

Official Study Title: mHealth for Patient Self-Management of Opioid Use Disorder

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**Consent to be part of a Research Study
To be conducted at**

University of Texas Health Science Center at San Antonio (UT Health San Antonio)

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – “Who is conducting this research?”

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Jennifer Sharpe Potter, PhD, MPH at UT Health San Antonio, Department of Psychiatry and Behavioral Sciences.

Conflict of Interest

The study PI, Dr. Jennifer Potter, is a paid consultant to Biomedical Development Corporation, a for-profit company sponsoring this study.

Funding

The National Institutes of Health, a federal agency that promotes scientific research, is funding this study. This organization is providing money to UT Health San Antonio so that the researchers can conduct the study.

Purpose of this study – “Why is this study being done?”

You are asked to participate in this research study of a software system and mobile app for the self-management of opioid use disorder. This study will evaluate the effectiveness of the software system and mobile app in a 13-week study. The software system and mobile app offer evidence-based behavioral strategies to help management of opioid use disorder outside the doctor's office or treatment facility.

The researchers hope to learn if the software system and mobile app can be used to enhance usual care for opioid use disorder to increase improvement in opioid use reductions.

Investigation Use of Device

This study involves the use of an investigational device called KIOS. “Investigational” means that the device has not yet been approved by the U.S. Food & Drug Administration (FDA) for treating opioid use disorder.

This study will help find out what effects, good and/or bad, this device has. The safety of this device in humans has been tested in prior research studies; however, some side effects may not yet be known.

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

Information about Study Participants – “Who is participating in this research?”

You are being asked to be a participant in this study because you are a patient with a diagnosis of opioid use disorder and are currently undergoing medication-assisted treatment at a clinic.

How many people are expected to take part in this study?

This study will enroll approximately 210 study participants.

Information about Study Procedures – “What will be done if you decide to be in the research?”

While you are taking part in this study, you will be asked to remotely complete 27 visits with the researchers or study staff. These visits will take approximately 30-45 minutes.

Screening – After you sign this consent to participate procedures may be done as described below to find out if you can continue in the study; this is called screening.

Screening Procedures

The first virtual visit will be an assessment visit to determine if you qualify for the study. A member of the research team will describe the study in detail, and you will have the opportunity to have all your questions answered. If you are still interested, you will be asked to sign the consent document. We will provide ample time to review any questions you may have, and to assure your understanding of the protocol and consent.

Once you have officially agreed to be in the study, you will complete questionnaires about your substance use, depression and anxiety, your pain ratings, and undergo a urine drug screen. We plan to use results from the procedures for this research study. The results of the screening procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible options.

Assignment to Study Groups –

When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to one of 2 study groups. For 13 weeks (after the initial screening visit), you will be assigned to either:

Group 1: Treatment group: In this group, you will be assigned to utilize a version of the KIOS software system and mobile app with **active** treatment components, in addition to usual care.

Group 2: Control Group: In this group, you will be assigned to receive a version of the KIOS software system and mobile app with **no active** treatment component, in addition to usual care.

You will not know whether you are in the active or the inactive group.

Study Procedures - as a participant, you will undergo the following procedures:

Regardless of the group to which you are assigned, you will continue with your usual care visits. You will complete assessments of craving and daily substance use at least 3 times per week (but no more than 1 time per day) via the KIOS software on their smartphone or tablet. You will complete survey assessments on a survey platform called REDCap. These surveys can be completed on your smartphone, computer or tablet. You will also complete twice weekly Zoom or phone interviews with study staff. You will also complete urine screening twice weekly. Study staff will mail you urine testing cups which you will use to provide a urine sample in your own home. You will log into a Zoom call to allow study staff to read the results of the urine test

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on the cup.

At the end of the study you will complete a few additional surveys that will ask about the ease of use and your satisfaction with the KIOS app.

You will work with a Tech Support specialist to download the application. You will be given an access code that will be used to access the application. In the app you will be prompted to create a password, after which the application will be accessible on your phone or tablet.

We will need to text and email you during your participation in this study. If you are not able to receive and send texts or emails, you may not be eligible to participate in the study.

Additionally, you will be asked to provide your email in order to download the KIOS app.

Future Use of Your Information Collected as Part of Your Participation

Your information collected as part of the research will not be used or distributed for future research studies even if identifiers are removed.

Ending Participation Early

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – “What are the risks of participation in the research?”

Risks from the research

The investigators have designed this study to learn how well the use of the software system in conjunction with your normal treatment compares to commonly accepted treatment. There is a risk that the effectiveness and/or safety of the software system in conjunction with your normal treatment may not be as good as the most commonly accepted treatments. The software system may not help treat your disease or it may make your condition worse.

Risks from the specific research procedures

Psychological risks are minimal and not different from those of equivalent non-study psychotherapeutic interventions. Computer-based interventions have been used safely in multiple investigations with a range of populations, and we are unaware of any reported risks associated with these interventions.

The data collected from interviews and self-report forms, as well as results from urine collection, carry no risk other than those normally associated with these procedures. For more information about risks and side effects, ask one of the researchers or study staff.

Risks associated with questionnaires and KIOS mobile application system

Less likely (less than 5-20 subjects out of 100) and Not Serious:

- Uncomfortable answering questions –If you feel uncomfortable answering questions, one of the investigators

will speak with you to help clarify your doubts. Your responses will be kept confidential. You do not have to respond to any question that you do not feel comfortable answering.

Rare (less than 5 subjects out of 100) and Serious:

- Breach of confidentiality- It is possible in a rare occurrence there may be a breach of confidentiality. However, the researchers have taken steps to minimize this risk such as keeping materials in a secure, locked location. If you are assigned to use the KIOS mobile application system, you are also asked to not enter any personal identifiable information in the journal section.

Rare (less than 5 subjects out of 100) and Serious:

- Possible disclosure of clear and credible threat or intention to do serious harm to him/herself or some other identifiable person, which could trigger a mandatory reporting law.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes normal visit procedures including completing surveys and urine toxicology screening. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?

Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is in reduction of substance use as a result of the study treatments. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

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Not participating in this research is an option. You have the option of declining to participate in this study. Alternative treatments for substance dependence are available, including the treatment you are currently receiving. The researcher will discuss all of your options with you.

Payments – Will there be any payments for participation?

The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of each study week. You will receive \$10 for each study visit, for a total of \$270 for your participation. Your name, address, date of birth and Social Security Number (SSN) or Taxpayer Identification Number (TIN) will be shared with a third-party solely for the purposes of compensation processing. If you have a missing, invalid, or do not wish to provide your Social Security or Taxpayer Identification Number, 24% of your study compensation will automatically be withheld for tax purposes. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

If you provide a TIN or SSN later, you will not automatically get back any previously withheld amounts, but any further withholding will stop. Withheld amounts may potentially be reclaimed from the IRS when you file your personal taxes.

In addition to the compensation on the card, you may also receive study-related messages (text and/or email). These messages will contain information confirming that money has been loaded onto your card. You may also receive reminder messages with information about your next appointment with researchers or study staff.

Costs – Will taking part in this study cost anything?

You will be asked to use your own preferred device to access the application. At the end of your participation, you will be asked to delete the application from your device and you will no longer have access to the software via your username and password.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Federal Government. With this Certificate, the researchers cannot be forced to disclose, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or any other person not connected to the research, your (or your family member's) name or any of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under certain

circumstances. Circumstances that warrant the release of your information without your permission include: abuse and/or neglect, intention to harm yourself or others, or certain communicable diseases, or other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research. Should you require medical treatment as it relates to the information, document, or biospecimen pertains, additional consent will be obtained.

Limits of Confidentiality

Even without your consent, suspected or known abuse or neglect of a child, disabled, or elder abuse, threatened violence to self or others or other local health reporting requirements will be reported to appropriate authorities.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: name, phone number, and e-mail address, responses to questionnaires and results from any urine screenings. We will obtain this information from questionnaires you complete during your participation in this study and urine toxicology.

How will your PHI be shared?

Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the members of the local research team
- the company which created the software, Biomedical Development Corporation
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- The Food and Drug Administration (FDA)

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the University of Texas Health Science Center at San Antonio for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

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You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Jennifer Sharpe Potter, Ph.D., M.P.H., at the University of Texas Health Science Center at San Antonio, Department of Psychiatry, 7703 Floyd Curl Drive, MS 7792, San Antonio, TX 78229-3900. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?

By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:

The Principal Investigator, Jennifer Sharpe Potter, Ph.D., M.P.H., can be reached at 210-562-5698. If you are calling afterhours (evenings, weekends), or if you wish to report a medical problem which may be related to this study, please call 210-617-3035.

If primary is not available, contact

Research Staff at 210-450-3760.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UT Health San Antonio, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Please initial below whether you would like Be Well Texas to contact you about future research opportunities.

____ Yes, please contact me about future research opportunities.

____ No, please do not contact me about future research opportunities.

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Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

_____	_____	_____	_____
Printed Name of Subject	Signature of Subject	Date	Time ^{AM} / _{PM}
_____	_____	_____	_____
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time ^{AM} / _{PM}

☐ Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____.

The specific means by which the subject communicated agreement to participate was: _____