BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

The development of a personalized, real-time intervention for alcohol-using emerging adults leaving psychiatric partial hospitalization

Sponsorship

This study is being paid for by the Advance-CTR program at Brown University.

Research Project Summary

You are invited to participate in a study designed to help emerging adults (individuals between the ages of 18-25 years) who are depressed and anxious learn to cope without drinking alcohol. You have been invited to participate because you are currently receiving treatment at Butler Hospital's Young Adult Partial Program (YAPH). Your participation in the study will involve 2 visits in our research offices at Butler Hospital. It will require approximately 1.5 hours total to complete each of these visits.

This study will begin with questionnaires about your mental health and substance use. If you decide to participate, you will complete questionnaires and then participate in an initial orientation session during your time in the YAPH (after daily scheduled activities) where a staff member of the research study will go over all the different parts of the program and give you feedback about your substance use. During the next 6 weeks, after you leave the YAPH program, you will be asked to respond to prompts on a secure app on your phone. These prompts will ask you about your mood, substance use, and any coping strategies you have used. You will spend about 5-10 minutes per day responding to prompts. You will be asked to return after 6 weeks to complete additional questionnaires and an in-person interview. The study will last 6 weeks.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, risks associated with the procedures, possible benefits of participation, and possible alternatives. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form. This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

Description of Procedures

If you decide to participate, you will complete several interviews as well as the 6-week app program. Each part of the study that you will participate in is described below:

Baseline Assessment

If you decide to participate, you will first sit down for an interview with one of our research staff to confirm that you are eligible for the study. In this interview, you will be asked questions about your mood and other psychological symptoms, and alcohol and drug use. This confidential interview will take approximately 1.5 hours and will be audiorecorded (voice taped). These recordings will be reviewed by the researchers for training/supervision purposes. You will also be asked to complete questionnaires, on a laptop computer or tablet device, about your attitudes, mood, alcohol use, and thoughts and feelings relevant to your alcohol use. It is possible that, based on the interview that you will not be found eligible to participate in the rest of this study.

App-Based Mood and Substance Use Assessment

After your baseline assessment, but before you are discharged from the YAPH, a study clinician will meet with you for about an hour to go over the program. You will discuss the structure of the study, and review the information that you provided in the baseline assessment. You will be provided personalized feedback

about your responses, based on your reported alcohol use and the coping strategies that you identified as being helpful to you. You will receive the smartphone app and learn how to respond to prompts. During the 6-week program (after discharge from the YAPH), the app will notify you at different times during the day to ask you brief questions about your mood, substance use, and coping strategies as well as provide encouragement to engage in healthy coping. You will also have the ability to answer these questions when you desire to have suggestions for coping: when you're feeling down or feel like drinking. Study staff will monitor use of the app and may contact you through the app system if you have not opened the app in several days to remind you to use the app. However, you will not be able to communicate with research staff through the app. If you have not used the app in several days and we are unable to communicate with you through the app, and if you have given permission to do so, study staff may also contact you by text message to remind you to fill out your daily responses.

Assessments

After the study has completed (week 6), you will be asked to come in to our research facility to complete in-person assessments. The assessment protocol will be similar to the assessment you did just before starting the program and will include questions about your mental health, and alcohol and drug use, as well as your impressions of the program. At this last study visit, the researcher will also remove the app from your phone.

Risks and Inconveniences

There are minimal risks associated with participating in this study. You may experience discomfort from some of the interview questions or discussion points during the study visits. You may refuse to answer any questions that make you feel uncomfortable and you can stop participating in the discussion at any time. All information obtained will be kept confidential. Your responses to the questions will not be linked to any information that can identify you as an individual. Your information will be available only to our research staff. In addition, the app will be password protected so that only you can have access to the information. Data from the app are stored on your mobile phones, encoded, and cannot be intercepted as long as you keep your phone in your possession and use a password to unlock the phone and the app. Data is stored on a secure cloud-based server that will only be accessible to the relevant research team members. Data will be downloaded and backed-up on the Butler Hospital secure network weekly. Your name will never be associated with publications from this project. We will make every effort to lessen any discomfort you may feel during this process.

Finally, you will be asked about your preferences for research staff contacting you. This may include telephone, mail, or text message. You will tell us all the ways you would like the study to contact you and sign the contact form so we have it for our records. When research staff contacts you at for appointment reminders, they will be as discrete as possible. If they contact you by phone they will not discuss the reason for the phone call with anyone other than you. You should be aware that there are risks associated with text messaging. There is always a risk that the message could be intercepted or sent to the wrong phone number. Only the research team will have access to your text messaging communications. Study staff will not send messages that contain urgent information or results of medical tests or diagnostic procedures. We will not send text messages that direct you to get medical care. If you share a cell phone with other family members and do not want them to know you are participating in this study, make sure you provide a phone number that only you can access and that you create a passcode for your phone. Your employer will have access to any text messaging communications sent or received on a work cell phone. However, it is remotely possible, although unlikely, that a court of law could require us to provide them with your information from the study. Your name will never be associated with publications from this project.

Text messages (communication outside of the app) to researchers should be constrained to scheduling appointments with researchers: text messages should not be used to report clinical concerns. Text messages may not be received by researchers on a regular basis. It is possible that a message you send

will go unnoticed, or will not be read by the research team for days or weeks. You should use the telephone to contact the research team for any urgent matters. Clinical issues that are not urgent matters should be directed to the research staff by telephone (401-455-6219) or in person. **If you experience a crisis or feel suicidal, you should contact your psychiatric clinician in the community or contact Butler Hospital, or go to a local emergency room.**

Benefits

We cannot and do not guarantee or promise that you will receive any benefits from this study. The knowledge gained in the study may aid in your mental health or substance use recovery process and may provide future benefits to individuals who have problems by furthering our understanding of the role of mood in substance use.

Economic Considerations

You will receive $20 gift cards at each assessment point. Additionally, you will be compensated with gift cards, which will be delivered to you by mail, for completion of app prompts at $0.50 per response at the conclusion of the study, for a maximum of $84 app compensation. Thus, you may receive a maximum of $124 for full participation.

Depending on the amount of payment you might receive for your participation in this study, you might have to provide your name, address, and taxpayer ID or Social Security number to the Butler/CNE Research Accounting Department. In order to receive payment of $300 or more for participation in this research, you will have to complete and sign a W-9 form. If you are paid $600 or more in any calendar year for research participation, the IRS will be notified of the total amount you were paid, in accordance with federal regulations. You should ask the researcher for more information if you have questions about this process.

Alternative Treatments/Alternative to Participation

We cannot guarantee that your participation in this study will produce treatment benefits related to your efforts to address alcohol use. Alternative treatments exist to assist you in these continued efforts and are available at other treatment centers and private clinics. These alternatives may include outpatient therapy or attending 12-step meetings.

Financial Disclosure

Not applicable.

Voluntary Participation

You are free to decide whether or not to participate in this study, and you are free to withdraw from the study at any time. A decision not to participate or to withdraw from the study will not adversely affect your current or future interactions with Butler Hospital or Care New England. Your participation in the study may be terminated by the researchers without regard to your consent; in that case, you are entitled to an explanation of the circumstances leading to that decision.

Confidentiality

Every effort will be made to keep your identifying information confidential. Personal identifiers will be removed from any identifiable private information about you in the final research dataset created by this study. The de-identified information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or the legally authorized representative). Your consent form and all other identifying information will be stored in a locked filing cabinet separate from questionnaire responses and any other written or computer stored data. You will not be personally identified in any reports or publications that may result from this study. Digital recordings of interviews will be downloaded to secure, password-protected computer servers that only research staff will have access to. These audiofiles will not have any personal identifying

information. Upon completion of the study, these recordings will be deleted. The confidentiality of the information you provide to us will be maintained in accordance with state and federal law. However, you should know that brief notes from your study assessments and phone counseling sessions will also be placed in your Butler Hospital medical record. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies. For example, if you are experiencing thoughts of suicide during an assessment, we will direct you to your counselor in the Young Adult Partial Hospital program or another relevant health professional.

Authorization for use/disclosure of Health Information that Identifies you for a Research Study

If you sign this document, you give permission to research staff in the Behavioral Medicine and Addictions Research Unit at Butler Hospital to use your health information that identifies you, for the purpose of conducting the research study described above. The information will not be available to others outside of the Research Unit.

Please note that:

- You do not have to sign this consent form, but if you do not, you may not participate in or receive research-related treatment in this study.
- Butler Hospital may not withhold treatment or refuse to treat you, based on whether you sign this consent form.
- You may change your mind and revoke (take back) this consent and authorization at any time. If you no longer want to give us permission to use your health information for this research study, you must contact the Principal Investigator, Ana Abrantes, Ph.D., and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, Butler researchers may still use or share health information about you that they already have obtained, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to your personal health information related to this research until the study is completed. At the conclusion of the research and at your request, you will have access to your health information that Butler Hospital maintains in a designated record set, according to the Notice of Privacy Practices provided to you by Butler Hospital. The designated record set includes medical information or billing records used by doctors or other health care providers at Butler Hospital to make decisions about individuals.
- Your health information will be provided to you or to your physician if it is necessary for your care.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

This Authorization does not have an expiration date.

Questions

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members. You should take as much time as you need to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

Authorization:
I have read this form and decided that _____
(name of participant)
will participate in the project described above. Its general purposes, the nature of my involvement, and possible hazards and inconveniences have been explained to my satisfaction. I have received a copy of this consent form.

_____ _____
Signature Date
Relationship: (self, parent, guardian)_____

_____ _____
Signature of Principal Investigator Date

~or~

_____ _____
Signature of Person Obtaining Consent Date

Telephone Number of Principal Investigator or Person Obtaining Consent_____

If you have further questions about this project or about research-related injuries, please contact Ana M. Abrantes, Ph.D., 401-455-6440. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at 401-455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

IRBNET ID# 1195299

BUTLER IRB REFERENCE# 1803-002

BY (ADMINISTRATOR): CCordeiro