Brooke Army Medical Center (BAMC)
CONSENT TO PARTICIPATE IN RESEARCH
Title: Comparing Individual versus Group Written Exposure Therapy among Active Duty Servicemembers: A Randomized Noninferiority Trial
Principal Investigator: Dr. Craig Woodworth, PsyD

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to take part in a voluntary clinical research study at the Jennifer Moreno Clinic and/or Troop Medical Clinic Department of Mental Health. This is a study designed to evaluate the efficacy of a gold-standard PTSD treatment (non-medication based), Written Exposure Therapy, when delivered either individually or in groups. Over the course of 6 weeks, the research study will include a baseline assessment session, potentially followed by 5 group or individual treatment sessions and 3 post-treatment assessment sessions at the following time intervals: immediately after treatment concludes, 3-month follow-up, and 6-month follow-up. Total participation will occur over 7 months.

Assessment sessions will include clinical interviews and self-report assessments to gather data on PTSD, mood (depression & anxiety), and other relevant symptoms (such as sleep). Treatment sessions will include information about PTSD, techniques to manage and/or recover from PTSD symptoms, and practice assignments. Possible benefits include improvement in PTSD symptoms and helping to advance the treatment of PTSD more broadly. Risks are minimal and may include emotional discomfort while initiating treatment for PTSD. Participation is voluntary and may be discontinued at any time without penalty. Should you decline to participate in this study or withdraw at any point, appointments to continue care through the BAMC Department of Mental Health will be facilitated.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because, based upon your answers to the screening questions, you have indicated that you (1) are an Active Duty Servicemember and (2) have symptoms of PTSD.

Our research team has designed a brief, non-medication intervention for PTSD that is meant to help Servicemembers improve their symptoms and recover from traumatic experiences. The

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purpose of this research study is to evaluate the intervention's effectiveness in use with Servicemembers in outpatient behavioral health settings. Participation in the complete study lasts approximately 7 months. If you are not offered treatment after the baseline assessment, you will be scheduled to continue care through the BAMC Department of Mental Health.

There will be about 126 people taking part in the study at the Jennifer Moreno Clinic and/or Troop Medical Clinic, over a period of approximately 2 years. During the study, you will have 6 in-person visits with members of the study team. You may need to return to the Jennifer Moreno Clinic and/or Troop Medical Clinic once per week while receiving the 5-session treatment.

This study is evaluating the efficacy of a trauma-focused behavioral intervention called Written Exposure Therapy (WET). Whereas WET is a gold-standard evidence-based psychotherapy for PTSD, there is limited research on different delivery modes for WET (e.g., group vs. individual).

At the end of this research study, the overall clinical results, including research results obtained by participant data will be aggregated and disseminated in traditional academic presentations (e.g., peer reviewed scholarly journals, academic conferences). No identifiable information or data will be stored, shared, or otherwise disseminated.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

When you spoke on the phone to schedule this meeting, you answered several screening questions confirming your eligibility to be assessed for this study. Before you can be assigned to either group or individual WET, you will need to provide some information so that the Investigator can confirm that the treatment is appropriate for you. If you are confirmed eligible for the treatment, you will be offered the opportunity to participate in the rest of the trial. If you are ineligible for the treatment, you will discontinue further participation in this research, and you will be scheduled to continue care through the BAMC Department of Mental Health.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you agree to participate, you will be asked to complete a baseline assessment session to provide information about your demographics and PTSD symptoms. If this screening determines you are ineligible for the treatment, you will discontinue further participation in this research, and you will be scheduled to continue care through the BAMC Department of Mental Health. If you are offered treatment, you will be asked to complete an online assessment describing your mood symptoms, sleep, thoughts about behavioral health treatment, and overall functioning.

You will be randomly assigned to one of 2 groupings. Randomization is a process like flipping a coin and means you will have an equal chance of being assigned to either of the groupings. That is, you will have a 1 in 2 chance of receiving the Written Exposure Therapy in either the *Individual* format or the *Group* format. Please only agree to participate in this research if you are willing to participate in whichever format of the treatment you are randomly assigned to (Individual or Group therapy).

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For the individual WET format will include 5 individual sessions lasting approximately 45 minutes each which focus on providing you with information about common reactions to trauma, writing techniques for processing traumatic experiences, and reviewing practice assignments. At the end of each writing session, the facilitator individually checks in with the participants about their experiences with the writing session for approximately 10 minutes.

Group WET follows a similar protocol. However, In Group WET, following the writing session, the facilitator will lead the group in a discussion of what the writing process was like for them, highlighting commonalities in their experiences. This is similar to most together types of group therapy. However, patients will be asked to not disclose the nature or any details of their traumatic experience with each other. 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.

Within 14 days of the last WET session, you will be asked to complete a post-treatment online assessment where relevant study measures will be re-administered. Online and/or phone assessments will also be conducted within +/- 14 days of the 3- and 6-month follow-up timepoints. All post-treatment assessments will be conducted electronically and/or telephonically and do not require you to be physically present at the study site.

Since this study involves asking you further information about your mood and issues pertaining to your safety, we want you to know that at any time if we are concerned about your safety, we will discuss it with you, if possible, or seek help from your primary care provider or other emergency services. At the discretion of the primary investigators, participants may be taken out of this study due to unanticipated circumstances, such as extreme distress. In other words, we may withdraw you from the study, should we judge your participation not to be in your best interest.

At any time, you can choose to discontinue the entire study, including all assessment sessions, or you can choose to discontinue the PTSD intervention and discontinue the assessment portion of the study.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

Most individuals will experience little, if any, risks from their participation in this study. Responding to questions during interviews may cause distress. Examples of distress include anxiety symptoms (e.g., shortness of breath, fear) or feeling down. If you experience distress during the interview, please discuss this with your interviewer. You may decide to stop the interview or talk to the on-call clinician. The interviewer will discuss with you what to do if you experience distress after the interview, which will include calling the on-call clinician.

The WET intervention may also initially produce mild increases in stress some people. If this occurs, it typically occurs in the first 1-2 weeks of the intervention. Your therapist will discuss safety precautions to take if this does occur. Finally, your therapist will discuss with you steps to take to minimize any other distress that may occur.

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Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. One potential issue where confidentiality will be broken is if you report being at imminent risk of harming yourself, others, or child abuse. If this is disclosed to research staff, we would discuss it further with you to ensure the safety of you and others. In certain situations (i.e., child abuse, neglect), staff may be mandated to report this information to the appropriate parties in order to protect the safety of persons involved. 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. There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

If you agree to take part in this study, there may or may not be direct medical benefit to you in terms of your PTSD or any other mental health or medical conditions. However, you will be receiving behavioral care for PTSD. We hope the information learned from this study will benefit other Servicemembers in the future. Previous studies using similar types of non-medication treatments for PTSD in Servicemembers have demonstrated that the risks associated with this type of study are minimal and that the benefits can be significant and durable. Without conducting research studies such as this one, we cannot identify which non-medication interventions can improve the PTSD, mood, and health of US Servicemembers.

If you are interested in learning more about clinical studies for a wide range of diseases and conditions, you may visit clinicaltrials.gov.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for treating PTSD. Alternative treatments and/or procedures that may be available to you include assessments and evaluations, counseling, medication, or further referral to specialty care in behavioral health. You should talk with your personal physician (if applicable) about these options.

Choosing not to take part in this research study is also an option.

There may be other research studies involving experimental treatments that could be helpful to your condition.

Your alternative is not to participate in this research.

You are not required to take part in this research study. Your participation is entirely voluntary. You can refuse to participate now, or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment and will incur no penalty or loss of benefits which you are otherwise entitled to as a patient.

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8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

In accordance with DoDI 3216.02, active-duty participants will only be compensated if study participation occurs during off-duty hours and does not adversely impact their ability to perform their assigned duties.

If enrolled for one of the treatments, you will be asked to complete several online self-report measures. If these measures are completed outside of duty hours, you will receive:

$50 for the completion of the initial assessment.
$50 for the completion of the post treatment assessment.
$50 for the completion of the 3 month post treatment assessment.
$50 for the completion of the 6 month post treatment assessment.

If you complete all of these assessments, you will also get a $50 bonus.

Your total compensation from today's baseline visit until the completion of the study is up to a total of $250 if you complete all sessions outside duty hours.

A gift card will be mailed to your address if you are unable to pick it up in person.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Dr. Craig Woodworth, PsyD
Board Certified Clinical Psychologist
Chief of Research and Program Development
Department of Mental Health, BAMC
Email: craig.a.woodworth.civ@health.mil

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Department of Defense. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

US Army MRDC, Military Operational Medicine Research Program (MOMRP)

13. LOCATION OF THE RESEARCH:

Jennifer Moreno Clinic and/or Troop Medical Clinic, Ft. Sam Houston, Texas

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14. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations (for example, if you report being at imminent risk of harming yourself, others, or child abuse/neglect, or if law enforcement officials request access to these data via a warrant). DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by staff from the BAMC Department of Mental Health, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: de-identification of data, dataset encryption, computer encryption via CaC access, firewall protection on encrypted BAMC network drives, locked cabinets, drawers, and offices at the Jennifer Moreno Clinic and/or Troop Medical Clinic, as well as departments accessible to preapproved staff with badge access.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

The results of this study may be published but your identity and records will not be revealed unless required by law. The only place we will store your name is on the consent form, locator form, and master tracking log. All study information will be kept in locked files and computer networks accessible only to research staff. Research personnel are carefully trained to maintain the confidentiality of the information collected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

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

For participants in the Group WET format, we also ask that each of you respect the privacy of everyone here and not share or repeat what is said here in any way that could identify anyone here. However, since someone in the group may not obey instructions to keep all comments confidential, we recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this session by not saying anything that would identify you or other participants.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command

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authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

1. The principal investigator and research study team members
2. The San Antonio Institutional Review Board
3. The San Antonio Human Research Protections Office representatives
4. Military Health System (MHS) representatives
5. State and Federal Government representatives, when required by law

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

15. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

16. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must inform research staff that you are no longer interested in participating in the study. If you do not follow these procedures, you may experience an incomplete trial of treatment and be encouraged to follow-up with your routine providers. If you decide to no longer participate in this research study, the researcher will discontinue data collection, and you may request that your data be deleted.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact the study staff or your personal provider to discuss clinical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research

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study at any time if they determine this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

17. OPTIONAL PARTICIPATION IN A FIREARM TRAINING SIMULATOR SUB-STUDY

You are also being asked to take part in an optional firearm training simulator sub-study. The purpose of the sub-study is to determine if WET has any impact on your cognitive and motor functions and your performance on the training simulator.

If you agree to participate in the sub-study, you will attend two additional in-person visits, one before your first WET session and another about 3 months after your final WET session. For the first part of those visits, you will complete questionnaires and a series of cognitive and motor tests at the Jennifer Moreno Clinic and/or Troop Medical Clinic Department of Mental Health. Afterwards, you will complete testing on the Dynavision and Firearm Training Simulator at the Center for the Intrepid. Testing on the Dynavison will utilize the reaction time testing scenario. For the firearm training simulator, you will perform marksmanship and target discrimination tests. The two visits are expected to last about 1 hour each.

Risks from the optional sub-study may include becoming tired, bored, nervous, or frustrated when completing the study tasks. The firearm training simulator has significantly reduced noise and recoil compared to a real firearm. The simulator 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. If you become uncomfortable during the testing, you can stop at any time.

Participation in the sub-study is optional. Should you decline, you will still be able to participate in the main study, attend the group or individual Written Exposure Therapy sessions, and complete all other research related activities. There is no additional compensation for participating in the optional sub-study.

If you take part in the sub-study, you anticipate remaining in the local area to complete the 3-month follow-up in person.

Please select one option below by marking your initials in the box:

☐ Yes, I agree to take part in this optional sub-study

☐ No, I do not agree to take part in this optional sub-study

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18. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Dr. Craig Woodworth, PsyD, ABPP
Phone: 210-539-1409
Mailing Address: ATTN: MCHE-DBH, 7E
3551 ROGER BROOKE DRIVE
FORT SAM HOUSTON, TX 78234-6200

BAMC Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator: Jennifer Sadler
Phone: 210-916-9425

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at: 210-916-2598 or usarmy.jbsa.medcom-bamc.mbx.bamc-irb@health.mil

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IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

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