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Mobile Interventions for Severe Mental Illness: Design and Preliminary Data from Three Approaches

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Abstract

Mobile devices can be used to deliver psychosocial interventions, yet there is little prior application in severe mental illness. We provide the rationale, design, and preliminary data from three ongoing clinical trials of mobile interventions developed for bipolar disorder or schizophrenia. Project 1 used a personal digital assistant to prompt engagement in personalized self-management behaviors based on real-time data. Project 2 employed experience sampling via text messages to facilitate case management. Project 3 built on group functional skills training for schizophrenia by incorporating between-session mobile phone contacts with therapists. Preliminary findings were of minimal participant attrition, and no broken devices; yet, several operational and technical barriers needed to be addressed. Adherence was similar to that reported in non-psychiatric populations, with high participant satisfaction. Thus, mobile devices appear feasible and acceptable in augmenting psychosocial interventions for severe mental illness, with future research in establishing efficacy, cost-effectiveness, and ethical and safety protocols.

Keywords

Bipolar disorder; schizophrenia; severe mental illness; psychosocial intervention; ambulatory monitoring; technology; ecological momentary assessment; experience sampling method

Introduction

Bipolar disorder and schizophrenia are among the most disabling conditions in the world (Murray et al, 1996), and there is a substantial need to improve access to effective psychosocial interventions that can reduce this disability(Harvey, 2006; Lehman et al, 2004). Mobile devices, such as cellular phones or personal digital assistants, are an emerging route to delivering psychosocial interventions (Heron et al, 2009; Patrick et al, 2008). Although mobile devices have been used to collect intensive longitudinal data on symptoms and other illness experiences in severe mental illness (SMI) (Granholm et al, 2008; Scharer et al, 2002), there is scant research as to how mobile devices could be used to deliver aspects of interventions for people with SMI (Spaniel et al, 2008). We provide a

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practical review of mobile interventions and then describe the rationale, design and preliminary feasibility data from three ongoing clinical trials employing mobile interventions developed for people with bipolar disorder or schizophrenia.

What are mobile interventions?

For the purposes of this manuscript, "mobile device" is defined as a cellular telephone, personal digital assistant (PDA) that allows users to utilize software applications but is not connected to a network, or a "smart" phone which integrates features of cellular phones and PDAs into a single device(Fjeldsoe et al, 2009; Heron et al, 2009). Mobile interventions are among other technological approaches to delivering psychosocial interventions outside of the traditional clinic setting, including telephone psychotherapy, videoconferencing, and internet-based interventions(Heron et al, 2009; Marks et al, 2009; Patrick et al, 2009; Piette, 2007; Strecher, 2007).

Broadly, mobile interventions can be categorized by their level of human interactivity(Simon et al, 2009). At the highest level of interaction are interventions that employ live therapist communication (e.g., telephone psychotherapy) that are delivered via mobile devices. Less interactive interventions may employ asynchronous communication (e.g., text messages), in which a clinician may interact with consumers. At the lowest level of human interaction are interventions that are completely autonomous. Another distinction among interventions is the level of personalization of communications, such as whether communications are standardized (e.g., simple medication reminders) or tailored based on point-in-time or accumulated user input (e.g., after an increase in symptoms). Interventions that are tailored based on user data are often extensions of ecological momentary assessment or experience sampling (Shiffman et al, 2008) wherein mobile devices repeatedly assess consumer experiences naturalistically. The level of interactivity of interventions influences the choice of device, as well as whether data obtained can be stored locally on the device or is uploaded to a centralized server. It is also possible to combine levels of interactivity in a single intervention, with more automated approaches leading to human interaction depending on responses (e.g., live communication after a reported increase in symptoms).

What are potential applications for mobile devices in psychosocial intervention for SMI?

Mobile devices could be used to overcome some of the barriers to accessing, sustaining, and benefiting from clinic-based services (see Table 1). Interaction via mobile devices may make it possible to reduce the intensity of interventions (e.g., reducing the number or duration of clinic-based sessions), extend the effect beyond the time constrains or between sessions (e.g., by providing booster sessions or in vivo practice via technology), or to replace in-person psychosocial intervention altogether. Lowering the intensity of interventions could translate to reduced costs. Greater than 80% of the U.S. population has a mobile phone and the computing capacity of these devices is improving exponentially while costs are declining (Reardon, 2008).

Reducing the resource intensity of psychosocial intervention may increase access and sustainability, which is particularly important for SMI. Utilization of psychosocial interventions is declining in bipolar disorder (Busch et al, 2007), despite mounting evidence for its role in augmenting pharmacotherapy (Miklowitz, 2008). In schizophrenia, the Patient Outcomes Research Team (PORT) report indicated poor utilization of psychosocial interventions in schizophrenia (Lehman et al, 2004). Moreover, even among people with SMI who do have access to treatment, the rate of session attendance is less than half of those allotted in some studies (Miklowitz, 2008). In community (vs. research) settings where psychosocial interventions typically have out-of-pocket costs and there are fewer supports to encourage retention, about one-third of people attend only one or two sessions (Olfson et al,

2002). In addition to costs, lack of transportation is a significant barrier to accessing and sustaining participation in psychosocial interventions in SMI (Kilbourne, 2005).

Mobile devices may help to enhance the transfer of skills to real world settings, which appears to be limited in many skills-training interventions (Intille, 2004a; Kopelowicz et al, 2006) by prompting individuals to engage in health-protective behavior in the environment outside of the clinic and closer in time to critical moments. In traditional clinic-based interventions, consumers are asked to translate session content to real-world behavior, which includes remembering to implement strategies or skills at a later time, in the naturalistic environment, when they identify an opportunity to apply their skills and/or notice a change in their symptoms, often when their mood is different than it was in the clinic. In contrast to land-lines and video conferencing, mobile phones offer greater opportunity to prompt behaviors in real time. For example, if the individual is in the process of transferring to a new bus, having the opportunity to speak with someone who can guide them through the process offers opportunity to problem solve. Additionally, mobile devices may facilitate greater flexibility in the duration, timing, and setting of interventions, which may enable greater consumer control over the therapeutic experience. Finally, mobile devices could provide updates to providers in order to identify consumers at risk for negative outcomes and to more efficiently allocate services.

What are potential concerns about mobile interventions for SMI?

Although previous studies have employed mobile technology to gather assessments without the intent of providing an intervention beyond self-monitoring(Granholm et al, 2008; Scharer et al, 2002), we identified only one prior report (Spaniel et al, 2008) describing an intervention designed for mobile devices in schizophrenia, and we found no studies in bipolar disorder. Spaniel et al. (2008) describe a one-year open trial with 45 consumers and 39 family members in which participants were sent a weekly 10-item questionnaire about early warning signs of schizophrenia via short message service (SMS). Responses were returned via SMS message, and if the total score exceeded a threshold, an alert was sent to their psychiatrist. Compared to the one year period prior to the intervention, there was a 60% reduction in the number of hospitalizations (Spaniel et al, 2008). There were also two additional interventions using telephones in interventions for schizophrenia (Beebe et al, 2004; Salzer et al, 2004).

Given the limited prior experience with mobile interventions for SMI, principal questions are: <u>Can</u> consumers use mobile devices in the context of an intervention? and <u>Will</u> they use devices and find them helpful? In terms of potential threats to feasibility, the same cognitive deficits that can derail transfer of clinic-based training to daily life may also limit performing complex tasks on handheld devices. Problems with adherence to mobile intervention protocols can include skipping interactions, 'fatigue' effects in which adherence declines over time, or random responding (Shiffman et al, 2008). Even though people with schizophrenia or bipolar disorder comply with mobile assessment protocols to a similar extent as people without psychiatric illnesses (Granholm et al, 2008), adding more complex interactive components may detract from adherence.

In terms of acceptability, as with other electronically mediated approaches, mobile interventions may create physical and emotional distance between therapist and consumer, and subsequently detract from the potent effects of the therapeutic alliance (Martin et al, 2000). In addition to questions as to whether consumers will use mobile devices, it is also unclear whether and how providers (if provided access) will use the ongoing data generated by these devices, or whether consumers will accept or appreciate "surveillance", despite the good intentions of the program.

Additionally, people with SMI are at high risk for self-harm and other psychiatric emergencies, and mobile interventions typically include assessments of clinical state that happen outside of the typical clinic workday. Although around-the-clock capability to assess and intervene with at-risk consumers may ultimately increase safety, potential clinical and ethical dilemmas are introduced. Finally, there is substantial amount of preparation time in programming, obtaining mobile telephone contracts if needed, and developing training and troubleshooting protocols – these all add to the start-up costs of mobile intervention studies which may eliminate potential cost savings.

In the next section, we summarize the rationale, design and preliminary feasibility and acceptability data from three ongoing intervention studies being conducted at the Advanced Center for Innovations in Services and Intervention Research (ACISIR) at University of California, San Diego that are employing mobile devices in interventions for bipolar disorder or schizophrenia. These interventions are presented in order from least to most human interaction. Table 2 summarizes the design elements of these three interventions.

Methods

Project 1. Personalized Real-Time Intervention for Stabilizing Mood (PRISM)

Rationale and Design—PRISM is a mobile intervention that integrates experience sampling (Shiffman et al, 2008) with aspects of an evidence-based brief psychoeducational intervention for bipolar disorder (Bauer et al, 2003). PRISM is an automated approach employing PDA that stores data directly on the device with no live interaction with therapists. Participants respond to questions about their mood state and illness triggers, similar a 'mood chart' frequently employed in interventions for bipolar disorders(Miklowitz, 2008; Scott et al, 2005). When participants signal that they are experiencing an exacerbation in symptoms or an illness trigger, a pre-selected self-management strategy appears on the PDA screen. For example, when the participant indicates they are "mildly depressed", the next screen presents them with the personally assigned adaptive strategy to that mood severity and polarity (e.g., "if you take the dog for a walk, you usually feel less depressed"). In this manner, participants' personalized adaptive strategies and early warning signs coupled with real-time assessment of clinical state.

Participants meet with a clinician for two clinic-based sessions to collaboratively identify personal symptoms of depression and mania and illness triggers, and identify adaptive responses to illness triggers and symptom exacerbations; these sessions are based on a manualized brief psychoeducational intervention for bipolar disorder; Life Goals (Bauer et al, 2003). Clinical trials suggest that Life Goals is effective in reducing symptoms of mania when it is coupled with frequent monitoring and practice improvements(Bauer et al, 2006a; Bauer et al, 2006b; Simon et al, 2002); however when evaluated as a stand-alone intervention, it has not produced symptom improvements and was associated with poor attendance (Sajatovic et al, 2009). The aim of PRISM is to extend the effect of Life Goals as a stand-alone intervention.

Intervention Development—Two successive pilot studies were conducted to develop PRISM. Because the intervention is dependent on the validity of consumer-reported outcomes obtained on the device, the psychometric properties of the assessment protocol to be uploaded onto the mobile device were assessed. Ten participants were administered a modified version of the Day Reconstruction Method, a diary-based measure that combines time-budget methodology with affective experience over a single day that is equivalent to experience sampling at the population level (Kahneman et al, 2004). In 10 people with bipolar disorder, and a comparison to a normal comparison (NC) group (n=95), data were assessed for a) missingness, b) differences between bipolar and NC samples in affective

entries.

ratings and time use, and c) correlations between symptom measures and affect ratings within the bipolar group. Nine activities were eliminated due to low probability of selection (<2 episodes total) and 2 affect ratings (interest/focused) for lack of variability across

Next, the survey was programmed on a PDA (HP IPAQ) using a freeware experience sampling program called Myexperience that runs on the Windows Mobile operating system (Froehlich et al, 2007a; Froehlich et al, 2007b). The experience sampling protocol occurred four times per day at random times with no less than two hours between surveys. In experience sampling over longer periods, there is a need to balance between "coverage" of affective experience and subject burden. Since the goal was to identify mood states and illness triggers, prompt participants to engage in self-management strategies, and then assess the effectiveness of strategies within the same day, four times per day represented an appropriate compromise between more intensive studies (10 per day) and retrospective once-per-day diaries. Participants were trained to use the devices in a single 30 minute session which was accompanied by a written manual.

Results

Open Trial

In the second pilot study, PRISM was evaluated in 10 outpatients with bipolar disorder who completed mobile intervention for up to 2 weeks. Mean age of the sample was 41.0 (sd=13.7). Mean symptom ratings were indicative of mild depression (Montgomery Asberg Depression Rating Scale=13.1,sd=8.6) and sub-threshold manic symptoms (Young Mania Rating Scale=2.7,sd=3.6).

All participants completed PRISM, there were no drop-outs, and all devices were returned to the investigators. The median percentage of completed surveys divided by the number possible was 78% (sd=14). There was no effect of study day on missing data (F(27,149)=0.613, p=0.915), thus there was no evidence of fatigue effects. The percent of surveys rated "depressed" correlated significantly and positively with within-subjects mean MADRS scores across the 2 time points (r=0.841,p=0.018). Percent of samples reporting manic symptoms (which were less prevalent) were nearly significant in relation to YMRS Scores (r=0.691,p=0.086). In terms of short-term effects, there was a significant pre-post reduction in MADRS scores in a paired t-test (pre=13.8,sd=8.5, post=8.2,sd=6; t(10)=3.5,p=0.005), but no significant change in YMRS Scores (t(10)=0.873,p=.405). There was a trend for greater compliance associated with more reduction in MADRS Score (rho=0.532,p=0.092).

Acceptability data was obtained by self-ratings and qualitative feedback. Median ratings on overall satisfaction with the intervention was 9 out of 10 (10=extremely satisfied). On a 5-point Likert scale (1=Strongly Disagree, 5=Strongly Agree), median ratings for difficulty operating the device was "Disagree", and participants median rating was "Strongly Agree" for "I would use this device again" and "This could be helpful to me in the future". Qualitative comments were consistent with increasing awareness of emotions and greater utilization of self-management behaviors. One participant said: "At first I thought it wouldn't be beneficial, but it did help me 'catch' myself when I started to feel down", and another "Helped make me think about what I am doing and whether I am using my strategies". One drew parallels with managing diabetes: "Reminded me of managing my diabetes, checking blood sugar and paying attention to my diet."

Post-study interviews with participants indicated several themes in regard to enhancing the long-term acceptability of the device. Participants requested to be able to view summaries of

the data obtained and to be able to provide this information to their providers. Additional requests were for the capability to enter text-based entries as well as to view a broader collection of self-management strategies than developed during the in-person sessions. An additional concern raised was what to say to others about the purpose of the device, particularly to others (e.g., coworkers) who may not be aware of the participant's diagnosis.

Methods

Project 2. Mobile Assessment and Therapy for Schizophrenia (MATS)

Rationale and Design-MATS uses automated text messaging on a mobile phone to obtain consumer reported data on psychotic symptom severity, social interactions, and medication adherence in individuals with psychotic disorders. These data are uploaded to a central server enabling consumers' providers on Assertive Community Treatment (ACT) teams to view consumers' data in real time. Email reports, including graphs of ratings in each of these domains, are also sent to ACT staff each Friday. The goal of feeding back these consumer reports is to enable ACT staff to remotely monitor their caseload, prioritize services, and enhance their capacity to prevent relapses. ACT is a team-based approach, customized to each consumer, in which staff is available 24 hours a day, with a primary goal of avoiding hospitalization and improving community functioning (Marshall et al, 2000). For ACT staff, the potential benefits of mobile monitoring would be in enabling better management of caseloads, more rapid relapse prevention, and effective intensive case management of severely ill frequent service users on ACT teams. Potential motivators for mental health administrators of mobile monitoring would include cost and productivity benefits (e.g., avoiding check-in visits when consumers report they are doing well), and a more efficient method of meeting mandated outcomes measurement goals (e.g., functioning, quality of life, service use). Additionally, MATS may reduce the amount of staff and clinician time required to gather consumer data for ongoing outcomes assessment.

As with PRISM, MATS uses the experience sampling approach to obtain consumer reported data. Consumers are asked to respond to surveys three times per day. Because the information must be able to be accessed in real time, the data are transmitted via SMS service via network connection rather than stored on the device as in PRISM. A centralized server automates sending and receiving of these text messages for each set of questions, and responses are time-stamped and stored in a database.

Similarly to PRISM, MATS includes both mobile assessment and intervention components. In addition to feeding back consumer status to case managers to enhance ACT, MATS includes cognitive and behavioral therapy interventions for 3 domains: auditory hallucinations, medication adherence, and socialization. Before commencing the trial, participants are asked to provide information regarding personal outcomes linked to experiencing hallucinatory experiences (e.g. "do you recall any instances in which you did not do what the voices directed? what happened afterwards?"), noncompliance with medication regimens (e.g. "do you recall any instances in which you decided to stop taking your medications?" what happened afterwards?"), and feelings associated with social activities (e.g." how do you typically feel when you are alone for a long time? are there any personal benefits to socializing with others?"). Individual responses are later integrated into the individualized text messages each person receives.

During the 12 week trial, each participant is engaged in "text exchanges" three times a day (morning, afternoon, evening) focusing on assessment and brief cognitive behavioral intervention for one of the domains in the following format: 1st text greeting the participant and asking a specific symptom related question (e.g. "have you been hearing voices today?"). The consumer's text response is relayed to the server, which sends a 2nd text

Intervention Development—Central tasks in developing MATS were in developing the device and case manager interfaces and 'back structure' for sending messages and storing data, pilot testing the feasibility of the approach with consumers, and investigating stakeholder experience with the device and data obtained (i.e., consumers, case managers, and administrators). To increase the likelihood of acceptance of MATS, stakeholders are involved in development of all aspects of the protocols, including procedures for crisis response intervention, question content and wording, momentary sampling (e.g., frequency of samples; incentive for completing assessments), training, nature of person-device interface (consumer and staff interface), data uploading, and analysis.

The research team repeatedly met with ACT providers to demonstrate the technology, learn firsthand which clinical areas were most relevant for their work with clients, and ask for feedback and suggestions. Two focus groups held with ACT case managers, clinical team leaders and directors revealed that ACT staff members were very enthusiastic about the project, but concerned regarding the number of daily assessments and effective ongoing reinforcement of client participation. Additional feedback was that client socialization is an area that clients would greatly benefit from ongoing assessment and intervention. Based on providers' feedback, assessments were limited to three per day, gift cards to local eateries were added as weekly positive reinforcement for client efforts, and socialization was added to auditory hallucinations and medication adherence as an area for assessment and intervention.

Results

Open Trial

The pilot trial is currently underway; eight participants have completed the 12 week study successfully, three participants withdrew. Of the participants that withdrew, two had very prominent negative symptoms and had difficulty maintaining motivation to continuously engage in the text exchanges and in responding to the text messages in the allotted time. Among the eight consumers who completed the trial to date, 75% consistently engaged in text exchanges for the entire 12 weeks. However, 25% showed a substantial drop in responsiveness in the second half of the trial.

Outcomes are pending completion of the entire sample, yet qualitative feedback indicated that participants were using the devices in intended ways. One participant noted that the text messages had increased her awareness of her voices, so that when she heard them, she was able to identify them as hallucinations and dismissed them more easily. Another participant who resides in an independent living facility commented that she had come to rely on the messages as reminders to take her medications.

In regard to improving feasibility, in response to ongoing participant feedback, the following changes were made: a) automatic cellular phone screen illumination was increased from 20 to 60 seconds, allowing participants longer time to read and respond to questions; b) the text message "inbox" was set to automatically empty after 3 days to allow for additional incoming messages and reduce confusion about which messages to respond to and; and c)

participants were provided with a written step by step guide for erasing messages and managing the necessary phone functions as a supplement to the formal lab training.

It is not yet clear why 25% of the sample reduced their responding to the messages. A larger sample should help identify consumer characteristics that are associated with dropout, as early observations are that MATS may not be useful for all types of consumers. It will also be important to focus on feedback to providers about consumer reports that could be helpful without increasing provider burden associated with the technology. Ongoing development is including a focus on the providers (e.g., ACT staff) and decision makers (e.g., program directors). Findings and experiences from the device adaptation and validation study described above will inform development from the perspective of the consumer.

Methods

Project 3. Skills Training and Empowerment Program (STEP)

Rationale and Design—STEP uses live therapist interaction to increase homework compliance in skills training for schizophrenia. STEP builds from Functional Adaptations and Skills Training (FAST), which is a 24-week intensive intervention aimed at increasing everyday living and social skills in middle-aged and older people with schizophrenia. In an RCT with 240 participants who were randomized to FAST or a time-equivalent attention control condition, FAST was associated with improvement performance-based measures of functioning (Patterson et al, 2003; Patterson et al, 2006). Despite these positive findings, the median number of sessions attended was 13 out of 24, and approximately 20% of participants attended fewer than 5 sessions.

In addition, the use of skills outside of sessions was suboptimal. Post-hoc analyses revealed approximately 68% of participants reported using the skills "not much" outside of the classroom setting and only 5% reporting using the skills "a lot". Post-hoc analyses revealed that participants in the FAST condition who reported engaging in home practice experienced greater change and higher end-state performance on performance based measures of functioning compared to participants who reported minimal use of skills. In post-study interviews, participants were asked about specific barriers to practicing skills outside of sessions, and common themes were: a) Forgetting (e.g., forgot what skills were taught or how to perform the skills), b) Structural barriers to skill implementation (e.g., don't know how to practice), and c) Conceptual barriers to transferring skills to the "real world" (e.g., "I don't know which bus to take"). Thus, there were significant limitations in the extent to which FAST was delivered in its full 'dose' of 24 sessions, as well as whether participants endorsed using the skills taught in sessions in their daily lives.

STEP was designed to reduce the number of sessions of FAST as well as to enhance the utilization of skills in the naturalistic environment. STEP is time equivalent to the 24 week FAST intervention, yet halves the number of in-person sessions from 24 to 12. Participants in STEP receive a cell phone, which includes basic call and text features and they are trained in its use. Participants may use the telephone for personal calls. As in FAST, the focus of in-person sessions is on everyday living skills (e.g., social interactions, medication management). Participants attend in person sessions every two weeks and receive 2 phone calls from a counselor between sessions. The content of these 20 minute phone calls follows a standardized agenda: a) "Check in", in which counselors summarize for participants the agenda for the cell-phone session, b) determine how the consumer is doing with regard to well-being, emotions, and symptoms, c) provide an overview of skills taught in the previous group session (e.g., how to make lists and follow them), d) remind participant of his/her homework assignment, and assess whether or not the consumer is practicing the skills they were taught and making progress toward a behavioral goal they selected for the week, e)

assess barriers to practicing skills and achieving goals, and f) reinforce achievements and problem-solve barriers and, where necessary, develop remedial measures to place consumer back on track to practicing skills and making progress toward goals.

Intervention Development—To develop STEP, consumers and counselors who participated were surveyed as the perceived advantages and disadvantages of utilizing cell phones in the course of treatment. Counselors expressed high interest, and some counselors indicated this would further help them work individually with consumers on specific skills or barriers.

As with PRISM and MATS, a formal training protocol was developed to train participants in the use of the device, using in vivo practice and a written manual that included an enlarged version of the phone with lines indicating specific phone features. In addition to training in how to use the basic features of the phone, consumers were also instructed in "phone etiquette." Consumers were advised on ways they could handle taking a call discretely to avoid disruption, such as in decreasing ringtone volume and how to silence the phone during a meeting. Consumers were assigned to practice using their phone over the following week by both making and receiving calls from the class leader and any others they were comfortable calling.

Results

Open Trial

For the STEP pilot study 9 male participants (mean age 46.5), who were diagnosed with schizophrenia, were enrolled. Mean Positive and Negative Syndrome Scale (PANSS) scores were 14.0, and the mean PANSS Negative score was 19.3. After 24 weeks, none of the participants dropped out of the intervention. Over the course of the intervention, no participants lost or damaged their cell phones, providing support that participants can care for and keep track of their phones. Based on call logs, eight of the nine participants used their cell phones outside of classes, and thus eight participants completed the study.

In terms of preliminary efficacy, results of eight STEP Completers were compared to that of a demographically-matched sample of 8 participants who completed the FAST program. Relative to matched FAST participants (mean change = 2.91 points), participants in the STEP condition showed greater improvement in functional outcomes as measured by the UCSD Performance Based Skills Assessment (mean change = 6.55 points). In addition, 86% of STEP participants reported "Some" or "A Lot" of skills utilization, higher than that in the FAST condition. In terms of acceptability, participants reported that they "very much" liked receiving calls on a weekly basis to help them practice their skills. One participant, in particular, said, "The weekly calls helped remind me to do my home practice." When asked how much they enjoyed the assignments, approximately 57% indicated they enjoyed their assignments "Very Much." Approximately 14% of participants stated that assignments helped them "Very Much" and 57% indicated "Moderately".

In terms of feasibility, there were a few identified problems. Among patients who lived in sheltered settings, some participants were concerned about having their phones stolen or lost, and so we kept them in a locked cabinet and were unable to be reached at all times. We remedied this by teaching them ways to keep the phones in their pockets and assuring them that they would become accustomed to remembering to not to lose the phones. An additional concern observed by the investigators was that call logs from participants were published in monthly billing statements, raising the risk of loss of personal information. This could was remedied by altering phone settings.

Discussion

Mobile devices may aid overcoming some of the barriers to accessing, attending, and benefiting from psychosocial intervention for people with SMI. The three interventions described here varied considerably in terms of purpose, design, and technology employed, yet they were consistent in supporting the feasibility and acceptability of mobile devices in augmenting existing psychosocial interventions for SMI. There were no evidence for overriding operational and logistic barriers (e.g., loss of devices), rates of adherence to mobile interactions were similar to that seen in other populations, and qualitative feedback from consumers indicated perceived usefulness. Thus, consumers with SMI can and will use mobile devices in the context of psychosocial interventions.

Next steps beyond this 'proof-of-concept' stage are larger randomized controlled trials to determine the incremental effectiveness, usability and long-term acceptability of these and other mobile interventions in SMI relative to standard approaches. The three intervention approaches described here build upon established evidence-based interventions for SMI, which provides a basis of comparison for gauging the incremental value of adding mobile components. Future clinical trials should incorporate a cost-effectiveness component to larger randomized controlled trials, which should include the costs of the devices as well as development time, network connections, and participant training.

There are several commonalities among the three pilot studies that likely enhanced the capacity of individuals to learn to use and to accept mobile devices. Multi-modal training procedures and extensive pilot testing may help to increase feasibility and reduce the likelihood of implementation problems in the field. We found that many participants did not have familiarity with mobile devices, particularly in the two studies enrolling patients with schizophrenia, and training participants in the use of devices combined of modeling, practice, and printed manuals. Manuals made use of 'worked examples' (Paas et al, 2004), which are diagrams or screenshots that describe user actions. Careful attention to operational problems is essential, as particularly in experience sampling, participants view the same questionnaire many times over the course of the study – therefore small problems or annoyances are amplified (Shiffman et al, 2008). In terms of increasing acceptance of mobile devices, we observed that early involvement of consumers and other stakeholders assists in fitting intervention with consumer preferences, helping to promote attitudes toward mobile device as a helpful tool rather than a nuisance, or worse, paternalistic. Increasing the perceived value of mobile devices can also be achieved by enabling participants to use other device features (e.g., cell phone calls, games, calendar functions). Permitting participants to schedule when prompts or phone calls occurred provides some user control over the experience. Rapid prototyping (Kinzie et al, 2002) that combines needs assessments, qualitative interviews, focus groups, and iterative truncated developmental trials in the population is an applicable approach to intervention development.

Although the studies reported here evidenced short-term adherence and acceptability, whether participants will continue to use mobile devices over long-term periods (i.e., > 3 months) remains unknown. It is likely impractical to maintain weekly contact with providers or respond to daily surveys *ad infinitum*. One direction is the development of 'stepped' approaches in which interventions can be increased to more frequent or more interactive during critical periods. There is a need better understanding about how interventions that collect intensive longitudinal data can visualize data streams to present to consumers or clinicians in compelling ways, which may further enhance acceptability and perceived value of the device.

Future work should also address novel potential ethical and clinical dilemmas that may arise with mobile interventions. Maintenance of confidential data on devices and networks can be enhanced by adding passwords, de-identification, and encryption. However, loss of confidentiality may be introduced in unforeseen ways with mobile devices. For example, in the PRISM intervention, consumers noted that they were asked by other people about the nature of the device they were carrying around; thus, there was a need to identify ways of describing the device to others without disclosing their diagnosis. In the STEP study, it was observed that call logs from network providers can reveal personal information. How best to inform consumers about these risks requires further research. In addition, although each of the three pilot studies had a specified protocol for safety, optimizing safety protection in high-risk consumers needs further work. Protocols for handling consumer emergencies used in interactive voice response may be applicable(Nierenberg et al, 2004).

Finally, although the interventions described here were developed to be consistent with established psychosocial interventions, there is the potential to create novel interventions that capitalize on the rapidly advancing capabilities of mobile devices. Smart phones have increasingly powerful processors that make them 'context aware' (Intille, 2004b), and could analyze data collected in the field to learn and provide feedback therapeutically relevant patterns of behavior (e.g., sleep/wake cycles), as well as to couple consumer-reported outcomes with biometric sensors (e.g., accelerometers, GPS, physiological monitors). Future work could also exploit communication capacities of mobile devices, such as providing 'virtual' peer support networks (Bank et al, 2006).

In summary, there is much to be learned about the potential roles and effectiveness of mobile devices in mental health interventions. However, the studies presented here should provide some confidence that mobile devices are feasible, acceptable, and can be used to augment evidence-based approaches for SMI. We hope that these experiences can help stimulate future work in this arena.

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Table 1

Potential Advantages and Limitations of Mobile Interventions for SMI

	Potential Advantages	Potential Limitations	
Application	 Increase access to psychosocial interventions Reduce resource intensity Increase transfer of skills and home practice assignments to real-world setting 	 Diminish therapeutic alliance Added cost of development, training, devices, and implementation Introduction of client burden in responding to assessments 	
Mobile Data Capture	Capacity to monitor consumer-reported outcomes in real-time, real-world contexts Collect unobtrusive continuous data	 Privacy concerns/Loss of confidentiality Data storage security Around the clock safety monitoring 	
Feasibility	• Feasibility established in assessment in SMI populations	 Cognitive impairments and symptoms associated with SMI may interfere with capacity to use devices Loss of device/technical problems Long-term adherence to use of device outside of clinic not established in SMI 	
Intervention Design	Flexibility in administrationPersonalization	Need for statistical analysis of complex longitudinal data	

Table 2

Comparison of Three Approaches Using Mobile Devices for Severe Mental Illness

Study	Personalized Real-Time Intervention for Stabilizing Mood (PRISM)	Mobile Assessment and Therapy for Schizophrenia (MATS)	Skills Training and Empowerment Program (STEP)
Target Population	Outpatients with bipolar disorder	Outpatients with schizophrenia who have case managers	Outpatients with schizophrenia who reside in board and care homes
Evidence-Based Treatment as Basis	Life Goals Psychoeducation (Bauer et al, 2003)	Cognitive Behavioral Therapy and Assertive Community Treatment (ACT)	Functional Adaptation Skills Training (Patterson et al, 2006)
Purpose of Mobile Device	To prompt consumers to engage in health protective behaviors in real time	To promote illness self- management and increase ACT staff efficiency in allocating services	To improve home practice on skills training
Primary Outcome	Mood symptoms	Community Functioning	Performance-based functioning
Mobile Interaction Type	Automated momentary assessment	Computer initiated text messaging	Live telephone interaction
Mobile Device Tested	HP IPAQ	Motorola V195s	Motorola C139
Number and Duration of Mobile Interactions	4/day; 2-3 minutes	3/day; 2-3 minutes; for 12 weeks	2/week
Content of Mobile Interactions	Ratings of mood, activity, sleep, social context, and symptoms; self- management prompts	Self-ratings and interventions for social interactions, psychosis, and medication adherence	Therapist assessment of home practice utilization, barriers, and mood state
Tailoring and Personalization	Timing Selection of self-management	Feedback reports Personalized evidence against maladaptive beliefs	Timing of call
Data Storage Method	Storage card on device	Web-based server	N/A