Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-37470
Status: Approved
Initial Submit Date: 6/23/2016
Approval Period: 10/19/2018 - 10/18/2019

Section Aa: Title & PI

A1. Main Title

ONE-DAY LIFE SKILLS WORKSHOP FOR VETERANS WITH MILD TBI, PAIN, AND PSYCHOPATHOLOGY

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

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Traumatic brain injury (TBI) is the signature wound of veterans returning from Operations Iraqi Freedom and Enduring Freedom (OIF/OEF). Among those with a mild TBI (mTBI) diagnosis, the majority also suffer from stress-based psychopathology including depression, post-traumatic stress disorder, and other anxiety disorders, as well as persistent pain. Poor management of multiple conditions results in increased morbidity and mortality, increased risk for suicide and significantly decreased quality of life. Importantly, the association between seeking mental health care and stigma among veterans is frequent. Veterans are often unwilling to seek mental health services due to conerns that receiving such care would

negatively impact their careers and the belief that they should be able to overcome psychological difficultires on their won. Furthermore, availability of speciality services is limited for those veterans living in rural settings. Thus the challenge for treatment providers is to provide a unified, efficient, accessible, and acceptable intervention for Veterans with these interdependent systemic comorbid concerns.

Acceptance and Commitment Therapy is a trans-diagnostic behavioral intervention aimed at helping individuals develop greater psychological flexibility in facing life's challenges. Its unified model of behavior change has shown promise in treating depression, anxiety, and chronic medical conditions. Importantly, ACT has been effectively implemented in various treatment-delivery formats, including 1-day workshops. This flexibility in delivery format allows focus to be placed on how best to package and deliver the intervention to meet the needs of this Veteran patient population, to ensure treatment adherence, and also to increase chances of dissemination into clinical settings. Providing a 1-day ACT "workshop" for veterans with mTBI, pain, and mental health problems will allow unitary comprehensive care for the range of emotional, physical, and cognitive symptoms experienced by these veterans. Presenting the treatment as a "workshop" rather than "therapy" will also be better suited for the veterans who may not be explicitly seeking specialized mental health care. Finally, a 1 day workshop ensures treatment adherence and completion, the lack of which is often the greatest obstacle to effective delivery of mental health services.

Section D: Purpose and Objectives

The aims of this study are to 1) develop a 1-day (6 hour) "ACT on Life" workshop tailored specifically for veterans with mild traumatic brain injury (mTBI), stress-based psychopathology, and pain; expert input from a multi-disciplinary team of a clinical psychologist, neuropsychiatrist, cognitive psychologist, and anthropologist will be utilized to produce the therapist intervention and patient manual; 2) enroll 10 veterans with mTBI, stress-based psychopathology, and pain in the "ACT on Life" workshop in order to obtain qualitative and quantitative feedback from veterans about the intervention; and utilize Veteran feedback to refine the treatment procedures and manuals; and 3) pilot the revised "ACT on Life" workshop in a new sample of 30 veterans with mTBI, stress-based psychopathology, and pain in order to examine the preliminary efficacy of the intervention on quality of life and functioning, stress-based symptoms of psychopathology, and pain.

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:
Patients

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 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:
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.
Advertising/Recruitment: Potentially eligible Veterans will be identified through the following means: 1)Posters will be placed in MEDVAMC, and will contain the PI's telephone number for either a phone or in person screening. 2) Brochures will also be handed out by faculty in clinics at MEDVAMC. These brochures will also have the PI's telephone number for a phone or in person screening. 3) Specific recruitment will be

targeted in the TBI clinic at MEDVAMC via posters, brochures, and faculty/staff and will contain information for screening. 4) Recruitment materials (flyers, brochures etc.) will be provided to local Veterans' community organizations and college campuses for distribution. 5) Recruitment flyers will be posted on social media pages of different veteran organizations and other community social media pages.

Screening: Once a patient has expressed interest in the study, he/she will undergo a brief in-person or phone screening prior to the first consent. During the screening process, the Veteran will be asked questions related to his age, OEF/OIF/OND status, and whether he/she has a history of mild TBI, any chronic pain difficulties, and a current level of distress (see attachment for screening). The research team member may answer any questions and describe the study to the participant as needed. If participant meets screening eligibility, he/she will be told briefly about the study and will be told that he/she can review the consent in detail during an in-person meeting.

Initial Assessment: At the beginning of the initial assessment, a team member will go over the consent and answer any questions the patient has regarding the study. If interested, the patient will sign the consent forms and study procedures will begin. The Veteran will undergo a clinical interview and complete self-report measures. This clinical interview will be used to confirm the presence of mTBI, significant distress, and pain. Those who are eligible will be invited to the treatment phase.

Pilot 1: The first 10 Veterans will be invited to participate in a one-day workshop focused on teaching coping skills. These 10 Veterans will also complete 2, 6, 12 week follow-up assessments and will provide feedback about the workshops.

Pilot 2. For the second pilot, all following Veterans who are eligible will be randomized at a 2:1 ratio to either the workshop group or treatment as usual group (TAU). These Veterans will also complete 2, 6, 12 week follow-up assessments. Veterans who were assigned to the workshop will also provide feedback about the workshops.

All participants will be given the opportunity to ask questions at any time throughout the study and will be reminded that participation is completely voluntary. They will also be told that this study will not affect their hospital care in any way.

Inclusion Criteria:

1) 18-60 years of age, 2) Clinically significant psychological distress as operationalized by a diagnosis of major depressive disorder, generalized anxiety disorder, or PTSD, 3) Life time history of Mild TBI; 4) Presence in medical chart of chronic pain including headache, musculoskeletal pain or neuropathic pain; 5) Stable dose of psychiatric medications for the past 4 weeks.

Exclusion Criteria:

1) History of primary psychotic disorder (e.g., schizophrenia, schizoaffective disorder); 2) a diagnosis of substance dependence in the year prior to enrollment in the study; 3) Active suicidal ideation; 4) Homicidal ideation.

F2. Procedure

Participants who are interested in the study will complete a brief (5 minute) screening (see attachment) either in-person or over the phone. This takes place even prior to consent. If screening criteria are met, the patient will be invited to the clinic for an in-person assessment/interview phase. At the beginning of the in-person visit, 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, he/she will sign the consent and complete an assessment. The initial assessment will take approximately 3 hours to complete.

The following measures will then be completed:

Clinical Interviews. The Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-IV) will be used to assess major DSM-IV Axis I diagnoses, including mood disorders, anxiety disorders, and other psychiatric disorders; the Clinician Administered PTSD Scale (CAPS), the gold standard in PTSD assessment, will be used to make a current, post-deployment, and/or lifetime diagnosis of PTSD.The Boston Assessment of TBI-Lifetime (BAT-L) will be used to determine history of blast exposure and subsequent blast-related TBI.

At baseline, pattern separation task will also be completed where participants will be shown pictures of everyday objects and asked to indicate if the picture is old, new, or similar which provides an assessment of memory performance. The delay between first presentation and repeated presentation of a lure or repeated image will vary. Images remained on the screen for 2 seconds, followed by a 500 millisec inter-stimulus interval. Participants will view a total of 324 images.

Self-Report Measures. Demographic questionnaire - The Depression Anxiety and Stress Scale (DASS-21) -The PTSD CheckList ¿ Civilian Version (PCL) - The McGill Pain Questionnaire - The Brief Pain Inventory (BPI) - The World Health Organization Disability Assessment Schedule II (WHODAS-II) - The World Health Organization-Quality of Life (WHO-QOL) - The Military to Civilian Questionnaire (M2C-Q) - Medication usage and therapy involvement - Brief Religious Coping Scale (R-COPE) - Chronic Pain Acceptance Questionnaire (CPAQ) - Cognitive Fusion Questionnaire (CFQ-13) - Acceptance and Action Questionnaire (AAQ-II) - Experiences Questionnaire (EQ) - Chronic Pain Values Inventory (CPVI) - Pain Intensity - Committed Action Questionnaire (CAQ) - Trauma Recovery Scale, Part III (TRS) - Impact of Events Scale (IES) - Social Network Index (SNI) - UCLA Loneliness Scale - Moral Injury Scale (MIS)

Treatment: Pilot 1. If the assessment confirms the presence of psychopathology and mTBI, the patient will be invited to attend a workshop called ACT on Life based on Acceptance and Commitment Training (ACT). 10 Veterans will complete this ACT on Life Workshop.

Workshop: Patients in the ACT condition will attend a 1-day group workshop. Each ACT group will be held at MEDVAMC, include 5-8 patients, and will last 6 hours. The ACT group will be conducted by the PI and a doctoral level psychologist or advanced doctoral student. The intervention includes: 1) Behavioral Change Training (2 hours) involving a) teaching patients how to recognize ineffective patterns of behavior and habits, b) exploring

and setting life goals and goals related to mental and physical health, and c) promoting effective and committed actions to achieve these goals despite the urge to do otherwise; 2) Mindfulness and Acceptance Training (2 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 can¿t take this pain anymore¿ or ¿I am not good enough¿) and learning how to face willingly experiences that cannot be changed; and 3) Education about PTSD, TBI, and chronic pain conditions (2 hours).

A total of 10 Veterans will complete the ACT on life Workshop in Pilot 1. These 10 Veterans will provide feedback about the workshop at 2-weeks and 12-week follow-up visits. The feedback will be used to make modifications to the ACT on Life workshop so that it is more Veteran-centric. All following eligible Veterans will be part of Pilot 2.

Pilot 2. If the assessment confirms the presence of psychopathology and mTBI, the patient will be randomized into either the ACT workshop or treatment as usual condition (TAU). The ACT workshop will be similar to that described above but will incorporate feedback from Veteran who completed Pilot 1 and any additional edits from the expert team.

An individualized phone booster session will take place 3-4 weeks following the workshop. During the phone call, we will ask participants if they are using the strategies taught, troubleshoot difficulties, and review some of the main concepts taught in the workshop. The booster session interview guide is attached.

Follow-up: At 2 weeks, 6 weeks, and 12 weeks, following the workshop, patients in both the ACT and Treatment as Usual (TAU) groups will complete assessments over the phone or in-person.

The follow-up assessments are expected to take 1 hour and are attached.

At the 2-week follow-up, the following self- report measures will be completed: Chronic Pain Acceptance Questionnaire (CPAQ) - Chronic Pain Values Inventory (CPVI) - Acceptance and Action Questionnaire (AAQ-II) - Experiences Questionnaire (EQ) - Group Climate Questionnaire (GCQ) - Client Satisfaction Questionnaire (CSQ) - Feedback about workshop - Pain Intensity Scale - Therapy and medication usage - Committed Action Questionnaire (CAQ) - Cognitive Fusion Questionnaire (CFQ-13) - Brief Religious Coping Scale (R-COPE) - Trauma Recovery Scale, Part III (TRS) - Impact of Events Scale (IES) - Social Network Index (SNI) - UCLA Loneliness Scale .

Feedback about the workshop will also be obtained from the Veterans.

At the 6-week follow-up, the following self-report measures will be completed: Chronic Pain Acceptance Questionnaire (CPAQ) - Chronic Pain Values Inventory (CPVI) - Acceptance and Action Questionnaire (AAQ-II) - Experiences Questionnaire (EQ) - Pain Intensity Scale - Therapy and medication usage -Committed Action Questionnaire (CAQ) - Cognitive Fusion Questionnaire (CFQ-13) - Brief Religious Coping Scale (R-COPE) - Trauma Recovery Scale, Part III (TRS) - Impact of Events Scale (IES) - Social Network

Index (SNI) - UCLA Loneliness Scale

At the 12-week follow-up, the following will be completed: Clinical Interviews. The Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-IV) - the Clinician Administered PTSD Scale (CAPS). Feedback about the workshop will also be obtained from the Veterans.

The pattern separation task will again be repeated at the 12 week follow-up.

Self-Report Measures. The Depression Anxiety and Stress Scale (DASS-21) -The PTSD CheckList ¿ Civilian Version (PCL) - The McGill Pain Questionnaire - The Brief Pain Inventory (BPI) - The World Health Organization Disability Assessment Schedule II (WHODAS-II) - The World Health Organization-Quality of Life (WHO-QOL) - The Military to Civilian Questionnaire (M2C-Q) - Medication usage and therapy involvement - Brief Religious Coping Scale (R-COPE) - Chronic Pain Acceptance Questionnaire (CPAQ) - Cognitive Fusion Questionnaire (CFQ-13) - Acceptance and Action Questionnaire (AAQ-II) - Experiences Questionnaire (EQ) - Chronic Pain Values Inventory (CPVI) - Pain Intensity - Committed Action Questionnaire (CAQ) - Trauma Recovery Scale, Part III (TRS) - Impact of Events Scale (IES) - Social Network Index (SNI) - UCLA Loneliness Scale.

Assessments and the treatment intervention will be audio-recorded. The audio recordings will be used for 1) assessment of treatment integrity (i.e., to ensure that therapists are following study procedures) and 2) for inter-rater reliability of the clinical interviews.

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 80 Worldwide: 80

Please indicate why you chose the sample size proposed:

80 Veterans with mTBI, stress-based psychopathology, and pain will be enrolled in this research study.

Initially, ten Veterans will be enrolled in the ¿ACT on Life¿ workshop and the PI will obtain their feedback on the intervention so that it may be adapted and refined to meet the unique needs of OIF/OEF/OND Veterans with these comorbid conditions; all remaining eligible and interested Veterans will be randomized at a ratio of 2:1 to the refined ¿ACT on Life¿ workshop or TAU in order to obtain preliminary data on the efficacy of this workshop on quality of life, functioning, distress, and pain interference.

Recruitment feasibility of approximately 4 subjects per month over the study period and budgetary restrictions were the main considerations for sample size determination. This study has adequate (i.e., 80%) power to detect at least Cohen¿s ds > 1 (i.e., large effect sizes) at a 5% significance level. Previous research has established that, when compared with TAU, ACT interventions have clinically relevant moderate effect sizes (i.e., smaller than the

effects this study is powered to detect). Thus, this study is underpowered to show clinically meaningful efficacy of ACT when compared to TAU. However, this is not an issue given the pilot nature of this RCT. This pilot RCT will allow to determine feasibility of a larger well-powered RCT. For instance, this pilot RCT will allow the PI to determine if recruitment, participants¿ randomization willingness and follow-up retention rates estimates are as anticipated and can be applied in the planning of a larger RCT in this population for which ACT will be developed for the first time in Aims 1 and 2 of this proposal.

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?

Frequency data will be gathered on the number of veterans screened for participation and the number willing to participate in the study, the number of Veterans who are not eligible to participate and the reasons for lack of eligibility will also be tracked to identify the proportion of Veterans who may have difficulties and may be in need of an intervention.

We hypothesize that at 3-month follow-up, Veterans randomized to ¿ACT on Life¿ will experience greater improvements in Quality of life (WHO-QOL), functioning (WHODAS-II), distress (DASS-21), and pain-interference (BPI) compared to the TAU group. Data collected at baseline, 2-, 6- and 12-weeks follow-up for each of the aforementioned outcomes of interest will be compared between the groups using a generalized linear mixed model (GLMM) that can accommodate repeated measures over time and missing data due to loss to follow-up or missed interviews. Based on our previous experience with this population and the high retention rates for 1-day ACT trials, we anticipate a 10% loss-to-follow-up rate at the 12-week evaluation. The GLMM model for each outcome will include group, week (continuous outcome) and group by week interaction as the predictors. The influence of key demographic variables (e.g., age, rural/urban, gender) on the outcomes of interest will also be explored by adding these variables as predictors to the linear models.

Co-I Martin will train the research assistant in qualitative data analysis techniques. Dr. Martin and the research assistant will complete an initial reading of the transcripts and develop a codebook containing inductive codes (i.e. codes that emerge out of participants¿ experiences) and deductive (i.e. a priori) codes based on the literature and ACT domains (e.g. acceptance, values, and committed action). Analysts will code the data using the Atlas.ti (v.7) software. Using a process of negotiated consensus, analysts will meet regularly to compare coding results, resolve discrepancies, refine the codebook and resulting themes. To optimize the validity of our findings, Dr. Dindo will independently review the results and meet regularly with analysts to provide expert feedback on the codebook development and final themes. Qualitative feedback from the Veterans will enable the PI to work with Co-Is Jorge, McGlinchey, and Martin to refine the ACT intervention to be more Veteran-centric (Aim 2.b).

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:

Risks associated with assessment phase: Clinical interviews and self-report assessments contain questions regarding sensitive personal information. As a result, participants may be embarrassed or distressed when discussing current or past difficult life events. Patients may also experience fatigue from completing interviews/questionnaires and physical strain of making the movements involved in pressing the buttons or moving a mouse for the pattern separation task.

Risks associated with the treatment phase: Patients may experience fatigue from a day-long intervention. Patients may feel uncomfortable being in a group with other patients. Patients may feel distress at addressing their difficulties.

To minimize risks associated with completing questionnaires, patients will be told that they do not have to answer any question that they do not want to. They will also be reminded of their right to discontinue participation at any time during the study.

To physical strain for the pattern separation task will be minimal and equal to or less than that associated with a brief period of playing an average, commercial video game.

In order to minimize fatigue associated with a day-long group treatment intervention, several breaks will be given throughout the day and food/drink will be provided. In order to minimize discomfort with being in a group treatment, patients will be reminded of the importance of confidentiality. Patients will also be reminded that they can disclose as little or as much information as they find comfortable. All participants will be encouraged to use only first names in the group for confidentiality purposes. Finally, patients will be able to discontinue the treatment at any time.

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.

We do not know if subjects will benefit from being in this study. However, we hope that some patients will experience some relief from psychological distress symptoms or improved quality of life following the study protocol.

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

TBI is the most common injury reported among veterans of OIF/OEF. Mild TBI and its associated conditions hamper the well being of returned veterans. Effective treatments are needed to improve the quality of life and functioning of these veterans. Results from a number of studies shows the effects of a 1-day ACT workshop to be positive on the functioning and emotions of patients with a variety of mood disorders and chronic cognitive impairments. We hope that this intervention, which is relatively brief and thus easier to access than weekly treatment, will improve stress-based psychopathology and general functioning in patients with mTBI and pain. This study is one of the first to develop a 1-day ACT treatment specifically for mTBI patients. If it shows positive effects, it could be applied more efficiently and cost-effectively than weekly psychotherapy to a larger group of patients.

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

This protocol has a favorable risk-benefit ratio because patients will be taught new skills to manage distress and pain 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 is required to review the records to determine their eligibility for the study. 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 and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

The probability of harm does not exceed what one might expect from daily life or from similar situations. Only the research team will be accessing the health records and nothing will be printed, removed, altered, or extracted from the patient's files.

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

The PHI access will only be used to determine patient's eligibility for the study and will not be shared outside of the research team. Patient's records will not be altered in any way, therefore there is no change to their healthcare welfare.

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.

It is a necessary tool to ensure that patient's qualify for the study. Oftentimes, patient's approach the research team and are interested about the study but do not qualify. In order to encourage optimal participation, it is appropriate for the research team to access and use patient's protected health information to ensure the study is appropriate for the patient.

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

The PHI access will only be used to determine eligibility for the study and will not be shared outside of the research team.

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.

All data will be destroyed, including identifiers, 6 years after the conclusion of the study but may be retained longer if federal regulations mandate it.

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 access will only be used to determine eligibility for the study and will not be shared outside of the research team.

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.

Since waiver is to screen patients for eligibility into a study, there would not be information to disclose to subjects.

J1a. Waiver of requirement for written documentation of Consent

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

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

The research population will be identified through various methods such as advertisements, posters, flyers, and brochures. Physicians and staff at the VAMC can provide Veterans with a brochure and/or our contact information and the Veteran can contact the PI and study staff if interested in participating. Recruitment materials (flyers, brochures etc.) will also be provided to local Veterans' community organizations and college campuses for distribution. In order to reach veterans that don't necessarily visit the VA, we will also post recruitment flyers on social media pages of different veteran organizations and other community social media pages.

Once a patient has expressed interest in the study, he/she may undergo an in person or phone screening prior to the first consent. During the screening call, the research team member may answer any questions and describe the study to the participant as needed. If participant continues to meet eligibility after screening, he/she will be told briefly about the study and will be told that he/she can review the consent in detail during an in-person meeting.

Interested individuals will have an appointment scheduled during which a member of the

research study staff (research assistant, PI and Co-Is) will obtain consent from research subjects which includes describing the study and review of the informed consent form, and explaining 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 and that they can withdraw from the study at any time without explaining why. Veterans interested in participating in the study will sign an IRB approved consent to participate in this 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:

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

At what institution will the physical research data be kept?

The research team will be working out of the Health Services Research & Development (HSR&D) and Michael E. DeBakey VA Medical Center (MEDVAMC). Data will be stored on VA servers and in locked filing cabinets in a locked room located at Health Services Research & Development Center of Excellence (HSR& D CoE) Nabisco building - 2450 Holcombe Blvd., Suite, 01Y Houston, Texas 77033, room 175.

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.

How will such physical research data be secured?

It will be secured at HSR&D at Michael E. Debakey VA Medical Center, Building 152, room 175. 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.

All sessions will be audio recorded by the Research Clinician using a Olympus DS-3500. The recorders are data encrypted and require a password to be heard. The recordings will be uploaded to the VA database and stored on the M drive. Once the recordings are downloaded to the M drive they will be deleted from the audio recorder. The database will be stored on a secure VA server located at the HSR&D facility which is located behind a firewall. These servers are password-protected and are behind a locked door with access limited to IT personnel. During non-business hours, the server is behind 3 locked doors. The

Center has restricted access and is not a patient-care facility. The servers are backed up automatically each night. The VA server is located under the server drive (M-HSRD, L-other).

At what institution will the electronic research data be kept?

Electronic data will be stored on the M drive (Nabisco) under the Projects folder - M:\Projects\Dindo . The database will be stored on a secure VA server located at the HSR&D facility which is located behind a firewall. These servers are password protected and are behind a locked door with access limited to IT personnel. During non-business hours, the server is behind locked doors. The Center has restricted access and is not a patient-care facility. The servers are backed up automatically each night. Data will not leave the MEDVAMC.

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):

The recordings will be uploaded to the VA database and stored on the M drive. Once the recordings are downloaded to the M drive they will be deleted from the audio recorder. The database will be stored on a secure VA server located at the HSR&D facility which is located behind a firewall. These servers are password-protected and are behind a locked door with access limited to IT personnel. During non-business hours, the server is behind 3 locked doors. The Center has restricted access and is not a patient care facility. The servers are backed up automatically each night. The VA server is located under the server drive (M-HSRD, L other).

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.

Data will not be submitted to sponsors and/or collaborators.

Will you obtain a Certificate of Confidentiality for this study?

No

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

All sessions will be audio recorded (both ACT workshop and clinical interviews) by the Research Clinician using a Olympus DS-3500. The recorders are data encrypted and require a password to be heard. The recordings will be uploaded to the VA database and stored on the M drive. Once the recordings are downloaded to the M drive they will be deleted from the audio recorder. The database will be stored on a secure VA server located at the HSR&D facility which is located behind a firewall. These servers are password-protected and are

behind a locked door with access limited to IT personnel. During non-business hours, the server is behind 3 locked doors. The Center has restricted access and is not a patient-care facility. The servers are backed up automatically each night. The VA server is located under the server drive (M-HSRD, L-other).

Approved staff from the VA Salt Lake City (VASLC) will transcribe the non-identifiable audio recordings of participants' workshop feedback. The VASLC has a Professional Transcription Service available to VA sites and monitored by their own IRB. The study audio recordings to be transcribed by VASLC staff will be labeled by the subject's unique ID number and saved behind the VA Firewall in secure shared project folder (Dindo Transcriptions) on the M- Drive of the VA computer. The VASLC transcription staff will be given access to a sub-folder within the secure project folder. Approved study staff will place a copy of the audio files in this folder for an approved VASLC transcriptionist to access for the purposes of transcription. The VASLC transcriptionist will transcribe each interview verbatim and save the completed transcript in the sub-folder using the same ID number. No data (audio files, in process transcripts, or completed transcripts) will leave the MEDVAMC secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub-folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses.

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:

155

Distribution Plan:

Enrolled participants will be paid $100 for completing assessments over the course of the study ($30 for baseline, $20 for 2 week follow-up, $20 for 6 week follow-up, and $30 for 3 month follow-up). We have also allocated $25 per participant for meals and snacks during the 6-hour workshop. Participants will also be reimbursed up to $30 per participant for mileage during in-person visits (for anyone living outside the immediate Houston area). ($6000 or $3,000 in each year of the project)

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)

None

Section R: Advertisements

Mode of Advertising: Other: Brochures

Exact language of Advertisement:

If the adjustment back to civilian life has been challenging, consider participating in a new study at the Michael E. DeBakey VA Medical Center.

What is the goal of the study? The goal of this study is to better understand the experiences of returning OIF/OEF/OND Veterans and to provide strategies to help Veterans develop resilience and adjust to new challenges.

What will happen during the study? If you agree to take part in this study, you may be invited to an 1-day group workshop with other Veterans who have had similar experiences. During the workshop, strategies and skills will be taught on how to develop resilience in the face of stress and difficulty

How do I join? Call 713-794-7493 to discover if you are eligible. If we are unable to answer your call, please leave a message and we will return your call promptly.