

Challenges and Hot Tips for Conducting Multi-Site Group-Based Clinical Trials

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Disclosure

The authors of this presentation have no conflicts of interest to disclose.



Panel Discussion Outline

Review Learning Objectives

Introduction to panelists and their studies

Open discussion with question prompts

Panelist final thoughts and suggestions for future study teams

Question and answer session



Learning Objectives

1

Attendees should be able to explain why group-based multi-site clinical trials are important for the field of integrative medicine.

2

Attendees should be able to articulate examples of how and why a group-based intervention design increases the complexity of multi-site trials.

3

Attendees should be able to identify 3 strategies to prevent and/or overcome common challenges related to group-based multi-site clinical trials.

Presenters



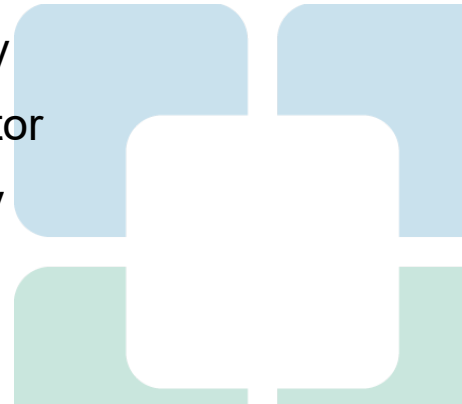
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Treatment for Migraine and Mood (TEAM-M)

Add study info here



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Comparing Two Dietary Approaches for Type 2 Diabetes: The LEGEND (Lifestyle Education about Nutrition for Diabetes) Study

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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

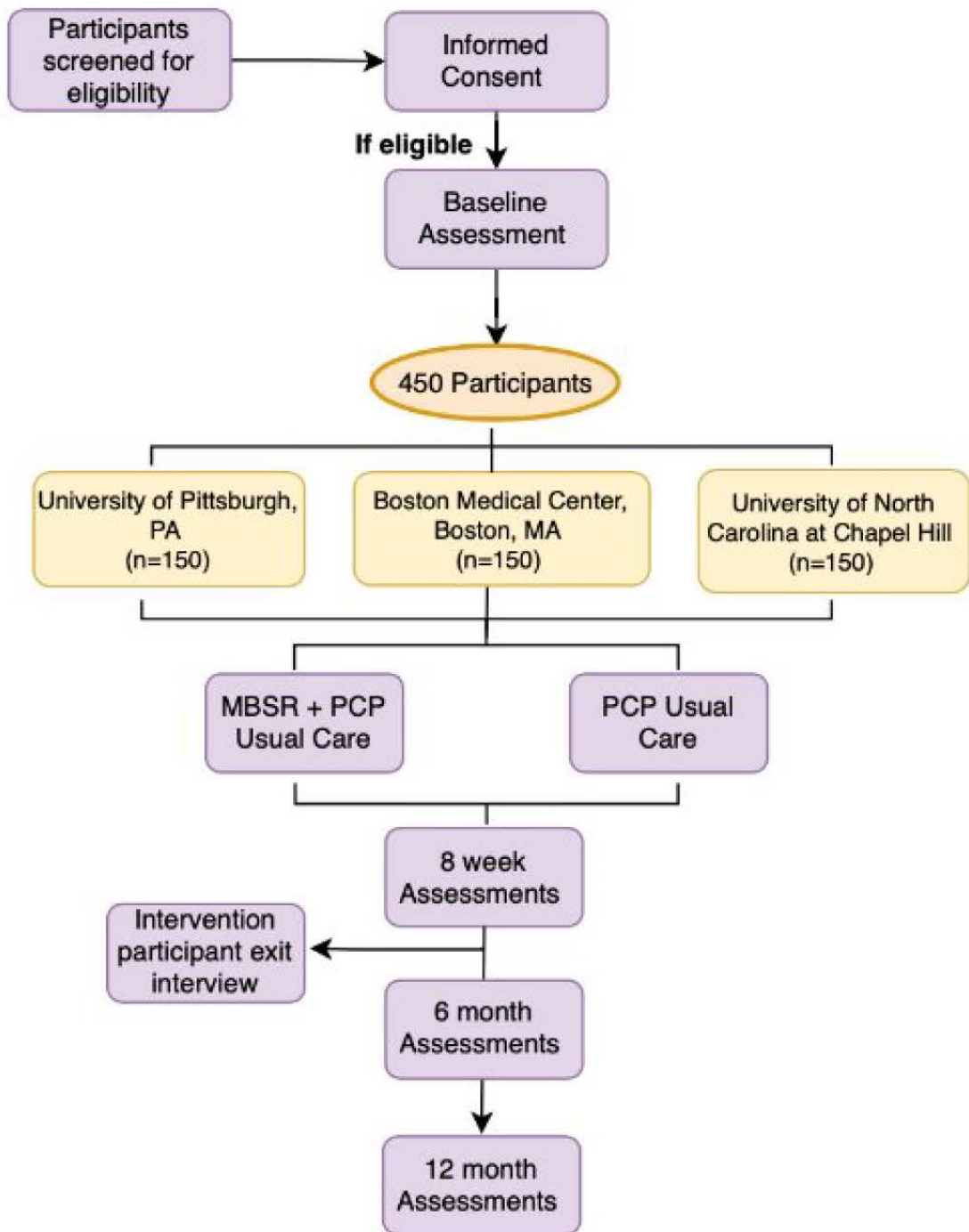


Control group

225 receive usual primary care

Outcomes

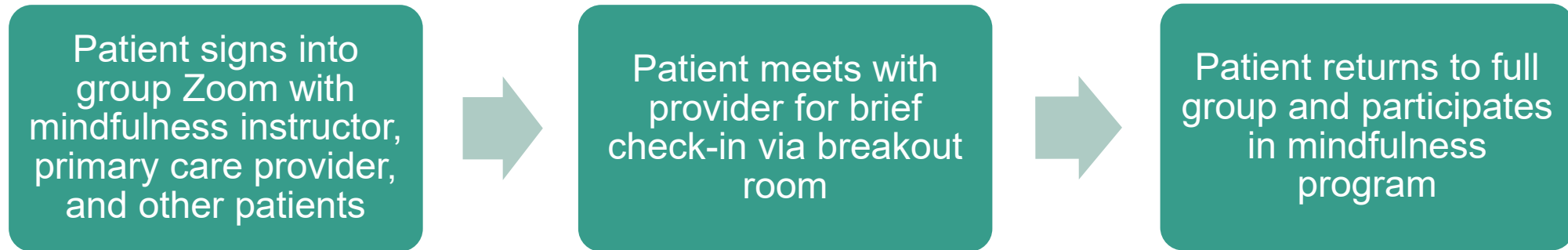
Mindfulness vs Usual Care	Baseline	w8	m6	m12
Pain Intensity & Pain Interference (PEG, Primary Outcome)				
Psychological function				
Physical function				
Healthcare utilization				
Pain medication/opioid use				



Optimizing Pain Treatment In Medical settings Using Mindfulness (OPTIMUM)



Optimizing Pain Treatment In Medical settings Using Mindfulness (OPTIMUM)



Question Topic: Recruitment and Intervention Delivery

What do you need to consider when coordinating recruitment and intervention delivery across sites?



Question Topic: Recruitment and Intervention Delivery

Are there benefits to mixing participants from various sites into one intervention group vs. having site-specific groups?



Question Topic: Site Coordination/Management

How do you manage scheduling group intervention visits when participants and intervention facilitators may have differing schedules and availability?



Question Topic: Site Coordination/Management

**How do you coordinate intervention delivery
across sites in different time zones?**



Question Topic: Site Coordination/Management

What are helpful approaches to working with underperforming sites?



Question Topic: Data Management

What are best practices for managing data collection and staffing across sites?



Question Topic: Data Management

Is it best to use a single data management project (e.g., REDCap) for all sites, or have individual data collection projects at each site?



Question Topic: Regulatory/IRB

What are the challenges with establishing the institutional review board (IRB) for multi-site group-based intervention studies? For example, should study teams submit their proposal to a third-party sIRB vs an sIRB at an academic institution?



Question Topic: Regulatory/IRB

Do all sites need to have IRB approval if they have limited involvement and may not be conducting “research activities”?



Question Topic: Final Thoughts

What suggestions do you have for current and/or future study teams conducting group-based multi-site integrative medicine research studies.



Q&A Session

Audience: What questions do you have for our panelists?





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