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Original Investigation

Mindfulness-Based Stress Reduction for Posttraumatic Stress Disorder Among Veterans

A Randomized Clinical Trial

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IMPORTANCE Mindfulness-based interventions may be acceptable to veterans who have poor adherence to existing evidence-based treatments for posttraumatic stress disorder (PTSD).

OBJECTIVE To compare mindfulness-based stress reduction with present-centered group therapy for treatment of PTSD.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial of 116 veterans with PTSD recruited at the Minneapolis Veterans Affairs Medical Center from March 2012 to December 2013. Outcomes were assessed before, during, and after treatment and at 2-month follow-up. Data collection was completed on April 22, 2014.

INTERVENTIONS Participants were randomly assigned to receive mindfulness-based stress reduction therapy (n = 58), consisting of 9 sessions (8 weekly 2.5-hour group sessions and a daylong retreat) focused on teaching patients to attend to the present moment in a nonjudgmental, accepting manner; or present-centered group therapy (n = 58), an active-control condition consisting of 9 weekly 1.5-hour group sessions focused on current life problems.

MAIN OUTCOMES AND MEASURES The primary outcome, change in PTSD symptom severity over time, was assessed using the PTSD Checklist (range, 17-85; higher scores indicate greater severity; reduction of 10 or more considered a minimal clinically important difference) at baseline and weeks 3, 6, 9, and 17. Secondary outcomes included PTSD diagnosis and symptom severity assessed by independent evaluators using the Clinician-Administered PTSD Scale along with improvements in depressive symptoms, quality of life, and mindfulness.

RESULTS Participants in the mindfulness-based stress reduction group demonstrated greater improvement in self-reported PTSD symptom severity during treatment (change in mean PTSD Checklist scores from 63.6 to 55.7 vs 58.8 to 55.8 with present-centered group therapy; between-group difference, 4.95; 95% CI, 1.92-7.99; $P = .002$) and at 2-month follow-up (change in mean scores from 63.6 to 54.4 vs 58.8 to 56.0, respectively; difference, 6.44; 95% CI, 3.34-9.53, $P < .001$). Although participants in the mindfulness-based stress reduction group were more likely to show clinically significant improvement in self-reported PTSD symptom severity (48.9% vs 28.1% with present-centered group therapy; difference, 20.9%; 95% CI, 2.2%-39.5%; $P = .03$) at 2-month follow-up, they were no more likely to have loss of PTSD diagnosis (53.3% vs 47.3%, respectively; difference, 6.0%; 95% CI, -14.1% to 26.2%; $P = .55$).

CONCLUSIONS AND RELEVANCE Among veterans with PTSD, mindfulness-based stress reduction therapy, compared with present-centered group therapy, resulted in a greater decrease in PTSD symptom severity. However, the magnitude of the average improvement suggests a modest effect.

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Posttraumatic stress disorder (PTSD) affects 23% of veterans returning from deployments in Afghanistan (Operation Enduring Freedom) and Iraq (Operation Iraqi Freedom).¹ Left untreated, it is associated with high rates of comorbidity, disability, and poor quality of life.² The US Department of Veterans Affairs (VA) has invested heavily in the dissemination of prolonged exposure therapy and cognitive processing therapy.³ Robust evidence supports the efficacy of these 2 first-line treatments.⁴ Yet 30% to 50% of veterans participating in prolonged exposure or cognitive processing therapy fail to show clinically significant improvements,^{5,6} and dropout is high, ranging from 30% to 38%⁵⁻⁷ in randomized trials and 32% to 44% in clinic-based studies.⁸⁻⁹ A recent chart review found that 60% of eligible Operation Enduring Freedom/Operation Iraqi Freedom veterans failed to begin or dropped out of these treatments.¹⁰ Avoidance and difficulties tolerating trauma-focused material likely contribute to dropout.^{7,11} Thus, research aimed at testing novel treatments for PTSD in this population is important.

CAPS Clinician-Administered PTSD Scale

DSM-IV Diagnostic and Statistical Manual of Mental Disorders [Fourth Edition]

FFMQ Five Facet Mindfulness Questionnaire

MCID minimal clinically important difference

PCL PTSD Checklist

PHQ-9 Patient Health Questionnaire 9

PTSD posttraumatic stress disorder

WHOQOL-BREF World Health Organization Quality of Life-Brief

Evidence suggests that mindfulness-based stress reduction, an intervention that teaches individuals to attend to the present moment in a nonjudgmental, accepting manner,¹² can result in reduced symptoms of depression and anxiety.¹³ By encouraging acceptance of thoughts, feelings, and experiences without avoidance, mindfulness-based interventions target experiential avoidance, a key factor in the development and maintenance of PTSD.¹⁴ This randomized clinical trial compared mindfulness-based stress reduction with an active, credible intervention, present-centered group therapy. We hypothesized that veterans randomly assigned to mindfulness-based stress reduction would show greater reductions in self-reported and interview-rated PTSD severity and loss of diagnosis after treatment and at 2-month follow-up compared with those randomized to present-centered group therapy.

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Methods

Participants

Participants were veterans who met the following inclusion criteria: (1) current full PTSD according to the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) (DSM-IV)¹⁵ or subthreshold PTSD, defined as endorsement of DSM-IV criterion A1 and at least 1 symptom each from criteria B, C, and D with significant impairment; (2) agreement to not receive other psychotherapy for PTSD during study; and (3) if being treated with psychoactive medications, a stable regimen for at least 2 months prior to study entry. Exclusion

criteria were (1) current substance dependence (except nicotine or caffeine); (2) current psychotic disorder (eg, schizophrenia, bipolar disorder); (3) prominent current suicidal or homicidal ideation; and (4) cognitive impairment or medical illness that could interfere with treatment.

Procedures

Patients were recruited through advertisements and clinical referrals at a large VA medical center. All patients provided written informed consent for participation in this study, which was approved by the Minneapolis VA Medical Center institutional review board. Participants completed a 5-hour eligibility and baseline assessment that included a structured clinical interview and self-report measures. Master's-level assessors supervised by study authors (C.R.E. and G.J.L.) served as independent evaluators blinded to treatment condition. Posttraumatic stress disorder and Axis I psychiatric disorders were assessed using structured clinical interviews.^{16,17} Outcomes were assessed before treatment, at 3-week intervals during treatment (weeks 3 and 6), after treatment (week 9), and at 2-month follow-up (week 17). Data collection was completed April 22, 2014.

Randomization was conducted using SAS PROC PLAN in blocks of 4 to ensure even randomization across the length of the study. A restricted electronic randomization chart was provided to the study coordinator by the statistician. Veterans were randomized approximately every 2 months over a 19-month period, for a total of 9 cohorts composed of 1 group each of the 2 conditions.

The trial protocol is available in the Supplement.

Treatment Conditions

Treatment was delivered in a group format according to manualized protocols by 2 instructors/clinicians. For mindfulness-based stress reduction, lead instructors completed a 9-day intensive practicum training at the University of Massachusetts Center for Mindfulness. Each lead instructor was assisted by a doctoral-level clinician. All instructors/clinicians completed a 2-day training and received weekly or biweekly supervision (by senior staff at the University of Minnesota Center for Spirituality and Healing for mindfulness-based stress reduction; by developer Melissa Wattenberg, PhD, for present-centered group therapy).

Mindfulness-Based Stress Reduction

Standard protocol consists of 8 weekly 2.5-hour group sessions and a daylong retreat.¹² The intervention was modified to include an orientation to the program that incorporated PTSD psychoeducation and treatment rationale (session 1), followed by 7 weekly 2.5-hour group sessions and a 6.5-hour retreat, for a total of 9 sessions. The program teaches participants to attend to the present moment (immediate emotional and physical states, including discomfort) in a nonjudgmental and accepting way. Sessions include didactic training and formal practice in 3 meditation techniques. The body scan is a guided exercise that systematically directs attention through various areas of the body. Sitting meditation involves developing capacity for sustained self-observation through direct-

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ing attention to specific experiences (eg, the breath, physical sensations, thoughts, emotions, sensory stimuli). Mindful yoga involves gentle stretches and movements practiced with present-moment attention, which encourages greater body awareness. Meditation techniques were taught in the same manner as is typical in programs offered in the community, and no modifications were made to specifically accommodate PTSD. The daylong silent retreat provides an opportunity for sustained practice of these techniques. Additionally, the program encourages individuals to practice meditation techniques at home and to cultivate present-moment awareness in ordinary daily activities (eg, mindful eating and driving).

Present-Centered Group Therapy

Present-centered group therapy is an active-control condition shown to benefit individuals with PTSD.^{18,19} It controls for nonspecific therapeutic factors by providing professional contact, a credible therapeutic rationale, and corresponding specific ingredients (eg, problem solving) for reducing distress, with positive therapeutic expectancy similar to mindfulness-based stress reduction.¹³ The intervention consists of 9 weekly 1.5-hour group sessions focused on current life problems as manifestations of PTSD.²⁰ Session 1 focuses on providing psychoeducation about PTSD and treatment rationale, building group cohesion, and goal setting. Sessions 2 through 8 focus on discussing daily difficulties. Session 9 focuses on reviewing accomplishments and planning for the future. Therapists are nondirective and encourage patients to provide each other with support, problem solving, and validation. There was no discussion of mindfulness meditation techniques or traumatic experiences.

Primary Outcome

The primary outcome, change in PTSD symptom severity over time, was assessed using the PTSD Checklist²¹ (PCL; range, 17-85; higher scores indicate more severe symptoms) at all assessment points (baseline and weeks 3, 6, 9, and 17). It has excellent internal consistency (Cronbach $\alpha = 0.94-0.97$), test-retest reliability (0.96), and concurrent validity.²² The minimal clinically important difference (MCID) for self-reported PTSD symptom severity is a reduction of 10 or more points on the PCL.²³

Secondary Outcomes

Diagnosis and symptom severity of PTSD were also assessed using the Clinician-Administered PTSD Scale (CAPS)¹⁶ before and after treatment and at 2-month follow-up (baseline, week 9, and week 17). Potentially traumatic events were identified using the Life Events Checklist and further assessed during interview.²⁴ We used the recommended 1/2 scoring rule, whereby a frequency score of 1 (0 = none of the time; 4 = most or all of the time) and intensity score of 2 (0 = none; 4 = extreme) is required to consider each symptom as present.²² Diagnoses were based on *DSM-IV* criteria for PTSD; a severity score was also calculated by summing frequency and intensity scores for all 17 symptoms (range, 0-136; higher scores indicate more severe PTSD). A reduction of 10 or more points is considered the MCID for the CAPS.⁵ Comorbid depression

symptoms were assessed using the Patient Health Questionnaire 9²⁵ (PHQ-9; range, 0-27; higher scores indicate more symptoms). The MCID for the PHQ-9 is a reduction of 5 or more points.²⁶ Quality of life was assessed using the World Health Organization Quality of Life-Brief (WHOQOL-BREF).²⁷ This study reports the summed total score (range, 0-130; higher scores indicate greater quality of life).

Mindfulness skills (observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience) were assessed using the Five Facet Mindfulness Questionnaire (FFMQ)²⁸ at all assessment points (range, 39-195; higher scores indicate greater mindfulness).

Participants' beliefs about the rationale and logic of the treatment (credibility scale range, 1-9; higher scores indicate more rationality/logic) and likelihood of the treatment's success (expectancy scale range, 1-9; higher scores indicate greater expectations of success) in reducing PTSD symptoms were assessed using the Credibility/Expectancy Questionnaire²⁹ at week 3. Participants reported treatment satisfaction at week 9 using a scale ranging from 1 to 4 with higher scales indicating greater satisfaction. Demographic information, including self-reported race/ethnicity, was collected at baseline to characterize the sample. Mental health treatment history and psychotherapy health care visits (individual and group therapy delivered both in specialty PTSD and mental health clinics) from October 1, 1999, to participants' baseline dates were extracted from VA electronic medical records. We determined the mean duration (in months) of previous mental health care, total number of psychotherapy mental health visits, and whether a participant had previously received 8 or more therapy sessions at baseline.

Treatment Fidelity

All treatment sessions were videotaped. Two senior clinicians independent of treatment delivery rated 10% of sessions from each condition using a rating tool adapted from other trials of PTSD group treatment.³⁰

Data Analysis

Intention-to-treat analyses were conducted for all outcomes. Baseline differences between groups were examined using analysis of variance for continuously measured variables and χ^2 statistics for noncontinuous variables. Mixed-effects models were used to analyze the efficacy of mindfulness-based stress reduction compared with present-centered group therapy in reducing PTSD symptoms over 9 weeks of treatment and at 2-month follow-up.³¹ Mixed-effects models are flexible regression methods for incomplete repeated-measures data and allow continuous and categorical covariates, fixed and time-dependent covariates, and a specification of unstructured as well as structured covariance matrix. The analysis for each outcome consisted of a maximum likelihood growth curve model that included treatment, time, and treatment \times time interaction as fixed effects and the intercept and slope as random effects with an unstructured covariance matrix. Since treatment groups are expected to be similar at baseline, the effect of treatment is captured

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through the treatment \times time interaction (ie, differential temporal patterns of PTSD symptoms for 2 treatment groups). Between-group effect sizes were computed as Cohen d , the standardized mean difference,³² and defined as small ($d = 0.25$), medium ($d = 0.50$), and large ($d = 0.80$). We calculated the percentage of participants who showed clinically significant improvement on primary and secondary outcomes based on MCIDs established in the literature. Finally, because of the sex imbalance between the groups, we also conducted a series of exploratory growth curve models adding sex as a control variable to determine the effect of this imbalance on study findings.

Power analyses were based on expected effect sizes (0.5-0.9) drawn from a prior pilot study³³ and estimates for means, standard deviations, and covariances from an unpublished open trial of mindfulness-based stress reduction in a group of 24 veterans with PTSD. Power analyses were conducted for the primary outcome (PCL score) using Nquery Advisor 4 (Statistics Solutions) under the following assumptions: (1) repeated-measures analysis of variance with main effects of treatment (mindfulness-based stress reduction vs present-centered group therapy), time (0, 3, 6, 9, and 17 weeks), and treatment \times time interaction; (2) compound symmetric covariance matrix; and (3) $\alpha < .05$ significance level. A sample size of 60 to 65 patients after attrition (we expected attrition of approximately 30%; hence, our initial recruiting goal was 90 per group) was estimated to provide 80% power to detect an effect size of $d = 0.52$. This effect size corresponds to a difference in total scores between groups of 6.4 for the PCL, 8.6 for the CAPS, 2.8 for the PHQ-9, and 7.6 for the WHOQOL-BREF. All analyses were conducted using SPSS software version 19.0 (IBM Corp). All tests were 2-tailed and $\alpha < .05$ was considered statistically significant. No adjustment for multiple comparisons were made, so secondary outcomes, including tests of MCIDs, should be considered exploratory.

Results

Figure 1 depicts participant flow through the study. **Table 1** provides information on demographics, mental health treatment history, and trauma exposure for the sample. There were no differences between groups in demographic characteristics with the exception of ethnicity and sex. There were more African American (10.3% [$n = 6$] vs 5.2% [$n = 3$]) and American Indian (3.4% [$n = 2$] vs 0%) patients in the present-centered therapy group, but there were more patients of mixed ethnicity (10.3% [$n = 6$] vs 0%) and more women (20.7% [$n = 12$] vs 10.3% [$n = 6$]) in the mindfulness-based stress reduction group. Groups were similar in terms of comorbid mood disorder, psychoactive medication use, mental health treatment history, number of traumatic events, combat exposure, and ratings of treatment credibility and expectancies. However, participants randomized to mindfulness-based stress reduction therapy more frequently reported a history of sexual trauma (37% [$n = 21$] vs 19% [$n = 11$]) and had greater severity of PTSD symptoms at base-

line as measured by the PCL (mean score, 63.6 vs 58.8) and CAPS (mean score, 69.9 vs 62.5) compared with participants randomized to present-centered group therapy. There was no difference in PTSD symptom severity as measured by the PCL between those who met full PTSD and those who met subthreshold PTSD (mean score, 61.2 vs 60.7). There were no differences between groups in depression symptoms (PHQ-9 mean score, 15.5 vs 14.6), quality of life (WHOQOL-BREF mean score, 75.6 vs 76.4), or mindfulness skills (FFMQ mean score, 105.7 vs 108.1) reported at baseline.

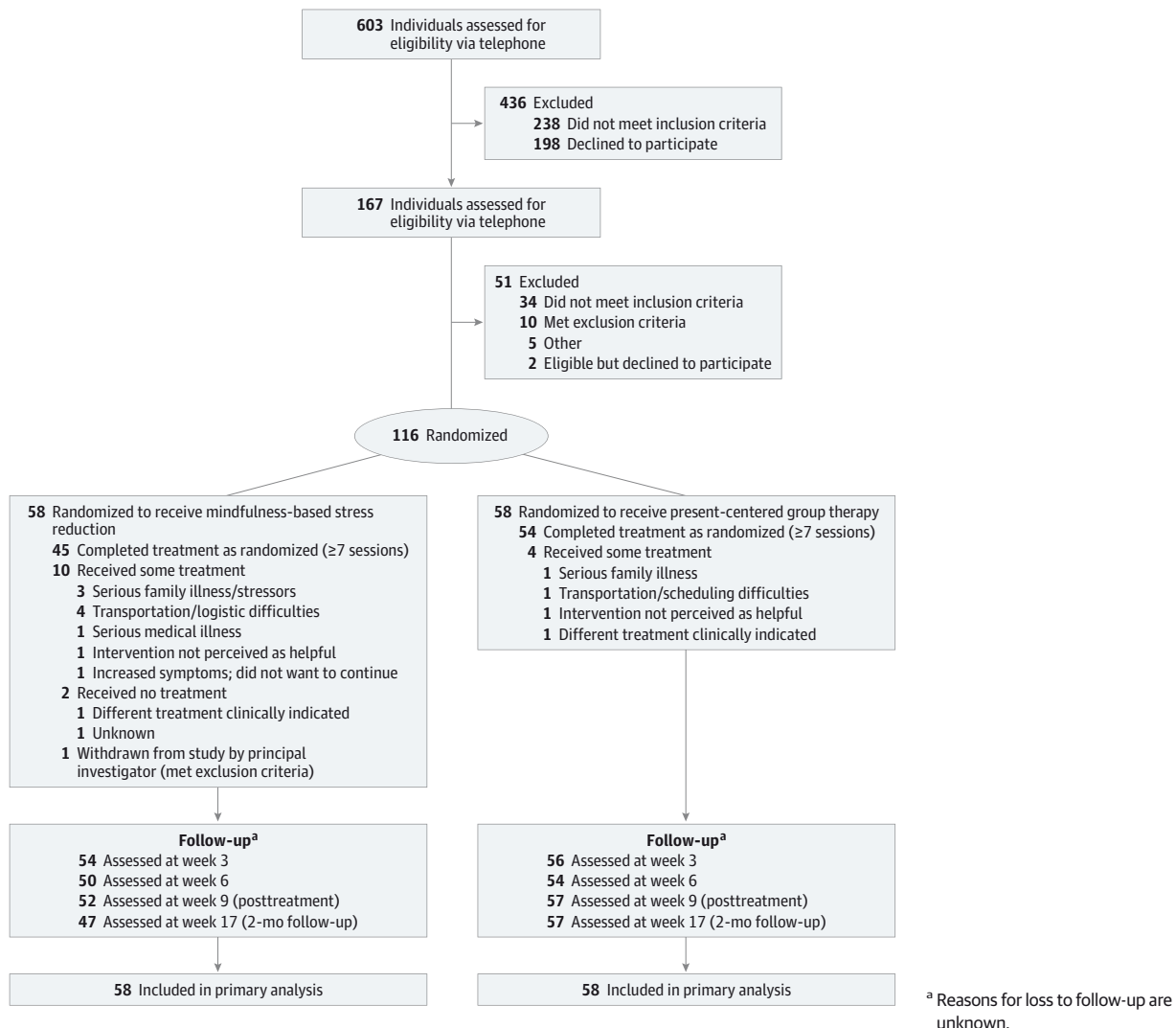
From March 2012 to December 2013, 603 veterans were screened and 167 completed clinical interviews to assess eligibility; 118 were eligible and 116 were randomly assigned to mindfulness-based stress reduction ($n = 58$) or present-centered group therapy ($n = 58$). For each cohort, there was an average of 6.4 (range, 4-11) veterans in each group. Recruitment was terminated prior to reaching the target recruitment goal of 90 per condition prior to attrition because of lower-than-anticipated attrition rates and lack of sufficient funds. Of the 116 participants randomized, 99 (85.3%) completed treatment, defined as receiving at least 7 of the possible 9 treatment sessions. The mean number of sessions attended was 6.96 (SD, 2.56) in mindfulness-based stress reduction and 8.08 (SD, 1.84) in present-centered group therapy ($P = .008$). Treatment dropout was higher in mindfulness-based stress reduction (22.4% [$n = 13$]) than in present-centered group therapy (6.9% [$n = 4$]; $\chi^2 = 5.58$; $P = .02$). There were no differences in demographic or baseline clinical characteristics between patients who completed treatment and those who dropped out. There was 1 serious adverse event in present-centered group therapy, in which a patient made a suicide attempt. Adherence to prescribed elements of the treatment was 96.25% for mindfulness-based stress reduction and 100% for present-centered group therapy; use of proscribed elements was extremely low, with no use of proscribed elements in mindfulness-based stress reduction. For our primary outcome, the PCL, we obtained 93.6% of all possible assessments. We obtained 93.4% of all possible interviewer-rated PTSD assessments and 93.5% of all possible secondary self-report outcomes. We found no evidence that missing data were due to any substantial demographic or clinical characteristics.

Primary Outcome

Figure 2 presents mean PCL scores from baseline to 2-month follow-up. There was an initial increase in PTSD symptom severity in both groups; however, this worsening of PTSD symptoms from baseline (mean score, 58.8) to week 3 (mean score, 61.7; $t_{55.8} = 8.4$; $P = .005$) was significant for present-centered group therapy participants only. There was a significant group \times time interaction in relation to PTSD symptom severity ($F_{1,106.9} = 8.78$; $P = .004$). **Table 2** shows that mean PCL scores improved from baseline to 2-month follow-up for both groups (mindfulness-based stress reduction, from 63.6 to 54.4; present-centered group therapy, from 58.8 to 56.0). However, growth curve mixed-effects models showed that improvement in mindfulness-based stress reduction was significantly greater than improvement in present-centered group

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Figure 1. Flow of Participants Through a Trial of Mindfulness-Based Stress Reduction vs Present-Centered Group Therapy for Treatment of Posttraumatic Stress Disorder



therapy (mean difference in improvement, 6.44; 95% CI, 3.34-9.53; $t = 4.08$; $P < .001$; $d = 0.40$).

Secondary Outcomes

All participants also showed significant improvements in interview-rated PTSD severity on the CAPS from baseline to 2-month follow-up. However, a significant group \times time interaction showed that improvement was greater in mindfulness-based stress reduction than in present-centered group therapy ($F_{1,106.8} = 4.75$; $P = .03$; mean CAPS score improvement: mindfulness-based stress reduction, from 69.9 to 49.8 vs present-centered group therapy, from 62.5 to 50.6; mean difference in improvement, 7.89; 95% CI, 2.58-10.6; $t = 2.91$; $P = .004$; $d = 0.41$). There was no difference between mindfulness-based stress reduction and present-centered group therapy in rates of loss of diagnosis at posttreatment (42.3% [$n = 22$] vs 43.9% [$n = 25$]; mean difference, 1.6%; 95% CI, -20.6% to 17.4%; $\chi^2 = 0.03$; $P = .87$) or at 2-month follow-up

(53.3% [$n = 24$] vs 47.3% [$n = 26$]; mean difference, 6.0%; 95% CI, -14.1% to 26.2%; $\chi^2 = 0.36$; $P = .55$).

Mindfulness-based stress reduction participants reported greater improvement in quality of life on the WHOQOL-BREF from baseline to 2-month follow-up than did those in present-centered group therapy (mean score improvement: mindfulness-based stress reduction, from 75.6 to 80.2 vs present-centered group therapy, from 76.4 to 75.8; mean difference in improvement, 5.22; 95% CI, 1.73-8.71; $t = 2.94$; $P = .004$; $d = 0.41$). While mindfulness-based stress reduction participants reported greater improvement in depressive symptoms on the PHQ-9 from baseline to 2-month follow-up than did those in present-centered group therapy, this differential did not reach the level of significance (mean score improvement: mindfulness-based stress reduction, from 15.5 to 13.3 vs present-centered group therapy, from 14.6 to 13.8; mean difference in improvement, 1.34; 95% CI, -0.07 to 2.75; $t = 1.87$; $P = .06$; $d = 0.26$).

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Table 1. Demographic Characteristics of the Intention-to-Treat Sample^a

Characteristics	Total (n = 116)	Mindfulness-Based Stress Reduction (n = 58)	Present-Centered Group Therapy (n = 58)
Male	98 (84)	46 (79)	52 (90)
Female	18 (16)	12 (21)	6 (10)
Age, mean (SD), y	58.5 (9.8)	57.6 (10.4)	59.4 (9.2)
Race			
White	97 (84)	47 (81)	50 (86)
Black	9 (8)	3 (5)	6 (10)
Other	4 (3)	2 (4)	2 (4)
Mixed	6 (5)	6 (10)	0
Service era			
OEF/OIF	11 (10)	6 (10)	5 (9)
Gulf War	17 (15)	9 (16)	8 (14)
Vietnam War	86 (75)	41 (70)	45 (77)
Other	2 (1)	2 (4)	0
Lifetime trauma exposure, mean (SD), No. of events	7.7 (3.1)	7.9 (3.3)	7.5 (3.0)
Event type ^b			
Combat exposure	86 (74)	39 (68)	47 (80)
Sexual trauma	32 (28)	21 (37)	11 (19)
Physical assault	76 (66)	39 (68)	37 (63)
Disaster exposure	50 (43)	25 (44)	25 (43)
Serious injury event	74 (64)	38 (67)	36 (61)
Life-threatening illness or injury	67 (58)	34 (60)	33 (56)
Other traumatic event (eg, sudden, unexpected death of someone close)	110 (95)	55 (97)	55 (93)
PTSD diagnosis			
Full PTSD criteria	113 (97.4)	57 (98.3)	56 (96.6)
Subthreshold PTSD	3 (2.6)	1 (1.7)	2 (3.4)
Comorbid mood disorder	49 (42.2)	26 (44.8)	23 (39.7)
Taking psychotropic medication	100 (86)	51 (89.5)	49 (86.0)
Mental health treatment history			
Duration of previous mental health care, mean (SD), mo	66.5 (9.2)	69.0 (53.3)	63.9 (45.2)
Total No. of psychotherapy mental health visits, mean (SD)	13.9 (28.7)	13.2 (28.3)	14.6 (29.2)
Receipt of ≥8 therapy sessions in PTSD or mental health clinic	43 (37)	19 (33)	24 (41)
Baseline psychological assessment scores, mean (SD) ^c			
Self-reported PTSD symptom severity on the PCL	61.2 (12.3)	63.6 (11.1)	58.8 (13.1)
Interview-rated PTSD severity on the CAPS	66.2 (16.5)	69.9 (15.5)	62.5 (16.9)
Self-reported depression symptom severity on the PHQ-9	15.0 (5.3)	15.5 (5.0)	14.6 (5.6)
Quality of life on the WHOQOL-BREF	76.0 (14.6)	75.6 (11.9)	76.4 (16.9)
Mindfulness skills on the FFMQ	106.9 (16.2)	105.7 (15.3)	108.1 (17.1)
Credibility/Expectancy Questionnaire scores at week 3, mean (SD) ^d			
Treatment credibility	6.62 (1.76)	6.49 (1.74)	6.74 (1.78)
Expectancy of therapeutic outcome	5.90 (1.83)	5.87 (1.72)	5.92 (1.95)
No. of treatment sessions completed, mean (SD)	7.53 (2.3)	6.96 (2.6)	8.08 (1.8)
Treatment dropouts	17 (14.7)	13 (22.4)	4 (6.9)
Treatment satisfaction scores at week 9, mean (SD) ^d	2.82 (1.11)	2.88 (1.20)	2.77 (1.03)

Abbreviations: CAPS, Clinician-Administered PTSD Scale; FFMQ, Five Facet Mindfulness Questionnaire; OEF/OIF, Operation Enduring Freedom/Operation Iraqi Freedom; PCL, PTSD Checklist; PHQ-9, Patient Health Questionnaire 9; PTSD, posttraumatic stress disorder; WHOQOL-BREF, World Health Organization Quality of Life-Brief.

^a Data are expressed as No. (%) unless otherwise indicated.

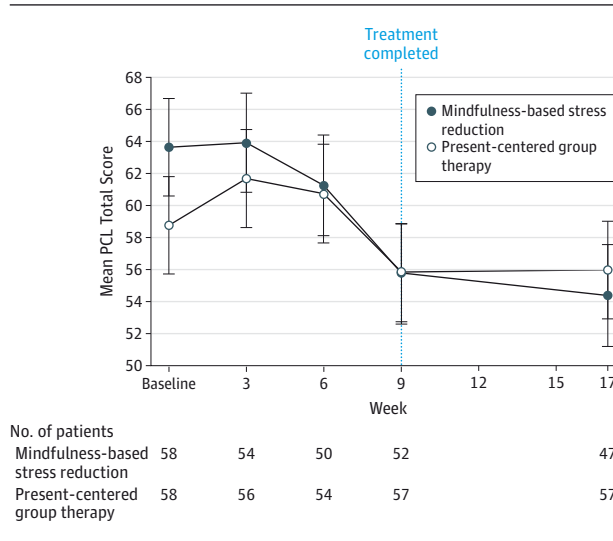
^b The 17 categories of the Life Events Checklist²⁴ were aggregated as shown to simplify presentation.

^c For descriptions of assessment tool score ranges, see footnote to Table 2.

^d For descriptions of score ranges, see the Methods section of the text.

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Figure 2. Posttraumatic Stress Disorder Symptom Severity on the PTSD Checklist (PCL) as a Function of Treatment Group



Data are intention-to-treat means; error bars indicate 95% CIs.

A significant group × time interaction was observed in relation to mindfulness skills from baseline to 2-month follow-up ($F_{1,118.5} = 12.7$; $P = .001$), with participants receiving mindfulness-based stress reduction therapy reporting greater improvement in mindfulness as measured by the FFMQ (mean score improvement, mindfulness-based stress reduction, from 105.7 to 116.3 vs present-centered group therapy, from 108.1 to 108.6; mean difference in improvement, 9.73; 95% CI, 4.42-15.04; $t = 3.59$; $P < .001$; $d = 0.36$). Improvement in FFMQ scores from baseline to posttreatment for participants receiving mindfulness-based stress reduction therapy was associated with greater reductions in PTSD symptom severity (PCL, $r = -0.46$; CAPS, $r = -0.33$) and depressive symptoms ($r = -0.44$) as well as improved quality of life ($r = 0.42$) at 2-month follow-up.

Clinical Outcomes

Using a 10-point or greater reduction on the PCL as an indicator of MCID,²³ we found that a greater percentage of participants receiving mindfulness-based stress reduction therapy showed clinically significant improvement in PTSD symptom severity at 2-month follow-up compared with participants receiving present-centered group therapy (48.9% [n = 23] vs 28.1% [n = 16]; mean difference, 20.9%; 95% CI, 2.2%-39.5%; $\chi^2 = 4.79$; $P = .03$). Using a 10-point or greater reduction on the CAPS, groups were similar in the percentage of participants showing clinically significant improvement in interview-rated PTSD symptom severity at 2-month follow-up (mindfulness-based stress reduction, 66.7% [n = 30] vs present-centered group therapy, 54.5% [n = 30]; mean difference, 12.1%; 95% CI, -7.5% to 31.7%; $\chi^2 = 1.52$; $P = .22$). Treatments showed similar percentages of participants reporting clinically significant improvement in depressive symptoms on the PHQ-9 (mindfulness-based stress reduction, 27.7% [n = 13] vs present-centered group therapy, 22.8% [n = 13]; mean difference, 4.9%; 95% CI, -12.2% to 21.9%; $\chi^2 = 0.32$; $P = .57$).

Exploratory Analyses

Due to the imbalance in sex distribution at baseline, we conducted a series of growth curve analyses controlling for sex. For our primary outcome, we continued to find a significant group × time interaction ($F_{1,106.7} = 8.80$; $P = .004$). For secondary outcomes, the group × time interaction for interview-rated PTSD severity was also significant ($F_{1,106.9} = 4.81$; $P = .03$), as were the interactions for the WHOQOL-BREF ($F_{1,109.4} = 4.99$; $P = .03$) and FFMQ ($F_{1,108.5} = 12.79$; $P = .001$). The group × time interaction for the PHQ-9 did not meet significance ($F_{1,107.8} = 2.22$; $P = .14$), as was the case before controlling for sex.

Discussion

Findings from the present study provide support for the efficacy of mindfulness-based stress reduction for the treatment of PTSD among veterans. Participants randomized to receive mindfulness-based stress reduction therapy showed greater improvement in self-reported PTSD symptom severity during treatment than those randomized to receive present-centered group therapy. However, the magnitude of the average improvement suggests a modest effect. Results of this study also support the modestly increased efficacy of mindfulness-based stress reduction therapy through the 2-month follow-up, with participants randomized to mindfulness-based stress reduction therapy showing greater improvement in both self-reported and interview-rated PTSD severity than those randomized to present-centered group therapy. Participants receiving mindfulness-based stress reduction therapy appeared to demonstrate improvements in depressive symptoms and quality of life after treatment, but these improvements were not observed among those who received present-centered group therapy.

These findings are consistent with previous studies demonstrating robust changes in anxiety and depressive symptoms between pretreatment and posttreatment.³⁴ However, pilot studies evaluating mindfulness-based stress reduction as a treatment for PTSD have shown mixed results. While promising, previous studies had methodological shortcomings, including small sample sizes,^{33,35,36} pre-post designs,^{33,37} and lack of blinding of outcome assessments^{33,35-37} and evaluation of treatment fidelity,^{33,35-37} which preclude clear conclusions regarding efficacy.¹³ Few previous studies have evaluated the efficacy of mindfulness-based stress reduction relative to active treatment controls.³⁶ Our findings add to the literature by demonstrating the comparative efficacy of mindfulness-based stress reduction for improving PTSD as well as possibly improving depressive symptoms and quality of life. Sustained improvements in PTSD symptoms observed at 2-month follow-up in the current study are consistent with pilot findings reported by Kearney et al³⁷ but challenge those of Kearney et al³⁵ showing no effect on PTSD and those of Niles et al³⁶ showing clinically significant albeit temporary improvements in PTSD symptoms following mindfulness-based stress reduction therapy.

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Table 2. Primary and Secondary Outcomes at Baseline, During Treatment, After Treatment, and at 2-Month Follow-up^a

Outcomes	Total (n = 116)	Mindfulness-Based Stress Reduction (n = 58)	Present-Centered Group Therapy (n = 58)	Between-Treatment Differences in Improvement From Baseline	P Value
Primary outcome: self-reported PTSD symptom severity scores on the PCL ^b					
Baseline	61.2 (59.0-63.4)	63.6 (60.6-66.7)	58.8 (55.7-61.8)		
Week 3	62.8 (60.6-65.0)	63.9 (60.8-67.0)	61.7 (58.6-64.8)	2.66 (-0.36 to 5.68)	.09
Week 6	61.0 (58.8-63.2)	61.3 (58.1-64.4)	60.7 (57.6-63.8)	4.45 (1.37 to 7.52)	.005
Posttreatment, week 9	55.8 (53.6-58.0)	55.7 (52.6-58.9)	55.8 (52.7-58.9)	4.95 (1.92 to 7.99)	.002
2-mo follow-up, week 17	55.2 (53.0-57.4)	54.4 (51.2-57.6)	56.0 (52.9-59.0)	6.44 (3.34 to 9.53)	<.001
Secondary outcomes					
Interview-rated PTSD severity scores on the CAPS ^c					
Baseline	66.2 (62.7-69.7)	69.9 (65.0-74.8)	62.5 (57.6-67.4)		
Posttreatment, week 9	54.0 (50.3-57.7)	56.3 (51.0-61.5)	51.7 (46.5-56.8)	2.35 (-2.75 to 7.45)	.37
2-mo follow-up, week 17	50.2 (46.4-54.0)	49.8 (44.3-55.3)	50.6 (45.4-55.8)	7.89 (2.58 to 10.6)	.004
Loss of diagnosis of PTSD, % (95% CI)					
Posttreatment, week 9	43.1 (.34-.53)	42.3 (.28-.56)	43.9 (.31-.57)	1.6 (-20.6 to 17.4)	.87
Two-month follow-up, week 17	50.0 (.40-.60)	53.3 (.38-.68)	47.3 (.34-.61)	6.0 (-14.1 to 26.2)	.55
Self-reported depression symptom severity scores on the PHQ-9 ^d					
Baseline	15.0 (13.9-16.1)	15.5 (13.9-17.0)	14.6 (13.1-16.2)		
Posttreatment, week 9	13.7 (12.6-14.8)	13.6 (12.0-15.1)	13.9 (12.3-15.4)	1.17 (-0.22 to 2.56)	.10
2-mo follow-up, week 17	13.6 (12.4-14.7)	13.3 (11.7-15.0)	13.8 (12.2-15.4)	1.34 (-0.07 to 2.75)	.06
Quality-of-life scores on the WHOQOL-BREF ^e					
Baseline	76.0 (73.1-78.9)	75.6 (71.6-79.7)	76.4 (72.3-80.4)		
Posttreatment, week 9	79.6 (76.7-82.5)	80.7 (76.5-84.8)	78.5 (74.4-82.6)	3.10 (-0.29 to 6.49)	.08
2-mo follow-up, week 17	78.0 (75.0-80.9)	80.2 (75.9-84.4)	75.8 (71.7-79.9)	5.22 (1.73 to 8.71)	.004
Mindfulness skills scores on the FFMQ ^f					
Baseline	106.9 (103.7-110.2)	105.7 (101.2-110.3)	108.1 (103.5-112.7)		
Week 3	106.4 (103.1-109.7)	106.7 (102.0-111.3)	106.1 (101.4-110.7)	2.63 (-2.58 to 7.84)	.32
Week 6	109.3 (106.0-112.7)	111.1 (106.3-115.9)	107.5 (102.9-112.2)	5.34 (0.02 to 10.65)	.05
Posttreatment, week 9	112.7 (109.4-116.0)	116.3 (111.6-121.0)	109.2 (104.5-113.8)	9.14 (3.91 to 14.37)	<.001
2-mo follow-up, week 17	112.4 (109.1-115.8)	116.3 (111.4-121.1)	108.6 (103.9-113.2)	9.73 (4.42-15.04)	<.001
Clinically significant improvement in outcomes, % (95% CI) [No. of participants]					
PCL scores ^b					
Posttreatment, week 9	29.4 (20.4-38.3) [n=32]	36.5 (24.0-49.0) [n=19]	22.8 (10.9-34.7) [n=13]	13.7 (-3.5 to 31.0)	.12
2-mo follow-up, week 17	37.5 (28.2-46.4) [n=39]	48.9 (35.1-62.8) [n=23]	28.1 (15.5-40.6) [n=16]	20.9 (2.2 to 39.5)	.03
CAPS scores ^c					
Posttreatment, week 9	56.3 (46.9-65.7) [n=61]	63.5 (49.8-77.1) [n=33]	49.1 (36.1-62.1) [n=28]	14.3-4.5 to 33.2	.13
2-mo follow-up, week 17	60.6 (50.8-70.4) [n=60]	66.7 (52.1-81.2) [n=30]	54.5 (41.4-67.7) [n=30]	12.1 (-7.5 to 31.7)	.22
PHQ-9 scores ^d					
Posttreatment, week 9	24.5 (16.3-32.8) [n=26]	29.4 (17.5-41.4) [n=15]	19.6 (8.2-31.0) [n=11]	9.8 (-6.7 to 26.3)	.24
2-mo follow-up, week 17	25.2 (16.7-33.8) [n=26]	27.7 (15.0-40.3) [n=13]	22.8 (11.3-34.3) [n=13]	4.9 (-12.2 to 21.9)	.57

Abbreviation: PTSD, posttraumatic stress disorder.

^a Data are expressed as mean [95% CI] unless otherwise indicated.^b PTSD Checklist [PCL] range: 17-84, higher scores indicate greater symptomatology with clinically significant improvement in PTSD symptom severity defined as reduction of 10 points or more on the PCL.^c Clinician-Administered PTSD Scale [CAPS] range: 0-136; higher scores indicate more severe PTSD with clinically significant improvement in interviewer-rated PTSD symptom severity defined as a reduction of 10 points or more on the CAPS.^d Patient Health Questionnaire 9 [PHQ-9] range: 0-27; higher scores indicate greater depressive symptoms with clinically significant improvement in depressive symptoms defined as a reduction of 5 points or more on the PHQ-9.^e World Health Organization Quality of Life-Brief [WHOQOL-BREF] range: 0-130; higher scores indicate greater quality of life.^f Five Facet Mindfulness Questionnaire [FFMQ] range: 39-195; higher scores indicate greater mindfulness.

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The findings of the present study are consistent with previous studies showing that mindfulness-based stress reduction is well tolerated by trauma survivors and veterans with PTSD.^{33,35,36} Although treatment dropout was higher among those randomized to mindfulness-based stress reduction therapy than to present-centered group therapy (22.4% vs 6.9%), dropout rates were lower than those reported for veterans receiving prolonged exposure (28.1%-44%)^{5,8,9,11} and cognitive processing therapy (26.8%-35%)^{6,7,19} in clinical trials and real-world treatment settings.

Half to two-thirds of patients who received mindfulness-based stress reduction therapy showed clinically meaningful treatment benefits at 2-month follow-up (48.9% based on the PCL; 66.7% based on the CAPS). These clinical response rates are similar to those reported for first-line PTSD treatments with veterans (49%-68.8%).^{5,6,11,19} Yet half of participants in both groups continued to meet criteria for PTSD diagnosis at 2-month follow-up.

Findings from the present study suggest that veterans who received mindfulness-based stress reduction therapy reported significant improvement in mindfulness skills after treatment, while there appeared to be little change in mindfulness skills reported by veterans who received present-centered group therapy. Moreover, findings suggest that greater reductions in PTSD symptom severity were associated with changes in mindfulness over the course of treatment. Improvements in quality of life made during treatment appeared to be maintained through the 2-month follow-up for participants receiving mindfulness-based stress reduction therapy, but reports of quality of life appeared to return to baseline levels for present-centered group therapy participants during this same follow-up period. Taken together, these findings suggest that mindfulness-based stress reduction may provide veterans with internal tools for promoting self-management of PTSD symptoms and quality of life.

The quality of scientific evidence supporting the efficacy of mindfulness-based interventions has recently been criticized.¹³ This study improves on shortcomings of previous trials by comparing mindfulness-based stress reduction with an active, credible control condition, taking steps to ensure

treatment fidelity, and using both patient-reported and blinded clinician ratings of PTSD outcomes.¹³ Although groups were structurally equivalent in number of weekly sessions, therapist training and qualifications, and group format, present-centered group therapy may not have fully accounted for all nonspecific factors present in mindfulness-based stress reduction (eg, therapist expectations) and was unequal in duration of sessions. Because our intent was to study mindfulness-based stress reduction in the format it is typically taught (2.5-hour group sessions) compared with present-centered group therapy as generally provided within the VA system (1.5-hour group sessions), participants received less contact with clinicians in the control condition (13.5 hours) than in mindfulness-based stress reduction (26.5 hours). Another important limitation was the short follow-up period. Given the chronicity of the study group in terms of treatment history and modest average treatment effects observed in this study, it is possible that some participants may have relapsed after the 2-month follow-up. Future trials with longer-term follow-up (≥ 6 months) are needed to evaluate the durability of treatment benefits over time. Despite randomization and inclusion criteria requiring diagnosis of PTSD or subthreshold PTSD, the 2 groups differed in baseline PTSD symptom severity, with present-centered group therapy participants reporting lower symptoms. This limitation may have influenced results. Current findings are also limited by the sample, predominantly white men from 1 geographical region who served during the Vietnam era, and results may not generalize to nonveterans or veterans from other eras or areas. Replication with more diverse samples at additional centers is needed.

Conclusions

Among veterans with PTSD, mindfulness-based stress reduction therapy, compared with present-centered group therapy, resulted in a greater decrease in PTSD symptom severity. However, the magnitude of the average improvement suggests a modest effect.

ARTICLE INFORMATION

Author Contributions: Dr Polusny had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Polusny, Erbes, Lamberty, Rodman, Lim.

Acquisition, analysis, or interpretation of data:

Polusny, Erbes, Thuras, Moran, Lamberty, Collins, Lim.

Drafting of the manuscript: Polusny, Thuras.

Critical revision of the manuscript for important

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Statistical analysis: Thuras.

Obtained funding: Polusny, Erbes, Lim.

Administrative, technical, or material support:

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