Optimizing Pain Treatment in Medical Settings Using Mindfulness (OPTIMUM) Study Results

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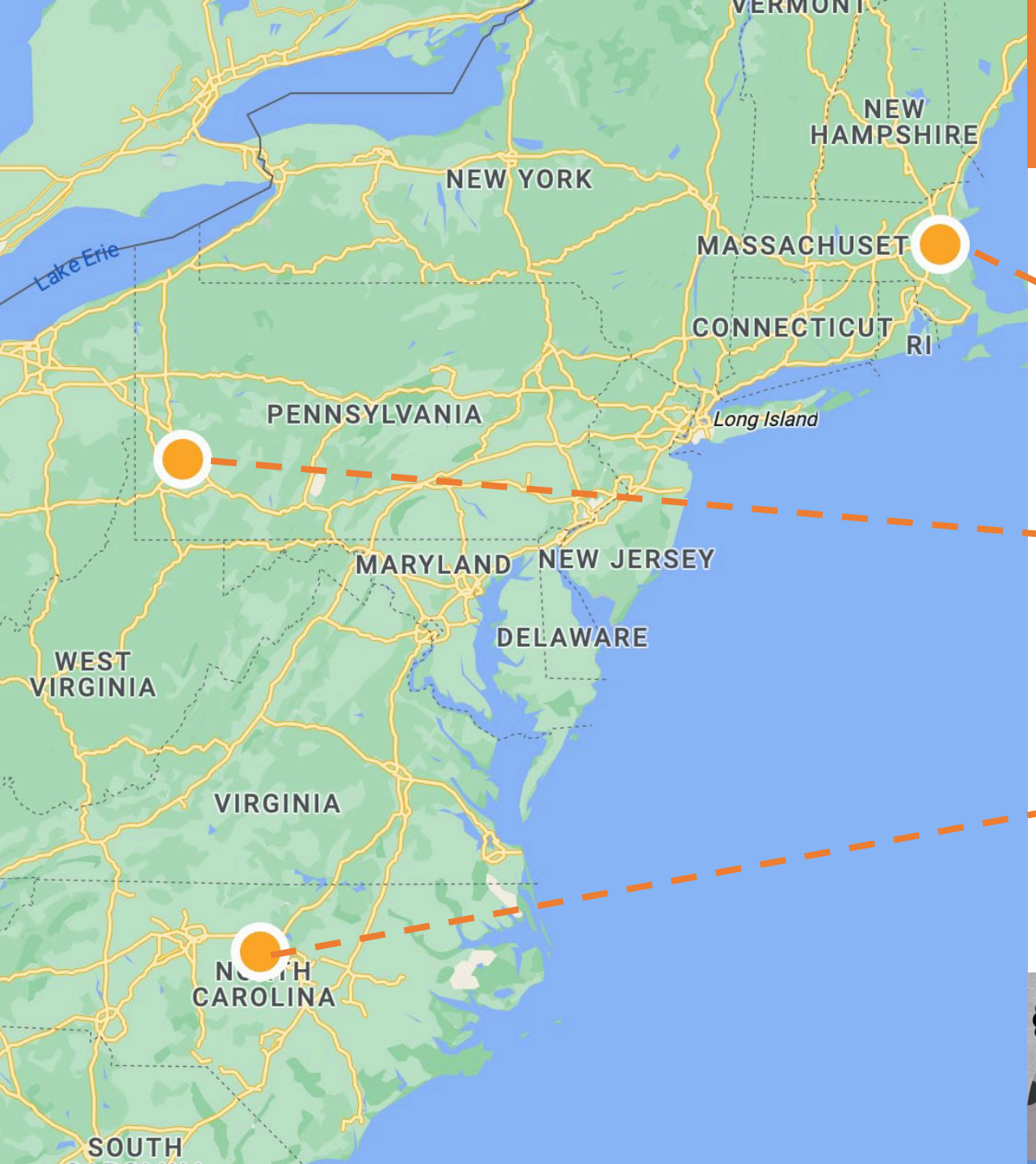




Acknowledgements

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- The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

OPTIMUM Locations



Boston Medical Center

University of Pittsburgh

University of North Carolina at Chapel Hill/Piedmont Health



OPTIMUM Pragmatic Clinical Trial

- **Eligibility**: Few eligibility criteria—chronic low back pain without signs of serious underlying cause
- **Recruitment**: medical record,referrals from providers, patient portals
- **Setting**: primary care clinics (online due to pandemic)
- **Organization**: Group medical visit with primary care provider and mindfulness instructor
- **Flexibility**: 8-week program, but adherence not different from expected in clinical care
- **Follow-up**: after intervention at 1, 6, 12 months
- **Primary outcome**: relevant to participants (pain, function, enjoyment)
- **Primary analysis**: Intention-to-treat

Study Flow Chart



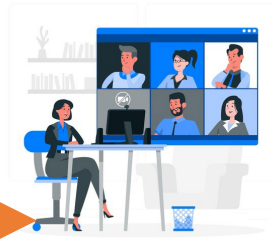
Participant has chronic low back pain.



Participant is interested, screened for eligibility, and consents to take part in the study.



Participant completes baseline surveys.



Participant gets group pain management program for 8 weeks



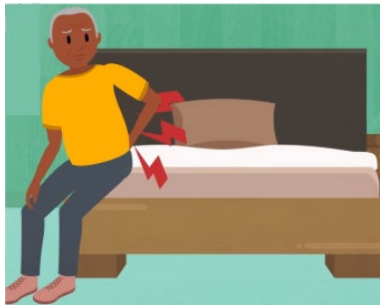
Control Group: Participant gets usual primary care by provider



Participant completes surveys monthly, after 8 weeks, 6 months and 12 months.

What Changes Were We Looking For?







Back Pain







General Activity





Enjoyment of Life

How Did We Measure The Changes?

PEG Scale: Pain, Enjoyment of Life, and General Activity

What number best describes your pain on average in the past week?

No Pain										Pain as bad as you can imagine
0	1	2	3	4	5	6	7	8	9	**10**

What number best describes how, during the past week, pain has interfered with your enjoyment of life?

Does not interfere										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	**10**

What number best describes how, during the past week, pain has interfered with your general activity?

Does not interfere										Completely interferes
0	1	2	3	4	5	6	7	8	9	**10**

To compute the PEG score, add the three responses to the questions above, then divide by three to get a final score out of 10.

How Did We Measure The Changes?

We also interviewed participants

- We wanted to understand what it was like for participants in the study.



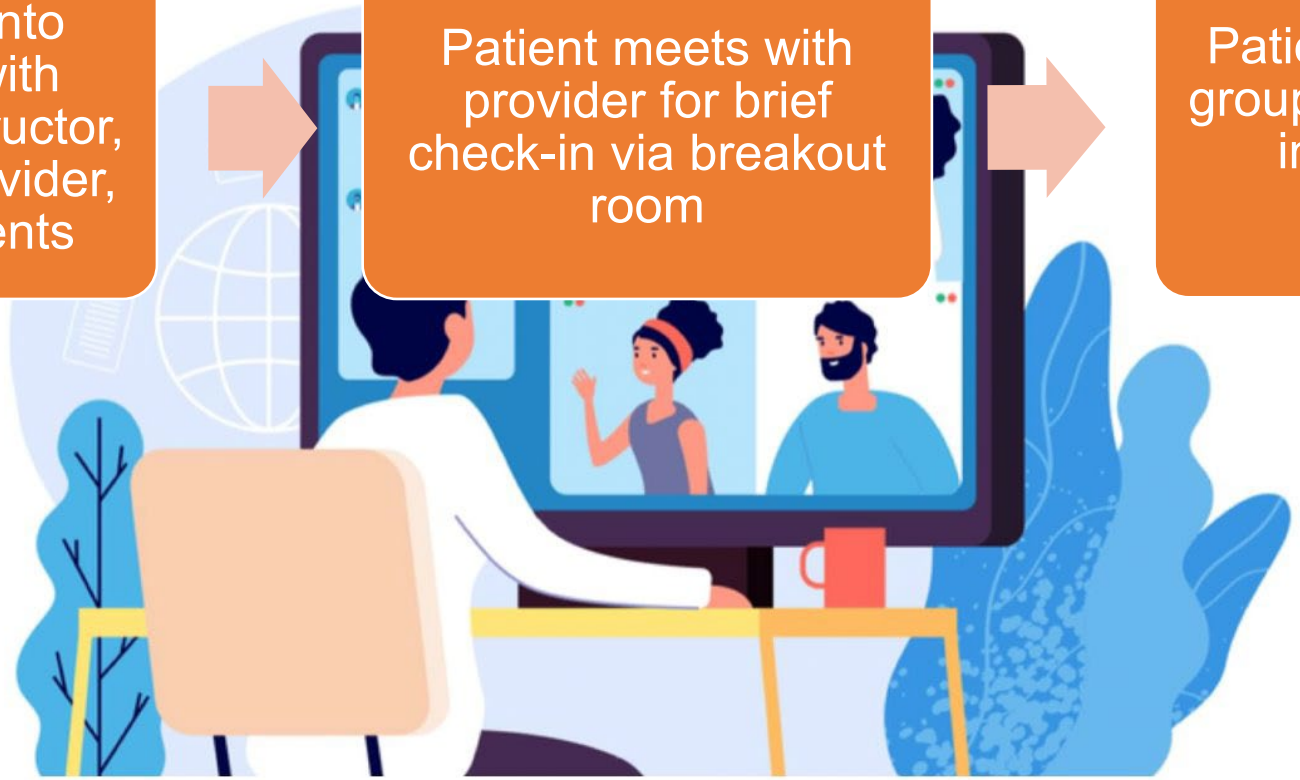


Group Medical Visit: Clinical Format to Deliver Intervention

Patient signs into 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



The OPTIMUM Mindfulness Program

Program Principles: Four methods of mindfulness meditation

- **Walking Meditation**
- **Body Scan**
- **Breath Focused Meditation**
- **Mindful Stretching**

Based on Mindfulness-Based Stress Reduction (MBSR)



OPTIMUM Fidelity rating project

Concise Fidelity tool for Online Mindfulness-Based Interventions (CoFi-MBI)

Four Domains:

1 – Session Logistics:
Rater Instructions, Session Date, Session Number, Staff Initials, Study Site, Cohort Number

2 – Session Content Elements:
Meditation Practice, Discussions, Break-out Sessions with Clinician, Home Practice Introduced

3 – Participant Engagement:
Likert Scales on *Proportion* and *Extent* of Participant Engagement

4 – Technology Obstacles:
Extent to Which Technology Obstacles Hindered Participants' Engagement (Audio/Video/Internet Connectivity/etc.)

Example questions: Session Content Elements

Mindfulness /meditation instruction and practice (e.g., raisin exercise, body scan, sitting meditation, walking meditation, yoga, focused attention)
☐ Y (1)
☐ N (2)
☐ NA (9)
1a Notes:

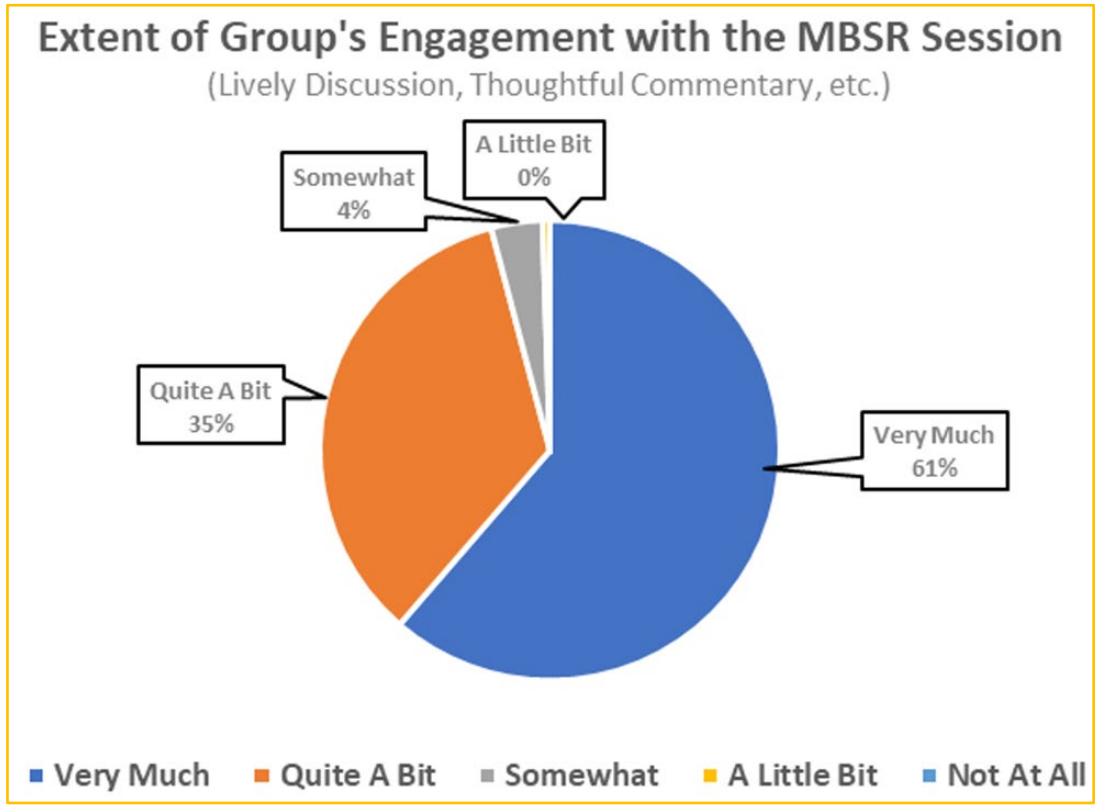
Discussion and Debrief (e.g., debrief meditation, discussion of home practice, pain / stress discussion)
☐ Y (1)
☐ N (2)
☐ NA (9)
2a Notes:

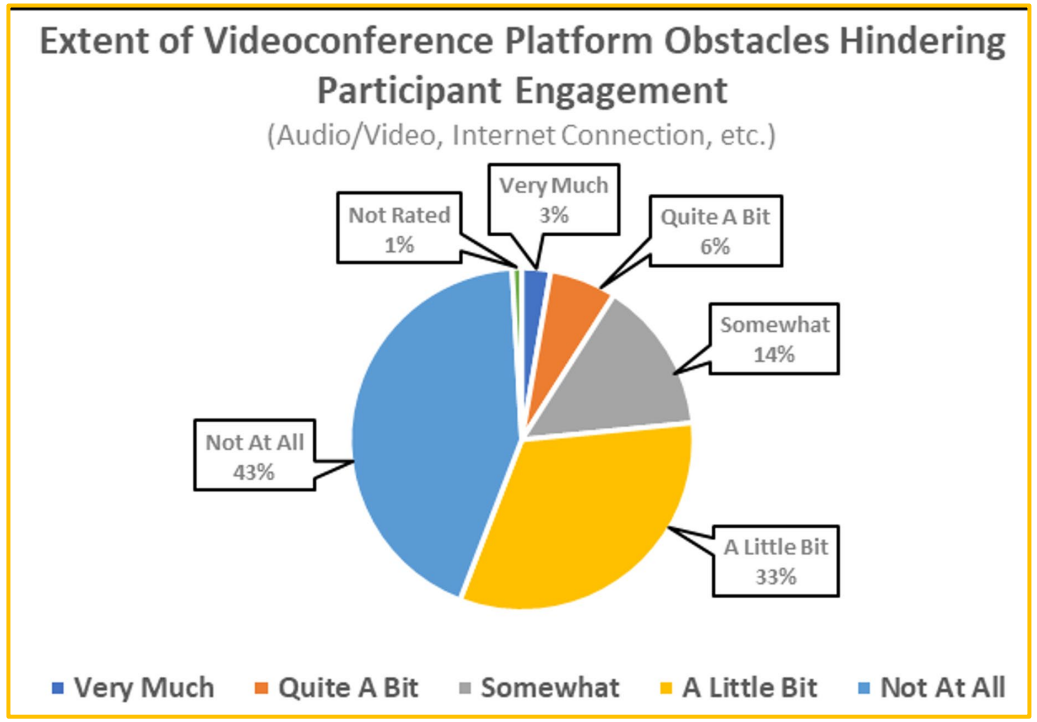
Breakout sessions with clinician -all participants in today's session attended a breakout
☐ Y (1)
☐ N (2)
☐ NA (9)
3a Notes:



OPTIMUM Intervention Fidelity

Results:
Session Content Elements occurred as intended in 94-100% of sessions





The CoFi-MBI fidelity tool is available to be used and adapted for online mindfulness-based interventions.

Greco CM, Dore GA, Weinberg JM, Roth I, Thomas HN, Lawrence S, Rodriguez R, McGillis M, Morone NE. A Brief Measure of Fidelity for Mindfulness Programs: Development and Evaluation of the Concise Fidelity for Mindfulness-Based Interventions Tool. Glob Adv Integr Med Health. 2023 Jul 1;12:27536130231174234. doi: 10.1177/27536130231174234. PMID: 37426338; PMCID: PMC10327996.



What Were The Study Results?

What Were The Study Results?

Assessed for eligibility	n=1367
Randomized	n=451
Allocated to intervention	n=224
Allocated to control	n=227
Week 8 assessment	n=440
Month 6 assessment	n=424
Month 12	n=401
Intention to treat analyses	n=451

What Were The Study Results?



Mindfulness group
participate in 8-week virtual Mindfulness Based Stress Reduction program

224



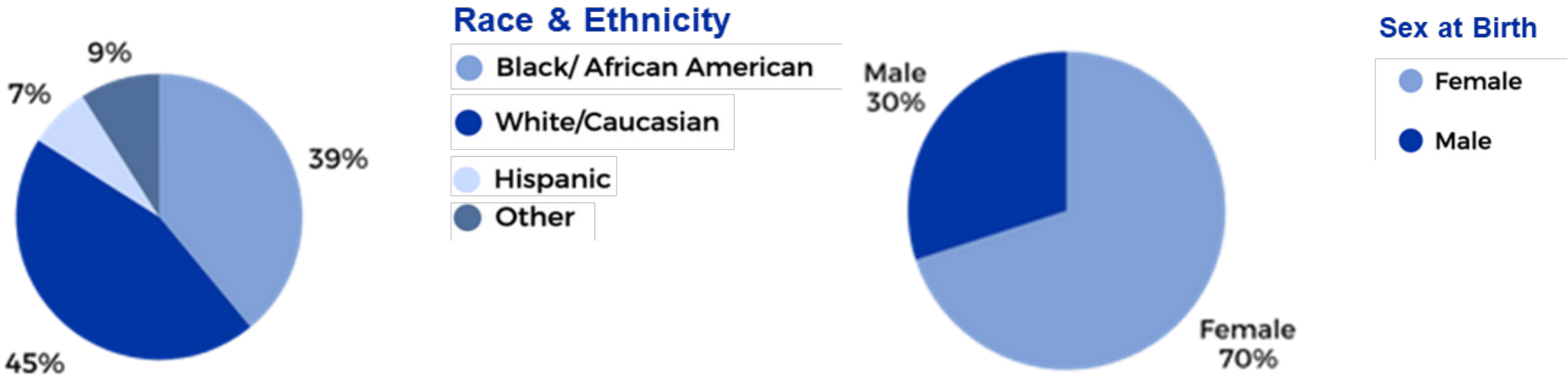
Usual care group
receive usual primary care

227

What Were The Study Results?

Population:

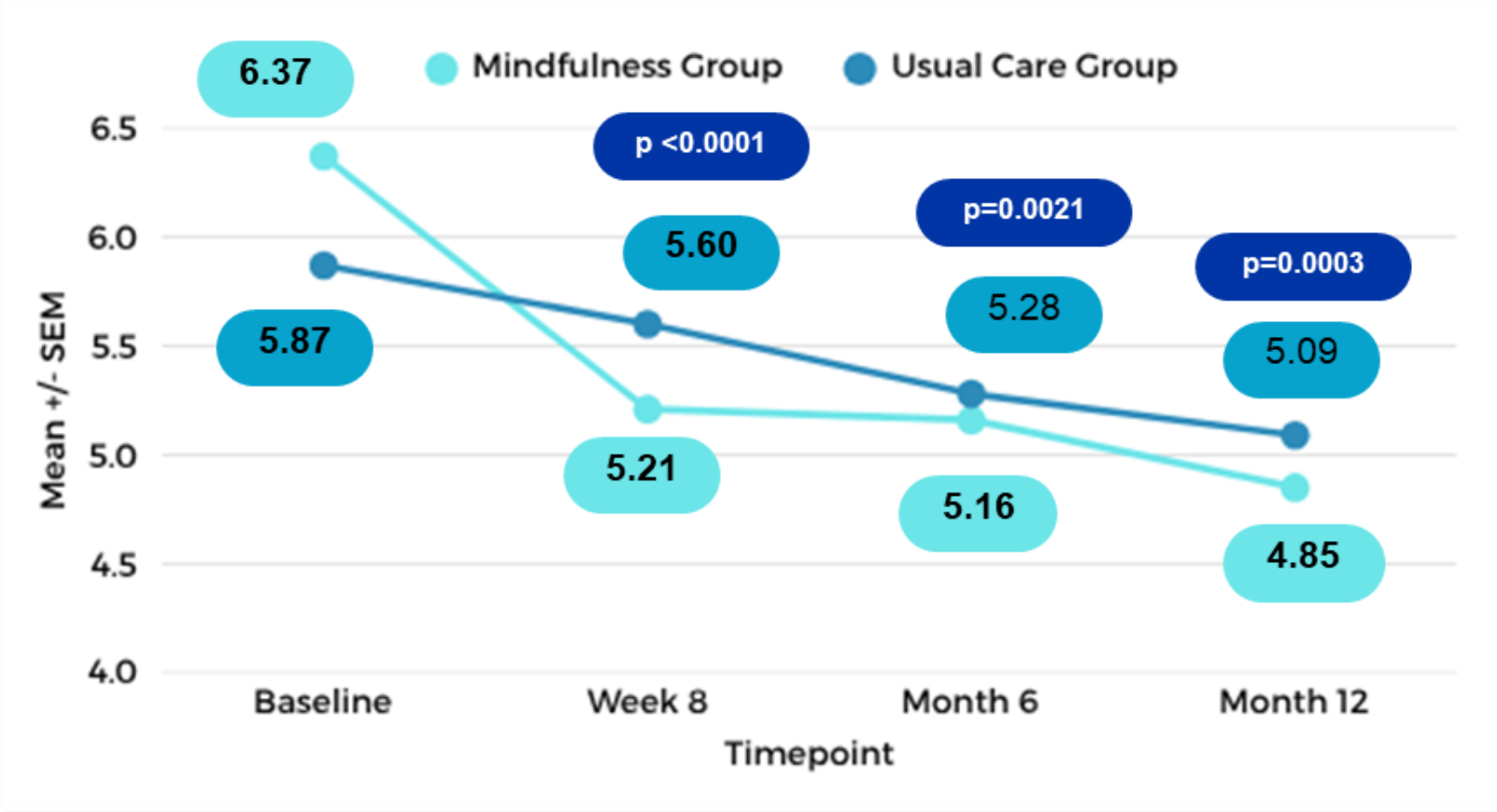
- **451** persons with chronic low back pain.
- Mean age of **52**.
- Age range: **18-88**.



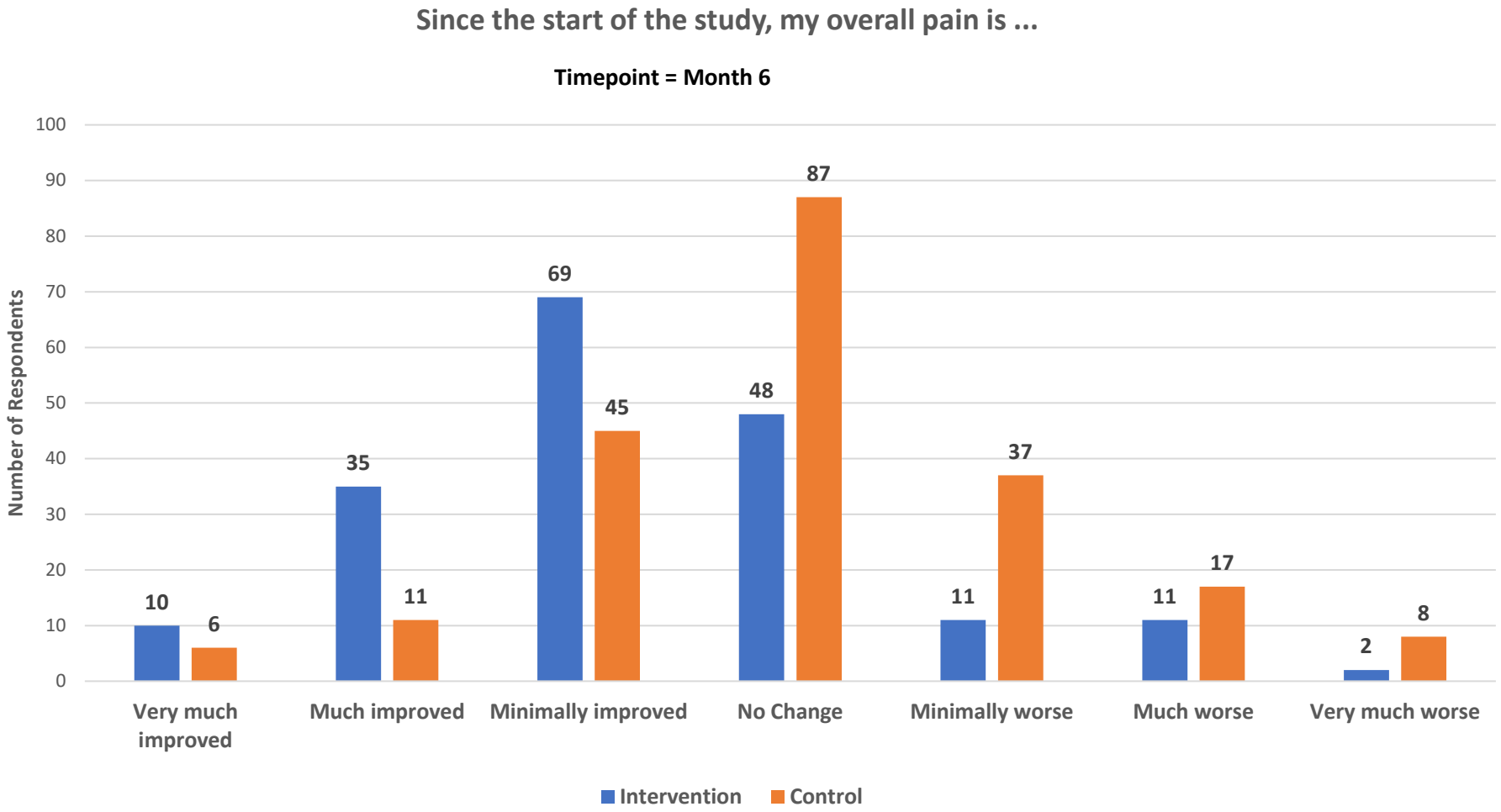
What Were The Study Results?

PEG Scale: Pain, Enjoyment of Life, and General Activity

- **Lower scores indicate less pain.**



What Were The Study Results?



Partner Engagement: Community Advisory Board

- Patients with chronic low back pain
- Mindfulness instructors
- Healthcare professionals
- Pain advocacy group leaders
- Administrators

- 10 members
- Met monthly 1 hour
- Reimbursed




ARE YOU BOTHERED BY CHRONIC LOW BACK PAIN?
You may be eligible to participate in a research project studying Mindfulness training for patients with chronic low-back pain
YOU MAY BE ELIGIBLE IF:
✓ You are 18 yrs and older
✓ You have chronic low back pain (3 months or more)
✓ The pain interferes with activities
PARTICIPATION IN THIS RESEARCH STUDY MAY INCLUDE:
✓ Completing surveys and video calls with research staff
✓ Attending weekly group sessions via zoom
✓ Compensation for participation
CONTACT US TO SEE IF YOU ARE ELIGIBLE!
Optimum


HAVE YOU THOUGHT ABOUT MINDFULNESS FOR YOUR CHRONIC LOW BACK PAIN?
PARTICIPATION MAY INCLUDE
• Completing surveys and video calls with research staff
• Attending weekly group sessions via zoom
• Compensation for participation
YOU MAY BE ELIGIBLE IF
• You are 18 yrs or older
• You have chronic low back pain (3 months or more)
• The pain interferes with activities
CONTACT US TO SEE IF YOU ARE ELIGIBLE
Optimum



Three OPTIMUM supplements



Isabel Roth, DrPH
Community Engagement Supplement



Jessica Barnhill, MD, MPH
Chronic Overlapping Pain Conditions Supplement



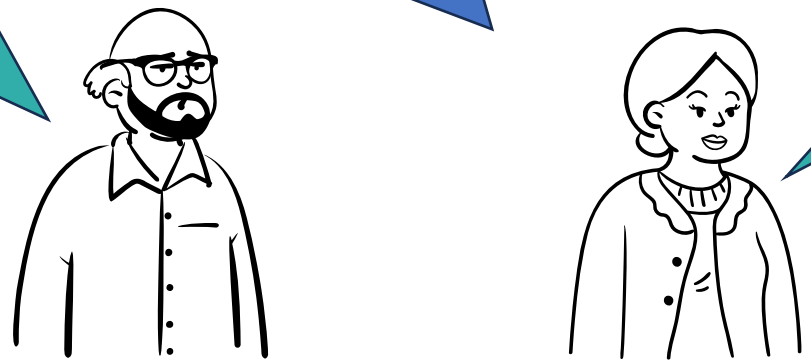
Nandie Elhadidy, MS
Diversity Supplement
Focus on Natural Products
(NCCIH 3UH3AT010621-03S1).

Post-participation interviews Major Themes and Subthemes

Ease
"there wasn't much to prevent me from being able to look at the phone and talk to people."

Levels of Support
"I'm new to all this technology and I've just given that up to the staff I am working with"

Struggle
"When you are looking at this little person on screen, it's hard to make connections"



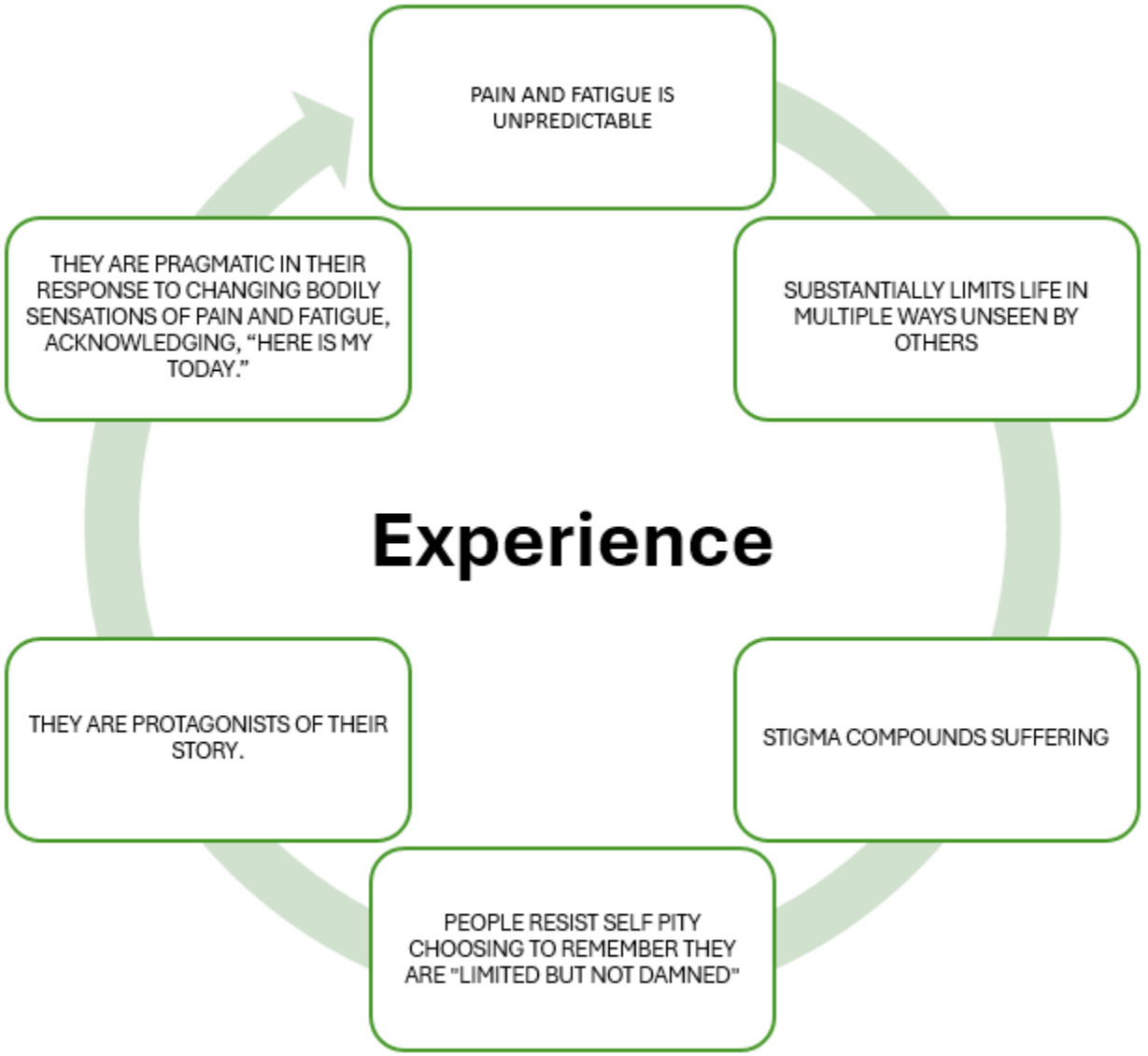
Major Themes and Subthemes from Post-participation interviews

Comfort
"able to be part of the study…in my own space"

Social Demands at Home
"My older kids come in…so it was hard to find that quiet peace"

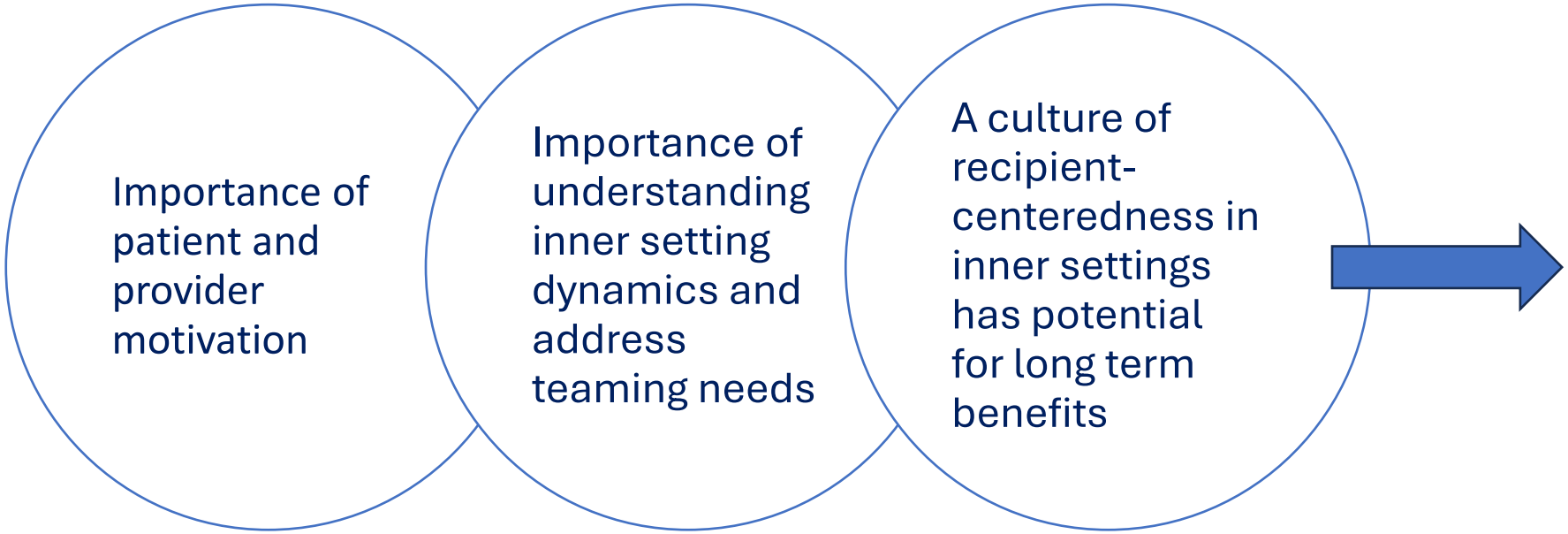
Sharing Personal Spaces
"I just didn't want that stress of what they could see and couldn't see"



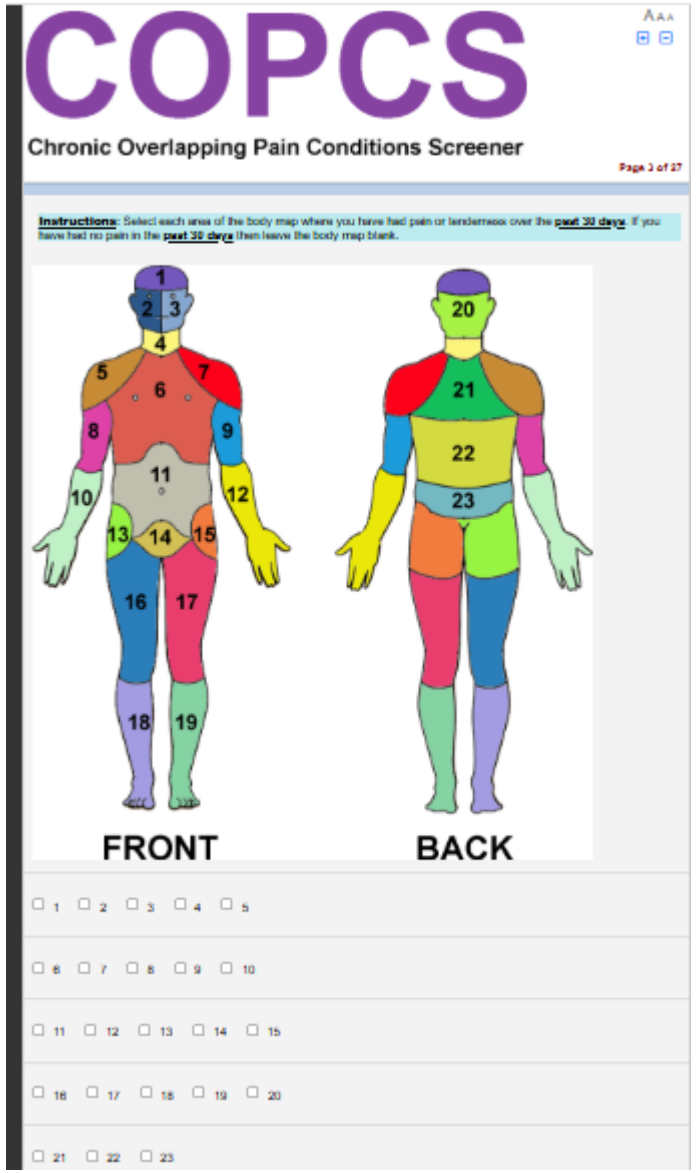

PAIN AND FATIGUE IS UNPREDICTABLE
SUBSTANTIALLY LIMITS LIFE IN MULTIPLE WAYS UNSEEN BY OTHERS
STIGMA COMPOUNDS SUFFERING
PEOPLE RESIST SELF PITY CHOOSING TO REMEMBER THEY ARE "LIMITED BUT NOT DAMNED"
THEY ARE PROTAGONISTS OF THEIR STORY.
THEY ARE PRAGMATIC IN THEIR RESPONSE TO CHANGING BODILY SENSATIONS OF PAIN AND FATIGUE, ACKNOWLEDGING, "HERE IS MY TODAY."
Experience

Summary of Community engagement findings

Updated Consolidated Framework for Implementation Research



- Who should lead MBSR Group Medical Visits?
- How should facilitators be trained?
- How should providers be involved?

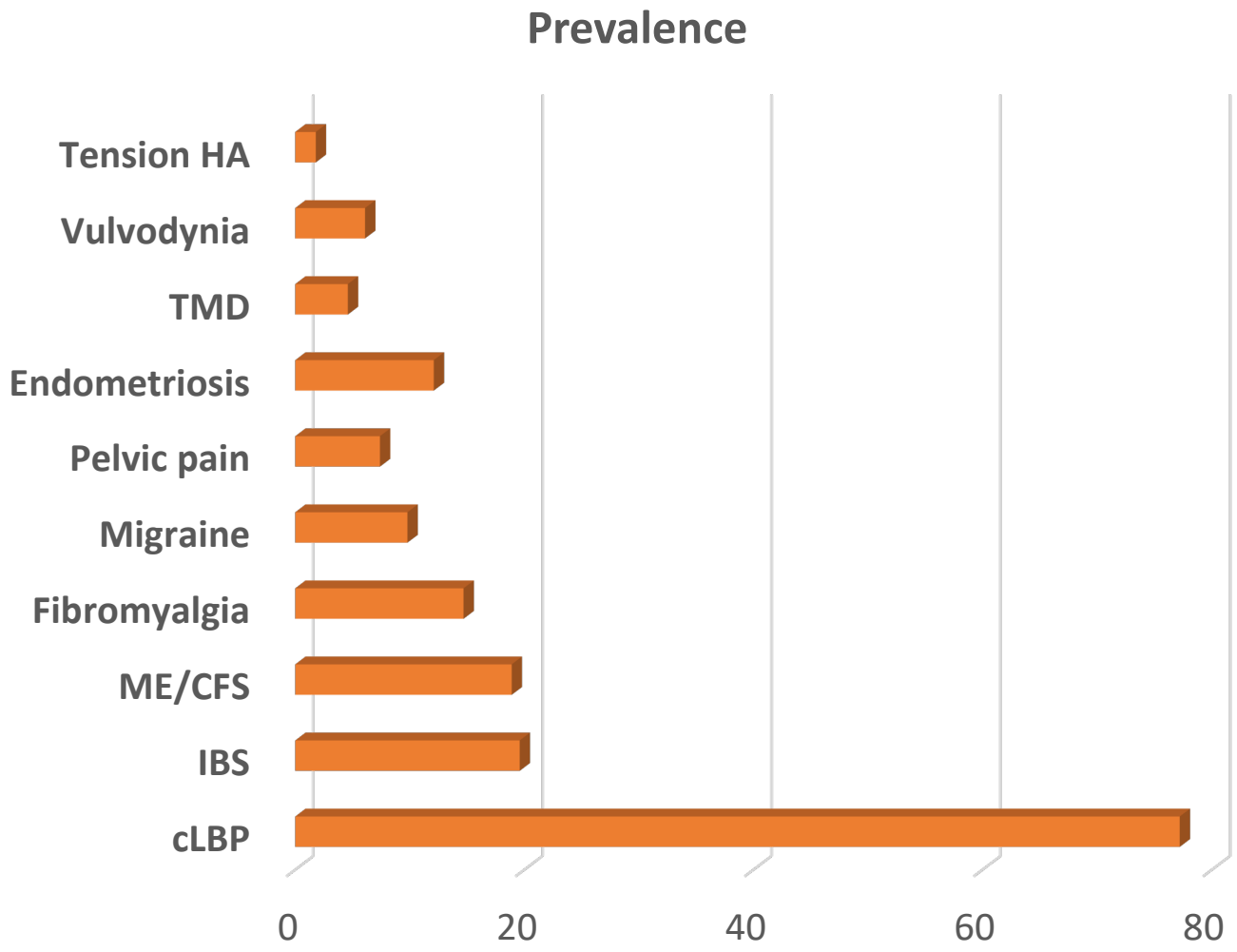


https://copcscreener.com/

- The Chronic Overlapping Pain Condition-Screener, an online, self-report, instrument validated for the identification of ten COPCs using a single tool.
- Administered at a single timepoint in the OPTIMUM study

- Schrepf A, Maixner W, Fillingim R, Veasley C, Ohrbach R, Smith S, Williams DA. The Chronic Overlapping Pain Condition Screener. The journal of pain : official journal of the American Pain Society 2023.

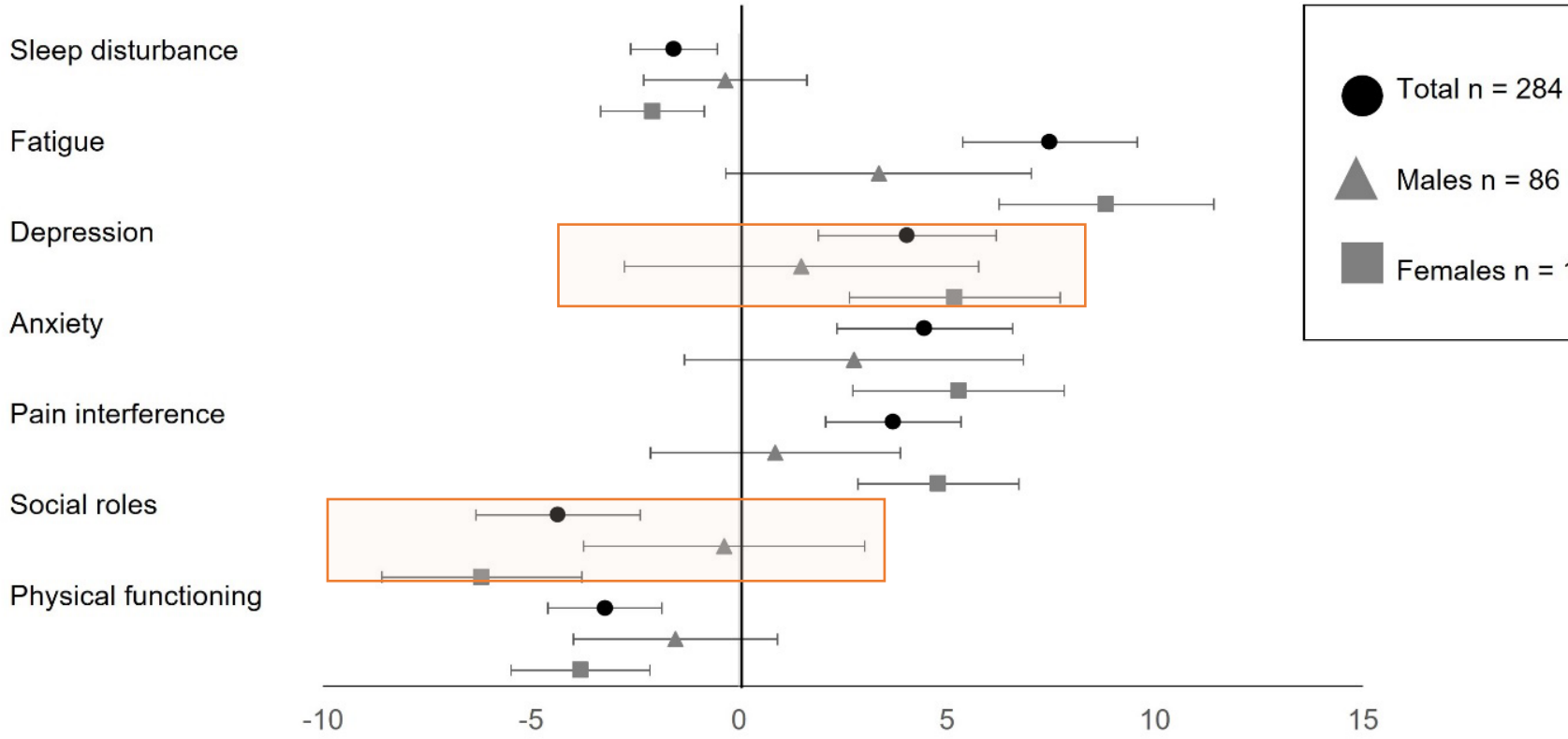
Findings



- Completed COPC screener (n=285)
- Age, sex, race matched overall study population
- 45% had at least one other COPC
- Overlapping cLBP and IBS most common (18%), then cLBP and ME/chronic fatigue (17%)

Association with other measures

- People with cLBP and additional COPC had significantly:
  - Higher pain catastrophizing scores
  - Higher fatigue scores
  - Higher pain interference scores
  - Lower physical functioning scores
  - Lower ability to function in social roles scores
  - Some variability by sex, with females more severely affected



Diversity supplement: Estimate prevalence of DSNPs for cLBP and characteristics of users
What are DSNPs?

Dietary Supplements

products taken by mouth that contain a "dietary ingredient" (fda.gov)









Natural Products

Cannabidiol (CBD), Cannabis, Kratom, or any other natural substance used by patients not classified as a dietary supplement (includes topical natural products)



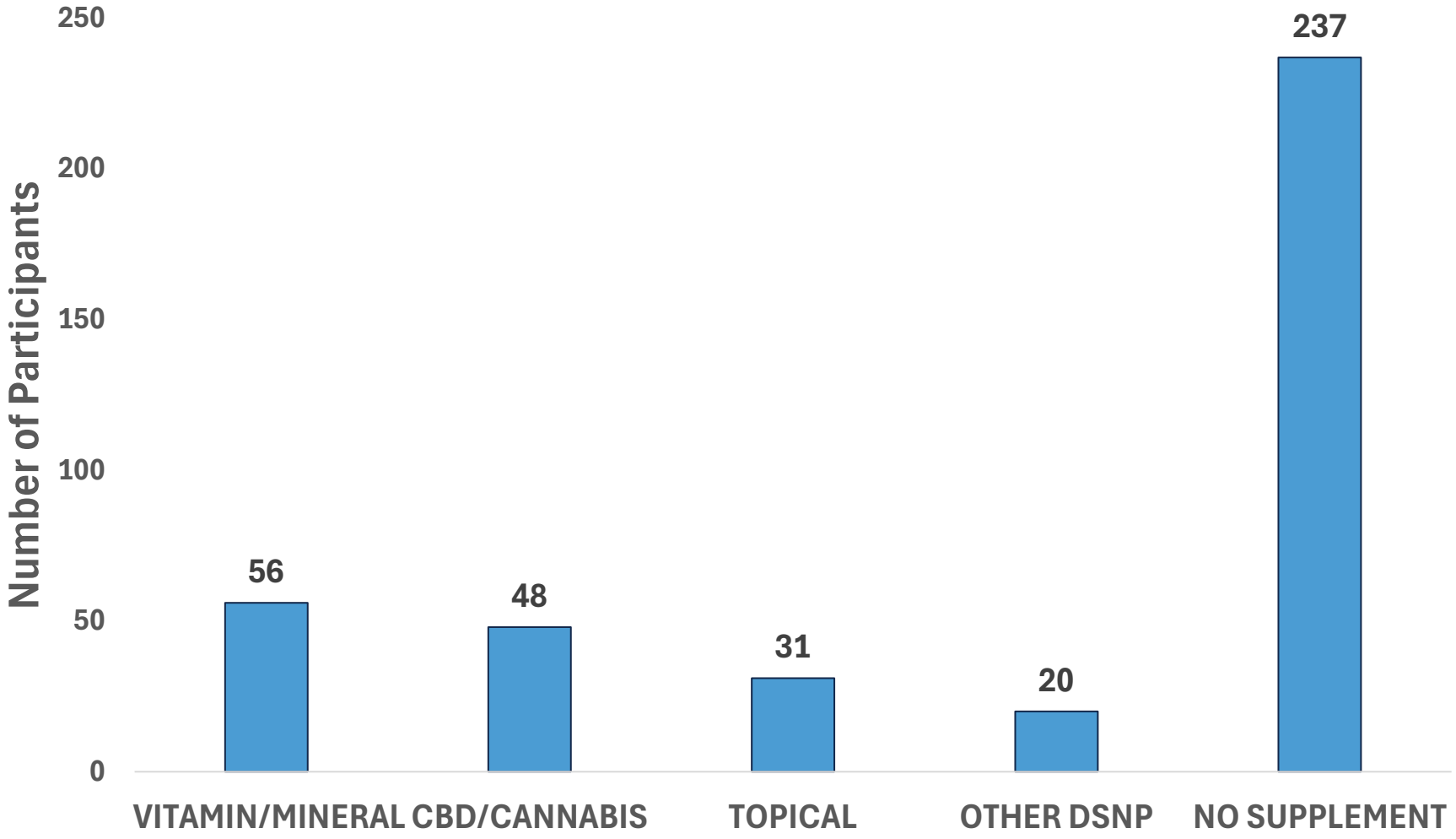




Distribution of prevalence of use for pain

N= 344 interviews

- Vitamin/Mineral - 16%
- CBD/Cannabis- 14%
- Topicals -9%
- Other DSNP- 6%
- No DSNP- 69%



No DSNP Use vs DSNP Use

	NO DSNP USE	DSNP USE
AGE	Mean=53 years old	Mean=50 years old
SEX	Female (68%)	Female (69%)
RACE	Black(44%), White (47%)	Black (48%), White (45%)
EDUCATION	High school graduates or less (40%)	High school graduates or less (52%)
INCOME	<$50,000 (49%)	<$50,000 (57%)
EMPLOYMENT	Not employed (57%)	Not employed (52%)

OPTIMUM Team

Boston

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Research Participants
Community Advisory Board
NIH Pragmatic Trials Collaboratory
NCCIH Program Officer Dr. Wendy Weber

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*Carol Greco
*Kathleen McTigue
Holly Thomas
Suzanne Lawrence
Janice Thieret
Graham Dore
Anna White







Thank You!

Any Questions?

OPTIMUM Study Website: optimum.pitt.edu
Contact: optimum@bmc.org



Extra Slides

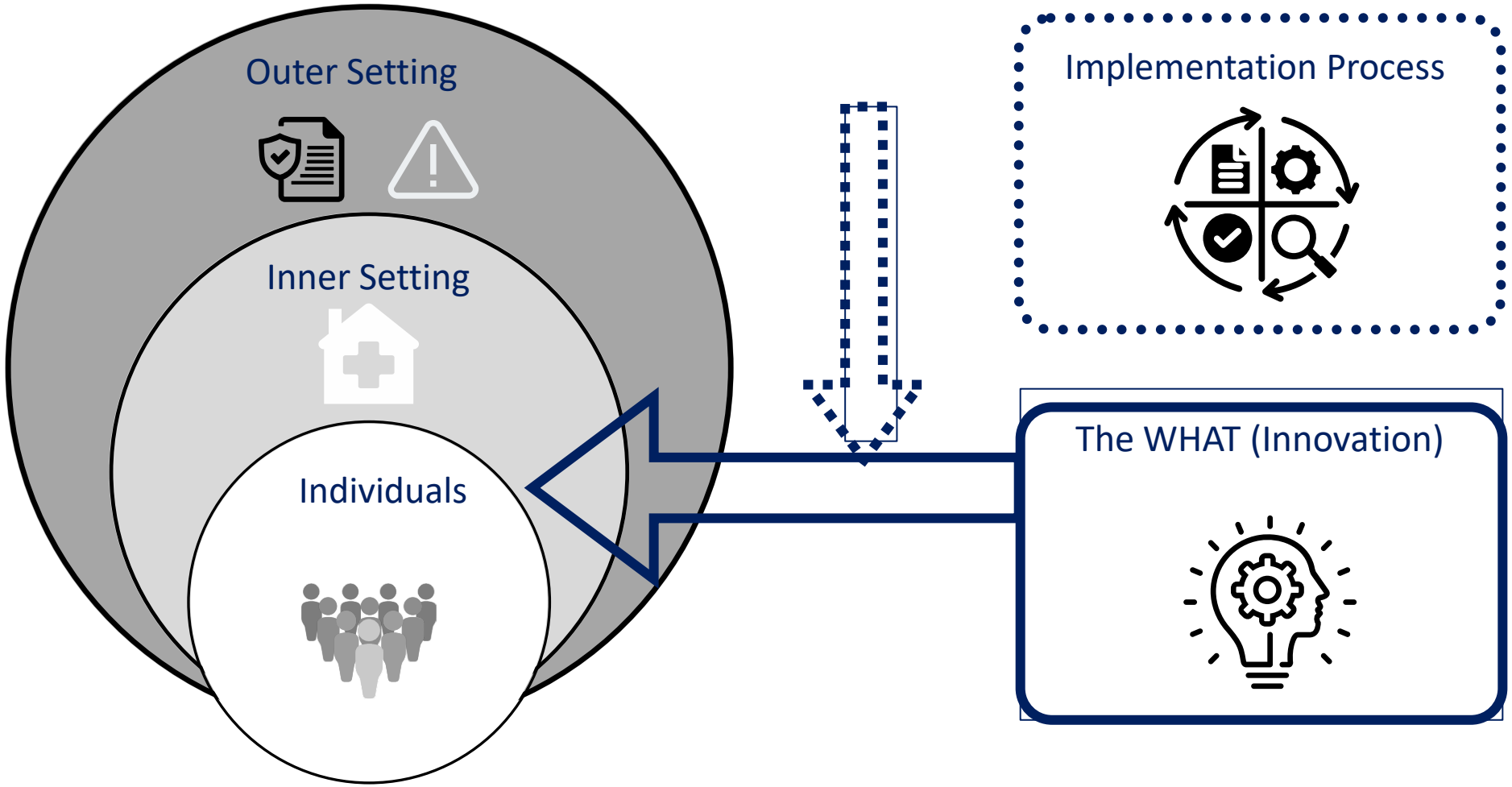
Stakeholder Engagement Supplement

- **Know**
- **Share**
- **Do**

- Identify challenges and facilitators to implementing mindfulness in primary care settings.



The Updated Consolidated Framework for Implementation Research



The Updated Consolidated Framework for Implementation Research

- Individuals
  - Innovation Deliverers: Capability & Motivation
  - “how many PCPs...**express the empathy** and are well suited to leading MBSR sessions?”
- Inner setting
  - Infrastructure needed
  - “Not all sites can or should implement group healthcare”
- Outer setting
  - Policies, Laws, Financing
  - “So the problem with Telehealth is that it's not certain that it'll continue to be available”

Eur J Pain. 2025 Oct;29(9):e70119. doi: 10.1002/ejp.70119.

Prevalence of Chronic Overlapping Pain Conditions in Participants With Chronic Low Back Pain Enrolled in a Pragmatic Trial of Mindfulness-Based Stress Reduction

Vanessa Eve Miller [1] [2], Jessica Barnhill [3], Carol M Greco [4], Gabriela Castro [5] [6], Tra P Nguyen [7] [8], Paula Gardiner [9] [10], Keturah R Faurot [3], Susan Gaylord [3], Janice M Weinberg [7], Holly N Thomas [11], Karim Sariahmed [12], Natalia E Morone [8] [12]

Diversity Supplement

Scoping review of use of dietary supplements and natural products for musculoskeletal pain

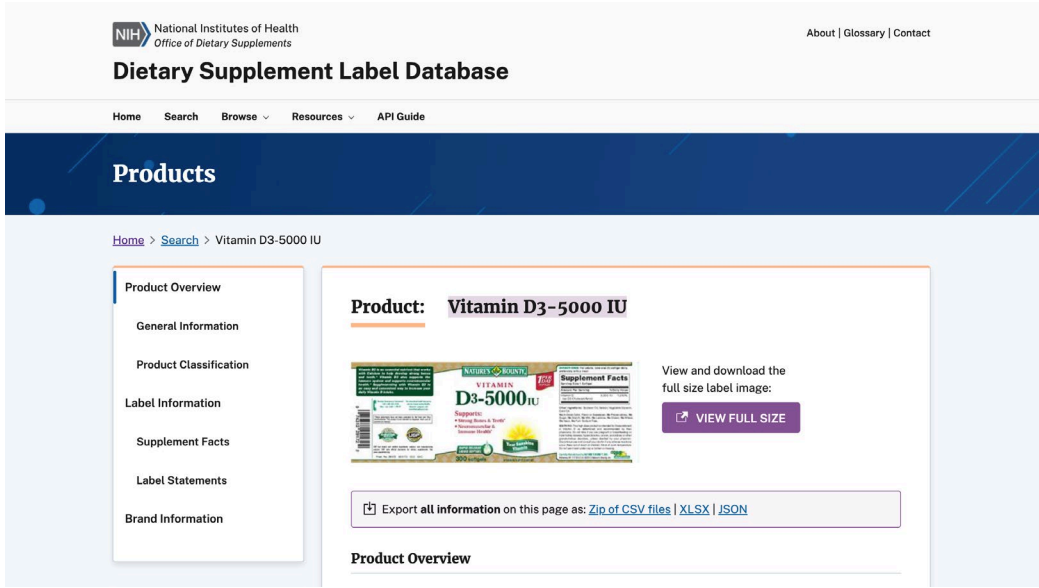
- 54 articles included in the review
  - 28 examined prevalence of chronic pain in cannabinoid users
  - 18 examined the prevalence of cannabinoids among people with chronic pain
  - 2 examined the use of kratom among people with chronic pain
  - 6 examined the use of dietary supplements among people with chronic pain
- Most studies used convenience samples
  - Yet much to be done to understand how individuals with chronic musculoskeletal pain employ self-care products

Methods

1. Complete Interview: Phone or on Zoom

2. Retrieve Label: Participant takes photo of product via phone
   - Sent via text or email
   - View label on zoom call

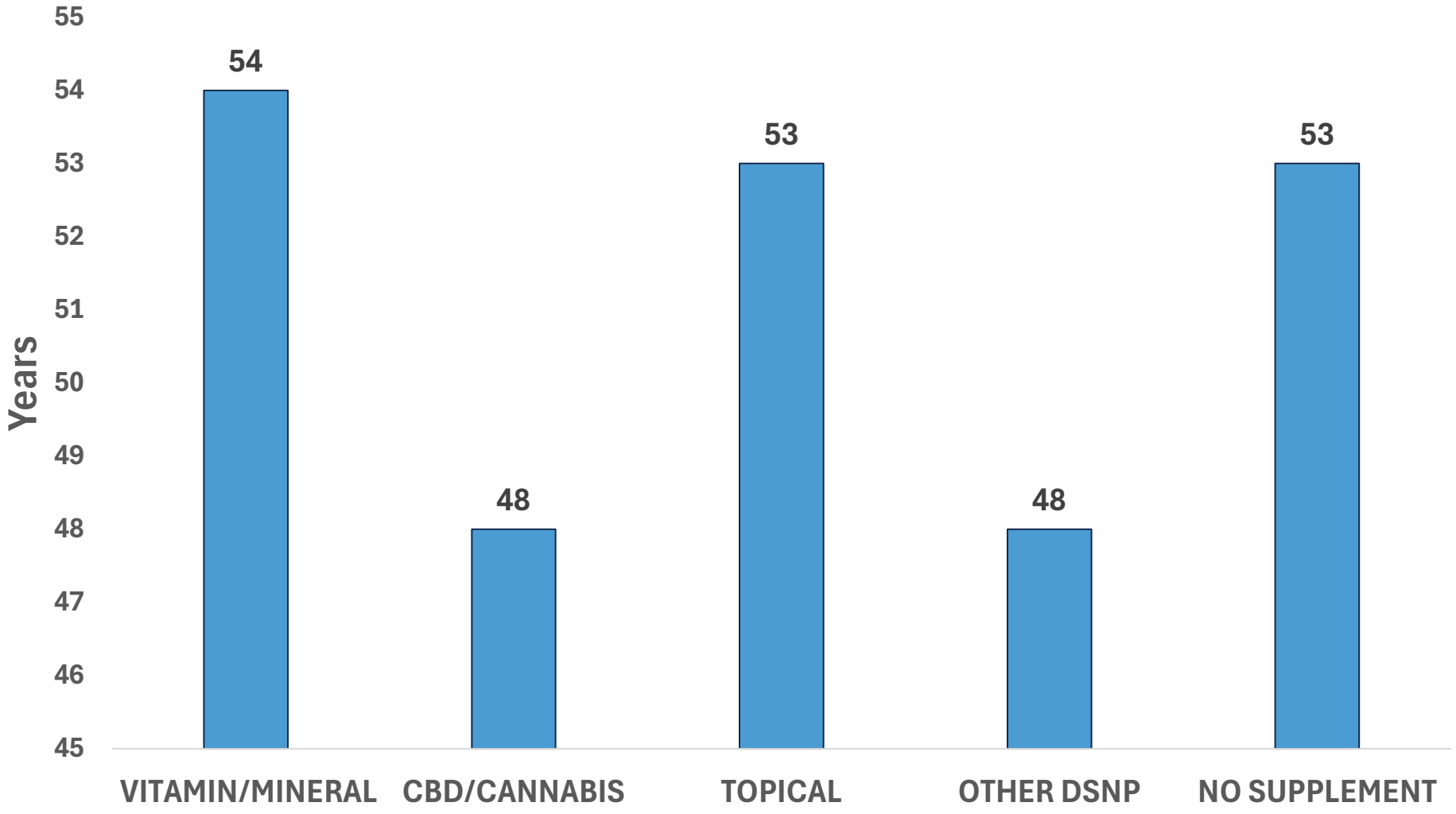
3. Verify Label
   - NIH Dietary Supplement Label Database
   - Google Search



Interview questions

- **Other than medications, what have you used to manage your pain in the past 30 days?**
- Have you taken any topical products for chronic pain, such as capsaicin, arnica, lavender, or castor oil?
- Have you taken any vitamin supplements like Vitamin B or Vitamin D?
- Have you used any CBD or natural cannabis products? Are you using Kratom?
- Have you taken any products containing herbal or botanical ingredients like ginkgo or ginseng?
  - Botanicals may also include medicinal teas.

Age: characteristics vary by type of product



	AGE Mean (SD)
Vitamin/ Mineral	54 (11)
CBD/ Cannabis	48 (14)
Topical	53 (11)
Other DSNP	48 (16)
No Supplement	53 (15)
Overall	53 (15)

Conclusion

- This analysis highlighted how virtual settings are simple and complex, mirroring the practice of mindfulness.

- A virtual setting appears with the press of a button. However, on closer look, there are multiple variables at play that differentially affect how participants interact with the virtual setting.

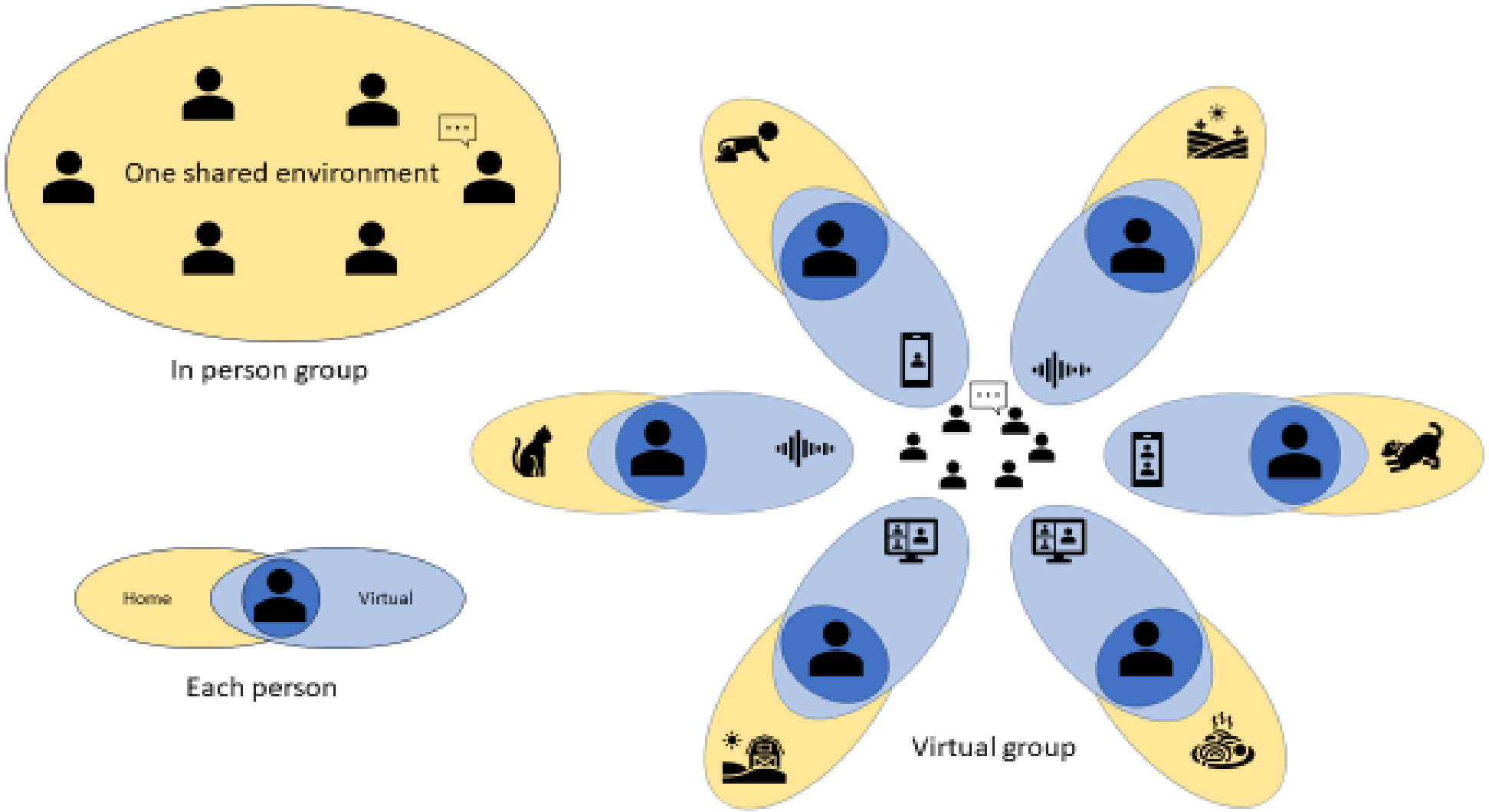


Figure: Complexity introduced by online verses in person group mindfulness training