Cover Page:
A RANDOMIZED CONTROLLED TRIAL OF INTEGRATED CBT FOR CO-OCCURING ANXIETY AND SUBSTANCE USE

NCT#: NCT04871100

IRB Approval Date (most recent update to ICF form): 8/25/25

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: ANTHONY ECKER **VAMC:** _____

H-53639 - A RANDOMIZED CONTROLLED TRIAL OF INTEGRATED CBT FOR CO-OCCURING ANXIETY AND SUBSTANCE USE

Many veterans experience PTSD anxiety disorders and alcohol use disorders (AUD). The cooccurrence of these two disorders present unique treatment needs. We are interested in providing treatment and learning more about Veterans outcomes and perspectives on how a UP-A could help Veterans.

Concise and Focused Presentation

The purpose of this research study is to examine Veterans' outcomes and obtain feedback on a mental health treatment program (UP-A) designed to help Veterans learn new strategies to improve/address emotional health concerns and drinking concerns. Benefits may include better understanding of your mental health and drinking, potential to learn skills to cope with mental health concerns. Risks include feeling discomfort answering questions about your thoughts, feelings, and behaviors, and therapy exercises that may be uncomfortable such as facing an anxiety provoking situation. The goal of this study is to provide treatment and evaluate the outcomes and obtain Veterans' thoughts about this program. Participation is voluntary, and you may stop participating at any time. Procedures include a phone interview with a study staff member about your thoughts, feelings, and behaviors. Following the interview, if eligibility criteria are met, you will be randomly assigned to 1 of 2 study treatments: (1) Unified Protocol- Alcohol (UP-A) or (2) Enhanced Usual Care, in which you will be provided information on how to obtain mental healthcare at MEDVAMC. Participants assigned to the UP-A condition will complete approximately 12 weekly 1 hour treatment sessions. Likelihood of being randomized to either condition is 50/50, like flipping a coin. Participants will complete assessments of thoughts, feelings, and behaviors 4 months after baseline. At the 4 month assessment, participants will also complete a brief interview about their experiences in either UP-A or enhanced usual care, which will be recorded.

Alternatives to participation include receiving treatment in your medical center or clinic using the standard procedures of the facility.

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study. We are interested in learning how to treat anxiety disorders and/or posttraumatic stress disorder (PTSD) and alcohol simultaneously using a cognitive behavior therapy that addresses mental health concerns and alcohol use (unified protocol-alcohol; UP-A). We would like to understand how to use this therapy tool to provide more comprehensive care for multiple issues that can be delivered by one provider. To learn how this treatment (UP-A) compares to treatment options currently available in the VA, some participants will receive this treatment, and others will directed to mental health treatment available at the VA (Enhanced Usual Care).

This research study is funded by VA Rehabilitation Research and Development Service

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Purpose

The purpose of this project is to explore the preliminary effect of UP-A on functioning outcomes, anxiety symptoms/alcohol use, and related problems through a pilot randomized controlled trial in which Veterans with anxiety or PTSD and problem alcohol use are randomized to receive UP-A or Enhanced Usual Care (EUC).

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center.
You will be one of 100 Veterans receiving care in this study. If you decide to be in this study, you will be assigned to one of two groups chosen by chance, like flipping a coin. There are 2 arms to this study- a treatment arm and a treatment as usual arm with a 50/50 chance of being included in the treatment arm (50 participants per arm).

Before being randomized, you will be asked to complete surveys that ask about your thoughts, feelings, and behaviors. This assessment will take approximately 90 minutes.

In the UP-A group, you will receive up to 12 weekly sessions of a talk therapy program, Unified Protocol-Alcohol, in which you will work with a study mental health provider over VA telehealth. In the other group (usual care), you will be provided with information on how to receive standard treatment provided at your facility for anxiety, PTSD, and substance use. Your sessions will be audiorecorded. This will allow us to make sure we have understood and accurately written down everything you have said. Recordings will only be made available to Dr. Anthony Ecker, research study staff, and personnel who are responsible for the protection of research subjects. The VA centralized transcription service will have access to the audio taping to transcribe the recording. Recordings will be destroyed 6 years after the study is completed. You will be given questionnaires about how you are doing prior to beginning treatment as well as upon completion (approximately 90-120 minutes). These questionnaires will ask about your thoughts, feelings, behaviors related to mental health and substance use. You will also be asked to provide feedback about the program upon completion during the assessment session after treatment. Finally 4 months after baseline you will complete questionnaires (approximately 90-120 minutes) about your thoughts, feelings, and behaviors regarding mental health and substance use. These recordings are being made to check that staff asked you questions correctly. You will not receive any feedback about the recordings.

During the study, should emergencies arise your providers will operate within their scope of practice and follow your facilities policies for providing the necessary care to ensure your safety.

If you decide to be in the study, you will be in the study for approximately 4 months.

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Before reviewing this consent form with you, we spoke to you on the phone to ask you some questions to find out if this study is a good fit for you. These questions were about your symptoms of anxiety and substance use. We want to remind you that we will use your answers to these questions as part of the research if you agree to be in the study. If you decide to be in this study, we will collect private information about you, including your name, birth date, age, telephone number, home address and email address. This information will be protected in the following ways:

All information will be kept secure and not shared. Only the study team will be able to see research records, questionnaires, and other identifying information or audio recordings. All information will be stored in a locked file cabinet in a locked storage room at the Michael E DeBakey VA Medical Center (MEDVAMC). We will also store information collected, including audio recordings, on a secure computer server behind the MEDVAMC firewall. This means that the information will be in a computer that no one outside the VA can get into. A number will be assigned to each patient, which will be kept separate from all identifying information, except for a password-protected master list stored on a secure server behind the MEDVAMC firewall. Your information will be combined with information from other people in the study . We will write about the combined information and not about you as a person. Talks or articles about this study will not identify you.

We will not share your records or identify you unless the law requires us to. There are times when we may have to show your records to other people; for example, to someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central Institutional Review Board (IRB), etc. The IRB, our local Research and Development Committee and other study monitors may look at or copy portions of records that identify you. In addition, if we suspect any abuse, we are required to report this to a State Authority.

Clinically Relevant Research Results

The study may show that individuals benefit from the treatment program. Individuals in the control condition can contact the study team to determine if treatment would be a good fit following study completion.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Confidentiality

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse

- Specific information concerning drug abuse
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Partial Social Security # (Last four digits)
- Photographs, videotapes, and/or audiotapes of you
- Questionnaire, Survey, and/or subject diary

Use or Disclosure Required by Law

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 Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Information regarding study participation will be included in your medical records.

The Certificate of Confidentiality will not be used to prevent disclosure of child abuse, neglect, or harm to self or others to state or local authorities.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

While the study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

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Potential Risks and Discomforts

This study poses very small risk. Talking about sensitive topics may create a mild, temporary increase in discomfort. Participants may decline to respond to any questions asked.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: You may benefit from these treatment services by improvement with anxiety symptoms and/or substance use. You may also benefit from information gathered during the assessments and learn more about mental health treatment.. However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Subject Costs and Payments

You or your insurance will not be responsible for costs related to this research. You nor your insurance will not be asked to pay any costs related to this research.

You will receive $30 for each assessment, at baseline and 4 months after baseline.

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Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, ANTHONY ECKER, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: ANTHONY ECKER at 713 440 4486 during business hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Under Federal Regulations, the VA Medical facility shall provide necessary medical treatment to you as a research subject injured as a result by participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Michael E. DeBakey VA Medical Center. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You do not waive any liability rights for personal injury by signing this form.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC. If you would like to verify the validity of the study and authorized contacts, you may speak with the Michael E. DeBakey Veterans Affairs Medical Center Research Office at 713-794-7918 or 713-794-7566.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness	Date