Postoperative Telehealth Mindfulness Intervention After Spine Surgery

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Detailed Protocol
Version 7; November 22, 2021

Title: Optimizing a Postoperative Telehealth Mindfulness Intervention to Improve Pain-related Outcomes and Reduce Opioid Use After Spine Surgery

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Design Synopsis

Title: Optimizing a Postoperative Telehealth Mindfulness Intervention to Improve Pain-related Outcomes and Reduce Opioid Use After Spine Surgery

Principal Investigator: Carrie E. Brintz, PhD

Participating Center: Vanderbilt University Medical Center

Sponsors: Osher Center for Integrative Medicine at Vanderbilt (7/1/20 - 6/30/21); NIH - National Center for Complementary and Integrative Health (8/5/21 - 7/31/26)

Type of study: Two-arm intervention development and feasibility pilot trial

Objective: The overall objectives of our preliminary, mixed-methods project are to optimize a mindfulness-based intervention (MBI) for patients recovering from lumbar spine surgery to improve pain-related outcomes and reduce post-surgical opioid use, and to evaluate its feasibility and acceptability. We will pilot an existing, group-based MBI for chronic pain patients[1] that we have formatted for both one-on-one and group telehealth delivery to postsurgical patients, and utilize participant feedback to tailor the intervention to post-surgical orthopaedic patients.

Specific Aim 1: To evaluate the feasibility and acceptability of the telehealth MBI. We will conduct a nonrandomized, sequential pilot test of the individual telehealth MBI (approximately 16 completers) and of the group telehealth MBI (approximately 8 completers) with patients recovering from lumbar spine surgery. We anticipate enrolling up to 34 participants to have 24 complete the study, Feasibility and acceptability of the individual and group intervention will be evaluated as recruitment rates, session attendance, home practice assignment, study retention, and participant satisfaction.

Hypothesis 1: a) Participants will be recruited at a rate of 50%; b) Participants will attend 90% of sessions on average; c) Participants will complete 80% of home practice assigned; d) Study retention will be 90% at post-intervention; e) 80% of participants will report moderate to high satisfaction with the intervention.

Specific Aim 2: To further tailor the telehealth MBI to post-surgical orthopaedic patients. Using structured qualitative interviews and a post-intervention satisfaction survey during the open-label pilot test, we will obtain participant feedback regarding the one-on-one telehealth format, intervention components, and relevance to post-surgical concerns. Qualitative interviews will be coded and analyzed to inform revisions to the intervention.

Expected outcome*:* The intervention will be revised based on participant feedback.

Post-op Telehealth Mindfulness Protocol for Spinal Surgery

Study design: Two-arm, nonrandomized mixed-methods behavioral intervention trial

Study duration: 1 year (1-month start-up; 7 months accrual; 2 additional months for intervention completion and data collection; 2 months for data analysis and intervention adaptation)

Sample size: Up to 34 eligible patients will be consented; Approximately 16 patients will complete the individual intervention; 8 patients will complete the group intervention (consented and completion sample size may vary depending on when data saturation from qualitative interviews is reached).

Number of study sites: 1

Inclusion criteria:
1) English-speaking adults
2) Between the ages of 18 and 90
3) Scheduled for a laminectomy and/or fusion
4) scheduled for their first lumbar spine surgery
5) Radiographic evidence of a degenerative condition including but not limited to *spinal stenosis, spondylosis with or without myelopathy, and spondylolisthesis*
6) Presence of back and/or lower extremity pain persisting for at least 3 months
7) Access to stable internet.
8) Able to participate in weekly, remote sessions with a study therapist for 8 weeks after surgery

Exclusion criteria:
1) Microsurgical technique as the primary procedure (i.e. isolated laminotomy or microdiscetomy)
2) Having surgery for the primary indication of a spinal deformity
3) Having surgery secondary to pseudarthrosis, trauma, infection, or tumor
4) Current/history of a primary psychotic or major thought disorder or hospitalization for reasons related to psychosis
5) Diagnosis of Alzheimer's disease or another form of dementia
6) Traumatic Brain Injury (greater than mild severity)
7) History of bipolar disorder or dissociative disorder
8) Schizophrenia or other psychotic disorder (e.g. brief psychotic disorder, delusional disorder)
9) Active substance use disorder (in past month)
10) Current Posttraumatic Stress Disorder (PTSD) symptoms (in past month)

Outcome measures:

Primary outcomes:
Intervention feasibility and acceptability (enrollment, session attendance, homework completion, intervention retention, intervention satisfaction, semi-structured interview).

Secondary Outcomes:
1) PROMIS-29 – Pain Intensity and Pain Interference

2) Pain Bothersomeness (1 item)
3) Oswestry Disability Index (ODI)
4) Self-reported and EMR-collected opioid dosage
5) PROMIS-29 – Depression scale
6) PROMIS-29 – Anxiety scale
7) Pain Self-efficacy questionnaire (PSEQ)
8) Five-Facet Mindfulness Questionnaire-15 (FFMQ-15)
9) Perceived Stress Scale – 4
10) Pain Catastrophizing Scale
11) Tampa Scale for Kinesiophobia - 13

Statistical analysis: *Primary outcomes*: Descriptive statistics to summarize feasibility and acceptability outcomes with numbers and rates. Qualitative interview analysis of transcribed interviews using line by line analysis and identification of themes and textual examples. Quantitative and qualitative data results will be merged to identify aspects of the telehealth MBI that need to be adapted to optimize acceptability for post-surgical patients. *Secondary outcomes:* Within-group, within-subject changes from baseline to the follow-up post-intervention assessment in pain-related outcomes, opioid use, and psychosocial characteristics will be explored by examining change in scores and their respective standard errors with 95% confidence intervals

Safety monitoring: The PI and research coordinator will monitor the accumulated data as the trial progresses to ensure patient safety, evaluate recruitment, and assess overall data quality.

1. Primary Hypothesis and Principal Objective

Lumbar spine pain is the leading cause of years lived with a disability[2] and affects over 50 million individuals in the United States.[3] As the population over age 60 grows, rates of spine surgeries performed to address degenerative spine conditions have increased markedly.[4] Yet, more than 40% of patients experience poor pain, functional, or quality of life outcomes after surgery.[5–7] Moreover, despite the limited efficacy and high risks associated with long-term prescription opioid use[8,9], up to 50% of patients are prescribed opioids 12 months following lumbar spine surgery.[5,10] Pre- and post-surgical psychosocial factors are robust determinants of long-term post-surgical outcomes[7,11–13] and continued opioid use.[14]

Psychosocially informed interventions are recommended after spine surgery but not standard practice.[15] Patients recovering from spine surgery identify a need for nonpharmacological strategies to decrease pain and emotional distress.[16] Mindfulness-based interventions (MBIs) demonstrate efficacy for improving chronic pain outcomes[17–20], reducing opioid use or desire[17,18,21], and favorably impacting pain sensitivity and psychosocial risk factors for persistent pain and disability.[22–28] To date, **no studies have** tested the usefulness of an MBI in patients following spine surgery to manage post-surgical pain and reduce long-term opioid use. The group-based, in-person delivery format renders the typical MBI highly impractical for post-surgical patients who live several hours away from the surgical centers of excellence. Prior work indicates that telehealth MBIs (via live, online video) are feasible in chronic pain populations[29] and are a promising alternative.

The overall objectives of our preliminary, mixed-methods project are to tailor an MBI for patients recovering from spine surgery and to evaluate its feasibility and acceptability. We will pilot an existing, group-based MBI for chronic pain patients[1] that the principal investigator (PI) modified for both one-on-one and group telehealth delivery for postsurgical patients, and utilize participant feedback to tailor the intervention to post-surgical orthopaedic patients. The purpose of the intervention is to improve pain-related outcomes and reduce post-surgical opioid use, so outcome measures will be collected to evaluate feasibility of data-collection procedures and pre-post changes.

2. Background and Significance

Lumbar spine surgery outcomes are poor for up to 40% of patients. Spine pain affects millions of individuals in the United States and results in poor quality of life, reduced mental and physical functioning, and billions of dollars in healthcare costs and lost productivity.[30] Complete resolution of chronic spine pain is uncommon. Lumbar spine surgery is the most common elected surgery to treat degenerative spinal conditions when conservative treatments are unsuccessful.[31] As the population of older adults grows, rates of lumbar spine surgery have increased markedly.[4,32] However, up to 40% of patients experience continued or worsening pain and disability following surgery. Studies find that patients' expectations for improvement after surgery exceed their experienced reductions in back pain and leg pain, and improvements in functioning.[16,33,34] A substantial number of patients who experience a significant reduction in pain intensity after spine surgery nonetheless report continued pain interference and disability[7], suggesting that multiple factors and not merely a reduction in pain intensity, contribute to improved functional outcomes.

Prolonged prescription opioid use is common following spine surgery. Studies indicate that 59%[14] to 65%[10] of patients taking opioids pre-operatively continue to receive opioids 12 months following spine surgery. Furthermore, as many as 26% of patients who were opioid-free prior to spine surgery do not achieve opioid independence 12 months after surgery.[14,35] These findings are concerning, given the numerous risks of prolonged opioid use, including tolerance, opioid-induced hyperalgesia (paradoxically increased pain sensitivity), misuse, abuse, and overdose[8,9,36–38], all of which can complicate post-surgical recovery. Effective strategies are needed to help patients reduce unnecessary or prolonged opioid use following surgery.

Psychosocial factors are key predictors of post-surgical outcomes and opioid use. It is widely recognized that pain is experienced through a complex interaction of physical/neural, cognitive, affective, behavioral, and social factors.[39] Studies consistently indicate that both pre and post-surgical psychosocial factors are robust predictors of surgical outcomes. Pre- and early post-surgical psychological distress, particularly depression and anxiety, significantly predict worse pain intensity and disability, physical functioning, and quality of life, as well as prolonged opioid use at 6 to 12 months following lumbar spine surgery.[12–14,40–44] Individual coping style and cognitive factors, such as passive avoidant coping, high fear avoidance beliefs, and pain catastrophizing are associated with worse spine surgery outcomes.[7,13,43,45,46] Conversely, higher levels of self-efficacy and positive affect are protective and associated with more favorable outcomes after orthopaedic surgery.[12,47,48]

Psychosocially informed interventions are recommended after surgery[15], but are not standard practice, despite promising research.[49–51] Patients indicate a need for nonpharmacologic strategies to cope with post-surgical pain and emotional distress and as alternatives to taking pain medication.[16,33] Randomized controlled trials demonstrate that biopsychosocial rehabilitation programs targeting cognitive and behavioral factors after lumbar spine surgery result in improved pain, mental and physical functioning, pain self-efficacy, fear of movement, and pain coping compared with exercise or education alone.[49,51,52] The majority of trials draw from traditional cognitive behavioral therapy for chronic pain. Although effective at improving pain-related outcomes, not all patients achieve benefit from cognitive behavioral therapy. Alternative biopsychosocial approaches to postoperative rehabilitation and pain management are needed in order to provide more widely effective and personalized treatment. The

proposed research will address this gap by establishing the feasibility and acceptability of an optimized mindfulness-based intervention (MBI), delivered using a telehealth approach (to maximize accessibility), for improving pain-related outcomes and opioid use.

MBIs have a well-established evidence base as efficacious interventions for reducing chronic pain symptoms. Well-controlled studies indicate that MBIs are efficacious for improving physical functioning and pain interference, and reducing commonly co-occurring symptoms such as depression and anxiety in chronic pain populations.[19,20,53] Furthermore, in RCTs targeting individuals taking opioid medications for chronic pain, MBIs were effective at reducing opioid misuse, craving, and/or opioid use.[18] MBIs are now recommended as first-line nonpharmacological treatment for chronic low back pain.[54] The most extensively studied MBIs (e.g. mindfulness-based stress reduction and mindfulness-based cognitive therapy), demonstrate similar efficacy as traditional cognitive behavioral therapy for chronic low back pain[19,22,53]. However, pilot research with chronic low back pain patients suggests that different patient characteristics predict better response to one type of treatment over another[55], lending support for research and dissemination of multiple psychosocial treatment options to which patients can be individually matched.

Central to MBIs is systematic and intensive training in mindfulness meditation practices.[56] Mindfulness skills involve the self-regulation of attention to present-moment experience and the development of non-judgmental awareness of moment-by-moment experience, including thoughts, emotions, or sensations that arise, even if unpleasant or unwanted.[57,58] Mindfulness meditation engages emotional, cognitive, and sensory networks in the brain that regulate pain[59], with meditators showing heightened sensory processing coupled with attenuated cognitive and emotional evaluation of pain sensations.[60] Patients with chronic low back pain who participated in an MBI reported reduced pain catastrophizing and increased pain acceptance and self-efficacy to manage pain.[22] Studies in low back pain patients and healthy participants demonstrated that after mindfulness training, participants experienced lowered pain sensitivity to thermal or electrical stimuli.[25,26] There are no prior studies that have tested an MBI early following spine surgery as a means to prevent or mitigate poor post-surgical outcomes.

Barriers to accessing MBIs impact successful implementation after spine surgery. The standard MBIs are typically located at major medical centers and offered as in-person, group-based interventions with 8 weekly sessions lasting 2 to 2 ½ hours each. This format is highly impractical for post-surgical spine patients, many of whom live hours away from surgical centers. Furthermore, group-based MBIs are frequently offered only a few times per year, and thus may not be available to patients early after surgery, a time when patients have indicated a need for additional nonpharmacological intervention to help optimize recovery. Telehealth is increasingly used in healthcare systems to reach patients across long distances who would not otherwise access healthcare services or research opportunities, and thus is a promising platform for reaching post-surgical patients.[61,62] The proposed study will leverage existing telehealth technology[62] to study a telehealth MBI (delivered live via online video platform) in both one-on-one and group formats and tailored specifically to address the needs of patients following spine surgery. The result will be a clinically significant advance in the care of the large population of patients undergoing spine surgery each year.

INNOVATION

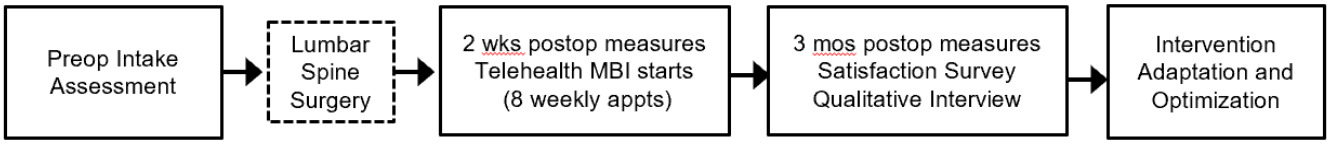
The proposed study is innovative in its tailoring of an existing MBI specifically for use in the orthopaedic surgery population. MBIs have been used for the management of chronic pain[1], but

patients may experience distinct concerns after orthopaedic surgery. For example, severe, acute post-operative pain due to surgical tissue damage can occur concurrently with residual chronic pain, and at times lead to new chronic pain. [63,64] Patients report experiencing post-operative distress, fear and avoidance of movement, and unmet expectations.[13,16,33,34,64] In addition, patients may desire to taper off of pain medications as quickly as possible after surgery.[33] Data from this study will help optimize an MBI for patients undergoing spine surgery, with application to other orthopaedic surgery populations. **The proposed study is also innovative in its use of telehealth technology,** which enables broad reach of the intervention to patients regardless of distance or transportation access and costs. Additional flexibility and opportunity to individually tailor the intervention is offered by the one-on-one, rather than group-based format. Telehealth delivery allows for the integration of a biopsychosocial approach into routine post-surgical spine care, as is recommended, without introducing substantial burden on patients. Other preliminary work by the principal investigator suggests that providing an MBI over telehealth is feasible in a chronic pain population[29], but has yet to be investigated in post-surgical spine patients. **Finally, the project is innovative in its integrated use of both quantitative and qualitative methods to produce an optimized MBI that is both feasible and acceptable in this population.**

3. Study Design

3.1. Design Overview. The study will use a two-arm, nonrandomized mixed-methods design to: 1) evaluate the feasibility and acceptability of a one-on-one telehealth MBI delivered via live, online video in approximately 24 patients following elective lumbar spine surgery for degenerative spine conditions, and 2) adapt the telehealth MBI to the specific concerns of post-surgical patients using both qualitative and quantitative data from post-intervention surveys and semi-structured interviews. Participants will be enrolled in either the individual intervention or the group intervention, and enrollment for each intervention will occur sequentially. Patient-reported outcomes (pain-related and psychosocial variables) and self-reported and electronically verified opioid use will be collected at pre-surgery, 2-weeks post-surgery (pre-intervention), and 3 months post-surgery (post-intervention). Semi-structured interviews will be conducted at post-intervention

Figure 1. Study Design



3.2 Telehealth Mindfulness Intervention. The telehealth MBI consists of 8, weekly sessions with a study interventionist. The one-on-one intervention sessions will each be 75 minutes long, with the exception of the first session, which will be 90 minutes long. The group interventions sessions will each be 90 minutes long. Participants will be asked to complete the 8 sessions within 10 weeks to allow for missed weeks. All sessions will be conducted using an IRB-approved HIPAA compliant telehealth platform in which the intervention is delivered via secure internet video link and audio-recorded for fidelity monitoring. The intervention is based on an existing manualized MBI (mindfulness-based cognitive therapy for chronic pain).[1] Mindfulness-based cognitive therapy was originally developed for preventing relapse of depression[65] and has since been adapted and tested in chronic pain populations, including chronic low back pain and headache pain.[24,53] The intervention, typically delivered in-person in a group setting, will be formatted for both one-on-one and group telehealth delivery, with subsequent data-driven adaptation planned. Participants who do not have their own device with microphone and video camera (e.g. computer, tablet, or smart phone) will be given a tablet to use during the study.

At the core of the telehealth MBI is systematic instruction and practice in mindfulness meditation, which trains the self-regulation of attention to present moment experience and fosters a nonjudgmental and accepting response to one's experience, including pain sensations.[53] Participants learn meditation practices that can be completed sitting or lying down as well as gentle mindful movement practices that can be completed while walking, standing, or sitting. Education on the brain-pain relationship (gate-control and neuromatrix theory) is also provided and mindfulness skills are discussed within the context of pain management. Because of the importance of cognition and emotion in pain processing, the intervention incorporates elements of cognitive therapy including exercises in recognizing the connection between thoughts, emotions, behaviors, and stress as they relate to chronic pain. Participants learn to become aware of the mental events and behavioral responses that amplify pain

interference and distress, and to process and respond to unpleasant sensations and emotions more skillfully. Each session focuses on didactic information (introduced interactively), practicing a new mindfulness skill with discussion, reviewing previous skills, and assigning home practices. Participants will be requested to keep track of their practicing by completing a Home Record Practice. The participants will be giving a paper copy and then asked to complete in a Survey electronically each week.

Interventionist Training and Fidelity Monitoring. The PI will oversee intervention training and delivery with Dr. Foote-Pearce (co-investigator). Our study interventionist will be a doctoral trained clinical psychologist who has completed prior training in mindfulness skills facilitation and cognitive therapy through graduate-level work and/or formal training workshop(s). The PI will provide structured training in the study intervention manual with a 1-day workshop covering intervention content. This workshop will cover each session module, with role-playing interactions. There will be weekly supervision of the study interventionist by the PI, through the review and discussion of audio-recorded sessions and fidelity checklists. All sessions of the first 2 patients will be monitored and reviewed and then 25% of the sessions will be randomly selected for review during weekly sessions. The interventionist will complete a checklist of all the components delivered during each session and make note of any protocol deviations.

Potential adverse effects: Based on results of previous literature, we expect there to be no more than minimal risk in this study; however, literature on mindfulness-based interventions have not systematically included adverse event reporting, although most studies have not reported any serious risk from participating. 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.[66] There is the potential for increased negative emotions at the beginning of the course, as well as the possibility that history of trauma, abuse, or substance addiction could heighten negative emotional reactions. With a trained interventionist, reactions can be managed and appropriate referrals made.[66] There also the possibility of emotional distress related to completing questionnaires about mood and pain-beliefs.

4. Patient Selection.

4.1. Overview and Clinical Centers. Approximately 34 patients scheduled to undergo lumbar spine surgery will be recruited from Vanderbilt University Medical Center. The Vanderbilt Comprehensive Spine center treats large numbers of lumbar degenerative conditions and has a proven track record for prospective study of patients having lumbar spine surgery. Eligible patients will be identified and recruited at the participating clinical center subject to the inclusion and exclusion criteria listed below.

Inclusion criteria:
1) English-speaking adults
2) Between the ages of 18 and 90
3) Scheduled for a laminectomy and/or fusion
4) scheduled for their first lumbar spine surgery

5) Radiographic evidence of a degenerative condition including but not limited to *spinal stenosis, spondylosis with or without myelopathy, and spondylolisthesis*
6) Presence of back and/or lower extremity pain persisting for at least 3 months
7) Access to stable internet.
8) Able to participate in weekly, remote sessions with a study therapist for 8 weeks after surgery

Exclusion criteria:
1) Microsurgical technique as the primary procedure (i.e. isolated laminotomy or microdiscetomy)
2) Having surgery for the primary indication of a spinal deformity
3) Having surgery secondary to pseudarthrosis, trauma, infection, or tumor
4) Current/history of a primary psychotic or major thought disorder or hospitalization for reasons related to psychosis
5) Diagnosis of Alzheimer's disease or another form of dementia
6) Traumatic Brain Injury (greater than mild severity)
7) History of bipolar disorder or dissociative disorder
8) Schizophrenia or other psychotic disorder (e.g. brief psychotic disorder, delusional disorder)
9) Active substance use disorder (in past month)
10) Current Posttraumatic Stress Disorder (PTSD) symptoms (in past month)

5. Trial Protocol

5.1. Overview. The patient-related activities of the postoperative telehealth mindfulness trial can be divided into the following phases.

Phase 1: Consent into study and screening for eligibility
Phase 2: Enrollment into trial prior to surgery, preoperative data collection
Phase 3: Postoperative Baseline data collection (2 weeks after surgery)
Phase 4: Intervention (8 weeks)
Phase 5: Post-intervention data collection and semi-structured interviews (3 months after surgery)

5.2. Phase 1: Consent into Study and Screening for Eligibility. Patients will be approached for their consent to participate in the study following their preoperative clinic visit either at the clinic as available or over the phone, with the permission of the treating surgeon. If over the phone, participants will sign an e-consent form through a REDCap survey link. The study coordinator will perform the consent process using a scripted dialogue and materials developed for the study.

Patients will then be screened for eligibility in the surgical center or over the phone by the research coordinator. Screening through the medical record will occur prior to surgery and a scheduled preoperative clinic visit. Additional screening will occur either immediately after the preoperative clinic visit at the Spine Center or after the visit over the phone by the study coordinator through a list of screening questions. All potentially eligible patients will be entered into REDCap, a study number assigned, and eligibility criteria confirmed.

5.3. Phase 2: Enrollment and Preoperative Data Collection. Once consented into the study and determined to be eligible, patients will complete a preoperative questionnaire using a REDCap survey either at the clinic after the visit, online after the visit, or over the phone after the visit if preferred. This self-report assessment will gather data on patient demographic and injury characteristics, medical and social history, pain self-efficacy, negative affect, dispositional mindfulness, concerns about pain, current opioid use and preoperative levels of pain and disability. Opioid prescription and dosages will also be extracted from the electronic medical record.

5.4. Phase 3: Baseline Data Collection (2 weeks after surgery). Study participants who complete surgery will be emailed or texted (based on participant preference) a REDCap survey to collect baseline data at two-weeks after surgery. They can also complete the survey at the postoperative clinic visit or over the phone. Similar to the pre-operative questionnaire, this self-report assessment will gather data on pain self-efficacy, negative affect, dispositional mindfulness, concerns about pain, current opioid use and levels of pain and disability. Opioid prescription and dosages will also be extracted from the electronic medical record.

At this time, participants will also meet with the research coordinator, either at their post-operative clinic visit or by phone, to become oriented to the telehealth platform that will be used during intervention sessions. If the participant does not have their own device for use during the intervention, they will be provided with a tablet by the research coordinator.

5.5 Phase 4: Treatment. Once the patient has been consented, undergone surgery for a lumbar degenerative condition, and completed the baseline assessment, the participant will begin the telehealth mindfulness intervention. The interventionist will call the participant to schedule the first treatment session. For participants enrolled in a group, the coordinator will gather participants' availability and schedule the group sessions at a time when the interventionist and as many participants as possible are available. Patients will complete 8, weekly sessions over telehealth (audio and video), and will have 10 weeks to complete the intervention to allow for 1 to 2 possible missed weeks. Participants will be asked to complete a paper form asking about their daily practice of what they have learned and then enter that information weekly into the Home Practice Record Survey electronically.

5.6. Phase 5: Post-Treatment Data Collection (3-months after surgery). After completing the intervention (3 months after surgery), participants will be emailed or texted a REDCap survey. They can also complete the survey at the postoperative clinic visit or over the phone. Similar to the pre-operative and post-operative baseline questionnaire, this self-report assessment will gather data on pain self-efficacy, negative affect, dispositional mindfulness, pain sensitivity, current opioid use and levels of pain and disability. It will also gather data on participant satisfaction with the telehealth mindfulness intervention. Opioid prescription and dosages will also be extracted from the electronic medical record.

The research coordinator will assist patients with scheduling a post-treatment qualitative phone interview, which will be conducted by a study investigator with qualitative research experience. Each phone interview will last approximately 30 minutes and be audio-recorded. The semi-structured interview guide consists of open-ended questions and probes focusing on obtaining participant

experiences and perceptions of the telehealth delivery format, intervention components (mindfulness skills, didactics, home practice), perceived benefits, relevance to post-surgical concerns, concerns not addressed by the intervention, barriers to participation, and suggestions to improve the intervention. The interview guide is designed to revised as needed throughout the study (e.g. changes in wording of questions and probes to be more clear; addition of questions that seem pertinent based on prior participants' responses to interview questions).

5.7. Primary and Secondary Outcomes

Primary outcomes:
Intervention feasibility and acceptability (enrollment, session attendance, homework completion, intervention retention, intervention satisfaction, semi-structured interview).

Secondary Outcomes:
1) PROMIS-29 – Pain Intensity and Pain Interference
2) Pain Bothersomeness (1 item)
3) Oswestry Disability Index (ODI)
4) Self-reported and EMR-collected opioid dosage
5) PROMIS-29 – Depression scale
6) PROMIS-29 – Anxiety scale
7) Pain Self-efficacy questionnaire (PSEQ)
8) Five-Facet Mindfulness Questionnaire-15 (FFMQ-15)
9) Perceived Stress Scale – 4
10) Pain Catastrophizing Scale (PCS)
11) Tampa Scale for Kinesiophobia - 13

5.8 Safety Issues.

5.8.1. Safety Concerns Related to the Therapeutic Treatment. We anticipate based on previous research of mindfulness training interventions that the study will pose minimal safety risk; most studies have not reported any serious risk from participating in structured MBIs. 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.[66] With a trained instructor, reactions can be managed. It is possible that history of trauma or substance addiction could heighten negative emotional reactions. Participants with unstable psychiatric illness or substance addiction will be excluded from participation.[66] There may also be distress related to answering questionnaires about mood and pain beliefs.

5.8.2. Safety Issues Related to Patient Privacy. Patients will only be identified by an identification code and not by their name, SSN, or hospital medical record number. Study personnel will maintain a separate confidential enrollment log which matches identifying codes with the patients' names and addresses (available only to study personnel). Enrollment logs will be kept in a secured, password-protected file on a VUMC-approved server. All study material will be maintained in strict confidence.

For participants enrolled in the group intervention, there is a risk to loss of confidentiality by nature of being in a group with other patients. All participants will be asked to agree to keep other participants' information confidential within the group setting.

5.9 Retention. The study participants will receive an honorarium in recognition of their time and effort. Participants will be compensated $20 each for completing the preop intake assessment survey, the 2-week postop baseline assessment survey, and the 3-month postop assessment and intervention assessment survey (up to $60) and $25 for completing the semi-structured phone interview, for a possible total of $85 per participant. Participants will not be compensated for completing the weekly Home Practice Record Survey. We will keep participants engaged through reminder emails and phone calls for intervention sessions and assessments.

5.10. Management of Concomitant Conditions. Concomitant conditions will be managed with the standards of care at the local treatment facility and should not be affected by study participation.

5.11. Adverse Event Reporting. We will monitor and report adverse events to ensure patient safety.

5.11.1. Definitions. We will use the following definitions in identifying adverse events.

- **Adverse event**. An adverse event is any untoward medical occurrence that may present itself during treatment or administration with clinical procedure and which may or may not have a causal relationship with the treatment. Adverse events include any unanticipated problems involving risks to participants, or breaches of protocol which might entail risk to participants. The term "unanticipated problem" includes both new risks and increased rates of anticipated problems.

- **Serious adverse event**. A serious adverse event (SAE) is an adverse event occurring at any time during the study that results in death, inpatient hospitalization or prolongation of existing hospitalization, or a persistent or significant disability/incapacity. Other events may also be considered an SAE if, based on medical judgment, the event jeopardized the patient to the point of requiring medical or surgical intervention to prevent the occurrence of any of the conditions for an SAE listed above.

- **Unexpected adverse event**. An unexpected adverse event is any adverse event with specificity or severity that is not consistent with the risk information in the study protocol.

- **Associated with the use of the treatment** means that there is a reasonable possibility that the adverse experience may have been caused by the treatment.

5.11.2. Monitoring and Reporting Adverse Events. Adverse events will be recorded on study data forms whether or not they are thought to be associated with the study or with one of the study treatments. Adverse events may be discovered during regularly scheduled visits or through unscheduled patient contacts between visits. IRB requirements for reporting adverse events will be followed. Where applicable, signs and symptoms associated with the adverse event will be graded as to severity by the clinical study staff as mild, moderate, or severe using the Common Terminology Criteria for Adverse Events.

5.11.3. Reporting Serious Adverse Events. Serious adverse events (SAE) must be reported upon discovery. This will involve completing an SAE case report form describing the severity and details of the event. IRB requirements for reporting SAEs will be followed.

6. Statistical Analyses.

6.1. Statistical Analysis Plan. Descriptive statistics will be used to summarize quantitative feasibility outcomes with numbers and rates. Benchmarks for success of the telehealth MBI will be: 1) enrollment rate of at least 50% of eligible patients; 2) 90% of sessions attended on average; 3) 80% of home practice completed on average; 4) intervention retention of at least 90%; 5) moderate to high intervention satisfaction rated by at least 80% of participants.

Transcription of interview data will be verified prior to analysis. The PI and study personnel will conduct line by line analysis using Dedoose analytic software. Themes and textual examples will be independently identified and subsequently discussed for consensus. Analysis will be an ongoing, iterative process following each 2 to 4 interviews to ensure that data saturation ultimately occurs before discontinuing interviews A codebook will be generated by isolating individual quotes and refined as additional interviews are coded. Thematic analysis of codes will be used to identify emergent themes, or patterns of meaning, found in the data[67] with regards to participant experiences with the telehealth MBI and specific post-surgical concerns. Quantitative and qualitative data results will be merged to identify aspects of the telehealth MBI that need to be adapted to optimize acceptability for post-surgical patients.

Within-group, within-subject changes from baseline to the follow-up post-intervention assessment in pain-related outcomes, opioid use, and psychosocial characteristics will be explored by examining change in scores and their respective standard errors with 95% confidence intervals.

7. Human Subjects Issues

7.1. Sources of Materials. All materials will be collected and recorded for research purposes. The socio-demographic, clinical, and outcomes information collected during this investigation will be obtained from multiple sources, including subjects directly, medical records, and hospital databases. These data will be entered directly into REDCap (a secure, web-based application. All data will be secured by password-only access for the purpose of confidentiality. The surgery and clinic notes will also be used to collect data. Outcomes data will be derived from questionnaires completed both in the clinic and online remotely, and through interactions between the patient and research personnel during semi-structured phone interviews.

7.2. Potential Risks. The risk to human subjects of participation in this study is minimal due to the nature of this behavioral treatment. The possibility exists that a participant may experience a degree of emotional discomfort related to intervention activities resulting in increased awareness of unpleasant experiences, or emotional distress due to completing questionnaires about mood and pain-beliefs. Research personnel and study interventionists will have referral sources available for individuals who request or are in need of further counseling or support. Study interventionists will be post-doctoral level psychologists with training in responding to potential increase in distress during the study, as well as

responding to reports of severe depression, suicidal ideation, or other medical/psychological problem requiring additional attention. If this should occur, the PI and referring surgeon will be notified and appropriate referrals arranged. There is a small risk of breach of confidentiality, but the data for this study will be secured in a password protected database. Access to this database will be limited to the investigators and study staff. Data will be deidentified for data analysis and interpretation.

7.3. Recruitment and Informed Consent. Prototype consent will be prepared for the trial. Before approaching patients for enrollment prior to surgery, discussions will be conducted with patients' surgeons to obtain permission. The surgeon and clinical staff will be fully informed of the nature of the study and any risks and benefits. The research coordinator will approach the patient after the preoperative clinic visit or a preoperative education class. The coordinator will meet with the patient, as well as family members if requested by patient, and will describe the proposed study protocol using a scripted dialogue and materials developed for the study. It will be emphasized to all study participants and family members that the data collected will be for research purposes and that refusal to participate in the investigation will have no effect on the patient's routine treatment. The person obtaining consent will inform the patient that there is no obligation to participate in the study, and will provide his/her name and phone number where he/she can be reached if they have further questions or wish to withdraw from the study at any time. The person obtaining the consent will also provide the patient with a copy of the consent forms and provide ample time for the patient and family to have questions answered prior to enrollment. Copies of the signed consent forms will be given to the patient, and this fact will be documented in the patient's record.

7.4. Protections Against Risk. Under the auspices of the Vanderbilt Institutional Review Board, all participants will be protected by the project's staff strict adherence to study protocols governing participant safety, data privacy, informed consent, withdrawal from the study without prejudice, and immediate reporting directly to the PI and the IRB of any adverse events involving the participants. Data obtained with subject identifiers will be kept in password protected electronic files on a VUMC server. All subjects will be assigned a unique study number for use in the REDcap database and all electronic data will be kept in password-protected files to ensure confidentiality. Participants will continue to have access to their usual sources of medical care throughout the study. These measures will provide a very high level of protection against risk to the participants.

7.5. Potential Benefits of the Proposed Research to Human Subjects and Others. All participants will gain additional assistance through the one-on-one or group telehealth mindfulness intervention in managing their pain and disability and we anticipate that patients in the study will report improvements in pain interference, function, and psychological well-being. There may also be a potential benefit derived from being enrolled in an investigation and having additional patient assessments. Such additional assessments may detect unrecognized clinical and health issues, which could be of benefit to patients' outcomes. Finally, participants may derive a great deal of personal comfort in knowing that their psychological distress are part of the surgical recovery process. Thus, a potential benefit may be a reduction in stress and anxiety over recovery. The potential for direct patient benefit outweighs any minimal risk of harm to the participants.

7.6. Importance of the Knowledge to be Gained. The proposed study is intended to provide new knowledge about the feasibility, acceptability, potential effects, and optimal approach to providing a behavioral intervention to a post-surgical population. Such knowledge is important because the

population of surgical spine patients is growing rapidly, the current treatment regimen appears insufficient based on outcome variability, and there are few other promising therapeutics alternatives for dealing with postoperative recovery.

7.7. Patient Confidentiality. All study forms, reports, and other records that are part of the study data collection materials will be identified by coded number to maintain patient confidentiality. All electronic records of study data will be identified by coded number. Clinical information will not be released without written permission of the patient, except as necessary for monitoring by the IRB. Consent procedures and forms, and the communication, transmission and storage of patient data will comply with IRB requirements for compliance with The Health Insurance Portability and Accountability Act (HIPPA).

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