Parenting Strength at Home- Parents Pilot

Protocol

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Central Texas VA Healthcare System research protocol.
Title: Adaptation, Refinement, and Open Trial of Parent Training for Veterans with PTSD
"Strength at Home – Parents Pilot"
Sponsor: VHA RR&D
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Appendices:
1. Study Measures
2. Recruitment Flyers
3. Telephone Scripts (veteran and partner)
4. Recruitment Letters

Study Overview: Symptoms of posttraumatic stress disorder (PTSD) after deployment have been shown to adversely impact family and close relationship functioning, including parent-child relationships[1-4]. **About 31% of U.S. Veterans are parents to children under the age of 18**[5]. In addition, a study of over 100,000 records of Iraq and Afghanistan Veterans indicated those with dependent children were 40% more likely to carry a diagnosis of PTSD compared to those without children[6]. Despite these large numbers and the known association between PTSD and parenting problems, there are no empirically validated parenting interventions within the VHA that address the unique needs of Veteran parents with PTSD[7], **nor is there evidence that existing treatments for PTSD improve family functioning**[8,9].This gap in both research and practice is significant given that parent-child functioning is a large component of recovery and reintegration into the community. Difficulties with parenting and the parent-child relationship are a vital influence on overall family functioning and quality of life. **It follows logically that an intervention that improves parenting will have a significant downstream impact on overall family and close relationship functioning and the Veteran's quality of life.**

This proposal will conduct the research necessary to adapt, refine, and conduct an open trial of Strength at Home – Parents (SAHP) - the new intervention incorporates the core clinical components of the empirically validated Strength at Home (SAH) interventions for improved family functioning among Veterans[11-13] and **targets key parenting behaviors and interpersonal relationship skills that can be impaired when a parent suffers from PTSD**.

Given that parenting challenges are not typically addressed within VHA[10,14], one reason prior national pilot efforts may have had trouble with enrollment and retention is a failure to address motivation and goal setting at the outset. It can be difficult for clients to be ready to change a problem when few resources have historically been available to address it. Therefore this proposal will pilot the feasibility of including a pre-treatment Motivational Interviewing Assessment (MIA[15]) to assist Veterans with PTSD in strengthening and building motivation to change their parenting behaviors. The MIA can result in higher rates of treatment retention during the first 4 weeks of treatment compared to treatment as usual[16]. Assessment approaches such as MIA that are personalized and collaborative have been shown to have a positive and clinically meaningful impact on treatment[17].

1) Aim 1 (completed): Refine and Pilot Test intervention for Veteran Feedback. Obtain and incorporate expert clinician and Veteran feedback on credibility, acceptability, and satisfaction with the intervention to ensure Veteran-friendly manual, materials, and processes. Aim 1 will be accomplished through two rounds of expert panel review of the treatment/MIA manual and two rounds of pilot testing of the treatment for Veteran feedback in 16 female and 16 male Veterans.

2) Aim 2 (ongoing): Open Trial for Feasibility. Evaluate feasibility of study recruitment, retention, assessment procedures and proposed methods of the intervention. Preliminary examination of whether intervention results in improvements to parenting behaviors, parenting satisfaction and overall family functioning. Aim 2 will

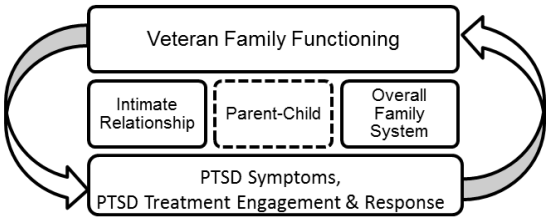
be accomplished through an open trial of the final intervention and MIA procedures in 3-5 groups of female Veterans (n = 24-40) and 3-5 groups of male Veterans (n = 24-40; total N = 48-80), with collateral partner assessment of outcomes where possible.

A. Background and Significance

A1. Prevalence of PTSD among veteran parents. Approximately 31% of Veterans (population 20 million) have at least one minor child living with them[5] and half of all service members who deployed as part of the military operations in Iraq (Operation Iraqi Freedom; OIF; Operation New Dawn; OND) and Afghanistan (Operation Enduring Freedom; OEF) are parents[18]. Recent estimates of the rate of posttraumatic stress disorder (PTSD) among returning Veterans seeking care at the Veterans Health Administration (VHA) have suggested it may be as high as 23%[19]. A study of the administrative records of over 100,000 OEF/OIF Veterans indicated those with dependent children were 40% more likely to carry a diagnosis of PTSD[6] and parent status is associated with higher PTSD symptom severity[20]. These statistics are alarming because a large body of research has also found that a diagnosis of PTSD is highly disruptive to the parent-child relationship as well as impairing family functioning[1-4]. Difficulties with family functioning undermine recovery and overall quality of life.

A2. PTSD and family functioning share a bidirectional association. Family functioning is an umbrella term encompassing intimate relationships, parent child functioning, and the functioning of the larger "family" system. A compelling line of research indicates that family functioning difficulties are magnified and co-occur with PTSD symptoms in Veteran and military populations[1-3]. These difficulties range from intimate relationship dissatisfaction and overall family dysfunction to increased rates of intimate partner violence[21]. A growing literature also suggests that specific family processes such as avoidance and accommodation may be important contributors to the development and maintenance of PTSD[22]. Evidence also links family functioning to PTSD treatment engagement and response[23-25]. <u>In sum, PTSD and family functioning appear to be reciprocally related, and therefore attention to family functioning may have great benefit for Veteran recovery. Unfortunately, existing treatments for PTSD do not appear to improve family functioning[8,9],</u> therefore adjunctive and novel treatment approaches are needed.

Figure 1.



A3. Addressing parenting as part of PTSD treatment. The need for direct attention to family functioning in addition to treatment for PTSD is highlighted by prior findings indicating that poorer family functioning predicts higher PTSD symptoms after treatment[25], therefore those with family functioning problems may have benefited less from PTSD treatment in the first place. In addition, gold standard treatments for PTSD do not include family functioning modules. Finally, families are systems and a pattern of interactions may have become stable over a long period, thus even when PTSD remits, direct intervention may be required to improve family functioning. Increases in PTSD symptoms over the year following combat deployment are associated with poorer

parenting behaviors[4]. Several studies describe a strong association between PTSD symptoms and Veterans' reports of increased parenting stress and decreased satisfaction with parenting[26-28]. The hyperarousal and avoidance/numbing symptoms of PTSD are particularly deleterious to parenting[26,29]. Research has also found that Veterans are greatly interested in family focused services that promote family involvement in their care[30]. In one study, more than 75% of Veterans referred for mental health evaluations at VHA reported difficulties in their romantic relationships or with their children[31]. Another study found the majority of Veteran parents surveyed were concerned about child rearing and felt that parenting was more stressful after deployment[32]. Taken together, PTSD appears to be associated with parenting difficulties, and Veterans report an interest in family focused care that includes interventions directed at improving parenting skills[10].

A4. Family-centered care at VHA. VA's transition to increased emphasis on family centered care began in 2004, after the President's New Freedom Commission on Mental Health made this a priority. Prior to that time, mental health services at VHA were focused on individual treatment models (to the exclusion of the family system). VA's transition to family-centered care was bolstered by decades of research indicating that family systems and individual mental health are reciprocally related and recognition that family functioning is a critical component of recovery. Policy changes secondary to the passage of P.L. 110-387 (The Veterans Mental Health and Other Care Improvement Act) allowed the expansion of marital and family therapy services at VHA. Thus, the last decade has seen a transformation in VA culture culminating in large scale dissemination of evidence-based family and couples' therapies, with an emphasis on providing these services to Veterans with PTSD[47]. Yet no parenting training program is currently available nationally.

Appeals to address parenting issues within VA are growing and they are now being voiced by Veterans[10], researchers[14,48-50], policy makers[51], and clinicians alike (see Preliminary Studies). The VA mandate specifies that family services are offered in service of the Veteran's treatment plan, therefore, parenting treatment focused on child behavior problems and that include dyadic parent-child models are best provided through community partners. However, recent data from a national, random sample of all OEF/OIF veterans who had returned through 2009 indicated that 2/3 of Veterans with probable PTSD had sought treatment, and most had done so at the VA[52]. Limited funding and limited community expertise with Veterans in general, and in areas such as military related PTSD specifically, will likely continue to drive Veterans to the VA[47]. Given that the VA has recognized family centered care in all other domains of family functioning, work to develop a parent training program that meets the unique needs of Veterans and VHA clinicians is critical.

A5. Need for a new intervention developed with and for Veterans. First, there are no evidence-based parent training programs that address the specific parenting behaviors and family dynamics that are likely to be impaired by PTSD symptoms (e.g. positive parenting, emotion regulation, avoidance, communication). Our pilot data indicated that PTSD symptoms explain greater variance in child psychosocial

functioning than parenting behaviors, which indicates that community treatments that address only parenting will not be sufficient in this population. Second, most evidence-based parenting programs for civilians are delivered in parent-child dyads and have an emphasis on child difficulties - a model that is not consistent with the VHA mandate. Third, interventions that do exist for improving parenting in military families were developed and tested to help families recover from deployment separation and stress. They were not designed to address the unique parenting and family dynamics that continue to be impacted by PTSD symptoms many years after military deployment. In 2014 PI Creech published a systematic review evaluating findings from 50 studies on Veterans/active duty military and parenting[7]. This review revealed that growth in research on parenting and Veterans has centered around deployment separation with almost no attention to the impact of post-deployment mental health problems on parenting. In sum, a brief treatment to improve the aspects of parenting and family functioning that are specifically impacted by PTSD symptoms is needed, but to be feasible and effective it must also be developed for delivery within the VHA system, and with Veteran input.

A6. Theoretical Frameworks. The theoretical frameworks informing SAHP are the Cognitive-Behavioral Interpersonal Theory of PTSD (C-BIT[56]) and the Military Family Attachment Network model[46]. Dekel & Monson's C-BIT posits that specific cognitive, behavioral and emotional processes impact the development and maintenance of PTSD and impair family functioning. Within this model, avoidance and accommodation refer to behaviors through which PTSD avoidance symptoms are negatively reinforced thereby maintaining trauma-related distress. Avoidance behaviors impact the family system by reducing positive family activities. Cognitive processes and thematic content refer to maladaptive schema about the world and past experiences and disruptions to core themes such as power, trust, control and intimacy[57]. These cognitive processes are theorized to impact family closeness by promoting avoidance behaviors, disrupting expressed emotions and intimacy, and impairing communication. Emotional disturbances such as blunted positive emotions and increased anger, shame, guilt and sadness are thought to further impair family processes[58]. Candice Monson, C-BIT developer, is an expert consultant on this proposal.

The Riggs & Riggs Military Family Attachment Network Model is a developmental-contextual theory that posits disruptions to attachment and a lack of clarity in family roles (e.g., parent-child role-reversal) are other mechanisms through which PTSD symptoms impact family functioning[46]. This theory argues attachment relationships and key family processes (e.g., belief systems, communication, organization) underlie the risk and resilience processes that influence post-deployment outcomes for service members and their families. Within this theory, attachment to significant others and family interaction patterns impact and are impacted by PTSD. Insecure attachment has been frequently associated with PTSD symptoms[59]. This model specifies that child functioning is determined by the extent to which PTSD symptoms impact parenting behaviors, parent-child attachment, family roles and communication patterns, and the level of violence and hostility in the home. Dr. Shelley Riggs, a developer of this theory, is a Co-I on this proposal.

A7. Motivational Interviewing Assessment. In order to proactively address enrollment and retention issues that some parenting programs at VA have reported, the intake assessment that occurs prior to treatment is conducted as a Motivational Interviewing Assessment (MIA). Parenting challenges are not part of standard VHA mental health assessments[14], therefore the pre-treatment assessment and interview that will occur prior to treatment may be the first time the Veteran is directly asked about their parenting and their interest in receiving such services. It can be difficult for clients to be ready to change a problem when few resources have historically been available to address it. Therefore we argue that directly targeting goal setting and motivation for change may be necessary to facilitate success in the intervention. Rather than conducting a standard clinical assessment, methodologies such as MIA are consistent with recent calls in the assessment field that psychological assessment can and should be conducted as a therapeutic intervention in its own right, as opposed to serving only as a necessary precursor to treatment. The process of conducting a psychological assessment in a collaborative and personalized manner combined with feedback is called *therapeutic assessment* [75]. A meta-analysis of 17 studies indicated therapeutic assessment has a positive and clinically meaningful impact on treatment[17].

Consistent with the principles of therapeutic assessment, motivational Interviewing (MI) was developed as a therapeutic strategy in recognition that clients present to treatment at different levels of readiness for change[76]. The Motivational Interviewing Assessment (MIA) is an outcome of the National Institute on Drug Abuse's (NIDA) Clinical Trials Network protocol in which one MIA session (lasting roughly 1.5 hours) resulted in higher rates of treatment retention during the first 4 weeks of treatment compared to treatment as usual[16]. MIA procedures call for use of a standardized and structured clinical assessment that is "sandwiched" between two 20-minute client-centered MI interventions. The MIA was selected because (1) its prior efficacy in improving treatment engagement, (2) data indicates it can be easily implemented by clinicians given proper training and supervision, and (3) we believe it will result in a therapeutic assessment process that has value to the Veteran. Dr. Jordan Braciszewski (Co-I) is an expert in MI and the MIA and he will provide training to study staff in both MI more generally and in the pre-treatment MIA. He will also work with the study team to develop and standardize the MIA assessment procedures for use in the future randomized clinical trial. During the open trial we will pilot the feasibility and acceptability of MIA prior to beginning treatment. Within the MIA, participants will identify their major goals for improving their parent-child functioning. Following MI mechanisms for change, we will also help participants identify their desire, ability, need, and reasons for change and we will share feedback with the Veteran on how they are doing based on the assessment measures they completed. Change talk, an MI term for a person's mention or discussion of their desires, ability, need and reason for change will be identified during the MIA and participants will be prompted with their individual change talk throughout treatment.

B. Study Methods

B1. Our primary objective is to adapt, refine, and conduct an open trial of the Strength at Home-Parents (SAHP) intervention for Veteran parents with PTSD. The outcome of this study will be a treatment manual that is designed specifically for the capabilities and organizational constraints of VA clinicians, treatment materials designed specifically for Veterans with PTSD, and refined assessment, recruitment, and retention procedures. This research will address feasibility and acceptability by incorporating Veteran and expert clinician feedback into treatment refinement. Positive evidence that the refined SAHP intervention and assessment procedures are feasible for delivery within the VHA will lead to a second merit application to test the hypothesis that relative to a control condition, SAHP improves parenting behaviors, parenting satisfaction and family functioning. This objective will be fulfilled by accomplishing the following aims:

Aim 1: Refine and Pilot Test SAHP for Veteran Feedback (completed). Obtain and incorporate expert clinician and Veteran feedback on credibility, acceptability, and satisfaction with the intervention to ensure Veteran-friendly SAHP manual, materials, and processes. Aim 1 will be accomplished through two rounds of expert panel review of the treatment/MIA manual and two rounds of pilot testing of the treatment for Veteran feedback in 16 female and 16 male Veterans.

Aim 2: Open Trial of the Refined SAHP Treatment for Feasibility (ongoing). Evaluate feasibility of study recruitment, retention, assessment procedures and proposed methods of the SAHP intervention. Preliminary examination of whether SAHP results in improvements to parenting behaviors, parenting satisfaction and overall family functioning. Aim 2 will be accomplished through an open trial of the final SAHP intervention and MIA procedures in 3-5 groups of female Veterans (n = 24-40) and 3-5 groups of male Veterans (n = 24-40; total N = 48-80), with collateral partner assessment of outcomes where possible.

Aim 1 was completed in January of 2020. In response to the COVID-19 pandemic the remainder of Aim 2 study activities will be completed remotely, and the protocol was edited to reflect these changes. Discrepancies between the protocol pre/post-COVID are clearly noted throughout the document.

Pre-COVID: In-Person groups and Assessments: This research will take place at the VISN 17 Center of Excellence for Research on Returning War Veterans in Waco, TX (CoE), the Olin Teague Veterans' Medical Center in Temple, TX and the Austin Outpatient Clinic in Austin, TX.

Post-COVID: Remote groups and Assessments: This research will be conducted remotely, and all assessment and treatment sessions will be completed through Central Texas VA-approved video technology platforms. Study assessment measures obtained at all timepoints (intake,treatment, post-treatment) will be completed through Qualtrics (as described on page 23). Prior to the start of assessment and intervention sessions

participants will be asked to provide their phone number and location, so they can be located if technological or safety issues were to arise.

Pre-COVID: Procedures for obtaining informed consent

Consent to participate in the study will be obtained during the first in-person assessment session. Veterans will read the consent documents and study staff obtaining consent will discuss discomforts/risks and potential benefits associated with the study. Any questions arising during the consent process will be answered.

Post-COVID: Procedures for obtaining informed consent:

Consent to participate in this study will be obtained by sending participants two signed copies of informed consent documents through the US Postal Service. The participant will read and sign consent documents, and mail one set of documents back to the study team located at the VHA VISN 17 Center of Excellence in Waco, TX using a pre-addressed envelope. Study staff obtaining consent will contact participants by phone to discuss discomforts/risks and potential benefits associated with the study. Any questions arising during the consent process will be answered. Veterans will be given another opportunity to ask questions and give verbal consent before the first assessment session.

Following RSD best guidance for obtaining informed consent through electronic methods, the following electronic methods for obtaining informed consent may be offered to veterans:

1) **Rights Management Services (RMS): Secure Transmission Using Encrypted Email with Return of Wet Signatures.** The Azure RMS VA cloud-based protection service may be used to securely transmit IRB-approved informed consent forms. Azure RMS uses encryption and authorization policies to help secure VA documents and emails containing sensitive data.
2) **MyHealtheVet: Secure Transmission Using Encrypted Email with Return of Wet Signatures.** MyHealtheVet may be used to send and return secure VA research informed consent forms (scanned or picture). MyHealtheVet provides encryption through secure messaging for compliance with FIPS 140-2 policy. Additionally, the MyHealtheVet enrollment process supports verifying a subject's identity before allowing access to the application for increased authentication.
3) **DocuSign Transmitting Informed Consent Forms and Obtaining Digital Signatures.** DocuSign can be used for the purpose of sending and signing digital documents to patients for their signatures.

   Similarly to the procedures outlined above, staff obtaining electronic consent will first contact participants by phone to discuss discomforts/risks and potential benefits associated with the study. Any questions arising during the consent process will be answered. Veterans will be given another opportunity to ask questions and give verbal consent before the first assessment session.

B2. Veteran Inclusion Criteria:

1) Age 18 years and older.

2) English speaking and able to provide written informed consent

3) Current parent to a child between the ages of 3 and 12. If the parent has more than one child within the target group, they will choose one of their children to be the index child for the purposes of SAHP (though we expect skills learned will translate to other children in the family). The child must reside with the Veteran or spend at least an average of two days per week with the Veteran.

4) Screen positive for elevated PTSD symptoms on the PTSD checklist for DSM 5 (PCL-5[80]). The PCL-5 is a 20 item self-report measure of PTSD symptoms in the past month. Items are rated on a 5 point Likert scale (0 = not at all, 4= extremely) and participants endorse symptoms based on "a very stressful experience." Items are summed with higher scores reflecting greater symptomatology. The measure evidences good reliability (Internal consistency = .96; test-retest = .84), discriminant and convergent validity[81] and takes 5-10 min. to complete.

5) Screen positive (above the 85th percentile) for parent-child functioning problems based on Parenting Stress Index- Short Form; PSI-SF. All three subscales and the total stress scale on the short-form are highly correlated with those on the long-form (.97-.99), and is expected to take respondents about 10 minutes to complete[82]. The total stress scale can successfully differentiate between different levels of risk for parent-child functioning problems and has strong convergent validity[83,84]. High Cronbach's alpha scores have been reported across all scales, ranging from .88 to .95[84].

B3. Exclusion Criteria: The intent of exclusion criteria for this study is to ensure study participants can provide informed consent and understand assessments/group materials, detect and provide referrals for urgent treatment of suicidality, substance dependence or psychosis, and protect the group environment so that individuals who might be disruptive to the group process due to unmanaged symptoms of psychosis or inability to attend the group free from intoxicants are not enrolled. Therefore, at the intake assessment we will screen for the following conditions:

1) Major neurocognitive disorder, including due to TBI. The adapted Ohio State Traumatic Brain Injury Identification Method (OSU TBI-ID[85]), is a 3-5 min. clinician administered interview for lifetime history of TBI. The OSU TBI-ID is a recommended common data element by NIH and evidences good- excellent reliability and validity[85,86]. The OSU TBI-ID will be used to identify severe TBI as defined as a score of 5. The participant's medical record may also be used for secondary verification in the case of TBI. For those scoring a 5, further referral and screening for comprehension ability will be recommended to determine exclusion (as the intent is to identify individuals who may not understand or comprehend study materials).

2) Untreated/poorly managed psychosis or substance dependence. The Mini-International Diagnostic Interview (MINI;[87]), is a structured diagnostic interview that can be completed in less than 10 minutes. It is one of the most widely used diagnostic

interviews and evidences psychometric properties that are like more complex and lengthier measures[88]. The psychotic disorders and substance dependence subscales of the MINI will be used to screen for DSM-V criteria for current psychosis and substance dependence. Participants meeting the diagnostic criteria above will be asked about their current treatment and if needed, the PI (licensed clinical psychologist) will speak with them regarding their current treatment plan and interest in referrals. Those not engaged in treatment (diagnosis without ongoing medication management or psychotherapy) and/or evidencing need for referral to detox (e.g. symptoms of withdrawal), and/or evidencing symptoms that interfere with the intake assessment will be excluded and referred for treatment. Where possible, a warm handoff will always be provided. Participants will be welcomed back to the study once stabilized.

3) Current suicide risk. The Beck Depression Inventory-II (BDI-II, [89]), a 21-item self-report measure of depression symptoms (5 min. to complete), will be used to assess for suicide risk as defined as a score of 2 or more on the BDI-II suicide item[89]. The BDI-II suicide item evidences a moderate correlation with the other scales of suicidal ideation in clinical samples, and has predictive validity[90]. Follow-up risk-assessment will be provided by the PI who is a licensed clinical psychologist. Individuals will be eligible after crisis intervention has been received.

Veterans will be asked if they have a partner (current or former) who participates in co-parenting with them. If affirmative, they will be asked to complete consent to partner contact and release of information form so that the study team can offer the partner a chance to participate in a phone or web-based assessment. This will not be required for study participation, and the study team will make clear to both the partner and the Veteran that no information will be shared between them regarding what the other person said or their scores on assessment measures.

B4. Partner Inclusion Criteria:
One goal of the proposed research is to determine whether collateral report of parent-child functioning is feasible, as this is a best practice in family functioning research. At the baseline assessment, Veterans will be asked to complete a consent for partner contact and release of information form to allow study staff to contact the partner. If the Veteran agrees, partners will be called and offered the chance to complete a brief assessment at pre-and post-treatment. Partners are eligible to participate in the phone interview if they are over 18 (assessed verbally) and give verbal assent to participate (or agree to participate using the online assessment system).

B5. Aim 1 (Months 0-18). Number of Subjects: 32.

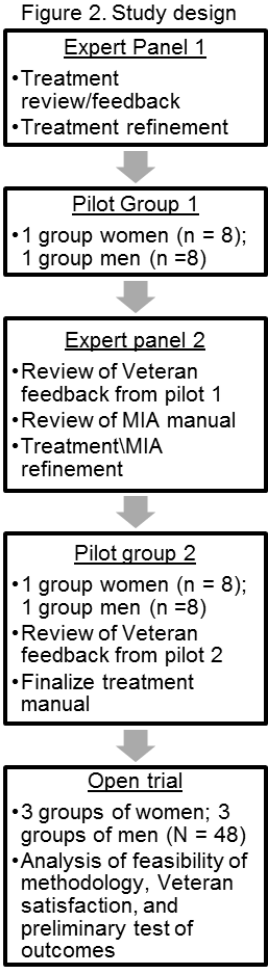
Obtain and incorporate expert clinician and Veteran feedback on credibility, acceptability, and satisfaction with the intervention to ensure Veteran-friendly SAHP manual, materials, and processes. Aim 1 will be accomplished through two rounds of expert panel review of the treatment/MIA manual and two rounds of pilot testing of the treatment/MIA for Veteran feedback (see Figure 1). First, the SAHP manual will be reviewed by a panel of expert clinicians who will provide feedback. Second, the revised SAHP manual will be piloted for Veteran feedback in 1 group of

women Veterans (n = 8) and 1 group of men Veterans (n=8). Third, the expert panel will convene again for consensus decision making regarding the Veteran feedback and additional adaptation of the SAHP manual. They will also review and provide feedback on the MIA manual and forms at this time. Finally, the revised manuals will be piloted a second time in 1 group of women Veterans (n = 8) and 1 group of men Veterans (n = 8) to ensure that revisions improved Veteran satisfaction with the treatment. Total N for Aim 1 is 32 Veterans.

B6. Aim 1 Procedure for intervention refinement:

Expert Panel 1: The first panel review will be a pre-assessment and refinement of materials. SAHP materials will be disseminated in month 1. Consultants will review and provide written feedback on the SAHP manual and they will be convened for a tele-conference in month 3 for a consensus discussion of needed modifications based on their considerable expertise and with consideration for effective presentation of material and ease of use by VHA clinicians. The manual will be revised accordingly.

Figure 2. Study design



Pilot Group 1: Veteran feedback (see measures and data sources) will be obtained through a pilot trial of SAHP in which they will assess the acceptability and credibility of SAHP strategies/content after each session. Investigators and facilitators will review session procedures and will use a template to make detailed notes after each module on phrasing, clarity, and participant engagement with material. There will be two pilot groups: 1 in women and 1 in men.

Expert Panel 2: The Veteran feedback from the first pilot round will be incorporated into a revised treatment manual during a second panel review. The panel will be provided with a summary of Veteran feedback and proposed manual revisions. Expert consultants will review and provide written feedback on the proposed revisions to the SAHP manual, and they will convene again by teleconference (month 12) for a consensus discussion of needed modifications. During the second panel the expert consultants will also evaluate and provide feedback on the MIA manual and forms. Veteran feedback on the MIA will not be assessed until the Open trial (Aim 2) because staff will still be training and achieving competence in MIA throughout Aim 1 (see Aim 1 MIA training). PI Creech and Co-I's Riggs, Taft and Braciszewski will make final revisions to the SAHP and MIA manual according to this feedback.

Pilot Group 2: The revised SAHP treatment will be piloted for Veteran feedback a second time to ensure revisions improve credibility, acceptability and satisfaction. As in pilot group 2 there will be two pilot groups held at this stage: 1 in women and 1 in men. Veteran feedback

will be used to make any final modifications to the treatment manual prior to the open trial.

B7. Aim 1 Procedure for pilot groups: The project coordinator and Research Technician will administer all assessment materials to Veteran participants. The PI and post-doctoral fellows will facilitate treatment groups.

Recruitment: Recruitment will use 2 main strategies: 1) Direct recruitment at local events, provider referrals, and flyers posted. 2) The study analyst will utilize VA administrative databases to request a list of all OEF/OIF/OND Veterans in our catchment area who have screened positive for PTSD on the Primary Care-PTSD Screen or who have a diagnosis of PTSD in their problem list. These Veterans will receive a letter informing them of the study and providing an opportunity to opt out of future contact.

Following standard VA procedures and data pull approval processes, the study analyst will pull the contact information of all Veterans in the Central TX VA catchment area with PTSD in their problem list, with dependents where possible, and without the exclusion criteria in their problem list. This will result in a large data pull, from which we will randomly select two batches to receive letters notifying them of the study and that they may receive a call. As one of the study aims is to measure the feasibility of recruiting veterans in the target group, we do not know how many veterans will truly meet inclusion criteria and how many will be interested. Starting with the larger group allows us the ability to estimate our needs better in the future, while also enhancing likelihood of recruiting success.

Eligibility screening: Those Veterans who are interested in participating will complete inclusion eligibility screening by telephone (15-20 minutes). Those who are eligible and interested based on the phone screen will be scheduled for an intake assessment (MIA).

Participant Remuneration: $50 pre- and post-assessment, $10 per post-intervention assessment for a total of $180. The $10 per post-intervention assessment is not reimbursement for participating in the intervention, but for time spent completing measures after each session. Partners will receive $20 for time spent completing each of 2 phone/web-based assessments.

Measures and Data sources for Pilot Groups (see Appendix for copies of measures): Credibility, acceptability, and satisfaction will be assessed with 4 measures. 1) The Credibility/Expectancy Questionnaire (CEQ[93]) will measure intervention credibility after each session. This measure has high internal consistency and test-re-test reliability[93]. Four questions on an 8-point Likert scale inquire about the logical nature of the intervention, willingness to recommend it to others, and expectations for the success of the intervention. Items are summed and scored, with higher scores representing greater credibility (possible range 0-32). 2) The Client Satisfaction Questionnaire-8 (CSQ[94]) assesses acceptability post-treatment. Eight items are scored on a 4-point scale

inquiring about quality of services, treatment satisfaction, and willingness to recommend the treatment to others. Ratings are summed, with higher scores representing greater acceptability ratings (possible range 4-32). This measure is commonly used in both clinical trials and program evaluation, and has been shown to correlate with treatment attendance and outcomes. It takes approximately three minutes to complete. Evaluations of the measure found it to be reliable, with high coefficient alphas (.83-.93) to support internal consistency, and that it evidences positive construct validity with other measures of satisfaction. Where available, mean CSQ ratings can also be compared against norms from other studies in similar populations[94]. 3) SAHP specific satisfaction questionnaire: Veteran feedback will be elicited after sessions using an open-ended measure to assess satisfaction with SAHP strategies and content. Satisfaction will be evaluated via Veteran ratings of how helpful the session was, how helpful the homework was (0 = ''not at all helpful,'' 8 = ''definitely helpful''), whether they learned anything during the session, and which components of each session were helpful or unhelpful. A modified version of this form will evaluate satisfaction with the MIA during the open trial. 4) Clinician notes after sessions will document phrasing and clarity of materials, and participant engagement with material. Clinicians will complete a template after each session documenting how role plays, examples, and language was received, any suggesting any changes.

Aim 1 Analysis Plan: Credibility ratings (CEQ) will be averaged to determine overall ratings for each session. Acceptability ratings (CSQ) will be averaged to determine overall acceptability and satisfaction for the intervention. The item-level and overall means on the CEQ/CSQ will be examined in concert with feedback from the open-ended SAHP specific questionnaires to guide further refinements to the treatment manual. Specifically, matrix displays will be used to organize and examine the qualitative and quantitative feedback from Veterans[92]. Matrix displays allow for within-case analyses (i.e., comparing a participant's satisfaction with different sessions) as well between-case analyses (i.e., comparing satisfaction for a session across groups) and comparisons with the quantitative data (CEQ, CSQ). A matrix format for entering and displaying data, which may include words, phrases, or direct quotes, will be based on the open-ended questions, with each of the primary topics (e.g., satisfaction with material, comments on practice assignments, intervention acceptability, etc.) having a separate matrix to identify common themes and concepts of importance. The analysis will guide adaptations to the intervention manuals. Data will be summarized for presentation to the expert panel that will evaluate additional refinements to the treatment manual. If major changes are made to the intervention in response to feedback from pilot 1, we will also examine whether there are changes in credibility and acceptability ratings from pilot 1 to pilot 2.

Motivational Interviewing Assessment (pre-treatment): The study assessor will be the post-doctoral associate and may include other CoE trainees (fellows and interns). The pre-treatment assessment will be conducted as a MIA which sandwiches two 20 min MI sessions around a structured clinical intake.

Aim 1 MIA training: Throughout aim 1, study assessors will be developing their MI skills and the focus will be on attaining MI competency. During this phase a project specific MIA protocol and manual will be developed and tested for use in the pilot and open trial and the future RCT. Dr. Braciszewski (CO-I) will provide centralized training in MI and the MIA to study staff beginning with a two-day training, followed by intensive fidelity coding and coaching. Dr. Braciszewski will collaborate with the study team members to draft the assessment protocol and manual and will provide ongoing consultation and training to staff in MI and the MIA for both assurance of training goals and fidelity to the model during the pilot and open trial.

Table 2: Research Timeline		Yr 1					Yr 2					Yr 3	
Quarters	0	1	2	3	4	5	6	7	8	9	10	11	12
Pre-Award Activities (completed)													
• IRB Application and staff hiring	X	X											
Motivational Interviewing Assessment Training (completed)													
• 2 day MIA training		X											
• Staff test out for MIA competency			X										
• SAHP/MIA protocol complete			X										
• All staff rated competent on MIA				X									
• Expert panel review of MIA protocol					X	X							
• MIA manual and forms finalized							X						
<u>Aim 1)</u> Refine and Pilot test SAHP (completed)													
• Panel review of treatment manual		X											
• Refine Manual		X	X										
• Recruitment			X	X									
• Pilot groups (n = 8 men and 8 women)				X	X								
• 2nd Panel review/Refine manual					X	X							
• Pilot groups (n = 8 men and 8 women)					X	X	X						
• Finalize treatment manual						X	X						
<u>Aim 2)</u> Open Trial and Feasibility evaluation (ongoing)													
• Recruitment							X	X					
• Pilot groups (n = 24-30 men; 24-30 women)								X	X	X	X	X	
• Analysis of findings											X	X	
• Dissemination of Results												X	X
• Application for IIR for clinical trial												X	X

<u>B8. Aim 2 (Months 18-36) (N = 48-60 Veterans; N=48-60 partner phone assessments)</u>

Evaluate feasibility of study recruitment, retention, assessment procedures and proposed methods of the SAHP intervention. Aim 2 will be accomplished through an open trial of the final SAHP intervention in 3-5 groups of female Veterans (n = 24-30) and 3-5 groups of male Veterans (n = 24-30; total N = 48-60). Research questions to be answered include: 1) feasibility of group modality, viability of gender specific cohorts/recruitment of women, timing and location of group sessions, and barriers to participation, 2) Veteran perceptions of/satisfaction with MIA, proposed RCT outcomes measures, and collateral partner report of parent-child functioning, 3) Feasibility of MIA as evidenced by clinician experiences using the MIA and clinician fidelity ratings throughout the open trial. MIA fidelity coding will be conducted by Dr. Braciszewski. Feasibility of collateral partner report of parent-child functioning. 4) Preliminary test of whether SAHP results in improvements to parenting behaviors, parenting satisfaction and family functioning.

B9. Procedures: All group procedures including recruitment, eligibility screening, inclusion and exclusion criteria for Aim 2 are the same as described above in Aim 1, with one exception – groups may now be facilitated by one facilitator (PI or post-doctoral fellow).

Measures and Data sources: Feasibility and acceptability will be assessed with three measures: 1) Number and rates of Veterans contacted, screened, assessed, enrolled, retained; 2) Veteran reasons for opting out or dropping out. 3) Veteran ratings of their satisfaction with treatment (CSQ; SAHP satisfaction). Feasibility and satisfaction with the pre-treatment MIA will be evaluated using the Client Evaluation of Motivational Interviewing Scale (CEMI[97]) and a study specific post-assessment feedback form that will assess for satisfaction (see appendix). The CEMI is an 11-item self-report measure of client perceptions of clinicians' use of MI during their session. Internal consistency is high across the two factors (a = .88, relational; a = .91, technical)[97,98]. Evaluations of CEMI validity found that client's experiences of clinician MI fidelity was generally consistent with other measures[99]. MIA fidelity ratings based on the MIA Interview Rating Guide[15] will be provided by Dr. Braciszewski to determine feasibility of clinicians providing MIA. Feasibility of collateral partner report of parent-child functioning will be determined based on the number of Veterans with a partner who could complete collateral report, the number who consent to partner contact, and data completion rates for this aspect of the study.

Five measures will be used as a preliminary assessment of treatment outcomes and a sixth measure will be used to understand co-morbidity in the study sample. These measures will be completed at intake and after session 8. In the case of drop-out, the post-treatment assessment will be scheduled within one week of what would have been session 8 and this will be done in person or over the phone. 1) The Parenting Stress Index, 4th edition (PSI[100]) is a 120-item measure on a five-point Likert scale yielding a parent and child domain scale measuring stress related to parent and child characteristics including relevant subscales. The PSI includes a scale examining support from a parenting partner. The PSI has high reliability coefficients (a = .75-.88), high internal consistency (a = .96), and high test-retest reliability. The measure has been validated across a variety of population, and takes 10 min. to complete. [82] 2) The Alabama Parenting Questionnaire (APQ[101]), contains 42 items examining positive and negative discipline and other parenting practices and takes 10 min. to complete. The measure evidences satisfactory reliability (*a* = .80-.92), and discriminant and convergent validity[102]. The parent report converges well with concurrent observational ratings of parenting[103]. 3) The 12-item general family functioning scale of the Family Assessment Device (FAD[104]) measures general family functioning and consists of statements about family functioning that respondents answer via a 4-point Likert scale and takes 5 min. to complete. Responses are added together, then divided by twelve to give a mean score ranging from one to four. The FAD has high Cronbach's alpha (.86), and split-half reliability (.83)[105]. Consistency between responses to the 12-item FAD, and related family variables provides validity evidence[106]. 4) The Pediatric Symptom Checklist (PSC[106]) measures parents' impressions of their child's psychosocial functioning and

takes 5 min. to complete. Parents complete 35 items reflecting a range of emotional and behavioral problems (e.g., "has trouble sleeping" or "feels sad, unhappy") that are scored on a 3-point scale reflecting the rating that best fits their child (0 = never, 1=sometimes, 2 = often). Items are averaged to create a total scale. Higher scores reflect greater psychosocial problems/impairment. The psychometric properties of the PSC have been established across diverse populations of children[107,108] and it has been validated in military populations[109,110]. 5) The Parenting Scale (PS; [111]), a 30-item measure of parenting practices will also be completed. The PS has demonstrated adequate internal consistency and reliability, and correlates well with observational measures of dysfunctional discipline and child misbehavior. Demographics will be collected (5 min.). 6) The Personality Assessment Screener (PAS [112]) is a brief, 5 minute 22-item screener that is adapted from the larger response item Personality Assessment Inventory (PAI). It will be used to screen for the presence of co-morbid disorders. Items are scored with higher scores ranging from mild to marked risk (possible range 15-23)[112,113]. The Personality Assessment Observer (PAS-O[112]) is designed as a parallel assessment to address the 22 corresponding items that the Veteran answered on the (PAS). It will be obtained through the spouse or partner of the Veteran and will help validate the Veterans' (PAS) results.

Feasibility of collateral partner assessment: Where possible, a co-parent will be asked to complete the PSI, the PSC, PAS-O and demographics in order to examine whether it will be feasible to gather external evaluation of parent-child functioning at intake and post-treatment. This will be conducted via phone or web-based assessment.

Aim 2 Analysis Plan. The combination of the data collected will allow us to evaluate whether there is sufficient evidence to scale up to an RCT. Feasibility, acceptability and satisfaction: Descriptive statistics, including means, standard deviation, numbers, and percentages will be used to summarize feasibility and acceptability variables as the measures are continuous and there is no validated cut-off. Participant attendance at sessions exceeding 70% will indicate feasibility about timing and location of the group. Numbers of Veterans screened, assessed and enrolled vs. the number contacted will be examined to calculate a screening to enrollment ratio that will guide the timeline and costs for the future RCT and help evaluate overall feasibility and efficacy of recruitment strategies. At each stage, we will also assess reasons for opting out or dropping out to evaluate the barriers to participating and the feasibility of the proposed methods. A recruitment milestone of 8 Veterans (one cohort) enrolled within a 3-month period is necessary to meet the study goals and a good estimate of the feasibility and viability of scaling up recruitment for the planned RCT. Veteran satisfaction and feedback on the pre-treatment MIA as well as rating of interview fidelity on the MIA will be used to determine whether there is preliminary evidence that that the MIA is feasible and satisfactory. Veteran willingness to sign a release for partner contact, and number of successfully completed partner assessments will help determine the feasibility of collateral partner assessment of parent-child functioning in the RCT. Preliminary effectiveness: As formal significance testing is not the goal of this study, we will test for a signal that SAHP results in changes to the Veteran-reported primary outcomes at $p < .10$. Outcome analyses will be conducted following both Intention-to-treat and per protocol principles. That is, first, we will examine pre-to post-treatment changes in the

primary treatment outcomes for all individuals assessed (ITT). Second, we will examine pre-to post-treatment changes in the primary treatment outcomes from all Veterans completing the group. Outcomes will be analyzed using one-way within-subjects' ANOVA (i.e., repeated measures) to assess change from pre- to post-intervention at $p < .10$. Analyses will also evaluate differences between Veterans who do and do not complete Time 2 data. The goal of partner reported outcomes is to determine whether it will be feasible to gather these data. If successful, we will look for a signal that SAHP results in changes in the partner-reported outcomes, particularly changes in the support from parenting partner scale of the PSI.

Schedule of Assessments						
		Phone Screen	Baseline	Weekly	Post-treatment	
		SAHP	SAHP	SAHP	SAHP	Measure Purpose
Reasons for opting out or dropping out		X	X	X	X	Feasibility
Eligibility/Clinical Scales	PCL-5	X	X		X	Eligibility/ Exploratory
	PSI-SF	X				Eligibility
	OSU TBI ID		X			Eligibility
	MINI		X			Eligibility
	BDI-II		X		X	Eligibility/Exploratory
AIM I (completed)	CEQ			X		Treatment Credibility
	SAHP Specific			X		Treatment Satisfaction
	Clinician notes			X		Exploratory
AIM II (ongoing)	SAHP Satisfaction				X	Primary Outcome
	CEMI		X		x	Feasibility Satisfaction
	PSI- Partner		X		X	Preliminary Outcomes
	PSC- Partner		X		X	Preliminary Outcomes
	PAS-O		X		X	Preliminary Outcomes
	CSQ				X	Primary Outcome

AIM I (completed) & AIM II (ongoing)	PSI		X		X	Preliminary Outcomes
	APQ/APQ-PR		X		X	Preliminary Outcomes
	FAD		X		X	Preliminary Outcomes
	PSC		X		X	Preliminary Outcomes
	PS		X		X	Preliminary Outcomes
	PAS		X		X	Preliminary Outcomes

*Measure Names: **PSI-SF** (Parenting Stress Index), **OSU TBI ID** (Ohio State University Traumatic Brain Injury), **MINI** (Mini International Diagnostic Interview), **BDI II** (Beck Depression Inventory), **CEQ** (Credibility and Expectancy Questionnaire), **CSQ** (Client Satisfaction Questionnaire), **SAHP** Specific (Satisfaction questionnaire), **CEMI** (Client Evaluation and Interviewing Scale), **PSI** (Parenting Stress Index), **APQ** (Alabama Parenting Questionnaire), **FAD** (Family Assessment Device), **PSC** (Pediatric Symptom Checklist). **PS** (Parenting Scale). **PAS/PAS-O** (Personality Assessment Screener/Other)

D. Data Management

D1. Identifiers: A study ID number will be used to identify each participant and their partner across assessments.

D2. Identifiers/linking data: A password protected master participant tracking spreadsheet will contain the linking information that matches the unique participant IDs to participant names. This spreadsheet will reside only on the secure research S drive. Other PHI such as participant addresses and phone numbers (for follow-up contact), and date of participation will be contained in the master tracker. This information will only be accessible to PI Creech and her research staff that is approved to work on the study. The Master tracker will be kept separately from study databases on the Central Texas secure research (S) drive. The paper files will be stored in locked file cabinet in a locked room at the VHA VISN 17 Center of Excellence in Waco, TX

D3. Confidentiality: No participant will be identified in any publications or presentations arising from this study. Records will be maintained in accordance with the Department of Veterans Affairs Record Control Schedule 10-1. It may be necessary or required for the study investigators to break confidentiality and release personal identifiers and health information when mandated by law. For example, state law requires health care workers to report any suspected abuse or neglect of a child, or person 65 years or older, or an adult with disabilities to the Texas Department of Family and Protective Services.

A Certificate of Confidentiality will be obtained from the National Institutes of Health prior to the commencement of research. The purpose of this certificate is to protect the identity of research subjects participating in studies that collect sensitive information. No information about participants will be released without their permission or where required by law (such as the examples given above).

All employees who are to handle data will be trained in confidentiality policies and procedures. If theft, loss, or other unauthorized access of sensitive data and non-compliance with security controls occur, study staff has been instructed to follow the CTVHCS standard operating procedure on incidence reporting.

Post-COVID: Prior to starting treatment and assessment sessions participants will be asked to confirm that confidentiality can be maintained at their location. Following confirmation, remote treatment and assessment sessions will be locked to maintain confidentiality. Only non-public facing VA-approved video technology platforms will be used for assessment and treatment sessions, and all available privacy and encryption modes will be enabled.

D4. Delineation of research tasks performed by VA and collaborators: Collaborators (as listed on p.1) are those individuals who are involved in specific aspects of the study (for example, drafting the treatment and assessment manual as described in Aim 1, "procedures for intervention refinement"), but who have no participant contact or contact with study data.

All participant contact activities will take place remotely via VA-approved video technology **(Post-COVID)** or place on the Austin, Temple or Waco campuses of CTVHCS **(Pre-COVID)** or via a telephone call between a study staff member and a participant. Participants will complete self-report study measures on Qualtrics (as described on pp. 23). Participant contact only occurs between CTVHCS participants and IRB approved individuals listed as key personnel or study staff.

D5. Primary users of the study dataset: are those individuals listed as key personnel or who are on the study staff list and are those individuals who will conduct pre-specified analyses consistent with the study's hypotheses and its primary, secondary and exploratory aims as described in the aims and analysis plan.

D6. Disposition of the data: Paper files containing identifiers will be kept in locked file cabinets in a locked room at the Center of Excellence in Waco, TX. Questionnaire data will be kept separately from data containing identifiers. Only approved study staff will have access to the files. Electronic data will be stored on the secure VA password-protected server with access restricted to research staff. These records will be maintained and retained in accordance with the Department of Veterans Affairs Record Control Schedule 10-1.

D7. Incident Reporting: Any incidents affecting the security of the data such as theft, loss, or unauthorized access of sensitive data will be reported to the ISO and PO per VA regulations.

D8. Data Use and Transfer within CTVHCS: Only IRB approved personnel on the study staff list will have access to the data collected in this study. Access to the study data will be terminated when personnel are no longer part of the research team. This study will recruit participants across the Central Texas VA Healthcare System. The recordings during intake assessments will be saved directly to the secure S drive. All original audio recordings are saved directly to the S drive.

Pre-COVID:The primary repository of paper files generated by the study is the VHA VISN 17 COE. Data to be transported to the COE includes: consent documents and measures completed after each session and at post-treatment. Study data collected at the Temple or Austin campus (post-session and post-treatment measures and consent

documents) will be transported to the approved data storage location at the Waco Campus where it will be uploaded to the secure research S drive. Personally-identifying information (e.g. Informed Consent Form with name and date of consent) will be kept in a separate locked carrying case from the data during transport. No other paper data is collected as part of this study.

Post-COVID: All assessment measures will be collected on the web-based survey application Qualtrics, and will be stored on a FIPS 140-2 compliant server.

D9. Coding of Recording Motivational Interviews: Recordings of the pre-treatment motivational interviews will be sent to Dr. Jordan Braciszewski, Henry Ford Healthcare System, for fidelity coding and feedback. Both the informed consent document (p. 5, item 1 informs participants this will occur) and the study HIPPA authorization document (p. 2, disclosure) describe this for participants. The interviewers will minimize verbalizations of PHI during the interviews, and files will be saved with code numbers only and password protected, however, it will not be possible to remove all PHI given that voice recordings themselves are PHI. The recordings will be encrypted and saved in a manner approved by the Central Texas Privacy Officer and Information Security Officer. Following completion of the applicable procedures documented in protocol section D11 and working in collaboration with the Central Texas Privacy Officer and Information Security Officer, a VA Materials Transport Agreement (MTA) will be completed and the recordings will be sent via an approved, secure chain of custody method (UPS) from Dr. Creech directly to Dr. Braciszewski. Once the interviews are coded, Dr. Braciszewski will return them using the same secure chain of custody method. Original copies will remain at VA.

D10. Records destruction information: "All paper AND electronic documentation containing confidential, personally identifiable information, protected health information, and any other sensitive information will be disposed/destroyed per current VA regulations at the time of disposal/destruction of documentation."

D11. Records retention information: "The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1)." All de-identified data will be managed in accordance with the VHA Handbook 1605.1 APPENDIX B.

All original data will be stored at VA.

D12. Reporting: Any incidents involving theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls will be immediately reported to the IRB chair, Privacy Officer and Information Security Officer.

D13. Data Analysis Software: Data will be analyzed using the software programs R, SPSS and MPLUS that are already owned by the VA either using local copies of the software or through VA Informatics and Computing Infrastructure (VINCI).

E. VINCI

E. VINCI: VINCI is a major informatics initiative of the Department of Veterans Affairs (VA) that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD). VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources. VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC), located in Austin, Texas. This secure enclave with 105 high-performance servers and 1.5 petabytes of high-speed data storage has multiple layers of security and disaster recovery to prevent data loss.

To ensure the protection of Veteran data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources are approved in accordance with the requirements of National Data Systems (NDS), VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. All data transferred from VINCI is subject to audit for compliance.

VA-credentialed research or operations staff are granted access to study-specific data along with tools for analysis and reporting in the secure, virtual working environment through a certified VHA network computer within the VA. If not working within a VA or VHA hosted office environment containing VA network access, researchers may apply for and then access VINCI through an approved Virtual Private Network (VPN) and Remote Desktop application. The remote computing environment enables data analysis to be performed directly on VINCI servers, offering several advantages: uniform security standards for access; a common point of entry for all investigators who use the data; tools for analysis and reporting; tighter and more consistent control of data quality; and the ability to standardize and update terminology and format as technology and methodology improve.

Only study team personnel explicitly authorized by data stewards will have access to project data. The study principal investigator has the responsibility for security of study. VINCI data managers and VA OI&T personnel not under the purview of the study principal investigator control the servers, network, processors, firewall and software in the VINCI environment, including access rights granted to study personnel.

When study personnel are no longer part of the research team, the study principal investigator will amend the data access request to terminate that person's access to all study data and notify the VA Information Security Officer of such action. No sensitive patient data may be shared with anyone who does not have a VA appointment. All study team personnel with access to sensitive patient data must stay current on required VA information security and privacy policy trainings.

Study data stored on VINCI servers is located at the Austin Information Technology Center, 1615 Woodward St., Austin, TX 78772-0001. The specific server where the data

are stored within the VINCI environment will be chosen by VINCI personnel. The server name and location within the Austin Information Technology Center may be changed at any time at the discretion of VINCI personnel.

Data from measurements collected at intake, treatment and post-treatment may be captured by secure, web-based survey application Qualtrics. Qualtrics has been approved by the VA as a secure data collection tool, and is considered *equivalent* to being behind the VA firewall**.** Within Qualtrics all web-based information is encrypted. Qualtrics stores all data on a FIPS 140-2 compliant server. Qualtrics is flexible enough to be used for a variety of types of research, and provides an intuitive interface for participants to complete surveys without an experimenter present. The survey will be created as an anonymous survey, such that no IP address, names, emails, or any other identifying information will be collected at the time of participation. Qualtrics is currently used by other research studies within the Central Texas VA Healthcare System, including the large-scale Project SERVE (Protocol #: 00390).

F. Data Safety and Monitoring

F1. Safety monitoring plan

Any breach of data or procedure will be reported immediately to the ISO, privacy officer and IRB. If any participant safety issues arise during the group sessions (participant discloses suicidal ideation or in intoxicated), the participant will be assisted in obtaining immediate medical attention and this will be reported to the IRB chair**.** All adverse events will be reported to the IRB within 24 hours of notification.

Monitoring of safety and data quality in the proposed study will be the responsibility of all personnel on the project, with primary responsibility and supervision by the PI. The Institutional Review Board at the Central Texas VA HCS will approve the Statement of Informed Consent for the study and this board provides oversight of data and safety issues. The study protocol will be approved prior to soliciting or consenting any participants. Any incidents that involve a breach of this plan or serious accident/injury will be reported to the IRB chair at CTVHCS. Potential, albeit minimally likely, include distress resulting from the study assessments, coercion through compensation, and breach of confidentiality.

In the case of an Adverse Effect (AE) or a Serious Adverse Effect (SAE), a written report of the AE or SAE will be prepared for submission to the IRB. Any such AEs or SAEs will be presented to the IRB within 24 hours of notification. The report of such AEs or SAEs will include whether they were expected or unexpected, a rating of severity of the event, a brief narrative summary of the event, a determination of whether a causal relationship existed between the study procedures and the event, whether the informed consent should be changed as a result of the event, and whether all enrolled participants should be notified of the event. All team meetings will begin by asking whether any adverse events have occurred and the team will regularly review the criteria for AEs and SAEs.

All required personnel proposed for this project will have the required human subjects and confidentiality training, including information about maintaining data integrity and security so that data quality and health information are protected.

All other identifying information (e.g., signed consent forms) will be stored separately from the research questionnaires. Separate locked, secure files will be used to store study materials for each participant to ensure confidentiality and safety. Methods for obtaining electronic informed consent forms are compliant with Department of Veterans Affairs (VA) Directive 6500, "VA Cybersecurity Program" and FIPS 140-2. Identity masking subject numbers assigned to each participant will be the only means by which collected information is labeled. Each participant will have his or her own. The only list that will link the names of the participants with their subject numbers will be kept in a secure, password-protected computer account accessible only to the PI and IRB approved personnel on the study staff list. Study results will be presented and/or published in a fashion to ensure that participants cannot be identified.

G. Risks/Benefits Assessment:

G1. Foreseeable risks: There are three major areas of low to moderate risk associated with participation in the proposed study: 1) In any research study there is risk to confidentiality and loss of privacy if identifying study data were to be hacked or breached. 2) When discussing PTSD symptoms or problems with parenting or family and relationship functioning, participants may become emotionally upset and distressed. 3) Some participants may feel coerced into participating in the research if compensation is too high.

Data and safety monitoring will take place to assure the safety of subjects. All participants will be reminded that their participation is voluntary and that they can withdraw at any time without penalty. Additionally, the risks described above will be minimized by the following procedures:

1. Confidentiality. We will take all necessary steps to protect patient privacy and confidentiality, in accordance with VA regulations and other applicable laws. We have undertaken several steps to ensure confidentiality and data security. First, we will eliminate any identifying information on study surveys and we will use unique numeric identifiers to label and track participant measures completed over the course of the study. Second, all data storage devices, including computers and servers, will be VA issued and monitored by VA information management services. Only study personnel authorized by the Principal Investigator (PI) will have access to the data, and the file server is protected from the internet by a firewall. Third, participant files will be stored in separate locked filing cabinets in a secure data storage room. Each participant will have their own subject number, and these numbers will be the only means by which subject information is identified. Subject numbers will mask identity. One list will be kept that will link the names of the participants with their subject numbers. Fourth, audio-recorded MIA sessions will be mailed to Dr. Braciszeski at Henry Ford using a secure chain of custody and they will be mailed back using the same method. The recordings will be encrypted and saved on a password protected manner, following procedures approved by the local ISO and PO. Fidelity ratings will not include subject information but only

interviewer information for the purpose of rating fidelity and providing coaching. Fifth, all electronic recordings from the MIA sessions will be stored electronically until such time as they need to be sent to Dr. Braciszewski. Data will be stored on a protected VHA server that is behind the firewall. Access to the server is limited to system administrators and project personnel will have access to the data. Results will only be reported in aggregate so no individual can be identified. **Post- COVID:** Sixth, all assessment and intervention sessions will be completed using non-public facing VA-approved video technology. Prior to the start of every session participants will be asked if confidentiality can be maintained at their location, and once confidentiality is confirmed sessions will be locked. All available encryption and privacy modes will be enabled.

2. Emotional distress. The primary risk in this study is that participants may become emotionally upset when discussing PTSD symptoms or family functioning problems. Participants will be made aware of what to expect during study procedures prior to their participation, and will be informed in the consent form that the procedures may potentially lead to more distress. Participants will also be informed that they may discontinue their participation at any time. At the end of participant's assessment sessions, each participant will be debriefed individually to ensure that they are not emotionally distressed. Licensed psychologists will be available always if a participant is or becomes emotionally distressed. In addition, appropriate treatment referrals will be made for study participants when necessary, and participants will be made aware of resources available to them.

If the participant volunteers information regarding self-harm at any point during the study (including during telephone screening), safety issues will be formally assessed and in conjunction with the Central Texas Suicide Prevention Coordinators. If imminently suicidal or homicidal, the participant will be evaluated for hospitalization per standard Medical Center procedures. This would involve a planned psychiatric evaluation in the ER, and participants will be instructed to come to the ER. If the participant is unwilling to seek care the police would be called. These procedures have been in place for other ongoing studies and have been approved by the IRB. All adverse events will immediately be reported to the IRB.

As needed, partners will be offered hotline numbers and local mental health resources, which can be given over the phone or mailed. For more serious concerns regarding risk for self or other harm, the partner will be offered a chance to talk the study PI for a safety assessment, and if necessary, will be encouraged to go to their local ER or the police will be called for a safety check. We do not expect this to occur since the partner call is brief, scripted and does not inquire into the partner's mental health. Nevertheless, all staff conducting these calls will be trained in safety procedures.

Due to our focus on improving parenting, the study team recognizes this may enhance concerns about child abuse or neglect. Participants who are justice-involved due to past concerns about child abuse or neglect will still be eligible for the study; however, they will be informed that the treatment will not meet criteria for any court-mandated treatment. All participants will also be informed at the beginning of every new contact (screening, interview, and group) that all members of the study staff are mandated reporters of any child abuse or neglect so that it will not be a surprise if this occurs (in

addition to being mandated reporters of elder abuse or intention to hurt oneself or someone else). Veterans will be encouraged to let study staff know if they have concerns regarding this issue. Though the study protocol and assessments do not measure child abuse, all study staff will be trained in procedures for what to do should they become aware of child abuse or any other mandated reporting issue.

3. Coercion through Compensation. A human subjects concern is whether the financial compensation is too high and therefore coercive to participants. That is, there is a concern that high reimbursement may coerce normally unwilling participants to participate in the study. The typical compensation rate used at the research site for research study participants and those in the current study is $25 per hour, a rate that aims to compensate for the cost of resultant travel (applies to **Pre-COVID** only) and child care, but does not constitute undue inducement. We believe that this proposed reimbursement fairly compensates participants for their lost work time and for taking time out of their schedules to participate. Therefore, we have proposed to compensate Veterans participants at the rate of $50 for each pre and post assessment, and $10 for time completing measures after each intervention session, for a total of $180. Partners will be compensated $20 each for their time completing two phone assessments.

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

G2. Referral to treatment and counseling during the study. No referral, or counseling will be withheld in any way at any time during the study. If participants request referrals, or it becomes clear they may benefit from a referral, study staff will facilitate this process.

G3. Potential Benefits of the Proposed Research to the Subjects and Others. There are no assured benefits but several potential benefits from participation in the proposed project. First, although discussing PTSD, parenting difficulties and family functioning may potentially lead to some emotional distress, this is also likely to be experienced as educational and possibly therapeutic for some participants. Participants will have the opportunity to learn more about problems they may be experiencing but poorly understand, and may gain a better understanding of their relationships through study

participation. Therefore, for some, the proposed project may assist in the patient's education and self-awareness. Participants may also experience a sense of relief through these study procedures, because they may not have discussed such issues with a therapist previously. Furthermore, the intervention itself may improve parent-child functioning, and overall family functioning which may also be of considerable value.

G4. Importance of Knowledge to be Gained Despite known bidirectional links between PTSD symptoms and family functioning impairment, including parent child functioning, there is no evidence-based intervention built specifically for VHA that seeks to improve parenting in Veterans who are diagnosed with PTSD. The knowledge that may be gained from this study will fill a gap in knowledge about evidence-based parent training for Veterans with PTSD. This research may also lead to an effective and evidence-based intervention to improve the lives of Veterans and their family members.

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