



Opinion paper

Rationale and design of an efficacy study of Group Prolonged Exposure for PTSD



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ABSTRACT

Introduction. Among health problems in the Veteran population, the most common is posttraumatic stress disorder (PTSD) and its effect on the quality of life. Prolonged Exposure therapy, based on emotional processing theory, is a first-line treatment for reducing PTSD symptom severity when delivered in an individual format, and its efficacy is well established. The primary objective of this study is to establish the efficacy of prolonged exposure delivered in a small 3-person group modality. Quality of life should improve with decreases in PTSD symptoms such as sleep disturbance, irritability, and hypervigilance. Stigma is associated with hesitation in seeking treatment and treatment dropout. A secondary objective is to measure the effect of group treatment on reducing the stigma surrounding PTSD. **Methods/design.** This study is a randomized controlled trial testing the efficacy of Group Prolonged Exposure (PE) for reducing PTSD symptom severity and improving quality of life in male Afghanistan and Iraq Veterans. All participants are randomly assigned to receive Group PE or Group Present-Centered Therapy (PCT) for 10-weekly, 90-min sessions. Group PE focuses on processing trauma memories, while the goal of Group PCT is improved psychosocial functioning through management of current stressors. The primary outcome is improvement in CAPS-5 PTSD symptom severity scores and quality of life measures (WHO-QOL and SF-36) from pre-treatment to post-treatment, 3-months post-treatment, and 6-months post-treatment. A secondary outcome is reductions in perceived self-stigma of mental illness based on the Stigma Scale at baseline and follow-up points. This study is designed to expand access to this first-line treatment for PTSD by delivering PE in a small group modality while conforming to the individual PE protocol, with group treatment reducing perceived stigma of mental illness.

1. Introduction

Since 1990, 3 million U.S. soldiers were deployed to the Middle East [1] and 2.2 million in Afghanistan and Iraq (OEF/OIF/OND). Currently, U.S. soldiers are serving in Afghanistan's Operation Freedom's Sentinel and in Iraq, Syria and the Levant under Operation Inherent Resolve. Among health problems in this population, the most common is post-traumatic stress disorder (PTSD). The lifetime prevalence rate for PTSD among civilian populations is approximately 6.8% [2], 31% among Vietnam Veterans, and, among OEF/OIF/OND Veterans it is much higher at 23% [3]. Enhancing access to treatment is a significant priority.

Exposure therapy is a first-line treatment for PTSD when delivered in an individual format [4] and its efficacy is well established [5,6]. While support for the efficacy of group exposure therapy is growing [7–11], studies of group-delivered exposure therapy typically deviate widely from Foa et al. [12] individual Prolonged Exposure (PE) protocol, particularly the imaginal exposure component [13]. For example, group size may limit members to 1 or 2 in-session imaginal exposures [14]; imaginal exposure may consist of imagery rehearsal based on recurrent nightmares [15]; exposure may be through writing about the traumatic event [16]; imaginal exposure is conducted in individual sessions while in-vivo exposure is a group exercise [17]; or another variation of Foa's PE protocol. Additional research is needed to further support the

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efficacy of group exposure, particularly forms that have high fidelity with individual PE. Further, a deeper understanding of the effect of treatment on perceived stigma is necessary to gain a greater understanding of the challenges this population faces and how these challenges may be improved through Group PE treatment.

Why group. Group delivery of treatment provides advantages over individual delivery, including increased efficiency of providing treatment to a population, but most importantly group exposure therapy draws on a number of curative factors that supplement the treatment intervention. Some curative factors outlined by Yalom [18,19] include Universality, Altruism, Imparting Information, Corrective Emotional Experience, and Catharsis. The factor of Universality is one of the most apparent to PTSD clients when individuals realize, after hearing the detailed stories and symptoms of others, they are not “crazy,” recognizing others struggle with similar problems and knowing there is better understanding of difficulties in coping with PTSD among others with PTSD. The factor of Altruism and Imparting Information both emerge when group members develop compassion for one another on hearing the trauma narratives of other Veterans. They can identify with one another, do not blame their peer, and consequently stop blaming themselves, resulting in a Corrective Emotional Experience. Although the Catharsis factor outlined by Yalom is based in psychodynamic theory, it essentially occurs during imaginal exposure, much like in the PE protocol, where Veterans release the intense emotions of the trauma. The therapist witness in individual PE is powerful, and even more so is the witness of their peers. Mott et al. [20] note concerns regarding re-traumatization in group-based exposure are lacking empirical support. Mott and colleagues [20] examined Veteran's perspectives on the tolerability of group-based exposure therapy for PTSD and reported reductions in PTSD symptoms without experiencing symptom exacerbation over the course of treatment. Further, Veteran group members described hearing other group members' trauma accounts served to normalize their own experiences, and indicated the feedback from group members as the most helpful aspect of treatment. In terms of concerns regarding the dosage of imaginal exposure, Nacash et al. [21] compared traditional 12-session 90-min individual PE sessions (40-min in-session imaginal exposure) to 60-min sessions (20-min in-session imaginal exposure) establishing 20-min imaginal exposure as noninferior to 40-min imaginal exposure in terms of reduction in PTSD symptoms.

Three-person groups and group drop-out. Sripada et al. [9] study found group psychotherapy members were more likely to persist with psychotherapy for PTSD than those treated individually, and Barrera et al. [13]. meta-analysis found no difference in attrition rates between individual and group exposure treatment for PTSD. In order to keep with the study protocol, in the event one group member drops out, the rest of the treatment sessions will be 60-min sessions; if 2 members drop out, the rest of the treatment sessions will be 30-min sessions.

Most group exposure studies have used wait list controls (WLC). However, one study's comparator group was a present-centered therapy group (PCT group) [14]. Treatment consisted of 30 weekly sessions plus 4 monthly booster sessions for both the trauma-focused group and the PCT group. The trauma-focused group consisted of cognitive restructuring and 2 in-session imaginal exposures. These researchers report reductions in PTSD for both groups with no between-group differences. Similar findings were reported in Classen et al. [22] study comparing present-focused group psychotherapy and semi-structured trauma-focused group psychotherapy. In terms of WLC studies, group exposure therapy was significantly better at reducing PTSD symptoms. Castillo [8] was the only trial to provide 4 repeated in-session imaginal exposures for each participant randomized to 16 weeks of group therapy that also included cognitive and skills components. Not surprisingly the trauma-focused group showed significantly greater reductions in PTSD symptoms compared to the WLC, and established the safety of providing exposure therapy in a group format. Beck et al. [23] randomized subjects to write the trauma account in session or to a WLC, and found similar results as Castillo [8]. Another study by Beidel et al. [24] randomized

subjects to individual exposure treatment plus social emotional rehabilitation group, or individual exposure treatment only, and found no between-group differences on PTSD symptoms. The preponderance of evidence so far is that PE delivered in group does not differ from other group treatments for PTSD. However, as noted, most studies of group therapy did not provide the full dosage of imaginal exposure, provided it in individual sessions, or as written. This study provided 7 in-session exposures.

Stigma. There is substantial stigma surrounding PTSD and other mental health illnesses which may interfere with treatment seeking and could potentially increase treatment dropout. Commonly perceived stereotypes of PTSD include labels like “dangerous”, “violent”, “crazy”, and when internalized are associated with low self-esteem and quality of life [25,26]. Among active duty soldiers, only about half seek mental health treatment [27–29]. Hoge et al. [30] investigation of barriers to mental health treatment revealed the most common concerns among post-deployed OEF/OIF soldiers was being “perceived as weak”; “being treated differently by unit leadership”; and “members of my unit having less confidence in me.” Anti-stigma interventions to reduce public stigma (e.g., psychoeducation about mental health) have been used with some success [31]; however, few studies have investigated the impact of treatment on perceived stigma.

Link and colleagues [32] modified labeling theory posits negative external perceptions or public stigma affects a person's internal sense of self resulting in self-stigma [33] or the fear of losing self-respect or self-esteem by seeking help [34]. Wade et al. [34] tested the effects of one session of group counseling on self-stigma for seeking help and found that participants reported significantly less self-stigma following the session; and self-stigma predicted the intention to seek help following the session. Likewise, Mittal et al. [35] suggest interacting with others may counteract stereotypes thus averting self-stigma. Stigma is also linked to treatment dropout [36]. Gould, Greenberg, and Hetherington [37] suggest clinicians ask about treatment attitudes (stigma) as a tool for informing treatment and improving outcomes through a better understanding of perceptions about mental illness, which may have the benefit of reducing treatment dropout.

This randomized controlled trial will determine whether Group PE produces improvements in PTSD symptoms from baseline to post-treatment, and at 3- and 6-month follow-up, and whether Group PE improves self-stigma related to a diagnosis of PTSD.

2. Methods

2.1. Study design

This study is a randomized controlled trial (RCT) with blinded assessment. Participants are male OEF/OIF/OND Veterans with PTSD who are eligible and agree to participate in the study. Veterans are randomly assigned to Group Prolonged Exposure (Group PE) or Group Present-Centered Therapy (Group PCT). The primary outcome is improvement in PTSD symptom severity as measured by change baseline to follow-up on the Clinician-Administered PTSD Scale for DSM-5 [38] (CAPS-5).

2.2. Research goals and hypotheses

The primary aim of this RCT is to establish the efficacy of delivering PE in a group format in order to expand options for first-line exposure therapy utilization. Dr. Foa's individual PE protocol [12] was adapted to guide this Group PE intervention. Our main hypothesis is that the Group PE treatment will significantly lower severity of PTSD symptoms compared to the control Group PCT, and an improvement in quality of life as measured by two instruments, WHO Quality of Life-BREF [43] and the Health-Related Quality of Life Medical 36-item Short-Form [44]. A secondary hypothesis is that perceived self-stigma associated with having a PTSD diagnosis and seeking treatment will significantly

decrease for subjects in Group PE compared with subjects in the Group PCT. Wade and colleagues [34] note group therapy may lower self-stigma because (1) group members are exposed to the therapy process with others, who may be peers; (2) PTSD symptoms will be normalized when hearing another's story, pain, or struggle; and (3) group members may then feel free to talk to other Veterans about the benefits of group therapy.

2.3. Sample size and power calculations

For a simple power analysis for the improvement in total CAPS-5 scores between Group PE and Group PCT, using the variability in preliminary data for the CAPS-5 from our study [39], the common standard deviation (SD) for pre and post therapy in the Group PE and Group PCT was 10.3. Assuming a moderate pre-post correlation of 0.7, the expected SD for the improvement in total CAPS scores will be 7.9. A sample size of 54 per arm is adequate to detect a 4.3 or more point difference in Total CAPS-5 scores between the two therapies with 80% power and $\alpha = 0.05$.

3. Study entry procedures

3.1. Recruitment and screening

Male OEF/OIF/OND Veterans are recruited from specialty clinics at a southwestern VA Hospital, Community Based Outpatient Clinics, Vet Centers, and from the community via newspaper advertisements. And, in addition to networking with Veteran's groups, the PI, Study Coordinator, and RA regularly attend clinical staff meetings of likely referral programs to present/recap the study and provide study materials. Interested Veterans are first screened with the Mini-Mental Status Exam [40] for cognitive impairment. Excluded are those with a score below 20 indicating cognitive impairment.

Inclusion Criteria. Male OEF/OIF/OND Veterans with a current diagnosis of PTSD or experiencing symptoms due to any type of trauma are invited to participate in the study if at least 3 months removed from the traumatic event; have a clear memory of the trauma sufficient for constructing a scene to be used in exposure; are willing to put off other psychotherapy for PTSD during the treatment phase of the study; and, for those taking psychotropic medications, be on a stable medication regimen for a minimum of one month prior to entering the trial. Psychotherapy for other problems, brief check-ins with an existing therapist, and attendance at self-help groups is allowed.

Exclusion Criteria: The target population is OEF/OIF/OND combat veterans. Women Veterans are excluded because of small numbers meeting this criteria in NM (around 1430). Veterans are assessed with the MINI International Neuropsychiatric Interview [41] and those diagnosed with a current psychotic disorder, mania or Bipolar disorder, suicidal or homicidal ideation, or recent self-mutilation, or moderate or severe alcohol or drug use disorder with less than 3 months remission are excluded from the study.

3.2. Informed consent, enrollment and randomization

Appropriate candidates are scheduled for a face-to-face intake assessment. Enrollment in the study, informed consent, and randomization are at intake. A randomization table was generated by the study statistician to randomize the groups instead of individual subjects. Following assessment, the 1st study subject is randomized based on the randomization table to either Group PE or Group PCT; the next 2 qualifying subjects (study subjects 2 and 3) are assigned to the same group as the 1st subject in order to have 3 group members in each group.

3.3. Data collection

Outcome measures are completed at study enrollment (pre-treatment) and at 3 follow-up points, post-treatment, 3-months, and 6-

months post-treatment. Within group changes in self-reported PTSD symptoms, depression symptoms, and group cohesion are measured by collecting this information at each treatment session. Covariates, including demographic variables, substance use, and comorbid disorders, are considered as moderators. Following is a schedule of assessments.

Covariates	Items	Minutes	Pre Tx	Post Tx	3-Mo	6-Mo
Demographics	26	10	X	-	-	-
^a MINI	-	60	X	-	-	-
^b SCID-5-PD	-	30	X	-	-	-
Outcome Measures						
^c CAPS-5	30	60	X	X	X	X
^d WHOQOL-BREF	32	5	X	X	X	X
^e SF-36	36	10	X	X	X	X
^f Stigma Scale	28	10	X	X	X	X
^g SSOSH	10	5	X	X	X	X
In-session						
^h PCL-5	20	5	At each group session			
ⁱ PHQ-9	9	2	At each group session			
^j GCQ	12	2	At each group session			
^k GSRs	4	1	At each group session			

^aMINI International Neuropsychiatric Interview [41].
^bSCID5-PD = Structured Clinical Interview for DSM-5-Personality Disorders [42].
^cCAPS-5 = Clinician Administered PTSD Scale for DSM-5 [38].
^dWHOQOL = World Health Organization Quality of Life-BREF [43].
^eSF-36 = Quality of Life-Short Form-36 [44].
^fStigma Scale [45].
^gSSOSH = Self Stigma of Seeking Help scale [46].
^hPCL-5 = PTSD Check List for DSM-5 [47].
ⁱPHQ-9 = Patient Health Questionnaire-9 [48].
^jGCQ-Group Climate Questionnaire [49].
^kGroup Session Rating Scale [50].

4. Outcome measures

4.1. PTSD outcome measures

The Clinician Administered PTSD Scale for DSM-5 [38] (CAPS-5) is a structured diagnostic interview, and is the gold-standard for diagnosing PTSD. The primary outcome is improvement in CAPS-5 PTSD symptom severity, which will also be used to compute clinical response defined as (1) improvement in severity of 10 + points, (2) loss of diagnosis (e.g., no longer meeting DSM-5 criteria), and (3) remission with loss of diagnosis plus a score below 20.

4.2. Quality of life outcome measures

The WHO Quality of Life-BREF [43] measures quality of life (QOL) and satisfaction across 4 domains: physical health, psychological health, social relationships, and environment, plus an overall QOL score. The WHOQOL-BREF has good to excellent psychometric properties of reliability and validity [51].

The SF-36 (Health-Related Quality of Life Medical 36-item Short-Form [44]) measures physical functioning, role limitations/physical, role limitations/emotional, energy/fatigue, emotional well-being, social functioning, pain, and general health. The SF-36 has excellent validity and reliability [52].

4.3. Stigma outcome measures

The Stigma Scale [45] measures perceived stigma of mental illness along 3 dimensions: (1) discrimination-negative reactions of other people, (2) disclosure-fear of what others will think, and (3) positive aspects-acceptance and positive changes. Cronbach's alpha for this scale was 0.87.

The Self-Stigma of Seeking Help Scale (SSOSH [46]) measures a single construct, how much self-esteem is being threatened by seeking

mental health treatment. Internal consistency and concurrent validity range from 0.80 to 0.92 [46,53].

4.4. Quality control

The psychology technician (psych tech) administers assessments and is kept blind to randomization. Recruitment and scheduling subjects for testing, randomizing eligible subjects, tracking and scheduling follow-up assessments are the responsibility of the research assistant.

Reliability monitoring. Quality control begins with the exact, standardized training of the psych tech. Twelve study subjects were recruited specifically for training the psych tech on the assessments. All study assessment sessions are audiotaped, and fidelity monitoring is conducted on at least 15% of the assessments. Throughout the study, data collection (baseline, post-treatment, 3- and 6-month follow-up assessments, and in-session assessments), data quality and completeness, and data entry are carefully verified. Data entry screens are programmed with upper and lower limits for each field, field length limits, and data type (numbers, text) limits, and there was double entry of all data.

5. Interventions

5.1. Therapist training and supervision and treatment fidelity

The PE protocol therapist is trained to standard by a National PE Trainer. The Veterans Administration (VA) national dissemination initiative trained 16 VA clinicians as Prolonged Exposure therapy trainers/consultants to train/certify other VA clinicians in delivery of PE. Therapist training required a commitment to attend a 3-day training and participate in weekly telephone consultations with a PE expert over the course of 6 months consulting on 2 training cases. The PCT therapist is trained to standard by the PI with experience in the Group PCT protocol. Both protocols are manualized and include a checklist to follow for each treatment session. All treatment sessions are videotaped and two video-recordings are selected at random from each set of 10 group sessions and reviewed by the PI, with feedback given to the study therapist during weekly supervision. The therapist notes protocol problems/inconsistencies/irregularities on the checklists, which are also reviewed/resolved during supervision.

5.2. Group Prolonged Exposure

This protocol is a modified version of Dr. Foa's individual Prolonged Exposure Therapy for PTSD [12] and Dr. Castillo's Group-Delivered Cognitive/Exposure Therapy [8], with the goal of developing a stand-alone Group PE treatment exclusive of other treatments and comparable to individual exposure in Foa's PE model. In individual PE, the trauma is recounted with minimal guidance, particularly the first 2 imaginal sessions, but later may include occasional prompting for sensory, cognitive, or emotional details to promote engagement, occasionally providing reinforcement and support, and promoting continued repetitions within the designated time frame. In Group PE, the therapist monitors the time, and guides the group member to include details such as thoughts, feelings, sensations, visual images, sounds, and smells [8] within the designated 20-min time frame. Following is a brief session-by-session description and comparison of the Individual PE (IPE) and Group PE (GPE):

Session 1:

- IPE/GPE: Overview of Program and Treatment Procedures
- IPE/GPE: How PTSD develops and gets worse
- IPE/GPE: Trauma discussion and identification of Index Trauma
- IPE/GPE: Present Rationale for Exposure Therapy
- IPE: Introduce relaxation technique

- IPE: Assign homework: listen to session recording, practice relaxation
- GPE: Assign homework: listen to session recording

Session 2:

- IPE/GPE: Discuss Common Reactions to Trauma
- IPE/GPE: Present Rationale for In-vivo Exposure
- IPE/GPE: Introduce/define Subjective Units of Distress Scale (SUDs; 0–100 scale)
- IPE/GPE: Generate anchor points and construct In-vivo Hierarchy
- IPE/GPE: Assign SUDs level to each exposure situation/item
- IPE/GPE: Assign In-vivo homework, 1–3 low-to-moderate SUDs level situations
- IPE/GPE: Assign homework: Listen to recording of Session 2

Session 3–10: Individual PE.

- Review rationale for imaginal exposure
- Imaginal revisiting of the trauma memory
 - o Imaginal begins with 45–60 min in the first session, 45 min in the following sessions, until the focus shifts to hot spots, which are typically 30 min, as is the final imaginal session.
 - o During worst parts of trauma (hot spots), intervene to slow down speeded-up narratives, return to the details of the trauma
 - o Titrate the experience if needed; if over-engaged, instruct patient to open eyes, use past tense, make reliving more conversational; if under-engaged, ask questions designed to encourage fuller engagement
 - o Elicit SUDs ratings every 5 min
- Post-exposure processing 15–20 min
 - o Discuss habituation (or lack thereof) with Veteran
 - o Ask what emerged or seemed important during the imaginal exposure
- Review In-vivo homework records and provide feedback
- Assign Homework
 - o Listen to recording of entire imaginal exposure once a day
 - o Introduce/assign the imaginal exposure record forms
 - o Continue/assign In-vivo exposure homework

Session 3: Group PE - As there are time limitations in GPE for reviewing in-vivo homework, session 3 is devoted to assuring each group member is proficient in how to choose, track, and execute his in-vivo homework.

- Detailed Review of In-vivo homework experience/explore any obstacles
- Continue Building the In-vivo Hierarchy for each group member
- Assign Homework
 - o Practice situations selected for In-vivo exposure
 - o Listen to recording of Session 3 one time
 - o Review In-vivo list of avoided situations and add new situations/objects

Session 4–10: Group PE.

At the first imaginal exposure a volunteer is solicited to go first and second. At the next imaginal, the second volunteer will go first, the third, second, the first volunteer goes last. This pattern is used for all imaginal sessions.

Session 4	Session 5	Session 6	Session 7	Session 8	Session 9	Session 10
1st						
volunteer2nd3rd1st2nd3rd1st2nd	volunteer3rd1st2nd3rd1st2nd3rd	volunteer1st2nd3rd1st2nd3rd				

- Briefly review rationale for imaginal exposure
- Imaginal revisiting of the trauma memory for 20 min per group member
- o Prompt group member to stay in the present-tense if needed
- o During worst parts of trauma (hot spots), if narrative is speeded up, intervene to slow it down, returning to the details of the trauma
- o Therapist monitors the time to ensure each group member has 20 min to describe the trauma
- o Titrate the experience if needed; if over-engaged, instruct patient to open eyes, use past tense, make reliving more conversational; if under-engaged, ask questions designed to encourage fuller engagement
- Elicit SUDs ratings every 5 min. At end of the 20-min trauma narrative, ask member to open his/her eyes, ask how he/she is doing, ask group members how they are doing, begin the 2nd group member's imaginal exposure; repeat this for third group member
- Post-exposure processing 5 min
- Briefly review In-vivo homework records and provide feedback
- Assign Homework
 - o Listen to recording of entire imaginal exposure once a day
 - o Introduce/assign the imaginal exposure record forms
 - o Continue/assign In-vivo exposure homework

Group PE Framework: The Group PE sessions are manualized and include a checklist for each session. Group members are reminded there is a reasonable expectation of privacy with regard to what is said in group, to listen with respect, and feedback is accepted during processing. Each group member is provided with a digital recorder to record educational sessions and their trauma narrative. During exposure, sessions 4–10, the therapist collects the digital recorders and individually and separately records trauma accounts. Each group member in turn is reminded of their identified index trauma narrative's beginning and ending points.

Group members are then given these instructions:

- You'll have 20 min to verbalize your trauma
- I'll guide you during the exposure, to prompt sensory experiences and slow the pace at the most difficult points in your trauma narrative
- I'll ask you to provide SUDs ratings about every 5 min; try to quickly give a rating without leaving the image
- We'll have 5 min to process any thoughts and feelings that come up for you
- I'll manage the time to make sure we stay on track

In session 10, a brief 15-min imaginal exposure is conducted individually with each group member. The rest of the session is devoted to evaluating each group members progress, reviewing the therapeutic techniques, and answering questions on management of active symptoms. Recommendations for continued application of strategies, such as daily journaling and direct confrontation of feared objects, activities, or situations (in-vivo exposure) are made.

A 90-min group consists of:

	Group PE		Individual PE
Imaginal exposure 20 min	20 min x 3	60 min	45 min
Process imaginal exposure	5 min x 3	15 min	20 min
Group process, imaginal and in-vivo		5 min	0 min
Assign in-vivo homework		<u>10 min</u>	<u>25 min</u>
		90 min	90 min

5.3. Group present-centered therapy

PCT is a structured treatment with the goal of improved psychosocial functioning through management of current stressors. It is non-trauma

focused and is not based on a cognitive-behavioral therapy framework. The aim of PCT is to alter current maladaptive relational patterns and behaviors by providing psychoeducation regarding the relationship between trauma and current relational patterns and behaviors, and teaching the use of problem-solving strategies to address present-life problems [14,54,55]. Frost et al. [56] meta-analysis found PCT to be a viable evidence-based treatment for PTSD.

PCT Framework: The manualized Group PCT sessions include a checklist for each session. Sessions 1–3 are didactic and include the rationale for Group PCT, psychoeducation about typical reactions to traumatic experiences, discussions about other consequences of PTSD, and outlining safety nets. Sessions 4–10 focus on the identification and discussion of each Veterans' problems and goals. Veterans use the Daily Record form, a small notebook, or their smart phones to monitor and record day-to-day activities, problems, and stressful situations for discussion in group. While the therapist in this condition may provide suggestions and advice about coping with symptoms and stress, there will not be any systematic training in the use of behavioral coping skills or trauma discussion. Each group member has about 25 min to raise specific issues that are discussed and addressed in group. If relevant, the therapist will discuss how PTSD symptoms may be playing a role in the topic raised. As Veterans practice adaptive problem-solving techniques, they experience improved functioning with a subsequent decrease in symptoms [14,54,55]. Session 10 is the wrap-up session and includes a discussion of unresolved issues from the previous week, followed by a review of the progress of each group member, and recommendations for continued application of problem-solving strategies.

5.4. Procedures for group attendance and non-attendance/dropout

There are 3 group members in each group, and groups meet for 10 weekly, 90-min treatment sessions. The group continues to meet even in the event only 1 or 2 group members attend. The group therapy time is adjusted to 60 min for 2 group members and 30 min for 1 group member, with adherence to the protocol.

6. Statistical methods

6.1. The superiority of group PE to group PCT in total CAPS-5 severity score improvement will be tested with an unpaired t-test of the improvement scores

To test maintenance of reduction in total CAPS-5 severity scores at 6 months, we will include the post, 3-month, and 6-month data in a repeated measures (RM) ANOVA (Analysis of Variance) with the 2 treatment arms as a grouping variable and the 4 assessments (baseline, post-treatment, 3- and 6-month follow-up) as the repeated factor. Intention-to-treat (ITT) analysis is considered conservative and posits participants in clinical trials should be analyzed in the groups to which they are randomized, even when lost to follow-up. ITT analyses will be performed by analyzing longitudinal data from all participants originally randomized. We use the MIXED procedure in SAS (version 9.2), which handles missing values well without deleting any participant's data.

To test whether missing data occurs at random, we will use logistic regression with the last outcome measures (6-month follow-up) available as predictors. If dropouts are not related to these measures, then the analysis with SAS PROC MIXED is valid. If dropouts are related, we will apply an imputation algorithm for missing values.

Prior to performing the above analyses, descriptive statistics (means, standard deviations, correlations) will be examined and statistical diagnostic tests will be performed. Attention will be given to the conditions that are required of a statistical method, such as linear model diagnostics (analysis of residuals for bias, non-homogeneous variances, and non-normality). When required assumptions are not satisfied, data transformations will be considered. Means ± standard deviations will be

reported and P-values ≤ 0.05 will be considered statistically significant.

Nesting within groups. Baldwin, Murray, and Shadish [57] suggest using group rather than individual as the unit of analysis to account for intraclass correlation (ICC) which occurs in studies of group treatments and controls for lack of independence of observation. Thus our 2 plans of analysis for participant nesting within group and possible ICC effects are (1) individual subjects as the unit of analysis in PROC MIXED and use group as a cluster allowing correlation among the 3 subjects in the group; and (2) using group as the unit of analysis by averaging group scores i.e., average the scores of the 3 subjects in the group as in Castillo et al. [8].

Completers/non-completers. Completers in terms of assessments are those who completed at least two of the follow-up assessments, post-treatment, 3-month, and/or 6-month. Completers in terms of attending treatment sessions are those who attended at least half of the 10 treatment sessions.

Our original power analysis was done with individual subjects as the units of analysis. This is the same as using groups if there were no ICC among the 3 subjects. This concept will be included in the analysis where we can test whether $ICC = 0$ in our data. If the ICC cannot be distinguished from zero, then our original power analysis is accurate. If the ICC is greater than zero then a post hoc power analysis will be performed to determine what effect size can be detected with 80% power. These concepts will be included in the methods section of the outcomes paper.

We will use multiple imputation (MI, PROC MI in SAS) which fills in all missing values in the database. This is randomly repeated multiple times, say 50 times, obtaining 50 complete databases. The analysis is carried out in each complete database and the 50 results are combined into one result using PROC MIANALYZE.

6.2. Data analytic strategy

Aim 1. We will test whether Group PE is superior to Group PCT as measured by the improvement in CAPS-5 severity scores (follow-up minus baseline). Comparing group changes in PTSD severity from baseline to post-treatment, and at 3- and 6-month follow-up will be done by RM ANOVA and with multiple imputation. Whether PE results in better quality of life (WHO Quality of Life and SF-36) compared to Group PCT will be tested as above. The analyses for completers will be similar.

Aim 2. We will examine changes in perceived stigma following the 10-week treatment protocol. The analyses of our measures of stigma will be analogous to the analyses for Aim #1. Data sources include the Stigma scale and the Self-Stigma of Seeking Help scale described above, at baseline, post-treatment, 3- and 6-month follow-up.

7. Summary

The effectiveness of exposure therapies, particularly Prolonged Exposure [12], delivered individually is well-established [5,6]. This manuscript presents a design to expand access to this first-line treatment for PTSD by delivering it in a small group modality, while adapting group to the individual PE protocol as closely as possible. While the dose of imaginal exposure in a group is smaller than in individual therapy, 40 vs 20 min, preliminary findings indicate dose did not result in a difference in PTSD symptom reduction [21]. Further, the group format may confer additional benefits above the individual protocol, such as improvement in quality of life by promoting mutual support, decreasing isolation, and providing opportunities to develop trusting relationships. Additionally, group attendance may engender a reduction in self-stigma [34–36], and Mott et al. [20] hypothesize commitment to other group members may facilitate treatment retention.

Implications. The need to expand availability of evidence-based psychotherapies for treating PTSD is evident. This RCT intends to build the evidence base around delivering PE in a group format. We

expect a sustained reduction of PTSD symptoms, greater ability to form relationships, improved physical, psychological, and social relationships, and significant change in attitudes about mental illness and help seeking.

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