A pragmatic trial of brief CBT for anxiety in VA primary care

NCT04523779

April 13, 2023

Participant Name:_____ Date:_____

Title of Study: A Pragmatic Trial of Brief Cognitive Behavioral Therapy for Anxiety in VA Primary Care

Principal Investigators: [redacted]

VA Facility: Michael E. DeBakey Veterans Affairs Medical Center, Houston, Texas

Principal Investigator for Multisite Study: [redacted]

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Office of Research and Development. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study will gather information on the safety and effectiveness of brief cognitive behavioral therapy (bCBT). BCBT is a treatment for anxiety. Anxiety or worry is common among Veterans and can sometimes lead to other illnesses and a poor quality of life. We hope to learn how to better meet the needs of Veterans with anxiety.

Your participation in this research will last 9 - 13 hours over a period of one year. This includes any time you might spend meeting with a VA mental health care provider. The entire study is expected to take about 4 years to complete.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you choose to volunteer for this study,

- Your participation may help you learn to feel less anxiety and worry.
- You may feel an improved ability to perform normal activities of daily life.
- You may benefit from using an easier option to receive mental health services -- VA Video Connect-Home treatment option.

There may or may not be any direct benefits to you by taking part in this research study. However, the information we get from this study might help us improve the care of future Veterans and patients.

For a complete description of benefits, refer to the Detailed Information section of this consent.

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PI/SC Approval Date: 04/13/23

LSI Approval Date: N/A

LSI Verification Date: N/A

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- Everyone who enrolls in the study will receive at least the usual care currently provided to patients with anxiety. Not everyone who enrolls will receive the study intervention.
- Some questions on the study interviews may seem personal or embarrassing. They may upset you. You may decline to answer any question you do not wish to answer.
- Audio recording your mental health appointment may make you uncomfortable. You mayrefuse to have your appointment audio recorded and still be in the study. If you agree to have your appointment audio recorded, you may ask to stop the audio recording at any time.

For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

No, you do not have to take part in the study. If you decide to take part in the study, it should be because you really want to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

[redacted] and others who work with them at the Michael E. DeBakey VA Medical Center, Houston, Texas will carry out this study. The study will be conducted at the Houston VAMC, New Orleans VAMC and San Antonio VAMC.

The person in charge of the study is [redacted] at the Michael E. DeBakey VA Medical Center, Houston, Texas. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study [redacted].

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Principal Investigators: [redacted]

VA Facility: Michael E. DeBakey Veterans Affairs Medical Center, Houston, Texas

Principal Investigator for Multisite Study: [redacted]

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By carrying out this research project, we hope to learn how to better treat Veterans with anxiety or worry. Anxiety disorders are common. They can take a large toll on your mood, health, and overall daily functioning. At the same time, anxiety is often not treated in primary care clinics. The treatments that are offered often do not include the most effective treatment approach, exposure therapy.

The study we are conducting will look at your experiences with and your opinions on a treatment for anxiety. The treatment in this study is called brief Cognitive Behavior Therapy (bCBT) for anxiety. This treatment includes exposure therapy. It will be offered in two ways: 1) in-person, and 2) by VA Video Connect-Home technology. Video Connect-Home may improve access to mental health services for Veterans. It allows you to interact with your therapist by video from home. Learning skills to change thoughts, beliefs and behaviors may help with treatment of anxiety.

HOW LONG WILL I BE IN THE STUDY?

We will recruit around 425 Veterans to be a part of the study. The entire research study is expected to take approximately 4 years. Your part in the project will last for 1 year. Your individual participation will take 9 - 13 hours during that year, including any time you might spend with a VA mental health care provider.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

All Veterans participating in this study are receiving services at VA Medical Centers. The VA Medical centers are in Houston, New Orleans, and San Antonio. You were invited to participate because anxiety symptoms are mentioned in your medical records.

Once you sign and return this Informed Consent Form, HIPAA Authorization, and medical records release form, you will be asked to complete a baseline (initial) assessment appointment. The baseline assessment will determine if you are eligible to take part in the

study. This assessment will take place within 2 weeks of receiving your returned, signed documents. A member of the study staff (Research Coordinator, Research Assistant, or Independent Evaluator) will call to schedule a convenient time for you to complete the assessment by telephone. The telephone appointment will take about an hour. The questions will tell us about your physical and mental health. We will collect basic demographic information, such as your age and income. This information will be kept confidential. With all study assessments, you are free to skip any questions you do not want to answer.

After the baseline assessment is completed, a member of the staff will contact you to let you know if you are eligible to participate. You will be assigned to either a talk-therapy (bCBT) group or to an enhanced usual care (EUC) group. The group you are assigned to will be decided at random (like the flip of a coin).

- Talk-therapy (bCBT) Group
  If you are assigned to the talk-therapy group (bCBT), a VA mental health provider will call you to schedule your first treatment session. The VA provider has been trained by our team to deliver the brief talk-therapy treatment. The talk-therapy may be as few as 4 sessions but could last as many as 9 sessions. These sessions will not extend out for more than 4 months. Each session will last 30-45 minutes. A note will be placed in your medical record alerting providers to the presence of anxiety.

  You will have a choice to participate in the talk-therapy sessions either in person or by VA Video Connect-Home. This technology can be used on your personal smartphone, computer, or iPad. Participants may choose the method they prefer. If you don't have your own device, we may be able to provide you with one to use inthe program, depending upon availability.

  Your provider will discuss audiotaping your sessions and ask for your permission. The recordings will help us improve the program. You may refuse to audiotape the sessions and still be enrolled in the study. The audio recordings will not be shared with anyone outside the study team. They will be used only for training VA providers. They will not identify the person recorded. The recordings of your bCBT sessions will be reviewed by our team to ensure your bCBT treatment has been administered properly.

- Enhanced Usual Care Group
  In the enhanced usual care group (EUC), you will receive information about your current functioning and a letter encouraging you to discuss treatment options with your VA care provider. You will receive educational materials by mail, and/or by weblink, on managing anxiety and 4 brief monthly check-in calls from study staff. A note will be placed in your medical record alerting providers to the presence of anxiety symptoms.

- Follow-Up Assessments
  You will receive 3 follow-up telephone appointments with a Research Coordinator to evaluate your functioning 4, 8, and 12 months after you join the study. Each telephone appointment will last about 1 hour. Veterans who participate will be asked to complete questionnaires about their health and well-being, and to provide feedback to improve the program.

By agreeing to participate in this study, you are not giving up any of your rights. Even after you have agreed to participate, you may change your mind at any time. If you decide to stop taking part in this study, please contact the study staff. 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. The VHA's National Data Safety Monitoring Board has approved this protocol and will monitor data and safety matters throughout the project. Data and safety monitoring will also be conducted at the local level.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- We ask you to send back this completed and signed Informed Consent Form and HIPAA Authorization.
  - We are required to keep the signed, original copy of this informed consent document in our records. We are not allowed to accept participants unless the signed form is returned.
- We ask you to keep your study appointments.
  - Let your VA provider know ahead of time if you are unable to meet for a scheduled appointment.

- If you are assigned to EUC, complete the 4 brief monthly check-in calls with our study staff.
- Contact the Research Coordinator to reschedule if you miss a follow-up assessment. We will schedule study appointments at times that are convenient with your schedule.
- Please respond to text messages or secure emails sent to you by the study team. These messages will not contain any personal information.

- Ask any questions you have about the study. We want you to be informed about the research and comfortable with your participation.
- There are no medications, blood draws or x-rays that are a part of this study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any study has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed below. Neither the brief Cognitive Behavioral Therapy (bCBT) or the Enhanced Usual Care (EUC) are expected to create any significant risk for participants. We have designed this study to decrease the burden on participants by including telephone assessments and VA Video Connect-Home treatment options. Participants will be informed about available alternative treatments including the use of psychotropic medications, additional medical treatment (where possible), and/or no treatment. Overall, the risks associated with this study are low, however rare, unknown, or unexpected risks may occur.

- Possible psychological discomfort associated with the assessment and/or treatment process of the study:
  - Some questions on the study interviews may seem personal or embarrassing. They may upset you. You may refuse to answer any of the questions you do not wish to answer and still be in the study.
  - bCBT participants may occasionally experience mild to moderate distress during treatment, particularly during exposure-based skill development sessions. The bCBT therapist will work with you to develop a gradual, step-by-step plan for engaging in exposures safely.
  - Both EUC and bCBT participants may experience mild distress during the baseline

and follow-up assessments related to answering personal questions and/or mental fatigue from responding to multiple questions at one time. You may ask to take a break during the assessment or stop the assessment at any time.

- bCBT participants completing the qualitative interviews may experience distress when reflecting on their treatment experiences. You may ask to take a break during this interview or stop the interview at any time

- Possible risk of loss of privacy:
  - We will take measures to protect the confidentiality of the information you provide. We will do this by keeping the information in locked file cabinets and in password-protected computer files.
  - We will identify all data with a code number, rather than a name. The file linking code numbers to the names is stored in a separate place.
  - All electronic data is kept on a password-protected VA secure server. All paper data will be kept in a locked file cabinet in a locked room in a VA research building.
  - Only the research study staff and the people who ensure quality from the institution where the research is being done, federal and other regulatory agencies will have access to the data.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Veterans participating in the study may experience some relief from symptoms of anxiety from the treatment being studied. Participants may feel less anxiety, worry, and associated symptoms. You may experience an improved ability to perform normal activities of daily life.

We do not know if you will get any direct benefits from taking part in this research study. However, the data obtained from this study may provide important information on the treatment for Veterans with anxiety.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Participation in this study is voluntary. You may choose NOT to participate in this study. You may obtain treatment for anxiety outside of participation in this study. You may discuss this option with your health care provider.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

The study is taking part at 3 sites (Houston, New Orleans, and San Antonio). Taking part in this study will involve collecting private information about you. This information will be sent to the site investigator of your facility to document your study participation in your medical record. This information will be protected in the following ways.

To maximize confidentiality:

- All personal data is identified with a code number, rather than a name, and that the file linking code numbers to names is stored in a separate place.
- Study paper data will be kept in locked file cabinet, in a data storage room that has a security keypad as entry.
- All electronic data files will be kept within the VA setting and behind the VA firewall.
- Electronic data files will be password protected for additional security.
- Only the study staff, and people who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to the research data.
- Participant's information collected as part of the research will not be used or distributed for future research studies.
- Veterans will not be individually identified in any reports on the study that may be published.

We do not foresee any study-related adverse events. Study participants are not required to take any study medication or have any invasive procedure.

Your health information will be used or disclosed when required by law. For example, 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 IRB, our

local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations, or interventions.

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

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

You can receive a total of $120 for completing the study assessments. You will receive $30 after completing each assessment. Assessments will be given at baseline (initial assessment), 4-, 8-, and 12-months. You can choose to receive payment by a VA electronic banking transfer (similar to travel pay), by a debit card (mailed by Direct Express), or with Veterans Canteen Service coupons (Canteen Bucks). Your Social Security Number will be required to be paid using the VA electronic banking transfer.

Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

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.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

[redacted]

AFTER HOURS:

[redacted]

You may also contact, [redacted] if you have any questions or concerns about the research.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. If you choose not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you decide to participate in the study and later withdraw, you will still receive the same standard of care that you would have otherwise received. If you decide to withdraw from the study, we ask that you inform the study staff of your withdrawal. The investigator may continue to review the data already collected prior to your withdrawal but cannot collect further information, except from public records, such as survival data.

Participant Name:_____ Date:_____

Title of Study: A Pragmatic Trial of Brief Cognitive Behavioral Therapy for Anxiety in VA Primary Care

Principal Investigators: [redacted]

VA Facility: Michael E. DeBakey Veterans Affairs Medical Center, Houston, Texas

Principal Investigator for Multisite Study: [redacted]

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

The investigator, [redacted] will try to answer all 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 [redacted] You may also contact the [redacted] if you have any questions or concerns about the research.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

CONSENT FOR CONTACT BY TEXT / SECURE EMAIL

If you agree to participate in this study and would like to receive information by text or secure email (i.e., reminders for study appointments and assessments, links to study materials),

Please initial below:

_____ I agree to allow the study team to contact me by text and/or secure email.

Please text me at: (_____) _____ - _____

Please email me at: _____ @ _____

_____ I do **NOT** agree to allow the study team to contact me by text or secure email.

CONSENT FOR AUDIO RECORDING

If you agree to participate in this study and are assigned to the bCBT group, we are requesting your consent to audio record your talk-therapy sessions. The recordings will help us improve the program. **You may refuse to audio record the sessions and still be enrolled in the study.**

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 04/13/23

LSI Approval Date: N/A

LSI Verification Date: N/A

The audio recordings will not be shared with anyone outside the study team. They will be used ONLY for training purpose so the VA providers directly involved in this study can receive feedback about their sessions. The recordings will not identify the person being recorded.

Your provider will discuss audio recording your sessions again at the time of your appointment. **Even if you sign this document agreeing to have your appointment audio recorded, you may refuse at that time.**

Please initial below:

_____ I agree to allow my talk-therapy sessions to be audio recorded.

_____ I do **NOT** agree to allow my talk-therapy sessions to be audio recorded.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. / Mr. / Ms. _____

Principal Investigator / Project Coordinator / Research Assistant

has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's PRINTED Name	_____ Participant's Signature	_____ Date

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