NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Nonpharmacologic Options in Postoperative Hospital-Based and Rehabilitation Pain Management (NOHARM)

Principal Investigators
Andrea Cheville, MD; Jon Tilburt, MD

Sponsoring Institution
Mayo Clinic Rochester, MN

Collaborators
· Mayo Clinic Rochester
· Mayo Clinic Florida
· Mayo Clinic Arizona
· Mayo Clinic Upper Midwest Health System

NIH Institute Providing Oversight
National Institute on Aging (NIA)

Program Official
Marcel Salive, MD (NIA)

Project Scientist
Theresa Cruz, PhD (National Institute of Child Health and Human Development [NICHD])

ClinicalTrials.gov Identifier
NCT04570371

ABSTRACT

Prescriptions for narcotic pain relief after surgery result in unintended prolonged opioid use for hundreds of thousands of Americans. That trend fuels an excess supply of opioids that can lead to dependence, addiction, diversion, and overdoses on a national scale. Nonpharmacologic pain care is effective and recommended by guidelines for perioperative pain while offering a more favorable risk-benefit ratio. However, nonpharmacologic pain care is rarely used as first- or second-line therapy after surgery. Patient and clinician decision support interventions are effective in encouraging patient-centered and guideline-concordant care, but these strategies have not been tested pragmatically as a bundle in everyday postoperative pain care.

The NOHARM trial will test an EHR-embedded, bundled intervention comprised of patient- and clinician-facing decision support components that enable patients to integrate nonpharmacologic pain care into their perioperative management. NOHARM will employ a stepped-wedge, cluster randomized pragmatic clinical trial design. Clusters throughout the Mayo Clinic Enterprise spanning 6 institutions in 4 states will participate. The NOHARM trial will evaluate whether pain and function, assessed with PROMIS tools, can be improved while honoring patient values and deemphasizing opioids in pain management.

MAYO CLINIC

HEALING AFTER SURGERY: MANAGING PAIN

Step 1: Register for the portal
The patient portal (Patient Online Services) allows you to be actively involved in planning how to manage your pain post-surgery. By logging on to the portal, you can learn more about different pain management strategies, try them out on your own, and indicate your preferences for your hospital stay. For assistance setting up a new patient portal account, you can call Mayo Clinic customer assistance at **1-877-858-0398** or you can visit window 17 or 18 on the ground floor of the Gonda building at Mayo Clinic's Rochester site.

Step 2: Learn about pain management options
Soon after your surgery is scheduled, you will receive a questionnaire called "Healing After Surgery" in your patient portal inbox. This questionnaire is different from other patient questionnaires. It includes information about different pain management options and guidance on how to practice them prior to your surgery.

Step 3: Choose pain management options
After learning about the different types of pain management options available to you, select the strategies that you are interested in trying during your hospital stay and after you return home. Your selections will then be shared with your care team, so that they can be used to assist with managing your pain during your recovery.

Step 4: Use pain management option at home
Once you are home and recovering from your surgery, you will be able to access videos and other resources that will help you in using your preferred pain management approaches. Just go to **healingaftersurgery.com**. Your care team may also follow up with you to ask how things are going and if you need any additional support.

MAYO CLINIC | 200 First Street SW | Rochester, MN 55905 | mayoclinic.org
©2020 Mayo Foundation for Medical Education and Research. All rights reserved. MAYO, MAYO CLINIC and the triple-shield Mayo Logo are trademarks and service marks of MFMER.
MC7823rev0420

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Accurately identifying and assigning the intervention to eligible patients within the electronic health record (EHR) in an automated way	The study implemented appropriate ordering, referring, and prescribing (ORP) codes for automatic assignment.
Helping clinic staff know which patients are enrolled in the NOHARM trial	The study added a banner in the Epic system to help clinical teams easily identify NOHARM patients.
Identifying and accounting for the number and variability of clusters based on size, geography, and median pain burden of the patient population	The team worked with the Biostatistics and Study Design Core to plan a "constrained randomization" design, which will help with managing varied cluster sizes, geographic locations, and practice volumes as part of the stepped-wedge, cluster randomized trial.
Modifying the primary outcome measure due to incomplete ascertainment	The team determined that pain interference and physical function measures would be co-primary endpoints at 1, 2, and 3 months.

"We are excited to bring our novel use of the EHR as a critical and central intervention component and to bring that approach to the Collaboratory so we can both teach and learn."

SELECTED PRESENTATIONS

- Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (2023)
- Article (Study Design): Non-pharmacological Options in Postoperative Hospital-Based and Rehabilitation Pain Management (NOHARM): Protocol for a Stepped-Wedge Cluster-Randomized Pragmatic Clinical Trial (2022)
- PCT Grand Rounds Presentation: Learning While Sprinting: A One-Year Retrospective from the NOHARM Pragmatic Trial (2020)

Access the complete set of NOHARM resources.