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Strategies for mHealth research: lessons from 3 mobile intervention studies

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Abstract

The capacity of Mobile Health (mHealth) technologies to propel healthcare forward is directly linked to the quality of mobile interventions developed through careful mHealth research. mHealth research entails several unique characteristics, including collaboration with technologists at all phases of a project, reliance on regional telecommunication infrastructure and commercial mobile service providers, and deployment and evaluation of interventions “in the wild”, with participants using mobile tools in uncontrolled environments. In the current paper, we summarize the lessons our multi-institutional/multi-disciplinary team has learned conducting a range of mHealth projects using mobile phones with diverse clinical populations. First, we describe three ongoing projects that we draw from to illustrate throughout the paper. We then provide an example for multidisciplinary teamwork and conceptual mHealth intervention development that we found to be particularly useful. Finally, we discuss mHealth research challenges (i.e. evolving technology, mobile phone selection, user characteristics, the deployment environment, and mHealth system “bugs and glitches”), and provide recommendations for identifying and resolving barriers, or preventing their occurrence altogether.

Keywords

Mobile Health (mHealth); e-Health; Mobile Interventions; Schizophrenia; Depression; Primary Care

Introduction

Over the last decade, the penetration of mobile phones coupled with infrastructure for telecommunication has been growing rapidly and expanding globally (WHO 2011). Mobile phone subscriptions have reached six billion worldwide, and are projected to reach 6.8

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billion by the end of 2013 (ITU 2013). Currently, ninety percent of the world is covered by a mobile cellular network, with approximately three-quarters of all mobile phones being used in low and middle income countries. The number of mobile phones being used in developed countries exceeds the population of those countries (ITU 2011). In the U.S., traditionally underserved minority groups are now using “smartphones” (i.e. mobile phones with computational capacities) as their primary method for accessing resources on the Internet (Smith, 2013). Recent research shows that even people with severe psychiatric disabilities and functional impairment, as well as many unsheltered homeless individuals, own and use mobile phones (Ben-Zeev et al. 2013; Eyrich-Garg 2010).

Mobile phones have become an integral part of our daily lives-- we use them for communication (e.g. talking, texting, email), social and professional networking, education, entertainment, navigation, shopping, gaming, banking, and more. In addition to these commercial purposes, mobile phones can serve as instruments that can be harnessed to support healthcare; they are carried on the person, typically turned on, and allow for bidirectional communication and on-demand access to resources (Proudfoot 2013). Thus, mobile phones can facilitate patient/provider contact, delivery of time-sensitive health information, and point-of-care resources (e.g. remote consultation, decision support systems). Smartphones can host health applications (apps) designed to be used by patients and providers for diagnostics, behavioral prompts, reminders, and continuous illness monitoring and self-management programs that extend well beyond the boundaries of a physical clinic (Ben-Zeev et al. 2012; Harrison et al. 2011; Luxton et al. 2011).

The enthusiasm for using mobile phones and other handheld devices for healthcare initiatives has led to the emergence of a novel interdisciplinary field called Mobile Health (*mHealth)*. More and more researchers from different health disciplines are interested in developing evidence-based mHealth interventions for a range of physical and mental health conditions (Heron and Smyth 2010; Kaplan and Stone 2013). But conducting mHealth research with mobile phones is complex; in addition to the host of challenges investigators typically face when conducting intervention research with human participants, mHealth studies entail characteristics with which many clinical researchers are unfamiliar. These include the need for close collaboration with technologists at all phases of a project, reliance on regional telecommunication infrastructure and commercial mobile service providers, and deployment and evaluation of interventions “in the wild”, with participants using their mobile phone-based mHealth tools in uncontrolled environments. Without realistic expectations and planning, integration of complementary sets of expertise in the research team, and an ability to remotely monitor, detect, and flexibly resolve obstacles as they arise, researchers will find mHealth projects to be daunting and difficult.

In the current paper, we summarize the lessons our multi-institutional/multi-disciplinary team has learned conducting a range of mHealth projects using mobile phones with different clinical populations. Our objective is to generate a resource that will help inform and prepare researchers venturing into the mHealth arena. First, we describe three ongoing projects that we will draw from to provide concrete illustrations throughout the paper. We then provide an example for multidisciplinary teamwork and collaborative mHealth intervention development that we found to be particularly useful. Finally, we discuss several obstacles

that arose with the deployment of our mHealth tools in the field, and provide recommendations for identifying and resolving barriers, or preventing their occurrence altogether.

mHealth project descriptions

Together, the authors have completed or are currently involved in over 20 projects that use mobile phones for monitoring, treatment, or self-management of physical or mental health conditions. We selected three ongoing projects that vary in design, objectives, and scope, to expose readers to a range of challenges and points for considerations.

The first project is a mobile phone application designed for the treatment of depression. This project is funded by a developing center grant from the National Institute of Mental Health that aims to develop novel systems of care that can provide efficacious, scalable, cost-effective, patient friendly behavioral intervention technologies. The application, called “Mobilyze”, represents one such system and is a smartphone intervention based on principles of behavioral activation, which aims to reduce depressive symptoms by increasing the user’s engagement in activities that are pleasurable or provide a sense of accomplishment. Patients receive didactic information, tools to help plan and track positive activities, and reminders. A novel goal of the Mobilyze project is to develop a context sensing system that harnesses data from sensors embedded within the smartphone to identify user states that may be relevant to treatment, such as location, activity, social context, and mood. A pilot study conducted with participants with major depressive disorder provided support for the intervention model, and initial development and evaluation of the context-sensing system (Burns et al. 2011).

The second project is funded by the National Institute of Mental Health through a grant mechanism designed to provide support for the initial development of a clinical trial. It focuses on improving adherence to antidepressant medication and provide guideline-congruent care for patients receiving treatment within primary care. MedLink is a mobile phone application that tracks medication adherence using a cellularly enabled pill bottle. The pill bottle notifies the system when the bottle has been opened. The system also periodically prompts patients to enter information about their symptom severity and medication side effects. Data collected via the pill bottle and the prompts allows tailored information on depression and side effect management and just-in-time reminders to be provided to the patient. Information on symptom severity, side effects, and adherence, along with decision support based on clinical guidelines are provided every 4 weeks to the care team and the patient, aimed at optimizing dose and selection of medication. In order to develop MedLink, we progressed through a staged process of user-centered design, laboratory usability testing, and a field trial of the MedLink application.

The third is a large multi-site project funded by the Centers for Medicare and Medicaid Services, focusing on improving the clinical care for high-risk patients with schizophrenia. The project is conducted in nine states in the U.S. and involves development of a new clinical workforce that trains individuals with schizophrenia recently discharged from psychiatric hospitalizations to use an array of newly developed intervention technologies. In

the context of this project, people with schizophrenia receiving outpatient care in the community are provided with a smartphone and trained to use FOCUS, a mobile system that delivers daily assessments and interventions designed to support self-management of their illness. The FOCUS system offers both system-prompted and on demand user-initiated interventions, including coping strategies for psychotic symptoms, social skills training, behavioral tailoring for medication adherence, mood regulation, guidance for sleep hygiene, and behavioral activation (Ben-Zeev et al., 2014). Reports summarizing user clinical status ratings and interventions deployed are displayed on a secure online dashboard that is accessible to their clinical care team. The system was developed through a staged approach in which both clients and practitioners at community mental health settings provided input regarding unmet clinical needs, viable treatment targets, and mobile system usability (Ben-Zeev et al. 2013).

All three interventions are delivered via mobile phones, and use behavioral strategies to help promote better coping with clinical conditions. The interventions are similar in that they have some level of flexibility (i.e. the frequency and intensity of administration is not fixed), entail some form of tailoring (i.e. intervention content and format is informed by participants' unique needs), and were designed with a specific clinical population's needs in mind. A summary of the main characteristics of the three projects is provided in Table 1.

Multidisciplinary Teamwork

With basic programming skills, clinical researchers can independently use available open source software that can support mobile assessment research (e.g. Ecological Momentary Assessment, Experience Sampling Methods) using personal digital assistants (PDAs) or mobile phones (e.g. The Experience Sampling Program, Purdue Momentary Assessment Tool, PACO, funf). But sophisticated mHealth interventions may require more technological expertise than most clinical researchers possess. In our work, we found that multidisciplinary teams comprised of clinical experts (e.g. clinical psychologists, physician-scientists, pharmacologists) and technologists (e.g. software programmers, health systems engineers, computer scientists) working together throughout the entire project period, are essential to the production of mHealth interventions that are designed, deployed, and adapted effectively.

Different aspects of an mHealth project are intellectually stimulating and rewarding to different members of the multidisciplinary team. What constitutes novelty and innovation is viewed differently from the vantage point of clinicians and technologists. Clinical researchers are often focused on harnessing existing technologies for new clinical applications, rather than optimizing or extending the technological methodologies themselves. While translation of existing interventions into technological mediums is important from a public health perspective, it is less likely to excite technologists who are focused on the cutting-edge of technological development.

Successful multidisciplinary teams overcome the hurdles associated with differences in scientific philosophy, training, communication, and professional cultures of each team members' specialized subfield. As multidisciplinary teams merge expertise to create more

sophisticated solutions, a growing focus on facilitating successful "team science" has emerged within behavioral sciences (Vogel et al., 2013). The first step in resolving these differences is clearly identifying them. In service of this goal, we highlight several challenges noted in our own work and offer solutions below. The National Cancer Institute's Team Science Toolkit (www.teamsciencetoolkit.cancer.gov) offers several practical tools to support multidisciplinary work as well.

Integrating Methods

Clinical researchers are trained in methodologies that assess whether a given intervention brings about an important change in clinical outcomes. The gold standard in this field is the Randomized Controlled Trial (RCT) (Chambless and Hollon 1998; Rounsaville et al. 2001) that if successful, allows researchers to conclude that a new intervention is effective compared with another treatment option. Technologists, use evaluation methods that focus on whether a newly developed product is usable and useful for the intended audience (Wichanksy 2000). In these fields, low-fidelity prototyping (Rudd et al. 1996), A/B testing (Hekler et al. 2013), iterative design (Pagliari 2007), and agile development (Martin 2003) are used to more rapidly create and refine products prior to evaluation as these designs preference adaptability and generating data early over the internal validity offered by RCTs. The ideal methodological resolution will likely need to encompass elements from both fields. For example, conducting early prototyping and iterative system improvements to inform development prior to an RCT to test efficacy. This progression, from early evaluations to an eventual RCT is similar to the Multiphase Optimization Strategy (MOST) that outlines stages of intervention conceptualization, refinement, and evaluation that occur before an RCT (Collins et al., 2011). Early evaluation and the MOST approach promotes the efficient use of resources and provides the opportunity to collect data to improve the intervention prior to an RCT.

Developing mHealth "Stories"

We find that breaking objectives into smaller, more proximate goals make them easier to discuss in multidisciplinary settings, easier to assess during initial development, and provides data that clinical researchers desire to guide their decision-making. For example, instead of discussing "how do we improve patient adherence to their medication regimen?" we will focus on "how will the patient be prompted to maintain adherence, by establishing consistent routines and overcoming barriers related to forgetfulness, side effects, and perceived lack of medication efficacy?"

Identifying these proximate goals, however, requires clinical experts to specify the specific behavior change strategies incorporated within their mHealth interventions (Klasnja et al. 2011). We make these specifications, in a format called "stories" (Cohn 2005). In a story, the stakeholders (ideally a combination of clinical experts, technologists, and representative users) specify the action that a user should be able to perform using a feature of the new technology. A story can be constructed using the following template: "As a <role>, I want <goal/desire> so that <benefit>" (Cohn, 2004; 2005). An example of a story shared among the three projects introduced above is "As a participant, I want to be prompted at various intervals so that I receive intervention content at the relevant time." The use of stories is

helpful for several reasons. First, it requires clinical experts to be more specific with the requests they make of programmers. Second, it provides the technologists an idea of the aim of the feature. Third, it allows for prioritization of intervention features. Fourth, it allows for coordination and transparency between stakeholders as each stakeholder is required to specify their goals and rationale in a manner that is succinct, descriptive, and understandable to other stakeholders.

When a single story can be used across several projects, it allows technologists to develop a shared architecture that can support the development of multiple mHealth resources. The three projects described in this paper have significant overlap in terms of necessary functional features. Their shared story architecture enabled us to reduce the complexity of producing three completely discrete platforms, increase exposure of the developed array of features to different devices and testing conditions, and reduce the risk of resource problems due to potential funding cuts. Focusing on elemental stories, rather than overall study objectives reduces the need to "reinvent the wheel" with each project, and promotes cross-study learning and resource sharing. Thus, troubleshooting resources are expanded during the initial prototype development phase, and future projects are more likely to be successful due to the lessons learned and experience gained developing and deploying technological tools.

Converging Work Styles

Clinical researchers often develop projects that require long-term investment, and are evaluated and modified relatively infrequently. Technologists work on products or features, and are used to rolling out and updating "current versions" rather than creating a final intervention that will then be deployed for evaluation. In the technology field, "hack-a-thons" or "codefests" represent a brief period of time with concerted effort to create a product. We attempt to bridge these styles, using both at different times. Ongoing projects typically involve weekly meetings to connect clinical researchers and those in the field with technologists to ensure that major project milestones are being met, and any technological problems that may be impacting mHealth system deployment are addressed. At various stages of the development process, we have found it useful to plan an intensive day or series of consecutive days to work on a single project to "push" it into a version that is ready for usability testing, field trial, or final deployment. In the case of Mobilyze, a full day of clinicians and technologists working side-by-side to develop intervention content along with the technology to import that content into a mobile application helped solidify a system that was ready for initial field testing. During periods of rapid development, key individuals from the technology and clinical teams often have daily check-ins. Such brief, focused meetings also reduce the need for reorientation between diverse stakeholders, a procedure that is invariably required with less frequent meetings.

Conceptual Work

From Clinic to Mobile Device

Clinicians and researchers are interested in using technology because they believe it will make their interventions more accessible, engaging, and potent. But mHealth resources are

not guaranteed to be useful and effective simply by virtue of their technological delivery platform. Instead, they require thoughtful design and consideration of the trade-offs associated with using technology. Many clinicians are interested in translating their existing interventions (often provided face-to-face by a clinician) into technological forms. When doing so, it is important to understand the unique properties of the technological medium and how it is used (Schueller et al. 2013). Clinical researchers may find it helpful to articulate the basic behavior change principles they are seeking to support, and the therapeutic mechanisms that will best accomplish this goal. Once these are clear, it is easier to determine how people use devices in ways that might support that behavior change principle. mHealth interventions are not going to mimic therapy sessions but will deliver the therapeutic content in an alternative format. For example, FOCUS draws intervention content from a range of psychotherapeutic models including Cognitive Behavioral Therapy for Psychosis, Anger Management, Sleep Hygiene, and Behavioral Activation. The content of these interventions is typically delivered in weekly face-to-face clinic-based sessions that may last anywhere from 45 minutes to 2 hours. But smartphone users can access applications on their device in any location, and do not typically use their device for such long uninterrupted periods. Rather, information (e.g. web searches, directions) and resources (e.g. call, text) are used as needed, and in short bursts throughout the day. To capitalize on the manner in which people are inclined to use their mobile phones, we shortened the clinical content substantially and distilled it to interactive modules that can be accessed on-demand, and completed in less than 4 minutes. Consequently, FOCUS interventions are less like psychotherapy sessions (i.e. low frequency, high intensity, longer time commitment), and more like typical smartphone use patterns (i.e. high frequency, low intensity, shorter time commitment).

New Interventions, Not Just New Modes of Delivery

Work in mHealth ranges from interventions that take content from another medium and provide it in technological formats (e.g., websites that are essential self-help books delivered online, Carlbring et al., 2005; Andersson et al., 2005) to interventions that link principles of behavioral change to the use of technological features (e.g., using mobile phone sensors to collect information and trigger intervention features, Faurholt-Jepseon et al., 2013). We suggest that this latter approach is a more valuable perspective to take in mHealth, as it allows mobile interventions to be additional tools to promote behavior change that might be useful in conjunction with existing resources. We caution against the use of skeuomorphs, i.e. maintaining an aspect of something that in an earlier version was a functional necessity, but is no longer required (e.g., fake shutter sounds for digital camera or weekly “sessions” for mHealth interventions; see Schueller et al. 2013). In the case of mHealth interventions, the expectation that users will log onto a website and site with a program for 50-minutes (much as they would engage in a therapy session) represents an example of such a skeuomorph. In all of our work, we have found it useful to distill concepts into shorter, more frequent interactions and to use features of the phone and operating system (e.g., notifications, widgets) to mirror interaction styles from other applications rather than standard face-to-face therapy. This allows the users to interact with the mHealth intervention in a manner that is similar to how they use other technological applications, rather than how

they would interact with a therapist. Applications that follow these principles might better be able to be deeply integrated into the daily lives of users.

Barriers to mHealth Research Implementation

The use of mobile technologies to improve the study, assessment, and treatment of mental health conditions has gained considerable momentum over the past decade (Ben-Zeev 2012; Luxton et al. 2011). This is not surprising, as technological features have the potential to significantly advance and alter the way research and practice are conducted (Marsch and Ben-Zeev 2012; Schueller et al. 2013). However, mHealth researchers may encounter several unique challenges in this line of research. We summarize some of the barriers we have encountered in our own work, and provide suggestions for methods for identifying and preventing problems ahead of time, or resolving them expediently.

Evolving Technology

mHealth is a rapidly changing discipline making use of consistently evolving technologies. The mobile technologies used (as well as the interventions they facilitate) can become outdated or obsolete quickly. Riley and colleagues (2013) discuss the technological advances that occur during the standard time period required for a typical RCT to move from grant submission to publication (Riley et al. 2013). In their example, they acknowledge releases of new devices (e.g., the iPhone and iPad) and platforms (e.g., Android). The number of times operating systems change during that period will also impact the development of mHealth applications that are designed to work with a particular version. The environment created by evolving technologies may mean that when a new system is ready to launch, it might not be compatible with recent external changes. For example, on the FOCUS project, an update from Android version 4.0.1 to 4.0.4 changed an essential feature that required a month of delays and software updates. As carrier upgrades are beyond the control of the research team, it leads to an inability to confirm or maintain a stable knowledge of the deployment environment.

Researchers use RCT study models because randomization gives us unbiased estimates. But these methodological practices may not be ideal for studies involving rapidly evolving mHealth technologies. A major workshop was convened at the National Institute of Health to discuss the evaluation of assessments and interventions related to mHealth and the process of evidence generation within this space (Kumar et al. 2013). The workshop produced several suggestions for treatment designs, but one particular important distinction is the proposal that designs be matched to the particular project phase (e.g., treatment develop stage vs. mature intervention testing). Elsewhere, we have argued that implementation of behavioral intervention technologies requires continuous evaluation methodologies that are consistent with how they are deployed and updated in practice (Mohr et al., 2013). mHealth development teams would benefit from maintaining flexibility regarding when an intervention is viewed as being “finished” or when certain design specifications become “locked.” In product development, many businesses seek to deploy a minimum viable product (MVP) that contains just the features that allow that product to be deployed and no more. mHealth researchers can learn from this model by focusing on the specific mechanisms of action they propose will lead to behavior change and omitting

unnecessary features. This has the benefit of allowing researchers to test specific hypotheses, while ensuring that those features work and are compatible with the rapidly changing environment.

Selecting a Mobile Phone

Anyone working within the field of mHealth will grapple with several decisions related to selecting mobile phones and operating systems. This often begins with deciding between using patients' or participants' own phones or providing study phones for the duration of their involvement in the project. This decision impacts the participant eligibility criteria for the study, which ultimately influences recruitment speed, generalizability of study results, and use of developed tools and features for subsequent projects. Benefits of providing mHealth resources that can be installed directly on the user's existing (and familiar) phone include a greater likelihood that they will intuitively understand how to use the system, and that the intervention will be readily accessible as they continue to use the device for other purposes. Moreover, use of other phones functions (beyond those outlined in the intervention) enable the capture of important data. For example, the Mobilyze project uses call logs, GPS location, and other data from the mobile phone as predictor variables in statistical models of user states (e.g., mood) or contexts (e.g., who the patient is with).

Relying on existing participant phones involves a host of complications. Different phones will have different carriers and data plans. Devices also have different screen sizes, processing capacities, and speed. Phones that participants already own might be damaged (e.g. cracked screen, malfunctioning microphone) or ill-suited for their needs (e.g. small displays for people with macular degeneration and vision impairment, tightly-spaced touchscreen buttons for people with Parkinson's disease and tremor). Moreover, it is more costly and labor intensive to develop applications that would be compatible for a wide range of systems rather than one, and it is unrealistic to plan for development of a system that would work well on all devices. To ensure that the FOCUS system was usable by participants with schizophrenia who might have a host of limitations (e.g. motor difficulties as a side effect of taking antipsychotic medications, limited resources to purchase a smartphone) we decided to provide all users with the same smartphone. The device had a large touchscreen as well as a slide-out keyboard that enabled participants to select the data entry and response method that was most convenient for them.

Providing participants with study phones instead of asking them to use applications on their own phones might decrease the frequency with which they use the device. Users might not migrate over their contacts, calendars, apps, or other data and thus continue to use their own phone for these functions and the study device only for mHealth interactions. Some researchers suggest asking participants to use the study smartphone as their primary device and work with them to transfer SIM cards, setting up their data plan, and migrate contacts (Bardram et al., 2013; Faurholt-Jepseon et al., 2013). However, not all participants will have the capacity to make these changes on their own, or will be interested in doing so (e.g. especially for shorter projects). Allowing participants to keep the mobile device at the end of the study may motivate them to make these changes, but this is not always feasible.

mHealth researchers and programmers must also decide which operating system to use. All of the projects described were developed for the Android smartphone platform and our development team currently programs exclusively for this system. In terms of current market penetration, only iOS (iPhone/iPad) and Android based devices have enough of the market share to suggest feasibility. The most recent figures from the United States show that these two platforms comprise over 90% of the market (42.5% for iOS and 51.5% for Android; Kantar Worldpanel ComTech report). We selected Android because it shows greater overall penetration across diverse user populations, and because many aspects of iOS limit what could be accomplished using that platform. Specifically, iOS does not allow for background data processing (preventing passive smartphone-sensor data collection) and has limited means for triggering patient interactions compared to Android devices.

Native Versus Web Applications

mHealth researchers and programmers need to weigh the pros and cons of developing a native application (i.e., runs on the device in the native operating system) versus a web application (i.e. an online resources that is accessed using the smartphone web browser). Native applications are preferable when the intervention requires access to various features and data contained within the phone. Currently, if the application needs to make use of other applications (alarm, calendar) or hardware (camera or sensors) this would only be achievable with a native application; however, in the future browser application programming interfaces may eliminate this distinction. An mHealth researcher designing a food logging application that instructs users to take pictures of their meals would not be able to accomplish this with a web-based application. As native applications are coded to run directly on the device, they will work more quickly (reduced load and processing times) and present a more consistent look and feel with the smartphone device. A web-based application could be designed according to Android or iOS standards, but would not automatically update when versions of the operating system change.

Native applications, however, require more specialized programming knowledge, which may not exist on many mHealth teams. A web application is usually coded in a browser-rendered language such as HTML or JavaScript, which is a more common expertise. Furthermore, Web applications, may be developed and iterated over more quickly. Once developed, they can be used across different operating systems (i.e., both Android and iOS). Thus, a web application might be preferable when the intervention is a highly specified, well-defined, and meant to be accessible across different platforms.

User Characteristics

Research participants enter mHealth studies with varying levels of familiarity with mobile technology. Some users are quite adept at using mobile phones and the associated features that might be necessary to participate in the study (e.g., touchscreens, mobile applications, text messaging, WiFi access). But in more cases than not, participants (even technologically savvy individuals) will be unfamiliar with the specific device/model or operating system used in the study. A host of user demographic (e.g. age, socioeconomic status, education), illness related (e.g. hearing/ vision impairments, dexterity and fine motor abilities, cognitive functioning), and environmental (e.g. access to electrical outlets for charging, regional

wireless infrastructure) factors will impact users' capacity to engage with a particular mHealth resource. Research teams may find it helpful to account for the time and effort that will be needed to provide appropriate training on basic use of the device, and additional training and resources for effective deployment of the mHealth intervention system. These factors are critical not only for the analysis (as possible moderators) and reporting of the results, but also in study design (e.g. deciding on intervention intensity and frequency, determining appropriate participant screening procedures, budgeting for ongoing technical troubleshooting and support staff).

In the FOCUS project, we took into consideration that individuals with schizophrenia may have some unique illness-related characteristics (e.g. information processing deficits, distraction due to psychotic symptoms, avolition, and difficulty in abstraction) that might make navigation of an electronic-based intervention more difficult. To ensure maximum usability by this specific target group, FOCUS was designed in accordance with principles for development of e-resources for people with serious mental illnesses and cognitive impairment (Rotondi et al. 2007). We tested early versions, adapted, and re-tested the modified system with user groups with schizophrenia who provided feedback and guidance to enhance usability (Ben-Zeev et al. 2013). As a result, the FOCUS system requires a minimal number of steps to access content; screens avoid complex or superfluous elements (that would otherwise improve the aesthetic appeal to other user groups) and include memory aids; we used simple sentence composition and concrete wording to minimize the need for abstract thinking; content was worded at a fourth through sixth grade reading level, and visual displays (e.g. photographs, cartoons, images of post–it notes with hand drawn messages) were interwoven to enhance user engagement. The end product does not require significant working memory load, as all question and response options appear on the same screen, with no need to scroll/scan/encode/recall. System prompts to the user are not subtle —a large written message appears in the center of the phone's homescreen, accompanied by a loud auditory signal. In the MedLink project, individuals being treated for depression were higher functioning overall, and were more educated. But despite these characteristics, we learned that most individuals still prefer shorter, simpler wording of text. Thus, we have some reason to believe that simple, parsimonious communication of text-based content is preferable.

We encourage researchers to conduct initial work to understand the characteristics of their specific target population and their ownership of smartphone devices. Although national statistics and results from other studies can be useful to describe overall trends, we have found that these statistics are oftentimes not applicable to many of the populations we work with (Ben-Zeev et al. 2013). Collecting this data on the target population ahead of time can give researchers a better idea of the trade-offs that can guide their decision of whether to use participants' phones or study phones, which model to support, and which operating system to program on.

Deployment Environment

mHealth interventions can be deployed in any clinical (e.g. inpatient unit, community outpatient care, independently downloaded by user directly from the Internet) or geographic

(e.g. urban, rural, cross-border) setting. Environment-related hurdles come in many forms; logistical, bureaucratic, infrastructural, and more. Developing an mHealth intervention for a rural environment or developing country will necessitate close consideration of the quality of local wireless connectivity (e.g. reception “dead zones”, wireless carrier reliability) the range and accessibility of an electrical grid (for device charging purposes), and technical troubleshooting capacity when something goes wrong (e.g. contacting research staff for support, access to replacement devices). Thus, there is a need to tailor the intervention not only for the clinical population, but also for their setting. For example, in areas with poor reception, real-time telehealth with clinicians will be challenging. Data will be transmitted from users’ devices to remote servers with less frequency. Messages or system updates sent to the user will be delayed. In such cases, mHealth researchers may consider using systems that can operate relatively independently (e.g. native applications rather than web-based tools, asynchronous data collection and locally stored data rather than real-time connection with a server; solar chargers rather than electrical) and with little maintenance needed (e.g. basic mobile phones rather than smartphones with the newest operating system, selecting models that are most common in the region).

Even relatively resource rich environments can be challenging. For example, in the FOCUS project, the smartphone intervention is deployed among outpatient users being served by different clinics, in different states in the U.S. Phone data plans were provided by the same national mobile carrier. Within several days of study commencement our research team was perplexed by the fact that the mHealth illness self-management system was operating as intended on some phones, but not others. Given that all users were provided with the same mobile device model, we realized that the Operating System installed on the phone was being updated by the mobile telecommunication carrier remotely, without our knowing, creating compatibility problems. Moreover, the carrier “pushed out” updates on a differential timeline across sites; devices in one region of the country received updates days and sometimes even weeks before others. In response, the research team needed to create adapted versions for the current Operating System used in each region, and monitor continuously when upgrades are made. The technical characteristics of the clinical sites differed as well. Case managers could log on to a web-based clinician dashboard to view reports of their patients’ use of the mobile system. But each site had different mandated IT regulations (e.g. versions of software on their computers, Internet browsers that their clinicians were allowed to use, unique firewalls). Thus instead of allowing all sites to use the browser that was best suited for the FOCUS system, the research team had to modify the system so that it would be compatible with as many of the sites as possible.

In the MedLink study, one of the difficulties that arose was how to address users travelling across different time zones. In the programming, MedLink medication adherence needs to be tied to a particular time point. When a user moves time zones, it is unclear if a missed dosage of medication (or an unanswered assessment question) should be based on when it was scheduled (or where the data is stored) versus the time it is when the person has the phone. An additional complication comes when phones are set up in one time zone and shipped to users in another time zone. This was addressed by changing the code such that it relied on the mobile phone itself (i.e., local time of the user) rather than the database or initial settings that referenced the time zone of the clinical research team.

"Bugs and Glitches"

mHealth researchers will inevitability face technical problems that will arise during the system development process. Even the most careful coding will result in some "bugs" in products (e.g. errors, incompatibilities, unforeseen contingencies). Our first recommendation for addressing this barrier is to include time for internal and external testing prior to beginning any trial of an mHealth intervention. In our experience, skipping over a small field trial to help identify and resolve "bugs" will not save any time; the first few participants that enter the trial will encounter enough problems that they will effectively be field trial users rather than participants in an RCT.

An important consideration, during these internal and external testing periods is to ensure close communication between clinical personnel and technologists. Typically, clinical personnel have more frequent interactions with patients, especially as it pertains to day-to-day use of applications. Thus, these clinical personnel will gain more knowledge of the technical problems participants are encountering, but in many cases will lack the ability to resolve them. Technologists are often called on to conduct technical support, but if contact is delayed, many users may be subjected to the same problems before a resolution is apparent. Daily check-in calls can significantly improve response times, but may be unsustainable. Furthermore, distance from the actual source of information can complicate the troubleshooting process. Thus, we suggest early internal testing include both clinical personnel and technologists, and that problems be recorded in as much detail as possible to pass this information to the programming team. Frequent check-in calls may be useful during the initial deployment but can reduce in frequency once the intervention appears to be working robustly in the deployed environment.

One caveat to this recommendation, however, is worth mentioning. The only way to ensure that an intervention and feature will work in all instances and in all places, is to deploy it in those instances and places. Given that resource constraints make this unfeasible, circumstances and situations will arise when certain features will not work. Thus, the standards that these features are held to need to match resource constraints and stakeholder expectations need to be managed such that they do not expect an intervention that will work flawlessly in all situations.

Another recommendation for addressing technical problems is to use test-driven development when possible (Beck 2003). In test-driven development, programmers write tests that provide notifications from the system (as opposed to from the user) when features fail. As an example, a researcher would first create a story that specifies part of the user-application interaction. In FOCUS, we encountered a problem when some users reported that prompts were not being delivered within a previously specified time frame. To examine this issue using test-driven development, we wrote the following story: "If a prompt is set to run between 9 AM and 1 PM, the system should report (a) that the time frame is set and (b) that the prompt ran within the time frame." Our programmer then wrote a test to evaluate this story, thus receiving notifications whether story conditions (a) and (b) were true or false. This process has only recently become possible for mobile frameworks and is costly. Furthermore, creating a test for every feature would be time consuming. Therefore, the investigators will need to decide which features are critical enough to require a test.

Nevertheless, when available and utilized, it is a powerful tool that gives the research team knowledge of problems as they occur, without relying solely on user reports.

Conclusion

mHealth is an exciting field that has the potential to facilitate a leap forward in the provision of healthcare. Thoughtful mHealth research will help generate tools that can have meaningful impact on the lives of people coping with physical and mental health conditions. But in order to reach a point where investigators have the ability to answer fundamental clinical questions (e.g. Will people use these tools continuously? Are the interventions effective?), they must first successfully address the challenges unique to mHealth research--negotiating multidisciplinary team efforts, conceptually shifting from clinic to mobile-based intervention design and delivery strategies, consideration of the characteristics of the intended user population and deployment environment, and monitoring and flexible resolution of ongoing technological challenges as they emerge.

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References

Aguilera A, Muñoz RF. Text messaging as an adjunct to CBT in low-income populations: A usability and feasibility pilot study. Professional Psychology: Research and Practice. 2011; 42:472–478.

Andersson G, Bergström J, Holländare F, Carlbring P, Kaldo V, Ekselius L. Internet-based self-help for depression: Randomised controlled trial. The British Journal of Psychiatry. 2005; 187(5):456–461. [PubMed: 16260822]

Bardram, JE.; Frost, M.; Szántó, K.; Faurholt-Jepsen, M.; Vinberg, M.; Kessing, LV. Designing mobile health technology for bipolar disorder: A field trial of the MONARCA system. Proceedings of the 31st ACM International Conference on Human Factors in Computing Systems, CHI; Paris, France. 2013 Apr. p. 2627-2638.2013

Beck, K. Test-driven development: By example. Addison-Wesley Professional; 2003.

Ben-Zeev D. Mobile technologies in the study, assessment, and treatment of schizophrenia. Schizophrenia Bulletin. 2012; 38(3):384–385. [PubMed: 22234487]

Ben-Zeev D, Brenner CJ, Begale M, Duffecy J, Mohr DC, Mueser KT. Feasibility, acceptability, and preliminary efficacy of a smartphone intervention for schizophrenia. Schizophrenia Bulletin. 2014

Ben-Zeev D, Davis K, Kaiser S, Krzos I, Drake RE. Mobile technologies among people with serious mental illness: Opportunities for future services. Administration and Policy in Mental Health and Mental Health Services Research. 2013; 40(4):340–343. [PubMed: 22648635]

Ben-Zeev D, Drake RE, Corrigan PW, Rotondi AJ, Nilsen W, Depp C. Using contemporary technologies in the assessment and treatment of serious mental illness. American Journal of Psychiatric Rehabilitation. 2012; 15(4):357–376.

Ben-Zeev D, Kaiser SM, Brenner CJ, Begale M, Duffecy J, Mohr DC. Development and usability testing of FOCUS: A smartphone system for selfmanagement of schizophrenia. Psychiatric Rehabilitation Journal. 2013; 36(4):289–296. [PubMed: 24015913]

Burns MN, Begale M, Duffecy J, Gergle D, Karr CJ, Giangrande E, Mohr DC. Harnessing context sensing to develop a mobile intervention for depression. Journal of Medical Internet Research. 2011; 13(3):e55. [PubMed: 21840837]

Carlbring P, Nilsson-Ihrfelt E, Waara J, Kollenstam C, Buhrman M, Kaldo V, Söderberg M, Ekselius L, Andersson G. Treatment of panic disorder: Live therapy vs. self-help via the Internet. Behaviour Research and Therapy. 2005; 43(10):1321–1333. [PubMed: 16086983]

Chambless DL, Hollon SD. Defining empirically supported therapies. Journal of Consulting and Clinical Psychology. 1998; 66:7–18. [PubMed: 9489259]

Cohn, M. Agile estimating and planning. Boston, MA: Addison-Wesley Professional; 2005.

Cohn, M. User stories applied: For agile software development. Boston, MA: Addison-Wesley Professional; 2004.

Collins LM, Baker TB, Mermelstein RJ, Piper ME, Jorenby DE, Smith SS, Schlam TR, Cook JW, Fiore MC. The multiphase optimization strategy for engineering effective tobacco use interventions. Annals of Behavioral Medicine. 2011; 41:208–226. [PubMed: 21132416]

Eyrich-Garg KM. Mobile phone technology: A new paradigm for the prevention, treatment, and research of the non-sheltered"street" homeless? Journal of Urban Health. 2010; 87(3):365–380. [PubMed: 20397058]

Faurholt-Jepsen M, VInberg M, Christensen EM, Frost M, Bardram J, Kessing LV. Daily electronic self-monitoring of subjective and objective symptoms in bipolar disorder – the MONARCA trial protocol (MONitoring, treatment and pRediCtion of bipolar disorder episodes): A randomised controlled single-blind trial. BMJ Open. 2013; 3:e003353.

Harrison V, Proudfoot J, Wee PP, Parker G, Pavlovic DH, Manicavasagar V. Mobile mental health: Review of the emerging field and proof of concept study. Journal of Mental Health (Abingdon, England). 2011; 20(6):509–524.

Hekler, EB.; Klasnja, P.; Froehlich, J.; Buman, M. Mind the theoretical gap: Interpreting, using, and developing behavioral theory in HCI research. Proceedings of the 31st ACM International Conference on Human Factors in Computing Systems, CHI; Paris, France. 2013 Apr. p. 3307-3316.2013

Heron KE, Smyth JM. Ecological momentary interventions: Incorporating mobile technology into psychosocial and health behaviour treatments. British Journal of Health Psychology. 2010; 15:1–39. [PubMed: 19646331]

ITU. The world in 2011: ICT facts and figures. 2011. Retrieved from http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2011.pdf

ITU. The world in 2013: ICT facts and figures. 2013. Retrieved from http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2013.pdf.

Kaplan RM, Stone AA. Bringing the laboratory and clinic to the community: Mobile technologies for health promotion and disease prevention. Annual Review of Psychology. 2013; 64:471–498.

Klasnja, P.; Consolvo, S.; Pratt, W. Proceedings of the 29th ACM International Conference on Human Factors in Computing Systems, CHI; Vancouver, BC, Canada. 2011 May. p. 3063-3072.2011

Kumar S, Nilsen WJ, Abernethy A, Atienza A, Patrick K, Swendeman D. Mobile health technology evaluation: The mHealth evidence workshop. American Journal of Preventive Medicine. 2013; 45:228–236. [PubMed: 23867031]

Luxton DD, McCann RA, Bush NE, Mishkind MC, Reger GM. mHealth for mental health: Integrating smartphone technology in behavioral healthcare. Professional Psychology: Research and Practice. 2011; 42(6):505–512.

Marsch LA, Ben-Zeev D. Technology-based assessments and interventions targeting psychiatric and substance use disorders: Innovations and opportunities. Journal of Dual Diagnosis. 2012; 8(4): 259–261.

Martin, RC. Agile software development: Principles, patterns, and practices. Englewood Cliffs, NJ: Prentice Hall; 2003.

Mohr DC, Cheung K, Schueller SM, Brown CH, Duan N. Continuous evaluation of evolving behavioral intervention technologies. American Journal of Preventive Medicine. 2013; 45(4):517–523. [PubMed: 24050429]

Pagliari C. Design and evaluation in eHealth: Challenges and implications for an interdisciplinary field. Journal of Medical Internet Research. 2007; 9:e15. [PubMed: 17537718]

Proudfoot J, Klein B, Barak A, Carlbring P, Cuijpers P, Lange A, Andersson G. Establishing guidelines for executing and reporting internet intervention research. Cognitive Behaviour Therapy. 2011; 40:82–97. [PubMed: 25155812]

Riley WT, Glasgow RE, Etheredge L, Abernethy AP. Rapid, responsive, relevant (R3) research: A call for a rapid learning health research enterprise. Clinical and Translational Medicine. 2013; 2:1–6. [PubMed: 23369533]

Rotondi AJ, Sinkule J, Haas GL, Spring MB, Litschge CM, Newhill CE, Anderson CM. Designing websites for persons with cognitive deficits: Design and usability of a psychoeducational intervention for persons with severe mental illness. Psychological Services. 2007; 4(3):202–224.

Rounsaville BJ, Caroll KM, Onken LS. A stage model of behavioral therapies research: Getting started and moving on from stage I. Clinical Psychology: Science and Practice. 2001; 8:133–142.

Rudd J, Stern K, Isensee S. Low vs. high-fidelity prototyping debate. Interactions. 1996; 3:76–85.

Schueller SM, Muñoz RF, Mohr DC. Realizing the potential of behavioral intervention technologies. Current Directions in Psychological Science. 2013; 22(6):478–483.

Smith, A. Pew internet and American life project: Smartphone Ownership 2013. 2011. Retrieved September 10, 2013 from http://pewinternet.org/Reports/2013/Smartphone-Ownership-2013.aspx

Vogel AL, Hall KL, Fiore SM, Klein JT, Bennett LM, Gadlin H, Stokols D, Nebeling LC, Wuchty S, Patrick K, Spotts EL, Pohl C, Riley WT, Falk-Krzesinsky HJ. The team science toolkit: Enhancing research collaboration through online knowledge sharing. American Journal of Preventive Medicine. 2013; 45(6):787–789. [PubMed: 24237924]

World Health Organization. Global Observatory for eHealth series – Volume 3: mHealth: New horizons for health through mobile technologies. Geneva, Switzerland: World Health Organization; 2011.

Wichansky AM. Usability testing in 2000 and beyond. Ergonomics. 2000; 43:998–1006. [PubMed: 10929833]

Table 1

Characteristics of the mHealth projects

	Mobilyze	**MedLink**	**FOCUS**
Target Mental Health Condition	Depression	Depression	Schizophrenia
Goal of Intervention	Decrease depressive symptoms	Optimize pharmacotherapy	Support self-management of illness
Theoretical Framework	Behavioral Activation	Wagner's Chronic Care Model	Cognitive Behavioral/Stress-Vulnerability Model
Target Setting	Not facility dependent. Users with compatible smartphones recruited online	Primary care facilities	Post-discharge from hospital outpatient treatment
Length of Intervention	8 weeks	12 weeks	24 weeks
Number of Expected Interactions with Intervention	Up to 10× per day	2× a week	3× a day and unlimited on-demand use
Component Types	Tailored didactic content System initiated self-report Passive sensor data collection Clinician dashboard	Didactic content System initiated self-report Tailored feedback Passive sensor data collection Administrator interface	Didactic content System initiated self-report Tailored feedback Clinician dashboard