Increasing the Effectiveness of CBT for Anxiety in Veterans by Involving Family Members

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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

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Section Aa: Title & PI

A1. Main Title

INCREASING THE EFFECTIVENESS OF CBT FOR ANXIETY IN VETERANS BY INVOLVING FAMILY MEMBERS

A2. Principal Investigator

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A3. Administrative Contact

None

A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: VA CENTRAL OFFICE, RR&D

A6a. Institution(s) where work will be performed:

Michael E. DeBakey Veterans Affairs Medical Center

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT05340478

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Anxiety disorders and posttraumatic stress disorder (PTSD) are highly prevalent among Veterans; estimates indicate that 30-40% of military service members experience at least one anxiety-based disorder, with PTSD being the most prominent. Prevalence estimates for posttraumatic stress disorder (PTSD) in Veterans range from 21-29%. Panic disorder (PD), generalized anxiety disorder (GAD), and social anxiety disorder (SAD) are common in Veterans, with prevalence estimates 6%, 8%, and 15%, respectively. Comorbidity among the anxiety disorders is also high and poses unique challenges to treatment. The process of recovery and community reintegration across the lifespan for Veterans with anxiety-based disorders is a significant problem.9 Resuming and participating in major social life roles within the community is challenging due to the debilitating nature of anxiety, which often results in avoidance of everyday activities and social withdrawal. Consequently, PTSD and anxiety are associated with substantial impairment in social, vocational, emotional, and physical functioning and high rates of suicide.

Cognitive behavioral therapy (CBT) is the front-line treatment for PTSD and anxiety disorders. Through the combination of psychoeducation, cognitive restructuring, and behavioral exposure to feared stimuli, patients are taught skills to overcome their fears. Although CBT for anxiety is effective, a significant proportion of patients (approximately 50%) do not achieve remission after completing treatment. For example, outcomes obtained from

military and Veteran populations indicate that up to 75% retained a PTSD diagnosis following CBT. Although different explanations exist for poor treatment response, treatment engagement is a common problem for those undergoing exposure-based treatments. LeBeau and colleagues reported that the degree to which adults engaged in CBT exposure exercises outside of session predicted treatment outcomes. Unfortunately, the very nature of anxiety motivates people to engage in avoidance behaviors related to their fears, which can undermine the effectiveness of treatment.

Recent research shows that interpersonal factors between a patient with anxiety and a family member may also function to maintain anxiety symptoms through a process known as accommodation. This occurs when family members adjust their own behaviors to help reduce the distress experienced by their loved one. This may take the form of the family member providing constant reassurance to the patient, using distraction, serving as a safety object by accompanying the patient outside of their comfort zones, warning others how to behave around the patient, and assuming more responsibilities typically handled by the patient. Although well-intentioned, accommodation behaviors by family members are detrimental and directly undermine the effectiveness of CBT approaches by facilitating further avoidance for the patient. Accommodation behaviors are associated with increased symptom severity and functional impairment. Over time, this pattern of responding becomes strenuous and exhausting to the family member and can deteriorate the relationship with the loved one. Thus, when a member of the family has mental illness, it impacts the family as a system by disrupting the equilibrium within that unit. In these instances, family members adjust patterns of how they respond and interact with the individual to restore balance to the family unit.

Despite this knowledge, the primary focus of most current evidence-based CBT approaches for anxiety continue to focus exclusively on treating the symptomatic individual. Only recently have researchers begun investigating brief interventions to target decreasing accommodation behaviors in family members of adult patients. Such interventions provide psychoeducation on how anxiety is maintained and teach family members new skills that will facilitate the patient¿s recovery from anxiety. These studies, along with results obtained from pediatric samples show that addressing accommodation behaviors in treatment is associated with reduced symptom severity, increased treatment response, satisfaction, and engagement by family, and improved remission rates.

Anxiety disorders and PTSD are highly prevalent among Veterans and service members but there has been limited focus on the development of CBT interventions that incorporate family members in the treatment provided to Veterans. Except for Cognitive-Behavioral Conjoint Therapy for PTSD, which provides treatment to couples in which one or both persons have PTSD, the majority of VA evidence-based psychotherapy (EBP) rollouts focus on treating the individual. Thus, novel and innovative approaches that involve family members and caregivers in treatments provided to Veterans are needed.

Section D: Purpose and Objectives

This study will examine the feasibility/acceptability of, and satisfaction with, a new intervention for family members of Veterans undergoing CBT for anxiety-based disorders. Adjunctive Family-CBT (AF-CBT) is framed within a family-systems approach, which addresses recovery of the Veteran within the context of the family unit rather than the patient as an individual. AF-CBT provides family members psychoeducation on anxiety and teaches skills that can be used to facilitate the recovery of Veterans who are in the process of completing treatment for anxiety.

A total of 47 Veterans and family member dyads (V/F dyad) will be recruited for this study. Phase 1 will recruit 12 V/F dyads for family members to receive AF-CBT while the Veteran undergoes CBT for anxiety. Each V/F dyad will participate in a post-treatment assessment that includes a semi-structured qualitative interview to gain a deeper understanding of their experience with the intervention and feedback on ways to refine the intervention. In this phase, AF-CBT will be delivered in three separate cohorts (approximately 4 V/F dyad in each cohort). The intervention will be refined using two adaptation frameworks (IM and FRAME) to guide the process, following completion of each cohort. Phase 2 of this study will recruit 35 additional V/F dyads to participate in the finalized version of AF-CBT.

Treatment feasibility, acceptability, and satisfaction will be evaluated via self-report assessment and qualitative interviews. The Family Accommodation Scale for Anxiety (FAS-A) will also be adapted for use with Veterans and administered at baseline and 1-month follow-up. The goal of this study is to further adapt and refine an adjunctive intervention for family members of Veterans who undergo CBT for anxiety. The long-term goal is to examine the effectiveness of AF-CBT as a therapeutic strategy to enhance the effectiveness of exposure-based treatments for anxiety for Veterans.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Mentally ill

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
Project staff will review information about the study with the patient, including the study procedure, patient's rights, risks and benefits of participation, and the methods that will be taken to protect the patient's confidentiality. The patient will have the opportunity to ask questions throughout the process. Patients will be asked to reiterate their understanding of the purpose and procedures related to the study. Study staff will clarify any necessary points and answer questions. Participants will not require a Legally Authorized Representative for this study.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:
c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.
This study examines the feasibility and acceptability of, and satisfaction with, a new intervention for family members of Veterans undergoing CBT for anxiety disorders/PTSD. A total of 47 V/F dyads will be recruited. Phase I will focus on refining the AF-CBT intervention, and Phase II will deliver the finalized AF-CBT protocol to V/F dyads.

In phase 1, 12 V/F dyads will be recruited to refine the adapted AF-CBT intervention. Family members will receive AF-CBT while the Veteran undergoes iCBT for anxiety. The AF-CBT intervention will be delivered in

separate cohorts (approximately 4 V/F dyads in each cohort). During the 1-month assessment, information obtained from qualitative interviews with each cohort will subsequently be used to refine the intervention in an iterative process. In phase 2, 35 V/F dyads will be recruited and administered the finalized version of AF-CBT following the same treatment and assessment format. Qualitative interviews will focus on each V/F dyad's experience with the AF-CBT intervention and whether specific components of the intervention facilitated the Veteran's recovery process.

Inclusion Criteria:

(1) Veteran at least 18 years old; (2) current diagnosis of at least one anxiety-based disorder: PTSD, PD, SAD, GAD, or Other Specified Anxiety Disorder (based on ADIS-5); (3) moderate-to-poor life enjoyment and satisfaction as indicated by a score of 47 or lower on the Q-LES-Q-SF (4) BAI score of 16 (moderate anxiety) or higher; (5) stable on psychotropic medication for 4 weeks before study participation; and (6) has a family member willing to participate in the study. The identified family member must be an adult over the age of 18 years who either lives with the Veteran or has frequent contact (>3 days/week) and can commit the time to attend the AF-CBT intervention.

Exclusion Criteria:

(1) Active symptoms of mania or psychosis at baseline (based on ADIS-5); (2) depression with active suicidal ideation/intent that would preclude treatment (based on ADIS-5 & BDI-II); (3) moderate-to-severe cognitive impairment as indicated by a score below 20 on the SLUMS; and (4) active drug/alcohol abuse during the initial 3-months of study enrollment (otherwise Veterans with comorbid substance/alcohol dependence are study eligible)

F2. Procedure

Recruitment: Veterans will be recruited through the Center for Innovative Treatment of Anxiety & Stress (CITRAS) at the Michael E. DeBakey VA Medical Center. CITRAS is an anxiety specialty clinic and receives direct referrals from clinics throughout the main hospital (e.g., General Mental Health Clinic, Post-Deployment Center, Primary Care Mental Health, PTSD Outpatient Clinic) and 11 community-based outpatient clinics (CBOCs). Flyers advertising the study will be posted throughout MEDVAMC and CBOCs, and the study will be advertised through electronic messaging boards throughout the hospital, posters, and VA approved social media outlets.

Procedure: Veterans expressing interest in the study will speak with a member of the study team who will provide information about the study. Veterans expressing interest in the study will be pre-screened with the Q-LES-Q-SF and BAI to determine if a moderate level of impairment in general functioning and anxiety are present (this data will not be included in research data set). If so, an appointment will be scheduled for interested Veterans and identified family members to complete a brief joint assessment, which will take about 2 hours. The Veteran will be scheduled for a separate appointment to complete a full baseline evaluation (where the Q-LES-Q-SF and BAI will be re-administered) approximately 2 weeks before receiving treatment. This appointment will last about 2.5 hours. The family member will start AF-CBT within 1-2 weeks of when the Veteran participates in anxiety treatment (delivered over 1 weekend). Approximately 2 weeks after the family member completes AF-CBT, the V/F dyad will meet with a study clinician for a conjoint (1.5 hour) booster session. The V/F dyad will be asked to complete a 1-month follow-up assessment, which will include a qualitative interview regarding their experience with the treatment (approximately 2.5 hours). It is anticipated that most participants will complete the study in approximately 4 months.

Assessments: Veterans will undergo two assessments (baseline & 1-month follow-up). The baseline evaluation will include a structured diagnostic interview (ADIS-5) and psychological screening measures to determine general emotional functioning and the presence of specific psychiatric disorders. All assessments will be supervised by a licensed psychologist. Veterans will be informed that study staff will need to access their medical records periodically to track relevant psychiatric and medical information. Protected health information that will be collected from Veterans in this study include: name, address, telephone numbers, dates of appointments related to the study, last four digits of social security number, and voice recordings. Demographic information, medications prescribed, and dates of mental health treatment appointments will also be collected. VA Quality Assurance and BCM IRB personnel responsible for providing general oversight of this study may also have access to research data. Study data regarding individual information that is not in the patient's medical record will remain confidential and inaccessible to other agencies. Family members will also be asked to complete a few brief measures at baseline and 1-month follow-up time points.

Qualitative Interviews: All V/F dyads who complete AF-CBT will be invited to participate in a qualitative interview following completion of AF-CBT. The purpose of the interview is to obtain V/F dyads' feedback about AF-CBT.

Collection and analysis of qualitative data will be overseen by Co-I, Dr. Drummond, and interviews will be conducted using a semi-structured interview guide (attachment in Section S) by Dr. Hinojosa-Lindsey (consultant). All interviews will be digitally audio-recorded using a microphone linked directly to a VA networked computer. De-identified audio recordings of the interviews will be saved to the MEDVAMC Research folder on the S Drive: Research-Data/Teng Lab. Lighthouse for the Blind will transcribe the audio recordings by accessing the research folder on the S Drive through their contractor PIV card or through receiving files via encrypted e-mail. Transcriptions will be saved to the research folder.

Measures: (1) Community Reintegration of Injured Service Members (CRIS), a commonly used measure of community reintegration following deployment; (2) Beck Anxiety Inventory (BAI) assesses the severity of anxiety symptoms, minimizing those that overlap with depression; (3) DASS; (4) Quality of Life Enjoyment and Satisfaction Questionnaire- Short Form (Q-LES-Q-SF) is a brief, 16-item measure of subjective functioning and satisfaction across a range of life domains including work, leisure activities, social relationships, and physical health; (5) Saint Louis University Mental Status Exam (SLUMS) is an 11-item clinician-administered screening measure of cognitive impairment; (6) Anxiety Disorders Interview Schedule DSM-5 (ADIS-5) is a gold-standard semi-structured clinician interview used to assess for the presence of all anxiety disorders including PTSD. Modules examining the presence of psychosis, mood and substance abuse disorders are also included; (7) Demographic and Military Survey is a brief questionnaire we have used in previous studies that inquires about general demographic and military information. Veterans are asked about their periods of service, deployment dates, whether they seek healthcare outside of VA, and other information pertaining to their education and employment history; (8) Client Satisfaction Questionnaire-8 (CSQ-8) is an 8-item measure that assesses overall treatment satisfaction; (9) Family Accommodation Scale is a 16-item self-report measure of anxiety symptom accommodation during the past month; (10) Couples Satisfaction Index (CSI) assesses satisfaction in the relationship; (11) Revised Dyadic Adjustment Scale (RDAS) assesses several domains of relationship quality; (12) Modified Treatment Evaluation Inventory (MTEI) is a brief 9-item measure that uses a 5-point Likert scale to assess acceptability of treatment components; and (13) Inventory of Psychosocial Functioning (IPS) a measure that assesses functioning across different domains of life. The ADIS-5, SLUMS, Demographics Form will be given at baseline only and the CSQ and MTEI will given at 1-month follow-up only. The remaining measures will be administered at both time points.

Treatments: Veterans will receive iTCBT, which is a transdiagnostic cognitive-behavioral group treatment for anxiety disorders. iTCBT is delivered over two consecutive days (1 weekend), lasting 8 hours each day. A maximum of 6 Veterans may be enrolled per group cycle. iTCBT includes psychoeducation about the nature of anxiety and skills training for changing maladaptive thoughts and behaviors. Family members of Veterans will receive AF-CBT, which is adapted from existing protocols that have been used with non-Veteran adult patients.AF-CBT is a brief intervention and consists of two 2-hour long sessions delivered in small groups of family members (maximum of 6). Two weeks after completion of AF-CBT, a conjoint booster session will be provided to V/F dyads to check in on progress and provide guidance in tailoring intervention components to the V/F dyad. In addition to psychoeducation on anxiety, how CBT works, the role of accommodation behaviors in maintaining anxiety and teaching alternative strategies for accommodation, AF-CBT includes modules that focus on improving communication and behavioral interactions between the V/F dyad.

Persons delivering AF-CBT and iTCBT will include trained masters-level and doctoral-level clinicians working under the direct supervision of the PI. Co-I's Dr. Clark and Ms. Myers will lead all AF-CBT sessions. Participants will be closely monitored by Drs. Teng and Clark, with their safety taking priority above the needs of the study. Our pilot work with Veterans at the MEDVAMC and community based outpatient clinics demonstrates the intensive weekend format to be a safe mode of treatment delivery. However, as an added level of precaution, the MEDVAMC has an emergency department with an on-call psychiatrist available 24 hours a day in the unlikely event that a patient needs immediate medical intervention.

Due to COVID-19 pandemic, participants will have the option to receive AF-CBT and iTCBT virtually via clinical video telehealth (CVT). At this time, the majority of outpatient mental health care at the MEDVAMC is being provided via CVT modalities and all clinicians are working remotely. Clinicians will provide treatments to participants in this study using approved platforms (e.g., VA Video Connect, BCM Zoom for Healthcare).

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 94 Worldwide: 94

Please indicate why you chose the sample size proposed:

The sample size proposed in this study is appropriate for a feasibility trial. A total of 12 V/F dyads (24 participants) will be recruited for Phase 1 to refine the adapted AF-CBT intervention. In Phase 2 a total of 35 V/F dyads (70 participants) will be recruited to determine the feasibility/acceptability of, and satisfaction with, the intervention. This sample size was determined based on the number of referrals CITRAS received in the past year and the rate of monthly Veteran enrollment (9-11 per month) in our current trial. Because this study requires involvement of a family member, we conservatively estimated that about half of the Veterans enrolled each month would be eligible for this study. Although we do not expect a high rate of attrition, the sample of 35 accounts for 20% attrition. This ensures enough participants to provide robust feedback and will allow us to draw meaningful conclusions about the feasibility, acceptability, and satisfaction associated with this treatment.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Specific Aim 1 involves the adaptation and refinement of AF-CBT through an iterative process, guided by two adaptation frameworks. Qualitative interviews involves a data-coding process will use conventional and directed content analysis/coding techniques. The data coding process will be divided into three steps: (1) Open Coding, in which Dr. Drummond and the PI independently review the recordings to identify key emerging themes; (2) Top-Level Coding will be applied to the remaining interviews and differences will be resolved through consensus. New themes that emerge will be added to existing codes. (3) Sub Coding will be applied to further refine broad constructs represented by top-level codes into sub-categories.

Specific Aim 2 will examine the feasibility/acceptability of, and satisfaction with, AF-CBT. Feasibility will be the percentage of V/F dyads who agree to participate out of the number invited to participate (benchmark of 50%). Retention rate will be the percentage of family members who attend both sessions of AF-CBT including the booster session (benchmark of 70%). Acceptability will be measured using the MTEI, in which a score > 27 indicates the treatment was found to be acceptable. Satisfaction will be assessed through the CSQ-8, where a score > 25 indicates satisfaction.

Specific Aim 3 will assess the internal validity and test-retest reliability of the FAS-A adapted for Veterans and their family members. Cronbach's alpha will be used to test the internal consistency of the measure and Pearson's r will be used to calculate test-retest correlation of the measure administered at different time points.

An exploratory aim will use Pearson's r to examine the association between changes on the Family Accommodation Scale-Anxiety with changes on the CRIS45 and BAI measures.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

The anticipated risks of participating in this study are minimal. However, as with any type of treatment for anxiety-based disorders, there is a chance that patients will not experience noticeable improvement in their anxiety symptoms; and some may find their symptoms worsen during treatment. At times, some patients may experience discomfort or embarrassment in disclosing personal information or in discussing issues typically addressed in therapy. While engaging in various cognitive and behavioral exercises, patients may experience momentary discomfort (e.g., talking about traumatic event, tensing parts of the body). Patients will be monitored closely by a trained clinician and will not be asked to engage in potentially anxiety-provoking exercises for prolonged periods of time or do more than they are willing. In the event that a patient remains distressed or upset after a therapy or evaluation session, that individual will be encouraged to speak to the therapist/interviewer or another mental healthcare professional. All patients will have access to study personnel during regular business hours and access to emergency services 24 hours a day, 7 days a week through the emergency department at their local hospital. The PI and Co-I, Dr. Clark, are experienced in the delivery of exposure-based treatments for anxiety disorders and will ensure that all patients are closely monitored, with their safety taking priority above the needs of the study.

As with any study, there is always a small risk for loss of confidentiality. However, study personnel will make every effort to minimize these risks by assigning participant numbers and storing documents with identifying information in password-protected files on a secured network. There are also certain situations in which study

staff may need to break confidentiality in order to protect you or others from direct harm. These situations include reports of abuse or neglect of a minor or vulnerable adult and plans to harm yourself or others. Participants in group treatments will be informed and reminded at the beginning of sessions to maintain confidentiality of session content by not sharing sensitive information with other people outside of group, including family members.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Veterans and their family members who participate in the study may experience functional and symptom improvement related to the Veteran's anxiety. Participants may also experience improvements in the quality of their relationships.

Describe potential benefit(s) to society of the planned work.

Information obtained from this pilot study will inform a larger clinical trial to evaluate the effectiveness of AF-CBT. Ultimately, if shown to be effective, this intervention will be among the first to incorporate family members of Veterans directly into the recovery process. Thus, potentially many more Veterans may benefit from this study.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

This protocol has a favorable risk-benefit ratio because CBT is an empirically validated procedure for treating anxiety-based disorders. Patients in this study have the added benefit of receiving close monitoring through regular assessment periods. Finally, the potential risks of the intervention are minimal and typically transient.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

A waiver of HIPAA authorization is requested for the entire study AND a waiver of consent is requested to access medical records for eligibility screening. No written HIPAA authorization forms will be collected from participants. This applies to all enrolled participants because this study is being conducted remotely through telehealth and obtaining verbal consent for HIPAA is not permitted.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

This research provides a behavioral intervention to help participants better understand anxiety and learn skills to reduce their anxiety. Behavioral interventions are a form of psychotherapy or talk therapy, in which participants learn about the causes of their anxiety and practice skills (e.g., changing their thoughts) to overcome their fears. Thus, this research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

The waiver will not adversely affect the privacy rights and welfare of the research subjects because our study team will continue to uphold and maintain the privacy rights of participants and place their welfare above the needs of the study. All members of the study staff must complete privacy and HIPAA training, and we have standard operating procedures in place to protect our participants welfare and privacy.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

Since the study is being offered virtually, obtaining HIPAA consent is not possible, as HIPAA consent cannot be obtained remotely. The study offers a behavioral intervention to Veterans and their family members, which requires access to protected health information.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

N/A

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

All research data in electronic form will be kept on a secure server of the MEDVAMC (2002 Holcombe Blvd, Houston, TX), which meets VA and BCM security requirements. The server is password-protected and access is limited to IT personal. During business and non-business hours, access to the server is behind locked doors. The server is backed up automatically each night. Data will be stored in VA-secured folders: (S:Reseach-Data/Teng Lab and M:\Research-data\Teng Lab Audio\H-51655 AF-CBT Audio & Media). Only the research staff will be given permission (requiring a logon and password) to access these folders.

Aside from the demographics form, data will not contain any HIPPA identifiers or other sensitive information. Each participant (V/F dyad) will be assigned a participant study number, which will be used to label all electronic data collected. A separate electronic document linking the subject number to participants' identifying information will be stored in a password-protected file in the PI's folder on the S drive, which is a secured server. Audio recordings of qualitative interviews will be reviewed by a member of the study team before transcription, and any identifying information will be scrubbed from the recordings. Results that are presented for publication will be reported in aggregate form, and therefore will not contain individual identifying information.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

The consent form that will be reviewed with all participants prior to study initiation describes the procedures in place to ensure that PHI will not be reused or disclosed to other persons or entities unless required by law or for oversight of the research. All participants, including non-Veterans, will receive a copy of the VHA Notice of Privacy Practices via DocuSign for their review, and VA Form 10-0483, Acknowledgement of the Notice of Privacy Practices, for their signature.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

Yes

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):
Yes

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
No

Will additional pertinent information be provided to subjects after participation?
No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.
The purpose of this study is to refine a behavioral intervention (in preparation for a larger study) for family members that can help Veterans who experience problems with anxiety. Thus, it is not anticipated that any new pertinent information will emerge from the study that will need to be conveyed to participants.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?
No

J2. Consent Procedures

Who will recruit subjects for this study?
PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.
The Center for Innovative Treatment of Anxiety and Stress (CITRAS) is a program in the Mental Health Care Line that provides specialty treatment of anxiety and stress-related disorders. Providers throughout the hospital including MEDVAMC community based outpatient clinics refer patients directly to CITRAS through an electronic consult for evaluation and specialty treatment. Veterans who are referred to CITRAS for treatment by their healthcare providers will be contacted by a CITRAS staff member and informed of treatment options including the opportunity to participate in this research study. If a patient expresses interest in participating in this study, we will discuss the protocol with them and schedule an appointment with them and their family members to meet with a member of the study team to discuss the study and conduct a baseline evaluation. If a patient is not interested in participating in this study but would nonetheless like treatment, they will be scheduled for treatment as routine clinical care.

Any member of the study staff may obtain consent from study participants. This study will include Veterans and family members recruited from Houston and surrounding areas. Participants may also self-refer to the study through posted advertisements in Veteran newsletters or Veteran list-serves. People who self-refer to the study will be asked to confirm Veteran status and if they are enrolled as a patient at the MEDVAMC. If they are, a study appointment will be scheduled; if they are not currently enrolled at the hospital, they will be provided with the phone number for patient enrollment and invited to contact study personnel once they have completed this process. During the study appointment, a member of the study staff will describe the study and review all information in the informed consent form (see attachment in Section S), explaining the risks and benefits of participation. The consent form will be sent to participants via DocuSign, which has been approved for use in this study by VA ORD (see attachment in Section S). Standard operating procedures for how DocuSign will be used to obtain consent and where the electronic documents will be stored is outlined in the attachment in Section S.

Are foreign language consent forms required for this protocol?
No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

Yes

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

Yes

Identifiable biospecimens

No

Other:

No

At what institution will the physical research data be kept?

This research involves electronic administration of questionnaires and will not result in any physical research data. All research data will be in electronic form and will be stored on a secure server of the MEDVAMC (2002 Holcombe Blvd, Houston, TX), which meets VA and BCM security requirements. The server is password-protected and access is limited to IT personal. During business and non-business hours, access to the server is behind locked doors. The server is backed up automatically each night. Data will be stored in VA-secured folders: (S:Reseach-Data/Teng Lab and M:\Research-data\Teng Lab Audio\H-51655 AF-CBT Audio & Media) and only the research staff will be given permission (requiring a logon and password) to access these folders.

The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

How will such physical research data be secured?

We do not anticipate having hard copy documents containing sensitive information. However, if we do obtain hard copy data, we will secure them in a locked filing cabinet in a locked office (Building 108-A, Room 206).

At what institution will the electronic research data be kept?

All research data in electronic form will be kept on a secure server of the MEDVAMC (2002 Holcombe Blvd, Houston, TX), which meets VA and BCM security requirements. The server is password-protected and access is limited to IT personal. During business and non-business hours, access to the server is behind locked doors. The server is backed up automatically each night. Data will be stored in VA-secured folders: (S:Reseach-Data/Teng Lab and M:\Research-data\Teng Lab Audio\H-51655 AF-CBT Audio & Media), and only the research staff will be given permission (requiring a logon and password) to access these folders.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

No

Such electronic research data will be secured via Other:

Yes, (describe below):
Electronic data will be stored on a VA secured server in the following folders: (S:Reseach-Data/Teng Lab and M:\Research-data\Teng Lab Audio\H-51655 AF-CBT Audio & Media)

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

Yes, identify the classes of the persons:
People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

No PHI will be transmitted to collaborators. Audio recordings will be made of qualitative interviews and deidentified recordings will be saved to the MEDVAMC Research folder on the M:\Research-data\Teng Lab Audio\H-51655 AF-CBT Audio & Media drive. Lighthouse for the Blind will transcribe the saved audio recordings by accessing the folder through their contractor PIV card or through receiving files via encrypted e-mail. Transcriptions will be saved to the VA-secured folder on the S drive.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

N/A

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

Veterans and family members who participate in this study will be engaging in research and will not be billed for services provided within this protocol.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

100

Distribution Plan:

Veterans will receive a payment voucher in the amount of $50 for completion of each assessment period (baseline and 1-month follow-up). The total amount they may receive is $100. Family members of Veterans who participate in the study will not receive payment for their participation as this is a VA-funded study, and payments are directed to Veterans. However, family members will receive a psychoeducational intervention that would otherwise not be available to them, free of charge.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q: Consent Form(s)

Anxiety Treatment for Veterans with Participation from Family Members (Veteran Version)

Anxiety Treatment for Veterans with Participation from Family Members (Family Member Version)

Section R: Advertisements

Mode of Advertising: Internet

Exact language of Advertisement:

(The information below will be posted on VA approved social media outlets such as Facebook and Twitter)

Struggling with anxiety? MEDVAMC is offering a research study for Veterans and family members. Participation involves assessment and weekend workshops. Compensation provided for participation. If interested, send an e-mail to CITRAS@va.gov or call (713) 791-1414 x26419.

Mode of Advertising: Other: Flyers, Posters, Newsletters, Electronic Message Boards

Exact language of Advertisement:

VETERANS: ARE YOU STRUGGLING WITH ANXIETY?

Symptoms of anxiety may include: constant nervousness, uncontrollable worry, panic attacks, fear or avoidance of situations, people, and places.

The MEDVAMC is conducting research on a new program for Veterans with anxiety that involves their family members. The program provides Veterans with a brief weekend treatment for anxiety and family members with a brief class that provides information about anxiety and teaches skills to support their loved ones. The study includes one follow-up visit. You may receive compensation for participating in the study.

If you have some of the symptoms listed above and would like more information, please contact us at CITRAS@va.gov or (713) 791-1414 ext. 26419.