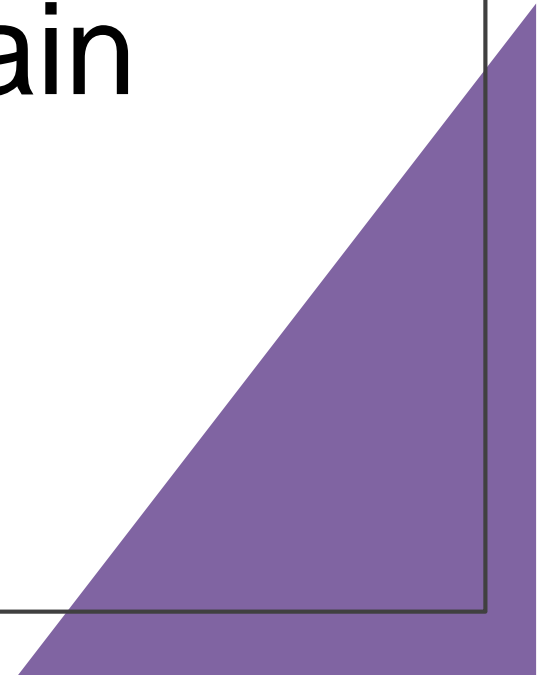


# A Telehealth-Delivered Pragmatic Trial of Mindfulness for Persons with Chronic Low Back Pain

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Associate Professor of Medicine  
Boston University School of Medicine  
Boston Medical Center  
March 25, 2022



# Outline

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Background Pain

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Evidence for Mindfulness  
& chronic low back pain

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OPTIMUM Study

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# Pain

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

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*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)*



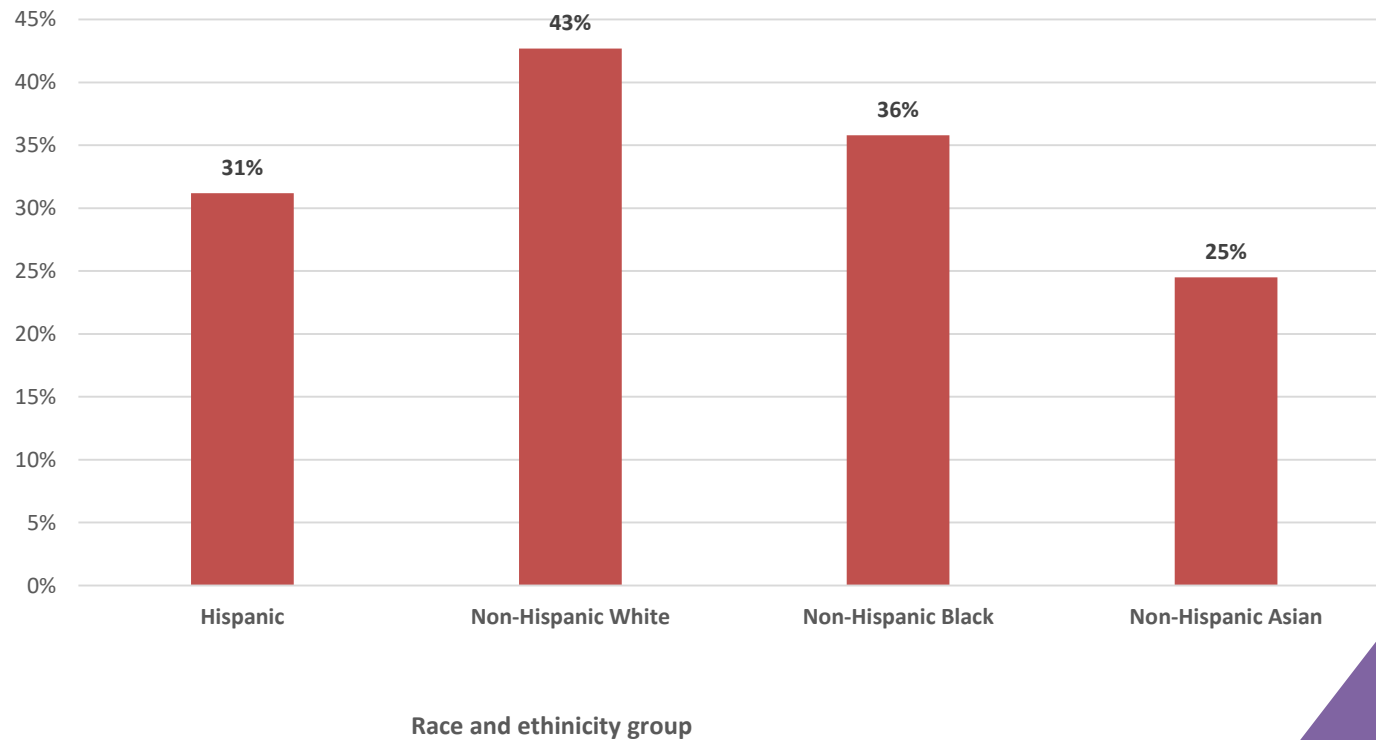
# Pain Experience

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

Luiggi-Hernandez, et al Pain Medicine 2017

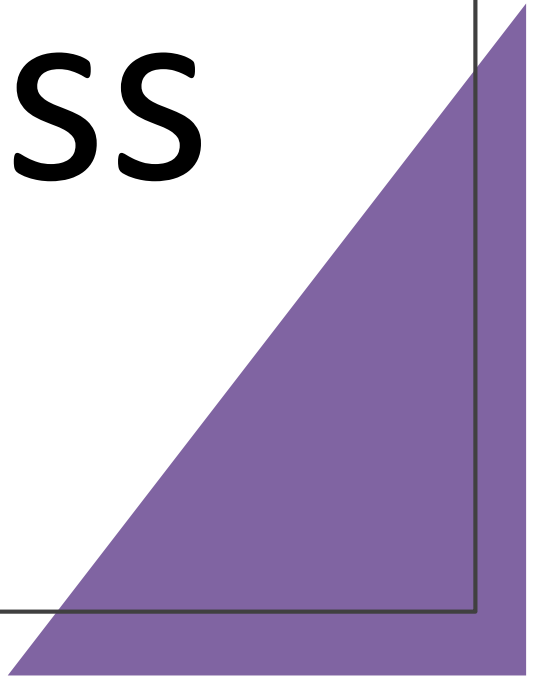


**Percentage of adults aged 18 and over  
who had back pain in the past 3 months, by race: United States,  
2019**

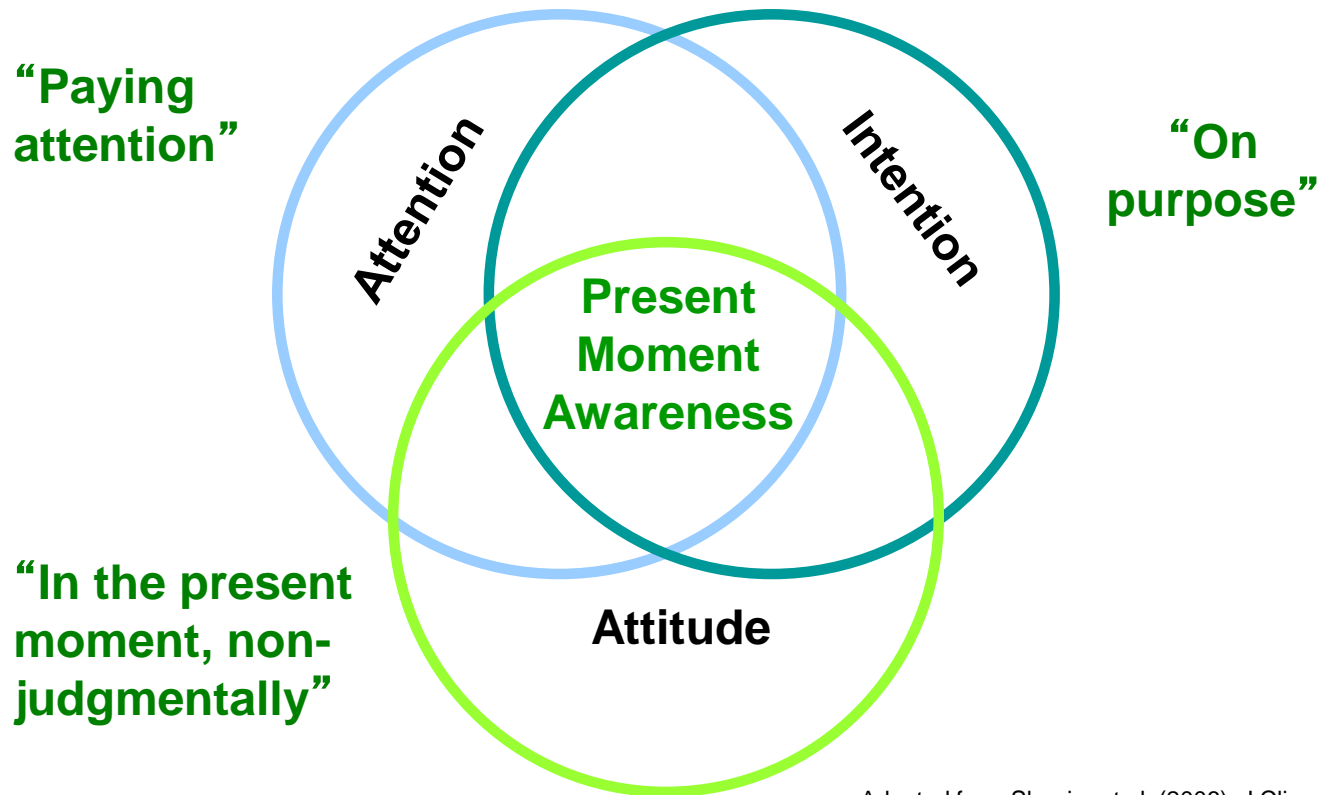


*Source: National Center for Health Statistics, National Health Interview Survey, 2019*

# Mindfulness

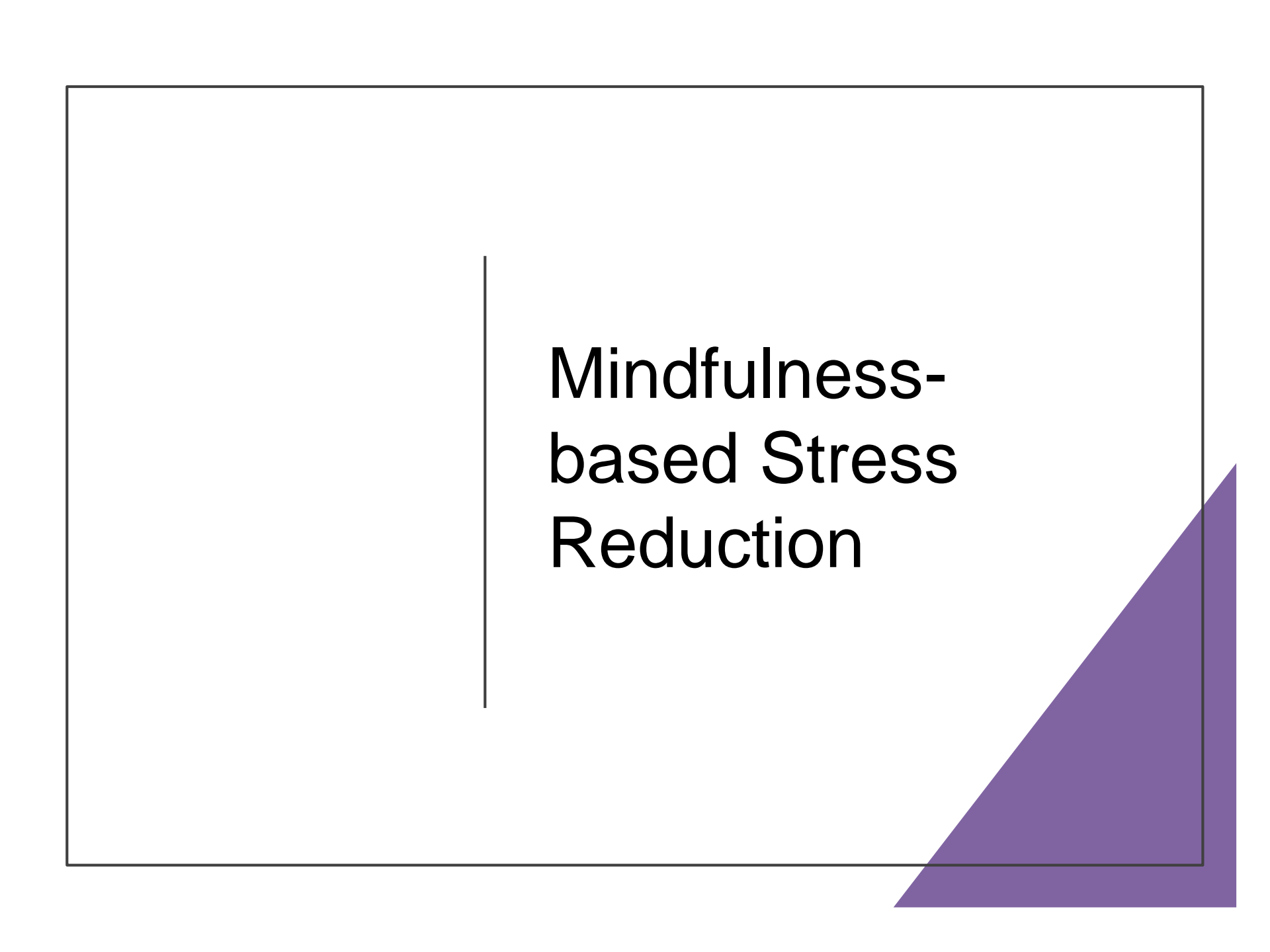


# Key Elements of Mindfulness



Adapted from Shapiro et al. (2006). J Clin Psychol.





# Mindfulness- based Stress Reduction

# Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; and Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians\*

**Description:** The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain.

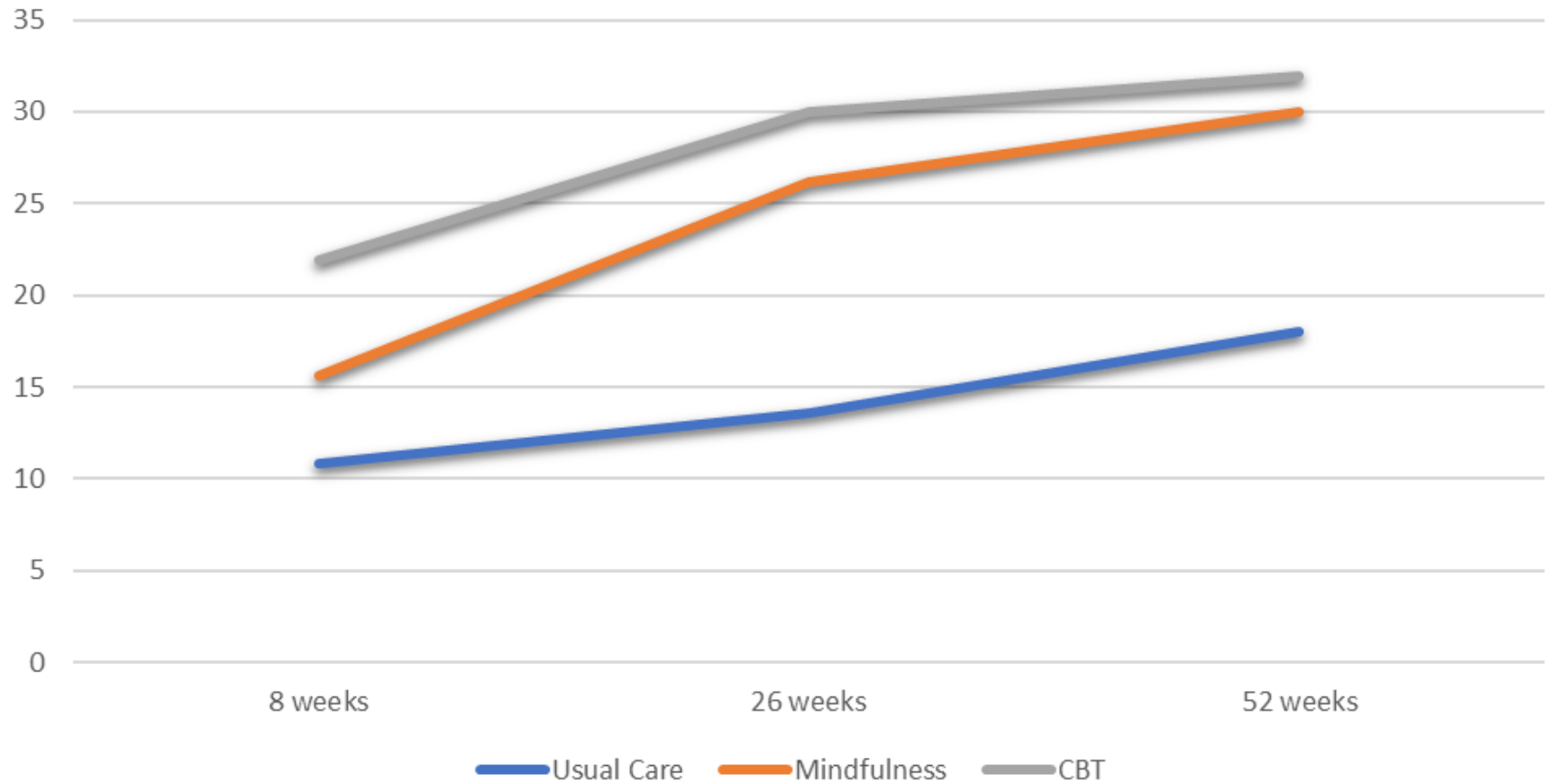
**Methods:** Using the ACP grading system, the committee based these recommendations on a systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and nonpharmacologic treatments for low back pain. Updated searches were performed through November 2016. Clinical outcomes evaluated included reduction or elimination of low back pain, improvement in back-specific and overall function, improvement in health-related quality of life, reduction in work disability, and return to work.

*muscle relaxants (moderate-quality evidence). (Grade: strong recommendation)*

**Recommendation 2:** *For patients with chronic low back pain, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence). (Grade: strong recommendation)*

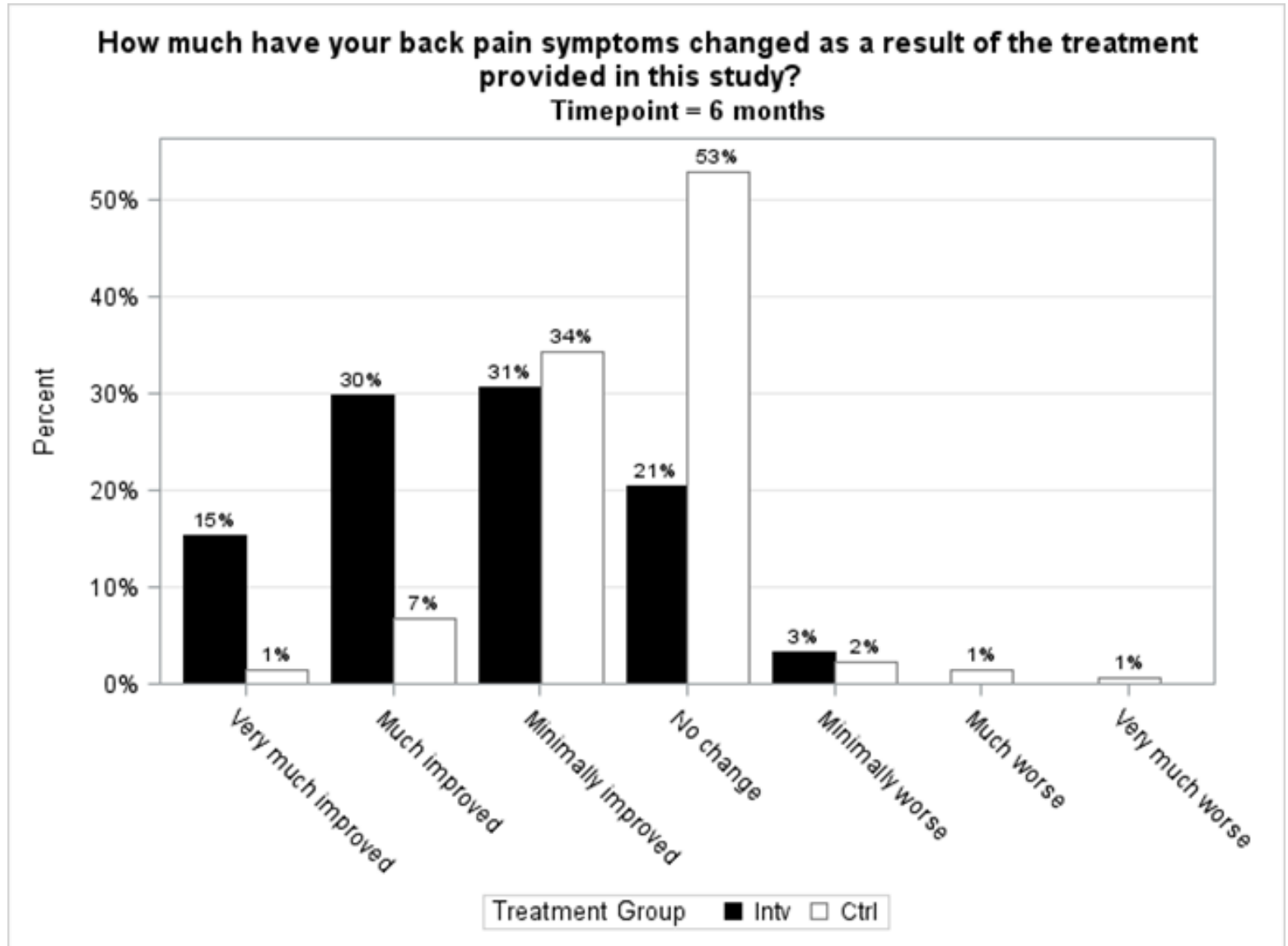
**Recommendation 2:** For patients with CLBP ...initially select nonpharmacologic treatment...**mindfulness-based stress reduction** (moderate-quality evidence)

## Percent of people rating back pain as "much better" or "completely gone"



Cherkin, D. C., Sherman, K. J., Balderson, B. H., Cook, A. J., Anderson, M. L., Hawkes, R. J., ... Turner, J. A. (2016). Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back Pain. *JAMA*, 315(12), 1240. <http://doi.org/10.1001/jama.2016.2323>

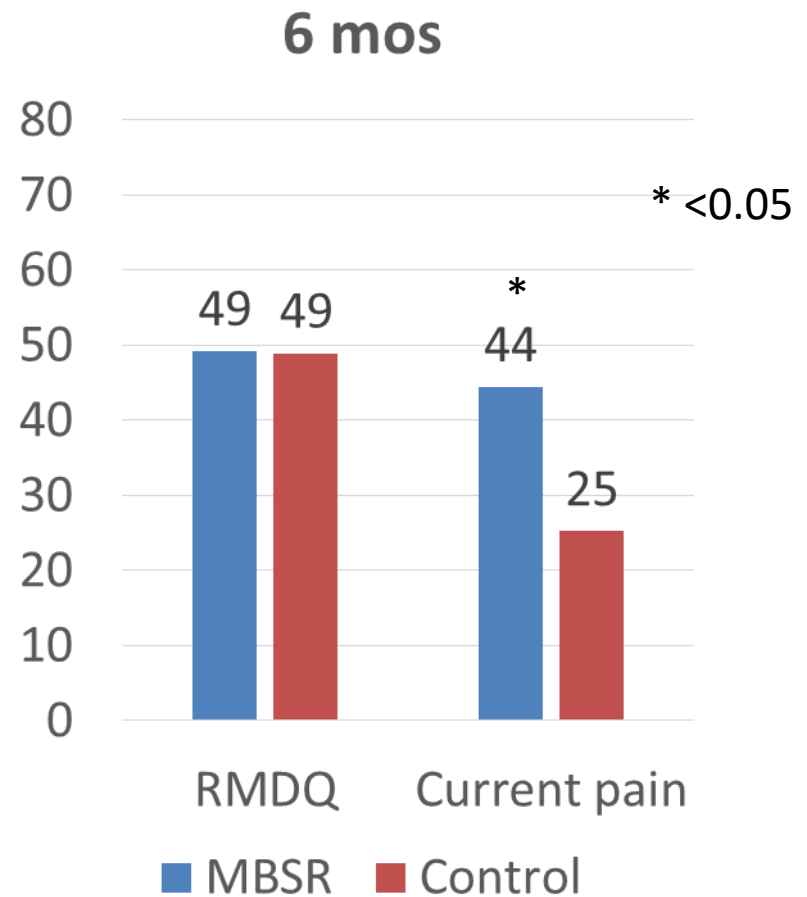
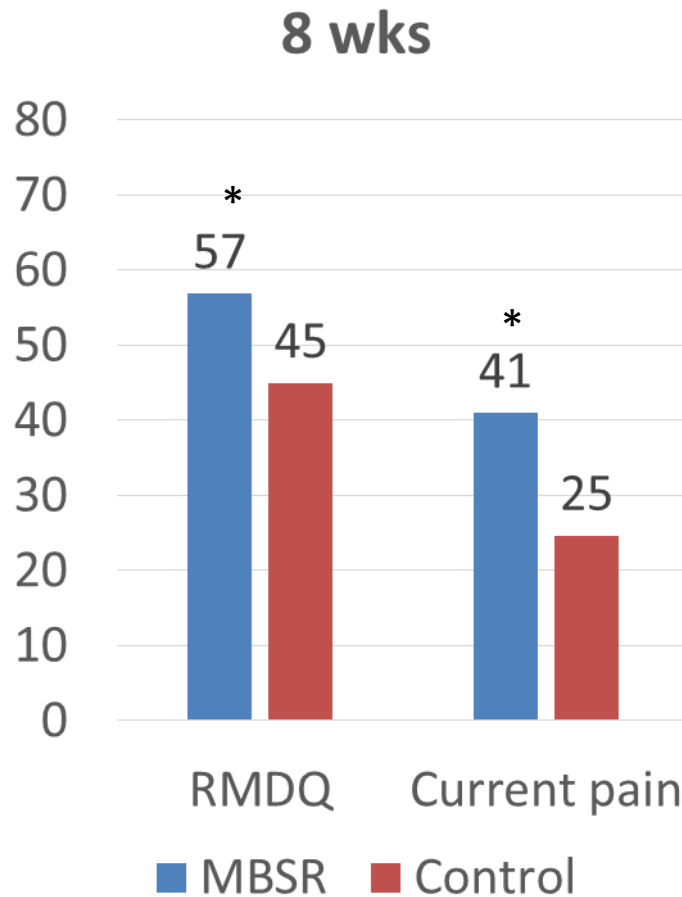
# Global Impression of Change



Morone et al.  
JAMA  
internal  
medicine.  
2016

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



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

Morone et al. JAMA  
internal medicine. 2016

# Barriers to clinical uptake

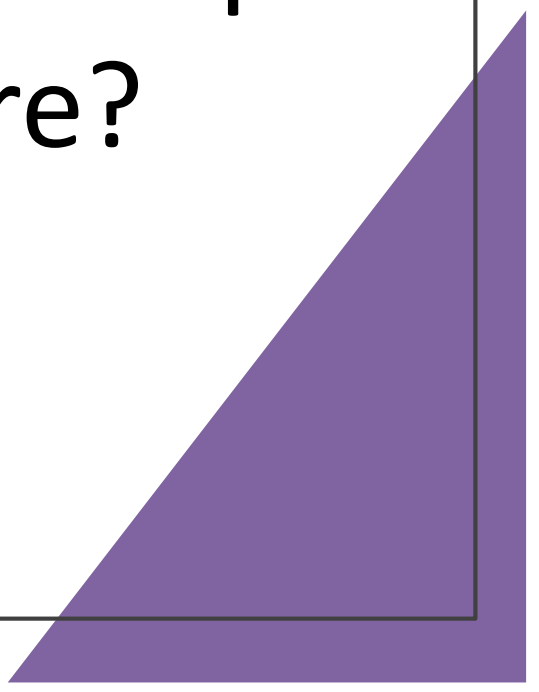
- Underutilized as not woven into outpatient clinical setting
- Not routinely reimbursed by health insurance companies for cLBP
- Next step is to inform how this program can work in a real-life setting

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.

How do we integrate  
mindfulness for low back pain  
into primary care?





# Optimum

## Optimizing Pain Treatment in Medical Settings Using Mindfulness

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

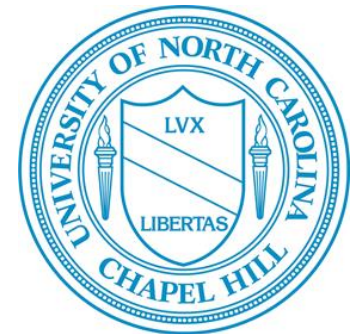
North Carolina, Chapel Hill



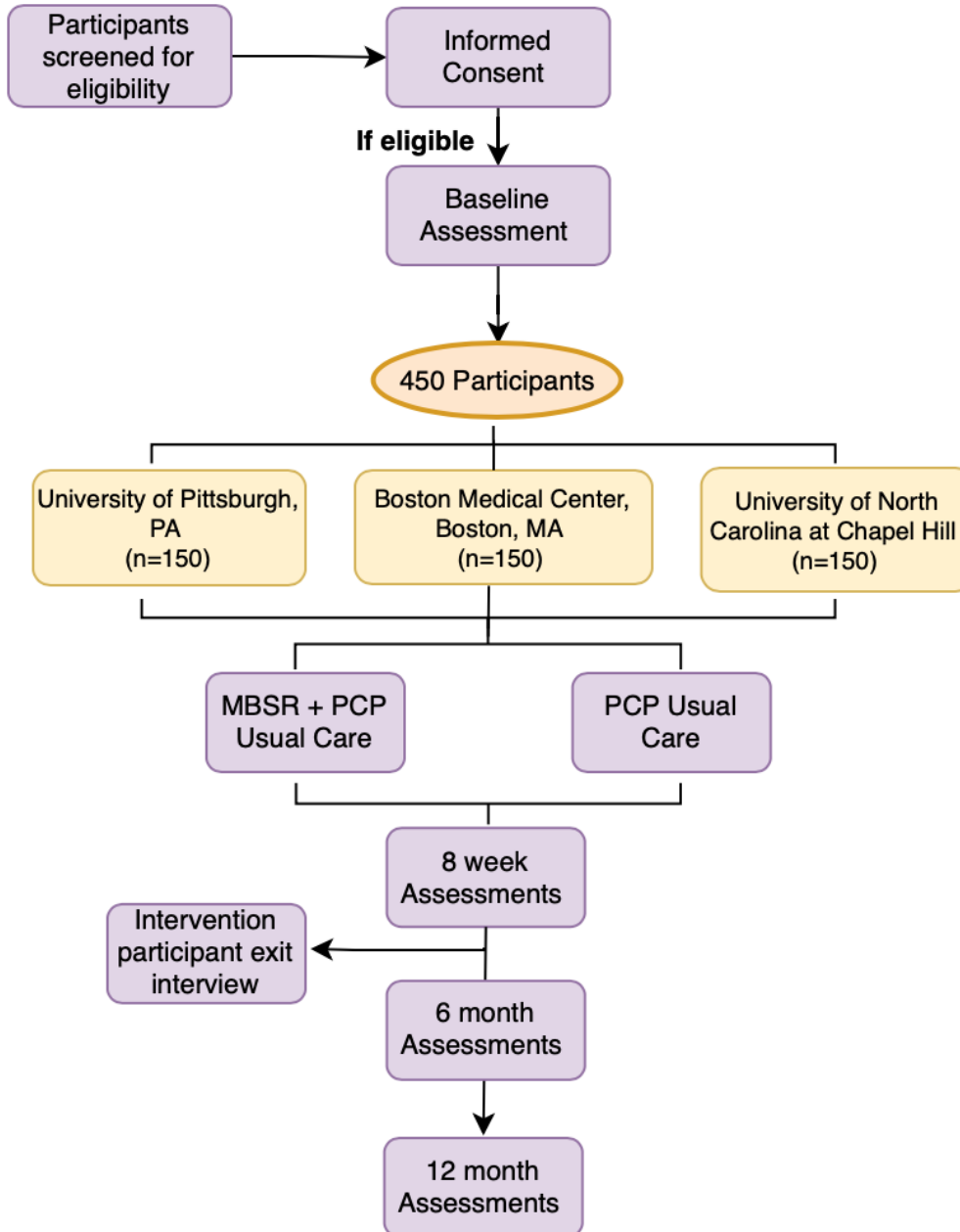


# Three Health Care Systems

- 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

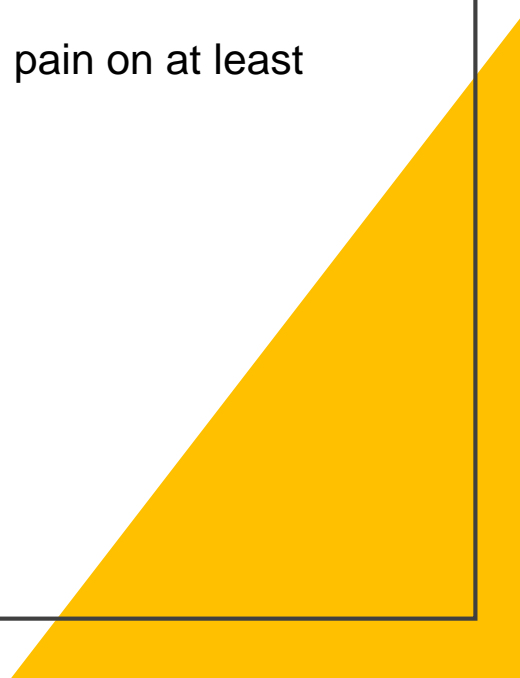


# Inclusion & Exclusion Criteria

## **Inclusion criteria**


1. Primary care patient at a participating practice
2. Age  $\geq 18$
3. cLBP, pain that persists for  $\geq 3$ -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
- 
- A large yellow triangle is positioned in the bottom right corner of the slide, pointing towards the top right.

# OPTIMUM: Primary Hypothesis

*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.

A large yellow triangle is positioned in the bottom right corner of the slide, pointing towards the top right.

## Secondary Outcomes

- Physical function
- Psychological function
- Opioid use
- Healthcare utilization
- Provider and clinic satisfaction with OPTIMUM program

<b>Patient-reported Measures</b>	<b>T1 Baseline</b>	<b>T2 8-wks</b>	<b>T3 6-mo</b>	<b>T4 12- mo</b>
*PEG	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 Medications (collected monthly)	X	X	X	X
Charlson Co-Morbidity Index	X			
Health Care System Utilization (self-report)		X	X	X
HEAL-CAM Attitudes/Expectation	X			

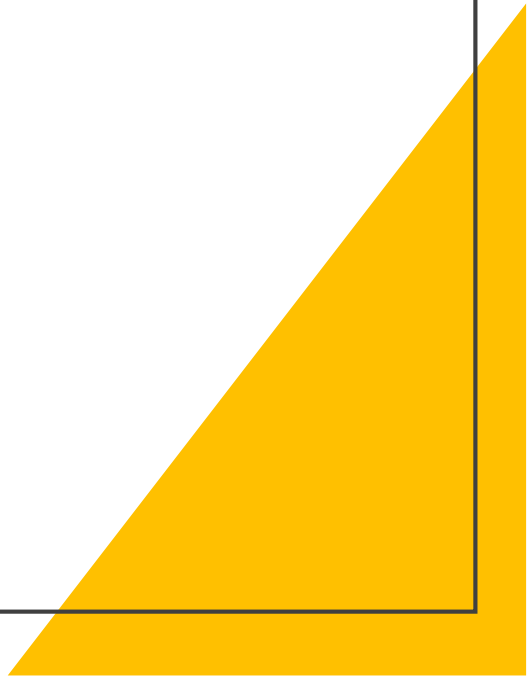
\*Primary outcome; \*\*Pain impact is defined as Pain intensity, pain interference and functional status PROMIS-29.  
PROMIS: patient reported outcomes measurement information system.

## **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. Primary Care Provider visits for LBP
8. Physical therapy referrals for LBP

# Randomization

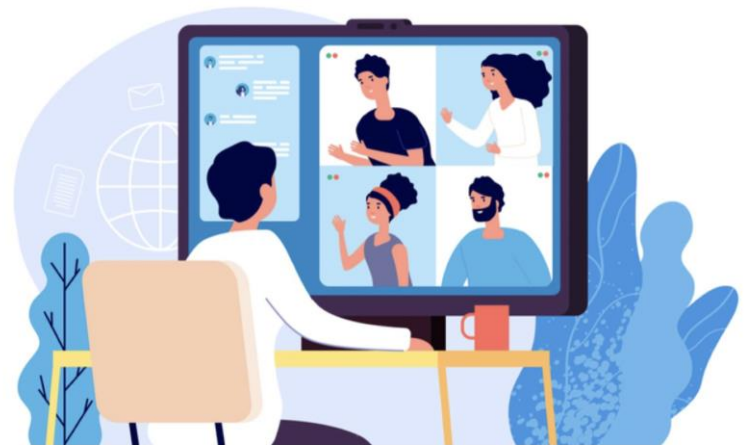
- Block randomization
- Stratified by clinic and sex
- Patient level randomization





# 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

Breath  
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



© Eleanor Mannikka

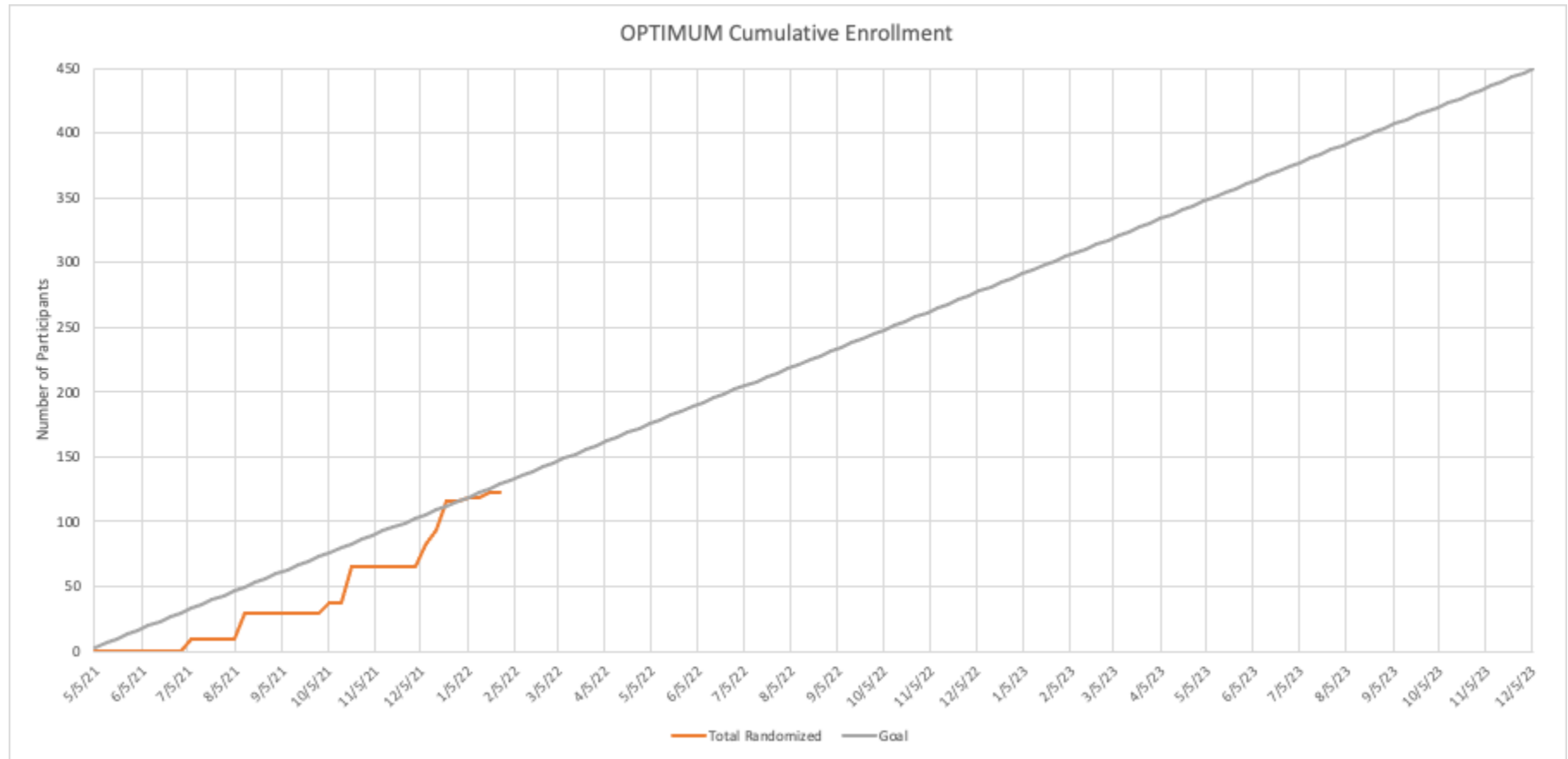
# Medical Group Visits Improve

- 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

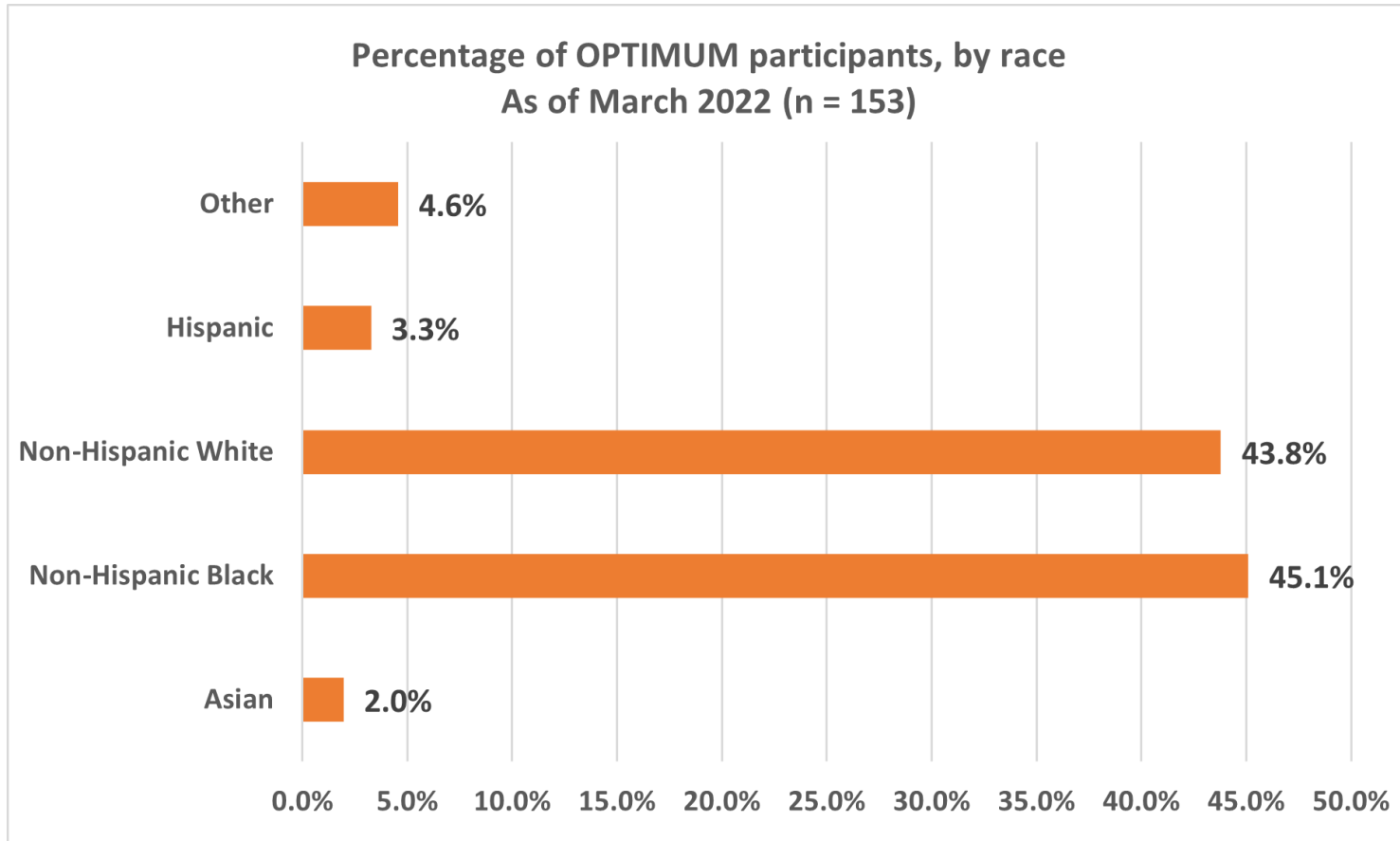
Jaber et al, 2006; Cramer et al, 2013; Berman et al, 2004; La Cour & Peterson 2015; Tsao 2007, Vickers et al.2012

Where are we now?

# OPTIMUM Cumulative Enrollment



# Racial Distribution of Participants



# Quotes

I mean the way it helps with your pain is, its 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.



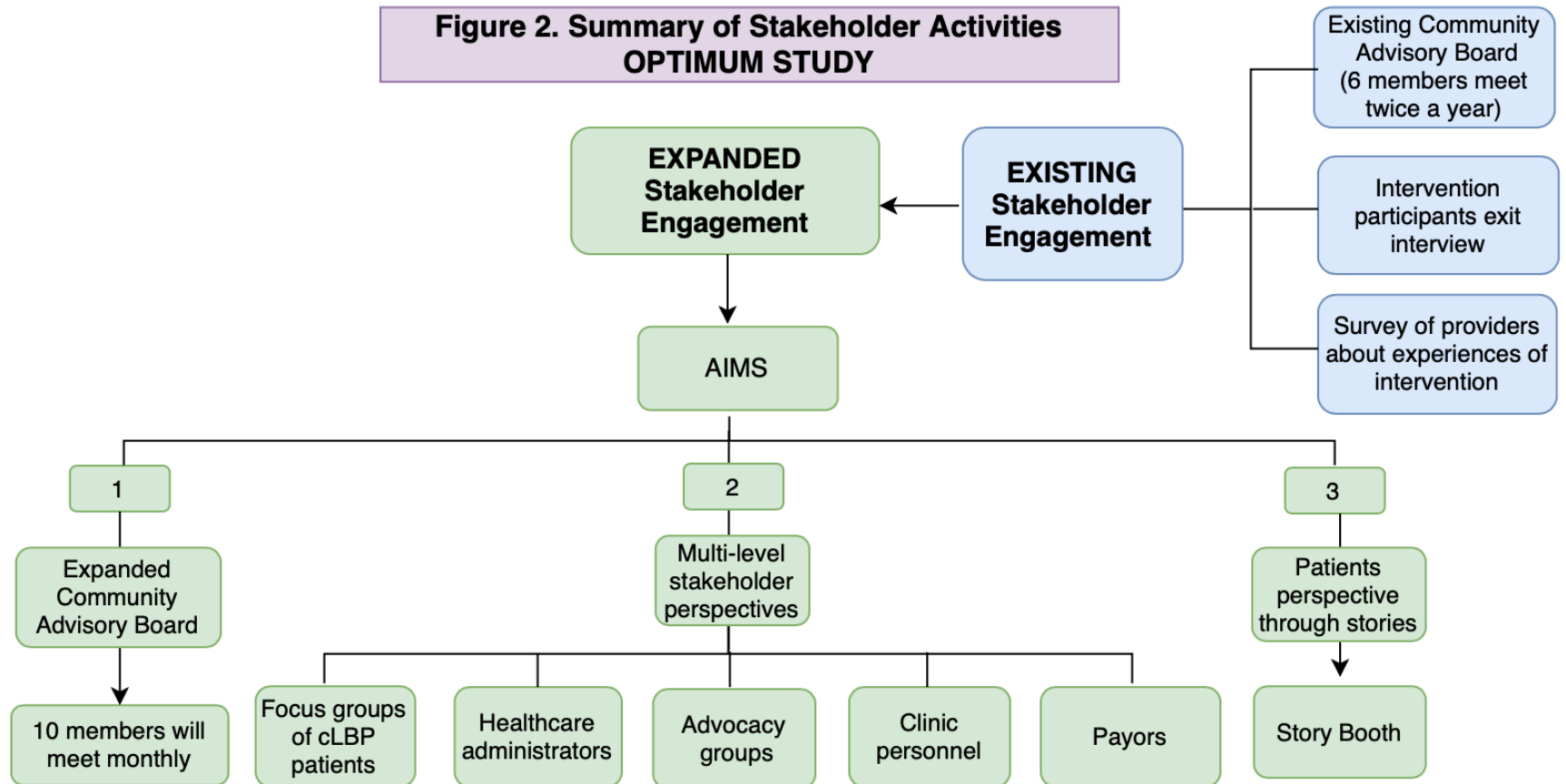
# STOP

- **S** Stop (come into **S**tillness)
- **T** Take time to breathe
- **O** **O**bserve & **O**pen to experience (body sensations, emotions, thoughts, impulses)
- **P** **P**roceed



# Supplement: Stakeholder

**Figure 2. Summary of Stakeholder Activities  
OPTIMUM STUDY**



# Supplement: Dietary Supplements for Pain

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

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Jessica Barnhill  
Gabriela Castro  
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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

