

Mindfulness Meditation Alleviates Depressive Symptoms in Women With Fibromyalgia: Results of a Randomized Clinical Trial

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Objective. Depressive symptoms are common among patients with fibromyalgia, and behavioral intervention has been recommended as a major treatment component for this illness. The objective of this study was to test the effects of the Mindfulness-Based Stress Reduction (MBSR) intervention on depressive symptoms in patients with fibromyalgia.

Methods. This randomized controlled trial examined effects of the 8-week MBSR intervention on depressive symptoms in 91 women with fibromyalgia who were randomly assigned to treatment (n = 51) or a waiting-list control group (n = 40). Eligible patients were at least 18 years old, willing to participate in a weekly group, and able to provide physician verification of a fibromyalgia diagnosis. Of 166 eligible participants who responded to local television news publicizing, 49 did not appear for a scheduled intake, 24 enrolled but did not provide baseline data, and 2 were excluded due to severe mental illness, leaving 91 participants. The sample averaged 48 years of age and had 14.7 years of education. The typical participant was white, married, and employed. Patients randomly assigned to treatment received MBSR. Eight weekly 2.5-hour sessions were led by a licensed clinical psychologist with mindfulness training. Somatic and cognitive symptoms of depression were assessed using the Beck Depression Inventory administered at baseline, immediately postprogram, and at followup 2 months after the conclusion of the intervention.

Results. Change in depressive symptoms was assessed using slopes analyses of intervention effects over time. Depressive symptoms improved significantly in treatment versus control participants over the 3 assessments.

Conclusion. This meditation-based intervention alleviated depressive symptoms among patients with fibromyalgia.

KEY WORDS. Mindfulness; Meditation; MBSR; Randomized trial; Fibromyalgia syndrome; Depression; Behavioral intervention; Chronic pain.

INTRODUCTION

This randomized trial tested the effects of Mindfulness-Based Stress Reduction (MBSR) on depressive symptoms in women with fibromyalgia syndrome. Fibromyalgia is a chronic pain disorder marked by joint and soft tissue pain, tenderness, and nonrestorative sleep (1). Diagnostic criteria include pain on palpation of established soft tissue loci

(2). Sleep difficulties, stiffness, and cognitive deficits including learning and memory problems are common (1,3–8). Neuroendocrine dysregulation has been noted (9,10), and functional impairment can be profound. Fibromyalgia is estimated to occur in 1–3% of US community samples, mainly affecting women (11).

Although not evident in all patients (12), symptoms of depression are common (13–15) and are exacerbated by physical symptoms (16–18). Current major depression is reported in 18% of patients, with lifetime prevalence rates ranging from 58% to 69% (1,16). Because medical treatments are often ineffective, patients may feel hopeless, adding to the severity of depressive symptoms (19).

Management of fibromyalgia is sometimes achieved with antidepressants, sleep, and/or antiinflammatory agents (20–23). Findings from several meta-analyses suggest that optimal care combines medication, exercise, and psychosocial intervention (20,24–28), and broad improvements have been observed with treatment plans that include nonpharmacologic intervention (24,29,30).

Patients with fibromyalgia experience high distress (31)

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and utilize health services extensively during stressful episodes (32,33). Psychiatric symptoms exacerbate pain and impairment, and may be more difficult to treat than physical symptoms (34). Thus, psychosocial interventions may be particularly helpful to these patients (35–37). Growing research suggests that meditation-based therapies may be useful as treatments for chronic medical conditions (38–41), although more research is needed before definite conclusions can be drawn (42,43).

The MBSR intervention was developed to relieve suffering among patients with chronic pain (44), and interest in this intervention has grown rapidly (39–41,45). MBSR utilizes stress-reduction skills including sitting meditation, hatha yoga, and a somatically focused technique called the body scan (44). Participants are encouraged to maintain attention on their immediate experience with an attitude of openness, acceptance, curiosity, and compassion (46,47). Based on the Buddhist vipassana meditation tradition, MBSR encourages nonjudgmental awareness of one's cognitive and somatic experience on a moment-by-moment basis (44). This decentered stance is believed to disconnect cognitive and affective mental events in an adaptive manner (48) and may reduce the negative impact of thoughts and sensations associated with chronic pain.

Effects of MBSR have been examined in health conditions (41) including eating disorders (49), cardiovascular disease (50), chronic pain (44), cancer (51–53), recovered major depression (48), and in heterogeneous patient samples (54). Empirical support for the utility of MBSR has been provided by a handful of randomized trials (39,55) reporting benefits with regard to depression in college students (56), medical students (57), and cancer patients (52,53). Segal and colleagues offer convincing evidence that the intervention helps prevent depression relapse (58). Recent reviews report large effect sizes for MBSR in chronic illness (41) with reduction of depressive symptoms reported in 5 studies (39).

Few trials have examined effects of MBSR among patients with fibromyalgia. In one nonrandomized prospective study, MBSR improved depressive symptoms among 67% of active treatment participants, reduced overall symptoms, and was associated with faster recovery (59). Another study randomized patients with fibromyalgia to either education/support or training in mindfulness meditation and Qi Gong practice for 8 weekly sessions (60). Both education/support and mindfulness meditation were associated with improvements in pain, depressive symptoms, and daily functioning and were equally effective in reducing distress (60). However, these trials were not designed to evaluate whether MBSR provides an advantage over standard treatment for depressive symptoms in patients with fibromyalgia. Evidence suggests that MBSR can reduce depressive symptoms, but the strength of this conclusion is tempered both by the limited number of studies and by methodologic limitations in their design.

PATIENTS AND METHODS

Participants. Women diagnosed with fibromyalgia syndrome ($n = 91$) were recruited via 2 brief media (televi-

sion) broadcasts and newspaper advertisements. Eligible women were age 18 years or older, currently able to attend a group that met weekly, and able to provide physician verification of their fibromyalgia diagnosis according to American College of Rheumatology criteria (2). Telephone respondents included 282 individuals, of whom 166 met the eligibility criteria. Reasons for ineligibility included providing no telephone number ($n = 1$), not returning telephone messages ($n = 25$), absence of confirmatory diagnosis ($n = 13$), declining to participate after hearing a detailed description of the study ($n = 43$), or not being available for the 8-week intervention ($n = 34$). Of 166 eligible candidates, 49 women (29.5%) did not attend a scheduled intake interview and could not be contacted thereafter, 24 (14.5%) were interviewed but did not provide complete baseline data, and 2 (1.2%) were excluded due to severe mental illness including psychosis and acute suicidality (Structured Clinical Interview for Diagnosis, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [61]). A total of 91 women were randomized after providing complete baseline data. The mean \pm SD age of the sample was 48.2 ± 10.6 years, with a mean \pm SD of 14.7 ± 2.3 years of education. Participants were predominantly white (96%), married (54%), and employed (53%), and reported an annual household income between \$40,000 and \$60,000.

Procedure. After providing informed consent and baseline demographic, medical, and self-report data, participants were randomly assigned to either the treatment or control group. Previous fibromyalgia intervention studies have had high dropout rates and poor attendance, e.g., 23% lost to followup (62). To protect against potential dropout effects on the group environment of MBSR, a 5:4 allocation ratio was used for randomization to the treatment versus control group. Sample size calculations were based on a desired power of 0.80, an alpha of 0.05, and the effect size and loss to followup reported in a previous study of a cognitive-behavioral stress reduction program for patients with fibromyalgia (59). A total of 51 women were randomized to MBSR treatment and 40 were randomized to a wait-list control group. MBSR was administered in 2 cycles of ~ 25 women each. Forty-two treatment participants (82%) were considered to have completed MBSR by virtue of their attendance during at least 4 of the 8 weekly group sessions (48,58,63), whereas 9 attended <4 sessions (18%). The sample is further described in Table 1.

There were 3 waves of data collection: at baseline prior to randomization, just after the end of the 8-week intervention, and 2 months after the end of the intervention. Of the 91 participants, 68 (74.7%) provided complete followup data, with no statistically significant difference in loss to followup among treatment versus control participants. Reasons for attrition at wave 2 were illness ($n = 1$), loss of interest/time constraints ($n = 10$), or unexplained dropout ($n = 15$). Attrition at wave 3 was due to illness ($n = 2$), death in the family ($n = 1$), loss of interest/time constraints ($n = 14$), or unexplained dropout ($n = 18$). Participants were not informed of study hypotheses and data entry personnel were blinded to experimental group.

Table 1. Demographic and medical characteristics and self-reported pain, sleep difficulties, and depressive symptoms for 51 treatment and 40 control participants*

	Treatment	Control
Age, mean \pm SD years	48.4 \pm 8.9	47.6 \pm 11.5
Years since diagnosis, mean \pm SD	4.5 \pm 3.6	4.9 \pm 5.2
Years of education		
<12	31.5	37.5
>14	66.7	62.0
No response	2.0	0
Income		
<39,999	39.2	47.5
>40,000	60.7	52.5
Ethnicity		
White	94.1	92.5
African American	3.9	5.0
Native American	2.0	2.5
Marital status		
Married	66.7	52.5
Divorced	19.6	30.0
Never married	7.8	12.5
Widowed	5.9	2.5
Separated	0	2.5
Medications		
Antidepressants	60.8	67.5
Currently meditate		
Yes	15.7	15.4
No	84.3	84.6
Fibromyalgia symptoms, mean \pm SD		
Physical function	1.28 \pm 0.72	1.17 \pm 75.0
Symptom severity	67.53 \pm 15.81	67.92 \pm 14.39
Pain	68.1 \pm 25.4	69.2 \pm 19.6
Sleep	9.4 \pm 3.3	9.3 \pm 3.1
Depressive symptoms		
BDI total score	15.6 \pm 7.0	14.7 \pm 6.9
Cognitive subscale	6.4 \pm 4.3	6.1 \pm 4.1
Somatic subscale	8.4 \pm 3.2	7.7 \pm 3.2

* Values are the percentage unless otherwise indicated. Reports collected at baseline prior to randomization. Medications reported among the sample included antidepressants (63.7%), anxiolytics (23.1%), and hypnotics (9.9%). Most (72.5%) of the sample reported comorbid medical disorders, the most common being arthritis, migraines, carpal tunnel syndrome, chronic fatigue syndrome, allergies, asthma, musculoskeletal disorders, and depression. BDI = Beck Depression Inventory.

Intervention. Treatment participants received MBSR in the 8-week format of the parent program (University of Massachusetts [64,65]), meeting weekly for 2.5-hour sessions led by a licensed clinical psychologist (PS) who was trained in MBSR at the University of Massachusetts Medical School. Techniques and materials developed by the parent program were used. Attendance was monitored and absent participants received a reminder phone call to attend subsequent sessions. The 3 major intervention components were introduced systematically and sessions focused on specific aspects of stress management. Home practice assignments were guided by a workbook and audiotapes (65). Daily home practice of 30–45 minutes' duration, 6 days per week, was encouraged. In accordance

with MBSR protocol, a day-long meditation retreat was held between weeks 6 and 7 of the program.

Control group. A wait-list control group design was used. Control participants were offered the MBSR program only after the conclusion of the study, subsequent to their provision of wave 3 data. Of the 40 wait-list control participants, 33 attended the first MBSR session. No further data were collected from control participants.

Medical and control variables. Prior to randomization, participants reported demographic data and medications taken during the month prior to study entry. At each assessment, participants characterized their current meditation practice including whether they meditated, what format they used, and how frequently (times per week). Participants who reported practicing any form of meditation at the conclusion of the study were categorized as meditators and those who reported no active meditation practice were categorized as nonmeditators.

Functional impairment was measured using the Fibromyalgia Impact Questionnaire, a 10-item Likert-type instrument that assesses physical functioning and symptom severity and has demonstrated adequate validity and reliability (66). Pain was assessed using a 4-item visual analog scale widely used in chronic pain assessment (67). The instrument provides a summary of pain in the past week, with scores ranging from 0 to 100. Sleep quality was assessed using the Stanford Sleep Questionnaire, a 4-item Likert-type scale that assesses sleep onset difficulties, nocturnal awakening, morning awakening, and daytime sleepiness. Test–retest reliability and validity have been established with patients with sleep disorders and normal controls (68).

Depressive symptoms. Depressive symptoms were assessed using the Beck Depression Inventory (BDI). This scale has high internal consistency ($\alpha = 0.86$) with psychiatric samples and a test–retest reliability >0.60 (69). The BDI discriminates between psychiatric and normal populations and correlates with clinical depression ratings. Outcomes included the total BDI score and the cognitive and somatic symptom subscales described by Peck and colleagues (70).

Statistical analyses. The success of randomization was assessed using *t*-tests and chi-square statistics to examine the balance of baseline demographic and medical characteristics, control variables, and depressive symptoms in the treatment group versus control group (Table 1). Independent sample *t*-tests compared baseline demographic, predictor, and outcome variables for participants who provided followup data versus those who did not.

Primary hypotheses tests examined MBSR effects on total BDI scores using strategies recommended by Pledger for maintaining intent-to-treat principles in studies with loss to followup (71). Importantly, all available data from patients lost to followup were included in primary analyses. Secondary analyses repeated hypothesis testing and utilized only the data from patients who returned for at

least 1 followup assessment. The results of both types of analyses are presented.

Primary analyses. In situations where loss to followup prevents inclusion of outcome data from all participants (72), a last observation carried forward (LOCF), or end point analysis, has been recommended (71). According to recommendations, baseline BDI values were inserted in place of posttreatment and followup scores for patients lost to followup. This conservative method was intended to protect against inflated treatment effects that could result from examining only the patients with followup data (73).

Immediate postprogram effects were evaluated using analyses of covariance (ANCOVAs) with postprogram BDI scores as the dependent variable and baseline BDI scores as the covariate. Slopes analyses tested the effects of MBSR over all assessments in a method incorporating baseline, postprogram, and 2-month followup assessments in 1 continuous outcome variable (74). BDI scores were regressed on time, yielding 2 summary measures for each patient: the intercept (an estimate of the true baseline BDI score) and the slope (an estimate of the direction and rate of change of depressive symptoms). Participants who provided data at only 1 followup had slopes calculated using just 2 points (baseline and 1 subsequent BDI score). After insertion of baseline values, individuals lost to followup had intercept values equal to their baseline BDI scores and slopes equal to zero. The effectiveness of the MBSR intervention was tested using ANCOVAs with slopes as the dependent variable and the treatment condition (meditation versus wait list) as the independent variable in the general linear model procedure (75). The BDI intercept value was the covariate in these analyses.

Secondary analyses. Recommendations for clinical trials with loss to followup are that data be evaluated using multiple analytic strategies and that all results be presented (72). Therefore, an alternate strategy was also used: primary analyses were repeated using data only from participants who provided at least 2 assessments (baseline plus wave 2 or wave 3), and hypothesis tests were repeated using outcomes calculated without replacement of missing data. Potential influences of pain, sleep, and antidepressants on effects of treatment were tested by including each of these factors as a covariate in the analysis of treatment effects.

Within the treatment group, potential dose-response effects of the intervention were tested in 2 ways. First, the predictive value of attendance (total number of sessions attended) was examined using hierarchical linear regression analyses with BDI slope as the dependent variable. Second, the practice of meditation at the conclusion of the study (wave 3) was used as the independent variable in an ANCOVA examining effects on the slope of change in depressive symptoms.

As noted, 2 treatment cycles were conducted. Even though both groups were led by the same instructor, differences in group dynamics could affect study outcomes. We tested for systematic differences between treatment

cycles by excluding control participants and using treatment cycle as the independent variable (cycle 1 versus cycle 2). As for the primary analyses, baseline BDI scores were controlled in the analysis of postprogram effects, and the BDI intercept scores were controlled in analyses of slopes of change.

RESULTS

Sample characteristics and randomization check. The sample ranged in age from 23 to 74 years (mean \pm SD age 48 ± 10 years). There were no significant differences between treatment and control participants on demographic or baseline medical variables, including impairment, pain, sleep difficulties, and depressive symptoms. There were no baseline differences in reported meditation experience (Table 1). The majority of patients randomized to the intervention (42 [82.3%] of 51) did complete treatment, which was previously defined for MBSR as attending ≥ 4 sessions (48,58,63). Mean \pm SD attendance was 5.5 ± 2.1 of 8 sessions. Attendance dropped from 90% to 57% between the first meeting and fourth meeting but stabilized thereafter. Sixty-eight participants (75%) provided data for at least 1 of the 2 followup assessments. In independent sample *t*-tests comparing demographic, predictor, and outcome variables, participants lost to followup had greater baseline symptom severity ($t[1,88] = 2.95, P < 0.005$) and poorer physical functioning ($t[1,89] = 2.10, P < 0.05$) than those who provided followup data. Importantly, a 2-way factorial analysis of variance demonstrated that this effect did not differ across treatment and control groups. There were no significant differences between the baseline BDI total or subscale scores of participants who provided followup data versus those who did not. A flow diagram of participant progress through the phases of this randomized trial is presented in Figure 1 (76).

Tests of primary hypothesis. Baseline BDI scores were inserted in place of posttreatment and 2-month followup scores for the 10 treatment and 13 control participants lost to followup. The depressive symptom scores for treatment versus control participants at baseline, postprogram, and 2-month followup are summarized in Table 2.

The MBSR intervention significantly reduced depressive symptoms in treatment versus control participants at the immediate postprogram assessment. Moreover, slopes analyses revealed a persistent treatment effect over all 3 assessments (Table 3).

Results of secondary analyses. Replication of the primary hypothesis tests utilizing data only from patients with at least 1 followup revealed that MBSR reduced depressive symptoms, with all results maintained at a similar significance level (Table 4). Tests of the intervention effects on cognitive versus somatic symptoms of depression revealed significant effects of the treatment on both subtypes of depressive symptoms (Table 4).

Analyses controlling for the effects of pain and sleep difficulties in the relationship between MBSR and depres-

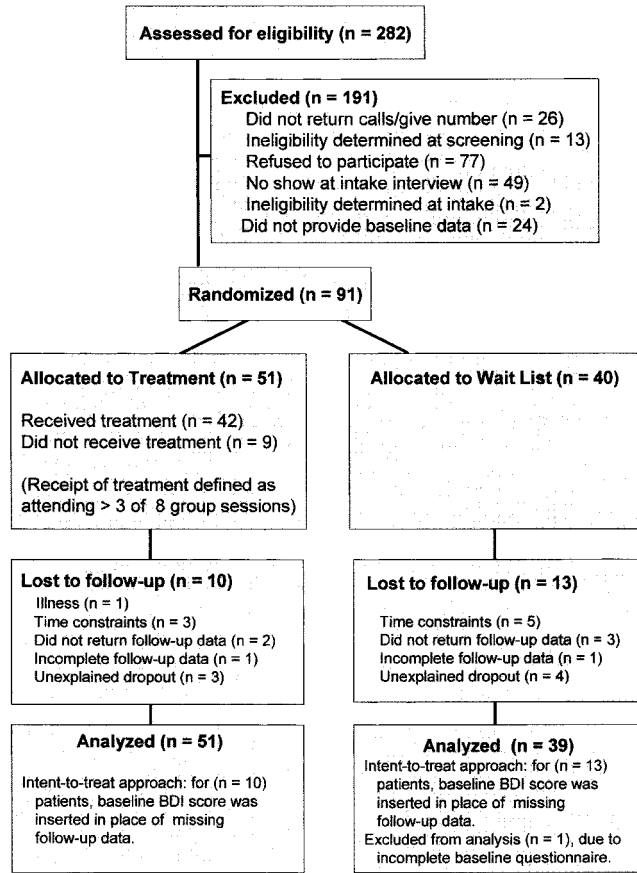


Figure 1. Flow diagram of participant progress through the phases of this randomized trial, adapted from Moher and colleagues (76). BDI = Beck Depression Inventory.

sive symptom reduction demonstrated a persistent effect of treatment with regard to total depressive symptoms and somatic symptom scores, but not cognitive symptoms ($P = 0.09$). All findings persisted when pain, sleep, and antidepressant medication use were controlled. Weekly group attendance demonstrated no predictive value with regard to outcome.

Fourteen participants (8 treatment and 6 controls) reported practicing meditation on a regular basis at baseline (median times per week 6.5 and 5.0, respectively), although none practiced mindfulness meditation per se. Reported practices were breathing ($n = 3$), prayer ($n = 3$), relaxation audio tapes ($n = 2$), hot baths ($n = 1$), Bible study ($n = 1$), centering ($n = 1$), “my own version” ($n = 1$), strength exercises ($n = 1$), and Transcendental Meditation ($n = 1$). At postprogram, 35 treatment participants (87.5%) and 3 control group participants (11.1%) reported meditating regularly (median number of times per week 5.0 and 5.0, respectively). The majority (86%) of participants in the treatment group reported using ≥ 1 of the MBSR techniques. Two women in the wait-list control group reported using mindfulness meditation techniques at the second assessment. At the third assessment, 24 treatment group participants (72.7%) and 3 control group participants (12.5%) reported meditating regularly (median times per week 7.0 and 4.0, respectively). Participants who still meditated at the end of the study had the greatest reduc-

Table 2. Mean \pm SD depressive symptom scores for treatment and control participants at baseline, immediately postintervention (Post), and 2-month followup (2-mo)*

	Treatment (n = 51)					Control (n = 39)				
	Baseline	Post	2-mo	Slope	Intercept	Baseline	Post	2-mo	Slope	Intercept
Primary (LOCF) analyses										
BDI total	15.7 \pm 7.1	12.4 \pm 7.4	13.3 \pm 7.5	-1.10 \pm 1.90	15.31 \pm 7.02	14.7 \pm 6.9	15.1 \pm 8.1	14.8 \pm 8.1	0.02 \pm 1.12	14.84 \pm 6.97
Cognitive/affective	6.4 \pm 4.3	5.0 \pm 4.0	5.3 \pm 4.2	-0.53 \pm 1.21	6.25 \pm 4.20	6.1 \pm 4.1	6.3 \pm 5.0	6.4 \pm 4.8	0.04 \pm 0.88	6.12 \pm 4.11
Somatic	8.4 \pm 3.2	6.5 \pm 3.7	7.4 \pm 3.5	-0.50 \pm 0.84	8.17 \pm 3.13	7.7 \pm 3.2	7.8 \pm 3.5	7.7 \pm 3.3	0.03 \pm 0.59	7.68 \pm 3.28
Secondary analyses										
BDI total	15.7 \pm 7.1	10.5 \pm 6.0	11.2 \pm 6.5	-1.37 \pm 2.03	15.14 \pm 6.43	14.7 \pm 6.9	14.1 \pm 7.9	14.2 \pm 8.1	0.02 \pm 1.35	13.67 \pm 5.96
Cognitive/affective	6.4 \pm 4.3	4.0 \pm 3.3	4.0 \pm 3.6	-0.66 \pm 1.32	6.07 \pm 3.99	6.1 \pm 4.1	5.9 \pm 5.2	6.3 \pm 5.1	0.06 \pm 1.06	5.57 \pm 3.85
Somatic	8.4 \pm 3.2	5.6 \pm 3.0	6.7 \pm 3.2	-0.62 \pm 0.89	8.08 \pm 2.71	7.7 \pm 3.2	7.3 \pm 3.2	7.3 \pm 2.0	0.05 \pm 0.71	7.10 \pm 2.82

* Slope of change and intercept scores were calculated over all 3 assessments. LOCF = last observation carried forward; BDI = Beck Depression Inventory.

Table 3. Primary results: last observation carried forward analyses testing effects of the intervention on immediate postprogram scores and on slopes of change in depressive symptoms over all 3 assessments*

	Postprogram				Slopes			
	F	df	P	Eta ² †	F	df	P	Eta ² †
Total BDI score	12.02	87	0.001	0.12	10.20	87	0.002	0.11
Cognitive/affective	5.88	87	0.017	0.06	6.39	87	0.013	0.07
Somatic	14.40	87	0.000	0.14	9.93	87	0.002	0.11

* BDI = Beck Depression Inventory.
† Eta² is the effect size indicating the proportion of the total variance attributed to the effect of treatment (calculated by dividing the sum-of-squares for an effect by the sum-of-squares total).

tion of depressive symptoms ($F[1,30] = 4.64, P < 0.05$). Significant effects of meditation practice were found for somatic symptoms ($F[1,30] = 5.17, P < 0.05$) but not cognitive symptoms of depression. Tests for differences between the 2 treatment cycles revealed no significant effect of cycle on the slope of the total depressive symptom score, cognitive, or somatic symptoms.

DISCUSSION

This randomized trial demonstrated MBSR to be more effective than standard treatment for reduction of depressive symptoms among women with fibromyalgia. Patients who participated in MBSR reported a marked reduction of depressive symptoms that persisted for 2 months after the intervention. This study supports the results of previous research showing that MBSR can alleviate depressive symptoms (39–41,77) among women diagnosed with fibromyalgia (60).

As is often the case in longitudinal research on self-reported outcomes, loss to followup provided an analytic challenge. However, the results are persuasive for several reasons: attrition did not differentially affect the treatment and control groups, and the primary hypothesis tests used LOCF analyses to guard against Type I error. Given this conservative strategy, it is remarkable that MBSR effects were marked and persistent. In further support, secondary results did not differ quantitatively or qualitatively from the LOCF findings. As noted by Friedman and colleagues (72), in clinical trials with missing outcome data, the con-

currence of multiple analytic strategies lends credibility to the findings.

The MBSR intervention appears to be a promising adjunctive treatment for depressive symptoms in patients with fibromyalgia, especially when viewed in light of the current gaps in medical management of this disorder (24–27). As in other chronic pain syndromes (54,78,79), depressive symptoms can interact reciprocally with physical symptoms to decrease quality of life. A behavioral intervention that reduces symptoms of depression may confer reciprocal benefits with regard to physical symptoms.

Because of the debilitating nature of this illness, employment (11) and other activities that require a regular schedule are often hindered. Such difficulties may explain the high proportion of respondents who initially scheduled but did not attend intake interviews (49 [29.5%] of 166), treatment participants who did not attend at least 4 sessions (9 [17.6%] of 51), and participants who did not respond to requests for provision of followup data (23 [25.3%] of 91). Impairment related to illness may also be at the root of our attrition, because greater baseline impairment was reported in patients subsequently lost to followup. Because of this concern and the bias inherent in this self-selected sample, these results are generalizable only to patients with fibromyalgia without severe functional impairment who have the interest and ability to participate in a meditation-based support group intervention. Nevertheless, the 75% retention rate is comparable with that of other behavioral intervention studies of fibromyalgia (59,62), and is equal to or greater than rates in

Table 4. Secondary results: analysis of data from 68 participants who provided both baseline and at least 1 followup score, tests of effects of the intervention on immediate postprogram scores and on slopes of change in depressive symptoms over all 3 assessments*

	Postprogram				Slopes			
	F	df	P	Eta ² †	F	df	P	Eta ² †
Total BDI score	12.00	61	0.001	0.16	8.70	65	0.004	0.12
Cognitive/affective	6.04	61	0.017	0.09	5.65	65	0.020	0.08
Somatic	13.84	61	0.000	0.20	8.24	65	0.006	0.12

* BDI = Beck Depression Inventory.
† Eta² is the effect size indicating the proportion of the total variance attributed to the effect of treatment (calculated by dividing the sum-of-squares for an effect by the sum-of-squares total).

other MBSR studies (39,80). Attendance rates dropped during the first 4 sessions and then stabilized, consistent with other MBSR studies in which dropouts occurred early (81).

The increase in meditation practice reported by the treatment group suggests that participants utilized the training and altered their behavior. The positive relationship between meditation practice and improvement in depressive symptoms is consistent with several previous studies (52,82).

This is the first study to differentiate effects of MBSR on cognitive versus somatic depressive symptoms. Both were reduced with MBSR. A larger postintervention effect size was observed for somatic symptoms, but by the 2-month followup this difference was less pronounced. It has been emphasized by Kabat-Zinn that mindfulness may operate by altering perceptions of depression or pain, thereby reducing their impact (44). Thus, MBSR may minimize the distinction between cognitive and somatic symptoms. If so, one would not expect a vastly different impact on these 2 symptom categories.

In contrast with techniques that directly promote relaxation, MBSR promotes self-observation, acceptance, and thoughtful responses to pain. This strategy may be particularly effective in fibromyalgia because it may disconnect the affective response to pain from ruminations about pain and consequent development of depressive symptoms. A recent fibromyalgia study demonstrated links between depressive symptoms and activation in brain regions involved in affective, but not sensory, pain processing (83). MBSR has also been linked to increased left brain activation, a pattern associated with positive affect. Taken together, these studies suggest that MBSR may specifically reduce affective pain processing (84). Our group has also demonstrated that MBSR appears to change the world view of the patient with fibromyalgia such that life is viewed as more comprehensible, manageable, and meaningful (85). MBSR may alter the framework through which difficult events and circumstances are viewed, resulting in more neutral assessment with somatic pain sensations less likely to engender affective responses to pain. These changes may be manifest in alterations of brain function (84) as well as a reduction in negative affective response.

This study incorporated methodologic recommendations recently summarized for research in MBSR (39–41) including clear inclusion and exclusion criteria, a successful simple randomization procedure with a usual treatment control group, and multiple followup assessments. Although these data strengthen evidence for benefits of MBSR (41,53), the real-world feasibility of this intervention is still questionable. Rigorous commitments of time are required for instructors and participants, presenting a potential obstacle to the wide use of MBSR. However, this is a promising adjunctive treatment for patients with a high desire for involvement in the management of their illness. Our data suggest that one-third of patients interested in psychosocial intervention might be willing to try MBSR, and of those, up to 80% might complete the training. Given the high prevalence of fibromyalgia, MBSR could help many of these patients cope more effectively.

Future studies are needed to examine the feasibility and cost effectiveness of this intervention on a wider scale.

Taken together with other recent data (86), these findings are encouraging. Future randomized studies should control for contact time with group leaders and other participants to separate the effects of meditation from those of attention and social support. The role of individual differences and the specific characteristics and processes of MBSR that provide benefit are of great interest. Recent advances include a proposed operational definition of mindfulness (46), a theoretical model (47), and several self-report instruments for the measurement of mindfulness characteristics (87). Studies designed with broad cultural and conceptual sensitivity (88) will lead to a rich understanding of the psychological and potential health benefits of MBSR. Future studies will be strengthened by the use of these theoretical and practical advances to provide structure for investigation.

AUTHOR CONTRIBUTIONS

Dr. Sephton 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 design. Drs. Sephton and Salmon.

Acquisition of data. Drs. Sephton, Salmon, Weissbecker, Hoover, and Ulmer, and Ms Floyd.

Analysis and interpretation of data. Drs. Sephton, Salmon, Weissbecker, Studts, and Ulmer.

Manuscript preparation. Drs. Sephton, Salmon, Weissbecker, Hoover, Studts, and Ulmer, and Ms Floyd.

Statistical analysis. Drs. Sephton, Weissbecker, and Studts.

Conduction of mindfulness meditation groups. Dr. Salmon.

Literature review. Drs. Sephton, Salmon, Weissbecker, Ulmer, and Hoover.

REFERENCES

- Wallace DJ. The fibromyalgia syndrome. *Ann Med* 1997;29:9–21.
- Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: report of the multicenter criteria committee. *Arthritis Rheum* 1990;33:160–72.
- Mease PJ, Clauw DJ, Arnold LM, Goldenberg DL, Witter J, Williams DA, et al. Fibromyalgia syndrome. *J Rheumatol* 2005;32:2270–7.
- Beck AT, Rush AJ, Shaw BF, Emery G. *Cognitive therapy of depression*. New York: Guilford Press; 1979.
- Lewisohn P. Clinical and theoretical aspects of depression. In: Calhoun KS, Adams HE, Mitchell KM, editors. *Innovative treatment methods in psychopathology*. New York: John Wiley; 1974.
- Lewisohn P, Hoberman T, Hautzinger M. An integrative theory of depression. In: Bootzin SR, editor. *Theoretical issues in behavior therapy*. New York: Academic Press; 1985.
- Wright J, Salmon PG. Learning and memory in depression. In: McCann CD, Endler NC, editors. *Depression: new directions in theory, research and practice*. Toronto: Wall & Emerson; 1990. p. 211–36.
- Sephton SE, Studts JL, Hoover K, Weissbecker I, Lynch G, Ho I, et al. Biological and psychological factors associated with memory function in fibromyalgia syndrome. *Health Psychol* 2003;22:592–7.
- Crofford LJ, Clauw DJ. Fibromyalgia: where are we a decade after the American College of Rheumatology classification criteria were developed? [editorial]. *Arthritis Rheum* 2002;46:1136–8.

10. Weissbecker I, Floyd A, Dedert E, Salmon P, Sephton S. Childhood trauma and diurnal cortisol disruption in fibromyalgia syndrome. *Psychoneuroendocrinology* 2006;31:312–24.
11. Wolfe F, Ross K, Anderson J, Russell IJ, Hebert L. The prevalence and characteristics of fibromyalgia in the general population. *Arthritis Rheum* 1995;38:19–28.
12. Ahles TA, Khan SA, Yunus MB, Spiegel DA, Masi AT. Psychiatric status of patients with primary fibromyalgia, patients with rheumatoid arthritis, and subjects without pain: a blind comparison of DSM-III diagnoses. *Am J Psychiatry* 1991;148:1721–6.
13. Blackburn-Munro G, Blackburn-Munro RE. Chronic pain, chronic stress and depression: coincidence or consequence? [review]. *J Neuroendocrinol* 2001;13:1009–23.
14. Fishbain DA, Cutler R, Rosomoff HL, Rosomoff RS. Chronic pain-associated depression: antecedent or consequence of chronic pain? A review. *Clin J Pain* 1997;13:116–37.
15. Schoenfeld-Smith KN, Nicassio PM, Radojevic V, Patterson TL. Multiaxial taxonomy of fibromyalgia syndrome patients. *J Clin Psychol Med Settings* 1995;2:149–66.
16. Epstein S, Kay G, Clauw D, Heaton R, Klein D, Krupp L, et al. Psychiatric disorders in patients with fibromyalgia: a multicenter investigation. *Psychosomatics* 1999;40:57–63.
17. Doan BD, Wadden NP. Relationships between depressive symptoms and descriptions of chronic pain. *Pain* 1989;36:75–84.
18. Parmelee PA, Katz IR, Lawton MP. The relation of pain to depression among institutionalized aged. *J Gerontol* 1991;46:P15–21.
19. Bennett RM. Multidisciplinary group programs to treat fibromyalgia patients. *Rheum Dis Clin North Am* 1996;22:351–67.
20. Goldenberg DL, Burckhardt C, Crofford L. Management of fibromyalgia syndrome [review]. *JAMA* 2004;292:2388–95.
21. Crofford LJ, Appleton BE. The treatment of fibromyalgia: a review of clinical trials. *Curr Rheumatol Rep* 2000;2:101–3.
22. Millea PJ, Holloway RL. Treating fibromyalgia. *Am Fam Physician* 2000;62:1575–82, 1587.
23. Clauw DJ. Treating fibromyalgia: science vs. art. *Am Fam Physician* 2000;62:1492, 1494.
24. Rossy LA, Buckelew SP, Dorr N, Hagglund KJ, Thayer JF, McIntosh MJ, et al. A meta-analysis of fibromyalgia treatment interventions. *Ann Behav Med* 1999;21:180–91.
25. Forseth KO, Gran JT. Management of fibromyalgia: what are the best treatment choices? [review]. *Drugs* 2002;62:577–92.
26. Buckelew SP, Conway R, Parker J, Deuser WE, Read J, Witty TE, et al. Biofeedback/relaxation training and exercise interventions for fibromyalgia: a prospective trial. *Arthritis Care Res* 1998;11:196–209.
27. Sandstrom MJ, Keefe FJ. Self-management of fibromyalgia: the role of formal coping skills training and physical exercise training programs. *Arthritis Care Res* 1998;11:432–7.
28. Quisel A, Gill J, Walters D. Exercise and antidepressants improve fibromyalgia. *J Fam Pract* 2004;53:280–91.
29. Wigers SH, Stiles TC, Vogel PA. Effects of aerobic exercise versus stress management treatment in fibromyalgia: a 4.5 year prospective study. *Scand J Rheumatol* 1996;25:77–86.
30. Redondo JR, Justo CM, Moraleta FV, Velayos YG, Puche JJ, Zubero JR, et al. Long-term efficacy of therapy in patients with fibromyalgia: a physical exercise-based program and a cognitive-behavioral approach. *Arthritis Rheum* 2004;51:184–92.
31. Wolfe F, Skevington SM. Measuring the epidemiology of distress: the rheumatology distress index. *J Rheumatol* 2000;27:2000–9.
32. Penrod JR, Bernatsky S, Adam V, Baron M, Dayan N, Dobkin PL. Health services costs and their determinants in women with fibromyalgia. *J Rheumatol* 2004;31:1391–8.
33. Dobkin PL, de Civita M, Bernatsky S, Kang H, Baron M. Does psychological vulnerability determine health-care utilization in fibromyalgia? *Rheumatology (Oxford)* 2003;42:1324–31.
34. Da Costa D, Abrahamowicz M, Lowensteyn I, Bernatsky S, Dritsa M, Fitzcharles MA, et al. A randomized clinical trial of an individualized home-based exercise programme for women with fibromyalgia. *Rheumatology (Oxford)* 2005;44:1422–7.
35. Crofford LJ, Appleton BE. Complementary and alternative therapies for fibromyalgia [review]. *Curr Rheumatol Rep* 2001;3:147–56.
36. Cymet TC. A practical approach to fibromyalgia. *J Natl Med Assoc* 2003;95:278–85.
37. Holdcraft LC, Assefi N, Buchwald D. Complementary and alternative medicine in fibromyalgia and related syndromes. *Best Pract Res Clin Rheumatol* 2003;17:667–83.
38. Lindberg DA. Integrative review of research related to meditation, spirituality, and the elderly. *Geriatr Nurs* 2005;26:372–7.
39. Baer R. Mindfulness training as a clinical intervention: a conceptual and empirical review. *Clin Psychol Sci Pract* 2003;10:125–43.
40. Bishop SR. What do we really know about mindfulness-based stress reduction? [published erratum appears in *Psychosom Med* 2002;64:449]. *Psychosom Med* 2002;64:71–83.
41. Grossman P, Niemann L, Schmidt S, Walach H. Mindfulness-based stress reduction and health benefits: a meta-analysis. *J Psychosom Res* 2004;57:35–43.
42. Canter PH, Ernst E. Insufficient evidence to conclude whether or not Transcendental Meditation decreases blood pressure: results of a systematic review of randomized clinical trials [review]. *J Hypertens* 2004;22:2049–54.
43. Krisanaprakornkit T, Krisanaprakornkit W, Piyavhatkul N, Laopaiboon M. Meditation therapy for anxiety disorders [review]. *Cochrane Database Syst Rev* 2006:CD004998.
44. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. *Gen Hosp Psychiatry* 1982;4:33–47.
45. Kabat-Zinn J. Mindfulness-based interventions in context: past, present, and future. *Clin Psychol Sci Pract* 2003;10:144–56.
46. Bishop SR, Lau M, Shapiro S, Carlson L, Anderson ND, Carmody J, et al. Mindfulness: a proposed operational definition. *Clin Psychol Sci Pract* 2004;11:230–41.
47. Shapiro SL, Carlson LE, Astin JA, Freedman B. Mechanisms of mindfulness. *J Clin Psychol* 2006;62:373–86.
48. Teasdale JD, Segal ZV, Williams JM, Ridgeway VA, Soulsby JM, Lau MA. Prevention of relapse/recurrence in major depression by mindfulness-based cognitive therapy. *J Consult Clin Psychol* 2000;68:615–23.
49. Kristeller JL, Hallett CB. An exploratory study of a meditation-based intervention for binge eating disorder. *J Health Psychol* 1999;4:357–63.
50. Tacon A, McComb J, Caldera Y, Randolph P. Mindfulness meditation, anxiety reduction, and heart disease: a pilot study. *Fam Community Health* 2003;26:25–33.
51. Carlson LE, Garland SN. Impact of mindfulness-based stress reduction (MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients. *Int J Behav Med* 2005;12:278–85.
52. Speca M, Carlson LE, Goodey E, Angen M. A randomized, wait-list controlled clinical trial: the effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosom Med* 2000;62:613–22.
53. Smith JE, Richardson J, Hoffman C, Pilkington K. Mindfulness-Based Stress Reduction as supportive therapy in cancer care: systematic review [published erratum appears in *J Adv Nurs* 2006;53:618]. *J Adv Nurs* 2005;52:315–27.
54. Reibel DK, Greeson JM, Brainard GC, Rosenzweig S. Mindfulness-based stress reduction and health-related quality of life in a heterogeneous patient population. *Gen Hosp Psychiatry* 2001;23:183–92.
55. Salmon P, Sephton S, Weissbecker I, Hoover K, Studts J. Mindfulness meditation in clinical practice. *Cog Behav Pract* 2004;11:434–46.
56. Astin JA. Stress reduction through mindfulness meditation: effects on psychological symptomatology, sense of control, and spiritual experiences. *Psychother Psychosom* 1997;66:97–106.
57. Shapiro SL, Schwartz GE, Bonner G. Effects of mindfulness-

- based stress reduction on medical and premedical students. *J Behav Med* 1998;21:581–99.
58. Segal ZV, Williams JM, Teasdale JD. *Mindfulness-based cognitive therapy for depression*. New York: Guilford Press; 2002.
 59. Goldenberg DL, Kaplan KH, Nadeau MG, Brodeur C, Smith S, Schmid CH. A controlled study of a stress-reduction, cognitive-behavioral treatment program in fibromyalgia. *J Musculoskelet Pain* 1994;2:53–66.
 60. Astin JA, Berman BM, Bausell B, Lee WL, Hochberg M, Forys KL. The efficacy of mindfulness meditation plus Qigong movement therapy in the treatment of fibromyalgia: a randomized controlled trial. *J Rheumatol* 2003;30:2257–62.
 61. Williams JB, Gibbon M, First MB, Spitzer RL, Davies M, Borus J, et al. The structured clinical interview for DSM-III-R (SCID). II. Multisite test-retest reliability. *Arch Gen Psychiatry* 1992;49:630–6.
 62. Kaplan KH, Goldenberg DL, Galvin-Nadeau M. The impact of a meditation-based stress reduction program on fibromyalgia. *Gen Hosp Psychiatry* 1993;15:284–9.
 63. Surawy C, Roberts J, Silver A. The effect of mindfulness training on mood and measures of fatigue, activity, and quality of life in patients with chronic fatigue syndrome on a hospital waiting list: a series of exploratory studies. *Behav Cogn Psychother* 2005;33:103–9.
 64. Kabat-Zinn J. *Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness*. New York: Delta; 1990.
 65. Santorelli S, Kabat-Zinn J. *Mindfulness-based stress reduction professional training resource manual*. Worcester (MA): The Center for Mindfulness in Medicine, Healthcare and Society; 2002.
 66. Burckhardt CS, Clark SR, Bennet RM. The fibromyalgia impact questionnaire: development and validation. *J Rheumatol* 1991;18:728–33.
 67. Callahan LF, Brooks RH, Summey JA, Pincus T. Quantitative pain assessment for routine care of rheumatoid arthritis patients, using a pain scale based on activities of daily living and a visual analog pain scale. *Arthritis Rheum* 1987;30:630–6.
 68. Douglass AB, Bornstein R, Nino-Murcia G, Keenan S, Miles L, Zarcone VP Jr, et al. The Sleep Disorders Questionnaire. I. Creation and multivariate structure of the SDQ. *Sleep* 1994;17:160–7.
 69. Beck AT, Steer RA, Garbin MG. Psychometric properties of the Beck Depression Inventory: twenty-five years of evaluation. *Clin Psychol Review* 1988;8:77–100.
 70. Peck JR, Smith TW, Ward JR, Milano R. Disability and depression in rheumatoid arthritis: a multi-trait, multi-method investigation. *Arthritis Rheum* 1989;32:1100–6.
 71. Pledger G. Basic statistics: importance of adherence. *J Clin Res Pharmacoevidemiology* 1992;6:77–81.
 72. Friedman L, Furberg C, DeMers D. *Fundamentals of clinical trials*. 3rd ed. New York: Springer-Verlag; 1998.
 73. Lachin JM. Statistical considerations in the intent-to-treat principle [published erratum appears in *Control Clin Trials* 2000;21:526]. *Control Clin Trials* 2000;21:167–89.
 74. Gibbons RD, Hedeker D, Elkin I, Waternaux C, Kraemer HC, Greenhouse JB, et al. Some conceptual and statistical issues in analysis of longitudinal psychiatric data: application to the NIMH treatment of Depression Collaborative Research Program dataset. *Arch Gen Psychiatry* 1993;50:739–50.
 75. SPSS. *SPSS Base 14.0 for Windows user's guide*. Chicago: SPSS, Inc.; 2005.
 76. Moher D, Schulz K, Altman D, and the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials 2001. *JAMA* 2001;285:1987–91.
 77. Ma SH, Teasdale JD. Mindfulness-based cognitive therapy for depression: replication and exploration of differential relapse prevention effects. *J Consult Clin Psychol* 2004;72:31–40.
 78. Shapiro SL, Bootzin RR, Figueredo AJ, Lopez AM, Schwartz GE. The efficacy of mindfulness-based stress reduction in the treatment of sleep disturbance in women with breast cancer: an exploratory study. *J Psychosom Res* 2003;54:85–91.
 79. Kabat-Zinn J, Wheeler E, Light T, Skillings A, Scharf MJ, Cropley TG, et al. Influence of a mindfulness meditation-based stress reduction intervention on rates of skin clearing in patients with moderate to severe psoriasis undergoing phototherapy (UVB) and photochemotherapy (PUVA). *Psychosom Med* 1998;60:625–32.
 80. Robinson FP, Mathews HL, Witek-Janusek L. Psycho-endocrine-immune response to mindfulness-based stress reduction in individuals infected with the human immunodeficiency virus: a quasiexperimental study. *J Altern Complement Med* 2003;9:683–94.
 81. Salmon PG, Santorelli SF, Kabat-Zinn J. Intervention elements promoting adherence to mindfulness-based stress reduction programs in the clinical behavioral medicine setting. In: Shumaker SA, Schron EB, Ockene JK, McBee WL, editors. *The handbook of health behavior change*. 2nd ed. New York: Springer Publishing Co, Inc; 1998. p. 239–66.
 82. Carlson LE, Ursuliak Z, Goodey E, Angen M, Specia M. The effects of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients: 6-month follow-up. *Support Care Cancer* 2001;9:112–23.
 83. Giesecke T, Gracely RH, Williams DA, Geisser ME, Petzke FW, Clauw DJ. The relationship between depression, clinical pain, and experimental pain in a chronic pain cohort. *Arthritis Rheum* 2005;52:1577–84.
 84. Davidson RJ, Kabat-Zinn J, Schumacher J, Rosenkranz M, Muller D, Santorelli SF, et al. Alterations in brain and immune function produced by mindfulness meditation. *Psychosom Med* 2003;65:564–70.
 85. Weissbecker I, Salmon P, Studts JL, Floyd AR, Dedert EA, Sephton SE. Mindfulness-Based Stress Reduction and sense of coherence among women with fibromyalgia. *J Clin Psychol Med Settings* 2002;9:297–307.
 86. Weiss M, Nordlie JW, Siegel EP. Mindfulness-based stress reduction as an adjunct to outpatient psychotherapy. *Psychother Psychosom* 2005;74:108–12.
 87. Baer RA, Smith GT, Hopkins J, Krietemeyer J, Toney L. Using self-report assessment methods to explore facets of mindfulness. *Assessment* 2006;13:27–45.
 88. Walsh R, Shapiro SL. The meeting of meditative disciplines and Western psychology: a mutually enriching dialogue [review]. *Am Psychol* 2006;61:227–39.