PI: Natalia Morone, MD, MS Boston Medical

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

Site share PI Carol Greco, PhD, University of Pittsburgh

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

OPTIMUM Team

Boston
Natalia Morone, MD, MS
Janice Weinberg ScD
Paula Gardiner, MD, MS
Tuhina Neogi, MD, PhD
Karen Lasser, MD, MPH

Pittsburgh
Kathleen McTigue, MD, MPH, MS
Carol Greco, PhD
Holly Thomas, MD, MS

Chapel Hill
Susan Gaylord, PhD
Kim Faurot, PhD
Gaby Castro, MD
SO: Luke Stoeckel, PhD

Background

- Mindfulness effective for the treatment of chronic low back pain (cLBP)
- Underutilized as not woven into outpatient clinical setting
- Not routinely reimbursed by health insurance companies for cLBP
- MBSR now part of evidence-based guidelines for treating cLBP
- Next step is a PCT to inform how program can work in a real-life setting

MBSR=Mindfulness-Based Stress Reduction

Morone NE, et al. *JAMA Intern Med.* 2016;176(3):329-337.
Cherkin DC, et al. *JAMA*. 2016;315(12):1240-1249.
Qaseem A, Wilt TJ, McLean RM, Forciea MA, Clinical Guidelines Committee of the American College of P. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med.* 2017;166(7):514-530.

OPTIMUM: Aims

- **UG3 Aim 1**. To plan and test a mindfulness clinical pain program, OPTIMUM, in the 3-HCS sites prior to the full PCT during the first 12-months of the project.

- **UH3 Aim 2:** 450 persons with cLBP ≥ 18 years of age will be individually randomized either to an 1) 8-week mindfulness clinical pain program (n=225) + PCP Usual Care or 2) PCP Usual Care (n=225).

  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.

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

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

All participants will provide informed consent

Randomization

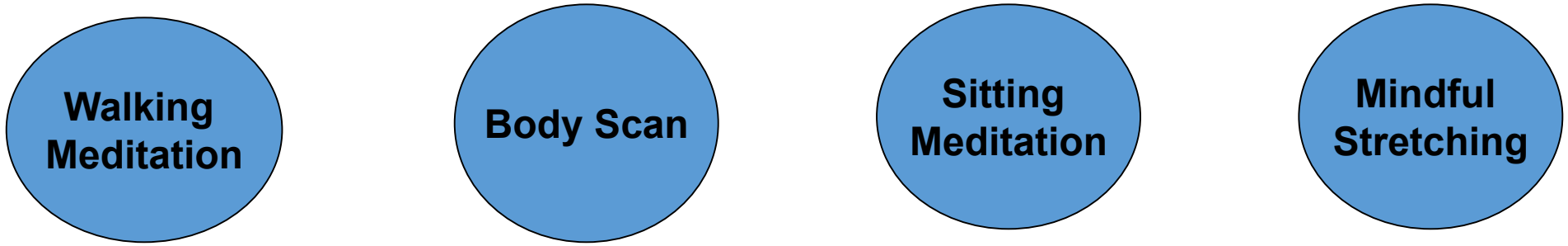
- Block randomization
- Stratified by clinic and sex
- Patient level randomization

OPTIMUM: clinical pain program

- Modeled on MBSR; our team previously demonstrated efficacy in a single-site RCT
- 8-weekly 90 minutes sessions, group-based, billed by clinical personnel
- Delivered in primary care through a medical group visit model

OPTIMUM Clinical Pain Program

Program Principles. Four methods of mindfulness meditation



Program Protocol. Using evidence-based protocol from our large clinical trial of MBSR for cLBP

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 (BP, dietary modifications, exercise)
- Quality of life
- Disease-specific outcomes

(Jaber et al, 2006; Cramer et al, 2013; Berman et al, 2004; La Cour & Peterson 2015; Tsao 2007, Vickers et al.2012)

Medical Group Visit

- Billing provider and MBSR instructor
- Patients arrive at once to clinic and sit in a room together (circle)
- Patients fill out intake form and record own vitals at start of each group
- Patients meet with the clinician before and after group
- Provider bills for an individual visit
- Provider documents note in electronic health record

Control

PCP Usual Care: standard of care for cLBP

Non-pharmacologic approaches

Pharmacologic approaches

Patient-reported Measures	**T1 Baseline**	**T2 8-wks**	**T3 6-mo**	**T4 12-mo**
*PEG	X	X	X	X
Pain Numeric Rating Scale, 3-items: present, mean, most severe	X	X	X	X
PROMIS, 4-items physical function	X	X	X	X
PROMIS-29: health related quality of life and pain impact**	X	X	X	X
Depression & Anxiety, PROMIS, 4-items each	X	X	X	X
Current Opioid Misuse Measure, 17-items, if taking opiate	X	X	X	X
CAMS-R (mindfulness)	X	X	X	X
Satisfaction, single item		X	X	X
Global Impression of Change, single item		X	X	X
Opioid Use, single item	X	X	X	X
Demographics	X			
Screening questionnaire	X			
Pain Medication (s)	X	X	X	X
Charlson Co-Morbidity Index	X			
Health Care System Utilization (self-report)		X	X	X
HEAL-CAM Attitudes/Expectation	X			

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

EHR Outcomes

1. Opioid prescriptions and other prescriptions for pain
2. CT/MRIs of lumbar-sacral spine
3. Injections of lumbar-sacral spine
4. ED/urgent care visits for LBP
5. Surgeries of lumbar spine
6. Hospitalizations for LBP
7. PCP visits for LBP
8. Physical therapy referrals for LBP

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

Barriers Scorecard

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

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

Thank You