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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Yale School of Medicine

Study Title: A Pilot Study of Telehealth Treatment of Opioid Use Disorders
Principal Investigator: Rebekah Heckmann, MD, MPH, MPA
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24-Hour Phone Number: (203) 785-4363

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to assess the use of a telehealth platform, RecoveryPad, in connecting adults with opioid use disorder to treatment.
- Study procedures will include accessing a telehealth platform on a secure web browser, participating in an electronic chat about your opioid use and interest in treatment, and may receive referrals to treatment based on your preferences. You will also be asked to complete a brief electronic survey at baseline, one month, and three months. We will collect information about your interest and attendance at treatment providers and ask for feedback about your experience.
- The study will last for three months. During the study, you will have unlimited access to the telehealth platform and be able to chat with a recovery coach as much as you want.
- You will receive up to $100 in gift cards for participating in the study. Payments include $25 after the initial chat, $25 after the one-month survey, and $50 after the three-month survey.
- There are some risks from participating in this study, including potential stress from talking about your opioid use and treatment. There is also a possibility that confidential information about you could be disclosed to someone outside of the study, but we will do everything possible to minimize these potential risks.
- The study may have no benefits to you. However, information from this study could help other individuals with opioid use disorder in the future. It is also possible that the discussions and referrals you receive during this study could improve your motivation to reduce opioid use or seek treatment.
- There are other choices available to you outside of this research. You can seek treatment outside of this study or decline discussions about treatment altogether.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because you have been identified as an individual who meets criteria for opioid use disorder. We are looking for up to 40 participants to be part of this research study.

Who is paying for the study?

This study is funded by a federal grant from the National Institute on Drug Abuse (NIDA) at the National Institutes for Health (NIH).

APPROVED BY THE YALE UNIVERSITY IRB 11/25/2024

What is the study about?
The purpose of this study is to explore whether a new telehealth platform, RecoveryPad, and the RecoveryPad chatbot (that has not been FDA-approved) could help reduce opioid use and improve treatment adherence in adults with opioid use disorder.

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen:

- After consenting, you will be asked to create an account with the telehealth platform. You will be prompted to complete a brief survey and initial chat through a secure web browser. During the chat which will occur with a chatbot, you will be asked about treatment preferences for opioid use disorder. You can also receive text-based help from a person, if you choose, by clicking a button in the web app. Based on your preferences, you will receive a referral for treatments, such as methadone, naltrexone or Suboxone, which could include either brick-and-mortar treatment or telehealth medication treatment on our platform/web app, if you would like. Once the chat is completed, you will receive a $25 gift card.
- You will have continued access to the telehealth platform during the three-month study period. During this time, you can chat anytime with our recovery coach and access support and information.
- At one month and three months after enrollment, you will be asked to complete a brief online assessment about your engagement and satisfaction with our platform and treatment. You will receive a $25 gift card after completion of the one-month assessment, and a $50 gift card after completion of the three-month assessment.
- Once you complete the three-month assessment, your participation in the study is complete. After the study, you will not have access to the telehealth platform but can continue with the same treatment and providers you connect with while using the platform.

What are my responsibilities as a participant in this research?
If you agree to take part in this study, this is what will happen:

- Immediately after consenting, you will be emailed a link to our web application (i.e., an app on a website that is NOT downloaded from the Apple App Store or Google Play) called, *RecoveryPad*. We would like you to:
    - Register for the RecoveryPad service
    - Engage in a “conversation” with the automated program
    - Decide whether or not you are interested in treatment referrals and follow up with them accordingly (go to an appointment in person or via telehealth)
    - Complete the assessments on the *RecoveryPad* web app and on our assessment website at the end of your first chat, 30 days later and 90 days later.
    - Text with a Recovery Coach on the web app
    - See your prescriber as recommended.
    - Let the research coordinator, recovery coach or prescriber know about any problems, questions or concerns.

What are the risks and discomforts of participating?
There are some risks from participating in this study, including potentially stress from talking about your opioid use and treatment. If you happen to disclose any suicidal or homicidal ideation, you will be strongly encouraged to seek help by calling the National Suicide Prevention Hotline at 988 and/or calling 911 and going to your nearest emergency department. If a member of the study team is concerned that you pose a risk to yourself, that individual may call 911 and direct emergency personnel to your last known location. There is also a possibility that confidential information about you could be disclosed to someone outside of the study, but we will do everything possible to minimize these potential risks, as outlined below. There may also be risks that are currently unforeseeable.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
The study may have no benefits to you. However, it is possible that the discussions and referrals you receive during this study could improve your motivation to reduce opioid use and/or improve adherence to treatment.

How can the study possibly benefit other people?
The benefits to science and other people may include a better understanding of motivation and engagement in treatment for opioid use disorder. The information from this study could also improve the way we deliver referrals to treatment for opioid use disorder.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include your time and the use of your smartphone, computer or tablet (standard texting rates may apply). You or your health insurance must pay for health services, including treatment for opioid use disorder. You will be responsible for any co-payments required by your insurance. You may also be provided a cell phone to facilitate your participation. If you are provided with a cell phone/device to use during the study, you will NOT be responsible for the cost if lost or damaged; however, the team may not be able to provide a replacement for a lost or damaged cell phone. The cell phone that may be provided to you as part of this study does not need to be returned at the end of the study. Finally, the study team staff can assist you with setting up an email address if needed.

Will I be paid for participation?
You will be paid for taking part in this study. You will receive up to $100 for participating in the study, including a $25 gift card after the initial enrollment, a $25 gift card after completion of the one-month assessment, and $50 after completion of the three-month assessment. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?
Instead of participating in this study, you have some other choices. You could:

- Get information about treatment for opioid use disorder without being in a study.
- Take part in another study.
- Decline any discussions about treatment for opioid use disorder.

Investigator Interest

Dr. Pantalon, an investigator for this study, and his spouse are officers, managers, and co-owners of, and receive salary from, the Center for Progressive Recovery (CPR), a behavioral health coaching company, which makes the RecoveryPad web app that is being tested, and that you will use, in this study. You may speak with Dr. Pantalon at any time should you have questions regarding institutional or investigator interests.

How will you keep my data safe and private?
We will keep information we collect about you confidential. We will share it with others if you agree to it or when U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person. The Food and Drug Administration (FDA) may inspect the research records. We will do everything we can to ensure that the information collected about you is kept private, including coding data with a unique identifier, storing all research materials in a locked cabinet, and storing all electronic data in password-protected programs and computers.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we will ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission. After completion of the study, all identifiers will be removed from the identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents 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 National Institute on Drug Abuse 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.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding opioid use and treatment for opioid use disorder.

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The manufacturer of RecoveryPad, The Center for Progressive Recovery, LLC

- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study
- The U.S.A. Food and Drug Administration (FDA). This is done so that the FDA can review information about the RecoveryPad chatbot, the device involved in this research.

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Rebekah Heckmann, M.D. at Yale School of Medicine, Department of Emergency Medicine, 464 Congress Avenue, Suite 260, New Haven, CT 06519 and rebekah.heckmann@yale.edu.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.
Yale School of Medicine does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

What will happen with my data if I stop participating?
If you withdraw from the study, you will no longer have access to the texting program (if applicable) and no additional information will be collected about you. However, all data collected up until you withdraw will be retained by the study team.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Rebekah Heckmann, MD, MPH, MPA at (203) 785-4363.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Future Research
The research team may wish to contact you in the future to invite you to participate in other relevant studies. Therefore, we ask your permission to contact you in the future. Giving your permission for the research team to contact you does not obligate you to answer any future questions, or to participate in any future research – you always have the right to decline further participation in research. Please indicate your preference about future contact by checking one of the spaces below:

____ Yes, I give the research team permission to contact me in the future.

____ No, I do not give the research team permission to contact me in the future.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study. You will receive a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date