Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-42354
Status: Approved
Initial Submit Date: 10/30/2017
Approval Period: 1/18/2018 - 11/14/2018

Section Aa: Title & PI

A1. Main Title

IMPROVING VETERAN FUNCTIONING WITH INTENSIVE TRANSDIAGNOSTIC CBT FOR ANXIETY

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

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

The process of recovery and community reintegration across the lifespan for Veterans with posttraumatic stress disorder (PTSD) and anxiety disorders (henceforth referred to as anxiety-based disorders) is a significant problem. 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. Consequences of untreated anxiety-based disorders range from substantial impairment in social, vocational, emotional and physical functioning to high rates of suicide.

Despite the effectiveness of evidence-based CBT for anxiety based disorders, a significant proportion of Veterans do not initiate treatment. Nationwide data indicate that less than 10% of recently deployed Veterans receive an adequate course of psychotherapy within the first year of being diagnosed with a mental health disorder. Avoidance associated with anxiety and fear-based disorders (e.g., PTSD) lead to low rates of treatment engagement and high rates of treatment dropout. For instance, attrition rates in PTSD treatment (20-40%) are similar to attrition rates (25%) for treatment of other disorders such as panic disorder and social anxiety disorder. Furthermore, length of time required to deliver evidence-based psychotherapies interferes with daily (family, work, school) activities and necessitate arranging time off work, scheduling around school schedules, and traveling to multiple appointments.

Novel and innovative approaches capable of improving community reintegration, quality of life, and clinical outcomes, while also keeping Veterans engaged in treatment are much needed. Given the impact PTSD and related anxiety disorders can have on family members, it is also important to learn about their perspectives regarding the advantages and disadvantages of new treatment approaches.

Section D: Purpose and Objectives

The overall objective of the proposed study is to improve reintegration across the lifespan and quality of life in Veterans with anxiety-based disorders including co-occurring depression. A randomized controlled trial will test the effectiveness of transdiagnostic group CBT delivered in an intensive weekend format. This transdiagnostic protocol addresses multiple anxiety-based disorders in a single protocol by incorporating general core components of CBT with additional skills-based modules that can be flexibly tailored to any anxiety disorder. Intensive CBT (iCBT) is an innovative and promising method of treatment delivery with the potential to produce rapid improvement in functional and clinical outcomes. The compressed format (e.g., weekend) of iCBT increases the likelihood that Veterans will engage in and complete treatment. During the course of the study, we will also gather qualitative data from Veterans who participated in the weekend treatment (and their family members) to obtain a deeper understanding of how iCBT and environmental barriers and facilitators have impacted their overall functioning and quality of life.

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 the consent form 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. Each patient will be given his/her own copy of the informed consent form to follow along by during the consent process and to keep for future reference. Patients will be asked to reiterate their understanding of the important points of the consent form to ensure that full informed consent is obtained. 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.

The clinical trial will compare the effectiveness of iCBT to standard CBT (sCBT) and treatment as usual (TAU). A total of 252 Veterans from all war eras will be recruited who have at least one of the following disorders: PTSD, panic disorder (PD), social anxiety disorder (SAD) and generalized anxiety disorder (GAD). Veterans with or without co-occurring depression will be included. Participants will be randomized to iCBT, sCBT, or TAU. The study design uses unequal randomization to the active intervention arms and to treatment as usual to reduce unnecessary recruitment. Thus, the percent chance that participants will be randomized to one of the three conditions are: 37% iCBT, 37% sCBT, and 24%TAU. Participants in iCBT will receive treatment over one weekend (16 total session hours); those in sCBT will receive the same treatment weekly, over 12 weeks (16 total session hours); and those assigned to TAU will receive routine clinical care. Assessments will be completed at four time points: baseline, 1-month, 3-months, and 6-months.

This protocol should be considered minimal risk because the likelihood and degree of discomfort anticipated in this intervention are lower than what people would encounter in daily life. This is a non-invasive behavioral intervention that is designed as a two-day workshop to teach participants about anxiety and provide them with opportunities to practice examining and adjusting their thoughts based on evidence. Participants have the benefit of having trained therapists available to guide and help them engage in these exercises. The workshop is similar to other classes and seminars people may attend in daily life. The room is set up as a classroom with individual desks and chairs for participants. Breaks are scheduled throughout the day, and participants are informed that they may take a break whenever they need.

It is important to note that the content of the treatment protocol is not new; cognitive behavioral therapy (CBT) is a well-established, empirically supported treatment for anxiety and mood disorders. In fact, it is the gold-standard treatment and recommended by NIMH as a first line intervention for anxiety and mood disorders. The PI of this study has been offering weekend CBT for anxiety disorders at the MEDVAMC for the past 10 years. The compressed weekend format for delivering this treatment has been established across several clinical trials to be a safe and feasible method of providing treatment. Veterans report high satisfaction with this treatment format and prefer it over standard weekly sessions (Teng et al, 2015, Journal of Anxiety Disorders, 33, 1-7). All of these factors support the rationale that the protocol should be considered minimal risk.

Inclusion Criteria:

(1) Veteran at least 18 years old; (2) current diagnosis of at least one anxiety-based disorder: PTSD, PD, SAD, or GAD (based on ADIS-5); (3) moderate-to-poor life enjoyment and satisfaction as indicated by a score of 42 or lower on the Q-LES-Q-SF (4) stable on psychotropic medication for 4 weeks before study participation; and (5) willing to be randomized to treatment condition. Inclusion criteria for family members of Veterans randomized to the weekend intervention who wish to participate in the qualitative interview: (1) at least 18 years old and (2) has regular contact with the Veteran (e.g., sees or talks with Veteran several days/week).

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; (4) active drug/alcohol abuse during the initial 3-months of study enrollment (otherwise Veterans with comorbid substance/alcohol dependence are study eligible); and (5) undergoing concurrent transdiagnostic CBT for anxiety.

F2. Procedure

Recruitment

Several methods of recruitment will be used in the study. Letters will be sent to Veterans enrolled for care at the MEDVAMC, including those scheduled for appointments in outpatient clinics (e.g., General Mental Health, Primary Care, Post Deployment, PTSD). In addition, flyers advertising the study will be posted throughout MEDVAMC, community based outpatient clinics affiliated with MEDVAMC, and Vet centers located in Houston. We will also recruit from non-profit organizations serving Veterans in the Houston community (e.g., U.S. Vets). The study will also be advertised through electronic messaging boards throughout the hospital, Veterans newsletters such as the "VA Star," and via free list-serves that Veterans subscribe to such as the "Houston Military Affairs" mail group.

Assessments

Participants will undergo a total of four in-person assessments. A pre-screening will be conducted using the Q-LES-Q-SF to determine a moderate level of impairment in general functioning. Veterans obtaining an impairment score of 42 or lower will be study eligible and complete a full baseline evaluation. Data obtained from the Q-LES-Q-SF at the pre-screen will not be used for research purposes. If the Veteran meets inclusion criteria and agrees to participate, s/he will be consented and re-administered this measure, which takes approximately 5-10 minutes to complete. The baseline evaluation will occur approximately 1-2 weeks before treatment. 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. During the pre-treatment appointment, it will be explained to the patient that that all assessment and treatment sessions will be supervised by a licensed psychologist (PI). Patients will also 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 (e.g., patient enrollment and consent forms) may also have access to research data. Specific data that may be accessed include symptom measures collected during the course of the study. Study data regarding individual information that is not in the patient's medical record will remain confidential and inaccessible to other agencies. Health records of participants in this study will be flagged since they are participating in an intervention for a psychiatric disorder.

Assessments at four time points (baseline, 1-month, 3-month, and 6-month follow-up) will be conducted for all three conditions. Diagnostic assessments will be conducted by study staff being directly supervised by the PI or another licensed psychologist. All assessments will be conducted in individual sessions that will occur either at the MEDVAMC or over the telephone (no social security numbers will be requested from subjects or potential subjects via phone). Veterans will be provided opportunities for breaks during in-person assessments and two phone appointments will be scheduled to reduce fatigue effects. Should a participant need immediate attention (e.g., expresses active suicidal intent or psychosis) during the assessment, the PI will ensure that the patient is seen by a provider through the walk-in clinic at the MEDVAMC that same day. Follow-up assessments will be conducted by an evaluator masked to treatment assignment.

Participants will receive a modest amount of monetary compensation for study participation, as detailed in Section L.

Assessment Battery

The assessment battery will consist of the following: (1) Community Reintegration of Injured Service members – Computer-Adaptive Test (CRIS-CAT), a commonly used measure of community reintegration following deployment; (2) Short-Form 12 Health Survey (SF-12), measures eight domains related to physical and mental health, health perceptions, and the impact of physical or emotional problems on general functioning via self-report; (3) Beck Anxiety Inventory (BAI) assesses the severity of anxiety symptoms, minimizing those that overlap with depression; (4) Beck Depression Inventory - Second Edition (BDI–II) assesses severity of depressive symptoms; (5) 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; (6) Saint Louis University Mental Status Exam (SLUMS) is an 11-item clinician-administered screening measure of cognitive impairment; (7) 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; (8) 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; (9) Perceived Barriers to Seeking Mental Health Services (PB-SMHS) assesses concerns specific to Veterans that are related to seeking mental health counseling and related services; and (10) Client Satisfaction Questionnaire-8 (CSQ-8) is a brief 8-item measure used to assess overall treatment satisfaction. All measures will be administered at each assessment period, except the ADIS-5, Q-LES-Q-SF, SLUMS, Demographic Questionnaire, and PB-SMHS, which will only be administered at baseline. The CSQ will only be administered at 1-month and 3-month follow-up periods. The complete battery of assessments can be administered in 2-3 hours.

Treatments

Participants will be randomly assigned to one of three treatment arms (iCBT, sCBT, TAU), described in detail below. Both iCBT and sCBT treatments are identical except for delivery format. Persons delivering the treatment will include a masters-level and doctoral-level interventionist who will be trained to deliver treatments in both intervention conditions under the supervision of Dr. Terri Barrera, a licensed psychologist and co-investigator on this project. Dr. Barrera is experienced in transdiagnostic treatment for anxiety and in the delivery of exposure-based treatments for anxiety disorders with Veterans. She will work closely with the interventionists to ensure that all patients are closely monitored, 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.

Standard Cognitive Behavioral Treatment: The sCBT condition consists of 12 treatment sessions delivered once weekly over a 12-week period. Duration of sessions will be approximately 90 minutes, depending on the session module. For example, psychoeducation sessions typically last 60 minutes, whereas cognitive restructuring and exposure sessions typically last up to 90 minutes. Thus, the entire treatment requires approximately 16 hours of direct patient contact. A maximum of 6 Veterans may be enrolled per group cycle. The transdiagnostic treatment protocol consists of (1) psychoeducation about the general treatment structure, the nature of anxiety disorders and co-occurring symptoms such as depression, and physiology underlying the fight/flight response; (2) cognitive restructuring, a method of challenging maladaptive thoughts that maintain negative affect and fears by examining evidence that replaces catastrophizing and overestimations in thinking; and (3) exposure to feared stimuli through imaginal, interoceptive, or in-vivo exercises. Treatment concludes with relapse prevention planning. Homework is completed regularly over the course of treatment. Patients will be asked to monitor and record their anxiety and mood symptoms, complete thought records, and engage in exposure exercises.

Intensive Cognitive Behavioral Treatment: The iCBT condition will contain the same treatment components as sCBT, but the intervention will be delivered over one weekend, lasting 8 hours each day (see weekend itinerary in Section S: file named "H42354 Study Measures). A maximum of 6 Veterans may be enrolled per group cycle. Veterans will be asked to complete practice assignments using thought records during the treatment. They will also be asked to monitor and record their anxiety and mood outside of treatment.

Treatment As Usual: The TAU condition consists of routine clinical care patients would typically receive at the MEDVAMC. This may include medication management alone (visits once every 4 months, on average) or in conjunction with other forms of individual or group therapies that involve supportive counseling or educational and skills-based classes (e.g., anger management, PTSD Recovery 101, etc.). These time-limited classes typically occur once per week for a total of 8 – 12 weeks. The TAU condition may also include Veterans who participate in disorder-specific evidence-based interventions such as cognitive-processing therapy or prolonged exposure therapy, as these treatments reflect the current standard of routine care in VA. Information on participants' engagement in these and all other forms of mental health treatment during the study will be collected via self-report and chart review. This information will be examined and if needed, will be controlled for in subsequent analyses. Upon completing the 6-month follow-up, patients in this condition will be offered iCBT or sCBT.

Interviews

A maximum of 40 Veterans who completed iCBT and their family members will be invited to participate in a

qualitative interview. The purpose of the interview is to obtain Veteran perspectives on the iCBT format. Using an interview guide (see Section S file named "H42354 Study Measures," the PI or another study staff member will conduct in-person interviews at the MEDVAMC approximately 1-month after completing treatment. The inclusion of up to 40 Veterans will be ample to achieve theoretical saturation concerning the impact of iCBT on the recovery process. Veterans will provide written informed consent (and sign a release of information form for family members present) before interviews begin and be compensated $25 upon completion. 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/H42354 Transdiagnostic.

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 335 Worldwide: 335

Please indicate why you chose the sample size proposed:

A total of 335 participants will be recruited for this study: 252 Veterans will be recruited to participate in the RCT; 40 Veterans who participated in iCBT and their family members (up to 40) will be invited to participate in the qualitative interview.

For the RCT, a total of 252 patients will be randomized across the 3 arms (95 to iCBT, 95 to sCBT, and 62 to TAU) to have 80% power to detect differences among groups in the primary outcomes. A recent meta-analysis of transdiagnostic treatment for anxiety demonstrated a medium effect size (g=.69) on quality of life outcomes. Based on these findings, we are using a more conservative effect size of 0.50 to calculate the sample size that will need to be recruited and randomized to draw conclusions. We will use unequal randomization to the active intervention arms and to treatment as usual to reduce unnecessary recruitment. We also inflated the sample size to account for intraclass correlations among patients and for attrition and loss to follow-up in order to obtain the number that must be recruited for the study. The recruited sample size of 95 for iCBT and 95 for sCBT, assuming 20% attrition at 1 month and accounting for clustering of patients within therapists, will result in 49 patients per group for analysis. For our primary analyses, this sample size will have 80% power to detect a medium effect size of .57 using a two-group t-test with á=.05 two-sided significance level.

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?

For our primary analyses, we will compare changes between the iCBT, sCBT, and TAU groups at all time periods in a single regression using a hierarchical mixed-model analysis. Because the number of patients randomized to the 3 groups is not equal, we will test for unequal variances and if necessary, will account for this in our regression models. For outcomes with unequal variances, in the mixed model, we will estimate the variances separately and adjust the degrees of freedom for the unequal variances. A priori covariates will also be included in the model. A significant time-by-treatment interaction will be followed by pairwise contrasts to determine whether the active interventions differed from TAU and whether the active treatments differed from each other. We will report the p-values and adjust p-values post-hoc using multiple comparisons procedures (e.g., Bonferroni) as recommended in the literature. For secondary analyses, we will run hierarchical linear regression models for each outcome using the baseline and 1 month data and with the a priori covariates. Hierarchical logistic regression models will be used to test differences in treatment engagement across conditions.

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. Barrera, 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.

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.

Patients who participate in the study may experience functional and symptom improvement related to their anxiety.

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

Information obtained from this study will be used to make the treatment more available to other Veterans experiencing similar problems. Based on findings from this study, the next project will evaluate broader dissemination of the treatment. 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?

No

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.

Any member of the study staff may obtain consent from study participants. This study will include Veterans from all war eras recruited from Houston and surrounding areas. Veterans may be referred from their healthcare providers at the MEDVAMC, community-based outpatient clinics, or Veterans Centers. 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 the informed consent form, explaining the risks and benefits of participation. Patients interested in participating in the study will sign VA Form 10-1086, Consent to Participate in VA Sponsored Research (see Section Q: Consent Form).

Veterans who participate in the weekend intervention (iCBT) will be invited to participate in an interview with study staff members to obtain their perspectives of this treatment format. From each weekend cohort, 1- 2 Veterans will be randomly selected to participate in the interview. At the time of setting up an appointment for the interview, Veterans will be informed that they may bring along a family member to the interview to share their perspectives with the study team. When participants arrive for the interview, a member of the study staff will describe the purpose of the interview and review the informed consent form, explaining the risks and benefits of participation. Veterans and family members who participate in the study will each sign a separate consent form (VA Form 10-1086, Consent to Participate in VA Sponsored Research).

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:

No

Specific information concerning drug abuse:

No

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:

Yes

Other:

No

At what institution will the physical research data be kept?

All paper forms of original data collected from this study will be stored in a locked cabinet in a secured office at the Michael E. DeBakey VA Medical Center, Houston, Texas. (MEDVAMC) (Room 6C-119) Paper data (aside from the consent and HIPAA forms) will not contain any HIPAA identifiers or other sensitive information. Each participant will be assigned a participant study number, which will be used on paper data. Paper data will not leave the MEDVAMC.

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?

Data will be stored at the MEDVAMC in building 100. Data will be kept in a locked file cabinet in room 6C-119.

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 folders on the S drive (S:Reseach-Data/Teng lab) and only the research staff will be given permission (requiring a logon and password) to access these folders. All paper forms of data collected from this study will be stored at the MEDVAMC in Building 100 in a locked cabinet in a secured office (Room 6C-119). Paper data (aside from the consent and HIPAA forms) will not contain any HIPAA identifiers or other sensitive information. Each participant will be assigned a participant study number, which will be used on paper data. Paper data will not leave the MEDVAMC. Results that are presented for publication will be reported in aggregate form, and therefore will not contain individual identifying information.

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):

Yes, (describe below): Electronic data will be stored on a VA secure server under the main "Research-Data" folder on the S drive. The pathway is: S Drive: Research-Data/Teng Lab/H42354 Transdiagnostic.

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 sponsors or collaborators. De-identified transcripts of interviews will be sent via overnight mail to co-investigator, Dr. Karen Drummond.

Will you obtain a Certificate of Confidentiality for this study?

No

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

Participants in the study will authorize digital audio recording of clinician administered interviews, treatment sessions, and qualitative interviews conducted during the study by signing the consent form. Audio recordings will be recorded using a microphone directly connected to a VA networked computer and the recording will be saved in a password-protected, encrypted file on the secure VA server, the S drive (S: Research-Data/Teng Lab/H42354 Transdiagnostic), that is accessible only by study staff and people who ensure quality from the institutions where the research is being done. The only individually identifiable information contained on the audio recording is the voice print. All recordings will be labeled with participant numbers.

Transcriptions of the qualitative interviews will be sent via overnight mail to Dr. Karen Drummond at 4300 W 7th St. Little Rock, AR 72205 with a tracking number. Transcriptions will not contain sensitive information or any of the 18 HIPAA identifiers

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.

Patients 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:

225

Distribution Plan:

Patients will receive a payment voucher in the amount of $50 for completion of each assessment period (baseline, 1-month, 3-month, & 6 month follow ups). The total amount they may receive is $200.

A subset of participants who complete treatment and participate in the qualitative interview will receive an additional $25. The total amount they may receive is $225.

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 that is not approved by the FDA?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q: Consent Form(s)

Transdiagnostic Treatment for Anxiety

Transdiagnostic Treatment for Anxiety Interviews

Section R: Advertisements

Mode of Advertising: Other: Flyers, Electronic Messaging Boards, Newsletters

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, places, to name a few.

The MEDVAMC is conducting research on a new brief treatment for Veterans with anxiety and related symptoms. The treatment is offered over one weekend or in weekly sessions and includes three follow-up visits. If you are eligible, you may receive this treatment for free and receive compensation for completing assessments over the course of the study.

If you have some of the symptoms listed above and would like more information, please contact the study coordinator at (713) 791-1414 ext. 26419.