

Mindfulness Meditation-Based Intervention Is Feasible, Acceptable, and Safe for Chronic Low Back Pain Requiring Long-Term Daily Opioid Therapy

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Abstract

Objective: Although mindfulness meditation (MM) is increasingly used for chronic pain treatment, limited evidence supports its clinical application for opioid-treated chronic low back pain (CLBP). The goal of this study was to determine feasibility, acceptability, and safety of an MM-based intervention in patients with CLBP requiring daily opioid therapy.

Design: 26-week pilot randomized controlled trial comparing MM-based intervention, combined with usual care, to usual care alone.

Setting: Outpatient.

Patients: Adults with CLBP treated with ≥ 30 mg of morphine-equivalent dose (MED) per day for 3 months or longer.

Interventions: Targeted MM-based intervention consisted of eight weekly 2-hour group sessions and home practice (30 minutes/d, 6 days/wk) during the study. “Usual care” for opioid-treated CLBP was provided to participants by their regular clinicians.

Outcome measures: Feasibility and acceptability of the MM intervention were assessed by adherence to intervention protocol and treatment satisfaction among experimental participants. Safety was evaluated by inquiry about side effects/adverse events and opioid dose among all study participants.

Results: Thirty-five participants enrolled during the 10-week recruitment period. The mean age (\pm standard deviation) was 51.8 ± 9.7 years; the patients were predominantly female, with substantial CLBP-related pain and disability, and treated with 148.3 ± 129.2 mg of MED per day. All participants completed baseline assessments; none missed both follow-up assessments or withdrew. Among experimental participants ($n = 21$), 19 attended 1 or more intervention sessions and 14 attended 4 or more. They reported, on average, 164.0 ± 122.1 minutes of formal practice per week during the 26-week study and 103.5 ± 111.5 minutes of brief, informal practice per week. Seventeen patients evaluated the intervention, indicating satisfaction; their qualitative responses described the course as useful for pain management ($n = 10$) and for improving pain coping skills ($n = 8$). No serious adverse events or safety concerns occurred among the study participants.

Conclusions: MM-based intervention is feasible, acceptable, and safe in opioid-treated CLBP.

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Introduction

CHRONIC LOW BACK PAIN (CLBP) is prevalent and challenging for patients, their clinicians, and society.¹ Its natural history and patient response to existing traditional therapies are often unfavorable.^{2,3} In addition, patients commonly face barriers to evidence-based pain care, such as limited availability of pain medicine specialists and specialty treatments, or inadequate insurance coverage, that further contribute to suboptimal outcomes.¹ Therefore, it is not surprising that patients with CLBP frequently turn to opioid therapy,⁴ which may have limited efficacy and lead to negative effects, including overdose.^{4,5} Transformation of care in chronic pain, with efforts focused on personalized and safe care that fosters self-management and addresses all components of the biopsychosocial model of chronic pain, is called for.¹

Psychological therapies and complementary and integrative health approaches are ideal for CLBP management. Psychological therapies, especially cognitive-behavioral therapy (CBT), have shown some benefit for reducing pain and improving function, mental health, and quality of life; complementary and integrative health approaches have been reported by patients to provide benefit.¹ Patient preference and satisfaction regarding therapeutic modalities for CLBP are essential considerations because they can affect treatment adherence and choices.^{6,7} Patients continue to show interest in new, less risky complementary and integrative health approaches,^{7,8} rendering these modalities more likely to result in a sustained patient engagement, which may further treatment benefits. Feasibility, acceptability, and safety, crucial aspects of patient satisfaction and treatment effectiveness,⁹ are important to address when considering different therapies.

Current research supports the use of mindfulness meditation (MM), a popular mind–body complementary and integrative health modality, for chronic pain. MM encourages the intentional engagement of acceptance and nonjudgmental attention to one's current state of body and mind, without becoming preoccupied by it.^{10,11} Through its “observe and accept” approach, MM can cultivate an ability to disentangle a given experience (e.g., pain) from associated emotions, thoughts, or reactions (e.g., catastrophizing) to decrease the experience of suffering and promote a more skillful response to challenges.^{12,13} MM practice can provide a foundation for engagement in life from a place of “being with” one's experiences that, when maintained over time, can have long-lasting effects.^{14–17} It can result in unique skills for chronic pain management, such as acceptance, complementing those acquired through CBT, a part of “usual care” for chronic pain,^{18–22} and potentially enhancing its benefits.^{21–26}

MM is perceived as safe and effective for pain reduction and has established empirical support for reducing symptoms of anxiety, depression, and stress—all problems commonly co-occurring with and affecting outcomes in chronic pain.^{27,28} Research has indicated that MM practice can influence function of the brain areas associated with pain, attention, and emotional response, implicating them as potential mechanisms of action.²⁹ However, evidence on MM's efficacy for chronic pain is limited and mixed, and MM and CBT interventions have not been sufficiently studied in patients with chronic pain requiring a long-term opioid therapy.^{18,19,23,27,28,30–35} A recent randomized controlled trial (RCT) ($n = 115$) found that a “mindfulness-

oriented recovery enhancement” intervention, combining MM and CBT, led to decreases in pain severity and opioid desire ratings in adults with opioid-treated chronic pain; however, opioid dose was not quantified in this study.²³

Although MM and CBT have been shown as feasible and acceptable interventions for many chronic health conditions,^{18,19,27} including depression, anxiety, and maladaptive stress or pain coping (problems commonly co-occurring with and affecting treatment outcomes in chronic pain^{11,27,36}), the Agency for Healthcare Research and Quality calls for systematic reporting on feasibility and safety of MM-based modalities.²⁷ It is important to evaluate the experience with, and effect of, these approaches among patients with opioid-treated chronic pain because their response to the MM intervention may differ from the response of those who do not require daily opioids. This population faces unique challenges related to both refractory pain and opioid therapy, including concerns about the ability to participate in and gain from a typical 8-week MM training, which requires multisession attendance and sustained attention on MM practice. Evaluation of an intervention, tailored to those with opioid-treated CLBP, is needed.

To address this gap, the authors developed an MM intervention for patients with opioid-treated CLBP, then tested its feasibility, acceptability, safety and efficacy in a 26-week pilot RCT. Efficacy results showed a decrease in pain severity ratings and sensitivity to experimental heat-pain stimuli at 26 weeks ($p < 0.05$) and are described elsewhere.³⁷ The current article presents the RCT's feasibility, acceptability, and safety findings, especially in relation to the MM intervention.

Materials and Methods

Trial design

The presented findings stem from the 26-week parallel-arm pilot RCT evaluating effects of the MM intervention, adjunctive to usual care (MM group), as compared with usual care alone (control group), among adults with opioid-treated CLBP. The control participants were offered the MM intervention after completing the study (wait-list). The procedures were approved by the institutional review board and registered with ClinicalTrials.gov before enrollment.

Participants

As detailed elsewhere,^{37,38} potential participants were adults treated for CLBP with long-term daily opioids (≥ 3 months, ≥ 30 mg/d morphine-equivalent dose [MED]), identified through a search of the University of Wisconsin-Madison Department of Family Medicine and Community Health electronic medical record data, and referral from clinicians or self-referral via study brochures. Potential participants were screened by the study coordinator by phone and, if eligible and interested, met with her to proceed with enrollment, baseline assessment, and randomization.³⁷

Interventions

Usual care for opioid-treated CLBP³⁹ was provided to all participants by their regular clinicians, per their recommendations.

The experimental group additionally received the MM intervention, patterned after existing MM-based programs,^{10,24–26}

and adapted to the psychophysical needs of the study population. The intervention was manualized and consisted of eight weekly 2-hour group sessions (Table 1) combining MM^{10,24–26} and pain-specific CBT⁴⁰ strategies. It was guided by two instructors (J.S. and S.M.), pain psychologists, each with more than 20 years of personal practice and more than 10 years of MM teaching experience. Each session included the review of home practice and questions; introduction to the session's core concepts; and session-specific exercises (concept application), followed by discussion of participant experiences and skills for coping with challenges related to opioid-treated CLBP. Session-specific exercises included extensive engagement in mindfulness techniques to facilitate learning of mindfulness-based pain coping.

Key MM techniques included (1) breath meditation practice of bringing awareness to the breath after the mind wanders away, providing practice of not becoming engaged in catastrophizing or rumination about pain; (2) body scan meditation practice of awareness of interoceptive, bodily sensations while engaged in acceptance and nonjudgment of present-moment experiences, including pain; (3) mindful walking, movement or stretching to further practice mindful awareness of interoceptive sensations, such as pain, during movement and facilitate better understanding of one's physical capacity, which, in turn, may promote a healthy engagement in physical activity; (4) loving kindness meditation to practice kindness to and acceptance of, rather than judgment of, one's pain experience; and (5) brief mindfulness techniques designed to be used throughout the day for an "informal" practice or for as-needed pain/stress coping. These "mini-meditations" included pain-wave surfing and SABER (stop, acknowledge, breathe, expand, respond) techniques (Table 1). Their goal was to enable practice of acceptance and nonjudgmental awareness of sensations, thoughts, and emotions within present-moment experiences to allow opportunity for a mindful, healthy response, rather than a habitual, maladaptive reaction (e.g., catastrophizing, rumination, acting out), to pain and other daily stressors.

Treatment fidelity was monitored⁴¹ by using protocol-driven therapist selection and training and intervention delivery, audio-recording and auditing of the sessions to ensure therapist adherence to the manual, and assessment of participant treatment receipt and enactment during each session.

In addition to attending the intervention sessions, MM participants were asked to practice MM formally at home (≥ 6 days per week, ≥ 30 minutes per day; e.g., sitting meditation) and engage daily in brief, "informal" exercises (e.g., pain-wave surfing, mindful pause, or SABER) throughout the study. To enhance practice, they received three CDs containing guided meditations, recorded by the study instructors (Table 1).

Procedures/settings

On the basis of previous research and clinical experience, the plan was to enroll a convenience sample of 20–50 participants (10–25 participants per group) to ensure an optimal setting for group sessions of the MM intervention and enable gathering of pilot data. Therefore, 52 randomization envelopes were prepared with the goal of 1:1 randomization ratio. During the designated recruitment period (January–

March 2013), 35 participants were enrolled, with 21 individuals randomly assigned to the MM group and 14 individuals to the control group.

Enrollment and assessment occurred at the University of Wisconsin-Madison's Clinical Research Unit (CRU). The intervention was delivered at one of the university's clinics (March–May 2013). Eligible participants met with the research coordinator to discuss study details and complete the written informed consent procedures, followed by baseline data collection and, finally, randomization (planned 1:1 ratio, with consecutively distributed sealed envelopes, prepared by the study statistician, using Minitab software, version 12).

After baseline data collection, experimental participants received information about the intervention, whereas controls were reminded about eligibility for crossover training after their study completion. Participants and study personnel were not blinded to group status.

Efficacy-related outcomes included self-reported, bio-marker, and pain sensitivity measures, collected at baseline, 8 weeks (post-intervention) and 26 weeks, and are described in detail elsewhere;³⁷ pain severity (0–10 numeric rating scale from Brief Pain Inventory⁴²) and physical function (0%–100% Oswestry Disability Index scale⁴³) served as primary outcome measures, and daily MED of opioids served as secondary outcome measure. Data were collected by phone or mail from those unable to follow up in person. Participants were reimbursed for time and effort (maximum \$180 for the assessment visits; a \$10 gas card for each attended intervention session).

Outcome measures

Feasibility and acceptability. Feasibility and acceptability of the MM intervention were assessed among MM participants ($n=21$) by their adherence to the intervention protocol and treatment satisfaction and experience evaluations.

Protocol adherence was measured by researcher-recorded participant intervention session attendance and participant-reported formal and informal home MM practice (number of days per week; number of minutes per day), enabling calculation of the number of practice minutes per week. During the intervention (weeks 1–8), participants logged their practice daily, with the logs collected weekly. During weeks 9–26, participants logged their practice weekly, with the logs collected at the 26-week follow-up. The logs were developed by the researchers.

Treatment satisfaction and experience were assessed at the final intervention session by using both quantitative (0–10 Likert scale responses; 10 = "very likely/very important") and qualitative, open-ended questions from the researcher-developed Treatment Satisfaction Survey.²⁵

Safety. Safety was assessed among all participants ($n=35$) by evaluating presence of side effects/adverse events at each contact (logged into a standardized CRU reporting form, then assessed by the study physician) and percentage of participants treated with high daily dose of opioids (MED >200 mg/d); treatment with high dose of opioids has been shown to increase the risk for opioid-related harm, including overdose death.⁴⁴ Average daily MED was calculated on the

TABLE 1. SESSION CONTENT OF THE MINDFULNESS FOR CHRONIC PAIN INTERVENTION FOR OPIOID-TREATED CHRONIC LOW BACK PAIN

<i>Session number and title</i>	<i>Session main topics</i>	<i>Session main exercises^a</i>
1. Automatic Pilot and Pain	Understanding the relationship between automatic pilot and pain and how it leads to our responses; defining MM, present-moment awareness, with acceptance and nonjudgment.	Learn basic meditation postures; “raisin activity”; breath meditation; body scan meditation
2. Awareness of Triggers and Automatic Reactions	Defining common challenges to MM practice; understanding triggers of automatic reactions to pain and stressors, and the effects of our interpretation of events on thoughts/emotions/behaviors; practicing present moment awareness without being pulled into automatic tendencies to judge, fix, or want things to be different than they are; practice acceptance and how to allow the unpleasant states of mind and body to simply “be.”	Body scan meditation; pain-wave surfing ^b exercise; mountain meditation
3. Mindfulness in Daily Life	Integrating mindfulness into daily life; brief MM practices to help become more aware of the inner experience of body and mind; SABER ^c mini-meditation as a way to “pause” before reaction to daily stresses; practice being aware of discomfort that can arise in the body and mind	SABER mini-meditation; “hearing” or “seeing” exercise; breath/body meditation; mindful walking or mindful movement
4. Staying Present and Aware (Mindful) in Challenging Pain Situations	Engaging MM techniques in challenging pain situations; identifying antecedents of perceived pain worsening; becoming aware of how the body and mind react during challenging situations and pain; identifying individual patterns of triggers for automatic reactions; noticing the sensations, thoughts, and emotions that are part of the automatic reaction to challenging pain situations and can make pain experience worse; practice staying with intense or uncomfortable sensations, emotions, and thoughts.	SABER mini-meditation in a challenging pain situation; meditation of breath, body, sounds, thoughts, and emotions; mindful stretching or mindful movement
5. Balancing Acceptance and Skillful, Mindful Action (Change)	Defining acceptance; how acceptance relates to pain perception and change; applying mindfulness as a coping strategy; cultivating a different relationship (acceptance) to unwanted experiences, such as pain, difficult emotions, change, and other people’s behavior.	Mindful walking or mindful stretching; SABER mini-meditation in pairs; SABER mini-meditation with acceptance of pain; sitting meditation
6. Are Thoughts Facts?	Defining thoughts; understanding the relationship between thoughts and pain, automatic reactions to pain, pain coping; defining catastrophizing and identifying unhealthy thought patterns versus “helpful thinking”; learn how automatic unhealthy thought patterns associated with pain can lead to worse coping.	“Thoughts” meditation; mindful movement or mindful stretching; “pain chain” worksheet; create “coping cards”; identification of common, personal pain-related catastrophizing thoughts
7. Self-Care and Life Balance	Recognizing early warning signs of and reducing vulnerability to automatic reactions to pain; understanding the effects of different coping styles on pain perception; identifying practices of self-care and life balance; identifying nourishing and depleting activities; exploring how MM practice can promote maintenance of a healthy lifestyle.	Loving kindness meditation; mindful walking or mindful movement; complete “coping cards.”
8. Balanced Living: Building Support Networks, Continuing to Live Mindfully	Understanding MM as a way to maintain balanced living; the value of taking care of oneself; healthy strategies for balanced living; how to develop a support network; identifying barriers to asking for help; identification of ways to continue incorporating MM into daily life.	Course reflection and evaluation; body scan meditation; breath and loving kindness meditation.

^aFor home practice, participants received three CDs containing seven guided meditations (body scan, mountain, two breath meditations, loving kindness, “silence with bells,” and SABER mini-meditation), recorded by the intervention instructors.

^bPain wave surfing: this exercise promotes staying present with uncomfortable pain sensations, without becoming overwhelmed by or automatically reacting to them (adapted from the “urge surfing” exercise).^{25,26}

^cSABER: stop, acknowledge, breathe, expand, respond. This is a brief five-step mindfulness practice that can be used in physically, mentally, or emotionally distressing situations to facilitate pausing, decrease inner suffering, and create a healthier, mindful response to the situation (adapted from the existing brief SOBER meditation).^{25,26}
MM, mindfulness meditation.

basis of participant self-reported daily use of opioid medications, verified against medication bottle information, for the “past 28 days,” using the timeline follow-back method, a reliable and validated tool for collecting daily substance use data,^{45,46} and a researcher-developed Medication Use Survey.

Statistical analysis

IBM SPSS Statistics (version 21) software was used to analyze numeric data. Statistical significance was set at a two-tailed p -value <0.05 . Because of the pilot nature of this study, no correction for multiplicity was applied. Success of randomization was evaluated by comparing the two groups on baseline characteristics, using the Mann–Whitney test for continuous data and chi-square test for nominal data. The paired Wilcoxon signed-rank test assessed within-group change in MM practice minutes during the study.

Qualitative analysis methods^{47,48} were applied to qualitative data on treatment satisfaction and experience using open coding. Two experienced coders (A.Z., C.B.) independently reviewed all qualitative comments for each open-ended question. The grounded theory approach was used to identify repeated, emerging ideas and concepts. The coders then discussed the results and finalized the coding protocol. They then independently coded data into the major themes and response categories for each question. Data categorization and quantification were finalized through an iterative process and a consensus approach to disagreements.

Results

Baseline characteristics

From among 304 identified prospective participants, 87 were screened (39 ineligible; 13 eligible, declined), and 35 (21 MM, 14 control) were eligible and enrolled.³⁸ As reported elsewhere, most participants were white (80%) and female (80%), with 66% reporting \$15,000 or less in individual annual income.³⁸ They were on average middle-aged (51.8 ± 9.7 years), with 14.2 ± 10.1 -year history of back pain and 7.9 ± 5.7 years of opioid therapy.³⁸ They reported substantial averaged pain severity (5.8 ± 1.4), at least severe disability (66.7 ± 11.4), and moderate- to high-dose opioid therapy (148.3 ± 129.2 mg/d MED) in the “past 28 days.” At baseline, the MM group reported worse pain than controls ($p=0.001$); otherwise the groups did not differ on sociodemographic characteristics, disability scores, or opioid dose ($p>0.05$) (Table 2).

Retention and primary outcome data collection

The 10-week recruitment period yielded 35 enrolled participants. No participant withdrew (100% retention). Primary outcome data were provided by all participants at baseline, 34 participants at 8 weeks (missing 1 MM participant), and 33 participants at 26 weeks (missing 1 MM and 1 control participant), yielding an overall 91.4% adherence rate. No participants missed both follow-ups.

Feasibility and acceptability of the MM intervention

Adherence to MM intervention ($n=21$). Session attendance and engagement in MM practice measured adherence to the MM intervention. Two MM participants did not

TABLE 2. BASELINE CHARACTERISTICS OF THE SAMPLE ($N=35$)

Variable	Experimental group ($n=21$)	Control group ($n=14$)
Women, n (%)	15 (71.4)	13 (92.9)
Age (yr)	52.7 ± 10.5	50.5 ± 8.6
Hispanic or Latino, n (%)	0 (0.0)	1 (7.1)
Race, n (%)		
White	16 (76.2)	12 (85.7)
Black/African American	4 (19.0)	2 (14.3)
Other	1 (4.8)	0 (0.0)
Relationship status, n (%)		
Single	10 (47.6)	4 (28.6)
In a relationship/married	11 (52.4)	10 (71.4)
Education		
High school/GED	11 (52.4)	10 (71.4)
College degree	8 (38.1)	3 (21.4)
Graduate degree	2 (9.5)	1 (7.1)
Current employment, n (%)		
Employed	6 (28.6)	7 (50.0)
Unemployed	6 (28.6)	3 (21.4)
Homemaker	4 (19.0)	1 (7.1)
Retired	5 (23.8)	3 (21.4)
Gross individual income, n (%)		
\leq \$15,000	12 (57.1)	11 (78.6)
\$15,001–\$30,000	6 (28.6)	1 (7.1)
\$30,001–\$45,000	1 (4.8)	1 (7.1)
$>$ \$45,000	2 (9.5)	1 (7.1)
Gross household income, n (%)		
\leq \$15,000	7 (33.3)	4 (28.6)
\$15,001–\$30,000	7 (33.3)	3 (21.4)
\$30,001–\$45,000	2 (9.5)	1 (7.1)
$>$ \$45,000	5 (23.8)	6 (42.9)
Averaged pain severity score	6.3 ± 1.2	4.9 ± 1.1
Oswestry Disability Index physical function, total score	68.1 ± 9.3	64.5 ± 14.1
Morphine-equivalent opioid dose (mg/d)	166.9 ± 153.7	120.3 ± 76.9

Values expressed with a plus/minus sign are the mean \pm standard deviation.

GED, general educational development.

attend any sessions, citing lack of interest/time, 5 attended 3 or fewer sessions, and 14 attended 4 or more sessions. Those attending 3 or fewer sessions stopped attendance in the first half of the intervention, reporting health ($n=2$), transportation ($n=1$), or scheduling ($n=1$) problems or lack of interest ($n=1$). There were no statistically significant differences in baseline characteristics between those who attended 4 or more and those who attended 3 or fewer sessions.

During the study, 19 MM participants provided complete data on their home MM practice, and 2 provided partial data that were used to estimate their average minutes of practice per week during a given assessment period. During weeks 1–8 (intervention period), MM participants reported approximately 3 hours of formal and 2 hours of informal practice (Table 3), conducted on 5.1 ± 2.1 and 4.9 ± 2.0 days per week, respectively, with 11 participants exceeding 180

TABLE 3. WEEKLY MINUTES OF HOME MM PRACTICE AMONG ALL EXPERIMENTAL PARTICIPANTS ($N=21$) AND THOSE ENGAGING IN HOME MM PRACTICE IN A CONSISTENT ($N=10$) VERSUS INCONSISTENT ($N=11$) MANNER DURING THE STUDY

Variable	Formal practice, min/wk			Informal practice, min/wk		
	Weeks 1–8	Weeks 9–26	p-Value ^a	Weeks 1–8	Weeks 9–26	p-Value ^a
All experimental participants ($n=21$)	188.3 ± 94.4	153.3 ± 139.6	0.159	110.1 ± 78.8	99.5 ± 131.3	0.147
“Consistent” meditators ($n=10$)	240.3 ± 73.4	261.2 ± 118.2	0.386	133.3 ± 92.5	162.1 ± 163.4	0.646
“Inconsistent” meditators ($n=11$)	141.1 ± 88.5	45.4 ± 36.0	0.015	89.1 ± 60.6	36.8 ± 30.9	0.008

^aPaired Wilcoxon signed-rank test was used to compare the change in a given MM practice over time; weeks 1–8 represented the intervention period.

Values expressed with a plus/minus sign are the mean ± standard deviation.

minutes of formal practice per week and 14 exceeding 150 minutes per week. During weeks 9–26, they maintained their practice minutes (Table 3), with 7 exceeding 180 minutes of formal practice per week and 10 exceeding 150 minutes per week; however, they decreased the number of formal and informal practice days per week compared with the intervention period (4.1 ± 2.6 days per week, $p=0.085$; 4.2 ± 2.5 days per week, $p=0.028$, respectively). Overall, during weeks 9–26, 18 patients continued MM practice, 2 stopped practicing, and 1 declined to provide data.

The consistency of a higher-dose MM practice was evaluated on the basis of the pattern of formal practice during the study’s three periods: weeks 1–8, 9–16, and 17–26. Those reporting on average at least 150 minutes of formal practice per week (representing over 80% of the study-recommended 180 minutes per week “dose”) during at least two thirds of the study periods were defined as “consistent” meditators ($n=10$), while the remaining participants ($n=11$) were classified as “inconsistent” meditators. “Consistent” meditators maintained a stable level of formal and informal practices, whereas “inconsistent” meditators showed a decline in both formal ($p=0.015$) and informal ($p=0.008$) practices over time (Table 3); these subgroups did not differ ($p \geq 0.05$) for baseline characteristics, session attendance (5.3 ± 2.5 versus 4.2 ± 3.1 , respectively), or treatment satisfaction ratings.

Treatment satisfaction and experience ($n=17$). Seventeen MM participants filled out the “satisfaction” survey, rating the intervention as “important” (8.0 ± 1.8) and “useful” for coping with back pain (7.2 ± 2.4) and stating they were likely to continue formal (8.1 ± 2.8) and informal (9.4 ± 1.0) practices. Responses to the open-ended treatment experience questions formed several themes (Table 4). When starting the intervention, participants hoped to improve pain control and coping skills, reduce reliance on analgesics, and learn to meditate. After the intervention, they indicated the MM training was useful for CLBP management and “general” coping and noted the importance of peer support. They identified pain flare and scheduling conflicts as main barriers to practice and suggested making the intervention longer and more available to others. Throughout their responses, participants emphasized the importance of brief, informal practices, describing them as “easy to fit them into my day,” “I can do this anywhere,” “It helps me in everyday living.”

Safety

During the study, none of the 35 participants reported serious or unexpected side effects or adverse events. Several MM participants noted self-limited, mild side effects during the intervention (increased pain with movement or while learning to “observe” pain experiences, $n=2$; increased anxiety/emotional distress during practice, $n=3$; increased cigarette smoking, $n=1$; and weight gain, $n=1$). The percentage of participants treated with more than 200 mg of MED per day decreased slightly in the experimental (from 28.6% to 20.0%) but not control (from 21.4% to 23.1%) group by 26 weeks (Table 5).

Discussion

Findings of this study document feasibility, acceptability, and safety of the MM intervention and other study methods among opioid-treated patients with disabling CLBP.

These findings are important for clinical practice and research. Patients with opioid-treated chronic pain are in a desperate need of new, effective, and safe treatments.⁴ Although research on the efficacy of MM-based interventions for reducing pain is promising, existing evidence on MM’s effects for pain and/or function in chronic noncancer pain is inconclusive and based on a limited number of rigorous RCTs.^{27,34,35,49} In addition, there is an overall scarcity of research on long-term efficacy of therapeutic modalities, including MM and CBT, in opioid-treated populations.^{5,18,19,27,34,35,49} Although MM modalities are overall considered feasible, acceptable, and safe, these aspects of MM interventions have not been well explored in, and evidence on their efficacy is insufficient for, opioid-treated CLBP.^{27,28}

Examining the details of MM practice is crucial for discerning whether particular practice patterns have a differential health impact.²⁷ This study extends the existing knowledge by evaluating effects of an MM intervention and reporting on the details of home MM practice among individuals with opioid-treated CLBP. The findings³⁷ of reduced pain severity and decreased pain sensitivity to nociceptive thermal stimuli in the MM group, as compared to the wait-list control group, during the 26-week study, are promising and consistent with those of an RCT by Garland et al.²³

Adherence to and high satisfaction with the MM intervention among the current study’s severely disabled, opioid-treated patients support its feasibility and are encouraging, especially because one of the common reported barriers to

TABLE 4. TREATMENT SATISFACTION, QUALITATIVE RESPONSES (N=17): EXAMPLES OF PARTICIPANT RESPONSES TO QUESTIONS, ORGANIZED BY MAJOR THEMES

<i>Theme</i>	<i>Examples of participant responses</i>
Q: Think back to when you first started the course; what did you hope to gain from it?	
Better pain control (n=8)	“I wanted another tool to deal with pain.” “A way to have control over my pain, instead of it having control over me.”
Learn how to meditate (n=5)	“I hoped to learn how to meditate and become comfortable doing so. I was curious as to how I could use mindfulness on a daily basis.”
Better coping skills in general (n=4)	“A new and different way of coping.”
Less reliance on pain medications (n=3)	“The ability to get away from the stress causing extra pain/worse pain.” “The ability to manage pain with less meds.”
Other (n=3)	“I wanted a way to decrease pain and get through pain flare ups without asking for more medications.” “Open-minded, increase focus.” “A support network.” “My doctor heard of this study—he thought I might be able to use less ‘heavy’ medication.”
Q: How important has this meditation course been to you?	
Helped with pain control (n=8)	“I needed other ways to cope with pain besides medication, and heat, ice, and rest.” “I think it’s one of several tools I can use when pain or stress is hard to handle.” “It has helped my pain a lot to meditate.” “Above all I learned that mindful meditation can help me be more positive about how I deal with my pain.”
Helped with things other than pain (n=8)	“Gave me another tool to deal with not only pain, but life situations.” “My sleeping habits have improved....” “[N]ew way to deal with stress.” “[T]his will help in my everyday life.” “Learning the importance of taking the time each day and what the results are from doing that.”
Other (n=4)	“I truly enjoyed meeting others who have similar struggles.” “Addition of resources (CDs, book, sessions) for my toolbox.”
Q: How useful has this course been in helping you improve coping with your chronic back pain?	
Useful for pain management (n=10)	“It didn’t take away the pain, it just made it easier to deal with it.” “It helped me leave somehow into a non-painful state.” “Taking the time to meditate and relax thereby keeping my body relaxed lessening the muscle spasms. That lessens the pain and is wonderful.” “I already coped with my pain pretty well. This was just a stepping stool, for me another way to cope a little better.”
Useful for coping in general/other aspects (n=6)	“[U]seful in so many ways from stopping arguments to doing dishes....” “[H]elps me pause my mind and change to a more positive direction.” “[D]ealing with stress which also helps with pain.” “Increase sleep and rest.”
Not helpful/tailored enough (n=3)	“I found that the constant focus on pain increased my pain....” “Did not help very specifically with back pain.” “I think it was for general pain.”
Q: What did you get out of participating in this study, if anything? What did you learn?	
Better coping skills in general (n=8)	“Learned how to have alternate ways to deal with life.” “I learned I have control/power over my thoughts. I have choices. I am not my pain.”
Learned how to meditate (n=8)	“A sense of a variety of ways to meditate and a chance to try them on for ‘size.’” “I learned how to meditate. ... I also learned how to be mindful.”
Better pain control (n=5)	“I learned to be mindful of my pain and how to meditate to relax and decrease focus from being negative when pain increases.” “I learned that I was much more physically tensed up which caused me excruciating pain....” “It helped me learn to let certain thoughts pass ... and accept that the pain comes and it will pass.”
Support from others (n=4)	“That I wasn’t alone.” “Support network.”
Other (n=3)	“Expanded growth, more attentive and aware.” “I... practice more self-care.”
Q: What, if anything, prevented you from coming to the sessions?	
No barriers (n=4)	“Made it to every session.”
Pain (n=5)	“I missed two sessions. Because of pain. I was very upset by this.” “I missed a few and my pain was too much to bear to sit through the session(s).”

(continued)

TABLE 4. (CONTINUED)

<i>Theme</i>	<i>Examples of participant responses</i>
Illness (<i>n</i> =4)	“[I] was just not feeling well....” “I was in the hospital....”
Scheduling conflict (<i>n</i> =3)	“Doctor appointment. Out of town.” “I started a new job”
Transportation problems (<i>n</i> =3)	“Transportation. Live at least 30 miles away or more.” “Car trouble.” “Not wanting to drive [in the] rain.”
Q: During the course, what were your biggest obstacles to a regular, daily meditation practice?	
None (<i>n</i> =3)	“Since I live alone in my own house, it’s very quiet, so [it] was very easy to [do].”
Difficulties with making time for practice (<i>n</i> =8)	“Just finding the time every day to do the meditation.” “I’m too busy sometimes to sit down and meditate formally. I do well with informal [practice] and incorporating mindfulness into my exercise.”
Illness (<i>n</i> =3)	“Didn’t feel well....” “Physical illness.”
Pain (<i>n</i> =2)	“[P]ain intensity.” “Managed to meditate, but sometimes my pain level made sitting still difficult.”
External distractions (<i>n</i> =2)	“[No obstacles] except when people were around.” “Interruptions from neighbor.”
Q: Please share with us your suggestions on how we can improve this and future projects.	
No change (<i>n</i> =3)	“Don’t change a thing. I loved it!”
Course structure and availability (<i>n</i> =6)	“More intense.” “A longer meditation class schedule. ...2 hours per class is perfect.” “Make sure you are adapting to disabilities....” “Expand [availability].”

Q, question.

MM intervention attendance and practice was pain flare. Teaching participants early-on techniques for pain flare management and/or providing an opportunity for “remote participation” (e.g., telemedicine) may help overcome these challenges, facilitating adherence. The evidence for efficacy of tele-delivered MM and CBT is promising⁵⁰ but has yet to be demonstrated among patients with opioid-treated chronic pain. Adherence may be further enhanced by extending this intervention to less affected patients, possibly preventing the need for opioid initiation or dose increase.

Improving adherence to MM practice and enactment of the intervention-taught skills is important, especially because MM skills can be retained and applied over the long term,¹⁷ and the efficacy findings (published elsewhere)³⁷ suggested a “dose-response” relationship between the consistency/amount of MM practice and the magnitude of outcome improvement. Interestingly, MM participants in this study self-selected early on to those engaged in a “higher-dose” consistent practice, and those practicing less. Perhaps the consistent meditators were more intrinsically motivated, whereas the inconsistent ones needed the external reinforcement and structure of the intervention for continued practice. Development of strategies for identifying those at risk for nonadherence and boosting their engagement during and after the intervention may extend the potential benefits of MM practice to a larger group of patients.

The perceived safety of MM-based interventions^{18,19,27,49} was corroborated by this research. It is in stark contrast to opioid therapy, which has been linked to dose-dependent harms.⁵ Safe interventions that may enable patients to rely less on opioids could benefit health of individuals with chronic pain and, potentially, the broader society, as the impact of prescription opioid abuse has risen to the level of a public health crisis.⁵¹ This experience and participant comments indicate the importance of adapting the intervention to the needs of this population. Although functional limitations were anticipated, after the first session it became clear that the severe physical disability of this population required further adaptations of the intervention manual, especially its “mindful movement” sections. Had the intervention not been cautiously tailored, the adherence could have been compromised.

TABLE 5. PARTICIPANTS TREATED WITH HIGH DAILY MORPHINE-EQUIVALENT DOSE (>200 MG/D) DURING THE STUDY

<i>Variable</i>	<i>MED ≤200 mg/d</i>	<i>MED >200 mg/d</i>
Experimental group ^a		
Baseline	71.4 (15)	28.6 (6)
8-wk follow-up	80.0 (16)	20.0 (4)
26-wk follow-up	80.0 (16)	20.0 (4)
Control group ^b		
Baseline	78.6 (11)	21.4 (3)
8-wk follow-up	71.4 (10)	28.6 (4)
26-wk follow-up	76.9 (10)	23.1 (3)

Values are expressed as percentage (number) of participants.

^aData provided by 21, 20, and 20 experimental participants at baseline, 8 weeks, and 26 weeks, respectively.

^bData provided by 14, 14, and 13 control participants at baseline, 8 weeks, and 26 weeks, respectively.

MED, morphine-equivalent dose.

Limitations, generalizability

Small sample size and medium-length follow-up duration may limit the generalizability of conclusions. In addition, patients who self-selected to the study may differ from their counterparts, potentially limiting result generalizability to a broader population of opioid-treated patients. Lack of blinding could have introduced bias, and lack of an active comparison group limits the ability to draw firm conclusions about the efficacy of the MM intervention because it does not allow disentangling of the effects related to the group experience (e.g., peer support; therapist contact) from those stemming from the intervention itself. Reliance on self-report as a means for tracking MM practice may not accurately reflect participant engagement in home practice. In addition, the responsibility of tracking and logging practice minutes may facilitate adherence to practice in a subgroup of participants. This can be an important consideration for MM programs, as strategies aimed at increasing adherence may potentiate therapeutic effects of MM intervention. Although the high rates of retention and adherence to primary outcome data collection in both groups suggest feasibility of the overall study methods, these measures are nonspecific, with their results potentially influenced by a variety of factors, including the monetary compensation offered to participants for the completion of study assessments. Evaluating the impact of specific elements of the study methods/intervention by future research could help identify components of feasibility and adherence that, if put into practice, may help enhance participant engagement.

Future directions

Patient interest in and satisfaction with MM, and promising evidence on salutary effects of MM and CBT, make MM-based interventions (especially those combining MM and CBT techniques) an excellent object of translational research. Future studies, evaluating effects of MM-based interventions for opioid-treated chronic pain, should consider using an active comparison group and assessing patient characteristics (“phenotype profiling”) and other factors that may predict patient engagement in a continued MM practice and favorable treatment response. The potential of MM intervention to help reduce patient reliance on opioids and opioid use could be of tremendous benefit to individual patients and society.

Conclusions

Findings of this study indicate that the targeted MM-based intervention is feasible and safe in patients with opioid-treated CLBP. MM-based interventions are particularly attractive for the treatment of chronic disabling conditions because they promote an acceptance-based, self-reflective process, which can encourage a patient-empowering and a personalized approach addressing the whole patient. This approach extends beyond the traditional, disease-focused treatment model of chronic pain and passive nature of pharmacotherapy, offering a valuable therapeutic option for those with refractory CLBP requiring daily opioid therapy.

Acknowledgments

The study is registered on ClinicalTrials.gov (NCT01775995). Dr. Zgierska’s work was supported by the

K23AA017508 award from the National Institutes of Health (NIH) National Institute on Alcohol Abuse and Alcoholism and by funds from the University of Wisconsin-Madison. The project was also supported by the Clinical and Translational Science Award program through the NIH National Center for Advancing Translational Sciences, grant UL1TR000427. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Author Disclosure Statement

No competing financial interests exist.

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