UNIVERSITY OF NOTRE DAME INFORMED CONSENT STATEMENT FOR RESEARCH

Better Experiences in Substance Treatment: A Brief Alcohol-focused Intervention Tailored for Patients in Opioid Agonist Treatment

Principal Investigator: Ryan W. Carpenter, PhD
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Project BEST (Better Experiences in Substance Treatment): Developing a modified brief alcohol-focused intervention tailored for patients with alcohol use disorder in opioid agonist treatment

Ryan W. Carpenter, Ph.D.

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer questions and learn new information. Some research might help change or improve the way we do things in the future. This consent form will give you information about the study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Notre Dame. Your decision to participate or not or leave the study will not have any impact on your relationship with your treatment providers and will never be shared with any of your treatment providers.

As an alternative to participating in the study, you may choose not to take part.

WHY IS THIS STUDY BEING DONE?

The goal of this study is to learn about the effects of a brief psychosocial therapy for alcohol use that was designed for people who are drinking alcohol while receiving buprenorphine for opioid use disorder.

You were selected as a possible participant because you completed an initial screening and reported that you are currently prescribed buprenorphine and that you currently drink alcohol.

The study is being directed by Dr. Ryan Carpenter, a faculty member of the Psychology Dept. at the University of Notre Dame. It is funded by the National Institute of Alcohol Abuse and Alcoholism (NIAAA), part of the National Institutes of Health (NIH).

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of about 90 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will be asked to do the following. You will first complete an initial interview session. During this session, you will be asked to complete a few questionnaires on a computer or tablet and then complete a one-on-one interview about your mental health with a research staff member. The interview will take place in a private room in our research space at the University of Notre Dame. You will answer questions about your personal experiences, your past use of different substances, and different difficulties or problems you may have had in your past. You have the right not to answer any question you do not wish to answer. The entire research session will last about 60-90 minutes. Interviews will be audio recorded to ensure accuracy of the assessment. Only trained research staff will have access to these recordings and they will be destroyed after they are reviewed. Video will not be recorded.

We will use the initial interview session to determine whether you are eligible for the remainder of the study. If you are eligible, you will either be selected to complete the brief psychosocial therapy or not. We will use a process that guarantees each participant has a 50/50 chance of being selected to complete the therapy or not.

If you are selected for the therapy, over the next four weeks, you will complete four one-on-one therapy sessions, one session per week, with a trained member of our research staff. Each session will last between 30 and 90 minutes and will take place in our research space. The sessions will cover topics that include better

understanding your goals and values, your alcohol use, your thoughts about cutting down your use, how your alcohol use compares to others, and possible harms and benefits of alcohol use. After the last session, you will complete a feedback interview with a member of our research staff, where you will be able to provide your thoughts and feelings about the therapy and how you think it could be improved.

All sessions and the feedback interview will be audio recorded. Recordings will be anonymized (references to names and places removed) and transcribed (turned into a written document) so that they cannot be associated with you.

If you are not selected to complete the therapy, you will not need to do anything for the next four weeks.

All participants, regardless of whether you completed the therapy or not, will complete three follow-up sessions. The first follow-up will take place one month from today, the second two months from today, and the third four months from today.These sessions can be completed either in-person or remotely over Zoom or phone, depending on your preference. You will complete a few questionnaires on a computer or tablet. If you want to complete these sessions remotely, you will need your own computer or tablet and internet access to complete the questionnaires. Follow-ups will take between 30 and 45 minutes.

If you are not selected to complete the therapy, you will have the opportunity to complete an informational session about your alcohol use that will take between 30 and 60 minutes. This session is optional and would take place after the four-month follow-up session. This session can occur in-person or remotely over Zoom.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

While participating in the study, the potential risks include:
Possible distress from some of the questions. Some of the questions you will be asked are personal and this may be uncomfortable or stressful for some people. You may skip any questions that you do not wish to answer and you are free to withdraw from the study at any time.

There is also a risk of breach of confidentiality where your information is accidentally given to or taken by someone who should not have it. All data, including your responses and the audio recording of your interview, will be stored on a secure server at the University of Notre Dame. To detect patterns in responses across everyone who participates in this study, recordings of the therapy sessions and feedback interviews will be transcribed and trained research staff will code your responses. Your responses, the transcriptions, and coded data will all be stored separately from the identifying information you provide. To protect your confidentiality, we have a Certificate of Confidentiality.

Certificate of Confidentiality:
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. Identifiable information that could still be disclosed beyond the research team: 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.

There may be certain 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 mental health professional on the study team to speak with you right away. If necessary, you may be referred to your treatment provider, 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. In the case that you experience a medical emergency during a session visit, including a possible overdose, we will contact emergency services via 911.

There are no known risks of this study to unborn children.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

If you complete the psychosocial therapy or if you complete the optional informational session following the study, you may find that participation leads you to make a change in regard to your alcohol use or how you engage in your treatment for opioid use disorder that you find beneficial. Otherwise, we don't expect you to receive any benefit from taking part in this study, but we hope to learn things that will help scientists in the future.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. We will do everything we can to protect your privacy. We will not share whether you participated in this study or any other information with any treatment provider. This includes, if applicable, any treatment provider who told you about this study. 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. No information which could identify you will be shared in publications about this study.

Only Dr. Carpenter and trained research staff will have access to recordings. Audio recordings of therapy sessions and feedback interviews will be anonymized and transcribed. Transcripts will be used for research purposes rather than audio recordings. Audio recordings will be destroyed at the end of data collection and transcripts will be stored securely on password-protected Notre Dame servers until they can be destroyed (7 years after the study).

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the University of Notre Dame Institutional Review Board or its designees, the National Institute on Alcohol Abuse and Alcoholism, and (as allowed by law) state or federal agencies, especially the Office for Human Research Protections (OHRP), who may need to access the research records.

We are recording audio as a part of the study. Please let us know whether you agree to us recording you:

_____ Yes, I agree to having my audio used in the study.

_____ No, I do not agree to having my audio used in the study.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. As identifying information will be removed, we will not ask for your additional consent.

NATIONAL INSTITUTE OF MENTAL HEALTH DATA ARCHIVE (NDA)

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. We will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. We will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

Please let us know whether you agree to us sharing your data with the National Institute of Mental Health Data Archive (NDA):

_____ Yes, I agree to having data shared with the NDA.
_____ No, I do not agree to having data shared with the NDA.

WILL I BE PAID FOR PARTICIPATION?

You will receive payments in the form of a Visa prepaid gift card. You will receive $50 for completing the baseline appointment,$50 for the 1- $60 for the 2- and $90 for the 4-month follow-up sessions.

WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?

No individuals involved in this study will benefit financially from this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Ryan Carpenter at 574-631-6650 or ryancarpenter@nd.edu.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, please contact Notre Dame Research Compliance at 574-631-1461 or at compliance@nd.edu.

WILL I BE CONTACTED ABOUT RESEARCH IN THE FUTURE?

If you agree, we may contact you after your participation is over to request additional information or to invite you to participate in another study. Please initial one of the following options:

_____ Yes, I agree to be contacted for the purpose of collecting additional information or to participate in another study.

_____ No, I do not agree to be contacted for the purpose of collecting additional information or to participate in another study

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____**Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____