

Smartphone-based Services for People Diagnosed with Opioid Use Disorder

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October 31, 2023

**Western Michigan University
Department of Psychology**

Principal Investigator: Dr. Anthony DeFulio, Ph.D.
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Title of Study: Smartphone-based services for people with opioid use disorder

You are invited to participate in this research project titled "*Smartphone-based services for people with opioid use disorder*"

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. Participation in this study is completely voluntary. The purpose of the research is to evaluate whether services and materials made available through a smartphone app are helpful to people who have been diagnosed with opioid use disorder. If you take part in the research, you will be asked to use the app to submit videos of yourself taking salivary (spit) drug tests to a secure online system and to earn rewards. Your time in the study will take place over the course of a year, and will include about 30 minutes each week submitting videos, an hour-long interview to get started, and hour-long interviews once every three months after that over the course of the year. Possible risk and costs to you for taking part in the study may be discomfort from answering sensitive questions, risk of others learning confidential information about you (such as through you sharing your phone), and the time it takes to complete videos and interviews. Potential benefits of taking part may be that the app and associated services you receive as part of this research might help with your recovery. An alternative treatment to taking part in the research study is to enroll in medication-assisted treatment for opioid use without also using the app. Your alternative to taking part in the research study is not to take part in it.

The following information in this consent form will provide more detail about the research study. Please ask any questions if you need more clarification and to assist you in deciding if you wish to participate in the research study. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form. After all of your questions have been answered and the consent document reviewed, if you decide to participate in this study, you will be asked to sign this consent form.

What are we trying to find out in this study?

We are trying to find out whether one set of smartphone-based services is better than another set of smartphone-based services in helping people who are seeking treatment for opioid use disorder.

Who can participate in this study?

Adults who are seeking treatment or are in treatment for opioid use disorder can participate in this study. People who have alcohol use disorder or who have some severe mental health conditions should not participate in this research. To find out whether you are eligible for this study we will conduct a brief interview, and also confirm some of the things we learn during the interview with one or more of your healthcare providers (e.g., your MAT provider, the medical facility where you typically or recently received treatment). You will need to give your

healthcare provider consent to share information with us so that we can confirm important information about you prior to you taking part in study activities such as using the app.

Where will this study take place?

This study takes place wherever you live. You do not need to travel to special locations to participate in this research. This is because the research involves the use of an app that works everywhere throughout the United States. Interviews will be conducted over the phone.

What is the time commitment for participating in this study?

It will be up to you to decide how much you would like to use the app. Part of what we are studying is whether you use the app and how long and how often you use it. You do not have to use it if you do not like it or you do not want to. In addition to using the app, we ask that you complete hour-long interviews with us on several occasions. The first interview will happen right away if you decide to join the study and are eligible to join it. The other interviews will happen 3, 6, 9, and 12 months from now.

What will you be asked to do if you choose to participate in this study?

The main thing you will do is use an app that might help you with your recovery. The most important feature of the app is that it allows you to record yourself taking saliva (spit) drug tests and send these videos to us in a way that is secure and protected. The app also has reading materials that may be of interest to you, and it can be used to set reminders and track appointments as well. Lastly, we will pay you for various activities that you complete. These payments will be made to you with a reloadable debit card that can be used almost anywhere, but will not work in ATMs to get cash.

What information is being measured during the study?

This section will describe the measurements that we are going to take during your participation in the study. The measurements include the results of the drug tests, whether or not you are in treatment, the ways in which you use the app, how much money you are paid, and the answers to the questions we ask in the interviews.

What are the risks of participating in this study and how will these risks be minimized?

Possible risk and costs to you for taking part in the study may be discomfort from answering sensitive questions, risk of others learning confidential information about you, and the time it takes to complete videos and interviews. To reduce your discomfort, you can decide to refuse to answer questions that you do not want to answer. To reduce the risk of others learning confidential information about you, you can password-protect your phone, and be sure to only use the app when you are in private spaces. To save the time it takes to complete videos or interviews, you can decide that you do not want to do those things.

What are the benefits of participating in this study?

Potential benefits of taking part in this study may be that the app and associated services you receive as part of this research might help with your recovery.

Are there any costs associated with participating in this study?

There are no costs associated with participating in this study. However, this study does not pay for your substance abuse treatment or for your smartphone service.

Is there any compensation for participating in this study?

You will receive compensation for completing each of five interviews (\$30 each), and for submitting a special monthly saliva (spit) drug test by mail (\$20 each for you and we pay for the shipping as well). If you complete all interviews and submit all of the monthly drug tests then you will earn \$410 over the course of one year [because $(30 \times 5 + 20 \times 13) = \410]. You can also earn up to \$30 per week for completing other activities such as submitting the regular drug test videos, up to a maximum of \$599 (not including the \$410 for completing the previously mentioned interviews and monthly drug tests). Adding these two numbers together (\$410 + \$599) makes for a possible maximum payment of \$1,009 over the course of one year.

Who will have access to the information collected during this study?

This information will be available to all approved members of the study team. In addition, the staff members of the company that provides the app and related services, DynamiCare Health, Inc., will also have some of your information. To protect your information, the study team and the people at DynamiCare Health will not share your information with anyone else. In addition, all of your information will be stored on encrypted servers that meet the highest standards for secure storage of health information. Also, this study is protected by a Certificate of Confidentiality issued by the National Institutes of Health. That means that information collected as part of this study is immune from the legal process and is not admissible as evidence without your consent.

What will happen to my information or biospecimens collected for this research project after the study is over?

After information that could identify you has been removed (by removing your name and other personal information), the resulting de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you. The saliva (spit) samples that you ship in the mail will be thrown away after they are tested and will not be used for any other purpose.

What if you want to stop participating in this study?

You can choose to stop participating in the study at any time for any reason. You will not suffer any prejudice or penalty by your decision to stop your participation. If you choose to stop participating in the study, then you will no longer receive payments related to participating in the study. The investigator can also decide to stop your participation in the study without your consent.

Should you have any questions prior to or during the study, you can contact Dr. Anthony DeFulio, Ph.D. at Western Michigan University at 269-387-4459 or anthony.defulio@wmich.edu or Rosemarie Davidson at Western Michigan University at 269-387-4338 or rosemarie.m.davidson@wmich.edu. You may also contact the Chair, Institutional Review Board at 269-387-8293 or the Vice President for Research and Innovation at 269-387-8298 if questions arise during the course of the study.

This study was approved by the Western Michigan University Institutional Review Board (WMU IRB) on (approval date).

Participating in this survey online indicates your consent for use of the answers you supply.