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Comparing written exposure therapy to Prolonged Exposure for the treatment of PTSD in a veteran sample: A non-inferiority randomized design

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ABSTRACT

Posttraumatic stress disorder (PTSD) is highly prevalent among veterans. Although there are effective treatment approaches for PTSD, such as Prolonged Exposure (PE) and Cognitive Processing Therapy, many providers trained in these approaches do not use them, or use them without sufficient fidelity, and veterans drop out of these treatments at very high rates. The time intensive nature of these treatments is frequently cited as a barrier to receiving the treatment among veterans and delivering the treatment among providers. According, there is an urgent need to establish more efficient and effective PTSD treatment approaches in order to meet the needs of veterans seeking care. Written exposure therapy (WET) is an efficient, exposure-based treatment, and may represent a plausible alternative treatment option to address PTSD in veterans. Although WET has been found to be effective and non-inferior to more time intensive trauma-focused treatment, it has not yet been investigated with a veteran sample. In an ongoing randomized controlled trial (RCT) we are investigating whether WET is non-inferior in treating PTSD compared with the more time intensive PE. The study sample will include 150 men and women veterans diagnosed with PTSD who are randomly assigned to either WET (n = 75) or PE (n = 75). Participants are assessed prior to treatment and 10-, 20-, and 30-weeks after the first treatment session. The primary outcome is PTSD symptom severity assessed with the Clinician Administered PTSD Scale for DSM-5. Establishing that PTSD can be treated effectively with fewer treatment sessions would represent a significant advance in improving access to evidence-based care for veterans with PTSD.

1. Introduction

Posttraumatic stress disorder (PTSD) is highly prevalent among veterans. Although the prevalence estimates vary widely across studies, available data suggest that a large proportion (e.g., 15–20%; see Ref. [1], for a review) of veterans are affected by PTSD. In response, the United States Department of Veterans Affairs (VA) increased the number of available mental health providers and instituted mandatory primary care screenings for PTSD. In addition, VA developed and implemented specialized provider training programs for evidence-based treatment of PTSD, including Cognitive Processing Therapy (CPT; [2]) and Prolonged Exposure (PE; [3]) therapy [4], making VA the largest provider of PTSD treatment in the world. Despite the extensive dissemination efforts, many providers trained in these treatments do not use them, typically because they have high PTSD caseloads but inadequate time and resources to manage caseload (e.g., Refs. [5–7]). Even when veterans have access to and start these treatments, many do not complete them because they are either too distressing or time intensive (e.g., 50%; [8,9]). Given these findings, it is clear that veterans need access to effective treatment alternatives that can surmount these numerous barriers to care so they can obtain relief from their PTSD symptoms.

Abbreviations: CAPS-5Clinician Administered PTSD Scale for *DSM-5*CEQCredibility/Expectancy QuestionnaireCPTCognitive Processing TherapyDoDDepartment of Defense*DSM-5Diagnostic and Statistical Manual of Mental Disorders*, 5th *Edition*EBTsevidence-based treatmentsIRBInstitutional Review BoardITTintent-to-treatLECLife Events ChecklistPCL-5PTSD Checklist for *DSM-5*PEProlonged ExposurePIprincipal investigatorPTSDposttraumatic stress disorderRCTrandomized clinical trialSCID-5*Structured Clinical Interview for DSM-5*SITBISelf-Injurious Thoughts and Behaviors InterviewVADepartment of Veterans AffairsWETWritten Exposure TherapyWAI-SRWorking Alliance Inventory-Short Revised

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Written exposure therapy (WET; [10]) is an alternate evidence-based PTSD treatment that is brief, effective, and associated with significantly fewer treatment dropouts when compared to PE or CPT. Although WET has already been included in the VA/DoD Clinical Practice Guidelines for the Management of PTSD (2017), there is limited data on its efficacy among veterans. To date, one open trial [11] demonstrated promising efficacy and low treatment dropout (i.e., 14%) and a subsample of 17 veterans included in a randomized controlled trial (RCT) of WET versus CPT found that veterans randomized to WET displayed a significant reduction in PTSD symptoms and only 5% dropped out [12]. However, these promising findings were preliminary and included a small sample.

The primary goal of this ongoing study is to use an appropriately powered non-inferior designed study to examine the effectiveness of WET for veterans with PTSD and to directly compare treatment outcomes for WET with treatment outcomes for PE. Although WET has been shown to be non-inferior to CPT, the treatment has not been directly compared to PE. Comparison to PE is of interest given that both WET and PE are exposure-based treatment approaches, with PE involving both imaginal exposure and in vivo exposure whereas WET involves imaginal exposure only. Based upon previously obtained effect sizes obtained for WET [11,13,14], we expect it to be non-inferior to PE and that observed treatment gains will be maintained at follow-up. The second aim of the study is to examine treatment differences in dropout. We anticipate that WET will have significantly fewer treatment dropouts relative to PE. The study is funded by Clinical Science Research and Development, Department of Veteran Affairs.

2. Materials and methods

2.1. Participants

We will randomize a total of 150 men and women veterans diagnosed with PTSD. Rather than restricting participation to individuals with a particular trauma type (e.g., combat trauma), we are including individuals with varied trauma histories, provided that they meet *DSM-5* PTSD Criterion A (American Psychiatric Association, 2013). The inclusion of veterans with heterogeneous trauma histories increases the generalizability of our findings to veterans presenting for PTSD treatment services at VA medical centers. We expect to recruit a racially diverse sample that will be approximately 60% White. We aim to recruit approximately 20% women veterans, consistent with the percent of women veterans presenting to VA medical centers for PTSD treatment services.

Veterans will be recruited from three VA medical centers, including VA Boston Healthcare System (Boston, MA), Ralph H. Johnson VA Medical Center (Charleston, SC), and William S. Middleton Memorial Veterans Hospital (Madison, WI). An approximately equal number of veteran participants will be randomized at each of the three sites.

2.1.1. Inclusion/exclusion criteria

Inclusion criteria include: 1) a current diagnosis of PTSD (American Psychiatric Association, 2013), 2) military veteran, 3) if taking psychotropic medication, then the dose must be stable for at least four weeks prior to study entry. Exclusion criteria are: 1) a current diagnosis of substance use disorder, severe (mild and moderate not excluded), 2) current psychotic disorder, 3) current unstable bipolar disorder, 4) current participation in another psychosocial therapy for PTSD, 4) significant cognitive impairment (assessed with clinical judgement), and 5) current high suicidal risk. Please refer to Table 1 for the list of inclusion and exclusion criteria and rationale (see Table 2).

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
Exclusion Criteria	*Rationale*
Substance use disorder, severe	Human subjects concern
Current psychotic disorder	Human subjects concern
Current unstable bipolar disorder	Human subjects concern
Currently in psychosocial treatment for PTSD	Treatment confound
Significant cognitive impairment	Human subjects concern
High suicidal risk	Human subjects concern

Table 2
Schedule of assessment measures.

Measure	Pre-Tx	1st Session	Every Tx Session	Last Session	10-week	20-week	30-week
CAPS-5	X				X	X	X
SCID-5	X				X	X	X
SITBI	X				X	X	X
LEQ	X						
PCL-5	X		X		X	X	X
BDI-II	X		X		X	X	X
TEQ		X					
CSQ				X			
WAI-SF				X			

Note. BDI-II = Beck Depression Inventory, 2nd edition; CAPS-5 = Clinician Administered PTSD Scale for DSM-5; CSQ = Client Satisfaction Questionnaire; LEQ = Traumatic Life Events Questionnaire; PCL-5 = PTSD Checklist for DSM-5; SCID = Structured Clinical Interview for DSM-5; SITBI = Self-Injurious Thoughts and Behaviors Interview; TEQ = Credibility Expectancy Questionnaire; TX = Treatment; WAI-SF = Working Alliance Inventory, short-form.

2.2. Study design and procedures

The study was designed and powered to investigate whether WET is non-inferior to PE, a more time and resource intense treatment approach. Participants (N = 150) will be randomly assigned to either WET (n = 75) or to PE (n = 75). Recruitment is occurring over the course of three years (starting September 2019). Because of the differences in treatment dosage (i.e., overall number and timing of therapy sessions), diagnostic assessments are scheduled to occur at pretreatment, as well as 10-, 20-, and 30-weeks following the first treatment session. Thus, assessments occur at the same time point for all participants regardless of treatment assignment; structuring the assessments in this manner controls for any possible effects of time on the evaluation of treatment outcome. Participants are compensated $50 for their time completing each of the assessment sessions; time to complete treatment sessions is not compensated. The entire study will to require four years to complete. See Fig. 1 for the planned participant flow.

The baseline assessment is conducted in two parts. The first part includes completion of informed consent followed by completion of a battery of self-report questionnaires. This part is either conducted with the project coordinator in either a face to face session or remotely using videoconferencing. If conducted remotely, participants are provided with an addressed stamped envelope to return their completed documents. Participants are then scheduled with a blinded assessor to complete the clinician-administered clinical measures. Participants who are eligible for the study based on the initial assessment are then randomized into one of the two treatment arms (see Fig. 1). Clinical assessments comprised of questionnaires and interviews occur at each of the assessment periods (baseline, 10-, 20-, and 30-week). In addition, participants complete self-report measures assessing symptoms of PTSD and depression at each treatment session. If conducting treatment re-

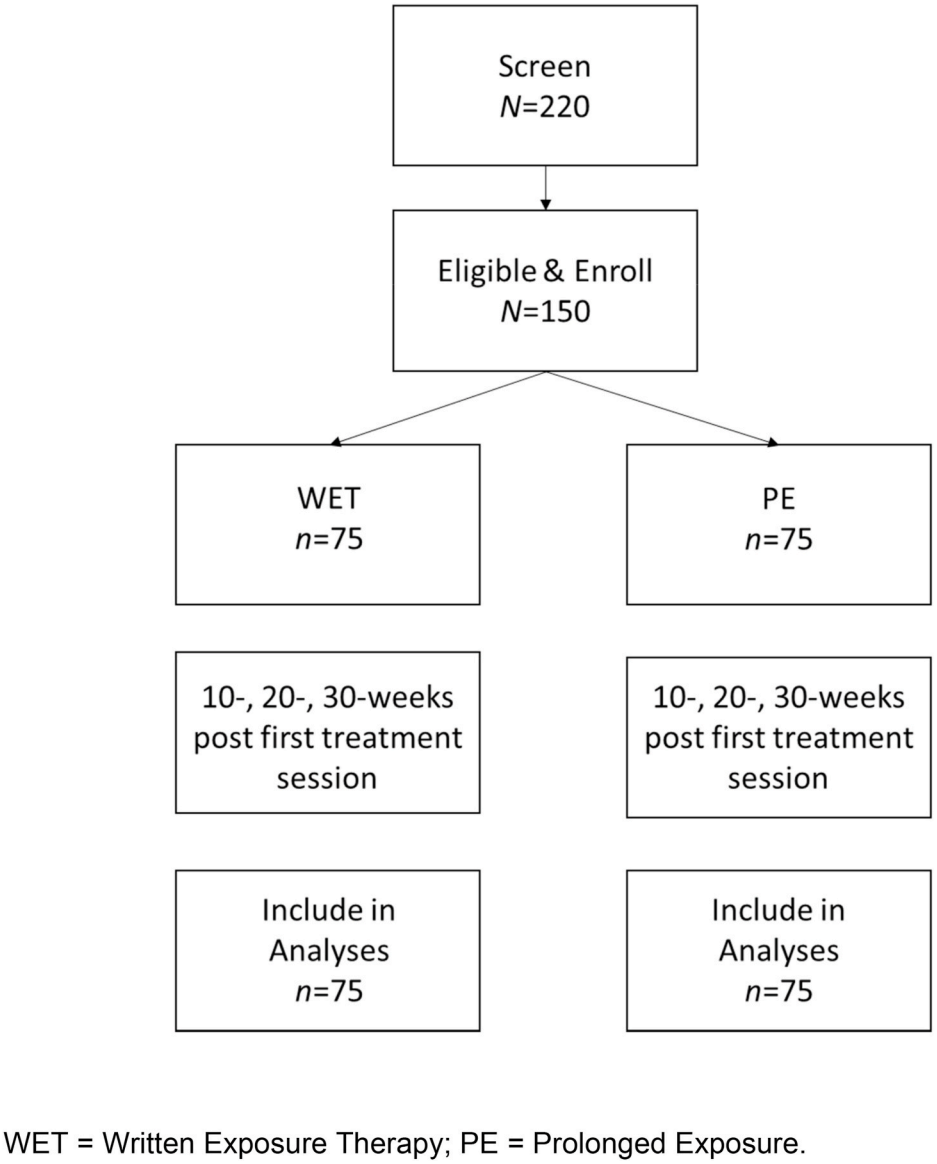

Fig. 1. Planned participant flow.

motely, participants are provided with a stamped envelope to return all treatment measures at the end of treatment.

2.2.1. Ethical oversight

The study protocol has been approved by the Investigational Review Boards (IRB) at each of the three recruitment sites, VA Boston Healthcare System, Ralph H. Johnson VA Medical Center, and William S. Middleton Memorial Veterans Hospital. Clinical trial registration was completed at ClinicalTrials.gov (NCT01800773). A Certificate of Confidentiality was obtained from the National Institutes of Health. The project is monitored by a centralized VA Data Monitoring Committee that reviews study progress and safety every six months.

2.2.2. Randomization

The blocked (site, sex) randomization sequence, using a 1:1 ratio, was entered by a study statistician into a secure, web-based application using SAS version 9.4 (SAS Institute Inc.), which is accessed by the primary site (VA Boston Healthcare System) project coordinator once a participant is deemed eligible to be randomized. Once a participant is randomized, the local project coordinator informs the participant of his or her treatment assignment and assigns a therapist. The participant is then contacted by the assigned study therapist to schedule the first treatment session.

2.3. Measures

The primary outcome measure is PTSD severity, as measured by the Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5; [15]), a structured diagnostic interview that assesses *DSM-5* criteria for PTSD and yields information about PTSD symptom severity. The CAPS-5 is administered at all major assessment points which include baseline and at 10-, 20-, and 30-weeks post first treatment session.

Participants complete the Life Events Checklist-5 [16] which is used to determine the presence of a traumatic life event(s). The LEC-5 includes the same list of 16 different potentially traumatic events (PTE) from the original LEC and is designed to facilitate PTSD diagnosis [16] For each PTE, respondents rate their experience of that event on a 6-point nominal scale. There are no published data on the psychometric properties of the LEC-5, but is nearly identical to the original LEC, which has high internal consistency and test-retest reliability [16]. The worst traumatic event identified at the initial assessment is recorded and used for all administrations of the CAPS-5.

The Structured Clinical Interview for *DSM-5* (SCID-5; [17]) is administered during the initial assessment session only to assess for exclusion criteria (e.g., psychotic disorder, substance use disorder) and general psychiatric comorbidity. The SCID is a clinician-administered interview with each symptom coded as present, not present, or probable, based on structured questions that map onto the DSM-5 (American Psychiatric Association, 2013) criteria. With the exception of the PTSD module, assessors administer the entire SCID for Axis I disorders.

In addition to the CAPS-5 and SCID-5, several treatment process measures are included in the study to be examined in an exploratory manner. These measures will be used to generate hypotheses about the impact of therapeutic processes on outcome.

The Treatment Expectancy Questionnaire (TEQ) is a widely-used measure of treatment credibility [18]. This measure is administered at the conclusion of the first treatment session (after the treatment rationale and specific procedures are explained). The TEQ 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. We anticipate treatment expectancy to be high for both treatment conditions but expectancy ratings may moderate treatment outcome in general.

The Client Satisfaction Questionnaire [19], a measure of participant satisfaction with treatment, is administered at the last treatment session. This 8-item measure assesses satisfaction with treatment and has demonstrated concurrent validity. We expect client satisfaction ratings to be high for both treatment conditions.

The Working Alliance Inventory – short form (WAI-SF; [20]), is a 12-item self-report measure of therapeutic alliance. The WAI-SF consists of three subscales: Goals, which reflects the agreement between therapist and patient on overall goals of treatment; Tasks, which reflects the agreement on the appropriate tasks on which to focus (to achieve goals); and Bond, the quality of the affective relationship between the therapist and the patient. Both the therapist (therapist version) and the participant (client version) complete the WAI-SF at the conclusion of treatment. In the event that a participant drops out of treatment prematurely, the WAI-SF is completed at the time of dropout. Although WET is a much shorter treatment, we expect client and therapist alliance ratings to be equally high for WET and PE.

Several measures are administered to assess and monitor safety. The PTSD Checklist for *DSM-5* (PCL-5; [21]) is administered at each assessment occasion, including baseline, and at the beginning of every treatment session to monitor for symptom worsening, defined as an increase from the initial assessment of at least 10 points that is sustained for at least three consecutive treatment sessions [22]. The PCL-5 is completed in reference to the identified criterion A event established at the baseline assessment. This is a psychometrically strong measure that is sensitive to change [21,23].

The Beck Depression Inventory-II (BDI-II; [24]) is a 21-item self-report measure assessing current depressive symptoms and has well-established reliability and validity [25]. The BDI-II is administered at each assessment occasion, including baseline, and the beginning of every treatment session to monitor exacerbation of depression symptoms associated with treatment, as well as to assess any changes in suicidal ideation.

The Self-Injurious Thoughts and Behaviors Interview (SITBI; [26]) is administered at each assessment occasion to evaluate suicidal risk. The SITBI is a structured clinical interview that assesses the presence, frequency, and characteristics of a wide range of self-injurious thoughts and behaviors, including suicidal ideation, suicide plans, suicide gestures, suicide attempts, and non-suicidal self-injury. The SITBI has demonstrated excellent psychometric properties in multiple samples, including strong interrater reliability, and test–retest reliability over a 6-month period. Moreover, concurrent validity was demonstrated via strong correspondence between the SITBI and other measures of suicidal ideation, suicide attempt, and non-suicidal self-injury.

Lastly, 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 last assessment visit and whether any hospitalizations have occurred since last assessment. All serious adverse events are reported within 48 business hours to the local IRB as well as to the Data Monitoring Committee.

2.3.1. Training and oversight of independent assessors

The blinded assessors are located at VA Boston Healthcare System and work within the Psychological Assessment Lab (PAL). The PAL was developed to provide reliable assessments conducted by highly skilled assessors to geographically disparate sites. The PAL, directed by the second author, currently includes seven assessors. All assessors, who are either advanced doctoral-level candidates or who hold doctorates in clinical psychology, are rigorously trained on a range of assessment tools. All assessors are trained to expert level on the CAPS-5. Training on the CAPS-5 involves a three-step process. First, assessors complete a 4-h training, which includes an opportunity for assessors to score along with a CAPS-5 fidelity monitor as she completes a CAPS-5 interview. Assessors provide their scores from this mock interview. Second, we review the assessor's scores on the mock CAPS-5 and discuss administration and scoring of each CAPS-5 item. Third, assessors are assigned to complete mock CAPS-5 interviews with other staff who simulate patients; these interviews are recorded and evaluated for competency in administration and scoring. Assessors-in-training are prohibited from conducting real assessments until 90% agreement on CAPS-5 scoring is achieved. Assessors are trained appropriately on other relevant measures (e.g., SCID-5) depending upon the needs of the studies using the services of the PAL. Assessors complete biweekly, 60-min reliability meetings to discuss complex cases and protect against assessor drift.

All assessments conducted by the PAL are conducted via telephone. The psychometric quality and acceptability to research participants of psychiatric remote interviews are now well-established in both Veteran [27–29] and non-Veteran [e.g., [30, 31, 32]] samples. For example, Magruder [28], using the CAPS with a sample of Veterans seeking VA primary care, found 100% agreement across in-person and telephone interviews. In fact, all these studies except Rhode et al. specifically focused on PTSD and used the CAPS; Rohde et al. [30] found that the inter-rater reliability of phone interviews was excellent (kappa = .96 for major depressive disorder and 0.87 for anxiety disorders).

The use of the phone permits assessments to be conducted easily across large geographic regions and is ideal for reducing in-person contact during the current pandemic. The PAL maintains a shared assessment calendar, which is accessed by project coordinators at each recruitment site to schedule assessments for participants in the study. The project coordinators provide PAL with contact information for a scheduled participant as well as contact information for local police and hospital for the scheduled participant in case of an emergency during the course of the assessment.

2.4. Treatment conditions

2.4.1. Written exposure therapy (WET)

The WET protocol was developed over the course of a systematic series of studies investigating the use of expressive writing for the treatment of PTSD [13,33–36]. WET consists of five weekly treatment sessions, with the first session lasting 1 h and each subsequent session lasting approximately 45 min. In the first session, the therapist educates the patient about common reactions to trauma and provides the rationale for WET as a treatment for PTSD. The therapist then described general instructions for completing the trauma narratives, followed by specific instructions for completing the first session. The patient then completes the first (30 min) writing session. Patients are instructed to write about the same trauma during each session. This event is the same event identified as the index trauma during the baseline assessment.

The importance of delving into one's deepest emotions surrounding the traumatic event is emphasized, as well as the importance of providing detailed information about the event. In each WET session, the therapist reads the specific writing instructions for that session and then the patient completes the 30-min writing session. After 30 min has elapsed, the therapist instructs the patient to stop writing. The therapist then checks in with the patient regarding their reaction to the writing session. The discussion of the patient's reaction to the writing session is kept brief (i.e., less than 10 min). The patient submits their narrative to the therapist at the end of the session.

Writing instructions begin with a focus on describing the details of the trauma as well as the emotions and thoughts that occurred during the traumatic event. They then change over the course of the sessions to focus more on the meaning of the trauma event (e.g., what the event has meant to the person, how it has changed the way the person views his or her life). No between-session homework assignments are included. Between sessions, the therapist reads the written narrative to make sure the participant followed the writing instructions. At the start of subsequent writing session, the therapist provides feedback to the patient regarding how well he or she followed the instructions. When feedback is given for how to improve upon the narrative, the therapist will ask the patient after the writing for that session if they were able to incorporate the feedback they were given in the narrative conducted that session (e.g., was the patient able to include more information about the emotions they were feeling during the trauma event?)

Although the core aspect of WET involves written trauma narratives, we have not found educational level or IQ to moderate treatment outcome of WET [10]. This is not surprising as the purpose of the writing is to confront one's trauma memory; the quality of how one writes does not matter.

In response to VA clinician feedback indicating that veterans sometimes avoid writing about traumatic event in the first and sometimes second writing session, the current study permits up to an additional two sessions to course correct. Specifically, if the veteran does not follow writing instructions in the first and/or second session, these sessions should be repeated to allow for necessary level of exposure to the traumatic event. However, additional sessions will not be provided if patient is not able to follow instructions for more than the first two sessions. The number of treatment sessions administered will be recorded for both treatment conditions.

2.4.2. Prolonged Exposure (PE)

PE is designed to be delivered in 90-min weekly sessions that can range from 8 to 15. The sessions are flexible according to the response of the patient. Stopping before 15 sessions should occur because (1) the patient has a stable score (i.e., at least two consecutive sessions) below the probable PTSD diagnosis cut score of 33 [23] and (2) the clinician and patient agree that substantial clinical gain has occurred and no additional sessions are needed. Up to 15 sessions are provided if the score remains above the probable PTSD cut score. Treatment response is determined based on PCL-5 measure administered at each treatment session.

The conceptual foundation of PE is based upon emotional processing theory (Foa & Kozak, 1986). The PE model proposes that chronic PTSD develops when there is a failure to process the traumatic memory because of extensive avoidance of trauma reminders. PE mimics the natural fear modification process. During PE, patients are encouraged to confront (or expose themselves) to safe but anxiety-eliciting situations, in both imagination and in vivo, with the goal of overcoming excessive fear and anxiety. Thus, PE includes the following core components: (a) psychoeducation about the common reactions to traumatic events and presentation of the rationale for PE, (b) repeated in vivo exposure to situations or objects being avoided due to distress and anxiety, and (c) repeated, prolonged imaginal exposure to memories of the event(s). The focus of treatment initially lies in educating the patient about the PTSD diagnosis, gathering of detailed information about the traumatic event, and providing a sound rationale for PE. Patients' understanding of the rationale for PE is important because recognition of the importance of breaking their patterns of avoidance is a key goal. Patients, together with their therapist develop a hierarchy of feared but safe trauma related situations and objects and are instructed to gradually approach these situations between sessions (in vivo exposure exercises). The structure of gradual exposure is fairly consistent with traditional exposure-based interventions such that anxiety-provoking stimuli (e.g., physical or verbal cues) are presented gradually. The third component of treatment is imaginal exposure. During this phase, therapists assist patients in repeatedly recounting their traumatic event in detail, including their thoughts, feelings, and reactions that occurred during the event(s). Imaginal exposure is conducted during sessions and is audiotaped for patients to listen to at home between sessions.

2.4.3. Mode of delivery

As noted previously, all clinical assessments are conducted via telephone. In contrast, the study began with the option of delivering treatment either in person or telehealth delivery via a videoconferencing platform. At the onset of the COVID-19 global pandemic, all VA medical centers were required to cease all face to face research interactions. Accordingly, beginning in April 2020, all treatment sessions were shifted to telehealth delivery only. We anticipate continuing to only use telehealth delivery of treatment until a vaccine is widely available throughout the United States, at which point we will return to offering both telehealth and in person treatment options.

When conducting treatment sessions remotely, patients are mailed a treatment packet of materials prior to their first treatment session. This packet includes self-report measures to be completed at each treatment session, along with several addressed and stamped envelopes that participants can use to return the self-report questionnaires at the end of treatment. In addition, for the WET condition, the treatment packet includes all of the information on psychoeducation of PTSD, treatment rationale for WET, and the writing instructions for each session along with paper to be used for writing the narratives. With the exception of the stamped envelopes, all of these materials are normally given to patients when WET is delivered in person. For PE, the packet of treatment materials includes all of the homework assignments that are typically provided to patients at each session when PE is delivered in person. When delivering treatment remotely, patients are asked to share their written materials (e.g., homework sheets in PE or trauma narratives in WET) either by holding the document up to their web camera so the therapist can take a screen shot of the document or by scanning the document and sending it to the therapist through the MyHealtheVet portal used by VA for secure messaging between providers and veteran patients.

2.5. Quality control

2.5.1. Training and supervision of therapists

All study therapists hold either a doctoral degree in psychology and have at least one year of experience in treating PTSD patients; however, most of the study therapists have many years of experience. Therapists are counterbalanced to treat participants across the two treatment conditions. Given the nature of the two treatment conditions in this study, the amount of training and supervision each treatment requires differs substantially. For PE, a 2-day workshop is completed by all therapists. For WET, a 4-h training session is required. Following completion of the initial training, therapists receive 30–60 min, weekly supervision from psychologists who have extensive experience with the respective treatment protocol. All treatment sessions are audio-recorded and available for supervision and fidelity assessment.

2.5.2. Assessment of fidelity

Treatment fidelity is assessed by two individuals who are otherwise unaffiliated with the study. These two individuals are selected based on their familiarity with either the WET or the PE protocol. For each treatment condition, 15% of the treatment sessions will be randomly selected, reviewed, and rated, using the adherence and competence forms.

2.6. Data analytic strategy

2.6.1. General

The similarity of the patients in the two treatment conditions on key baseline variables (e.g., age sex, racial background, PTSD symptom severity, depression severity) will be examined using *t*-tests (e.g., sex), nonparametric equivalence, or chi-square tests, (racial background) depending on the type (continuous or dichotomous) and distribution (normal or non-normal) of the data. Any variable that statistically differs among groups will be used as covariates in the final analyses.

Missing Data. The proposed likelihood-based analyses are valid when the assumption that data is missing at random (MAR) holds. We will examine whether data are MAR using several approaches. First, we will perform [37] Missing Completely At Random test (MCAR). Second, we will compare those who are lost to outcome assessment with those available on baseline characteristics and response until dropout. If a statistical model predicting discontinuation can be developed, it can be the basis for inverse propensity weighting, a method that gives more weight to patients who are similar to those lost to follow-up [38]. On the other hand, Little [39] suggests that non-MAR situations are best handled by simple sensitivity analyses, where the assumptions are clear. For example, if a subset of the dropouts are thought to have an NMAR mechanism, the model might assume the mean of the predictive distribution of those values deviates from the distribution assumed under MAR by some specified amount, say 0.2 or 0.5 times the residual standard deviation given known variables for that case. The results from "tilting" the MAR model in this way can then be assessed." Enders [[40], p.289] describes a very similar process calling it "Rubin's ad hoc sensitivity analysis." He suggests performing a series of multiple imputation analyses using a range of plausible constant values. This multiple imputation approach is now implemented in SAS/STAT version 9.4's PROC MI with the inclusion of a new NMAR option [41], which permits systematically shifting imputed values by a constant amount or percent. It also can base the imputation model either on the complete sample or on a subset of cases such as the control group, as suggested by Mallinckrodt et al.'s [42] "worst case scenario." In the end, Demirtas and Schafer [[43], p. 2574] conclude: "To us, an ignorability-based analysis that includes good predictors of attrition often seems more plausible than a non-ignorable model that assumes that the probability of dropout is a known function of the outcome being measured."

2.7. Analysis of study aims

To test the hypothesis the primary aim of the study is that WET is non-inferior to PE, analyses will be conducted using the intent-to-treat (ITT) sample. The ITT sample will consist of participants who are randomized. The primary outcome measure will be PTSD symptom severity as indexed by the CAPS-5 total score. Consistent with Sloan et al. [14], a difference of 10 points (or less) on the CAPS-5 will be used to define noninferiority. The study includes assessments at 10-, 20-, and 30-weeks after the first treatment session. In order to examine treatment change over time, each of the three assessments will be examined and it is anticipated that WET will be non-inferior to PE at each of these assessments.

The second aim of the study is to examine whether treatment dropout is significantly lower among participants randomly assigned to WET than among participants randomly assigned to PE. Participants who are considered to have dropped out are those who do not complete the treatment protocol. However, because we are interested in dropout related to tolerability of the treatment, participants will not be included as a dropout if they report that they dropped out of treatment before completion because they felt they had achieved sufficient treatment gain. Moreover, for a fair comparison, we will only compare dropout during the first seven sessions in both treatment conditions.

Analysis of proportions (i.e., percentage of dropouts) is straightforward with contingency tables, chi-square tests, and logistic regression, but that approach requires unambiguous coding of outcomes for all cases. That is problematic for those pulled out or lost to follow-up for extraneous reasons (e.g., removed due to deployment). Excluding those cases will not bias analyses if their departure is assumed to be unrelated to treatment, but it may reduce power. Survival analysis deals well with cases lost to follow-up. The Kaplan-Meier (product limit) survival curve estimates the proportions of participants dropping out over time with log-rank, Wilcoxon and likelihood ratio tests of differences between groups in the survival functions. Cox proportional hazard regression is a flexible method of survival analysis to analyze of predictors of time to event that can include time-dependent predictors that change over time [55,56] compared four alternative data analysis methods for the study of time to event (in their case the event was recovery) and concluded that survival analysis was most powerful. Consequently, comparison of results with both approaches will most informative.

2.7.1. Power analysis to determine sample size

A power analysis was conducted with the focus being the primary study aim to test noninferiority based on the CAPS-5 PTSD total symptom severity score. Following the practice of Sloan et al. [14], an outcome difference of 10 points or more on the CAPS-5 total severity score was chosen as the "noninferiority margin." Differences smaller than 10 points would be considered clinically insignificant, so noninferiority will be declared if the upper bound of the 95% one-sided confidence limit of the difference between group means is less than 10. Using the CAPS for *DSM-IV*, Schnurr et al. [29] reported the standard deviation of the CAPS to be 20, so this represents a standardized mean difference in Cohen's [44] terms of $d = 0.50$, a conventional medium effect.

Sample size was determined using the module for noninferiority tests in the NCSS/PASS power software [45]. Specifications were a 10-point noninferiority margin, a standard deviation of 20 [29], a true difference between treatment groups of zero, one-sided noninferiority test at $p = .05$, desired power = .80 and equal allocation to the two treatment groups. With these specifications, PASS indicated that $N = 50$ per group is required. This number was increased by 25% to account for unavoidable loss to follow-up. This is the basis for proposed recruitment of 150 participants. The sample size is consistent with other previously conducted PTSD noninferiority trials [46,47].

Power analysis was also conducted for the second study aim testing dropout differences between the two treatment conditions. Sample size was determined using NCSS/PASS software [45]. Power would be at least 0.80 for a chi-square test of differences predicting dropout in PE of 30–40% and 5–10% in WET. For survival analysis with a sample size of 150 and 20% attrition using Cox proposal hazard model or log-range test has power of 0.87 for the smallest of these values (i.e., 30%–10%). Finally, logistic regression with a sample size of 100 and a binary predictor (treatment) has power ranging from 0.75 to 0.90. Taken together, the sample size to be recruited in the study will provide sufficient power to test the second aim of the study.

3. Discussion

PTSD is highly prevalent among veterans and is associated with substantial impairment. Despite the deleterious effects associated with PTSD, and the availability of effective psychosocial treatment approaches, veterans are reluctant to engage in these treatments. Even

when they do initiate treatment many do not complete it, with attrition sometimes as high as 50% [8,9]. Treatment dropout typically occurs within the first few sessions [8] before veterans are able to reap any benefit. For instance, Hoge and colleagues [48] found that the median number of treatment sessions attended by military service members diagnosed with PTSD was four. The low number of initiating treatment and treatment engagement among veterans and service members is worse than what is observed among other trauma exposed samples with PTSD [49,50]. Further, PTSD treatment outcomes are usually less robust for military service members and veterans than in treatment outcome studies with non-military and non-veteran samples [50].

One clear reason for the low treatment initiation and engagement among veterans is time restrictions. Given that most PTSD treatments involve at least 12 sessions and include a substantial amount of between session assignments, the time needed to complete PTSD treatment is significant and is more than what most veterans are able to commit given their other obligations (e.g., work, school, caring for young children).

The availability of a brief PTSD treatment that does not require between session assignments may increase treatment initiation and adherence. The current study will provide important information on whether WET is an effective treatment for veterans with PTSD. If we find that it is non-inferior to the more time intensive PE, then we can offer an exposure-based treatment that is more efficient for both veterans and the provider. That is, not only would WET be more easily completed by patients simply by virtue of reduced session length and elimination of intersession homework, but it would also be more efficient for providers who could treat a greater number of veterans in need of PTSD treatment services relative to the same amount of effort devoted to PE. An ongoing implementation study of WET in the VA mental health clinics is demonstrating that the amount of time needed to effectively train providers in WET is also much less [51] than what is involved in other trauma-focused treatments such as PE and CPT [4], speaking to organizational efficiency in addition to patient and provider gains.

Being able to receive treatment remotely also increases treatment retention [52], as does being able to receive treatment in one's own home rather than having to drive to a clinic. Indeed, Rosen and colleagues [53] found that veterans were less likely to initiate PTSD treatment if they lived further away from a VA clinic, and the extremely easy adaptation of WET to telemedicine delivery is a potential strength.

As mentioned, the study described here began the by offering treatment delivered either face to face or remotely, with most individuals opting for face to face. However, because of the COVID-19 pandemic, we were recently required to switch to entirely remote delivery of both treatments. We expect to be able to offer in person treatment in the last year of recruitment in the study. If we have sufficient sample sizes in both treatment delivery options, we will investigate whether there are differences in treatment outcome and dropout in the two delivery modalities. However, we do not expect differences in treatment outcome given that no differences have been found when PTSD treatment is delivered remotely versus in person with Veteran samples [54–58].

Our study will also address an important question regarding the number of treatment sessions, and the amount of therapeutic exposure, necessary to successfully treat PTSD. In recent years there is growing evidence that PTSD can be successfully treated in fewer therapy sessions than previously thought [59,60,61]. Our study is directly comparing two, exposure-based treatments although WET consists of imaginal exposure only with no between session assignments, whereas PE includes of both imaginal exposure and in vivo exposures with considerable between session assignments (repeatedly listen to imaginal exposure conducted in session and conduct in vivo exposures of avoided stimuli related to the trauma experience). In prior WET studies, we have found that patients begin confronting previously avoided stimuli related to the trauma event without instructions to do so [13]. Thus, the skills learned in the sessions needed to confront the trauma memory generalize to confronting other stimuli outside of sessions. Accordingly, findings from our study will add to the growing literature regarding how much treatment is necessary for beneficial outcomes.

In summary, the findings of our in progress non-inferiority will potentially substantially improve the number of veterans who initiate and engage in PTSD treatment as WET addresses the time and effort barriers frequently cited by veterans as a reason for not engaging in PTSD treatment. As a result of the COVID-19 pandemic we hope to also be able to examine if treatment dropout rates are reduced with remote treatment delivery compared to in person treatment delivery.

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Declaration of competing interest

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References

[1] M.A. Gates, D.W. Holowka, J.J. Vasterling, T.K. Keane, B.P. Marx, R.C. Rosen, Posttraumatic stress disorder in veterans and active duty military personnel: epidemiology, screening & case recognition, Psychol. Serv. 9 (4) (2012) 361–382, https://doi.org/10.1037/a0027649.

[2] Resick PA, Monson CM, Chard KM. Cognitive Processing Therapy for PTSD: a Comprehensive Manual. New York: Guilford Press; 2016.

[3] Foa EB, Hembree E, Rothbaum BO. Prolonged Exposure Therapy for PTSD: Emotional Processing of Traumatic Experiences Therapist Guide. New York: Oxford University Press; 2007.

[4] B.E. Karlin, J.I. Ruzek, K.M. Chard, et al., Dissemination of evidence-based psychological treatments for posttraumatic stress disorder in the Veterans Health Administration, J. Trauma Stress 23 (6) (2010) 663–673, https://doi.org/10.1002/jts.20588.

[5] E.V. Borah, E.C. Wright, D.A. Donahue, et al., Implementation outcomes of military provider training in cognitive processing therapy and prolonged exposure therapy for post-traumatic stress disorder, Mil. Med. 178 (2013) 939–944, https://doi.org/10.7205/milmed-d-13-00072.

[6] E.P. Finley, H.A. Garcia, N.S. Ketchum, et al., Utilization of evidence-based psychotherapies in Veterans Affairs posttraumatic stress disorder outpatient clinics, Psychol. Serv. 12 (1) (2015) 73–82, https://doi.org/10.1037/ser0000014.

[7] B.V. Watts, P.P. Schnurr, L. Mayo, Y. Young-Xu, W.B. Weeks, M.J. Friedman, Meta-analysis of the efficacy of treatments for posttraumatic stress disorder, J. Clin. Psychiatr. 74 (6) (2013) e541–e550, https://doi.org/10.4088/JCP.12r08225.

[8] S.M. Kehle-Forbes, L.A. Meis, M.R. Spoont, M.A. Polusny, Treatment initiation and dropout from prolonged exposure and cognitive processing therapy in a VA outpatient clinic, Psychol. Trauma 8 (1) (2016) 107–114, https://doi.org/10.1037/tra0000065.

[9] B.L. Niles, C.P. Polizzi, E. Voelkel, E.S. Weinstein, K. Smidt, L.M. Fisher, Initiation, dropout, and outcome from evidence-based psychotherapies in a VA PTSD outpatient clinic, Psychol. Serv. 15 (4) (2018) 496–502, https://doi.org/10.1037/ser0000175.

[10] Sloan DM, Marx BP. Written Exposure Therapy for PTSD: a Brief Treatment Approach for Mental Health Professionals. Washington, DC: American Psychological Press; 2019.

[11] D.M. Sloan, D. Lee, S. Litwak, A.T. Sawyer, B.P. Marx, Written exposure therapy for veterans diagnosed with PTSD: a pilot study, J. Trauma Stress 26 (6) (2013) 776–779, https://doi.org/10.1002/jts.21858.

[12] J. Thompson-Hollands, B.P. Marx, D.J. Lee, P.A. Resick, D.M. Sloan, Long-term treatment gains of a brief exposure-based treatment for PTSD, Depress. Anxiety 35

(2018) 985–991, https://doi.org/10.1002/da.22825.
[13] D.M. Sloan, B.P. Marx, M.J. Bovin, B.A. Feinstein, M.W. Gallagher, Written exposure as an intervention for PTSD: a randomized clinical trial with motor vehicle accident survivors, Behav. Res. Ther. 50 (2012) 627–635, https://doi.org/10.1016/j.brat.2012.07.001.
[14] D.M. Sloan, B.P. Marx, D.J. Lee, P.A. Resick, A brief exposure-based treatment vs cognitive processing therapy for posttraumatic stress disorder: a randomized noninferiority clinical trial, JAMA Psychiatr. 75 (3) (2018) 233–239, https://doi.org/10.1001/jamapsychiatry.2017.4249.
[15] Weathers FW, Blake DD, Schnurr PP, Kaloupek DG, Marx BP, Keane TM. The clinician-administered PTSD scale for DSM-5 (CAPS-5). Instrument available from the national center for PTSD at www.ptsd.va.gov; 2013.
[16] Weathers FW, Blake DD, Schnurr PP, Kaloupek DG, Marx BP, Keane TM. The life events checklist for DSM-5 (LEC-5). Instrument available from the national center for PTSD at https://www.ptsd.va.gov/professional/assessment/te-measures/life_events_checklist.asp; 2013.
[17] First MB, Williams JBW, Karg RS, Spitzer RL: Structured Clinical Interview for DSM-5—Research Version (SCID-5 for DSM-5, Research Version; SCID-5-RV). Arlington, VA, American Psychiatric Association, 2015.
[18] T. Borkovec, S. Nau, Credibility of analogue therapy rationales, J. Behav. Ther. Exp. Psychiatr. 3 (4) (1972) 257–260, https://doi.org/10.1016/0005-7916(72)90045-6.
[19] D. Larsen, C. Attkisson, W. Hargreaves, T. Nguyen, Assessment of client/patient satisfaction: Development of a general scale, Eval. Progr. Plann. 2 (1979) 197–207, https://doi.org/10.1016/0149-7189(79)90094-6.
[20] R.L. Hatcher, J.A. Gillaspy, Development and validation of a revised short version of the Working Alliance Inventory, Psychother. Res. 16 (1) (2006) 12–25, https://doi.org/10.1080/10503300500352500.
[21] Weathers FW, Litz BT, Keane TM, Palmieri, PA, Marx BP, Schnurr PP. The PTSD checklist for DSM-5 (PCL-5). Scale available from the national center for PTSD at https://www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp; 2013.
[22] E.B. Foa, L.A. Zoellner, N.C. Feeny, E.A. Hembree, J. Alvarez-Conrad, Does imaginal exposure exacerbate PTSD symptoms?, J. Consult. Clin. Psychol. 70 (2002) 1022–1028, https://doi.org/10.1037/0022-006x.70.4.1022.
[23] M.J. Bovin, B.P. Marx, F.W. Weathers, et al., Psychometric properties of the PTSD checklist for diagnostic and statistical manual of mental disorders–fifth edition (PCL-5) in veterans, Psychol. Assess. 28 (11) (2016) 1379–1391, https://doi.org/10.1037/pas0000254.
[24] Beck AT, Steer RA, Brown GK. Manual for Beck Depression Inventory II (BDI-II) San Antonio, TX: Psychology Corporation; 1996.
[25] D.J.A. Dozois, K.S. Dobson, J.L. Ahnberg, A psychometric evaluation of the Beck depression inventory-II, Psychol. Assess. 10 (2) (1998) 83–89, https://doi.org/10.1037/1040-3590.10.2.83.
[26] M.K. Nock, E.B. Holmberg, V.I. Photos, B.D. Michel, Self-injurious thoughts and behaviors interview: development, reliability, and validity in an adolescent sample, Psychol. Assess. 19 (3) (2007) 309–317, https://doi.org/10.1037/1040-3590.19.3.309.
[27] M.A. Aziz, S. Kenford, Comparability of telephone and face-to-face interviews in assessing patients with posttraumatic stress disorder, J. Psychiatr. Pract. 10 (5) (2004) 307–313, https://doi.org/10.1097/00131746-200409000-00004.
[28] K.M. Magruder, B.C. Frueh, R.G. Knapp, et al., Prevalence of posttraumatic stress disorder in Veterans Affairs primary care clinics, Gen. Hosp. Psychiatr. 27 (3) (2005) 169–179, https://doi.org/10.1016/j.genhosppsych.2004.11.001.
[29] P.P. Schnurr, M.J. Friedman, D.W. Foy, et al., Randomized trial of trauma-focused group therapy for posttraumatic stress disorder: results from a department of veterans affairs cooperative study, Arch. Gen. Psychiatr. 60 (5) (2003) 481489, https://doi.org/10.1001/archpsyc.60.5.481.
[30] P. Rohde, P.M. Lewinsohn, J.R. Seeley, Comparability of telephone and face-to-face interviews in assessing Axis I and II disorders, Am. J. Psychiatr. 154 (11) (2006) 1593–1598, https://doi.org/10.1176/ajp.154.11.1593.
[31] C.E. Sartor, V.V. McCutcheon, E.C. Nelson, A.E. Duncan, K.K. Bucholz, A.C. Heath, Investigating the association between childhood sexual abuse and alcohol use disorders in women: does it matter how we ask about sexual abuse?, J. Stud. Alcohol Drugs 73 (5) (2012) 740–748, https://doi.org/10.15288/jsad.2012.73.740.
[32] A.Y. Shalev, Y. Ankri, Y. Israeli-Shalev, T. Peleg, R. Adessky, S. Freedman, Prevention of posttraumatic stress disorder by early treatment: results from the Jerusalem Trauma Outreach and Prevention study, Arch. Gen. Psychiatr. 69 (2) (2012) 166–176, https://doi.org/10.1001/archgenpsychiatry.2011.127.
[33] D.M. Sloan, B.P. Marx, A closer examination of the structured written disclosure procedure, J. Consult. Clin. Psychol. 72 (2004) 165–175, https://doi.org/10.1037/0022-006X.72.2.165.
[34] D.M. Sloan, B.P. Marx, E.M. Epstein, Further examination of the exposure model underlying written emotional disclosure, J. Consult. Clin. Psychol. 73 (2005) 549–554, https://doi.org/10.1037/0022-006X.73.3.549.
[35] D.M. Sloan, B.P. Marx, E.M. Epstein, J. Lexington, Does altering the instructional set affect written disclosure outcome?, Behav. Ther. 38 (2007) 155–168, https://doi.org/10.1016/j.beth.2006.06.005.
[36] D.M. Sloan, B.P. Marx, E.M. Greenberg, A test of written emotional disclosure as an intervention for posttraumatic stress disorder, Behav. Res. Ther. 49 (2011) 299–304, https://doi.org/10.1016/j.brat.2011.02.001.
[37] R.A. Little, A test of missing completely at random for multivariate data with missing values, J. Am. Stat. Assoc. 83 (404) (1988) 198–1202 1988, https://doi.org/10.1080/01621459.1988.10478722.
[38] K. Hirano, G.W. Imbens, G. Ridder, Efficient estimation of average treatment effects using the estimated propensity score, Econometrica 71 (2003) 1161–1189 2003, https://doi.org/10.1111/1468-0262.00442.
[39] Little R. Selection and pattern-mixture models. In Fitzmaurice G, Davidian M, Verbeke G, Molenberghs G, (Eds.), Longitudinal Data Analysis (pp. 409-432). Boca Raton, FL: Chapman & Hall/CRC 2009.
[40] Enders CK. Models for not missing at random data. Applied Missing Data Analysis. New York: Guilford Press. 2010.
[41] Yuan Y. Sensitivity Analysis in Multiple Imputation for Missing Data. Rockville, MD: SAS Institute, Inc.
[42] C.H. Mallinckrodt, Q. Lin, M. Molenberghs, A structured framework for assessing sensitivity to missing data assumptions in longitudinal clinical trials, Pharmaceut. Stat. 12 (1) (2012) 1–6 2012, https://doi.org/10.1002/pst.1547.
[43] H. Demirtas, J.L. Schafer, On the performance of random-coefficient pattern-mixture models for non-ignorable drop-out, Stat. Med. 22 (16) (2003) 2553–2575, https://doi.org/10.1002/sim.1475.
[44] Cohen J. Statistical Power Analysis for the Behavioral Sciences. second ed. Hillsdale, NJ: Erlbaum; 1988.
[45] Hintze J. NCSS and PASS, Number Cruncher Statistical Systems. Kaysville, UT: NCSS Statistical Software; 2019.
[46] J.C. Markowitz, E. Petkova, Y. Neria, et al., Is exposure necessary? a randomized clinical trial of interpersonal psychotherapy for PTSD, Am. J. Psychiatr. 172 (5) (2015) 430–440, https://doi.org/10.1176/appi.ajp.2014.14070908.
[47] L.A. Morland, M.A. Mackintosh, C.S. Rosen, et al., Telemedicine versus in-person delivery of cognitive processing therapy for women with posttraumatic stress disorder: a randomized noninferiority trial, Depress. Anxiety 32 (11) (2015) 811–820, https://doi.org/10.1002/da.22397.
[48] C.W. Hoge, S.H. Grossman, J.L. Auchterlonie, L.A. Riviere, C.S. Milliken, J.E. Wilk, PTSD treatment for soldiers after combat deployment: low utilization of mental health care and reasons for dropout, Psychiatr. Serv. 65 (8) (2014) 997–1004, https://doi.org/10.1176/appi.ps.201300307.
[49] Z.E. Imel, K. Laska, M. Jakupcak, T.L. Simpson, Meta-analysis of dropout in treatments for posttraumatic stress disorder, J. Consult. Clin. Psychol. 81 (3) (2013) 394–404, https://doi.org/10.1037/a0031474.
[50] M.M. Steenkamp, B.T. Litz, C.W. Hoge, C.R. Marmar, Psychotherapy for military-related PTSD: a review of randomized clinical trials, J. Am. Med. Assoc. 314 (2015) 489–500, https://doi.org/10.1001/jama.2015.8370.
[51] Worley CB, Losavio ST, Aajmain SA, Rosen C, Stirman SW, Sloan DM. Training during a pandemic: successes, challenges, and practical guidance during a virtual facilitated learning collaborative for written exposure therapy. J. Trauma Stress. in press.
[52] R. Acierno, R. Knapp, P. Tuerk, et al., A non-inferiority trial of Prolonged Exposure for posttraumatic stress disorder: in person versus home-based telehealth, Behav. Res. Ther. 89 (2017) 57–65, https://doi.org/10.1016/j.brat.2016.11.009.
[53] C.S. Rosen, N.C. Bernardy, K.M. Chard, et al., Which patients initiate cognitive processing therapy and prolonged exposure in department of veterans affairs PTSD clinics?, J. Anxiety Disord. 62 (2019) 53–60, https://doi.org/10.1016/j.janxdis.2018.11.003.
[54] R. Acierno, D.F. Gros, K.J. Ruggiero, et al., Behavioral activation and therapeutic exposure for Posttraumatic Stress Disorder: a non-inferiority trial of treatment delivered in person vs home-based telehealth, Depress. Anxiety 33 (5) (2016) 415–433, https://doi.org/10.1002/da.22476.
[55] R. Acierno, R. Knapp, P. Tuerk, et al., A non-inferiority trial of Prolonged Exposure for Posttraumatic Stress Disorder: in person versus home-based telehealth, Behav. Res. Ther. 89 (2017) 57–65, https://doi.org/10.1016/j.brat.2016.11.009.
[56] L.E. Egede, R. Acierno, R.G. Knapp, et al., Psychotherapy for depression in older veterans delivered via telemedicine: a randomized non-inferiority trial, Lancet Psychiatr. 2 (8) (2015) 693–701, https://doi.org/10.1016/S2215-0366(15)00122-4.
[57] L.E. Egede, R. Acierno, R.G. Knapp, et al., Psychotherapy for depression in older veterans via telemedicine: effect on quality of life, satisfaction, treatment credibility, and service delivery perception, J. Clin. Psychiatr. 77 (12) (2016) 1704–1711, https://doi.org/10.4088/JCP.16m10951.
[58] L.A. Morland, M.A. Mackintosh, C.J. Greene, et al., Cognitive processing therapy for posttraumatic stress disorder delivered to rural veterans via telemental health: a randomized noninferiority clinical trial, J. Clin. Psychiatr. 75 (5) (2014) 470–476, https://doi.org/10.4088/JCP.13m08842.
[59] A. van Minnen, E.B. Foa, The effect of imaginal exposure length on outcome of treatment for PTSD, J. Trauma Stress 19 (4) (2006) 427–438, https://doi.org/10.1002/jts.20146.
[60] N. Nacasch, J.D. Huppert, Y.J. Su, et al., Are 60-minute prolonged exposure sessions with 20-minute imaginal exposure to traumatic memories sufficient to successfully treat PTSD? A randomized noninferiority clinical trial, Behav. Ther. 46 (3) (2015) 328–341, https://doi.org/10.1016/j.beth.2014.12.002.
[61] T.E. Galovski, L.M. Blain, J.M. Mott, L. Elwood, T. Houle, Manualized therapy for PTSD: flexing the structure of cognitive processing therapy, J. Consult. Clin. Psychol. 80 (6) (2012) 968–981, https://doi.org/10.1037/a0030600.