

# Increasing Diversity and Inclusion in Clinical Trials: Lessons Learned and Lessons Learning

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# Lessons from ACTION & LAMP trials

- Trials of nonpharmacological pain treatment (NPTs) for Veterans with chronic pain in the VA healthcare system
- Racial/ethnic minority Veterans in VA:
  - Predominantly Black
  - More likely to be younger & female than non-Latinx whites (but still mostly male)
  - Shared experiences in military & VA healthcare system (e.g., pain treatment, for women, high rates of military sexual trauma)

# ACTION (Taking ACTION to improve pain)

- A walking-focused, proactive coaching intervention aimed at addressing contributors to racial disparities in pain
- Exceeded enrollment goals for Black patients:
  - Goal: 250/500
  - Actual 380/500

**Funded by VA HSR&D IIR #13-030-2**

**Study team:** Diana J. Burgess, Emily Hagel Campbell, Patrick Hammett, Kelli D. Allen, Steven S. Fu, Alicia Heapy, Robert D. Kerns, Sarah L. Krein, Laura A. Meis, Ann Bangerter, Lee J. S. Cross, Tam Do, Michael Saenger, Brent C. Taylor

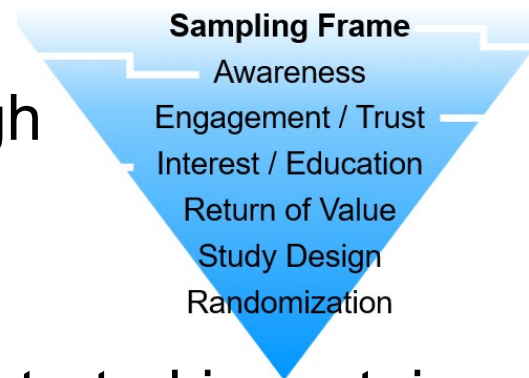


- Mindfulness-based intervention to improve chronic pain outcomes among VA patients (in progress)
  - Focus on addressing needs of women Veterans

**Funded by the Department of Defense** under Award W81XWH-18-2-0003. Part of the NIH-DoD-VA Pain Management Collaboratory

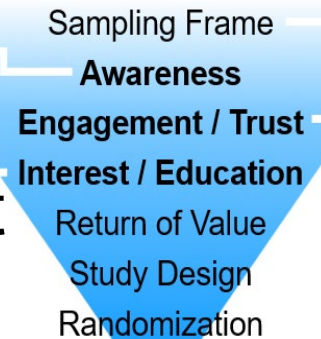
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## Lesson #1: Choose study sites with high % racial/ethnic minority patients



- Racial/ethnic minority patients concentrated in certain healthcare facilities
- ACTION delivered via phone, allowing us to choose a study site with a high % of Black patients (Atlanta VA)
- LAMP – chose sites with higher % racial/ethnic minorities
- Choice of sites are affected by composition of study team/social networks (certain sites overrepresented)
  - Broaden ways we recruit study teams
  - Sponsor level: review criteria to increase diversity of sites & teams

## Lesson #2: Proactive outreach can help address barriers of awareness, engagement, interest, knowledge, mistrust



- Systems-level strategy & patient engagement model
- Identify & reach out to patients to connect them with treatment
- LAMP & ACTION: Recruitment packets sent to VA patients with chronic pain diagnoses in EHR
  - Developed with input from patients to overcome barriers (e.g., mistrust, knowledge)
  - Followed by phone calls with staff, trained in communication skills

# Lesson #3. Patient input & patient advisory boards helped address numerous barriers (engagement, trust...)



Sampling Frame  
Awareness  
**Engagement / Trust**  
Interest / Education  
Return of Value  
Study Design  
Randomization



**LAMP Veteran Engagement Panel**



# Focus groups with Black VA patients with chronic pain gave critical input on ACTION recruitment materials

## Initial reactions to recruitment brochure & letter:

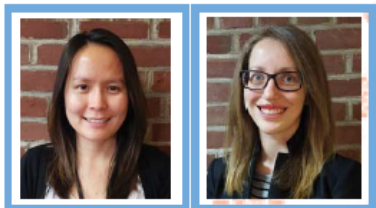
- **Mistrust** about involvement of VA
  - Occurred during VA's efforts to reduce opioids
  - Who is doing the research & why?
- **Skepticism about intervention**
  - How does this intervention actually work?
  - How can walking help me with my pain?
  - I already know I should exercise – how will this help?
  - How can someone coach me over the phone?
  - Is this like telemarketing?



# Lesson #4: Make sure your materials are motivating to potential participants & convey the “what” and the “why”

## About our coaches

You will work with the same coach each time, so the two of you can build a relationship. Many Veterans have told us that they really like having a coach who really listens, encourages and supports them, and who cares about the progress they make. Your coach cares about working with Veterans, and understands the sacrifices you have made for your country. All coaches have an advanced degree in counseling and have training in pain management techniques.



## About the study team

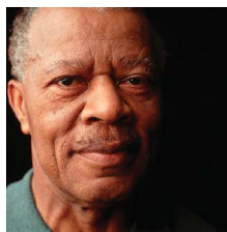
We are a team of researchers and VA providers who are committed to studying how to improve pain care for Veterans.

## Why walk?

Walking is a safe, low impact exercise and is widely recommended for people with pain. It can help you:

- Move more easily and be more active
- Reduce your pain
- Feel more energized
- Improve your mood
- Gain muscle strength
- Sleep better

**ACTION** is a personalized coaching program, designed to reduce your pain and improve your mood, energy and quality of life, by helping you to increase your physical activity.



## What will I be doing?

You will meet with your personal coach over the phone, 6 times over the course of 3 months, at a time that works for you in the convenience of your home. Your coach will work with you to develop a tailored pain management program, incorporating walking and movement, focused on your particular needs and goals.

**In the first session** you and your coach will get to know each other, set some goals, and create a plan for how you will gradually increase your current level of walking and movement.

**Over the next 3 months** you will meet with your coach to check in, talk about what went well and what didn't, and develop your walking plan for the coming week or two. You will also learn how to pace yourself so you don't get too tired and you don't hurt yourself. Depending on your goals you might also focus on relaxation or sleep management techniques, on learning how to walk safely and avoid falls, and incorporating other forms of movement.

**By the end of the program, you will have the tools you need to manage your pain.**

You will receive a pedometer to help you track the steps you walk. Your pedometer will help you figure out how to build in more steps throughout your day. You will learn how just small increases in walking over the course of your daily routine can lead to real improvement in how you feel. **You don't need to walk a lot to feel better.**



# Lesson #5: Build trust by explaining who you are and why you care about pain research

## Q & A with Sean Green, U.S. Army Veteran and Member of LAMP Study Advisory Panel



**Q:** Can you tell us about who you are and why pain research is important to you?

**A:** I am a U.S. Army Veteran who enjoys human anatomy coloring books, watching sitcoms from the 90's, and listening to music from the 80's. My initial interest in pain management research began with an insatiable thirst for knowledge to help me in managing my own chronic pain. The main reason why pain management research is important to me is because I personally know many Veterans who have an extremely difficult time in managing their pain. Often Veterans are simply not aware of the myriad of modalities, strategies, and resources available to adjunct their current pain management protocol. This is why I'm a staunch advocate of pain research, as well as advocating pain research strategies for Veterans.

**Q:** Why should Veterans consider participating in LAMP?

The information the LAMP study will provide will be another tool the Veteran may find extremely useful in managing their chronic pain. The LAMP study's team is comprised of researchers, health care providers, and fellow Veterans that are committed to improving pain care for Veterans.

**Q:** What would you say to a Veteran who feels isolated or hopeless about his or her pain?

**A:** If a fellow Veteran is feeling isolated or hopeless about their pain, I would inform them they do not have to navigate this chronic pain management journey alone. I would recommend the Veterans Affairs Veteran Crisis Line, where the Veteran can confidentially talk, text, or chat with qualified responders, in which many of the responders are Veterans.

<https://www.veteranscrisisline.net/>

**Q:** What other resources would you recommend to Veterans, to help them with their pain?

**A:** One other resource that comes to mind is the VA "Whole Health" program. This is a program that is highly patient centered and focuses on "what matters" to the Veteran. A team of Veterans Affairs professionals assist in developing a personalized health plan based on the Veteran's pain management needs and goals. Whole Health considers the Veteran's physical, emotional, mental, social, spiritual, and environmental influences in their lives. This is incredibly important in the realm of managing one's chronic pain.

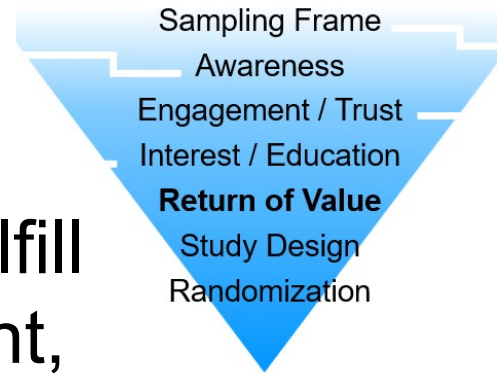
<https://www.va.gov/wholehealth/>

## The LAMP Team

We are a team of researchers, healthcare providers, and Veterans who are committed to improving pain care for Veterans.



## Lesson #6: Choose an intervention that is of high value to your population



- Trials of NPTs (LAMP & ACTION) fulfill unmet needs for better pain treatment, especially those not involving medication
- Appeal of coaching (in ACTION), especially among those with comorbid mental health conditions & unmet mental health needs  
(ACTION focus group participant said coaching calls would “give him hope”)

# Focus groups of Black VA patients with chronic pain pointed to need for NPTs

- “I think about the time that we got into the military, it was great, everything was fine. Our health was good. And we would like to continue with the same thing once we gotten out or finished. But we can't because it seems like it gave us more pain. It hurt us more. We're out there helping the people, but it hurt us more. Our bodies. Then when we ask for the help, we can't get the help. But we gave them the help.”
- “And it's getting progressively worse...And then they give us drugs. Yeah, there you go. Percocet, Tramadol, Vicodin. I said I don't want any more drugs. So, I'm just, you know, I'm dealing with the pain without drugs.”
- “There's no other support...Just pain meds and that's it.”

# Lesson #7: Counter cultural messages about NPTs/CIH approaches

- Most (but not all) studies find CIH more likely to be used by non-Latinx whites (& higher SES), including for pain
- Myriad barriers for racial/ethnic minorities who want NPTs/CIH approaches, including representation



## Lesson #8: Pay attention to discrimination & hostile climate issues that may exist within clinical settings where studies are conducted

- Example: 24% of female Veterans experienced sexual harassment at their VAs & 15%-40% experienced military sexual trauma
  - Issue for LAMP, which focused on female Veterans & included in-person mindfulness groups
  - Raised by LAMP Veteran and Stakeholder Engagement Panel members
  - Switch to virtual groups due to COVID eliminated some barriers
  - Other solutions: monitor climate, choose sites carefully

## Future: Promise & potential perils as more studies are conducted virtually

- Able to reach underserved populations (e.g., rural, racial/ethnic minority) outside healthcare facilities where investigators are located
- Some access barriers reduced; others increased
- Example from LAMP:
  - Worked with patient panel to create materials and processes to help participants become comfortable with the technology
  - Added extra training sessions
  - Re-allocated resources to provide additional support