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ID: 1147099-1 Primary Care Brief Mindfulness Training for Veterans With PTSD NCT03352011

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Posttraumatic Stress Disorder (PTSD) is highly prevalent in Veterans Health Administration (VHA) primary care patients (~11.5%) and is associated with significant functional impairment, compromised health, and economic costs. Although effective psychotherapies for PTSD are available in specialty mental health care settings, primary care patients do not routinely follow through on referrals for a number of reasons, including fears about stigma or reluctance to disclose emotional problems. When Veterans do engage in evidenced-based PTSD psychotherapies, approximately 1/3 to 1/2 either drop-out or do not adequately respond. Therefore, alternative delivery models are needed to provide primary care patients with treatment for their PTSD symptoms and functional concerns. This application integrates two lines of research: mindfulness training and peer-support services to test a low-stigma intervention in primary care: Primary Care Based Mindfulness Training (PCBMT).

Mindfulness training is a patient-centered approach based on the belief that at the core of every individual is enormous potential for healing. We propose that the skills taught in mindfulness training (e.g., attentional control, present focus, non-judgement, acceptance, and compassion) will impact two specific outcomes for primary care veterans with PTSD: 1) reduce psychosocial distress and dysfunction (including PTSD symptoms) and 2) serve as a gateway to more intensive treatments for Veterans who are not yet willing to discuss their trauma histories or transition to a specialty care environment. Our previous research demonstrated that participation in PCBMT (a 4-session version of Mindfulness Based Stress Reduction [MBSR]) was associated with significant reductions in PTSD severity compared to primary care treatment as usual. However, PCBMT was delivered by a non-VHA expert facilitator and only 55% of Veterans attended the first mindfulness class. Therefore, further protocol refinement is needed before full-scale testing can occur.

We propose that the addition of peer support services to PCBMT will both increase veteran participation in mindfulness training and maximize veteran benefits for the two primary PCBMT outcomes: reduction of psychosocial distress and engagement in additional mental health treatments post-PCBMT. Empirical evidence demonstrates that peer support is associated with improved social functioning and engagement in treatment. Within PCBMT, peers can 1) provide a low-stigma introduction to mindfulness training prior to the first formal class, 2) help “interpret” class material to make it more personally meaningful to Veterans, 3) make ecologically valid suggestions on how participants can apply mindfulness skills to address daily struggles with PTSD-related concerns, 4) decrease social isolation by role modeling healthy social interactions during mindfulness classes, 5) provide hope for recovery by sharing their own recovery story, and 6) connect patients to additional services by acting as peer navigators.

This application aims to refine our existing PCBMT to be co-delivered by VHA mental health providers and peer support specialists and then test important aspects of feasibility to prepare for a future full-scale pragmatic clinical trial. We propose to first gather feedback from mental health providers and peers to further refine PCBMT. For this phase, providers and peers will participate in a PCBMT led by study investigators who are certified MBSR instructors. Next, study staff will gather feedback from the trained providers and peers for further adaptation and implementation. After this, providers and peers interested in being trained as PCBMT interventionists will be trained by study investigators. In the subsequent phase of the project we will conduct a pilot randomized clinical trial (RCT) comparing the refined PCBMT to a primary care-based PTSD psychoeducation group. In this pilot RCT, both treatment conditions will consist of four, 90-minute group sessions co-facilitated by a mental health provider and peer.

The long-term goal of this research is to improve clinical and personal recovery outcomes for Veterans with PTSD. Our immediate goals are to refine PCBMT based on provider, and peer feedback and then test the methods needed to conduct a future full-scale RCT, in accordance with the following aims:

1. Gather VHA mental health provider (n=5) and peer (n=5) feedback to refine PCBMT to a) ensure successful implementation in the VHA setting (including creation of a provider manual and standardized provider/ peer training curriculum), and b) maximize Veteran skill development to reduce psychosocial distress and prepare Veterans for future participation of evidence-based treatment for PTSD.
2. Assess the feasibility of conducting a pilot RCT (N=60) comparing PCBMT to a PTSD psychoeducation group on the following outcomes:
   - **a.** Rates of recruitment and study retention
   - **b.** Participant adherence and retention in treatments, provider and peer treatment fidelity
   - **c.** Participant acceptability (satisfaction, perceived helpfulness) in PCBMT and control condition
   - **d.** Measuring key outcomes to prepare for the future larger trial including: Patient well-being measured by PTSD severity, depression, health promoting behaviors, recovery orientation.

**Study Design**

This study will provide the necessary data to apply for a NCCIH R01 focused on a full-scale trial of PC-based Mindfulness Training for Veterans with PTSD. The feasibility study will be conducted in two phases (Figure 2). Phase 1 will collect qualitative feedback on how best to refine and implement PCBMT from VHA providers and peers. Phase 2 will be a feasibility RCT comparing PCBMT to a PTSD psychoeducation group (EDU). Participants will be recruited from two neighboring sites: primary care clinics at the Syracuse and Canandaigua Veterans Affairs Medical Center.

**C.1.1 Phase 1 Participants:** VHA providers and peers will first participate in PCBMT led by certified MBSR instructors (co-Is Treatman and Bergen-Cico). VHA providers experienced in the treatment of PTSD will be encouraged to participate. We are selecting these providers because 1) they will know what skills (e.g. emotional regulation) will be most useful for future participation in evidence-based treatment (EBT) for PTSD and can emphasize those skills when they deliver PCBMT in Phase 2, 2) they have specialized knowledge about Veterans with PTSD, so will provide the research team with quality feedback to refine PCBMT, 3) they will be able to provide EBT for participants who opt to step-up to specialty care following PCBMT, easing the difficult transition from primary to specialty care. This protocol will involve VHA specialty MH providers delivering care in PC, which we believe will increase feasibility because PC-MHI providers often do not have time to deliver treatment outside the brief (i.e., 30 minute), population-based model. Peers will be VHA certified peer support specialists (PSS) currently employed at the Syracuse and Canandaigua VHA. Based on our recent discussion with providers and peers at our recruitment sites, we estimate that 6 providers and 4 peers will be interested and have to time to participate in Phase 1. We are not eliciting feedback from Veteran patients on how to adapt PCBMT because we already obtained helpful patient feedback in our pilot study.[34]

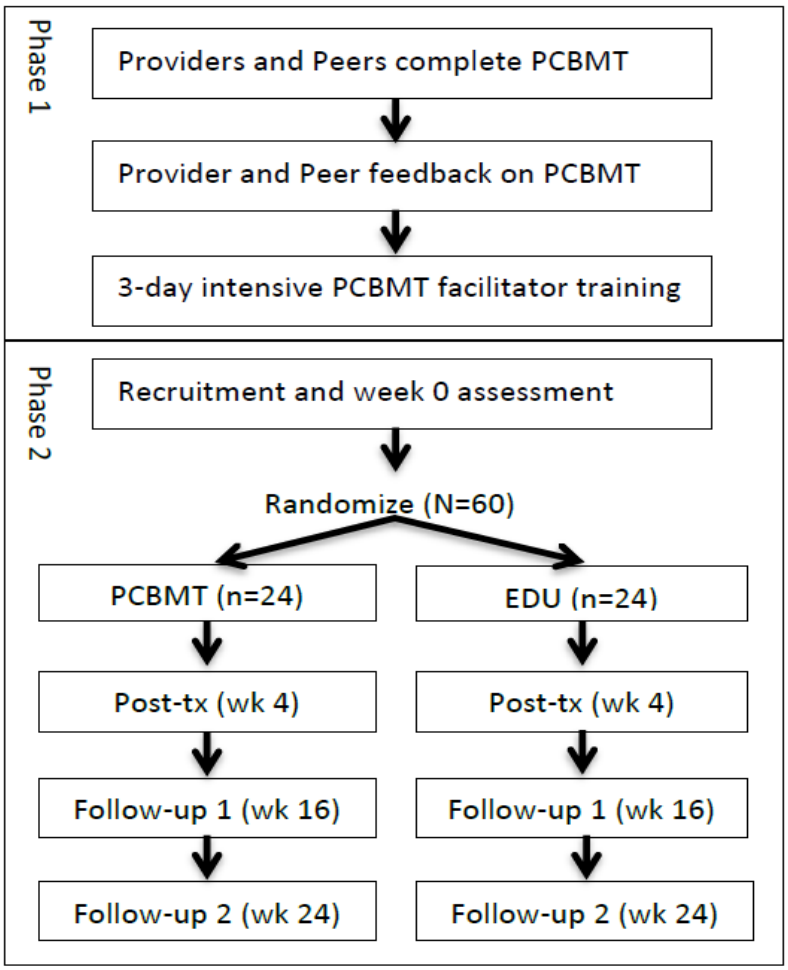

Figure 2. Overview of Study Procedures

**C.1.2 Phase 1 Procedure:** Following completion PCBMT training, staff will conduct one-on-one 30-minute interviews (Appendix 1) to gather qualitative feedback from providers and peers to guide adaptation and implementation. Interviews will cover: perceived helpfulness of PCBMT for Veterans, fit with local VHA practices, suggested modifications to tailor PCBMT to address recovery and improve psychosocial functioning, and defining roles for the provider and peer co-leaders. Interested providers and peers will then be trained to deliver treatment in the RCT, via a 3-day intensive workshop led by Bergen-Cico and Treatman. Providers and peers will be evaluated as competent by Co-I's before serving as RCT providers.

To illustrate what type of modifications may result from this feedback, possible input could include: 1) Spend less time in discussion and more time in sitting meditation. 2) When discussing how to apply a skill (e.g., non-reactivity to stress) to real life, use examples that are specific to PTSD such as struggles with irritability instead of examples of general stressors. 3) The loving-kindness meditation may not be well-received by all patients. After introducing it, ask participants to try it once then suggest that a previously learned, alternative sitting practices (e.g. body scan) can be used by those who don't like it. 4) I found walking meditation to be very helpful. Introduce this before the 4th session. We expect that modifications will adjust specific aspects to make the training more patient-centered and recovery-oriented, while maintaining the core mindfulness pieces.

**C.2.1 Phase 2 Participants:** For the RCT, 60 eligible patients will be enrolled and randomized to PCBMT or EDU. This sample size was chosen because it will require us to recruit 5 participants per month, which is the

rate of recruitment we believe we will need in a subsequent fully-powered RCT (based on a medium intervention effect size and having 3 years to recruit). We have achieved this rate of recruitment in previous studies with similar samples and methods (see B.1., B.4., B.5.).

Primary care patients will be recruited and assessed pre and post intervention and at 16 and 24 week follow-up time points. Each quarter, two months will be spent recruiting and 1 month will be used to conduct the intervention groups. Ideal group size is 6 participants. We anticipate running up three consecutive groups (PCBMT and EDU) at each of the two sites. However, our timeline allows for addition groups as needed. To be eligible, participants must be 1) enrolled in primary care at the Syracuse or Canandaigua VAMC and 2) report significant PTSD symptoms (qualifying criterion A traumatic event plus at least a 31 on the PCL-5). Exclusion criteria are minimized because we seek to include any primary care patients with troubling PTSD symptoms that would normally receive treatment in primary care. Patients will be excluded if they demonstrate symptoms that would not allow them to actively participate in PCBMT: 1) gross cognitive impairment (>16 on the Blessed OMC), 2) suicide attempt or desire to commit suicide in the last month (as measured by P4 screener). To allow the study to isolate the effects of the intervention and ensure patient treatment preferences are honored, patients will be excluded if they 3) have received psychotherapy or change in psychiatric medication outside of VHA primary in the last 2 months, [42-44] or 4) voice a preference to be directly referred to specialty mental health care. Veterans with depression, anxiety disorders, mild TBI, and alcohol/ substance use disorders will not be excluded, because these problems commonly co-occur with PTSD, and individuals with these conditions have previously benefited from mindfulness training.[12] Patients who receive PC-MHI services will not be excluded, as this is part of the usual primary care services that all Veterans can receive.

**C.2.2. Phase 2 Recruitment:** Recruitment will use a method used by the PI in several other studies, including the ones detailed in B.3. and B.4. Veterans who screen positive on the annual PC-PTSD screen or have active PTSD symptoms will be referred by their primary care or PC-MHI providers. Referrals will be facilitated with a case-finding procedure: study staff will use medical record data to identify patients that may be eligible for the study based on the annual PTSD screening given to all VHA primary care patients (PC-PTSD). For patients who screen positive, we will ask their primary care providers if a recruitment letter can be sent. All referred Veterans will be sent a letter introducing the study and then will be screened over the phone. In our pilot study, PC-MHI providers were a major source of study referrals. Referral from VHA peer support specialists will also be encouraged. Based on our prior recruitment experience (see B.4., B.5.) we are confident we can recruit 5 participants per month to reach 60 enrolled in one year.

**C.2.3 Phase 2 Procedures:** The baseline session will an include informed consent process (Appendix 2) followed by administration of study measures. Participants will be screened for cognitive impairment with the Blessed Orientation Memory and Concentration measure[45] and suicidality with P4 Screener.[46] The P4 Screener assessed past history, plan, probability, and preventive factors and then classifies respondents as minimal, lower or higher risk for suicide. At the baseline assessment, higher risk participants will be connected to VHA Suicide Prevention Services prior to continuing them in the study. In addition to assessing primary outcomes and patient safety, we plan to test the feasibility of measuring concerns that commonly co-occur with PTSD (depression, insomnia, pain, and alcohol/substance misuse) and potential mediators of the relationship between receiving mindfulness training and changes in PTSD symptoms and psychosocial functioning (mindfulness and emotion regulation skills). Pilot data in this area will help us plan for a future full-scale investigation of potential mediators. Post-treatment assessment will occur upon completion of the assigned intervention. We will re-assess participants at two follow-up points: 16 weeks and 24 weeks post-baseline. This will allow the opportunity to test the feasibility of retaining participants over time so that in the full-scale future trail we can test if any changes observed post-treatment are maintained over time. Given that an aim of this line of research is for PCBMT to serve as a bridge to other more intensive PTSD treatments, within the full-scaled trial, data from the 24 week follow-up will also allow the ability to measure changes associated with any new treatments initiated post study treatment. All research assessments will be administered by research staff blinded to randomization outcome. Participants will be reimbursed $25 per assessment ($100 total). Randomization will be stratified based on baseline PCL-5 scores (31-40 vs. >40) to equate groups at baseline.

**C.2.4. Measures**

Trial Feasibility will be assessed with several metrics recommended by Leon et al.[47]

<u>Aim 2.a. (recruitment and study retention)</u>

- Number of participants screened per month
- Number enrolled per month
- Proportion of screened participants who are eligible to enroll
- Completion rates of follow-up assessments

Aim 2.b. (participant adherence and retention in treatments, provider and peer treatment fidelity)

- Retention rates in both study interventions
- PCBMT facilitator fidelity. PCBMT facilitators will complete a checklist of essential elements after each class. Co-I's Bergen-Cico or Treatman will observe 25% of all classes and independently rate the fidelity assessment piloted in our earlier PCBMT study (Appendix 3). This assessment was developed based on the guidelines published by Borrelli et al.[48] and documents observations on the delivery and enactment of treatment skills.

Aim 2.c. (intervention acceptability) will be measured at post-treatment by 2 measures.

- The *Client Satisfaction Questionnaire (CSQ)* is an 8-item self-report measure with strong psychometric properties: higher scores are related to treatment completion and symptom reduction.[49]
- *Intervention Acceptability* is a self-report measure created for this study to assess participants' reactions to their assigned intervention, including perceived helpfulness of core intervention components, specific symptoms or functional concerns that improved, and if and how the intervention contributed to meeting the participants' personal recovery goals. Retention (# of sessions attended) will also contribute to measuring intervention acceptability.

Aim 2.d.i. (patient functional status) will be measured at baseline, post-treatment and 16 and 24 week follow-up by 3 measures.

- *PTSD Checklist-5 (PCL-5)* is a 20-item self-report measure that asks respondents to rate how much they have been bothered by DSM-5 PTSD symptoms in the past month.[50] We will administer this with the extended assessment of traumatic events to ensure that the symptoms reported are related to an event that meets criteria for a traumatic event. Early psychometric study of the PCL-5 indicates excellent reliably and validity. A cut point of 31 along plus meeting Criterion A will be required for study inclusion[51] to allow Veterans with subthreshold PTSD to participate. The total score will be used to indicate PTSD severity at each time point. Since participants must wait to begin the intervention until enough participants are enrolled to form a group, the PCL-5 will be re-administered if participants do not attend class 1 within one month of their baseline interview.
- *Recovery Assessment Scale (RAS)* is a 24-item self-report measure that will assesses various aspects of recovery from the perspective of the Veteran, with an emphasis on hope and self-determination.[52] It covers 5 domains: personal confidence and hope; willingness to ask for help; goal and success orientation; reliance on others; and no domination by symptoms. It has high reliability and good concurrent validity.[53]
- *Patient Health Questionnaire-9 (PHQ-9)* assesses 9 symptoms of depression on a 4-point scale.[56] Participants who endorse the suicidality item will also be administered the P4 screener which assess past history, plan, probability, and preventive factors for suicide.[46]
- *Health Promoting Lifestyle Profile II*

Hypothesized mediators will be assessed with 2 psychometrically sound measures at each time point.

- *Self-Compassion Scale- Short Form*
- *Five Facet Mindfulness Questionnaire (FFMQ)* is a 39-item scale measuring observing, describing, acting with awareness, non-judging, and non-reactivity.[62]
- *Emotion Regulation Questionnaire (ERQ)* is a 10-item self-report measure designed to assess the use cognitive reappraisal and expressive suppression.[63,64]

**C.2.5. Intervention Conditions:** The PCBMT and EDU groups will share several structural features: both will be 1) located in primary, 2) co-led by a licensed mental provider (psychologist, clinical social worker, mental health counselor) and a Veteran peer support specialist, 3) consist of four 90-minute weekly sessions, 4) Peers will meet briefly (30 minutes) to guide participants in completing the Personal Health Inventory (PHI) prior to starting their assigned treatment condition. The PHI was developed by the VHA Office of Patient Centered Care and Cultural Transformation and is a commonly used by VHA peers support specialists. The PHI will allow participants to engage in self-reflection regarding what matters most to them in their lives (Appendix 4). This discovery process will inform the identification of personal health goals that align with their values and priorities, and thus ideally increase patient activation and engagement. This process supports the delivery of personalized, proactive, and patient-driven care. Completed PHIs will be shared with the group facilitators to help personalize the intervention. 4) During the meeting with the peers, participants will also watch a video to orient them to their assigned condition. PCBMT participants will watch the 7-minute "What is Mindfulness?" video from the VHA OPCC.[38] EDU participants will watch two 3.5-minute whiteboard videos "What is PTSD?" and "Treatment: Know Your Options" from the VHA National Center for PTSD.[65] 6) Printed instructions for homework will be provided and participants will be asked to submit simple forms during each class that record the type and number of minutes of at home practice completed. For PCBMT this will include time spent in

formal and informal meditation. 7) Peer co-leaders will act as peer-navigators to help participants connect to any additional MH, case management, or medical care needed.

PCBMT is a manualized intervention that is a brief adaptation of MBSR (Table 3, appendix 5). It was developed by Co-I, Dr. Treatman over the last decade and is regularly delivered to community members. It's delivery to Veterans is described in B.1. PCBMT consists of four 90-minute group classes (360 total minutes of classes). Instruction encompasses sitting meditation, body scan, moving meditation, gentle yoga, and group discussion on topics such as non-judging, patience, trust, non-striving, acceptance, and letting go. Drs. Bergen-Cico and Treatman will provide weekly group supervision for the mental health providers and peers that are delivering PCBMT. The aim of supervision is to strengthen program quality through discussion of how PCBMT is being enacted, processing challenges as they arise, and modeling skillful inquiry. Supervision is also an opportunity for providers and peers to examine their PCBMT teaching and facilitation skills. In addition, the PI will meet with all peers delivering PCBMT for an additional weekly supervision that focuses on peer-specific roles and challenges including completing the Patient Health Inventories and peer treatment navigation. The PI will dedicate the time to meet the on-going educational needs of peers (e.g., additional training in PTSD concerns or treatment options), advise on non-specific treatment factors (e.g., active listening skills), and how best to use their own lived experiences to help participants in their recovery. The PI is currently providing peer supervision for the study described in B.3 and is the clinical supervisor of a peer who delivers non-research services in primary care.

Table 3. Primary Care Brief Mindfulness Training Session-by-Session Content

| **Group #: Theme** | **Session Content** | **Weekly Assignment *** |
|---|---|---|
| #1: There is more right with you than wrong with you | • Introduction (expectations, ground rules)<br>• Brief exercise: "The Well" (Why are we here?)<br>• What is mindfulness? (foundation, intention & commitment, integrating into daily living)<br>• Raisin meditation<br>• Body Scan – 20 minutes<br>• Brief sit with breath awareness | • 20 minute body scan daily and mini-sitting on CD<br>• Using breath awareness in stressful situations<br>• Mindful eating<br>• Mindfulness of routine activities<br>• Daily log of minutes spent on various mindful activities<br>• Readings: "Incline your Mind" by the group facilitator; Chapters 1-3 of "Full Catastrophe Living" (Kabat-Zinn, 1990) |
| **#**2**:** Perception and creative responding | • Review past week (issues with meditations, seeing change, difficulties)<br>• 20 minute sitting – breath awareness, physical sensations, sounds<br>• Stress reactivity vs. response (using mindfulness to short circuit reaction)<br>• Yoga and awareness | • Alternate stretching/mini-body scan* with 20 minute sitting<br>• Capturing pleasant & unpleasant moments<br>• Using the breath to slow things down<br>• Awareness of what we take in (substances, sounds, violence)<br>• Daily log of minutes spent on various mindful activities<br>• Readings: "Thoughts on Thoughts". "Why Meditate" NY Times articles by Dr. Treatman. |
| #3: Communication, expression of feelings, maintaining one's center in interpersonal relationships | • Brief sitting<br>• Review of past week<br>• Communication styles, separating fact from story, awareness of emotional reaction, focus on content<br>• Mindful listening exercise<br>• Introduce Metta meditation | • Alternate "Metta" with any other 20 minute meditation<br>• Awareness of difficult communications (observing reactivity, using the breath to try to minimize reactivity)<br>• Observation of diet (underlying emotions, slowing down)<br>• Daily log of minutes spent on various mindful activities<br>• Readings: Cultivating Self-Compassion" and "Mindfulness & Mastery" by Dr. Treatman. |
| #4: Making this practice your own | • Yoga followed by body scan<br>• Review of past week | • Final Reading: "Continue Down the Mindful Path" by Dr. Treatman. |

| | |
|---|---|
| • Introduce walking meditation<br>• Brief sitting, loving-kindness | • Resources for continued practice. |

* Participants are asked to use the provided 2-minute Chill Out audiorecording at least once daily on all weeks.

EDU is a class designed to provide a supportive environment for learning about PTSD-related issues and to help Veterans determine what recovery strategies will be most helpful for them. Session themes include "Civilian Readjustment and PTSD," "Trust, Safety, and Healing" and "Treatment Strategies." This group is currently delivered at the Syracuse site (co-led by a licensed mental health provider and a peer) and a very similar class is delivered at the Canandaigua site. Therefore EDU is an active, PTSD-specific, primary-care based "treatment as usual" comparison group (Appendix 6). These classes were developed locally and no research has been conducted on them. However, psychoeducation for PTSD is often described as an ideal introductory intervention for individuals first entering treatment.[66]

**C.3 Analysis Plan**

Aim 1: Gather VHA mental health treatment provider and peer feedback to adapt PCBMT. Co-I Beehler will oversee Aim 1 analyses using a Rapid Assessment Process (RAP).[67] This approach is ideal when data needs to be collected and analyzed in one year or less, when only key informants will be interviewed, and when analyses will be deductive.[67] The PI and project coordinator with conduct interviews together with the PI primarily asking questions and the coordinator typing detailed field notes to document responses. A template will be created with a domain name for each interview question (e.g., activating patients, peer roles). The PI, coordinator, and Dr. Beehler will review the first few sets of field notes collaboratively and summarize content into the domains on the template. After consistency is reached, coders will review the remaining field notes (≈7) independently. Led by Dr. Beehler, coders will then meet again to analyze summaries and identify suggestions for revisions or aspects seen as helpful that should be maintained within each domain. The PI and Co-Is Pigeon, Treatman and Bergen-Cico will then meet and collectively decide how to modify the protocol. Modifications will only be made if the resulting PCBMT protocol is: 1) feasible to deliver in VHA primary care and 2) stays true to the core mindfulness components. Modifications will be prioritized that are expected to 3) help Veterans develop skills for PTSD symptom management, 4) increase the training's patient-centeredness, and 5) will affect multiple qualitative domains.

Aim 2: Conduct a pilot RCT (N=60 randomized, n=48 completers) comparing PCBMT to EDU.

**2a.** As this trial will provide us with feasibility information for a larger trial, we will describe the number of participants screened and enrolled per month, proportion of screened participants who are eligible to enroll, completion rates of follow-up assessments, retention rates in study conditions, and the rate and timing of patient drop-out. Recruitment over twelve months will be displayed by plotting the cumulative number of patients enrolled into our study and compared to the anticipated rate of recruitment. Graphs will also be utilized to display rates of intervention and assessment retention at each measurement time. Ninety five percent confidence intervals will be calculated and used in design considerations of a larger trial.

**2.b.** Participant retention rates in both study interventions will be described with mean, standard deviations and confidence intervals. PCBMT facilitator fidelity with be described quantitatively with the mean number of items endorsed on fidelity checklists. Also items that had lower fidelity will be described to inform future PCBMT training curriculums. Inter-rater reliability will be reported for the 25% of classes rated by an expert observer.

**2.c.** Veteran acceptability (satisfaction, perceived helpfulness, treatment retention*):* Total CSQ scores and scores on individual CSQ items and Intervention Acceptability items will be described with means, standard deviations and confidence intervals to understand the satisfaction and acceptability in each condition.

**2.d.i.** Patient well-being measured by PTSD severity, depression, health promoting lifestyle behaviors and recovery orientation will be will be described with means, standard deviations and confidence intervals at each time point by condition. To show central tendency, variation and potential trends over time, means and 95% confidence intervals will be plotted across time for each condition. Additional line plots connecting means across time will overlay the confidence intervals to help illustrate trends. We will also generate an effect size at post-treatment and at each follow-up assessment. Effect sizes will be calculated by dividing the mean difference between conditions by the pooled standard deviation. Then, 95% confidence intervals will be calculated on the effect size by using the non-central t distribution method discussed by Cummings.[68] Graphical methods will be used to plot effects and associated confidence intervals across time which will be used to help design a larger trial. Multi-level modeling will be used to examine group by time effects for each outcome.

**Handling Missing Data.** Multiple Imputation (MI) will be used for missing data.[69-71] Missing values for variables are predicted using existing values from other variables. These predicted values, called imputes, replace the

missing values resulting in a full analyzable data set. This process is performed multiple times resulting in many data sets each of which is then analyzed to produce multiple sets of results. The results are then summarized to produce a single solution.[70] The advantage of MI over other methods, such as last observation carried forward, mean substitution, and expectation maximization, is that it preserves associations with other variables, adds variability during the imputation process and accounts for variability due to multiple imputes resulting in efficient and unbiased parameter estimates.[71] Valid critics of MI pertain to the variables used to fill-in the missing values, which may differ among analysts and lead to biased parameter estimates.[72,73] To address this criticism, we plan to use recommendations from Schafer[74] and VanBuuren[75] as well as practical guidelines in our imputation model. Our guideline encompasses inclusion of all items from the respective measure, variables that are correlated with the analysis variable and variables that predict the missingness.[70]