

# Partner engagement for planning and development of non-pharmacological care pathways in the AIM-Back trial

*Clinical Trials*

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## Abstract

**Background/Aims:** Embedded pragmatic clinical trials are increasingly recommended for non-pharmacological pain care research due to their focus on examining intervention effectiveness within real-world settings. Engagement with patients, health care providers, and other partners is essential, yet there is limited guidance for how to use engagement to meaningfully inform the design of interventions to be tested in pain-related pragmatic clinical trials. This manuscript aims to describe the process and impacts of partner input on the design of two interventions (care pathways) for low back pain currently being tested in an embedded pragmatic trial in the Veterans Affairs health care system.

**Methods:** Sequential cohort design for intervention development was followed. Engagement activities were conducted with 25 participants between November 2017 and June 2018. Participants included representatives from multiple groups: clinicians, administrative leadership, patients, and caregivers.

**Results:** Partner feedback led to several changes in each of the care pathways to improve patient experience and usability. Major changes to the sequenced care pathway included transitioning from telephone-based delivery to a flexible telehealth model, increased specificity about pain modulation activities, and reduction of physical therapy visits. Major changes to the pain navigator pathway included transitioning from a traditional stepped care model to one that offers care in a feedback loop, increased flexibility regarding pain navigator provider type, and increased specificity for patient discharge criteria. Centering patient experience emerged as a key consideration from all partner groups.

**Conclusion:** Diverse input is important to consider before implementing new interventions in embedded pragmatic trials. Partner engagement can increase acceptability of new care pathways to patients and providers and enhance uptake of effective interventions by health systems.

**Trial registration:** NCT#04411420. Registered on 2 June 2020.

## Keywords

Partner engagement, non-pharmacological, care pathways, pain navigator, pragmatic clinical trial

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## Background

Patients with chronic musculoskeletal pain, including low back pain,<sup>1</sup> are prescribed opioids more frequently than physical therapy, counseling, and other non-pharmacological treatments.<sup>2</sup> However, evidence for the effectiveness of opioids is limited and the risk of serious harm from opioid therapy can be high.<sup>3</sup> As such, multiple federal agencies and professional societies (e.g. Centers for Disease Control and Prevention;<sup>4</sup> American College of Physicians)<sup>5</sup> have advocated for broader implementation of non-pharmacological pain management strategies. Although individual non-pharmacologic therapies for low back pain have demonstrated effectiveness,<sup>5</sup> there is a persistent and compelling need for research on how best to organize and deliver these treatments in the context of existing health care systems.

Embedded pragmatic clinical trials (PCTs) are a useful design for non-pharmacologic pain care research because they enable testing intervention effectiveness for broad patient groups using existing clinical resources under “real-world” conditions.<sup>6–8</sup> Engaging health system, patient, and community partners who will be affected by or responsible for health care delivery that may be informed by research is vital for PCTs.<sup>9,10</sup> Community-engaged research is the “process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people.”<sup>11</sup> In PCTs, partner engagement could help make interventions more patient-centered, increase their relevance to a wider audience,<sup>12</sup> and enhance their potential to determine treatment effectiveness.<sup>13</sup> Partner engagement is particularly important for the successful implementation of PCTs that study non-pharmacological pain management strategies given the complexity of these interventions.<sup>14</sup> For example, many non-pharmacological interventions involve a mind–body emphasis that is contingent on high-quality provider–patient interaction and gathering patient and provider perspectives on ways to overcome the complexities associated with these types of interventions may lead to more success with their implementation.

Building on decades of experience in program development, there is growing recognition of the importance of partner engagement in health-related research. However, in research reports, the benefits of interactions with patients or community partners are often described in general terms. There is a lack of literature assessing the specific impact, or value, of partner input in pain intervention development and implementation of research.<sup>15–19</sup> Partner recruitment strategies, sampling methods, and engagement activities are widely variable and underreported. Specific to our purpose, engaging community partners could be a way to decrease challenges associated with successfully

implementing non-pharmacologic care pathways in a pragmatic trial.<sup>10</sup> Meaningful engagement requires significant time from research teams and involved patients and community participants; thus, examination of case examples is needed to inform decisions about building in time and resources for partner engagement in future clinical trials. Therefore, the purpose of this article is to summarize the impact of partner engagement on the development process of two multimodal care pathways intended to improve access to non-pharmacological treatments for veterans with low back pain.

## Methods

### *Trial overview*

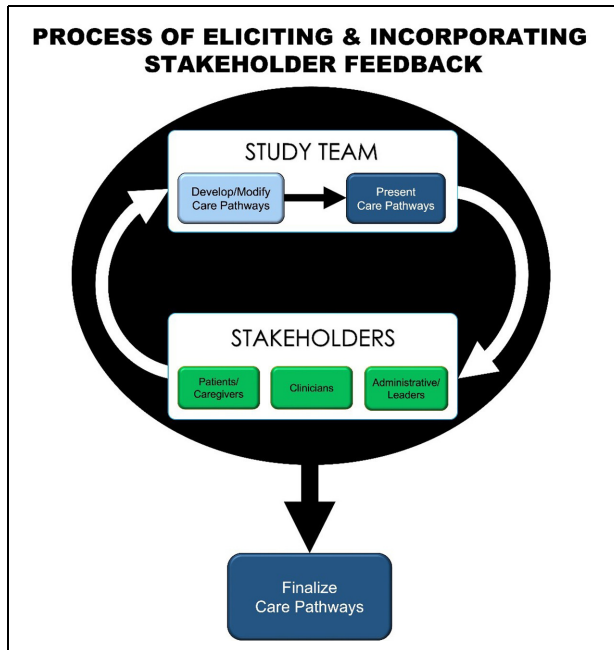
The Improving Veteran Access to Integrated Management of Low Back Pain (AIM-Back) embedded PCT consists of a 2-year planning and 4-year demonstration phase. During the planning phase, AIM-Back investigators highlighted partner input for intervention development as one of several priorities. The activities described in this manuscript took place during the 2-year planning phase. In addition, intervention alterations that resulted from partner engagement did not require revisions to the overall trial analysis plan because feedback was incorporated into the study protocol that was finalized at the end of the planning period. For more details on the AIM-Back trial, refer to the protocol paper.<sup>20</sup>

### *Engagement design*

The main objective of partner engagement was to give community partners the opportunity to voice their views on two care pathways and to guide the research team with planning, implementation, and evaluation related to the pathways from the beginning of the process. Partner engagement was initiated and directed by members of the AIM-Back trial team and followed a sequential cohort design where feedback was solicited from multiple groups at multiple time points. Figure 1 outlines the overall structure of the engagement process. Partner engagement involved multiple methods and was conducted in two parts as a function of community partner type, (Part 1: clinicians and administrators, Part 2: patients and caregivers). The arrows represent an iterative process between the partner cohorts and the study team which allowed for multiple rounds of intervention modifications.

### *Partner engagement process to modify care pathways*

The initial versions of both pathways were developed by AIM-Back team members with expertise in non-pharmacological care. The first iteration of the sequenced care pathway which integrates pain



**Figure 1.** Structure of partner engagement process.

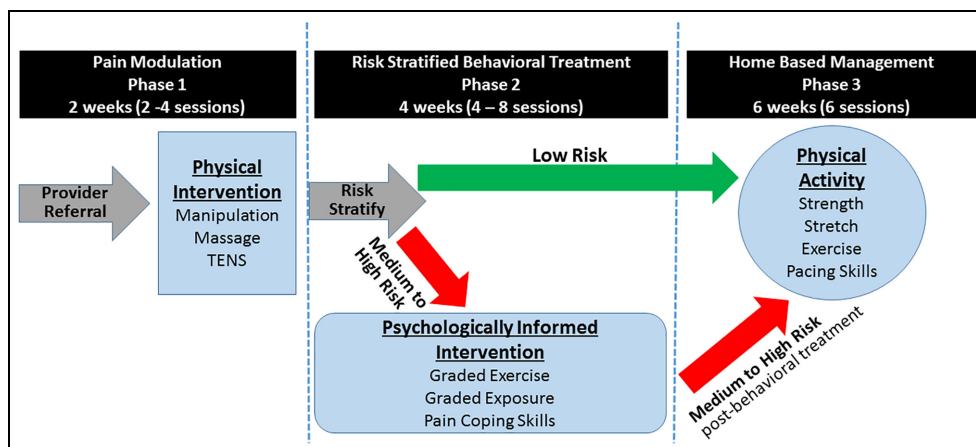
modulation, tailored behavioral treatment, and home-based activity is depicted in Figure 2. In this version of the pathway, eligible veterans referred by their provider start with Phase 1 (Pain Modulation) and then progress through the pathway to Phase 2 (Risk Stratified Behavioral Treatment). Phase 2 consists of risk stratification that determines the need for psychologically informed physical therapy. Veterans who are low risk for continued low back pain disability transition to Phase 3 (Home Based Management), while veterans who are medium or high risk for continued disability receive psychologically informed physical therapy consisting of behavioral interventions and pain coping skills training. Progress through each phase is determined by set criteria, and veterans enrolled in the study are monitored as

per standard clinical procedures. Non-pharmacological interventions in each phase are depicted in blue.

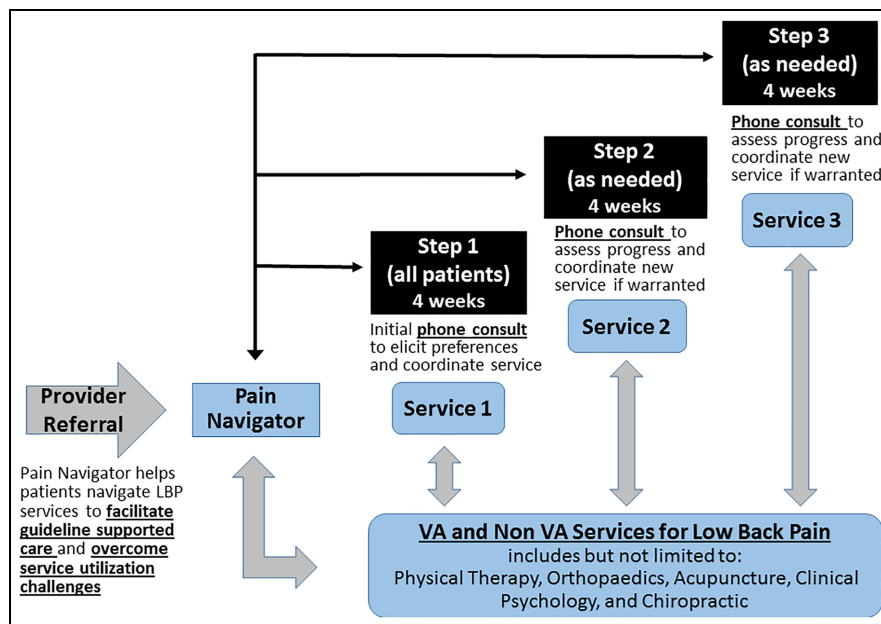
The first iteration of the coordinated, pain navigator pathway is depicted in Figure 3. The intervention in this pathway—navigation to available Veterans Affairs (VA) and non-VA guideline recommended services—is meant to be delivered entirely via telehealth. Patients are first referred to their clinic’s pain navigator during a primary care visit for low back pain. The pain navigator educates the patient about resources available for low back pain care via three telephone calls, identifies patient preferences for non-pharmacologic approaches, and facilitates access to services in three 4-week steps. The pain navigator pathway most closely resembles a stepped care model<sup>21</sup> and attempts to overcome challenges of over and underutilization of existing services by empowering the pain navigator to facilitate guideline recommended care options.

**Part 1—VA leadership, management, and clinicians.** The first cohort of partners represented frontline staff, various levels of management, national leadership, and both VA and non-VA providers. We purposefully selected different types of clinicians (e.g. physicians, nurses, physical therapists) who would have a role in the two clinical pathways. This group was chosen from local and national settings and included clinicians who also had research experience to obtain diverse viewpoints through involvement of research and non-research perspectives.

Partner engagement began in November 2017 with a semi-structured interview conducted by two investigators with content expertise (SG and CS) with local VA clinician leadership in the areas of physical medicine and rehabilitation and physical therapy. The purpose of this introductory meeting was to initiate feedback on overall design and potential barriers to implementing the pathways. Two similar meetings were held in



**Figure 2.** First version of sequenced care pathway.



**Figure 3.** First version of pain navigator pathway.

January and February 2018 with VA physicians and physical therapists. The purposes of these meetings were to (1) gather input on current care delivery for veterans with back pain; and (2) determine feasibility and ways to maximize existing VA infrastructure.

After approximately 3 months of iterative pathway development by the research team, additional partner engagement meetings were held by both a content expert (CS or SG) and an expert in partner engagement, implementation, and qualitative methodology (HK). From May through July 2018, the team held eight separate meetings with clinician and administrative/leadership partners. Each meeting consisted of the following structure: (1) initial thoughts on the pathways; (2) similarities or differences from the partners' current VA care delivery; (3) suggested changes to the pathways; (4) pathway elements that are exciting/not exciting; (5) feasibility (i.e. barriers and facilitators) of implementation; and (6) questions for the investigator team about the pathways. After approximately two partner meetings, data were shared and discussed at the larger investigator team meeting where recommended pathway modifications were determined based on consensus. Subsequently, the intervention development team modified the pathways based on these recommendations and the engagement team carried the new pathway models forward to the next partner engagement meeting. This cycle continued for approximately four iterations.

**Part 2—veterans and caregivers.** During the second part of the engagement process, four investigators (SH, SG, CS, HK) attended a Veteran Research Engagement Panel (VetREP) meeting in July 2018 (approximately

1.5 h in duration) and facilitated a group discussion regarding the newest iterations of the care pathways. This partner group represented individuals with patient and caregiver experience in the VA Health Care System, as well as those who would be impacted by the proposed care pathways. At this session, there were nine veterans, two care partners, and one civilian care partner in attendance. The Panel was 33% women, 33% African American, and included veterans who served in Vietnam, Gulf War, and Operation Iraqi Freedom/Operation Enduring Freedom/Operation New Dawn. Feedback from this session was documented and provided by VetREP leadership. Subsequently, this feedback was presented to the larger AIM-Back investigator team and further changes were made to the pathways. Table 1 further outlines the two parts of the engagement process, including sample questions and partner characteristics.

**Other input sources.** Another partner engagement resource which informed pathway development was an ongoing national Partner Engagement Workgroup led by the Pain Management Collaboratory. This was a monthly meeting attended by representatives from all 11 studies funded under the NIH-VA-DOD Pain Management Collaboratory to query other study teams on pathway implementation. In this way, the investigator team was able to leverage valuable information learned from veterans, caregivers, clinicians, and leaders situated nationally. This was another important resource since the plan was to embed the pathways within national VA sites.

**Table 1.** Partner engagement process summary.

Engagement step	Sample questions	Partner characteristics
Part 1 <sup>a</sup>	<p>“How are these pathways similar or different to your current care processes/patterns of care?”</p> <p>“Feasibility? What are important factors to consider, that is, likely barriers/facilitators (e.g. choice, timing, etc.)?”</p> <p>“What are key sources of variation in back pain care at other Veterans Affairs (VA) Medical Centers that we should be aware of?”</p>	<p>Clinicians and Administrative/Leaders: (n = 13):</p> <p>Nurses</p> <p>Physical therapists</p> <p>Psychologists</p> <p>Physicians</p> <p>Social workers</p>
Part 2 <sup>b</sup>	<p>“How do each of these pathways align/not align with veterans’ needs, preferences, and expectations related to low back pain?”</p> <p>“Specific to Integrated Care Pathway: In this pathway, veterans will receive individualized physical activity instruction one time per week for 6 weeks, via phone or telehealth. How do you think veterans will respond to this approach?”</p> <p>“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?”</p>	<p>Patients and caregivers (n = 12):</p> <p>Nine veterans</p> <p>Two veterans who are care partners of veterans</p> <p>One civilian care partner of a veteran</p> <p>The focus group comprised male and female veterans with a variety of military service backgrounds from the Vietnam, Gulf War, and OEF/OIF/OND eras.</p>

OEF: Operation Enduring Freedom; OIF: Operation Iraqi Freedom; OND: Operation New Dawn.

Outline of the two parts of the engagement process, including sample questions and partner characteristics.

<sup>a</sup>Clinician and administrative group.

<sup>b</sup>Patient and caregiver group.

**Sample size.** The AIM-Back investigator team reflected on the 7Ps Framework<sup>9</sup> (patients and the public, providers, purchasers, payers, policy makers, product makers, and principal investigators) to assess the representativeness of partners included in the engagement process. This framework is used to identify partners and develop engagement strategies for research activities. The following questions<sup>9</sup> guided our post hoc review of relevant partners selected to ensure that we had relevant categories of partners represented:

1. What topic(s) does the research address?
2. What health care decision(s) is the research meant to inform?
3. Who are the decision makers responsible for these decision(s)?
4. Who are the individuals and groups that are affected by these decisions?

Based on the 7Ps review and the concept of “information power,” our sample size (i.e. number and type of partners engaged) was deemed adequate to justify an end to our initial partner engagement activities with plans for continued engagement with those already involved.<sup>22</sup>

**Analyses.** Our aim for the partner engagement process was fairly narrow, sample specific, and quality of dialogue high, and thus we employed a structured analysis strategy that was less exploratory in nature.<sup>22</sup> Informed

by rapid qualitative analysis, data (i.e. detailed notes and documentation of feedback) was organized in response to the a priori questions contained in the question guides.<sup>23</sup> Two team members, including one qualitative methodologist and one subject matter/clinical expert, independently examined the information for salient (i.e. recurring and/or important) emergent and a priori categories and main topics/concepts with a focus on benefits and concerns (Table 2). A systematic process of mutual consensus was used with the larger study team also providing input and feedback.<sup>24–28</sup>

## Results

### *Themes from engagement part 1*

Analysis revealed that this partner group (clinicians and administrators) thought that the sequenced care pathway was consistent with existing care processes within the VA and that the pain navigator pathway would be a unique way to improve care management and patient follow-up. They endorsed the importance of both care pathways focusing on non-pharmacological pain management. Also, it was mentioned that use of communication strategies—such as shared decision making—had the potential to improve dialogue between patients and providers in both care pathways.

Partners reported that it would be helpful to consider a patient’s prior pain management utilization as an indication of future success within the pathways. They also stated that it would be important that the

**Table 2.** Part I partner engagement concepts.

	Integrated care pathway	Coordinated care pathway
Benefits	Virtual care/telehealth is aligned with existing Veterans Affairs (VA) initiatives. Waiting lists for pain coping skills and behavioral health is very long. Central delivery of care may be preferred over community care because of more quality control.	Pain Navigator role is uncommon, but veterans would like it. Primary Care Physicians would welcome others help to coordinate pain care.
Concerns	Often significant delay of time from consult to initial physical therapy (PT) visit. Number of PT visits is limited due to staffing/space constraints—2 sessions is customary. Credentialing requirements for Central Provider may be cumbersome. Ability to perform exercises correctly when delivered remotely.	Need a well-trained Navigator that could handle difficult conversations. Upper limit for times to cycle through Navigator. Navigator workload and ability to enter consults.

providers in each of the pathways be equipped to address patients' mental health concerns. Some potential barriers to the success of the pathways were identified as timing of when a patient could access a pathway versus timing of the ability to seek outside care, ability to staff the pathways, as well as frontline staff buy-in.

Specific single remarks considered important mentions, included: notice of VA access referral requirements that might alter the pathways; concern about timely patient follow-up to the physical therapist in the sequenced care pathway; concern about connecting with older veterans via telehealth; and uncertainty about how to use patient satisfaction measures to guide future care in the pain navigator pathway. Additional pathway-specific themes from Part 1 are specified in Table 2.

### *Themes from engagement part 2*

The second partner group (veterans and their caregivers) indicated that the sequenced care pathway would be a good way to incorporate multiple provider perspectives on addressing chronic pain. However, the group also indicated that it would be important to consider how this pathway would be presented to veterans. They stated that it would be better to frame the psychologically informed interventions as an extension of skill building and self-management training, rather than mental health treatment due to the stigma associated with mental health care.

For the pain navigator pathway, the group indicated that it would be important that the pain navigator was someone with whom veterans felt comfortable interacting. This person should be someone who is compassionate and nurturing and had an understanding of the veteran experience. Partners also indicated that it would be helpful if this person could use simple terms to discuss the different treatment options rather than using complex medical jargon.

### *Final pathway visualization*

Each pathway went through multiple iterations throughout the planning phase of the project. The sequenced care pathway transitioned from a telephone-based delivery model to a flexible telehealth model that allows for patient preference of delivery. In the final version of the care pathway, patients can choose to conduct their psychologically informed care exclusively via telephone calls or via video calls. This flexibility allows for synchronous, confidential appointments at designated times where the patient and provider can interact via the modality preferred by patients. Partner feedback also changed the sequenced care pathway to include physical activity coaching delivered via telehealth as a core component of the intervention, as opposed to requiring the patient to attend additional in-person physical therapy appointments. Finally, there was a strong preference from the veteran and caregiver partner group that physical therapists deliver the psychologically informed care. The final version of the sequenced care pathway is presented in Figure 4. There were three major changes made to the original version of the sequenced care pathway: (1) specifying the type of pain modulation activities that would take place during the physical therapy initial evaluation; 2) reducing the number of physical therapy visits due to system constraints; and 3) integrating physical activity counseling between physical therapy visits.

Several partner-driven changes were also made to the pain navigator pathway. Partner feedback optimized this pathway from a traditional stepped care model to one that offers stepped care in a feedback loop, with a return to primary care at the conclusion of multiple services without improvement in symptoms. This inclusion of a feedback loop ensures that the primary care provider will be aware of patient progress along the pain navigator continuum and is the gatekeeper of care escalation. Another change to the pain

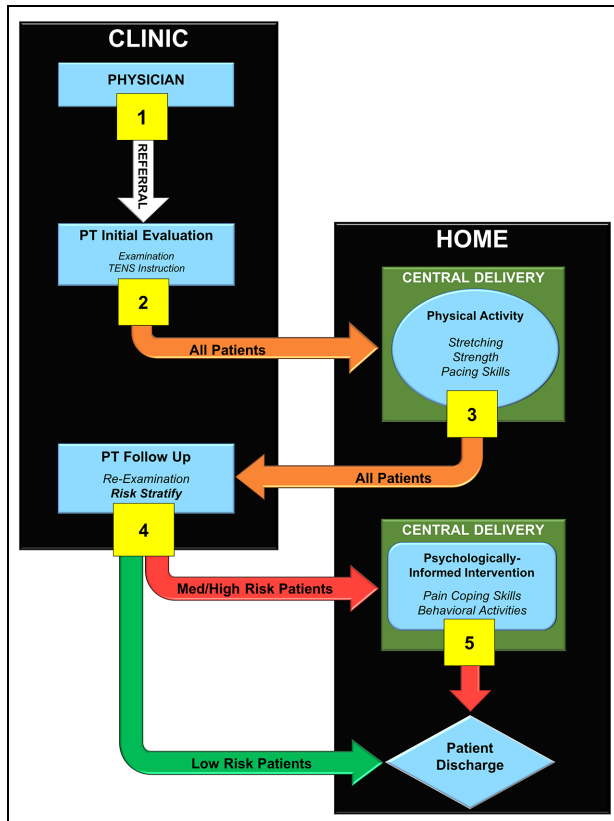


Figure 4. Sequenced care pathway.

navigator pathway was increased flexibility of the type of provider that could fill the pain navigator role such

as a nurse or social worker. Expanding potential providers will increase site autonomy by allowing each participating clinic to choose who would be the best fit for the role of pain navigator at their medical center. Figure 5 depicts the final version of the pain navigator pathway. Four major changes based on partner engagement were (1) allowing flexibility in the type of providers that could serve as pain navigators; (2) including various types of telehealth interactions (phone and video rather than just phone); (3) limiting the number of times a patient could access the pathway loops; and (4) being more specific about criteria for patient discharge from the pathway.

AIM-Back embedded PCT status

The AIM-Back trial is ongoing. Nineteen VA primary care clinics have agreed to participate and been randomized to be trained to deliver one of the two care pathways. As of December 31, 2022, 1133 patients had received care for low back pain through the AIM-Back study.

Discussion

In the AIM-Back PCT, the phased design allowed for early partner engagement that enhanced development of multimodal non-pharmacological treatment pathways.<sup>20</sup> Key changes included expansion of provider types and re-framing of the interventions intended to

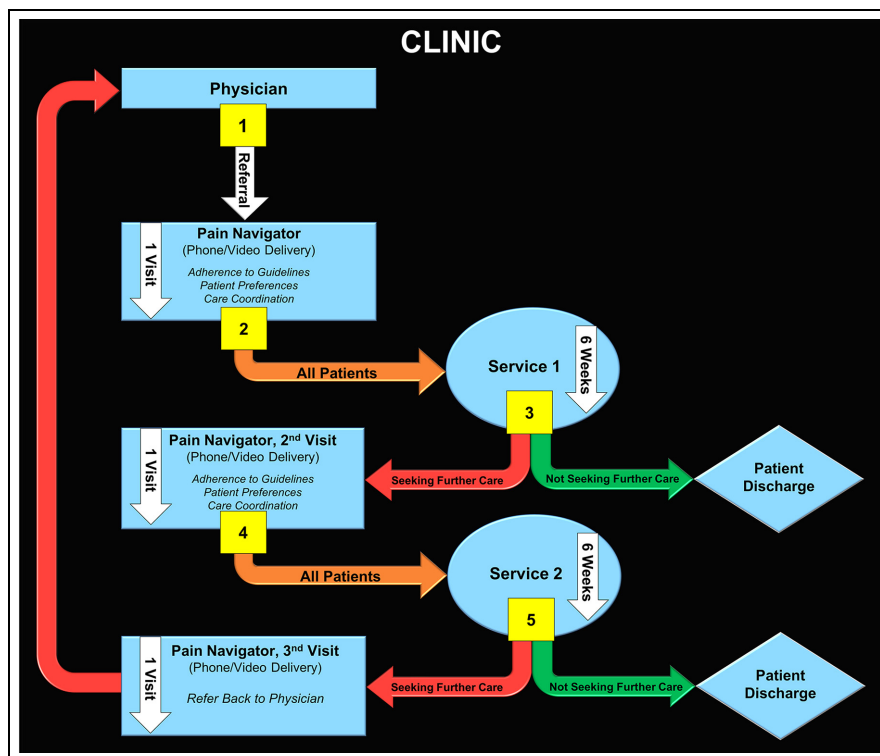


Figure 5. Pain navigator pathway.

improve patient experience and enhance patient participation. Other main changes such as the inclusion of a primary care feedback loop and established discharge criteria focused on reducing interference of clinical workflow and increasing provider engagement and buy-in.<sup>8,29</sup> These changes were precipitated by unexpected findings from the partner cohorts that included the length of time between physical therapy initial evaluation and follow-up for many VA sites (often exceeding 4 weeks), clinical care terminology with potential stigmas (e.g. psychological), and variability in current standard of VA care (e.g. non-VA care referrals). The fact that changes were made in multiple domains, from patient-provider communication to operational efficiency, suggest that seeking input from individuals with diverse roles and perspectives was essential in helping the research team avoid “blind spots” that could have threatened successful implementation of the care pathways to be tested in the study. AIM-Back’s successful recruitment of 19 clinics who all had to agree, pre-randomization, that they would be willing to implement either pathway using existing clinical resources, supports the acceptability of the refined care pathways. Similarly, patients have embraced the care pathways as evidenced by more than 1100 veterans to date engaging with AIM-Back for low back pain care.

Most non-pharmacological pain treatments are more challenging to deliver than medications or surgical interventions due to the importance of provider–patient interactions, difficulty with sustaining behavior change, and logistical considerations like scheduling and patient transportation.<sup>13,14</sup> In the SMART trial, for example, TRICARE beneficiaries (service members, dependents, veterans), primary care physicians, physical therapists, behavioral health providers, clinic and department chiefs, and policy makers were engaged to improve recruitment and data collection for a stepped care approach to managing low back pain.<sup>30</sup> Similarly, in the wHOPE trial, VA leadership, veteran participants, primary care providers, and integrative health providers (e.g. physical therapists, yoga instructors, psychologists, chiropractors) were engaged during the intervention development phase to understand barriers and facilitators of implementation of the study interventions across a wide range of enrollment sites.<sup>31</sup> Due to the complexity of these interventions, studies examining their effectiveness should consider early engagement of diverse partners in order to identify nuances that accompany the delivery of non-pharmacological treatments.

Longer-term impacts of partner engagement on development of non-pharmacological care pathways cannot be assessed as the trial is ongoing; however, there are early indications that partner engagement had a positive influence on the AIM-Back study by placing more emphasis on veteran preferences and increasing delivery options. In addition, there has been ongoing

partner engagement that has resulted in site-specific intervention and delivery adaptations. Given that many partner-driven changes addressed pathway progression, staffing concerns, and the impact of medical center variability on pathway success, the PCT design may increase the likelihood of developing other non-pharmacological pathways that are responsive to the needs of patients; and be a more efficient way to conduct a PCT.<sup>10</sup> Partner-driven changes will potentially enhance the feasibility and acceptability of the interventions by addressing other known best practices with implementation of PCTs such as developing strong and trusting partnerships between study investigators and health care leadership.<sup>32</sup> Most importantly, increased use of partner engagement may enhance the sustainability of an intervention after a study is completed.

Our findings add to the existing literature by providing an exemplar process for partner engagement in developing non-pharmacologic pain interventions for testing in ePCTs. Partner engagement for the AIM-Back trial took place within the VA health care system which is the largest integrated health care system in the United States and serves more than nine million veterans through regional systems of care.<sup>33</sup> This large, integrated health care system allows for unique considerations for veteran-focused feedback on non-pharmacological pain treatment pathways. There are avenues in place to gather veteran feedback at local VA facilities like Patient Advisory Councils and Patient Advocacy Programs; however, there is no consensus agreement on best practice methods for patient involvement in improving VA care delivery.<sup>34</sup> Other types of settings (ie non-VA) likely already have similar types of advisory panels in place that could be used to solicit important non-pharmacologic intervention feedback.

A strength of the partner engagement process was our comprehensiveness in gathering perspectives from a diverse group of partners interested in improving non-pharmacological care delivery for low back pain. However, our process was not without limitations. For example, while there was diversity of clinical staff and leadership levels, as well as both patients and caregivers, most feedback was confined to a single geographic area. A further limitation could be that we did not record and transcribe engagement sessions and may have missed feedback—though we tried to counter this by having multiple research staff take detailed, structured notes during each partner session.

## Conclusion

Non-pharmacological treatments are difficult to implement due to the increased importance of provider–patient interactions, the need for sustained behavior change, and logistical complexities.<sup>10,13</sup> Eliciting diverse partner input on implementation considerations for

intervention development may be especially important for embedded, pragmatic trials. In the AIM-Back partner engagement process, centering patient experience emerged as a key consideration from all partner groups. The inclusion of patient experience considerations will potentially enhance care pathway acceptability as more non-pharmacological options are offered for treatment of low back pain.

### Acknowledgement

For more information about the AIM-Back study, visit <https://sites.duke.edu/aimback/learn-about-aim-back/>. For more information about the NIH-DOD-VA Pain Management Collaboratory, visit <https://painmanagementcollaboratory.org/>.

### Contributors

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### Availability of data and materials

The data set(s) and materials supporting the conclusions of this article are included within the article and additional files are available upon request from the corresponding author.

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