
PI: Natalia Morone, MD, MS Boston Medical

Site shared PI: Kathleen McTigue, MD, MPH, University of Pittsburgh

Site shared PI Carol Greco, PhD, University of Pittsburgh

Site shared PI: Susan Gaylord, PhD, University of North Carolina, Chapel Hill

Site shared PI: Kim Faurot, PhD, University of North Carolina, Chapel Hill

# Brief Overview

**Summary**

A pragmatic clinical trial integrating a telehealth group-based mindfulness stress reduction program into primary care settings for persons with chronic low back pain

**Study design**

Pragmatic randomized controlled trial

One year follow-up

**Population**

450 patients with chronic low back pain ≥18 years of age

Three healthcare systems: Boston Medical Center, UPMC, North Carolina

**Comparison**

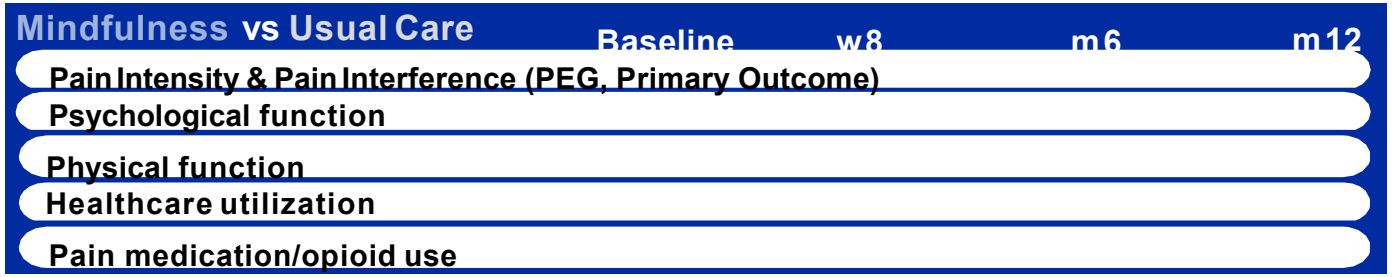
**Intervention group**

**225** participate in 8-week Mindfulness Based Stress Reduction program

**Control group**

**225** receive usual primary care

**Outcomes**



# Current Status

| Description | All Sites (N/N, %) |
|---|---|
| Number screened eligible | 801/1247, 64% |
| Number screened ineligible | 443/1247, 36% |
| Number consented | 452/801, 56% |
| Number consented but withdrawn before randomization | 31/452, 7% |
| Number assigned to cohort | 376/421, 89% |
| Number completed baseline | 379/421, 90% |
| Number randomized | 366/421, 87% |

Optimum

# Barriers Scorecard

| Barriers | Level of Difficulty* | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 |
| Enrollment and engagement of patients/subjects | | | x | | |
| Engagement of clinicians and health systems | | | x | | |
| Data collection and merging datasets | | | x | | |
| Regulatory issues (IRBs and consent) | | | | x | |
| Stability of control intervention | | x | | | |
| Implementing/delivering intervention across healthcare organizations | | x | | | |
| Maintaining integrity of mindfulness program | | x | | | |

*Your best guess!
1 = little difficulty
5 = extreme difficulty

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

# Top Challenges

- Keeping up the momentum of recruitment
- Engagement in the intervention
- Preparing for the final phase of the trial

# Recent Generalizable Lesson Learned

Stakeholders such as a community advisory board can have a lasting and positive impact on a trial

# Data Sharing Plan

Data available to other investigators under a formal data-sharing agreement that:

(1) Demonstrates commitment to use data for research purposes only

(2) Demonstrates commitment to use appropriate information technology systems to keep data secure

(3) Demonstrates commitment to returning or destroying data after analyses are complete

(4) Outlines the intended use of data with specific variables outlined and analyses described

(5) Demonstrates data will only be shared provided IRB approval is obtained or evidence of IRB exemption is received

# What data from OPTIMUM will be shared?

- Group-level data
- Individual-level data with potential exclusions

# Current Data Sharing Obstacles

- The process for creating datasets that are understandable to those unfamiliar with the data

- Deciding what data should require permission to use vs data that is freely available

# Thank You