Study Protocol

Teaching Loved Ones to Help Veteran Optimize their PTSD Care and Healing (COACH)

Funding Agency: VA RR&D

Principal Investigator: Laura A Meis, PhD

Version 11: February 24, 2022

Tool Revision History

Version number 1
Version date: June 8, 2020
Initial protocol version first submitted to IRB for project PI/SC.

Version number 2
Version date: October 27, 2020
Summary of revisions made: Amendment 1; Putting study surveys on the online version on VA approved Qualtrics FedRAMP software; using email correspondence to send survey links to participants; providing a telemedicine option for treatment; modifying our inclusions/exclusions to requiring patients be seen via telehealth when in-person treatment options aren't available.

Version number 3
Version date: January 27, 2021
Summary of revisions made: Amendment 2; revising our study materials document; finalizing the study surveys, including survey timelines and survey measures; increasing compensation for patient compensation for study survey completion; adding study brochures and flyer.

Version number 4
Version date: February 19, 2021
Summary of revisions made: Amendment 3; revising the Loved One screener; adding new inclusionary criteria that couples must live in state; adding the CSI-16.

Version number 5
Version date: March 24, 2021
Summary of revisions made: Amendment 4; updating the inclusions/exclusions to exclude or delay individual's entry to the study on a case-by-case basis based on their clinical presentation; updating HIPAA form; ability to respond to emails from potential participants.

Version number 6
Version date: April 19, 2021
Summary of revisions made: Amendment 5; adding monthly survey emails; increasing enrollment goal; creating Facebook study group and Facebook study post; adding study therapists; remove requirement that couples must live in state.

Version number 7
Version date: June 9, 2021
Summary of revisions made: Amendment 6; addition of Docusign as a manner of signing informed consent forms and HIPAA authorization electronically; addition of a final contact letter.

Version number 8
Version date: June 24, 2021
Summary of revisions made: Amendment 7; requiring participants to retake baseline surveys or assessments if they expire more than 2 months (60 days).

Version number 9
Version date: August 3, 2021
Summary of revisions made: Amendment 8; updating incentive amounts; removing payment for symptoms assessments given weekly; reducing baseline survey amount to $40.

Version number 10
Version date: October 13, 2021
Summary of revisions made: Amendment 11; request to use Keystrokes transcription services to obtain transcriptions of patient recorded interviews.

Version number 11
Version date: February 24, 2022
Summary of revisions made: Amendment 14; adding a 3-month follow-up survey.

Abstract

Impacts. We aim to improve the mental health, family functioning, and well-being of veterans with posttraumatic stress disorder (PTSD) through developing and evaluating a trauma-focused, couple therapy for PTSD. We will use strategies from Integrative Behavioral Couple Therapy (ICBT) to help loved ones support veterans during exposure therapy for PTSD (Prolonged Exposure; PE). We anticipate this approach will increase veterans' engagement in PE, but also improve relationship functioning, family functioning, and social functioning. Family involvement has been highlighted as a fertile avenue for improving the outcomes for patients with PTSD, yet families are infrequently integrated into evidence-based psychotherapies (EBPs). Our goals are highly is consistent with RR&D's mission to promote research that leverages family support as a pathway to reintegration and optimizes meaningful recovery and functioning.

Background. PTSD occurs in as many as 17% of US military veterans and is associated with a host of negative, long-term consequences to the individual, their families, and society at large. EBPs, such as PE, result in clinically significant symptom relief for many. Yet, these therapies have proven less effective for military personnel and veterans and treatment dropout rates are high. Our team surveyed veterans initiating EBPs for PTSD and a family member across four VA medical centers (N = 598; Project HomeFront). We found that veterans were more than twice as likely to complete EBPs when loved ones encouraged them to confront distress and that veterans experienced greater treatment gains when they shared more with their loved ones about their treatment. A couples-based, exposure therapy for PTSD that integrates loved ones into every session of PE could provide the opportunity to mobilize the whole household in the service of EBP engagement, while extending the goals of therapy beyond symptom reduction to family functioning. We anticipate this intervention will teach couples to embrace a lifestyle that supports confronting trauma-related distress, so the veteran and his/her family can achieve optimal functional outcomes.

Objectives. We will complete stages 1A and 1B of the Stage Model of Treatment Development. Specifically, we will: (1) Expand our treatment outline using content experts and feedback from key stakeholders (veterans, loved ones, providers, and VA mental health leadership). (2) Conduct a pilot open trial to assess (a) the acceptability of treatment components, structure, and materials, (b) the feasibility of the intervention (retention and intervention fidelity), and (c) the study approach (screening, recruitment, and assessment process). (3) Explore the preliminary effects of the intervention on select outcomes including overall functioning, mental health functioning, social functioning, family functioning, and potential mechanisms (social control, subjective norms, and the degree to which veterans rely on their partners for support).

Methods: To accomplish Aim 1, we will expand the outline for the intervention into an initial treatment manual through meetings with content experts and stakeholder feedback. Next, we will develop fidelity checklists and revise the treatment manual through conducting the intervention with 2-3 couples. To accomplish Aims 2 and 3, we will evaluate the intervention in a non-randomized, open trial with 12 veterans diagnosed with PTSD and their loved ones. Veterans will complete baseline and posttreatment structured diagnostic interviews. Both members of the couple will complete baseline surveys, surveys during treatment, posttreatment surveys, and posttreatment qualitative exit interviews. Using data obtained from the open trial, we will assess the intervention's acceptability, feasibility, mechanisms, and outcomes. Upon completion of this proposal, we will be well positioned to apply for Merit funding for a randomized clinical trial (Stage 2 of the Stage Model of Treatment Development) of this innovative, exposure based, couple therapy.

List of Abbreviations, Acronyms, and Symbols

BFT	Behavioral Family Therapy
CAPS-5	Clinician-Administered PTSD Scale for DSM-5
CCDOR	Center for Care Delivery & Outcomes Research
CES	Credibility Expectancy Scale
CE	Studio Community Engagement Studio
Co-I	Co-Investigator
COACH	Teaching Loved Ones to Help Veterans Optimize their PTSD Care and Healing
CPT	Cognitive Processing Therapy
CSQ-8	Client Evaluation of Services Questionnaire
DSM-5	Diagnostic and Statistical Manual of Mental Disorders
DoD	Department of Defense
EBP	Evidence Based Psychotherapy
FES	Family Environment Scale
HSR&D	Health Services Research and Development
HW	Homework
IPF	Inventory of Psychological Functioning
IIR	Investigator-Initiated Research
IRB	Institutional Review Board
ICBT	Integrative Behavioral Couples Therapy
LO	Loved Ones
MI	Motivational Interviewing
MH	Mental Health
N/A	Not Applicable
OCD	Obsessive Compulsive Disorder
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
OMHS	Office of Mental Health Services
PEAS	Patient Exposure and Response Prevention Adherence Scale
PCL	Posttraumatic Stress Disorder Checklist (DSM-IV)
PCL-5	Posttraumatic Stress Disorder Checklist (DSM-5)
PE	Prolonged Exposure
PHQ-9	Patient Health Questionnaire
PI	Principal Investigator
PTSD	Posttraumatic Stress Disorder
RCT	Randomized Controlled Trial
SCID-5-CT	Clinical Trials Version of the Structured Clinical Interview for DSM-5
VA	Veterans Affairs
VAHCS	Veterans Affairs Health Care System
VHA	Veterans Health Administration

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Protocol Title: Teaching Loved Ones to Help Veteran Optimize their PTSD Care and Healing (COACH)

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2.0 Introduction

PTSD is a prevalent and potentially debilitating condition associated with a host of negative, long-term consequences and functional impairment.[2,3,5,6,28] In response, the VA has made two EBPs widely available, PE and CPT. The evidence for the effectiveness of these therapies is

strong.[8] In randomized controlled trials, these and other trauma-focused EBPs yield large symptom improvements, and most patients recover or improve[29]. However, residual symptoms are common,[29] treatment response for military personnel lags behind other populations,[12] and dropout rates are high.[30] For example, among a large sample of post-9/11 veterans who initiated PE or CPT with a VA clinic over a 15-year period, 60% failed to complete an adequate dose of treatment.[30] PE and CPT are intensive treatments that require weekly, sustained attendance (10-12 weeks) and frequent, ideally daily, practice of the skills learned. In PE, this home practice is designed to break destructive habits of avoidance through repeated and sustained revisiting of traumatic memories (imaginal exposure) and approach of avoided activities in real life (*in vivo* exposure). Greater engagement in these activities predicts a two-fold increase in the odds of patients achieving good end state functioning and remission.[14] However, patient engagement in these activities can be poor.[13] Among HomeFront veterans who *completed* PE or CPT, only 38.7% finished most of their homework, and an important minority (20.3%) finished 25% or less of these assignments. Efforts to optimize the quality of veteran engagement in PE may hold promise as a pathway for maximizing the gains a given patient can reach.

Teaching family members to support and coach veterans through these difficult activities provides one innovative approach to increasing engagement. Our prior work shows intimate relationships play a critical role in influencing OIF veterans' treatment seeking[22] and that veterans themselves are highly motivated to involve their partners in their PTSD care.[21] Generally, family involved psychotherapies result in comparable or better outcomes than patient-only treatments for a number of mental health conditions.[31–33] Ongoing efforts to integrate family members into PTSD treatment fall into two categories: (1) novel couple therapies designed to treat both relationship strain and PTSD[34,35] and (2) brief family-engagement strategies that educate families early in treatment (Improving Veteran Adherence to Treatment for PTSD Through Partnering with Families; PI: Meis; An Adjunctive Family Intervention for Individual PTSD treatment; PI: Thompson-Hollands). Novel couple therapies demonstrate promise,[34,35] but their efficacy compared to EBPs for PTSD is not established. Brief family-engagement strategies for EBPs are under evaluation, including our own (Improving Veteran Adherence to Treatment for PTSD through Partnering with Families; Partner Enhanced PE; PE[2]; PI: Meis). These approaches aim to increase family support for treatment and decrease family behaviors that may undermine treatment in one to three family-member sessions.

For some, one to three sessions with a family member may be insufficient. Relationship strain predicts poorer response to PTSD treatment,[36,37] and HomeFront findings indicate family encouragement to confront distress may be less effective in strained relationships.[24] Ingrained and complex patterns of family interaction may stymie loved ones' (LOs') effectiveness in supporting veterans, and these patterns are difficult to adequately identify, challenge, and shape quickly. Lastly, the brief family-engagement strategies described end family members' session attendance before initiating imaginal exposure. This is when most of the difficult work of PE begins. Without weekly interaction, therapists cannot help couples manage unanticipated challenges like symptom exacerbation, interpersonal conflict, or partners' frustrations with the veterans' pace of change. We propose to adapt strategies from

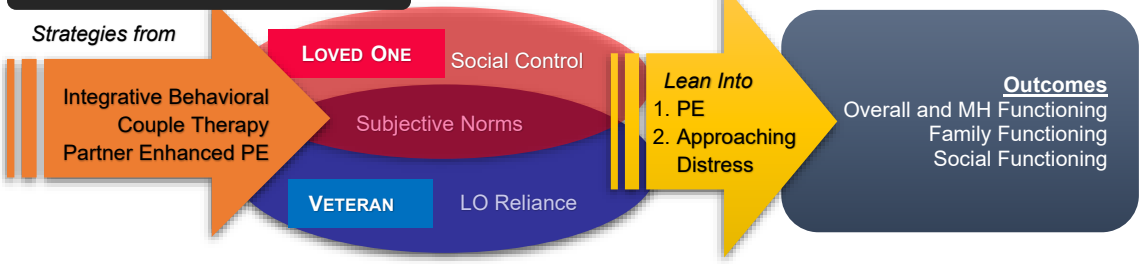
Integrative Behavioral Couples Therapy (ICBT),[38] an efficacious, evidence-based martial therapy intervention, to help couples support each other during this intensive therapy. The ICBT techniques we are adapting are most relevant to romantic couples and may look different for other veteran-LO relationships. If effective, we will explore how these approaches extend to other family constellations in future research.

2.1 Preliminary Studies.

Using strategies from ICBT and our ongoing trial (PE^2), we plan to target three mechanisms that we anticipate will help couples lean into PE: social control efforts, subjective norms supporting PE participation, and greater veteran reliance on LOs as supports during treatment (Figure 1). By altering these mechanisms, we anticipate veterans will complete at-home exercises with greater quantity and quality than they are likely to do alone and better embrace the PE philosophy of approaching trauma-related distress. This will yield optimal symptom reductions and a corresponding improvement in general mental health and overall functioning. Through tackling this treatment together using ICBT strategies, we also anticipate couples will grow in their communication skills and acceptance of each other, improving their overall relationship functioning. A healthier intimate relationship and optimized PTSD symptom response should translate into healthier overall family functioning. In follow-up HomeFront surveys, we found that greater reductions in PTSD symptoms from baseline to follow-up predicted greater improvements in veteran-child relationships (β = -.23, p = .019) and greater reductions in LO reported caregiver burden (β = .18, p = .004). Lastly, many standard *in vivo* exercises are designed to improve veterans' comfort in social situations (e.g., go to restaurants, family gatherings, concerts, the mall). Completing more of these exercises with greater skill may lead to greater comfort with and enthusiasm for social activities, improving social functioning.

Data from HomeFront support our proposed mechanisms. First, we found that veterans were more than twice as likely to complete an EBP when a LO encouraged them to confront distress.[24] This is a form of social control, which includes overt efforts by a LO to urge or

Figure 1. COACH Conceptual Model



encourage a person to change a targeted behavior.[39,40] Initial HomeFront findings examining treatment response found that, when veterans indicated their families supported PE/CPT participation (i.e., subjective norms), veterans reported lower symptom severity in follow-up surveys (β = -.16, p = .013, controlling for baseline PTSD symptoms). Additionally, when veterans relied more on their LOs for support during treatment through talking with them more about their mental health treatment (β = -.14, p = .002) and discussing their homework (β = -.13, p = .004), veterans reported lower follow-up PTSD symptom severity, controlling for baseline.

2.2 Significance.

The influence of a successful course of PTSD treatment on a veteran's life is considerable. In addition to reducing symptoms of PTSD and associated mental health problems (e.g., depression), successful PTSD treatment improves, reduces, and may even reverse the negative physical health effects associated with PTSD.[10,41] Family involvement has been highlighted as a fertile avenue for improving the outcomes for patients with PTSD.[7,27] Yet, despite congressional legislation and national mandates within VA/DoD for family involvement in PTSD care,[7,8,42,43] family inclusion in PE and CPT is infrequent (17% among HomeFront veterans). Concordant with the Behavioral Health & Social Reintegration Program, this proposal will support work on an intervention intended to promote higher rates of recovery from PTSD, better overall functioning, greater family functioning, and greater social functioning. These outcomes are consistent with those patients likely find meaningful.[27] Our stakeholder engagement strategies, described below, provide an additional pathway to ensuring COACH aligns with what LOs, providers, and VA leadership need in a family intervention for PTSD, building a more patient-centered approach to treating PTSD. Overall, this work is highly consistent with the explicit goals of the Behavioral Health & Social Reintegration Program to promote research that uses "family support as a means to reintegration" and leads veterans to "function more fully in society" and "embrace social situations".

3.0 Specific Aims

Posttraumatic stress disorder (PTSD) occurs in as many as 17% of US military veterans[1] and is associated with long-term functional impairment, poor quality of life, family problems, unemployment, and suicidality.[2–6] Evidence-based psychotherapies (EBPs) such as Prolonged Exposure (PE) and Cognitive Processing Therapy (CPT) result in clinically significant symptom relief for many,[7,8] improving physical health, social and work functioning, and quality of life.[9–11] Yet, **these therapies are less effective for military personnel and veterans**, with up to one-half of patients failing to achieve meaningful recovery.[12] Efforts to optimize veteran engagement in PE and CPT may hold promise as a pathway for maximizing gains. PE and CPT are intensive treatments requiring weekly, sustained attendance (10-12 weeks) and frequent, ideally daily, practice of the skills learned. Engagement in these activities can be highly variable.[13,14] Yet, they are an important predictor of treatment response.[13–18]

Partnering with veterans' significant others may provide a powerful method for helping veterans get more out of their PTSD treatment. Even with high rates of intimate relationship difficulties and divorce among veterans with PTSD,[19] many are (a) married or living with an intimate partner[20] and (b) interested in including their partners in their care.[21] Family members can help patients with PTSD initiate[22,23] and stay in mental health care.[24] Our team surveyed veterans initiating EBPs for PTSD and a family member across four VA medical centers (N = 598; Project HomeFront). We found that veterans were more than twice as likely to complete an EBP when a loved one encouraged them to confront distress[24] and that veterans experienced greater treatment gains when they share more with their loved ones about their treatment.

Creating a couple-therapy approach to exposure therapy provides an opportunity to mobilize the whole household in the service of EBP engagement, while providing an opportunity to further extend the goals of therapy beyond symptom reduction. Through integrating a loved one in PE, we can simultaneously address relationship functioning and family functioning. We could also improve social functioning through increasing the quality and quantity of participation 'in real life' (*in vivo*) exposure exercises by asking couples to confront avoided social situations together. **Our overall goal is to develop and pilot a couple-therapy approach to Prolonged Exposure that integrates loved ones into every session of PE.** We will combine techniques from Integrative Behavioral Couples Therapy and a brief, three-session approach to involving family in PE (Partner Enhanced Prolonged Exposure). We anticipate this intervention will teach couples to embrace a lifestyle that supports confronting trauma-related distress, so the veteran can achieve optimal functional recovery, while improving both social and family functioning. We will complete stages 1A and 1B of the Stage Model of Treatment Development.[25] This includes the following aims:

Aim 1: Expand our treatment outline using content experts and feedback from key **stakeholders** (veterans, loved ones, providers, and VA mental health leadership).

Aim 2: Conduct a pilot **open trial** to assess (a) the acceptability of treatment components, structure, and materials, (b) the feasibility of the intervention (retention and intervention fidelity), and (c) the study approach (screening, recruitment, and assessment process).

Aim 3: Explore the preliminary effects of the intervention on select outcomes including overall functioning, mental health functioning, social functioning, family functioning, and potential mechanisms (social control, subjective norms, and the degree to which veterans rely on their partners for support).

Impact: PTSD treatments (including PE and CPT) have been criticized for a narrow focus on symptom gains over goals that may be more meaningful to veterans, such as greater quality of life, interpersonal connections, and social functioning.[26,27] Our proposal aims to expand the explicit targets of PE to these patient-centered outcomes. If our approach to a couple-based exposure therapy demonstrates promise, this proposal could provide the first step in a series of studies that **feed the evolution of one-on-one symptom-focused psychotherapies into family-based interventions designed to lift the whole household**. Our approaches could inform adaptations to interventions for a myriad of problems including suicide prevention, TBI rehabilitation, and pain management, contributing to a broader evolution towards evidence-based, family-inclusive care focused on outcomes with meaning to veterans.

4.0 Resources and Personnel

4.1 Research Site

1. Center for Chronic Disease Outcomes Research, Minneapolis VA, Minneapolis, MN. Activities that take place include the following:
    a. Data extraction
    b. Recruitment, obtaining informed consent, and data collection, including interviews by trained staff, who are the study coordinator and study manager
    c. Intervention administration/delivery
    d. Data analysis

4.2 Principal Investigator.

Laura Meis, PhD, LP

a. Will have access to protected health information

b. Will be involved in recruiting subjects; obtaining informed consent; supervising and administering interview procedures/conduct of interviews, training and supervising providers in intervention delivery, and performing data analysis

4.3 Co-Investigators.

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    b. Will have access to protected health information
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4. Afsoon Eftekhari, PhD; Afsoon.eftekhari@va.gov, (650) 493-5000 ext. 22393, VA employee, Palo Alto VA
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4.4 Study Personnel.

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   b. Will be involved in recruiting subjects; obtaining informed consent; supervising and administering interviews and surveys, fidelity coding, data collection
   c. Will have access to protected health information
2. Ann Bangerter, BS; ann.bangerter@va.gov, 612-467-1384; VA employee Minneapolis VAHCS
   a. Role: programmer
   b. Will have access to protected health information
   c. Will not have contact with research participants
3. Emily Hagel Campbell, MS; emilyhagelcampbell.@va.gov, 612-725-2000 x7451; VA employee Minneapolis VAHCS
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   b. Will not have access to protected health information
   c. Will not have contact with research participants
   d. Will be involved in performing data analysis of de-identified quantitative data
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   a. Role: programmer
   b. Will have access to protected health information
   c. Will not have contact with research participants
5. Emily Campbell, MS; Emily.Campbell5@va.gov, 612-629-7381; VA employee Minneapolis VAHCS
   a. Role: Project Coordinator
   b. Will assist with recruiting subjects; obtaining informed consent; administering interviews and surveys, fidelity coding, data collection
   c. Will have access to protected health information
6. Camryn Kostick, BA, Camryn.Kostick@va.gov; (651) 325-7025; VA WOC, Minneapolis VAHCS
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   c. Will have access to protected health information
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   a. Role: Study assessor
   b. Will have access to protected health information
   c. Will have contact with study participants

5.0 Study Procedures

5.1 Study Design

First, we will expand the treatment outline for COACH (see Appendix 1) into an initial treatment manual through meetings with content experts and stakeholder feedback. Next, we will develop fidelity checklists and revise the treatment manual through a ”test run” with 2-3 couples. The resultant intervention will then be evaluated in an open trial with 12 veterans diagnosed with PTSD and their loved ones. During the course of the open trial, we will refine fidelity checklists and develop a provider training program. Using data obtained from the open trial, we will assess the intervention’s acceptability, feasibility,[44] mechanisms, and outcomes. Lastly, using clinical observations, participant feedback from qualitative exit interviews, and additional stakeholder feedback, we will make final edits to the manual, yielding a manual suitable for a future RCT (Stage II Manual).[25] Upon completion of this proposal, we will be well positioned to apply for Merit funding for a randomized controlled efficacy trial.[25]

5.2 Delivery by Telemedicine

We will recruit participants and offer to provide treatment within the study using telemedicine. The telemedicine option would use VA approved electronic communication methods (e.g., VA Video Connect, Webex, Teams) and information technology to provide the COACH therapy to patients by study clinicians. This option would greatly benefit participants. A telemedicine option is necessary during COVID-19. For the safety of both staff and patients, staff are teleworking. Because of this, a telemedicine option will allow Veterans to still participate in the study treatment during COVID-19 restrictions. Psychotherapy is currently widely available within VA by telemedicine to improve Veteran access to care. The major benefit of telemedicine is that it eliminates travel that may be unsafe or costly to patients. Allowing a telemental health option for PE therapy would ease these burdens by making services more accessible to patients, especially during the current COVID-19 directives.

Furthermore, many individuals in need of specialized PTSD services live in geographically remote regions. Additionally, individuals needing mental health services may have physical limitations or disabilities. Providing therapy to these individuals solely in medical centers can impose a tremendous financial, travel, or personal burden. Allowing a telemental health option for PE therapy will ease these burdens by making services more accessible to patients.

Our study site has robust telemedicine programs that provide PE by telemedicine. We will follow all procedures and regulations that are currently in place at their VA hospital and surrounding CBOCs to ensure services provided to Veterans are safe and accurate. Additionally, all practitioners treating patients using telemedicine will be qualified to deliver the level of consultation, care, and treatment involved. Lastly, if during the course of the study, it becomes safe to deliver the intervention in person, we will offer in-person delivery as well. Any in-person visits will follow the Minneapolis VA’s guidelines and Team L’s (trauma mental health clinic) procedures for providing in-person care safely.

5.2 Initial Treatment Manual.

5.2A. Intervention Overview. COACH is a flexible length loved one-assisted treatment for PTSD that draws from PE, ICBT, and PE^2. Sessions take place weekly and are 90 minutes

each. Treatment is typically between 13 and 15 sessions, but can be fewer or more based on patient need and symptom response. Consistent with IBCT, the treatment will take place in phases. The first phase focuses on gathering information from both the veteran and his/her loved one and creating a treatment frame that conceptualizes struggles in a fashion that is acceptable to both partners and that highlights ineffective change strategies. In COACH, this treatment frame also incorporates 1) the role of PTSD in disrupting relationships and intimacy, 2) the role of avoidance in maintaining PTSD and couple conflict, and 3) existing strengths or coping strategies that can be capitalized on in PE. In this way, the treatment frame serves as a contextualized and focused introduction to both key PE principles and key couples dynamics that will be challenged in treatment. In the 'active treatment' phase, sessions will focus on (1) reviewing *in vivo* exposure exercises completed at home, (2) shaping the couple's support for each other's efforts to practice a lifestyle of approach, and (3) imaginal exposure and emotional processing. The final session includes reflection on the therapy experience and building an action plan for continued work at home.

5.2B. Manual Expansion. In months 1-5, we will expand the treatment outline into an initial manual through weekly meetings with the investigator team (Meis, Erbes, Kehle-Forbes, Glynn, Eftekhari). Our team is comprised of content experts in delivering and implementing PE (Kehle-Forbes; Glynn' Eftekhari) and couple therapy (Meis, Glynn, Erbes). The team will review, discuss, and revise intervention materials for each treatment session, led by Dr. Meis. This work will generate key questions for the first stakeholder meetings described below.

5.2C. Stakeholder Feedback. To elicit feedback from the end users of COACH, we will employ a model of stakeholder engagement that Dr. Meis has adapted and implemented at the Minneapolis VA (Community Engagement Studios; CE Studios).[45] The model guides the structure and conduct of meetings between researchers and stakeholders to ensure the experience is successful, focused, and effective. Studios begin with a presentation from the PI that cumulates in two to three key questions (e.g., "How can we help veterans feel more comfortable reaching out to their spouses for support when PE feels hard?"). Presentations will be prepared in consultation with a veteran moderator to maximize the clarity and focus of the presentation with the stakeholder audience in mind. Notes are taken during the meeting, reviewed immediately following the meeting, and later summarized. Summaries will be distributed to investigators and stakeholders. Feedback will be used by the investigator team to identify issues with the intervention to resolve or expand upon.

5.2D. Identifying Stakeholders. Our key stakeholders include patients (veterans), LOs, providers, and leadership. Veteran and LO groups will meet separately to optimize the depth of feedback received from these two groups.[46,47] Dr. Meis is currently leading CCDOR's efforts to create a standing panel of veterans with lived-experience with PTSD to consult with researchers at the Minneapolis VA. We will work with this group of veterans to obtain stakeholder feedback. In months 1-3, using CCDOR's established stakeholder recruitment processes, including posting fliers at strategic Minneapolis VA locations, snowball sampling through existing stakeholder panel members, and distributing fliers through social media and local relevant advocacy groups and non-profit organizations. Veteran and LO stakeholders will be compensated $100 for each meeting.

Provider stakeholders will include Minneapolis VA providers who deliver marital and family therapy (n = 3-4) or PE (n = 3-4). Dr. Meis will reach out by email to PE and family therapy providers at the Minneapolis VA. Dr. Meis has used similar strategies to recruit providers for focus groups, qualitative interviews, and to serve as study therapists for her ongoing PE[2] trial. Leadership stakeholders will include the coordinator of the PTSD clinical team (Kaler), director of the family therapy training clinic (Chuick), and the chief of psychology (Leskla). Provider and leadership interviews will take place in smaller groups and in one-on-one meetings, as schedules allow. These interviews will include a discussion of provider training needs and challenges to conducting COACH in a VA setting (e.g., “Are there pre-existing skillsets providers need to be successful delivering this treatment?”, “How can we address challenges with scheduling sessions given providers have limited openings and couples have limited availability?”).

5.2E. Manual Refinement. For any psychosocial intervention, critical insight is gained through actual delivery of the treatment. we will conduct a “test run” of the treatment manual with 2-3 cases. Early experience with these test cases will help identify sections of the treatment manual that prove difficult to implement or are unclear. The PI (Meis) and study Co-Investigator (Erbes) will serve as the study providers. Of note, while Dr. Meis is a licensed psychologist, she is a Research Service employee and does not currently have Minneapolis VA privileges. She will treat cases under this IRB protocol and under the supervision of a privileged VA provider. After completing each of the sessions, Drs. Meis and Erbes will compose a memo for the larger team that identifies (1) what went well and why, (2) what proved more challenging and why, and (3) time stamps from session recordings that correspond to these observations. Memoranda will be sent out to the team of investigators in advance and discussed in weekly intervention refinement meetings. The team will brainstorm solutions to problems and identify expansions needed to the manual to capture clinical observations. This work will generate the key questions for veteran and LO stakeholder meetings. These meetings will focus on problems with implementing ideas within the manual (e.g., “How can we help couples do a given at-home exercise more effectively?”). The study PI will draft manual revisions and distribute revisions to the team to review. During this time, Dr. Glynn will also draft initial fidelity checklists, which will be reviewed and refined in team meetings.

5.3 Open Trial.

5.3A. Sample Identification & Recruitment. Participants will be ten veterans with PTSD at the Minneapolis VA and their loved ones. Although the Stage Model of Treatment Development does not recommend a sample size for stage 1B activities, published accounts of psychotherapy treatment development frequently report on samples of ten to twelve participants.[48–51] Veterans must meet full criteria for PTSD on the CAPS-5[52] and have been in an intimate relationship for the last six months. Both members of the couple must be willing to participate together in therapy and deny any episodes of severe relationship violence in the past year. We will exclude veterans who are typically excluded from trauma-focused treatment due to counter-indications, including severe substance use, uncontrolled psychosis or mania, and

active suicidal or homicidal ideation, which should be the focus of clinical attention. Lastly, we will exclude dyads in which the loved one also screens positive for PTSD.

Clinic referrals, announcements to veteran groups, and strategically placed study fliers in appropriate clinic locations will provide our first-line recruitment source. We are proposing to enroll one couple per month over 10 months (months 9-18). Using similar inclusion/exclusion criteria and strategies in PE^2, our team has received 72 referrals over the past 10 months and randomized 18 dyads at the Minneapolis VA. Eleven of these cases have been in intimate relationships (M = 1.10 per month). Of note, we are proposing to start recruitment for COACH after PE^2 recruitment efforts are planned to end.

Veterans identified through the above-mentioned means will be sent a brochure describing the study and a cover letter, informing them they will be contacted and how to decline participation. They will then be contacted by telephone by a trained interviewer to discuss the study, for consent, and for initial screening including an assessment of the status of their intimate relationship. With permission, their loved one will be recruited and consented by telephone. Veterans remaining eligible (i.e., partner agrees to participate, denies intimate partner violence (IPV), and screens negative for PTSD) will be scheduled for a diagnostic interview (Clinician-Administered PTSD Scale for DSM-5, CAPS-5[52]; Clinical Trials Version of the Structured Clinical Interview for DSM-5, SCID-5-CT).[53] Diagnostic interviews will be conducted by a study staff member with a master's degree in clinical or counseling psychology under the supervision of a licensed clinical psychologist from the study team. To ensure our sample is representative of those receiving PE, we will enroll at least three women and three OEF/OIF Veterans. To ease anticipated barriers to couples attending therapy sessions, we will offer compensation for costs for childcare and travel and offer participation through telemedicine.

5.4 Limitations and Design Considerations.

Due to the open trial design, we will be unable to evaluate COACH next to a comparator condition. However, others have cautioned against using pilot studies to inferentially compare interventions as small sample sizes lead to imprecise effect size estimates.[44] A design with a comparator would offer the opportunity to evaluate the feasibility and acceptability of a comparator arm in preparation for a RCT. However, this would require reducing the sample size for the COACH-arm or an infeasible sample size for both arms. A second limitation is the pre-post treatment design. A longer follow-up may increase the chances of detecting improvements in functional outcomes. However, a longer-term follow-up would come at the expense of sample size, reducing the feedback we will obtain from delivering COACH with more couples. It is important to note that our approach to family inclusion could also prove viable for CPT. We elected to start with PE as veterans may find it more challenging, given some evidence drop out may be worse for PE than CPT.[65] Additionally, Cognitive Behavioral Conjoint Therapy, one of the novel couple therapies described above,[34] incorporates many of the cognitive restructuring strategies of CPT. Consequently, we perceive a greater need for couple adaptation for PE. Lastly, whenever one seeks to add a family member to the process of mental health care, one adds a layer of challenges. For example, for every one individual interested in treatment, you must identify, recruit, and schedule two individuals. The second individual may be less interested or pose any myriad of additional challenges. Our team is prepared to manage these

complications. Team members include VA central leadership in implementing family therapies (Glynn) and investigators with long histories of navigating these challenges (Meis, Erbes, Glynn). We also have first-hand experience with the potential for transformative change when you extend the therapy circle beyond the patient to mobilize her most important LOs in the act of change. This is the very spirit of the high risk-high reward research for which this funding mechanism is designed.

5.5 Project Management.

Study activities are detailed in Table 2. Dr. Meis will be responsible for the overall conduct and integrity of the project, facilitating stakeholder meetings, writing and implementing revisions to the provider manual, delivering the intervention, and qualitative and quantitative analysis. Dr. Erbes will lead efforts to develop the provider training program, deliver the intervention, assist with quantitative data analysis, and provide expertise in ICBT. Dr. Glynn will lead efforts to develop the fidelity rating instrument and provide expertise in implementing family therapy in VA. Dr. Kehle-Forbes will provide oversight for qualitative data collection and analysis and provide clinical and academic expertise in PE. All investigators will participate in intervention development and refinement, data interpretation, and dissemination. Our team is well-positioned to take on this effort. Team members have served as PI, Site PI, or Co-I for 13 different ongoing or completed randomized controlled trials of behavioral interventions for patients with mental health conditions and their families, including 11 multisite trials. This includes enrolling and randomizing over 1300 participants.

Table 2. Timeline of Major Tasks

Activity / Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Recruit LO stakeholders	X	X	X																					
Initial treatment manual	X	X	X	X	X																			
Stakeholder meetings				X			X									X							X	
Test cases						X	X	X																
Refine treatment manual						X	X	X																
Recruitment								X	X	X	X	X	X	X	X	X	X	X						
Open trial enrollment									1	2	3	4	5	6	7	8	9	10						
Treatment delivery									X	X	X	X	X	X	X	X	X	X	X	X	X			
Posttreatment assessments												X	X	X	X	X	X	X	X	X	X			
Qualitative analyses													X	X	X	X	X	X	X	X	X	X		
Quantitative analysis																					X	X		
Finalize stage II manual																			X	X	X	X	X	X

Table 1. Abbreviated Measures (see Materials document for exhaustive list of measures and items)

Domain	Reporter V	Reporter LO	Source S	Source I	Source A	Measure
Acceptability						
Treatment Structure	X	X	X	X		CES[56]; CSQ-8[57]
Materials	X	X		X		N/A
Feasibility						
Treatment Retention	X	X		X	X	N/A

Treatment Fidelity					X	Fidelity instrument[b]
Screening Approach					X	N/A
Recruitment Approach					X	N/A
Assessment Process	X	X	X	X		All survey measures
Outcomes: Functioning						
Overall functioning	X	X	X			Short Form Survey[58]
MH functioning	X	X	X	X		CAPS[52], PCL-5[59];PHQ-9;[60]
Self-care functioning	X	X	X			IPF[55]
Family functioning	X	X	X			IPF[55]
Romantic functioning	X	X	X			IPF[55]
Communication	X	X	X			Prepare/Enrich[61]
Conflict Resolution	X	X	X			Prepare/Enrich[61]
Parenting	X	X	X			IPF[55]
Social functioning	X	X	X			IPF[55]
Outcomes: *Mechanisms*						
Session Attendance					X	N/A
HW Compliance					X	PEAS[62]
Social control	X	X	X			Emotional and Problematic Support[63]
Subjective Norms	X	X	X			Subjective Norms-PTSD[a]
LO Reliance	X	X	X			Treatment Discussions[a]

[a]Unpublished scale from Project HomeFront.[b]Developed during the study
V = Veteran; LO = Loved One; A = Administrative data; S = Survey; I = Interview.

5.6A. Risk to Subjects

A.1. Human Subjects Involvement and Characteristics

We aim to enroll 12 Veterans with PTSD at the Minneapolis VA and their loved ones. Veterans must (1) meet full criteria for PTSD on the CAPS[52] and (2) have been in an intimate relationship for the last six months. Both members of the couple must be (3) willing to participate together in therapy, and (4) deny any episodes of severe relationship violence in the past year. We will exclude veterans who are typically excluded from trauma-focused treatment due to counter-indications, including (1) severe substance use, (2) uncontrolled psychosis or mania, and (3) active suicidal or homicidal ideation, which should be the focus of clinical attention. Lastly, (4) we will exclude dyads in which the loved one also screens positive for PTSD. See below for exhaustive list of inclusions/exclusions.

A.2. Data Sources

Data sources will include surveys, semi-structured qualitative interviews, and administrative data. Veterans and their LOs will complete surveys prior to treatment (baseline), during treatment, after their final COACH session, and 3-months after their final COACH session. Those who do not attend their final session will receive their survey by mail or email (Qualtrics link) using CCDOR's modified-Dillman protocol.[54]

Veterans will also complete a posttreatment structured clinical interview for PTSD symptoms.[52] Veterans and LOs will also complete 90-minute semi-structured qualitative exit interviews. All interviews will be conducted in person or by phone, based on the interviewee's preference, and will be audio-recorded. Qualitative exit interviews (Appendix 2) will assess (1) attitudes about intervention components, structure (e.g., level of therapist contact), and materials (e.g.,

handouts), (2) acceptability and efficacy of COACH, including suggestions for intervention improvement, (3) engagement with COACH, including retention and barriers/facilitators to

engaging with the program, (4) perceptions of the impact of the program on the intervention targets (e.g., functioning, social control, subjective norms, and LO reliance) and exploration of unexpected domains impacted by the program, and (5) the completeness and time burden of the survey battery. We will also extract the following administrative data: (1) the number of sessions attended (from electronic medical record; retention), (2) the number of participants screened each month (screening), and (3) the number of eligible Veterans and LOs who declined participation (recruitment), and therapists ratings of homework compliance using two

items adapted from the Patient Exposure and Response Prevention Adherence Scale (PEAS) for Obsessive Compulsive Disorder (also a cognitive-behavioral exposure therapy).[62]

Table A. Data Sources				
Reporter	Baseline	During Treatment	Posttreatment	3-month follow-up
Veteran	Structured Interview Online survey measures	Surveys assessing symptoms, weekly questions in preparation for therapy sessions for therapists, and treatment mechanisms	Structured Interview Online survey measures Qualitative Interview	Online measures
LO	Online survey measures	Surveys assessing symptoms, weekly questions in preparation for therapy sessions for therapists, and treatment mechanisms	Online survey measures Qualitative Interview	Online measures

A.3. Potential Risks

This study involves minimal risk. COACH is a flexible length cognitive-behavioral, loved one-assisted, treatment for PTSD that draws from PE, ICBT, and PE^2. Treatment is typically between 13 and 15 sessions, but can be fewer or more based on patient need and symptom response. There are no anticipated physical risks in this study. Economic risks include potential loss of wages when traveling to and participating in the research intervention. The questionnaires ask questions consistent with those included in routine clinical care, and participants can refuse to answer any question(s). Individuals may experience some psychological or social discomfort during the course of the study; however, the intervention is likely to increase their well-being. Additionally, the risks are no greater than those encountered in routine clinical care.

5.6B. Protection Against Risk

B.1. Social and Psychological

Appropriate safeguards will be in place if screening interviews, assessments, interviews, or therapy sessions cause any psychological distress, a psychiatric emergency emerges among participants, or severe interpersonal violence (SIV) is reported. Severe violence will be defined as one or more episodes of severe violence in the past year (e.g., beating up, threatening with a knife or gun). The PI has expertise in assessing and managing risk for SIV, including within a clinical trial, and will closely train and supervise study staff in assessing and managing risk for SIV.

All surveys will be screened upon receipt by study staff. If a psychiatric emergency is reported on surveys (i.e., expression of risk for suicide or homicide), veterans MH providers will be notified. MH providers will follow-up as they deem clinically indicated. If the participant does not

have a MH provider or this provider cannot be reached, the site PI, or in case of her unavailability, a Co-I will contact the disclosing participant by phone, assess for risk and safety, and provide the participant with appropriate referrals. We will utilize access to local and national mental health resources available through the VA, including the suicide prevention hotline, risk assessments through Mental Health during regular business hours (Psychiatry Urgent Care), or the facility's Emergency Room during off hours. In the unusual event of an on-site psychiatric emergency involving a participant who is not a Veteran, including threats of or acute risk for SIV, the participant will be triaged within VA facilities. If indicated based on psychiatric evaluation, non-Veterans will be transferred for appropriate care in community. Once stabilized, they will be eligible to enter or re-enter the study.

All staff with contact with study participants will be trained on how to recognize, assess, and intervene, in a manner appropriate to their training backgrounds, in the case of a psychiatric emergency. They will be trained and supervised by an on-site licensed clinical psychologist and study team member (Co-I or PI).

If IPV is directly reported to a study staff member (e.g., during a screening call), the study staff member will (1) ensure the participant is speaking privately (e.g., if disclosed by phone), (2) ask if the participant currently feels safe, (3) offer immediate assistance (i.e., warm transfer to the national domestic violence hotline or contact the police), (4) offer to have a MH provider from the study reach out, and (5) offer local and national resources for IPV.

MH providers on the study will receive training on how to assess and intervene when IPV is reported. This includes training on assessing IPV severity and intervening on IPV, including safety plans, no aggression contracts, and time out procedures. When IPV is reported to a study MH Provider, they will discuss it privately with the reporter and intervene as clinically indicated, keeping the safety of the reporter of paramount concern. Providers will not breech the reporter's confidentiality unless they have the reporter's verbal permission or are concerned they must do so to prevent imminent harm.

All potential collaborators and study therapists on these research activities will have completed comprehensive training in the areas of research ethics, protection of human subjects, and suicide prevention. They will also have completed all VA required trainings pertinent to cyber security, VHA privacy policy (HIPAA), research data security and privacy, ethical principles of human subjects' protection, good clinical practice, and suicide prevention. In addition, Dr. Meis's graduate coursework included a three-credit course on ethics.

IPV reports on surveys. Surveys ask about intimate partner violence (IPV). IPV reports are not routinely considered psychiatric emergencies that warrant breaching participants' confidentiality. Additionally, reaching out to all those who endorse IPV may have unintended negative consequences. Reaching out when uninvited to ask IPV victims to further discuss their IPV may be distressing and bring up traumatic memories. The outreach may be unwelcome, perceived as intrusive, and discourage future reporting. Discussing violence over the phone may also place the victim at risk to be overheard by the abuser, other loved ones, or children in the home. Consequently, a list of resources will be provided to participants, including for IPV. Correspondence accompanying surveys will encourage respondents to contact study staff if they would like to discuss any of their survey responses. We will rely on participants to contact study staff if they wish to discuss their IPV experiences further. If participants are excluded due

to IPV, the staff member notifying the reporter of their exclusion will offer local and national resources for IPV.

Managing risk from CBOCs and in-home video telehealth sessions. Due to the nature and distance between the Veteran and telemental health provider incurred in telemedicine practice, additional measures will be taken to ensure patient safety. These procedures will be in place during all telemedicine sessions:

a. Study providers will follow the guidelines detailed in the 2017 Department of Veteran Affairs National Telemental Health Supplement and the 2012 Telemental Health Suicide Prevention and Emergency Care manual.
b. All study providers will follow the Minneapolis VA's local telemental health policies and emergency procedures at each facility and clinic.
c. Telemental health provider will have detailed contact information from the patient with particular attention to who could be contacted in the event of an emergency. All emergency contact information, local police phone numbers and local emergency room contact information should be readily retrievable during all sessions.
d. Providers will use the National Telehealth Help Desk when necessary: 1-866-651-3180.

Additional manners to manage risk from CBOCs.

a. For all telemental health sessions at CBOC locations, a CBOC staff person will be available to assist Veteran should the need arise.
b. CBOC staff will be available by telephone for the remote telemedicine study provider should they need to emergently contact an on-site VA staff.
c. If a patient becomes suicidal, homicidal, psychotic, or agitated, the Telehealth provider will ask for assistance from the CBOC staff who would help in deescalating the patient and/or initiating commitment.

Additionally, the study will abide by the requirements contained in the VHA Handbook for the credentialing of VHA practitioners who provide clinical services using telemedicine. All practitioners treating patients using telemedicine will be qualified to deliver the level of consultation, care, and treatment involved.

B.2. Economic:

Participants may choose to take time off work or may incur transportation costs because of participating in this study. Every effort will be taken to schedule assessments and therapy sessions at times convenient to participants to minimize loss of wages.

B.3. Loss of Confidentiality

DATA SECURITY. All data will be stored on the servers of the Center for Chronic Diseases Outcomes Research (CCDOR) at the Minneapolis VAHCS. CCDOR has well-established procedures to protect the privacy of research participants. Names, social security numbers, and contact information will not appear on any study materials. Instead, only unique study identification numbers randomly assigned to each unique record will be used. Only lead investigators, project coordinators, and study programmers (when extracting data to obtain treatment adherence and compare survey responders to non-responders for the survey) will have access to an encrypted crosswalk table linking study identification numbers to identifying information. The CCDOR Statistical and Data Management (SDM) team, in partnership with IRM staff, maintain several secure servers, access to which is granted only to SDM members who have been screened and assigned appropriate security clearance to work with patient data.

One common-access server contains individual project data. Access to individual project data on this server is granted only to project staff by an SDM team member, as authorized by the study investigator. Identifiers will be destroyed as quickly as possible. Audio and video recordings will be stored digitally on CCDOR servers and only accessible to the principal investigator and project coordinator. Participants will be asked not to use last names or provide identifying information during recorded interviews.

CONFIDENTIALITY. For all projects, strict confidentiality procedures will be maintained to minimize the potential risk of loss of confidentiality. Participant privacy will be further assured by conducting interviews in a private office and by assigning arbitrary identifiers in place of individual names in the field notes. Data analysis, interpretation, and reporting will be based on these de-identified field notes and transcriptions. Since subject responses will not be linked to identifying information, participant confidentiality will be assured. The time commitment will be explained to all participants prior to their participation in the study. Every effort will be made to minimize the length of time and maximize the convenience of the interviews. Participants will be assured that participation is completely voluntary and that they have the right to stop participation, decline answering any questions, or change the course of the interviews for any reason, including potential feelings of discomfort.

5.6C. Potential Benefits of the Proposed Research to the Subject and Others

Participants will receive $40 for participating in Baseline surveys, $50 for baseline diagnostic interviews (Veterans only), $60 for posttreatment surveys, $60 for posttreatment diagnostic interviews (Veterans only), and $60 for one-time qualitative exit interviews. Both veterans and intimate partners will complete monthly surveys for outcomes and treatment mechanisms. They will receive $25 for each of these surveys. Additionally, participants receive $70 for completing a 3-month follow-up survey. A possible total of $415 for veterans and $305 for loved ones.

5.6D. Importance of Knowledge to be Gained

The influence of a successful course of PTSD treatment on a Veteran's life is considerable. In addition to reducing symptoms of PTSD and associated mental health problems (e.g., depression), successful PTSD treatment improves reduces, and may even reverse, the negative physical health effects associated with PTSD.[10,41] Family involvement has been highlighted as a fertile avenue for improving the outcomes for patients with PTSD.[7,27] Yet, despite congressional legislation and national mandates within VA/DoD for family involvement in PTSD care,[7,8,42,43] family inclusion in PE and CPT is infrequent (17% among HomeFront veterans). Concordant with the Behavioral Health & Social Reintegration Program, this proposal will support work an intervention intended to promote higher rates of recovery from PTSD, better overall functioning, greater family functioning, and greater social functioning. These outcomes are consistent with those patients likely find meaningful.[27] Our stakeholder engagement strategies, described below, provide an additional pathway to ensuring COACH aligns with what LOs, providers, and VA leadership need in a family intervention for PTSD, building a more patient-centered approach to treating PTSD. Overall, this work is highly is consistent with the explicit goals of the Behavioral Health & Social Reintegration Program to promote research that uses "family support as a means to reintegration" and leads veterans to "function more fully in society" and "embrace social situations".

5.6E. Data and Safety Monitoring Plan

This project will operate under the oversight of the Minneapolis VA Health Care System's IRB for Protection of Human Subjects. The IRB reviews research projects which involve human subjects to ensure that two broad standards are upheld: first, that subjects are not placed at undue risk; second, that they give uncoerced, informed consent to their participation. After initial review, each approved project is re-evaluated annually. The Minneapolis VA Health Care System's IRB works with investigators to modify projects to ensure adequate protection for its subjects' welfare and right of self-determination. VA regulations require that all investigators and individuals who work on the study undergo comprehensive training annually in research integrity and protection of human subjects.

E.1. Privacy Protections:

CCDOR protects data collected for the purpose of conducting research projects at a level higher than that provided for clinical encounters. We use "stand-alone," secure data servers that are accessible only to designated, security-cleared, and trained personnel and data are de-identified as quickly as is feasible. Details about CCDOR's specific data privacy assurance procedures to be employed for this study are provided below.

E.2. Maintaining Secure Servers:

CCDOR maintains three secure computer servers that are protected under the Minneapolis VA Windows 2000 network. All individuals with administrative access privileges to CCDOR's servers, including IRM personnel and the CCDOR Statistical & Data Management Team, have been screened and assigned a security clearance putting them in trusted positions of the hospital with clearances to work with patient level data. These individuals and their access to the CCDOR servers is ultimately monitored and controlled by Sean Nugent, Senior Program Analyst for the CCDOR Statistical & Data Management Team. IRM's access to the data is strictly limited to backing up server data, which prevents catastrophic loss of data. Backups are written to tapes that are stored in a secure location accessible only to IRM personnel. CCDOR's Statistical & Data Management Team members maintain permissions, data storage, and all server applications.

ORGANIZATION AND ACCESS TO RESEARCH DATA: With the exception of one server, named the "CCDOR Server," only the CCDOR Statistical & Data Management Team has access to remaining Center servers. Data on the "CCDOR Server" are organized by projects within folders designated by each investigator. Only members of a given project have access to a specific project folder on the "CCDOR Server." Even then, access to project data is obtained through Windows authentication (i.e., user's name and password to the network). It is virtually impossible for any person without a login name and password to the VA hospital's domain network to access data on the Center's servers. Thus, all data housed on the "CCDOR Server" are extremely secure, and access by unauthorized persons highly unlikely. Data containing patient identifying information are not stored on the CCDOR Server but are stored on the servers accessible only to CCDOR Statistical & Data Management Team members who are directly involved in the project. Thus, not even the PI can link individual names to their PHI without first obtaining permission to do so from the Statistical & Data Management Team. These protections exceed the usual protections provided PHI by the VA system.

SECURING CONFIDENTIAL RESEARCH DATA: Data collected for individual Center projects are often obtained through primary (e.g., surveys) or secondary (e.g., VISTA and Austin databases) sources. All extractions of secondary data collection are stored on servers accessible to the CCDOR Statistical & Data Management Team only. Secondary data used for a study are de-identified according to HIPAA criteria and provided a random study identification number. A crosswalk table is created linking the study id with the primary key of the secondary data source. These data are only accessible to those employees of the Statistical & Data Management Team who have undergone the necessary security background checks, received appropriate security clearances, and are an integral part of an IRB-approved study. Primary data that involves surveys contain only the coded study identification number to identify study participants. The paper version of these forms/surveys is kept in locked cabinets within a locked room. Data from these surveys/forms are scanned or data entered by project staff or CCDOR Statistical & Data Management Team members to a secure folder. This secure folder is on a server accessible only to the CCDOR Statistical & Data Management Team members directly involved in the study. This protects the integrity of the data as well as its confidentiality. Primary data collection involving direct data entry is performed through a custom application written by a CCDOR Statistical & Data Management Team programmer. This ensures that data is in a secure environment and accessible to only those individuals with permission to access the data. Only individuals with a need to access the data, as vetted by the project's Principal Investigator are granted access. Even then, only the absolute minimum number of data elements is released.

E.3. Data Used for Analysis:

For all projects conducted in CCDOR, the final data is constructed in Statistical Analysis Software (SAS) data sets. Analyses are mostly conducted by statisticians assigned to the project or by other members of the project (e.g. Principal Investigators). All data collected are stored in individualized SAS data sets pertaining to the specific type of analyses to be performed. These SAS data sets will be de-identified according to HIPAA criteria, using only subjects' coded identification number as the primary key. The de-identified data set will be made accessible to those project members who are conducting analyses. Only the data elements required for the analysis under consideration are released. In summary, a separate workspace on a server accessible only to project Statistical & Data Management Team members will be created to work with administrative data. Any of the administrative data containing patient level data will be encrypted when not being used by a project programmer. All patient-identifying information will be removed from the administrative records. Upon completion of all study data, de-identified analysis data sets will be created in SAS that will use the subjects' coded study identification numbers as the only key.

E.4. Transcriptions

We will use Keystrokes Transcription services to obtain transcriptions of patient recorded interviews. Recorded individual patient interviews will be identified only by a coded facility identification number. Interviews will be conducted by telephone and will be recorded directly to a password protected project file on a center server. Recordings will be transferred using a secure portal (Reflection FTP Client) to the identified transcription company (Keystrokes). Once recordings have been transcribed, the recordings will be deleted by the transcription company.

For all projects conducted in CCDOR, the final quantitative data is constructed in Statistical Analysis Software (SAS) data sets. Qualitative data includes audio recordings of interviews that are transcribed and then stripped of all identifiers. De-identified transcripts are then coded by study staff and/or uploaded into qualitative analysis software (NVIVO). Quantitative analyses are mostly conducted by statisticians assigned to the project or by other members of the project (e.g. Principal Investigator or Project Manager). Qualitative analyses are conducted by study investigators with qualitative expertise. All data sets and qualitative transcripts will be de-identified according to HIPAA criteria, using only subjects' coded identification number as the primary key. The de-identified data set will be made accessible to those project members who are conducting analyses. Only the data elements required for the analysis under consideration are released.

5.6F. Inclusion of Women and Minorities.

Women and minorities will be represented in our study sample. Any patient who enters the Minneapolis, Ann Arbor, or Atlanta outpatient PCT clinics during the study period and meets inclusion criteria will be eligible for participation regardless of gender or race.

5.6G. Inclusion of Children.

All study subjects are expected to be 18 years of age or older.

5.7 Recruitment Methods

5.7A. Study Setting

The study will be based in the Center for Chronic Disease Outcomes Research (CCDOR). All data collection will take place at the Minneapolis VAHCS.

5.7B. Recruitment Training

Given the importance of recruitment to the success of any study, staff will be trained in established best-methods for recruiting for behavioral intervention trials (e.g., Leonard, Lester, Rotheram-Borus, Mattes, Gwadz, & Ferns, 2003). Staff will know how to handle difficult situations while maintaining boundaries, establish and maintain rapport while not antagonizing or alienating participants, and handling reports of IPV or other risk issues. Regular recruitment supervision meetings will occur. Given the importance of establishing rapport to successful participant recruitment[107] and plans for careful training and supervision, staff will be trained in the use of scripts as guides to avoid impersonal or alienating recitation of scripts. Reading scripts verbatim may interfere with establishing rapport, adaptive social norms that promote asking questions, and a safe environment for individuals share when they do not understand or have concerns about the study. See Study Materials for example scripts.

5.7C. Referral Sources.

We will rely on three methods of identifying potentially eligible Veterans: 1) provider referral, 2) self-referral, and 3) identification from hospital records.

Provider Referral. Provider referral will provide our first-line recruitment source, as this will mirror how the intervention is delivered in typical clinic care. We will make announcements about the study in multiple settings and forums (e.g., announcements at team meetings, presentations at grand rounds). We will provide flyers and brochures to providers and discuss the study with them to inform them about the study. As providers and patients/significant others (e.g., caregivers) may prefer to discuss the study together, prior to referring the patient/caregiver to our team, fliers and brochures with assist in these efforts. Providers may or may not choose to discuss the study with the Veteran or caregiver first. We will then receive contact information for potentially eligible participant (i.e., veterans interested in PTSD care or trauma-focused treatments; caregivers of with trauma-related mental health concerns) by (1) providers or by (2) team-leads in specialty clinics notifying study staff as patients are referred for evidence based PTSD treatment. Study staff will be provided with the potential participant's contact information through secure email, verbally, or through a cosigned CPRS note that an individual is interested in trauma-focused care (with subsequent communication verbally or through secure messaging).

Self-Referral. To facilitate self-referral, we will use study fliers and brochures strategically placed in appropriate clinic locations and make announcements to inform others about the study. We will also distribute fliers and brochures, make announcements, and provide presentations to community organizations to facilitate self-referral. Individuals who are self-referred to the study will reach out to study staff to express their interest directly. We will also distribute study fliers and brochures through social media groups and listservs (e.g., Facebook groups for veterans, emails to community groups). If potentially interested participants reach out to us via email, we will respond back thanking them for their email and interest in the study and asking them to talk by phone to protect their privacy. Distributing advertisements through social media and electronically is especially important given the ongoing pandemic.

Identification from Hospital Records. If approaches self and provider referral prove insufficient to reach recruitment goals, we will identify potentially eligible Veterans who have a diagnosis of PTSD through an administrative data pull and recruit these Veterans through the mail and telephone, using the same methods employed for provider referral participants.

5.7D. Recruitment Processes

Provider Referral.

Referral sources (e.g. providers) can talk about the study with their patients, their significant others/caregivers and provide them with a study brochure detailing the project. During this time, providers will ask if the individual is interested in being contacted about a research study for PTSD. This will give the individual an opt out option. If the individual responds "no", clinic staff will not contact study staff members. If the individual responds "yes" and would like to be called regarding a research study, the provider/staff will notify study staff. When a provider or off-team staff member refers an individual who has expressed an interested in being called regarding a research study, study staff will mail the individual information about the study and call the individual as soon as possible to give them information about the study.. This eliminates a delay in getting couples into care and follows the current clinic mandates regarding minimum

wait times for evidence-based treatment for PTSD. Off-team individuals will not make any efforts to recruit the individual and will refer the individual to study staff with any questions.

Alternatively, individuals' who have not been asked if study staff can contact them will be sent a letter in the mail and brochure about the study, informing them they will be contacted and how to decline study recruitment efforts. In this case, staff will attempt to reach the individual 7 days after the letter is sent.

Prior to initiating contact with the individual, study staff will review the veteran's hospital records to determine the presence of any study exclusionary criteria (e.g., the patient is currently hospitalized for a psychiatric emergency or reporting active psychotic symptoms).

Individuals will then be contacted by telephone by a trained interviewer to discuss the study and for initial screening. We will make up to 3 calls a week for 3 weeks, unless the individual declines recruitment or requests an alternative schedule (e.g., if he/she asks us to call more often to try to catch them at a time when they aren't busy or are somewhere in private). We will leave up to one message per week, unless the individual requests no voicemails or requests an alternative schedule. See Materials for an example voicemail script.

Upon contact with the individual, with their permission, a trained interviewer will then discuss the study and complete an initial screening, including for the presence of a significant other with whom they have been in a relationship with for at least 6 months, willingness to include the LO in treatment, presence of moderate intimate partner violence (SF CTS-2), and (for veterans) the presence of symptoms of PTSD on the PC-PTSD-5 (see inclusion/exclusion criteria for further detail).

The study procedures (assessment data gathering, intervention, session recording) and study design (including the nature of randomization to condition) will be fully described to the participant at the time of the initial contact (and again at the time that consent is documented). See script for initial screening call in Materials. For interested and eligible individuals, we will begin recruitment efforts for their significant other and begin or schedule the over-the-phone informed consent meeting with the significant other to complete enrollment.

For individuals who have expressed interest in the study (i.e., study staff spoke with them over the phone, completed screener, and/or completed informed consent), if at any time during the recruitment process study staff are unable to reach them, we will send them one final letter. The letter will inform the participant that we have been unable to reach them and that without contact within 2 weeks, we will have to close their case from our study records. The letter informs the individuals that we will no longer attempt to contact them and gives them the opportunity to reach out to study staff if they still have interest in participation in the study.

<u>Self-referral and Referral through Identification from Hospital Records</u>.
Procedures will follow the same general process as above with a few exceptions. For self-referrals, these individuals will be contacting study staff first, so we will immediately initiate

efforts to return their calls while also sending them an introductory letter and study brochure. See Materials for Introductory Letter.

For individuals identified through hospital records, the volume of mailings anticipated makes individual review of patients' records prior to their initial mailing impractical, so this component of the process will not take place prior to mailing for individuals referred through this channel. Additionally, as these individuals are not necessarily seeking treatment, we will wait 7 days after the initial mailing before attempting to contact them by telephone.

5.8 Informed Consent Procedures

5.8A. Veteran Informed Consent.

After completing the recruitment steps described above, Veterans will participate in informed consent procedures. Veteran participants will participate in informed consent over the telephone with a study staff member. Subjects can meet with a study staff member for in-person informed consent if they prefer.

Veteran participants will receive all of the information contained within informed consent by mail or electronically through Docusign. The mailing will contain an opt-out option for those who do not want to be contacted any further along with 1) information explaining the risks and benefits of study participation, 2) their rights as study participants and their privacy rights and 3) required elements of informed consent 4) HIPAA authorization. This material will then be reviewed by telephone prior to participation. When the telephone consent is obtained, they will have already had the opportunity to review study details, consider their participation, and consult with loved ones about participation. Discussing this material with a staff member over the phone will provide greater time and freedom to consider or decline study participation, prior to investing more time and energy in the study. Staff will solicit and answer all questions, and they will also ask the participants questions to ensure participant comprehension of the informed consent document including, but not limited to, what their understanding is of the risks and benefits of participation, when assessments will occur and what topics they will cover. The team is sensitive to the importance of the informed consent process and will make every effort to ensure that participants give their consent voluntarily and fully informed about the potential risks and benefits. If a participant agrees to participate in the study, an informed consent form and HIPAA authorization form will be signed by hand or electronically via Docusign by the participant. If signed by hand, the participant will mail the form back to study staff.All signed forms will be kept locked in staff file cabinets in a locked office. When signed electronically using Docusign, staff can access the signed form in the online Docusign sharepoint space and will export the document to study files.

If a participant requests to have an informed consent meeting face-to-face with a study staff member, this will be permitted. Some participants may prefer to coincide other appointments at the VA with an in-person consent meeting with our study staff. Participants meeting in-person for informed consent will also be required to sign an official informed consent form, and a HIPAA authorization form.

Informed consent will be obtained before obtaining any Baseline self-reports or Baseline clinical interviews. As these Baseline procedures are also necessary for establishing final eligibility (SCID-5-CT and CAPS-5; IC: PCL-5, PHQ-9, AUDIT, DAST), Veterans will be notified that the baseline procedures are necessary for establishing final eligibility and they may be deemed ineligible for the study after these procedures. They will receive notification of their edibility and contacted by staff to schedule their first therapy appointment. Individuals deemed ineligible will be told by telephone and Veterans referred back to their referring providers.

When Veterans are deemed ineligible by a study assessor after completion of the Structured Clinical Interview (i.e., positive screens for psychosis, substance use, suicidality, homicidally, etc.), study staff will communicate the assessment results of these ineligible subjects back to the treatment team (non-study clinical staff) for purposes of patient treatment planning and continuity of care. Conveying a patient's assessment results to the treatment team allows patients to be referred to appropriate treatment in a timely manner, while also eliminating any inconvenient and redundant reassessments. This will be proposed to participants during informed consent, and patients will have the ability to decline this request

5.8B. LO Informed Consent

Loved ones will be sent a letter and brochure describing the study, an informed consent form, and a HIPAA authorization form. The letter will inform them that they will be contacted and how to decline study recruitment efforts. They will then be contacted by telephone by a trained interviewer to discuss the study, their interest, and assess the presence of severe relationship violence. The study procedures (assessment data gathering, intervention, audio/videotaping) will be fully described to the participant at the time of the initial phone call. Participants will be informed of the study design (including randomization to condition) before they decide to participate. If the participant agrees to take part in the study, they will sign the informed consent form and HIPAA authorization by hand or electronically via Docusign. If signed by hand, the participant will mail the form back to study staff. All signed forms will be kept locked in staff file cabinets in a locked office. When signed electronically using Docusign, staff can access the signed form in the online Docusign sharepoint space and will export the document to study files.

If Veterans are deemed ineligible due to inclusion/exclusion criteria or lack of interest, LOs will be informed that full inclusion/exclusion criteria were not met for the Veteran and thus the dyad is no longer eligible for enrollment. Specific details on which inclusion/exclusion criteria (including level of interest in the study) will not be disclosed. The same approach will be used for LOs who decline participation or report severe relationship aggression (i.e., Veterans will be informed that full inclusion/exclusion criteria were not met for the Veteran and thus the dyad is no longer eligible for enrollment). Appropriate alternative referrals to mental health treatment, including substance use treatment or psychotherapy, or to address relationship aggression will be made as upon request and when clinically indicated (i.e., positive screens for psychosis, substance use, suicidality, homicidally, etc.).

5.8C. Retaking Baseline Assessments

For safety and risk implications, we will require Veteran and SP participants to retake the baseline survey and preclinical assessment if the therapy start date would occur 2 months after their baseline data was collected. Time gaps between baseline data and therapy start dates can occur for various reasons, including scheduling issues, provider availability, patient travel arrangements, etc. It is important that patient baseline data is as close to therapy start dates as possible, as clinical data can change over several weeks. For example, in the gap between assessment and therapy start, patients could have a serious substance use relapse or a suicide attempt that would then make it clinically inappropriate for them to begin a trauma-focused therapy, prior to addressing their more pressing concerns around establishing their safety or sobriety. Additionally, we expect many of the constructs we assess to naturally change with time (e.g., family functioning, relationship satisfaction). So, baseline assessments that are more than 2 months old at the time of therapy start may no longer truly represent the patient, support person, or family functioning at the beginning of treatment, confounding study results.

Subjects will be informed of this requirement during the informed consent process and on the information packet or informed consent form. Participants would get paid again for retaking these assessments ($50 for the baseline survey; $60 for the preclinical interview).

5.8D. Incentives.

Participants will receive $40 for participating in Baseline surveys, $50 for baseline diagnostic interviews (Veterans only), $60 for posttreatment surveys, $60 for posttreatment diagnostic interviews (Veterans only), and $60 for one-time qualitative exit interviews. Both veterans and intimate partners will complete monthly surveys for outcomes and treatment mechanisms. They will receive $25 for each of these surveys. Additionally, participants receive $70 for completing a 3-month follow-up survey. A possible total of $415 for veterans and $305 for loved ones.

Participants will receive payment by direct deposit or debit card after completion of their baseline assessment and interview, post treatment assessment and interview, and exit interview.

5.9 Inclusion/Exclusion Criteria

See Table X. With the exception of criteria relevant to LO inclusion (criteria 3, 4, 10, & 11), inclusion/exclusion criteria reflect those consistent with PE delivery within VA. Participants must meet diagnostic criteria for PTSD,[91] assessed using the gold-standard Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; Item 2).[3] Structured clinical interview for inclusion/exclusion criteria will be administered by trained and supervised assessors (Items 10, 11, 12).

Table x. Inclusion/exclusion criteria

Inclusions	Measure	Exclusions	Measure
1. Male or female Veterans at least 18 years old. Enrolled in VHA care.	CPRS	9. Recent suicidal or homicidal ideation with intent and/or plan that, in the judgment of the investigator, should be the focus of treatment	SCID-5-CT[12]

2. Participant meets full DSM-5 diagnostic criteria for PTSD.	CAPS-5	10. Hospitalized or meets DSM-5 criteria for a manic, hypomanic, or psychotic episode in the past 3 months	SCID-5-CT[12]
3. Has an intimate partner with whom they've been in a committed relationship with for the last 6 months and have some form of contact with at least 5 days a week.	Self-report item	11. Meets DSM-5 diagnostic criteria for a severe substance use disorder in the past 3 months. Of note, subjects can be abusing or dependent upon nicotine or marijuana and still be included in the study	SCID-5-CT[12]
4. Interested in participating weekly psychotherapy for PTSD with this person.	Self-report item	12. Moderate relationship violence between the identified partner and the Veteran, defined as one or more episodes of severe violence in the past year (e.g., punched, kicked, or beat up).	IPSVS Adapted[108]
5. Provides informed consent.	Self-report item	13. Partner screens positive for PTSD on a self-report instrument (PCL).	PCL-5
6. Speaks and reads English.	Self-report item	14. Having an ongoing medical condition that would interfere with ability to attend weekly treatment sessions.	Self-report item
7. Willing to have their therapy sessions recorded.	Self-report item	15. Having any planned upcoming major medical procedure or personal event over the next several months that would prevent them from attending weekly treatment sessions.	Self-report item
8. Willing and able to be seen via telehealth when in-person treatment options aren't available.	Self-report item	16. Severe cognitive impairment	CPRS
		17. Fails to complete baseline survey.	

Relationship violence will be assessed by telephone from both Veteran and LO-report (Item 13). We will exclude Veteran participants if he/she has an underlying medical condition or a medical procedure (item 15 and 16) planned that would greatly impair their ability to participate in a weekly psychotherapy (i.e., a severe seizure disorder making weekly attendance difficult or a planned major surgery within a month of beginning treatment). This item will be assessed during the initial phone screening. Items 3, 4, 8, and 14 will also be assessed by phone screen. See materials document for screening items. We will administer a PTSD screen including the PCL-5, PHQ9, and questions regarding prior hospitalizations for MH concern, by telephone. If the loved one has (1) a PCL score above a 32, (2) a PHQ9 score of 9 or 10, and (3) they have ever had a hospitalization for MH or SUD concerns, a further case review will be conducted by a psychologist on the team. LOs and Veterans will be required to complete a baseline survey assessment before they can be randomized to a study arm. Failure to complete the baseline survey will result in study ineligibility (item 18).

We will exclude dyads in which either the Veteran or LO report moderate relationship violence (item 12), defined as one or more episodes of severe violence in the past year (e.g., kicked or beat up) on the IPSVS Adapted Scale[106]. It would be counter-indicated for providers to proceed with PTSD treatment, without addressing ongoing significant relationship violence first. This is similar to the requirement that the patient must not be actively psychotic, manic, suicidal, or dependent on substances. Consequently, the reporting dyad member(s) will be provided with resources and referrals for IPV (see IPV risk algorithm). The dyad may be re-evaluated for eligibility when this exclusionary criteria has been resolved (i.e., one year has passed without an episode of severe violence). Finally, we can delay or end treatment, when clinically indicated, based on case review. For example, if the veteran is new to mental health care at the Minneapolis VA and

has a history of suicidal ideation, the team can elect to delay entry into the study until the patient has established mental health care with the Minneapolis VA (e.g., assignment of an mental health treatment coordinator and a treatment plan) to determine if the patient needs a higher level of treatment than is provided by the limited services in the study before proceeding.

6.0 Data Collection & Study Evaluations

6.1 Data Collection.

Data collected will include surveys, semi-structured qualitative interviews, and administrative data. The outcomes of interest for Aims 2 & 3 (acceptability, feasibility, functioning, and mechanisms), their source, and the specific measure (as applicable) are presented in Table 1. Couples will complete surveys prior to treatment (baseline), during treatment, and within four weeks of their final COACH session. Those who do not attend their final session will receive their survey by mail using CCDOR's modified-Dillman protocol.[54]

Consistent with recommendations, we will obtain collateral reports on veteran functioning by asking LOs to report on the veterans' functioning on the Inventory of Psychological Functioning (IPF).[55] Veterans will also complete a posttreatment structured clinical interview for PTSD symptoms.[52] Lastly, veterans and LOs will complete 90-minute semi-structured qualitative exit interviews.

All interviews will be conducted in person or by phone, based on the interviewee's preference, and will be audio-recorded. Qualitative exit interviews (Appendix 2) will assess (1) attitudes about intervention components, structure (e.g., level of therapist contact), and materials (e.g., handouts), (2) acceptability and efficacy of COACH, including suggestions for intervention improvement, (3) engagement with COACH, including retention and barriers/facilitators to

Table 1. Select Measures. See materials document for full list.	Reporter		Source			
Domain	*V*	*LO*	*S*	*I*	*A*	*Measure*
Acceptability						
Treatment Structure	X	X	X	X		CES[56]; CSQ-8[57]
Materials	X	X		X		N/A
Feasibility						
Treatment Retention	X	X		X	X	N/A
Treatment Fidelity					X	Fidelity instrument[b]
Screening Approach					X	N/A
Recruitment Approach					X	N/A
Assessment Process	X	X	X	X		All survey measures
Outcomes: Functioning						
Overall functioning	X	X	X			Short Form Survey[58]
MH functioning	X	X	X	X		CAPS-5[52], PCL-5[59];PHQ-9;[60]
Self-care functioning	X	X	X			IPF[55]
Family functioning	X	X	X			IPF[55]
Romantic functioning	X	X	X			IPF[55]
Communication	X	X	X			Prepare/Enrich[61]
Conflict Resolution	X	X	X			Prepare/Enrich[61]
Parenting	X	X	X			IPF[55]
Social functioning	X	X	X			IPF[55]
Outcomes: *Mechanisms*						
Session Attendance					X	N/A
HW Compliance					X	PEAS[62]
Social control	X	X	X			Emotional and Problematic Support[63]
Subjective Norms	X	X	X			Subjective Norms-PTSD[a]
LO Reliance	X	X	X			Treatment Discussions[a]

[a]Unpublished scale from Project HomeFront.[b]Developed during the study
V = Veteran; LO = Loved One; S = Survey; I = Interview; A = Administrative Data.

engaging with the program, (4) perceptions of the impact of the program on the intervention targets (e.g., functioning, social control, subjective norms, and LO reliance) and exploration of unexpected domains impacted by the program, and (5) the completeness and time burden of the survey battery. We will also extract the following administrative data: (1) the number of sessions attended (from electronic medical record; retention), (2) the number of participants screened each month (screening), and (3) the number of eligible veterans and LOs who declined participation (recruitment), and therapists' ratings of homework compliance using two items adapted from the Patient Exposure and Response Prevention Adherence Scale (PEAS) for Obsessive Compulsive Disorder (also a cognitive-behavioral exposure therapy).[62]

6.2 Fidelity Checklists and Provider Training.

Over the course of the open trial, Dr. Glynn will lead efforts to finalize fidelity checklists, and Dr. Erbes will lead efforts to develop the provider training program. We anticipate the provider training program will follow a structure similar to that of the VA's national PE and ICBT trainings. These include an initial didactic training with role plays (PE is 4 days; ICBT is 2.5 days) followed by two training cases with individual feedback and weekly case consultation. Additional materials needed for the training program (e.g., powerpoint, clinical vignettes, role play exercises) will be included in the final RCT manual for COACH. Each therapy session will be recorded. We will apply the fidelity checklists to one randomly selected session for each couple. We will identify gaps in content covered by checklist items and items that are unclear, difficult to rate, or not consistently applicable. Items will be revised and finalized for the final Stage II Manual.[25]

6.3 Final RCT Manual.

During the conduct of the open trial, Drs. Meis and Erbes will meet weekly and the larger team will meet monthly to discuss new observations, successes, and challenges. They will identify

portions of session recordings to review to illustrate examples. These discussions will be used to refine and expand the manual and to identify key questions for stakeholder meetings. We will meet with veteran and LO stakeholder groups once during the conduct of the open trial. Final stakeholder meetings, with all stakeholder groups, will take place during month 23 to review preliminary findings and obtain feedback on the Stage II manual.

6.4 Online Surveys

Survey administration format will take place on Qualtrics FedRAMP electronic survey software accessed via the VA cloud OR the VA mPRO (mobile Patient-Reported Outcomes) mobile application. This will support data collection during the COVID 19 pandemic. Social distance guidelines and pandemic related challenges have made routine paper survey mailings unreliable. Participants can complete surveys over-the-phone with study staff if they prefer. Paper versions will also be available, if requested.

Qualtrics FedRAMP has been approved for use from the VA OIT Security standpoint (Authority to Operate or ATO). The ATO status is currently approved for 1 year and a full 3-year ATO is in the works. Qualtrics FedRAMP surveys will contain a study ID number, time of data entry and limited individually identifiable information. Within the VA firewall, the study team at the VA will create a custom- built tracking app that will track each participant's enrollment and study status. Data will be routinely extracted from Qualtrics FedRAMP in the VA cloud and stored on secure CCDOR servers, using SQL database connections. All data will be stored and utilized within secure CCDOR servers that are part of the Minneapolis VAMC network and which operate behind the VA firewall. All data is tracked using a SQL database, with a GUI-front end system that restricts access to only those with approval to study data.

Participants will be sent Qualtrics surveys via a generic email to their personal email address, if the patient opts in for email usage. Prior to emailing participants, we will contact them by phone to ask permission to use their email for this purpose. If the participant does not opt in for email usage, they will be given the Qualtrics survey URL verbally over-the-phone or written on the recruitment and/or follow-up letters sent to them in the mail. All emails to participants will be extremely generic and will follow VA guidelines; they will not mention details of the study in the body of the email, participant names and PHI will not be used. For emailed survey links, we will use CCDOR's well-established modified-Dillman protocol with repeated mailings and an incentive to boost response rates (see example of Dillman protocol chart below).

MPRO. The mPRO mobile app is designed to deliver research and quality improvement surveys to Veterans and their family members. The app allows VA researchers to select and create assessments and assign them to participants using fully deidentified invite codes. Participants then use their invite codes to sign into the mPRO mobile app.

To manage the risk of app-related information being intercepted by a third party, the following steps will be taken. First, the mPRO app will not be used (cannot be used) to collect any personally-identifying information and does not contain any open text fields that would allow a user to enter personally-identifying information. Second, any app usage data that is transmitted from a participant's phone to the research team will be linked only with a non-identifying subject identification code. In order to mitigate privacy risks that are inherent to using mobile phones or websites, we will be implementing several strategies. Participants will receive a unique invitation code that can be used to download and unlock the mPRO study app, and this unique code will be used to examine patient-reported outcomes. App usage data will be fully de-identified.

Qualtrics FedRAMP and mPRO surveys will contain minimal individually identifying information. The only identifying information will be information that is self-reported by the participants (e.g. name, phone, email, which is best method of contact). No sensitive data will be stored outside of the VA protected environment. Once data are transferred for data analysis, data will be maintained on password-protected VA computers in the VA environment and on secure VA servers. Study staff will monitor the functioning of the Qualtrics FedRAMP and mPRO applications. Only staff affiliated with this research protocol will have access to Qualtrics FedRAMP and mPRO data collected for this study. The PI or her designee will be responsible for monitoring data storage location and transfer of data between the VA cloud and VA server.

Study providers will also use email to contact participants using Mpls VA approved email protocol when patients opt in for personal email usage.

Table 1. Multi-modal follow-up protocol for baseline surveys for both Veterans and LOs.

Day	A) US Postal Mail	B) Email Contact	C) Phone Contact
1: Recruitment Package	Delivery of info sheet, opt-out, Letter 1 (B1.V.L or B1.LO.L)		
2: Day 0 – Phone screening (participant opts in or out of email usage)	Give participant personal code after consent; tell them to use URL from recruit letter.	Email (B2.V.E or B2.LO.E) with link to survey after email address and consent is obtained	Call participant, discuss study using script (see study materials), obtain consent, screening, obtain verbal permission to send emails, provide link to survey and pin verbally.
3: Day 3		First email reminder with survey link to non-responders (B3.E.)	
4: Day 7		Second email reminder with survey link to non-responders (B4.E.)	First weekly outreach call to non-responders. Provide link to survey and pin verbally. (no script)
5: Day 14			Second weekly outreach call to non-responders. Provide link to survey and pin verbally. (no script)
6: Day 21		Third and final reminder email with survey link to non-responders (B6.E.)	Third weekly outreach call to non-responders. Provide link to survey and pin verbally. (no script)
***Day of survey completion**			Thank you phone call and schedule assessment when applicable (veterans only)

Table 2. Multi-modal protocol for monthly surveys for both Veterans and LOs.

Day	A) US Postal Mail	B) Email Contact	C) Phone Contact

1: Day 0		Email (M1.E) with link to monthly survey.	Call participant to inform them of fup survey; inform them of survey link email OR provide link to survey and pin verbally.
2: Day 3		First email reminder with monthly survey link to non-responders (M2.E.)	
3: Day 7		Second email reminder with monthly survey link to non-responders (M3.E.)	First weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)
4: Day 14			Second weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)
5: Day 21		Third and final reminder email with monthly 1 survey link to non-responders (M5.E.)	Third weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)

Table 3. Multi-modal follow-up protocol for fup surveys for both Veterans and LOs.			
Day	**D) US Postal Mail**	**E) Email Contact**	**F) Phone Contact**
1: Prenotice	Fup prenotice letter to dropout dyads only (FU1.V.L or FU1.LO.L)	Fup prenotice emails to dropout dyads only (FU1.V.E or FU1.LO.E)	
2: Day 0		Email (FU2.V.E or FU2.SP.E) with link to fup 1 survey.	Call participant to inform them of fup survey; inform them of survey link email OR provide link to survey and pin verbally.
3: Day 3		First email reminder with fup survey link to non-responders (FU3.E.)	
4: Day 7		Second email reminder with fup survey link to non-responders (FU4.E.)	First weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)
5: Day 14			Second weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)
6: Day 21		Third and final reminder email with fup 1 survey link to non-responders (FU6.E.)	Third weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)

Table 4. Multi-modal follow-up protocol for 3M fup surveys for both Veterans and LOs.	

Day	D) US Postal Mail	E) Email Contact	F) Phone Contact
1: Prenotice		3M fup prenotice emails (3M1.E)	
2: Day 0		Email (3M2.E) with link to 3M fup 1 survey.	Call participant to inform them of 3M fup survey; inform them of survey link email OR provide link to survey and pin verbally.
3: Day 3		First email reminder with 3M fup survey link to non-responders (3M3.E.)	
4: Day 7		Second email reminder with 3M fup survey link to non-responders (3M4.E.)	First weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)
5: Day 14			Second weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)
6: Day 21		Third and final reminder email with 3M fup 1 survey link to non-responders (3M6.E.)	Third weekly outreach call to non-responders. Inform them of survey link email OR provide link to survey and pin verbally. (no script)

7.0 Data Analysis

7.1 Qualitative Data Analysis.

We will utilize an efficient, rapid turn-around analytic approach well-suited to short-term projects, interviews that use targeted guides, and projects that lend themselves to straightforward explanatory analyses.[64] This approach uses data reduction, rather than coding, as the first step of analysis. Qualitative interviews will be transcribed verbatim. Following transcription of the first three interviews, Dr. Kehle-Forbes (with feedback from co-investigators) will develop a draft template that will be used to summarize each transcript. The template will include sections for each main topic of inquiry, unexpected findings, and exemplary quotes. After fielding the template and making any necessary revisions, Dr. Meis and the project manager (trained by Dr. Kehle-Forbes) will carry out the data reduction process. After all transcripts have been summarized, the project manager will transfer the summary points to a data matrix that organizes the summary points along each of our domains (acceptability, feasibility, and outcomes). Finally, following discussion of the matrix with the investigator team, Dr. Meis will create a memorandum summarizing findings and key themes.

7.2 Quantitative Data Analysis.

To evaluate acceptability of COACH, we will calculate the percentage of participants who report neutral or better treatment credibility and expectancy on the Credibility-Expectancy scale (CES)[56] and examine the distribution of scores on the Client Satisfaction Scale (CSQ-8).[57] To assess feasibility, descriptive statistics and graphical representations depicting intervention

fidelity, screening, and treatment retention will be generated. We will calculate rates of survey non-response and item missingness for assessment feasibility. To preliminarily evaluate outcomes, we will calculate and graphically display the direction and magnitude of change from baseline to follow-up for outcomes outlined in Table 1. We will also calculate the percentage of participants who improved, worsened, and experienced no change for each of these measures. We will calculate descriptive statistics and pre-to-post treatment effect sizes. Lastly, we will triangulate our quantitative data with qualitative themes through matrices with exemplary quotations. Themes that emerge from the interviews will be stratified by participants' scores on relevant quantitative scales (e.g., participants' acceptability themes stratified by their Credibility-Expectancy and Satisfaction scores; feasibility themes stratified by number of sessions attended).

7.3 Withdrawal of Subjects

Participants can withdraw from the study at any point in time and for any reason by contacting study personnel in person, by telephone, or by mail, and requesting to withdraw. We anticipate termination of participation if:

1. The participant becomes ineligible to participate.
2. The participant does not follow instructions from the researchers.
3. The study is unexpectedly suspended or canceled.

8.0 Reporting

We will follow the VA Central IRB Table of Reporting Requirements for all issues that must be reported (i.e. summary of adverse events, unexpected problems and any actions or changes with respect to the protocol).

Adverse events (AE) include any untoward medical occurrence in a patient or clinical investigation subject administered an intervention and which does not necessarily have a causal relationship with this treatment. We will collect the following safety information (adverse events) that occurred within 7 days leading up to the final assessment.

1. Suicide attempts
2. Hospitalizations for mental health
3. Episodes of severe IPV

Therapists will be instructed to notify study staff immediately when such events occur during treatment delivery. Staff will report directly to the PI regarding any events. Therapists will also meet regularly for case consultation, where the occurrence of any of these events will be further discussed and tracked. Questions regarding the occurrence of each of these three events will be included in posttreatment assessments. Data obtained from participants will be reviewed for safety concerns. In the case of problems, the staff will discuss this with the PI.

Of note, survey reports of IPV on posttreatment and follow-up surveys will be reported when respondents endorse items consistent with severe violence. This includes the following: (1) hit my partner with a fist or something hard, (2) kicked my partner, (3) slammed my partner against something, (4) beat my partner, (5) burned my partner on purpose, (6) tried to hurt my partner by choking or suffocating him/her, or (7) used a knife or gun on my partner. Examples of serious adverse effects, according to the FDA, include death, life- threatening adverse events, suicide attempts, and hospitalization. Consequently, endorsement of items 6 or 7 will be considered a SAE. Given the population, some incidents of severe IPV are expected. Reports of moderate to severe IPV on baseline surveys are part of our exclusionary criteria (see inclusions/exclusions). Thus, severe IPV in reported in baseline surveys will not be reported as adverse events.

The PI and Co-Is are all licensed clinical psychologists. Events will be immediately communicated to the study PI. The team will in turn will report any problems to the IRB. Once the PI learns of any SAEs, UAP, compliance issues, RCO, and/or protocol deviation, the team will report these events. If there are modifications or amendments to the study the study PI will also submit appropriate amendments and wait for approval prior to implementation.

9.0 Privacy and Confidentiality

Protected Health Information will need accessed for the conduct of this study, but PHI will not be disclosed. Steps to ensure confidentiality and secure data are described below.

9.1 Confidentiality

For all participants, strict confidentiality procedures will be maintained to minimize the potential risk of loss of confidentiality. Participant privacy will be further assured by conducting interviews in a private office and by assigning arbitrary identifiers in place of individual names in the field notes. Data analysis, interpretation, and reporting will be based on these de-identified field notes and transcriptions. Since subject responses will not be linked to identifying information, participant confidentiality will be assured. The time commitment will be explained to all participants prior to their participation in the study. Every effort will be made to minimize the length of time and maximize the convenience of the interviews. Participants will be assured that participation is completely voluntary and that they have the right to stop participation, decline answering any questions, or change the course of the interviews for any reason, including potential feelings of discomfort.

9.2 Data Security

All data will be stored on the servers of the Center for Chronic Diseases Outcomes Research (CCDOR) at the Minneapolis VAHCS. CCDOR has well-established procedures to protect the privacy of research participants. Names, social security numbers, and contact information will not appear on any study materials. Instead, only unique study identification numbers randomly assigned to each unique record will be used. Only study team members and study programmers (when extracting data to obtain treatment adherence and compare survey responders to non-responders for the survey) will have access to an encrypted crosswalk table linking study identification numbers to identifying information. The CCDOR Statistical and Data Management (SDM) team, in partnership with IRM staff, maintain several secure servers, access to which is granted only to SDM members who have been screened and assigned appropriate security clearance to work with patient data. One common-access server contains individual project data. Access to individual project data on this server is granted only to project staff by an SDM team member, as authorized by the study investigator. Identifiers will be destroyed as quickly as possible. Audio and video recordings will be stored digitally on CCDOR servers and only accessible to the principal investigator and project coordinator. Participants will be asked not to use last names or provide identifying information during recorded interviews.

CCDOR protects data collected for the purpose of conducting research projects at a level higher than that provided for clinical encounters. We use “stand-alone,” secure data servers that are accessible only to designated, security-cleared, and trained personnel and data are de-identified as quickly as is feasible. Details about CCDOR’s specific data privacy assurance procedures to be employed for this study are provided below.

9.2A. Maintaining Secure Servers.

CCDOR maintains three secure computer servers that are protected under the Minneapolis VA Windows 2000 network. All individuals with administrative access privileges to CCDOR's servers, including IRM personnel and the CCDOR Statistical & Data Management Team, have been screened and assigned a security clearance putting them in trusted positions of the hospital with clearances to work with patient level data. These individuals and their access to the CCDOR servers is ultimately monitored and controlled by Sean Nugent, Senior Program Analyst for the CCDOR Statistical & Data Management Team. IRM's access to the data is strictly limited to backing up server data, which prevents catastrophic loss of data. Backups are written to tapes that are stored in a secure location accessible only to IRM personnel. CCDOR's Statistical & Data Management Team members maintain permissions, data storage, and all server applications.

9.2A.1 Organization and Access to Research Data. With the exception of one server, named the "CCDOR Server," only the CCDOR Statistical & Data Management Team has access to remaining Center servers. Data on the "CCDOR Server" are organized by projects within folders designated by each investigator. Only members of a given project have access to a specific project folder on the "CCDOR Server." Even then, access to project data is obtained through Windows authentication (i.e., user's name and password to the network). It is virtually impossible for any person without a login name and password to the VA hospital's domain network to access data on the Center's servers. Thus, all data housed on the "CCDOR Server" are extremely secure, and access by unauthorized persons highly unlikely. Data containing patient identifying information are not stored on the CCDOR Server but are stored on the servers accessible only to CCDOR Statistical & Data Management Team members who are directly involved in the project. Thus, not even the PI can link individual names to their PHI without first obtaining permission to do so from the Statistical & Data Management Team. These protections exceed the usual protections provided PHI by the VA system.

9.2A.2 Securing Confidential Research Data. Data collected for individual Center projects are often obtained through primary (e.g., surveys) or secondary (e.g., VISTA and Austin databases) sources. All extractions of secondary data collection are stored on servers accessible to the CCDOR Statistical & Data Management Team only. Secondary data used for a study are de-identified according to HIPAA criteria and provided a random study identification number. A crosswalk table is created linking the study id with the primary key of the secondary data source. These data are only accessible to those employees of the Statistical & Data Management Team who have undergone the necessary security background checks, received appropriate security clearances, and are an integral part of an IRB-approved study. Primary data that involves surveys contain only the coded study identification number to identify study participants. The paper version of these forms/surveys is kept in locked cabinets within a locked room. Data from these surveys/forms are scanned or data entered by project staff or CCDOR Statistical & Data Management Team members to a secure folder. This secure folder is on a server accessible only to the CCDOR Statistical & Data Management Team members directly involved in the study. This protects the integrity of the data as well as its confidentiality. Primary data collection involving direct data entry is performed through a custom application written by a CCDOR Statistical & Data Management Team programmer. This ensures that data is located in

a secure environment and accessible to only those individuals with permission to access the data. Only individuals with a need to access the data, as vetted by the project's Principal Investigator are granted access. Even then, only the absolute minimum number of data elements is released.

9.2B. Data Used for Analysis.

For all projects conducted in CCDOR, the final quantitative data is constructed in Statistical Analysis Software (SAS) data sets. Qualitative data includes audio recordings of interviews that are transcribed and then stripped of all identifiers. De-identified transcripts are then uploaded into qualitative analysis software (NVIVO). Quantitative analyses are mostly conducted by statisticians assigned to the project or by other members of the project (e.g. Principal Investigator). Qualitative analyses are conducted by study investigators with qualitative expertise (e.g., Kehle-Forbes and study PI).

SAS data sets and qualitative transcripts will be de-identified according to HIPAA criteria, using only subjects' coded identification number as the primary key. The de-identified data set will be made accessible to those project members who are conducting analyses. Only the data elements required for the analysis under consideration are released. In summary, a separate workspace on a server accessible only to project Statistical & Data Management Team members will be created to work with administrative data. Any of the administrative data containing patient level data will be encrypted when not being used by a project programmer. All patient-identifying information will be removed from the administrative records. Upon completion of all study data, de-identified analysis data sets will be created in SAS and NVIVO that will use the subjects' coded study identification numbers as the only key.

10.0 Communication Plan

P.I. Dr. Laura Meis will meet regularly with Erin Linden, the project manager. At these meetings, Dr. Meis will check in with Ms. Linden to ensure that the following key communications occur:

1. Ensure that required approvals are obtained
2. IRB of any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study.
3. Notify facility directors when the study reaches the point that it no longer requires engagement of the local facility

The study team will also review relevant sections of the protocol periodically, so that we can make sure that the phases of the study are conducted according to the IRB-approved protocol.

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