# Trial Registry Data Set:

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| **First Submitted Date** | November 2, 2019 |
| **First Posted Date** | November 6, 2019 |
| **Actual Study Start Date** | February 21, 2020 |
| **Current Primary Outcome Measures   (submitted: June 8, 2021)** | * Opioid Pain Medication Usage [ Time Frame: Month 12 ]   The primary outcome of the single-arm pilot study will be the utilization of opioid pain medication at 1 year after the operation. This value will be compared to the 23% of a historical control cohort reporting continuing to use opioids a year post operation.   * Change in Pain Management Questionnaire (PMQ) Score [ Time Frame: Day 1 (during inpatient hospitalization), Week 2, Week 6, Month 3 ]   For participants in the dual-arm, clinical trial portion of the study, the risk of opioid misuse is assessed with the PMQ. 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.   * Change in Prescription Drug Use Questionnaire - Patient Version (PDUQp) Score [ Time Frame: Day 1 (during inpatient hospitalization), Week 2, Week 6, Month 3 ]   For participants in the dual-arm, clinical trial portion of the study, prescription drug use is assessed with the self-report version of the Prescription Drug Use Questionnaire. The PDUQp includes 31 items which are responded to as "yes" or "no". Responses of "yes" are coded as 1. Only 30 items are summed to provide a total score which can range from 0 to 30. Higher responses indicate opioid misuse behaviors.   * Change in Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance - Short Form Score [ Time Frame: Day 1 (during inpatient hospitalization), Week 2, Week 6, Month 3 ]   For participants in the dual-arm, clinical trial portion of the study, severity of insomnia, sleep disruption, and sleep quality over the past seven days is assessed with the 4-item PROMIS Sleep Disturbance - Short Form. Responses are given on a 5-point Likert scale where 1 is equivalent to best possible and 5 is equivalent to worst possible. Raw scores are converted to t-scores ranging from 0 to 100, with a mean of 50 and standard deviation of 10. Scores below 50 indicate better sleep than the average person.   * Change in PROMIS Physical Function - Short Form Score [ Time Frame: Day 1 (during inpatient hospitalization), Week 2, Week 6, Month 3 ]   For participants in the dual-arm, clinical trial portion of the study, self-reported capability to conduct physical activity is assessed with the PROMIS Physical Function - Short Form. Responses to the 4 items are given on a 5-point Likert scale where 1 = unable to do and 5 = without any difficulty. Raw scores are converted to t-scores ranging from 0 to 100, with a mean of 50 and standard deviation of 10. Scores above 50 indicate better physical function than the average person.   * Change in PROMIS Pain Interference - Short Form Score [ Time Frame: Day 1 (during inpatient hospitalization), Week 2, Week 6, Month 3 ]   For participants in the dual-arm, clinical trial portion of the study, the extent to which pain has impeded engagement with social, cognitive, emotional, physical, and recreational activities over the past 7 days is assessed with the PROMIS Pain Interference - Short Form. Responses to the 4 items are given on a 5-point Likert scale where 1 = not at all and 5 = very much. Raw scores are converted to t-scores ranging from 0 to 100, with a mean of 50 and standard deviation of 10. Scores below 50 indicate less pain interference than the average person.   * Change in Opioid Literacy Tool (OLT) Score [ Time Frame: Day 1 (during inpatient hospitalization), Month 3 ]   For participants in the dual-arm, clinical trial portion of the study, accuracy of knowledge about opioids (3 questions) and opioid-related risks (5 questions) is assessed with an OLT. Accuracy of opioid knowledge responses are given on a dichotomous scale (yes/no). 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, total scores range from 5 to 35 and higher scores indicate improved literacy (accurate understanding of prescription opioid addiction-risk, opioid dependance and risk of opioid overdose).   * Change in Primary Care Posttraumatic Stress Disorder Screen (PC-PTSD-5) Score [ Time Frame: Day 1, Month 3 ]   For participants in the dual-arm, clinical trial portion of the study, the Primary Care Posttraumatic Stress Disorder (PTSD) Screen for the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; PC-PTSD-5) will be administered. The PC-PTSD-5 is a 5-item instrument used to assess previous exposure to traumatic events and subsequent presence of the DSM-5 diagnostic criteria for PTSD. Responses are given as "yes" or "no" and each response of "yes" is scored as one point. Total scores range from 0 to 5 where higher scores indicate greater symptoms of PTSD. In primary care settings, a minimum of 3 points is considered probable PTSD. |
| **Original Primary Outcome Measures   (submitted: November 5, 2019)** | Opioid Pain Medication Usage [ Time Frame: Month 12 ]  The primary outcome of the study will be the utilization of opioid pain medication at 1 year after the operation. This value will be compared to the 23% of a historical control cohort reporting continuing to use opioids a year post operation. |
| **Current Secondary Outcome Measures   (submitted: June 8, 2021)** | * Change in Numeric Rating Scale Average Pain Score [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2), Week 6, Month 3 ]   For participants in the single-arm pilot study and in the dual-arm, clinical-trial portion of the study, daily pain within the last 24 hours will be assessed using a 10-point Likert scale where 1 = no pain and 10 = severe pain. After Week 2, pain will be assessed only during the follow up visits.   * Change in Opioid Utilization [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2), Week 6, Month 3 ]   For participants in the single-arm pilot study, and in the dual-arm, clinical-trial portion of the study, opioid utilization will be recorded in daily morphine milligram equivalents. After Week 2, opioid utilization will be assessed only during the follow up visits.   * Change in Average Steps Per Day [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2) ]   For participants in the dual-arm, clinical trial portion of the study, wrist-actigraphy devices will capture continuous postoperative functional outcomes among patients during their hospitalization and up to 2-weeks postoperatively. Activity will be measured as the average number of steps per day.   * Change in Total Sleep Time [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2) ]   For participants in the dual-arm, clinical trial portion of the study, wrist-actigraphy devices will capture continuous postoperative functional outcomes among patients during their hospitalization and up to 2-weeks postoperatively. Total sleep time is assessed in minutes of sleep per night.   * Change in Sleep Latency [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2) ]   For participants in the dual-arm, clinical trial portion of the study, wrist-actigraphy devices will capture continuous postoperative functional outcomes among patients during their hospitalization and up to 2-weeks postoperatively. Sleep onset latency is assessed as the length of time, in minutes, that it takes to transition from wakefulness to sleep.   * Change in Sleep Fragmentation [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2) ]   For participants in the dual-arm, clinical trial portion of the study, wrist-actigraphy devices will capture continuous postoperative functional outcomes among patients during their hospitalization and up to 2-weeks postoperatively. Sleep fragmentation is assessed as the number of awakenings and sleep stage shifts divided by sleep time.   * Change in Wake After Sleep Onset [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2) ]   For participants in the dual-arm, clinical trial portion of the study, wrist-actigraphy devices will capture continuous postoperative functional outcomes among patients during their hospitalization and up to 2-weeks postoperatively. Wake after sleep onset is assessed as the periods of wakefulness occurring after sleep onset.   * Change in Sleep Efficiency [ Time Frame: Day 1 (during inpatient hospitalization) up to discharge (until week 2) ]   For participants in the dual-arm, clinical trial portion of the study, wrist-actigraphy devices will capture continuous postoperative functional outcomes among patients during their hospitalization and up to 2-weeks postoperatively. Sleep efficiency is the percentage of time in bed spent sleeping (total sleep time/sleep period time x 100).   * Patient Satisfaction Survey [ Time Frame: Week 2 ]   For participants in the single-arm pilot study and in the dual-arm, clinical-trial portion of the study, patient satisfaction with 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. |
| **Original Secondary Outcome Measures   (submitted: November 5, 2019)** | * Change in Pain Score [ Time Frame: Week 2, Week 6, Month 3, Month 6, Month 12 ]   Pain will be assessed using an 11-point Likert scale where 0 = no pain and 10 = severe pain.   * Change in Opioid Utilization [ Time Frame: Day 1 (at hospital discharge), Week 2, Week 6 ]   Opioid utilization will be recorded in morphine equivalents. |
| **Brief Title** | **Life** Care **Specialists** (LCS) With a Focus on Patient **Pain** Management and Prevention of Substance Misuse |
| **Official Title** | **Life** Care **Specialists** (LCS) With a Focus on Patient **Pain** Management and Prevention of Substance Misuse |
| **Study Type** | Interventional |
| **Study Phase** | Not Applicable |
| **Study Design** | Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description:  There were 121 participants in the single-arm pilot trial of this study where the intervention was refined. The clinical trial portion of this study randomizes participants to receive the intervention or the standard of care.  Masking: None (Open Label) Primary Purpose: Prevention |
| **Condition** | Opioid Use |
| **Intervention** | * Behavioral: **Pain** Management Strategies   The **Life** Care **Specialist** (LCS) teaches evidence-informed behavioral interventions and will work with the patient to develop personalized **pain**management strategies focused on behavioral education, including progressive muscle relaxation (PMR), the Community Resiliency Model (CRM®), motivational interviewing, and reflective listening.   * Behavioral: **Life** Care **Specialist** (LCS) Intervention   The **Life** Care **Specialist** (LCS) uses a two-arm approach to education by initially assessing participants general understanding of opioids upon which targeted education is tailored and applied and secondly, building a longitudinal relationship with each patient to increase the saliency of administered opioid education during postoperative follow-up. Information includes proper disposal, common symptoms of opioid use, signs of dependence and overdose and use of naloxone. Information is disseminated orally with adjunct physical resource guides including visual representations and literature.  Other Name: Opioid Education   * Other: Clinical Coordination with Referrals   The **Life** Care **Specialist** (LCS) can help arrange a referral for the participant, should a medical or social issue be identified during LCS intervention, including mental health services, addiction medicine services, housing insecurity referrals, food insecurity referrals, and amputee support. When giving referrals, the LCS works closely with physicians and nurses to make sure that the participant is a good fit for the referral program. |
| **Study Arms** | * Experimental: Pilot Study of **Pain** Management Strategies   Orthopedic trauma patients will work with a **Life** Care **Specialist** (LCS) and will receive personalized **pain** management strategies to avoid potential opioid misuse. Participants will be followed for one year post operation. An official **pain** management protocol will be developed during the pilot portion of this study.  Intervention: Behavioral: **Pain** Management Strategies   * Experimental: **Life** Care **Specialist** (LCS) Intervention   In addition to receiving current standard-of-care for **pain** management in the aftermath of trauma, participants will have the full communication of opioid risk - via the validated Opioid Risk Tool (ORT) and a detailed substance abuse and mental health screening. As part of the daily LCS intervention, the inpatients will engage in behavioral **pain** management, opioid education and harm-reduction strategies (naloxone education), while also being screened for eligibility for respective referrals for complex needs, such as mental health and substance use disorders. Upon discharge, each participant will be educated by the LCS on future available modes of contact (telephone, email, video-call, follow up- visits at 2-, 6- and 12-weeks).  Intervention: Behavioral: **Life** Care **Specialist** (LCS) Intervention   * Active Comparator: Standard of Care with Clinical Coordination   Participants will receive the current standard-of-care for **pain** management in the aftermath of trauma, including a standardized prescription protocol, and hospital-system approved discharge instructions which provide written instruction on how to taper opioid use and links to written/online resources for opioid misuse, overdose prevention, and State-approved disposal options.  Intervention: Other: Clinical Coordination with Referrals |
| **Recruitment Status** | Enrolling by invitation |
| **Estimated Enrollment    (submitted: June 8, 2021)** | 321 |
| **Original Estimated Enrollment    (submitted: November 5, 2019)** | 200 |
| **Estimated Study Completion Date** | January 2022 |
| **Estimated Primary Completion Date** | January 2022   (Final data collection date for primary outcome measure) |
| **Eligibility Criteria** | Inclusion Criteria for Single-Arm Pilot Portion of this Study:   * Orthopaedic trauma patients with planned surgical procedure * Informed consent obtained   Exclusion Criteria for Single-Arm Pilot Portion of this Study:   * 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 or Spanish at elementary school level   Inclusion Criteria for Clinical Trial Portion of this Study:   * Orthopaedic trauma patients with an isolated injury requiring surgery * Informed consent obtained * Functioning cellphone   Exclusion Criteria for Clinical Trial Portion of this Study:   * 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 or Spanish at elementary school level * Unlikely to complete surveys at home, access to phone * Unlikely to respond to opioid utilization text messaging (SMS) * Incarcerated * Pregnant |
| **Sex/Gender** | |  |  | | --- | --- | | Sexes Eligible for Study: | All | |
| **Ages** | 18 Years and older   (Adult, Older Adult) |
| **Accepts Healthy Volunteers** | No |
| **Listed Location Countries** | United States |
| **NCT Number** | NCT04154384 |
| **Other Study ID Numbers** | IRB00115061 |
| **IPD Sharing Statement** | |  |  | | --- | --- | | Plan to Share IPD: | Yes | | Plan Description: | Deidentified, individual participant data will be made available for sharing upon request from other researchers. | | Supporting Materials: | Study Protocol | | Supporting Materials: | Statistical Analysis Plan (SAP) | | Time Frame: | Individual participant data will be available for sharing following publication of the findings from this study until 5 years after publication. | | Access Criteria: | Researchers interested in accessing data should provide a description of the proposed project to Dr. Schenker at mara.schenker@emory.edu. | |
| **Study Sponsor** | Emory University |
| **Collaborators** | Christopher Wolf Crusade (CWC) |
| **Investigators** | |  |  |  | | --- | --- | --- | | Principal Investigator: | Mara Schenker, MD | Emory University | |