Preoperative Mindfulness Meditation for Total Knee Arthroplasty: A Pilot Study

FUNDER: Anesthesiology Research Department

PROTOCOL NO.: 2023-2131

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PROTOCOL SYNOPSIS

Protocol Title:	Preoperative Mindfulness Meditation for Total Knee Arthroplasty: A Pilot Study
Protocol Number:	2023-2131
Protocol Date:	
Sponsor:	Anesthesiology Research Department
Principal Investigator:	Christopher Li, MD
Products:	N/A
Objective:	This study will investigate the effect of a preoperative mindfulness meditation intervention (MMI) on outcomes for total knee arthroplasty (TKA) patients at the Hospital for Special Surgery in a randomized controlled trial.
Study Design:	Randomized Clinical Trial
Enrollment:	30
Subject Criteria:	Inclusion: • Adult patients undergoing primary total knee arthroplasty with a participating surgeon • Patients on these medications for depression/anxiety; Fluoxetine, Paroxetine, Citalopram, Escitalopram, Escitalopram, Sertraline, Fluvoxamine, Venlafaxine, Duloxetine, Levomilnacipran, Desvenlafaxine, Bupropion, Mirtazapine, Amitriptyline, Nortriptyline, Clonazepam, Alprazolam, Lorazepam, Diazepam, Oxazepam, Chlordiazepoxide • Patients receiving intraoperative auricular acupuncture as part of participating surgeon's preferred anesthetic care • Patients fluent in English • ASA I-II • BMI < 40
	Exclusion: • Patient not fluent in English (inability to understand the intervention video will likely affect ability to utilize the mindfulness techniques taught) • Pediatric patients < 18 years of age • Patients with contraindications to intra-op protocol

	• Patients with contraindications to auricular acupuncture (non-native ear, active ear infection, gauges in the ears) • Patients unable/unwilling to participate in the questionnaires or listen to the scripted intervention • Patients scheduled for consecutive or staged surgeries • Patients allergic to local anesthetics or study medications • Patients who have kidney disease
Study Duration:	• 6 months
Data Collection:	**Sources:** EPIC, Medical Records, and Patient Reported **Variables:** Name, MRN, Date of birth, Email, Race, Gender, Ethnicity, Height, Weight, Body mass index, Co-morbidities, Medications to manage pre-existing conditions, Surgery details, Anesthesia details, DVT prophylaxis medications ordered and/or administered, PHQ-9, GAD-7, PROMIS Global health v1.2, Brief resilience scale, NRS pain scale, Pain unpleasantness scale, KOOS-Jr, Pain catastrophizing scale, MMI Practice survey, Patient satisfaction survey, Exit survey
Statistical Analysis:	Proposed analysis: t-test as there are two groups Interim analysis planned? No Alpha level: 0.05 Beta or power level: N/A Pilot study Number of groups being compared: 2 Resulting number per group: 12 Total sample size: 30 (20% standard anticipated drop out rate)

1.0 INTRODUCTION

Total joint arthroplasty is a commonly successful, elective procedure that, with an aging population that is experiencing a higher incidence of obesity, is significantly increasing in implementation. While patients are usually satisfied post-operatively some are afflicted with anxiety, depression, and/or pain catastrophizing. This mental status is often correlated with worse postoperative functional outcomes, patient satisfaction, and greater postoperative pain experience. Novel interventions are needed to address this mental status optimization issue for these patients with the goal of improving patient satisfaction, perception of pain, and symptoms of anxiety/depression for TKA.

2.0 OBJECTIVE OF CLINICAL STUDY

This study will investigate the effect of a preoperative mindfulness meditation intervention (MMI) on outcomes for total knee arthroplasty (TKA) patients at the Hospital for Special Surgery in a randomized controlled trial. Mindfulness meditation is a practice well-known to psychology research based on sustained attention on the present and a non-judgment of one's current situation. It has been used for numerous psychological issues including stress, anxiety, and depression. This intervention group will be compared against a waitlist control group (patients will be told they are on a waitlist to receive the mindfulness intervention, which will occur after data collection has finished for their group). This control has been utilized in several mindfulness meditation studies.

3.0 STUDY HYPOTHESES

Hypothesis 1: We hypothesize that this MMI will be feasible here at HSS and that we will successfully recruit, enroll, and analyze the data from this pilot study.

Hypothesis 2: We hypothesize that this pilot study will provide an estimate of both the control and intervention group’s central tendency and variability.

Hypothesis 3: We hypothesize that in a study with sufficient power, the MMI will have a positive effect on mental and physical health as well as patient satisfaction scores. We hypothesize that in this study, the MMI will increase resilience scores within the intervention group.

4.0 STUDY DESIGN

4.1 Study Duration

6 months

4.2 Endpoints

4.2.1 Primary Endpoint

- Feasibility: The MMI practice survey and the exit survey (ease, helpfulness of MMI) helps to assess enrollment, retention, intervention completion and use measured by time to full enrollment, dropout number/proportion, number of MMI views/uses. The MMI practice survey is asked to the intervention group in pre-operative holding, post-operative day 14 and post-operative day 90. The exit survey is given to the intervention group on post operative day 14 and given 2 weeks after post-operative day 90.
- Mental health: Anxiety and depression severity, overall mental health scores, resilience. PROMIS Mental Health Questionnaire is to assess general mental health in patients 1 week prior to surgery, post operative day 14, and post operative day 90. Generalized Anxiety Disorder Assessment (GAD-7) to assess severe anxiety in patients 1 week prior to surgery, post operative day 14, and post operative day 90. The Patient Health Questionnaire (PHQ-) is to assess depression in patients 1 week prior to surgery, post operative day 14, and post operative day 90.
- Physical health: Function and overall physical health. PROMIS Physical Health Questionnaire is used to assess general physical health in patients 1 week prior to surgery, post operative day 14, and post operative day 90. The KOOS-JR questionnaire will assess knee health after a total knee replacement surgery 1 week prior to surgery, and preoperative holding.

4.2.2 Secondary Endpoints

- Pain outcomes: Pain severity. The Pain Unpleasantness scale which describes pain via a verbal descriptor at 1 week prior to surgery, day of surgery, post-acute care unit (PACU), post operative day 14, and post operative day 90. The pain catastrophizing scale assess pain experience and ability to cope with pain 1 week prior to surgery. The NRS assesses pain levels on a scale from 0-10 in the operative knee 1 week prior to surgery, day of surgery, post-acute care unit (PACU), post operative day 14, and post operative day 90.
- Resilience training: The Brief Resilience Scale is used to assess the ability to recover from stress 1 Week prior to surgery, post operative day 14, and post operative day 90
- Patient satisfaction: The patient satisfaction survey will assess patient satisfaction with results of the total knee replacement surgery taken on post operative day 14.

4.3 Study Sites

Hospital for Special Surgery – Main Campus

5.0 STUDY POPULATION

5.1 Number of Subjects

A total of 30 subjects will be enrolled

5.2 Inclusion Criteria

Subjects of either gender will be included if they:

- Adult patients undergoing primary total knee arthroplasty with a participating surgeon
- Patients on these medications for depression/anxiety; Fluoxetine, Paroxetine, Citalopram, Escitalopram, Escitalopram, Sertraline, Fluvoxamine, Venlafaxine, Duloxetine, Levomilnacipran, Desvenlafaxine, Bupropion, Mirtazapine, Amitriptyline, Nortriptyline, Clonazepam, Alprazolam, Lorazepam, Diazepam, Oxazepam, Chlordiazepoxide
- Patients receiving intraoperative auricular acupuncture as part of participating surgeon's preferred anesthetic care
- Patients fluent in English
- ASA I-II
- BMI < 40

5.3 Exclusion Criteria

Subjects will be excluded from the study if they:

- Patient not fluent in English (inability to understand the intervention video will likely affect ability to utilize the mindfulness techniques taught)
- Pediatric patients < 18 years of age
- Patients with contraindications to intra-op protocol
- Patients with contraindications to auricular acupuncture (non-native ear, active ear infection, gauges in the ears)
- Patients unable/unwilling to participate in the questionnaires or listen to scripted intervention.
- Patients scheduled for consecutive or staged surgeries.
- Patients allergic to local anesthetics or study medications
- Patients who have kidney disease

5.4 Randomization

A computer-generated, 1:1 ratio randomization schedule with blocks of sizes 4 and 6 will be created by a statistician not otherwise involved in the study.
Participants will be randomized to 1 of 2 groups:

- Group 1 will receive the Mindfulness Meditation Intervention prior to their day of surgery.
- Group 2 will receive the Mindfulness Meditation Intervention 90 days after their day of surgery

6.0 PROCEDURES

6.1 Surgical Procedure

Total knee arthroplasty

6.2 Medical Record Requirements

Epic

6.3 Data Collection

The following data will be collected:

Pre-operative/Baseline

- basic demographic data
- patient weight & height, BMI

Surgical procedure

- date of surgery
- type of surgery
- anesthesia details

Follow-up visits (Pre-intervention, DOS, PACU, 14 days post-op, 90 days post-op)

- PHQ-9
- GAD-7
- PROMIS Global Health v1.2
- Brief resilience scale
- NRS Pain Scale
- Pain Unpleasantness Scale
- KOOS-JR
- Pain catastrophizing scale
- MMI Practice Survey
- Patient Satisfaction Survey
- Exit Survey

6.4 Schedule of Assessments

Procedures	Pre-Intervention	Day of Surgery	PACU	14 days post-op	90 days post-op	2 Weeks post-MMI
Identify eligible patients before surgery	X					
Obtain e-consent	X					
Access to MMI	X (Intervention group)				X (Intervention Group)	
PHQ-9	X			X	X	
GAD-7	X			X	X	
PROMIS Global Health v1.2	X			X	X	
Brief Resilience Scale	X			X	X	
NRS Pain Scale	X	X		X	X	
Pain Unpleasantness Scale	X		X	X	X	
KOOS-JR	X			X	X	
Pain catastrophizing Scale	X					
MMI Practice Survey		X		X	X	
Pain satisfaction survey				X		
Exit Survery				X (Intervention Group)		X (Intervention Group)

7.0 STATISTICAL ANALYSIS

Proposed analysis:

t-test as there are two groups

Interim analysis planned? No

Alpha level: 0.05

Beta or power level: N/A Pilot study

Number of groups being compared: 2

Resulting number per group: 12

Total sample size: 30 (20% standard anticipated drop out rate)

8.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report. Definitions for Adverse Event (AE) used in this study are listed below and are based on FDA and international guidelines:

8.1 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product.

8.2 Serious Adverse Events (SAE)

The event is serious and should be reported to FDA when the patient outcome is:

Death, Life-threatening, Hospitalization (initial or prolonged), Disability or Permanent Damage, Congenital Anomaly/Birth Defect, Required Intervention to Prevent Permanent Impairment or Damage (Devices), Other Serious (Important Medical Events).

8.3 Adverse Event Relationship

Relationship to study: definitely, probably, possibly, not related.

9.0 INVESTIGATOR RESPONSIBILITIES, RECORD AND REPORTS

9.1 Subject Consent and Information

Research assistants will screen the co-investigating surgeons' patients undergoing ambulatory total knee arthroplasty surgery. Screening will involve reviewing the patient's EPIC chart to ensure that they meet the inclusion criteria and are not excluded due to any of the exclusion criteria listed. Patients who meet the inclusion criteria will be identified as potential study participants. After the investigating anesthesiologists have confirmed the eligibility of all potential participants, one of the investigating anesthesiologists will approach the potential patients in the pre-operative holding area, explain the rationale for the study, and ask if the patient is interested in participating.

9.2 Subject Data Protection

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by the Research Director and accessible only to the principal investigator, in addition to other IRB-approved study personnel. Each subject will be assigned a unique study number for identification in the study database. This unique study number will not be derived from or related to information about the individual. The key linking this unique study number to patient identifiers (i.e., name, medical record number, date of birth, registry number) will be maintained in a different password-protected database maintained by Research Director, to which only the primary investigator will have access.

9.3 Staff Information

Primary Investigator: Christopher Li, MD
Research Assistant: Angela Puglisi, 646-714-6849
Research Assistant: Marko Popovic, 646-797-8948

9.4 Protocol Reviews

Study protocol reviewed and approved by:

- Anesthesiology CRP
- Hospital for Special Surgery Institutional Review Board

10.0 REFERENCES

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