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.

Study Protocol

Date: 06/22/2021

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1. Title: MOVED: A Pilot Study of a Web-Based Intervention
Start Date: 07/01/2019
Anticipated End Date: 07/29/2022

2. Investigators:

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Dr. Erickson has contributed to the development of the manual and will play a role in interpreting findings as a moral elevation expert. This collaborator will not have access to data and no research activities take place outside of the VA.

3. Location of Study:

1. CTVHCS Building 93, 4800 Memorial Dr, Waco TX 76711
    a. Interview Rooms: BB-103, BB-104, BB-105, BB-111, BB-117, BB-118
2. CTVHCS Building 202, 1901 Veterans Memorial Dr, Temple TX 76504
    a. Interview Rooms: D2-230, D2-232, D2-233, D2-235

4. Time Required to Complete: 6 weeks

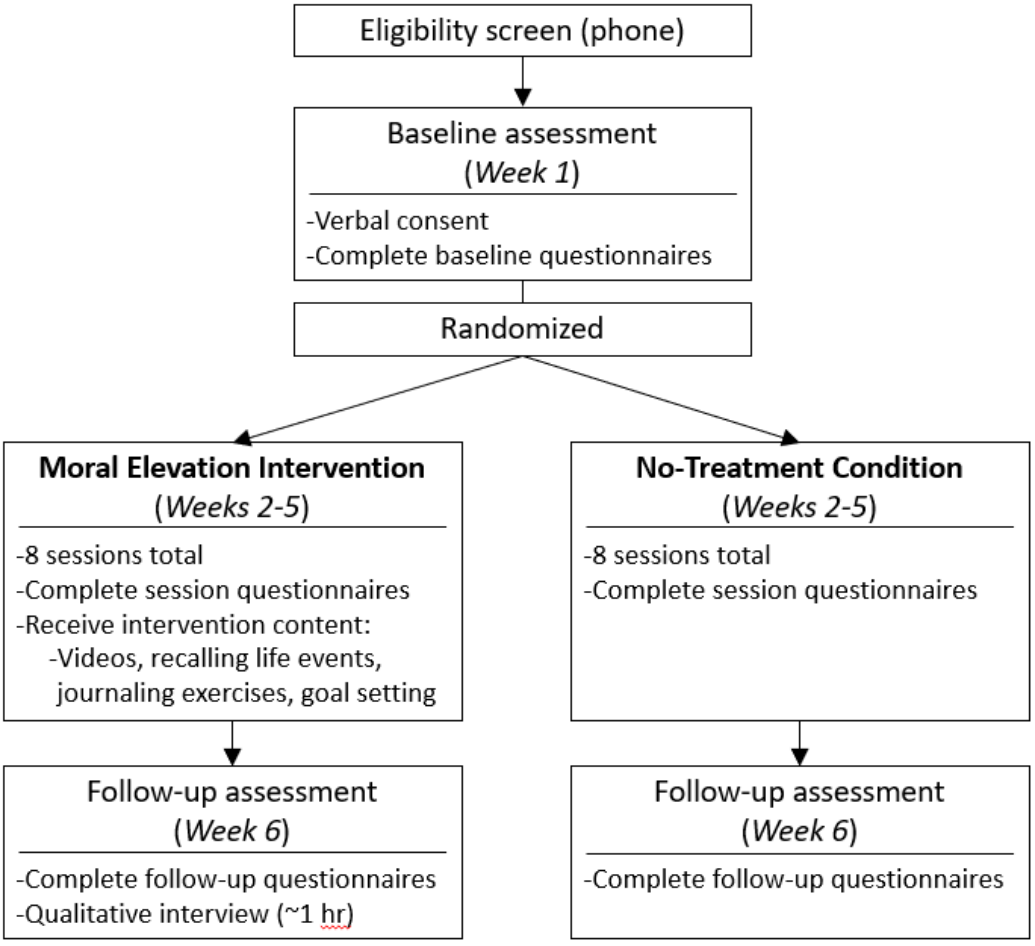

Figure 1. Participation Timeline

5. Objectives

5.1 Specific Aims

Despite the use of evidence-based psychotherapies (EBPs) for posttraumatic stress disorder (PTSD), two-thirds of Veterans report continued problems as indicated by sustained PTSD symptoms, functional impairment, and poor social functioning after PTSD treatment.[1] Increasing evidence suggests that for some Veterans, non-response to PTSD treatments may be in part because EBPs do not address co-occurring moral injury (MI) distress[2,3] and shared features (e.g., emotional numbing). Existing PTSD treatments are also limited as they do not directly facilitate building positive resources to enhance social functioning. Given the prevalence of trauma distress[4,5] and the limitations of existing treatments, novel approaches are needed to (1) target both PTSD and MI and (2) directly impact psychosocial growth and functional recovery. To address this need, this study will pilot a new positive psychology intervention, as current positive psychology interventions effectively enhance well-being through cultivating positive emotions. This pilot trial focuses on moral elevation—a distinct, positive emotional state described as feeling uplifted and inspired by others' virtuous actions[6]—which is relevant to PTSD and MI recovery because it encourages social engagement and serves as a template for interpreting the world in a healthier way. Higher levels of moral elevation are associated with fewer mental health symptoms,[7] a strong desire to engage with others, and increased prosocial behavior.[8-10] Promising preliminary results have showed that moral elevation is negatively correlated with PTSD avoidance symptoms and MI.[11] Although there is evidence that moral elevation may benefit those with significant trauma distress, it is unknown whether moral elevation can be cultivated in Veterans with PTSD and MI and if such an intervention would be accepted by this population. The lack of such knowledge is an important problem because the capacity of moral elevation to target psychological health and social functioning could be used to facilitate trauma recovery for Veterans.

Our long-term goal is to improve trauma treatment so that it effectively targets both PTSD and MI distress, while simultaneously facilitating psychosocial growth and functional recovery in Veterans. The **objective of the present study** is to assess whether a brief, web-based moral elevation intervention is a feasible and acceptable therapeutic approach for Veterans of Operations Enduring Freedom (OEF), Iraqi Freedom (OIF), and New Dawn (OND). If Veterans are willing and able to complete a web-based moral elevation intervention and it has beneficial effects, then it could be utilized as a potential catalyst for cognitive, emotional, and behavioral experiences linked to trauma recovery. Further, this study will provide pilot data for a future comprehensive test of a moral elevation intervention in a clinical trial that could determine if this novel approach leads to beneficial outcomes.

We plan to accomplish this objective through the following two specific aims:

Aim 1: Conduct a pilot trial of an 8-session, 1-month-long web-based moral elevation intervention to assess:

a. Feasibility of recruitment, retention, and completion of the intervention;
b. Ability of the intervention to elicit moral elevation in OEF/OIF/OND Veterans who have experienced amorally injurious event and meet criteria for a current diagnosis of PTSD; and

c. Acceptability of and satisfaction with moral elevation exercises, the intervention's general structure, and proposed methodology through qualitative measurement and analysis.

<u>Aim 2</u>: Conduct a no-treatment condition (i.e., comparison group) in preparation for future randomized controlled trials (RCTs) to assess:

a. Feasibility of randomization and completion of a no-treatment condition; and
b. Retention and completion of assessments at baseline, repeated measures, and follow-up.

The proposed work is innovative because it aims to elicit the benefits of moral elevation to target trauma distress—a novel approach that is not currently used to treat Veterans, but is a promising area of research with significant support in other populations. We expect that OEF/OIF/OND Veterans will be able to complete this online intervention, and that their feedback will inform how to best implement moral elevation interventions in a Veteran population. Qualitative data will also be used to develop study methods for a future RCT to test the efficacy of a moral elevation intervention for targeting desired outcomes. Positive results from this study would indicate that this low-cost, web-based intervention could be easily disseminated to a wide range of Veterans and clinics, spanning from Veterans who are not actively engaged in care to those attending in-person treatment. Further, with replication, these findings could implicate moral elevation as a transdiagnostic tool that positively impacts complex psychological health needs (i.e., PTSD and MI), while also facilitating recovery through enhanced social functioning.

Keywords: web-based intervention, pilot study, moral elevation, veterans, PTSD, moral injury

5.2 Rationale for Research

A. Treating PTSD and MI: Overview and Gaps. Combat Veterans are at increased risk for posttraumatic stress disorder (PTSD) and moral injury (MI). PTSD is characterized by exposure to a traumatic event and 4 core symptom clusters: re-experiencing or intrusion, avoidance, changes in cognitions and mood, and arousal symptoms.[12] MI occurs when a person witnesses or performs an act that violates their deeply held values and is associated with clinically significant levels of guilt, shame, and anger.[13-14] MI is an emerging concern for Operations Enduring Freedom (OEF), Iraqi Freedom (OIF), and New Dawn (OND) Veterans, with upwards of 80% of Veterans reporting to have experienced a potentially morally injurious event (e.g., I saw things that were morally wrong),[15] and 38% endorsing significant distress directly related to at least 1morally injurious event.[16] Treatment for PTSD and MI is a high priority because both are associated with poor mental health outcomes, functional impairment, decreased social engagement,[17-19] and thus, poor reintegration into civilian life. Although distinct, PTSD and MI can co-occur[20,21] and share features (e.g., emotional numbing, isolation) that could be more effectively targeted than by current therapeutic approaches; therefore, treatments that adequately address both PTSD and MI are needed. Trauma treatments available to Veterans primarily consist of psychotherapy for PTSD; however, current approaches are limited for two main reasons: 1) Results from clinical trials indicate that two-thirds of Veterans who complete evidence-based PTSD psychotherapies report continued or clinically elevated symptoms at follow-up.[1] Research also suggests that PTSD treatments are not effective for MI distress, a shame- or guilt-based response distinct from the fear-based response in PTSD.[2,3] Accordingly, clinicians report concerns that PTSD therapies do not effectively treat MI distress.[22] 2) Despite a call to facilitate psychosocial growth and maximize recovery in trauma-exposed Veterans,[21,22] psychotherapy typically aims to alleviate symptoms and does not directly target building positive resources that increase social functioning. Therefore, there is a major need for novel treatment approaches that (1) target both PTSD and MI distress following combat trauma, and (2) directly impact psychosocial growth and functional recovery.

B. Moral Elevation: Definition. A potential way to address the areas wherein trauma treatment falls short is through relevant positive psychology constructs, such as moral elevation (hereafter, "elevation"), a positive emotional state that encourages social engagement. Elevation is specifically defined by a distinct trigger and action tendency. Elevation is triggered after witnessing another person perform a virtuous act (e.g., courage, generosity), which can lead the observer to feel inspired and uplifted, accompanied by positive physical sensations (e.g., tears, lump in the throat). This is typically followed by a strong desire to emulate the witnessed virtuous behavior (e.g., I want to act generously too), become a better person, and engage with others. These distinct benefits of elevation are related to improved psychological health, as evidenced in a study that linked daily elevation to lower daily symptoms of anxiety, dysphoria, and hostility in a civilian sample of anxious and depressed patients.[7] In experimental and observational studies with nonclinical populations, elevation is linked to features of social engagement such as increased affiliation urges, greater responsiveness to others' needs, increased compassion, and more prosocial behavior.[8-10] Thus, elevation is a causal emotion for improving psychological health and social functioning.

C. Theoretical Framework. While trauma leads to the strong negative effects of PTSD and MI, research indicates elevation is antithetical to trauma distress and leads to positive effects on

psychological health and social functioning. Thus, elevation may have the capacity to reverse the negative effects of PTSD and MI through emotional, cognitive, and behavioral experiences linked to trauma recovery. As many Veterans with PTSD or MI report difficulty experiencing positive feelings,[21,23] repeated exposure to positive emotions like elevation may target the numbing features of trauma distress. Interventions that elicit elevation and increase a Veterans' tendency to be aware of others' virtuous behavior (i.e., recognizing the goodness in others) may aid in reducing maladaptive beliefs (e.g., You cannot trust other people[13]). The action tendency may also motivate Veterans to engage in behaviors that require greater social interaction, counteracting isolation tendencies and increasing the likelihood of connecting with others or reintegrating into civilian life.

D. Significance. There is a critical need for new treatments that improve the effectiveness of trauma treatment for both PTSD and MI, while also directly impacting psychosocial growth and functional recovery in Veterans. This study aims to address this need by piloting a web-based elevation intervention designed to elicit elevation and its benefits. Using elevation as a therapeutic tool falls within the broader theory of positive psychology—an emerging field with effective interventions aimed to enhance well-being through positive emotions,[24] such as elevation. Studies have yet to test an elevation-based intervention in a trauma-exposed population. This project could advance the scientific knowledge of trauma recovery and positive psychology by identifying elevation as an innovative tool for clinical practice, which would extend trauma treatment beyond the amelioration of distressing symptoms to also encourage enhanced social functioning and psychosocial growth among trauma-exposed Veterans. This project also has the potential to affect the delivery of trauma recovery services by testing a web-based elevation intervention that increases the accessibility of growth-oriented therapeutic approaches, impacting Veterans already engaged in care who wish to further enhance their well-being as well as Veterans who may be reluctant to initiate in-person treatment due to stigma or impairing avoidance symptoms associated with trauma distress.

6. Design and Methods

6.1 Methods Objectives

A 2-year pilot trial of a web-based elevation intervention for Veterans who experienced significant distress regarding a morally injurious event and with a current diagnosis of PTSD is proposed to assess: 1) feasibility of recruitment, retention, and completion of 8 sessions over a 1-month period; 2) ability of the intervention to elicit elevation; 3) acceptability of and satisfaction with elevation exercises, the intervention's general structure, and proposed methods; and 4) feasibility of randomization to a no-treatment condition to be used in future randomized controlled trials (RCTs) and completion of all assessments within this condition.

Participants will complete self-report measures that assess PTSD symptoms, MI distress, and social functioning as measured by prosocial behavior and quality of social relationships at baseline (BL; i.e., pre-intervention) and follow-up (FU; i.e., post-intervention). To supplement self-report measures and fully capture the potential impact on social functioning, each participant will invite 1 significant other (SO; e.g., spouse, friend) to complete measures based on observations of the Veteran's social behavior at baseline and follow-up. Veteran participants will be randomly assigned to an elevation intervention condition or a no-treatment control condition. Each condition comprises 2 web-based sessions per week (Monday and Thursday) for 1 month, totaling 8 sessions (<30 min/session).

Veteran participants will also complete repeated measures at each session, and Veterans in the intervention condition will complete an individual qualitative interview (~1 hr) with a qualified member of the study team at follow-up. The duration of the entire study for each Veteran participant is 6 weeks total. See Table 1 for a study timeline.

Table 1. Study Timeline, Procedures, and Recruitment Goals

Year	Pre	1				2			
Quarter	Pre	1	2	3	4	1	2	3	4
Pre-Award Activities									
Obtain IRB approval; Hire psychology technician; Prepare online materials	■								
Training & Preparation									
Train psychology technician; Prepare recruitment/screening materials; Obtain list of eligible participants via VA CDW		■							
Conduct Pilot Study									
Telephone/eligibility screening assessment (n=5/month; total n=60)			■	■	■				
BL assessment & randomization (n=4/month; total n=48)			■	■	■				
8 online sessions (n=2/month; total n=24)				■	■	■			
FU assessment & qualitative interview* (n=2/month; total n=24) *Qualitative interview to be completed by treatment condition only				■	■	■			
Analyses									
Analyses of qualitative data; Analyses of recruitment & retention data							■	■	■
Formulate future research (RCT grant proposal) based on results								■	■
Disseminate results via national academic conferences & scientific journals									■

6.2 Participants

The targeted sample size for study completion is 24 Veterans, 12 per group.[25] Given that positive psychology web-based interventions have an average attrition rate of approximately 50% for clinical populations,[26] we aim to recruit and randomize 48 eligible Veterans within the initial baseline assessment to account for the expected attrition and to reach the goal of 24 Veteran completers. Specifically, "eligible" status is determined by passing the initial pre-screen over the phone, then passing the final screen for all inclusion and exclusion criteria after completion of the baseline assessment. For all Veterans who are determined eligible after the baseline appointment, one Significant Other will be recruited to complete observational measures for each Veteran. Therefore, we aim to recruit 48 eligible Veterans and 48 corresponding Significant Others. Given that participants need to verbally consent to the baseline appointment to determine final eligibility for full enrollment and randomization, it is possible that some consenting Veterans will not meet the inclusion criteria after consenting at baseline. In other words, consent does not automatically equal randomization. Any Veteran who consented but was then deemed ineligible based on the results of the baseline assessment would not be considered as contributing to the minimum sample size of 48 eligible Veterans. We anticipate that 2 out of every 3 participants is likely to be eligible after conducting a baseline appointment; therefore, we aim to obtain verbal consent from approximately 72 Veterans to meet the sample size required for eligible and enrolled Veterans. When combining the 48 Significant Others who are expected to consent after a Veteran is enrolled and randomized, we aim to recruit a total of 120 participants.

6.3 Inclusion Criteria

Veteran Participants: Veterans must meet all of the following to participate: 1) ≥18 years of age; 2) OEF/OIF/OND Veteran enrolled in CTVHCS; 3) English-speaking and able to provide written informed consent; 4) Internet access for web-based sessions and measures; 5) Screen positively for a PTSD diagnosis based on empirically-validated cutoffs on the PTSD Checklist for DSM-5 (PCL-5;[27] ≥33); 6) Screen positively for experiencing ≥1 morally injurious event and endorse some distress (≥4 on any distress item) related to that event based on the Moral Injury Events Scale (MIES);[28] 7) Willing to complete study procedures and identify a Significant Other who will complete observational measures; and 8) Willing to be randomized.

Significant Other Participants: Significant Others must meet all of the following to participate: 1) ≥18 years of age; 2) Designated as a Significant Other by the Veteran participant, and the Veteran participant has provided consent for the study team to contact that potential Significant Other; 3) English-speaking; 4) Internet access for web-based observational measures; 5) Interact with the Veteran ≥1 time per week; and 6) Willing to complete study procedures.

6.4 Exclusion Criteria

Veteran Participants: The intent of exclusion criteria for this study is to ensure that study participants are able to provide informed consent, understand study materials, and complete study-related tasks, and for the study team to detect and provide referrals for urgent treatment of suicidality. Therefore, Veterans will be screened for the following exclusion criteria and will be excluded if any exclusion criteria are met: 1) History of severe traumatic brain injury (TBI) indicated by medical review and the Ohio State Traumatic Brain Injury Identification Method (OSU TBI-ID);[29] 2) Psychosis or current substance use disorder indicated by medical review and the Mini International Neuropsychiatric Interview (MINI);[30,31] or 3) Current suicide risk based

on the Beck Depression Inventory-II (BDI-II; score of ≥2 on suicide item indicates risk warranting crisis intervention[32]). Veterans will not be excluded if they are enrolled in other treatments, including psychotherapy or pharmacotherapy, and they will be allowed to engage in and/or initiate other treatments during the study if desired. Ineligible participants based on Exclusion Criteria 1 and 2 will be identified first in the initial medical record review (database query from the VA Corporate Data Warehouse [CDW]) and will be excluded (i.e., will not receive a mailed invitation to participate in this study). Screening for exclusion criteria will be verified during the pre-intervention assessment (i.e., at baseline) with the OSU TBI-ID, MINI, and BDI-II. The BDI-II is a 21-item self-report measure of depression symptoms, which will be used to assess for suicide risk as defined by a score of ≥2 on the BDI-II suicide item.[32] The BDI-II suicide item evidences a moderate correlation with other scales of suicidal ideation in clinical samples and has predictive validity.[33] Follow-up risk-assessment will be provided (see Section 8.2, B.2 [Protection against risk of emotional distress] for additional details).

Significant Other Participants: None.

6.5 Recruitment

Veteran participants will be recruited through advertisement at enrollment sites, vet centers, Veteran's networks and service organizations, through in-service presentations to primary care staff, mental health staff, and other relevant VA staff (e.g., OEF/OIF/OND coordinators, etc), and through the community (e.g. grocery stores and shopping centers). In-person recruiting will also be conducted at enrollment and community sites if it is deemed safe to do so in accordance with recommendations for public health and safety. In these cases, one or more research team members will sit at a table/booth in a high visibility area (e.g., a main VA lobby or outside of a grocery store) with a sign indicating that OEF/OIF/OND Veterans are being recruited to participate in a research study. Staff members will provide interested Veterans with a flyer (see Appendix A) about the study. In addition, Veterans interested in participating in the study will be given the option of providing staff members with their contact information so that they can be contacted by phone at a later point in time to complete a telephone screen interview. If a private office is available, as a convenience, participants may be given the option to complete the screening interview in person. We will also place advertisements (Appendix A) in local community-based advertisement sources, on local Craigslist pages, and in other locally-based media platforms, on relevant VA and other Veteran-oriented websites, and social media outlets, pending required approvals from VA public relations office.

We also request permission to conduct periodic queries to recruit new participants using VISTA, VINCI, the Corporate Data Warehouse (CDW), or other approved VA methods for accessing Veteran mailing list information (frequency approximately 2x/year, to be determined based on the number of names generated; i.e. if there are too few or too many names we will adjust the frequency correspondent with staffing so potential participants would not need to wait too long for a research appointment; as the list is exhausted, we will update the list more frequently; maximum number of names generated = 100,000). We will use these VA approved methods to identify Veterans who meet some of our inclusion criteria (e.g. PTSD diagnosis) so that we can reach out to potentially eligible Veterans to let them know that the study is being conducted. An invitation letter will be sent to potentially eligible participants (see Appendix B). Depending on recruitment flow from these letters, we retain the option to attempt to contact potential

participants by telephone after the letter has been sent (allowing at least 1 week for them to receive the letter before calling). If a Veteran says he/she is not interested at any point in this process (e.g., after the first letter or during the follow-up call), their name will be marked on the list and they will not be contacted again. Interested Veterans will complete a telephone screen to determine their eligibility (see Appendix C). This recruitment procedure requires a waiver of consent and waiver of HIPAA authorization (attached). The retrieval of names and addresses to recruit study participants involves no more than minimal risk to subjects and will not adversely affect the rights and welfare of subjects. This waiver is important to successful recruitment of participants as it enables us to reach out to as many Veterans as possible to make participation in the study available to them. The mailing list of contact information generated by the methods detailed above will be stored electronically on the secure VA S:\Research\2. PROJECTS\McGuire\MOVED and the VINCI project folder for this study, depending on the required data storage location associated with the approved method of requesting and storing this information. After a Veteran contacts the COE (or we contact the Veteran per above), a brief screening will be conducted by telephone.

6.6 Screening Procedures

The brief screening assessment by telephone will be conducted by a trained psychology technician. The screening assessment (see Appendix C) includes questions regarding inclusion criteria and the administration of self-report questionnaires (MIES & PCL-5). A brief screening assessment should help minimize participant burden, as those who are not eligible will be saved time associated with completing a full baseline assessment. If the Veteran is determined to be ineligible based on the eligibility screening procedure, we will not collect any personally identifying information. For veterans determined to be eligible, we will collect identifying information for the purpose of scheduling a baseline appointment to determine final eligibility. This identifying information will be recorded on an electronic screen registry of initially-eligible participants, including Screen ID#, date of screen, salutation, name, contact information, whether or not it is ok to leave telephone messages (e.g., for appointment reminders), the appointment date/time, enrollment date, and reason not enrolled (e.g., unable to schedule, no longer has time to participate). This information is stored in a password-protected registry on the secure S:\ drive (S:\Research\2. PROJECTS\McGuire\MOVED). Following the pre-screen (phone screen), for those deemed initially eligible, a cover letter will be mailed to the Veteran in advance of the baseline assessment appointment along with a document that reviews all aspects of participating in the study (i.e., Review of Research Participation), direct deposit form. Coded hardcopy eligibility screening documents will be stored in separate files for those deemed initially eligible versus ineligible. Pre-screen information will be used in aggregate to report the recruitment process (e.g., number screened, number eligible, number ineligible, percentage/reasons for ineligibility, etc). In the event that a Veteran displays a high level of suicidality or reports that they are in crisis during the telephone screen, research staff will assess the risk and consult with an on-site, licensed clinical psychologist or psychiatrist to determine an appropriate course of action. The principal investigator will be notified of any such incidents immediately. The principal investigator will supervise all assessments. Notably, all research staff are trained in suicide prevention and risk assessment.

6.7 Informed Consent Procedures

Veteran Participants: Following the pre-screen, study staff will schedule a baseline assessment appointment to be completed by phone. A copy of the Review of Research Participation Form will be mailed to the Veteran in advance of the baseline appointment for the Veteran to read and consider participation. This procedure will reduce participants' time burden on the day of the assessment, as Veterans will have had the time to read and consider the Review of Research Participation Form prior to the initial baseline appointment. At the start of the appointment, Veterans will be asked if s/he had a chance to read the Review of Research Participation Form, and if not, will be asked to read the form carefully at that time. It should be noted that, regardless of whether or not participants read the Review of Research Participation Form ahead of time, the study staff member will always explain the nature of the study to participants at the beginning of the appointment, as well as the potential risks/benefits of participating in the study. For this study, we will obtain verbal consent, rather than written consent. Verbal consent will only be obtained prior to the baseline assessment and will not be obtained until the researcher is satisfied that the participant has a good understanding of the risks/benefits of participating in the study. All team members with patient contact including consenting procedure will be appropriately trained, assigned duties and documented as per VA regulations

Significant Other Participants: Upon obtaining informed consent from the Veteran participant to allow the study team to initiate contact with the Significant Other (SO), study personnel will call the SO and obtain verbal consent over the phone. This procedure requires a waiver of consent and waiver of HIPAA authorization on behalf of the Significant Other Participant (attached).

6.8 Assessment Schedule

Baseline Assessment: Verbal consent will be obtained at the beginning of the appointment. Following verbal consent, all Veteran participants will complete the baseline assessment. The Veteran baseline assessment is expected to last approximately 40 minutes. This baseline assessment will serve as the final screen to determine full eligibility—indicated by evidence that the Veteran meets all inclusion criteria and does not meet any exclusion criteria. Only after full eligibility is determined will the Veteran be enrolled in the remaining portion of the study and randomized to one of two study conditions.

Upon obtaining verbal consent from the Veteran participant to allow the study team to initiate contact with the Significant Other (SO), study personnel will call the SO and obtain verbal consent over the phone. Once verbal consent is obtained from the SO, the SO will be emailed a web-based link to complete the web-based assessment on Qualtrics, which is HIPAA-compliant and has been approved by the CTVHCS IRB for use in other CoE/ORD-funded studies. The SO baseline assessment is expected to last approximately 35 minutes.

Session Assessments: Veterans will be randomized to either the elevation intervention condition or a no-treatment condition. Both conditions will require Veterans to access a web-based link to Qualtrics twice every week (approximately every Monday and Thursday) for 4 weeks, with 8 sessions in total. For both conditions, Veteran participants will be asked to complete a battery of self-report measures at each session (8 session assessments in total). One session assessment is expected to last approximately 20 minutes.

Follow-up Assessment: Within 1 week of completing the web-bases sessions, Veterans and SOs will be asked to complete a follow-up assessment. The SO will be emailed another web-based link to complete the assessment online using Qualtrics. Veteran participants will be offered the option of completing the assessment online or over the phone. In addition to the follow-up assessment, an audio-recorded qualitative, semi-structured interview will be conducted with Veterans randomized to the elevation intervention condition. The qualitative interview is expected to last approximately 1 hour and will be conducted over the phone.

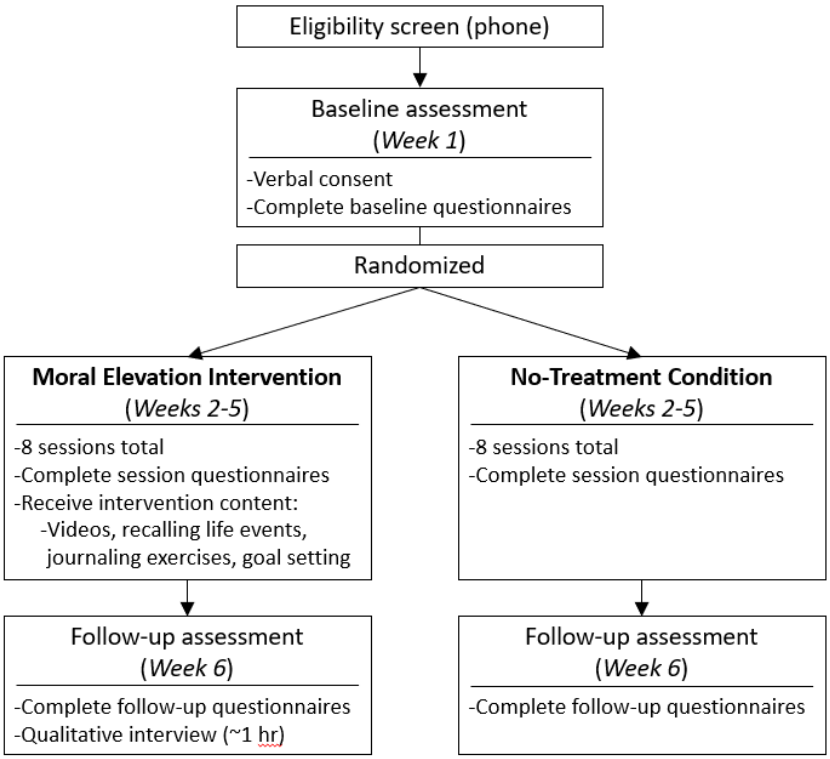

Figure 1. Participation Timeline

6.9 Measures

All assessment instruments are presented in Table 1. Broadly, assessments were include self-report measures that are valid and reliable.

Table 2. Assessment Instruments

Measure	Items	Participant	Purpose	Ph screen	BL	Sessions	FU
Moral Injury Events Scale (MIES)[28]	9	V	E	■			
PTSD Checklist for DSM-5 (PCL-5)[27]	20	V	E	■			■

Beck Depression Inventory-II (BDI-II)[32]	20	V	E				
Mini International Neuropsychiatric Interview (MINI)[30]	-	V	E				
Ohio State Traumatic Brain Injury Identification Method (OSU TBI-ID)[29]	-	V	E				
Demographic Questionnaire and Military History	20	V	SC				
Expressions of Moral Injury Scale (EMIS-M)[34]	17	V	RCT				
World Health Organization Quality of Life (WHOQOL-BREF)[35]	26	V	RCT				
Positive and Negative Affective Scale – Short Form (PANAS-SF)[36]	10	V	RCT				
Positive and Negative Social Exchanges (PANSE)[37]	24	V	RCT				
Response to Positive Affect Scale (RPA)[38]	17	V	RCT				
Compassionate Goals (CG)	7	V	RCT				
Prosocialness Scale (PS)[39]	16	V; SO	RCT				
Impact Message Inventory (IMI)[40]	59	SO	RCT				
Elevation Scale (ES)[41]	13	V	SA1B				
Exercise-Specific Satisfaction Survey (ESSS)	4	V	SA1C				
Treatment Evaluation Inventory-Short Form (TEI-SF)[42]	7	V	SA1C				
Client Satisfaction Questionnaire-8 (CSQ-8)[44]	8	V	SA1C				
Ph = Phone; BL = Baseline; FU = Follow-up; V = Veteran; SO = Significant Other; E = Eligibility; SC = Sample Characteristics; SA = Specific Aim; RCT = Feasibility for use in future RCT							

6.10 Conditions

Following the baseline assessment, Veterans will be randomized to either the elevation intervention condition or a no-treatment condition. Instructions, intervention content for the intervention condition, and session measures for both conditions will be administered online using a web-based link to Qualtrics (see Appendix G), which is HIPAA-compliant and has been approved by the CTVHCS Institutional Review Board (IRB) for use in other CoE/ORD-funded studies.

Elevation Intervention: The intervention will use a spaced, mixed design that includes 2 types of moral elevation exercises: 1) viewing an elevation video (Sessions 1-4); and 2) a recall exercise (Sessions 5-8), which include a brief reflection period wherein the participant journals about their reaction. For Session 1, participants will also be asked to read brief educational materials that will introduce the structure of the intervention, define elevation, and define several virtues (e.g., courage). Defining virtues is expected to help increase participants' awareness and recognition of virtuous acts performed by others, thus increasing the likelihood they will experience elevation throughout the intervention. The primary exercise in Sessions 1-4 will include viewing validated videos[10] (≤5 min in length) that elicit elevation. The primary exercise in Sessions 5-8 will include recalling a specific time since the last session that the participant witnessed a virtuous act and to describe it in detail, with prompts (e.g., What virtue[s]? Who was

involved?). Consistent with positive psychology interventions,[43] participants will be instructed to journal about their reaction (~10 min) in all sessions. After the journaling exercise, participants will be presented with a brief goal to be completed prior to the next session that is intended to facilitate greater social engagement. They will report on the completion of that goal in the next session. The goal will be predetermined in Sessions 1-2. Participants will be instructed to generate unique goals for the remaining sessions as it relates to any drives or motivations they may have experienced in response to elevation stimuli (e.g., "After witnessing that virtuous act, what is one action you feel like doing that could be completed before the next session?"). Participants will complete brief, self-report measures at the end of each session (~20 min). Veterans will be compensated for time spent completing measures at each session.

No-treatment Control Condition: Veterans randomized to the no-treatment condition will access Qualtrics twice per week and complete the same repeated assessments as those in the intervention condition. They will not be exposed to the intervention components (i.e., educational content defining virtues and elevation, viewing videos, recalling elevation-eliciting life events, and journaling exercises).

6.11 Statistical Analysis Plan

Aim 1.A: Assess the feasibility of recruitment, retention, and completion of an 8-session, 1-month-long web-based moral elevation intervention.

Analysis Plan: The number and rates of Veterans screened and enrolled versus those retained through 8 sessions and the follow-up assessment will be examined. At all stages, efforts will be made to assess reasons for opting/dropping out to evaluate barriers to participating and feasibility of the proposed methods. The number of sessions completed for Veterans retained through 8 sessions will be examined.

Aim 1.B: Evaluate the ability of the intervention to elicit moral elevation.

Analysis Plan: Scores on the ES will be aggregated across several categories including each session (1-8), session type (video vs. life event recall), and the entire intervention. Mean scores >30, the mid-point of the ES (range=10-50), will be considered to adequately represent medium to high elevation responses to the exercises. We will conduct a visual inspection for trends in mean scores across session numbers and types, and for a signal that ES scores increase over time within each participant (i.e., trajectories across Sessions 1-8).

Aim 1.C: Assess the acceptability of and satisfaction with moral elevation exercises, the intervention's general structure, and the proposed methods.

Analysis Plan: Quantitative measures of acceptability and satisfaction ratings as measured by the TEI-SF and ESSS will be averaged across all participants in the intervention. Mean scores greater than the mid-point of each measure (TEI-SF=18; ESSS=22.5) will be considered trending in support of acceptability and satisfaction. Qualitative interviews will be transcribed. NVivo qualitative software will be used to organize and support coding of data. Methods of the intervention may be adapted immediately based on Veteran feedback if alternative approaches are needed to complete recruitment goals (e.g., retention problems).

Aim 2: Assess the feasibility of randomization to a no-treatment condition and completion of assessments at BL, repeated measures, and FU.

Analysis Plan: The number and rates of Veterans who were randomized to the no-treatment condition and retained through the FU assessment will be examined. The number of repeated measures completed (8 sessions) will also be examined.

6.12 Alternative Strategies

In the event the proposed methodology proves to be ineffective in eliciting high levels of moral elevation, alternative strategies could be implemented. One alternative approach to eliciting higher levels of moral elevation is to present participants with longer videos ($\geq$ 6 min) that may have a greater impact. Additionally, presenting more than 1 video may increase the likelihood that participants report an emotional response to virtuous behavior. Although the videos that will be used have been validated and repeatedly demonstrated desired effects in past studies, a final alternative approach would be to find more videos that feature a Veteran demonstrating virtuous behavior, as greater similarities between the stimulus and the participant may elicit higher levels of moral elevation.

In response to the recent COVID-19 outbreak and safety concerns related to in-person appointments, this version of the protocol (Version 1.01) is proposing an alternative strategy that would make all aspects of study participation virtual (i.e., online and phone).

If alternative strategies are needed, such as those described above, any modifications to study procedures will be submitted to the CTVHCS IRB for review in a timely manner.

7. Data

7.1 Data collection procedures

We will collect archival administrative patient data, assessment data (self-report measures), study retention records, and audio recorded qualitative interviews. An electronic database will be generated to contain data from this project. All electronic data will be coded, with no HIPAA identifiers. Data will be stored on the CTVHCS W drive at the following location: S:\Research\2. PROJECTS\McGuire\MOVED. Assessment data will be collected electronically through the use of Qualtrics, a secure web-based survey application. Qualtrics is a secure web-based application for building and managing online surveys and databases, which is HIPAA-compliant and has been approved by the CTVHCS Institutional Review Board (IRB) for use in other CoE/ORD-funded studies. Qualtrics is also FedRamp Authorized and meets or exceeds the minimum requirements as outlined in FIPS Publication 200.

This system is similar to REDCap and is flexible enough to be used for a variety of types of research, and provides an intuitive interface for participants to complete surveys. It also offers easy data manipulations with audit trails for reporting, monitoring, and querying patient records, and an automated export mechanism to common statistical packages. As with REDCap, all web-based information transmission is encrypted. Data acquired from this study will be stored on VA servers, including data downloaded/exported from Qualtrics. Data will be managed using VA-owned statistical software (SPSS, SAS, Stata, R/S-Plus). Interview and self-report data will be entered continuously by staff members as the data are collected. Data entry training will consist of both didactic sessions in which staff members are provided with information about the data entry system in place at the COE as well as actual entry of mock data as a validity and accuracy check.

All identifiable data committed to paper will be kept locked in a filing cabinet in the PI's office (locked), Room 2A-120.

Access to identifiable paper data will be limited to study personnel specifically credentialed for this access in their scope of duty stored behind a locked door in the approved locked office that has limited access.

7.2 Disposition of data:

Each subject will be assigned two unique ID codes (6-digit numbers, randomly generated) after the pre-screen—a primary and secondary code. The primary ID code will be used to label the data on subject test forms at the baseline assessments. The secondary ID code will be used to index email addresses that will be entered into the web-based survey platform, Qualtrics. Qualtrics is a VA-approved platform that is HIPAA-compliant and FedRamp Authorized. Data from the session measures and follow-up assessment will be downloaded from Qualtrics at the completion of the study (see Appendix H). Data will be combined into one, master electronic database. The master electronic database will only include unique ID codes, it will not include PHI, and it will be password protected (located on the secure S: drive). Regarding paper documentation, only two paper documents will contain PHI recorded on paper (, Patient Contact form, Payment form). One master key will be stored electronically in a secure location on VA servers (S: drive), which will include PHI in addition to participants' primary ID code and

secondary code. This master key will be the only document that will link PHI with identifiers. As described below, we will protect the confidentiality of sensitive research data by coding most of the data, only making electronic transcriptions of PHI when absolutely necessary, and limiting access to the materials.

Use of Data: Subject data will be submitted to coded data analysis.

All de-identified data will be as such in accordance with the VHA Handbook 1605.1.

7.3 PHI data:

1. Payment Forms: The Payment Forms will be temporarily stored in Room 2A-120 with Dr. Adam McGuire (PI) until it is moved to long-term storage in the locked/secured records room (Room 1A-137). 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.
2. Patient Contact Form: The paper form containing PHI (Patient Contact Form) will be stored long-term locked in PI offices and to be used to contact the participant to schedule the appointment if scheduling did not occur over the phone or in person upon completion of the pre-screen assessment. The form will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation.
3. Qualtrics Contact List (Appendix H): Participants' email addresses will be stored in the secure Qualtrics database using the "Contact List" feature. The Contact List is a feature within a PI's individual, password protected, online Qualtrics account. This feature allows the PI and approved study personnel to create a list of study participants and their emails. Only through this feature are study personnel able to send an individualized link via an email from Qualtrics to each participant. Only approved study staff personnel will have access to this online account and will be able to enter or see participants' email addresses. No PHI will be sent or received using this feature. The Contact List will simply store email addresses and this feature will allow for the distribution of an individualized link to every participant, which will not require participants to provide any identifying information whatsoever (because the link is unique to each person). For further description of the Qualtrics information security structure, please see Appendix I.
4. Keys: Separate VA keys linking names, addresses, SSN and identifier codes will be kept in different locations on the S:\ drive until completion of the study. The keys will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation.
5. Termination of data access will take place when members are removed from the study team. They will no longer have any access to all data pertaining to the study.

7.4 De-identified data

1. Database: De-identified, non-PHI data generated during the study will be placed in a master electronic database. The electronic data will be maintained indefinitely, with no personal identifiers.
2. Records Retention: The required records, including the investigator's research records; must

be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1).

8. Human Subjects Issues

8.1 Risks to Subjects (from consent)

A. Human Subjects Involvement and Characteristics:

All contact with participants will be conducted in a manner consistent with both Health Insurance Portability and Accountability Act (HIPAA) and Institutional Review Board (IRB) guidelines to ensure that the utmost care is taken to protect the welfare and interests of human subjects. This study will be conducted within the Central Texas Veterans Health Care System (CTVHCS). Study personnel will be primarily located at the VA VISN 17 Center of Excellence for Research on Returning War Veterans (CoE) in Waco, Texas, where all administrative and data management tasks will occur. All personnel will be thoroughly trained in the conduct of research involving human subjects and will complete all required trainings and research credentialing prior to initiating contact with potential research participants. This study will enroll 48 Operations Enduring Freedom (OEF), Iraqi Freedom (OIF), and New Dawn (OND) Veterans who are enrolled in the CTVHCS. Participants will be randomized to either an elevation intervention condition or a no-treatment condition. Male and female Veterans from all racial/ethnic backgrounds who have experienced a morally injurious event and have a current diagnosis of posttraumatic stress disorder (PTSD) will be considered for study enrollment. This study will also include 1 Significant Other (SO) participant for each Veteran participant, who will complete observational measures of the Veteran's social behavior. The SO participant will be chosen by the Veteran participant; therefore, it is possible that the SO may not be a Veteran. For this study, assessing the feasibility of including a potentially non-Veteran observer who has frequent contact with the Veteran participant is important because their observational data could assist in more comprehensively capturing the impact of a moral elevation intervention on a Veteran's social functioning in future randomized controlled trials. Further, observational data will inform how participation in the intervention changes the way a Veteran is being perceived by those around him/her, which directly impacts a Veteran's ability to reintegrate into civilian life.

B. Sources of Materials:

Data for this project will be obtained specifically for research purposes. Six sources of data will be included in this project:

(a) Archival administrative patient data: Data regarding inclusion and exclusion criteria will be collected from the VA CDW to identify potentially eligible Veteran participants who may receive mailed study invitations inquiring about potential participation in this study.

(b) Initial telephone/eligibility screen (Appendix C): Prior to scheduling a baseline assessment, each potential Veteran participant will complete a brief telephone screening with the trained Psychology Technician to determine initial eligibility status based on internet access, willingness to complete study procedures, PCL (i.e., total score $\geq$33) and the MIES (i.e., whether the Veteran experienced $\geq$1 morally injurious event and currently endorses moderate distress related to the event). Veterans' contact information will be stored separately from the screening information.

(c) Questionnaires (Appendix F): Data will be obtained from Veteran-completed questionnaire-based measures administered during the study. Data obtained from these measures will include

information regarding Veterans' PTSD symptoms, moral injury-related distress, prosocial behaviors, quality of social relationships, and acceptability and satisfaction of the intervention. Baseline and follow-up assessments will be administered within one-week of the start and completion of online sessions. Brief self-report measures will also be administered during each online session. All questionnaires (baseline, session, and follow-up assessments) will be completed using the VA-approved, HIPAA-compliant Qualtrics (web-based platform). Veteran participants will complete Qualtrics-based assessments on their personal devices. Additional data will be obtained from baseline and follow-up assessments completed by SO (observer) participants using Qualtrics on the SO's personal devices. Information entered at each assessment will be identified with only unique numerical identifiers assigned to each participant.
(d) Audio recordings of post-treatment qualitative interviews: Veterans randomized to the elevation intervention condition will participate in a post-intervention qualitative interview to assess the acceptability of and satisfaction with moral elevation exercises, the intervention's general structure, and proposed study methods. This assessment will be conducted over the phone and will be audio-recorded. Audio recordings will be identified with only unique numerical identifiers assigned to each participant (the primary ID code).
(e) Verbatim transcriptions of audio-recorded interviews: Audio-recorded interviews will be transcribed verbatim by project personnel. Transcriptions will be coded for qualitative analysis by the study Psychology Technician. Transcription data will be identified with only unique numerical identifiers assigned to each participant (the primary ID code).
(f) Intervention feasibility information: Recruitment and retention rates will be carefully collected to determine feasibility of the web-based moral elevation intervention, the no-treatment control condition, and overall methodology. This information will be collected in aggregate and will not contain any protected health information (PHI).

Identity-masking numbers assigned to each participant will be the only means by which collected information is labeled. Each Veteran participant will have a primary and secondary ID code assigned to them. SO participants will only have one unique assigned ID code because they will be completing all measures online using Qualtrics. The only list that will link the names of the participants with their ID codes will be kept in a secure, password-protected computer account behind the VA firewall and accessible only to the Principal Investigator (PI) and Psychology Technician. The same password-protected document will contain a key to link the dyads of Veteran and their designated SO. Any paper copies of study materials will be stored in a separate locked, secure file at the CoE. All electronic data entered through the web-based platform (Qualtrics) will be downloaded/exported from Qualtrics to the VA secure server behind the VA firewall and encrypted.

C. Potential Risks:
C.1 Breach of Confidentiality: There is a risk that there will be a breach of confidentiality during the study. This could occur if there is a malicious data breach, such as through hacking or staff negligence. We believe that the likelihood of this risk is minimal, based on staff training and data security procedures implemented (described below).
C.2 Emotional Distress: Participants may become emotionally upset or aroused when completing self-report measures regarding PTSD symptoms, moral injury distress, or social functioning. We believe that this risk is minor and typically temporary.
C.3 Coercion through Compensation: Another potential concern is whether the financial

compensation offered is too high and therefore coercive to participants. That is, high reimbursement may coerce normally unwilling participants to participate in the study. This risk is unlikely given the informed consent process that will (a) clearly describe all study tasks involved (i.e., clarify amount of time and energy expected in participation), (b) explain that participation is voluntary and decisions will not affect current or future healthcare, and (c) Veterans will be informed that s/he may discontinue participation at any time or revoke consent without any professional or personal consequences.

8.2 Adequacy of Protection from Risks (from consent)

A. Recruitment and Verbal Consent:

Dr. McGuire, the PI, will oversee the Psychology Technician and monitor the recruitment process, overseeing the scheduling of participants and pre-participation screening, the assessments and intervention, and the verbal consent process.

A.1 Veteran Participants: Potential participants will be recruited via the VA CDW. Efforts will be made to recruit from diverse gender, racial, and ethnic groups. Potential participants will be informed about the study using recruitment materials approved by the local IRB. Potentially eligible Veterans will be mailed a letter that describes the study and provides a study telephone number as well as an opportunity to opt out of future contact. Veterans who do not opt out will be contacted by the Psychology Technician by phone. From this pool of potentially eligible Veterans, we will then conduct a more in-depth eligibility screening by phone. During the initial phone contact, research staff will provide a brief overview of the study goals and procedures, including the types of questions that will be asked. Those interested in proceeding and who provide verbal informed consent will complete an eligibility screening procedure by phone. If the potential participant is initially eligible based on the screen, a baseline (pre-intervention assessment) appointment will be scheduled, at which time verbal consent will be obtained and final eligibility will be determined. These recruitment procedures require obtaining a waiver of informed consent and HIPAA authorization for identifying potentially eligible participants through the CDW, and a waiver of documentation of informed consent given that the baseline assessment (and all other study tasks) will be conducted virtually by phone or online. Verbal consent will be obtained from Veterans who wish to enroll in the study during the baseline appointment. The Psychology Technician will be trained by the PI in this process and in conducting the eligibility screen over the phone.

The Psychology Technician will initiate the verbal consent procedure at the start of the baseline assessment appointment. The Psychology Technician will explain the purpose of the study, the risks and benefits of participation, and that discontinuation of participation or revocation of consent is permitted at any time and without any consequence. The staff member will also explain that this study involves observer ratings by another person who has frequent contact with the participant (i.e., SO), to be designated by the Veteran participant. The Psychology Technician will explain that verbal consent to participate in this study includes consent to allow study personnel to contact the SO observer, with contact information provided by the Veteran participant, to complete online questionnaires at baseline and follow-up. The potential participant will receive a Review of Research Participation Form in the mail prior to this appointment, outlining all features of study involvement. Any additional questions/concerns will be addressed once the potential participant has thoroughly read the Review of Research Participation Form.

The potential participant will be given the option to receive a return phone call from study staff if they wish to take additional time to consider study participation in private (i.e., not on the phone with study staff). If the potential participant decides to participate after the described information has been reviewed and questions/concerns have been addressed, they will provide their verbal consent over the phone and the staff member will sign and date a Verbal Consent form indicating they obtained verbal consent on that date. The participant will be encouraged to contact the PI at any time during the consent process or thereafter should s/he wish to do so.

Upon verbal consent, Veteran participants will complete a final set of screening measures to determine eligibility status, including exclusion criteria for history of severe traumatic brain injury, psychosis, current substance use disorder, and suicide risk warranting crisis intervention.

Although mailing invitations is the primary recruitment method, in-person recruitment may be implemented at the PTSD clinics within CTVHCS (Austin, Temple, and Waco, Texas) if recruitment goals are not met and it is deemed safe to do so in accordance with recommendations for public health and safety. In the case of in-person recruitment, interested participants would provide contact information and the Psychology Technician would provide a follow-up phone call to administer the initial eligibility screen and schedule a baseline assessment, if interested and initially eligible.

A.2 Significant Other Participants: One SO participant will be identified by each Veteran participant during the baseline assessment. Veteran participants will provide the study team with the designated SO's contact information after consenting. After the Veteran's baseline assessment, study personnel will contact the SO, explain study procedures, and obtain verbal consent over the phone. SOs will not be asked to provide written informed consent given that their participation involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. This requires a waiver of consent (see attached).

B. Protection Against Risk:

B.1 Breach of Confidentiality: We will take all necessary steps to protect participants' privacy and confidentiality in accordance with VA regulations and other applicable laws. We have undertaken several steps to ensure confidentiality and data security. First, Veteran and SO participants will each be assigned unique numerical codes that will be applied to all data. The code will mask the participant's identity and be used to label and track participant measures completed over the course of the study. An electronic file containing a master key to decipher the unique identification code and link it to the particular participant will be secured by an electronic password and kept under a restricted VA drive accessible only to the PI and Psychology Technician. This file will also contain a key to link the dyads of Veteran and their designated SO. Second, all self-report measures and questionnaires will be entered electronically using the VA-approved, HIPAA-compliant Qualtrics, a secure, web-based platform that has been approved by the CTVHCS IRB for use in other CoE/ORD-funded studies. The use of Qualtrics to complete all measures will decrease the risk of a breach in confidentiality due to lost documents as it will reduce the number of paper copies of survey data.

PHI in the form of email addresses will be entered and stored on the Qualtrics platform (*see*

Appendix H for illustrations of storage and processes related to participants' email addresses). This is essential to the efficient distribution of links to online sessions and will facilitate greater retention in responses to web-based questionnaires. To protect participants' privacy, we will use a secondary ID code that will be linked to the email address stored on Qualtrics. The names and primary ID code will not be visible to any study staff who have access to this study's Qualtrics site. Furthermore, the study's Qualtrics site will be password protected and only approved study staff will have access to the administrative features of the site. All email addresses will be deleted from the Qualtrics Contact List at the completion of the study.

Data entered in Qualtrics will be downloaded/exported to an encrypted file stored on a VA IRB-approved server (S:\Research\2. PROJECTS\McGuire\MOVED). The encrypted file will omit identifying information (including email addresses) and will only include the unique identification numbers to identify participants. Third, all data storage devices, including computers and servers, will be VA-issued and monitored by VA information management services. Only study personnel authorized by the PI will have access to the data, and the file server will be protected by the VA firewall. Fourth, any identifiable data that is committed to paper (e.g., payment form) will omit the unique identification number and be stored in locked filing cabinets in a locked office (Building 93, 2A-120), stored separately from coded data. Only study personnel will have access to the de-coded data. Fifth, audio-recorded qualitative interviews will be stored electronically on a protected VA server that is behind the firewall (S:\Research\2. PROJECTS\McGuire\MOVED). Access to the server is limited to system administrators. Only project personnel will have access to the data. All transcriptions will be completed by project personnel who have already been approved and granted access to the project folder. All data will be permanently stored according to the current VA regulations regarding record retention policies. Results will be reported in aggregate, so no individual can be identified.

Access to identifiable data will be terminated when staff are no longer part of the team. Procedures are in place for reporting any incidents (i.e., theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls) by reporting to respective parties (i.e., privacy officer and/or information security officer, IRB, first line supervisor).

Every effort will be made to keep information both private and confidential. Study records may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. Records may be reviewed by the U.S. Food & Drug Administration (FDA), other U.S. government agencies, Institutional Review Boards including the Central Texas Veterans Health Care System Institutional Review Board and by staff at these institutions that deal with research as part of their official duties. As a result, they may see participant names; however, they are also bound by rules of confidentiality.

All study staff will complete the privacy and data security trainings required by CTVHCS and will be research credentialed. Data will also be protected as mandated by the VA IRB and HIPAA guidelines. All paper and electronic data will be maintained, stored, and destroyed in accordance with VA regulations and the Records Control Schedule (RCS-10-1) approved by the Archivist of the United States. Additionally, in accordance with VA Handbook 6500.2

(Management of Breaches Involving Sensitive Personal Information), incidents (i.e., theft or loss of data or storage media), unauthorized access of sensitive data or storage devices, or non-compliance with security controls will be reported immediately to the VA Police and Security Service (Information Security Officer [ISO] and Privacy Officer [PO]).

B.2 Emotional Distress: Emotional distress or discomfort due to the nature of the assessment questions is expected to be minor and transient. Licensed psychologists will be available at all times in the event that a participant experiences significant emotional distress. In addition, appropriate treatment referrals will be made for study participants when necessary, and participants will be informed of resources available to them.

If the Veteran participant shares information regarding suicidal ideation at any point during the study (including during telephone screening), the PI or, should the PI be unavailable, a designated licensed psychologist on the study team will be notified immediately, and safety issues will be formally assessed by the PI or designated licensed psychologist using a structured suicide risk assessment interview (adapted from VA's standard CPRS template for suicide risk assessment). If imminently suicidal, the participant will be evaluated for hospitalization according to standard CTVHCS procedures. This would involve a planned psychiatric evaluation in the emergency room (ER). If the participant is on VA grounds, they will be escorted to the ER. If they are at home, they will be instructed to come to the ER. If the participant is unwilling to seek care, the police will be called. These procedures have been in place at the study site for other ongoing studies and have been approved by the IRB. All adverse events will immediately be reported to the IRB.

B.3 Coercion through Compensation: A human subjects concern is whether the financial compensation is too high and therefore coercive to participants. That is, high reimbursement may coerce normally unwilling participants to participate in the study. We believe that the proposed reimbursement amount fairly compensates participants for their lost work time and for taking time out of their schedules to participate. Therefore, Veteran participants will be compensated $30 for completing the baseline assessment and $15 for their time completing measures after each intervention session. Veteran participants randomized to the no-treatment condition will be compensated $30 for the follow-up assessment, whereas Veteran participants randomized to the elevation intervention condition will be compensated $40 for their follow-up assessment as it includes an additional 1-hour-long qualitative interview. Therefore, Veterans may receive up to $180 or $190 for completing assessments. To create flexibility regarding payment and to allow Veteran participants the freedom to choose the best option for their unique situation, we will offer three options for payment: 1) gift cards mailed to their physical address, 2) direct deposit payments after they complete and submit a direct deposit form, and 3) cash vouchers that can be submitted in-person for cash payments at the Waco, Temple, or Austin VA clinics. For Veterans who choose the cash voucher option, they will be required to travel to the Center of Excellence to pick up the voucher in-person. As Texas is a rural state, Veterans who travel more than 20 miles in one direction between their home and the Center of Excellence will also receive compensation for travel (i.e., gas/mileage), calculated on the rate of $0.415 per mile. We also propose to compensate SO participants $20 for completing each observer-rated questionnaire, both at baseline and follow-up, given that SOs will be able to complete the surveys online and are not required to attend an in-person assessment.

We will minimize the risk of potential coercion by obtaining verbal consent using many of the same standard procedures for obtaining informed consent. We will begin this process during the intake for the screening phase and the trial phase, where we will clarify the nature of the study upfront. Prior to enrolling Veterans in the study, we will fully explain the study procedures, risks, and benefits. Participants will be reminded that study participation is voluntary and that refusing to participate or withdrawing from the study at any time will not impact in any way their relationship to the Central Texas VA or any other VAMC, or existing services they receive within the community. Participants will have the opportunity to discuss any uncomfortable feelings with the assessment or intervention with the research assistant who will be available during both the assessment and intervention. The Veteran will also be informed that the veteran's well-being and safety takes priority over research considerations. Furthermore, the veteran will be informed that should they experience any problems, they should report them to the research assistant or to the principal investigator of this study. All reimbursements for participating will be commensurate with participants' time required for participating in the research.

8.3 Potential Benefits of Proposed Research to Subjects and Others (from consent)

There are no assured benefits, but there are several potential benefits from participating in this project. Veteran participants who complete the moral elevation intervention may experience decreased PTSD symptoms, moral injury distress, and improved social functioning. It is also possible that Veteran participants may benefit from increased monitoring that is beyond the standard of care. For example, if a participant discloses suicidality during an assessment, s/he may benefit from clinical referrals. Additionally, there is potential for other Veterans diagnosed with PTSD and/or experiencing moral injury distress to benefit from the findings of this project. Specifically, findings from the proposed project will inform efforts to improve treatment of trauma distress and potentially lead to advances in the amelioration of PTSD and moral injury distress and the facilitation of psychosocial growth and functional recovery.

8.4 Compensation

Veteran participants will each be compensated $30 for completing the baseline (pre-intervention) assessment and $15 for completing session measures for each online session (total of 8 online sessions; $120 for all sessions). Veteran participants in the elevation intervention condition will receive $40 for completing the 1-week follow-up (post-intervention) assessment and qualitative interview, whereas Veteran participants in the no-treatment condition will each be compensated $30 for completing the follow-up assessment (no qualitative interview). Thus, the maximum compensation for completing assessments is $190 for Veterans in the intervention condition and $180 for Veterans in the no-treatment condition. Significant Other participants, designated by Veteran participants, will be compensated up to $40 for completing the observer assessments based on the following schedule: $20 for the baseline assessment and $20 for the 1-month follow-up assessment. Participants can choose between three payment options: 1) gift cards mailed to their physical address, 2) direct deposit payments after they complete and submit a direct deposit form, and 3) cash vouchers that can be submitted in-person for cash payments at the Waco, Temple, or Austin VA clinics. Participants will be paid according to their preferred method.

Additionally, previous CoE studies have found that reimbursing travel costs significantly contributes to recruitment and retention. For Veterans who choose the cash voucher option, they will be required to travel to the Center of Excellence to pick up the voucher in-person. Therefore, Veteran participants who travel >20 miles each direction between his/her home address and the Center of Excellence to pick up the voucher will be reimbursed for travel; calculated based on the shortest calculated distance x 2 x standard VA rate of $0.415 per mile.

9. Adverse events

An Adverse Event (AE) is any untoward physical or psychological occurrence in a human subject participating in research. These incidents will be reported to the IRB on annual review.

Expected AEs that are more severe than that described in the informed consent documents will be reported to the IRB on annual review.

Unexpected AEs (UAEs) that meet criteria for Unanticipated Problems Involving Risks (UPIR) will be reported to the IRB within 5 business days. Unanticipated and unexpected refer to an event or problem in human research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol documents and the characteristics of the study population.

A Serious Adverse Event (SAE) is an untoward occurrence in human research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome. SAEs will be reported to the IRB within 5 business days after discovery of a SAE that is both unanticipated and related to the research.

Local Research Deaths will be reported by oral notification to the Institutional Review Board (IRB) immediately upon becoming aware of any local research death that is both unanticipated and related to the research.

10. Description of Protocol Drugs or Devices:
None.

11. Modification of the Protocol.

Modification to the protocol, consent form and/or questionnaires will be submitted to the CTVHCS IRB for review prior to implementation.

12. Departure from the Protocol.

12.1 Minor departures from protocol

Minor or administrative protocol deviations are defined as those which do not affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects. Minor deviations do not result in or require any substantive action to be taken or result in any change to the subject's condition or status (i.e., did not affect the subject's participation in any way, did not result in a change to the subject's emotional or clinical condition, did not cause an adverse experience or require a change to the clinical care of the subject, etc.).

12.2 Departures from protocol

Protocol deviations are defined as those which affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects. These will require substantive action because the event affects the subject's participation, results in a change to the subject's emotional or clinical condition or requires a change to the clinical care of the subject. An example of a protocol deviation would be an administrative error resulting in a missing page on the informed consent document that was signed by the subject, indicating the subject may not have been fully informed about the protocol before signing the document. Another example would be a fire alarm intrusion into testing session that resulting in a truncated testing session, and resulting in a change in the subject's emotional state due to fear of bodily harm. We will report protocol deviations to the local IRB for review and approval within 5 days of becoming aware of the deviation.

13. References

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