A Brief Exposure-Based Treatment vs Cognitive Processing Therapy for Posttraumatic Stress Disorder
A Randomized Noninferiority Clinical Trial
Denise M. Sloan, PhD; Brian P. Marx, PhD; Daniel J. Lee, PhD; Patricia A. Resick, PhD

IMPORTANCE Written exposure therapy (WET), a 5-session intervention, has been shown to efficaciously treat posttraumatic stress disorder (PTSD). However, this treatment has not yet been directly compared with a first-line PTSD treatment such as cognitive processing therapy (CPT).

OBJECTIVE To determine if WET is noninferior to CPT in patients with PTSD.

DESIGN, SETTING, AND PARTICIPANTS In this randomized clinical trial conducted at a Veterans Affairs medical facility between February 28, 2013, and November 6, 2016, 126 veteran and nonveteran adults were randomized to either WET or CPT. Inclusion criteria were a primary diagnosis of PTSD and stable medication therapy. Exclusion criteria included current psychotherapy for PTSD, high risk of suicide, diagnosis of psychosis, and unstable bipolar illness. Analysis was performed on an intent-to-treat basis.

INTERVENTIONS Participants assigned to CPT (n = 63) received 12 sessions and participants assigned to WET (n = 63) received 5 sessions. The CPT protocol that includes written accounts was delivered individually in 60-minute weekly sessions. The first WET session requires 60 minutes while the remaining 4 sessions require 40 minutes.

MAIN OUTCOMES AND MEASURES The primary outcome was the total score on the Clinician-Administered PTSD Scale for DSM-5; noninferiority was defined by a score of 10 points. Blinded evaluations were conducted at baseline and 6, 12, 24, and 36 weeks after the first treatment session. Treatment dropout was also examined.

RESULTS For the 126 participants (66 men and 60 women; mean [SD] age, 43.9 [14.6] years), improvements in PTSD symptoms in the WET condition were noninferior to improvements in the CPT condition at each of the assessment periods. The largest difference between treatments was observed at the 24-week assessment (mean difference, 4.31 points; 95% CI, -1.37 to 9.99). There were significantly fewer dropouts in the WET vs CPT condition (4 [6.4%] vs 25 [39.7%]; \( \chi^2 = 12.84, \) Cramer V = 0.40).

CONCLUSIONS AND RELEVANCE Although WET involves fewer sessions, it was noninferior to CPT in reducing symptoms of PTSD. The findings suggest that WET is an efficacious and efficient PTSD treatment that may reduce attrition and transcend previously observed barriers to PTSD treatment for both patients and providers.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01800773

Supplemental content

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he recently revised Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder (PTSD) and Acute Stress Disorder1 strongly recommends the use of individual, manualized trauma-focused psychotherapies that have a primary component of exposure and/or cognitive restructuring, such as prolonged exposure2 and cognitive processing therapy (CPT).3 Also included in this recommended group of treatments is written narrative exposure, which the clinical practice guideline notes is a simple, yet effective, way to deliver exposure therapy for PTSD.

Included among written narrative exposure treatments is written exposure therapy (WET), a brief (ie, 5 sessions) trauma-focused intervention in which individuals are asked to write about their traumatic experience following scripted instruction. The first session includes psychoeducation about PTSD along with a treatment rationale followed by 30 minutes of writing. At the beginning of each subsequent session, therapists provide feedback to individuals about the degree to which they followed the writing instructions during the prior session and offer suggestions for adhering to the treatment protocol. After this feedback, individuals write for 30 minutes without interruption. Written exposure therapy does not include any assignments between sessions. Written exposure therapy also involves considerably less therapist training and supervision to successfully implement than do either prolonged exposure or CPT. Prior research has shown WET to significantly reduce the severity of PTSD symptoms in a variety of trauma survivors, with effect sizes similar to those associated with CPT and prolonged exposure,4 and to have substantially fewer treatment dropouts than these other treatments.4,5 However, WET has not yet been directly compared with either of these treatments in the same study.

This study examined if WET is noninferior to CPT. Cognitive processing therapy was selected because it is widely recognized as a first-line treatment approach for PTSD and is 1 of 2 treatments that has the strongest empirical support. Also, CPT includes a written narrative account as part of the treatment and the developer of CPT (one of us, P.A.R.) agreed to oversee supervision and training of the CPT arm of the study, thereby ensuring high-quality administration of this treatment. We expected that individuals who were randomly assigned to WET would report reductions in PTSD symptoms similar to those seen in individuals assigned to CPT. Consistent with findings on treatment dropout from prior studies,6,7 we also expected significantly less treatment dropout for WET relative to CPT.

Methods

Participants

Demographic characteristics are displayed in Table 1. Participants were 126 adults (60 women and 66 men) aged 18 years or older seeking treatment for PTSD in Boston, Massachusetts. Recruitment was designed to be broadly inclusive. Eligibility required meeting DMS-5 criteria for PTSD and, if taking psychotropic medication, taking a stable dose for at least 4 weeks. Participants were asked to keep their medication regimen unchanged throughout the treatment period in consultation with their prescribers. Minimal exclusion criteria consisted of current high risk for suicide, active psychosis or mania, severe cognitive impairment, current diagnosis of substance dependence, and concurrent psychosocial treatment for PTSD. Measures

Clinical interviews were administered by 4 independent evaluators who had at least a master's degree in psychology and who were blinded to treatment conditions. Assessments were conducted at baseline and 6, 12, 24, and 36 weeks after the first treatment session. Given the substantial difference in treatment sessions between the 2 treatments, a structured time approach for assessments was used rather than assessing after treatment and conducting follow-up from the completion of treatment. Assessment points were selected based on the approximate completion of WET (6 weeks) and CPT (12 weeks). The primary measure used to assess PTSD diagnostic status and symptom severity was the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5).8,9 The Structured Clinical Interview for DSM-IV (SCID)10 was used to assess for exclusion criteria and baseline psychiatric comorbidity. This measure was included at the baseline assessment only; the version of the SCID that corresponds to the DSM-5 was not available at the start of this study. Interrater reliability was very good (CAPS-5, κ = 0.85; SCID, κ = 0.78). To examine treatment dropout, we compared the number of participants in each treatment condition who left treatment before completion. We also assessed participants' beliefs about expected outcome of treatment at the end of the first treatment session using the Treatment Expectancy Questionnaire11 and treatment satisfaction, assessed at the last treatment session, using the Client Satisfaction Measure.12

Key Points

Question Is a brief, exposure-based treatment noninferior to the more time-intensive cognitive processing therapy in the treatment of posttraumatic stress disorder?

Findings In this randomized noninferiority clinical trial of 126 adults who received a diagnosis of posttraumatic stress disorder, those treated with written exposure therapy, a 5-session treatment, and those treated with cognitive processing therapy improved significantly, with large effect sizes observed. Despite the substantial dose difference, written exposure therapy was noninferior to cognitive processing therapy.

Meaning The findings provide evidence that written exposure therapy and cognitive processing therapy are effective for treatment of posttraumatic stress disorder, and that posttraumatic stress disorder can be effectively treated with a 5-session psychotherapy.
Participants were recruited from advertisements and direct referrals from community health care professionals. From February 28, 2013, to November 6, 2016, the research team prescreened 361 individuals for eligibility via telephone. Approximately 113 individuals were ineligible or declined participation. A total of 190 individuals consented to this study and completed an eligibility and baseline assessment and 126 were randomized. All study procedures took place at the Veterans Affairs Boston Healthcare System. Training and fidelity of independent evaluators are described in eAppendix 2 in Supplement 1.

Randomization and Blinding
After participants were deemed to be eligible, a study staff member who was not involved in the evaluations randomized participants using a computerized block randomization with a 1:1 allocation ratio to WET and CPT conditions. The project coordinator who was responsible for final determination of study eligibility was blinded to the randomization sequence. Participants were unaware of study hypotheses and were instructed not to reveal their randomization status to the independent evaluators prior to each assessment. To further protect blinding, independent evaluators were located separately from the therapists, and a new rater was assigned in the event of an unintentional unblinding.

Treatment
As previously described, WET includes 5 sessions in which patients are instructed to write about a specific traumatic event, with a focus on details of the event and thoughts and feelings that occurred during the event, for 30 minutes each session. No assignments between sessions are included in WET. Cognitive processing therapy is a 12-session trauma-focused therapy in which patients are taught to recognize and challenge dysfunctional cognitions about their traumatic event and current thoughts about themselves, others, and the world. In the original CPT protocol (CPT plus written account), which was used in this study because it has been disseminated widely and has accumulated the most empirical support, individuals also write 2 trauma accounts. These accounts are written at home after sessions 3 and 4. In these written accounts, participants provide sensory details, thoughts, and feelings associated with the trauma. Unlimited time is allotted for the narrative and once it is completed patients are to read the account daily until the next session. In addition to these assignments to write 2 trauma accounts, additional between-session assignments are given after each treatment session. Cognitive

Table 1. Demographic and Background Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Treatment Condition, No. (%) of Participants*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All (N = 126)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>43.9 (14.6)</td>
</tr>
<tr>
<td>Male</td>
<td>66 (52.4)</td>
</tr>
<tr>
<td>Military veteran</td>
<td>33 (26.2)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>12 (9.5)</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>114 (90.5)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>4 (3.2)</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>African American or black</td>
<td>43 (34.1)</td>
</tr>
<tr>
<td>Pacific Islander or Native Hawaiian</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>White</td>
<td>69 (54.8)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (5.6)</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
</tr>
<tr>
<td>≤High school</td>
<td>33 (26.2)</td>
</tr>
<tr>
<td>Some college</td>
<td>50 (39.7)</td>
</tr>
<tr>
<td>College degree</td>
<td>26 (20.6)</td>
</tr>
<tr>
<td>Graduate or professional degree</td>
<td>17 (13.5)</td>
</tr>
<tr>
<td>Annual household income ≤$25 000</td>
<td>67 (53.2)</td>
</tr>
<tr>
<td>Index event of worst trauma</td>
<td></td>
</tr>
<tr>
<td>Combat related</td>
<td>16 (12.7)</td>
</tr>
<tr>
<td>Sudden death (noncombat) or violence to a friend or loved one</td>
<td>13 (10.3)</td>
</tr>
<tr>
<td>Adult nonssexual assault</td>
<td>24 (19.1)</td>
</tr>
<tr>
<td>Adult sexual assault</td>
<td>19 (15.1)</td>
</tr>
<tr>
<td>Child nonssexual assault</td>
<td>11 (8.7)</td>
</tr>
<tr>
<td>Child sexual assault</td>
<td>20 (15.9)</td>
</tr>
<tr>
<td>Motor vehicle crash</td>
<td>10 (7.9)</td>
</tr>
<tr>
<td>Injury from other accidental causes</td>
<td>13 (10.3)</td>
</tr>
</tbody>
</table>

Abbreviations: CPT, cognitive processing therapy; WET, written exposure therapy.
* Percentages have been rounded and may not total 100.
Figure 1. CONSORT Flow Diagram

364 Individuals prescreened
172 Excluded
  84 Not eligible
  36 Eligible but cancelled assessment
  52 Declined or not interested
192 Signed consent form and completed initial assessment
48 Excluded
  39 Did not meet PTSD criteria
  3 Did not complete assessment
  2 Current psychotic symptoms
  1 Current substance dependence
144 Eligible
  18 Declined to participate
126 Randomized (ITT sample)
63 Randomized to receive WET
  59 Received WET as randomized
  4 Did not receive WET as randomized (dropped out)
  1 Did not attend
60 Completed 6-wk assessment
  1 Did not attend or not found
62 Completed 12-wk assessment
  3 Did not attend or not found
57 Completed 24-wk assessment
  4 Did not attend or not found
  2 Declined
55 Completed 36-wk assessment
  6 Did not attend or not found
  1 Declined
  1 Hospitalized
63 Included in primary analysis
  0 Excluded
63 Randomized to receive CPT
  37 Received CPT as randomized
  26 Did not receive CPT as randomized
  25 Dropped out
  1 Administratively withdrawn
54 Completed 6-wk assessment
  8 Did not attend or not found
  1 Declined
52 Completed 12-wk assessment
  10 Did not attend or not found
  1 Declined
49 Completed 24-wk assessment
  8 Did not attend or not found
  6 Declined
46 Completed 36-wk assessment
  6 Did not attend or not found
  6 Declined
63 Included in primary analysis
  0 Excluded

CONSORT diagram for study comparing cognitive processing therapy (CPT) and written exposure therapy (WET) for participants with posttraumatic stress disorder (PTSD). ITT indicates intent to treat.

Brief Exposure-Based Treatment vs Cognitive Processing Therapy for PTSD

processing therapy and WET were delivered individually and treatments consisted of weekly sessions.

Consistent with the intent-to-treat approach, all individuals who dropped out of treatment prematurely were asked to complete all assessments included in the study. A structured protocol was used for each therapy condition. Training and fidelity of the therapists are described in detail in Supplement 3 in Supplement 1. Adherence and competency ratings were good to excellent for both treatment conditions. For detailed information on study design, see the study by Sloan et al.13

Statistical Analysis

Because the noninferiority margin for CAPS-5 scores has not yet been determined, we calculated the reliable change index14 to use as the noninferiority margin. Using the pooled SD (9.5) for CAPS-5 scores at baseline, and the published test-retest value for the CAPS-5 (r = 0.78),9 the SE of the difference between the 2 groups was 6.28. With this information, we determined that the CAPS-5 reliable change index is 13 points. Thus, any difference between WET and CPT in CAPS-5 reliable change index scores greater than 13 points indicates that the difference is statistically significant and not owing to measurement error. Recognizing that a 13-point noninferiority margin may be too lenient, a more conservative 10-point noninferiority margin for the prior version of the CAPS was used.

Sample size was determined using the module for noninferiority tests in the Power Analysis and Sample Size (PASS) Software.15 Specifications were the 10-point noninferiority margin, an SD of 20 for CAPS-5 severity scores,16 a true difference between treatment groups of 0, a 1-sided noninferiority test at P = .05, desired power of 0.80, and equal participant allocation to the 2 treatment groups. With these specifications, PASS indicated that 50 participants per group were required. This number was increased twice, first by 15% to account for unavoidable loss to follow-up, and then by an additional 10% to deal with the then-unknown psychometric properties of the CAPS-5; this increase resulted in a total sample size of 126. The sample size is similar17 or larger than other PTSD noninferiority trials.18,19

Hierarchical linear modeling20 was also conducted to determine within-condition effect of treatment on symptoms of PTSD. All analyses were conducted using an unstructured covariance matrix. Analyses were conducted using all data points for all participants who were randomized (ie, intent to treat). Within- and between-condition effect sizes (Cohen d) were calculated and interpreted using guidelines from Cohen.21

Results

Participants assigned to WET and CPT conditions did not significantly differ in age, educational level, or household income, and were not more likely in either condition to identify as male, Hispanic, or be a military veteran. Likewise, participants did not significantly differ in PTSD symptom severity at baseline (t124 = -0.57; P = .57).

Treatment Process Measures

Participants assigned to CPT and WET did not significantly differ in terms of treatment expectations (t123 = -1.57; P = .12), with generally high expectations indicated for both treatments (WET: mean [SD], 26.24 [5.47]; CPT: mean [SD], 27.81 [5.72]). Similarly, participants in both treatments had high levels of satisfaction with the treatment they received (WET: mean [SD], 28.34 [3.74]; CPT: mean [SD], 29.30 [4.84]), with no significant between-condition differences observed (t100 = -1.12;
Table 2. Outcome Measures by Condition and Time Point

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Baseline</th>
<th>6 wk</th>
<th>12 wk</th>
<th>24 wk</th>
<th>36 wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPS-5 Total Score, mean (SD)</td>
<td>36.10 (8.91)</td>
<td>30.90 (11.70)</td>
<td>26.63 (13.00)</td>
<td>25.23 (13.20)</td>
<td>23.26 (13.33)</td>
</tr>
<tr>
<td>WET</td>
<td>37.10 (10.07)</td>
<td>32.94 (12.94)</td>
<td>24.81 (13.86)</td>
<td>20.92 (16.30)</td>
<td>21.37 (15.28)</td>
</tr>
<tr>
<td>Difference</td>
<td>1.00</td>
<td>2.04</td>
<td>1.82</td>
<td>4.31</td>
<td>1.89</td>
</tr>
<tr>
<td>CAPS-5 PTSD diagnosis, No./Total No. (%)</td>
<td>63/63 (100)</td>
<td>44/62 (71.0)</td>
<td>33/60 (55.0)</td>
<td>25/57 (43.9)</td>
<td>26/54 (48.1)</td>
</tr>
<tr>
<td>Difference</td>
<td>1.00</td>
<td>2.04</td>
<td>1.82</td>
<td>4.31</td>
<td>1.89</td>
</tr>
</tbody>
</table>
| PTSD, posttraumatic stress disorder; and RCI, reliable change index.

PTSD Severity and Diagnosis

Descriptive statistics for outcome of PTSD symptoms are provided in Table 2. This table also displays the CAPS-5 symptom severity treatment condition difference score. Within-condition hierarchical linear modeling analyses indicated that CAPS-5 total scores showed significant effects of linear change over time in both the WET (B = -2.33; SE = 0.35; t = -6.68; P < .001) and CPT (B = -3.43; SE = 0.44; t = -7.70; P < .001) conditions. In addition, a quadratic growth term explained significant variance over and above a linear term in both the WET (B = 0.80; SE = 0.23; t = 3.50; P = .001) and CPT (B = 1.05; SE = 0.25; t = 4.24; P < .001) conditions.

Figure 2 illustrates mean difference between treatment conditions with 95% CIs for changes in CAPS-5 scores over time. The noninferiority hypothesis was supported by the finding that CAPS-5 severity scores for participants in the WET condition were not inferior to those for participants in the CPT condition at any assessment period. Within-condition effect sizes were large in both conditions for the 12-week through the 36-week assessments (Table 3). With the exception of the 24-week assessment, between-condition effect sizes were small at the assessments (ie, <0.20). The 24-week assessment between-condition effect size was 0.29, with CPT showing a slightly larger change from baseline than WET (4.31 points’ difference between the 2 groups). Fewer than half of participants continued to meet diagnostic criteria for PTSD in both conditions at the 24- and 36-week follow-ups (Table 2). Participants were not more likely to meet PTSD diagnostic criteria in one condition or the other at any assessment.

We were unable to conduct a completer analysis owing to the significant difference between WET and CPT in the number of participants who dropped out of treatment. However, the difference between the 2 treatments is similar to that of the intent-to-treat sample (eTable in Supplement 1).

Adverse Events

Six patients randomized to CPT (9.5%) reported a total of 7 adverse events and 5 patients randomized to WET (7.9%) reported a total of 7 adverse events. There were no significant differences in the nature, frequency, or severity of adverse events reported. More details about events, which were primarily injuries or illnesses, are provided in eAppendix 4 in Supplement 1.

Discussion

Although prior studies have shown WET to significantly reduce PTSD symptoms among trauma survivors, no prior study had compared WET directly with another PTSD treatment strongly recommended in the revised Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder.1 Our analyses indicate that WET did not differ from CPT in reducing symptoms of PTSD or in the percentage of participants who met diagnostic criteria for PTSD at any assessment point. Furthermore, participants assigned to the 2 treatments did not differ significantly in treatment expectations or the degree to which they were satisfied with the treatment they received.

Our results add to mounting research showing that the dose of therapy needed for beneficial outcomes for individuals with PTSD is not as large as was once previously thought.19,22,23 Our findings extend those prior studies by demonstrating that not only can PTSD symptoms be reduced significantly with less therapeutic exposure but that not as many therapy sessions

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Abbreviations:
CAPS-5, Clinician-Administered PTSD Scale for DSM-5;
CPT, cognitive processing therapy;
PTSD, posttraumatic stress disorder;
WET, written exposure therapy.

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are required. The fact that fewer sessions and less exposure are necessary to result in beneficial outcomes underscores the need to investigate the necessary and sufficient treatment elements for successful outcomes. Written exposure therapy differs from CPT in other potentially important aspects. For instance, written narratives are conducted within the sessions for WET, whereas the narrative written trauma accounts are completed between sessions in CPT. Moreover, CPT has between-session assignments after each treatment session, whereas no between-session assignments are included in WET. The amount of therapist interaction is also significantly less in WET than in CPT.

Our findings have important implications for treating individuals with PTSD, especially given the high clinical demand for PTSD treatment among veterans and military service members. The availability of a treatment that is time efficient for both the patients and the clinicians may address some of the barriers to care that have been identified in the Veterans Affairs and Department of Defense settings. The version of CPT used in this study included the written accounts that have been found to be associated with 15% more dropouts and with no value added in 1 study. In our study, the dropouts typically occurred early in the course of treatment when the written trauma accounts were assigned. The dropout rate for CPT in our study is similar to that observed in other studies, which have also noted a pattern of early treatment dropout. These findings suggest that it may be easier for individuals to complete written trauma accounts during treatment sessions within a clinic setting rather than as assignments to be completed outside of the clinic. Future research should examine whether dropout rates are reduced with the version of CPT that does not include written accounts. Overall, the greater treatment dropout rate in CPT in our study was not merely owing to more treatment sessions. It is also not the case that individuals dropped out of CPT prematurely because of perceived treatment gain; only 1 person stated this as the reason for premature treatment dropout.

Although there were no significant differences between WET and CPT at any time point, we did find a somewhat larger between-group difference at the 24-week assessment. More important, this is the assessment time point that captures treatment completion for all CPT participants, although there was considerable variability within the CPT group for time to treatment completion. This slightly larger between-condition difference was not maintained at the next assessment at 36 weeks. Thus, it was not a difference that was maintained or grew over time.

Limitations

This study has some limitations that should be considered. First, a mixed trauma sample was examined rather than focus on a specific trauma sample, such as military veterans or individuals who experienced interpersonal violence. A mixed trauma sample was included to increase generalizability of the findings obtained. However, there is some evidence that trauma-focused PTSD treatments have lower efficacy with certain trauma samples, such as military veterans and military service members. Accordingly, it would be important to investigate whether WET is noninferior to CPT using a sample of military veterans or military service members. Second, we were unable to conduct completer analyses owing to the significantly greater number of participants who dropped out of CPT. It could be argued that WET is better tolerated than CPT but could have a weaker effect size than CPT if only the individuals completing the full course of WET and CPT could be compared. Even with the 39.7% who dropped out early included, the outcomes for CPT were not significantly different than for WET. Nonetheless, the pattern of findings for the completer sample is similar to that of the intent-to-treat sample. Third, the noninferiority margin used in this study may need to be reexamined once additional data for CAPS-5 are available. Finally, we examined stability of psychotropic medication via self-report.

Conclusions

To our knowledge, this study is the first to directly compare WET, a brief exposure-based treatment approach, with CPT, a first-line PTSD treatment. Findings indicate that WET is noninferior to CPT despite the significantly reduced treatment dose with WET. The findings provide additional efficacy support for an efficient PTSD treatment that is well tolerated by patients. Written exposure therapy should be considered by clinicians to be a viable treatment option that can address some of the barriers to receiving and implementing CPT and prolonged exposure that have been noted in health care settings.
the integrity of the data and the accuracy of the data analysis. Study concept and design: Sloan, Marx. Acquisition, analysis, or interpretation of data: All authors. Drafting of the manuscript: Sloan, Marx. Critical revision of the manuscript for important intellectual content: All authors. Statistical analysis: Sloan, Marx. Lee. Obtaining funding: Sloan, Marx. Administrative, technical, or material support: Sloan, Resick. Supervision: Sloan, Marx. Conflict of Interest Disclosures: None reported. Funding/Support: This study was funded by grant ROMH0957373 from the National Institute of Mental Health.

Role of the Funder/Sponsor: The funding source had no role in the design or conduct of the study; collection, management, analysis, and interpretation of data; preparation, review or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The views expressed in this article are solely those of the authors and do not reflect the endorsement or the official policy or position of the Department of Veteran Affairs or the US government.

Additional Contributions: Jenny Lee, BA, Michele Strage, BA, Sara Lowmaster, PhD, and Johanna Thouin-Hollands, PhD, Veterans Affairs Boston Health Care System and Boston University School of Medicine, served as study coordinators and research assistants. Michelle Bovin, PhD, Jon Greene, PhD, Cassidy Gutner, PhD, Jane Jun, PhD, Sarah Kleinman, PhD, and Scott Litwack, PhD, Veterans Affairs Boston Health Care System and Boston School of Medicine, served as study therapists. Alexandra Dick, MA, Sarah Danitz, MA, Katherine Smith, MA and Sarah Williston, MA, Boston University School of Medicine, served as independent evaluators. These contributors received no extra compensation other than regular salary.

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