RCT: Life Care Specialist (LCS) - Pain management and prevention of substance misuse

Short study title: Life Care Specialist (LCS)

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Introduction and Background:

Opioids are psychoactive substances (narcotics) primarily used for pain relief by producing euphoric effects. Although regularly prescribed by physicians, opioids are highly addictive. Examples include, but are not limited to, morphine, codeine, and oxycodone. Opioids block feelings of pain and trigger a release of dopamine. Dependence occurs with repeated use, as the parts of the brain naturally responsible for releasing dopamine rely on the drug for proper function. When avoided, patients can quickly experience severe withdrawal symptoms similar to the flu.

In the United States, more than 115 people die from opioid overdose every day. Despite a year-over-year increase in opioid overdose deaths since the year 2000, opioids remain among the most effective medications providers can offer to control pain. In 2019, the Centers for Disease Control and Prevention (CDC) was granted 475 million research dollars for opioid overdose prevention and surveillance. Reducing dependence upon opioids has become a national priority. Evidence has shown that while prescription of analgesic opioids has declined, it has come at the expense of effective pain control. This is particularly true in the field of orthopaedic trauma where pain management continues to be centered around opioid pharmaceutical analgesia. Trauma patients are more likely than other types of patients to be under the influence of psychoactive drugs and alcohol use. The strongest risk factor for developing opioid use disorder is pre-existing substance use disorder. Risk factors for opioid overdose mortality include: middle age, history of substance abuse, including prescription and illicit drugs and alcohol, comorbid mental and medical condition, methadone use, unemployment, polysubstance abuse, opioid naivety, sleep apnea, and pain intensity; these are all conditions representative of typical U.S. trauma patient populations. This significant overlap places high importance on implementing alternative solutions to pain management

within this population, and aligns with the CDC NCICP research priority alignment to develop and evaluate an innovative prevention strategy to prevent overdose, including those at greatest risk.

Addiction treatment costs near $78.5 billion and rising, less than 10% of people in need receive treatment.

According to studies of patients discharged from the hospital after being prescribed a new medication:

- 86% were aware that they had been prescribed new medications.
- Fewer could identify the name (64%) or number (74%) of their new medications of their dosages (56%), the schedule to take them (68%), or the purpose of the prescription (64%.)
- Only 22% could name at least one adverse effect.
- Only 11% could recall being told of any adverse effects.

Further, orthopaedic surgeons are the third-most frequent providers of opioid prescription medications among physicians, and orthopaedic surgical patients are at the highest risk of chronic postoperative opioid use. Orthopaedic trauma surgeons face a very difficult task in managing acute pain and the consequences associated with over-prescription of opioid analgesics. Most patients with orthopaedic trauma injuries have very painful injuries and need appropriate pain control. What we largely fail to understand as providers and then fail to convey to patients is that opioid dependence exists on a continuum: from pain-related appropriate use to dependence – and that addiction can happen to anyone holding a prescription. Orthopaedic trauma surgeons have very little training in acute pain management, yet are treating the highest risk patients with opioids every single day.

Within the orthopaedic trauma population at Grady, 20% of patients report a history of substance abuse, 30% have previously used opioid medications for pain, and nearly 25% report taking opioid pain medications up to 1 year after their trauma (*Schenker et al. manuscript in preparation*). Trauma patients are particularly at high risk.

In pediatrics, there is evidence that non-pharmacological interventions by Certified Child Life Specialists (CCLS) has led to more cooperation, reduction in perceived pain, and higher satisfaction scores. The use of CCLS in children who suffer from orthopaedic trauma is associated with fewer opioid prescriptions.

The Christopher Wolf Crusade (CWC) is a 501C3 non-profit providing preventative solutions, education, and advocacy for the American opioid epidemic. Founded by Cammie Wolf Rice in 2018, CWC is on a mission to save lives worldwide.

CWC proposes to introduce a Life Care Specialist (LCS) as an integral member of the clinical team, with a focus on "pain coaching" for trauma patients. In an analogous role served by CCLS in pediatrics, the LCS will introduce orthopaedic trauma patients to non-pharmacologic coping strategies for pain. Further, they will provide much needed patient-centric education on individualized risk for opioid misuse, as well as overdose prevention and safe disposal of unused opioids.

CWC's primary focus is to introduce a behavior-specific intervention at the time of inpatient hospitalization for trauma to decrease overall opioid utilization and improve pain control in the post-trauma time period. We are collaborating with key stakeholders in the opioid epidemic to develop an official pain management protocol, as well as conducting an introductory study for a new field of Pain Management. The goal is to see Life Care Specialists (LCS) staffed in hospitals to focus on pain management and addiction prevention for patients. The LCS position does not currently exist in the healthcare field. The LCS is a behavior-based pain "coach" who educates patients on risks of opioid dependence and offers non-traditional non-pharmacologic options for pain control. In addition, the LCS will act as a liaison between the patient and

the physician – to ensure that traditional pharmacologic-based pain control regimens are optimized. Current post-operative protocols for pain management in trauma are very opioid-based. They lack multimodal non-opioid based pharmacologic options and they have no non-pharmacologic behavioral-based component.

All LCS involved in the research study will become certified as a teacher of the Community Resiliency Model (CRM). CRM is an evidence-based model of wellbeing created by Elaine Miller-Karas of the Trauma Resource Institute.

LCS Role and Responsibilities will be overseen by CWC:

- The LCS will provide patients with individualized risk assessment for opioid misuse.
- LCS will act as patient's "Pain Coach." Providing targeted education and behavior-based pain treatment options.
- LCS will train and provide CWC evidence based non-pharmaceutical pain management techniques, using the Community Resiliency Model.
- The LCS will use the Opioid Risk Tool (ORT) as the method to identity the risk of substance misuse.
- LCS will provide education, support and resources.
- The LCS will provide local, state, and national resources to enhance the whole health aspect of the position. These resources include but are not limited to: written documents that outline the key concepts of the pain management techniques taught by the LCS and a list of hotlines and websites.
- LCS, when applicable, will provide education for caretakers on the risk of opioid use and the non - pharmaceutical pain management protocol.
- LCS will provide follow up for all patients in intervention group.

Objectives:
The overall hypothesis of this pilot randomized-controlled trial is that the introduction of an LCS as a novel member of the clinical care team will help reduce opioid utilization, decrease pain scores, and improve patient understanding of their addiction risk in the aftermath of orthopaedic trauma.

The first aim will evaluate the effectiveness of LCS intervention on pain control and opioid utilization; the second aim will evaluate the effectiveness of LCS intervention on the patient perspective and understanding of their risks; and the final aim will provide early evidence into which patients benefit most from LCS intervention.

All patients will be assessed with a comprehensive social determinants of health survey at the beginning of the study, and follow-up assessments will include actual morphine equivalents utilized (inpatient and outpatient), pain scores (inpatient and outpatient), and substance use surveys up to 1-year post-trauma.

Study design and methods:
The pilot trial will include 200 patients – 100 randomized into LCS intervention. Prior to randomization, all patients will be given a standardized, validated, comprehensive social determinants of health assessment.

Patients will be randomized to either:

(1) 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), progressive muscle relaxation, sound therapy. *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.

(2) No LCS intervention - Patients will receive the current standard-of-care for pain management in the aftermath of trauma, 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.

Patients will be monitored throughout the course of the 1-year study for outcomes. They will also have the same quantity and quality of interaction with their usual clinical providers (orthopaedic trauma surgeon, physician's assistant).

This pilot trial will provide information on the effectiveness of LCS for pain intervention, as well as on study design, retention, effect sizes, and outcomes assessment. Our long-term goals are to determine whether LCSs are beneficial for decreasing opioid risk and improving pain management, and if so identify (1) the key effectiveness factors to the LCS intervention, (2) whether the LCS intervention can decrease overdose-related deaths, and (3) how to scale this model nationally, similar to the Child Life Specialist model.

Study Procedures/Assessments:

Potential patients will be identified during the daily orthopaedic trauma morning report. Eligibility will be determined by the clinical research coordinator (CRC).

If the patient meets inclusion criteria, he/she will be approached by the CRC, and if informed consent is obtained, they will be enrolled into RedCAP for randomization into Group 1 (non- LCS) or Group 2 (LCS). 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 (See Table).

Each day throughout hospitalization, the average pain score over the past 24-hours will be recorded via the nursing staff. During their follow up visits with the surgical team at Grady Hospital scheduled at 2-weeeks, 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 postage to return them.

The following data will be collected on the patients:

- Demographics:
  Name, date of birth, date of admission, gender, ethnicity, body mass index.
- Trauma registry data:
  Data abstraction that is completed by a separate quality team contained within the trauma department. i.e., injury severity score, mechanism, drug screen on arrival, alcohol screen, pre-existing conditions, inpatient complications.
- Comprehensive social determinants of health (SDOH) survey:
  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 (attached).

- 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.[47,48] Recently a shortened revised ORT was recently developed and will be used in this study.[48] 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.[48]
- Short Form 36 Health Survey Questionnaire (SF-36):
  The SF-36 is a measure of health status and is commonly used in health economics as a variable in the quality-adjusted life year calculation to determine the cost-effectiveness of a health treatment. Including this measure will enable us to capture changes in quality of life over time as it is correlated to the intervention.
- Pain Management Questionnaire (PMQ):
  The risk of opioid misuse is assessed. The PMQ is a 26-item questionnaire where responses are given on a 5-point Likert scale where 0 = disagree and 4 = agree. Total scores range from 0 to 104, where higher scores indicate increased risk of opioid misuse.
- Prescription Drug Use Questionnaire (PDUQ):
  The risk of drug misuse is assessed, by collecting longitudinal data on prescription drug use during the study period.
- 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.[46] 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.
- PROMIS:
  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.[42] 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.[43] 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' saw 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. [36,37] *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.[15] 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.[38-41] 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)."

- Opioid Literacy Tool (OLT):
  This survey is designed to assess the accuracy of knowledge about opioids (3 questions) and opioid-related risks (5 questions). Accuracy of opioid knowledge responses are given on a dichotomous scale (yes/no) and a pick-N scale, the latter of which will represent a percent accuracy of identified opioids and/or opioid-containing medication. Responses for accuracy of knowledge about opioid-related risks are given on a 7-point scale where 1 = definitely true and 7 = definitely false. For these 5 questions, a total score ranges from 5 to 35 and higher scores indicate improved literacy (accurate understanding of prescription opioid addiction-risk, opioid dependance and risk of opioid overdose).
- Patient Satisfaction Survey:
  Patient satisfaction with received clinical care will be assessed with a modified Press Ganey Integrated Survey. Integrated study-specific questions will align with the conventional rating scale of "strongly agree" – "strongly disagree". This survey will capture a comprehensive picture of each participant's care experience. Higher scores indicate higher satisfaction and will be compared among study arms and to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) comparative feedback database.
- Naloxone Questionnaire:
  Each participant will complete a Naloxone questionnaire evaluating knowledge and details of utilization, if applicable.
- Inpatient Pain and Opioid utilization :
  Inpatient 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. *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. [26] 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.
- Medication Electronic Monitoring (MEMS) devices:
  These 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.
- Defense and Veterans Pain Rating Scale (DVPRS):
  The DVPRS is a validated pain assessment tool used to measure the degree to which pain influenced a respondent's ability to function over the prior 24 hours. The DVPRS incorporates a numerical rating scale, as well as functional word descriptors, color coding, and pictorial facial expressions matched to pain levels. DVPRS average pain scores can range from 0, "no pain," to 10, "as bad as it could be, nothing else matters." The DVPRS is used to assess current pain, average pain, and worst pain over the prior 24 hours. The DVPRS includes four supplemental questions examining how pain

impacts activity, sleep, mood, and stress on a numeric scale. Collectively, the DVPRS advances pain assessments beyond traditional 0-to-10 pain intensity scores and toward a better understanding of the impact pain has on an individual.

- Discharge data:
  Inpatient morphine equivalents (24 hours prior to discharge), average pain score (24 hours prior to discharge), discharge pain medications prescribed, discharge morphine equivalents prescribed, hospital length of stay and discharge disposition.
- 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 their hospitalization and throughout their recovery until their 2-week follow up appointment with the surgical team. 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.[30,31] 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.[32] The sleep data will be computed using the Cole-Kripke algorithm, which accurately distinguishes sleep from wakefulness approximately 88% of the time.[33] Metabolic equivalent of tasks and energy expenditure will be measured with the Freedson algorithms.[34] 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.[35]
- Patient Assessment of Constipation Symptoms (PAC-SYM): This questionnaire is a 12-item self-report instrument divided into abdominal, rectal and stool domains. Across 12 items participants report their discomfort related to constipation ranging from 0, never, to 4, always. A total score is computed based on the average of all 12 items.
- 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*
  - Patients will be provided with alternative non-pharmaceutical pain management options
  - Breathing techniques
  - Guided imagery

- Progressive muscle relaxation
- The Community Resiliency Model
  - Tracking
  - Resourcing
  - Grounding
  - Gesturing
  - Shift and Stay
  - Help Now!
- Hospital-approved essential oil therapy
- Motivational Interviewing
- Reflective Listening

- *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.

VISIT SCHEDULE AND ASSESSMENTS

Assessment	Visit 1: Inpatient Hospitalization	Visit 2: 2 Weeks (± 7 days)	Visit 3: 6 Weeks (± 14 days)	Visit 4: 3 Months (± 14 days)
Demographics	X			
Trauma registry data	X			
Comprehensive Social Determinants of Health (SDOH) Survey	X			
Revised Opioid Risk Tool (ORT)	X			
Short Form 36 Health Survey Questionnaire (SF-36)	X			X
Pain Management Questionnaire (PMQ)	X	X	X	X
Prescription Drug Use Questionnaire (PDUQ)	X	X	X	X
PTSD Screener	X			X
PROMIS: Sleep Disturbance	X	X	X	X
PROMIS: Physical Function	X	X	X	X
PROMIS: Pain Interference	X	X	X	X
PROMIS: Prescription Pain Medication Misuse				X
Opioid Literacy Tool (OLT)	X			X
Patient Satisfaction Survey		X		
Naloxone Questionnaire		X	X	X
PAC-SYM	X	X	X	
Inpatient Opioid Utilization (MME/day)	X			
Inpatient Numerical Rating Scale (NRS) Pain Score	X	X	X	X
Medication Electronic Monitoring (MEMS) devices:		X	X	X
Defense and Veterans Pain Rating Scale (DVPRS)	X	X	X	X

Inpatient Sleep Actigraphy	X			
Field notes and participant quotes	X	X	X	X
Participant Compensation	X	X		X

Questionnaires/surveys and meetings with the Life Care Specialist will occur during scheduled telehealth appointments. No charges will be generated specifically relating to the research components.

Eligibility Criteria:
The inclusion criteria are:

- Male and female patients 18 years of age or older
- Orthopaedic trauma patients with an isolated injury requiring surgery
- Informed consent obtained
- Working cellphone

The exclusion criteria are:

- Enrolled in a study that does not permit co-enrollment
- Unlikely to comply with the follow-up schedule
- Unable to converse, read or write English at elementary school level
- Unlikely to complete surveys at home, access to phone
- Incarcerated
- Pregnant
- COVID positive

Patients will be free to withdraw from the study at any time, for any reason.

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.

Informed Consent Process:
Consent will be obtained via REDCap after a thorough consent process and after patients have been given the opportunity to answer any questions. Patients will read the consent form first, and then the explanation will be given. Finally, patients will be asked if they would like to participate. Patients will be allowed to take a copy of the consent with them if they require more time.

Compensation for time and effort:
Both intervention and control participants will receive compensation at the following visits:

- Enrollment / Hospitalization – gift bag and a $10 gift card
- 2 week – $20 gift card
- 3 month – $20 gift card

Data and Safety Monitoring and Reporting:
The Life Care Specialist (LCS) and/or study personnel will respond to study patients to employ behavioral and non-pharmacologic strategies that are designed to decrease opioid utilization, improve pain control via alternative techniques, and educate patient on pain management. Enrolled patients will receive support, direct connection to resources, and follow-up with the LCS during their participation in the program. The patients enrolled in the intervention arm of the RCT will receive direct support and regular follow up with the LCS in obtaining necessary services and ensuring an appropriate level of education is met.

There will be no direct intervention other than education, mentoring, and advocacy on behalf of the patient by study personnel therefore minimizing risk of misusing prescriptions.

Confidentiality:
The Life Care Specialist and the study personnel will ensure that the patient's anonymity is maintained, and that the patient identity is protected from unauthorized parties. The patients will have a designated identification code rather than being identified by their names. All study files and documents will be locked in file cabinets and accessible only to the study personnel.

Though study participants will be using pain medications as prescribed, the investigators acknowledge that participants are asked to quantify their consumption of a controlled substance, which may be a sensitive matter for some participants. Thus, in order to further protect the confidentiality of participants' responses to survey questions and online survey responses will be stored as a set of numbers only, without identifying the question to which those numbers pertain. This data will be stored in an encrypted fashion on a commercial cloud server, which is password protected and only accessible by Emory research staff. The survey key linking the questions to the patient responses will also only be available to Emory investigators.

Statistical Analysis:
Aim 1: *Examine differences in post-surgical patient-reported pain related outcomes between those in the intervention compared to the control arm.* A multivariable mixed effects logistic regression model will be constructed to test the hypothesis that participants in the intervention arm have lower average NRS pain scores and PROMIS scores postoperatively compared to participants in the control arm. A separate linear mixed effects model will be constructed for each outcome. This modeling approach will enable the team to examine the mean differences in each patient-reported pain related outcome while adjusting for covariates (e.g., mental health history, BMI, surgery type, etc.).[49] The mixed effects modeling will account for potential collinearity between participants seen by the same surgeon by fitting a random effect for both factors. Models will be constructed using a Least Absolute Shrinkage and Selection Operator (LASSO) method.[50,51] An extension of traditional ordinary least squares regression model building, LASSO is a machine learning method capable of balancing bias and variance to build the most predictive model with a large subset of covarying factors using a penalized approach. A LASSO approach enables the team to systematically evaluate the variance introduced into regression modeling by hundreds of potential confounders. This unique quantitative capability will allow the research team to exploit the hundreds of data points collected from the electronic health records and the patient-reported outcomes collected per participant. The inclusion of these longitudinal measures makes it feasible to reduce statistical variation in the mixed effects models over time and therefore isolate the effect of the intervention. The fit of the most appropriate and still parsimonious model produced by the LASSO will be assessed based on the AIC score.

Aim 2*: Evaluate the effectiveness of Life Care Specialist intervention on reducing long-term postoperative opioid medication utilization.* As described above, a systematic machine learning guided model construction approach will be used to also test the *working hypothesis* that participants in the intervention will report decreased utilization of opioid pain medications both in the inpatient and outpatient setting up to 3-months postoperatively. Separate mixed-effects models will be constructed to estimate differences in average MME/day during inpatient hospitalization as well as to estimate difference in average MME/day over every study follow up point up to 3-months postoperatively.

Aim 3: *Explore the feasibility of utilizing actigraphy devices to capture postoperative functional outcomes among patients during their hospitalization and up to 2-weeks postoperatively following orthopaedic trauma*. Generalized estimating equations (GEE) will be used to explore changes in functional outcomes over the 2-

week postoperative period. For example, activity will be measured as average step per day and sleep will be measured as average nightly sleep efficiency and duration. Separate GEE will be computed for each actigraphy related measure. In the event a significant change in any of the objective outcomes, a linear mixed-effect model will be constructed to ascertain any significant differences in actigraphy collected outcomes exist between participants in the intervention and the control arms over the two-week postoperative period.

Power: A sample of 200 provides 85% power (α=0.05) to detect a difference as small as 0.5 in the mean pain score between the intervention arm and the controls using repeated measures mixed effects modeling (Power Analysis and Sample Size Software, NCSS, Kaysville, UT, USA). All analyses will be conducted in R (R Core Team, Vienna, Austria) by the Co-PI and his team at the Nell Hodgson Woodruff School of Nursing (NAG). The *glmnet* package will be used to determine which variables should be included in the regression models using a LASSO approach, the *lme4* package will be employed to compute final regressions and assess fit.[52,53] Post hoc power analyses will be conducted when exploring differences in outcomes based on demographics (e.g., gender).

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