Opening the Implementation Blackbox for Non-Pharmacologic Pain Interventions

by

Lindsay A. Ballengee

Department of Population Health Sciences
Duke University

Defense Date: July 18, 2024

Approved:

Steven Z. George, Supervisor

Leah Zullig, Co-Chair

Devon Check

Trevor Lentz

Dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Population Health Sciences in The Graduate School of Duke University
2024

ABSTRACT

Opening the Implementation Blackbox for Non-Pharmacologic Pain Interventions

by

Lindsay A. Ballengee

Department of Population Health Sciences
Duke University

Defense Date: July 18, 2024

Approved:

Steven Z. George, Supervisor

Leah Zullig, Co-Chair

Devon Check

Trevor Lentz

An abstract of a dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Population Health Science in The Graduate School of
Duke University
2024

Abstract

Musculoskeletal pain remains a pervasive public health challenge affecting over 80% of Americans with substantial economic costs[1,2]. Non-pharmacologic interventions such as physical therapy and cognitive-behavioral therapy are recommended as first-line treatments for musculoskeletal pain but face significant implementation barriers in clinical practice[3,4]. This dissertation investigated strategies to optimize the implementation of non-pharmacologic pain interventions in real-world settings.

The first project explored the relationship between intervention complexity and adaptations across 24 pragmatic trials using the Intervention Complexity Tool for Embedded Pragmatic Clinical Trials (ICT-ePCT)[5] and a survey analysis. Our findings suggest that intervention delivery complexity may be higher for pragmatic trials that are investigating non-pharmacologic pain interventions versus non-pain trials but only in very specific areas. Additionally, changes in workflow was an important consideration for intervention delivery for all trials in our study. Future research should capture detailed, real-time information about the nature of intervention delivery complexity, adaptions, and implementation success to help improve delivery of non-pharmacologic pain interventions. These findings underscore the importance of understanding and systematically documenting adaptations to enhance intervention fit within diverse healthcare environments.

The second project investigated clinically relevant contextual factors influencing patient enrollment in multimodal LBP interventions across different healthcare centers.

Using the Basel Approach for Contextual Analysis (BANANA), we quantitatively and qualitatively analyzed clinically relevant contextual factors such as number of referring providers and institutional characteristics[6]. This contextual analysis provided key insights into the influence of contextual factors on referral processes for low back pain care. While both pathways achieved their enrollment goals within a similar timeframe, there were several differences in relationships of contextual factors between the two pathways, highlighting the importance of using tailored implementation strategies in future studies. Our qualitative findings emphasize the significance of ongoing provider engagement and communication in enhancing referral processes. Additionally, beliefs about program effectiveness and referral priorities underscore the need for targeted educational interventions and provider training to optimize program adoption.

The third project evaluated the feasibility of implementing an evidence-based pain cognitive-behavioral therapy (CBT) protocol among oncology nurses. Surveys and qualitative interviews explored nurses' perceptions and barriers to implementing pain-CBT and revealed important insights into feasibility and acceptability within oncology settings. The study findings highlight specific opportunities for future research focused on the design and evaluation of interventions that use a nurse-specialist model of pain coping skills training for patients with cancer. Future studies should use a hybrid effectiveness-implementation design to (1) evaluate the impact of the nurse-specialist model on clinical pain outcomes and (2) test strategies for the initial training and ongoing support of nurse-specialists delivering the intervention. This project contributes valuable

data on strategies to support effective implementation of behavioral pain management strategies.

This dissertation contributes to bridging the gap between evidence and practice in non-pharmacologic pain interventions by systematically examining intervention complexity, contextual factors, and implementation outcomes. By elucidating the adaptation process and identifying facilitators of successful implementation, this research informs efforts to enhance the availability and effectiveness of recommended non-pharmacologic pain treatments in routine clinical care.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

AI	Artificially Intelligent
BCBT-CP	Brief Cognitive Behavioral Therapy for Chronic Pain
BHC	Behavioral Health Consultant
BSN	Bachelor of Science in Nursing
CBOC	Community Based Outpatient Clinic
CBT	Cognitive Behavioral Therapy
CFIR	Consolidated Framework for Implementation Research
Chiro	Chiropractor
Co-CARE-AD	Collaborative Care Coordination Program for Alzheimer's Disease and Related Dementias
COPES ExTRA	Co-operative Pain Education and Self-management: Expanding Treatment for Real-world Access
COPES	Co-operative Pain Education and Self-management
DCC	Dementia Care Consultation
FRAME	Framework for Reporting Adaptations and Modifications to Evidence- Based Interventions
FRAME-IS	Framework for Reporting Adaptations and Modifications to Evidence- based Implementation Strategies
HCS	Healthcare Delivery Systems
LBP	Low Back Pain
MC	Medical Center
MHS	Military Health Systems
PCST	Pain Coping Skills Training
PT	Physical Therapist

QoL	Quality of Life
RN	Registered Nurse
SCP	Sequenced Care Pathway
SD	Standard Deviation
WH	Whole Health

Acknowledgements

I would first like to thank my supervisor, Dr. Steven Z. George. Dr. George has been an incredible mentor, advocate, and supporter from the moment I stepped into his office in 2017 asking him for advice on how to become a pain researcher. He has always been there with a joke and smile while also encouraging me to go beyond the status quo. I am so grateful for the opportunity work with him and will forever be appreciative of all the time and effort he has spent to help me along this path. Thank you to Dr. Leah Zullig, who has served as a wonderful implementation science mentor to me throughout the PhD process. She is a rockstar researcher who goes above and beyond to push the implementation science field and I hope to follow in her footsteps. Thank you also to Drs. Trevor Lentz, Adam Goode, and Maggie Horn for training and mentoring in the role of clinician-scientist, especially in the areas of quality improvement and musculoskeletal research. Finally, thank you to Dr. Devon Check for teaching me valuable skills in qualitative study design and implementation science.

I would also like to thank the Department of Population Health Sciences, Department of Physical Therapy, Department of Orthopaedic Surgery, and the NIH Pragmatic Trials Collaboratory for their support and assistance in my training. Thank you to my PhD cohort for contributing to a fun and supportive research culture. Thank you to also to Drs. Shefali Christopher and Laura Pietrosimone for providing additional mentorship during important breakfast and lunch outings.

Thank you also to my friends and family who supported me endlessly throughout this process. Thank you to my Mom, Dad, and brother Garrett for the endless

encouragement and shoulders to cry on when things got hard. You have all taught me the value of working hard and given me the conviction that you really can do anything if you put your mind to it. Thank you also to my extended Ballengee and Burzminski families for their support. Finally, my biggest thank you goes to my husband and true partner, Chris and my two little guys, Ollie and Milo. Chris has shouldered the biggest burden of the PhD process and has been steadfast in his encouragement and support, especially during high stress times. I am forever grateful to have him by my side. Ollie and Milo have also been amazing throughout this process both through their willingness to take my mind off of all things PhD, as well as by showing me that it's all "small stuff" in the end. I couldn't have done any of this without them.

Chapter 1. Introduction

For the last three decades musculoskeletal pain has been a leading cause of disability and a significant public health problem[1,2,7]. Over 80% of Americans experience low back pain (LBP) in their lifetime and the cost of LBP alone to the US economy is estimated to be up to $635 billion each year[4]. While medication is indicated in some cases, non-pharmacologic interventions (e.g. physical therapy, cognitive behavioral therapy) are the recommended first line treatment for most patients[4]. These interventions are often resource intensive and involve multifaceted healthcare interactions that limit their use in routine clinical practice[3]. Because of these challenges, non-pharmacologic pain interventions often need to be modified to improve implementability and enhance fit in different clinical contexts. There is strong evidence supporting the importance of adapting evidence-based interventions within specific contexts to increase the likelihood of adoption and improve patient outcomes[8]. Adaptation is the process of making purposeful modifications to the design or delivery of an intervention, with the goal of improving fit or effectiveness[9,10]. An adaptation can be enhancing in that it can be made without changing the core elements of an intervention or detracting where it loosens the structure of an intervention and results in loss of fidelity[10]. Adaptations may be unnecessary in explanatory trials because of the high control the research team has in intervention delivery. However, for pragmatic trials, knowledge of effective adaptations is important for testing intervention effectiveness in real world settings.

For complex interventions like non-pharmacologic pain treatments, evaluating adaptations within local contexts could help to improve clinical outcomes, reduce

unnecessary testing like imaging, and limit exposure to higher risk treatments by increasing the likelihood of implementation success[11]. Therefore, this dissertation seeks to investigate the relationship between intervention complexity and adaptation, as well as identify optimal contextual factors for implementing non-pharmacologic pain care in routine care settings.

This dissertation is organized into five chapters. Chapter One is this introduction. Chapter 2 is an investigation of the relationship between intervention complexity and adaptations to explore the impact on implementation outcomes. In this study we surveyed 24 pragmatic trials across multiple NIH collaboratories to gather information about trial intervention delivery complexity and related adaptations[12]. Descriptive statistics were calculated for all survey respondents and intervention complexity categories were mapped to types and frequencies of adaptations. The findings suggest that intervention delivery complexity may be higher for pragmatic trials that are investigating non-pharmacologic pain interventions versus non-pain trials but only in very specific areas. Additionally, changes in workflow was an important consideration for intervention delivery for all trials in our study.

In Chapter 3, we characterize clinically relevant contextual factors for enrolling patients in a multimodal, non-pharmacologic LBP intervention across different health care centers through use of a mixed-method contextual analysis. Contextual factors like provider expertise, facility geography, and institutional policies were coded using the Basel Approach for Contextual Analysis (BANANA) and analyzed descriptively to assess which factors impact enrollment outcomes[6]. While both pathways achieved their

enrollment goals within a similar timeframe, there were several differences in relationships of contextual factors between the two pathways, highlighting the importance of using tailored implementation strategies. Our qualitative findings emphasize the significance of ongoing provider engagement and communication in enhancing referral processes. Additionally, beliefs about program effectiveness and referral priorities underscore the need for targeted educational interventions and provider training to optimize program adoption.

In Chapter 4, we explored the feasibility of implementing an evidence-based pain cognitive-behavioral therapy (CBT) protocol among oncology nurses using a survey and qualitative interviews of nurses within oncology clinics. Questions focused on pain self-management strategies and attitudes towards implementing a pain-CBT program and were analyzed using descriptive statistics and rapid qualitative analysis. We found specific opportunities for future research focused on the design and evaluation of interventions that use a nurse-specialist model of pain coping skills training for patients with cancer. Future studies should use a hybrid effectiveness-implementation design to (1) evaluate the impact of the nurse-specialist model on clinical pain outcomes and (2) test strategies for the initial training and ongoing support of nurse-specialists delivering the intervention.

Chapter Five summarizes key findings and lessons learned across these three chapters which have exposed me to different methodologies, patient populations, and clinical settings. This dissertation seeks to showcase various factors that influence implementation success of non-pharmacologic pain interventions within routine clinical

practice. This work helps to identify characteristics of healthcare settings that are more likely to be successful on their own when implementing non-pharmacologic pain interventions versus those who may need increased implementation assistance. This knowledge is critical to understanding how to improve the availability of recommended non-pharmacologic pain care.

I am the first author on all Chapters of this Dissertation. Chapter 2 will be submitted to *Contemporary Clinical Trials*, Chapter 3 will be submitted to *Journal of Pain* and Chapter 4 will be submitted to *Journal of Pain and Symptom Management*. Members of the Departments of Orthopaedic Surgery and of Population Health Sciences within Duke University Health System, including experts in implementation science, multiple methodologies, and clinical areas reviewed findings, and helped to refine results and recommendations of the resulting work. While several researchers were critical in review, enhancements, and dissemination of this work, I led and performed all aspects of the analysis and writing for this Dissertation.

Chapter 2. The Impact of Intervention Delivery Complexity and Adaptations on Implementation of Non-Pharmacologic Pain Interventions Within Pragmatic Trials

2.1 Introduction

Delivering evidence-supported patient interventions remains a challenge across healthcare settings. The volume of clinical guidelines and treatment recommendations has increased exponentially, and research on delivering intervention has also advanced. Yet, translating these evidence-based clinical guidelines and interventions into consistent, high-quality patient care is elusive, especially for complex conditions like chronic musculoskeletal pain. For the last three decades musculoskeletal pain has been a leading cause of global disability[1,2,7]. Over 80% of Americans experience musculoskeletal pain in their lifetime and the cost of treating low back pain alone is estimated to be $635 billion each year[4]. While medication is indicated in some cases, non-pharmacologic interventions like physical therapy, cognitive behavioral therapy, and chiropractic care are now widely recommended in clinical practice guidelines as first line treatments for many pain conditions [4,13,14]. However, implementing these types of interventions can be challenging due to each of them having multiple core intervention components, various implementation strategies, and the need for interactions with multiple people throughout the intervention life cycle.

Non-pharmacologic pain interventions have been demonstrated as efficacious and have a low risk of side-effects; however, these interventions can be resource intensive and complicated to implement due to staffing needs and multistep feedback loops. Thus,

they represent a challenge to deliver "at scale" in many care settings[15]. These interventions have been well-studied in highly controlled clinical trials, but little is known about the challenges of moving them into routine clinical practice[15]. Similarly, while explanatory trials provide valuable insights into pain treatments within tightly controlled settings, pragmatic trials offer a more nuanced perspective on how they may perform in real world settings[16]. Pragmatic trials examine how pain interventions fare when delivered in diverse clinical environments and by studying pain intervention delivery in its natural habitat we can uncover the impacts of important considerations like contextual factors[17].

Adaptation is one common occurrence during pragmatic trial intervention delivery, regardless of the treatment being studied. Adaptation is the process of making purposeful modifications to the design or delivery of an intervention, with the goal of improving fit or effectiveness[9,10]. When an intervention is not aligned with the context in which it is being implemented, implementors may make changes either to the intervention itself or change how it is being delivered[18]. This is often done in a "black box" where changes are made organically, without proactive consideration of how or why they were made. Additionally, when we fail to see expected improvements in clinical outcomes at trial completion (i.e. when efficacy does not result in effectiveness), it's hard to know if the lack of improvement is because of failed delivery, adaptation of the intervention, or the intervention itself. Gaining a better understanding of how adaption occurs to the intervention itself or implementation strategies used during

pragmatic trials could be a critical next step to improving treatment delivery of non-pharmacologic pain interventions.

Evaluating intervention delivery adaptations for non-pharmacologic pain treatments within real-world settings could help to improve clinical outcomes, reduce unnecessary testing like imaging, and limit exposure to higher risk treatments by increasing the likelihood of implementation success through proactive implementation strategy mapping and resource planning[11]. However, we know very little about the intersection of intervention delivery for pain treatment and adaptations. Since non-pharmacologic pain interventions are often complex by involving individualized, multistep processes with different types of providers and multiple feedback loops, there is a high likelihood that adaptations will be made during implementation. Thus, comparing intervention delivery complexity and adaptations in pragmatic trials for non-pharmacologic pain interventions to those that are investigating less complex interventions like delivery of a medication adherence nudge or an electronic decision support alert could contribute valuable insights into future intervention delivery success.

This study investigated the connection between intervention delivery complexity and adaptations within pragmatic trials investigating non-pharmacologic pain interventions and to provide context for those trials we also included trials investigating non-pain interventions. Understanding the relationship between intervention delivery complexity and adaptations may guide future investigations of the effectiveness of non-pharmacologic pain interventions by illuminating potential implementation challenges. Additionally, knowing which intervention delivery complexity domains are likely to

require adaptations may help with planning future pragmatic trials through informing implementation resource allocation or highlighting where intervention fidelity issues may be likely to arise. Including two different trial types in this study may allow for identification of factors specific to the delivery of non-pharmacologic pain interventions.

Therefore, we will explore : 1) differences in intervention delivery complexity between nonpharmacologic pain and non-pain trials, 2) types and frequencies of adaptations across intervention delivery complexity domains between nonpharmacologic pain and non-pain trials, and 3) the relationship between intervention delivery complexity and delivery adaptations for six domains (i.e., workflow, training demand, number of intervention components, number of healthcare systems, dependency on setting for implementation, and the number of steps between the intervention and the outcome) within the two types of trials.

2.2 Methods

2.2.1 Participants

From July to October 2023, principal investigators and/or implementation team members of three NIH Trial Collaboratories were invited to complete an online survey about intervention delivery complexity and adaptations during their pragmatic trial. Trial team members were contacted by the NIH Pragmatic Trials Collaboratory leadership. Inclusion criteria included membership of the NIH Pragmatic Trial Collaboratory, Pain Management Collaboratory, or IMPACT Collaboratory as an upcoming, ongoing, or

completed trial. This study was approved by the Duke University Health System Institutional Review Board (Protocol number 00113504).

2.2.2 Procedures

Emails inviting study participation were sent to members of the three NIH Trial Collaboratories outlined above and were sent by NIH Pragmatic Trials Collaboratory leadership. The invitation email described the purpose of the study, provided contact information for the study team, brief instructions on who should fill out the survey (i.e., anyone who was familiar with the plans for intervention delivery implementation), and included an option to opt out of future emails. The invitation email was sent three times. For those interested in study participation, they completed an electronic informed consent. Participants completed the survey via a link to a Qualtrics Survey and all results were blinded. Due to blinding we are unable to list all trials that completed surveys so representative trials from each Collaboratory are summarized in Table 2.1.

2.2.3 Survey Measures

Participant demographic and background characteristics were assessed by self-report in the Qualtrics survey and included NIH Collaboratory membership, trial role, phase, and type, experience with conducting pragmatic trials, primary training discipline, level of implementation science training, and level of familiarity with the concept of intervention adaptation.

2.2.4 Intervention Delivery Complexity

The Intervention Delivery Complexity Tool was developed by the NIH Pragmatic Trials Collaboratory as a standardized way to address the challenges of intervention delivery within a pragmatic trial[5]. Survey participants were asked to rate their trial's intervention delivery complexity across six different items. The 6-item tool consists of internal and external factors. Internal factors pertain to the intervention itself and include workflow, training, and the number of intervention components. External factors are related to intervention delivery at the system level including differences in healthcare systems, the dependency on setting for implementation, and the number of steps between the intervention and the outcome[5]. Output from the Intervention Delivery Complexity Tool is calculated on a scale and results in a horizontal bar graph to show where self-reported intervention delivery complexity falls on each of the six domains.

2.2.5 Intervention Delivery Adaptations

Survey participants were asked if any adaptations were made within each of the six domains from the Intervention Delivery Complexity Tool (i.e. workflow, training, number of intervention components, etc.). Questions about intervention delivery adaptations were modified from two existing frameworks: the FRAME (Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions) and the FRAME-IS (Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies)[9,19]. When adaptations were made, respondents were asked about the primary goal of the adaptation, an example of an adaptation, and perceived

success of the adaptation. Participants were also asked to rank how challenging it was to make adaptations across the six intervention delivery complexity items (from 1 (most challenging) to 7 (least challenging).

2.2.6 Survey Tool Development

We developed the survey by asking study investigators (n=8) and implementation team members (n=7) of multiple pragmatic trials (n=4) for verbal and written feedback on an initial version of survey measures that included an intervention delivery complexity tool, an adapted version of the Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions (FRAME), and demographic information[5,9]. Feedback was given over two months by the same study investigators and implementation team members. Each time new survey iterations were developed (approximately 10) until feedback consensus was reached. The final version of the survey was 42 questions and was estimated to take approximately 15 minutes to complete.

2.2.7 Analysis of Survey Data

2.2.7.1 Intervention Complexity

We investigated the differences in intervention delivery complexity between pain and non-pain trials. Descriptive differences between trial type and intervention complexity were reported as the frequency of intervention complexity reported within each domain. To further investigate differences between trial types, we created a summative quantitative variable to compare intervention complexity between trial types. We recoded the six categorial variables representing each domain (i.e., workflow,

training, number of intervention components, etc.) into interval variables. Each domain was recoded (1-4). One represents least complex and 4 represents most complex. We then calculated sum and mean scores to create an "intervention delivery complexity" score and reported means with standard deviations with 95% confidence intervals.

2.2.7.2 Intervention Delivery Adaptions

We investigated the difference in the number and type of adaptations within each intervention delivery complexity domain and between trial types. We reported the frequencies of adaptations selected within each domain. A site could select more than one adaptation per domain. Next, we quantitatively compared adaptations between trial types by creating a summative variable, "Number of Adaptations," that represents the total number of adaptations across all six domains. We compared the total number of adaptations by trial groups using independent t-tests. We then calculated the sum of the number of adaptations for each of the six domains. Next, we ran independent t-tests to look at differences in the sum of adaptations between pain and non-pain trials.

2.2.7.3 Intersection of Intervention Complexity and Intervention Delivery Adaptations

We investigated the relationship between intervention delivery complexity and number of delivery adaptations required to deliver the intervention within each of the six domains. We collapsed the number of delivery adaptations into two binary variables (0= no adaptation reported, 1= one or more adaptations reported). We then compared the frequency of adaptations by domain (i.e., overall complexity) using a chi-squared analysis. The intervention delivery complexity domain, workflow, did not have any "zero

adaptations" answers, therefore we analyzed the workflow adaptations individually. Normality was tested using the Shapiro-Wilk test and 2-sided P-values.

2.3 Results

2.3.1 Summary of Participants

We collected surveys for 12 pain studies and 12 non-pain studies. Study investigators were most likely to complete the survey and intervention versus usual care (A vs. A+) was the most common trial type for both pain and non-pain trials. Medicine was the most common training discipline and levels of implementation science training and familiarity with adapting intervention delivery were at similar levels for both types of trials (Table 2.2).

2.3.2 Intervention Delivery Complexity between Pain and Non-Pain Trials

Table 2.3 shows the self-reported intervention delivery complexity for both types of trials. When aggregated, the average overall intervention delivery complexity score was not discernibly different between the two trial types, however, pain trials did have a slightly higher average complexity (i.e., pain=3.02, non-pain=2.79). New tasks with modified workflows were common experiences, with 100% of pain trials and 92% of non-pain trials reporting new tasks with modified workflows. There were no differences between the two trial types for intervention delivery complexity at the domain level, however, the workflow domain had the biggest difference between pain and non-pain trials (i.e., pain=3.58, non-pain=3.08). Similarly, fifty-eight percent of pain trials reported three or more intervention components in their trial versus 33% of non-pain trials. The

training demand, number of health systems, number of steps for intervention delivery, and dependency on setting showed similar complexity across pain and non-pain trials. Table 2.3 shows the self-reported intervention delivery complexity for both types of trials.

2.3.3 Adaptations Across Intervention Delivery Complexity Domains between Pain and Non-Pain Trials

Like overall intervention delivery complexity, total adaptations by domain showed no discernible difference between pain and non-pain trials (Table 2.4). However, pain trials reported a higher average number of adaptations to workflow than any other domain (i.e., pain=2.42, non-pain=1.58). Pain trials reported 29 adaptations to the workflow domain and non-pain trials reported 21 adaptations. The most common adaptation to workflow was a change in how patients were recruited or enrolled for both trial types, followed by a change in communication strategies between trial and intervention teams. The most common reason for adapting workflows for pain trials was to increase reach or enrollment versus to improve fit with recipients for non-pain trials. The overall number of adaptations for training demand, intervention components, number of healthcare systems/clinics, number of steps, and dependency on setting were similar across the two trial types. Finally, neither type of trial reported that their adaptations were unsuccessful. When aggregated, the total number of adaptations by domain for both trial types were highest for number of healthcare systems/clinics, changes to pathways, and workflow (Table 2.5).

2.3.4 Relationship between Intervention Delivery Complexity and Adaptations for Six Domains

When looking at adaptations categorically (i.e., no changes at all versus at least one change), workflow was the only domain among pain and non-pain trials where there were zero reports of "no changes" (i.e., all pain trials adapted their workflows in some way). Finally, when asked which domain was the most challenging to adapt, the most challenging was workflow (54%), followed by training demand (15%), and adapting the number of intervention steps (9%) across both trial types.

2.4 Discussion

Non-pharmacologic pain interventions have the potential to have high intervention delivery complexity and the need for more adaptations to successfully deliver the intervention. Persistent pain is difficult to treat and non-pharmacologic interventions that have been guideline recommended as early treatment options (e.g. physical therapy, cognitive behavioral therapy, chiropractic care) often involve multifaceted treatment plans. Thus, introducing these non-pharmacologic interventions into existing workflows within a health system may be potentially more complicated than implementing simpler interventions like pharmacologic treatments. In this study, we found that there were some specific differences based on trial type for the complexity of intervention delivery and adaptations made during a pragmatic trial (Figure 1). However, when we examined these phenomena collectively, we found no wide-ranging differences in intervention delivery complexity and the associated adaptations between pain and non-pain trials.

Workflow did have the highest signal for intervention delivery complexity and need for adaptations, especially among pain trials. This finding aligns with other research regarding the complicated nature of implementing non-pharmacologic pain interventions, however our study is one of the first to investigate intervention delivery complexity. Prior research has focused on provider perspectives of challenges to implementing pain interventions or issues with payment models for pain care. For example, Ng et al. add year conducted a systematic review to investigate barriers and facilitators to adopting biopsychosocial approaches to pain care and found barriers at the individual practitioner level including misconceptions about practice guidelines, at the mesolevel including funding models and workforce training issues, and at the macrolevel including health policy and organizational, factors[20]. Similarly, George et al. have discussed barriers to implementing non-pharmacologic pain care such as primary care providers citing short consultation times that prevent them from exploring non-pharmacologic options or patient level barriers like the belief that imaging must be done before proceeding with non-pharmacologic pain interventions[21]. Both studies cite multilevel workflow domain factors that may account for higher intervention delivery complexity and the need to adapt workflows within pain trials.

We identified evidence that pain trials had increased intervention delivery complexity due to adding new tasks, modifying existing workflows, and having an additional number of intervention components. However, a lack of discernible differences between the two trial types may indicate that the burden of making any type of change, no matter the trial type, will affect other processes. This could be because any time a new

task or process is added to a system, regardless of the magnitude of the change, other areas of the system are affected. Healthcare delivery happens within an interconnected system where individuals have the autonomy to act in ways that may not follow predictable patterns and these individual actions influence contextual factors throughout that system[22,23]. Thus, while it may seem that more complex intervention processes would require a greater number of adaptations, our study results did not strongly support such an assertion. Generally, non-pharmacologic pain interventions may show isolated areas of increased intervention delivery complexity but overall, they may not be more complicated to implement than any other type of intervention. Similarly, what is "complicated" to implement for one healthcare system may be easier for another system that has implemented similar interventions previously. Future research could investigate these areas of increased delivery complexity and could look at adaptations over time to see if they become static or are constantly evolving. There could be some intervention delivery domains that are easily implemented and minorly adapted, while others may require constant monitoring.

There are several potential explanations as to why pain trials were not discernibly different from non-pain trials in intervention delivery complexity in our study. First, we chose to survey the NIH Collaboratories that focus on pragmatic trials and this could have resulted in selection bias for higher complexity trials, regardless of intervention type. Additionally, all trials from the Pain Management Collaboratory took place in either the Department of Veteran's Affairs or the Military Health System which are both closed, hierarchical systems. It could be less complicated to implement interventions in these

types of systems which could also contribute to the lack of discernible differences in intervention delivery complexity between the two trial types. Future research can address this issue by studying complexity and adaptation outside of these groups. Another potential explanation is that our survey did not capture the level of detail required to expose a true difference in intervention delivery complexity or related adaptations between the two types of trials. For example, the Intervention Delivery Complexity Tool was originally designed to be concise and facilitate communication between the trial team and health system partners, not to provide an exhaustive complexity list. While using this tool in our survey was helpful to show high-level information related to six intervention delivery complexity domains, we were not able to capture the intricacies of intervention delivery during the trials. Future research could highlight potential modifications to the tool for a more comprehensive picture of intervention delivery complexity. Similarly, development of a standardized tool to capture intervention delivery adaptations throughout the trial process could help to provide a more systematic way of identifying common delivery modifications. Finally, all trials in our study were pragmatic in some form. Intervention delivery complexity and subsequent adaptations could be similar across pragmatic trials regardless of the treatment being tested.

Additionally, information about intervention delivery complexity and adaptations were captured retrospectively for 8 completed trials and prospectively for 3 trials in the planning phase (out of 24). While having trials in multiple phases allowed us to see adaptations across a spectrum, gathering this type of information retrospectively for the completed trials may not provide the most accurate information due to recall bias.

Similarly, asking trials that are in their planning phase to comment on intervention delivery complexity does not allow for consideration of what happened during the trial. It may be that trials rated themselves less complex during the planning phase. Importantly, we did not ask trial teams about fidelity consistency with their reported adaptations. Adaptations that are made proactively during pre-implementation based on what's anticipated to happen could be inherently different than adaptations that are made during the implementation process. Adaptations made during pre-implementation are more likely to be fidelity consistent versus those that are made in response to real-time health system or patient needs. Future research could investigate a higher number of trials in each phase to capture a more complete picture of complexity and delivery modifications across the trial lifespan. Also, the information gathered on the survey is subjective and different trial team members may have differing perspectives on delivery complexity or adaptation. Investigators accounted for 75% of survey participants for both type of trials and an investigator's perspective on adaptations could be different from members of the implementation team as they may be more aware of everyday implementation challenges.

Future investigations on implementing non-pharmacologic pain interventions should have a real-time method of capturing intervention delivery adaptations rather than relying on retrospective data collection. Based on our investigation, capturing adaptations retrospectively may provide a limited perspective. Real-time assessment may be more accurate and objective given our survey seemed to only capture adaptations that were successful. Trial specific adaptation checklists could be added to electronic health records or trial team data captures where designated team members could gather detailed

information about why an adaptation is being made, who made the adaptation, whether it was successful, etc. Use of a framework on adaptions is helpful for deciding what adaptation data to capture[9,19]. Gathering this type of implementation data will allow other investigators and implementation team members to see what may or may not work as they're trying to implement a similar intervention. Relatedly, using an adaption framework to capture real-time adaptation data may help with choosing future implementation strategies that may be a better fit for that type of intervention delivery which could improve implementation success. Other ways to shed more light on the relationship between intervention delivery complexity, adaptations, and implementation success could be to conduct primary implementation studies to look at differences in adaptations between comparison groups that were implementing the same intervention or to gather qualitative data about adaptations to get a more nuanced perspective on what is happening during intervention delivery.

2.5 Conclusion

This study investigated the relationship between intervention delivery complexity, adaptations, and implementation by comparing non-pharmacologic pain and non-pain intervention pragmatic trials. Our findings suggest that intervention delivery complexity may be higher for pragmatic trials that are investigating non-pharmacologic pain interventions versus non-pain trials but only in very specific areas. Additionally, changes in workflow was an important consideration for intervention delivery for all trials in our

study. Future research should capture detailed, real-time information about the nature of intervention delivery complexity, adaptions, and implementation success to help improve delivery of non-pharmacologic pain interventions.

Table 2.1: Sample of interventions being tested from participating NIH Collaboratories

Pragmatic Trials Collaboratory[24]	Pain Management Collaboratory[25]	Impact Collaboratory[26]
Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction): The study will compare a standard 3-month course of acupuncture with an enhanced course of acupuncture (3-month standard course, plus 3-month maintenance course) to usual medical care for cLBP.	**Co-operative Pain Education and Self-management: Expanding Treatment for Real-world Access (COPES ExTRA):** The trial objective is to compare an interactive voice response-based form of CBT-CP called Co-operative Pain Education and Self-management (COPES) versus in-person CBT-CP provided by clinicians previously trained through VHA's evidence-based psychotherapy program.	**Collaborative Care Coordination Program for for Alzheimer's Disease and Related Dementias (Co-CARE-AD):** The Dementia Care Consultation (DCC) program, delivered by a care consultant over a 6- month period, provides an in-depth, personalized service for individuals and families facing ADRD. The program consists of comprehensive needs assessments, creation and implementation of personalized care plans, monitoring and revising care plans, disease education and support coaching, referrals to community-based organizations for service and support, and access to assistance.
Fibromyalgia TENS in Physical Therapy Study (FM-TIPS): The trial objective is to assess the feasibility of using TENS in addition to physical therapy for treatment of patients with fibromyalgia using a cluster-randomized pragmatic clinical trial of routine physical therapy with or without TENS.	**Targeting Chronic Pain in Primary Care Settings Using Behavioral Health Consultants:** The trial objective is to assess the effect of monthly telehealth booster contacts on long-term Brief Cognitive Behavioral Therapy for Chronic Pain (BCBT-CP) pain outcomes compared to BCBT-CP without a booster in a sample of Military Health Systems (MHS) beneficiaries referred to a Behavioral Health Consultant (BHC) for pain management using BCBT-CP.	**Improving How People with Dementia are Selected for Care Coordination: A Pragmatic Clinical Trial Embedded in an Accountable Care Organization:** The intervention is a novel approach to assign care coordinators to PLWD whose care partners report problems with care coordination based on a survey of perceptions of care coordination. By contrast, usual care assigns PLWD to care coordinators after hospital discharge.
Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge): The trial objective is to employ population-level pharmacy data and to deliver nudges via cell phone text messaging and artificially intelligent (AI) interactive chat bot to improve medication adherence and patient	**Improving Veteran Access to Integrated Management of Low Back Pain (AIM Back):** The trial compares the effectiveness of two LBP care pathways designed to enhance access to nonpharmacologic pain treatments according to the most recent practice guidelines and a biopsychosocial approach to care; the first pathway is	**Mitigation of Postoperative Delirium in High-Risk Patients:** The intervention consists of clinical decision support alerts in the electronic health record directed towards anesthesiologists caring for patients with preexisting cognitive impairment. This intervention will promote 12 evidence-based best

outcomes in 3 integrated healthcare delivery systems (HCS).	a sequenced, multi-modal integrated approach incorporating pain modulatory treatment, tailored behavioral treatment, and home-based activity. The second pathway is care management via pain navigator that facilitates coordinated use of existing pain management resources.	practices during care for perioperative patients.

Table 2.2: Survey participant characteristics

	Pain	Non-Pain
N	12	12
Trial Role, category (%)		
Investigator	9 (75.0)	9 (75.0)
Implementation Specialist	1 (8.3)	3 (25.0)
Other	1 (8.3)	0 (0.0)
Unknown	1 (8.3)	0 (0.0)
Trial Phase, category (%)		
Complete	3 (25)	5 (41.7)
Ongoing	8 (66.7)	4 (33.3)
Planning	0 (0.0)	3 (25.0)
Unknown	1 (8.3)	0 (0.0)
Trial Description, category (%)		
Intervention vs usual care	7 (58.3)	8 (66.7)
Comparative effectiveness	3 (25.0)	3 (25.0)
Other	1 (8.3)	1 (8.3)
Unknown	1 (8.3)	0 (0.0)
Pragmatic Trial Experience		
None	4 (33.3)	4 (33.3)
1 Trial	2 (16.7)	2 (16.7)
2-3 Trials	3 (25.0)	2 (16.7)
4-5 Trials	2 (16.7)	0 (0.0)
>5 Trials	0 (0.0)	0 (0.0)
Unknown	1 (8.3)	4 (33.3)
Primary training discipline		
Medicine	4 (33.3)	5 (41.7)
Physical Therapy	3 (25.0)	0 (0.0)
Psychology	2 (16.7)	1 (8.3)
Public Health	1 (8.3)	2 (16.7)
Health Services	1 (8.3)	0 (0.0)
Unknown	1 (8.3)	4 (33.3)
Level of implementation science training		
None	3 (25.0)	1 (8.3)
A little	2 (16.7)	2 (16.7)
Moderate amount	7 (58.3)	4 (33.3)
A lot	0 (0.0)	1 (8.3)
Unknown	0 (0.0)	4 (33.3)
Level of familiarity with concept of intervention adaptation		
None	2 (16.7)	0 (0.0)
A little	2 (16.7)	2 (16.7)
Moderate	7 (58.3)	5 (41.7)
A lot	1 (8.3)	0 (0.)
Unknown	0 (0.0)	5 (41.7)

Table 2.3: Intervention delivery complexity by domain

	Pain	Non-Pain
Workflow		
No changes were made to this domain	0 (0.00%)	2 (16.67%)
Modified workflow, no new tasks	0 (0.00%)	1 (8.33%)
Modified workflow, new tasks	5 (41.67%)	8 (66.67%)
New workflow, new tasks	7 (58.33%)	3 (25.00%)
Missing	0 (0.00%)	0 (0.00%)
Total	**12 (100.00%)**	**12 (100.00%)**
Training Demand		
No training	1 (8.33%)	2 (16.67%)
Refresh of existing skills	3 (25.00%)	3 (25.00%)
Training for a new skill	6 (50.00%)	5 (41.67%)
Training of multiple new skills	2 (16.67%)	2 (16.67%)
Missing	0 (0.00%)	0 (0.00%)
Total	**12 (100.00%)**	**12 (100.00%)**
Intervention Components		
Three+ components	7 (58.33%)	4 (33.33%)
Two components	1 (8.33%)	2 (16.67%)
One component	4 (33.33%)	6 (50.00%)
Missing	0 (0.00%)	0 (0.00%)
Total	**12 (100.00%)**	**12 (100.00%)**
Number of Health Systems		
4 or more systems	7 (58.33%)	6 (50.00%)
3 systems	1 (8.33%)	2 (16.67%)
2 systems	0 (0.00%)	1 (8.33%)
1 system	4 (33.33%)	3 (25.00%)
Missing	0 (0.00%)	0 (0.00%)
Total	**12 (100.00%)**	**12 (100.00%)**
Number of Steps in Pathway		
Pathway is short (only one or two steps between intervention and outcomes), direct, and linear	4 (33.33%)	5 (41.67%)
Pathway is longer (three or more steps between intervention and outcomes) but still linear	3 (25.00%)	3 (25.00%)
Non-linear (including the potential for more than one provider)	1 (8.33%)	1 (8.33%)
Variable steps, long pathway, multiple providers	4 (33.33%)	3 (25.00%)

Missing	0 (0.00%)	0 (0.00%)
Total	**12 (100.00%)**	**12 (100.00%)**
Number of Clinics		
4 or more clinics	10 (83.33%)	9 (75.00%)
3 clinics	0 (0.00%)	0 (0.00%)
2 clinics	1 (8.33%)	0 (0.00%)
1 clinic	1 (8.33%)	1 (8.33%)
Missing	0 (0.00%)	2 (16.67%)
Total	**12 (100.00%)**	**12 (100.00%)**
Dependency on Setting		
Not dependent on setting (could be delivered in any setting)	1 (8.33%)	2 (16.67%)
Minimally dependent on setting (could be delivered in low resource setting)	4 (33.33%)	4 (33.33%)
Moderately dependent on setting	5 (41.67%)	5 (41.67%)
Largely dependent on setting (could only be delivered in a high resource setting)	2 (16.67%)	1 (8.33%)
Missing	0 (0.00%)	0 (0.00%)
Total	**12 (100.00%)**	**12 (100.00%)**

Table 2.4: Total adaptations by domain

	Pain			Non-Pain			
Domain	**M**	**SD**	***n***	**M**	**SD**	***n***	**p (95%)**
Workflow	2.42	1.38	12	1.58	1.24	12	0.134
Training Demand	0.83	0.58	12	0.75	0.45	12	0.698
Intervention Components	1.00	1.13	12	0.67	0.65	12	0.385
Number of Health Systems/Clinics	2.92	1.44	12	2.92	1.31	12	1.000
Number of Steps in Pathway	2.42	1.31	12	2.17	1.27	12	0.640
Changed Setting	3.58	0.99	12	3.50	1.168	12	0.850

Table 2.5: Total number of adaptations by domain for both types of trials

Domain	**M**	***SD***	***n***	SE_M	***Mdn***	**Min**	**Max**
Workflow	2.00	1.35	24	0.28	2	0	5
Training Demand	0.79	0.51	24	0.1	1	0	2
Intervention Components	0.83	0.92	24	0.19	1	0	4
Number of Health Systems/Clinics	2.29	1.27	24	0.26	2	1	4
Number of Steps in Pathway	2.92	1.35	24	0.28	4	1	4
Changed Setting	3.54	1.06	24	0.22	4	1	4

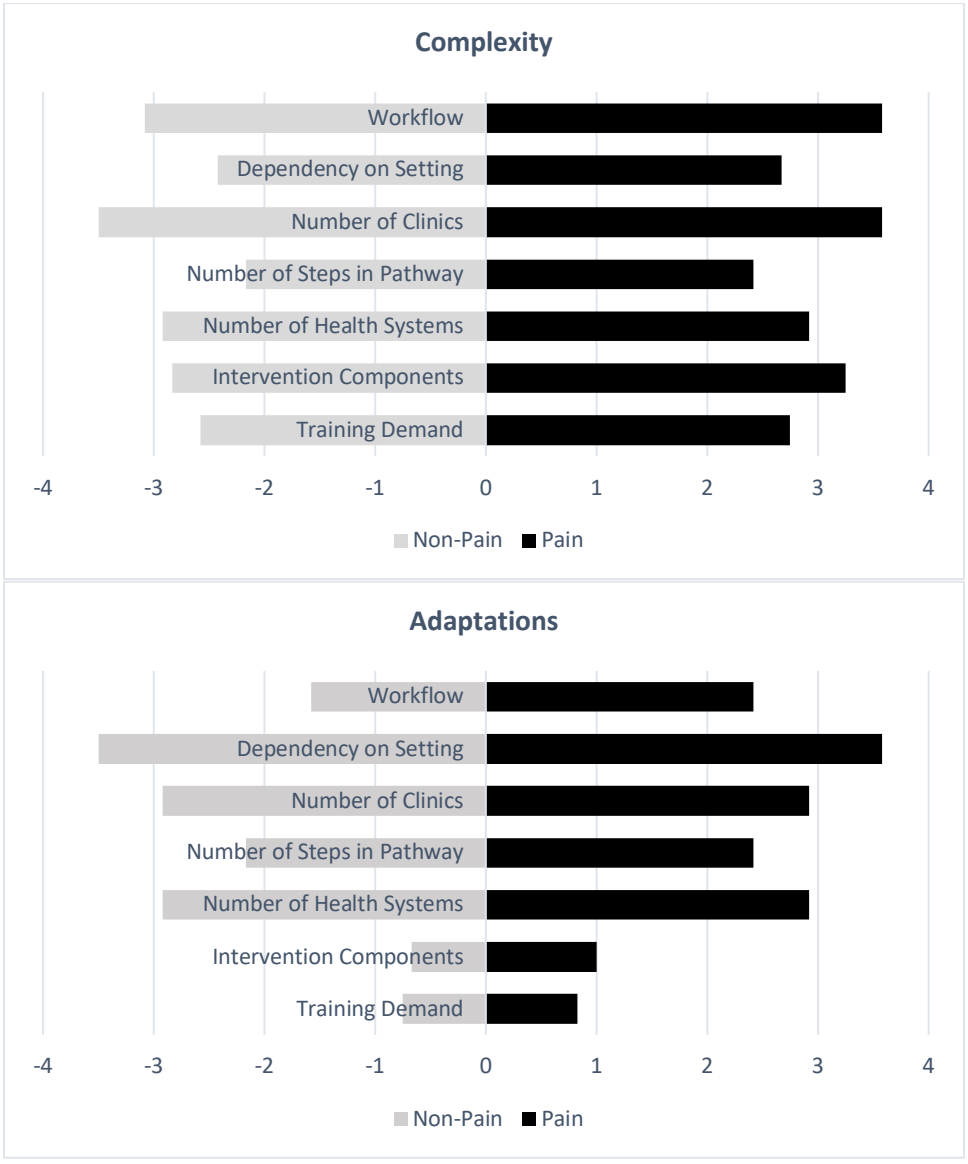


Figure 2.1: Overall complexity and adaptations by domains for pain trials vs non-pain trials

Chapter 3. Clinically Relevant Contextual Factors for Enrolling Patients in a Pain Intervention Across Multiple Health Care Centers

3.1 Introduction

Low back pain (LBP) poses a significant public health challenge worldwide with a prevalence estimated to affect up to 20% of the global population[27]. Beyond its public health impact, LBP imposes substantial financial burdens with costs associated with medical treatments, disability compensation, and lost productivity reaching billions of dollars annually[28]. In response to these challenges, due to their efficacy, safety, and potential to mitigate the risks associated with pharmacotherapy, clinical guidelines recommend non-pharmacologic interventions as first-line treatments for LBP [13]. Non-pharmacologic interventions encompass diverse modalities like physical therapy, exercise, cognitive-behavioral therapy, and mindfulness-based practices to address both physical and psychosocial dimensions of pain[11]. Despite growing recognition of their effectiveness, adoption of non-pharmacologic interventions in routine clinical practice remains a notable challenge for many health systems, underscoring the need for further research to optimize delivery methods and enhance accessibility for patients with LBP[21,29].

One key barrier lies in the difficulty of implementing multistep, multimodal interventions within healthcare systems that operate with time, resource, and reimbursement constraints[30]. Additionally, the heterogeneity of LBP presentations and diverse needs of patients often require tailored interventions, yet evidence-based

strategies for optimal implementation of these types of interventions remain scarce. Furthermore, healthcare providers may lack sufficient training or resources to deliver these interventions effectively, leading to variations in practice and potentially contributing to suboptimal outcomes for patients[3,15]. Addressing these challenges requires a concerted effort to develop and disseminate standardized implementation protocols that address documented barriers and facilitators to implementation success.

One promising approach to better understand implementation of non-pharmacologic interventions is through contextual analysis[31,32]. Contextual analysis involves comprehensively mapping qualitative and quantitative data about the intervention implementation environment[6]. This data may include information about social, organizational, and environmental implementation influences at multiple levels of the healthcare system[33]. Contextual analyses offer valuable insights about the interplay between intervention delivery and the healthcare system by illuminating contextual factors that influence implementation success or failure[34]. Studies across various healthcare domains have demonstrated the utility of contextual analysis in identifying key implementation determinants and informing the development of tailored strategies to optimize implementation outcomes[35,36]. Examples of how contextual analyses have been used include a wide range of settings and interventions such as HIV testing in primary care, buprenorphine initiation for patients with opioid use disorder in the emergency department, and advance care planning in nursing homes[37].

One specific approach that holds promise for studying implementation of non-pharmacologic interventions is the Basel Approach for Contextual Analysis

(BANANA)[6]. The Basel Approach provides a structured yet flexible framework for systematically analyzing context and guides researchers throughout a project's life cycle on how to use findings from the contextual analysis to inform subsequent phases of the project. Applied to the study of non-pharmacological interventions, BANANA may enable researchers to explore how factors such as organizational culture, provider attitudes, and patient preferences shape the adoption and delivery of these interventions within diverse healthcare settings. By systematically mapping relevant contextual factors, researchers and practitioners can identify modifiable implementation challenges that may allow for targeted strategies to optimize uptake and sustainability of non-pharmacologic interventions.

This contextual analysis is part of a larger health system embedded pragmatic clinical trial that is studying the effectiveness of two different care pathways for low back pain[38]. Embedded trials provide a unique vehicle for contextual analyses as they are attempting to deliver a new type of care within real-world clinic settings. Using the BANANA approach, we characterized clinically relevant factors for enrolling patients in care pathways across multiple health care centers by 1) identifying factors that are associated with successful patient enrollment and 2) categorizing barriers and facilitators to successful patient enrollment from a provider perspective. Findings from this contextual analysis may help to guide future non-pharmacologic care pathway design, inform decisions on implementation approaches, and provide insights into the interpretation of effectiveness results.

3.2 Methods

3.2.1 Data Source

Data for this investigation come from the Improving Veteran Access to Integrated Management of Back Pain (AIM-Back) Trial, an embedded pragmatic trial conducted at 17 primary care clinics within the VA Healthcare System[38]. AIM-Back is a cluster randomized pragmatic trial that is comparing the effectiveness of two LBP care pathways initiated in the primary care setting: a sequenced care pathway that integrates in-person physical therapy with psychologically informed treatment via telehealth and a care management pathway that uses a pain navigator to facilitate patient access to non-pharmacologic pain treatments. Individual informed consent was not required for patients to participate in the AIM-Back pathways, as these were deemed non-research activities. The clinicaltrials.gov ID is NCT04411420.

AIM-Back takes place in 17 VA primary care clinics, with clinics randomized to each care pathway. Eligibility criteria included individuals must be ≥18 years old and referred to AIM-Back by a participating provider. Figure 3.1 shows an overview of the steps of the sequenced care pathway. For this pathway, referred Veterans start Phase 1 with in-person care delivered by a physical therapist plus weekly physical activity training via telehealth. Phase 2 begins at 6 weeks with a return visit to their physical therapist and risk stratification using a self-reported screening tool to determine the need for psychologically informed treatment. Veterans who are low risk for continued LBP

disability transition to home based activity while Veterans who are medium or high risk receive 6 weeks of psychologically informed practice through telehealth. Figure 3.2 shows the navigator pathway. For this pathway, Veterans are referred to their clinic's pain navigator during a visit for LBP with their primary care provider. During a phone or video call, the pain navigator educates the patient about resources available for care, identifies patient preferences for non-pharmacologic approaches, and facilitates access to services.

Information about clinically relevant contextual factors (e.g. medical center type, number of referring providers, staff turnover, etc.) was prospectively captured throughout the trial process (5/2020-5/2024) by AIM-Back implementation team members to enhance the implementation process. This data was collected to track variations in implementation. More detailed descriptions of these pathways are located in the AIM-Back trial protocol paper, as well as a description of our stakeholder engagement process, and use of the sequenced care pathway[38–40].

3.2.2 Basel Approach for Contextual Analysis

Our contextual analysis was guided by the Basel Approach for Contextual Analysis (BANANA). BANANA was developed as a way to help implementation teams and researchers plan, execute, and describe contextual factors as new interventions are being implemented to inform future intervention development and match implementation strategies[6]. The BANANA method is comprised of six components that can be carried out sequentially or concurrently. For our contextual analysis, the components included: (1)

choose a theory, model, or framework to guide the contextual analysis (2) use empirical evidence derived from primary and/or secondary data to identify relevant contextual factors; (3) involve partners throughout the contextual analysis; (4) choose a study design to assess context; (5) determine contextual factors' relevance to implementation strategies/outcomes and intervention co-design; and (6) report findings of contextual analysis[6]. Figure 3.3 shows the specific components that were used for this contextual analysis.

3.2.3 Data analysis

Using the Basel Approach for Contextual Analysis, we analyzed 10 contextual factors across 17 different sites (e.g., number of navigators, number of referring providers, rural versus urban medical center, etc.)[6] using parallel qualitative and quantitative methods to evaluate context alongside enrollment outcomes. The choice of the 10 contextual factors originated from Component 2 of the BANANA approach where empirical evidence derived from primary and/or secondary data is used to identify potentially relevant factors. For our analysis, we chose factors that were based on the trial implementation team's prior experience on patient enrollment drivers, as well as a literature search on patient enrollment within embedded pragmatic trials[41,42]. Some factors were the same across both pathways, however, each pathway did have some pathway-specific factors that we were interested in exploring. For example, we chose to investigate the impact of telehealth participation and provider experience level in the sequenced care pathway and potential care options in the navigator pathway.

Qualitative data was obtained in parallel (i.e., independently) to quantitative contextual factor data through semi-structured, in-depth interviews with clinical pathway personnel from each pathway arm. In sampling for interviews, we gathered perspectives from both high and low referring primary care providers from each pathway (n=12) with geographical variation to ensure representation from clinic sites around the country. All interview participants were invited to participate by email. The interview guide was based on domains from the Consolidated Framework for Implementation Research (CFIR) and focused on clinical program implementation and organizational context[33]. CFIR was chosen to guide the interviews because of its systematic way of helping to identify multi-level barriers and facilitators to implementation. CFIR Respondents were asked about their organizational climate; the importance of the clinical pathways to their facility; key conditions for successful implementation at their facility; the impact of the clinical pathways on their workload; changes made to care delivery and content; barriers to implementation; satisfaction with the process; and recommended changes to the pathways.

Participant interviews averaged 30 minutes in duration and 12 provider interviews from each clinical pathway were included in the analysis. They were audio-recorded but not transcribed, consistent with a rapid approach to qualitative analysis[43,44]. The study interviewer (CL), an experienced qualitative analyst, took notes during each interview and then rewatched each interview to complete the interview summary template. Templated summaries were created by organizing interview notes into a set of pre-determined domains based on the interview guide. We then reduced the interview notes

to summarize the key points within each domain with a focus on referral determinants. When all interviews had been analyzed and templated summaries were completed, summary points were transferred into a matrix for each pathway (i.e., respondents x domains). Using the matrix, analysts (LB, CB) developed summaries for each domain. Responses were coded at individual levels to develop macro-level summaries of relevant referral-based contextual factors that corresponded with each question domain. Qualitative description was used to describe the experiences of the participants who were involved in the implementation process. Qualitative description is an appropriate methodology for this investigation as it seeks "to understand a phenomenon, a process, or the perspectives and worldviews of the people involved"[45].

The main outcome for our analysis was time (in months) to the minimum number of patients enrolled in the AIM-Back program as measured two ways 1) by days from initial site training to first patient enrolled and 2) time to minimum enrollment (n=65) from initial site training. Contextual factors for both pathways include clinic type, number of referring providers, number of referring providers trained, first site visit impact, and staff turnover. Contextual factors specific to the navigator pathway were navigator discipline, number of navigators, and number of care options available. For the sequenced care pathway, specific factors included physical therapist experience level and percent of care provided via telehealth. Correlations between contextual factors were measured using Pearson's correlation coefficient with a priori cutoffs chosen to report moderate or strong associations only due to sample size. All statistical analyses were done using JMP statistical software.

3.3 Results

3.3.1 Quantitative Analysis

Tables 3.1 and 3.2 show the contextual factors that were analyzed for each of the two pathways. For the navigator pathway (Table 3.1), there were nine sites that implemented the navigator program. Six of the navigator sites were sites within large medical centers and the remaining three sites were all smaller community-based outpatient clinics. The most common navigator discipline was physical therapist (n=6) followed by nurses (n=3) and the average number of navigators per site was 2.2 with some navigator teams representing different disciplines. These sites made it to their initial enrollment goal (n=65) at an average of 15.9 months with the fastest site taking 12 months and the slowest site taking 24 months. Similarly, the average amount of time it took the navigator sites to enroll their first patient in the program was 17.2 days with the fastest site taking three days and the slowest site taking 37 days.

For the sequenced care pathway (SCP) (Table 3.2), there were eight total sites who participated with only seven sites who made it to their initial enrollment goal. Clinic H never made it to their goal, but projections based on their average weekly enrollment rate estimated them reaching their goal at 38 months and this number was used in the analysis. The SCP sites made it to their goal at an average of 15.7 months with the fastest site reaching 65 patients at 3.5 months and the slowest site at 38 months (projected). The average amount of time it took the SCP sites to enroll their first patient in the program was 47.5 days with the fastest site taking 14 days and the two slowest sites taking 95 days. Three of the SCP sites were medical centers and the other five sites were all

community-based outpatient clinics. The average number of physical therapists in this arm was two per site with an average experience level of 10.2 years.

Figure 3.4 shows the distribution of time to 65 between the navigator arm and the sequenced care arm. The navigator arm has lower variability around an average of 15 months while the sequenced care arm appears to have a higher variability. However, both pathways took just under 16 months to reach the minimum enrollment goal on average, but with considerable differences in variation of time to 65 participants. Several of the other contextual factors were investigated with correlations and found to have moderate to strong association. For example, the number of referring providers trained and the amount of time to initial enrollment in the SCP was negatively correlated at r= -0.72. Other variable pairs that showed a signal for significant correlation included initial enrollment time and time to 65 in the SCP (r=.68), as well as number of referring providers and initial enrollment (r=-.69). None of the contextual factors in the navigator arm were correlated.

3.3.2 Qualitative Analysis

Qualitative results are organized into 10 areas (plus Final Thoughts) that correspond with the CFIR domains from the interview guide. Table 3.3 shows key themes across both care pathways.

1. Familiarity with clinical program: Navigator pathway

Key themes: Provider's Role, Referral Process, Key Resources, and Provider Knowledge

Providers saw their main role in AIM-Back was to refer patients to the program by using their clinical judgment with the overarching goal of ensuring Veterans received appropriate care for their low back pain. Providers generally understood the AIM-Back program and their role in referring patients, but some struggled with communication with the trial team and fully grasping how the program worked. Some reported that vital resources for the program included embedded referral forms and open communication channels with the AIM-Back team. Overall, providers liked how simple it was to refer patients to the program and liked that Veterans had access to different treatment options.

Familiarity with clinical program: SCP pathway

Key themes: Overview of AIM-Back, Provider Roles, Areas for Improvement

SCP providers reported that AIM-Back's primary goal was to assist Veterans with managing chronic low back pain through exercise and other behavioral therapies. Providers felt that they played an essential role in explaining the program to Veterans, placing consults, and evaluating patient responses to the program. Some providers expressed the need for more immediate responses from the AIM-Back team regarding patient referrals and better communication channels for receiving feedback on patient progress within the program.

2. Preparation to refer patients to program: Navigator pathway

Key themes: Provider Comfort, Holistic Approach, Challenges with Referrals

Providers reported different levels of readiness, but overall, most providers stated they felt comfortable with referring patients with low back pain to AIM-Back. Some providers liked the program's comprehensive approach to pain care and the range of

treatments offered, such as chiropractic care and acupuncture. Some providers reported difficulties with referring patients, mainly due to patient reluctance, especially among older Veterans and those less comfortable with technology. Some providers were also unsure about how AIM-Back managed patient records and completed reports.

Preparation to refer patients to program: SCP pathway

Key themes: Provider Comfort, Challenges with Specific Patient Demographics, Importance of Feedback

Providers generally felt comfortable referring patients to AIM-Back and found the referral process straightforward, however, some providers faced challenges with referring specific demographics, such as older patients or Veterans who preferred hands-on or local visits over remote consultations. Multiple providers emphasized the significance of feedback on the referral process. They suggested that patient feedback could drive future referrals and highlighted the importance of receiving timely patient input to gather real-time information to improve the program.

3. Belief about effectiveness of clinical program: Navigator pathway

Key themes: Holistic Pain Management, Recognition of Potential, Beneficial Centralized Process

Providers report that they favored a holistic approach to managing pain and were willing to consider non-medication options. While some providers were unsure about AIM-Back's specifics, many acknowledged its potential effectiveness in offering coordinated, multidisciplinary care and saw AIM-Back as a potential solution for addressing specific back pain issues and offering alternative modalities beyond

medication. AIM-Back's centralized process was viewed positively by both patients and providers and is seen as offering a streamlined approach to exploring treatment options.

Belief about effectiveness of clinical program: SCP pathway

Key themes: Complementary Role of AIM-Back, Value of Patient Feedback, Desire for Enhanced Integration

Providers generally expressed satisfaction with AIM-Back and viewed it as a complement to regular physical therapy and a way to expand back pain management options. Although limited, patient feedback is considered valuable for assessing program effectiveness and addressing individual needs. There was also a desire for more seamless integration of AIM-Back into referring providers' notes to provide timely information on patient progress and outcomes. Additionally, improved accessibility to timely program provider follow-ups and face-to-face interactions were seen as potential factors for enhancing patient engagement and program success, particularly if AIM-Back were available locally for easier referral and participation.

4. Referring to this clinical program vs other programs: Navigator pathway

Key themes: Simplicity of Referral, Referral Considerations, Patient Suitability

Providers appreciate the simplicity and efficiency of the referral process to AIM-Back. They considered various factors when determining suitability for AIM-Back referral, including chronicity of back pain, willingness to try alternative treatments, and absence of major surgical needs. Patients who may not be suitable for AIM-Back included those with acute pain, those on long-term opioid medication, or patients who are resistant to alternative therapies.

Referring to this clinical program vs other programs: SCP pathway

Key themes: Ease of Referral Process, Criteria for Good Candidates, Challenges with Certain Patient Demographics

Multiple providers found the AIM-Back referral process straightforward and less complicated compared to other consults. They appreciated the streamlined approach and shorter consultation time. Providers noted that good candidates for AIM-Back tended to be younger with less complicated pain, an absence of psychological issues, and a high level of motivation for a program like AIM-Back. Providers reported that poor matches for AIM-Back referrals include older Veterans, individuals who are less technologically savvy, those with more complicated pain and/or psychological issues, and those who require more in-person accountability.

5. Feedback from patients: Navigator pathway

Key themes: Importance of Feedback, How Providers Use Feedback

Multiple providers stressed the importance of patient feedback in assessing effectiveness of care and identifying areas for improvement. Providers use patient feedback to inform referral decisions, share testimonials with colleagues, and adapt clinic practices based on patient experiences. Despite some providers not yet receiving patient feedback, there was a consensus on the importance of patient input in evaluating program effectiveness and refining referral practices.

Feedback from patients: SCP pathway

Key themes: Importance of Feedback, Variability in Patient Responses, Desire for More Feedback

Several providers mentioned the significance of patient feedback in evaluating the effectiveness of programs like AIM-Back. Patient responses to AIM-back varied, with some expressing positive experiences and others reporting minimal changes in pain. Multiple providers expressed a desire for more feedback from AIM-Back and patients to gauge program effectiveness and to better understand the patient experience.

6. Priority of referring to this clinical program: Navigator pathway

Key themes: Influence of Clinic Dynamics, Leadership Support Drives Engagement, Variability in Priorities

Clinic and site dynamics impacted AIM-Back referral rates and engagement with factors like staff shortages and overwhelming caseloads affecting participation. Encouragement and support from site directors and leadership can influence provider engagement and program visibility within the clinic. Site-wide priorities and engagement varied, with some providers feeling uncertain about the program's status and effectiveness within their clinic. Regular communication, such as weekly emails, served as a reminder for providers to refer patients to AIM-Back and keeps the program on their radar for potential referrals.

Priority of referring to this clinical program: SCP pathway

Key themes: Variability in Engagement, Factors Influencing Referral Decisions, Role of Patient Preferences and Education

Providers varied in their engagement with AIM-Back, with some considering it a priority and actively referring patients, while others were less inclined to use it as a primary referral option. The decision to refer often depended on individual provider

preferences and the perceived importance of non-pharmacologic options in pain management. Regular emails and reminders about the program served as motivators for some providers to consider AIM-Back as a treatment option. Patient preference played an important role in referral decisions, with providers considering it a priority alongside their own clinical judgment and clinic protocols. Some providers noted the importance of educating veterans about AIM-Back to further increase participation.

7. Adjustments to clinical program needed: Navigator pathway

Key themes: Support for New Providers, Strategies for Program Awareness, Enhancing Visibility

New providers may require refresher meetings to ensure they remember to use AIM-Back, especially with the availability of additional options like physical therapy and Whole Health programs. Strategies to increase program awareness include multiple exposures, highlighting AIM-Back on the consult tab, and regular follow-up meetings with providers. Improving visibility of AIM-Back through hands-on materials like brochures could also optimize the referral process and bridge the gap between referrals and enrollments.

Adjustments to clinical program needed: SCP pathway

Key themes: Provider Engagement, Improvement Suggestions

Efforts to engage providers more effectively were mentioned by multiple providers including strategies like implementing reminders for referrals without overwhelming providers, and involving site leadership to support and re-engage if referrals are lacking. Multiple providers mentioned suggestions to improve education and

resources for both providers and patients. Some specific suggestions include providing clearer information on consult orders and offering mini speeches for providers to explain the program to patients.

8. Organization culture impact on implementation: Navigator pathway

Key themes: Cultural Shifts, Organization Support, Uniqueness of Program

Multiple providers mentioned a general observance of a cultural shift towards prescribing fewer opioids and a more open culture conducive to adopting programs like AIM-Back within the organization. There were efforts from supervisors towards increasing AIM-Back referrals which seemed to indicate an alignment with organizational goals and values. AIM-Back is recognized as a unique program within the VA system and seems to reflect the organization's ongoing commitment to improving pain management practices.

Organization culture impact on implementation: SCP pathway

Key themes: Integrative Pain Management, Patient Preferences, Logistical Considerations

Multiple providers mentioned the VA's emphasis on an integrative approach to pain management and utilizing programs like the AIM-Back as part of a broader strategy. Patients exhibit varying preferences regarding treatments for mental and behavioral health with some favoring non-medication options. Some logistical challenges were mentioned such as patient reluctance to travel long distances for treatment and preferences for face-to-face interactions over virtual visits. Administrative buy-in is

important for ensuring provider awareness and patient access to programs like AIM-Back.

9. Clinical program's fit with existing processes: Navigator pathway

Key themes: Workflow Integration, Increasing Patient Awareness, Ease of Integration

Providers found AIM-Back fits well into their workflow with the consultation process being straightforward. A few providers emphasized the need for patient awareness and engagement, such as having brochures in the lobby for patients to read while waiting. Some providers found it simple to integrate AIM-Back discussions into post-exam treatment discussions.

Clinical program's fit with existing processes: SCP pathway

Key themes: Convenience of Process, Patient Engagement, Treatment Preferences

The consultation process was described as convenient and seamless, with minimal additional work required compared to other consultations. Multiple providers emphasized the importance of patient engagement for program buy-in. One provider mentioned that patient treatment preferences tend to lean towards options that facilitate returning to work and include education on ergonomics and lifestyle changes. One provider mentioned it would be helpful for providers to have more built-in time to explain the program so that patients might have better buy-in.

10. Feedback from clinical program team regarding participation: *Navigator pathway*

Key themes: Appreciation for Updates, Time Challenges, Need for Detailed Feedback

Reports and updates about referrals and participation were appreciated, but some providers thought they lacked detailed feedback on patient outcomes or reasons for patient not being enrolled in program. Providers may not always have the time to fully engage with AIM-Back materials or read in-depth emails due to clinic busyness.

Feedback from clinical program team regarding participation: *SCP pathway*

Key themes: Interest in Understanding Referral Process, Desire for Data, Engagement with Trial Team

Multiple providers stated that they were interested in understanding the referral process better, including where potential drop-offs (e.g., referral to enrollment) occur. Some providers expressed interest in receiving program survey data from participants to further inform their referrals. Providers mentioned engaging with the AIM-Back team through various communication channels, including site visits, emails, and newsletters and they appreciate these avenues to keep their engagement with referring to the program.

11. Final thoughts: Navigator pathway

Key themes: Positive Program Reception, Challenges and Impacts on Referrals, Suggestions for Improvement

Providers generally viewed AIM-Back favorably, recognizing its potential benefits in pain management and holistic care. Some providers noted challenges, such as slow adoption rates or reluctance from patients to participate which can impact referral patterns. Suggestions to improve included additional training sessions, clearer communication, and the need for champions within the organization. Several providers

also mentioned the importance of feedback and program evaluation to better understand patient experiences and to accurately assess AIM-Back's impact.

Final thoughts: SCP pathway

Key themes: Process Appreciation, Positive Feedback, Recognition of Program Impact

Providers appreciated the program's ease of use and its seamless integration into daily practice. However, there was a desire for more feedback about program evaluation to determine its effectiveness and impact on patient outcomes like reduced emergency room visits and decreased medication usage. Overall, providers gave positive feedback about AIM-Back and recognize its effectiveness in managing back pain. Multiple providers praised the program's impact and the efforts of the AIM-Back team and express hope for its continued availability and success.

3.4 Discussion

Contextual analyses provide insight into the interplay between intervention delivery and a healthcare setting with the goal of illuminating contextual factors that influence implementation success. Our quantitative analysis offers important insights about the impact of different contextual factors on the referral processes of two different pathways for low back pain care. Even though both pathways made it to their minimum enrollment goals (n=65) in just under 16 months, the sequenced care sites had notably more variability in time to reaching this goal. This wide distribution could be because the sequenced care referral steps are more linear in that each step is dependent on the final

step of reaching one type of provider (e.g. physical therapist) versus the navigator referral process has more provider types to choose from (e.g. physical therapy, chiropractor, acupuncture, etc.) thus potentially eliminating referral bottlenecks. This linearity of the sequenced care referral process could also explain the longer amount of time to initial patient enrollment over the navigator pathway. Additional variation could also be explained by the qualitative data that mentions occasional Veteran preference for telehealth, resistance to behaviorally informed care, or Veteran technological hesitancy. Another possible explanation for the increased variability in sequenced care could be due to staff turnover since this was slightly higher in the sequenced care pathway (n=6 vs n=4).

When looking at the correlations of contextual factors in both pathways, the relationship between number of referring providers trained and time to initial enrollment was highly correlated in the SCP pathway only. This could be due to the perceived "comfort" with a clinical pathway like sequenced care that uses familiar processes and interventions (i.e. physical therapy) versus the navigator pathway that uses a new role and clinical processes that are potentially less familiar to referring providers. Interestingly, the number of referring providers trained and time to minimum enrollment were not correlated in either pathway. These findings could be explained by the qualitative findings that mentioned the importance of keeping the AIM-Back program top of mind for providers by continuing to remind them of the program through clinical reminders in the electronic healthcare record, real-time feedback from patients, and hands-on program materials like brochures. Similarly, the number of referring providers and time to initial

enrollment approached significance in the SCP, but number of referring providers seemed to have no impact on initial enrollment in the navigator arm. These findings align with qualitative findings from the navigator pathway that mention factors like staff shortages, overwhelming caseloads, and clinic busyness from the "Priority of referring to this clinical program" domain that could have impacted referral rates. Whereas, in the same domain from the SCP, referring providers focused on factors like provider preferences, perceived importance of non-pharmacologic pain management, and Veteran preferences when thinking about referring to AIM-Back.

While multiple providers from both pathways mentioned their appreciation for the ease of the referral process to AIM-Back, there were several recommendations on how it could be improved. For example, both sets of providers, regardless of pathway, highlighted the importance of receiving timely patient feedback such as their experience with the care pathways or progress with their pain for aiding future referrals. This theme of receiving timely patient feedback is important not just in guiding future referrals, but contributes to healthcare quality improvement overall[46]. Gathering real-time patient feedback about their experiences with a program, intervention, or provider goes beyond a generic global patient satisfaction rating and reveals important patient-level insights and preferences which are the foundation of patient centered care[47]. As these authors and our qualitative findings reveal, simply gathering patient feedback is not enough. There must be a process in place to communicate patient feedback data to healthcare teams to make a difference in care delivery[46].

Our findings could help to inform future investigations of non-pharmacologic interventions by highlighting potential implementation-related issues, specifically with referral patterns. For example, the TARGET trial investigated the effectiveness of a specific non-pharmacologic intervention (e.g. psychologically informed physical therapy-PIPT) for patients with chronic low back pain[48]. The intervention included electronic health record alerts to initiate referrals for PIPT. However, despite creating an automated process of identifying appropriate patients and generating referrals for PIPT, only half of the patients received a referral which was far below expectations of the study team and their research partners[48]. Similarly, in another randomized controlled trial to investigate the effectiveness of non-pharmacologic care for low back pain in Danish primary care, they had significant issues with getting patients referred to physical therapy[49]. The study team extended the recruitment period and added clinician types to refer to the study, but still only managed to recruit half of the intended patients[49]. Neither of these studies mention gathering patient experience feedback as a potential implementation tool. The TARGET Trial relied on automated alerts while the Danish trial relied on study team visits and reimbursement to encourage referrals, all of which may have been aided by a patient experience feedback mechanism.

While our study provides valuable insights into important contextual impacts, it is not without limitations. The focus on VA clinics may limit the generalizability of our findings to other healthcare settings. Additionally, the chosen quantitative measures may overlook nuanced aspects of program implementation and different contextual measures like “readiness to change” may provide a more comprehensive picture of provider

experiences. Similarly, the outcome measure of "time to minimum enrollment" as a measure of implementation feasibility may not translate into a meaningful clinical outcome. While our qualitative analysis provides valuable information about provider perspectives and referral patterns in the VA, the setting may limit generalizability due to the higher prevalence of high impact chronic pain in the Veteran population and our sample may not capture the full range of provider experiences. Future research should explore referral influences in diverse healthcare settings to enhance the transferability of findings.

Additionally, there may be important differences between implementing an intervention as a clinical program versus as an embedded pragmatic trial. While both approaches aim to evaluate the effectiveness of an intervention, they differ significantly in their execution and implications. Implementing an intervention as a clinical program involves integrating it into routine practice, allowing for real-world implementation with all its inherent complexities and variations. This approach offers the advantage of directly impacting patient care and outcomes within the clinical setting, potentially leading to more immediate benefits for patients. However, conducting an intervention as an embedded pragmatic trial offers its own set of advantages and disadvantages. On the positive side, it allows for rigorous evaluation of the intervention's effectiveness while maintaining the integrity of real-world clinical practice. By embedding the trial within existing healthcare systems, researchers can assess how the intervention performs in diverse clinical settings and patient populations and potentially enhancing the

generalizability of findings. Additionally, pragmatic trials can provide valuable insights into the feasibility and scalability of implementing the intervention on a larger scale.

Building on our findings, future research should continue to explore specific processes underlying referrals to non-pharmacologic pain interventions. The variability in enrollment times and the correlations between certain contextual factors underscore the need for tailored implementation strategies to optimize program success. Providers' perceptions of program effectiveness and ease of referral play a crucial role in shaping patient engagement and program utilization. The identified challenges, such as patient reluctance and logistical barriers, emphasize the importance of addressing provider concerns and streamlining referral processes.

3.5 Conclusion

Contextual analyses are rarely conducted within real world settings and are seldom used to inform trials or interventions when partnered with health care systems. This contextual analysis provides key insights into the influence of contextual factors on referral processes for low back pain care within an embedded pragmatic trial. While both pathways achieved their enrollment goals within a similar timeframe, there was much higher variability in the SCP pathway. Also, there were several differences in relationships of contextual factors between the two pathways, highlighting the importance of using tailored implementation strategies in future studies. Our qualitative findings emphasize the significance of ongoing provider engagement and communication in enhancing referral processes. Additionally, beliefs about program effectiveness and

referral priorities underscore the need for targeted educational interventions and provider training to optimize program adoption.

Based on these findings, several recommendations emerge for enhancing program implementation and provider engagement:

1. Tailor implementation strategies to fit the specific intervention and its delivery method to enhance overall success.
2. Customize communication strategies to meet the unique needs of referring providers to ensure effective information exchange.
3. Emphasize program effectiveness and ease of referral to increase provider engagement and encourage greater utilization of clinical pathways.

These recommendations are aimed at optimizing program implementation and fostering stronger engagement with referring providers.

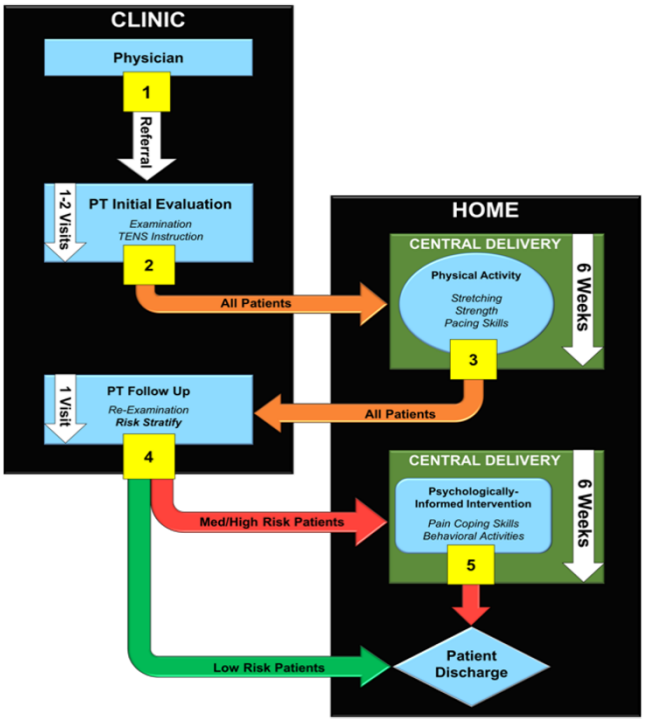


Figure 3.1: Sequenced care pathway

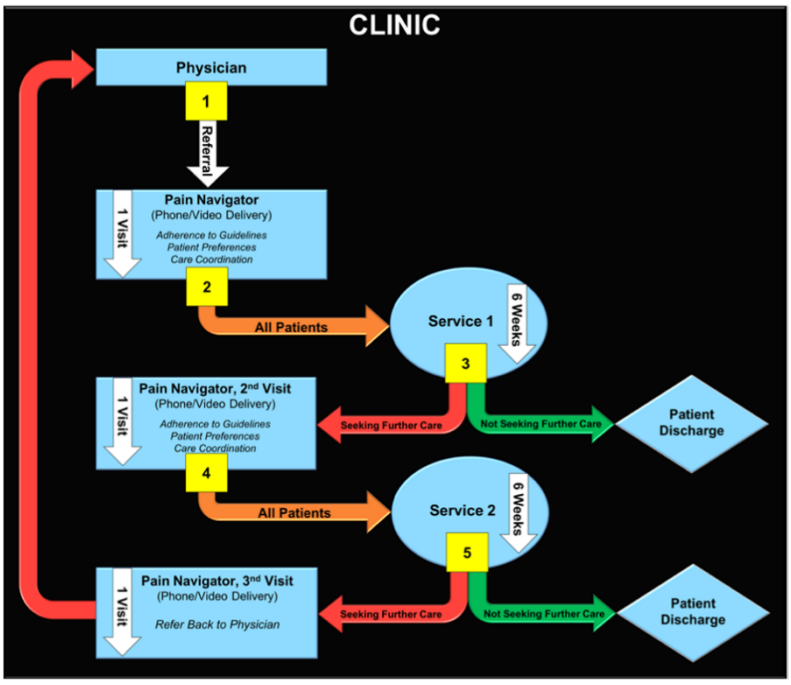


Figure 3.2: Navigator pathway

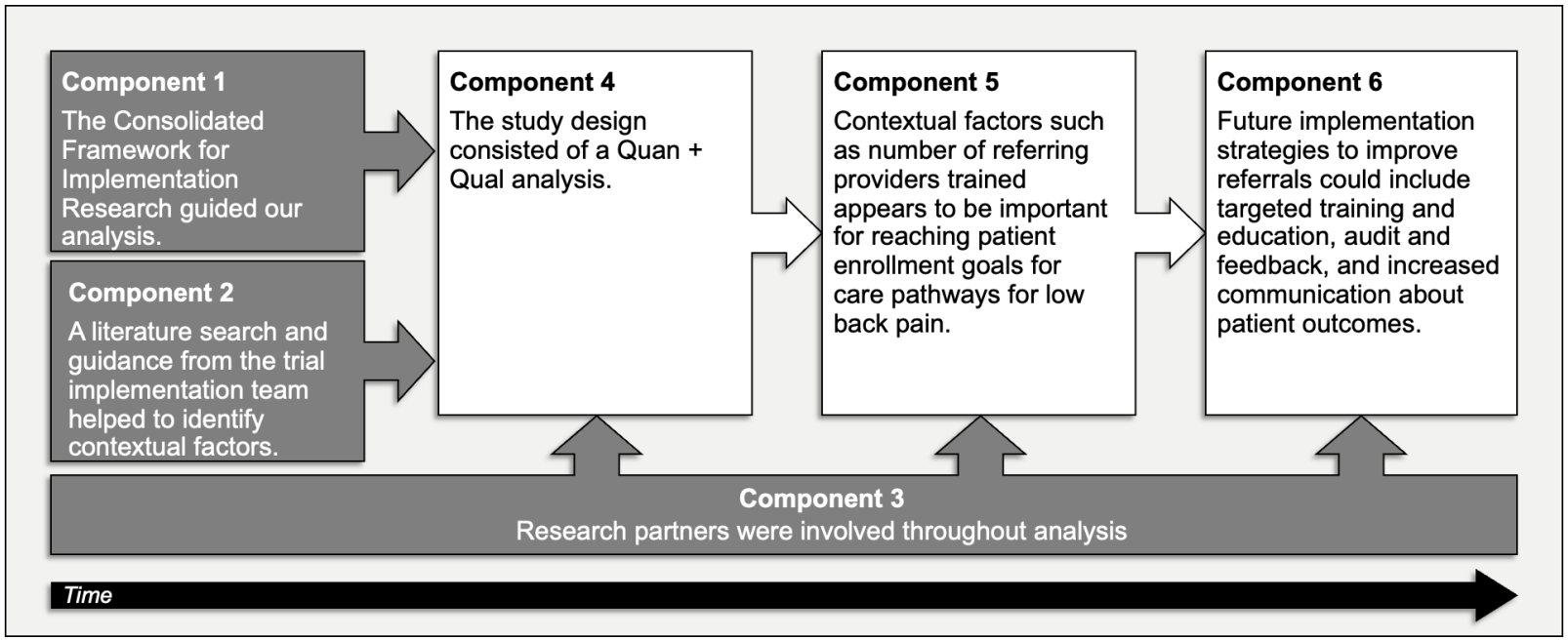


Figure 3.3: Components of the Basel Approach for Contextual Analysis for this study

Table 3.1: Contextual factors for navigator pathway

Clinic ID	Time to 65 (mos)	Initial enrollment (days)	Clinic type	Nav Discipline	# of Nav	# of referring PACT teams	# of providers trained	# of referring providers	# of care options	First site visit impact	Staff turnover
A	12	3	MC	PT, RN, Chiro	4	14	25	19	11	133%	1
B	12	8	MC	PT	1	5	18	16	12	567%	0
C	12.5	18	MC	Nurse	2	7	69	46	14	0%	1
D	14	34	MC	PT	1	12	27	16	10	200%	0
E	15	37	CBOC (urban)	PT	2	1	9	7	12	N/A	1
F	16	10	CBOC (rural)	PT, MD	2	2	10	7	13	550%	0
G	16	29	MC	PT	3	3	19	14	10	145%	0
H	22	9	CBOC (rural)	Nurse, WH coach	4	1	6	7	11	1500%	1
I	24	7	MC	OT	1	3	17	14	10	400%	0

MC=Medical Center
CBOC=Community Based Outpatient Clinic
PT=Physical Therapist
RN=Registered Nurse
Chiro=Chiropractor
WH=Whole Health

Table 3.2: Contextual factors for sequenced care pathway

Clinic ID	Time to 65 (mos)	Initial enrollment (days)	Clinic type	% telehealth	# PTs in SCP	PT experience (years)	# of referring providers trained	# of referring providers	First site visit impact	Staff turnover
A	3.5	35	CBOC-urban	100%	2	38	13	12	N/A	1
B	4	35	MC	50%	6	8.2	20	15	N/A	1
C	6.5	21	CBOC-urban	0%	3	5	17	17	N/A	0
D	10.5	14	MC	0%	1	4	12	9	1367%	1
E	19.5	95	CBOC-rural	10%	1	1	4	4	600%	0
F	20	60	CBOC-rural	100%	1	9	5	5	300%	1
G	23.5	25	MC	50%	1	14	22	21	350%	0
H	38	95	CBOC-rural	40%	1	3	9	8	300%	2

MC=Medical Center
CBOC=Community Based Outpatient Clinic

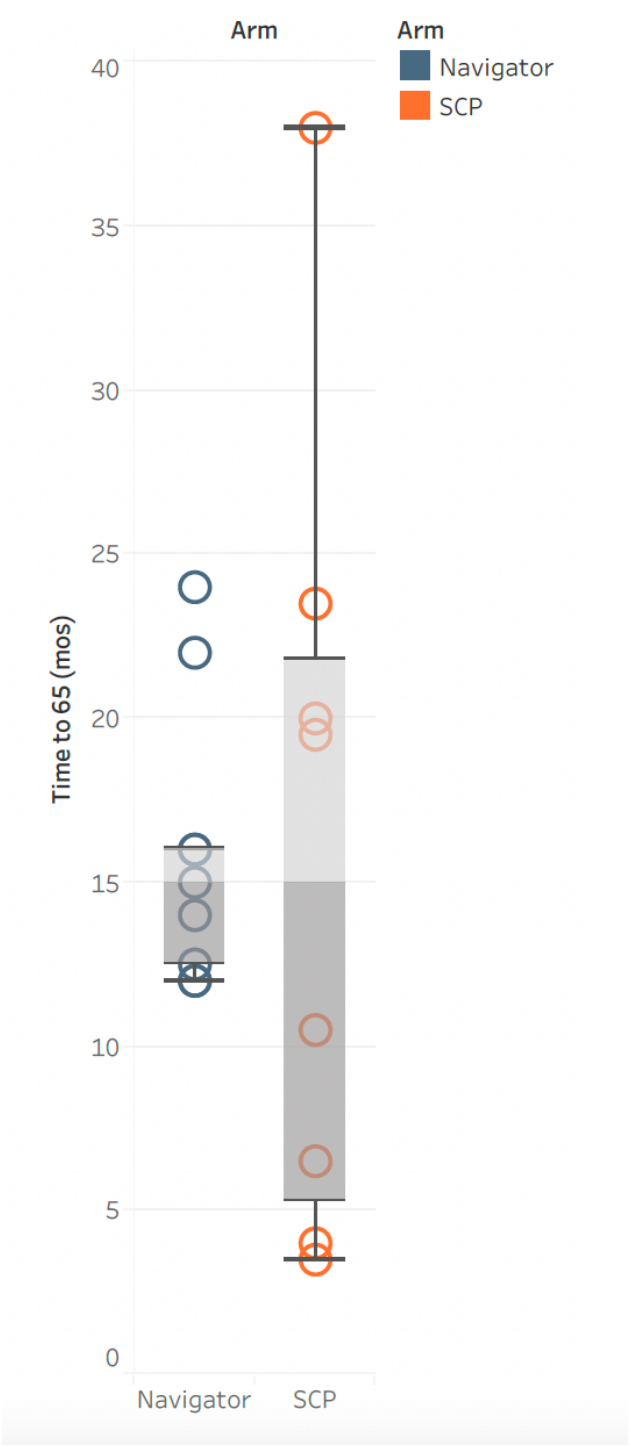


Figure 3.4: Distribution of time to 65 between two arms

Table 3.3: Key themes across both care pathways

Provider's Role	Providers recognize their role in referring patients to AIM-Back but may struggle with communication and understanding the program's specifics, highlighting the need for clearer communication channels and provider education.
Referral Process and Resources	Providers appreciate the simplicity of the referral process and value embedded referral forms and open communication channels with the AIM-Back trial team.
Challenges with Referrals	Providers generally feel comfortable referring patients to AIM-Back but may face challenges with specific patient demographics or understanding how AIM-Back manages data.
Belief in Holistic Approach	Providers believe in the potential effectiveness of AIM-Back in offering coordinated care and favor its holistic approach to pain management.
Comparison with Other Programs	Providers find AIM-Back's referral process straightforward compared to other programs and appreciate its streamlined approach and shorter consultation time.
Importance of Patient Feedback	Providers emphasize the importance of patient feedback in evaluating program effectiveness and desire more feedback to gauge program effectiveness and understand the patient experience.
Impact of Culture	AIM-Back seems to fit within the organization's culture with its emphasis on integrative pain management.
Fit with Existing Processes	AIM-Back fits well into providers' workflow, and they appreciate its convenience and seamless integration into existing processes.
Desire for Detailed Feedback and Data	Providers appreciate updates about referrals but desire more detailed feedback on patient outcomes and reasons for non-enrollment in the program.
How to Improve	Providers generally view AIM-Back favorably and recognize its potential benefits but suggest improvements such as additional training sessions, clearer communication, and the need for champions within the organization.

Chapter 4. Anticipated Feasibility, Acceptability, and Appropriateness of Implementing Nurse-Led Cognitive Behavioral Therapy for Pain in Cancer Centers: A Mixed-Methods Approach

4.1 Introduction

Patients with cancer consistently rate pain among their most prevalent and distressing symptoms[50,51]. When not adequately managed, cancer-related pain can cause anxiety and emotional distress[50,51], lead to avoidable emergency department visits and hospitalizations[52,53], interrupt life-saving or life-prolonging treatment[54], and impair quality of life (QoL)[51,55]. Opioid therapy continues to be a mainstay of cancer-related pain management; however, potentially more effective, and safer approaches to managing pain integrate evidence-based behavioral interventions alongside pain medications[56]. Based on a recent systematic review, patients with opioid-treated cancer or non-cancer pain who also participated in behavioral interventions—particularly interventions using a cognitive behavioral therapy (CBT) framework—experience greater improvements in pain outcomes and are more likely to reduce their opioid use[57]. Specific to cancer, in their 2012 review, Gorin et al. concluded that the size and stability of the effects of CBT-based interventions on cancer pain outcomes are sufficient to warrant their systematic implementation in routine care[58]. Yet implementation of CBT for cancer pain has been extremely limited.

One documented barrier to implementing CBT for cancer pain is the shortage of practitioners who are equipped to deliver it[59]. In most trials, practitioners delivering CBT for cancer pain have been expert pain therapists—typically PhD-level clinical

psychologists—who are not routinely available outside of the major cancer centers where CBT-based interventions for pain have been developed and tested[59]. Most patients with cancer are not treated in these major cancer centers but, rather, in community-based settings where access to clinical psychologists and masters-level behavioral health practitioners is limited[60]. Registered nurses (RNs) are a potentially underutilized resource in community-based cancer centers and may be well-positioned to deliver CBT for pain as nurses play a central role in pain management. Moreover, the oncology nursing profession emphasizes the importance of empowering patients to take an active role in managing their pain by providing them with education and counseling around pain self-management behaviors (e.g., goal-setting and action plans, activity pacing and scheduling)[61]. Several studies conducted in cancer have tested nurse-led CBT-based interventions for pain and found reductions in pain intensity and psychological distress, as well as improvements in QoL and functioning [62–65].

While nurse-led models of CBT for cancer pain appear to be effective, to our knowledge, no prior studies have explored their potential for real-world implementation. In this context, our study aimed to assess perceived feasibility and acceptability of and identify potential barriers to implementing nurse-led CBT for cancer pain from the perspective of outpatient oncology nurses. Our goal was to help inform the design of (1) feasible models of nurse-led CBT for cancer pain and (2) accompanying implementation strategies to overcome identified barriers and/or leverage facilitators.

4.2 Materials and Methods

4.2.1 Study Design

We used a convergent mixed-methods design, including a survey and semi-structured interviews. Quantitative (survey) and qualitative (interview) data were collected and analyzed separately but during a similar timeframe. Results were integrated at the analysis and interpretation stage. This study was exempted from IRB approval by the Duke Health Institutional Review Board.

4.2.2 Setting and Participants

We recruited nurses from one health system comprised of an academic cancer center and two smaller cancer centers affiliated with community-based hospitals. All nurses currently practicing in an outpatient oncology clinic were eligible to participate. With support from local nursing leadership, a member of the study team (SG) invited eligible nurses to participate via email. Email invitations included a link to the survey, administered through REDCap™[66,67]. If they did not respond to the initial email invitation, nurses received up to 3 email reminders.

4.2.3 Quantitative Data Collection and Analysis

Study investigators (DC, TS, DA) developed the survey to assess nurses' familiarity with and current use of cognitive and behavioral pain management strategies. The survey also assessed nurses' opinions about a specific evidence-based pain CBT protocol (described in more detail below) and anticipated barriers to/facilitators of its implementation in practice. These questions were based on select constructs from the

Consolidated Framework for Implementation Research (CFIR). Specific constructs included Intervention Characteristics—Complexity, Evidence; Outer Setting—Patient Needs and Resources, Policies and Incentives; Inner Setting—Compatibility, Implementation Climate; Characteristics of Individuals—Knowledge and Beliefs, Motivation. Questions about nurses' familiarity with/current use of behavioral pain management strategies and their opinions about the pain CBT protocol used a 5-point Likert scale. Questions about anticipated barriers and facilitators were 'select all that apply.' Prior to finalizing the survey, we collected and integrated feedback from three practicing oncology nurses. As part of the REDCap™ survey, nurses provided basic information about their demographic and professional characteristics, and indicated whether they were willing to be contacted about participating in a study interview. Descriptive statistics for nurse characteristics were calculated for all survey respondents. Counts and percentages of Likert scale responses were calculated and presented as tables and Likert plots. Frequencies of endorsed barriers/facilitators were expressed as percentages and visually summarized as bar plots. All statistical analyses were performed in R version 4.1.0.

4.2.4 Qualitative Data Collection and Analysis

Qualitative data were collected via semi-structured telephone or Zoom interviews with a subset of survey respondents who indicated they were willing to be contacted about an interview. In sampling for interviews, our goal was to maximize variation by practice setting (academic vs. community-based). As with the survey, nurses were invited

to participate by email. Similar to the survey, the interview guide was informed by select CFIR constructs. Questions focused on current pain management practices and the role of behavioral pain management strategies, perceived effectiveness of behavioral pain management strategies, feasibility and acceptability of having oncology nurses deliver the CBT protocol, and strategies that might support effective implementation. Interviews averaged 33 minutes in duration. They were audio-recorded but not transcribed, consistent with a rapid approach to qualitative analysis[43,44,68]. The study interviewer (SG), an experienced qualitative analyst, took notes during each interview. A second study team member and qualitative analyst (CO) listened to the interview recordings, made any needed additions or revisions to the notes, and created a templated summary for each interview. Creating a templated summary involved organizing notes into a set of pre-determined domains based on the interview guide and reducing notes to summarize the key points within each domain. When all interviews and templated summaries were completed, summary points were transferred into a matrix (i.e., respondents x domains). Using the matrix, analysts (SG, CO, LB) developed summaries for each domain.

4.2.5 CBT Protocol: Pain Coping Skills Training (PCST)

PCST uses CBT principles to teach patients coping skills that can enhance their pain management. PCST was originally developed for patients with non-cancer pain[69,70]. The intervention has subsequently been adapted for and tested among patients with cancer[71,72]. In addition to including cancer-specific content, adaptations have included

condensing the protocol into fewer sessions and enabling delivery via videoconference. Figure 1 contains the description of the PCST protocol used in the survey and interview.

4.3 Results

4.3.1 Participant Characteristics

Ninety-nine nurses participated in the survey (46% response rate) and 13 nurses participated in the follow-up interviews. Table 4.1 shows the professional characteristics of survey and interview participants. Most were female (89%), had a Bachelor of Science in nursing (BSN) degree (67%), and a nursing certification in oncology (51%). Additionally, most nurses worked in community-based settings (52%).

4.3.1.1 Familiarity with and Current Use of Pain Self-Management Strategies

On the survey, most nurses indicated that they were moderately or very familiar with four of the nine pain self-management strategies mentioned: advising patients about lifestyle changes (81%), using behavioral activation (63%), helping patients with problem-solving related to pain management (59%), and engaging patients in goal setting and action planning (53%). Nearly half were moderately or very familiar with teaching patients about skills like progressive muscle relaxation (49%) and attention diversion (49%). A similar percentage (49%) were moderately or very familiar with helping patients to cope with difficult emotions related to pain. In contrast, fewer than one-quarter of nurses were moderately or very familiar with cognitive restructuring of catastrophic thinking related to pain (22%) and pain avoidance beliefs (23%). Slightly over half of the respondents were not familiar with cognitive restructuring strategies. A

Likert plot displaying information about nurses' familiarity with pain self-management strategies is shown in Figure 4.2.

Reported use of pain self-management strategies with patients (Figure 4.3) was low relative to familiarity ratings. For example, while 62% of nurses reporting being moderately or very familiar with behavioral activation, in practice, only 27% reported using this strategy with patients a moderate amount or a great deal. The pain self-management strategy that nurses most often described as using with patients to a moderate or great extent was advising about lifestyle changes (48%).

Interview responses likewise reflected limited use of pain self-management strategies in practice. Most nurses described the primary pain management strategy in their clinics was the use of pain medications; many also acknowledged that pain medications have limitations and recognized an opportunity to better attend to the psychosocial factors that contribute to pain. As one nurse described, "There's a lot of emotions wrapped up in living with chronic pain and that's really evident in our patient population. I think that we could do better at addressing the emotional needs of pain as well as the physical." The same nurse went on to say, "I think that my patient population could definitely benefit from some thought- and emotion-centered work." (N003)

A few nurses described occasionally working with patients to use pain self-management strategies like pleasant imagery or distraction in an informal or unstructured way, such as during a potentially distressing procedure (e.g., port placement). Nurses who did occasionally use these strategies were familiar with them from use in previous

professional positions or for their own self-management. For example, one nurse described skills she learned while working in a different clinical setting:

> In that situation there was a lot of painful dressing changes and things like that. [Another clinician] would come and just try to help the patients with guided imagery and such, and I would listen in a lot to what he was saying with the patients and that's where I learned my tips – that, along with my psychology background. So there, I just try to talk about 'what makes you happy?' 'where's your happy place?'...I try to just use whatever tidbit I know about the patient or what physical things that they have – 'hey, tell me about your [university] t-shirt'. (N007)

4.3.1.2 Acceptability and Appropriateness of Nurse-Led PCST

Overall, nurses had positive attitudes about PCST (Figure 4.4). On the survey, approximately 66% of nurses either agreed or strongly agreed that the intervention was appealing and 58% felt that delivering PCST would be personally rewarding. The majority (78%) thought PCST would benefit their patients. Those that were less sure of the benefit stated that patients may not be open to complementary therapies. In follow-up interviews, nurses reinforced that PCST and similar interventions could be beneficial for many patients in their clinics. Several suggested that PCST may be particularly helpful for patients experiencing chronic pain and anxiety. For example, as one nurse described:

> I think especially for patients who are experiencing longer term pain - cancer pain, oncology pain that's not going to ever go away. I think that it can be very, very important, because most of it, I feel, is decreasing the anxiety around the pain. People who are afraid that they're going to run out of pain medications have that anticipatory pain. They're already hurting, even though they're nowhere close to running out of medication yet, but their anxiety is ramping up their perception of the pain, so I really think helping people to just kind of reframe that, I think can be very, very beneficial. (N011)

While nurses generally agreed that PCST should be considered for many patients, some acknowledged that the intervention may not well work for everyone. For example, one nurse (N008) mentioned that patients with decreased cognitive capacity (e.g., due to neurologic effects of cancer and/or its treatment) may not be able to effectively engage in PCST.

With respect to appropriateness of nurse-led PCST (Figure 4.4), on the survey, most nurses (77%) agreed or strongly agreed that PCST seemed to be within the scope of oncology nursing practice and 58% reported that it would be a good fit with their roles and responsibilities as an oncology nurse. Several interviewees spoke to the compatibility of PCST with their current professional role. For example, one interviewee anticipated that, with training, she could likely integrate teaching patients pain coping skills into her current practice. According to this interviewee, "Just looking at some of these [skills] I can definitely see where I could integrate it just in my conversations I have with my patients, but just getting some extra skill level about how to incorporate it as I'm just having conversations with my patients…it would be fairly easy to do, I think." (N001)

Along the same lines, on the survey, 62% of nurses endorsed that training and support from a PCST expert would be a key facilitator (Figure 4.5). During the interviews, suggestions for training included use of mock or experiential learning sessions. Interview responses also underscored the need for ongoing support. According to one interviewee:

> I see the biggest resource would be maybe having someone to kind of bounce things off of, maybe a guide or someone who's a little more experienced in

> [PCST], I guess maybe a coach? A coach for the coach. Someone that you could just pick someone's brain or say, 'am [is] what I'm using effective?' (N009)

4.3.1.3 Feasibility of Nurse-Led PCST, Barriers, and Facilitators

Results from both the survey and interviews highlighted key concerns related to the feasibility of nurses delivering PCST. As summarized by one interviewee, "I think nurses are very qualified to do it, if you had the time and the resources, I just don't think the environment lends itself to it." (N009) On the survey, over 73% of nurses indicated that lack of time in their current role was a barrier (Figure 4.5). Interviewees elaborated on lack of time as a barrier. As one interviewee described:

> I really think the main barrier is time because at the cancer center right now we just had a staff meeting yesterday and they're like, 'we've got to get these visit times down, we're implementing this whole new system where we're going to use location management to see exactly where the patient is and how long they've been there so that we know who to blame when they get held up' (N003)

A related barrier mentioned by interviewees was nursing staff shortages. As one interviewee described, "In my work in infusion rooms it is 'go go go' and it's something that we've been dealing with for a while, just with the low staffing of our entire clinic. Like I think right now we have 12 or 13 open nursing positions and it's just – like you don't have time to do that [PCST]." (N006)

Moreover, on the survey, 29% of nurses endorsed lack of space as another barrier. Interview participants likewise emphasized the importance of having a private and quiet space to deliver PCST, which many noted can be difficult to find in a busy outpatient or infusion clinic.

> We're already tight in chairs since we're a smaller infusion center, so I feel like this wouldn't be something that's like – obviously, if we had patients that we needed to schedule for chemo, that would take precedence over somebody coming in to get [PCST]. (N002)

Participants identified several potential strategies to help overcome identified barriers. On the survey, about 60% of nurses indicated that developing a dedicated nurse pain specialist role could facilitate PCST implementation in oncology clinics. Interviewees reinforced that a dedicated nurse specialist model is likely most feasible. According to one nurse:

> I think it would have to be like a few people per unit kind of thing because there would have to be obviously some sort of training so that the nurse understands how to implement this with the patient correctly. I think if a few nurses per unit say, 'we're trained to do this', and the patient was having a really hard time, the nurse could come in and offer [PCST]." (N003)

In interviews, other potential strategies for making PCST work for both cancer center staff and patients included delivery during infusion appointments due to their often-long duration and videoconference-based delivery to make participation more convenient for patients. As one nurse explained, "I think patients, especially the patients who are stuck in [infusion] for extreme amounts of time, I think it even gives them – it's entertainment, it's human interaction which is beneficial in and of itself." (N011) However, interviewees acknowledged that both delivery strategies might introduce challenges, at least for certain groups of patients. One interviewee described that some patients might receive sedating medications in conjunction with infusions and might not be able to participate in PCST in the clinic due to associated drowsiness (N006). With respect to videoconference-based

delivery, another interviewee recognized that some patients would not have the requisite technology or skills to participate (N012).

4.3.1.4 Patient Perspective

Survey and interview responses provided some insight into potential patient perspectives on PSCT. For example, 32% of nurses felt that lack of patient engagement in PCST could be a key barrier to its implementation. In interviews, nurses shared that some patients may not be open to trying PCST due to competing demands on their time, hesitancy to learn something new, or desire for instant pain relief from medications. Relatedly, to optimize patient receptiveness to PCST, they also suggested that careful consideration should be given to how PCST is introduced, for example, emphasizing that PCST is meant to be used alongside existing medications. As one nurse described:

> I think it could be very well received, especially since a lot of these things are going to be in conjunction with medication. It seems like when you're doing these kinds of interventions, you're not taking it [medications] away from the patient, that they can have the medication that they trust and believe will work for them, so it's not necessarily framing it as an 'either/or' – either you can have medication or you can have these sessions, but not both. So making sure that it's not an 'either/or' situation… (N011)

Another interviewee suggested it would likely be important to have the treating oncologist encourage participation in PCST (N005).

4.4 Discussion

We used mixed methods to investigate the anticipated feasibility of and potential barriers associated with implementing nurse-led CBT for pain as part of routine cancer care, from the perspective of oncology nurses. We focused on a specific evidence-based

CBT intervention for cancer pain (PCST). Most participants were generally familiar with pain self-management strategies and acknowledged their importance. Most also viewed delivering the PCST intervention as consistent with their professional role and recognized that the intervention would likely help many of their patients. However, nurses' current use of pain self-management strategies was low overall, and many nurses reported limited capacity to deliver interventions like PCST alongside other responsibilities and within existing workflows. Several nurses also identified strategies that could help to overcome identified barriers, such as having a dedicated nurse-specialist (or specialists) to deliver PCST and using innovative delivery methods (e.g., delivering PCST during chemotherapy infusions or alongside other appointments, leveraging telehealth).

One important study finding was the support for a nurse-specialist role to deliver PCST. Historically, use of a dedicated pain specialist has been limited to medical practice with physicians from backgrounds in anesthesiology, physical medicine and rehabilitation, neurology, and psychiatry undergoing specialized training in pain management.[73] However, over the past 20 years, there has been increasing recognition of the importance of a biopsychosocial approach to pain care through the use of multidisciplinary treatment teams[4,11,74]. As such, pain specialists are increasingly common in other health care professions. For example, in both physical and occupational therapy there are now certifications and advanced training available to support pain specialists in each of these professions[15,75]. In physical therapy, there are multiple avenues for undergoing advanced training in psychologically informed methods where physical therapists incorporate behavioral interventions alongside traditional treatment

methods[76,77]. These treatment models incorporate approaches that utilize both dedicated pain specialists who treat most patients with persistent pain in a given practice, as well as generalist models where all clinicians in a practice have been trained to use some form of psychologically informed interventions. Based on the results of our study, a dedicated pain specialist model may be most feasible in the oncology nursing context.

Comprehensive training in PCST and access to ongoing support after completion of training were commonly reported needs of nurses to perform PCST. Several other studies have investigated training needs for psychologically informed interventions like PCST and have identified multiple training models that can lead to successful competency[15,76,77].While the intensity of training differs across models, many training programs incorporate a mix of didactic and experiential learning alongside ongoing mentoring and feedback which aligns with the recommendations from nurses who participated in our study. From an implementation science perspective, implementation strategies such as technical assistance, learning collaboratives, and audit and feedback have all been used to support clinicians' application of new skills in different clinical contexts.[78,79] There are ongoing efforts to compare the effectiveness of different implementation strategies in promoting oncology nurses' adoption of and fidelity to other evidence-based supportive cancer care interventions[80].

While this study did not seek patient perspectives directly, some nurses did remark on potential patient engagement challenges and, relatedly, the importance of flexible modes of intervention delivery (e.g., in-person versus telehealth, video versus telephone). Other pain management interventions that have utilized a flexible approach

include hybrid and telehealth models, as well as group-based approaches[81–83]. These are examples of patient-driven approaches that could be good models for nurse-led PCST. Additionally, several nurses acknowledged that, to optimize patients' acceptance of PCST, it would likely be important to clearly introduce the intervention as an adjunct to (versus replacement for) existing pain medication regimens. Therefore, including expectation management within the PCST for nurses could help with patient acceptability and buy-in[84–86].

Our study has some important limitations. Although we included a balance of perspectives from nurses in academic and community-based cancer centers, all nurses were affiliated with the same large health system. It is possible that some of the challenges and opportunities they identified are unique to that system or the surrounding region, and that different challenges and opportunities could be identified in other settings. Another limitation is that our survey was designed to be completed anonymously, consistent with guidance from local nursing leadership. Thus, we were unable to conduct purposive sampling for interviews based on whether survey respondents conveyed a particularly positive or negative view of the PCST intervention. Conducting purposive sampling might have yielded additional insights about barriers and facilitators that we were not able to explore.

4.5 Conclusion

These study findings highlight specific opportunities for future research focused on the design and evaluation of interventions that use a nurse-specialist model of PCST

for patients with cancer. Future studies should use a hybrid effectiveness-implementation design to (1) evaluate the impact of the nurse-specialist model on clinical pain outcomes and (2) test strategies for the initial training and ongoing support of nurse-specialists delivering the intervention.

Table 4.1: Professional characteristics

	Survey Participants	Interview Participants
N	99	13
Years in practice, total (Mean (SD))	18.57 (12.46)	14.46 (9.77)
Years in practice, category (%)		
<5 years	9 (9.1)	1 (7.7)
5-15 years	43 (43.4)	8 (61.5)
16-30 years	28 (28.3)	3 (23.1)
>30 years	18 (18.2)	1 (7.7)
Unknown	1 (1.0)	0
Years in practice, oncology (Mean (SD))	11.85 (10.77)	10.65 (7.67)
Years in oncology practice, category (%)		
<5 years	31 (31.3)	3 (23.1)
5-15 years	34 (34.3)	7 (53.8)
>15 years	32 (32.3)	3 (23.1)
Unknown	2 (2.0)	0
Years in current clinic (Mean (SD))	3.71 (3.38)	4.93 (2.71)
Years in current clinic, category (%)		
<1 year	17 (17.2)	0
1-5 years	59 (59.6)	9 (69.2)
6-10 years	17 (17.2)	4 (30.8)
>10 years	5 (5.1)	0
Unknown	1 (1.0)	0
Employment status		
Full-time	85 (85.9)	Unknown
Part-time	10 (10.1)	Unknown
Other/unknown	4 (4.0)	Unknown
Nursing degree(s) obtained		
Diploma	8 (8.1)	0
ADN/ASN	33 (33.3)	1 (7.7)
BSN	67 (67.7)	11 (84.6)
MSN	17 (17.2)	1 (7.7)
Other degrees	14 (14.1)	0
Nursing certification(s) obtained		
Hospice and Palliative Care	3 (3.0)	0
Oncology	51 (51.5)	10 (76.9)
Other	13 (13.1)	1 (7.7)
Pain Management	2 (2.0)	0
Unknown	30 (30.3)	2 (15.4)

Organization type		
Academic	42 (42.4)	7 (53.8)
Community	52 (52.5)	6 (46.2)
Unknown	5 (5.1)	0
Clinic type		
Ambulatory oncology clinic	69 (69.7)	7 (53.8)
Infusion clinic	23 (23.2)	6 (46.2)
Unknown	7 (7.1)	0

Pain Coping Skills Training (PCST) Overview

We would like to hear your thoughts about a program designed to help cancer patients control their pain. This program is called Pain Coping Skills Training (PCST).

PCST uses cognitive behavioral therapy principles to teach patients coping skills that can lessen the impact of pain on their daily lives.

Basic information about PCST:

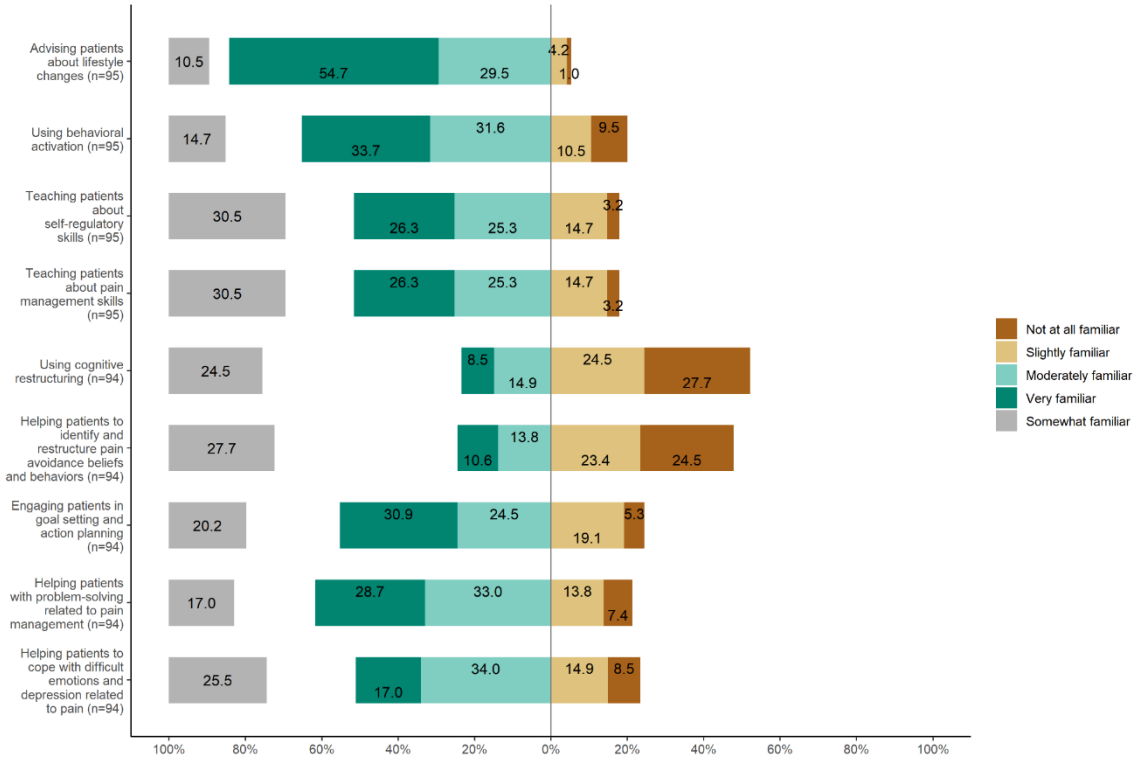
- Delivered over 4 or 5 weekly sessions
- Sessions range from 30 to 45 minutes in duration
- Can be delivered in-person or over videoconference
- Usually delivered by a psychologist, but can also be delivered by other health care workers, like physical therapists or nurses

Each session covers a different skill:

- Progressive Muscle Relaxation: Relaxing different muscle groups in the body, one at a time, to reduce tension and distress
- Activity-Rest Cycles: Setting a time limit for activities that patients tend to overdo, and a time limit for rest and relaxation afterwards
- Pleasant Activity Planning: Identifying and scheduling activities that bring patients a sense of accomplishment, joy, or pleasure
- Positive Thinking: Learning how to identify unhelpful and negative thoughts about pain, and to change those thoughts to be more neutral or positive
- Imagery: Learning to use patients' imagination to create an image or scene that is calming and peaceful. This helps with reducing stress and pain and helps patients to pay less attention to pain.

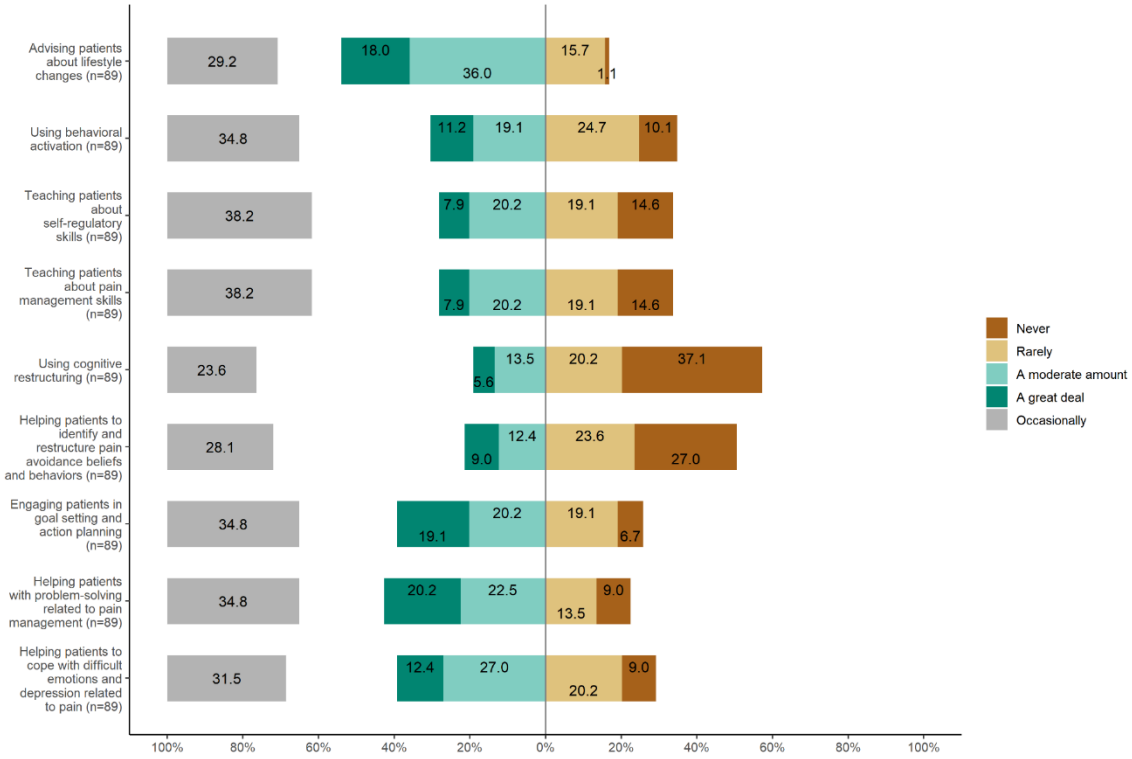
In research studies, PCST has decreased patients' pain and improved their quality of life.

Figure 4.1: Description of PCST used in survey and interviews



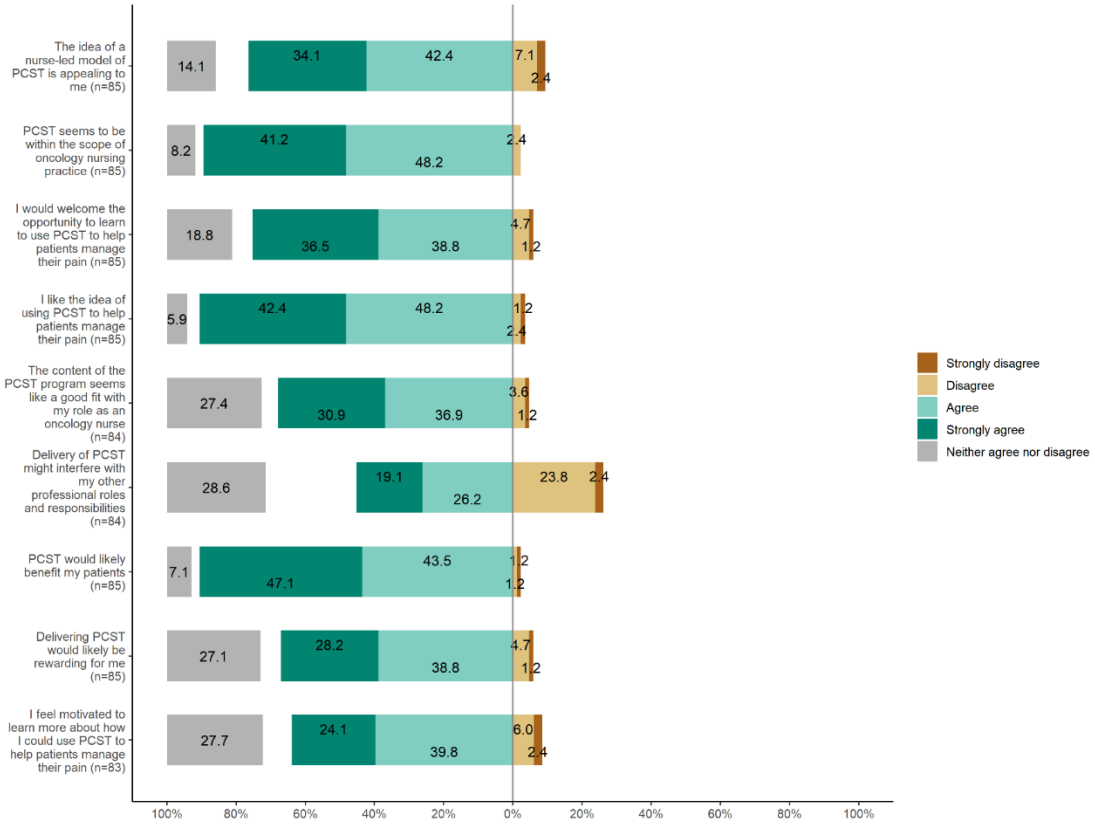
Note: Percentages reported in Likert plot exclude missing responses (i.e., N=95, minus 4 missing responses).

Figure 4.2: Likert plot displaying familiarity with pain management strategies



Note: Percentages reported in Likert plot exclude missing responses (i.e., N=95, minus 4 missing responses).

Figure 4.3: Likert plot displaying current use of pain management strategies



Note: Percentages reported in Likert plot exclude missing responses (i.e., N=95, minus 4 missing responses).

Figure 4.4: Likert plot displaying opinions of PCST

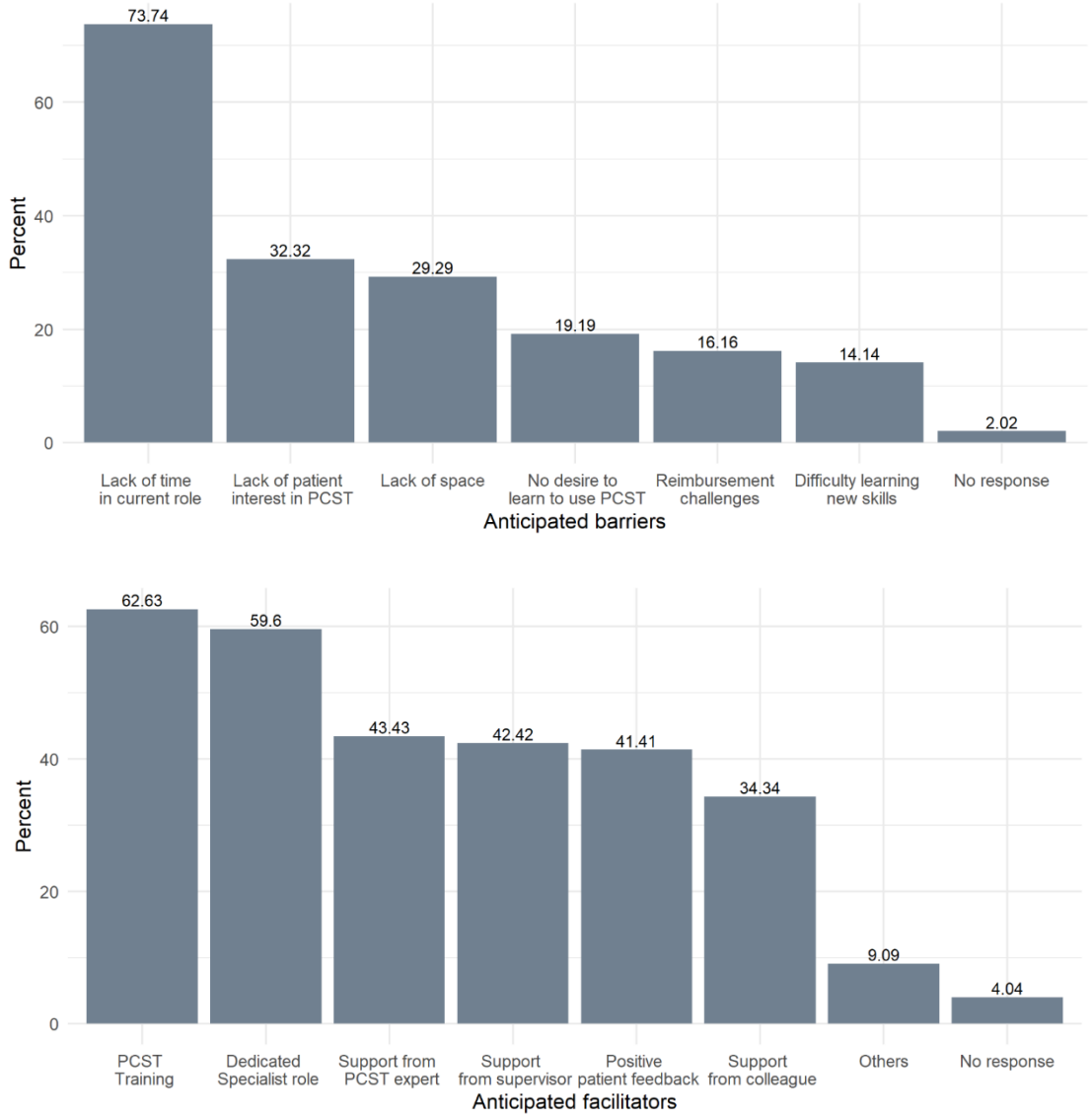


Figure 4.5: Anticipated barriers to and facilitators of implementing nurse-led PCST

Chapter 5. Conclusion

This research aimed to investigate the relationship between intervention complexity and adaptation, as well as identify optimal contextual factors for implementing non-pharmacologic pain care in routine care settings. Understanding these relationships may help to guide future investigations of non-pharmacologic pain interventions through bridging the efficacy to effectiveness gap for translation of evidence-based interventions. In this dissertation, I have addressed three aims aimed at enhancing our understanding of non-pharmacological pain intervention implementation and adaptation in the context of complex healthcare settings.

Aim 1: Investigate intervention complexity and adaptations to explore the impact on implementation outcomes. Our study delved into the relationship between intervention delivery complexity, adaptations, and implementation, comparing non-pharmacologic pain and non-pain intervention pragmatic trials. We found that while intervention delivery complexity may be higher for pragmatic trials investigating non-pharmacologic pain interventions in specific areas, changes in workflow were significant considerations across all trials. This underscores the need for capturing detailed, real-time information to improve the delivery of non-pharmacologic pain interventions and enhance implementation success.

Aim 2: Characterize clinically relevant contextual factors for enrolling patients in multimodal, non-pharmacologic pain intervention pathways across different health care centers. Through our contextual analysis, we gained insights into the influence of contextual factors on referral processes for low back pain care. While both pathways

achieved their enrollment goals within a similar timeframe, differences in the relationships of contextual factors between the pathways underscored the importance of tailored implementation strategies. Our findings highlight the significance of ongoing provider engagement, communication, targeted educational interventions, and streamlined referral processes for promoting program uptake and optimizing the delivery of non-pharmacologic pain interventions.

Aim 3: Explore the feasibility of implementing an evidence-based pain cognitive-behavioral therapy (CBT) protocol among oncology nurses. Our study findings illuminate opportunities for future research focused on the design and evaluation of interventions using a nurse-specialist model of pain CBT for patients with cancer. Recommendations include employing a hybrid effectiveness-implementation design to evaluate the impact of the nurse-specialist model on clinical pain outcomes as well as testing implementation strategies for initial training and ongoing support of nurse-specialists in delivering pain CBT.

This dissertation sought to open the implementation black box for non-pharmacologic pain interventions by using a rigorous, systematic way of evaluating the relationship between intervention complexity, adaptations, and implementation. Investigating contextual factors and adaptations that were made within multiple pain trials have shown how real world non-pharmacologic pain intervention implementation is happening and may help with identifying where more implementation assistance is needed. Additionally, seeking input from front-line providers on the feasibility of delivering a non-pharmacologic pain intervention has increased our understanding of

potential barriers and facilitators to increasing patient access to an important pain intervention. As this proposal uses information from multiple types of non-pharmacologic pain interventions (e.g., physical therapy, cognitive behavioral therapy), we have a better understanding of important implementation factors that will help healthcare teams more readily implement pain interventions into routine clinical settings. In conclusion, this dissertation advances our understanding of non-pharmacologic pain intervention implementation and adaptation in complex healthcare settings by addressing key research aims and generating actionable recommendations. By recognizing the importance of intervention delivery complexity, context, and implementation feasibility, we pave the way for more effective and sustainable healthcare interventions to improve patient outcomes.

References

1. Wu A, March L, Zheng X, et al. Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017. *Ann Transl Med*. 2020;8(6):299. doi:10.21037/atm.2020.02.175

2. Jackson T, Thomas S, Stabile V, Shotwell M, Han X, McQueen K. A Systematic Review and Meta-Analysis of the Global Burden of Chronic Pain Without Clear Etiology in Low- and Middle-Income Countries: Trends in Heterogeneous Data and a Proposal for New Assessment Methods. *Anesth Analg*. 2016;123(3):739-748. doi:10.1213/ANE.0000000000001389

3. Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet*. 2018;391(10137):2368-2383. doi:10.1016/S0140-6736(18)30489-6

4. Simon LS. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. *Journal of Pain & Palliative Care Pharmacotherapy*. 2012;26(2):197-198. doi:10.3109/15360288.2012.678473

5. Staman KL, Check DK, Zatzick D, et al. Intervention delivery for embedded pragmatic clinical trials: Development of a tool to measure complexity. *Contemp Clin Trials*. 2023;126:107105. doi:10.1016/j.cct.2023.107105

6. Mielke J, Leppla L, Valenta S, et al. Unraveling implementation context: the Basel Approach for coNtextual ANAlysis (BANANA) in implementation science and its application in the SMILe project. *Implement Sci Commun*. 2022;3:102. doi:10.1186/s43058-022-00354-7

7. Kim LH, Vail D, Azad TD, et al. Expenditures and Health Care Utilization Among Adults With Newly Diagnosed Low Back and Lower Extremity Pain. *JAMA Netw Open*. 2019;2(5):e193676. doi:10.1001/jamanetworkopen.2019.3676

8. Escoffery C, Lebow-Skelley E, Haardoerfer R, et al. A systematic review of adaptations of evidence-based public health interventions globally. *Implement Sci*. 2018;13(1):125. doi:10.1186/s13012-018-0815-9

9. Wiltsey Stirman S, Baumann AA, Miller CJ. The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Science*. 2019;14(1):58. doi:10.1186/s13012-019-0898-y

10. Wiltsey Stirman S, Gamarra JM, Bartlett BA, Calloway A, Gutner CA. Empirical Examinations of Modifications and Adaptations to Evidence-Based Psychotherapies: Methodologies, Impact, and Future Directions. *Clinical Psychology: Science and Practice*. 2017;24(4):396-420. doi:10.1111/cpsp.12218

11. Chou R, Deyo R, Friedly J, et al. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Ann Intern Med*. 2017;166(7):493-505. doi:10.7326/M16-2459

12. Intervention Complexity Tool for Embedded Pragmatic Clinical Trials (ICT-ePCT) Version 1.0. Accessed September 21, 2022. https://duke-som.shinyapps.io/ICT-ePCT/

13. Qaseem A, Wilt TJ, McLean RM, Forciea MA. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Annals of Internal Medicine*. 2017;166(7):514-530. doi:10.7326/M16-2367

14. WHO guideline for non-surgical management of chronic primary low back pain in adults in primary and community care settings. Accessed March 20, 2024. https://www.who.int/publications-detail-redirect/9789240081789

15. Ballengee LA, Zullig LL, George SZ. Implementation of Psychologically Informed Physical Therapy for Low Back Pain: Where Do We Stand, Where Do We Go? *J Pain Res*. 2021;14:3747-3757. doi:10.2147/JPR.S311973

16. Ford I, Norrie J. Pragmatic Trials. *New England Journal of Medicine*. 2016;375(5):454-463. doi:10.1056/NEJMra1510059

17. Concannon TW, Guise JM, Dolor RJ, et al. A National Strategy to Develop Pragmatic Clinical Trials Infrastructure. *Clinical and Translational Science*. 2014;7(2):164-171. doi:10.1111/cts.12143

18. Chambers DA, Norton WE. The Adaptome: Advancing the Science of Intervention Adaptation. *American Journal of Preventive Medicine*. 2016;51(4, Supplement 2):S124-S131. doi:10.1016/j.amepre.2016.05.011

19. Miller CJ, Barnett ML, Baumann AA, Gutner CA, Wiltsey-Stirman S. The FRAME-IS: a framework for documenting modifications to implementation strategies in healthcare. *Implementation Science*. 2021;16(1):36. doi:10.1186/s13012-021-01105-3

20. Ng W, Slater H, Starcevich C, Wright A, Mitchell T, Beales D. Barriers and enablers influencing healthcare professionals' adoption of a biopsychosocial approach to musculoskeletal pain: A systematic review and qualitative evidence synthesis. *Pain*. Published online January 29, 2021. doi:10.1097/j.pain.0000000000002217

21. George SZ, Lentz TA, Goertz CM. Back and neck pain: in support of routine delivery of non-pharmacologic treatments as a way to improve individual and population health. *Transl Res*. Published online April 23, 2021. doi:10.1016/j.trsl.2021.04.006

22. Plsek PE, Greenhalgh T. Complexity science: The challenge of complexity in health care. *BMJ*. 2001;323(7313):625-628. doi:10.1136/bmj.323.7313.625

23. Matlow AG, Wright JG, Zimmerman B, Thomson K, Valente M. How can the principles of complexity science be applied to improve the coordination of care for complex pediatric patients? *Qual Saf Health Care*. 2006;15(2):85-88. doi:10.1136/qshc.2005.014605

24. NIH Collaboratory Rethinking Clinical Trials - The Living Textbook. Rethinking Clinical Trials. Accessed November 15, 2023. https://rethinkingclinicaltrials.org/

25. PMC3 | NIH-DoD-VA Pain Management Collaboratory. Accessed November 13, 2019. /home/pmc3/

26. Demonstration Projects Program. NIA IMPACT Collaboratory. Accessed April 23, 2024. https://impactcollaboratory.org/grants-and-training/demonstration-projects/demonstration-grants-program/

27. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. *Lancet*. 2018;391(10137):2356-2367. doi:10.1016/S0140-6736(18)30480-X

28. Dieleman JL, Baral R, Birger M, et al. US Spending on Personal Health Care and Public Health, 1996-2013. *JAMA*. 2016;316(24):2627-2646. doi:10.1001/jama.2016.16885

29. George SZ, Goertz C, Hastings SN, Fritz JM. Transforming low back pain care delivery in the United States. *Pain*. 2020;161(12):2667-2673. doi:10.1097/j.pain.0000000000001989

30. Henschke N, Kamper SJ, Maher CG. The Epidemiology and Economic Consequences of Pain. *Mayo Clinic Proceedings*. 2015;90(1):139-147. doi:10.1016/j.mayocp.2014.09.010

31. Wells M, Williams B, Treweek S, Coyle J, Taylor J. Intervention description is not enough: evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials*. 2012;13:95. doi:10.1186/1745-6215-13-95

32. Pfadenhauer LM, Gerhardus A, Mozygemba K, et al. Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. *Implementation Science*. 2017;12(1):21. doi:10.1186/s13012-017-0552-5

33. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50. doi:10.1186/1748-5908-4-50

34. Aarons GA, Hurlburt M, Horwitz SM. Advancing a Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors. *Adm Policy Ment Health*. 2011;38(1):4-23. doi:10.1007/s10488-010-0327-7

35. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci*. 2015;10:21. doi:10.1186/s13012-015-0209-1

36. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *Milbank Q*. 2004;82(4):581-629. doi:10.1111/j.0887-378X.2004.00325.x

37. Mielke J, Brunkert T, Zúñiga F, Simon M, Zullig LL, De Geest S. Methodological approaches to study context in intervention implementation studies: an evidence gap map. *BMC Med Res Methodol*. 2022;22(1):1-19. doi:10.1186/s12874-022-01772-w

38. George SZ, Coffman CJ, Allen KD, et al. Improving Veteran Access to Integrated Management of Back Pain (AIM-Back): Protocol for an Embedded Pragmatic Cluster-Randomized Trial. *Pain Med*. 2020;21(Suppl 2):S62-S72. doi:10.1093/pm/pnaa348

39. Ballengee LA, King HA, Simon C, et al. Partner engagement for planning and development of non-pharmacological care pathways in the AIM-Back Trial. *Clin Trials*. 2023;20(5):463-472. doi:10.1177/17407745231178789

40. Lentz TA, Coffman CJ, Cope T, et al. If You Build It, Will They Come? Patient and Provider Use of a Novel Hybrid Telehealth Care Pathway for Low Back Pain. *Phys Ther*. 2024;104(2):pzad127. doi:10.1093/ptj/pzad127

41. Oude Rengerink K, Kalkman S, Collier S, et al. Series: Pragmatic trials and real world evidence: Paper 3. Patient selection challenges and consequences. *Journal of Clinical Epidemiology*. 2017;89:173-180. doi:10.1016/j.jclinepi.2016.12.021

42. Hohenschurz-Schmidt D, Kleykamp BA, Draper-Rodi J, et al. Pragmatic trials of pain therapies: a systematic review of methods. *PAIN*. 2022;163(1):21. doi:10.1097/j.pain.0000000000002317

43. Nevedal AL, Reardon CM, Opra Widerquist MA, et al. Rapid versus traditional qualitative analysis using the Consolidated Framework for Implementation Research (CFIR). *Implementation Science*. 2021;16(1):67. doi:10.1186/s13012-021-01111-5

44. Lewinski AA, Crowley MJ, Miller C, et al. Applied Rapid Qualitative Analysis to Develop a Contextually Appropriate Intervention and Increase the Likelihood of Uptake. *Med Care*. 2021;59(Suppl 3):S242-S251. doi:10.1097/MLR.0000000000001553

45. Bradshaw C, Atkinson S, Doody O. Employing a Qualitative Description Approach in Health Care Research. *Global Qualitative Nursing Research*. 2017;4:2333393617742282. doi:10.1177/2333393617742282

46. Kumah E, Osei-Kesse F, Anaba C. Understanding and Using Patient Experience Feedback to Improve Health Care Quality: Systematic Review and Framework Development. *J Patient Cent Res Rev*. 2017;4(1):24-31. doi:10.17294/2330-0698.1416

47. Institute of Medicine (US) Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academies Press (US); 2001. Accessed May 20, 2024. http://www.ncbi.nlm.nih.gov/books/NBK222274/

48. Delitto A, Patterson CG, Stevans JM, et al. Stratified care to prevent chronic low back pain in high-risk patients: The TARGET trial. A multi-site pragmatic cluster randomized trial. *eClinicalMedicine*. 2021;34. doi:10.1016/j.eclinm.2021.100795

49. Morsø L, Olsen Rose K, Schiøttz-Christensen B, Sowden G, Søndergaard J, Christiansen DH. Effectiveness of stratified treatment for back pain in Danish primary care: A randomized controlled trial. *Eur J Pain*. 2021;25(9):2020-2038. doi:10.1002/ejp.1818

50. Wells N, Murphy B, Wujcik D, Johnson R. Pain-related distress and interference with daily life of ambulatory patients with cancer with pain. *Oncol Nurs Forum*. 2003;30(6):977-986. doi:10.1188/03.ONF.977-986

51. Shi Q, Smith TG, Michonski JD, Stein KD, Kaw C, Cleeland CS. Symptom burden in cancer survivors 1 year after diagnosis. *Cancer*. 2011;117(12):2779-2790. doi:10.1002/cncr.26146

52. Caterino JM, Adler D, Durham DD, et al. Analysis of Diagnoses, Symptoms, Medications, and Admissions Among Patients With Cancer Presenting to Emergency Departments. *JAMA Netw Open*. 2019;2(3):e190979. doi:10.1001/jamanetworkopen.2019.0979

53. Park EM, Check DK, Song MK, et al. Parenting while living with advanced cancer: A qualitative study. *Palliat Med*. 2017;31(3):231-238. doi:10.1177/0269216316661686

54. Wyatt G, Sikorskii A, Tesnjak I, Victorson D, Srkalovic G. Chemotherapy Interruptions in Relation to Symptom Severity in Advanced Breast Cancer. *Support Care Cancer*. 2015;23(11):3183-3191. doi:10.1007/s00520-015-2698-5

55. Katz N. The impact of pain management on quality of life. *J Pain Symptom Manage*. 2002;24(1 Suppl):S38-47. doi:10.1016/s0885-3924(02)00411-6

56. Page R, Blanchard E. Opioids and Cancer Pain: Patients' Needs and Access Challenges. *JOP*. 2019;15(5):229-231. doi:10.1200/JOP.19.00081

57. Garland EL, Brintz CE, Hanley AW, et al. Mind-Body Therapies for Opioid-Treated Pain: A Systematic Review and Meta-analysis. *JAMA Intern Med*. 2020;180(1):91-105. doi:10.1001/jamainternmed.2019.4917

58. Sheinfeld Gorin S, Krebs P, Badr H, et al. Meta-analysis of psychosocial interventions to reduce pain in patients with cancer. *J Clin Oncol*. 2012;30(5):539-547. doi:10.1200/JCO.2011.37.0437

59. Nicholas MK. Expanding access to effective psychologically based treatments: training nurse practitioners yields dividends. *Pain*. 2014;155(9):1679-1680. doi:10.1016/j.pain.2014.06.021

60. Copur MS, Ramaekers R, Gönen M, et al. Impact of the National Cancer Institute Community Cancer Centers Program on Clinical Trial and Related Activities at a Community Cancer Center in Rural Nebraska. *J Oncol Pract*. 2016;12(1):67-68, e44-51. doi:10.1200/JOP.2015.005736

61. Vallerand AH, Musto S, Polomano RC. Nursing's role in cancer pain management. *Curr Pain Headache Rep*. 2011;15(4):250-262. doi:10.1007/s11916-011-0203-5

62. Dysvik E, Kvaløy JT, Natvig GK. The effectiveness of an improved multidisciplinary pain management programme: a 6- and 12-month follow-up study. *J Adv Nurs*. 2012;68(5):1061-1072. doi:10.1111/j.1365-2648.2011.05810.x

63. Dalton JA, Keefe FJ, Carlson J, Youngblood R. Tailoring cognitive-behavioral treatment for cancer pain. *Pain Manag Nurs*. 2004;5(1):3-18. doi:10.1016/s1524-9042(03)00027-4

64. Given B, Given CW, McCorkle R, et al. Pain and fatigue management: results of a nursing randomized clinical trial. *Oncol Nurs Forum*. 2002;29(6):949-956. doi:10.1188/02.ONF.949-956

65. Given C, Given B, Rahbar M, et al. Effect of a cognitive behavioral intervention on reducing symptom severity during chemotherapy. *J Clin Oncol*. 2004;22(3):507-516. doi:10.1200/JCO.2004.01.241

66. Pa H, R T, R T, J P, N G, Jg C. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of biomedical informatics*. 2009;42(2). doi:10.1016/j.jbi.2008.08.010

67. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform*. 2019;95:103208. doi:10.1016/j.jbi.2019.103208

68. Qualitative Methods in Rapid Turn-Around Health Services Research. Published December 11, 2013. Accessed August 1, 2023. https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=780

69. Keefe FJ, Caldwell DS, Williams DA, et al. Pain coping skills training in the management of osteoarthritic knee pain: A comparative study. *Behavior Therapy*. 1990;21(1):49-62. doi:10.1016/S0005-7894(05)80188-1

70. Keefe FJ, Caldwell DS, Baucom D, et al. Spouse-assisted coping skills training in the management of osteoarthritic knee pain. *Arthritis & Rheumatism*. 1996;9(4):279-291. doi:10.1002/1529-0131(199608)9:4<279::AID-ANR1790090413>3.0.CO;2-6

71. A Behavioral Cancer Pain Intervention: A Randomized Noninferiority Trial Comparing In-person to Videoconference Delivery - PMC. Accessed August 24, 2023. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10141528/

72. Somers TJ, Winger JG, Fisher HM, et al. Behavioral cancer pain intervention dosing: results of a Sequential Multiple Assignment Randomized Trial. *Pain*. 2023;164(9):1935-1941. doi:10.1097/j.pain.0000000000002915

73. Insightmg. AAPM Statement on Scope of Practice in Pain Medicine. AAPM. Published April 3, 2019. Accessed May 22, 2023. https://painmed.org/aapm-statement-on-scope-of-practice-in-pain-medicine/

74. Borrell-Carrio F. The Biopsychosocial Model 25 Years Later: Principles, Practice, and Scientific Inquiry. *The Annals of Family Medicine*. 2004;2(6):576-582. doi:10.1370/afm.245

75. Reeves L, OTD, Sako OM, et al. Role of OT in comprehensive integrative pain management | AOTA. Published May 2, 2022. Accessed June 16, 2023. https://www.aota.org/practice/practice-essentials/quality/quality-resources/role-of-ot-pain-management

76. Coronado RA, Brintz CE, McKernan LC, et al. Psychologically informed physical therapy for musculoskeletal pain: current approaches, implications, and future directions from recent randomized trials. *PAIN Reports*. 2020;5(5):e847. doi:10.1097/PR9.0000000000000847

77. Godfrey E, Wileman V, Galea Holmes M, et al. Physical Therapy Informed by Acceptance and Commitment Therapy (PACT) Versus Usual Care Physical Therapy for Adults With Chronic Low Back Pain: A Randomized Controlled Trial. *J Pain*. 2020;21(1-2):71-81. doi:10.1016/j.jpain.2019.05.012

78. Powell BJ, Beidas RS, Lewis CC, et al. Methods to Improve the Selection and Tailoring of Implementation Strategies. *J Behav Health Serv Res*. 2017;44(2):177-194. doi:10.1007/s11414-015-9475-6

79. Edmunds JM, Beidas RS, Kendall PC. Dissemination and Implementation of Evidence-Based Practices: Training and Consultation as Implementation Strategies. *Clin Psychol (New York)*. 2013;20(2):152-165. doi:10.1111/cpsp.12031

80. L Z, Kd L, Jn DO, et al. A cluster randomized controlled trial comparing Virtual Learning Collaborative and Technical Assistance strategies to implement an early palliative care program for patients with advanced cancer and their caregivers: a study protocol. *Implementation science : IS*. 2021;16(1). doi:10.1186/s13012-021-01086-3

81. Perez J, Niburski K, Stoopler M, Ingelmo P. Telehealth and chronic pain management from rapid adaptation to long-term implementation in pain medicine: A narrative review. *Pain Rep*. 2021;6(1):e912. doi:10.1097/PR9.0000000000000912

82. Tauben DJ, Langford DJ, Sturgeon JA, et al. Optimizing telehealth pain care after COVID-19. *Pain*. 2020;161(11):2437-2445. doi:10.1097/j.pain.0000000000002048

83. Barrett D, Brintz CE, Zaski AM, Edlund MJ. Dialectical Pain Management: Feasibility of a Hybrid Third-Wave Cognitive Behavioral Therapy Approach for Adults Receiving Opioids for Chronic Pain. *Pain Medicine*. 2021;22(5):1080-1094. doi:10.1093/pm/pnaa361

84. McCormick ZL, Walega DR. Managing Patient Expectations Is Vital to Successful Pain Management. *Pain Medicine*. 2019;20(7):1453-1454. doi:10.1093/pm/pny301

85. Wiering B, de Boer D, Krol M, Wieberneit-Tolman H, Delnoij D. Entertaining accurate treatment expectations while suffering from chronic pain: an exploration of treatment expectations and the relationship with patient- provider communication. *BMC Health Services Research*. 2018;18(1):706. doi:10.1186/s12913-018-3497-8

86. Geurts JW, Willems PC, Lockwood C, van Kleef M, Kleijnen J, Dirksen C. Patient expectations for management of chronic non-cancer pain: A systematic review. *Health Expect*. 2017;20(6):1201-1217. doi:10.1111/hex.12527