A Telehealth-Delivered Pragmatic Trial of Mindfulness for Persons with Chronic Low Back Pain

Natalia E. Morone, MD, MS
Associate Professor of Medicine
Boston University School of Medicine
Boston Medical Center
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Pain

An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage

*International Association for the Study of Pain*
Chronic Pain

Chronic pain results from combined biologic, psychologic, and social factors, and most often requires a multifactorial approach to management.

*Up To Date (electronic clinical resource)*
Pain Experience

It was something that had the power to grip me...a stabbing knife...[something that] had mechanical power to grab me and inject pain into me. . . . It was something [out of] a monster show that could grab you and hurt you

Percentage of adults aged 18 and over who had back pain in the past 3 months, by race: United States, 2019

Source: National Center for Health Statistics, National Health Interview Survey, 2019
Mindfulness
Key Elements of Mindfulness

"Paying attention"

"In the present moment, non-judgmentally"

"On purpose"

Adapted from Shapiro et al. (2006). J Clin Psychol.
Mindfulness-based Stress Reduction
Recommendation 2: For patients with CLBP ...initially select nonpharmacologic treatment...mindfulness-based stress reduction (moderate-quality evidence)
The intervention participants had more improvement in their back pain symptoms compared to the control participants ($P<.0001$).
Proportion with clinically meaningful change after MBSR

**8 wks**
- RMDQ: MBSR 57, Control 45
- Current pain: MBSR 41, Control 25

**6 mos**
- RMDQ: MBSR 49, Control 49
- Current pain: MBSR 44, Control 25

RMDQ = Roland & Morris Disability Questionnaire
MBSR = Mindfulness Based Stress Reduction

Morone et al. JAMA internal medicine. 2016
Barriers to clinical uptake

• Underutilized as not woven into outpatient clinical setting

• Not routinely reimbursed by health insurance companies for cLBP

• Next step is to inform how this program can work in a real-life setting

How do we integrate mindfulness for low back pain into primary care?
PI: Natalia Morone, MD, MS Boston University/Boston Medical Center
Site shared PIs: Kathleen McTigue, MD, MPH, Carol Greco, PhD, University of Pittsburgh
Site shared PIs: Susan Gaylord, PhD, Kim Faurot, PhD, University of North Carolina, Chapel Hill
Three Health Care Systems

• Boston Medical Center: safety net health system

• UPMC, Pittsburgh, PA: large academic health system

• UNC Chapel Hill in Partnership with Piedmont Health Services: federally funded health centers
OPTIMUM STUDY

Participants screened for eligibility → Informed Consent

If eligible → Baseline Assessment

450 Participants

University of Pittsburgh, PA (n=150) → MBSR + PCP Usual Care

Boston Medical Center, Boston, MA (n=150) → PCP Usual Care

University of North Carolina at Chapel Hill (n=150)

8 week Assessments → Intervention participant exit interview

6 month Assessments

12 month Assessments
Inclusion & Exclusion Criteria

Inclusion criteria
1. Primary care patient at a participating practice
2. Age ≥ 18
3. cLBP, pain that persists for ≥ 3-months and has resulted in pain on at least half the days in the past 6 months
4. Speak English

Exclusion criteria
1. Red flags
2. Pregnancy
3. Metastatic Cancer
4. Same household
5. Not a patient in a participating clinic
Primary Hypothesis: patients in OPTIMUM will have significantly improved pain intensity and interference as measured by the PEG composite score at completion of the program and 6- and 12-months later, as compared to PCP Usual Care.
Secondary Outcomes

- Physical function
- Psychological function
- Opioid use
- Healthcare utilization
- Provider and clinic satisfaction with OPTIMUM program
### Patient-reported Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>T1 Baseline</th>
<th>T2 8-wks</th>
<th>T3 6-mo</th>
<th>T4 12-mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>*PEG</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>PROMIS, 4-items physical function</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>PROMIS-29: health related quality of life and pain impact**</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Depression &amp; Anxiety, PROMIS, 4-items each</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Current Opioid Misuse Measure, 17-items, if taking opiate</td>
<td>X</td>
<td>X</td>
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<tr>
<td>CAMS-R (mindfulness)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Satisfaction, single item</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Global Impression of Change, single item</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Opioid Use, single item</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Demographics</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Screening questionnaire</td>
<td>X</td>
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<tr>
<td>Pain Medications (collected monthly)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Charlson Co-Morbidity Index</td>
<td>X</td>
<td></td>
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<tr>
<td>Health Care System Utilization (self-report)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>HEAL-CAM Attitudes/Expectation</td>
<td>X</td>
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</tbody>
</table>

*Primary outcome; **Pain impact is defined as Pain intensity, pain interference and functional status PROMIS-29.

PROMIS: patient reported outcomes measurement information system.
<table>
<thead>
<tr>
<th>EHR Outcomes</th>
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<tbody>
<tr>
<td>1. Opioid prescriptions and other prescriptions for pain</td>
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<tr>
<td>2. CT/MRIs of lumbar-sacral spine</td>
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<tr>
<td>3. Injections of lumbar-sacral spine</td>
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<td>4. ED/urgent care visits for LBP</td>
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<td>5. Surgeries of lumbar spine</td>
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<td>6. Hospitalizations for LBP</td>
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<td>7. Primary Care Provider visits for LBP</td>
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<td>8. Physical therapy referrals for LBP</td>
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Randomization

- Block randomization
- Stratified by clinic and sex
- Patient level randomization
OPTIMUM: clinical pain management program

• Modeled on the Mindfulness-based Stress Reduction Program

• 8-weekly 90 minutes sessions, group-based

• Delivered in primary care through a telehealth medical group visit model
OPTIMUM: clinical pain management program

Program Principles. Four methods of mindfulness meditation

- Walking Meditation
- Body Scan
- Focused Meditation
- Mindful Stretching

Program Protocol. Using evidence-based protocol from our large clinical trial of MBSR for cLBP
Patient signs in to group Zoom with mindfulness instructor, primary care provider, and other patients

Patient meets with provider for brief check-in via breakout room

Patient returns to full group and participates in mindfulness program
Medical Group Visits Improve

• Access and amount of time with a clinician
• Patient satisfaction
• Health services utilization (ED visits, repeat admissions)
• Medication adherence
• Health behaviors (dietary modifications, exercise)
• Quality of life
• Disease-specific outcomes

Where are we now?
OPTIMUM Cumulative Enrollment
Racial Distribution of Participants

Percentage of OPTIMUM participants, by race
As of March 2022 (n = 153)

- Other: 4.6%
- Hispanic: 3.3%
- Non-Hispanic White: 43.8%
- Non-Hispanic Black: 45.1%
- Asian: 2.0%
Quotes

I mean the way it helps with your pain is, it's not going to take it fully away, but if you can catch it early on, you can definitely take that meditation and ease it, and help you, and cope with the pain a lot better than before.

...when I put myself in that state. I relax more therefore I think my nerves relax as well. And they don't really--instead of cringing, they kind of take a break and there's no pressure on my nerves, so I don't feel as much pain....

It impacted my tongue. I grab my tongue and watch what I say.
STOP

• **S** Stop (come into **S**tillness)

• **T** Take time to breathe

• **O** Observe & **O**pen to experience (body sensations, emotions, thoughts, impulses)

• **P** Proceed
Supplement: Stakeholder

Figure 2. Summary of Stakeholder Activities

OPTIMUM STUDY

EXPANDED Stakeholder Engagement

EXISTING Stakeholder Engagement

AIMS

1. Expanded Community Advisory Board
   - 10 members will meet monthly

2. Multi-level stakeholder perspectives
   - Focus groups of cLBP patients
   - Healthcare administrators
   - Advocacy groups
   - Clinic personnel
   - Payors

3. Patients perspective through stories
   - Story Booth

Existing Community Advisory Board
- (6 members meet twice a year)

Intervention participants exit interview

Survey of providers about experiences of intervention
Aim 1: Estimate the prevalence of dietary supplement and natural product use, including cannabis, and cannabidiol use for chronic pain in the United States and Canada

Aim 2: Characterize dietary supplement and natural product use within the OPTIMUM cohort through qualitative assessments
OPTIMUM Team

Boston
Janice Weinberg
Jose Baez
Paula Gardiner
Tra Nguyen
Ruth Rodriguez
Megan McGillis
Bella Patel
Kristina Astone
Tuhina Neogi
Karen Lasser
Daniel Schenck
Dhanesh Binda

University of North Carolina at Chapel Hill
Susan Gaylord
Kim Faurot
Christine Lathren
Isabel Roth
Jessica Barnhill
Gabriela Castro
Nandie Elhadidy
Kelly Marie Eason
Malik Tiedt
Elondra Harr
Paula Huffman

Pittsburgh
Carol Greco
Kathleen McTigue
Holly Thomas
Suzanne Lawrence
Janice Thieret
Graham Dore
Anna White

NIH Pragmatic Trials Collaboratory
NCCIH Program Officer Dr. Wendy Weber
NIA Scientific Officer Dr. Luke Stoeckel

“Piglet noticed that even though he had a Very Small Heart, it could hold a rather large amount of Gratitude.”
- A.A. Milne, Winnie-the-Pooh
Thank You
Questions Welcomed