Effects of Participation in a Mindfulness Program for Veterans With Posttraumatic Stress Disorder: A Randomized Controlled Pilot Study

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Objective: To assess outcomes associated with Mindfulness-Based Stress Reduction (MBSR) for veterans with PTSD. **Methods:** Forty-seven veterans with posttraumatic stress disorder (PTSD; 37 male, 32 Caucasian) were randomized to treatment as usual (TAU; n = 22), or MBSR plus TAU (n = 25). PTSD, depression, and mental health-related quality of life (HRQOL) were assessed at baseline, posttreatment, and 4-month follow-up. Standardized effect sizes and the proportion with clinically meaningful changes in outcomes were calculated. **Results:** Intention-to-treat analyses found no reliable effects of MBSR on PTSD or depression. Mental HRQOL improved posttreatment but there was no reliable effect at 4 months. At 4-month follow-up, more veterans randomized to MBSR had clinically meaningful change in mental HRQOL, and in *both* mental HRQOL and PTSD symptoms. Completer analyses (≥ 4 classes attended) showed medium to large between group effect sizes for depression, mental HRQOL, and mindfulness skills. **Conclusions:** Additional studies are warranted to assess MBSR for veterans with PTSD. © 2012 Wiley Periodicals, Inc. J. Clin. Psychol. 69:14–27, 2013.

Keywords: mindfulness; posttraumatic stress disorder; acceptance; depression; meditation

Posttraumatic stress disorder (PTSD) is a common consequence of trauma that can persist for decades (Kessler, 2000). The lifetime risk of developing PTSD is estimated to be 8.7% for the general U.S. population (Kessler et al., 2005), and veterans are at particular risk of developing PTSD given their increased exposure to traumatic stressors (Eisen et al., 2004; Thomas et al., 2010). The clinical hallmarks of PTSD include recurrent, intrusive recollections or reexperiencing of a traumatic event, avoidance of external or internal cues that can trigger reexperiencing, emotional numbing, and hyperarousal (American Psychiatric Association [APA], 2000). PTSD has been shown to have a greater effect on quality of life than major depression and obsessive-compulsive disorder (Davidson, Stein, Shalev, & Yehuda, 2004). PTSD also confers a significant lifetime risk of suicide; the risk of suicidality is higher than any other anxiety disorder (Kessler, Borges, & Walters, 1999). Persons with PTSD often experience disrupted interpersonal relationships, reduced ability to work, and increased risk of physical illnesses, substance abuse, and affective disorders (Davidson, 2001; Dobie et al., 2002; Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995).

The Veterans Affairs (VA) National Center for PTSD recommends evidence-based pharmacologic and behavioral interventions for PTSD (U.S. Department of Veterans Affairs / Department of Defense, 2010). Selective serotonin reuptake inhibitors (SSRIs) produce improvement in the major symptom clusters of PTSD, although the magnitude of the treatment effect is modest (Schoenfeld, Marmar, & Neylan, 2004). Prazosin, an alpha-antagonist, reduces trauma-related nightmares and has also been found to have a significant effect on all of the PTSD symptom clusters (Schoenfeld et al., 2004). The primary empirically supported behavioral treatments that the VA recommends to treat PTSD are prolonged exposure (PE) and cognitive processing therapy (CPT). Despite these treatments, many persons with PTSD continue to experience persistent

PTSD symptoms (Ravindran & Stein, 2010). Given the large number of veterans with PTSD, not all of whom will opt for or benefit sufficiently from PE or CPT, additional cost-effective treatments suitable for broad implementation are needed to address residual symptoms and persistent reductions in quality of life.

Recently, it has been suggested that acceptance and mindfulness-based approaches may be useful in the treatment of PTSD (Orsillo & Batten, 2005), though currently outcome data are lacking. Mindfulness has been defined as "the awareness that emerges by way of paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment" (Kabat-Zinn, 2002, p. 732). Mindfulness practice has been postulated to promote acceptance as well as constructive cognitive and behavioral changes, including less experiential avoidance (Baer, 2003). In addition, mindfulness practice has been hypothesized to represent a form of exposure therapy (Baer, 2003). Mindfulness exercises encourage individuals to approach, rather than avoid, distressing thoughts and feelings, and consistent engagement in mindfulness exercises over time has been hypothesized to hold the possibility of decreasing avoidance behaviors for persons with PTSD (Vujanovic, Niles, Pietrefesa, Schmertz, & Potter, 2011). The attitudinal qualities fostered in mindfulness practice, which encourages a kind, open, curious stance toward experience (including difficult or painful experience), would also be hypothesized to result in enhanced functionality despite ongoing symptoms.

Mindfulness training has also been shown to reduce rumination (Williams, 2008), and rumination might be an additional mechanism through which mindfulness interventions could influence PTSD symptoms, given evidence that rumination mediates the relationship between beliefs about the trauma memory and PTSD symptoms (Bennett & Wells, 2010). Mindfulness practice could also be hypothesized to reduce the level of distress caused by intrusive thoughts and the tendency to avoid or suppress these thoughts. Thought suppression paradoxically increases reexperiencing for persons with PTSD (Shipherd & Beck, 2005). In mindfulness practice, thoughts (including distressing thoughts) are regarded without judgment as passing mental events, and there is evidence that enhanced mindfulness is associated with reduced thought suppression (Bowen, Witkiewitz, Dillworth, & Marlatt, 2007). Additional support for the possible role of mindfulness training in the treatment of PTSD comes from preliminary evidence that the brain regions enhanced by mindfulness practice include areas that play a role in extinction of conditioned fear responses (Hölzel et al., 2011a), which is a process that is dysfunctional in PTSD (Milad et al., 2009). The above-mentioned comments provide a theoretical rationale for the incorporation of mindfulness training in the treatment of PTSD, but there are few clinical studies of mindfulness training for persons with PTSD.

A common clinical method of teaching mindfulness is an 8-week class series called mindfulness-based stress reduction (MBSR; Baer, 2003), in which participation is associated with increased mindfulness skills (Baer et al., 2008; Carmody & Baer, 2008) and potentially salutary changes in brain function (Davidson, 2003) and structure (Hölzel et al., 2011b). Two nonrandomized studies have assessed the efficacy of MBSR in the setting of PTSD, with evidence of improved PTSD symptoms and depression (Kearney, McDermott, Malte, Martinez, & Simpson, 2012; Kimbrough, Magyari, Langenberg, Chesney, & Berman, 2010). An additional nonrandomized study examined the relationship between participation in a weekly mindfulness group for veterans (N = 149) in residential PTSD treatment, and found that although the overall scores for mindfulness skills did not change, improvement on a mindfulness skills subscale ("acting with awareness") was associated with improvement in clinician-rated PTSD severity (Owens, Walter, Chard, & Davis, 2011). A cross-sectional survey of firefighters (N = 124) found that greater mindfulness skills were associated with fewer PTSD symptoms, depressive symptoms, physical symptoms, and alcohol problems (Smith et al., 2011). Randomized controlled trials of mindfulness interventions for PTSD are needed.

A pilot study, designed as a practical clinical trial with broad inclusion criteria, was conducted to assess the effect of participation in MBSR (in a form that is currently widely available, i.e., without specific modification for PTSD) on veterans with PTSD. The aim of this study was to assess mindfulness training as an adjunct to usual care for veterans with PTSD to gather pilot data on the safety, feasibility, and effect of this group intervention. It was hypothesized that participation in MBSR would be associated with improvement in PTSD symptoms, depression,

and mental health-related quality of life (HRQOL) for veterans with PTSD, relative to treatment as usual (TAU).

Methods

A randomized controlled trial of MBSR as compared to TAU for veterans with PTSD was performed. All recruitment and study procedures were approved by the institutional review board and research and development committees of VA Puget Sound Health Care System (PSHCS) in Seattle, WA. Participants gave written informed consent prior to enrollment. No monetary compensation was provided for study participation.

Participants

During an 11-month period veterans with an established diagnosis of chronic PTSD at PSHCS were enrolled. Exclusion criteria, determined by review of the medical record, are as follows: (a) any past or present psychotic disorder, (b) mania, or poorly controlled bipolar disorder, (c) borderline or schizoaffective personality disorder, (d) current suicidal or homicidal ideation, and (e) active substance abuse or dependence. One hundred sixty-seven patients were referred to the hospital's MBSR clinical program during the study period and were assessed for eligibility for the study (Figure 1). Eighty-three appeared eligible according to review of the electronic medical record (i.e., they had a diagnosis of PTSD recorded in their medical record and there was no mention of the above-mentioned exclusion criteria recorded in notes by clinicians in the medical record). Seventy attended a group orientation session, at which time they were offered the opportunity to meet with a study coordinator and enroll in the study. A convenience sample of 49 chose to meet with the study coordinator and gave informed consent. Two patients were excluded after further assessment revealed that one did not have PTSD and one had a psychotic disorder. Forty-seven subjects were randomized to MBSR or TAU. Data were collected on 25 patients in the intervention group and 22 in the control group at baseline; two patients dropped out of the MBSR treatment arm of the study and one patient dropped out of the TAU treatment arm.

Measures

Assessments were performed at baseline, posttreatment (2 months after baseline) and 4 months postintervention (4-month follow-up). Demographic characteristics were assessed using a written questionnaire.

PTSD symptoms. The PTSD Checklist-Civilian version (PCL-C; Weathers, Litz, Herman, Huska, & Keane, 1993) is a 17-item questionnaire that assesses Criteria B, C, and D for PTSD, consistent with the DSM-IV (APA, 2000). Participants rated how much they were bothered in the past month by each symptom on a 5-point scale ranging from 1 (*not at all*) to 5 (*extremely*). The PCL-C had a Cronbach alpha of 0.97 in a sample of veterans seeking PTSD treatment (Weathers et al., 1993).

Traumatic events. The number and type of traumatic events sustained was assessed by the Life Events Checklist (LEC; Blake et al., 1995; Gray, Litz, Hsu, & Lombardo, 2004). The LEC was used to describe the study population, and to establish likely PTSD diagnostic status.

Depression. The Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001) assesses depression. The sensitivity and specificity of the PHQ-9 compare favorably with structured psychiatric interviews and the Cronbach alpha was 0.89 in a sample of primary care patients (Kroenke et al., 2001).

Health-related quality of life. The Short Form-8 (SF-8; Ware, Kosinski, Dewey, & Gandek, 2001) assesses health status and HRQOL. Both Physical and Mental Component Summary Scores (SF-8-PCS and SF-8-MCS) were calculated. The Cronbach alpha for SF-8-MCS and SF-8-PCS summary scores of the SF-8 are 0.82 and 0.88, respectively (Ware et al., 2001).
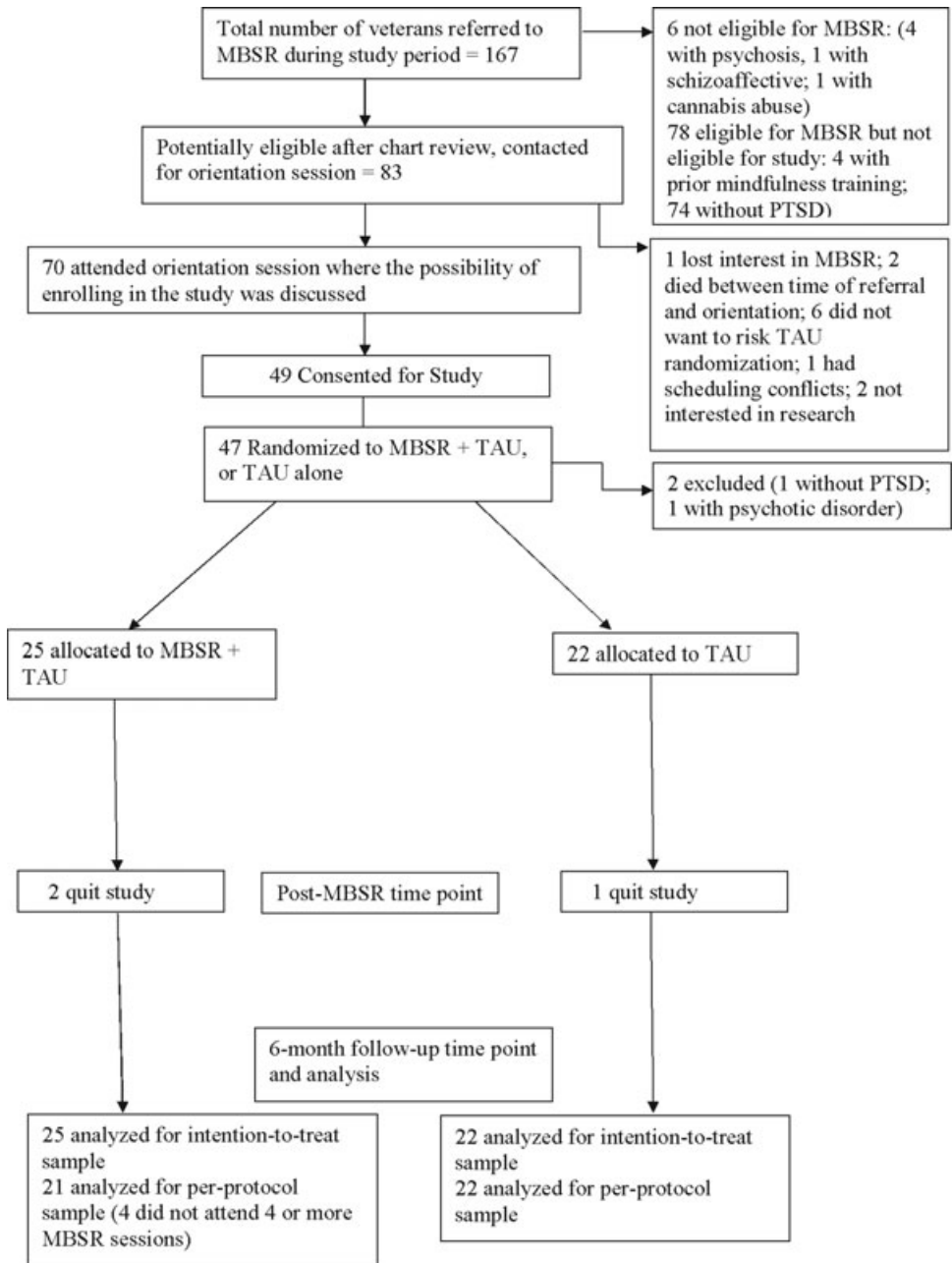
Figure 1. Recruitment and retention of participants in the study.

Mindfulness. The Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2008) assesses mindfulness skills with 39 items covering nonreactivity to internal experience, observing internal experience, acting with awareness, describing internal experience, and nonjudgment of experience. Higher scores on the FFMQ reflect greater mindfulness skills. The FFMQ has adequate convergent validity and incremental validity in the prediction of psychological symptoms (Baer et al., 2008).

Behavioral activation. The Behavioral Activation for Depression Scale (BADS; Kanter, Rusch, Busch, & Sedivy, 2009) assesses the ability to engage in activities to achieve goals despite aversiveness. Twenty-five items are rated on a 7-point scale ranging from 0 (*not at all*) to 6 (*completely*). Higher scores reflect greater behavioral activation and less avoidance. Cronbach alpha for The BADS was 0.92 in a community sample (Kanter et al., 2009).

Procedure

Veterans either self-referred or were referred by one of their providers to the MBSR program. The study coordinator reviewed each medical record, as approved by the PSHCS IRB, to determine likely eligibility according to the inclusion/exclusion criteria listed above. Those who appeared eligible were contacted by the study coordinator and provided information about the research opportunity and those interested in learning more attended an initial orientation session. Veterans who agreed to participate in the research protocol provided written informed consent and underwent additional in-person screening and baseline assessment. After baseline assessment subjects were randomized using concealed allocation to the intervention group (an 8-week MBSR course plus TAU) or to the control group (TAU). At study completion, controls were given the opportunity to enroll in MBSR. All participants continued to receive usual care for PTSD without intervention from the study team.

Intervention: MBSR. MBSR classes closely followed the format originally developed at the University of Massachusetts Medical School (Kabat-Zinn, 1982) and were taught by experienced instructors who meet professional guidelines for teaching MBSR. At the VA medical center where the study was conducted MBSR is available as a clinical intervention for patients with a variety of problems. The research subjects participated in MBSR groups with other veterans referred to MBSR for clinical indications. Approximately 5–10 PTSD study subjects participated in each MBSR group of 20–30 male and female veterans. The MBSR groups met once per week (2.5 hours per session) for 8 weeks, plus a 7-hour session on a Saturday. During each class veterans practiced and received instructions on mindfulness meditation, discussed homework assignments, and had the opportunity to ask questions (Kabat-Zinn, 1990). Between weeks six and seven of MBSR, the class met for 7 hours on a Saturday for a "daylong retreat," which was held mostly in silence.

During the daylong retreat, participants practiced mindfulness exercises more intensively. Attentional skills taught in MBSR include developing the ability to place and sustain attention on a specific aspect of experience (e.g., the breath), as well as flexibility of attention (e.g., the ability to let go of ruminative cycles of thought and return attention to the breath or body). MBSR instructions emphasized bringing an attitude that is curious, kind, and nonjudging to present-moment experience, including difficult or unpleasant experience (Shapiro, Carlson, Astin, & Freedman, 2006). The experiential exercises taught included the "body scan" (a 45-minute exercise in which attention is systematically directed to each part of the body), sitting meditation, and gentle yoga (taught as mindful movement; Kabat-Zinn, 1990). Homework assignments included daily meditation or yoga for 45 minutes per day, 6 days per week, using CDs as a guide. Informal homework practices involving bringing mindful attention to experiences in daily life were also assigned each week.

TAU. All participants continued to receive usual care for PTSD within the same VHA health care system. TAU received by study subjects is summarized in Table 1. Throughout the study period, adverse events were monitored.

Statistical analyses. The primary analysis was conducted on an intention-to-treat basis. Independent sample *t* tests and chi square tests were used to evaluate baseline differences between treatment arms. Standardized mean differences (i.e., Cohen's d effect sizes) with 95% confidence intervals (CI) were calculated between baseline and each follow-up time point within groups and at follow-up time points between groups. Total scores were used for each instrument. The proportion of subjects who had a clinically meaningful change (from baseline) in PTSD

Table 1
Baseline Participant Characteristics According to Treatment Group

Characteristics	MBSR (n = 25)	TAU (n = 22)
Male	20 (80.0)	17 (77.3)
Age ($M \pm SD$)	52 ± 13.4	52 ± 11.7
Ethnicity/Race		
Caucasian	19 (76.0)	13 (59.1)
African American	5 (20.0)	2 (9.1)
Hispanic/Latino	0 (0)	3 (13.6)
Asian/Pacific	0 (0)	3 (13.6)
Islander/Native American		
Other	1 (4.0)	1 (4.5)
Religious affiliation		
Christian	13 (52.0)	13 (59.1)
Buddhist	1 (4.0)	0 (0)
Other	0 (0)	4 (18.2)
Unknown	11 (44.0)	5 (22.7)
Other	2 (8.0)	1 (4.5)
Lifetime trauma exposure		
No. of categories (of 17) reported ($M \pm SD$)	10 ± 5	10 ± 5
Use of psychotropic medications		
Antidepressants	16 (64)	14 (64)
Benzodiazepines[*]	4 (16)	10 (45)
Antipsychotics	2 (8)	3 (14)
Prazosin	8 (32)	5 (23)
Lithium	2 (8)	0 (0)
Carbamazepine	0 (0)	1 (5)
Number of psychotherapy sessions ($M \pm SD$ in 6 months prior to baseline)		
Individual mental health visits	5.5 ± 6.7	7.8 ± 8. 2
Group mental health visits	6.2 ± 9.9	7.2 ± 12.5
Inpatient mental health days	0.84 ± 2.8	0.45 ± 2.1
Categories of mental health services utilized: No. (%) who utilized each modality during the study period		
Supportive individual therapy	6 (24)	11 (50)
Supportive group	3 (12)	8 (36)
CBT individual therapy	1 (4)	2 (9)
CBT group	2 (8)	1 (5)
CPT	1 (4)	0
PE	0	0
Inpatient psychiatry admission	1 (4)	1 (5)
Addiction treatment (individual)	2 (8)	0
Addiction treatment (group)	3 (12)	1 (5)
Medication management +/- supportive treatment	19 (76)	18 (82)
Any mental health treatment	22 (88)	22 (100)

Note. MBSR = mindfulness-based stress reduction; TAU = treatment as usual; M = mean; SD = standard deviation; CBT = cognitive behavioral therapy; CPT = cognitive processing therapy; PE = prolonged exposure therapy.
Data are expressed as No. (%) unless otherwise indicated.
[*]$p < 0.05$.

symptoms and HRQOL was calculated posttreatment and at 4-month follow-up, using the reliable change index (Jacobson & Truax, 1991). For PTSD symptoms, a clinically meaningful change was defined as a change of 10 or more points on the PCL (Monson et al., 2008) and for HRQOL, a clinically meaningful change was defined as a change of 10 or more points on the SF-8-MCS summary score (Ferguson, Robinson, & Splaine, 2002). For secondary analyses, identical comparisons were conducted limiting the intervention group to patients randomized

to MBSR who attended ≥4 classes (n = 21; "completer" analyses; Teasdale et al., 2000). In a post hoc analysis, the proportion of subjects with clinically meaningful change in *both* PTSD symptoms (PCL) and HRQOL (SF-8-MCS score) was compared according to the treatment arm.

A two-sided *p* value of less than 0.05 was considered statistically significant. All statistical analyses were performed using Stata (Release 11 College Station, TX: StataCorp LP).

Results

Participants did not differ significantly at baseline on PTSD (PCL) or depression severity (PHQ-9), behavioral activation (BADS), mindfulness (FFMQ), or either mental or physical HRQOL (SF-8-MCS, SF-8-PCS). The characteristics of the study population are summarized in Table 1. There were no significant differences on categories of usual care between MBSR and TAU at baseline, except that significantly more veterans in the TAU treatment arm received benzodiazepines. During the study period, there was not a significant difference in the likelihood of obtaining mental health care between randomization arms, $\chi^2 (1, 47) = 2.83$, $p = 0.237$.

Using a definition of compliance as participation in four or more MBSR classes (Teasdale et al., 2000), 21 of 25 veterans (84%) randomized to MBSR were compliant (see also Figure 1). The mean number of classes attended for veterans randomized to MBSR was 7 ± 2, and the modal number of classes attended was nine (attendance at all sessions). One patient in each treatment arm of the study had an inpatient psychiatry admission related to worsening PTSD symptoms during the study period. Neither of these patients expressed suicidality, and each was discharged after supportive care and adjustment of medications. No participants in the MBSR treatment arm of the study withdrew from the intervention due to worsening of PTSD symptoms or other difficulties with the intervention.

Treatment Effects on Self-Reported Mental Health Outcomes and Quality of Life

Table 2 shows the mean scores for the outcome measures at each assessment point, with between group effect sizes and 95% CIs.

Intention-to-treat analyses. For PTSD, depression, and behavioral activation, the 95% CIs for between group effect sizes included zero at the posttreatment and 4-month time points. For mental HRQOL there was a medium-to-large effect size at posttreatment, but at 4 months the 95% CI included zero. For physical HRQOL the 95% CI for effect size at posttreatment included zero but there was a medium-to-large effect size at 4 months. For mindfulness there was a medium-to-large effect size at posttreatment and at 4 months.

Within group effect sizes were calculated as the change from baseline to each follow-up time point within each treatment arm of the study. For veterans randomized to MBSR, at the posttreatment time point there were medium-to-large effect sizes for PTSD (d = −0.63, 95% CI, −1.22 to −0.05; *p* = 0.035), depression (d = −0.65, 95% CI, 1.24 to −0.06; *p* = 0.033), and mental HRQOL (d = 0.77, 95% CI, 0.17 to 1.37; *p* = 0.013), whereas effect sizes for behavioral activation, physical HRQOL, and mindfulness included zero and mean scores were not significantly different than baseline. For veterans randomized to MBSR, at 4 months follow-up, there was a medium to large within group effect size for mental HRQOL (d = 0.68, 95% CI, 0.09 to 1.26; *p* = 0.025), whereas effect sizes for other outcome measures included zero. For veterans randomized to TAU, within group effect sizes included zero at all time points.

"Completer" analyses. Veterans randomized to MBSR who attended at least four classes (defined as completers) were compared with patients in the TAU treatment arm (Table 2). At baseline there were no significant differences between arms of the study for any of the measures, except for physical HRQOL, which was higher in the MBSR treatment arm (*p* = 0.019). For PTSD the 95% CIs for between-group effect sizes included zero at the posttreatment and 4-month time points. For depression there was a medium-to-large effect size at posttreatment, but at 4 months the 95% CI included zero. For behavioral activation there were medium-to-large

Table 2
Mean Summary Scores and Cohen's d Effect Sizes With 95% CI for MBSR (n = 25) versus TAU (N = 22) for Intention-to-Treat and Completer Samples

	Intention-to-treat (N = 25)			Completers (N = 21)		
Summary scores	Baseline mean ± SD	Posttreatment mean ± SD	4 months mean ± SD	Baseline mean ± SD	Posttreatment mean ± SD	4 months mean ± SD
PCL						
MBSR	59.88 ±11	52.45 ± 13	54.43 ± 15	59 ±11.5	52 ±13.1	54 ±14.8
TAU	62.91 ±11	58.5 ± 11	60.16 ± 13	63 ±10.8	59 ±11	60 ±12.5
Between group effect size		−0.51 (−1.12 to 0.11)	−0.42 (−1.03 to 0.2)		−0.56 (−1.19 to 0.07)	−0.47 (−1.10 to 0.16)
PHQ-9						
MBSR	15.92 ± 6	12 ± 6	12.39 ± 6	15 ±6.21	12 ±5.69	12 ±5.84
TAU	16.55 ± 5	15.45 ± 5	15.61 ± 5	17 ±5.49	15 ±5.06	16 ±5.03
Between group effect size		−0.62 (−1.24 to 0)	−0.55 (−1.18 to 0.08)		**−0.70 (−1.34 to −0.06)**	**−0.73 (−1.38 to −0.08)**
BADS						
MBSR	65.38 ± 20	75.33 ± 26	76.39 ± 25	70 ± 16.1	79 ± 22.3	80 ±23.6
TAU	65.71 ± 21	64.21 ± 15	65.68 ± 19	66 ± 21.1	64 ± 15	66 ±19.1
Between group effect size		0.52 (−0.11 to 1.15)	0.47 (−0.15 to 1.09)		**0.79 (0.13 to 1.46)**	**0.66 (0.02 to 1.3)**
SF-8-MCS						
MBSR	30.87 ± 9	38.27 ± 10	37.46 ± 10	31 ± 9.34	39 ± 10.4	38 ±10.6
TAU	30.41 ± 8	31.4 ± 10	32.17 ± 7	30 ± 8.14	31 ± 9.56	32 ±7.47
Between group effect size		**0.69 (0.07 to 1.32)**	0.57 (−0.06 to 1.2)		**0.75 (0.11 to 1.4)**	0.59 (−0.05 to 1.24)
SF-8-PCS						
MBSR	43.43 ± 10	41.42 ± 10	43.53 ± 10	46 ±8.79	42 ± 9.68	44 ± 10.2
TAU	39.02 ±10	37.39 ± 11	36.60 ± 9	39 ±10.2	37 ± 10.9	37 ± 8.51
Between group effect size		0.39 (−0.22 to 1.00)	**0.73 (0.09 to 1.37)**		0.45 (−0.18 to 1.07)	**0.82 (0.17 to 1.48)**
FFMQ						
MBSR	105.96 ± 20	115.32 ± 18	114.04 ± 21	107 ± 19.9	118 ±14.9	116 ±19.4
TAU	103.05 ± 19	101.65 ± 24	99.22 ± 24	103 ± 19	102 ±23.6	99 ± 23.9
Between group effect size		**0.65 (0.03 to 1.27)**	**0.67 (0.04 to 1.31)**		**0.83 (0.18 to 1.47)**	**0.78 (0.12 to 1.43)**

Note. CI = confidence interval; PCL = PTSD Checklist; PHQ-9 = Patient Health Questionnaire-9; BADS = Behavioral Activation for Depression Scale; SF-8-MCS = Mental Component Summary Score of SF-8; SF-8 = PCS Physical Component Summary Score of SF-8; FFMQ = Five Facet Mindfulness Questionnaire.
Bold = 95% confidence interval for between group effect size does not include zero.
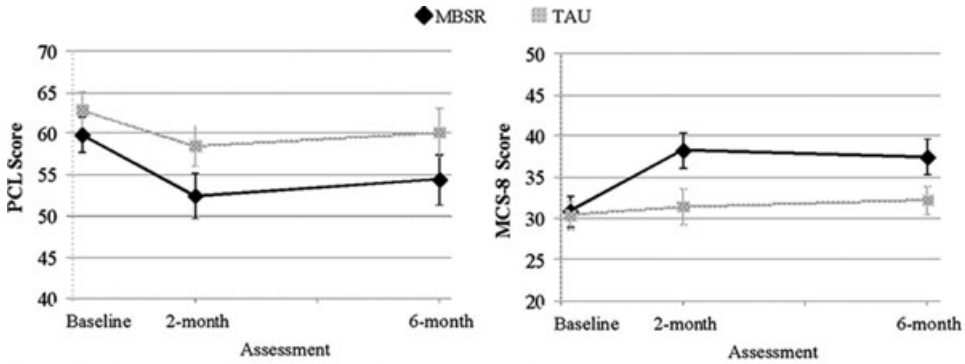
Note: PTSD = posttraumatic stress disorder, PCL = PTSD checklist;
MSC-8 = mental component score of SF-8;
MBSR = Mindfulness-Based Stress Reduction;
TAU = Treatment as Usual Data represented are observed mean scores with standard error bars.

Figure 2. PTSD symptom severity (PCL score) and MCS-8 score as a function of treatment group.

effect sizes at posttreatment and at 4 months. For mental HRQOL there was a medium-to-large effect size at posttreatment, but at 4 months the 95% CI included zero. For physical HRQOL the 95% CI for effect size at posttreatment included zero, but there was a large effect size at 4 months. For mindfulness there were large effect sizes at posttreatment and at 4 months.

Figure 2 depicts mean physical and mental HRQOL scores over time.

The proportion of subjects in each treatment arm of the study with clinically meaningful change in physical and mental HRQOL scores is summarized in Table 3. The percentage with clinically meaningful change in mental HRQOL scores at the 4-month follow-up was significantly greater for those randomized to MBSR, χ^2 (4, 40) = 9.55, $p = 0.049$, whereas there were no significant differences for PTSD at either time point, or mental HRQOL at posttreatment. For PTSD, when analyzed as the percentage of subjects with clinically meaningful change, there was no significant difference between arms of the study in the percentage of subjects with a clinically meaningful change at posttreatment, MBSR 36.4% versus TAU 25.0%; χ^2 (1, 42) = 0.63,

Table 3
Proportion With Clinically Meaningful Change in PTSD Symptoms and Mental Health-Related Quality of Life for MBSR and TAU (Intention-to-Treat)

Summary scores	Posttreatment		4 months	
	Change < 10 points	Change ≥ 10 points	Change < 10 points	Change ≥ 10 points
PCL				
MBSR	15 (63.6)	8 (36.4)	14 (60.9)	9 (39.1)
TAU	15 (75.0)	5 (25.0)	14 (73.7)	5 (26.3)
SF-8-MCS				
MBSR	12 (57.1)	9 (42.9)	14 (63.6)	8 (36.4)[*]
TAU	15 (75.0)	5 (25.0)	17 (94.4)	1 (5.6)
PCL and SF-8-MCS				
MBSR	19 (90.5)	2 (9.5)	16 (72.7)	6 (27.3)[*]
TAU	18 (90)	2 (10)	18 (100)	0 (0.0)

Note. MBSR = Mindfulness-Based Stress Reduction; TAU = treatment as usual; PCL = PTSD Checklist; SF-8-MCS = Mental Component Summary Score of SF-8.
[*]p < 0.05.

$p = 0.426$, or at 4-month follow-up, MBSR 39.1% versus TAU 26.3%; χ^2 (1, 42) = 0.77, $p = 0.381$. For mental HRQOL, there was no significant difference in the percentage of subjects with clinically meaningful change posttreatment, MBSR 42.9% vs. TAU 25.0%; χ^2 (1, 41) = 1.45, $p = 0.228$, but at 4-month follow-up a significantly greater percentage of subjects randomized to MBSR had clinically meaningful change in mental HRQOL, MBSR 36.4% versus TAU 5.6%; χ^2 (1, 40) = 5.39, $p = 0.020$. The proportion of subjects with clinically meaningful change in *both* PTSD symptoms and mental HRQOL did not differ posttreatment, MBSR 9.5% vs. TAU 10.0%; χ^2 (1, 41) = 0.003, $p = 0.959$, but was significantly greater at 4-month follow-up for those randomized to MBSR, MBSR 27.3% vs. TAU 0%; χ^2 (1, 40) = 5.78, $p = 0.016$.

Discussion

This study found that veterans with PTSD who took part in MBSR reported improvement in mindfulness skills as compared with those assigned to TAU. For those randomized to MBSR, there was also significant improvement in mental HRQOL posttreatment, which waned slightly at 4-month follow-up and did not meet statistical significance. Of note, those assigned to MBSR also had greater physical HRQOL at 4-month follow-up, but this was primarily due to a decline in this outcome score in the TAU treatment arm, rather than an increase for subjects who underwent MBSR. When clinically meaningful change was evaluated according to the reliable change index, more veterans randomized to MBSR had a clinically significant improvement in HRQOL (as assessed by the mental component summary score), but not PTSD symptoms, at 4-month follow-up. There were no significant changes in PTSD symptoms according to the treatment arm in the study. In a post hoc analysis, significantly more veterans had clinically meaningful change in *both* PTSD symptoms and HRQOL at 4-month follow-up (27.3%) as compared to TAU (0%). We also found that those who completed at least 4 MBSR classes (see Teasdale et al., 2000) were more likely to report salutary changes in depression as well as functional status (behavioral activation and improvement in HRQOL) relative to those in the control condition. Overall, these results suggest that veterans with PTSD are able to learn mindfulness skills, and that MBSR may hold promise as an additional resource for enhancing the HRQOL for veterans with PTSD.

In this study, MBSR was offered in its widely available form, without modification. We consider the question of whether it would be helpful to modify MBSR to better serve the needs of persons with PTSD to be an unanswered and important question, particularly given the lack of specific effect on PTSD symptom severity for those assigned to MBSR relative to those assigned to TAU. The attentional skills taught in mindfulness practice encourage persons with PTSD to bring an attitude of curiosity and nonjudgment to experience, including difficult experience, which over time may result in extinction of conditioned phobic responses. For veterans with PTSD who participated in this study, manifestations of PTSD, such as avoidance tendencies, unresolved anger, guilt, shame, hypervigilance, emotional numbing, and intrusive thoughts or recollections of past traumatic events often came to the surface during mindfulness practice. When these issues arose during class sessions, participants were given instruction and encouragement on how to bring mindful attention to these manifestations of PTSD.

In our setting, many veterans with chronic PTSD have received education about PTSD before entering MBSR, and, partly for this reason, we felt that it was possible to offer MBSR in its standard form, without additional education regarding PTSD. However, persons with PTSD might benefit from a more targeted focus on subtle manifestations of avoidance and specific assistance staying present with a nonjudgmental attitude when trauma cues are present. Thus, future studies should evaluate whether a modified MBSR course is more effective at affecting the core symptoms of PTSD than the standard course. Precedents for such tailoring of mindfulness interventions include mindfulness-based cognitive therapy (MBCT) for depression, which found benefit for those with three or more episodes of major depression relative to TAU (Teasdale et al., 2000), and modification of MBSR to address issues affecting teens (Biegel, Brown, Shapiro, & Schubert, 2009).

Our study found some evidence of improvement in HRQOL for veterans with PTSD randomized to MBSR, and we suggest that future studies place a greater emphasis on this as

an outcome measure. Surprisingly, little attention has been paid to the role of HRQOL in anxiety disorders (Mogotsi, Kaminer, & Stein, 2000). When these measures have been reported in PTSD trials, they have generally been included as secondary measures and have received minimal attention in analyses or discussion (Gladis, Gosch, Dishuk, & Crits-Christoph, 1999). When the effect of PTSD on quality of life was quantified, one study found that 59% of PTSD patients had severe quality of life impairment (Rapaport, Clary, Fayyad, & Endicott, 2005). The avoidance/numbing symptom cluster of PTSD is most strongly associated with impaired psychosocial functioning and reduced life satisfaction/well-being (Gladis et al., 1999; Lunney & Schnurr, 2007).

Although some psychotherapeutic interventions have demonstrated improvement in HRQOL for PTSD (Ehlers et al., 2003; Foa et al., 1999), others have found no significant improvement (Foa et al., 2005; Schnurr et al., 2003), only modest improvement (e.g., between group effect size, $d = -0.21$ for prolonged exposure; Schnurr et al., 2007), or change in this variable was not reported (Monson et al., 2006; Resick, Nishith, Weaver, Astin, & Feuer, 2002). There is evidence that reductions in PTSD symptoms (such as emotional numbing, hyperarousal, and nightmares) are necessary for improvement in most domains of HRQOL (Lunney & Schnurr, 2007; Schnurr, Hayes, Lunney, McFall, & Uddo, 2006), although there is also some evidence in support of a reverse relationship–that improvement in HRQOL leads to improvement in PTSD symptoms (the effects of which lag in time; Schnurr et al., 2006).

Measurement of HRQOL thus allows a more complete assessment of whether a treatment is successful by taking into account not only symptom improvement but also the patient's perception and the effect of the treatment on multiple domains of health (Gladis et al., 1999). It has been proposed that improvement in *both symptoms and quality of life* is necessary for a treatment to be considered clinically successful (Gladis et al., 1999). In a post hoc analysis designed to assess this perspective, we found that a significantly greater proportion of veterans randomized to MBSR had clinically meaningful change in *both* PTSD symptoms and HRQOL; we feel this warrants investigation in future trials.

The present study has a number of limitations. It was performed as a pilot study, and as such lacks adequate statistical power to detect differences. A randomized trial with 80% power to detect a between group effect size of 0.50, (which accounts for an intraclass correlation of measurement within groups = 0.05 and a two-tailed alpha = 0.05), would require at least 196 participants. In this pilot study we did not adjust alpha, so as not to miss potentially meaningful associations that could lead to additional treatments for PTSD, though this may have led to spurious findings and increased Type I error. Also, a TAU control arm, such as one employed in this study, accounts for changes due to regression to the mean, but does not allow discrimination between changes due to the intervention versus nonspecific effects of participation in a group. An active control group, in which controls spend the same amount of time with an attentive provider, is needed to determine whether changes between randomization arms are related to MBSR.

Although we used the standard definition of MBSR "completer" typically used in mindfulness treatment studies (Teasdale et al., 2000) that requires attendance of four or more classes, this is actually quite a liberal definition of treatment completion as it is less than half of the available nine class sessions (eight weekly sessions plus a full-day session on a Saturday). That said, it is useful to know that even a relatively modest dose of MBSR (10 hours or more of in-session class time) is associated with salutary changes in functionality, HRQOL, depression, and mindfulness.

Another potential limitation is the lack of a formal assessment of PTSD diagnostic status at baseline as part of the inclusion criteria (a chart diagnosis of PTSD was used). Also, although the MBSR classes were taught by experienced MBSR instructors, treatment fidelity was not assessed. Compliance with MBSR homework practice was not evaluated. Although formal screening for alcohol use was not performed, this trial excluded persons with alcohol abuse clearly documented in the medical record, which limits the ability to generalize these findings to persons with documented ongoing alcohol abuse. Finally, a greater proportion of subjects in the TAU control arm had received a prescription for benzodiazepines, which could influence the results in unknown ways.

Despite these limitations, we feel that the findings regarding improved mindfulness and HRQOL support performance of an adequately powered randomized controlled trial of MBSR for veterans with PTSD, with an active control group and mediation analyses.

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