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Automated SMS in international settings Use of an Android phone application for automated text messages in international settings – A case study in an HIV clinical trial in St. Petersburg, Russia

Leah S Forman¹, Gregory J Patts¹, Sharon M Coleman¹, Elena Blokhina², John Lu¹, Tatiana Yaroslavtseva², Natalia Gnatenko³, Evgeny Krupitsky^{2,4}, Jeffrey H Samet^{5,6}, and Christine E Chaisson¹

¹Data Coordinating Center, Boston University School of Public Health, Boston, MA, USA

²Laboratory of Clinical Pharmacology of Addictions, First St. Petersburg Pavlov State Medical University, St. Petersburg, Russia

³Department of Medicine, Section of General Internal Medicine, Clinical Addiction Research and Education Unit, Boston Medical Center, Boston, MA, USA

⁴Department of Addictions, Bekhterev Research Psychoneurological Institute, St. Petersburg, Russia

⁵Department of Medicine, Section of General Internal Medicine, Clinical Addiction Research and Education Unit, Boston University School of Medicine/Boston Medical Center, Boston, MA, USA

⁶Department of Community Health Sciences, Boston University School of Public Health, Boston, MA, USA

Abstract

Background / Aims—Reproducible outcomes in clinical trials depend on adherence to study protocol. Short message service (SMS) (also known as text message) reminders have been shown to improve clinical trial adherence in the United States and elsewhere. However, due to systematic differences in mobile data plans, languages, and technology, these systems are not easily translated to international settings.

Methods—To gauge technical capabilities for international projects, we developed SMSMessenger, an automated Android application that uses a US server to send medication reminders to participants in a clinical trial in St. Petersburg, Russia (Zinc for HIV Disease among Alcohol Users – An RCT in the Russia ARCH Cohort).

The application is downloaded once onto an Android study phone. When it is time for the text message reminders to be sent, study personnel access the application on a local phone, which in

Corresponding Author: Leah S. Forman, Boston University School of Public Health, 85 East Newton St., M921, Boston, MA 02118, lsforman@bu.edu, Telephone: 617-638-5017, Fax: 617-638-5066.

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The authors declare that there are no conflicts of interest.

turn accesses the existing clinical trial database hosted on a US web server. The application retrieves a list of participants with the following information: phone number, whether a message should be received at that time, and the appropriate text of the message. The application is capable of storing multiple outgoing messages. With a few clicks, text messages are sent to study participants who can reply directly to the message. Study staff can check the local phone for incoming messages.

The SMSMessenger application uses an existing clinical trial database and is able to receive real-time updates. All communications between the application and server are encrypted and phone numbers are stored in a secure database behind a firewall. No sensitive data are stored on the phone, as outgoing messages are sent through the application, and not by messaging features on the phone itself. Messages are sent simultaneously to study participants, which reduces the burden on local study staff. Costs and setup are minimal. The only local requirements are an Android phone and data plan.

Conclusions—The SMSMessenger technology could be modified to be applied anywhere in the world, in any language, script, or alphabet, and for many different purposes. The novel application of this existing low-cost technology can improve the usefulness of text messaging in advancing the goals of international clinical trials.

Keywords

SMSMessenger; automated text messaging; international settings; medication reminders; mobile health intervention

Introduction

Text message/Short Messaging Service (SMS) based reminders are an effective method for improving clinical trial adherence.^{1–3} To gauge technical capabilities for international projects, we incorporated use of a custom-developed mobile application for SMS/text messaging through a local phone plan on a randomized controlled trial taking place in St. Petersburg, Russia. The randomized clinical trial, ZINC (Zinc for HIV disease among alcohol users – an RCT in the Russia Alcohol Research Collaboration on HIV/AIDS cohort) tests whether zinc supplementation, compared to placebo, improves HIV outcomes among study participants. HIV outcomes being tested include mortality, HIV disease progression, risk of myocardial infarction, and biomarker levels of microbial translocation and inflammation. The study protocol requires for study medication to be taken daily for 18 months. With the goal of increasing medication adherence, we planned to send daily reminder text messages, and looked for a commercially available system that would allow us to automate this process. While prior studies have used such systems locally, we could not find one that was both affordable and flexible enough to meet the needs of our project. Therefore we developed SMSMessenger, an automated Android phone software application that sends medication reminders to trial participants on a predetermined schedule. The purpose of this paper is to describe a case study of a flexible and cost effective text messaging reminder application used in an international setting. Study trials with data housed in a secure database and access to a qualified web developer could develop a similar, low cost application specific to the needs of the individual project.

Text message reminders

SMS reminders have effectively improved clinical trial adherence in a number of different settings.^{1,2} A meta-analysis investigating the effectiveness of text messaging interventions included sixteen randomized controlled trials conducted in the United States (US), China, and countries throughout Europe and Africa.³ It included studies of a number of different diseases and treatments, including, among others, HIV and antiretroviral therapy initiation, epilepsy treatments, asthma, and diabetes. Fifteen of sixteen studies compared a text messaging intervention to standard therapy, while one study had a control arm which was provided with a 1-way pager. The content of the text messages varied and included the following: medication and appointment reminders, motivational messages, disease education, and one- and two-way patient communications. The pooled analysis found that medication adherence was significantly improved with text messaging, and that the significant association did not depend on the specific characteristics of the text message intervention. For instance, improved adherence was found both when text messages were sent daily and less than daily, when two-way communication was available or not available, and when the intervention duration was greater than twelve weeks or less than twelve weeks. However, the authors note that caution should be used when interpreting these results as study follow-up duration was often short (median intervention duration was 12 weeks), and adherence was measured by self-report.³

The effectiveness of SMS reminders has also been shown specifically among research participants with HIV. In a meta-analysis of eight randomized controlled HIV trials, text messaging interventions were found to significantly improve adherence when compared to controls who did not receive text messaging interventions.⁴ Studies cited in this analysis included a Boston study that found higher antiretroviral therapy adherence over a six week period among patients who received text message reminders compared to those who had a beeper reminder,⁵ and a Brazilian study that concluded that SMS messaging could be a useful way to help HIV infected women adhere to antiretroviral therapy.⁶

Improved adherence to HIV treatment due to text message reminders was also found in resource limited settings. In Kenya, studies have found that, compared to those who did not receive SMS reminders, patients who received these reminders had improved adherence to antiretroviral therapy medication,^{7,8} improved rates of viral suppression,⁷ and were less likely to experience treatment interruptions.⁸ In a study conducted in rural Uganda, participants who received pre-scheduled SMS reminders had higher antiretroviral therapy adherence and fewer treatment lapses than both participants who received reminders only after missed doses, and patients who did not receive SMS reminders.⁹

Responses to text message interventions

In addition to improving adherence, studies have shown that participants generally respond well to text message reminders. Among patients in a Finnish clinical trial who were on antipsychotic medication, 72% were satisfied with daily SMS reminders, while more than half (61%) found them useful. A full 87% of participants felt that the SMS reminders did not cause harm, and almost all (98%) found them easy to use.¹⁰ The Ugandan study cited above had a qualitative component that asked patients about their experiences with text message

reminders. Participants reported that the text messages made them feel like the health system ‘cared’ about them and their health, which in turn, improved adherence.²

Difficulties with text message interventions

Although text messaging can be an effective tool that improves study medication and treatment adherence, implementation of these reminder systems can be difficult for a number of reasons. Due to systematic differences in mobile data plans, languages, and technology, it may be difficult to implement text messaging systems in international settings. In addition, sending messages manually adds extra burden on the part of the study staff, especially with large study populations and multiple messages and messaging schedules. Sending messages in multiple languages, scripts, or alphabets may also introduce challenges. In order to address these issues around the implementation of text messaging systems, we developed an Android application housed on a local smartphone in Russia that accesses a server in the United States and automatically sends medication reminders, in Russian, to participants enrolled in our clinical trial.

Methods

The ZINC study includes 254 participants who are HIV-infected, report heavy drinking in the past 30 days, and live in or near St. Petersburg, Russia. Participants were randomized to one of two medication arms: zinc supplementation or placebo. Results from this National Institutes of Health funded study, being conducted in an ongoing collaboration between investigators in the US and Russia, are pending and not yet published. Randomization was double blinded, and all participants were given identical medication instructions and assessments. The study involved one baseline and three full-length follow-up assessments at six, twelve, and eighteen months post baseline during which blood was drawn, and a study assessment administered. Participants also completed four shorter medication visits at six weeks, twelve weeks, nine months, and fifteen months post-baseline. These visits were comprised of an abbreviated assessment for symptom monitoring, medication adherence, and antiretroviral therapy use, and provided study medication. The full study assessment included questions about medication intake as well as questions on demographics, HIV symptoms, depression, social support, stigma, and alcohol and drug use. Adherence measures collected at each visit included pill count data and self-reported percentage of medication taken using a visual analog scale. Riboflavin, which can be easily detected in the urine if ingested within the past 24 hours, was added to both ZINC and placebo pills to provide a biological assessment of adherence. The final adherence measure was visual inspection of a urine sample using ultraviolet light to check for past 24 hour medication use. Institutional Review Boards of Boston University Medical Campus and First St. Petersburg Pavlov State Medical University approved this study.

Study staff described SMSMessenger to all participants at their baseline assessment, and asked all participants if they wanted to receive text message reminders. Participants received automated text messaging reminders twice per week for the first six weeks and were able to opt out or reduce the frequency of the messages at their 6-week visit or at any time throughout the study. The application was downloaded once onto an Android phone, which

was kept on site in the main study office. Study personnel accessed the application on the phone on a regular schedule (every Tuesday and Friday) to send messages. The application existed on the local Android phone which connected to a database set up for the clinical trial hosted on a secure web server in the US. It retrieved a list of participants who were due a message that specified: the phone number, whether the participant should receive a message at that time, and the text of the message they should receive. The application is capable of storing multiple outgoing messages, and can support all phonetic alphabets. With just a few clicks, text messages are sent simultaneously to study participants, who can, if they wish, reply directly to the message. Study staff can then check the phone for any incoming messages.

World Health Organization mobile health evidence reporting and assessment checklist

Mobile health (mHealth) interventions are interventions that attempt to improve health outcomes by utilizing mobile and wireless technologies. In an effort to improve completeness in reporting these interventions, the World Health Organization developed the mHealth evidence reporting and assessment checklist containing 16 items which represent a “minimum set of information needed to define what the mHealth intervention is (content), where it is being implemented (context), and how it is implemented (technical features)”.¹¹ In the following paragraphs, we will use the structure of this checklist to describe the features of SMSMessenger (see Figure 1).

Infrastructure (population level)

Two features in our system utilize local infrastructure: text messaging and cellular data used to access a server in the US via the Android application. Therefore, as long as data and SMS plans are available, no other local infrastructure is required. Fortunately, in both high and low income countries, geographical coverage of mobile technologies is high, and a majority of the population already owns a mobile phone.¹ A 2013 United Nations study found that “of the world’s seven billion people, six billion have mobile phones”. In fact, more people have access to mobile phone technology than have access to working toilets.¹² According to The World Development Report on Digital Dividends published by the World Bank in 2016, mobile phone ownership in the developing world has reached 8 out of 10 people.¹³

Technology platform

The reminder system is an Android application developed at the Data Coordinating Center at the Boston University School of Public Health in Boston, Massachusetts. The infrastructure involved is a structured query language (SQL) database, housed on a US server, which contains a list of telephone numbers, message content, and mobile messaging schedules. The technology required to implement this intervention is a secure server with SQL server installed, and an Android phone with a local data plan, housed in the country in which the study is taking place, that can access the server (see Figure 2). The server and phone may be in different locations (in this instance the server was in the USA and the phone in Russia). Once set up, the SQL server requires only minimal maintenance, as would any server/database, with study-specific changes required only when related to changes in message

content, message scheduling, or participant contact information. Setup of the backend database requires more effort. We did not develop the application for commercial distribution and thus it is not commercially available. However, technical specifications may be provided upon request (see author contact information).

Interoperability / Health information systems context

The intervention does not require integration with existing health information systems. Instead, a separate database containing contact information (mobile phone numbers) for study participants is required. Since most studies already collect contact information on their participants, entering information into this database does not require additional effort. In addition, the database can be set up to pull the needed information from most participant tracking systems that already exist for particular studies.

Intervention delivery

For the current trial, all participants receive messages on a pre-determined schedule – twice a week, on Tuesdays and Fridays. SMS messages (in Russian) were sent out simultaneously to all participants throughout the time they are enrolled in the study. Participants who do not wish to receive messages can either opt out completely, or reduce their message frequency to one time per week. The application can be modified to meet the requirements of future studies in which it is used. For instance, message timing can be based on enrollment dates, and can vary for each individual participant.

Intervention content

Participants in the current trial receive SMS messages that simply remind them to take their study medication: “Please take Zinc study medication regularly”. As with the delivery of the intervention, the content of the intervention can change depending on the needs of the specific study, and any kind of message can be programmed into the database. For example, medication and appointment reminders, motivational messages, and instructions for use are just a few of the available variations on intervention content.

Usability / content testing

The current randomized control trial participants are the first to utilize this Android application. Before implementing the reminder system with study participants, we tested SMSMessenger across a variety of cellphone carriers and plans with test subjects both inside and outside the US. We entered phone numbers of study staff into the application database, accessed the application, and confirmed that text messages were received as scheduled. Our office in Boston keeps an identical phone to the one used by study staff so that we can ensure operating software updates do not interfere with the application and to locally troubleshoot any problems that arise with intervention delivery. SMSMessenger works on all Android phones, and is not limited to a particular Android phone version, as long as the phone works both in the US and at the international study site. However, both phones must be the same version so that troubleshooting can happen locally.

User feedback

Of the 254 trial participants, all consented to receive text messages at enrollment. Although participants are not asked to comment specifically on the text messaging intervention, very few have complained to study staff about receiving SMS reminders. Participants are asked at each visit if they would like to stop receiving messages, and only 3% (n=8/254) of participants have asked to stop receiving messages over the 18 month study period. Study staff also report that the application is easy to use, and the burden of sending reminders is greatly reduced when compared to sending them manually.

Access of individual participants

Minimal (to no) barriers to the adoption of the intervention were noted by study participants. As described above, mobile phone access is widespread throughout the world, including in developing countries. The only requirement of SMSMessenger for study participants is that they have access to a mobile phone that can receive SMS messages. As such, we see no reason for individual participants to be limited in their access to SMSMessenger.

Cost assessment

The majority of costs for SMSMessenger are related to programming and set-up at the beginning. For projects that house databases on secure servers and have access to web-developer time, costs would be minimal. Once the application is up and running maintenance costs are minimal. Other than basic mobile messaging costs, the intervention costs nothing for participants. With regard to study staff and operations, it requires the purchase of two Android phones: one Android phone for the study center, and another identical phone to be kept in the US for trouble shooting. Other minor costs include data plans and minimal programmer time to manage software updates and troubleshoot.

Adoption inputs / programme entry

Participants are informed about the SMS reminders when they enroll in the study. No training for participants is required, as they simply receive and read messages. The SMS intervention does not require any other action on the part of study participants.

Limitations for delivery at scale

There are no expected challenges related to scaling up of the intervention. All of the programming is done up front through the database, and the intervention is delivered automatically. Some service providers may become concerned with the volume, frequency, and timing of messages since multiple messages are sent all at once. Study staff need to confirm that their data plan can handle all of the messaging, and may have to communicate with the individual service provider in the event that service is suspended due to increased activity.

Contextual adaptability

Adaptability is one of the main strengths of the current intervention. It is capable of storing multiple outgoing messages, and can support all languages and phonetic alphabets. The only requirement for participants is that they have access to a mobile phone which is pervasive

throughout the world, and agree to receive messages. SMSMessenger, therefore, can be easily adapted to work in many different kinds of studies, and in many different international contexts, including in low resource settings. In addition, because the application accesses the database each time it is run, any changes to the database are automatically transferred to the application, allowing for automated real time updates.

Replicability

The current SMSMessenger application is a case study investigating a possible solution to a technological problem for which we found no such affordable solution in the literature. In particular, the challenges of sending text messages in international settings. The mobile application currently connects directly to our web service which is, in turn, connected to our study database. [At present], in order to replicate SMSMessenger, other research groups would have to have some knowledge about building simple Android applications. In addition, sites would have to ensure that they have robust data protection protocols in place. As discussed in more detail below, no sensitive data are stored on the phone. However, phone numbers and names stored in the database are sensitive data, and great care needs to be taken to ensure the back-end security meets all ethical and legislative requirements. Further development will help make SMSMessenger more widely available and replicable.

Data security

The only identifiable data required to implement the intervention is telephone number. That information should be kept on a secure server. In the current study, a secure server is set up in Boston, and all communications between SMSMessenger and server are encrypted. No sensitive data are saved on the phone, since the phone accesses the database each time it sends messages.

Compliance with national guidelines or regulatory statutes

Study staff should take care when composing the SMS message content to ensure that no sensitive data or personal health information is included in the message(s) that the participants receive, which are not encrypted. In addition, no personal information about participants should be, or need be, stored on the phone itself. All required personal information (phone numbers of study participants) is stored in the backend database. As with all other identifiable information related to the study, study staff must ensure that the backend database is stored on a secure server behind a firewall. These precautions ensure that the risk of releasing personal health information is no greater for studies that use the application than it is for any other clinical trial.

Fidelity of the intervention

The SMS reminders have been delivered twice per week as planned with very few issues. Each individual participant received, on average, 160 messages throughout the 80 weeks they were enrolled in the study. With 246 participants consenting to receive messages throughout the study period, we estimate that SMSMessenger sent out around 39,360 messages total. There have been occasions where updates to the phone at the study site

caused the application to malfunction. We were able to download the same update to the phone kept in Boston and successfully troubleshoot those instances with minimal downtime.

Discussion

In order to successfully test an intervention, randomized clinical trials require that a percentage of patients receive the intervention. Adherence can be particularly challenging in the case of HIV and other chronic diseases where treatment is long term and continuous, a number of different medications are required, dosing schedules are complex, and medication can be poorly tolerated.³ Even in the case of clinical trials with definitive endpoints, and where there is more regular, focused, and direct patient attention, adherence rates often remain low, especially in those trials that involve management of chronic diseases.¹⁴

The risk for non-adherence was especially high in the current study population, even within the context of HIV and chronic disease. Among our participants, there was a high occurrence of heavy alcohol use (an inclusion criterion for the ZINC study), and drug use (highly prevalent among participants, with 37% reporting past 30 day injection drug use). These risk behaviors have been associated with lower medication adherence in HIV-infected populations,¹⁵ and a number of studies have found associations between alcohol use and low adherence to HIV treatment. A meta-analysis of 40 different studies concluded that alcohol drinkers were only about half as likely to adhere to antiretroviral therapy treatment compared to abstainers or those who drank less.¹⁶

We developed the messaging application in an attempt to address these concerns about non-adherence. SMSMessenger is a prototype that has worked well for our study, and addresses a practical technical challenge (SMS messaging in international studies) for which we found no low cost commercially available solution. Feedback from study staff and participants has been largely positive, showing that it was a positive addition to our study protocol. The automated system eases the burden of having to send manual reminders to participants, and only a small minority of participants have opted out of receiving the messages. We have encountered a very small number of issues, primarily related to software updates, and all were resolved with minimal interruptions in message receipt.

Limitations

The primary aim of the ZINC trial was to test the effectiveness of zinc supplementation, and not to test the effectiveness of text messaging. As such, all participants in the study received text messages, and we are not able to specifically test whether or not the SMS intervention successfully increased adherence. The goal of the application and the current paper is to present a solution that can help meet the challenges of international studies, specifically text messaging, not to evaluate the SMS intervention itself. We present SMSMessenger as a case study of one possible solution to an area of the literature that appears largely lacking. Although SMSMessenger requires further development before it can be made available commercially or as an open source application, we have found a technical solution that works well and can be modified to adapt to a number of different settings.

Data messaging itself is not encrypted, and neither is the study phone. As such, no identifiable information, including specific clinic dates or diagnoses, can be part of the messages themselves. In addition, no identifiable information should be stored on the phone. Although participants can respond to the study phone via SMS, their numbers and names should not be saved on the study phone. If study staff receive a message from a participant, they have to look up that phone number in the study database in order to determine the identity of the sender.

Conclusion

SMSMessenger is designed to automate the process of sending study adherence reminders and to reduce the burden on study staff. Although our study was not designed to demonstrate whether SMS reminders improve study medication adherence, we do demonstrate that this automated messaging application is an easily implemented tool and can be applied in international studies. Given SMS reminders' proven usefulness to improve medication adherence in a number of different settings and the worldwide access to mobile phones, this application holds valuable potential for dissemination. Notably, the infrastructure to implement the application already exists, and costs and setup are minimal. The application's ability to support multiple languages and alphabets, receive real time updates, and provide encrypted transmissions between the phone and database are valuable features. Although further development is needed to make the technology more widely available, it can eventually be modified to be implemented anywhere in the world, in any alphabet, and for many different purposes.

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Infrastructure (population level)	•Data and SMS plans - widely available in both high and low income countries
Technology Platform	•Limited requirements: secure SQL server, Android Phone
Interoperability / Health Information Systems (HIS) Context	•Connects to a separate database with phone numbers for study participants
Intervention Delivery	•Messages are sent on a predetermined, but flexible, schedule
Intervention Content	•SMS messages with variable content
Usability/Content Testing	•Tested in the US pre-implementation, with continued troubleshooting as it's used
User Feedback	•Almost entirely positive
Access of Individual Participants	•Very accessible to anyone with a mobile phone
Cost Assessment	•Minimal costs: free for participants outside the (preexisting) cost of their standard mobile phone
Adoption Inputs / Programme Entry	•No participant training required
Limitations for Delivery at Scale	•Minimal. The phone company may need to be notified of extra activity
Contextual Adaptability	•Can support all languages and phonetic alphabets, database changes are automatically transferred
Replicability	•Easily replicable: the only requirements are a web service and database
Data Security	•Encrypted communication, no sensitive data are stored on the phone
Compliance with National Guidelines or Regulatory Statutes	•No personal information about participants is stored on the phone, it is all on a secure server
Fidelity of the Intervention	•Troubleshooting can be done with minimal downtime

Figure 1.
mHealth evidence reporting and assessment guidelines

Figure 2.
Architecture diagram for SMSMessenger