

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

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**ClinicalTrials.gov Identifier**

[NCT04129450](#)

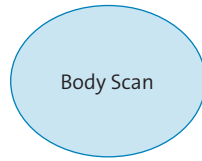
## ABSTRACT

Chronic low back pain (cLBP) is one of the most common conditions treated in the primary care setting, yet treatment remains unsatisfactory for many patients. The opioid crisis has underscored the urgency of alleviating patients' cLBP with effective therapies, including evidence-based nonpharmacologic approaches. Mindfulness is effective for the treatment of cLBP but remains underutilized as it has not been regularly integrated into the outpatient clinical setting.

Mindfulness-Based Stress Reduction (MBSR) is now recommended by the American College of Physicians for initial treatment of cLBP. The primary goal of OPTIMUM is to determine the impact of a group-based mindfulness intervention under usual care circumstances. The implementation phase will integrate MBSR, delivered online, in a primary care setting with 450 patients  $\geq 18$  years of age who have cLBP, comparing mindfulness plus usual care versus usual care alone. Among the hypotheses are that, 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 cLBP compared with those receiving usual care. Another aim of the trial is to evaluate the use of, satisfaction with, and integration of this innovative intervention delivered in a real-world setting.

## OPTIMUM CLINICAL PAIN PROGRAM

**Program principles:** Four methods of mindfulness meditation



**Program protocol:** Use evidence-based protocol from large clinical trial of mindfulness-based stress reduction for chronic low back pain

## WHAT WE'VE LEARNED SO FAR

Challenge	Solution
The global COVID-19 pandemic thrust remote healthcare into the spotlight. Delivering the mindfulness intervention remotely (via Zoom) was challenging because of potential technical difficulties, mostly related to unstable network connections and familiarizing participants with Zoom.	A dedicated team provided technical support throughout the pilot intervention. The team decided to call participants in advance to help minimize the likelihood of technical problems during each session. This solution allowed the team to troubleshoot internet issues.
With a new way of delivering mindfulness, there were challenges in keeping the participants actively participating and engaged during the sessions.	The mindfulness instructors worked efficiently to create interactions that encouraged session completion. The technical support helped make this possible by assuring good visibility, among other elements, between the instructors and the participants.
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.	The study team created spreadsheets to track patients' availability and determine the best day and time to deliver the mindfulness intervention. Conducting sessions in the late afternoon or early evening was the most feasible solution across sites.

*“We need to demonstrate to patients, clinicians, and administrators how mindfulness can be woven into primary care and what the results are when delivered in a real-world setting.”*

## SELECTED PUBLICATIONS & PRESENTATIONS

- Article (Study Design): [The Design and Methods of the OPTIMUM Study: A Multisite Pragmatic Randomized Clinical Trial of a Telehealth Group Mindfulness Program for Persons With Chronic Low Back Pain](#) (2021)
- Presentation: [Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee](#) (2023)

Access the complete set of [OPTIMUM resources](#).