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

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Center for Care Delivery and Outcomes Research

LAMP™ Learning to Apply Mindfulness to Pain

pmc painmanagement collaboratory

It takes a village!

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Rationale for LAMP

- Veterans are disproportionately affected by chronic pain, comorbid conditions (PTSD, substance abuse, depression) and opioid harms (opioid use disorder, opioid overdose)
- Evidence-based nonpharmacologic treatments for chronic pain (NPTs) including Complementary and Integrative therapies are recommended, yet underutilized due to multi-level barriers, including in VHA
- Mindfulness-Based Interventions (MBIs): evidence-based NPTs; also address comorbidities affecting Veterans (e.g., depression, PTSD, sleep disorders)
- Many MBIs such as Mindfulness-Based Stress Reduction (MBSR) have features that pose significant patient- and system-level implementation barriers (time-intensive, need trained instructors, etc.)
- LAMP MBIs –scalable; use innovative approaches to address implementation barriers
- LAMP – addresses needs of women Veterans (disproportionately impacted by chronic pain & comorbidities); oversample women

Burgess DJ, Evans R, et al. Learning to apply mindfulness to pain (LAMP): Design for a pragmatic clinical trial of two mindfulness-based intervention for chronic pain 2020. *Pain Medicine.*

Mindfulness & Mindfulness-Based Interventions

- Mindfulness: “Awareness that arises through paying attention, on purpose, in the present moment, non-judgmentally” (Kabat-Zinn)
  - Characterized by curiosity, openness, and acceptance

- Mindfulness-Based Interventions (MBIs): Training & practice in mindfulness → attention regulation, body awareness, emotional regulation, shifts in self-perception

- “MBIs are effective for improving many biopsychosocial conditions, including depression, anxiety, stress, insomnia, addiction, psychosis, pain, hypertension, weight control, cancer-related symptoms and prosocial behaviours.” Zhang, 2021; systematic review.

https://www.va.gov/WHOLEHEALTH/circle-of-health/mindful-awareness-resources.asp

LAMP Overview

Objective: Test effectiveness of two approaches for delivering MBIs that address multi-level implementation barriers, at improving Veterans' chronic pain and biopsychosocial outcomes

LAMP INTERVENTIONS: Core elements of Mindfulness-Based Stress Reduction; grounded in behavioral change strategies using the Behavioral Change Wheel Model.

- ***Group MBI**
  - Eight 90-minute structured group sessions + session 0
  - Delivered via videoconferencing; pre-recorded mindfulness education and skill training videos by an experienced instructor, with facilitated discussions by VA staff.

- **Self-paced MBI**
  - Eight 30- to 60-minutes weekly modules
  - Same pre-recorded videos; completed asynchronously; supplemented by three individual facilitator calls by VA staff.

All participants: encouraged to practice on their own between sessions, using a workbook, mobile app, and study website

*Development led by Co-I Evans; Based on R33AT009110, Evans, Mindful Movement for Physical Activity and Wellbeing in Older Adults: A Community Based Randomized Hybrid Effectiveness-Implementation Study.

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, including needs of women Veterans
- Trauma-informed
- Mobile version

Developed MBI package (e.g., mobile app, videos, workbook, facilitator training manual) through **iterative stakeholder feedback**, guided by COM-B model

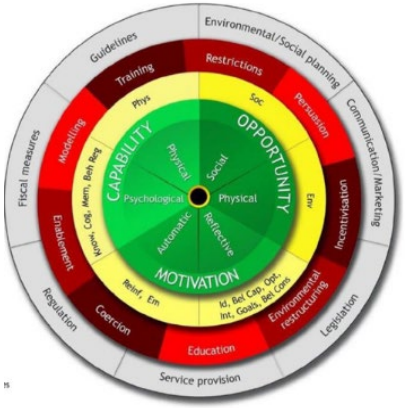
- Veteran Engagement Panel (VEP)
- Stakeholder Advisory Panel (SAP)
- Experts (e.g., expertise in mindfulness, technology; Veteran end-users)
- Pilot study data

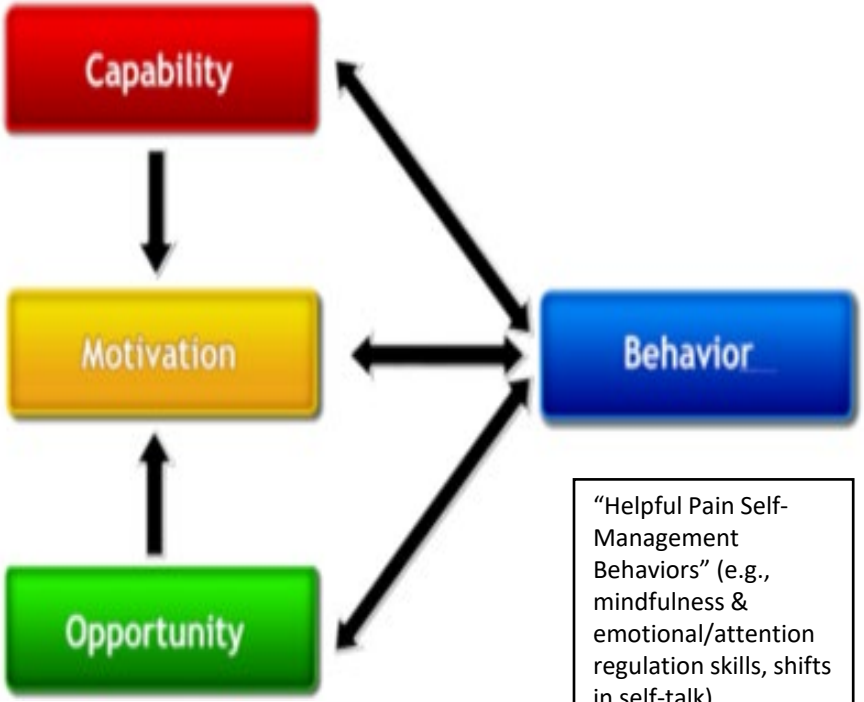
Our goal: Better understand Veterans' Capability, Opportunity and Motivational needs for engaging in MBIs to support adaptive pain Behaviors

See 5/20/2021 CIH CyberSeminar
https://hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=3972

COM-B Model & Behavioral Change Wheel Guided Intervention Design, Optimization, & Evaluation

The Behavior Change Wheel (Michie, 2014):
Synthesis of 20 behavioral models





"Helpful Pain Self-Management Behaviors" (e.g., mindfulness & emotional/attention regulation skills, shifts in self-talk)

Results: What did Veterans' want/need for engaging in MBIs?

Capability-related needs:

- Information offered in shorter segments; more clarity
- **Information put in context: "How can mindfulness help me with my pain?"**

Opportunity/resource-related needs:

- App usability, flexibility
- Cues, reminders, written materials
- Shorter session lengths (90 minutes vs 180 minutes)
- Flexibility/opportunity to make up for missed sessions

Motivation-related needs:

- Less mindfulness jargon, more secular
- Support from other Veterans
- Support from facilitators to keep group sessions on track, provide reminders & guidance for home practice
- Guided meditations in female voice (women)

Design, Setting, Eligibility

DESIGN: 3-arm (Group MBI; Self-paced MBI; Usual Care) Hybrid Type 1 Effectiveness-Implementation Pragmatic Clinical Trial (811 participants)

SETTING: Minneapolis, Durham, and Greater Los Angeles VA Health Care Systems

ELIGIBILITY:
(1) 2 qualifying pain diagnoses in EHR
(2) pain duration ≥ 6 months
(3) pain intensity score of ≥ 4 during past week
(4) access to a smart phone and internet
(5) not currently enrolled in another pain study or MBSR.
(6) No Dx of schizophrenia, bipolar disorder, or active psychosis within the past 18 months. No current psychotic symptoms, suicidality, severe depression, a manic episode, poorly controlled bipolar disorder, or serious behavioral problems

Burgess DJ, Evans R, et al. Learning to apply mindfulness to pain (LAMP): Design for a pragmatic clinical trial of two mindfulness-based intervention for chronic pain 2020. *Pain Medicine.*

Primary Outcome: Pain-related function (Brief Pain Inventory [BPI] interference scale) over 12 months* Range 0-10; higher scores = worse function.

Secondary Outcomes:*

Pain

- Pain intensity (BPI)
- Patient Global Impression of Change (PGIC)
- Percentage improvement in pain functioning

Psychological

- Anxiety symptoms (PROMIS)
- Depressive symptoms (PHQ-8)
- Post-traumatic stress disorder PTSD (PCL5)

Health

- Physical function (PROMIS)
- Fatigue (PROMIS)
- Sleep disturbance (PROMIS)

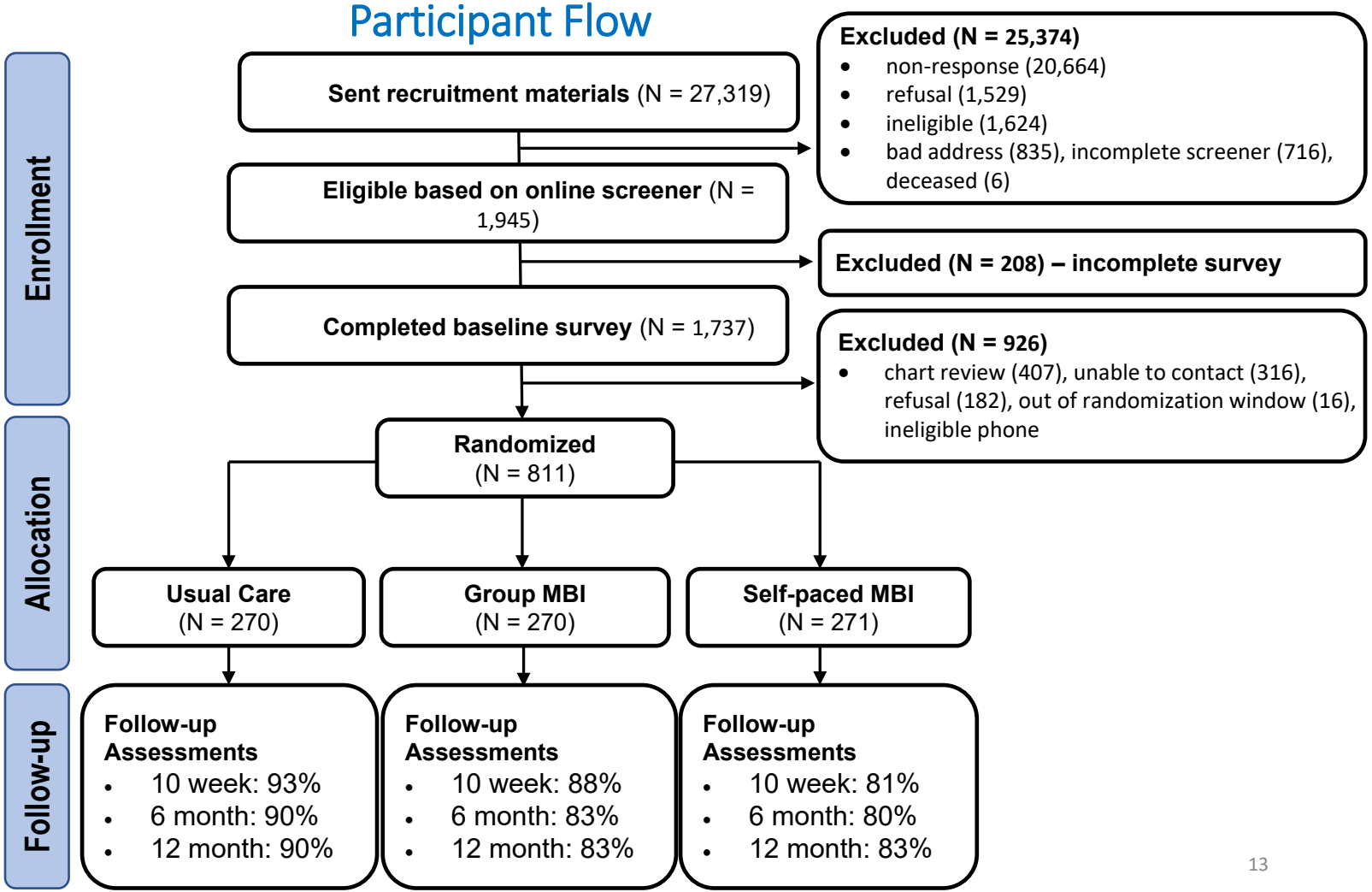
Social

- Participation in social roles and activities (PROMIS)

*Outcomes assessed at baseline, 10 weeks, 6 months, and 12 months; PGIC – not assessed at baseline

Results

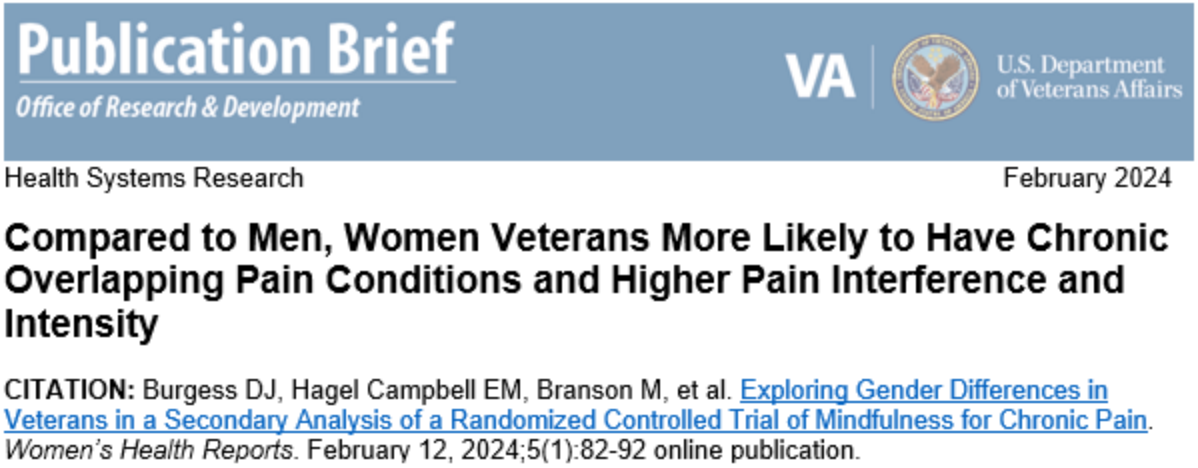
Participant Flow



Baseline Participant Characteristics

52% Men; 48% Women
68% White; 26% Black
Mean age: 54.6 years (SD: 12.9)
94% at least some college education
31% described household financial situation as “live comfortably”
41% employed, 25% retired; 22% disabled
63% had at least 1 mental illness diagnosis in EHR
40% Depressive disorders
25% Anxiety disorders
25% Post-Traumatic Stress Disorder
7.5% Substance Use Disorder
Most prevalent pain conditions: 69% extremity pain/arthritis 48% back pain 27% fibromyalgia/widespread muscle pain 26% neck pain 17% headache
Pain-related function (BPI – Pain Interference); Mean: 5.6 (SD: 2.0)
Pain Intensity (BPI – Pain Intensity); Mean: 5.5 (SD: 1.6)

Baseline Gender Comparisons



Publication Brief
Office of Research & Development
VA U.S. Department of Veterans Affairs

Health Systems Research February 2024

Compared to Men, Women Veterans More Likely to Have Chronic Overlapping Pain Conditions and Higher Pain Interference and Intensity

CITATION: Burgess DJ, Hagel Campbell EM, Branson M, et al. Exploring Gender Differences in Veterans in a Secondary Analysis of a Randomized Controlled Trial of Mindfulness for Chronic Pain. *Women's Health Reports*. February 12, 2024;5(1):82-92 online publication.

Women: higher prevalence of psychiatric and sleep disorder diagnoses, **greater levels of** depression, anxiety, post-traumatic stress disorder, fatigue, sleep disturbance, stress, and pain catastrophizing, and lower levels of pain self-efficacy and participation in social roles and activities.

Women: less likely to smoke or have a substance abuse disorder **and used more** nonpharmacological pain treatment modalities.

Adherence

Group MBI: 8 x 90 minutes structured sessions + session 0; Weekly practice

- 69%: at least six visits (considered “adherent”)
- 26%: all 9 sessions

Self-paced MBI: Eight 30- to 60-minutes weekly modules; 3 coaching calls; weekly practice

- 76%: at least two calls (considered “adherent”)
- 62%: all 3 calls

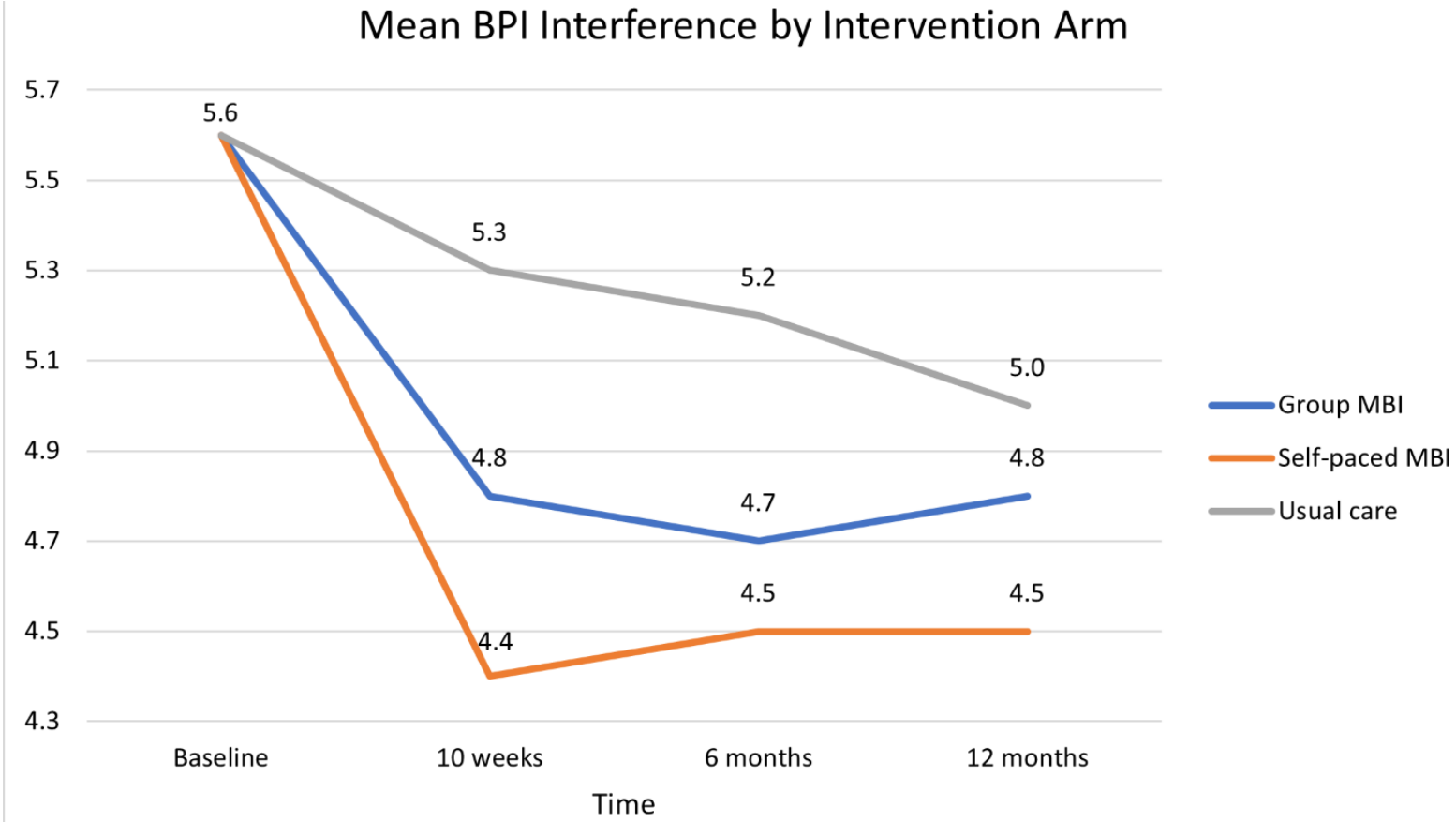
Snapshot - weekly practice adherence: In both groups >90% reported weekly practice (mindful mini-practices) at 10 weeks; >80% continued to engage in the mindful mini-practices at 12 months

Primary Analysis

Primary Outcome: BPI Interference scale (Pain-Related Function)
Time Points: 10 weeks, 6 months, and 12 months
General Framework:

- **Intention-to-treat**
- Linear mixed model for repeated measures with random intercepts for participants, with all time points.
- **Adjusted for design factors** of the gender stratified sampling frame, survey wave, site, **baseline BPI Interference**, and baseline pain self-efficacy (differed at baseline)
- Missing Outcome Data: Multiple imputation with chained equations (MICE) stratified by intervention to generate 200 imputed datasets. Imputation models included all variables specified for primary analysis and additional auxiliary variables based on results from stepwise regression hypothesis testing with a significance level of $p<0.10$

Pain improved more in the two MBIs compared to Usual Care



Baseline-adjusted model. All estimates adjusted for design factors and pain self-efficacy.

Averaged over 3 timepoints, BPI pain interference score was lower for those in both MBIs vs UC. The two MBIs did not significantly differ from one another.

	Group MBI vs. Self-Paced MBI Difference	Group MBI vs. UC Difference	Self-Paced MBI vs. UC Difference
Outcome	(95% CI)	(95% CI)	(95% CI)
Averaged over 3 timepoints	0.3 (0.0, 0.6)	-0.4 (-0.7, -0.2)	-0.7 (-1.0, -0.4)
Overall p-value (sig. threshold = 0.0167)	p = 0.031	p = 0.002	p = <0.001

Adjusted Percent with 30% & 50% Reduction in Pain Interference

	Treatment groups			Group differences (95% CI)		
	Group MBI	Self-paced MBI	Usual care	Group minus Self-paced	Group minus Usual care	Self-paced minus Usual care
10 Week						
≥30%	**33.6**[1]	**40.3**[1]	15.9	-6.7 (-15.4 , 1.9)	17.6 (10.2, 25.0)	24.4 (16.6, 32.1)
≥50%	**14.0**[1]	**21.3**[1]	6.6	-7.3 (-14.2, -0.5)	7.4 (2.1, 12.7)	14.7 (8.6, 20.8)
6 Month						
≥30%	**34.4**[1]	**38.2**[1]	22.2	-3.8 (-12.5, 4.8)	12.2 (4.3, 20.1)	16.0 (7.8 , 24.2)
≥50%	14.7	**19.2**[1]	10.4	-4.5 (-11.4, 2.4)	4.2 (-1.8, 10.2)	8.7 (2.3, 15.2)
12 Month						
≥30%	30.3	**42.2**[1]	24.1	-12.0 (-20.5, -3.4)	6.2 (-1.7, 14.0)	18.1 (9.9 , 26.3)
≥50%	16.6	**20.8**[1]	13.3	-4.2 (-11.2, 2.8)	3.3 (-3.0, 9.6)	7.5 (0.9, 14.1)

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

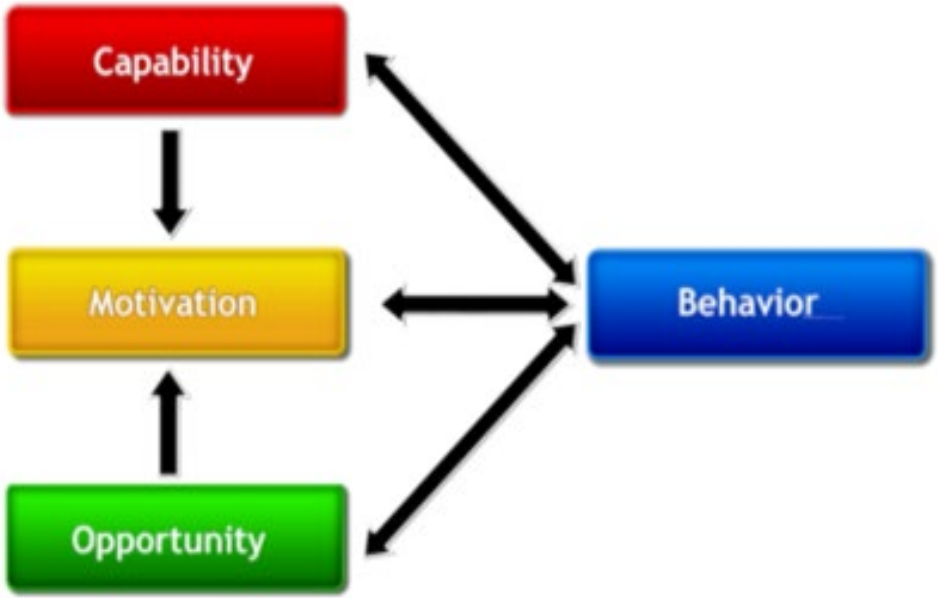
[1]**Different from usual care arm at $p \leq 0.05$**

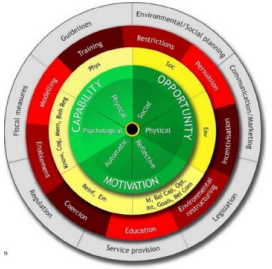
Adjusted secondary outcomes averaged over 12 months

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

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

Qualitative results illustrate how LAMP improved Veterans' Capability, Motivation and Opportunity





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

Capability (knowledge and skills)

It helps bring attention to the fact that some pain can be overcome, and that we can still have a "normal" life with chronic pain

I definitely find myself using the mindful practices and movements more to clear my mind and replace negative thought spirals.

Opportunity

It was great to talk to other Veterans especially the females to know I was not alone

The group interaction was so beneficial to me. Hearing what others do and the pain they experience and manage helped my perspective

Motivation

When the pain wakes me I use the meditation and breathing to focus on relieving the pain. This does help and lessens the time I am, awake before the pain is reduced and I can again sleep. I am going to try doing the meditation before going to sleep and see if that helps. (goals)

This program helped me get out of the mind set and learn to be kind to my body when it was telling me to stop, as opposed to getting angry that I was in pain and unable to do things I used to do. (emotions)

Bottom line: Two scalable, telehealth approaches to delivering MBIs improved pain-related function and other biopsychosocial outcomes compared to UC, among Veterans with chronic pain and high levels of psychiatric comorbidity.

- Effects were consistent across outcomes and were sustained over 12 months
- The two MBIs did not significantly differ from one another on the primary outcome and most secondary outcomes
  - Differences emerge on “responder analysis”
- No gender differences on primary outcome

Next steps

- Analyses to explore:
  - Why group MBI wasn't superior to self-paced MBI
  - Characteristics of intervention responders versus non-responders/subgroup analyses
  - Mediators
  - Effects of dose (sessions attended, home practice)
  - Responder analysis with secondary outcomes
  - Gender; focus on Women Veterans

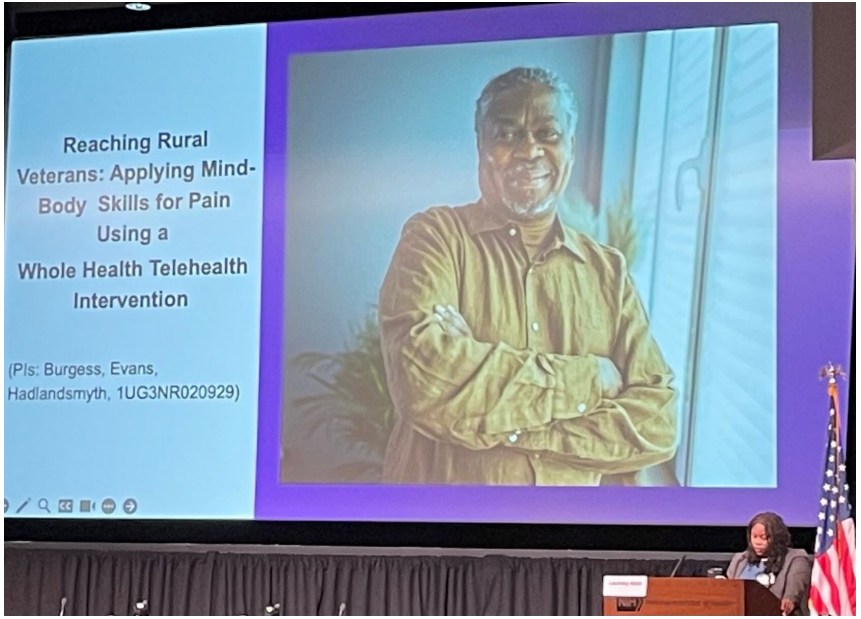
- RE-AIM analyses (in progress)
- Work with OPCC&CT to implement self-paced MBI in VHA Whole Health system, delivered by Whole Health coaches
- Package interventions for broader dissemination

RAMP: Will test a CIH intervention that addresses needs of rural VA patients and overcomes existing barriers to pain care

RAMP
Rural Veterans Applying Mind Body Skills for Pain

Funded by the National Institute of Nursing Research, as part of the NIH HEAL Initiative (1UG3NR020929-01)

MPIs: Diana Burgess, Roni Evans, Katie Hadlandsmyth
Co-Investigators: Robin Austin, John Ferguson, Alex Haley, Brent Leininger, Marianne Matthias, Brent Taylor, Stephanie Taylor; **Consultant:** Greg Serpa. **Project staff:** Ann Bangerter, Lee Cross, Emily Hagel Campbell, Mallory Mahaffey, Kim Behrens



Slide from 2024 NIH Pain Consortium Symposium on Advances in Pain Research (5/30/24)

Rationale for RAMP

- Rural America is disproportionately affected by chronic pain
  - Higher rates of chronic pain
  - More likely to be prescribed opioids & less likely to use non-opioid interventions

- Rural patients in the Veterans Healthcare Administration (VA) with chronic pain:
  - Are less likely to receive comprehensive and specialty pain care
  - Are more likely to be prescribed opioids
  - Are less likely to use self-management for pain
  - Have less access to Complementary and Integrative Health (CIH) treatment for pain

RAMP Overview

- RAMP program: cohesive, scalable multi-component CIH intervention, delivered by Whole Health coaches via telehealth, that addresses rural Veterans' needs and overcomes existing barriers to pain care
- Designed to be implemented within the VA through its nationwide Whole Health System initiative
- We will assess effectiveness of RAMP at improving pain and secondary outcomes among rural VA patients with chronic pain (n = 500) and collaborate with patients, community advisors, and VA healthcare system leaders to co-develop, evaluate intervention implementation strategies used in the trial and adapt these strategies to scale up RAMP within the national VA healthcare system

RAMP

Thank-you!

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