# JAMA Psychiatry | Original Investigation

# Effect of Group vs Individual Cognitive Processing Therapy in Active-Duty Military Seeking Treatment for Posttraumatic Stress Disorder A Randomized Clinical Trial

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**IMPORTANCE** Cognitive processing therapy (CPT), an evidence-based treatment for posttraumatic stress disorder (PTSD), has not been tested as an individual treatment among active-duty military. Group CPT may be an efficient way to deliver treatment.

**OBJECTIVE** To determine the effects of CPT on PTSD and co-occurring symptoms and whether they differ when administered in an individual or a group format.

**DESIGN, SETTING, AND PARTICIPANTS** In this randomized clinical trial, 268 active-duty servicemembers consented to assessment at an army medical center from March 8, 2012, to September 23, 2014, and were randomized to group or individual CPT. Inclusion criteria were PTSD after military deployment and stable medication therapy. Exclusion criteria consisted of suicidal or homicidal intent or psychosis. Data collection was completed on June 15, 2015. Analysis was based on intention to treat.

**INTERVENTIONS** Participants received CPT (the version excluding written accounts) in 90-minute group sessions of 8 to 10 participants (15 cohorts total; 133 participants) or 60-minute individual sessions (135 participants) twice weekly for 6 weeks. The 12 group and individual sessions were conducted concurrently.

MAIN OUTCOMES AND MEASURES Primary measures were scores on the Posttraumatic Symptom Scale–Interview Version (PSS-I) and the stressor-specific Posttraumatic Stress Disorder Checklist (PCL-S); secondary measures were scores on the Beck Depression Inventory–II (BDI-II) and the Beck Scale for Suicidal Ideation (BSSI). Assessments were completed by independent evaluators masked to treatment condition at baseline and 2 weeks and 6 months after treatment.

**RESULTS** Among the 268 participants (244 men [91.0%]; 24 women [9.0%]; mean [SD] age, 33.2 [7.4] years), improvement in PTSD severity at posttreatment was greater when CPT was administered individually compared with the group format (mean [SE] difference on the PSS-I, -3.7 [1.4]; Cohen d = 0.6; P = .006). Significant improvements were maintained with the individual (mean [SE] PSS-I, -7.8 [1.0]; Cohen d = 1.3; mean [SE] PCL-S, -12.6 [1.4]; Cohen d = 1.2) and group (mean [SE] PSS-I, -4.0 [0.97]; Cohen d = 0.7; mean [SE] PCL-S, -6.3 [1.4]; Cohen d = 0.6) formats, with no differences in remission or severity of PTSD at the 6-month follow-up. Symptoms of depression and suicidal ideation did not differ significantly between formats.

**CONCLUSIONS AND RELEVANCE** Individual treatment resulted in greater improvement in PTSD severity than group treatment. Depression and suicidal ideation improved equally with both formats. However, even among those receiving individual CPT, approximately 50% still had PTSD and clinically significant symptoms. In the military population, improving existing treatments such as CPT or developing new treatments is needed.

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osttraumatic stress disorder (PTSD) is a serious problem among active-duty military personnel, especially those returning from a combat deployment. <sup>1-3</sup> However, little research has been done on the treatment of PTSD in active-duty military. Cognitive processing therapy (CPT) is an evidenced-based, trauma-focused cognitive therapy for PTSD that has been found to be efficacious in civilian and veteran randomized clinical trials, <sup>4-8</sup> with long-lasting results for 5 to 10 years among civilians. <sup>9</sup> Three meta-analyses <sup>10-12</sup> found that CPT had the largest mean effect size of any PTSD treatment.

Additional data are needed on the efficacy of group and individual treatment among active-duty military samples. Research on group treatment for PTSD has lagged behind the study of individual treatment, although groups are used widely. 13 Cognitive processing therapy was developed as a group treatment,14 and several studies demonstrate its efficacy in this format. A randomized clinical trial in the Democratic Republic of Congo<sup>7</sup> found group CPT to be more effective than individual support and resources, with large differences over time, although therapists and participants had limited education, requiring the protocol be modified. Group CPT was found to be efficacious in a noninferiority (equivalence) trial comparing in-person and telehealth group treatment among male veterans.<sup>8</sup> Resick et al<sup>15</sup> compared group CPT with group present-centered therapy among active-duty military members and found that CPT produced statistically greater reductions in PTSD and depression, demonstrating that group CPT can effect improvements in an active-duty population. However, a meta-analysis by Haagen et al<sup>10</sup> concluded that group therapy alone was inferior to individual therapy and recommended against its use as a sole treatment. Based on those findings, the present study with active-duty military compared CPT delivered in group and individual formats, which to our knowledge has not yet been examined in this population.

## Methods

# **Participants**

Participants were 268 active-duty US Army soldiers (244 men and 24 women) 18 years or older seeking treatment for PTSD at Fort Hood, Texas, after deployments to or near Iraq or Afghanistan (Table 1). Eligibility required experience of a criterion A traumatic event as defined by the DSM-IV-TR16 that occurred during military deployment. However, the diagnosis of PTSD could have been based on another criterion A event. At baseline, participants taking psychotropic medications maintained a stable regimen for at least 6 weeks. Participants were asked to keep their medication regimen unchanged throughout the treatment period in consultation with their prescribers but could continue other therapy (eTable 1 in Supplement 1). Participants received approval from their unit commanders to participate. Minimal exclusion criteria consisted of current suicidal or homicidal risk meriting crisis intervention, active psychosis or mania, severe traumatic brain injury, and concurrent PTSD treatment. Participants with comorbid con-

# **Key Points**

**Question** Are individual and group cognitive processing therapy conditions efficacious for treating combat-related posttraumatic stress disorder (PTSD) in active-duty military?

**Findings** In this randomized clinical trial of 268 active-duty military servicemembers with PTSD, those treated in individual or group cognitive processing therapy formats improved significantly with large effect sizes, but individual cognitive processing therapy produced significantly greater improvement.

**Meaning** The results provide evidence that cognitive processing therapy is an effective treatment for combat-related PTSD for many patients in this setting; however, room for improvement remains.

ditions (eg, substance abuse, current mild to moderate post-concussive syndrome) were not excluded. Figure 1 shows the CONSORT diagram for specifics of recruitment and participation; eMethods 1 in Supplement 1 provides a complete list of reasons for noncompletion. This study was approved by institutional review boards at Brooke Army Medical Center, San Antonio, Texas; the University of Texas Health Science Center at San Antonio; Duke University, Durham, North Carolina; and Veterans Affairs Boston Healthcare System, Boston, Masschusetts. All participants provided written informed consent. The full study protocol can be found in Supplement 2.

#### Measure

All interview and self-reported measures were administered by independent evaluators who were masked to treatment condition. Assessments were scheduled at baseline and at 2 weeks and 6 months after treatment. A diagnostic assessment was performed before randomization with the Posttraumatic Symptom Scale-Interview Version (PSS-I)17 and repeated at follow-up assessments. The PSS-I is a 17-item clinical interview that evaluates DSM-IV PTSD symptoms on a frequency and severity scale (score range, 0-51, with higher scores indicating worse symptoms). The stressor-specific Posttraumatic Stress Disorder Checklist (PCL-S)<sup>18</sup> is a self-reported measure of PTSD symptoms in the past month (range, 17-85; with higher scores reflecting greater PTSD severity). 19 Secondary measures included the Beck Depression Inventory-II20 measuring depressive symptoms (range, 0-63, with higher scores indicating worse depression) and the Beck Scale for Suicidal Ideation (BSSI)21 to assess suicidal ideation (using a dichotomous rating of 0 for absent and 1 for present). For demographics, the 10-item Alcohol Use Disorders Identification Test-Interview Version (AUDIT)<sup>22</sup> assessed baseline alcohol consumption<sup>23</sup> (range, 0-40, with a score of 8 or higher indicating hazardous drinking). Traumatic brain injury was measured by the 3-item Brief Traumatic Brain Injury Screen, which was scored dichotomously as 0 for no and 1 for yes, ongoing postconcussive symptoms.<sup>24</sup> The reports of current symptoms are listed in Table 1. Mini-International Neuropsychiatric Interview<sup>25</sup> modules C (for mania) and K (for psychosis) were administered before treatment for possible exclusion.

Table 1 Demo	granhics an	d Backgroun	d Characteristics

	Treatment Condition, No. (%) of Patients <sup>a</sup>					
Variable	All (N = 268)	Group CPT (n = 133)	Individual CPT (n = 135)			
Age, mean (SD), y	33.2 (7.4)	33.8 (7.7)	32.6 (7.1)			
Time in service, mean (SD), y	10.9 (6.3)	11.1 (6.0)	10.6 (6.7)			
No. of deployments, mean (SD)	2.3 (1.1)	2.4 (1.0)	2.2 (1.1)			
Rank, No. (%) <sup>b</sup>						
E2-E4	87 (33.6)	38 (30.2)	49 (36.8)			
E5	75 (29.0)	41 (32.5)	34 (25.6)			
E6	54 (20.8)	28 (22.2)	26 (19.5)			
E7-E9	36 (13.9)	17 (13.5)	19 (14.3)			
W02-W04	3 (1.2)	2 (1.6)	1 (0.8)			
02-04	4 (1.5)	0	4 (3.0)			
Baseline symptom severity, mean (SD) score						
PSS-I <sup>c</sup>	24.3 (6.0)	24.4 (6.1)	24.2 (6.0)			
PCL-S <sup>d</sup>	55.1 (10.5)	55.2 (10.2)	55.0 (10.8)			
BDI-IIe	29.4 (11.3)	29.5 (11.8)	29.2 (10.8)			
BSSI, % suicidal ideation <sup>f</sup>	47 (17.5)	25 (18.8)	22 (16.3)			
Educational level						
High school or less	69 (25.7)	43 (32.3)	26 (19.3)			
Some college	149 (55.6)	66 (49.6)	83 (61.5)			
Associate degree	29 (10.8)	14 (10.5)	15 (11.1)			
College or graduate degree	21 (7.8)	10 (7.5)	11 (8.1)			
Married or cohabiting	182 (67.9)	90 (67.7)	92 (68.1)			
Male sex	244 (91.0)	123 (92.5)	121 (89.6)			
Ethnicity or race						
Black	75 (28.0)	39 (29.3)	36 (26.7)			
Hispanic	62 (23.1)	31 (23.3)	31 (23.0)			
White	108 (40.3)	52 (39.1)	56 (41.5)			
Other	23 (8.6)	11 (8.3)	12 (8.9)			
Index event of worst trauma						
Combat-related	244 (91.0)	125 (94.0)	119 (88.1)			
Death (noncombat)	10 (3.7)	4 (3.0)	6 (4.4)			
Sexual assault	6 (2.2)	1 (0.8)	5 (3.7)			
Physical assault	5 (1.9)	2 (1.5)	3 (2.2)			
Accident	3 (1.1)	1 (0.8)	2 (1.5)			
AUDIT hazardous drinker (score ≥8) <sup>9</sup>	45 (16.8)	26 (19.5)	19 (14.1)			
Current postconcussive symptoms	173 (64.6)	87 (65.4)	86 (63.7)			
Current psychotropic medications	153 (57.1)	75 (56.4)	78 (57.8)			
Concurrent other therapy, No.	162 (60.4)	79 (59.4)	83 (61.5)			
Outpatient individual	61 (22.8)	30 (22.6)	31 (23.0)			
Outpatient group	14 (5.2)	6 (4.5)	8 (5.9)			
Marriage or family	9 (3.4)	3 (2.3)	6 (4.4)			

Abbreviations: AUDIT, Alcohol Use Disorders Identification
Test-Interview Version; BDI-II, Beck Depression Inventory-II; BSSI, Beck Scale for Suicide Ideation; E, enlisted; PCL-S, stressor-specific Posttraumatic Stress Disorder Checklist; PSS-I, Posttraumatic Symptom Scale-Interview Version; WO, warrant officer; O, officer.

- <sup>a</sup> Percentages have been rounded and may not total 100.
- <sup>b</sup> Because of missing data, numbers may not sum to column totals.
- <sup>c</sup> Scores range from 0 to 51, with higher scores indicating worse symptoms.
- <sup>d</sup> Scores range from 17 to 85, with higher scores indicating greater PTSD severity.
- e Scores range from 0 to 63, with higher scores indicating worse depression.
- f Scores use a dichotomous rating of O for absent and 1 for present.
- g Scores range from 0 to 40, with higher scores indicating hazardous drinking.

#### **Procedures**

Participants were recruited from advertisements and direct referrals from military providers. From March 8, 2012, to September 23, 2014, the STRONG STAR Research Clinic at Fort Hood, Texas, prescreened more than 1000 individuals for eligibility in 4 concurrently enrolling research studies via telephone. Approximately 280 individuals were ineligible or declined participation in the studies; 424 consented to an alternate study; and 427 participants consented to this study. Participants completed an eligibility and baseline assessment, including structured interviews and self-report mea-

sures. Training and fidelity of independent evaluators are described in eMethods 2 in Supplement 1.

Computerized block randomization into group or individual therapy formats occurred after eligibility was determined. Groups consisting of 8 to 10 participants (15 cohorts total) and individual participants were treated concurrently. Before starting treatment, participants met individually with the therapist to review their trauma history and confirm the index event to target initially in treatment. Groups met twice weekly for 6 weeks for 90-minute sessions. Participants were dropped from group treatment if they missed 4 treatment ses-

sions but were asked to continue with assessments for intention-to-treat (ITT) analyses. Individual sessions were 60 minutes, scheduled twice weekly. If individuals could not complete treatment in 3 months for reasons other than military assignments, treatment was ended and follow-up assessments were attempted. Participants were not paid for their participation. Adverse events were monitored using a rigorous method similar to that of medication clinical trials, an approach seldom used in psychotherapy trials. <sup>26</sup>

#### Treatment

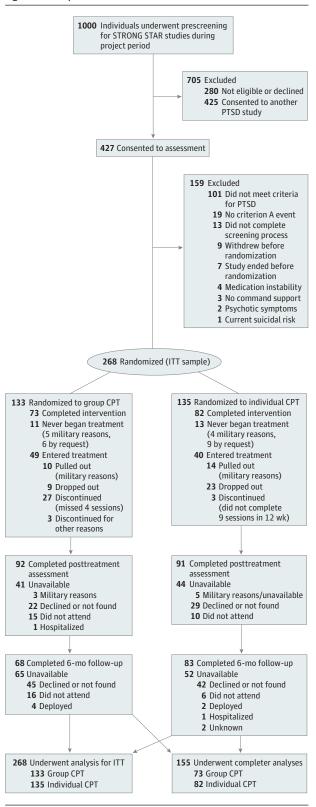
Cognitive processing therapy is a 12-session, trauma-focused cognitive therapy in which patients are taught to recognize and challenge dysfunctional cognitions (termed stuck points) about their traumatic event(s) and current thoughts about themselves, others, and the world. Patients learn to label events, thoughts, and emotions, while therapists help them to examine the facts and context of the trauma through Socratic questioning.<sup>27</sup> Using progressive worksheets, patients are taught to examine their thoughts and emotions and develop more balanced thinking about traumatic events. Cognitive processing therapy followed the specific manual developed for military and veterans<sup>28,29</sup> and incorporated special considerations for working with active-duty military that are further described elsewhere. 30 In a dismantling study, a cognitiveonly version excluding written trauma accounts was as effective as CPT with written accounts<sup>31</sup>; therefore, the cognitiveonly version was used in this study. Training and fidelity of therapists are described in eMethods 3 in Supplement 1.

#### **Data Analysis**

The sample size was originally determined to be 300 to obtain power of 0.80 to detect a relatively small effect size difference of Cohen d = 0.30 between the 2 treatment groups in change of PTSD symptom severity. An interim analysis of the primary outcome was requested for government programmatic review when 90% had enrolled. The analysis indicated that the effect was twice as large as originally hypothesized. The data safety monitoring board was consulted and concurred with the decision to terminate the trial at that point. SAS SEQDESIGN software (SAS Institute Inc) indicated 2-sided stopping boundaries of 0.039 using the methods of O'Brien and Fleming<sup>32</sup> and 0.035 using the methods of Pocock<sup>33</sup> to maintain P = .05 for the interim analysis performed when 90% of the sample was collected. At the time of our interim analysis, the P values for the primary hypothesis tests as reported in our results were well below those criteria.

The primary analyses of PSS-I and PCL-S scores used the ITT sample of all participants who were randomized regardless of how many sessions of therapy they received. Completer analyses were conducted for those participants who completed at least 9 of the 12 treatment sessions (75%) to match the number of missed sessions allowed in the group format. Primary hypothesis tests were tests of change between baseline and posttreatment assessment on the measures of PTSD severity. Follow-up data bear on stability of treatment effects but were underpowered owing to smaller sample size. The PSS-I, PCL-S, and Beck Depression Inventory-II severity scores

Figure 1. Participant Flow



CONSORT diagram for study comparing individual- and group-format cognitive processing therapy (CPT) for servicemembers with posttraumatic stress disorder (PTSD). ITT indicates intent to treat.

Table 2. PTSD Posttreatment Outcomes<sup>a</sup>

	Posttreatment Outcome by Treatment Condition		Between-Condition Differences			
			Difference (SE)	Statistical Significance		
	Group CPT (n = 133)	Individual CPT (n = 135)		Unadjusted P Value	Effect Size	
Dimensional scales, baseline to posttreatment change, least squares means (SE) <sup>b</sup>						
PSS-I total score	-4.0 (1.0)	-7.8 (1.0)	27/14)	.006	Cohen <i>d</i> = 0.6	
Effect size	Cohen <i>d</i> = 0.7	Cohen <i>d</i> = 1.3	-3.7 (1.4)			
PCL-S total score	-6.3 (1.4)	-12.6 (1.4)	5 2 (5 8)	.001	Cohen <i>d</i> = 0.6	
Effect size	Cohen <i>d</i> = 0.6	Cohen <i>d</i> = 1.2	— <b>-</b> 6.3 (1.9)			
Categorical measures, No./total No. of patients (estimated proportion [SE]] <sup>c</sup>						
Remission of PSS-I diagnosis <sup>d</sup>	32/82 (37[5])	40/83 (49[5])	12 (8)	.11	NNT = 8.3	
PSS-I RCI <sup>e,f</sup>	15/82 (17[4])	35/83 (43[5])	26 (7)	<.001	NNT = 3.8	
PCL-S RCI <sup>e,g</sup>	28/92 (30[5])	47/90 (52[5])	21 (7)	.003	NNT = 4.7	

Abbreviations: CPT, cognitive processing therapy; NNT, number needed to treat to get 1 additional good outcome; PCL-S, stressor-specific Posttraumatic Stress Disorder Checklist; PSS-I, Posttraumatic Symptom Scale-Interview Version; PTSD, posttraumatic stress disorder; RCI, reliable change index.

equations for binary data. The numbers are the raw numbers in each cell. The minor differences between raw and model-based estimates in some cells are the result of loss to follow-up.

were analyzed using general linear mixed regression models using SAS PROC MIXED software (version 9.3; SAS Institute Inc), with fixed effects of group and time and their interaction. Proportions of participants in each treatment arm no longer meeting PTSD diagnostic criteria after treatment and follow-up underwent analysis using a generalized linear proportions model for binary data (SAS GENMOD with generalized estimating equations; SAS Institute Inc), as was the BSSI for suicidal ideation. The dependent variable for the BSSI was a dichotomous classification based on 2 threshold items that separate those with and without suicidality. Repeated measures were modeled using an unstructured covariance matrix based on likelihood criteria (Akaike information criterion).

To supplement estimates of group means, we calculated the reliable change index (RCI) based on PSS-I and PCL-S in each treatment arm.  $^{34,35}$  The RCI represents an amount of change expected to happen no more than 5% of the time by chance fluctuations due to unreliability. The RCI is based on the standard error of measurement, which is a function of the baseline SDs (PSS-I, 6.0; PCL-S, 10.5) and  $\alpha$  coefficients (PSS-I, .62; PCL-S, .85). Effect sizes for dimensional scales (Cohen  $\emph{d}$ ) are standardized mean differences using the baseline SDs. Effect sizes for proportions are the number needed to treat to achieve 1 additional good outcome.

Adverse effects are presented descriptively and examined statistically as the probability of adverse effects per weeks assessed using Poisson regression models, with summary counts of adverse effects as the dependent variable and the log of weeks assessed as an offset variable. In all analyses, clustering effects of patient cohort (group) as a random effect were explored in preliminary analyses. In every case, Wald tests were

nonsignificant and substantive results were unchanged; therefore, these random effects were dropped from the final models. Hypothesis tests were performed at unadjusted P = .05 indicating significance.

# Results

# Posttreatment PTSD Severity and Diagnosis on the PSS-I

The study population included 268 active-duty servicemembers (244 men [91.0%]; 24 women [9.0%]; mean [SD] age, 33.2 [7.4] years). **Table 2** lists the results for the ITT analyses for all outcomes, and eTable 2 in **Supplement 1** includes complete analyses. **Figure 2** depicts findings for the PSS-I and the PCL-S. On the PSS-I (condition × time interaction,  $F_{2,266}$  = 3.98; P = .02), patients in both formats improved, with individual patients improving about twice as much as group patients at 2-week posttreatment assessment. The estimated proportions (SEs) no longer meeting PSS-I diagnostic criteria for PTSD after treatment did not differ significantly between treatment conditions (49% [5%] in individual CPT and 37% [5%] in group CPT; number needed to treat, 8.3).

# Posttreatment PTSD Severity on the PCL-S

Participants receiving individual CPT improved more and did so more rapidly (condition × time interaction,  $F_{2,266}$  = 5.42; P = .005), but both treatment arms improved significantly on the PCL-S (group treatment, –6.3 [SE, 1.4]; Cohen d = 0.6; individual treatment, –12.6 [SE, 1.4]; Cohen d = 1.2). Table 2 presents the mixed model results. Change from before to after treatment was almost twice as large for individual vs group CPT.

<sup>&</sup>lt;sup>a</sup> Complete analysis results are in eTable 3 in Supplement 1. All of the variables listed as significant at P < .05 remain significant at P = .04 (adjusted for interim analysis) after Bonferroni adjustment for 5 tests.

<sup>&</sup>lt;sup>b</sup> All within-group tests, P < .001.

<sup>&</sup>lt;sup>c</sup> The proportions (SEs) for categorical outcomes are model-based estimates from generalized linear probability models with generalized estimating

<sup>&</sup>lt;sup>d</sup> Indicates did not meet PSS-I criteria for PTSD diagnosis.

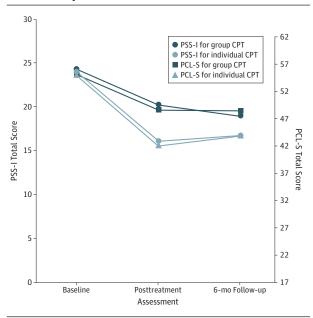
 $<sup>^{</sup>m e}$  Indicates an amount of change expected to happen no more than 5% of the time by chance fluctuations due to unreliability.

<sup>&</sup>lt;sup>f</sup> PSS-I a = 0.62 (SD, 6.0).

 $<sup>^{</sup>g}$  PCL-S  $\alpha$  = 0.85 (SD, 10.5).

Effect sizes were very large for individual treatment and medium for group CPT, with a between-condition effect size at posttreatment of Cohen d = 0.6. At 6-month follow-up, change

Figure 2. Change in Posttraumatic Stress Disorder (PTSD) Measures Across the Study Period



The Posttraumatic Symptom Scale–Interview Version (PSS-I) evaluates frequency and severity of *DSM-IV* PTSD symptoms (range, 0-51, with higher scores indicating worse symptoms). The stressor-specific Posttraumatic Stress Disorder Checklist (PCL-S) measures self-reported PTSD symptoms (range, 17-85, with higher scores indicating greater PTSD severity. CPT indicates cognitive processing therapy.

from baseline remained significant in the individual (-10.7 [SE, 1.6]; Cohen d = 1.0) and group (-6.5 [SE, 1.7]; Cohen d = 0.6) treatment arms. Correlations between PSS-I and PCL are given in eTable 3 in Supplement 1.

## **Posttreatment RCI**

Treatment condition differences were significant. In the ITT analysis, reliable change on the PSS-I occurred in an estimated 43% of patients receiving individual treatment and 17% of patients receiving group treatment ( $\chi_1^2$  = 15.0; P < .001). On the PCL-S, an estimated 52% of patients receiving individual treatment vs 30% of patients receiving group treatment had reliable change ( $\chi_1^2$  = 8.9; P = .003) (Table 2).

## Six-Month Follow-up

Table 3 presents the PTSD outcomes at the 6-month followup. Within-group improvements in PTSD symptom severity remained highly significant in both treatment formats on the PSS-I (individual treatment arm, -7.1 [SE, 1.1]; Cohen d = 1.2; group treatment arm, -5.2 [1.1]; Cohen d = 0.9) and PCL-S (individual treatment arm, -10.7 [SE, 1.6]; Cohen d = 1.0; group treatment arm, -6.5 [SE, 1.7]; Cohen d = 0.6) (all P < .001), with large effect sizes in individual treatment and moderate to large improvements in group treatment. Outcomes at the 6-month follow-up were very similar to the posttreatment results. The differences between the outcomes at posttreatment (Table 2) and follow-up (Table 3) were uniformly small and nonsignificant, with a mean P value of .43 (range, .15-.85), a mean Cohen *d* of 0.16 (range, 0.02-0.3), and a mean NNT of 27 (range, 11-76). However, sample sizes and the between-group effect sizes were both smaller at follow-up, and only the betweengroup difference in the proportions achieving reliable change

Table 3. PTSD Outcomes at 6-Month Follow-up<sup>a</sup>

	6-mo Outcome, Tr	eatment Condition	Between-Condition Differences		
			Difference (SE)	Statistical Significance	
	Group CPT	Individual CPT		Unadjusted P Value	Effect Size
Dimensional scales, baseline to posttreatment change, least squares means (SE) <sup>b</sup>					
PSS-I total score <sup>b</sup>	-5.2 (1.1)	-7.1 (1.1)	-1.9 (1.6)	.22	d = 0.3
Effect size	d = 0.9	d = 1.2			
PCL-S total score	-6.5 (1.7)	-10.7 (1.6)	-4.2 (2.3)	.06	d = 0.4
Cohen d	0.6	1.0			
Categorical measures, No. of patients (estimated proportion [SE]) <sup>c</sup>					
Remission of PSS-I diagnosis <sup>d</sup>	18/51 (39[7])	27/64 (43[6])	4 (9)	.64	NNT = 24.3
PSS-I RCI <sup>e,f</sup>	8/51 (21[5])	24/64 (39[6])	17 (8)	.02	NNT = 5.7
PCL-S RCI <sup>e,g</sup>	22/69 (32[6])	39/83 (47[5])	14 (8)	.07	NNT = 7.0

Abbreviations: NNT, number needed to treat to get 1 additional good outcome; PCL-S, stressor-specific Posttraumatic Stress Disorder Checklist; PSS-I, Posttraumatic Symptom Scale–Interview Version; RCI, reliable change index: SE. standard error.

equations for binary data. Raw numbers are given in each cell. The minor differences between raw and model-based estimates in some cells are the result of loss to follow-up.

<sup>&</sup>lt;sup>a</sup> Complete analysis results are in eTable 3 in Supplement 1. None of the between-group differences at follow-up are significant at *P* = .04 (adjusted for interim analysis) after Bonferroni-adjustment for 5 tests.

 $<sup>^{\</sup>rm b}$  All within-group tests, P < .001.

<sup>&</sup>lt;sup>c</sup> The proportions (SEs) for categorical outcomes are model-based estimates from generalized linear probability models with generalized estimating

d Indicates did not meet PSS-I criteria for posttraumatic stress disorder diagnosis.

<sup>&</sup>lt;sup>e</sup> Indicates an amount of change expected to happen no more than 5% of the time by chance fluctuations due to unreliability.

f PSS-I a = 0.62 (SD, 6.0).

g PCL-S a = 0.85 (SD, 10.5).

on the PSS-I was statistically significant (17% [SE, 8%]; unadjusted P=.02).

## **Depression and Suicidality**

Depression measured by the Beck Depression Inventory-II improved significantly in both treatment arms (overall effect of time,  $F_{2,266}$  = 30.95; P < .001). Within-condition effect sizes were Cohen d = 0.8 from pretreatment to the 2-week posttreatment assessments and Cohen d = 0.8 from pretreatment to the 6-month follow-up assessment for individual CPT compared with Cohen d = 0.5 and Cohen d = 0.7for group CPT, respectively. Improvements were stable, with neither condition changing significantly between the 2-week posttreatment and 6-month assessments in both treatment arms (eTable 3 in Supplement 1). None of the tests of differences between treatment arms produced statistically significant results. The proportions with suicidality (BSSI) dropped in both treatment arms during treatment (overall effect of time,  $\chi_2^2$  = 13.0; P = .002), but betweencondition differences were small and nonsignificant. Complete results are included in eTable 3 in Supplement 1.

## **Treatment Completers**

The completer analyses are presented in eTable 4 in Supplement 1 for all 4 outcome measures. The results are similar to the ITT findings.

#### **Adverse Events**

Seventeen psychological events were judged by participants to be at least possibly related to the study, and these occurred because of increased symptoms evoked by baseline assessment procedures (4 patients) or the trauma focus of therapy (7 patients in group CPT and 6 patients in individual CPT). During the study, 2 unsuccessful suicide attempts occurred in patients randomized to group CPT (1 before the start of treatment and 1 during treatment); neither was judged to be study related as per participant report. More detail about adverse events, which were primarily injuries and illnesses, are provided in eMethods 4 in Supplement 1.

# Discussion

Individual CPT was more efficacious than group CPT at reducing PTSD severity. Patients in both treatment conditions experienced significant decreases in PTSD symptoms over time, with large effect sizes for individual therapy and medium effect sizes for group therapy, but patients randomized to individual CPT had approximately twice as much improvement (PSS-I: Cohen d=0.6). The conditions also differed on RCI, with significantly more patients in individual treatment meeting those criteria. The loss-of-diagnosis findings were comparable to or better than most veteran studies of CPT, but group and individual treatment did not differ significantly.  $^{4,5,8,37}$ 

Several possible explanations exist for why group CPT did not perform as well as individual CPT. First, participants in group CPT who missed sessions lost content that could not be replaced, whereas participants in individual therapy were able to reschedule if needed. Second, because patients received less individual attention in the group setting, those who had difficulties with content may not have received sufficient support. Conversely, in the individual treatment condition, full attention is given throughout the sessions, which also facilitates the ability to address multiple traumatic events and ensures understanding and deeper Socratic questioning about multiple events. Third, patients in group sessions may feel less accountable for completing practice assignments, perhaps resulting in reduced engagement with treatment.

We found no significant differences between conditions for depression in the ITT analysis, but patients in both therapy formats improved, with large effect sizes for individually treated participants and medium effects for group-treated patients for depression and significant reductions in suicidality. Although mean depression scores improved from the severe range, the mean depression scores at the posttreatment assessment still reflect moderate depressive symptoms. The sample demonstrated complicated co-occurring conditions, with 173 (64.6%) reporting current postconcussive symptoms and 45 (16.8%) reporting hazardous levels of drinking at the pretreatment assessment, which could contribute to symptoms and outcomes. These factors often lead to exclusion from other clinical trials.

Cognitive processing therapy did not increase suicidal ideation on the BSSI or reported adverse effects despite the trauma focus. In fact, the BSSI showed a significant and steady decrease in suicidal ideation in both treatment formats. This finding should help to alleviate concerns that engagement in trauma-focused treatment might increase suicidal ideation and even suggests that PTSD treatment may reduce suicidality in active-duty military members.<sup>38</sup>

#### Limitations

Several limitations to the study should be noted. Although the voluntary dropout rate before or during treatment was low (47 [17.5%]), 33 patients (12.3%) were lost to treatment owing to military discontinuation and high attrition in data collection in the subsequent 6 months that may not be found in less mobile populations. The within-condition results did not change significantly from the posttreatment to 6-month follow-up assessments; thus, the smaller sample size and less power in part accounts for the lack of statistical differences between conditions at the 6-month follow-up. Also, the small number of women enrolled in the study prevented examination of sex differences. Women may have responded differently than men, although further research is needed.

Our finding that individual treatment is more efficacious than the group-only format with regard to PTSD is consistent with a recent meta-analysis  $^{10}$  that reported effect sizes of 1.2 for individual and 0.6 for group therapy, virtually identical to those found herein. Those authors concluded that group-only formats should not be used for PTSD. However, given that an effect size of 0.7 is a medium to large effect, ruling out group treatment for everyone may be premature.

Our results are also consistent with another recent review of primarily veteran samples reporting statistically large improvements with evidence-based treatments for the "aver-

age" patient but high treatment nonresponse rates for many individuals.<sup>39</sup> We found large mean changes in PTSD severity in individually treated patients; however, even among those who completed treatment, approximately half still had PTSD and many still had clinically significant symptoms after treatment. Our findings thus contribute to the growing literature suggesting that combat-related PTSD is complex and difficult to treat with existing therapies. Like treatments for most disorders, CPT did not work for everyone. We therefore agree that more effort is required to treat deployment-related PTSD effectively in active-duty military members.

Future research should focus on specific issues found in military populations that may affect PTSD treatment. Areas inviting study include the roles of comorbidities, such as concurrent depression, substance abuse, traumatic brain injury, and sleep disorders; the potential effect of moral injury (an event that conflicts with deeply held morals and beliefs) re-

sulting from combat trauma; and high rates of witnessing or dealing with the aftermath of deaths of others, including gruesome deaths of friends. Other treatments, adjunctive therapy, and treatment matching should also be examined, as well as whether varying lengths of treatment may be more beneficial. 40,41

# Conclusions

Cognitive processing therapy delivered in an individual format was more efficacious in treating symptoms of PTSD compared with CPT delivered in a group format. Significant reductions in PTSD were maintained during a 6-month follow-up. To our knowledge, these findings are the strongest to date with regard to existing treatments for PTSD in active-duty military and veterans, but more work is required to improve outcomes.

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#### REFERENCES

- 1. Hoge CW, Castro CA, Messer SC, McGurk D, Cotting DI, Koffman RL. Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. *N Engl J Med*. 2004;351(1):13-22.
- 2. Office of The Surgeon General, United States Army Medical Command. Office of the Command Surgeon Headquarters (USCENTCOM); Office of the Command Surgeon, US Forces Afghanistan (USFOR-A). Mental Health Advisory Team 9 (MHAT 9), Operation Enduring Freedom (OEF) 2013 Afghanistan. http://armymedicine.mil/Documents/MHAT\_9\_OEF\_Report.pdf. Published October 10, 2013. Accessed X.
- 3. Tanielian TL, Jaycox L. Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery. Santa Monica, CA: RAND Corp; 2008.

- **4.** Forbes D, Lloyd D, Nixon RDV, et al. A multisite randomized controlled effectiveness trial of cognitive processing therapy for military-related posttraumatic stress disorder. *J Anxiety Disord*. 2012;26(3):442-452.
- Monson CM, Schnurr PP, Resick PA, Friedman MJ, Young-Xu Y, Stevens SP. Cognitive processing therapy for veterans with military-related posttraumatic stress disorder. J Consult Clin Psychol. 2006;74(5):898-907.
- 6. Resick PA, Nishith P, Weaver TL, Astin MC, Feuer CA. A comparison of cognitive-processing therapy with prolonged exposure and a waiting condition for the treatment of chronic posttraumatic stress disorder in female rape victims. J Consult Clin Psychol. 2002:70(4):867-879.
- 7. Bass JK, Annan J, McIvor Murray S, et al. Controlled trial of psychotherapy for Congolese survivors of sexual violence. *N Engl J Med*. 2013; 368(23):2182-2191.
- **8**. Morland LA, Mackintosh M-A, Greene CJ, et al. Cognitive processing therapy for posttraumatic stress disorder delivered to rural veterans via telemental health: a randomized noninferiority clinical trial. *J Clin Psychiatry*. 2014;75(5):470-476.
- **9.** Resick PA, Williams LF, Suvak MK, Monson CM, Gradus JL. Long-term outcomes of cognitive-behavioral treatments for posttraumatic stress disorder among female rape survivors. *J Consult Clin Psychol.* 2012;80(2):201-210.
- Haagen JF, Smid GE, Knipscheer JW, Kleber RJ.
   The efficacy of recommended treatments for veterans with PTSD: a metaregression analysis. Clin Psychol Rev. 2015;40:184-194.
- 11. Watts BV, Schnurr PP, Mayo L, Young-Xu Y, Weeks WB, Friedman MJ. Meta-analysis of the efficacy of treatments for posttraumatic stress disorder. *J Clin Psychiatry*. 2013;74(6):e541-e550.
- 12. Cusack K, Jonas DE, Forneris CA, et al. Psychological treatments for adults with posttraumatic stress disorder: a systematic review and meta-analysis. Clin Psychol Rev. 2016;43:128-141.
- 13. Institute Of Medicine. *Treatment Of Posttraumatic Stress Disorder: An Assessment of the Evidence*. Washington, DC: National Academic Press; 2008
- 14. Resick PA, Schnicke MK. Cognitive Processing Therapy for Rape Victims: A Treatment Manual. Thousand Oaks, CA: Sage Publications Inc; 1993.
- 15. Resick PA, Wachen JS, Mintz J, et al. A randomized clinical trial of group cognitive processing therapy compared with group present-centered therapy for PTSD among active duty military personnel. J Consult Clin Psychol. 2015;83(6):1058-1068.
- **16**. American Psychiatric Association. *Diagnostic* and *Statistical Manual of Mental Disorders*. 4th ed,

- text revision. Washington, DC: American Psychiatric Association; 2000.
- **17**. Foa EB, Riggs DS, Dancu CV, Rothbaum BO. Reliability and validity of a brief instrument for assessing post-traumatic stress disorder. *J Trauma Stress*. 1993;6(4):459-473.
- 18. Weathers F, Litz B, Herman D, Huska J, Keane T. The PTSD Checklist (PCL): reliability, validity, and diagnostic utility. Paper presented at: 9th Annual Meeting of the International Society for Traumatic Stress Studies; October 1993; San Antonio, TX.
- 19. Monson CM, Gradus JL, Young-Xu Y, Schnurr PP, Price JL, Schumm JA. Change in posttraumatic stress disorder symptoms: do clinicians and patients agree? *Psychol Assess*. 2008;20(2):131-138.
- **20**. Beck AT, Steer RA, Brown GK. *Manual for the Beck Depression Inventory-II*. San Antonio, TX: Psychological Corp; 1996.
- 21. Beck AT, Steer RA. *Beck Scale for Suicide Ideation: Manual*. San Antonio, TX: Psychological Corp. 1991.
- 22. Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG. The Alcohol Use Disorders Identification Test (AUDIT): Guidelines for Use in Primary Care. 2nd ed. Geneva, Switzerland: World Health Organization Dept of Mental Health and Substance Dependence; 2001.
- 23. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption-II. Addiction. 1993;88(6):791-804.
- **24.** Schwab KA, Ivins B, Cramer G, et al. Screening for traumatic brain injury in troops returning from deployment in Afghanistan and Iraq: initial investigation of the usefulness of a short screening tool for traumatic brain injury. *J Head Trauma Rehabil.* 2007;22(6):377-389.
- 25. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry. 1998;59(suppl 20):22-33.
- **26.** Peterson AL, Roache JD, Raj J, Young-McCaughan S; STRONG STAR Consortium. The need for expanded monitoring of adverse events in behavioral health clinical trials. *Contemp Clin Trials*. 2013;34(1):152-154.
- **27**. Resick PA, Monson CM, Chard KM. *Cognitive Processing Therapy Veteran/Military Version: Therapist's Manual*. Washington, DC: Dept of Veterans Affairs; 2010.
- **28**. Resick P, Monson C, Chard K. *Cognitive Processing Therapy: Veteran/Military Manual.* Washington, DC: Dept of Veterans Affairs; 2010.

- 29. Chard K, Resick P, Monson C, Kattar K.
  Cognitive Processing Therapy Therapist Group
  Manual: Veteran/Military Version. Washington, DC:
  Dept of Veterans Affairs; 2009.
- **30**. Wachen JS, Dondanville KA, Pruiksma KE, et al. Implementing cognitive processing therapy for posttraumatic stress disorder with active duty US military personnel: special considerations and case examples. *Cognit Behav Pract*. 2015;23(2):133-147.
- **31**. Resick PA, Galovski TE, O'Brien Uhlmansiek M, Scher CD, Clum GA, Young-Xu Y. A randomized clinical trial to dismantle components of cognitive processing therapy for posttraumatic stress disorder in female victims of interpersonal violence. *J Consult Clin Psychol*. 2008;76(2):243-258.
- **32**. O'Brien PC, Fleming TR. A multiple testing procedure for clinical trials. *Biometrics*. 1979;35(3): 549-556.
- **33.** Pocock SJ. Group sequential methods in the design and analysis of clinical trials. *Biometrika*. 1977;64(2):191-199.
- **34.** Jacobson NS, Truax P. Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *J Consult Clin Psychol.* 1991;59(1):12-19.
- **35**. Jacobson NS, Follette WC, Revenstorf D. Psychotherapy outcome research: methods for reporting variability and evaluating clinical significance. *Behav Ther.* 1984;15(4):336-352.
- **36**. Agresti A. *Categorical Data Analysis*. Hoboken, NJ: Wiley & Sons; 1980.
- **37**. Morland LA, Mackintosh MA, Rosen CS, et al. Telemedicine vs in-person delivery of cognitive processing therapy for women with posttraumatic stress disorder: a randomized noninferiority trial. *Depress Anxiety*. 2015;32(11):811-820.
- **38**. Bryan CJ, Clemans TA, Hernandez AM, et al. Evaluating potential iatrogenic suicide risk in trauma-focused group cognitive behavioral therapy for the treatment of PTSD in active duty military personnel. *Depress Anxiety*. 2016;33(6):549-557.
- **39**. Steenkamp MM, Litz BT, Hoge CW, Marmar CR. Psychotherapy for military-related PTSD: a review of randomized clinical trials. *JAMA*. 2015;314(5): 489-500.
- **40**. Resick PA, Monson CM, Chard KM. *Cognitive Processing Therapy for PTSD: A Comprehensive Manual*. New York, NY: Guilford Press. In press.
- **41**. Ehlers A, Hackmann A, Grey N, et al. A randomized controlled trial of 7-day intensive and standard weekly cognitive therapy for PTSD and emotion-focused supportive therapy. *Am J Psychiatry*. 2014;171(3):294-304.