One-day Life Skills Workshop for Veterans with TBI, pain, and Psychopathology: Evaluating efficacy and mechanism of change

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SERVE
SUPPORT & EDUCATION FOR RETURNING VETERANS

Please read this information and feel free to ask any questions before you agree to take part in the study. A team member will also go over this information with you and you will be given a copy of this information sheet to keep.

Summary:

You are invited to take part in this research study because you have indicated that you are experiencing some post-deployment difficulties. The purpose of this research it to see whether a 5 hour group skills workshop, that teaches coping skills, will help you adjust to post-deployment difficulties and to improve your quality of life and participation in day to day activities.

Taking part in this research study is completely voluntary and if you decide to participate, your participation will last from now to about 6 months following the workshop. Your participation will involve an in-person or phone interview and filling out several surveys and if you are eligible, you will be randomly assigned to receive one of the two study interventions. Each workshop is approximately five hours and will be held virtually (online) over a secure zoom platform or at MEDVAMC or a local VA or non-VA facility with other Veterans. The content of the workshop will depend on what group you are assigned to, but will broadly focus on teaching coping skills and providing education on common difficulties of returning veterans. You will also be among other Veterans with similar previous experiences. Lunch will be provided (for in-person workshops only) and breaks will be offered to minimize fatigue.

You will be compensated for your time. The risks of participating are very low. We don't know if you will benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because of knowledge gained about this treatment for veterans with emotional distress.

Background:

You are invited to take part in this research study because you have indicated that you are experiencing some post deployment difficulties. This study is attempting to better understand the experiences and difficulties of returning veterans and to offer a 1-day workshop to help with adjustment to these difficulties. This research study is funded by VA CENTRAL OFFICE, RR&D. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose:

The purpose of this research it to see whether a 5 hour group skills workshop , that teaches coping skills, will help you adjust to post-deployment difficulties and to improve your quality of life and participation in day to day activities. We also want to see if it helps reduce your distress and strengthen your relationships with other people.

Procedures:

The research will be conducted at Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center.

If you agree to take part in this study, your involvement will last from now to about 6 months post workshop. At your initial assessment, we will first go over this form, answer questions you have and will ask you to verbally consent if you are interested in participating in the research study. A specially trained clinician will ask questions about your TBI, your personality and emotions, and about your general approach to life. You will also fill out, on your own, some questionnaires about your daily functioning, mood, quality of life, and pain. You may skip any question you prefer not to answer. The first assessment will last approximately 2 hours.

If your pain and your emotional distress are below a certain limit, then your involvement in this study will end at this point. If your pain and your emotional distress are above a certain limit, then you are eligible to continue in the study and will be scheduled to attend a skills workshop.

On the day of the skills workshop, you will be randomly assigned to receive one of the two study interventions. This means that whichever study intervention you receive will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving any one of the study interventions.

Both interventions involve attending a 5 hour skills workshop to be held virtually (online) over Zoom OR in-person at the MEDVAMC or a local VA or non-VA facility with other Veterans that will be facilitated by two psychotherapists. For the virtual (online) workshop, a secure zoom platform will be used where attendees will be provided a password to be able to join the workshop. This way only invited participants will be able to join the workshop to maintain privacy of our participants. If you are scheduled to attend the virtual workshop, a team member will contact you on the phone to help set up.

The content of the workshop will depend on what group you are assigned to, but will broadly focus on teaching coping skills and providing education on common difficulties of returning veterans. Lunch will be provided (only at the in-person workshop) and breaks will be offered to minimize fatigue. In these workshops, all participants will be encouraged to use only first names in the group for confidentiality purposes. Travel reimbursement will also be given.

Post-Workshop Follow-up Schedule:
Approximately 2 & 4 weeks after the workshop, you will receive a 20 minute follow-up call to review the material covered during the skills workshop. During the phone call you will also be asked about your experiences since the workshop as well as progress made and skills utilized. At 6 weeks, 3 months and 6 months following the workshop, you will be asked to complete follow-up surveys online or over the phone or in-person. The assessments will be about your daily functioning, mood, healthcare utilization etc. You may skip any question you prefer not to answer.

All interviews, workshops & booster sessions will be recorded for quality control and will only be reviewed by the PI and PI- approved study staff of this study. The recorders are data encrypted and require a password to be heard. Recordings will be stored on a VA-approved, internal, encrypted site with access restricted only to the PI and PI-approved study staff. Upon completion of this study, data will be stored for the length required per VA and BCM policy guidelines and then, also per policy, fully destroyed so that no evidence of it remains.

Upon enrollment, you will be provided with the phone number of the Michael E. DeBakey VAMCs Suicide Prevention Coordinator as well as the Veteran crisis hotline. If at any point during study procedures, you provide information that leads us to believe that you are at risk for harming yourself or others, we will contact a study psychologist to perform a risk assessment. We may contact your current mental health provider (for example, your psychiatrist) to allow him/her to do what is necessary to help you. If you do not have a mental health provider, we may contact a close friend or family member to ensure your safety. If you would rather, we not contact anyone and we still feel you or someone else might be in danger, our study psychologists will determine what else can be done to help you. This may include recommending you go to the emergency room. Also, if you suggest that suicide is imminent you will be excluded from participation in the study.

Clinically Relevant Research Results:

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information:

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Confidentiality:

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security # (only for the purpose of compensating you)
- Partial Social Security # (Last four digits)
- Photographs, videotapes, and/or audiotapes of you

Use or Disclosure Required by Law:

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts:

You may experience emotional discomfort answering some of the question during the assessments. If you ever feel uncomfortable or embarrassed, let the research staff know. You may skip any questions you do not wish to answer.

During the workshop, you may feel uncomfortable being in a group setting and you may also experience fatigue because you are spending the whole day in the workshop. Confidentiality will be stressed in the group and breaks will be given to reduce fatigue. Also, during the workshop if you are experiencing distress and an increase in symptoms, please notify the workshop facilitator or study staff so that additional support can be provided.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits:

We don't know if you will benefit from being in this study. Results from a preliminary study show the effects of a 1-day skills workshop on the functioning and emotions of patients with a variety of conditions to be positive. Thus, we hope that participants in this study will also show improvements in functioning and mood However, you may receive no benefit from participating.

Alternatives:

The following alternative procedures or treatments are available if you choose not to participate in this study: Instead of being in this study, you could see a Psychologist or Psychiatrist to address your emotional difficulties and distress. A member of the research team can provide you with referrals if you are interested.

Subject Costs and Payments:

You will not be asked to pay any costs related to this research.
You will be paid a total of $120 over the course of your participation in the study according to the following schedule:

- Completion of initial assessment: $30
- Completion of 6-week follow-up assessment: $30
- Completion of 3-month follow-up assessment: $30
- Completion of 6-month follow-up assessment: $30

In addition, travel compensation of $20 will be provided to attend the workshop. If you live outside the immediate Houston area, you will also be reimbursed up to $25 for additional

mileage during in-person visits (initial visit and workshop). You will also receive lunch on the day of the workshop.

Payment will be issued via Direct Deposit via the VA payment system using the VA payment voucher.

Subject's Rights:

Your verbal consent means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this information sheet to keep. You are not giving up any of your rights by verbally consenting. Even after you have verbally consented, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, LILIAN DINDO, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: LILIAN DINDO at 713 440 4637 during the day.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Under Federal Regulations, the VA Medical facility shall provide necessary medical treatment to you as a research subject injured as a result by participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Michael E. DeBakey VA Medical Center. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You do not waive any liability rights for personal injury by signing this form.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC. If you would like to verify the validity of the study and authorized contacts, you may speak with the Michael E. DeBakey Veterans Affairs Medical Center Research Office at 713-794-7918 or 713-794-7566.