

**Implementing and Evaluating the Effect of Personalized Pain Coaches  
After Orthopaedic Surgery for Patients with Sports Medicine Injuries  
to Improve Postoperative Outcomes**

STUDY00004925

Date: February 22, 2024

NCT05821699

**Protocol Title:** Implementing and Evaluating the Effect of Personalized Pain Coaches After Orthopaedic Surgery for Patients with Sports Medicine Injuries to Improve Postoperative Outcomes

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**VERSION:** 8

**FUNDING SOURCE:** National Football League

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**REVISION HISTORY**

Revision #	Version Date	Summary of Changes
2	10/07/2022	Adding e-consent option and study visit window periods
3	03/09/2023	Updating incentive timing and sample size
4	08/03/2023	Adding recruitment flyers and transportation assistance
5	10/06/2023	Actigraphy watch return moved to the final visit instead of the first follow up visit
6	10/27/2023	Removing BMI requirement for eligibility
7	12/11/2023	Extending the age requirement from 18-45 years to 15-45 years
8	02/01/2024	Actigraphy watch return moved to the first follow up visit instead of final visit; Adding Secure Chat on Epic as a contact method during recruitment

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## 1. Study Summary

<b>Study Title</b>	Implementing and Evaluating the Effect of Personalized Pain Coaches After Orthopaedic Surgery for Patients with Sports Medicine Injuries to Improve Postoperative Outcomes
<b>Study Design</b>	Three arm randomized control trial
<b>Primary Objective</b>	The objective of this randomized controlled trial is to examine how the integration of a trained Life Care Specialist improves postoperative recovery related to patient-reported pain outcomes following orthopaedic injury
<b>Secondary Objective(s)</b>	Examine how the integration of a trained Life Care Specialist improves postoperative recovery related to opioid utilization and objective functional outcomes following orthopaedic injury
<b>Research Intervention(s)/Interactions</b>	The LCS will work with the patient to create a pain management plan focused on behavioral education. The LCS interventions can encompass all, but not limited to, the information included below: <ul style="list-style-type: none"><li>• Opioid Risk Education</li><li>• Therapeutic Intervention</li><li>• Clinical Pain Coordination</li></ul>
<b>Study Population</b>	Orthopaedic patients seen at Emory and Grady
<b>Sample Size</b>	150
<b>Study Duration for individual participants</b>	~90 days
<b>Study Specific Abbreviations/ Definitions</b>	LCS, Life care specialist
<b>Funding Source (if any)</b>	National Football League (NFL)

## 2. Objectives

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The *objective* of this randomized controlled trial is to examine how the integration of a trained Life Care Specialist improves postoperative recovery related to patient-reported pain outcomes, opioid utilization, and objective functional outcomes following orthopaedic injury.

**Aim 1:** Examine differences in post-surgical patient-reported pain related outcomes and opioid utilization between participants in the intervention arms compared to those in the control arm.

*Hypothesis 1.1:* Those randomized to the intervention arms will report improved average patient-reported pain related outcomes compared to participants in the control, standard of care, arm.

*Hypothesis 1.2:* Participants in the intervention arms will have decreased utilization of opioid pain medications both in the inpatient and outpatient setting.

**Aim 2:** Compare postoperative functional outcomes among intervention and control groups during their hospitalization and postoperatively.

*Hypothesis 2:* Objective functional outcomes captured from actigraphy devices will indicate improved physical functioning among those in the intervention arms compared to participants in the control arm.

**Aim 3:** Evaluate patient-reported pain related outcomes and opioid utilization between participants randomized to the in-person intervention and the telehealth delivered intervention arms.

*Hypothesis 3:* Improvements in patient-reported outcomes and opioid utilization will be similar across study arm groups, thereby indicating the utility of delivering the intervention both in person or remotely to improve care outcomes.

### **3. Background**

Longitudinal analyses indicate that both greater pain severity and duration precede poor functioning and prolonged opioid use.(Althaus et al., 2014; Kent et al., 2021) This finding suggests that optimizing pain management, soon after painful events, such as orthopaedic injury, is vital to reducing risks related to prolonged opioid use. However, opioid dominant pain management, which remains the standard of care across many health systems and in orthopaedic surgery, elevates the risks for ineffective pain management and, subsequently, opioid dependency by only targeting a select number of pain receptors.(Bedard et al., 2018; Hadlandsmyth et al., 2018) Multimodal analgesia, which combines analgesic drugs from different classes and employs analgesic techniques that target multiple pain-related receptors, is recommended in the treatment of acute postoperative pain because its synergistic effect maximizes pain

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relief at lower analgesic doses, thereby reducing the risk of adverse opioid-related effects and chronic pain.(Polomano et al., 2017) Multimodal analgesia includes the use of nonpharmacological pain management approaches. Patients can implement nonpharmacological pain management techniques themselves, or ideally work with clinical team members to be educated on and implement them, as part of multimodal opioid-sparing postoperative pain management. However, limited access to non-pharmacologic pain services is associated with initiating opioid prescriptions and persistent pain.(Karmali et al., 2021) Therefore, patients without access to and training on evidence-based non-pharmacological pain management approaches face higher risks of receiving opioid dominant pain management. Novel approaches are needed to expand patients access to and understanding of multimodal pain management approaches after sustaining sports medicine related injuries.

Our interdisciplinary team has developed and tested a novel clinical care team role focused on optimizing pain management after surgery, known as a Life Care Specialist. Life Care Specialists provide patient-centered pain management care coordination, teach patients how to implement non-pharmacological pain management approaches, and deliver opioid safety focused pain education, not only during acute hospitalization but also throughout postoperative recovery. All Life Care Specialists have advanced degrees and are certified to provide patients with non-pharmacologic pain management strategies, including progressive muscle relaxation, music therapy, diaphragmatic breathing, aroma therapy, and also assist patients with implementing best practices to promote sleep hygiene to enable restful restorative sleep after surgery. Life Care Specialists provide pain focused care coordination for patients with complex needs after orthopedic injury, including communicating patient care needs and goals of care to clinical care team members (e.g. surgeons, acute pain service, physical therapy, nursing staff), connecting patients to yoga instructors, massage therapists, and engaging behavioral health consults to work with patients over time to improve biopsychosocial pain presentations. The role of the Life Care Specialist was based on success seen in introducing paraprofessionals and peer navigators into other clinical practice settings. For example, in pediatric settings there is significant evidence showing that non-pharmacological interventions delivered by Certified Child Life Specialists leads to more cooperation, reduction in perceived pain, and higher satisfaction scores from patients and their families.(Bandstra et al., 2008; Sanchez Cristal et al., 2018) Patients navigators have been shown to improve care outcomes and pain for patients with numerous chronic conditions.(Macdonald et al., 2017; Natale-Pereira et al., 2011) Similar to these other paraprofessional roles, Life Care Specialist help to improve postoperative care outcomes by leveraging their specialized training to implement systematic biopsychosocial pain assessments as well as increase access to and providing care coordination for utilizing non-pharmacological pain management approaches. The Life

Care Specialist serves as a point of contact to curate the often-disjointed care patients face during their postoperative recovery and when accessing non-pharmacological approaches.

#### **4. Study Endpoints**

During the conduct of this study, assessments will occur one month to one week prior to surgery, 2 weeks, 6 weeks, and 3 months postoperatively. Study measures at these points will assess patient-reported outcomes using surveys, opioid consumption using both electronic health records and remote monitoring, and functioning using wearable actigraphy devices.

#### **5. Study Intervention/Design**

Patients will be randomized to either:

- (1) In person LCS intervention** - With *Opioid Risk Education*, patients will receive opioid education after completing the validated Opioid Risk Tool (ORT), a detailed substance abuse survey and mental health screening, and Naloxone education. *Therapeutic Intervention* will include the Community Resiliency Model (CRM). *Clinical Pain Coordination* will include directed referrals for complex needs, including mental health and substance use disorders, as needed. In addition to above mentioned 3 intervention components, all patients in the LCS intervention arm will also receive the current standard-of-care. The Community Resiliency Model (CRM) is a noncognitive variant of mindfulness, emphasizing attunement to interoceptive and exteroceptive signaling cues for regulation of autonomic responses to stress (Grabbe, Higgins, Baird, Craven & San Fratello, 2020). CRM was derived from somatic psychotherapy and self-stabilization interventions using body sensation awareness. Body sensation awareness is called introspection and is a key component of mindfulness. Awareness of internal body sensation occurs in the insular cortex and adjacent brain structures, which serve as cerebral centers regulating emotional regulation, empathy, and social interaction (Simmons et al., 2013). Implementing these techniques may preventatively attenuate the immediate impact of stressors. For example, the CRM model has been implemented across several settings and populations and has been associated with improved well-being, resiliency, and physical symptoms (Grabbe et al., 2020; Grabbe et al., 2021; Habimana et al., 2021). CRM skills are introduced over a sixty-to-ninety-minute session, allowing for a brief introduction and application of skills by participants.

- (2) **Virtual LCS intervention** - With *Opioid Risk Education*, patients will receive opioid education after completing the validated Opioid Risk Tool (ORT), a detailed substance abuse survey and mental health screening, and Naloxone education. *Therapeutic Intervention* will include the Community Resiliency Model CRM).. *Clinical Pain Coordination* will include directed referrals for complex needs, including mental health and substance use disorders, as needed. In addition to above mentioned 3 intervention components, all patients in the LCS intervention arm will also receive the current standard-of-care.
- (3) **No LCS intervention** - Patients will receive the current standard-of-care for pain management in the aftermath of surgery, which includes: a standardized prescription protocol, hospital-system approved discharge instructions which provide written instruction on how to taper opioid use, links to written/online resources for opioid misuse, overdose prevention, and State-approved disposal options.

## **6. Procedures Involved**

If the patient meets inclusion criteria, the CRC will visit patient during their preoperative consult or call the referred patient through his/her number listed on Epic. If unable to visit in person and reach through call, the CRC will message patient through the Secure Chat feature on Epic to potentially schedule an e-consent. If informed consent is obtained, they will be enrolled into REDCap for randomization into one of the three groups. A simple number generator, within RedCap, will sequentially randomize participants into control or one of the two intervention arms. After consenting, enrolling, and allocation, research staff will administer a battery of measures on tablets stored in REDCap, or on paper and later transcribed into REDCap to all participants. In the event the participant is unable to complete study measures during the clinic visit they will be emailed a secure link to RedCap to complete the consent form and the study measures.

Those randomized to the intervention will either meet with a Life Care Specialist for 1 hour before surgery, either in person or via Zoom® during their preoperative consult or at another time no later than 24 hours before surgery.

During their follow up visits with the surgical team at Grady Hospital or Emory Orthopaedics scheduled at 2-weeks, 6-weeks, and 3-months postoperatively participants will again be provided a tablet to complete outcome measures. In the event participants cannot physically travel to the clinic, appointments will be conducted over video conferencing and participants will have the option to be emailed the outcome measures to complete. If they are unable to complete the measures via email within 72-hours study staff will call participants to complete measures over the phone. If no response, paper copies of the measures will be mailed to participants with prepaid

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postage to return them or QR code post cards to complete surveys. There is a one week window for the first follow up visit, two week window to complete measures for the second follow up study visit, and four weeks for the last study visit. Study staff will call participants and offer to video conference with them within 48 hours of surgery to review how to wear the actigraphy device and use the MEMS cap.

The following data will be collected on the patients:

- Demographics: Name, date of birth, date of admission, gender, ethnicity, body mass index, zip code, insurance
- Health record data: Data abstraction from health records include injury severity score, mechanism, drug screen on arrival, alcohol screen, pre-existing conditions, inpatient complications, surgical time, regional anesthesia, medication received, and opioid medication doses discharged with.
- Comprehensive social determinants of health (SDOH) survey: This measure includes assessments of housing, financial stability, education, community context, intimate partner violence, health literacy, prior personal and family substance use, a validated measure of post-traumatic stress disorder, adverse childhood experiences, and mental illness. This has been utilized in prior research by this team and takes approximately 20-25 minutes to complete.
- Revised Opioid Risk Tool (ORT): The ORT is a self-reported measure used to ascertain a participant's current and future risk of aberrant drug-related behaviors in patients prescribed opioid therapy.(Cheatle et al., 2019; Webster & Webster, 2005) Recently a shortened revised ORT was recently developed and will be used in this study.(Cheatle et al., 2019) Across 9-items, this tool assesses family history of substance abuse, personal history of substance abuse, age range, and current psychological disease. Each endorsement is scored as 1 for a total score ranging from 0 to 9. Scores of 3 or greater are predictive of high risk for opioid use disorder.
- PTSD screener: This screener is a 5-item screening tool used to assess previous exposure to traumatic events and subsequent presence of the DSM-V diagnostic criteria for PTSD.(Prins et al., 2016) Each item respondents report "Yes" to can be scored as a point so that a minimum of 3 points is used in primary care settings to be considered probable PTSD.
- Sleep Disturbance, Physical Function, Pain Interference, Prescription Pain Medication Misuse: The *PROMIS Sleep Disturbance* examines respondent's global severity of insomnia, sleep disruption, and sleep quality over the past seven days. This PROMIS scale is more sensitive at detecting sleep problems than historical measures, such as the Pittsburgh Sleep Quality Index.(Yu et al., 2012) Again, each of the 4 Likert scale items' raw score are converted to t-scores, ranging from 0 to 100. Like all PROMIS measures, t-scores are normed to the US population, with a mean of 50 and standard deviation of 10.(Cook et al., 2014) Lower scores indicate better sleep. *PROMIS Physical Function* measures participants' self-reported capability to conduct physical activity. This includes capturing function in upper extremities and

lower extremities (walking or mobility) as well as a respondent's ability to conduct activities of daily living. There are 4-items on the short form questionnaire and respondents report their capabilities to perform each task on a Likert scale from 5, "without any difficulty", to 1, "unable to do". All 4-items' raw scores are summed before being transformed into t-scores ranging from 0 to 100. Higher scores are better and indicate greater physical function. The validated instrument is comparable to numerous legacy measures often used across diverse patient populations. (Jensen et al., 2015; Schalet et al., 2016) *The PROMIS Pain Interference* scale assesses the extent to which pain impedes engagement with social, cognitive, emotional, physical, and recreational activities over the past 7 days. Pain interference is an essential aspect of pain management to capture in order to better understand how pain impacts the activities of individuals rather than subjective severity alone.<sup>15</sup> On each of the scale's 4-items respondents choose how much pain impeded a specific function or activity, ranging from 1, "not at all", to 5, "very much". Scores are summed across all items and transformed to a t-score ranging from 0 to 100, with lower t-scores indicate less interference due to pain. The *PROMIS Pain Interference* scale has been found to be comparable in responsiveness to traditional measures of pain interference used including the Brief Pain Inventory Interference subscale and the 36-Item Short Form Survey (SF-36) Bodily Pain scale. (Askew et al., 2016; Chen et al., 2019; Raichle et al., 2006; Stone et al., 2016) *The PROMIS measure of Prescription Pain Medication Misuse* assesses current abuse of prescription pain medication, chiefly opioids. The scale has been validated in patient populations with chronic non-cancer pain and has been found to be highly correlated with the Pain Medication Questionnaire (PMQ)."

- Naloxone Questionnaire: Each participant will complete a Naloxone questionnaire evaluating knowledge and details of utilization, if applicable, and signs and symptoms of an overdose. The Opioid Overdose Knowledge Scale is a validated instrument where higher scores indicate greater understanding.
- Opioid utilization: Inpatient and operating room opioid utilization will be extracted from the electronic health record (EHR) by study staff upon participants' discharge from the hospital. Opioid medication dosage will be transformed to a total universal measure known as morphine milligram equivalent (MME). MME will be averaged over the length-of-stay (LOS) for a daily dosage, known as MME/day. Additionally, the study team will review participants' EHR at each study time point up to 3-months to determine MME throughout postoperative recovery and rehabilitation. Medication Electronic Monitoring (MEMS) devices will be used to assess medication utilization and adherence rates. They are Bluetooth enabled caps that fit on standard medicine bottles and record participants' medication utilization. Participants will be dispensed their opioid medication by the pharmacy in the MEMS equipped containers and informed to return their bottle at their next follow up visit.
- Pain numerical rating scale (NRS): The NRS requires respondents to rate the intensity of their pain on a defined scale from 0, "no pain", to 10, "the worst pain imaginable". The NRS is a commonly used pain assessment tool in both clinical practice and

research. (Farrar et al., 2010) However, the NRS is a single static measure of pain and does not capture the biopsychosocial presentations of pain including physical functioning. As such a battery of objective (e.g. actigraphy) and patient-reported outcomes are needed to best ascertain patient participants' pain experiences. Inpatient NRS, which is recorded by the clinical care team throughout each day, will be extracted from the electronic health record (EHR) by study staff upon participants' discharge from the hospital.

- Mindful Attention Awareness Scale: The MAAS is a validated 15-item scale designed to assess a core characteristic of dispositional mindfulness, namely, open or receptive awareness of and attention to what is taking place in the present.
- Actigraphy based sleep and activity data (e.g. average hours of sleep, average daily steps): Study participants will be provided with a wrist actigraphy device to wear during a week before their hospitalization and throughout their recovery until their 2-week follow up appointment with the surgical team or until the watch battery loses its charge, whichever occurs first. Participants will return their actigraphy devices at the 2-week follow up appointment or be provided a pre-paid envelope to take home and mail back the device after the visit. Wrist actigraphy is a valid and objective tool to measure activity patterns and sleep-related parameters, which has been used in patient populations with both acute and chronic pain.(An et al., 2020; Smith et al., 2018) Actigraphy data includes objective quantitative measures of sleep, such as total sleep time, sleep latency, fragmentation, wake after sleep onset, and sleep efficiency. Additionally, activity level is also captured using wrist actigraphy, including total activity time, steps, physical activity intensity, and total energy expenditure. Participants will receive, and be trained on how to wear, a screen-less actigraphy device on their wrist (GT3XP-BTLE, Actigraph, LLC, USA). Devices will be set to record in 30-second epochs at a medium sensitivity level for scoring sleep and wake time. Wear time validation will be accomplished using the Choi algorithm, as it more accurately estimates time worn accounting for forward and backward motions.(Choi et al., 2011) The sleep data will be computed using the Cole-Kripke algorithm, which accurately distinguishes sleep from wakefulness approximately 88% of the time.(Cole et al., 1992) Metabolic equivalent of tasks and energy expenditure will be measured with the Freedson algorithms.(Freedson et al., 1998) By uniquely pairing actigraphy data with PROMIS patient-reported pain, sleep, and physical function measures, this study will be one of the first to provide a robust analysis of sleep quality and activity in tandem to pain presentations in adult surgical patient populations during hospitalization and throughout immediate post-discharge recovery following surgery. These research efforts adhere to recommended best practices for using actigraphy to examine health outcomes.(Berger et al., 2008)
- Field notes and participant quotes: Field notes are widely recommended in research as a means of documenting needed contextual information and accurately capturing participants' statements in real time. As such study staff will transcribe notes on their encounters with research participants, including summary of interaction and representative quotes from participants.

The LCS will work with the patient to create a pain management plan focused on behavioral education. The LCS interventions can encompass all, but not limited to, the information included below:

- *Opioid Risk Education*
  - Patients will be provided with education about substance misuse and the opioid epidemic
  - Patients will be educated by the LCS on safe methods for disposal of unused pain medications
- *Therapeutic Intervention*
  - The Community Resiliency Model skills
    - Tracking
    - Resourcing
    - Grounding
    - Gesturing
    - Shift and Stay
    - Help Now!
- *Clinical Pain Coordination*
  - The LCS team will work closely with the Dr. Mara Schenker as well as pain specialists Dr. Wesley Glick, Co-Director of the acute pain service at Grady and Dr. Alaina Steck, Director of the Medication Assisted Opioid Therapy Clinic.
  - LCS will complete the Behavioral pain assessment tool. The Checklist of Nonverbal Pain Indicators (CNPI) is a quick behavioral assessment used by clinicians to assess nonverbal indicators of potential pain patients are in such as grimacing, bracing, rubbing, and restlessness at rest and when moving.

## **7. Data Specimen Banking**

Survey data and wearable device collected data from participants will be de-identified prior to sharing via REDCap exported files. No PHI will be shared and demographic data with less than 5 responses per field will be excluded to ensure privacy. No biological samples will be collected nor banked.

## **8. Sharing of Results with Participants**

Aggregate findings from this work will be shared with participants via email in the form of peer-reviewed publications if requested.

## **9. Study Timelines**

Study will commence upon IRB approval. Individuals undergoing surgery will be referred by their surgeon to the team who will then contact them to screen for eligibility and interest in enrolling. Study staff will meet with participants during their preoperative visit or over zoom to administer baseline surveys. Those randomized to the intervention arms will also meet with the study intervention team member during that visit. Study staff will meet with participants at each of their postoperative visits, 2 weeks, 6 weeks,

and 3 months. Participants will be discharged from the study at 3 months. Enrollment will continue for 1 year after the start of the study (estimated November 2022–November 2023), data collection will be completed 6 months after (estimated May 2024). Data analyses will be completed by November 2024. Study duration for participants is approximately 90 days.

#### **10. Inclusion and Exclusion Criteria**

We will recruit 150 participants from the orthopaedic sports medicine service at Grady and Emory Healthcare for this study. Individuals between 15–45 years old, scheduled for orthopaedic surgery due to sports medicine injuries (e.g., anterior cruciate ligament tears, meniscus injury, rotator cuff injury, etc.), and those who are actively employed or full-time athletes prior to injury will be eligible. Individuals unable to provide consent, those undergoing revision procedures, individuals without access to an internet connected device, and individuals who are unemployed or retired at time of injury will be ineligible. No one will be excluded from participation based on gender, race, or ethnicity. Individuals who are incarcerated or pregnant will not be eligible. Individuals unable to consent and those unable to communicate in English will be excluded since all surveys are validated in English.

#### **11. Population**

Any individual with an orthopaedic sports medicine related injury.

#### **12. Vulnerable Populations**

Our research may involve teenagers between the ages of 15 to 17 years. If so, proper assent and parental consent will be obtained.

#### **13. Local Number of Participants**

150 patient participants

#### **14. Recruitment Methods**

Potential patient participants will be identified during the daily orthopaedic morning report by surgeons and their staff. Additionally, flyers with study information and brief videos on study will be placed in the clinic waiting room areas and provided to potential participants from their surgical teams to contact the study team and let them know study staff may contact them. The CRC will visit patient during their preoperative consult or call the referred patient through his/her number listed on Epic. If unable to visit in person and reach through call, the CRC will message patient through the Secure Chat feature on Epic (MyChart) to potentially schedule an appointment to review eligibility, provide e-consent, and complete study baseline activities before surgery. A member of the research team will conduct the informed consent discussion with patients and will obtain consent using the IRB-approved consent form either in person or through e-consent in RedCap.

If the patient is a minor, the research team member will conduct the informed consent discussion with both the patient and at least one of the parents/legal guardians, and obtain the patient's assent with parental permission using the IRB-approved consent form. This can also be done in person or through e-consent in RedCap.

Informed voluntary consent will be obtained from each subject in a non-coercive manner.

#### **15. Withdrawal of Participants**

Individuals may withdrawal from the study at any point by emailing the PI or study coordinator. A patient may also be withdrawn/removed by the study team, if necessary, to protect the patient's health. Once a patient withdraws, the reason will be documented.

#### **16. Risk to Participants**

We anticipate inconveniencing some participants due to the lengthened provider-patient interaction during the enrollment, LCS intervention, and subsequent surveying process. Some participants may find questions on surveys related to family history of substance use or their own substance use uncomfortable and may skip questions at any point. There is a minor risk of loss of privacy or breach of confidentiality. To address the risk for loss of confidentiality associated with conducting research and collecting data, rigorous procedures will be in place to ensure the security and confidentiality of the dataset during analyses. As noted previously, all data will be coded when stored on a secure Emory University server using Redcap. Access to the data will be limited to the study PI, co-investigators, approved research personnel. The PI and collaborators have completed in depth online and in-person training in human subjects training at Emory University. Participants may find the wearable devices uncomfortable and will be educated on how to properly wear them and check for as well as prevent skin irritation (e.g., taking off to shower or if wet allowing band to dry or use replacement band).

#### **17. Potential Benefits to Participants**

We anticipate that those participants randomized to the LCS interventions will have decreased pain scores and improved functioning.

#### **18. Compensation to Participants**

Participants will receive a \$50 clinical gift card, reloadable card, upon finishing baseline study visit and upon study completion and returning study equipment for a total of \$100. Additionally, the team will reimburse those needing assistance to attend study visits up to \$20 via gift card if they cannot secure personal or public transportation to attend sessions.

#### **19. Data Analysis, Management and Confidentiality**

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Descriptive statistics will be used to examine the sample's characteristics and demographics (e.g., means, frequencies). Paired t-tests will be used to examine changes within participants from pre- to post-surgery. Mixed effects modeling will be used to examine mean change in outcomes over time and based on demographics as well as differences between those who do and do not work with the LCs while wearable devices are collecting data. Surveys will be coded with study participant ID numbers. All hard copies will be stored in locked filing cabinets in the PI's office. Paper survey data will be entered into RedCap. A master list of study ID # and names with emails of participants will be stored on Emory servers and only accessible to the PI and the coordinator.

**20. Provisions to Monitor the Data to Ensure the Safety of Participants**

No DSMB will be convened given the minimal risks involved in this study.

**21. Provisions to Protect the Privacy Interest of Participants**

To address the risk for loss of confidentiality associated with conducting research and collecting data, rigorous procedures will be in place to ensure the security and confidentiality of the dataset during analyses. As noted previously, all data will be coded when stored on a secure Emory University server using RedCap. Access to the data will be limited to the study PI, co-investigators, approved research personnel. The PI and collaborators have completed in depth online and in-person training in human subjects training at Emory University. The PI will continue to participate in the Office of Nursing Research's monthly colloquia on conducting ethical research and the responsible conduct of research. These monthly lectures and seminar series are led by research experts across the University and address a wide array of maintaining ethical standards and quality throughout the research process. All data will be reported in the aggregate in peer-reviewed publications to ensure participant privacy. Data shared with the funder and other collaborators will be identified and no PHI will be collected. All participants will receive a handout with the contact information of employee health services to help address any symptoms they may be experiencing. Symptom level data will not be analyzed in real time and therefore cannot be monitored to inform individuals connecting to services.

**22. Economic Burden to Participants**

There is no cost for participants to be in this study.

**23. Informed Consent**

Consent will be given in person or as e-consent in RedCap at baseline, which will occur in a private space within Emory Healthcare or Grady. If the patient is between the ages of 15 to 17 years, the informed consent discussion will also include one of the patient's parents/legal guardians. For these cases, we will require the signature of the subject's assent and the signature of the person soliciting assent of the subject.

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The study staff will provide an overview of the study's purpose, benefits, anticipated risks, and copies of the consent if requested with the surveys and be available to read the consent or answer any questions participants may have. The script, as well as the coordinator, will emphasize in the verbal instructions that the study is voluntary and that participants may opt out of the study or surveys at any time point and still participate in the training. Further, individuals will be told that opting out of any surveys or study components will not impact their employment.

#### **24. HIPAA**

HIPPA Authorization will be collected from all participants. A partial waiver will be requested for screening participants for eligibility based on their medical record once referred by their physician.

#### **25. Setting**

The study will take place across Grady and Emory Health's orthopaedic clinics.

#### **26. Resources Available**

**Offices/Computing.** All faculty members in the School of Nursing, including Dr. Giordano, have private offices with full computing capabilities networked to printers. Each research faculty has a separate research office space for housing research nurses and activities. Conference rooms and medical media service are provided throughout the relevant buildings. Each office is equipped with desk space, telephone, computer, and file storage space as well as convenient access to photocopying, and conference rooms. Financial and administrative support is readily available and located in offices near the investigators. Through the Emory network faculty can use the Emory Integrated Computing Core (EICC) for analyses exceeding their desktop machines' capabilities. For more computing power, Emory faculty can now access the cloud computing resources of Amazon Web Services. The study team has continuous blood pressure monitoring devices, actigraphy devices, and the necessary software to analyze data generated from these devices on school furnished computers.

#### **27. References**

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