Results from the Learning to Apply Mindfulness to Pain (LAMP) Study: A Pragmatic Clinical Trial

Diana J. Burgess, PhD

Core Investigator, Center for Care Delivery and Outcomes Research, Minneapolis VAHCS

Professor, University of Minnesota Medical School

Director, VA QUERI Complementary and Integrative Health Evaluation Center (CIHEC)

Funded by the Department of Defense through the Pain Management Collaboratory - Pragmatic Clinical Trials Demonstration Projects under Award No. #W81XWH-18-2-0003

University of Minnesota
Driven to Discover®

CCDOR
Center for Care Delivery and Outcomes Research

LAMP
Learning to Apply Mindfulness to Pain

pmc painmanagement collaboratory

LAMP - Background

- Mindfulness-Based Interventions (MBIs): effective nonpharmacological treatment for pain and comorbid conditions (e.g., anxiety, PTSD, sleep)
- Many MBIs (such as Mindfulness-Based Stress Reduction) have features that pose significant patient- and system-level implementation barriers
- LAMP MBIs - use innovative approaches to address these barriers

Learning to Apply Mindfulness to Pain (LAMP): Overview

Objective: Test two approaches for delivering MBIs designed to address key implementation barriers, for improving Veterans' chronic pain and biopsychosocial outcomes

- Powered to examine results by gender

Hybrid Type 1 Design

- **Effectiveness**: 3-site, 3-arm, pragmatic randomized trial with blinded outcome assessment
  - Primary Outcome: Pain-related function (Brief Pain Inventory [BPI] interference scale) over 12 months (assessed at baseline, 10 weeks, 6 months & 12 months)
  - Secondary biopsychosocial outcomes
- **Implementation:** Multi-level qualitative and quantitative data guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework

Interventions

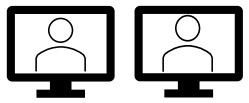
Grounded in behavioral change strategies and designed to optimize engagement, adherence, fidelity, and sustainability & reach large numbers of Veterans

Group MBI

- 8 x 90 minutes structured sessions
- Session 0 (technical)
- 9 Weeks
- Led by VA Staff

Workbook reflections

Mindfulness videos



Group discussions

Mobile App

Self-paced MBI

- 8 weekly modules

Mobile App

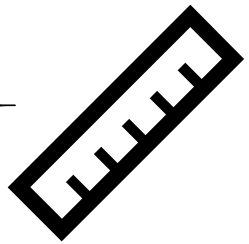
Workbook reflections

Mindfulness videos

3 facilitator calls

Behavior Change Techniques

- Information
- Review goals
- Social support
- Social reward
- Problem solving
- Instruction
- Practice & rehearsal
- Verbal persuasion



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

Participant Characteristics

811 participants
52% Men; 48% Women
68% White; 26% Black
Mean age: 55 years
94% at least some college education
30% described financial household situation as “comfortable”
41% employed, 25% retired
63% had at least 1 mental illness diagnosis in EHR
Mean pain-related function: 5.6 (SD = 2.0)
69% extremity pain/arthritis, 48% back pain

Retention and Adherence

Assessment completion rate

87% at 10 weeks

84% at 6 months

86% at 12 months

Group MBI Adherence Rates

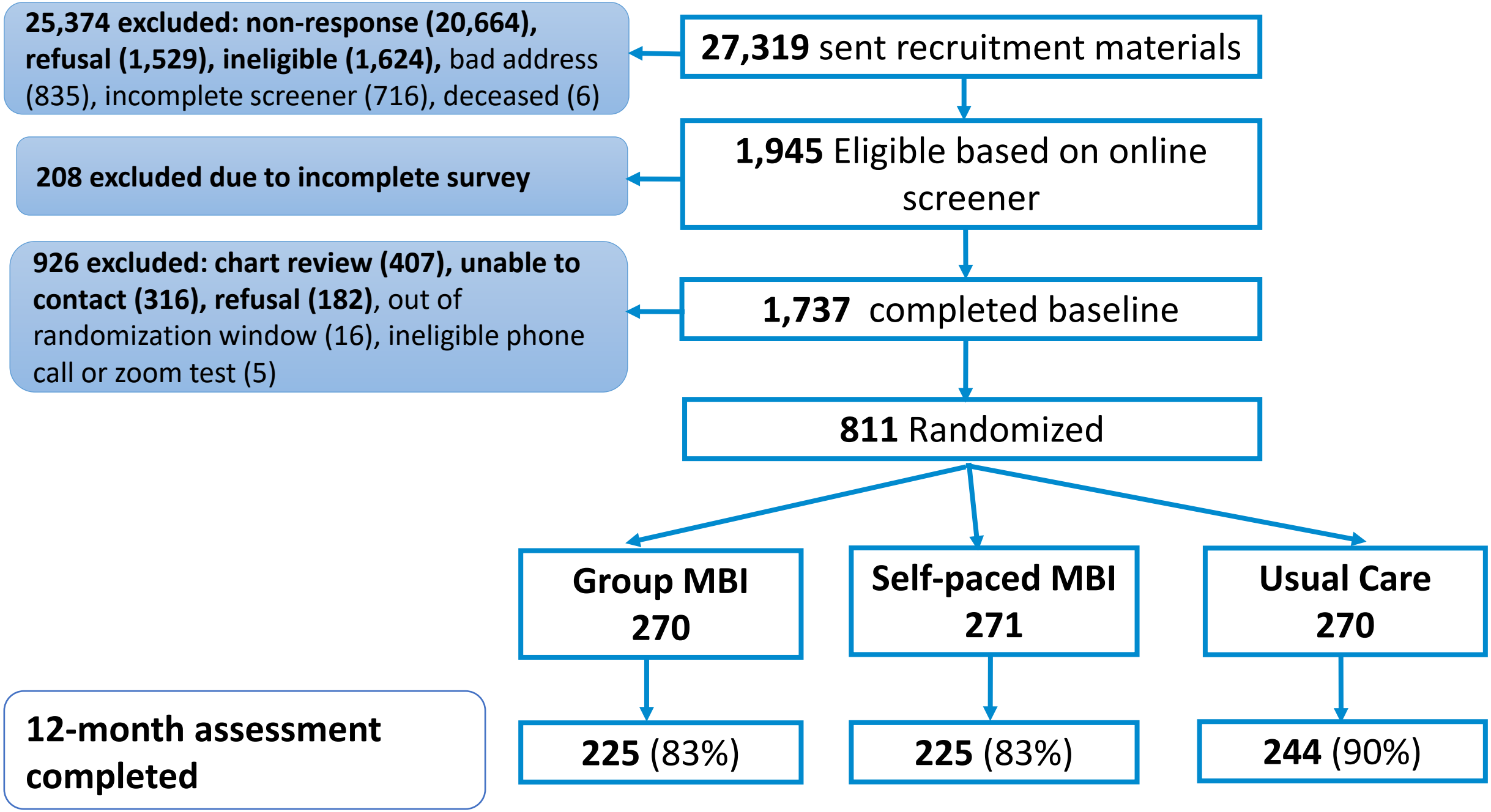
26%: all 9 sessions

69%: 6/9 sessions

Self-paced MBI Adherence Rates

62%: all 3 calls

76%: 2/3 calls


25,374 excluded: non-response (20,664), refusal (1,529), ineligible (1,624), bad address (835), incomplete screener (716), deceased (6)
27,319 sent recruitment materials
208 excluded due to incomplete survey
1,945 Eligible based on online screener
926 excluded: chart review (407), unable to contact (316), refusal (182), out of randomization window (16), ineligible phone call or zoom test (5)
1,737 completed baseline
811 Randomized
Group MBI 270
Self-paced MBI 271
Usual Care 270
12-month assessment completed
225 (83%)
225 (83%)
244 (90%)

Primary & secondary outcomes averaged over 12-month follow-up adjusted for baseline, design factors and missingness

	Group	Self-paced	Usual care
Pain-related function	**4.8 (0.1)[1]**	**4.5 (0.1) [1]**	5.2 (0.1)
Pain intensity	**4.7 (0.1)[2]**	**4.6 (0.1)[2]**	5.1 (0.1)
Perceived change in pain	**3.4 (0.1)[2]**	**3.3 (0.1)[2]**	4.1 (0.1)
Physical function	**13.3 (0.1)[2]**	**13.3 (0.1)[2]**	12.7 (0.1)
Anxiety	9.2 (0.1)	**8.8 (0.2)[2]**	9.4 (0.1)
Fatigue	**12.9 (0.2)[2]**	**12.7 (0.2)[2]**	13.5 (0.2)
Sleep disturbance	**13.3 (0.2)[2]**	**13.3 (0.2)[2]**	13.9 (0.2)
Participation in social roles/activities	**12.0 (0.2)[2]**	**11.9 (0.2)[2]**	11.0 (0.1)
Depression	**8.2 (0.2)[2]**	**8.2 (0.2)[2]**	9.1 (0.2)
PTSD	**22.8 (0.6)[2]**	**22.7 (0.6)[2]**	24.9 (0.6)

[1]The p-value threshold for the primary outcome was adjusted for multiple comparisons, from 0.05 to 0.0167.

[2]Different from usual care arm at $p \leq 0.05$. For primary and most secondary outcomes, two MBIs did not differ.

	Group	Self-paced	Usual care
10 Week			
No reduction, or worsening	**33.8[1]**	**30.7[1]**	43.7
≥30%	**33.6[1]**	**40.3[1]**	15.9
≥50%	**14.0[1]**	**21.3[1]**	6.6
≥75%	2.2	**7.1[1]**	1.7
6 Month			
No reduction, or worsening	**32.7[1]**	**30.0[1]**	41.7
≥30%	**34.4[1]**	**38.2[1]**	22.2
≥50%	14.7	**19.2[1]**	10.4
≥75%	4.0	**6.6[1]**	2.2
12 Month			
No reduction, or worsening	33.5	29.2	37.4
≥30%	30.3	**42.2[1]**	24.1
≥50%	16.6	**20.8[1]**	13.3
≥75%	7.6	7.9	4.7

[1]Different from usual care arm at p≤0.05

Probability estimates for changes in pain-related function, adjusted for baseline pain-related function, design factors and missingness

30% & 50% reduction from baseline = moderate & substantial improvement

Discussion

- Two scalable, telehealth approaches to delivering MBIs improved pain-related function and other biopsychosocial outcomes compared to usual care among Veterans with chronic pain and high levels of psychiatric comorbidity.
- Could help accelerate the implementation of nonpharmacological pain treatment in healthcare systems.
- The two MBIs did not significantly differ from one another on the primary outcome and most secondary outcomes.
- The viability and similarity of both these approaches for delivering MBIs increases patient options for meeting their individual needs.
- Future analyses to explore characteristics of intervention responders.

Acknowledgements

Research Team: Co-Investigators/Authors: Kelli Allen, Gert Bronfort, Collin Calvert, Roni Evans, Alex Haley, John Ferguson, Jessica Friedman, Brent Leininger, Marianne Matthias, Laura Meis, Melissa Polusny, Brent Taylor, Stephanie Taylor; Consultant: Greg Serpa

Data/Stats: Ann Bangerter, Emily Hagel Campbell

Facilitators: Kimberly Behrens, Mallory Mahaffey

Project Staff: Mariah Branson, Lee Cross, Sierra Hennessy

Veteran Engagement Panel: Lawrence Clardy, Jason Gladney, Rose M. Glenn, Rebecca A. Keller, and Donna Swenson

Additional thanks: Andrea Cutting, Tam M. Do

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. This work was supported by the Assistant Secretary of Defense for Health Affairs endorsed by the **Department of Defense**, through the Pain Management Collaboratory - Pragmatic Clinical Trials Demonstration Projects under Award No. W81XWH-18-2-0003. Research reported here was supported by Grant Number U24AT009769 from the National Center for Complementary and Integrative Health (NCCIH), and the Office of Behavioral and Social Sciences Research (OBSSR). This material is the result of work supported with resources at the Minneapolis VA Health Care System, Durham VA Health Care System, and VA Greater Los Angeles Healthcare System. This is a product of the NIH-DOD-VA **Pain Management Collaboratory (PMC)**. For more information about the Collaboratory, visit https://painmanagementcollaboratory.org/. Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Department of Defense, NCCIH, OBSSR, National Institutes of Health, U.S. Department of Veterans Affairs, or United States Government.