Study Purposes and Objective

We propose to conduct a randomized clinical trial to determine the impact of three different types of psychosocial support for pre-operative joint replacement patients. This project will be conducted in an existing pain management program within the University of Utah Orthopedic Clinic which currently employs mental health professionals to teach patients preparing for surgery pain management strategies. We wish to evaluate the differential impact of three therapeutic approaches (i.e., mindfulness training, therapeutic suggestion, and CBT psychoeducation) by randomly assigning patients to one of the three approaches.

Aim 1. To assess the differential effects of a brief mindfulness training session versus therapeutic suggestion session or a CBT psychoeducational session on preoperative pain, anxiety, and pain medication desire for patients preparing for surgery as well as postoperative physical functioning.

Hypotheses: Mindfulness training and therapeutic suggestion will decrease pain, anxiety, and pain medicine desire as well as increase postoperative physical function to a significantly greater extent than CBT psychoeducation.

Participants

Inclusion criteria: English-speaking males or females 18 or older within the University of Utah Hospital system that are enrolled in the University Orthopedic Clinic's Joint Academy in preparation for a knee or hip replacement.

Exclusion criteria: Altered mental status due to delirium, psychosis, or pharmacological sedation as determined by clinical assessment conducted by a mental health professional.

How will participants be recruited or identified for inclusion in the study?

Patients enrolled in the University of Utah Orthopedic Center's Joint Academy will be recruited during the Joint Academy's standardized, 2-hour pre-operative information program.

At the time that the mental health professional makes contact with the potential participant, the patient will be presented with a fact sheet about the study, which the mental health professional will discuss with the patient. Their willingness to answer study questions and participate in the psychosocial supportive intervention with the mental health professional will indicate their consent.

Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

Patients enrolled in the Joint Academy will be randomized to either a brief mindfulness training, therapeutic suggestion, or CBT psychoeducation condition (allocation ratio 1:1:1) using a pre-generated random number table, determining the type of psychosocial supportive intervention introduced during the Joint Academy's 2-hour information session. The visiting mental health professional will be notified of the random assignment prior to Joint Academy.

The patient will attend Joint Academy as part of standard care. At Joint Academy, the mental health professional makes will make contact with the potential participant, the patient will be presented with a fact sheet about the study, which the mental health professional will discuss with the patient. Patients' willingness to answer study questions and participate in the psychosocial supportive intervention with the mental health professional will indicate their consent.

Patients will be asked to complete the following 9 validated questions:

1. Please rate your pain by choosing the number that tells how much pain you have right now? (from the Brief Pain Inventory; Cleeland, 1994)
2. How unpleasant is your pain right now? (Garland et al., 2017)
3. How much do you want to take pain medicine right now? (Garland et al., 2014)
4. How anxious are you right now? (Lang et al., 2006)
5. In the past 15 minutes, I experienced all things seeming to unify into a single whole. (Hanley, Nakamura & Garland, 2018)
6. In the past 15 minutes, I experienced all sense of self and identity dissolve away. (Hanley, Nakamura & Garland, 2018)
7. In the past 15 minutes, I felt surrounded and filled with a blissful warmth or energy. (Hanley, Nakamura & Garland, 2018)
8. In the past 15 minutes, I had moments when I felt alert and aware. (Tanay & Bernstein, 2013)
9. In the past 15 minutes, I watched my thoughts, feelings, and sensations without getting lost in them. (Baer et al., 2006)

Once these questions are answered, the mental health professional will provide one of three study interventions: A) 15 minute mindfulness session, B) a 15 minute therapeutic suggestion session, or C) a 15 minute CBT psychoeducation session.

Following the 15 minute psychosocial supportive intervention, participants will be asked the same 9 questions listed above.

Once per month, the UU Hospital data warehouse will provide the PI with the following pre-, peri-, and postoperative data for each Joint Academy attendee: patient age, gender, admitting diagnosis, CAPA scores, PROMIS scores, dosages of pain medicine received during hospital stay (Tramadol, Oxycodone, Hydrocodone, Morphine, Fentanyl, Hydromorphone, Acetaminophen, Ketorolac, Ibuprofen, Naproxen, Celecoxib), heart rate, blood pressure, post-acute care, and hospital readmission

Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.

Effects of treatment on outcomes (change in pain severity, pain unpleasantness, anxiety, pain medication desire, and physical functioning) will be evaluated using linear mixed models were outcome variables are regressed on intervention group (mindfulness vs. hypnotic suggestion vs. cognitive-behavioral psychoeducation) after covarying baseline values. Models will also be adjusted for age, sex, proximity of outcome measurement to surgery, and admitting diagnosis. All tests and CIs will be 2-sided and statistical significance will be defined as a *P* value less than .05. All linear models will be conducted using SPSS version 25.

Little's MCAR test will be used to determine if data are Missing Completely at Random (an ideal that is rarely met with longitudinal data). There is no definitive test for Missing at Random (MAR), which describes data that are random conditional on observed data. We will use maximum likelihood estimation procedures to deal with missing data according to an intent-to-treat philosophy that is robust against the most common patterns of missing longitudinal data. Maximum likelihood estimation is based on all data observations; no values will be deleted or imputed.

A priori power analysis was conducted using Optimal Design. An estimated total sample size of 250 participants in 47 cohorts will be necessary to detect an overall between-group effect on baseline-adjusted outcomes (f=0.25, or of small size) with 80% power, two-sided $p < 0.05$.