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CONSENT FOR RESEARCH PARTICIPATION

Understanding Alcohol-Opioid Co-Use Among Young Adults: Examining Usability of a
Mobile Health Smartphone App
Protocol Number: 2023003557
Version 3, 31DEC2025

Investigator: Dr. Robert Miranda Jr. - (401)863-6658 - robert_miranda_jr@brown.edu

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary. This form describes the study, and a member of the study team will explain it to you and answer any questions.

- **PURPOSE:** This study will examine a smartphone app that provides strategies to help people think about and potentially reduce their use of alcohol and opioids together.
- **PROCEDURES:** During study visits, you will be asked personal questions (e.g., questions about alcohol & drug use, mental health, etc.). You will also use a mobile health (mHealth) intervention on a smartphone app in your daily life.
- **TIME INVOLVED:** The study takes about 4 weeks to complete. In total, participation will take 5 hours of your time.
- **COMPENSATION:** If you complete the study, you will receive up to \$320 for your time.
- **RISKS:** Possible risks or discomforts include answering personal questions, possible loss of confidentiality, and undue pressure.
- **BENEFITS:** There are no direct benefits from participating in this study.

1 Why am I being invited to take part in a research study?

We invite you to take part in Brown University research study because you are a young adult who reports a history of using alcohol and opioids at the same time.

2 What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- If you have any questions about which entities fall under the above hospital or academic systems, please ask the study team.

3 Why is this research being done?

The purpose of this study is to examine a smartphone app that provides strategies to help people think about and potentially reduce their use of alcohol and opioids together. We hope that this app may help young adults cut back or quit using these substances together. We will enroll about 30 young adults. Everyone who participates in the study will receive the smartphone app.

4 How long will the research last and what will I need to do?

We expect that you will be in this research study for 4 weeks.

You will be asked to complete three study visits via Zoom and use an app on your smartphone for 28 days.

More detailed information about the study procedures can be found under *“What happens if I say yes, I want to be in this research?”*

5 Is there any way being in this study could be bad for me?

There are risks, discomforts, and inconveniences associated with any research study. Our study team will do our best to make sure you are comfortable during the study. The main risks for this study are minimal and unlikely.

More detailed information about the risks of this study can be found under *“Is there any way being in this study could be bad for me? (Detailed Risks)”*

6 Will being in this study help me in any way?

We do not know if you will be helped by being in this study. We may learn something that will someday help other young adults who are trying cut back or quit using alcohol and opioids together. But we cannot and do not guarantee or promise that you or anyone else will receive any benefits from this study.

7 What happens if I do not want to be in this research?

Participation in this study is entirely voluntary. You do not have to be in this study if you do not want to participate. Even if you decide to enroll in this study, you can change your mind and stop at any time by contacting the study team.

If you decide to stop your participation in this study, it is important to tell the study team so that we can pay you for any study activities you completed. Stopping participation in this study will not affect your benefits or medical care to which you are entitled or your current or future relationship with Brown University, Dr. Miranda or other researchers, or any health care service providers.

If you choose not to be in this study, we do not offer any other research study. Participation in this study does not involve treatment. If you are looking for treatment, your choices may include getting standard clinical care for alcohol, opioid, or other drug problems, either through your current treatment provider or another treatment provider, without being in this study or not getting any treatment.

8 Detailed Information:

The following is more detailed information about this study in addition to the information listed above.

8.1 Who can I talk to?

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may contact them at irb@brown.edu or (401) 863-3050 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

8.2 How many people will be studied?

We expect about 30 people will be in this research study.

8.3 What happens if I say yes, I want to be in this research?

If you decide to be in this study, here's what will happen:

- You will complete a screening visit (~ 30 minutes) to see if this study is right for you. This visit will be done by Zoom video conference. You will complete an interview and survey forms that ask personal and sensitive questions about your alcohol and other drug use, mental health, and any counseling or therapy you

receive. You may refuse to answer or skip any questions or parts of the study you don't want to complete or stop the study at any time.

- If you're eligible after the screening visit, this study takes about 5 hours and involves 3 study visits.
- Study visits will be done by phone or Zoom video conference. You may be asked to sign in or download an app to use Brown University's Zoom platform, depending on your device, and you will need internet connection. You will be asked to provide your current location (i.e., street address) at the start of all remote visits in case you report you've been thinking about harming yourself or someone else (see Section 8.6). This information will be destroyed immediately after the visit.
- In the first 4 weeks, you will be asked to:
 - Complete a study-start visit (~1 hour) that involves answering questions about your alcohol and other drug use, mental and physical health, relationships, and any counseling or therapy or other treatment you receive. You will also learn how to answer questions using the study app on your smartphone.
 - Complete a mid-study visit at Week 2 (~30 minutes). You will answer questions about your initial views and thoughts about the app.
 - Complete an intervention in your daily life as you see fit. Throughout the day you will answer questions on the app about how you are currently feeling and whether you are using alcohol or opioids. Based on your answers, the app may suggest options for strategies that you can try. These strategies might be related to changing your substance use, ways to improve your mood, ways to talk to other people, or similar. You will also be able to go into the app at any time to review these strategies. Please note that no one on the study team is monitoring your answers to these smartphone questions at any particular time. And so, other than during visits done remotely using Zoom, no member of the study team will know about your location, activities, mood, etc. in real time during the study.
- After answering questions on your smartphone for 28 days, you will receive a Qualtrics link to complete an end-of-study survey (~30 minutes). This survey involves answering questions about your alcohol and other drug use, and your views of the smartphone app. You will also answer interview questions about your experiences using the smartphone app in your daily life over the past 4 weeks. You can skip questions you do not want to answer. Skipping questions will not change your participation in the study or any payments you receive. Interviews will be audio recorded and transcribed or turned into a written document. Any references to names and places will be removed from the written document so that your answers cannot be associated with you. Audio recordings will be stored securely on password-protected Brown servers and destroyed after

they are transcribed or the study ends, whichever comes first. Video will not be recorded.

- At each study visit, we will update your contact information to help us keep in touch with you during the study. We will also ask you to provide us with contact information for family and friends who may know the best way to reach you in case we have trouble contacting you. If we need to contact those individuals, the study team will not reveal any information about the study or your treatment.

Timetable of Study Assessments

	Screening Visit	Study Start Visit	Mobile Health Intervention				End of Study Visit
			Week 1	Week 2	Week 3	Week 4	
Interviews & survey forms	•	•		•			•
Smartphone app			•	•	•	•	

8.4 What happens if I say yes, but I change my mind later?

If you decide not to take part in this study, there will be no penalty to you. Refusing or stopping participation in this study will not affect the benefits or medical care to which you are entitled or your current or future relationship with Brown University, Dr. Miranda or other researchers, or any health care service providers.

The study team may stop you from taking part in this research study at any time if they believe it is in your best interest (e.g., continuing participation could be harmful to you), if you do not follow the study procedures or the instructions of the study team, or if the study is cancelled.

8.5 Is there any way being in this study could be bad for me? (Detailed Risks)

There are risks, discomforts, and inconveniences associated with any research study. Our study team will do our best to make sure you are comfortable during the study. The main risks for this study are minimal, unlikely, and include:

- You might feel uncomfortable, embarrassed, or bored by some of the questions. You may refuse to answer or skip any questions or parts of the study you don't want to complete or stop your participation at any time. You may also request to schedule a time speak with Dr. Miranda, a board-certified licensed clinical psychologist, if you experience emotional distress regarding study assessments or procedures.

- You will be asked to answer personal and sensitive questions, such as questions about your alcohol and other drug use, mental and physical health, and any counseling or therapy you receive. There is a risk of loss of privacy or confidentiality of this information. We take this risk very seriously, and we will take steps to protect your personal information. To protect your privacy during study visits, we will make sure no one can overhear the conversation. We ask you to use headphones if possible and have others leave the room for visits, which will be conducted remotely by phone or video conference. Additionally, you will be able to choose a day and time for remote visits to help ensure privacy.

Your name will never be recorded on any study assessments or data. All information that could identify you, such as your name, email address, phone number, etc., will be kept in a separate file from your research data. A study number unique to you will be used to identify all study assessments and research data. The link between your identity and the study number is confidential and will be kept separate from all study data. Only the principal investigator and members of the study team who have direct contact with you will have access to your identity. Research data is kept in file cabinets located in our locked offices at Brown University. These file cabinets are locked except when in use. Computer data files will be kept on secure servers at Brown University and saved with password protection. For more information about how we will protect your information, see Section 8.6.

When we are finished doing this study, we will write reports about what we learned. These reports will not list your name. Your identifiable private information will be stripped of identifiers and may be used for future research.

There is a possibility that someone outside the study will see the private text messages sent by the study team to you reminding you to: (a) attend upcoming study visits and (b) answer questions on the study smartphone app. All text messages from the study team will be limited to simple general reminders; no message will include or request any personal or sensitive information. We encourage you to use a strong password or passcode on your smartphone to help reduce any privacy-related issues concerning study messages on your phone.

There is a possibility that others may see you answer questions on the study smartphone app when you are in public places or with others. We encourage you to answer smartphone questions in private. We also urge you not to read or respond to study text messages or answer smartphone questions while you are driving or in other situations where it is unsafe. You should wait until you are in a safe and private place before doing study-related activities on your phone.

As with any research study, there may be risks that are not yet known or expected. We will let you know if we learn of anything new about our study that

might change your mind about participating. Please tell us about any concerns that come up while you're in this study.

- Sometimes people can feel pressured to participate in a research study. This pressure can happen if they are offered a lot of money or a reward for their participation. Such pressure is unlikely in this study because the payment is fair for the time and effort required, and it is like similar studies. There will be no other rewards or payments. You will be paid using gift certificates or ClinCard as you complete each part of the study, as described in the payment schedule (see Section 9). You will not receive cash or a large sum at the end of the study. Additionally, even if you stop participating for any reason, we will pay you for any parts of the study you complete.

8.6 What happens to the information collected for the research?

Any information we collect as part of this study that identifies you will remain confidential. Only a study number will be used to identify your private information; your name will not be matched with your private information. We will keep all information about you locked up and password protected. It will be disclosed only with your permission or as required by law.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If you give us your consent by signing this document, information that does not identify you by name may be used for scientific purposes, including teaching or publication.

How will my information be stored?

We maintain all research data and records in a locked secure location at Brown University. Research data is kept in file cabinets located in our locked offices at Brown University. These file cabinets are locked except when in use. Computer data files will be kept on secure servers at Brown University and saved with password protection. Only authorized individuals will have access to it.

Which people and agencies will have access to my information?

Your research record will be kept confidential, and only authorized people and agencies will have access to your information. Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

In addition, the following people or agencies might have access to your information:

- The principal investigator and his study team, which includes people who are part of the Lifespan health system
- The study sponsor (i.e., National Institutes of Health)
- The Institutional Review Board(s) that approves and monitors this research study
- Doctors, nurses, and other mental health professionals on the study team
- The Department of Health and Human Services

There may be other times when we need to release your information. If at any time during this research study you tell us you've been thinking about harming yourself or someone else, we will ask a doctor or other mental health professional on the study team to speak with you right away. If necessary, you may be referred to a local hospital or mental health service for further evaluation and treatment. Other times when we may need to share your private information are if you tell us about child abuse or neglect or elder abuse, neglect, or exploitation.

8.7 Will my data or samples be used for future research?

Identifiers will be removed from your identifiable private information, and after such removal the information could be used for future research studies by the study team without additional informed permission from you.

8.8 Can I be removed from the research without my OK?

The study team may stop you from taking part in this research study at any time if they believe it is in your best interest (e.g., continuing participation could be harmful to you), if you do not follow the study procedures or the instructions of the study team, or if the study is cancelled.

9 What else do I need to know?

Financial support for this study is provided by the National Institutes of Health.

You will receive up to \$320.00 for your participation. At each study visit and at the end-of-study online survey, you will be paid for all parts of the study you complete even if you stop the study early for any reason. You will be paid \$20 for the screening visit even if you are found to be ineligible.

The payment schedule is as follows:

Study Activity	Total Possible Compensation
Screening visit	\$20
Study-start visit	\$50
Week 2 check-in visit	\$100
Week 4/End-of-study	\$150
Total = \$320	

Payment for participating in this study will be made using gift certificates or ClinCard, a pre-paid Mastercard that works like a debit card. If you choose ClinCard, you will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that use ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule (see above). You can use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from the study team for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn \$600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating. If your card is lost or stolen, please call the study team

for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

In this study we will be audio recording your voice as you share your thoughts and reactions, so that we can review what you said later and incorporate your feedback. We will use Zoom to record your audio only. We will keep this information confidential. We will store it for 1 year. At the end of that time, we will destroy it.

You will install the free application on your phone via the Apple Store or Google Play store. The app is supported by both Android and IOS. Your Apple ID or Android account will not be required to install the app. Research staff will be available via Zoom to assist with installation and training. No identifiable information is collected by the app including GPS, cookies, or IP addresses. The app collects your answers to the self-report questions and does not collect other data. The app is not an Apple research app and will not share data with Apple Health.

10 Signature Page

This form contains important information to help you decide if you want to join this study. If you have any questions that are not answered in this form, ask the principal investigator or another study team member.

Before you say yes or no to being in this study, we want to make sure you fully understand what this study is about and what you would be asked to do if you decide to enroll. Before signing this consent form, please answer the following six questions.

1. Can you tell me what this study is about?
2. What is something that you will be asked to do in the study?
3. Can you tell me the risk of the study?
4. Will this study help you?
5. Will the researchers ever tell someone you were in this study?
6. Do you have to be in this study?

Please answer YES or NO to the following questions:

1. Is this document in a language you understand?

Circle
Yes or No

Yes No

- | | | | |
|----|--|-----|----|
| 2. | Do you understand the information in this form? | Yes | No |
| 3. | Have you been given enough time to ask questions and talk about the study? | Yes | No |
| 4. | Have all your questions been answered to your satisfaction? | Yes | No |
| 5. | Do you think you received enough information about the study? | Yes | No |
| 6. | Do you give your consent of your own free will and without being pressured by the principal investigator or other members of the study team? | Yes | No |
| 7. | Do you know that you can leave the study at any time without giving a reason and without affecting your health care? | Yes | No |
| 8. | Do you know that your records from this study may be reviewed by the study sponsor and by government authorities? | Yes | No |

You must also be able to answer "Yes" to questions 1 to 8 listed directly above.

Please check YES or NO and write your initials to let us know whether you agree to be recontacted to learn about future studies. Your answer to this question will not influence in any way your ability to participate in this study.

____ Yes

____ No

Initials _____

Your signature below shows that you have read and understood the information in this document. The study team has answered your questions to your satisfaction, and you agree to volunteer as a research participant for this study.

You will be given a copy of this form.

Printed Name of Study Participant (*Age 18 or older*)

Signature of Study Participant (*Age 18 or older*)

Date/Time

Printed Name of Person Explaining Consent Form

Signature of Person Explaining Consent Form

Date/Time