

Novel approaches to recruiting clinical sites for embedded pragmatic clinical trials: Insights from the AIM-back trial

Trevor Lentz, PT, PhD

Tyler Cope, PT, DPT, ATC

Duke Clinical Research Institute

Duke Department of Population Health Sciences

Durham Veterans Administration



Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE

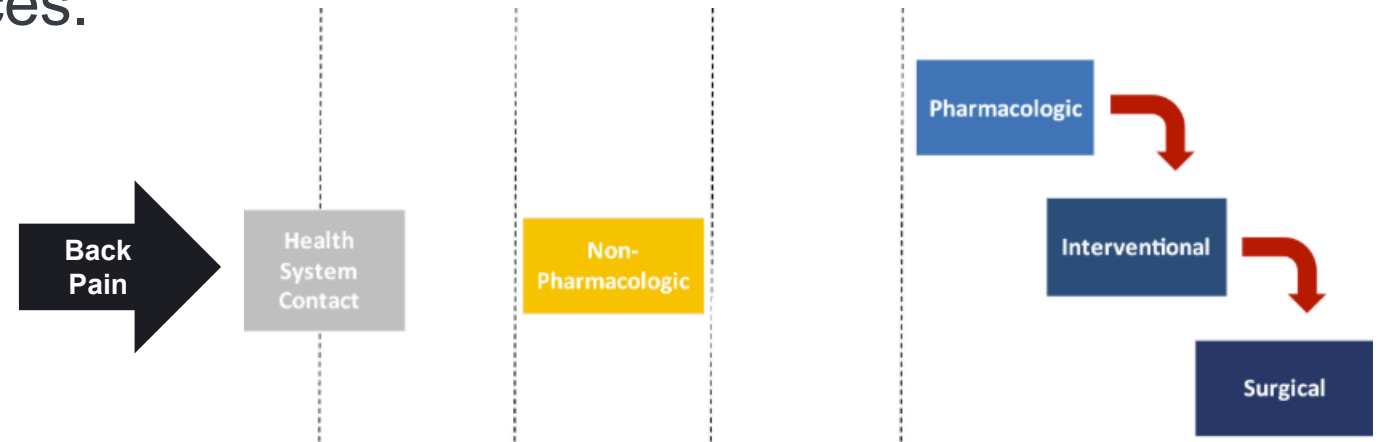
Disclosures

- This work is supported through cooperative agreement 4UH3AT009790-03 from the National Center for Complementary & Integrative Health (NCCIH).
- This manuscript/presentation is a product of the Pain Management Collaboratory.
- This material is the result of work supported with resources and the use of facilities at the Durham VA Medical Center in Durham North Carolina.
- The content of this work does not represent the views of the U.S. Department of Veterans Affairs or the United States Government.



Motivation for AIM-Back

- Low back pain (LBP) is a leading cause of disability among US Veterans.
- Non-drug treatments for LBP have been endorsed by clinical guidelines and multiple entities like CDC, WHO, ACP.
- Goal of restructuring care processes and pathways to promote use of existing guideline-supported clinical practices.



What is AIM-Back?



- Embedded pragmatic cluster randomized trial comparing two novel clinical programs that promote early access to non-pharmacologic care for low back pain in the VA



What is AIM-Back?

- **Embedded pragmatic cluster randomized** trial comparing two novel clinical programs that provide early access to non-pharmacologic care for low back pain in the VA



Pragmatic vs Explanatory Randomized Trial



Embedded and Pragmatic

- Delivery of core components protocolized; implementation strategies & non-core components flexible
- Trial outcomes (PROs) collected through clinical care encounters
- No financial support from AIM-Back to clinical sites

Cluster Randomized

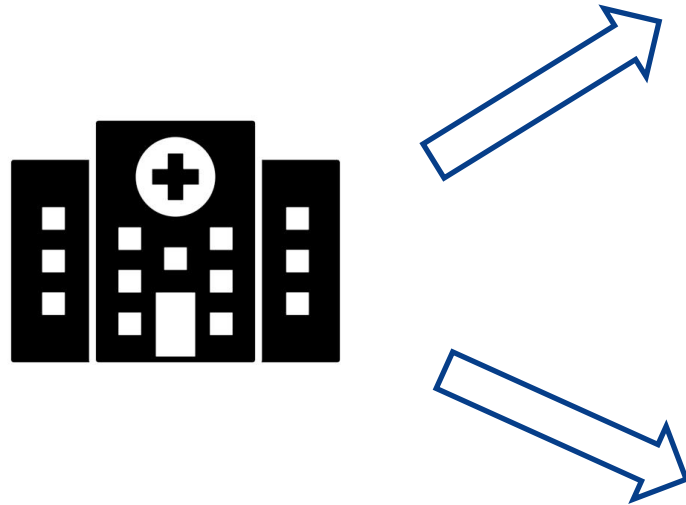
- Sites delivering guideline-concordant care
 - No patient-level consent in AIM-Back



What is AIM-Back?

- Clinics asked to deliver one of two guideline-concordant LBP care pathways
- Pathways designed with input from VA clinicians, Veterans, and caregivers
- Care pathways initiated by referral from primary care
- Effectiveness measured by improvements in PROMIS pain interference and PROMIS physical function

Care Pathways in AIM-Back



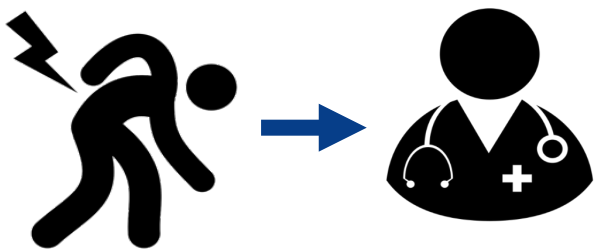
Sequenced Care Pathway

- Onsite physical therapy
- Telehealth physical activity (PA) training and psychologically-informed practice (PiP) delivered by a central provider

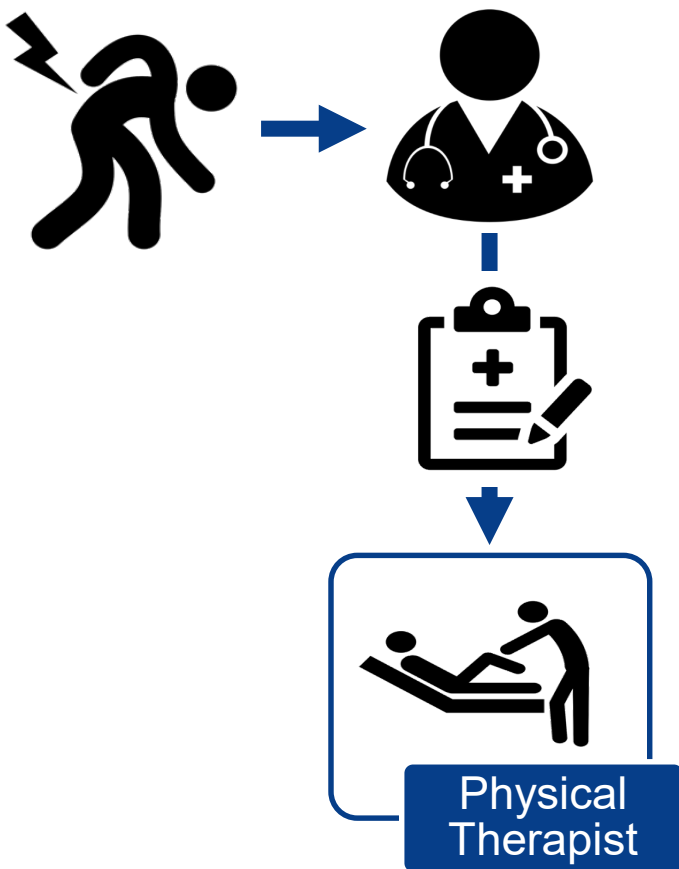
Pain Navigator Pathway

- A “navigator” in the VA provides practical support with treatment decision-making and scheduling.

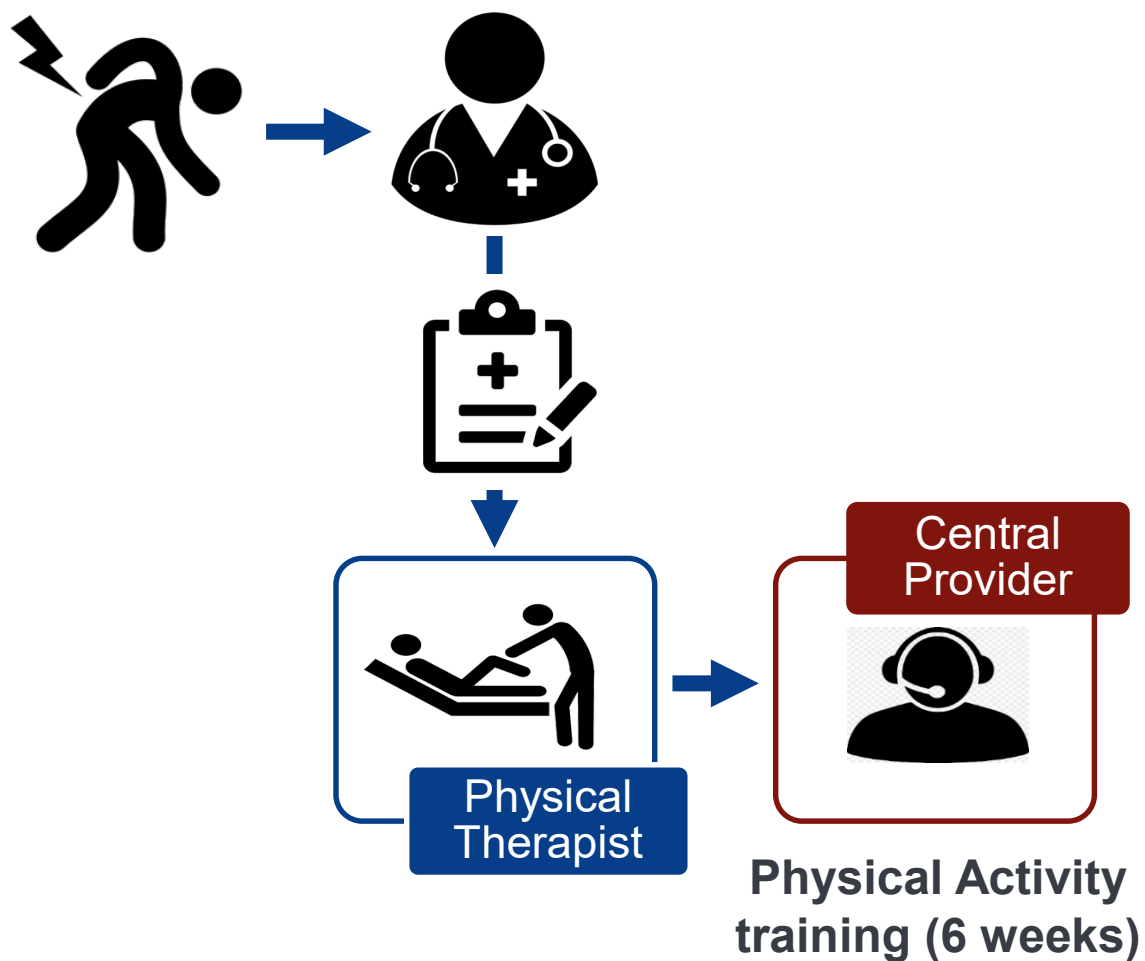
Sequenced Care Pathway



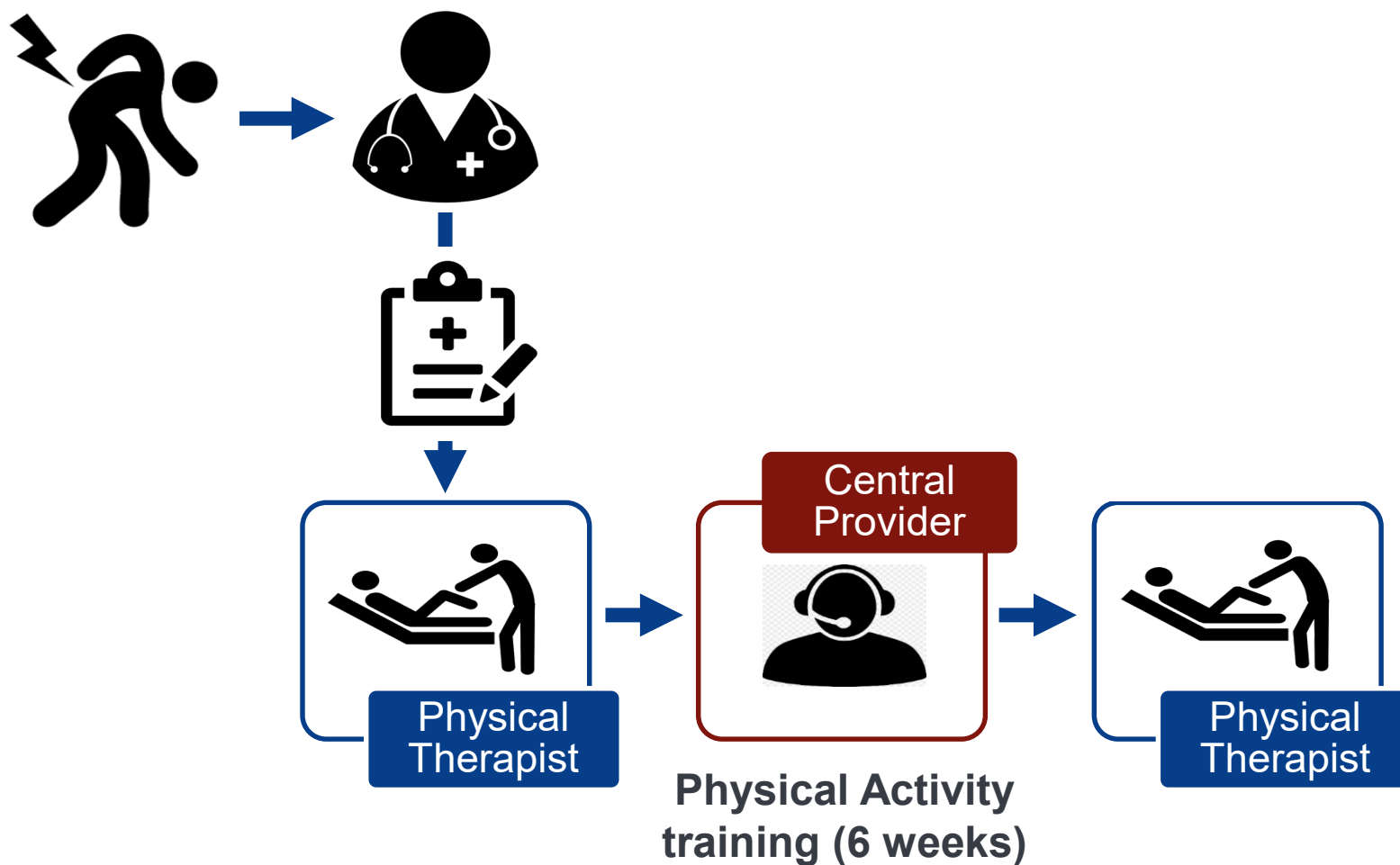
Sequenced Care Pathway



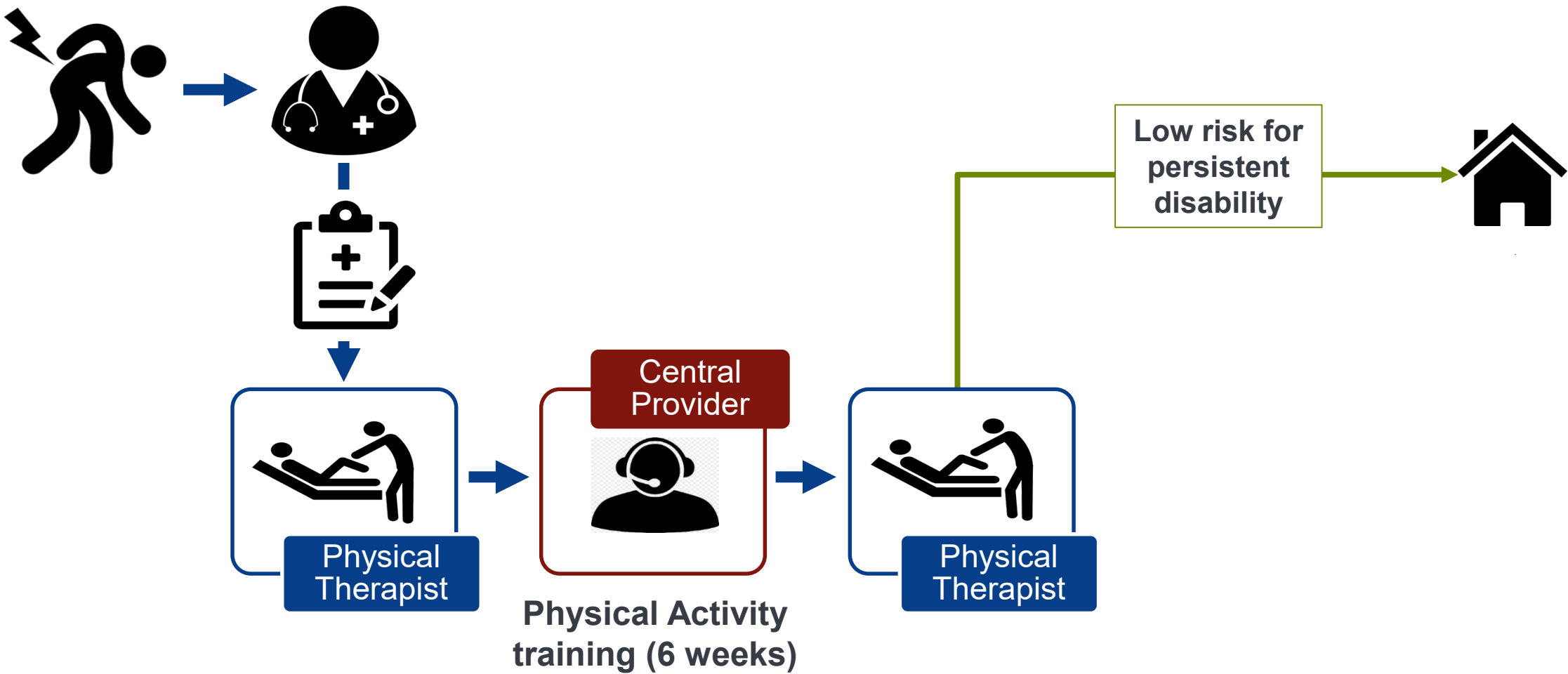
Sequenced Care Pathway



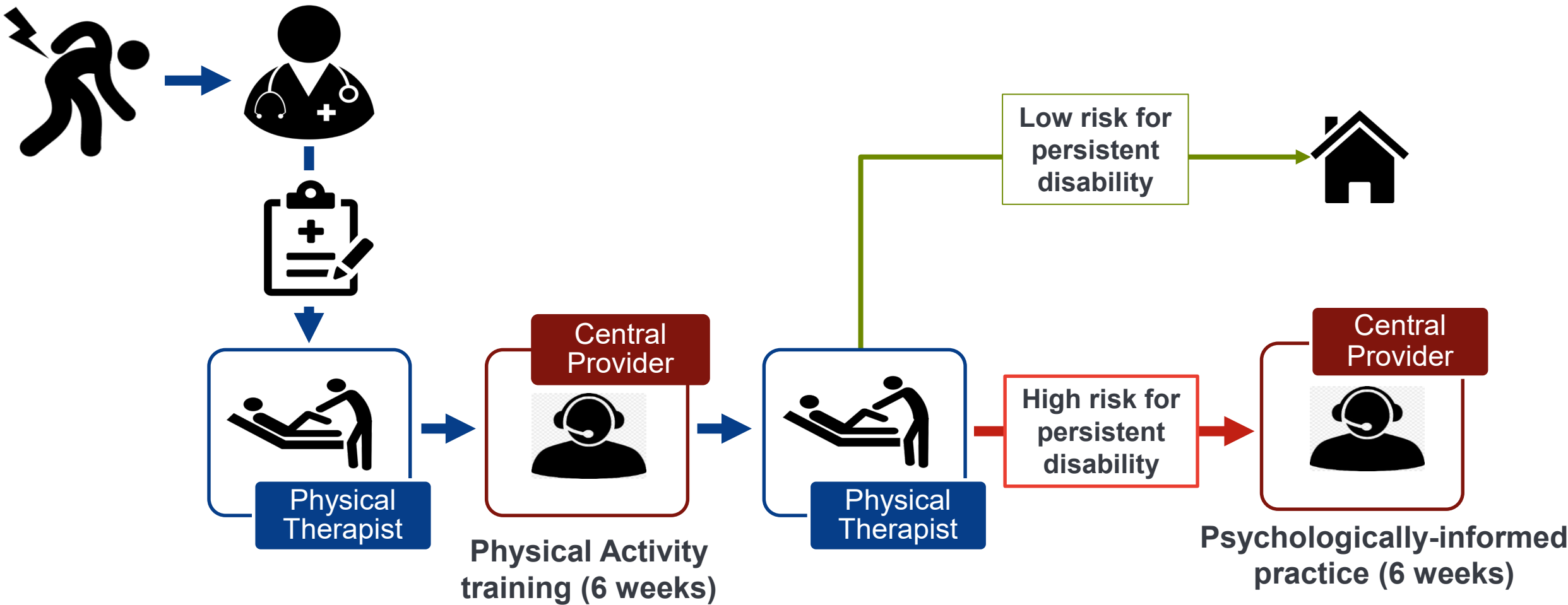
Sequenced Care Pathway



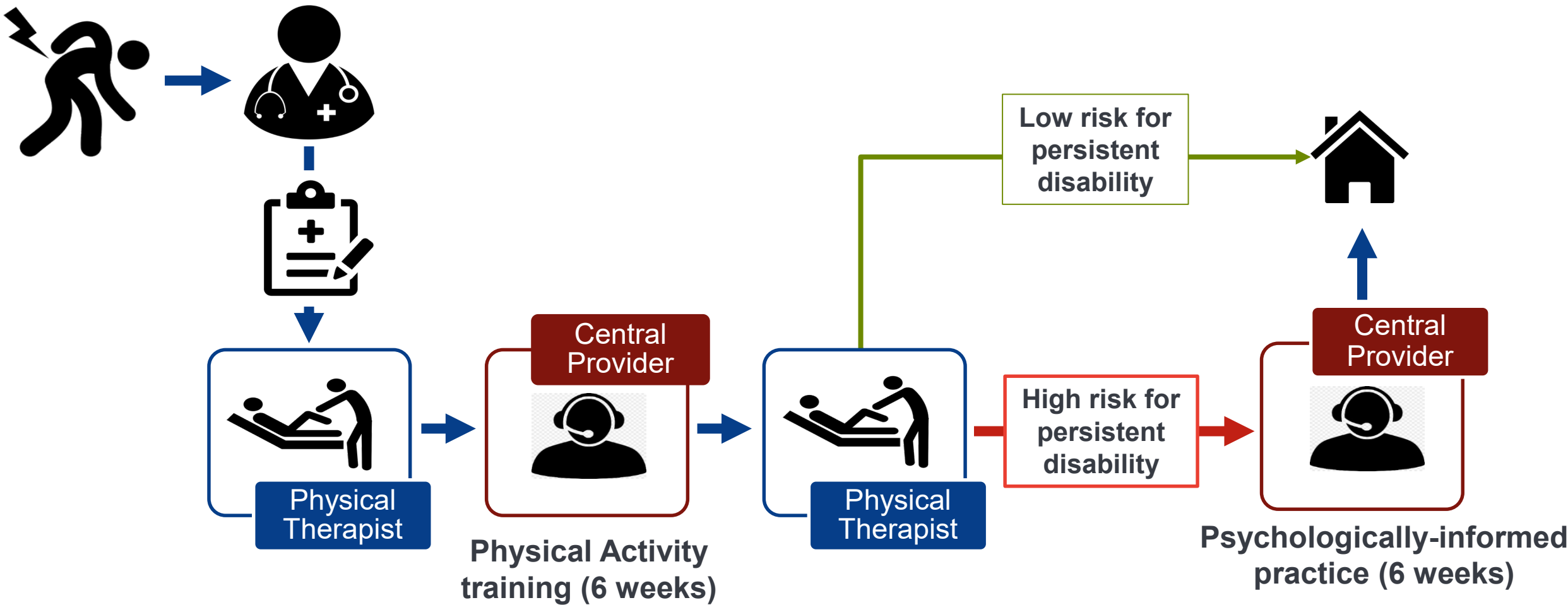
Sequenced Care Pathway



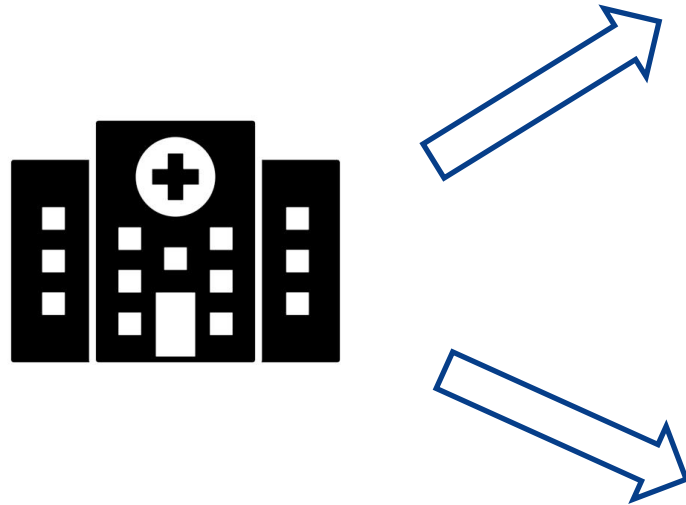
Sequenced Care Pathway



Sequenced Care Pathway



Pain Navigator Pathway



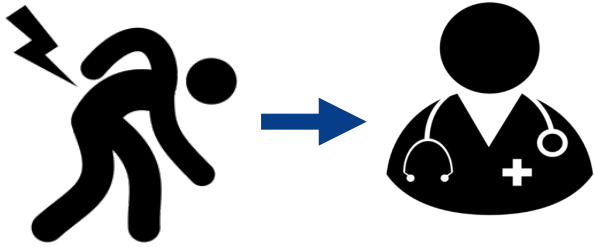
Sequenced Care Pathway

- Onsite physical therapy
- Telehealth physical activity (PA) training and psychologically-informed practice (PiP) delivered by a central provider

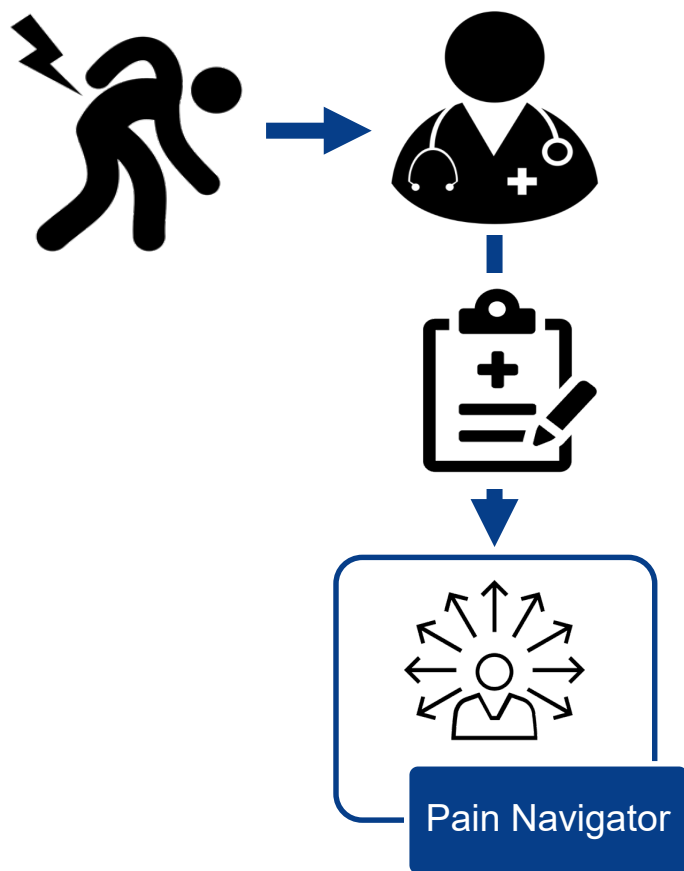
Pain Navigator Pathway

- A “navigator” in the VA provides practical support with treatment decision-making and scheduling.

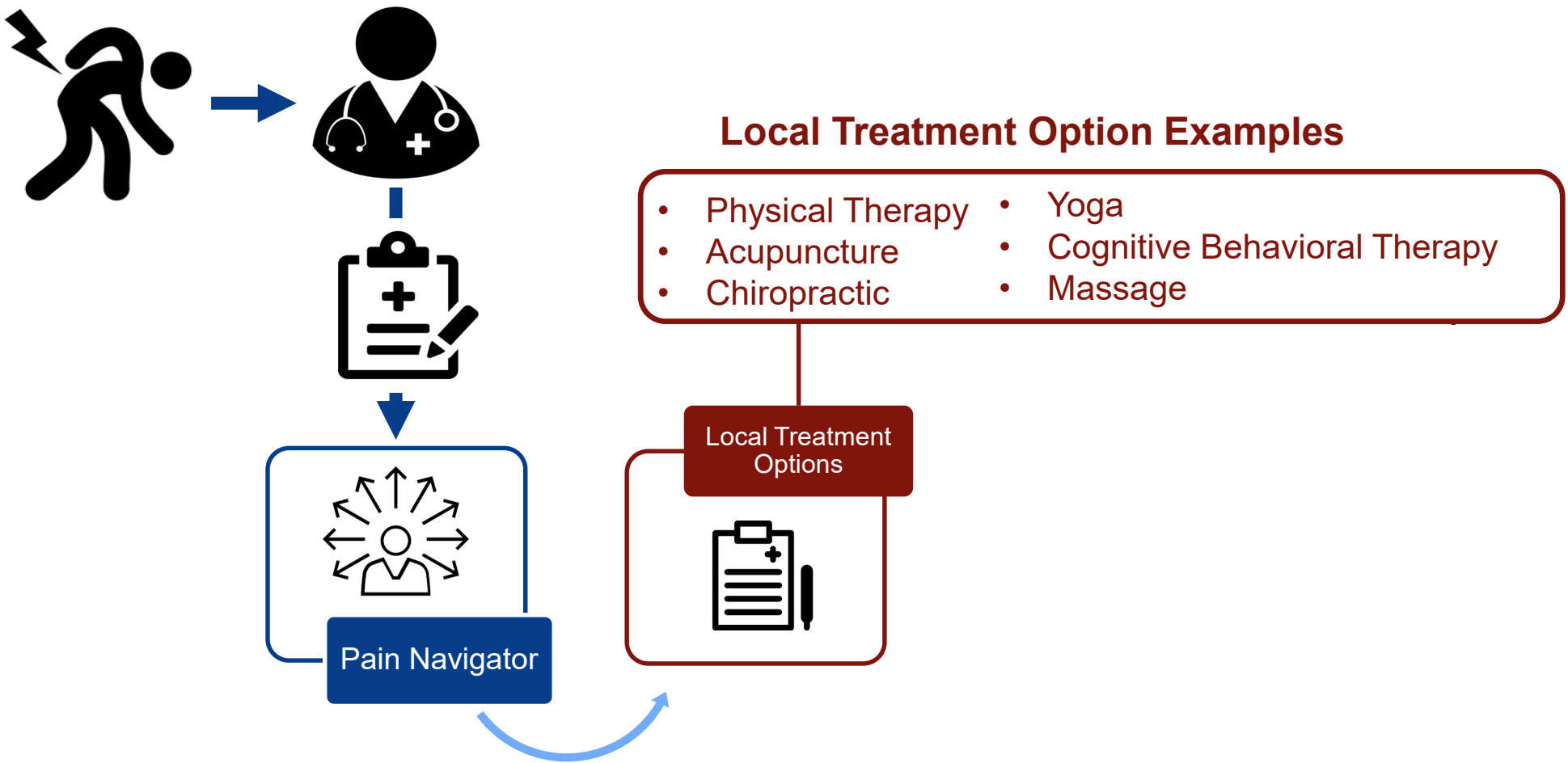
Pain Navigator Pathway



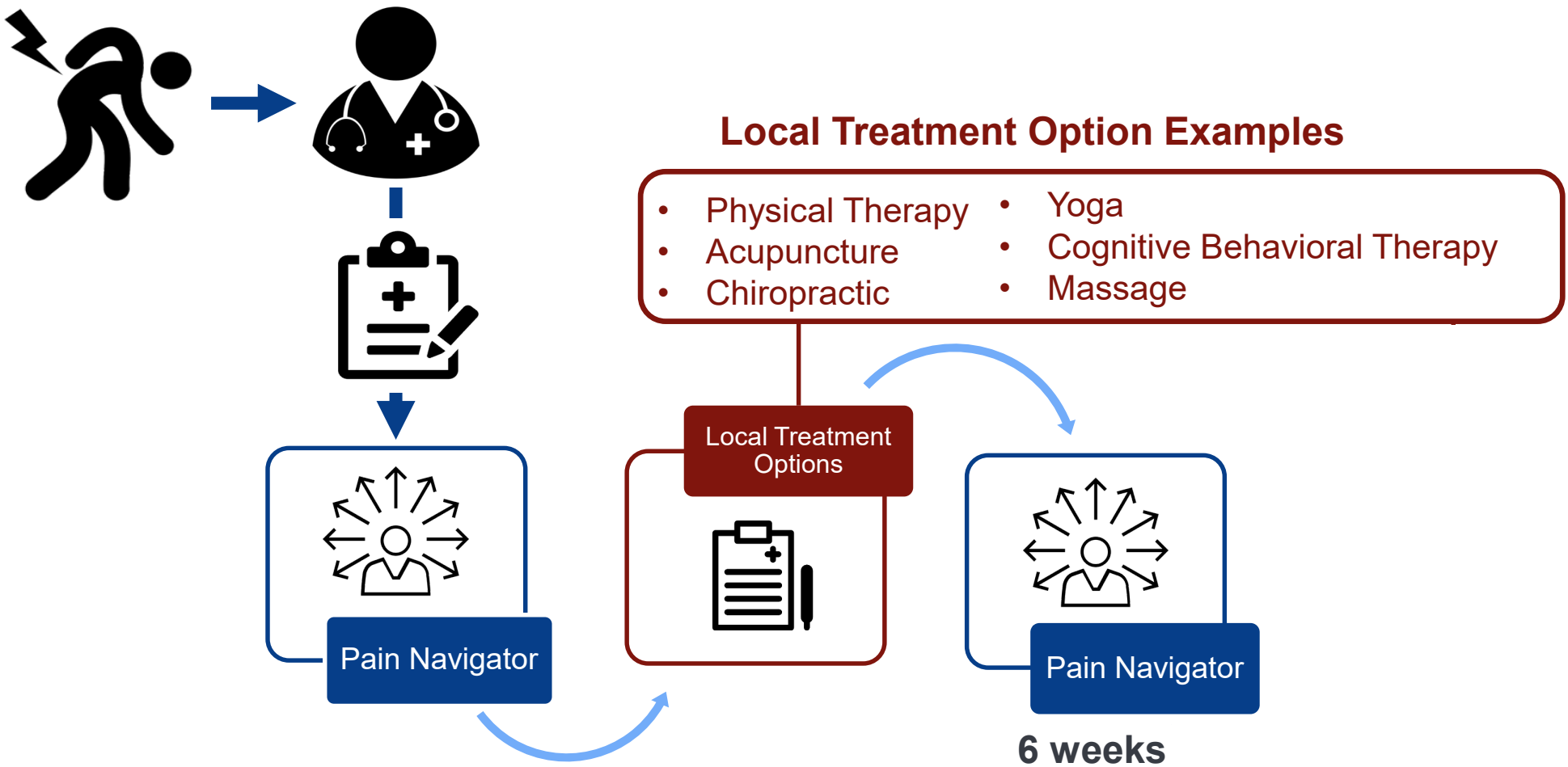
Pain Navigator Pathway



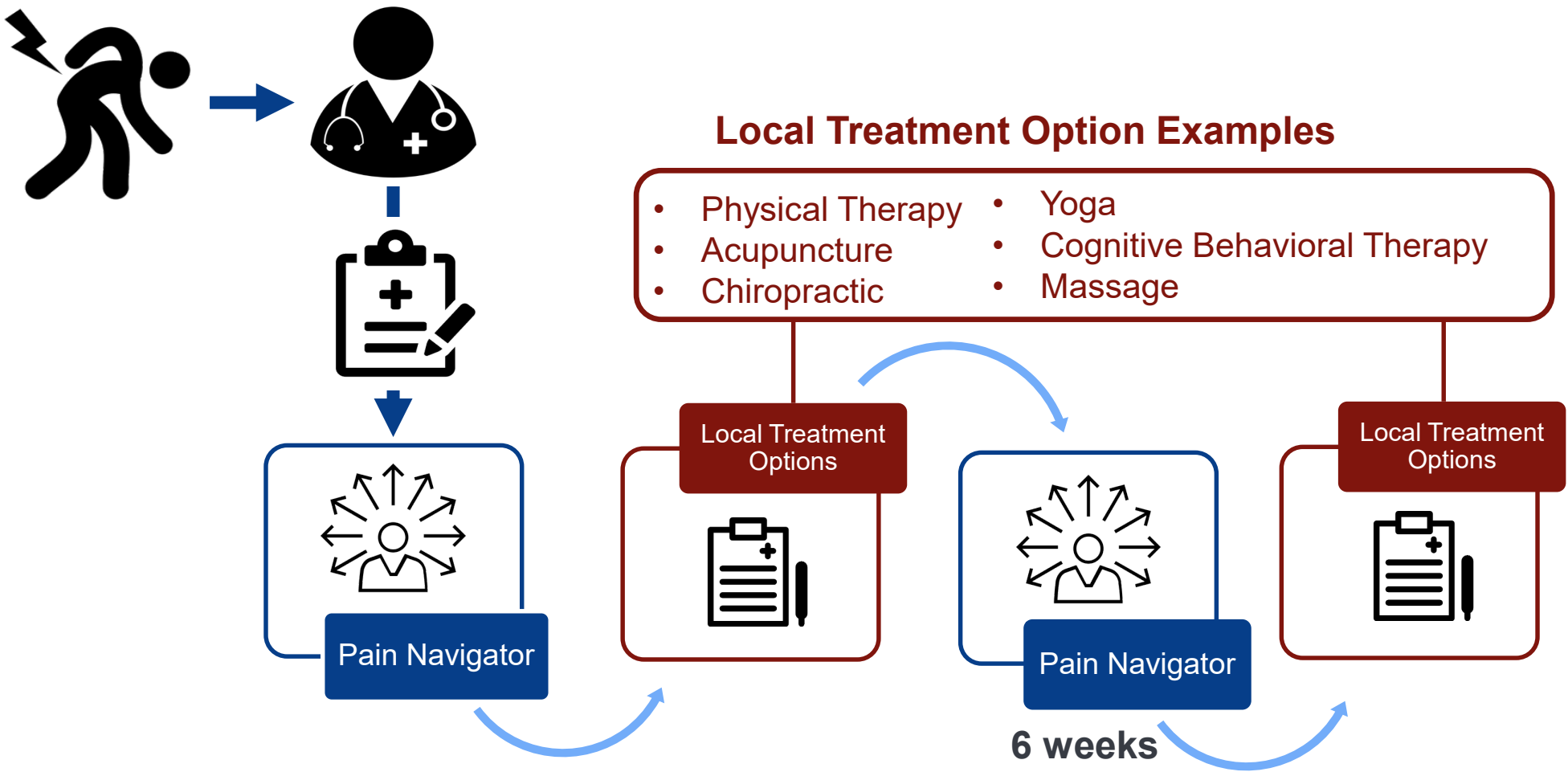
Pain Navigator Pathway



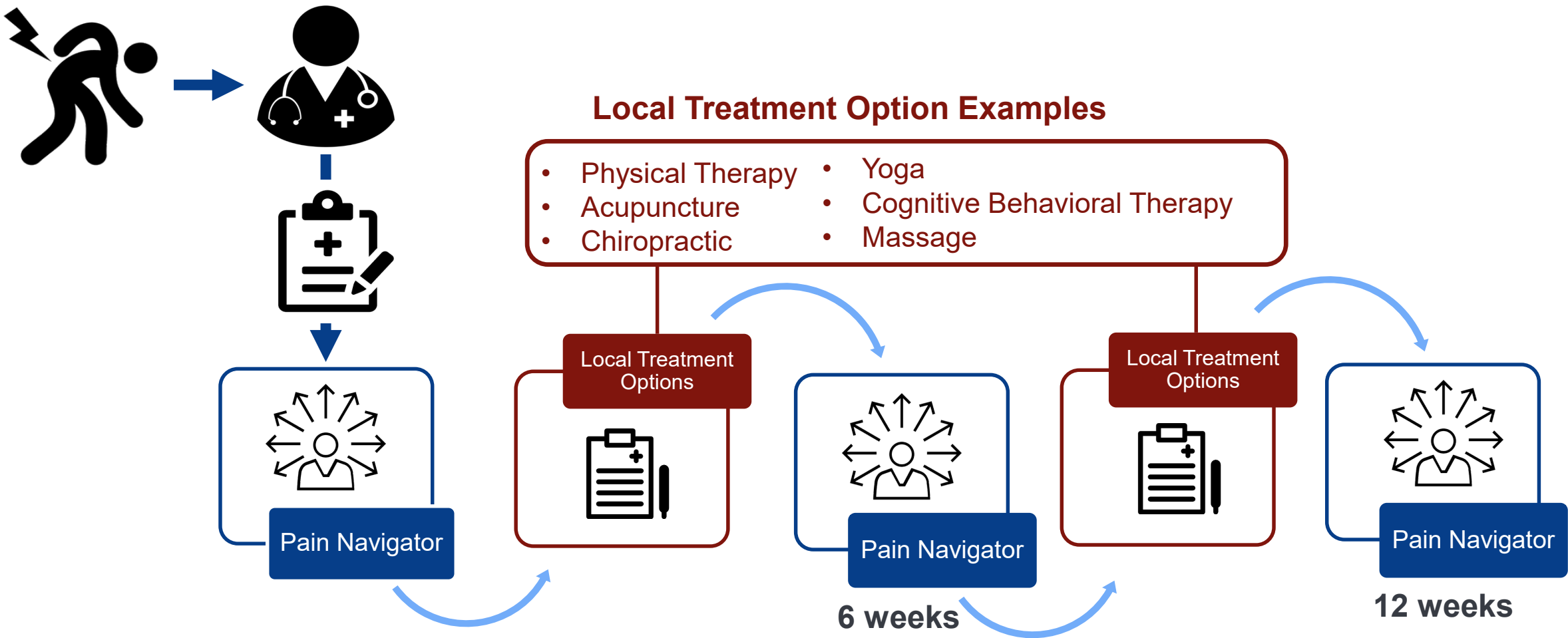
Pain Navigator Pathway



Pain Navigator Pathway



Pain Navigator Pathway



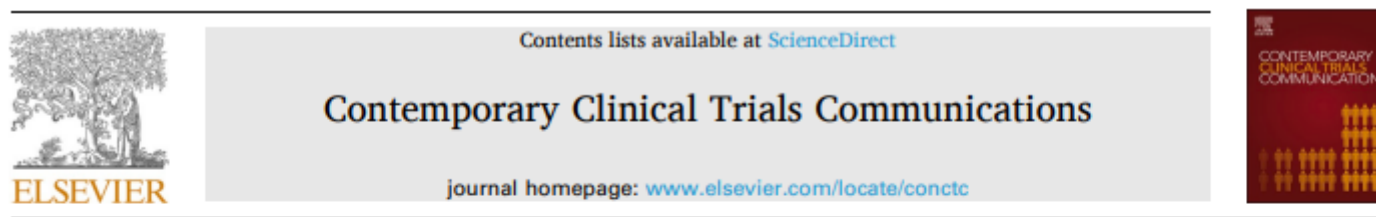
AIM-Back Timeline






- Wave 1 randomization: October 2020
- First participant enrolled: February 2021
- Wave 2 randomization: October 2021
- Final participant enrolled: February 2024
- *Primary results are in review*



Operationalizing Site Recruitment



Novel approaches to recruiting clinical sites for embedded pragmatic clinical trials: Insights from the AIM-back trial

Tyler L. Cope^{a,b,*} , Steven Z. George^{a,b,c}, S. Nicole Hastings^{b,d,e} , Courtni France^d,
Christa Tumminello^d, Cynthia J. Coffman^{d,f} , Ashley Choate^d, Trevor A. Lentz^{a,c,g}

^a Duke Clinical Research Institute, Durham, NC, USA

^b Department of Population Health Sciences, Duke University School of Medicine, Durham, NC, USA

^c Department of Orthopaedic Surgery, Duke University School of Medicine, Durham, NC, USA

^d Center of Innovation to Accelerate Discovery and Practice Transformation, Durham Veteran Affairs Medical Center, Department of Population Health Sciences, Duke University School of Medicine, Durham, NC, USA

^e Department of Medicine, Duke University School of Medicine, Durham, NC, USA

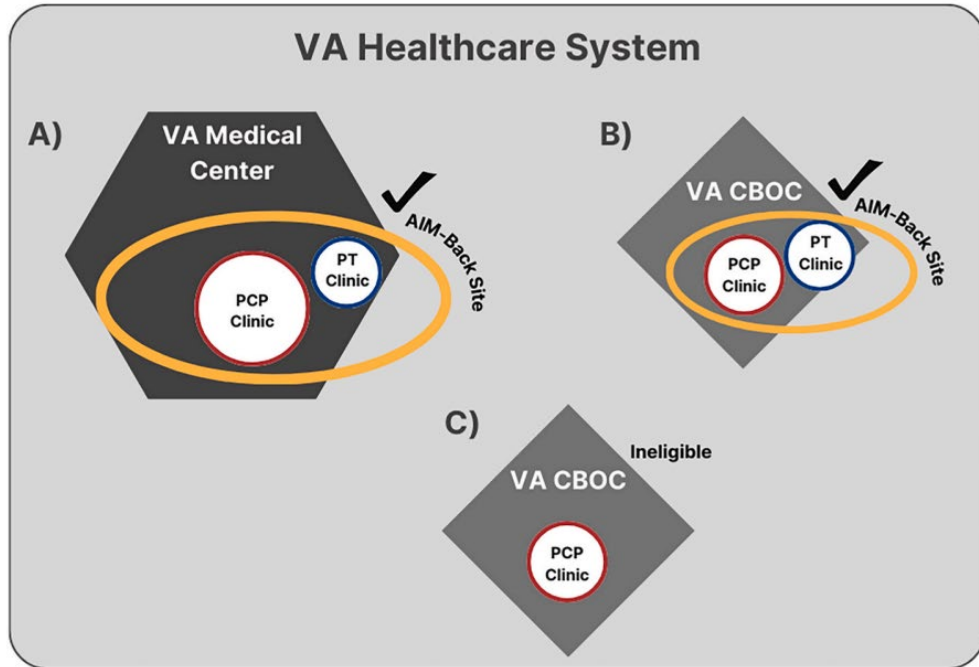
^f Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, NC, USA

^g Duke-Margolis Institute for Health Policy, Duke University, Durham, NC, USA



Who Were We Recruiting?

Participation Eligibility



Goal: 18-20 Clinical Sites

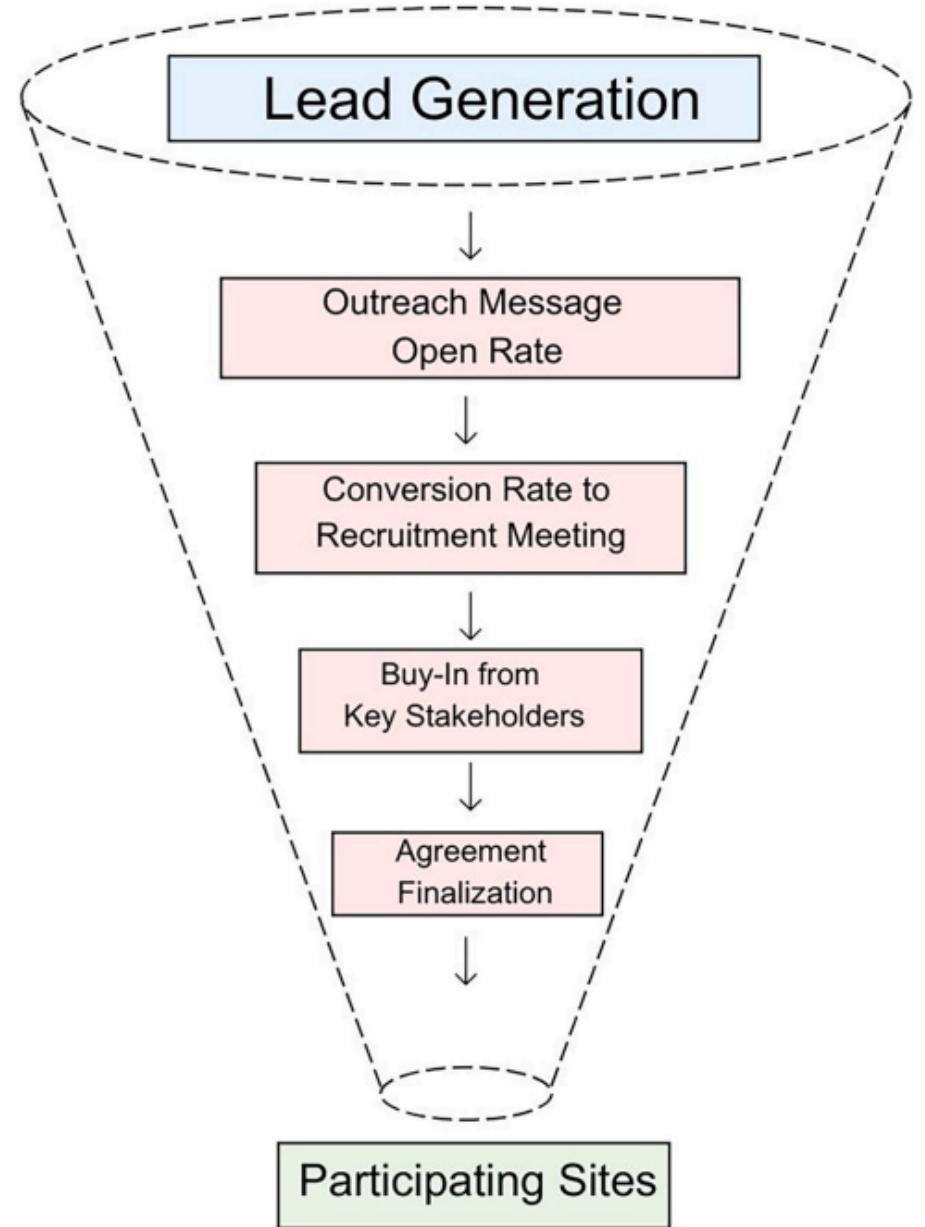
- ✓ VA PT clinic with clinical capacity
- ✓ Leadership buy-in
- ✓ No referral/staff overlap with other sites
- ✓ ≥ 800 to ≤ 5000 annual LBP visits**



Our Recruitment Approach

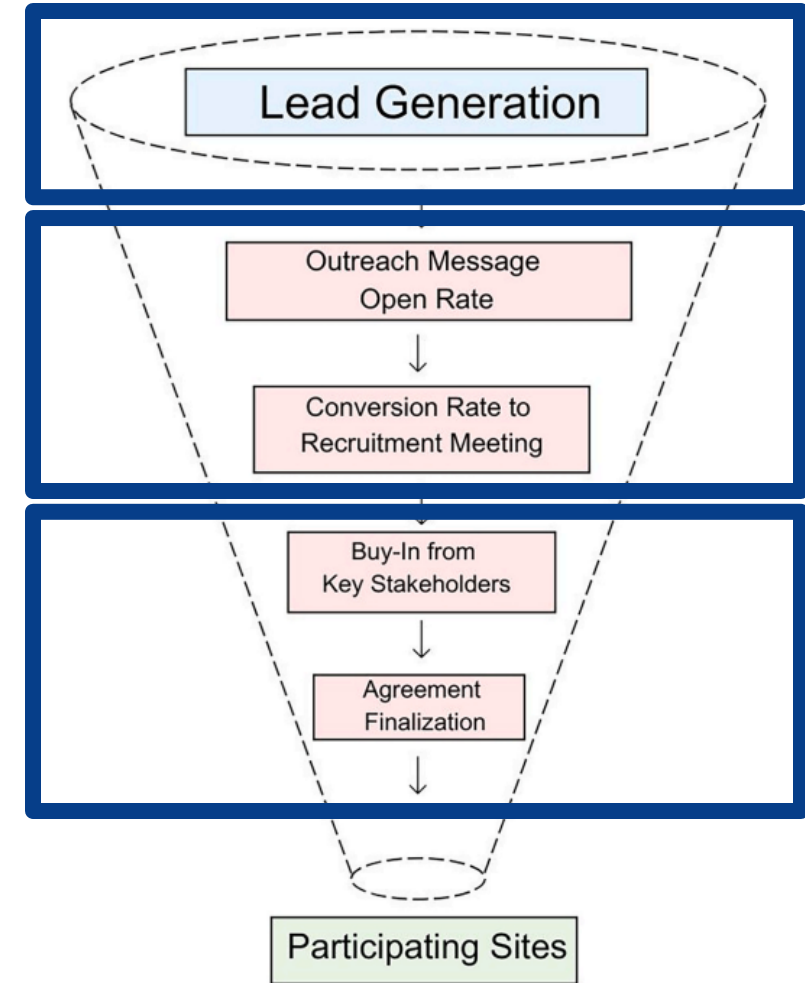
- Adapted business sales funnel
- Systematic *identification, qualification, conversion*
- Wide lead pool → staged engagement → site selection

🔑 Identify funnel *bottlenecks*



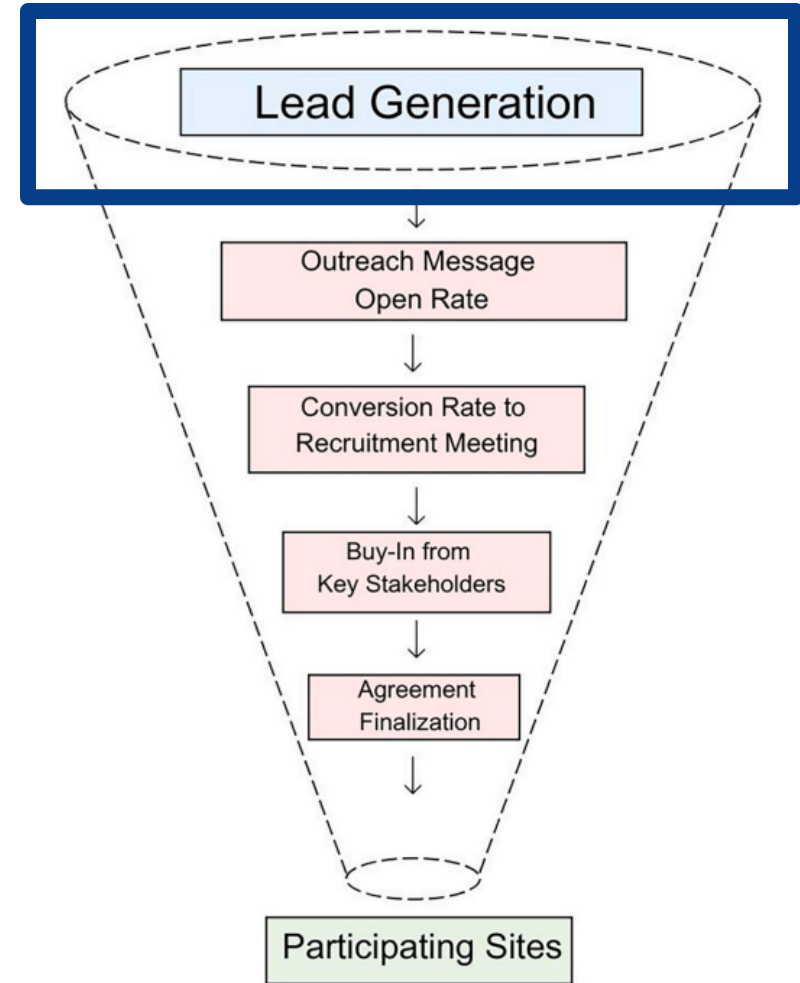
Three-Step Site Recruitment Framework

- 1) Identify
- 2) Approach
- 3) Engage & Select



Step 1: Identifying Recruitment Leads

- **Warm Market Engagement**
(Personal contacts, re-approached prior leads)
- **Leveraging Data**
 - VA CDW, LinkedIn: targeted by provider type and LBP volume
- **Promotional Outreach**
 - National VA webinars, VISN calls, alumni listservs

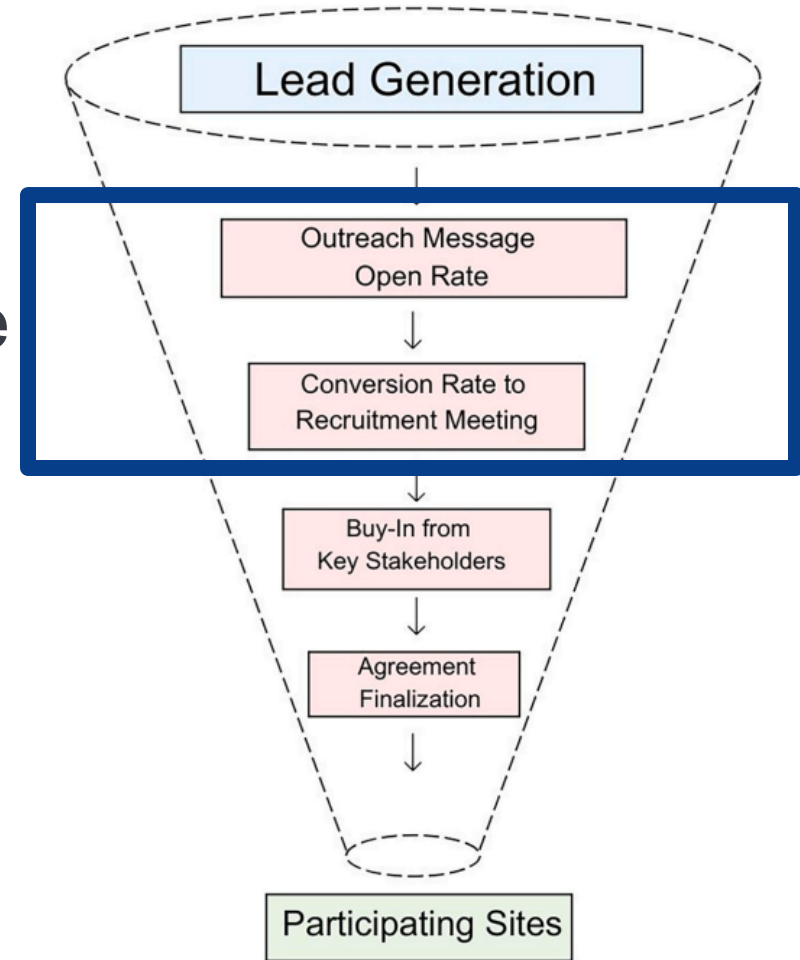


Step 2: Approaching Leads

High-volume, tailored outreach optimized for responsiveness

- *Open rates* – Dependent on subject line
- *Conversation rates* – Dependent on value proposition

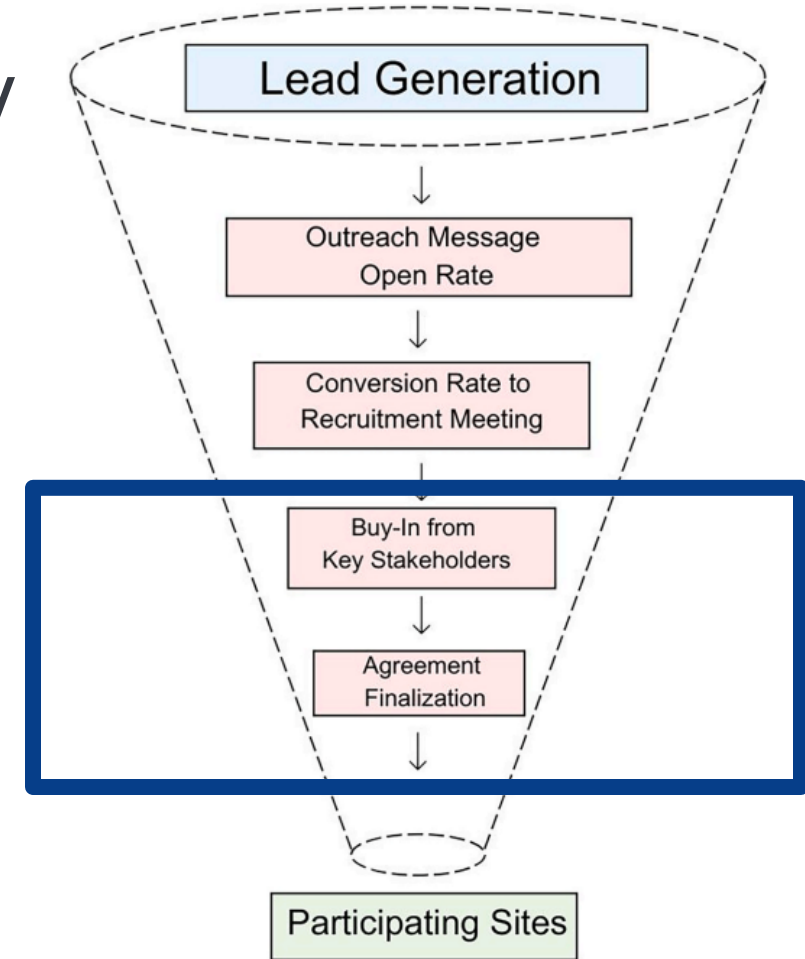
Messaging focused on helping clinicians solve *their* problems — not asking for their help with *our* research.



Step 3: Engaging & Selecting Sites

Virtual recruitment meetings with key stakeholders

- Engage personnel at all levels involved
- Assess *feasibility* and *buy-in*
- Focus on local value proposition and alignment



ABC: Always Be Closing



Recruitment Outcomes

184 leads (53 VA HCS)

23 VA HCS with Recruitment Meetings

10 VA HCS Agreed to Participate

19 Sites Selected

**17 Sites
Participated**




VA HealthCare Systems Participating (N= 10 HCS / 19 Clinics)

Recruitment Strategies

- Warm Market Engagement: **4 (21.1%)**
- Leveraging Data: **6 (31.6%)**
- Promotional Efforts: **9 (47.4%)**

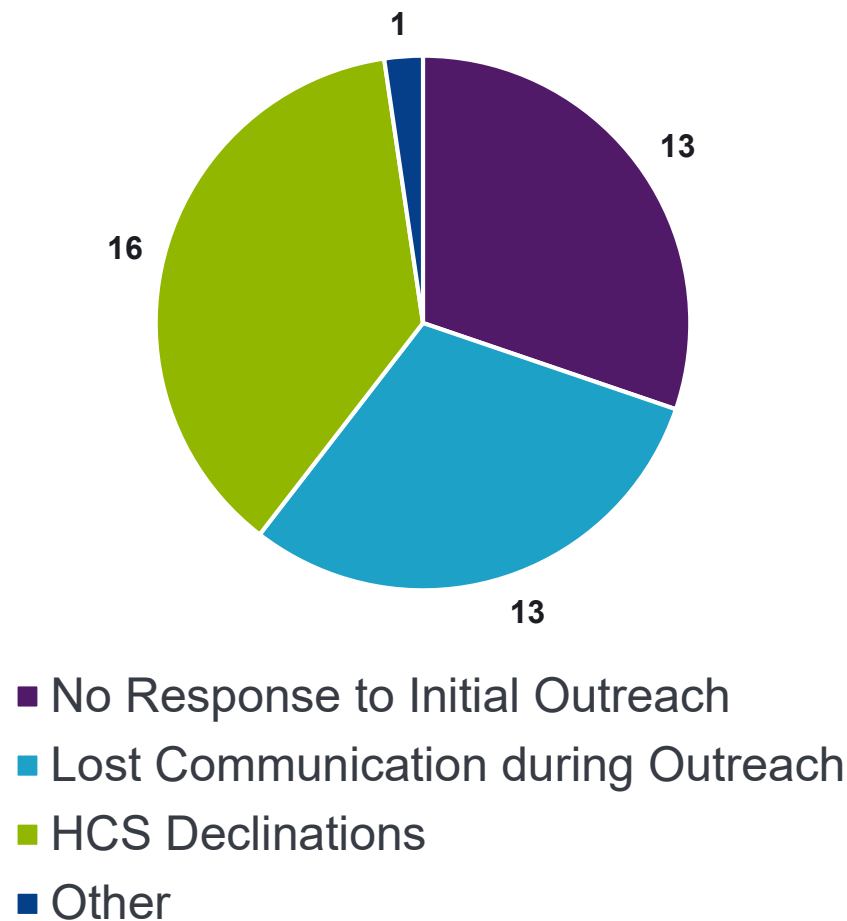
Median time from *initial contact* to *participation*

- Block 1: **3.8** months
- Block 2: **3.6** months



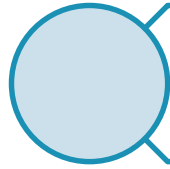
| Site Veteran Enrollment (n=1817 Veterans) | | |
|------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------|
| Below Minimum Enrollment <65 (n=1 Sites) | Met Minimum Enrollment $65 \leq x \leq 105$ (n=4 Sites) | Met Target Enrollment Goal >105 (n=12 Sites) |

VA HealthCare Systems Not Participating (N=43)



| Reason for HCS Declination | # HCS (16) |
|-------------------------------------------------|------------|
| <i>Reluctance to alter existing programs</i> | 6 |
| <i>Resource Constraints</i> | 4 |
| <i>Participation in Competing Trials</i> | 3 |
| <i>Insufficient infrastructure or personnel</i> | 2 |
| <i>No Reasons Identified</i> | 1 |

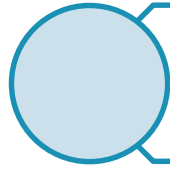
What Worked Well



Focused on clinician leads, not researchers



Recruitment Challenges



Time-intensive process



Considerations Beyond the Veterans Administration

| Lead Source | Details |
|---------------------------|----------------------------------------------------------------------------------|
| NPI Registry | Public national database of all U.S. providers |
| LinkedIn | Professional networking/search platform |
| HRSA Data Warehouse | Federal list of FQHCs and safety-net clinics |
| Professional Societies | Professional society directories by specialty (e.g., APTA / ACP / AMSSM) |
| Hospital Directories | Information kept on all clinician personnel |
| Conference Attendee Lists | Webinar, town hall, or conference registration/contact lists |
| ClinicalTrials.gov | Public trial registry with site info |



Practical Takeaways for Trialists

Do

- ✓ Build a wide lead list using multiple sources
- ✓ Tailor the value proposition to each stakeholder
- ✓ Track leads systematically and plan bottlenecks
- ✓ Identify site champions early

Don't

- ✗ Underestimate # leads required
- ✗ Rely solely on administrative approval
- ✗ Leave meetings without next steps



Acknowledgements



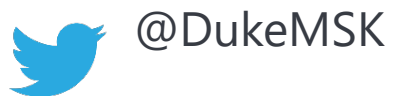
- S. Nicole Hastings, MD, MHS
- Steven Z. George, PT, PhD, FAPTA
- Cynthia J. Coffman, PhD
- Ashley Choate, MPH
- Corey B. Simon, DPT, PhD
- Trevor Lentz, PT, PhD, MPH
- Zachary Stearns, PT
- Courtni France, MS
- Micaela Gladney, MPH
- Chad Cook, PT, PhD, FAPTA
- Francis Keefe, PhD
- Christa Tumminello, MPH
- Kelli Allen, PhD
- Catherine Stanwyck
- Heather King, PhD
- Adam Goode, PT, PhD
- Lindsay Ballengee, PT, DPT
- Chanee Lynch
- Travis Linton, PT, DPT
- Jennifer Naylor, PhD
- Leo Brothers
- Colleen Burke, PT, DPT
- Sandra Woolson
- Wendy Chai





Tyler.cope@duke.edu

Trevor.lentz@duke.edu



 **AIM-Back**



Scan here to read *“Novel approaches to recruiting clinical sites for embedded pragmatic clinical trials: Insights from the AIM-back trial”*

