

Development and Initial Validation of Mindfulness-Based Pain Reduction (MBPR) in Patients With Chronic Low Back Pain

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Purpose: Mindfulness-Based Stress Reduction (MBSR) has shown efficacy for alleviating chronic low back pain (cLBP) and is included in current treatment guidelines. However, benefits are moderate. We aimed to optimize MBSR for chronic pain by using recent research to develop Mindfulness-Based Pain Reduction (MBPR) and test it in patients with cLBP.

Patients and Methods: Phase 1: We modified the MBSR curriculum with theory-driven components and convened focus groups with local and international mindfulness and clinical pain management experts to refine an 8-week MBPR program. Phase 2: We recruited participants with cLBP from Northern California using outreach in newsletters, social media, and other methods to test and iteratively modify the curriculum. MBPR was delivered in a group format by videoconference. The first three groups received MBPR; a fourth group was randomized to MBSR or MBPR to assess randomization feasibility. We assessed feasibility and acceptability by attendance, practice logs, and exit interviews. We assessed changes in patient-reported outcome measures for low back pain trials using a single arm (treatment group only) approach at 2 and 6 months with linear mixed models (primary: pain intensity and interference (PEG) scores).

Results: Phase 1: The MBPR curriculum included: 1) mindful interoceptive exposure to pain, 2) pain neuroscience education, and 3) yoga postures specifically for cLBP. Phase 2: we enrolled 58 patients in 4 cohorts; 49 completed post-intervention and 41 completed 6-month follow-up assessments; 29 of the 41 received MBPR. Participants attended a mean of 80% of sessions and 23 of 24 participants accepted randomization in the 4th cohort. Mean PEG scores improved for 20 of 29 MBPR participants in a clinically meaningful way (PEG scores >30%).

Conclusion: MBPR was feasible and acceptable. Two-thirds of MBPR participants experienced clinically meaningful improvements in pain intensity and interference scores. MBPR warrants further investigation through a randomized, controlled trial.

Keywords: chronic pain, pain management, interoception, interoceptive exposure, mindfulness, attention

Introduction

Chronic low back pain (cLBP) is a leading cause of disability and a major burden for patients and health systems worldwide.¹ Current treatment guidelines recommend an initial trial of evidence-based non-pharmacologic treatments such as exercise, mindfulness-based stress reduction (MBSR), or cognitive behavioral therapy.² Perhaps the most important trial of MBSR for cLBP was a trial by Cherkin et al that compared three treatment arms: MBSR, CBT, and usual care. MBSR was superior to usual care. The proportion of patients, who experienced clinically meaningful improvement in pain bothersomeness at 26 weeks was 43.6% in the MBSR group, compared with 26.6% in the usual care group ($p = 0.01$). However, MBSR was no better than CBT, in which 44.9% of participants had clinically meaningful

improvement in pain bothersomeness. The fact that with MBSR fewer than half of the participants improved in a clinically meaningful way indicates that there may be room to improve outcomes from a mindfulness-based intervention for cLBP.

Although MBSR was originally developed by Kabat-Zinn for patients with chronic pain,³ it is designed to be applied to treat a broad variety of health conditions that are sensitive to stress. In its current standardized version,⁴ it is an 8-week curriculum with weekly sessions of 2½ hours each and an all-day retreat. Originally developed as an in-person group program, it is now relatively widely accessible in an online group format over videoconference platforms. MBSR and other mindfulness-based programs^{5,6} teach mindfulness and aim at changing the way we relate to thoughts and body sensations. The standard MBSR program⁴ includes educational modules related to stress, its science and management, and key elements of mindfulness, such as present-moment awareness, decentering and meta-awareness, concentration and open monitoring, and the suspension of evaluative thinking and judgment. Practices include the body scan, sitting meditation, and grounding with mindful movement activities such as meditative walking and yoga.

In the almost 5 decades since MBSR was developed,⁷ the science of pain has markedly advanced and produced results that suggest potential ways to optimize MBSR for cLBP. We identified three areas of weakness in the standard MBSR course that recent research suggests could improve the efficacy of MBSR for cLBP. The three areas were: 1) including yoga exercises that specifically target cLBP and have shown benefits, 2) strengthening mindful interoceptive exposure by including the pain sensation itself into present-moment awareness, and 3) incorporating pain education based on neuroscience. We aimed to address these three areas in a modified version of MBSR that more specifically targets patients with chronic pain, which we have called Mindfulness-Based Pain Reduction (MBPR). The evidence and rationale for incorporating these three areas is as follows.

1. MBSR includes yoga exercises that are intended to embody present-moment awareness in bodily sensations generally and sensations related to physical contact with the floor and sitting surface more specifically. These yoga exercises were not selected for managing cLBP. In the Cherkin study, 29% of MBSR participants had adverse experiences, mostly temporarily increased pain with yoga.⁸ Unrelated to MBSR, Dr. Sherman and her team developed and tested a yoga program that was designed specifically for patients with cLBP and was shown to be effective.⁹ We considered that including yoga exercises that specifically designed for cLBP may improve outcomes for people with cLBP and decrease the risk of injuries.
2. Distraction and ignoring are common habitual coping mechanisms for pain.¹⁰ Although these may work for acute pain,¹¹ they have questionable benefits for chronic pain at best.^{12,13} A meta-analysis of studies with both experimental and clinical pain comparing distraction to sensory monitoring did not find one superior to the other.¹³ None of the reviewed studies included mindful pain exposure, a specific style of attention towards pain from a perspective that is less anxiety-driven and instead more non-judgmental, non-evaluative, detached, de-realization and decentering-based. The latter attention style emphasizes curiosity for and an inquiry into the immediacy of sensory awareness over narrative and evaluative thinking.¹⁴ Evidence that this attention style may be beneficial has come in recent studies of Mindfulness-Oriented Recovery Enhancement (MORE),¹⁵ Mindfulness-integrated Cognitive Behavioral Therapy (MiCBT),¹⁶ and our Mind your Pain study using an attention exercise with a phone app.¹⁷ These interventions apply a mindful focus toward the sensory details and characteristics of the experience of pain. Based on findings from this research, we included the practice and regulation of mindful attention to the immediate sensory experience of pain itself in the curriculum.
3. As perceived stress is a key target of the MBSR program, the standard MBSR curriculum includes education on the psychophysiology of stress. To optimize the program for patients with cLBP, we included neuroscientific pain education and emphasized pain education over stress education. Such neurophysiological pain education has been shown efficacious by itself in patients with cLBP.^{18,19}

The long-term goals of efforts to optimize an MBSR-related program for cLBP pain are to improve outcomes for patients, provide additional treatment options for clinicians, and strengthen research on evidence-based treatments for chronic pain. The objectives of this initial pilot study were to: 1) iteratively refine and manualize the MBPR

intervention, 2) assess the feasibility and acceptability of the MBPR intervention and of randomizing participants to MBPR vs MBSR, and 3) evaluate the potential pain-related benefits of MBPR for patients with cLBP before performing larger clinical trials comparing MBPR to MBSR for improving pain outcomes.

Methods

Study Design and Procedures

This was a mixed-methods study with two phases:

Phase 1

We developed a preliminary curriculum for MBPR based on the 8-week MBSR curriculum with modifications in the three areas described above. The study was supported by the National Center for Complementary and Integrative Health (NCCIH). Phase 1 was approved by the University of California San Francisco IRB (20–32,511).

To refine the preliminary curriculum, we convened two group meetings with experts in this field for an online panel discussion via Zoom. We invited regional and international experts in pain education to consult us on key materials to be included in the MBPR curriculum. The expert panel consisted of the core research team (FH, CW, KR, WM), which met for 2 hours with four regional psychologists, who had many years of clinical experience in behavioral pain management and education, as well as with three international experts in clinical practice and research of Mindfulness-Based Cognitive Therapy, MBSR and CBT for cLBP, and neurophysiological pain education (see in Acknowledgement). Panelists were provided with preparatory information about the planned intervention and questions for discussion. The meetings were video recorded, transcribed, summarized, and discussed in subsequent research team meetings. Patterned after the MBSR curriculum, a preliminary MBPR curriculum for a 1 ½-hour orientation class, eight 2 ½-hour MBPR classes, and a 6-hour retreat day was designed that included printed hand-outs, links to educational YouTube videos and guided meditations, and a published guidebook on mindfulness for pain (April 2021).²⁰

We consulted an expert yoga instructor who had prior experience with mindfulness and academic research and who had additionally been trained in the manualized program applied in Dr Sherman's yoga trial.²¹ We produced five yoga videos, each about 30 minutes long, that were introduced during classes, and that participants could use for practicing at home through a private YouTube channel. These videos built progressively on each other and allowed for different levels of movement ability and fitness including patients who—due to LBP—were not able to sit or stand for half an hour.

Phase 2

In Phase 2, the MBPR curriculum was tested using a single-arm design (all participants received MBPR) in three subsequent cohorts of patients with cLBP and iteratively modified based on participants' feedback after each cohort completed the intervention. Following the third cohort, we convened a second meeting with our consultants (January 2023) to develop the final curriculum. Participants were then enrolled in a fourth cohort and randomly assigned (1:1) to receive either MBSR or MBPR to assess the feasibility of randomization. Each cohort was followed for 6-months to assess outcomes. Phase 2 was approved by the University's IRB (21–34357; November 2021) and registered with ClinicalTrials.gov (NCT04980612). Our study complies with the Declaration of Helsinki. The first cohort started January 2022. The last cohort ended in May 2023, and 6-month follow-up assessment was completed by December 2023.

All MBPR participants were interviewed by videoconference (Zoom) within one week following their last class. The interviewer, one of the study PIs (WM) who attended all of the MBPR classes, used a semi-structured interview guide (see [Supplemental Information](#)). The questions asked about satisfaction with the study intervention, suggestions for further improvement, the main take-home messages, perceived shortcomings, what participants learned, and benefits from their participation. If participants agreed, the interview concluded with a micro-phenomenological inquiry²² into the momentary sensory experience of pain. A more in-depth analysis of the micro-phenomenological inquiry will be reported separately.

Participants

We recruited participants through university newsletters, research and study websites, flyers, and social media. Participants needed to speak English, be aged 18–70, and have cLBP as defined by the NIH Research Task Force

Recommendation on Research Standards for cLBP:²³ pain at least half the days in the past 6 months, by using 2 questions and a human figure drawing illustrating the pain region. Participants had to own a smartphone and/or a computer. Average pain in the last month had to be at least 3 on the 1–10 numeric rating scale (NRS).

Potential participants who visited the study website could check their preliminary eligibility. If they agreed, they were screened over the phone by a clinical research coordinator. We excluded patients with current or history of spine infection, spine tumor, vertebral fracture, cauda equina syndrome, patients with substance abuse, significant mental health or other medical conditions (malignancies, liver failure, renal failure, pain conditions from inflammatory diseases, malignancies, abdominal aortic aneurysm, muscle weakness from radiculopathy), and pain from other body sites worse than their cLBP. Radiculopathy or sciatic pain was not excluded if the condition was stable and did not lead to significant movement restrictions or muscle weakness. Regular opioid prescription was not an exclusion if stable over the past 3 months. We excluded patients involved in a lawsuit or Worker's Compensation claim related to their back; patients who received steroid or Botox injections near the spine in the past 3 months; women who were pregnant, planning to get pregnant in the next months, or were <3 months post-partum.

The discussion of the electronic consent occurred by videoconference (Zoom). After electronically signing informed consent, participants answered questionnaires online at home using REDCap.²⁴ The consent included the publication of anonymized direct interview quotes. Electronic consents were stored on the secure university server.

In an ancillary, separately funded study (NIAMS), a subsample of our participants agreed to undergo pre- and post-intervention fMRI assessments with an innovative attention task in the scanner. These participants had to be assessed for MRI eligibility according to a lengthy battery of questions answered through REDCap.²⁴ This ancillary study was included in the consenting process, led by IS, and will be reported separately.

Interventions

MBPR

As described above, the MBPR curriculum was based on the MBSR structure and included three key modifications to it that we described earlier. It was iteratively modified after each of the three cohorts completed its 8-week program. Group size was targeted to be 10 participants per cohort. Sessions were delivered using videoconference (Zoom). The final version of the curriculum is included in [Supplementary Materials](#) (S1File). The yoga videos were provided by giving participants access to a private YouTube channel (these may be viewed upon request addressed to the corresponding author). Participants were given access to the free InsightTimer app (<https://insighttimer.com>) by registering with a deidentified log-in provided by the research assistant. In this way, we were able to track the participants' app use without compromising privacy. The app included guided meditations for body scans at different lengths.

MBSR

For the fourth cohort, half of the participants were randomly assigned to receive MBSR at no cost to the participants. This online course was part of the UCSF regular clinic service program for the general public with up to 20 participants per group and was led by a university-employed instructor highly experienced with the standard MBSR program. Patients attended a 1 ½-hour group orientation and were individually interviewed by the instructor before the first class; both were done via videoconference (Zoom). The comparison group was included to test feasibility of randomization and was not intended to provide efficacy data.

Measures

At baseline, we collected demographic information including age, sex, gender, race, ethnicity, education, employment, and relationship status, in addition to low back pain duration. Participants were assessed with self-report questionnaires measuring pain and psychosocial variables using REDCap online at baseline, after completing the intervention, and at 6-month follow-up.

Feasibility and acceptability: We collected data on study retention, intervention completion, number of intervention sessions attended out of 9 including the orientation (MBPR Cohorts only), number of class recordings listened to when unable to join the class (MBPR Cohorts only), completion of home meditation practices (MBPR Cohorts only), and

intervention completion by randomization assignment (MBPR vs MBSR) during Cohort 4. Home practice completion was assessed by tracking use of the InsightTimer app for the duration of the MBPR program. In addition, we provided a daily log (participants could choose between paper or electronic forms) to assess daily home practice completion during the weeks between sessions 1 and 2 and between sessions 7 and 8.

Pain and psychosocial measures: We used standard outcome measures for LBP research. The questionnaires were identical to the required instruments in the BACPAC study of the NIH HEAL Initiative.²⁵ We defined the mean change in the three item Pain, Enjoyment of Life and General Activity (PEG) scale score and the proportion of participants that improved on the PEG scale by $\geq 30\%$ (“responders”) as our primary clinical outcomes.²⁶

The PEG Scale assesses pain intensity (one item) and interference (two items), each on a 0–10 scale to create a summary score between 0 and 30 “in the past week”. Cronbach’s alpha in our sample was 0.93.

Other pain and psychosocial measures were the following:

1. Low-back pain intensity, last month: Numeric Rating Scale 0 to 10, high values indicating higher intensity, the standard single-item measure for pain intensity.^{27,28} We used the scale for a 1-month pain recall.
2. Pain Impact:²³ Pain Impact is a 9-item composite measure derived from PROMIS-29 as suggested by the NIH Chronic Low Back Pain Task Force for any research on cLBP. It includes pain intensity, pain interference, and physical function. It uses the raw scores on the items and overall scores range from 8–50, with arbitrary cut-offs for mild 8–27, moderate 28–34, and severe ≥ 35 . Cronbach’s alpha in our sample was 0.94.
3. Pain Self-Efficacy Questionnaire (PSEQ-4):²⁹ is a short version of the 10-item PSEQ. Both versions are adequately responsive instruments in patients with cLBP.²⁹ Scores range from 0–24. Cronbach’s alpha in our sample was 0.91. PSEQ assesses attitudes and beliefs that people with chronic pain hold to carry out certain daily activities, even in the presence of pain.
4. PROMIS measures: The Patient-Reported Outcomes Measurement Information System (PROMIS) uses item-response theory to weight item responses.³⁰ <https://www.healthmeasures.net/explore-measurement-systems/promis>. Scores are based on a T-score metric that standardizes score values around the mean of a normative population sample can range from 0–100 with 50 indicating the population mean. We used the T-scores for PROMIS Pain Interference 4a, PROMIS Physical Function 6b, PROMIS Anxiety 4a, PROMIS Depression 4a, PROMIS Social Role Ability 4a, PROMIS Sleep Disturbance 6a, PROMIS Fatigue 4a.
5. Pain Catastrophizing Scale PCS-6 [0–24]:³¹ The PCS is widely used internationally as a key parameter for changes in catastrophizing that have been reported as mediating therapeutic improvements for cLBP. The PCS has 3 subscales for Rumination, Magnification, and Helplessness. Overall alpha was 0.90 in our sample.³¹
6. Fear-Avoidance Beliefs Questionnaire Physical Activity FABQ-PA:³² The Physical Activity (PA) scale consists of 5 items on a 7-point Likert scale and reflects the belief that activity may result in (re)injury or increased pain. Reliability, validity and sensitivity to change are well supported.³³ Cronbach’s alpha in our sample was 0.86.
7. Chronic Pain Acceptance Questionnaire CPAQ-8:³⁴ The CPAQ-8 has 8 items with a summary score from 0–48 and two factors: Activity Engagement and Pain Willingness. Acceptance of chronic pain has been shown to be modifiable by MBSR.³⁵ It is a precondition for the capacity to develop mindful interoceptive awareness of pain. Cronbach’s alpha in our sample was 0.89.
8. Five-Facet Mindfulness Questionnaire FFMQ:³⁶ The short form of the FFMQ measures dispositional mindfulness and includes 24 items for 5 scales: Acting with Awareness, Describing, Non-Judging, Non-Reactivity, and Observing. Overall Cronbach’s alpha in our sample was 0.86.
9. Multi-dimensional Assessment of Interoceptive Awareness – Version 2 (MAIA-2):³⁷ The MAIA is a self-report measure for interoceptive awareness or sensibility, purportedly a key mechanism of action for mind-body interventions.³⁸ Its eight scales have shown to be strong predictors of treatment response for cLBP:³⁹ Noticing, Not-Distracting, Not-Worrying, Attention Regulation, Emotional Awareness, Self-Regulation, Body Listening, and Trusting, all answered on a 6-point Likert scale.³⁷ It includes 37 items and each scale is scored by calculating the average of the items in each scale. The total scale score is the average of the eight scale scores. Cronbach’s alpha for the entire scale in our sample was 0.91.

10. Primary Care PTSD screening tool⁴⁰ uses a single screening question to determine lifetime exposure to a traumatic event that, if answered positively, branches out to 5 questions with yes or no responses about how the trauma has affected them over the past month. Scores range from 0 to 5 with higher scores indicating greater symptom severity.
11. Patient Global Impression of Change (PGIC) scale:^{41,42} provides a brief outcome measure of the study participant's global impression of change from an intervention and is recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group for studies of chronic pain. It is a single-item rating by participants of their improvement with treatment during a clinical trial on a 7-point scale that ranges from "very much improved" to "very much worse" with "no change" as the mid-point.

We also used Ecological Momentary Assessment (EMA) with twice daily notifications during the first and last week of participants' classes for momentary pain intensity and pain interference on the 0–10 numeric rating scale.

Our study was supported by a Data Safety Monitoring Board. We collected data for serious and other adverse events. No serious adverse events were reported by our participants. In the discussion of the informed consent, we had included that pain could potentially worsen with the yoga activities. This occurred in one patient who subsequently modified her exercises and was able to complete the study intervention.

Analyses

Preliminary analyses were performed to confirm that key data variables were clean and complete. Quantitative feasibility and acceptability outcomes involved descriptive statistics, such as proportions and means calculated using standard methods. Recognizing the challenge of missing data, we took concerted steps to limit missing data, such as repeated phone calls to participants to remind them to fill out the surveys. Analyses of within-group change used linear mixed models, which are robust to missing data.

Quantitative Analysis

Linear mixed models with a fixed effect for time point and a random intercept for person to account for the correlation of repeated measures were used to evaluate change over time within the MBPR participants. We present the coefficients on post-treatment and 6-month follow-up, which represent the change from baseline with their 95% confidence intervals and *p*-values, along with marginal means at each time point. Models are based on intention-to-treat and include all participants (*N* = 41) who enrolled in the MBPR intervention, whether unrandomized (cohorts 1–3, *n* = 29) or randomized as part of cohort 4 (*n* = 12). We examined the association of baseline variables and attendance and adherence metrics with responder status among participants in MBPR using logistic regression analyses. In addition, we had calculated that with a total MBPR sample size of 40, we would have 80% power (two-tailed $\alpha = 0.05$) to detect a statistically significant correlation for psychological variables with key outcome measures if the correlation coefficient is 0.43 or greater.

Qualitative Analysis

We followed a five-phased inductive thematic analysis process (data familiarization, open coding, generating initial themes, developing and reviewing themes, refining and naming themes)⁴³ using a qualitative descriptive approach to summarize participants' experiences with the intervention components and capture some of the variability in experiences related to acceptability and feasibility.⁴⁴ The resulting themes summarize the data topics from all study participants. The authors' interpretations are situated in a phenomenological framework of understanding pain as a biopsychosocial experience potentially modifiable by mind-body approaches that emphasize mindful interoceptive awareness. Here, we report on the participants' feedback on their acceptance and feasibility of the curriculum, with a focus on the curriculum elements that were modified from MBSR. We will report in-depth findings from the micro-phenomenological interview component of the participants' experience of their pain and their learning from the intervention separately.

Results

Phase 1

We identified several key points from our expert consultants that were incorporated into the preliminary MBPR curriculum to be delivered to participants in Phase 2. Regarding pain neuroscience education, the preliminary curriculum provided a conceptual model of pain emphasizing the role of pain as a danger signal processed and regulated in the brain that is not an accurate gauge for damage to body tissue. Consultants recommended acknowledging participants' imaging findings (eg, structural MRI), but not emphasizing them as a primary determinant of pain. Rather, participants were interactively invited to notice and describe variations in their pain experience and influencing factors such as thoughts, emotions, and behaviors, thus challenging a purely biomedical model of pain.

The preliminary curriculum emphasized cultivating a new relationship to pain through mindfulness training, in which aversive pain is a sensation that can be explored with curiosity while noticing and redirecting from automatic, pain-related thoughts. Thus, the teachings emphasized the difference between thinking about versus sensing pain with invitations to set aside pain narratives and even use words other than pain to describe "regions of intensity". With mindful exposure to painful sensations, practices guided participants to intentionally direct and consciously vary the width of attentional focus from wide focus including healthy body parts to narrow focus on the "loudest" sensations. Consultants recommended spending less time explaining these concepts and more time on experiential practice to increase participants comfort with attending to their own discomfort with kindness and compassion. It was recommended that the curriculum explicitly introduce the concept of self-compassion and awareness of self-critical and self-blaming thoughts around pain.

To facilitate the integration of mindfulness practices into daily life, consultants recommended providing brief drop-in practices such as the 3-minute breathing space or a brief body scan and to provide variation in lengths of body scan and sitting meditation recordings. Activity pacing (adapting activity to below functional capacity and increasing in specified steps) was viewed as a key ingredient in CBT-based interventions for cLBP and added to the curriculum. It was recommended that participants should be instructed to carefully and slowly explore with curiosity their range of motion where it does not hurt and to use that pain-free range: curiously exploring rather than distracting from pain.

Phase 2

Participants: In Phase 2, Cohorts 1–4, we prescreened 429 potential participants, and phone-screened 149 ([Figure 1](#)). Of these, 71 participants did not meet the inclusion criteria, and an additional 21 were not responsive or not interested. During enrolment, four potential participants dropped out due to the delayed start of group classes caused by unforeseen scheduling difficulties and other commitments of the class instructor. We enrolled 53 potential participants, with 29 participants in MBPR Cohorts 1–3. In Cohort 4, 24 participants were randomly allocated to MBPR ($n = 12$) or to MBSR ($n = 12$). Prior to starting the intervention, one participant withdrew from the MBSR group due to a scheduling conflict and one due to disappointment with the allocation. In Cohorts 1–4 combined, 41 participants were allocated to MBPR and started MBPR.

The 41 participants in Cohorts 1–4 who started MBPR were on average 48.0 years old [range 19–70], 73% were female, 56% white, 22% Asian, 83% college-educated, average pain duration of 8 years, with median household income between \$100,000 and \$200,000 ([Table 1](#)). The mean pain intensity for the past week at baseline was 4.8 ± 1.9 on the NRS, and the mean physical function by PROMIS T-score was 42.0 ± 6.7 . The mean Pain Impact score was in the "mild" range, with 23.9 ± 7.2 .

Quantitative Feasibility and Acceptability Outcomes

Six of the 41 participants, who were assigned to and started MBPR (14.6% of assigned to MBPR), discontinued the study due to other commitments and scheduling conflicts; one additional participant who completed the intervention failed to fill out the post-intervention questionnaires when planned due to travel abroad but did fill out the 6-month follow-up questionnaires later. At average, participants attended 8.3 (91.8%) out of 9 classes (including orientation). The 41 participants who started the MBPR program (including those who did not complete it), attended a mean of 7.24 (80.4%)

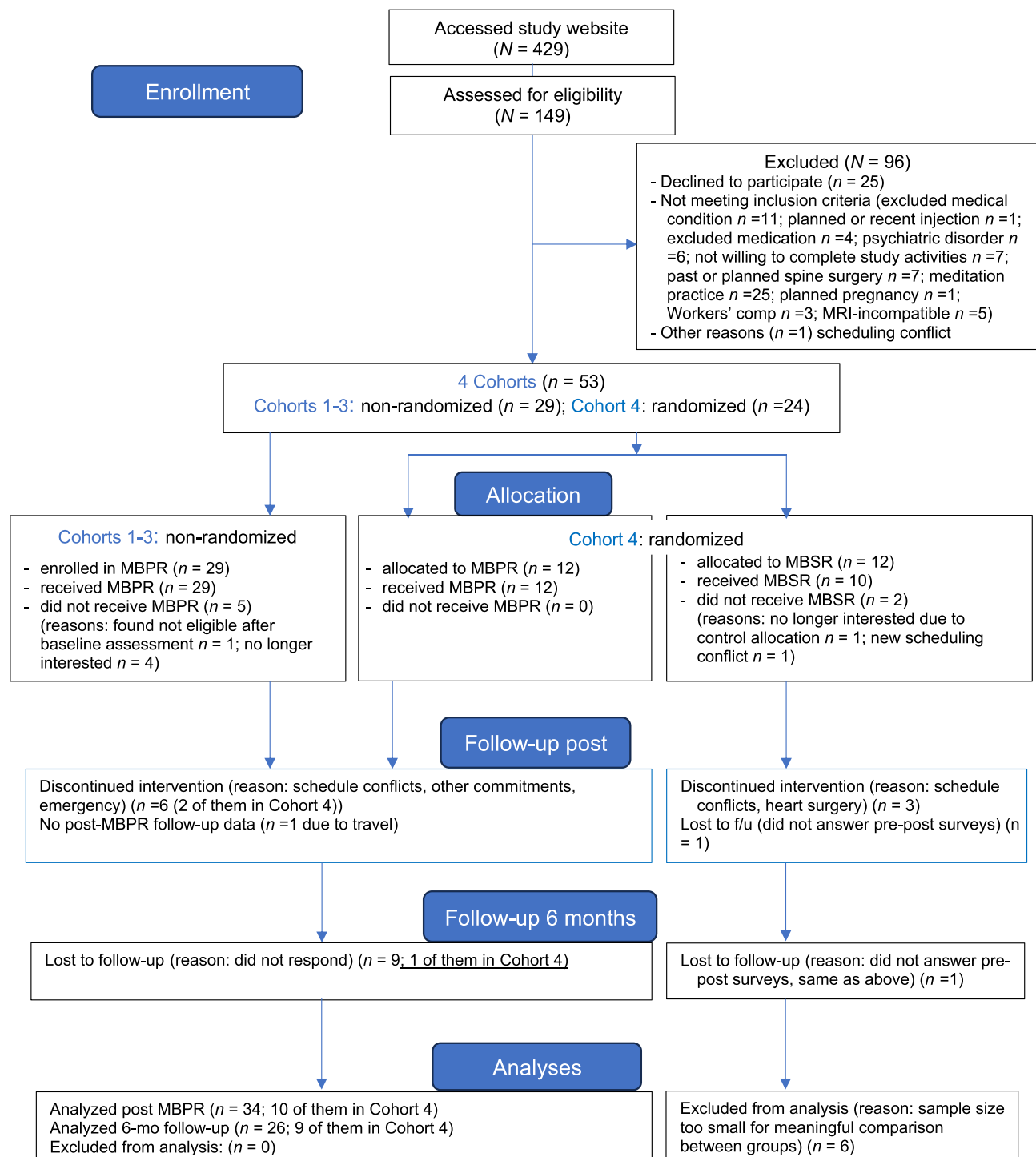


Figure 1 Participant Flow Diagram.

of the 9 classes. Of all 41 participants who started MBPR, 17 listened to at least one class recording, and nine of these to more than one when they were unable to attend the class on Zoom. Participants used EMA during the first and the eighth (completers only) week to document their home practice. Those participants who completed MBPR reported an average of 27.6 minutes of meditation [range 1.4–125.1] and 9.8 minutes of yoga [range 0–35.6] per day in weeks 1 and 8 combined. Participants were connected to the InsightTimer® app for guided meditation over 8 weeks of the MBPR

Table 1 Baseline Characteristics of Participants Assigned to MBPR (N =41)

Age	47.95 (13.15)
Pain duration, months	103.44 (133.75)
Sex at Birth	
Female	30 (73.2%)
Male	11 (26.8%)
Gender	
Female	29 (70.7%)
Male	10 (24.4%)
Other	2 (4.9%)
Race and Ethnicity, collapsed categories	
American Indian or Alaska Native	1 (2.4%)
Asian	9 (22.0%)
Black or African American	1 (2.4%)
Hispanic/Latino	3 (7.3%)
White	23 (56.1%)
More than one	2 (4.9%)
Unknown/Declined to Answer	2 (4.9%)
Education	
High School Diploma	3 (7.3%)
Associate's or Technical Degree	4 (9.8%)
4-year College Degree	21 (51.2%)
Doctoral or Postgraduate Education	13 (31.7%)
Employment	
Full Time Employment	17 (41.5%)
Part Time Employment	11 (26.8%)
Not Employed	13 (31.7%)

Notes: Continuous variables at the top of the table are summarized as mean (standard deviation), and categorical variables in lower portion of table summarized as n (%).

program for an average of 27.6 minutes per day [range 0 to 234.3] and practiced on average about 5 times as much meditation as yoga [yoga/meditation 0.20; range 0–1.5].

Regarding the feasibility of randomizing participants into MBPR versus MBSR, one MBSR participant withdrew due to disappointment with being randomized to MBSR, and one participant assigned to MBSR did not start the intervention due to a scheduling conflict. Of the randomized participants who started MBPR, 83.3% completed the post-intervention survey (73.9% of assigned to MBPR) while only 60% of randomized participants who started MBSR completed the post-intervention survey (50% of those randomized to MBSR).

Qualitative Feasibility Outcomes From Exit Interviews

Overall Satisfaction With MBPR Course

Participants expressed high satisfaction with the course, with many stating that it met or exceeded their expectations and some that it partially met their expectations. Many participants, when asked about their overall satisfaction with the program, described the course as providing useful tools for managing pain and/or pain-related distress:

this is a tool that will help going forward and I now know, okay, I have a tool, use the too and overall, I think it's fantastic. I really think it's such a valuable skill to learn.

For several participants with a remote history of previous mindfulness and/or yoga practices, having the course focused on chronic pain was a positive experience, with participants sharing that it was

completely new and different and that this new way of accessing mindfulness to deal with the chronic pain, that was a huge breakthrough for me.

For some, it helped go to “new levels” compared with practicing mindfulness before or added new practices that were helpful or provided more structure to develop a consistent home practice.

Many expressed that they plan to continue practicing mindfulness after the course, recognizing that “this is something I can really apply for the rest of my life” and that continued practice is necessary for having mindfulness permeate into one’s life, not solely used in response to a particular challenge.

Acceptability of Course Curriculum

MBPR-Specific Elements (Modified From MBSR)

Participants had largely positive feedback regarding the videos demonstrating yoga and mindful walking as well as the videos explaining pain neuroscience concepts and spine anatomy, curriculum elements that were added in the modification of MBSR for chronic low back pain. Some participants wanted to have these video resources even earlier in the program.

For many participants, the pain neuroscience education was described as eye-opening information. Several participants expressed a desire for more revisiting of those concepts during the class time. A small number of participants shared, however, that the educational information was less helpful than the experiential mindfulness practices and would have preferred that less time were spent on the concepts in class. For a few participants, learning about the anatomy and location of the spine in the body (ie, situated with the weight bearing lumbar vertebral bodies and disks being in the very center of the body rather than in the back) paired with specific mindful movements and diaphragmatic breathing, was an “aha-moment” or “a breakthrough”.

Many participants described the low-back pain specific yoga as a pleasantly surprising change from prior yoga experiences or expectations. Several participants shared that they had been hesitant to engage in yoga in the past or that when they had, they experienced difficulties doing the movements or experienced increased pain. Some participants described that at least one of the provided yoga formats (standing, seated on a chair, laying on a mat, in bed) were beneficial, did not cause additional pain, and prevented “overdoing it”. However, one participant noted that it was challenging to set aside their previous notions of how to do yoga “so as not to kind of aggravate things”. Another participant shared that the yoga during class caused “much more intense pain”, explaining that certain postures were held too long. Others felt that sufficient modifications were provided to individually tailor the yoga. The various formats were described as portable, with participants noting they were able to practice the yoga in settings such as at a work desk or on a plane. Participants perceived benefits from yoga including increased body connection and awareness, building core and upper body strength, and pain reduction.

Most participants became aware of their usual habit of trying to ignore their pain or distracting themselves from it and shared that paying sensory attention to and engaging directly with painful sensations (mindful interoceptive exposure) was an interesting new way of coping with pain, surprisingly served to reduce pain levels, or helped cope with the pain differently. In focusing on their pain, several participants became aware of muscular tensions and their association with emotional life events, which they had not noticed before, and were able to improve their pain by “letting go”.

The importance of self-compassion and loving kindness, a curriculum element that was emphasized in relation to pain, was mentioned frequently by participants. These participants became more aware of their tendencies to criticize themselves or to push themselves without regard to their bodies, which had a negative impact on their pain and sense of self-worth. They shared that practicing compassionate self-talk combined with pacing activity helped to prevent over-doing activity and then feeling bad about themselves for taking time for self-care. When describing the impact of self-compassion, one participant shared

It’s not like oh, I didn’t check off all these things, five things on my to-do list. I feel bad about myself. It’s more like, I took time to just be instead of running from one thing to another.

Although many participants found the self-compassion and loving-kindness to be a highly impactful part of the program, a few participants found it challenging or “couldn’t get into it”.

Acceptability of Course Structure

Many participants desired a longer program, with some suggesting adding two additional weeks for a total of 10 weeks. One participant felt additional classes would provide more time for review of concepts to reinforce learning. Only one participant shared that 8 weeks were too long. There were mixed feelings about the length of each class, with several participants saying 2 ½ hours was too long for them and others sharing that the length was fine.

Well, sometimes the class was long. It's hard to cut out that much time in the day. But after every class, I was happy that I did it.

Some desired more breaks during the weekly classes, sharing that classes were “cognitively draining”. The length of the retreat day was described as quite challenging for some. Regarding the length of meditation practices, several participants felt that more than 30 minutes was too long, with suggestions to offer “a shorter tool” or a few practices of 10–15 minutes duration.

Several participants did not like the videoconference format, stating that “it felt a little isolating”. To facilitate forming deeper social connections, there were suggestions to have the retreat day in person and to form smaller breakout groups during classes (two participants in a breakout group instead of four). Participants shared that the break-out groups provided an opportunity to see oneself “mirrored” in others, which was supportive.

Additional suggestions to improve the course structure included providing instructional audio recordings of the written handouts and simplifying the home practice logs which were described as “confusing”.

Iterative Curriculum Modifications

We used the information provided by participants during exit interviews to iteratively improve our curriculum between cohorts. Curriculum modifications are described in [Table 2](#).

Quantitative Exploratory Outcomes

In exploratory analyses ([Table 3](#)) including MBPR participants from Cohorts 1–4 ($n = 41$), the mean PEG score (our primary clinical outcome) improved significantly from 14.2 (95% CI 12.4–16.0) pre-intervention to 8.6 (95% CI 6.6–10.5) post-intervention ($p < 0.0001$) and 9.3 (95% CI 7.2–11.5) at 6-month follow-up ($p < 0.0001$). Twenty-six of the 41 participants (63%) who started MBPR and 76% of the 34 participants who received and completed MBPR

Table 2 Iterative Modifications to MBPR Curriculum Based on Qualitative Exit Interviews

Preliminary Curriculum Element	Curriculum Modifications Based on Participant Feedback from Cohorts 1–3
Pain science education (modified from MBSR)	<ul style="list-style-type: none"> Introduced material earlier in the program Reviewed and revisited concepts and videos in subsequent classes
Back pain-specific yoga (modified from MBSR)	<ul style="list-style-type: none"> Incorporated more movement into the course instead of only formal yoga Used the term “mindful movement” in addition to yoga, which can be intimidating Provided and repeated clearer choices and modifications to postures
45-minute Body Scan	<ul style="list-style-type: none"> Provided guided practices of a variety of shorter lengths, included on the Insight Timer app.
Loving-Kindness practice	<ul style="list-style-type: none"> Provided participants fore-warning about the Loving Kindness practice possibly bringing up difficult emotions and trauma Provided more time for debriefing after the practice
Break-out groups	<ul style="list-style-type: none"> Included a few longer breakout groups early in the program to help with group cohesion and comfort with sharing openly Reduced size of break-out groups (no more than 3 participants)
Home practice and readings	<ul style="list-style-type: none"> Provided clear and earlier advice to help participants proactively block out home practice time Included greater incorporation of the “somewhat elusive” homework readings into group discussions to strengthen accountability

Table 3 Summary of Intention-to-Treat Linear Mixed Models With a Fixed Effect for Time Point, and a Random Intercept for Person to Account for the Correlation of Repeated Measures. Models Include Participants Who Started the MBPR Intervention, Whether Randomized as Part of Cohort 4 (n =12) or Unrandomized (Cohorts 1–3, n =29)

Variable	Pre	Post	Change	Change 95% CI	p	6-mo	Change	Change 95% CI	p
PEG Score	14.2	8.6	−5.7	−3.8 — −7.6	<0.0001	9.3	−4.9	−2.8 — −7.0	<0.0001
Pain Intensity	4.8	3.7	−1.1	−1.8 — −0.4	0.003	3.8	−1.0	−0.2 — −1.8	0.012
Pain Impact	23.9	21.2	−2.8	−0.4 — −5.1	0.020	20.8	−3.1	−0.6 — −5.7	0.016
PROMIS Pain Interference (T)	58.9	55.8	−3.1	−0.8 — −5.4	0.009	56.3	−2.6	0.0 — −5.1	0.050
PROMIS Physical Function	42.0	42.1	0.1	−1.7 — 1.9	0.90	44.5	2.5	0.53 — 4.4	0.012
PROMIS Social Role (unreversed)	45.4	48.2	2.8	0.5 — 5.1	0.015	48.3	2.9	45.3 — 51.2	0.021
Pain Catastrophizing	10.0	7.2	−2.8	−1.2 — −4.5	0.001	6.9	−3.1	−1.2 — −4.9	0.001
- Rumination	3.6	2.5	−1.1	−0.4 — −1.8	0.001	2.5	−1.1	−0.4 — −1.9	0.003
- Magnification	3.6	2.5	−1.1	−0.4 — −1.7	0.001	2.4	−1.2	−0.5 — −1.9	0.001
- Helplessness	2.8	2.2	−0.7	−0.1 — −1.3	0.030	2.1	−0.8	−0.1 — −1.5	0.025
Fear Avoidance Beliefs	16.9	14.6	−2.3	−0.5 — −4.1	0.011	14.8	−2.2	−0.2 — −4.2	0.032
Pain Self-Efficacy	15.4	16.9	1.6	−0.2 — 3.4	0.087	17.9	2.6	0.6 — 4.5	0.011
CPAQ Pain Willingness	11.6	12.7	1.1	−0.2 — 2.4	0.10	13.3	1.7	0.2 — 3.1	0.022
CPAQ Activity Engagement	15.6	15.9	0.3	−1.8 — 1.8	0.66	17.6	2.0	0.4 — 3.6	0.013
Perceived Stress	8.2	8.6	0.4	−0.3 — 1.1	0.23	8.2	0.0	−0.8 — 0.8	1.00
PANAS Negative Affect	11.1	10.2	−1.0	−0.0 — −1.9	0.042	9.6	−1.5	−0.5 — −2.5	0.003
PANAS Positive Affect	17.0	18.0	1.0	−0.2 — 2.1	0.094	16.8	−0.2	−1.5 — 1.0	0.73
PASS Escape Avoidance	10.6	10.2	−0.4	−1.7 — 1.0	0.59	8.9	−1.7	−0.2 — −3.1	0.024
PASS Physiological Anxiety	5.8	5.1	−0.8	−1.9 — 0.4	0.21	4.4	−1.5	−0.2 — −2.8	0.021
FFMQ total	79.9	81.5	1.6	−1.7 — 4.9	0.35	84.3	4.4	0.9 — 7.9	0.014
- Observation	15.8	15.8	0.0	−0.7 — 0.8	0.93	16.2	0.4	−0.4 — 1.2	0.31
- Description	17.7	17.7	−0.0	−1.1 — 1.0	0.96	18.9	1.2	0.1 — 2.4	0.032
- Aware Action	15.5	15.5	0.0	−1.0 — 1.1	0.94	16.8	1.3	0.1 — 2.5	0.028
- Non-Judgmental	16.5	17.5	1.0	−0.2 — 2.2	0.096	17.0	0.5	−0.8 — 1.8	0.44
- Non-Reactivity	14.2	14.0	0.8	−0.2 — 1.9	0.10	15.6	1.4	0.3 — 2.5	0.010
MAIA total	2.7	3.1	0.4	0.2 — 0.6	0.0001	3.3	0.6	0.4 — 0.8	<0.0001
- Noticing	3.0	3.3	0.3	−0.1 — 0.6	0.13	3.3	0.3	−0.1 — 0.6	0.16
- Not Distracting	2.2	2.3	0.0	−0.3 — 0.4	0.82	2.1	−0.1	−0.5 — 0.3	0.71
- Not Worrying	2.6	2.9	0.3	−0.0 — 0.6	0.070	3.2	0.7	2.4 — 3.1	0.0003
- Attention Regulation	2.7	3.6	0.9	0.5 — 1.3	<0.0001	3.8	1.1	0.7 — 1.5	<0.0001
- Emotional Awareness	3.2	3.6	0.3	0.0 — 0.7	0.046	3.8	0.6	0.2 — 0.9	0.002
- Self-Regulation	2.8	3.3	0.5	0.2 — 0.8	0.004	3.4	0.6	0.2 — 1.0	0.002
- Body Listening	2.0	2.6	0.6	0.6 — 0.9	0.001	3.0	0.9	0.6 — 1.3	<0.0001
- Trusting	2.6	3.0	0.3	0.0 — 0.7	0.051	3.5	0.9	0.5 — 1.3	<0.0001
PROMIS Sleep	54.7	52.1	−2.6	−0.1 — −5.1	0.041	52.0	−2.7	−5.4 — 0.1	0.056
PROMIS Anxiety	54.4	52.6	−1.8	−4.3 — 0.6	0.14	53.9	−0.5	−3.2 — 2.2	0.72
PROMIS Depression	52.1	51.0	−1.3	−3.4 — 0.7	0.21	52.3	0.2	−2.1 — 2.5	0.85
PROMIS Fatigue	56.5	53.8	−2.8	−5.8 — 0.2	0.071	52.4	−4.1	−0.8 — −7.4	0.014

Table 4 Patient Global Impression of Change

PGIC Rating	Post Intervention (n =34)	6-Month Follow-Up (n =26)
Very much improved	3 (8.8%)	4 (15.4%)
Much improved	7 (20.6%)	9 (34.6%)
Minimally improved	19 (55.9%)	5 (19.2%)
No change	3 (8.8%)	5 (19.2%)
Minimally worse	1 (2.9%)	1 (3.9%)
Very much worse	1 (2.9%)	2 (7.7%)

(improved their PEG score by more than 30%, generally considered a clinically meaningful improvement. Pain intensity and Pain Impact statistically significantly improved from baseline to post-intervention and 6-month follow-up (Table 3). The mean Pain Impact score changed from 23.9 (95% CI 21.5–26.4) to 21.2 (95% CI 18.6–23.8; $p = 0.020$) post-intervention. The mean PROMIS Pain Interference showed a 3-point pre-post T score change from 58.9 (95% CI 56.6–61.2) to 55.8 (95% CI 53.4–58.2; $p = 0.009$), which is in the range of a minimal clinical important difference according to literature that supported a 1-level change on the patient-reported global change scale as minimally important⁴⁵ At six months, the change in Pain Impact was maintained (20.8; 95% CI 18.0–23.6; $p = 0.016$), whereas the PROMIS Pain Interference slightly worsened (56.3; 95% CI 53.7–59.0; $p = 0.050$) but still remained statistically significantly improved compared to baseline.

On the PGIC (Table 4), participants rated their pain as much- or very much improved at post-intervention (29.4%) and at 6-month follow-up (50%), whereas few participants rated their pain as minimally worse to very much worse at post-intervention (5.8%) or at 6-month follow-up (11.6%).

Among secondary exploratory outcomes (Table 3), mean values for PROMIS Social Role; PCS Catastrophizing; Fear Avoidance Beliefs; PROMIS Sleep; and MAIA Attention Regulation, Self-Regulation, Emotional Awareness, Body Listening, and total scores improved significantly from baseline to post-intervention and 6-month follow-up. Several other psychological parameters showed significantly improved mean values only at the 6-month follow-up: Pain Self-Efficacy, PROMIS Fatigue, PROMIS Physical Function, CPAQ Pain Willingness and Active Engagement for pain anxiety; iPANAS Negative Affect; PASS Escape Avoidance and Physiological Anxiety for pain anxiety symptoms; MAIA Not Worrying and Trusting; and FFMQ Non-Reacting, Aware Actions, Describing, and total score for mindfulness.

Neither minutes of practicing meditation nor yoga nor minutes of InsightTimer®- guided meditation predicted responder status. We explored whether baseline values or EMA measures predicted responder status, defined as showing 30% or greater improvement in PEG Score from pre- to post-intervention. We applied logistic regression models (one model per predictor) to $n = 34$ participants in the MBPR study who underwent the MBPR intervention and completed the post-intervention survey. This included $n = 10$ participants in Cohort 4 randomized to the intervention and $n = 24$ non-randomized participants in Cohorts 1 through 3. Practice time at home for meditation or yoga by EMA documentation and number of attended classes did not predict responder status nor did demographic data (age, education, income, financial strain, or a history of childhood trauma. Baseline pain intensity, expectations of pain relief, and psychological baseline parameters did not predict responder status except one: higher scores on the Fear Avoidance Beliefs Questionnaire appeared to decrease the chances to respond to the intervention, with a 1-point increase on the 20-point scale being associated with a 10% lower odds to respond to the intervention (OR 0.90; 95% CI 0.80 to 1.00; $p = 0.050$).

Discussion

In this study, we aimed to optimize the MBSR program for pain management in patients with cLBP by including an interoceptive awareness practice with sensory pain exposure, cLBP-specific yoga movements, and neurophysiological pain education. We further developed the MBPR curriculum over four consecutive implementations through feedback

from participant observations, participant interviews, and international expert consultants. Based on attendance and practice logs the intervention appeared to be acceptable and feasible. Qualitative data from exit interviews corroborated this assessment with largely positive perceptions of the intervention components that were modified from MBSR.

The number of participants who were assigned to MBPR but did not receive it indicates that in a future efficacy trial, great attention would need to be paid to ensuring the participants are committed to following through with the program prior to randomization. In addition, further steps could be taken to ensure retention for follow-up assessments.

Randomization to MBSR versus MBPR during the last cohort was acceptable. However, there was a differential follow up which may be due to different effort on the part of study staff to reach participants and encourage survey completion or due to lower engagement overall in the MBSR group. In future studies, additional efforts to improve retention and obtain surveys from the control group are warranted.

In participants who were assigned to MBPR and started the intervention, about two-thirds of the participants reported at least a 30% improvement in combined pain intensity and pain interference (PEG) scores, which generally is considered clinically meaningful for patients with cLBP. For participants who completed the intervention, three-quarters of participants reported being improved in a clinically meaningful way at the end of the intervention. Pain interference as measured by PROMIS Pain Interference showed similar improvement with mean improvement by 3 points, viewed previously as clinically meaningful, although it has been shown to be less sensitive to change from treatment intervention compared to the PEG score.⁴⁶

Because this feasibility study was not designed to test efficacy, we cannot infer that the intervention caused an improvement in the participants' pain experience. However, a comparable study of MBSR for patients with cLBP showed a clinically meaningful improvement, assessed by a 30% improvement in pain bothersomeness, at 8-week post-intervention follow-up for 35.4% and at 26-week for 44.1% of the MBSR group participants.⁴⁷ The higher rates of improvement among MBPR participants in our study could be due in part to the fact that in Cherkin et al's study, only 51% of those randomized to MBSR attended ≥ 6 of the 8 sessions, whereas in our study 34 of 41 (83%) attended ≥ 6 of the 8 sessions, rather than to differences in the two interventions (MBPR versus MBSR) themselves. However, there was no association between class attendance and responder status ($p=0.59$) in our study. Another difference between the two studies is the percentage of college-educated participants: 52% versus 83% in our study.⁴⁷ However, we found no association between education and responder status and rather a decreased odds ratio of being among responders for the 19 post-graduate-level educated participants (0.29; 95% CI 0.02 to 3.48; $p=0.33$).

Regarding secondary outcomes, as expected, a series of psychological variables improved from baseline to post-intervention and 6-month follow-up, such as catastrophizing, fear avoidance beliefs, and several dimensions of interoceptive awareness, namely Attention Regulation, Self-Regulation, Emotional Awareness, and Body Listening. For quality of life, measures of social role and sleep improved. Numerous psychological parameters appeared to take longer to change and significantly improve only over the 6-month follow-up: pain self-efficacy, fatigue and physical function, chronic pain acceptance; negative affect; pain anxiety symptoms; worrying and trusting; and non-reacting, aware actions, describing for mindfulness. This is in contrast to some of the secondary results of the study by Cherkin et al,⁴⁸ in which similar psychological mechanisms such as pain self-efficacy, domains of mindfulness on the FFMQ, and chronic pain acceptance each significantly improved immediately post-MBSR, with improvements largely maintained at follow-up time points. Unfortunately, we did not collect additional data for practice times during the 6-month follow-up period which may have explained the late response of these variables. In addition, because the study was not designed to test causal mediation, we were unable to conduct such analyses to better understand mechanisms underlying possible intervention effects.

Similar to other studies,¹⁷ we did not find any association between the quantity of practice time spent or the engagement of our participants with the intervention, and the likelihood of achieving at least 30% reduction on the PEG scale. The depth and quality of the participants' engagement may be more important than attendance or practice time.⁴⁹

Higher baseline scores on the Fear Avoidance Beliefs Questionnaire (FABQ) appeared to decrease the chances of responding to the MBPR intervention. Fear avoidance has been shown to be a prognostic factor for low back pain outcomes.^{50,51} Relatively few studies of mindfulness-based interventions have evaluated the effects on fear avoidance

beliefs,⁵² and to our knowledge none have tested the moderating role of baseline levels of fear avoidance on response to mindfulness interventions. If our result—that FABQ scores may decrease responsiveness to MBPR—is confirmed in future work, fear avoidance may need to be given more targeted attention within the curriculum. Alternatively, in the frame of precision medicine, MBPR may not be the appropriate intervention for patients with cLBP and high fear avoidance.

Conclusion

In this study, we aimed to improve the Mindfulness-Based Stress Reduction (MBSR) curriculum for managing chronic low back pain (cLBP). We changed the curriculum in three major ways: 1) We integrated mindful interoceptive awareness and exposure to the pain sensation itself, which has shown benefits with cLBP.¹⁷ 2) We included modules for pain education patterned after the neurophysiological pain education of Lorimer Moseley.¹⁸ 3) Yoga exercises were specifically designed for the treatment of cLBP based on the study by Sherman.⁹ We found that this modified curriculum with Mindfulness-Based Pain Reduction (MBPR) was feasible and acceptable and showed initial preliminary benefits for our participants with cLBP. Since this is a feasibility study, we cannot infer that MBPR is, in fact, an improvement for the pain management of cLBP. The next step would be a comparison study of MBPR versus MBSR.

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