Passive Mobile Self-Tracking of Mental Health by Veterans with Serious Mental Illness

NCT05023252

May 17, 2023

Participant Name: _____ **Date:** _____

Study Title: Pilot Study of Mobile Sensing Data to Evaluate Mental Health Status

Principal Investigator: Alexander S. Young, MD, MSHS

INTRODUCTION

You are being invited to take part in a research study at the VA Greater Los Angeles Healthcare System under the direction of Dr. Alexander Young and his research team. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits to you and/or to the future population of individuals you represent.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

Your participation in this study is voluntary. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled.

BACKGROUND AND PURPOSE

The purpose of this project is to study a mobile phone-based sensing platform (a mobile application or "app") that might be able to detect some mental health trends or stress. The application collects information from your mobile phone and transmits it to the research team. Such information could help improve mental health assessment and care in the future. This project will study the platform to see how useful it is in detecting mental health problems.

You are being asked to participate because you are an adult with a diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, or PTSD who is at risk of symptoms and who owns a phone running Android OS or iOS and you are currently receiving care at this facility.

About 150 people will take part in this study at VA Greater Los Angeles Healthcare System. Your participation in this research study is voluntary.

DURATION OF THE RESEARCH:

Your participation in the project will last about 9 months.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen:

1. Answer questions to determine if you are eligible:

- Meet with a research staff member in a private office or by phone.
- To determine if you are eligible we will ask you a few questions. Questions include information about your diagnoses, symptoms, whether or not you have a conservator /legally authorized representative who makes your medical decisions, and your cell phone ownership. For individuals participating in the MIRECC Treatment and Clinical Neuroscience Repository, we will also ask about your risk for symptoms and where you get your VA medical services.
- We will also look in your medical record and confirm information with your psychiatrist. This means that we will confirm your diagnoses and other information that we discussed.
- This will take approximately 10 minutes of your time and will be done prior to completing this consent form.

2. Complete a survey and download the study mobile application:

- In a private office or virtually online, you will be asked to complete a survey about your basic information (gender, race, ethnicity, contact information, education, current living situation, current employment, phone ownership, phone service package, previous app usage). You will also be asked questions about your mental health symptoms.
- Meet with the research staff in a private office or virtually online and download the study mobile application and open it on your phone.
- This will take approximately60 to 90 minutes.
- The app will passively collect data in three domains: your sociability, activities, and sleep.
- Sociability is assessed by collecting information on calls and texts made with the phone (the content of these communications is not assessed or recorded; and assesses public interaction by measuring ambient sound in social environments (the sound is not recorded).
- Activities measures assess day-to-day routine by monitoring activity, movement, location, and habits.
- Sleep measures assess regular, uninterrupted sleep by collecting data on ambient light, ambient sound, phone movement, lack of communication, and lack of use of the phone.

3. Leave the study mobile application open and answer phone surveys:

- You will be asked to leave the app open for the duration of the study, which will capture an array of non-identified (except for location and a user name that you select) data (measures of sociability, activities, and sleep data) for a period of nine months. Wear the phone as you

normally do; there is no need to change when or how you wear it. The app will automatically securely transfer your data to the project server once per day. This may use some wireless data. We will show you how to monitor data usage on your phone.

- If you want to stop participation in data collection, you can stop the mobile app on your phone or contact research staff.
- You will be called once per week by research staff and asked questions about your social activity, activities, sleep, and symptoms. The total time for these is estimated to be 15 minutes.
- You will be able to view the tracking of your activities, sociability and sleep over time, similar to how people currently view their step counts on their phones.
- Additionally, if collected data indicates that you may be at high risk of relapse, research staff will be notified and will review your available data. After review of data, if risk appears accurate, you will be contacted and asked to notify your clinician, and one day later your clinician will be notified by research staff.

4. Complete 3 month and 9 month surveys:

- At the end of 3 months and 9 months, we will schedule an in-person or virtual appointment for you to meet with research staff for follow-up interviews which will include the same questions about mental health symptoms as in the first interview. At the 9 month interview, the app will be deleted from the phone, and you will be notified that it is no longer functional.

5. Complete additional semi-structured interviews (sub-set only):

- A subset of participants will complete a semi-structured interview at 3 months and 9 months after downloading the app, which will assess the acceptability of mobile sensing, what you liked and did not like and why, your perception of the usefulness of mobile sensing as a tool to improving care and recommendations for program improvements. The total time for each of these interviews is estimated to be 15 minutes.

Your responsibilities include:

- Keep your study appointments. If it you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Ask questions as you think of them.
- Tell the research staff if you want to skip any questions that you do not wish to answer.
- Tell the investigator or research staff if you change your mind about staying in the study.
- Keep the app running on your phone and wear the phone as you normally do; complete your surveys as instructed.
- Call a member of the research team if you lose your phone or have a problem with the app.

POSSIBLE RISKS OR DISCOMFORTS

In this study there are no anticipated risks or discomforts. Rare, unknown, or unforeseeable (unanticipated) risks may occur.

- You may feel discomfort in answering questions as part of the surveys or having the app on your phone. You can choose to skip questions that cause discomfort. You can stop doing the surveys at any time, take a break, or continue the surveys at another time. You can remove the app from your phone and choose to stop participating at any time.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

POTENTIAL BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that you provide may help us design a mobile sensing platform that is effective in helping treat future patients.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- All data that could identify you (except location and username) will be stored electronically behind firewalls on a VA Research computer server.
- All non-identified data collected from the app will be stored electronically behind firewalls on a server at UCLA which meets VA data security standards.
- We will collect the last 4 digits of your Social Security number in order to facilitate reviewing your medical record. This will be stored electronically behind firewalls on a VA Research server and will not leave the VA.
- All data kept locally on the mobile application are fully encrypted. Similarly, all data transmitted between the device and the server, and all data on the server, will be protected with approved encryption technology
- The app will collect information on the use of applications, location, movements, light, phone screen on-time, and ambient sound (this does not assess or record the language content of the sound). The app will also monitor messages and phone calls; however, it will not monitor or record content of communications.
- Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.
- All study documents will be retained for seven years from the date of study closure as required by National Archives and Records Administration and will be destroyed as outlined in the VHA's

Records and Control Schedule (RCS10-1). We will not use names or other identifying information on study documents or on the data from the app. A code number will be used on all data. The data from the app will be linked by your code number. The links will be kept in a password protected file on a secure VA server; this file is only accessible to the PI and study staff with relevant privileges.

- Most of the research records will be kept electronically in a password-protected computer file that only the study team can access. This information is stored on a secure VA server, behind firewalls. Any hard copy records will be stored in locked filing cabinets in locked VA offices of research staff.
- The non-identified (except location) data from the app that is stored electronically at UCLA will be securely transferred to VA for permanent storage.
- Note that we will require your social security number to process voucher payments.

This informed consent form will have to have your real name. This form will be kept separately, also in a locked storage area separate from other study documents.

You will be asked to sign a separate HIPAA Authorization Form to allow the VA to share your Personal Health Information with the research team for use in this study. Your separate signature on this form will reflect your official authorization.

We will not share your records or identify you unless we have to by law. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Greater Los Angeles IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

In accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others, or becomes aware that acts of child abuse or elder abuse may have occurred.

COSTS TO PARTICIPANTS AND PAYMENT

You will not be charged for any treatments or procedures that are part of this research study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

All efforts will be made to schedule your research appointments at a time that is convenient for you, but it is possible that you may incur additional costs, such as transportation costs or time away from work.

If you do not have an unlimited data plan, there is a possibility of incurring additional costs on your monthly cellular telephone bill due to the phone transmitting data for the study. Research staff will help you understand your plan, how to monitor data use on your mobile device, and understand any additional data plan charges, should there be any.

Payment Offered for Participation:

- In return for your time and inconvenience, you will be paid $50 for the first survey (baseline interview). You will receive $10.00 for each week during which you complete a weekly assessment. You will also be given 2 bus tokens, if desired. You will be paid $50 for the 3 month survey and $50 for the 9 month survey and $10 for each of the qualitative semi-structured interviews, if selected for participation.
- You will be paid at the time of each research interview. You will not be reimbursed for completing the screening and consent process.
- Payment will be in the form of a gift card or a voucher, which you can submit at the Agent Cashier's office for cash. You may also choose to set up direct deposit and be paid through direct deposit throughout the study.
- Note that we will require your social security number to process voucher payments. In addition, it is VA policy that the amount you receive from this study may be reported to the Internal Revenue Service (IRS) and may be considered taxable income.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. Emergency and ongoing medical treatment will be provided as needed.

In the event that you have a question about the research or experience a research related injury, adverse reaction, or have concerns, please immediately contact:

During business hours:

- Alexander S. Young, MD, MSHS

After hours (emergency for psychiatric or medical issues):

- Dial 911 or go to your nearest emergency room
- You may also use the National Suicide Prevention Lifeline: 1-800-273-8255

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

YOUR RIGHT TO TERMINATE PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient. If you decide to withdrawal from the study, the research staff may continue to review data already collected, but cannot collect further information, except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

The study principal investigator has the right to end your participation in this study for any of the following reasons:

a. It would be dangerous for you to continue;
b. You do not follow study procedures as directed by the study doctors;

Any time your participation is ended, you will be asked to complete the procedures the doctor considers necessary for your safety.

PERSONS TO CONTACT ABOUT THIS STUDY

During business hours: Dr. Alexander S. Young, MD, MSHS

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Greater Los Angeles Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Greater Los Angeles IRB at 310-268-4437 if you have questions, complaints or concerns about the study, or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

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You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will be retained in the investigator's research records.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date

RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.