Title: Pilot Study Testing a Web-Based Moral Elevation Intervention for Veterans with PTSD and Moral Injury
ID: D3035-P
NCT: NCT03906240

Principal Investigator: Adam McGuire, Ph.D.

Informed Consent Form

Note: This study was granted a waiver of documentation for informed consent; therefore, participants received the following document (Review of Research Participation), reviewed the document over the phone with study staff, then provided verbal consent for participation.

Date: 07/22/2020

KEY INFORMATION FOR
MOVED: A PILOT STUDY OF A WEB-BASED INTERVENTION

We are asking you to choose whether or not to volunteer for a research study that aims to better understand how emotions impact returning war Veterans and how they might inform ways to improve treatment of PTSD. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The full title of this study is, "Moral Elevation Online Intervention for Veterans Experiencing Distress Related to PTSD and Moral Injury (MOVED): A Pilot Study of a Web-Based Intervention." By doing this study, we hope to learn how Veterans with PTSD symptoms and moral injury might benefit from a brief, web-based intervention that focuses on experiencing positive emotions. Previous studies suggest experiencing positive emotions is linked with a variety of benefits for one's physical and mental health; however, past research has largely focused on civilians and/or non-clinical populations. Therefore, the research team aims to pilot this web-based intervention to determine whether it is a feasible and acceptable intervention component for the treatment of PTSD and moral injury. Your participation in this research will last about 6 weeks as described below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you are randomized to the elevation intervention condition, a potential benefit of being in the study is that the problems you are experiencing in your life related to PTSD, moral injury, and social functioning may improve. Additionally, for all participants, your participation may lead to knowledge that will help other veterans experiencing trauma-related distress and help inform efforts to improve treatment for PTSD and moral injury. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The most important reason a participant might NOT want to volunteer for this study could be the time required to complete this study given that it requires two assessments and eight online sessions over a 6-week period. Someone might also NOT want to volunteer because there is slight risk that recalling prior experiences and completing questionnaires related to traumatic events could affect your mood. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Adam McGuire, Ph.D. (Principal Investigator) of the Central Texas Veterans Health Care System, at the VA Integrated Service Network 17 (VISN 17) Center of Excellence (CoE) for Research on Returning War Veterans. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 254-297-5094

If you have any questions, suggestions or concerns about your rights as a voluntary research participant, you should contact the Institutional Review Board Chairperson at (254) 654-6758.

DETAILED DESCRIPTION

The study you are being asked to volunteer to take part in involves research. This research study takes place at the Central Texas Veterans Health Care System (CTVHCS). It is important that you read and understand the information on this form. Using Moral Elevation to Improve Functioning in Veterans with PTSD and Moral Injury: A Pilot Study of a Web-Based Intervention is a research study conducted at the VA Veterans Integrated Service Network 17 (VISN 17) Center of Excellence (CoE) for Research on Returning War Veterans. You are being asked to volunteer to take part in this study, which aims to better understand how emotions impact returning war Veterans and how they might inform ways to improve treatment of PTSD.

PURPOSE OF THIS RESEARCH

The purpose of this research is to advance our scientific understanding of how Veterans with PTSD symptoms and moral injury might benefit from a brief, web-based intervention that focuses on experiencing positive emotions. Previous studies suggest experiencing positive emotions is linked with a variety of benefits for one's physical and mental health; however, past research has largely focused on civilians and/or non-clinical populations. Therefore, the research team aims to pilot this web-based intervention to determine whether or not it is a feasible and acceptable intervention component for the treatment of PTSD and moral injury. This research study is a local research project being conducted by Dr. Adam McGuire, which will study approximately 48 subjects. Participation in this study will last approximately 6 weeks as described in detail below.

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

To participate you must:

1. be at least 18 years of age;
2. have been deployed in support of Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn;
3. be enrolled in the CTVHCS;
4. be able to understand the information presented in this form;
5. have Internet access to complete web-based sessions and measures;
6. be diagnosed with PTSD or currently experiencing significant and impairing PTSD symptoms;
7. currently experiencing distress related to an experienced morally injurious event;
8. be able to complete the questionnaires;
9. be able willing to be randomized into either an intervention or no-treatment condition;
10. be able and willing to invite another person (e.g., partner, spouse, family member, friend) to complete observational measures of your behavior.

To be clear regarding the involvement of another person who would complete observational measures, you will not be eligible to participate in this study if you do not agree to allow study staff to contact a "significant other" of your choosing.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

All research procedures will be completed either by phone or online, which can be done from your home. The initial baseline appointment that will be conducted by phone will take about 40 minutes. The total amount of time you will be asked to volunteer for this study is approximately 4-6 hours over the next 6 weeks. For a specific breakdown of procedures and time required for each task, see "WHAT WILL I BE ASKED TO DO?" below.

WHAT WILL YOU BE ASKED TO DO?

If you consent to participate in this research study, the following assessments and procedures will occur:

1. Baseline assessment. First, you will be asked several questions by a member of research team. Then, you will complete a set of questionnaires online. The questionnaires will ask about your psychological functioning in the past

30 days. The baseline assessment will take approximately 40 minutes to complete and will confirm your final eligibility.

2. Online sessions. One week after your baseline assessment (pending confirmation of final eligibility), you will be randomized (i.e., placed by chance) to either the elevation intervention condition, or a no-treatment condition. You will have a 50/50 chance of being placed in either condition. Both conditions involve 8 online sessions—one session every Monday and Thursday for 4 weeks (i.e., 2 sessions per week). For both conditions, you will receive an email with a web-based link for each session. During sessions, you will be asked to complete brief self-report measures on your experiences in the past few days. If you are randomized to the elevation intervention condition, you will also be presented with content about positive emotions and asked to complete additional tasks including brief writing exercises and setting goals to be achieved before the next session. Each online session is expected to last approximately 20-30 minutes. To help facilitate full completion of the sessions, you will receive an email reminder every evening the session is due and a phone call the following day if you did not complete the session. You will be given 24 hours to complete the missed session.

3. Follow-up assessment. A follow-up assessment will be conducted approximately one week after you complete the online sessions, which will include several questionnaires repeated from prior assessments. This assessment may be completed over the phone or online and is expected to take approximately 40 minutes to complete.

4. Interview. If you are randomized to the elevation intervention condition, you will also be asked to participate in a 1-hour long interview to be completed at the same time as the follow-up assessment. This interview will be completed over the phone and will be audio-recorded and reviewed by study staff specifically authorized to do so.

5. Significant Other assessments. Participation in this study also requires that you identify a Significant Other (e.g., partner, spouse, friend, family member) who would be willing to complete baseline and follow-up assessments. These assessments will be focused on the Significant Other's perceptions and observations of your behavior. This information is important because we are trying to understand how improvements in trauma-related symptoms might impact improvements in relationships or connections to the important people in your life. We will ask you to provide the name and contact information for the person of your choosing. After you consent to participate in the study, we will contact your designated Significant Other and obtain their verbal consent to participate over the phone. At the same time you complete the baseline and follow-up assessments, the Significant Other will receive an email with a web-based link to complete their assessment online. Their participation is expected to last approximately 35 minutes for each assessment.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

1. Only minor, transient side effects are expected as part of this study.

2. There is a slight risk that recollections of prior experiences during interviewing or filling out forms could affect your mood or make symptoms of mental stress worse. Expected minor reactions include sadness or anxiety in remembering past experiences. These discomforts are usually short-lived and usually resolve without treatment. Everyone will be provided with a referral sheet with information about how to access local VA and non-VA mental health care for a variety of mental health needs. If you are in distress and need or request counseling, you will be offered immediate access to counseling.

3. We will guard your personal health information to prevent it from being inadvertently revealed to anyone other than the researchers. However, because of the need to give certain information to review boards, absolute confidentiality cannot be guaranteed, and there is a slight risk that sensitive information collected in this study, could inadvertently be revealed to someone who does not have a right to see it.

4. The time that you spend in research could otherwise be spent earning money, so participating in this study carries a financial risk.

5. There are no other known physical, psychological, social, financial, employment, privacy, or legal risks of participating in the study.

6. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, if you are randomized to the elevation intervention condition, a potential benefit of being in the study is that the problems you are experiencing in your life related to PTSD, moral injury, and social functioning may improve. Additionally, our research team members are available to help connect you with mental health services that are not part of the study but from which you may benefit. For all participants who take part in this study, your participation may lead to knowledge that will help other veterans experiencing trauma-related distress and help inform efforts to improve treatment for PTSD and moral injury.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are other choices such as evidence-based psychotherapies for PTSD that are available and effective for many people. You may discuss these options with study staff and with your doctor.

WHAT WILL IT COST YOU TO PARTICIPATE?

Veteran participants and non-Veteran participants do not pay for treatment associated with participation in a VA research project except in accordance with federal law. There will be no costs to you for any of the treatment or testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. The type of data collected and procedures for protecting confidentiality of data include the following.

1. Identifiable data: Identifiable data that we are collecting on you include your name, social security number, date of birth, email address, and address including zip code. All study materials that identify you such as keys, contact information, and forms with personally identifiably information will be stored in a locked office at the Waco Campus of the CTVHCS in a physically secure environment that includes controlled access and locking the materials in file cabinets. Study staff will transport data from the data collection locations to the locations where the data will be entered and stored using approved procedures and with specific authorization from the Medical Center to transport this sensitive information. All collected data will be marked with a code number. The coded data will be stored separately from where the master list linking names and code numbers is stored. Identifiable data from this study will not be transferred to another entity outside the VA. Additionally, your email address will be stored on Qualtrics—a secure, web-based program that will be used to administer online questionnaires. Adding your email address is critical to sending you links through Qualtrics that will give you access to each online session. When your email address is entered, we will NOT enter any other identifiable data (i.e., we will not include your name, SSN, date of

birth, etc.) into Qualtrics. Instead, we will use a distinct code number (see De-identified data below) to link your responses when data is downloaded and analyzed. Under normal circumstances, only the PI and the designated research team members have access to these materials. By consenting to participate in this study, you are agreeing to allow VA research team members to store and analyze data obtained in this study.

2. De-identified data: All data collected from assessments will be coded so that it cannot be identified with you and compiled into an electronic database and analyzed to produce scientific results. The electronic database will be stored on a secure VA server, and only approved members of the research team will have access to this de-identified database. Every participant will be given two numeric codes for de-identification. One code will be used for the baseline assessment and any potential paper copies, if applicable. The second code will be entered into Qualtrics along with your email. The first and second code will be two distinct numeric codes that will only be linked by ***one master list to be stored on a secure VA server***. So that scientists may learn as much as possible from the information you provide us, de-identified data collected in this research study may be shared with research collaborators from other institutions outside of the VA. By consenting to participate in this study, you are agreeing to allow research team members to store, analyze, and share de-identified data obtained in this study. IRBs and other committees will monitor and approve this future use of the data, and IRB approval to send the de-identified data other sites will be obtained before data is transferred to collaborators outside of the VA. The de-identified data will be used by research team members for an indefinite time period after the study is completed.

3. Procedures for this study include completing online questionnaires using Qualtrics. Qualtrics is a secure, web-based program to capture data. That data will be downloaded from Qualtrics and stored on a secure VA server as de-identified data (see further description above). We will make every effort to safeguard your data in Qualtrics. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

4. Any and all paper AND electronic documentation containing confidential, personally identifiable information, protected health information, and any other sensitive information will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation. Research files will be maintained, stored and destroyed in accordance with the Record Control Schedule (RCS-10-1) approved by the Archivist of the United States.

5. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your private information will be maintained according to this medical center's requirements.

6. Your medical and research records will be maintained according to this medical center's requirements. There is a possibility that the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), VA Office of Inspector General (OIG), Veterans Health Administration (VHA), other oversight agencies including the Office of Research Oversight (ORO), the Research Compliance Officer, Institutional Review Board members or other research staff may have access to your research and/or medical records or may inspect the records. Every effort will be made to keep information about you both private and confidential. Codes (not your name and social security number) will be used for all reports generated, to help maintain your confidentiality.

7. Per regulation 38 USC 7332, information about alcohol and drug use is highly protected. This information is obtained because it is important to understand your medical history and the potential relationship between substance use and the experience of PTSD symptoms. Therefore, the collection of this information is crucial to the research project. As part of this study, you consent for your drug and alcohol information history to be reviewed and released to the research team as stated in this form.

8. Study procedures include completing questionnaires online using Qualtrics. Qualtrics is a secure, web-based program to capture and store data. We will make every effort to safeguard your data in Qualtrics. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. You may withdraw from the study verbally or in writing. Withdrawal from the study will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. However, we ask that you please let the investigator know if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Adam McGuire at 254-297-5094 immediately. At any time, if you are experiencing a mental health crisis or are having thoughts of harming yourself, you may contact the Veterans Crisis Line at 1-800-273-TALK (1-800-273-8255).

VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, the necessary care must be provided in VA Medical facilities. Exceptions include: situations where VA facilities are not capable of furnishing the care or services required; and situations involving a non-veteran research subject. Under these circumstances, Directors *may* contract for such care. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. All regulations pertaining to the participation of veterans as participants, including requirements for indemnification in case of research-related injury, pertain to non-veteran participants enrolled in VA-approved research. (For additional information on research related injuries, see 38 CFR 17.85). Please note that for Department of Defense-sponsored research, Department of Defense components may have stricter requirements than the Common Rule requirements for research-related injury.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Being in the study will require some extra time and effort on your part. You will be paid for your time during the assessments. You will be paid after finishing each assessment. You will be paid in cash or via electronic payment (direct deposit). To the extent possible, you will be paid according to your preferred method, although there are times when it may not be possible to make cash payments due to the VA cashier being closed. If you meet all study criteria and complete all the assessments you will be paid a total of $180 *or* $190 as follows:

- $30 for completing the baseline assessment (40 minutes)
- $15 per online session for completing a brief questionnaire at each session (total of $120).
- Payment for completion of the follow-up assessment based on condition:
    - No-treatment condition: $30 for completing the follow-up assessment (40 minutes)
    - Elevation intervention condition: $40 for completing the follow-up assessment and 1-hour long interview (1 hour 40 minutes)

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to provide verbal consent a second time if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

You will not receive a report of the aggregate results or any results specific to your participation at the end of the study. However, you may contact Dr. Adam McGuire and request a summary of the study's findings be sent to your physical address.

WHAT ELSE DO YOU NEED TO KNOW?

1. Voluntary participation. You are not required to take part in this study: your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent. Refusal to participate now or discontinuation of participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled.

2. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

3. This study is sponsored by the VISN 17 Center of Excellence for Research on Returning War Veterans and VA Rehabilitation Research and Development (RR&D). RR&D provides financial support for this study.

4. Person to Contact. If you have any questions or concerns about the study, you can contact the Principal Investigator, Dr. Adam McGuire, at the Waco VA campus, at 254-297-5094. As a research participant in this study, if you have a complaint about any issue regarding the study, or the research investigator; or if you have questions about your rights as a research participant, you may contact The Institutional Review Board at (254) 654-6758.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.