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Cognitive-behavioral group treatment for veterans diagnosed with PTSD: Design of a hybrid efficacy-effectiveness clinical trial

Denise M. Sloan^{a,b,c,*}, William Unger^d, and J. Gayle Beck^e

^aVA Boston Healthcare System, United States

^bVA National Center for PTSD, United States

^cBoston University School of Medicine, United States

^dVA Providence Medical Center, United States

^eUniversity of Memphis, United States

Abstract

Despite significant advances in individual treatment approaches for PTSD, knowledge of group approaches has lagged behind. Much of the reason knowledge about group treatment for PTSD has been limited is due to the complexity of conducting randomized controlled trials in the group treatment context. This limited empirical knowledge is unfortunate given the frequency with which group treatment for PTSD is used in clinical settings, including the Department of Veteran Affairs. The goal of this study is to examine the efficacy of a group cognitive-behavioral treatment (GCBT) for PTSD relative to group supportive counseling approach (i.e. group present centered treatment; GPCT). The sample consists of 196 veterans diagnosed with PTSD who are randomly assigned to either GCBT ($n = 98$) or GPCT ($n = 98$). Both treatments are administered by two therapists over the course of 14 sessions. Assessments take place at baseline, mid-treatment, post-treatment and 3-, 6-, and 12-month follow-up. The primary outcome measure is the PTSD symptom severity assessed with a semistructured diagnostic instrument. Given the substantial rise of veterans presenting for PTSD treatment services, identifying an efficacious group treatment approach is invaluable.

Keywords

Clinical trial; Posttraumatic stress disorder; Cognitive behavioral therapy

1. Introduction

Posttraumatic stress disorder (PTSD) is a chronic and debilitating disorder that is associated with numerous deleterious outcomes (e.g., [25, 36]). PTSD is prevalent in the general population, with an even greater prevalence in the active duty and veteran population. Specifically, the prevalence of PTSD in service men and women deployed post 9/11 is

*Corresponding author at: VA Boston Healthcare System (116-B), 150 S. Huntington Avenue, Boston, MA 02130, United States, denise.sloan@va.gov (D.M. Sloan).

estimated to be at least 10% immediately post-deployment, with an approximate doubling of the prevalence within five years after deployment [19,38,39].

Fortunately, substantial progress has been made in identifying effective individual treatment approaches for PTSD, with cognitive behavioral treatments (CBT) having the strongest empirical support [13,21]. CBT is a type of psychotherapy that uses systematic techniques based on learning theory and cognitive psychology to help patients identify and correct dysfunctional thoughts, behaviors, and emotions. Although effective individual PTSD treatment approaches are available, the development of effective group CBTs has lagged (for a review see, [6]). Unlike the literature on individual treatment for PTSD, the group treatment literature for PTSD has generally not conducted more than one randomized controlled trial of a specific group treatment protocol. This has left a significant gap in the literature as there is currently no established effective group treatment approach for PTSD ([13,21]). This is unfortunate given patient preferences for group treatment and the care demands in mental health [10,15,43]. Within the VA healthcare system (the largest provider of PTSD treatment in the world), group interventions are highly prevalent [21,28]. This has resulted in group treatment as the most frequently used PTSD treatment in the VA system ([21,28]). With recognition that treatment formats need to be more efficient, it is imperative that group CBTs (GCBTs) are developed and tested.

This paper describes a randomized controlled trial (RCT) that builds on the group treatment literature by testing the superiority of group cognitive behavioral treatment (GCBT), composed of components that have each been shown empirically to be effective, in relation to a comparison treatment that controls for nonspecific therapeutic effects. The study design is a hybrid efficacy–effectiveness model in which the efficacy of GCBT is being tested in the VA setting (i.e. routine practice setting) with VA mental healthcare providers serving as study therapists. Moreover, participants are drawn from veterans presenting to the VA medical center. The study is a multi-site, five-year RCT investigating whether GCBT is superior to a group supportive counseling treatment approach. The study is funded by the Department of Veteran's Affairs (I01 CX000467-01A1).

2. Materials and methods

2.1. Participants

Participants are 196 male veterans diagnosed with PTSD. We do not limit inclusion to combat-related trauma, instead veterans who meet diagnostic criteria for PTSD related to any trauma event are included. This broad inclusion of trauma type to leads to greater generalizability of the findings obtained.

Given the demographics of veterans presenting for services at the recruitment sites included in this study, we expect approximately 65% of the participants will be White, a third will be veterans of post 9/11 conflicts with another one third representing Vietnam-era veterans [14]. In terms of trauma types, we expect at least 50% to have combat-related PTSD with the remaining 50% to be a mix of trauma types (e.g., military sexual assault, childhood sexual assault, adult physical assault, motor vehicle accident). These percentages represent the type

of trauma-related problems of veterans presenting to PTSD specialty clinics at the respective recruitment sites [14].

The study does not include women for several reasons. First, the number of female veterans represents only 11% of the veterans presenting to the VA healthcare system for PTSD services [14]. Second, women veterans presenting with PTSD are more likely to have PTSD resulting from sexual trauma relative to male veterans (approximately 71% among women compared with 4% for men; [17]). Due to the small number of women presenting to VA for services, it is not feasible to recruit the number of participants needed for a group treatment trial (i.e. 14 participants recruited at the same time for randomization to one of the two treatment group conditions). The possibility of conducting groups of mixed men and women veterans was considered. However, given the high rate of sexual assault among women veterans diagnosed with PTSD, we believed women veterans would not be comfortable participating in a trauma-focused group with male veterans. Consequently, women veterans are excluded from the study.

Although women are not included in this study, we recognize it is important to gather information about women veterans. Thus, we plan to conduct pilot groups of women veterans at both recruitment sites during the final year of the project. These pilot groups will permit examination of the feasibility of recruiting women only trauma-focused groups as well as provide preliminary outcome data on the efficacy of GCBT for women veterans. We also anticipate that the pilot groups with women veterans will enable us to evaluate whether additional modifications to the GCBT protocol are needed.

2.1.1. Inclusion/exclusion criteria—Inclusion criteria consist of a current diagnosis of PTSD [2]. As previously stated, in order to increase generalizability of the obtained findings, we are including PTSD related to any trauma. If taking psychotropic medication, the participant must be on a stable dose for at least 4 weeks in order to reduce confound in treatment gains related to changes in psychotropic medication. Lastly, due to human subject concern, participants must be free of current psychotic symptoms. This is a frequent exclusion criterion in PTSD clinical trials due to concerns regarding exacerbation of psychotic symptoms (e.g., [27,30,32]). Exclusion criteria include a current diagnosis of substance dependence (substance abuse is not an exclusion). This exclusion is due to human subject concern of exacerbation of substance use in order to cope with increases in PTSD symptoms that may occur during the course of exposure-based treatment. We also exclude individuals with unstable bipolar disorder or significant cognitive impairment due to concerns about ability to engage in trauma-focused treatment as well as concerns about exacerbation of bipolar symptoms in the context of trauma-focused treatment. Participants are also excluded if they are currently involved in psychosocial therapy for PTSD as it would be difficult to discern the reason for observed treatment gain. Lastly, women veterans are excluded due to reasons previously described. Table 1 provides a listing of inclusion and exclusion criteria and rationale.

2.2. Study Design

The study design is a hybrid efficacy–effectiveness trial, in keeping with current translational emphasis to produce information about treatment outcomes that generalize to routine care clinics. Thus, participants are recruited from veterans presenting to VA for services, existing VA mental health care providers serve as study therapists, and the study takes place at two VA medical centers (VA Boston Healthcare System and VA Providence Medical Center). An equal number of participants are recruited at each site. Participants ($N = 196$) are randomly assigned to either a GCBT ($n = 98$) or to group present centered treatment (GPCT, $n = 98$). Seven cohorts consisting of 14 participants per cohort are recruited at each site over the course of four years ($n = 98$). Assessments take place at pre-treatment, mid treatment, post-treatment, and 3-, 6-, and 12-month follow-up. The initial assessment requires approximately four hours, whereas the assessments at post-treatment, 3-month, and 12-month follow-up require approximately three hours to complete. The assessments at mid-treatment and 6-month follow-up require less time (i.e. 1.5 h). The entire study will require five years to complete. See Fig. 1 for the planned participant flow for the study.

2.2.1. Ethical oversight—The study protocol is approved by the Investigational Review Boards (IRB) at the VA Boston Healthcare System, VA Providence Medical Center, and University of Memphis. Clinical trial registration was completed at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT01544088). A Certificate of Confidentiality was obtained from the National Institutes of Health.

2.3. Study procedures

2.3.1. Recruitment—One of the challenges in conducting a study on any group treatment is that participants who have enrolled in the study must wait until a sufficient number of individuals have been collected to form a group cohort. In the current RCT, two approaches are used to manage this difficulty. First, recruitment occurs in “waves,” meaning that there are two month time frames during which study referrals are actively sought. During these waves, efforts to screen and assess potential participants are maximized, to concentrate resources on the formation of a cohort (14 participants). Thus, the interval between completion of the initial assessment and the start of treatment is no more than eight weeks. The second approach involves careful clinical management of participants who are waiting prior to the beginning of group treatment.

Veterans are recruited using a variety of strategies. Flyers are posted throughout the VA medical center describing the study and directing interested veterans to contact study staff for additional information. Recruitment also takes place at primary care clinics and mental health specialty clinics (e.g., substance use clinic, PTSD clinic, general mental health) throughout the VA medical center. In addition, recruitment occurs at local Vet Centers and veteran student centers at regional colleges and universities. Although a variety of strategies are being used, we expect that the majority of the participants will be recruited through the PTSD specialty clinic. The study tracks the source of recruitment for each participant and will examine whether referral source needs to be statistically controlled in final analyses.

2.3.2. Screening—Veterans who contact study staff to express interest are first provided with a detailed description of the study, including required time commitment. If the veteran is interested in participating, a phone screen is conducted. During the phone screen, study staff briefly assesses for all inclusion/exclusion criteria (see Table 1). To assess for the presence of PTSD, study staff ask the veteran whether or not he has experienced a traumatic event, and if so, if he has experienced any of the core symptoms of PTSD in the past two weeks. The veteran is also asked about current substance use, symptoms of bipolar disorder, and past or current symptoms of psychosis. Study staff then ascertains if the veteran previously completed a full course of trauma-focused treatment, if he is currently enrolled in psychosocial treatment, or if he is taking psychotropic medications. The rationale for excluding veterans in concurrent PTSD treatment or veterans who are not stable on medication is always provided regardless of the veteran's current status.

Veterans who appear eligible based on the phone screen are then scheduled for an initial assessment. The assessment begins with obtaining informed consent. Next, the clinician-administered measures are administered, followed by the questionnaire battery (see Section 2.5.). As previously mentioned, all assessments for a group cohort take place within a two month period to minimize wait time for the start of group treatment. Appropriate referrals within VA are made for veterans who are ineligible to enroll based on the initial assessment. Based on our prior experience recruiting for PTSD treatment studies as well as data from VA PTSD treatment studies [30,32], we anticipate enrolling 70% of the participants who complete the initial assessment.

2.4. Randomization

Randomization is stratified by site. As previously described, each group cohort consists of 14 participants (7 assigned to each treatment condition). We use the sealed envelope program to generate randomization. After all participants in a potential group cohort have completed their initial assessments, randomization occurs by opening sealed envelopes that reveal the treatment assignment (GCBT or GPCT). Envelopes are opened for each participant in the order they are recruited for the group cohort. The project coordinator then informs all group cohort members of their group assignment.

2.5. Assessment instruments and procedures

All clinician-rated assessments are conducted by independent evaluators (IEs) who are unaware of treatment assignment. The IEs are Doctoral-level psychologists or Masters-level clinicians experienced in the administration of structured clinical interviews. All IEs receive further training and certification for this study under the direction of an IE trainer. Monthly inter-rater reliability checks for the assessments are undertaken by IEs who did not conduct the initial assessment. The ratings are used to calculate kappa coefficients and to facilitate supervision, during which potential disagreements are discussed and instruction is provided to enhance inter-rater reliability. Twenty-percent of the assessments are randomly selected for reliability checks. See Table 2 for a schedule of assessment instruments.

2.5.1. Primary outcome measures—The Clinician Administered PTSD Scale (CAPS-5; [40]) is the primary outcome measure for the study. The CAPS-5 is a structured

diagnostic interview and gold standard for assessing PTSD for the DSM-5 [2]. The scale also assesses social and occupational functioning, dissociation, and the validity of symptom reports. The CAPS-5 uses a 5-point ordinal rating scale to measure symptom severity (0 = absent, 1 = mild/subthreshold, 2 = moderate/threshold, 3 = severe/markedly elevated, 4 = extreme/incapacitating). Symptom severity ratings combine information about symptom frequency and intensity obtained by the interviewer. Development of CAPS-5 was completed at the time this study started recruitment, thus, we elected to include CAPS-5 in order to assess PTSD symptom severity according to DSM-5 criteria. Although the CAPS-5 is a new measure, initial psychometric properties indicate high criterion and construct validity and high agreement with a self-report measure of PTSD [29]. Total PTSD symptom severity serves as the primary outcome measure.

As PTSD diagnosis requires the presence of a traumatic life event, such events are determined at the initial assessment with administration of the Life Events Checklist for DSM-5 (LEC-5; [41]). The LEC-5 includes the same list of 16 different potentially traumatic life events from the original LEC that are commonly associated with PTSD symptoms and is designed to facilitate PTSD diagnosis [41]. There is also space for specifying an additional stressful event not encompassed in the 16 events. For each potentially traumatic life event, respondents rate their experience of that event on a 6-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = part of my job, 5 = not sure, and 6 = doesn't apply). The primary addition to the LEC-5 is a category involving occupational exposure ("for example, paramedic, police, military, or other first responder"). There has not been a publication on the psychometric properties of the LEC-5, but the measure is nearly identical to the original LEC, with high internal consistency and test-retest reliability [41]. The traumatic event identified at the initial assessment is recorded and used for all subsequent administrations of the CAPS-5.

2.5.2. Secondary outcome measures—The Structured Clinical Interview for DSM-IV (SCID; [37]) is administered to assess psychiatric comorbidity. The SCID is a clinician-administered interview with each disorder coded as present, not present, or probable, based on structured questions that map onto the DSM-IV [1] criteria. Unlike the CAPS measure, the version of the SCID that corresponds to DSM-5 was not available at the time participant recruitment began. Thus, we were not able to include the SCID for DSM-5 in this project.

2.5.3. Treatment process measures—Five treatment process measures are included in the study to be used in an exploratory fashion. These measures will be used to generate hypotheses about the impact of therapeutic processes on outcome. The first measure of treatment process is the number of treatment sessions attended. As well, a widely-used measure of treatment credibility [9] is administered at the conclusion of the first treatment session (after the treatment rationale and specific procedures are explained). This measure asks the individual to rate on a 10-point scale how logical the treatment seems, the participant's confidence in undergoing the treatment and recommending it to others, and their expectations for the treatment's success.

The Client Satisfaction Questionnaire [22], an 8-item measure of participant satisfaction with treatment, is administered at the last treatment session (e.g., "How would you rate the

quality of service you have received?” “If a friend were in need of similar help, would you recommend our program to him or her?” “Have the services you received helped you to deal more effectively with your problems?”). The CSQ has demonstrated concurrent validity.

The California Group Psychotherapy Alliance Scales (CALPAS-P; [18]), a measure of therapeutic alliance, is administered. The 24 items of the CALPAS load on 4 subscales: Patient working capacity, Patient commitment, Working strategy consensus, and Therapist understanding and involvement. The CALPAS (Patient version) shows good psychometric properties. This measure is administered twice (at Sessions 7 and 14) in order to evaluate participants' perceptions of the group.

Homework compliance is evaluated with a homework compliance form that is completed by study therapists. Separate homework compliance forms are available for GCBT and GPCT given the differences in homework assignments between the two treatments. Therapists rate the percentage of each homework assignment that each participant completes each week and provide a rating of homework quality, following Primakoff et al. [7] and successfully used in other RCTs (e.g., [45]).

2.6. Treatment conditions

In designing this trial, we selected one GCBT [4] for several reasons. First, each element of this GCBT protocol has extensive empirical support and the intervention has shown robust results when delivered in an individual format (see [8]); this group protocol has been shown to have an effect size of $d = 0.67$ (compared with a minimum attention control, [5]), using clinician-measured PTSD. At the time that this study was being designed, this was one of the larger effect sizes noted in the CBT literature on group treatment for PTSD [6].

Additionally, as noted below, the protocol contains psychoeducation, trauma exposure, cognitive therapy interventions, behavioral activation, training in assertion, and discussion of relapse prevention. In light of considerable comorbidity among veterans with chronic PTSD, it was felt that a package CBT program would perhaps fit best with the clinical needs to this population.

We carefully considered possible options for the comparison condition and selected GPCT for several reasons. First, GPCT controls for nonspecific treatment effects, which is a salient concern in establishing efficacy and effectiveness [31,35]. Second, GPCT is thought to be similar to the on-going group treatment programs that are conducted in the VA system. As such, it represents a “treatment as usual” comparison condition and falls well within guidelines for human subjects for RCTs. Third, GPCT can be expected to be somewhat efficacious, based on related research. As summarized by Bradley et al. [11], supportive therapy has an average effect size of $d = 0.59$ across studies. As such, it is a somewhat efficacious comparison condition, which can be expected to benefit participants to some extent. Lastly, many treatment studies within the PTSD literature have not yet advanced to include comparison conditions that control for nonspecific therapy effects. Most studies rely on waitlist control conditions [6], which only control for threats to internal validity and cannot allow conclusions regarding construct validity. This issue is particularly salient for group treatment for PTSD, which has lagged considerably behind the individual treatment

for PTSD literature. It is also of note that GPCT has been used as the treatment comparison condition for other group treatment of PTSD randomized controlled trials [12,27,32].

2.6.1. Group Cognitive Behavior Therapy—The Group Cognitive Behavior Therapy (GCBT) protocol spans 14 sessions, which are scheduled across 16 weeks (sessions 1 through 12 occur every week, with a one-week break between session 12 and 13 and again between session 13 and 14). GCBT is designed to be administered by two trained therapists. The design of GCBT focuses on nurturing group cohesion, while introducing cognitive-behavioral interventions. Considerable emphasis is placed on between-session practice (homework), in an effort to foster generalization of skills. In particular, group members select specific exposure items to practice between-sessions, as well as other skills, such as progressive muscle relaxation, specific cognitive interventions, or assertiveness. Considering the specific skills, session 1 is primarily an introductory session, where group members are introduced to one another, the treatment guidelines, confidentiality, and the CBT format. During session 2, group members learn more about PTSD, especially avoidance, and begin to construct a trauma hierarchy that will be used during *in vivo* exposure. In session 3, the hierarchy is finalized and the rules of exposure are discussed. It is at this point that group members are asked to begin their exposure homework. During session 4, group members write a description of their trauma during session (written exposure). This aspect of treatment was modified from Cognitive Processing Therapy [26]. Sixteen-muscle group progressive muscle relaxation is introduced at the end of the session to reduce distress. Session 5 is an extension of session 4 as the group members re-write their trauma descriptions, which is followed by progressive muscle relaxation. Cognitive therapy for PTSD is introduced in session 6 and discussed further in sessions 7 and 8. Sessions 9 and 10 focus on anger, while session 11 focuses on participants' feelings of depression. Following a discussion of the role that social support can play in recovery from PTSD in session 12, group members are asked to find pleasant events that they could engage in with a supportive other. Session 13 focuses on the risk of relapse in PTSD, with presentation of relapse prevention skills. Session 14 serves as a general review of the previous sessions, a review of treatment gains made by each group member, and suggested individualized strategies for each group member to maintain and build upon treatment gains. Each session lasts 2 h, permitting discussion of each individual's homework as well as introduction of one new skill per session.

2.6.2. Group Present Centered Therapy—Group Present Centered Therapy (GPCT) was developed for use in the Veterans Administration Cooperative Study # 420 on Group Treatment of PTSD [32,33]. GPCT focuses on learning to manage active symptoms in a group context by increasing awareness of the cognitions and emotions being experienced in the present. The core components of GPCT include psycho-education, peer support and the development of peer-facilitated problem solving. GPCT does not include trauma-focused work or the delivery of clinician instruction in skill development. Instead, GPCT promotes the development of client-centered management of ongoing psychiatric symptoms.

The GPCT protocol in the present study consists of 14 sessions, of two-hour duration, that take place during the course of 16 weeks, with a one-week break between session 12 and 13

and again between session 13 and 14. During session 1, group introductions are made and a rationale for the group is presented as well as a discussion of group guidelines. In sessions 2 and 3, psychoeducation concerning PTSD symptoms is presented. Members are also asked to develop treatment goals regarding improvements in their PTSD symptoms for the group. A brief check-in and check-out is conducted at the start and finish of all 14 sessions, respectively. Weekly home-therapy log assignments are presented by the clinicians, concerning reactions to the session content from the previous week, as well as the symptom management concerns experienced by group members during the week. These homotherapy assignments are reviewed during the following session. The clinicians provide guidance for peer-facilitated problem solving on the identified issues. During sessions 4 to 9, therapists review the homotherapy assignments and ask group members for issues to place on the agenda for the session. Group members are also assisted with the identification of symptom management techniques presented and utilized by the group concerning items placed on the agenda.

Sessions 10 to 13 includes the work started in previous sessions (i.e. 4 to 9). Specifically, group members focus on difficulties encountered while utilizing group identified skills and coping strategies. Therapists guide the discussion concerning mechanisms to promote symptom management. In the last session, group members reflect on the group experience, treatment goals and the maintenance of treatment gains. Lastly, the group therapists promote discussion concerning termination and follow-up services if needed.

2.6.3. Training, supervision, and adherence of study therapists—Two therapists lead each group cohort, drawn from existing mental health providers at each site. Therapists are nested within treatment conditions. We decided to nest rather than cross therapists because we were concerned about the potential for elements of the two treatments to be mixed if therapists were conducting both treatments (i.e. crossed design). Moreover, from a logistical standpoint, it would be difficult for the same two therapists to conduct both group treatments as the groups are conducted concurrently. Conducting both groups at the same time would require four hours per week for the treatment groups plus an additional two hours per week for supervision. Such a large time commitment would place an unreasonable burden on the mental health providers.

In order to ensure that therapists at both sites are trained thoroughly and consistently, a two-day training was scheduled at the start of the project. Because all study therapists are experienced in treating PTSD in veterans, emphasis was placed on mastery of the specific components of GCBT and GPCT during training. Training included discussion concerning expected, acceptable, and prohibited elements, in keeping with the design of this RCT. The training workshop was video-recorded so that study therapist who might join the study after it began would have access to the same workshop.

Following completion of the workshop, therapists receive one hour, weekly supervision from one of the authors (J.G.B. for GCBT and W.U. for GPCT). Each of the supervisors has extensive experience with the respective group protocols.

Treatment fidelity is assessed by two individuals who are otherwise unaffiliated with the study. These two individuals were selected owing to their familiarity with either the GCBT or the GPCT protocol. For each treatment condition, 20% of the treatment sessions are randomly selected, reviewed and rated, using the adherence and competence forms developed for each of the treatment conditions.

2.7. Between site coordination

A challenging aspect of a multi-site trial is ensuring consistency across sites. To facilitate consistency across the two sites, a detailed study procedure manual was written. This manual is followed by study staff at the two sites. In addition, conference calls take place every two weeks throughout the duration of the study. During these calls, study staff provides site updates and the study team problem-solves any issues that arise.

2.8. Safety protocol

In order to optimize safety of participants in the study, we do not include participants with substantial suicidal risk or substantial cognitive impairment. Suicidal risk is determined with the administration of the Mini International Neuropsychiatric Interview (MINI; [23,34]) suicide module. Individuals are excluded from enrolling in the trial if they score 17 or higher (i.e. high risk) on the MINI at the initial assessment.

To monitor suicide risk during the treatment phase, the BDI-II [3] is administered at every other treatment session. The MINI suicidal module is administered if a participant endorses suicidal ideation at any level in response to item 9 on the BDI-II (suicidal thoughts or wishes). The Mini suicide module also is administered to each participant at each follow-up assessment session for continued monitoring of suicidal risk.

The PTSD Checklist for DSM-5 (PCL-5; [42]) is administered every other treatment session to monitor potential worsening of symptoms. Worsening of symptoms is defined by an increase from initial assessment of at least 10 points that is sustained for at least three weeks [16]. Adverse events are assessed at each assessment visit by inquiring whether any major change in mental or physical health has occurred since the participant's previous visit.

2.9. Strategies to minimize attrition

Several procedures are used to minimize study attrition. First, the project coordinator has weekly contact with each participant from the time they complete the initial assessment until the start of their treatment group. Next, the project coordinator regularly checks in with the participant between scheduled assessment sessions to make sure any change in contact information (e.g., phone numbers, residence) is appropriately documented. Next, at the completion of each assessment session, the participant is provided with an appointment card with the tentative date and time of the next scheduled appointment. These appointments are important in the event that project staff are unable to contact the participant to schedule the next assessment session (e.g., if the participant moves). Lastly, one month prior to a scheduled assessment session, a letter is sent to the participant reminding them of their upcoming appointment and requesting that they contact the project coordinator if they need to reschedule their appointment. The project coordinator calls the participant to confirm their

appointment (two weeks before the scheduled assessment appointment, as well as the day before).

During the treatment phase, the study therapists follow up by phone with participants who do not attend a treatment session. For participants who miss two or more consecutive sessions, the project coordinator assumes the responsibility of contacting the participant to inquire about the reason for the missed session. Every effort is made to bring the participant back to the treatment sessions. The groups have a policy that if a participant misses more than three sessions, the group will discuss whether or not the participant can continue with the group. This policy is in place due to the importance of group cohesion and the inability for participants to make up missed group sessions.

2.10. Data analytic strategy

2.10.1. General—We will assess the equivalence of the treatment groups on key baseline variables (demographics and psychological variables) using t-tests, nonparametric equivalence, or Chi-square tests, depending on the type (continuous or dichotomous) and distribution (normal or non-normal) of the data. Any variables that differ among groups will be used as covariates in the final analyses.

2.10.2. Between group differences in primary outcomes—To test the primary hypothesis that GCBT will show greater reductions in PTSD symptom severity (CAPS-5 score) relative to GPCT, multilevel latent growth modeling will be used. Whereas a traditional latent growth model approach would suffice in many instances (e.g., when participants are treated individually), the delivery of treatment in a group format is likely to result in the violation of the assumption of independent observations (i.e., within-group similarity on treatment outcomes and process variables; cf. [31,32]). In the initial analyses, we will evaluate the extent of dependency (i.e., clustering) by calculation of intraclass correlations (ICCs) using variance estimates from unconditional cell means models of key outcome variables (cluster = treatment group). The total sample of 196 will be clustered into 14 treatment groups per condition. This design can be characterized as a two-level model (i.e., latent growth factors are nested under treatment groups) where time-invariant covariates (i.e., dummy codes for treatment condition) are included to account for the within-group and between-group variability in initial status (pre-treatment) and symptom change (improvement at post-treatment and follow-up).

2.11. Power analysis to determine sample size

Power calculations were determined using the primary outcomes and previous PTSD group clinical trial data [5,11], as well as taking into account the cluster effect of groups (expressed as ρ , the intraclass correlation coefficient). In the computation of sample size, we used 0.80 power level. With a proposed group size of 7, a maximum ρ of 0.11, and $d = 0.50$, we estimated a total n of 162, using $p < 0.05$. Based on prior PTSD treatment research (e.g., [11,32]), we expected a 20% dropout rate. Thus, we increased our sample size to 196 in order to account for the predicted dropout rate.

3. Discussion

This study examines whether a cognitive behavioral group treatment approach is superior in reducing PTSD symptom severity relative to group supportive counseling treatment among veterans diagnosed with chronic PTSD. Although there is a wealth of studies investigating the efficacy of group treatment for PTSD, the majority of these studies have used either an open trial design or await list comparison condition [6]. Thus, the current study will advance our knowledge of cognitive behavioral group treatment using a rigorous comparison treatment condition. Moreover, participants will be assessed for one year following completion of treatment and comorbid psychiatric diagnoses as well as health care utilization will be examined in addition to the primary treatment outcome variable of PTSD symptom severity. There is a great need to identify efficacious group treatment approaches for PTSD given the preference for these treatments in the clinical settings [21] in combination with patient preferences for group treatment approaches [15].

We expect that participants assigned to GCBT will display significantly greater reductions in PTSD symptoms at post-treatment assessment relative to participants assigned to GPCT. In addition, we anticipate that the significantly greater reductions in PTSD symptoms will continue to be displayed for one year following treatment completion. Although we do expect significant reductions in PTSD symptoms at the post-treatment assessment relative to baseline for participants assigned to GPCT based on prior efficacy findings for this treatment [27,32], these initial reductions are not expected to be sustained at subsequent follow-up assessments.

It is important to highlight that we do expect the GPCT condition to be moderately efficacious based on prior efficacy findings for this treatment [27,32]. Thus, although we expect the GCBT condition to display superior outcome to the GPCT in PTSD symptom reduction, we do expect significant reduction in PTSD symptoms from baseline for the GPCT condition at posttreatment. We do not anticipate that these initial treatment gains will be maintained by the one year follow-up assessment as we predict that any initial treatment gains will be the result of group support.

Although we do not expect to find treatment dropout differences between GCBT and GPCT, recent meta-analysis findings by Imel et al. [20] suggest significantly lower treatment dropout rates in present centered treatment (PCT) relative to trauma-focused treatment approaches. Given that the majority of studies in the meta-analysis were based on individual PCT, we do not believe these treatment dropout rates will be observed in a group treatment trial given the social support component of group treatment [44]. Moreover, other studies using a GPCT have not observed treatment dropout differences relative to trauma-focused group treatment (e.g., [27]).

We have included a number of treatment process measures to conduct exploratory analyses. Specifically, these measures are included in order to investigate how treatment processes might moderate treatment outcome effects. It is possible that group cohesion will moderate treatment outcome for both treatment conditions, with greater group cohesion leading to greater reductions in PTSD symptom severity. We also anticipate that greater ratings in

treatment credibility will lead to greater treatment gains, as treatment buy-in is an important predictor of treatment outcome (e.g., [24]).

Limitations of the study include the inclusion of only males. As described, women veterans were not included in this study due to both scientific and logistical concerns. However, we plan to conduct pilot work by running at least two GCBT groups for female veterans in the last year of the project. We will use these pilot groups to determine whether modifications are needed to the GCBT protocol as well as to collect preliminary efficacy data with women veteran participants. In general, it is important to include both men and women in future studies. Other than the inclusion of only men, participants in the study will be diverse in terms of age, racial background, and trauma type (e.g., sexual assault, combat trauma — including combat era, serious car accident). The inclusion of a heterogeneous sample will permit greater generalizability of the obtained findings.

Another possible limitation concerns generalizability of the findings to other VA sites. Although this study does include two recruitment sites, both sites are located in the same geographic area. Thus, the findings obtained in this study may not replicate to other VA settings. We hope to be able to obtain funding within VA to conduct a larger scale study to investigate the efficacy of GCBT that would include multiple recruitment sites selected across the VA system. It is also important to note that the findings may not replicate outside of the VA system with non-veteran individuals. However, the study is not limiting inclusion to combat-related PTSD only. Instead, PTSD related to any traumatic event is permitted in an attempt to increase generalizability of the findings obtained. Moreover, the initial efficacy findings for GCBT was based on a civilian sample [5]

To summarize, the study has the potential to make a substantial contribution to the existing literature on group treatment for PTSD. The current study uses a RCT design, a treatment comparison condition that controls for nonspecific treatment effects (e.g., therapist contact, treatment dose, group support), a sample size that takes into account the group cluster effect (i.e. adequately powered to detect between group differences), and assessment of treatment outcome that takes place over the course of one year post treatment. Thus, the current study will represent a substantial advance in the existing literature on group treatment for PTSD, given the frequent lack of a comparison treatment condition that controls for nonspecific therapy effects, small sample sizes that are not sufficiently large to account for the group cluster effect, and limited follow up assessment [6]. Unlike the literature on individual treatment for PTSD, the group treatment literature for PTSD has generally not conducted more than one RCT of a specific group treatment protocol. This has left a significant gap in the literature as there is currently no evidence-based group treatment approach for PTSD. As previously indicated, this is a notable gap in the field given the frequency with which group PTSD treatment is used in clinical settings. We look forward to completing the current study in an effort to move the field forward.

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Fig. 1. Planned participant flow. Note: GCBT = Group Cognitive Behavior Therapy; GPCT= Group Present Centered Therapy; tx = treatment.

Table 1

Inclusion and exclusion criteria and rationale.

Inclusion criteria	Rationale
Current PTSD diagnosis	Population under study
Stable medication dose for at least 4 weeks	Treatment confound
Free of psychosis	Human subjects concern
Exclusion criteria	Rationale
Women	Insufficient number to recruit group cohort
Current substance dependence diagnosis	Human subjects concern
Current unstable bipolar disorder	Human subjects concern
Currently in psychosocial treatment for PTSD	Treatment confound
Significant cognitive impairment	Human subjects concern

Table 2

Schedule of assessment measures.

Measure	Pre-Tx	1st session	During Tx	14th session	Mid-Tx	Post-Tx	3-Month	6-Month	12-Month
CAPS-5	X				X	X	X	X	X
SCID	X					X	X		X
LEC-5	X								
CEQ		X							
CALPAS-P			X	X					
CSQ				X					

Note. CALPAS-P=California Group Psychotherapy Alliance Scales—Patient version; CAPS-5=Clinician Administered PTSD Scale for DSM-5; CEQ=Credibility Expectancy Questionnaire; CSQ = Client Satisfaction Questionnaire; LEC-5= Life Events Checklist for DSM-5; SCID= Structured Clinical Interview for DSM-IV.