

Expanding ePCTs in Primary Care: How Do We Get There?

Moderator: Wendy Weber, NCCIH



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What will we talk about?

- Research in primary care vs other settings
- Identifying relevant and meaningful research questions
- Different kinds of primary care settings for research



Panelists



Julie Fritz
BeatPain Utah



Natalia Morone
OPTIMUM



Sebastian Tong
AIM-CP

See handout for trial details



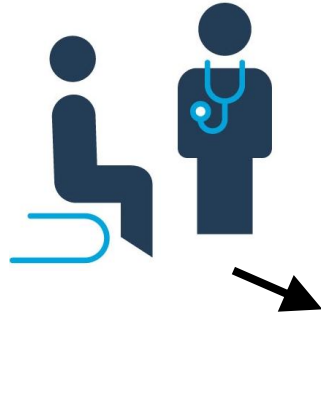
A Pragmatic Clinical Trial to Improve Nonpharmacologic Pain Management in Federally-Qualified Health Centers

Patient with chronic LBP in clinic

E-referral sent from clinic EHR to BEAT PAIN team

E-referral received by BEAT PAIN team

BEAT PAIN team contacts the patient



Enroll in BEAT PAIN

Long-Term Follow-Up
Phone or web-based

Post Phase II Follow-Up
Phone or web-based

Telehealth PT

TREATMENT RESPONDER?

Post Phase I Follow-Up
Phone or web-based

Brief TH Consult

Brief TH Consult

Telehealth PT

R

52-week follow-up 26 week follow-up 12 week follow-up PHASE I TREATMENT ENROLLMENT



A Pragmatic Clinical Trial to Improve Nonpharmacologic Pain Management in Federally-Qualified Health Centers

EMBEDDED WITHIN PRIMARY CARE

- Referral procedures leveraged clinic EHR and the usual work flows for submitting external referrals
- Feedback returned to referring provider via the EHR
- All research methods are decentralized
- Providers engaged through staff meetings and brief instructions on program and procedures for submitting referrals



A Pragmatic Clinical Trial to Improve Nonpharmacologic Pain Management in Federally-Qualified Health Centers

SOLUTIONS/LESSONS LEARNED

- Unique considerations for primary care settings
 - Multiple competing demands for attention and focus
 - Expectation of being offered clinical trial participation for a condition is lower than in specialty care settings
- Unique considerations for CHC primary care settings
 - Less familiarity with research process than academic/urban settings
 - Fewer resources that can be diverted to research-related tasks
 - Alignment of research with data reporting standards



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Optimizing Pain Treatment in Medical Settings Using Mindfulness

(OPTIMUM)

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

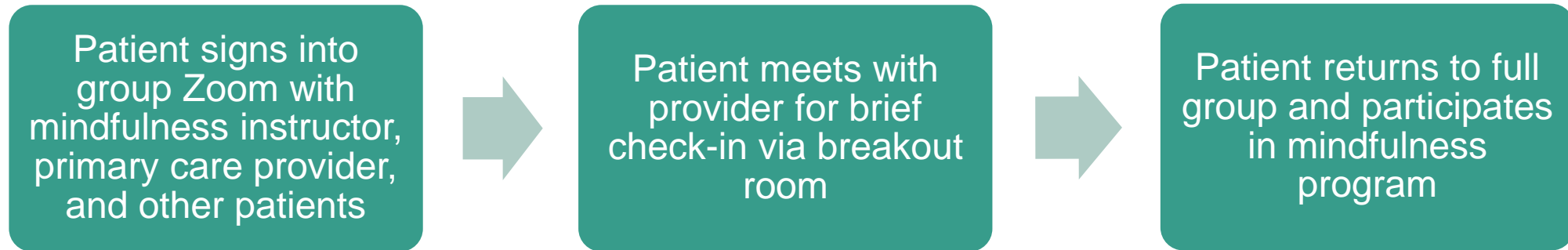
Mindfulness vs Usual Care	Baseline	w8	m6	m12
Pain Intensity & Pain Interference (PEG, Primary Outcome)				
Psychological function				
Physical function				
Healthcare utilization				
Pain medication/opioid use				

Embedded in Primary Care

- Internal Medicine and Family Medicine Clinics
- Group Medical Visit Format
- Primary Care Provider participated in sessions and met briefly with everyone
- Telehealth




Optimizing Pain Treatment In Medical settings Using Mindfulness (OPTIMUM)



Expanding ePCTs in Primary Care: How do we get there?

Adapting and Implementing a Nurse Care Management Model to Care for
Rural Patients with Chronic Pain (AIM-CP)



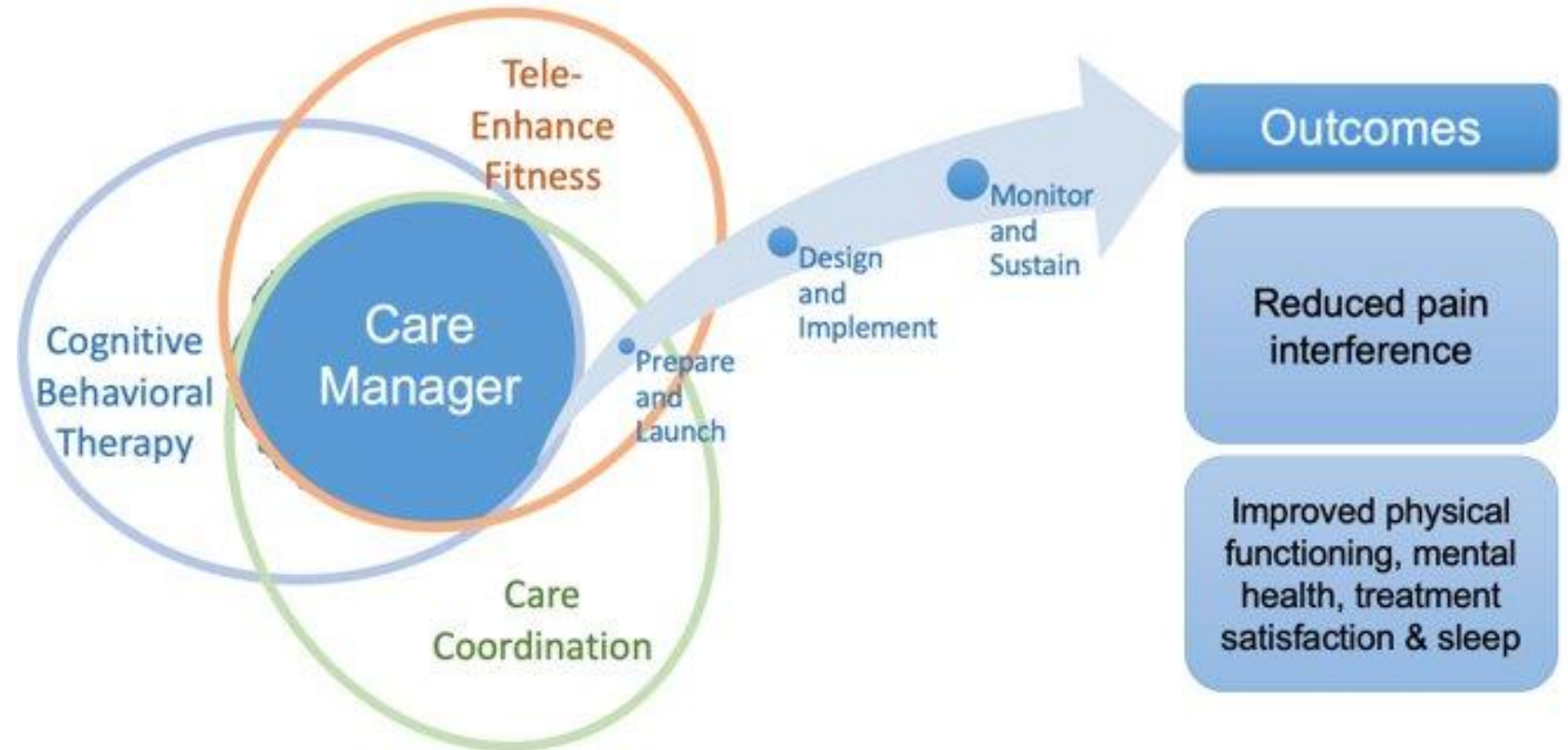
Co-PIs: Sebastian Tong, MD, MPH; Kushang Patel, PhD, MPH

NIH Collaboratory Steering Committee Annual Meeting

May 2025

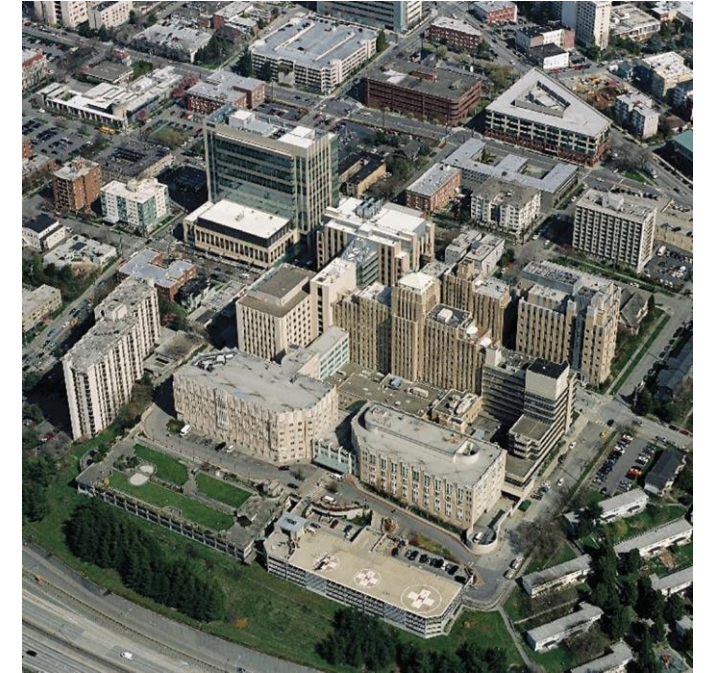
Nurse Care Management Model

- Rural primary care practices across Pacific NW and North Carolina
- Currently completed pilot with 31 participants
 - Mean -0.9 reduction in PEG score (effect size 0.50)
 - Reduction in pain catastrophizing and increase in health satisfaction
- Planning for UH3 RCT with 450 participants



Approaches to Primary Care Engagement

Approach	Description
Regional Engagement Specialists	<ul style="list-style-type: none">• Research staff with lived experience who have ties to rural community
Listening Sessions	<ul style="list-style-type: none">• Facilitated dialogues with clinic, health system and community leaders in rural communities to inform research priorities and topics
Partner panel for research	<ul style="list-style-type: none">• Brief surveys or interviews to inform research priorities/topics and identify barriers/ facilitators to participating in research
Flexibility in approach	<ul style="list-style-type: none">• Identifying core elements of each intervention and allowing for flexibility in recruitment
Learning collaborative	<ul style="list-style-type: none">• Regular sessions for bidirectional learning
Advisory groups	<ul style="list-style-type: none">• Patient, clinician and/or staff groups



Thank you!

- National Institute of Nursing Research (UG3NR020930)
 - Karen Kehl, PhD, RN, FPCN
 - Alexis Bakos, PhD, MPH, RN

Lets discuss how you are...



Adapting ePCT
for primary care
vs. specialty
care setting?



Identifying
research
questions and
outcomes of
relevance?



Distinguishing
between
the contexts of
primary care
setting issues?



Handling
regulatory
challenges of
sites that are not
affiliated with
academia or
HCS?

How is conducting ePCTs in a primary care setting different than specialty care?



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How did you go about identifying the research question and outcomes of relevance to primary care?



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Can you talk about how the context of the primary care setting influenced how you conducted your ePCT?



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How have you addressed the regulatory challenges of working with primary care sites that are not affiliated with an academic institution or HCS?



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Thoughts on...

- Key ways to differentiate between a clinical program and research
 - Implications for billing for care in research



- Primary care patient expectations about being involved in research

Discussion



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