

Engagement as the Cornerstone in Pragmatic Research

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Optimizing Pain Treatment in Medical Settings Using Mindfulness

Summary

A pragmatic clinical trial integrating a telehealth group-based mindfulness stress reduction program into primary care settings for persons with chronic low back pain

Study design

Pragmatic randomized controlled trial



One year follow-up

Population



450 patients with chronic low back pain ≥18 years of age



Three healthcare systems: Boston Medical Center, Pittsburgh/UPMC, North Carolina

Comparison



Intervention group
225 participate in 8-week Mindfulness Based Stress Reduction program



Control group
225 receive usual primary care

Outcomes

Mindfulness vs Usual Care	Baseline	w8	m6	m12
Pain Intensity & Pain Interference (PEG, Primary Outcome)				
Psychological function				
Physical function				
Healthcare utilization				
Pain medication/opioid use				



Partner Engagement



Partners

- **Partners** are people who come from groups and organizations, such as healthcare administrators, insurers, patients, advocates, community members, or policymakers
- A partner may serve multiple roles and bring several perspectives to a project
- **Community Advisory Board (CAB) members** are **partner** from various backgrounds, who each have unique perspectives and expertise they can offer

Partners: Community Advisory Board Member Contributions

- **Provide feedback** on the needs of persons living with chronic Lower Back Pain
- **Advise** on the best ways to engage with local providers and serve potential participants
- **Advise** on the best ways to provide mindfulness in primary care
- **Provide advice** on patient resistance to mindfulness for treating pain
- **Assist with tailoring** study recruitment and methods
- **Provide advice** on “next steps” once the study is completed

Our partners: one time interview

- Medical Director Internal Medicine Clinic
- Executive Director Group Medical Visit business
- Healthcare Business Development/Policy Lead
- Pain Advocacy Group Leader
- Family Medicine Physician (MGV leader)
- Mindfulness Based Stress Reduction Instructor
- Family Medicine Director of Community Health Initiatives
- Insurance representative

Interview guides evolved with the interviews

Our partner: Community Advisory Board

- Patients with chronic low back pain
 - Mindfulness instructors
 - Healthcare professionals
 - Pain advocacy group leaders
 - Administrators
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- 10 members
 - Meet monthly 1 hour
 - Reimbursed



Training

Connecting Community to Research: A Toolkit

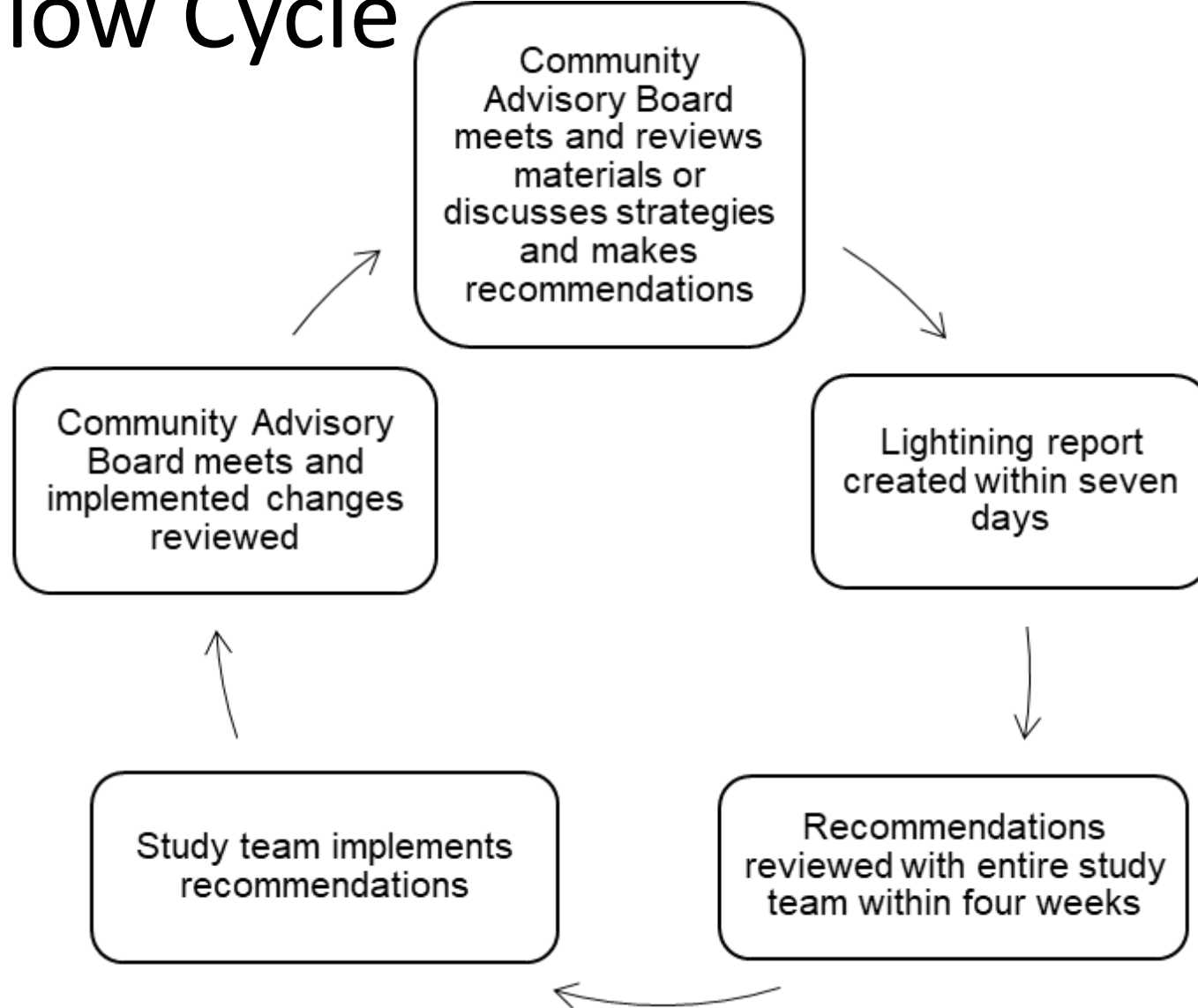
Tracy Battaglia, Jennifer Pamphile, Nikki Spencer, Penny Price Johnson, and Sharon Bak

Women's Health Unit, A DHHS Center of Excellence in Women's Health
Boston Medical Center
Boston University Clinical and Translational Science Institute

- A step-by-step guide to train the CAB by introducing the research process and developing an understanding of the CAB's contribution as partners in our research study
- The CAB participated in a two-hour training

<https://www.pcori.org/engagement/engagement-resources/Engagement-Tool-Resource-Repository/connecting-community-research>

CAB Work Flow Cycle



Monthly Meeting Topics Include

Recruitment: feedback on flyers, website, animated video

Language used in study materials

Brainstorm strategies for study participation

Updates on study progress

Monthly Meeting Topics Changed Over Time

Review manuscripts

Review partner interviews

Brainstorm strategies for dissemination

Brainstorm next steps

Challenges

Partners provide inconsistent facts:

- Medical group visits not possible in primary care
- Providers not interested in medical group visits
- Mindfulness for chronic low back pain is not evidence-based

Conclusions

- Engagement is critical to pragmatic trials as it provides critical perspectives to move the research forward
- Investigators and staff familiar with engagement are necessary to carry out engagement successfully
- Engagement should begin even before a trial starts, but there is no current funding or mechanism for this
- Partners provide perspectives and recommendations that assist in identifying barriers and provide possible solutions
- CAB topics changed over time depending on the stage of the study
- Partners perspectives may be inconsistent with the facts uncovering opportunities for intervention and dissemination to address the inconsistencies

OPTIMUM Team

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CAB Members

Study Participants

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Thank You

