

Fostering Development of Up-and-Coming ePCT Investigators

Emily O'Brien, PhD

Associate Professor in Population Health Sciences

Associate Professor in Neurology

Core Faculty Member, Duke-Margolis Center for Health Policy

Duke Clinical Research Institute



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Collaboratory Training Activities



WORKSHOPS



LIVING
TEXTBOOK



EDUCATIONAL
RESOURCES



WEBINARS



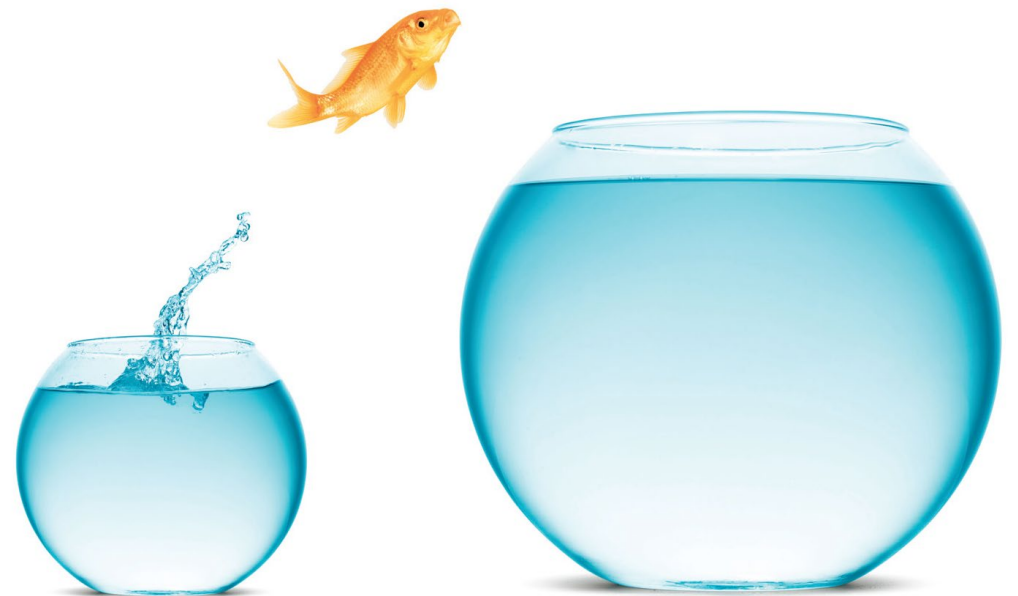
ONLINE
LEARNING



FELLOWSHIPS

Need to Diversify ePCT Research Teams

- Small number have knowledge and experience to conduct ePCTs
- Few training opportunities
- NIH Collaboratory has concentration of expertise
 - Participation primarily from senior investigators at academic research centers



Meet Our Fellows

- Lindsay Ballangee, DPT
 - PhD Candidate
 - Department of Population Health Sciences, Duke University School of Medicine
 - Collaboratory Fellow
- Kaitlyn McLeod, MD
 - PGY-3, Internal Medicine Residency Program, University of Colorado
 - Collaboratory URM Fellow



Fellowship Co-Chairs

- Rosa Gonzalez-Guarda
- Kevin Weinfurt

Trial Mentors

- Ardith Doorenbos
- Mike Ho
- Prateeti Khazanie
- Mitch Knisely

Core Mentors

- Hayden Bosworth
- Devon Check
- Rosa Gonzalez-Guarda
- Cherise Harrington

Coordinating Center

- Alex Fist
- Steve George
- Elizabeth McCamic
- MariJo Mencini
- Tammy Reece

All of you for sharing your knowledge!

Fostering Development of Up-and-Coming ePCT Investigators: Past, Present, and Future Directions

Lindsay Ballengee, DPT

PhD Candidate

Department of Population Health Sciences

Duke University School of Medicine



**NIH PRAGMATIC TRIALS
COLLABORATORY**

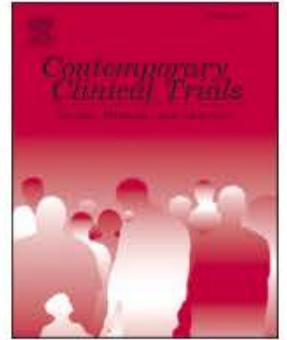
Rethinking Clinical Trials®



Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial



Intervention delivery for embedded pragmatic clinical trials: Development of a tool to measure complexity

Karen L. Staman^a, Devon K. Check^b, Doug Zatzick^c, Vincent Mor^d, Julie M. Fritz^e, Kathleen Sluka^f, Lynn L. DeBar^g, Jeffrey G. Jarvik^c, Angelo Volandes^h, Gloria D. Coronadoⁱ, David A. Chambers^j, Kevin P. Weinfurt^b, Steven Z. George^{k,*}

Highly Controlled Trials

Evidence base for efficacy is large, but we don't know the best way of moving into real-world

AIM 1
Investigate intervention delivery complexity, adaptations, and implementation

AIM 2
Characterize clinically relevant contextual factors for enrolling patients in a pain intervention

AIM 3
Explore feasibility of implementing an evidence-based pain-CBT protocol

Real World Trials

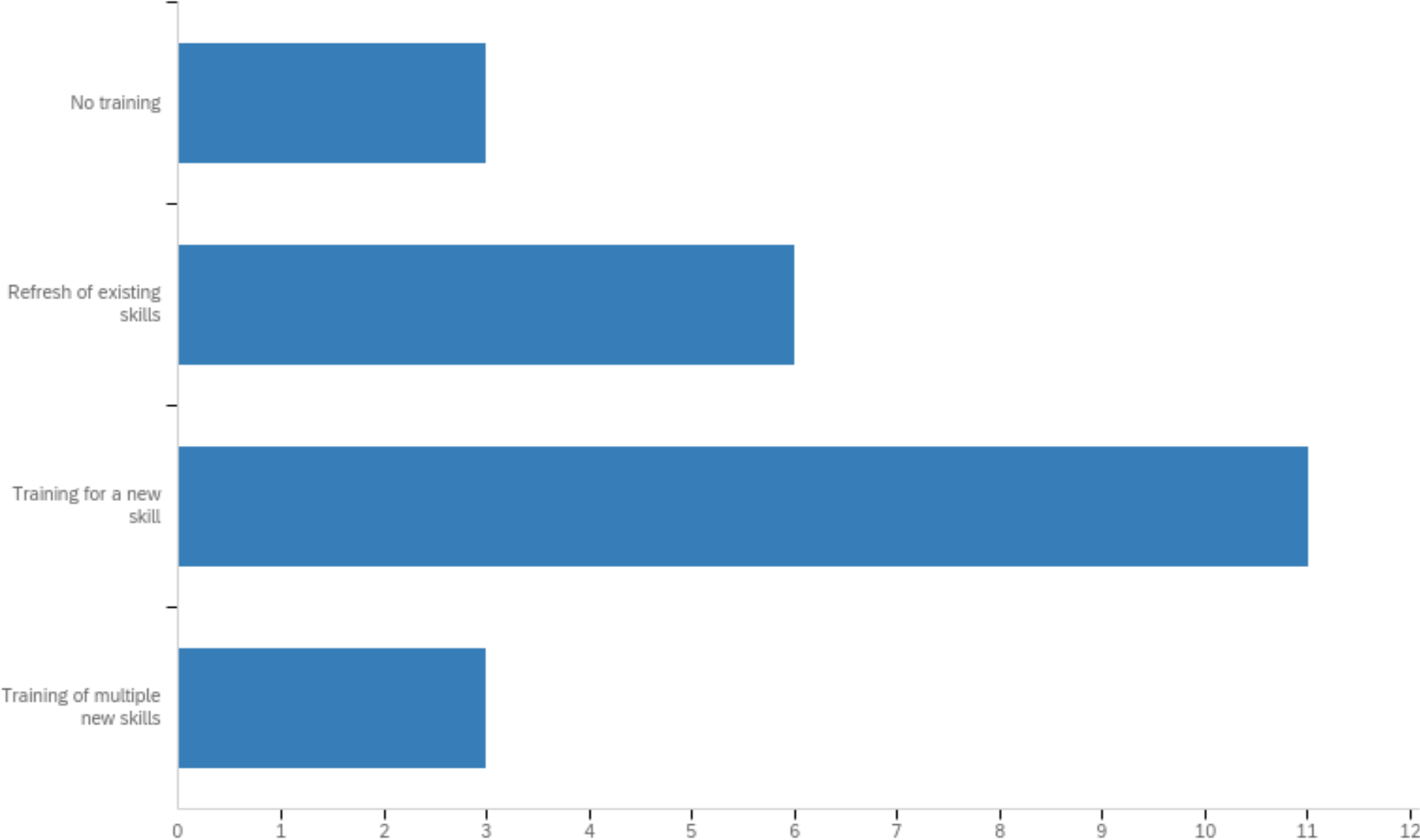
Effectiveness evidence base is hard to interpret

← **Closing the Gap for Non-Pharm Pain Interventions** →

Cross-Collaboratory Collaboration



Training demand (i.e., level of familiarity or extra training needed for those delivering the intervention)



Future Directions



Explore intervention delivery complexity and adaptations over time to see evolution throughout trial process



Investigate potential adaptations to IDC tool as we learn more about how it may inform future pragmatic trials



Develop real-time methods to capture intervention adaptations and impacts on implementation

NIH Pragmatic Trials Fellowship Experience

KAITLYN
MCLEOD, MD

HEALTH EQUITY CORE

- Understanding current health equity practices in the Collaboratory

PCT KNOWLEDGE

- Attending Core Meetings
- Self-paced Curriculum

THE NUDGE STUDY

- Language-based differences in patient satisfaction
- Effect modification of Area Deprivation Index in Nudge

CAREER DEVELOPMENT

- Fellowship application
- Defining future reserach goals

Health Equity Core- State of the Science

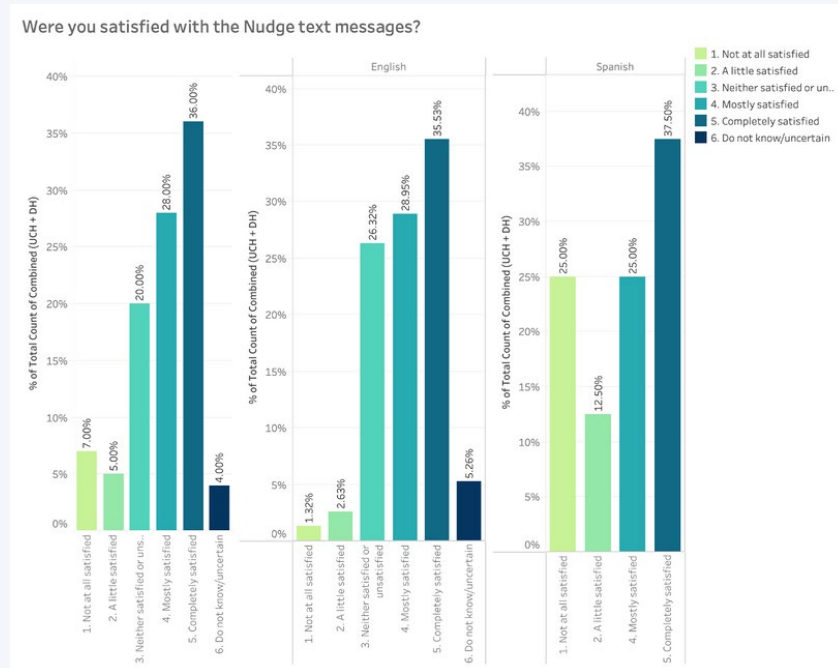
Semi-structured interviews



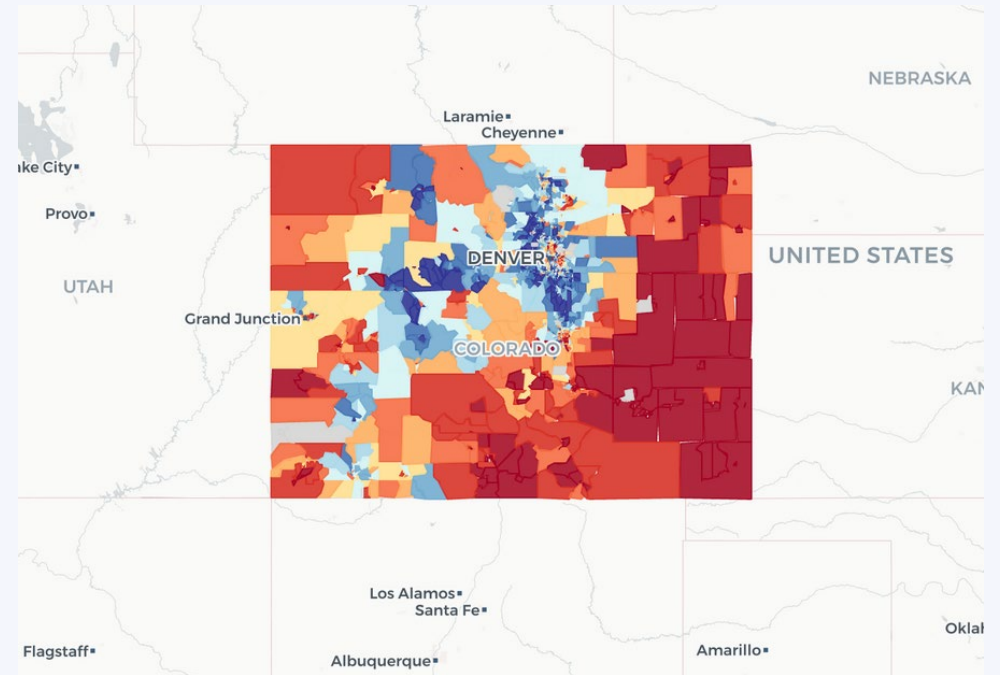
Survey

The Nudge Study

Patient Satisfaction



Area Deprivation Index

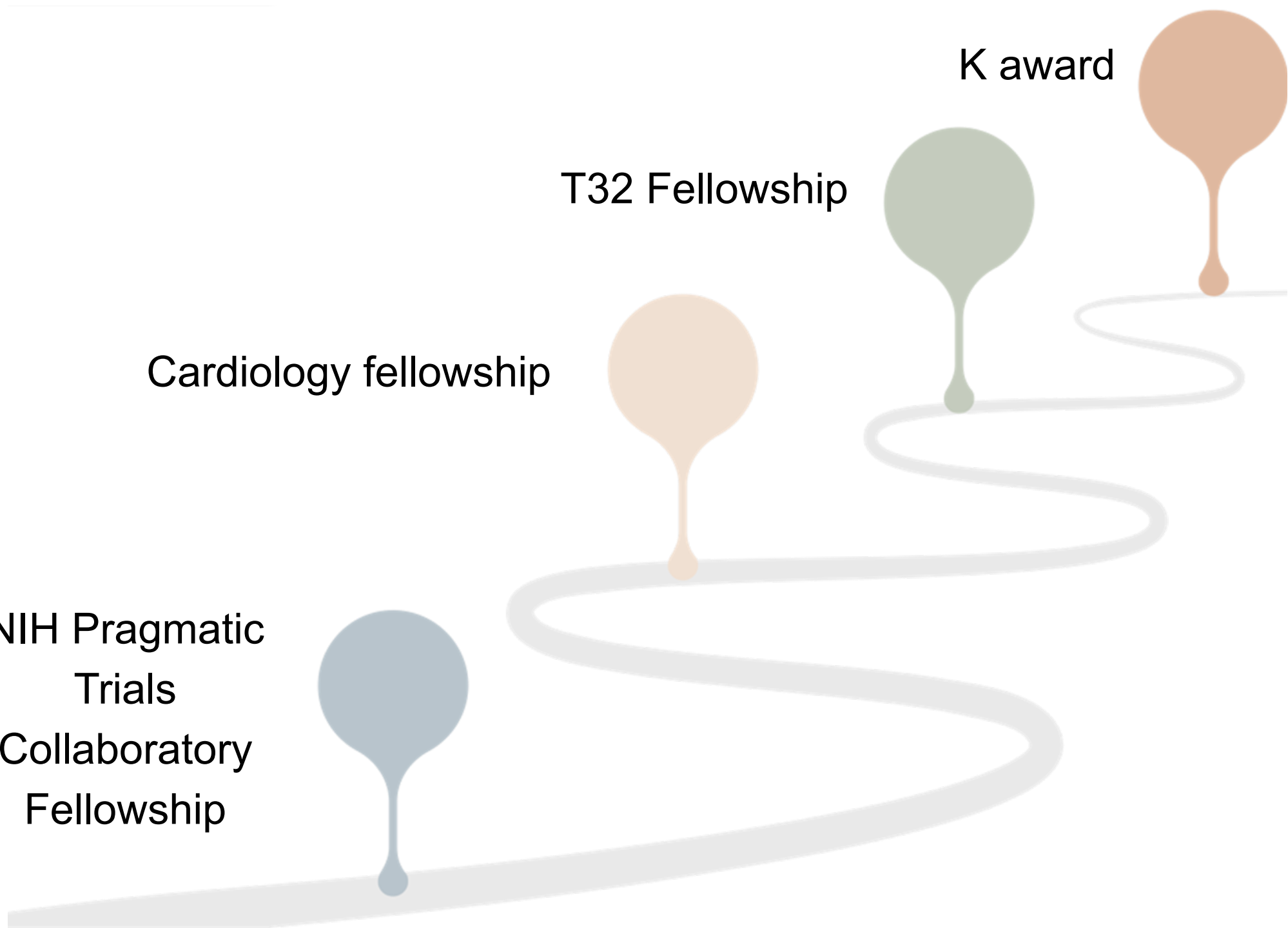


NIH Pragmatic
Trials
Collaboratory
Fellowship

Cardiology fellowship

T32 Fellowship

K award



*Thank
you!*

The Nudge Study Team- Prateeti Khazanie, Michael Ho, Sheana Bull, Lisa Sandy Caputo, Joy Waughtal, Sylvie Novins-Montague, Patrick Hosokawa, Ben Allshouse

Health Equity Core Leadership-Cherise Herrington, Rosa Gonzales-Guarda, PIs and research staff that participated in interviews

NIH Pragmatic Trials Collaboratory/Coordinating Centers-Alex Fist, Tammy Reece, Marijo Mencini, Stephanie Ibemere, Devon Check, Hayden Bosworth, Leslie Curtis, Adrian Hernandez, Kevin Weinfurt

Questions