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ORIGINAL ARTICLE

Effect of Mindfulness-Based Stress Reduction in Rheumatoid Arthritis Patients

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Objective. **To assess the effect of a meditation training program, Mindfulness-Based Stress Reduction (MBSR), on depressive symptoms, psychological status, and disease activity in patients with rheumatoid arthritis (RA) through a randomized, waitlist-controlled pilot study.**

Methods. **Participants were randomized to either an MBSR group, where they attended an 8-week course and 4-month maintenance program, or to a waitlist control group, where they attended all assessment visits and received MBSR free of charge after study end. Participants received usual care from their rheumatologists throughout the trial. Self-report questionnaires were used to evaluate depressive symptoms, psychological distress, well-being, and mindfulness. Evaluation of RA disease activity (by Disease Activity Score in 28 joints) included examination by a physician masked to treatment status. Adjusted means and mean changes in outcomes were estimated in mixed model repeated measures analyses.**

Results. **Sixty-three participants were randomized: 31 to MBSR and 32 to control. At 2 months, there were no statistically significant differences between groups in any outcomes. At 6 months, there was significant improvement in psychological distress and well-being ($P = 0.04$ and $P = 0.03$, respectively), and marginally significant improvement in depressive symptoms and mindfulness ($P = 0.08$ and $P = 0.09$, respectively). There was a 35% reduction in psychological distress among those treated. The intervention had no impact on RA disease activity.**

Conclusion. **An 8-week MBSR class was not associated with change in depressive symptoms or other outcomes at 2-month followup. Significant improvements in psychological distress and well-being were observed following MBSR plus a 4-month program of continued reinforcement. Mindfulness meditation may complement medical disease management by improving psychological distress and strengthening well-being in patients with RA.**

KEY WORDS. Rheumatoid arthritis; Meditation; Psychological distress; Depressive symptoms; Mindfulness; Mindfulness-Based Stress Reduction program; DAS28.

INTRODUCTION

Meditation has been a practice of contemplative traditions for centuries. The study of its therapeutic properties has occurred more recently, with investigations suggesting benefits ranging from reduced cardiovascular risk factors to improved psychological status (1,2). Rheumatoid arthritis (RA) is accompanied by increased risk of various forms of psychological distress (3). Conservative estimates indicate a 2-fold risk of depressive symptoms compared with the healthy population (4,5), accompanied by increased health care utilization (6). Increasingly, patients with RA are turning to complementary and alternative therapies (7), among which meditation may hold promise in addressing the emotional strain of RA. The question considered in this study is whether a meditation-based interven-

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tion would effectively improve depressive symptoms in patients with RA, and whether disease activity, psychological distress, well-being, and mindfulness would be improved by the program.

The Mindfulness-Based Stress Reduction (MBSR) program is a meditation training course developed by Dr. Kabat-Zinn and colleagues at the University of Massachusetts Medical School (8). "Mindfulness" is defined as moment-to-moment nonjudgmental attention and awareness actively cultivated and developed through meditation (9). MBSR teaches participants to notice and relate differently to thoughts and emotions, with a sense of compassion for self and others underlying the endeavor. By continually bringing the mind back to the present moment, mindfulness meditation is thought to increase clarity, calmness, and well-being. A number of descriptive and controlled studies have provided evidence that MBSR leads to improvement of various measures of psychological symptoms in patients with chronic pain (8,10,11), anxiety disorders (12,13), fibromyalgia (14–16), cancer (17–21), multiple sclerosis (22), and in recovery from organ transplant (23,24). MBSR has been associated with reductions in depressive symptoms (12,17,19,23,25,26) and has been shown to significantly reduce relapse among patients in remission for major depressive disorder (27,28). However, prior to our current study, there have been no studies of the effect of MBSR on depressive symptoms among patients with RA.

To assess this approach in the context of RA, we conducted the Mindfulness Intervention for Rheumatoid Arthritis (MIRA) study, a randomized, waitlist-controlled pilot study of MBSR. The main outcome of the MIRA study was change in depressive symptoms, with secondary outcomes of change in psychological distress, well-being, mindfulness, and RA disease activity.

PATIENTS AND METHODS

Patients. A sample size (n = 80) was calculated assuming an α error of 0.05, a β error of 0.20, an effect size of 0.70, and accounting for an 18% noncompletion rate, all using baseline means and standard deviations estimated from the RA and MBSR literature. Adult patients with RA were recruited through advertisements in Baltimore newspapers, presentations to rheumatologists, presentations at community health fairs, and informational flyers widely distributed through the Maryland Chapter of the Arthritis Foundation. Respondents were screened by telephone and, if able and eligible, invited to attend the baseline session. Inclusion criteria were a physician's diagnosis of RA, age $\geq$18 years, and, at baseline assessment, not in remission of RA according to criteria established by the American College of Rheumatology (formerly the American Rheumatism Association) (29). Exclusion criteria included major psychiatric illness, active alcohol or drug dependency, diagnosis of fibromyalgia, inability to attend study sessions, concurrent participation in another clinical trial, and scheduled major surgery. All patients received their prescribed medications and were under the regular care of their rheumatologists throughout the study.

Procedure. Participants deemed eligible following baseline assessment were randomly assigned to either the intervention (MBSR) group or the waitlist (control) group. Those in the intervention group participated in the MBSR class for 8 weeks, after which all participants returned for a 2-month followup visit. The intervention continued with participants attending 3 refresher classes over the following 4 months, with the final assessment made 6 months postbaseline. Participants in the waitlist control group were offered MBSR free of charge at the end of the study. Two cohorts of participants took part: cohort I (18 MBSR members, 18 controls) was conducted from March through September in 2004 and cohort II (13 MBSR members, 14 controls) was conducted from September 2004 through March 2005.

Randomization was assigned by a computer program and carried out by the research director, who had no patient contact. The general features of the assignment process were as outlined by Meinert (30), and included a documented, reproducible generation scheme. Allocation codes were not assigned until eligibility was determined, consent obtained, and baseline data collected. The assignment schedule involved a fixed allocation ratio of 1:1 treatment to control participants, stratified on antidepressant medication status (current prescription or not), using random treatment assignment within randomly selected block sizes to force balance within antidepressant categories.

RA disease activity was evaluated by physical examination and blood test, and psychological outcomes were assessed by self-report questionnaires. Both sets of data were collected at baseline, 2-month, and 6-month assessment points. Participants could submit self-report questionnaires by mail if they were unable to attend assessment visits, but the RA disease evaluation required their physical presence.

Adverse events were monitored at each visit and were reported in accordance with procedures of the University of Maryland Human Research Protections Office, which approved the protocol.

Outcome measures. The Symptom Checklist-90-Revised (SCL-90-R) was used to evaluate depressive symptoms and psychological distress. The SCL-90-R is a self-report questionnaire with demonstrated reliability and validity (31) that has been used previously in several studies of MBSR to measure psychological status (8,10–12,14,26,32). The 90-question instrument is divided into 9 subscales, including depressive symptoms. One summary measure, the general severity index (GSI), is a measure of overall psychological distress. The total scale scores on both the depressive symptoms scale and GSI range from 0–4, with higher values indicating greater symptom severity (31).

RA disease status was assessed by the Disease Activity Score in 28 joints (DAS28), a continuous measure reflecting the number of tender and swollen joints, erythrocyte sedimentation rate, and patient's assessment of disease on a 100-mm visual analog scale (33). The score ranges from 0–10, with higher scores indicating greater disease activ-

ity. Two physicians conducted the tender and swollen joint assessments, both blinded to treatment status; each physician conducted all assessments for 1 of the 2 cohorts. The Seditainer assay (Becton-Dickinson, Franklin Lakes, NJ) was used to evaluate erythrocyte sedimentation rate, with blood technicians blinded to treatment status.

Well-being was measured by the Psychological Well-Being Scales (34). This instrument measures qualities of positive affect associated with successful life experience in the face of difficult circumstances (35). The questionnaire results in scores for 6 dimensions. A summary score combining all dimensions was used, ranging from 42–252, with higher scores indicating increased well-being.

The concept of mindfulness is integral to MBSR. The Mindfulness Attention Awareness Scale (MAAS) was created to assess the state of mindfulness by evaluating one of its core characteristics: attention to what is taking place in the present (36). The range of the MAAS score is 1–6, with higher scores indicating greater mindfulness.

Psychological intervention. The MBSR course was 8 weeks in length, with participants meeting once weekly for 2.5 hours, and also attending a full-day retreat. Classes consisted of conceptual training in mindfulness, discussions of its application in daily life, and experiential training in meditation and gentle yoga. Meditation was introduced in 4 formats: sitting meditation using the breath as an anchor of attention, sitting meditation characterized by a state of open awareness, progressive body relaxation meditation, and contemplative walking. Yoga poses were tailored to accommodate patients with RA. Participants were asked to practice at home 45 minutes a day, 6 days a week, aided by an audio CD. Three certified MBSR teachers taught the classes, all trained through the Center for Mindfulness at the University of Massachusetts Medical School. Standard course materials were used. Intervention participants were asked to document the number of minutes spent daily on each practice at home in the first 2 months.

Statistical analysis. To assess the effect of the intervention, adjusted means and a priori-defined outcomes of adjusted mean change from baseline at 2 and 6 months were estimated in 2 (treatment group) × 2 (time) mixed model repeated measures regression analyses, with MBSR and control conditions compared using group contrasts, as implemented by the MIXED procedure in SAS version 9.1 (SAS Institute; Cary, NC; 2003). The effect of the 8-week MBSR class as a stand-alone intervention was evaluated by the response at 2 months, and the effect of the class plus 4-month maintenance program was estimated by results at 6 months. Means were adjusted for confounding variables, which were those that changed the group (intervention/control) β coefficient by more than 10% and remained significant when included in the multivariable model. Analyses were carried out on an intent-to-treat basis, with all available participant data included, regardless of compliance to protocol (37). To evaluate the effect of missing data, all models were rerun with missing data imputed as last value carried forward. Because results using imputed data were similar to those using nonimputed data, we elected to use the latter in the final analyses. Factors associated with the intervention, such as class attendance and the sum and frequency of practice time over the first 2 months, were assessed within the treatment group alone, using linear regression models for outcomes at 2 months and 6 months separately.

RESULTS

The study flowchart (based on the Consolidated Standards of Reporting Trials recommendations) is shown in Figure 1 (38). Telephone screenings were carried out with 332 persons who responded to advertisements. Potential participants were deemed ineligible for the following reasons: did not have RA (n = 57), did not return telephone calls (n = 71), scheduling problems (n = 100), major illness/upcoming surgery (n = 33), in remission at baseline (n = 1), and missed baseline appointment (n = 7). The time commitment required for the study appeared to be an issue in recruitment, with scheduling problems being the most common reason for ineligibility. Therefore, those who eventually enrolled may not be representative of the overall population of patients with RA in terms of schedule availability or interest. Sixty-three people were eligible and were randomized to either MBSR (n = 31) or to the control group (n = 32). Noncompleters (3 in the MBSR group, and 2 in the control group) were those for whom no data were available at the 6-month visit. The reasons for leaving the study were initiation of chemotherapy (n = 1), relocation away from area (n = 2), and scheduling problem

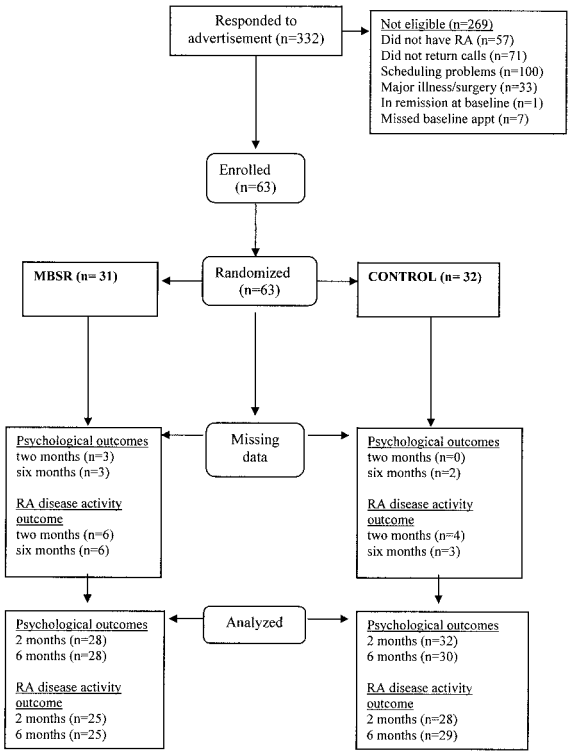

Figure 1. Flowchart of the Mindfulness Intervention for Rheumatoid Arthritis study (n = 63). RA = rheumatoid arthritis; MBSR = Mindfulness-Based Stress Reduction group.

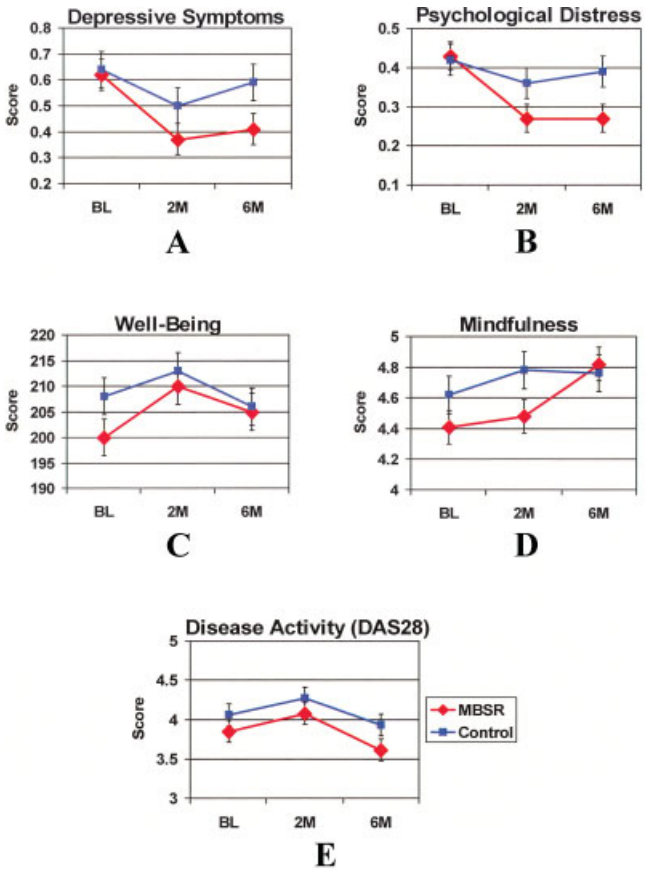

Figure 2. Unadjusted means at baseline (BL), 2 months (2M), and 6 months (6M) in the Mindfulness Intervention for Rheumatoid Arthritis study (n = 63). **A,** Depressive symptoms, **B,** psychological distress, **C,** well-being, **D,** mindfulness, **E,** disease activity (assessed by the Disease Activity Score in 28 joints [DAS28]). Error bars denote standard error. MBSR = Mindfulness-Based Stress Reduction group.

(n = 2). There were no significant differences between completers and noncompleters with respect to baseline psychological or disease activity outcomes (data not shown). The unadjusted means by visit of each outcome are show in Figure 2.

Baseline analyses. Baseline characteristics are described in Table 1. Most of the participants were female, white, married, had a family income above $50,000 a year, and possessed a college degree or higher. The mean age was 54 years. Although the proportion of those taking antidepressants upon enrollment was equal by virtue of the stratified randomization, the proportion of individuals having a history of clinical depression was not. By chance, all such individuals were assigned to the control group (Fisher's exact test $P = 0.01$). This variable was identified as a confounder; thus, all outcome models were adjusted for history of clinical depression. The difference in mean duration of RA between the 2 groups was marginally significant, and the proportions of those taking disease-modifying antirheumatic drugs appeared to differ, if not statistically so. These 2 variables were evaluated in all models and found not to be confounders. There were no other statistically significant differences between groups.

Two-month outcome. Results at 2 months are shown in Table 2. There were no significant differences between groups in any of the outcomes at 2 months.

Six-month outcome. Results at 6 months are shown in Table 3. The model for depressive symptoms had a marginally significant group × time interaction (F = 3.16, 56 df, $P = 0.08$), suggesting a trend toward treatment effect over 6 months. There was a significant impact of the intervention on psychological distress (F = 4.02, 56 df, $P = 0.04$). Although reductions of similar magnitude were observed for depressive symptoms and psychological distress, only the latter was statistically significant; this is likely due to the smaller variance observed for psychological distress. There also was a significant impact on well-being (F = 5.23, 56 df, $P = 0.03$). The improvement in mindfulness was marginally significant (F = 2.96, 56 df, $P = 0.09$). No impact of the intervention was observed on RA disease activity (F = 0.50, 52 df, $P = 0.48$).

Practice variables. With respect to the relation between the practice of MBSR and outcomes within the treatment group alone, neither overall sum of practice time nor sum of time spent on a specific practice predicted change in any measure by 2 months. However, frequency was important. From baseline to 2 months, each 1-day increase in practice was associated with improvement of −0.03 in depressive symptoms ($P = 0.01$) and −0.01 in psychological distress ($P = 0.09$). These small changes were associated with larger improvements when multiplied, such that practicing MBSR 40 versus 30 days, for example, was associated on average with improvement of −0.10 in psychological distress, or 23% of the baseline mean. At 6 months, no MBSR class variable was associated with change, except having been taught by 1 specific teacher of the 3 who participated. Being taught by this teacher for the course and maintenance program was associated with improvement of −0.30 ($P = 0.03$) in depressive symptoms and −0.15 ($P = 0.05$) in psychological distress when compared with the other 2 teachers.

Compliance to MBSR class attendance and practice was high. Of a total of 8 classes, the median (interquartile range [IQR]) was 8 (6–8). Participant logs indicated the mean ± SD total home practice time was 47.12 ± 21.26 hours, or just over an hour a day for 6 days a week. Of 49 possible days during which practice could have been undertaken, the median (IQR) was 42 (40–48) (data not shown).

At the 6-month interview, 85.7% of MBSR participants present reported undertaking MBSR practices in the 2 weeks before the visit, indicating continued engagement with the program. These MBSR participants reported receiving very high value from using the mindfulness techniques in everyday life situations (71.4%), learning/personal growth (85.7%), socializing in class (67.9%), and meeting study staff (78.6%) (data not shown). There were no study-related adverse events reported at any time.

DISCUSSION

We conducted a pilot study with a randomized, waitlist-controlled design to assess an intervention comprising an

Table 1. Baseline characteristics of 63 patients participating in the Mindfulness Intervention in Rheumatoid Arthritis study*

Characteristic	MBSR group (n = 31)	Control group (n = 32)	*P*†
Female	26 (84)	29 (91)	0.47
White	22 (71)	25 (78)	0.57
College degree or higher	17 (55)	22 (69)	0.30
Married	18 (58)	22 (69)	0.44
Family income ≥$50,000	17 (55)	22 (69)	0.31
History of clinical depression	0 (0)	7 (22)	0.01
Age, mean ± SD years	56 ± 9	53 ± 11	0.23
Duration of RA, mean ± SD, years	6 ± 7	11 ± 12	0.06
Pain past week, mean ± SD (on 0–100 scale)	42 ± 25	43 ± 18	0.80
RA medications			
DMARDs	27 (87)	22 (69)	0.13
Corticosteroid	13 (42)	12 (38)	0.80
Biologic response modifiers	6 (19)	5 (16)	0.75
NSAIDs‡	8 (26)	8 (25)	1.00
Baseline outcome scores, mean ± SD			
Depression	0.62 ± 0.51	0.64 ± 0.54	0.84
Psychological distress	0.43 ± 0.34	0.42 ± 0.31	0.91
Well-being	199.71 ± 27.96	207.75 ± 28.60	0.26
Mindfulness	4.41 ± 0.93	4.62 ± 0.95	0.36
RA disease activity (DAS28)	3.85 ± 1.10	4.06 ± 1.19	0.47

* Values are the number (percentage) unless otherwise indicated. MBSR = Mindfulness-Based Stress Reduction meditation; DMARD = disease-modifying antirheumatic drug; NSAID = nonsteroidal anti-inflammatory drug; RA = rheumatoid arthritis; DAS 28 = Disease Activity Score in 28 joints.
† Frequencies tested by Fisher's exact test, means by Student's *t*-test.
‡ Including cyclooxygenase 2 inhibitors.

Table 2. Adjusted mean outcomes at baseline and 2 months of 63 patients participating in the Mindfulness Intervention in Rheumatoid Arthritis study*

Outcome	Adjusted mean ± SE†			Group × time interaction	
	MBSR	Control	*P*	F (df)	*P*
Depressive symptoms‡				0.43 (58)	0.52
Baseline	0.66 ± 0.09	0.56 ± 0.09	0.44		
2 months	0.43 ± 0.08	0.40 ± 0.08	0.78		
Change	−0.23 ± 0.07	−0.16 ± 0.07	0.52		
Psychological distress‡				1.27 (58)	0.27
Baseline	0.44 ± 0.06	0.37 ± 0.06	0.42		
2 months	0.30 ± 0.05	0.30 ± 0.05	0.97		
Change	−0.14 ± 0.04	−0.08 ± 0.04	0.27		
Well-being§				2.23 (57)	0.14
Baseline	198.18 ± 4.98	210.47 ± 4.88	0.09		
2 months	207.24 ± 5.06	213.47 ± 4.91	0.39		
Change	9.08 ± 2.93	2.99 ± 2.82	0.14		
Mindfulness§				0.33 (58)	0.57
Baseline	4.33 ± 0.17	4.73 ± 0.17	0.10		
2 months	4.34 ± 0.16	4.85 ± 0.15	0.03		
Change	0.01 ± 0.14	0.12 ± 0.13	0.57		
DAS28‡				1.04 (51)	0.31
Baseline	3.93 ± 0.19	4.04 ± 0.18	0.67		
2 months	4.14 ± 0.20	4.02 ± 0.19	0.68		
Change	0.22 ± 0.17	−0.02 ± 0.16	0.31		

* MBSR = Mindfulness-Based Stress Reduction meditation group; DAS28 = Disease Activity Score in 28 joints.
† By mixed model repeated measures analyses, adjusted for history of clinical depression.
‡ Negative change indicates improvement.
§ Positive change indicates improvement.

Table 3. Adjusted mean outcomes at baseline and 6 months of 63 patients participating in the Mindfulness Intervention in Rheumatoid Arthritis study*

Outcome	Adjusted mean ± SE†			Group × time interaction	
	MBSR	Control	*P*	F (df)	*P*
Depressive symptoms‡				3.16 (56)	0.08
Baseline	0.70 ± 0.09	0.57 ± 0.09	0.32		
6 months	0.44 ± 0.08	0.51 ± 0.08	0.56		
Change	−0.26 ± 0.08	−0.06 ± 0.08	0.08		
Psychological distress‡				4.02 (56)	0.04
Baseline	0.48 ± 0.06	0.38 ± 0.06	0.23		
6 months	0.31 ± 0.05	0.34 ± 0.05	0.67		
Change	−0.17 ± 0.05	−0.03 ± 0.05	0.04		
Well-being§				5.23 (56)	0.03
Baseline	197.24 ± 5.13	212.08 ± 5.09	0.05		
6 months	202.79 ± 5.25	206.60 ± 5.15	0.62		
Change	5.55 ± 3.44	−5.47 ± 3.38	0.03		
Mindfulness§				2.96 (56)	0.09
Baseline	4.31 ± 0.17	4.74 ± 0.17	0.08		
6 months	4.76 ± 0.14	4.83 ± 0.14	0.71		
Change	0.45 ± 0.15	0.09 ± 0.14	0.09		
DAS28‡				0.59 (52)	0.45
Baseline	3.92 ± 0.20	4.02 ± 0.21	0.72		
6 months	3.62 ± 0.21	3.90 ± 0.18	0.34		
Change	−0.30 ± 0.17	−0.12 ± 0.16	0.45		

* MBSR = Mindfulness-Based Stress Reduction meditation group; DAS28 = Disease Activity Score in 28 joints.
† By mixed model repeated measures analyses, adjusted for history of clinical depression.
‡ Negative change indicates improvement.
§ Positive change indicates improvement.

8-week MBSR class and a 4-month maintenance program. We looked at the impact of this intervention on depressive symptoms, psychological distress, well-being, mindfulness, and disease activity in patients with RA. Significant effects associated with the intervention were observed by 6 months in psychological distress and well-being, with marginally significant improvements seen at that time in depressive symptoms and mindfulness. To our knowledge, this is the first study of MBSR or meditation to be conducted with patients with RA. The intervention was safe and compliance to study protocol was high, with participants reportedly receiving high value from the intervention. The design of the trial allowed us to distinguish patterns relating to real life applications of MBSR, with changes observed at 2 months reflecting those following a typical MBSR course, and those at 6 months suggesting changes after the class plus continued involvement with mindfulness practices over a longer period.

Despite overall promising results, it is striking that there were no significant differences between the MBSR and control groups in any outcome at 2 months immediately postintervention. These results are atypical for 8-week MBSR interventions, which tend to reliably reduce negative emotions measured in a variety of ways (psychological distress, depressive symptoms, anxiety, stress, etc.) (2). The reason for the lack of effect at 2 months is unclear. There was likely a floor effect in our study, with participants being not very poorly off in terms of depressive symptoms or psychological distress at the outset. The mean baseline level of depressive symptoms was lower than reported in the RA literature; in one study, a similar sample of patients with RA evaluated with the same instrument had a psychological distress baseline mean 72% higher than in our study (39). Mean baseline psychological distress in our study was 45% lower than that seen using the same instrument in previous MBSR studies of patients with chronic pain (8). This may have reduced our ability to detect an effect.

Additionally, both the control group and the intervention group improved at 2 months with respect to depressive symptoms, psychological distress, well-being, and mindfulness, rendering group comparisons uniformly nonsignificant. By 6 months, however, gains realized in the control group had largely disappeared, while those in the MBSR group were maintained through study end. The divergence of trajectories after 2 months suggests different mechanisms underlying the later changes. MBSR participants reported continued practice of mindfulness through 6 months, while maintaining or continuing to improve in psychological outcomes. With controls returning essentially to baseline levels by study end, their 2-month improvements appear to have been placebo or Hawthorne effect-related. The opportunity to observe group comparisons from a 6-month perspective allowed us to see the sustained influence of mindfulness meditation above and beyond what was, perhaps, the nonenduring influence of being in a clinical trial or receiving study staff attention. The importance of employing a controlled design when evaluating an intervention such as this is highlighted by these findings.

By study end, the MBSR group achieved a significant 35% reduction in psychological distress. The net improvement, above and beyond that of the control group, was a reduction of 0.14 in the GSI score. This translates into a change of 12.6 points among the 90 symptoms comprising the GSI. In terms of clinical significance, this is equivalent to approximately 6 symptoms that were "extremely" distressing before the intervention becoming "moderately" so thereafter, 3 symptoms that were "extremely" distressing becoming "a little bit" so, or 12 symptoms that were "a little bit" distressing disappearing altogether by study end. In terms of the population norms established for the GSI (31), the intervention group's adjusted mean at baseline indicated psychological distress that was, on average, greater than 76% of the population. After the 6-month intervention, this was reduced to psychological distress that was, on average, greater than 58% of the population, or closer to midlevel. In spite of this improvement, at no time did the mean psychological distress level approach that which has been established to identify psychiatric disorder in nonpsychiatric populations (31). Rather, the intervention may have helped ordinary participants cope with somewhat elevated intensity of distress.

A puzzling finding in our study was the lack of difference between groups in the outcome of mindfulness at 2 months, immediately following the MBSR class. One explanation may be insight gained through the course about the extent to which one lives without mindfulness, operating on auto-pilot in daily actions. Because the MAAS instrument includes assessment of compulsive or automatic behaviors (36), initially unchanged scores in MBSR may reflect keener self observation. However, continued practice may have increased mindfulness, with the improvement marginally significant by study end. The extended time period needed to shift MAAS scores in this population may point to a need for longer-term studies of mindfulness practices.

To our knowledge, this is the only randomized study to examine a 6-month MBSR intervention. Another study evaluated cancer patients before and after MBSR and again at 6 months (18). Significant reductions in mood disturbance and symptoms of stress were observed following the intervention, and benefits maintained to 6 months. However, few studies of MBSR have included longer-term followup and none have used a randomized design to asses a maintenance period of ongoing practice reinforcement.

In our study, we found that sum of practice time was not related to outcome change. A similar lack of correlation has been seen in some MBSR studies (20,23,40), while a positive relation has been observed elsewhere (17,21). In contrast, frequency of practice was associated with improvement at 2 months in our study, suggesting that regular practice, regardless of duration, is important. However, neither quantity nor frequency of practice the first 2 months was related to change by 6 months; at that time, the only predictive variable was having been taught by one particular MBSR teacher. This teacher was the most experienced, having had over 20 years of meditation practice and 10 years of teaching experience. However, because this teacher was responsible for all students in the first cohort, it is impossible to rule out a cohort effect. Cohort I showed greater initial distress than cohort II, and had higher mean psychological symptoms at baseline. This raises the question of what role teaching and personal meditation experience have in engendering change within the context of MBSR, and whether the intervention itself has greater efficacy among those more highly distressed at the outset.

There was no impact of the MBSR intervention on RA disease activity, a finding consistent with other studies of psychological interventions in this population. In a randomized study of stress reduction that did not involve meditation, no effect was seen in active joints using the Ritchie Articular Index, while a significant impact of the intervention was observed on increased coping and self efficacy (41). In a randomized trial of individually tailored cognitive behavioral therapy for patients with RA, no effect on disease activity (measured by the DAS28) was seen, despite a significant reduction in depression and fatigue (42). Another randomized trial of cognitive behavioral therapy saw an effect on depressive symptoms postintervention and at 6 months, which was accompanied by reduced active joints at 6 months but not immediately postintervention (43). As we found in our own study, it may prove difficult to shift overall RA disease activity, despite improvement in psychological outcomes. One exception to this may be found in a randomized trial that showed an effect on disease activity 4 months after writing about stressful experiences at baseline (44).

This study had limitations, primary among them a small sample size. Nonetheless, a study of 63 participants provided valuable data on feasibility and plausibility. Another limitation was a control group that did not receive equivalent attention. An alternative design would provide weekly meetings and home practice to controls, and future studies should include a sample sufficiently large to detect a difference between such interventions. In the case of our study, we speculated that with participants in waitlist control eventually receiving the program, dropouts would be minimized. This proved true, with 94% of the control group providing complete data. Finally, a floor effect might be avoided in future studies by implementing stricter inclusion criteria, requiring participants to be at higher states of psychological distress and RA disease activity at baseline.

This randomized, controlled pilot study is the first to test the MBSR intervention with patients with RA. The study demonstrated that for patients with RA under routine medical supervision, an 8-week MBSR class plus a 4-month maintenance program had beneficial effects, and that it was safe and appealing to participants. For doctors wishing to offer patients a complement to medical management, mindfulness meditation may offer hope for improving psychological distress and strengthening well-being in patients with RA.

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AUTHOR CONTRIBUTIONS

Dr. Pradhan 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. Pradhan, Baumgarten, Langenberg, Handwerger, Kaplan Gilpin, Magyari, Hochberg, Berman.

Acquisition of data. Pradhan, Baumgarten, Kaplan Gilpin, Magyari.

Analysis and interpretation of data. Pradhan, Langenberg, Handwerger, Hochberg, Berman.

Manuscript preparation. Pradhan, Baumgarten, Langenberg, Handwerger, Magyari, Hochberg, Berman.

Statistical analysis. Pradhan, Langenberg.

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