlobe (40)	.76	No	<.001
	App C finger (40)	.27	No	.10
	App C earlobe (40)	.46	No	.003
	App D finger (40)	.90	Yes	<.001
Koenig et al	80 randomly chosen intervals at rest or after exercise (68)	>.99	Yes	<.001 ^c
	At rest (43)	.94	Yes	<.001 ^c
Los-Iglesias et al	Sitting up (46)	.95	Yes	<.001
Matsumura et al	All conditions (12)	.99	Yes	<.001 ^c
Wackel et al	App 1 sinus rhythm (17)	.99	Yes	<.001 ^c
	App 1 tachycardia (10 succeeded attempts)	.56	No	.01 ^c
	App 2 sinus rhythm (17)	.99	Yes	<.001 ^c
	App 2 tachycardia (5 succeeded attempts)	-.43	No	.09 ^c

^a r value of Pearson correlation coefficient.

^b P value calculated with Pearson correlation.

^cData based on own calculations.

The correlation between heart rate measurements made by a smartphone and a control instrument was analyzed in a random-effects model (Figure 3). The pooled correlation coefficient made the assumption that on average measurements made by a smartphone are highly correlated to those made by a control instrument (correlation coefficient .951; 95% CI 0.906-0.975; $P < .001$). Of note, statistical heterogeneity was high ($I^2 = 93.8\%$; $P < .001$), indicating variability across the studies.

Table 4 shows the 95% limits of agreement for the MD between measurements with a smartphone and a validated method. This statistic was reported in 4 studies [80,82,85,88]. For 2 studies,

it was calculated manually [68,73]. In all studies, the limits of agreement did not exceed 10 beats per minute.

Correlations With the Mean Difference

The correlation between the mean heart rate measured by a validated method, the sample size of the included studies, and the year of publication of the included studies and the mean difference was analyzed in Figures 4-6, respectively. Correlations between the mean difference and the mean heart rate measured by a validated instrument ($r = .13$) and sample size ($r = -.06$) were not significant. However, data showed a moderately strong correlation between the year of publication and the mean difference ($r = -.69$; $P < .001$).

Figure 3. Forest plot for the meta-analysis of Pearson correlation coefficient.

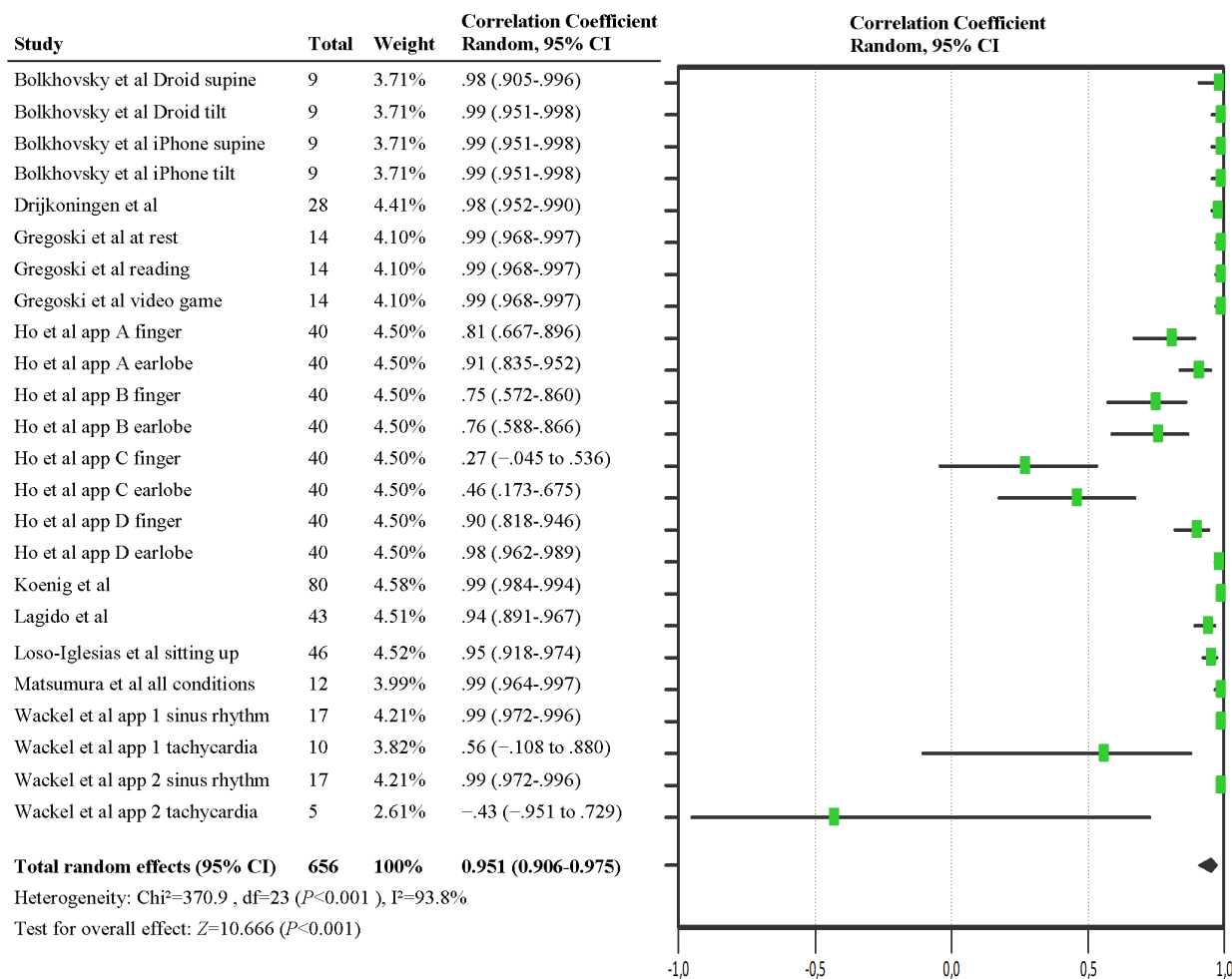


Table 4. Results for heart rate: 95% limits of agreement.

Study	Conditions (sample size)	95% LOA ^a (BPM ^b), control—smartphone
Bolkhovskiy et al	iPhone supine (9)	-0.4 to 0.2 ^c
	iPhone tilt (9)	-0.3 to 0.3 ^c
	Droid supine (13)	-3.4 to 3.0 ^c
	Droid tilt (13)	-1.7 to 1.1 ^c
Gregoski et al	Video game (14)	-3.9 to 3.7 ^c
Loso-Iglesias et al	Sitting up (46)	-8.5 to 2.0
Matsumura et al	All conditions (12)	-1.0 to 1.4
Nam et al	At rest, sitting up (11)	-5.6 to 5.5
Pot et al	Average all smartphones (10)	-4.1 to 1.2

^aLOA: limits of agreement.

^bBPM: beats per minute.

^cData based on own calculations.

Figure 4. Scatter plot comparing correlation between mean heart rate measured by control and mean difference.

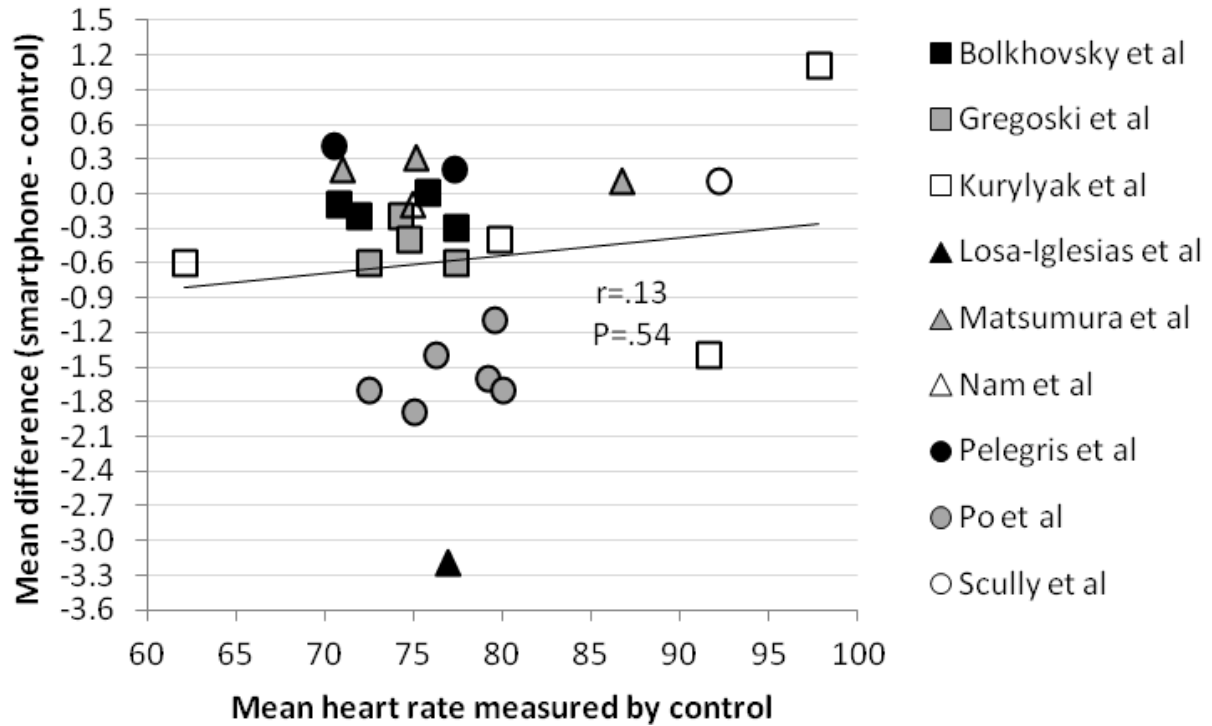


Figure 5. Scatter plot comparing correlation between sample size and mean difference.

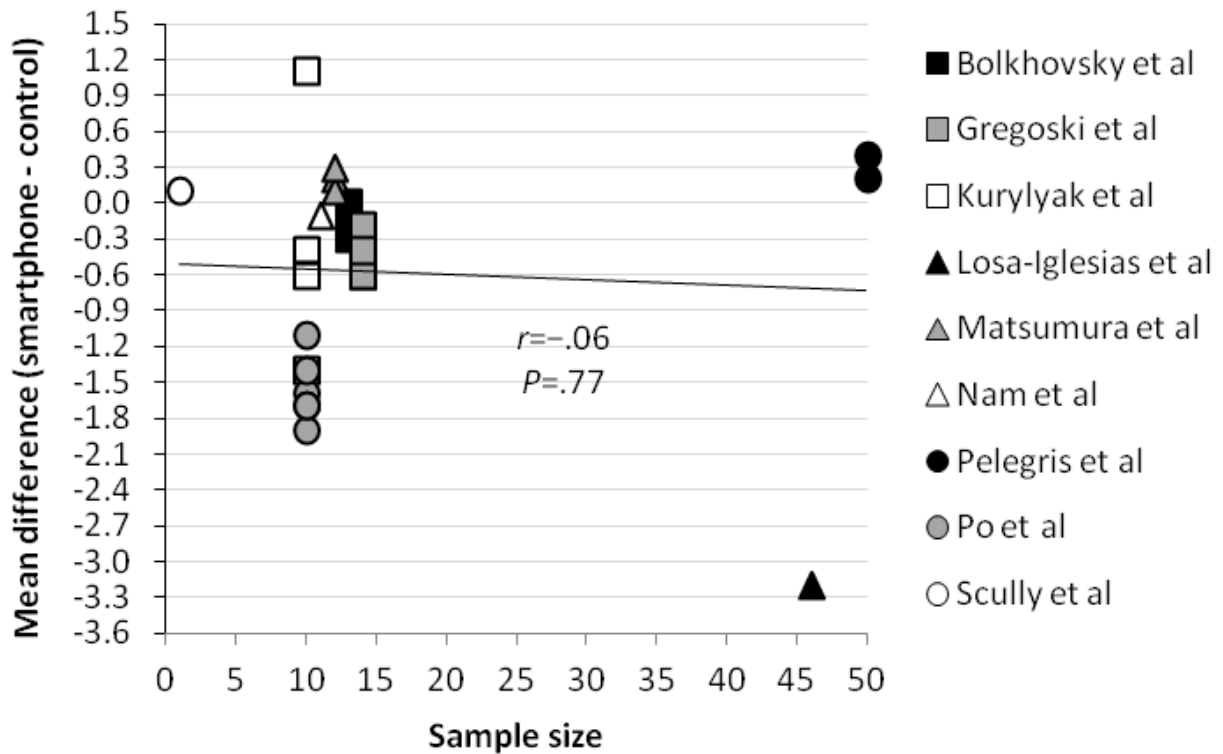
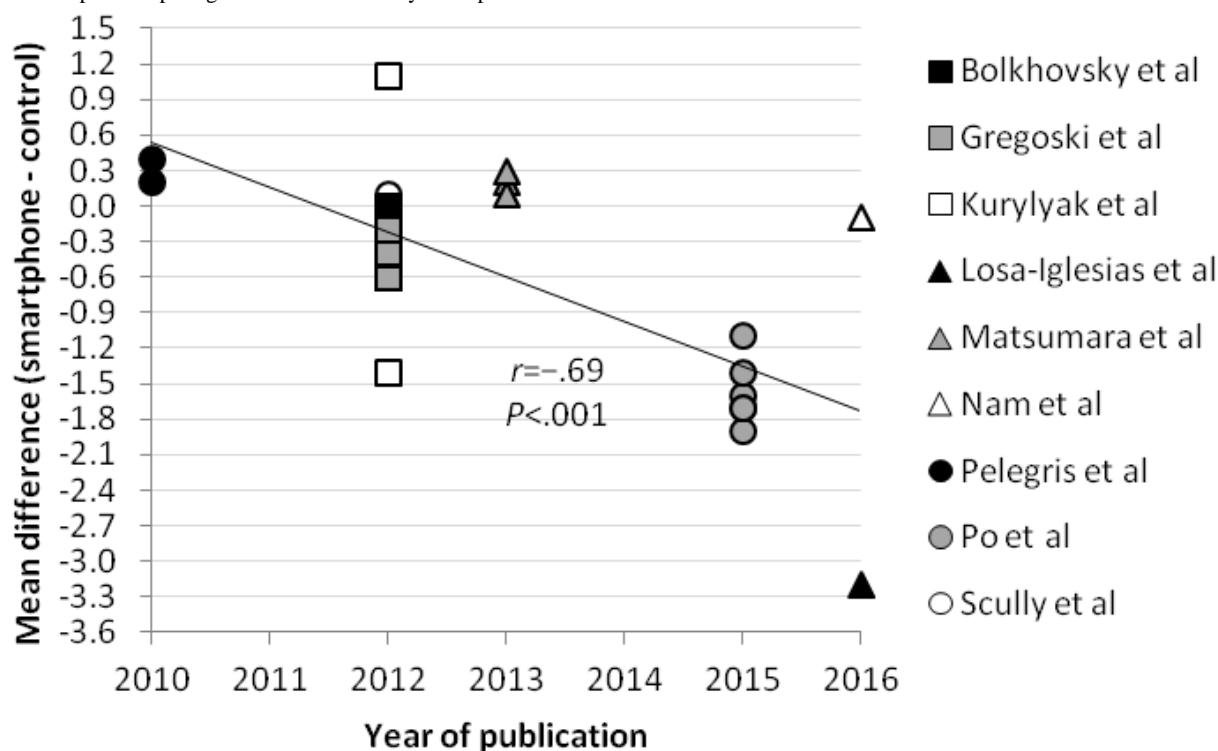


Figure 6. Scatter plot comparing correlation between year of publication and mean difference.



Discussion

Principal Findings

The meta-analysis of the mean difference showed no statistical difference between the measurement of heart rate by a smartphone and a validated method (mean difference -0.32 ; 99% CI -1.24 to 0.60 ; $P=.37$). The pooled correlation coefficient between heart rate measurement by a smartphone and a validated method was more than .90 and statistically significant (correlation coefficient .951; 95% CI 0.906-0.975; $P<.001$). Reported 95% limits of agreement had a narrow range and therefore showed good agreement between a smartphone and a validated method. These results suggest that a smartphone app deriving heart rate from a PPG signal could be used as an alternative for already validated methods such as an ECG or pulse oximeter in an adult population in resting sinus rhythm. However, the significant negative correlation between the year of publication of the included studies and the mean difference ($r=-.69$; $P<.001$) suggests that smartphone technology for measuring heart rate did not improve over time. There was no significant correlation between the mean difference and the mean heart rate measured by a validated method ($r=.13$; $P=.54$) or the sample size of the included studies ($r=-.06$; $P=.77$), which suggests that smartphone results are consistent for heart rate measurements between 60 and 100 beats per minute.

Considerations

First, the results of the studies in a pediatric population showed that it is not advisable yet to use these apps in children. A possible cause is that because of the smaller size of children's fingertips, the pulsatile flow may be less consistently detected. The use of the earlobe as a measuring point may present a possible solution. Children may also have difficulties in

containing the appropriate pressure on the camera lens and keeping their finger motionless to make a good measurement [73,75,90].

A second issue is heart rate measurement during periods of arrhythmia [4]. The low correlation between measurements with a smartphone and a validated method during periods of supraventricular tachycardia in children suggests that current apps do not give adequate results during periods of extremely high heart rates [90]. Moreover, the smartphone apps in the studies used PPG, calculating the heart rate on basis of the pulse rate. Hence, the results may not be accurate enough during periods of arrhythmia with variations in pulse rate and amplitude due to heart rhythm irregularities [4,82]. A solution is to improve sensitivity and specificity of the apps for deviant heart rhythms depending on the purpose of the apps [62].

Third, previous research stated that heart rate measurement can be susceptible to environmental or human factors such as ambient light, motion [4,93], or skin color [7]. In total, 3 studies reported about lighting conditions [87,88,91]. In these studies, ambient light did not seem to have an influence, but it should still be taken into account. On the basis of this review, it is not possible to say something about the influence of motion, as none of the included studies tested whether accurate pulse rate is measurable by the smartphone apps during exercise. However, several studies do mention this limitation in their discussion. Wearable devices using PPG possibly provide better results during exercise [94]. Only 1 paper mentioned to have included participants with a variety of skin colors but did not make a comparison between different skin types [73]. Hereby, we cannot come to a conclusion about the topic in this review. When using PPG to measure heart rate, it should be taken into account to use a proper light wavelength that gives equal results for people with different skin types [95].

Fourth, it was remarkable that in the included studies the mean difference became more and more negative over time. A plausible explanation is that every paper focuses on (a) certain type(s) of smartphone model(s) or app(s). Consequently, the results cannot be automatically projected to other smartphones and apps [4]. The use of certain smartphones or apps could lead to better results.

Strengths and Limitations

First of all, to the best of our knowledge, this was the first systematic review and meta-analysis evaluating smartphone apps using PPG to measure heart rate. A comprehensive search strategy was used, including every paper investigating smartphone apps deriving heart rate measurement from a PPG signal. At last, there was a focus on different statistics for assessing agreement between methods.

Nevertheless, there were some limitations of the included studies. First, the methodological quality was often low, reflected by the fact that only 3 studies scored 12 or more out of 14 on the quality assessment questions [73,80,82].

Second, most of the mean heart rates that were reported lay between 70 and 80 beats per minute. As a result, it was not possible to investigate whether smartphones could be used to measure the higher physiological ranges of heart rate.

Third, only 8 of the included studies [68,70,73,78,80,82,85,88] used the most appropriate method to determine agreement between the 2 methods, the Bland-Altman plot [96,97]. Of these studies, only 2 mentioned a conclusion of the results, which were in line with the findings of the review [70,78]. A consideration about this method is that it is not easy to determine good agreement [96]. In the literature, no description was found of the maximum heart rate deviation to be clinically relevant. A deviation of under 10 beats per minute has no important clinical implications but does indicate small alterations when repeating the measures. The other methods can support the findings but have their limitations. A Pearson correlation gives information

about the relation between methods, but a high correlation does not necessarily mean that the 2 methods agree [97,98]. When using a mean difference, poor agreement can be hidden by looking at the mean difference, without exploring the individual values (eg, an overestimation of high heart rates in combination with an underestimation of low heart rates will also give a mean difference of 0) [97].

A fourth and last limitation is a high statistical heterogeneity between studies on the level of correlation coefficients. This is likely attributable to clinical heterogeneity caused by differences in patient characteristics (eg, adults vs children), the conditions in which the heart rates were measured (eg, at sinus rhythm vs during a period of tachycardia), and which smartphone or app was used [12].

All these factors may influence the generalizability of the results.

In addition, there were some limitations specific to the review. The data were extracted by the first author only; however, they were thoroughly reviewed by the other authors, of which one is specialized in cardiology. In addition, 2 studies were excluded because the full text could not be retrieved [69,77]; the results described in the abstracts of those studies agreed with the pooled results, so their exclusion would probably have a minimal effect.

Conclusions

This meta-analysis suggests that heart rate measured by smartphone apps performing PPG agrees with a validated method in an adult population in resting sinus rhythm, provided that during measurement the measuring point was kept still and that appropriate pressure was maintained. In a pediatric population, the use of these apps can currently not be supported, especially not during periods of tachycardia. Future research with a larger and more diverse study population should be conducted. The technology should also be tested in more varied clinical situations evoking variations in normal heart rate and during arrhythmias.

Authors' Contributions

BDR made most of the contributions to conception and design, to the acquisition of data, and to analysis and interpretation of data. The other authors played an important role in acquiring missing data and revising it critically for important intellectual content. All authors reviewed and approved the data and the final text.

Conflicts of Interest

None declared.

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Abbreviations

CASP: Critical Appraisal Skills Programme

ECG: electrocardiogram

PPG: photoplethysmography

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Original Paper

A Novel Intelligent Two-Way Communication System for Remote Heart Failure Medication Uptitration (the CardioCoach Study): Randomized Controlled Feasibility Trial

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Abstract

Background: European Society of Cardiology guidelines for the treatment of heart failure (HF) prescribe uptitration of angiotensin-converting enzyme inhibitors (ACE-I) and β -blockers to the maximum-tolerated, evidence-based dose. Although HF prognosis can drastically improve when correctly implementing these guidelines, studies have shown that they are insufficiently implemented in clinical practice.

Objective: The aim of this study was to verify whether supplementing the usual care with the CardioCoach follow-up tool is feasible and safe, and whether the tool is more efficient in implementing the guideline recommendations for β -blocker and ACE-I.

Methods: A total of 25 HF patients were randomly assigned to either the usual care control group (n=10) or CardioCoach intervention group (n=15), and observed for 6 months. The CardioCoach follow-up tool is a two-way communication platform with decision support algorithms for semiautomatic remote medication uptitration. Remote monitoring sensors automatically transmit patient's blood pressure, heart rate, and weight on a daily basis.

Results: Patients' satisfaction and adherence for medication intake (10,018/10,825, 92.55%) and vital sign measurements (4504/4758, 94.66%) were excellent. However, the number of technical issues that arose was large, with 831 phone contacts (median 41, IQR 32-65) in total. The semiautomatic remote uptitration was safe, as there were no adverse events and no false positive uptitration proposals. Although no significant differences were found between both groups, a higher number of patients were on guideline-recommended medication dose in both groups compared with previous reports.

Conclusions: The CardioCoach follow-up tool for remote uptitration is feasible and safe and was found to be efficient in facilitating information exchange between care providers, with high patient satisfaction and adherence.

Trial Registration: ClinicalTrials.gov NCT03294811; <https://clinicaltrials.gov/ct2/show/NCT03294811> (Archived by WebCite at <http://www.webcitation.org/6xLiWVsgM>)

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KEYWORDS

heart failure; telemedicine; clinical decision support; drug monitoring; drug utilization; call centers

Introduction

Heart failure (HF) is a major health problem affecting more than 10% in the elderly over the age of 70 years [1-5]. Mortality rates are high, with only 50% of patients surviving up to 5 years after first diagnosis. Hospitalization rates are even higher with 1-year hospitalization rates of approximately 40% and a readmission rate of 30% to 45% within 6 months after initial admission [6-9]. These high (re)admission rates put a large burden on the current health care system [10-12].

Improvements in treatment strategies have reduced mortality and (re)hospitalization rates. In 2016, the updated guidelines of the European Society of Cardiology (ESC) concerning the diagnosis and treatment of acute and chronic HF with reduced ejection fraction were published [1]. These guidelines prescribe uptitration of angiotensin-converting enzyme inhibitors (ACE-I) and β -blockers to the maximum-tolerated, evidence-based dose in function of a patient's weight, blood pressure, heart beat, and kidney function. There is strong evidence that adherence to guidelines and optimal drug treatment leads to a better clinical outcome and reduced mortality and (re)hospitalizations [1]. HF disease management programs are widely used to facilitate the implementation of guideline-recommended treatment strategies [13-17]. Unfortunately, studies have proven that they are still insufficiently implemented in practice [15,18-20].

The addition of remote monitoring combined with integrated clinical decision support in this aspect could provide added value for both the health care provider and the patient. Remote monitoring of vital parameters and other patient information could allow care givers to evaluate and adjust patients' medication schemes remotely according to ESC guidelines [21]. Remote β -blocker uptitration based on patient's self-collected physiologic data transmitted by phone has been previously studied and showed a positive impact on β -blocker use [21-23]. The IN-TOUCH trial was one of the first studies to investigate the value of a decision support algorithm for medication uptitration in addition to remote monitoring (ie, weight, blood pressure, and electrocardiogram) compared with remote monitoring alone. However, this study lacked a usual care control group and could not show differences in clinical outcome [24,25]. Kropf et al also developed a remote monitoring strategy with integrated clinical decision support, but the algorithm was only retrospectively analyzed with existing remote monitoring datasets [26]. The aim of Kropf et al was to prospectively study this strategy in a large-scale randomized trial, but unfortunately, the trial was stopped and no results are available. Therefore, the CardioCoach study is the first to study the feasibility of remote monitoring with integrated decision support on HF drug treatment optimization.

The CardioCoach study combines a two-way communication platform with decision support algorithms together with remote monitoring sensors for active medication uptitration. The study will verify whether supplementing the guideline-driven usual care with this two-way communication platform can implement the guideline recommendations for β -blocker and ACE-I more efficiently. This paper focusses on the feasibility of the communication platform for adjusting HF medication remotely

and for detecting early deterioration by monitoring blood pressure, heart rate, and weight changes. Patient's vital measurements and therapy adherence were actively encouraged by the smartphone app and were evaluated together with the patient's satisfaction of the CardioCoach tool.

Methods

Study Design

This is a prospective single-center randomized control feasibility trial conducted in a Belgian tertiary care center (Jessa hospital, Hasselt, Belgium) with a specialized HF disease clinic. Newly diagnosed patients with HF and initiation of β -blocker and/or ACE-I therapy or patients with known HF but on suboptimal dosage of β -blocker and/or ACE-I therapy were approached. Upon inclusion, block randomization was used to divide patients in either the usual care control group or the CardioCoach intervention group (clinical trial registration with www.clinicaltrials.gov; identifier NCT03294811). All patients provided written informed consent and were followed for 6 months after study enrolment. The study complies with the Declaration of Helsinki, and the study protocol was approved by the local committee on human research.

Usual Care Control Group

ESC guidelines on uptitration of β -blocker and/or ACE-I therapy are primarily intended to be used by physicians. Therefore, medication dose adaptations were performed during occasional outpatient visits to the cardiologist or general practitioner. Medication doses were determined based on patient's vital sign measurements, overall well-being, and symptoms. Besides an additional follow-up visit at 3 months, we did not modify the usual care as per standard practice organized in the institution where patients have a scheduled follow-up visit at 6 months.

CardioCoach Intervention Group

Patients allocated to the CardioCoach intervention group also had a scheduled follow-up visit at 3 months and 6 months. For these patients, the usual care was supplemented with the CardioCoach follow-up tool to proactively uptitrate β -blocker and ACE-I treatment and improve medication adherence for β -blocker, ACE-I, and diuretic treatment. In terms of diuretic treatment, only medication adherence was monitored because it was not part of the active uptitration protocol. This intervention included a two-way communication platform connected to remote monitoring devices such as a weighing scale and blood pressure monitor to collect vital measurements (ie, weight, blood pressure, and heart rate), in which patients were followed by technical and clinical call centers. Medical follow-up (eg, medication uptitration, alerts on threshold crossing) was done by the clinical call center in the hospital, whereas technical follow-up (eg, missed transmissions, technical issues) was done by Remedus (Aartselaar, Belgium). Both call centers were active during working hours; notifications received during the weekend were read on Monday.

The CardioCoach Follow-Up Tool for Semiautomatic Medication Uptitration

The two-way communication platform consisted of a smartphone with the preinstalled CardioCoach app, a blood pressure monitor, weighing scale, and a Web-based health management server (Remecare) with a clinical dashboard for the care provider (HF nurse). An overview of the CardioCoach follow-up tool can be found in [Figure 1](#).

The CardioCoach app was used to trigger the patient to conduct different actions, such as record a vital sign measurement, complete a questionnaire, and confirm medication intake by sending reminders at predefined time points. For each action, a 5-hour time window was set in which the patient could record all necessary data. This time window could be customized for each patient and was made available an hour before and 4 hours after the ideal recording time. All vital sign measurements were transmitted automatically to the CardioCoach app without manual patient input. The patient-specific medication scheme for β -blocker, ACE-I, and diuretic treatment was automatically uploaded to the patients' smartphones every morning to inform them about their actual medication dose for that day. When changes were applied to the medication scheme, the patient was notified via a pop-up message, which he/she had to confirm. In addition, a daily education tip was pushed by the smartphone app to the patient covering different HF disease aspects (eg, tips to manage fluid and salt restriction, exercise). Screenshots of the CardioCoach app are shown in [Multimedia Appendix 1](#).

All information gathered via the CardioCoach smartphone app (ie, vital signs, questionnaires, medication intake) was automatically transmitted to a secured Web-based health management server (ie, Remecare) without patient input. On this server, the completeness of patient data and possible

deviations of vital signs based on predefined thresholds were verified.

When a patient does not record medication intake or vital sign data or does not complete a questionnaire, a pop-up message was pushed 2 hours after the ideal recording time via the smartphone to inform the patient about the missed registration and stress the importance of this information for the medication uptitration process. If the patient still did not complete the required action 4 hours after the ideal recording time, a *no registration* tag was recorded in the clinical database and the patient was contacted by the technical call center within 12 hours. In case of missed medication intake, the technical call center asked whether the patient forgot to register the medication intake or whether the patient forgot to take the required medication. In case of vital sign thresholds crossings for 3 consecutive days ([Table 1](#)), an automatic custom-made HF questionnaire was pushed to the patient via the CardioCoach smartphone app to gain insight about his/her general well-being or symptoms related to deviating vital signs, and a message was sent to the clinical call center to review the vital sign data and questionnaire ([Multimedia Appendix 2](#)).

CardioCoach Medication Uptitration With Clinical Decision Support Algorithm

In the CardioCoach intervention group, β -blocker and ACE-I medication uptitration was supported by a clinical decision support algorithm, initiated at study inclusion. The algorithm generated a medication uptitration proposal at fixed moments in time during the first 3 months of follow-up, known as the active uptitration phase. Moreover, every 2 weeks, the algorithm alternately generated a medication uptitration proposal for either the β -blocker or ACE-I.

Figure 1. Overview of the CardioCoach follow-up tool.

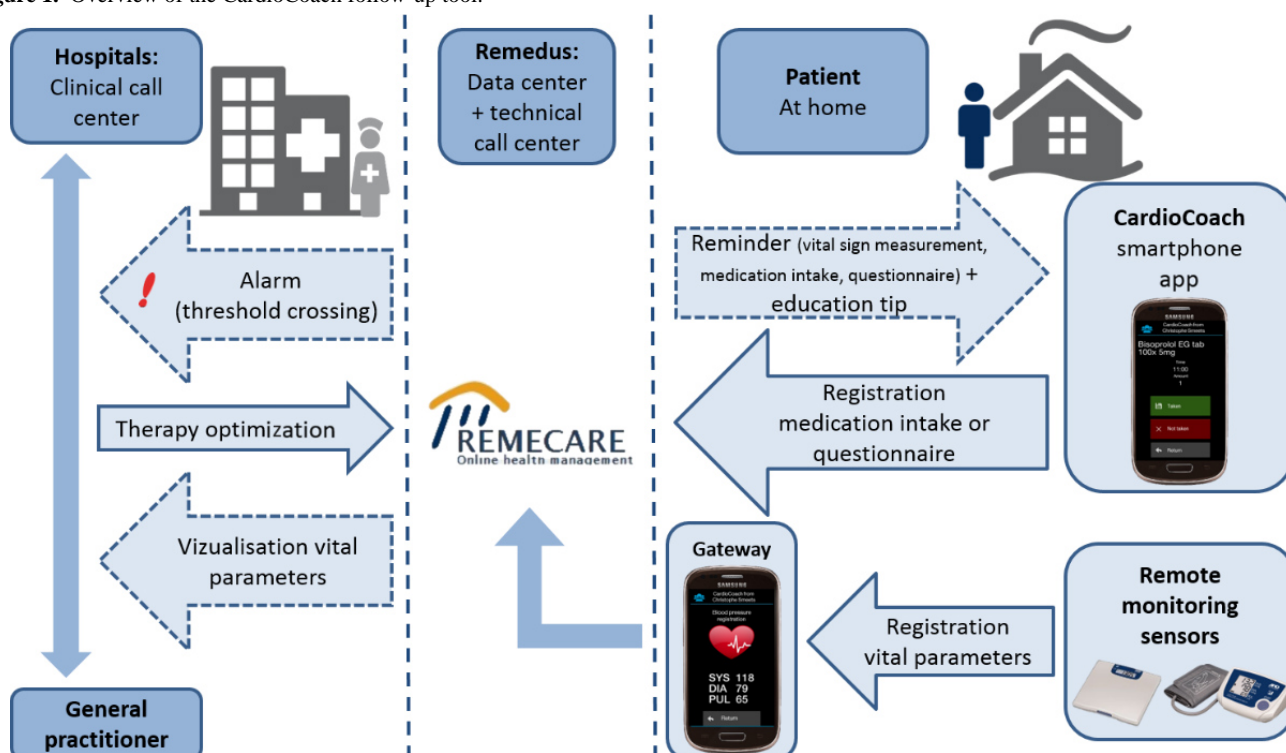


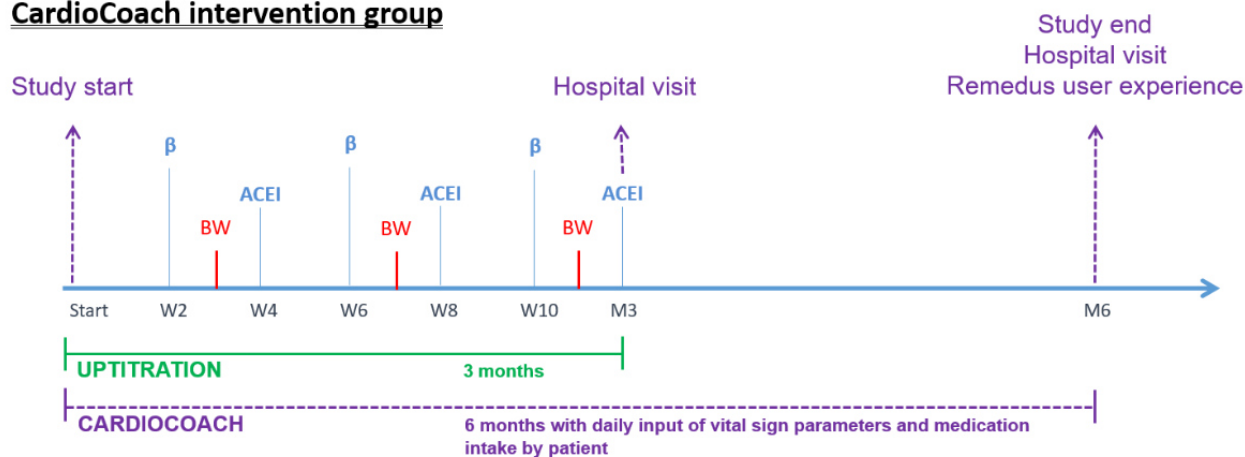
Table 1. Vital sign thresholds.

Parameter	Thresholds for 3 consecutive days
Weight	Baseline weight + 2 kg
Heart rate	<60 bpm ^a or >100 bpm
Systolic blood pressure	<90 mm Hg or >160 mm Hg
Diastolic blood pressure	<60 mm Hg or >95 mm Hg

^abpm: beats per minute.

Figure 2. Overview of the study protocol for both the CardioCoach intervention group and usual care control group. ACE-I: angiotensin-converting enzyme inhibitors; BW: blood withdrawal.

CardioCoach intervention group



Usual care control group



At the beginning of week 2, the first proposal was generated, which comprised β -blocker uptitration, followed by another proposal for ACE-I uptitration at week 4. In total, there were 6 uptitration proposals during the first 3 months. Before each proposal, the short version of the custom-made HF questionnaire (Multimedia Appendix 2) was pushed to the patient's smartphone to enquire about his/her general health and expose possible medication-induced side effects, which would help in deciding the safety of medication uptitration to the next level. A week before the ACE-I uptitration proposal, the algorithm generated a blood withdrawal request for analysis on kidney function (Figure 2). The type of proposal, generated by the algorithm, was generated based on predefined decision trees, taking into account all gathered patient information (vital signs, blood parameters, and questionnaires), which could include the following: (1) medication uptitration to the next level, (2) no uptitration or (3) medication uptitration to the next level only possible after evaluation by the HF nurse due to incomplete data, aberrant vital sign data, or aberrant blood parameters.

Before implementation of the updated medication scheme on the patient's smartphone app, every proposal of the algorithm was reviewed by a dedicated HF nurse. The nurse could either choose to confirm the proposal, to call the patient before taking a decision, to make other changes to the patient's medication scheme or to leave it unchanged, or indicate that the optimal medication dose had been reached. During the last 3 months of follow-up (ie, from 3 to 6 months), the active uptitration algorithm was deactivated and was followed by a less intensive follow-up phase during which medication intake and vital sign parameters were still monitored and medication uptitration on the discretion of the HF nurse could still proceed.

Finally, at 6 months of follow-up, patients from the CardioCoach intervention group were provided with a CardioCoach user experience questionnaire to gain feedback on the use of the CardioCoach smartphone app, the remote monitoring sensors, the contact with HF nurses and technical follow-up team.

Table 2. Maximum daily dose as recommended by European guidelines.

Active ingredient	Max daily dose (mg)
ACE-I^a	
Perindopril	10
Enalapril	10
Ramipril	10
Lisinopril	20
Candesartan	16
Losartan	100
β-blocker	
Bisoprolol	10
Nebivolol	5

^aACE-I: angiotensin-converting enzyme inhibitors.

Outcome Measurements

Outcome measures included CardioCoach user experience, (therapeutic) adherence, call center statistics, algorithm performance, and the number of patients on guideline-recommended medication dose for β-blocker and ACE-I (Table 2) at both 3 and 6 months of follow-up.

Statistical Analysis

Demographic and functional characteristics were compared using descriptive statistics. Continuous variables were expressed as mean ± standard deviation if normally distributed, or otherwise as median (interquartile range, IQR). To define statistical differences between both groups, the independent samples student *t* test and Mann-Whitney *U* test were used for normally and not normally distributed continuous variables, respectively. The chi-square test and Fisher exact test were used accordingly for categorical variables. To define statistical differences between New York Heart Association class, the Kruskal-Wallis test was used. The significance level for tests was two-sided with an alpha of .05. All statistical analyses were performed using the Statistical Package for Social Sciences version 24.0 (IBM SPSS Inc, Chicago, Illinois, USA).

Results

Study Population

In total, 25 patients were included in the CardioCoach study. One patient dropped out before 3 months of follow-up and was therefore excluded from analysis. After 3 months of follow-up, 2 more patients dropped out but were still included in the analysis until 3 months of follow-up, because they completed the active medication uptitration phase. The final study population consisted of 24 patients: 14 patients were included in the CardioCoach intervention group and 10 patients were included in the usual care control group. Baseline characteristics of the study population at the time of inclusion are provided in Table 3. At the time of study enrollment, no significant

between-group differences were observed in clinical characteristics or the use of medications commonly prescribed to patients with HF.

CardioCoach Medication Uptitration With Clinical Decision Support Algorithm

On the basis of gathered data, the CardioCoach algorithm generated 72 medication uptitration proposals in total. In 7% (5/72) of the cases, the algorithm generated a conclusive proposal, whereas in 93% (67/72) of cases, the decision was left up to the HF nurse. This was mainly due to aberrant (67%, 48/72) or incomplete (25%, 18/72) data. Table 4 summarizes the frequency of the different algorithm uptitration proposals.

After each automatic uptitration proposal from the algorithm, the HF nurses in the clinical call center received a notification, which they had to consider. Nurses could respond in different ways to the uptitration proposal (Table 5). The algorithm proposal was confirmed by the HF nurse in 69% (50/72) of cases, and in 35% (25/72) of cases the patient was contacted for further interrogation before decision. No adverse events or false positive uptitration proposals were reported.

Therapeutic Adherence

Overall, therapeutic adherence as confirmed by the patient via the smartphone app (8315/10,825, 76.81%) or via the technical call center after contacting the patient (1703/10,825, 15.73%) for the 3 drug treatments was 92.55% (10,018/10,825), with, respectively, 97.12% (3239/3335) for β-blockers, 94.89% (3549/3740) for ACE-I, and 86.13% (3230/3750) for diuretics. In 1 out of 5 cases, patients did not record medication intake into the CardioCoach smartphone app, and the technical call center had to contact the patients to verify medication intake (Table 6). In terms of vital sign registration, patient adherence was 94.66% (4504/4758). In 12.65% (602/4758) of these cases, technical issues hindered automatic transfer of vital sign data to the online database, and the technical call center had to contact the patient to receive the data, and in 5.34% (254/4758) no vital sign measurement was recorded (Table 6).

Table 3. Baseline characteristics of the study population at the moment of study inclusion (N=24). Continuous data are expressed as mean (SD) if normally distributed, and dichotomous data are expressed as n (%).

Variables	CardioCoach intervention group (n=14)	Usual care control group (n=10)	P value
Male gender, n (%)	9 (64)	6 (60)	>.99
Age, years, mean (SD)	63 (15)	60 (15)	.55
Body mass index, mean (SD)	28 (5)	28 (5)	.88
Heart rate, mean (SD)	73 (13)	73 (13)	.99
Systolic blood pressure, mean (SD)	112 (14)	127 (25)	.08
Diastolic blood pressure, mean (SD)	75 (12)	75 (12)	.98
New York Heart Association functional class (II/III), n (%)	6 (43)/6 (43)	4 (40)/5 (50)	.92
Left ventricular ejection fraction percentage, mean (SD)	28 (7)	29 (7)	.84
QRS width, ms, mean (IQR ^a)	100 (90-121)	100 (92-121)	.89
Ischemic cardiomyopathy, n (%)	4 (29)	1 (10)	.36
Dilated cardiomyopathy, n (%)	5 (36)	5 (50)	.68
Risk factors and comorbidities, n (%)			
Obesity	9 (64)	3 (30)	.10
Arterial hypertension	9 (64)	3 (30)	.10
Smoking	9 (64)	9 (90)	.34
Family history of cardiovascular diseases	7 (50)	4 (40)	.70
Hypercholesterolemia	9 (64)	5 (50)	.68
Chronic kidney disease	2 (14)	0 (0)	.49
Atrial fibrillation	6 (43)	4 (40)	>.99
Diabetes	3 (21)	1 (10)	.62
Chronic obstructive pulmonary disease	1 (7)	1 (10)	>.99
Pro-Brain Natriuretic Peptide, mean (IQR)	559 (118-1278)	262 (129-467)	.44
Estimated glomerular filtration rate, mean (SD)	50 (28)	65 (19)	.16
Medication use, n (%)			
Angiotensin converting enzyme inhibitor	7 (50)	3 (30)	.42
β-blocker	7 (50)	3 (30)	.42
Spironolactone	1 (7)	1 (10)	>.99
Loop diuretic	1 (7)	2 (20)	.39
Statin	7 (50)	3 (30)	.42
Calcium channel blockers	0 (0)	1 (10)	.42
Antidiabetic medication	1 (7)	1 (10)	>.99
Technological experience, n (%)			
Normal cell phone	8 (57)	6 (60)	>.99
Smartphone	3 (21)	3 (30)	.67
Computer at home	7 (50)	4 (40)	.70
Internet connection at home	2 (14)	3 (30)	.62
Tablet at home	7 (50)	4 (40)	.70

^aIQR: interquartile range.

Table 4. Overview of the different algorithm uptitration proposals and their frequency.

Type of uptitration proposal	Full sample (N=72), n (%)	β -blocker group (n=41), n (%)	ACE-I ^a group (n=31), n (%)
Uptitration to next level	1 (1)	1 (2)	0 (0)
No uptitration to next level	4 (6)	3 (7)	1 (3)
Uptitration dependent on evaluation by heart failure nurse, due to incomplete data	18 (25)	11 (27)	7 (23)
Uptitration dependent on evaluation by heart failure nurse, due to aberrant data	48 (67)	26 (63)	22 (71)
Uptitration dependent on evaluation by heart failure nurse, due aberrant blood parameters	1 (1)	0 (0)	1 (3)

^aACE-I: angiotensin-converting enzyme inhibitors.

Table 5. Overview of the different responses of the heart failure nurses to the algorithm uptitration proposals.

Response of nurses to uptitration proposal	Full sample (N=72), n (%)	β -blocker group (n=41), n (%)	ACE-I ^a group (n=31), n (%)
Confirm algorithm proposal	50 (69)	29 (71)	21 (68)
Patient was contacted before decision was made	25 (35)	17 (41)	8 (26)
Change of other medication	10 (14)	8 (20)	2 (6)
Optimal medication dose reached	25 (36)	13 (32)	12 (39)

^aACE-I: angiotensin-converting enzyme inhibitors.

Table 6. Therapeutic adherence for medication intake and vital sign measurement recording.

Therapeutic adherence	n (%)
Medication intake (N=10,825)	
Confirm via smartphone	8315 (76.81)
Confirmed via Remedus	1703 (15.73)
Declined via smartphone	351 (3.24)
Declined via Remedus	456 (4.21)
Vital sign measurement (N=4758)	
Confirm via smartphone	3902 (82.00)
Confirmed via Remedus	602 (12.65)
No recording	254 (5.34)

Technical Call Center Statistics

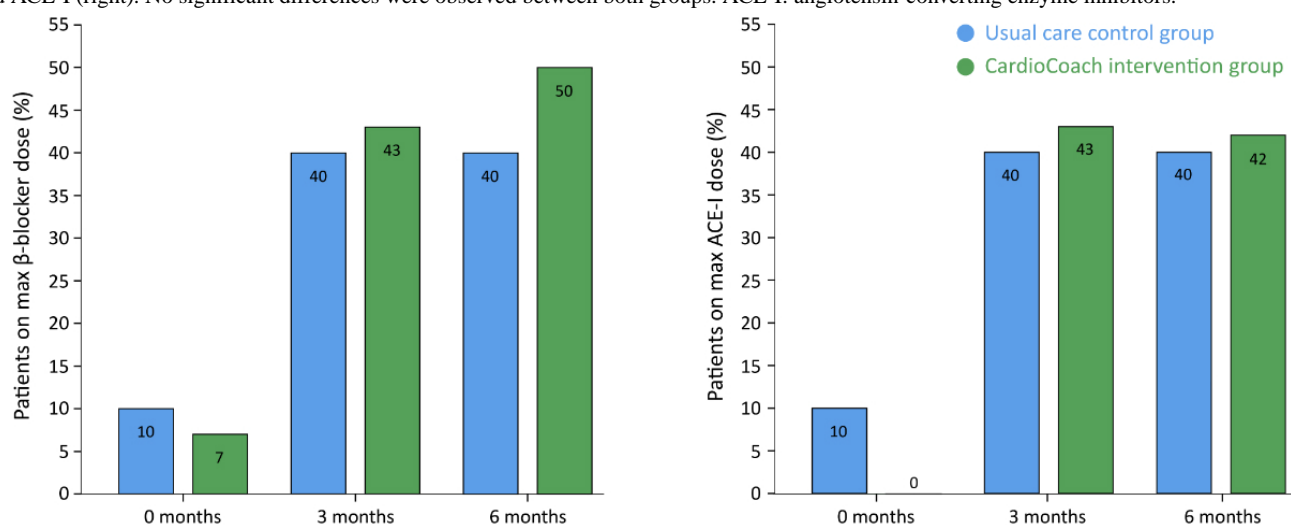
For the 14 CardioCoach patients, the Remedus call center made 831 phone calls in total, with a median of 41 phone calls per patient (IQR 32-65). Phone calls were initiated in case of missed vital sign measurements (n=136), missed medication intake (n=661; diuretic intake 44.0% [291/661], ACE-I intake 34.9% [231/661], and β -blocker intake 21.0% [139/661]), or missing questionnaires (n=34). Due to the limited technical skills of the study participants, technical problems could hardly be solved remotely, and therefore, a device swap was performed in 10 patients: 4 patients had 1 device swap, 5 patients had 2 device swaps, and 1 patient had 3 device swaps.

CardioCoach User Experience

Among the CardioCoach user experience questionnaire, 4 questionnaires were missing: 3 due to early study termination

and 1 due to an issue with the Web-based questionnaire platform. Detailed results of these questionnaires can be found in [Multimedia Appendices 3-5](#). In general, patients were very satisfied, and mentioned the ease of use of the smartphone app and remote monitoring sensors. Daily coaching tips were reviewed as being positive and stimulating. In addition, patients experienced an extra sense of safety, and 50% of patients were eager to continue using the CardioCoach follow-up tool after the study ended. Due to the CardioCoach app, 80% of patients reported an increased medication adherence. Patients reported a positive experience in terms of communication with both the technical and clinical call centers. Interestingly, patients were indifferent about the fact that their parameters were being reviewed by an external, home nursing company. Finally, patients did mention a large number of technical issues (eg, connectivity issues, problems with the remote monitoring sensors).

Figure 3. The number of patients on maximum daily dose as recommended by European Society of Cardiology guidelines for both β -blockers (left) and ACE-I (right). No significant differences were observed between both groups. ACE-I: angiotensin-converting enzyme inhibitors.



Medication Uptitration

No significant differences were observed in the number of patients on guideline-recommended maximum β -blocker dose in the CardioCoach intervention group when compared with the usual care control group at both 3 months (43% vs 40%, $P > .99$) and 6 months (50% vs 40%, $P = .69$) of follow-up (Figure 3).

Additionally, in terms of ACE-I uptitration, no significant differences were observed at both 3 months (43% vs 40%, $P > .99$) and 6 months (42% vs 40%, $P > .99$) of follow-up (Figure 3). In addition, there was no difference in terms of time taken to uptitrate to guideline-recommended medication dose. All patients who reached the guideline-recommended dose did so before 3 months of follow-up (except 1 case for β -blockers).

Discussion

Principal Findings

Since 1997, ESC guidelines for the diagnosis and treatment of acute and chronic HF have recommended the optimization of drug treatment as the first step in patients diagnosed with HF [1,27]. Unfortunately, these guidelines are insufficiently implemented in clinical practice and many HF patients are still on suboptimal medication dose [15,18-20]. This paper describes the rationale and feasibility of a novel two-way communication platform with decision support algorithms, in combination with a smartphone app, blood pressure monitor, and weighing scale, intended to support β -blocker and ACE-I uptitration remotely. The success rate of studies monitoring weight, blood pressure, and heart rate to improve clinical outcome is rather low, probably because they are unable to capture the complexity of HF disease progression, which often involves multiple comorbidities [28-33]. However, the benefits of monitoring weight, blood pressure, and heart rate for medication uptitration have only recently been studied [21,26].

The results of this feasibility study with 24 patients, monitored for a period of 6 months, showed a marginal increase in the number of patients on guideline-recommended β -blocker and

ACE-I dose when using the CardioCoach remote monitoring follow-up tool compared with usual care alone. However, in comparison with previous studies, both our intervention and control group consisted of a higher number of patients, who were on guideline-recommended medication dose. Maggioni et al [18] and Heywood et al [19] reported, respectively, 29% and 35% of patients on target dose for ACE-I and 17% and 15% for β -blockers. This suggests that the usual care provided in our institution is superior to the standard care described in literature, and the addition of the CardioCoach follow-up tool can lead to comparable and even slightly better results. Hence, remote monitoring could be a suitable method for increasing the number of HF patients on guideline recommended target dose, especially in centers with less intensive usual care follow-up.

Feedback received from the patients using the CardioCoach follow-up tool revealed overall good patient satisfaction in terms of both the use of the remote monitoring devices and the contact between the patient and technical and clinical call centers. This resulted in excellent overall therapeutic adherence of the patients during the entire study period for medication intake (92.55%, 10,018/10,825) and vital sign measurements (94.66%, 4504/4758). In spite of the frequent reminders via the smartphone, the CardioCoach follow-up tool was well accepted by the patients as compared with remote monitoring strategies used in previous studies [34,35]. Unfortunately, patients did mention many technical issues, which are deduced from the large number of phone calls between the patient and the technical call center of Remedus. In 1 out of 5 cases, patients were contacted by the technical call center to verify medication intake. In most of these cases, the patients confirmed medication intake, but due to the technical issues, this information was not transmitted to the Remecare platform. Only 7.45% (807/10,825) of cases reported that the patient had not taken his/her medication. This was rarely due to the forgetfulness of the patient, but mostly because of a change in patient's medication scheme outside the CardioCoach environment (eg, by a general practitioner). In terms of vital sign measurements, 12.65% (602/4758) of the measurements were collected over the phone by the technical call center as technical issues hindered automatic transfer of vital sign data to the Remecare Platform.

These technical issues also included issues that arose because of the technophobe elderly study population (eg, problems changing/charging device batteries, reboot smartphone). In 5.34% (254/4758) of cases, defective remote monitoring sensors made it impossible to record a vital sign measurement. The high number of technical issues clearly demonstrates the need for a separate technical call center to handle these issues, avoid extra work burden for the clinical call center, and ensure complete data for clinical decision making. Although the next generation of seniors will probably be more familiar with technical developments, technical improvements are still necessary to further decrease these issues.

In this study, the algorithm was built with a large safety margin to avoid false positive up-titration proposals, which has led to a low number of conclusive proposal by the algorithm (7%, 5/72). In addition, every proposal had to be validated by a dedicated HF nurse. In 69% (50/72) of the cases, the HF nurse confirmed the algorithm proposal. This shows that parameter thresholds can be confined. In this sense, the current feasibility study was very useful for the future development and improvement of an optimal two-way communication system between patients and caregivers. On the basis of feedback from both patients and HF nurses, improvements can be made to the next generation, which will take into account the work efficiency of the HF nurses and enable a customized approach for patients (eg, patient-specific or less confined parameter thresholds, patient-specific up-titration scheme). The CardioCoach follow-up tool is very efficient in facilitating information exchange between the different care providers (ie, HF specialist, HF nurse, general practitioner, home nurse) and enables a safe way for medication up-titration, as there were no adverse events or false positive up-titration proposals reported. The use of the CardioCoach follow-up tool has been shown to be feasible when combined with a technical call center to handle technical issues and reduce the workload of the clinical call center. This study was unable to demonstrate a significant improvement of the CardioCoach follow-up tool on the number of patients on maximum guideline-recommended β -blocker and ACE-I dose. Probably, this is related to the fact that patients in the control group were also enrolled in a dedicated HF outpatient disease management program, where HF medication dosages were being optimized by intensive follow-up by specialized HF nurses and HF specialists. Hence, the CardioCoach follow-up tool might be more suitable in centers with less intensive HF disease management programs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

<http://cardio.jmir.org/2018/1/e8/>

Study Limitations

This feasibility study should be interpreted in the light of some limitations to place the study findings into a correct context. First, the small sample size and the single-center character may impact its external validity. Therefore, these results should be interpreted as hypothesis generating, and an additional multi-center study is necessary to confirm these results. In this study, the control group received the usual care as per standard practice organized in the institution and received no remote monitoring sensors. This is a general issue in multiple remote monitoring studies, which should be taken into account when interpreting study findings as relevant information from the control group may be missing. An alternative control group could be a group in the same setting (ie, with remote monitoring sensors), but without a physician reviewing the data. Next, technical improvements (eg, Bluetooth connectivity, battery autonomy) are necessary to improve the efficiency of the CardioCoach follow-up tool. Finally, the patient population used to conduct the feasibility study was recruited in a tertiary care center with a specialized HF clinic. Due to the high quality of the usual care provided (reflected by the high number of patients on maximum guideline-recommended medication dose in the usual care group compared with literature) with intensive outpatient follow-up, the institution under study may not have been the optimal choice to demonstrate a potential benefit of the CardioCoach follow-up tool on medication up-titration.

Conclusions

This study shows the feasibility and safety of a novel two-way communication platform with decision support algorithms in combination with remote monitoring sensors in implementing guideline recommendations concerning β -blocker and ACE-I up-titration. In addition, the CardioCoach follow-up tool was found to be efficient in facilitating information exchange and improving coordination among different care providers. Patients' satisfaction was reported to be high, which has led to excellent adherence rates during a relative long follow-up period of 6 months. Many technical issues arose, clearly indicating the need for a technical call center. A larger multicenter randomized controlled trial needs to be conducted in centers with minimal usual care follow-up to assess the potential benefits of guideline-recommended medication dose.

Screenshots from the CardioCoach smartphone app with from top to bottom registration of medication intake, weight, blood pressure, and heart failure questionnaire.

[[PNG File, 4MB - cardio_v2i1e8_app1.png](#)]

Multimedia Appendix 2

Custom-made heart failure questionnaire pushed to the patient before an uptitration proposal or in case of aberrant vital sign data.

[[JPG File, 99KB - cardio_v2i1e8_app2.jpg](#)]

Multimedia Appendix 3

Detailed results of the CardioCoach user experience questionnaire (Part 1).

[[PNG File, 85KB - cardio_v2i1e8_app3.png](#)]

Multimedia Appendix 4

Detailed results of the CardioCoach user experience questionnaire (Part 2).

[[PNG File, 84KB - cardio_v2i1e8_app4.png](#)]

Multimedia Appendix 5

Detailed results of the CardioCoach user experience questionnaire (Part 3).

[[PNG File, 103KB - cardio_v2i1e8_app5.png](#)]

Multimedia Appendix 6

CONSORT - EHEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 678KB - cardio_v2i1e8_app6.pdf](#)]

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Abbreviations

ACE-I: angiotensin-converting enzyme inhibitors

ESC: European Society of Cardiology

HF: heart failure

IQR: interquartile range

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Review

Mobile Phone Apps to Support Heart Failure Self-Care Management: Integrative Review

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Abstract

Background: With an explosive growth in mobile health, an estimated 500 million patients are potentially using mHealth apps for supporting health and self-care of chronic diseases. Therefore, this review focused on mHealth apps for use among patients with heart failure.

Objective: The aim of this integrative review was to identify and assess the functionalities of mHealth apps that provided usability and efficacy data and apps that are commercially available without supporting data, all of which are to support heart failure self-care management and thus impact heart failure outcomes.

Methods: A search of published, peer-reviewed literature was conducted for studies of technology-based interventions that used mHealth apps specific for heart failure. The initial database search yielded 8597 citations. After filters for English language and heart failure, the final 487 abstracts was reviewed. After removing duplicates, a total of 18 articles that tested usability and efficacy of mobile apps for heart failure self-management were included for review. Google Play and Apple App Store were searched with specified criteria to identify mHealth apps for heart failure. A total of 26 commercially available apps specific for heart failure were identified and rated using the validated Mobile Application Rating Scale.

Results: The review included studies with low-quality design and sample sizes ranging from 7 to 165 with a total sample size of 847 participants from all 18 studies. Nine studies assessed usability of the newly developed mobile health system. Six of the studies included are randomized controlled trials, and 4 studies are pilot randomized controlled trials with sample sizes of fewer than 40. There were inconsistencies in the self-care components tested, increasing bias. Thus, risk of bias was assessed using the Cochrane Collaboration's tool for risk of selection, performance, detection, attrition, and reporting biases. Most studies included in this review are underpowered and had high risk of bias across all categories. Three studies failed to provide enough information to allow for a complete assessment of bias, and thus had unknown or unclear risk of bias. This review on the commercially available apps demonstrated many incomplete apps, many apps with bugs, and several apps with low quality.

Conclusions: The heterogeneity of study design, sample size, intervention components, and outcomes measured precluded the performance of a systematic review or meta-analysis, thus introducing bias of this review. Although the heart failure-related outcomes reported in this review vary, they demonstrated trends toward making an impact and offer a potentially cost-effective solution with 24/7 access to symptom monitoring as a point of care solution, promoting patient engagement in their own home care.

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KEYWORDS

heart failure; self-care management; mobile health

Introduction

Background

Heart failure (HF) affects 6.5 million Americans and over 26 million people globally, which causes significant symptom burden and human suffering with considerable economic burden due to hospital readmissions [1,2]. The prevalence of HF is expected to increase 46% by 2030 [2]. A recent scientific statement from the American Heart Association indicates that self-care research and clinical efforts have been hindered by the perceptions of both patients and providers that pharmacological interventions are more effective than lifestyle change, thus warranting researchers to focus on self-management and lifestyle interventions for HF [3]. HF self-care requires patients to perform daily self-monitoring for changes in weight and symptoms, practice decision making for symptom changes, and adhere to prescribed medication, diet, physical activity, and follow-up care [4]. Living with HF imposes significant stressors for patients in following daily self-care tasks and lifestyle changes to maintain functional independence and quality of life [5]. Clinical outcomes in HF depend largely on how well a patient carries out self-care practices at home and seeks early care for symptoms. A metasynthesis of 47 studies recommends that self-care approaches must reflect both perception- and action-based strategies to effectively manage HF [5]. In order for self-care of any chronic condition such as HF to be sustained, self-management techniques need to be integrated into one's lifestyle.

Given the complexity of HF self-care, assisting patients to manage their own care at home is a key component of HF management. Mobile health (mHealth) technology is defined as the "use of smartphones, tablets and other mobile devices to deliver health care and preventive health services" [6]. Given the explosive growth in mHealth for consumers, the World Health Organization predicted that over 500 million patients will be using mHealth apps by the end of this decade [6]. Personal mobile devices are portable and stay with the owner throughout the day. Thus, the mHealth market has taken root and seen exponential growth recently. Big technology companies such as Google, Apple, Microsoft, and IBM are partnering with health care organizations such as the American Diabetes Association and pharmaceutical companies in designing mHealth apps and systems to improve health care for people with chronic diseases [7]. Currently, mobile phones contain sensors such as accelerometers and cameras that have been leveraged in health care for health education, health management, and medical imaging such as electrocardiogram [8], as well as monitoring of pulmonary congestion in HF patients [9]. Among a sample of HF patients, 96% owned a mobile phone and 32% relied on the mobile phone for Internet access, searched health information, and reported moderate self-confidence in using mobile apps [10].

Emerging evidence suggests that mobile technology can serve as a form of support for patients with HF and may enhance patient-provider collaboration for self-management [11].

An integrative review of 11 studies provided an insight into user perception and experience with mobile apps: regardless of

the user's age and experience, mHealth tracking apps offered a sense of empowerment and control of chronic health conditions [12]. According to the Pew Research Center, 40% of American adults use mobile phones, which has more than doubled since 2013 [7]. Given the growing trend in the use of mHealth technology and mobile phone apps, this review is timely to discuss available evidence on the use of mHealth in HF self-care.

Rationale for This Review

About 95% of Americans own a mobile phone of some kind and 40% of American adults are "mobile phone-only" Internet users [7]. Over 50% of mobile phone users are projected to have downloaded at least 1 health app to their phone in 2017 [7]. Currently, more than 150,000 apps are available, of which about 40,000 are mHealth apps for self-care management of chronic diseases commercially available on the market for management of asthma [13], diabetes [14], depression [15], smoking cessation [16], and weight management [17]. Over 700 apps are specifically available for patients with cardiovascular disease, many including blood pressure and heart rate tracking [18]. According to a review, 34 apps are commercially available for use by HF patients that have no established usability or efficacy data [19]. Other systematic reviews provided evidence on the use of telephone-based technology or structured telephone support [20] and remote telemonitoring [21-24]. Given the emerging evidence on the usability and efficacy of mHealth and the use of mobile phone apps, another review is deemed necessary to describe the current body of literature on mHealth apps for self-care management in HF. A prior review of HF apps included commercially available mobile apps [19], and a different review missed several newer mobile apps and systems [24]. Therefore, this review focused on mHealth apps and systems that included usability or potential efficacy tested on patients with HF and differentiated the commercially available mobile apps in the market.

Aim of This Review

Mobile health is defined in detail by the World Health Organization as "the use and capitalization on a mobile phone's core utility of voice and short messaging service as well as more complex functionalities and applications including general packet radio service, third and fourth generation mobile telecommunications (3G and 4G systems), Global Positioning System, and Bluetooth technology" [6]. Health apps are defined as any commercially available health or fitness apps with capacity for self-monitoring and improving patient compliance with treatment recommendations [6].

There has been explosive growth in mHealth apps with an estimated 500 million patients potentially using mHealth apps for supporting health and self-care of chronic diseases. However, commercially available apps are often not tested for usability and efficacy. The purpose of this review was to identify and assess the functionalities of mHealth apps that have usability and efficacy data and are available commercially on the market. All of the mHealth apps reviewed support HF self-care to improve treatment compliance, thus impacting HF outcomes.

The most effective self-management strategies include complex medication regimen, diet, and exercise recommendations and

modification of behavior according to HF symptoms [25]. Protocol-driven disease management along with education, self-monitoring of HF symptoms, a flexible diuretic regimen, early care-seeking, prompt health care responses, psychosocial interventions, and professional coordination are successful strategies for self-management [25]. Less than half a percentage change on behavioral outcomes results from each self-care component, thus prompting recommendation of interventions with multiple self-care components for a cumulative effect on behavioral outcomes [26]. Also, novel mHealth technologies are recommended to serve as conduits for self-management in HF [27]. Therefore, given the complexity of HF self-management, multiple self-care components specific for patients with HF are recommended to achieve desired health outcomes [28]. A meta-analysis of 66 clinical trials from 18 countries recommended multiple strategies to reduce HF readmissions [29].

Methods

Objective

This review has 2 parts and is part of an overarching project on the development of a comprehensive mHealth app for HF self-management. The first part identifies mHealth apps that have been tested for usability and potential efficacy of mHealth apps for HF patients. The second part explored commercially available apps for HF that lacked usability and efficacy data, and apps were rated using the Mobile Application Rating Scale (MARS) [30].

Selection Criteria

For the first part of the review, studies were included if they met the following criteria: (1) used a randomized controlled trial or quasi-experimental design or a pre-post-test design, (2) provided usability or potential efficacy data, (3) tested interventions using a mobile platform (by itself or as part of a mobile system), (4) included HF patients aged 18 years and older, and (5) were published in English. Excluded for part 1 were (1) studies that tested traditional remote telemonitoring interventions, transitional care, and structured telephone support in HF; (2) studies that tested mHealth apps on chronic conditions other than HF; (3) articles not in English; (4) studies that tested games; (5) studies that tested mHealth on other cardiac conditions such as cardiac rehabilitation and atrial fibrillation; (6) studies that included only clinical measures such as electrocardiogram on mobile phones with no self-care measures; and (7) protocols and nonresearch articles. For part 2 of the review, commercially available apps for HF from Google Play and Apple App Store were included.

Literature Search

A search of published, peer-reviewed literature was conducted for articles published from April 2008 to August 2017 that studied mobile technology-based interventions that used mobile apps specifically for HF. The researchers used key search terms

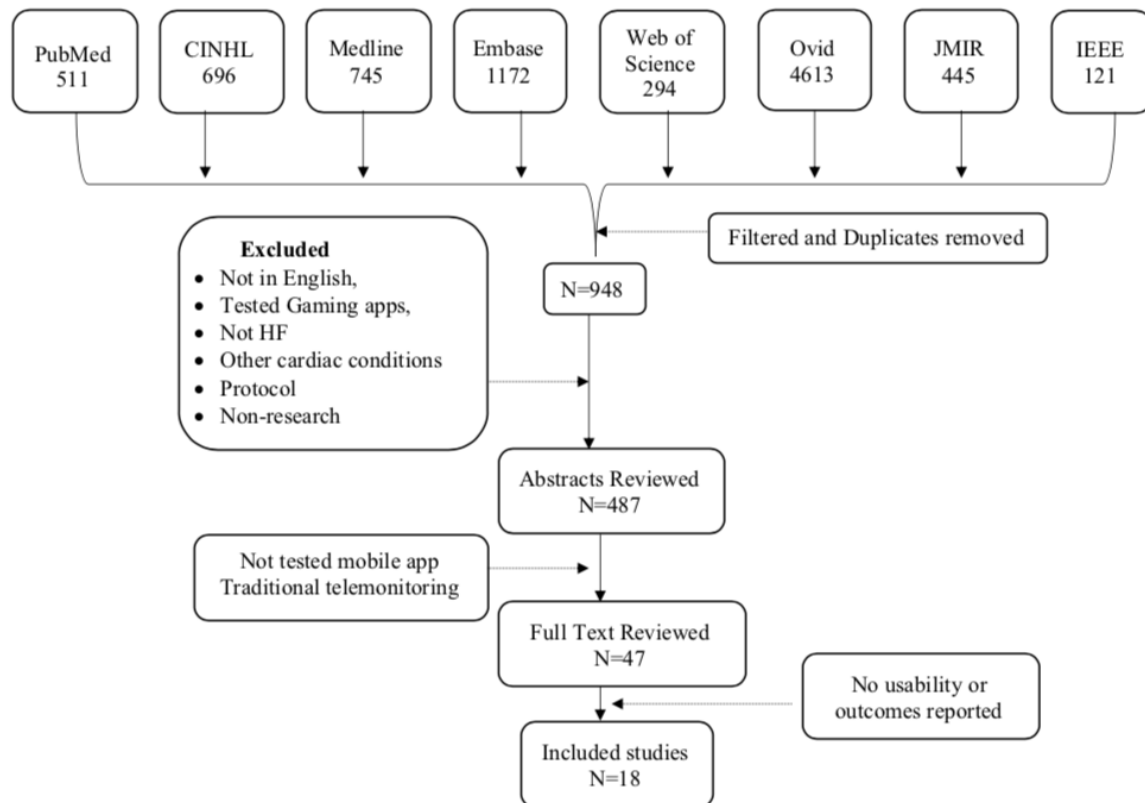
to identify potential articles and systematic reviews and meta-analyses. Medline, PubMed, Cumulative Index to Nursing and Allied Health Literature, Embase, Web of Science, PsycINFO, Computer Source, Computers and Applied Sciences Complete, Journal of Medical Internet Research (JMIR), and Institute of Electrical and Electronics Engineers journal and conference proceedings were searched, and personal communications were included. Only articles published after 2008 were considered because that was the year the first app-ready mobile phone entered the market. For the second part of the review, Google Play and Apple App Store were searched for commercially available mHealth apps on the market for HF.

Keywords used: smartphone OR mobile phone OR mobile device OR tablet OR iPhone OR mobile technology OR iPad OR mHealth OR Android OR Windows; AND app OR apps OR mobile app OR application; AND heart disease OR heart failure; AND behavior OR behavior OR intervention OR controlled trial OR RCT.

Search Result

The initial database search yielded 8597 citations from the 10 databases. After the predefined filters of language and HF were applied, 948 citations remained. A total of 487 abstracts remained after duplicates were removed. Each of the 487 abstracts was reviewed for articles that met the predetermined inclusion criteria. After articles that used traditional telemonitoring, remote telemonitoring, and other self-care interventions such as transitional care were excluded, 47 potential articles remained. Full-text evaluations of the 47 articles were conducted. Authors were contacted to obtain full-text articles if those were not available in PubMed or JMIR. Articles that did not test outcomes such as usability or potential efficacy and protocols were excluded. Finally, a total of 18 articles that tested mobile app or tablet-based mobile interventions in HF were included in this review (Figure 1). These mobile apps or systems are not available on the market.

For the second part, Google Play and Apple App Store were searched for health care apps with key words “heart failure,” “cardiac failure,” and “congestive heart failure.” The original search yielded over 4000 apps, which included apps for heart diseases. We excluded apps that were common for cardiovascular diseases, apps that track only blood pressure and heart rate, and apps that track general medications management or physical activity by syncing wearable such as the FitBit. After the exclusion criteria were applied, 56 mHealth apps from Google Play and Apple App Store were downloaded and examined to determine if they supported self-management in HF. Apps that included self-care components for general cardiovascular conditions such as hypertension or atrial fibrillation, tracked blood pressure, heart rate, or electrocardiogram for atrial fibrillation, or assessed heart rhythm were excluded. Finally, 26 apps that met the criteria for HF self-care were reviewed.

Figure 1. Flowchart on literature review and retrieval process.

Results

Summary

In general, results indicated that mHealth apps for self-care in HF developed and tested recently are novel, and most are still testing usability in small numbers of HF participants. However, sample sizes from the 18 studies ranged from 7 to 165 with a total sample size of 847 participants from all 18 studies. The review was separated into apps that included efficacy outcomes data (Table 1) and apps that only included usability outcomes (Table 2).

All of the studies included in this first part of the review had usability or outcome assessment completed. Nine studies assessed usability of the newly developed mobile system, of which 7 included only usability data. Details of the studies included are depicted in Tables 1 and 2. Seven of the included studies were randomized controlled trials (RCTs), and 4 studies were pilot RCTs with sample sizes of less than 20 [30-33]. There were inconsistencies in the HF self-care components tested and included in the mobile app system, increasing bias, which is depicted in Multimedia Appendix 1. Risk of bias was assessed using the Cochrane Collaboration's tool in all studies included. A few studies failed to provide enough information to allow for a complete assessment of bias (see Table 3).

After we applied the predetermined exclusion criteria, 56 mHealth apps from Google Play and Apple App Store were

downloaded and examined for supporting self-management in HF. A total of 26 apps that met the criteria were rated using MARS [30] (see Table 4). MARS includes 19 items with 4 subscales that include engagement, functionality, aesthetics, and information quality [30]. The MARS items are scored using a 5-point Likert scale (1=inadequate, 2=poor, 3=acceptable, 4=good, and 5=excellent). MARS demonstrated excellent internal consistency ($\alpha=.90$) and interrater reliability intraclass correlation coefficient ($ICC=.79$). MARS has been used by authors in evaluating commercially available mobile apps [19].

Current Mobile Phone Interventions in Heart Failure

Ten of the 18 studies included in this review had small sample sizes of 40 or fewer participants (8 studies assessed usability of the mobile system for refinement or further development of an algorithm [31-40]), 4 studies had sample sizes of 41 to 99 [41-44], and 4 studies had 100 or more participants (but fewer than 200) [45-48]. Four of the 18 studies reviewed were pilot RCTs [32,34,42,44], and only 2 RCTs had 100 or more participants [47,48]. Total sample from all 18 studies was 847 participants. All 18 studies used mHealth technology via mobile phones or tablets as the medium for self-care intervention. A total of 11 studies reported outcome data (Table 1), 7 studies reported only usability of the mobile technology (Table 2), and 1 study developed an algorithm to differentiate HF but did not provide usability or efficacy data [40].

Table 1. Mobile health apps or systems that tested usability and/or potential efficacy on patients with heart failure.

Author	Study type	Intervention components	Outcomes measured	Results
Athilingam [32]	Pilot study (n=18) compared mobile app (HeartMapp) with HF education-only app, follow-up in 30 days	Symptom assessment, weight, blood pressure, medication management, alert and cues for action, mood and cognition assessment, deep breathing exercise for improved psychological health, track physical activity, support and communication with self-identified circle, track performance statistics	SCHF ^a , KCCQ ^b , MMAQ ^c , AHFKT ^d , PHQ-9 ^e , SE ^f , SUS ^g	Trends of improved self-management, knowledge, and QoL ^h . Usability established. Partial eta squared indicated small-to-moderate effect sizes (self-care 0.249, HF ⁱ knowledge 0.337, QoL 0.156). Completion rate was 80%.
Austin [41]	Pre-post evaluation (n=60)	Daily interactive voice messages on educational tips	Readmission	Reduced readmission rate by 50% in 30 days; 25% dropout rate.
Dang [42]	RCT ^j (n=61), intervention group (n=42), usual care (n=19)	Mobile system to alert for symptom assessment, weight, and blood pressure; mobile phone-assisted case management program in VA ^k evaluated self-care efficacy, knowledge, behavior, and QoL; follow-up 3 months	EHFScBS ^l , DHFKS ^m , HDS ⁿ , HFSE ^o , MLHFQ ^p , SEMCD ^q , SF-36 ^f	Usability established on minority population, program satisfaction scores (mean 6.84 [SD 0.46]), self-efficacy and QoL improved; 15% never used the app after enrollment.
Hagglund [44]	RCT (n=72), intervention (n=32), control group (n=40)	Weight and symptom assessment and HF education with a new system called home intervention system (HIS ^s , OPTILOGG)	EHFScBS, DHFKS, KCCQ, SF-36	Improved self-management, QoL, and physical function (all $P < .05$). Median adherence was 88%.
Hale [34]	Pilot RCT (n=25), intervention group (n=11), control (n=14)	MedCentry for medication management with alerts and dispensing medication on time. Measured medication adherence objectively on the device and subjectively using questionnaire	MLHFQ, MMAQ, PHQ-8 ^t , readmission, usability of device	High medication adherence rate (95%), decreased hospitalization among intervention group 9% versus 50%, QoL improved ($P = .02$).
Pai [45]	Pre-post evaluation (n=130)	Weight, blood pressure, symptom assessment, alerts, medication management, track physical activity, used video education and clinician connect for care access	Readmission	53% reduction in readmission rate after rolling out the app.
Nundy [35]	Pilot, quasi-experimental (n=15)	Only text messages on HF education	SCHF	Reported improved self-management ($P = .002$).
Piette [46]	Comparative effectiveness (n=165) study	Interactive voice response system with care partners in VA. Tracked weight, symptom assessment, medication management, alerts, and support system with care partners	NSSQ ^u , CES-D ^v	Improved medication adherence ($P = .032$).
Scherr [47]	RCT (n=108, equal 54 in groups)	MOBITEL platform used weight, blood pressure, and mobile phone for notification and access to data	Readmission, usability survey	Intention-to-treat 33% (1 death, 17 hospitalizations) in control group compared with 17% (0 deaths, 11 hospitalizations) in the intervention group; relative risk reduction 50% (95% CI 3%-74%, $P = .06$).
Seto [48]	RCT (n=100) mobile phone app and usual care with 6-month follow-up	Daily weight, symptom assessment, blood pressure, and EKG ^w reading	SCHF, MLHFQ, EKG, readmission	Improved self-care score ($P = .03$) and QoL ($P = .05$) among intervention group.
Suh [37]	Pilot study (n=26) pre-post evaluation	Weight, blood pressure, symptom assessment, reminder, and activity tracking	HFSAS ^x , readmission, observation of usability	Reported improved outcome on weight assessment. Patients reduced 5.6% of weight and blood pressure ($P = .002$).

^aSCHF: Self-Care of Heart Failure Index.

^bKCCQ: Kansas City Cardiomyopathy Questionnaire.

^cMMAQ: Morisky Medication Adherence Questionnaire.

^dAHFKT: Atlanta Heart Failure Knowledge Test.

^ePHQ-9: Patient Health Questionnaire–9 item.

^fSE: Self-Efficacy Scale.

^gSUS: System Usability Scale.

^hQoL: quality of life.

ⁱHF: heart failure.

^jRCT: randomized controlled trial.

^kVA: Veterans Administration.

^lEHFScBS: European Heart Failure Self-Care Behavior Scale.

^mDHFKS: Dutch Heart Failure Knowledge Scale.

ⁿHDS: Health Distress Scale.

^oHFSE: Heart Failure Self-Efficacy scale.

^pMLHFQ: Minnesota Living With Heart Failure Questionnaire.

^qSEMCD: Self-Efficacy for Managing Chronic Disease.

^rSF-36: Short Form–36 item.

^sHIS: home intervention system.

^tPHQ-8: Patient Health Questionnaire–8 item.

^uNSSQ: Norbeck Social Support Questionnaire.

^vCES-D: Center for Epidemiologic Studies–Depression scale.

^wEKG: electrocardiogram.

^xHFSAS: Heart Failure Somatic Awareness Scale.

Despite the varying self-care components implemented, 8 of the 18 studies assessed HF-related readmission reporting a trend or significant reduction in readmission [31,34,37,38,41,45,47,48]. The Health Recovery Solution (HRS) Patient Connect study used a tablet-based mobile system that provided alerts; monitored weight, blood pressure, symptom assessment, and medication management; tracked physical activity; and used video education and clinician connect for care access. Postevaluation after implementing the intervention among 130 HF patients demonstrated a 50% decrease in HF-related readmission [45]. Implementing HF education alone demonstrated a significantly reduced 50% readmission rate in 30 days [49].

A comparative effectiveness study (n=165) in Veterans Administration (VA) patients demonstrated improved medication adherence [46]. Recently, a usability study among minorities in the VA population (n=61) reported moderate program satisfaction scores (mean 6.84 [SD 0.46]) and improved self-efficacy and quality of life [42]. Another comprehensive app established usability and improved self-management and quality of life in a pilot RCT [10,32]. Providing HF education via MP3 player showed reduced readmission rates [41]. Providing only mobile text messages on HF education in a pilot study improved self-management measured by a self-care of HF index questionnaire [35].

Seven of the included studies assessed self-management, of which 3 studies used the Self-Care of Heart Failure Index (SCHFI) [32,35,48], 2 studies used the European Heart Failure Self-Care Behavior Scale (EHFScBS) [42,44], 1 study used the Heart Failure Somatic Awareness Scale (HFSAS) [37], and 1 study used the personalized self-management system created within the mobile app [33]; all 7 of these studies reported improved self-management. Quality of life was measured by most studies, of which 5 used Minnesota Living With Heart Failure Questionnaire (MLHFQ) [31,34,39,42,48], 2 studies used the Kansas City Cardiomyopathy Questionnaire (KCCQ) [32,44], and 2 studies used the Short Form–36 (SF-36) [42,44]. All of the studies reported in general a trend for significant improvement in quality of life. The Norbeck Social Support Questionnaire (NSSQ) was used in 1 study to assess caregiver support [46]. The Dutch Heart Failure Knowledge Scale

(DHFKS) was used to assess HF knowledge in 2 studies [42,44], and another used the Atlanta Heart Failure Knowledge Test (AHFKT) [32]. All 3 studies reported improved knowledge.

Two of the 18 studies measured depression using the Patient Health Questionnaire–9 (PHQ-9) [32,34], and another used the Center for Epidemiologic Studies–Depression (CES-D) scale [46]. Only 1 study used the data to offer deep breathing exercises to offset depression [32]. In addition to measuring self-care and quality of life, 1 study measured HF self-efficacy using the Self-Efficacy for Managing Chronic Disease (SEMCD) and program satisfaction scores and reported a moderate program satisfaction score (6.84 [SD 0.46]) [42]. Another study used the Short Portable Mental Status Questionnaire (SPMSQ) and the Technology Experience Questionnaire (TEQ) and reported overall adherence rates for blood pressure at 75%, weight at 82%, monitoring physical activity at 77%, and the mean usability rating among participants at 80% [43].

Some mHealth apps are in early stages of development in other countries: Canada [48], China [40], England [33], and Sweden [44]. One study measured N-terminal probrain natriuretic peptide (NT-proBNP) and other physiological measures of blood pressure and heart rate to develop a risk prediction model [40]. One study reported having an algorithm for fall detection with no result on fall or fall prevention [37]. In addition to self-care components, 1 study used single-lead electrocardiograms transmitting data to clinicians and reported inconclusive benefits; 14% of the patients randomized into the intervention group never used the system, and only 55% of the patients used the system at least 3 times per week [48].

Attrition or study completion was reported in 8 of the 18 studies, and adherence to mHealth intervention ranged from 50% to 80% [29,31,39-44]. Only the mobile system MedSentry, which not only reminded patients but also distributed medication on time, reported medication adherence, at 95% [34]. One study reported a 50% to 80% attrition rate because they gave every participant a locked phone with the mobile app, and patients reported that they did not like to carry an additional phone and wanted an app in their own phone [33]. Another study reported 80% completing a 30-day follow-up, and this decline in using the app was attributed to the chest-worn Bluetooth device used to track heart rate [32].

Table 2. Mobile health apps or systems that tested only usability on patients with heart failure.

Author	Study type	Interventions included	Outcomes measured	Results
Alnosayan [31]	Usability study (n=8) HF ^a , postdata collection at 6 months	Included symptom assessment, weight and blood pressure tracking, nurses followed patient report and supported patient	MLHFQ ^b , SUS ^c , readmission	User satisfaction was ranked at 73%.
Bartlett [33]	Usability assessed (n=7)	Symptom assessment, weight, and blood pressure, activity level, performance report, HF education. Patients were given a research phone, which they did not like to carry; wanted an app in their own phone	PSM ^d , SUS	Showed evidence of encouraging self-care, knowledge, and physical activity. Blood pressure was measured on 84% of the days, weight on 88%, walking for 51% of the days.
Evans [43]	Pilot usability study (n=41) among patients with HF and without HF using tablet	Weight and blood pressure, survey using tablet, track physical activity with a watch	SPMSQ ^e , SUS, TEQ ^f	Overall adherence for blood pressure 75%, weight 82%, watch monitor 77%. Usability rating was 80%. Adherence was reported 71% to 82%.
Portz [36]	Usability study (n=30), acceptability of the new HF symptom tracker app	Track daily weight and symptom assessment and give feedback as graph	Usability survey only	Usability established, mean score 3.5 (usability score ranged from 1.7 to 4.7). Older age was significantly associated with a self-identified need for help in the use of the HF app ($r=.462$, $P=.01$).
Triantafylidis [38]	Observation study (n=26), SUPPORT-HF ^g (Seamless User-Centered Proactive Provision of Risk-Stratified Treatment for Heart Failure)	Used tablet computers and commercially available sensing devices (blood pressure monitor, set of weighing scales, and pulse oximeter), symptom-specific questionnaires, review their personal readings, view educational material	Readmission, observation for usability	Established usability; 23 patients (88%) used the system at least once and 16 patients (62%) used at least 3 times.
Zan [39]	Pilot feasibility study (n=21), follow-up 3 months	Web- and mobile-based intervention to monitor weight, blood pressure, heart rate, and symptoms	MLHFQ, SUS, satisfaction	Demonstrated feasibility; device under development based on feedback.
Zhang [40]	Pilot evaluation (n=34), 22 HF and 12 non-HF patients as controls and 30-day follow-up	Weight, blood pressure, physical activity, and HF symptom assessment. Offered feedback via text messages or emails from doctors.	HFRS ^h , HFSAS ⁱ , NT-proBNP ^j	SVM ^k -based mobile system that developed algorithm for HF risk prediction and determined prediction accuracy of 79.4%. No efficacy testing was done. The study is of poor quality.

^aHF: heart failure.

^bMLHFQ: Minnesota Living With Heart Failure Questionnaire.

^cSUS: System Usability Scale.

^dPSM: Personalized Self-Management System Score.

^eSPMSQ: Short Portable Mental Status Questionnaire.

^fTEQ: Technology Experience Questionnaire.

^gSUPPORT-HF: Seamless User-Centered Proactive Provision of Risk-Stratified Treatment for Heart Failure.

^hHFRS: Heart Failure Risk Score.

ⁱHFSAS: Heart Failure Somatic Awareness Scale.

^jNT-proBNP: N-terminal probrain natriuretic peptide.

^kSVM: structured support vector machine.

Table 3. Assessment of risk of bias of the selected studies.

Studies	Selection bias	Performance bias	Detection bias	Attrition bias	Reporting bias
Alnosayan [31]	3 ^a	3	2 ^b	2	1 ^c
Athilingam [32]	2	3	2	3	2
Austin [41]	3	3	2	3	2
Bartlett [33]	3	3	2	2	2
Dang [42]	2	2	3	2	2
Evans [43]	3	3	2	2	2
Hagglund [44]	2	2	2	3	2
Hale [34]	2	3	3	2	2
Pai [45]	2	1	1	1	1
Nundy [35]	3	2	2	2	2
Piette [46]	2	2	2	2	2
Portz [36]	2	3	1	2	2
Scherr [47]	2	3	2	2	2
Seto [48]	2	2	2	2	2
Suh [37]	3	3	2	2	2
Triantafylidis [38]	3	1	2	2	1
Zan [39]	3	3	3	2	2
Zhang [40]	3	2	3	3	2

^aHigh risk of bias.

^bLow risk of bias.

^cUnknown risk of bias.

A total of 7 studies assessed only usability or patient satisfaction (see Table 2) in using the mobile app [31-33,36,38,39,42,43]; 2 studies that reported HF outcomes also assessed usability [32,42]. Two of the studies used survey methods to assess usability [36,47], and 2 studies observed patient data to measure usability of the components included in the mHealth app [37,38]. Four studies used validated questionnaires to measure usability of mHealth apps [31-33,43].

Components of Heart Failure Self-Care Included in the Mobile Apps

All 18 studies included in this review varied widely on components of self-care management tested including medication management [32,34,46]. Most of the mobile technology included weight and symptom assessment [31-33,36-40,42-46,48], mobile messaging on HF self-management [32,35,40,41], and HF education [32,33,35,38,41,44,45]. Among the studies included, 7 of them considered mobile systems that included self-care components and clinical variable assessment. The HRS Patient Connect mobile system including weight, blood pressure, symptom assessment with feedback, medication management, and HF education using video reported reduced readmission rates at 3 months [45]. Similarly, 2 studies tested mobile systems among veterans and reported significantly improved HF outcomes [42,46]. Another mobile app, HeartMapp, tested acceptability and reported improved self-management in a pilot RCT [32]. HeartMapp is the only app that included biofeedback

deep-breathing exercise to mitigate stress, 6-minute walk test to assess physical function, and mood and memory assessment [32]. In addition, 1 app included assessment of oxygen saturation [38], another included a single-lead electrocardiogram [48], and a third used NT-proBNP to develop an algorithm to calculate a risk score for HF, although this study did not include any usability or efficacy data [40] (see Multimedia Appendix 1).

Eight of 18 studies provide alerts or reminders to perform self-care. However, this aspect of the interventions is confusing, since data from these alerts are inconclusive or not reported, especially on the response to the alerts generated by the systems [31,32,34,37,41,42,45,46]. Only 1 study reported the reaction time (median 1 day, interquartile range 0 to 6) [35]. It is not known how many of these alerts were false or not responded to by participants. The other studies reported providing alerts and tracked their response with no results included.

Assessment of Risk of Bias

The Cochrane Collaboration's tool was used for assessing risk of bias in order to appraise the rigor of the included studies [50]. This tool has been tested in systematic reviews of health care interventions that frequently include RCTs [51] and non-RCTs [52]. This tool assesses for risk of selection, performance, detection, attrition, and reporting biases. Risk assessments of the included studies are presented in the form of a table containing the risk ratings (high, low, or unclear risk) [50]. In an effort to minimize various forms of research bias, studies are

encouraged to assess for internal and external threats to validity. This tool was developed to assess risk of bias in RCTs and served as an objective measure to appraise bias of the HF studies included in this review. It should be mentioned that this analysis of the risks of bias is based on the current Cochrane tool; limitations and challenges still exist [53]. The Cochrane risk of bias tool aims to support researchers to enhance future study designs in order to translate them into practice.

The risk of bias tool was used because this tool is based on narrative descriptions of evidence-based methodological features known to increase the risk of bias in trials. Therefore, for a review that included studies with varying samples and pilot trials, we decided to use this tool to assess bias. The 2 authors of the study independently assessed the studies for bias. Most studies included in this review were underpowered and had high bias across all categories indicating varying ranges of methodological rigor. Studies that demonstrated high risk of selection bias provided inadequate data on randomization or lack thereof [31,33,35,37-41,43]. Several studies did not include information on blinding either the participants or study personnel, which increases internal threat to validity and results in high risk of performance bias [31-34,36,39,41,43,47]. There were only 2 studies that posed high risks of detection bias based on repeated testing methods [34,42]. Two studies have unknown risk of performance bias due to lack of information on blinding

[38,45]. Attrition bias was determined if the outcome data were incomplete. Lastly, it was determined that all studies except the 3 found to lack information were determined to have unclear risks [31,38,45].

Mobile Health Apps Commercially Available in the Market for Heart Failure

Forbes reported that over 50,000 mHealth apps are available that look to benefit our health, particularly physical fitness, mental health, general well-being, or management of chronic diseases [54]. As mentioned earlier, our search yielded 26 mHealth apps specific for HF self-care after applying our inclusion and exclusion criteria. These commercially available mobile apps have not been tested for usability or efficacy in impacting HF outcomes.

The 2 authors of this paper objectively evaluated and rated these commercial apps independently using MARS to determine the quality of the apps and if the apps support components of self-management of HF [30]. MARS functionality scores focus on performance, ease of use, navigation, and gestural design of the app. Functionality was assessed based on components of HF self-management, the type of self-management, amount of support or feedback provided, and quality of the app. Table 4 shows the 26 mHealth apps available on the market that are specific for use by HF patients with number of components and ratings included.

Table 4. Apps commercially available for patients with heart failure and number of self-care components monitored.

App name	Heart failure self-care components	Access/cost in USD	MARS ^a score				Total MARS
			Engagement	Functionality	Aesthetics	Information	
AskMD patient app	7	Free	4.8	4.8	5.0	4.6	4.8
Heart Failure Health Storylines	7	Free	4.8	4.4	3.5	4.8	4.4
WebMD patient app	7	Free	4.0	4.6	4.5	4.2	4.3
Continuous Care Health App	6	Free	4.0	4.6	3.2	4.2	4.0
HeartKeeper	5	Free	4.0	4.2	3.4	4.4	4.0
Manage HF	6	\$0.99	4.0	4.0	3.0	4.0	3.8
HF Defender	5	Free	3.8	4.0	3.0	3.8	3.7
WOW ME 2000mg	7	Free	3.0	4.6	3.0	3.0	3.4
Beat HF	4	Free	3.8	3.8	2.8	3.0	3.3
HeartPartner	5	Free	3.5	3.8	3.0	3.0	3.3
MyHeartApp	4	Free	3.0	3.2	2.8	3.0	3.0
Heart Failure coach	4	\$49.99	3.5	3.0	3.0	3.0	3.1
Med-HF	4	Free	3.0	3.0	2.5	2.5	2.8
Health Manager	4	Free	3.0	3.0	2.0	3.0	2.8
HF Buddy	4	Free	3.0	3.0	2.0	3.2	2.8
Manage HF for Life	4	Free	2.8	3.0	2.0	2.5	2.6
MyHF	4	Free	2.5	3.0	2.0	2.0	2.4
Track your Heart Failure Zone	2	Free	2.0	1.0	1.0	1.0	1.3
HeartScribe	2	Free	1.0	1.0	1.0	1.0	1.0
Heart Log	2	Free	1.0	1.0	1.0	1.0	1.0
QardiyoHF	2	Free	1.0	1.0	1.0	1.0	1.0
My Symptom Guide	1	Free	1.0	1.0	1.0	1.0	1.0
Heart Failure monitoring	1	Free	1.0	1.0	1.0	1.0	1.0
SelfCare-MHR	1	Free	1.0	1.0	1.0	1.0	1.0
Signs and symptoms of HF	1	Free	1.0	1.0	1.0	1.0	1.0
Cardio	1	Free	1.0	1.0	1.0	1.0	1.0

^aMARS: Mobile Application Rating Scale.

Discussion

Principal Findings

In general, the first part of the review included studies that have tested an mHealth app in patients with HF. The second part included mHealth apps that are commercially available on the market for self-care of patients with HF. Most of the studies reviewed lack high-quality design and included a limited number of participants. Only 4 of the 18 studies reviewed included a sample size over 100 [45-48]. Of the 4, 2 were RCTs [47,48], 1 was a pre-post evaluation [45], and 1 was a comparative effectiveness analysis [46]. However, all 18 studies included 1 or more HF-specific self-care components provided on a mobile platform.

Most studies (14/18) monitored self-care components including weight, blood pressure, and HF symptoms. However, only 1

study assessed the severity of HF using a built-in algorithm based on the New York Heart Association classification. This classified patients into zones using American Heart Association categories of green, yellow, orange, and red zones and offered cues for action for values outside the range of the green zone [32]. Two studies reported using the HFSAS for HF symptom assessment with built-in algorithm but did not indicate if feedback was provided for patients to take action for values outside of range [37,40]. Most other apps only monitored the patients' weight and HF symptoms and provided no feedback for values outside of range or left the responsibility to providers. This defeats the purpose of mHealth apps in helping patients develop a habit of adhering to self-care recommendations.

As indicated earlier, clinical outcomes in HF depend largely on how well a patient follows self-care and seeks care for symptoms early. Supporting patients through care transitions has been identified as a way to avoid hospital readmissions [55]. Mobile

phones are carried by people and are always with them. Therefore, mHealth technology could potentially produce similar positive results if used beyond simple remote monitoring but targeted at behavior change based on behavior change theories, assisting patients to develop self-care as a habit and thus impacting outcomes. In a prior systematic review of 20 studies, the authors concluded that the use of technologies in managing HF patients at home had a positive impact on hospital readmission by 45%, improved mortality by 40%, and HF outcomes by 35% [56]. The key difference is that this review mainly focused on mHealth apps or systems that included 1 or more self-care components. Several of these studies demonstrated usability and potential efficacy for improving HF outcomes. Evidence shows that few mHealth apps are under development in countries such as Russia [57] and Iran [58]. Given the global public health burden of HF, large-scale studies to test these mHealth apps or systems for efficacy is warranted in America and around the world.

Attrition or study completion was reported in only half of the studies, with 1 study reporting as high as 80% attrition. In the study, researchers gave each participant a locked phone with the mobile app, and patients reported that they did not like to carry an additional phone and wanted an app on their own phone [33]. Only 1 study reported using participants' own mobile phone to download the app [32], and other studies provided no details. A review recommended using a "bring your own device (BYOD)" strategy for research for sustainability [59]. The majority of people use their own mobile device for a variety of work-related communications and surfing the Internet. The BYOD strategy was successfully incorporated in education sectors [60] and thus is recommended for research to enhance customer satisfaction and long-term benefit [59].

Usability of the mHealth system was assessed in 9 studies, of which only 2 pilot studies reported potential efficacy along with usability [32,42] and 1 study provided only the algorithm developed for assessing risk [40]. Only 4 studies used validated questionnaires. None of the studies used the Android guidelines by Google that measure users' quality of experience. A study that measured users' quality of experience following Android guidelines by Google reported that many of the commercially available apps lack assessment of quality and usability, and many apps are low quality or incomplete with bugs [61]. The authors strongly recommend mHealth app developers use the recommended techniques to test quality of the apps before releasing them to market for customer use [61]. None of the 18 studies used the Android guidelines to assess their mHealth apps; 1 of the 26 apps available on the market was recently evaluated using Android guidelines and is undergoing refinement to fix flaws [62].

The prevalence rate of depression in HF patients ranges from 24% to 42%, and depression is graded as an independent risk factor for readmission to the hospital, functional decline, and mortality in patients with HF [63]. Three of the 18 studies measured depression or mood using the PHQ-9 or CES-D [32,42,46]. One study provided detail on mood assessment and offering deep-breathing exercise to offset depression [32]. Researchers need to keep this factor in mind as depression could reduce the use of the app. Various measures of physical function

have been shown to predict rehospitalization and survival in patients with HF. Patients with HF commonly experience a highly variable symptom burden that is associated with reduced physical activity [64]. Six out of 18 studies tracked physical activity, and only 1 study included the 6-minute walk test to track progress and offer feedback [32]. The 6-minute walk test is a simple and useful prognostic marker for patients with mild-to-moderate HF [62]. Only 1 study reported tracking distance walked in 6 minutes to offer feedback on physical ability [34].

Limitations

A major limitation of this review pertains to the characteristics of study design or methodology and a total sample of 847 from 18 studies that ranged from 7 to 165 participants. Most of the studies included are poor quality, with 4 studies having 100 or more participants, of which only 2 are RCTs, indicating a methodological bias. The other RCTs are pilot studies with small samples. A study with a sample as low as 7 subjects compromised generalizability, applications to practice, and utility of findings from this review. Finally, the heterogeneity of study design, intervention components, and outcomes measured precluded the performance of a systematic review, and thus introduced bias to this review. The review was solely conducted by the 2 authors of the review, and thus we feel that we may have included bias and the results are not generalizable. There could be other studies and other mHealth apps that this review may have missed.

This review included studies that tested mHealth apps for usability and potential efficacy in improving HF outcomes. The review also rated commercially available mHealth apps specific for HF that lacked evidence of usability or efficacy data. Although the HF-related outcomes reported in this review vary widely, a trend toward making an impact was observed. Mobile health may offer a potentially cost-effective solution with 24/7 access to symptom monitoring as a point of care solution in promoting patient engagement in their own care at home. Considering the novelty of mHealth interventions in HF and emerging evidence on mHealth app development around the world, we feel strongly that another review may be warranted.

Future Research

Given the number of incomplete and poor-quality apps available on the market, focusing on improving apps that are already commercially available is a viable option. In addition, this review indicated that several mHealth apps for HF are under development around the world. mHealth app developers and researchers should collaborate with health care organizations and providers to align guideline-specific components in the app to improve outcomes. App developers are strongly advised to use the Android guidelines by Google to assess quality of user experience [61]. The authors recommend that the use of these tools by app developers may improve global acceptance of the apps and evaluation by the users. Evaluating the apps using valid tools such as MARS, complying with Google guidelines, and testing the apps for usability and potential efficacy of behavior change are warranted prior to making apps available for download by patients. The portability, connectivity, and touchscreen capabilities of mobile devices have the potential

to revolutionize mHealth. As one author pointed out, “data integration should take place within the context of robust organizational governance frameworks that take into consideration the evaluation of clinical outcomes” [65]. App developers also should explore options for data migration within patient portals of electronic health records. In order for self-care of any chronic condition like HF to be sustained, self-management techniques need to be integrated into the patient’s life. Therefore, the researchers should also consider

using a patient-centered approach during development of the app.

Conclusion

This review indicates that mHealth in HF is novel, and new apps are under development. A few apps have assessed usability and are under development based on feedback from participants. The impact of mobile phone-based HF interventions on HF-related outcomes was inconclusive; however, use may enhance patient engagement in their care at home.

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Conflicts of Interest

None declared

Multimedia Appendix 1

Heart Failure Self-Management Components Included in Studies Reviewed.

[PDF File (Adobe PDF File), 106KB - [cardio_v2i1e10057_app1.pdf](#)]

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Abbreviations

- AHFKT:** Atlanta Heart Failure Knowledge
BYOD: Bring Your Own Device
CES-D: Center for Epidemiologic Studies–Depression scale
DHFKS: Dutch Heart Failure Knowledge Scale
EHFScBS: European Heart Failure Self-Care Behavior Scale
EKG: electrocardiogram
HDS: Health Distress Scale
HF: heart failure
HFRS: Heart Failure Risk Score
HFSAS: Heart Failure Somatic Awareness Scale
HFSE: Heart Failure Self-Efficacy scale
HIS: home intervention system
HRS: Health Recovery System
ICC: intraclass correlation coefficient
KCCQ: Kansas City Cardiomyopathy Questionnaire
MARS: Mobile Application Rating Scale
MLHFQ: Minnesota Living With Heart Failure Questionnaire
MMAQ: Morisky Medication Adherence Questionnaire
NSSQ: Norbeck Social Support Questionnaire
NT-proBNP: N-terminal probrain natriuretic peptide
PHQ-8: Patient Health Questionnaire–8 item
PHQ-9: Patient Health Questionnaire–9 item
PSM: Personalized Self-Management system score
QoL: quality of life
RCT: randomized controlled trial
SCHFI: Self-Care of Heart Failure Index
SE: Self-Efficacy scale
SEMCD: Self-Efficacy for Managing Chronic Disease
SF-36: Short Form–36 item
SPMSQ: Short Portable Mental Status Questionnaire
SUPPORT-HF: Seamless User-Centered Proactive Provision of Risk-Stratified Treatment for Heart Failure
SUS: System Usability Scale
SVM: structured support vector machine

TEQ: Technology Experience Questionnaire

VA: Veterans Administration

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Original Paper

Remote Monitoring of Patients Undergoing Transcatheter Aortic Valve Replacement: A Framework for Postprocedural Telemonitoring

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Abstract

Background: The postprocedural trajectory of patients undergoing transcatheter aortic valve replacement (TAVR) involves in-hospital monitoring of potential cardiac rhythm or conduction disorders and other complications. Recent advances in telemonitoring technologies create opportunities to monitor electrocardiogram (ECG) and vital signs remotely, facilitating redesign of follow-up trajectories.

Objective: This study aimed to outline a potential set-up of telemonitoring after TAVR.

Methods: A multidisciplinary team systematically framed the envisioned telemonitoring scenario according to the intentions, People, Activities, Context, Technology (iPACT) and Functionality, Interaction, Content, Services (FICS) methods and identified corresponding technical requirements.

Results: In this scenario, a wearable sensor system is used to continuously transmit ECG and contextual data to a central monitoring unit, allowing remote follow-up of ECG abnormalities and physical deteriorations. Telemonitoring is suggested as an alternative or supplement to current in-hospital monitoring after TAVR, enabling early hospital dismissal in eligible patients and accessible follow-up prolongation. Together, this approach aims to improve rehabilitation, enhance patient comfort, optimize hospital capacity usage, and reduce overall costs. Required technical components include continuous data acquisition, real-time data transfer, privacy-ensured storage, automatic event detection, and user-friendly interfaces.

Conclusions: The suggested telemonitoring set-up involves a new approach to patient follow-up that could bring durable solutions for the growing scarcities in health care and for improving health care quality. To further explore the potential and feasibility of post-TAVR telemonitoring, we recommend evaluation of the overall impact on patient outcomes and of the safety, social, ethical, legal, organizational, and financial factors.

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KEYWORDS

transcatheter aortic valve replacement; postoperative care; electrocardiography; telemonitoring; telemedicine

Introduction

Transcatheter Aortic Valve Replacement and Cardiac Conduction Disorders

Transcatheter aortic valve replacement (TAVR) is a relatively new therapy for severe aortic valve stenosis, in which a valve prosthesis is positioned percutaneously within the diseased native aortic valve under radiological guidance [1].

Currently, the number of patients undergoing TAVR is growing fast, which stems from the increasing prevalence of aortic stenosis and the rising number of studies reporting similar to favorable outcomes for TAVR as compared to conventional valve surgery [2-4]. Furthermore, indications for TAVR are evolving to intermediate-risk patients and might even include low-risk patients in the future.

With this growth of TAVR procedures, optimization of patient outcome and the periprocedural trajectory is desired. Hence, prevention and adequate management of complications are key. Currently, one of the most common complications after TAVR is the development of cardiac conduction defects (CCD) or arrhythmias, of which left bundle branch blocks and first or third degree atrioventricular blocks have been most commonly reported [3,5-7].

In 60-83% of the patients with new-onset CCDs after TAVR, the CCDs develop during the procedure or within 24 hours after the procedure [8-10]. However, CCDs can develop up to days or even weeks after the TAVR procedure, during which the incidence of new-onset CCDs decreases in time [11]. Due to the development of CCDs, implantation of a permanent pacemaker (PPI) may be required. The risk of PPI depends on various factors including, but not limited to, sex, preexistence of right bundle branch blocks, prosthesis dimensions, and mitral valve calcification [8,12-14]. According to a meta-analysis including 41 studies that included >11,000 patients, the average risk of PPI after TAVR is about 17%, but rates between 2-51% have been reported [15]. With this, the occurrence of CCDs is a prominent and costly issue of TAVR.

Postprocedural Monitoring

To follow up on pacemaker dependency or CCDs, continuous bedside or ambulatory electrocardiogram (ECG) telemetry is an essential part of in-hospital TAVR patient monitoring. According to the "ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement," continuous monitoring of the ECG for the purposes of pacemaker-dependency identification is currently recommended for a minimum of 72 hours, depending on the valve type [16]. However, TAVR enables fast postprocedural recovery and mobilization of the patient, which is already possible from several hours after the procedure in the absence of adverse events.

Furthermore, all other aspects of in-hospital postprocedural care, such as neurologic evaluation and administration of postoperative medication, are only protocol for 24 hours after the procedure [16]. Accordingly, ECG monitoring as protocol is often the only indication for prolongation of hospital stay

after 1-2 days when no complication presents. This is a major concern as it conflicts with the belief that hospital stays should be minimized to promote rapid recovery [17].

Early hospital dismissal enables early resumption of the daily life routine of patients, which is expected to improve patient comfort, and supports re-establishment of a stable condition [18,19]. Furthermore, reduction of length of stay can minimize the susceptibility for hospital-acquired complications and minimize the burden on hospital capacity. Driven by these advantages, fast-track protocols aiming for early ambulation are currently being developed for the TAVR population [20]. Yet, even with the introduction of fast-track routines, postprocedural ECG monitoring remains an obstacle for timely discharge. Therefore, new approaches of patient monitoring rejecting the need for hospital stays are warranted.

Remote Patient Monitoring

In recent decades, global digitalization and the development of mobile medical technologies have increased the ability to transfer health-related data from one place to another and to perform physiological measurements in an outpatient setting. A particularly interesting application of mobile health is telemonitoring, in which mobile sensor applications facilitate remote follow-up of physiological parameters. Accordingly, telemonitoring systems that track vital parameters can create alternative strategies for current in-hospital monitoring. With this approach, patients are no longer confined to the hospital for follow-up of the ECG or other vital signs, which opens doors to redesigning the postprocedural patient trajectory.

For the TAVR population, the introduction of remote monitoring technologies raises the possibility of shortening hospital stay length in eligible patients without abstaining from follow-up of pacemaker dependency. As mentioned previously, this can promote fast rehabilitation, procure a patient-friendly postprocedural trajectory, and optimize use of hospital bed capacity.

Further, remote measurements of the ECG waveform and additional parameters including respiratory rate and activity level may help detect overall physical deteriorations in an outpatient setting. Thus, the monitoring intensity and period can be personalized easily. By adding this more continuous monitoring to the intermittent controls of conventional post-hospital follow-up, late-onset CCDs as well as physical deteriorations can be detected earlier and be acted on quickly, which could prevent further worsening and re-admissions. This approach can be valuable on its own in any patient and also complement the remote follow-up of patients dismissed early.

Together, it is expected that the introduction of telemonitoring can improve patient outcome and enhance patient comfort. Moreover, telemonitoring can increase the efficiency of patient care and reduce overall costs, which is critical to cope with the growing demand on health care. So, there is potential, but the question is how to use and select such new technology, for whom is it suited, and how telemonitoring should be embedded in clinical routine.

In this paper, we outline a potential scenario for the use of telemonitoring after TAVR, assess technological components

that are needed, and evaluate factors that are essential for the implementation of this new approach to patient management.

Methods

A multidisciplinary team was put together of medical and technical professionals with expertise on TAVR patient management, cardiac monitoring, CCDs, and telemonitoring. The expert team consisted of 2 interventional cardiologists, of which one was working as head of the TAVR team and the other as clinical chief of the cardiac monitoring unit; an electrophysiologist; and 2 technical physicians from the Academic Medical Center (Amsterdam, The Netherlands), which holds a center of expertise for TAVR. A professor in telemedicine from the University of Twente (Enschede, The Netherlands) also joined the team.

The expert team assembled to discuss and frame a potential future application of telemonitoring after TAVR using the early phase requirement elicitation methodology described by Larburu et al [21]. This scenario-based approach is specifically designed for telemedicine applications and is suitable for a multidisciplinary collaboration of medical practitioners and engineers as it promotes a mutual understanding of the desired user activity and user-system interactions. Accordingly, a concept scenario was defined using the “intentions, People, Activities, Context, and Technological components” (iPACT) framework for telemonitoring.

Next, the “Functionality, Interaction, Content, and Services” (FICS) descriptions were assessed, which were used to identify relevant user-system interactions and system functionalities. The iPACT and FICS were formulated using observations in current practice, international guidelines, and experiences and visions of the expert team members. Using the iPACTS and FICS as endpoints, the main requirements of the telemonitoring system were specified.

Results

Envisioned Scenario

The expert team agreed on an extensive scenario description framed by the iPACT and FICS and corresponding system criteria. The main principle of the formulated scenario described by the iPACT framework is that remote monitoring allows a reduction of hospital stay length by replacing in-hospital rhythm follow-up and facilitates prolongation of patient monitoring (Figure 1). The eventual goals (“Intentions”) of this approach are encouraging improved patient outcome and fast rehabilitation while increasing health care efficiency and cost reduction.

The suggested application of telemonitoring applies to patients who undergo TAVR and are subsequently admitted to the monitoring unit for postprocedural follow-up (“People”). Early hospital dismissal is indicated only in hemodynamically stable patients who have a low-risk profile for development of complications other than CCDs.

Risk stratification may involve conventional methods such as the Society of Thoracic Surgeons predicted risk of mortality (STS-PROM) score or the European System for Cardiac Operative Risk Evaluation (EuroSCORE), or new risk scores specifically developed for the TAVR population and postprocedural setting [22,23]. Patients with a complicated procedure or admission may not be suitable for early dismissal. In eligible patients, hospital dismissal will be possible from the moment that rhythm observation is the only indication for prolongation of hospital stay.

Use of telemonitoring for additional monitoring after a conventional hospital stay can apply to any TAVR patient. However, follow-up prolongation is particularly recommended in patients with doubtful recovery or with increased risks for late development of CCDs or other complications.

The scenario describes the actions that are undertaken (“Activities”), in which setting (“Context”), and with which tools telemonitoring (“Technology”) is procured (Figure 2).

Figure 1. Presentation of the pathway following transcatheter aortic valve replacement (TAVR) in current practice; in the setting of early dismissal involving telemonitoring as partial replacement of current hospital stay; and in the setting of follow-up prolongation using telemonitoring subsequent to current hospital stay length.

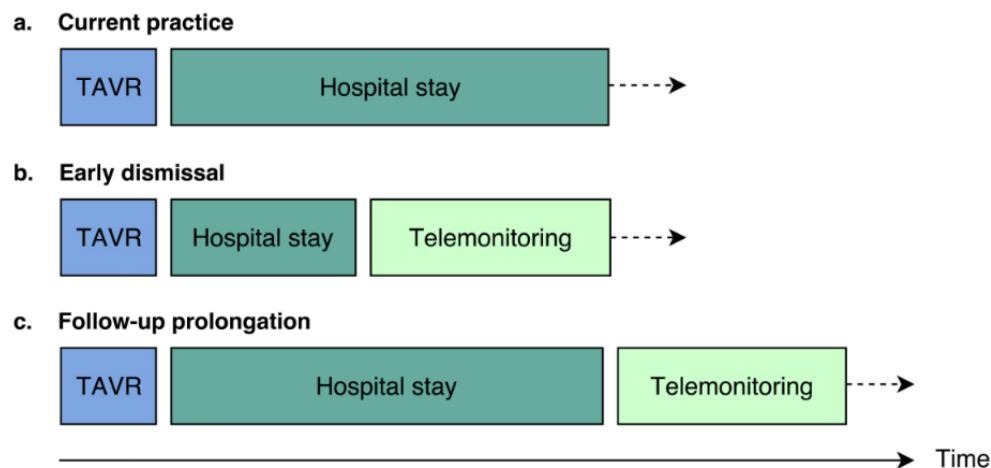
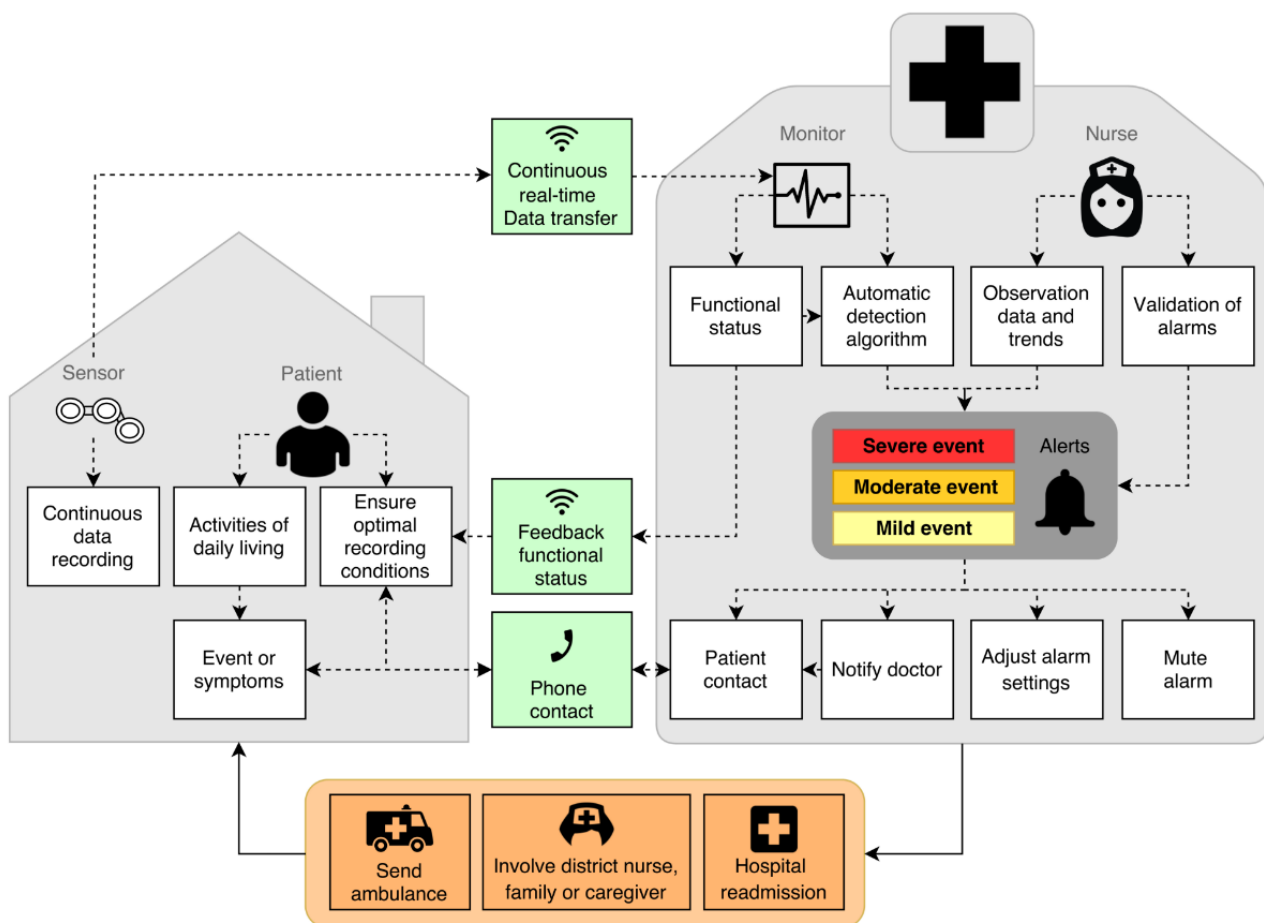


Figure 2. Overview of the suggested telemonitoring scenario.



If patients are considered eligible for early dismissal or additional follow-up by the treating physician, they are equipped with a mobile sensor system that automatically provides continuous registration of the ECG in any ambulant setting. The system should also facilitate continuous registration and analysis of the respiratory rate and type or level of activity. Optionally, body temperature and blood pressure can be added, which are measured with connected arm cuff and thermometer. Last, incorporating a digital application with an interactive interface to allow symptom registration by the patient would be beneficial.

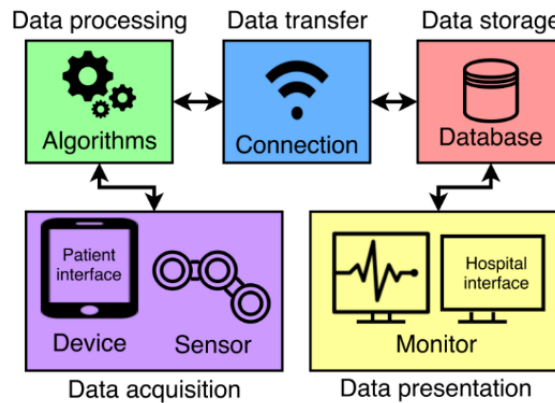
These measurements provide complementary information about the patient's condition and recording setting, which may be valuable to contribute to ECG interpretation. Furthermore, these parameters may support trend analysis and trend identification of physical deteriorations leading to personalized (medical) advice. This is of particular interest for patients with congestive heart failure, kidney disease, or cardiorespiratory comorbidities where hemodynamic instability may occur. Furthermore, this approach might be desirable in patients where new valve types are implanted and where the risk of conduction disorders is still unknown.

In both applications of telemonitoring, the recorded ECG and additional data are continuously transferred to the central monitoring unit allowing real-time processing and patient monitoring conform clinical standards by dedicated care providers. To support the notification of events, the system

automatically analyzes data and generates alerts in case of abnormalities and gradual deteriorations, adapted to the specific patient's needs. Supported by this system, the patient can be dismissed from the hospital and resume the activities of daily life again while being monitored as long as needed. If the patient is not (yet) self-supportive, transfer to a convalescent home or additional home care can be considered.

With this envisioned approach, telemonitoring itself is essentially similar to standard telemetry monitoring despite the fact that the patient is no longer physically present within the hospital and that vital signs are assessed more continuously. However, the management of adverse events differs from current practice. For minor events or unforeseen system malfunctioning, the care provider may need to contact the patient by (video)phone to check the current physical status. Similarly, patients can contact or alert the monitoring unit when they are symptomatic by phone or by pushing an emergency button. The physician in charge can then decide to provide advice, recall the patient to hospital, or activate help from nearby caregivers if needed. In situations where the ECG shows increasing instability like prolongation of the atrioventricular conduction time interval or onset of atrial fibrillation [11], preventive measures can be taken such as further in-hospital observation and prescription of anticoagulants, respectively. This also applies to abnormal trends in vital signs, which may indicate development of cardiorespiratory instability. In case of emergencies, an ambulance team should be sent.

Figure 3. Overview of the processes and corresponding technical components of a telemonitoring system.



Technology

According to this scenario, the telemonitoring system should manage several processes and provide multiple services described by the FICS. In summary, these processes and services involve management of clinically, patient-, or system-related data (“Content”). Required processes (“Functions”) include data acquisition, data processing, data transfer, data storage, and data presentation. To procure these processes, the system should provide a sensor device, algorithms, wireless connection, database, and interfaces for patients and clinicians (Figure 3). All components should be embedded using software that manages the data processes (“Interactions”) to enable system control and patient observation (“Services”). The minimum required processes are shown in Figure 4.

Technical Needs and Requirements

To provide a suitable alternative for in-hospital ECG monitoring, the telemonitoring system should primarily enable remote evaluation of pacemaker dependency. Second, the system should instantaneously notify development of cardiac arrhythmias and conduction defects that result in life-threatening or dangerous conditions to enable fast activation of acute care. According to these endpoints and desired system functionalities described by the iPACT and FICS, technological components should meet multiple criteria.

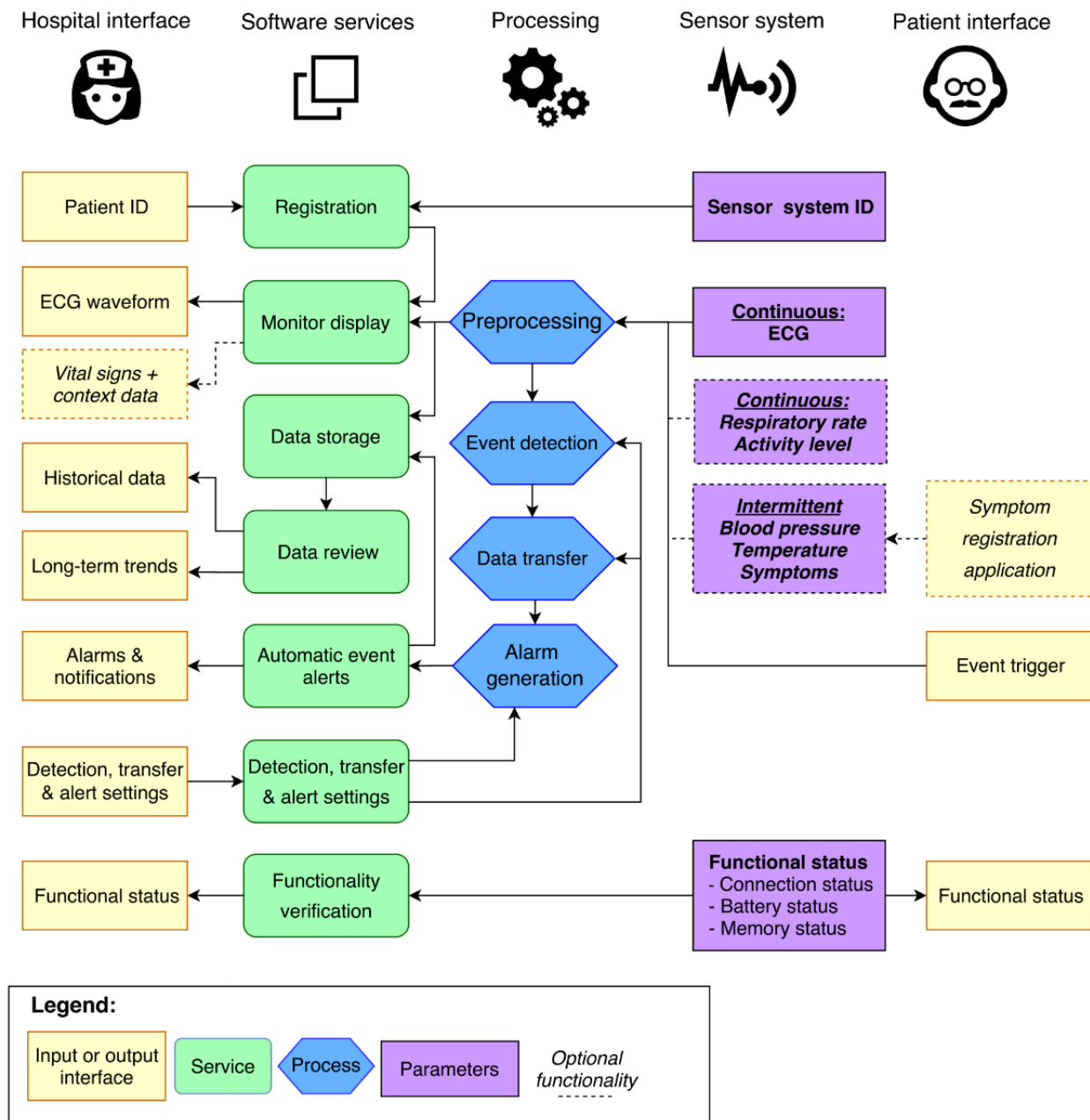
First, the system needs to provide clinically usable data. Accordingly, the mono- or multiple lead ECG should be of sufficient quality to identify rhythm and conduction disorders. Likewise, the additional parameters including respiratory rate and activity should be reliable and presented in such a way that interpretation of the ECG and patient’s status is supported. Next, the system should enable continuous real-time monitoring in a remote setting, in which a stable connection and robust data processing are essential. The sensor recordings should be transferred according to a protocol in which the continuous data are transferred directly in case of a detected event or in case the nurse or patient activates a trigger. Otherwise, the data are transferred periodically in batches every 10 minutes. These data

provide the full ECG waveform and an average value of respiratory rate and activity level values calculated every 2 minutes. The reason for using periodic transfer instead of standard continuous transfer is limited power consumption. Additionally, this approach prevents an overload of information. With this, the observing nurse is less prone to information fatigue and can focus on critical issues more easily, which allows observation of multiple patients.

To support timely identification of rhythm or conduction defects, advanced validated algorithms must be incorporated that trigger alerts in case of ECG abnormalities at the patient site. Also warranted are additional algorithms to notify of the presence of deviant trends and abnormalities in vital signs. Although further research is required in order to specify alert conditions and effective detection methods, we suggest using analytical methods that assess not only the absolute values but also the time trends or patterns of vital signs to promote accuracy [24-26]. To improve abnormality detection, it might be useful to integrate information from different sources as well. For example, accelerometry may help anticipate motion artefacts, adapt the threshold for tachycardia or tachypnea during physical activity, or perform fall detection [27]. Last, the algorithms should be personalized, where threshold values are based on the patient’s history using static or self-learning methods. To prevent alarm fatigue and support fast response in urgent situation, alerts should be classified according to the priority level (ie, mild, moderate, severe events).

Since the patient has no support from health care professionals in their home environment, it is also important that the system is user friendly and comfortable to ensure correct use and acceptance by the TAVR population. Furthermore, the sensor system should be small and preferably worn under clothes, as visibility of the system could stigmatize the patient as being ill. Last, the system should be safe and ensure privacy. Specification of the requirements and corresponding priority level is provided for each of the technical components level in [Multimedia Appendix 1](#). Together, these criteria require a combination of dedicated and advanced technology.

Figure 4. The processes facilitated by the telemonitoring system. ECG: electrocardiogram.



Discussion

Principal Consideration

In this approach to telemonitoring after TAVR, the ECG and patient’s status are evaluated remotely. Patients are no longer confined to the hospital for postprocedural rhythm observation, which facilitates early dismissal of eligible patients. Furthermore, telemonitoring enables prolongation of the monitoring period, promoting detection of late conduction disorders or physical deteriorations.

Telemonitoring is expected to positively impact patient outcome and patient comfort resulting in higher quality of care. In addition, it enables more optimal use of hospital bed capacity by relieving the burden on monitoring capacity. This approach suits the increasing (need for) decentralization of health care

and can provide durable solutions to handle the increasing demand on health care with limited resources.

Technological Potency

Ambulatory ECG monitoring itself is nothing new, as Holter and telemetry systems have been used for years. Yet, this suggested telemonitoring application requires more advanced mobile ECG systems in which continuous recordings, real-time data transfer, and remote use are integrated. With the fast expanding field of mobile health technologies and development of wireless networks, new solutions providing this feature combination seem to be entering the market [28,29]. Hence, it is likely that suitable telemonitoring systems will be available in the coming years. However, in our experience, currently available systems are not yet compliant with all requirements. This often relates to restricted battery duration of sensors,

unsatisfactory data quality in remote settings, connection issues, or limited interoperability with current hospital systems. Also, many systems rely either on traditional rhythm detection methods or on threshold-based vital sign assessment, while the proposed application needs algorithms that take into account context and personal characteristics as well. In order to help telemonitoring systems find their place in health care settings, it is essential that all involved parties within and outside the hospital collaborate closely in system development and implementation.

Feasibility

As depicted in this telemonitoring framework, successful implementation of remote patient monitoring does not only require suitable technology but involvement of the complete chain of health care delivery as well. With the relocation of health care, roles and responsibilities will be redistributed [30,31]. Although the concept of health care decentralization is gaining support worldwide, most health care systems are not yet ready for this approach [32,33]. As a result, various safety, organizational, financial, legal, and social issues may need to be addressed before telemonitoring can become embedded.

To facilitate telemonitoring, the organizational structure and workflow of first and second line health care providers need to be adapted. To start with, this requires allocation of a nurse for observation, organization of a process for routine distribution and technical maintenance of monitoring systems, and establishments of protocols for all involved caregivers. Correspondingly, the legal responsibilities have to be reevaluated in which the interposition of physical distance between patient and physician and the increased dependency on technology have to be taken into account.

In terms of social impact, there needs to be investigation into what extent the patient and their family support transfer of monitoring activities in a home environment, as this may require a certain level of self-support and anticipation of technology. This also applies to medical professionals, who need to be willing to adopt novel manners of patient management.

Last, to finance the implementation of telemonitoring, further clarification of the distribution of financial expenses and profits is needed to identify structural yields and find investors. In this process, the reimbursement policy plays a critical role, which varies per country [34].

Patient Safety

Patient safety is a serious issue in remote patient practices. Post-TAVR telemonitoring can enhance patient safety when used for prolongation of the conventional monitoring period. However, safety may be a factor if the physical distance between patient and caregiver delays delivery of care. The actual overall risk may be limited as CCDs mostly present within the first 24 hours after TAVR and rarely lead to emergency situations where immediate action is required. In addition, current follow-up policy does not prevent certain events occurring after hospital dismissal either. Altogether it is a matter of creating minimal risks, which underlines the importance of easily accessible follow-up tools and careful selection of patients eligible for

early discharge. Nevertheless, it is essential that telemonitoring be implemented step-by-step, with safety constantly evaluated. Furthermore, use of strict protocols and establishment of collaboration with professional emergency teams or remote first line caregivers is critical.

Limitations

By assembling a multidisciplinary expert team representing various medical and technical disciplines, we pursued proposition of an adequate and realizable telemonitoring concept. Yet despite the promising prospects, it is not clear to what extent the intended goals will be obtained in real practice. Further research regarding the effectiveness of this concept is required, involving evaluation of the overall effects on patient outcome, efficiency, and cost-effectiveness. Furthermore, multicenter studies are recommended to assess the need for center-specific adaptation of the scenario or system requirements.

Future Perspective

The introduction of telemonitoring provides the opportunity to relocate follow-up of ECG and vital signs, which supports reorganization of the postprocedural follow-up trajectory. Meanwhile, alternative approaches for post-TAVR monitoring are considered as well, such as the introduction of risk profiles to select patients for telemetry [11,35]. Although this approach is of potential interest to reduce redundant telemetry use, this may be applicable to only a part of the TAVR population. To verify the most optimal strategy for ECG follow-up, further evaluation of patient eligibility, patient safety, and efficiency is required.

To expand the value of telemonitoring, the remote system may incorporate extra services for patients such as training exercises or medication alerts to enhance rehabilitation and therapy loyalty. Additionally, creating a secured platform where patients can access and share their historical data can promote patient empowerment. The proposed telemonitoring set-up can be applied as an unobtrusive alternative for in-hospital telemetry or for real-time or off-line monitoring of many other patient groups. This may be valuable for postprocedural monitoring, therapeutic guidance, patient coaching, and many other diagnostic or therapeutic aims.

Conclusions

Overall, the introduction of telemonitoring creates the opportunity to redesign the postprocedural trajectory of TAVR patients, enabling early hospital dismissal in eligible patients or prolongation of the period of monitoring in a daily life setting. To the end, this approach may not only be beneficial to improve health care quality but also inevitable to manage the increasing health-care demand and decentralization. Therefore, we recommend further exploration of the technical possibilities, optimal implementation, and overall impact at clinical, social, ethical, legal, safety, organizational, and financial levels. Accordingly, solutions may arise for more efficient and rehabilitation-supporting postprocedural monitoring that favor hospitals and patients.

Conflicts of Interest

JB Jr received an unrestricted research grant from Edwards Lifesciences and is proctor for Edwards Lifesciences.

Multimedia Appendix 1

System requirements.

[[PDF File \(Adobe PDF File\), 34KB - cardio_v2i1e9_app1.pdf](#)]

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Abbreviations

- CCD:** cardiac conduction defects
- ECG:** electrocardiogram
- FICS:** Functionality, Interaction, Content, and Services
- iPACT:** intentions, People, Activities, Context, and Technology
- PPI:** permanent pacemaker implantation

TAVR: transcatheter aortic valve replacement

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Original Paper

HerzMobil, an Integrated and Collaborative Telemonitoring-Based Disease Management Program for Patients With Heart Failure: A Feasibility Study Paving the Way to Routine Care

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Abstract

Background: Heart failure is a major health problem associated with frequent hospital admissions. HerzMobil Tirol is a multidisciplinary postdischarge disease management program for heart failure patients to improve quality of life, prevent readmission, and reduce mortality and health care costs. It uses a telemonitoring system that is incorporated into a network of specialized heart failure nurses, physicians, and hospitals. Patients are equipped with a mobile phone, a weighing scale, and a blood pressure and heart rate monitor for daily acquisition and transmission of data on blood pressure, heart rate, weight, well-being, and drug intake. These data are transmitted daily and regularly reviewed by the network team. In addition, patients are scheduled for 3 visits with the network physician and 2 visits with the heart failure nurse within 3 months after hospitalization for acute heart failure.

Objective: The objectives of this study were to evaluate the feasibility of HerzMobil Tirol by analyzing changes in health status as well as patients' self-care behavior and satisfaction and to derive recommendations for implementing a telemonitoring-based interdisciplinary disease management program for heart failure in everyday clinical practice.

Methods: In this prospective, pilot, single-arm study including 35 elderly patients, the feasibility of HerzMobil Tirol was assessed by analyzing changes in health status (via Kansas City Cardiomyopathy Questionnaire, KCCQ), patients' self-care behavior (via European Heart Failure Self-Care Behavior Scale, revised into a 9-item scale, EHFSB-9), and user satisfaction (via Delone and McLean System Success Model).

Results: A total of 43 patients joined the HerzMobil Tirol program, and of these, 35 patients completed it. The mean age of participants was 67 years (range: 43-86 years). Health status (KCCQ, range: 0-100) improved from 46.2 to 69.8 after 3 months. Self-care behavior (EHFSB-9, possible range: 9-22) after 3 months was 13.2. Patient satisfaction in all dimensions was 86% or higher. Lessons learned for the rollout of HerzMobil Tirol comprise a definite time schedule for interventions, solid network structures with clear process definition, a network coordinator, and specially trained heart failure nurses.

Conclusions: On the basis of the positive evaluation results, HerzMobil Tirol has been officially introduced in the province of Tyrol in July 2017. It is, therefore, the first regular financed telehealth care program in Austria.

KEYWORDS

heart failure; telemedicine; delivery of health care, integrated; program evaluation

Introduction

Heart Failure as a Major Public Health Problem

Heart failure is approaching epidemic proportions worldwide and represents a major public health problem. Prevalence of heart failure is estimated to be 1% to 2% of the adult population, rising to 10% and more in persons aged 70 years and older [1,2]. Heart failure is the leading cause of hospitalization among elderly patients [3]. Rates of death and readmission remain high despite considerable advances in medical therapy. Mortality rate within the first year approaches 40%, and up to 50% of patients are readmitted within 6 months of discharge [4-6]. Repeat hospitalizations are associated with higher mortality and contribute substantially to the enormous overall economic burden of the disease [7]. The risk of readmission and death is greatest in the early period after discharge [7-9]. These findings suggest a role for increased surveillance in the early postdischarge period of greatest vulnerability after heart failure admission. It is estimated that up to two-thirds of readmissions for acute heart failure are triggered by potentially remediable factors including “poor discharge planning, nonadherence to recommendations regarding diet and medical treatment, inadequate follow-up, poor social supports, and delays in seeking medical attention” [10].

Heart Failure Disease Management Programs

Multidisciplinary postdischarge disease management programs have been established to prevent readmission and to reduce mortality and health care costs. A recent systematic review of 47 trials took into account the heterogeneity in models of care used in different studies: multiprofessional heart failure clinics, multiprofessional follow-up without heart failure clinics, telephone contact, primary care follow-up, and enhanced patient self-care [11]. In this review, home-visiting programs and clinic-based multidisciplinary programs reduced all-cause readmission within 3 to 6 months by 25% and 30%, respectively. Comparable results have also been reported in elderly patients [12,13]. Interestingly, a more recent review published by Ong et al showed no significant differences in 30-day readmission rate or 180-day mortality, but a significant difference in 180-day quality of life between the intervention group comprising nursing-lead phone calls and telemonitoring and the usual care group [14].

On the basis of this evidence, the European Society of Cardiology recommends heart failure care delivered in a multidisciplinary program with high priority [15]. The fundamental role of heart failure nurses is particularly emphasized [16]. In addition, a recent position paper of the Austrian Society of Cardiology recommends multidisciplinary disease management programs with monitoring of high-risk heart failure patients [17]. Exact workflow definition and the specific role of participating stakeholders in a multidisciplinary

telemonitoring-based disease management program, however, still have to be defined.

HerzMobil Tirol is such a multidisciplinary disease management program for heart failure care. It was developed and implemented in the Austrian province of Tyrol.

Objectives

The objectives of this study were to evaluate the feasibility of HerzMobil Tirol by analyzing changes in health status as well as patients' self-care behavior and satisfaction and to derive recommendations for implementing a telemonitoring-based interdisciplinary disease management program for heart failure in everyday clinical practice.

Methods

HerzMobil Tirol

HerzMobil Tirol is a multidimensional postdischarge disease management program for heart failure patients using a telemedical monitoring system incorporated in a comprehensive network of specialized heart failure nurses, private practice physicians, and 3 secondary and 1 tertiary referral centers. The aim of HerzMobil Tirol is to achieve relevant and stable impact on readmission rates, mortality, quality of life, and overall health care costs.

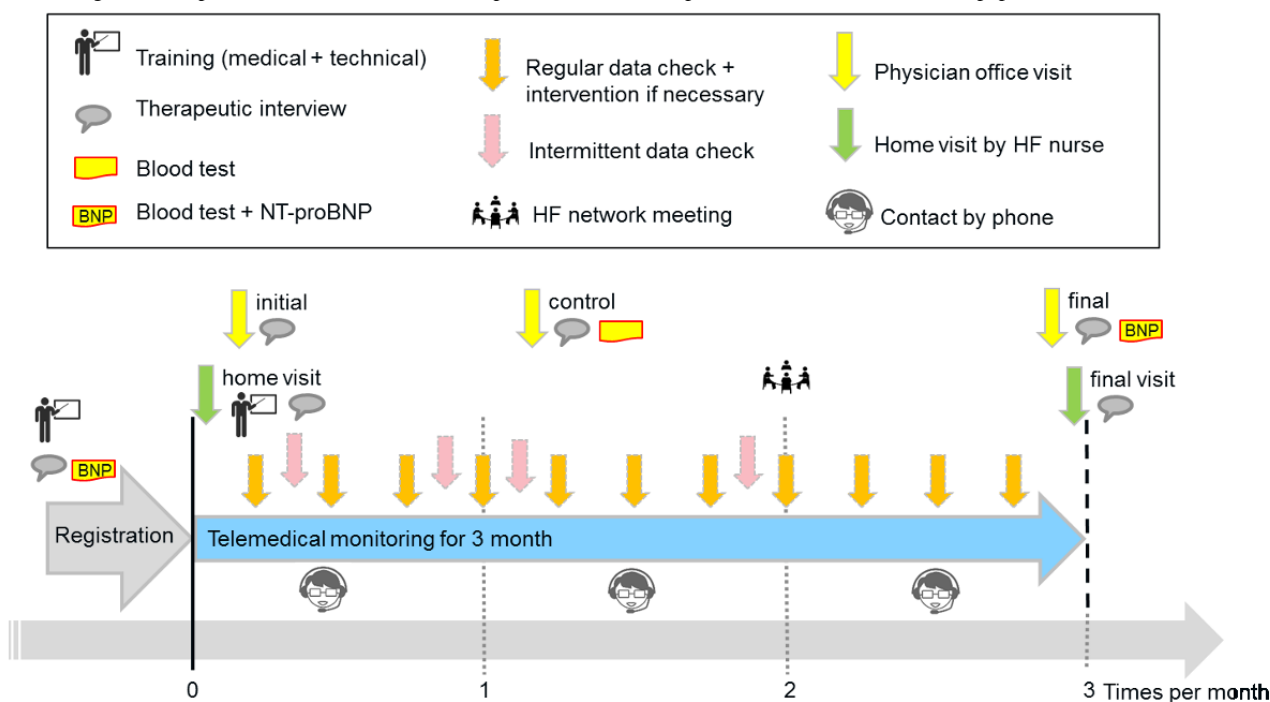
The program builds on several pillars: patient education to improve patient empowerment; patient-held mobile phone for daily data acquisition and transmission of blood pressure, heart rate, weight, well-being, and drug intake; physician-controlled telemonitoring of these data; nurse-led care for early detection of imminent decompensation; continuous optimization of guideline-based heart failure therapy for long-term stabilization; and finally, network communication to assure comprehensive heart failure management across venues.

The program was gradually developed, with all phases accompanied by program evaluation. First, between 2010 and 2015, shared decision making, responsibilities and liabilities of stakeholders, workflow and communication, information technology infrastructure, inclusion and exclusion criteria, duration and intensity, organizational integration, health care cost-effectiveness analysis, remuneration of stakeholders, and business models were implemented, evaluated, and continuously improved. A total of 137 patients were managed in these early phases of the HerzMobil Tirol program.

Disease Management Processes in HerzMobil Tirol

All participants of HerzMobil Tirol (physicians and nurses) communicate regularly to ensure optimal patient treatment without delay. Relevant information is shared on a Web-based telehealth software [18]. [Figure 1](#) shows details of the process of patient management.

Figure 1. Integrated care process of HerzMobil Tirol. NT-proBNP: N-terminal prohormone of brain natriuretic peptide; HF: heart failure.



Heart failure patients enter the HerzMobil Tirol program after being hospitalized for acute heart failure. On discharge, each patient is assigned to one of the network physicians in private practice. This network physician supervises the heart failure management of the patient and optimizes the therapy. Discharge information from the hospital is communicated to the assigned network physician via the telehealth software.

Within HerzMobil Tirol, patients are supervised for 3 months. This period can be prolonged for another 3 months in case of heart failure instability. Over these 3 months, the network physician reviews telemedical patient data (blood pressure, heart rate, weight, well-being, and drug intake) and commentaries of the heart failure nurse at least once a week (regular data check). Out-of-limit data that are detected automatically by the telehealth system are highlighted and reviewed daily so that interventions, for example, adjustment of diuretics, can be taken immediately (intermittent data check).

Follow-up face-to-face visits of the patient with the network physician are scheduled 1, 4, and 12 weeks after discharge. Blood tests, for example, renal function tests, electrolytes, and N-terminal prohormone of brain natriuretic peptide, taken at hospital discharge and follow-up visits at the physician's office allow for targeted optimization of medical therapy.

After entering the program, although the patient is still in the hospital, a heart failure nurse provides patient education both on the disease as well as on the mobile technology. During the 3 months of monitoring, these nurses are also responsible for compliance monitoring, phone contact with patients if required, and adjustments of medical therapy according to instructions of network physicians. To support this, a home visit by the heart failure nurse is scheduled immediately after discharge to finalize disease- and equipment-related education and to make sure that prescribed medication is available.

After 3 months, at the end of the managed care program, structured transfer of patients to regular care is organized.

Regular heart failure network meetings of all stakeholders (physicians and nurses) are scheduled every 3 months to support the exchange of experiences and the optimization of the technical and organizational network.

Telemedical Technology in HerzMobil Tirol

HerzMobil Tirol uses an integrated concept called Keep-In-Touch (KIT) to facilitate efficient and reliable daily data documentation and transfer of blood pressure, heart rate, weight, well-being, and drug intake [19]. Every patient included in HerzMobil Tirol is provided a blood pressure and heart rate monitor and a weighing scale as well as a near-field communication-enabled mobile phone for daily data acquisition and transmission.

Heart failure nurses introduce patients to this equipment. Patients can call a helpdesk in case of technical problems. As most of the patients are elderly patients, the dialogue-oriented and process-supporting KIT technology and the mobile app are designed to support the patients at home in easy and secure handling of the daily data acquisition process [20].

To identify upcoming adverse events, signal processing algorithms are used to analyze the transmitted physiological data [20]. Automatic event detection that identifies both missing values as well as off-limit measurements indicates the need for immediate actions and fosters attention to those patients who might need early therapeutic intervention. The limits used for automatic event detection are individually defined and regularly adapted for each patient by the network physician.

The Web-based telehealth software is made available to all stakeholders (network physicians, nurses, helpdesk, and network coordinator) and supports their individual tasks by user-specific

dashboards (Figure 2). Each user can access the telehealth software using personal login information, normally via their computer or laptop. After login, a list of patients who are monitored by the user (eg, all patients being monitored by the network physician as user) is displayed. After selecting a patient, the monitoring interface, as shown in Figure 2, is shown.

The Web-based telehealth software is not integrated into the electronic health records of the various users because of the heterogeneity of the used software products (all hospitals and all network physicians are using electronic health records from different vendors).

Data Collection

Ethical approval for the study was given by the ethical committee of the Medical University of Innsbruck.

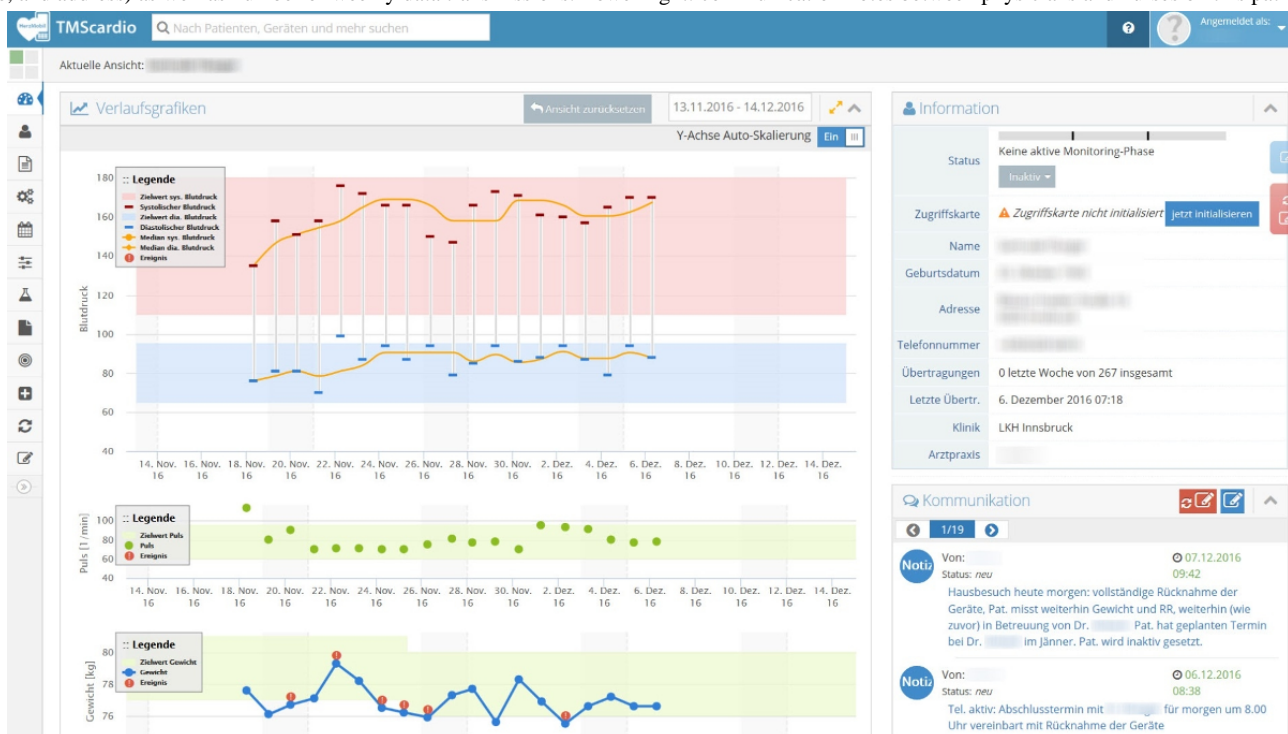
During the prospective, pilot, single-arm study, the network comprised 16 physicians and 5 nurses. Patients hospitalized at the University Hospital of Innsbruck for acute heart failure during January and September 2016 were assigned to HerzMobil Tirol irrespective of the underlying heart disease. Patients with end-stage heart failure or relevant comorbidities (Charlson comorbidity score >5) associated with a life expectancy of less than 6 months or patients who could not use the provided devices were excluded from the program.

Patients were recruited during hospitalization and were surveyed at baseline as well as after 3 months using the following instruments:

- Kansas City Cardiomyopathy Questionnaire (KCCQ) is a validated 23-item survey to assess the health status and quality of life of patients with cardiomyopathy [21]. It addresses physical limitation, symptoms, self-efficacy, social limitations, and quality of life. A summary score and a clinical score are calculated. The scores range from 0 to 100, with higher scores indicating better health status.
- European Heart Failure Self-Care Behavior Scale (EHFScB-9) is a 9-item scale to assess self-care behavior of heart failure patients. It has been validated [22] and is available in German [23]. Overall self-care behavior is calculated by adding the scores of the 9 items, leading to scores from 9 to 45. A score of 9 indicates best self-care behavior.
- Information System Success Model Survey was developed based on the Delone and McLean Information System Success Model [24]. It consists of questions on the 6 dimensions: information quality (3 items), system quality (6 items), service quality (4 items), intention to use (7 items), user satisfaction (3 items), and net benefits (9 items). The instrument also contains 6 open questions on benefit and possibilities for improvements. The instrument was adapted from earlier studies, but is not formally validated.

In addition, the project team conducted 3 workshops with all network physicians and nurses to discuss the feasibility of HerzMobil and to derive lessons learned for future improvements of both organizational and technical components.

Figure 2. Stakeholder-specific dashboards of the Web-based telehealth system HerzMobil. Top chart: systolic (red) and diastolic (blue) blood pressure with daily measurement (–) and target range (red/blue area). Middle chart: heart rate with daily measurements (green dots) and target range (yellow area). Bottom chart: weight with daily measurements (blue dots) and target range (yellow area). Red exclamation marks: automatic alert on an event that has to be dealt with (eg, sudden change of weight or reaching predefined alerting values). Upper right: demographics of the patients (name, birth date, and address) as well as number of weekly data transmissions. Lower right: communication notes between physicians and nurses on this patient.



Results

Participants

A total of 50 patients were eligible and contacted between January and September 2016. From these patients, 43 patients agreed to join the HerzMobil Tirol program. Seven patients left the program because of incompletion or technical problems. Moreover, 1 patient died before completion. Of the remaining 35 patients, 28 completed all questionnaires. Mean age of these patients was 67 years (range: 43-86 years), 23 were male, and 5 were female (see Table 1).

The patients had between none and 6 comorbidities (median: 2), mostly history of myocardial infarction (7 patients), light

liver disease (5 patients), and peripheral arterial occlusive disease (5 patients). A total of 15 of the 28 patients (15/28, 54%) had used computers before the study, and 16 patients (16/28, 57%) had used mobile phones.

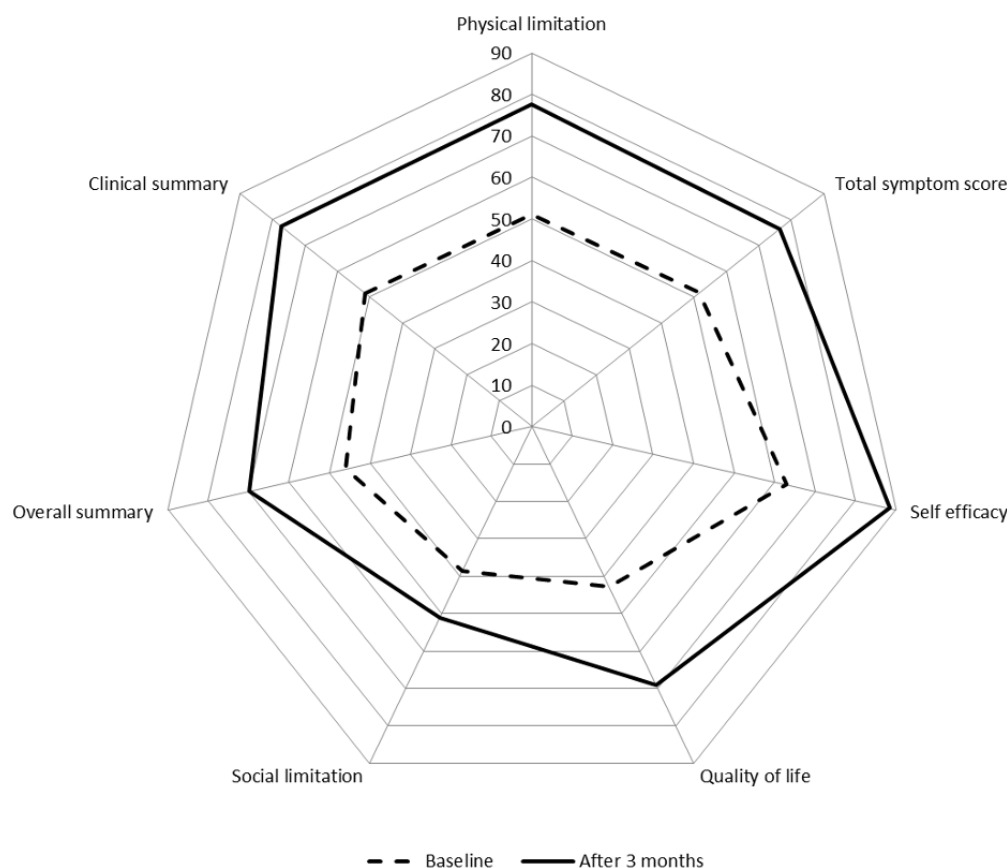
Kansas City Cardiomyopathy Questionnaire Health Status

The overall summary KCCQ score (range: 0-100) increased from 46.2 at baseline to 69.8 after 3 months. The clinical summary KCCQ score increased from 51.4 to 77.3 (see Figure 3). Physical limitation increased from 51.1 to 77.5; self-efficacy increased from 63.0 to 88.4; quality of life increased from 42.9 to 69.1; social limitation increased from 38.5 to 51.1; and the total symptom score increased from 51.6 to 76.3. All changes were significant ($P < .05$) with the exception of social limitation.

Table 1. Number and age of participants.

Participants	All	Male	Female
Recruited for study, n (%)	50 (100)	37 (74)	13 (26)
Never beginner, n (%)	7 (100)	5 (71)	2 (29)
Dropped out or died during study, n (%)	8 (100)	5 (62)	3 (38)
Completed participation in study, n (%)	35 (100)	27 (77)	8 (23)
Mean age of participants in years (minimum-maximum)	67.1 (43-86)	65.6 (43-6)	71.5 (43-85)
Completed all questionnaires (return rate)	28 (80)	23 (85)	5 (63)

Figure 3. Change of health status (Kansas City Cardiomyopathy Questionnaire score; n=28; 0=minimum, 100=maximum) at baseline and after 3 months.



European Heart Failure Self-Care Behavior Scale, Revised Into a 9-Item Scale, Self-Care Behavior

EHFScB-9 self-care behavior score after 3 months was 13.2 (SD 4.3), range was 9 to 22, with 9=best self-care behavior (see Figure 4).

Patient Satisfaction

In all 6 dimensions of the Information System Success Model survey (range 0%-100%), mean results were 86% and higher (Figure 5), indicating high patient satisfaction.

A majority of patients (25/28, 89%) considered HerzMobil Tirol a good idea (D2, Figure 6) and would recommend it to others (D3). More than half of the patients (15/28, 53%) indicated that they would like to continue to use the telemonitoring system (F4). After 3 months, the majority of patients (22/28, 79%) indicated that they feel confident to be able to take care of their health without telemonitoring (F3).

In free text answers, 11 patients stated that they feel more secure because of the daily monitoring, and 4 patients stated that they are more confident in actively managing their disease. Moreover, 6 patients noted that the technology was somewhat unreliable and that the mobile phone was too complex for them.

Figure 4. European Heart Failure Self-Care Behavior scale, revised into a 9-item scale, self-care behavior scores (n=29) after 3 months.

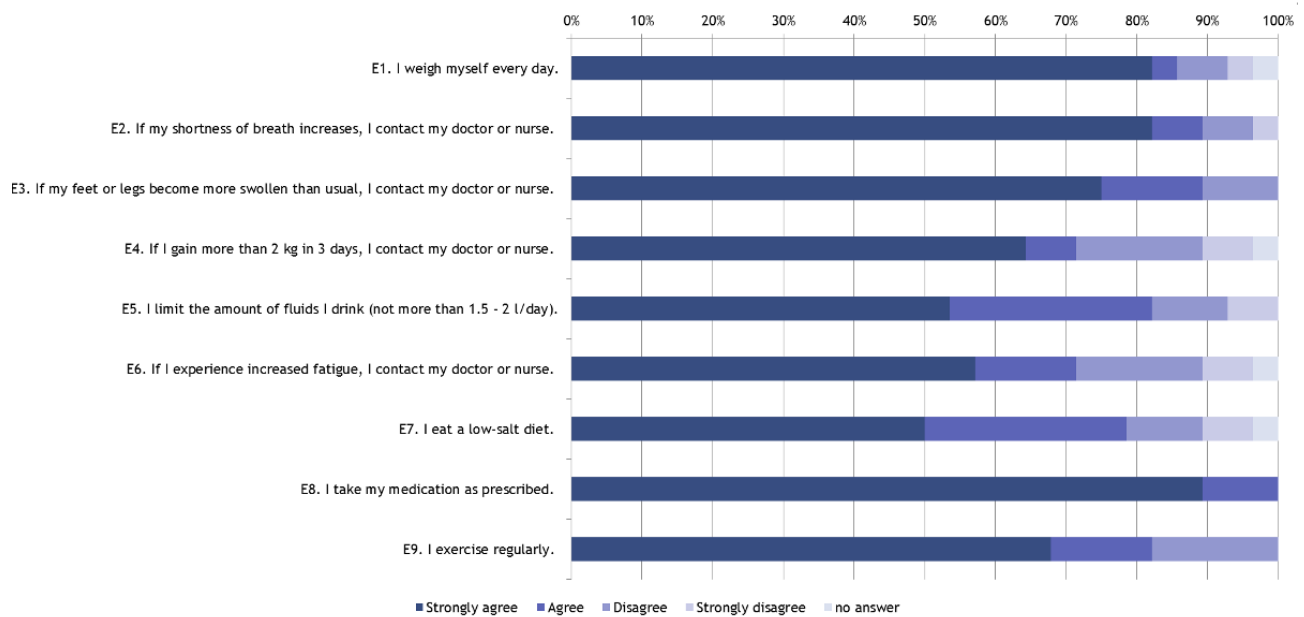


Figure 5. Aggregated results from the Information System Success Model survey (n=28) after 3 months (minimum=0%, maximum=100%). Information quality 95.2%; system quality 92.3%; service quality 95.8%; user satisfaction 95.2%; net benefit 87.1%; and intention to use 86%.

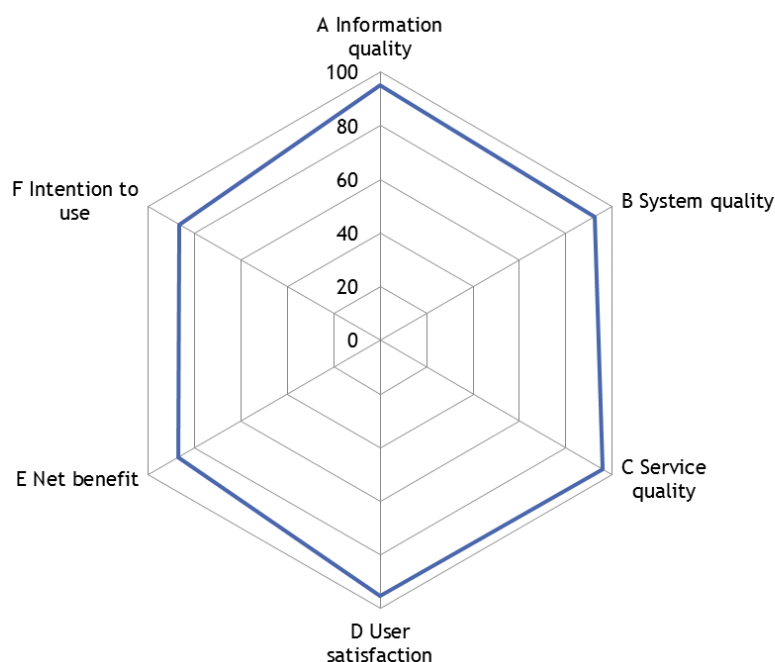
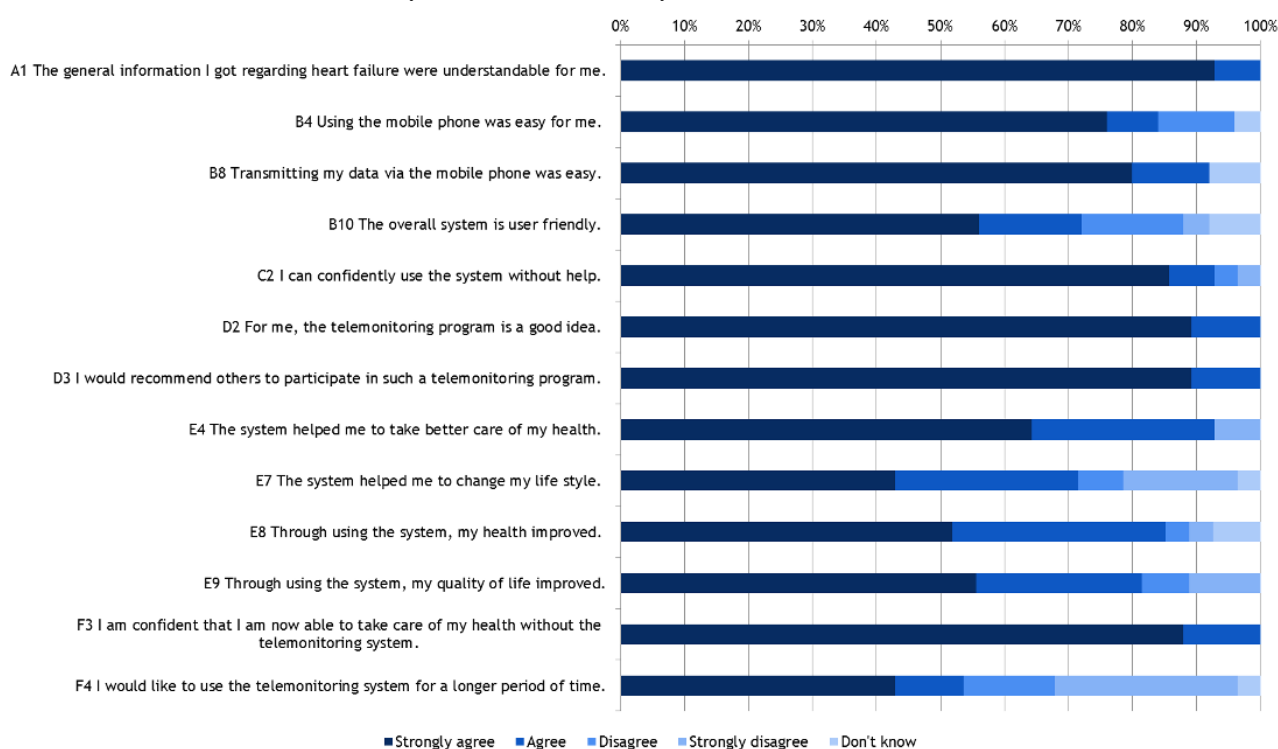


Figure 6. Selected items from the Information System Success Model survey (n=28) after 3 months.

Discussion

Several studies already showed that home telemonitoring could reduce hospitalizations and mortality for patients with heart failure [25]. Here, we show our data on feasibility of home telemonitoring as part of a multidisciplinary postdischarge disease management program in everyday clinical practice. In addition, we will present lessons learned derived from this pilot study for further rollout of the program in the state of Tyrol.

Summary of Study Results

Our results indicate that health status clearly improved in the most vulnerable phase of heart failure, as indicated by improved KCCQ and EHFS_{CB-9} scores. Patients reported a high level of satisfaction with the quality of the system and the support and with the individual benefits of participation and showed good self-care behaviors after 3 months. In particular, the elderly patients seemed quite capable of using the mobile phone for data acquisition and data transmission. Only 5 patients (18%) stated that they received help from relatives. Thus, although age is often seen as a barrier to the use of technology [26], we found that this barrier can be addressed with patient education, good support by relatives, and a dedicated helpline. It must be noted, however, that 7 patients left the HerzMobil Tirol program because of in compliance or technical problems and were thus not included in data analysis.

HerzMobil Tirol as a Disease Management Program

The transition between hospital and home after admission for acute heart failure is a vulnerable period marked by unplanned emergency room visits, hospital readmissions, and a high risk of death [8,9]. The importance of effective communication between health care professionals involved with inpatient and community care [27], intense patient education to improve

self-empowerment, constant medication reconciliation and therapy optimization according to prevailing guidelines, structured outpatient follow-up for early indicators of clinical decompensation for a seamless transition from the hospital to community, and the central role of specialized heart failure nurses in this complex interplay is well recognized [11,27-29]. A reliable and stable telemedical network is the facilitator for such an organizational network.

HerzMobil Tirol is designed as such a multidisciplinary postdischarge disease management program for heart failure patients using a telemedical monitoring system incorporated in a comprehensive network of specialized heart failure nurses, nonhospital-based physicians, and referral centers. The telemonitoring system HerzMobil Tirol relays physiological data, information on patient's symptoms, and drug adherence for review to the health care professionals. The gradual development of the program finally resulted in the decision to offer a concentrated 3-month health care service covering the most vulnerable phase after discharge.

Nonhospital-based network physicians and heart failure nurses play a central role in this network program. Shared decision making and effective communication between heart failure nurses and network physicians are based on the well-defined workflow and responsibilities. Intense education of patient and their families within and outside the hospital by trained heart failure nurses and structured follow-up by network physicians are central for sustained disease stabilization. Meticulous pre- and postcare evaluation of patients ensures quality control, thus continuous optimization of the program.

Comparison With Other Studies

Health status of patients at discharge in HerzMobil Tirol measured by the KCCQ score was lower than that in other

studies, indicating better health status. Improvement in the KCCQ score after 3 months was higher than that in other studies (Figure 7): Boyne et al measured KCCQ for 382 patients with stable heart failure who received 6 months of daily telemonitoring, combined with 2 hospital check visits [30]. Qian et al measured KCCQ for 1427 patients with recent inpatient treatment for heart failure who received 6 months of daily telemonitoring [31]. Bekelmann et al [32] measured KCCQ for 392 patients with known heart failure who participated in a collaborative heart failure network combined with 6 months of telemonitoring. Köberich et al [33] measured KCCQ for 122 patients who were hospitalized due to heart failure, received special training, and then a 3-month phone-based monitoring. Although the studies of Boyne and Bekelmann included patients with stable heart failure, Qian and Köberich included patients with unstable heart failure, which is comparable with HerzMobil Tirol. Still, patients in HerzMobil Tirol showed the strongest improvement of the KCCQ score (Figure 7).

Self-care behavior measured by the EHfScB-9 after 3 months of care (mean: 13.2) indicated better self-care behavior compared with the following studies: Lee et al reported a mean EHfScB-9 score of 18.1 for 200 heart failure patients [22]. Koeberich et al found a mean EHfScB-9 score of 19.9 for 109 heart failure patients [23]. The same group showed a mean EHfScB-9 score of 19.6 at baseline and of 16.5 after 3 months for a group of 58 discharged heart failure patients who received special training, combined with telephone support over 3 months [33]. Comparatively, the mean EHfScB-9 score in HerzMobil Tirol patients of care was lower.

Limitations of the Study

The study was designed as a pilot study without a control group. Hence, analyses are limited to pre- and postcomparisons and comparison with published data. It cannot be entirely excluded that improvement in health status after 3 months is part of a gradual stabilization after hospitalization. Yet, comparison with published data from other studies suggests a better outcome of patients in HerzMobil Tirol with regard to health status and self-care behavior.

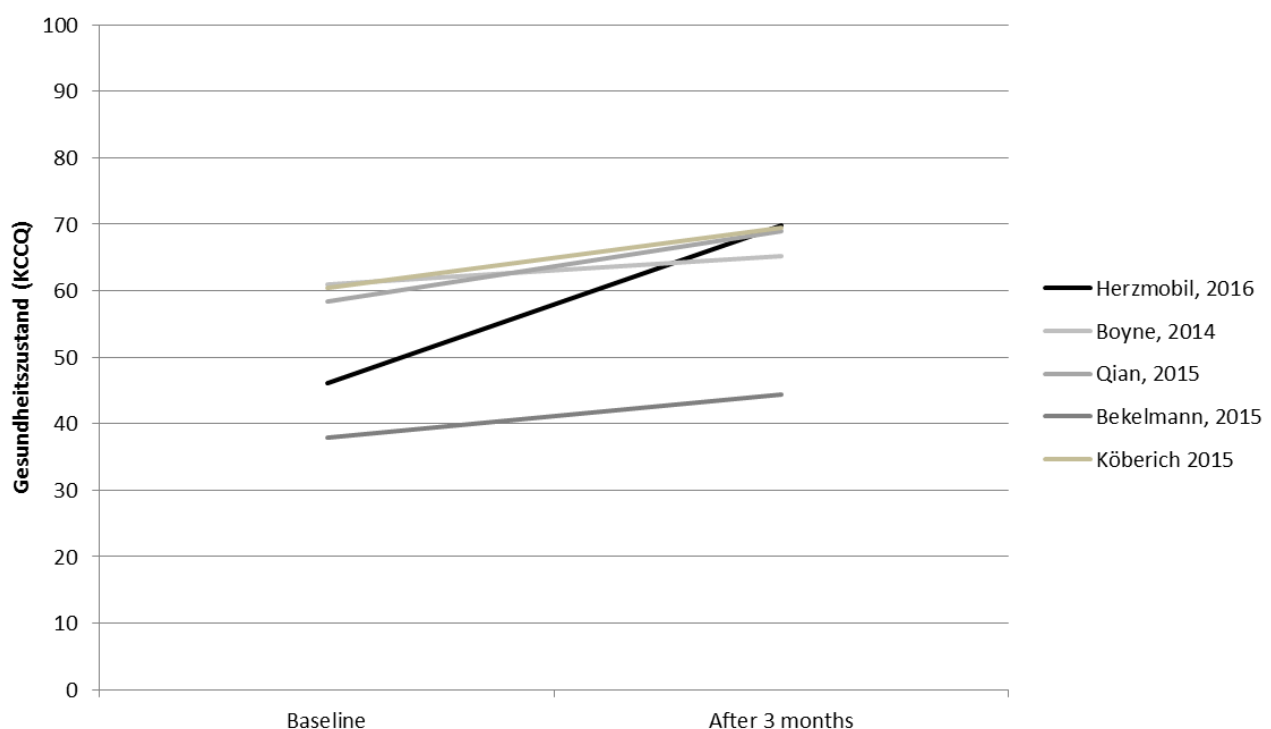
Self-care behaviors were measured only at the end of the third month. To address this limitation, self-care behaviors of HerzMobil Tirol patients were also compared with data from other studies.

Outcome was measured using survey instruments. As of now, no long-term evaluation of rehospitalization and other adverse events is available for HerzMobil Tirol.

Implications and Recommendations for Practice

Telemonitoring for heart failure patients is not new, and several studies have established the feasibility of these approaches and its positive impact on clinical outcome [34-36]. However, HerzMobil Tirol is a telemonitoring project that was able to transform from a pilot study to a routine care project. On the basis of the experiences in transferring from a pilot to routine care, several lessons can be derived. They were developed in repeated workshops with network physicians and network nurses and may be useful for other disease management programs for heart failure. These recommendations are also supported by a recent position paper on disease management of heart failure of the Austrian Society of Cardiology that also stresses these aspects [17].

Figure 7. Change of health status (Kansas City Cardiomyopathy Questionnaire, KCCQ score) in HerzMobil Tirol at baseline and after 3 months in comparison with 4 other studies.



First, it is crucial to decide on the temporal positioning of managed care in the trajectory of heart failure. In the vulnerable period that is directly after discharge, focus in HerzMobil Tirol is on the seamless transition from the hospital to the telemedical network and on a 3-month monitoring. Effective communication between health care providers in various sectors is mandatory in this phase. This requires a well-organized telemedical platform that can be easily and safely accessed by all stakeholders. In contrast, in programs supporting the chronic phase, the length of telemonitoring is often not clearly defined, and communication between sectors of care, in general, is less challenging here.

Second, in the vulnerable period, patient education and constant optimization of disease-modifying therapy are particularly important. Defining the predominant gaps in health care in a region and building HerzMobil Tirol on existing health care infrastructures are essential for a high acceptance by payers and caregivers.

Third, a solid network structure and well-defined processes are more important than the specific telemonitoring tools that are used. For example, remote follow-up either by telephone or by telemonitoring must be made available in a well-functioning network of health care professionals to ensure constant review and timely response.

Fourth, the implementation process must be clear and transparent and avoid work overload, particularly to the heart failure nurses. A dedicated program coordinator is helpful to orchestrate all stakeholders and manage efficient cooperation of all partners. This strengthens the acceptance by health care professionals. In addition, legal aspects and adequate remuneration of stakeholders have to be settled.

Fifth, because of the central role of heart failure nurses, providing specialized training for nurses is a mandatory prerequisite before commencing such a program. In addition, meticulous introduction of all stakeholders into the processes and clear definition of the particular role as well as constant training for the entire personnel has to be organized.

Sixth, the first months after commencing a program are mostly dedicated to the optimization of organizational issues. Hence, it is helpful to avoid inclusion of multimorbid patients in this initial phase to not push the boundaries of the program by too complex interventions.

Summarizing, to establish a multidisciplinary postdischarge disease management network for heart failure patients, a large

number of organizational, technical, legal, and economic questions have to be answered and tested in pilot projects before such a program can be transferred from a project status into routine care. In the case of HerzMobil Tirol, this process took 6 years overall.

Conclusions

The steady increase in the number of chronic patients due to the demographic trend and the ongoing medical progress shows the weaknesses of the Austrian health care system. A historically grown separation between in-patient and out-patient care leads to an insufficient consideration of the medical needs of patients along with their carers.

Telehealth care, as HerzMobil Tirol, can to some extent solve this problem and should be seen as a strategical investment to improve medical care. The telemedical information and communication technologies used in HerzMobil Tirol can help to overcome organizational and sectoral boundaries.

The role and competencies of the involved health professionals also have to be defined. HerzMobil Tirol has highlighted, for example, that specialized heart failure nurses will gain importance. Especially for Austria, which has a lot of potential for improvements in this field, this is an important insight.

Telehealth care is far more than a technology project. Instead, it enables lasting innovations for the health care system. HerzMobil Tirol showed that telehealth care is a trigger for change and innovation in the health care system. This is an important finding, especially in complex and change-resistant systems such as the health care system.

HerzMobil Tirol was officially introduced in the province of Tyrol in July 2017. This is the first telehealth care program in Austria regularly financed by health insurances. On the basis of the positive experiences, the province of Tyrol is also willing to establish further telehealth care projects in other relevant indications. The rollout in Tyrol will be done gradually. At the moment, specific regions are selected where more HerzMobil Tirol networks of hospital(s), physicians, and nurses are being established. Experiences from the already running regions are made available to the new regions to facilitate fast rollout. Further evaluation of long-term impact of HerzMobil Tirol is planned. Experiences of HerzMobil Tirol are also made available to other Austrian federal states, yet Austrian-wide rollout is dependent on political and financial decisions that are outside the control of the project team.

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Conflicts of Interest

HerzMobil Tirol is funded by the state of Tyrol. RMO and GP are project managers of HerzMobil Tirol. Other authors have no conflicts of interest to declare.

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Abbreviations

- EHFScB9:** European Heart Failure Self-Care Behavior Scale
KCCQ: Kansas City Cardiomyopathy Questionnaire
KIT: Keep-In-Touch

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Original Paper

Mobile Technology Utilization Among Patients From Diverse Cultural and Linguistic Backgrounds Attending Cardiac Rehabilitation in Australia: Descriptive, Case-Matched Comparative Study

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Abstract

Background: Barriers to attending cardiac rehabilitation (CR), including cultural and linguistic differences, may be addressed by recent technological developments. However, the feasibility of using these approaches in culturally and linguistically diverse patients is yet to be determined.

Objective: This study aims to assess the use of mobile technologies and features, as well as confidence in utilization across patients speaking different languages at home (ie, English, Mandarin Chinese, and a language other than English and Mandarin [other]) and are both eligible and physically suitable for CR. In addition, the study aims to determine the sociodemographic correlates of the mobile technology/feature use, including language spoken at home in the three groups mentioned above.

Methods: This is a descriptive, case matched, comparative study. Age and gender-matched patients speaking English, Mandarin and other languages (n=30/group) eligible for CR were surveyed for their mobile technology and mobile feature use.

Results: Participants had a mean age of 66.7 years (SD 13, n=90, range 46-95), with 53.3% (48/90) male. The majority (82/90, 91.1%) used at least one technology device, with 87.8% (79/90) using mobile devices, the most common being smartphones (57/90, 63.3%), tablets (28/90, 31.1%), and text/voice-only phones (24/90, 26.7%). More English-speaking participants used computers than Mandarin or "other" language speaking participants ($P=.003$ and $.02$) and were more confident in doing so compared to Mandarin-speaking participants ($P=.003$). More Mandarin-speaking participants used smartphones compared with "other" language speaking participants ($P=.03$). Most commonly used mobile features were voice calls (77/82, 93.9%), text message (54/82, 65.9%), the internet (39/82, 47.6%), email (36/82, 43.9%), and videoconferencing (Skype or FaceTime [WeChat or QQ] 35/82, 42.7%). Less Mandarin-speaking participants used emails ($P=.001$) and social media ($P=.007$) than English-speaking participants. Speaking Mandarin was independently associated with using smartphone, emails, and accessing the web-based medication information (OR 7.238, 95% CI 1.262-41.522; $P=.03$, OR 0.089, 95% CI 0.016-0.490; $P=.006$ and OR 0.191, 95% CI 0.037-0.984; $P=.05$).

Conclusions: This study reveals a high usage of mobile technology among CR patients and provides further insights into differences in the technology use across CALD patients in Australia. The findings of this study may inform the design and implementation of future technology-based CR.

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KEYWORDS

cultural and linguistic diverse; cardiac rehabilitation; technology; mobile technology; information technology

Introduction

Cardiac disease is a leading cause of morbidity and mortality worldwide [1]. Despite advancements in treatment and secondary prevention, the recurrence rate of cardiac events remains high [2], especially among specific sociodemographic groups, such as patients from culturally and linguistically diverse (CALD) backgrounds [3]. Cardiac rehabilitation (CR), a structured program of exercise and risk reduction education and counseling designed to promote healthy living with heart disease, effectively supports secondary prevention [4]. In addition, CR has been shown to reduce overall and cardiovascular-related morbidity and mortality, as well as hospital readmissions and length of hospital stay [5-11].

Despite established health benefits, CR remains underutilized. Globally, attendance rates remain as low as 15%-30% after a cardiac event [12-14], which, in fact, are attributed to provider-level barriers, such as the limited availability of services and inadequate referral, as well as patient-level characteristics, including old age, being female, and low socioeconomic status [14-20]. For example, people of CALD background are underrepresented in CR services [6,15,19,21,22]. Besides general barriers to CR, CALD patients experience unique challenges, such as limited English language proficiency, which render them less likely to be referred [21,23]. Transport difficulty [23], financial issues, and misperception of CR [23,24] are additional barriers to using the services once referred.

Of note, low attendance in CR among CALD patients is a characteristic of Western countries. Australia comprises an increasingly heterogeneous population. In 2015, approximately 6.7 million (28.2%) of the total Australian population were born outside of Australia [25]. At present, 1 in 5 Australians speaks a language other than English at home, of which Mandarin, Italian, and Arabic are the most common [26]. Chinese is one of the most rapidly growing CALD groups and has doubled in the past decade, currently constituting 2.2% of the Australian population [25]. A recent meta-analysis reported that Chinese living in Western countries have poorer short-term survival outcomes after a cardiac event [27] compared with Caucasians, which could be attributed to poor disease self-management [28]. In addition, Chinese immigrants are documented to be underserved by the current healthcare system because of incongruence between needs for support and available healthcare services such as CR services [29-31].

The ubiquity of mobile phones and advancements in mobile technology have facilitated the advent of new preventive delivery strategies which supplement center-based CR services to expand capacity. Contemporary mobile technology-based

CR aims to monitor physical function, promote medication adherence, manage lifestyle, and provide health education to aid individuals manage their cardiac conditions [32,33]. The emerging evidence reveals that these programs could potentially attain similar benefits compared with center-based CR in decreasing risk factors and mortality in patients with coronary heart disease (CHD) [34]. In addition, the mobile technology-based CR could reach traditionally “hard-to-reach” populations, as delivery is not constrained by language, time, or transportation [33,35-37]. Furthermore, mobile technology-based CR is cost-effective for both service providers and patients [38], as it can save up to 80% of travel costs for patients compared with center-based CR [37].

Despite this promising potential, little investigation has been conducted on the utilization of mobile technology and the feasibility of the mobile technology-based CR in patients. In fact, no study has assessed how CALD patients might differ in their use of mobile technology and related features compared with other patients. Perhaps, comprehending the utilization of technological devices and mobile features, as well as the factors related to the use of these technologies among CALD patients, would facilitate the identification of CALD patients who might benefit from the mobile technology-based intervention.

This study aims to assess the relative use of mobile technologies and features, as well as confidence in utilization across patients speaking different languages at home [ie, English, Mandarin Chinese, and a language other than English and Mandarin (other)] and both eligible and physically suitable for CR. In addition, the study aims to determine the sociodemographic correlates of the mobile technology/feature use, including language spoken at home in the three groups mentioned above.

Methods

Study Design

This descriptive, case-matched, comparative study collaborated with a larger study that investigated cardiac patients' use of mobile technology and variations among age groups after adjusting for education, employment, and confidence in using the mobile technology. The larger study surveyed 282 English-speaking CR patients on the mobile technology use in nine hospital and community sites across metropolitan and rural New South Wales, Australia [39]. This study enrolled 30 English-speaking patients from the large study to match with a separated Mandarin-speaking group and reported on multilingual groups recruited from this study site that has not been published previously.

Setting

The study was conducted in a metropolitan teaching hospital in South Eastern Sydney Local Health District (New South Wales, Australia). The selected health district represented approximately 12% of the New South Wales population; with 37% born in countries outside of Australia and 27% in a non-English-speaking country, the selected health district comprised the most diverse population [40]. Of all, China-born residents constituted the largest proportion of the population from a non-English-speaking background, followed by people born in Greece and Indonesia. Of those born in countries outside of Australia, approximately 10% reported that they either do not speak English well or at all [41].

Sample Eligibility and Exclusion Criteria

We recruited a stratified and matched convenience sample in this study. The inclusion criteria were as follows: (1) the presence of a cardiac diagnosis, such as angina, myocardial infarction (MI), ischemic heart disease (IHD), valve surgery, coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI), the absence of severe comorbidities, and physically suitable to be referred to the exercise-based group CR program; and 2) could speak and understand adequate English or Mandarin for consent and questionnaire processes. Patients with a neurocognitive disorder were excluded from the study. We matched each Mandarin-speaking patient by age (within ± 5 years) and gender with a patient from the other two linguistic backgrounds to minimize the demographic variability across groups. Furthermore, the sample size was predetermined to be 30 per group per previous study protocols [42,43].

Measurement

We used a previously developed checklist to collect sociodemographic and clinical data [44]; the information comprised participants' age, gender, country of birth, ethnicity, home language, education, marital and employment status, and admission diagnosis.

Then, we developed the survey based on previously validated and used questionnaires where possible; the list of the most common devices (ie, smartphones, computers, and tablets) and mobile features (ie, browsing the internet, text messages, emails, and social media) was based on previously determined parameters [45,46]. The survey comprised 11 questions overall, and the questionnaire was pilot-tested in a small sample ($n=15$) of cardiac patients similar to the sample. Moreover, the content of the questionnaire was reviewed and amended to improve the ease of use, accuracy, and specificity. Furthermore, the questionnaire was used in a larger study including 282 English-speaking patients [39].

Questions regarding each device were clarified using an illustration (Textbox 1). Most questions (questions 1, 3-9) were in the checklist format, where respondents ticked the technological devices or features that they (1) used, (2) used confidently, (3) would like to learn, and (4) used for health purposes. In addition, we developed a question (question 2) on self-efficacy in using a new computer program based on the speed with which participants could learn a new computer program and used a 4-point scale anchored with responses “very

slowly” (1) and “very quickly” (4). Furthermore, we included two open-ended questions (questions 10 and 11) where respondents could provide additional information on the mobile app they used along with details of the health-related app. Notably, respondents who answered the first question with “not using any technology” were not required to complete the remainder of the questionnaire.

Finally, the questionnaire was translated into Mandarin by a certified translator and back-translated for verification. A minor amendment was made to item seven that inquired about the videoconferencing use—WeChat or QQ was surveyed instead of Skype or FaceTime because it was more popular in Mandarin-speaking communities.

Procedure

The study protocol was approved by Northern Sydney Local Health District Human Research Ethics Committee (LNR/15/HAWKE/450). All patients were screened for the eligibility by a CR staff (a clinical nurse specialist) or the bilingual researcher (LZ) upon their admission to a cardiac ward of the hospital or upon referral to the outpatient CR programs at the study site between April and September 2016. Those who fulfilled the inclusion criteria were approached by the CR staff or LZ to participate in the study and provided them with information and time to consider participation. Mandarin-speaking patients were approached by a bilingual Mandarin-speaking CR staff member or LZ. All staff members were trained in using the questionnaire to ensure a standardized approach. Finally, patients who provided written consent were surveyed in this study. The CR staff or LZ collected demographic and clinical data of enrolled patients, and any uncertainty regarding diagnoses was clarified using the medical records. Notably, the questionnaire was self-administered. Of 134 CR patients approached, 10 declined because of the lack of interest, with the final response rate of 92.5%. We surveyed 94 patients from English and “other” language-speaking background for the ongoing matching purpose; of these, 60 participants were matched and enrolled in the final data analysis.

Statistical Analyses

The responses in Mandarin were translated into English by LZ for data entry. Data analyses were performed using IBM SPSS, version 24. In addition, means, SDs, frequencies, and percentage were used to present the demographic and clinical characteristics of the study cohort. Frequencies and percentages were used to describe technology device and feature use, confidence in use, and use for health. Furthermore, categorical variables were reported as a percentage within a language group and tested for differences across language groups using chi-square tests.

We used generalized linear mixed model analysis (GLMM) to ascertain whether the language spoken at home correlated with the mobile device and feature use. In addition, GLMM was used as patients in each language group were selected to be matched for age and gender. Each group of three (one from each language group) was assigned the same group identification (ID; 30 in all) besides a unique individual ID. As outcomes (ie, whether specific types of technology or features were used) were dichotomous, we selected the binary logistic regression function.

Textbox 1. Technology questionnaire.

1. Which of the following do you currently use?
Computers, Tablets, Mobile phones, Smartphones, Activity trackers, None

2. How quickly can you work out how to use new computer programs? Select one answer.
Very slowly, Fairly slowly, Fairly quickly, Very quickly

For the following questions apply to:
Computers, Tablets, Mobile phones, Smartphones, Activity trackers, None

3. I feel confident using these devices:

4. I share health information through these devices:

5. I do not use these devices but would like to learn:

6. I think I could easily learn how to use these devices:

7. What do you regularly use your mobile/smartphone or tablet for?
Voice calls, Text messages, Skype or FaceTime (WeChat or QQ), Browsing the internet, Checking emails, Social media, Schedule/calendar, Using mobile apps

8. Do you use the internet for accessing information on any of the following?
Health conditions, Medication, Heart conditions, Heart treatments, Lifestyle changes, Health resources

9. Do you use the internet for communicating with?
Health professionals, other heart patients

10. How many apps are currently on your phone?

11. Please list any health-related apps you use:

Adjusted models comprised age, gender, years of education, marital status, and employment status in the model along with language spoken at home. Furthermore, we explored devices and mobile features that were reported the most prevalent in participants' report or those that had the highest potential for CR interventions. Then, we assessed correlates of using devices (ie, smartphone, computer, and tablet) and mobile features (ie, the internet, emails, apps, and social media). Finally, the internet use for health was categorized into individual items, including sharing health information, accessing information about general health, medication, and lifestyle. In this study, odds ratios (OR), 95% CI, and *P* values are reported, and $\alpha=0.05$. $P \leq .05$ was considered statistically significant (two-tailed).

Results

Descriptive Statistics

In this study, the final sample comprised 90 patients (mean age 66.7, SD 13 years; range 46-95 years); of these, 53.3% (48/90) were males, 55.6% (50/90) completed high school, and 63.3% (57/90) were not in the workforce. More than half of the participants were admitted with CHD (52/90, 57.7%), with the leading procedures or diagnoses being PCI, angina, and MI (Table 1). In the "other" language group, the most common languages spoken at home were Greek (7/30, 23.3%), Arabic (6/30, 20%), and the remainder comprised Macedonian, Vietnamese, Hungarian, Italian, Russian, Indonesian, Portuguese, Philippine, Japanese, Samoa, French, Bulgarian, and Czech language. We observed no significant difference in education, marital status, living arrangement, and employment status across the three home language groups.

Use of Mobile Technology by the Home Language Group

Most participants (82/90, 91.1%) reported using, at least, one of the following devices: computers (desktops or laptops), tablets, smartphones, text/voice-only phones, and activity trackers (Figure 1). Mobile devices, such as tablets, smartphones, text/voice-only phones, and activity trackers, were used by most participants ($n=79$, 87.8%), the most common of which were smartphones (57/90, 63.3%), followed by tablets (28/90, 31.1%), and text/voice-only phones (24/90, 26.7%). In addition, 33.3% (8/24) of text/voice-only phone users displayed their interest in learning to use a smartphone in the future. The mean score on how quickly one could learn a new computer program was 2.16 (SD 1.0), with 1 representing "very slowly," 2 representing "fairly slowly," 3 representing "fairly quickly," and 4 representing "very quickly," suggesting that the participants on average could learn a new computer program but might require time.

In this study, the three language groups were similar in the mobile technology use, except for the smartphone use. The proportion of smartphone users in the Mandarin-speaking group was significantly higher compared with "other" language-speaking group (80.0% vs 53.3%; $P=.03$). The confidence in the current mobile technology use was similar across groups, except for the confidence in using text/voice-only phones. A larger proportion of participants in the "other" language-speaking group were only confident in using text/voice-only phones compared with the Mandarin-speaking group (51.9% vs 17.2%; $P=.006$).

Table 1. Sample characteristics and technology use compared by the home language group.

Characteristics	Overall	English ^a	Mandarin ^b	Other ^c	<i>P</i>
Age (mean, SD)	66.7 (13.1)	66.6 (13.7)	66.9 (13.9)	66.4 (12.0)	.99
Gender (male), n (%)	48 (53.3)	16 (53.3)	16 (53.3)	16 (53.3)	>.99
Completed high school, n (%)	50 (55.6)	15 (50.0)	19 (63.3)	16 (53.3)	.56
Employed, n (%)	33 (36.7)	13 (43.3)	9 (30.0)	11 (36.7)	.56
Married or partner, n (%)	62 (68.9)	20 (66.7)	24 (80.0)	18 (60.0)	.39
Living with family, n (%)	75 (83.3)	23 (76.7)	29 (96.7)	23 (76.7)	.06
Admitted with CHD ^d , n (%)	52 (57.7)	16 (53.3)	17 (56.7)	19 (63.3)	.65
Technology use					
Mobile technology ^e , n (%)	79 (87.8)	23 (76.7)	29 (96.7)	27 (90.0)	.06
Mobile apps, n (%)	42 (46.7)	18 (69.2)	14 (48.3)	10 (37.0)	.06
Learn a new computer program (1—lowest, 4—highest), mean (SD)	2.16 (1.00)	2.54 (0.99)	1.97 (0.91)	2.00 (1.04)	.06

^aEnglish-speaking group.

^bMandarin-speaking group.

^cLanguage other than English and Mandarin.

^dCHD: coronary heart disease.

^eThe mobile technology includes tablets, smartphones, text- or voice-only phones, and activity trackers.

Figure 1. Technology device use by home language group.*Mandarin-speaking group vs Language other than English and Mandarin speaking group ($P=.03$); **English-speaking group vs Mandarin-speaking group ($P=.003$); English-speaking group vs Language other than English and Mandarin speaking group ($P=.02$).

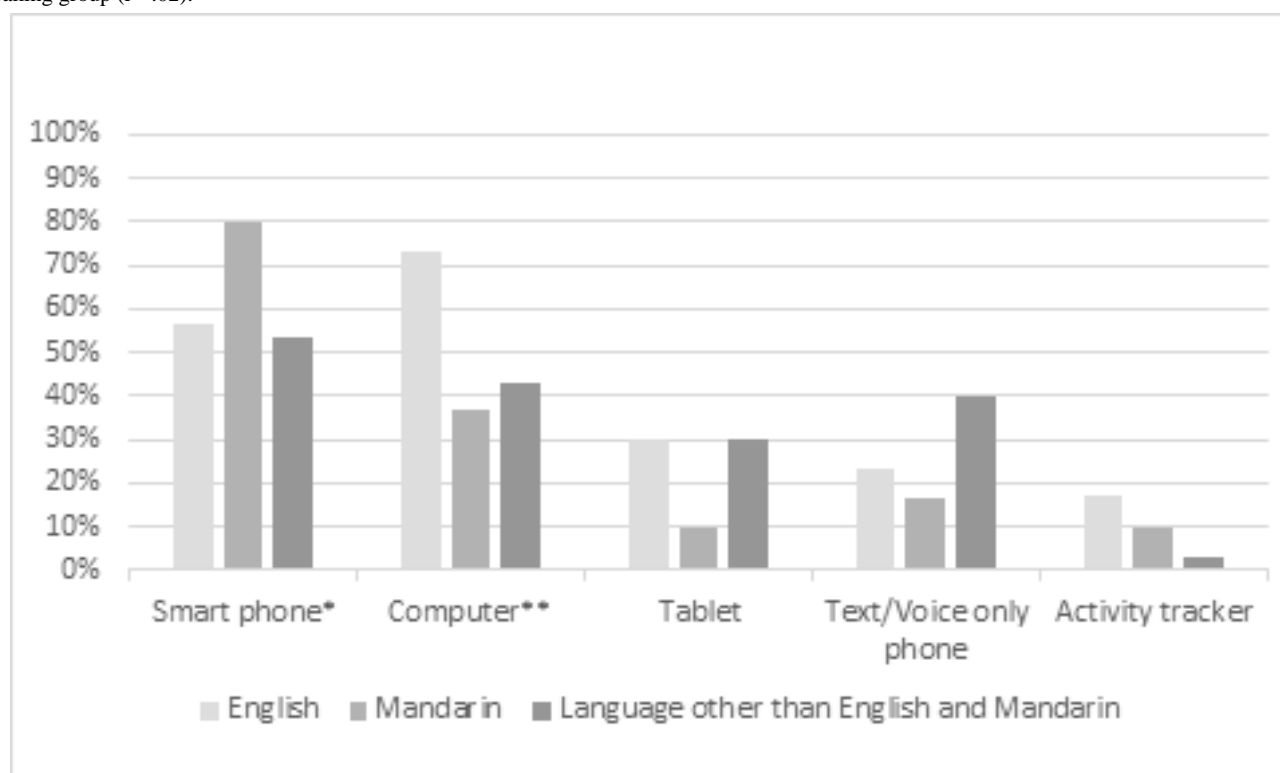
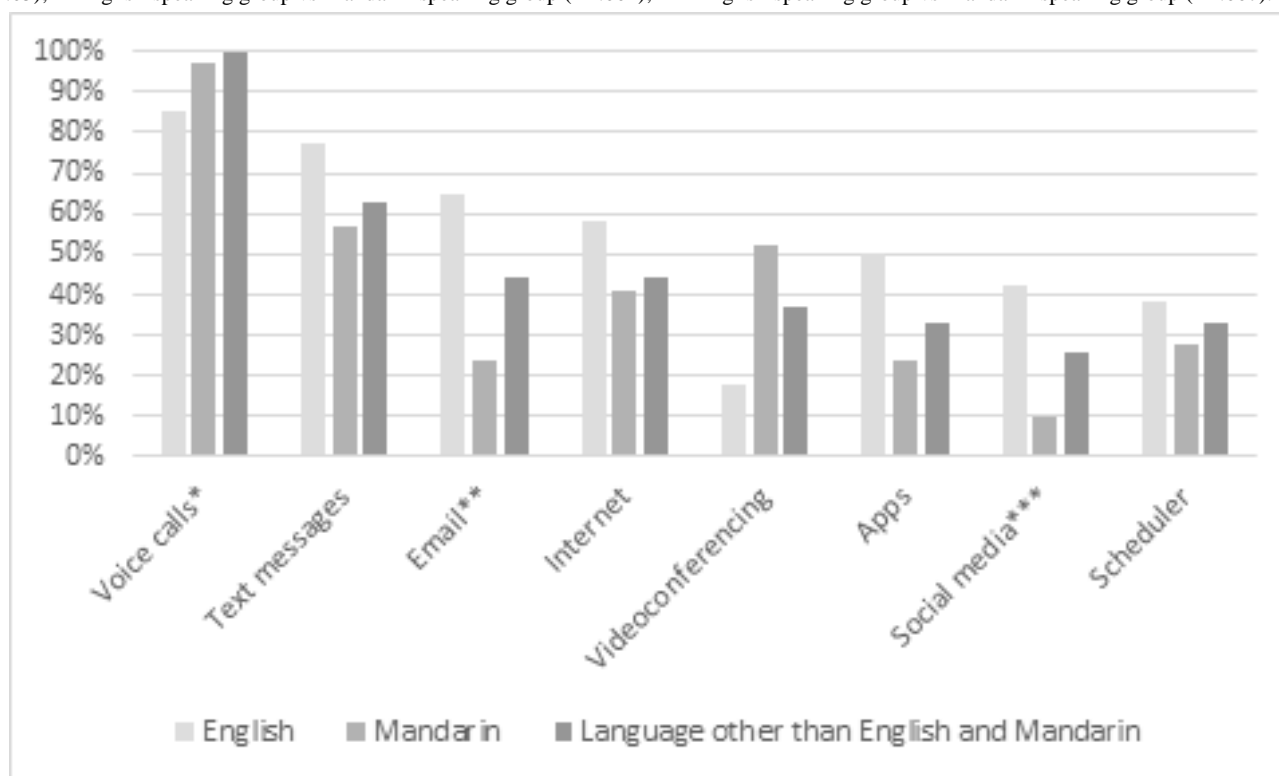


Figure 2. Technology feature use by home language group. *English-speaking group vs Language other than English and Mandarin speaking group ($P=.05$); **English-speaking group vs Mandarin-speaking group ($P=.001$); *** English-speaking group vs Mandarin-speaking group ($P=.007$).



However, computer use significantly differed across home language groups, with more English-speaking participants using computer compared with Mandarin or “other” language-speaking participants (English: 73.3% vs Mandarin: 36.7%, $P=.003$; English: 73.3% vs “other” language: 43.3%; $P=.02$). Furthermore, the proportion of participants confident in using a computer was significantly higher in the English-speaking group compared with the Mandarin-speaking groups (73.1% vs 35%; $P=.003$).

Use of Mobile Features by Language Group

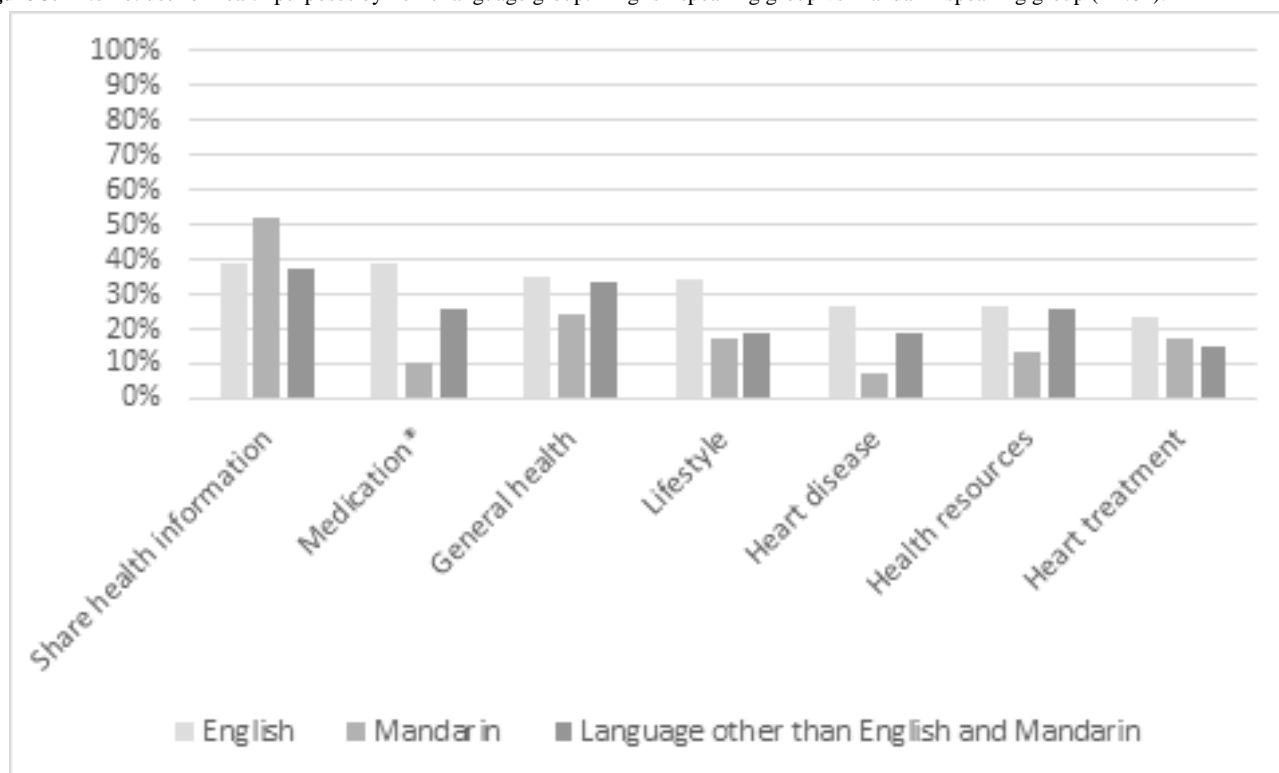
Mobile features most commonly used among participants using mobile device were voice calls (77/82, 93.9%), text messages (54/82, 65.9%), the internet (39/82, 47.6%), emails (36/82, 43.9%), videoconferencing (Skype or FaceTime [WeChat or QQ]; 35/82, 42.7%; [Figure 2](#)). In addition, fewer Mandarin-speaking participants used emails (24.1% vs 65.4%; $P=.001$) and social media (10.3% vs 42.3%; $P=.007$) compared with English-speaking participants.

Overall, 44.4% (36/81) of the participants who engaged with technology used the internet for health ([Figure 3](#)), used most often for sharing health information (35/81, 42.7%) and accessing information about general health (25/81, 30.5%), medication (20/81, 24.4%), and lifestyle (19/81, 23.2%). We

observed no significant difference across groups in using the internet for health, except that a higher percentage of English-speaking participants accessed the web-based medication information than Mandarin-speaking participants (38.4% vs 10.4%; $P=.02$).

Correlates of Using Mobile Devices and Features

After adjusting for age, gender, years of education, marital status, and employment status, Mandarin-speaking participants exhibited increased odds of using smartphones (OR 7.238, 95% CI 1.262-41.522; $P=.03$) but decreased odds of using emails (OR 0.089, 95% CI 0.016-0.490; $P=.006$), and accessing the web-based medication information (OR 0.191, 95% CI 0.037-0.984; $P=.05$) compared with English-speaking participants ([Tables 2](#) and [3](#)). In addition, other factors associated with mobile devices and features use; for an additional year in age, the odds of using smartphones and emails decreased (OR 0.118, 95% CI 0.809-0.961; $P=.005$; OR 0.104, 95% CI 0.820-0.978; $P=.02$). Furthermore, participants who were employed exhibited increased odds of using Apps and social media compared with their nonworking counterparts (OR 6.052, 95% CI 1.256-29.175; $P=.03$; OR 16.455; $P=.01$). Male participants exhibited decreased odds of using a tablet compared with females (OR 0.163, 95% CI 0.044-0.600; $P=.007$).

Figure 3. Internet use for health purposes by home language group.*English-speaking group vs Mandarin-speaking group ($P=.02$).**Table 2.** Correlates of using technological devices, based on logistic regression models mutually adjusted for all variables listed in the table.

Characteristic	Smartphones			Computers			Tablets		
	OR ^a	95% CI	<i>P</i>	OR	95% CI	<i>P</i>	OR	95% CI	<i>P</i>
Age	0.882	0.809-0.961	.005	0.979	0.919-1.043	.51	0.974	0.913-1.039	.42
Gender (male)	0.618	0.141-2.703	.52	0.949	0.271-3.319	.93	0.163	0.044-0.600	.007
Years of education	1.093	0.935-1.278	.26	1.163	1.001-1.350	.05	1.122	0.973-1.295	.11
Married	3.258	0.757-14.018	.11	3.583	0.863-14.874	.08	2.64	0.685-10.175	.16
Employed	2.114	0.247-18.106	.49	7.537	1.366-41.602	.02	2.718	0.542-13.629	.22
Language									
Mandarin vs English ^b	7.238	1.262-41.522	.03	0.120	0.027-0.546	.007	1.361	0.371-4.991	.64
Other vs English ^c	0.948	0.200-4.490	.95	0.223	0.051-0.974	.05	1.282	0.344-4.772	.71

^aOR: odds ratio.^bMandarin-speaking group vs English-speaking group.^cLanguage other than English vs Mandarin-speaking group.

Table 3. Correlates of using mobile features, based on logistic regression models mutually adjusted for all variables listed in the table.

Characteristic	Internet			Emails			Apps			Social media		
	OR ^a	95% CI	P	OR	95% CI	P	OR	95% CI	P	OR	95% CI	P
Age	0.968	0.904-1.035	.33	0.896	0.820-0.978	.02	0.960	0.888-1.037	.30	0.947	0.861-1.042	.26
Gender (male)	1.228	0.357-4.230	.74	0.504	0.120-2.114	.34	1.239	0.340-4.521	.74	0.368	0.071-1.911	.23
Years of education	1.034	0.897-1.193	.64	1.106	0.954-1.283	.18	1.059	0.916-1.226	.43	0.956	0.808-1.131	.59
Married	1.915	0.477-7.696	.36	2.146	0.470-9.804	.32	2.634	0.595-11.662	.20	0.862	0.174-4.276	.85
Employed	4.332	0.897-20.924	.07	2.519	0.487-13.019	.27	6.052	1.256-29.175	.03	16.455	1.937-139.767	.01
Language												
Mandarin vs English ^b	0.579	0.140-2.397	.45	0.089	0.016-0.490	.006	0.297	0.065-1.354	.12	0.199	0.035-1.121	.07
Other vs English ^c	0.653	0.160-2.658	.55	0.345	0.075-1.588	.17	0.557	0.137-2.274	.41	0.529	0.123-2.285	.39

^aOR: odds ratio.

^bMandarin-speaking group vs English-speaking group.

^cLanguage other than English vs Mandarin-speaking group.

Discussion

Principal Findings

To the best of our knowledge, this is the first exploratory study on the mobile technology use among CALD patients in the CR setting. Overall, the study suggests that technology might provide an alternative secondary prevention delivery strategy in the future to bridge the gap between growing demands and limited resources, as population aging and CVD prevalence continues to rise. Given the increasing use of technology-based interventions in CVD secondary prevention, this study reveals the unique patterns of use among CALD patients. In addition, the findings indicate that a variation in technology use warrants consideration while developing or delivering technology-based CR to these groups. The study determined that CALD patients are not disadvantaged in using certain types of mobile technology; thus, technology-based interventions could offer a potential solution to overcome their barriers to attending CR, such as communication and transportation difficulties. Meanwhile, the technology use patterns among the study groups revealed that selecting appropriate delivery media is essential for reaching different patients groups to improve the CR uptake.

Although several CALD patients are non-computer users, possibly because they had few opportunities to acquire computer skills during their education and work [47,48], they are not disadvantaged in some mobile technology use, especially not in the smartphone use. Consistently, the smartphone ownership is the highest among CALD groups [49], offering a great promise for implementing smartphone-based interventions in these populations. An important principle for adapting health promotion interventions in CALD populations is to determine and address the barriers to access and participation to decrease disparities [50]. Traditionally, patients from CALD backgrounds

have been identified among those who are least likely to attend CR programs [51], especially if they do not speak English, do not drive a car, have lower education or income, or have cultural barriers such as embarrassment of participation [14,21,23,51]. Technology-based CR could potentially address these barriers, as the program can be adapted to different languages and is not constrained by facilities, transportation, and time. Furthermore, it can be used in a patient-preferred environment [51] to improve the patient's participation, engagement, and overall experience [38].

The variation in the mobile technology use among CALD groups warrants elucidation and accommodation when developing or delivering these interventions. In addition, evaluating the usage of mobile technology before developing or delivering to the targeted population is imperative. For instance, no overall significant difference has been reported in the internet use for health between CALD patients and others in this study, implying that internet-based interventions could potentially reach CALD as well as English-speaking patients. Evidence from this and other studies suggests that people from CALD backgrounds tend to access the internet more by smartphones rather than computers or laptops [49]. Thus, internet-based programs should be user-friendly for both computer and smartphone users to encourage participation. Furthermore, smartphone users use mobile features differently. For example, Mandarin-speaking patients tend to use emails less compared with English-speaking patients. Thus, email-based communication in CVD secondary prevention might not be feasible among certain CALD groups [47]. Reportedly, selecting an appropriate delivery method for CR interventions is the key to improving participation among CALD patients [52].

Overall, the ubiquity of mobile technology could potentially enable technology-based interventions in the future to fulfill

the increasing demand for CR in CALD patients. Presumably, the population aged >60 years will increase from the current 800 million (representing 11% of the world population) to >2 billion in 2050 (representing 22% of the world population) [53], which would result in a tremendous challenge for health care in dealing with the increasingly prevalent noncommunicable diseases such as CHD. Meanwhile, mobile technology ownership has also witnessed an exponential upsurge [54,55]. Unlike the initial digital divide that placed the computer use and internet access beyond the reach of many older and lower-income individuals, the mobile technology has been extensively adopted across populations [54,56]. A well-established interest in technology enabled CR [57,58], implies that this new form of intervention and delivery might provide an alternative to meet the increasing demands [59]. In addition, some preliminary evidence suggest that technology-based CR has the potential for cost-saving compared with center-based CR [37,38]. However, age-related differences in the mobile feature use suggest that voice call- and text message-based interventions could be superior in reaching current older CR patients [57,58]. Furthermore, apps- and social media-based interventions could have great potential for future CR delivery when young users of today become tomorrow's CR patient population [58].

Limitations

This study has several limitations. First, the predetermined sample size is relatively small, and the sample was enrolled from a single hospital in Australia, which might limit the generalizability of the findings to the larger CR population. However, this study does provide crucial insights into the future research. Second, this study primarily aimed to assess the role of Mandarin as a home language in the technology use compared

with other language groups. Given that English language users experience different challenges to non-English language users, we recruited two samples to compare with Mandarin-speaking patients. The "other" language-speaking group provides scope for comparison of the effects of a home language other than English that contrast Mandarin speakers. In addition, language spoken at home might be a marker for people's acculturation level and English language proficiency, which were not assessed. Further studies are required to investigate the subgroups of language and cultures within this diverse group. Furthermore, any differences identified might represent the CALD experience in Australia and, thus, might not be able to be extrapolated to CALD populations in other countries. Third, we did not correct alpha for multiple pairwise comparisons and acknowledge the risk of type I errors because of the exploratory nature of the study and the small sample size. Finally, data collection using self-administered questionnaires is subject to recall and social desirability biases. Hence, further studies should complement self-administered questionnaire with objective measures and in-depth investigation of the role of home language and other correlates of technology use.

Conclusions

This study reveals a high usage of mobile technology among CR patients and provides further insights into differences in technology use across CALD patients in Australia. The findings of this study could be used to guide the design and implementation of the technology-based CR. Furthermore, mobile technology-based CR interventions seem promising to patients from CALD backgrounds, and the identification of the relevant technology use is the key to a successful implementation.

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Conflicts of Interest

None declared.

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Abbreviations

- CABG:** coronary artery bypass graft
CALD: culturally and linguistically diverse
CHD: coronary heart disease
CR: cardiac rehabilitation
GLMM: generalized linear mixed model
IHD: ischemic heart disease
MI: myocardial infarction
PCI: percutaneous coronary intervention

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Viewpoint

Digital Health Innovation: A Toolkit to Navigate From Concept to Clinical Testing

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Abstract

Digital health technologies such as smartphone apps, Web-based platforms, and wearable devices are rapidly emerging as promising interventions for acute and chronic disease management, particularly in the field of cardiovascular medicine. However, there is limited guidance on how to effectively develop and rigorously test digital health interventions (DHIs). Through our experience with innovating Corrie, a smartphone-based app paired with a smartwatch and blood pressure monitor for myocardial infarction recovery in the acute setting, we aim to provide a toolkit for navigating the digital health technology development and clinical testing processes. The toolkit consists of 6 steps: step one emphasizes concept generation by defining a specific clinical problem and the existing solutions aimed to address it; step two aims to recruit a multidisciplinary team within an academic institution; step three leverages technology accelerators and industry partnerships; step four develops the digital health technology with continuous feedback from patient and family end-users; step five solicits feedback from a diverse array of stakeholders; and step six performs a clinical study at a single site that, if successful, rapidly scales to multiple sites. DHI development is often a complex and vastly uncharted territory. By exploring the steps we took from concept to clinical testing with the first cardiology CareKit app, we hope to provide useful insights to teams that are starting out on their path to digital health innovation. We emphasize the central importance of embracing transdisciplinary work to move from silos to synergy.

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KEYWORDS

digital health innovation models; mHealth; innovation framework; development of smartphone applications; wearable technology; healthcare transformation

Introduction

Cardiovascular disease management is being redefined by the unprecedented innovation in digital health technologies for health care delivery, patient empowerment, and engagement. The opportunities for developing, testing, and disseminating digital health interventions (DHIs) continue to grow exponentially as industry forecasters predict that global smartphone ownership will reach 90% by 2020 [1]. DHIs are defined as any form of software or hardware app used to

improve the quality, access, efficacy, or efficiency of health care delivery [2]. DHI modalities span a wide range, from mobile apps to telemedicine, email, text messaging services, and wearable devices [3], and are being used in a variety of contexts, such as smoking cessation [4], behavioral modification [5], and weight loss [6]. Cardiology-focused digital health technologies, as in other fields, remain in beta testing [7]. Such technologies have provided potential glimpses into the future, and encouraging early results support the feasibility of large-scale, smartphone-based lifestyle measurement [8]. Provocative early studies further suggest that text messaging

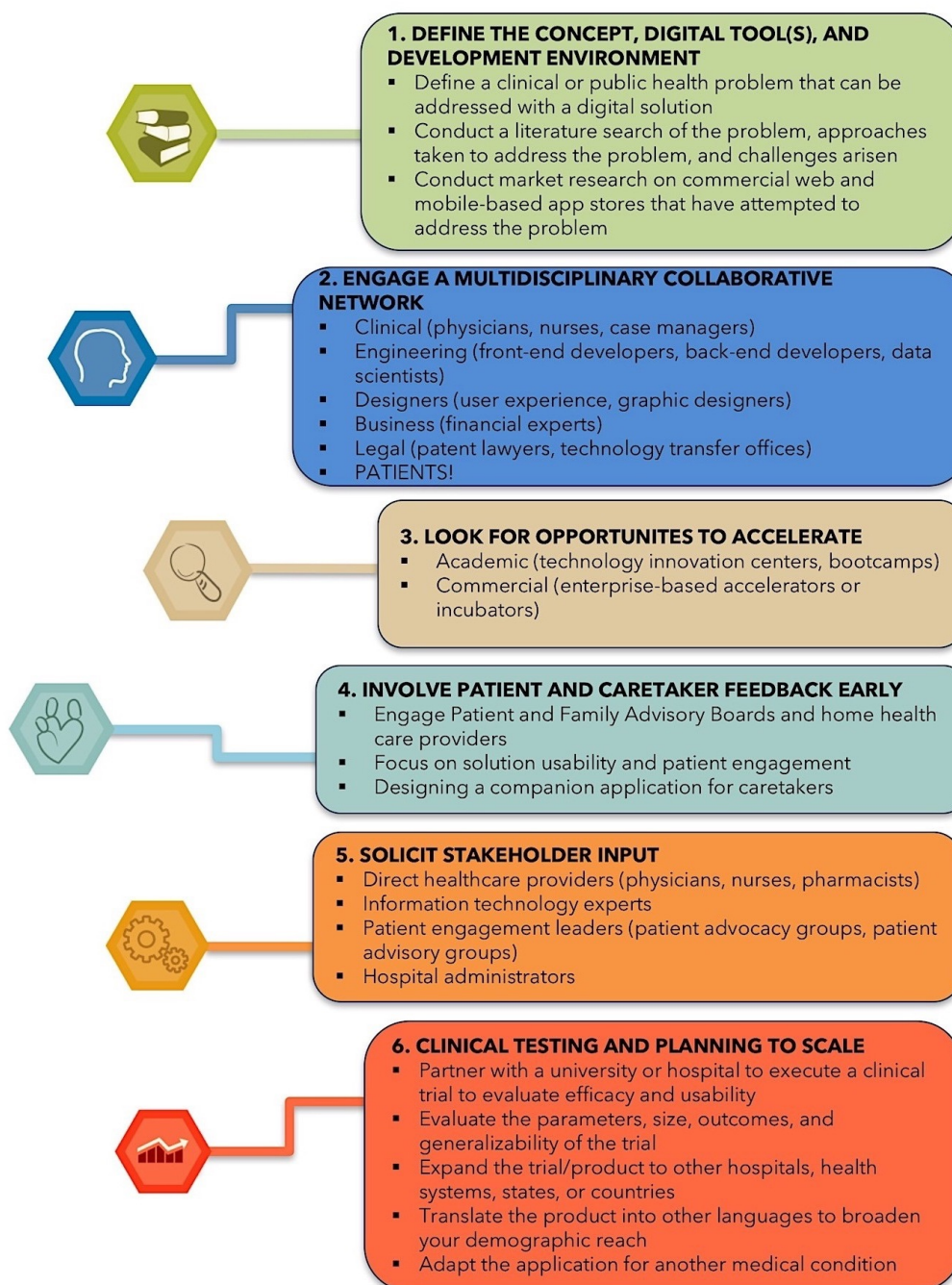
can positively impact physical activity [9], cardiac risk factors [10], and medication adherence [11].

Momentum is building for DHIs to reinvent cardiovascular care delivery. A Johns Hopkins-based smartphone app, *Corrie Health*, is an example of such a DHI that is transforming the hospital discharge process by delivering the key components of discharge instructions early during hospitalization via an engaging patient-centered app and smartwatch, rather than in static paper form during the final minutes of hospitalization. This approach represents a complete reengineering of the discharge process to empower patients in skill-building, monitoring, access to care, and self-management to promote

high-value care as patients make the risky transition from hospital to home.

Both academia and industry are driving forces in this emerging field, but the limitations in their digital health products suggest a need for even greater collaboration. For example, apps originating from industry often lack behavioral theoretical basis and clinical foundation [12], and academia faces challenges with keeping updated with technological advancements and end-user experience [13]. The creation of DHIs requires intensive collaborative efforts. Just as technology development leaders may be sequestered in silos of computing and engineering, health care experts are often isolated in centers of biomedical research and academic hospital settings.

Figure 1. Digital health intervention innovation roadmap.



To bridge the gap between technology development and health care, it is particularly valuable to have a roadmap for developing safe, effective, and evidence-based DHIs, and incorporating mobile technology into health care based on an interdisciplinary perspective. Here we aim to contribute a step-wise approach to smartphone-based DHIs with practical guidance for each step. By delineating the steps we took from concept to clinical testing (Figure 1), we seek to provide useful insights to teams that are interested in building a smartphone app and starting out on their path to digital health innovation.

Innovation Toolkit (Steps 1-6)

1. Define the Problem, Concept, and Digital Tool(s)

Begin by defining a distinct clinical problem that may be addressed with a DHI. Conduct a literature search to investigate the current understanding of the issue, the methods that researchers have used to address the question, and the challenges that have arisen throughout their experiences. Simultaneously conduct market research on Web- and mobile-based app stores for solutions that have already been produced, taking note of their strengths, weaknesses, and receptivity in order to understand how innovative your concept is. For example, with *Corrie*, research was conducted on the Apple iTunes Store [14], Google [15], Skyscape [16], and Unbound Medicine [17] at the outset of the project using the terms “cardiology,” “self-management,” “medications,” “inpatient,” and “follow-up.” This search generated approximately 125 apps. Similar apps identified in the search were analyzed by their functional capabilities, target condition, content, layout, and design. We found no apps that combined medication management, education, follow-up coordination, and inpatient deployment for acute myocardial infarction recovery.

To build a solution, there are 3 large categories of mobile tools to draw from: mobile apps, short message service (SMS) messaging, and wearables/sensors. Consider device and software integrations and how to link data monitoring with action. The development context may be selected from native app development in Apple, Android, Windows/Nokia, Blackberry, or cross-platform (eg, Ruby and Rails, Appcelerator, PhoneGap)

that can be used across platforms as HTML-based apps. Although there are multiple platforms, iOS and Android account for 99.6% of all smartphone sales, according to the latest industry report [18]. In our experience, we started with a cross-platform build and later transitioned to native app development, which allows utilization of intrinsic smartphone features (eg, camera, contacts, calendar); this created a significant advantage for feature scope and an improved user interface (see Figure 2).

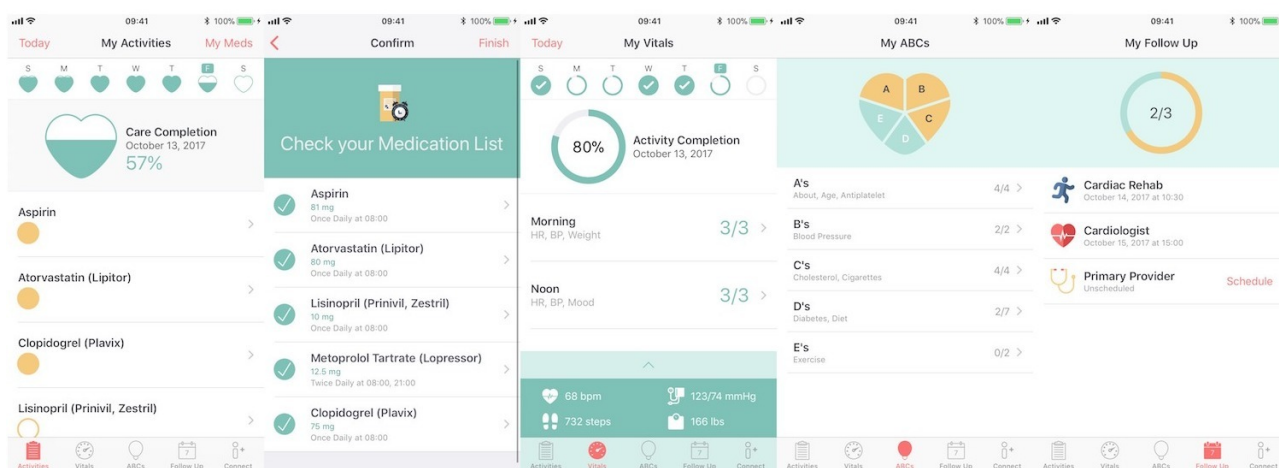
2. Build a Multidimensional Collaborative Team

Digital health calls for interdisciplinary teamwork, which is an aspect that renders it challenging but also uniquely rewarding. Members of a team may include physicians, nurses, pharmacists, case managers, and engineers, as well as experts in behavioral science, graphic design, informatics, human-computer interaction, business, and last but not least, patients.

We built our internal team primarily by networking within our university. To recruit the clinical team we aimed for cardiologists, internal medicine physicians, housestaff, nurses, medical students, premedical students, and pharmacists; all of whom possessed an interest in digital health, innovation, implementation research, and health care transformation. We sent recruitment emails via departmental electronic mailing lists and also gave numerous project presentations at digital health interest groups, academic teaching conferences, and individual faculty audiences. A growing number of academic centers, including Johns Hopkins (where *Corrie* was created), have opportunities for collaboration through Technology Innovation Labs [19,20], Biomedical Engineering Programs [21,22], and Healthcare Transformation Labs [23]. Our *Corrie* team opted to recruit expertise within the Johns Hopkins University system, which allowed for dynamic bidirectional collaboration in real time, rather than funding an outsourced mobile health (mHealth) app development team to create a product based on specifications.

Similar to the clinical team recruitment, we recruited technical expertise for software, frontend, and backend requirements of a project with recruitment emails, presentations at Technology Innovation interest groups, and individual presentations.

Figure 2. Corrie Health app screenshots.



Of note, given the importance of data security and Health Insurance Portability and Accountability Act (HIPAA) regulations for patient health information, it is key to have a technical engineer skilled in data security, data management, and backend engineering to meet the requirements for data security at the university and institutional review board (IRB) levels. The health system's HIPAA compliance office can be a resource as questions arise.

Business expertise may be required to build financial models of how the product might sustain itself before and after reaching the market. Early on, innovators at academic centers should also engage their Technology Transfer Office, which provides guidance with intellectual property protection (potential patents and/or copyrights), disclosure of inventions, and commercialization opportunities. Additional resources for team building can be found by participating in professional mHealth training networks [24] and health transformation fellowships [25].

3. Accelerate Development of Technology and Diffusion of Innovation

Once a multidisciplinary team is established, the next step is to begin building the solution as efficiently and effectively as possible due to the rapidly evolving nature of digital health. As we started to build a native iOS App, Apple Inc. (Cupertino, California) introduced an open-source framework for clinical data collection in 2015 called *ResearchKit* [26], and in 2016 the company released a patient-facing framework with modules for care plan visualization, symptom and objective measurement tracking, and care team engagement called *CareKit* [26]. We found that the goals of these initiatives were aligned with ours and that using these software frameworks accelerated our development. The *Corrie* team sought opportunities to accelerate development, and at early stages we participated in a clinical and technology development accelerator [27], a bootcamp in technology development [28], and a patient safety and quality improvement fellowship at Johns Hopkins [29].

Funding acquisition is another important aspect to fuel project momentum. To fund the time of software engineers, we applied for innovation grants (academic and state-based), business grants (ie, seed grants for health care innovation), and patient safety and quality improvement funding. Both academic and industry health transformation challenges (ie, "shark tanks") were additional funding sources.

4. Involve Patients and Families Early and Often Throughout Development

Patients will only use new technologies if they find them relevant, engaging, and easy-to-use. Also important are the needs of those who are peripherally involved and affected, including partners, family members, and caretakers. In developing *Corrie*, we engaged acute myocardial infarction patients as partners early in the design process through the following pathways: (1) performing demonstrations for feedback at Patient and Family Advisory Boards [30]; (2) recruiting patients who were end-users of *Corrie* to serve on our own Patient Advisory Board; and (3) inviting patients to participate as part of our research team, which is a growing trend in digital

health innovation [31]. To keep patients and families connected and invested in *Corrie's* ongoing development, we created a monthly e-newsletter as well as *Corrie* Facebook, Instagram, and Twitter social media outlets.

5. Seek Feedback From a Diverse Array of Stakeholders

While patient and caretaker feedback is a priority, many other stakeholders can provide valuable input into a DHI. We sought a diverse range of feedback from ground level health care providers, informational technology experts, patient engagement leaders, and hospital administrators. Each group provides a unique perspective on critical components for the solution to work within the system. To successfully connect with stakeholders and facilitate a meaningful collaboration, it is extremely beneficial to have a well-designed introductory slidedeck consisting of 10 slides that explain the significance of the problem, how your solution addresses it, a summary of your solution, and the potential impact, which concludes with your "asks" for the stakeholder (eg, feedback, recruitment, funding). Maintaining updated slide sets, as well as having an introductory video and website, can help disseminate the project and facilitate connections.

6. Perform Clinical Testing

Each prior step is preparation for this final one, which is critical for adoption. Rigorous clinical testing remains the exception rather than the rule in digital health. However, there is now a deep need for high-quality evidence generation to start catching up with the pace of technology. Innovative trial designs, such as microrandomization (or n-of-1 randomization), may help to build effective interventions more quickly. However, we cannot skip fundamental steps like establishing that our app's measurements are accurate or that our platform is usable. Therefore, our clinical evaluation of *Corrie* is beginning with a focus on validation, feasibility, and usability in the Johns Hopkins *Myocardial infarction COmbined-device Recovery Enhancement* (MiCORE) study [32]. Between the piloting stage of work and efficacy trials powered for clinical events, there is a wide, open space in which much can be done to understand impact (ie, proximal patient-centered outcomes such as knowledge, engagement, activation, and satisfaction).

We had the advantage of working within a health system and therefore a direct path to patient testing. For innovators working outside of a health system, consider partnering with a local university or hospital to get your solution in the hands of patients to validate feasibility, usability, and efficacy.

Take time to consider the parameters, size, outcomes, and generalizability of your trial. One key consideration is the demographic of your trial population. Elderly populations are less likely to use mobile technology, yet have a higher prevalence of chronic conditions [33]. For example, *Corrie's* target age group is 40 to 85 years old, so we collaborated with Apple to optimize intuitive design and user-friendly interfaces that emphasized color contrast, larger buttons and text size, and also minimized hierarchy (ie, number of screens to navigate through for each feature).

Powered by automation, digital health technologies lend themselves to scaling, which offers a significant advantage for dissemination of solutions in this space. However, scaling a digital technology is not easy; it is likely a multistage process with a variety of options to consider. One can scale up, for example, by taking the solution to another hospital, state, or country. One can translate the solution into another language by adapting it for another culture, or adapt it for another health condition. In our experience, we have grappled with balancing the potential benefits of scaling versus the risk of diluting our efforts. Creating processes such as data security/storage and patient use agreements across all components of the app to use outside of the primary institution from which it was developed is important. It is also important to develop a sustainable business model to address the reimbursement and policy landscapes.

Future Directions

Digital health technologies are poised to transform patient care. One significant barrier to the adoption and diffusion of such

technologies is insufficient collaboration between key stakeholders in developing and testing the most promising DHIs. In this article, we described our firsthand experience with developing a DHI through a step-wise approach. In the future, to make this pathway more seamless, we recommend: (1) early multidisciplinary accelerators comprised of a variety of stakeholders, such as patients, physicians, nurses, technologists, informaticians, designers, business leaders, administrators, and cross-industry leaders; (2) establishment of institutional navigators who can provide a pathway through institutional roadblocks and operational factors; (3) encouraging mentorship and championship from faculty-level and administration; (4) devotion of administrative/business/finance leadership to create sustainable business models to address the reimbursement and policy landscapes; (5) creation of expedited IRB pathways for low-risk DHIs; and (6) the design of a systematic processes to access patient evaluations of new technologies and consumer-centered design.

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Abbreviations

DHI: digital health intervention

HIPAA: Health Insurance Portability and Accountability Act

IRB: institutional review board

mHealth: mobile health

MiCORE: Myocardial infarction COmbined-device Recovery Enhancement

SMS: short message service

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Original Paper

Enhancing User Experience Through User Study: Design of an mHealth Tool for Self-Management and Care Engagement of Cardiovascular Disease Patients

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Abstract

Background: As patient communication, engagement, personal health data tracking, and up-to-date information became more efficient through mobile health (mHealth), cardiovascular diseases (CVD) and other diseases that require behavioral improvements in daily life are now capable of being managed and prevented more effectively. However, to increase patient engagement through mHealth, it is important for the initial design to consider functionality and usability factors and accurately assess user demands during the developmental process so that the app can be used continuously.

Objective: The purpose of the study was to provide insightful information for developing mHealth service for patients with CVD based on user research to help enhance communication between patients and doctors.

Methods: To drive the mobile functions and services needed to manage diseases in CVD patients, user research was conducted on patients and doctors at a tertiary general university hospital located in the Seoul metropolitan area of South Korea. Interviews and a survey were performed on patients (35 participants) and a focus group interview was conducted with doctors (5 participants). A mock-up mobile app was developed based on the user survey results, and a usability test was then conducted (8 participants) to identify factors that should be considered to improve usability.

Results: The majority of patients showed a positive response in terms of their interest or intent to use an app for managing CVD. Functional features, such as communication with doctors, self-risk assessment, exercise, tailored education, blood pressure management, and health status recording had a score of 4.0 or higher on a 5-point Likert scale, showing that these functions were perceived to be useful to patients. The results of the mock-up usability test showed that inputting and visualizing blood pressure and other health conditions was required to be easier. The doctors requested a function that offered a comprehensive view of the patient's daily health status by linking the mHealth app data with the hospital's electronic health record system.

Conclusions: Insights derived from a user study for developing an mHealth tool for CVD management, such as self-assessment and a communication channel between patients and doctors, may be helpful to improve patient engagement in care.

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KEYWORDS

cardiovascular disease; mHealth; mobile application; app; user-centered design

Introduction

Cardiovascular disease (CVD) causes death and disabilities worldwide, with the number of deaths caused by this disease expected to reach 22.2 million by 2030 [1]. Among the risk factors of CVD, 80% pertain to smoking, drinking, and other unhealthy lifestyle habits [2]. Since the majority of these risk factors are preventable, having an accurate understanding of these factors and correcting one's lifestyle is extremely important for preventing CVD [1]. Lifestyle behavior changes include regular daily exercise, eating healthy foods, abstaining from smoking, abstaining from alcohol, and taking medications in a set routine according to one's prescriptions [3].

Mobile health (mHealth), which makes use of mobile phone apps and wearable devices, is growing rapidly in the health care industry. It offers patient communication, personal health tracking, and up-to-date information regardless of the time and place. Through continuous guidance on health activities, it is anticipated that health can be increased with little financial burden or effort. This can improve patients' health-related activities or conditions to ultimately prevent their health from worsening or prevent further diseases. It may also be effective in preventing and managing chronic diseases such as CVD, for which self-care through improving one's behaviors is an important factor.

According to study results of the American Heart Association, in April 2015 there were 12,991 apps on iTunes and 1420 apps on Google Play about weight management, exercise, smoking cessation, diabetes control, blood pressure management, cholesterol management, and medication management through mHealth for CVD prevention [4]. This shows that many apps for CVD are already being developed and researched. However, whether or not these apps are being actively used is as yet unknown. Many mobile programs have low utilization rates [5], and surveys show it is difficult for most mobile apps to exceed 3 months' of use after the initial download [6,7].

To increase patient engagement with mHealth, apps must be designed from the user's point of view so that they can be used effectively. Apps with a user-centered design have high usability and lower risk of failure, reduced costs from a long-term perspective, and improved overall quality [8]. The provision of evidence-based customized content that reflects the needs of the patient is also a very important factor.

Hence, this study aimed to develop a customized mHealth service optimized for patients with CVD through user research and usability testing. The purpose of the study was to provide information for developing an mHealth tool with features that support health connections between patients and doctors, and to improve the usability of such a tool.

Methods

To develop an mHealth tool targeting patients with CVD, three types of user research and user experience investigations including surveys and interviews with patients, focus group interviews with doctors, and a usability test were conducted (Figure 1).

This study was approved by the Institutional Review Board of Seoul National University Bundang Hospital, and individuals who consented to take part in this study became the research participants (IRB No: B-1612-373-308).

Survey and Interview With Patients With Cardiovascular Disease

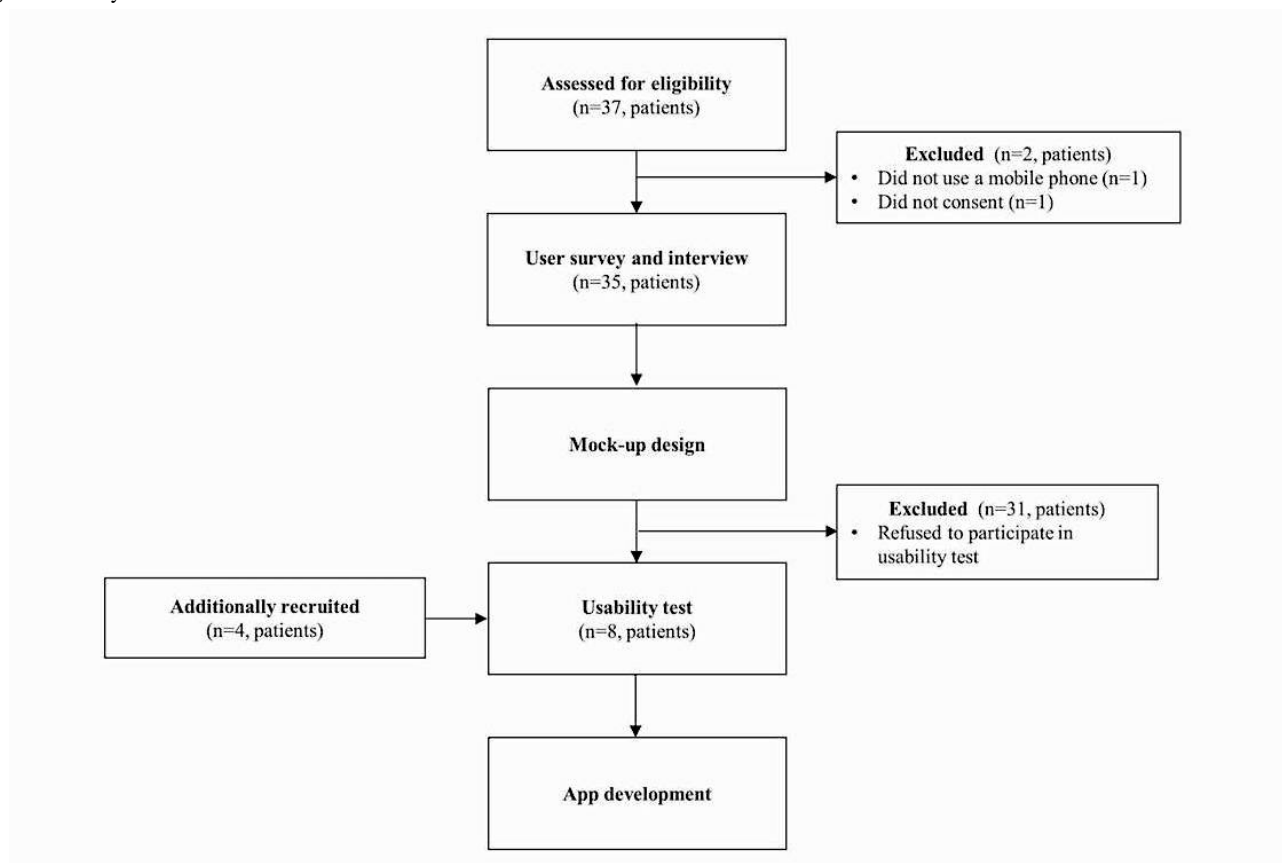
To enable sustainable use of a mobile service, characteristics of users must be assessed and their demands and needs accurately understood [9]. To this end, user research was conducted through face-to-face interviews and a survey targeting patients with CVD.

The survey questionnaire was drafted based on a survey from existing mHealth-related literature [10,11], and the final version was completed after review and discussion by a group of experts, including two doctors from a cardiology department, one medical informatics professor, one nurse, two researchers, and three developers. The survey questions were divided into the three major categories of participant demographics (4 questions), current health care status (8 questions), and health app perceptions and demands (16 questions), for a total of 28 questions.

Study enrollment targeted outpatients and inpatients from the cardiology department of a tertiary general university hospital located in the Seoul metropolitan area of South Korea. The inclusion criteria were patients with CVD aged 30 years or older with their own mobile phone. The exclusion criteria were those with psychiatric disabilities, such as delirium, or diagnosed with unrelated CVD that was not covered by the high-risk and low-risk groups of CVD disease. Patients were classified as high risk if they had received a diagnosis of unstable angina, non-ST-elevation myocardial infarction, ST-elevation myocardial infarction, myocardial infarction, coronary disease, coronary atherosclerosis, angina pectoris, or acute myocardial infarction. Patients were classified as low risk if they had received a diagnosis of atrial fibrillation, hypertension, chest pain, vasovagal syncope, variant angina, hypertension, and dyspnea on exertion.

The survey period spanned 17 days from January 9 to 25, 2017; a structured self-reported survey and fact-to-face interviews were conducted with 35 of 37 patients after excluding two patients who did not use a mobile phone or who did not consent to the study.

Figure 1. Study overview.



The survey and interview was conducted by two researchers. When a patient agreed to participate, a researcher first provided a thorough explanation of the study overview, survey method, and privacy and security policies regarding collected data before conducting the survey with the patient. After finishing the survey, an open-ended interview was conducted. Examples of the interview questions include:

1. What signs and symptoms of cardiovascular disease have you ever had?
2. How did you manage your health before the symptoms appeared?
3. How have you managed your health since you developed the disease?
4. What barriers or difficulties exist when managing your disease?
5. What do you think you need more of to manage your disease effectively?

In addition, participants were free to speak about the expected effects of mHealth tools for CVD. Various experiences and perspectives on disease management were collected from participants in an informal atmosphere. During the user research, one researcher led the survey and interview, and the other documented all questions, answers, and opinions from participants [12]. The interview was audio-recorded and fully transcribed by the interviewer. Each transcript was supplemented and compared with the interview notes to ensure its accuracy

The interview transcripts were analyzed using the constant comparative method [13]. First, two researchers conducted open coding of the transcripts to identify distinct opinions. After the

initial coding, researchers continuously and repeatedly reviewed the transcripts to group or regroup concepts to determine users' requirements of an mHealth tool for cardiovascular patients.

The data collected from the survey were analyzed using the R 3.3.1 software version.

Focus Group Interview With Cardiologists

The focus group interview method is a qualitative data collection technique used to obtain detailed information on the thoughts, emotions, attitudes, or experiences of participants. It is a suitable model for sharing patient care experiences [14,15]. The purpose of this part of the study was to conduct a focus group interview with doctors from the cardiology department to derive needs and demands regarding mobile services based on their experiences of daily clinical practice. We asked five cardiologists to participate in the focus group interview and they all agreed to do so.

The focus group interview lasted approximately 90 minutes and was moderated by a user research expert. After introducing the research overview, the moderator provided five discussion topics, including criteria on target patients as end users of the cardiovascular mHealth tool, available assessment tools, available questionnaires, education materials useful for personalized education, and mHealth app functions useful for managing cardiovascular disease. Each topic was freely discussed for 15 minutes. Additionally, doctors were asked to provide a layout sketch for a doctors' Web screen that would be linked with the hospital's electronic health record (EHR) system and the mHealth app. All sessions were audio-recorded and all field notes of participating coresearchers were collected.

Table 1. Scenarios of the usability test on the mHealth cardiovascular disease mock-up app.

Task	Task item	Test activity
1	Log-in	Logging in to the app using a given test user account
2	My health	Checking one's comprehensive health status
3	Daily mission	Checking one's daily mission, as prescribed by a physician
4	Health information	Finding the health information one wants, which can be tailored to one's disease
5	Health questionnaire	Sounding an alarm for a new questionnaire survey after which participants try to fill in
6	Self-management (blood pressure, blood sugar test, body weight)	Inputting a given blood pressure value (eg, 120/80) into the app, then viewing the blood pressure trend via a graph
7	Diary	Choosing an appropriate icon based on one's daily moods and symptoms

Two researchers analyzed the opinions from doctors using a card-sorting method [16] to derive key functions for the cardiovascular mHealth tool. Researchers extracted meaningful sentences or words from the recorded interviews and categorized them into groups. These groups were each given a topic. Doctors were interviewed on each of these topics and their responses were analyzed.

Usability Test With Patients With Cardiovascular Disease

The usability test is a method to evaluate how easily the end user understands, learns, and uses software or an app under specific conditions [17]. The purpose at this stage of the study was to (1) test the usability of cardiovascular care apps developed through prototypes and (2) develop an actual app based on user experiences and needs that were derived through testing.

This study conducted a usability test on an app that would be offered to patients based on functions derived through a literature review and the aforementioned user research and focus group interview with patients and doctors, respectively. A mobile phone app designed using a mock-up tool was used as the test tool. Mock-ups are visualizations that enable users to experience the functions that will be implemented in an app [18,19]. For this study, a free HTML5-based Web app prototyping online tool was used to create a user interface that was similar to the actual app screen that would be developed. The usability test was conducted with actual users through an Android mobile phone.

The test was conducted over 2 weeks from March 6 to 20, 2017, with eight participants, including four patients with CVD among the user survey participants and four patients with CVD who were additionally recruited voluntarily through poster advertisements in the hospital. Although the usability test was offered to all participants in the initial user survey, only four agreed to participate in the test. The inclusion and exclusion criteria for the usability test were the same as those for the survey and interview. The test was conducted in a separate space. A researcher provided the mock-up app for the participants and observed and recorded whether they were able to proceed with the given test scenario on their own.

The test scenario involved having the participant directly inquire about and enter information according to a given task (Table 1) by focusing on the main menu (log-in, my health, daily mission,

health information, health questionnaire, self-management, diary), and intervention by the test administrator was minimized during testing. A face-to-face interview about the first impression of the app, overall satisfaction, service inconveniences, and improvements followed thereafter.

Results

Survey and Interview Demographics

Of the 35 survey participants who were patients, there were more males (n=28, 80%) than females (n=7, 20%). Regarding age, 17 were younger than 60 years (49%) and 18 were 60 years or older (51%). The majority of patients were outpatients of the cardiology department (31/35, 89%), 18 of whom (51%) were in the high-risk group and 17 of whom (49%) were in the low-risk group based on their diagnoses. Fourteen participants (40%) had comorbidity, seven had diabetes, and six had hyperlipidemia. All participants owned a mobile phone, and most were Android users (34/35, 97%) (Table 2).

Patients' Perceptions of Health Management

Of the six items (exercise, dietary control, blood pressure measurements, abstaining from smoking, abstaining from alcohol, and weight management) that were previously surveyed to be important for CVD prevention and care in existing literature [20], patients were asked to select three items that they believed were important and three items that they practiced. The results are shown in Figure 2.

The top three items that patients thought were important included exercise, dietary control, and weight management, and the items that they practiced included exercise, dietary control, and measuring blood pressure. Many participants selected exercise and dietary control as both important items and items they practiced, whereas weight management was found to be an item that patients believed was important but had difficulty practicing.

Patients' Perceptions of the Use of Mobile Apps for Health Management

According to the survey results on awareness regarding apps among the 35 participants, 74% (26/35) were aware of mobile phone apps, but only 20% (7/35) had experience using a health care app. However, the majority of participants (94%, 33/35) responded positively that they were interested and would be willing to use apps for managing CVD (Figure 3).

Table 2. Demographic information of patients who participated in the survey and interview (N=35).

Variables	n (%)
Gender	
Male	28 (80)
Female	7 (20)
Age (years)	
<60	17 (49)
≥60	18 (51)
Number of years visited hospitals	
<3 years	20 (57)
≥3 years	15 (43)
Treatment type	
Inpatient	4 (11)
Outpatient	31 (89)
Risk group	
High risk	18 (51)
Low risk	17 (49)
Comorbidity	
Yes	14 (40)
No	21 (60)
Mobile device type	
Android	34 (97)
iOS	1 (3)

Patients' Perceptions of Useful Functions of Apps for Cardiovascular Disease

On surveying the usefulness of 10 different functions to be implemented in the CVD app on a 5-point scale, there were positive reactions to all functions, with scores of 3.5 points or higher on all. Advice from doctors was highest with a mean score of 4.77 (SD 0.49), followed by self-assessment of risk with mean 4.46 (SD 0.98), and exercise management with mean 4.40 (SD 0.98). The medication alarm function had the lowest score of mean 3.57 (SD 1.61) (Figure 4).

Other Patients' Interview Results

During the survey, face-to-face interviews were also conducted with each participant, who provided three to four different opinions on the requirements of the mHealth tool. The most frequently and commonly required features were (1) easy app control and use, (2) up-to-date information on disease and health, (3) management of presymptoms of CVD and self-assessment, (4) check of current health status, and (5) communication with doctors.

Focus Group Interview Results With Cardiologists

Based on the results of the interview conducted with doctors from the cardiology department, key functions of the app that

would be provided to their patients were identified. The cardiologists indicated that personal health data involved in self-care for managing CVD, such as blood pressure, blood glucose, and step count, must be linked to various devices, in addition to the manual entry function, for the user's convenience and data accuracy. Diet information is extremely important for managing CVD; however, because it is cumbersome and difficult to consistently collect through an app, this service was suggested to be excluded.

Various health questionnaires are utilized during treatment; therefore, a health questionnaire feature was recommended to be implemented in the app. This would improve the effectiveness of treatment by allowing patients to complete questionnaire items in advance before consultations. However, the health questionnaire period must be set to an appropriate time interval so that patients do not receive too many alerts. In addition, because personal/family events are important regarding patient health status, a memo function was requested to allow patients to record daily or unexpected events.

Beyond the app provided to patients, there was also a need for an app through which doctors can view patients' behavioral data. This must be linked with the hospital's EHR system so that patients' entries into the app can be viewed simultaneously with EHR clinical data.

Figure 2. Comparison between patients' perceptions of importance and actual practice regarding their management of cardiovascular disease.

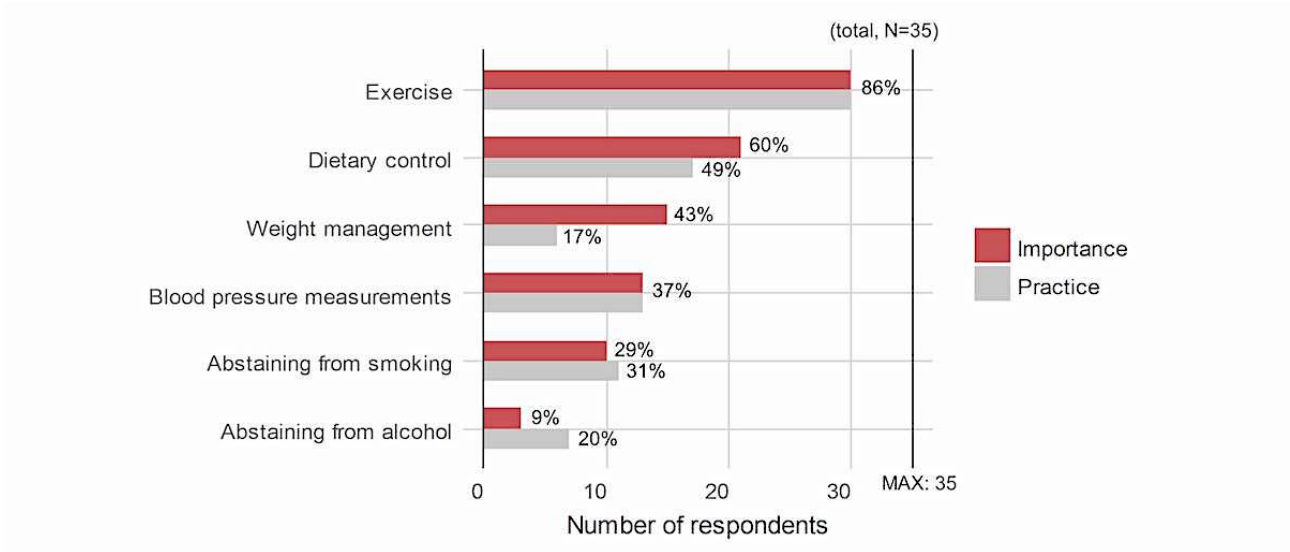


Figure 3. Perceptions of the use of mobile apps for health management.

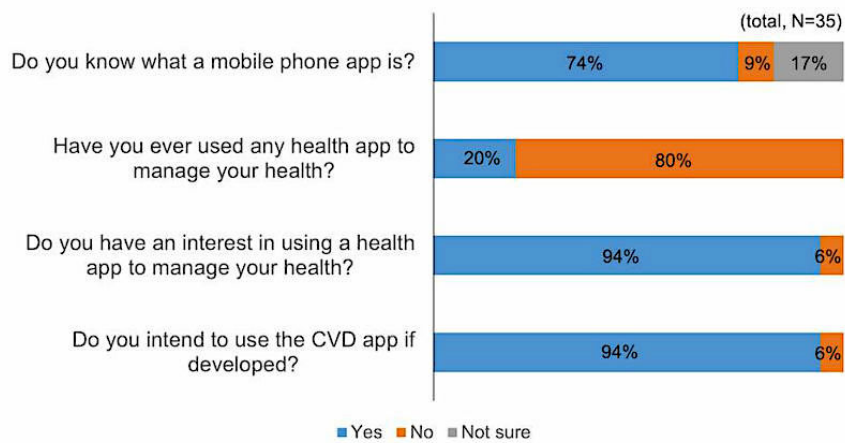


Figure 4. Patients' perception of the usefulness of various functions of cardiovascular disease mobile apps (error bars represent standard deviation).

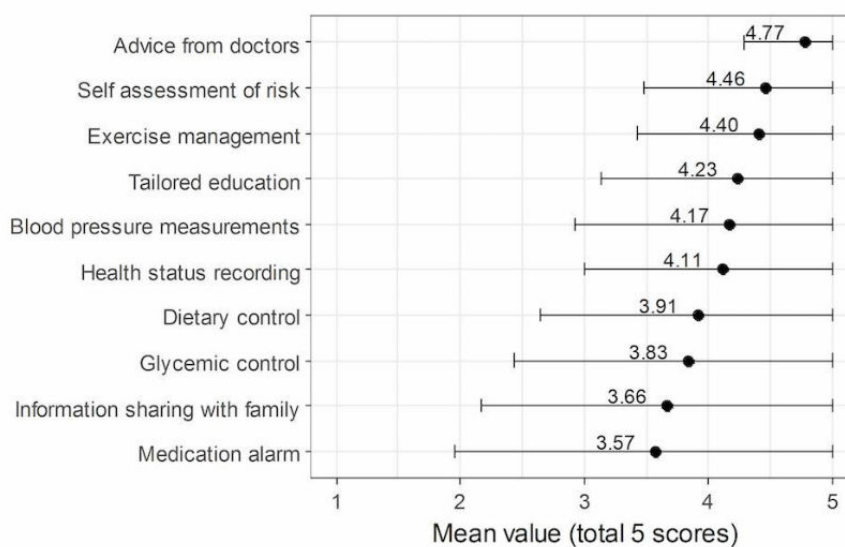
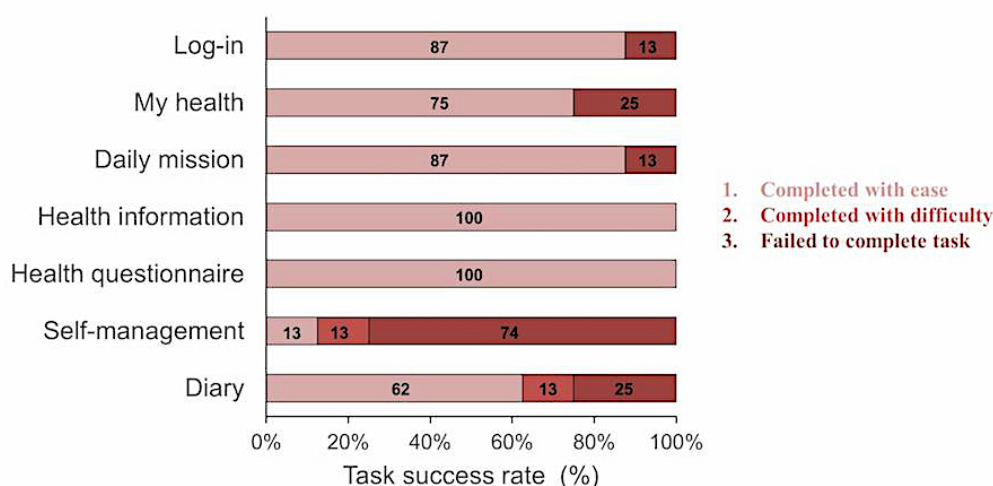


Figure 5. Participants' success rate using the app by task (n=8).**Table 3.** Functions and issues/implications of the mock-up design of the user interface for a cardiovascular disease app. EHR: electronic health record.

Menu	Function	Issues	Implications
My health	Framingham risk score [21]; laboratory test results (triglycerides, low-density and high-density lipoprotein cholesterol, and glycated hemoglobin A _{1c})	Uncertain what the score means	A detailed description of the risk score must be provided
Daily mission	Target values of body weight, blood sugar, and steps, as prescribed by the physician; my health status	Medical terms are difficult to understand	Medical terms used should be changed to simple, easy-to-understand terms for elderly patients
Health information	Education materials (PDF file, video) [22,23]; scope: hypertension, myocardial infarction, cardiac rehabilitation, angina pectoris	The users want personalized health information	Medical education materials should be tailored according to the patients' diseases and conditions
Health questionnaire	Various questionnaires; basic questionnaire: anthropometry (height, body weight), blood pressure, smoking, hypertension drugs, diabetes, family history; outpatient questionnaire: drug compliance, dietary supplement, Canadian Cardiovascular Society [24], New York Heart Association [25], edema assessment; periodic questionnaire: depression, Patient Health Questionnaire (PHQ-2) [26]	Recognition of click icon buttons and their images is low; alarm fatigue is a concern	Easy-to-understand icon designs are needed; alarms for questionnaires should be minimized or set by individual users
Self-management	Self-management (device interface or manual input); items: body weight, blood pressure, blood glucose test, steps; trend view of health status via graph	The input button is hard to find and the recognition of the graph value is difficult	Easy-to-understand icon design and a detailed description of graph value are needed
Diary	Daily mood and symptoms (view by week and month); write memos on recent events	The icon image is not clear; it is hoped that the input data are shared with physician	Overall design of icons should be improved; any data input by the patient must/should appear in the physician's EHR

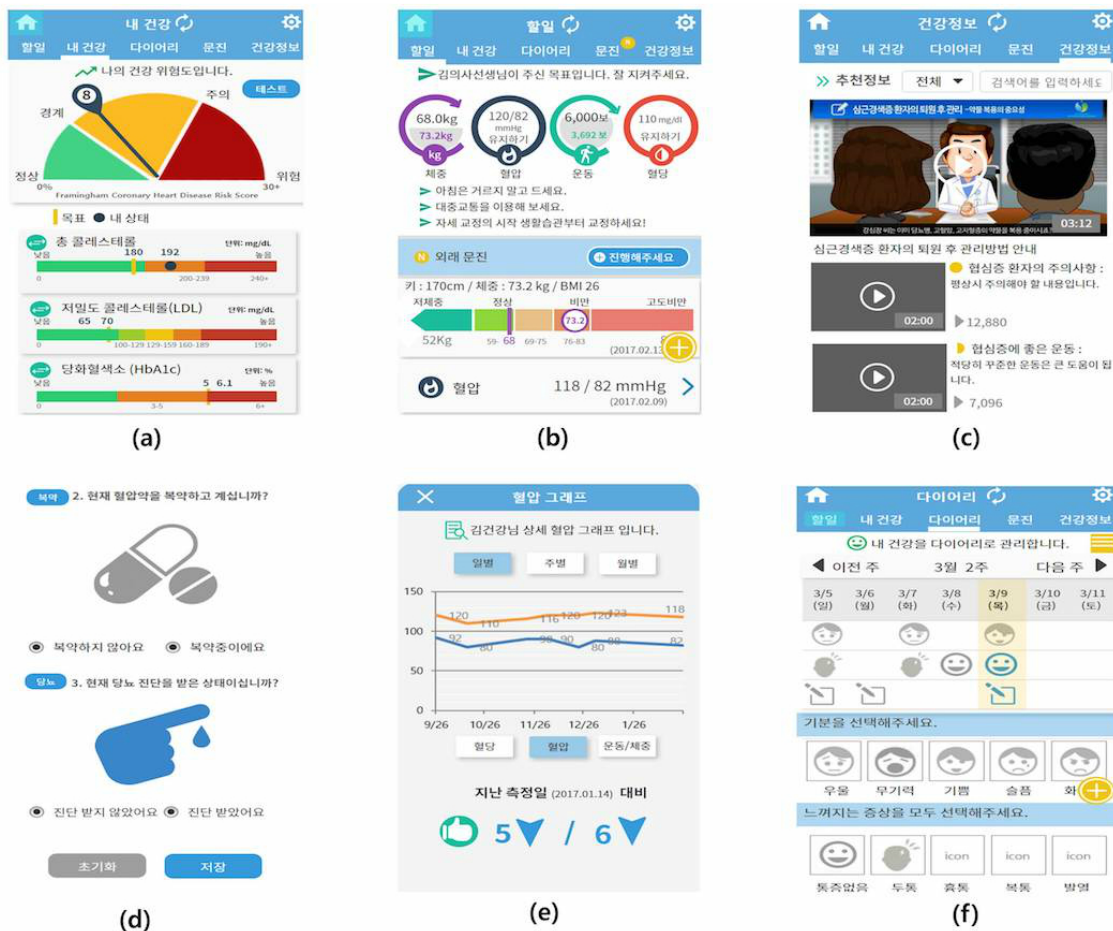
Usability Test Results

Of the eight patients who participated in the usability test on the mock-up mobile app, six were male and two were female. Seven participants were younger than 60 years and one was 60 years or older. Their mean age was 52.5 (SD 10.5) years.

Regarding the success rate of a given task, results were divided into three types (completed with ease, completed with difficulty, failed). In terms of the categorization, "completed with ease" reflected when the participant was able to complete tasks on

their own by looking at the scenario; "completed with difficulty" was when the participant was unable to succeed on his/her own, but completed the tasks after receiving help from the researcher; and "failed" was when the participant was unable to complete the task or understand despite the researcher's help. The success rate was 100% for tasks 4 (health information) and 5 (health questionnaire), and most other tasks had a success rate of at least 70%. This showed that users were able to use the app with relative ease. But the success rate for task 6 (self-management) was 25% and most participants failed. This shows that this menu user interface (UI) required overall improvement (Figure 5).

Figure 6. User interfaces of the mock-up design for a cardiovascular disease app: (a) my health, (b) daily mission, (c) health information, (d) health questionnaire, (e) self-management, and (f) diary.



Regarding the participants' satisfaction with the app, the score was mean 3.6 (SD 1.2) out of 5 points, which shows that they were somewhat satisfied with the overall design or function. They responded that this mHealth tool would be very useful for patients who did not know or have an accurate understanding of how to manage CVD. They also anticipated that they would be able to manage their disease more efficiently if the data that they normally recorded manually on a daily basis could be easily entered in the app or linked and shared with their doctors. However, there were also issues and inconveniences for each menu that were identified through the usability test.

Table 3 shows the issues and matters for improvement that were derived from the usability test with the UI (Figure 6) and functions defined through literature review, user study, and focus group interviews. There were many requests for additional explanations on the information provided and to improve the image icon so that it could be seen intuitively.

Discussion

Principal Findings

Many mHealth programs are already being developed and actively researched to prevent and manage CVDs. It has been reported that when patients with CVD use digital tools as mediators there are positive effects such as improved outcomes, which can result in a reduction of risk factors that lead to CVD

[27,28]. However, to maintain positive outcomes, it is important to design a model that can make the program sustainable. To this end, characteristics of end users of the program must first be accurately assessed. Users must also directly participate from the initial development stage, so that the program can be developed with a design and content that reflects their opinions.

This study designed an mHealth tool for patients with CVD from the perspective of actual users including both patients and doctors through the user study and usability testing. The majority of users were 60 years of age or older and 40% of the participants had comorbidity such as diabetes or hyperlipidemia. Most participants had very little experience with using a health care mobile app; however, their interest or intent to use an app for managing CVD was high, despite the fact that most were seniors who were unfamiliar with the information technology environment. In previous studies, there were many elderly users aged 65 years or older within the mHealth domain for CVD care [29]. Although the ripple effect was extremely low in terms of app use because it was difficult for them to adapt to technology, their interest or intent to participate was still reported to be very high [27,28].

This implies that a CVD management program that utilizes mHealth must be developed based on such high user interest and intent. However, additional supplementation is required for these programs to be used effectively. To this end, characteristics of elderly users, who are the majority of this demographic, must

be sufficiently reflected and the program must be supported by profound evidence-based content so that comorbidity can be managed. One of the reasons why many health-related apps fail is because they lack evidence-based content [30-33].

Evidence-based content for CVD management programs includes known CVD risk factors through previous research results [34], the majority of which are behavioral factors that can be modified from an individual's lifestyle. The seven behaviors, which are known as Life's Simple 7 recommended by the American Health Association, include sufficient exercise, healthy eating habits, abstaining from smoking, maintaining an appropriate body mass index, and managing blood pressure, cholesterol, and blood glucose at normal levels. If this type of healthy lifestyle and health figures can be maintained, the mortality rate from cardiac diseases could potentially decrease by up to 20% by the year 2020, owing to a state of "ideal cardiovascular health" [20]. In this study, an app was created to reflect the requirements of users during content creation so as to make it an easy-to-use tool that offered updated information and enabled self-assessment [21]. Moreover, because advice from doctors or communication with them, which received the highest score from the perspective of usability out of all the app functions, is an important factor in a successful mHealth model [35], a Web portal that is visible to medical professionals during treatment should be also developed so that patient-reported health data can be shared and a bidirectional service model can be implemented.

During the focus group interview with doctors, one requested that a health questionnaire service related to CVD be included so that doctors could refer to these data during consultations. A health questionnaire that can assess depression was included, in which patients inputted their daily mood and symptoms so that their doctors could immediately assess their mood and changes during treatment and take necessary action. Depression is reported to be a critical factor that increases the risk and mortality rate of CVD [36]. However, because it is a difficult disorder to assess during short consultation times, if the patient's mood can be assessed through mHealth and revealed to the medical professionals, this will be helpful for the patient's course of treatment.

User-centered design is an important matter of consideration in addition to content while developing a service. According to surveys from existing studies, apps that manage chronic diseases must have user-centered design features, including visualizing patient-related trends through a graph, sending alerts when care or follow-up is required, and urging users to continuously

manage their conditions through communication functions such as text messages. Providing visual educational materials using videos, proposing tailored goals, accessing patients' health record data, and including functions that enable patients to record their status were also mentioned as important factors of user-centered design features [37]. This study developed an app reflecting all these factors, and improved the UI and naming for some menus based on issues that were identified through the usability test.

Going forward, app usability must be evaluated in an actual clinical environment through clinical testing using an app that has been developed based on the results of this study, and its potential and usability as a sustainable model must also be studied. Further, an effective way to input diet information in a mobile environment should also be considered. The clinical effectiveness of the CVD mHealth tool will also be evaluated in the future.

Limitations of the Study

A limitation of this study was that the patient's diet, which was found to be an important item for managing CVD in previous literature reviews and user research, was excluded. Because each individual's eating habits differ and there is a large amount of data that must be entered, we followed the results of the focus group interview discussion that this function would make the app cumbersome to use. Additionally, because the usability test was conducted through an app that was created using a mock-up tool, there may be differences in usability compared to that of the actual app that is developed.

Conclusions

This study developed an mHealth tool that can effectively manage CVDs through user research that involved the direct participation of doctors from the cardiology department and patients with CVD. The field of mHealth may most effectively mediate an individual's health behaviors. For diseases such as CVD that are highly influenced by various lifestyle habits and chronic diseases, the provision of a program that uses mHealth may greatly assist in the management and prevention of diseases.

There is a demand for an mHealth tool to include functions that effectively support communication between patients and doctors, self-assessment and evaluation of risk, and exercise management, all which were deduced through user research in this study with respect to CVD management. The functional features should be provided to patients with high usability to ensure sustainable use of mHealth tools and enhance patient engagement in the medical environment.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CVD: cardiovascular disease
EHR: electronic health record
mHealth: mobile health
UI: user interface

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Original Paper

Exploring Health Information-Seeking Preferences of Older Adults With Hypertension: Quasi-Experimental Design

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Abstract

Background: Patients' engagement in health care decision making is constituted by at least two behaviors: health information seeking and active involvement in medical decisions. Previous research reported that older adults desire a lot of information, but want to participate in decision making to a lesser degree. However, there is only limited evidence on the effect of desire for health information on seniors' perceived confidence in making an informed choice (ie, decision self-efficacy).

Objective: The goal of this study was to investigate the role desire for health information has for older patients. More specifically, it tested whether decision self-efficacy increases as a function of an assisted computer-based information search. Additionally, the study allowed insights into the sources seniors with hypertension prefer to consult.

Methods: A sample of 101 senior citizens (aged ≥ 60 years) with high blood pressure in the Italian-speaking part of Switzerland answered a questionnaire before and after an informational intervention was applied. The intervention consisted of offering additional information on hypertension from five different sources and of providing the information the participant desired. Preference for receiving this information was the major independent variable. The main outcome measure was decision self-efficacy (assessed at baseline and posttest). Analyses of covariance were conducted to detect differences between and within who desired additional hypertension-related content (intervention group) and "information avoiders" (control group).

Results: Health care professionals firmly remain the preferred and most trusted source of health information for senior patients. The second most consulted source was the internet (intervention group only). However, among the total sample, the internet obtained the lowest credibility score. A significant increase in decision self-efficacy occurred in seniors consulting additional information compared to information avoiders ($F_{1,93}=28.25$, $P<.001$).

Conclusions: Consulting health information on a computer screen, and assistance by a computer-savvy person, may be a helpful activity to increase perceived confidence in making treatment decisions in seniors with hypertension.

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KEYWORDS

desire for health information; assisted computer-based information search; decision self-efficacy; medical decision making; senior hypertensive patients; quasi-experimental design; Switzerland

Introduction

In health care, active involvement of patients has proved to be a beneficial but complex process to achieve, especially for the

senior population. The active involvement of patients in their health care can manifest in at least two ways [1]. First, patients can actively request information from different sources and concerning different aspects of their treatment. Second, the patient can be involved in the medical decision-making process

itself. Therefore, “desire for information and a wish to assume responsibility for decision making” are two distinct concepts in the context of patient participation (p 1144 [2]) [3]. Some measures of patients’ participation preferences are based exactly on this distinction, for example, the Krantz Health Opinion Survey [4]. The inconsistency between information seeking and willingness to contribute to medical decision making has also been reported in qualitative research with seniors [5].

There are a variety of different channels and sources that patients can use to consult information. The most important source may be the patient’s doctor [6-8]. “However, clinicians tend to underestimate the amount of information that patients require” [9-13]. Therefore, patients need to actively seek the information from their health care provider or other sources. This may be particularly challenging when older adults feel more passive and reliant on health care professionals [3,14]. Indeed, during consultations, older adults rarely ask important questions unless they are invited to [15]. When asked for the reason, many patients state that they “assume that the doctor would have told them everything relevant, others worry that they will appear foolish if they reveal their ignorance by asking questions, and some feel that they have already taken up too much of the busy doctor’s time” [13,15,16].

Being informed is a prerequisite for involvement in decision making and has been associated with outcomes including perceptions of quality of care, quality of life, psychological well-being, and improved health [17], as well as “adaptation to illness and treatment” [13,18,19], perception of control [20], and adherence [7,21].

Recent studies have investigated the antecedents to engage in a health information seeking. Apart from sociodemographic factors (eg, age, education), knowledge scores (eg, health and new media literacy), and disease complexity, information seeking was also influenced “by the individual’s personality characteristics, such as locus of control, self-efficacy, and preference for information” [19,22-24]. A recent study revealed that psychological empowerment proved to be a strong predictor of Swiss seniors’ ideal and actual role in treatment decisions [25].

To our knowledge, no study in Switzerland has yet examined the potential relationships between health information preference and decision self-efficacy with a sample composed of chronically ill seniors. To provide health-related information that was relevant to all potential participants, this study was condition-specific, with older adults (aged 60 years and older) suffering from high blood pressure. This condition was chosen because it requires constant treatment and thereby increases medical decision making (eg, [5,26]), and because one adult in four suffers from it in Switzerland [27].

This study tested whether decision self-efficacy increases as a function of desire for health information. Additionally, the experiment allowed insights into the antecedents of desire for information as well as the channels older patients prefer to consult.

In light of this, our first hypothesis is that participants showing higher desire for health information will report higher decision

self-efficacy levels (measured at baseline and posttest) than seniors who did not engage in the consultation task offered (information avoiders). Moreover, we predict the desire to consult additional health information will be influenced by hypertension-related knowledge (hypothesis 2), psychological empowerment (hypothesis 3), eHealth literacy (hypothesis 4), trust in physician (hypothesis 5), and age (hypothesis 6).

Methods

Sampling Procedure

For this experiment, a sample composed of senior patients with hypertension (HT) was approached, between June and July 2017, via the following recruitment strategies: (1) older adults’ recreational or therapeutic day centers, (2) word of mouth, and (3) public settings such as bars and city parks. Seniors eligible for the study had to (1) be 60 years or older, (2) be residents in the Swiss-Italian region (Canton Ticino), (3) understand the Italian language, and (4) be formerly diagnosed with HT. To know the prospective participants’ HT status, the principal researcher had to ask if he/she was either currently suffering from high blood pressure or presently taking an antihypertensive drug. For respondents attending a recreational or therapeutic day center, the centers’ coordinators (or their assistants) indicated eligible seniors. A total of 101 senior patients with HT constituted the final sample. For time constraints, during the data collection process, HT status was assessed through a self-reported measure (ie, Charlson Comorbidity Index [CCI]) [28]. The study protocol was approved by the Ethical Review Board of the Università della Svizzera italiana on March 13, 2017.

Intervention Procedure and Design

Before the study, all participants received relevant information about the researcher, his institution, and the aims of the study. After explicitly agreeing to participate in the study, respondents had to sign a written consent form. All respondents had to sign a form demonstrating their consent to participate in the controlled trial experiment.

An interview session consisted of a baseline measurement, the application of an assisted computer-based information search intervention, and a posttest measurement. Measurement was done by a self-administered computer questionnaire or face-to-face, depending on the respondent’s preference.

The intervention began with all participants reading a short text with basic information on HT shown on the computer screen. They then had to indicate whether they wished to obtain more information or not. If the participant desired further information, he or she was asked which from five sources they would like to consult: a doctor, a brochure, another HT patient, the Internet, or a friend (information seekers). If the participant did not desire additional information, he or she was asked to indicate the reasons why (information avoiders). For completion of the intervention, participants were given all the information pieces they desired. Information was provided as text on the computer screen or as a video. The information presented by each of the sources was edited according to the requirements of the source chosen. Each information source treated a different aspect

related to this chronic condition or its management. [Table 1](#) shows the five different health information sources with their respective topic designation and format ([Multimedia Appendix 1](#) displays three information resources developed). The intervention was completed when the respondent had read all the information resources available or when the respondent felt he or she had read enough. The postintervention measurement was applied immediately after.

The basic information as well as the additional information were grounded on evidence-based information retrieved mainly from a brochure (“Arterial Hypertension: Information for Patients”) published by the Swiss Cardiology Association (*Fondazione Svizzera di Cardiologia*).

Classification of respondents into control group (ie, information avoiders) and experimental condition (ie, information seekers) was automatically achieved by the participant’s willingness to consult further information. In this sense, no randomization procedure could be applied. Therefore, this study represents a quasi-experimental design.

Measurements

Baseline Survey Items/Scales

Subjective health status was measured through the single item developed by Renner and Schwarzer [29]. The presence of one or more chronic diseases was assessed via the CCI [28].

A set of single-items related to the participants’ HT condition (ad hoc created):

1. Hypertension degree asked seniors if they knew the degree (or severity) of their HT condition before adhering to the treatment regimen prescribed with response options: (1) first-degree HT, (2) second-degree HT, (3) third-degree HT, (4) systolic isolated HT, and (5) I don’t know/remember.
2. Hypertension personal history asked participants to report when they were diagnosed with HT.
3. Hypertension family history solicited participants to report whether any family member or relative suffered from HT.
4. Anti-HT drugs (names) asked whether the participant was currently taking one or more anti-HT drugs (dichotomous response option: no/yes). In case the participant answered affirmatively, he or she was prompted to recall the name(s) of each anti-HT drug.
5. Regular measurement of blood pressure asked HT patients if they are measuring their blood pressure levels on a regular basis (dichotomous response option: no/yes).
6. Smoke status simply asked respondents if they smoked on a regular basis.
7. Physical activity status asked seniors if they were currently participating in physical activity on a regular basis (walking on a regular basis was considered a physical activity).

A set of items related to health information and health information-seeking behavior:

1. General health information-seeking behavior (adapted from [30]) was measured via a single item asking: “Have you ever looked (or asked) for health-related information/advice (apart from that obtained from your doctor)?” (4-point scale ranging from 1=never to 4=very often).
2. Trust in different health information sources (adapted from [31]) was measured with the following item: “In general, how much would you trust information about health or medical topics obtained from each of the following sources?” (4-point scale ranging from 1=no trust at all to 4=a lot of trust).

Perceived competence in using information communication technologies (ICTs) was measured through the following single item: “How would you describe your competences in using ICTs?” (7-point scale ranging from 1=very bad to 7=very good).

The frequency of ICT use was collected via the following three single-items: “How often do you use the computer/smartphone/tablet?” (5-point scale ranging from 1=never to 5=always).

Internet health literacy ($\alpha=.96$) was measured with the eHealth Literacy Scale (eHEALS) translated and validated into Italian by De Caro and colleagues (I-eHEALS [32]; original English version [33]).

Hypertension knowledge ($\alpha=.75$) was evaluated with the Hypertension Knowledge-Level Scale (HK-LS) developed by Erkoç and colleagues [34]. In order to reduce the cognitive effort of the senior respondents in this study, only 11 (of 22) items yielding the higher factor loadings were retained (ie, two items comprising the “definition” subdimension and the first three items of the “medical treatment,” “drug compliance,” and “complications” subdimensions). To obtain the maximum score of 11, participants have to interpret four statements as “incorrect” and seven as “correct.” Incorrect statements were reverse coded. Higher values indicate higher hypertension knowledge.

Psychological empowerment ($\alpha=.94$) was appraised with the multidimensional Spreitzer’s scale [35], but adapted to the HT context [36].

Independent Variable

The independent variable (intervention factor) was represented by the senior’s willingness to consult further information about hypertension (information seekers). Participants were asked the following two single-items: “Do you want to consult (or obtain) further information on the relevant aspects related to hypertension?” (ie, dichotomous response option: no/yes). The same question was asked for a maximum of five times. If the participant answered positively, he or she was asked: “From which of the following sources would you like to obtain further hypertension-related information?”

Table 1. Health information sources, topic designation, and formats.

Source	Content designation	Format
No source mentioned (basic)	Introduction on hypertension	Written on personal computer (PC)
Doctor ^a	The dangers of hypertension	Video on PC
Brochure ^a	The causes of hypertension	Screenshot of a brochure on PC
Other hypertension patient	Lifestyle change	Written on a screen
Internet ^a	Antihypertensive drugs	Screenshot of a webpage on PC
Friend	Blood pressure measurements	Written on PC

^aAvailable in [Multimedia Appendix 1](#).

Dependent Variable

The dependent variable was the Decision Self-Efficacy scale developed by O'Connor [37] (pretest: $\alpha=.96$; posttest: $\alpha=.97$). The scale (adapted to the HT context) "measures self-confidence or belief in one's abilities in decision making, including shared decision making" (p 1 [37]). The measure is composed of 11 items (eg, "I feel confident that I can: get the facts about the anti-HT medication choices available to me" item 1) with five response categories ranging from 0=not at all confident to 4=very confident. All items are then summed, divided by 11, and multiplied by 25. Scores range from 0=very low self-efficacy to 100=very high self-efficacy (page 4 [37]).

Posttest Survey Items/Scales

Participant's mood was evaluated through the Global Mood Scale developed by Denollet (positive affect: $\alpha=.86$; negative affect: $\alpha=.94$) [38].

Trust in physician ($\alpha=.88$) was measured through the Abbreviated Wake Forest Physician Trust Scale (A-WFPTS) developed by Dugan and associates [39].

The posttest also included a set of sociodemographic items, such as gender, age, background origin, living situation, marital status, education, and length of doctor-patient relationship.

Statistical Analyses

The collected data were analyzed quantitatively with SPSS version 21. Internal consistency tests were conducted to establish the reliability and validity of the main scales. Descriptive frequencies were provided for the main measures appraised. To assess the pure effect of the model conceptualized, and to partial out any potential variance of the groups at baseline, various independent-sample *t* tests and contingency coefficients were conducted. Different ANCOVAs were conducted to establish whether there were significant mean differences between the control group and the quasi-experimental condition while controlling for the influence of the outcome measure assessed at baseline. Factors assumed to be relevant for the variance of the outcome measure (ie, bivariate correlations), were included into the model as covariates. To provide more advanced analyses, the independent variable was dummy coded as follows: 0=no health information sources consulted, 1=one health information source consulted, and 2=two or more health information sources consulted. By doing so, planned contrasts can be derived from the ANCOVA tests. A priori power analysis

was performed to provide an estimate of the acceptable sample size threshold. According to data from a pilot test ($N=20$), and in line with a recent study comparing older users and nonusers of online health information ($N=225$) [8], we set the control group average decision self-efficacy score to mean 48.3 (SD 23.6). As we hypothesized in our first hypothesis, we expected from the experimental group a 15-point increase in the average decision self-efficacy score (ie, mean 63.35). With an $\alpha=.05$ and power $\beta=.90$, the estimated sample needed with this effect size was approximately $N=104$.

Results

Participant Characteristics

A total of 107 participants showed initial interest to participate in the study. Of these, two did not complete the online survey and one, after a preliminary screening of the data, had his information discarded because he filled out the questionnaire inappropriately. Data from three additional seniors, who auto-completed the survey, were also discarded because they declared not to suffer from hypertension.

The final sample ($N=101$) was majority female, married or widowed seniors, with children, living independently at home, and with a Swiss-Italian or Italian background origin. All participants' sociodemographic features can be seen in [Table 2](#). Most respondents preferred to complete the survey as a face-to-face interview ($n=97$, 96.0%), rather than auto-complete it. Average duration time to complete the online survey was mean 35.11 (SD 11.47, range 14.88-67.12) minutes.

Main Analyses

Control and Quasi-Experimental Group

Of 101 senior respondents, 60 (59.4%) decided not to consult further health information (information avoider), whereas the remaining 41 showed interest in reading more information related to HT (40.6%; information seekers). The majority of these 41 individuals decided to stop the guided information search task after one health information resource (70%), 10 accessed two information resources (24%), and only two participants consulted three information sources. In the first consulting session, 15 participants preferred to watch the doctor's piece of information (ie, video format; 37%), eight the Internet webpage (20%), and six seniors selecting either a brochure's screenshot (15%), a text written by another HT patient (15%) or contents disclosed by a friend (15%). None of

the participants consulted more than three different sources out of a maximum of five. These findings confirm the dominant position of health care providers and the emergent interest in turning to the Internet to obtain health information. In light of

the small sample size, all main analyses were conducted for the two main groups, namely “health information avoiders” and those health information seekers.

Table 2. Participants’ characteristics for the total sample and by intervention groups.

Item/Scale	Total (N=101)	Health information seekers (n=41)	Health information avoiders (n=60)
Gender (male), n (%)	38 (37.6)	11 (26.8)	27 (45)
Age (years), mean (SD)	74.9 (8.1)	74.4 (7.1)	75.3 (8.7)
Marital status, n (%)			
Married	50 (49.5)	22 (53.7)	28 (46.7)
Widowed	34 (33.7)	15 (36.6)	19 (31.7)
Separated	4 (4.0)	— ^a	4 (6.7)
Divorced	8 (7.9)	4 (9.8)	4 (6.7)
Single (never married)	5 (5.0)	—	5 (8.3)
Children (yes), n (%)			
Number of children, mean (SD)	2.4 (1.1)	2.3 (1.1)	2.5 (1.2)
Living situation, n (%)			
I live independently at home	71 (70.3)	31 (75.6)	40 (66.7)
I live at home with the support of family members	12 (11.9)	5 (12.2)	7 (11.7)
I live at home with the social service support (eg, food)	7 (6.9)	—	7 (11.7)
I live at home but I receive a homecare service (eg, SCUODO)	8 (7.9)	4 (9.8)	4 (6.7)
I live in a retirement house	3 (3.0)	1 (2.4)	2 (3.3)
Day center attendance (yes), n (%)	51 (50.5)	18 (43.9)	33 (55)
Background origin, n (%)			
Swiss-German	7 (6.7)	2 (4.9)	5 (8.3)
Swiss-Italian	49 (48.5)	18 (48.9)	31 (51.7)
Italian (Italy)	25 (24.8)	13 (31.7)	12 (20.0)
German (Germany)	1 (1.0)	1 (2.4)	—
French (France)	1 (1.0)	—	1 (1.7)
Other origins	18 (17.8)	7 (17.1)	11 (18.3)
Educational level, n (%)			
No degree obtained	9 (8.7)	1 (2.4)	8 (13.3)
Primary school degree	39 (38.6)	15 (36.6)	24 (40.0)
Apprenticeship degree	22 (21.8)	10 (24.4)	12 (20.0)
College or similar degree	19 (18.8)	11 (26.8)	8 (13.3)
Applied university degree	1 (1.0)	—	1 (1.7)
University of polytechnic degree	11 (10.9)	4 (9.8)	7 (11.7)
Health-related profession (yes), n (%)	13 (12.9)	5 (12.2)	8 (13.3)
Doctor-patient relationship length (years), mean (SD)	17.5 (11.8)	14.7 (11.4)	19.5 (11.7) ^b
Doctor visits a year, mean (SD)	3.6 (3.2)	3.5 (3.1)	3.6 (3.2)

^aNo participants apply to item.

^b $P=.047$.

Between-Group Differences

No significant differences were found between information seekers and avoiders in terms of gender, age, marital status, living situation, having children, education, day center attendance, health status, comorbidity index, hypertension personal and family history, smoke status, physical activity status, perceived competence in using ICTs, eHealth literacy, positive and negative mood subscales, trust in physician, and number of visits with the doctor per year.

However, some significant between-group differences emerged: information seekers, in comparison with information avoiders, were more aware of their HT condition (73% vs 52%), conducted more blood pressure measurements on a regular basis (83% vs 60%), used a mobile phone more frequently (mean 3.12, SD 1.81 vs mean 2.38, SD 1.80), perceived the ability to access health-related resources online as more important (mean 3.12, SD 1.33 vs mean 2.48, SD 1.30), had higher trust in online health information sources (mean 1.61, SD 0.77 vs mean 1.32, SD 0.62) and magazines (mean 3.02, SD 1.04 vs mean 2.38, SD 1.04), and had a shorter average doctor-patient relationship length (mean 14.73, SD 11.44 vs mean 19.45, SD 11.69). At the same time, the quasi-experimental group reported higher

decision self-efficacy (at baseline: mean 57.37, SD 20.19 vs mean 44.96, SD 26.98), psychological empowerment (mean 2.47, SD 0.67 vs mean 1.94, SD 0.75), and hypertension-related knowledge (mean 7.66, SD 1.94 vs mean 6.12, SD 2.80) levels than the information avoiders. To address the assumption regarding independence of the covariate and treatment effect [40], all variables achieving a significant difference between the two subsets of the sample were not included into subsequent analyses. The only exception was decision self-efficacy, which was the main outcome measure and the only scale administered both at baseline and posttest.

Hypothesis Testing

To identify all the relevant covariates that might influence the posttest scores of decision self-efficacy, bivariate correlation coefficients were derived. Pearson correlation coefficients equal to or greater than $r=.40$ (moderate effect size; [41]), were included in the analysis of covariance. Furthermore, to be included into the main analyses, a covariate had to satisfy the assumption of independence of the treatment effect. Table 3 shows the bivariate correlations obtained and the presence or absence of any between-group differences on the two groups of the study.

Table 3. Bivariate correlations between decision self-efficacy (posttest) and its antecedents, including between-group differences.

Item/scale ^a	Correlation of decision self-efficacy (posttest) and its antecedents, r	Between-group differences ^b
1 DSE Scale (baseline)	.94 ^c	Yes
2 HK-LS	.55 ^c	Yes
3 Health Empowerment Scale	.71 ^c	Yes
4 ICTs' Perceived Competence	.59 ^c	No
5 I-eHEALS	.67 ^c	No
6 General (HIS) behavior	.63 ^c	Yes
7 Positive mood subscale (GMS)	.41 ^c	No
8 Negative mood subscale (GMS)	-.41 ^c	No
9 Education	.59 ^c	No
10 Age	-.24 ^d	No
11 Health status	.28 ^c	No
12 Comorbidity index (CCI)	-.25 ^d	No
13 Doctor visits (per year)	-.28 ^c	No
14 Doctor-patient relationship length	-.24 ^d	Yes
15 Trust-in-physician scale (A-WFPTS)	-.34 ^c	No
16 HT personal history (years with HT)	-.15	No

^aA-WFPTS: Abbreviated Wake Forest Physician Trust Scale; CCI: Charlson Comorbidity Index; DSE: Decision Self-Efficacy; GMS: Global Mood Scale; HIS: health information seeker; HK-LS: Hypertension Knowledge-Level Scale; HT: hypertension; ICT: information communication technology; I-eHEALS: Italian version of the eHealth Literacy Scale.

^bIndependent-sample t tests between control and intervention group.

^c $P<.001$.

^d $P<.05$.

Based on the two previous tests, main variables included into the model as covariates were decision self-efficacy (baseline), eHealth literacy, positive and negative affect subscales of the GMS, education, and perceived competence in using ICTs.

Our first hypothesis forecast that decision self-efficacy of seniors with HT increases as a function of the preference for more health information. The main covariates included in the model were decision self-efficacy assessed at baseline and eHealth literacy, whereas the independent variable was the willingness to obtain supplementary health information. The ANCOVA test revealed that decision self-efficacy assessed at baseline was significantly related to seniors' decision self-efficacy evaluated in the posttest ($F_{1,93}=307$; $P<.001$, $r=.88$). By interpreting the estimates of effect size derived, we can conclude that baseline levels of decision self-efficacy had a very strong influence on the outcome measure's scores ($r=.88$). All other covariates yielded nonsignificant relationships with the dependent variable. On the other hand, there was a statistically significant main effect of the treatment condition on levels of decision self-efficacy measured at posttest while controlling for the effects of decision self-efficacy levels in the preexperimental phase, eHealth literacy, and the remaining covariates of the model ($F_{1,93}=28.25$, $P<.001$; partial $\eta^2=.23$). Based on these findings, we can accept our first hypothesis. Analyses were repeated with the independent variable dummy coded into three groups: 0=no health information sources consulted ($n=60$), 1=one health information source consulted ($n=29$), and 2=two or more health information sources consulted ($n=12$). The same variables confirmed the findings. Planned contrasts revealed that both treatment conditions increased posttest decision self-efficacy compared to the control group (one health information source consulted: $t_{92}=8.48$, $P<.001$; two or more health information sources consulted: $t_{92}=10.73$, $P<.001$). Nevertheless, pairwise comparisons showed that consulting two or more health information sources rather than only one did not significantly increase posttest decision self-efficacy levels.

All the remaining hypotheses could be tested by the same independent-sample t tests conducted to spot any between-group difference (refer to Between-Group Differences). Health information seekers reported significantly higher scores on the hypertension-related knowledge and psychological empowerment scales than information avoiders; therefore, our hypotheses that the desire to consult additional health information will be influenced by hypertension-related knowledge (hypothesis 2) and psychological empowerment (hypothesis 3) were confirmed. On the other hand, differences were not detected in levels of eHealth literacy, trust in physician, and age; therefore, our hypotheses that the desire to consult additional health information will be influenced by eHealth literacy (hypothesis 4), trust in physician (hypothesis 5), and age (hypothesis 6) were all rejected.

Discussion

Principal Results and Prior Work

Overall, the present quasi-experiment showed that seniors with HT wishing to engage in an assisted consulting health

information session via a personal computer substantially increased their perceived confidence in making an informed choice about treatment (ie, decision self-efficacy). This finding is in line with past evidence, which established a relationship between fulfillment of health information needs and perceptions of control [19,20,22,23,42]. As the two quasi-experimental groups did not differ in terms of posttest decision self-efficacy average scores, it may be assumed that the number of health resources consulted is not as influential as the mere willingness to obtain supplementary contents in general. Nevertheless, due to the small and unequal split of the sample, this advanced analysis (ie, pairwise comparisons) has to be considered with caution and possibly tested in future studies reaching bigger samples. The impact of receiving the health information desired is not only ascribed to foster seniors' self-efficacy and empowerment beliefs. Indeed, past evidence has also demonstrated that the influence of such a construct has to be extended also to actual behavior change and health outcomes, such as improved adherence in general [21,43], and for senior patients with HT in particular [7]. This indicates the pronounced influence of fulfilling health information needs on psychological and health-enhancing behaviors.

Moreover, this study aimed to investigate the antecedents of seniors' health information needs. As expected, knowledge about hypertension, psychological empowerment, and decision self-efficacy (at baseline) largely contributed to distinguish senior information seekers from the so-called "information avoiders." These results are also consistent with available evidence investigating health information-seeking behaviors [19,22-24,42]. Based on our results, adult patients with HT desiring more information feel more empowered and self-confident in making medical decisions compared to avoiders and are more knowledgeable about their HT condition, conduct more blood pressure measurements on a regular basis, and attribute higher trust/importance on online health information resources.

It has to be noted that levels of decision self-efficacy (posttest) were highly correlated with psychological empowerment, hypertension-related knowledge, education, eHealth literacy, positive and negative mood (negative correlation), perceived competence in using ICTs, and past information-seeking behavior. In this sense, their large influence on seniors' perceived confidence in making informed decisions about anti-HT treatment have to be investigated further. Future experimental efforts have to be designed with more sophisticated randomization procedures to ultimately allow the inclusion of all these relevant constructs.

In terms of trust toward different health-related resources, health care professionals remain the most trusted source for senior patients with HT, and the Internet is the least trusted. Seniors not engaging in the assisted health information search (information avoiders) rated as the second most trusted source family members and/or friends, whereas information seekers ranked magazines as the second most reliable channel. This divergence might be explained by the fact that health information avoiders prefer to approach a "living source" of information, which requires less effort and skills to access it [44]. The majority of information seekers preferred to obtain

contents disseminated by a health care provider followed by the Internet. These results are consistent with previous research emphasizing the prominent role of doctors as preferred health information source [6,8,45] and the emergent interest of seniors toward online health resources [8,46-48]. Nevertheless, to properly use this technology to access health content*, and thereby satisfy this “e-interest,” seniors need specific guidance and training (ie, computer and eHealth literacy; [49]). Indeed, according to Chew and Yuqian, “eHealth literacy empowers individuals to take better care of their health and can be enhanced through training” (p 323 [50]). In turn, this might lower the high level of mistrust that senior patients actually attribute to the Internet [51]. At the same time, future efforts developing measures to assess “Internet-based decision aid tools to determine how better to advise and direct patients to useful online decision tools” are warranted (p 757 [8]).

Limitations

First, due to time constraints, the study did not use a random sample. Therefore, reported findings are generalizable only to adults (60 years and older) with hypertension, and residing in the Italian-speaking region of Switzerland. Second, the unequal split between the control and quasi-experimental conditions, coupled with the lack of a proper randomization technique, hindered the possibility to derive more sophisticated results. Indeed, main analyses were conducted only for the two main groups (information seekers vs avoiders), and the inclusion of control variables presumed to be relevant was limited (ie, knowledge about hypertension, empowerment). Third, because the majority of respondents preferred to complete the survey face-to-face (96%), and the principal researcher conducted most of them (92%), a potential interviewer effect could not be excluded. Moreover, participants may have answered the survey items in a socially desirable way in front of the interviewer. The application of self-reported measures is also subject to social desirability and response bias.

Finally, approximately 40% of the respondents were approached in public locations (eg, bars, parks). This aspect may have limited their willingness to initiate (or extend) the assisted health information task offered. Indeed, none of the respondents consulted more than three different sources out of a maximum of five.

Conclusion

Our quasi-experiment investigated the effects of an assisted computer-based health information search on seniors’ perceived confidence in making informed decisions about HT treatments (decision self-efficacy). Antecedents of seniors’ desire for detailed health information, trust, and preferred sources of HT-related content were also evaluated. The results showed significant differences between senior information seekers and avoiders. Engaging in a guided computer-based health information search session proved to be a helpful approach boosting seniors’ perceived ability to make treatment decisions. Future research has to empirically replicate these findings with a representative random sample of seniors with HT. Qualitative research may also be helpful to explore in depth the findings of this study. Although health care professionals remain the dominant source of health information for older adults, new patterns of health information seeking emerged. The growing interest of the Internet as a health information channel might positively influence involvement preferences in medical decision making by satisfying information needs of chronically ill seniors. Nevertheless, to overcome the perceived obstacles to use the World Wide Web, and foster acceptance and trust among elderly people, educational interventions are required (eHealth literacy). When designing health education materials, public health organizations have to tailor health information (ie, with different formats and styles) in a way that will equally satisfy and reach seniors with high information needs and those showing a low desire for accessing health content.

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Authors' Contributions

GS and PJS conceived the study design. GS led the data collection process, main analyses, and outlined the manuscript. PJS contributed to the statistical analyses and supervised the drafting phase of the manuscript. PJS reviewed preliminary paper versions and accepted the final form of the submitted manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Health information resources.

[[PDF File \(Adobe PDF File\), 2MB - cardio_v2i1e12_app1.pdf](#)]

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Abbreviations

A-WFPTS: Abbreviated Wake Forest Physician Trust Scale

CCI: Charlson Comorbidity Index

DSE: Decision Self-Efficacy

eHEALS: eHealth Literacy Scale

GMS: Global Mood Scale

HIS: health information seeker

HK-LS: Hypertension Knowledge-Level Scale

HT: hypertension

ICT: information and communications technology

I-eHEALS: Italian eHealth Literacy Scale

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Original Paper

Food Addiction Support: Website Content Analysis

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Abstract

Background: Food addiction has a long history; however, there has been a substantial increase in published literature and public media focus in the past decade. Food addiction has previously demonstrated an overlap with overweight and obesity, a risk for cardiovascular disease. This increased focus has led to the establishment of numerous support options for addictive eating behaviors, yet evidence-based support options are lacking.

Objective: This study aimed to evaluate the availability and content of support options, accessible online, for food addiction.

Methods: A standardized Web search was conducted using 4 search engines to identify current support availability for food addiction. Through use of a comprehensive data extraction sheet, 2 reviewers independently extracted data related to the program or intervention characteristics, and support fidelity including fundamentals, support modality, social support offered, program or intervention origins, member numbers, and program or intervention evaluation.

Results: Of the 800 records retrieved, 13 (1.6%, 13/800) websites met the inclusion criteria. All 13 websites reported originating in the United States, and 1 website reported member numbers. The use of credentialed health professionals was reported by only 3 websites, and 5 websites charged a fee-for-service. The use of the 12 steps or traditions was evident in 11 websites, and 9 websites described the use of food plans. In total, 6 websites stated obligatory peer support, and 11 websites featured spirituality as a main theme of delivery. Moreover, 12 websites described phone meetings as the main program delivery modality, with 7 websites stating face-to-face delivery and 4 opting for online meetings. Newsletters (n=5), closed social media groups (n=5), and retreat programs (n=5) were the most popular forms of social support.

Conclusions: This is the first review to analyze online support options for food addiction. Very few online support options include health professionals, and a strengthening argument is forming for an increase in support options for food addiction. This review forms part of this argument by showing a lack of evidence-based options. By reviewing current support availability, it can provide a guide toward the future development of evidence-based support for food addiction.

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KEYWORDS

food addiction; self-help groups; social support

Introduction

Food Addiction

Food addiction is a growing area with increasing evidence suggesting that some vulnerable individuals, with issues related to overeating, report a response to food that is likened to other addictions, such as alcohol and gambling—for example continued consumption despite negative consequences or craving [1]. There is current debate around whether food addiction is closely aligned to substance addiction (alcohol and drug addiction), behavioral addiction (gambling addiction), or neither [2], with some arguing that the more appropriate nomenclature being eating addiction as opposed to food addiction [3-5]. However, the lay public show a strong belief in food addiction as one of the contributing causes to overweight and obesity [6]. On the basis of the literature to date and for the purpose of this review, food addiction is defined as the compulsive consumption of highly palatable foods [4,7-9]. With obesity being a primary modifiable risk factor for cardiovascular disease (CVD), support for addictive eating behaviors could assist in the modification of weight status and benefit those at risk [10]. Treatment of addiction often requires behavior change specialists, given addictions are a complex process often comprising a number of components [11]. These include a strong attachment to the substance or behavior, craving, uncontrolled emotions, self-blame, and internal conflict [11].

Prevalence

The majority of existing research in the area is focused on cross-sectional surveys of young adults, mainly female. Food addiction, as defined by self-report survey tools, is approximately 20% [9]. However, this is highly variable (range 5.4%-56.8%) depending on the population group [12], with higher prevalence more common among females and populations with eating disorders, particularly binge eating disorder [9]. A positive relationship has been observed between addictive eating behaviors and overweight or obesity [13]. Systematic reviews investigating food addiction, via the use of the Yale Food Addiction Scale (YFAS) tool, demonstrate an increase in the reporting of addictive eating and associations with increased consumption of energy-rich, nutrient-poor food by the general population and those with food addiction [9,14]. This overconsumption, combined with a strengthening link between food addiction, obesity, and mental health status [7], lends support to the argument of the need for specific support for individuals with self-reported food addiction.

History of Food Addiction Support

The concept of food addiction is not new and has quite a historical perspective [4]. In 1956, Randolph described the use of food in an addictive manner to improve the symptoms of those reporting melancholic mood [15]. In addition, Orford [11] described, in 2001, eating as an excessive appetite in comparison to addictive models such as those styled for gambling and tobacco smoking. It was in the years following that the establishment of self-help groups for food addiction appeared to emerge. Although the subject of food addiction remains controversial, the development and use of the validated YFAS 2.0 tool to evaluate the prevalence of the condition, via

self-report symptom data, combined with studies in population groups [1,6,16,17] demonstrating public support and acceptance of food addiction, warrants investigations into support availability [16,18]. Public views suggest that food addiction is seen as a type of illness and may be caused by being unhappy with aspects of life such as relationships [1,16,17]. Although not formally recognized as a medical condition, many people perceive themselves as being addicted to certain foods [8]. Therefore, the development of an evidenced-based approach to support for food addiction is warranted [11]. The majority of published scientific research has focused on cross-sectional surveys, to identify individuals with addictive eating behaviors, with very few studies evaluating treatment options for food addiction [19-21]. Published interventions for food addiction are limited. A total of 3 published studies that have evaluated interventions have been limited in scope, with 2 of the 3 interventions including solely female participants [19,21], whereas the third was focused on children and adolescents [20]. Hilker et al [19] and Weinstein et al [21] focused interventions on female populations and incorporated psychoeducation sessions and self-help sessions, respectively. Both interventions were informed by already established treatment options with Hilker et al [19] basing an intervention around an existing treatment for Bulimia Nervosa. This involved 6 weekly group psychoeducation sessions, as their basis for the treatment, with positive short-term results in reducing symptoms of food addiction in participants. However, the distinction between food addiction and eating disorders is an area of ongoing research and debate, making it difficult to separate the 2 conditions due to likely symptom crossover [22,23]. Weinstein et al [21] evaluated outcomes over a 5-year period from a 12-step self-help group modeled on Overeaters Anonymous (OA), which works on the idea of abstaining from problem foods [24]. Participation included females (n=60), with meetings for the group held face-to-face once per week with measures of food addiction, assessed using the YFAS, and mental health status taken at baseline, 1 year, and 5 years [21]. Results at both follow-up time points demonstrated that symptoms of food addiction and overall self-efficacy did not change significantly; however, anxiety and depression measures improved after 5 years [21]. In a similar abstinence concept to OA, Pretlow et al [20] used a model of addiction that focused on gradual withdrawal from self-identified, problematic foods, and overeating to treat child and adolescent obesity (n=43) using smartphone technology. The main limitation of this intervention was that it targeted weight loss and was not specific to individuals with food addiction [20].

Self-Help Support for Food Addiction

Numerous alternative self-help groups exist to assist those seeking support for food addiction and overeating. These groups could be beneficial as they offer to service a condition that has strong public acceptance [16]. Conversely, these self-help groups could also be perceived as problematic for individuals involved, as there are no apparent evidence-based support options for food addiction that have been rigorously evaluated. This lack of evaluation leaves individuals open to relapse, or unsuccessful outcomes of behavior change unaccounted for.

Due to the current lack of evidence-based support options for food addiction, and the apparent high demand for access to self-help groups [24], self-help groups may play an important role as the first option for where there is otherwise a lack of support. There is minimal evidence to suggest that self-help groups assist recovery for other addictions relating to alcohol and drugs [25,26]. Treatments for other addictions that utilize a self-help model often include core elements and key strategies such as a focus on interpersonal relationships to improve community experiences and spirituality for growth on a personal level [27]. The aim of addiction self-help groups is for participants to feel empowered and be provided with peer support by individuals who have had similar experiences to the group participants [28]. The self-help group model appears as a popular support option for food addiction; however, the evidence used for the self-help approach in relation to food addiction remains unclear. Therefore, the aim of this review was to evaluate the availability and content of support options, accessible online, for food addiction.

Methods

Web Search

A Web search was conducted using 4 search engines to identify current support availability for food addiction. In total, 3 of the most commonly used search engines [29] (Google [30], Bing [31], and Yahoo [32]) and 1 additional search engine, DuckDuckGo [33], were used. DuckDuckGo was chosen to broaden the scope of the search, and to ensure the search conducted was comprehensive and covered possible options for those seeking help for food addiction. It differs from the other 3 search engines by not saving details or storing cookies on computers from previous searches conducted. This is important to include to ensure rigor and a broad search as it delivers a more varied range of results with repeated searches when compared with the mainstream search engines such as Google. These search engines were chosen as they are commonly used in existing search engine analysis reviews of health within the past 5 years, [29,34,35] and use different search principles.

The following terms were used for the Web searches across all 4 search engines: food addiction treatment, food addiction group, food addiction recovery, and food addiction help. These terms were selected and based on keywords from published papers in the area of food addiction [4,8,17,21] and an analysis of Google Trends [36] to cover a large scope of what individuals with food addiction may enter into a search engine when looking for assistance. Searches were conducted in and websites reviewed in April 2017.

Due to the large number of results to be retrieved from the search (128-22,400,000 from each search engine per search; Refer to [Multimedia Appendix 1](#)), it was decided to prioritize and review the first 50 retrieved websites (not including paid

advertised sites identified as advertisements on the search engine results pages). To ensure rigor and completeness of the review, the number of websites for possible inclusion was selected for several reasons. First, it has been previously acknowledged that individuals undertaking Internet searches rarely view past the first 2 pages of results [37,38]. Second, a pilot of the search procedure was undertaken, and this identified that a number of different levels of the same website were being retrieved, that is, all webpages linked to the website's index or home page, and therefore, each result returned was not a unique website. Where multiple pages of a website were retrieved, these were counted as one website, with the website then viewed in its entirety for data extraction purposes. For these reasons, the first 50 websites were chosen; this is consistent with similar review strategies of website content analysis [34,35].

To be included in this review, the website needed to meet the following 3 criteria: (1) to specifically treat those with food addiction, (2) included meetings or interventions involving participant and group leader or counselor, and (3) the website was in English. Exclusion criteria were as follows: websites that included the support or treatment of multiple forms of addiction (ie, drugs or alcohol in addition to food) and websites including multiple treatments where it was not clear how specific support for food addiction was delivered, thus creating difficulties for analysis of available support options. Once the websites had undergone review (RM), the included websites were analyzed for content by 2 independent reviewers (RM and JS).

Data Extraction

A standardized extraction form ([Multimedia Appendix 2](#)) was developed and piloted for the purpose of the website review. The extraction factors were based on similar reviews [29,34,35] previously conducted and related to the program or intervention characteristics, fundamentals, support modality, social support offered, program or intervention origins, member numbers, and program or intervention evaluation. These aspects were selected as they were able to inform specific points of comparison between websites. The data extraction form was initially piloted with 7 websites with slight modifications made to ensure enough detail was extracted to enable comparisons and descriptions. The information extracted from the websites was entered in a preformatted table. The data were extracted by 2 separate reviewers to increase accuracy and completeness, and any discrepancies were checked by a third reviewer. Once data were extracted, this information was summarized narratively with content evaluated to assess methodological characteristics of food addiction support. Where possible frequencies were tallied (ie, support delivery mode), and means and ranges calculated (ie, cost).

For the purposes of data extraction, the standard definitions were used. These are outlined in [Table 1](#).

Table 1. Definitions used in data extraction.

Data	Definition
Member numbers	The number of members (ie, Individuals attending meetings) as stated on the website
Establishment year	The year the group or program was first established (not the year the website was established)
Country of origin	Country where the program was established
Fees	Cost associated with involvement in the program
12 steps and traditions	Defined as the general practice followed for self-help groups meetings as originally set out for Alcoholics Anonymous. The 12 steps are underpinned by the 12 traditions of how meetings are to be facilitated, and the belief in most cases that addiction possesses medical and spiritual elements [25]
Food plans	Considered if the website stated that a predesigned daily food plan was to be followed during participation in the program
Abstinence from food	Included if there was an expectation that group participants would exclude specific foods or food groups such as sugar and wheat from their diets
Sponsorship	Defined as a support relationship provided by another group member of the program
Spirituality	Defined as participants being required to align with religion or a spiritual notion to be involved in the program
Involvement of health professionals	Considered if the program was established or delivered by an individual with a university health qualification
Face-to-face meetings	Defined as a meeting where program participants meet at a predetermined venue
Phone meetings	Defined as a meeting that is held as a dial-in phone meeting at a predetermined time. Considered both group phone meetings and individual phone meetings
Online meetings	Defined as a meeting that is held online either by a program such as Skype or an online messaging forum at a specified time
Podcasts	Defined as audio recordings on the website available to individuals
Newsletter	Defined as a compilation of written articles on the website available to individuals or written articles emailed on a regular basis to those who sign up on the website to receive newsletters
Retreats	Considered if a website advertised a program delivered over 2 or more days at a predetermined destination
Evaluation	Defined as the assessment of the program to determine outcomes for participants
Social media closed groups	Considered if the website stated that group participants would be given access to an online forum that was only accessible by other group members

Results

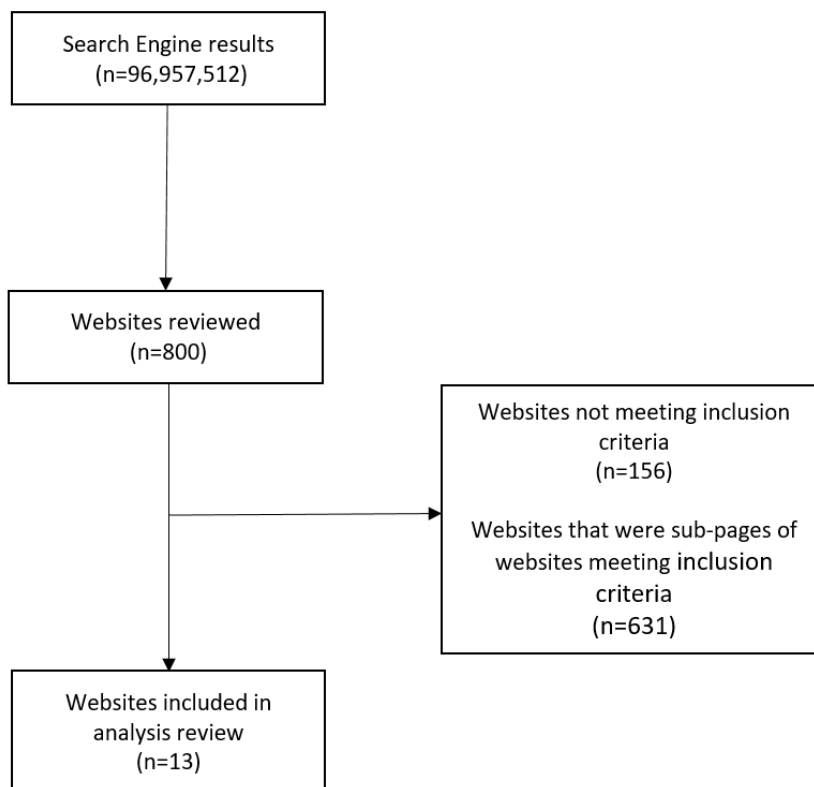
Website Inclusion

Of the 800 records retrieved across the 4 search platforms (Figure 1), 156 (19.5% 156/800) did not meet the inclusion criteria. In total, 13 (1.6% 13/800) websites met the inclusion criteria, and of the 644 (80.5% 644/800) remaining websites, all were subpages of the 13 (1.6% 13/800) uniquely identified websites reporting on individual support groups for food addiction. The major reason for exclusion was that websites report support or treatment of multiple addictions (n=23).

Program Origins, Membership, and Facilitation

All 13 websites (Tables 2-4, Multimedia Appendix 3) reported originating in the United States. Only 1 website reported on member numbers (n=54,000). However, it was not reported when this membership number was from or how membership

numbers were obtained. The use of credentialed health professionals in the establishment or delivery of the programs was reported by 3 websites only with counselors (n=2), psychotherapists (n=1), and social workers (n=1) used. Moreover, 2 websites encouraged, but did not enforce, the use of general practitioners and dietitians. Costs for the self-help groups were highly variable (free to US \$5300), 8 websites reported that programs were offered free of charge. Of these 8 free programs, 4 websites encouraged individuals to purchase specified literature related to the program, 1 website held an annual convention that included a registration fee, and 3 websites had no fees or other costs associated for individuals. A total of 5 websites reported having a fee-for-service ranging from US \$15 (group membership) to US \$5300 (retreat style support). No websites reported their program had been evaluated for outcomes of diet, food behaviors, or success rates of food addiction symptoms.

Figure 1. Flow diagram of websites included in analysis.**Table 2.** Frequency of location, format, and delivery mode on websites (N=13).

Website features	n
Country of origin	United States, n=13
Format	
Fees	5
12 steps/traditions	11
Food plans	8
Abstinence from foods	8
Sponsorship	6
Spirituality based	11
Health professional involvement	3
Delivery mode	
Face-to-face meetings	7
Phone meetings	12
Online meetings	4
Social support	
Podcasts	2
Newsletter	5
Social media closed groups	5
Retreats	5
Program evaluation	0

Table 3. Website extraction data (websites 1-6).

Website features	Website 1 [24]	Website 2 [39]	Website 3 [40]	Website 4 [41]	Website 5 [42]	Website 6 [43]
Member numbers	54,000	N/A ^a	N/A	N/A	N/A	N/A
Establishment year	1960	N/A	1998	N/A	1979	N/A
Country of origin	United States	United States	United States	United States	United States	United States
Fees	✗ ^b	✗	✗	✗	✗	✗
12 steps/traditions	✓ ^c	✓	✓	✓	✓	✓
Food plans	✗	✓	✓	✓	✓	✗
Abstinence from foods	✗	✗	✓	✓	✓	✓
Sponsorship	✓	✓	✓	✓	✓	✗
Spirituality based	✓	✓	✓	✓	✓	✓
Involvement of health professionals	✗	✗	✗	✗	✗	✗
Face-to-face meetings	✓	✓	✓	✓	✓	✗
Phone meetings	✓	✓	✓	✓	✓	✓
Online meetings	✓	✓	✗	✗	✓	✗
Podcasts	✓	✗	✗	✗	✓	✗
Newsletter	✓	✗	✓	✗	✗	✗
Social media closed groups	✓	✗	✓	✗	✗	✗
Retreats	✗	✗	✓	✗	✗	✗
Evaluation	✗	✗	✗	✗	✗	✗

^aN/A=Information not available on website.

^b✗ indicates information was not provided on website.

^c✓ indicates information was provided on website.

Fundamental Features and Requirements of Participants

The most common fundamental feature of the websites was the inclusion of the 12-step guideline as a core program element, and spirituality as a main theme of how the program was to be interpreted and delivered. The 12 steps and 12 traditions (Multimedia Appendices 4 and 5) were present in 11 out of the 13 included websites. The 12-step guidelines have been adapted from their use in alcohol and drug addiction programs; however, the steps varied slightly in definition between the food addiction self-help groups. Moreover, 7 out of 11 websites stated their 12 steps using the term “food,” eg, participants would “admit they were powerless over food.” Furthermore, 2 websites included specific foods or nutrients including sugar, flour, and wheat; 1 website used the general terms “addictions and compulsive behaviors”; and 1 website did not state the wording of the 12 steps followed. The use of food plans was described in the majority of websites (n=9). In addition, 2 websites made the

food plan available online. A total of 2 websites required financial commitment to their program before gaining access to the food plan. Moreover, 1 website required participants to purchase a book containing the food plan and 4 websites use food plans, but these only become available to participants when they commenced attendance at program meetings. Furthermore, 8 websites required participants to abstain from particular foods during program participation. The foods most commonly abstained from were sugar (n=5), flour (n=3), and wheat (n=2). A total of 3 websites did not specify which food to abstain from but reported some form of food abstinence was required. The remaining 5 websites stated sugar was to be abstained from and included combinations of either wheat, flour, grains, or “refined carbohydrates.” In all, 1 website required abstinence specifically from sweeteners including natural (eg, stevia) and artificial (eg, aspartame), as opposed to sugar. Peer support was obligatory in 6 of the 13 websites with sponsorship by other members required to participate in the program. Moreover, 11 websites stated spirituality as a main theme of their program.

Table 4. Website extraction data (websites 7-13).

Website features	Website 7 [44]	Website 8 [45]	Website 9 [46]	Website 10 [47]	Website 11 [48]	Website 12 [49]	Website 13 [50]
Member numbers	N/A ^a	N/A	N/A	N/A	N/A	N/A	N/A
Establishment year	N/A	2000	N/A	N/A	N/A	N/A	N/A
Country of origin	United States	United States	United States	United States	United States	United States	United States
Fees	✓ ^b	✗ ^c	✗	✓	✓	✓	✓
12 steps/traditions	✓	✓	✓	✓	✗	✓	✗
Food plans	✓	✓	✗	✓	✗	✗	✓
Abstinence from foods	✓	✓	✗	✓	✓	✗	✗
Sponsorship	✗	✓	✗	✗	✗	✗	✗
Spirituality based	✓	✓	✓	✓	✗	✓	✗
Involvement of health professionals	✓	✗	✗	✓	✗	✗	✓
Face-to-face meetings	✓	✗	✗	✗	✗	✗	✓
Phone meetings	✓	✓	✓	✓	✓	✗	✓
Online meetings	✗	✗	✗	✓	✗	✗	✗
Podcasts	✗	✗	✗	✗	✗	✗	✗
Newsletter	✓	✗	✗	✓	✗	✓	✗
Social media closed groups	✗	✓	✓	✗	✓	✗	✗
Retreats	✓	✗	✗	✓	✗	✓	✓
Evaluation	✗	✗	✗	✗	✗	✗	✗

^aN/A=Information not available on website.

^b✓ indicates information was provided on website.

^c✗ indicates information was not provided on website.

Mode of Delivery

The most frequently used mode of delivery among the programs was phone meetings between participant and group leaders or counselors, with 12 out of the 13 programs opting for this type of delivery. The frequency of phone meetings differed greatly between the 12 groups with phone meeting occurring daily (n=5), 6 times per week (n=1), 4 times per week (n=3), once per week (n=1), or phone meetings were held only with the individual at a time convenient to the individual (n=2). For group phone meetings, participants are provided with a phone number, and a specific time to call the number, to join the meeting. The times of the phone meetings varied with 9 websites not specifying the length of their phone meetings. Moreover, 1 website stated their phone meetings were 60 min in length, 1 website specified a length of 30 min, and another website stated that their phone meetings vary anywhere from 60, 75, and 90 min to an unspecified length of time. The content and structure of phone meetings was reported by 5 websites, with content and structure not reported, and therefore unclear for 7 websites. A total of 7 websites stated face-to-face delivery of meetings, the most common places for meetings were at religious facilities, such as churches or community centers. The least frequent was group online meetings, with 4 programs choosing this type of delivery.

Social and/or Peer Support

Newsletters (n=5), closed social media groups (n=5), and retreat programs (n=5) were the most popular forms of social support. A total of 2 websites provide access to program-related podcasts.

Discussion

This review set out to evaluate the content of websites for support options available to those seeking help specifically with addictive eating behaviors. Overall, self-help groups for food addiction appear to be the main source of support available for those seeking help with their addictive eating behaviors, with few evaluations found in published research. It was identified that there is minimal evidence surrounding the effectiveness of self-help groups for addiction, and although there was a reported focus on food and emotional recovery, the specialized input of credentialed health professionals is rarely used.

It is interesting to note that research in food addiction has a long history, with the support services from website 1 commencing in 1960. However, it is only since 2008 that the amount of published scientific literature has rapidly increased [4]. The establishment of the support group from website 1 was well before food addiction became a more popular scientific research area and topic in lay media and before the commencement of the *obesity epidemic*, with steady body weight increases beginning to occur in the 1970s [51]. The 1930s and 1940s saw

the establishment of 12-step programs as a prominent treatment for alcohol addiction [25], presenting a 30-year time period before the same format began being applied to food. The writings of Randolph [15] in 1956 could be assumed to have led to the idea that the treatment of food addiction be found within the same addiction model as alcohol; however, this remains unclear.

The 12-step format used by OA, although never evaluated for its effectiveness for the specific treatment of food addiction, has led to the formation of multiple 12-step support programs offered to those seeking help with addictive eating behaviors. The support provided by OA has been reviewed in the past; however, these reviews investigated the outcomes for eating disorders and weight loss [52-55] as opposed to food addiction. In addition, this research was undertaken before 2008 and therefore, before the rapid rise of interest in food addiction. Tools such as the YFAS were not developed and made available until 2009, making reporting on food addiction as an outcome more difficult. Another explanation for this may be the crossover between binge-type eating disorders and food addiction. From the 1980s until around 2008, addictive eating was foremost viewed as disordered eating. The concept of recurrent binge eating was introduced to the DSM-III (Diagnostic and Statistical Manual of Mental Disorders) in 1980, and binge eating disorder was included as a stand-alone diagnosis in the DSM-5 in 2013, and therefore a main outcome measure for overeating self-help groups [4,56]. Current approaches to food addiction support are rarely externally evaluated and reported on. Rather, the majority of outcomes reported are personal anecdotes or testimonials on group websites, likely skewing perceptions of effectiveness for potential participants.

A total of 9 out of the 13 support programs reviewed follow the 12-step program based on the original foundations for food addiction support as established by OA. It could be surmised that other programs have been designed to address a more modernized view of food addiction—for example, supporting the belief that sugar produces neurochemical effects in the brain and is an addictive substance to be abstained from. However, to date, there is no strong scientific evidence in humans to suggest that foods, or nutrients, such as sugar are in fact addictive in a neurochemical context [57]. Given the lack of evidence for any neurochemical addictive properties of food in humans, it is noteworthy that 8 of the 13 websites recommended or required abstinence from particular foods during program participation, with sugar, wheat, and flour being reported as the most common. These foods are targeted as highly consumed foods and high consumption of refined versions of these foods has been linked to an increased risk of obesity and CVD [58]. The presumed belief behind this food abstinence is, following the same model as drug and alcohol addiction, that a substance must be abstained from to overcome the addiction. This is a point of difference between the more recent programs and OA, where the latter views abstinence as abstaining from compulsive eating behavior, not from individual foods or nutrients [24]. When considering the application of the 12-step program format from alcohol or drug addiction to food addiction, it is important to note the current evidence base. To date, evidence has been inconclusive in the effectiveness of 12-step programs in the

treatment of addiction [25,26]. Therefore, if strong evidence in support of 12-step programs, in general, is yet to be established, it is difficult to state if a direct format transfer from alcohol or drug to food is permissible.

The United States was the sole country of origin for all websites. If the rates of other addiction are considered in the United States, alcohol dependence occurs at a rate of 5.6%, with global rates at 4.9%. The United States has the highest prevalence of cocaine addiction, yet Australasia has the highest rate of opioid and amphetamine addiction [59]. The prevalence data for rates of food addiction in the United States are variable, ranging from 5.8% to 56.8% when measured by the YFAS, and this variability is consistent with other global food addiction data [9]. Therefore, addiction rates in the United States do not appear to be significantly higher than the rest of the world, yet the mainstream support options for food addiction have all originated in the United States. This is, however, unsurprising as research has shown individuals in the United States obtain the assistance of self-help groups for addiction more than any other type of treatment, including health professionals [60]. Self-help groups for food addiction may be prevalent in other countries; however, due to inclusion criteria requiring sole support of food addiction, and not broader addictions, these may not have been included in this review.

The majority of websites (n=10) did not involve the participation of qualified health professionals in their programs. Qualified counselors, psychotherapists, and social workers were utilized in 3 programs; however, interestingly, dietitians were not involved in the development or delivery of any of the program features on the website. This is noteworthy considering the substantial emphasis on food consumption and restriction within the programs offered, and most websites offering food plans. In addition, 2 of the websites encouraged participants to seek input from general practitioners and dietitians to assist them in their recovery, but this does not appear to be considered as essential by the self-help groups in most cases.

The format of the meetings offered within the website programs is an important element. It has been suggested that by participating in group support, social relationships are formed and there is an increase in peer abstinence, which in turn promotes abstinence within the individual [61]. Spirituality is another element included in the majority of websites, with some research proposing it plays a role in the continuation of abstinence and that an individual does not have to be spiritual to benefit from the program offered [60,62]. There are only few studies that specifically consider spirituality and addiction, with further research needed to investigate any ongoing benefits of spirituality.

Face-to-face, phone, and online group meeting formats were the majority among websites, indicating their support in the belief of greater outcomes of abstinence within social settings. In contrast, online social support such as podcasts and newsletters were not commonly used among website support programs, as it appears the main focus of the support programs is to engage people in group situations and encourage the forming of relationships, as opposed to listening to podcasts or reading newsletters unaided.

This review was limited mainly due to the restriction placed on pages to be reviewed from searches. This occurred to ensure the review was completed in a timely manner and was based on evidence of the number of pages commonly reviewed by individuals [34,35]. In the fast-paced Web-based world, it is difficult to ensure that information provided in this review can be reapplied to the websites in their current state. The website search was conducted by 1 reviewer, which left the review open to human error, with a website fitting the inclusion criteria being overlooked and adding possible bias. This review did not consider any online support options for multiple addictions where food may have been listed as an addiction in conjunction with other addictions such as alcohol or drug addiction. As the programs are mostly delivered outside of the website format,

the content of complete program material could not be evaluated. It was also limited to those websites published in English. The results of this review should be interpreted in regard to these limitations and provide only a snapshot of available online self-help groups directed solely at food addiction support.

This is the first review to analyze online support for food addiction. Results show 13 Web-based programs exist that are often complemented with phone support, programs vary in cost, and rarely utilize trained health professionals. The abundance of food addiction support programs available on the web displays the perceived need by the general public to have access to these types of services. By reviewing current food addiction support availability, it can provide a guide toward the development of evidence-based support for food addiction.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of search results by search engine.

[PDF File (Adobe PDF File), 21KB - [cardio_v2i1e10_app1.pdf](#)]

Multimedia Appendix 2

Food addiction website criteria extraction.

[PDF File (Adobe PDF File), 21KB - [cardio_v2i1e10_app2.pdf](#)]

Multimedia Appendix 3

Included websites.

[PDF File (Adobe PDF File), 30KB - [cardio_v2i1e10_app3.pdf](#)]

Multimedia Appendix 4

The AA 12 steps.

[PDF File (Adobe PDF File), 52KB - [cardio_v2i1e10_app4.pdf](#)]

Multimedia Appendix 5

The AA 12 traditions.

[PDF File (Adobe PDF File), 54KB - [cardio_v2i1e10_app5.pdf](#)]

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Abbreviations

- CVD:** cardiovascular disease
- DSM:** Diagnostic and Statistical Manual of Mental Disorders
- OA:** Overeaters Anonymous
- YFAS:** Yale Food Addiction Scale

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Corrigenda and Addenda

Correction: Assessing the Use of Wrist-Worn Devices in Patients with Heart Failure: Feasibility Study

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The authors of the paper “Assessing the Use of Wrist-Worn Devices in Patients with Heart Failure: Feasibility Study” (*Cardio JMIR* 2017;1 (2): July-Dec) made a mistake by including a patient who had heart failure with preserved ejection fraction. This finding was just brought to the authors’ attention. They apologize for this oversight but have taken all measures to ensure that correct data is displayed in the article.

In the Introduction section, the following has been removed from the end of the final sentence:

...with reduced ejection fraction (HFrEF; ejection fraction <40%) and NYHA Class II and III, as measured by daily steps by these two devices.

In the Methods section, the mention of “HFrEF” has been changed to “HF”. “HFrEF” has also been removed from the paper’s Abbreviations list.

In the Results section, the second and third sentences of the paragraph beginning with “Table 1...” has been changed to the following:

Patients were predominantly male (5/8, 63%), with an average age of 58 years and ischemic cardiomyopathy (5/8, 63%). All patients were on guideline-directed medical therapy including a betablocker and either an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) when indicated.

Specifically, the text which was previously “(6/8, 75%)” now reads “(5/8, 63%)”. The average age was “57” and is now “58”, and the phrase “when indicated” has been added to the end of the latter sentence.

The caption for Table 1 has been shortened from “Demographics and baseline data of patients included in phase 2 of the study” to “Demographics and baseline data”. In Table 1 itself, data for Patient 7 has been changed under the following columns:

Age (years): “51” changed to “58”

Gender: “Male” changed to “Female”

LVEF^a, %: “35” changed to “60”

Etiology of HF^b: “Ischemic” changed to “Familial”

Medications^d, Betablocker: “Carvedilol 12.5 mg” changed to “None”

Medications^d, Other: “Ramipril 10 mg” changed to “None”

The updated version of Table 1 is available below.

The corrected article will appear in the online version of the paper on the JMIR website on May 4, 2018, together with the publication of this correction notice. Because this was made after submission to PubMed, Pubmed Central, and other full-text repositories, the corrected article also has been re-submitted to those repositories.

Table 1. Demographics and baseline data.

Number	Age (years)	Gender	LVEF ^a , %	Etiology of HF ^b	NYHA ^c class	Medications ^d		
						Betablocker	Amiodarone	Other
1	67	Male	40	Ischemic	3	Bisoprolol 2.5 mg	None	Candesartan 8 mg
2	68	Male	18	Ischemic	2	Bisoprolol 10 mg	200	Irbesartan 300 mg
3	63	Male	25	Ischemic	3	Bisoprolol 10 mg	None	Perindopril 8 mg
4	61	Female	27	Non-ischemic	2	Bisoprolol 10 mg	None	Perindopril 4 mg
5	52	Male	25	Ischemic	2	Bisoprolol 10 mg	None	Perindopril 8 mg
6	57	Female	27	Non-ischemic	3	Carvedilol 25 mg	None	Ramipril 2.5 mg
7	58	Female	60	Familial	2	None	None	None
8	35	Male	33	Hypertrophic	3	Carvedilol 50 mg	None	Ramipril 10 mg

^aLVEF: left ventricular ejection fraction.

^bHF: heart failure.

^cNYHA: New York Heart Association.

^dDrug doses are total daily dose.

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Original Paper

Monitoring Patients With Implantable Cardioverter Defibrillators Using Mobile Phone Electrocardiogram: Case Study

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Abstract

Background: Preventable poor health outcomes associated with atrial fibrillation continue to make early detection a priority. A one-lead mobile electrocardiogram (mECG) device given to patients with an implantable cardioverter defibrillator (ICD) allowed users to receive real-time ECG readings in 30 seconds.

Objective: Three cases were selected from an institutional review board-approved clinical trial aimed at assessing mECG device usage and satisfaction, patient engagement, quality of life (QoL), and cardiac anxiety. These three specific cases were selected to examine a variety of possible patient presentations and user experiences.

Methods: Three ICD patients with mobile phones who were being seen in an adult device clinic were asked to participate. The participants chosen represented individuals with varying degrees of reported education and patient engagement. Participants were instructed to use the mECG device at least once per day for 30 days. Positive ECGs for atrial fibrillation were evaluated in clinic. At follow-up, information was collected regarding their frequency of use of the mECG device and three psychological outcomes in the domains of patient engagement, QoL, and cardiac anxiety.

Results: Each patient used the technology approximately daily or every other day as prescribed. At the 30-day follow-up, usage reports indicated an average of 32 readings per month per participant. At 90-day follow-up, usage reports indicated an average of 34 readings per month per participant. Two of the three participants self-reported a significant improvement in their physical QoL from baseline to completion, while simultaneously self-reporting a significant decrease in their mental QoL. All three participants reported high levels of device acceptance and technology satisfaction.

Conclusions: This case study demonstrates that ICD patients with varying degrees of education and patient engagement were relatively active in their use of mECGs. All three participants using the mECG technology reported high technology satisfaction and device acceptance. High sensitivity, specificity, and accuracy of mECG technology may allow routine atrial fibrillation screening at lower costs, in addition to improving patient outcomes.

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KEYWORDS

atrial fibrillation; ICD; ECG; mobile phone monitoring; mobile health; electrophysiology

Introduction

Background

Implantable cardioverter defibrillators (ICDs) have demonstrated a mortality advantage in randomized clinical trials compared with usual care and antiarrhythmic drug treatments in at-risk patients [1]. The full suite of diagnostic capabilities of ICDs, such as detection of atrial arrhythmias, provide additional value to health care professionals. However, patients with ICDs have not had equal access to this information. Recently, multiple consumer products have been approved for cardiac monitoring, including mobile phone-based systems that provide physician-interpreted electrocardiograms (ECGs) on demand. The overall impact and value of engaging patients in the use of these services continues to emerge, but the utility of potentially detecting the initiation of atrial fibrillation could be significant.

Atrial fibrillation is the most common cardiac arrhythmia worldwide and continues to be a major burden to public health [2]. It affects up to 6 million American adults, which is expected to double over the next 25 years [2]. Furthermore, atrial fibrillation is associated with a five-times increased risk of stroke [2] and a three-times increased risk of heart failure [3]. Approximately one of three patients with atrial fibrillation have “silent” or underdetected symptoms, highlighting the potential importance of intermittent ECG data acquisition [4]. Many of the associated poor outcomes of atrial fibrillation are thought to be highly preventable, making early identification of atrial fibrillation a priority issue.

Patient Engagement and Self-Management

Patient engagement refers to the attitudes and behaviors of patients, and the ways in which they interact with their own health care management plans [5,6]. Research has shown that patients who are more engaged in managing their health care needs may yield more positive clinical outcomes than their less-engaged peers [5,7]. Positive patient engagement helps promote good health behaviors and can increase overall life satisfaction [5,8]. Due to advances in technology, patients are now increasing their patient engagement and self-management through the use of health-related mobile phone-based apps.

KardiaMobile by AliveCor

For ICD patients, using a KardiaMobile by AliveCor, Inc [9] device with the associated Kardia app has been one way that patients are able to increase their patient engagement. The KardiaMobile mobile ECG (mECG) device is one of many recently developed, noninvasive diagnostic tools. Although using these devices does not replace the need for regularly scheduled 12-lead ECG readings, more frequent screening allows patients to play a more substantial role in their health care. The KardiaMobile mECG device is half the size of a credit card and can securely attach to the back of a mobile phone or tablet. This one-lead device is cleared by the US Food and Drug Administration and can accurately detect atrial fibrillation in 30 seconds [4]. The instantaneous analysis of the user’s ECG reports three different outcomes: “normal,” “possible atrial fibrillation,” and “unclassified.” The development of mobile-supported health apps may allow patients and their health

care providers to use medical information to improve patient satisfaction and health security, reduce costs, and improve health outcomes. However, no research to date has investigated usage and satisfaction with the KardiaMobile device, or the psychosocial correlates. The purpose of this case study is to examine the utility and impact of mobile phone-based ECG readings in three ICD patients who are enrolled in a clinical study.

Methods

Patients with ICDs were approached for study participation at their regularly occurring device-check appointments. Three unique cases were selected from an institutional review board-approved clinical trial aimed at assessing KardiaMobile device usage and satisfaction, patient engagement, QoL, and cardiac anxiety. The three cases chosen were selected to examine a variety of possible patient presentations and user experiences. Participants were not compensated for their participation, but they were allowed to keep their KardiaMobile devices free of charge at the conclusion of the study period.

The first participant was selected because they reported a high percentage of atrial fibrillation readings in comparison to other patients. The second participant was selected to include a participant who reported above average QoL scores and high overall KardiaMobile device usage. The third participant was included because they reported low baseline QoL in both the physical and mental health domains.

Patients were administered the Cardiac Anxiety Questionnaire (CAQ), which is an 18-item self-report measure designed to assess cardiac anxiety [10]. Higher mean scores indicate greater cardiac anxiety symptoms. Participants also completed the Short Form Health Survey version 2 (SF-12v2), a 12-item questionnaire used to measure functional health and well-being from a patient perspective [11]. These measures were administered at baseline and at 30- and 90-day follow-ups. The SF-12v2 provides two summary scores of QoL: a mental health subscale and a physical health subscale (higher scores indicate greater QoL). KardiaMobile usage reports were also collected at the 30- and 90-day follow-up research appointments. Patients were asked at the 30-day follow-up if they would like to continue using the KardiaMobile device. Additionally, patients self-reported on an item which stated, “I am satisfied with my use of the KardiaMobile device” and responded on a 5-point Likert scale from “strongly disagree” to “strongly agree,” at each follow-up administration.

Results

Participant 1

The first participant was a married, white woman (age approximately 60 years), who held a graduate degree and reported an annual income of US \$50,000 to US \$74,000. Her cardiac medical history included diagnoses of atrial fibrillation, congestive heart failure, ventricular tachycardia, and nonischemic cardiomyopathy. Her KardiaMobile usage reports indicated that at 30-day follow-up she had used her device 34 times (0%, 0/34 normal readings; 59%, 20/34 atrial fibrillation

readings; 41%, 14/34 unclassified readings). She agreed to continue using the device for an additional 60-day period, and at the 90-day follow-up she had used the device a total of 109 times (3.7%, 4/109 normal readings; 77.1%, 84/109 atrial fibrillation readings; 19.3%, 21/109 unclassified readings). As shown in [Table 1](#), participant 1 reported very strong agreement to being satisfied with use of the device at both 30-day and 90-day follow-ups. Participant 1 reported average mental and physical well-being across all time points. She also reported below average cardiac anxiety across all time points (see [Figure 1](#)).

Participant 2

The second participant was a married, white male (age approximately 70 years) who had completed some college and reported an annual income of US \$30,000 to US \$39,999. His medical history included atrial fibrillation, coronary artery disease, hypertension, sustained ventricular tachycardia, and

Twiddler's syndrome. KardiaMobile usage reports indicated that at 30-day follow-up he had used his device 37 times (89%, 33/37 normal readings; 5%, 2/37 atrial fibrillation readings; 5%, 2/37 unclassified readings). He agreed to continue using the device for an additional 60-day period, and at the 90-day follow-up he had used the device a total of 139 times (88.5%, 123/139 normal readings; 9.4%, 13/139 atrial fibrillation readings; 2.2%, 3/139 unclassified readings). Participant 2 agreed very strongly to being satisfied with use of the device at both 30-day and 90-day follow-ups. Participant 2 reported high mental well-being and low physical well-being at baseline (see [Table 1](#)). His reported physical QoL increased significantly from baseline to 30-day follow-up. His mental well-being dropped slightly over time; however, his score continued to suggest good mental QoL. His score on the CAQ indicated below average cardiac anxiety, and his score remained stable across time points (see [Figure 1](#)).

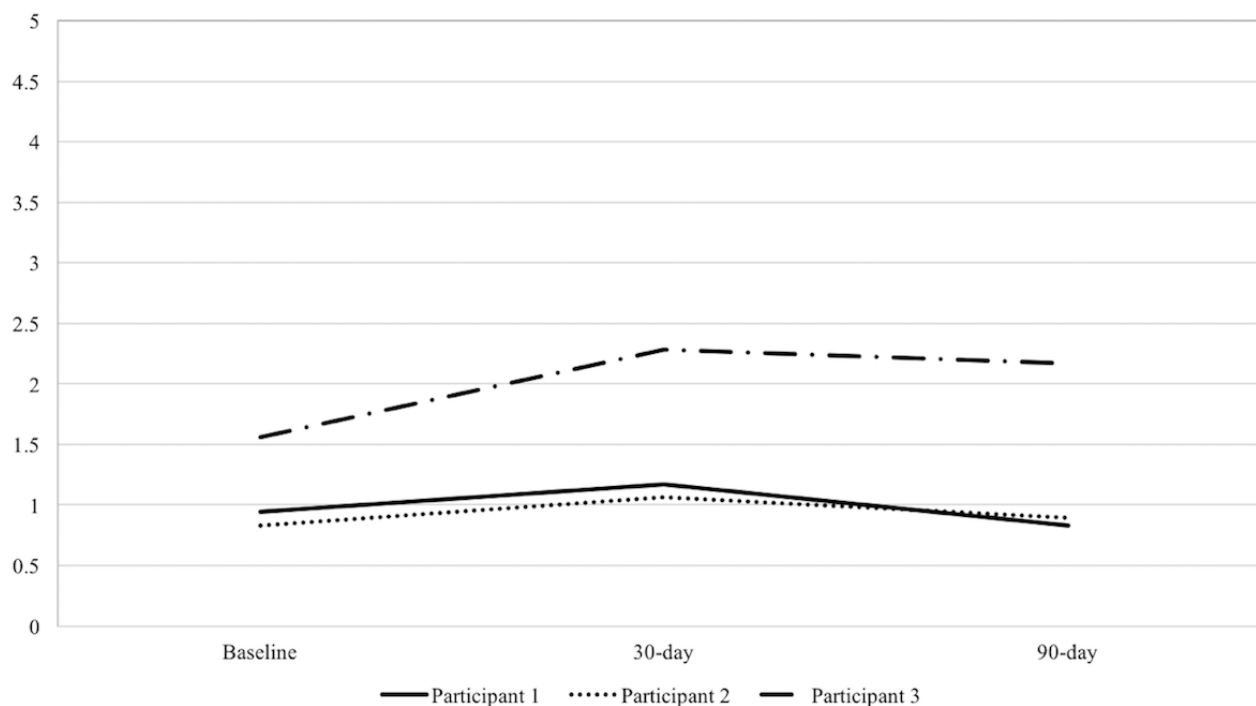
Table 1. Outcomes following KardiaMobile usage in three patients with implantable cardioverter defibrillators.

Outcomes	Participant 1	Participant 2	Participant 3
Usage (30-day), n			
Total	34	37	25
Normal	0	33	23
Atrial fibrillation	20	2	0
Unclassified	14	2	2
Usage (90-day), n			
Total	109	139	61
Normal	4	123	56
Atrial fibrillation	84	13	2
Unclassified	21	3	3
CAQ^a, score			
Baseline	0.94	0.83	1.56
30-day	1.17	1.06	2.28
90-day	0.83	0.89	2.17
SF-12v2 Physical^b, score			
Baseline	57	22	28
30-day	55	44 ^c	31
90-day	54	35 ^c	34 ^c
SF-12v2 Mental^b, score			
Baseline	56	72	24
30-day	58	65 ^c	23
90-day	58	67	18 ^c

^aCAQ: Cardiac Anxiety Questionnaire. The development paper of the CAQ reported a mean total score of 1.67 (SD 0.81) in a sample of 42 cardiac patients [10].

^bSF-12v2: 12-Item Short Form Survey version 2. Mean scores on both SF-12 subscales were 50 (SD 10).

^cIndicates a significant change (5 points) on an SF-12v2 subscale.

Figure 1. Cardiac Anxiety Questionnaire scores at baseline and at 30- and 90-day follow-ups (N=3).

Participant 3

The third participant was a married, African-American male (age approximately 60 years), who had completed a high school degree and reported an annual income of US \$30,000 to US \$39,999. His cardiac medical history included myocardial infarction, peripheral artery disease, ischemic cardiomyopathy, and hypertension. KardiaMobile usage reports indicated that at 30-day follow-up he had used his device 25 times (92%, 23/25 normal readings; 0%, 0/25 atrial fibrillation readings; 8%, 2/25 unclassified readings). He agreed to continue using the device for an additional 60-day period, and at the 90-day follow-up he had used the device a total of 61 times (92%, 56/61 normal readings; 3%, 2/61 atrial fibrillation readings; 5%, 3/61 unclassified). Participant 3 reported very strong agreement to being satisfied with use of the device at both 30-day and 90-day follow-ups. Participant 3 reported low QoL in both the physical health and mental health domains, in comparison to SF-12v2 norms for US adults, across all time points (see Table 1). Participant 3's physical QoL slightly improved from baseline to 90-day follow-up; however, he also reported a slight decline in mental well-being during this time period. He reported high cardiac anxiety, which increased from baseline to 30-day follow-up. In comparison to the CAQ development norms [12], his score at 30-day follow-up fell to the 80th percentile (see Figure 1).

Discussion

The current case series demonstrated that ICD patients with varying degrees of education and patient engagement were relatively active in their use of mobile phone-based ECGs. At baseline, patients were asked to use the KardiaMobile device at least once per day. Across patients presented, each patient used the technology approximately daily or every other day. At

the 30-day follow-up, usage reports indicated an average of 32 readings per month per participant. At 90-day follow-up, usage reports indicated an average of 34 readings per month per participant. All three participants exhibited high levels of device acceptance, but the appraisals associated with usage is likely to be different for each individual user. Patients with ICDs may benefit from increased access to cardiac technical information because it is available to them, or patients may feel overburdened. For instance, cardiac anxiety, which was elevated in participant 3, is associated with excessive symptom monitoring, and increased access through mobile monitoring could maintain problematic checking behaviors and other symptoms of anxiety in some patients [13]. However, patients who experience cardiac anxiety maintained by the avoidance of heart-related stimuli could benefit from exposure related to mobile monitoring. Nonetheless, patient engagement in this new technology appears to be high and associated with limited negative effects.

Other psychological factors associated with KardiaMobile usage should be explored further. High usage may be driven by the novelty of the product and positive feelings associated with the ability to self-monitor (ie, positive reinforcement). However, high usage in some individuals could be driven by negative reinforcement (ie, when a behavior is strengthened because it provides escape from aversive stimuli) through excessive reassurance-seeking behaviors. Excessive reassurance seeking (eg, excessively seeking attention of family members to physiological symptoms due to fear of dysfunction) provides feelings of relief in the short term, but may sustain fears and anxiety about health in the long term [10]. KardiaMobile use and other patient-centered technologies have the potential to serve as a real-time reassurance mechanism, but providers should pay attention to problematic excessive use patterns that could be maintaining health anxiety.

There were several limitations associated with the current study. Patients with ICDs are inherently reliant on their implantable devices due to the nature of their disease state, which may have increased mECG device acceptance. Additionally, the opt-in nature of the research may have led to an overestimation of technology satisfaction. Although KardiaMobile has been clinically validated for general population use, the overall utility of mECG devices is largely unknown in patients with diagnosed conditions. It is likely that patients with known symptoms would have increased motivation for symptom monitoring. However, the mECG device used in this study has been validated as a diagnostic tool, but its clinical utility for continued management and monitoring of treatment effect has not been investigated. Mobile ECG devices have been marketed toward users with previously undetected symptoms, and “silent” symptoms of atrial fibrillation occur in approximately one in three patients with atrial fibrillation [4].

Patients are increasingly being asked to be key shareholders of their health care teams, and condition-specific medical technology is now allowing patients to monitor signs and symptoms from the comfort of their own homes. KardiaMobile is one example of how the patient engagement movement is allowing users to become more involved by putting ECG technology in the hands of the person most affected. However, hypervigilance and checking behaviors have been shown to be associated with an inflated sense of responsibility, which is a potential risk for mECG users [14]. Although it is still unclear whether or not this novel technology has positive or negative effects on cardiac-related anxiety or physical/mental health components, the most significant findings of this report show

that despite a number of differences in background and presentation of illness, all three users reported high levels of technology satisfaction using the KardiaMobile device. Ongoing registry research will provide additional information.

Finally, the effect of increased patient engagement with specific medical technology on physician well-being should be considered because these devices could be perceived as an additional burden. Driven by ever-increasing expectations and responsibilities, occupational burnout rates are high among cardiologists, and successful mitigation of burnout will require adaptations by providers, patients, and health care systems [15]. Critical evaluation of this technology by patients and providers is needed, and the consequences related to tasking patients with data acquisition and symptom interpretation requires thoughtful consideration before clinical implementation. Employment of new technology will be most successful when providers are able to see these adaptations not as additional clinical duties, but as part of their overall mission to provide patient-centered care.

The KardiaMobile device by AliveCor is a novel way for cardiac patients to monitor and track their own ECG recordings and share them with their medical providers. This technology may not be indicated for all patients, especially for users with preexisting cardiac-related anxiety. However, there is preliminary data to suggest that many users would have high technology satisfaction using the device. As advances in mobile technology continue to evolve the landscape of health care, ICD patients are encouraged to work collaboratively with their providers to answer the question, “Is smartphone ECG technology the ‘smart’ option for me?”

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Conflicts of Interest

SFS has received honoraria/consulting fees and research grants from Medtronic and Zoll Medical. All funds are directed to East Carolina University. All the other authors declare that they have no competing interests.

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Abbreviations

- CAQ:** Cardiac Anxiety Questionnaire
ECG: electrocardiogram
ICD: implantable cardioverter defibrillator
mECG: mobile electrocardiogram
QoL: quality of life
SF-12v2: 12-Item Short Form Survey version 2

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