University of Arizona

Consent to Participate in Research

Study Title: Digital Self-management System to Support Blood Pressure Medication Adherence

Principal Investigators: Kathleen Insel and Raksha Mudar

Sponsor: National Institutes of Health, National Institute of Nursing Research

Disclosure: The investigators have intellectual property rights over the mobile application technology being investigated in this study.

Summary of the research

This is a consent form for participation in a research project. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

This is a study about testing the use of technology to help improve taking prescribed medications for high blood pressure among older adults. You are being invited to participate in this study because you are 60 years of age or older, self-manage at least one prescribed medication for high blood pressure, use a smartphone, have indicated or been told you have some difficulty with memory, and can speak, read, and understand English.

Why is this study being done?

The purpose of this study is to examine the benefits of a smartphone technology mobile application (app) to help improve taking prescribed medications for high blood pressure among older adults with memory difficulties.

What will happen if I take part in this study?

If you take part in this study, you will be asked to meet with study personnel four times in person and once on phone or video call over the course of 4 months. All study visits will be held at a location convenient to you (University of Arizona, home, senior center, etc.).

Visit 1: During the first visit, you will be asked to respond to questions about your demographics, health, medication(s), memory, and experiences using technology. Your blood pressure will also be taken twice during this visit, both sitting and standing. This visit will take approximately 90-120 minutes. You will be asked to transfer one of your prescribed medications for high blood pressure to a medication container with a special cap. This special cap helps us count how many times this medication is taken. If you use a medication organizer, we will provide you with a customized pillbox with seven compartments to fit the container with a special cap. You will be paid $30 at the end of this visit.

Visit 2: After one month of using the medication container with the special cap, you will be asked to meet again with study personnel at a time and location that is convenient to you. During this visit, we will show you how to use your smartphone to support you to take high blood pressure medications. During this visit, you will be randomly assigned to one of two groups. The assignment to the study groups is by chance, like flipping a coin.

Both groups receive information about high blood pressure, the importance of taking medications, and links to credible resources to learn more about managing blood pressure. Additionally, both groups will use their smartphones to access information about high blood pressure and high blood pressure medications and websites where you can obtain more information about high blood pressure and healthy lifestyles.

Only one group, in addition to the above, will also receive access to the investigational smartphone technology mobile application.

Regardless of what group you are in, we will provide you with a blood pressure monitor to help you monitor your blood pressure at home. We will show you how to use the blood pressure monitor and smartphone to support you in taking your high blood pressure medications.

We will record your blood pressure. You will continue using the medication container with the special cap. This visit will take 90-120 minutes. You will be paid $30 at the end of this visit.

Brief Check-in: One week after visit 2, we will do a brief check-in by phone or video call to inquire if you have any questions about using the smartphone to support you taking high blood pressure and medication. This visit will last approximately 15-20 minutes.

Visit 3: Four weeks after visit 2, study personnel will visit you again at a time and location convenient to you. During this visit, study personnel will look at your medication container, take your blood pressure twice, both sitting and standing, and ask you to complete some questionnaires. We will also ask for your feedback about using smartphone technology in an interview, which will be recorded for later analysis. You will continue using the medication container with the special cap. This visit will take 90-120 minutes. You will be paid $30 at the end of this visit.

Visit 4: Two months after visit 3, study personnel will meet with you for a final visit at a time and location convenient to you. The study staff will take your blood pressure, both sitting and standing, ask that you complete some questionnaires, get your feedback about using the smartphone technology, and collect the special bottle cap and pillbox. We will answer any questions you have about the study and thank you for your participation in the study. This will take 30-45 minutes. You will be paid $30 at the end of this visit.

How long will I be in the study?

The study will take place over four months with four in-person meetings at your preferred location(s) and one phone or video-call check-in. We will ask you to use the medication container with the special cap for four months.

How many people will take part in this study?

A total of 100 people will take part. The study is taking place both at the University of Arizona and at the University of Illinois.

Can I stop being in the study?

Your participation is voluntary. Your participation in this study is voluntary. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Your decision will not affect your future relationship with the University of Arizona or the University of Illinois. If you decide to withdraw from the study, any data collected up to that time will be kept and used in our data analysis. The researchers also have the right to stop your participation in this study if they believe it is in your best interest.

What risks or benefits can I expect from being in the study?

Potential Benefits: You will receive information on managing high blood pressure and medications. Your medication taking may improve and you may gain knowledge about the use of smartphone technology.

Potential Risks: When completing the questionnaires during the visits, you may feel tired or frustrated. We will provide scheduled breaks, encouragement, and a supportive environment to make participation an interesting and beneficial experience. You are not required to answer any questions you do not wish to answer.

If you currently use a pillbox or organizer, using the medication container with the special cap can interfere with your existing strategies to remind you to take your medication. For this reason, we will give you a pillbox that allows you to move the medication container with the special cap from one day to the next. The box will be labeled with the days of the week, the same as most pill organizers.

There is risk related to inadvertent loss of one's health-related information. To avoid the loss of your information, the data collected in this study will not be identifiable. Participants will be assigned a code. Your name will not be on any of the questionnaires. All questionnaires will only have the code number on them. Only one form will have your name and code. This form will be kept in a password-protected file and maintained in a secure server. It will be destroyed after 10 years.

Will I be paid for participating in the study or experience any costs?

There are no costs involved with participating in the study aside from your time. If you decide to participate, for each in-person visit you will be paid $30, or a total of $120. Payment will be in the form of a check, gift card, Amazon e-code or cash. You may select the form of payment you prefer.

Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. Please note, if you are an employee of the University of Arizona, any compensation from a research study is considered taxable income. For any compensation you receive, we are required to obtain identifiable information such as your name, address, and social security number for financial compliance purposes. Identifiable information collected for financial compliance purposes will not be linked to your research data. If you do not want us to collect this information, you can still participate in this study, but you will not be able to receive any payment for your participation.

Will my study-related information be kept confidential?

The information that you provide in this study will be handled confidentially. Participant names will not be kept with the data. All data files will be assigned a code number identifier and stored

on a secure server. The link between your name and code will be kept in a password-protected file. When this research is discussed or published, no one will know that you were in the study.

We will not give anyone any information about you. However, there may be circumstances where this information must be released or shared as required by law. The University of Arizona Institutional Review Board; other federal, state, or international regulatory agencies; or the sponsor of the study, may review the research records for monitoring purposes.

Will audio recordings be made of me during the study?

With your permission, we will audio record the visits including the final visit to ensure the study staff are following protocol and when we ask about your opinion to learn about your experience using the smartphone. The audio recordings will be put on a secure server. Your name will not be on the audio file. Only the research team will have access to the file containing your responses.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will my study-related information be used for future research?

Your study-related information will be placed on a secure server. Please note that only de-identified data will be stored with no links to your name. We may use this information in future research projects or share it with other researchers studying ways to use technology to help patients take their medication.

Are you interested in participating in future research opportunities?

☐ Yes, the study staff may contact me about future research opportunities.

☐ No, the study staff may not contact me about future research opportunities.

Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the Principal Investigator Dr. Kathleen Insel at (520) 626-6220 or insel@arizona.edu, or (520) 626-2250.

For questions about your rights as a participant in this study, or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at (520)-626-8630 or online at research.arizona.edu/compliance/human-subjects-protection-program.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of participant	Signature of participant	Date

RCT Informed Consent

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