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Bibliographic Data	
Authors	Daniel C. Cherkin, Karen J. Sherman, Benjamin H. Balderson, and et al.
Title	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
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Other information if relevant	TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01467843

Methods	
Aim of study	To evaluate the effectiveness of mindfulness based stress reduction (MBSR) for chronic low back pain (LBP) vs cognitive behavioral therapy (CBT) or usual care.
Design	Single-blind randomized clinical trial

Participants	
Population from which participants are drawn	Members of Group Health, a large integrated health care system in Washington State were recruited via mailed letters describing the trial and inviting participation who met the electronic medical record inclusion/exclusion criteria, and to random samples of residents in communities served by Group Health.
Setting (location and type of facility)	University of Washington study in Seattle. Screened and enrolled by telephone.
Age	adults 20 to 70 years of age, mean age 49.3 years
Sex	117 men, 224 women
Total number of participants for whom outcome data were reported	341
Inclusion criteria	20 to 70 years of age with nonspecific low back pain that persisted at least 3 months
Exclusion criteria	Back pain associated with a specific diagnosis (e.g. spinal stenosis), compensation or litigation issues, 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.
Other information if relevant	At baseline, all 3 groups were similar in sociodemographic and pain characteristics. The mean (SD) Roland Disability Questionnaire (RDQ) score (11.4 [4.8]) and pain bothersomeness rating (6.0 [1.6]) indicated moderate levels of severity. Mean duration of back pain was 7.3 years.

Intervention Groups

Group 1	
Group name	Mindfulness-Based Stress Reduction Program (MBSR) -Intervention
Number in group	116
Description of intervention	The intervention was modeled on the 8-week Mindfulness-Based Stress Reduction program that focuses on increasing awareness and acceptance of moment to moment experiences including physical discomfort and difficult emotions. These techniques take regular activities such as sitting, walking, and lying down and transform them into a meditation through directed breathing and mindful awareness of thoughts and sensations. The methods used included the body scan, yoga, meditation (attention to thoughts, emotions, and sensations in the present moment without trying to change them).
Duration of treatment period	8 weeks, 2 hour weekly group sessions
Co-interventions if reported	optional 6 hour retreat
Additional information if relevant	Using methods to challenge dysfunctional thoughts were forbidden.

Group 2	
Group name	Cognitive Behavioral Therapy (CBT)
Number in group	112
Description of intervention	(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.
Duration of treatment period	8 weeks, 2 hour weekly group sessions
Co-interventions if reported	No optional retreat
Additional information if relevant	Using mindfulness, meditation, and yoga techniques were forbidden.

Group 3	
Group name	Usual Care
Number in group	113
Description of intervention	Received $50, but no formal treatment. Participants were free to seek whatever treatment, if any, they desired.
Duration of treatment period	8 weeks
Co-interventions if reported	No optional retreat
Additional information if relevant	

Coprimary outcomes	
Outcome name and criteria for definition	1) Back pain–related functional limitation was assessed by the Roland and Morris Disability Questionnaire (RDQ) and modified to 23 (vs the original 24) items and to ask about the past week rather than today only. 2) 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 examined the percentages of participants with clinically meaningful improvement (≥30% improvement from baseline) on both measures. Secondary analyses compared the adjusted mean change from baseline between groups.
Time points measured and/or reported	Baseline (before randomization), after randomization at weeks 4 (mid-treatment), 8 weeks (posttreatment), 26 weeks (primary end point), and 52 weeks. Interviewers were blinded to treatment group.
Differences between groups	1) At the 26-week primary end point, the groups differed significantly (*P* = .04) in percent with clinically meaningful improvement in **function** on the RDQ (MBSR 60.5%, CBT 57.7%, usual care, 44.1%). Participants randomized to receive MBSR were significantly more likely than those randomized to usual care to show meaningful functional improvement on the RDQ (RR 1.37, 95% CI, 1.06-1.77), but did not differ significantly from those randomized to CBT (RR 0.95, 95% CI 0.77-1.18). Participants randomized to receive CBT were also significantly more likely than those randomized to usual care to show meaningful functional improvement on the RDQ (RR 1.31, 95% CI 1.01-1.69). 2) The overall difference among groups in clinically meaningful improvement in **pain** bothersomeness at 26 weeks was also statistically significant (MBSR 43.6%, CBT 44.9%, usual care 26.6%, *P* = .01). Participants randomized to receive MBSR were significantly more likely to show meaningful improvement in pain 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). Participants randomized to receive CBT were also significantly more likely than those randomized to usual care to show meaningful improvement in pain (RR 1.69, 95% CI 1.18-2.41). 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. The significant differences between CBT and usual care in percent with meaningful function and pain improvement found at 26 weeks did not persist at 52 weeks. Treatment effects of MBSR and CBT were not apparent before end of treatment (8weeks).
Additional information if relevant	Secondary analyses comparing the adjusted mean change from baseline also showed significant differences at 26 weeks for all groups for both function (MBSR -4.33,CBT -4.38, usual care -2.96, *P* = .03) and pain (MBSR -1.48,CBT -1.56, usual care -0.84, *P* = .02) with slightly greater changes that persisted at 52 weeks. Intention- to- treat analyses were used.

Secondary outcomes	
Outcome name and criteria for definition	Depression, anxiety, pain intensity, Patient Global Impression of Change, physical and mental general health status
Time points measured	Baseline (before randomization), 8 weeks (posttreatment), 26 weeks (primary end point), and 52 weeks. Interviewers were blinded to treatment group.
Differences between groups	Mental health outcomes (depression, anxiety, SF-12 Mental Component) differed significantly across groups at 8 and 26 weeks. No overall differences in treatment effects were observed for the SF-12 Physical Component score. Groups differed at 26 and52 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.
Additional information if relevant	Thirty of the 103 (29%) participants attending at least 1 MBSR session reported an adverse event (mostly temporarily increased pain with yoga). No serious adverse events were reported.
Conclusions	
Key Conclusions Of Study Authors	- 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. - 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. - These findings suggest that MBSR may be an effective treatment option for patients with chronic low back pain, and may provide patients with long-lasting skills effective for managing pain due to the persistent effects at 52 weeks. - CBT was superior to MBSR on the depression measure at 8 weeks, but the mean difference between groups was small. - 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.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	The stratified randomization sequence was generated by the study biostatistician using R statistical software after baseline measures were completed
Allocation concealment *(selection bias)*	Low	The randomization sequence was stored in the study recruitment database and concealed from study staff until randomization.

Blinding of participants and personnel *(performance bias)*	High	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. Patients were only aware of which group they were in when they attended their first session, and it was not possible to blind them after that. The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	Low	All outcome assessments were conducted by staff members blinded to intervention assignment.
Incomplete outcome data *(attrition bias)*	Low	Loss to follow up was relatively equal between groups at 20%. The study attempted to correct for bias from missing data in the analyses by using imputation methods. Loss to follow up was mostly due to time conflicts or illness.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered at clinicaltrials.gov and the primary outcome reported in the protocol was the same as that reported in the trial.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Research reported in this article was supported by the National Center for Complementary and Integrative Health (NICCIH) of the National Institutes of Health (NIH). The NICCIH had no role in the design and conduct of the study or in the collection, management, analysis, and interpretation of the data.	
Possible conflicts of interest for study authors	None declared	
Notes:		

Comments by DOWC staff

- Overall MBSR was more effective than usual care for both pain and function as the authors hypothesized, but it was not superior to CBT for chronic low back pain.

- The authors exaggerated the effects of the MBSR and CBT treatments calling them moderate in size when in reality the effects were small in size. The adjusted mean changes from baseline on the RDQ for function were -4.33 points for MBSR, -4.38 for CBT, and -2.96 for usual care. These statistically significant improvements from all 3 groups do represent clinically meaningful improvement from baseline ($\geq$ 2.5 points), and attain the MCID of 2.5 to 5 points on the RDQ, but the effects are still small in size. The adjusted mean changes from baseline on the pain scale were -1.48 points for MBSR, -1.56 for CBT, and -0.84 for usual care. These statistically significant improvements from all 3 groups represent a marginally important clinical improvement for the MBSR and CBT groups, but not the usual care group. The 2 treatment groups attain the MCID of 1.5 points on a 10 point scale, but the effects are still small in size.

- The MBSR treatment compared to usual care sustained its significant effects on function and pain at one year post treatment, whereas CBT did not.

- Study strengths included a large sample size with adequate statistical power to detect clinically meaningful effects, close matching of the MBSR and CBT interventions in format and time, and a long-term follow-up.

- CBT may be more effective when delivered individually. The generalizability of the study findings to CBT delivered in an individual rather than group format is unknown and perhaps CBT would have shown greater effects if individual sessions were delivered.

- One limitation of the trial was a lack of a comparison group controlling for the nonspecific effects of instructor attention and group participation, and a time matched treatment program.

- Approximately 20% of participants randomized to the MBSR and CBT groups were lost to follow-up. The study attempted to correct for attrition bias from missing data in the analyses by using imputation methods.

- Overall follow-up response rates were relatively good even in the long term at 84.8% at 52 weeks and were even higher in the usual care group at 93.8%, but attendance at at least 6 sessions was only 50.9% in the MBSR group and 56.6% in the CBT group. The benefits shown for MBSR and CBT are remarkable in light of these rather low attendance rates, and it behooves us to wonder how much more effective these modalities would be if attendance was even higher. Attendance and adherence may have been improved if patients were able to preferentially choose their treatment versus being randomized into it.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☒ High quality ☐ Adequate ☐ Inadequate	This high quality study provides good evidence that in the setting of chronic low back pain, an 8-week mindfulness based stress reduction meditation program with yoga or 8 weeks of Cognitive Behavioral Therapy resulted in small, significant improvements in physical function and reduction in pain compared to usual care at 26 weeks with no significant differences in outcomes between the 2 treatments.

If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
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