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Development of a Multicomponent Mindfulness and Movement Program for Lumbosacral Radicular Pain: A Mixed Methods Protocol

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protocol

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Abstract

BACKGROUND

Lumbosacral radicular pain (LRP) is a highly disabling condition frequently accompanied by pain-related fear, reduced physical activity, and difficulty engaging in daily activities. Although mindfulness-based and movement-based interventions are recommended for chronic low back pain, few programs have been specifically designed for individuals with LRP or developed using patient-centered, theory-informed methods. Before large-scale evaluation, early-phase work is needed to establish the feasibility and acceptability of such interventions and their associated study procedures. This protocol describes the development and pilot testing of Move-MORE, a multicomponent, digitally delivered mindfulness and movement intervention for adults with LRP and elevated kinesiophobia.

METHODS

This study uses an iterative convergent mixed methods design comprising two sub-studies. Study 1 is a qualitative-dominant intervention development study involving patient focus groups (n = 10) and clinician interviews (n = 10) conducted using the Person-Based Approach to refine intervention content and delivery. Study 2 is a single-arm pilot feasibility trial (n = 32) enrolling adults aged 18–75 with LRP and elevated kinesiophobia. Move-MORE will be delivered virtually in a group format with primary outcomes of feasibility and acceptability, including recruitment, retention, adherence, engagement, safety, and data completeness. Acceptability will be assessed using validated satisfaction and expectancy measures and qualitative exit interviews. A comprehensive set of patient-reported outcomes, ecological momentary assessment, actigraphy, quantitative sensory testing, and biomechanical assessments will be collected to characterize participants, evaluate data collection procedures, and inform outcome selection and design considerations for a future randomized controlled trial. Quantitative analyses of patient reported outcomes and objective assessments will be descriptive. Finally, patient partners were involved throughout the study using a patient-engaged research approach, including participation in focus groups to inform intervention development, review of participant-facing materials, and input on interpretation and dissemination of study findings.

DISCUSSION

This protocol outlines a systematic, patient-engaged approach to developing and testing the feasibility of a novel multicomponent intervention tailored to individuals with LRP. Findings will inform refinement of the Move-MORE intervention, feasibility benchmarks, and methodological decisions needed to support subsequent efficacy testing in a randomized trial.

TRIAL REGISTRATION: Clinicaltrials.gov #: NCT07125027

1.0 INTRODUCTION

Lumbosacral radicular pain (LRP), commonly referred to as “sciatica” or spine-related leg pain,[1] is a debilitating condition that is characterized by neuropathic pain radiating from the lower back into the lower extremities. LRP is often accompanied by sensory disturbances, motor deficits, and functional impairments that significantly impact an individual’s quality of life. The prevalence of LRP is high, with some studies estimating that up to 43% of individuals with chronic low back pain develop radiating symptoms.[2,3] Despite its widespread occurrence and array of treatment options, many patients experience long-term pain and disability.

Traditional biomedical treatments for LRP, including surgery, epidural steroid injections, and pharmacologic interventions, have demonstrated mixed efficacy. While surgical interventions can provide short- to medium-term relief for select patients, long-term outcomes often show no significant advantage over conservative management.[4–7] Additionally, opioid-based pain management strategies carry risks of dependency and adverse effects, underscoring the need for non-pharmacologic alternatives.[8,9] Given the recognition of chronic pain as a complex biopsychosocial phenomenon,[10] there is a growing interest in complementary and integrative health interventions as potential solutions.[11]

Mindfulness-based interventions and movement-based therapies have emerged as promising approaches for chronic pain management and are considered first-line treatment for chronic low back pain in clinical practice guidelines.[12] Mindfulness-based interventions have been shown to enhance attentional control, promote reappraisal of pain, and foster emotional regulation, all of which contribute to improved pain coping and resilience.[13–16] Previously, we evaluated Mindfulness-Oriented Recovery Enhancement (MORE) for patients with LRP and found that MORE significantly reduced daily pain intensity as compared to patients undergoing treatment as usual (-14% vs. -6.8%, $p = 0.04$).[17] Meanwhile, structured movement interventions, including tai chi, qi gong, yoga, and other forms of therapeutic exercise, have demonstrated effectiveness in improving physical function and reducing kinesiophobia in chronic pain patients – an important contributor to disability among individuals with LRP.[18] When paired with coaching techniques (e.g., motivational interviewing, guided inquiry) in behavioral health interventions, these interventions may further enhance patient engagement and adherence, leading to better long-term outcomes.[19,20]

Here, we present the study protocol for an iterative convergent mixed methods intervention development process which aims to develop Move-MORE, a multicomponent mindfulness and physical activity intervention designed for LRP patients with elevated kinesiophobia. The study aims to evaluate the feasibility and acceptability of Move-MORE as a potential intervention for LRP patients. By conducting a single-arm pilot trial to assess key feasibility indicators, including recruitment, retention, adherence, and patient satisfaction, this study will provide needed insights for the design of a larger randomized controlled trial to evaluate the clinical efficacy of the intervention. Exploratory outcomes related to pain severity, disability, psychosocial sequelae, physical activity, pain sensitivity, and lumbar motion will also be collected. To ensure the study design, implementation and interpretation are informed by, and

consistent with, lived experience, this study will involve patient advisors through every stage of intervention development to ensure that Move-MORE is feasible for chronic pain patients.

2.0 METHODS

2.1 Study Setting

The study will be conducted at the Helfgott Research Institute, National University of Natural Medicine (NUNM) in Portland, Oregon. Move-MORE will be delivered virtually to enable broad accessibility for participants with mobility or transportation challenges.

2.2 Theoretical Framework for the Intervention Development

Move-MORE will be grounded in Self-Determination theory (SDT), a comprehensive framework for understanding human motivation and behavior change. SDT posits that sustained behavioral change and psychological well-being arise when the basic psychological needs for autonomy (self-direction), relatedness (connection), and competence (self-efficacy), are satisfied.[21]

The mindfulness component of the program has been adapted from MORE. MORE is designed to help participants develop self-directed awareness for overcoming reactive patterns. It has previously been evaluated in populations with chronic pain, opioid addiction, and stress.[22] The movement component of the program will be adapted to the capabilities and needs of LRP patients to encourage autonomy while providing achievable movement goals to build self-efficacy to overcome kinesiophobia.

Move-MORE will be delivered in a group format to provide a space for participants to share experiences with each other and for trained facilitators to provide empathetic support and navigate new experiences through MORE's model of therapeutic processing: PURER (Phenomenological, Utilization, Reframing, Education, and Reinforcement).[23] Delivering Move-MORE in a group setting aligns with the SDT basic psychological need for relatedness by creating opportunities for participants to feel supported and connected with others facing similar challenges, thereby enhancing engagement and reinforcing new coping strategies.

Overall, we aim to achieve a synergistic effect of mindfulness and movement and meaningfully incorporate behavior change principles through the use of SDT (see Move-MORE's conceptual model in Fig. 1). The integration of mindfulness and movement is also theoretically anchored in contemplative traditions like yoga which has been previously evaluated in chronic pain patients.[24] These practices develop interoceptive awareness and attention regulation, creating the foundation necessary for effective physical activity.[25] Conversely, gentle movement practices provide embodied experiences that reinforce mindfulness principles while directly addressing kinesiophobia.

2.3 Iterative Convergent Mixed Methods Design

This protocol employs an iterative convergent mixed methods design comprising two interconnected studies. Using Alwashmi et al.'s (2019) framework for the iterative convergent approach to intervention development (Fig. 2), we aim to develop a multicomponent behavioral health intervention for patients with LRP.[26] Using this process, which is consistent with established user-centered design principles,[27] we have conceptualized intervention development as a continuous, data-driven process that allows ongoing improvement of the intervention.

The overall study design encompasses two sub-studies: 1) a qualitative-dominant mixed methods study (n = 20) to understand the needs and challenges of patients with LRP to support intervention development and 2) a single-arm pilot trial (n = 32) to evaluate the feasibility and acceptability of Move-MORE (Fig. 3). To maintain methodologic integrity and prevent contamination between the intervention development and intervention evaluation studies, participants who contribute to the intervention development process (Study 1) will not participate in the intervention evaluation phase (Study 2). Similarly, having Move-MORE naive participants in the clinical trial will allow for candid feedback without being influenced by prior exposure to intervention materials.

In Study 1, we will conduct rapid qualitative analysis using the Person-Based Approach, enabling iterative refinement of intervention components based on stakeholder feedback.[28–30] The Person-Based Approach prioritizes a detailed understanding of users' lived experiences, contextual constraints, and perceived barriers and facilitators to engagement, ensuring that intervention content is both theoretically grounded and acceptable in real-world settings. These components will be aligned with Self-Determination Theory to create an intervention manual that incorporates key stakeholder perspectives (patients, patient partners/advisors, clinicians, and intervention instructors) while ensuring that behavior change principles remain central.

2.3.a Integration Framework:

There are multiple unique sources of qualitative and quantitative data. Study 1 will collect qualitative data from patient focus groups (n = 10 patients) and clinician interviews (n = 10). Focus groups were selected for data collection with patients to mimic the style of group treatments planned for the clinical trial in Study 2. Quantitative data will also be collected from patient-reported outcomes (see section 2.8 for outcome measures) and a post-focus group survey. Qualitative and quantitative data collection will inform each other bidirectionally using multiple mixed methods data integration strategies. Constructs between the two data collection strands will be matched to facilitate mixed methods integration, focused on diffracting.[31,32] In analysis, we will use a combined independent and interactive data analysis process and joint displays will be developed to visualize core constructs across qualitative and quantitative data.

The design encompasses three distinct types of data integration: 1) a convergent design within Study 1 will allow for synthesis of patient-reported outcomes with qualitative findings to generate insights for intervention development; 2) sequential integration connecting Study 1 findings to Study 2 will apply qualitative themes to inform selection of outcome measures and shape intervention components (i.e.,

building[32]), and 3) iteration across cohorts of the feasibility trial will allow for continued refinement of the intervention throughout the single-arm pilot trial.[32] Rather than treating each cohort as a simple replication, this iterative process will allow us to improve the intervention over successive cohorts. The systematic nature of this approach will ensure that modifications are based on emerging findings from the intervention.

2.4 Patient Engagement Plan

This study was designed in accordance with the GRIPP2 (Guidance for Reporting Involvement of Patients and the Public) reporting checklist to ensure transparent documentation of the aims, methods, and impacts of patient involvement throughout intervention development and evaluation (see Supplemental File 1). Following GRIPP2 enhances the reproducibility and rigor of patient engagement and supports alignment with contemporary recommendations for pain and behavioral health research.[33]

In this study, patient engagement refers to the meaningful and active participation of individuals with lived experience of chronic pain in the planning, conduct, and dissemination of the research. Patient engagement will position patients as partners who contribute experiential expertise to shape the study design, refine intervention components, interpret findings, and guide dissemination. Patient engagement will operate at multiple levels depending on the phase of the research. During Study 1 (intervention development), engagement is primarily collaborative, with patient partners contributing to refinement of the focus group guide, participation in analytic discussions, and shaping intervention components through iterative feedback. During Study 2 (single-arm pilot trial), engagement will be a combination of consultation and collaboration, with patient partners providing input on participant-facing materials, recruitment procedures, study visits, feasibility challenges, and intervention refinement needs between cohorts.

Patient partners, JP and LV, will be involved throughout all phases of Study 1 and Study 2 (Fig. 4). In phase 1, patient partners will be engaged to provide feedback on the design of the focus group guide. In phase 2, patient partners will assist in the interpretation and utilization of focus group responses for intervention development and adaptation. Patient partners will undergo human subjects training through the University of Illinois CIRTification program and will be added to the study protocol as co-investigators.[34] The CIRTification program introduces patient partners to the fundamentals of human research, covering research standards and best practices for recruitment and informed consent, collection and protection of data, managing challenges that may arise during participant interactions, and the role of the Institutional Review Board. In addition, a Community Advisory Board (CAB) will be developed via convenience sampling from the study focus groups. In Phase 3, the CAB will help in providing oversight of the pilot trial and improve the participant experience throughout the intervention. Finally, the CAB will be engaged to guide the dissemination of study findings. The CAB will function in a primarily consultative capacity and be asked to provide structured feedback on participant experience, safety considerations, and dissemination strategies.

To support CAB members, we will hold monthly CAB meetings. CAB members who express interest in learning about research will be directed to the Patient Centered Outcomes Research Institute's (PCORI) course Research Fundamentals: Preparing You to Successfully Contribute to Research.[35,36] This is a free module-based course offered through the PCORI website developed in partnership with a Stakeholder Advisory Group. This program is designed to support patient partners in learning about the research process and constructively contributing their personal experiences to help conduct rigorous science. We expect this approach will alleviate concern from patient partners regarding a lack of sufficient knowledge to make meaningful contributions to the scientific process – a common experience previously reported in the literature.[36] Patient partners and CAB members will be compensated for completion of the online CIRTification and PCORI trainings, review of study materials, and participation in monthly meetings. Across the project period, the research team will maintain records of engagement-related expenditures (compensation, staff effort, software, transcription, and meeting costs) to inform budgeting and resource allocation for subsequent grant applications.

Finally, the patient engagement process will be evaluated semi-annually using the Public and Patient Engagement Evaluation Tool (PPEET) and at the end of the project using the Patient Engagement in Research Scale (PEIRS).[37,38] These tools will assess stakeholder perceptions of the engagement process and document patient partner and CAB member contributions to study design and intervention development. This design will ensure that the Move-MORE intervention is relevant to the lived experiences of individuals with chronic LRP.

2.5 Study Design

This protocol has been developed in accordance with SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines to ensure comprehensive and transparent reporting of study design and procedures (see Supplemental File 2).[39] This is a single-site, investigator-initiated pilot feasibility study. No independent steering committee or data monitoring committee has been established due to the feasibility-focused aims and minimal risk nature of the intervention. Overall study oversight is provided by the Principal Investigator, with support from the study coordinator and research staff at the Helfgott Research Institute. Data collection and management are conducted by the study team using REDCap. The Institutional Review Board at the National University of Natural Medicine provides ethical oversight and reviews any protocol amendments and reportable events. Any substantive protocol modifications (e.g., changes to eligibility criteria, intervention procedures, or outcome assessments) will be reviewed and approved by the NUNM IRB prior to implementation. Approved amendments will be communicated to relevant parties, including study staff, participants (when applicable), and ClinicalTrials.gov, in accordance with regulatory and reporting requirements.

2.5.1 Qualitative Study Design (Study 1)

For patient participants (n = 10), Study 1 consists of an online prescreening survey, a telephone screening and informed consent, and two virtual focus groups (n = 5 each). Potentially eligible patients

will be contacted via email with information about the study and a prescreening survey to assess initial eligibility. If eligible, a study team member will confirm eligibility criteria over the phone and review the informed consent. Once enrolled, patients will be sent a series of patient reported outcomes (see section 2.8.2) to complete prior to focus group participation. Present at the focus groups will be the study PI, a study staff member (e.g., study coordinator or research assistant), and a Move-MORE instructor. After focus group participation, patients will be asked to complete a focus-group follow-up survey.

During focus groups, Move-MORE instructors will guide participants through portions of the Move-MORE manual to acquire feedback on the draft version of the program. These sessions will be recorded and transcribed for subsequent qualitative analysis and review by the research team and patient partners. Consistent with the iterative convergent mixed methods design, focus group guides and the specific sections of the Move-MORE manual reviewed will be iteratively refined across groups based on emerging findings. Preliminary analytic summaries will be reviewed by the research team and patient partners between focus groups to inform adjustments to subsequent sessions. Patients who provide significant contributions to the focus groups, may be invited to participate in the CAB. For clinician participants (n = 10), this study will consist of a demographics and professional characteristics survey and a semi-structured interview. During the semi-structured interview, clinicians will be asked about their attitudes and beliefs related to non-pharmacologic and behavioral pain management programs and what components they see as crucial for meeting the needs of LRP patients.

2.5.2 Single-Arm Pilot Feasibility Trial (Study 2)

Study 2 is a single-arm mixed methods pilot feasibility trial implementing the Move-MORE intervention in adults with LRP. This study has been registered on Clinicaltrials.gov (NCT07125027) and approved by the Institutional Review Board at the National University of Natural Medicine (RW6625). As a single-arm pilot feasibility trial, no randomization or masking will be performed. The study is designed to evaluate feasibility and acceptability of the intervention and explore its impact on pain, disability and an array of psychosocial sequelae of chronic pain. The intervention will be delivered to four cohorts of 6–12 participants each, in line with recommendations for delivery of group psychological interventions.[40,41] Cohorts will meet once per week for two hours via Zoom, where the Move-MORE intervention will be administered by trained facilitators. These sessions will be monitored and recorded so that participants can watch them outside of group meeting times in order to practice Move-MORE on their own and so that instructors can continue to refine intervention material for subsequent cohorts. Between weekly synchronous sessions, participants will also be asked to track their home practice, daily pain intensity, and any adverse events via ecologic momentary assessment. At the end of the study, participants will be invited to complete a semi-structured exit interview which will inquire about their experience in the intervention. Outcome measures include parameters of feasibility and acceptability (i.e., retention, adherence, adverse events, satisfaction, and expectancy), PROs on psychosocial sequelae of pain (e.g., depression, anxiety, ability to participate in social roles), physical activity monitoring, quantitative sensory testing, and biomechanical assessment of lumbar motion (see 2.8.2 for more detail). Figure 5

illustrates the overall participant timeline, including recruitment, intervention components, assessment timepoints, and follow-up procedures.

2.5.2a Recruitment and Retention Plan

Participants will be recruited from the Portland Metropolitan Area including the NUNM Health Center and Oregon Health & Science University (OHSU) Spine Center and Comprehensive Pain Center. We will recruit via targeted clinical recruitment in the NUNM EPIC electronic health records system by working with an internal EPIC specialist to create a list of candidate participants based on ICD-9/10 codes. Recruitment emails will be sent to potentially eligible patients followed by recruitment phone calls to ascertain interest. We will also recruit patients from the greater Portland community through recruitment flyers posted at clinics, hospitals, fitness studios, and community centers.

Patients who express interest in participation will undergo a pre-screening questionnaire, administered via Research Electronic Data Capture (REDCap). Eligible patients will be scheduled for an in-person clinical screening and baseline study visit. The informed consent will be reviewed upon completion of the clinical screening visit prior to beginning data collection for the baseline study visit.

To enhance retention and promote complete data collection, the study will employ several participant support strategies. Participants will receive reminders for Move-MORE sessions, ecological momentary assessment, and outcome assessment reminders through email or SMS. Study coordinators will conduct reminder calls for missed sessions or incomplete assessments and will offer flexible scheduling for follow-up visits when possible. To reduce participant burden, the study will provide clear expectations at enrollment, brief orientation to the technology used for surveys and actigraphy, and ongoing technical support throughout the intervention period. Participants will receive compensation tied to completion of key study activities: $100 for the baseline visit, $50 for the midpoint visit, $1/day for EMA completion up to $50, $100 for the follow-up visit, $50 for the 3-month follow-up visit, and $50 for a study exit interview. These strategies aim to maximize participant engagement, minimize missing data, and ensure high-quality feasibility and acceptability metrics.

2.6 Eligibility Criteria

The eligibility criteria for Study 1 and Study 2 differ due to the distinct objectives and requirements of each study (Table 1). Study 1 employs broader eligibility criteria to capture diverse patient perspectives essential for intervention development. Since participants in Study 1 will not receive the intervention, the inclusion criteria are less restrictive to include patients across a wider spectrum of LRP severity and functional status. This ensures comprehensive feedback on intervention design and acceptability. Broader eligibility criteria will also allow for the identification of patient subgroups who may need specialized considerations in the final intervention design.

Study 2 employs more stringent eligibility criteria to ensure participant safety and support clear interpretation of feasibility and acceptability outcomes. For example, a clinical exam will be used to confirm the presence of LRP, participants must demonstrate sufficient motivation (≥ 4/10; 0 = not

motivated at all, 10 = highly motivated) to engage with the intervention 4–5 times weekly, and the study excludes participants with recent lumbosacral injections and/or surgery and recent exercise changes to ensure stable baseline conditions across participants. Participants will be permitted to continue stable, ongoing treatments established prior to enrollment, including unchanged prescription medications, physical therapy, chiropractic care, acupuncture, massage, and home exercise programs, provided these treatments have remained consistent for at least two weeks before baseline. Any changes in health status requiring urgent or emergent care will be documented, and participants will remain in the study unless such treatments compromise safety or conflict with protocol requirements. This approach ensures that intervention development (Study 1) benefits from broad stakeholder input while intervention evaluation (Study 2) focuses on participants most likely to safely complete and potentially benefit from the intervention, thereby optimizing both scientific rigor and participant safety.

The Move-MORE intervention is designed to target maladaptive pain-related fear and promote confidence in performing activities of daily living. Therefore, we are intentionally recruiting LRP patients who experience kinesiophobia (Tampa Scale of Kinesiophobia ≥ 23). Kinesiophobia, fear of movement due to concerns about pain or reinjury, is a common and clinically meaningful barrier to functional recovery in this population and represents a core mechanistic target of the intervention.[42–45] Including participants with heightened movement-related fear ensures that the intervention is evaluated among those most likely to benefit from the addition of movement to MORE.

Table 1
Eligibility Criteria for Study 1 and Study 2

Study 1: Qualitative Study	Study 2: Single Arm Pilot Feasibility Trial
Inclusion Criteria	
Presence of previous diagnosis of LR: ● Presence of self-reported lumbosacral radiculopathy/radiculitis symptoms that extend below the knee secondary to low back pain for greater than 12 weeks OR ● Diagnosis of lumbosacral radiculopathy/radiculitis secondary to low back pain that extends below the knee, with symptoms present for greater than 12 weeks. ○ ICD-10 codes used for diagnostic inclusion: M51.16, M51.17, M47.26, M47.27, M54.41, M54.42, G54.4, M54.16, M54.17, M54.18, M54.3, M54.4	Presence of previous diagnosis of LR: ● At least one positive physical examination finding consistent with lumbosacral radiculopathy, including at least one of the following: ○ Positive straight leg raise test (eliciting radicular pain below the knee at ≤ 70 degrees of elevation); ○ Positive Valsalva maneuver; ○ Positive slump test; ○ Neurological deficit in a lumbar nerve root distribution, including at least one of the following: ■ Dermatomal sensory loss (L3, L4, L5, S1), ■ Myotomal weakness (L3, L4, L5, S1), or ■ Reduced or absent deep tendon reflexes (patellar or Achilles reflex)
At least 18 years of age and not older than 65 at the time of enrollment	At least 18 years of age and not older than 65 at the time of enrollment
Able to speak, read, and understand the English language	Able to speak, read, and understand the English language
Tampa Scale of Kinesiophobia score ≥ 23	Tampa Scale of Kinesiophobia score ≥ 23
Oswestry Disability Index score > 10	Moderately motivated to participate as reported on a numeric rating scale (≥ 4/10; 0 = not motivated at all, 10 = highly motivated)
Numeric Rating Scale for Pain Intensity ≥ 4	Willingness to refrain from unnecessary or self-directed pain management/treatment plan changes during study enrollment and to report necessary changes made to the study team
	Daily access to the internet via cell phone, tablet, or computer
	Willing to engage in Move-MORE 4–5 times per week at home
	Willing to wear an actigraphy device all day, every day, and while sleeping, for the duration of study participation and willing to keep it charged
	Willing to respond to a daily online survey for the duration of study participation

Study 1: Qualitative Study	Study 2: Single Arm Pilot Feasibility Trial
Inclusion Criteria	
Exclusion Criteria	
Concurrent diagnosis of cancer	Concurrent diagnosis of cancer
Current unmanaged or uncontrolled mental illness known to cause psychosis: schizophrenia and schizotypal disorders, bipolar I disorder with psychosis, major depressive disorder with psychosis	Current unmanaged or uncontrolled mental illness known to cause psychosis: schizophrenia, schizotypal disorders, bipolar I disorder with psychosis, major depressive disorder with psychosis
	Clinical signs or symptoms suggestive of cauda equina syndrome, including any of the following: ● New-onset urinary retention or overflow incontinence not attributable to other known causes; ● Fecal incontinence; ● Severe or progressive bilateral lower extremity weakness; ○ Participants with suspected cauda equina syndrome will be referred for immediate medical attention.
	Presence of moderate to severe foot drop, defined as noticeable weakness in ankle dorsiflexion that interferes with walking or requires the use of an assistive device (e.g., ankle-foot orthosis). Participants with suspected or worsening foot drop will be referred for further evaluation.
	Have received a lumbosacral epidural steroid injection in the prior 3 months
	Have received a lumbosacral nerve ablation in the prior 3 months
	Have received a surgical intervention for low back pain or lumbosacral radiculopathy in the previous 6 months
	Current active mindfulness meditation practice 1 time/week or more, and/or history of formal training in mindfulness/meditation practice

2.7 Intervention Description

The program will consist of weekly virtual sessions integrating:

- Mindfulness Training: Adapted from MORE, emphasizing attentional control, pain reappraisal, and savoring positive experiences.

- Movement Therapy: Guided physical activity targeting kinesiophobia and functional limitations.
- Motivational Support informed by Self-Determination Theory: Behavioral coaching to enhance self-efficacy and adherence to home practices.

The Move-MORE intervention will be delivered by trained mindfulness instructors who are certified in MORE and have prior experience facilitating group-based behavioral health interventions and working with individuals with chronic pain. Instructors include clinicians and advanced-level practitioners with backgrounds in mindfulness-based programs, qi gong or therapeutic movement practices, and supportive behavioral coaching. All instructors will complete a study-specific training process that includes review of the intervention manual, orientation to SDT principles, calibration meetings to ensure consistency in delivery, and group practice sessions. Instructors will also receive ongoing supervision including review of session recordings and feedback from the investigator team. This approach ensures consistent, high-quality facilitation across cohorts and supports iterative refinement of the intervention.

Participants will complete daily mindfulness and movement exercises at home and engagement will be monitored through weekly check-ins and electronic surveys. Participants who miss a Move-MORE session will be able to review the session recording so that they can continue on in the program.

2.8 Outcome Measures

In the sections below, 2.8.1 will describe the rationale for the selection of outcome measures and their utility in the intervention development process (Study 1), and 2.8.2 will describe all measures used within the pilot trial (Study 2) as well as measure descriptions.

2.8.1 Study 1 Outcome Measures

Qualitative Measures

Patient Focus Groups: Four 2-hour focus groups with LRP patients (2 sessions x 2 groups) will explore lived experience, prior treatment experiences, and preferences regarding the Move-MORE program. We will present patients with pilot content from Move-MORE and ask for feedback on specific practices and techniques used.

Clinician Interviews: We will conduct individual semi-structured interviews with clinicians from diverse disciplines (e.g., physical therapy, pain management, acupuncture, primary care) to acquire perspectives on clinical feasibility, safety and contraindications, and necessary content for mind-body interventions for LRP patients.

All focus groups and interviews will be recorded, transcribed, and analyzed using a rapid analysis technique informed by the Person-Based Approach.[28–30]

Quantitative Measures

Three patient-reported outcome measures will be administered to focus group participants before sessions to characterize the sample and provide data on hypothesized mechanistic targets of the intervention: Tampa Scale of Kinesiophobia-11, Oswestry Disability Index, and the Visual Analog Scale for Pain Intensity. In addition, the Illness Perception Questionnaire-Revised will be used to capture illness representations, offering insight into patients' internal illness models and perceived control over symptoms. Detailed descriptions of these measures and their psychometric properties can be found in section 2.8.2. Finally, a brief questionnaire will be administered immediately after each session to assess participants' impressions of the mindfulness or movement activity introduced during the focus group. Likert scales will be used to evaluate perceived acceptability, safety, ease of use, self-efficacy, and potential symptom benefits. Survey items will ask participants to rate agreement with statements such as "I would feel confident practicing this activity on my own" and "This activity could improve my overall well-being if I practiced it regularly." This data will be used to triangulate qualitative feedback and identify which components were most likely to be perceived as feasible and useful by LRP patients.

2.8.2 Study 2 Outcome Measures

This study is funded by the NIH HEAL Initiative; therefore, all required NIH HEAL core common data elements (CDEs) will be collected within the clinical feasibility trial. These core CDEs include standardized measures of pain intensity, pain-related interference, physical function, substance use, and key demographic and clinical characteristics, and are intended to promote consistency, comparability, and data sharing across HEAL-funded pain studies. Wherever possible, HEAL supplemental CDEs will also be used to assess additional constructs relevant to chronic pain and behavioral intervention research (e.g., psychosocial functioning, sleep, and quality of life). In addition to HEAL CDEs, study-specific measures were selected to support feasibility assessment and exploratory evaluation of hypothesized mechanistic targets of the Move-MORE intervention, including kinesiophobia, mindfulness, interoception, and self-efficacy.[46] Table 2 shows the timepoints at which all study outcomes will be administered.

Participant Data

Demographics: A questionnaire to collect basic demographic data including age, sex, race/ethnicity, highest education, income, disability status, and contact information.

Health History: We will collect LR history including duration of symptoms, treatments attempted, and history of surgeries and injections. Questions pertaining to other medical conditions and medications will also be obtained.

Anthropometric Measurements: Blood pressure, heart rate, height, and weight.

Feasibility and Acceptability

Retention: Measured using a participant tracking spreadsheet.

Acceptability/Satisfaction: Measured using the Client Satisfaction Questionnaire (CSQ-8). The CSQ-8 is a widely used and validated measure of perceived satisfaction with health services. The CSQ-8 consists of eight items rated on a 4-point Likert scale, generating a total score ranging from 8 to 32, with higher scores indicating greater satisfaction. Items assess perceived quality of services, the degree to which the intervention met participants' needs, and participants' willingness to use or recommend the program in the future.[47–50]

Enrollment Rate: Measured using a participant tracking spreadsheet.

Adverse Events: Monitoring of AEs (prompted or self-reported/spontaneous), including whether serious or non-serious, and whether participants who experience a non-serious AE elect to complete or withdraw from the study (i.e., clinical safety and tolerability).

Adherence: Weekly program adherence will be measured using a class attendance log. A separate daily survey will prompt participants to record their daily practice time, report their daily pain intensity rating, and provide an opportunity to journal about their experiences with Move-MORE practices at home.

Qualitative Exit Interview: Semi-structured interviews will inquire about participants' experience with the intervention. Findings from the study exit interviews will be used to iteratively improve the Move-MORE intervention.

Prior Treatment and Substance Use

HEAL Opioid MME Survey: We will collect data on participant use of opioid pain medication throughout their active engagement with the intervention using the standardized HEAL Opioid MME Survey.

Nonpharmacological and Self-Care Approaches Measure from PMC (NSCAP): The NSCAP is a self-report instrument developed by the NIH Pain Management Collaboratory to assess the frequency and types of nonpharmacological and self-care strategies individuals use for managing pain and improving health. It captures engagement in approaches such as physical activity, meditation, massage, heat/cold therapy, and dietary changes over a specified timeframe.[51]

Tobacco, Alcohol, Prescription medications, and other Substance (TAPS): The TAPS Tool is a validated screening instrument developed by the NIH to assess recent use and associated risk related to tobacco, alcohol, prescription medications, and other substances. It consists of a brief initial screen followed by a more detailed assessment of frequency and severity of use for substances endorsed, facilitating identification of substance use and potential substance use disorders in adult populations.

Pain and Disability

Oswestry Disability Index (ODI): The ODI is designed to assess the impact of pain on participants' ability to perform activities of daily living such as personal care, lifting, walking, and sitting. The ODI has good sensitivity, specificity, validity, and test-retest reliability for patients with low back pain.[52–54]

painDETECT Questionnaire: The PD-Q is designed to screen for the presence of neuropathic pain. The PD-Q is scored from − 1 to 38 where scores 19 or greater indicate likely neuropathic pain, scores 12–18 are ambiguous to neuropathic pain, and scores below 12 indicate an absence of neuropathic pain. The PD-Q has been found to have high sensitivity, specificity, and validity in patients with low back pain and LRP.[55–57]

Pain Intensity Visual Analog Scale: Participants will be asked to report their pain intensity on a 0–10 scale by marking their pain intensity on a line from “no pain” to “worst pain imaginable”. The VAS has been used in many pain intervention studies and has shown to have high reliability, validity, specificity, and sensitivity.[58,59] This measure will be collected daily throughout the intervention period.

Complex Multi-Symptom Inventory (CMSI): A questionnaire to assess pain hypersensitivity and allodynia. The CMSI inquires about participants’ pain experiences specifically related to hypersensitivity and allodynia to discern whether an individual may experience central sensitization. Currently, no direct measures of self-reported nociplastic pain exist, thus measures of central sensitization can be used as surrogate measures for this construct.[60] Importantly, the CMSI characterizes the breadth and intensity of sensory symptoms rather than classifying pain mechanisms.

Nociplastic Pain Questionnaire (NPQ): The NPQ is a screening tool designed to identify characteristics of nociplastic pain, which arises from altered nociception without clear evidence of tissue damage or somatosensory system disease. The NPQ assesses symptoms such as widespread pain, fatigue, sleep disturbance, and cognitive difficulties, helping to differentiate nociplastic pain from nociceptive and neuropathic pain mechanisms.[61] In contrast to the CMSI, which assesses symptom expression, the NPQ focuses on identifying symptom patterns consistent with altered nociceptive processing.

Illness Perceptions Questionnaire-Revised (Study 1 Only): A validated measure assessing cognitive and emotional representations of illness, including beliefs about timeline, consequences, control, and coherence. The IPQ-R will be used to characterize participants’ pain-related beliefs and to explore whether shifts in illness perceptions accompany changes in movement-related fear and functional engagement during the Move-MORE intervention.[62,63]

Psychosocial Assessments

Patient Global Impression of Change (PGIC): The PGIC is a single-item, patient-reported outcome measure that captures a participant’s overall perception of improvement or decline in health status since the start of an intervention. Rated on a 7-point Likert scale ranging from “very much improved” to “very much worse,” the PGIC provides a global assessment of treatment effectiveness from the patient’s perspective.

The Pain, Enjoyment of Life and General Activity (PEG-3): The PEG-3 is a brief, 3-item measure derived from the Brief Pain Inventory that assesses pain intensity and its impact on enjoyment of life and general activity. Each item is rated on a 0–10 scale, with higher scores indicating greater pain-related

interference. The PEG-3 is a validated tool commonly used in both clinical and research settings to monitor pain outcomes efficiently.[64]

Tampa Scale of Kinesiophobia (TSK-11): The TSK-11 is designed to assess the presence of fear of movement. This measure has previously been validated in populations of patients with chronic non-specific low back pain and shown to have good reliability.[42]

Pain Catastrophizing Scale-6 (PCS): The PCS-6 is used to assess pain catastrophizing via its subscales: helplessness, rumination, and magnification. It has primarily been used and validated in patients with low back pain.[65]

PROMIS Self-Efficacy for Managing Symptoms 8a: The PROMIS Self-Efficacy for Managing Symptoms 8a is an 8-item patient-reported measure assessing an individual's confidence in managing symptoms related to their health conditions. It evaluates domains such as controlling symptoms, performing tasks despite symptoms, and coping with the impact of symptoms on daily life. Higher scores indicate greater self-efficacy in symptom management. This tool helps capture patients' perceived ability to handle their health challenges and is useful for tailoring interventions and tracking progress in clinical research.

PROMIS Ability to Participate in Social Roles 4a: This validated patient-reported outcome measure assesses individuals' perceived ability to engage in usual social roles and activities, including work, family responsibilities, and participation in social life. The instrument captures functional participation beyond physical capacity alone, reflecting how pain and related symptoms affect engagement in meaningful daily roles. In the context of Move-MORE, this measure provides a complementary indicator of functional recovery by assessing whether changes in pain-related fear and activity confidence translate into improved participation in valued social roles.[66]

PROMIS Sleep Disturbance 6a + Sleep Duration Question: This is a validated patient-reported outcome measure assessing perceived sleep quality and sleep disturbances over the past 7 days. The 6-item Sleep Disturbance short form (6a) evaluates aspects such as difficulty falling asleep, staying asleep, and overall sleep satisfaction, while an additional question captures average sleep duration. Scores provide insight into sleep problems that may affect health and functioning.

Whole Person Health Index: The WPHI is a self-report survey that provides a comprehensive snapshot of a person's health. The WPHI can serve as an anchor or reference point for connecting diverse health data, all while keeping the individual's personal health perspective at its core. The WPHI is based on nine questions developed and validated through a collaboration between the National Center for Complementary and Integrative Health (NCCIH) and the National Center for Health Statistics/Centers for Disease Control and Prevention.[67,68]

Patients Endorsement of a Biopsychosocial Model of Chronic Pain Scale (PEB): The PEB is designed to assess patient beliefs about the biopsychosocial model of chronic pain. It has been previously shown to

have good internal consistency and reliability and has been recommended for use in longitudinal studies to assess patients' attitudes towards long-term pain management.[69]

World Health Organization Quality of Life Questionnaire – 2 (WHOQOL-2): The WHOQOL-2 is a brief, validated instrument developed by the WHO to assess an individual's perceived quality of life across multiple domains, including physical health, psychological well-being, social relationships, and environment. It provides a global measure of overall life satisfaction and well-being. The WHOQOL-2 has been shown to have acceptable internal consistency and is responsive to change.[70]

Patient Health Questionnaire – 8 (PHQ-8): The PHQ is a widely used self-report instrument for assessing the presence and severity of depressive symptoms over the past two weeks. The PHQ-8 excludes the item on suicidal ideation found in the PHQ-9, making it suitable for general population surveys and clinical research where suicide risk assessment is conducted separately. The PHQ has previously been shown to have good reliability and validity in patients with a variety of chronic pain conditions.[71–74]

Generalized Anxiety Questionnaire-7 (GAD-7): The GAD-7 is a brief, validated self-report questionnaire used to screen for and assess the severity of generalized anxiety disorder symptoms. It consists of seven items asking respondents how often they have been bothered by anxiety-related problems over the past two weeks. Scores help categorize anxiety severity from minimal to severe and assist clinicians and researchers in monitoring anxiety symptoms and treatment response. The GAD-7 is widely used in both clinical and research settings for its reliability and ease of administration. The GAD-7 has previously been shown to have good reliability and validity in patients with a variety of chronic pain conditions.[75–78]

Treatment Self-Regulation Questionnaire (TSRQ): The TSRQ is a validated self-report measure designed to assess individuals' motivation behind engaging in health-related behaviors. It evaluates the degree to which behavior change is driven by autonomous (intrinsic) versus controlled (extrinsic) motivation, grounded in Self-Determination Theory. The TSRQ helps identify the reasons patients choose to adhere to or modify treatments, providing insights into their internalization of health goals. It is commonly used in research to understand motivational factors influencing treatment adherence and lifestyle changes.[79–81]

Five Facet Mindfulness Questionnaire (FFMQ): The FFMQ is a self-report questionnaire that assesses trait mindfulness using five subscales: Observing, Describing, Acting with Awareness, Nonjudging of Inner Experience, and Nonreactivity to Inner Experience. The FFMQ has demonstrated good construct, discriminant and predictive validity, and internal consistency.[82–84]

Mindful Reappraisal of Pain Scale (MRPS): The MRPS is a self-report questionnaire designed to quantify mindful reappraisal of pain, measured on a scale from 0, "never do that," to 6, "always do that". It has demonstrated good convergent and discriminant validity when compared to other mindfulness questionnaires and is sensitive to change in participants undergoing mindfulness interventions.[85]

Multidimensional Assessment of Interoceptive Awareness – Version 2 (MAIA-2): The MAIA-2 was designed to assess interoceptive awareness. It is made up of eight subscales including: noticing, not-distracting, not-worrying, attention regulation, emotional awareness, self-regulation, body listening, and trust. It has previously demonstrated good internal consistency, validity, and reliability.[86–88]

Purpose in Life Scale-6: The Purpose in Life Scale is a self-report instrument designed to assess an individual's sense of meaning, purpose, and direction in life.[89,90] It measures the extent to which a person feels their life has meaning and goals that give motivation and fulfillment. This scale is commonly used in psychological and health research to evaluate well-being, resilience, and overall mental health. Higher scores indicate a stronger sense of purpose in life, which is associated with better psychological outcomes and coping abilities.

International Physical Activity Questionnaire (IPAQ) Short Form: The IPAQ captures information about physical activity frequency, intensity, time, and type. The IPAQ has been shown to have high repeatability and high criterion validity.[91,92] Reliability and validity have also been assessed in various languages and populations. Responses can be converted to metabolic equivalents by activity.[93–95]

PROMIS Physical Functioning Short Form 6b: The PROMIS Physical Functioning Short Form 6b is a brief, validated patient-reported outcome measure that assesses an individual's ability to perform everyday physical activities. It includes six items focused on mobility, self-care, and upper extremity function, capturing the impact of health conditions on physical functioning. Scores provide a standardized assessment of physical capabilities, with higher scores indicating better physical function. This tool is widely used in clinical and research settings to monitor physical health status and track changes over time.

Objective Assessments

Actigraphy: Physical activity and sleep will be tracked using the Actigraph LEAP 2.0. This device will track participants' sedentary and active time and several parameters of sleep (e.g., sleep efficiency, sleep fragmentation, number of awakenings).[96]

Conity Motion Analysis System: Motion assessments of the lumbar spine will be performed using the Conity system which uses inertial measurement units to non-invasively assess human kinematics. The Conity system has previously been used to evaluate functional outcomes after lumbar spine surgery, with change in measured kinematics using the tool associated with improvements in self-reported pain, disability, and fear-avoidance.[97]

Michigan Visual Aversion Stress Test (M-VAST 3): Visual Stressors will be used to probe mechanisms of global or generalized sensory sensitivity that bypass somatic peripheral receptors and the spinal cord, which are increased in many chronic pain patients. For visual testing, participants will be presented with a flashing annular checkerboard pattern at varying illumination levels.[98] Participants will be acclimated to a dark room and exposed to a high resolution, calibrated LED monitor displaying the visual stimulus.

Each visual stimulus intensity level and the entire task will be rated on both sensory intensity and unpleasantness scales with overall task ratings and stimulus-response curves generated for analysis. Participants who report visually evoked migraines or seizures will not undergo the M-VAST.

Algometry (Pressure Pain Threshold): Algometry (Algomed Digital Algometer - Medoc) is an objective measure of pain used to quantify tenderness via pressure pain threshold measurement and pain sensitivity via pressure pain tolerance measurement. Digital algometers have shown good validity in patients with migraine and low back pain.[99,100] In this study, algometry will be used to assess pressure pain threshold at a control site, the low back, and the area of most pain.

Pinprick: Pinprick testing assesses mechanical pain threshold, a measure of nociceptive sensitivity to punctate mechanical stimuli. Standardized, weighted pinprick stimulators, 256-millinewtons will be applied perpendicularly to the skin at three sites: volar forearm, low back, and the area of most pain. This test is used to evaluate central sensitization. Pinprick testing is non-invasive, well-tolerated, and commonly included in quantitative sensory testing (QST) protocols to assess changes in mechanical pain sensitivity.[96] QST (i.e., algometry, pinprick, M-VAST-3) will be administered by trained research personnel using standardized protocols. All assessors will complete structured training and competency verification prior to data collection, with periodic refresher training and protocol review throughout the study to ensure consistency.

Stroop Color Word Task: The SCWT is a measure of cognitive control used to assess a person's attentional interference or the ability to inhibit the interruption of a second stimulus while continuing to process an original stimulus. The SCWT will be conducted online using the Testable platform. In the SCWT, the words RED, YELLOW, and GREEN will be presented in one of the alternate font colors and the participant will be asked to press the first letter of the font color on a keyboard rather than the color of the word itself.[43]

Table 2
Outcome Measures

PRO Name	Domain	Study 1	Study 2 Timepoints
Demographics	Demographics	✓	T1
Health History Questionnaire	Health History		T1
Opioid MME Survey*	Opioid Use		T1, T3
Nonpharmacological and Self-Care Approaches Measure from PMC (NSCAP)	Pain Self-Management		T1, T3
Credibility Expectancy Questionnaire	Expectancy		T1, T2
Oswestry Disability Index (ODI)	Disability	✓	T1, T2, T3, T4
Tampa Scale of Kinesiophobia	Kinesiophobia	✓	T1, T2, T3, T4
Client Satisfaction Questionnaire	Satisfaction		T3
PEG*	Pain Intensity + Interference		T1, T2, T3, T4
PROMIS Physical Functioning Short Form 6b*	Physical Function		T1, T2, T3, T4
PROMIS Sleep Disturbance 6a + Sleep Duration Question*	Sleep		T1, T2, T3, T4
PHQ-8*	Depression		T1, T2, T3, T4
GAD-7*	Anxiety		T1, T2, T3, T4
PGIC*	Change in Symptoms		T2, T3, T4
TAPS1	Substance Use		T1
WHOQOL-2*	Quality of Life		T1, T2, T3, T4
painDETECT Questionnaire (PDQ)	Neuropathic Pain		T1, T2, T3, T4
Complex Medical Symptoms Inventory (CMSI)	Nociplastic Pain		T1, T2, T3, T4
Nociplastic Pain Questionnaire (NPQ)	Nociplastic Pain		T1, T2, T3, T4
Pain Catastrophizing Scale (PCS)	Pain Catastrophizing		T1, T2, T3, T4
PROMIS Self-Efficacy for Managing Symptoms	Self-Efficacy		T1, T2, T3, T4
PROMIS Ability to Participate in Social Roles 4a	Ability to Participate in Social Roles		T1, T2, T3, T4
Patient's Endorsement of a Biopsychosocial	Biopsychosocial Pain		T1, T2, T3, T4

PRO Name	Domain	Study 1	Study 2 Timepoints
Model of Chronic Pain Scale (PEB)			
Five Facet Mindfulness Questionnaire (FFMQ)	Trait Mindfulness		T1, T2, T3, T4
Mindful Reappraisal of Pain Sensations (MRPS)	Reappraisal of Pain		T1, T2, T3, T4
Multidimensional Assessment of Interoceptive Awareness (MAIA-2)	Interoception		T1, T2, T3, T4
Treatment Self-Regulation Questionnaire (TSRQ)	Motivation		T1, T2, T3, T4
Purpose in Life Scale	Purpose/Meaning		T1, T2, T3, T4
Visual Analog Scale + Journal Prompts	Daily Pain Intensity		Daily from T1-T3
Objective Assessments			
Michigan Visual Aversion Stress Test (M-VAST 3)	Photosensitivity		T1, T3
Algometry	Pressure Pain Threshold		T1, T3
Pinprick	Mechanical Detection Threshold		T1, T3
Conity Lumbar Motion Assessment	Lumbar Kinetics		T1, T3
Actigraphy			Daily from T1-T3
Stroop Test	Attentional Interference		T1, T3
* Required HEAL CDE T1 = Baseline, T2 = Midpoint, T3 = Primary Endpoint, T4 = 3 Month Follow-Up			

2.9 Harms

We will use the Common Terminology Criteria for Adverse Events. Adverse events (expected), unexpected adverse events, and serious adverse events will all be described using a detailed documentation form and logged in the REDCap.[101,102] Safety information will be routinely summarized, reported to the institutional IRB and included in future publications. Expected adverse events described in consent documentation include mental health exacerbations or triggers associated with meditation and/or completing self-report questionnaires. In addition, participants may experience acute pain exacerbations and there is a minor risk of physical injury while engaging in the movement program. The PI and clinical investigator will oversee safety and conduct AE review. Serious or severe AEs will be reported promptly to the IRB according to institutional policies. The study team will modify or

discontinue intervention components for participants experiencing intolerable side effects or safety concerns, with referral to appropriate medical or mental health services as needed.

2.10 Sample Size

The sample size for the single-arm pilot trial has been determined based on feasibility considerations consistent with recommendations for early-phase studies. A sample size of 32 will allow us to estimate key feasibility parameters, including our target retention rate of 75%, with adequate precision for planning a future randomized trial.[103]

2.11 Analysis Plan

2.11.1 Quantitative Analysis

Feasibility and Acceptability Metrics: Our analysis will address feasibility and acceptability, following recommendations for feasibility study design and reporting.[104] We will use descriptive statistics to summarize feasibility outcomes, including retention, enrollment, adherence (class attendance and home practice), and adverse events. We will calculate proportions, means, and standard deviations (or medians and interquartile ranges, as appropriate) for each domain of the Bowen framework (acceptability, demand, implementation, practicality, adaptation). For acceptability and accessibility, we will report mean scores and standard deviations for the Client Satisfaction Questionnaire and Credibility/Expectancy Questionnaire.[104]

Patient Reported Outcomes: We will analyze changes in PROs (e.g., pain, disability, central sensitization, psychosocial factors, quality of life, mindfulness, and interoception) across timepoints. For each outcome, we will report mean changes with 95% confidence intervals.

Actigraphy: We will summarize daily step count, active minutes, sedentary time, and sleep parameters at each timepoint using means and standard deviations. We will explore correlations between changes in actigraphy data and changes in PROs using Pearson or Spearman correlation coefficients.

Conity Motion Analysis, Stroop Test, and Quantitative Sensory Testing: We will analyze changes in lumbar motion, attention interference, QST tests (algometry, pinprick, and visual sensitivity), respectively, across timepoints via mean change scores with 95% confidence intervals. We will examine associations between QST changes and changes in PROs and actigraphy data using correlation and regression analyses.

Missing Data and Sensitivity Analyses: We will summarize the extent and patterns of missing data across outcome domains (e.g., PROs, EMA, actigraphy, and objective assessments) using descriptive statistics. Missingness will be reported as proportions at each assessment timepoint. This data will be used to evaluate feasibility of data collection procedures and to inform outcome selection, assessment frequency, and analytic planning for a future randomized trial. Given the feasibility-focused aims and small sample size, no formal imputation or sensitivity analyses are planned.

2.11.2 Qualitative Analysis

Qualitative data from Study 1 (i.e., patient focus groups and clinician interviews, discussions with Move-MORE instructors, field notes) will be analyzed using the Person-Based Approach to guide iterative refinement of Move-MORE. This approach will prioritize understanding participants lived experiences, contextual needs, and perceived barriers or facilitators to engagement with mindfulness, movement practices, and motivational components. The analytic process will involve rapid, matrix-based qualitative analysis to identify key usability and acceptability issues as well as the guiding principles necessary to support autonomy, competence, and relatedness within the intervention.[28,30]

To ensure cultural and contextual appropriateness, findings will be further interpreted through the Ecological Validity Model (EVM), focusing on dimensions of the intervention (e.g., concepts, persons, methods, content). This framework will help assess whether the intervention aligns with participants' day-to-day realities, symptom patterns, mobility limitations, and recovery expectations in the context of lumbosacral radicular pain.[105]

Proposed refinements emerging from qualitative data will be organized and prioritized using the MoSCoW criteria ("Must have," "Should have," "Could have," "Would like to have"), allowing the research team to distinguish essential modifications from lower-priority enhancements based on feasibility, participant burden, and alignment with intervention goals. Patient partners will contribute to this prioritization process, ensuring that decisions about intervention refinement reflect patient needs and practical considerations.

Mixed methods data integration will be conducted using joint displays to explicitly link qualitative and quantitative findings and inform intervention refinement. Joint displays will align core constructs (e.g., kinesiophobia, perceived safety, engagement) with qualitative themes and corresponding quantitative indicators to support meta-inferences and guide design decisions. These displays will be used iteratively by the investigator team and patient partners to prioritize and operationalize intervention modifications.

Machine Learning-Assisted Analysis for Iterative Refinement

Tools such as natural language processing are being increasingly used to support qualitative analysis and mixed methods due to their capacity to decrease analysis time and research team burden.[106,107] To enable systematic analysis between Move-MORE cohorts within Study 2, we will employ machine learning tools to accelerate qualitative data processing. Previously, we conducted a longitudinal qualitative analysis of session transcripts from a clinical trial of MORE and this codebook will be used as a starting point for rapid qualitative analysis of Move-MORE sessions.[23] This process tags transcript segments according to identified stages of mindfulness progression including 1) attention regulation, 2) experiential avoidance, 3) metacognitive awareness, and 4) pain reappraisal. The machine learning system will generate frequency counts for each code per session which will enable rapid identification of prevalent themes. For each session and cohort, we will generate a summary report documenting the

most frequent qualitative codes to identify potential areas for intervention refinement, such as sessions where multiple participants express similar challenges or weeks showing consistent drops in practice completion.

Between cohorts, we will track changes in code frequencies and aggregate outcomes to assess whether intervention modifications have adequately addressed identified challenges. All modification decisions will be made by consensus of the Move-MORE instructors and investigator team. The primary value of this ML-assisted approach lies in reducing the time required for transcript coding. By automating qualitative coding, the intervention team can focus on refining intervention materials. This approach will support the expertise of intervention instructors in identifying areas for intervention refinement.

2.12 Data Management

All quantitative study data will be collected and managed using REDCap, hosted on secure, firewall-protected servers at the NUNM. Participant information will be stored using unique study identification numbers, and identifiable information (e.g., names, contact details) will be stored in a separate, access-restricted linkage file. Prior to analysis, all datasets will be de-identified by removing direct identifiers and limiting indirect identifiers. Access to study data will be role-based and restricted to authorized study personnel who have completed required training in human subjects protection and responsible conduct of research. Audit trails within REDCap will document all data modifications, and regular data quality checks will be performed to ensure accuracy and completeness. Data will be retained according to institutional and federal guidelines and will be destroyed after the required retention period.

3.0 DISCUSSION

The Move-MORE protocol addresses an important gap in non-pharmacologic treatments for LRP by systematically developing an intervention that targets both the physical and psychosocial dimensions of pain. Our two-phase approach including qualitative stakeholder engagement followed by the iterative pilot feasibility trial and overseen by patient advisors will ensure that the intervention is theoretically grounded and practically relevant to patients' lived experience.[26]

A major strength of this study is its integration of stakeholder input throughout intervention development and testing. Consistent with the principles of patient engagement in research as described by the IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) recommendations and the guiding principles of PCORI[36] this study will integrate patient partners in the planning and conduct of the study as well as the dissemination of study findings. Study 1 prioritizes the voices of patients and clinicians through qualitative engagement and structured feedback, ensuring that the resulting intervention is both relevant and acceptable to its intended users. This design process is further enhanced by the involvement of patient partners who will contribute across the full arc of the research. These participatory elements position our study protocol as a model for patient-engaged intervention development.

The study also benefits from methodological rigor in its use of real-time, mixed methods data integration. While the use of machine learning tools in qualitative and mixed methods research is an area of active methodological debate, our approach is intentionally designed for rapid feedback and is human-guided. Machine learning will be used solely to accelerate transcript processing and pattern identification, with all analytic decisions, interpretation, and intervention modifications determined by the investigator team and Move-MORE instructors. The iterative refinement process used in Study 2 will allow for ongoing improvements to the Move-MORE program based on both quantitative and qualitative findings. Additionally, the strict inclusion criteria, including verification of radiculopathy through physical exams in Study 2, will ensure that our findings can be meaningfully interpreted in the context of patient care.

Nonetheless, several challenges are anticipated. While digital delivery is beneficial for many chronic pain patients with limited mobility or transportation challenges, this format may also pose accessibility barriers for some patients who experience difficulty with technology. In addition, this format introduces limitations to hands-on form correction from instructors, and participant apprehension to physical activity at home without in-person supervision.

This study will lay the foundation for a future randomized controlled trial and offers a model for developing scalable, mechanism-informed, nonpharmacologic treatments for chronic pain. As healthcare systems increasingly seek integrative, patient-centered solutions, the Move-MORE intervention has the potential to inform both research and clinical practice.

4.0 CONCLUSION

The Move-MORE protocol outlines a patient-centered, mixed-methods approach to developing and refining a novel intervention for patients with lumbosacral radicular pain. By integrating stakeholder perspectives, undergoing iterative intervention refinement, and maintaining a focus on feasibility, this study lays essential groundwork for further optimization. The findings will contribute to the growing body of evidence regarding nonpharmacologic strategies for chronic pain management.

Abbreviations

• CAB
Community Advisory Board
• CDE
Common Data Elements
• CMSI
Complex Multi-Symptom Inventory
• CSQ
Client Satisfaction Questionnaire
• EMA

Ecological Momentary Assessment
• EVM
Ecological Validity Model
• FFMQ
Five Facet Mindfulness Questionnaire
• GAD
Generalized Anxiety Questionnaire
• GRIPP2
Guidance for Reporting Involvement of Patients and the Public
• HEAL
Helping End Addiction Long-Term
• IMMPACT
Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
• IPAQ
International Physical Activity Questionnaire
• LRP
Lumbosacral Radicular Pain
• MAIA
Multidimensional Assessment of Interoceptive Awareness
• MORE
Mindfulness-Oriented Recovery Enhancement
• MoSCoW
Must have, Should have, Could have, Would like to have
• MRPS
Mindful Reappraisal of Pain Scale
• M-VAST
Michigan Visual Aversion Stress Test
• NCCIH
National Center for Complementary and Integrative Health
• NIH
National Institutes of Health
• NPQ
Nociplastic Pain Questionnaire
• NSCAP
Nonpharmacological and Self-Care Approaches Measure from PMC
• NUNM
National University of Natural Medicine
• ODI
Oswestry Disability Index
• OHSU

Oregon Health & Science University
• PCORI
Patient Centered Outcomes Research Institute
• PCS
Pain Catastrophizing Scale
• PD-Q
painDETECT Questionnaire
• PEB
Patients Endorsement of a Biopsychosocial Model of Chronic Pain Scale
• PEIRS
Patient Engagement in Research Scale
• PHQ
Patient Health Questionnaire
• PPEET
Patient Engagement Evaluation Tool
• PROs
Patient Reported Outcomes
• PROMIS
Patient Reported Outcomes Measurement Information System
• PURER
Phenomenological, Utilization, Reframing, Education, and Reinforcement
• QST
Quantitative Sensory Testing
• REDCap
Research Electronic Data Capture
• SCWT
Stroop Color Word Test
• SDT
Self-Determination theory
• SPIRIT
Standard Protocol Items: Recommendations for Interventional Trials)
• TAPS
Tobacco, Alcohol, Prescription medications, and other Substance
• PGIC
Patient Global Impression of Change
• PEG
The Pain, Enjoyment of Life and General Activity Scale
• TSK
Tampa Scale of Kinesiophobia
• TSRQ

Treatment Self-Regulation Questionnaire
• WHOQOL
World Health Organization Quality of Life Questionnaire
• WPHI
Whole Person Health Index

Declarations

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study and its informed consent procedures have been approved by the National University of Natural Medicine Institutional Review Board (RW6625).

CONSENT FOR PUBLICATION

Not applicable.

Competing Interests

Dr. Rudin has a small revenue share with GreenCape Health, a small digital health company, unrelated to this work. All other authors have no conflicts of interest to report.

DISSEMINATION

Study findings will be disseminated through multiple channels to ensure broad accessibility and impact. Results from the qualitative study and pilot trial will be presented at national and international scientific conferences focused on pain, integrative health, and clinical trial methodology. Manuscripts describing the intervention development process, feasibility outcomes, and exploratory findings will be submitted to peer-reviewed journals. In alignment with principles of public engagement, the study team and CAB will create plain-language summaries to share results with participants, clinicians, and patients generally.

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Author Contribution

RSW and WB were responsible for drafting the initial version of the manuscript with critical edits provided by MB, MF, VL, DS, AV, JP, AP, AP, SW, JF, AK, BZ, DW, and RB. All authors approved the final version of the manuscript.

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Data Availability

Consistent with NIH HEAL Initiative data-sharing requirements, de-identified study data and associated documentation will be deposited in the HEAL Data Ecosystem according to the program's timelines and standards. All shared data will be de-identified prior to submission, and materials will be prepared to enable secondary use while protecting participant privacy.

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Figures

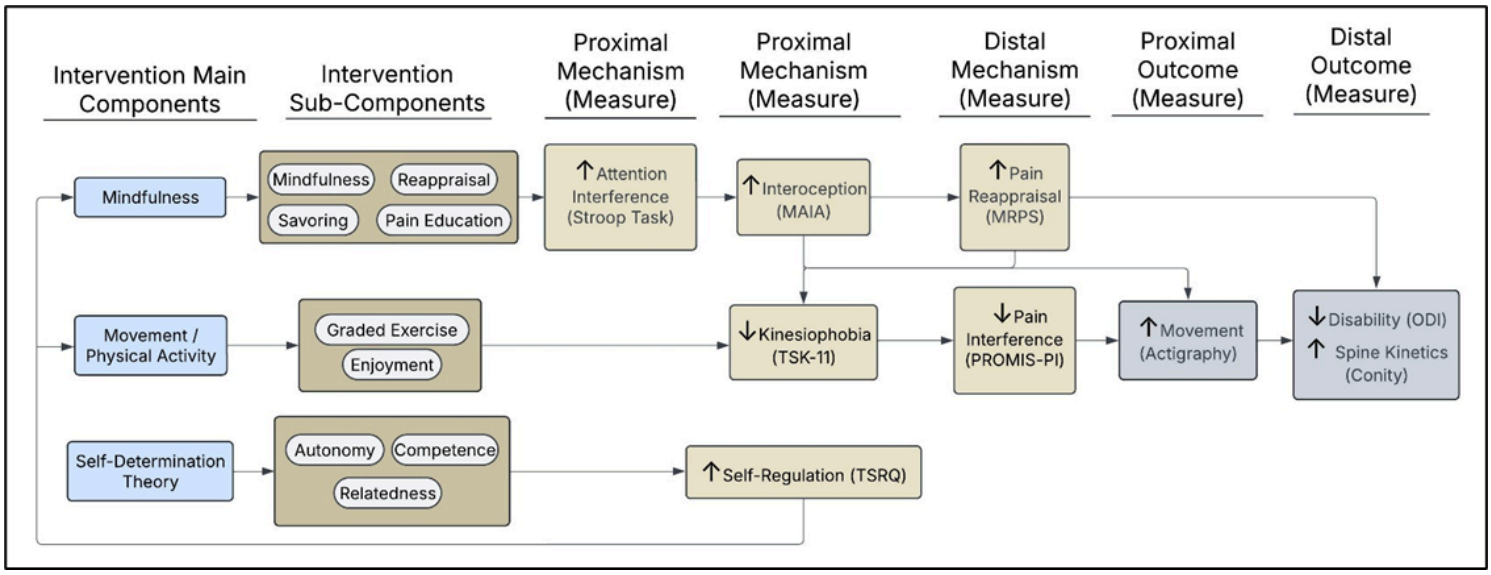


Figure 1

Conceptual Model of Move-MORE

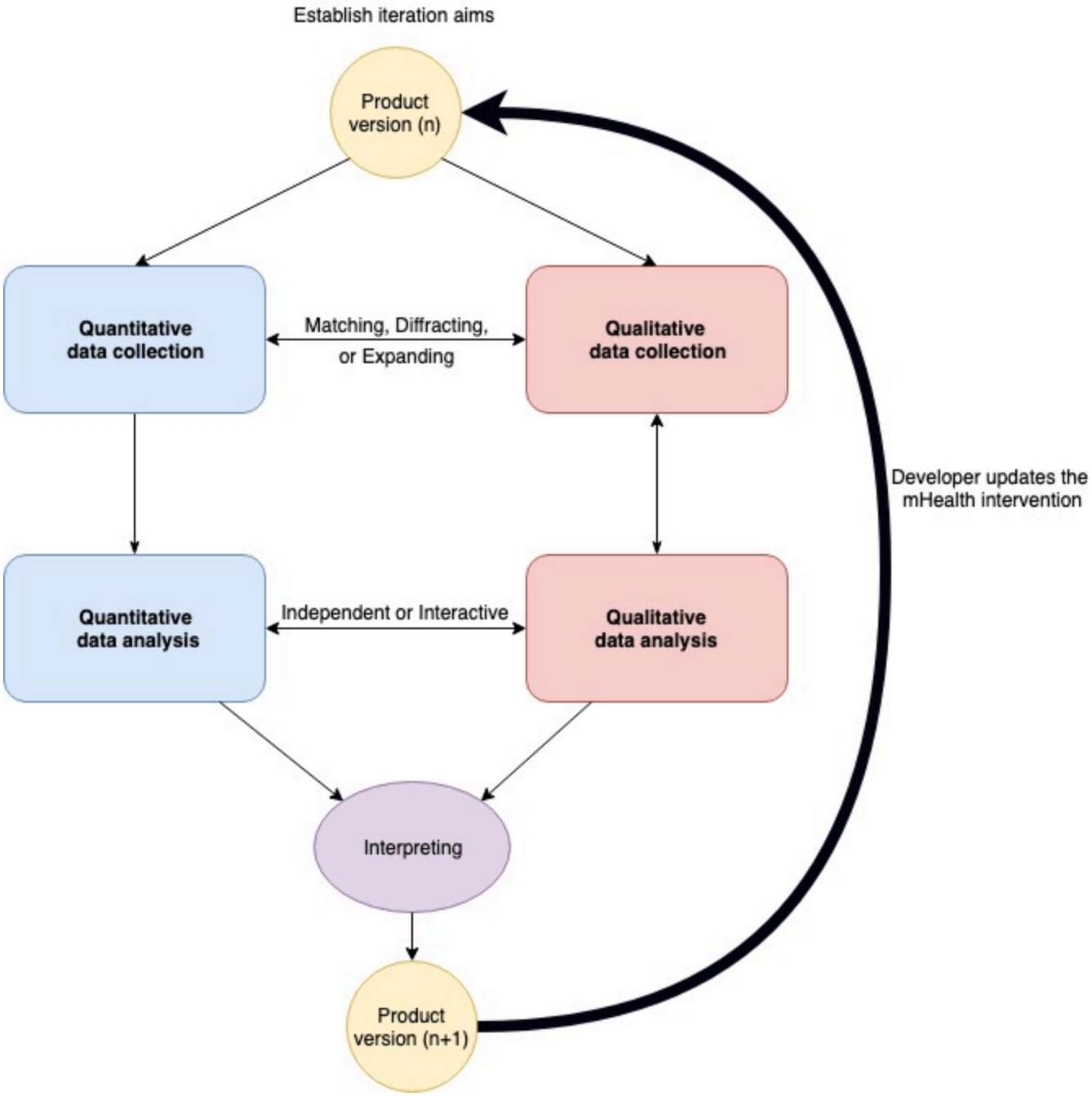


Figure 2

The iterative convergent mixed methods research design.26 Reproduced from Alwashmi et al. (2019), originally published in JMIR mHealth and uHealth, under the terms of the Creative Commons Attribution License (CC BY 4.0; https://creativecommons.org/licenses/by/4.0/). The original article is available at https://mhealth.jmir.org/

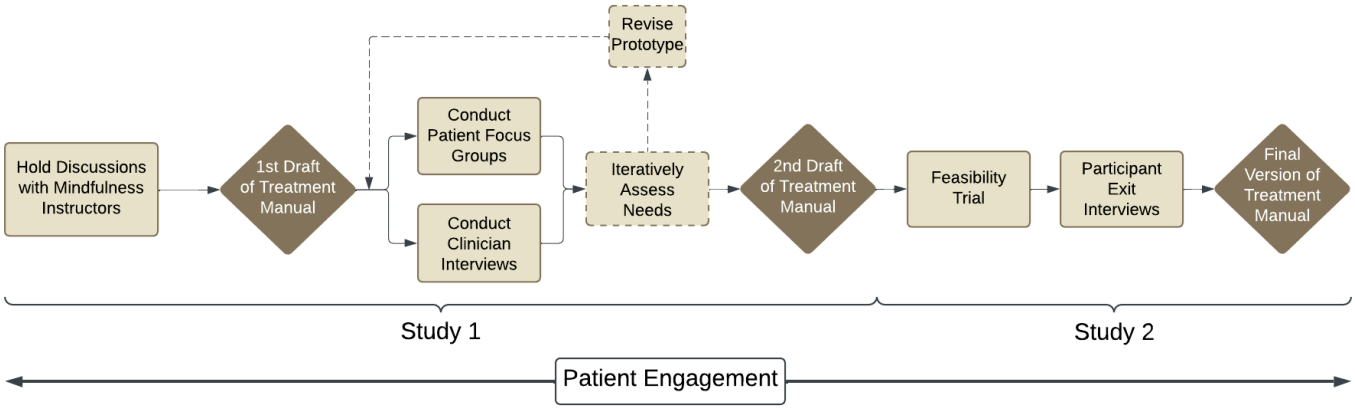


Figure 3

Intervention Development Process for Move-MORE

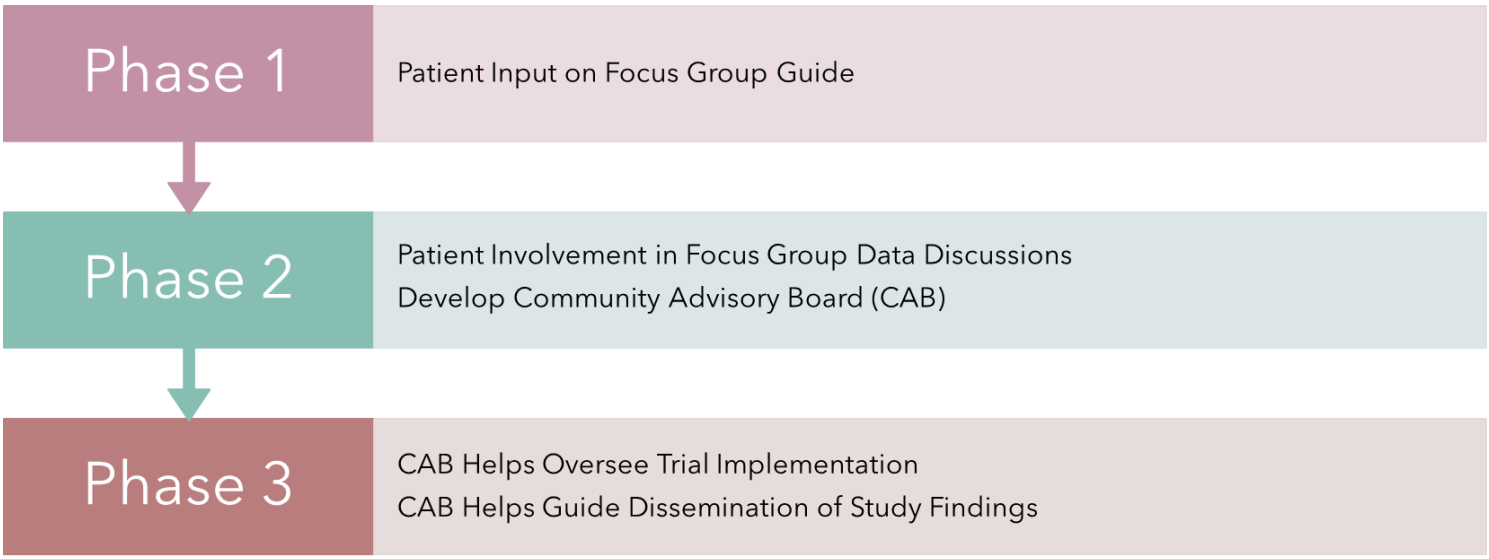


Figure 4

Patient Engagement Plan

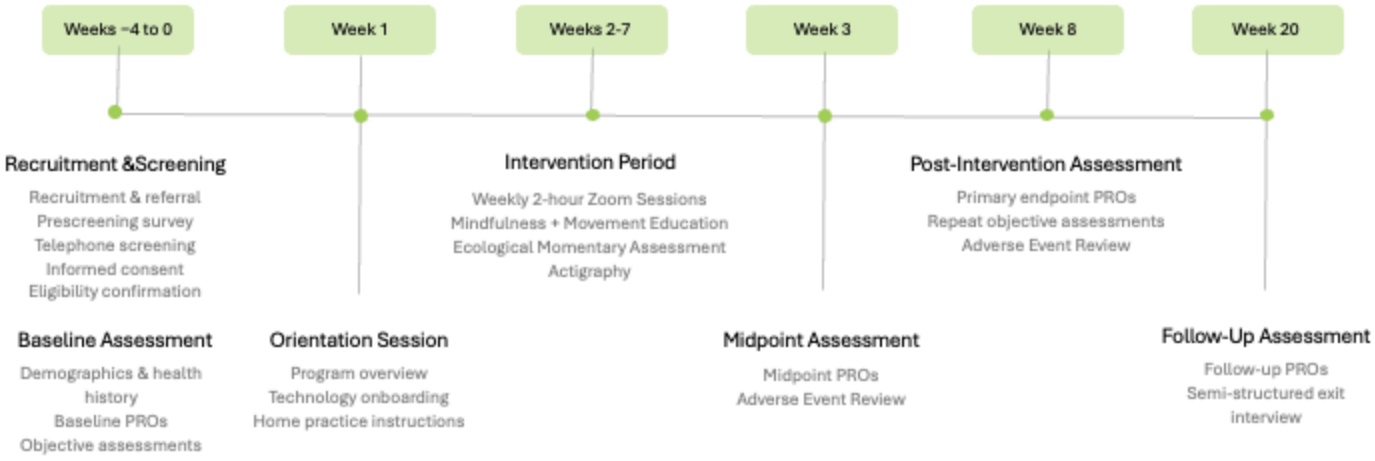


Figure 5

The timeline depicts key study phases for the Move-MORE trial, including recruitment and screening, baseline assessment, intervention delivery, midpoint and post-intervention assessments, and follow-up.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementalFile1GRIPP2Checklist.xlsx
- SupplementalFile2SPIRIT2025Checklist.docx