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Contents

Original Papers

Original Paper

Assessing the Utility of a Novel SMS- and Phone-Based System for Blood Pressure Control in Hypertensive Patients: Feasibility Study

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Abstract

Background: Although hypertension (HTN) is a major modifiable risk factor for arterial damage, blood pressure (BP) remains poorly controlled in the hypertensive population. Telemedicine is a promising adjunct intervention that may complement traditional therapies and improve adherence rates; however, current approaches have multiple barriers to entry, including the use of relatively expensive Bluetooth devices or the dependence on smart phone utilization, which tend to exclude low-income and more elderly populations.

Objective: The aim of this study was to design and implement a new phone call- and short message service text messaging-based intervention, Epharmix's EpxHypertension, in a quality improvement project that demonstrates the feasibility of this system for BP control in a family medicine setting.

Methods: We recruited 174 patients from a community clinic in St Louis from a database of patients diagnosed with HTN. An automated call or text messaging system was used to monitor patient-reported BPs. If determined to be elevated, physicians were notified by an email, text, or electronic medical record alert. Mean systolic BPs (SBPs) and diastolic BPs (DBPs) were compared at the beginning and end of 12 weeks.

Results: After 12 weeks on the system, patients with a baseline SBP of 140 mm Hg or higher reduced SBP by 10.8 mm Hg (95% CI −14.5 to −7.2, $P<.001$) and DBP by 6.6 mm Hg (95% CI −9.9 to −3.4, $P=.002$), but no significant changes were observed in overall BPs and BPs in the group with baseline SBP less than 140 mm Hg.

Conclusions: EpxHypertension provides a viable means to control HTN in patients with high baseline BPs despite previous therapy. This community implementation study demonstrates the feasibility of implementing EpxHypertension across a primary care setting without the need for smartphones or Bluetooth-linked BP cuffs. Future studies should evaluate its effectiveness in a randomized control trial compared with standard of care.

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KEYWORDS

telemedicine; hypertension; quality improvement; text messaging; primary care; eHealth; mHealth; disease management

Introduction

Hypertension (HTN) is a major risk factor for cardiovascular events such as stroke, heart failure, and myocardial infarctions [1]. Over 85.7 million adults in the United States have HTN [2]. In 2013, the estimated direct and indirect cost of HTN was US $51.2 billion [2]. Although lowering blood pressure (BP) has been shown to improve outcomes [3,4], only 54% of hypertensive patients in the United States are considered to have controlled HTN [5]. In strategies to manage BP, self-monitoring has been shown to predict health outcomes better than office BP measurements [6,7] and lead to a lowering of BP over time [8]. However, manual BP logs that are typically used to record at-home measurements [8,9] are often lost or not adequately utilized for clinical management.

Telemedicine has been studied as a promising and efficacious way to improve health outcomes across many conditions, including HTN [10-13]. Many tools have utilized smartphone apps or Internet-linked BP cuffs [14-17], but several studies have experienced barriers such as connectivity issues, low health literacy, and high cost while using these technologies [16,18]. Significant overhead cost is a limiting factor for utilization in socioeconomically disadvantaged populations and prohibits widespread use in the general population. For example, Internet or Bluetooth-linked cuffs can be up to tenfold more expensive than nonlinked cuffs and require patients to use a smartphone device to directly connect. These higher technological requirements also tend to discriminate against elderly patients.

Utilizing short message service (SMS) text messaging is a potential solution to some of these obstacles because of its high accessibility: 86% of American adults who earn less than $30,000 in a year own a cell phone [19]. Studies have shown that SMS usage can increase treatment compliance, including medication adherence [20]. Various telemedicine HTN interventions have shown some success in improving health outcomes, including call-based [21] and SMS-based [22] interventions. Despite the recent developments of telemedicine interventions for HTN, the feasibility of combined text messaging and phone calls without the need for Internet-linked platforms for HTN management has not been extensively studied [23]. Although there are SMS-based systems with Internet-linked platforms that have demonstrated BP management, there are no telemedicine interventions that have found significant reductions in BP using a combination of phone call and text messaging for patients with nonlinked cuffs.

We hypothesized that patients would be willing and able to both regularly measure and manually report their BP along with important contextual information via automated phone calls and text messages, thereby expanding the population who can benefit from mobile health (mHealth) solutions. To test this question, we utilized Epharmix, an automated calling and text messaging platform that sends standardized condition-specific messages to patients and their health care providers to track symptoms longitudinally in real time, provides educational content to patients, and triggers alerts to providers when patients report concerning symptoms or behaviors. In this study, we developed and examined the utilization and effect of a BP monitoring system, EpxHypertension, a phone and SMS text messaging system for patients with nonlinked cuffs. We hypothesized that providing clinicians with real-time data would allow them to appropriately intervene for patients exhibiting poorly controlled HTN, thereby leading to improved BP control for the patients enrolled in EpxHypertension.

Methods

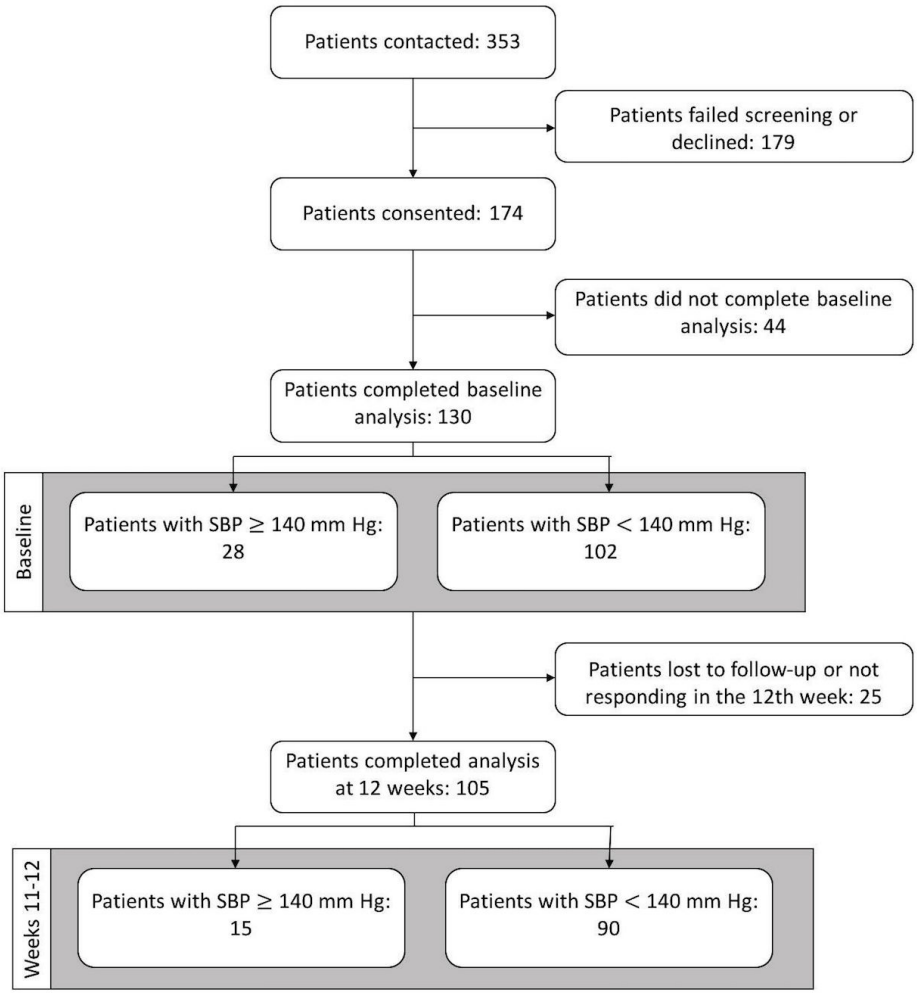
Our quality improvement study was designed to evaluate the feasibility of the EpxHypertension system for BP control. A list of patients with a documented diagnosis of HTN via the International Statistical Classification of Diseases and Related Health Problems, Ninth Revision (ICD-9) and ICD-10 code was created from a community clinic in St Louis, Missouri. Participants were enrolled from June 27, 2016 to September 10, 2016 and followed for 12 weeks. Assistants called each patient to explain the intervention and offer enrollment pursuant to institutional policies. We contacted 353 patients, and 174 patients consented to being enrolled in EpxHypertension. The consenting patients were then enrolled in either the text messaging (58.6%, 102/174 patients) or phone call (41%, 72/74 patients) system according to their preference. For patients who were unable to text for technological or personal preference, an identical automated phone call was sent following the same algorithm as the text messages. Eligible patients were above the age of 18 years, had access to a phone, and owned an at-home ambulatory BP monitor. No exclusions were made based on the type of monitor (wrist vs upper arm), and no additional instruction was given on how to measure BP. To design an effectiveness study, it was impractical to control the exact type of BP monitor being used across the population, especially as implemented at this scale. However, this did add the limitation of adding more potential noise from inaccurate results. Of the 174 patients who consented, 44 never responded to the initial automated message or phone call sequence and were not sent any future messages or calls. A total of 105 patients had completed through to week 12 of the study at the time of analysis.

For the first 2 weeks, patients were asked to measure and report their BP to the automated system on a daily basis, at the same time each day, with instructions to measure their BP after sitting for at least 5 min if they had recently been physically active. Baseline was defined as the mean of the first 5 responses within the first 2 weeks. After 2 weeks, the system's dynamic scheduling algorithm adjusted message frequency based on BP control. If baseline systolic BP (SBP) was 140 mm Hg or higher or diastolic BP (DBP) was 110 mm Hg or higher, texts or calls were sent daily asking for self-reported BP values. If baseline SBP was less than 140 mm Hg and DBP was less than 110 mm Hg, texts were sent 3 times per week. Our smart schedule system also set message frequency to 3 times a week if a patient's most recent bimonthly (every 2 weeks) average SBP and DBP were less than 140 mm Hg and 100 mm Hg, respectively. Message frequency was increased to daily if a patient's most recent bimonthly average SBP and DBP were greater than/equal to 140 mm Hg and 100 mm Hg, respectively.

The system automatically alerted a physician if the patient's SBP was outside the threshold range (system default or set by the provider), and the patient was prompted to contact his or her provider immediately. The default threshold range set by the system for SBP was between 90 and 180 mm Hg and between 60 and 110 mm Hg for DBP for one-time measurements, along with a bimonthly mean DBP of more than 100 mm Hg. These thresholds were made based on the recommendations by the American Heart Association (AHA), which designate high BP to be 140/90 mm Hg or higher and a hypertensive urgency to be 180/110 mm Hg or higher [20]. The threshold range could be modified by the provider for each patient, if necessary. The physician was recommended to call patients back as he or she deemed necessary within 2 weeks of receiving the alert and utilize the data at follow-up appointments. The messages, however, were left to the provider's discretion and followed standard HTN management protocols as defined by the AHA. For longitudinal monitoring, providers also received a triaged bimonthly report prioritized based on each patient's average BP values.

Aggregate deidentified data were provided by Epharmix for analysis. We analyzed 12 weeks of BP data for average change in BP, response rate, and number of hypotensive and hypertensive events (defined as SBP or DBP outside the threshold range). Comparison between the beginning and end of the study period were made using paired *t*-tests (Microsoft Excel 2016) and included patients with at least 5 baseline measurements and at least 2 final measurements. Additional analysis on patient response rate was performed using unpaired *t*-test, Pearson's correlation, and Fisher's exact test (Microsoft Excel 2016 and Graphpad Prism). In the analysis, patients were risk stratified based on SBP into two categories: baseline greater than/equal to and less than 140 mm Hg. Automated monthly satisfaction questionnaires were also administered via automated text message or phone call. Patients were asked to assess numerically (Likert-type scale) the overall quality of care, quality of communication with their provider, and satisfaction with frequency of messages or calls. Patients were also able to provide qualitative feedback in the form of text or recorded voice messages in the same survey.

Figure 1. Study flow diagram detailing the stages of the implementation and the number of patients.



Results

Response Rate

At the end of the enrollment period, 174 patients diagnosed with HTN were enrolled (Figure 1). In 12 weeks, we received responses for 4781 of the 7345 (65.09%) sent messages and detected 31 events of self-reported SBP and 0 events of self-reported DBP outside the threshold range. Providers were notified about the generated alerts and responded based on their clinical judgment. Of the 130 patients who completed baseline analysis, 105 patients completed the final analysis at week 12. Figure 1 also shows the proportion of enrolled patients reporting SBPs of greater than/equal to and less than 140 mm Hg at baseline and week 12.

Excluding patients who did not complete baseline analysis (44/174), the total response rate was 65.78% (3193/4854 messages). The group with baseline SBP of 140 mm Hg or higher had an average response rate of 62.72% (969/1545 messages), whereas the lower baseline SBP group had an average response rate of 67.21% (2224/3309 messages, *P*=.22). Although there was no significant correlation between change in SBP and response rate, a greater proportion of patients with a response rate of 80% or higher achieved a BP of less than 140 mm Hg by the end of 12 weeks: only 9% (5/58) of patients with a response rate of 80% or higher had an SBP greater than/equal to 140 mm Hg at weeks 11 to 12, compared with 21% (10/47) of patients with a response rate of less than 80% (odds ratio 2.9, 95% CI 0.93-7.94, *P*=.09). Baseline SBPs were comparable in these two groups: 128.4 mm Hg (95% CI 124.8-132.1 mm Hg, n=47) for patients with less than 80% response rate; 130.9 mm Hg (95% CI 128.2-133.6 mm Hg, n=58) for patients with greater or equal to 80% response rate; delta SBP at baseline was 2.5 mm Hg (*P*=.29).

Patients reported an average satisfaction of 8.7 out of 9 (Likert-type scale, 9 is the maximum score) with the service. In a separate question from the same survey assessing patient satisfaction with message frequency, the majority of patient responses (67.3%, 167/248 survey responses) reported the frequency of messages as “perfect” (Figure 2).

Improvements in Blood Pressure

The average baseline BP for all patients completing 12 weeks was approximately 129.8/76.4 mm Hg. By the end of the evaluation period, SBP reduced by 10.8 mm Hg (95% CI −14.5 to −7.2) and DBP reduced by 6.6 mm Hg (95% CI −9.9 to −3.4) in the group with baseline SBP of 140 mm Hg or higher, whereas BP for all patients and in the lower baseline SBP group did not change significantly (Table 1).

Figure 2. Patient satisfaction with message frequency.

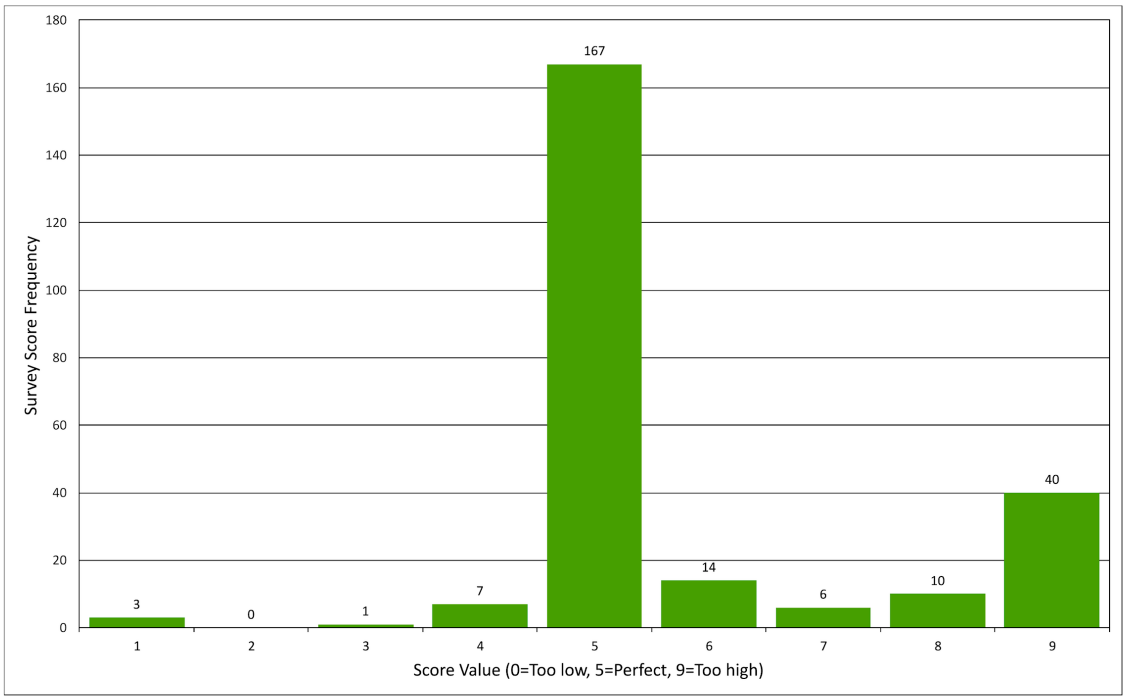


Table 1. Comparison of average blood pressure (BP) at baseline and at weeks 11-12 for the 105 patients who completed week 12 analysis. Significant decreases in systolic BP (SBP) and diastolic BP were found in patients with baseline SBP greater than/equal to 140 mm Hg.

Blood pressure description		Baseline mean	Weeks 11-12 mean	Difference	95% CI	*P* value
Baseline SBP[a] ≥140 (n=22)						
	SBP	147.3	136.4	−10.8	−14.5 to −7.2	<.001
	DBP[b]	82.4	75.8	−6.6	−9.9 to −3.4	.002
Baseline SBP<140 (n=83)						
	SBP	125.2	126.1	1.0	−1.1 to 3.1	.35
	DBP	74.8	74.8	0.08	−1.6 to 1.8	.90
All patients (n=105)						
	SBP	129.8	128.3	−1.5	−3.5 to 0.5	.15
	DBP	76.4	75.0	−1.3	−2.8 to 0.1	.06

[a]SBP: systolic blood pressure.

[b]DBP: diastolic blood pressure.

The proportion of all patients reporting SBP greater than/equal to 140 mm Hg each week showed a steady decline over the 12 weeks (Figure 3). Of the 28 patients whose baseline SBP was 140 mmHg or higher, 22 (79%) patients provided sufficient data for analysis at 12 weeks, where 14 out of 22 (64%) reported a final bimonthly average SBP less than 140 mm Hg (Figure 4).

Figure 3. Change in self-reported bimonthly average systolic blood pressures (SBPs) for all patients. No response indicates patients who did not report any BPs during the 2-week period.

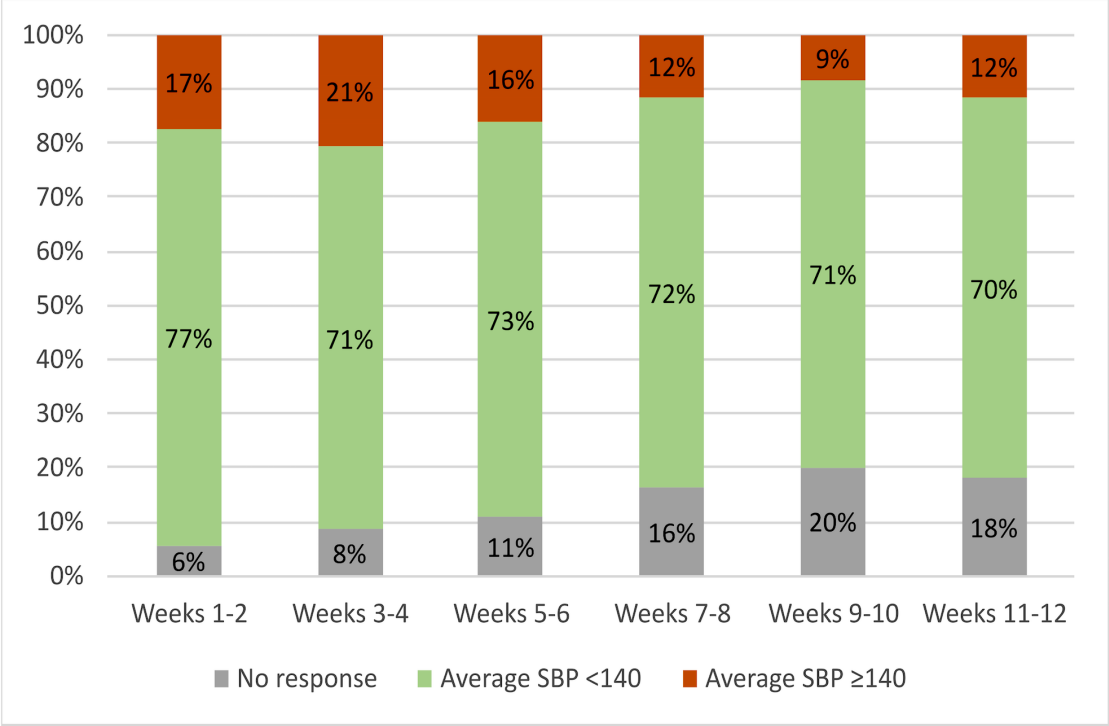
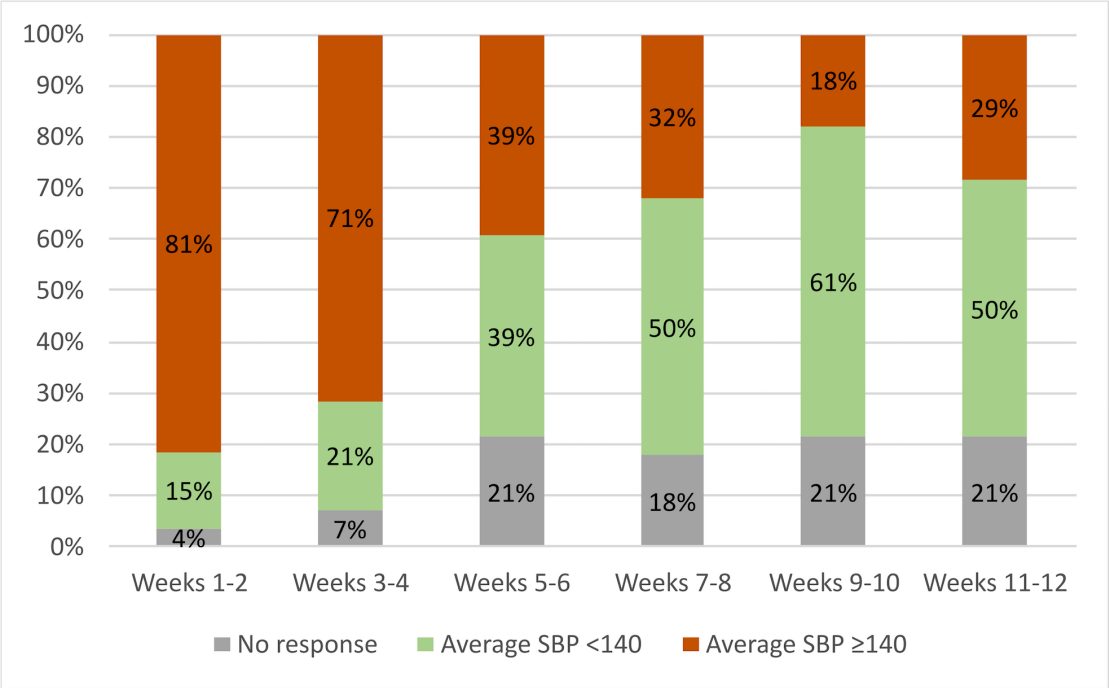


Figure 4. Change in self-reported bimonthly average systolic blood pressures (SBPs) for patients with a baseline SBP greater than or equal to 140 mm Hg. Within the subpopulation of patients with a baseline greater than or equal to 140 mm Hg, there is a significant decline in the proportion of reported SBP averages greater than/equal to 140 mm Hg. The 44 enrolled patients who did not complete baseline analysis and illogical self-reported BPs because of SMS formatting discrepancies were excluded from the analysis. No response indicates patients who did not report any BPs during the 2-week period.



Discussion

Response Rate

In this feasibility study, the main outcome is the acceptance of the system, which can be analyzed via response rate and patient satisfaction. Throughout the study, the overall response rate declined slightly (Figure 3); however, among those who responded to the system, 43.8% (57/130) of patients had response rates higher than 80% (data not shown), which suggests the acceptability of the system. We incorporated differential messaging frequency based on level of BP control (2-week mean) where patients who were reporting consistently elevated BP received messages more frequently. However, patients with baseline SBP greater than or equal to 140 mm Hg did not have significantly lower response rates, despite the higher message frequency. The majority of patients in the satisfaction surveys indicated the message frequency to be "perfect," further supporting the acceptability of this system. Thus, EpxHypertension was uniquely able to monitor BP regularly while maintaining patient satisfaction and a high response rate using the smart scheduling system.

Of note, a higher proportion of patients with greater than 80% response rates achieved mean SBP values below 140 mm Hg when compared with all study participants, thereby suggesting that patients who were more engaged with the intervention have better outcomes.

Improvements in Blood Pressure

Over the 12-week study period, patients with baseline SBP of 140 mm Hg or higher showed significant reduction in self-reported BP values. Although the overall BP change for all patients was not significant, most patients in the study did not have a baseline BP exceeding 140 mm Hg. Our results demonstrate the value of this intervention for patients who struggle most with BP control and who are subsequently at a higher risk for complications. Whereas a similar phone-based intervention demonstrated effectiveness in reducing BP [24], there have been no validated phone call and text messaging platforms that have demonstrated a significant reduction [25]. We attribute the effectiveness of this system to the unique bidirectional messaging model that allows more active monitoring by patients' health care teams while simultaneously increasing patient investment in self-health. There is demonstrated stability for patients with baseline SBP less than 140 mm Hg as expected. For patients with an SBP greater than or equal to 140 mm Hg, we demonstrate the ability to drive patients to lower their BP.

Feasibility in an Outpatient Setting

Our findings arise from the use of EpxHypertension as part of routine clinical practice without additional novel equipment or staff, which demonstrates the applicability and utility of this system in the management of HTN in the standard outpatient setting. Figure 2 presents a favorable scenario in the application of the system in a real-world setting while factoring in likely response rates. As mentioned in the Methods section, the content of the messages were left to the discretion of the providers, which helps demonstrate the external validity of our study and therefore the feasibility of our intervention.

The system has additional benefits of being accessible to patients who may be at a socioeconomically disadvantage, by using

user-friendly language that takes into account variability in health literacy and offering free-to-patient text messages and calls. Our intervention aims to facilitate collaborative patient-provider relationships, which have been shown to improve medication adherence in vulnerable, low-income populations [26]. Additionally, poorly controlled HTN is correlated with increased physician visits [27]. We believe EpxHypertension improves patient-provider communication and has the potential to bring HTN under control, which can have a beneficial impact in decreasing the number of in-office visits while placing little additional burden to the health network infrastructure. Reduced in-office visits would be economically beneficial for low-income patients because of fewer missed work hours and fewer transportation costs. Our data demonstrate that patients are willing and able to use nonlinked BP cuffs in combination with EpxHypertension to improve the management of BP.

Scalability and Reach

Whereas there have been a multitude of telemedicine interventions studied for BP management in hypertensive patients [12,28], EpxHypertension is uniquely beneficial because of its low intensity that will allow large-scale implementation of this intervention. Few telemedicine interventions for chronic disease management in the past decade have taken into account cost in their analysis [28]. Many of these studies provide participants with devices such as BP monitors or smartphones free of charge, which, in addition to increasing overhead costs, also require additional time for installation and participant training. By being able to use any BP cuff and any landline or cell phone, we demonstrate that this system has a potentially higher reach in the populations (ie, lower socioeconomic status [SES] and elderly populations) than those systems described previously. Considering that 40.8% (71/174) of our patients preferred phone calls to SMS text messaging, we believe that the option of using phone calls is appreciated and more convenient than SMS text messaging for a large portion of the patient population at the community clinic.

Study Limitations and Future Directions

EpxHypertension was designed to collect data and provide clinically important information to providers in a timely manner, thereby allowing them to intervene per their judgement. As such, we have not delineated specifically how providers responded to this new information. Providers may have changed medications or patients may have changed their lifestyle in ways that were not assessed. Baseline demographic data were not collected for this study of community patients. Furthermore, it is possible that the effectiveness of mHealth interventions could vary with a patient's functional status, health literacy, SES, or other demographic factors not captured in this analysis. Additionally, all data were self-reported, and some measurements could theoretically be fabricated [29], yet the inaccuracy rate was shown to be as low as 16% in underserved patients using a telemedicine intervention [30] and may not be clinically significant. We allowed patients to use their own home BP monitors without additional training, which introduces inherent variability in values recorded and which we recognize as a limitation, although this is more consistent with practical clinical implementation. Most importantly, there was no standard-of-care comparison group in this prospective cohort study. Future studies should therefore evaluate the effectiveness of this intervention with a prospective randomized-controlled trial to test the validity of results presented in this study and to measure additional outcomes such as the total number of in-office visits and medication changes resulting from improved monitoring of BP in patients.

Conclusions

Epharmix's EpxHypertension, a bidirectional automated phone and text messaging service, is well accepted by both patients and providers in a community clinic setting based on response rate and patient satisfaction survey results. It has demonstrated feasibility by helping higher-risk hypertensive patients (ie, higher baseline BPs) achieve capturable BP reductions. This cost-effective and widely accessible intervention is a promising new tool for the management of hypertensive patients, especially in the outpatient setting. Future clinical trials are needed to test efficacy and confirm the effectiveness of this intervention in controlling patients' BPs, as compared with standard of care.

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Authors' Contributions

KJ, RP, JH, JB, JG, and AS developed the HTN intervention. RP, ES, and KP were involved in study design and implementation. RP, RX, NS, and KJ helped with data analysis. RP, RX, NS, KJ, and ES wrote the manuscript, and all the authors edited the manuscript. JH, JB, WR, and AB were involved with providing advice and mentorship. JB contributed to the implementation of the service.

Conflicts of Interest

Both Avik Som, the cofounder and the chief medical officer of Epharmix, and Jacob Groenendyk have a financial conflict of interest. All other authors report no conflicts of interest.

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Abbreviations

AHA: American Heart Association
BP: blood pressure
DBP: diastolic blood pressure
HTN: hypertension
ICD: International Statistical Classification of Diseases and Related Health Problems
mHealth: mobile health
SBP: systolic blood pressure
SES: socioeconomic status
SMS: short message service

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Original Paper

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

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Abstract

Background: Exercise capacity and raised heart rate (HR) are important prognostic markers in patients with heart failure (HF). There has been significant interest in wrist-worn devices that track activity and HR.

Objective: We aimed to assess the feasibility and accuracy of HR and activity tracking of the Fitbit and Apple Watch.

Methods: We conducted a two-phase study assessing the accuracy of HR by Apple Watch and Fitbit in healthy participants. In Phase 1, 10 healthy individuals wore a Fitbit, an Apple Watch, and a GE SEER Light 5-electrode Holter monitor while exercising on a cycle ergometer with a 10-watt step ramp protocol from 0-100 watts. In Phase 2, 10 patients with HF and New York Heart Association (NYHA) Class II-III symptoms wore wrist devices for 14 days to capture overall step count/exercise levels.

Results: Recorded HR by both wrist-worn devices had the best agreement with Holter readings at a workload of 60-100 watts when the rate of change of HR is less dynamic. Fitbit recorded a mean 8866 steps/day for NYHA II patients versus 4845 steps/day for NYHA III patients (P=.04). In contrast, Apple Watch recorded a mean 7027 steps/day for NYHA II patients and 4187 steps/day for NYHA III patients (P=.08).

Conclusions: Both wrist-based devices are best suited for static HR rate measurements. In an outpatient setting, these devices may be adequate for average HR in patients with HF. When assessing exercise capacity, the Fitbit better differentiated patients with NYHA II versus NYHA III by the total number of steps recorded. This exploratory study indicates that these wrist-worn devices show promise in prognostication of HF in the continuous monitoring of outpatients.

(JMIR Cardio 2017;1(2):e8) doi:10.2196/cardio.8301

KEYWORDS

MeSH: exercise physiology; heart rate tracker; wrist worn devices; Fitbit; Apple watch; heart failure; steps

Introduction

Exercise capacity and raised heart rate (HR) are important prognostic markers in patients with heart failure (HF) [1,2]. In clinic, we rely on patients' self-reported exercise capacity and classify their symptoms based on the New York Heart Association (NYHA) scale. Although widely used, this classification is subjective and poorly reproducible [2]. Furthermore, clinicians are exposed to only a snapshot of the patients' HR in the ambulatory setting. There has been

significant growth in wrist-worn fitness devices that track activity and HR [3]. These wearable devices use infrared and green light emitting diodes to track HR using the photoplethysmography (PPG) method [4]. The aim of this study was to validate the accuracy of HR monitoring using Fitbit and Apple Watch at rest and during structured cardiopulmonary exercise testing in healthy individuals and to then examine the relationship of physical activity in patients with HF.

Methods

We conducted a two-phase study assessing the accuracy of HR using Apple Watch and Fitbit wrist-based devices in healthy participants and then as continuous HR monitoring in patients with HF. In Phase 1, 10 healthy individuals wore a Fitbit, an Apple Watch, and a GE SEER Light 5-electrode Holter monitor while exercising on a cycle ergometer with a 10-watt step ramp protocol. During the first 60 seconds of the test, the workload was set to 0 watts and followed by increments of 10 watts with a maximum workload of 100 watts. In the recovery period, the workload was decreased to 10 watts. In Phase 1, two participants were excluded as data from one device could not be recorded. In Phase 2, 10 patients with HF with NYHA Class II-III symptoms wore both wrist devices for 14 days to capture overall step count/exercise levels. Two patients were excluded due to incomplete data recorded.

For Phase 1, we calculated a single measures intraclass correlation (ICC) and a 95% confidence interval, specific to each exercise workload, between HR measured by Holter (gold standard) and HR measured by the Fitbit and Apple Watch devices. The mean ICC and 95% confidence interval for each device against the Holter as the gold standard was plotted against exercise workload.

For Phase 2, we used a Kruskal-Wallis rank test to compare the mean number of steps, calculated by either device, between patients in NYHA Class II or III. We used STATA 13.1 and SPSS 22 statistical packages for our statistical analysis. The study protocol was approved by the University Health Network Research Ethics Board.

Results

Recorded HR by both devices was not significantly related with the Holter HR at rest (Fitbit ICC=.263, 95% CI 0.257-0.447, Apple Watch ICC=.218, 95% CI 0.010-0.408). However, with cycle ergometer workloads of 60-100 watts, both devices had stronger agreement with the Holter HR (Figure 1).

Table 1 shows the baseline demographics of the patients included in Phase 2. 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. As shown in Figure 2, Fitbit recorded a mean 8866 steps/day for NYHA II patients versus 4845 steps/day for NYHA III patients (*P*=.04). In contrast, Apple Watch recorded a mean 7027 steps/day for NYHA II patients and 4187 steps/day for NYHA III patients (*P*=.08).

Figure 1. Intraclass correlation curves (solid) with 95% confidence intervals (dotted) for workload comparing Fitbit to Holter and Apple Watch to Holter in healthy individuals.

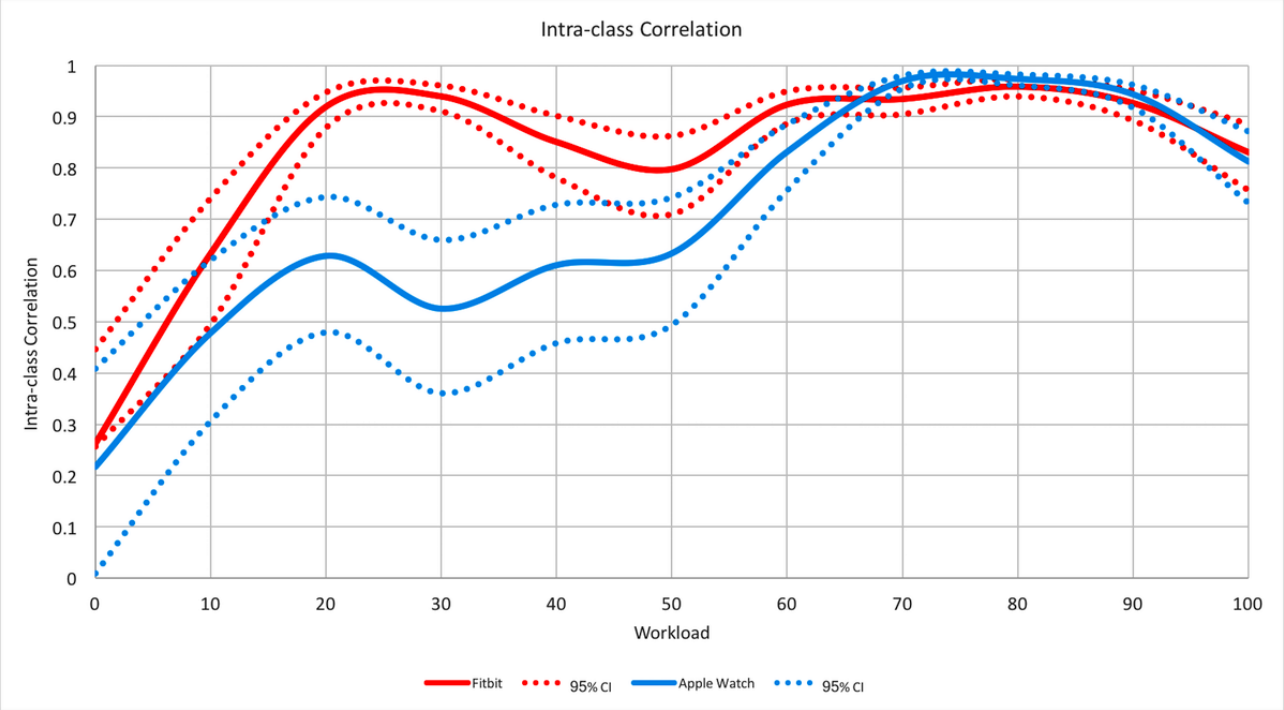


Table 1. Demographics and baseline data.

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

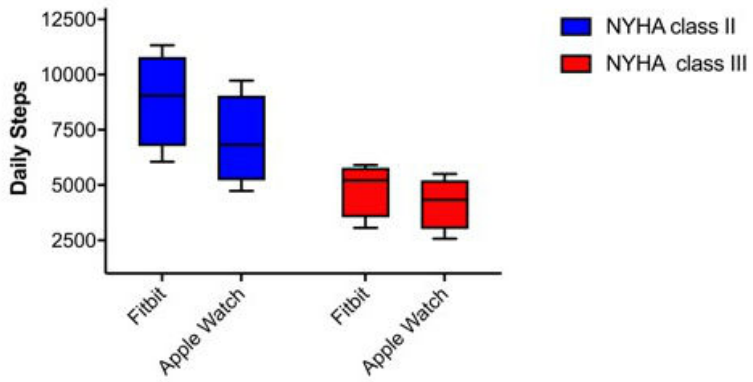
[a]LVEF: left ventricular ejection fraction.

[b]HF: heart failure.

[c]NYHA: New York Heart Association.

[d]Drug doses are total daily dose.

Figure 2. Total daily steps recorded (with 95% confidence interval) by Fitbit and Apple watch over 14 days for patients with New York Heart Association (NYHA) Class II and III symptoms .



Discussion

Principal Findings

In this study, both PPG-based monitors had difficulty predicting HR when compared to a 5-lead electrode electrocardiogram (ECG) Holter as the gold standard in a cardiopulmonary study where HR is expected to change quickly over a 10-minute period. A recent study by Wang et al reported similar variability among four popular wrist-worn devices in relation to standard ECG limb leads and a Polar H7 chest strap monitor [5]. The HR underestimation was due to the inherent limitation of PPG that requires a longer settling time processing and averaging to eliminate optical and motion artifact. As a result, PPG monitors underestimated HR and showed poor correlation until the latter stages of the ramp study where HR would tend to saturate and the settling time was sufficient for the PPG HR estimation to compare favorably to the ECG gold standard. Although this indicates that PPG is less suited for dynamic HR measurements, in an outpatient monitoring context, PPG may be suitable for long-term static measurement of HR over long periods of time where settling time would not be an issue [6].

Strengths and Limitations

When assessing exercise capacity, the Fitbit better differentiated patients with NYHA II versus III by the total number of steps recorded. The limitations in this study include the small sample size; larger studies will be needed to confirm these findings. This is the first study in the literature that suggests the possibility of better classifying patients, quantitatively, and potentially remotely, rather than the current practice of determining class through self-reported symptoms with its inherent limitations. Reductions in daily step counts may herald the onset of progressive NYHA symptoms alerting physicians to assess patients in a timely manner.

Conclusion

This exploratory study indicates that wrist-worn devices show promise in prognostication of HF in the continuous monitoring of outpatients, but they require further validation.

Conflicts of Interest

None declared.

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Abbreviations

ACE: angiotensin-converting enzyme
ARB: angiotensin-receptor blocker
ECG: electrocardiogram
HF: heart failure
HR: heart rate
ICC: intraclass correlation
NYHA: New York Heart Association
PPG: photoplethysmography

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Original Paper

A Mobile Health Intervention to Improve Self-Care in Patients With Heart Failure: Pilot Randomized Control Trial

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Abstract

Background: Heart failure (HF) is a progressive chronic disease affecting 6.5 million Americans and over 15 million individuals globally. Patients with HF are required to engage in complex self-care behaviors. Although the advancements in medicine have enabled people with HF to live longer, they often have poor health-related quality of life and experience severe and frequent symptoms that limit several aspects of their lives. Mobile phone apps have not only created new and interactive ways of communication between patients and health care providers but also provide a platform to enhance adherence to self-care management.

Objective: The aim of this pilot study was to test the feasibility of a newly developed mobile app (HeartMapp) in improving self-care behaviors and quality of life of patients with HF and to calculate effect sizes for sample size calculation for a larger study.

Methods: This was a pilot feasibility randomized controlled trial. Participants were enrolled in the hospital before discharge and followed at home for 30 days. The intervention group used HeartMapp (n=9), whereas the control group (n=9) received HF education. These apps were downloaded onto their mobile phones for daily use.

Results: A total of 72% (13/18) participants completed the study; the mean age of the participants was 53 (SD 4.02) years, 56% (10/18) were females, 61% (11/18) lived alone, 33% (6/18) were African Americans, and 61% (11/18) used mobile phone to get health information. The mean engagement with HeartMapp was 78%. Results were promising with a trend that participants in the HeartMapp group had a significant mean score change on self-care management (8.7 vs 2.3; t3.38=11, *P*=.01), self-care confidence (6.7 vs 1.8; t2.53=11, *P*=.28), and HF knowledge (3 vs −0.66; t2.37=11, *P*=.04. Depression improved among both groups, more so in the control group (−1.14 vs −5.17; t1.97=11, *P*=.07). Quality of life declined among both groups, more so in the control group (2.14 vs 9.0; t−1.43=11, *P*=.18).

Conclusions: The trends demonstrated in this pilot feasibility study warrant further exploration on the use of HeartMapp to improve HF outcomes.

Trial Registration: Pilot study, no funding from National agencies, hence not registered.

(JMIR Cardio 2017;1(2):e3) doi:10.2196/cardio.7848

KEYWORDS

heart failure; mobile applications; self-care; quality of life

Introduction

Heart failure (HF) is a progressive disease affecting 6.5 million Americans, with costs exceeding US $39.2 billion annually [1]. Presently, treatments for HF largely comprise drug therapies targeting pathophysiology and complex educational interventions targeting self-care practices [2]. Self-care regimens for patients with HF are complex and multifaceted, and patients often find it hard to understand how to monitor HF symptoms and understand weight fluctuations and to seek care without delay [2,3]. It appears that increased knowledge of self-care alone does not often translate to changes in self-care practice [4]. Poor self-care is associated with delay in seeking care for HF symptoms [5], poor medication adherence [6,7], reduced quality of life [8], increased hospital readmissions, and mortality [7]. A meta-analysis suggested that telemonitoring for HF patients can reduce hospitalization [9]. However, a large Telemedical Interventional Monitoring in HF study demonstrated no significant improvement in HF-related outcomes [10]. Similarly, the large Better Effectiveness After Transition-Heart Failure study that provided remote monitoring intervention with nurse call failed to demonstrate significant reduction in readmission rates [11]. A qualitative study that interviewed 18 patients with HF and 5 health care professionals reported that the remote home monitoring systems for HF have not been widely adopted by patients because the currently available home monitoring devices are not personalized to meet the patients' needs [12]. In the same study, HF nurses reported that telemonitoring devices offered false hope to patients of being monitored continuously by providers, and the patients lacked development of independent self-care behavior [12]. A recent meta-synthesis of 9 systematic reviews of telemonitoring of physiological parameters and telephone support significantly reduced HF-related readmissions, whereas no impact was reported from telephone-only interventions and a variable effect reported on hospital admissions [13]. These findings resulted in an approach to develop a personalized mobile health (mHealth) coach (HeartMapp) that is easy for use by older adults with HF with physiological monitoring using a chest-worn Bluetooth device.

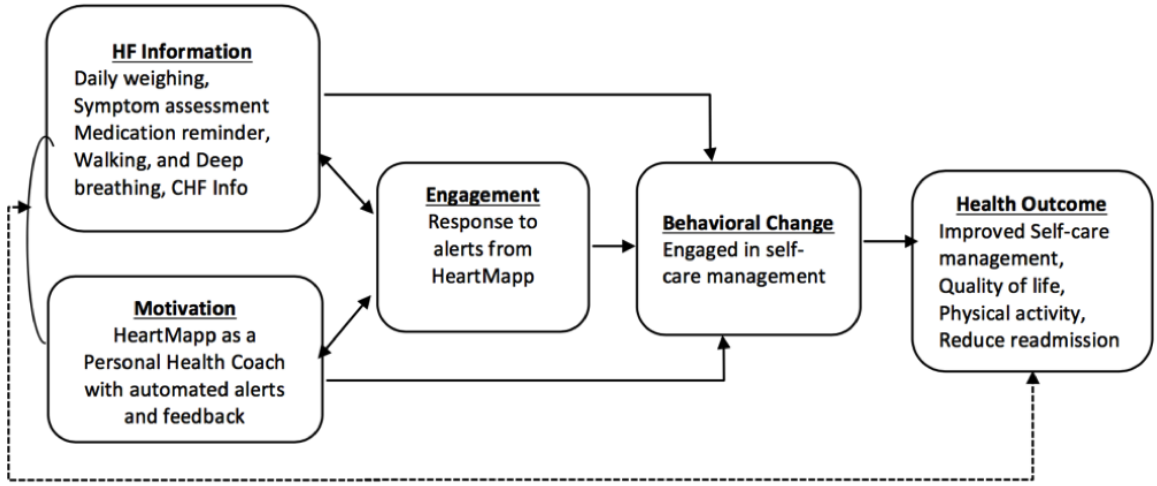
Methods

Conceptual Framework

Patients who are engaged as decision makers in their care tend to be healthier and have better outcomes [14]. Thus, in developing a conceptual framework for this research, Carmen's multidimensional framework of patient engagement was used to achieve persistent behavior change in patients with HF [15]. Patient engagement was augmented with the use of information-motivation-behavioral skills (IMB) model in the development of the conceptual framework [16]. Essentially, the IMB model asserts that people who are well informed and motivated are likely to engage in activities that enhance knowledge and skills needed to perform focused behavior, which allows them to reap greater health benefits [16]. Enabling mHealth has been supported as a pathway to inform patients. This pilot study paired information (HF self-management skills and knowledge) and motivation (using HeartMapp as a health care coach) to promote and support intrinsic motivation in patients and to increase engagement in behaviors required to manage their condition effectively [16]. It is proposed that increased engagement with HeartMapp may reduce symptom burden in patients with HF (see Figure 1).

An iterative patient-centered approach was adopted during the design of HeartMapp by leveraging mobile phones to target individualized alerts focused on patient needs to improve self-care and medication adherence, which could be used in a real-life setting as and when needed. HeartMapp also used a Zephyr BioHamess-3 chest strap [17] that connects to the Android device via Bluetooth to monitor physiological data, including heart rate, heart rate variability, and accelerometer data. During the development process, multiple iterations were made based on feedback from patients with alpha and beta testing and a usability study [18]. On the basis of feedback from patients with HF and providers who cared for them, additional features were added to the HeartMapp system. The HeartMapp mobile system was pilot-tested for feasibility with regard to use by patients with HF.

Figure 1. Conceptual framework of information, motivation, and behavior, and patient engagement.



Design and Method

This was a pilot randomized controlled trial (RCT). The overall goal of the pilot RCT was to examine feasibility of HeartMapp use by patients with HF and to compute effect sizes for sample size estimation for a larger RCT. The pilot study enrolled 18 participants with HF; the intervention group (n=9) received all 6 features of the HeartMapp, and the active wait-listed control group (n=9) received only HF education (congestive heart failure [CHF] info feature of the HeartMapp). The apps were downloaded onto their mobile phone for daily use. The active wait-listed control group was given access to 4 additional features of the HeartMapp at the 30-day follow-up. Participants were block randomized as (3:3; 2:2; 3:3; 2:2; 3:3; 2:2; 3:3; 2:2).

This is a pilot feasibility trial which received no NIH or other organizational funding; hence, it was not registered.

Patient Recruitment

Upon obtaining approval by the University's institutional review board (IRB), participants were recruited from a tertiary hospital. The IRB-approved brochures were made available at inpatient units. The discharge care coordinators referred potential HF participants for the study.

Inclusion and Exclusion Criteria

Textbox 1 below summarizes the inclusion and exclusion criteria. To assure that the eligible participants could properly understand how to use the HeartMapp, all participants were screened for adequate hearing acuity (thresholds of 4000 dB HL [decibels Hearing Level] or better) in the midfrequency range in at least one ear measured using a handheld combination otoscope and audiometer (Audioscope by Welch Allyn) [19]; vision (corrected near visual acuity of 20/50 or better) on the Snellen chart [20]; and assessed for cognitive function using the Montreal Cognitive Assessment (MoCA) [21]. The MoCA is a valid and reliable cognitive screening tool (Cronbach alpha=.83) and has been validated in HF patients in a prior study [22]. Patients who did not own an Android mobile phone were loaned one with Wi-Fi capability.

Study Procedures

A research assistant (RA), a research nurse, approached participants who had indicated interest and were ready for discharge. The RA explained the study requirements and sought consent from the participants using the IRB-approved informed consent document. Consented participants were screened for eligibility. Participants who failed screening were referred for further clinical evaluation. Within 3 to 7 days after discharge, 2 RAs scheduled a time to meet the patients in their home. During the home visit, the RAs confirmed their willingness to participate in the study and collected baseline data.

HeartMapp Intervention Group (n=9)

The intervention group had HeartMapp downloaded onto their Android phone or a loaner phone. The participants were trained on HeartMapp features, including daily weighing, symptom assessment, responding to tailored alerts, vital sign monitoring using BioHarness-3 chest strap, HF education (CHF info), and performing breathing exercise and walking. Participants were asked to use HeartMapp daily from home for a total of 4 weeks. The details of the 6 features of the HeartMapp are provided below (see Figure 2).

Textbox 1. Inclusion and exclusion criteria.

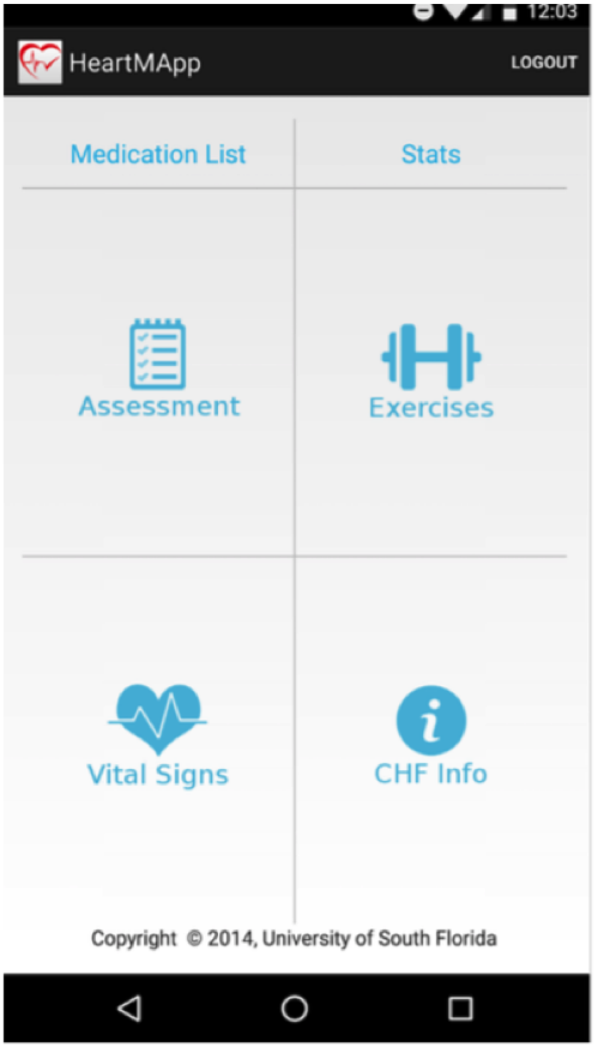
Inclusion criteria

- Clinical diagnosis of congestive heart failure (CHF) as defined by the International Classification of Diseases (ICD-10 codes) and recent hospitalization for CHF
- New York Heart Association (NYHA) classification II-III
- Adults aged 30 years or above
- Ability to speak, understand, and read English
- Vision must be 20/50 or better
- Adequate hearing
  - Hearing thresholds of 4000 dB HL or better
- Must be willing to use the mobile app (HeartMapp or CHF info) and the Bio-Harness-3 chest-worn Bluetooth device

Exclusion criteria

- Listed for heart transplant as status 1A; or on home milrinone or dobutamine infusion
- Enrolled in a palliative or hospice care program
- History of stroke within the past year
- Major disability such as aphasia
- Uncontrolled psychiatric disorders
- Cognition: Montreal Cognitive Assessment score <20
- Living in a setting where they are not able to independently engage in self-care (eg, skilled nursing facility)

Figure 2. HeartMapp features.



Medication Tracker

The medication tracker allows patients to add and edit their medications and activate reminders to take medications (eg, push notification). This feature can also assist home health nurses to update their patients' medications list collaboratively. Given the success of related product features in other populations (eg, Text4Baby), this mechanism may improve behavioral outcomes in HF [23]. In fact, a meta-analysis of 16 studies reported that text messaging significantly improved medication adherence (odds ratio 2.11; 95% CI 1.52-2.93; P<.001) among patients with chronic diseases [24].

Assessment of HF Symptoms

HeartMapp provides a self-care management point-of-care tool where tailored automated reminders are sent to patients to check their weight and complete HF symptom assessment questions. Although symptoms are the hallmarks of severity of HF, patients' experience of symptom clusters and symptom intensities vary and may reflect the personal and social experiences of illness, cultural differences in the interpretation of symptoms, and responses to the illness—all of which may influence HF self-care practices and care-seeking behavior [25]. Evidence suggests that symptom recognition may be impaired in the elderly population [26,27]. Furthermore, patients often misinterpret symptoms of HF and decline to seek early medical care, which results in higher readmission rates.

Once users have registered with HeartMapp with baseline height, weight, and health care provider information, they receive tailored daily prompts and are provided access to the assessment window to check weight, blood pressure, and answer the short questionnaires on HF symptoms. HeartMapp then classifies users via the HF severity index based on the New York Heart Association (NYHA) functional classification [28]. The algorithm in HeartMapp uses the information entered by patients on weight and HF symptoms to classify the patients into (1) Green Zone, if HF symptoms are reported as stable or no change in weight; (2) Yellow Zone, if HF symptoms are reported as mild and a weight gain of 3 pounds in 1 day or 5 pounds in a week; (3) Orange Zone, if symptoms are moderate and a weight gain of more than 5 pounds; or (4) the Red Zone, if HF symptoms require immediate attention. On the basis of the information gathered, the HeartMapp provides an alert with the following feedback at the end: the Green Zone ("stable with no change-continue current self-care practices"); the Yellow Zone

("take an extra dose of water pill if prescribed by your doctor and call the home care staff if receiving home care or your doctor's office"); the Orange Zone ("call home care staff or the doctor's office now" and open the phone number on the file provided during registration of the app to alert the study coordinator); and the Red Zone (automatically dials 911 and sends a panic alert to the study coordinator and home care staff). Random text alerts are designed based on key evidence from HF literature and patient preference. In fact, a pre-post pilot study that provided text messages to patients with HF (n=15) reported an increase in mean composite score of HF self-care maintenance from 49 to 78 (P=.003), and self-care management increased from 57 to 86 (P=.002) at 4 weeks [29]. Furthermore, regular app usage provides useful metrics of patient engagement.

Patients with HF have an increased prevalence of cognitive impairment with 4 times higher risk of developing dementia compared with healthy adults of the same age. The etiology is believed to be of vascular origin because of hypoperfusion to the brain resulting from reduced cardiac function. Therefore, HeartMapp includes a memory screener and simple naming tasks to measure cognition using Boston Naming Test criteria with 9-items [30]. Patients with early vascular dementia caused by cerebral hypoperfusion in HF displayed more naming errors overall [31].

Physiological Exercises

The exercise feature includes animated biofeedback deep breathing exercises and walking. Deep breathing interventions deployed in HeartMapp use biofeedback mechanism to reset the autonomic nervous system by reducing sympathetic activity and increasing parasympathetic activity [32,33]. Also, HF patients have 2 to 3 times higher incidence of depression compared with general population [34]. Therefore, HeartMapp is designed to teach patients about using biofeedback to attain 6 breaths per min and offer feedback on their performance. Controlled breathing at 6 breaths per min, compared with spontaneous breathing at 15 breaths per min, has been shown to reduce fluctuations in blood pressure and significantly increase baroreflex sensitivity measured by spectral analysis electrocardiogram in a study among 81 patients with HF (from 5.0 [SD 0.3] to 6.1 [SD 0.5] ms/mm Hg, P<.001), compared with 21 healthy controls [35].

HeartMapp encourages walking 3 to 4 times a week and provides feedback to patients on performance. The walking test is a simple measure of functional capacity that predicts survival in patients with moderate HF. Patients with HF who have an ejection fraction of less than 30% have been shown to improve exercise tolerance and physical ability [36]. Therefore, HeartMapp is built to encourage physical activity and tracks distance walked. HeartMapp also gives feedback to patients on their performance by utilizing the distance walked by individuals based on their age, gender, height, and weight.

Performance Tracker (Stats)

Performance tracking features in the HeartMapp include a graphical module that displays trends in patient performance, including weight, blood pressure, HF symptoms, and physiological measures such as heart rate and exercise activity. These data serve as a tool for triage by home health nurses to understand early decline and thus prevent readmission and or emergency room visits by quickly intervening (eg, by providing an extra dose of diuretic or an early office visit for evaluation).

Vital Signs Monitoring

Monitoring of vital signs is captured via integration of an open application programming interface (API) from BioHarness-3 from Zephyr technology [17]. Because wearable devices for continuous vital sign monitoring are expected to revolutionize health care services, particularly in the home setting [37], the BioHarness-3 was used to obtain heart rate and accelerometer data.

HF Education (CHF Info)

HF education (CHF-info feature) includes 10 educational modules specific for HF and common chronic diseases associated with HF. Evidence indicates that traditional patient education using printed materials does not support self-care skill development; thus, novel patient-teaching strategies and persistent engagement of patients are needed to support the development of tactical and situational skills [38]. The HF-info feature in the HeartMapp includes audio-enabled interactive teaching tools on the nature of heart failure, importance of low-salt diet, exercise regimen, HF medications, and managing other chronic diseases or conditions and feelings about HF as well as heart and brain connection. Theory-based development and beta testing of embedding HF education within HeartMapp has been published [39].

Active Wait-Listed Control Group (n=9)

The control group (n=9) received only HF info downloaded onto their mobile phone, as shown in Figure 3. These patients were encouraged to use 3 modules per week and complete all 10 modules by 4 weeks. Participants were assured that they will receive the additional features at the 4-week follow-up. At the end of the follow-up, they were given access to 4 features of the HeartMapp, with the exception of vital signs monitoring using the chest strap BioHarness-3.

Patient Safety and Monitoring

A study coordinator (doctoral student and nurse practitioner) called all participants 3 times a week during the first week and once a week for the remaining 3 weeks to make sure that they completed their tasks and answered any questions that came up, checked the dashboard daily to monitor participants' progress, and triaged for further management per protocol. No participants during the study period were referred to a cardiologist (project consultant) for HF symptoms warranting immediate attention.

Outcome Measures

Patient engagement and HeartMapp usage were assessed based on the duration for which the participants accessed HeartMapp features that were timestamped and recorded on a secured website.

Self-confidence in using HeartMapp questionnaire, which was designed based on Bandura's self-efficacy scale [40], was completed by participants who used HeartMapp at the 30-day follow-up. This questionnaire has 10 Likert scale questions and was validated in a prior usability study (r=.98) [18].

Figure 3. Congestive heart failure (CHF) info app.

The *usability of HeartMapp* questionnaire validated in a prior study (r=.468-.635) [18] has a total of 25 questions in a 5-point Likert scale [16]. This questionnaire assessed the ease of use, problem-solving capabilities, accuracy and clarity of presentation, and satisfaction with the use and design of HeartMapp. Open-ended questions were included at the end for comments on specific task needs.

Self-care behavior in HF was assessed using the *Self-Care of Heart Failure Index* [41] that has been used in multiple studies involving HF patients. Reliability of the Self-Care Maintenance subscale had a score of (r=.56), whereas the scores of Self-Care Management and Self-Care Self-Confidence were (r=.70) and (r=.82), respectively [41]. Higher score indicates better self-care.

Medication adherence was assessed using the 8-item self-*administered Morisky Medication Adherence Questionnaire*, with lower score indicating better adherence (r=.83) [42].

The HF-specific knowledge was assessed using the *Atlanta Heart Failure Knowledge* Test [43]. This questionnaire has 30 questions with a possible score of 0 to 30 (r=.84 for patients); higher score indicates better knowledge [43].

Participants' perception about clinical changes in quality of life was measured using the *Kansas City Cardiomyopathy Questionnaire* (KCCQ) [44]. This 23-item scale has 5 clinically relevant domains for persons with HF, which include physical limitations, symptoms (frequency, severity, and change over time), quality of life, social interference, and self-efficacy (r=.66-.95) [44]. Lower score indicates worse symptoms and worse quality of life.

Patient Health Questionnaire (PHQ-9), a self-administered depression scale, which scores each of the 9 Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition criteria as 0 (not at all) to 3 (nearly every day), was used to examine depression [45]. Higher score indicates worse depression. Scores of 5, 10, 15, and 20 represent cutpoints for mild, moderate, moderately severe, and severe depression, respectively. A PHQ-9 score of ≥10 has a sensitivity of 88% and a specificity of 88% for major depression and has been validated in 247 patients with HF (r=.82) [45].

Demographic variables including age, gender, ethnicity, and marital status as well as clinical variables on medications, ejection fraction, and NYHA were collected at baseline [46,47]. Illness burden was measured using *Cumulative Illness Rating*

Scale that measures illness burden on a 5-point scale with scores ranging from 0 to 56, which demonstrated an interclass correlation coefficient of .78 on illness burden [48]. The Duke-UNC short-version 8-item *Functional Social Support Questionnaire* (FSSQ) assessed social support (*r*=.50-.85). The FSSQ uses a 5-point Likert scale (1=much less than I would like and 5=as much as I would like) [49].

Data Analysis

Baseline and 30-day follow-up data were collected at participants' home. Partial eta squared for effect sizes were computed from group mean differences using linear regression. Furthermore, *t*-tests were performed to compare mean differences between intervention and control groups and between time points (post- and preintervention scores). Exploratory correlation analyses were performed to evaluate changes in outcome measures relative to baseline performance on assessments.

Results

Of the 20 patients who were screened for eligibility, 1 participant gave us a wrong home address and could not be tracked, and another participant refused to be a part of the study after eligibility screening. All participants met the inclusion criteria, including normal hearing and vision as well as normal cognition with mean MoCA score of 26.3 (SD 2.4). A total of 18 participants met the inclusion criteria and were block randomized to HeartMapp (n=9) and active wait-listed control (n=9) to HF education (CHF info, one feature of the HeartMapp) on the mobile phone for the first 30 days. Only 13 participants (72%), 7 in the HeartMapp group and 6 in the HF info group completed the 30-day follow-up. As mentioned earlier, an Android phone was loaned for the study period for the participants who did not own a phone.

Demographic Data

Participants' mean age was 53.06 years; 56% (10/18) of the participants were females, 61% (11/18) lived alone (divorced, never married, or widowed), 33% (6/18) were African Americans, and 17% (3/18) were Hispanics. Only one participant, 6% had less than high school education, 89% (16/18) had non-ischemic cardiomyopathy, and 67% (12/18) had HF for over a year. Mean ejection fraction was 28%, 67% (12/18) were in HF stage C, and 61% (11/18) were in NYHA class II (see Table 1 for detail).

On the illness burden scale measured by the Modified Cumulative Illness Rating Scale, 78% (14/18) of participants rated cardiac condition as severe to extremely severe (3-4) burdensome; whereas 17% (3/18) reported severe burdensome for endocrine problems (diabetes), 11% (2/18) rated severe burdensome for psychiatric problems and kidney diseases. All participants owned a mobile phone, one participant owned an Apple phone, and 63% (11/18) used a mobile phone to get health information.

Mean Difference in HF Outcomes Between Intervention and Control Groups (Post-Pre Scores) and Baseline Versus 30-Day Follow-Up Scores

Mean for baseline and 30-day follow-up scores were computed, which demonstrated an improvement in almost all outcomes. An independent *t*-test was used to compute mean change scores of HeartMapp and control group at baseline and 30-day follow-up (30-day score-baseline score) for the 72% (13/18)) participants (7 HeartMapp and 6 control group) who completed the 30-day follow-up. The results showed statistical significance in few of the outcomes.

In general, trend on improvements were noted at 30-day follow-up on all outcomes among groups. Among patients in HeartMapp group, a mean score change on self-care management by 8 points was noted, whereas the control group improved by 2 points (*P*=.01); self-care confidence improved by 7 points in HeartMapp group compared with an increase of 2 points among controls (*P*=.03). Mean score change on HF knowledge among HeartMapp group was 3 points, whereas the control group declined (*P*=.04). Quality of life measured by KCCQ declined by 2 points in HeartMapp group, whereas the control group declined by 9 points (*P*=.18). Medication adherence improved among both groups (see Table 2).

Effect Size Calculation Using Partial Eta Squared

We computed the partial eta squared as the effect sizes from group mean differences using linear regression. The partial eta squared indicates the percentage of variance in each of the effects (or interaction) and its associated error that is accounted for by that effect (or interaction) [50]. The partial eta squared indicated small to moderate effect sizes (self-care 0.249; HF knowledge 0.337; quality of life 0.156; depression 0.262; and medication adherence 0.036).

Patient Satisfaction and Usability of HeartMapp

Seven participants from HeartMapp group who completed the 30-day follow-up were asked to rate the HeartMapp usability questionnaire that assessed HeartMapp features and self-confidence in using HeartMapp questionnaire (see Table 3).

Engagement With HeartMapp

The details on participants' access to HeartMapp features were stored and time stamped on a secure website for analysis. A mean of 78% engagement with HeartMapp was noted among all participants randomized to HeartMapp. Of the nine participants randomized to HeartMapp, 43% (4/9) accessed HeartMapp daily and completed the assessment of HF symptoms and exercise (walking) daily. Five participants accessed HeartMapp features over 24 days or 80% of the time. The multivariate regression analysis did not predict any association with patient engagement or HeartMapp access time with HF outcome. However, other features of the HeartMapp were accessed by participants inconsistently. The features consistently accessed were the medication tracker and breathing exercise. The least accessed feature was the vital signs monitoring using the chest-worn Bluetooth device (BioHarness-3).

Table 1. Sample characteristics.

Characteristics	n (%) (N=18)	Mean (standard deviation)
Age, in years		
≥65	12 (66.7)	53.06 (4.02)
Gender		
Female	10 (55.6)	
Living status		
Never married	4 (22.2)	
Married	7 (38.9)	
Widowed, separated	7 (38.9)	
Race		
White	9 (50)	
African American	6 (33.3)	
Hispanic	3 (17)	
Education		
More than 1 or more college	11 (61.1)	
High school	6 (33.3)	
Less than high school	1 (5.6)	
Ejection fraction		28.09 (14.61)
Etiology of HF[a]		
Nonischemic	16 (88.9)	
NYHA[b] class		
Class I	1 (5.6)	
Class II	11 (61.1)	
Class III	6 (33.3)	
HF stage		
Stage B	6 (33.3)	
Stage C	12 (66.7)	
Body mass index		36.55 (13.12)
Cognitive score at baseline (MoCA[c] score)		26.33 (2.40)
Social support at baseline (FSSQ[d] score)		34.94 (6.63)
Illness burden (MCIR[e] score)		22.72 (4.16)
Owned a mobile phone	18 (100)	
Type of phone		
Apple iPhone	1 (5.6)	
Android	11 (61.1)	
Analog	6 (33.3)	
Use of mobile phones		
Very well	7 (38.9)	
Moderately well	11 (61.1)	
Mobile phone use		
Texting	18 (100)	
Health information	11 (61.1)	

[a]HF: heart failure.

[b]NYHA: New York Heart Association.

[c]MoCA: Montreal Cognitive Assessment.

[d]FSSQ: Functional Social Support Questionnaire.

[e]MCIR: Modified Cumulative Illness Rating.

Table 2. Mean difference between HeartMapp and control groups at baseline and 30 days.

Outcome measures	HeartMapp Baseline Mean (SD)	HeartMapp 30-days Mean (SD)	Control Baseline Mean (SD)	Control 30-days Mean (SD)	*t*	Significant *P* value
Self-Care Maintenance	22.86 (2.41)	28.29 (2.81)	17.67 (3.61)	22.83 (5.56)	0.083	.93
Self-care Management	12.00 (2.77)	20.71 (1.11)	9.67 (2.66)	12.33 (3.03)	3.38	.01
Self-care Confidence	12.43 (2.94)	19.46 (4.05)	14.67 (3.01)	16.50 (2.07)	2.53	.03
Med. Adherence	3.00 (1.73)	3.23 (1.64)	3.50 (1.65)	2.33 (1.50)	0.408	.53
HF Knowledge	24.29 (1.56)	27.28 (2.29)	24.83 (2.13)	24.17 (1.71)	2.37	.04
Quality of Life	20.71 (9.09)	23.43 (6.50)	19.69 (7.64)	27.5 (8.52)	1.43	.18
Depression	8.14 (5.60)	7.00 (6.13)	8.50 (5.36)	3.33 (2.94)	1.97	.07

Table 3. Patient Self-Confidence and Usability of HeartMapp.

Descriptors for measures	Mean (SD)
Ease of using the HeartMapp	24.86 (4.02)
Accuracy of contents of HeartMapp	19.43 (4.50)
Use and design of the HeartMapp	17.86 (2.67)
Problem-solving feature of HeartMapp	15.57 (6.24)
Self-confidence in using the HeartMapp	18.00 (15.74)

Open-Ended Questions on the Usability Scale

Assessment of open-ended questions using descriptive and thematic analysis suggested that 86% (8/9) of the participants preferred a wrist-worn Bluetooth device. The chest-worn Bluetooth device (BioHarness-3) was reported by more than half of the participants (>50%) as uncomfortable, and all the participants reported poor battery life, with the need to charge the device twice a day. This indicated noncompliance in using the chest strap.

Discussion

Principal Findings

The result of this pilot study is promising in that the HeartMapp intervention showed trends in improving several HF outcomes, especially self-care management, self-care confidence, and HF knowledge. A comprehensive review of 34 commercially available mobile apps for HF symptom monitoring and self-care rated Heart Failure Health Storylines, Symple, ContinuousCare Health App, WebMD, and AskMD as the highest performing apps and recommended future studies to test the usability and effectiveness of the available apps [51]. On the other hand, several intervention studies demonstrated inconclusive results, including the Heart Smart symptom training [52], the large Comparison of Outcomes and Access to Care for Heart Failure study (n=1023) on intense disease management [53], motivational interviewing in HF [54], transitional care [55], and a nurse-led cognitive behavioral intervention [56] that demonstrated no difference or improvement in HF outcomes. Also, the Alere Day-Link monitor that used electronic scale and a computer-based individualized symptom response [57] also did not demonstrate significant improvement in HF outcomes. Thus, a large-scale study is warranted to test HeartMapp for functionality and improved HF outcomes.

A systematic review on remote telemonitoring interventions reduced the relative risk of all-cause mortality (0.60-0.85) and HF-related hospitalizations (0.64-0.86) compared with usual care. Improvements in HF-related hospitalizations appeared to be more pronounced in patients with stable HF (hazard ratio 0.70; 95% CI 0.34-1.5), indicating appropriate selection of patients who are not in the refractory or end-stage HF [58]. This is possibly true in this pilot study, as 61% of the patients were in NYHA class II.

A pilot study that offered text messaging to HF patients after discharge demonstrated significant improvement in HF self-management [29], as seen among participants who used HeartMapp. Similarly, Weight and Activity with Blood Pressure Monitoring System (WANDA), which comprises wireless sensors and a mobile device, enabled the patients to reduce 5.6% of weight and blood pressure values that were out of the

acceptable range; however, this system is still under updates before becoming commercially available [59]. Therefore, the trends observed on improved HF outcomes in this pilot study warrant an exploration in a well-designed RCT.

The result of this pilot study indicated that only 72% of participants completed the 30-day follow-up, which is very low and the reason most reported was the use of BioHarness-3 chest strap. An attrition rate of 35% has been reported in prior studies among HF population [60]. Those who completed the follow-up did not use the BioHarness-3 consistently. A mean of 78% engagement with HeartMapp was noted among all participants randomized to HeartMapp. Again, this may be because of the challenges faced in using the BioHarness-3 chest strap. The engagement with HeartMapp observed in this sample is comparative with the national data from Common Wealth Fund (2016) that showed engagement at 16% for Android apps and 6% for iPhone operating system (iOS) and usefulness at 43% for iOS apps and 27% for Android apps [61]. Although these are general data, the 78% engagement with HeartMapp seen in this small sample could be because of the features tailored specifically for HF patients.

One in 6 (15%) consumers in the United States currently uses wearable technology, mostly smart watches or fitness bands [37]. Over 80% of the study participants reported a preference for wrist-worn Bluetooth device to track vital signs, physical activity, and sleep, but they did not use the chest-worn Bluetooth device. Therefore, the team is currently testing several wrist-worn Bluetooth devices with open API in the laboratory (ie, Microsoft Band-2, Fitbit Charge HR, and Moto 360). An open API allows all developers by offering one piece of software to interact with another piece of software. Thus, the research team hopes to tap into the consumer health wearables using one of the wrist-worn devices for a larger clinical trial to test with HeartMapp.

This pilot study only enrolled a small sample of 18 HF patients, with only 72% completing the 30-day follow-up; thus, the results are not generalizable. The small number of participants rated high satisfaction with the ease of using HeartMapp, which supported the results of the prior usability study [18]. Gerber and colleagues [62] supported that older adults and marginalized segments of the population have better access and uptake of mobile technology. However, technology use has been observed to decrease significantly with greater limitations in physical capacity such as vision impairment and memory limitations [63]. Therefore, the inclusion screening criteria was stringent in patients for vision, hearing, and cognitive function, which needs further exploration in a larger study. Lessons learned in this pilot study helped the team to refine a few features in HeartMapp and to overcome shortcomings in a future larger trial.

Conclusions

There is currently an urgent unmet need for HF-targeted patient-centered interventions that are easy to use by older adults with HF who experience cognitive difficulties and lack social support. Participants in this study reported that HeartMapp is easy to use. However, there is need for updates on integrating a wrist-worn Bluetooth device for monitoring of vital signs, which the team is currently addressing. In the current market, there are a few other apps being tested that track patients' self-care such as weight and symptoms. HeartMapp not only tracks patient performance, it provides alerts and feedback on patient performance; it also provides interventions to perform deep breathing exercises and to encourage physical activity. HeartMapp also includes HF-related education. Further exploration in a larger trial is warranted to test the feasibility of utilizing HeartMapp over time to improve short-term and long-term HF outcomes.

Conflicts of Interest

The corresponding author, Ponrathi Athilingam and the co-author Miguel Labrador have received funding from the Florida Hi-Tech Corridor and the Charles Stark Draper Laboratory as well as National Science Foundation Innovation-Corps award as Co-PIs for the development of the mobile Health Application "HeartMapp". This pilot study was made possible from funding from University of South Florida, College of Nursing. The HeartMapp is copyrighted by University of South Florida and patent pending for Drs Ponrathi Athilingam and Miguel Labrador. The authors declare no conflicts of interest in the development of this manuscript.

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Abbreviations

API: application programming interface
CHF: congestive heart failure
FSSQ: Functional Social Support Questionnaire
HF: heart failure
IMB: information-motivation-behavioral skills
iOS: iPhone operating system
IRB: institutional review board
KCCQ: Kansas City Cardiomyopathy Questionnaire

MCIR: Modified Cumulative Illness Rating scale
mHealth: mobile Health
MoCA: Montreal Cognitive Assessment
NYHA: New York Heart Association
PHQ-9: Patient Health Questionnaire
RA: research assistant
RCT: randomized controlled trial

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Original Paper

A Web-Based Tailored Intervention to Support Illness Management in Patients With an Acute Coronary Syndrome: Pilot Study

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Abstract

Background: Illness management after an acute coronary syndrome (ACS) is crucial to prevent cardiac complications, to foster participation in a cardiac rehabilitation (CR) program, and to optimize recovery. Web-based tailored interventions have the potential to provide individualized information and counseling to optimize patient's illness management after hospital discharge.

Objective: We aimed to assess the feasibility and acceptability of a Web-based tailored intervention (TAVIE@COEUR) designed to improve illness management in patients hospitalized for an ACS. Illness management outcomes were operationalized by self-care, medication adherence, anxiety management, cardiac risk factors reduction, and enrollment in a CR program.

Methods: This posttest pilot study was conducted with one group (N=30) of patients hospitalized for an ACS on the coronary care unit of a tertiary cardiology center. TAVIE@COEUR comprises three Web-based sessions, with a duration ranging from 10 to 45 min and is structured around an algorithm to allow the tailoring of the intervention to different pathways according to patients' responses to questions. TAVIE@COEUR includes 90 pages, 85 videos, and 47 PDF documents divided across session 1 (S1), session 2 (S2), and session 3 (S3). These sessions concern self-care and self-observation skills related to medication-taking (S1), emotional control and problem-solving skills (S2), and social skills and interacting with health professionals (S3). Throughout the videos, a virtual nurse (providing the intervention virtually) guides the participants in the acquisition of self-care skills. Patients completed S1 of TAVIE@COEUR before hospital discharge and were asked to complete S2 and S3 within 2 weeks after discharge. Feasibility indicators were extracted from the TAVIE@COEUR system. Data regarding acceptability (satisfaction and appreciation of the platform) and preliminary effect (self-care, medication adherence, anxiety management, risk factor reduction, and CR enrollment) were assessed through questionnaires at 1 month following discharge. Preliminary effect was assessed by comparing baseline and 1-month illness management variables.

Results: Of the 30 participants, 20 completed S1, 10 completed S2, and 5 completed S3. Good acceptability scores were observed for ease of navigation (mean=3.58, standard deviation [SD]=0.70; scale=0-4), ease of understanding (mean=3.46, SD=0.63; scale=0-4), and applicability (mean=3.55, SD=0.74; scale=0-4). The lowest acceptability scores were observed for information

tailoring (mean=2.93, SD=0.68; scale=0-4) and individual relevance (mean=2.56, SD=0.96; scale=0-4). With regard to preliminary effect, we observed an overall self-care at 1 month following discharge score higher than at baseline (mean at 1 month=54.07, SD=3.99 vs mean at baseline=49.09, SD=6.92; scale-0-60).

Conclusions: Although participants reported general satisfaction and appreciation of TAVIE@COEUR, acceptability and feasibility results show the need for further development of the Web-based intervention to enhance its tailoring before undertaking a full-fledged randomized controlled trial. This may be accomplished by optimizing the adaptability of TAVIE@COEUR to patients' knowledge, needs, interests, individual capabilities, and emotional and cognitive responses during session completion.

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KEYWORDS

nursing informatics; health behavior; self-care; acute coronary syndrome; pilot study

Introduction

Health behavior change and illness management play a critical role in the treatment for patients with an acute coronary syndrome (ACS) [1,2]. However, the short hospitalizations following an ACS leave little time for health professionals to provide tailored information and support to patients before discharge [3-6]. This often results in patient's information needs not being met and, in turn, makes it challenging for them to engage in healthful behaviors and illness management [1,5,7-9]. Illness management is defined as a broad set of strategies and self-care–related behaviors that can be enacted by patients to optimize recovery, reduce their susceptibility to relapses, cope effectively with their symptoms, and manage the impacts of the illness of their quality of life [10]. In the context of cardiovascular diseases, many aspects of illness management such as self-care, medication adherence, anxiety management, cardiac risk factor reduction, and enrollment in a cardiac rehabilitation (CR) program are essential for optimizing recovery and preventing cardiac complications [1,5]. Medication adherence can reduce the risk of all-cause mortality by 35% [7]. Similarly, symptom management and reduction of cardiac risk factors, as promoted in CR programs, are positively linked to cardiac patient outcomes, including increased quality of life and lowered health care services utilization [1,11]. Anxiety management is vital after an ACS, since anxiety may modulate other risk factors such as depression, smoking, sedentary lifestyle, substance abuse, and overweight [12]. Moreover, anxiety is a negative and independent factor influencing adherence to treatment in patients with acute coronary syndrome [13]. Intervention efforts should then focus on engaging ACS patients in practicing self-care, being adherent to their medication, managing their anxiety and cardiac risk factors, and enrolling in a CR program [5,14].

Health professionals in clinical settings play a crucial role in helping patients initiate illness management and health behavior change [1,5]. Clinical practice guidelines clearly state that tailored counseling on the part of health professionals in primary health care settings is a key factor to help patients initiate such behaviors and reduce cardiovascular risk [15-18]. However, it is often reported that nurses and other health professionals neither have the time nor the resources to provide such information and coaching in a timely manner while the patient is hospitalized [19-22]. A recent study on the matter concluded that patient education requires advanced communication skills and pedagogical competences on the part of health professionals. Such skills and competences are needed to provide effective counseling that will result in patients initiating and maintaining illness management–related behaviors [19]. We must then consider that although it is essential to provide tailored counseling to patients following an ACS, only a few health professionals have the necessary knowledge and skills to do so.

Web-based interventions are promising avenues to enhance patient access to information resources post discharge [1,9,23]. Although the number of these technology-driven interventions is growing exponentially in the health care field [24], results on their efficacy remain unclear [1,9,23]. Indeed, some studies have shown that the use of information and communications technologies (ICTs) can positively affect illness management [25,26]. On the other hand, other authors argue that home Internet access, prior Internet experience, and engagement of patients are challenges that must be resolved for Web-based interventions to have a significant effect [27]. A systematic review examining mobile Web-based interventions for self-care related to medication intake showed significant improvement in medication adherence in 18 out of 29 studies [28]. Another systematic review on the same topic by Anglada-Martinez et al [29] showed positive outcomes in 65% of studies, with the authors emphasizing the need for more extensive research. Moreover, to our knowledge, only a few studies have assessed Web-based tailored interventions to improve illness management with ACS patients specifically.

Therefore, the purpose of this pilot study was to develop TAVIE@COEUR, a Web-based tailored intervention including videos showcasing a virtual nurse, and assess its acceptability, feasibility, and preliminary effect for improving illness management in patients hospitalized for an ACS.

Methods

Study Design and Setting

The pilot study used a posttest design with one group of ACS patients hospitalized on the Coronary Care Unit (CCU) in a tertiary cardiology center in Canada. The study was approved by the institutional review board of the Montreal Heart Institute Research Center (project number: 11-1320). Our study is reported in accordance with the CONSORT-EHEALTH checklist version 1.6.1. (see Multimedia Appendix 1) [30]. No content or methodological modifications were made after study commencement.

Participants

We recruited a convenience sample of patients hospitalized at the CCU. To be included in the study, participants had to be aged >18 years, be hospitalized for an ACS, be discharged to home within 7 days, understand written and spoken French, and have the physical and cognitive abilities to participate. Patients were excluded if they were hospitalized on the CCU for more than 7 days because this would reflect a more difficult ACS recovery, potentially interfering with their physical abilities to participate.

Procedure

Enrollment and follow-up occurred from June 2014 to August 2015. Participants were recruited during face-to-face encounters with the project nurse at the CCU. After receiving an explanation regarding the study and providing written consent, patients completed a baseline questionnaire. An individual identification number, username, and password were then provided to participants to allow them to log in to the TAVIE@COEUR Web-based platform. The project-dedicated nurse then showed participants how to use TAVIE@COEUR on a tablet computer and invited them to complete the first session (20 min) at the CCU. Participants were then asked to complete the next two sessions of TAVIE@COEUR at home within 2 weeks of discharge.

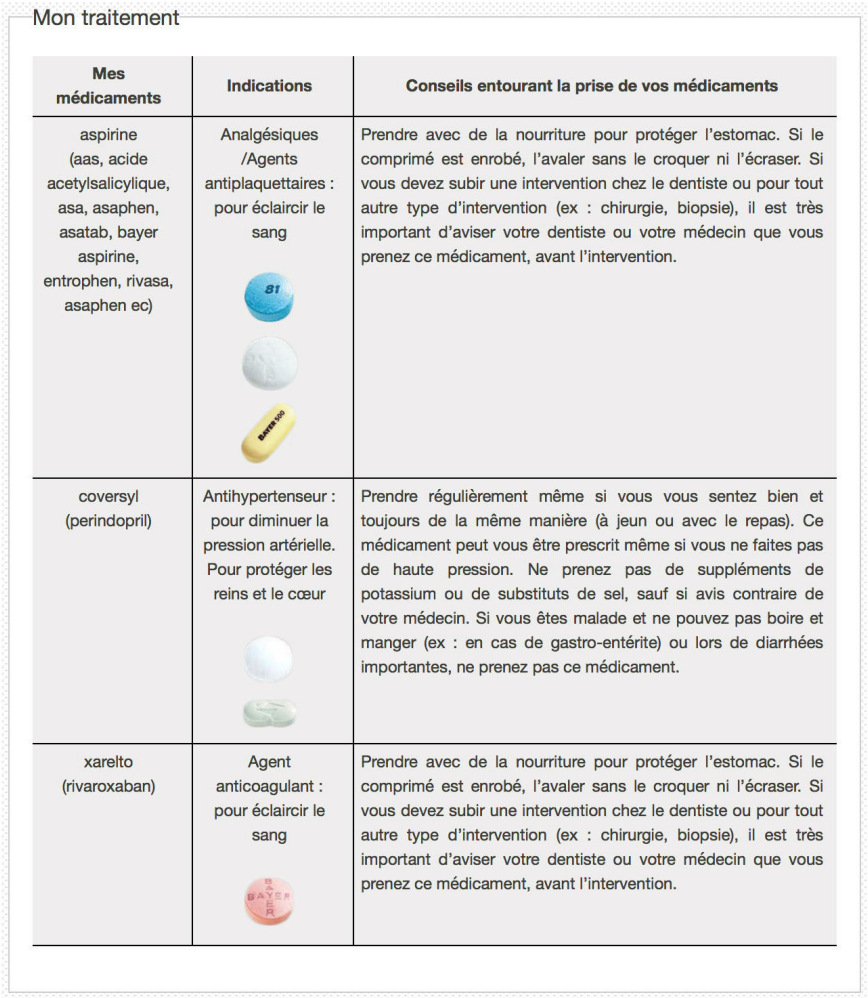
All patients received usual care during their hospitalization, including a predischarge teaching session by the bedside nurse on resuming activities of daily living, cardiovascular risk factors, and new medications. This included a pamphlet about medication, prevention of complications, local CR program, and postangioplasty care, which is provided to all patients discharged from the CCU following a coronary event.

The TAVIE@COEUR Web-Based Tailored Intervention

TAVIE@COEUR (in French, which translates as YOURLIFE@HEART in English) is a Web-based tailored intervention, including videos in which a virtual nurse interacts with the patient. The ultimate goal of TAVIE@COEUR is to improve patient illness management by providing information and resources tailored to the needs of every patient, while being easily accessible from home. TAVIE@COEUR is completely asynchronous and led by a virtual nurse who guides patients through a learning process regarding the development of illness management skills for self-care and medication adherence (see Figure 1).

Figure 1. TAVIE@COEUR homepage and virtual nurse (in French).

Figure 2. Example of specific information provided regarding the medication of each patient (generic and commercial names, indications and tips - in French).


Mon traitement

Mes médicaments	Indications	Conseils entourant la prise de vos médicaments
aspirine (aas, acide acetylsalicylique, asa, asaphen, asatab, bayer aspirine, entrophen, rivasa, asaphen ec)	Analgésiques /Agents antiplaquettaires : pour éclaircir le sang	Prendre avec de la nourriture pour protéger l'estomac. Si le comprimé est enrobé, l'avaler sans le croquer ni l'écraser. Si vous devez subir une intervention chez le dentiste ou pour tout autre type d'intervention (ex : chirurgie, biopsie), il est très important d'aviser votre dentiste ou votre médecin que vous prenez ce médicament, avant l'intervention.
coversyl (perindopril)	Antihypertenseur : pour diminuer la pression artérielle. Pour protéger les reins et le cœur	Prendre régulièrement même si vous vous sentez bien et toujours de la même manière (à jeun ou avec le repas). Ce médicament peut vous être prescrit même si vous ne faites pas de haute pression. Ne prenez pas de suppléments de potassium ou de substituts de sel, sauf si avis contraire de votre médecin. Si vous êtes malade et ne pouvez pas boire et manger (ex : en cas de gastro-entérite) ou lors de diarrhées importantes, ne prenez pas ce médicament.
xarelto (rivaroxaban)	Agent anticoagulant : pour éclaircir le sang	Prendre avec de la nourriture pour protéger l'estomac. Si le comprimé est enrobé, l'avaler sans le croquer ni l'écraser. Si vous devez subir une intervention chez le dentiste ou pour tout autre type d'intervention (ex : chirurgie, biopsie), il est très important d'aviser votre dentiste ou votre médecin que vous prenez ce médicament, avant l'intervention.

Development Process

TAVIE@COEUR is based upon the TAVIE virtual nursing assistance and education Web platform developed by Côté et al [31]. The TAVIE platform was evaluated in different populations such as human immunodeficiency virus (HIV)-positive patients [32].

The TAVIE@COEUR platform was designed with an interdisciplinary team of researchers, nurse practitioners, managers, pharmacists, physicians, and computers scientists. This ensured that everybody involved would agree on the information and content of the platform. All professionals involved in the project team (nurses, pharmacists, and physicians) validated the content, including the information about medication, side effects, therapeutic goals, misuses of medication, and treatment. To ensure feasibility, the managers of the CCU validated the format of the TAVIE@COEUR platform, such as the duration and sequence of sessions. Computer scientists provided feedback on the structure and content of TAVIE@COEUR, as well as measures of acceptability.

To ensure the preservation of data related to TAVIE@COEUR, the website and data regarding its use were hosted on secure computer servers at the research setting.

TAVIE@COEUR Access

TAVIE@COEUR could be accessed via a fixed URL. Participants could log in to their account on their home computer or tablet computer using their personal log-in credentials created during their stay at the CCU.

TAVIE@COEUR Content

A general overview of the content of the three sessions of TAVIE@COEUR is presented in Table 1. The TAVIE@COEUR intervention is based on a motivational and self-efficacy enhancing framework. More specifically, the interventions of the virtual nurse throughout the 85 videos of TAVIE@COEUR are based on the beliefs and representations of individuals (self-regulation theory by Leventhal; [33]), integrate motivational counseling (works by Miller and Rollnick; [34]), and take into account the stages of change of Prochaska [35].

Table 1. General overview of the content of TAVIE@COEUR.

Sessions and general theme	Number of Web pages	Number of videos	Number of PDF documents
Home page	1	1	0
Session 1: Self-care and self-observation skills	17	14	35
Session 1 objectives	1	1	0
Taking your medication	3	3	0
Identifying or finding out about your medication	2	0	0
Getting motivated to take your medication	1	1	3
Associating a positive image to your medication	3	3	0
Observing your own behavior	1	2	0
Identifying adverse effects or discomfort	1	1	2
Managing adverse effects or discomfort	2	0	19
Documenting adverse effects or discomfort	1	1	2
Tips to avoid adverse effects or discomfort	1	1	0
Integrating strategies for medication-taking	1	1	9
Session 2: Emotional control and problem-solving skills	31	28	7
Session 2 objectives	1	1	0
Assessing the efficacy of advice	1	0	0
Managing adverse effects or discomfort	4	2	0
Associating a positive image to your medication	6	5	0
Observing your own behavior	3	2	0
Managing challenges in medication-taking	3	5	0
Recognizing and changing negative thoughts	2	4	1
The DECIDE[a]approach	6	8	4
Identifying or finding out about your medication	2	0	0
Managing adverse effects or discomfort	2	0	0
Documenting adverse effects or discomfort	1	1	2
Session 3: Social skills and interacting with health professionals	41	42	5
Session 3 objectives	2	2	0
Associating a positive image to your medication	9	7	0
Observing your own behavior	6	4	0
Managing negative feelings	6	7	0
The DECIDE approach	1	1	0
Recognizing the importance of support	2	2	1
Listening and communication skills	3	3	1
Resources, services, and health professionals	3	12	2
Practicing the session strategies	2	1	1
Managing adverse effects or discomfort	4	2	0
Identifying or finding out about your medication	2	0	0
Documenting adverse effects or discomfort	1	1	0
Total	90	85	47

[a]DECIDE is an acronym designed for helping patients solve problems. D=Describe the situation in which the oversight occurred to identify your difficulty; E=Express a list of possible strategies to address this challenge; C=Choose the strategy that is most likely to be effective and with which you feel comfortable; I=Imagine yourself using this strategy; D=Decide to take action and face the situation by putting this strategy into practice; E=Evaluate

results and resume problem-solving skills when you are not satisfied with the results.

In session 1 (S1), the overarching goal is to develop self-care and self-observation skills. The virtual nurse invites the participant to identify and find out about his medication, while normalizing any possible omission of medication (see Figure 2). She also encourages the participant to continue with successful techniques to optimize medication adherence and recognize signs and symptoms of deterioration or medication side effects. The virtual nurse then suggests possible solutions to any problems in these areas. Session 2 (S2) focuses on emotional control and problem-solving skills. The session addresses possible difficult situations that may lead to nonadherence, for example, travel, restaurants, or activities that can interfere with the daily routine. Negative feelings toward medication, fear of side effects, and confusion about interaction between illicit drugs and prescribed medications are also discussed. Finally, session 3 (S3) focuses on developing patients' social skills and interactions with family and health care professionals to strengthen their support system and to improve illness management.

TAVIE@COEUR Structure

TAVIE@COEUR comprises three Web-based sessions, each with a mean duration of 30 min. However, the duration of each session could vary between 10 and 45 min, depending on the needs of each patient and their answers during the navigation. TAVIE@COEUR includes 90 pages, 85 videos, and 47 PDF documents divided across S1, S2, and S3.

TAVIE@COEUR is based on an algorithm allowing a tailored intervention, meaning that throughout the intervention, participants are asked 46 questions (S1: 5 questions, S2: 16 questions, and S3: 25 questions) to tailor the information and resources to their individual needs. For instance, participants are asked to enter their prescription drug information, allowing tailored information to be provided on these specific medications throughout the 3 sessions of the intervention. An example of question asked is: "Do you take ONE of the following medications: Acetylsalicylic Acid, Clopidogrel, Prasugrel, or Ticagrelor?" If the patient answers yes, another question is asked: "During the past week, have you forgotten taking any of your antiplatelet medication?" If the patient answers yes again, a video is presented to provide specific information regarding the benefits of antiplatelet medication and motivational counseling regarding this subject. If the patient answers no to these questions, the intervention proceeds to the next subject. The tailoring of TAVIE@COEUR means that some pages are mandatory for all patients, whereas other pages appear depending on patients' personal responses. Additionally, PDFs can be accessed to get more detailed information on subjects of interest for the patient.

Use Parameters

Participants completed S1 on tablet computers at the CCU with headphones. We asked participants to complete the two other sessions at home within 2 weeks of discharge.

Level of Human Involvement and Cointerventions

The Web-based tailored intervention was completely asynchronous. The research team was available to provide technical support via mail or telephone. No other intervention was performed during the study.

Measures

Sociodemographic and Clinical Data

Baseline sociodemographic and clinical variables were collected for all participants. Some variables were obtained from medical charts such as age, gender, medical diagnosis, and both cardiovascular and noncardiovascular antecedents. Other variables were self-reported, including employment status, education, marital status, and place of residence.

TAVIE@COEUR Feasibility

Feasibility determines "whether the intervention, study design, and procedures can be successfully executed by the researcher and delivered to the participants as planned" [36]. The indicators of feasibility of TAVIE@COEUR were the following: (1) the number of patients who browsed each session, (2) the number of patients who completed each session, and (3) the duration of each session for those who completed it.

TAVIE@COEUR Acceptability

Acceptability determines "the suitability of the intervention and the study procedures from the perspective of the clinical population of interest, the intervention providers, or the health professionals who provide care to the population of interest" [36]. The acceptability of TAVIE@COEUR was measured by the Web-based Nursing Intervention Acceptability Scale developed by Côté et al [32]. The scale includes 21 items assessing satisfaction in 8 dimensions: ease of navigation, ease of understanding, credibility, tailoring of information, individual pertinence, applicability, appreciation of user interface design, and general appreciation. Patients indicated the degree to which they agreed with each statement from *not at all* (0) to *totally* (4). The score for each dimension was calculated by summing the scores for the items therein and dividing the result by the number of items in the dimension to standardize the reported means and allow comparison between dimensions. A higher total score for each dimension indicates greater acceptability (possible range: 0-4).

TAVIE@COEUR Preliminary Effect

Preliminary effect measures in illness management (self-care, medication adherence, anxiety management, cardiac risk factors reduction, and CR enrollment) were assessed at baseline and at 1 month after discharge by telephone. Enrollment in a CR program, hospitalizations, and emergency visits were assessed at 1 and 3 months.

Self-care was assessed with the Therapeutic Self-Care Scale (TSCS) that measures actions taken by a patient to promote, maintain, or improve health; prevent sickness; detect and manage symptoms; and regain normal functioning [37]. Patients indicated whether they agreed with each statement from *not at all* (0) to *totally* (5), with higher total scores indicating better self-care reported abilities (possible range: 0-60). Cronbach alpha coefficients for the total score were ranged between .88 and .93 [38]. We also used the three subscores proposed by

Chaboyer et al [39], who conducted a principal component analysis. The three subscores included perceived capabilities of *taking medications* (alpha: .80 and .79 for the 3- and 6-months data, respectively, in their study), *recognizing and managing symptoms* (alpha: .71 and .70 for the 3- and 6-months data, respectively), and *managing changes in health conditions* (alpha: .48 and .50, for the 3- and 6-months data, respectively) [39].

Medication adherence was assessed with the Morisky Self-Reported Medication-Taking Scale (SRMTS) [40] that assesses reasons for nonadherence. Patients indicated whether (1) or not (0) they forgot, omitted, were careless, or stopped their medication when feeling better at 30 days after discharge (possible range: 0-4). A total score of zero (0) represents no omission of medication, reflecting high adherence; a score of 1 or 2, medium adherence; and a score of 3 or 4, low adherence [40]. Morisky et al [40] reported a Cronbach alpha of .61.

Anxiety was assessed with the State-Trait Anxiety Inventory–State version [41] that includes negatively-worded and positively-worded items. Patients indicated whether they agreed with each statement from “not at all” (1) to “a lot” (4). Higher scores indicate higher anxiety levels (possible range: 20-80). Spielberger et al [41] reported internal consistency coefficients ranging from .86 to .95 and test-retest reliability coefficients ranging from .65 to .75 over 2 months [42].

Cardiac risk factors were assessed using the questionnaire *Do you have a healthy heart?* [43] that measures the following risk factors: age, gender, menopausal status, heredity, physical exercise, smoking, waist size, weight, diabetes, arterial tension, as well as levels of cholesterol (total, high- and low-density lipoprotein) and of triglycerides. Each item is rated differently. For instance, for physical activity, the following question is asked: “In general, how many days per week are you physically active for at least 30 minutes (walking, dancing, sports, workout, etc; does not have to be a continuous 30 minutes).” Possible answers include less than once a week, 1 to 2 times per week, and 3 to 4 times per week. Scores for each item were added to obtain a total score representing a patient’s level of risk; higher scores representing a higher level of risk (possible range: 0-144). No studies have yet established the validity of the scale, which was created by experts for clinical purposes. However, in a previous study, the Cronbach alpha was .71 [44].

Information on enrollment in a local CR program, hospitalizations, and emergency room visits was collected from the electronic medical charts of the research hospital.

Sample Size

In accordance with pilot study guidelines, we targeted a sample size of 30 participants [45,46]. No power analyses were performed in the context of a pilot study.

Statistical Analysis

Descriptive statistics such as means and standard deviations (SDs) were used for continuous variables, whereas count and percentage were used for dichotomous variables. As this was a pilot study, no inferential analyses were planned; preliminary effect results being provided strictly for illustrating general trends as recommended in pilot study methodology [46].

Results

Characteristics of the Sample

Participants (N=30) were enrolled in the study from May 2014 to June 2015. Most participants were men, with a mean age of 59 years (SD 9). The majority of the participants were born in Canada and living with a partner (see Table 2).

Table 2. Participants' baseline sociodemographic and clinical data (N=30).

Characteristic	n (%)
Sex (male)	26 (87)
Place of birth (Canada)	24 (80)
Living situation (with a partner)	23 (77)
Employment status (employed)	16 (53)
Education (high school or higher)	15 (50)
Medical antecedents (≥1)	20 (67)
Cardiovascular antecedents (≥1)	11 (37)
Medical diagnostic	
Myocardial infarction (STEMI)	18 (60)
Myocardial infarction (NSTEMI)	7 (23)
Unstable angina pectoris	5 (17)
Cardiovascular risk factors	
Alcohol use	19 (63)
Hypertension	16 (53)
Hypercholesterolemia	15 (50)
Physical inactivity	15 (50)
Stress	15 (50)
Family history of cardiovascular disease	14 (47)
Smoking	13 (43)
Obesity	10 (33)

TAVIE@COEUR Feasibility

As shown in Table 3, S1, S2, and S3 were browsed by 30, 17, and 10 participants, respectively. Of these participants, 20 out of 30 completed the mandatory pages in S1, 10 participants completed the mandatory pages in S2, and 5 participants completed the mandatory pages in S3. For those who completed the mandatory pages, the first session lasted a mean of 25 min, whereas the second and third sessions lasted around 16 min.

TAVIE@COEUR Acceptability

The general level of satisfaction toward TAVIE@COEUR stayed mostly the same following S1 and following either S2, S3, or both (see Table 4). Items that scored the highest on the acceptability scale were related to the ease of navigation throughout TAVIE@COEUR and the ease of understanding the textual and video content of TAVIE@COEUR. Items that scored the lowest were related to the tailoring of the information and the individual relevance of content in TAVIE@COEUR. Patients identified other areas for improvement such as the pacing of the intervention by the virtual nurse, which they felt was not tailored to their needs. Some believed the content to be less suitable for people who already had a good knowledge of disease and drugs, whereas other patients would have preferred more information on how to prevent the recurrence of cardiac events.

Certain aspects of the intervention scored higher after S1 (tailoring of information and individual relevance), whereas other factors pertaining to the interface scored higher after S3 (ease of navigation and user interface design).

Table 3. Feasibility of TAVIE@COEUR (N=30).

Feasibility outcomes	Mean (SD[a]) or n (%)
Session 1	
Participants who began the session, n (%)	30 (100)
Participants who completed the session, n (%)	20 (67)
Mean duration of session if completed, in minutes, mean (SD)	25 (9)
Session 2	
Participants who began the session, n (%)	17 (57)
Participants who completed the session, n (%)	10 (33)
Mean duration of session if completed, in minutes, mean (SD)	16 (7)
Session 3	
Participants who began the session, n (%)	10 (33)
Participants who completed the session, n (%)	5 (17)
Mean duration of session if completed, in minutes, mean (SD)	16 (5)

[a]SD: standard deviation.

Table 4. TAVIE@COEUR acceptability (n=26).

Outcome variable	Number of items	Possible range	Standardized mean (SD[a]) score after session 1	Standardized mean (SD) score after sessions 2, session 3 or both
Ease of navigation	2	0-4	3.35 (0.74)	3.58 (0.70)
Ease of understanding	2	0-4	3.43 (0.78)	3.46 (0.63)
Credibility of the information	1	0-4	2.91 (0.92)	3.27 (0.70)
Tailoring of the information	4	0-4	3.26 (0.57)	2.93 (0.68)
Individual relevance	4	0-4	2.97 (0.73)	2.56 (0.96)
Applicability	1	0-4	3.09 (0.87)	3.55 (0.74)
Appreciation of user interface	5	0-4	2.94 (0.67)	3.04 (0.74)
General appreciation	2	0-4	3.27 (0.72)	3.24 (0.87)
General satisfaction score	21	0-4	3.14 (0.57)	3.02 (0.61)

[a]SD: standard deviation.

TAVIE@COEUR Preliminary Effect

We observed that an overall self-care score 1 month post discharge was higher than the baseline score (see Table 5). Moreover, post-intervention scores for the three dimensions of self-care (medication-taking, recognizing and managing symptoms, and managing changes in the health condition) were all higher than baseline scores.

Responses on the medication adherence scale were skewed toward the score of 0: half of patients reported no omission (score of 0) of medication at 1 month after discharge. Therefore, patients were classified as either reporting no omission (score of 0) versus scores ≥1 omissions. When examining each of the four items of the SRMTS scale, the main reason for nonadherence was *forgetting* (item 1) to take medication. Seven percent (2 out of 27) of patients scored on either items 2 to 4 on *omission*, *being careless*, and *stopping medication when feeling better*. Patients generally reported a low anxiety level at 1 month post discharge.

Table 5. TAVIE@COEUR preliminary effect.

Outcome variable	Number of items	Possible range	Mean (SD[a]) score at baseline (n=30)	Mean (SD) score or n (%) at 1 month (n=27)
Overall self-care	12	0-60	49.09 (6.92)	54.07 (3.99)
Self-care related to medication-taking	3	0-15	11.35 (2.41)	13.74 (1.32)
Self-care related to recognizing and managing symptoms	4	0-20	15.69 (3.49)	16.86 (2.36)
Self-care related to managing changes in health condition	3	0-15	13.24 (2.29)	14.19 (1.47)
Medication adherence (no omission), n (%)	NA	NA	NA	14 (52)
Anxiety	20	20-80	NA	33.36 (12.28)
Cardiac risk factors	25	0-144	NA	83.96 (11.25)
Enrollment in cardiac rehabilitation, n (%)	NA	NA	NA	12 (40)

[a]SD: standard deviation.

Discussion

Principal Findings

We developed and pilot-tested TAVIE@COEUR, a Web-based tailored intervention aimed at supporting illness management in patients hospitalized for an ACS. Feasibility and acceptability results suggest some strengths such as the ease of navigation and the content of TAVIE@COEUR but also underline the need for further development of TAVIE@COEUR. Indeed, we believe that further tailoring of TAVIE@COEUR should be done before undertaking a full-fledged randomized controlled trial (RCT). This may be necessary to increase the engagement of participants to complete all sessions, possibly by interchanging some concrete and more abstract content across the sessions. Preliminary effect results are promising, with improved self-care scores 1 month post discharge related to medication-taking, management of symptoms, and management of changes in the health condition.

Although acceptability scores regarding the TAVIE@COEUR Web-based tailored intervention were generally good, the low completion rate of the 3 sessions underline the significant challenges related to optimizing engagement and adherence in Web-based interventions for illness management. Participants appreciated the ease of navigation throughout the Web-based platform, the ease of understanding of the textual and multimedia content, and the applicability of the information in TAVIE@COEUR. However, relatively low scores were observed for other dimensions of the acceptability questionnaire, such as individual relevance and tailoring of the information; some participants felt that TAVIE@COEUR was not tailored enough to their needs. Moreover, feasibility was not optimal since the global participation rate in the Web-based intervention decreased over the three sessions: 20 out of 30 participants completed S1 (at the CCU), 10 completed S2 (at home), and 5 completed S3 (at home). The lower-than-normal participation rate in the second and third sessions of TAVIE@COEUR may be explained by a variety of factors, including lower motivation to continue the intervention up to the end and lack of individual relevance of the intervention content in the third session. Indeed, it is possible that the content of S3, focusing on social skills and interactions with health professionals, was seen less relevant to participants' needs, especially because they received all crucial information on medication adherence during the first two sessions. However, the mean duration of sessions was consistent throughout the intervention, suggesting that participants who completed S3 were similarly engaged in the intervention.

More and more electronic health (eHealth) apps and Web-based interventions are addressing health behavior change and are being evaluated in patients with various chronic illnesses [47-49]. Patients' engagement in completing Web-based interventions is often reported in eHealth intervention research as being about 50% of patients recruited [50,51]. This means that dropout rates of around 50% are observed in several Web-based interventions, limiting their effectiveness in initiating and maintaining changes in health behaviors in patients with cardiovascular diseases [47,48,51-54]. This phenomenon is explained at least, in part, by the fact that most existing Web-based interventions, even those that are called *individualized*, do not take into account the navigation behavior, knowledge, preferences, and individual objectives of the real-time users [51].

We believe the true challenge lies in developing new strategies for engaging participants with various information needs and individual capabilities in Web-based interventions, such as TAVIE@COEUR. In this study, tailoring was ensured by participants following their own paths, choosing to skip or view the videos, and selecting the appropriate resources to match their needs. However, the general theme of the intervention (illness management geared toward medication-taking) was similar for all participants. We observed that, whereas all participants went through the same life-threatening coronary event and associated medical treatment, their information needs varied widely, more than anticipated with the tailoring allowed in TAVIE@COEUR. Some participants felt the content of TAVIE@COEUR provided more than enough information for their needs, whereas other patients would have liked different resources not related to medication-taking because they were already accustomed to taking medication regularly.

The findings of this study suggest the need for more variety in the options offered to each individual to better match the individual needs of each patient [55,56]. For instance, intelligent

tutoring systems (ITS) show great promise to provide tailored resource to patients by adapting the structure and content of the training to learners' knowledge, preferences, and individual capabilities by using some components of artificial intelligence [57]. ITS are generally conceptualized using four models: (1) the interface model, by which the participant interacts with the ITS; (2) the domain model, which represents the knowledge to learn (clinical and theoretical content); (3) the learner model, which takes into account the knowledge, preferences, and individual capabilities of each participant; and (4) the tutor model representing the pedagogical strategies used throughout the ITS [58]. The combination of these four models, through the use of machine learning and data mining, allow for the tailoring of the instruction to each participant [58]. Whereas ITS with various levels of complexity have been evaluated in academic settings with positive results, very few ITS have been assessed with patients in health care settings [59,60]. We can hypothesize that user-modeling at the beginning of TAVIE@COEUR could allow to better target patients with illness management problems related to medication-taking and redirect those who are okay to other resources related, for example, to nutritional guidelines or ACS pathophysiology. In this sense, we believe a widest range of content should be developed to better represent the interests and needs of patients affected by cardiac diseases.

Future research should also focus on developing new strategies for engaging participants in Web-based interventions, such as interactive feedback based on real-time emotional and cognitive responses, online support groups, serious games, and blended Web-based or in-person interventions. Increasing the accessibility of such interventions is also an important challenge; researchers should make sure that Web-based interventions are adaptive to the devices preferred by each patient (ie, mobile phone, tablet, or computer) [28,29].

Strengths and Limitations of the Study

The strengths of the study include adherence to the pilot study protocol and the development of an innovative and complex Web-based tailored intervention.

The limitations of this study mostly relate to pilot study characteristics; the single-group, pre-post study design did not allow for causal inferences or for having enough statistical power to detect statistically significant differences. However, this is expected in a pilot study [45,46]. High dropout rates were observed, particularly in the second and third session of the intervention, leading us to believe that changes must be made to the TAVIE@COEUR Web-based intervention before undertaking an RCT. Finally, we observed in our results that the Morisky SRMTS was not designed for properly quantifying the percentage of medication adherence [38]. Future studies should consider using a different tool or scale for measuring more precisely adherence, such as the medication possession ratio [6,52].

Conclusions

Web-based tailored interventions such as TAVIE@COEUR show potential to support illness management for patients in all clinical settings. However, significant challenges remain, and future research must be conducted to optimize factors related to the tailoring of such interventions to patients' knowledge, needs, interests, and individual capabilities. We strongly believe the right combination of these factors could contribute to the way in which care is provided in health care settings for years to come. With continued population acceptance of Internet use, Web-based interventions are expected to grow exponentially in content and in complexity. Health professionals have an important role to play in keeping these interventions focused on patients and their families to optimize clinical outcomes.

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Authors' Contributions

All authors contributed to manuscript writing, as well as read and approved the final manuscript. SC and JC contributed to study conception and design, data collection and conception of the analytical plan, manuscript writing, and final approval of the manuscript; GR contributed to study conception and design of the content of the Web-based tailored intervention, and final approval of the manuscript; MR and SH contributed to study conception and design and final approval of the manuscript; TM and GF contributed to study conception and design, patient recruitment and follow-up, statistical analysis, manuscript writing, and final approval of the manuscript; CC contributed to statistical analysis and final approval of the manuscript; and JFT and JD contributed to study conception and design and final approval of the manuscript.

Conflicts of Interest

SC and JC have financial stakes in TAVIE@COEUR, which could be commercialized in a near future, as discussions are ongoing with a third party having expressed interest in the application.

Multimedia Appendix 1
CONSORT E-HEALTH Checklist.
[PDF File (Adobe PDF File), 820KB - cardio_v1i2e4_app1.pdf]

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Abbreviations

ACS: acute coronary syndrome

CCU: Coronary Care Unit
CR: cardiac rehabilitation
eHealth: electronic health
HIV: human immunodeficiency virus
ICTs: information and communications technologies
ITS: intelligent tutoring systems
RCT: randomized controlled trial
RN: registered nurse
SD: standard deviation
SRMTS: Self-Reported Medication-Taking Scale
TSCS: Therapeutic Self-Care Scale

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Original Paper

The Atrial Fibrillation Health Literacy Information Technology System: Pilot Assessment

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Abstract

Background: Atrial fibrillation (AF) is a highly prevalent heart rhythm condition that has significant associated morbidity and requires chronic treatment. Mobile health (mHealth) technologies have the potential to enhance multiple aspects of AF care, including education, monitoring of symptoms, and encouraging and tracking medication adherence. We have previously implemented and tested relational agents to improve outcomes in chronic disease and sought to develop a smartphone-based relational agent for improving patient-centered outcomes in AF.

Objective: The objective of this study was to pilot a smartphone-based relational agent as preparation for a randomized clinical trial, the Atrial Fibrillation Health Literacy Information Technology Trial (AF-LITT).

Methods: We developed the relational agent for use by a smartphone consistent with our prior approaches. We programmed the relational agent as a computer-animated agent to simulate a face-to-face conversation and to serve as a health counselor or coach specific to AF. Relational agent's dialogue content, informed by a review of literature, focused on patient-centered domains and qualitative interviews with patients with AF, encompassed AF education, common symptoms, adherence challenges, and patient activation. We established that the content was accessible to individuals with limited health or computer literacy. Relational agent content coordinated with use of the smartphone AliveCor Kardia heart rate and rhythm monitor. Participants (N=31) were recruited as a convenience cohort from ambulatory clinical sites and instructed to use the relational agent and Kardia for 30 days. We collected demographic, social, and clinical characteristics and conducted baseline and 30-day assessments of health-related quality of life (HRQoL) with the Atrial Fibrillation Effect on Quality of life (AFEQT) measure; self-reported medication adherence with the Morisky 8-item Medication Adherence Scale (MMAS-8); and patient activation with the Patient Activation Measure (PAM).

Results: Participants (mean age 68 [SD 11]; 39% [12/31] women) used the relational agent for an average 17.8 (SD 10.0) days. The mean number of independent log-ins was 19.6 (SD 10.7), with a median of 20 times over 30 days. The mean number of Kardia uses was 26.5 (SD 5.9), and participants using Kardia were in AF for 14.3 (SD 11.0) days. AFEQT scores improved significantly from 64.5 (SD 22.9) at baseline to 76.3 (SD 19.4) units at 30 days ($P<.01$). We observed marginal but statistically significant improvement in self-reported medication adherence (baseline: 7.3 [SD 0.9], 30 days: 7.7 [SD 0.5]; $P=.01$). Assessments of acceptability identified that most of the participants found the relational agent useful, informative, and trustworthy.

Conclusions: We piloted a 30-day smartphone-based intervention that combined a relational agent with dedicated content for AF alongside Kardia heart rate and rhythm monitoring. Pilot participants had favorable improvements in HRQoL and self-reported

medication adherence, as well as positive responses to the intervention. These data will guide a larger, enhanced randomized trial implementing the smartphone relational agent and the Kardia monitor system.

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KEYWORDS

atrial fibrillation; mHealth; health-related quality of life; medication adherence

Introduction

Atrial fibrillation (AF) is a chronic and highly prevalent heart rhythm condition [1]. Treatment for AF requires long-term adherence to complex therapies that include anticoagulants and medications for heart rate and rhythm control [2]. AF has variable symptoms that fluctuate in severity and is associated with increased risks of adverse outcomes such as heart failure, stroke, hospitalization, and mortality [3]. The diverse treatments, symptoms, and potential for adverse outcomes combine to make AF a challenging condition for patients, which is associated with poor health-related quality of life (HRQoL) [4-6]. AF professional guidelines prioritize routine symptom assessment and monitoring to guide the treatment course [2]. Patients may have varying access to care, which may be further compromised by challenges to health literacy and obstacles to medication adherence [7]. Similarly, intermittent visits are the standard for clinical care, and patients may experience problems related to this chronic, complex disease between such visits.

Mobile health (mHealth) technologies have the potential to enhance multiple aspects of patient care by providing education, monitoring, of symptoms, and encouraging and tracking adherence to long-term pharmacological therapies or behaviors. We have developed and used relational agents in prior contexts to augment patient-centered health care. The relational agent is an animated character that provides health education, monitoring, and problem solving with speech, facial expression, and body gestures. Users converse and respond with on-screen selections, which in turn activate further dialogue with the agent. Figure 1 shows screenshots of the relational eliciting symptoms pertinent to AF and gesturing to enhance educational content. We propose the relational agent as a vehicle for improving chronic disease self-management, which provides practical strategies to negotiate the long-term self-care and medication adherence that are essential for patient's success with a chronic disease such as AF [8].

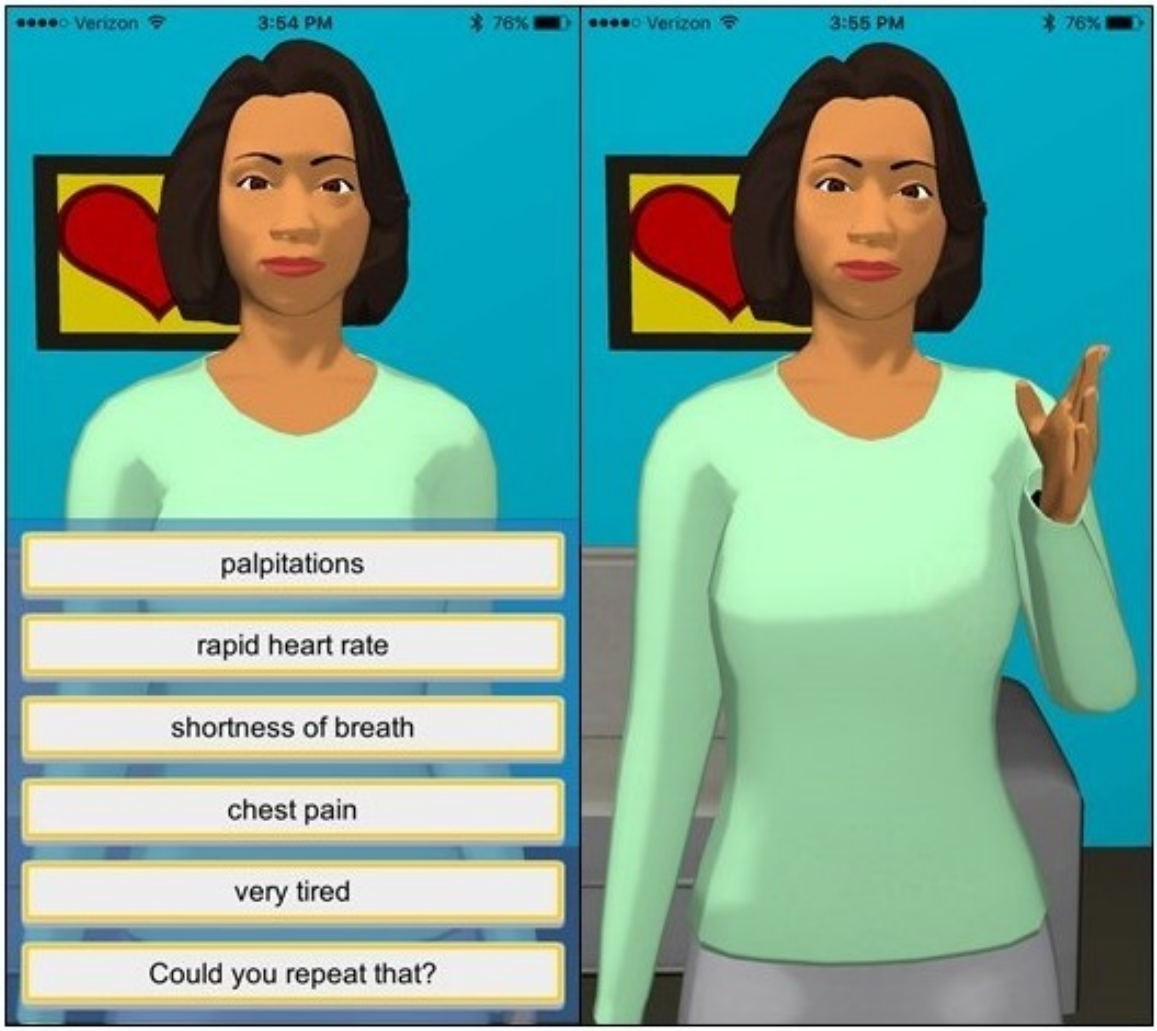
Our prior work has demonstrated that a relational agent is an effective health educator for all levels of health literacy and improves self-management and HRQoL [9-13]. In randomized studies, we have demonstrated that the use of the relational agent improves pharmacological adherence, diet, and physical activity, and it reduces the likelihood of hospital readmission [14-16]. Specific examples of our application of the relational agent to improve adherence include a clinical trial with 263 older adults to increase adherence over 12 months of routine physical activity [17] and the promotion of adherence to antipsychotic medication in schizophrenia (n=20) [18]. In an additional larger application, we examined the effect of the relational agent to improve communication with patients at hospital discharge (N=764) and found that the agent was associated with reduced rates of readmission and improved patient satisfaction [19]. The relational agent is a multifaceted intervention. It serves as a nonjudgmental empathetic coach and educator to provide patient-centered guidance.

To our knowledge, relational agents have had limited application in cardiovascular disease and have not been used in AF previously. Current ambulatory monitoring in AF focuses predominantly on AF detection [20-22]. Although such efforts have a clinical application, they may not provide patient-centered health coaching. The relational agent, in contrast, can assist patients to develop essential skills to understand monitoring results and respond to them.

Relational agents may be combined with other mHealth technology to augment their health-related impact. The AliveCor Kardia mobile heart rhythm monitor (AliveCor, Inc, Mountain View, CA) or Kardia for simplicity, allows individuals to monitor heart rate and rhythm with the help of a smartphone with results being uploaded for centralized review. Kardia has been used prospectively in various studies, again principally for AF detection [23-25]. We consider that Kardia may be combined with the relational agent described here to use the two synergistically. Kardia may facilitate correlation of symptoms reported to the relational agent, and relational agent content may reciprocally encourage individuals to take Kardia recordings. For example, patients may report symptoms to the relational agent, which in turn could prompt relational agent content that encourages Kardia use, and both applications may corroborate and support the documentation provided by the other. As the use of the relational agent and Kardia are time-stamped, the results may be incorporated as data to guide and direct clinical management.

We developed a relational agent for AF that integrated with Kardia. We sought to pilot this mHealth intervention and then use the results to guide the development of the clinical trial, the Atrial Fibrillation Health Literacy Information Technology Trial (AF-LITT), registered at ClinicalTrials.gov (NCT03093558). We report here on the initial pilot (n=31) of this mHealth intervention for preliminary results to guide and enhance the randomized controlled trial (RCT).

Figure 1. Screenshots of the relational agent: (a) symptoms menu and (b) an emphatic gesture.



Methods

Relational Agent Development and Content

The intervention includes a computer-animated relational agent that simulates a face-to-face conversation with a health counselor or coach using synthetic speech that accompanies animated conversational behavior (Figure 1) [10,13,16,26,27]. Our prior work has demonstrated that the relational agent as a vehicle for human-computer interaction is accessible to individuals with limited computer literacy and to older adults [11,26,27]. Our work has further shown that the relational agent fosters a therapeutic alliance with patients of diverse socioeconomic backgrounds and health literacy [28-30].

Users make selections via the smartphone's touch screen, and this selection directs further interaction and content provided by the relational agent. Communication with users includes nonverbal conversational behaviors, such as facial expressions for empathy or hand gestures for emphasis, which reinforce communication and facilitate empathetic expression. The content may be tailored for individual use, such that the relational agent addresses users by name and appropriate time context (eg, Good morning). In addition, the relational agent may be programmed to refer to prior content areas to obtain repeated assessments and follow the resolution of reported problems. We provided the agent with a name to facilitate user interaction, which is consistent with our other relational agent interventions; in this case, we designated the agent as "Tanya".

The relational agent content was developed by review of patient-centered domains, review of the literature, and qualitative interviews with patients with AF. In brief, we had a focus group consisting of patients with AF and receiving chronic anticoagulation. We asked patient participants open-ended questions about their experience of AF and the challenges and gaps that they experienced in their care. Our work is consistent with others in that the patients have a poor understanding of the condition, experience myriad symptoms, and find adherence challenging [31]. We consequently used these domains to develop the pilot of the relational agent, listed in Table 1.

Table 1. Summary of relational agent domain content.

Domain	Module content
Education	Causes of AF[a]
	AF treatment strategies
	Stroke prevention in AF
	AliveCor Kardia use, troubleshooting
Symptoms	Overview of common symptoms
	Chest pain and chest pressure
	Heart racing or palpitations
	Dyspnea and shortness of breath
	Fatigue
Adherence	Overview of adherence
	Adherence to medications
	Adherence barriers
	Strategies to address barriers
Patient activation	Goals for self-management
	Preparing for the medical encounter

[a]AF: atrial fibrillation.

Education spanned the causes of AF and its associated risk factors, treatments, and adverse events. Symptoms consisted of assessment of frequency and severity of shortness of breath, chest pain or discomfort, fatigue, and palpitations or the sensation of a racing or irregular heartbeat. Adherence content focused on common challenges to medication adherence, such as forgetfulness, affordability, access to medications, transportation, and the patient-physician relationship, along with general strategies to address these obstacles. Activation content entailed articulating goals of care and preparing for the medical encounter. For the concomitant use of Kardia, users were prompted to use Kardia daily and when they experienced symptoms.

Relational Agent and Kardia Use Ascertainment

The relational agent application and the Kardia monitor transmitted their data to a central server for monitoring, data collection, and analysis. Relational agent data included the date and time of use, duration, and specific domains of content accessed. Kardia data included the date of recording and recording results with a classification of heart rhythm (AF, sinus, or other) and heart rates in AF.

Cohort Participants

Participants were recruited from a convenience cohort of patients with prevalent AF, who were receiving care at ambulatory facilities of the University of Pittsburgh Medical Center in Pittsburgh, PA. Inclusion criteria included adult (age ≥18), a diagnosis of nonvalvular AF as ascertained by review of the electronic health record, CHA_2 DS_2-VASc score ≥2 [32], and receiving oral anticoagulation. Participants were excluded for having an identified extracardiac cause of AF (such as sepsis or thyroid disease), as the management of AF in such context may differ based upon the underlying etiology [2]; inability to provide accurate three-word recall; inability to provide informed consent; or being non-English speaking. Individuals were provided with an iPhone 6 (Apple, Cupertino, CA) for the duration of the study and instructions on the use of the relational agent and Kardia system. The study was approved by the University of Pittsburgh School of Medicine's Institutional Review Board.

Participant Assessments

Age, race, smoking status, highest level of education (less than high school, high school graduate, or vocational or trade school; some college with no degree or associate degree; bachelor degree; or graduate or postcollege professional school), and annual income (up to US $19,000; US $20-34,999; US $35-49,999; US $50-74,999; and ≥US $100,000) were obtained by participant self-report. Date of diagnosis with AF was obtained by self-report and the medical record. Body mass index (BMI) was calculated from weight (kg) divided by height (meters squared). Smoking status (current or prior smoking) and pack-years were obtained by self-report. Clinical covariates were derived from medical record problem lists and included hypertension, diabetes, cardiovascular disease, heart failure, and prior stroke or transient ischemic attack. Medications (anticoagulants, antiarrhythmics, and rate control agents) and treatment for AF (history of pharmacological or electrical cardioversion, pulmonary vein isolation) were obtained by self-report with corroboration from the medical record. Health literacy was measured by the Short-Test of Functional Health Literacy in Adults (S-TOFHLA) [33], which was selected for its broad use as a measure for health literacy assessment, scored from 1 to 36, with a score of ≤23 indicating limited health literacy.

The Atrial Fibrillation Effect on Quality of life (AFEQT) [34], the Morisky 8-item Medication Adherence Scale (MMAS-8)

[35], and the Patient Activation Measure (PAM) [36] were administered to participants at baseline and at study completion, that is, day 30. HRQoL was ascertained with the AFEQT questionnaire, a validated instrument specific to AF-related HRQoL. The AFEQT consists of a 20-item instrument that measures the effects of AF on HRQoL in the domains of symptoms, daily activities, treatment concerns, and treatment satisfaction, in addition to providing a global measure. Scores range from 0 to 100, with higher scores indicating superior HRQoL. Medication adherence was determined by self-report with the MMAS-8, which has been validated in diverse clinical conditions and is additionally used in studies of participants with limited health literacy [37,38]. The MMAS-8 ranges from 0 to 8, with higher scores indicating greater medication adherence. The 13-item PAM was used to ascertain patient activation, which has been conceptualized as the confidence, skills, and knowledge for patient self-management. PAM scores are tabulated from 0 to 100 and then converted from level 0 to level 5 as described elsewhere [39]. We elected not to include an assessment of AF patient knowledge, as the evidence that patient knowledge improves medication adherence in AF is scant [40].

Coaching, Acceptability, and Remuneration

Participants were contacted by telephone at their primary phone number on days 7, 14, and 21 to discuss problems with using the relational agent or Kardia. Individuals without relational agent use for ≥3 days were additionally contacted for support and troubleshooting. Qualitative interviews were conducted with participants at 30 days. Participants completed a 22-item instrument that evaluated their experience with the relational agent using 7-point Likert scale items. Pilot study participants received US $20 for the initial and final visit, and they were provided with a payment of US $1/day each for the use of the relational agent and Kardia, as an incentive for use and continued adherence. Therefore, the participants were able to receive a maximum of US $100 for two study visits and 30-day use of both instruments.

Statistical Analysis

We summarized the distributions of categorical and continuous variables. We used paired, 2-tailed *t* tests to examine the differences at baseline and 30 days in HRQoL with the AFEQT, self-reported adherence with the MMAS-8, and patient activation with the PAM. A *P* value of <.05 was considered statistically significant.

Results

The pilot cohort enrolled 31 participants with a mean age of 68 (SD 11) years, 39% of the participants were women, and predominantly belonging to the white race (94%, 29/31). Further characteristics of the cohort, which are summarized in Table 2, included both limited education (not having completed college, 68%, 21/31) and annual income (<US $35,000, 39%, 12/31; with the majority reporting <US $19,000). Obesity was common, with a mean BMI of 30.8 (SD 8.1), and multiple participants had diabetes, cardiovascular disease, a history of heart failure, or prior stroke or transient ischemic attack.

Table 2. Descriptive characteristics of the pilot cohort (N=31).

Characteristics	Cohort (N=31)
Age in years, mean (SD)	68 (11)
Women, n (%)	12 (39)
White race, n (%)	29 (94)
Education, <College, n (%)	21 (68)
Annual income, <US $35,000, n (%)	12 (39)
S-TOFHLA[a]≤23, n (%)	7 (23)
BMI[b], kg/m, mean (SD)	30.8 (8.8)
Current smoker, n (%)	5 (16)
Hypertension, n (%)	21 (68)
Diabetes, n (%)	4 (13)
Prevalent CVD[c], n (%)	4 (13)
Prevalent heart failure, n (%)	7 (23)
Prior stroke or TIA[d], n (%)	5 (16)

[a]S-TOFHLA: Short-Test of Functional Health Literacy in Adults.

[b]BMI: body mass index.

[c]CVD: cardiovascular disease.

[d]TIA: transient ischemic attack.

Table 3. Selected assessments of the pilot cohort at baseline and 30 days.

Assessments	Baseline	30 days	*P*
AFEQT[a], global score	64.5 (22.9)	76.3 (19.4)	<.01
AFEQT domains			
Symptoms	74.6 (24.1)	80.7 (21.4)	.07
Daily activities	56.0 (27.8)	65.2 (26.1)	.01
Treatment concerns	66.7 (26.2)	74.6 (22.6)	.08
Treatment satisfaction	71.2 (25.4)	72.9 (27.6)	.71
MMAS[b]	7.3 (0.9)	7.7 (0.5)	.01
PAM[c]	3.0 (0.8)	3.4 (0.7)	.33

[a]AFEQT: Atrial Fibrillation Effect on Quality of life.

[b]MMAS: Morisky 8-item Medication Adherence Scale.

[c]PAM: Patient Activation Measure.

Study participants used the relational agent for a range extending from 3 to 30 days, with a median of 20 days' usage that averaged 17.8 (SD 10.0) days of use. The number of log-ins to the relational agent ranged from 4 to 43, with a median of 20 and average of 19.6 (SD 10.7) uses. The median number of Kardia uses was 29, extending from 5 to 30, with a mean of 26.5 (SD 5.9) uses. Participants were in AF, a median of 13 days during the 30-day study period.

The baseline and 30-day assessments of AFEQT, self-reported adherence, and PAM scores are summarized in Table 3. The global AFEQT score was significantly improved from baseline to day 30, as was the daily activity component of the AFEQT. The domains of symptoms and treatment concerns had improvement from baseline to day 30 that was not statistically significant. The AFEQT domain of treatment satisfaction remained unchanged from baseline to day 30. Self-reported adherence with the MMAS-8 was marginally but significantly improved. The improvement in patient activation as measured by the PAM did not reach statistical significance.

Table 4. Relational agent acceptability assessment using a Likert-score ranging from 1 to 7.

Item	Description of range	Median (range)
How satisfied were you with Tanya?	1=Not at all; 7=Very satisfied	5 (1-7)
How easy was talking to Tanya?	1=Easy; 7=Difficult	1 (1-7)
How much would you like to continue working with Tanya?	1=Not at all; 7=Very much	5 (1-7)
How much do you like Tanya?	1=Not at all; 7=Very much	5 (1-7)
How would you characterize your relationship with Tanya?	1=Complete stranger; 7=Close friend	4 (1-7)
How much do you trust Tanya?	1=Not at all; 7=Very much	5 (3-7)
How much do you feel that Tanya cares about you?	1=Not at all; 7=Very much	5 (3-7)
How much do you feel that you and Tanya understand each other?	1=Not at all; 7=Very much	5 (1-7)
I feel uncomfortable with Tanya.	1=Disagree completely; 7=Agree completely	1 (1-5)
Tanya and I understand each other.	1=Disagree completely; 7=Agree completely	4 (1-7)
I believe Tanya likes me.	1=Disagree completely; 7=Agree completely	4 (1-7)
I believe Tanya is genuinely concerned about my welfare.	1=Disagree completely; 7=Agree completely	5 (1-7)
Tanya and I respect each other.	1=Disagree completely; 7=Agree completely	5 (1-7)
I feel that Tanya is not totally honest about her feelings toward me.	1=Disagree completely; 7=Agree completely	1 (1-5)
I am confident in Tanya's ability to help me.	1=Disagree completely; 7=Agree completely	5 (3-7)
I feel that Tanya appreciates me.	1=Disagree completely; 7=Agree completely	4 (1-7)
Tanya and I trust one another.	1=Disagree completely; 7=Agree completely	4 (1-7)
My relationship with Tanya is very important to me.	1=Disagree completely; 7=Agree completely	4 (1-7)
I have the feeling that if I say or do the wrong things, Tanya will stop working with me.	1=Disagree completely; 7=Agree completely	4 (1-7)
I feel Tanya cares about me even when I do things she does not approve of.	1=Disagree completely; 7=Agree completely	1 (1-4)

Our postuse assessments of the relational agent showed moderately strong acceptability of the agent. Thirteen of 31 participants reported either 6 or 7 on a 7-point Likert scale (1=Not at all; 7=Very satisfied) concerning their satisfaction with Tanya. Twenty-three participants selected 1 on the 7-point Likert scale, indicating that talking with Tanya was easy (1=Easy; 7=Difficult). When asked about continuing to work with Tanya, 17 indicated a strong willingness to continue, 9 would consider continuing with additional modules, whereas 5 indicated no interest. When scoring how much participants liked Tanya, 21 indicated a 5 or higher on the 7-point Likert scale (1=Not at all; 7=Very much). Participants further endorsed comfort with the agent and a belief that the agent is genuinely concerned about their welfare. These results and the remaining assessments of participants' experience with the relational agent are summarized in Table 4.

Discussion

Principal Findings

We piloted a 30-day intervention that combined a smartphone-based relational agent and the AliveCor Kardia heart rhythm monitor. Our chief findings were that the participants in this small-sized pilot reported improved HRQoL specific to AF and self-reported medication adherence. We tracked use of the relational agent and Kardia and identified that participants used them reliably over the 30-day intervention period. Finally, we demonstrated that the relational agent developed for this intervention had moderate to high acceptability by study participants.

There is a growing interest in mHealth to enhance patient engagement and improve patient outcomes. Our work focuses on implementing a relational agent, termed here the relational agent, which has distinct advantages as a mHealth intervention. The agent uses conversational behaviors—empathic tone, hand gestures, and facial expressions—to convey information. The responses to our postsurvey acceptability assessment suggest that users find the agent accessible, informative, and trustworthy. These results are similar to our prior work with relational agents, where we have used the relational agent as a nonjudgmental, empathetic coach to offer patient-centered guidance [15,41,42]. Relational agents provide an effective medium for health communication and counseling, especially for patients with limited health literacy. Health literacy is associated with poor self-management in multiple diverse conditions [11,43-45]. In our prior work, we have used the relational agent to improve health outcomes in individuals with limited health literacy [11,26,27] and have developed the content of our relational agent for AF to be accessible for such individuals. Health literacy has relevance to mHealth development, accessibility, and successful implementation; mHealth focused toward health literacy has the potential to reduce disparities in vulnerable populations, where limited health literacy is more prevalent [27].

In addition, the relational agent has the potential to assist users in real time. Content may be programmed to address immediate problems, suggest solutions, and then track their resolution. The relational agent content used in this pilot focused on major symptoms and then inquired about their status. Such content and the monitoring of responses may be implemented in conjunction with the Kardia. Thus, it is feasible to track symptoms while assessing their correlation with simultaneous heart rhythm or rate monitoring. In our next iteration, we expect to use symptoms and Kardia rate and rhythm monitoring to guide interventions in real time. We expect in our RCT to follow participants prospectively and longitudinally using a dashboard; so, we can respond to assist clinicians with enhanced management strategies.

The relational agent can promote self-management that is central to success with a chronic disease. The self-management model recognizes chronic disease management as a long-term endeavor with an uncertain prognosis and varied course [46]. AF is well suited for the self-management model because of its complex treatments, the potential for myriad complications, and necessity of patient adherence and engagement. We have developed our relational agent content guided by the self-management model because of the focus on sustained self-care and prevention in a chronic disease such as AF. The relational agent can promote patient education essential to self-management [47]. mHealth interventions that promote the self-management model must have the capacity to address the long-term aspects of chronic disease management. The relational agent is well suited, given its accessibility by a smartphone and capacity for expanded content delivered by the agent.

The adverse impact of AF on HRQoL has been well established [48-50]. The strengths of the AFEQT include its validation and development as a measure specific to AF [34,51]. A systematic review concluded that the AFEQT has stronger construct validity than other HRQoL measures specific to AF [52]. HRQoL has received increased emphasis as a patient-reported outcome, but it remains absent from many cardiovascular trials, including those focused on AF [53]. Although we observed a significant difference in baseline and 30-day AFEQT scores, the change did not meet the 19-unit, minimal important difference in the instrument that has previously been identified [51]. However, that threshold for a minimal important difference was ascertained over 3 months in a much larger cohort (n=210). In addition, we observed significant changes in the global AFEQT score and its domain of daily activities, and a trend toward improvement in symptoms and treatment concerns that did not reach our threshold for statistical significance. We did not observe improvement in treatment satisfaction, possibly because our 30-day intervention was too limited in duration for participants' treatment to undergo modification. We intend to conduct a more sustained intervention, which will provide confirmation of the efficacy of the relational agent to improve HRQoL. Real-time monitoring with targeted interventions may also improve treatment satisfaction.

Medication adherence is a prominent goal for chronic disease management and crucial in AF. In addition to increased medical costs and hospitalization risk, AF is associated with adverse events such as strokes and heart failure. Strokes may be prevented with regular use of anticoagulation, either vitamin K antagonist, such as warfarin, or one of the newer oral anticoagulants that do not require routine monitoring. However, poor adherence to anticoagulation in AF is common.

Discontinuation rates in clinical trials for the novel oral anticoagulants (NOAC) were 15% to 34% [54-56]. Claims data indicate that only 49% to 67% of NOAC users have satisfactory fill rates 9 to 12 months following the initial prescription [57,58]. For warfarin users, annual discontinuation reaches 27% to 33% [59]. Clinical trials and registries further affirm high discontinuation rates for both warfarin and NOAC users [57,60]. As AF is a lifelong condition, deescalation of anticoagulation is only justified if continued treatment is contraindicated, and long-term adherence is essential for stroke prevention. We expect to continue to refine and develop the relational agent used in this application. Our goals include enhanced adherence content for active problem solving of adherence challenges and obstacles; determining the reliability of the relational agent to measure adherence, compared with a gold standard such as medication event monitoring systems; and measuring the efficacy of the relational agent to improve adherence using objective measures rather than relying on self-reporting, which is subject to multiple biases [61].

Limitations

We also consider that our pilot study reported here has important limitations. First, the study sample was small (n=31), selected as a convenience cohort, and without randomization. We recognize a biased selection approach that may likely influence our results. For example, individuals recruited for this pilot may be more enthusiastic about the use of new technology, and they, consequently, demonstrate a greater likelihood of daily use than a more generalizable cohort. Second, individuals received repeated assessments using the same instruments over the 30-day study period. It is possible that the repeat measurement may modify or influence participant's self-report of HRQoL or medication adherence. Third, participants were contacted during the study and offered support using the technology. Participants' use of the intervention may have been influenced by such contact. However, for mHealth to be successful, it must be accessible to users. Fourth, our limited pilot cohort is racially homogeneous, as only 2 participants belonged to the nonwhite race. Enhanced recruitment of ethnic and racial minorities—those most likely to experience more severe differences in AF outcomes [62]—is critical to address disparities in AF. Fifth, we recruited from a limited number of ambulatory sites without control for practice patterns or clinical approaches. It is possible that there is residual confounding due to how clinicians caring for such a small-sized cohort may approach AF. Sixth, we had variable adherence to the intervention in this pilot. We are using these results to refine and improve relational agent content. Finally, the statistical assessments used to compare the baseline and 30-day measures were not adjusted for age, sex, and duration of AF, health literacy or other covariates. Such factors may have influenced adherence to the relational agent and consistency of use. Given our small sample size, stratified analyses would neither be statistically efficient nor meaningful. Furthermore, identifying which components of the multifaceted intervention promoted use would be challenging in this sample size. In subsequent, larger studies, we intend to measure the effects of the relational agent on prespecified subgroups.

Conclusions

In conclusion, we present results on the pilot use of a smartphone-based relational agent in combination with heart rate and rhythm monitoring. In our limited-sized pilot study conducted over 30 days, we identified strong adherence to the intervention and showed significant improvements in HRQoL and self-reported adherence. Participants found the relational agent acceptable. These results will guide the development and implementation of a more comprehensive relational agent for guiding long-term AF management to improve patient self-management and the experience of a highly morbid condition.

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Conflicts of Interest

None declared.

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Abbreviations

AF: atrial fibrillation
AF-LITT: Atrial Fibrillation Health Literacy Information Technology Trial
AFEQT: Atrial Fibrillation Effect on Quality of life
HRQoL: health-related quality of life
mHealth: mobile health
MMAS-8: Morisky 8-item Medication Adherence Scale
NOAC: novel oral anticoagulants
PAM: Patient Activation Measure
S-TOFHLA: Short-Test of Functional Health Literacy in Adults

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Original Paper

My Hypertension Education and Reaching Target (MyHEART): Development and Dissemination of a Patient-Centered Website for Young Adults with Hypertension

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Abstract

Background: Young adults (18 to 39 years old) with hypertension have the lowest rates of blood pressure control (defined as blood pressure less than 140/90 mmHg) compared to other adult age groups. Approximately 1 in 15 young adults have high blood pressure, increasing their risk of future heart attack, stroke, congestive heart failure, and/or chronic kidney disease. Many young adults reported having few resources to address their needs for health education on managing cardiovascular risk.

Objective: The goal of our study was to develop and disseminate a website with evidence-based, clinical information and health behavior resources tailored to young adults with hypertension.

Methods: In collaboration with young adults, health systems, and community stakeholders, the My Hypertension Education and Reaching Target (MyHEART) website was created. A toolkit was also developed for clinicians and healthcare systems to disseminate the website within their organizations. The dissemination plan was guided by the Dissemination Planning Tool of the Agency for Healthcare Research and Quality (AHRQ).

Results: Google Analytics data were acquired for January 1, 2017 to June 29, 2017. The MyHEART website received 1090 visits with 2130 page views; 18.99% (207/1090) were returning visitors. The majority (55.96%, 610/1090) approached the website through organic searches, 34.95% (381/1090) accessed the MyHEART website directly, and 5.96% (65/1090) approached through referrals from other sites. There was a spike in site visits around times of increased efforts to disseminate the website.

Conclusions: The successfully implemented MyHEART website and toolkit reflect collaborative input from community and healthcare stakeholders to provide evidence-based, portable hypertension education to a hard-to-reach population. The MyHEART website and toolkit can support healthcare providers' education and counseling with young adults and organizations' hypertension population health goals.

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KEYWORDS

hypertension; young adults; World Wide Web; quality improvement; patient engagement

Introduction

Prevalence of Hypertension among Young Adults

Uncontrolled hypertension among young adults (18 to 39 year-olds) [1] is an enormous public health burden [2,3]. In the United States, over 10 million 18 to 39 year-olds (1 in 5 men; 1 in 6 women) have hypertension [4-7], increasing their risk of premature heart failure, stroke, and chronic kidney disease [4,8-11]. Young adults with hypertension have a high lifetime risk for cardiovascular disease due to the longer exposure to high blood pressures and ongoing risk of organ damage [11-17]. Hypertension control reduces morbidity, mortality, and future healthcare costs [18-22]. Yet, only 40% of young adults with hypertension in the United States have achieved blood pressure control (defined as a blood pressure less than 140/90 mmHg) [23-27]. Our prior research demonstrated that within 1 year of developing hypertension, almost half of young adults do not receive guideline recommended lifestyle counseling [28]. Young adults are also less likely to receive a hypertension diagnosis and, if necessary, medication initiation compared to middle-aged and older adults [29,30].

Hypertension Control Barriers among Young Adults

To further understand barriers to young adults achieving hypertension control, we engaged racially and ethnically diverse young adults in 6 focus groups and conducted one-on-one interviews with primary care providers [31,32]. Two focus groups were conducted at each site: 1 academic, 1 urban, and 1 rural healthcare system [31,32]. The young adult respondents identified hypertension education topics that were not commonly addressed in current educational materials [32]. Young adult respondents shared their preferred social media channels and requested Web-based education to provide flexible access to hypertension information "when they wanted it" [32]. Primary care providers shared similar views of lacking hypertension materials and/or the time for extended education for young adults [31]. Both groups also highlighted other common barriers (eg, transportation, work-life balance, financial limitations) to hypertension care delivery. The combined qualitative and quantitative data highlighted the need to provide a website tailored to young adults with hypertension.

Prior studies demonstrated that when patients with hypertension receive health education targeted to their needs, their self-management of hypertension improves (eg, behavior changes, home blood pressure monitoring) [33]. In addition, patient education should provide a sense of personal medical empowerment to promote, initiate, and maintain health behavior changes [32,34]. Finally, hypertension education can serve as a bridge between clinic visits. To address an unmet need in the delivery of hypertension care for young adults, we developed the My Hypertension Education and Reaching Target (MyHEART) program, a young adult hypertension education program.

Rationale for Development of the MyHEART Website

The aims of MyHEART are to (1) decrease barriers to young adult hypertension care delivery; and (2) improve hypertension control in this hard to reach population. It is known that website education alone is insufficient for long-term health behavior change; however, it can be effective as an additional component to ongoing hypertension control initiatives [35]. Therefore, the goals of the MyHEART website [36] are to (1) be a portable resource for young adults' questions and challenges with managing blood pressure; and (2) supplement the hypertension clinical care and education of healthcare teams and organizations. The aims of this proposal were to (1) develop the architectural structure of the MyHEART website through community engagement partnerships; and (2) launch and disseminate the MyHEART website to clinicians, healthcare systems, and community organizations committed to hypertension control.

Methods

Ethics

Prior studies [31,32,37] that informed the MyHEART website development were approved by the University of Wisconsin-Madison Health Sciences Institutional Review Board (IRB) and informed consent was obtained from patient and clinician stakeholders. Neither IRB approval nor written consent were needed to design or implement this website because the data that informed MyHEART development was already described in the original IRB submission for the prior studies.

MyHEART Website Development

Community Stakeholders

Our stakeholders consisted of 38 young adult patients with a mean age of 26.7 (SD 9.6) years old and were 34% (13/38) male, 45% (17/38) Black, and 42% (16/38) with 1 or more years of college [32]. In addition, there were 15 primary care clinicians [31] and 3 hypertension quality improvement teams across multiple healthcare systems. The Wisconsin Network for Research Support (WINRS) is a community and patient engagement resource based at the University of Wisconsin-Madison School of Nursing. WINRS developed the Community Advisors on Research Design and Strategies (CARDS), an innovative consultation service that engages lay community members. CARDS includes members from diverse backgrounds, including underrepresented communities and "hard to reach" populations. Members are trained to (1) review project materials (eg, websites, survey questions, mobile phone apps); and (2) provide unique feedback for research, education, and outreach. For our website development, 10 to 12 CARDS members were engaged monthly for 6 months, either in-person or by electronic communication, for feedback on content, architecture, and dissemination plans [38]. In addition, there were 2 90-minute meetings with the CARDS group to discuss updated MyHEART versions and pilot test the user-interface,

website usability, and technological options for accessing Web information (eg, mobile phone, tablet).

Website Architecture

We built the website in partnership with the University of Wisconsin Health Innovation Program (HIP) using the Drupal 7 Content Management Framework (TurnKey Linux). Based on stakeholder input, the MyHEART website has the following 3 main categories (Multimedia Appendix 1): (1) defining blood pressure and understanding high blood pressure; (2) information on initiating and maintaining behaviors to control blood pressure; and (3) relevant resources, such as exercise options, questions for clinicians, and recipes via website links to the American Heart Association (AHA), Centers for Disease Control (CDC), and National Institutes of Health (NIH). We also feature peer-reviewed publications on cardiovascular health in young adults from established scientific resources (eg, NIH, CDC, AHA) because young adult focus group informants requested to be kept up-to-date [32]. A Twitter feed (@MyHeartMyChoice) was included as another means of sharing important health topics with young adults. A discussion forum is being designed and will be added in the future as the MyHEART program staff expands to support the exchange of ideas.

Iterative Website Design Process

The website's architectural structure was cyclically evaluated by the lay advisory group (CARDS), information technology specialists, and clinical content experts (ie, physicians, nurses) using established categories: internal reliability, external security, content usefulness, navigation usability, and system interface attractiveness [39,40]. A sample of the detailed notes on MyHEART's architectural structure is in shown in Multimedia Appendix 2; CARDS lay advisory group full meeting notes are available upon written request to the corresponding author. The educational content for the website was formatted with a Flesch-Kincaid readability of the 6th grade or less [41]. Website edits continued over 12 months, with testing on desktop and mobile computer devices, until the final iteration was launched in January 2017.

Website Toolkit

A toolkit was developed for the MyHEART website to assist clinicians and healthcare systems with incorporating the website in clinical practice and community outreach. The toolkit provides customizable materials and Web and social media communication drafts to share the website with members of their organization (Multimedia Appendix 3).

Website Dissemination

The Dissemination Planning Tool of the Agency for Healthcare Research and Quality (AHRQ) [42] was used to outline and navigate the dissemination plan that was started in February 2017. The website and toolkit were first disseminated through HIPxChange [43] in association with the University of Wisconsin HIP. In late 2012, HIP launched HIPxChange to disseminate evidence-based programs, tools, and other materials for free to the public [44]. The goal of HIPxChange is to accelerate the translation of new and existing knowledge into clinical practice to improve healthcare delivery and health outcomes.

Additional dissemination avenues included clinician notifications, academic and healthcare marketing teams, university/campus health centers, research communities, and public community announcement boards (eg, grocery stores, coffee shops, etc). Regional dissemination efforts include the Wisconsin Collaborative for Healthcare Quality (WCHQ). This is a voluntary consortium of 37 Wisconsin healthcare organizations (physician groups, hospitals, health plans) that has led the nation in measuring and improving healthcare quality for multiple chronic conditions [45,46]. Social media streams (eg, Facebook, Twitter, health blogs) have been activated.

Results

Google Analytics data were acquired for January 1, 2017 to June 29, 2017. In this time, the MyHEART website received a total of 1090 visits, with an average of 1.95 pages/session (range 1 to 7 pages/session for 95% of users). The number of site visits were in line with our expectations during this implementation period. Among the site visitors, 81.01% (883/1090) were new visitors (Figure 1). The majority (55.96%, 610/1090) approached the website through organic searches, 34.95% (381/1090) accessed the MyHEART website directly, and 5.96% (65/1090) approached through referrals from other sites. Overall, 40 sessions (3.67%, 40/1090) were referred from social media; 23 (2.11%, 23/1090) from Twitter, and 17 (1.56%, 17/1090) from Facebook, with Facebook demonstrating a greater number of unique visitors (10) than Twitter (2 unique visitors).

Among new users, the bounce rate was 77%, while the bounce rate among returning users was 49%. Most users spent a short time on the site (0 to 10 seconds), but the time among the remaining users was approximately evenly distributed between 11 and 1800 seconds. The page with the largest number of views among new users was "What do the blood pressure numbers mean?" (eg, understanding blood pressure values). Interestingly, among new users who accessed that page, the majority (89.8%, 495/551 of page views) accessed the page by conducting an organic search; new users spent an average of 2 minutes and 32 seconds on this page. Across all viewers, the most viewed content was the "What do the blood pressure numbers mean?" (55.41%, 604/1090 views), followed by the MyHEART website home page (47.06%, 513/1090 views). The spike in website visits noted during February and May 2017 (Figure 2) likely reflects stages of the MyHEART website dissemination plan and viewers directly accessing the MyHEART website via academic center emails, newsletters, and media inquiries.

Figure 1. Percentage of new versus returning visitors to the MyHEART website from January 1, 2017 to June 29, 2017 (N=1090).

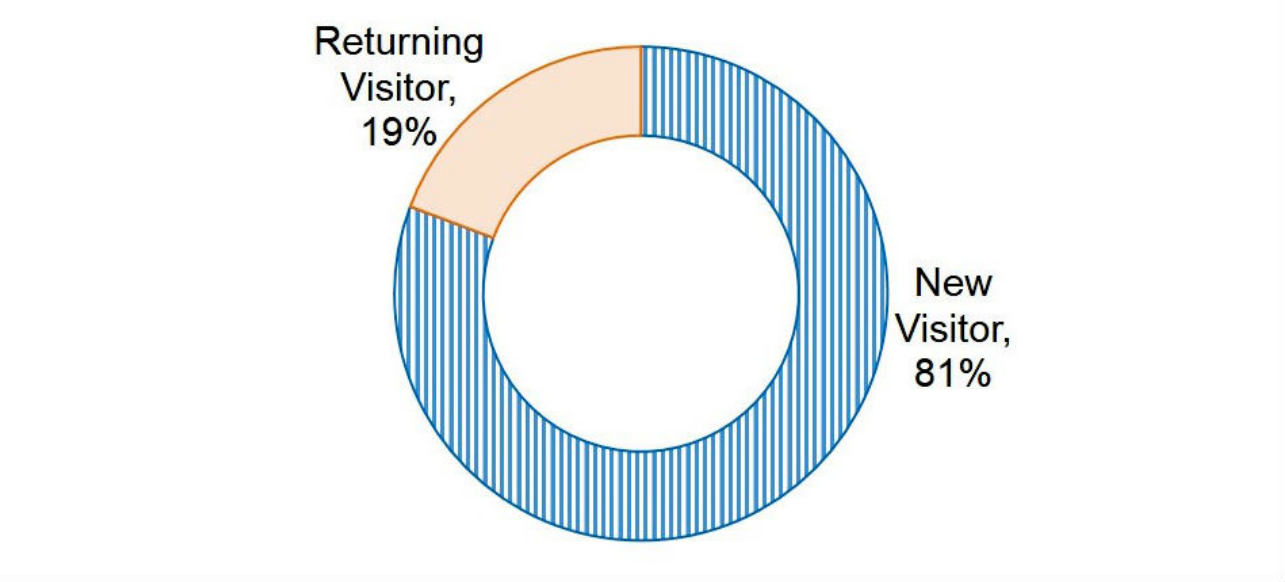
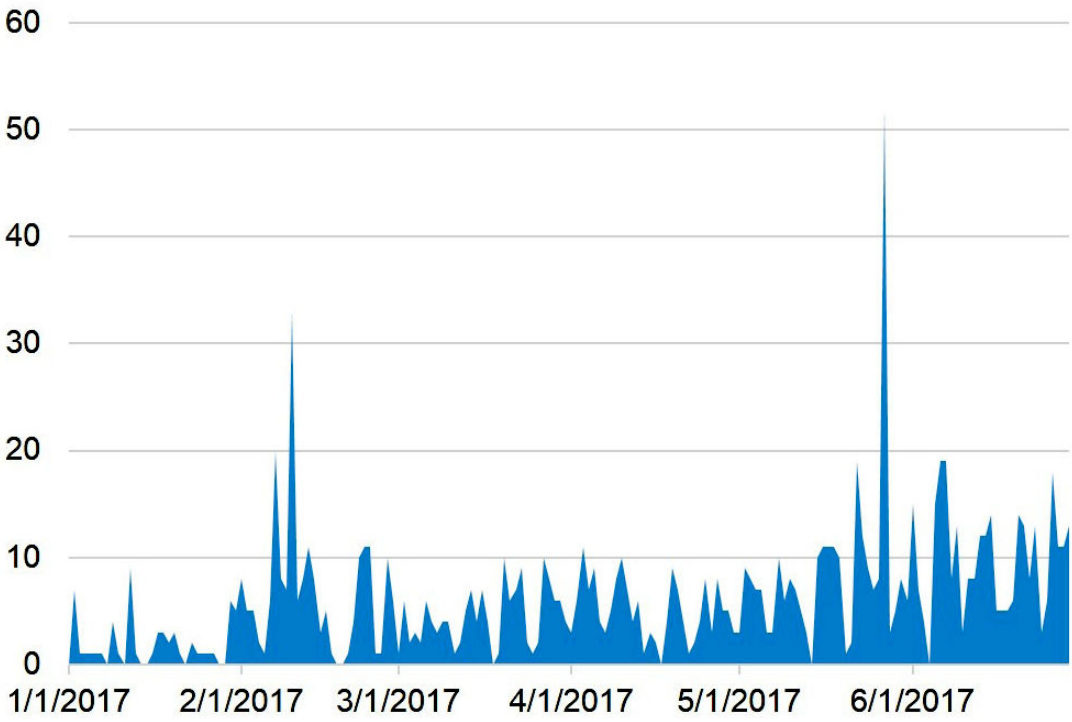


Figure 2. Number of visitors per day to the MyHEART website from January 1, 2017 to June 29, 2017.



Discussion

Principal Findings

The MyHEART website and corresponding toolkit were successfully developed with diverse young adult, community, and academic stakeholders. The website can provide young adults with evidence-based hypertension information to support their self-management goals. The corresponding toolkit can support clinicians' efforts to share knowledge about hypertension with young adults and offer counseling about behavior change. The authors successfully engaged clinical staff and their patients across healthcare systems and are actively working to engage young adults in the community (with limited healthcare access). The MyHEART website's accessibility on mobile platforms helps target the young adult population. However, the authors are learning how to increase the duration of engagement of young adults on the website. For example, an interactive functionality is in development with the goal of increasing the length of time young adults use the website and acquire hypertension information.

Limitations

We recognize that the website and toolkit were created in English, limiting access to young adults and clinicians who are not fluent in English. However, our team plans to make these

materials available in Spanish. The website also currently lacks interactivity, but we plan to add this in the near future. Finally, we did not conduct a comparative analysis with other technology or programs. We are continuing to expand our dissemination activities and will develop multidimensional interventions in the future.

Conclusions

In collaboration with young adults, health systems, and community stakeholders, the MyHEART young adult website is a portable resource to provide evidence-based information to a hard-to-reach population. The MyHEART website and toolkit provide resources for patients, clinicians, and healthcare organizations to improve hypertension control in young adults

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Authors' Contributions

HJ and JL conceptualized and designed the study. HJ, JL, CB, RW, LZ, RH, KS, and DL were responsible for the acquisition of data, analysis and interpretation of data, drafting the manuscript, revising the manuscript critically for important intellectual content, and final approval of the version to be submitted. The authors greatly appreciate the time and continued dedication of the CARDS lay advisory group who provided the foundation for the MyHEART website. We are also grateful for the staff and students at the University of Wisconsin HIP who provided assistance with proofreading the website.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Selected screenshots of the MyHEART website.
[PDF File (Adobe PDF File), 379KB - cardio_v1i2e5_app1.pdf]

Multimedia Appendix 2
Sample of detailed notes from CARDS Lay Advisory Group meeting on MyHEART's architectural structure.
[PDF File (Adobe PDF File), 218KB - cardio_v1i2e5_app2.pdf]

Multimedia Appendix 3
Examples of promotional materials for healthcare providers in the MyHEART toolkit.
[PDF File (Adobe PDF File), 97KB - cardio_v1i2e5_app3.pdf]

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Abbreviations

AHA: American Heart Association
AHRQ: Agency for Healthcare Research and Quality
CARDS: Community Advisors on Research Design and Strategies
CDC: Centers for Disease Control
HIP: Health Innovation Program
IRB: Institutional Review Board
MyHEART: My Hypertension Education and Reaching Target
NIH: National Institutes of Health
WCHQ: Wisconsin Collaborative for Healthcare Quality
WINRS: Wisconsin Network for Research Support

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Original Paper

Patients With Implantable Cardioverter Defibrillators on Social Media Report More Shock Anxiety Than Clinic Patients: Results From an Online Survey

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Abstract

Background: Coping with heart disease and the potential for implantable cardioverter defibrillator (ICD) shocks challenges the psychological adjustment of patients with ICDs. Social media use may be used to seek education and support from others.

Objective: The aim of this study was to examine the content of information sought online and whether a social media sample of patients with ICDs report more device-specific anxiety than clinic-based normative samples.

Methods: A total of 196 participants were recruited via social media messages and invited to complete an online survey.

Results: It was found that the information most often sought by online users (62.4%, 123/196) involved both emotional support (eg, gaining emotional support from other patients with ICDs) and technical information (52.6%, 103/196) (eg, dealing with magnetic interference). The online sample reported more shock anxiety than a typical clinical sample with mean values of 22.75 (SD 10.06) and 15.18 (SD 6.50), respectively (P<.001).

Conclusions: Collectively, these results suggest that patients with ICDs that are online are seeking emotional information and support, and that they report increased shock anxiety relative to typical clinic-based patients. Future research should examine how online information and clinical-based information form a composite understanding and adjustment for patients ICDs.

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KEYWORDS

health communication; social media; implantable cardioverter-defibrillator; cardiology patients; shock anxiety

Introduction

Background

The implantable cardioverter defibrillator (ICD) has demonstrated successful reduction of mortality in patients at risk for life threatening arrhythmias. Living with an ICD includes managing the stress of cardiac disease, accepting the ICD, and minimizing distress [1]. The unique aspect of living with an ICD is the possibility of experiencing a painful high-energy shock necessary to terminate a potentially life-threatening cardiac arrhythmia. Psychological distress is common, with approximately 20% of patients reporting anxiety and/or depression [2].

Risk and resilience factors for psychological distress have also been established. Individuals who are younger than age 50, women, and having experienced an ICD shock are known risk factors. Resilience factors include optimism, faith in their ICD, and confidence in their doctor [3]. Patients with ICDs may attempt to address their concerns via social media. Non-randomized, Internet-recruited patients can provide insight

and potentially help ICD providers to clarify issues in clinic that are currently primarily addressed by social media.

Social Media as a Health Communication Resource

Patients are increasingly using social media to share information and support with other patients and experts. These interactions may help individuals learn about what they should be expecting as well as ways to cope with their health issues [4]. Health issues explored include social support and advice [5], mental health concerns [4], diabetes [6], and public health [7]. Nearly 70% of Americans use social media and 68% of adults use Facebook [8]. A meta-analysis revealed the benefits of health communication via social media include increased interaction, shared and tailored information, increased access to health information, and peer, social, and emotional support [9]. Understanding how communicating about ICD via social media benefits patients with ICDs could prove valuable for disseminating information and meeting the needs of this unique population.

Objectives

The objectives of this study were (1) to examine what information is sought via social media by patients with ICDs; and (2) to determine whether a social media sample of patients with ICDs report more device-specific anxiety than clinic-based normative samples. This information is important for creating a greater understanding of what information is valuable to patients with ICDs and better understanding how anxiety influences their information seeking. Together, these could lead to improvements in the quality of life of all patients with ICDs by providing the information they value most, which may decrease their anxiety.

Methods

Participants

The non-randomized sample consisted of 196 patients with ICDs recruited through Facebook groups that were affiliated with heart disease and ICD topics. Facebook was chosen over other social media sites because patients with ICDs on this site engaged with one another on a more consistent basis and were more receptive to the survey. Researchers created a Facebook profile that identified the principal investigator and created posts with the details of the study including the following requirements for participation: individuals who currently had an ICD and who were at least 18 years of age. Participants were informed that if they completed the survey they would be eligible for a US $25 Amazon gift card. The recruitment period was June 2014 through January 2015. Participants were asked to complete standardized and validated questionnaires in an online survey. The study, funded by a university grant and approved by the Institutional Review Board (IRB), was made electronically available to participants after obtaining informed consent.

Two strategies prevented those without an ICD from participating in the survey. First, individuals were asked if they had an ICD. Those who answered “no” were immediately removed from the survey. Second, individuals were asked to indicate the brand of their ICD. If they did not know, they too were immediately removed.

Demographic Variables

Information on gender, age, and educational level was obtained from the survey. The amount of time since the implant of the ICD, how recently the patient had experienced ICD-administered shock, and the number of ICD shocks were also assessed in the survey.

Shock Anxiety

The Florida Shock Anxiety Scale (FSAS) contains 10 items that contribute to the subscales “triggers” and “consequences”. A total score is determined by summing the items. The FSAS is a reliable measure (alpha = .925). Respondents rate each item on a 5-point Likert scale ranging from 1 (not at all) to 5 (all the time). Higher scores indicate greater shock anxiety. The FSAS has been utilized as a shock anxiety measure internationally with studies in Australia [10] and Canada [11].

Social Media Use

Participants were asked to identify who they discussed the ICD with through social media. Participants selected from a list that included doctors, nurses and other healthcare providers, patients, friends, and “other.” A list of common concerns of patients with ICDs was provided along with the prompt:

> *What type of information or support about ICD have you looked for online or discussed on social media? Select all the reasons that apply*

Participants were also asked which sites they visited to discuss ICDs (ie, Facebook, Twitter, Pacemaker Club, YouTube, American Heart Association, and “other”).

Recent Shock

Participants were asked to indicate when they had received their last shock and the following groups were created: (1) Group 1, those whose most recent shock occurred less than 4 months ago; (2) Group 2, those whose most recent shock occurred more than 4 months ago; and (3) Group 3, those who had never experienced a shock from their ICD.

Statistical Methods

Categorical variables were compared between groups using the Pearson chi-square or Fisher test with frequencies and percentages reported. Continuous variables were compared between groups using the Student *t* test. All tests were 2-tailed with significance level of .05. Analyses were performed with SPSS version 20. When the Levene test for the assumption of homogeneity of variance was not met for this data, Welch statistics were used for calculating and reporting degrees of freedom.

Results

Demographics

The sample consisted of 196 patients with an ICD that completed the survey: 130 (66.3%, 130/196) were women and 66 (33.7%, 66/196) men. Participant age ranged from 18 to 70 with an average age of 45.61 (SD 12.54); 60.1% (113/188) were

under age 50. The amount of time since implant of the ICD were as follows: 18.4% (36/196) had the ICD for less than 1 year, 25.0% (49/196) for 1 to 2 years, 27.6% (54/196) for 3 to 5 years, 14.8% (29/196) for 6 to 10 years, and 14.3% (28/196) for more than 10 years. The sample was almost entirely White (91.3%, 179/196) with 85.2% (167/196) reporting at least some post-secondary education.

Implantable Cardioverter Defibrillator Concerns

A list of topics related to the ICD and the percentage of survey participants who indicated that they go online or use social media to discuss the topic is shown in Table 1.

Participants were asked to respond to the following and were supplied a list of 20 possible topics:

> *What type of information or support about ICD have you looked for online or discussed on social media? Select all the reasons that apply.*

The most common topics selected were social support and shock anxiety, with more than half of the sample, 62.8% (123/196) and 55.6% (109/196) selecting the items “gaining emotional support from others going through the same thing as me” and “anxiety about my ICD”, respectively, as reasons why they chose to use social media.

The gender distribution of incidence of shock is shown in Table 2. Almost half of the participants (49.0%, 96/196) had experienced at least 1 shock from their ICD, with 40.8% (53/130) of women and 65% (43/66) of men indicating that they had been shocked at least once.

Shock Anxiety Comparisons

Comparisons on shock anxiety between the online sample and the typical clinical sample [12] confirmed that the online ICD group reported higher shock anxiety (t_{189} = 10.36, P<.001) (Table 3). Analysis of variance (ANOVA) revealed that recent shock was also a significant factor in shock anxiety. A main effect on shock anxiety for those experiencing the most recent shock was found ($F_{2,186}$= 33.19, P<.001).

Table 1. Communicating about implantable cardioverter defibrillator topics through an online social media modality (N=196).

Topic	Participants, n (%)
Gaining emotional support from others going through the same thing as me	123 (62.8%)
Anxiety about my ICD[a]	109 (55.6%)
Information about magnetic interference	103 (52.6%)
Keeping up-to-date on ICD news	89 (45.1%)
Camaraderie with others	84 (42.9%)
Travel or vacation with ICD	82 (41.8%)
Fatigue	79 (40.3%)
Exertion while exercising	79 (40.3%)
Activity restrictions	74 (37.8%)
Fear of shocks	68 (34.7%)
Device recalls	68 (34.7%)
Expectations for the future	54 (27.6%)
Sports participation	46 (23.5%)
Appearance of ICD	46 (23.5%)
Pain	40 (20.4%)
Family matters	35 (17.9%)
Concerns about sexual activity with ICD	25 (12.8%)
Body image concerns	19 (9.7%)
ICD and pregnancy	17 (8.7%)
Other	15 (7.7%)

[a]ICD: implantable cardioverter defibrillator.

Table 2. Participant's most recent shock by gender (N=196).

Gender	Most recent shock, n (%)		
	Less than 4 months ago	More than 4 months ago	Never
Women (n=130)	12 (9.2%)	41 (31.5%)	77 (59.2%)
Men (n=66)	19 (28.8%)	24 (36.4%)	23 (34.8%)

Table 3. Summary of means, standard deviations, and standard errors for scores on the Florida Shock Anxiety Scale (FSAS).

Variable	n (%)	Mean (SD[a])	SE[b]
FSAS[c] total sample	190 (100%)	22.75 (10.06)	
FSAS clinic[d]	443	15.18 (6.50)	
FSAS male	61 (32.1%)		1.49
FSAS female	122 (64.2%)		0.78
FSAS age less than 50	109 (57.4%)		0.98
FSAS age greater than 50	74 (38.9%)		0.98

[a]SD: standard deviation.

[b]SE: standard error.

[c]FSAS: Florida Shock Anxiety Scale.

[d]Clinical results from Ford et al, 2012. All other FSAS scores reported reflect the current sample.

Shock history was further investigated related to 3 recent shock conditions: Group 1 (less than 4 months ago); Group 2 (more than 4 months ago); and Group 3 (never shocked). Bonferroni pairwise comparisons revealed significant differences between Group 1 compared to Group 2 with a mean difference of 13.07 (P<.001), and Group 1 compared to Group 3 with a mean difference of 14.79 (P<.001). The pairwise comparison between Group 2 and Group 3 was not significant.

Discussion

Principal Findings

This study revealed that the most common reasons to go online are to gain emotional support from others and to express anxiety to the community of patients with ICDs. Communicating about their ICD through social media allows patients to share their interests and concerns with others who are similarly interested in discussing the ICD, beyond existing face-to-face support groups and visits to a healthcare clinic. Benefits include offering and receiving practical advice, support, and meaningful information related to all aspects of living with the device [13]. Patients with ICDs can connect with others online immediately to anonymously obtain information about the ICD or to provide and/or receive social support.

Online Health Information

Along with the benefits accrued from social media interaction about ICD, there may be some drawbacks. Group norms that develop in online ICD groups may be beneficial or harmful for participants and should be studied. Information shared online may be inaccurate or biased [9]. Misinformation can quickly spread through social media, with the potential to raise anxiety in patients with ICDs. Future research should explore the best ways to monitor the accuracy, validity, and reliability of the ICD information shared online through social media. Presumably the effects of misinformation could be mitigated by seeking multiple sources of information and through discussions with their provider [14]. Other areas of interest relate to time since implantation as patients with an ICD for longer than 1 year have had time to broaden their online engagement regarding their ICD. During the first year after implant of the device, patients have frequent meetings with healthcare providers to ensure the device is working properly and to assuage patient concerns. In subsequent years, patients are increasingly independent, relying on remote monitoring and less frequent visits with healthcare providers. It is reasonable to assume patients would increase their reliance on social media for support and information after the first year.

Online Shock Anxiety

The current study indicated that patients with ICDs who use social media to communicate about their ICD reported significantly greater shock anxiety than the general population of patients with ICDs. Highly anxious patients may be more likely to overestimate the personal risk of adverse events from generic information or probabilities without information specific to their condition. Nonetheless, online engagement may be the most accessed information for these patients because it is always available. These results suggest that clinicians may want to increase their online information offerings to include both information and a “relevance test” of information for patients to contact clinicians about specific probable risks versus possible risks and anxieties about their ICD. Clinicians should also inquire further about what information patients preferentially used Internet sources to obtain instead of in-clinic conversations. Ideally, multiple, reliable sources could be accessed as needed to learn about technical issues and more personal issues such as emotional functioning or supportive conversations.

Limitations

The current study has some limitations to consider while interpreting its results. Because the participants were recruited through Facebook groups, they had online information-seeking skills and experience communicating through the Internet, possibly influencing their choices regarding the sharing of ICD information and thoughts online. Despite efforts to recruit participants from a variety of social media sites such as YouTube, Twitter, and Instagram, only Facebook groups yielded individuals willing to complete the survey, which may limit the results to those who are active participants in social media groups and chose to participate in the survey. Future research should expand the number and variety of participants by recruiting from additional social media sites to assess whether the results are generalizable across the social media landscape. Whether the patients with ICDs who participated in the study

are representative of the population of patients with ICDs who use social media to communicate about their device cannot be determined. The conclusions in this study show only associations, not causation. In addition, although researchers attempted to screen out individuals who did not have an ICD, it is possible that an individual could provide false answers to gain access to the proffered incentive. Answers to the survey were self-reported, relying on the integrity of the participants to respond to survey questions honestly and accurately. Further, the current study did not control for previous history of medical and/or psychological difficulties that may have impacted the results and reduced the general application of results.

Conclusion

This study examined the content of information sought online and whether a social media sample of patients with ICDs report more device-specific anxiety than clinic-based normative samples. Patients with ICDs most often sought information focused on both emotional support (62.8%, 123/196) and technical information (52.6% 103/196). This study of patients with ICDs recruited online indicated higher levels of shock anxiety than a typical clinical sample. Higher shock anxiety was associated with recent shock. This study demonstrated that patients with ICDs seek up-to-date information and emotional support on social media, and younger patients are increasingly likely to use social media to discuss their ICD concerns. While patients with ICDs have access to face-to-face healthcare professionals in clinics and support groups, there is substantial interest among patients to share information and support through social media. Delivery of high quality, appropriate, cost effective online support for patients with ICDs offers the potential for better psychological adjustment to the realities of life with an ICD.

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Conflicts of Interest

Dr Sears has no competing financial interests, but would like to disclose honoraria/consulting fees (Medtronic, Boston Scientific, Spectranetics, St Jude Medical, Zoll Medical) and research grants (Medtronic). All funds are directed to East Carolina University.

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Abbreviations

ICD: implantable cardioverter defibrillator
FSAS: Florida Shock Anxiety Scale

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