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Yoga vs Cognitive Processing Therapy for Military Sexual Trauma–Related Posttraumatic Stress Disorder

A Randomized Clinical Trial

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Abstract

IMPORTANCE First-line treatment for posttraumatic stress disorder (PTSD) in the US Department of Veterans Affairs (VA), ie, trauma-focused therapy, while effective, is limited by low treatment initiation, high dropout, and high treatment refraction.

OBJECTIVE To evaluate the effectiveness of Trauma Center Trauma-Sensitive Yoga (TCTSY) vs first-line cognitive processing therapy (CPT) in women veterans with PTSD related to military sexual trauma (MST) and the hypothesis that PTSD outcomes would differ between the interventions.

DESIGN, SETTING, AND PARTICIPANTS This multisite randomized clinical trial was conducted from December 1, 2015, to April 30, 2022, within 2 VA health care systems located in the southeast and northwest. Women veterans aged 22 to 71 years with MST-related PTSD were enrolled and randomized to TCTSY or CPT.

INTERVENTIONS The TCTSY intervention (Hatha-style yoga focusing on interoception and empowerment) consisted of 10 weekly, 60-minute group sessions, and the CPT intervention (cognitive-based therapy targeting modification of negative posttraumatic thoughts) consisted of 12 weekly, 90-minute group sessions.

MAIN OUTCOME AND MEASURES Sociodemographic data were collected via self-report survey. The primary outcome, PTSD symptom severity, was assessed using the Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5) and PTSD Checklist for *DSM-5* (PCL-5). Assessments were conducted at baseline, midintervention, 2 weeks post intervention, and 3 months post intervention.

RESULTS Of 200 women veterans who consented to participate, the intent-to-treat sample comprised 131 participants (mean [SD] age, 48.2 [11.2] years), with 72 randomized to TCTSY and 59 randomized to CPT. Treatment was completed by 47 participants (65.3%) in the TCTSY group and 27 (45.8%) in the CPT group, a 42.6% higher treatment completion rate in the TCTSY group ($P = .03$). Both treatment groups improved over time on the CAPS-5 (mean [SD] scores at baseline: 36.73 [8.79] for TCTSY and 35.52 [7.49] for CPT; mean [SD] scores at 3 months: 24.03 [11.55] for TCTSY and 22.15 [13.56]) and the PCL-5 (mean [SD] scores at baseline: 49.62 [12.19] for TCTSY and 48.69 [13.62] for CPT; mean [SD] scores at 3 months: 36.97 [17.74] for TCTSY and 31.76 [12.47]) ($P < .001$ for time effects). None of the group effects or group-by-time effects were significant. Equivalence analyses of change scores were not significantly different between the TCTSY and CPT groups, and the two one-sided test intervals fell within the equivalence bounds of plus or minus 10 for CAPS-5 for all follow-up time points.

(continued)

Key Points

Question What is the effectiveness of Trauma Center Trauma-Sensitive Yoga (TCTSY) compared with first-line cognitive processing therapy (CPT) for posttraumatic stress disorder (PTSD) related to military sexual trauma in women veterans?

Findings In this randomized clinical trial of 131 women veterans with PTSD who use US Department of Veterans Affairs health care, TCTSY had large within-group effect sizes, equivalent effectiveness to CPT, and a 42.6% higher treatment completion rate than CPT.

Meaning The findings demonstrate that TCTSY is a cost-effective means to expand Veterans Affairs PTSD treatment options; increase access to acceptable, patient-driven, and effective PTSD treatment for women veterans; and provide a treatment option that could improve associated symptoms (eg, depression, anxiety).

+ Visual Abstract

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

CONCLUSIONS AND RELEVANCE In this comparative effectiveness randomized clinical trial, TCTSY was equivalent to CPT in reducing PTSD symptom severity, with both groups improving significantly. The higher treatment completion rate for TCTSY indicates its higher acceptability as an effective and acceptable PTSD treatment for women veterans with PTSD related to MST that could address current VA PTSD treatment limitations.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT02640690

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Introduction

Posttraumatic stress disorder (PTSD) is prevalent and harmful to veterans' physical and mental health, functioning, and well-being and has tremendous societal costs.[1] The harmful consequences of PTSD for women veterans and associated economic costs to the Veterans Health Administration are increasing exponentially. One in 5 women patients in the Veterans Health Administration had PTSD in 2015, a 300% increase in prevalence from 2000.[2] Military sexual trauma (MST) also is prevalent (38%) among women veterans and is their leading cause of military service–related PTSD.[3,4] Military sexual trauma is defined by the US Department of Veterans Affairs (VA) as threatening sexual harassment or sexual assault while serving in the military.[5] It is associated with numerous physical and psychiatric conditions, increased mortality due to suicide, and deficits in social determinants of health (eg, housing instability).[6-8] Yet, many veterans do not engage in VA health care provided at no cost for MST-related conditions.[9,10] Some MST survivors perceive that US military institutions have failed to act in ways that prevent harm or have created environments that can lead to or fail to ameliorate harm (ie, institutional betrayal).[11] Institutional betrayal related to MST has been associated with more severe depression and PTSD; suicidal, self-directed violence[12,13]; and lower willingness to use VA health care.[13] This reticence to seek PTSD treatment in the VA is compounded by the lack of PTSD treatments that are both effective and acceptable to veterans, particularly those who experienced MST.

First-line, evidence-based treatments (EBTs) for PTSD offered by the VA are trauma-focused psychotherapies, eg, prolonged exposure and cognitive processing therapy (CPT); however, these therapies lack acceptability and have high treatment dropout and incomplete effect, with more than one-half of treatment completers retaining their PTSD diagnosis.[14-16] Veterans' preference for and use of yoga for PTSD treatment have grown significantly and are supported by VA expansion of access to complementary and integrative health (CIH) modalities.[17] Evidence of the effectiveness of yoga to treat PTSD is growing.[18-22]

In this multisite, randomized clinical trial (RCT), we examined the effectiveness of Trauma Center Trauma-Sensitive Yoga (TCTSY), a Hatha-style yoga intervention designed for women who experienced childhood sexual trauma. In contrast to cognitively based EBTs, TCTSY is a body-based intervention that focuses on reducing stress reactions of the body by cultivating interoception.[23,24] This study is the first fully powered RCT to compare a yoga modality with a gold-standard PTSD treatment (CPT) and builds on our prior work.[20,25] The primary aim of this study was to evaluate the effectiveness of TCTSY compared with CPT on outcomes of PTSD, chronic pain, and insomnia. We hypothesized that there would be a difference in PTSD outcomes between the interventions. Previous interim results demonstrated significant reductions in PTSD severity with large effect sizes for both TCTSY and CPT without significant differences between groups.[22] Here, we present the final PTSD outcomes, including additional post hoc equivalence analyses.

Methods

Setting, Study Design, and Participants

For this RCT, we recruited participants from VA PTSD and other clinics from December 5, 2015, through June 22, 2020. In March 2020, due to the COVID-19 pandemic, we adapted enrollment, data collection, and intervention delivery from in-person to virtual methods.[26] The study protocol including these changes is provided in Supplement 1. The data analysis was conducted from December 1, 2015, to April 30, 2022. This RCT was approved by the Emory University institutional review board and relevant VA institutional review boards and research committees. All participants gave written informed consent. The Consolidated Standards of Reporting Trials (CONSORT) reporting guideline was followed.

Participants were randomized to TCTSY or CPT using randomization sequences initially in groups of 24, then in 16 to 20 due to lower-than-expected enrollment (details reported elsewhere[22]). Group allocation was revealed following the baseline assessment. Additional assessments were conducted at midintervention, 2 weeks post intervention, and 3 months post intervention.

Participants were women veterans aged 22 to 71 years at southeast (site 1) and northwest (site 2) VA health care systems. Sociodemographic data were collected via self-report survey. We included race and ethnicity as a variable because the existing literature on yoga as a treatment for PTSD is largely conducted with White populations, lacking diversity. We also included it because the racial and ethnic profile of the 2 study sites were substantially different. Inclusion criteria were (1) enrolled in VA care, (2) experienced MST, (3) had a current PTSD diagnosis with MST as the index trauma, and (4) had insomnia. Exclusion criteria included current EBT or yoga practice; suicidal ideation with intent or plan; moderate or severe traumatic brain injury or cognitive impairment; and moderate or severe substance abuse disorder, psychosis, or mania. Of the 200 women who consented to participate, 132 were eligible and randomized; the final intent-to-treat (ITT) sample was 131 participants (**Figure 1**; eFigures 1 and 2 in Supplement 2).

Outcome Measures

The primary outcome of PTSD symptom severity was assessed using the Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5) and PTSD Checklist for *DSM-5* (PCL-5).[27-29] The CAPS-5 measures 20 PTSD symptoms on a Likert scale (0-4) that are summed for a total severity score of 0 to 80. The CAPS-5 interviews were audio recorded; data quality was maintained via review of 10% or more of recordings and ongoing CAPS-5 supervision by study investigators (B.Z. and M.P.). The PCL-5 self-report measure uses a Likert scale (0-4) to quantify the extent to which the respondent is bothered by 20 PTSD-related symptoms that are summed for a total severity score of 0 to 80. Additional primary outcomes were chronic pain and insomnia. Given the clinical complexity of these symptoms in the context of PTSD and the multiple moderators we considered (eg, obstructive sleep apnea), pain and insomnia outcomes will be reported elsewhere along with secondary outcomes.

Interventions

Each intervention was delivered by 2 interventionists using established manualized protocols. Site 1 conducted sessions in person for 9 cohorts, except for the second half of the ninth cohort, which was conducted virtually, as was the single cohort at site 2. We provided a no-cost intervention crossover option for participants in the first 8 cohorts.

Trauma Center Trauma-Sensitive Yoga

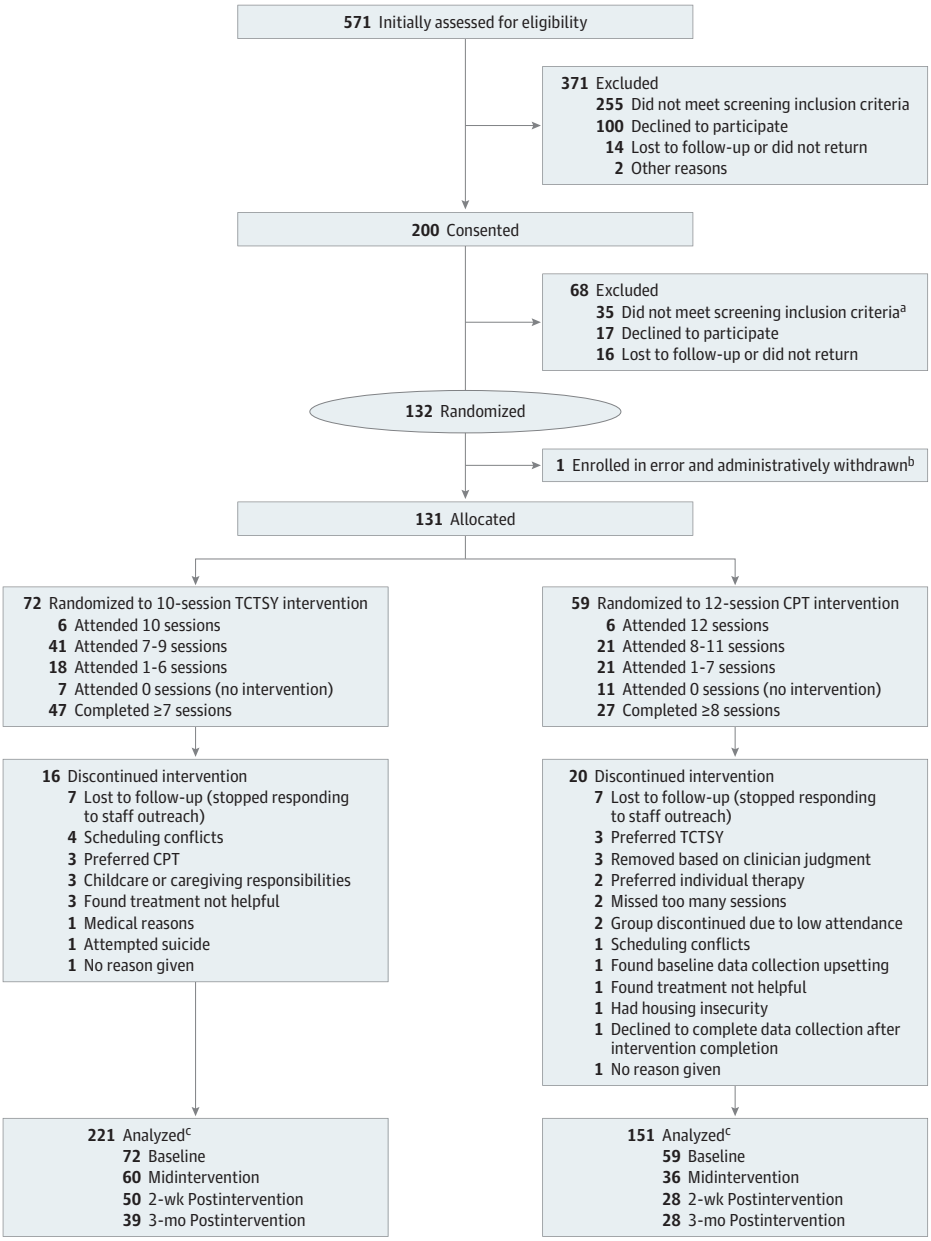
Trauma Center Trauma-Sensitive Yoga consisted of 10 weekly, 60-minute group sessions (10 hours of contact time). The treatment was created for survivors of sexual trauma; its foundations include trauma theory, attachment theory, and neuroscience.[30-32] The core components of TCTSY are interoception, invitational language, choice making, noncoercion, and shared authentic experience. The TCTSY treatment centers around power sharing between facilitator and participant, emphasizes

identification and clarification of body sensations as experienced within the physical yoga forms, and facilitates participants' experiences of choice and noncoercion and taking effective action. The treatment was provided by TCTSY-certified facilitators who held registered yoga teacher credentials from the Yoga Alliance of at least 200 training hours.

Cognitive Processing Therapy

Cognitive processing therapy consisted of 12 weekly, 90-minute group sessions (18 hours of contact time). The therapy involves modification of negative posttraumatic cognitions[33,34]; it helps patients identify the impact of traumatic events, including their sense-making of why the trauma occurred and how it has changed their views about themselves, others, and the world. Clinicians use Socratic

Figure 1. CONSORT Chart for Combined Sites



Postrandomization attrition for the Trauma Center Trauma-Sensitive Yoga (TCTSY) intervention was 23 of 72 (31.9%) and for the cognitive processing therapy (CPT) intervention, 27 of 59 (45.8%).

[a] After consent, full assessments were completed to confirm eligibility.

[b] Participant was consented in error; did not meet eligibility criteria for posttraumatic stress disorder related to military sexual trauma.

[c] Analytic sample sizes vary for CAPS-5 and PCL-5 due to participants completing PCL-5 but not CAPS-5

dialogue and progressive worksheets that help the patient learn how to challenge their trauma-related stuck points (ie, unrealistic beliefs) and generate more balanced, realistic thoughts. The therapy was provided by VA CPT-certified licensed clinicians.

Treatment Supervision and Fidelity Monitoring

The TCTSY facilitators completed standardized session and fidelity notes immediately after each session. Supervision was provided by a cofounder of TCTSY (D.E.) via weekly meetings with the facilitators. These meetings included fidelity feedback between the co-facilitators' (D.E. and U.A.K.) review of fidelity notes with the TCTSY facilitators, debriefing of each session, and ongoing supervision. One TCTSY facilitator conducted sessions in all 9 cohorts at site 1 and supervised the TCTSY facilitators at site 2 with D.E., enhancing consistency in intervention delivery.

For CPT, clinicians maintained fidelity to the 2014 protocolized treatment manual,[34] using the VA CPT SharePoint site for resources, case consultation, and a community practice call. Supervision was provided by a co-investigator (M.P.), a VA CPT trainer. Seven of the 9 CPT cohorts at site 1 were conducted by the same 2 clinicians, enhancing consistency in intervention delivery.

A data and safety monitoring board was established with the addition of site 2. There were no clinically significant adverse events reported throughout the trial.

Data Plan

The study was proposed to have a final sample size of 104 participants (52 per group) after expected levels of 50% attrition from 208. This sample size was powered at 80% to detect moderate effect sizes for differences between the groups (Cohen d = 0.555 for differences in continuous outcomes and Cohen ω = 0.274 for differences in proportions), as well as moderate to large effect sizes for differences between the groups over time (group-by-time interaction effect size f = 0.28).[35] Power analyses were completed using Power Analysis and Sample Size Software, version 13.0.8.[36] The final sample size was 103 participants, close to the planned sample size (Figure 1).

Statistical Analysis

Prior to analysis, all data were reviewed for completeness, missingness, and normality assumptions. Multilevel linear models with random effects for participants were used to compare the longitudinal outcomes over the 4 time points between the 2 groups for the CAPS-5 severity and PCL-5 scores, where group and time were fixed effects.[37] For testing the main group and time effects and the group-by-time interaction effects, we used post hoc tests to compare changes from baseline to the 3 follow-up time points and differences between the 2 groups at each time point using Šidák pairwise error rate adjustment.[37] We computed point estimates (means, SDs, 95% CIs, and effect sizes [Cohen d]).[35] The study was designed to compare the gold standard of CPT with TCTSY using inequality hypothesis testing and an ITT approach, including data from all participants who had baseline outcome data, regardless of further study engagement. Additional analyses were performed for treatment completers, ie, an adequate dose per protocol (PP). Treatment completion definitions were 7 or more out of 10 for TCTSY sessions and 8 or more out of 12 for CPT sessions, consistent with the VA literature (eFigure 3 in Supplement 2).[38-40]

While the study was designed to test for group differences between CPT and TCTSY, given the lack of significant differences between the 2 treatments, we followed up our analyses with tests of equivalence to make specific estimates about the effect size we deemed worthwhile to examine.[41] The equivalence tests compared the means between the 2 groups using two one-sided tests (TOSTs) via the TOSTER, version 0.4.0 package in R (eMethods 1 in Supplement 2).[41,42] Participants' change scores from baseline to each follow-up time point were used to perform TOSTs to test for equivalence between the 2 groups relative to the smallest effect size of interest. A smallest effect size of interest margin of 10 was used for the change score differences on the CAPS-5 and PCL-5 between the treatment groups, similar to previously published approaches for a clinically meaningful difference of plus or minus 10 for the CAPS-5 and PCL-5.[43,44]

Four clinically relevant end points (CAPS-5) are reported at each time point for the percentage of participants who (1) still met the criteria for a PTSD diagnosis, (2) achieved a clinical response (reduction of CAPS-5 severity scores of ≥10 points), (3) had a loss of diagnosis (≥10-point improvement, no PTSD diagnosis, and CAPS-5 severity score <25), and (4) achieved remission (loss of diagnosis plus CAPS-5 score <12).[44] Statistical analyses were completed using SPSS, version 27.0.0.0[45] and R, version 4.1.2[46] software. A 2-sided $P < .05$ was considered significant. Given the COVID-19–related protocol adaptions, sensitivity analyses were conducted while running all the analyses described above with and without site 2 (virtual) and with and without the last cohort of site 1 (hybrid in person and virtual) (eMethods 2 in Supplement 2).

Results

The ITT sample (n = 131) had a mean (SD) age of 48.2 (11.2) years; 95 (72.6%) self-identified as African American or Black; 11 (8.4%) as American Indian or Alaska Native, Asian, multiracial, or other race; and 25 (19.1%) as White. Detailed demographic information and clinical characteristics are provided in **Table 1** (eTable 1 in Supplement 2 provides similar data and trauma exposure by study site). Participant dropout before the first intervention session was nearly double for CPT (11 [18.6%]) than for TCTSY (7 [9.7%]). Attrition post randomization through final intervention sessions was higher for CPT (27 of 59 [45.8%]) than for TCTSY (23 of 72 [31.9%]) (Figure 1). Nearly two-thirds (47 [65.3%]) of the TCTSY group completed treatment compared with less than one-half (27 [45.8%]) of the CPT group; ie, TCTSY had a 42.6% higher treatment completion rate than CPT, a significant difference ($P = .03$).

Both groups improved over time in the ITT analysis for CAPS-5 (mean [SD] scores at baseline: 36.73 [8.79] for TCTSY and 35.52 [7.49] for CPT; mean [SD] scores at 3 months: 24.03 [11.55] for TCTSY and 22.15 [13.56]) and the PCL-5 (mean [SD] scores at baseline: 49.62 [12.19] for TCTSY and 48.69 [13.62] for CPT; mean [SD] scores at 3 months: 36.97 [17.74] for TCTSY and 31.76 [12.47]; $P < .001$); these improvements were also seen in the PP analysis (**Table 2**; eTables 2 and 3 and eFigures 4 and 5 in Supplement 2). None of the group effects or group-by-time effects were statistically significant. None of the post hoc group comparison tests were significant, and all effect sizes for group differences were small (Cohen $d < 0.367$) (Table 2), indicating similar results in both groups. Nearly all within-group improvements in CAPS-5 and PCL-5 outcomes had moderate to large effect sizes for TCTSY and CPT (eTable 4 in Supplement 2).

Subsequent analyses indicated treatment effectiveness equivalence between TCTSY and CPT on the CAPS-5 and PCL-5 (eTable 5 in Supplement 2). None of the change scores were significantly different between the TCTSY and CPT groups, and all TOST intervals fell within the equivalence bounds of plus or minus 10 for CAPS-5 and PCL-5 for every follow-up time point except PCL-5 changes from baseline to 3 months, which fell slightly outside the equivalence bounds (**Figure 2**; eTables 5 and 6 in Supplement 2). The average mean differences in change scores for both CAPS-5 and PCL-5 at each follow-up were less than 5 (or greater than −5), indicating small differences between TCTSY and CPT improvements (ie, treatment equivalence) in both the ITT and PP analyses. Analysis of clinically relevant outcomes at the study end point showed no significant differences between TCTSY and CPT for the presence of a PTSD diagnosis, a clinical response, loss of diagnosis, or remission (**Figure 3**; eTable 7 in Supplement 2).

Discussion

The significant effectiveness of TCTSY for PTSD and the equivalence of TCTSY to CPT in improving PTSD outcomes confirm and extend our earlier findings.[22] Notably, TCTSY had higher treatment initiation, retention, and completion than CPT. The TCTSY group had more robust symptom improvement early on, which may have contributed to higher retention and treatment completion

than in the CPT group (eFigures 4 and 5 and eTables 2 and 3 in Supplement 2). However, the fraction of CPT participants who completed treatment continued to improve from 2 weeks to 3 months after treatment, while improvement leveled off for TCTSY participants. It is important to note the differences in total treatment time (18 hours [CPT] vs 10 hours [TCTSY]). While the TCTSY completion rate was higher at end point, the majority of participants who did not complete CPT dropped out within the first few sessions, not as a result of a longer time frame for treatment.

The TCTSY within-group effect sizes in this study (CAPS-5 ITT Cohen *d* = −0.90 to −0.93) compare favorably to those reported in a systematic review of 7 RCTs of yoga for PTSD, which indicated a postintervention average weighted Cohen *d* of 0.48 for PTSD symptoms.[21] The TCTSY

Table 1. Demographic and Clinical Characteristics

Characteristic	No. (%)		
	TCTSY (n = 72)	CPT (n = 59)	Total (N = 131)
Age, mean (SD) [range], y	48.2 (11.0) [26-70]	48.3 (11.6) [22-71]	48.2 (11.2) [22-71]
Race			
African American or Black	51 (70.8)	44 (74.6)	95 (72.6)
American Indian or Alaska Native	0	1 (1.7)	1 (0.8)
Asian	1 (1.4)	0	1 (0.8)
White	14 (19.4)	11 (18.6)	25 (19.1)
Multiracial[a]	4 (5.6)	3 (5.1)	7 (5.3)
Other[b]	2 (2.8)	0	2 (1.5)
Relationship status			
Nonpartnered	43 (57.7)	44 (74.6)	87 (66.4)
Married or partnered	29 (40.3)	15 (25.4)	44 (33.6)
Education level			
Less than college	27 (37.5)	26 (44.1)	53 (40.5)
College degree or more	45 (62.5)	33 (55.9)	78 (59.5)
Monthly income,[c] $			
<2000	25 (35.2)	24 (40.7)	49 (37.7)
≥2000	46 (64.8)	35 (59.3)	81 (62.3)
Employment status			
Less than full time	47 (65.3)	45 (76.3)	92 (70.2)
Full time	25 (34.7)	14 (23.7)	39 (29.8)
BDI total score[c]			
Mean (SD)	28.0 (9.8)	29.0 (11.8)	28.5 (10.7)
Range	5-55	8-58	5-58
BDI total categories[c]			
Minimal (0-13)	4 (5.8)	6 (10.5)	10 (7.9)
Mild (14-19)	10 (14.5)	6 (10.5)	16 (12.7)
Moderate (20-28)	22 (31.9)	17 (29.8)	39 (31.0)
Severe (29-63)	33 (47.8)	28 (49.1)	61 (48.4)
MINI			
Suicidality (past month)			
No	50 (69.4)	33 (55.9)	83 (63.4)
Yes[d]	22 (30.6)	26 (44.1)	48 (36.6)
Suicidality (lifetime attempt)			
No	56 (77.8)	42 (71.2)	98 (74.8)
Yes	16 (22.2)	17 (28.8)	33 (25.2)
Suicidality rating[d]			
Low (1-8)	12 (54.5)	12 (46.2)	24 (50.0)
Moderate (9-16)	2 (9.1)	4 (15.4)	6 (12.5)
High (≥17)	8 (36.4)	10 (38.5)	18 (37.5)

Abbreviations: BDI, Beck Depression Inventory; CPT, cognitive processing therapy; MINI, Mini International Neuropsychiatric Interview; TCTSY, Trauma Center Trauma-Sensitive Yoga.

[a] Four women self-reported as also Hispanic or Latino.

[b] For the 2 women who self-reported other, 1 reported as being "African American, Caucasian" and 1 as "West African."

[c] Missing income for 1 participant; missing BDI total score for 5 participants.

[d] Suicidality rating only completed for the 48 subjects who said yes for any lifetime suicide.

and CPT groups also showed similar declines in all the clinically relevant end points described by Schnurr et al,[44] ie, continued PTSD diagnosis, clinical response, loss of diagnosis, and remission.

The TCTSY treatment completion rate was 42.6% higher than the CPT rate and is perhaps the most valuable finding, given the limited engagement in and completion of EBTs, particularly among women veterans.[13,47,48] This higher completion rate indicates that TCTSY is more acceptable than CPT, which has higher treatment completion than prolonged exposure.[44] This finding is critical given the personal burden and consequences of untreated or unresolved PTSD in women veterans,[49,50] as well as the health care costs of PTSD. The total cost of PTSD for military populations in 2018 was $42.7 billion, driven by disability and direct health care costs.[1]

Yoga modulates the stress response, regulates the sympathetic nervous system, and activates the parasympathetic nervous system.[51] Theoretically, via these mechanisms, in addition to improving

Table 2. Posttraumatic Stress Disorder (PTSD) Outcomes Intent-to-Treat and Per-Protocol Group Difference Effect Sizes

	Baseline		Midpoint		2 wk Post intervention		3 mo Post intervention	
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)
CAPS-5 (intent to treat)[a]								
TCTSY	71	36.73 (8.79)	59	26.32 (10.09)	50	23.24 (11.68)	39	24.03 (11.55)
CPT	58	35.52 (7.49)	34	28.97 (12.20)	26	27.77 (14.77)	27	22.15 (13.56)
Effect size		0.148		−0.243		−0.354		0.151
CAPS-5 (per protocol)[b]								
TCTSY	46	35.13 (8.36)	45	26.56 (10.04)	45	23.51 (11.60)	36	24.08 (11.49)
CPT	27	37.22 (8.51)	24	30.58 (12.54)	20	28.05 (15.03)	21	22.00 (13.46)
Effect size		−0.249		−0.367		−0.357		0.170
PCL-5 (intent to treat)[c]								
TCTSY	71	49.62 (12.19)	59	42.49 (14.25)	50	38.68 (15.72)	39	36.97 (17.74)
CPT	59	48.69 (13.62)	35	45.83 (15.77)	27	39.00 (17.65)	27	33.59 (15.51)
Effect size		0.072		−0.225		−0.019		0.200
PCL-5 (per protocol)[d]								
TCTSY	47	47.02 (12.07)	45	41.69 (15.00)	45	39.04 (15.71)	36	36.22 (17.36)
CPT	27	47.48 (15.53)	25	44.04 (15.36)	21	37.52 (16.76)	21	31.76 (12.47)
Effect size		−0.034		−0.155		0.095		0.283

Abbreviations: CAPS-5, Clinician-Administered PTSD Scale for *DSM-5*; CPT, cognitive processing therapy; PCL-5, PTSD Checklist for *DSM-5*; TCTSY, Trauma Center Trauma-Sensitive Yoga.

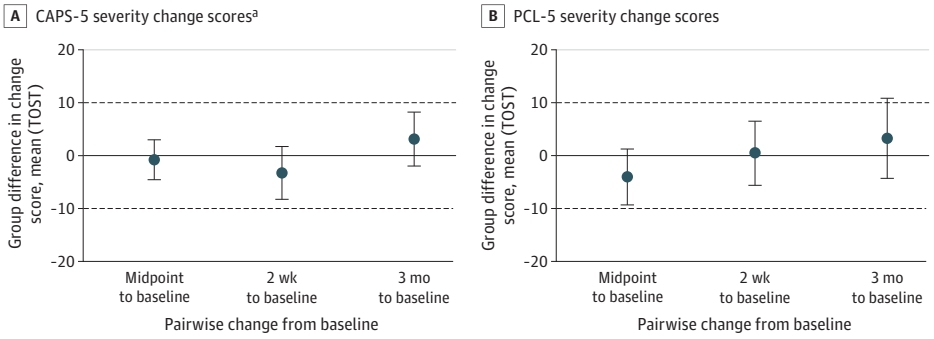
[a] Group: $F_{(1,141.6)} = 0.00$, $P = .98$; time: $F_{(3,258.6)} = 48.13$, $P < .001$; group by time: $F_{(3,258.6)} = 1.87$, $P = .14$.

[b] Group: $F_{(1,73.6)} = 1.00$, $P = .32$; time: $F_{(3,189.8)} = 31.77$, $P < .001$; group by time: $F_{(3,189.8)} = 1.61$, $P = .19$.

[c] Group: $F_{(1,139.2)} = 0.17$, $P = .68$; time: $F_{(3,257.2)} = 23.30$, $P < .001$; group by time: $F_{(3,257.2)} = 1.55$, $P = .20$.

[d] Group: $F_{(1,74.1)} = 0.10$, $P = .76$; time: $F_{(3,192.5)} = 16.71$, $P < .001$; group by time: $F_{(3,192.5)} = 1.27$, $P = .29$.

Figure 2. Equivalence Test Limits for Differences Between Groups for Clinician-Administered Posttraumatic Stress Disorder (PTSD) Scale for *DSM-5* (CAPS-5) Severity and PTSD Checklist for *DSM-5* (PCL-5) Change Scores



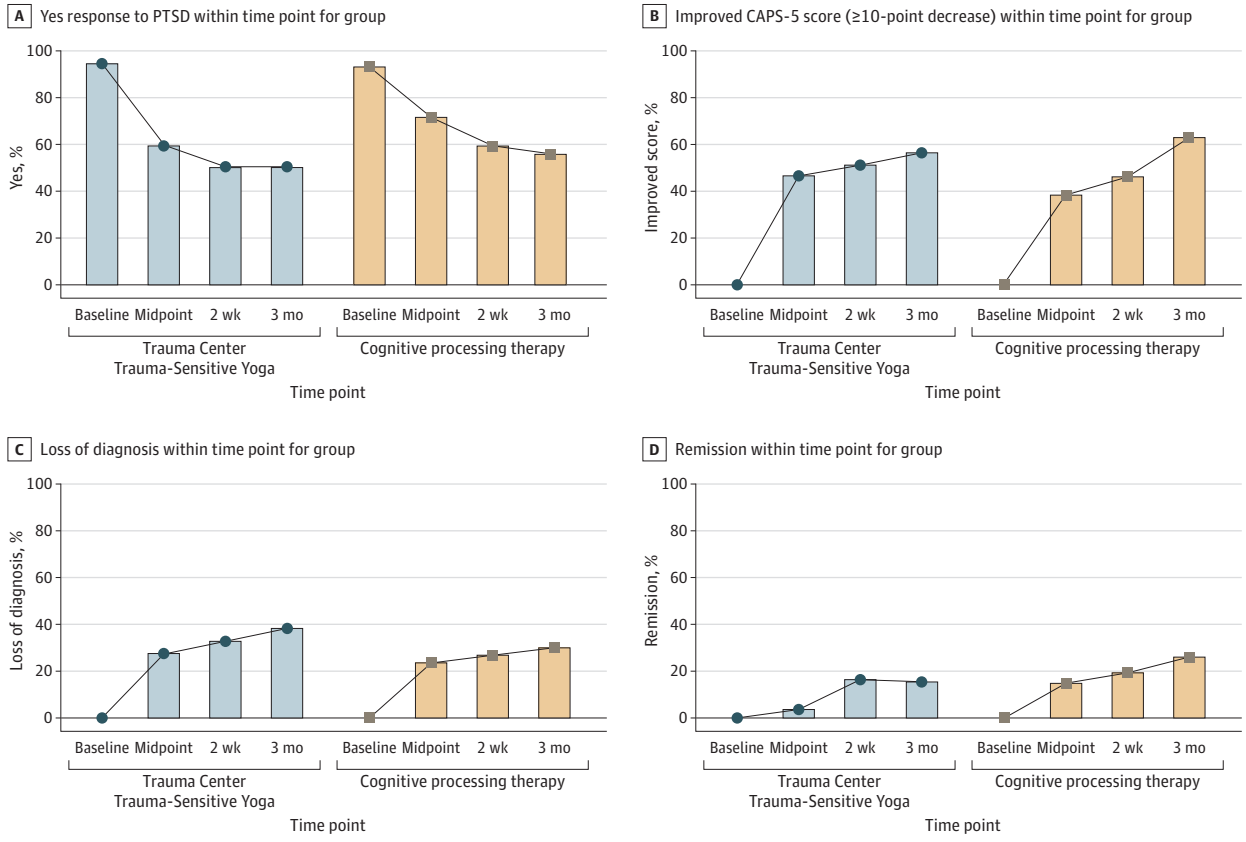
Mean difference less than 0 indicates better improvement in 1 intervention over the other. Dots indicate the mean group difference in CAPS-5 change scores; bars, upper and lower bounds of the two one-sided test (TOST) intervals, dashed lines, plus or minus 10 equivalence bounds.

autonomic nervous system dysregulation in PTSD,[52] yoga improves cross-cutting symptoms of stress, anxiety, depression, and pain.[53,54] As such, yoga may be appealing to individuals who are experiencing these and other stress-related symptoms in the absence of an established PTSD diagnosis or awareness that their symptoms represent PTSD.[55]

Treatment for PTSD that uses different theoretical frameworks and mechanisms of action is needed for veterans for whom existing EBTs are unacceptable or ineffective. Our premise was that sexual trauma is experienced by the body first and primarily. As such, an embodied treatment approach provides a direct trajectory for healing as opposed to the indirect pathway of cognitively based EBTs. However, yoga modalities in studies of yoga for PTSD have varied widely. The TCTSY modality was designed for women with complex trauma (childhood sexual abuse) and chronic, treatment-resistant PTSD, features shared by the clinical population of VA-using women veterans with PTSD related to MST. This design of TCTSY might explain the more robust CAPS-5 and PCL-5 change scores in the TCTSY group compared with those in a study by Davis et al[18] of a Hatha yoga–based holistic yoga program for PTSD. The implication is that the mechanisms of yoga may differ across yoga types; thus, it is important to match the theorized mechanism of a yoga intervention to the target phenomena and outcomes, ie, TCTSY for PTSD related to sexual trauma.

Treatment of PTSD that is acceptable and effective is medical care to which all veterans are entitled and that is currently lacking. The robust equivalence results combined with the notably higher TCTSY completion rate indicate that TCTSY is such a treatment. While no single PTSD treatment will be acceptable and effective for everyone, TCTSY may help women veterans overcome resistance to seeking care at the VA and provide effective PTSD treatment, an acceptable first option for PTSD treatment, or an option for those who withdraw from or do not improve sufficiently with

Figure 3. Clinical Posttraumatic Stress Disorder (PTSD) Diagnostic Changes



CAPS-5 indicates Clinician-Administered PTSD Scale for *DSM-5*.

EBTs. Additionally, TCTSY is more widely available in community settings, such as wellness programs, yoga programs, and independent TCTSY facilities, than CPT, providing improved access to treatment for a broader population of women veterans and civilian women with PTSD related to sexual trauma.

Limitations

This study has several limitations. First, the study end point of 3 months post intervention precluded determination of even longer-term sustained effects of the interventions. Second, the CAPS-5 assessors were not blinded, introducing a risk of bias. Third, participants may have participated in unreported CIH modalities or psychotherapy that could have confounded the results. Finally, the final cohort at site 1 and the only cohort at site 2 were conducted during the COVID-19 pandemic, introducing additional stressors, isolation, restricted access to health care, and a pivot of study procedures to virtual delivery, all potential confounders of study data during that time.

Conclusions

The costs of untreated or incompletely treated PTSD to women veterans and their families, the VA, and society are sizable. The VA is facing exponential increases in the number of women enrolled and with PTSD. Given the limitations of first-line EBTs in the VA, new acceptable and effective PTSD treatments could reduce the economic costs of PTSD and the burden on women veterans and their families. The findings of this RCT demonstrate that TCTSY is an effective and acceptable treatment to be added to current EBTs. Policy and practice changes to include TCTSY could be a cost-effective means to expand PTSD treatment options; provide a treatment that could improve associated symptoms, such as depression and anxiety; potentially mitigate PTSD-related physical symptoms and comorbidities; address veterans' preferences for CIH therapies; and increase access to acceptable, patient-driven, and effective PTSD treatment.

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SUPPLEMENT 1.
Trial Protocol

SUPPLEMENT 2.
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SUPPLEMENT 3.
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