Clinical trials of health information technology interventions intended for patient use: Unique issues and considerations

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Background   Despite the proliferation of health information technology (IT) interventions, descriptions of the unique considerations for conducting randomized trials of health IT interventions intended for patient use are lacking.

Purpose   Our purpose is to describe the protocol to evaluate Pocket PATH® (Personal Assistant for Tracking Health), a novel health IT intervention, as an exemplar of how to address issues that may be unique to a randomized controlled trial (RCT) to evaluate health IT intended for patient use.

Methods   An overview of the study protocol is presented. Unique considerations for health IT intervention trials and strategies are described to maintain equipoise, to monitor data safety and intervention fidelity, and to keep pace with changing technology during such trials.

Lessons Learned   The sovereignty granted to technology, the rapid pace of changes in technology, ubiquitous use in health care, and obligation to maintain the safety of research participants challenge researchers to address these issues in ways that maintain the integrity of intervention trials designed to evaluate the impact of health IT interventions intended for patient use.

Conclusions   Our experience evaluating the efficacy of Pocket PATH may provide practical guidance to investigators about how to comply with established procedures for conducting RCTs and include strategies to address the unique issues associated with the evaluation of health IT for patient use. *Clinical Trials* 2013; **10**: 896–906. http://ctj.sagepub.com

Introduction

Health information technology (IT) represents one of the 'transforming' advancements that impact the way patients manage their health information, communicate with health-care providers, and support the goal for patients to be informed, active participants in their health care [1–3]. The recent proliferation of health IT interventions intended for patient use and the growing recognition of the importance of rigorous trials to evaluate such interventions [4] revealed several substantial issues that

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can arise in such trials. A description of the unique considerations for conducting randomized trials of health IT interventions intended for patient use is therefore warranted and timely.

Maintaining equipoise

The ethical basis for medical research involving assignment of participants to different interventions requires investigators to maintain equipoise during the conduct of the trial [5,6]. Equipoise refers to a state of genuine uncertainty regarding the comparative therapeutic merits of different arms of an intervention trial [7]. Evidence suggests that even when consent forms include clear statements about equipoise, the majority of participants remain unaware that the best intervention is in fact unknown [5,8–10]. Participants often hold a preference for one intervention over another based on personal values and interest [11,12], suggesting that equipoise may not be fully understood [7].

While a full discourse of culture and technology is beyond the scope of this article, it is in this context that the issue of maintaining equipoise between technological and nontechnological interventions is situated [13] and is thus an important consideration for health IT researchers. In our society, technology often is granted sovereignty [14]. The success of technology in providing convenience, comfort, and speed has led our society to view nontechnological alternatives as naturally inferior. Technology often is equated with progress and promise and, as such, implies that technology is better than traditional or conventional approaches that are considered old-fashioned and outdated [14,15]. In trials where participants are assigned randomly to different interventions, at least one of which is technology-based, it is important to provide assurance that none of the participants, including those randomized to a standard care control group, are being harmed by having a chance of receiving an inferior therapy.

Monitoring data and safety

While investigators conducting research on human beings are obligated to guard the safety and well-being of study participants, data and safety monitoring (DSM) procedures may or may not be required depending on the complexity or risks involved in the study. According to the codes of ethics developed to address the obligations of researchers employing electronic data collection and communication *via* the Internet and other health technologies [16–19], researchers need to establish procedures to monitor the health indicators collected as outcome data of a health IT intervention,

so that worrisome condition changes are detected and patient safety is ensured.

Maintaining intervention consistency amidst the changing pace of technology

A hallmark of intervention trials is achievement of internal validity of the intervention (i.e., keeping the intervention constant over the course of a trial). Such consistency is necessary for drawing accurate conclusions about the relationship between the intervention and the effects that are examined in the study. However, achieving intervention consistency may be particularly challenging in the case of health IT interventions when IT itself is an integral part of the intervention, not merely a mode of intervention delivery. The speed of technology development clearly outpaces the timeline required to develop and conduct a typical full-scale intervention trial [20]. During the same study period, new technologies and applications are constantly being developed and entering the technological landscape. New developments may be problematic because the health IT interventions under study may rely on technology platforms and applications that are either merely outdated, at best, or, at worst, completely obsolete by the end of the trial period. Conversely, the inability to use the newer technologies and hardware that become available during the trial is also problematic, since the latest technologies are often simpler for designers to program and more intuitive for users. Furthermore, new and independent technologies targeting the same health outcomes may be introduced to the market and thus available to the participants during the course of the study.

Riley and others [21–24] have suggested strategies for conducting trials of health IT interventions in order to keep pace with technology development, including such strategies as focusing on testing the core components of the health IT intervention rather than a specific delivery platform, leveraging a variety of technologies to deliver the health IT intervention during the trial, shortening follow-up periods to accommodate changes in technology, evaluating proximate outcomes and model or simulated more distal outcomes, or using alternative designs in order to identify combinations of intervention components that optimize outcomes.

Monitoring intervention fidelity for health IT

The importance of customizing the intervention fidelity evaluation plan to the unique components of each intervention has been established, as have the challenges associated with evaluating fidelity of complex interventions [25]. Because

implementation of most health IT interventions involves a dynamic interplay between the participant and a technological application or interface and can vary at any stage of the process (delivery, receipt, acceptance, and intention to use), models of intervention fidelity that focus exclusively on intervention delivery are deemed inadequate for evaluating the fidelity of health IT interventions. An assessment of human factors, such as receipt and acceptance, known to influence user adoption and intended behavior change [26–30] should also be included in monitoring to ensure that the health IT intervention is implemented as planned.

We describe a randomized controlled trial (RCT) designed to evaluate the effects of Pocket PATH® (Personal Assistant for Tracking Health), a novel health IT intervention, to promote self-care agency (the capability and willingness to engage actively in self-care behaviors), the performance of self-care behaviors, and ultimately, transplant-related health outcomes among patients with chronic illness to illustrate how we addressed the issues unique to trials of health IT intended for patient use. Because our trial tests Pocket PATH in a specific patient population (recipients of lung transplants), we also provide a brief overview of this population and the relevance of health IT to it.

Methods

Health IT and lung transplantation

Barely 84% of lung transplant recipients (LTRs) survive the first year after transplantation, and only 64% and 53% of LTRs are alive by third and fifth years, respectively [31]. LTRs experience more transplant-related complications, higher health resource utilization, and higher mortality than recipients of other solid organs [32]. Prevention and detection of early complications is known to reduce the likelihood of future impairments in lung function and, therefore, morbidity and mortality [33]. However, no RCT has tested health IT interventions designed to promote self-care and improve health after lung transplantation.

The features of Pocket PATH were designed to support patients' self-care agency and performance of self-care behaviors, such as adhering to the medical regimen, performing self-monitoring, and communicating condition changes to clinicians after lung transplantation. These behaviors are known to promote better health outcomes for persons with a variety of chronic illnesses; thus health IT interventions designed to support self-care behaviors among different patient populations are likely to include similar features, although the details of the regimens and particular health indicators may differ among types of chronic illnesses. Therefore, the issues associated with conducting a RCT of Pocket PATH are likely to be generalizable to other IT interventions with similar goals.

Pocket PATH provides the LTR a Smartphone with customized programs for recording vital signs, symptoms and values from laboratory assays, graphical displays of changes in those values over time, and automatic generation of feedback messages to provide decision-support for LTRs about when and what to report to their transplant providers (see Table 1).

Based on the success of Pocket PATH in promoting self-care and quality of life in the early posttransplant period [34], a full-scale RCT to compare the efficacy of Pocket PATH for promoting self-care agency (the capability and willingness to engage in self-care behaviors), self-care behaviors, and hence, improving transplant-related health during the first 12 months after lung transplantation relative to standard care is nearing completion.

Design and setting

The Pocket PATH trial uses an RCT design with repeated measures. The RCT is conducted in association with University of Pittsburgh Medical Center Cardiothoracic Transplant Program and is approved by the University of Pittsburgh Institutional Review Board.

Specific aims

The primary aims of the Pocket PATH trial are to (1) compare the effects of Pocket PATH versus standard care on self-care agency and self-care behaviors at 2, 6, and 12 months post-discharge after lung transplantation and (2) compare the effects of Pocket PATH versus standard care on transplant-related health (posttransplant complications, rehospitalizations, and health-related quality of life) at 2, 6, and 12 months post-discharge after lung transplantation. A secondary aim of the study is to explore intervention fidelity, patient acceptance, and adoption of the Pocket PATH intervention to support the processes of self-care after lung transplantation.

Sample

Eligible participants include adult LTRs who are recovering on the cardiothoracic transplant stepdown unit prior to hospital discharge and are able to read and speak English. LTRs excluded had received a prior organ transplant (to avoid experiential effects) or were experiencing a condition that precluded discharge from the hospital or limited their
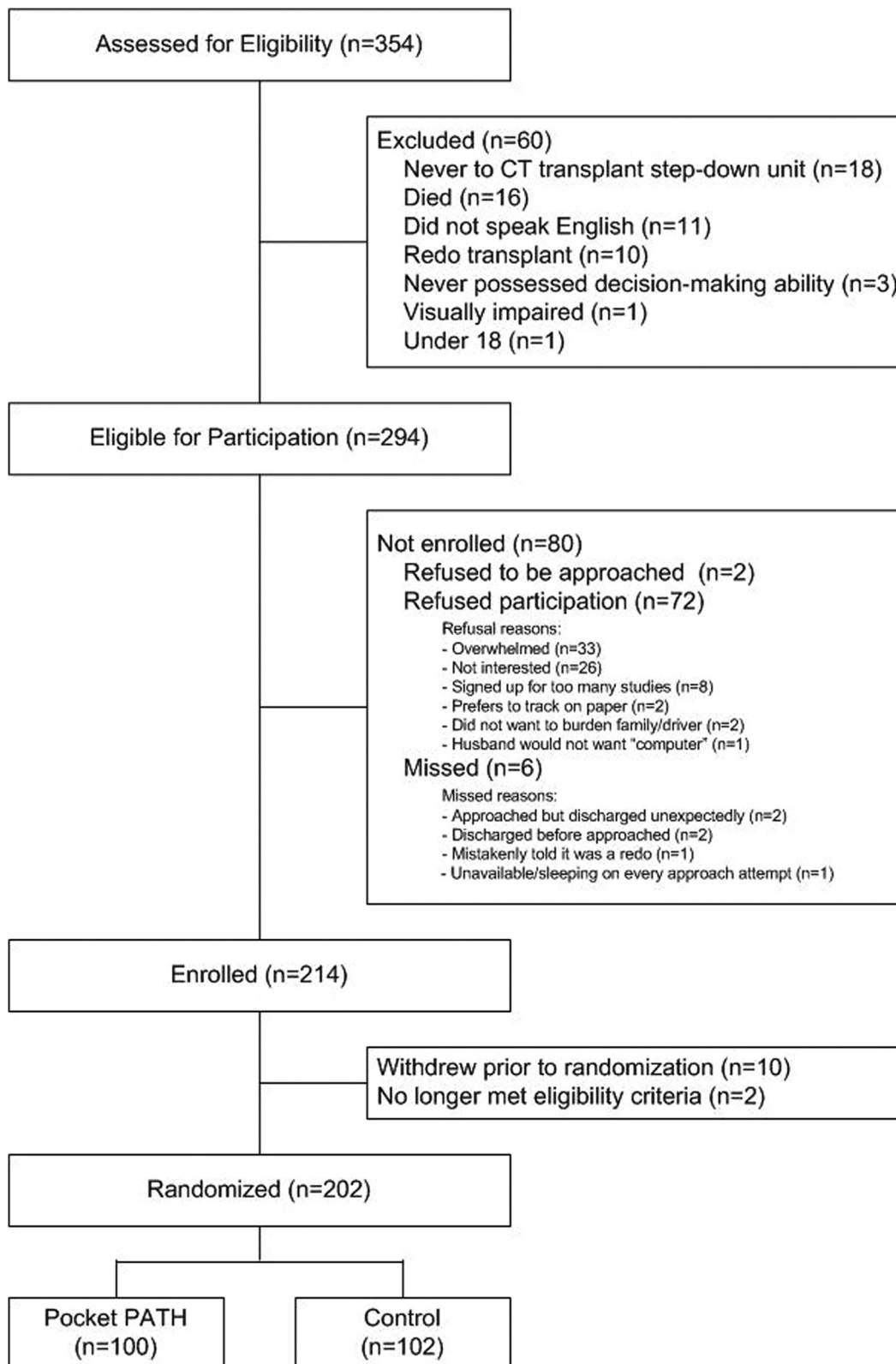
Figure 1. Flow diagram of recruitment and randomization.

Table 1. Features of Pocket PATH® intervention to support self-care behaviors

Features to support self-monitoring
Direct data entry (vital signs, symptoms, lab values)
Data display options (log and graphs)
Critical values indicated on graphs
Features to support adhering to regimen
Calendar
Reminder systems
Note-keeping option
Features to support communicating with transplant team
Automatic feedback messages generated when critical values are entered
Log of all previously generated feedback messages

ability to be actively involved in their posttransplant care. The targeted sample size of 202 was set to provide 80% power to detect an effect size of 0.45 [34] for the performance of self-care behaviors at a two-tailed significance level of 0.05 using a *t*-test for independent samples.

After baseline measures were collected and discharge was imminent, recipients were assigned randomly to either the Pocket PATH intervention group or the standard care control group. Recruitment and randomization for the study were completed in December 2011 (see Figure 1).

Trial arms

Control group: standard care

Standard preparation of LTRs for discharge and transition to home included a one-on-one, educational session delivered by the transplant nurse coordinator of the clinical team prior to hospital discharge. During the session, 'Need to Know' topics (e.g., self-monitoring and medication-taking) were reviewed with each LTR and typically a family caregiver(s). A home reference binder was provided to each recipient that included paper-and-pencil 'Log Sheets' and instructions to record daily health indicators (e.g., pulse, blood pressure, temperature, spirometry, and symptoms). LTRs were also given written instructions describing parameters for 'when to call' the transplant team if changes in these health indicators occurred. After discharge, a referral for at least one home visit was arranged. All LTRs were scheduled to return to the transplant center for routine follow-up evaluations within the first week, then monthly for the first 3 months, at least quarterly for the first year, and more frequently as needed. The transplant nurse documented the delivery of each component of the discharge educational session in the recipient's medical record.

Intervention group: Pocket PATH intervention in addition to standard care

The core components of the Pocket PATH intervention, goals, and the corresponding interventionist behaviors are shown in Table 2. Components included defining self-care agency (i.e., what it means for patients to actively participate in their care), the importance of performing recommended self-care behaviors, and the role of Pocket PATH in promoting higher levels of patient activation and self-care. LTRs were also provided the Pocket PATH device and trained to use its features and custom programs, including return demonstrations of competency using the device for self-monitoring, adhering to the regimen, and decision-support about reporting condition changes to the transplant providers. The training session lasted approximately 30 minutes and was delivered by one of two trained study interventionists. Following training, recipients were instructed to use the device and its programs to track health indicators and to report changes in their conditions according to the coordinator's discharge instructions. Recipients were given a Pocket PATH User Support Manual and a toll-free number to call for help with technical problems with the device that was answered by research staff members during regular business hours. In the event that recipients were not able to perform the tasks after training, remedial training was provided on an individual basis. Because the device was intended to assist with self-care behaviors, data recorded on it were logged and graphed for each recipient to view (see Figure 2). The device was programmed to generate automatic decision-support messages reminding recipients to report changes to the transplant clinicians whenever health indicators reached the threshold for reporting changes described in the standard discharge instructions. Data were not shared directly with clinicians; instead, the data were uploaded automatically to the research project's database daily *via* secure cellular connection. Throughout the training session and subsequent contacts, trainers stressed to LTRs, both orally and in the training materials, that the transplant team maintained responsibility for managing all clinical care and that changes in clinical data should be reported to the transplant care providers. Whenever an LTR contacted the research staff about a clinical issue, the research team redirected him or her to a member of the clinical transplant team.

Measures

Outcome measures

Self-care behaviors (performing self-monitoring, adhering to the regimen, and communicating

Table 2. Core components, measurable goals and interventionists' behaviors

| Core component and goal	Interventionists' behaviors
I. Introduction and preparation. **Goal:** patient at ease and prepared for learning	(a) Introduce self and session (b) Acknowledge the challenges of performing self-care after transplantation (c) Assess barriers to performing self-care (medication timing, effects, symptoms, motor skills)
II. Discussion of activation and self-care. **Goal:** patient understands the importance of being an activated patient and performing recommended self-care activities	(a) Define an activated patient (one who performs self-care and is an active partner with transplant providers) (b) Define self-care activities (self-monitor, follow regimen, notify coordinator of changes) (c) Explain importance of being an active partner and performing self-care activities
III. Explanation of Pocket PATH® **Goal:** patient understands the role of technology in promoting higher levels of patient activation	(a) Explain the importance of balancing use of technology (Pocket PATH) with human factors of technology acceptance
IV. Demonstration; goal: patient engages in hands-on practice using Pocket PATH features	(a) Review personal interpretation of events as the primary source of information; technology only secondary (b) Introduce device, user training manual (c) Introduce features of Pocket PATH and link to care expectations regarding self-care (d) Demonstrate features (e) Observe patient return demonstration of features
V. Evaluation of patient competence. **Goal:** patient demonstrates competence in using Pocket PATH features and draws linkages between use and improved patient activation and self-care	(a) Evaluate competence of patient using Pocket PATH (b) Self-monitoring (entering, viewing, and interpreting data) (c) Adhering (using reminders and calendars) (d) Communicating condition changes appropriately (based on automatic decision-support feedback messages)
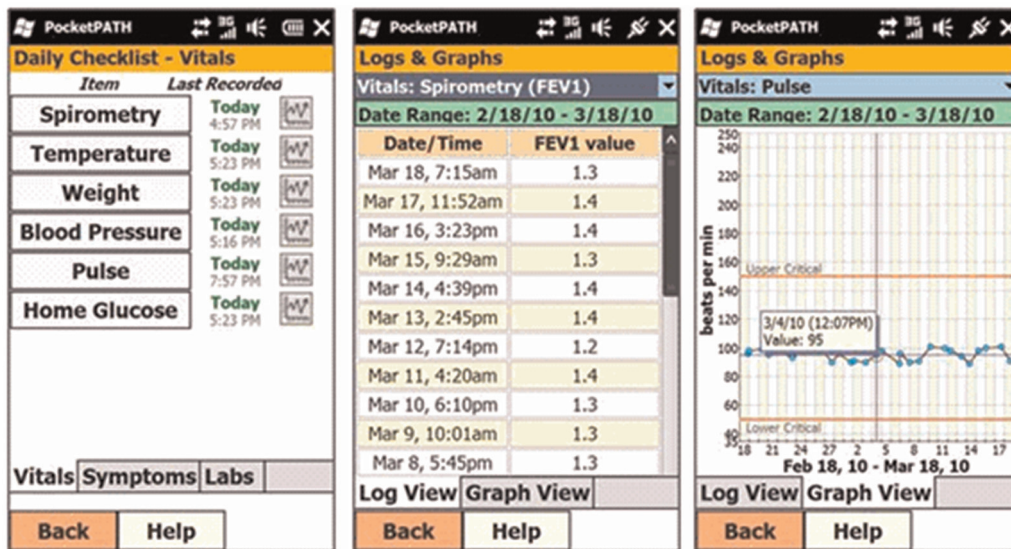
Figure 2. Selected screenshots of the Pocket PATH® graphic user interface.

changes in clinical condition) and transplant-related health outcomes (complications, rehospitalizations, psychological distress, and health-related quality of life) were assessed at 2, 6, and 12 months post hospital discharge. These intervals were selected because (1) they coincided with return visits for routine

posttransplant evaluations, (2) we detected effects by 2 months post-intervention in the pilot RCT [30], (3) studies have shown that patients' orientation toward sharing responsibility with their healthcare providers is malleable, with intervention effects seen as early as 8 weeks [35,36], and (4) variation in transplant-related health outcomes are evident as early as 6 weeks post transplant [36,37]. Patient characteristics that may account for variation in intervention effects (sociodemographic characteristics, self-care agency, quality of relationship with primary lay caregiver, and health locus of control beliefs) were assessed at baseline prior to randomization.

Health IT measures

Four measures of technology acceptance [38,39], based on concepts of the Technology Acceptance Model (TAM) [40,41], were assessed: Perceived Ease of Use, Perceived Usefulness, Attitudes Toward Using, and Intention to Use the Technology. The range of scores for the four technology acceptance measures is 1–7; lower scores reflect higher levels of technology acceptance. Consistent with the developers' recommendations, they were administered by a trained data collector (noninterventionist) after the Pocket PATH intervention had been delivered and the LTR had demonstrated receipt but before they had experience using Pocket PATH independently. Evidence that these technology acceptance measures predict a substantial portion of the use and acceptance of technologies abounds [42–48]. The measures are standardized, reliable [38], and valid [49] and have been used across different settings. The After Scenario Questionnaire (ASQ) [50], a 3-item, reliable, and valid questionnaire of satisfaction with training to use a technology, was administered by a trained data collector (noninterventionist) after completion of the TAM scales. The ASQ assesses user satisfaction with the ease of task completion, the amount of time it took to complete a task, and the adequacy of support information (such as a user manual or help screens) during the training session. Items are rated on a 7-point Likert-type scale (1 = Strongly Agree to 7 = Strongly Disagree); lower scores reflect higher levels of satisfaction with technology training.

Technology adoption

Data were collected for utilization of Pocket PATH based on time-stamped data uploaded from each device over the course of the study. Patterns of usage were examined for changes over time. We limited this evaluation to data related to participants' technology acceptance and satisfaction with technology

training for several reasons: (1) satisfaction and acceptance were assessed early in the study period prior to participants' independent use of Pocket PATH, (2) final data regarding Pocket PATH adoption and its impact on self-care and transplant-related health for the 12-month study period for all participants are not yet available, (3) there is insufficient power to draw conclusions about adoption and impact of Pocket PATH on self-care and health outcomes until all participants have completed the trial, and (4) our purpose is to raise awareness of issues and considerations for conducting trials of health IT intended for patient use.

Results

Participants' scores for the measures of health IT demonstrated high levels of acceptance of the device by those assigned to receive it and satisfaction with the Pocket PATH training session (see Table 3). Scores close to 1 indicate greater acceptance (TAM) and greater satisfaction with training (ASQ).

Lessons learned

Maintaining equipoise between technology-based interventions and control conditions

When the Pocket PATH trial was getting underway, both transplant clinicians and potential study participants expressed preconceptions about the superiority of the health IT intervention compared to standard care. Our research team employed several strategies to promote equipoise throughout the Pocket PATH trial. We intentionally referred to the trial as *The Study Comparing Methods for Tracking Health at Home* when communicating with the transplant clinicians, potential study participants,

Table 3. Mean and standard deviation for health IT measures (TAM and ASQ), IT intervention arm only

	Mean score	Standard deviation
Technology Acceptance Model (TAM)*		
Perceived Ease of Use	1.44	.67
Perceived Usefulness	1.40	.57
Attitudes Toward Using Technology	1.34	.53
Intention to Use the technology	1.28	.80
After Scenario Questionnaire (ASQ)**	1.25	.52

IT: information technology.

*N = 65; TAM measures were added to the battery of instruments after the start of study. Possible scores for the TAM measures ranged from 1–7, with lower scores indicating greater acceptance.

**N = 93; 6 participants did not complete the ASQ. Scoring was based on a 7-point scale; lower scores indicate greater satisfaction.

and the Institutional Review Board. Terms such as Pocket PATH and references to Smartphone or technology were explicitly omitted from the trial title, from conversations about the study, and on the consent form. Because the nurses and other members of the transplant team served as liaisons to identify LTRs who met the eligibility criteria, educational sessions about the study and the need to maintain equipoise were provided to members of the clinical lung transplant surgical team; informational flyers were posted in the staff lounges to increase awareness of the study and the need for equipoise. The consent materials included explicit statements regarding the uncertainty of intervention benefits, and hence, the need to conduct the trial. Whenever a LTR or clinician expressed an opinion about the superiority of the Pocket PATH intervention, he or she was reminded that the integrity of the trial depended on suspending beliefs about the superiority of technology.

Employing appropriate safety monitoring procedures

Data from the Pocket PATH devices were uploaded automatically to the project web site in order to track patients' utilization of the device and its features, but these data were not shared automatically with the treating clinicians. We considered it our responsibility to monitor data that may have indicated an unsafe change in a patient's clinical condition and outlined steps for handling worrisome values. If during the process of monitoring participants' use of Pocket PATH the research team became aware of worrisome values, these data could not be ignored. We developed a protocol for the research team to follow when critical values were uploaded to ensure participant safety while keeping threats to study integrity to a minimum. The aim was to follow a series of steps from the least to most intrusive to ensure that the patient was safe (e.g., reviewing the electronic medical record to see whether a critical value had been entered erroneously or the values had returned to normal) before resorting to contacting the patient or clinical team directly to avoid influencing the outcomes of interest. Since the purpose of the trial was to determine the impact of technology-enabled interventions on self-care and thus patient outcomes, the protocol specified that only if the more conservative actions were ineffective and the project staff judged the threat to be critical would a clinical provider be notified. If such an intervention were necessary, it would be duly recorded for analysis purposes. While it was important to include clinician notification in the protocol, in the end, this step was not necessary during the entire Pocket PATH trial.

In studies such as this one, unexpected risks may be detected more readily when the responsibility for safety monitoring rests with a single member of the research team who can perform close monitoring of individual participant data; therefore, the project director who had the clinical experience to detect unanticipated changes in participant conditions was responsible for (1) reviewing uploaded data every 72 h to ensure that changes were detected in a timely manner and (2) following the established protocol for handling any critical values. Our monitoring plan also included a mechanism for objective review and oversight of the process. On a quarterly basis, de-identified data were reviewed by a clinical expert in lung transplantation who assessed whether all critical values had been detected and handled appropriately according to our protocol. The expert was also poised to review the impact of notifying clinicians of critical values had this final protocol-defined action been warranted. A full description of our monitoring plan and recommendations for developing monitoring procedures for other trials involving health IT have been published [51]. The monitoring strategies included risk-monitoring procedures, automatic surveillance to detect critical values, and procedures for timely and appropriate action to ensure participant safety [52]. Data recorded by participants in the standard care group were not available to the research team until participants shared their health logs with their transplant clinicians during their regularly scheduled return clinic visits to the transplant center, which coincided with our data assessment time points.

Maintaining intervention consistency amidst the changing pace of technology

Some health IT trials may be better able than others to maintain intervention consistency while keeping pace with technological developments; the trial of the Pocket PATH intervention exemplifies strategies for dealing with changes beyond the control of the trial designers. The Pocket PATH software was originally developed for the iPAQ (HP iPAQ hx2755 Pocket PC; Hewlett Packard; Microsoft® Windows Mobile™ 2003 Second Edition). Although at the time the iPAQ was among the most versatile pocket personal computers, it relied on modem connectivity to upload data remotely. By the time the RCT was ready to begin, cellular connectivity became available, and so we abandoned the iPAQ in favor of a Smartphone. We decided to provide LTR Smartphones (e.g., Tilt, HTC, Windows Mobile Professional 6) loaded with the Pocket PATH programs. To avoid having to rewrite the graphic user interface programs, our choices were limited to phones that used Windows Mobile with similar screen

dimensions. As new versions of .NET and Open-NETCF (the frameworks used for developing the programs) were released, we migrated to the newer versions not only because they added more features and simpler ways of doing things but also because the older versions were no longer supported. Migrations almost always led to compatibility problems with what we had already built, thus requiring adjustments to the source code. Each migration required testing to ensure Pocket PATH worked as well for users as before the changes.

Ultimately, as often occurs, as new device models were introduced, the older Tilt models were no longer available for purchase, so we had to change models (Pure, HTC, Windows Mobile Professional 6.5). Migrating from iPAQ to Smartphones presented challenges, especially to adapt the graphing functionality to work with any screen resolution. However, since the Tilt and Pure phones used versions of Windows Mobile different from the iPAQ, to keep the user interface and features consistent, our software engineer had to ensure that the Pocket PATH programs worked seamlessly across different versions of Windows Mobile. Even upgrading from version 6 to 6.5 caused problems as some things were not backward compatible. Uploading mechanisms had to be modified between the Tilt and Pure versions because version 6.5 of Windows Mobile added certain restrictions to Internet connectivity from within applications. Additionally, while we were able to maintain consistency with our original intervention, every time we were forced to switch to a different mobile device we had to update our training manuals and educational materials to match the newer model, adding cost and effort to an already expensive intervention trial. After changing platforms three times, we purchased enough Pure models to complete the study rather than having to change phone platforms again.

In spite of essential modifications, we believe we were able to maintain consistency in the user interface and functionality, so that each LTR in the intervention arm had a comparable experience with Pocket PATH. However, some health IT interventions may be linked inextricably to certain technologies, applications, or interfaces and less able to be modified to keep pace with newly introduced technologies and applications. Depending on the health IT intervention under study, investigators may be forced to maintain intervention consistency over the course of the trial at the risk of evaluating an intervention that is outdated and possibly obsolete by the end of the trial.

Maintaining intervention fidelity for health IT interventions

A variety of models of intervention fidelity exist, but we adopted the following definition: the degree to which the intervention implementation process is an effective realization of the intervention as planned [53]. We developed an intervention fidelity framework to guide the development of a multicomponent plan to evaluate intervention fidelity for the Pocket PATH trial. A full description of the components of the framework, how each is measured, and how the data regarding fidelity are used to test the relationships purported in the model and to draw conclusions about the consistency, validity, and effectiveness of the Pocket PATH intervention have been published [54]. The concepts included in the model of intervention fidelity for health IT interventions go beyond delivery (the extent to which the intervention is delivered as intended) and receipt (the extent to which the intervention is received as intended) to include the concept of technology acceptance (the extent to which the subject has positive perceptions, attitudes, and intention to use the intervention). Although these concepts are believed to apply to fidelity of all health IT interventions, the information that is monitored and the types of data available are intervention specific [34,35,45]. We believe that this multidimensional view of intervention fidelity allows for a better understanding of the role that technology acceptance plays in the adoption of health IT interventions and thus enactment of the behaviors the interventions are intended to promote.

Discussion and conclusion

In this study, we used a novel health IT application to maximize the contribution of LTRs themselves in preventing and detecting posttransplant complications. Health IT interventions may be particularly appropriate for organ-transplant recipients because most live outside the local region of the transplant center and no other personal computer support is required in the home. All LTRs were expected to perform the self-care activities supported by Pocket PATH; ratings of technology acceptance by participants in the IT intervention arm were high, but it is as yet unknown whether the use of this health IT device will prove to be superior to standard care in promoting self-care behaviors and transplant-related health outcomes. Data analysis of the trial outcome measures was underway at the time of acceptance of this article for publication.

The protocol to evaluate the efficacy of Pocket PATH provides practical guidance to investigators who wish to evaluate other health IT interventions, particularly those designed to promote self-care behaviors among patients with other chronic illnesses. Issues of compliance with established procedures for conducting RCTs and strategies to address the issues uniquely associated with the evaluation

of health IT intended for patient use in the Pocket PATH trial included maintaining equipoise (i.e., uncertainty regarding the outcome of the study), ensuring an appropriate level of safety monitoring surveillance, ensuring the validity and integrity of trial data, customizing the plan for monitoring intervention fidelity (i.e., including all potentially variable aspects of intervention fidelity, including delivery, receipt, acceptance, and intention to use), and adopting strategies to keep pace with technology change.

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Conflict of interest

None declared.

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