Comparing Individual Versus Group Written Exposure Therapy Among Active Duty Servicemembers

Study Protocol and Statistical Analysis Plan

NCT: TBD

26 OCT 2026

EIRB Protocol Template (Version 1.24)

1.0 General Information

***Please enter the full title of your protocol:**

Comparing Individual versus Group Written Exposure Therapy among Active Duty Servicemembers: A Randomized Noninferiority Trial

***Please enter the Protocol Number you would like to use to reference the protocol:**

Group WET Noninferiority Trial
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site protocol (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add sites

2.1 List sites associated with this study:

Is Primary?	Site Name
◉	**P and R** - Brooke Army Medical Center (BAMC)

3.0 ■ Assign project personnel access to the project

3.1 * Please add a Principal Investigator for the study:

Name	Role	Training Record
Woodworth, Craig Adam, PsyD	**Principal Investigator**	**View Training Record**

Responsibility

☐ Student
☐ Resident
☐ Site Chair
☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Name	Role	Training Record

Barnicott, Shannon Lynn, MOT, OTR/L	**Associate Investigator**	View Training Record
DE VITA, Martin Joseph, PhD MAJ	**Associate Investigator**	View Training Record
Fitzgerald, Scott Michael	**Associate Investigator**	View Training Record
Judkins, Jason Lee, PhD, DSc LTC	**Associate Investigator**	View Training Record
Levine, Nicholas Arthur, PhD	**Associate Investigator**	View Training Record
Moore, Bret Andrew	**Associate Investigator**	View Training Record

B) Research Support Staff

Name	Role	Training Record
Borrego, Marina A	**Research Coordinator**	View Training Record
Eaton, David Scott	**Team Member**	View Training Record
Haugen, Tara Ann	**Team Member**	View Training Record
Hernandez-Rojero, Yocelin	**Team Member**	View Training Record
Logeais, Meghan Terese, OTD	**Team Member**	View Training Record
Logsdon, Jason William, MSW	**Team Member**	View Training Record
Montano, Stefanie Lopez, CPT	**Team Member**	View Training Record
Thompson, Holly Layton, MAJ	**Team Member**	View Training Record

3.3 *Please add a Protocol Contact:

Name	Role	Training Record
Woodworth, Craig Adam, PsyD	**Study Contact**	View Training Record

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Name	Role	Training Record
No Designated Department Approval have been added		

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * Is this protocol in support of a Graduate Health Science or other Allied Health Education Program?

○ Yes ◉ No

4.2 * What department(s) will be associated with this protocol?

	Psychology

4.3 * Is the IRB of record for this study an IRB/HRPP that does NOT use EIRB? If Yes, complete the application according to the IRB /HRPP Determination.

If your Projects or Protocols are under the oversight of another IRB that does use EIRB, stop this submission and contact the core site and request an invitation as a performing site.

If your Project or Protocol is now being submitted for the first time to an IRB that does use EIRB, continue with this application and answer the questions to be reviewed by the IRB.

Answering yes means the board of record is an IRB that does NOT use EIRB.

○ Yes ◉ No

4.4 * Is this protocol research, expanded access, or humanitarian use device?

◉ Yes ○ No

4.5 * What type of protocol is this?

- ☐ Behavioral Research
- ☐ Biomedical Research
- ☐ Clinical trial (FDA regulated)
- ☐ Educational Research
- ☐ Expanded Access
- ☐ Humanitarian Use Device (HUD)
- ☑ Psychosocial Research
- ☐ Oral History
- ☐ Other

4.6 Are you conducting this project in pursuit of a personal degree?

○ Yes ◉ No

4.8 * Is this human subjects research? (As defined by 32 CFR 219) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

◉ Yes ○ No

4.9 * Do you believe this human subjects research is exempt from IRB review?

○ Yes ◉ No

5.0 Personnel Details

5.1 Does the Principal Investigator have a Permanent Change of Station (PCS) Date or Estimated Institutional Departure Date (EIDD)?

○ Yes ◉ No

5.2 List any Research Team members without EIRB access that are not previously entered in the protocol:

No results found

5.3 Are any Contractors or Subcontractors involved in this study? If yes, please list them and describe their role.

◉ Yes ○ No

Name: (Last, First, M.I.) TBD Role on Protocol: Behavioral Scientist	Phone Number:	Email Address:	Associated Institution: Contract position hired through 59th MDW ST
Name: (Last, First, M.I.) TBD Role on Protocol: Behavioral Scientist	Phone Number:	Email Address:	Associated Institution: Contract position hired through 59th MDW ST
Name: (Last, First, M.I.) TBD Role on Protocol: Project Coordinator	Phone Number:	Email Address:	Associated Institution: Contract position hired through 59th MDW ST

5.4 Will you have a Research Monitor for this study?

○ Yes
◉ No
○ N/A

6.0

Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

○ Yes ◉ No

7.0 Funding and Disclosures

7.1 Is this study funded?

◉ Yes ○ No

Funding Source	Funding Type	Amount
: Military Operational Medicine Research Program (MOMRP) (JPC-5)	: Research Development Testing and Evaluation (RDT&E) funds	1549071

Total amount of funding:

1549071

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

All personnel engaged in research must complete and attach a Conflict of Interest (COI) form.

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

○ Yes ◉ No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
No results found						

Other:

Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site
No results found					

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

○ Yes ◉ No

8.4 Is this an OCONUS (Outside Continental United States) study?

○ Yes ◉ No

9.0 Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

Posttraumatic stress disorder, PTSD, group therapy, written exposure therapy, trauma focused therapy, cognitive outcomes, integration outcomes, motor tests, military readiness.

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

Posttraumatic Stress Disorder (PTSD) is a highly prevalent condition that incurs an economic burden in excess of $232 billion annually in the United States alone.[1] Approximately 6% of the US population is experiencing PTSD.[2,3] Lifetime prevalence of PTSD in Servicemembers from recent conflicts (i.e., OIF/OEF; 29%) is nearly 5 times greater than the rate observed in the US general population (i.e., 6%).[2,3] As this rate has increased, demand for trauma-focused behavioral health services has consistently increased in recent decades.[4,5]

Written Exposure Therapy (WET) has emerged as a gold-standard treatment for PTSD in the most recent clinical practice guidelines from ISTSS and the Departments of Veteran Affairs and Defense (VA/DoD).[6-8] WET has consistently demonstrated large and clinically significant treatment effects in clinical trials, including the most recent randomized clinical trial demonstrating that 5 sessions of WET was as efficacious as 12 sessions of Cognitive Processing Therapy (CPT) in Veteran and non-Veteran adults treated for PTSD.[9,10] WET also has demonstrated significantly lower drop-out rates than other trauma-focused therapies, in the range of 5-10%, suggesting that it has increased tolerability and overcomes typical barriers to PTSD treatment, such as extensive homework.[9,10] The relatively shorter protocol for WET may make it a more efficient and cost-effective option in certain settings when compared to longer trauma-focused therapies.

Despite its efficiency, access to this effective treatment for PTSD remains limited.[5] Similar to other trauma-focused treatments, WET requires specialized provider training and the treatment is primarily delivered individually.[11] Whereas other evidence-based psychotherapies for PTSD have been adapted to group formats (e.g., CPT, TF-CBT), there have been limited efforts to develop and validate a protocol that adapts WET to be delivered in groups. Group therapies have been recognized as cost-effective, feasible, and efficacious approaches to treating conditions while increasing access to care. In addition, the original WET protocol was intended only for use by mental health professionals working in clinical care settings who have familiarity with other trauma-focused psychotherapies, a firm understanding of the theoretical foundation supporting exposure therapy, and experience treating patients with PTSD.[12]

Given the relative simplicity of this intervention as compared to prior evidence-based treatments for PTSD, the goal of the proposed study is to adapt WET to a group format and test for noninferiority when compared to individually delivered WET on clinical measures among active duty Servicemembers who currently meet diagnostic criteria for PTSD. Given the critical negative impact of PTSD, successfully adapting WET to a group format would greatly expand access to a potent and effective trauma-focused treatment.

Optional Firearm Training Simulator Sub-Study

Symptoms associated with PTSD have shown to compromise cognitive and motor functions.[13-15] Among service members, this can contribute to a decline in military performance and operational readiness.[16] Although numerous studies have highlighted the efficacy of exposure therapy for PTSD symptom reduction, few have investigated its direct effect on military performance and operational readiness.[17]

The ability to maintain cognitive functions and perform high-level mental processes is critical in military positions, where decision-making is required.[18] To address cognitive and motor deficits among individuals, assessment and simulation tools have been implemented within the military environment. Dynavision, a visuomotor training device, is utilized to assess an individual's reaction time to central and peripheral stimuli through illuminating lights.[19,20] Firearms training simulators (FATS), used for weapons training by providing force-to-force scenarios, aims to enhance skills relevant for overall operational readiness.[21,22] As these tools and simulators have shown to increase skills at training and rehabilitation levels, research contributions regarding their use to measure exposure therapy treatment outcomes remains limited.[20,22]

The goal of the optional sub-study is to validate a FATS to measure treatment outcomes following the delivery of WET among active-duty service members who currently meet the diagnostic criteria for PTSD. Given the impact of PTSD among service members, measuring performance as an outcome of PTSD treatment would demonstrate that exposure therapies have a direct effect on military performance and operational readiness. Furthermore, the cognitive and motor functions contributing to higher levels of performance on the FATS can be determined.

9.3
Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions /hypotheses

Hypotheses: For Aim 1, we hypothesize that 1a) Group Written Exposure Therapy (G-WET) will be noninferior to individually-delivered Written Exposure Therapy (WET) on measures of PTSD, depression, anxiety, insomnia, and functional impairment. For Aim 2, we hypothesize that 2a) there will be no differences between treatment conditions on measures of fidelity and acceptability; and 2b) Treatment cost will be significantly lower for the G-WET condition when compared to the cost of WET. Fidelity will be measured by a checklist completed by therapist. Acceptability will be measured by patient drop out, the Treatment Acceptability/Adherence Scale (TAAS), the Thoughts About Psychotherapy Survey (TAPS), and BHDP treatment alliance/patient satisfaction questions. Cost will be reflected by a ratio of treatment effect size to provider hours.

Objective: Our objective is to examine whether G-WET is noninferior to WET in changing symptoms (e.g., PTSD, depression, anxiety, insomnia) and functioning among active duty Servicemembers. We also aim to examine implementation related outcomes, including treatment acceptability, fidelity, and costs. We envision that this knowledge will help inform clinical guidelines and improve access and availability to gold-stand evidence-based trauma focused psychotherapies.

Specific Aim 1: To test the direct effects of G-WET, compared to WET on trajectories of PTSD, depression, anxiety, and insomnia symptoms, as well as functional impairment at pre-treatment, post-treatment, 3- and 6-month follow-up assessments.

Specific Aim 2: To examine the treatment acceptability, fidelity, and costs of G-WET compared to WET.

Optional Firearm Training Simulator Sub-Study

1. a) Does Written Exposure Therapy improve cognitive and motor outcomes thought to be affected by PTSD? (b) Does Written Exposure Therapy improve integration outcomes thought to be affected by PTSD?

2. Do cognitive and motor variables mediate the relationship between treatment and integration outcomes?

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

The proposed study will employ a prospective, between groups, repeated measures, randomized controlled design primarily powered to test noninferiority based changes in PTSD, depression, anxiety, and insomnia symptom severity.

Optional Firearm Training Simulator Sub-Study
This is a prospective interventional pilot study looking at changes in cognitive and motor performance in a group of ADSMs treated with Written Exposure therapy for PTSD.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

Active-duty Servicemembers who currently meet diagnostic criteria for PTSD

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

There is a large need to overcome challenges that act as barriers to successful PTSD treatment.[24,33] Whereas first-line treatments for PTSD (e.g., Prolonged Exposure; PE) have been shown to be effective at improving symptoms, features of these protocols (e.g., 10-12 weekly, 90-minute sessions with an individual therapist) may limit an ability to meet increasing demand for trauma-focused treatment.[24] In making efforts to implement trauma-focused Evidence-based practices (EBPs) in military treatment facilities, barriers to care may include provider variables (e.g., limited number of providers, limited training in trauma-focused EBPs) and time-related variables (e.g., limited provider availability, lengthy wait-times, EBP protocol and session length).[24,25] Alth ough military Servicemembers are disproportionately affected by traumatic events, there is a recognized need to enhance treatment engagement and accessibility.[24,29,33-35,41]

As a potential solution to this barrier, our team has leveraged its significant clinical and research expertise to adapt a brief (5 sessions), gold-standard, trauma-focused treatment for PTSD, Written Exposure Therapy (WET)[9,10,12,42] to be delivered in a group format. There are multiple advantages to this approach; MTFs can deliver treatment to more patients with fewer providers and resources in less time. As an initial step, our research team consulted directly with colleagues at the VA National Center for PTSD, including individuals involved in the development and validation of the WET manual. After receiving feedback and input from these individuals, our team developed a manualized Group WET protocol and have successfully deployed the treatment among an initial cohort of PTSD patients at BAMC's Department of Mental Health. No pilot study was conducted prior to receiving grant funding from Military Operational Medicine Research Program (MOMRP) for the current study.

This study seeks to examine whether WET delivered via group format is noninferior to individual treatment. At the same time, the proposed study would seek to compare implementation factors (i.e., costs, fidelity, acceptability) between WET formats to confirm whether Group WET offers enhanced treatment capabilities. Thus, the proposed project represents an innovative step towards addressing a critical readiness issue while resolving several barriers to care that we have identified in our previous work. Success in this regard would have the potential to improve the readiness and behavioral health of our Servicemembers across the force.

Optional Firearm Training Simulator Sub-Study

By measuring performance on a firearm training simulator as an outcome of PTSD treatment, we can demonstrate that exposure therapies for PTSD have a direct effect on military performance and operational readiness. We can also determine what cognitive and motor functions contribute to higher levels of performance on the firearm training simulator.

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

Initiate recruitment, screening, and enrollment of eligible participants: Participants will be 126 adults recruited from non-emergency, active duty, personnel experiencing mental health concerns. Participants will be recruited from the Joint Base San Antonio, Texas community through the use of MTF referrals and media advertisements. Study activities will take place at the Jennifer Moreno Clinic and/or Troop Medical Clinic. First, there is a phone screen that potential participants must complete (screen script and question included as an attachment).

First, respondents will be screened by phone for the inclusion/exclusion criteria. Prospective participants will be informed that treatment will consist of 5 weekly sessions of Written Exposure Therapy delivered individually or via group format, and that randomization procedures will determine which treatment they are assigned to if deemed eligible. Individuals will also be informed that separate assessment appointments will occur after the last WET session, and at 3- and 6-month follow-up appointments. Prospective participants will also be informed of an optional sub-study consisting of 2 additional performance sessions of cognitive and motor tests. Participation in the treatment conditions and follow-up assessment appointments will be contingent upon confirming eligibility by completing the comprehensive baseline assessments. Preliminarily eligible individuals will be offered the opportunity to schedule a baseline assessment appointment to confirm eligibility.

After telephone screening, interested individuals will be scheduled for a baseline assessment appointment where inclusion/exclusion criteria will be confirmed. This first in-office visit will include a check on the inclusion/exclusion criteria by re-administering the screening questions in person and ensuring consistency with their phone screen responses. Next, upon obtaining written informed consent, participants will complete several assessment measures. Demographic information will be collected (e.g. age, sex, ethnicity, etc.; see demographic survey attached). The MINI psychosis and mania modules will be administered to confirm absence of exclusionary psychiatric symptoms, and the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)[43]will be administered to confirm the presence of PTSD. After completion of baseline assessment measures, ineligible participants (e.g., participants not meeting diagnostic criteria for PTSD) will discontinue further participation in the study. Eligible participants will be enrolled, randomized, and scheduled for all treatment and follow-up assessment appointments. During the consent process, eligible participants will be presented with the opportunity to participate in an optional sub-study. Individuals will be informed that additional study procedures will include attending 2 sessions of cognitive and motor tests over the course of 3 months, each approximately 1 hour long. Participants will be given the option on the informed consent to initial yes or no for whether they are electing to participate. If they choose to participate, participants will be scheduled for cognitive and motor tests before and after their WET treatment sessions.

Participants will then be sent a link, via email, to a secure, HIPAA-compliant, survey platform (e. g. Microsoft Forms). Pre-treatment clinical measures for Aim 1 and implementation metrics for Aim 2 will be administered, including the PTSD Checklist for DSM-5 (PCL-5);[44] Patient Health Questionnaire-9 (PHQ-9);[45] Generalized Anxiety Disorder-7 (GAD-7);[46] the Insomnia Severity Index (ISI);[37] the Thoughts about Psychotherapy Survey (TAPS); and the Bedtime Procrastination Scale (BPS)[58]. In Aim 2, we will evaluate treatment related processes and compare them for noninferiority between Written Exposure Therapy delivered individually or in group format. Data on acceptability, fidelity, and costs will help characterize implementation differences between Group WET and Individual WET that extend beyond their impact on clinical symptoms. The primary source of recruitment will be through Brooke Army Medical Center's Department of Mental Health (DMH). Serving as the Deputy Chief of Research and Education and the Program Director of Trauma Treatment and Healthcare Delivery Fellowship at BAMC (APA Accredited), Dr. Woodworth has an established history of supporting and facilitating research recruitment for human subjects studies involving active duty Servicemembers.

(Optional Firearm Training Simulator Sub-Study) Pre-WET Cognitive & Motor Tests: Participants opting to participate in the optional sub-study will be scheduled for the initial baseline performance measurement session prior to their first WET treatment session. The performance session will include the completion of self-report measures and a series of cognitive and motor tests. The first part of the performance session will take place at the Jennifer Moreno Clinic and/or Troop Medical Clinic Department of Mental Health. Participants will be administered the Lethality Scale, a validated self-report scale that provides a proximal indicator for an individual's objective lethal potential in deployed combat settings.[59] Next, participants will complete the following cognitive and motor tests: finger tapping, the Connors Continuous Performance Test (CPT), and the Motor-Free Visual Perception Test – Fourth Edition (MVPT-4). The second part of the performance session will take place at the BAMC Center for the Intrepid (CFI). Participants will complete the following cognitive and motor tests: Dynavision and Firearm Training Simulator (FATS). Testing on the Dynavision will utilize the reaction time testing scenario and the FATS will utilize marksmanship and target discrimination tests. The initial baseline performance visit is expected to last about an hour long.

Deliver Written Exposure Therapy conditions in accordance with random assignment to either Group WET or Individual WET: After completing the baseline assessment session (and the optional sub-study initial baseline performance measurement session), participants will complete 5 weekly sessions of WET delivered in the format that corresponds to their random assignment (i.e., Group WET or Individual WET). The Written Exposure Therapy (WET) manualized protocol has been developed and validated as an evidence-based psychotherapy for PTSD.[6-8] Measurement based care is performed virtually before each appointment using the Behavioral Health Data Portal (BHDP) and will be configured to administer the PCL-5, PHQ-9, GAD-7, ISI, and Walter Reed Functional Impairment Scale. The first session involves providing psychoeducation about common reactions to trauma, the WET rationale, and instructions for completing trauma narratives. Participants complete a 30-minute writing session relating to their index trauma and their emotional reactions. The following sessions (2 through 5) involve providing verbal feedback on the previous week's writing, instructions for the current writing session, and permitting participants a 30-minute writing session without interruptions from the therapist. At the end of each writing session, the facilitator checks in with the participants about their experiences with the writing session for approximately 10 minutes. Group WET follows a similar protocol, starting with the first session providing the same psychoeducation components (common reactions to trauma, WET rationale, and instructions for narratives). In each session, each patient will independently complete the 30-minute writing period in the group room with no interaction or interruptions. In Group WET, following the writing session, the facilitator will lead the group in a discussion of their collective writing experiences, highlighting commonalities in their experiences. Both before and after the writing session, patients are instructed to not disclose the nature or details of their traumatic experience with each other. Instead, specific instructions will be given about talking about the experience of writing their trauma (the impact of writing) rather than specific details about the trauma. In follow up sessions, general feedback on the previous writing exercise will be discussed with the whole group, and patient-specific feedback will be written down by the facilitator and provided to each patient for review before starting the next writing session.

Complete follow-up assessments with post-treatment, 3-month, and 6-month appointments: Within 14 days of the last WET session, participants will complete a post-treatment online assessment where relevant study measures will be re-administered. Online and /or phone assessments will also be conducted at the follow up appointments scheduled within +/- 14 days of the 3- and 6-month points after completion of WET. All post-treatment assessments will be conducted electronically and/or telephonically and do not require participants to be physically present at the study site. Post-treatment, 3-month follow-up, and 6-month follow-up assessments completed outside of the +/- 14 day window from participants last WET session will be accepted.

(Optional Firearm Training Simulator Sub-Study) Post-WET Cognitive & Motor Tests: 3 months following their final WET session, participants will attend an in-person post-treatment performance measurement session at the Jennifer Moreno Clinic and/or Troop Medical Clinic and CFI. The Lethality Scale will be re-administered to participants, and they will re-take all cognitive and motor tests mentioned in the pre-treatment session. The post-treatment performance visit is expected to last about an hour long. At the end of the study, participants will receive a study debriefing.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

We will collect data from self-report measures, including de-identified demographic information (e.g. age, sex, ethnicity, etc.; see demographic survey attached), treatment process measures (acceptability, fidelity), and clinical measures (PTSD, depression, anxiety, insomnia, functional impairment) data for 126 active duty Servicemembers during assessment (pre-treatment, post-treatment, 3-, 6-month follow-up) and/or clinical appointments at the Jennifer Moreno Clinic and /or Troop Medical Clinic. In addition, we will generate additional outcomes (cost, fidelity, acceptability) from process measures observed throughout the study (i.e., treatment engagement, dropout rates). De-identified written trauma narratives will also be collected at the end of each clinical session to facilitate fidelity measures. Narratives will be scanned using the encrypted workflow scanning capabilities of Jennifer Moreno Clinic and/or Troop Medical Clinic print stations. Specifically, authorized study staff will log in to the secured Jennifer Moreno Clinic and/or Troop Medical Clinic print station (connected to the BAMC network) using their Common Access Card, configure workflow scanning to transfer a PDF scan directly to the corresponding secure location on the networked BAMC drive. If the participant requests the research team to shred it, the physical narrative will immediately be deposited into a HIPAA compliant receptacle specifically dedicated to destroying paper documents containing protected information.

We will collect assessment self-report data (PCL-5, PHQ-9, GAD-7, ISI, Walter Reed Functional Impairment Scale, and BPS) for 126 active duty Servicemembers virtually using the Behavioral Health Data Portal. Data will be exported at regular intervals to encrypted excel spreadsheets on secure BAMC servers. For statistical analyses, excel datasets will be de-identified, reduced, cleaned, and exported to SPSS files encrypted for additional security on the BAMC servers. De-identified datasets will only be accessible to approved research staff.

For implementation outcomes (acceptability, fidelity, cost), the following strategies will be employed:

1. Participants will complete measures that evaluate different aspects of treatment acceptability. At the end of session 1 (after treatment rationale and procedures are explained), the Treatment Expectancy Questionnaire (TEQ) and the Treatment Acceptability/Adherence Scale (TAAS) will be administered. At the end of the last treatment session, the Client Satisfaction Questionnaire (CSQ) will be administered. We will also determine the rate of participant enrollment and engagement of the treatments in each condition within the trial timeline. We additionally will quantify the rate of treatment dropout percentage for each treatment condition.
2. At each of the 5 clinical sessions, the interventionist will complete a Treatment Fidelity checklist. Finally, writing assignments will be reviewed to evaluate how well participants adhered to the instructions comprised of critical interventional components.
3. The overall cost of WET delivered via group or individual formats will be calculated using a ratio of inputs (i.e., time) to outputs (i.e., symptom reduction).

Optional Firearm Training Simulator Sub-Study

We will collect self-report data for up to 126 active-duty service members by administering the Lethality Scale to participants during the pre- and post- treatment performance measurement sessions (see measurement scale attached). The Lethality Scale will measure participants confidence in the basic skills necessary to be lethal during combat.[59]

Finger tapping is a simple measure of fine motor speed in the dominant and non-dominant hands. Performance is compared against normative data for age, sex, and handedness to determine z-scores. The Connors CPT is a computer-administered test provides objective performance data on inattentiveness, impulsivity, sustained attention, and vigilance. Scores are converted to T-scores and compared to a normative group, providing a percentile ranking. The MVPT-4 is a test that measures visual perception skills independent of motor ability. It has five specific visual-perceptual subscales (visual discrimination, spatial relationships, figure-ground, visual closure, and visual memory), with results presented as either a standard score or percentile rank.

The Dynavision D2 is a computerized light-based training device with a large interactive board that is often used as a rehabilitation device that helps users improve visual-perceptual and motor skills by reacting to sequences of lights. This task requires a synthesis of several skills, including reaction time, hand-eye coordination, spatial awareness, impulsivity, and attention. The Dynavision records response time and error rates as outcome measures.

The Firearm Training Simulator (FATS) is an advanced, interactive simulator that combines realistic firearms, projection screens, and computer software to provide immersive training. Participants will complete the Army standard marksmanship qualification, as well as a "Shoot /Don't Shoot" scenario that assesses judgement and impulsivity. These tasks also measure a range of integrated skills, including reaction time, hand-eye coordination, spatial awareness, and attention. Measured outcomes include rates of accuracy as well as reaction times.

Responses will be scanned using the encrypted workflow scanning capabilities of Jennifer Moreno Clinic and/or Troop Medical Clinic print stations. Specifically, authorized study staff will log in to the secured Jennifer Moreno Clinic and/or Troop Medical Clinic print station (connected to the BAMC network) using their Common Access Card, configure workflow scanning to transfer a PDF scan directly to the corresponding secure location on the networked BAMC drive. Data will be exported at regular intervals to encrypted excel spreadsheets on secure BAMC servers. For statistical analyses, excel datasets will be de-identified, reduced, cleaned, and exported to SPSS files encrypted for additional security on the BAMC servers. De-identified datasets will only be accessible to approved research staff.

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

(•) Yes ( ) No

10.4 Review the definitions below and respond to the following two questions. If you are not sure of the answers, email DHA. PrivacyBoard@mail.mil for assistance. The *Military Health System (MHS)* is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force *MHS workforce members* are employees, volunteers, trainees, and other persons whose conduct, in the performance of work for the MHS, is under the direct control of the MHS, whether or not they are paid by the MHS. *MHS business associates* are persons or entities that provide a service to the MHS and require protected health information (PHI) to provide the service.

Are you an MHS workforce member?

(•) Yes, I am an MHS workforce member
( ) No, I am not an MHS workforce member

10.5 Have you consulted with an MHS data expert to determine the data elements required for your study?

Consulting with a data expert often saves time later in the compliance process because the data expert can advise on the data available in the numerous MHS information systems, the quality of that data and the methods for encrypting and collapsing data. To schedule a consult with an MHS data expert, send an email to: (**DHA.PrivacyBoard@mail.mil**)

( ) Yes, then complete the questions below according to the data consult
(•) No, then complete the questions below according to the best of your knowledge

10.6 Indicate how you will request data from the MHS. Select all that apply.

[ ] Talking with MHS health care providers or MHS health plans about specific research participants
[ ] Obtaining MHS hard copy records specific to research participants
[x] Obtaining data from an MHS information system(s)

10.7 If you are obtaining data from an MHS information system(s), indicate whether you plan to receive a data extract or whether you plan to access an MHS information system directly to create a data set.

A data extract is when the MHS or a contractor provides the data set directly to the researcher. When receiving a data set through data extract, the researcher may indicate whether the data elements should be provided as is, encrypted or collapsed. In contrast to a data extract, access to an information system means that the researcher may directly access an MHS information system and create a data set for the research study

[x] Data Extract
[ ] Access

10.8 Do you intend to request de-identified data from the MHS in your research study?

There are different two methods for de-identifying data pursuant to HIPAA:

1) Safe Harbor Method: Removing all of the identifiers listed in Table 1 below, provided that the researcher does not have actual knowledge that the remaining data can be used alone or in combination with other information to identify the individual who is the subject of the information
2) Statistical Method: An expert, with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, determines that the data is not individually identifiable

○ Yes ◉ No

10.9 Indicate the MHS information system(s) from which you will seek to obtain data

If you do not know which system(s) contains the data elements you need, refer to the Guide for DoD Researchers on Using MHS Data or request guidance from an MHS data expert at: **DHA.PrivacyBoard@mail.mil**.

Below is a list of commonly used MHS systems. If the system from which you seek to obtain data is not listed below, list the name of the system in the "Other MHS Systems" category below
PHI Systems:

MHS Information System	Requesting Data
: MHS Genesis	: Yes

PII-Only Systems:

MHS Information System	Requesting Data

De-Identified Data & Other Systems:

Information System	Requesting Data
Other MHS System May include PII and/or PHI List other system here: Behavioral Health Data Portal (BHDP)	: Yes

10.10 Do you intend to merge or otherwise associate the requested data with data from any sources outside of the MHS, including other DoD systems that are not part of the MHS?

○ Yes, will merge data
◉ No, will not merge data

10.11 Indicate the data elements about research participants or relatives, employers, or household members of the research participants that you will request from MHS hard copies or from MHS information systems.
If you will merge data, also indicate non-MHS data elements about research participants or relatives, employers, or household members of the research participants that you will have access to in any form or medium.

Direct and Indirect Identifiable Data Elements	DHA Hard Copies	DHA Data Elements to be Accessed	DHA Data Elements Verbal	Extracted DHA Digital Data	Downloaded DHA Digital Data	Non-DHA Hard Copies or Digital
1. Names	☐	☐	☐	☐	☐	☐

2. Postal address with only town, city, state, and zip code	☐	☐	☐	☐	☐	☐
3. Postal address with all geographic subdivisions smaller than state, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census: 1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 2) the initial three digits of a zip code from all such geographic units containing 20,000 or fewer people is changed to 000	☐	☐	☐	☐	☐	☐
4. Dates including all elements (except year) directly related to an individual, including birthdate, admission date, discharge	☐	☑	☐	☐	☐	☐

date, and date of death						
5. Ages over 89 and all elements of dates (including year) indicative of such age, unless you will only request a single category of "age 90 or older"	☐	☐	☐	☐	☐	☐
6. Telephone Numbers	☐	☐	☐	☐	☐	☐
7. Fax Numbers	☐	☐	☐	☐	☐	☐
8. Email Addresses	☐	☐	☐	☐	☐	☐
9. Social Security Numbers	☐	☐	☐	☐	☐	☐
10. Medical Record Numbers (MRN) (including record ID)	☐	☐	☐	☐	☐	☐
11. Health Plan Beneficiary Numbers (including DEERS ID, Electronic Data Interchange Personal Identifier (EDIPI) or Number (EDIPN))	☐	☑	☐	☐	☐	☐
12. Account Numbers	☐	☐	☐	☐	☐	☐

13. Certificate /License Numbers	☐	☐	☐	☐	☐	☐
14. Vehicle identifiers and serial numbers, including license plate numbers	☐	☐	☐	☐	☐	☐
15. Device identifiers and serial numbers	☐	☐	☐	☐	☐	☐
16. Web Universal Resource Locators (URLs)	☐	☐	☐	☐	☐	☐
17. Internet Protocol (IP) address numbers	☐	☐	☐	☐	☐	☐
18. Biometric identifiers, including finger and voice prints	☐	☐	☐	☐	☐	☐
19. Full-face photographic images and any comparable images	☐	☐	☐	☐	☐	☐
20. Any other unique identifying number, characteristic, or code (including non-military provider IDs)	☐	☐	☐	☐	☐	☐
21. Free Text Fields	☐	☐	☐	☐	☐	☐

If you are obtaining SSNs, provide a justification as to why and explain why a substitute cannot be used.

Due to guidelines stated within DoDI 1000.30, Reduction of SSN Use within DoD, the reduction or elimination of SSN usage must occur wherever possible. If SSNs are required to complete the project, the PI must provide a justification and explanation as to why a substitution cannot be used.
For example:

- If alternatives to SSN (e.g., EDIPNs or pseudo person IDs) are sufficient in other instances, will those alternatives to SSN usage be sufficient to respond to Congressional inquiries and /or Senior DoD stakeholders inquiries?
- Are alternatives to SSN used first?
- Are those alternatives to SSN insufficient to combine data from multiple data sources? Is the issue that some individuals do not possess alternatives ID numbers and SSN is the only way to identify them?

a. Will you receive or obtain health information?

> ***Note:*** *If you indicate you are not receiving health information, the answer must be consistent with the DHA data source. For a non-health information data request, if you are a non-MHS employee or non-MHS business associate, you may not access an information system that has PHI or LDS. For both MHS and Non-MHS employees and MHS business associates, you may* ***NOT*** *include data elements in the above table on: 1) lines 10 or 11, 2) line 21 if the free text field comes from a PHI or LDS system, and 3) lines 12, 13, or 18 if the account numbers, certificate and license numbers, biometric data, or any other data elements are health information created or received by an MHS health care provider, health plan, or business associate in relation to the physical or mental health or condition of an individual or payment for health care.*

- (●) Yes, I will receive or obtain health information
- ( ) No, I will not receive or obtain health information

b. If no data elements were checked in the above table, is it possible that the requested DHA data is or will be identifiable because of any unique data elements, triangulation, or small cell size*?*

- [x] Data elements were checked in the above table, STOP HERE.

NOTE: *A unique data element includes any unique features that alone are not identifiable but that could be used to identify an individual within the context of other information, such as any type of code (such as diagnosis or procedural), rank of general or admiral, sex, or race. Triangulation means using different data elements that when combined can be used to identify an individual, such as including the above lists of unique data elements in a data set. Determining whether an individual is identifiable through triangulation requires consideration of all data elements in combination. Within the military, the use of rank and/or diagnosis code, procedural codes, or any other code that changes on a predictable basis, increases the possibility of identification. Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Department of Defense Manual 6025.13, Medical Quality Assurance and Clinical Quality Management in the Military Health System MHS, provides that the threshold for de-identifying data within the MHS requires a cell size of three, but also states that the de-identification standards must meet the DoD implementation of the HIPAA Privacy Rule. Centers for Medicare and Medicaid also gives guidance on small cell size stating that no data cell less than 11 may be published or displayed. However, the Office for Civil Rights' OCR, which is the official regulatory office for the HIPAA Privacy Rule, provides that OCR does not designate a universal value for small cell size in accordance with the de-identification standard; instead, the cell size should be set at a level that is appropriate to mitigate risk of identification by the anticipated recipient of the data set. This means that a cell size of 3 or 11 may not meet the HIPAA Privacy Rule requirements if the cell size level does not appropriately mitigate risk of identification by the anticipated recipient of the data set.*

Note: If dates are altered as a means of de-identifying the data, diagnosis and procedural codes need to be rolled-up or collapsed. If dates are provided "as time between events," the roll-up is not necessary.

- [ ] Yes, the DHA data will become identifiable
- [ ] No, the DHA data will not become identifiable

10.12 Do you believe it is possible for the MHS data to become identifiable because of triangulation, a small cell size, or any unique data element(s)?

Triangulation means using different data elements that are not themselves identifiable but that when combined can be used to identify an individual. For example, triangulation would use rank and race together to determine the identity of an individual with a particular health condition.

Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Guidance for acceptable cell size is available from the Centers for Medicare and Medicaid Services. For example, the rank category of four star generals with a particular diagnosis may be less than 30, so the rank category may need to be expanded to include lower ranks.

A unique data element includes any unique features that are not explicitly enumerated in the categories of data in rows 1 – 20 of the table above (in Section 10.10), but that could be used to identify an individual. Unique data elements include characteristics that are not themselves identifying, such as the rank of general or admiral, or a race or sex, but within the context of other information could be identifiable.

- ○ Yes, I believe there is a reasonable possibility the MHS data will become identifiable
- ◉ No, I believe there is no reasonable possibility the MHS data will become identifiable

10.13 Have you completed and uploaded an appropriate HIPAA document (i.e. HIPAA Authorization will be obtained or Waiver/alteration of HIPAA Authorization is being requested)?

- ◉ Yes
- ○ No
- ○ N/A

If yes, please check which one.

- [x] HIPAA Authorization
- [ ] HIPAA Waiver (Full or Partial)
- [ ] Other (please provide copies when uploading Other Study Documents)

10.14 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for this Study:

Include in this section the plan for acquiring data (both electronic and hard copy), access during the study, data/specimen storage and length of time stored, shipment/transmission, and the plan for storage and final disposition at the conclusion of the study. Describe any data agreements in place for accessing data within and/or outside of your institution (e.g., Data Sharing Agreement, Data Use Agreement, Business Agreements, etc.)

Data Management Plan: This describes the data we plan to generate throughout the course of the proposed research, as well as how we will share and preserve the data. The term "data" in this context refers to all raw data that form the basis for the analyzed data presented in a publication.

Data Collection: We will collect data from self-report measures, including de-identified demographic information (e.g. age, sex, ethnicity, etc.; see demographic survey attached), treatment process measures (acceptability, fidelity), and clinical measures (PTSD, depression, anxiety, insomnia, functional impairment) data for 126 active duty Servicemembers during assessment (pre-treatment, post-treatment, 3-, 6-month follow-up) and/or clinical appointments at the Jennifer Moreno Clinic and/or Troop Medical Clinic. In addition, we will generate additional outcomes (cost, acceptability) from process measures observed throughout the study (i.e., treatment engagement, dropout rates). De-identified written trauma narratives will also be collected at the end of each clinical session to facilitate fidelity measures. Narratives will be

scanned using the encrypted workflow scanning capabilities of Jennifer Moreno Clinic and/or Troop Medical Clinic print stations. Specifically, authorized study staff will log in to the secured Jennifer Moreno Clinic and/or Troop Medical Clinic print station (connected to the BAMC network) using their Common Access Card, configure workflow scanning to transfer a PDF scan directly to the corresponding secure location on the networked BAMC drive. If the participant requests the research team to shred it, the physical narrative will immediately be deposited into a HIPAA compliant receptacle specifically dedicated to destroying paper documents containing protected information.

After obtaining Institutional Review Board (IRB) and Office of Human Research Oversight (OHRO) approvals, we will collect assessment self-report data for 126 active duty Servicemembers virtually using the Behavioral Health Data Portal. Data will be exported at regular intervals to encrypted excel spreadsheets on secure BAMC servers. For statistical analyses, excel datasets will be de-identified, reduced, cleaned, and exported to SPSS files encrypted for additional security on the BAMC servers. De-identified datasets will only be accessible to approved research staff.

Documentation and Metadata: For each complete dataset, the content and format are as follows:

- Self-report and study process data: Excel, SPSS format

All subjects will provide written informed consent, and all protocols will receive IRB and HRPO approvals.
We do not anticipate any ethical or legal issues associated with the computed data.

Storage and Backup
BAMC and the Department of Mental Health have sufficient storage for data preservation and backup. Each staff member has a PC connected to the BAMC network via a gigabit network to three dedicated BAMC servers. Data are backed up to the server daily. All data on the PCs and servers are backed up on a regular basis to separate DBH specific drives connected to the BAMC network. In the event of an incident, the BAMC IMD team will be responsible for recovering the data from backup.

Managing access and security: The computer databases at the BAMC are protected by several security layers, including access restrictions/encryptions (users must have a CAC with privileges enabled by BAMC IMD), password protection of participant data and a firewall around the entire Research Computing Network. Access to PCs is only available to authorized users who have security badge access to BAMC facilities, as approved by the BAMC Provost Marshall. File transfers will be executed via secure transfers within the BAMC network or other secure approved platforms (e.g., DoDSafe).

Selection and Preservation
We will permanently archive the data generated in this project on the BAMC servers. All BAMC research staff members will be Health Insurance Portability and Accountability Act (HIPAA) trained annually. File transfers are executed via secure transfers within the BAMC network or other secure approved platforms (e.g., DoDSafe). Upon receipt, the data are reviewed and moved to the appropriate read-only project folder for use and storage. Upon acceptance of a manuscript, staff members archive all relevant data (including raw data, metadata, analyzed data, and any associated codes) in a project-specific folder for permanent storage and preservation.

Data Sharing
We will deposit final peer-reviewed manuscripts with the appropriate publication metadata as generated from the proposed work as required by the funding agency within 1 month of the final publication date.

We will prepare and make available curated data from our analyses to the fullest extent possible through the use of publication websites and publicly accessible data banks appropriate to the subject area. The research project metadata will describe the data and the conditions under which the data were collected so that an individual who is skilled in this project's field of study can properly interpret the findings and use the data in a scientifically valid manner for further analysis. Access to the data will be provided through a written request to the PI, including a description of the requested data, the research question being investigated, and a brief description of the proposed research method. In addition to PI approvals, Requests will require approvals from BAMC OHRO and PAO

Responsibilities and Resources

The PI, Co-Is and BAMC IMD will be responsible for implementing the Data Management Plan, and ensuring that it is reviewed and revised. Approved research team staff will also be responsible for all data management activities under this award. BAMC and the Department of Mental Health have the necessary hardware and software to deliver the Data Management Plan. In addition, the IT specialists at BAMC IMD have the knowledge and expertise to implement the plan. Because support of the BAMC IMD team is embedded in our overhead, no additional financial resources need to be identified to support full implementation of the herein described data management plan.

Is this a data repository?

○ Yes ◉ No

10.15 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for Future Research:

If the study involves collecting, storing, or banking human specimens, data, or documents (either by the Investigator or through an established repository) for FUTURE research, address. How the specimens/data will be used, where and how data/specimens will be stored (including shipping procedures, storage plan, etc.), whether and how consent will be obtained, procedures that will fulfill subjects' request as stated in the consent, whether subjects may withdraw their data/specimens from storage, whether and how subjects may be recontacted for future research and given the option to decline, whether there will be genetic testing on the specimens, who will have access to the data/specimens, and the linkage, the length of time that data/specimens will be stored and conditions under which data/specimens will be destroyed.

Is this a data repository?

○ Yes ◉ No

11.0 Statistical/Data Analysis Plan

11.1 Data Analysis Plan and Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any subgroup analyses (e.g., sex or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis.

Baseline descriptive statistics will be calculated to characterize the sample. Distributional assumptions will be considered, and transformations (e.g., logarithmic, square root) will be applied when indicated to improve data normality. Bivariate correlations will test associations between baseline self-report measures and primary outcomes. Between-subjects variables that are significantly associated with dependent variables will be considered for inclusion as potential moderators or covariates in subsequent analyses. To test the Aim 1 hypotheses that Group WET is noninferior to Individual WET in improving clinical outcomes, mixed-effects regression models with repeated measures will be performed using the intent to treat (ITT) sample comprised of randomized participants who complete at least 1 treatment session. The mixed-effects model will consist of fixed effects of time, intervention group, and the time by intervention group interaction. Change score comparisons will examine differences in symptom reduction by intervention from pre-treatment to post-treatment, 3-month follow-up, and 6-month follow-up. Noninferiority will be defined as the difference between the 2 treatment conditions being less that the upper limit of the 1-sided 95% confidence interval with margins specified for each clinical outcome (based on values reported in the literature) as follows: 10 points on the CAPS-5; [10] 7.5 points on the PCL-5;[54] 3 points on the PHQ-9;[55] 2.5 points on the GAD-7;[55] 2 points on the ISI;[56] and 2 points on the WRAIR, Functional Impairment Scale.[57] For Aim 2, ANOVA (ANCOVA if appropriate covariates are identified) will be used to test for significant differences between the 2 treatment conditions on measures of acceptability, fidelity, and costs.

Optional Firearm Training Simulator Sub-Study

Following data collection, all data will be assessed for normality, and appropriate follow up statistical testing will be performed. his project will use Structural Equation Modeling (SEM), a

statistical technique used to analyze complex relationships among observed and latent (unobserved) variables. It combines aspects of factor analysis and multiple regression, allowing the investigators to test theoretical models involving multiple dependent and independent variables simultaneously. Latent variables, such as motor skills, attention, and executive functioning will be inferred from observed variables (e.g. cognitive tests). Path diagrams are then built to represent hypothesized relationships, and tested using fit indices (e.g., RMSEA, CFI) to determine how well the proposed model fits the actual data. We will use a geral linear mixed effects regression model with repeated measures at baseline and 3-month follow-up. Advantages of mixed-effect regression models include the relaxation of the assumption of equal variances, specification of data distributions other than normal, and ability to analyze longitudinal data in the presence of missing data given the assumption that data are missing at random. Statistical Models will include the fixed the effects of time, clinical symptom scales, cognitive testing, motor testing, and integrative task performance (Dynavision & FATS). To handle confounding variables, covariates will include baseline symptom severity as measured by the PHQ9, PCL5, GAD7, and ISI, as well as demographic factors (age, gender). The accepted threshold for statistical significance will be $p < 0.05$ for primary outcomes.

11.2 Sample Size:

126

11.3 Total number of subjects requested (including records and specimens):

126

11.4 Are you recruiting participants by study arm?

(•) Yes ( ) No

If yes, please identify the arms of the study and how many subjects will be enrolled in each arm.

Group Written Exposure Therapy = 63
Individual Written Exposure Therapy = 63

11.5 Please provide a justification for your sample size

To determine a target sample size, we examined effect sizes reported in the literature from studies that tested Written Exposure Therapy on PTSD symptoms (i.e., CAPS-5 severity scores). 9,10,32 Thus, power analyses for this proposal were calculated to estimate the sample size required for noninferiority effects hypothesized in Aim 1. Consistent with previous PTSD noninferiority trials,9,10,32,42,43 an outcome difference of 10 or more points on the CAPS-5 total score will serve as the noninferiority margin. Noninferiority will be inferred if the difference between group means had an upper bound 95% 1-sided confidence limit of less than 10 on the CAPS-5. Thus, a sample size of 100 participants (50 participants per group) was estimated to afford a power of .80 to detect medium-sized effects using a 1-sided noninferiority test at $p = .05$ (95% CI) and a standard deviation of 20.10,43 An estimated 25% loss to follow-up will be accounted for by recruiting an additional 26 participants, for a total target sample size of 126.

12.0 Participant Information

12.1 Subject Population:

Active-duty service members seeking treatment who currently meet diagnostic criteria for PTSD in the San Antonio DHA Market

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [ ] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [x] 45-54
- [x] 55-64
- [ ] 65-74
- [ ] 75+

12.3 Sex:

- [x] Male
- [x] Female
- [ ] Unknown

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen
- [x] Active Duty Military Personnel
- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons
- [ ] Educationally Disadvantaged Persons
- [ ] Physically Challenged (Physical challenges include visual and/or auditory impairment)
- [ ] Persons with Impaired Decisional Capacity
- [ ] Prisoners
- [ ] Pregnant Women, Fetuses, and Neonates
- [ ] Non-English Speakers
- [ ] International Research involving Foreign Nationals - Headquarters Review is necessary

You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e.

12.5 Inclusion Criteria:

Order Number	Criteria
1	1) 18 years old or older 2) ability to speak and read English 3) currently serving as an active duty Servicemember in the US Military 4) currently meet diagnostic criteria for PTSD 5) participants anticipate remaining in the local area with no changes in duty station for in-person procedures

12.6 Exclusion Criteria:

Order Number	Criteria
	1) significant alcohol/substance use disorders requiring immediate attention

1	2) history of and/or current psychotic or bipolar disorder 3) current participation in another psychological treatment for PTSD 4) significant cognitive impairment 5) pending a change in duty station or active duty status (i.e., PCS, ETS) 6) recent medication changes that have not been stable for at least 4 weeks 7) current suicidal/homicidal risk.

13.0 Recruitment and Consent

13.1 Will subjects be identified and selected for study participation?

(•) Yes ( ) No

If yes, please describe the recruitment process, including how subjects will be identified and selected for the study

Participants will be recruited from non-emergency, active duty, personnel experiencing mental health concerns. Participants will be recruited from the Joint Base San Antonio, Texas community through the use of MTF referrals and media advertisements. Investigators will brief clinic providers on the study availability and inclusion criteria. Recruitment flyers will also be given to clinic providers to refer to when discussing the study with potential participants. If a clinic provider believes a patient meets the inclusion criteria, they will provide the patient with the recruitment flyer and offer them the opportunity to speak with the project coordinator.

13.2 Will subjects be compensated for study participation?

(•) Yes ( ) No

If yes, please describe the total amount and schedule for subject compensation

In accordance with DoDI 3216.02, active-duty participants will be compensated if study participation occurs during off-duty hours and does not adversely impact their ability to perform their assigned duties. Participants will be paid $50 for the completion of the initial online baseline assessment. Enrolled participants will also be compensated $50 each time they complete the post-test, 3-month follow-up, and 6-month follow-up assessments. To promote retention across all follow-up assessments, participants will earn an additional $50 for completing all follow-up assessments. In total, each participant can earn up to $250 for completing all study assessments sessions. Servicemembers will only be compensated for evaluations that take place outside of duty hours.

Under standard operating procedures, participants will receive their gift card compensation in person from a study team member and will provide a signature to acknowledge the receipt of funds. Because data collection for the post-test and all subsequent follow-up assessments will be conducted electronically, participants are not required to be physically present at the study site. In the event that a participant undergoes a Permanent Change of Station (PCS) or a similar change in duty station that prevents them from signing for or picking up a gift card in person, the gift card will be mailed to the participant's provided mailing address without requiring an in-person signature for receipt.

Optional Firearm Training Simulator Sub-Study
Participants will not receive any additional compensation for participating in the optional firearms training simulator sub-study, including the 2 performance measurement sessions.

13.3 Will pre-screening of subjects occur?

(•) Yes
( ) No
( ) N/A

If yes, please describe the pre-screening process

Respondents will be screened by phone for the inclusion/exclusion criteria.

13.4 Consent Process: Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

At the initial baseline session an approved research staff member will give a verbal overview of the study and provide a written copy of the consent form. The researcher will go through each section to ensure the participant understands, while providing ample opportunity to ask the researcher questions before agreeing to participate. Participants will also be informed that if they want time to consider their participation, they can take the consent form home to review, and another appointment will be scheduled should they decide to continue participation in the study. The researcher will inform the participant that they are not required to participate in this study; They may decline to participate and this will not have any negative influence on relevant standings. Participants will be informed that they do not have to answer any questions they do not wish to answer, and can discontinue participation at any time without penalty. Prospective participants will be asked to read the consent form and they will have an opportunity to ask any questions before signing the consent document. The project coordinator will then obtain their signed informed consent for participation. Baseline measures will only be collected for those that consent to participate.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

◉ N/A
○ Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

Participants will have the right to terminate their participation at any time and without prejudice. Their withdrawal from research procedures will not result in any loss of benefits nor affect the services they are receiving. Study staff will work with withdrawing participants to ensure continuation of care with all service providers. We do not foresee any consequences of early withdrawal on the participant. Unforeseen consequences will be reported per DHA policy.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

It is possible that responding to questions on surveys may cause mild discomfort (e.g., sensitive questions related to mental well-being). Risks include temporary fluctuations in symptomatology and breach of confidentiality similar to routine behavioral health care. Whenever one works with networked systems (e.g., BHDP), there is always the risk of compromising privacy, confidentiality, and/or anonymity. Participant confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the internet by third parties. In addition, there is risk due to asking participants about illegal activities (i.e., alcohol use for those younger than 21), as the researchers would not be immune to legal subpoena about these activities. If law enforcement officials request access to these data via legal means (e.g., warrant), we would have to provide them.

Optional Firearms Training Simulator Sub-Study
Participants may become tired, bored, nervous, or frustrated when completed the study tasks.

14.2
Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

Procedures have been adapted to minimize the risks we have stated above. Contact information for Behavioral Health Resources across JBSA and the San Antonio community will be provided in the consent form. The risk of legal subpoena, though unlikely, will be explained to participants in the consent. Participants will be given the opportunity to ask questions during the informed consent procedure, and will be reminded by research staff that they do not have to participate, and could withdraw from the study at any time. As an added measure of safety/good practice, two members of the research team will be present during all sessions. Participants will be informed at several points throughout the study that they may choose to withdraw from the study at any time. Additionally, Drs. Woodworth, De Vita, and Moore are all licensed clinical psychologists trained in risk assessment and crisis intervention. If a participant demonstrates signs of acute medical illness the researcher will alert the PI and direct the servicemember to the appropriate clinical setting (e.g., Emergency Department).

Study staff will be trained to minimize the burden on participants by scheduling interviews at times that are convenient for the active-duty Service members.

Randomly generated ID numbers will be used to mitigate risks to privacy. This number will be attached to all data (assessments, MSAT data) and no one outside of the research team will know which subject is associated with which data. Data collected from networked systems (e.g., BHDP) will require double-encrypted authentication (1: CaC + pin to login to computer; 2: CaC + pin to login to system) which will only be accessible to authorized study staff. Physical systems will be locked in secure facilities that require at least to entry control points accessible only via pre-authorized badge access. De-identified data will be maintained on secure, encrypted, non-networked devices.

Optional Firearms Training Simulator Sub-Study
The FATS has significantly reduced noise and recoil compared to a real firearm. The FATS will not be set up to simulate a combat environment; all environments and targets are adapted from the Army's marksmanship certification that is required for all Soldiers annually. It will be reiterated that participation is voluntary and can be discontinued at any time.

14.3
Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e. g., child or spouse abuse

The computer databases at the Jennifer Moreno Clinic and/or Troop Medical Clinic and BAMC are protected by several security layers, including access restrictions/encryptions (users must have a CAC with privileges enabled by BAMC IMD), password protection of participant data and a firewall around the entire Research Computing Network. Access to PCs is only available to authorized users who have security badge access to BAMC facilities (i.e Jennifer Moreno Clinic and/or Troop Medical Clinic), as approved by the BAMC Provost Marshall. File transfers will be executed via secure transfers within the BAMC network or other secure approved platforms (e.g., DoDSafe).

14.4
Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

Participants may experience improvement in post-traumatic stress symptoms from participating in this study.

14.5
Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

Only the IRB approved researchers will have access to the data. Study staff will be trained extensively in experimental procedures and the importance of privacy and confidentiality. All study staff will have undergone the mandatory CITI training, which include specific modules on privacy and confidentiality. Initial consent and all data collection will be done in a private setting within approved clinical facilities, in an in-person format, by study personnel. Data will be de-identified to protect privacy, and all data will be collected and/or stored on devices with multi-layered encryption. De-identified data will be stored on non-networked devices to enhance privacy further. All study materials will be stored in highly secured at the Jennifer Moreno Clinic and/or Troop Medical Clinic

14.6
Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

During the assessment phases it would be an incidental or unexpected finding for the participants to report severe symptoms either verbally or on any assessment measures. In the case of severe mental impairment or unstable psychiatric illness such as active psychosis, recent hospitalization, current suicidal/homicidal intent, etc., the clinician will assess whether the subject should be referred for further evaluation and management, as well as assess whether the participant is appropriate to remain in the research trial. These participants will be given verbal and written information on how to access support services if so desired. These would include but not be limited to going to the Mental Health Clinic during walk-in hours, contacting chaplain counseling services, or MFLC services.

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- (•) DSMP
- ( ) DSMB
- ( ) Both
- ( ) Not Applicable

A DSMP should describe the plan to monitor the data to verify that the data are collected and analyzed as specified in the protocol. Include who will conduct the monitoring, what will be monitored, and the frequency of monitoring. It should also include the plan to ensure the safety of subjects

DATA AND SAFETY MONITORING PLAN

General description of monitoring plan
BAMC and its Institutional Review Board (IRB) and the investigators Drs. Woodworth, De Vita, and Moore, share responsibility for monitoring the study. Safety monitoring decisions will take place after discussion among the investigative team. These include decisions such as whether any reported incident is unanticipated and/or places participants or others at greater risk of harm, if protocols or consent processes need to be modified, and if the incident must be reported to the IRB and/or funding agency. The principal risk is loss of confidentiality. Loss of confidentiality is unlikely, but if it occurs, could have serious repercussions. The remaining risks are minimal.

Unanticipated problems are defined as events that are 1) unanticipated, 2) involved risk to participants or others, and 3) was possibly related to the research procedures. Unanticipated problems must be reported to the IRB as soon as possible, but no later than 3 days of the investigator learning of the incident. The Investigators are responsible for the accurate documentation, investigation, and follow-up of all unanticipated problems involving risk to participants or others that occur at the site in which the Investigator is responsible for the conduct of the research.

As in any experimental study, it is possible (although unlikely) that participants could react adversely during the assessment and/or experimental procedures. All adverse events will be carefully monitored by the investigator. The occurrence of any serious adverse event will be reported. Specifically, research personnel will report the occurrences of serious adverse events to Dr. Woodworth, who will in turn report to the IRB within 48 hours of learning of such occurrences. Information also is included in the Informed Consent materials so that participants are aware about the handling of these issues. In the event of a serious adverse reaction, the PI will determine the most appropriate manner in which to intervene. During the project, as part of the safety monitoring procedures, Drs. Woodworth, De Vita, and Moore will train all personnel and will be responsible for protecting the confidentiality of the trial data and the results of monitoring. Additionally, they will conduct weekly meetings with study personnel for the purposes of supervision and monitoring the procedural outcomes and study progress.

Risk assessment
Participation in the study proposed herein is "minimal risk" which is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests," (from 45 CFR 46.102(i)), with the exception of the risk of loss of confidentiality. This risk is addressed above. The risk of breach of confidentiality is best addressed by appropriate study procedures; however, the PI will be responsible for assuring that study procedures are adhered to regarding data security, transfer, and communications in tracking participants by meeting regularly with study staff, reviewing procedures and performing quality control reviews of study forms.

Anticipated adverse events, monitoring, and safety review (including personnel and frequency)
Any participant who voices concerns about serious adverse events during a research activity will be reported to the PI immediately. Any adverse events related to study procedures will be monitored by the study using a study adverse event form and reviewed at meetings of the study team. Other serious adverse events reported to research staff will be reviewed by the PI and handled similarly. These events will be reported on a study adverse event form and

reviewed by the project manager and PI as they occur. The project manager and investigators will review aggregate data regularly.

Assurance that trained personnel will be present or on call when specific study procedures take place, based on the level of risk and consistent with approved protocol, policies and guidance from the local IRB and/or other regulatory and monitoring entities. Trained personnel will be present or on call when data collection is taking place. Research assistants will be trained in participant safety monitoring.

We have several procedures for data quality assurance and protecting confidentiality of participant data. First, participant questionnaires will be identified by a unique code rather than name. Records of participants' names, contact information, and consent forms will be collected and kept separately from the questionnaires. All data will be kept in a secure file accessible only to primary research personnel. After completion of the project, the master list connecting participants' names to their id numbers will be destroyed. There are four specific precautions in place to ensure that the individual's data are protected.

1. Confidentiality will be maintained by means of identifying protocols by code only. A master list linking names to codes will be kept in a locked file accessible only to designated research staff. This master list will be kept for purposes of contacting participants as needed.

2. At no time does the participant's name or other personal identifying information appear together in data files.

3. Data from the questionnaires will be stored using BHDP servers, which are protected by firewall systems, and vulnerability scans are performed regularly. Complete penetration tests are performed yearly. All services have quick failover points and redundant hardware, and complete backups are performed nightly. All data at rest are encrypted, and data on deprecated hard drives are destroyed by U.S. DOD methods and delivered to a third-party data destruction service.

4. Data is stored on password-protected computers.

Stopping rules: The trial will stop if there is clear evidence of harm based on review of adverse events that are unanticipated problems.

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

All events requiring prompt reporting will be sent within three (3) business days of the research team's knowledge of the event by phone (210-916-2598) or by e-mail (**usarmy.jbsa.medcom-bamc.mbx.bamc-irb@health.mil**) to the office of the San Antonio Institutional Review Board. A complete written report will follow the initial notification within ten (10) business days.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

(•) Yes ( ) No

Please describe:

Only the optional sub-study will involve the use of a Firearms Training Simulator and Dynavision D2.

This is a non-medical device used for research purposes, only.

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- [ ] Drugs
- [ ] Dietary Supplements
- [ ] Biologics
- [ ] Devices
- [x] N/A

18.5 Sponsor (organization/institution/company):

- [x] N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- ( ) Registration is not required
- (•) Registration pending
- ( ) Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- (•) Registration is not required
- ( ) Registration pending
- ( ) Registration complete

20.0 References and Glossary

20.1 References:

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20.2 Abbreviations and Acronyms:

ADSM	Active-Duty Service Member
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
APA	American Psychological Association
BAMC	Brooke Army Medical Center
BHDP	Behavioral Health Data Portal
BPS	Bedtime Procrastination Scale
CAPS-5	Clinician-Administered PTSD Scale for DSM-5
CFI	Center for the Intrepid
CI	Confidence Interval
CPT	Cognitive Processing Therapy
CSQ	Client Satisfaction Questionnaire
Co-I	Co-Investigator
DBH	Department of Behavioral Health
DHA	Defense Health Agency
DoD	Department of Defense
DSM-5	The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EBP	Evidence-Based Psychotherapy
EMDR	Eye Movement Desensitization and Reprocessing Therapy
ETS	Expiration Term in Service
FATS	Firearm Training Simulator
GAD-7	Generalized Anxiety Disorder-7
IRB	Institutional Review Board
ISI	Insomnia Severity Index
ITT	Intent-to-treat
JBSA	Joint Base San Antonio
MINI	The Mini International Neuropsychiatric Interview
MTF	Medical Treatment Facility
MVPt-4	Motor-Free Visual Perception Test - Fourth Edition
PCS	Permanent Change of Station
PCL-5	PTSD Checklist for DSM-5

PE	Prolonged Exposure Therapy
PHQ-9	Patient Health Questionnaire-9
PI	Principal Investigator
PTSD	Posttraumatic Stress Disorder
SEM	Structural Equation Modeling
TAAS	Treatment Acceptability/Adherence Scale
TAPS	Thoughts about Psychotherapy Survey
TEQ	Treatment Expectancy Questionnaire
TF-CBT	Trauma-Focused Cognitive Behavioral Therapy
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
WET	Written Exposure Therapy