# The Learning to Apply Mindfulness to Pain (LAMP) Trial: Unpacking the Key Components of a Mindfulness-Based Intervention for Chronic Pain

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## **Acknowledgements**

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Thanks to the Pain Management Collaboratory (PMC) Coordinating Center and PMC investigators.

#### Today's Talk

- Overview of the LAMP study
- II. Zoom in on the LAMP interventions
  - Underlying frameworks that inform key intervention components
  - How we developed it
  - Design features aimed at enhancing accessibility, engagement,
     adherence, fidelity, sustainability, and scalability
- III. Questions

#### **Poll Question #1**

- What is your primary role in VA? (choose 1)
  - student, trainee, or fellow
  - clinician
  - researcher
  - administrator, manager or policy-maker
  - other

#### **Poll Question #2**

- Which best describes your experience and familiarity with mindfulness? (choose all that apply)
  - I am not familiar with mindfulness
  - I am familiar with mindfulness
  - I am familiar with the research on mindfulness-based interventions
  - I have conducted mindfulness research
  - I have participated in a mindfulness-based intervention, such as Mindfulness-Based Stress Reduction (MBSR)
  - I practice or have practiced mindfulness meditation on my own

#### I. Overview

"Dual public health crises" of chronic pain & opioids

 Need to shift from "opioid-centric" pain management to multi-modal models that use evidence-based non-pharmacological treatments (NPTs), including CIH approaches

Strategy



CLINICAL GUIDELINES | 4 APRIL 2017

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; Mary Ann Forciea, MD, for the Clinical Guidelines Committee of the American College of Physicians \*

# VA/DoD CLINICAL PRACTICE GUIDELINE FOR OPIOID THERAPY FOR CHRONIC PAIN





Though use of NPTs are up, they remain underutilized, including in the VHA

# Veterans disproportionately affected by chronic pain & opioids

- Up to 50% of male Veterans & 78% of female Veterans report pain (Haskell, 2006; Kerns; 2003; Nahin, 2017; Gironda, 2006)
- Chronic pain co-exists with mental and physical health conditions that affect Veterans (e.g., PTSD, substance abuse, depression; Stecker, 2010)
- VA patients: almost 2X rate of accidental fatal poisoning; opioid analgesics are drug class most commonly involved (Bohnert, 2011)

# NIH-DoD-VA Pain Management Collaboratory (PMC) Initiative

- Study effectiveness of nondrug approaches to chronic pain management in military and Veteran health care delivery systems
- \$81 million in grants over 6 years
- Funds Coordinating Center & 11 pragmatic trials of NPTs, including LAMP

## The Learning to Apply Mindfulness to Pain (LAMP) Trial

- Objective: Test effectiveness of 2 Mindfulness-Based Interventions (LAMP MBIs) for improving Veterans' chronic pain and mental health comorbidities
  - Oversample women Veterans
- LAMP MBIs: Grounded in behavioral change strategies & designed to optimize engagement, adherence, fidelity, and sustainability <u>and</u> reach large numbers of Veterans.

## Development Phase ("UG3"): May 2018-May 2020

- Develop and implement an Engagement Plan to involve Veterans and stakeholders as partners.
- 2. Use iterative user-centered design methods to adapt 2 MBIs for Veterans with chronic pain
- 3. Conduct a 3-arm pilot RCT (N=48)
- Also... translated intervention to virtual delivery due to COVID-19







## Trial Phase ("UH3"): May 2020- May 2024\*

- 3-arm pragmatic randomized controlled trial (N = 750) of VA patients with chronic pain at 4 VA facilities (Minneapolis, Durham, Los Angeles, Indianapolis)
  - Mobile+Group LAMP
  - Mobile LAMP
  - Usual Care control group
- Recruitment through EHR followed by screener (via internet) & chart review
- Primary outcome: (Brief Pain Inventory interference score) repeated at 10 weeks, 6 months, and 12 months)
- Secondary outcomes include key comorbidities (e.g., post-traumatic stress disorder, depression)
- Will examine results by gender
- Implementation analysis guided by RE-AIM framework

<sup>\*</sup>Details in Burgess et al, 2020 Pain Medicine.

# **Enrollment is going well! (Goal, N = 750)**

As of 5/13/21			
	Male	Female	Total
Cohort 3: Eligible based on			
screener. Need chart review (in			
progress) & pre-randomization call	356	123	479
Cohort 3: Expected Enrolled	150*	93	243
Enrolled (Cohort 1 & 2)	111	33	144
Expected total (Enrolled + Cohort			
3 Expected Enrolled	261	126	387

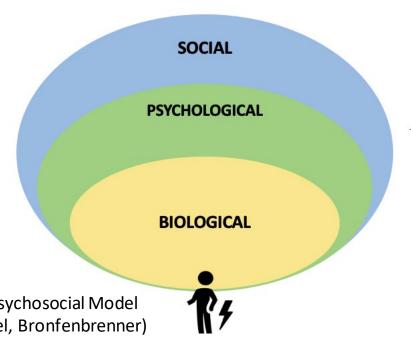
<sup>\* ~120</sup> males waitlisted to cohort 4

II. Unpacking the Key Components of the LAMP

Mindfulness-Based Intervention for Chronic Pain

#### Chronic Pain

- Complex 'biopsychosocial' phenomenon
- Growing recognition that pain requires 'management' versus 'cure'
- Emphasis on <u>adaptive or resilient pain behaviors</u>
  - More self-management...
    - Less use of substances
    - More physical activity
    - More social interaction
    - More emotional regulation



Dynamic Biopsychosocial Model (Lehman, Engel, Bronfenbrenner)

## Mindfulness-Based Interventions (MBIs)

- Mindfulness: Self-regulation of attention on present moment experience
   Characterized by curiosity, openness, and acceptance
- MBIs: Training & practice in mindfulness → attention regulation, body awareness, emotional regulation, shifts in self-perception
- Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn): predominant MBI

# Mindfulness Based Interventions (MBIs): evidence-based NPTs

 Systematic reviews show MBIs improve pain & comorbid conditions (e.g., depression, anxiety, sleep difficulties)\*

"The evidence of benefits of MBIs on pain is abundant among different populations." (Zhang, 2021; systematic review)

\*Bawa 2015; Chiesa, 2011; Gotnik, 2015; Hilton, 2016; Rosenzweig, 2010; Zhang, 2021

### **Despite the promise of MBIs...**

- Effect sizes are often small and vary across studies
- Often low engagement & adherence
- Issues with fidelity & reproducibility
- "Significant gaps in the literature" regarding the use of MBIs for Veterans (Marchand, 2021)
- Complex intervention with multitude of potentially active elements

#### **MBSR** - implementation issues for VHA

- > 9 million patients in VHA; many with chronic pain
- Demand for CIH exceeds supply (Fletcher, 2016)
  - Lack of time, space, funding, staff training
- MBSR very resource-intensive (e.g., requires certified instructors, 2 ½ hr. sessions + daylong retreat)
  - Issues of scalability, engagement & adherence
- Access barriers due to in-person format
- Women Veterans may feel uncomfortable with group format

#### **LAMP Interventions**

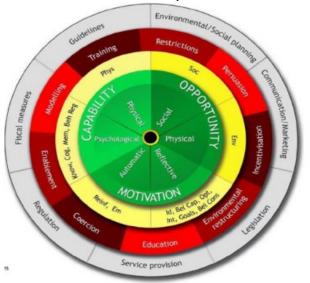
 Mobile+Group LAMP: Prerecorded modules presented by a mindfulness instructor that are viewed in an online group setting and interspersed with discussions led by a facilitator\*

 Mobile LAMP: Same prerecorded modules but does not include a group component. 3 facilitator calls to increase engagement.

\*Built on project led by Co-I Evans (NIH #5R33AT009110-04)

# LAMP: uses behavioral change strategies to optimize MBIs to meet adaptive pain behavior goals

 Informed by Behavioral Change Wheel Model (synthesizes 19 behavior change frameworks)





#### Adaptive pain behaviors

More self-management More emotional regulation

- Less use of substances
- More physical activity
- More social interaction

Michie et al (2014). The Behavior Change Wheel: A Guide to Designing Interventions

# Intervention Design

- 1. What are the target behaviors?
- 2. What do pain sufferers need (capabilities, opportunities, motivations)?
- 3. What are appropriate intervention strategies?
- 4. What content, behavior change techniques should be included?
- 5. What modes of delivery should be used?



Michie et al (2014). The Behavior Change Wheel: A Guide to Designing Interventions. Silverback Publishing.



- ✓ Affordable
- ✓ Practical
- ✓ Effective
- ✓ Acceptable
- ✓ Safe
- ✓ Equitable

#### Development: MBI Refinement (led by Dr. Roni Evans)

**Intervention Mapping** 

Needs Assessment

Grounded in behavioral change theory

Project Management Tools & Process

Mind Map

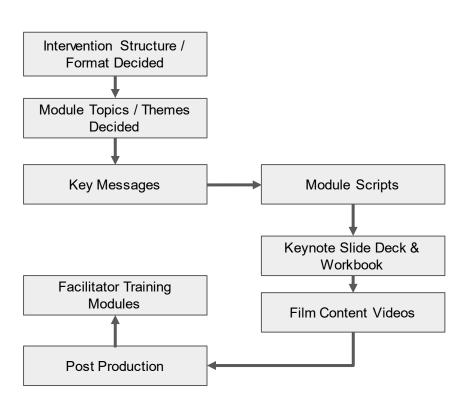
Intervention Spreadsheet

"Learnings"

Design & Development Process

Process diagram

### **Intervention Development Process Diagram**



#### Intervention spreadsheet

- Columns: Weekly Sessions; Topic (1-8)
  - Activity (1 − 7)
    - Learning Objective(s)
    - COM/Intervention Function
    - Format
    - Time (min)
    - Behavior Change Technique(s)
- Rows (assets)
  - Script Link
  - Presentation/Slide Link
  - Video Link
  - Workbook Link

#### Example: Week 1 – Mindfulness and Pain; Activity 3-Educational Video

Learning Objectives [Primary Behavior Change Techniques]	COM- (TDF)/Intervention Function 3	Format	Time	Behavioral Change Techniques by Intervention Function
1.Provide information that engaging in healthy behaviors, like pain can be difficult and stressful for anyone; physical and psychological discomfort, is part of being human and is normal (prevalence of pain, impacts of pain) [INFORMATION]  2.Provide information about what mindfulness is, related terms (attention, intention, attitude—IAA), and why it matters for wellbeing and pain [INFORMATION]  Provide information about what it means to be non-judgmentally aware of present moment experiences in relationship to pain, and why it is	Address: C-Pyschological Capability (Knowledge) using Education M-Reflective Motivation using Persuasion	Educational Video	12	Education -Information about what mindfulness is in relation to pain -Information about health and emotional consequences (e.g. information about health impacts, emotional impacts related to being/not being mindful in daily life, related to pain)
important [INFORMATION]  3.Provide information about the consequences (emotional, health) of mindfully approaching pain (can lead to new perspective about pain; new feelings about one's own ability/self-efficacy related to pain; new positive/adaptive ways to manage some of the challenges/barriers to pain); versus not being mindful when approaching/dealing with pain [INFORMATION EMOTIONAL, HEALTH CONSEQUENCES]; [SALIENCE OF HEALTH CONSEQUENCES]  4.Provide information on common barriers/facilitators to learning mindfulness skills—course has been designed to provide strategies, tools to overcome the barriers, but like any skill, need to practice (will get out of it, what you put into it) [INFORMATION]  5.Provide information on human capacity for mindfulnesswithin everybodys' reach; individual has capacity for mindfulness; is a skill that can be developed with practice, through meditation, mindful movement,	Script Link Presentati Video Link Workbook	on/Slide Link		Persuasion -Verbal persuasion about capabilitymindfulness is within everyone's reach; how mindfulness can help with tuning into body's cues, making helpful pain choices; how program can help overcome barriers/challenges to learning mindfulness -Salience of health consequences (e.g. story about health consequences about being/not being mindful in daily life, pain)

## Veteran and stakeholder partners

- Veteran Engagement Panel (VEP): Racially diverse, mixed-gender group of Veterans with chronic pain
  - Engagement, adherence, making it Veteran-centric
- Stakeholder Advisory Panel (SAP): Includes VA leaders in Whole Health, Pain Management, Women Veterans; non-VA experts
  - Engagement, adherence, sustainability & scalability
- SAP & VEP: Adaptations to COVID-19 & broader shift to virtual care

#### MBI + Group

- 9 x 90 minutes structured sessions
- 9 Weeks
- Led by VA Staff



Workbook reflections



Group discussions



Mindfulness videos

Home Practice





#### **Primary Targets of Intervention**

#### **Capabilities**

#### **KNOWLEDGE**

- What mindfulness is, how it can help with pain
- Key mindfulness concepts—what they are, why they matter for pain (e.g., consequences)
- Mind-body connection
- o Thoughts, feelings
- Kindness to self, others
- Perspective

#### **SKILLS**

#### Mindfulness practices to develop mindfulness skills

- Attentional focus breath, feedback from body, noticing when the mind moves away from the body, reconnecting back to the body
- Noticing when judgement arises, starting again with compassion
- Paying attention to habitual negative perspectives, considering alternative perspectives, shifting perspectives

#### Motivations

#### **BELIEFS, OPTIMISM**

- There are things one can do to make pain more manageable
- Mindfulness is one way to do this
- Mindfulness is a skill that can be developed with practice
- Capability: you can do it!
- You can do things, even if you have pain

# Opportunities

Skills Training

Education

Core

Elements

**Enablement** 

**Persuasion** 

- √ Affordable
- ✓ Practical
- ✓ Effective
- Acceptable
- ✓ Safe
- ✓ Equitable

# Example: Session 6

Facilitator Presentation Behavior Change Techniques

Information

Review goals

Social support

Social reward

Problem solving

Instruction

Practice & rehearsal

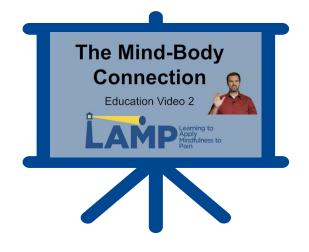
Verbal persuasion







Time Track	Time (min)	Activity # Format	Specific Elements	Slide # Other materials
	3	#1 Facilitator Presentation	☐ Welcome & Introductions ☐ Today's Activities Outline	Slide(s): 1-2
	Reflection & own)		<ul><li>☐ Workbook Reflection (on own)</li><li>☐ Group Discussion</li></ul>	Slide(s): 3 Workbook
			☐ Educational video (Finding the Positive)	Slide(s): 4
	I I		☐ Mindful Movement Video (Video C)	Slide(s): 5
	10	#5	Break	Slides: 6
	9	#6 Video	☐ Guided Meditation (Video 5-Experiencing Openness-Alex)	Slide(s): 7
	20	#7 Reflection & Group Discussion	☐ Workbook Reflection (on own)☐ Group Discussion	Slide(s): 8 Workbook
	4	#8 Facilitator Presentation	☐ Review Session 2 Checklist	Slide(s): 9 Workbook
	2	#9 Facilitator Presentation	☐ Reminders, questions	Slide(s): 10-11
	89 min			



**Educational Videos** 



**Meditation Videos** 



Mindful Movement Videos



All videos are on the app

### **LAMP MBIs vs Other Programs**

#### **SIMILARITIES**

- General principles and concepts
- Content presented by experts



# DIFFERENCES (to enhance accessibility, engagement, adherence, fidelity, sustainability, and scalability)

- Shorter length
- Integrates specific behavior change techniques
- Less jargon
- Recorded sessions by expert instructor, facilitated by non-experts
- More structured sessions
- Specific to pain
- Customized for Veterans
- Mobile version

# III. Questions/Comments? Diana.Burgess@va.gov

Pain Management Collaboratory
<a href="https://painmanagementcollaboratory.org">https://painmanagementcollaboratory.org</a>