Peer Enhanced Prolonged Exposure

NCT02818114

Most recent protocol change approved by IRN 5/1/17

## 2.A. RESEARCH PLAN

### A. BACKGROUND AND SIGNIFICANCE

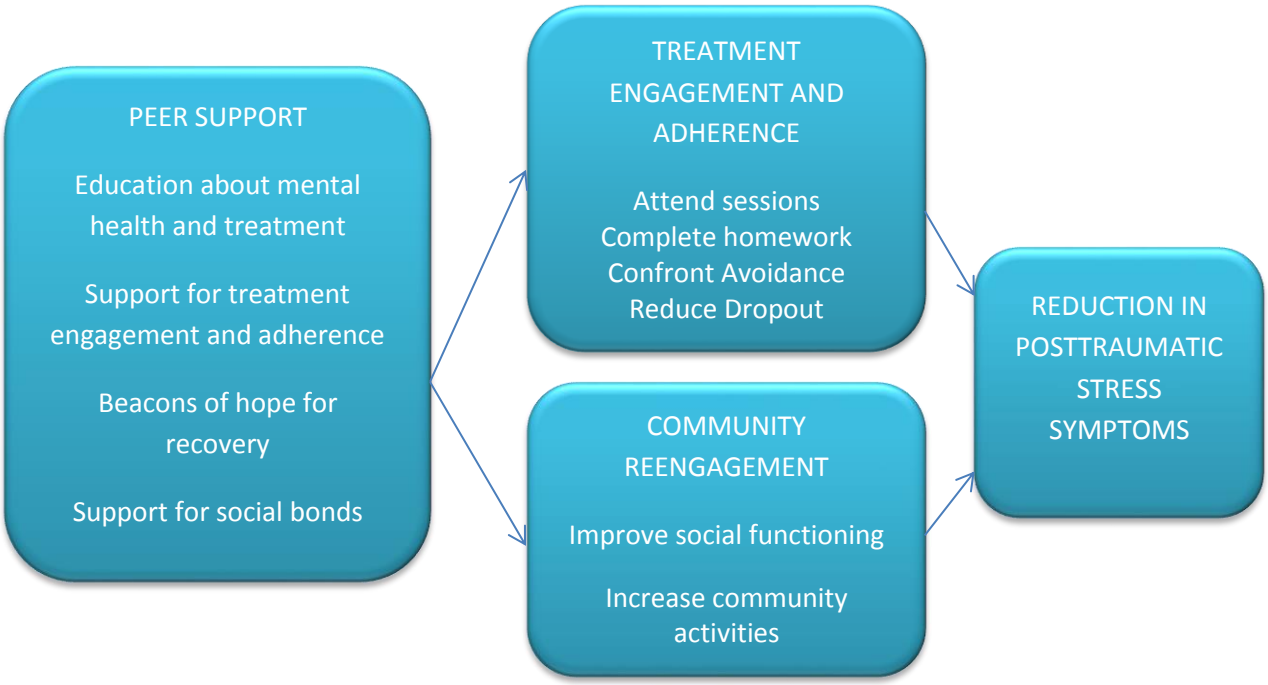
**A.1. Posttraumatic Stress Disorder (PTSD) is a Debilitating Psychiatric Condition and High Priority for Rehabilitation.** Guided by the World Health Organization's International Classification of Functioning, and VA Rehabilitation Research & Development's State of the Art Working Group on Community Reintegration, we define community reintegration as meaningful participation in activities, effective role functioning, and satisfaction across domains including intimate relationships, social, leisure, and work.[2,3] PTSD is associated with poor work, intimate partner, and parenting functions.[4-8] Several studies have found that PTSD leads to deterioration of social resources over time, resulting in isolation and alienation.[9,10] Given social deficits leading to a spiral of losses, community reintegration is a key rehabilitation target for Veterans with PTSD. Improving rehabilitation services for PTSD by targeting social functioning and community reintegration has the potential to mitigate significant costs, and substantially improve quality of life for affected Veterans and their families.[11]

**A.2. Efficacious PTSD Treatments Exist, but their Effectiveness is Threatened by Poor Engagement and High Dropout.** Robust evidence supports the efficacy of Prolonged Exposure (PE) in reducing PTSD symptoms,[12] and the VA has invested heavily in PE as an Evidence-Based Psychotherapy (EBP).[13-15]

***A.2.a. Veterans have difficulty engaging in first-line PTSD treatments.*** Studies estimate only 6-11% of all Veterans with PTSD actually start an EBP.[16,17] Among those who do, 30% to 50% fail to show clinically significant improvements.[18,19] This may be due in part to dropout, which ranges from 30% to 38% in randomized trials[18-20] and 32% to 49% in clinic based studies.[19-21] In a sample of 427 Veterans who were scheduled to begin PE or CPT in a VA PTSD Clinic, only 51% completed treatment: 17% dropped out before the first session and 34% dropped out later.[19] *Studies of reasons for dropout have found only a few predictors; younger Veterans, Veterans in PE (as compared to CPT), and Veterans using benzodiazepines or alcohol are more likely to drop out.*[19,45] Social and work functioning improve for PE completers, but not for those who drop out or evidence poor adherence.[22] Given that PE treatment engagement is low,[16,17, 19,20] interventions that improve treatment engagement and adherence could improve rehabilitation outcomes.

**A.3. New Rehabilitation Approaches are Needed to Improve PTSD and Rehabilitation Outcomes**

**Figure 1: Model of Peer Support in Trauma Recovery**




***A.3.a. Peer support services represent a promising strategy for enhancing adherence and improving rehabilitation outcomes.*** Peer specialists (PS's) are individuals in recovery from mental health challenges who are trained and supervised to use their lived experience to serve as role models, teachers, supporters, and "beacons of hope" for others.[23] The VA's Uniform Mental Health Services Handbook mandates

peer support services. . Results of feasibility and pilot studies indicate that Veterans readily accept peer support services.[24-27] Despite these promising findings and VA mandates for increased peer-support services, there is a lack of well-structured models for incorporating peer support into evidence based care for PTSD.

**Table 1: PE Interventions, PEET Interventions, and Model Elements**

| Session | PE Intervention | PEET Intervention | Model Elements |
|---|---|---|---|
| | | Invitation Phone Call | Education, Hope, Treatment Engagement |
| **0** | Assessment, Orientation, Informed Consent | Education, Modeling, Establish Rapport | Education, Hope, Treatment Engagement |
| | | PS coaching calls (available throughout) | Hope, Treatment Engagement, Social Bonds |
| **1** | • Overview Treatment Rationale<br>• Trauma Assessment<br>• Breathing Retraining | Group1: Rapport, purpose, motivation | Treatment Engagement, Hope |
| **2** | • PTSD psychoeducation<br>• Rationale for in vivo Exposure<br>• Construct In Vivo Exposure Hierarchy<br>• Begin In Vivo Exposure | Group 2:Coping strategies for adherence | Treatment Engagement, Hope |
| **3** | • Rationale for Imaginal Exposure<br>• Initial Imaginal Exposure, Processing<br>• Continue In Vivo Exposure | Group 3: Follow-up on adherence | Treatment Engagement, Hope |
| | | Telephone check-in | Treatment Engagement, Hope, Social Bonds |
| **4-5** | • Continue Imaginal Exposure, Processing<br>• Continue In Vivo Exposure, working through hierarchy | Group 4: PTSD and relationships | Social Bonds, Community Reintegration |
| | | Discretionary Intervention: Individual facilitation for in vivo exposure | Treatment Engagement and Community Reintegration |
| | | Group 5: Follow-up on relationships | Social Bonds, Community Reintegration |
| **6-9** | • Continue Imaginal Exposure, working through Hot Spots and processing<br>• Continue In Vivo Exposure, working through hierarchy | Groups 6-9: Community activities | Community Reintegration |
| **10** | • **Final Imaginal Exposure and processing**<br>• **Review In Vivo Hierarchy**<br>• **Discuss what was helpful/not helpful in treatment**<br>• **Relapse prevention plan** | **Final Group session: Termination** | Community Reintegration |

***A.3.b. Conceptual model of peer supported PTSD treatment.*** Figure 1 above illustrates our recovery-oriented conceptual model for peer support services adjunct to PE. Peer support has the potential to enhance PTSD and rehabilitation outcomes by targeting treatment engagement, adherence, social functioning and community reintegration. *This model is supported by evidence that those receiving adjunctive peer support are more likely to initiate treatment, attend sessions, complete homework, and perceive stronger treatment alliance.[28-30, 46,47] Peer support services enhance social functioning and community reintegration.[30-36] Studies show peer support is associated with reduced hospitalization as well as increased empowerment, hope, and self-efficacy.* There is strong potential for such interventions to enhance rehabilitation outcomes among Veterans seeking treatment for PTSD.

***Translating the Model into Practice:*** *In this intervention, PS's will provide education about mental health care in an initial telephone call, the joint education/orientation session with the therapist and Veteran, and as needed during subsequent telephone coaching and support groups. This may include basic information such as therapy schedules and social norms in individual and group modalities, as well as personal experiences in mental health treatment. PS's will support recovery orientation (i.e., hope for recovery) in the initial phone call, the joint education/orientation session with the therapist and Veteran, and as needed in telephone coaching and support groups. Support for recovery orientation will take the form of sharing the PS's personal recovery story, initially describing success in therapy and mastery of symptoms. As the intervention moves to focus on social functioning and community reintegration, the PS should include stories of his or her own successes in improving relationships and increasing community functioning. PS's will promote social bonds by a) offering social support before and during the initial orientation session, b) providing social support during coaching calls and during support group meetings, c) facilitating social support between Veterans at support group meetings, and d) facilitation of improved relationship functioning in the Veteran's community of support. Increased richness in social relationships should result in increased involvement with others in the community, enhancing community reintegration.*

***A.3.c. Adjunctive peer support services for PE.*** Standard PE includes education about PTSD, followed by imaginal and in vivo exposure. This series of therapeutic activities provokes and then facilitates habituation to arousal, allowing sufficient processing to desensitize clients to inappropriately feared stimuli. *Based on*

*empirical support for our model noted above*, we have reason to expect that adjunctive peer support services can enhance treatment engagement, adherence, social functioning and community reintegration. Within the context of supporting PE, PS's could be trained and supervised to: 1) provide telephone support to promote recovery and encourage session attendance and treatment adherence, 2) educate Veterans and significant others about treatment and serve as a positive role model when the treatment is described, 3) facilitate weekly peer support groups to enhance education, increase available social support, promote treatment engagement and adherence to homework, and promote community reintegration and *4) facilitate in vivo exposure as recommended by PE providers*. This may include facilitating resumption of valued activities by leading group outings to community settings (e.g., using public transportation, engaging in community activities). *By refining an intervention manual with standardized procedures for training and supervising PS's, we can facilitate empirical evaluation of adjunctive peer support services, and likely improve rehabilitation outcomes.*

**A.4. Significance of the Research.** Development of effective treatment for PTSD is a top priority for the VA; a chief goal of VA's Strategic Plan is the development of recovery-oriented care that emphasizes evidence-based practices to promote Veterans' psychosocial rehabilitation and community reintegration. VA has been on the forefront of efforts to implement peer support services to create more patient-centered, recovery-oriented care. Yet, little research has examined the efficacy of adjunctive peer support services for enhancing PTSD and rehabilitation outcomes. This study supports VA Rehabilitation Research and Development priorities in that it will a) use Veterans' qualitative data to create patient-centered care, b) capitalize on peer support to establish a recovery-oriented, adjunctive rehabilitation intervention, and c) improve functioning and community reintegration outcomes among Veterans with PTSD.

## B. PRELIMINARY STUDIES

**B.1. Research team is well qualified to undertake this novel treatment development project.** The proposed project builds on the experience of a strong interdisciplinary team with complementary expertise in peer support services, novel treatments for PTSD, and rehabilitation. All of the investigators are experienced in PTSD research and rehabilitation. Drs. Harris, Jain, and Hundt are leaders in peer support, Drs. Erbes, Harris, Jain, Strom, and Hundt have experience in intervention development and/or dissemination, and Drs. Erbes and Polusny have experience in qualitative methods that are critical in early stages of intervention development.

**B.1.a. Team has expertise in peer support interventions.** Drs. Harris, Jain, Hundt and Strom are experienced peer support supervisors, and Drs. Harris and Jain were involved in the creation of VA peer support services at the dawn of the discipline. Dr. Hundt is experienced in peer support and PTSD research and is currently developing a manual for peer support services as an adjunct to PTSD treatment. Dr. Harris created policies and procedures for MVAHCS's peer support services in cooperation with VACO. In that role she became a central source of peer support training/supervision expertise for VISN 23. Dr. Jain is a leading source of peer support research in PTSD,[27,36] has developed a comprehensive model of peer support services and is the project director of the Peer Support Program, a clinical demonstration project that integrates peer support into the mental health treatment of rural Veterans.

**B.1.b. Team has expertise in PE, rehabilitation outcomes, intervention development and qualitative methods.** As national trainers and consultants Drs. Strom and Polusny bring expertise in PE, and Dr. Strom has experience as a peer support supervisor. Dr. Polusny has collaborated on studies of dropout from EBPs for PTSD.[19] Drs. Erbes & Polusny have generated analyses of PTSD symptoms and social functioning over time[8,9] and one of the first reports on vocational functioning among National Guard soldiers.[7] Dr. Harris has developed an intervention designed to reach Veterans who eschew mental health services, and is currently leading a large RCT.[38] Dr. Jain has developed peer support interventions detailed above. Dr. Strom is currently involved in a clinical trial of vocational rehabilitation for Veterans with PTSD. Dr. Erbes has evaluated novel treatments for PTSD including the use of Narrative Therapy,[40] and Drs. Polusny and Erbes recently published results of a clinical trial of mindfulness-based stress reduction.[14] Drs. Erbes and Polusny have experience with qualitative methods necessary to move peer support interventions closer to evidence based practice. Dr. Erbes has worked with qualitative data related to relationship functioning among Veterans with PTSD,[7] and Veterans with amputation. Dr. Polusny is PI of a study using qualitative methods to understand chronic pain.

## C. RESEARCH DESIGN AND METHODS

The National Institutes of Health (NIH) identify six stages of treatment development: Stage 0 (Discovery/Basic Research), Stage I (Intervention Generation/ Refinement), Stage II (Pilot/Proof of Concept), Stage III (Hybrid Efficacy-Effectiveness), Stage IV (Effectiveness), and Stage V (Implementation and Dissemination). Basic research (Stage 0) is summarized above. The current proposal focuses on Stage I; initial development/

feasibility testing. Stage IA includes development of the theoretical rationale, intervention manuals, training materials, fidelity monitors, and outcome measures. Stage IB includes pilot feasibility testing.[41] The resulting products will be used in future research addressing Stages II through V.

**C.1. Overview of Study Design. This pilot refinement/feasibility study of Peer Enhanced Exposure Therapy (PEET) will move from Stage IA (Intervention Development/Refinement) through Stage IB (Feasibility) in Years 1 and 2.** The goal of this project is to refine and pilot test an adjunctive peer support intervention manual suitable for implementation and evaluation in VA clinics. The adjunctive intervention, PEET, is designed to improve treatment engagement/adherence, and optimize rehabilitation outcomes by improving social functioning and community reintegration.

**C.2. Specific Aim 1: Refinement of Preliminary Manual and Training Materials for PEET (Stage IA).** In Year 1, we will revise our preliminary manual and PS training materials for PEET. The intervention is adapted from our model[37] of peer support for PTSD treatment and will be refined based on feedback from focus groups with Veterans and PE providers. Focus groups will review components of the intervention manual, and provide feedback on each type of intervention (orientation, telephone support, group support, and support for in vivo exposure). We will review this data in collaboration with national leaders in peer support and PE, then revise the initial framework for the PEET intervention.

***C.2.a. Focus group participants.*** *A sample of 12-16* ***Veterans*** *who have used PE will be invited to participate in one of 4 focus groups. We will use purposeful sampling stratified by treatment engagement (50% who engaged and 50% who dropped out). A sample of 8-12* ***VA providers*** *with at least 2 years of experience implementing PE will be recruited from the Minneapolis VA Health Care System (MVAHCS) PTSD treatment team to participate in two focus groups. We will strive to include a diverse set of providers, including psychologists, social workers, and psychiatrists. Sample size and number of groups were determined on the basis of information power, [57] a new and more easily operationalized means of proactively estimating numbers needed to attain saturation. The information power for this design is quite high, as a) the goal is feedback on a well-defined stimulus, b) the population to be sampled is very specific, c) the procedure is informed by an established model[36] d) the interviewers are experienced with the information content and qualitative interviewing, and e) the analysis plan is highly structured; given the high level of information power available, the recommendation is for 2 focus groups per category of participants.[57,58] Based on this we will schedule 2 focus groups for PE completers, 2 for PE dropouts, and 2 for PE providers.*

***C.2.b. Focus group procedures.*** *Separate focus groups will be conducted with Veterans and Providers. During 60-90 minute focus groups, participants will be provided with information about the intervention and asked for feedback about a) the initial, invitation call, b) co-facilitation of orientation sessions with the PE provider, c) peer support coaching calls, d) the peer support group, and e) support for in vivo exercises. (See Appendix 6 for focus group protocol.) Focus groups will be recorded in digital audio format and transcribed.*

***C.2.c. Qualitative analyses.*** Drs. Harris, Erbes, and the coordinator will conduct qualitative analyses. We will use a rapid turn-around analytic approach.[42] This technique is well-suited to short-term projects, focus groups using targeted interview guides and *has been cited over 200 times in the research literature, including 2 VA treatment development studies.[59,60]* This process improves on past rapid procedures through its systematic, rigorous approach. While this does not yield the nuanced understanding of older analytic techniques, it is more efficient. The rapid turn-around approach uses data reduction (i.e, it sorts, focuses and organizes data[43] rather than coding as the first step of analysis). Following focus groups, Drs. Harris, Erbes, and the coordinator will develop a draft template summarizing each data collection episode (e.g. each transcript). The template will be organized with a separate area for each focus group question, unexpected findings, and exemplary quotes. The coordinator will field the draft to assess the guide. Following any revisions, Dr. Harris will apply the template to remaining transcripts. After transcripts are summarized, Dr. Harris will transfer the summary points in a data matrix that organizes the summary points for each main topic of inquiry by population (e.g. Veterans, Providers). This will allow the investigators to systematically assess similarities, differences, and trends in responses across the focus groups.[44] Finally, following an all-staff meeting allowing investigators and expert consultants to provide their impression of the matrix contents, Dr. Harris will create a final memo summarizing the findings and noting key themes that emerged from the data.

***C.2.d. Treatment and training manual revision.*** Using focus group findings, Drs. Harris, Jain, *Strom and Hundt* will *revise and refine our* a) intervention manual, b) PS training materials, d) fidelity monitors, and e) outcome measures. These materials will be iteratively reviewed by the study team, which includes active PE

providers, nationally recognized leaders in PE, peer support services, and PS's (to be named). In addition, we will seek feedback from Dan O'Brien-Mazza, the National Director of VA Peer Support Services, and a national network of PE trainers and consultants, including *Drs. Polusny and Strom*. When the team and expert consultants are satisfied with the intervention materials, Drs. Harris, *Strom, and Polusny* will provide initial training to 2 PS's; training will be evaluated based on written tests and role-played, rated performance of manualized techniques.

**C.3. Specific Aim 2: Examine the Feasibility of PEET.** In the second half of Year 1, we will begin pilot testing PEET (Stage IB) to determine feasibility and acceptability using a series of at least 12 Veterans treated by 2 providers and 2 PS's. Veterans referred for PE will be invited to take part in the study. Trained PS's delivering the intervention will be provided with weekly individual and group supervision, and sessions will be recorded so that interventions can be rated for fidelity to the manual.

***C.3.a. Participants.*** Veteran participants will be individuals appropriate for PE, i.e., Veterans who a) are currently seeking PE, b) meet DSM-5 criteria for PTSD or subthreshold PTSD, c) are competent to consent to research, and d) do not have levels of other types of psychopathology that would prevent successful participation in the intervention.

***C.3.b. Peer Training, Supervision, and Fidelity Monitoring.*** *PS's hired for this study will be state-certified. They will also be able to personally describe and demonstrate high levels of functional recovery from PTSD, and a history of successful participation in PE.* Drs. Harris, *Strom and Polusny will* jointly provide PS's with training on a) PTSD, b) principles of PE, c) the new intervention, and d) the importance of fidelity to the treatment manual. PS training will be assessed using a) a written knowledge test, b) role-played peer support techniques, and c) written and verbal feedback from PS's solicited at the end of training, and at the end of the study. Dr. Harris will provide at least one hour of individual supervision and 2 hours of group supervision per week, with focus on a) reviewing recordings of interventions, b) Veteran safety, and c) model fidelity. Both Dr. Harris and the study coordinator will review at least 50% of the peer support sessions and use the developed monitoring instrument to assess fidelity. Interrater reliability for fidelity monitoring will be assessed as well.

***C.3.c. PE Providers.*** Drs. Strom and Polusny, both licensed mental health providers and national PE trainers and consultants, will serve as PE therapists for this study.

***C.3.d. Quantitative Assessment.*** Measures will be used to characterize the pilot sample, provide information on acceptability and perceptions of the treatment, and test the measurement battery that will be used in later Stage II clinical trials. In order to evaluate eligibility for the study, the Clinician Administered PTSD Scale for DSM-5 will be administered by the PI. Those Veterans who have a diagnosis of PTSD or subthreshold PTSD will then complete a battery of self-report measures *for symptoms and quality of life indicators*[68] at baseline and post-treatment. *Table 2 outlines the measurement to be used to assess key aspects of our theoretical model, as well as schedule for administration and respondents . This battery is being administered to 1) verify that outcomes are, at least on their face, similar to those obtained in existing studies of PE with this population and 2) pilot the feasibility and utility of the assessment protocol for future clinical trials. Post-treatment interviews will be used to solicit Veteran, provider, and peer specialist feedback on each component of PEET, especially with regard to dropout risks and dropout prevention (see interview schedule, Appendix 6). Interviews will also seek feedback on adequacy of PS training and coordination of PEET and PE services. Medical records will be reviewed to assess signals for dropout risk, specifically the number of sessions attended and the percentage of session notes indicating adherence to homework.*

***C.3.f. Analysis.*** We will examine responses to the follow-up interviews with Veterans, PE providers, and PS's using the same rapid-turnaround qualitative approach outlined above. ***Feasibility*** will be analyzed based on a) qualitative feedback, b) PS scores on fidelity instruments, c) indicators of treatment engagement (session attendance, homework adherence), d) SES ratings and e) pre-post changes on the MCQ, APQ and CSI. ***Acceptability*** will be analyzed based on a) qualitative feedback and b) scores on the CES, and CSQ. This sample, while small, will be sufficient to provide a preliminary evaluation of the feasibility, and acceptability of the intervention.

***C.3.g. Refinement of the Treatment Manual.*** After completion of the pilot trial, we will review data from Veterans, providers, and PS's, to make edits to the manual and plan for Stage II trials.

| Table 2: Feasibility Trial Measurement | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Domain/Measure** | **Type** | **#Items** | **α** | **Administered by** | **Respondents** | **Week 1** | **Week 10 or Dropout** |
| **Symptoms** | | | | | | | |
| CAPS[48,49] | Interview | 30 | n/a | Harris | Veterans | x | |
| PTSD Checklist[50-52](PCL) | Self-Report | 20 | .89-.97 | Coordinator | Veterans | x | x |
| **Hope** | | | | | | | |
| Credibility-Expectancy Scale [53](CES) | Self-report | 6 | .79 | Coordinator | Veterans | x | |
| **Engagement/Adherence** | | | | | | | |
| Client Satisfaction Scale-8[54](CSQ) | Self-report | 8 | .91 | Coordinator | Veterans | | x |
| Service Engagement Scale[56](SES) | Provider Rating | 14 | .76-.90 | Coordinator | Providers | | x |
| Number of PE sessions attended/ Treatment Completion | Medical Record | n/a | n/a | Coordinator | Providers | | x |
| Homework completion | Medical Record | n/a | n/a | Coordinator | Providers | | x |
| Endpoint Interview | Interview | 3 | n/a | Harris | Veterans Providers PS | | x |
| **Social Functioning** | | | | | | | |
| Alabama Parenting Questionnaire[64](APQ) | Self-Report | 9 | .58-.77 | Coordinator | Veterans | x | x |
| Couples Satisfaction Index[65](CSI) | Self-Report | 4 | .98 | Coordinator | Veterans | x | x |
| Endpoint Interview | Interview | 3 | n/a | Harris | Veterans Providers PS | | x |
| **Community Reintegration** | | | | | | | |
| Military to Civilian Questionnaire[55] | Self-Report | 16 | .95 | Coordinator | Veterans | x | x |
| Endpoint Interview | Interview | 1 | n/a | Harris | Veterans Providers PS | | x |

This design will be limited to preliminary intervention refinement and pilot feasibility; given preliminary work with small N's, findings will be qualitative foundations for further research. The type and quantity of data collected will be insufficient for parametric statistics; future studies will assess effectiveness of PEET.

**C.4. Timeline and Management.** As shown in Table 3, Year 1 will include project preparation, recruiting/implementation/analysis of focus group data, intervention manual revision, and training of PS's. Year 2 will include the initial trial of the PEET intervention.

***Table 3. Project Timeline***

| *Task* | *Q1* | *Q2* | *Q3* | *Q4* | *Q5* | *Q6* | *Q7* | *Q8* |
|---|---|---|---|---|---|---|---|---|
| *Hire/Train Staff* | ■ | | | | | | | |
| *Obtain IRB approval* | ■ | ■ | | | | | | |
| *Recruit focus group participants(Veterans and PE Providers)* | | ■ | | | | | | |
| *Implement Focus Groups (Veterans and PE Providers)* | | ■ | ■ | | | | | |
| *Qualitative Analysis* | | | ■ | | | | | |
| *Review Qualitative Data in Collaboration with PE and Peer Support Leaders* | | | ■ | | | | | |
| *Intervention Manual Revision* | | | | ■ | | | | |
| *Train PS's* | | | | ■ | | | | |
| *Implement Intervention* | | | | ■ | ■ | ■ | ■ | |
| *Semi-structured endpoint interviews/measures* | | | | | ■ | ■ | ■ | |
| *Second Intervention Manual Revision* | | | | | | | ■ | ■ |
| *Write/disseminate findings* | | | | | | | ■ | ■ |

As PI, Dr. Harris will be responsible for all aspects of the program; managing staff, implementing focus groups, analyzing data, writing the manual, training/supervising PS's, fidelity ratings, and writing results. Dr. Erbes will serve as the data analyst, analyzing focus group and interview data, and writing results. He will also co-facilitate the Veterans' focus groups. Drs. Polusny and Strom will serve as the PE experts on the team, working with the provider focus groups, assisting in interpreting findings, training PS's, contributing to the manual and training materials, and writing results. Drs. Jain and Hundt will serve as Peer Support experts in interpreting focus group data and writing the intervention manual, as well as results. The study coordinator will assist in administrative aspects of the study, including coordination with IRB, recruiting and consenting participants, coordinating assessments, and participating in qualitative analysis.

AMENDMENT REQUEST FOR IRB REVIEW
Minneapolis VA Health Care System

RECEIVED IRB OCT 4 2017
ENTERED OCT 0 4 2017

| | |
|---|---|
| Date | 10/3/17 |
| IRB Study Number | 4663-B |
| Principal Investigator | J. Irene Harris, Ph.D. |
| Study Title | PE$^2$ - Peer Enhanced Prolonged Exposure |

| Contact | Phone | Mail code | Email |
|---|---|---|---|
| Mary Evans-Lindquist | X4946 | 868-2 | Mary.Evans-Lindquist@va.gov |

RECEIVED IRB OCT 4 2017

1. Please describe the content of your amendment in detail. Include versions and/or dates if applicable.

We are changing the study model from GROUP interventions to INDIVIDUAL interventions/one-on-one appointments.
Changes are as follows:

1. Protocol (Harris_Protocol_5-26-17) has been updated to reflect individual interventions (i.e. one-on-one appointments) and the removal of the Homework Coaching Line and Community Reintegration Group (subjects were not using these interventions).
2. Previous Consent (Approved 06/17/2017) has been updated to reflect individual appointments rather than group attendance any reference to Homework Coaching Line and/or Community Reintegration have been removed.
3. HIPAA –NO CHANGE
4. Participant Handouts: All 4 previous handouts are no longer needed. A SINGLE, new participant handout has been made.

2. What is your reason or justification of making the change?

Feedback from the initial 6 participants strongly indicates that the Group Interventions were not working. Participants stated that they did NOT wish to discuss their PTSD Trauma Event(s) in the presence of other Veterans. Because of this, a number of Study Interventions were not being utilized. Therefore, the study has been modified to better serve the Veterans taking part in this study and to increase the number of study services being used.

3. Are you changing the Principal Investigator? Yes ☐ No ☒

| First name | Last name | Mail code | Phone | Pager | Email |
|---|---|---|---|---|---|
| | | | | | |

| SOP/Training Current?* | Degrees | Department | Employment status | Consenting subjects? | Exposed to hazards? |
|---|---|---|---|---|---|
| Yes or No? | | | Select... | Yes or No? | Yes or No? |

Attach **ALL** of the following (found under *NEW IRB SUBMISSIONS* on the IRB SharePoint):

- Attestation of the Principal Investigator
- Conflict of Interest form specific to Investigator role
- If not previously a PI at MVAHCS, submit a completed Investigator Data Form

a. Please select the current PI's **new** role on the study:
   a. ☐ Current PI will become co-Investigator
   b. ☐ Current PI is to be removed from the study

4. Are you updating the protocol or Investigator's Brochure? **Protocol, only.** Yes ☒ No ☐

Submit both an electronic and a paper copy to the IRB.
☑ Please name the file with IRB number, description of content, & version date, e.g., **1234 protocol 2014-05-01** and email to IRBMN@VA.GOV
☑ Send a paper copy with this amendment

5. Was the change in the research initiated to eliminate an apparent or immediate hazard to subjects? Yes ☐ No ☒
Describe the change, reason, and status of subjects in detail.

6. Could this change affect subjects' willingness to continue to be in this study? Yes ☒ No ☐