Feasibility of a 4-week, Adapted Mindfulness Program for Adults with Chronic Pain

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Complete Title: Feasibility of a 4-week, Adapted Mindfulness Program for Adults with Chronic Pain

Short Title: 4-week Mindfulness Program for Chronic Pain Management

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Sponsor: The North Carolina Translational and Clinical Sciences (NC TraCS) Institute

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
CNCP	Chronic non-cancer pain
MBSR	Mindfulness-based Stress Reduction
RA	Research assistant
PROMIS	Patient-Reported Outcomes Measurement Information System
QOL	Quality-of-life
AE	Adverse Event
SAE	Serious Adverse Event

PROTOCOL SYNOPSIS

Study Title	Feasibility of a 4-week, Adapted Mindfulness Program for Adults with Chronic Pain
Funder	North Carolina Translational and Clinical Sciences (NC TraCS) Institute
Clinical Phase	Phase I
Study Rationale	Chronic pain is a costly and debilitating condition affecting over 100 million U.S. adults.[1] Over 10% of North Carolinians are affected by chronic low back pain alone.[2] The nonpharmacologic management of CNCP is strongly recommended by the CDC. Mindfulness Based Stress Reduction (MBSR) is an established mind-body intervention shown to improve QOL, functioning and depression across pain conditions.[3] However, the time demand of standard MBSR (26 class hours in 8 weeks) is a key barrier for those whose condition or circumstances limit ability to participate.[4,5] Brief mindfulness programs have not been studied in groups with CNCP of varied etiologies in a clinical setting.
Study Objective(s)	**Primary** • To determine the feasibility and acceptability of a 4-week mindfulness training program adapted from MBSR for adults with CNCP recruited from UNC pain management clinics **Secondary** • To test the preliminary effects of the mindfulness training program on pain-related, quality of life (QOL), and psychological outcomes.
Test Article(s) *(If Applicable)*	The intervention is based on MBSR, an 8-week mindfulness training program developed to help people manage stress-related and chronic conditions. The adapted mindfulness intervention will consist of four, weekly 1 hour and 30 minute group sessions that are modified from the original program to fit the shorter length and to directly address chronic pain management.
Study Design	This feasibility study uses a single-arm, mixed-methods repeated measures design, with quantitative measures administered within 1 week pre and post-intervention, and qualitative semi-structured interviews administered within one to two weeks post-intervention.
Subject Population	**Inclusion Criteria**

key criteria for Inclusion and Exclusion:	1. Adults aged 18 and older who are able to read and speak English 2. Diagnosed with one or more CNCP conditions (daily pain at least 3 months duration) who report more than minimal pain bothersomeness and interference with activities 3. Has established care with provider who manages pain **Exclusion Criteria** 1. Diagnosis of mental illness with psychotic features 2. History of inpatient admission for psychiatric disorder in past 2 years 3. Active substance abuse within the past year 4. Completed an MBSR or other mindfulness course; has had a regular mindfulness practice during the course of the chronic pain condition
Number Of Subjects	24
Study Duration	Each subject's participation will last up to 12 weeks including possible wait-time between screening and intervention start. The entire study is expected to last up to 12 months.
Study Phases Screening Study Treatment Follow-Up	(1) Screening: Phone screening with study personnel to determine eligibility for study. If eligible, the consent form will be reviewed with the participant over the phone and online written consent will be obtained after the phone call and before completing baseline measures. (2) Baseline Measures: Administered via online self-report questionnaires (3) Intervention: Four weekly, 1 hour 30 minute group mindfulness training sessions co-facilitated by an experienced mindfulness instructor (Faculty advisor Gaylord) and a clinical psychologist with pain psychology training (PI Brintz). (4) Post-measures: Within 1-2 weeks after intervention, administered via online self-report questionnaires and with semi-structured phone interview.
Efficacy Evaluations	Feasibility and acceptability will be measured with 1) enrollment statistics, 2) study retention, 3) assessment completion, 4) session attendance, 4) home practice diaries, and 5) credibility questionnaire and semi-structured phone interviews assessing participant satisfaction. Secondary outcomes will be measured with self-report questionnaires.

Pharmacokinetic Evaluations	N/A
Safety Evaluations	Participant self-report of adverse experiences in response to mindfulness meditation practice. Will assess during intervention sessions. Will monitor AEs/SAEs that may or may not be study related as reported by participants.
Statistical And Analytic Plan	Primary feasibility/acceptability outcomes will be analyzed using percentages and 95% CIs. The qualitative description method will be used for interview data by identifying major themes within the content and producing a descriptive summary of the data. Secondary outcomes will be analyzed using paired t-tests and by examining the pre/post intervention change in scores and their respective standard errors with 95% confidence intervals.
DATA AND SAFETY MONITORING PLAN	The PI (Brintz) is responsible for data quality management and ongoing assessment of participant safety. The faculty advisor (Gaylord) will advise PI Brintz on issues of data quality management and assessment of safety.

1 BACKGROUND AND RATIONALE

1.1 Introduction

Chronic pain is a costly and debilitating condition affecting over 100 million U.S. adults.[1] Over 10% of North Carolinians are affected by chronic low back pain alone.[2] Chronic non-cancer pain (CNCP) is commonly treated with pharmacotherapy, with 3-4% of the entire U.S. population prescribed long-term opioid therapy.[3] Remarkably, the effectiveness of long-term opioid use for CNCP has limited evidence[4,5]; furthermore, chronic opioid use can lead to increased pain sensitivity[6] and increased risk for opioid use disorders and overdose.[7,8] Thus, the nonpharmacologic management of CNCP is strongly recommended by the Centers for Disease Control and was named a top scientific priority of the NIH-National Center for Complementary and Integrative Health.[9]

CNCP is associated with disability, decreased quality of life (QOL) and emotional distress.[10] Mindfulness Based Stress Reduction (MBSR) is an established mind-body intervention shown to improve QOL, functioning and depression across pain conditions.[11] It has led to clinical improvements (>30%) in functional disability in 61% of low back pain patients, similar to cognitive behavioral therapy and more effective than usual care.[12] Mindfulness training targets changing one's reaction to painful experiences with nonjudgmental, present-moment awareness[13], and improves the self-management of pain through increased self-regulation of emotions and attention.[14] Mindfulness training has decreased opioid use disorders and cravings.[15] However, the time demand of standard MBSR (26 class hours in 8 weeks) is a key barrier for those whose condition or circumstances limit ability to participate.[16,17] Brief mindfulness training programs based on MBSR have been piloted for specific chronic pain conditions such as tension-type headache[18] and low back pain[19], but have not been studied in groups with CNCP of varied etiologies in a clinical setting.

1.2 Name and Description of Investigational Product or Intervention

The current study will use an adapted version of the established mindfulness training program called Mindfulness-based Stress Reduction (MBSR). MBSR is the most popular and well-tested format for teaching mindfulness skills in the U.S. MBSR was developed by Dr. Jon Kabat-Zinn to teach a range of mindfulness skills to help individuals better manage chronic and stress-aggravated illnesses.[20,21] Mindfulness skills involve the intentional self-regulation of attention to present-moment experience, combined with releasing cognitive fixation on thoughts and emotions regarding the past or future.[13] The MBSR program teaches a range of mindfulness-related skills, typically in an eight-week, 2.5 hour per week group format, with a 6-hour weekend day of mindfulness retreat. It is generally available to medical patients and community members with a wide range of stress-related problems or medical conditions. The current study will use an adapted version of this program, adapted by PI Brintz and Faculty Advisor Gaylord. It will be adapted to fit the shorter length (4 weeks; 1 hour, 30 minute sessions) and will be directly related to chronic pain management and coping. See **Appendix B** for a breakdown of sessions content and mindfulness skills taught.

1.3 Non-Clinical and Clinical Study Findings

Potential benefits: Studies indicate that mindfulness-based interventions such as MBSR may have a number of pain-related and psychological benefits for individuals with chronic pain of mixed etiologies. In studies of CNCP, mindfulness intervention have been shown to reduce depression[22,23], anxiety, perceived stress, and pain perception[23] and improve quality of life[22], physical functioning[12], and pain acceptance.[24]

Potential risks: Based on results of previous literature, we expect there to be no more than minimal risk in this study; however, literature on MBSR has not systematically included adverse event reporting, although most studies have not reported any serious risk from participating in MBSR. There have been reports of increased emotional distress and increased awareness of both positive and negative experiences, which may initially increase distress when participants are not used to directing attention towards unpleasant thoughts, feelings, and sensations.[25] The MBSR curriculum guide by Dr. Jon Kabat-Zinn notes the potential for increased negative emotions at the beginning of the course, as well as the possibility that history of trauma, abuse, recent loss, or substance addiction could heighten negative emotional reactions. With an experienced instructor, reactions can be managed and appropriate referrals made.[25]

2 STUDY OBJECTIVE

The objective of this study is to determine the feasibility and acceptability of a 4-week mindfulness program adapted from MBSR for adults with CNCP treated in UNC clinics.

2.1 Primary Objectives:

1: Determine the feasibility of recruiting via pain management providers and online advertisement, retaining participants, session attendance, and online data collection of quantitative measures during a 4-week mindfulness program for adults with CNCP

2: Determine participant acceptability and satisfaction with the intervention using quantitative measure of intervention credibility and with individual semi-structured interviews.

2.2 Secondary Objective:

Assess preliminary effects of the intervention on self-reported functioning, quality-of-life, depressive and anxiety symptoms, pain severity and interference, and other psychological variables that have been shown to improve with mindfulness training and may have beneficial impacts on chronic pain management.

3 INVESTIGATIONAL PLAN (brief overview)

3.1 Study Design

This is a single-arm, mixed-methods, repeated-measures study of a 4-week mindfulness training program for adults being treated for CNCP within UNC pain management clinics.

Screening: Potential participants will hear about this study through their pain management providers (physician/PA/nurse/clinical pharmacist/mental health) or flyer advertisements, and interested patients will contact study personnel for complete a phone screening interview. If a participant is deemed eligible, the PI/research assistant will review the information in the consent form with the participant over the phone and answer any questions. Participants will provide written consent online via a REDCap survey link.

Baseline: Baseline measures will be completed by participants within the week prior to starting the intervention. Participants will receive an email with a link to a REDCap survey containing the self-reported questionnaires. Questionnaires should take approximately 30 minutes to complete. **Intervention:** The intervention will consist of four weekly, 1 hour and 30 minute group mindfulness training sessions. It will take place at a UNC clinic or conference room location. The intervention will be adapted from the standard 8-week MBSR program to fit the shorter class duration and to pertain specifically to chronic pain management. Mindfulness skills will include sitting meditation with attention to breathing, body scan meditation, mindfulness of daily routine activities, and expanding practice to notice and release fixation on thoughts, emotions, or sensations. Participants will be given guided audio recordings of mindfulness practices and course handouts and asked to complete home practice assignments daily during the course. They will also be sent a brief REDCap survey daily to record their daily home practice of mindfulness skills and daily pain intensity.

Follow up: Post-intervention measures will be completed by participants via an online REDCap survey within one to two weeks after the final intervention session. Also within one to two weeks of the final intervention session, participants will be scheduled to complete a 20 to 30 minute semi-structured phone interview assessing their experience (satisfaction, challenges, suggestions for improvement) with the intervention.

3.2 Allocation to Treatment Groups and Blinding (if applicable)

Not applicable – all eligible participants who provide consent will be enrolled in the mindfulness training intervention. The first 12 eligible participants will be enrolled in one cohort, and the next 12 eligible participants will be enrolled in the second cohort receiving the same intervention.

3.3 Study Duration, Enrollment and Number of Subjects

If recruitment proceeds as planned, the study from the beginning of enrollment to the last point of data collection could last approximately 6 months. However, up to one year will allocated should there be any issues with recruitment that need to be resolved or there is a need to wait to enroll between the first and second cohorts because of the time of year (e.g. holidays that would interfere with intervention sessions occurring for 4 consecutive weeks). One year is the allowable funding period. Participants will be enrolled on a rolling basis as they learn about the study, contact the study PI, and complete screening and consent procedures. We will attempt to limit each recruitment period to approximately 4 to 6 weeks to reduce the likelihood of attrition resulting from a prolonged waiting period between enrollment and the start of the group intervention. 12 participants will be enrolled in each group for a total of 24 participants.

3.4 Study Population

Participants will be patients in UNC Clinics that assist with pain management, including but not limited to the Department of Anesthesiology Pain Clinic, the Spine Center, Physical Medicine and Rehabilitation, and Internal Medicine.

Inclusion Criteria

1. Adults aged 18 and older
2. Diagnosed with one or more CNCP conditions (daily pain for at least 3 months duration)
4. Established with one or more physician providers for pain management (e.g. primary care physician, pain specialist, etc).
5. Report more than minimal pain bothersomeness (>3 on 0-10 scale) and/or pain interference with activities (>2 on a 0-10 scale).
6. Able to read, understand and speak English

Exclusion Criteria

1. Diagnosis of mental illness with psychotic features
2. History of inpatient admission for psychiatric disorder in past 2 years
3. Active substance abuse within the past year
4. Has completed an MBSR or other mindfulness course; has or previously had a regular mindfulness meditation practice.
5. Unable or unwilling to comply with study procedures (online questionnaires and practice diaries, 4 weekly intervention sessions, home practice, and one semi-structured phone interview).

4 STUDY PROCEDURES (what will be done)

See **Appendix A** for the schedule of evaluations.

4.1 Screening procedures

Interested individuals will contact study personnel to complete a phone screening interview. Alternatively, if potential participants give permission to the referring provider to be contacted, the screener will initiate phone contact. The screener will provide individuals with a description of the study and the screening procedure and ask for permission from the individual to continue with the screening. If the individual provides verbal consent to the phone screening, they will be asked several questions to determine their eligibility based on age, chronic noncancer pain diagnosis, established care with physician, pain bothersomeness/interference, history of mindfulness training, psychiatric hospitalization, or psychosis, as well as active substance abuse in the past year. If they are deemed eligible based on the phone screening, the screener will verbally review the consent form with the individual, and written consent will be obtained following the phone call via an online consent form through REDCap. Individuals who provide online consent will be enrolled in the study.

4.2 Baseline procedures

Participants will be emailed a link to a REDCap survey, where they will complete self-report questionnaires on 1) demographic information, 2) current pain medications and doses, 3) the PROMIS-29 Profile with physical functioning and health-related quality of life domains, depression, anxiety, pain interference/severity, 4) psychological variables including pain catastrophizing, pain acceptance, mindfulness, positive affect, and emotional and behavioral self-regulation. The survey should take approximately 30 minutes to complete.

4.3 Intervention procedures (by visits)

The mindfulness intervention will consist of four, weekly group mindfulness skills sessions each lasting 1 hour and 30 minutes. Each session will allow time for a 5-minute break in the middle. Sessions will be co-instructed by PI Brintz and faculty advisor Gaylord. All sessions will take place at the same location. See **Appendix B** for session-by-session content and home practice assignments. Participants will receive guided audio recordings for mindfulness skills practice, in addition to a binder with course handouts. The instructor will send one email to each participant the day after each session summarizing the session content and home practice assignments and encouraging participants to complete the daily mindfulness practice diaries. Sessions will be recorded to monitor fidelity to the intervention protocol. Participants will be asked to complete daily home practice and pain intensity diaries between session weeks 1 and 4 via online REDCap surveys that will be sent by email on a daily basis.

4.4 Follow- up procedures (by visits)

Post-Test Questionnaires: After the final intervention session (week 4), participants will be emailed a link with a REDCap survey containing all of the questionnaires from the

baseline survey, excluding demographic information. It will also include questions on intervention credibility.

Post-Test Interview: With-in 1 to 2 weeks after the final session, participants will be scheduled for a 15 to 30-minute semi-structured phone interview with the PI to assess participants' experience with the intervention sessions and overall study. Questions will address the following: satisfaction and usefulness of the skills and content, acceptability of the format, any challenges, and any suggestions for improvement of the intervention or study procedures.

4.5 Unscheduled visits

We do not anticipate having unscheduled visits. Study staff may speak with participants over the phone outside of scheduled visits should participants have questions about the study, their participation, or experience any adverse events during their study participation

4.6 Concomitant Medication documentation

Data will be collected regarding participants' pain medication use at the baseline and post-intervention assessments. As this study is a behavioral intervention trial and other types of medication are not of importance for the research, we do not anticipate needing to document other concomitant medications.

4.7 Rescue medication administration (if applicable)

Not applicable

4.8 Subject Completion/ Withdrawal procedures

Subject Completion: Participants' enrollment in the study will be considered complete once the intervention sessions have ended, post-test measures and phone interview are complete, and study compensation provided. Should participants not complete the post-test survey or phone interview, their participation will be complete when the window to complete such assessments has passed and they have been compensated for any completed study procedures.

Subject Withdrawal: Should a participant choose to withdraw from the study for any reason, their withdrawal will be documented in the case report form **(see Appendix D)** and they will be provided with any study compensation that may still be pending based on completed study procedures. Should any adverse event occur during study enrollment that prohibits a participant from completing study procedures, the participant will be withdrawn from the study and provided with any study compensation that may still be pending based on completed study procedures.

4.9 Screen failure procedures

Individuals who are deemed ineligible during the phone screen will be informed by the screener that they are not eligible and thanked for their time. The screener will provide a reason for exclusion if requested by the individual.

5 STUDY EVALUATIONS AND MEASUREMENTS (how measurements will be made)

All study evaluations and measurements will be made via the following methods: 1) Participant self-report (online survey questionnaires, phone screening, phone interview, adverse experience/event reporting during or between sessions), 2) Behavioral observation of instructor fidelity to the intervention protocol during intervention sessions, and 3) documentation of feasibility variables, including participants' session attendance, survey completion, enrollment and withdrawal. No variables will be abstracted from medical charts. See **Appendix C** for all self-report measures included and **Appendix D** for case report forms.

5.1 Efficacy Evaluation (if applicable)

Not applicable – this is a feasibility study and is not designed or powered to test efficacy of the intervention

5.2 Pharmacokinetic Evaluation (if applicable)

Not applicable

5.3 Safety Evaluations

Participants will be asked to report on any unwanted reactions to the mindfulness skills practice. Reports will be collected via online surveys daily when collecting home practice data. Observations will be made during intervention sessions.

6 STATISTICAL CONSIDERATION

A repeated-measures single group design will be used to test the feasibility and acceptability of the intervention. The study is not powered to test efficacy or significant changes in secondary outcome measures. There is no control group, as the research question pertains to feasibility and acceptability of the mindfulness skills group.

6.1 Primary Endpoint

The primary outcomes are feasibility and acceptability of the intervention and study procedures. Feasibility will be assessed as 1) ability to enroll 12 participants for one intervention group within 4-6 weeks, 2) participant retention, with a goal of 85% retention, 3) session attendance, with a goal of 75% sessions attended, 4) proportion of completed assessments and practice forms.

Acceptability will be assessed via credibility questionnaire and semi-structured interview assessing satisfaction with the intervention, barriers to engagement, and suggestions for improving the intervention or study procedures.

6.2 Secondary Endpoint

Secondary outcomes will all be measured via self-report and include 1) PROMIS-29 adult profile measuring physical functioning and health-related quality of life domains, pain intensity/interference, anxiety and depressive symptoms, 2) psychological variables including pain acceptance, pain catastrophizing, positive affect, emotional/behavioral self-regulation, and mindfulness. Adverse events will be evaluated via self-report, and participants will have the opportunity to report adverse events during intervention sessions, and by contacting study staff at any time during participation in the study..

6.3 Statistical Methods

Quantitative Analyses*:* Baseline demographic, pain medication use, and pain condition variables will be characterized using means and percentages and their standard deviations. Primary feasibility/acceptability outcomes will be analyzed using percentages (proportions) and 95% confidence intervals (CIs). Secondary outcomes will be analyzed by using paired t-tests and examining the pre/post intervention change in scores and their respective standard errors with 95% confidence intervals. Influence of the pretest score on change (i.e., ceiling and floor effects) will be investigated.

Qualitative Analyses: The qualitative description method will be used for interview data.[26] Major themes within the content will be identified and a codebook created. A test sample of interviews will be coded and the codebook refined, followed by coding remaining interviews. The outcome will be a descriptive summary of the contents of the data.

6.4 Sample Size and Power

Anticipating a participant retention proportion of 0.85, the estimated half-width of a 95% CI for the proportion based on 24 enrolled participants is 0.14, which would give a CI of (0.71,0.99). Assuming the overall proportion of sessions attended is 0.75 and an intra-participant correlation of 0.10, the estimated half-width of a 95% CI for the proportion out of a total of 96 possible participant-sessions is 0.10, which would give a CI of (0.65,0.85). Assuming a 15% dropout rate, a sample size of 20 across two groups at post-test is adequate to estimate the feasibility and to generate preliminary data for planning a larger trial.

6.5 Interim Analysis

We are not planning any pre-specified interim analyses for any reason. The study may be suspended by the PI if a serious adverse event occurs that is deemed to be secondary to our intervention. We do not expect any serious adverse events given the low risk of this study.

7 STUDY INTERVENTION (drug, device or other intervention details)

The mindfulness intervention will consist of four, weekly group mindfulness skills sessions each lasting 1 hour and 30 minutes. Each session will have approximately 85 minutes of intervention material scheduled, with time for a 5-minute break in the middle. Sessions will be co-instructed by PI Brintz and faculty advisor Gaylord. All sessions will take place at the same UNC clinic or conference room location on a week-day or week-night. Participants will receive guided audio recordings for mindfulness skills practice, in addition to a binder with course handouts. Participants will be asked to practice for up to 30 minutes daily and to log their practice in the home practice questionnaires that will be emailed and completed using REDCap surveys. Home practice questionnaires will ask about which mindfulness skills were practiced and the number of minutes practiced. Participants will be asked to attend all four sessions as is possible and session attendance data will be collected and evaluated.

Mindfulness skills taught will include sitting meditation with mindfulness of breath, thoughts, emotions, or physical sensations; body scan meditation; walking meditation; and mindfulness of routine daily activities. Mindfulness training involves the intentional self-regulation of attention towards a specific aspect of present-moment experience (e.g. the breath, physical sensations, thoughts, emotions, sounds) while noticing and releasing cognitive fixation on thoughts and emotions about the past or future, or judgments and resistance towards present-moment experience. Didactic content will be presented and discussed amongst the group, with content focusing on topics such as defining mindfulness and how it can help with stress and pain management, the difference between mindfulness and being on autopilot, stress and its relationship to chronic pain, how our perceptions affect stress, the relationship between pain and distressing thoughts and emotions, acceptance of pain and unwanted experiences, using mindfulness in daily life. See **Appendix B** for session-by-session content and home practice assignments.

8 STUDY INTERVENTION ADMINISTRATION(if applicable)

Not applicable – this is a single-group study, so participants will not be randomized, and it is not possible to blind to intervention condition.

9 SAFETY MANAGEMENT

Adverse Event/Serious Adverse event monitoring procedures: Participant safety will be monitored through contact with the intervention instructors (PI and faculty advisor) and

RA. If study staff should learn of any safety issues or injuries among study participants, the appropriate information will be gathered by the PI, including the date of event/injury, the nature/description of the event or injury, and any treatment received as a result of the event or injury. This information will be recorded in adverse event monitoring forms (**see Appendix D**). We anticipate based on previous research of mindfulness training interventions that the study will pose minimal safety risk; however, AEs/SAEs will be assessed by PI Brintz, faculty advisor Gaylord, and Co-I Kim Faurot as to the likelihood that the event is study-related and appropriate action taken if necessary (e.g. participant withdrawal from study). In addition, participants will have opportunities to report any unwanted experiences related to practice of mindfulness skills or participation in the group sessions (e.g. emotional or physical discomfort or distress) during intervention sessions, home practice questionnaires, post-intervention interview, and by contacting the study staff between sessions. Participants will be made aware that they can contact study staff to discuss any discomfort they experience as a result of the intervention at any time.

Adverse Event/Serious Adverse Event reporting procedures: All AEs/SAEs will be monitored by the PI, who will gather all safety-related information from participants, record the event in the monitoring form, and report events as soon as possible (same day or next business day) to the UNC IRB.

Medical Emergency Procedures: Participants will be informed in the consent form and upon enrolling in the study that they should call 911 or go to their nearest emergency department should they experience a medical or psychiatric emergency during the time of their study participation. Should a medical emergency occur during a study intervention session, the emergency department will be contacted immediately.

10 DATA COLLECTION AND MANAGMENT

All participant self-report questionnaires will be completed through secured data collection programs (REDCap). Every participant will have a unique identifier and will receive unique survey links connected with their identifier. After data collection, raw survey responses will be converted into the required file types for analysis. Case report forms (see **Appendix D**) will be used to monitor safety and to record feasibility data, such as eligibility, attendance, assessment completion, and study withdrawal. All case report forms, survey responses, and data files will be stored on UNC's secure network, and will be accessible by approved study staff only in a secured network folder. Participant identifying information (name, birth date) will be kept in a separate secured file on UNCs secure server, linking each participant to their unique study identifier, and will not be linked to any study data. This file will only be accessible by the PI and any approved study staff. All study staff will have completed a required training course in

the protection of human subjects before interacting with research participants or with study-related files or data.

11 RECRUITMENT STRATEGY

We will recruit via pain management providers within UNC clinics and by UNC email advertising. Providers and clinic staff in UNC clinics that assist with pain management will be informed of the study, given a brief written description of the study, and given written information (flyers) to provide to patients that includes study information and contact information. Providers may also ask patients for verbal permission to give the study investigator their name and contact information so study personnel can contact them directly about the study. Clinics will include but not necessarily be limited to the Department of Anesthesiology Pain Clinic, the Spine Center, Physical Medicine and Rehabilitation, and Internal Medicine.

12 CONSENT PROCESS

Individuals will complete phone screening with the PI or RA. Participants will be given information about the nature of the phone screening and asked if they give permission to continue with the phone screen. If an individual is eligible for the study, the screener will review the information provided in the consent form with the individual over the phone, including the purpose of the research, the nature of involvement, the estimated risk of involvement, the potential benefits of participation, the right to stop participation at any time, and who to contact with questions about the research or consent process. The individual will have the opportunity to ask any questions over the phone. They will then be sent an email with the link to the online consent form, asked to read the consent form, and if they agree to participate, to sign the online consent form. Participants will have the opportunity to contact study staff to ask additional questions after reading the online consent form and before signing it.

13 PLANS FOR PUBLICATION

A manuscript reporting the results of this study with regards to feasibility, acceptability, and preliminary effects of the intervention will be submitted for publication in a peer-reviewed journal that has interest in nonpharmacological interventions and/or mindfulness-based interventions for chronic pain management. The results may also be disseminated at a conference (e.g. American Pain Society, Integrative Medicine and Health), and results will be used to provide preliminary data for future grant proposals.

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APPENDIX A.

Schedule of Evaluations

Assessment	Phone Screening	Consent: Online form	Pre-test: Online Survey	Treatment Visit 1 (Week 1)	Treatment Visit 2 (Week 2)	Treatment Visit 3 (Week 3)	Treatment Visit 4 (Week 4)	Post-test: Online Survey	Post-test: Phone Interview
Inclusion/Exclusion Criteria	X								
Informed Consent Review and Form	X	X							
Feasibility: Enrollment, retention, attendance, data collection	X	X	X	X	X	X	X	X	X
Acceptability: Satisfaction, barriers, suggestions to improve intervention								X	X
Demographics, pain conditions/regions			X						
Instructor fidelity to intervention protocol				X	X	X	X		
Daily home practice and pain intensity/interference (exploratory outcomes)				X	X (daily from W1-2)	X (daily from W2-3)	X (daily from W3-4)		
Pain medication usage			X					X	
Secondary outcomes: PROMIS outcomes, psychological variables			X					X	
Credibility Questionnaire					X				
Adverse Reactions/Events				X	X	X	X		

Appendix B. Measures

Scale or Item	Description
Screening Measures/Items	
Drug Abuse Screening Test[27] (DAST)-10	10 items; assess drug use in the past 12 months
Alcohol Use Disorders Identification Test (AUDIT)[28,29]	3 items; assesses alcohol consumption, drinking behaviors, and alcohol-related problems
Chronic pain	Have you experienced pain on a daily basis for at least 3 months?
Pain bothersomeness	How bothersome was your pain in the previous week? (rating scale 0-10).
Pain interference with general activities	How much did your pain interfere with your general activities in the past week? (rating scale 0-10).
Diagnosis of mental illness with psychotic features	Have you ever been diagnosed with schizophrenia, schizoaffective disorder, or another psychiatric disorder with psychotic symptoms?
Psychiatric hospitalization in past 2 years	Have you ever been hospitalized for mental health reasons? When was the last hospitalization?
Previous mindfulness training	Have you ever participated in mindfulness training or course? Have you ever had a regular mindfulness practice? When?
Baseline-only Measures	
Demographic variables	Age, race/ethnicity, education, income, marital status
Pain conditions and regions	e.g. fibromyalgia, osteoarthritis, low-back pain, migraine, neck pain, etc
Baseline and Post-test Measures*	
Pain Medication Use	Pain medications taking, frequency, and dose
Physical Function (short-form 4a)[30]	4 items; difficulty with activities of daily living
Anxiety (sf 4a)	4 items; suggestive of anxiety in the past 7 days
Depression (sf 4a)	4 items; suggestive of depressed mood in past 7 days
Sleep Disturbance (sf 4a)	4 items; sleep quality and disturbance in past 7 days
Pain Interference (sf 6b)	6 items; degree to which pain interferes with life
Pain Intensity	1 item; average pain intensity past 7 days (0-10)
Positive Affect and Wellbeing	9 items;
Perceived Stress Scale – 4	4 items; global measure of perceived stress
Pain Catastrophizing Scale[31]	13 items; 3 subscales characterizing thoughts and feelings when in pain – rumination, magnification, helplessness
Chronic Pain Acceptance Questionnaire[32]	20 items; acceptance of experiencing pain
Freiberg Mindfulness Inventory	14 items; measures all aspects of mindfulness
Intervention Satisfaction	1 likert-type item asking how satisfied are with the intervention oveall
Credibility Questionnaire[34,35] (after session 2)	5 items assessing opinions about the intervention including how logical it seems, confidence, likelihood of recommending it, importance, and success

*Italicized items are PROMIS Measures

Appendix C. Case Report Forms

Phone-Screening

Screen ID	Date	Eligible (Y/N)	Reason Ineligible

Subject Status

Participant ID	Date Enrolled	Group (1,2)	Date Completed Study	Study Status	Reason for Withdrawal	Baseline Assessment (Date) Incentive?	Post-Intervention Assessment (Date) Incentive?	Post-Intervention Phone Interview (Date) Incentive?

Status:
A = Active W = Withdrew
C = Completed L = Lost to follow-up

Session Attendance

Pt. ID	Session 1 (Y/N)	Session 2 (Y/N)	Session 3 (Y/N)	Session 4 (Y/N)	Notes (reasons missed)

Pt. ID	AE Onset	AE End	Severity	SAE? (Y/N)	Relatedness	Action Taken	Outcome	Comments

Adverse Events

Severity of AE:
1 = Mild
2 = Moderate
3 = Severe
4 = Life threatening or disabling

Relatedness to Intervention:
0 = Definitely unrelated
1 = Unlikely
2 = Possibly related
3 = Probably related
4 = Definitely related