

Mindfulness-Based Interventions may be Effective for Reducing Functional Limitations in Clients with Chronic Musculoskeletal Pain

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CLINICAL SCENARIO:

Chronic musculoskeletal pain affects people all over the world (Mourao, Blyth, Branco, 2010). Statistics on the prevalence of chronic pain in Canada vary widely, possibly due to differences in definitions (Schopflocher, Taenzer, & Jovey, 2011). It can have a significant impact on the daily functioning of sufferers (Cimmino, Ferrone, & Cutolo, 2011), as well as economic impact directly from health care costs, and indirectly from loss of wages due to absenteeism (Roelofs et al., 2007). Clinical experience shows clients with chronic muscle tension often experience functional limitations due to pain, and get only short term relief (hours to days) from manual therapies such as massage. Increasing research attention to Mindfulness (Davidson & Kaszniak, 2015; Keng, Smoski, & Robins, 2011), as well as this author's practical experience with present moment body-mind awareness, give rise to the clinical question below.

FOCUSED CLINICAL QUESTION:

In adult clients with chronic¹ musculoskeletal pain, do mindfulness² based interventions decrease functional limitations³?

¹ As defined by NIH Medline Plus (2011), "any pain lasting more than 12 weeks."

² As defined by CINAHL (n.d.) scope note: "The psychological state of conscious awareness of thoughts, feelings, bodily sensations, and surroundings"

³ As defined by Reiman & Manske (2011), "limitation in performance at the level of the whole organism or person."

SUMMARY of Search, 'Best' Evidence' Appraised, and Key Findings:

Search of CINAHL, MEDLINE and PsycINFO resulted in 8 original studies, and 4 related studies. The 5 most recent randomized controlled trials showed promising results, though specific mindfulness-based interventions varied. Cherkin et al (2016) and Metikaridis et al (2017) showed statistically significant improvements in functional disability for chronic low back pain (CLBP) and neck pain respectively. Morone et al (2016) found an improvement in short term function for CLBP sufferers, but results were not maintained long term. Van der Maas et al (2016) and Seferiadis et al (2016) found improvements in body awareness were related to less disability in patients with various chronic pain conditions and neck pain respectively.

CLINICAL BOTTOM LINE:

While evidence indicates mindfulness based interventions may reduce functional limitations in adults with chronic musculoskeletal pain, more high quality research is needed. Replication studies with a clearly defined approach to mindfulness, such as Mindfulness-Based Stress Reduction (MBSR), are indicated. Future research could explore what specific aspects of 'mindfulness' are beneficial, as well as reasons for high attrition rates in intervention groups (Cherkin et al., 2016).

Limitation of this CAT:

This critically appraised topic was prepared for a graduate course assignment and was reviewed by an instructor (PM).

SEARCH STRATEGY:**Terms used to guide Search Strategy:**

- **P**atient/Client Group: adults with chronic musculoskeletal pain
- **I**ntervention: mindfulness based interventions
- **C**omparison: (compared to manual therapy alone)
- **O**utcome: decrease functional limitation

Databases and Sites Searched	Search Terms	Limits Used
CINAHL Complete MEDLINE PsycINFO	<p>Both subject heading and keyword terms used when possible.</p> <p>Population terms:</p> <ul style="list-style-type: none"> • Back Pain • Low Back Pain • Chronic Pain • Neck Pain • Shoulder Pain • myalgia • musculoskeletal pain* <p>Intervention terms:</p> <ul style="list-style-type: none"> • Mindfulness • Guided Imagery • Mental Healing • MBSR • (body or present moment or self) awareness • body scan • somatic experienc* <p>Outcome terms:</p> <ul style="list-style-type: none"> • Functional Status • Functional Assessment • functional (limitation* or performance test*) • roland-morris disability question* <p>Population & intervention combined with AND, then combined with AND outcome.</p>	<p>English, and adults age 19 to 65+</p> <p>Past 10 years</p> <p>NOT cancer</p> <p>NOT headach*</p>

INCLUSION CRITERIA:

1. Intervention included some combination of breath, muscle and/or body awareness
2. focused on nonspecific musculoskeletal pain
3. outcome included functional limitations – self reported and/or objective measures

EXCLUSION CRITERIA:

1. did not address functional limitations
2. did not test a mindfulness-based intervention
3. intervention focused on subconscious processes

4. headaches and cancer related pain
5. commentaries on relevant studies

RESULTS OF SEARCH: 8 original studies and 4 related studies were located and categorised.

Table 1: Summary of Study Designs of Articles Retrieved

Study Design/ Methodology of Articles Retrieved	Level*	Number Located	Author (Year)
Original studies			
Randomized Clinical Trial (RCT)	Level 2	7	Cherkin et al. (2016) Esmer et al. (2010) Metikaridis et al. (2017) Morone et al. (2016) Seferiadis et al. (2016) van der Maas et al. (2015) Verkaik et al. (2014)
Longitudinal	Level 3	1	Rosenzweig et al. (2010)
Related studies			
Follow up or pilot study to above mentioned RCT	Level 3	3	Cherkin et al. (2017) Morone et al. (2009) van der Maas et al. (2016)
Protocol for above study	N/A	1	Cherkin et al. (2014)
* The Oxford 2011 Levels of Evidence (Howick et al., 2011)			

BEST EVIDENCE:

The following study was identified as the best evidence and selected for critical appraisal:

Cherkin, D. C., Sherman, K. J., Balderson, B. H., Cook, A. J., Anderson, M. L., Hawkes, R. J., Hansen, K. E., & Turner, J. A. (2016). 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. *Journal of the American Medical Association*, 315(12), 1240-1249.

Reasons for selecting this study were:

- RCT study design appropriate to determine question of effectiveness
- highest level of evidence available
- most recent study directly related to PICO

1. 'usual care' control may include massage or other manual therapies (Cherkin, 2012)
 2. MBSR has a well-defined intervention protocol (Cherkin, 2012) making applicability and future replication more feasible than less known mindfulness-based interventions
- reputability of Journal

SUMMARY OF BEST EVIDENCE

Table 2: Description and appraisal of 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 by Cherkin, Sherman, Balderson, Cook, Anderson, Hawkes, Hansen, & Turner, 2016.

Aim/Objective of the Study:

To assess the effectiveness of mindfulness-based stress reduction (MBSR) vs cognitive behavioral therapy (CBT) or usual care in patients with chronic low back pain.

Study Design:

The Cherkin et al (2016) study was a single blind, randomized clinical trial, using a stratified randomization sequence that was concealed until randomization. Participants were randomized into one of two intervention groups (MBSR or CBT) or a control (usual care) group. Participants in intervention groups attended weekly 2 hour classes for 8 weeks, plus daily home practice and follow-up interviews. Primary outcomes were measured at baseline, 4, 8, 26 (primary end point) and 52 (follow-up) weeks. Participants were compensated for each interview completed.

Setting:

Both intervention groups attended classes at Group Health facilities in large, quiet classrooms, located in Western Washington, and accessible to people with physical limitations.

Participants:

A purposive sample of 342 participants were recruited through Group Health Cooperative between September 2012 and April 2014. Medical records were searched to identify potential subjects who met the following eligibility criteria:
- low back pain (LBP) without specific diagnosis, for at least 3 months

- self reported measures (0 = least to 10 = most) of “pain interference with activities” (p.1241) at least 3/10 and “pain bothersomeness” (p.1241) at least 4/10.

Exclusion criteria included:

- pain attributed to specific cause
- “compensation or litigation issues” (p.1241)
- language barrier or unable to attend classes
- already had a mind-body practice to help with LBP
- did not meet eligibility criteria (above)

Participants were aged 20–70 years, with mean age 49.3 years, mean duration of pain 7.3 years, and 65.7% women. Groups were similar at baseline on key demographic characteristics, with the exception of more women in usual care, and less educated in the MBSR group. Block stratified randomization ensured similarity between groups for primary outcome measure of functional limitation.

Overall follow up response rate was 84.8% at 52 weeks, but there was a 20% loss to follow up in the intervention groups, with only 50.9% of MBSR participants completing at least 6 sessions. A table outlined number of drop-outs and reasons, when known.

Sample size was justified to provide 90% power to detect 25% difference between MBSR and usual care.

Intervention Investigated:

The study protocol was described in sufficient detail to be reproduced and is published separately (Cherkin, 2012). Participants were assigned to intervention groups MBSR (n=116) or CBT (n=113) or a usual care control group (n=113). MBSR and CBT were provided at a Group Health facility with median group size of 12.5 participants. Interventions consists of 8 weekly sessions, each 2 hours long. Both groups were given workbooks, audio CDs, instructions for home practice, and were requested to keep a journal of their experience with the intervention.

The MBSR training included mindfulness meditation, body scan and yoga. It was provided by 8 instructors, all with a minimum 5 years of experience in MBSR.

The CBT training aimed to change pain-related thoughts and behaviours. Usual care was whatever patient usually received; all participants received usual care throughout study.

Sessions were audio recorded. Research assistants and the study investigator regularly checked that protocols were being followed.

Outcome Measures:

The primary outcome measure for functional limitation was a modified Roland Disability Questionnaire (RDQ) range 0-23, with higher scores indicating greater functional limitation due to back pain. Modifications included using 23 instead of 24 items, and inquiring about the past week instead of past 1 day. RDQ has been shown to be a valid measure with good internal reliability (Turner, Fulton-Kehoe, Franklin, Wickizer, & Wu, 2003). Use of the Graded Chronic Pain Scale (GCPS, 0 to 10) as a secondary outcomes measure may add to the study's evidence of reduced functional limitation. According to Cherkin (2012), the GCPS is validated with good psychometric properties, and may help determine the extent to which pain interferes with activities of daily living.

Outcome measures were assessed through blinded interviewers, using a computer-assisted telephone interview program "to minimize errors and missing data" (Cherkin, 2012, p.20). The program contained range and logic checks for consistency.

Main Findings:

Regression model analysis was used to assess differences of the primary outcome (RDQ) between the three groups and from all four time-points post baseline. A separate model was used for the secondary outcomes. The models incorporated time-point, randomization group and interactions between the variables to estimate intervention effects at each time point. Model fit was analysed using generalized estimating equations to account for correlation within individuals. Separate estimators were used for binary and continuous data measures. Statistical significant of intervention effects were analysed at each time-point separately. The Fisher protected least-significance difference approach was used to project against multiple comparisons (to reduce type 1 error).

The Primary analysis was based on a clinically meaningful improvement, defined as 30% or more improvement on RDQ from baseline to the main end point of 26 weeks. $P < 0.05$ was used to determine statistical significance of intervention effects at 4, 8, 26 and 52 weeks. Researchers predetermined they would only deem MBSR effective if the 26 week time point was significant. The MBSR group improved 60.5% compared to usual care at 44.1%. This finding is based on an intention-to-treat analysis (overall $p = .04$, relative risk [RR] for MBSR vs usual care, 1.37 [95% CI, 1.06-1.77]. This was considered a moderate sized effect, and held true at 52 weeks.

The secondary analysis was between groups (adjusted mean differences) and showed no statistically significant difference between the MBSR and CBT groups.

Original Authors' Conclusions:

Authors concluded that MBSR may be an effective treatment (though *not* more effective than CBT) for adults who suffer from chronic low back pain.

Critical Appraisal (McMaster format)(Law, Stewart, Pollock, Letts, Bosch, & Westmorland (1998). Critical Review Form – Quantitative Studies)

Validity:

PEDro score of 6, with 3 points lost due to lack of blinding of subjects, therapists and assessors (considered self-reported measures, despite blinded interviewers collecting data). 1 point lost for less than 85% data for key outcome measure (only 59 of 116 MBSR group completed 6 to 8 sessions).

The study purpose was clear, and authors reviewed relevant background literature, justifying the need for this study.

The block stratified randomised clinical trial was appropriate to address the effectiveness question and helped reduce selection bias. 10 cohorts of participants were recruited, helping reduce the effects of time over the 2 year study period.

Ethical considerations were well outlined in the MAP protocol (Cherkin, 2012) and included a Data Safety Monitoring Body to ensure the safety of participants.

Informed consent was obtained verbally at initial phone call & written on 1st night of intervention. Outcome measures used have been shown to be valid and reliable (Cherkin et al, 2016).

Stratified randomization was conducting to ensure similarity of the groups at baseline, and demographic and symptom data was presented. While the authors stated similarity on all but two factors (more women in one group and fewer college graduates in another), they did not present any statistical analyses to validate this comment.

The sample size was well justified to provide 90% power to detect clinically meaningful (2.95 point difference on RDQ) differences between intervention groups and usual care control. Estimates were appropriately informed from analyses of previous study trial data. Group allocation was done by computer-generated sequence of random numbers which could not be changed after randomization.

Intervention protocol was based closely on MBSR standardized protocol, and was described thoroughly, making it reproducible by qualified individuals. Protocol was monitored closely to ensure it was being followed.

Data was analysed using intention to treat analysis, which helps minimise bias due to attrition. All analysis methods, including regression model to estimate relative risk, Omnibus test, Fisher's protected least significance approach, and generalized estimating equations were clearly outlined in the MAP protocol and were appropriate given the multiple variables and time points involved in the analyses (Cherkin, 2012). Contamination was *not* avoided; usual care groups were allowed to seek whatever treatments they wanted. They *could have* received counselling with CBT or found their own MBSR group to attend. This may increase the improvement of usual care group, showing a smaller effect size of interventions than reality (bias against effectiveness of intervention).

Co-intervention was *not* avoided; usual care was carried on for all participants which makes it less possible to attribute positive effects to the intervention (bias in favour of intervention effectiveness). Effect of possible maturation bias was decreased due to use of usual care group.

The high loss to follow up (20%) in intervention groups may have introduced attrition bias. That only 59 of 116 participants in the MBSR group completed 6 or more sessions is a limitation of this study. This is compared to 64 of 113 who completed 6 or more CBT sessions. Researchers attempted to obtain, and use, data from all participants regardless of their completion of the intervention classes. Although the total sample size (294 completed 26 weeks) exceeds the target sample size, the 88 per group needed to provide adequate power to detect meaningful differences was *not* satisfied. Intention to treat analysis was performed to address the risk of error.

The authors provide a well outlined method for accounting for missing data and attempt to minimize non-response bias by use of "an imputation method for non-ignorable non-response" (Cherkin, 2012, p.28).

As there was no attention control, other possible biases include Hawthorne effect, due to attention from being in the study, and Rosenthal effect; participants may perform better because they're expected to (bias in favour of the intervention groups).

Interpretation of Results:

With the medium effect size found in this study, the minimal clinically important difference was still a positive effect (1.37 [95% CI, 1.06-1.77]). This indicates MBSR may be a beneficial intervention for clients open to a mind-body approach in improving their functional limitations due to lower back pain. More research is needed to confirm generalizability to other nonspecific musculoskeletal pain, though Cherkin et al (2016) suggests that mindfulness based interventions “may provide patients with long-lasting skills effective for managing pain” (p.1248).

Cherkin et al (2016) summarize that findings in their study are consistent with a 2011 systematic review, and only partially consistent with the other large RCT of MBSR chronic LBP (which showed function benefits post treatment, but didn't hold true at 6 month follow up). The authors acknowledge possible limitation in generalizing to other populations is unknown (this population was generally highly educated, and in single health care system).

Summary/Conclusion:

Despite some question as to the strength of their clinically meaningful calculations (due to high attrition in intervention groups), this study provides evidence of the effectiveness of mindfulness based interventions in reducing functional limitations in adults with chronic non-specific musculoskeletal pain.

IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH

Based on the above critical appraisal, MBSR or CBT may be useful interventions to suggest to adult clients with non-specific musculoskeletal pain. The MBSR program is available in person through several trained instructors in the Vancouver area, with cost ranging from \$360 (Mindful Living, n.d.) to \$450 (Al Mashat, n.d.) for 8 to 9 week group sessions. It is also available for free in an 8 week online format (Palouse Mindfulness, n.d.). To provide MBSR, one needs to be certified through The Center For Mindfulness, part of the University of Massachusetts Medical School. Though training is a significant time and financial commitment (Center For Mindfulness, n.d.), a referral to a certified MBSR teacher may be of high value to clients' healing process. It may provide a less stigmatized and more affordable option compared to CBT. As CBT is offered in British Columbia by Clinical Counsellors and Psychologist, the rate for a 50 minute session may be \$140-230 (Carr, n.d.; Jericho Counselling, n.d.). A brief internet search for CBT groups for chronic pain in Vancouver BC yielded zero results.

Future research would be useful to determine reasons for high drop-out rate, as well as effectiveness of MBSR after the 1 year mark (Cherkin et al, 2016) and generalizability to other non-specific musculoskeletal pain.

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