| **Critique author** | Linda Metzger |
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| **Bibliographic Data** | |
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| Authors | Natalia E. Morone, MD, MS; Carol M. Greco, PhD; Charity G. Moore, PhD and et al. |
| Title | A Mind-Body Program for Older Adults<br>With Chronic Low Back Pain<br>A Randomized Clinical Trial |
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| Citation | *JAMA Intern Med*. 2016; 176(3):329-337. |
| Other information if relevant | TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01405716 |

| **Methods** | |
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| Aim of study | To determine the effectiveness of a mind-body program (mindfulness meditation) at increasing function and reducing pain in adults 65 years or older with chronic low back pain (LBP). |
| Design | Single-blind randomized clinical trial |

| **Participants** | |
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| Population from which participants are drawn | Independent, community-dwelling adults 65 years or older who were recruited from metropolitan Pittsburgh, Pennsylvania. |
| Setting (location and type of facility) | University of Pittsburgh study. After completion of the intervention, monthly 60-minute booster sessions were held via telephone |
| Age | adults 65 years or older, mean age 74.5 years |
| Sex | 95 men, 187 women |
| Total number of participants for whom outcome data were reported | 282 |
| Inclusion criteria | 65 years or older, spoke English, had intact cognition, had functional limitations owing to their chronic LBP (defined as a score of ≥11 on the Roland and Morris Disability Questionnaire (RMDQ), and had self-reported moderate chronic pain levels on a verbal descriptor scale (measured on a visual scale as; pain as bad as it could be, extreme, severe, moderate, mild, or no pain) occurring daily or almost every day for at least the previous 3 months. |
| Exclusion criteria | Participated in a previous mindfulness meditation program, had serious underlying illness (such as malignant neoplasms, infection, unexplained fever, weight loss, or recent trauma) causing their pain, were nonambulatory, had severe impaired mobility, had visual or hearing impairment that interfered with assessments, had pain in other parts of the body more severe than their chronic LBP or acute back pain, had an acute or a terminal illness, or had moderate to severe depressive symptoms. |

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| Other information if relevant | The baseline mean (SD) RMDQ scores for the intervention and control groups were 15.6(3.0) and 15.4 (3.0), respectively.<br>The baseline mean (SD) on the Numeric Pain Rating Scale (NRS, range 0-20) for the intervention and control groups were 11.0 (4.0) and 10.5 (4.2), respectively. |

**Intervention Groups**

| **Group 1** | |
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| Group name | Mindfulness-Based Stress Reduction Program (MBSR) -Intervention |
| Number in group | 140 |
| Description of intervention | The intervention was modeled on the 8-week Mindfulness-Based Stress Reduction program. Four methods of mindfulness meditation 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. The methods used included the body scan, sitting practice, walking meditation, and mindful stretching. |
| Duration of treatment period | 8 weeks, 90-minute sessions + 6 monthly one hour booster sessions after completion of the 8-week intervention |
| Co-interventions if reported | chair stretches |
| Additional information if relevant | |

| **Group 2** | |
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| Group name | Control group |
| Number in group | 142 |
| Description of intervention | An 8-week group health education program based on a successful aging curriculum known as the “10 Keys to Healthy Aging”. Pain information is not a component. It teaches an interactive, dynamic program to older adults on key health topics relevant to healthy aging such as hypertension management. |
| Duration of treatment period | 8 weeks, 90-minute sessions + 6 monthly one hour booster sessions after completion of the 8-week intervention |
| Co-interventions if reported | The same chair stretches taught in the intervention were taught in the control program. |
| Additional information if relevant | The control group controlled for time, group size, attention, homework, and facilitator time, and received an equal amount of attention and social support as the intervention group. |

| **Primary outcome** | |
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| Outcome name and criteria for definition | Clinically meaningful improvement ($\geq$ 2.5 points) in physical function on the Roland and Morris Disability Questionnaire (RMDQ) after 8 weeks |
| Time points measured and/or reported | Baseline, at program completion at 8 weeks for the main analysis, and also at 6 months after program completion. |

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| Differences between groups | At 8 weeks, the mindfulness group showed a statistically significant improvement of an additional −1.1 points on the RMDQ compared to the control group, and a non-significant improvement of −0.4 points at 6 months. The effect size between groups at 8 weeks was small (−0.23), and insignificant at 6 months (−0.08). |
| Additional information if relevant | The mindfulness group had a mean change from baseline of −3.5 points on the RMDQ at 8 weeks and −3.4 points at 6 months. The control group had a mean change of −2.3 points at 8 weeks and −2.8 points at 6 months. At 8 weeks, 56.8% of participants in the mindfulness group and 44.9% in the control group had at least a 2.5 point clinically meaningful improvement in function, but this difference did not reach statistical significance (*P* = .051). By 6 months, 49.2% of participants in the mindfulness group and 48.9% in the control group had a clinically meaningful improvement in function (≥ 2.5 points) which was again not significantly different (*P* = .97). |

| **Secondary outcomes** | |
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| Outcome name and criteria for definition | Pain (present, average, and most severe during the past week) was measured by self-report with the Numeric Pain Rating Scale (NRS; range, 0-20, with higher scores indicating worse pain). |
| Time points measured | Baseline, at program completion at 8 weeks for the main analysis, and also at 6 months after program completion. |
| Differences between groups | At 6 months, the mindfulness group showed a statistically significant improvement of an additional −1.8 points for NRS current pain compared to the control group, and a non-significant improvement of −1.0 points for most severe NRS pain. The effect size between groups for current pain was small (−0.33), and even smaller for most severe NRS pain (−0.19). |
| Additional information if relevant | At 8 weeks, more participants in the intervention group compared with the control group achieved a 30% improvement on the current (40.9% vs 24.6%; *P* = .004) and most severe (36.4% vs 21.7%; *P* = .008) NRS pain measures for the past week. Similar differences were found at 6 months for both current and most severe NRS pain measures for the past week. |
| **Secondary outcomes** | |
| Outcome name and criteria for definition | Global Impression of Change (perceived improvement in pain) |
| Time points measured | 8 weeks and 6 months |
| Differences between groups | The mindfulness participants reported more improvement in their back pain symptoms at 8 weeks compared with the control participants (*P* < .001). At 8 weeks, 80.3% in the mindfulness program had at least minimal pain improvement, compared with 37.0 % in the control program. At 6 months, 76.1% stated at least minimal improvement compared with 42.2% in the control group. |
| Additional information if relevant | No adverse events related to the intervention or control group were noted. |

| **Conclusions** | |
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| Key conclusions of study authors | - This RCT found that the mindfulness group significantly improved in short-term function at 8 weeks. The mindfulness group also showed significantly reduced current and most severe pain for the past week during the course of the 6-month follow-up.<br>- Learning mindfulness resulted in a clinically meaningful mean RMDQ improvement of −3.4 points, but by 6 months, the comparison group had also improved by a mean of −2.8 points. This improvement corresponded to 49.2% and 48.9% of participants in the respective groups with a clinically meaningful improvement in function.<br>- The mindfulness group also had a statistically and clinically significant 30% improvement in current and most severe (in the past week) pain intensity compared with the control group.<br>- This clinical trial suggests that mindfulness has a role in the treatment of chronic LBP in the older adult. |

| **Risk of bias assessment** | | |
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| Domain | Risk of bias<br>Low High Unclear | Comments |
| Random sequence generation *(selection bias)* | Low | Randomization was generated using SAS Software. |
| Allocation concealment *(selection bias)* | Low | Only after baseline measures were completed was the allocation available for access by the project coordinator who then communicated the assignment to the participant in person or by telephone. |
| 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 (8weeks), 132 participants in the intervention group (94.3%) and 138 in the control group (97.2%) completed assessments. Six months after program completion, 118 in the intervention group (84.3%) and 135 in the control group (95.1%) underwent assessment. Loss to follow up was mostly due to noninterest 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** | | |
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| Study funding sources if reported | None | |
| Possible conflicts of interest for study authors | None declared | |
| Notes: | | |

**Comments by DOWC staff**

- The statistically significant improvements in short-term physical function were small in both groups. Both groups attained clinically meaningful improvement from baseline (≥ 2.5 points) in physical function. The minimal clinically important difference (MCID) between groups was only −1.1 points on the RMDQ at 8 weeks and showed a statistically significant improvement in the mindfulness group. However, the improvement of only 1.1 points is not clinically important and does not meet the MCID. The effect size favoring the mindfulness group at 8 weeks was also small (−0.23). The proportion of participants in both groups that had a clinically meaningful improvement in function was not significantly different between groups, but roughly half of all participants in both groups achieved a clinically meaningful improvement in function of at least 2.5 points.
- At 6 months, the mindfulness group showed a statistically significant improvement of an additional −1.8 points for NRS current pain compared to the control group, and a non-significant improvement of −1.0 points for most severe NRS pain. On a 20 point NRS scale, these differences are not clinically important and do not meet the MCID for pain. The effect size between groups for current pain was small (−0.33), and even smaller for most severe NRS pain (−0.19). However, at both follow ups, more participants in the intervention group compared with the control group achieved a 30% statistically significant improvement on the current (40.9% vs 24.6%; *P* = .004) and most severe (36.4% vs 21.7%; *P* = .008) NRS pain measures for the past week. Participants' perceived improvement in pain on the Global Impression of Change seems to confirm these findings.

| **Assessment by DOWC staff** | |
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| Overall assessment as suitability of evidence for the guideline<br>☒ High quality<br>☐ Adequate<br>☐ Inadequate | This study is adequate for some evidence that in the setting of chronic low back pain for older adults, an 8-week mind-body program that taught mindfulness meditation methods resulted in significant improvements in short-term (8 weeks) physical function and long term (6 months) current and most severe pain in the past week compared to a healthy aging education program. |
| If inadequate, main reasons for recommending that the article not be cited as evidence | |

| **Additional references if relevant** |
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