Promoting Patient Engagement in ePCTs

Steven George, PT, PhD, FAPTA
Duke University
(AIM-Back)

Natalia Morone, MD
Boston Medical Center
(OPTIMUM)

Eric Roseen, DC, MSc
Boston Medical Center
(TIACHIKNEE)

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Overview of the Session

- Brief Introduction
- Engagement from NIH Collaboratory Trials
- Questions and Discussion
- Engagement from Pain Management Collaboratory Trial
- Questions and Discussion

Goals of the Session

- Review the Coordinating Center's efforts to support patient engagement
- Hear from NIH Collaboratory Trials on challenges and methods for engaging patients in ePCTs
- Highlight a trial example from Pain Management Collaboratory to show cross-collaboratory efforts in patient engagement

Introduction – Some Basics

Promoting Patient Engagement in ePCTs

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Shameless Plug for Living Textbook Chapter

PATIENT ENGAGEMENT

SECTION 1

Introduction

— Contributors

Steven Z. George, PT, PhD

Contributing Editor

Hannah Webster, MPH

Gina Uhlenbrauck

Karen Staman, MS

Pragmatic clinical trials (PCTs) are research studies that are conducted in the context of routine clinical care and therefore have the potential to represent and prioritize the perspectives of an array of key individuals, including patients

SECTIONS

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Shameless Plug for Living Textbook Chapter

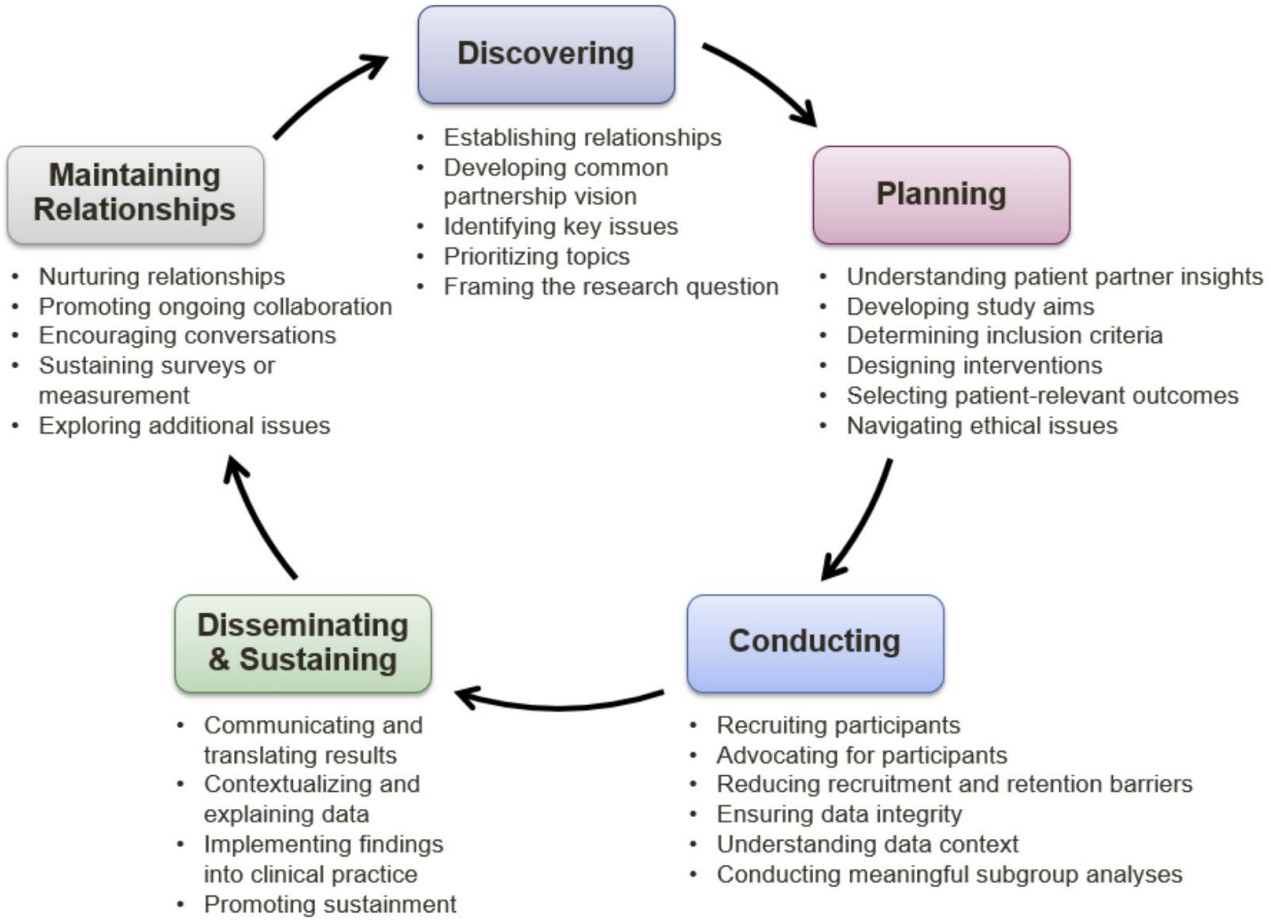
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Key Principles – RECCC

- Reciprocal/bi-directional relationships
- Effective communication
- Co-learning
- Compensation
- Cultural humility

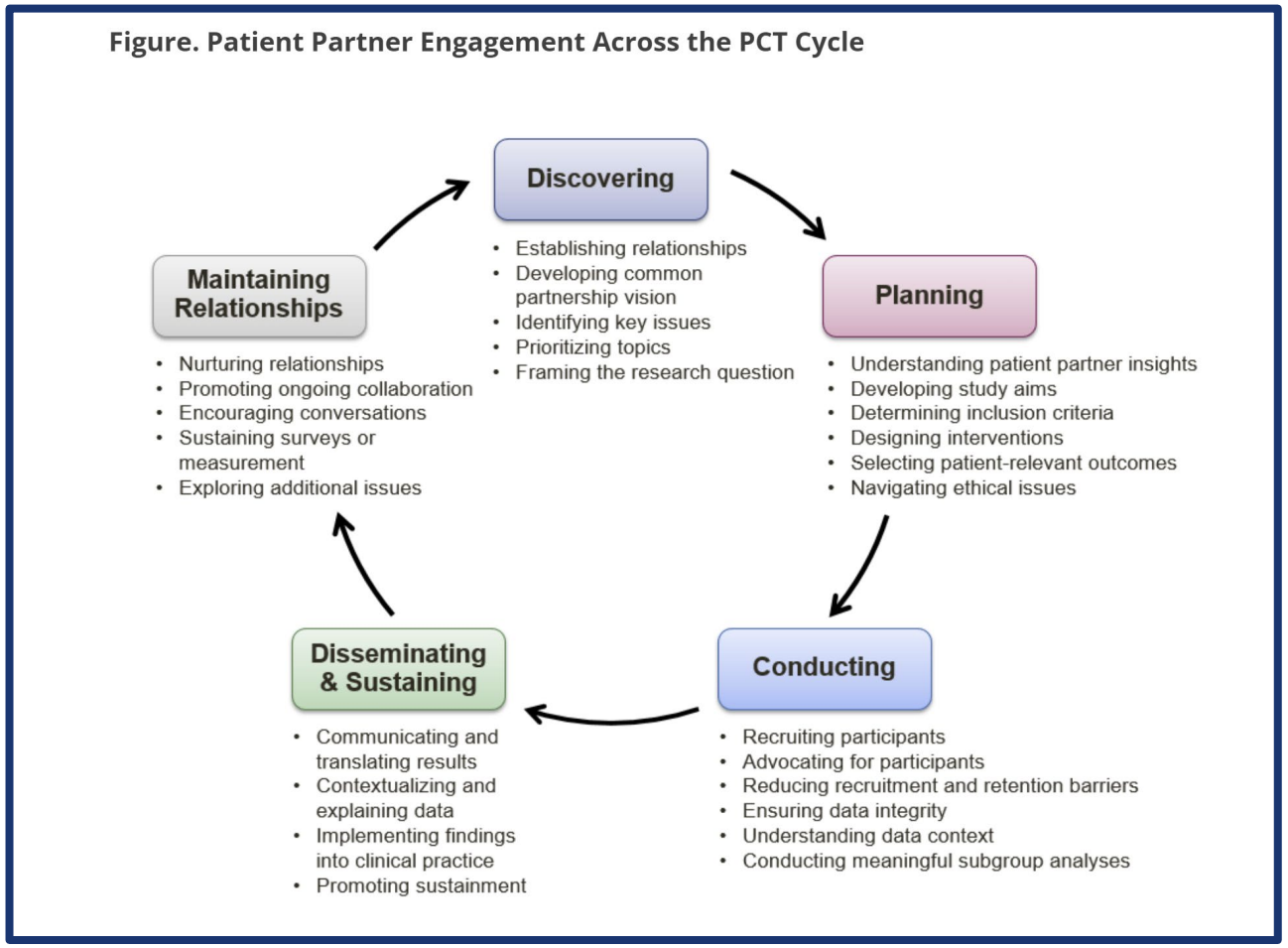
Throughout the ePCT Lifecycle

Figure. Patient Partner Engagement Across the PCT Cycle



NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Throughout the ePCT Lifecycle



A menu of evidence-based resources for co-designing a trial specific framework maybe the most effective option (Greenhaulgh et al 2019)

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Value of Patient Engagement - BEVEST

- Burden of living with or managing a health condition
- Expectations of benefits
- Views on importance of potential treatment outcomes
- Experience with treatments, including side effects
- Symptoms experienced and how these affect day-to-day functioning
- Tolerance for harms or risks, including what acceptable trade-offs

Examples from NIH Collaboratory Trials

Chenchen Wang, MD, MSc – Tufts Medical Center
Eric Roseen, DC, PhD – Boston Medical Center
Robert Saper, MD, MPH – Cleveland Clinic
Helen Lavretsky, MD, MS – UCLA Health

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

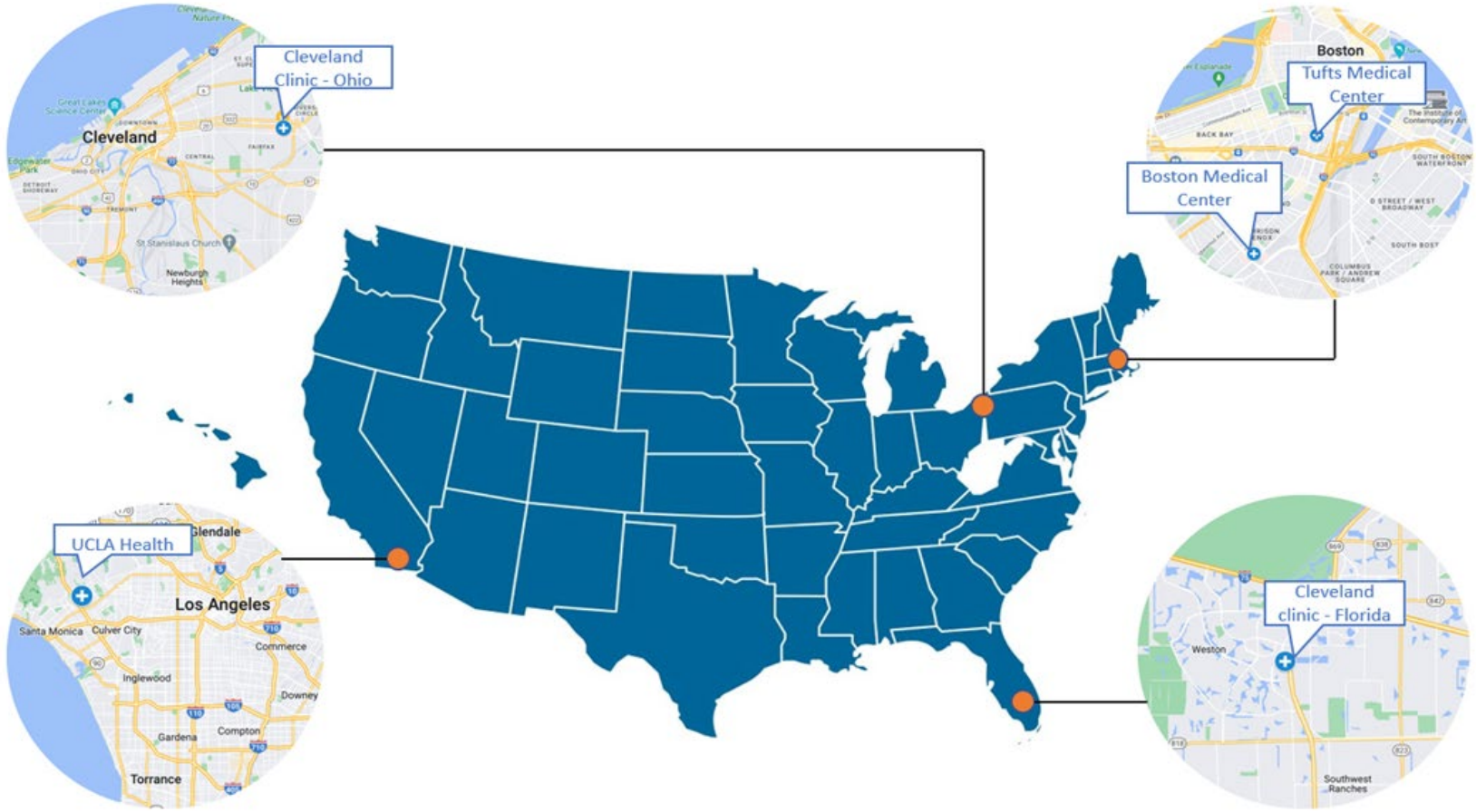
TAICHIKNEE

Remote Tai Chi for Knee Osteoarthritis: an Embedded Pragmatic Trial

- **UG3:** Compare the effects of a remotely delivered **web-based Tai Chi intervention** versus routine care for patients with knee pain due to osteoarthritis
- 20-25 clinics across 4 health systems
- 600 expected patients
- Patient-level randomization stratified by site
- Pain interference

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

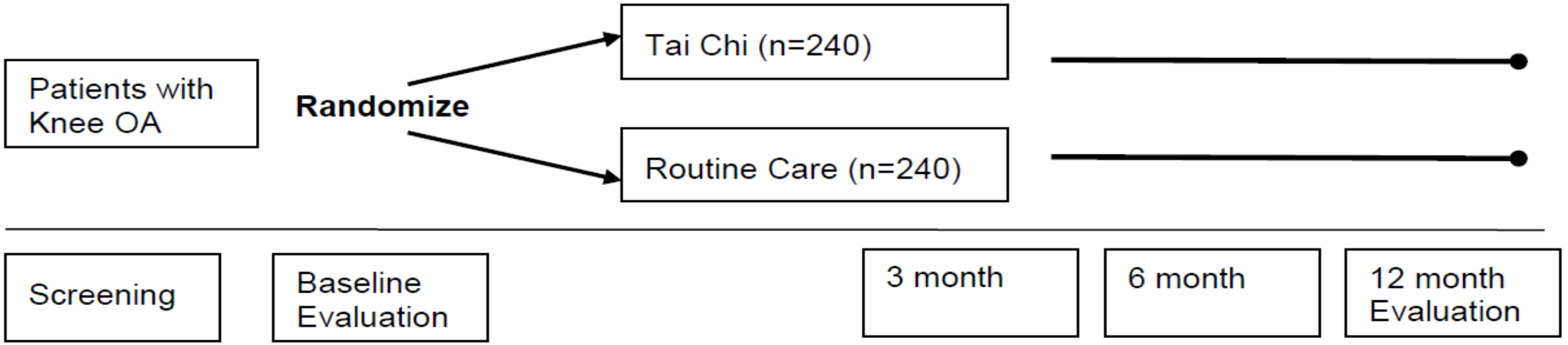
Large and diverse population in four geographic regions



Major Goal: To study "real world" effectiveness and implementation of Tai Chi versus routine care for Knee Osteoarthritis (OA) Pain across four US Health Care Systems.

TAICHIKNEE Trial Overview

Population	Adults over 50 years with Symptomatic knee OA (ACR Criteria)
Setting	Primary care clinics in four healthcare systems
Design	A hybrid type 1 effectiveness-implementation pragmatic trial
Interventions	Remote tai chi (3-month twice weekly) versus Routine Care
Clinical outcomes	Pain interference (primary) Knee Pain, Function, Pain medication, Quality of life (secondary)
Implementation outcomes	Feasibility of implementation strategies



Purpose

- Evaluate barriers/facilitators to Tai Chi adoption for knee OA in four healthcare systems.

- To inform a large hybrid type 1 effectiveness-implementation pragmatic trial of remotely-delivered Tai Chi for knee OA.

UG3 planning phase: Identify multilevel (patient, provider, instructor, and health system leadership) barriers and facilitators of embedding a web-based Tai Chi intervention.

Stakeholder type	Total (n=55)	Cleveland (n=17)	BMC (n=14)	Tufts (n=12)	UCLA (n=12)
Patients w knee OA	10	3	1	3	3
Primary care provider	13	4	3	3	3
Tai Chi Instructor	12	1	5	3	3
Healthcare system leader	15	5	5	2	3
Other*	5*	4*	0	1*	0

In-depth stakeholder interviews among 55 participants from four healthcare systems revealed key barriers/facilitators

Common Barriers/Facilitators: The adaptability of Tai Chi, challenge of describing Tai Chi to patients, and ability to make referrals in electronic health record

These will inform a pragmatic effectiveness-implementation trial of remote Tai Chi for 480 patients with knee OA across four large healthcare systems.

Participant characteristics

Characteristics	Total **(n=55)**	Cleveland **(n=17)**	BMC **(n=14)**	Tufts **(n=12)**	UCLA **(n=12)**
Mean Age	57	56	57	58	57
Age Range	36-85	36-85	38-80	45-72	38-76
Female, %	55	59	50	33	75
Hispanic ethnicity, %	9	18	7	8	0
Race, %					
White	51	59	57	67	17
Black	20	18	36	8	17
Asian	20	18	7	17	42
Ever practiced tai chi? Yes, %	54	41	50	58	75
Prior healthcare for knee pain? Yes, %	54	53	57	67	42

Discussion and Questions, Part 1

Promoting Patient Engagement in ePCTs

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Example from a NIH Collaboratory Trial

Natalia E. Morone, MD, MS
Boston University/Boston Medical Center

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

OPTIMUM *Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting*

- **UH3:** Evaluating effectiveness of a **group-based mindfulness intervention** for patients with chronic low back pain in a usual care setting
- 3 health systems
- 450 expected patients
- Individual randomization
- Pain, enjoyment of life, and general activity (PEG scale)

Optimum
Optimizing Pain Treatment in Medical Settings Using Mindfulness

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

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, 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				

Optimum

Barriers

- Patient not familiar with technology
- Patient with competing obligations
- Patient not understanding why patient reported outcomes are asked more than once

Optimum
Optimizing Pain Treatment
in Medical Settings
Using Mindfulness

Approaches

- Technology orientation/one-on-one time
- Offer telehealth group medical visit when most convenient (participants asked) and flexible around where they participate (in their car-not driving)
- Describe PROs and their purpose in different settings (not only informed consent but during routine follow up)

Optimum
Optimizing Pain Treatment in Medical Settings Using Mindfulness

Example from a PMC Collaboratory Trial

Steven George PT, PhD, FAPTA
Duke University

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Improving Veteran Access to Integrated Management of Back Pain (AIM-Back): An Embedded Pragmatic, Cluster Randomized Trial

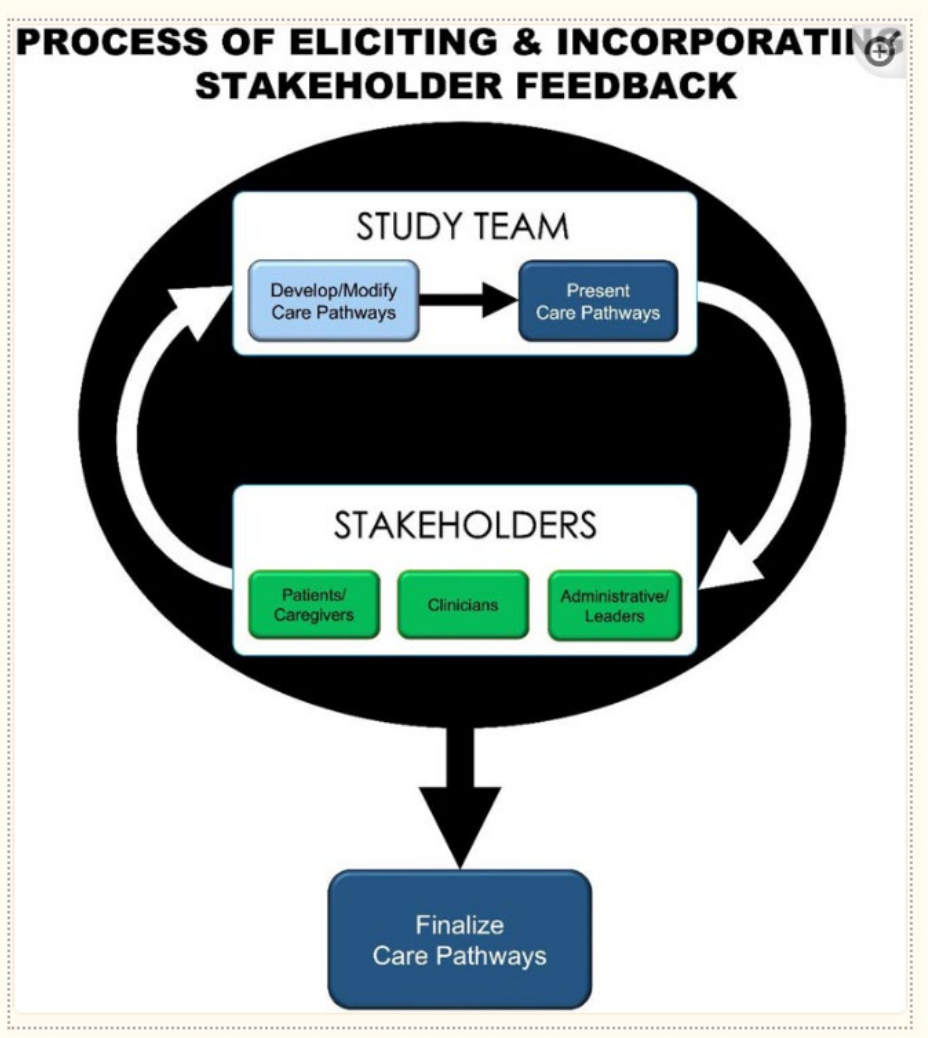
- **UH3:** Comparative effectiveness of two different non-pharmacologic care pathways for Veterans with low back pain
- 1 health system (VA)
- 9 primary care clinics, 9 states
- 1815 enrolled
- Cluster randomization (2 blocks)
- Pain interference and physical function (PROMIS-SF)

AIM-Back

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

AIM-Back Engagement Process

(Ballengee et al, *Clin Trials*, 2023)



Part 2[2]	"How do each of these pathways align/not align with Veterans' needs, preferences, and expectations related to low back pain?" "Specific to Integrated Care Pathway: In this pathway, Veterans will receive individualized physical activity instruction one time per week for six weeks, via phone or telehealth. How do you think Veterans will respond to this approach?" "Specific to Coordinated Care Pathway: What type(s) of health care professional(s) do you think Veterans would feel most comfortable interacting with in the Pain Navigator Role?"	Patients and caregivers (n=12): Nine Veterans Two Veterans who are care partners of Veterans One civilian care partner of a Veteran The focus group was comprised of male and female Veterans with a variety of military service backgrounds from the Vietnam, Gulf War, and OEF/OIF/OND eras.

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

AIM-Back Engagement Process

(Ballengee et al, *Clin Trials*, 2023)

Barriers

- Care for low back pain is highly variable
- Local resources available for care delivery variable too
- Creating and implementing two structured nonpharmacologic care pathways with equipoise

Approach

- Engage with multiple groups for pathway input
- Sequential cohort design
- Feedback solicited from multiple groups at multiple time points

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

AIM-Back Engagement Process

(Ballengee et al, *Clin Trials*, 2023)

Sequenced Care

- Specifying type of pain modulation that can be received during in person visits
- Reducing total number of physical therapy visits
- Integrate physical activity counseling between in person visits

Pain Navigator

- Flexibility in providers that can be navigators and medium for telehealth interactions (phone and video)
- Move away from stepped care model, towards one with feedback loops
- Specifying criteria for patient discharge

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Discussion and Questions, Part 2

Promoting Patient Engagement in ePCTs

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®