COVER PAGE - CONSENT FORM

Study Title: Augmenting Massed Prolonged Exposure with a Stellate Ganglion Block to Treat Posttraumatic Stress Disorder (PTSD) in Active Duty or Retired Service Members: A Pilot Study

NCT number: NCT04302181

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Title of Study: Augmenting Massed Prolonged Exposure with a Stellate Ganglion Block to Treat Posttraumatic Stress Disorder in Active Duty or Retired Service Members: A Pilot Study

Concise Summary

Important Information
This information gives you an overview of the research. More information about these topics are found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. In this study, researchers are testing whether Prolonged Exposure (PE), an evidence-based treatment for posttraumatic stress disorder (PTSD) can be augmented with a stellate ganglion block (SGB) to get better results from the PE. For more information, please see the ***Why is this study being done* section** below.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?
After consenting to be in the study, you will be asked to complete a baseline assessment of your psychological and physical health that will determine whether you are able to participate in the study. If you are traveling significant distances to participate in treatment then you will be provided the option to complete the initial screening baseline electronically and through audio teleconferencing. You will be asked to participate in PE, which includes 10 days of treatment provided over 2 consecutive weeks. Each treatment day consist of a 90-minute therapy session followed by various activities. In between the 1st and 2nd PE sessions, you will receive the SGB. At the end of each treatment week, you will be asked to fill out self-report questionnaires. You will be offered 3 booster sessions 1, 3, and 7 weeks after treatment is completed. Finally, you will be asked to complete assessments 1- and 3-months after you finish with treatment. All procedures conducted as part of this study will be for research purposes. For more information, see the ***What will be done if you decide to be in the research*** section.

You do not have to participate in the study. You can also receive treatment for PTSD at other clinics within the community. Other treatments can include other talk therapies or medication that may help manage PTSD symptoms. The Pain Management Clinic may be willing to place a stellate ganglion block for PTSD, but this is not their usual practice. Additionally, there may be other research studies that treat PTSD.

<u>Comparison with Usual Care:</u>
PTSD treatments offered in the community can vary greatly. Most patients are asked to complete an intake session. Individuals are likely to receive weekly sessions of talk therapy for 3 or more months. Patients are often asked to complete homework assignments and weekly self-report questionnaires as part of treatment. Medication treatments require appointments for adjustments in dosage and refills. In Usual care, it is less likely that assessments following treatment are done. Stellate ganglion blocks are not part of usual care.

3. How much time will I spend on the study?
You will be asked to complete a total of 14 visits, which includes 3 assessment visits (up to 4 hours each), 10 PE treatment visits (up to 90-minutes each day), 1 visit to have the SGB placed, and three booster sessions (up to 60 minutes each). Altogether, you will spend up to 33 hours in this study over the next four to five months.

4. Could taking part in the study help me and are there risks?
Participating in this study may help you reduce your PTSD symptoms. Risks include temporary increases in emotional, relationship distress, PTSD, depression, or anxiety symptoms as well as temporary drooping of one

side of your face, bleeding, or skin infection from the block. For more information, please *see **How could you or others benefit from your taking part in this study*** section. For details and a list of risks you should know about, please see the ***What are the risks of participation in the research*** section below.

5. What else should I consider before I make my decision?
It is helpful to select a two-week period in which you can minimize outside appointments and obligations.

Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.

Consent to be part of a Research Study
To be conducted at
the University of Texas Health Science Center at San Antonio and Brooke Army Medical Center

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you. Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Overall Principal Investigator and On-Site PI at UTHSCSA:
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Alan Peterson, PhD, APBB, Division of Behavioral Medicine, Department of Psychiatry and Behavioral Sciences, University of Texas Health Science Center at San Antonio (UTHSCSA).

On-Site Investigator at BAMC:
The Site PI is LTC John P. McCallin III, MD, FAAPMR, Interdisciplinary Pain Management Center Department of Rehabilitation Medicine, Brooke Army Medical Center (BAMC).

Purpose of this study – "Why is this study being done?"

This study is being done to see if Prolonged Exposure (PE), a well-researched, very effective individual (one-to-one) behavioral therapy designed to help people to directly deal with traumatic events they have suffered in the past, can be augmented with a single stellate ganglion block (SGB). A SGB is an injection of local anesthetic (numbing medicine) to block the sympathetic nerves located on near the voice box in the neck. An injection at these nerves may reduce the anxious feelings experienced with PTSD especially when talking about your trauma during the PE therapy.

Investigation Use of Procedure & Drug for PTSD: This study involves the use of an investigational procedure (SGB) using the local anesthetic ropivacaine (also known as Naropin) to augment treatment for PTSD. "Investigational" means that the procedure using this drug has not yet been approved by the U.S. Food

& Drug Administration (FDA) for treating PTSD. The safety of this procedure with this drug in humans has been tested in prior research studies; however, the amount of benefit of the procedure with this drug above and beyond PE therapy alone has not been determined.

This trial will be registered on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information about Study Participants – "Who is participating in this research?"

You are being asked to take part in this research study because you are an active duty service member or recently discharged veteran who is experiencing trauma-related symptoms consistent with posttraumatic stress disorder (PTSD).

How many people are expected to take part in this study?
This pilot study will enroll up to 27 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

The preferred method of both assessment and therapy is face-to-face in San Antonio. However, there may be circumstances when you can complete the assessments electronically and over the telephone and part or all of the therapy can be administered through telebehavioral health (i. e., phone session or using a HIPAA-compliant video calling platform (Zoom)). Decisions will be made on a case-by-case as issues arise for individuals (such as travel restricted because of a worsening of the pandemic or the need for child care) and in discussion with the treatment team. Patients who do not have internet access will need to receive treatment in person.

Baseline/Screening: After you sign this consent to participate, you will be asked to complete a series of questionnaires and then meet with an evaluator who will assess your mental and physical health. Females who are able to become pregnant will also have a urine pregnancy test. You cannot take part in this study if you are pregnant or breastfeeding. The baseline/screening process will take approximately 3-4 hours. The results of these screening procedures will be reviewed to determine whether it is appropriate for you to continue in the study. If at any point during the baseline process it is determined that it ***would not*** be appropriate for you to continue in the study OR if you choose not to enroll, then the researcher will discuss the reasons with you and coordinate appropriate follow-up outside of this study.

You have my permission to use assessments collected as part of the screening for another UTHSCSA STRONG STAR study or program as baseline data for my participation in this study.

Circle one: N/A YES NO

_____ Initials of Participant

_____ Date

Study Procedures: As a participant, you will be asked to:

- Meet with a member of the research team to review your assessment findings and discuss treatment.
- Participate in 10 Prolonged Exposure sessions over two consecutive weeks. Sessions will be held at the University of Texas Health Science Center at San Antonio STRONG STAR offices or by telebehavioral/telemedicine health and will each last approximately 90 minutes.
- Three booster sessions each up to (60 minutes in length) scheduled for one-, three-, and seven-weeks after the completion of treatment will be offered in-person for those from the local area or by telebehavioral health for those traveling within Texas.
- Complete out-of-session treatment assignments daily.

- Have a stellate ganglion block placed at the Brooke Army Medical Center Pain Management Clinic between the first and second Prolonged Exposure sessions. An IV will be placed in your hand or arm to be used only in the event of an emergency. You will not be sedated for this procedure, but a local anesthetic will be used to numb the site where the stellate ganglion block will be placed. Placement of the block will be done using either ultrasound or fluoroscopy. Ropivacaine will be the anesthetic used in the stellate ganglion block. You will need a driver to bring you to the hospital as well as drive you to the STRONG STAR offices and then home again after your Prolonged Exposure session later the same day.
- Refrain or postpone from changing your medications or working with another provider on problems related to PTSD, anxiety, or depression while you are in the study. This will help us better understand how the treatment in this study impacts you. However, if you feel that you do need to work with another provider on your PTSD, please be sure to let us know so that we can coordinate your care accordingly. Also, if you and your prescriber feel that a change in your medication is needed please let a member of the research team know so that we can record the change in your research file.

Since the study is examining an outpatient treatment for PTSD, you have the option of having the study team work with you and your commander or supervisor to ensure you have the time to attend all of the treatment and assessment sessions. With your permission, one of the members of the research team will contact your commander or supervisor to get his or her support for you to participant in this study. If you choose to have the research team contact your commander or supervisor, your commander or supervisor will be told that you have agreed to participate in a research study and will be given your treatment and assessment schedule.

Assessments: In addition to the treatment sessions, you will be asked to complete an assessment halfway through treatment and another assessment prior to your final treatment session. This assessment can take up to 30 minutes to complete. One- and three-months after you have completed treatment, you will be asked to complete a longer, more comprehensive assessment similar to what you did for the assessment prior to starting treatment, which can each last up to 4 hours. Assessments can include both self-report questionnaires and an interview with a trained assessor.

Even if you choose to stop treatment, we will ask that you complete these assessment visits. This will help us understand how the treatment works for all different types of people. Your participation in all parts of this study is very important.

Recordings: All treatment and assessment sessions will be recorded to make sure that the study staff members are correctly following the study procedures. Assessment visits and therapy sessions will be audio-recorded using an independent recording device separate from the phone or conferencing platform, Zoom. These recordings will be reviewed by research experts who are part of the research team. By signing this consent, you are giving your permission for recordings.

Time Commitment: While you are taking part in this study, you will be asked to attend approximately 17 visits, which includes 3 assessment visits (up to 4 hours each), 10 PE treatment visits (up to 90-minutes each day), 1 visit to have the SGB placed, and 3 booster sessions. You will be asked to participate in 10 treatment sessions over two consecutive weeks and three additional booster sessions following the completion of treatment. Therapy sessions and related activities will be completed Monday through Friday during regular business hours. The booster sessions will take up to 60-minutes each. Altogether, you will spend up to 33 hours in this study over the next four to five months.

Long-Term Study Data Storage and Future Use of Your Information

The researchers will be asking your permission to store your questionnaire answers and audio-recordings with your personal identifying information after this study is completed in the STRONG STAR Repository. The

Repository is designed to be used for other research investigating the causes, consequences, and treatment of PTSD and related conditions. Your consent to allow us to store your information, or request not keep your information, will be given in a separate consent document. Your participation in the current study does not depend on your decision to participate or not in the Repository. Please note however that if you decide not to participate in the Repository, the researchers intend to keep and use the information collected as part of this study, but your personal identifiers (such as name, SSN, and contact information) will be permanently destroyed so that it can never be linked to you again.

Ending Participation Early – "*Could your participation end early?"*

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – "What are the risks of participation in the research?"

Risks from the research

There are risks to taking part in this research study. One risk is that you may have side effects while in the study. Everyone taking part in the study will be watched carefully for any side effects. However, the study staff do not know all of the side effects that may happen. Be sure to tell your study therapist immediately about any side effects that you have while taking part in the study. The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

The following section will describe the risks related to your participation in this research study, including your participation in the assessment visits, two-week treatment program, and booster sessions. These risks apply whether you complete the booster sessions in person or over the phone. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

The following section will describe the risks related to your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Risks related to the stellate ganglion block:

Likely but Not Serious (expected to occur in more than 20 out of 100 participants):

- Temporary change in skin temperature on one side of your face and/or arm following the stellate ganglion block.
- Temporary hoarseness, voice changes or loss of voice.
- Horner's Syndrome (i.e., temporary drooping upper eyelid; contracted pupil; and dryness on one side of the face) following the stellate ganglion block.

Rare, but Serious Risks (expected to occur in less than 5 out of 100 participants):

- Bleeding from a broken blood vessel that results in a hematoma
- Injury to the nerves around the injection site
- Injury to the esophagus
- Pneumothorax (collapsed lung)

- Spinal cord trauma
- Infection of the tissues of the neck, nerves, bone, or disc material in the area of the stellate ganglion block or the arm or hand where the IV is placed
- Incomplete recovery of normal function.
- If fluoroscopy is used -- Normally, fluoroscopy is used for less than one minute, and you may experience a very slight increase in the chance of contracting cancer. If fluoroscopy is used for a prolonged time to guide the placement of the block, you may experience reddening of the skin.

Risks related to ropivacain used in the stellate ganglion block:

Likely but Not Serious (expected to occur in more than 20 out of 100 participants):

- Signs of an allergic reaction: hives or red skin rash; dizziness; sneezing; difficulty breathing; nausea or vomiting; sweating; swelling of your face, lips, tongue, or throat
- Gastrointestinal distress: nausea, vomiting
- Pain: headache, back pain
- Skin: itching
- Numbness or tingly feeling
- Fever
- Genital-urinary: Problems with urination or sexual function.

Rare, but Serious Risks (expected to occur in less than 5 out of 100 participants):

- Feeling anxious, restless, confused, or like you might pass out
- Problems with speech or vision
- Ringing in the ears, metallic taste, numbness or tingling around your mouth, or tremors
- Seizure (convulsions)
- Weak or shallow breathing
- Slow heart rate, weak pulse or fast heart rate, gasping, feeling unusually hot.

Risks related to Massed Prolonged Exposure and Neurological/Psychological Assessments

Likely but Not Serious (expected to occur in more than 20 out of 100 participants):

- Emotional distress including experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events.
- Temporary increase in relationship distress.

Rare, but Serious Risks (expected to occur in less than 5 out of 100 participants):

- A temporary or occasional increase in symptoms of depression, anxiety, or other pre-existing psychiatric symptoms.
- 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.

Risks to Confidentiality

- 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.

- Due to the use of online conferencing systems and the possibility for someone to overhear your discussions or our conferencing systems to be accessed, your privacy and confidentiality is not guaranteed.

Reproductive Risks:
Concerns for sexually active women: It is not known whether ropivacaine and fluoroscopy, if used, can cause birth defects or other problems in an unborn child. If you are a FEMALE ABLE TO BECOME PREGNANT and you want to take part in this study, you should know that ropivacaine and fluoroscopy, if used, might be harmful to (1) an unborn child if you are pregnant; or (2) an infant if you are breast-feeding. You should not get pregnant or breastfeed while in this study. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy. If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document

If you are a woman who is pregnant or could be pregnant, you cannot take part in this study because we do not know how the drugs/procedures might affect a developing fetus. We will do a pregnancy test before you start treatment to make sure you are not pregnant.

Risks to babies who are being breastfed: Women who are breastfeeding cannot take part in this study because we do not know what effect the drugs/procedures might have on their breast milk.

Risks whether you participate in this research or not:
Individuals with PTSD may have suicidal thoughts or attempt suicide. This is a risk to you whether you are being treated for PTSD or not. Therefore, the risk of suicide is not any higher in the study than it would be if you were not in this study. Your treatment may require you to talk about some things that might be painful or uncomfortable for you, which could cause increased emotional distress and the possibility of increased suicide risk, which can result in death. In the event that you are thinking about hurting yourself, please tell your therapist. Your therapist will work with you to develop a plan of specific steps for you to follow when in crisis. If we believe that you are at high risk for hurting yourself, we might also decide to include your family and social support network in your care to maintain your safety.

If at any time you are feeling significant distress or if you are having thoughts of hurting yourself or someone else, please notify your therapist or come into the clinic as soon as possible. You can also be seen in a Hospital Emergency Room after 1630 and on weekends and holidays at any time. Active duty service members and veterans may be eligible to seek care at the Emergency Department at Brooke Army Medical Center.

For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue to take part.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the research team. If you decided to withdraw, we may ask you if you are willing to participate in a brief assessment with a study clinician either in-person or by phone just to assess your condition and make appropriate referrals if necessary. We are also interested in following up with you at the times you would have been assessed if you had completed all of the sessions to answer some questionnaires. However, your participation in the follow-up assessments is completely your choice. There is no risk to you if you do not complete the final withdrawal procedures, and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may affect the results of the studies. You should not take part in more than one study without discussing it with the researchers of both studies. If you have had radiation (like x-rays) to your head or neck before, please tell us now. We want to make sure that the amount of radiation you have received within the past year is within safe limits.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
The possible benefit of your participating in this study is a potential reduction in your symptoms associated with PTSD, which may positively affect your overall health and well-being. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"
There are other options available to you. Your other choices may include:
- Not participating in the study
- Receiving psychotherapy (talk therapy)
- Medications
- A Pain Management Clinic may be willing to place a stellate ganglion block, but this is not their usual practice for PTSD.
- There may be other research studies involving experimental treatments that could be helpful to your conditions.

Payments – Will there be any payments for participation?
No, you will not receive any compensation for participating in this study.

Costs – Will taking part in this study cost anything?
There are no treatment or assessment costs associated with taking part in this study.

Confidentiality – How will your records be kept confidential?
Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Based on the screening we will do to be sure it is safe for you to participate in this study, we may find out that you are having unusual mental health symptoms, are consuming dangerous amounts of alcohol, or are feeling like hurting yourself or others. While we are not required to report any of this to your military unit, we will want to work with you to get you the care you need. However, suspected or known abuse or neglect of a child, a disabled person, or an elder or threatened violence to yourself or others must and will be reported to appropriate authorities in accordance with state law. There are other local health-reporting requirements that need to be reported. If you have additional questions about this, please speak with your therapist or a member of the research team.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: name, address, phone numbers, and email address to be able to contact you and make follow-up appointments; social security number to review and make notes in your medical record; medical history to be sure we understand your medical and treatment history as well as any ongoing care that you receive while participating in this study; and questionnaire answers that you provide us as part of this study.

We will get this information by asking you. We will also get this information by looking at your military electronic health record.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- Members of the STRONG STAR research team at UTHSCSA
- The STRONG STAR Data Core, developer of the electronic consent form
- The STRONG STAR Data & Safety Monitoring Board which is a committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- Other U.S. State and Federal Government agencies when required by law.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information within the limits of the law. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. You need to be aware that some parties receiving your protected health information may not have the same obligations to protect your protected health information and may re-disclose your

protected health information to parties not named here. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name to identify your health information. These code numbers will be used on any copy of our study records and other study materials containing health information. If the results of the study are reported in medical journals or meetings, you will not be identified.

STRONG STAR strictly controls access to study data only allowing researchers associated with this study to review your data. However, complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities. For example, if you indicate you have thoughts of harming yourself of others the research team will want to immediately work with you to get you help.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Alan Peterson
University of Texas Health Science Center at San Antonio
Department of Psychiatry and Behavioral Sciences – Mail Code 7747
7550 IH10 West, Suite 1325, San Antonio, Texas 78229

If you tell the researchers to stop using your health information, the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over. If you also decide to participate in the STRONG STAR Repository, you will agree to let us use and disclose your health information in accordance with the Repository's authorization.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Principal Investigator: Alan Peterson, PhD, ABPP, who can be researched at 210-562-6700.

If primary is not available, contact
Sub-Investigator: Tabatha Blount, PhD, who can be reached at 210-562-6718.

Site Principal Investigator: LTC John P. McCallin II, MD, FAAPMR, who can be reached at 210-916-2888.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

The lawyers at the UT Health San Antonio require patients participating in research studies who are receiving part of their research by phone or a video platform to read and sign this form voluntarily requesting UT Health San Antonio and such research associates, residents, research assistants and other research health care providers as needed ("UT Health San Antonio Telemedicine/Telebehavioral Providers") to participate in your research care through the use of telemedicine. You understand that UT Health San Antonio (i) may practice in a different location than where you present for medical care, (ii) may not have the opportunity to perform an in-person interview, and (iii) will rely on information provided by you. You acknowledge that UT Health San Antonio research Telemedicine/Telebehavioral Providers' will not provide advice, recommendations about your routine health care. No decisions or recommendations for your care outside of this research project will be made. You acknowledge that it is your responsibility to provide information about your medical history, condition and care that is complete and accurate to the best of your ability, you understand that the practice of medicine is not an exact science and that no warranties or guarantees are made to you as to result or cure. If UT Health San Antonio Telemedicine/Telebehavioral Providers determine that the telemedicine services do not adequately address your medical needs, they may require an in-person psychological evaluation. In the event the telemedicine session is interrupted due to technological problem or equipment failure, alternative means of communication may be implemented, or an in-person psychological evaluation may be necessary. If you experience an urgent matter, such as a bad reaction to any treatment after a telemedicine session, you should alert your primary care provider and, in case of emergencies dial 911 or go to the nearest hospital emergency department.

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

Title of Study: Augmenting Massed Prolonged Exposure with a Stellate Ganglion Block to Treat Posttraumatic Stress Disorder in Active Duty or Retired Service Members: A Pilot Study

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time (AM / PM)

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time (AM / PM)

☐ Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English.

The method used for communication with the subject was: _____.
The specific means by which the subject communicated agreement to participate was:
_____