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User-Centered Adaptation of an Existing Heart Failure Telemonitoring Program to Ensure Sustainability and Scalability: Qualitative Study

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Abstract

Background: Telemonitoring interventions for the management of heart failure have seen limited adoption in Canadian health systems, but isolated examples of telemonitoring programs do exist. An example of such a program was launched in a specialty heart failure clinic in Toronto, Canada, and a recent implementation evaluation concluded that reducing the cost of delivering the program is necessary to ensure its sustainability and scalability.

Objective: The objectives of this study were to (1) understand which components of the telemonitoring program could be modified to reduce costs and adapted to other contexts while maintaining program fidelity and (2) describe the changes made to the telemonitoring program to enable its sustainability within the initial implementation site and scalability to other health organizations.

Methods: Semistructured interviews probed the experiences of patients (n=23) and clinicians (n=8) involved in the telemonitoring program to identify opportunities for cost reduction and resource optimization. Ideas for adapting the program were informed by the interview results and prioritized based on (1) potential impact for sustainability and scalability, (2) feasibility, and (3) perceived risks to negatively impacting the program's ability to yield desired health outcomes.

Results: A total of 5 themes representing opportunities for cost reduction were discussed, including (1) Bring Your Own Device (BYOD), (2) technical support, (3) clinician role, (4) duration of enrollment, and (5) intensity of monitoring. The hardware used for the telemonitoring system and the modalities of providing technical support were found to be highly adaptable, which supported the decision to implement a BYOD model, whereby patients used their own smartphone, weight scale, and blood pressure cuff. Changes also included the development of a website aimed at reducing the burden on a technical support telehealth analyst. In addition, the interviews suggested that although it is important to have a clinician who is part of a patient's circle of care monitoring telemonitoring alerts, the skill level and experience were moderately adaptable. Thus, a registered nurse was determined to be more cost-effective and was hired to replace the existing nurse practitioners in the frontline management of telemonitoring alerts and take over the technical support role from a telehealth analyst.

Conclusions: This study provides a user-centered example of how necessary cost-reduction actions can be taken to ensure the sustainability and scalability of telemonitoring programs. In addition, the findings offer insights into what components of a telemonitoring program can be safely adapted to ensure its integration in various clinical settings.

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KEYWORDS

telemonitoring; mHealth; diffusion of innovation; heart failure

Introduction

Background

Meta-analyses have shown that telemonitoring for patients with heart failure (HF) can improve patients' health outcomes and reduce health care utilization [1-4]. However, when one considers that HF directly impacts 1 million Canadians [5] and that in 2013 only 5000 patients across all disease types were enrolled in a telemonitoring program [6], it is clear that the diffusion of telemonitoring is lagging. This can partly be explained by higher than anticipated costs of implementing these programs and the lack of user input in the conception of such interventions [7]. In addition, although meta-analyses generally conclude positive outcomes, inconsistencies at the individual study level, particularly with respect to the economic impact, are difficult for stakeholders to ignore [8]. We have proposed in a previous work that this heterogeneity is caused by variances in the characteristics of (1) patients enrolled, (2) the intervention (eg, telemonitoring system used, clinician involvement, and supporting health services), and (3) fidelity with which the intervention is administered over time [8].

Adaptability is Needed for Scalability

Although differences in the way telemonitoring interventions are delivered can lead to contradictory evidence, understanding these differences and how they might influence outcomes could hold one of the keys to scalability. This is because theories of diffusion of innovation have suggested that to be sustained and scaled, interventions must be able to adapt if they are to be embedded within local conditions [9,10]. This notion of adaptability is a prominent theme in studies of delivering digital health interventions at scale, which reinforce the view that a *one-size-fits-all* approach does not work [11]. The challenge is determining how to undertake necessary adaptations without compromising program fidelity [12].

A useful analogy used by theorists to discuss the notion of adaptability is the idea that health interventions have a *hard core* and a *soft periphery* [13-15]. The hard core represents the essence of an intervention, in other words, the central mechanism(s) for producing desired health outcomes in the intervention's theory of change [12]. When considering telemonitoring, the hard core can be conceptualized as an intervention that leverages technology to enable the collection and transmission of patient biometric data to be viewed and acted upon by a clinician at a distant location [1].

In contrast, the adaptable soft periphery represents the different ways this intervention can be delivered in practice. Adaptability of this soft periphery to local contexts allows innovations to spread without negatively impacting the intervention's ability to yield desirable outcomes [15], thus maintaining intervention fidelity. As it relates to telemonitoring, elements of the soft periphery may include differences in the hardware used, intensity of clinician monitoring, duration of a telemonitoring program, and format of training or technical support services. However, many of these program components are essential for a telemonitoring program to function. Therefore, delineating the line between the hard core and soft periphery of complex interventions such as telemonitoring programs is particularly difficult. Despite this challenge, implementation and scaling require a clear definition of a program's core components to ensure that fidelity is maintained when adaptations are undertaken to ensure implementation and scaling success [10,12].

Sustaining and Scaling a Smartphone-Based Heart Failure Telemonitoring Program

In fall 2016, an HF telemonitoring program was made available to patients of a heart function clinic at an urban hospital in Toronto, Canada. A previous study concluded the initial implementation to be a success based on the degree of integration within the clinic, number of patients enrolled, and fidelity of program delivery as part of the standard of care [16]. However, this study also identified important barriers related to the cost of the equipment and supporting human resources, which could hinder the sustainability and scalability of this program [16]. The objectives of this paper were to (1) understand which components of the telemonitoring program could be modified to reduce costs and adapted to other local contexts while maintaining program fidelity and (2) describe the changes made to the program to enable its sustainability within the initial implementation site and scalability to other health organizations.

Methods

Study Design

This qualitative study was designed to elicit insights from end users to better understand the hard core and soft periphery of an existing telemonitoring program. These insights would inform adaptations required to reduce costs of delivering the intervention. Semistructured interviews were conducted within the context of a larger quality improvement program evaluation [17], which was approved by the University Health Network (UHN) Research Ethics Board (16-5789).

The Existing Heart Failure Telemonitoring Program

Integration Within the Standard of Care

The *Medly* program was implemented as part of the standard of care at the UHN Heart Function Clinic in Toronto, which

serves patients with complex and advanced HF. Other services currently embedded within the clinic include in-depth teaching from clinic staff about the chronic nature of HF, necessary lifestyle changes, and how to manage complex medication schedules. Typically, relatively stable patients are seen for regular follow-up visits every 6 months, with more acute patients seen more frequently as required. It is also not uncommon for patients to consult with clinic staff over the phone or by email in between visits. The *Medly* program is intended to enhance these existing health services, not replace them.

The Medly Telemonitoring System and Services

Central to the *Medly* program is an algorithm-based smartphone app, which patients use to record daily weight, blood pressure, heart rate, and symptoms as soon as they wake up. If there are signs of deterioration in a patient's health, the *Medly* algorithm triggers a self-care message displayed to the patient in the *Medly* app. In addition, an alert is sent to both a nurse practitioner (NP; via a secure Web-based clinical dashboard) and the most responsible physician (MRP) via automated emails (Figure 1). The MRP is the physician who has overall responsibility for directing the medical care of a patient; in the context of the *Medly* program, this refers to the staff cardiologist responsible for the longitudinal care of patients in the Heart Function clinic. Typically, the NPs are responsible for acting on the alerts during weekdays, with the MRP taking over responsibility for more critical alerts and for responding to all alerts during off hours (evenings and weekends). An earlier version of this intervention was evaluated in a randomized controlled trial of 100 patients that demonstrated improved patient self-care and quality of life compared with a control group [18].

The decision to enroll patients is based on clinicians' judgment in collaboration with patients. To decide whether someone would be a good candidate, clinicians consider disease severity (usually New York Heart Association [NYHA] classification class 2 or 3), need for self-care support, and a perception that they can adhere to taking daily measurements and be engaged enough to follow self-care instructions provided by the telemonitoring system or the care team. Similarly, the decision to end participation in the *Medly* program is determined jointly between the patient and clinicians. Unlike many other telemonitoring interventions, there is currently no specified end date; patients remain in the program for as long as they are perceived to be benefiting.

Figure 1. Existing roles and information flows in the *Medly* program.

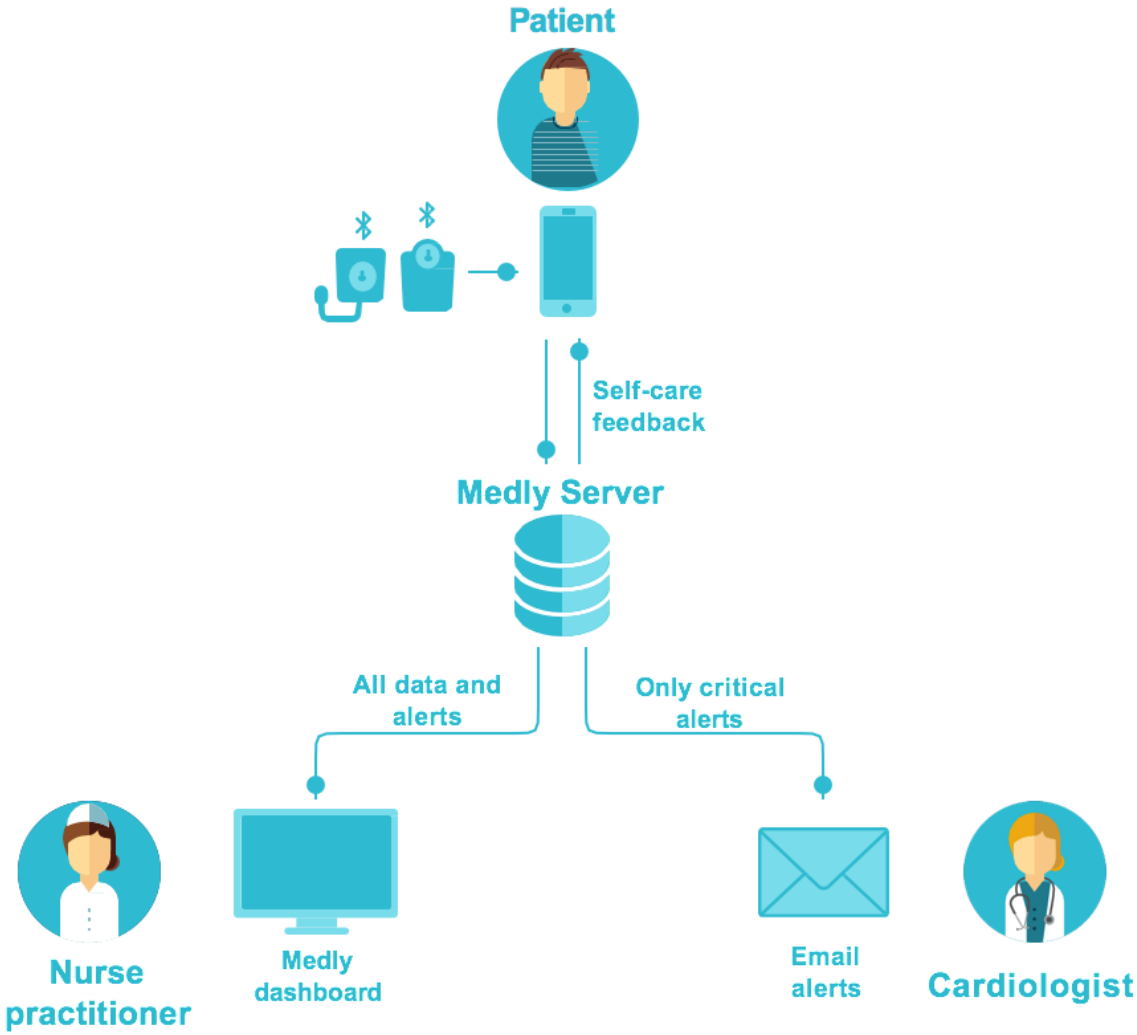

Table 1. Opportunities for program adaptation probed in the user interviewers.

Program component	Rationale
Peripheral devices	To understand if providing all patients with standardized Bluetooth-enabled peripheral devices free of charge is an essential component of a telemonitoring program. A *bring your own device* (BYOD) model, whereby patients use existing equipment (smartphone, blood pressure cuff, and weight scale), would drastically reduce costs of delivering the program.
Technical support services	One-on-one technical support is resource intensive. Exploring alternative modalities of offering this service could lower direct and opportunity costs by decreasing the time taken to perform these tasks.
Clinician role	Knowing the minimal clinician qualifications for monitoring alerts could save costs because of differences in salary, reimbursement models, and scopes of practice across professions.
Duration of patient enrollment and intensity of monitoring (business hours vs 24/7)	The literature neither provides consistent answers regarding the optimal duration of enrollment nor the intensity of monitoring in a telemonitoring service [8]. Understanding the degree to which these program components can be adapted while maintaining fidelity can produce cost savings through the optimization of resources and inform scaling strategies for telemonitoring programs.

The program was launched by providing patients with a *Medly* kit, which includes a smartphone installed with the *Medly* app, a Bluetooth-enabled weight scale, and a blood pressure cuff, which allows for automatic data transfer from these devices to the *Medly* app. A telehealth analyst (THA) role was created within UHN's telehealth department to provide technical support by telephone, email, or in person to both patients and clinician user groups. In addition, the THA role included the management of inventory and onsite face-to-face training for each new user. Further details of the program have been published elsewhere [16,17].

Interview Guide Development

Separate interview guides were developed for patients and clinicians to inform possible strategies for lowering costs and improving program efficiency by gaining a better understanding of the program's soft periphery. Specifically, participants were asked to comment on the topics presented in Table 1. In their responses, participants were encouraged to consider HF telemonitoring in general, and not just the *Medly* program. The *Medly* software (with embedded rules-based algorithm) was developed around the program's theory of change [19]. As such, it is considered part of the program's hard core; thus, no probes related to this component were included.

Recruitment

Patients (n=23) were identified through purposeful sampling based on age, gender, and time since enrollment in the *Medly* program to ensure a variety of perspectives. This included patients who were interviewed immediately after enrollment and, thus, had no prior experience being monitored in the program. Interviews with patients were conducted until theme saturation was reached (no new themes or perspectives were found in the data) [20]. This was achieved by setting an a priori target of 20 patient interviews. Three additional interviews were conducted, which yielded no new findings, thus confirming theme saturation. All clinicians actively monitoring patients using the *Medly* system at the time of the interviews (n=4) were invited to participate. In addition, 4 clinicians within the UHN Heart Function Clinic who had not yet begun using the system were also interviewed to obtain the views of nonusers. Written informed consent was obtained from all participants.

Interview Procedures and Analysis

Patients had the option of being interviewed in a private room at the UHN Heart Function Clinic during one of their regularly scheduled visits or over the phone. Clinicians were interviewed in their private offices. Interviews lasted 15 to 60 min and were recorded and transcribed verbatim. Transcripts were analyzed using conventional content analysis [21]; PW and KG each independently coded the transcripts and then met to discuss the results and discrepancies with themes. Once a finalized coding scheme was agreed upon, it was used to code the transcripts before a final analysis of themes. NVivo version 11 (QSR International, Doncaster, Victoria, Australia) was used to organize the data analysis.

Adapting the Telemonitoring Service

On the basis of the qualitative findings, PW and KG interpreted the degree to which each of the *Medly* program components explored in the interviews could be adapted without impacting program fidelity. Ideas for redesign were discussed during biweekly operations meetings and prioritized for implementation according to their (1) potential to impact sustainability and scalability through cost reductions and optimization of clinic resources, (2) feasibility of implementing the change, and (3) perceived risks of negatively influencing program fidelity (and ultimately effectiveness).

Results

Demographics

The demographic characteristics for the patients interviewed were representative of the patients enrolled in the *Medly* program. The average age was 60 years (SD 15) and 74% were male (17/23); see additional demographic characteristics and clinical variables (*NYHA* and left ventricular ejection fraction) in Table 2.

Table 2. Characteristics of patient interview participants.

Characteristic	Statistics
Age (years), mean (SD)	60 (15)
Sex, n (%)	
Male	17 (74)
Female	6 (26)
Ethnicity, n (%)	
White	14 (67)
Other	7 (33)
Place of birth, n (%)	
Canada	12 (57)
Other	9 (43)
Highest education achieved, n (%)	
Less than high school	1 (5)
High school	6 (29)
College or university	14 (67)
Rurality, n (%)	
Urban	8 (38)
Suburban	9 (43)
Rural	4 (19)
Income in Can $, n (%)	
<$15,000	3 (14)
$15,000-$49,999	8 (38)
>$50,000	6 (29)
Preferred not to answer	4 (19)
Supplementary health insurance, n (%)	
Yes	14 (70)
No	6 (30)
New York Heart Association classification, n (%)	
Class 2	12 (52)
Class 3	11 (48)
Left ventricular ejection fraction, mean (SD)	33 (13)

At the time of the interviews, 13% (3/23) of patients had been enrolled for 12 months; 48% (11/23) had been enrolled for 6 months; and 9% (2/23) had been enrolled for 1 month. In addition, 22% (5/23) were interviewed immediately after receiving training on their first day and, thus, had no prior experience being monitored in the *Medly* program. Of the 8 clinicians who participated, 2 NPs and 2 cardiologists had 9 to 12 months of experience monitoring patients with the *Medly* system. The remaining 4 cardiologists had no first-hand experience monitoring patients in the *Medly* program.

Interview Findings

The following is a discussion of participants' perceptions of opportunities for adapting existing program components aimed at reducing costs and optimizing clinic resources. Themes included were as follows: (1) Bring Your Own Device (BYOD), (2) technical support, (3) clinician role, (4) duration of patient enrollment, and (5) intensity of monitoring.

Bring Your Own Device

When the *Medly* program was launched, the intent was to shift to a BYOD model; however, at the time of the interviews, only minimal plans had been made to operationalize this change. The interviews highlight that clinicians were generally supportive of patients using their own equipment as it was necessary to ensure the sustainability of the program:

> *I think (a BYOD model) is excellent. In fact, I've had patients ask me about it...I think, for sure that would be helpful and certainly, more cost effective because*

> *we obviously can't give kits to everybody.* [Clinician 3]

Some concerns were raised about the questionable quality of patients' current equipment and the fact that, in the absence of Bluetooth data transfer, patients may accidentally manually enter values incorrectly. The possibility of patients purposefully entering inaccurate information was raised by 4 clinicians, but it was ultimately believed that mutual trust between parties is a prerequisite for any telemonitoring program to be effective:

> *I guess the only thing you'd have to really make sure of is that they typed things in properly. People make typos, but I guess there would have to be something factored in for a double-check...I don't believe that people are going to be lying about their numbers. If I thought people were going to lie right, left, and centre, then no, that would be ridiculous and I wouldn't want to participate in that. But I'd like to believe that if you're going to commit enough to take the time to take those readings and enter them every day, then I think you're doing it correctly.* [Clinician 3]

Although clinicians believed a BYOD model is required for the financial sustainability of the program, they believed some kits need to be available to ensure equitable access to the program. The general opinion was that *Medly* kits should be available for distribution on a case-by-case basis and could be informed by the patients' socioeconomic status, degree of cognitive impairment, and level of dexterity:

> *I think there's still a role for a hybrid kind of model where some people are provided with (the full Medly kit) and some people are provided with the less expensive intervention. You pick your battles and you'd be extremely cautious as to giving a BYOD to someone who has dexterity problems for instance.* [Clinician 6]

Most patients who received a full *Medly* kit as part of the program said that they would prefer downloading the *Medly* app to their personal smartphone. Common reasons include the inconvenience of being responsible for multiple phones, unfamiliarity with the smartphone provided, and feeling that their health data could be more transportable if it were on their personal device:

> *I just wish I had more control over it through my [personal] phone because the[n]...I could pull out all those reports from Medly myself and give it to a doctor, a walk-in, anywhere...I was given a phone that I was not familiar with...so it took me awhile to learn it and to get familiarized with it.* [HFpro064]

One patient who did not own a smartphone said they would prefer if the *Medly* app was available on a tablet:

> *The only reason why I haven't bothered getting an iPhone is I have an iPad...I like my iPad because the screen is nice and big...It was never important to me to have a phone that has all the bells and whistles.* [HFpro159]

A minority of patients interviewed said they preferred having the separate *Medly* phone because they like to keep all the equipment together. Although a separate phone was their preference, all patients said they would use their own device if that was the only option. Many patients understood the economic implications and felt it was reasonable:

> *I think that it makes it so much easier to have [the phone, weight scale, and blood pressure cuff] all together...I know it might be more cost-effective but it is so much easier on your mental being that you go in, you do what you have to do..[But] you do what you have to do.* [HFpro052]

A clear majority of patients preferred the convenience of Bluetooth data transfer but also said they would manually enter biometric data if their existing peripheral devices were not Bluetooth-enabled:

> *The bonus of this whole system is the Bluetooth...Typing in numbers, you [would] get tired of it...For me if I'm looking at my own health, it wouldn't bother me a bit but I'm different from someone else.* [HFpro089]

> *I like the fact that [the data transfer] is done for you. If I had no other choice, then you have no other choice.* [HFpro154]

Approximately half of the patient participants said they would purchase Bluetooth devices out-of-pocket, but some participants perceived this option as being unfair, echoing clinician concerns of accessibility:

> *I might [purchase the equipment]...[but] I'm not sure it's really fair to ask people to do that because you'd automatically filter out a lot people who either couldn't claim it on insurance or weren't going to do that...(the) system would all go wrong; it would just be upper middle-class people.* [HFpro061]

Technical Support

Clinicians, not having had direct experience with training and giving technical assistance to patients, did not have strong feelings regarding the format of technical support. However, 1 clinician stated there is an opportunity to minimize resources required for onboarding a patient:

> *It would be nice as much as possible to automate aspects of the onboarding...because I think actually paying somebody to be there to onboard people will be difficult to scale.* [Clinician 1]

Another clinician said that although the format of training needs to be appropriate, it is also important that the patient can start with the program immediately after the decision is made as opposed to scheduling training on a future date:

> *When you go in as a clinician and you have a conversation with the patient about a plan of care and the role of [telemonitoring], what it can offer and why it's important. You [need] an immediate..."Okay here's your system, you've been immediately trained, you've been setup," versus them going home, 2-3*

> *weeks going by [with the patient thinking] "Oh maybe it's not that important.*" [Clinician 2]

All patients described a positive experience with the face-to-face onboarding, but when asked if it was essential, many reflected that it might not be because the system was intuitive to use. Even those who were not tech savvy said they could figure it out at home by themselves or with the help of a family member, especially if they could follow along with a video:

> *I think the face-to-face was good because I watched [the THA] as she was putting the stuff in and I'm a visual learner...If I see it, it makes perfect sense...I tell people all the time, if you're stuck on something there's a video on YouTube of everything...I mean, it was nice having the face-to-face but that's not always an option.* [HFpro159]

Although most patients had positive things to say about calling the technical support services, others hesitated before seeking help for fear of being a burden and confusion about who to call:

> *Well [I didn't contact technical support because] I just don't want to bother anybody.* [HFpro064_6m]

> *It wasn't Bluetoothed properly [and] I didn't really know who to call. I probably had [the] number, but that was kind of a little bit bothersome.* [HFpro106_6m]

Clinician Role

Clinicians believed that the scope of practice of a registered nurse (RN) or NP is well suited for triaging and addressing many telemonitoring alerts. All clinicians agreed that an MRP with HF experience needs to be involved, particularly to deal with the more serious alerts:

> *I think that the first line of defense is totally appropriate to be nursing with some training in HF because Medly] is a rules-based system and therefore critical alerts should escalate to the physician. The non-critical alerts I absolutely believe that the first line of defense could be a nurse, nurse practitioner, physician assistant, all would be appropriate.* [Clinician 1]

> *It's ultimately a great role for nurse practitioners to champion because you need to have that person that can assess and make a clinical decision about changing a med[ication] or bringing someone in urgently to be seen in the clinic.* [Clinician 2]

Regardless of the type of professional involved, most respondents believed that telemonitoring programs would be most effective if the clinician receiving and responding to alerts was part of the patient's care team as opposed to the alerts being sent to a third-party telehealth clinician:

> *I think one of the issues with Medly...is you still need to have the most responsible person for the Medly involved in the actual patient's clinical care in some way.* [Clinician 2]

Patients generally agreed with this sentiment, expressing that they prefer the person receiving telemonitoring alerts to have the ability to act immediately. One patient made this point by contrasting the *Medly* program with their previous experience with another telemonitoring program:

> *I accepted [to be enrolled because they] said [my health information] would go straight to [UHN]...I think [with my previous telemonitoring system] they sent it to [various people] and eventually [my doctor] would see it. But he might be 4th or 5th down the line.* [HFpro159]

Duration of Patient Enrollment

Clinicians felt that patients could eventually be removed from a telemonitoring program if they were no longer actively benefitting (ie, had learned how to self-care or their condition had stabilized). However, a generalizable duration of enrollment could not be established:

> *Some [patients] just might like the comfort of knowing that [they]'re tied into a clinical team that's still there if you need help. But I think you have to look at it from your larger team because you can't just have endless people enrolled in the program, you probably will have to have a maximum at some [point]...I think if someone's been really stable for 6 months, they haven't had a lot of alerts, they are very confident as to what their target weight is, what they need to do in terms of lifestyle modifications and symptoms to watch for, then they've learned what they needed to learn in that 6 months and they don't require [the program].* [Clinician 2]

> *I think there may be an optimal time to improve self-care...there may be a curve and the curve plateaus and there may not be any further incremental benefit to self-care other than knowing that there is this rules-based system keeping an eye on them right. So it may be that you optimize self-care within 3 months...but patients [might] want to stay on it. And again, if you can really demonstrate value I don't have a problem with that.* [Clinician 1]

Many patients spoke of HF as being a lifelong condition and that they would like to stay in the program for as long as possible or until something came up that made the program unnecessary, such as undergoing a heart transplant:

> *I think for me [HF is] a lifestyle thing now. I think I'd be a fool not to use [Medly], I guess that sums it up. I was so sick and dead that I take my recovery very seriously...I think I'd be a fool not to take advantage of it.* [HFpro107]

> *I've got a lifelong condition so I don't really see an end time, unless I end up going for a heart transplant, which I'm not going to hopefully have to do anytime soon. So yeah, I think [my participation] will be ongoing.* [HFpro019]

Intensity of Monitoring

Clinicians recognized that asking clinicians to be available at all times to receive and respond to telemonitoring alerts is not scalable. However, they also strongly felt that these interventions

are most effective if there is someone monitoring alerts 7 days per week:

> *It's not really fair for a single person to be on-call 24/7. You have to take that into consideration in terms of physician burnout and all those things. There should be a mechanism to deal with that, whether it goes to the physician on-call or something like that. But I do think that in order for this to be effective, a 24/7 tool would be more appropriate than a business hours tool because it's not like people get sick only during business hours.* [Clinician 6]

Although participating clinicians said they would strive to have alerts monitored 7 days per week, their responses also highlighted that the requirements for intensity of monitoring are dependent on the telemonitoring system itself. For example, many clinicians highlighted that the rules-based algorithm in the *Medly* system provides patients with clinically validated messages, allowing for a form of 24/7 feedback even if a clinician is not always available:

> *I may be camping somewhere where I am not accessible. But I think the whole thing of the Medly system is it doesn't rely on me [seeing] the alerts, the patients are instructed to do things [by the algorithm]. We have set up a plan and they have to act accordingly. They don't have to wait for me to respond to [follow the instructions].* [Clinician 8]

Patients both with and without experience in the *Medly* program felt that someone should be available to respond to alerts 7 days per week but that this may also be contingent on the disease severity of the patients enrolled in the program:

> *If somebody weren't that sick and they just had a bit of a heart issue, I don't know if they would like this big brother, big sisterly thing where the [clinicians] call first thing in the morning on Sunday...I love that part. I think that's the essence of the system...I mean [my doctor] is a world-renowned cardiologist and she calls me on Sunday morning at 7, because my reading is a little high. I can't believe it, it's the ultimate professionalism. If she didn't, I wouldn't be heartbroken, but I just think that she uses the system as it should be used.* [HFpro107]

Redesign of the Medly Program for Sustainability and Scalability

Qualitative results related to opportunities to modify components of the *Medly* program were interpreted and classified according to the degree to which they could be adapted while maintaining program fidelity. As shown in Figure 2, the format of technical support and the peripheral equipment used were considered highly adaptable and, thus, clearly part of the *Medly* program's soft periphery. The participation of a clinician (role and intensity of monitoring) and the monitoring of patients over time are central components of any telemonitoring program theory of change, indicating some overlap with the intervention's hard core. However, the interviews suggest some degree of adaptability depending on contextual factors, which explains why intensity of monitoring, clinician role, and duration of enrollment were classified as moderately adaptable and part of a *fuzzy boundary* between the hard core and soft periphery. These findings informed the decisions to adapt the *Medly* program as described in Table 3.

Figure 2. Hard core and soft periphery of the Medly program as informed by user interviews and its role in the intervention's theory of change.

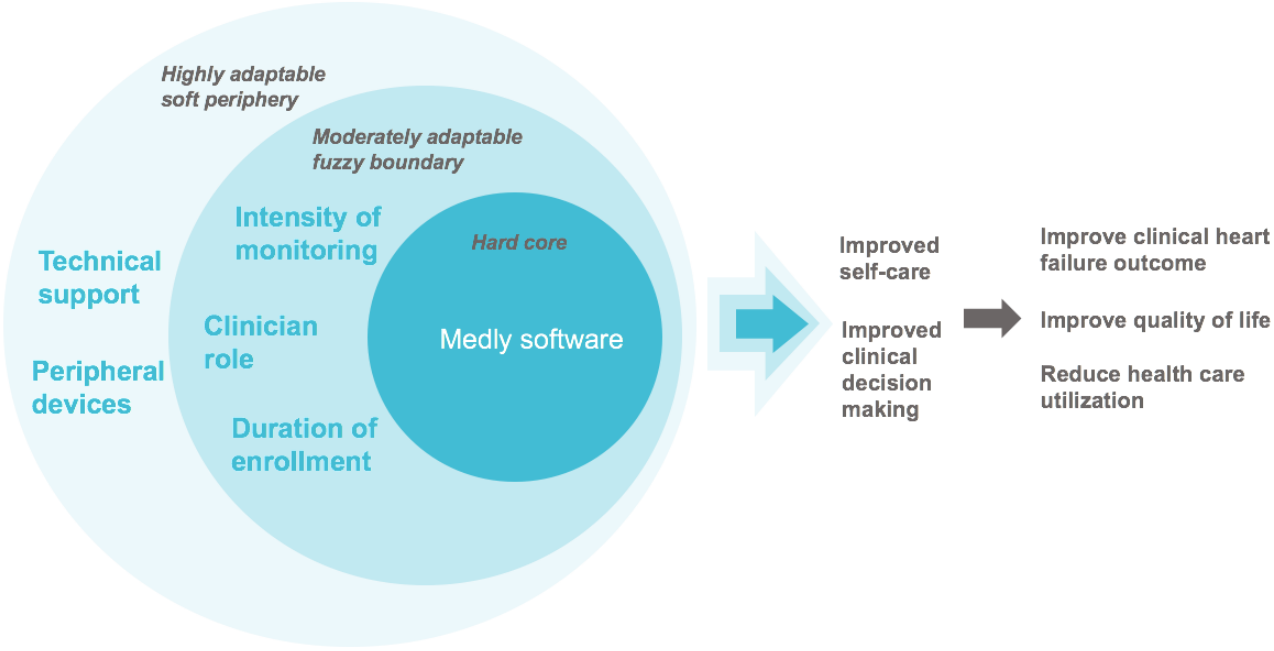

Table 3. Adaptations to the *Medly* program to ensure sustainability and scalability.

Opportunities for adaptation	Decisions related to the *Medly* program
Peripheral devices	Move forward with the implementation of a hybrid Bring Your Own Device model, whereby most patients use their own mobile and peripheral devices with some *Medly* kits still being distributed to patients in need (eg, lack of ability to pay, low cognitive ability, and dexterity problems). This involved change to the operational procedures, including (1) generation of a list of recommended clinically valid weight scales and blood pressure cuffs for patient purchase, (2) clinician prescription of peripherals so that costs can be reimbursed by private medical insurance or tax deductions, and (3) expanding technical troubleshooting procedures to cover the most common devices on the market. Software development needed to implement this decision included (1) the development of a manual entry version of the *Medly* app with features to protect against inaccurate data entry and (2) adapting the *Medly* app for tablets. The one-time costs of this developmental work are being incurred by the organization developing the *Medly* system. Thus, it is not considered part of the program's implementation costs.
Technical support	A website was built containing patient training content and an extensive frequently asked questions section. It is expected that this website will allow patients to be more self-sufficient and greatly reduce the number of calls made for technical support. In addition, development is underway to build a self-training feature directly into the *Medly* app. This will also increase the feasibility of providing same-day onboarding by minimizing scheduling challenges that exist with face-to-face training. The shift toward lower-touch technical support made it possible for most of the frontline technical support tasks (patient training, managing inventory, and basic troubleshooting) to be taken up by clinic staff. It is believed that this model more closely resembles what will be feasible in most health care settings, and it is expected to improve the patient experience by having a single point of contact.
Clinician role	An RN[a] was hired to take over the primary clinical management of alerts from the existing nurse practitioners as well as the technical support role from the existing telehealth analyst. This RN was responsible for triaging alerts and escalating clinical issues to MRPs[b] when necessary.
Duration of patient enrollment	No change. A universally applicable duration of enrollment could not be determined as it depends on patient characteristics.
Intensity of monitoring	No change. The 7 days/week monitoring will be maintained at the HF clinic with cardiologists volunteering their time to cover weekend alerts and transferring alerts to a colleague if they will be unavailable for extended periods. Modifications are being made to the *Medly* dashboard to facilitate the transfer of alerts from one MRP to another.

[a]RN: registered nurse.

[b]MRP: most responsible physician.

Discussion

Principal Findings

This qualitative study is the first to describe adaptations to an existing HF telemonitoring program aimed at enabling its sustainability and scalability. The redesign was informed by interviews with clinicians and patients to identify which program components could be adapted while maintaining program fidelity. User perceptions helped identify that the type of peripheral devices used and the format of technical support were highly adaptable, making them ideal targets for cost reduction measures. This led to the decision to move forward with a hybrid BYOD model and lower-touch technical support services, which would substantially reduce the cost burden to the clinic for delivering the program. In addition, findings related to the clinician role confirmed that frontline alert management should be done by someone within the patient's immediate circle of care rather than being outsourced to an offsite telehealth clinician. This informed a more cost-effective model in using an RN to replace the existing NPs as the frontline manager of telemonitoring alerts and to absorb the technical support functions previously performed by the THA. The notion of an RN playing both the central clinical and operational roles within telemonitoring services is supported in the literature [22,23]. In this case, hiring of an RN made sense as a resource optimization measure because of the existing program structure, which involves escalating alerts to an MRP. In sites where a physician is not as readily available, a professional with an ability to make medication changes (eg, NP) might be more appropriate to lead a telemonitoring service.

Because no generalizable dose with respect to duration of enrollment and intensity of monitoring could be established, no changes were made at the existing program site. However, the moderately adaptable nature of these components may reveal opportunities for scaling as they might be tailored to allow for program integration within sites with different patient populations, resources, and objectives. For example, although rapid feedback from a clinician is often described as the most important component of a telemonitoring service [24], a clinical site serving patients with a lower disease severity may not require 7 days per week monitoring. In addition, a site with resource constraints may wish to prioritize improving patient self-care, in which case, a 3- to 6-month duration might represent an optimized duration of enrollment. Alternatively, sites with available resources and different organizational values may wish to prioritize the patient's experience in addition to improving self-care and decide to monitor patients indefinitely. Finally, although the clinicians in this study felt comfortable receiving alerts during off hours, the medicolegal implications of continuous monitoring must be considered on a site-by-site

basis. For example, it is possible that 7 days per week monitoring is deemed important for a specific patient population but that receiving alerts during off hours represents a medicolegal concern that cannot be addressed through the hiring of additional staff or on-call personnel. Such a situation may leave a site no choice but to offer a weekday-only telemonitoring program, with the understanding that the impacts of the program may be suboptimal.

Comparison With Prior Work

Several studies have explored the barriers to and facilitators of implementing telehealth systems [25,26] but few have described the process of adapting an existing program to ensure its sustainability and scalability. One multiple case study by Taylor et al describes a participatory approach to implementing solutions for expanding a telehealth program [27], but the description of these activities remained high level without concrete examples, leading to limited transferability of results.

Many authors cite the ubiquity of smartphones as an opportunity for delivering telemonitoring services at a lower cost [28,29]. However, most studies of mobile phone–based telemonitoring have provided patients with this mobile equipment [30], and little is known about clinicians' and patients' perceptions of a BYOD model. From a usability perspective, there is a clear preference among patients, both in the literature [24,31,32] and in this study, for using Bluetooth-enabled peripheral devices. However, what appears most important is that patients can access telemonitoring services using devices they are most familiar with (ie, personal smartphones and tablets) [33-35] and that the perceived advantages of a telemonitoring program are greater than any usability inconveniences caused by manually entering biometric data [36-38]. To our knowledge, ours is the first study to confirm that BYOD is perceived by both clinician and patient users as a viable option for delivering telemonitoring services with a caveat that considerations are required to ensure universal accessibility.

The finding that clinicians believe patients could exit a telemonitoring program after they have stabilized or gained self-care skills is supported by other studies [39]. We found a similar perspective among clinicians in this study, but we also found that many patients grow accustomed to being remotely monitored and would like to continue over a longer term. Until now, considerations about the duration of telemonitoring interventions have primarily been driven by costs. However, this perspective ignores the natural history of HF, whereby although patients may stabilize for a period, they will rarely improve [40]. Therefore, as opportunities are leveraged to deliver telemonitoring interventions at lower costs (including clinicians' time through the development of more sophisticated decision-support capabilities), it is conceivable that the costs of delivering certain telemonitoring programs will become sufficiently low so that it removes the need to ration their use. Thus, future work should seek to answer whether it is better (from the patient, clinician, and health system perspectives) to (1) remove patients from a low-cost telemonitoring program when they have stabilized only to reinstate them in the program when their condition has worsened or (2) leave them enrolled in the program indefinitely.

Limitations

First, although participants were asked to consider their responses with respect to telemonitoring in general, it is likely that their responses were influenced by their experiences with the *Medly* program. In stating this limitation, we emphasize that our intent was to describe adaptations to a specific telemonitoring program rather than to provide a detailed blueprint for implementing all HF telemonitoring interventions in any given clinical context. We argue that the context-dependent nature of implementing complex interventions makes the creation of such a blueprint impossible. Rather, we have sought to provide foundational considerations for developers of telemonitoring programs and for implementation scientists who wish to sustain and scale existing telemonitoring programs to other clinical sites and health care organizations. Second, the pragmatic nature of this study meant that patients can be enrolled in the *Medly* program without consenting to participate in the evaluation activities, making them ineligible to participate in the interviews. Our inability to purposely sample these patients may have led to selection bias. Third, the interview guides were developed to probe the opinions of users on specific program components. We recognize that our approach for compartmentalizing and defining the various components of this complex intervention was subjective and context specific; this should be considered when determining the transferability of results to alternative settings. Finally, although the resulting user-guided adaptations are expected to maintain the fidelity of the intervention, the true impact of these changes was not empirically tested in this study. This important question will be evaluated as part of a subsequent publication on the overall impacts of the *Medly* program as well as patient adoption and adherence to the intervention.

Conclusions

Theories of diffusion of innovation suggest that one of the keys to scaling health interventions lies in adapting elements of its delivery to better fit the implementation context. However, this is only true if fidelity of the intervention can be maintained and its potential effectiveness is not compromised. This concept has informed the implementation of cost reduction measures of an existing HF telemonitoring program to ensure its sustainability. Our findings suggest that the peripheral devices used in telemonitoring programs and the format of technical support are highly adaptable, making them ideal targets for cost reduction measures. Duration of enrollment and intensity of monitoring are inextricable components of a telemonitoring intervention, but the dose of these components required to yield expected outcomes is highly context dependent. Our efforts provide a user-centered example of how necessary actions can be taken to improve the sustainability and scalability of telemonitoring programs.

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Authors' Contributions

PW led the overall design, data collection, data analysis, and write-up of this study. HJR, AL, JAC, and ES contributed to the design. KG contributed to the analysis and interpretation of the qualitative data. All authors reviewed and edited the manuscript. All authors read and approved the final version of the manuscript. This study was conducted as part of the PhD dissertation work of PW who receives a stipend from the Institute of Health Policy, Management and Evaluation at the University of Toronto.

Conflicts of Interest

HJR, JAC, and ES hold intellectual property in the *Medly* system and may profit from future commercialization of the technology.

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Abbreviations

BYOD: bring your own device
HF: heart failure
MRP: most responsible physician
NP: nurse practitioner
NYHA: New York Heart Association
RN: registered nurse
THA: telehealth analyst
UHN: University Health Network

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Original Paper

A Remote Patient Monitoring Intervention for Patients With Chronic Obstructive Pulmonary Disease and Chronic Heart Failure: Pre-Post Economic Analysis of the Smart Program

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Abstract

Background: Exacerbation of chronic obstructive pulmonary disease (COPD) and chronic heart failure (CHF) are associated with high health care costs owing to increased emergency room (ER) visits and hospitalizations. Remote patient monitoring (RPM) interventions aim to improve the monitoring of symptoms to detect early deterioration and provide self-management strategies. As a result, RPM aims to reduce health resource utilization. To date, studies have inconsistently reported the benefits of RPM in chronic illnesses. The Smart Program is an RPM intervention that aims to provide clinical benefit to patients and economic benefit to health care payers.

Objective: This study aims to economically evaluate the potential benefits of the Smart Program in terms of hospitalizations and ER visits and, thus, associated health care costs from the perspective of the public health care system.

Methods: Seventy-four patients diagnosed with COPD or CHF from one hospital site were included in this one-group, pre-post study. The study involved a secondary data analysis of deidentified data collected during the study period – from 3 months before program initiation (baseline), during the program, to 3 months after program completion (follow-up). Descriptive analysis was conducted for the study population characteristics at baseline, the clinical frailty score at baseline and 3-month follow-up, client satisfaction at 3-month follow-up, and number and costs of ER visits and hospitalizations throughout the study period. Furthermore, the cost of the Smart Program over a 3-month period was calculated from the perspective of the potential implementer.

Results: The baseline characteristics of the study population (N=74) showed that the majority of patients had COPD (50/74, 68%), were female (42/74, 57%), and had an average age of 72 (SD 12) years. Using the Wilcoxon signed-rank test, the number of ER visits and hospitalizations, including their associated costs, were significantly reduced between baseline and 3-month follow-up (P<.001). The intervention showed a potential 68% and 35% reduction in ER visits and hospitalizations, respectively, between the 3-month pre- and 3-month postintervention period. The average cost of ER visits reduced from Can $243 at baseline to Can $67 during the 3-month follow-up, and reduced from Can $3842 to Can $1399 for hospitalizations.

Conclusions: In this study, the number and cost of ER visits and hospitalizations appeared to be markedly reduced for patients with COPD or CHF when comparing data before and after the Smart Program implementation. Recognizing the limitations of the one-group, pre-post study design, RPM requires an upfront investment, but it has the potential to reduce health care costs to the system over time. This study represents another piece of evidence to support the potential value of RPM among patients with COPD or CHF.

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KEYWORDS

chronic heart failure; chronic obstructive pulmonary disease; costs; economic analysis; emergency department visits; hospitalizations; health service utilization; remote patient monitoring

Introduction

Chronic obstructive pulmonary disease (COPD) and chronic heart failure (CHF) are associated with a high burden (ie, high health care cost) to the system [1,2]. The cost of 1 hospital stay for COPD and CHF in Canada was estimated to be Can $6038 and Can $6222, respectively [3]. Therefore, innovative interventions aimed to reduce the burden on our system (eg, reduce hospitalization) would be beneficial. An example of such interventions is remote patient monitoring (RPM), which aims to provide the "appropriate care at the appropriate time and place in the most appropriate manner" [1], focusing on better disease management [4,5].

A growing amount of literature exists on the potential value of RPM for patients with COPD and CHF; however, the literature has shown both supportive and opposing evidence for RPM [1,6,7]. For example, RPM has been shown to reduce health service utilization and costs (eg, hospitalization and emergency room [ER] visits) among patients with CHF [2,8-12], whereas other studies did not find similar findings [6,7,13,14]. Conversely, some studies reported inconclusive findings [15-17]. Among patients with COPD, evidence was also inconclusive where RPM was found to be an economically attractive option in some studies but not in others [6,18-23]. Furthermore, a number of studies reported the need for more research [24,25].

This study aims to build on and contribute to the current literature by showing a potential value of RPM. Understanding the impact of a health intervention on the cost of hospitalization and ER visits may increase understanding regarding how the intervention will affect the health care system.

The research question was "What was the cost of hospitalization and ER visits of patients receiving RPM over the study period among patients diagnosed with COPD or CHF?" Specifically, based on this one-group, pre-post study design, we aimed to describe the study population and report the use and cost of ER visits and hospitalizations over the study period (from 3 months before program initiation, baseline, to 3 months after program completion, and follow-up) from the perspective of a public health care system in Ontario, Canada.

Methods

Study Population and Setting

The study population comprised 74 patients diagnosed with COPD or CHF in 1 hospital site in Toronto, Canada. The inclusion criteria included the following: aged ≥18 years; diagnosed with either COPD or CHF for a minimum of 6 months; ability to communicate in English; and cognitively capable of giving consent. Patients who were unable to provide consent, were a part of a competing program within the same hospital, or had a life expectancy of <6 months were excluded from this study.

This study received a research ethics approval from Southlake Regional Health Centre and St. Michael's Hospital in Toronto, Ontario, Canada.

Intervention

The AlayaCare/CBI Smart Program was a collaboration between Southlake Hospital, CBI Health Group, and AlayaCare. The project was conducted between August 2016 and May 2017 on both patients with COPD and CHF to reduce both patient ER visits and hospitalizations. The Smart Program, a type of RPM, was the intervention under study. The RPM is a form of health care that allows patients to use medical devices in the comfort of their home to perform routine tests and send results automatically to their home health care professional. This digital software aims to improve the management of patients' chronic illness through multisource, self-management techniques, including patient self-identification of symptoms and problem-solving strategies, which will result in the stabilization of their illness status.

Data Collection and Management

Data were collected by nurses at the point of care through the AlayaCare mobile app or by patients themselves through the AlayaCare RPM app and were stored in the AlayaCare's secure cloud app. Data were collected at 3 time-points as follows: *baseline* (within 3 months before the program initiation); *during the program*; and *follow-up* (at 3 months after the program completion). During the follow-up period, patients were no longer using the intervention. The deidentified patient-level data were transferred to the research team using encryption and secure internet transmission and used for the economic analysis.

Variables

The economic analysis conducted in this study was a secondary data analysis that used deidentified data that were collected for the study. Specifically, we descriptively reported patients' age, sex, medication use, regular medical follow-ups, and the number of patients with, at least, 1 alert for blood pressure, blood oxygen, and weight, including a score from the clinical frailty scale (Table 1).

Table 1. The definition of each level on a clinical frailty scale.

Level	Definition
1	Very fit
2	Well
3	Well, with treated comorbidities
4	Apparently vulnerable
5	Mildly frail, some dependence on others for activities of daily living
6	Moderately frail, help needed with instrumental activities of daily living
7	Severely frail

Health Service Utilization and Cost

Health service utilization data were collected at 3 time-points as follows: *baseline* (within 3 months before the program initiation); *during the program*; and *follow-up* (at 3 months after the program completion). The main types of health service of interest included hospitalization and ER visit, which can be expressed in monetary terms (ie, ER visit cost and hospitalization cost). Subsequently, we converted health service utilization to health care cost using data on health service utilization from the study and standard costing sources for information on the unit cost of hospitalization and ER visit. The unit cost of 1 ER visit was estimated to be Can $159 and was obtained from the Canadian Institute of Health Informatics [26]. A general cost for 1 hospital stay in Ontario was estimated to be Can $5364 [3,27]. Of note, all costs were reported in 2016 Canadian dollars (Can $). Costs from other years were converted to 2016 Can $ using Consumer Price Index under Health Care category published by Statistics Canada [28].

Statistical Analysis

Descriptive analysis on baseline variables was conducted on age, sex, medication use, regular medical follow-ups, and the number of patients with, at least, 1 alert for blood pressure, blood oxygen, and weight. Descriptive findings on the clinical frailty score were reported at baseline and 3-month follow-up, client satisfaction at 3-month follow-up, and number and costs of ER visits and hospitalizations throughout the study period. The Wilcoxon signed-rank test [29,30] was used to compare the number and cost of ER visits and hospitalizations between baseline and 3-month follow-up, recognizing that the data were from the same individuals. The test focused on the difference in values for each pair of observations. The chosen statistical analysis, the Wilcoxon signed-rank test, adjusted for the nonnormality of health service utilization and cost data [29,30]. Over the study period, the patients' health service utilization and costs were examined.

In addition, cost description of the program was conducted from the perspective of the potential implementer (eg, the Local Health Integration Network [LHIN]), to report the total cost of delivering the program over a 3-month period. In Ontario, publicly funded health care services are administered on a regional basis by LHINs, which serve as the regional health authority. Each of the 14 LHINs is responsible for a distinct geographical location [31]. The costs associated with delivering the program captured in this study were personnel and supplies and miscellaneous costs.

Results

Baseline Characteristics

This study reports descriptive findings on the following: baseline characteristics of the study population; clinical frailty score at baseline and 3-month follow-up; client satisfaction with the intervention at 3-month follow-up; health service utilization that includes the number and costs of ER visits and hospitalizations at baseline, during the program, and follow-up; and cost description of delivering the program over a 3-month period.

Overall, 74 patients were enrolled in the program at baseline. However, at 3-month follow-up, only 67 patients completed the data collection, as 2 people died and 5 were lost to follow-up. The 2 people who died were assessed to be mildly frail with unknown cause of death.

Table 2 reports the baseline characteristics of the study population. The majority of patients had COPD (50/74, 68%). The average age of patients was 72 (SD 12) years, where 42 patients (42/74, 57%) were females. Of all, 60 patients (60/74, 81%) were on, at least, 1 medication, with the number of medications ranging from 1 to 26. For alerts, 29 patients (29/74, 39%) had, at least, 1 weight alert, 68 (68/74, 92%) had, at least, 1 blood pressure alert, and 68 (68/74, 92%) had, at least, 1 blood oxygen alert during the program. Over 85% (64/74) of patients had regular medical follow-ups.

Table 2. The baseline characteristics of the study population (N=74).

Variable	Value
Age, mean (SD), range	71.6 (12.0), 44-98
Sex, n (%)	
Female	42 (57)
Male	32 (43)
Medications	
Had, at least, 1 medication, n (%)	60 (81)
Number of medications, mean (SD), range	10.0 (5.2), 1-26
Have regular medical follow-ups, n (%)	64 (86)
Had at least 1 weight alert, n (%), range	29 (39), 1-29
1 alert	8
2 alerts	3
3-5 alerts	9
6-10 alerts	6
10+ alerts	3
Had at least 1 blood pressure alert, n (%), range	68 (92), 1-59
1-5 alerts	24
6-10 alerts	15
11-20 alerts	16
20+ alerts	13
Had at least 1 blood oxygen alert, n (%), range	68 (92), 1-89
1-5 alerts	22
6-10 alerts	16
11-20 alerts	14
20+ alerts	16

Clinical Frailty

At baseline, the majority of patients (50/74, 68%) reported clinical frailty score to be between 3 (well, with treated comorbidities) and 4 (apparently vulnerable). The level 3 clinical frailty score increased from 27% (20/74) at baseline to 39% (26/67) at 3-month follow-up (Figure 1).

Between the 2 time-points (baseline and follow-up), the majority of patients (49/67, 73%) reported the same score of clinical frailty scale. Approximately 22% (15/67) of patients reported improved score on the frailty scale, while 5% (3/67) reported worsened score.

Satisfaction

For patient satisfaction with the Smart Program, 91% (61/67) of patients responded at 3-month follow-up. Almost 70% (42/61) of patients strongly agreed that they felt more confident managing their signs and symptoms related to diagnosis. In addition, 97% (59/61) recognized when they should be going to the emergency department, when they could monitor at home, or when they should go to see their physician before a flare-up. Next, 90% (55/61) of patients rated their satisfaction with the Smart Program as very good or excellent, whereas just over 55% (35/61) rated their satisfaction with the use of equipment as very good or excellent. All patients agreed (either somewhat or strongly) that the Smart Program had helped them learn more about their disease, the Smart Program had made a positive difference in their life, and that they would recommend the program to a friend or family member.

Health Service Utilization

For ER visits, 96% (71/74) of patients had, at least, 1 ER visit during the 3-month period before the program started at baseline; this percentage dropped to 28% (19/67) at 3 months after the program finished. At baseline, exacerbation of chronic disease accounted for the majority of hospitalizations (69%, 51/74) with falls and infections being the other reasons for hospitalization.

During the program, 22% (16/74) of patients had, at least, 1 ER visit, and 9% (7/74) of patients had, at least, 1 hospitalization. The number of ER visits and hospitalizations ranged from 0 to 4 and 0 to 3, respectively. The exacerbation of chronic disease accounted for almost 40% of ER visits, and >70% of hospitalizations. Other reasons included falls and infections.

Figure 1. The clinical frailty score at the baseline and 3-month follow-up.

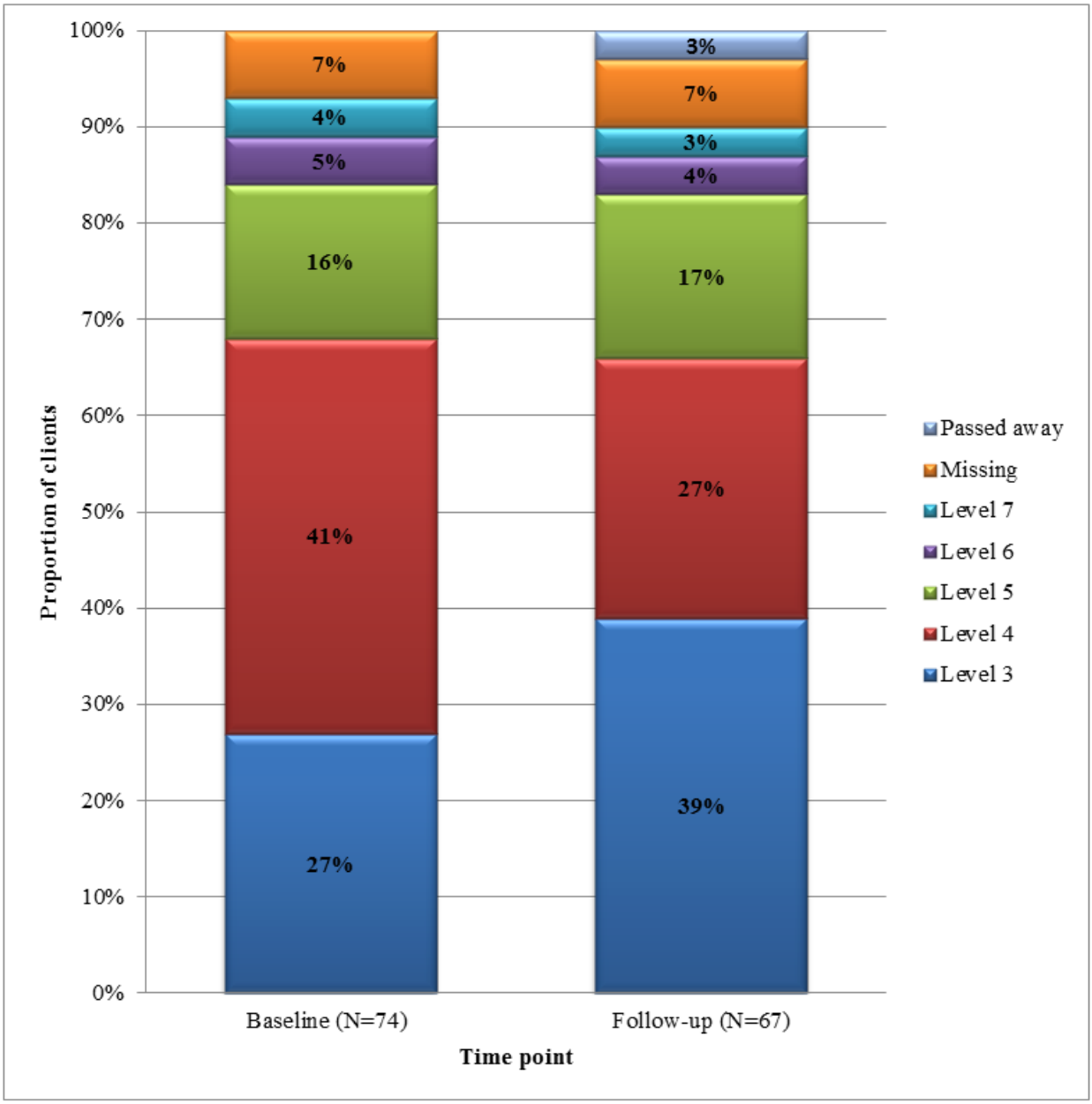

Figure 2 presents the number of ER visits over the study period (N=74 at baseline, ie, 3 months before the program, N=74 during the program, and N=67 at 3-month follow-up). At baseline, the number of visits ranged from 0 to 5, whereas the range was from 0 to 3 at follow-up. At baseline, the majority of patients had, at least, 1 ER visit, whereas the majority of patients had 0 visits during the program and at 3-month follow-up.

Figure 3 presents the number of hospitalizations over the study period. At baseline, the number of hospitalizations ranged from 0 to 4, whereas the range was from 0 to 2 at follow-up. At baseline, the majority of patients (42/74, 57%) had, at least, 1 hospitalization, whereas the majority of patients had 0 hospitalizations during the program and, at 3-month follow-up, only 22% (15/67) of patients had at least 1 hospitalization.

The total number of ER visits and hospitalizations appeared to decline over time in this study population. The number of ER visits and hospitalizations was 71 and 42, respectively, at baseline, and 19 and 15, respectively, at 3-month follow-up.

Table 3 summarizes the costs of ER visits and hospitalizations over the study period. Between baseline and 3-month follow-up, the number of ER visits and hospitalizations, including their associated costs, was significantly different ($P<.001$) in the direction of lower cost in the follow-up period (Figure 4). Specifically, the average cost for ER visit reduced from Can $243 at baseline (3 months before the program started) to Can $67 during the follow-up (3 months after the program finished; $P<.001$). Similarly, the average hospitalization cost reduced from Can $3842 to Can $1399 ($P<.001$). When considering only patients with, at least, 1 visit, the average costs of ER visit and hospitalization was similar across the 3 time-points (Figure 5).

Figure 2. The number of emergency room visits over the study period.

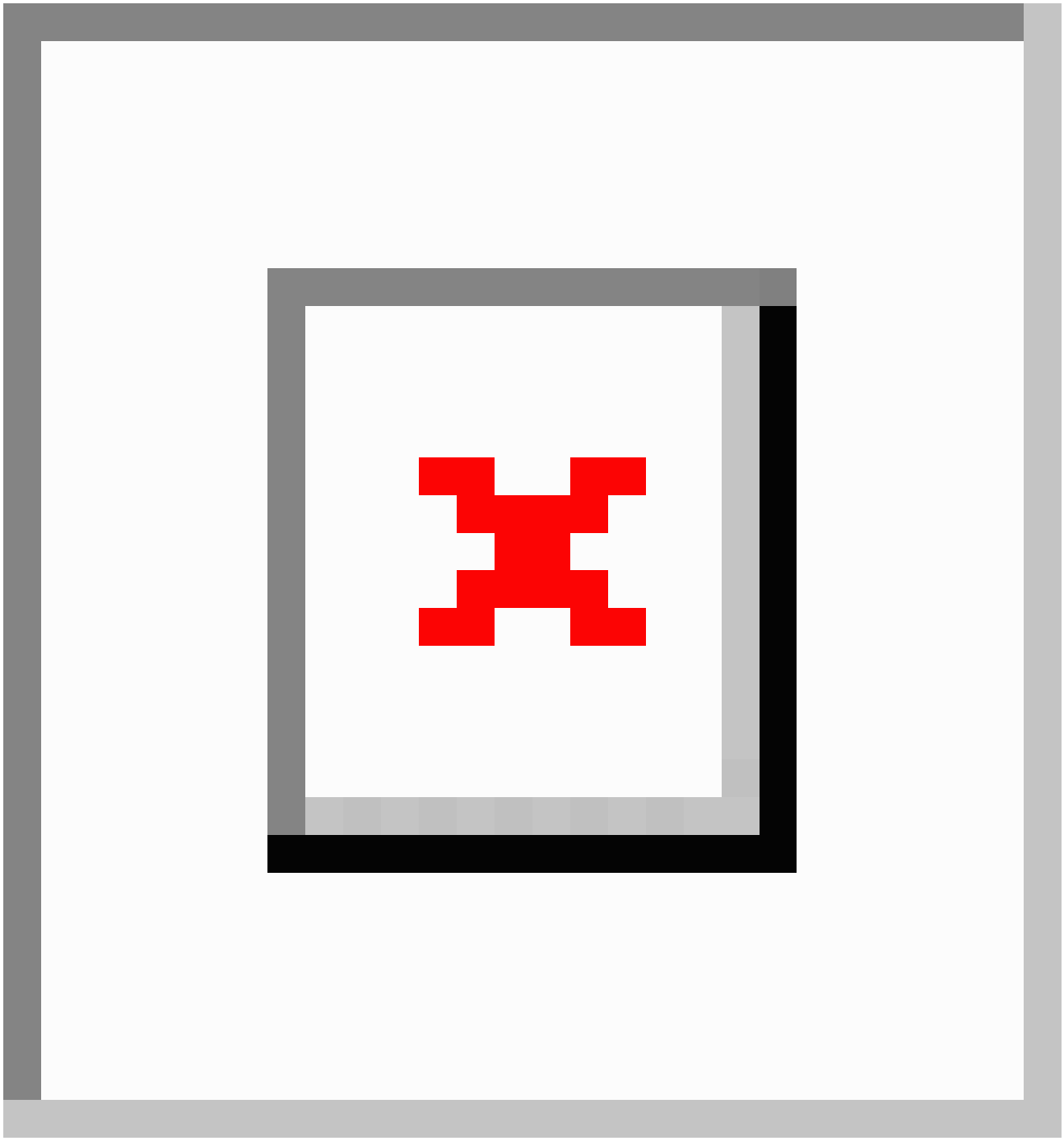

Figure 3. The number of hospitalizations over the study period. ER: emergency room.

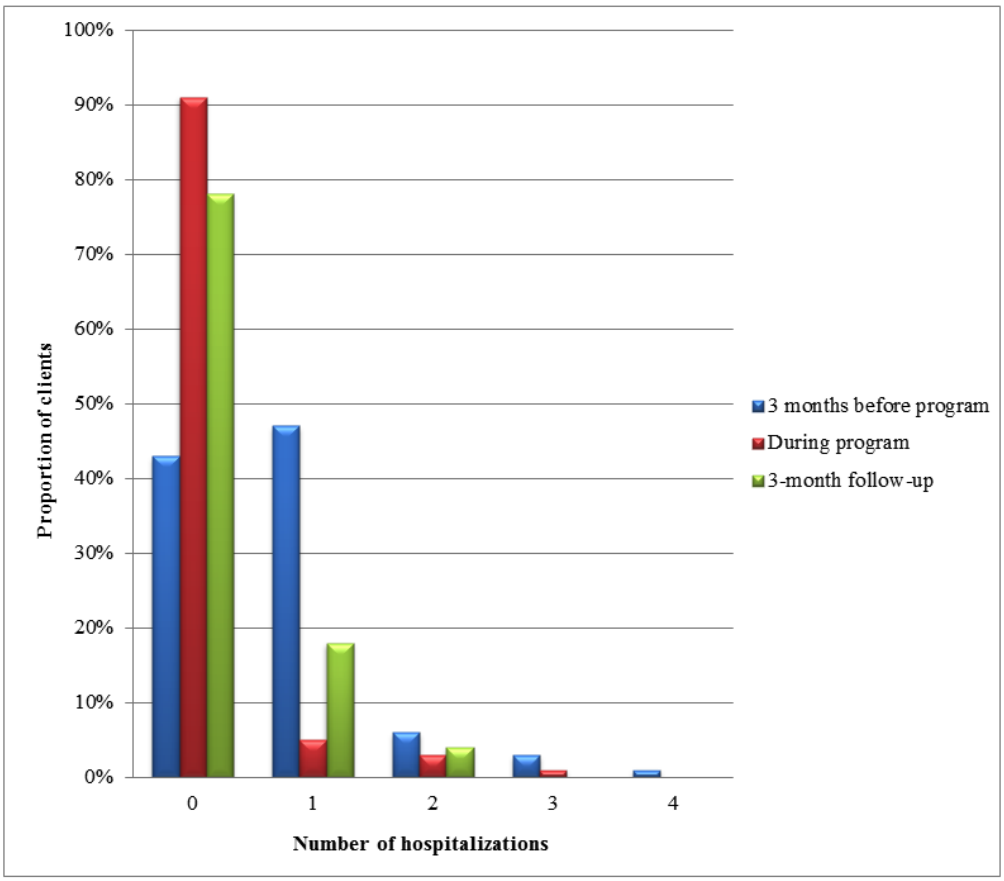

Table 3. Costs of emergency room visit and hospitalization over the study period.

Cost at each time point	Mean cost (SD) in Can $
At baseline	
ER[a] visit cost	243 (137)
ER visit cost among users (n=71)	253 (131)
Hospitalization cost	3842 (4306)
Hospitalization cost among users (n=42)	6769 (3566)
During program	
ER visit cost	58 (130)
ER visit cost among users (n=16)	268 (150)
Hospitalization cost	797 (2763)
Hospitalization cost among users (n=7)	8429 (4220)
At 3-month follow-up	
ER visit cost	67 (129)
ER visit cost among users (n=19)	243 (134)
Hospitalization cost	1399 (2858)
Hospitalization cost among users (n=15)	6437 (2221)

[a]ER: emergency room.

Figure 4. Costs of emergency room visit and hospitalization over the study period.

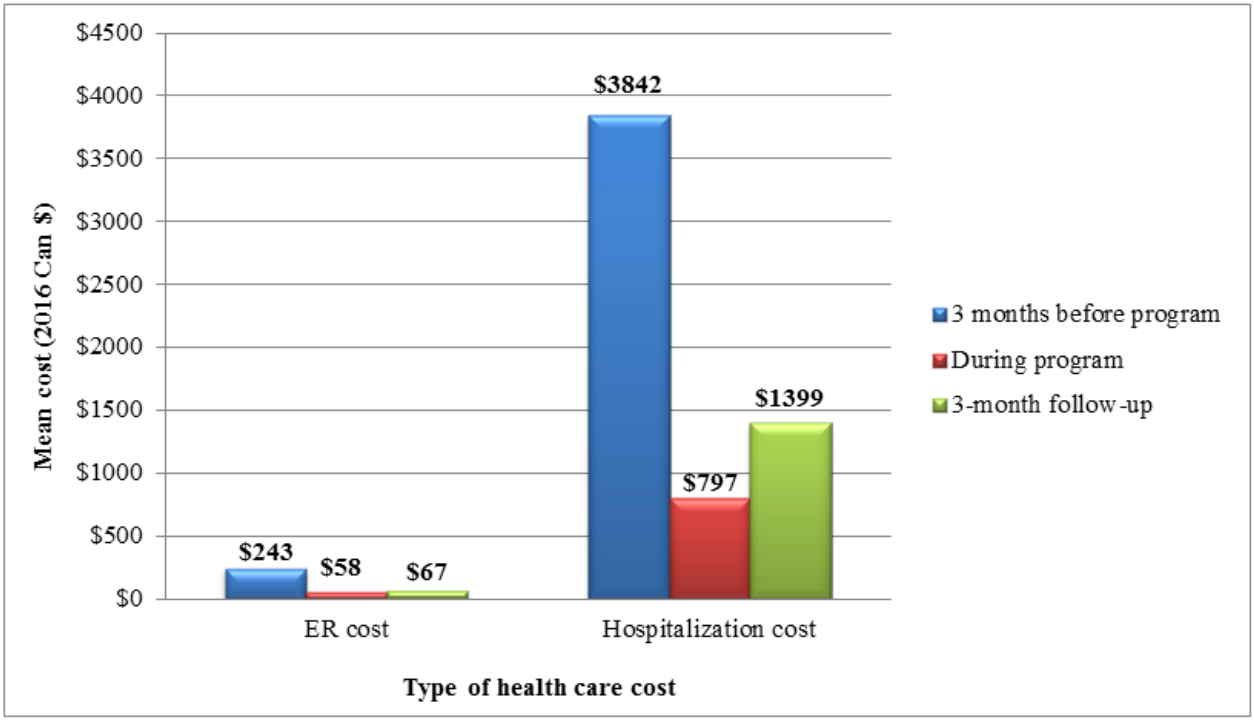

Figure 5. Costs of emergency room visit and hospitalization over the study period among those with at least one visit and hospitalization. ER: emergency room.

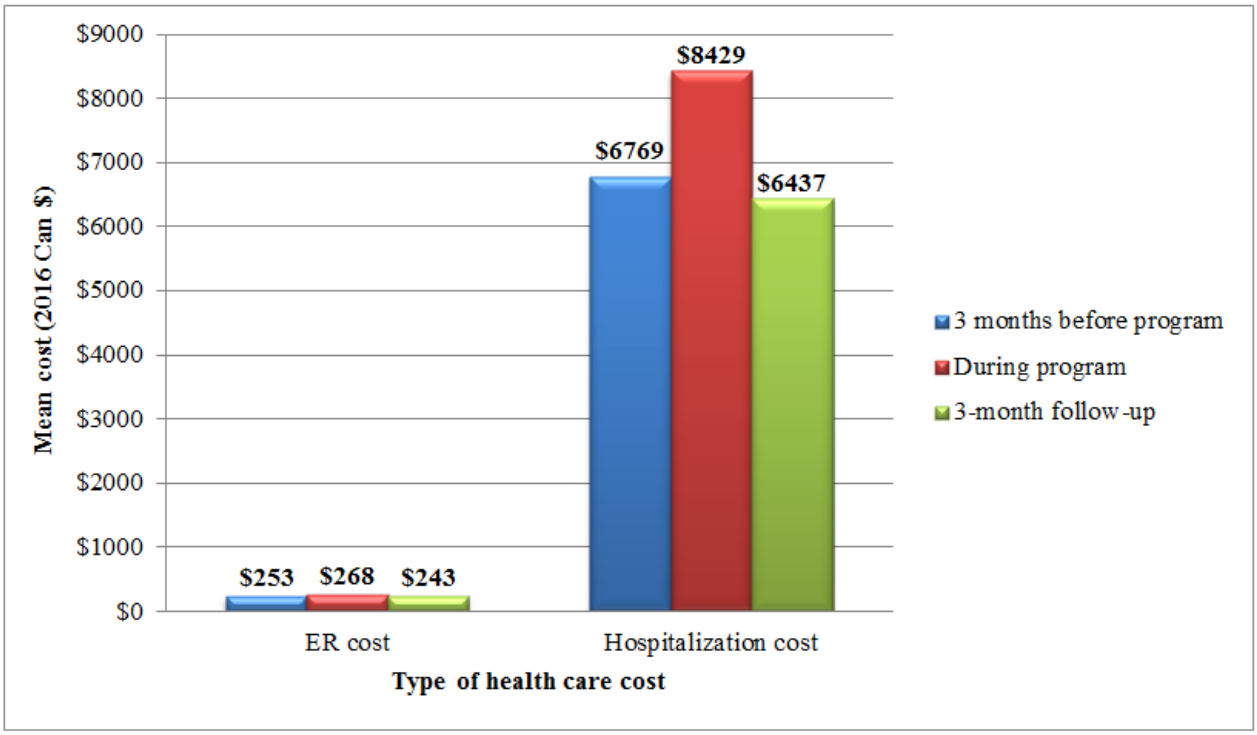

Table 4. Cost components of the Smart Program per patient over a 3-month period.

Cost component	Unit cost in Can $	Number of units	Total cost in Can $
Telehealth nursing cost	34.81/hour	9.4 hours	327.21
Hardware amortized over 3 years	—[a]	—	41.87
Remote patient monitoring software	—	—	105
Case conference (twice per patient)	65	2	130
Wireless data	15/month	3 months	45
Total cost over a 3-month period	—	—	649

[a]Not applicable.

Cost Description

Over a 3-month period, the total cost to deliver the program was Can $649 per patient; this amount accounted for both personnel and supplies and miscellaneous costs. Personnel costs comprised salary and benefits for a telehealth nurse. Supplies and miscellaneous costs included hardware, RPM software, case conferences (2 times per patient), and wireless data. Table 4 presents the cost of providing the Smart Program over a 3-month period.

Discussion

Principal Findings

This study analyzed the baseline characteristics of the study population and examined the number and cost of ER visits and hospitalizations over the study period from the perspective of a public health care system in Ontario, Canada. Of 74 patients included in this study, a majority had COPD (50/74, 68%), were female (42/74, 57%), and had an average age of 72 (SD 12) years. Approximately 80% (60/74) were on, at least, 1 medication, and >85% (64/74) of patients had regular medical follow-ups. For alerts, 39% (29/74) had, at least, 1 weight alert, 92% (68/74) had, at least, 1 blood pressure alert, and 92% (68/74) had, at least, 1 blood oxygen alert during the program. The proportion of patients with the clinical frailty score of 3 (well, with treated comorbidities) also increased from 27% (20/74) at baseline to 39% (26/67) during the 3-month follow-up period, which showed favorable outcomes with the use of the Smart Program.

Among patients diagnosed with a chronic illness of COPD or CHF, the number and cost of ER visits and hospitalizations appeared to be markedly reduced when compared between the 3-month period before the program started and the 3-month period after the program finished. The average cost of ER visit reduced from Can $243 at baseline to Can $67 at follow-up, and reduced from Can $3842 to Can $1399 for hospitalizations. These reductions were partly attributed to the findings that the number of ER visits and hospitalizations reduced, while this intervention costs approximately Can $649 to implement for 1 patient over a 3-month period. Notably, when considering only patients with, at least, 1 visit, the average costs of ER visit and hospitalization were similar across the 3 time-points.

The RPM literature provides both supportive and opposing evidence to verify the value of RPM. For example, a reduction in direct health care cost was found in a review by Seto to be between 1.6% and 68.3% [2], and in a study by Scalvini et al to be approximately 10% [10]. This study reports the reduction of hospitalization to be 35% and of ER visits to be 68%. These differences could be attributed to a number of factors such as target population, the range of supports provided as part of the RPM, and settings.

Strengths and Limitations

This study has strengths and limitations. As the literature has recommended RPM that can support more than one condition [32], this study shows that an RPM system targeting more than one condition can be successfully implemented. A review [33] suggested that more details on cost, including amortization, should be made explicit as we have done here. This study represents a case study to support the potential value of RPM by examining both costs and outcomes of RPM where the outcomes (measured in hospitalization and ER visits) have been converted to monetary values.

Given the nature of the study design (one-group, pre-post study design), the findings contributed only to the trends of health service utilization and cost over the study period. Future research could build on this work and design a study with a comparator group to comprehensively examine the potential impact of RPM in the study population. In addition, future research could explore the options to conduct the analysis with a longer follow-up time from another perspective, which could include other costs (eg, costs to patients and caregivers, which has been suggested to be an important element [34]), and other outcomes such as the quality of life and productivity loss. Furthermore, a subgroup analysis (eg, patients with comorbidities) could be explored to validate the impact of RPM.

Conclusions

In summary, RPM (in this case, the Smart Program) may require upfront investment but it has the potential to reduce health care costs to the system over time. This study represents a piece of evidence to support the potential value of RPM among patients with COPD or CHF. This intervention shows a potential 68% reduction in ER visits and a 35% reduction in hospitalizations between the 3-month pre- and 3-month postintervention period. Recognizing the limitations of the one-group, pre-post study design, RPM could be an economically attractive option to explore for a health system in savings from reductions in ER visits and hospitalizations among patients with COPD or CHF.

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Authors' Contributions

WI was involved in the study design, data collection, data analysis, and manuscript writing. OR and PC were involved in the project initiation and data collection. AS and JV were involved in the project initiation and delivery of supporting information technology system. TVM was involved in the data collection and project management.

Conflicts of Interest

AS, TVM, and JV are employees of AlayaCare who provided the remote patient monitoring software. Other authors have no conflicts of interest to declare.

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Abbreviations

CHF: chronic heart failure
COPD: chronic obstructive pulmonary disease
ER: emergency room
LHIN: Local Health Integration Network
RPM: remote patient monitoring

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Original Paper

Feasibility of Telemonitoring Blood Pressure in Patients With Kidney Disease (Oxford Heart and Renal Protection Study-1): Observational Study

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Abstract

Background: Blood pressure (BP) is a key modifiable risk factor for patients with chronic kidney disease (CKD), with current guidelines recommending strict control to reduce the risk of progression of both CKD and cardiovascular disease. Trials involving BP lowering require multiple visits to achieve target BP, which increases the costs of such trials, and in routine care, BP measured in the clinic may not accurately reflect the usual BP.

Objective: We sought to assess whether a telemonitoring system for BP (using a Bluetooth-enabled BP machine that could transmit BP measurements to a tablet device installed with a bespoke app to guide the measurement of BP and collect questionnaire data) was acceptable to patients with CKD and whether patients would provide sufficient BP readings to assess variability and guide treatment.

Methods: A total of 25 participants with CKD were trained to use the telemonitoring equipment and asked to record BP daily for 30 days, attend a study visit, and then record BP on alternate days for the next 60 days. They were also offered a wrist-worn applanation tonometry device (BPro) which measures BP every 15 minutes over a 24-hour period. Participants were given questionnaires at the 1- and 3-month time points; the questionnaires were derived from the System Usability Scale and Technology Acceptance Model. All eligible participants completed the study.

Results: Mean participant age was 58 (SD 11) years, and mean estimated glomerular filtration rate was 36 (SD 13) mL/min/1.73m2. 13/25 (52%) participants provided >90% of the expected data and 18/25 (72%) provided >80% of the expected data. The usability of the telemonitoring system was rated highly, with mean scores of 84.9/100 (SE 2.8) after 30 days and 84.2/100 (SE 4.1) after 90 days. The coefficient of variation for the variability of systolic BP telemonitoring was 9.4% (95% CI 7.8-10.9) compared with 7.9% (95% CI 6.4-9.5) for the BPro device, P=.05 (and was 9.0% over 1 year in a recently completed trial with identical eligibility criteria), indicating that most variation in BP was short term.

Conclusions: Telemonitoring is acceptable for patients with CKD and provides sufficient data to inform titration of antihypertensive therapies in either a randomized trial setting (comparing BP among different targets) or routine clinical practice. Such methods could be employed in both scenarios and reduce costs currently associated with such activities.

Trial Registration: International Standard Randomized Controlled Trial Number ISRCTN13725286; http://www.isrctn.com/ISRCTN13725286 (Archived by WebCite at http://www.webcitation.org/74PAX51Ji).

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KEYWORDS

chronic kidney disease; blood pressure; telemonitoring; mobile phone

Introduction

Chronic kidney disease (CKD) is estimated to affect between 5% and 14% of the adult population worldwide [1,2] and is strongly associated with cardiovascular disease (CVD) [3,4]. Blood pressure (BP) rises in patients with CKD due to salt and water retention, increased sympathetic nervous system activity, activation of the renin-angiotensin-aldosterone system, and reduction in endogenous vasodilators. BP has a strong positive association with cardiovascular events in the general population [5] and among patients with CKD (once confounding by prior CVD is properly accounted for) [6]. Therefore, the relationship between raised BP and CKD and the potential for therapeutic interventions addressing BP in this population are an important focus of research.

The beneficial impact of BP lowering in the CKD population has not yet been fully established. First, it has been suggested that BP lowering reduces the risk of progression among patients with proteinuric CKD [7]. However, it is uncertain whether BP is causally related to the progression of CKD, and overall, it is not clear whether BP lowering reduces the risk of progression [8]. Second, the benefit of BP lowering on CVD in patients with CKD has not yet been fully elucidated. In the general population, lowering systolic BP (SBP) by 10 mm Hg reduces the risk of cardiovascular events by about 20% [8]. There is some evidence that this treatment effect is attenuated among patients with CKD (relative risk per 10 mm Hg reduction among patients with CKD 0.84, CI 0.73-0.96; relative risk per 10 mm Hg reduction among patients without CKD 0.68, CI 0.62-0.75; *P* value for interaction=.01); however, few patients with more advanced CKD (eg, estimated glomerular filtration rate [eGFR]<45 mL/min/1.73 m^2) were included in these trials [8,9]. Finally, the safety of BP lowering in patients with CKD is less well established in part due to the higher baseline risk of acute kidney injury (a recognized hazard of intensive BP lowering) among patients with CKD [10]. Studies are needed to assess BP lowering in patients with advanced CKD and to compare more- versus less-intensive BP reduction, but such trials are potentially expensive in part due to the requirement for frequent visits to measure BP and titrate BP-lowering treatment.

Nevertheless, BP control remains a key focus of those managing patients with CKD. BP measurements in the clinical setting are somewhat imprecise measures of long-term average BP (because of "white-coat" and "masked" hypertension [11,12]), and clinic measurements do not detect short- to medium-term within-person BP variability. A method through which BP can be measured frequently at home may, therefore, be of utility to clinical teams and those designing and conducting trials.

Home BP monitoring, as an intervention, has previously been the subject of trials looking to improve BP control [13,14]. It has been shown that self-monitoring improves BP control [15]. Telemonitoring is an evolving topic of interest in the management of chronic conditions including hypertension [16], with evidence of acceptability in certain patient groups [17]. Telemonitoring technology is now available, which allows such home measurements to be automatically transferred to a central computer where they can be reviewed by and responded to by medical staff as necessary. Telemonitoring has now been proposed as a novel approach for data collection in trials involving BP lowering for patients with CKD and as an enhancement to standard clinical care. This feasibility study aims to examine the potential for BP telemonitoring in terms of participant acceptability and consequent concordance with the technology infrastructure for patients with advanced CKD with the long-term goal of randomized trials investigating BP lowering in this cohort and improving routine clinical care.

Methods

Aims

The primary aim of the study was to assess the participants' acceptability of BP telemonitoring over 3 months, determined by the proportion of patients providing at least 90% of expected data. Expected data were defined as daily readings for 30 days and alternate daily readings for a further 60 days.

The 4 secondary aims were as follows: (1) to examine the usability and tolerability of the telemonitoring system as assessed using a questionnaire at the 1- and 3-month time points; (2) to determine the intraindividual variability in BP; (3) to quantify the proportion of patients reaching target BP by follow-up; and (4) to compare the telemonitoring measurements (and their variability) with those taken by an applanation tonometry device ("BPro") [18,19] that measures BP every 15 minutes over 24 hours in a subset of participants. Patients were eligible if they had evidence of CKD at risk of progression (detailed eligibility criteria and participant flow diagram can be found in Multimedia Appendices 1 and 2) [20].

Study Methodology

The study consisted of 2 phases: intensive monitoring and titration. During the first month intensive monitoring phase, participants were asked to measure their BP daily after resting for 5 minutes, with 3 measurements on each occasion. Changes in BP medication were avoided during this period, unless required by a local clinical team. At the end of the intensive monitoring phase, participants were offered a BPro device to wear for 24 hours. Irrespective of the use of the BPro device, a titration phase followed lasting a further 2 months. During titration, participants were instructed to reduce the frequency of their BP measurements to alternate days, and additional antihypertensive agents were introduced, as necessary, by a study clinician, according to concomitant medications and comorbidities, with a target SBP of <140 mm Hg (urine albumin/creatinine ratio <3 mg/mmol) or <130 mm Hg (urine albumin/creatinine ratio ≥3 mg/mmol); ie, according to current clinical guidelines [21]. At the 1-month and 3-month time points,

participants attended the Unit and were asked to complete a questionnaire assessing their confidence in using the telemonitoring system and its acceptability. The questionnaire included 2 sections, one derived from the System Usability Scale [22], asked at 1 and 3 months, and a second derived from the Technology Acceptance Model [23], asked only at month 3 (Multimedia Appendix 3). Statistical methods can be found in Multimedia Appendix 1.

Telemonitoring System

Participants were provided with an "off-the-shelf", Bluetooth-enabled BP monitor (A&D medical UA-767PBT-Ci) and a tablet computer with custom-developed software ("app"; Multimedia Appendix 4). Patients used the app to receive instructions about the measurements and then used the monitor to measure their BP. Readings were transferred wirelessly from the BP monitor to the tablet computer. Shortly after, the tablet computer would synchronize with the study central system. The central system was hosted by the Oxford University Hospitals National Health Service Foundation Trust and was managed by the local Information Management and Technology team. Its software comprised a database, where all the data were stored, and a password-protected Web interface for the study management. The interface allowed researchers to remotely monitor the home-recorded BP readings and the completed symptom questionnaires. Mobile internet connection was required for the readings to be transferred. The mobile app was capable of storing data in case of no connectivity and up until the tablet computer was in a location with sufficient internet access. If participants had a problem recording their measurements, they were able to contact the coordinating center during working hours. If the coordinating center did not receive BP readings within 5 days, the participant was contacted to identify and seek to resolve any problems.

Results

Between June 2016 and April 2017, 25 patients were recruited. Mean participant age was 58 (SD 11.0) years, with about half the cohort being >60 years old (Table 1). Among the 25 participants, 21 (84%) were male. The average BP at entry was 152/82 mm Hg and the mean eGFR was 36 (SD 13.3) mL/min/1.73 m^2. The most common primary causes of CKD were diabetes, glomerulonephritis, and hypertension.

Among the 25 participants, 18 (72%) provided >80% of the expected data and 13 (52%) provided >90% of the expected data throughout the whole study period (Figure 1). The results were similar for the intensive monitoring and titration phases, with 52% (13/25) subjects providing >90% expected data at both time points. BP data provided according to baseline characteristics are shown in Multimedia Appendix 5. The average number of readings provided via BPro (among the 13 participants who accepted it) was 51 (out of a maximum of 96; ranging from 7 to 75).

The telemonitoring system was found to be a generally acceptable method to record home BP, with mean (SE) System Usability Scale score of 84.9 (2.8) after the 1-month intensive monitoring phase (Multimedia Appendix 6). After the 2-month titration phase, the mean score was 84.2 (4.1). At the end of the study, an additional 6 questions assessing overall participant impressions of telemonitoring were asked (Multimedia Appendix 7), demonstrating good overall acceptance.

Intraindividual variability was calculated for each participant over the intensive monitoring phase. Among all participants, means of the SD values of intraindividual SBP and diastolic BP (DBP) were 13.8 and 7.4 mm Hg, respectively (Figure 2 and Multimedia Appendix 8). Among the 13 participants who accepted a BPro device, the mean BPro intraindividual SD (over 24 hours) was 10.4 mm Hg for SBP and 6.1 mm Hg for DBP. The SBP coefficient of variation for telemonitoring versus BPro was 9.4% (95% CI 7.8-10.9) versus 7.9% (95% CI 6.4-9.5; P=.05), and the DBP coefficient of variation for telemonitoring versus BPro was 9.7% (95% CI 7.2-11.5) versus 7.4% (95% CI 6.5-8.3; P=.01; Multimedia Appendix 9). The average SBP values provided by BPro and the telemonitoring systems were similar: telemonitoring mean SBP 140.6 mm Hg versus BPro mean SBP 138.1 mm Hg; telemonitoring mean DBP 80.1 mm Hg versus BPro mean DBP 83.6 mm Hg. At the individual participant level, the mean SBP difference was +3.1 mm Hg (SE 4.7) and the mean DBP difference was −3.4 mm Hg (SE 2.1).

A *post hoc* analysis showed that the coefficient of variation for SBP measured using telemonitoring over 1 week was 8.3% (95% CI 5.6-10.9), similar to that for a longer period.

There was an improvement in the proportion of patients in target BP range over the course of the study from 3 to 9. The mean SBP at baseline, 152.5 (SD 16.2) mm Hg, reduced to 138.52 (SD 14.3) mm Hg at 3 months (mean individual change −14.0 [SE 3.7] mm Hg). A change in dose (5 participants) or choice (8 participants) of antihypertensive medication was made in 13 of 25 subjects.

Table 1. Baseline characteristics of the participants.

Baseline characteristics	Participants
Age in years, mean (SD)	58 (11)
<40, n (%)	2 (8)
≥40 to <60, n (%)	11 (44)
≥60, n (%)	12 (48)
Sex, n (%)	
Male	21 (84)
Female	4 (16)
Systolic blood pressure in mm Hg, mean (SD)	152 (16)
<130, n (%)	2 (8)
≥130 to <150, n (%)	6 (24)
≥150, n (%)	17 (68)
Diastolic blood pressure in mm Hg, mean (SD)	82 (13)
<80, n (%)	11 (44)
≥80 to <90, n (%)	7 (28)
≥90, n (%)	7 (28)
Estimated glomerular filtration rate in mL/min/1.73 m^2, mean (SD)	36 (13)
<30, n (%)	11 (44)
≥30 to <45, n (%)	9 (36)
≥45, n (%)	5 (20)
Urine albumin:creatinine ratio in mg/mmol, median (interquartile range)	36.6 (101)
<3, n (%)	9 (36)
≥3 to <30, n (%)	1 (4)
≥30, n (%)	15 (60)
Cause of kidney disease, n (%)	
Diabetes	5 (20)
Glomerulonephritis	5 (20)
Hypertension	3 (12)
Other or unknown	12 (48)
Smartphone owner, n (%)	
Yes	17 (68)
No	8 (32)

Figure 1. Primary aim: proportion of days with at least 1 blood pressure (BP) measurement during intensive monitoring phase. OXHARP-1: Oxford Heart and Renal Protection Study-1.

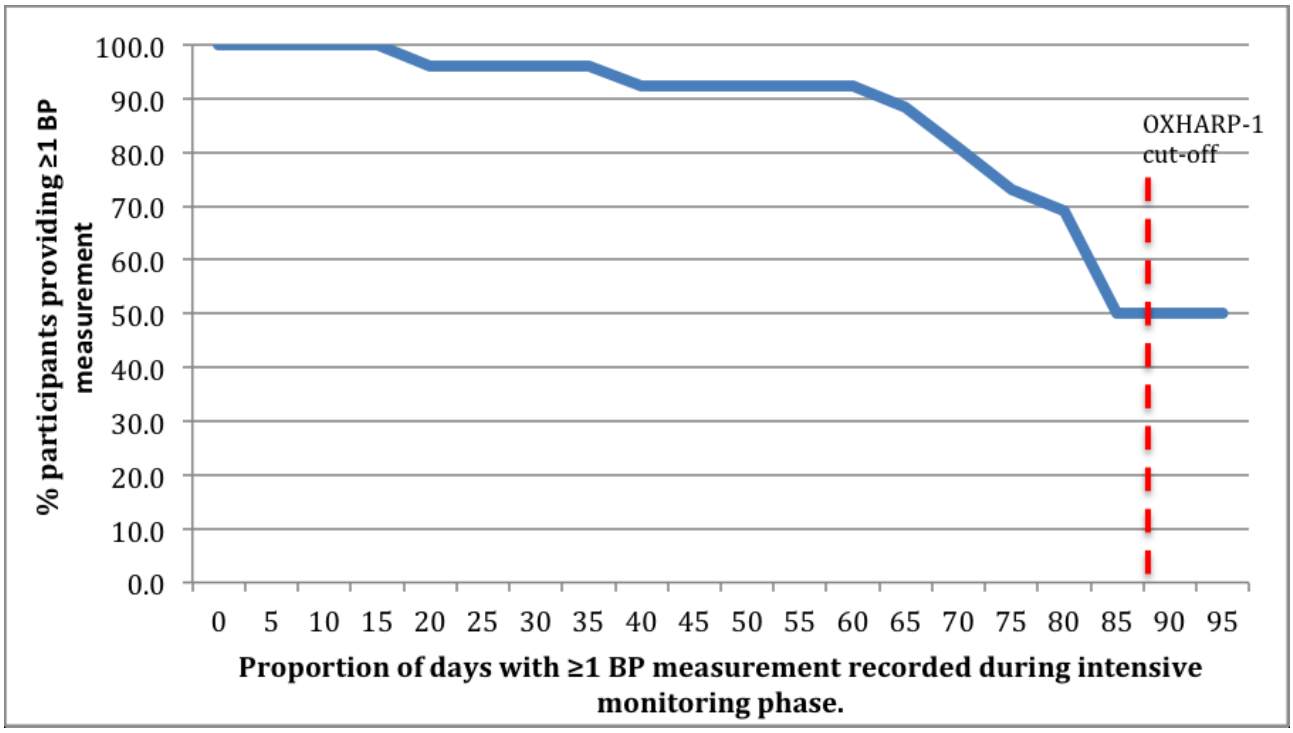
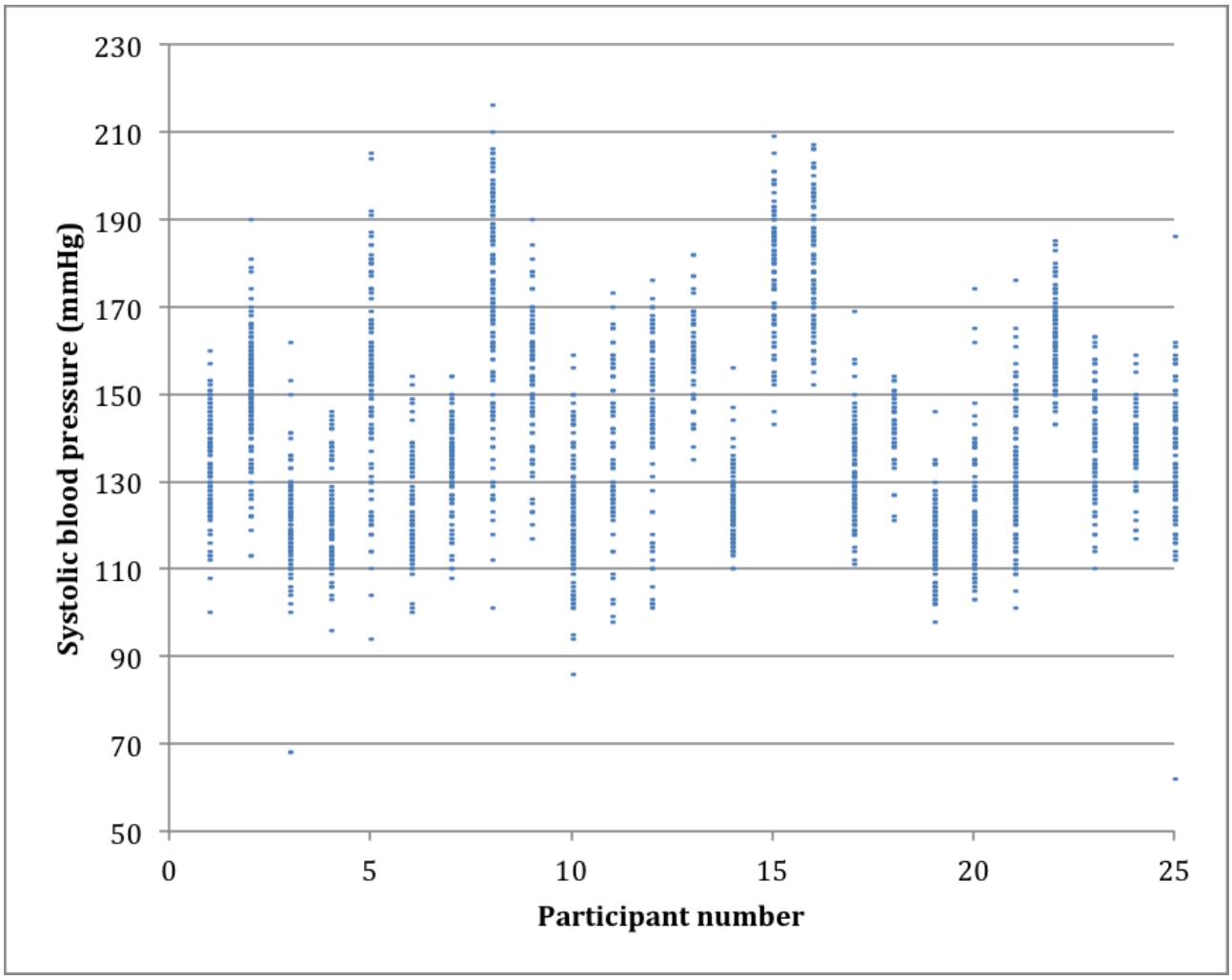


Figure 2. Individual systolic blood pressure measurements over the 3-month study period.



Discussion

The Oxford Heart and Renal Protection Study-1 suggests that telemonitoring among patients with CKD is feasible and well tolerated. Telemonitoring has previously been used in the management of heart failure [24], type 2 diabetes [25], and hypertension [13]. This is the first feasibility study looking at BP telemonitoring as a potential data collection method for randomized controlled trials in patients with CKD.

Recording of regular BP readings is beneficial in both routine care and clinical trials. Home monitoring reduces the need for clinic visits, which can be time consuming and expensive for both the participant and clinical center, with suggestions that telehealth interventions such as telemonitoring have an overall favorable cost-effectiveness profile [26]. Furthermore, central analysis of BP readings can improve safety by allowing clinicians to instigate more timely interventions in cases of prolonged hypo- or hypertension. To assess the primary aim of participants' acceptability of BP telemonitoring over 3 months, a threshold was set at subjects providing >90% of the expected BP data (54 readings in a 90-day period). Accordingly, 52% (13/25) of the subjects provided the target of >90% possible data, but when the threshold was set at 80%, 72% (18/25) of the subjects provided the requisite data and 92% (23/25) of subjects provided >65% of the possible BP readings. Therefore, this system provides sufficiently complete data to support either randomized trials or clinical care.

Our quantitative data are supported by questionnaire data, which suggests that participants found the technology usable. Estimation of longer-term acceptance also scored high, with all analyzed constructs being evaluated with acceptable results. Patients who owned a smartphone, that is, who are likely to be more confident with similar technology, were more positive in almost every area, while patients without a smartphone increased their questionnaire score from the 1-month to the 3-month time point. This may suggest that additional education of patients without smartphones before using similar equipment could be beneficial.

Telemonitoring equips patients with knowledge, skills, and technology to facilitate shared responsibility for their health care management. This must be balanced against the potential reduced patient-clinician contact and consequent missed opportunities to identify concerns. In order for a satisfactory quantity of data to be obtained so that home BP monitoring is feasible, participants must be able to understand and feel comfortable with the technology.

Recording and analysis of large numbers of BP readings by the patients at home allows for assessment of BP variability and gives a more accurate indication of a patient's true usual (ie, long-term average) BP status rather than isolated clinic readings [27]. As expected, there was considerable variability in the BP values provided by each individual over the period of monitoring. In order to compare the telemonitoring system with other available BP measurement technologies, the BPro system was given to a sample of our patients. The 2 systems produced similar overall average SBP and DBP measurements, although telemonitoring samples BP over a 1-month period compared with just 24 hours for BPro. The variability observed with telemonitoring was also similar to that observed over a 1-year period in the UK Heart and Renal Protection-III trial [28], which had identical inclusion criteria and found coefficients of variation of 9.0% and 9.0% for SBP and DBP, respectively. These results suggest that variability in BP is largely short term, with little additional variability over longer periods, suggesting that variability can be measured over relatively short periods [6].

The BP variability seen in our cohort indicates that more intensive monitoring would be of use in both trial settings and routine clinical care. Furthermore, BP variability may be associated with cardiovascular and mortality outcomes over and above the effect of mean BP [29,30], and thus, measuring this variability may refine risk prediction models.

The number of participants in our study was small, in keeping with a pilot study, which may limit generalizability of the results. Follow-up was only for 3 months; thus, we did not assess how durable the compliance with the study protocol would be in a long-term trial or routine clinical care. Telemonitoring in combination with clinical review of BP measurements and consequent modification of antihypertensive medication has previously been shown to have efficacy in improving BP control [14,30]. However, not all trials involving telemonitoring have achieved overall reduction in BP, and a longer trial duration is needed to assess whether this positive outcome is sustainable. Future work could aim to investigate the effect of an intensive versus standard BP-lowering strategy (using telemonitoring to monitor and direct treatment) on kidney function.

We found that the telemonitoring technology is a practical means of collecting large amounts of BP data with the additional benefit of enabling the recording of BP variability. BP telemonitoring, therefore, has potential in both future studies of CVD management and in improvement of routine clinical care in this at-risk group.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary methods: eligibility criteria and statistical methods.
[PDF File (Adobe PDF File), 25KB - cardio_v2i2e11332_app1.pdf]

Multimedia Appendix 2
Participant flow.
[PDF File (Adobe PDF File), 10KB - cardio_v2i2e11332_app2.pdf]

Multimedia Appendix 3
Participant questionnaires.
[PDF File (Adobe PDF File), 17KB - cardio_v2i2e11332_app3.pdf]

Multimedia Appendix 4
Screenshot of telemonitoring intervention as viewed by participants, illustrating trend of blood pressure and heart rate over two-week period.
[PNG File, 93KB - cardio_v2i2e11332_app4.png]

Multimedia Appendix 5
Blood pressure data provided according to baseline demographics.
[PDF File (Adobe PDF File), 26KB - cardio_v2i2e11332_app5.pdf]

Multimedia Appendix 6
System usability scale (SUS) scores at one month and three months.
[PDF File (Adobe PDF File), 8KB - cardio_v2i2e11332_app6.pdf]

Multimedia Appendix 7
Three-month questionnaire scores assessing overall participant impressions of telemonitoring at the end of the trial.
[PDF File (Adobe PDF File), 24KB - cardio_v2i2e11332_app7.pdf]

Multimedia Appendix 8
Individual diastolic blood pressure over the three-month trial period.
[PNG File, 51KB - cardio_v2i2e11332_app8.png]

Multimedia Appendix 9
Individual systolic blood pressure according to the BPro device (over 24 hours) and the telemonitoring system (over one week at the period of the BPro measurements) for 13 patients.
[PNG File, 139KB - cardio_v2i2e11332_app9.png]

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Abbreviations

BP: blood pressure
CKD: chronic kidney disease
CVD: cardiovascular disease
DBP: diastolic blood pressure
eGFR: estimated glomerular filtration rate
SBP: systolic blood pressure

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Original Paper

Multidisciplinary Smartphone-Based Interventions to Empower Patients With Acute Coronary Syndromes: Qualitative Study on Health Care Providers' Perspectives

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Abstract

Background: Postdischarge interventions are limited in patients with acute coronary syndrome (ACS) due to few scheduled visits to outpatient clinics and travel from remote areas. Smartphones have become a viable lifestyle technology to deliver educational and health interventions following discharge from hospital.

Objective: The purpose of this study was to identify the requirements for the delivery of a mobile health intervention for the postdischarge management of patients with ACS via a multidisciplinary focus group.

Methods: We conducted a focus group among health care professionals (n=10) from a large metropolitan hospital in May 2017. These participants from a multidisciplinary team contributed to a 1-hour discussion by responding to 8 questions relating to the applicability of smartphone-based educational and health interventions. Descriptive statistics of the focus group data were analyzed using SPSS. The qualitative data were analyzed according to relevant themes extracted from the focus group transcription, using a qualitative description software program (NVivo 11) and an ontology-based concept mapping approach.

Results: The mean age of the participants was 47 (SD 8) years: 3 cardiologists; 2 nurse practitioners; 2 clinical nurses; 2 research scientists; and 1 physiotherapist. Of these participants, 70% (7/10) had experience using electronic health intervention during their professional practice. A total of 7 major themes and their subthemes emerged from the qualitative analysis. Health care providers indicated that comprehensive education on diet, particularly providing daily meal plans, is critical for patients with ACS. In terms of ACS symptoms, a strong recommendation was to focus on educating patients instead of daily monitoring of chest pain and shortness of breathing due to subjectivity and insufficient information for clinicians. Participants pointed that monitoring health measures such as blood pressure and body weight may result in increased awareness of patient physical health, yet may not be sufficient to support patients with ACS via the smartphone-based intervention. Therefore, monitoring pain and emotional status along with other health measures was recommended. Real-time support via FaceTime or video conferencing was indicated as motivational and supportive for patient engagement and self-monitoring. The general demographics of patients with ACS being older, having a low educational level, and a lack of computer skills were identified as potential barriers for engagement with the smartphone-based intervention.

Conclusions: A smartphone-based program that incorporates the identified educational materials and health interventions would motivate patients with ACS to engage in the multidisciplinary intervention and improve their health outcomes following discharge from hospital.

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KEYWORDS

acute coronary syndrome; focus group; health care professionals; mobile phone; multidisciplinary; thematic analysis

Introduction

Information and communication technologies are changing the form and quality of the delivery of health-related services, commonly known as electronic health (eHealth). As an emerging field in the intersection of medical informatics, public health, and business, eHealth refers to health services and information delivered or enhanced through internet-based technologies [1]. Mobile health (mHealth) is the subset of eHealth that refers to the delivery of health-related services via mobile communications technology. The examples of mHealth solutions include patient-provider communication, point-of-care data exchange, remote monitoring of medical devices, public health alerts, patient education, and clinical trials information [1].

mHealth applications play a significant role in shaping the future of the health care delivery system and have captured the attention of health care stakeholders. mHealth interventions range from sending simple short message service (SMS) text message reminders to attend health care appointments and downloading health-related applications for use on mobile phones, to more complex technology that records real-time patient-generated data from wearable and nonwearable sensors. Recent research has explored the potential use of mHealth interventions in improving patient health outcomes, as well as its efficacy in managing chronic conditions such as diabetes, heart disease, and cystic fibrosis [2,3].

Among mHealth interventions, evidence regarding the feasibility and acceptance of smartphones is encouraging. As portable, cheap, and convenient devices [4,5], smartphones make good candidates for the delivery of behavioral interventions [4,5]. Furthermore, they offer the opportunity to bring behavioral interventions into important real-life contexts, which facilitate decision making and self-management of patients with chronic conditions particularly [5,6]. In addition to facilitating the sharing of behavioral and clinical data with health care professionals or peers, smartphones use internal sensors to infer contexts such as user location, movement, and emotion [7,8]. This facilitates continuous and automated tracking of health-related behaviors to provide timely and tailored interventions for patients.

Despite the vast attention paid to this new field, encouraging and sustained changes in health behavior require robust evidence to understand which methods are appropriate to develop smartphone interventions and who needs to be involved in the design and development of such interventions. Recent studies have addressed the lack of evidence with respect to health care professionals' involvement in the design and development of mHealth interventions, raising concerns regarding the reliability and accuracy of their medical content and the consequences for patient safety [9]. Since the very nature of smartphones poses a potential risk, and medical apps are increasingly used to support the diagnosis and management of diseases, facilitating health care professionals' involvement in the developmental process is crucial. Although vital, there is little in-depth, qualitative research that allows health care providers to describe their experiences, views, and strategies in providing mHealth interventions for patients with chronic conditions [10].

One appropriate method for mHealth development and customization is conducting focus groups [11]. Focus groups have several benefits for research since the qualitative contexts provide insight into social relations, and the information obtained during the discussion reflects the social and overlapping nature of knowledge. This is more informative than a summation of individual narratives through interviews and surveys [12]. Furthermore, the focus group discussion enables researchers to collect and analyze three forms of data including individual, group level, and the data generated based on participant interaction [13]. Although it is a well-established method in qualitative research, there is a lack of guidance regarding the use of focus groups for the development of digital interventions. Focus groups are a valuable tool for identifying and dissecting the knowledge, attitudes, and perceptions that influence an individual's behavior, as well as the barriers to and facilitators of behavioral change [14]. We used a qualitative focus group of health care professionals to identify the delivery requirements for an mHealth intervention for the postdischarge management of patients with ACS and to understand possible barriers and facilitators. To the best of our knowledge, this has not been addressed in this cohort of patients.

Methods

Study Aim

The present qualitative study was conducted as part of the Mobile Technology Enabled Rehabilitation-Acute Coronary Syndrome (MoTER-ACS) project. The overall aim of this project was to provide smartphone-based postdischarge educational and health interventions for patients with ACS. There were several reasons why focus group interviews were chosen as the method of data collection. First, this allowed us to identify a wide range of feelings, beliefs, and perspectives on the topic. Second, a group interview generates interaction and makes participants think about specific examples of strategies that would remain uncovered when using other methods of data collection, such as questionnaires or individual interviews. This interaction also makes it much easier to avoid suggestive or leading questions that hint at a specific strategy.

Participants

We conducted a focus group with health care professionals to explore their unique viewpoints. All participants were recruited from the Department of Cardiology at the Prince Charles Hospital (TPCH), Queensland, Australia. The focus group (n=10) consisted of a multidisciplinary team of cardiovascular experts, including 2 nurse practitioners, 3 cardiologists, 2 research scientists, 2 clinical nurses, and 1 physiotherapist.

Procedures

Participants were asked to provide written consent to the audiotaping of the session and completed a short questionnaire

on demographics information and their professional roles in the Department of Cardiology. Subsequently, the topic of the focus group was introduced, and to facilitate an open discussion, it was emphasized that participants were free to express their opinions, with both positive and negative responses being respected. In order to help the health care professionals become familiar with the specifications of the MoTER-ACS application and its Web portal, we presented a short video clip and a PowerPoint presentation of the features of a previously developed application and its portal for cardiac rehabilitation [15]. The smartphone app and its Web portal were used for the demonstration of graphs, content, and exercises.

In order to obtain standardization and consistency, a semistructured questioning guide had been developed by the researcher, which started with an icebreaker question asking participants about their experiences of using information communications technology-based interventions during their professional practice. The questioning guide included topics relevant to the contents and strategies that health care providers are interested in when considering a smartphone-based app, and the possible barriers to the engagement of patients with the intervention. Examples of topics and related questions are presented in Table 1. The study procedure was approved by the TPCH Human Research Ethic Committee.

Data Analysis

Two different methods were used for the analysis of focus group data. Figure 1 shows an overview of the study data analysis methods. The first method was an inductive content analysis that resulted in themes emerging from the data [16]. Verbatim transcriptions of the audiotaped session were generated, which then researcher read to familiarize herself with the data. The focus group transcriptions were imported into NVivo 11.0 for thematic analysis [17]. The NVivo software helps researchers to manage and organize data, facilitating the process of analysis, the identification of themes, the collection of insight, and the drawing of conclusions [18].

Thematic analysis allows the identification of themes from different levels within the data. An important part of this qualitative method of analysis was to devise a coding framework that helped to structure and reveal themes within the text [19]. We assigned codes to the text fragments, reflecting the words spoken by the participants in a more abstract way. Finally, the number of codes was reduced by combining similar codes into more comprehensive themes [16], and the expectations per questions resulted in a recommendation to include (clear majority of positive expectations) or exclude (clear majority of negative expectations) each theme in a smartphone-based intervention. NVivo requires the researcher to code the data and develop themes or categories; therefore, one can argue that the data analysis is principally subjective and allows the researcher to engage more meaningfully in the process of analysis. In order to reduce bias toward the identification of subjective themes, we investigated the impact of medical domain concepts on the analysis of the focus group data in our second approach. We employed semantic technologies, more concretely domain ontologies, which contain domain "concepts," their definitions, and their semantic relationships to each other, to extract the medical or clinical concepts from the focus group transcriptions.

Table 1. Examples of the questions used in the focus group discussion.

Domain	Question
Previous experience in the use of information communication technology (ICT) interventions	Did you have experience using any ICT based intervention for patient in your clinic or ward?
Contents of a smartphone-based postdischarge intervention for patients with acute coronary syndrome	In your opinion, what are the needs of patient with acute coronary syndrome that can be addressed via mobile phone based clinic? What don't you like to consider in the mobile phone based multidisciplinary clinic?
Concerns regarding a smartphone-based postdischarge intervention for patients with acute coronary syndrome	In your opinion, what are some concerns about the mobile phone–based clinic?

Figure 1. An overview of data analysis methods.

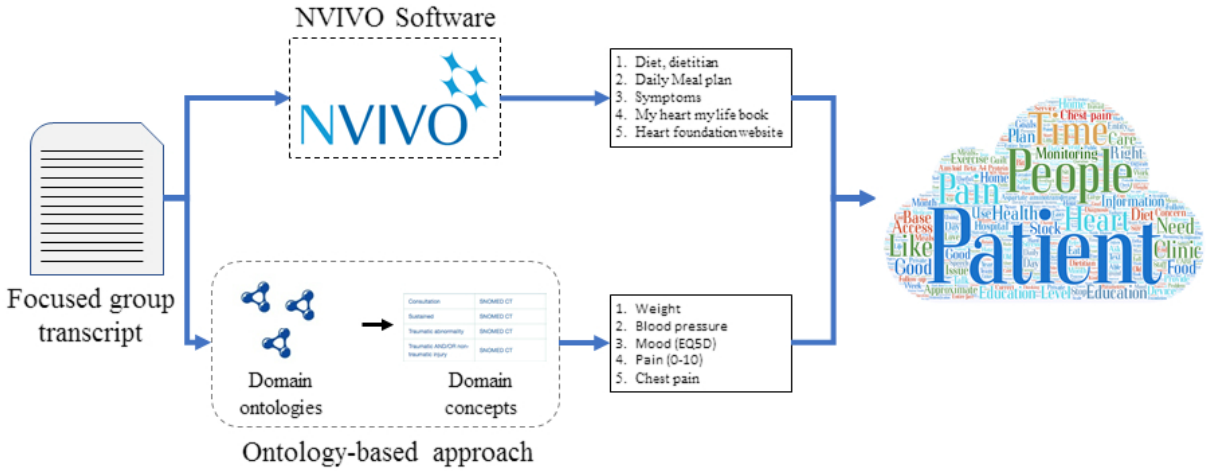

Table 2. Summary of selected ontologies.

Ontology	Description	Selection criterion
SNOMED CT	Systematized Nomenclature of Medicine - Clinical Terms	Quantitative
LOINC	Logical Observation Identifier Names and Codes	Quantitative
MESH	Medical Subject Headings	Quantitative
NCIT	National Cancer Institute Thesaurus (a vocabulary for clinical care, translational and basic research, and public information and administrative activities)	Quantitative
RCD	Read Codes, Clinical Terms Version 3	Quantitative
NIC	Nursing Interventions Classification	Qualitative
ICNP	International Classification for Nursing Practice	Qualitative
NCCO	Nursing Care Coordination Ontology (contains activities in which nurses engage while coordinating care among patients)	Qualitative
APAONTO	Psychology Ontology	Qualitative
ONTOPSYCHIA	OntoPsychia, social module (ontology of social and environmental determinants for psychiatry)	Qualitative

Due to their narrative nature, the transcriptions of the focus groups usually exhibit noisy and inconsistent characteristics in terms of the terminologies used throughout the discussion (eg, "heart attack" disorder may be referred to as "cardiac infarction," "myocardial infarction," or simply "MI" by different participants in the focus group). The main advantage of considering concepts in such analyses compared with a word-level analysis is that by normalizing the transcriptions to their concepts, semantically similar terms and phrases are consolidated and a large portion of unrelated terms are removed. Hence, this concept-level representation of the transcripts can provide a solid platform for more effective pinpointing of the essential themes. Our concept-level analysis was performed through the following steps: (1) selecting the appropriate ontology, (2) annotating the transcripts using the selected ontologies, and (3) analyzing the extracted concepts and mapping or deriving codes or themes from them. The details of these steps are described below.

Ontology Selection

We selected the most appropriate ontologies based on 2 different quantitative and qualitative criteria. In the former method, the ontologies were selected according to an ontology recommender system [20] that is available from National Center for Biomedical Ontology (NCBO) BioPortal [21]. The NCBO BioPortal [21] is a comprehensive repository of ontologies, which hosts over 500 different ontologies in the biomedical domain [22]. For a given dataset or corpus, the NCBO ontology recommender system ranks the suitability of the ontologies according to their coverage (ie, the more the concepts from an ontology appear in the given corpus, the higher their final ranking). As shown in Table 2, we reviewed the top 5 ontologies for each question in the focus group that were suggested by the ontology recommender system, finally selecting the 5 most frequent ontologies among the questions. From the qualitative perspective, we searched and reviewed medical ontologies and their descriptions to find more related ontologies in terms of their relatedness to the core disciplines to which our focus group belong (ie, mHealth, nursing, and psychology). In this approach, we retrieved and analyzed the available ontologies in the NCBO BioPortal, which led us to select 3 ontologies in the nursing domain and 2 ontologies in the realm of psychology (to the best of our knowledge, there is no available mHealth-related ontology in the NCBO BioPortal).

Annotation

The next step after ontology selection was the annotation process (ie, locating spans of text in the transcripts that refer to the concepts defined in the ontologies). In order to annotate the collected answers to the questions within the focus group data, we employed the NCBO concept annotator [23]. We developed a Java program that submits the text to the annotator through a RESTful API, a technology to communicate with Web services or applications, and processes the returned annotations (in an XML format) to extract the annotated concepts [24].

Concept Analysis and Code Derivation

The extracted concepts from all ontologies were combined, followed by calculation of their frequencies, both at the question level and the full transcript level. The analysis of the more frequent concepts led us to derive a number of new themes and to support the identified codes chosen during the manual analysis of the transcripts in the above-mentioned method.

Results

Main Findings

In total, 10 health care providers from the Department of Cardiology took part in this study. Among these, 70% (7/10) had experience in using mHealth interventions in their clinic or ward. Participants' characteristics are depicted in Table 3, demonstrating the diversity of health care providers with a range of disciplines and backgrounds. The study results are presented as major themes in Table 4. We presented recommendations for a mobile phone–based app and its Web portal to provide health interventions to patients with ACS.

Educational Instructions

The first topic that participants recommended for consideration with respect to patients with ACS was educational materials, including instructions on diet, providing daily meal plans, and education on ACS symptoms and its concepts, considering the patient's condition. Participants recommended to use the Heart

Foundation website and the "My heart, my life" book as resources for patient education [25].

> *More education can balance the symptoms to qualify chest pain.*
>
> *Education of ACS symptoms is necessary.*
>
> *From my point of view as physio, education and exercise are essential for our patients.*
>
> *When we educate the patients we introduce them the 'my heart my life' book published by the Heart Foundation. And when the time comes, they know couple of meal options that they like and have an idea about the portion sizes that they can and can't eat. All the patients find it very helpful.*
>
> *That's why they are very keen on the information they can get, they do like a meal plan.*

Health Measures

Four items were identified by the health care providers to be measured via the smartphone-based app, including body weight, blood pressure, mood, and pain. The use of the tool "European Quality of life Questionnaire-five dimensions" [26] was recommended to assess patients' health status. Health care providers recommended assessing the pain level of patients with ACS using a scale of 0-10.

> *Yes that's EQ5D, 10 points is great for mood assessment.*

Not Recommended for Self-Monitoring

Two ACS symptoms, shortness of breath and chest pain, were identified as items that health care professionals provided a negative opinion regarding daily monitoring via the smartphone app. Furthermore, participants indicated that assessing patients' electrocardiographs is not useful.

> *Shortness of breathing is the biggest issue to measure through phone apps. When I have started my ACS clinic, on the first 6 months, I see all the patients have chest pain. Then you start to work out how to differentiate that type of shortness of breath vs sleep apnoea vs asthma vs life time smoker, COPD type disease. I think if we put generalised options such as pre-chest pain, chest tightness, shortness of breath, we would get this very long by some patients as they are very good at writing in.*
>
> *You can't put that [the options in app that asks about patient's chest pain], because I think they would actually record chest pains. For example, if I press here I can get a sort of chest pain right now.*
>
> *How do we then have to react to that, can we just say it doesn't mean anything?*

Table 3. Participant characteristics.

Characteristics	Value
Age in years, mean (SD)	47 (8)
Gender, n (%)	
Male	5 (50)
Female	5 (50)
Marital status, n (%)	
Widowed or divorced	0 (0)
Married	8 (80)
De facto or other	1 (10)
Single	1 (10)
Highest level of education, n (%)	
<12 years	0 (0)
High school diploma	1 (10)
Some college or associates degree	0 (0)
Postgraduate degree	9 (90)
Profession, n (%)	
Cardiologist	3 (30)
Nurse practitioner	2 (20)
Research scientist	2 (20)
Clinical nurse	2 (20)
Physiotherapist	1 (10)

Table 4. Major themes.

Major themes and subthemes	References extracted from the transcription, n (%)
Educational instructions	
Diet, dietitian	11 (10.6)
Daily meal plan	7 (6.7)
Symptoms (define concepts)	7 (6.7)
"My heart, my life" book	4 (3.8)
Heart Foundation website	5 (4.8)
Health measures	
Weight	4 (3.8)
Blood pressure	4 (3.8)
Mood (European Quality of Life Questionnaire-five dimensions)	8 (7.7)
Pain (0-10)	6 (5.8)
Not recommended for self-monitoring	
Electrocardiograph	3 (2.9)
Chest pain	5 (4.8)
Shortness of breath	5 (4.8)
Real-time communication	
Nonverbal	3 (2.9)
FaceTime	4 (3.8)
Video calling	4 (3.8)
Engagement or motivational barriers	
Older age	5 (4.8)
Educational level	2 (1.9)
Access to technology	2 (1.9)
Staff workload	3 (2.9)
Monitoring or alarm	
Monitoring mechanism	3 (2.9)
Contacting patient when alarm is off	4 (3.8)
Intervention follow-up	
Long-term vs short-term	4 (3.8)

Real-Time Communication

Another strategy mentioned by the focus group participants was providing a communication facility for health care providers with which to communicate with patients when required. Video conferencing applications (eg, FaceTime) were identified as useful tools that facilitate communication between health care providers and patients. Nonverbal communication and observation of patients' body language through videoconferencing were also identified as useful assessment tools.

> *Ideally daily monitoring; but you can't see a patient in clinic every day. Realistically, you see a patient in a month or few months in clinic.*

> *Because there is so much nonverbal guide and I hate communication through phone because you don't get the non-verbals.*

> *Adding a FaceTime-equivalent option to phone calls is great. Because health related video calls might be more useful than just phone calls.*

Engagement or Motivational Barriers

Older age, low educational level, and lack of access to technology were identified as patient barriers to engage with smartphone-based interventions. Participants also mentioned that staff workload may increase due to monitoring and providing online support and this would be considered as a potential barrier from health care providers' perspective.

> *Younger population shouldn't be a problem, but, there are concerns about older population.*

They have to have internet access. They have to have mobile phone and they have to have an educational level where they have ability to read and understand.

Such phone-based intervention is great and will improve patient care but it can also add lots of workload on us through increase of online patients communications. In a classic way, we only see patients at clinic and then they go home but with this we need to follow-up.

Monitoring Mechanism or Alarm

Health care providers pointed out using a monitoring mechanism or alarm system within the portal to inform clinicians of patients' daily health measures and intervention usage.

I think you should identify what you just said when an alert goes off something needs to be done so people don't start dropping down with their exercise and if there's a red flag someone has to call them and get them to do what we want and see's what happens if they don't.

There should be a monitoring mechanism in place when an intervention is implemented and we should find out for how long monitoring is required.

Intervention Follow-Up

Participants acknowledged the importance of long-term follow-up versus short-term to achieve sustainability of the smartphone-based intervention for postdischarge patients.

Well, the advantages of phone-based intervention become apparent from a long-term perspective rather than a short-term follow-up period. Because, just fall back into their old habits after a while.

We need to implement it in a way to be able to follow them through a 6 and then 12 months periods. We get patients' initial compliance and then gradually decrease their involvement over time period.

Discussion

Principal Findings

In this qualitative study, we investigated the expectations of health care professionals with respect to a smartphone-based app and its portal to empower patients with ACS. The focus group resulted in useful feedback regarding different contents and features of such an application to provide postdischarge support and health management for patients with ACS. The important themes that emerged were educational instructions, health measures (body weight, blood pressure, mood, and pain), not recommended for self-monitoring (chest pain, shortness of breath), real-time communication, engagement and motivational barriers, monitoring or alarm mechanism, and intervention follow-up.

Health care professionals were most positive about providing educational instructions related to diet and ACS symptoms. Providing patients with daily meal plans and information related to healthy eating were strongly recommended by the participants. This is consistent with the current evidence showing that healthy eating is associated with a lower mortality risk in a large cohort of cardiac patients [27].

The most negative feedback received from the health care professionals was about the daily monitoring of ACS signs and symptoms, including chest pain and shortness of breath, via the mobile phone app. Participants pointed out that these health measures are subjective and vague and that it is required for patients to adequately understand symptoms associated with their condition and recognize the possible underlying reasons.

The health care providers suggested that measuring patient health status, including emotions and pain, would be informative in providing sustainable postdischarge support for patients with ACS. It is evidenced that depression is common after a coronary event [28], and it continues to remain underrecognized and poorly treated in the cardiac population [29]. Previous research has shown that patients with ACS benefit from cognitive behavioral therapy following an episode of myocardial infarction [30]; therefore, measuring emotional status will assist clinicians to identify depressive symptoms.

Based on our focus group results, a visual communication tool is required to assess patient health status and to provide psychosocial support and encouragement during the intervention. Studies in the fields of chronic disease and rheumatology have also found that patients considerably value face-to-face supervision by a health care professional [31,32]. Furthermore, it is known that multiple communications with clinicians result in a lower dropout rate and better adherence to interventions [33]. Accordingly, this will increase patient motivation and engagement and improve their empowerment.

Being older, having a low educational level, and lacking computer skills were identified as engagement and motivational barriers. This is consistent with the current evidence describing potential barriers for mHealth interventions. While mHealth technologies have the potential to improve population health outcomes and the delivery of health care services, there is a need to use and develop mHealth applications with caution. Using smartphone-based SMS text messaging requires a certain level of literacy. In addition, researching the use of "apps" to provide education and patient engagement in elderly populations may be hindered by the prevalence or access of certain technologies, such as smartphones, within this population. While the mobile platform remains flexible to engage patients via written, verbal, or video interactions, there is a need to consider how the elderly or individuals without advanced technical skills will interact with the device or participate in the intervention [34].

Strengths and Limitations

The strengths of the study design include providing structured questions during the focus group, as well as screenshots of the smartphone app. Furthermore, the themes that emerged from the thematic analysis were validated using concept mapping methodology. Facilitators were successful in creating a comfortable conversation environment, and participants felt confident in raising their positive and negative opinions on smartphone interventions for the postdischarge management of patients with ACS. A few limitations should be considered. Due

to time restrictions, we did not ask participants to discuss application usability or appearance; hence, this will be investigated in a future study with patient participants. Although clinicians are one of the key stakeholders in the use of mHealth technologies, the development of such interventions requires an iterative process of obtaining information and guidance from all stakeholders, including patients, information technology specialists, and providers. In this study, we aimed to focus on clinician perspectives, and patient perspectives will be investigated in a future study using different methodologies.

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Conflicts of Interest

None declared.

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Abbreviations

ACS: acute coronary syndrome
eHealth: electronic health
mHealth: mobile health
MoTER-ACS: Mobile Technology Enabled Rehabilitation-Acute Coronary Syndrome
NCBO: National Center for Biomedical Ontology
SMS: short message service

TPCH: The Prince Charles Hospital

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Short Paper

Quality of Medical Advice Provided Between Members of a Web-Based Message Board for Patients With Implantable Defibrillators: Mixed-Methods Study

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Abstract

Background: Patients use Web-based medical information to understand medical conditions and treatments. A number of efforts have been made to understand the quality of professionally created content; however, none have described the quality of advice being provided between anonymous members of Web-based message boards.

Objective: The objective of this study was to characterize the quality of medical information provided between members of an anonymous internet message board addressing treatment with an implantable cardioverter-defibrillator (ICD).

Methods: We quantitatively analyzed 2 years of discussions using a mixed inductive-deductive framework, first, for instances in which members provided medical advice and, then, for the quality of the advice.

Results: We identified 82 instances of medical advice within 127 discussions. Advice covered 6 topical areas: (1) Device information, (2) Programming, (3) Cardiovascular disease, (4) Lead management, (5) Activity restriction, and (6) Management of other conditions. Across all advice, 50% (41/82) was deemed generally appropriate, 24% (20/82) inappropriate for most patients, 6% (5/82) controversial, and 20% (16/82) without sufficient context. Proportions of quality categories varied between topical areas. We have included representative examples.

Conclusions: The quality of advice shared between anonymous members of a message board regarding ICDs varied considerably according to topical area and the specificity of advice. This report provides a model to describe the quality of the available Web-based patient-generated material.

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KEYWORDS

education of patients; information sharing; implantable cardioverter-defibrillator, data accuracy

Introduction

The vast majority of adults use the internet to research health issues to inform decisions, including whether or not to accept certain tests, medications, or devices[1,2]. Sources of Web-based information include both professionally created websites (eg, WebMD, Mayo Clinic, and industry materials) and user-created content on social media [3]. Web-based medical information fills a critical need for patient education, decision making, and emotional support [4,5]. Therapeutic interventions in many areas of medicine are becoming more complex, and patients forget 40%-80% of the information provided during medical appointments [6]. In contrast, patients can access Web-based information at any time and review it indefinitely. Web-based information fills the educational needs of patients outside of appointments as patients report acting on advice they find [7] and report being satisfied with the information and support they receive through Web [8].

The quality of information that patients encounter on Web varies, including the materials created by professionals. One investigation found that internet resources for ventricular assistance device candidates universally discussed the benefits of therapy, but only half reported risks and only 2 (of 77) mentioned palliative care or hospice[9]. Another examination of webpages of 262 transcatheter aortic valve replacement centers found that all discussed benefits of treatment, but only 26% mentioned any risk [10]. Such limitations within resources created by professionals are likely reflected in information shared between anonymous members of Web-based communities, where patient users logically have less access to the population-based information needed to contextualize advice about complex therapies. Nevertheless, patients who engage in a comprehensive Web-based search will encounter both forms of information.

We chose implantable cardioverter-defibrillators (ICDs) as a model to explore the quality of user-provided information appearing on medical message boards. Decisions regarding whether or not to implant an ICD involve trade-offs. ICDs may lengthen patients' lives, but have potential risks including infection, lower quality of life, increased hospitalizations, and potential suffering at the end of life [11-13]. Ongoing self-management and decision making are critical in ICD care. Therefore, it is important to ensure the accuracy of advice being acted upon by patients. While our prior work demonstrates that patients report learning about their ICDs from internet message boards [4], the quality of this information is unknown. This project sought to characterize the quality of medical information provided between commenters on an internet message board for patients with ICDs.

Methods

We utilized a mixed inductive-deductive approach for characterizing and quantifying the quality of medical information shared on an ICD message board. This approach was adapted from one used previously by our group [14]. To focus the content of discussions under analysis and allow for our ability to acquire permission to conduct the described analysis from the site's webmaster, we limited our search to comment threads appearing on 1 ICD-specific message board. The message board itself (which will not be identified per our agreement with the webmaster) required users to register a username and email address in order to compose posts or answer others' questions. No member of the research team had known relationships with the commenters, and no attempt was made to identify or contact commenters (whose posts were labeled with self-chosen avatars).

We included all discussions posted between January 1, 2015, and December 31, 2016. Each discussion was uploaded into Dedoose analytic software v 7.1.3 (SocioCultural Research Consultants, Los Angeles, CA) to facilitate team-based analysis. The project was deemed exempt by the local Institutional Review Board.

The analysis was conducted using a progressive deductive, inductive, and quantifying process adapted from our earlier inductive-deductive toolkit [14-15]. After converting all discussions appearing on the message board for analysis, the discussions were coded using a two-stage process, each of which was double coded by at least two members of the authorship team. First, the complete Web-based discussion threads were deductively coded for instances in which one commenter provided another with any form of medical advice. This included coding by two primary analytic team members (CK and HS), with any differences adjudicated by team consensus. Next, the primary author and a board-certified cardiac electrophysiologist (CK and LM, respectively) inductively coded each instance in which medical advice was provided by one commenter to another, creating a framework for analyzing both the topic discussed and the quality of advice. The resulting quality categories included the following: (1) Generally appropriate; (2) Controversial; (3) Inappropriate for most patients; and (4) Without sufficient context to support. Finally, we quantified the proportions of the quality of advice provided between commenters within each topical area.

Results

Advice Provided

The total corpus of data included 127 threaded discussions, having been composed by users with 234 unique avatars. During the study period, users posted an average of 2.74 (median 1) comments. Within these discussions, we identified 102 separate instances in which one member provided advice to another. We excluded 20 comments that discussed psychosocial adjustment to ICD placement or shock, leaving 82 pieces of explicit medical advice.

Topical Areas and Quality

Commenters provided advice in 7 conceptual areas: (1) Device information (n=19); (2) Programming (n=16); (3) Cardiovascular disease (n=9); (4) Procedures (n=6); (5) Lead management (n=4); (6) Activity restriction (n=15); and (7) Management of other conditions (n=13). The overall quality of advice provided was mixed, with 50% (41/82) advice deemed generally appropriate, 24% (20/82) inappropriate for most patients, 6% (5/82) controversial, and 20% (16/82) without sufficient context.

Table 1. Quality of information by topical category.

Topic category	Total, N	Generally appropriate, n (%)	Controversial, n (%)	Inappropriate, n (%)	Without sufficient context, n (%)
Device information	19	12 (63)	0 (0)	4 (21)	3 (16)
Programming	6	7 (41)	0 (0)	3 (18)	6 (35)
Cardiovascular disease	9	5 (56)	0 (0)	1 (11)	3 (33)
Lead management	4	2 (50)	2 (50)	0 (0)	0 (0)
Activity restriction	15	10 (67)	0 (0)	5 (33)	0 (0)
Procedures	6	2 (33)	0 (0)	4 (67)	0 (0)
Other disease management	13	3 (23)	3 (23)	3 (23)	4 (31)

However, the proportionate quality of advice provided within each of these categories varied considerably (Table 1).

Device Information

Information pertaining to ICD devices themselves, including basic functionality, battery life, and typical care processes, was either generally appropriate (12/19, 63%) or inappropriate (4/19, 21%). This advice typically focused on components of ICD systems, terminology, and capabilities.

> *They can implant a 3 lead with a defib as you stated...or deactive it and give you a S-ICD...defib only.* [Generally appropriate]

Programming

The quality of advice regarding the ICD programming, particularly pacing parameters, antitachycardia pacing, and arrhythmia detection algorithms, was mixed (7/16, 41%, appropriate; 3/17, 18%, inappropriate; and 6/17, 36%, without sufficient context).

> *After the MADIT-RIT study, ICDs are very rarely programmed to shock at heart rates lower than 200 or 220.* [Generally appropriate]

Comments coded as being without sufficient context included information regarding specific programming parameters and algorithms that may be appropriate in some, but not all, clinical circumstances.

> *AAIR (atrial rate adaptive) pacing may be preferable to DDDR (dual chamber rate adaptive) by avoiding an abnormal ventricular activation pattern.*
>
> *The pacemaker part of your implant does not limit you to 80 bpm.* [Without sufficient context]

Cardiovascular Disease

The quality of information addressing cardiovascular disease was similarly mixed, with 56% (5/9) coded as generally appropriate, 33% (3/9) as without sufficient context to support, and 11% (1/9) as inappropriate.

> *SSS stands for sick sinus syndrome. The sinus node is the heart's natural pacemaker. The SA node sends the electrical impulse to the atria to initiate a beat. When the SA node doesn't work properly, the PM steps in.* [Generally appropriate]

Pieces of advice coded as being without sufficient context to support again pertained to information only accurate to some clinical situations.

> *You could be in the 10% to 13% of patients (depending on which scientific publication you read) whom experience early heart failure hospitalization associated with "conventional pacing." Historic pacing bypasses the cardiac conduction system.* [Without sufficient context]

Lead Management

Only 4 instances including advice regarding lead management were identified, and these were split between being generally appropriate (2/4, 50%) and controversial (2/4, 50%). These comments were related to the advantages and disadvantages of lead extraction, a potentially high-risk procedure associated with ICDs.

> *They can be capped off and left there indefinitely. Extraction is a more specialized surgery, requiring an expert in the field and it has some risk. I would not do it unless it was necessary. There are no additional precautions to follow.* [Generally appropriate]
>
> *They do not have to leave leads in. I for one am not a damn junk yard and will not accept unused trash to be left behind...lead removal is quite common and not much of a big deal.* [Controversial]

Activity Restriction

Advice addressing whether or not patients with ICDs should avoid certain activities or environments was common (15 instances) and either generally appropriate (10/15, 67%) or generally inappropriate (5/15, 33%).

> *When people say 8 weeks, that's for lifting heavy and raising the arm overhead. Most docs say 4-6 weeks for that. And other than those two limits—overhead and lifting heavy—you can and should use the arm normally* [Generally appropriate]

Instances in which commenters incorrectly advised patients to avoid small electrical devices (electric razors, tattoo needles, etc) were particularly common among those coded as generally inappropriate.

Just don't get a tattoo directly over the device. Anywhere else is ok. [Generally inappropriate]

Procedures

While less common (6 instances), advice related to procedures was more problematic. All instances in this category were determined to be either generally appropriate (2/6, 33%) or inappropriate for most patients (4/6, 67%). The specificity of the advice related to quality, with general advice being coded as appropriate and specific advice being inappropriate.

(In reference to a question regarding an upcoming noncardiovascular procedure) Just make sure the surgeon and anesthesiologist know in advance. [Generally appropriate]

You were one of the less than 1% of PM patients that is inflicted with an infection. Should you need surgery again they will take extra precautions as a result. That makes the likelihood of another infection even less than 1% for you. [Generally inappropriate]

Other Disease Management

Advice regarding other approaches to managing cardiovascular disease and arrhythmias varied considerably in terms of quality, with 23% (3/13) of such comments being coded as generally appropriate, generally inappropriate, or controversial and 31% (4/13) deemed to not have sufficient context to support. Within this category, more specific advice (eg, to begin or stop specific medications or vitamins) were likely to be categorized as generally inappropriate or controversial.

I would advise you to start taking some vitamins; I buy them from this web site that I found here: (redacted) and I buy from this site: (redacted) I don't know if you can buy them from UK, but try to find similar ingredients. Also, doctors recommend to stay always hydrated which is mean to drink water with a bit sea salt or buy smart water that already have some ingredients. [Generally inappropriate]

If your ICD was implanted because you were losing consciousness, removal of that device or turning it off could mean that you lose consciousness while driving and would possibly kill yourself and/or someone else. Also if your heart has actually stopped and an ICD was implanted to restart your heart, turning it off could have fatal consequences. [Controversial]

Discussion

This analysis of the quality of medical information exchanged between members of an ICD-specific Web-based message board provides unique insight into the quality and accuracy of the advice patients will find on such websites. An accurate understanding of the quality of this information is critical, as patients or caregivers will use Web-based resources to help navigate complex decisions regarding ICDs [4]. Because the use of Web-based resources is a common component of more general efforts to learn and guide disease self-management behaviors in cardiovascular care [4,5,7], providers can use these findings to help guide patients to appropriate, accurate, and helpful resources and warn them of dangers particular to others with inaccurate, decontextualized, or controversial advice.

While the quality of advice shared between members of an ICD-specific Web-based forum was mixed, half of such advice was generally appropriate. The proportion of appropriate advice differed among aspects of ICD treatment. As little as a quarter of the advice regarding other disease management and as much as two-thirds related to activity restriction was of generally good quality. In many cases, the quality of any individual piece of advice was inversely related to its specificity. That is, nonspecific and context-independent advice is of higher quality in this venue. Examples include descriptions of cardiovascular disease, the general utility of devices, and encouraging patients to discuss individual questions with their health care providers. Conversely, controversial or inappropriate advice featured prominently in more specific discussions, including those addressing specific device programming parameters (which vary depending on individual patient characteristics), and discussions of device and procedure risks. Interestingly, risks associated with device implant and lead extraction procedures tended to be understated, while risks associated with everyday activities (use of electronic devices in particular) were generally overstated.

In cases where members sought general information about ICDs and their functionality, the advice provided on this message board provides a succinct, accessible, and well-organized resource of basic information of interest to ICD patients and candidates. In this sense, anonymously submitted information appearing on this internet message board acts as a resource that might help avoid gaps in fundamental understanding among patients observed previously [16-17] and may provide a reliable reference to which providers can refer patients. Unfortunately, other recent investigations into how patients with cardiovascular disease act on the information they find on message boards suggest that the questions they seek answers to on Web are highly specific in nature [7], which in our sample were more likely to produce problematic information. In this way, health care providers may be best served to prospectively advise patients to avoid acting on Web-based information, which is highly context and patient specific.

While these findings are relevant to patient education, they should be considered within several limitations. First, we only analyzed conversations occurring on a single message board and the quality of information elsewhere may differ, including discussions occurring on social media platforms (eg, Facebook and LinkedIn) [5], which allow for conversations on member and organization pages in addition to dedicated message boards. The anonymity offered by the avatar-based system used on the site we analyzed may increase the honesty and frankness of discussion [18], but may alter the questions asked and advice provided if compared to a similar discussion occurring on Facebook. Second, we did not make any effort to determine whether any members had specific expertise that would influence the quality or accuracy of the advice they provide to other members. While no members identified themselves as health care providers during the project period, it may be possible that some members were providing information as they

would to patients in a professional capacity. Nonetheless, these data may be representative of the quality of medical information appearing on many unmoderated, anonymously sourced message boards specific to cardiovascular and other treatment experiences.

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Conflicts of Interest

None declared.

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Abbreviations

ICD: implantable cardioverter-defibrillator

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Original Paper

A Mobile Phone–Based Healthy Lifestyle Monitoring Tool for People With Mental Health Problems (MyHealthPA): Development and Pilot Testing

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Abstract

Background: People with mental health disorders live, on average, 20 years less than those without, often because of poor physical health including cardiovascular disease (CVD). Evidence-based interventions are required to reduce this lifespan gap.

Objective: This study aimed to develop, test, and evaluate a mobile phone–based lifestyle program (MyHealthPA) to help people with mental health problems improve key health risk behaviors and reduce their risk of CVD.

Methods: The development of MyHealthPA occurred in 3 stages: (1) scoping of the literature, (2) a survey (n=251) among people with and without the experience of mental health problems, and (3) program development informed by stages 1 and 2. A small pilot trial among young people with and without mental health disorders was also conducted. Participants completed a baseline assessment and were given access to the MyHealthPA program for a period of 8 weeks. They were then asked to complete an end-of-treatment assessment and a follow-up assessment 1 month later.

Results: In the study, 28 young people aged 19 to 25 years were recruited to the pilot trial. Of these, 12 (12/28, 43%) had been previously diagnosed with a mental illness. Overall, 12 participants (12/28, 43%) completed the end-of-treatment assessment and 6 (6/28, 21%) completed the follow-up assessment. Small improvements in fruit and vegetable consumption, level of physical activity, alcohol use, and mood were found between baseline and end of treatment and follow-up, particularly among people with experience of mental health issues. Most participants (history of mental illness: 4/7, 57%; no history of mental illness: 3/5, 60%) reported the program had above average usability; however, only 29% (2/7, no history of mental illness) to 40% (2/5, history of mental illness) of participants reported that they would like to use the program frequently and would recommend it to other young people. Participants also identified a number of ways in which the program could be improved.

Conclusions: This study describes the formative research and process of planning that formed the development of MyHealthPA and the evidence base underpinning the approach. The MyHealthPA program represents an innovative approach to CVD risk reduction among people with mental health problems. MyHealthPA appears to be an acceptable, easy-to-use, and potentially effective mHealth intervention to assist young people with mental illness to monitor risk factors for CVD. However, ways in which the program could be improved for future testing and dissemination were identified and discussed.

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KEYWORDS

telemedicine; mental health; cardiovascular diseases; mhealth; smartphone; mobile phone

Introduction

People with mental health disorders live on average 20 years less than the general population [1]. Cardiovascular disease (CVD) is the leading cause of this excess mortality and is responsible for more deaths in this population than suicide [2]. Smoking, alcohol misuse, physical inactivity, and poor diet are consistently identified as the top 4 behavioral risk factors associated with CVD in the general population [3]. These modifiable behavioral risk factors are over-represented among people with mental health problems [4]. These behaviors also commonly co-occur in clusters, which presents opportunities to adopt a multiple health behavior–change approach, in which behavioral risk factors are targeted together, rather than in isolation.

Recent research has shown that changing multiple behavioral risk factors and reducing CVD risk is possible among people with mental health problems [5]. However, because of time constraints and lack of awareness, training, and resources, mental health services often confine their services to mental health issues alone, neglecting physical health and CVD risk [6]. In addition, many people with mental health problems do not access treatment for their concerns, with Australian data indicating that only around one-third of people with mental health problems in the past 12 months accessed treatment [7]. There is a need to develop effective interventions to address CVD risk among this population and that are accessible both within and outside mainstream health and mental health services. It is also imperative that these interventions are scalable and of low burden to both clinicians and patients.

Mobile phone–based interventions to reduce CVD risk may be able to address these needs. Through mobile devices, individualized interventions can be provided inexpensively to a large number of people, including those who are geographically isolated, at a time and place when they are ready to engage in treatment [8]. Mobile phone–based interventions have been shown to be effective in improving a range of behavioral risk factors associated with CVD, including physical activity, weight loss, alcohol use, and smoking cessation, as well as mental health problems, including depression and anxiety [9]. They may also be especially useful in engaging people with mental health problems with treatment. In a recent systematic review, Donker et al [10] found adherence rates for smartphone apps targeting a range of mental health issues were high [10]. This study describes the development and initial evaluation of the first mobile phone–based monitoring tool to target multiple modifiable CVD behavioral risk factors (smoking, alcohol misuse, poor diet, and inadequate physical activity) for people with mental health problems (MyHealthPA).

Methods

The development of MyHealthPA occurred in 3 stages: (1) scoping of the literature, (2) survey among people with and without experience of mental health problems, and (3) program development. These stages are detailed below.

Stage 1: Scoping of the Literature

This stage aimed to identify, from previous research, the key strategies required to improve behavioral risk factors associated with CVD and develop a mobile phone–based tool for people with mental health problems. The main features considered in our examination of the existing literature included the intervention content and the delivery and design of the intervention.

Intervention Content

Ward et al [11] conducted a meta-review of nonpharmacological lifestyle interventions for CVD risk factors among the general population and those with severe mental disorders. All of the interventions they identified addressed behavior change related to diet or exercise and revealed a number of common factors for success in these interventions. This was a common observation among the existing literature identified (ie, a focus on diet and exercise and not tobacco or alcohol misuse, despite these being key behavioral risk factors for CVD and highly prevalent among people with mental health disorders). The review by Ward et al [11] reported that many successful interventions employed cognitive behavioral therapy (CBT) techniques (eg, goal setting, self-monitoring of food intake and physical activity, and the use of a structured curricula to encourage behavior change), with use of a greater number of strategies associated with improved results. Other key elements of successful interventions included the use of multiple components (eg, addressing diet and exercise and using CBT techniques), personalization of diet and exercise regimens, increased duration of the intervention, higher frequency of contact, and multidisciplinary teams. Of note was that face-to-face interventions (as opposed to computer-based interventions) were associated with better results in this meta-review. However, Ward et al [11] only included studies published before 2012 and did not include any mobile phone–based interventions. The field of technology-based behavior change interventions has grown considerably since that time, and thus, this particular observation may no longer be valid. Although fewer reviews of interventions among individuals with severe mental illness were identified, Ward et al [11] found that among this subpopulation, single component programs were also less effective than those employing multiple components. However, few interventions among this population actually employed multiple components. Manualized interventions were also rarely employed, group sessions rather than individually personalized interventions were more commonly used, and interventions were often of short duration.

Baker et al conducted the only trial to-date of interventions for people with mental health disorders targeting smoking and alcohol use as well as diet and exercise [5]. The trial compared an intensive face-to-face intervention with a brief telephone-based intervention, both of which used CBT and motivational interviewing techniques, including self-monitoring and goal setting, to encourage behavior change across multiple targets. In both conditions, there were significant improvements in smoking abstinence, cigarettes per day, and expired carbon monoxide at 15-week and 12-month follow-up. A significant reduction in 10-year CVD risk of participants was observed at

15-week follow-up, which continued to the 12-month follow-up for the brief telephone-based condition. In a subsequent trial by the same group, a telephone-based intervention targeting fruit and vegetable consumption, leisure screen time (a newer health behavior of increased research interest), and alcohol use was also associated with significant improvements in fruit and vegetable consumption, quality of life, and leisure screen time and sitting time (also a new health behavior receiving increasing research interest) [12] in people with mental health problems.

Key CBT techniques such as self-monitoring and goal setting have been identified as central to successful CVD risk–reduction interventions among people with and without mental health problems. Meta-analyses provide evidence for the efficacy of self-monitoring of diet, physical activity, weight, and tobacco and alcohol use [13-16]. The ability of patients to easily monitor their behaviors and moods, set goals, and track their progress through mobile phone–based interventions has also been identified as one of the many advantages of using mobile devices to deliver health and mental health interventions [10,17]. Electronic self-monitored mood has also been found to be valid compared with clinical rating scales of depression [18].

Delivery and Design of the Intervention

The available literature suggests that even the most popular existing mobile health apps (eg, MyFitnessPal) have poor usability, even among the general population [19]. People with mental health problems, particularly those with severe mental illnesses, can experience concomitant cognitive impairments, which may mean mobile phone–based interventions using standard design principles are less usable [8,20].

Rotondi et al [20] conducted a series of design and usability studies among people with severe mental illnesses to create the first empirically based design model for the development of eHealth tools for this population. Their Flat Explicit Design Model (FEDM) contains 18 design recommendations that aim to reduce the cognitive effort required to effectively use an eHealth tool and thus allow these tools to be usable by people with severe mental illnesses. This model recommends a *flat design* (with no more than 2 levels in the site structure of the website or the app), using descriptive labels and explicit instructions (as opposed to succinct, but often abstract labels or symbols) and using text written at a low reading level [20,21]. Employing this approach is argued to reduce the need for users to think abstractly, rely on working memory to create a mental model of the website or app, use executive functions to search for information or explore the website or app effectively, and concentrate to filter out distracting contents.

Ferron et al [21] conducted some of the only research to investigate the usability of publicly available mobile health apps among people with mental health problems. They investigated whether smoking cessation apps are usable by smokers with psychotic disorders. Overall, 21 smokers with a psychotic disorder assessed the usability of 9 smoking cessation apps (previously rated to be of high quality by expert reviewers). Their research identified multiple features of currently available smoking cessation apps that caused these apps to be inaccessible or ineffective among most smokers with psychotic disorders. These barriers included the use of text-heavy designs; difficulty navigating the apps because of the use of jargon and abstract symbols; and the use of subtle directions, such as the provision of only small symbols or 1-word instructions as cues how to use the apps [21].

Stage 2: Survey Among People With and Without Experience of Mental Health Problems

To ensure the MyHealthPA program was tailored to the needs of people with mental health problems, scoping research with potential end users of the program was conducted.

Participants and Procedure

Participants were recruited via paid and unpaid advertisements on social media to participate in a brief survey of attitudes toward using mobile phone–based technology for health-related behaviors. Those who clicked on the study advertisements were directed to a Web-based information statement and consent form and then directed to the self-report questionnaire hosted by the Web-based survey program Fluid Surveys if they chose to participate. The survey was also sent to 200 members of a community research register who were asked to return the consent form and self-report questionnaire in a reply-paid envelope. Participants were required to be aged over 18 years and currently living in Australia.

Measures

The survey included items regarding demographic characteristics, mobile phone access and use, and openness to using mobile phone technologies for health purposes. Participants were also asked to indicate if they had ever been diagnosed with a mental illness. Current psychological distress was assessed using the Patient Health Questionnaire, PHQ 4 [22]. Participants indicated if they were a current smoker (yes or no) and their use of tobacco and alcohol in the past 3 months (never, once or twice, monthly, weekly, and daily or almost daily).

Findings

Of the 722 people who accessed the Web-based survey, 334 (334/722, 46.2%) provided consent and were eligible to participate in the study and 249 (249/722, 34.4%) provided sufficient data to be included in the analysis of this study. Of the 200 members of the community research register contacted, 35 (35/200, 17.5%) returned completed questionnaires. The final sample of 284 participants was aged between 18 and 77 years (mean 30.64, SD 14.49). The majority of participants were females (152/284, 53.5%), held a university degree (141/284, 49.6%), were employed (156/284, 54.9%), and lived in a major city (223/284, 78.5%). Approximately half of participants reported a history of mental illness (137/284, 48.2%), including 109 with a history of depression, 108 with a history of anxiety, 5 who had been previously diagnosed with a psychotic disorder, 11 with an eating disorder, 5 with a bipolar disorder, 8 with a borderline personality disorder, and 6 with a posttraumatic stress disorder. However, most (181/251, 72.1%) reported no (or mild) current psychological distress.

Of the 251 participants who provided information about their mental health status, 144 (144/251, 57.4%) reported experiencing mental health problems, including 61 (61/251,

24.3%) who reported a history of mental illness and current psychological distress, 73 (73/251, 29.1%) reporting a history of mental illness but no current psychological distress, and 10 (10/251, 4.0%) reporting current psychological distress but no history of mental illness. Overall, 107 participants (107/251, 42.6%) reported neither a history of mental illness nor current psychological distress.

Participants reported extremely high levels of access to mobile phone technology, with 93.5% to 100% of participants reporting they owned or had easy access to a mobile phone. The majority of participants had previously used their mobile phone to access information or treatment for physical health concerns (184/251, 73.3%). Most participants with a history of mental illness or current psychological distress had also done so specifically for mental health concerns (114/144, 79.2%). Fewer had accessed information or treatment for drug and alcohol concerns (52/144, 36.1%). Across these different types of health concerns, most participants reported that they would consider accessing treatment via a mobile phone (62.3%-75.8%).

When asked if they were interested in receiving information or treatment via a mobile phone about a range of health concerns, few participants (12.5%-29.1%) were interested in specifically addressing CVD (see Table 1). However, more participants did express interest in addressing key CVD behavioral risk factors. For example, most participants were interested in addressing physical activity (116/190, 61.1%) and diet (93/190, 49.0%) via mobile phone. Among those with mental health problems (ie, a history of mental illness or current psychological distress, n=111), the majority were also interested in addressing mood (60.0%-64.6%) and mental health issues (72.9%-87.5%).

Although very few participants, overall, were interested in addressing smoking (20/190, 10.5%) or alcohol use (24/190, 12.6%) via a mobile phone, interest in addressing these issues was higher among frequent users of these substances. Among participants reporting daily (or almost daily) use of alcohol, 60% (6/10) of participants with a mental health problem (Those with current distress, a history of mental illness or both) reported that they would be interested in addressing alcohol use via a mobile phone. Only 17% (2/12) of daily drinkers without a mental health problem were interested in addressing alcohol use via a mobile phone. Similarly, among daily smokers, 81% (13/16) of participants with mental health problems were interested in addressing smoking, and 75% (3/4) of smokers without a mental health problem were interested in addressing smoking.

Stage 3: Program Development

The initial content of MyHealthPA was informed by the scoping of the literature and survey research described above. This study suggested it is appropriate to address risk of CVD for people with mental health problems using a mobile phone–based intervention. It also highlighted that the MyHealthPA program needed to, at a minimum, include self-monitoring and goal-setting techniques, provide feedback on behaviors of the users, adopt a multiple health behavior change framework, and should address individual risk factors as opposed to CVD specifically. The initial content was written so that it was brief, there was minimal introductory content, it explicitly communicated concepts, and it was easy to read, in line with the principles of the FEDM [20].

Furthermore, 2 academics and 2 clinicians with expertise in health behavior change among people with mental health problems reviewed the initial written content. Feedback on the initial content was that it was accurate and correct in accordance with the most current research and behavior change techniques. Any information that was queried was checked with the literature and changed accordingly. Minor changes to the language to improve the readability of content were also made.

A beta version of the MyHealthPA program was then developed. Initial usability testing was first undertaken, and any technical issues identified were resolved before the app was reviewed by 2 academics, 2 clinicians, and 2 mental health consumers. These reviewers provided feedback regarding the final content, usability, and appeal of the program. The beta version of MyHealthPA was informed by the FEDM [20]. For example, the program was designed so that it had a shallow hierarchy; therefore, to access the majority of features of the program, users need to go only 1 level past the initial home screen and only 2 levels for a minimal number of features. A simple pop-up menu bar at the top left of the home screen was used to facilitate navigation and comprehension, and a relatively plain visual design was employed to reduce distractions for users. During the beta feedback phase, reviewers were asked to rate their mood using a set of *emoticons* representing different ways they might be feeling (eg, happy, calm, tired, lonely, sad, angry, and depressed) to determine the validity of using these images and labels to represent mood.

The key change made to the program based on feedback from reviewers was that the emoticon mood-rating system was changed to a 10-point Likert scale where users answer the question “How do you feel today?” Descriptors of 1 = the worst I have ever felt of could ever imagine feeling; 5 = in the middle, neither very bad or very good; and 10 = the best I have ever felt or could ever imagine feeling were used to help guide users’ responses. If users select *1* on this scale, they are automatically presented with a pop-up message asking if they are ok, provided with the contact details for emergency helplines (eg, Lifeline and Kids helpline), and instructed to call emergency services if life is in danger or they are in need of emergency assistance.

The MyHealthPA Program

MyHealthPA provides users with feedback regarding smoking, alcohol use, fruit and vegetable consumption, and physical activity; allows users to easily record their health behaviors and mood on any mobile device; and track their progress over time. Users can also set health behavior goals, and reminders are sent to record behaviors (see Figure 1).

When users first access MyHealthPA, they are asked to complete a brief questionnaire regarding their health behavior and mood, at the end of which they are provided with personalized feedback regarding their health behaviors based on national guidelines [23-25]. Users can then access the full MyHealthPA program, which consists of the following 7 pages or sections:

1. Home page: This page provides a simple and visual portrayal of the diary entry of the current day, a motivational

quote from the Personal Assistant avatar, and a menu to access all other pages.

2. My Diary: This page allows users to record their mood and health behaviors (number of cigarettes, number of alcoholic drinks, minutes of physical activity, and/or serves of fruits and vegetables consumed) for the day. Participants can also record if they have taken any medications as prescribed that day and any withdrawal (scale name) or adverse psychiatric symptoms (scale name) they may have experienced.
3. My Progress: This page allows users to view their progress via an interactive graph that users can use to display changes in multiple health behaviors and/or mood over time.
4. My Goals: This page allows users to set goals, including due dates for these goals, related to each of the measured health behaviors (eg, set a quit date and quit smoking, reduce the number of alcoholic drinks in a day to XX, eat 2 servings of fruit per day, and exercise XX times per week) and displays any current goals they have set. A pop-up textbox also provides users with tips on setting Specific, Measurable, Active, Realistic, and Time-limited (SMART) goals.
5. My Profile: On this page, users can enter and edit their personal information (eg, name, gender, height, weight, contact details, and any medications they are taking) and customize the notifications they receive from the program.
6. Resources: This page provides links to Web-based resources that contain extra information and tips about changing health risk behaviors.
7. Emergency: This page provides contact details for relevant helplines. Participants are instructed to contact one of these services or contact emergency services if they are thinking about suicide or experiencing a personal crisis.

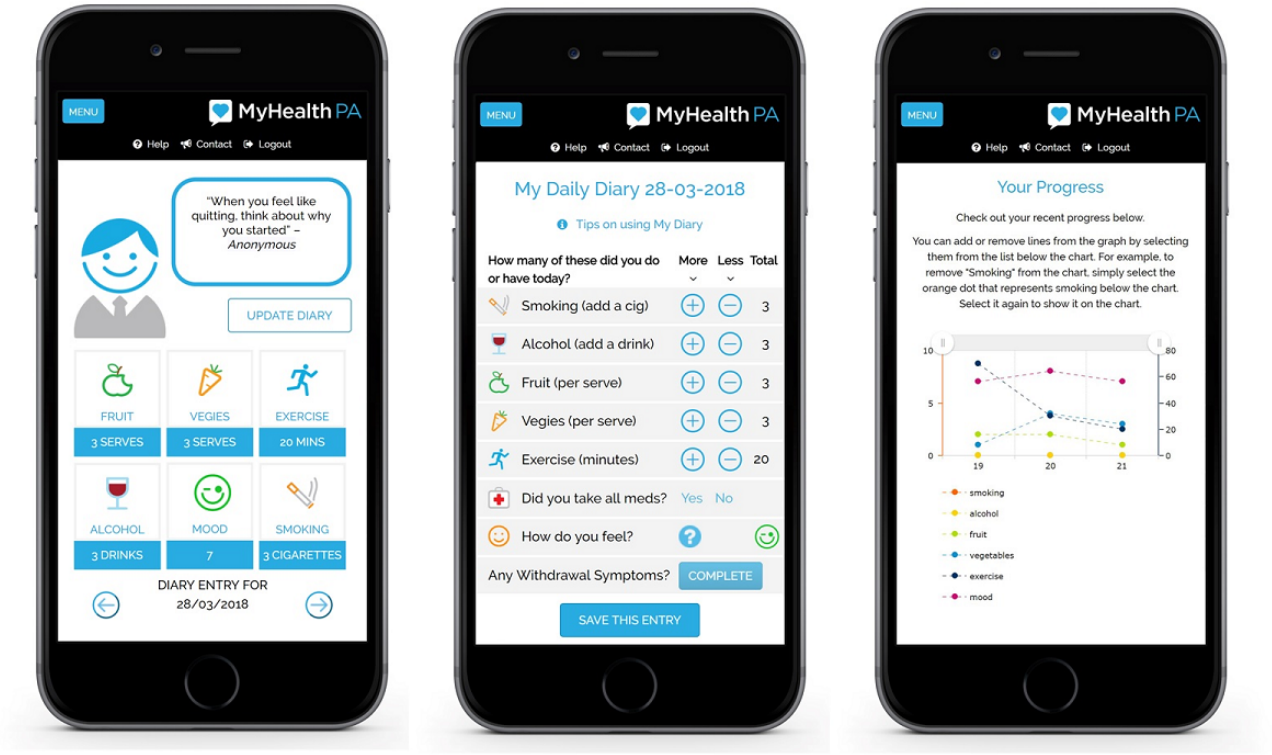
MyHealthPA was developed as a responsive website (as opposed to a native and downloadable app) optimized for use on a mobile phone, but that also allowed users to view the program on any device with internet access.

Table 1. Interest in addressing specific health issues via a mobile phone.

Health issue	History of mental illness, current distress[a] (N=48), n (%)	History of mental illness, no distress (N=55), n (%)	No mental illness, current distress (N=8), n (%)	No mental illness, no distress (N=79) n (%)
Diet	23 (48)	30 (55)	3 (38)	37 (47)
Physical activity	29 (60)	37 (67)	5 (63)	45 (57)
Cardiovascular disorder	7 (15)	16 (29)	1 (13)	16 (20)
Smoking	9 (19)	6 (11)	1 (13)	4 (5)
Alcohol use	7 (15)	12 (22)	1 (13)	4 (5)
Mood	31 (65)	33 (60)	5 (63)	18 (23)
Mental health	35 (73)	41 (75)	7 (88)	30 (38)

[a]Distress: psychological distress.

Figure 1. Screenshots of the MyHealthPA program.



Pilot Testing

To evaluate the feasibility and potential efficacy of MyHealthPA, particularly among people with mental health problems, a pilot study was conducted among young people with and without a previous diagnosis of a mental illness. The pilot study used a pre-post design. Participants were recruited via flyers placed on university campuses, paid and unpaid advertisements on social media (eg, Facebook or Twitter), and on the institution website of the lead author.

Potential participants were asked to complete an initial Web-based screening questionnaire. To be eligible, participants were required to be aged 18 to 25 years, live in Australia, and have access to a mobile phone with internet access. Upon meeting eligibility criteria, participants were asked to provide informed consent and complete a Web-based baseline assessment. They were then given access to the MyHealthPA program for a period of 8 weeks, after which they were asked to complete a Web-based end-of-treatment assessment and a Web-based follow-up assessment 1 month later (12 weeks after baseline). All Web-based assessments were hosted by Survey Monkey.

Measures

The baseline assessment contained items regarding demographic characteristics; medical history, including if they had ever been diagnosed with a mental illness; frequency of mobile phone use; use of mobile health apps; current health behaviors; and current psychological distress (using the 4-item version of the PHQ 4) [22].

The health behaviors measured were smoking (smoking status and cigarettes per day), alcohol use (Alcohol Use Disorders Identification Test—Consumption items, AUDIT-C [26], a brief measure of hazardous and harmful alcohol use), diet (serves of fruits and vegetables consumed per day), and physical activity (International Physical Activity Questionnaire [27]). This information was then used to calculate participants' Lifestyle Risk Index (LRI) [28]. The LRI is a composite score, which represents compliance with national guidelines for the 4 health behaviors. Each behavior is assigned a score of *0* (compliance with guidelines, *not at-risk*) or *1* (noncompliance with guidelines, *at-risk*). Scores are then summed for an overall LRI score. The LRI method has been previously validated by Ding et al [28] in a large cohort of Australian adults. Furthermore, such an approach has been recommended for generating quantifiable outcomes in interventions for multiple risk factors [29].

Health behaviors and current psychological distress of participants were also assessed at end of treatment and follow-up. In addition, as a part of the end-of-treatment assessment, participants were asked to answer a series of questions related to the usability and acceptability of MyHealthPA, which included the System Usability Scale (SUS) [30], and open-ended questions regarding which sections of the program participants' felt worked well or did not work well and any suggestions to improve the program.

Results

Overview

A total of 102 participants completed the initial Web-based screening questionnaire. Of these, 35 (35/102, 34.3%) were eligible to participate and provided informed consent; however, 7 (7/35, 20%) did not complete the Web-based baseline questionnaire, leaving a total of 28 (28/35, 80%) participants who were included in the pilot study and granted access to the

MyHealthPA program. A total of 12 (12/28, 43%) participants also completed the end-of-treatment Web-based assessment, and 6 (6/28, 21%) participants completed the follow-up assessment 1 month later.

Participant Characteristics

A total of 12 (12/28, 43%) participants reported that they had previously been diagnosed with a mental illness. Descriptive statistics are reported separately for participants with and without a history of mental illness. Of these, 9 (9/12, 75%) participants reported having previously been diagnosed with depression, 9 (9/12, 75%) with anxiety, 2 (2/12, 17%) with an eating disorder, 2 (2/12, 17%) with a bipolar disorder, and 1 (1/12, 8%) with a borderline personality disorder. As shown in Table 2, the majority of participants in both groups were females. Participants had a mean age of 21 years, most were single and had never been married, were born in Australia, and had a high level of education. Overall, 7 (7/28, 25%) participants identified as belonging to the lesbian, gay, bisexual, and transgender community (including half of the participants with a history of mental illness).

Both groups of participants described frequent mobile phone use. All participants used their mobile phone every day, and most of them used it at least once every hour (history of mental illness = 9/12, 75%, no history of mental illness = 12/16, 75%). Most participants (history of mental illness = 11/12, 92%, no history of mental illness = 12/16, 79%) had also previously used their mobile phone to look for health or medical information or track health and fitness data, with many reporting they did so on a weekly or daily basis (history of mental illness = 6/12, 50%, no history of mental illness = 5/16, 31%). The majority of participants also reported having a range of health apps installed on their mobile phone, particularly exercise (history of mental illness = 8/12, 67%, no history of mental illness = 9/16, 56%), diet (history of mental illness = 11/12, 92%, no history of mental illness = 14/16, 88%), sleep (history of mental illness = 67%, no history of mental illness = 31%), and mood apps (history of mental illness = 50%, no history of mental illness = 13%). However, most participants with these apps installed on their mobile phone reported rarely using them (history of mental illness = 5/12, 42% to 12/12, 100%, no history of mental illness = 11/16, 69% to 16/16, 100%).

Table 2. Participant characteristics at baseline.

Characteristics	History of mental illness (N=12)	No history of mental illness (N=16)
Age (years), range	19-25	18-25
Age (years), mean (SD)	21.2 (2.1)	21.81 (2.3)
Gender (female), n (%)	10 (83)	10 (63)
Lesbian, gay, bisexual, and transgender, and intersex, n (%)	6 (50)	1 (6)
ATSI[a], n (%)	0 (0)	0 (0)
Marital status, n (%)		
Defacto	1 (8)	1 (6)
Never married or single	11 (92)	15 (94)
Born in Australia, n (%)	9 (75)	14 (88)
First language other than English, n (%)	1 (8)	3 (19)
Highest education, n (%)		
High school (Grade 11-12)	9 (75)	9 (56)
University degree	3 (25)	7 (44)
Employment status, n (%)		
Employed (full or part time and casual)	2 (17)	4 (25)
Student	9 (75)	9 (56)
Unemployed	0 (0)	1 (6)
Other	1 (8)	2 (13)
Health risk behaviors, n (%)		
At risk—alcohol	5 (46)	5 (33)
At risk—smoking	1 (14)	2 (13)
At risk—diet	12 (100)	15 (100)
At risk—physical activity	5 (46)	6 (40)
Lifestyle Risk Index, mean (SD)	1.90 (0.57)	1.86 (0.92)
PHQ 4[b], mean (SD)	5.67 (2.96)	2.60 (2.07)

[a]ATSI: Aboriginal and Torres Strait Islander.

[b]PHQ 4: 4-item Patient Health Questionnaire.

Use of MyHealthPA

As can be seen in Table 3, use of the MyHealthPA program varied widely among participants. Overall, 4 (4/12, 33%) participants with a history of mental illness and 2 participants without a history of mental illness (2/16, 13%) never accessed the program. Out of a possible 56 days, participants accessed MyHealthPA on a mean of 3.82 days. As can be seen in Figure 2, among the 22 participants who accessed MyHealthPA, most stopped accessing it after 1 day of use. Only 41% of participants continued to use the program past this point. However, past day 5, remaining participants went on to be active users of MyHealthPA for between 3 weeks and the full 8 weeks of the study.

Usability and Acceptability

The 12 participants who completed the end-of-treatment assessment reported that MyHealthPA had average usability. The mean SUS scores were 67.1 among participants without a history of mental illness and 64.5 among those with a history of mental illness, with a slight majority (history of mental illness = 4/7, 57%, no history of mental illness = 3/5, 60%) reporting the MyHealthPA program had above-average usability (as indicated by a score of 68 or more on the SUS [30]). Specifically, as can be seen in Table 4, although only 29% (2/7) of participants without a history of mental illness and 40% (2/5) of participants with a history of mental illness agreed or strongly agreed that they would like to use the MyHealthPA program frequently, most participants agreed or strongly agreed that the program was easy to use and thought the program was consistent. Similarly, most participants disagreed or strongly disagreed that they would need the support of a technical person to use MyHealthPA and that they needed to learn many things before they could get going with the program. In addition, 43% (3/7) of participants without a history of mental illness and 60% (3/5) of participants with a history of mental illness thought MyHealthPA would help people to change their lifestyle behaviors. The majority thought the content of MyHealthPA

was relevant to young people (history of mental illness = 4/5, 80%, no history of mental illness = 5/7, 71%), but only 29% (2/7) of participants without a history of mental illness and 40% (2/5) of those with a history of mental illness would recommend MyHealthPA to other young people.

When participants were asked what aspects of MyHealthPA they felt did not work well, a key theme of *difficulty accessing the program* emerged. Participants mentioned that the need to access the program via a Web browser on their mobile phone rather than simply opening a native app was a barrier to use, saying it "involved opening too many windows and logging in constantly."

Similarly, participants found it difficult to remember to access the program regularly:

> *I found it difficult to remember to use it every day—in fact I completely forgot about it until I got the email to do this survey. A phone app with daily reminders would be a good idea.*

The length of the adverse symptoms questionnaire was also cited as a barrier to use, and 1 participant without a history of mental illness questioned the simplicity of the program: "Maybe a bit TOO simple—didn't really see the point in using it."

Table 3. Participants' use of MyHealthPA.

MyHealthPA use	Mean (SD)	Range
History of mental illness (N=12)		
Number of days accessed MyHealthPA	3.17 (8.47)	0-30
Number of times access MyHealthPA	6.42 (13.69)	0-39
Number of pages access	5.0 (11.49)	0-41
Number of diary entries	9.50 (20.59)	0-54
Number of goals set	0.25 (0.62)	0-2
No history of mental illness (N=16)		
Number of days accessed MyHealthPA	4.31 (6.75)	0-24
Number of times access MyHealthPA	7.13 (11.79)	0-38
Number of pages access	11.25 (14.59)	0-44
Number of diary entries	10.0 (16.56)	0-54
Number of goals set	0.75 (1.07)	0-3

Figure 2. Attrition among MyHealthPA users.

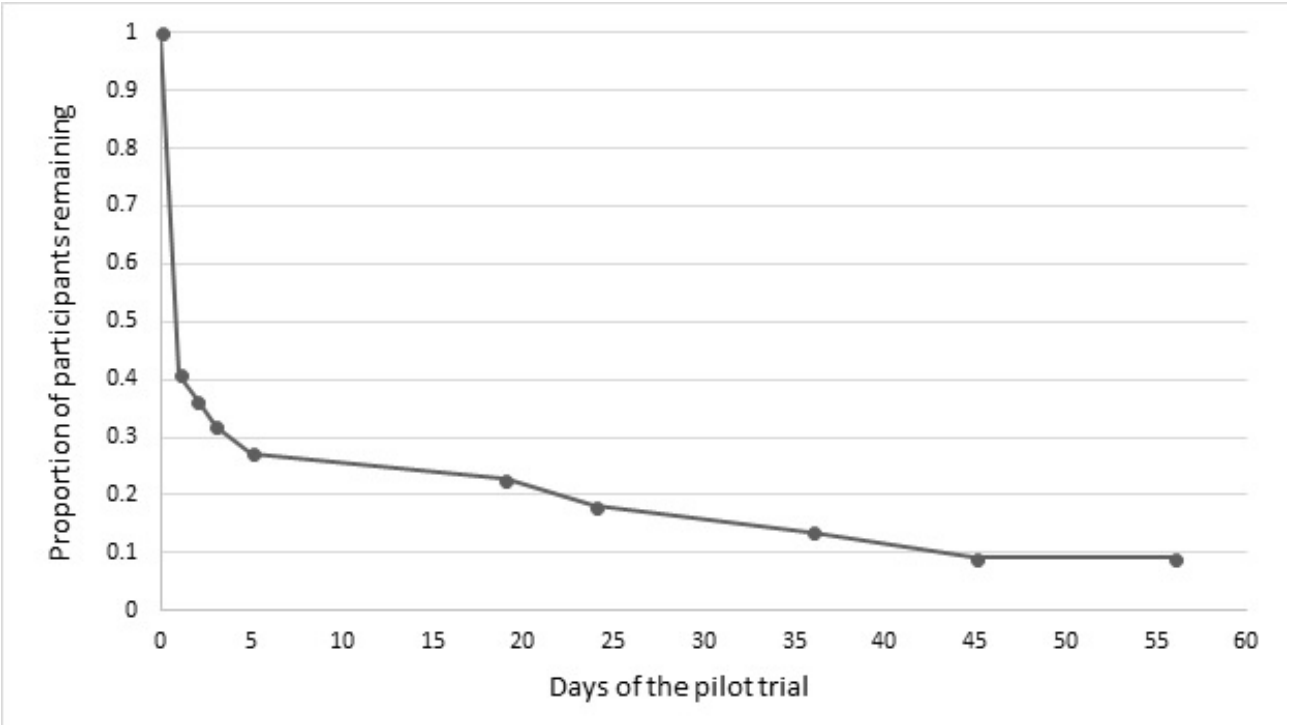


Table 4. System Usability Scale scores.

System usability scale	History of mental illness (N=5), n (%)	No history of mental illness (N=7), n (%)
I think that I would like to use the MyHealthPA app frequently		
Strongly disagree	1 (20)	0 (0)
Disagree	1 (20)	3 (43)
Neutral	1 (20)	2 (29)
Agree	1 (20)	2 (29)
Strongly agree	1 (20)	0 (0)
I found the MyHealthPA app unnecessarily complex		
Strongly disagree	2 (40)	0 (0)
Disagree	2 (40)	3 (43)
Neutral	1 (20)	2 (29)
Agree	0 (0)	2 (29)
Strongly agree	0 (0)	0 (0)
I thought the MyHealthPA app was easy to use		
Strongly disagree	0 (0)	0 (0)
Disagree	0 (0)	0 (0)
Neutral	2 (40)	3 (43)
Agree	3 (60)	3 (43)
Strongly agree	0 (0)	1 (14)
I think that I would need the support of a technical person to be able to use the MyHealthPA		
Strongly disagree	1 (20)	4 (57)
Disagree	3 (60)	1 (14)
Neutral	0 (0)	2 (29)
Agree	0 (0)	0 (0)
Strongly agree	0 (0)	0 (0)
I found the various functions in the MyHealthPA app were well integrated		
Strongly disagree	0 (0)	0 (0)
Disagree	1 (20)	1 (14)
Neutral	1 (20)	2 (29)
Agree	1 (20)	4 (57)
Strongly agree	0 (0)	0 (0)
I thought there was too much inconsistency in the MyHealthPA app		
Strongly disagree	0 (0)	2 (29)
Disagree	4 (80)	1 (14)
Neutral	1 (20)	4 (57)
Agree	0 (0)	0 (0)
Strongly agree	0 (0)	0 (0)
I would imagine that most people would learn to use the MyHealthPA app very quickly		
Strongly disagree	0 (0)	0 (0)
Disagree	0 (0)	0 (0)
Neutral	3 (60)	1 (14)
Agree	2 (40)	3 (43)
Strongly agree	0 (0)	3 (43)

System usability scale	History of mental illness (N=5), n (%)	No history of mental illness (N=7), n (%)
I found the MyHealthPA app cumbersome to use		
Strongly disagree	0 (0)	2 (29)
Disagree	2 (40)	1 (14)
Neutral	1 (20)	3 (43)
Agree	1 (20)	1 (14)
Strongly agree	1 (20)	0 (0)
I felt very confident using the MyHealthPA app		
Strongly disagree	0 (0)	0 (0)
Disagree	0 (0)	1 (14)
Neutral	3 (60)	2 (29)
Agree	1 (20)	2 (29)
Strongly agree	1 (20)	2 (29)
I needed to learn a lot of things before I could get going with the MyHealthPA app		
Strongly disagree	1 (20)	3 (43)
Disagree	3 (60)	2 (29)
Neutral	1 (20)	2 (29)
Agree	0 (0)	0 (0)
Strongly agree	0 (0)	0 (0)

When asked what they thought worked well about the program, the primary theme mentioned by participants was simplicity and ease of use of MyHealthPA. Participants liked the simple interface, how easy the program was to use, and how quickly users could enter their information, saying, “It’s easy to use, it works well on mobile, and doesn’t take much time.”

Participants also enjoyed being able to track and view their health behaviors and mood and how they interacted over time as highlighted by the following participant with a history of mental illness:

> *Could easily track my progress and see how my lifestyle had changed. It also made me aware of what I was eating, because I didn’t eat many vegetables or fruit before, but when I wrote it down I became aware of how unhealthy my lifestyle was. I found it interesting that when I started eating healthier and exercising a little bit more, my mood increased quite dramatically.*

Finally, the key changes to the MyHealthPA program recommended by the participants were converting the program to a native app format and allowing continual log-in. Other suggestions included adding a calendar view of diary entries, allowing information from other health tracking apps to be integrated into MyHealthPA, providing more (but customizable) reminders to use the program, and providing extra information such as recipe and exercise ideas.

Health Behavior Change

As can be seen in Table 5, the greatest improvements were observed in fruit and vegetable consumption and physical activity of participants, where both groups reported improvements in these behaviors between baseline and end of treatment and baseline and follow-up. Some improvement in alcohol use among participants with a history of mental illness was observed, particularly between baseline and follow-up; however, participants with no history of mental illness actually reported a slight increase in the harmfulness of their alcohol use at both time points. Similarly, although no change in the number of cigarettes smoked per day was reported between baseline and end of treatment among participants with a history of mental illness, a slight increase at follow-up and among participants without a history of mental illness was reported. Participants with a history of mental illness reported improvement in psychological distress (as measured by the PHQ 4) at end of treatment and follow-up.

Participants with a history of mental illness also maintained their LRI score at end of treatment and improved it by follow-up. On the other hand, a slight increase in mean LRI among people without a history of mental illness was observed at end of treatment. Specifically, as can be seen in Table 6, one participant without a history of mental illness was no longer at risk for 1 behavior at end of treatment, whereas 1 had increased his or her risk behaviors by 2 at end of treatment. By follow-up, 3 participants with a history of mental illness were no longer at risk for 1 behavior they had previously been at risk for, 1 maintained his or her level of risk, and 1 increased his or her risk by 1 behavior. The remaining participants without a history of mental illness reported maintaining their level of risk between baseline and follow-up.

Table 5. Change in health behavior and mood outcomes between baseline, end of treatment, and follow-up.

Outcome measures	Baseline to end of treatment, mean change (SD)		Baseline to follow-up, mean change (SD)	
	History of mental illness (N=5)	No history of mental illness (N=7)	History of mental illness (N=5)	No history of mental illness (N=1)
AUDIT-C[a] score	0.00 (1.73)[b]	2.14 (1.86)	−1.00 (1.73)[b]	4.0 (N/A[c])
No. of cigarettes per day	0.00 (0.00)[b]	1.50 (2.12)	0.33 (0.58)	N/A
No. of fruit and vegetables per day	0.50 (1.00)[b]	0.71 (1.38)[b]	1.0 (1.58)[b]	3.0 (N/A)[b]
IPAQ[d] score	864.60 (1104.83)[b]	745.5 (1555.13)[b]	1518.20 (1162.87)[b]	1523.5 (N/A)[b]
PHQ 4[e]	−1.4 (4.51)[b]	0.29 (3.73)	−2.4 (2.88)[b]	0 (N/A)[b]
LRI[f]	0.00 (0.00)[b]	0.14 (0.89)	−0.40 (0.89)[b]	0.00 (N/A)[b]

[a]AUDIT-C: Alcohol Use Disorders Identification Test–consumption items.

[b]Change in desired direction or no change.

[c]N/A: not applicable.

[d]IPAQ: International Physical Activity Questionnaire.

[e]PHQ 4: 4-item Patient Health Questionnaire.

[f]LRI: Lifestyle Risk Index.

Table 6. Change in Lifestyle Risk Index.

Change in risk behaviors	Baseline to end of treatment		Baseline to follow-up	
	History of mental illness (N=5), n (%)	No history of mental illness (N=7), n (%)	History of mental illness (N=5), n (%)	No history of mental illness (N=1), n (%)
Change of −1	0 (0)	1 (14)	3 (60)	0 (0)
No change	5 (100)	5 (71)	1 (20)	1 (100)
Change of +1	0 (0)	0 (0)	1 (20)	0 (0)
Change of + 2	0 (0)	1 (14)	0 (0)	0 (0)

Discussion

Principal Findings

The results of the initial pilot study of the MyHealthPA program suggest that MyHealthPA is an acceptable, easy-to-use tool that may help people to reduce key health risk behaviors associated with CVD, especially people with mental health problems. Although only a slight majority of participants thought the program had above-average usability, most participants described it as easy to use. Unlike previous literature that has found difficulty using diary features to be a common criticism of health apps [31], participants in this study reported that the MyHealthPA diary feature was simple and quick to use. It is unclear why people with a history of mental illness have reported more positive health behavior changes than people without a history of mental illness. Potentially, these results indicate that although the FEDM may mean eHealth tools designed using this model are more acceptable and effective among people with mental health problems, it may result in tools that are perceived to be too simple and are less effective among people without mental health problems. Promisingly, participants with a history of mental illness also did not report increases in their psychological distress over the study period.

Limitations

The pilot study had a number of limitations, including the use of self-report measures only, which meant that participant characteristics and results were unable to be independently validated. As such, these results should be interpreted with a degree of caution. Another key limitation was the high rate of participant dropout between the baseline, end-of-treatment, and follow-up assessments. Participants did not receive any incentives or compensation for completing each of the assessment points beyond receiving an extra entry into a draw to win an iPad. In previous research conducted by the research team that has achieved much higher follow-up rates, an incentive of Aus $20 to Aus $50 per assessment has been offered to participants. Unfortunately, resource limitations meant that similar incentives were unable to be offered in this pilot study. This lack of incentive may have been responsible for the low follow-up rates observed, highlighting the potential importance of incentives or compensation for participation in this kind of research.

In addition, despite receiving reminders to access the program after 2 and 5 days of inactivity, large proportion of participants never accessed MyHealthPA or accessed the program on only a few occasions. For example, out of a possible 56 days on which participants could have accessed the program, the maximum number of days the program was accessed was 30,

with a mean of just under 4 days. In this way, their minimal use mirrored their SUS responses, which indicated few participants would like to use MyHealthPA frequently, as well as their reported patterns of use of other health apps and other mobile health trials [32]. As highlighted by participants, this lower-than-desired use of the program may have been influenced by the responsive website platform of the program. It is anticipated that converting the MyHealthPA program to a native app format may help to increase the frequency with which users want to access MyHealthPA. Other strategies to increase the use may include building rewards into the program where users could earn stars or badges for recording behaviors or meeting set goals. Similarly, it has been suggested that greater tailoring or personalization in mobile health apps may promote greater use and engagement [32]; however, more work is needed to determine the best ways to encourage frequent use of health apps over an extended period.

Finally, these results may need to be interpreted with caution, as the participants recruited to this pilot study may not be representative of the wider population of people with experience of mental health problems. Participants with a history of mental illness in this pilot were highly educated and mostly studying or employed. Despite these limitations, these initial results are promising. Further testing of the efficacy of the MyHealthPA program, including determining the optimal way to integrate this program into existing clinical and public health care, is warranted.

Conclusions

The aim of this study was to describe the formative research and process of planning that formed the development of the MyHealthPA program. MyHealthPA was developed to address the need for scalable and effective interventions to address the risk of CVD among people with mental health problems that are of low burden to both clinicians and consumers. MyHealthPA is unique, as it targets the top 4 behavioral risk factors associated with CVD (smoking, alcohol misuse, physical inactivity, and poor diet), which are also extremely common among people with mental health problems, while also addressing mood and the way in which mood and psychiatric symptoms might interact with these health behaviors. Although many apps purporting to help users improve their health have been developed for use by the general population, MyHealthPA is the first to specifically target people with mental health problems and aims to help them improve their health behaviors and decrease their cardiovascular risk. The program was designed to employ evidence-based techniques, such as self-monitoring, goal setting, and addressing multiple health behaviors simultaneously [11]. It was also designed to overcome some of the potential obstacles to the use of mobile health tools designed for the general population among people with mental health problems by adopting Rotondi et al's FEDM [20]. In addition, the mobile phone–based platform of the program signifies that MyHealthPA could drastically extend the reach and scalability of CVD risk reduction programs for people with mental health problems. It is hoped that subject to further testing in fully powered trials and conversion to a native app format, MyHealthPA could be accessed directly by people with mental health problems who want to improve their health and/or used by health professionals to engage their patients with mental health problems with the treatment of their physical health and prevention of CVD. This program could be particularly useful for consumers and health professionals in rural or remote communities where access to other treatment options is limited or in situations where waiting periods before and between appointments are particularly lengthy.

The design process employed to develop MyHealthPA was time and resource efficient. A key strength was the inclusion of a range of perspectives (ie, expert researchers, clinicians, and potential end users) in the design process via the scoping survey and review of the of the written content and beta version of the app. Additional focus or laboratory-based testing (eg, using a think-aloud protocol [33] to gain a better understanding of how end users might navigate to and through the program) may have meant that the issues with the website delivery method were identified earlier in the design process. However, given the resource constraints of this particular project, using this simplified design process and a responsive website, as opposed to a native app, meant that a product could be developed and initial feasibility and effectiveness testing could be conducted. This allowed this study to show for the first time that using a mobile phone–based program to help people with mental health problems improve their health risk behaviors and reduce their CVD risk may be feasible and effective.

Overall, the MyHealthPA program represents an innovative approach to CVD risk reduction among people with mental health problems. It appears that MyHealthPA is acceptable, easy to use, and potentially effective. A large-scale clinical trial employing MyHealthPA in groups of people with mental health problems is indicated.

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Conflicts of Interest

None declared.

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Abbreviations

AUDIT-C: Alcohol Use Disorders Identification Test–consumption items
CBT: cognitive behavioral therapy
CVD: cardiovascular disease
FEDM: Flat Explicit Design Model
SMART: Specific, Measurable, Active, Realistic, and Time-limited
SUS: System Usability Scale
LRI: Lifestyle Risk Index
PHQ 4: 4-item Patient Health Questionnaire

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Original Paper

Implantable Cardioverter Defibrillator mHealth App for Physician Referrals and eHealth Education: ICD-TEACH Pilot Study

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Abstract

Background: Mobile health (mHealth) decision tools for implantable cardioverter defibrillator may increase physician knowledge and overall patient care.

Objective: The goals of the ICD-TEACH pilot study were to design a smartphone app or mHealth technology with a novel physician decision support algorithm, implement a direct referral mechanism for device implantation from the app, and assess its overall usability and feasibility with physicians involved in the care of patients with an implantable cardioverter defibrillator.

Methods: The initial design and development of the mHealth or smartphone app included strategic collaboration from an information technology company and key stakeholders including arrhythmia specialists (electrophysiologists), general cardiologists, and key members of the hospital administrative team. A convenience sampling method was used to recruit general internists or cardiologists that refer to our local tertiary care center. Physicians were asked to incorporate the mHealth app in daily clinical practice and avail the decision support algorithm and direct referral feature to the arrhythmia clinic. Feasibility assessment, in the form of a physician survey, was conducted after initial mHealth app use (within 3 months) addressing the physicians' overall satisfaction with the app, compliance, and reason for noncompliance; usability assessment of the mHealth app was addressed in the physician survey for technical or hardware problems encountered while using the app and suggestions on improvement.

Results: A total of 17 physicians agreed to participate in the pilot study with 100% poststudy survey response rate. Physicians worked in an academic practice, which included both inpatient and ambulatory care. System Usability Scale was applied with an average score of 77 including the 17 participants (>68 points is above average). Regarding the novel physician decision support algorithm for implantable cardioverter defibrillator referral, 11% (1/9) strongly agreed and 78% (7/9) agreed that the algorithm for device eligibility was easy to use. Only 1 patient was referred through the direct referral system via the mHealth app during the pilot study of 3 months. Feasibility assessment showed that 46% (5/11) strongly agreed and 55% (6/11) agreed that the mHealth app would be utilized if integrated into an electronic medical record (EMR) where data are automatically sent to the referring arrhythmia clinic.

Conclusions: The ICD-TEACH pilot study revealed high usability features of a physician decision support algorithm; however, we received only 1 direct referral through our app despite supportive feedback. A specific reason from our physician survey included the lack of integration into an EMR. Future studies should continue to systematically evaluate smartphone apps in cardiology to assess usability, feasibility, and strategies to integrate into daily workflow.

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KEYWORDS

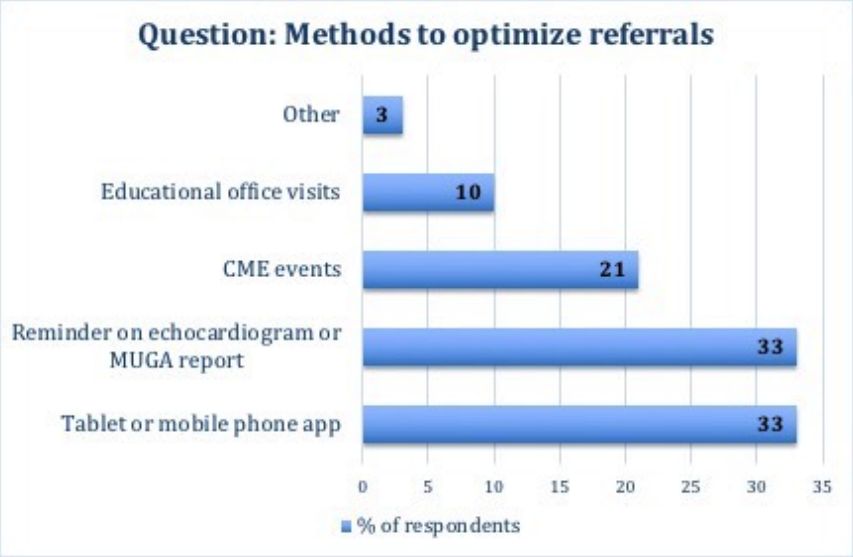
mHealth; smartphone app; implantable defibrillator cardioverter; ICD; physician decision; eHealth; mobile phone

Introduction

Guideline-recommended primary and secondary prevention of sudden cardiac death in high-risk patients includes placing an implantable cardioverter defibrillator in these patients [1,2]. Despite continuing medical education and physician-based interventions, there still remains a large population of eligible patients who may not be receiving such therapy [3]. Identifiable reasons for the lower than expected physician implantable cardioverter defibrillator referral rate have been attributed to misperception about the benefit of implantable cardioverter defibrillator therapy and patient eligibility, as well as the lack of awareness about the device implantation process. To understand the barriers of knowledge and potentially minimize care gaps that exist between evidence-based recommendations and current practice for implantable cardioverter defibrillator referral, a Web-based questionnaire was conducted predominantly including community-based family physicians and general internists. In this small sample of 24 physicians, 42% (10/24) of the participants were not familiar with current implantable cardioverter defibrillator guidelines, while a small number also believed implantable cardioverter defibrillator therapy did not improve quality of life. When asked about different methods to optimize referrals, a tablet or mobile phone app to help identify potential patients as well as reminders on echocardiograms or multigated acquisition report were highly selected (Figure 1).

Smartphone apps or mobile health (mHealth) technology are part of daily life, with continued growth gaining popularity among health care providers. Incorporated into the daily lives of both physicians and patients, mHealth has the ability to provide evidence-based guidance in a Web-based, engaging, and user-friendly format with instant knowledge acquisition [4]. As an adjunct to behavior modeling, the intervention of mHealth has demonstrated early success in improving patient and physician outcomes [5]. The purpose of the ICD-TEACH study was to design a smartphone app or mHealth technology with a novel physician decision support algorithm, implement a direct referral mechanism for implantable cardioverter defibrillator implantation from the app, and assess its overall usability and feasibility with physicians involved in the care of these patients.

Figure 1. Questionnaire results. CME: continuing medical education; MUGA: multigated acquisition.



Methods

ICD-TEACH was a single-center pilot study designed to assess the usability and feasibility of mHealth for implantable cardioverter defibrillator physician decision support and direct referral to a regional arrhythmia center. The initial design and development of the mHealth or smartphone app included strategic collaboration from an information technology company and key stakeholders including arrhythmia specialists (electrophysiologists), general cardiologists, and key members of the hospital administrative team. The mHealth app included an interactive, user-friendly algorithm to determine patients eligible for implantable cardioverter defibrillator implantation with instant feedback and the option for direct referral to our regional arrhythmia referral center in Ontario, Canada (Table 1). The mHealth app also provided education to physicians about ventricular arrhythmias, congestive heart failure, sudden cardiac death, procedure information, current guideline recommendations for device therapy, quality of life, day-to-day or frequently asked questions, and the ability to refer patients to a regional arrhythmia clinic, embedded within the app (Figure 2).

Table 1. Rule-based algorithm answered by the user to determine implantable cardioverter-defibrillator (ICD) indication. All recommendations based upon the Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines.

Question	Strong recommendation		Weak recommendation	
	Rule 1	Rule 2	Rule 1	Rule 2
Is the patient's left ventricular ejection fraction <55%?				
Yes	✓	✓	✓	✓
No				
The patient's ejection fraction is:				
>54%				
36%-54%				
31%-35%			✓	✓
≤30%	✓	✓		
Does the patient exhibit indications of:				
Ischemic heart disease or prior myocardial infarction	✓		✓	✓
Nonischemic cardiomyopathy		✓		
None of the above apply				
Ischemic cardiomyopathy: Has at least 40 days passed since the most recent myocardial infarction or 3 months postrevascularization? Nonischemic cardiomyopathy: Has at least 3 months passed with the patient on optimal medical therapy?				
Yes	✓	✓	✓	✓
No				
Is the patient's expected survival with a good functional status ≥1 year?				
Yes	✓	✓	✓	✓
No				
The patient has familial or personal history of arrhythmogenic right ventricular dysplasia, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, long QT syndrome, short QT syndrome, or hypertrophic cardiomyopathy?[a]				
Yes				
No				

[a]Answer does not affect algorithm.

The next phase of this pilot study included rollout of the mHealth app to cardiology and internal medicine physicians to assess its usability and feasibility. A convenience sampling method was used to recruit general internists or cardiologists who refer patients to our local tertiary care center. Physicians were eligible to participate if their current practice pattern included patients with congestive heart failure and if they were current smartphone users (Apple-, Android-, or Blackberry-based platforms with access to mobile data).

Participating physicians were asked to independently review a document about the mHealth app and project goals. Instructions were provided to review the app content and assess patient eligibility for implantable cardioverter defibrillator therapy using the algorithm. Physicians were asked to incorporate the mHealth app in daily clinical practice and avail the decision support algorithm and direct referral feature to the arrhythmia clinic (Figure 3). A physician survey was conducted after initial mHealth app use (within 3 months) to assess physicians' overall satisfaction with the app, compliance, reason for noncompliance, technical or hardware problems encountered while using the app, and suggestions on improvement. Reminders were provided via email at 1 week, 4 weeks, and 3 months to reiterate the benefit and promote the mHealth app.

The primary outcome of this study was to assess the feasibility of incorporating an mHealth app into daily clinical practice. A descriptive analysis was performed based on the structured questionnaire regarding satisfaction of completing the task, overall compliance, the reason for noncompliance, technical or hardware problems encountered while using the app, and suggestions on improvement. We also tracked the number of referrals to the regional arrhythmia service clinic through the app. Our usability assessment included the System Usability Scale incorporated into the survey, which has been validated for health care-related smartphone apps; this scale consists of specific questions evaluating mHealth technology with a 5-point Likert scale [6]. A score >68 points is above average and indicates adequate usability. The authors had full access to the data and take full responsibility for its integrity. The study was approved by the Hamilton Integrated Research Ethics Board (HIREB Project #15-208).

Figure 2. ICD-TEACH initial dashboard at log-in (left) and indication survey (right). Upon completing the indication survey, the algorithm provides a recommendation for implantable cardioverter defibrillator (based upon the Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines). Users were also given the option to directly refer to the arrhythmia clinic.

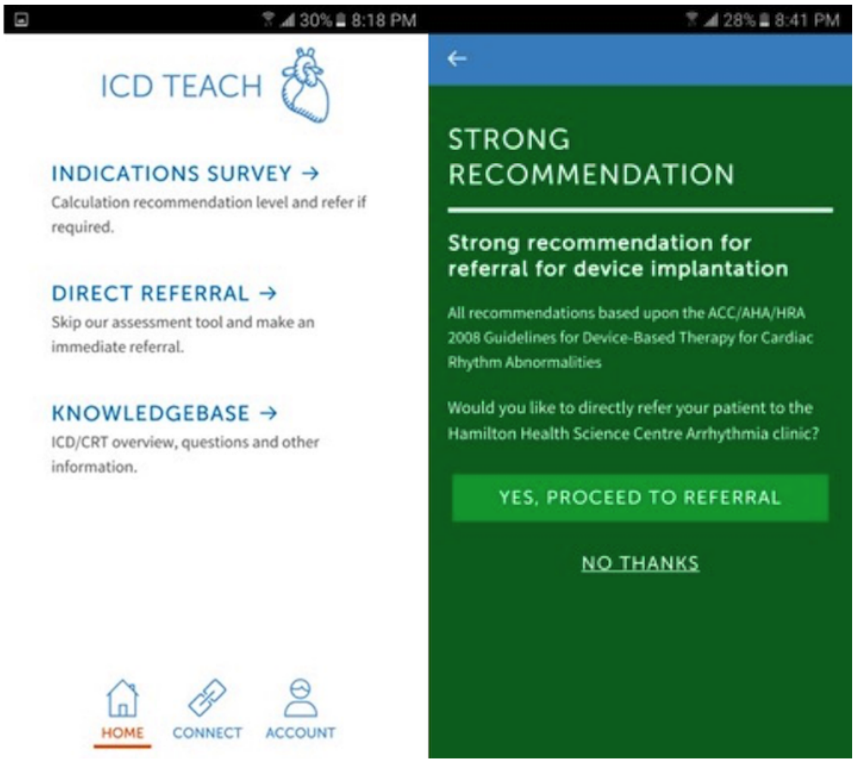


Figure 3. Direct referral: option to directly refer to the arrhythmia clinic.

Results

Survey Results

Physician recruitment was performed from January 1 to 30, 2017. Participating physicians were able to use the app for a total of 3 months, and final survey results and the pilot study were completed by May 1, 2017. A total of 17 physicians agreed to participate in the study with a 100% survey response rate. Physicians worked in an academic practice, which included both inpatient and ambulatory care; 76% (13/17) participants were general cardiologists or residents and 26% (4/17) were general internal medicine specialists. Among the respondents, 14% (2/14) agreed that the current paper- or fax-based system for device referral was difficult, 29% (4/14) disagreed, and 57% (8/14) were neutral. Furthermore, 21% (3/14) agreed that they enjoyed using the current system for implantable cardioverter defibrillator referral, while 21% (3/14) disagreed. Participating physicians thought the app was not difficult to download or install on the smartphone device and did not take too long to download.

Regarding usability, the System Usability Scale was applied with an average score of 77 including the 17 participants (>68 points is above average). Furthermore, regarding the novel physician decision support algorithm for implantable cardioverter defibrillator referral, 11% (1/9) strongly agreed and 78% (7/9) agreed that the algorithm for device eligibility was easy to use (Figure 4). For the direct referral option to our regional arrhythmia center, 88% (7/8) agreed and 12% (1/8) strongly agreed that the direct referral process was also easy to use. When asked about whether they would use this mHealth app for direct referral, 25% (2/8) strongly agreed, 50% (4/8) agreed, 13% (1/8) disagreed, and 13% (1/8) were neutral. Respondents felt that the education material was beneficial such as procedure information (6/8, 75%, agreed and 2/8, 25%, strongly agreed), device therapy information (2/7, 29%, strongly agreed and 4/7, 57%, agreed), and common frequently asked questions (1/7, 14%, strongly agreed and 5/7, 71%, agreed). Meanwhile, 67% (8/12) disagreed that the current traditional paper- or fax-based system was more efficient, while 17% (2/12) agreed.

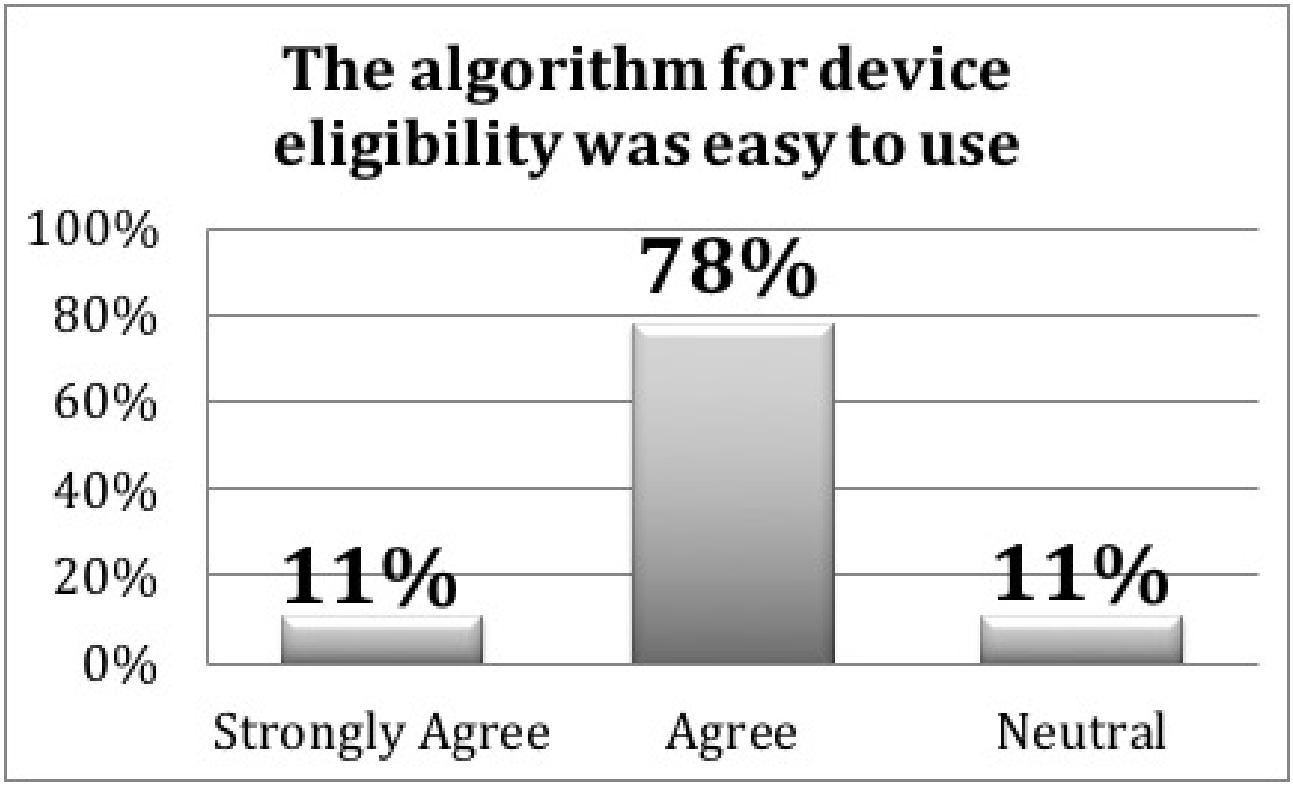
The majority of physicians felt that this mHealth app should be available to all physicians in the province of Ontario (3/7, 43%, strongly agreed and 3/7, 43%, agreed). Moreover, when asked whether entering patient information into the app was difficult, 9% (1/11) strongly disagreed and 46% (5/11) disagreed. When asked whether they did not trust or rely on the app to submit private information, 27% (3/11) disagreed and 9% (1/11) strongly disagreed, while 46% (5/11) were neutral, 9% (1/11) agreed and 9% (1/11) strongly agreed. Among the respondents, 18% (2/11) disagreed and 9% (1/11) strongly disagreed with the comment that they did not need an algorithm for the device when a patient needed an implantable cardioverter defibrillator, while 55% (6/11) were neutral and 18% (2/11) agreed or strongly agreed.

Feasibility or Uptake of the mHealth App

Physician referrals using the mHealth app were tracked during the study period. Only one patient was referred through the direct referral system via the mHealth app during the pilot study of 3 months. Feasibility assessment showed that 46% (5/11) strongly agreed and 55% (6/11) agreed that mHealth app would be utilized if integrated into an electronic medical record (EMR) where data are automatically sent to the referring arrhythmia clinic. This was also reflected in the free-text comments provided by physicians at the end of the survey. Moreover, 91% (10/11) agreed and 9% (1/11) strongly agreed that the mHealth app should be available in a Web or browser format.

Further feedback included that during the pilot study, overall patient encounters (case numbers to use the mHealth tool) where patients needed to be referred for device implantation was low. Physicians also mentioned that in their current practice, it would be easier to fill out a referral form than submit through the app and that most cardiologists did not frequently need a decision support algorithm for device referral.

Figure 4. Poststudy survey results.



Discussion

Principal Findings

The results of the ICD-TEACH pilot study revealed that our novel implantable cardioverter defibrillator decision support algorithm and direct referral mechanism was easy to use with adequate usability. Physicians did not find entering patient information cumbersome, felt comfortable submitting patient information through the mHealth app, and believed that the algorithm tool should be disseminated widely. The education materials regarding procedural information, device therapy, guideline summaries, and frequently asked questions were useful and informative. Despite majority of the physicians stating that they would use the direct referral mechanism, we received only one direct referral through the mHealth app during the study period of 3 months.

Several challenges were faced in integrating this mHealth technology into the routine practice of physicians. We initially anticipated 40-50 physicians for enrollment into the pilot study; however, after recurrent contact through email, the response to the recruitment email (accept or not accept) was low. Although speculative, this may be due to the fact that physicians already have a current system that is efficient and did not want to spend additional time learning a new system if significant efficiency was not to be gained. This may be reflected in that we only received one direct referral through the mHealth app. Our survey results suggested that cardiologists did not need an algorithm for device implantation and that the current paper- or fax-based system was efficient enough for daily use. Our population of cardiologists and general internists who participated in this pilot study worked in a tertiary care or urban center; they may have different perceptions than physicians in rural settings, who may not have timely access to subspecialty referral. The ICD-TEACH app may offer more benefits to physicians practicing in rural areas, medical students or resident physicians, and primary care physicians looking for further education about implantable cardioverter defibrillator referral as well learning guideline-based indications for device referral through the algorithm.

One important insight gained from our pilot study through the survey and free-text comments is that the optimal utilization of an mHealth app with a decision support algorithm and direct referral mechanism should be linked directly to an EMR system. In this manner, once the decision to refer a patient for implantable cardioverter defibrillator is made, the EMR system would autopopulate the patient information fields and also send the appropriate information to the arrhythmia clinic (such as patient history, medications, blood work, and key investigations). A limitation of our pilot study is that our current health care network does not have an EMR or an electronic referral mechanism; we could have seen more direct referrals if the ICD-TEACH app was integrated into an EMR software.

With the rise of health care-related mHealth technology, it is important that the medical community evaluates such tools in a systematic manner. Cardiovascular societies and health care organizations should look to formally test health care mHealth apps for usability and feasibility to gain further insight and feedback, in the form of pilot studies or focus group testing. A goal of our pilot study was to assess the feasibility of incorporating a physician decision support tool for implantable cardioverter defibrillator through mHealth technology. Several pitfalls were highlighted, which clearly demonstrate that before mHealth technology integration, there has to be an incentive to increase efficiency as well as a platform for ease of access (such

as EMRs) in order for a direct referral process to be successful. To the best of our knowledge, our objective usability assessment is one of the first to be tested on physician decision tools through mHealth. These findings will further allow us to make changes to the mHealth tool to optimize use in the future.

Conclusion

The ICD-TEACH pilot study revealed high usability features of a physician decision support algorithm and direct referral mechanism for implantable cardioverter defibrillator. We received only 1 direct referral through our app despite supportive feedback. Specific reasons from our physician survey included the lack of integration into an EMR, as well as perceived efficiency of the current paper- or fax-based system. Future studies should continue to systematically evaluate smartphone apps in cardiology to assess their usability and feasibility and to assess the strategies for their integration into daily workflow.

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Conflicts of Interest

None declared.

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Abbreviations

EMR: electronic medical record
mHealth: mobile health

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