



OPTIMUM Case Study

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Essentials of Embedded Pragmatic Clinical Trials

Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting (OPTIMUM)

Rationale:

- Mindfulness is effective for the treatment of chronic low back pain but remains underutilized as it has not been regularly integrated into the outpatient clinical setting

Primary hypothesis:

- Compared with usual care, patients receiving the intervention will have improved pain intensity, pain interference, and improved psychological function at the completion of the program and at 6 and 12 months, and that patients will be less likely to start and more likely to reduce or stop an opioid prescription for chronic low back pain

OPTIMUM Demonstration Project

- Pragmatic trial testing an evidence-based group mindfulness pain program across 3 diverse healthcare systems
- Goals are to assess the program's impact on patient outcomes and to inform decision makers about how this program can work in a real-life clinical setting

Study design

- 8 weekly, 90-minute, group-based mindfulness sessions delivered virtually
- Patients with chronic low back pain are referred by a primary care physician (PCP) at a participating practice to these 2 study arms:
 - Usual care with a PCP, consisting of both pharmacologic and nonpharmacologic approaches to pain management
 - Mindfulness intervention plus usual care with a PCP
- Questionnaires and follow-up will be the same for both study arms

Potential barriers

- Pivoting to virtual mindfulness group sessions was challenging because of potential technical difficulties, mostly related to unstable network connections and familiarizing participants with Zoom
- Asking participants to attend and commit to multiple remote sessions for a period of time added a layer of complexity to the overall scheduling challenge

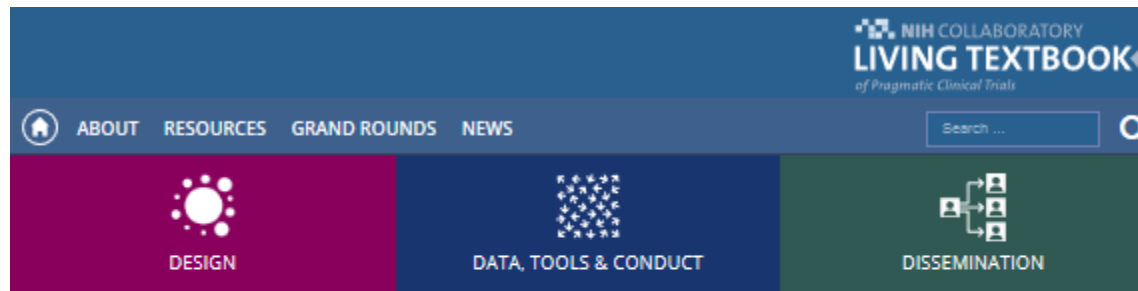


Lessons learned

- Having a dedicated team provide technical support throughout the pilot intervention was important
- Conducting sessions in the late afternoon or early evening was the most feasible solution across sites



Resource: The Living Textbook



UH3 Project: Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting (OPTIMUM)



Principal Investigator: [Natalia Morone, MD](#)

Sponsoring Institution: Boston Medical Center

Collaborators:

- Boston Medical Center, MA
- University of Pittsburgh Medical Center, Pittsburgh, PA
- Piedmont Health Services, in partnership with the University of North Carolina, Chapel Hill

NIH Institute Providing Oversight: [National Center for Complementary and Integrative Health \(NCCIH\)](#)

Program Official: Wendy Weber, ND, PhD, MPH (NCCIH)

Project Scientist: Luke Stoeckel, PhD ([National Institute on Aging \(NIA\)](#))

ClinicalTrials.gov Identifier: [NCT04129450](#)

Trial Status: Not yet recruiting

[Study Snapshot](#)

Video



Principal Investigator Dr. Natalia Morone discusses the OPTIMUM Demonstration Project.

Data and Resource Sharing

[OPTIMUM Ethics and Regulatory UH3 Follow-up](#)

[OPTIMUM Ethics and Regulatory Discussion](#)

News and Interviews

[October 6, 2020: Four PRISM Demonstration Projects Awarded Continuation from Planning to Implementation Phase](#)

[Dr. Natalia Morone Introduces the OPTIMUM Demonstration Project](#)

[March 2, 2020: OPTIMUM to Bring Mindfulness-Based Stress Reduction to the Clinic: An Interview With Dr. Natalia Morone](#)