NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

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

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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 (NPPC) into their perioperative management. NOHARM will employ a stepped-wedge, cluster-randomized pragmatic clinical trial design. Clusters throughout 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.

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 Collaboratory's 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.