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

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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

Video
Principal investigator Dr. Natalia Morone discusses the OPTIMUM Demonstration Project.

Data and Resource Sharing
OPTIMUM-Ethics and Regulatory UH3 Followup
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