Concise Summary

Important Information: More information is on the pages that follow.

Voluntary Participation	It is your choice to take part or not.
Purpose	Researchers are testing 2 couple-based interventions to treat posttraumatic stress disorder (PTSD) and improve relationships delivered over a weekend.
Duration	About 7 months.
Procedures	• Baseline assessment • 1 pre-retreat meeting • 2-day retreat • 1 post-retreat check-in • Follow-up assessments 1-, 3-, and 6-months after the weekend retreat
Benefits?	We hope to reduce PTSD symptoms and improve your relationship.
Risks?	Possible risks from being in this study are emotional discomfort or distress, or a temporary increase in symptoms.
Alternatives to participating?	• Individual or couples usual care treatment from other providers. • Getting no treatment
Payment	Funding is available to offset the costs of participating in this study and for completing the follow-up assessments.

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 (UTHSCSA)

Information about this form

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

Please take time to read this information. Talk to the researchers about the study and ask any questions you have. You may want 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 benefits.

Please tell the researchers if you are taking part in another study.

You do not have to participate if you don't want to. You may also leave the study at any time. Whatever you decide, there is no penalty to you.

General Information – "Who is conducting this research?"

Principal Investigator
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 Overall PI for this study is Steffany Fredman, Ph.D., who works in the Department of Human Development and Family Studies at The Pennsylvania State University. The PI for this study at the University of Texas Health Science Center at San Antonio (UTHSCSA) is Alan Peterson, Ph.D., ABPP, Lt Col, U. S. Air Force (retired) who works in the Department of Psychiatry and Behavioral Sciences, Division of Behavioral Medicine.

Funding
This study is being funded by the U.S. Army Medical Research and Development Command Traumatic Brain Injury and Psychological Health Research Program through a research award to The Pennsylvania State University.

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

The purpose of this study is to compare 2 couple-based programs to treat posttraumatic stress disorder (PTSD) and to enhance relationships in couples delivered as a weekend group retreat. The names of the programs are:

- Abbreviated, Intensive, Multi-couple Cognitive-Behavioral Conjoint Therapy for PTSD (AIM-CBCT for PTSD)
- Prevention and Relationship Education Program (or PREP)

A description of this study is on http://www.ClinicalTrials.gov.

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

You and your partner are being asked to consider taking part in this study because you or your partner are an active duty service member or veteran and one of you has PTSD. You must be married or cohabitating as a couple for at least 3 months and be willing to make a commitment to treatment on this study.

This study will consent approximately 200 couples (400 individuals) over 4 years.

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

While you are taking part, you will be asked to meet with the study staff 6 times plus one entire weekend. Your participation in the study will last up to 6-7 months including follow-up assessments.

The weekend retreats will be held in-person, face-to-face at a hotel in San Antonio. For assessments, the preferred method of meeting is face-to-face. However, there may be times when assessments and check-ins can be done electronically over the telephone or on the web.

Screening Procedures: After you and your partner sign this consent, you will be asked to complete questionnaires and meet with an evaluator who will assess your mental, physical, and relationship health. The screening process takes 3-4 hours. The assessment process can also be completed over the phone or on the web through a secure link on the STRONG STAR database. The results of the screening will be reviewed by the researchers to determine if it is appropriate for you to continue in the study. If you continue, the study staff will let you know the dates of upcoming retreats so you can be scheduled. If it is decided that this study is not appropriate for you and your partner, we will tell you why and can help you to find other care.

If you were screened for another STRONG STAR study, we may be able to use the assessments you already completed.

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

Circle one: N/A YES NO _____ _____
Initials Date

If it is decided that this study is appropriate for you and your partner, you and your partner will receive one of the two study treatments described below.

Assignment to Study Groups
Couples will be assigned by chance (like flipping a coin) to one of two weekend programs:

- AIM-CBCT for PTSD
- PREP

Treatment & Evaluation Procedures:

- You and your partner will be one of several couples who will receive either AIM-CBCT for PTSD or PREP in a group with other couples over a 2-day weekend retreat. The retreats will be held at a hotel in San Antonio. Retreats are scheduled every month. You and your partner will pick a weekend date best for you.
- In the two weeks before the retreat, you and your partner will meet as a couple with one of the study therapists who will also be the group leader. The therapist will explain what will happen over the weekend and ask you questions about your relationship (for example, how long you have been a couple) to begin to get to know you better as a couple.
- For the weekend retreat, you and your partner will check-in to the hotel Friday evening or Saturday morning to participate in group activities throughout the day Saturday and Sunday.
- You will learn new skills in 60–90-minute lessons, including time to practice the skills. Breaks will occur throughout the day and for lunch. Group-related activities will take about 8 hours each day. You may also be asked to practice the skills outside of the group-related activities.
- Two weeks after the retreat, you and your partner will have a check-in to find out how you are doing.
- Follow-up assessments will be scheduled 1-, 3-, and 6-months after the retreat. Each follow-up assessment will take between 2 and 3 hours.
- Participants will have the option of having their Command or employer notified by the Research Staff to ensure you are afforded the time to participate in the study.

Telehealth Visits: The lawyers at UTHSCSA 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 UTHSCSA and research staff to participate in your research care using telemedicine. You understand that UTHSCSA (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 UTHSCSA research Telehealth Providers will not provide advice or 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 guarantees are made to you as to result or cure. If UTHSCSA Telehealth Providers determine that the telemedicine services do not adequately address your medical needs, they may require an in-person evaluation. In the event the telemedicine session is interrupted due to a technological problem or equipment failure, other means of communication may be used, or an in-person visit 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. Please note that privacy and confidentiality during virtual interactions with study staff cannot be guaranteed as it can during face-to-face meetings due to the nature of the conferencing platforms that could be used.

If, at any time during screening, treatment, or evaluation your thoughts or feelings become too uncomfortable, you may stop the task at any time.

Recordings: The 2-day retreat, individual couple meetings with your study therapist, and all evaluation sessions will be recorded. The retreat will be video recorded. Individual couple meetings and evaluations will be audio recorded. Research therapy experts will review these therapy and assessment recordings to be sure that the study staff members are correctly following the study procedures.

Any remote and/or virtual research appointments with our research staff will be recorded using an independent device separate from the conferencing platform (for example, Zoom or the phone).

Future Use of Your Information Collected as Part of Your Participation

The researchers are asking your permission to store your questionnaire answers with your personal identifying information after this study is completed in a Repository. Your consent to allow us to store 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 will keep and use the data collected as part of this study, without your personal identifiers. Your data will be used for future research studies or given to other researchers for future research studies without additional informed consent from you.

Could your participation end early? There are reasons why the researchers may end your participation in the study. 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 care when your participation in this study ends.

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

Risks from the research: Risks related to the research assessments include those which are:

Likely Risks, but Not Serious (expected to occur in approximately 10 out of 100 subjects):

- Mental distress or discomfort when answering questions. You do not need to answer any questions you are not comfortable answering. You will be given ways to contact your group therapists during duty hours. You will be encouraged to contact your group therapists if you stay upset after the 2-day retreat or any interview. If you need to speak with someone and your group therapist is not available, we will arrange for you to meet with an experienced mental health professional. If at any time during screening, treatment, or evaluation your thoughts or feelings become too upsetting, you may stop the task. You can also be seen in an emergency room at any time.
- Discussing personal information in front of others during the group or hearing other group members discuss their personal information may cause some discomfort.

Risks to Confidentiality:

- There is a possibility that a group member might reveal information about something said in the group to someone outside of the group, even though we ask group members to keep the discussion confidential. To minimize this risk, the group therapists will emphasize the importance of confidentiality during the discussion of the group rules.
- With the handling of your medical and research records, there is a chance of a breach of your confidentiality. Every effort is made to protect your privacy. Every member of the Research Team is trained and monitored about how to handle and protect your records. The Research Team controls access to study data, only allowing researchers associated with this study to view your data.

Risks whether you participate in this research or not: People with PTSD may have suicidal thoughts or attempt suicide. This is a risk to you even if you are not in the study. Being in the study does not make your risk higher. Your treatment may require you to talk about things that might be uncomfortable. That can cause increased distress and the possibility of wanting to kill yourself, which can result in death.

If you are thinking about hurting yourself, please tell your therapists or come into the clinic as soon as possible. We will develop a plan that will include specific steps for you to follow when in crisis. If we believe you are at high risk for hurting yourself, we might also include your family and friends in your care to maintain your safety. You can also be seen in an emergency room after hours and on weekends and holidays at any time.

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 that develop during the research which may relate to your willingness to continue taking part.

Are there Risks related to withdrawing from the study? You may withdraw your consent at any time and stop being in this study. Please talk with one of the therapists to be sure there is no risk to you of withdrawing. We also would be interested in seeing how you are doing at the times you would have been assessed if you had stayed in the study (at 1-, 3-, and 6-months after the treatment weekend). However, this would be completely your choice.

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 discuss it with the researchers of both studies.

What if a research-related injury occurs?

You may still experience problems or side effects, even though the researchers have taken steps to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please contact the research team. See the section "Contact Information" for phone numbers and additional information.

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If you are hurt because of your participation in this research and you are a DoD healthcare beneficiary, you are authorized space-available care in a DoD facility. If you get care for injuries outside of a DoD facility, you will not be paid back. Travel will not be provided or paid for by DoD. No compensation is available for research-related injuries. You are not waiving any legal rights.

What if an injury occurs off-site?
UTHSCSA does not own, operate, control, or maintain the hotel where the workshops will take place. UTHSCSA has no legal authority to direct the premises and UTHSCSA and the premises are separate legal entities.

Benefits – "How could you or others benefit from your taking part in this study?"

A possible benefit to you as a research participant is that treatment could help reduce your or your partner's PTSD symptoms and improve your relationship with your partner. However, there is no guarantee that you will benefit from being in this research.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

Other treatments for PTSD that are available to you include the following.

- Various forms of psychotherapy (talk therapy).
- Drug treatments.
- There may be other research studies that could be helpful to your condition.

Not participating in this study is an option. The research team can discuss all of your options with you.

Payments – Will there be any payments for participation?

For participation you and your partner will be given $150 to cover costs of meals, activities, and incidentals during the weekend retreat. Additionally, each participant can be compensated up to $180 for completion of follow-up assessments ($50 for the 1-month post-treatment assessment, $60 for the 3-month follow-up assessment, and $70 for the 6-month follow-up assessment). Hotel cost and the cost for breakfast and lunch will be paid directly by the study. Active duty participants are eligible for compensation if participation in the research does not conflict with your military duties.

You will be paid on a rechargeable MasterCard® ClinCard. The ClinCard funds will be available to you within 1 business day and can be used as you choose. Your name, address, and date of birth will be shared with a third-party only for payment processing. If you have any questions about your card or payments, refer to the paperwork that was provided to you with the MasterCard® or ask a member of the study team.

Costs – Will taking part in this study cost anything?

No, there are no costs to you for taking part in this research study other than getting yourself to the retreat and clinic for scheduled visits. The sponsor will provide the therapy at no cost to you during this study.

Confidentiality – How will your records be kept confidential?

The information we learn about you in this study will be handled in a private manner, within the limits of the law. We will need to provide the hotel with your name so that we can pay for your hotel room directly without your having to pay out-of-pocket. The Institutional Review Board and other groups that monitor research may want to see study records which identify you as a subject in this study. When we publish the results of the study in a scientific journal or book, we will not identify you.

Limits of Confidentiality
Even without your consent, suspected or known abuse or neglect of a child, disabled, or elder abuse, threatened violence to self or others or other local health reporting requirements will be reported to appropriate authorities.

Research policies require that private information about you be protected. This is especially true for your health information. However, the law sometimes allows or requires others to see your information. Complete confidentiality cannot be promised for military personnel. Information about your health may need to be reported to appropriate medical or command authorities. 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)? PHI is health information that can be linked to you. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by DoD, permits the Military Health System (MHS) to use or disclose your health information with your permission. The health information we will see and use about you will include:

- Name
- Address
- Phone Numbers
- Email address
- Diagnosis and health history
- Information from clinical interviews and assessment measures
- Information you share during therapy sessions.

We will get this information by interviewing you to ask about your mental, physical, and relationship history and asking you to complete questionnaires about symptoms you may be experiencing.

The use of your PHI is needed to conduct the research. Records of your participation in this study may only be disclosed to others in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a and the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 CFR 160 & 164). Please note that PHI of military service members may be used or disclosed for activities deemed necessary by appropriate military command authorities to ensure the proper execution of the military mission.

How will your PHI be shared? Your PHI may be used and shared with:

- The Principal Investigator and research study team.
- The UTHSCSA approved texting platform.
- The UTHSCSA REDCap, developer of the electronic consent form.
- The UTHSCSA STRONG STAR Data & Safety Monitoring Board, which is a committee that checks the study data to determine if the study should be stopped for any reason.
- The UTHSCSA Institutional Review Board and the Compliance Office and other groups that oversee how research studies are carried out.
- The Pennsylvania State University Institutional Review Board.
- The Research offices at the University of Texas Health Science Center at San Antonio and the Pennsylvania State University.
- Representatives of the Department of Defense (DoD) only as allowed by law and federal regulation.

The researchers and those listed above agree to keep your health information safe by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law.

You need to be aware that some parties receiving your PHI may not have the same duty to protect your PHI. They may re-disclose your PHI to parties not named here. If your PHI is re-disclosed, it may no longer be protected by state or federal privacy laws.

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How will your PHI be protected? 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 copies of your study records and other study materials containing health information that are sent outside of STRONG STAR for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information? You do not have to allow 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. However, you need to put 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
7703 Floyd Curl Drive, San Antonio, TX 78229

If you tell the researchers to stop using your health information, your participation in the study will end and 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 to review your PHI collected for this study.

How long will your PHI be used? Until the end of the study and all required study monitoring is over.

How you may be contacted throughout the Study.

The research team will ask you how you prefer to be contacted about your research visits.

The research team would like to communicate with you regarding your research visits via email, which uses an "encrypted" method for secure transmission. When one of the research team sends you an email, you will receive an email that says "[SECURE MESSAGE]" from a research team member with a link to open the message. When you click on the link it will take you to a secure website where you can read the message and reply after successful authentication.

The research team may also communicate with you regarding your participation via text message. These messages may include information related to your participation in the study and payment information. In order to do this, we will share your name and phone number with one of UTHSCSA's secure texting platforms. Standard text messaging rates will apply if you do choose to receive the text messages.

Just as with the telehealth interactions, please note that privacy and confidentiality during electronic interactions cannot be guaranteed like it can during face-to-face meetings due to the nature of the conferencing platforms that could be used.

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

If you have questions, ask us at any time. If you have questions, concerns, comments, or complaints or you wish to report a problem which may be related to this study please contact:

The Primary contact:

- The Overall Study Principal Investigator: Steffany Fredman, PhD, who can be reached at (814) 867-5296 in University Park, PA

If Dr. Fredman is not available, contact:

- The San Antonio Principal Investigator: Alan Peterson, PhD, ABPP, who can be reached at (210) 562-6700 in San Antonio, TX

If neither of these individuals is available, or if you need assistance after business hours, you can be seen in an emergency room.

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

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 copy of this form to keep. Please let us know if you would like a copy of the form with your signature. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

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

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 were 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: