Developing a brief early cognitive intervention for PTSD and alcohol misuse

NCT02808468

05/02/2017

UNIVERSITY OF WASHINGTON
CONSENT FORM

Project BRITE

Brief Restructuring Intervention after Trauma Exposure

Researchers: Principal Investigator: Michele Bedard-Gilligan, Ph.D. Assistant Professor (206-616-4215)
Study Contact Person: Heidi Ojalehto, Study Coordinator (206-543-7850)
Department: Psychiatry and Behavioral Sciences

24 hour emergency number: King County Crisis Line 206-461-3222

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of this study is to test an intervention for unhelpful thoughts about a recent unwanted sexual experience and alcohol use. After experiencing an unwanted sexual experience many individuals have difficulty coping and may develop symptoms such as nightmares, avoidance of objectively safe situations, beliefs about blaming themselves, or feeling easily startled and on edge. In addition, some individuals may begin to use alcohol or increase their alcohol use to try and manage these symptoms. This study is testing an intervention following an unwanted sexual experience for these behaviors, incorporating both in-person and telephone components.

In this study, we are comparing a brief cognitive intervention (to be described in detail below) to simply monitoring your reactions to an unwanted sexual experience. If eligible, you will be randomly assigned (like a flip of a coin) to either "intervention" or "assessment only". If assigned to the "assessment only" group, you have the option of receiving the intervention at the end of the study (after 3 month follow-up).

The results of your progress will be used to better understand the helpfulness of this intervention, which is described below. You may benefit from participating, but that cannot be guaranteed. We hope to better understand how women cope following unwanted sexual experiences and to help women recover more effectively.

STUDY PROCEDURES

Participation in this study is voluntary. This study involves 7 time-points: baseline assessment, intervention session/online assessment, 4 weekly coaching calls and/or online assessments, and one follow up assessment. The baseline session will last approximately 60-90 minutes and will

consist of interview and self-report questionnaires. Baseline will be conducted by a study assessor. During this visit we will ask you questions about your mood, recent history of unwanted sexual experiences, alcohol use, and symptoms you have related to the unwanted sexual experience (e.g., nightmares). The interview will be audio recorded to ensure that it is being administered as intended and will only be accessed by trained study staff. If after this interview, it is determined that you are a good fit for the study you will be randomly assigned to either the intervention condition or the assessment only condition (described below). You may refuse to answer questions or may withdraw from the study at any time. If you withdraw, you will be compensated for any time spent and activities done up to that point.

Intervention Condition

If you are assigned to the intervention condition, you will be scheduled to return in approximately one week to meet with a study interventionist for a 90 minute in-person intervention meeting. At that time you will again be asked to complete self-report questionnaires on drinking and symptoms around the unwanted sexual experience. You will meet with the study interventionist who will try to help you learn new ways of coping with the unwanted sexual experience and talk with you about your alcohol use. They will ask you to talk about ways you think about the unwanted experience and behaviors that have changed for you since that experience. You will be free to share as much or as little as you wish with the interventionist. At this visit you will also be provided with paper copies of intervention materials as well as a USB drive. This USB drive is yours to keep even after study participation is over and will include electronic copies of all intervention materials and an audio recording of the main concepts of the intervention read by a study therapist to help you remember key concepts if you choose to listen to it. The intervention session will be audio recorded to ensure that treatment is being administered as intended and will only be accessed by trained study staff.

For the next four weeks, you will be asked to complete weekly 20 minute coaching calls with the same study interventionist, one call per week. Prior to each coaching call you will be prompted to complete on-line self-report questionnaires of symptoms related to the unwanted sexual experience and alcohol use, which take about 30 minutes to complete. During these coaching calls the interventionist will talk with you about opportunities to practice new ways of thinking and any problems that may arise. They will also provide you with general support and suggestions for coping. If you are unable to complete a coaching call one week, we will work with you to reschedule that call. However, you are still able to continue in the study even if you do not complete all four coaching calls. We will allow six weeks after your in person meeting with the interventionist to complete the four calls. After six weeks, even if you have not completed all four calls we will schedule your final visit to complete the follow up assessment. This assessment will occur 3 months after your final coaching call and will include interviews of PTSD and alcohol use, and self-report measures of alcohol and drug use, PTSD, depression, treatment satisfaction, and treatment received. This assessment will again be audiotaped.

If you decide you do not want to do the intervention session or the coaching calls you are still eligible, and are encouraged, to do the questionnaires and follow up assessment.

Assessment Only Condition

If you are randomly assigned to the assessment only group, you will be asked to complete weekly self-report forms on the internet for the five weeks following the baseline assessment-

one week post randomization and then weekly for the next four weeks. Finally, 3 months after your last survey you will be asked to come in for one final visit to complete a follow up assessment which will include interviews of PTSD and alcohol use, and self-report measures of alcohol and drug use, PTSD, depression, treatment satisfaction, and treatment received. This assessment will again be audiotaped.

RISKS, STRESS, OR DISCOMFORT

Risks posed by the research are primarily related to the sensitivity of some of the questions we ask. Possible breaches of confidentiality also pose a potential risk of this study. It is possible that over the course of the study you may experience increased negative affect and alcohol use. For those in the intervention condition, your study therapist will be available throughout the study if you experience a worsening of symptoms. Participants in the assessment only condition, at the conclusion of the study (3 month follow-up) will be offered the one session intervention with coaching calls. In addition, we will offer all participants, regardless of study condition, referrals for additional services. Finally, if at any point during the assessment phase of the study you report significant worsening of symptoms to a potentially dangerous level (e.g., potentially lethal alcohol consumption, suicidality) you will be contacted and provided with resources and referrals. No participants will be excluded from seeking additional services while part of this study.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate in this study, referrals to other community agencies that provide services following unwanted sexual experiences will be provided.

BENEFITS OF THE STUDY

Through participation in the research, you will receive assessments that may benefit you by providing information about your PTSD symptoms and drinking behavior. If you are randomized to the intervention condition, you will receive an intervention session and coaching calls that may benefit you by providing strategies that may help you cope more effectively. If you are randomized to the assessment only condition, you will be offered this intervention following completion of the 3 month follow-up. Further, if you wish, you can receive referral information for other clinical services. Society may benefit from the proposed research by having an increased understanding of recovery following unwanted and distressing sexual experiences. If the intervention is found effective it would have great public health significance in offering a form of treatment for individuals suffering following unwanted sexual experiences.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Institute on Alcoholism and Alcohol Abuse, a division of the National Institutes of Health, to conduct this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

Data will be linked to your address and phone number. This is necessary in order for us to contact you for coaching calls and your follow up assessment. We will audio record the

assessments and intervention sessions to ensure that assessments and treatment are being administered as intended. You will have the option to review and to delete any portion of the audio recording at your discretion. The audio recordings will only be accessed by trained study staff. Audio recordings will be made using a digital recording device and will be uploaded to our secure online server. Audio recordings will be retained until one year after data analysis is complete and then will be destroyed. The server is physically located in a secure, commercially protected facility with 24 hour locked and monitored key-card access, within a locked room, within a locked server rack, with a locking face-plate protecting the server itself from physical access without authorization. Electronic protection is provided by a commercial-grade firewall, with continuous monitoring of the server for any attempts at electronic invasion.

Numerous interviews and self-report measures will be administered in order to better understand your history of unwanted sexual experiences, coping strategies, alcohol use, and emotional experiences. All of the data will be recorded and maintained on file for purposes of analysis and will be used only for research purposes. Participants' names, addresses, and phone numbers will be maintained in a locked, secure location in order to get in touch with you for telephone contacts and study visits. These data will not be shared with individuals who are not directly involved in the study. All other data that you provide will be coded in a way that does not contain any participant identifiers. The linkage code will be kept in a locked file and a computer file with restricted access and will not be available to the public or individuals not directly involved in the research. We will maintain the link for 1-year after the end of the study to ensure that all data are accounted for and no further subject contact is required. One year after the end of the study we will also destroy all participant contact information.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- State and local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Even if you withdraw from the study at any time you will be compensated for any time spent and activities done up to that point.

All compensation is provided as Amazon gift cards that will be distributed via email. At baseline you will be compensated with a $30 gift card. If you are eligible for the study and agree to participate, you will be compensated with a $10 gift card for completing the questionnaires the following week online or at the intervention session. You will be compensated with a $10 gift card for each on-line assessment you complete; if you complete all 4 you will receive a $20 bonus (up to $60 in gift cards total). Payment for completion of the weekly on-line assessments, and the bonus, will be provided via email. Finally, you will be paid with a $50 gift card for completing a follow up assessment which will be provided at the time of that assessment. Thus, you may be compensated up to $150 total in gift cards for participation.

RESEARCH-RELATED INJURY

If you think you have been harmed by this research, contact Dr. Michele Bedard-Gilligan at (206-616-4215) right away. She will treat you or refer you for treatment.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the University of Washington Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject