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PT-IN-MIND: study protocol for a multisite randomised feasibility trial investigating physical therapy with integrated mindfulness (PT-IN-MIND) for patients with chronic musculoskeletal pain and long-term opioid treatment who attend outpatient physical therapy

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ABSTRACT

Introduction Many individuals receiving outpatient physical therapy have musculoskeletal pain and up to one-third use prescription opioids. The impact of physical therapist-led mindfulness-based interventions integrated with evidence-based physical therapy (I-EPT) to manage patients with chronic musculoskeletal pain and long-term opioid treatment has not been elucidated. This project evaluates the feasibility of conducting a cluster randomised trial to test the effectiveness of I-EPT.

Methods and analysis Study 1 aim: Refine and manualise the I-EPT treatment protocol. Our approach will use semistructured interviews of patients and physical therapists to refine an I-EPT training manual. Study 2 aim: Evaluate different intensities of physical therapist training programmes for the refined I-EPT treatment protocol. Physical therapists will be randomised 1:1:1 to high-intensity training (HighIT), low-IT (LowIT) training and no training arms. Following training, competency in the provision of I-EPT (LowIT and HighIT groups) will be assessed using standardised patient simulations. Study 3 aim: Evaluate the feasibility of the I-EPT intervention across domains of the Reach, Effectiveness, Adoption, Implementation, Maintenance implementation framework. The refined I-EPT treatment protocol will be tested in two different health systems with 90 patients managed by the randomised physical therapists. The coprimary endpoints for study 3 are the proportions of the Pain, Enjoyment of Life and General Activity Scale and the Timeline Followback for opioid use/dose collected at 12 weeks.

Ethics and dissemination Ethics approval for the study was obtained from the University of Utah, University of Florida and Florida State University Institutional Review Boards. Informed consent is required for participant enrolment in all phases of this project. On completion, study data will be made available in compliance with NIH data sharing policies.

Trial registration number NCT05875207.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will use qualitative methods to refine a protocol for physical therapists to use mindfulness-based treatments for patients with chronic musculoskeletal pain and long-term opioid treatment.
⇒ Physical therapists from two different health systems will be randomised to high-intensity training (HighIT), low-IT (LowIT) and no training groups.
⇒ Physical therapists randomised to the HighIT and LowIT training groups will pilot test the protocol.
⇒ This feasibility study is not designed to investigate effectiveness or powered to detect differences in outcomes between training groups.

INTRODUCTION

Chronic musculoskeletal pain is the leading cause of years lived with disability worldwide[1] and the costliest health condition in the USA with total spending exceeding US$260 billion in 2016.[2] The burden and economic impact of chronic musculoskeletal pain has escalated rapidly in the past few decades.[3] Practice guidelines for chronic musculoskeletal pain recommend non-pharmacological care,[4 5] yet medication management,

specifically prescription opioid therapy, remains a mainstay in this population.[6] Musculoskeletal pain diagnoses impact over 100 million Americans[7] and are the most common diagnoses associated with an opioid prescription.[8] An estimated 20%–30% of persons with chronic musculoskeletal pain use opioids for pain management.[6] In recent years, the prevalence of long-term opioid treatment has increased in patients with musculoskeletal pain.[9] Particularly concerning are the significant long-term opioid treatment-related risks (eg, opioid misuse, opioid use disorder (addiction), overdose and death).[10]

Physical therapy is a common non-pharmacological treatment recommended for chronic musculoskeletal pain.[4] The majority of patients in outpatient physical therapy clinics have musculoskeletal pain and many of these individuals are taking an opioid for pain during physical therapy management. For example, among those who attended physical therapy for knee osteoarthritis, more than 30% were prescribed an opioid within 1-month preceding or during care.[11] For persons with Medicaid who attend physical therapy for low back pain, over 17% of patients were prescribed an opioid within the 2-week period preceding physical therapy. Some individuals attending physical therapy will have long-term opioid treatment. Physical therapy is effective for chronic musculoskeletal pain, with significant effects on pain intensity and disability. Studies suggest that physical therapy for musculoskeletal pain may reduce the likelihood of initiating opioid therapy[12] and may protect against long-term opioid treatment.[13] Physical therapy is a recommended part of a multidisciplinary approach to managing patients with chronic musculoskeletal pain and long-term opioid treatment.[14] Combining exercise-based interventions with mindfulness practices is effective for patients with chronic musculoskeletal pain[15] and engaging in mindfulness practices leads to a reduction in opioid dose in patients with chronic pain and long-term opioid treatment.[16] Physical therapists may use mindful movement approaches such as yoga[17] or tai chi during patient management.[18] However, the impact of combining physical therapy with mindfulness-based treatments that are operationalised for use in the outpatient physical therapy setting for patients with chronic musculoskeletal pain and long-term opioid treatment has not been elucidated. Such mindfulness interventions used in this project are typically provided in behavioural health settings. Mindfulness interventions provided by physical therapists remove this siloed approach to healthcare and could lead to improved and more efficient management of patients with chronic musculoskeletal pain and long-term opioid treatment.

Physical therapists have been gaining more exposure to training programmes aimed at integrating principles from psychological-based therapies.[19] Training physical therapists in these and other psychologically based skills known to benefit persons with long-term opioid treatment would create effective physical therapist delivery of interventions for both functional and opioid use outcomes.

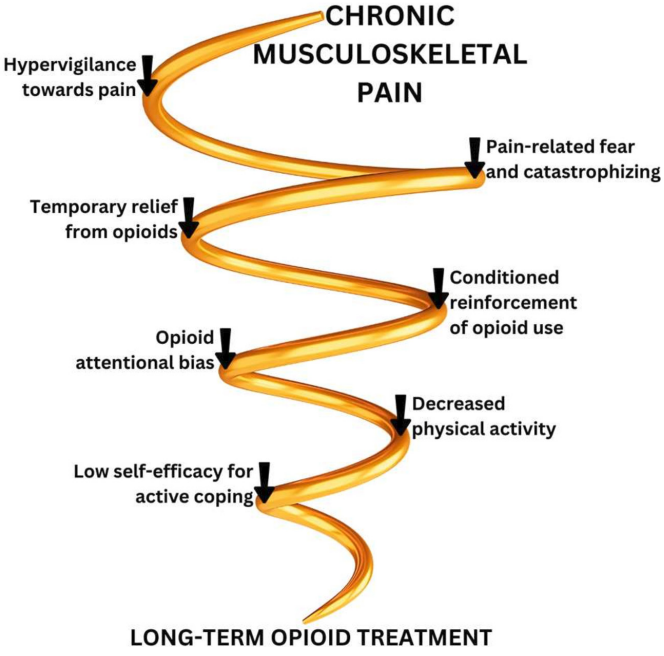

Figure 1 Expansion of the downward spiral model linking chronic musculoskeletal pain to long-term opioid treatment.

Similar approaches to integrate mindfulness interventions should also be undertaken. Therefore, our overall goal is to optimise the effectiveness of physical therapy for patients with chronic musculoskeletal pain and long-term opioid treatment. To achieve this goal, we are preparing a future, multisite, fully powered effectiveness cluster randomised clinical trial that will evaluate mindfulness integrated in evidence-based physical therapy (I-EPT) on pain and opioid use outcomes. However, conducting such a trial in busy outpatient physical therapy settings requires feasibility assessment. Physical therapy with integrated mindfulness (PT-IN-MIND) will investigate the feasibility and implementation of providing I-EPT to patients with chronic musculoskeletal pain and long-term opioid treatment. Thus, we describe our protocol to evaluate the feasibility of conducting a cluster randomised trial to test the effectiveness of I-EPT.

Conceptual model

PT-IN-MIND is grounded in our Downward Spiral Model linking pain to opioid dose escalation. This project expands the model linking chronic musculoskeletal pain and long-term opioid treatment (Figure 1). Key considerations are the powerful cognitive and emotional responses to chronic pain including hypervigilance, fear and catastrophic pain appraisals.[20 21] While opioids have limited analgesic effect, their use may persist as a strategy to manage these aversive emotions. Long-term opioid treatment, however, serves to increase reactivity to emotional distress[22] and sensitisation to pain (ie, hyperalgesia).[23] Prolonged opioid use and attentional bias also reinforce preferences for passive coping along with poor self-efficacy about one's ability to actively manage pain.[24] Thus, patients are caught in a downward spiral where

the perceived solution (opioid use) to their problem (negative emotions) may only magnify the problem which increases negative emotions in a self-perpetuating cycle. The Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework will guide our PT-IN-MIND feasibility evaluation.[25] Briefly, the RE-AIM framework consists of five dimensions (reach, effectiveness, adoption, implementation and maintenance) with unique feasibility measures that are pertinent to this study (table 1). For example, the extent to which I-EPT is implemented by physical therapists will be assessed with the Modified Mindfulness-Oriented Recovery Enhancement

Table 1 The RE-AIM domains with corresponding measures and benchmarks

Domain	Definition	Feasibility measures used	Benchmarks
Reach	The extent to which the target population for the intervention was reached	The percentage of patients with CMP and LTOT offered participation who choose to enrol.	>75%
		Percentage of patients screened who are eligible.	% of patients screened that are eligible
		The percentage of PTs who have a patient enrolled on their schedule.	>90%
Efectiveness	The impact of the interventions on important outcomes	Adherence by patients will be measured by the number of the recommended visits attended.	>80% will attend 75% of recommended visits
		Adherence by the patients to the protocol will be measured by the number minutes spent practising mindfulness, reappraisal or savouring each day.	>80% will report practising 15 min per day
		The percentage of all patient-reported outcomes collection using REDCap.	>80%
		Percentage of Timeline Followback collected.	>80%
Adoption	The representativeness of the intervention providers and practice settings	Qualitative interviews of PT and patient participants will be used to understand potential barriers and facilitators to adoption of I-EPT.	--
		Percentage of patients enrolled that report receiving any MORE component.	>80%
		Percentage of PTs presented the study who choose to enrol in the study	--
		Percentage of PTs who attend the competency assessment	--
		Percentage of patients managed by study PTs who are retained at baseline, 6-week and 12-week follow-up.	>95% will provide baseline data, 90% will provide 6-week follow-up data and 80% will provide 12-week follow-up data
Implementation	The extent to which the intervention is implemented as intended	Percentage of patients managed by a single trained PT.	>90%
		The percentage of PTs who participate in the fidelity assessments.	>80%
		MORE-Functional Measure (Modified MORE-FM) fidelity measure during patient encounters.	>80% average score of 3 on MORE-FM during direct observation
		Qualitative interviews of PT and patient participants will be used to understand potential barriers and facilitators to implementation of I-EPT.	--
		Qualitative interviews of key stakeholders will be used to understand potential barriers and facilitators to maintenance of I-EPT.	--
Maintenance	The sustainability of implementation over time	Qualitative interviews of key stakeholders will be used to understand potential barriers and facilitators to maintenance of I-EPT.	--

No benchmark established.
CMP, chronic musculoskeletal pain; I-EPT, Mindfulness Integrated in Evidenced-Based Physical Therapy; LTOT, long-term opioid treatment; MORE, Mindfulness Oriented Recovery Enhancement; PT, physical therapist; RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance; REDCap, Research Electronic Data Capture.

Fidelity Measure (MORE-FM) described in greater detail below.[26]

METHODS

The study protocol for aim 1 was approved by the University of Utah Institutional Review Board (IRB) on 19 November 2022, the University of Florida IRB on 23 March 2023. The protocol for aims 1–3 was registered with ClinicalTrials.gov (NCT05875207) on 15 May 2023. Enrolment for aim 1 is underway and expected to end in January 2023. We anticipate enrolment for aims 2 and 3 to begin in April 2024 and end in January 2025. Single-site IRB approval for aims 2 and 3 was obtained from the University of Utah IRB on 26 February 2024.

Study design overview

PT-IN-MIND is a multisite, randomised feasibility trial investigating PT-IN-MIND for patients with chronic musculoskeletal pain and long-term opioid treatment. First, we will refine the I-EPT intervention protocol (study 1 aim). I-EPT is currently being studied in patients after spine surgery (NCT04770480),[27 28] however, key stakeholder feedback from physical therapists and patients is needed to refine the protocol (ie, stakeholder suggestions to maximise the acceptability of the protocol to both patients and physical therapists) for patients with chronic musculoskeletal pain and long-term opioid treatment. Second, we will evaluate the I-EPT training programme with respect to intensity to inform future study planning (study 2 aim). Third, we will evaluate physical therapists' fidelity to the I-EPT refined treatment protocol and assess key feasibility outcomes (study 3 aim). These study aims will be carried out sequentially. We will evaluate feasibility of procedures needed to conduct our future trial; therefore, the results of an early study aim may require modification of certain procedures during a later study aim. This flexibility will allow for thorough methodological evaluation to maximise the likelihood of successfully conducting our future trials. Any important modifications to the protocol will be submitted the National Institutes of Health (NIH)/ National Center for Complementary and Integrative Health (NCCIH), the University of Utah IRB and ClinicalTrials.gov as necessary.

Project aims

Study 1 aim: Refine and manualise the I-EPT treatment protocol for patients with chronic musculoskeletal pain and long-term opioid treatment.

Study 2 aim: Evaluate different intensities of a physical therapist training programme for the refined I-EPT treatment protocol.

Study 3 aim: Evaluate the feasibility of the I-EPT intervention across domains of the RE-AIM framework.

Settings and participants

This multisite feasibility study will be conducted at University of Utah Health in Salt Lake City, Utah and Brooks Rehabilitation in Jacksonville, Florida.

Study 1 aim: refine and manualise the I-EPT treatment protocol for patients with chronic musculoskeletal pain and long-term opioid treatment

The I-EPT treatment protocol is currently used by members of our study team for an ongoing trial (NCT04770480) examining patients after spine surgery.[27 28] The protocol integrates principles of MORE, a treatment that integrates mindfulness training, cognitive reappraisal skills and positive emotion regulation into a therapeutic approach designed to reduce opioid overuse, opioid misuse and functional interference resulting from chronic pain.[16 29–31] MORE is an evidence-based intervention that has been tested in multiple RCTs[32]; in the largest clinical trial of MORE conducted to date (N=250), MORE reduced opioid dose by more than 50% compared with a support group which demonstrated a 15% reduction in opioid dose, and 50% of patients reported clinically significant decreases in chronic pain severity.[33] MORE is composed of three core components[29 31] that the I-EPT protocol integrates across eight physical therapy sessions: (1) mindfulness to reduce pain and increase self-regulation over opioid use (integrated into physical therapy sessions 2 and 3); (2) reappraisal to regulate negative emotions and promote active coping instead of catastrophising and opioid self-medication (physical therapy session 5); and (3) savouring to promote a focus on positive daily experiences as a means of boosting motivation and restoring dysregulated reward neurocircuitry function associated with pain and opioid use after spine surgery (physical therapy session 7). The integration of MORE core components within the physical therapy episode of care is described in table 2 which includes minor modification to the protocol being used after spine surgery[27] for adaptation within the civilian outpatient physical therapy setting. Physical therapists trained to provide I-EPT integrate MORE practice components (mindfulness, reappraisal and savouring exercises) into EPT activities, (eg, integrating mindfulness into a walking programme and using body scan meditation while stretching). Brief didactic components covering mindfulness, mindful savouring or mindful reappraisal are included in treatment sessions 2, 3, 5 and 7 are provided while patients are exercising or receiving other interventions (eg, manual therapy) depending on the preferences of patients and physical therapists. This approach will be used as a starting point with which to refine the I-EPT treatment for patients with chronic musculoskeletal pain and long-term opioid treatment who attend outpatient physical therapy.

Study 1: study design and methods

An iterative approach will be used to refine the current version of the I-EPT treatment protocol. We will conduct

Table 2 Mindfulness Integrated in Evidence-Based Physical Therapy

Visit	Physical therapy (PT) session content
1	Evidence-based PT (education, exercise and manual therapy tailored to the patient)
2	Mindfulness component: discuss the nature of pain and introduce practice of mindfulness and body scan meditation Evidence-based PT
3	Mindfulness component: debrief daily mindfulness/body scan practice, discuss mindfulness and automaticity in coping with pain and/or stress Evidence-based PT
4	Evidence-based PT
5	Mindfulness component: debrief daily mindfulness/body scan practice, discuss positive cognitive reappraisal and reappraisal exercise Evidence-based PT
6	Evidence-based PT
7	Mindfulness component: debrief daily mindfulness/body scan practice, discuss mindful savouring and exercise (10 min) Evidence-based PT
8	Evidence-based PT Finalise ongoing exercise and mindfulness practices for self-management

PT, Physical Therapy.

semistructured qualitative interviews with separate cohorts of two key stakeholder types who we will identify through purposeful sampling; 15 physical therapists (7 from Utah; 8 from Florida) who manage patients with chronic musculoskeletal pain and 15 patients (7 from Utah; 8 from Florida) with chronic musculoskeletal pain and long-term opioid treatment. Four weeks prior to the interviews, we will provide the physical therapists with the I-EPT treatment protocol manual (including the modifications noted above) developed by members of our study team for use with patients after spine surgery. A summary of the protocol in the form of an online voiceover virtual slide presentation will be provided to the patients 4 weeks prior to their interviews. This presentation will include a description of mindfulness and specific examples of mindfulness activities I-EPT. A coinvestigator or a trained research assistant (RA) will conduct the interviews after the physical therapists and patients review the protocol.

After the semistructured interviews, members of the PT-IN-MIND team will review the qualitative results from the analytical process described below (study 1 aim: analysis plan—qualitative data). To ensure the accuracy of our interpretation of qualitative data at this stage, we will conduct a member-check[34] by sharing qualitative results with physical therapists and patients that we interviewed. The results will be used to arrive at an adapted, refined and manualised version of the I-EPT treatment protocol to be used in aims 2 and 3 of this study.

Study 1: eligibility, recruitment and consent of participants

Physical therapists

Purposeful sampling of physical therapists for study 1 will be used to avoid study 2 contamination (ie, exposing physical therapists to treatment manual). Representatives from health systems in different geographical regions in the USA will be contacted and asked to disseminate this opportunity to physical therapists in their respective health systems. Interested physical therapists will then contact the study coordinator to learn more about the project and provide informed consent if appropriate. All physical therapists who are employed at least 0.05 full-time equivilant (FTE) and self-report managing patients with chronic musculoskeletal conditions (ie, low back, neck or shoulder pain, hip, or knee osteoarthritis) will be eligible.

Patients

At the University of Utah and Brooks Rehabilitation, research staff and investigators will give an overview of the project at routinely scheduled staff meetings and invite physical therapists to assist with recruitment of patients by providing study flyers to patients with information to contact study personnel to learn more about study. At University of Utah Health, a backup recruitment method will use reports generated by the patient scheduling programme. Study staff will review the clinic schedules for potential patients with chronic musculoskeletal pain. These patients will be sent an IRB-approved opt-out letter via email or traditional mail inviting them to contact study personnel to learn more about the study. Study personnel will screen the patients for eligibility criteria (box 1). Interested patients will meet remotely with the study coordinator to insure eligibility. Online supplemental appendix 1 contains the IRB-approved informed consent document for study 1.

Eligible physical therapists and patients will indicate consent using a consent cover letter administered

Box 1 Patient's inclusion and exclusion criteria

Patients (aims 1–3)

Inclusion criteria

- Age 18–75.
- English-speaking.
- Diagnosis of musculoskeletal pain condition involving the spine and/or peripheral joint(s).
- Current musculoskeletal pain present for greater than or equal to 3 months.
- Use of prescription opioids for most of the last 90 days (self-report).

Exclusion criteria

- Currently pregnant.
- Currently receiving mind-body treatment for musculoskeletal pain from a healthcare provider (eg, PT, chiropractic, massage therapy).
- Currently receiving treatment for a substance use disorder.
- Musculoskeletal pain condition related to a fracture or surgical procedure in the past 6 months.

PT, physical therapy.

through Research Electronic Data Capture (REDCap), a HIPPA compliant data collection and storage platform.[35]

Study 1: qualitative interviews

Interview scripts (online supplemental appendix 2) will be piloted prior to use and will include open-ended questions that explore: the physical therapist and patient impressions of the I-EPT treatment protocol, the likelihood of physical therapist and patient acceptability and how the protocol could be improved for use in routine outpatient physical therapy practice. Qualitative results will inform potential modifications to the treatment protocol while maintaining the core components of MORE (mindfulness, reappraisal and savouring).[31] Consent for audio recorded interviews lasting approximately 30 min will be requested. Participants will be provided US$50 for participation in the qualitative interviews.

Study 1: analysis plan: qualitative data

Rapid content analysis (RCA) using a team approach will be used to analyse qualitative interview data in preparation for training physical therapists in the refined I-EPT treatment protocol. RCA is a valid alternative to more time intensive analytic strategies,[36] which is important as study 1 results are required prior to advancing to study 2. First, we will create targeted domains that represent each interview question and are guided by aim 1. These domains will then be organised in a case summary template. Next, we will test the case summary template for usability and relevance on a subset (two physical therapists and two patients) interview transcripts. Testing will involve identifying missing domains, checking for appropriate labelling and determining whether the domains will allow the PT-IN-MIND team to meet the goals of study aim 1. After establishing agreement among the analysis team on the case summary template's usability, the transcripts will be divided among team members and summarised. Direct interview quotes will populate each case summary template's domains, with paraphrasing used for long or complicated responses. Each case summary will be transferred into a single case summary matrix which the team will use to identify trends in responses across groups of respondents. Domains across respondents will be summarised and used to inform the refinement of the I-EPT treatment protocol manual.

Study 2 aim: evaluate different intensities of a physical therapist training programme for the refined I-EPT treatment protocol

Our future trial will randomise physical therapists to manage patients with chronic musculoskeletal pain and long-term opioid treatment using usual care (UC) or the refined I-EPT treatment protocol. The optimal programme used to train physical therapists in the provision of I-EPT is unknown. Therefore, the primary objective of study 2 aim is to evaluate which training approach (high-intensity training (HighIT) or low-IT (LowIT)) is a likely candidate to use for training physical therapists for a future clinical trial. LowIT is a manualised, LowIT approach; the physical therapists will be provided with a mindfulness-based training manual for self-study and no other training activities. HighIT is a hybrid, HighIT approach; the physical therapists will be provided with the same manual as in the LowIT approach and they will asynchronously view prerecorded mindfulness-related didactic lectures online then attend a live virtual mindfulness-based training session. The primary endpoint for the study 2 aim is physical therapist competency for providing mindfulness-based interventions I-EPT following training. We will also assess our recruitment and randomisation procedures for physical therapists.

Study 2: study design and methods

Physical therapists will be recruited and randomised 1:1:1 from University of Utah Health (n=21) and Brooks Rehabilitation (n=24) to no training, LowIT and HighIT training arms with block size of 3–6 stratified by healthcare system (figure 2, red box). Each training arm is described in greater detail below. Both and LowIT arms educate physical therapists in provision of the revised I-EPT treatment protocol developed in study 1. The training programmes for HighIT and LowIT can be modified for future use, and both are candidates for training a larger group of physical therapists for our future trial. The control arm will receive no training. Four to six weeks after HighIT and LowIT trainings the Modified MORE-FM[26] will be used to assess individual physical therapist competency in the provision of the I-EPT treatment during mock patient encounters using trained actors as standardised patients. This extended time will allow trained physical therapists to implement I-EPT in clinical practice prior to competency assessment. Assessing competency will provide vital information to help us determine which training programme to use in our future trial. This randomised study design will also allow for assessment of several feasibility outcomes for patients managed by trained and untrained physical therapists (study 3 aim).

Study 2: eligibility, recruitment and consent of participants

Recruitment of physical therapists will occur by research staff and investigators providing an overview of the project at routinely scheduled University of Utah Health and Brooks Rehabilitation staff meetings. Eligibility and consent of physical therapists will follow similar methods as described for the study 1 aim with the following exclusion criteria to ensure that physical therapists randomised to the training and no training arms will be naive to mindfulness interventions. These criteria will also help ensure that those in the no-training arm are naive to the I-EPT protocol. For study 2 aim, physical therapists must not have (1) attended any experiential (ie, practice sessions with real or simulated patients) mindfulness training to be used for patient care; (2) attended any training on using mindfulness in patient care lasting more than 3 hours; (3) self-reported using mindfulness interventions such as savouring and cognitive reappraisal (core

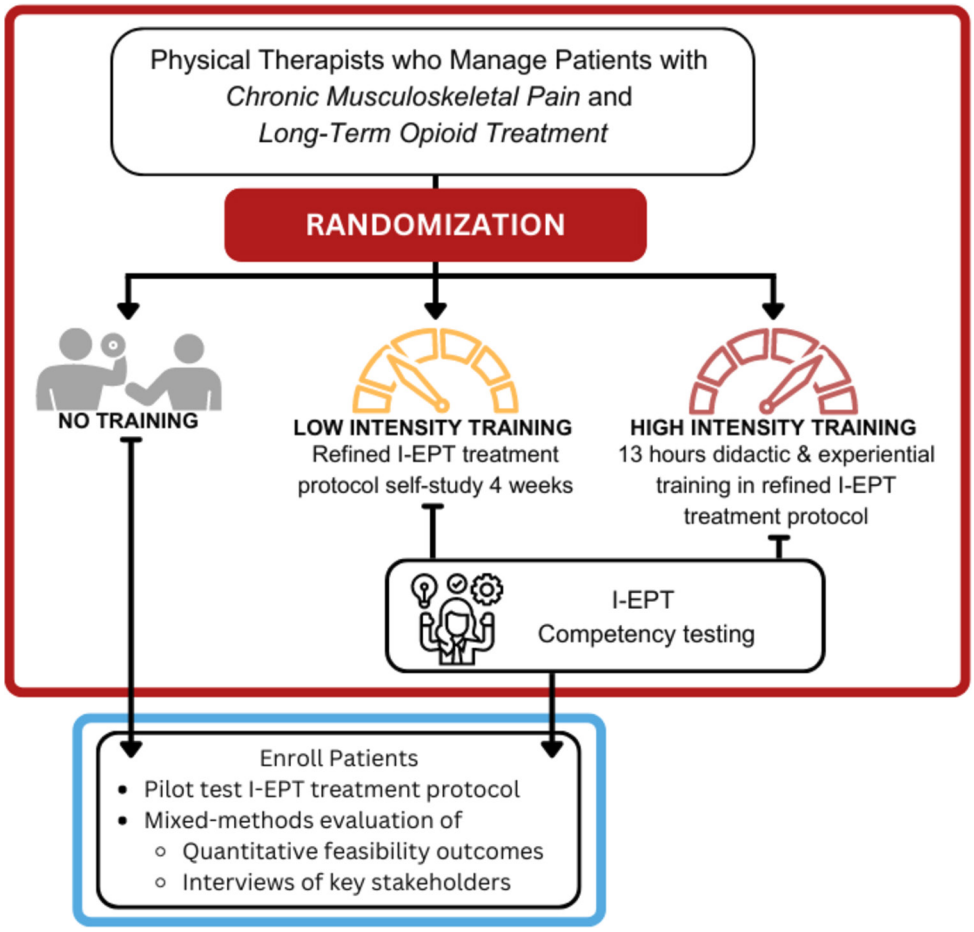

Figure 2 Study design and flow for aim 2 (red box) and aim 3 (blue box). I-EPT, Mindfulness Integrated Evidence-Based Physical Therapy.

components of MORE) as a primary intervention strategy for the majority of their caseload for patients with chronic musculoskeletal conditions. Online supplemental appendix 3 contains the IRB-approved informed consent document for study 2.

Study 2: randomisation and blinding

A computer-generated randomisation schedule will be developed prior to enrolment by a separate unblinded biostatistician and implemented using the randomisation function in REDCap.[35] The study PI at both clinical sites and leading biostatistician will remain blinded until the study database is locked. Study coordinators, RAs and investigators involved in the training and competency assessment will be unblinded.

Study 2: intervention arms

We will include three separate intervention arms for this study (figure 2, red box).

LowIT arm

Physical therapists randomised to the LowIT arm will be provided with a manual of the refined I-EPT treatment protocol (refined in study 1). This manual will provide specific details about how physical therapists should (1) use mindfulness to strengthen self-regulation of habitual and compulsive opioid use, and to mitigate pain by reinterpreting these experiences as innocuous sensory information, (2) use reappraisal to reframe stressors and maladaptive thoughts to decrease negative emotions and engender meaning in life, (3) use savouring of pleasant events and pleasurable sensations to enhance positive emotions and reward and (4) integrate mindfulness, reappraisal and savouring with evidence-based physical therapy for patients with chronic musculoskeletal pain and long-term opioid treatment. After 4–6 weeks to review the manual and an additional 6 weeks to practise what they learnt from the manual, physical therapist competency in the provision of I-EPT will be assessed using methods outlined below (study 2 aim: competency assessment).

HighIT arm

Physical therapists randomised to the HighIT arm will receive training overseen by study team members (AH and EG) who have extensive experience training providers in mindfulness practices including for patients with chronic musculoskeletal pain.[37] The HighIT training approach will occur virtually over approximately 13 hours. The first 6 hours consist of prerecorded didactic lectures that the participant can view on their own time. After viewing the

lectures, participants will attend 7 hours of live experiential instruction to promote trainee competence across items of the MORE-FM.[26] During the live experiential training, physical therapists randomised to the HighIT arm will learn how to integrate into patient care items 1–4 outlined above for the LowIT training group. Competency testing will occur for participants in the HighIT arm 4–6 weeks after the training. Team members will oversee the development and delivery of the of the evidence-based physical therapy management for patients with chronic musculoskeletal pain. Each physical therapist assigned to HighIT will be provided the same manual as those in the LowIT training approach.

No training arm

Physical therapists randomised to the no training arm will receive no manual or training in mindfulness practices.

Study 2: competency assessment

Team members will oversee the competency assessments. Approximately 6 weeks after participating in LowIT or HighIT training approaches, physical therapists will apply their skills in teaching mindfulness-based treatments, during mock patient encounters using trained actors as standardised patients. These physical therapists will have had approximately 6 weeks to practice integrating the core components of MORE into the management of their patients prior to the competency assessment. Physical therapist competency will be assessed during these mock patient encounters using a Modified version of the MORE-FM V.2.0.[26] Each item is scored 0–6 with scores summed and averaged. A mean score of >3 (ie, at least 'adequate' skill on each item) on a 0–6 point scale on the items MORE-FM indicates that the physical therapist provided I-EPT with acceptable competency. MORE-FM scored will be manually entered into REDCAp by study staff. Physical therapists will be provided US$50 for their participation in training programme and competency assessment.

Study 2: analysis plan

Descriptive statistics will be computed to summarise physical therapist characteristics within each group (LowIT, HighIT and No Training) and by healthcare system (Utah or Florida). Measures of central tendency and dispersion will be computed for continuous data, and frequency distributions will be checked for categorical data. Transformations of variables will be sought for variables with skewed distribution. Any observed differences in MORE-FM scores between LowIT and HighIT arms and between Utah and Florida physical therapists will be discussed among study investigators to inform which training programme to use in a future study.

Study 3 aim: evaluate the feasibility of the I-EPT intervention across domains of the RE-AIM framework

The primary objective of study 3 Aim is to evaluate our ability to deliver I-EPT, enrol and retain patients and longitudinally collect patient-reported outcomes. The coprimary endpoints for study 3 aim are the 12-week Pain, Enjoyment of Life and General (PEG) scale[38] and the Timeline Followback (TLFB)[39] collection rates. We will also (1) evaluate our ability to enrol patients for management by physical therapists randomised to the training and no training groups; (2) assess our longitudinal data collection procedures; (3) measure physical therapist I-EPT treatment fidelity; (4) evaluate for differences in feasibility outcomes between patients managed by physical therapists who received HighIT or LowIT training approaches to inform future study planning and (5) interview key stakeholders to learn about their lived experiences in providing or receiving the refined I-EPT treatment.

Study 3: study design and methods

The RE-AIM framework (table 1) will guide the mixed-methods feasibility evaluation for this study. First, we will enrol patients with chronic musculoskeletal pain and long-term opioid treatment who meet our eligibility criteria (box 1), and pilot test the refined I-EPT treatment protocol (figure 2, blue box). We will collect and evaluate key quantitative feasibility outcomes for patients managed by physical therapists randomised to the training and no training arms described in study 2 aim. Next, we will conduct semistructured interviews with key multilevel stakeholders (ie, patients, physical therapists, support staff, clinic managers and health system leadership) who had experience with the I-EPT treatment protocol to learn from their experiences (ie, was I-EPT difficult to integrate into clinical practice; was the treatment acceptable to patients and physical therapists) and gain further insight into our quantitative feasibility results.

We will use a Quan->QUAL sequential collection and analysis of quantitative feasibility measures and qualitative data (our semistructured interviews). Quantitative feasibility data will be collected and analysed first. Qualitative data will then be collected to explore the quantitative results. 'Expansion' (ie, using a qualitative data set to answer questions raised by a quantitative data set) is an additional function of this mixed method design.[40] Through this process, we will achieve triangulation in data findings (ie, confirmation of results obtained via qualitative and quantitative methods).[41 42] Descriptions of quantitative and qualitative procedures are described in greater detail below.

Study 3: eligibility, recruitment and consent of participants

Patients with chronic musculoskeletal pain and long-term opioid treatment meeting our eligibility criteria (box 1) and scheduled with a participating physical therapist are eligible to participate in the pilot testing component of this study. Randomised physical therapists will identify potentially eligible patients during the initial physical therapy consultation and interested patients will be referred to a study coordinator for obtaining informed consent. Online supplemental appendix 4 contains

Table 3 Patient-reported outcome measures for study 3

Study patient self-report measures		Time		
		T0	T1	T2
Demographics	Core HEAL Demographics	X		
HEAL Core & Supplemental Adult Chronic Pain Common Data Elements	Pain, Enjoyment, General Activity Scale	X	X	X
	PROMIS Physical Function Short Form 6b (PROMIS-6b)	X	X	X
	PROMIS Sleep Disturbance Short Form 6a	X	X	X
	Sleep Duration Question	X	X	X
	Pain Catastrophising Scale-Short Form 6	X	X	X
	Patient Health Questionnaire-2	X	X	X
	Generalised Anxiety Disorder-2	X	X	X
	Patient Global Impression Scale-Change		X	X
	Pain Self-Efficacy Questionnaire (10-item version)	X	X	X
I-EPT components	Mindfulness-Five Facet Mindfulness Questionnaire	X	X	X
	Cognitive Emotional Regulation Questionnaire (Reappraisal subscale)	X	X	X
	Savouring Beliefs Inventory	X	X	X
Therapeutic alliance	Working Alliance Inventory–Short Revised–Client Version		X	X
Physical activity	International Physical Activity Questionnaire–Short Form	X	X	X
Opioid use	Timeline Followback	x	Monthly	
Economic	Participant-report healthcare utilisation measures		Monthly	
Treatment acceptability	Short Assessment of Patient Satisfaction		X	X

PROMIS = Patient-Reported Outcomes Management Information System

HEAL, Health Education and Adult Literacy; I-EPT, Mindfulness Integrated in Evidence-Based Physical Therapy; T0, time point baseline; T1, time point week 6; T2, time point week 12.

the IRB-approved informed consent document for the patients participating in Study 3.

Study 3: baseline and follow-up assessments of patients

Patient self-reported measures will be collected via REDCap.[35] At each assessment, participants will input data directly into REDCap. If a participant is unable to directly input data using a computer, paper forms will be available with data uploaded later by a blinded RA. At each assessment, participants will also be interviewed to collect information about their opioid use (see below for information on the TLFB). Baseline data will be collected after enrolment (T0) and, depending on the outcome measure, the majority of follow-up data will be collected 6 weeks (T1) and 12 weeks (T2). Enrolled participants will be supported with US$25 per T0–T2 assessments for a potential total of US$75.

Study 3: patient self-report measures

Patient self-report measures will assess the impact of the I-EPT treatment (table 3). This study will have two coprimary outcomes to assess the feasibility of collecting chronic musculoskeletal pain and long-term opioid treatment measures; the percentage of scores collected at 12 weeks for the PEG and for the TLFB. The PEG is a validated measure derived from the Brief Pain Inventory that includes three items, each assessed on a 0–10 scale.[38] The items ask about Pain intensity in the past week, interference with Enjoyment of life, and interference with General activity. The total score is the average of the items (range 0–10; higher scores indicate worse pain impact). The TLFB is a valid measure used to track substance use for periods up to 90 days or greater.[39] A trained RA will administer the TLFB over the phone.[43] Data obtained during the TLFB interview will be used to calculate the patient's total morphine milligram equivalents (MMEs) used between assessment periods. We will use conversion reference tables from the US Centers for Disease Control and Prevention to calculate MMEs for opioid prescription.[44]

This study will also collect several secondary outcomes used to assess the feasibility of collecting chronic pain, mindfulness integration and treatment acceptability measures.

Chronic pain outcomes

Physical functioning will be assessed with the Patient-Reported Outcomes Management Information System (PROMIS)-6b.[45] Sleep quality and duration will be assessed with the PROMIS Sleep Disturbance 6a+Sleep Duration Questions.[46] Pain catastrophising will be assessed with the Pain Catastrophising Scale (Short Form 6).[47] Depression will be assessed with the Patient Health Questionnaire-2.[48] Generalised anxiety will be assessed with the Generalised Anxiety Disorder-2.[49] Global satisfaction with treatment will be assessed with the Patient Global Impression Scale.[50] The 10-item Pain Self-Efficacy Questionnaire will assess pain-related self-efficacy.[51] The International Physical Activity Questionnaire–Short Form will assess physical activity.[52]

Mindfulness-related outcomes

Mindfulness will be assessed using the Five-Facet Mindfulness questionnaire.[53] Reappraisal will be assessed via the reappraisal subscale of the Emotional Regulation Questionnaire.[54] Savouring will be assessed with the momentary savouring scale from the Savouring Beliefs Inventory.[55]

Treatment acceptability

The Short Assessment of Patient Satisfaction will assess satisfaction with the I-EBT treatment provided in this study.[56]

Therapeutic alliance

The Working Alliance Inventory–Short Revised will assess the therapeutic alliance between the patient and the physical therapist from the patient's perspective.[57]

Economic measure

The number of chronic pain-related provider visits, imaging studies and prescription and over-the-counter pain medications obtained will be collected to assess the economic impact I-EPT.

The feasibility of collecting each of the secondary patient-reported outcome measures above will be reported as the percentage of patients with each outcome collected at baseline at each follow-up time point.

Study 3: pilot testing I-EPT treatment

Physical therapists who received I-EPT training will be encouraged to manage the patients based on the refined treatment protocol developed in aim 1. Physical therapists who did not receive I-EPT training will manage their patients according to their usual clinical practice.

Study 3: fidelity assessment

Fidelity to the refined I-EPT treatment protocol will be measured by audio recording of patient encounters across an episode of care for each visit for one patient managed by each physical therapist randomised to the LowIT and HighIT training arms described in study 2 aim. The number of recorded visits will be based on the recommended number of visits in the refined I-EPT treatment protocol, which, we anticipate, could be up to eight visits. Trained RAs will listen to each recorded visit and assess treatment fidelity using the Modified MORE-FM described above.[26] This fidelity assessment, combined with the immediate assessment of I-EPT treatment competency described in study 2 aim, provides us information with which to determine which I-EPT training approach (HighIT or LowIT) to consider for training physical therapists in our future trial. Research staff performing these fidelity assessments will be blinded to whether the physical therapist received the LowIT or the HighIT training approach.

Study 3: RE-AIM feasibility measures

To assess our ability to recruit and retain patients, achieve treatment fidelity and collect patient outcome data across physical therapists located in Utah and Florida, we will track important feasibility measures with corresponding a priori benchmarks (table 1). Failure to achieve any of the benchmarks will prompt the PT-IN-MIND team to develop solutions that will be used for future study planning.

Study 3: analysis plan (quantitative feasibility measures)

Analyses will be conducted separately for training and no training arms and also stratified by HighIT and LowIT training approach subgroups. We will check for potential outliers and aberrant measurements (eg, those extremes beyond third IQR). Following data quality checks, descriptive statistics will be used to characterise patients. Proportions will be used to report each feasibility measure with corresponding 95% CIs. We will also calculate the change in each secondary outcome from baseline to each follow-up time point.

We will conduct planned interim analyses. After the first 20 patients are managed by the trained physical therapists, an unblinded research team member will access the data to identify patients who were non-adherent and contact them to enquire about their reasons for non-adherence.

Study 3: patient enrolment target

We plan to enrol two patients scheduled for management by each physical therapist randomised in study 2 aim, yielding a total of 90 patients for enrolment. The pragmatic sample size for this aim is based on recommendations for determining the sample size for feasibility studies.[58] Further support for this pragmatic sample size includes (1) testing the feasibility of recruiting and retaining patients for management by physical therapists randomised in study 2 aim and (2) enrolling and retaining patients under the challenges of delivering a complex intervention in outpatient physical therapy during routine clinical practice.

Study 3: eligibility and recruitment of key stakeholders for qualitative interviews

Purposeful sampling will be used to identify key stakeholders (patients, physical therapists, support staff, clinic managers and health system leadership) with experience providing or receiving the I-EPT treatment protocol. We expect to recruit 2 separate cohorts of 28 participants from Utah and 28 from Florida. Each cohort will contain approximately 8 physical therapists (4 each from the HighIT and LowIT training approaches), 13 patients and 7 between support staff and clinic managers. Eligible physical therapists must have been randomised to the LowIT or HighIT training arms. Eligible patients must have been managed by physical therapists randomised to the LowIT or HighIT training arms and meet the eligibility criteria (box 1). Recruitment of patients will occur as described for aim 1. During routinely scheduled staff meetings, we will invite support staff and clinic managers to participate in qualitative interviews. In order to participate in the interviews, all stakeholders must be aged 18 years or older. Online supplemental appendix 5 contains the IRB-approved informed consent document for the stakeholders participating in the study 3 interviews.

Study 3: qualitative interviews

Consent for audio recorded interviews lasting approximately 60 min will be requested. We will conduct qualitative semistructured interviews with enrolled patients, physical therapists, clinic managers, support staff and members of health system executive teams (ie, outpatient division leadership) from both Utah and Florida. Qualitative interview data will be used to (1) confirm findings from the quantitative feasibility data (eg, validation or convergence of findings); (2) gain insight into the process through which patients are enrolled and retained that may not be easily determined from the quantitative data alone (eg, complementarity of findings) and (3) assist in the planning and execution of our future fully powered clinical trial. Additionally, during the interviews, we will ask organisational contextual questions on barriers and facilitators to providing I-EPT to inform future study planning. Participants who are interviewed will each receive US$50. Interviews will be professionally transcribed.

Study 3: analysis plan (qualitative data)

We anticipate achieving thematic saturation with our data that combine individual interviews from patients and physical therapists as saturation can be achieved with as few as 10 interviews.[59] These interviews will be complemented by the interviews with clinic managers and support staff. Codebook construction will follow the qualitative editing method as outlined by Crabtree and Miller which is designed for research conducted within the health sciences.[60] The construction of the codebook will begin after one-third of that data have been collected per cohort and transcribed to ensure a thorough understanding of potential themes. Audit trails will be employed to document the creation of codes for the codebook. The codebook will be modified, as needed, to incorporate new themes gained through the iterative analytical approach of coding with new codes applied to all relevant transcripts. Using the codebook, study staff will use a grounded theory approach[61] to code the interviews. As part of the coding process, the analysts will meet and process any differences in the assessment of codes for each case until agreement is achieved. The codes determined through this agreement process will then be recorded in a master file, which will become the basis for the final analysis.

Patient and public involvement

No patient involved.

Independent monitoring committee

An Independent monitoring Committee (IMC) composed of one PhD biostatistician, one internal medicine physician and two PhD physical therapists will oversee the conduct of studies 2 and 3. The IMC is guided by the studies' data safety monitoring plan. Physical therapist participants will be instructed to report any adverse events among their patient participants to the study staff who will relay the information on the adverse event to the PI. The PI will report any adverse events to the IMC and follow-up as necessary with the participant who experienced the adverse event.

DISCUSSION

Co-occurrence of chronic musculoskeletal pain and long-term opioid treatment is well established. Despite physical therapy utilisation by individuals with chronic musculoskeletal pain, physical therapists have not engaged in efforts to directly address long-term opioid treatment. Physical therapy and mindfulness interventions can operate along common mechanistic pathways to disrupt the downward spiral of pain, catastrophic appraisal and unconscious behavioural response including long-term opioid treatment (figure 1). Integrating physical therapy and mindfulness treatments may be especially beneficial for persons with co-occurring chronic musculoskeletal pain and long-term opioid treatment. PT-IN-MIND will refine an intervention that combines physical therapy and mindfulness interventions using the principles of MORE for patients with chronic musculoskeletal pain and long-term opioid treatment. Physical therapist competency with this combined treatment approach will be assessed and feasibility will inform future clinical trial planning.

There are several strengths to this project. First, we will integrate therapeutic approaches (physical therapy and mindfulness) that have established evidence of benefit for persons with chronic musculoskeletal pain and opioid use and that operate along common mechanistic pathways to reduce catastrophising appraisals, pain-related fear and hypervigilance. Second, we will engage a large group of providers (physical therapists) who frequently work with patients with chronic musculoskeletal pain and

long-term opioid treatment but have not yet broadly and explicitly addressed opioid outcomes alongside a traditional focus on pain and function. Professional engagement in addressing the opioid crisis has primarily focused on physicians, but recognition is increasing that providers such as nurses, pharmacists and physical therapists can play a critical role.[62–64] Physical therapists are well positioned to effectively manage patients with chronic musculoskeletal pain and co-occurring long-term opioid treatment and help prevent the transition from opioid misuse to opioid use disorder (or addiction). Many of these patients begin their healthcare journey seeking pain management from a physical therapist. Failing to engage patients in this setting in efforts to mitigate opioid use and decrease the risk of progression to opioid misuse and opioid use disorder is a missed opportunity. Third, the provision of effective psychological-based therapies for persons with chronic musculoskeletal pain and opioid misuse has been hindered by shortages and unequal geographic distribution of qualified behavioural health providers.[65] Evidence supports the ability of physical therapists to integrate psychological principles into their treatments[19]; however, integration of mindfulness principles into physical therapy for persons with co-occurring chronic musculoskeletal pain and long-term opioid treatment has not been examined. If this integration proves an effective strategy, the potential for future scalability would be high considering the size of the physical therapy workforce. Finally, this multisite-feasibility clinical trial is innovative in its explicit attention to evaluating different scalable protocols for training physical therapists in the provision mindfulness-based interventions like MORE I-EPT.

There are several limitations in the design of PT-IN-MIND that should be acknowledged. Self-selection of physical therapists for participation in this study may limit generalisability. Fidelity monitoring relies on audio recordings of patient encounters. Physical therapists may feel compelled to manage their patients differently while having clinical encounters audio recorded. There is a possibility that patients may receive care from more than one physical therapist during an episode of care, therefore, we will strongly encourage each trained physical therapist not to share in the management of their patients with chronic musculoskeletal pain and long-term opioid treatment. To monitor this, we will track whether patients are managed by multiple physical therapists as part of our quantitative feasibility measures. There is also a possibility for contamination of information about how to manage patients using the I-EPT treatment protocol between trained and untrained physical therapists, therefore, we will ask physical therapists to report such protocol deviations.

In summary, the PT-IN-MIND feasibility trial will investigate PT-IN-MIND principles from MORE for patients with chronic musculoskeletal pain and long-term opioid treatment. We expect the PT-IN-MIND feasibility trial will provide important information to inform future clinical trial planning. I-EPT could reduce the impact of chronic musculoskeletal pain and lead to reductions in opioid dose in patients with chronic musculoskeletal pain and long-term opioid treatment. Successful completion of this and our subsequent clinical trial will provide strong support for a needed paradigm shift in physical therapy management for patients with chronic musculoskeletal pain and long-term opioid treatment.

Ethics and dissemination

Ethics approval for the study was obtained from the University of Utah, University of Florida and Florida State University Institutional Review Boards. Informed consent is required for participant enrolment in all phases of this project. On completion, study data will be made available in compliance with NIH data-sharing policies.

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Contributors JM, JF, AJG and JB provided expertise and wrote the protocol. AH provided methodological expertise. EG provided methodological expertise. JS provided methodological expertise. ES provided methodological expertise. PB provided methodological expertise. TM provided methodological expertise. All authors read, contributed to and approved the final version. The guarantor of the study, JM accepted full responsibility for the finished work and/or the conduct of the study and controlled the decision to publish this protocol.

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Competing interests AJG receives an honorarium for an online chapter on alcohol management in the perioperative period from the UpToDate online reference (https://www.uptodate.com/home). This effort is not related to the contents of this manuscript. In the last three years, AJG has been on the board of directors for the American Society of Addiction Medicine (ASAM; https://www.asam.org), the Association for Multidisciplinary Education and Research in Substance use and Addiction (AMERSA; https://amersa.org) and the International Society of Addiction Journal Editors (ISAJE; https://www.isaje.net), all non-for profit organisations. AJG does not receive remuneration for these duties and all organisations are non-for profit. AJG also deem these relationships not related to the contents of this manuscript.EG is the Director of the Centre on Mindfulness and Integrative Health Intervention Development. The Centre provides Mindfulness-Oriented Recovery Enhancement (MORE), mindfulness-based therapy, and cognitive behavioural therapy in the context of research trials for no cost to research participants; however, EG has received honoraria and payment for delivering seminars, lectures and teaching engagements (related to training clinicians in MORE), including those sponsored by institutions of higher education, government agencies, academic teaching hospitals and medical centres. EG also receives royalties from the sale of books related to MORE. EG is also a licensor to BehaVR.

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