Biobehavioral Pathways Underlying Alcohol Use and Health

ClinicalTrials.gov Identifier: NCT05135767

Sponsor:

Brown University

Collaborators:

National Institute of General Medical Sciences (NIGMS)
Rhode Island Hospital

Information provided by (Responsible Party):

Brown University

BROWN

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Biobehavioral Pathways Underlying Alcohol Use and Health
Version 6, March 22, 2022

KEY INFORMATION:
You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: The purpose of this study is to understand how biology and behavior are related before, during, and after individuals receive counseling.
- PROCEDURES: You will be asked to meet with a study counselor via video conference or phone call to have an open conversation about your alcohol use; come to our laboratory or other local clinical laboratory to provide blood, urine, and breath samples; answer questions about your mental well-being and other health-related behaviors; and answer questions about your alcohol and other substance use and emotions on a smartphone in your daily life.
- TIME INVOLVED: The study will take up to 14 hours of your time in total over a little over 3 months.
- COMPENSATION: You will receive up to $532 for your time. You will be compensated separately for an in-person laboratory screening, an initial laboratory visit, three shorter weekly visits, a 3-month follow-up laboratory visit, attending your video or phone counseling sessions, and completing your smartphone reports. You will be eligible to receive three weekly bonuses for completing your smartphone reports.
- RISKS: Although your information is kept confidential, there is some risk to your privacy. Risks of having your blood drawn include infection, pain, bleeding, and fainting. Some people report emotional discomfort from answering questions about their alcohol and other drug use and mental well-being. It is also possible that you will experience craving for alcohol after being shown your preferred alcoholic beverage. It is important that you understand you may withdraw from the study at any time without penalty, but, even so, there is some risk of feeling pressure to continue.
- BENEFITS: You will receive free counseling as part of this research, which you may or may not consider a benefit to you. You are not likely to benefit personally in other ways from this research. The outcome may increase scientific knowledge and help people in the future.

- ALTERNATIVES TO PARTICIPATION: Your alternative is to choose not to participate.

1. Researcher(s):

The primary investigator is Hayley Treloar Padovano, PhD, who can be reached by phone at [redacted] or email at [redacted]. Your usual contact person will be her research assistant, [redacted], who can be reached by phone at [redacted], by text message at a number he can provide to you, and by email at [redacted]. The study physician who may also be your clinical provider is Kittichai Promrat, MD, who can be reached by phone at [redacted].

2. What is this study about?

The purpose of this study is to understand how biology and behavior are related before, during, and after individuals receive counseling that may help to reduce craving for alcohol and improve mental and physical well-being. You are being asked to be in this study because you are an adult age 18 years or older who reported drinking alcohol in the past three months. About half of the individuals who are invited to participate will have alcohol-associated liver disease. About half of the individuals who are invited to participate will not have alcohol-associated liver disease. The in-person screening will help determine whether you meet requirements to participate. This form and research staff are here to provide you with information about what you would be asked to do if you chose to be a part of this study. If at any point during the in-person screening you decide you do not wish to continue, please let us know. If at any point after you sign this form you change your mind and do not want to continue, please let us know. Your comfort is the top priority of this research team.

3. What will I be asked to do?

After today's visit, you will be asked to come to our laboratory or local clinical laboratory five more times. This will be for an initial in-person visit, three weekly visits, and a final visit 3 months later. You will also be asked to do research activities for us outside of our laboratory. This will include answering questions on a smartphone as you go about your daily activities.

One of the goals of this study is to make our procedures better for future studies. This includes providing better estimates of how long our study visits will take to complete. To help you plan how long you will need to set aside for each visit, we estimate below how long each visit will take. Everyone is different, though, and your sessions could be a bit shorter or longer than what is listed here. If you have any questions, please let us know. We are here to answer any questions you have about your research participation at any time.

Today

Today's visit will start with a screening to make sure you meet the requirements to participate. This session will last up to 2 hours. You will provide a breath sample before signing this form and at the start of all in-person study visits to ensure that you have not had alcohol before the visit. Today, you will be interviewed by our research assistant or study nurse practitioner. A portion of your session will be audio recorded for the purpose of rating the quality of these interviews. You will be reminded that you are being audio recorded before this recording is started, and you will be told when the audio recording is ended. You will provide a urine and blood sample. We will measure your height and weight. If you still appear to meet the requirements for the study, you complete a physical exam with our study nurse practitioner or physician. We may learn things about your health that require immediate attention. If this happens, the nurse practitioner or physician will provide you with this information as soon as they become aware. We may not be able to confirm that you meet all study requirements until we receive the results of your blood test. If this is the case, we are typically able to inform you within one to two days.

At the end of screening, you will meet with the research assistant to review how to download our study application to your smartphone. If you do not have a smartphone or do not wish to use your smartphone for this study, we will provide one for you to use during the study. The research assistant will go through all of the questions you will answer on the phone. You will answer questions on the phone for about one week before starting the main part of the study. Your answers to questions on the phone will not be used to determine whether you are eligible for the study, and we will not review your answers to the questions in real time. This means that if you tell us about an experience, such as a really negative mood, we will not be looking at this response right away. Your study counselor will receive a printout of some of your responses, such as your urges to drink alcohol or how you've been feeling, to go over with you in your counseling sessions. These print-outs will be prepared by a study research assistant before your sessions.

Your Next In-Person Visit

Your next in-person visit will "start" the main part of the study. This will be your longest visit and will last up to 2 hours. This visit will include interviews, questionnaires, laboratory task assessments, and collection of breath and urine samples. The laboratory task assessments will include a procedure that requires you to answer questions about your urges to drink while you view and smell your preferred alcoholic beverage. Another task will ask you about the number of alcoholic drinks you would buy at various prices.

Counseling Sessions

You will receive free counseling with a trained counselor who has their doctoral degree in counseling or clinical psychology. There will be two main sessions, one at the end of your in-person visit to start the study, which will last up to 1 hour, and one at the end of your week-3 in-person visit, which will last up to 30 minutes. In addition, you will be asked to complete two, brief check-ins about how you've been doing. These will last up to 15 minutes and will be completed at weeks 1 and 2. As mentioned above, your counselor will receive a printout of some of your smartphone responses, as well as results of your blood and urine tests to review with you. All of your counseling sessions will be completed either in the laboratory via video conference software or over the phone. Sessions will be audio recorded for the purpose of rating the quality of service your counselor is providing.

In-Person Weekly Visits

At the end of week 1 and week 2, you will come to our laboratory for a brief check-in with our study staff that will last up to 45 minutes and 1 hour, respectively. Both visits will include collection of breath and urine samples, and the week 2 visit will include collection of a blood sample. At the end of week 3, you will come to our laboratory for a final visit that will last up to 1.5 hours. The week-3 visit will include interviews, questionnaires, the same laboratory tasks completed at the in-person visit that started the study, and collection of breath and urine samples. You will also be asked about your experience of being in the study, and your answers will be audio recorded and used to improve future studies.

Your Last Visit

Three months after your last weekly in-person visit, you will come back to our laboratory for a final in-person visit. This will last up to 1.5 hours. This visit will include interviews, questionnaires, the same laboratory task assessments completed at the in-person visit that started the study, and collection of blood, breath, and urine samples.

4. Will I be paid?

You will be compensated up to $60 for your time to complete the in-person screening today, regardless of whether you continue with the study. If you choose to continue with the study, and you meet all of the requirements to continue, you will be compensated up to $532 for your total participation. The schedule of participation and compensation follows below. In addition, you will be compensated for transportation to our laboratory and parking. If you do not appear to meet the requirements to participate in the study, you will be compensated for your time in the form of an Amazon gift card. If you meet the requirements to participate, compensation will made using ClinCard, a pre-paid Mastercard that words like a debit card. This process will be described by the research assistant and is also explained below.

BROWN

Participant compensation schedule.

Study component	Estimated time to complete	Compensation	*Note.*
Today's in-person screening	2 hours	$60	
Your next visit to start the study	2 hours	$60	
Week 1 Visit	45 min	$40	
Week 2 Visit	1 hour	$50	
Week 3 Visit	1.5 hours	$60	
Last Visit (3 months later)	1.5 hours	$70	
Smartphone report daily amounts	~ 10 total min / day	$112	*Up to $4 per day for 28 days.*
Smartphone report bonuses	Not applicable	$80	*Up to $20 per week for 4 weeks.*
		Total compensation for the study is up to $532.	

Compensation via ClinCard

You will be given the ClinCard or we will mail it to you. You will be provided 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 uses 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 compensation schedule as listed above. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet we provide to you 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 research assistant at (401)863-3328 for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

Compensation in Case of Injury

Many kinds of research involve some risk of injury. Even though the investigators are careful to prevent any harm, you might develop medical problems from being in this study. If you do

have problems, the researchers will give you information that may be of help to you in getting proper medical care, if you ask for it. Brown University does not pay for medical or other costs. Signing this form does not mean that you give up any liability rights for personal injury.

5. What are the risks?

All research includes risks. If you experience a study related injury, illness, or distress, please call the study primary researcher, Dr. Hayley Treloar Padovano, at (401) 863-6623, right away. The potential risks for you to consider as you choose whether to participate in this research include:

1. Risk of someone finding out about you participating in the study or accessing your data. We make every effort to keep your information safe and minimize risk that someone will find out about your participation in this study or access your study data. We take many precautions to protect the privacy of your information, but no system is 100% guaranteed. Please review Section 7 below for details about privacy protections and confidentiality of research data.
2. Risks associated with providing a blood sample. Risks of blood draw include infection, pain or discomfort, hematoma (collection of blood under the skin), and an adverse reaction or fainting. Serious risks are not common when best practices are used. In this study, a licensed professional will use sterile instruments, disinfecting agents, and non-latex materials for all blood draws.
3. Discomfort from answering questions about sensitive information. This study asks questions about sensitive subjects, including your alcohol or other drug use, medical problems, and mental health and well-being. These are asked in interviews, questionnaires, and on smartphone reports completed in your daily life.
4. Elevated urges to drink in response to laboratory tasks. You will be asked to view and smell your preferred alcoholic beverage in our laboratory as you answer questions about your urge to drink alcohol. Your heart rate and blood pressure will also be continuously monitored during this task. It is possible that you may continue to have a desire to drink alcohol after this task is completed. If your urge to drink alcohol is greater than it was when you arrived at our laboratory for your session, we have trained study personnel who can meet with you to discuss your urges to drink.
5. Risk of feeling pressure to continue with the research. All research is voluntary. Even if you agree to participate today, you may stop participating in the study at any time. This is your right. Please feel comfortable asking us why we need to collect any information. Please feel comfortable telling us if you do not want to participate in this study.

6. What are the benefits?

You may not directly benefit from being in this research study. You may receive free counseling, which you may or may not consider a benefit to you, but you are not likely to benefit personally in other ways from this research. The outcome may increase scientific knowledge and help people in the future.

7. How will my information be protected?

Your study data will be coded, meaning that we collect personally identifiable information, but this is linked to your data by a screening or participant identification number. The code linking your data to your personally identifiable information is stored separately from your data and destroyed upon completion of this research study.

Privacy Protections. The consent process and all study procedures involving collection of sensitive information are conducted in private locations. All meetings with your study counselor will be completed over the phone or via HIPAA-compliant video conference software approved for use by Brown University. In the event that Brown University restricts access to our research laboratory for health-related reasons, we may request to conduct interviews that are typically completed in person over the phone or via HIPAA-compliant video conference software approved for use by Brown University. Our study personnel are highly trained in privacy protections on a regular basis using structured trainings required by the Brown University Institutional Review Board (IRB). When using video conference software or conducting an interview by phone, our study personnel will be in a private location to minimize any possibility that your responses would be overheard by others. You should take care to protect your privacy in this same way by making sure you are in a private location when responding to any study questions. For instances when you are in public and answering study questions by tapping on the screen of your phone, please take care to ensure the privacy of your information by making sure your phone screen is not visible to others.

Confidentiality of Research Data. All paper and electronic files are accessible only to personnel associated with this study. All of your personally identifying information, such as your name, phone number, and email address, will be stored separately from your responses to interviews, questionnaires, smartphone questions, audio recordings, and all other study data. Any blood or urine samples you provide to us will be marked with a screening or participant identification number, rather than your name or other personally identifying information. The link between your personally identifying information and your screening or participant identification numbers is kept only until completion of the study in a password-protected electronic file that is stored on secure server and only accessed by trained personnel associated with this study. The file is destroyed by the primary researcher when the study is completed.

For this study, portions of the in-person screening visit, counseling sessions and an exit interview will be audio recorded. Counseling sessions will be audio recorded via Zoom

videoconferencing software, with only the audio file recorded; we will not record any videos of you at any time. The exit interview and portions of today's visit will be audio recorded with a handheld audio recording device. All audio recordings will be uploaded to our secure server using only a participant identification number immediately following your session. Original audio recordings will be deleted from Zoom and the audio recording device immediately after they are uploaded to our secure severe. All aspects of research are voluntary. You may request that we do not audio record you at any time.

For this study, you will answer questions in your daily life using a smartphone application that has been reviewed by the Brown University IRB and Computing and Information Services (CIS). You will create your own password to access study questions through the smartphone application. When you submit a response using the smartphone application or sensor data is passively logged and the smartphone is connected to the internet, encrypted data are immediately sent to secure servers and removed from your smartphone at that time. If internet is not available, the data are temporarily stored on your smartphone in an encrypted format until an internet connection is detected and the encrypted data can be securely transmitted. The smartphone application will assign a unique identification code to you and use this code to make sure your smartphone responses are not directly associated with your personally identifiable information (e.g., name, email, phone number). Your data are stored with the unique code and data are encrypted and stored separately from any personally identifiable information. The companies that host our smartphone application and sensor equipment and software are reviewed by Brown CIS to ensure they have administrative, physical, and technical safeguards to protect your data.

<u>Your information is kept confidential, meaning that it is not shared with anyone outside of the study except under the circumstances as follows</u>:

- 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.
- The funding agencies which sponsor this study may review records for quality assurance purposes.
- If you report imminent risk of harming yourself or others, or abuse or neglect of a child or elderly person, these events will be reported to the appropriate authorities to keep you and others safe.
- For your blood samples to be processed, the laboratory order may include your first name, sex at birth, and year of birth. We will share this information with the local laboratory, when applicable. The laboratory is required by law to maintain the privacy of information that identifies you.

Upon completion of this study, your data will be anonymized, meaning that all links between your personally identifiable information and your data will be permanently destroyed, making the data de-identified. In other words, there is no way for someone to know that the data came from you. Anonymized data will be kept and used for future research on chronic disease and substance use. This includes your biospecimens. We may share your de-identified data and biospecimens with researchers at Brown or other institutions. It is unlikely but possible that biospecimens may be used to generate discoveries or other applications for commercial profit. You will not share in any profit arising from such uses.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal administrative, legislative, or other proceedings; for example, if there is a court subpoena. 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 federal government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse or neglect, or harm to self or others.

A description of this clinical trial will be available on http://www.Clinical Trials.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 results. You can search this website at any time.

8. Are there any alternatives to this study?

The alternative is to not participate. The research team has no alternatives to offer at this time. If you are seeking treatment for a mental health problem or alcohol or other substance use disorder, this study may not be able to provide the type of assistance you need. We will offer a list of resources for mental health and well-being and list of substance-use treatment services everyone who reviews this form with us. If you do not meet the requirements of this study or decide it is not a good fit for you, we will give you these lists today. If you decide to participate, you will be given the lists upon completion of the study. You may also request at any time to speak with the primary researcher, Dr. Hayley Treloar Padovano, who is a licensed clinical psychologist in the state of Rhode Island, to review these lists with you and help you

find the type of assistance you need. If you speak only Spanish, a member of Dr. Treloar Padovano's team who is fluent in Spanish will meet with you together with Dr. Treloar Padovano, or another team member who is fluent in Spanish and has a counseling or clinical doctoral degree may meet with you.

9. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with Brown University, Lifespan, the Providence VAMC, or any member of our investigative team including Dr. [redacted], who may be your health provider in other settings, will not be affected.

10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call the primary researcher, Dr. Treloar Padovano at [redacted] or email [redacted], or the research assistant, Gabriel Muro, at [redacted], or email [redacted].

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

BROWN

Participant's Signature and Date	/	PRINTED NAME
Research Staff Signature and Date	/	PRINTED NAME