UNIVERSITY OF SOUTH FLORIDA

Informed Consent to Participate in Research and Authorization to Collect, Use, and Share your Health Information

Information to Consider Before Taking Part in this Research Study

Title: Effects of Remote Motivational Enhancement and MySafeRx on Post-Detox Engagement and Retention in Buprenorphine Treatment

Pro # 00038163

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Kathleen Moore, Ph.D. who is a Research Associate Professor at the University of South Florida. This person is called the Principal Investigator. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at The Agency for Community Treatment Services (ACTS) in Tampa, Florida and is supported/sponsored by The Centers for Disease Control and Prevention (CDC). Cambridge Health Alliance (CHA) is the collaborating institution on this project. The purpose of this study is to learn about how to help people with opioid use prevent overdose after they leave detox. Studies show buprenorphine prevents overdose, prevents withdrawal, and helps people lead lives with sustained recovery.

Participants: You are being asked to take part because you have recent opioid use and you are currently a patient in detox at ACTS AND you are considering if buprenorphine might be an option after detox to help you stop using opioids.

Voluntary Participation: **Your participation is voluntary**. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. **You will be compensated up to $225 for your participation if you are assigned to the *MySafeRx* group and up to $195 if you are assigned to the Standard Care group.** This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. Your information or biospecimens collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

Why are you being asked to take part?

We are asking you to take part in this research study because:

You have recent opioid use and you are currently a patient in detox at ACTS

AND

You are considering if buprenorphine might be an option after detox to help you stop using opioids.

This study looks at the role of coaching on recovery choices and the use of a new mobile technology called *MySafeRx* to support people who are prescribed buprenorphine to take medication regularly at home, while preventing it from being stolen or lost. We want to see how much you like, or dislike, the coaching and the new way of taking your medication. If you decide to be a part of the study, we will ask your opinions about this program to help us decide whether or not *MySafeRx* would be a good way of offering medications for recovery from opioid use. **In this study, we are testing how to put several tools, such as pill dispensers, text messages, and video meetings, together in a new way that we believe will help people in early recovery**. All these devices are secured with encryption technology to protect your personal privacy.

Study Procedures: What will happen during this study?

If you take part in this study, you will be asked to:

- Complete a baseline assessment at ACTS detox, lasting approximately 1.5 hours, which will include this consent form to help you understand the study, your providing information about yourself, your substance use and treatment history, and do some brief tasks on a tablet.
- Read information about buprenorphine.
- Consider starting buprenorphine free of charge to prevent withdrawal symptoms during your detox stay and then choose either to detox from opioids or to be stabilized on the medication for at least 6 months.
- If you choose to be stabilized on medication for at least 6 months, then you will be asked to complete at least 2 weeks of in-person, onsite daily dosing after leaving detox, which include prescriber meetings, urine screening, and engagement with ACTS treatment program staff and local resources for additional support.
- You will be randomized to either *MySafeRx* or standard treatment as usual. It is not guaranteed that you will be assigned to *MySafeRx*.
- If you are assigned to *MySafeRx* you will be given a MedicaSafe device. This device will require you to return to ACTS detox once a week to pick up a new MedicaSafe device (refill your prescription) which is filled by a local pharmacy partner. You will be given 7 days' worth of medication in your MedicaSafe device and an additional emergency lockbox in case of malfunction. In a case of malfunction, your mobile recovery coach will still be able to provide you with a code after your daily sessions.
- Participate in 6 follow-up assessments at week 4, week 8, week 12, week 16, week 20, and week 24, lasting approximately 15-30 minutes, at the ACTS facility.
- **You will also be expected to provide urine samples to ACTS at least once weekly for 24 weeks.**

- **You will be randomized to either standard care daily in-person dosing at ACTS OR motivational coaching with option for *MySafeRx* dosing from home after 2 weeks.**
- You may be asked to participate in 24 weeks of in-person, onsite, daily supervised buprenorphine dosing for assessment and stabilization. No matter what arm of the study you are assigned to you may at any time be asked to return to in-person, on-site daily supervised buprenorphine, based on ACTS clinical requirements, safety concerns, or your individual needs.

If you are assigned to receive *MySafeRx*, you will also be asked to:

- Watch a video about buprenorphine treatment.
- **Meet with a mobile recovery coach during detox and then 2 times a week while at ACTS during the first 2 weeks of in-person, onsite medication dosing.**
- Start the *MySafeRx* program after 2 weeks of in-person, onsite dosing, if you have taken your medication daily during the first 2 weeks through standard, in-person, on-site dosing at ACTS (on at least 10 of 14 days) and you meet ACTS clinical requirements.
- Participate in at least 10 weeks of daily *MySafeRx* mobile recovery coach check-ins with medication dosing **at home.**
- Work with your ACTS recovery support specialist or ACTS counselor, and mobile recovery coaches to discuss aftercare plan options during study week 8.
- You will be required to return the electronic pill dispenser and switch to a convenient, easy-to-use, standard lock-box at the end of study week 12.
- Participate in reduced *MySafeRx* mobile recovery coach check-ins during study weeks 12-16 and transition to dosing from a standard lockbox and attending either individual or group sessions at ACTS.
- **If you do not own a smartphone, *MySafeRx* will provide you with a loaner smartphone for the duration of the study which you will need to return at the end of the study. If you already have an Android smartphone you will be asked to download *MySafeRx* software onto your device.** Then you will be able to start *MySafeRx* and take buprenorphine each day from home using a secure pill dispenser while meeting with a mobile recovery coach using video on a smartphone.

Based on your ACTS re-assessment at week 12 you may have the following options:

1. Continuing reduced *MySafeRx* mobile recovery coach check-ins 2-3 times per week, for another 4 weeks (until study week 16). This will include observed dosing over videoconference with mobile recovery coaches using the standard lock-box.
2. Combining both *MySafeRx* mobile recovery coach check-ins 2-3 times per week as described in option 1 with ACTS in-person individual or group sessions between weeks 12-16.
3. Return back to ACTS group or individual sessions 2-3 times per week between weeks 12-16.

- Between weeks 16-24, you will be asked to follow ACTS standard care procedure of at least 3 weekly individual or group sessions, while still using the take-home lockbox for medication dosing.

Regardless of your treatment assignment:

- You will have buprenorphine medication paid for and available up to 24 weeks after starting the study.

- The project coordinator will begin talking with you about aftercare options at study week 8.
- You will have a clinical assessment at ACTS at study week 12.
- The project coordinator will remain in contact with you through week 24 for study follow-up activities.
- You will meet with an ACTS recovery support specialist or your ACTS counselor to solidify your transition into an aftercare program after 24 weeks.

Total Number of Participants

Approximately **200** individuals will take part in this study at all sites.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study. You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

You can decide after signing this informed consent document that you no longer want to take part in this study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- The *MySafeRx* platform is an adjunct to, and does not replace, the primary treatment you are receiving from your assigned ACTS physician.
- If you decide to stop, we will tell you how to stop safely and you can continue getting care from your regular ACTS physician.

Please note, even if you want to stay in the study, there may be reasons we will need to withdraw you from the study. You may be taken out of this study if we find out it is not safe for you to stay in the study or if you are not coming for the study visits when scheduled. We will let you know the reason for withdrawing you from this study.

Benefits

We hope that you will benefit from participating in this study but we are unsure if you will receive any benefits by taking part in this research study.

Risks or Discomfort

This particular treatment may involve risks to you (or to the embryo or fetus, if you are or may become pregnant), which are currently unforeseeable. If you are assigned to the *MySafeRx* intervention, there is a risk for application and device malfunction. Based on prior data, there is less than a 1% chance that you will have a malfunction. In the case of malfunction, you will be provided with an emergency lockbox. Your mobile recovery coach will have this code in case of an emergency. If possible, we ask for you to bring the device to ACTS detox as soon as you can. The project coordinator will contact the local pharmacy partner and have a new device delivered to ACTS detox. If there is a device malfunction there is a risk that you not receive your medication in an appropriate amount of time

Video and Audio Recording

We are requesting your permission to video and audiotape you as part of this study. If you're assigned to the *MySafeRx* intervention, you will need to use video chatting to communicate with your mobile recovery coach. This will also be required to receive your dispenser code for your medication. We will videotape your sessions with your mobile recovery coach so that we may review the tapes to ensure he/she is implementing the intervention as it was outlined.

I agree that (check all that apply):

_____ video

_____audiotape may be taken of me as part of the study entitled: MySafeRx

The recordings may be used for (Check all that apply)

a. _____ any purpose relevant to research, evaluation, training

b. _____ purposes of evaluating mobile recovery coaches only

Compensation

If you are assigned to the *MySafeRx* condition, you may be compensated up to $225.

If you are assigned to the Standard Care ACTS daily dosing condition, you may be compensated up to $195.

You will earn $20.00 for completion of your screening assessment and $10.00 for your baseline study assessment, which will be paid upon your being randomized and starting the study. **You will also earn a bonus 50 cents each day that you are observed taking your buprenorphine medication during the first 90 days of the study up to $45 dollars, which will go into a study account and will be paid to you as a completion bonus after you complete your week 12 study visit**. You will earn $20.00 for each of the six study assessment sessions that you complete, which will be paid upon completion of your last two study assessments at week 20 and week 24. You will receive up to $60.00 (compensation for assessments 1-3) at week 20 and up to $60.00 (compensation for assessments 4-6) at week 24.

If you are assigned to *MySafeRx*, you will be asked to return your medication dispenser in working condition during the week 12 study assessment, then you will receive the extra bonus compensation you have earned. If you return the study smartphone in its original condition by the end of week 16, then you will receive an extra $30 bonus compensation. **If these items are not returned in good condition, you will not receive the extra bonus compensation. We will use those funds to replace or repair the devices.**

All compensation will be given in the form of Amazon electronic gift cards.

Costs

It will not cost you anything to take part in the study. If are randomized to *MySafeRx* and you have a smartphone with a data plan, then you will need to ensure you do not go beyond your monthly data limit. If you do not have a data plan, then a study smartphone will be provided free of charge.

Compensation for Research Related Injuries

If you are experiencing an emergency, call 911. If you believe you have been harmed as a result of participating in this study, you should call *Dr. Kathleen Moore* at *(813) 974 - 2295* as soon as possible. The University of South Florida has not set aside money to pay for illness or injury that may result from your participation in research.

Before you agree to take part in this study, you may want to find out whether your insurance will cover injuries that result from taking part in research. You may be responsible for any deductible, co-insurance, or co-payments that result from such care. If you are injured, the University of South Florida has also not set aside money for lost wages, discomfort, or disability you may experience as a result of a research-related injury. By signing this form, I acknowledge the University of South Florida will not pay for the costs of medical care and treatment, or any associated costs such as lost wages, due to injury arising from participation in this study. You do not give up your legal rights by signing this form. In addition to contacting the study investigator, you should also contact the USF Institutional Review Board (IRB) at 813-974-5638 or RSCH-IRB@usf.edu if you believe you have been injured as a result of taking part in this study.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the Center for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. **Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below);** if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The Center for Disease of Control and Prevention which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

Conflict of Interest Statement

The PI has no conflict of interest associated with this study.

Privacy and Confidentiality

We will do our best to keep your records private and confidential.. Your information will be assigned a code number. Your name will not be used in any report. After completion of the study, versions of the data, with all identifying information removed, will be made available so that other researchers can evaluate it.

Certain people may need to see your study records. These individuals include:

- The USF and Cambridge Health Alliance (CHA) research teams, including the Principal Investigators, study coordinators, and all other research staff.

- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP).
- The USF Institutional Review Board (IRB) and its related staff who has oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.
- The CHA Institutional Review Board (IRB) and its related staff who has oversight responsibilities for this study.
- MySafeRx, Inc.
- Center for Disease Control & Prevention
- The Food and Drug Administration (FDA)

We are careful to protect the identities of the people in this study. All of the information that we collect about you during this study will be kept confidential and private. However, **details from your urine toxicology (and pregnancy test if applicable) results will be shared with your Mobile Recovery Coaches and your daily interactions with the Mobile Recovery Coaches WILL be shared with your medical providers in order to continue to provide you with appropriate medical care.** Survey data will only be collected by members of the research team.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

A description of this clinical trial will be available on 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.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available. Significant new findings developed during the course of the research, which may relate to your willingness to continue participation, will be provided to you.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Dr. Kathleen Moore at (813) 974-2295. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu**.**

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study.
- Each research site for this study including ACTS and Cambridge Health Alliance (CHA).
- Any laboratories, pharmacies, technology companies, or others who are part of the approved plan for this study.
- The USF Institutional Review Board (IRB) and their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research.
- The CHA Institutional Review Board (IRB) and their related staff who have oversight responsibilities for this study.
- Data Safety Monitoring Boards or others who monitor the data and safety of the study.
- The Food and Drug Administration (FDA)

Anyone listed above may use consultants in this research study and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information:

- Your research records
  All your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to, records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;

- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this form, please write to:

Principal Investigator
For IRB Study #00038163
Department of Mental Health Law & Policy – MHC 2712 Louis de la Parte Florida Mental Health Institute University of South Florida
13301 Bruce B. Downs Blvd.
Tampa, FL 33612

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Consent to Take Part in Research

I freely give my consent to take part in this study**.** I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

_____

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research participant speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research participant has provided legally effective informed consent.

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent