Title: One-day Life Skills Workshop for Veterans With TBI, Pain, and Psychopathology: Evaluating Efficacy and Mechanism of Change

NCT04143243

Date: March 22,2024

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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: **H-46432**
Status: Approved
Initial Submit Date: 10/28/2019
Approval Period: 8/27/2021 - 8/27/2026

Section Aa: Title & PI

A1. Main Title

SUPPORT & EDUCATION FOR RETURNING VETERANS

A2. Principal Investigator

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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?

No

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:
NCTD3117-R

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Over two million service members have been deployed to military operations in Iraq and Afghanistan since 2001. Mild traumatic brain injury (mTBI) has been identified as the signature wound of these conflicts with up to 20 percent experiencing persistent post-concussive symptoms. Among those with an mTBI diagnosis, the majority also have a mental health disorder, including depression, PTSD, or another anxiety disorder, as well as chronic pain. For example, a RAND community based survey found that 37.5 percent of Veterans with a history of mTBI also had PTSD or depression. A survey of Veterans accessing the VHA between 2009 and 2011 found that approximately half of those with an mTBI diagnosis also had PTSD and pain. Recent data from studies of OIF/OEF/OND Veterans suggest that each of these problems-mTBI, stress-based psychopathology, and chronic pain rarely occurs by itself; in fact, the three conditions most often occur in combination with one another.

Mild TBI, stress-based psychopathology, and chronic pain are each associated with significant negative consequences. The interacting effects of these conditions, however, leads to additive, if not multiplicative, negative sequelae. This polytrauma clinical triad is associated with profound emotional distress, difficulties with family and community reintegration, functional impairments in daily living and employment, and increased risk for suicide, morbidity, and mortality.

To cope with distress, pain, and other difficulties, Veterans may turn to maladaptive coping strategies which offer short term relief but have detrimental long-term effects. Behavioral, emotional, and cognitive avoidant coping strategies, such as avoidance of important activities, using distraction techniques, mental disengagement, and denial, are common coping strategies among patients with PTSD, depression, anxiety, and chronic pain. For example, Veterans with PTSD often avoid going to public places to avert possible negative outcomes; they may drink alcohol to avoid the experience of emotional distress; and they may avoid going to places that remind them of a past trauma. Patients with chronic pain may take pain killers to reduce the intensity of pain or may avoid activity to reduce the likelihood of pain. Although these strategies lead to short term relief of symptoms such as decreased anxiety and emotional pain, they do not effectively solve the problem in the long run. In fact, they maintain or worsen the problems. Chronic avoidance serves to maintain functional limitations associated not only with mood, anxiety, and PTSD symptoms, but also with pain and post-concussive symptoms. Importantly, these coping strategies have severe costs to reintegration, quality of life, and social and occupational functioning. For example, the regular use of either alcohol or pain killers to reduce emotional distress or pain could lead to long term addiction problems and problems with work and family. Avoidance of social activity over extended periods leads to social isolation and fewer meaningful relationships. An intervention that helps Veterans to recognize the long-term negative effects of avoidance on their life and provides Veterans with the motivation and skills needed to re-engage in meaningful activities is urgently needed and could improve health outcomes.

Despite the documented need for mental health care and post-deployment support , a national survey of OEF/OIF/OND Veterans found that only 25% had ever sought outpatient mental health services. Among those with a PTSD diagnosis, less than half had received any mental health treatment in the previous 6 months.

Recent studies have identified key factors impacting Veterans treatment-seeking and engagement in care, including stigma or denial, and competing priorities/time constraints. Many Veterans avoid engaging in mental health treatment due to perceived social stigma, denial of the need for help, and/or perception that available treatments do not address their primary concerns. For Veterans with polytrauma, treatments focused only on chronic pain that ignore the Veterans distress may lead to poor adherence and satisfaction. Many Veterans avoid seeking treatment due to practical barriers, including time constraints, distance from a treatment facility, and competing priorities (e.g., work and family demands). Thus, the typical standard of care models, which target one diagnosis at a time, and offer multiple sessions for several months at a VHA clinic does not reflect optimal care or the preferences or utilization practices of many Veterans. There is a clear need for innovative approaches to delivering evidence-based therapies in ways that address these barriers to optimal care.

Acceptance and Commitment Therapy (ACT) is transdiagnostic, targets avoidance, cultivates acceptance-based coping and engagement in valued-life areas, and is flexibly delivered. ACT helps patients to overcome behavioral, cognitive, and emotional avoidance by promoting acceptance-based coping and engagement in meaningful and valued-life activities. More specifically, ACT confronts avoidance and encourages individuals to 1) identify their fundamental hopes, values, and goals (e.g., their post-deployment mission, being there for ones family, helping other Veterans, leading a collaborative life); 2) cultivate the habit of committing to doing things in line with their identified hopes, values, and goals; 3) willingly accept the unwanted feelings inevitably elicited by taking difficult actions, particularly those consistent with their values; 4) notice thoughts for what they are rather than as truths to be obeyed; 5) remain flexibly and purposefully in the present moment by being mindful of thoughts, feelings, bodily sensations, including during distressing experiences; and 6) enhance their perspective-taking skills. These are psychological skills that can be enhanced in any domain of living. The ACT focus on values is consistent with military culture whereby considerable emphasis is placed on acting in accordance with values regardless of limitations. Veterans deployed to a war-zone engaged in difficult tasks even when they may have been reluctant and afraid because these tasks were consistent with their values and their mission. Asking Veterans to clarify their life values or the new mission after returning to civilian life enhances patient-centeredness and provides the motivation for Veterans to re-engage in life in more meaningful ways, even when difficult. The focus on enhancing acceptance-based coping is particularly important in this Veteran population with polytrauma. They face certain situations that cannot be changed or fully influenced difficult memories and beliefs from deployment that may be realistic, pain symptoms that fail to respond well to medication, and/or physical changes or disabilities. Encouraging Veterans to practice acceptance of difficult memories and thoughts can help them to realize that these internal experiences can be faced with honor rather than avoidance.

Offering a workshop format rather than therapy is better suited for Veterans for whom seeking mental health care is associated with stigma. A recent review of mental health services provided to Veterans deployed to Iraq and Afghanistan showed that Veterans make 3-4 visits to primary care annually. Thus, embedding a workshop within a primary care setting can be a valuable way to improve access to mental health services and reduce the effects of stigma. A 1-day workshop also ensures treatment adherence and completion. A meta-analysis of 125 studies on outpatient psychotherapy found that 50% of patients drop out of treatment prematurely, and nearly 40% terminate treatment after the first or second visit. Similar results are found in studies of Veterans; for example, among Veterans newly diagnosed with PTSD, depression, or anxiety, half receive only 1-3 sessions. An effective intervention that can be completed in one day (6-7 hours)would address these problems while providing patients with more contact time than is routinely available in outpatient settings; as such, it provides an attractive alternative to the regularly prescribed weekly treatments. A 1-day workshop is also more accessible and feasible than weekly treatments, particularly for Veterans who live in rural communities. Over one-third of VHA enrollees live in rural areas.

It is important to examine not only whether treatments work, but how they work. Understanding the specific mechanisms or processes that mediate clinical improvement in symptoms of distress and reintegration will allow for intervention optimization by refining and emphasizing the components responsible for change and eliminating non-active ingredients. As noted above, avoidance-based coping has been associated with poorer psychological and health outcomes. Veterans with PTSD, depression, and/or anxiety disorders exhibit more avoidance behaviors than those without these problems. Avoidance of activities in medical patients is associated with elevated vulnerability to depression, reduced quality of life, and increased disability. Patients with chronic pain exhibit more avoidance behaviors than healthy controls and more pain-related interference and disengagement from activities. In contrast, acceptance entails that an individual reduces unsuccessful attempts to avoid uncomfortable experiences and focus instead on participation in meaningful activities and the pursuit of personally relevant goals. Acceptance-based coping and active engagement in meaningful life activities has been associated with reduced psychopathology, enhanced physical and social functioning, and greater pain tolerance in patients with mental health and medical problems.

It is equally important to examine whether treatment benefits are constrained or influenced by specific patient factors. For example, does time since deployment have an influence on outcomes? Does the severity of the mTBI have an influence on outcomes? A greater understanding of moderating effects of deployment history, demographics, and type and severity of mental health and medical conditions will allow for modifications to be made to the intervention to better meet the needs of subpopulations of Veterans.

Section D: Purpose and Objectives

Primary Aim: To examine the efficacy of a 1-day ACT+ERS (ACT on Life) workshop compared to an Education, Resources, & Support only workshop (ERS) at the 6-month follow-up.

Secondary Aim: To determine whether changes in avoidance at 3-months follow-up mediate the changes in symptoms of distress and reintegration at 6 months follow-up.

Exploratory Aim: To a) compare ACT on Life and ERS on service utilization patterns and medication use at the 3- and 6-month follow-up; and b) examine whether improvements in primary outcomes at 6-months follow-up are constrained by demographics, baseline mTBI characteristics, and severity of distress and dysfunction, number and type of coexistent psychiatric and medical conditions, medications, and deployment history.

If successful, this intervention would address an important priority area of RR&D: to improve the psychological health status of Veterans and enable them to function more fully in society.

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)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Both patients and healthy, non-patient, normals

Which if any of the following vulnerable populations will be recruited as subjects?
Employees or lab personnel

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
As part of our recruitment efforts, we may include interested MEDVAMC-employed Veterans and/or Veterans who are students. We will obtain verbal informed consent from each eligible Veteran student and/or employee and give ample time to ask questions and decide whether he/she wants to take part in study. Veterans will be reminded that participation in this study is voluntary. We will further assure employee Veterans that their employment and benefits will NOT be affected if they choose to participate or not.

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:

d) Questionnaire/survey/interview

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 will use a cluster randomization approach where the unit of randomization will be the workshops. Randomization will occur at the start of each workshop so that participants that had confirmed attendance to the workshop will be assigned to the randomized intervention (ACT+ERS or ERS) for the workshop. Cluster randomization is being used to facilitate adequate workshop group size, and improve blinding. This will also enable scheduling the workshops sooner in contrast to the randomization at the subject level where there is a longer wait time until enough participants have been randomized to an intervention arm. Study statistician will generate the randomization sequence using PLAN procedure (SAS v9.4). Randomization of workshops will occur in permuted blocks of 4 or 6 to ensure approximately equal distribution of the two interventions over the study period. The randomization sequence will be generated at the start of the study and will be provided to the study coordinator via a password protected file. Allocation to intervention group will remain concealed until the beginning of the workshop when all invited participants have arrived. Those in attendance will receive the assigned intervention. Participants scheduled to attend a workshop but provide notification of not being able to come to the workshop prior to randomization of the workshop, i.e. start of the workshop, will be rescheduled to a future workshop. Participants that do not show-up to their scheduled workshop without prior notification are considered as randomized to that workshops intervention group for ITT analysis. No-show participants will be allowed to attend another workshop, but since type of intervention is not known in advance, they will be included in their original randomized intervention for the ITT analysis, regardless of the actual intervention workshop attended. This will be noted as a protocol violation- missed workshop with no prior notification- and the actual intervention recorded. This allocation approach will minimize pre-treatment withdrawals, and the potential for experimenter and participant bias by protecting the randomization sequence in a central location, maintain concealment of treatment allocation until the last possible moment, and keeping the participants and outcome assessors blinded to treatment.

Inclusion Criteria:

Inclusion criteria has a two-step process. First participants will complete a screening either by phone or by web or in person. This will be brief and will take place prior to any consent process. If they screen positively, then they will be invited for an in-depth (in person or phone) assessment. Consent will occur only if a person screens positively for the study. Screening positively involves the following (unless noted as optional): 1) 18 -64 years of age; 2) Veteran serve in the military during OEF/OIF/OND missions in Iraq and Afghanistan time periods; 3)Optional- endorse at least one item within each of the four sections of the TBI Screener; 4) Score 10 or higher on PHQ-8 OR GAD-7; 5) endorse pain and have a score 3 or greater on 1-10 pain scale OR has a current pain interference of 5 or more on a 1-10 interference scale OR presence in medical chart of CURRENT chronic pain including headache, musculoskeletal pain or neuropathic pain AND verified with participant; 6) been on a stable dose of psychiatric medications for the past 6 weeks If the above screening criteria are met (unless noted as optional), participant will be invited for an in-depth assessment. In order to be further eligible in the study, they need to meet the following criteria (unless noted as optional). 1) stress-based psychopathology, as operationalized by a diagnosis of major depressive disorder, generalized anxiety disorder, and/or PTSD on the M.I.N.I. International Neuropsychiatric interview (M.I.N.I.), 3) Optional- Deployment-related mild TBI (as defined by the VA/DOD Clinical Practice Guidelines) determined by interview on the Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID); 4) average pain intensity OR ANY interference reported to be greater than or equal to 5 (moderate) on the Defense and Veterans Pain Rating Scale (DVPRS)

Exclusion Criteria:

1) History of bipolar disorder or primary psychotic disorder (e.g., schizophrenia, schizoaffective disorder) on the M.I.N.I.; 2) a current diagnosis of severe substance use disorder (on substances other Marijuana) on the M.I.N.I. ; 3) Moderate to severe suicide risk (as indicated by current intent and plan) on the suicidality scale of the M.I.N.I.; and 4) History of neurological illness not related to TBI; 5)Severe medical illness (e.g. liver failure, severe coronary artery disease and /or heart failure) posing a new and significant stress burden and requiring intensive treatment.

F2. Procedure

OEF/OIF/OND Veterans with deployment-related mTBI(optional), stress-based psychopathology, and pain will be recruited from the MEDVAMC and surrounding Community-Based Outpatient Clinics (CBOCs). At the MEDVAMC, OIF/OEF/OND Clinic, Womens Health Clinic, Mental Health Care Line (MHCL), the Pain and Post-Deployment clinics as well as other outpatient clinics from other care lines will be targeted for recruitment. We will meet with key staff and providers from clinics, local Veterans' community organizations, college campuses etc. to inform them about the study, provide copies of study recruitment materials, and ask them to tell Veterans about the study. We will also identify potential participants through advertisements posted in these clinics, community organizations, colleges and social media page.

Advertisements will list a phone number to call for more information and for a brief screening. Veterans who call, are interested, and deemed eligible after completion of screening questionnaire will be invited to review consent material and for a more in-depth assessment with a research assistant. We will also draw participants from the Translational Research Center for TBI and Stress Disorders (TRACTS) at the MEDVAMC under the direction of co-PI Dr. Jorge. We will also identify patients through the VA Informatics and Computing Infrastructure (VINCI) & CPRS screening who fit our eligibility criteria. A letter of invitation & brochure to participate in the study will be mailed to eligible Veterans, with information on how to opt out. Approximately 1 week after the mailing, a member of the study team will follow-up with potential participants by phone to describe the study, confirm eligibility (by completing screener) and schedule those who are eligible for the first in-person or phone assessment. If the team is unable to reach the participant over phone, a follow-up email will be sent with a secure link to complete the screening surveys online if they are interested in participating. A 2 stage process will be used to screen for enrollment. First, potential Veterans will complete a 5-10 minute telephone or in person or online screening. This takes place even prior to consent. Those who meet screening criteria will be invited for an in-person or phone assessment. At the beginning, the consent document will be reviewed with the patient and all questions pertaining to the study will be answered. If the patient is interested in the study, a record that the participant verbally consented will be stored in the study database. The patient will also receive Team contact sheet & Study timeline.The initial assessment will take approximately 2 hours to complete. Baseline will consist of a clinical interview and self-report measures. Please refer to attached 'Schedule of Measures' for measures/questionnaires completed at each time point in the study. All clinical interviews will be audio-taped to assess reliability. Participants will also complete a Contact Information form. All self-report assessments will be completed in Qualtrics online or on paper. The medical record will be reviewed for this same information (i.e. demographics, medical information, medications). Any discrepancies in medical information will be discussed with the participant to facilitate complete and accurate data. If the participant doesn't meet study criteria, they will be thanked and given a resource booklet (attached). If they meet study eligibility, the patient will be scheduled to attend an in-person or virtual workshop. Virtual workshops will be set up securely on Zoom using a password enabled zoom invitation and waiting room function feature which ensures that only the invited participants join the workshop. Participants will be randomized to either of the treatment group- 1-day ACT+ERS (ACT on Life) or an ERS only workshop. Enrolled participants will be sent an invitation ('Workshop Invitation') approximately 1 week before workshop. If scheduled for a virtual workshop, documents on how to set-up will also be included (Virtual workshop set-up) and team will trouble shoot set-up issues prior to the workshop on phone. We may also give a reminder call or send messages before the workshop as requested by the participant. In-person workshops will be held at the MEDVAMC or a local VA or non-VA facility that participant can conveniently access. All workshops will include 4-8 Veterans,will be led by two trained co-facilitators and last approximately 5 hours. Food and travel money will be provided to facilitate attendance for in-person workshop. To ensure treatment fidelity and adherence to intervention protocols by workshop facilitators, an independent study personnel will complete a fidelity evaluation of some workshops. The ACT on Life intervention will include: 1) Acceptance and Mindfulness Training (2-3 hours) emphasizing new ways of managing troubling thoughts, feelings, and physical sensations (e.g., learning how to recognize, and develop cognitive distance from unhelpful thoughts, such as I don't belong in society, or no one can understand me) and strategies to willingly face experiences that cannot be changed; 2) Committed Action Training (2-3 hours) involving helping Veterans clarify what matters most to them (e.g., valued domains including family, friends, environment,spirituality, career, and romantic relationships) and what they want to stand for in life, how they want to behave, and what sorts of strengths and qualities they want to develop. Within this context, the workshop will encourage engagement in, rather than avoidance of, actions consistent with valued directions; 3) Education, Resources, and Support (1 hour): educational topics listed below will be covered without detailed discussion of the topics.Participants in the ACT on Life workshop will receive two manuals - ACT Patient Manual and ERS manual. These manuals summarize the main concepts presented during the workshop and will be sent home with participants, so they can review content when needed. They will also receive a deck of ACT therapy cards. The ERS workshop will include education about 1) symptoms of depression, anxiety and PTSD and how these conditions do and do not impact daily life and functional ability; 2) common difficulties and challenges with reintegration into civilian life; 3) mild TBI, differences between civilian and Veteran TBIs, hared/crossover symptoms; 4) chronic pain; how it is often misinterpreted as on-going damage, leading to fear of physical activities and resulting in increased sedentary behavior and declines in physical functioning; and 5) treatment options and resources. Basic resource counseling will include guidance on the evidence-based treatments available at VHA for PTSD; and other VHA clinical mental health, case management, and social work services. These topics will be provided to help increase awareness, normalize Veterans experiences, and increase the likelihood of participation in other treatments and/or community activities. Psychoeducation and group discussion can contribute to the de-stigmatization of psychological illness and reduce barriers to engagement in care. Participants in the ERS workshop will receive only the ERS manual and problem solving pages. Workshop materials will be mailed to the participants attending the virtual workshop. For Veterans attending the virtual workshop and who do not have access to a computer at home we will put in a request with VA Telehealth for a VA iPad for the duration of their participation in the study.Participants will receive a 'Certificate of Completion' at the end of each workshop. A homework assignment will also be given at the end of each workshop. Veterans in the ACT workshop will be given homework related to implementing a key coping skill; those in the ERS workshop will be asked to review the ERS patient manual and document any questions they may have. These homework assignments will be reviewed during the individualized phone booster sessions, which will be completed at approximately 2 & 4 weeks after the workshop. Each booster will be approx. 20 minutes. The booster sessions for both groups will begin with a general assessment of patient experiences since the workshop as well as progress made and skills being utilized. For Veterans who attended the ACT workshop, the therapist will then review the Veterans life values, some key concepts from the workshop and the homework assigned during the workshop. The therapist will offer targeted, individualized guidance on how ACT skills taught during the workshop can be applied to the Veteran's current experiences. Any questions the Veteran has will be answered. For those in ERS, the facilitator will offer support, reinforce education and respond to any questions the Veteran may have. The date and time of the phone calls will be scheduled with the Veteran at the end of the workshop to optimize the likelihood of reaching him/her by phone. Booster session guides attached. All workshops and phone booster sessions will be recorded; 20% will be randomly chosen and provided to an independent rater to complete fidelity and competency checks. Veterans in both conditions will complete self-report assessments at 6 weeks, 3 and 6-months following the intervention. At each follow-up Veterans will receive a secure online survey invitation from Qualtrics to complete the surveys. If the participant prefers paper

version of surveys, we will mail or an appointment will be scheduled or surveys will be completed over the phone. Management of Suicidal Ideation (SI) or Behavior: SI with intent or plan is a rule-out criterion for this study. However, given that this is a study of treatment for distress, a plan for addressing suicidal behavior at any time during the study (including at screening) was developed. At the start of the study, all participants who are randomized into study will be asked to provide an emergency contact number of a family member or friend and the contact number for their PCP or psychiatrist if they have one. Any increases in distress will be captured during the regular assessments incorporated in the study protocol and appropriate measures will be taken. If the patient endorses SI, s/he will be immediately evaluated by the one of the PIs. The PI will do further assessment of the patient to determine, together with the participant, the appropriate actions. If indicated, a referral will be made for further evaluation and treatment (including hospitalization if necessary). With the participants consent, the PCP and psychiatrist (if one exists), will be contacted, the family emergency contact person will be notified by phone, and appropriate follow-up care will be discussed. The Veteran will also be given the phone number for the Veterans Crisis Hotline. The patient will be made aware of this plan before entering into the study and he or she will be reminded that it applies to assessments occurring throughout the study period. Intervention Training, & Adherence: PI will be responsible for the training and implementation of the interventions. Dr. Marsh, executive director of VA Mental Health Services is very supportive of this study and has agreed to provide resources needed, including the participation of MH Care Line clinicians. Thus, at least 4 therapists from the MHCL who have prior expertise in ACT will be trained in the ACT workshop and will help with workshop facilitation. The training of existing therapists at the VAMC will ensure dissemination of this treatment in the future. Bi-weekly supervision meetings with the therapists will be held to maintain fidelity to the treatments. The Area Deprivation Index associated with each participant's home address will be obtained through the use of the Neighborhood Atlas (https://www.neighborhoodatlas.medicine.wisc.edu/). Participant address information is not stored or collected by the Neighborhood Atlas geocoder.

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 600 Worldwide: 600

Please indicate why you chose the sample size proposed:

A proposed sample size of n=180 (90 per group) will be used to test for mean change from baseline to 6 months in the primary outcome measures between ACT+ERS and ERS at the 0.05 (two-tailed) significance level. Assuming an average of 5 participants per workshop (cluster), with ICC estimated from our pilot data of 0.215 for DASS-21 and 0.093 for M2CQ, the statistical test will be able to detect with 0.80 power a treatment by time interaction effect corresponding to difference in mean change at 6 months between treatment groups of at least 14.2 for DASS-21 and 5.9 for M2CQ for the proposed sample size. The corresponding detectable effect size of 0.58 for DASS-21 and 0.50 for M2CQ is smaller than the overall weighted effect size of 0.66 from a meta-analysis that examined the efficacy of ACT compared to other treatments/wait-list/treatment on psychological outcomes in those with acquired brain injury. 600 sample size provided is to account for attrition / screen failures in order to meet the actual proposed sample size goal of n = 180.

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?

Our primary aim is to examine whether the ACT+ERS condition will result in greater reductions in distress and improvements in reintegration, compared to ERS only, at the 6-month follow-up. Analyses will be done on an intention-to-treat basis. Consistent with CONSORT recommendations, we will not test for differences in baseline characteristics or adjust subsequent analyses for any variables not selected a priori (i.e., change in medications/use of psychotherapy/counseling) to use in the linear models. Longitudinal, linear mixed-model analysis will compare ACT+ERS and ERS changes over time. The primary outcomes, stress-based symptoms of psychopathology (DASS-21 total) and community reintegration (M2CQ), will be treated as continuous dependent variables for the linear mixed model analyses. The fixed effects in the mixed model will include treatment; time period (0 and 6 months); treatment by time interaction; and a priori covariates. Covariates will include the differential changes over time between treatment groups in psychotherapy and psychiatric medications, which will be defined as psychotherapy involvement during the previous time period at 0, 3, and 6-months (for baseline, it will be the 6 weeks before time 0) and whether psychotropic medications were started or changed during the previous period. The primary aim will be assessed from the result of the test for treatment by time interaction to determine if the within group change at 6 months differs between the 2 treatment groups. Patients will be nested within clinician teams (workshops) to account for correlations among patients treated by the same clinicians. Similar analytic strategies will be utilized to examine effects of the intervention on secondary outcomes of PTSD symptoms and pain impact. A separate analysis will be performed to examine the effect of attendance to a booster on the outcome measures. The number of subjects with and without booster sessions will be noted, and demographic and clinical characteristics of these subjects will also be compared. Booster session attendance status and an interaction effect with intervention group will be included in the mixed model analysis. Since the study is not powered to detect for such an interaction effect, the mixed model analysis with booster by treatment interaction effect will be used to obtain an estimate of the treatment effect (with adjusted 95% confidence interval) by booster session attendance. This will be used to examine the possible difference in the effect of booster session attendance, but no inferential test will be performed For the secondary aim, mediation analysis will

explore the causal pathway between intervention (ACT+ERS or ERS alone) and improvements in distress and functioning from baseline to 6 months, and increases in acceptance-based coping and reductions in behavioral avoidance from baseline to 3 months as mediators. With the independent variable X (intervention) randomized to workshops (clusters), and the mediator variables M (increases in acceptance-based coping, and reductions in behavioral avoidance), and the dependent variable Y (changes in distress & reintegration) measured at the subject level within clusters, we have a two-level hierarchy with a 2-1-1 design. For this multilevel design, multilevel structural equation modeling (MSEM) will be used to estimate and test the direct and indirect effects to assess multilevel mediation as described by Preacher, Zyphur, and Zhang. For the exploratory aim, we will compare ACT+ERS and ERS on service utilization and medication use obtained at the 3- and 6-month follow-up from the Service Utilization and Medication Use Questionnaire. Questionnaire responses consist of Yes/No answers which will be analyzed using generalized linear model for a binary response (with logit link function). This model will be fitted using the generalized estimating equations (GEE) method to account for correlation of responses from subjects within the same workshop. Medications will be classified as antianxiety (benzodiazepine, buspirone, or other), antidepressant (SSRI, SNRI, TCA, or other), antipsychotic or as medication for medical problems (e.g., pain, hypertension). Frequencies of drug use within each of these categories will be calculated and distributions examined to determine whether each variable should be analyzed as categorical or continuous. Medication change across classifications will be examined for potential use as an explanatory variable. The second exploratory aim will examine if treatment benefits are constrained by demographics, severity of distress and dysfunction, number and type of coexistent psychiatric disorders and medical comorbidity (e.g., substance use, type and severity of mTBI), time since deployment and number of deployments. We will estimate treatment effects in subgroups to address conditions in which ACT+ERS may be optimally useful.Moderation will be tested by including each separate moderator and interaction term between treatment condition and the moderator. A significant interaction will indicate that differences in treatment effects depend on the moderator. Simple slopes analyses will be conducted to follow-up significant interactions.

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:

Overall, this study poses low risks to the Veterans. No deception is involved in any of the interventions. Potential risks for the patients include 1) discomfort or negative response to the psychosocial intervention, 2) exacerbation of negative emotions, 3) the disclosure of confidential material, and 4) fatigue or boredom related to the assessments. 1) Discomfort or negative response to psychosocial interventions: The interventions will include scheduled breaks, during which the trained providers will discuss their assessments of individual group members needs. Efforts will be made to engage all participants in a positive manner. Being in the study is optional thus all participants will be given the opportunity not to participate, stop the study at any time he/she likes, and ask questions at any time.

2) Exacerbation of negative emotions: Some participants may not improve with the workshop or may experience an increase of distress-based symptoms that requires professional help. Those assigned to the ERS group may also experience an increase of distress-based symptoms. Alternative treatments are available to Veterans at the VAMC. These would include antidepressant medications and psychotherapy. Appropriate referrals will be made for Veteran participants who request it.

3) Disclosure of confidential material: All participants in the group will be encouraged to only use their first names for confidentiality. Additionally, participants in the group will be asked to keep personal disclosures of other group members confidential. Questionnaires and data will be labeled only with a participant ID number. Names will not be tied directly to the data. Patients will be informed that they do not need to answer any questions that they do not feel comfortable answering. Research staff will respect any requests by patients to not answer questions for the study.

4) Fatigue or boredom related to the assessments: Participants will be allowed to either skip any questions that they would prefer not to answer or not complete any task at their request. This information will be kept confidential and only available for the use of the research team. Boredom, fatigue, and anxiousness could occur during this testing. The research team member administering the tests and tasks will provide breaks or will allow testing to cease if necessary.

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.

The benefits to patients include a thorough psychiatric assessment that might uncover depression, anxiety, or another significant psychiatric disorder that might benefit from treatment regardless of whether the participant elects to, or is found to be eligible to, participate in the study.

Patients may also experience benefit from being in a group of other participants who are experiencing similar difficulties. Finally, participants may experience benefit from contributing to knowledge through participation in research.

Findings will also provide helpful insights into the feasibility and preliminary efficacy of Acceptance Commitment Therapy (ACT) on improving veteran quality of life, functioning, distress, and pain-interference. If effective, this intervention has the potential of improving outcomes for veterans with mTBI, stress-based psychopathology, and pain.

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

Although mTBI, stress-based psychopathology, and pain are common in OIF/OEF/OND Veterans, there are limited acceptable interventions for Veterans with these difficulties. The contribution of the proposed research will be to examine the efficacy of a 1-day Acceptance and Commitment Therapy (ACT) workshop for Veterans with co-occurring mTBI, pain, and stress-based psychopathology. We selected a 1-day format for ease of implementation in primary care settings, allowing more unitary care for the stress-based psychopathology and other medical problems. This format is also cost effective, more accessible and feasible than weekly treatments for Veterans who live in rural communities or suffer other barriers to accessing care,and ensures treatment adherence and completion. It is also unique because it is implemented over one day. It is hoped that this unique delivery model can be easily disseminated in primary care. Finally, presenting it as a workshop rather than as a treatment may help circumvent the stigma associated with mental health care.

This study will inform the efficacy of ACT for Veterans with these problems. This contribution will be significant because already trained therapists in the VA system will be able to provide an effective intervention for those veterans who are suffering from co-occurring medical and psychiatric problems, thereby improve their productivity, quality of life and longevity.

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

This study has a favorable risk-benefit ratio because participants will be taught new skills to manage distress and will be given the opportunity to talk about their general functioning with a trained member of the study team. The potential risks of the study are minimal.

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 consent and HIPAA authorization is requested to review Veteran's medical records in CPRS to determine eligibility for recruitment portion of the study.

Additionally, a waiver of HIPAA authorization is requested for the entire study for the following reason: To reduce participant burden, verbal consent is being obtained for study participation (see request to waive written documentation of consent in J1a.). Therefore, we request a waiver of the requirement for HIPAA authorization for study participation.

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.

The use of Veteran subject's PHI is strictly for identifying study candidates, and information will be maintained behind two locks, or behind a lock and password protected computer, and shared only with research staff on the study team. The probability and magnitude of harm or discomfort does not exceed what one might expect from daily life or similar situations occurring in a hospital or clinical setting.

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.

Additionally, the workshop (intervention) and research assessments are non-invasive in nature and almost exclusively involve teaching coping skills, providing education on common difficulties of returning veterans and assessment of participant functioning. Significant protections are in place to minimize the risk of breach of privacy. All PHI will be kept secure and not shared.

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

The PHI accessed will only be used to determine whether or not a patient may qualify for research and will not be released or shared outside of the research team. Screening patient's records is a passive activity that does not alter their records, and therefore, does not change their healthcare or welfare.

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.

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.

Without the waiver, researchers would need to rely on subjects self-identifying themselves as potential subjects, which is not an optimal method of recruitment. Sometimes subjects do not fit study criteria, nor do they volunteer at high rates without the use of widespread recruitment media.

Being able to review patients' PHI before inviting them to participate narrows down the pool of subjects to one that is more manageable and more likely to qualify for the study. This saves, both researcher and patient time. The researcher would not expend valuable work hours interviewing subjects who clearly do not qualify and patients would not waste their work or school hours visiting the MEDVAMC for fruitless interviews.

We are also requesting to verbally consent participants by telephone or in person and to waive HIPPA authorization for the entire study to afford us greater opportunities to increase our outreach to patients and decrease participant burden in this minimal risk study. In the current climate of COVID-19 where most Veterans are requesting to complete the consent & baseline procedures over the phone, a verbal consent is more advantageous as it doesn't require the added effort on the part of the participant to sign and return it by mail. Receiving completed consent & HIPAA forms in the mail also causes unnecessary delays often due to disruptions in postal delivery system. Additionally, for those participants that prefer to complete consent and baseline procedures in person (after the VA ORD hold on in-person contact for research is lifted), a verbal consent will also help minimize contact by reducing pen exchange etc. between research staff and participants.

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.

The PHI accessed will only be used to determine whether or not a subject may qualify for the study and will not be released or shared outside the research team. Screening patients' record is a passive activity that does not alter their records, and therefore, does not change their healthcare or welfare.

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 completion of 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 PHI will not be reused, 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 PHI would be permitted under the Privacy Rule.

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 #:
Yes

Partial Social Security # (Last four digits):
Yes

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

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.
A waiver of written consent is requested only for screening purposes and to be able to mail the recruitment letter. After a veteran has expressed interest in the study, the veteran's verbal consent will be taken to ask the screening questions in person or over the phone. Please see attached screening questionnaire. These are basic questions that will be obtained and hence involves no more than minimal risk and will not adversely affect the privacy or welfare of those involved. If the veteran does not screen positive, the screening data will be destroyed. If the veteran screens positive, they will be invited for an in-person or phone appointment where a research team member will go over the study consent form, obtain verbal consent and answer questions they may have.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?
Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.
We are requesting permission to verbally consent participants. Given the workshop (intervention) and research assessments are non-invasive in nature and almost exclusively involve teaching coping skills, providing education on common difficulties of returning veterans and assessment of participant functioning, we have

established procuring verbal consent to decrease participant burden, minimize contact (by reducing pen exchange etc.) and allow for 6 feet distance between research staff and participants. To further improve this process, we are requesting to verbally consent participants to afford us greater opportunities to increase our outreach to Veterans that would otherwise decline participation due to the burden of having to mail the signed consent form in the event they would prefer to complete the consent and study procedures over the phone due to risks of exposure to COVID-19. Other advantages include, enrolling distressed Veterans who may not be accessing care because they see paperwork such as signing consent forms as a deterrent to seek help.

Patients will be initially introduced to the study and screened by telephone. Veterans who wish to participate and meet screening eligibility, will be provided the informed consent document without signature lines, study timeline and team contact sheet. A team member will then review the consent document, provide the opportunity to ask questions and complete the baseline assessments. A record that the participant verbally consented will be stored in the study database, along with the date consent was obtained and the name of the research staff that completed the consent procedures. For participant that prefer to do the consent procedure over the phone, the informed consent document without signature lines, study timeline and team contact sheet will be mailed prior to the phone appointment. The study coordinator or other research staff will then follow up with the patient by telephone. Telephone consent will occur before administering baseline measures. Our protections for confidentiality are described below.

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.

OEF/OIF/OND Veterans with deployment-related mTBI (optional), stress-based psychopathology, and pain will be recruited from the MEDVAMC, Community-Based Outpatient Clinics (CBOCs) and Vet Centers. At the MEDVAMC, OEF/OIF/OND Clinic, Womens Health Clinic, Mental Health Care Line (MHCL), the Pain and Post-Deployment clinics as well as other outpatient clinics from other care lines will be targeted for recruitment. We will meet with key staff and providers from clinics, local Veterans' community organizations, college campuses etc. to inform them about the study, provide copies of study recruitment materials, and ask them to tell potentially eligible Veterans about the study. We will also identify potential participants through advertisements (flyer attached) posted in these clinics, community organizations, colleges and social media pages of these Veteran friendly places seeking OEF/OIF/OND Veterans over 18 years of age. Advertisements will list a phone number to call for more information and for a brief screening. We will also draw participants from the Translational Research Center for TBI and Stress Disorders (TRACTS) at the MEDVAMC under the direction of co-PI Dr. Ricardo Jorge. We will also identify OEF/OIF/OND patients through the VA Informatics and Computing Infrastructure (VINCI) & CPRS screening who fit our eligibility criteria. A letter of invitation & brochure to participate in the study will be mailed to eligible Veterans, with information on how to opt out. Approximately 1 week after the mailing, a member of the study team will follow-up with potential participants by phone to describe the study, confirm eligibility (by completing attached screener) and schedule those who are eligible for an in-dept assessment. If the team is unable to reach the participant over phone, a follow-up email will be sent with a secure link to complete the screening surveys online if they are interested in participating. Veterans who call and are interested, will also complete the screening process. Screening will take approximately 5-10 minute and takes place even prior to consent. During the screening, the research team member may describe the study to the participant as needed and will obtain the subject's verbal consent for the screening questions to determine eligibility to participate in the study. If participant continues to meet eligibility after screening, he/she will be invited to review consent material and for a more in-depth assessment with a research assistant. At this time, the Veterans will be provided the informed consent document without signature lines. A team member will then review the consent documents, provide the opportunity to ask questions, and explain the risks and benefits of participation. Study staff will explain to the participants that participation in the study is voluntary and will in no way affect his/her treatment/ benefits and that they can withdraw from the study at any time without explaining why. If the Veteran agrees, a record that the participant verbally consented will be stored in the study database, along with the date consent was obtained and the name of the research staff that completed the consent procedures. However, if the potential participant does not wish to travel for this appointment or has scheduling difficulties (on the part of the patient) but is still interested in participating, we will offer to obtain informed consent over the phone and we will send the patient the consent materials . We will call the subject approximately 5 days later and review the consent materials with them over the phone and answer any questions they may have. After this, if the patient agrees to participate, a record that the participant verbally consented will be stored in the study database, along with the date consent was obtained and the name of the research staff that completed the consent procedures.The assessments for these Veterans may be completed over the phone and through Qualtrics or mail.

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:
Yes

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

Full Social Security #:
Yes

Partial Social Security # (Last four digits):

Yes

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Will identifiable biospecimens be stored for future research?
NA

If yes, is the storage of biospecimens optional for subjects?
NA

Will identifiable private information be stored for future research?
NA

If yes, is the storage of information optional for subjects?
NA

Questionnaire, Survey, and/or subject diary
NA

Other:
No

At what institution will the physical research data be kept?
The research team will be working out of the HSR&D. Paper data will be stored in locked filing cabinet in a locked file storage room #201 located at: Michael E. DeBakey VA Medical Center Health Services Research & Development Center for Innovations in Quality, Effectiveness and Safety(HSR&D IQuESt) Nabisco Building 2450 Holcombe Blvd., Suite 01Y Houston, TX 77021

How will such physical research data be secured?
It will be secured at HSR& D at Michael E. Debakey VA Medical Center. The data will be in a locked cabinet behind a locked door - (double locked environment); HSR&D is a controlled access environment and only research staff has privilege to. 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.

At what institution will the electronic research data be kept?
Electronic data, including workshop (in-person audio recordings and Zoom recordings) that are recorded will be stored on the M drive (Nabisco):M drive/RESEARCH/Dindo_L_SERVE_H-46432. The database will stored in the above folder on the M drive using a VA computer so that the data is kept behind the VA firewalls. The IQuESt M drive is on the VA virtual server which is located at the MEDVAMC main hospital, 2002 Holcombe Blvd, Houston, TX 77030

Electronic data will be also be managed with an on-line tool, Qualtrics Survey Software 62. Qualtrics is a secure, web-based application designed to support data capture for research studies. All Qualtrics accounts are password protected and only study team members have access to the account. Once the surveys are created, it will be dispatched electronically to study participants if they prefer completing the surveys online. Each participant gets a unique link to the survey, which can be used only once, and no identifying information is collected in the survey. Completing on-line questionnaires eliminates the need for in-person visits or for mailing out paper surveys. This is especially valuable for Veterans that are unable to present for in-person visits during regular business hours or who live far. Finally, completing surveys on-line is more acceptable and accessible to OIF/OEF/OND Veterans who are very familiar and comfortable with electronic devices.

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):

Audio and zoom recordings & Qualtrics data will be downloaded and stored on the M drive (Nabisco):M drive/RESEARCH/ Dindo_L_SERVE_H-46432. The IQuESt M drive is on the VA virtual server which is located at the MEDVAMC main hospital, 2002 Holcombe Blvd, Houston, TX 77030. Once the recordings are downloaded to the M drive they will be deleted from the audio recorder.

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.

Study personnel will have access to the study electronically via a shared folder that will be stored on the M drive (Nabisco):M drive/RESEARCH/ Dindo_L_SERVE_H-46432. Non-sensitive research data will be collected via Qualtrics and then downloaded from Qualtrics website (https://capresearchbcm.az1.qualtrics.com/Q/MyProjectsSection) and saved to the M Drive in the project's folder.

Will you obtain a Certificate of Confidentiality (COC) for this study?

No

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

Olympus DS 7000 and DS 9500 will be used for audio recordings. The recorders are data encrypted and require a password to be heard. The recordings will be uploaded to the study folder on the M drive. Once the recordings are downloaded to the M drive they will be deleted from the audio recorder. Only the study personnel will have access to all study data electronically via a shared folder that will be stored on the M drive (Nabisco):M drive/RESEARCH/ Dindo_L_SERVE_H-46432.

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.

Subjects will not be responsible for research related costs.

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:

120

Distribution Plan:

Participants can receive a total of $120 for completing assessments over the course of the study ($30 for baseline, $30 for 6 week follow-up, $30 for 3 month follow-up & $30 for 6 month follow-up).

Veterans will also be provided with $20 travel compensation to attend the workshop. And, Veteran participants living outside the immediate Houston area will also be reimbursed up to $25 for mileage during in-person visits (baseline visit and workshop).

All payments are issued via Direct Deposit via the VA payment system using the VA payment voucher.

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(other than food) 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)

None

Section R: Advertisements

Mode of Advertising: Bulletin Board

Exact language of Advertisement:
Flyer (for bulletin board and social media) is attached to Section S- Serve Flyer

Mode of Advertising: Other: Study Brochure

Exact language of Advertisement:
Study Brochure is attached to Section S. - Serve Brochure