Original Investigation

Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back Pain
A Randomized Clinical Trial

Daniel C. Cherkin, PhD; Karen J. Sherman, PhD; Benjamin H. Balderson, PhD; Andrea J. Cook, PhD; Melissa L. Anderson, MS; Rene J. Hawkes, BS; Kelly E. Hansen, BS; Judith A. Turner, PhD

IMPORTANCE Mindfulness-based stress reduction (MBSR) has not been rigorously evaluated for young and middle-aged adults with chronic low back pain.

OBJECTIVE To evaluate the effectiveness for chronic low back pain of MBSR vs cognitive behavioral therapy (CBT) or usual care.

DESIGN, SETTING, AND PARTICIPANTS Randomized, interviewer-blind, clinical trial in an integrated health care system in Washington State of 342 adults aged 20 to 70 years with chronic low back pain enrolled between September 2012 and April 2014 and randomly assigned to receive MBSR (n = 116), CBT (n = 113), or usual care (n = 113).

INTERVENTIONS CBT (training to change pain-related thoughts and behaviors) and MBSR (training in mindfulness meditation and yoga) were delivered in 8 weekly 2-hour groups. Usual care included whatever care participants received.

MAIN OUTCOMES AND MEASURES Coprimary outcomes were the percentages of participants with clinically meaningful (≥30%) improvement from baseline in functional limitations (modified Roland Disability Questionnaire [RDQ]; range, 0-23) and in self-reported back pain bothersomeness (scale, 0-10) at 26 weeks. Outcomes were also assessed at 4, 8, and 52 weeks.

RESULTS There were 342 randomized participants, the mean (SD) [range] age was 49.3 (12.3) [20-70] years, 224 (65.7%) were women, mean duration of back pain was 7.3 years (range, 3 months-50 years), 123 (53.7%) attended 6 or more of the 8 sessions, 294 (86.0%) completed the study at 26 weeks, and 290 (84.8%) completed the study at 52 weeks. In intent-to-treat analyses at 26 weeks, the percentage of participants with clinically meaningful improvement on the RDQ was higher for those who received MBSR (60.5%) and CBT (57.7%) than for usual care (44.1%) (overall P = .04; relative risk [RR] for MBSR vs usual care, 1.37 [95% CI, 1.06-1.77]; RR for MBSR vs CBT, 0.95 [95% CI, 0.77-1.18]; and RR for CBT vs usual care, 1.31 [95% CI, 1.01-1.69]). The percentage of participants with clinically meaningful improvement in pain bothersomeness at 26 weeks was 43.6% in the MBSR group and 44.9% in the CBT group, vs 26.6% in the usual care group (overall P = .01; RR for MBSR vs usual care, 1.64 [95% CI, 1.15-2.34]; RR for MBSR vs CBT, 1.03 [95% CI, 0.78-1.36]; and RR for CBT vs usual care, 1.69 [95% CI, 1.18-2.41]). Findings for MBSR persisted with little change at 52 weeks for both primary outcomes.

CONCLUSIONS AND RELEVANCE Among adults with chronic low back pain, treatment with MBSR or CBT, compared with usual care, resulted in greater improvement in back pain and functional limitations at 26 weeks, with no significant differences in outcomes between MBSR and CBT. These findings suggest that MBSR may be an effective treatment option for patients with chronic low back pain.

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Author Video Interview and JAMA Report Video at jama.com

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Author Affiliations: Group Health Research Institute, Seattle, Washington (Cherkin, Sherman, Balderson, Cook, Anderson, Hawkes, Hansen); Department of Health Services, University of Washington, Seattle (Cherkin); Department of Family Medicine, University of Washington, Seattle (Cherkin); Department of Epidemiology, University of Washington, Seattle (Sherman); Department of Biostatistics, University of Washington, Seattle (Cook); Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle (Turner); Department of Rehabilitation Medicine, University of Washington, Seattle (Turner).

Corresponding Author: Daniel C. Cherkin, PhD, Group Health Research Institute, 1730 Minor Ave, Ste 1600, Seattle, WA 98101 (cherkin.d@ghc.org).

Low back pain is a leading cause of disability in the United States.[1] Despite numerous treatment options and greatly increased medical care resources devoted to this problem, the functional status of persons with back pain in the United States has deteriorated.[2,3] There is need for treatments with demonstrated effectiveness that are low risk and have potential for widespread availability.

Psychosocial factors play important roles in pain and associated physical and psychosocial disability.[4] In fact, 4 of the 8 nonpharmacologic treatments recommended for persistent back pain include mind-body components.[4] One of these, cognitive behavioral therapy (CBT), has demonstrated effectiveness for various chronic pain conditions[5-8] and is widely recommended for patients with chronic low back pain. However, patient access to CBT is limited. Mindfulness-based stress reduction (MBSR),[9] another mind-body approach, focuses on increasing awareness and acceptance of moment-to-moment experiences including physical discomfort and difficult emotions. MBSR is becoming increasingly popular and available in the United States. Thus, if demonstrated as beneficial for chronic low back pain, MBSR could offer another psychosocial treatment option for the large number of US residents with this condition. MBSR and other mindfulness-based interventions have been recognized as helpful for a range of conditions including chronic pain.[10-12] However, only 1 large randomized clinical trial (RCT) has evaluated MBSR for chronic low back pain,[13] and that trial was limited to older adults.

This RCT compared MBSR with CBT and with usual care. We hypothesized that adults with chronic low back pain randomized to receive MBSR would show greater short- and long-term improvement in back pain–related functional limitations, back pain bothersomeness, and other outcomes as compared with those randomized to usual care. We also hypothesized that MBSR would be superior to CBT because it includes yoga, which has been found to be effective in treating chronic low back pain.[14]

Methods

Study Design, Setting, and Participants

The Mind-Body Approaches to Pain (MAP) trial protocol has been previously published[15] and is shown in Supplement 1. The primary source of participants was Group Health, a large integrated health care system in Washington State. Letters describing the trial and inviting participation were mailed to Group Health members who met the electronic medical record inclusion/exclusion criteria and to random samples of residents in communities served by Group Health. Individuals who responded to the invitations were screened and enrolled by telephone (**Figure**). Potential participants were told that they would be randomized to receive one of "two different widely-used pain self-management programs that have been found helpful for reducing pain and making it easier to carry out daily activities" or to continued usual care plus $50. Those assigned to receive MBSR or CBT were not informed of their treatment allocation until they attended the first session. Participants were recruited from 6 cities in 10 separate waves.

Recruited individuals were 20 to 70 years of age with non-specific low back pain that persisted at least 3 months. Individuals with back pain associated with a specific diagnosis (eg, spinal stenosis), with compensation or litigation issues, who would have difficulty participating (eg, unable to speak English or unable to attend classes at the scheduled time and location), or who rated pain bothersomeness at less than 4 or pain interference with activities at less than 3 on 0- to 10-point scales were excluded. Inclusion and exclusion criteria were assessed using data from electronic medical records for the previous year (for Group Health enrollees) and screening interviews. Participants were enrolled between September 2012 and April 2014. Because of slow enrollment, after 99 participants were enrolled, exclusion was discontinued of individuals aged 64 to 70 years, Group Health members without recent visits for back pain, and patients with sciatica. The trial protocol was approved by the Group Health Human Subjects Review Committee (see trial protocol in Supplement 1). All participants provided oral informed consent for trial participation and written informed consent for participation in classes.
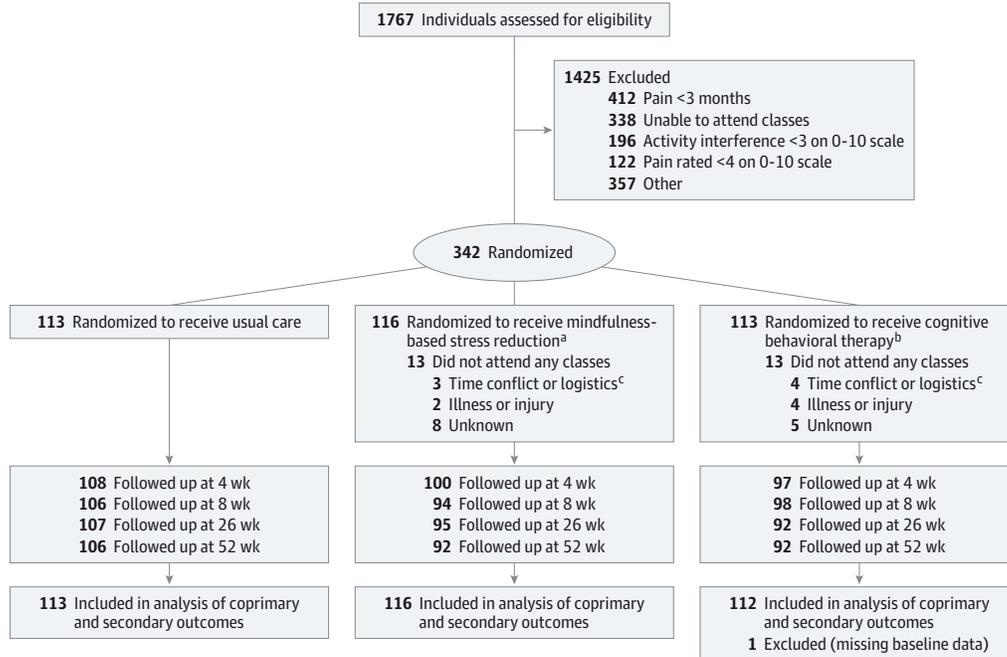
Randomization

Immediately after providing consent and completing the baseline assessment, participants were randomized in equal proportions to the MBSR, CBT, or usual care group. Randomization was stratified by the baseline score (≤12 vs ≥13 on a 0-23 scale) on the modified Roland Disability Questionnaire (RDQ)—one of the primary outcome measures.[16] Participants were randomized within these strata in blocks of 3, 6, or 9. The stratified randomization sequence was generated by the study biostatistician using R statistical software,[17] and the sequence was stored in the study recruitment database and concealed from study staff until randomization.

Interventions

All participants received any medical care they would normally receive. Those randomized to the usual care group received $50 but no MBSR training or CBT as part of the study and were free to seek whatever treatment, if any, they desired.

The interventions were comparable in format (group), duration (2 hours/week for 8 weeks, although the MBSR program also included an optional 6-hour retreat), frequency (weekly), and number of participants per group (see intervention details).[15] Each intervention was delivered according to a manualized protocol in which all instructors were trained. Participants in both interventions were given workbooks, audio CDs, and instructions for home practice (eg, meditation, body scan, and yoga in MBSR; relaxation and imagery in CBT). MBSR was delivered by 8 instructors with 5 to 29 years of MBSR experience. Six of the instructors received training from the Center for Mindfulness at the University of Massachusetts Medical School. CBT was delivered by 4 licensed PhD-level psychologists experienced in group and individual CBT for chronic pain. Checklists of treatment protocol components were completed by a research assistant at each session and reviewed weekly by a study investigator to verify that all treatment components were delivered. In addition, sessions were audio recorded and a study investigator monitored instructors'

Figure. Flow of Participants Through Trial Comparing Mindfulness-Based Stress Reduction With Cognitive Behavioral Therapy and Usual Care for Chronic Low Back Pain

a Of the 116 participants randomized to receive mindfulness-based stress reduction, 103 attended at least 1 class and 59 attended at least 6 classes. For those who attended at least 1 class, the median (interquartile range [IQR]) was 6 (3-7) classes per participant. Participants were recruited in 10 separate waves (median 12.5 [IQR, 7-16] participants per wave).

b Of the 113 participants randomized to receive cognitive behavioral therapy, 100 attended at least 1 class and 64 attended at least 6 classes. For those who

attended at least 1 class, the median (IQR) was 6 (3-7) classes per participant. Participants were recruited in 10 separate waves (median 13 [IQR, 5-14] participants per wave).

c Logistics, given as a reason for not attending any classes, specifically refers to transportation problems (no car or acceptable bus schedules) or obtaining child care during classes.

adherence to the protocol, either in person or via audio recording, for at least 1 session per group.

MBSR was modeled closely after the original MBSR program[9]—adapted from the 2009 MBSR instructor's manual[18] by a senior MBSR instructor. The MBSR program does not focus specifically on a particular condition such as pain. All classes included didactic content and mindfulness practice (body scan, yoga, meditation [attention to thoughts, emotions, and sensations in the present moment without trying to change them, sitting meditation with awareness of breathing, and walking meditation]).

The CBT protocol included CBT techniques most commonly applied and studied for chronic low back pain.[8,19-22] The intervention included (1) education about chronic pain, relationships between thoughts and emotional and physical reactions, sleep hygiene, relapse prevention, and maintenance of gains; and (2) instruction and practice in changing dysfunctional thoughts, setting and working toward behavioral goals, relaxation skills (abdominal breathing, progressive muscle relaxation, and guided imagery), activity pacing, and pain-coping strategies. Between-session activities included reading chapters of *The Pain Survival Guide: How to Reclaim Your Life*.[21] Mindfulness, meditation, and yoga techniques were proscribed in CBT; methods to challenge dysfunctional thoughts were proscribed in MBSR.

Follow-up

Trained interviewers, masked to treatment group, collected data by telephone at baseline (before randomization) and after randomization at weeks 4 (midtreatment), 8 (posttreatment), 26 (primary end point), and 52. Participants were compensated $20 for each interview.

Measures

Sociodemographic and back pain information was obtained at baseline (Table 1). All primary outcome measures were administered at each time point; secondary outcomes were assessed at all time points except 4 weeks.

Coprimary Outcomes

Back pain-related functional limitation was assessed by the RDQ[16] and modified to 23 (vs the original 24) items and to ask about the past week rather than today only. Higher scores (range 0-23) indicate greater functional limitation. The original RDQ has demonstrated reliability, validity, and sensitivity to clinical change.[23] Back pain bothersomeness in the past week was measured on a 0 to 10 scale (0 indicates not at all bothersome; 10 indicates extremely bothersome). Primary analyses of this study examined the percentages of participants with clinically meaningful improvement (≥30% improvement from baseline)[24] on each measure. Secondary

Table 1. Baseline Characteristics of Participants by Treatment Group

	No. (%)			
	All (n = 341)	Usual Care (n = 113)	Mindfulness-Based Stress Reduction (n = 116)	Cognitive Behavioral Therapy (n = 112)
Sociodemographic Characteristics				
Age, mean (SD), y	49.3 (12.3)	48.9 (12.5)	50.0 (11.9)	49.1 (12.6)
Women	224 (65.7)	87 (77.0)	71 (61.2)	66 (58.9)
Education				
≤High school	26 (7.6)	5 (4.4)	14 (12.1)	7 (6.3)
Some college or vocational school	114 (33.4)	37 (32.7)	41 (35.3)	36 (32.1)
College graduate	201 (58.9)	71 (62.8)	61 (52.6)	69 (61.6)
Race				
White	278 (82.5)	88 (80.0)	97 (84.4)	93 (83.0)
Asian	13 (3.9)	3 (2.7)	4 (3.5)	6 (5.4)
African American	11 (3.3)	3 (2.7)	4 (3.5)	4 (3.6)
Other[a]	35 (10.4)	16 (14.6)	10 (8.7)	9 (8.0)
Hispanic ethnicity	23 (6.8)	8 (7.1)	5 (4.3)	10 (8.9)
Married or living as married	249 (73.0)	79 (69.9)	85 (73.3)	85 (75.9)
Annual family income > US $55 000	206 (62.6)	72 (66.1)	66 (58.4)	68 (63.6)
Employed	263 (77.1)	89 (78.8)	87 (75.0)	87 (77.7)
Back Pain History and Expectations				
≥1 Year since 1 week without LBP	269 (78.9)	86 (76.1)	93 (80.2)	90 (80.4)
Had spinal injection for LBP	8 (2.7)	3 (3.1)	3 (3.0)	2 (2.0)
Currently reporting "a lot of pain" in site other than back	100 (29.3)	35 (31.0)	34 (29.3)	31 (27.7)
Back pain in last 180 days, median (IQR), d	160 (100-180)	160 (100-180)	170 (115-180)	160 (100-180)
Expects LBP to "be much better or gone" in 1 year	101 (29.8)	36 (31.9)	34 (29.6)	31 (27.9)
Expects LBP self-management program will be helpful, mean (SD), score[b]	7.5 (1.9)	7.8 (1.8)	7.6 (2.0)	7.2 (1.8)
Baseline Measures of Primary Outcome Scores				
RDQ (modified), mean (SD)[c]	11.4 (4.8)	10.9 (4.8)	11.8 (4.7)	11.5 (5.0)
Pain bothersomeness rating, mean (SD)[d]	6.0 (1.6)	6.0 (1.6)	6.1 (1.6)	6.0 (1.5)
Baseline Measures of Secondary Outcome Scores				
Characteristic pain intensity, mean (SD)[d]	5.9 (1.3)	5.8 (1.3)	6.0 (1.3)	5.8 (1.2)
PHQ-8, mean (SD)[e]	5.6 (4.1)	5.3 (3.8)	5.7 (4.0)	5.7 (4.4)
GAD-2, mean (SD)[f]	1.4 (1.5)	1.5 (1.3)	1.4 (1.5)	1.4 (1.5)
GAD-2, median (IQR)[f]	1 (0-2)	1 (0-2)	1 (0-2)	1 (0-2)
SF-12 Physical, mean (SD)[g]	39.1 (7.9)	39.7 (7.6)	38.2 (7.5)	39.4 (8.6)
SF-12 Mental, mean (SD)[g]	39.9 (7.9)	39.8 (7.4)	40.6 (8.1)	39.4 (8.2)
Baseline Measures of Other Secondary Outcomes				
Any medication use for LBP in past week	252 (73.9)	82 (72.6)	85 (73.3)	85 (75.9)
Opioids use for LBP in past week	38 (11.1)	12 (10.6)	14 (12.1)	12 (10.7)
Back-specific exercise ≥3 days in past week	137 (40.2)	44 (38.9)	48 (41.4)	45 (40.2)
General exercise ≥3 days in past week	167 (49.0)	53 (46.9)	57 (49.1)	57 (50.9)

Abbreviations: GAD-2, Generalized Anxiety Disorder-2; IQR, interquartile range; LBP, low back pain; PHQ-8, Patient Health Questionnaire-8; RDQ, Roland Disability Questionnaire; SF-12, 12-Item Short Form Health Survey.

[a] Race/ethnicity subcategory of *Other* indicates multiracial (19), other (not specified [9]), missing (5), Native American/Pacific Islander (2).

[b] LBP self-management score range is 0 to 10. Higher scores indicate more program success.

[c] Modified RDQ score range is 0 to 23. Higher scores indicate worse function.

[d] Pain bothersomeness rating and characteristic pain intensity score ranges are both 0 to 10. Higher scores indicate greater pain.

[e] PHQ-8 score range is 0 to 24. Higher scores indicate more depression.

[f] GAD-2 score range is 0 to 6. Higher scores indicate more anxiety.

[g] SF-12 physical and mental component scores range from 0 to 100. Lower scores indicate poorer health status and higher ones indicate higher function.

analyses compared the adjusted mean change from baseline between groups.

Secondary Outcomes

Depressive symptoms were assessed using the Patient Health Questionnaire-8 (PHQ-8; range, 0-24; higher scores indicate greater severity).[25] Anxiety was measured using the 2-item Generalized Anxiety Disorder scale (GAD-2; range, 0-6; higher scores indicate greater severity).[26] Characteristic pain intensity was assessed as the mean of 3 ratings (gauged on a 0-10 scale; current, worst, and average back pain in the previous month; range; higher scores indicate greater intensity) from

the Graded Chronic Pain Scale.[27] The Patient Global Impression of Change scale[28] asked participants to rate their improvement in pain on a 7-point scale (completely gone, much better, somewhat better, a little better, about the same, a little worse, and much worse). Physical general health status and mental general health status were assessed with 12-item Short-Form Health Surveys (SF-12 Physical and SF-12 Mental) (0-100 scale; lower scores indicate poorer health status).[29] Participants were also asked about their use of medications and exercise for back pain during the previous week.

Adverse Events

Adverse events were identified during intervention sessions and by follow-up interview questions about significant discomfort, pain, or harm caused by the intervention.

Sample Size

A sample size of 264 participants (88 in each group) was chosen to provide adequate power to detect meaningful differences between MBSR and CBT and usual care at 26 weeks. Sample size calculations were based on the outcome of clinically meaningful improvement (≥30% from baseline) on the RDQ.[24] Estimates of clinically meaningful improvement in the intervention and usual care groups were based on unpublished analyses of data from our previous trial of massage for chronic low back pain in a similar population.[30] This sample size provided adequate power for both coprimary outcomes. The planned sample size provided 90% power to detect a 25% difference between MBSR and usual care in the proportion with meaningful improvement on the RDQ, and at least 80% power to detect a 20% difference between MBSR and CBT, assuming 30% of usual care participants and 55% of CBT participants showed meaningful improvement. For meaningful improvement in pain bothersomeness, the planned sample size provided at least 80% power to detect a 21.8% difference between MBSR and usual care and a 16.7% difference between MBSR and CBT, assuming 47.5% in usual care and 69.3% in CBT showed meaningful improvement.

Allowing for an 11% loss to follow-up, we planned to recruit 297 participants (99 per group). Because observed follow-up rates were lower than expected, an additional wave of participants was recruited. A total of 342 participants were randomized to achieve a target sample size of 264 with complete outcome data at 26 weeks.

Statistical Analysis

Following the prespecified analysis plan (Supplement 1), differences among the 3 groups on each primary outcome were assessed by fitting a regression model that included outcome measures from all 4 time points after baseline (4, 8, 26, and 52 weeks). A separate model was fit for each coprimary outcome (RDQ and pain bothersomeness). Indicators for time point, randomization group, and the interactions between these variables were included in each model to estimate intervention effects at each time point. Models were fit using generalized estimating equations (GEEs),[31] which accounted for possible correlation within individuals. For binary primary outcomes, a modified Poisson regression model with a log-link and

robust sandwich variance estimator[32] to estimate relative risks (RRs) was used. For continuous measures, linear regression models to estimate mean change from baseline were used. Models were adjusted for age, sex, education, pain duration (<1 year vs ≥1 year since experiencing a week without back pain), and the baseline score on the outcome measure. Evaluation of secondary outcomes followed a similar analytic approach although models did not include 4-week scores because secondary outcomes were not assessed at 4 weeks.

Statistical significance of intervention effects at each time point was evaluated separately. An a priori decision was made to consider MBSR successful only if group differences were significant at the 26-week primary end point. To protect against multiple comparisons, the Fisher protected least-significant difference approach was used,[33] which required that pairwise treatment comparisons be made only if the overall omnibus test was statistically significant.

Because observed follow-up rates differed across intervention groups and were lower than anticipated in this study (Figure), an imputation method for nonignorable nonresponse was used as the primary analysis to account for possible nonresponse bias. The imputation method applied a pattern mixture model framework using a 2-step GEE approach.[34] The first step estimated the GEE model previously outlined with observed outcome data adjusting for covariates but further adjusting for patterns of nonresponse. Missing pattern indicator variables included the following: missing 1 outcome, missing 1 outcome and assigned to receive CBT, missing 1 outcome and assigned to receive MBSR, and missing at least 2 outcomes (no further interaction with group was included because very few usual care participants missed ≥2 follow-up time points). The second step estimated the GEE model previously outlined, but included imputed outcomes from step 1 for participants with missing follow-up times. The variance estimates were adjusted to account for using imputed outcome measures for unobserved outcomes.

All analyses followed an intention-to-treat approach. Participants were included in the analysis by randomization assignment regardless of level of intervention participation. All tests and CIs were 2-sided and statistical significance was defined as a P value of .05 or less. All analyses were performed using the statistical package R version 3.0.2.[17]

Results

Participant flow through the study is reported in the Figure. Among 1767 individuals expressing interest in study participation and screened for eligibility, 342 were enrolled and randomized. The main reasons for exclusion were pain lasting less than 3 months (412), inability to attend treatment sessions (338), minimal pain bothersomeness (122), or interference with activities (196). All but 7 participants were recruited from Group Health. There were 203 (88.6%) participants randomized to receive MBSR and CBT who attended at least 1 session, but only 59 (50.9%) in the MBSR group and 64 (56.6%) in the CBT group attended at least 6 sessions. Only 30 (26%) participants ran-

Table 2. Coprimary Outcomes: Percentage of Participants With Clinically Meaningful Improvement by Treatment Group and Relative Risks Comparing Treatment Groups (Adjusted Imputed Analyses)[a,b]

Follow-up Week	% (95% CI) With Clinically Meaningful Improvement				Relative Risk (95% CI)		
	Usual Care	Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy	P Value for Omnibus[c]	Mindfulness-Based Stress Reduction vs Usual Care	Cognitive Behavioral Therapy vs Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy vs Usual Care
Roland Disability Questionnaire Results							
4	27.3 (20.3-36.6)	34.5 (26.8-44.3)	24.7 (18.1-33.8)	.23	1.26 (0.86-1.86)	0.72 (0.48-1.07)	0.91 (0.59-1.39)
8	35.4 (27.6-45.2)	47.4 (38.9-57.6)	51.9 (43.6-61.7)	.04[d]	1.34 (0.98-1.84)	1.10 (0.84-1.42)	1.47 (1.09-1.98)[d]
26	44.1 (35.9-54.2)	60.5 (52.0-70.3)	57.7 (49.2-67.6)	.04[d]	1.37 (1.06-1.77)[d]	0.95 (0.77-1.18)	1.31 (1.01-1.69)[d]
52	48.6 (40.3-58.6)	68.6 (60.3-78.1)	58.8 (50.6-68.4)	.01[d]	1.41 (1.13-1.77)[d]	0.86 (0.70-1.04)	1.21 (0.95-1.54)
Pain Bothersomeness Results							
4	20.6 (14.6-28.9)	19.1 (13.3-27.4)	21.7 (15.3-30.6)	.88	0.93 (0.56-1.52)	1.14 (0.69-1.87)	1.05 (0.65-1.71)
8	24.7 (18.1-33.6)	36.1 (28.3-46.0)	33.8 (26.5-43.2)	.15	1.46 (0.99-2.16)	0.94 (0.67-1.32)	1.37 (0.93-2.02)
26	26.6 (19.8-35.9)	43.6 (35.6-53.3)	44.9 (36.7-55.1)	.01[d]	1.64 (1.15-2.34)[d]	1.03 (0.78-1.36)	1.69 (1.18-2.41)[d]
52	31.0 (23.8-40.3)	48.5 (40.3-58.3)	39.6 (31.7-49.5)	.02[d]	1.56 (1.14-2.14)[d]	0.82 (0.62-1.08)	1.28 (0.91-1.79)

[a] Estimates from generalized estimating equations 2-step imputed model adjusting for baseline outcome score, sex, age, education, and pain duration (<1 y vs ≥1 y since experiencing a week without back pain).

[b] n = 341 Included in the analysis; 1 randomized participant who did not complete the baseline survey was excluded. Follow-up rates (sample sizes before imputation) at each time point by randomization group are detailed in the Figure. In addition, 1 participant in the mindfulness-based stress reduction group at 8 weeks and 1 in the usual care group at 26 weeks were missing data for the pain bothersomeness outcome. Sample sizes before imputation for each outcome at each time point are provided by randomization group (eTable in Supplement 2).

[c] Wald P value.

[d] P value is less than .05 for pairwise comparisons.

Table 3. Coprimary Outcomes: Mean (95% CI) Change by Treatment Group and Mean (95% CI) Differences Between Treatment Groups (Adjusted Imputed Analyses)[a,b]

Follow-up Week	Change From Baseline, Mean (95% CI)				Between-Group Differences, Mean (95% CI)		
	Usual Care	Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy	P Value for Omnibus[c]	Mindfulness-Based Stress Reduction vs Usual Care	Cognitive Behavioral Therapy vs Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy vs Usual Care
Roland Disability Questionnaire Results							
4	−1.28 (−1.91 to −0.65)	−1.93 (−2.61 to −1.25)	−1.44 (−2.10 to −0.78)	.37	−0.65 (−1.59 to 0.28)	0.49 (−0.46 to 1.45)	−0.16 (−1.07 to 0.76)
8	−1.83 (−2.59 to −1.07)	−3.40 (−4.22 to −2.59)	−3.37 (−4.14 to −2.60)	.005[d]	−1.57 (−2.70 to −0.45)[d]	0.04 (−1.11 to 1.18)	−1.54 (−2.61 to −0.46)[d]
26	−2.96 (−3.79 to −2.14)	−4.33 (−5.16 to −3.51)	−4.38 (−5.3 to −3.47)	.03[d]	−1.37 (−2.55 to −0.19)[d]	−0.05 (−1.31 to 1.21)	−1.42 (−2.66 to −0.18)[d]
52	−3.43 (−4.33 to −2.52)	−5.3 (−6.16 to −4.43)	−4.78 (−5.67 to −3.89)	.01[d]	−1.87 (−3.14 to −0.60)[d]	0.51 (−0.75 to 1.78)	−1.36 (−2.63 to −0.08)[d]
Pain Bothersomeness Results							
4	−0.68 (−0.98 to −0.38)	−0.57 (−0.87 to −0.27)	−0.79 (−1.13 to −0.44)	.66	0.11 (−0.32 to 0.53)	−0.21 (−0.67 to 0.25)	−0.11 (−0.56 to 0.35)
8	−0.67 (−1.02 to −0.33)	−1.40 (−1.71 to −1.10)	−1.28 (−1.62 to −0.94)	.005[d]	−0.73 (−1.19 to −0.27)[d]	0.12 (−0.34 to 0.58)	−0.61 (−1.09 to −0.12)[d]
26	−0.84 (−1.21 to −0.46)	−1.48 (−1.86 to −1.11)	−1.56 (−2.02 to −1.11)	.02[d]	−0.64 (−1.18 to −0.11)[d]	−0.08 (−0.68 to 0.51)	−0.73 (−1.32 to −0.13)[d]
52	−1.10 (−1.48 to −0.71)	−1.95 (−2.32 to −1.59)	−1.76 (−2.14 to −1.39)	.005[d]	−0.85 (−1.39 to −0.32)[d]	0.19 (−0.33 to 0.71)	−0.67 (−1.20 to −0.13)[d]

[a] Estimates are from generalized estimating equations 2-step imputed model adjusting for baseline outcome score, sex, age, education, and pain duration (<1 y vs ≥1 y since experiencing a week without back pain).

[b] There were 341 participants included in the analysis. Sample sizes before imputation for each outcome at each time point are provided by randomization group (eTable in Supplement 2).

[c] Wald P value.

[d] P value is less than .05 for pairwise comparisons.

domized to receive MBSR attended the 6-hour retreat. Overall follow-up response rates ranged from 89.2% (305 participants) at 4 weeks to 84.8%(290 participants) at 52 weeks and were higher in the usual care group (95.6% [108] at 4 weeks and 93.8% [106] at 52 weeks).

At baseline, treatment groups were similar in sociodemographic and pain characteristics except for more women in usual care and fewer college graduates in the MBSR group (Table 1). Overall, 269 (78.9%) reported at least 1 year since a week without back pain and most reported pain on at least 160 of the previous 180 days. Mean duration of back pain was 7.3 years (range, 3 months-50 years). The mean (SD) RDQ score (11.4 [4.8]) and pain bothersomeness rating (6.0 [1.6]) indicated moderate levels of severity. Opioids use for pain during

Table 4. Mean Change From Baseline of Continuous Secondary Outcomes by Treatment Group and Between-Group Comparisons (Adjusted Imputed Analyses)[a,b]

	Change Estimates, Mean (95% CI)				Between-Group Differences, Mean (95% CI)		
Follow-up Week	Usual Care	Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy	P Value for Omnibus[c]	Mindfulness-Based Stress Reduction vs Usual Care	Cognitive Behavioral Therapy vs Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy vs Usual Care
Depression (PHQ-8)							
8	−0.12 (−0.74 to 0.50)	−1.60 (−2.15 to −1.05)	−2.29 (−2.66 to −1.92)	<.001[d]	−1.48 (−2.31 to −0.64)[d]	−0.69 (−1.35 to −0.02)[d]	−2.17 (−2.89 to −1.45)[d]
26	−0.64 (−1.23 to −0.06)	−1.32 (−1.81 to −0.83)	−1.80 (−2.35 to −1.26)	.02[d]	−0.68 (−1.45 to 0.09)	−0.48 (−1.21 to 0.26)	−1.16 (−1.95 to −0.37)[d]
52	−0.88 (−1.50 to −0.27)	−1.51 (−2.09 to −0.92)	−1.72 (−2.28 to −1.16)	.13	−0.62 (−1.48 to 0.23)	−0.21 (−1.03 to 0.61)	−0.83 (−1.67 to 0.00)
Anxiety (GAD-2)							
8	−0.09 (−0.32 to 0.13)	−0.33 (−0.56 to −0.10)	−0.51 (−0.69 to −0.33)	.02[d]	−0.24 (−0.56 to 0.09)	−0.18 (−0.47 to 0.11)	−0.41 (−0.70 to −0.13)[d]
26	0.02 (−0.24 to 0.28)	0.00 (−0.28 to 0.28)	−0.49 (−0.72 to −0.25)	.005[d]	−0.02 (−0.41 to 0.37)	−0.49 (−0.85 to −0.12)[d]	−0.51 (−0.86 to −0.16)[d]
52	−0.14 (−0.40 to 0.12)	−0.15 (−0.40 to 0.10)	−0.39 (−0.59 to −0.18)	.23	0.00 (−0.37 to 0.36)	−0.24 (−0.56 to 0.08)	−0.24 (−0.58 to 0.09)
Characteristic Pain Intensity							
8	−0.37 (−0.62 to −0.12)	−1.00 (−1.28 to −0.73)	−0.86 (−1.12 to −0.59)	.002[d]	−0.63 (−1.01 to −0.26)[d]	0.15 (−0.24 to 0.53)	−0.49 (−0.84 to −0.13)[d]
26	−0.65 (−0.95 to −0.35)	−1.10 (−1.42 to −0.77)	−1.15 (−1.44 to −0.86)	.04[d]	−0.45 (−0.89 to −0.01)[d]	−0.05 (−0.50 to 0.39)	−0.50 (−0.92 to −0.09)[d]
52	−0.79 (−1.10 to −0.48)	−1.42 (−1.72 to −1.12)	−1.40 (−1.74 to −1.05)	.007[d]	−0.63 (−1.06 to −0.19)[d]	0.02 (−0.44 to 0.48)	−0.61 (−1.07 to −0.14)[d]
SF-12 Physical Component Score							
8	2.21 (1.12 to 3.30)	3.69 (2.61 to 4.77)	3.24 (2.21 to 4.27)	.16	1.48 (−0.06 to 3.02)	−0.45 (−1.95 to 1.05)	1.03 (−0.48 to 2.54)
26	3.27 (2.09 to 4.44)	3.58 (2.15 to 5.01)	3.78 (2.56 to 5.00)	.84	0.31 (−1.53 to 2.16)	0.20 (−1.69 to 2.10)	0.52 (−1.19 to 2.22)
52	2.93 (1.70 to 4.16)	3.87 (2.55 to 5.19)	3.79 (2.55 to 5.03)	.50	0.94 (−0.86 to 2.74)	−0.08 (−1.91 to 1.75)	0.86 (−0.87 to 2.60)
SF-12 Mental Component Score							
8	−0.65 (−1.86 to 0.55)	1.68 (0.57 to 2.79)	1.77 (0.82 to 2.72)	.004[d]	2.33 (0.68 to 3.99)[d]	0.09 (−1.37 to 1.54)	2.42 (0.87 to 3.97)[d]
26	−1.11 (−2.39 to 0.17)	0.45 (−0.85 to 1.76)	2.13 (0.86 to 3.40)	.002[d]	1.57 (−0.27 to 3.40)	1.68 (−0.12 to 3.47)	3.24 (1.44 to 5.04)[d]
52	0.75 (−0.58 to 2.08)	2.01 (0.74 to 3.28)	1.81 (0.59 to 3.03)	.36	1.26 (−0.60 to 3.11)	−0.19 (−1.95 to 1.56)	1.06 (−0.75 to 2.88)

Abbreviations: GAD-2, Generalized Anxiety Disorder-2; PHQ-8, Patient Health Questionnaire-8; SF-12, 12-Item Short Form Health Survey.

[a] Estimates are from generalized estimating equations 2-step imputed model adjusting for baseline outcome score, sex, age, education, and pain duration (<1 y vs ≥1 y since experiencing a week without back pain).

[b] There were 341 participants included in the analysis. Sample sizes before

imputation for each outcome at each time point are provided by randomization group (eTable in Supplement 2).

[c] Wald P value.

[d] P value is less than .05 for pairwise comparisons.

the past week was reported by 38 participants (11.1%). Seventeen percent had at least moderate levels of depression (PHQ-8 scores ≥10) and 18% had at least moderate levels of anxiety (GAD-2 scores ≥3).

Coprimary Outcomes

At the 26-week primary end point, the groups differed significantly (P = .04) in percent with clinically meaningful improvement on the RDQ (MBSR 60.5%, usual care 44.1%, CBT 57.7%; Table 2). Participants randomized to receive MBSR were more likely than those randomized to usual care to show meaningful improvement on the RDQ (RR, 1.37 [95% CI, 1.06-1.77]) but did not differ significantly from those randomized to CBT. The overall difference among groups in clinically meaningful improvement in pain bothersomeness at 26 weeks was also sta-

tistically significant (MBSR 43.6%, usual care 26.6%, CBT 44.9%; P = .01). Participants randomized to receive MBSR were more likely to show meaningful improvement when compared with usual care (RR, 1.64 [95% CI, 1.15-2.34]) but not when compared with CBT (RR, 1.03 [95% CI, 0.78-1.36]). The significant differences between MBSR and usual care and the nonsignificant differences between MBSR and CBT, in percent with meaningful function and pain improvement, persisted at 52 weeks, with RRs similar to those at 26 weeks (Table 2). CBT was superior to usual care for both primary outcomes at 26 weeks but not 52 weeks. Treatment effects of MBSR and CBT were not apparent before end of treatment (8 weeks). Generally similar results were found when the primary outcomes were analyzed as continuous variables, although more differences were statistically significant at 8 weeks, and the

Table 5. Binary Secondary Outcomes by Treatment Group and Between-Group Comparisons (Adjusted Imputed Analyses)[a,b]

Follow-up Week	% (95% CI)			P Value for Omnibus[c]	Relative Risk (95% CI)		
	Usual Care	Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy		Mindfulness-Based Stress Reduction vs Usual Care	Cognitive Behavioral Therapy vs Mindfulness-Based Stress Reduction	Cognitive Behavioral Therapy vs Usual Care
Global Improvement (Pain Much Better or Completely Gone)							
8	10.8 (6.5-17.8)	15.6 (10.4-23.5)	21.9 (15.9-30.3)	.06	1.45 (0.76-2.78)	1.40 (0.84-2.35)	2.04 (1.12-3.69)
26	13.6 (8.6-21.5)	26.2 (19.3-35.7)	30.1 (22.7-39.9)	.01[d]	1.93 (1.12-3.32)[d]	1.15 (0.76-1.73)	2.21 (1.30-3.76)[d]
52	18.0 (12.1-26.7)	30.0 (22.6-39.8)	31.9 (24.5-41.6)	.048[d]	1.67 (1.03-2.71)[d]	1.06 (0.73-1.55)	1.78 (1.11-2.85)[d]
Used Medications for Low Back Pain in Past Week							
8	63.3 (55.6-72.1)	53.4 (45.9-62.2)	53.2 (46.1-61.4)	.09	0.84 (0.70-1.02)	1.00 (0.82-1.21)	0.84 (0.70-1.00)
26	54.2 (46.2-63.6)	43.4 (35.9-52.6)	50.9 (43.4-59.7)	.18	0.80 (0.63-1.02)	1.17 (0.92-1.49)	0.94 (0.76-1.16)
52	52.9 (45.1-62.0)	46.8 (39.2-55.9)	42.1 (34.9-50.9)	.17	0.89 (0.70-1.11)	0.90 (0.70-1.16)	0.80 (0.63-1.01)
At Least 3 Days of Back Exercise in Past Week							
8	42.3 (34.5-51.8)	66.3 (58.2-75.6)	59.1 (51.1-68.4)	.001[d]	1.57 (1.23-2.00)[d]	0.89 (0.74-1.08)	1.40 (1.09-1.79)[d]
26	36.4 (28.4-46.7)	42.0 (34.3-51.5)	41.8 (34.1-51.3)	.62	1.15 (0.84-1.59)	0.99 (0.75-1.32)	1.15 (0.84-1.58)
52	35.0 (27.5-44.5)	51.4 (42.9-61.5)	41.0 (33.0-50.9)	.04[d]	1.47 (1.09-1.98)[d]	0.80 (0.60-1.05)	1.17 (0.85-1.61)
At Least 3 Days of General Exercise in Past Week							
8	54.0 (45.9-63.4)	64.4 (57.2-72.5)	62.5 (55.1-70.9)	.20	1.19 (0.98-1.45)	0.97 (0.82-1.15)	1.16 (0.95-1.41)
26	60.1 (52.0-69.5)	51.3 (43.7-60.2)	50.7 (42.7-60.1)	.21	0.85 (0.69-1.05)	0.99 (0.79-1.24)	0.84 (0.68-1.05)
52	56.2 (48.0-65.7)	62.6 (55.1-71.1)	52.4 (44.7-61.5)	.19	1.11 (0.91-1.36)	0.84 (0.69-1.02)	0.93 (0.75-1.16)

[a] Estimates are from generalized estimating equations 2-step imputed model adjusting for baseline outcome score, sex, age, education, and pain duration (<1 y vs ≥1 y since experiencing a week without back pain).

[b] There were 341 participants included in the analysis. Sample sizes before imputation for each outcome at each time point are provided by randomization group (eTable in Supplement 2).

[c] Wald P value.

[d] P value is less than .05 for pairwise comparisons.

CBT group improved more than the usual care group at 52 weeks (Table 3).

Secondary Outcomes

Mental health outcomes (depression, anxiety, SF-12 Mental Component) differed significantly across groups at 8 and 26 weeks but not 52 weeks (Table 4). Among these measures and time points, participants randomized to receive MBSR improved more than those randomized to usual care only on the depression and SF-12 Mental Component measures at 8 weeks. Participants randomized to receive CBT improved more than those randomized to MBSR on depression at 8 weeks and anxiety at 26 weeks and more than the usual care group at 8 and 26 weeks on all 3 measures.

Improvement in characteristic pain intensity differed significantly between groups at all 3 time points, with greater improvement in MBSR and CBT than in usual care and no significant difference between MBSR and CBT groups (Table 5). No overall differences in treatment effects were observed for the SF-12 Physical Component score or self-reported use of medications for back pain. Groups differed at 26 and 52 weeks in self-reported global improvement, with both the MBSR and CBT groups reporting greater improvement than the usual care group, but not differing significantly from each other.

Adverse Events

Thirty of the 103 (29%) participants attending at least 1 MBSR session reported an adverse event (mostly temporar-

ily increased pain with yoga). Ten of the 100 (10%) participants who attended at least 1 CBT session reported an adverse event (mostly temporarily increased pain with progressive muscle relaxation). No serious adverse events were reported.

Discussion

Among adults with chronic low back pain, both MBSR and CBT resulted in greater improvement in back pain and functional limitations at 26 and 52 weeks when compared with usual care. There were no meaningful differences in outcomes between MBSR and CBT. The effects were moderate in size, which has been typical of evidence-based treatments recommended for chronic low back pain.[4] These benefits are remarkable given that only 51% of those randomized to receive MBSR and 57% of those randomized to receive CBT attended at least 6 of the 8 sessions.

The findings of this study are consistent with the conclusions of a 2011 systematic review,[35] which reported that "acceptance-based" interventions such as MBSR have beneficial effects on the physical and mental health of patients with chronic pain, comparable to those of CBT. They are only partially consistent with the only other large RCT of MBSR for chronic low back pain,[13] which found that MBSR, as compared with a time- and attention-matched health education control group, provided benefits for function at posttreatment (but not at 6-month follow-up) and for average pain at

6-month follow-up (but not posttreatment). Several differences between our trial and theirs (which was limited to adults ≥65 years and had a different comparison condition) could be responsible for differences in findings.

Although our trial lacked a condition controlling for nonspecific effects of instructor attention and group participation, CBT and MBSR have been shown to be more effective than control and active interventions for pain conditions. In addition to the trial of older adults with chronic low back pain,[14] which found MBSR to be more effective than a health education control condition, a recent systematic review of CBT for nonspecific low back pain found CBT to be more effective than guideline-based active treatments in improving pain and disability at short- and long-term follow-ups.[7] Further research is needed to identify moderators and mediators of the effects of MBSR on function and pain, evaluate benefits of MBSR beyond 1 year, and determine its cost effectiveness. Research is also needed to identify reasons for session nonattendance, ways to increase attendance, and ways to determine the minimum number of sessions required.

Our finding of increased effectiveness of MBSR at 26 to 52 weeks relative to posttreatment for both primary outcomes contrasts with findings of our previous studies of acupuncture, massage, and yoga conducted in the same population as the current trial.[30,36,37] In those studies, treatment effects decreased between the end of treatment (8-12 weeks) and long-term follow-up (26-52 weeks). Long-lasting effects of CBT for chronic low back pain have been reported.[7,38,39] This suggests that mind-body treatments such as MBSR and CBT may provide patients with long-lasting skills effective for managing pain.

There were more differences between CBT and usual care than between MBSR and usual care on measures of psychological distress. CBT was superior to MBSR on the depression measure at 8 weeks, but the mean difference between groups was small. Because our sample was not very distressed at baseline, further research is needed to compare MBSR to CBT in a more distressed patient population.

Limitations of this study must be acknowledged. Study participants were enrolled in a single health care system and generally highly educated. The generalizability of findings to other settings and populations is unknown. Approximately 20% of participants randomized to the MBSR and CBT groups were lost to follow-up. We attempted to correct for bias from missing data in our analyses by using imputation methods. The generalizability of our findings to CBT delivered in an individual rather than group format is unknown; CBT may be more effective when delivered individually.[40] Study strengths include a large sample with adequate statistical power to detect clinically meaningful effects, close matching of the MBSR and CBT interventions in format, and long-term follow-up.

Conclusions

Among adults with chronic low back pain, treatment with MBSR or CBT, compared with usual care, resulted in greater improvement in back pain and functional limitations at 26 weeks, with no significant differences in outcomes between MBSR and CBT. These findings suggest that MBSR may be an effective treatment option for patients with chronic low back pain.

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