Critique author	Linda Metzger

Bibliographic Data	
Authors	Wong SYS, Frank WKC, Wong RLP, et al.
Title	Comparing the Effectiveness of Mindfulness-based Stress Reduction and Multidisciplinary Intervention Programs for Chronic Pain- A Randomized Comparative Trial
PMID	21753729
Citation	Clin J Pain 2011; 27(8) 724-734.
Other information if relevant	trial registration with the Centre for Clinical Trials, the Chinese University of Hong Kong

Methods	
Aim of study	To evaluate the clinical effectiveness of the Mindfulness-Based Stress Reduction program (MBSR) with a multidisciplinary pain intervention (MPI) program in terms of pain intensity, pain-related distress, quality of life, and mood in patients with chronic pain.
Design	Single-blind randomized clinical trial

Participants	
Population from which participants are drawn	Recruited from Hong Kong's primary care, geriatric, and pain clinics in community based clinics and service centers, and the hospitals which most chronic pain patients had been found to attend.
Setting (location and type of facility)	Hong Kong community based clinics and service centers
Age	Adults between 18 and 65 years, mean age 47.9 years
Sex	Majority were women, groups were stratified by gender due to the low number of male participants
Total number of participants for whom outcome data were reported	99
Inclusion criteria	1. Age between 18 and 65 years 2. The presence of chronic pain for at least 3 months at the moderate-to-severe level (at least 4 of 10 on Numerical Rating Scale (NRS) pain score) 3. Agreement not to receive other new treatments during the intervention, including taking new medications, or other nonpharmacological treatments 4. Ability to give a written consent.
Exclusion criteria	1. Receiving concurrent treatment with therapies other than medications for pain or psychological symptoms 2. Having a known, concurrent doctor-diagnosed DSM-IV Axis I disorder 3. Having previously participated in an MBSR program 4. Having been engaged, currently or previously, in the practice of meditation or relaxation techniques 5. Illiteracy

Other information if relevant	Baseline pain intensity and pain-related distress did not differ between MBSR and MPI groups. The baseline means (SD) on the Numeric Pain Rating Scale (NRS, range 0-10) for the MBSR intervention group and the MPI control groups were 6.55(1.5) and 6.76 (1.26) for pain intensity, and 6.49(2.12) and 6.75 (1.81) for pain-related distress, respectively.

Intervention Groups

Group 1	
Group name	Mindfulness-Based Stress Reduction Program (MBSR) -Intervention
Number in group	51
Description of intervention	The intervention was modeled on the 8-week Mindfulness-Based Stress Reduction program. Mindfulness, meditation, relaxation, yoga, and the body-mind-connection were taught. 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. It included experiential group practice of meditation and yoga and group activities.
Duration of treatment period	8 weekly group sessions, each of 2 ½ hours, with a 7-hour "retreat" session.
Co-interventions if reported	Yoga
Additional information if relevant	Participants were given a CD and were instructed to practice mindfulness meditation exercises and yoga daily. Practice diaries were recorded daily. Sessions were taught by a clinical psychologist.

Group 2	
Group name	Multidisciplinary pain intervention (MPI) -control group
Number in group	48
Description of intervention	MPI included a set of educational instructions on management of chronic pain, based on a self-help book, "Managing Pain Before It Manages You". Any mind-body connection and cognitive techniques introduced in the book were not taught. Lectures focused on the basic understanding of chronic pain, factors that increase or decrease chronic pain, and effective ways for participants to signal their chronic pain to others.
Duration of treatment period	8 weekly group sessions, each of 2 ½ hours, with a 7-hour "retreat" session.
Co-interventions if reported	Exercises for chronic pain
Additional information if relevant	Participants were given a CD of classical music and were instructed to listen to the CD daily. Practice diaries were recorded daily. The MPI group acted as a control for therapists' attention and contact time, and for any unmeasured effects of taking part in a group intervention. Sessions were taught by a clinical psychiatric nurse with a session taught by a physiotherapist and a dietician.

Coprimary outcomes	
Outcome name and criteria for definition	Self-reported pain intensity and pain-related distress, measured by two separate 11-point Numeric Pain Rating Scales (NRS, range 0-10) with higher scores indicating worse pain.

Time points measured and/or reported	Baseline, at program completion at 8 weeks, and also at 3 and 6 months after program completion.
Differences between groups	The pain intensity and pain-related distress of both MBSR and MPI groups improved significantly from baseline. At 8 weeks, pain intensity was reduced by 0.57 points in the MBSR group and 0.61 points in the MPI group, and pain-related distress was reduced by 0.37 points in the MBSR group and 1.08 points in the MPI group. There was no statistically significant difference in pain intensity between the 2 groups, but there was a statistically significant difference between the 2 groups in pain-related distress at 8 weeks (P=0.046) with participants in the MPI group having more reduction of pain-related distress (a difference of 0.71 points). There were no significant differences in either outcome between the 2 groups at all other time points.
Additional information if relevant	There were no statistically significant differences between the 2 groups in baseline demographics or outcome measures. A total of 80 participants completed all 4 questionnaires. Analyses followed the intention-to-treat principle. Participants in the MPI group demonstrated significantly higher adherence (attending more than half of the 8 sessions) when compared with those of the MBSR group (P=0.04). In the MBSR group 39 of 51 participants (76%) attended at least 5 sessions compared to 44 of 49 (90%) in the MPI group. MBSR participants practiced meditation 3.6 times per week, whereas participants in the MPI group practiced prescribed exercises 3.9 times per week. This difference was not statistically significant (P=0.61).

Secondary outcomes	
Outcome name and criteria for definition	Mood, depression, anxiety, Quality of life, and number of sick leave days.
Time points measured	Baseline, at program completion at 8 weeks for the main analysis, and also at 3 and 6 months after program completion.
Differences between groups	There was one statistically significant "between group" difference in the Profile of Mood States (POMS) vigor-activity component score immediately postintervention (P=0.04), although there were no significant differences at 3 months and 6 months. There were no other statistically significant "between group" differences for any of the secondary outcomes (mood, depression, anxiety, quality of life, and number of sick leave days) at any time points.
Additional information if relevant	When the results were analyzed per protocol on those who only attended for >50% of the sessions in each group, the results were unchanged.
Conclusions	
Key conclusions of study authors	- This RCT showed that both MBSR and a multidisciplinary intervention group reduced pain intensity and pain related distress, although there were no statistically significant differences in these outcomes between the 2 groups at 6 months after intervention. - The decrease in pain intensity and pain-related distress seen in both groups was small and inconsistent, suggesting that the effects from both interventions were rather weak. - One possible way to improve treatment efficacy in psychological research for chronic pain is to better match treatments to patient characteristics, treatment components, and patient treatment interactions.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	Randomization was generated using a predetermined random table in Microsoft Excel 2002.
Allocation concealment *(selection bias)*	Low	Only after baseline measures were completed was the allocation available for access by the researchers. The allocation was unknown to the participants until the first appointment.
Blinding of participants and personnel *(performance bias)*	High	Patients were aware of which group they were in, and it was not possible to blind them. 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 program completion (6 months), 38 participants in the MBSR group (74.5%) and 42 in the MPI group (85.7%) completed all 4 assessments.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with the Centre for Clinical Trials, the Chinese University of Hong Kong.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Funded by The Health and Health Services Research Fund and granted by the Food and Health Bureau, Hong Kong SAR Government, Hong Kong	
Possible conflicts of interest for study authors	None declared	
Notes:		

Comments by DOWC staff

- At postintervention at 8 weeks, the MPI group did show a statistically significant improvement of an additional –0.71points for pain related distress on the NRS scale compared to the MBSR group. However, on an 11 point NRS scale, this difference is not clinically important and does not meet the minimal clinically important difference (MCID) for pain. Both groups improved from baseline where pain-related distress was reduced by 0.37 points in the MBSR group and 1.08 points in the MPI group at 8 weeks, but these improvements are small, and also do not meet the MCID (1.5 points) for pain.

- Adequate sample size planning determined that this study was robust enough to detect any statistical significant difference between the 2 groups in pain outcomes with a sample size of 100.

- Since this RCT studied the effects of MBSR on chronic pain in a non-White population, it may not be appropriate to generalize the results to the US population.

- This study excluded highly depressed patients which may limit the general applicability of the results to chronic pain patients with depression which is quite common among chronic pain patients.

- One strength of this study was that results were analyzed using both per protocol and intention-to-treat analysis, which yielded similar results.

- Additional strengths of the study included an active control group, adequate randomization, and clinical trial registration.

- Limitations of the study include no designated primary follow-up endpoint, no functional outcome, and no long-term follow-up beyond 6 months,

- Numbers of males versus females included in the RCT or in each group was not reported.

- Overall, MBSR participants practiced meditation 3.6 times per week, whereas participants in the MPI group practiced prescribed exercises 3.9 times per week. If participants had better adherence and practiced their meditation or exercises daily as recommended, results may have been different.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This study is adequate for some evidence that in the setting of chronic pain, both an 8-week mindfulness based stress reduction meditation program with yoga and an 8-week multidisciplinary pain intervention program with exercise resulted in small, significant reductions in pain intensity and pain-related distress postintervention, but with no significant differences in outcomes between the 2 programs.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant