Pain Management Strategies in Patients with Knee Osteoarthritis and Hypertension: Use, and Differences in Pain and Arthritis Pain Self-Efficacy

by

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University of Pittsburgh, 2022

Background: Chronic pain caused by knee osteoarthritis has a negative impact on patients' quality of life. The prevalence of hypertension is high among patients with knee osteoarthritis, and usage of pain medications can increase patients' blood pressure.

Purpose: 1) Describe characteristics of pain and non-pharmacological pain management strategies used by participants with knee osteoarthritis and hypertension in daily life; 2) Categorize pain management strategies and assess frequency and patterns of strategies patients used; and 3) Examine the effectiveness of pain management strategies on pain, and their relationship with pain self-efficacy.

Method: This secondary analysis of data from a randomized controlled trial used qualitative and quantitative methods to address the aims. Seventy individuals from the 6-month intervention arm were included in this study. Qualitative data for Aims 1 and 2 were collected by semi-structured interview. Quantitative data for Aim 3 included participants' knee pain, bodily pain, and pain self-efficacy, measured by Western Ontario and McMaster Universities Osteoarthritis Index, Short Form-36v2 Bodily Pain subscale, and Arthritis Pain Self-efficacy subscale, respectively, at baseline, immediate post-intervention, and 6 months post-intervention. Constant comparative and content analyses were used in Aims 1 and 2, respectively, to describe and summarize pain and pain management strategies that participants used. Linear mixed modeling was used in Aim 3 to assess differences in pain and pain self-efficacy for pain management strategies over time.

Results: On average, participants employed five pain management strategies. The most commonly used strategies were practicing physical self-care activities, performing psychological self-care activities, being active, changing position, and avoiding overuse. Pain management strategies were categorized into treatment strategies only and both preventative and treatment strategies. Participants who only used treatment strategies reported significantly lower bodily pain (b=-7.94, p=.017) compared with participants who used both preventative and treatment strategies. A mediating effect of self-efficacy on the association between pain management strategies and pain was not found.

Conclusion: Participants used multiple pain management strategies to control pain, and treatment strategies were favored, which health care providers can recommend to patients. Health care providers can suggest preventative strategies that are evidenced-based and that patients find effective to control their pain.

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Preface

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1.0 Proposal

1.1 Specific Aims

Symptomatic knee osteoarthritis (OA) affects approximately 14 million Americans (Deshpande et al., 2016), significantly negatively impacts health-related quality of life including physical limitations and psychological burden and is a leading risk factor for disability (Helminen et al., 2016; Litwic et al., 2013; Zhang & Jordan, 2010). Living with chronic knee OA also imposes a financial burden, either directly from increased medical expenses or indirectly due to time lost from employment and disability (Bitton, 2009; Gupta et al., 2005). The mainstay of pharmacologic treatment for chronic knee pain due to OA is acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs) (Crofford, 2013). However, side effects of these drugs include hypertension (HTN) and, in the case of NSAIDs, increased risk for development of cardiovascular disease and stroke (Crofford, 2013; Rubin, 2005; Verdecchia et al., 2010), which is particularly a problem for persons with pre-existing HTN. Unfortunately, at least half the persons with symptomatic knee OA have co-existing HTN (Eymard et al., 2015). Given that use of acetaminophen and NSAIDs in persons with co-existing knee OA and HTN results in poorer blood pressure control, and increased morbidity and mortality, it is vital to examine non-pharmacologic pain management strategies for this population.

The long-term goal of this research trajectory is to develop effective non-pharmacological pain management strategies for people with chronic OA pain and HTN, which could be used in their daily lives to help them increase their pain self-efficacy, control their pain without prescribed medication, and therefore to improve their health-related quality of life. To achieve the long-term

goal, an important first step and the purpose of this study is to describe common strategies that older adults with co-existing knee OA and HTN self-select to use or intend to use to manage their pain. This study will also evaluate the effect of non-pharmacologic pain management strategies prescribed by their study physical therapists (PTs) on changes in pain and arthritis pain self-efficacy. Some research studies have demonstrated that the prevalence of use of one or more non-pharmacologic pain management strategies in older adults with OA, such as cognitive-behavioral therapy and physical activities, had meaningful mitigating effects on their pain and pain self-efficacy (Bennell et al., 2016; Bennell et al., 2017; Dixon et al., 2007). Therefore, it is hypothesized that older adults with both knee OA and HTN who use non-pharmacological pain management strategies prescribed by PTs will experience less chronic pain and greater pain self-efficacy. It is also hypothesized that arthritis pain self-efficacy will act as a mediator of the effect of interventionist-prescribed non-pharmacologic pain management strategies on pain level, based on Bandura's self-efficacy theory where self-efficacy was defined as people's self-judgment of their ability to perform a behavior, which may in turn assist them to control an outcome in given situations (Bandura, 1986).

This dissertation study proposes a secondary analysis of data collected during a randomized controlled trial of a 6-month physical activity intervention (Staying Active with Arthritis [STAR]) vs. attention control of health education to improve physical activity among older adults with both knee OA and HTN (R01 NR010904, PI Schlenk, ClinicalTrials.gov: NCT01280903). Qualitative and quantitative data from 70 participants who were randomized to the intervention group and completed Unit 4 of the STAR intervention in the parent study were used. The Specific Aims are to:

Aim 1: Identify, categorize, and describe characteristics of pain and pain management collected by a semi-structured questionnaire using content analysis, which include the following dimensions:

a) Perceived causes of pain, conditions that increase pain, activities that are discontinued due to pain, responses to pain, satisfaction with baseline pain management, intention to improve pain management, and times of day and specific activities during which improvement in pain management is desired
b) Pain management strategies that were used and tried in the past to improve the pain, used in the past that did not work, currently used for everyday pain and severe pain and their perceived effectiveness.
c) Pain management strategies prescribed by PTs considered for everyday pain and severe pain.

Aim 2: Examine the effect of the pain management strategies prescribed by study PTs on changes in pain and changes in arthritis pain self-efficacy from baseline to immediate post-intervention and from baseline to 6 months post-intervention in the parent study.

Hypothesis 2.1: There will be differences in changes in pain and changes in arthritis pain self-efficacy among the different pain management strategies prescribed by study PTs.

Hypothesis 2.2: Changes in arthritis pain self-efficacy will mediate the effect of the pain management strategies prescribed by study PTs on changes in pain.

This study is impactful as it is the first to qualitatively and quantitatively describe the non-pharmacological pain management strategies that people with both knee OA and HTN use in their daily life and examine the effect of pain management strategies prescribed by PTs on changes in arthritis pain and changes in arthritis pain self-efficacy. Results can guide health care professionals

to recommend non-pharmacological pain management strategies for patients with both knee OA and HTN to effectively manage their chronic pain without using traditional OA medications, which can worsen their HTN, thereby reducing HTN-related morbidity and mortality in this population.

1.2 Background

1.2.1 The Problem of Knee OA Pain

OA is one of the most prevalent chronic diseases affecting more than 30 million US adults in 2018, and the prevalence is rising as the population of older adults increases (Centers for Disease Control and Prevention, 2020). Knee OA is one of the most common forms of OA (Centers for Disease Control and Prevention, 2020). More than 19% of American adults older than 45 years are diagnosed with knee OA, and recent analyses of existing epidemiologic data demonstrate that knee OA prevalence in the US has been underestimated, especially among adults younger than age 65 years (Deshpande et al., 2016).

The knee pain caused by knee OA has significant negative impacts on health-related quality of life (Farr et al., 2013). First, knee OA can lead to physical limitations, such as walking, carrying, housekeeping, and climbing stairs, which greatly interferes with activities of daily living and recreation (Guccione et al., 1994). Second, knee pain contributes to substantial psychological burden such as depression and anxiety, which could also exacerbate the pain experience (Phyomaung et al., 2014; Ray, 2017). Third, knee pain can cause disability. OA accounted for 6.3% of all years of life lost to disability, ranking it third behind depression and alcohol use (Michaud et al., 2006). Finally, knee pain caused by OA is associated with significant economic

burden for people in the US and worldwide, due to direct medical costs and indirect costs secondary to time lost from employment owing to the disability. The total annual earning losses due to the chronic pain caused by OA are estimated at $81 billion per year (Bitton, 2009; Gupta et al., 2005). Therefore, it is important and necessary to find effective strategies to help people with knee OA manage their pain, decrease the overall costs of medical care, reduce the risk of disability, and improve their health-related quality of life.

1.2.2 Possible Treatments of Knee OA

OA is a long-term, chronic disease with no curative treatment except for total knee arthroplasty in those with severe OA. Treatment focuses on providing strategies to patients with knee OA to help them control their symptoms, such as pain, stiffness, and swelling, and improve their mobility and health-related quality of life (Arthritis Foundation, n.d.). The treatment of knee OA can be divided into three different categories: pharmacologic, non-pharmacologic, and surgical management.

1.2.3 Pharmacologic Treatment of Knee Pain, and Consequences for Persons with HTN

The most common pain management strategies patients with OA pain use are pharmacological treatments including acetaminophen and NSAIDs (Crofford, 2013). However, long-term use of any NSAIDs in doses adequate to reduce inflammation and pain can increase blood pressure in both normotensive and hypertensive individuals with an average rise in blood pressure being 1.5 mmHg, although this varies considerably (Aljadhey et al., 2012). Several studies have demonstrated that patients who use NSAIDs to manage OA pain have a significantly

higher risk of having HTN compared to patients who did not use NSAIDS (Verdecchia et al., 2010). NSAIDs induced a rise in mean BP that averaged 3.3 mmHg in hypertensive patients (Pope et al., 1993). Therefore, pharmacological treatment of OA is a problematic strategy for people to manage the chronic pain, especially for people with both OA and HTN, due to the adverse effects of analgesics and NSAIDs on blood pressure. Unfortunately, the prevalence of HTN among older persons with OA is much higher than the general population (Veronese et al., 2018). More than half of patient with OA are diagnosed with HTN. The prevalence of HTN among OA patients is even higher among men and those older than 65 years. The usage of NSAIDs can reduce the effectiveness of all antihypertensive drugs, which makes the blood pressure more difficult to control, worsens HTN, and increases the mortality rate caused by cardiovascular diseases among the people with both OA and HTN (Fanelli et al., 2017). Therefore, it is necessary to develop non-pharmacological strategies to decrease side effects of pain medication for people with both OA and HTN.

1.2.4 Non-Pharmacologic Treatment Options

Previous studies have demonstrated that non-pharmacologic approaches play an important role in management of chronic pain among people with OA, such as exercise and cognitive-behavioral therapy (Arthritis Foundation, n.d.), but the effectiveness among patients with both OA and HTN is not clear. Although some studies demonstrated the prevalence of use of one or more non-pharmacologic pain management strategies in older adults, there is limited evidence demonstrating which categories of non-pharmacologic pain management strategies older adults with both OA and HTN use and the effectiveness of these categories with respect to pain management, making it difficult for health care professionals to make recommendations.

1.2.5 Surgical Treatment Options

Surgical management, involving Total Joint Arthroplasty (TJA), is a major advance in the treatment of knee OA for patients for whom conservative medical therapy has failed. During the procedure, the damaged joint is removed and replaced by a metal, plastic, or ceramic device called a prosthesis (OrthoInfo, 2014). Although TJA is a relatively safe procedure and has good effectiveness for OA symptoms, studies have identified potential risks of readmission and complications following the surgery (Courtney et al., 2017). At the same time, recovery from total knee procedures involves discomfort, rehabilitation, time off work, and potential out-of-pocket costs. Therefore, these burdens of surgical treatment provide further motivation for maximizing the usage of non-pharmacological approaches (Hung, et al., 2019).

1.2.6 Theoretical Model

This proposed research is guided by Bandura's (1986) self-efficacy theory derived from social cognitive theory, which explains how an individual's beliefs about their capability to deal with challenges can influence their behavior choices and therefore determine their final outcomes. Self-efficacy theory posits that the types of outcomes depend largely on people's judgment of their ability to control the outcome in given situations. People who believe they have the ability to control the situation are likely to utilize the coping skills they learned to decrease the negative outcome (Bandura, 1986). Based on results of previous studies and Bandura's self-efficacy theory, there are reciprocal relationships between pain and pain self-efficacy (Figure 1), but in this study, we postulate that arthritis pain self-efficacy is a mediator mediating the relationship between

interventionist-prescribed pain management strategies and pain. Of interest is the cause and effect of pain self-efficacy on pain.

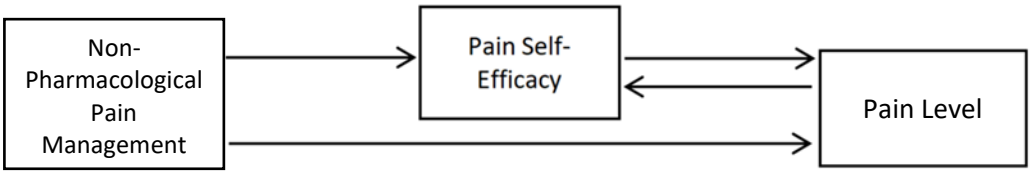


Figure 1 Study Model

1.2.7 The Role of Self-Efficacy

Based on previous studies related to non-pharmacological treatments for people with OA, pain self-efficacy is an important mediator increased by using non-pharmacological pain managements, such as physical activities and cognitive behavioral therapy (Miles et al., 2011). However, this relationship is not clear among people with both OA and HTN. Understanding the association between non-pharmacological pain management strategies and pain self-efficacy, the association between non-pharmacological pain management strategies and pain level, and the association between pain self-efficacy and pain level is necessary for health care providers to develop more effective pain management strategies for people with both OA and HTN to help them improve pain self-efficacy and therefore decrease their pain level.

1.3 Significance

Our study is significant because the results can guide health care professionals to recommend categories of much safer non-pharmacological pain management strategies for patients with OA and HTN to effectively manage their chronic pain. Using non-pharmacological pain management strategies can decrease the usage of pain medication and therefore prevent the prescription cascade, decrease the likelihood of aggravation of HTN caused by pain medication strategies for people with HTN, and reduce the HTN-related morbidity and mortality. The contribution of this proposed study is to examine the effectiveness of pain management strategies used daily by patients and find effective non-pharmacological pain management plans for people with both OA and HTN, which could have a significant positive impact on the field of public health because it can help them to: 1) decrease the chronic OA pain, 2) reduce the side effect of NSAIDs, 3) better control the blood pressure, and 4) decrease the morbidity and mortality caused by cardiovascular diseases. Understanding the current strategies that older adults with co-existing knee OA and HTN use, and the effect of pain management strategies prescribed by PTs on changes in pain is the first step to develop effective non-pharmacological treatment for people with OA and HTN. This knowledge can inform the development of guidelines for non-pharmacological pain management categories that patients can use to control the OA pain without the influence on blood pressure.

1.4 Innovation

The proposed study is the first study to (1) quantify qualitative data describing the non-pharmacologic pain management strategies used and intended for use by older adults to relieve OA knee pain, (2) examine the effect of interventionist-prescribed pain management strategies on changes in pain and changes in arthritis pain self-efficacy, and (3) examine arthritis pain self-efficacy as a mediator of the effect of interventionist-prescribed pain management strategies on pain.

This proposed study challenges the current use of pain medication for older people with knee OA pain and HTN and provides a new direction to control the chronic pain caused by knee OA. This study will investigate effective non-pharmacological pain management categories for these patients to substitute for the use of traditional pharmacological treatment for chronic knee OA pain and therefore decrease medication side effects. Over-the-counter medications will not be included in non-pharmacological pain management categories. Content analysis is an effective way to assess the prevalence of use of different non-pharmacological pain management strategies in people's daily life compared with the qualitative methods used in previous studies. The results can be used to inform future non-pharmacologic pain management interventions, with the goal of reducing the reliance on NSAIDs and opioids to manage pain.

1.5 Preliminary Studies

The PhD candidate co-authored a narrative review about evidence-based practices for osteoarthritis management, which is summarized here (Schlenk & Shi, 2019). OA is a painful,

chronic joint disorder that primarily affects the hands, knee, hips, and spine. OA risk factors can be categorized as personal and joint-related, such as genetics, age, female gender, obesity, joint injury, and vigorous usage of joints (Deshpande et al., 2016). The most common symptoms are pain, stiffness, and impaired function. The focus of OA management is on promoting self-management, reducing pain, improving function, and modifying the disease process (Fernandes et al., 2013; Geenen et al., 2018). There are published clinical guidelines providing recommendations for managing OA of the hand, knee, and hip. The OA management can be categorized into three groups, pharmacological treatments, non-pharmacological treatments, and surgery (Hochberg et al., 2012). Among pharmacological treatments, the most commonly used medications for OA symptoms are acetaminophen, topical capsaicin, NSAIDs, and opioids. Patients need to pay attention to the dosage, medication contraindications, and medication side effects when they use these drugs. Non-pharmacological strategies also play important roles in OA symptom management. Non-pharmacological strategies include thermal therapy, exercise, self-management, and psychological interventions. Thermal therapy can be used along with cold therapy and is indicated to reduce the muscle spasm and decrease the pain at free nerve endings. Patients with hip or knee OA can do appropriate therapeutic exercises under PT supervision to improve muscle strength and stabilize the knee joint. Self-management education aims to improve patients' skills in goal setting, decision-making, self-monitoring, and problem-solving by changing patients' behaviors including participation in physical activities, communication with health care providers, cognitive symptom management, problem-solving, and action planning. Self-management treatment has shown to produce positive outcomes in controlling OA pain, improving function and mood, and decreasing fatigue. Patients with severe pain, which does not respond to non-pharmacological treatments or medications, may need TJA. Multiple strategies can be used to

improve the OA symptoms and nurses should stay alert for updates of all different OA management strategies (Fernandes et al., 2013; Geenen et al., 2018).

1.6 Research Design and Methodology

1.6.1 Study Design

The proposed study will use a both qualitative and quantitative method. Descriptive qualitative design and longitudinal comparative design will be used in this study for qualitative and quantitative methods, respectively. For Aim 1, content analysis will be used to identify, categorize, and describe the quantified qualitative data collected from participants during Unit 4 of the parent study, Being Physically Active When You Have Pain, including the (1) assessment of pain, such as the cause of pain, conditions that increase pain, and activities and responses when having pain, and (2) evaluation of pain management, such as satisfaction, intention to modify pain management strategies, and personal goal of pain management. For Aim 2, based on the similarity of non-pharmacological pain management strategies suggested by the study PTs at the end of Unit 4, participants will be classified into at least 3 groups for use in the quantitative data analysis. A longitudinal comparative design will be used to examine the effect of the categorized pain management strategies suggested by study PTs and used by participants on the following quantitative data: changes in pain scores and changes in arthritis pain self-efficacy scores from baseline to immediate post-intervention and from baseline to 6 months post-intervention (See Appendix A).

1.6.2 Setting and Sample

The sample for this proposed study is comprised of 70 community-living participants randomly assigned to the intervention arm of the parent study (Staying Active with Arthritis or STAR, R01 NR010904, PI Schlenk, ClinicalTrials.gov identifier: NCT01280903) who completed Unit 4 Being Physically Active When You Have Pain in the parent study. The parent study was a randomized controlled trial of a 6-month self-efficacy based physical activity intervention with 6-month follow-up delivered in 6 weekly face-to-face sessions with study PTs and 9 bi-weekly telephone sessions with project nurses to 182 older adults with both knee OA and HTN (Schlenk et al., 2020). The inclusion criteria included: (1) age 50 years or older, (2) has OA of knee defined as knee pain lasting at least a month within the previous year, and (3) has HTN for which antihypertensive monotherapy or combination pharmacological treatment is prescribed. People who received cortisone or Synvisc injection in the past 6 month or were scheduled to undergo a major surgical procedure in the next 13 months were excluded from the parent study. Seventy participants will be included in this dissertation research. To be included in this proposed study, participants must (1) have participated in the intervention arm of the parent study, (2) have completed Unit 4 Being Physically Active When You Have Pain, and (3) have Time 0 (baseline) data on the pain and arthritis pain self-efficacy measures in the parent study. (See Figure 2)

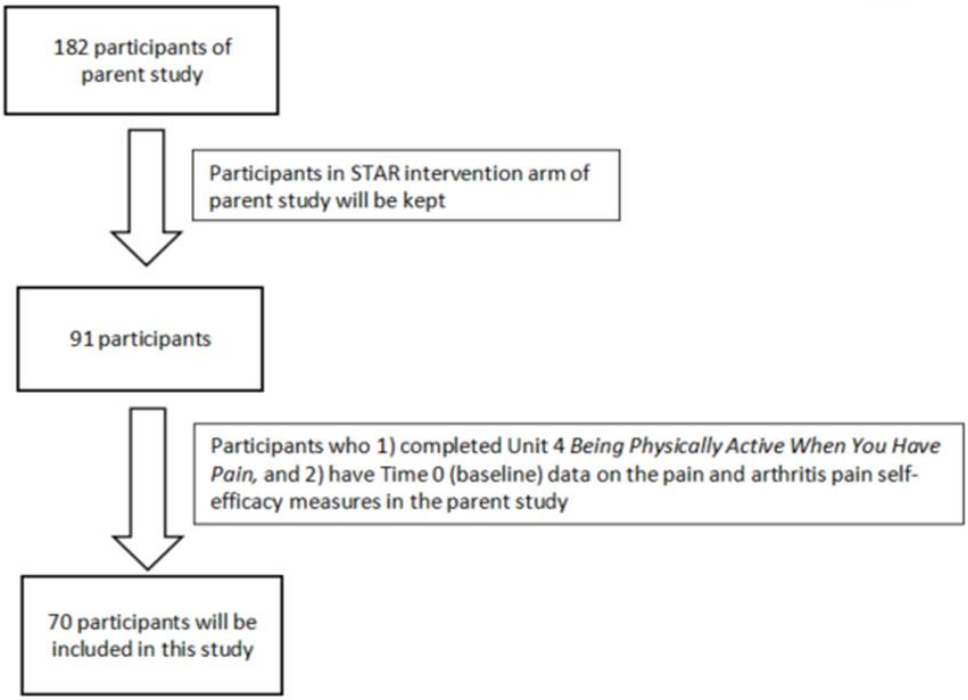


Figure 2 Participant Selection Flowchart

1.6.3 Protection of Research Participants

The University of Pittsburgh Human Research Protection Office granted approval for this dissertation study (see Appendix B). This proposed study and the parent study follow the United States Federal Policy for the Protection of Human Subjects. Prior to participation in the parent study, the participants completed informed consent procedures.

1.6.4 Description of Variables and Measures

1.6.4.1 Aim 1: Pain Management Strategies

Pain management strategies were assessed with a 20- to 30-minute interview in the parent study using 12 open-ended questions and 5 yes-or-no questions during Unit 4 (see Appendix C).

These questions covered the following areas: (1) perceived causes of pain, conditions that increase pain, activities that are discontinued due to pain, responses to pain, satisfaction with baseline pain management, intention to improve pain management, and goals to improve pain management during which times of day and which activities; (2) pain management strategies that were used and tried in the past to improve the pain, used in the past that did not work, currently used for everyday pain and severe pain and their perceived effectiveness; and (3) pain management strategies prescribed by study PTs considered for everyday pain and severe pain.

1.6.4.2 Aim 2: Independent Variable: Pain Management Strategies Prescribed by the Study PTs

At the end of Unit 4, the study PTs would provide one or more pain management strategies based on the participants' responses to the questions described above. The types of strategies that the study PTs may have prescribed included the following: physical activity, relaxation, massage, distraction, warm bath or shower, heat or cold treatment on joints, balance of activity and rest (pacing), sleep hygiene, strategies to manage stress and depression, and other (specify) (see Table 1). Based on a preliminary review of Unit 4 interview data, to make the sample size large enough for each pain management strategy group, the PhD candidate anticipates that similar pain management strategies will be collapsed into about two, possibly three groups and participants will be equally divided into these three categories of non-pharmacological intervention prescribed by study PTs. The reasons and procedure of collapsing pain management strategies will be explained in 1.6.5 and 1.6.8.1. The potential problem related with collapsing of pain management strategies will be discussed in 1.6.9.2 and 1.6.9.3.

Table 1 Codes for Pain Management Strategy Categories

Code	Pain Management Strategy Categories	YES = 1	NO = 0
PA	Be physically active		
R	Find ways to relax		
M	Use massage		
D	Find way to distract yourself from the pain		
PBS	Use a heated pool, bath, or shower		
HC	Use heat or cold treatment on painful joints		
AR	Find ways to balance activity with rest		
S	Get enough sleep		
SD	Find ways to decrease stress and depression		
OT	Other (specify)		

1.6.4.3 Aim 2: Dependent Variables

1.6.4.3.1 Pain

Pain was defined as an unpleasant subjective sensation influenced by many psychological and behavior factors. It was measured by self-report at three time points in the parent study; the proposed study will use data from these assessments at baseline, immediate post-intervention, and 6 months post-intervention. Two subscales measured pain: the Pain subscale of the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index and the Bodily Pain subscale of the Short Form-36v2 (SF-36v2). The WOMAC Osteoarthritis Index Pain subscale consists of a 5-item, 5-point Likert scale and measures knee joint pain for the past 48 hours. Possible scores range from 0 to 20 with higher scores indicating higher pain. Scores for the items for each knee are summed and the summed scores for the right and left knee are averaged. The WOMAC Pain subscale has good convergent validity (r = -.61), adequate 1-week test-retest reliability (r = .68), and moderate internal consistency reliability (alpha = .86) (Bellamy, 2002; Bellamy et al., 1988). The internal consistency reliability of the WOMAC Pain subscale was moderate in the parent study (alpha = 0.89).

The SF-36v2 Bodily Pain subscale consists of two items, one on a 5-point Likert scale and another on a 6-point Likert scale, and measures generalized pain over the past four weeks. Scores are standardized; possible scores were transformed with range from 0 to 100 and higher scores indicating lower pain. The SF-36 Bodily Pain subscale has good construct validity and moderate internal consistency reliability (Cronbach's alpha = .82) (McHorney et al., 1994; McHorney et al., 1993; McHorney et al., 1992). The internal consistency of the SF-36v2 Bodily Pain subscale was moderate in the parent study (Cronbach's alpha = 0.78) (see Appendix D)

1.6.4.3.2 Pain Self-efficacy

Pain self-efficacy was defined as people's beliefs about their capability to deal with pain. It was measured by self-report at three time points in the parent study; the proposed study will use data from these assessments at baseline, immediate post-intervention, and 6 months post-intervention. Self-efficacy was measured by the Arthritis Pain Self-efficacy subscale consisting of a 5-item, 10-point Likert scale that assessed the self-efficacy to perform behaviors to self-mange arthritis pain (Lorig et al., 1989). The Arthritis Pain Self-efficacy subscale has adequate construct validity, internal consistency reliability of 0.76, and test-retest reliability of 0.87 at 2-29 days (Brady, 2011). The internal consistency reliability was moderate in the parent study (Cronbach's alpha = 0.86) (see Appendix D).

1.6.4.4 Aim 2: Covariates: Demographic and Clinical Variables

Demographic and clinical variables were collected by self-report using a questionnaire during the baseline screening. Demographic variables include age, sex, race/ethnicity, marital status, education, and employment status. Clinical variables include the years of having OA and comorbid HTN.

1.6.5 Justification of the Sample Size

For Aim 1, our sample size is large enough to obtain data saturation, which means when adding more participants to the study there will be no more new perspectives or information added to the results. Previous studies suggested the minimum sample size of at least 12 to reach data saturation, so a sample size of 70 was deemed sufficient for the qualitative analysis (Clarke & Braun, 2013; Fugard & Potts, 2014; Guest, Bunce, & Johnson, 2006). The PhD candidate

anticipants collapsing the 10 pain management strategies prescribed by study PTs into three groups containing similar strategies under the guidance of the dissertation committee. After imputation of missing data, the sample size will be 70 at each of the three time points. The sample size and power analysis were computed using the statistical software PASS version 16. Hypothesis 2.1: Assuming that the participants will be equally distributed in three groups, for a linear mixed model with 70 participants total and about 23 participants per category of pain management strategies, the minimum mean difference of pain measured by WOMAC Pain subscale that can be detected is 0.82 with sufficient power (0.80) when testing hypotheses at a significance level of 0.05, intraclass correlation assumed is 0.02, and SD reported in a similar previous study and parent study being about 3.0 (Pignato et al., 2018; Schlenk et al., 2020). The previous study results reported that the effect size of non-pharmacological treatment on pain was 0.89 (Helminen et al., 2015). Hypothesis 2.2: Based on a study by Cheng et al. (2018), the correlation between self-efficacy and pain intensity is r = -0.50. Inclusion of 70 participants will permit sufficient power (.80) to detect an association as small as r = -.327 between the changes in arthritis pain self-efficacy and pain scores from baseline to immediate post-intervention and from baseline to 6 months post-intervention when testing hypotheses at a significance level of 0.05.

1.6.6 Procedure for Data Collection

1.6.6.1 Aim 1: Procedures to Collect Data

Aim 1 will focus on the STAR intervention group and the data collected during Unit 4 from Step 4 through Step 8 (see Appendix C). The participants responded to a series of questions from the study PTs during Unit 4. These questions included (1) perceived causes of pain, conditions that increase pain, activities that are discontinued due to pain, responses to pain, satisfaction with

baseline pain management, intention to improve pain management, and goals to improve pain management during which times of day and which activities; (2) pain management strategies that were tried in the past to improve the pain, used in the past that did not work, currently used for everyday pain and severe pain and their perceived effectiveness; and (3) pain management strategies prescribed by study PTs considered for everyday pain and severe pain (see Figure 3).

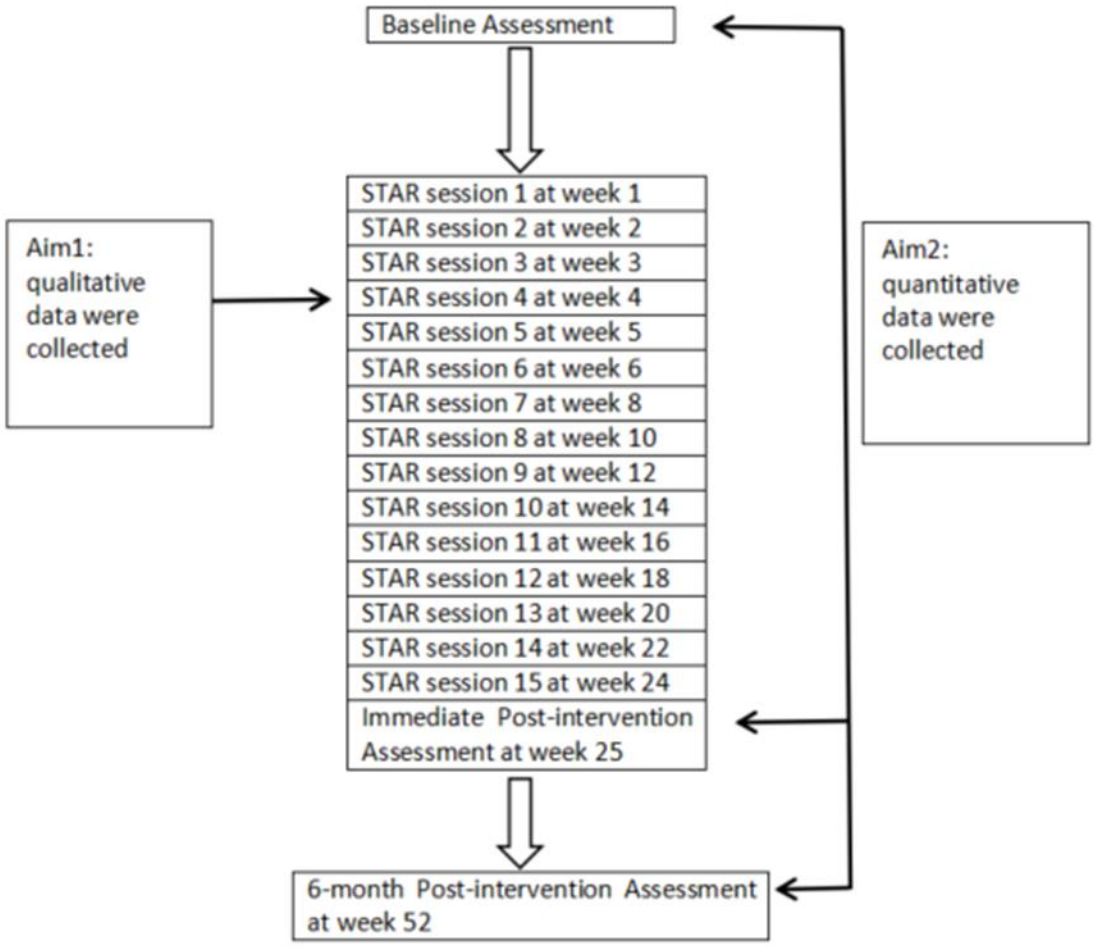


Figure 3 Timeline for Parent Study and Dissertation Study

1.6.6.2 Aim 2: Procedures to Collect Data

As Figure 3 shows, at the end of Unit 4, based on the participants' responses to the questionnaire described above in 1.6.6.1, the participants received instruction from the study PTs on pain management strategies, such as using heat and cold, relaxation strategies, pacing activities, and doing physical activities (Table 1). Participant were taught to set up individualized pain management plans according to their evaluation of their current and past pain management strategies and the pain management strategies suggested by study PTs. Based on a preliminary review of Unit 4 interview data, the PhD candidate anticipates that similar pain management strategies prescribed by study PTs will be collapsed into three groups for analysis purposes. If a participant intends to use multiple pain management strategies, a new category of the combined strategies will be established.

Pain was measured by WOMAC Osteoarthritis Index Pain subscale and the SF-36v2 Bodily Pain subscale and was assessed at baseline, immediate post-intervention, and 6 months post-intervention in the parent study. Pain self-efficacy measured by Arthritis Pain Self-Efficacy subscale was also assessed at baseline, immediate post-intervention, and 6 months post-intervention (see Figure 3).

1.6.7 Reliability and Validity of the Qualitative Coding

Reliability and validity of the qualitative coding will be addressed through establishing credibility, trustworthiness, dependability, and confirmability of the data. The University Center for Social and Urban Research (UCSUR) transcribed the audio recordings. The PhD candidate will randomly choose 5 transcripts (3 from female participants and 2 from male participants) and use these 5 transcripts to develop the codebook under the guidance of Dr. Jennifer Seaman, one of

dissertation committee members with qualitative expertise. Dr. Jennifer Seaman will also independently code an additional transcript to ensure validity of the codes, and the PhD candidate will then make any necessary refinements to the codebook. To calculate the inter-rater reliability, first, 3 transcripts will be randomly chosen and assessed by dual coding the records and computing the Cohen's Kappa (κ), where a $\kappa \geq 0.60$ will be considered acceptable (Viera & Garrett, 2005). If the $\kappa \geq 0.60$, the PhD candidate will start to code the transcripts; if not, the PhD candidate will revise the codebook and randomly choose another 3 transcripts for dual coding and calculate the Cohen's Kappa (κ). Second, to make sure that the reliability is stable during the entire coding process, the PhD candidate will randomly pick one transcript in every 5 transcripts for dual coding the records and computing the Cohen's Kappa (κ). A trained research assistant will dual code the transcripts with the PhD candidate.

1.6.8 Data Analysis

1.6.8.1 Aim 1: Qualitative Data Analysis

Qualitative data will be analyzed within a content analysis framework using NVivo Qualitative Software (Erlingsson & Brysiewicz, 2017; Zamawe, 2015). The PhD candidate will analyze each transcript and use memos to identify the key points, which will then be categorized to form initial classes used to code the transcripts. The initial classes will then be refined to identify main themes. Using NVivo Qualitative Software (Zamawe, 2015), the PhD candidate will use frequencies and percentages of themes to describe the following data:

1a: (1) perceived causes of pain, (2) conditions that increase the pain, (3) activities that are discontinued due to pain, (4) responses to pain, (5) satisfaction with baseline pain management,

(6) intention to improve pain management, and (7) goals to improve pain management during which times of day and which activities.

1b: (1) pain management strategies that were used in the past to improve the pain, and (2) the pain management strategies used in the past that did not work.

1c: baseline pain management strategies used for everyday and severe pain and their perceived effectiveness.

1d: pain management strategies prescribed by study PTs considered for everyday pain and severe pain.

For Specific Aim 1d, the PhD candidate will analyze each transcript and memo to identify the key points, which will be categorized into the 10 binary independent variables shown in Table 1. The frequency of each category will be counted as Yes or No for the participants. The original 10 pain management strategies prescribed by study PTs will be collapsed into three groups based on their similarity and overlap to ensure that a category has at least 23 participants to guarantee adequate power. The potential problem and solutions related with the sample size in each intervention category group would be discussed in 1.6.9.2 and 1.6.9.3. If a participant intends to use multiple pain management strategies, a new category of the combined strategies will be established.

1.6.8.2 Aim 2: Quantitative Data Analysis

1.6.8.2.1 Data Screening Procedures

1.6.8.2.1.1 Treatment of Missing Data

The randomness of missing data between participants and within a given participant will be investigated using available information on participant characteristics to help determine the patterns and possible mechanisms of missing data. The missing values of pain scores and arthritis pain self-efficacy scores at baseline, immediate post-intervention, and 6 months post-intervention will be dealt with by multiple imputation, imputing data for each category of pain management strategies prescribed by study PTs separately to allow for complete-data analysis, which is easy to understand and implement. The longitudinal modeling strategies will also be applied, which can accommodate data if all the missing data are either missing completely at random or missing at random.

1.6.8.2.1.2 Outlier Assessment

The outliers of categorical variables including the number of participants using different categories of pain management strategies and demographic characteristics will be checked by displaying frequency distributions. Categories with percentages lower than 10% will be considered as outliers and meaningfully combined with other categories as possible. Boxplots will be used to check the outliers of changes in WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, and Arthritis Pain Self-efficacy subscale scores from baseline to immediate post-intervention and from baseline to 6 months post-intervention for participants within each category of pain management strategies prescribed by study PTs. Outliers will be retained if results do not show significant change ($p < 0.05$) compared with the results after deleting outliers using likelihood ratio test. If there is significant difference between the results with and without identified outliers, outliers will be dealt with by using score alteration to reduce their impact and retain all participants in the study because of small sample size.

1.6.8.2.1.3 Multicollinearity

Multicollinearity will be checked by examining the correlation matrix and Variance Inflation Factors (VIF) among the predictor variables. Correlation coefficients lower than 0.90 and VIF value lower than 10 will be considered as no serious multicollinearity (Dohoo et al., 1997; Lin, 2008). If any (correlation coefficient or VIF) critical value is higher than described above, either one of the correlated predictors will be removed, or two models, each with different correlated predictors, will be estimated.

1.6.8.2.1.4 Checking Underlying Assumptions for Linear Mixed Modeling

Linear mixed modeling will be used to investigate the relationship between categories of non-pharmacologic pain management strategies prescribed by the study interventionist and changes in pain and changes in pain self-efficacy. There are some assumptions that need to be satisfied before starting the data analysis using linear mixed modeling.

1) Independent variable and dependent variables should be linear related. Since the independent variable is categorical, it is not necessary to check the linearity between non-pharmacologic pain management strategies and changes in pain and changes in pain self-efficacy. For other continuous covariates, scatterplots of the relationship between the covariates and changes in pain and changes in pain self-efficacy will be generated.
2) There should be absence of multicollinearity. This assumption can be checked by procedure described in 1.6.8.2.1.3.
3) Residuals of the difference between observed values and predicted values must be normally distributed. The normality of residuals of each outcome at each time point will be screened both statistically and graphically, with graphical assessment including histograms and quantile-quantile plots, and statistical assessment including the estimation of skewness and kurtosis and application of the Shapiro-Wilk test for distribution of residuals at each time point. If the assumption of normality is violated, data transformations will be applied to induce normality.
4) Residuals should have equal variance across groups, which is called homogeneity of variance. Homogeneity of the error term will be checked by plotting the residuals against the fitted values for each outcome at each time point.

1.6.8.2.1.5 Transformation of Data

Transformation will be used if residual normality and linearity is not satisfied. Histograms of residuals can be used to determine which transformation should be applied. A square root transformation can be used if the difference between sample distribution and normal distribution is moderate. A log base 10 transformation or inverse transformation can be considered if there is a substantial difference between sample distribution and normal distribution.

1.6.8.2.1.6 Treatment of Covariate Variables

Demographic variables including age, sex, race/ethnicity (Non-Hispanic White and others), marital status (married/partnered or not), education (the years of formal education), and employment status (full-time/part-time working or not working/retired) and clinical variables including the years of having OA and comorbid HTN will be entered in the linear mixed model as covariates.

1.6.8.2.2 Descriptive Statistics

For categorical independent variables and demographic variables, frequency counts and percentages will be used to describe the categorical variables including the number of participants using the three collapsed categories of pain management strategies prescribed by study PTs and to summarize participants' categorical baseline demographic characteristics including sex, race/ethnicity, marital status, and employment status.

For continuous dependent variables and demographic and clinical variables, descriptive statistics including means, standard deviations, and ranges will be used to describe baseline WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, Arthritis Pain Self-efficacy subscale scores, age, education, and years of having OA and comorbid HTN. Also, means, standard deviations, and ranges will be used to summarize the changes in WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, and Arthritis Pain Self-efficacy subscale scores from baseline to immediate post-intervention and from baseline to 6 months post-intervention for participants using each of the three collapsed groups of pain management strategies prescribed by study PTs. Distribution of changes in WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, and Arthritis Pain Self-efficacy subscale scores will be depicted in histograms and checked by quantile-quantile plots. If the normal distribution assumption is not satisfied, medians and range will be reported.

1.6.8.2.3 Statistical Analysis of Demographic and Clinical Characteristics

To compare the difference of demographic and clinical characteristics of participants using three collapsed categories of non-pharmacological interventions prescribed by interventionists, one-way ANOVA for continuous variables and Pearson Chi-Square test will be used for continuous and categorical variables, respectively. If the cell size is smaller than 5, Fisher's exact test will be used for categorical variables.

Two assumptions related with one-way ANOVA should be checked before conducting the analysis: normality of dependent variables and equal variance. It is not necessary to check the normality of continuous demographic and clinical characteristics in each of the three collapsed groups since the one-way ANOVA is considered a robust test against the normality assumption. For homogeneity of variances, Levene's test will be applied, and if the data fail this assumption, Welch adjustment will be used to adjust the results.

1.6.8.2.4 Statistical Analysis of Hypothesis 2.1

To test Hypothesis 2.1 (There will be differences in changes in pain and changes in arthritis pain self-efficacy among the different pain management strategies prescribed by PTs), the PhD candidate will perform repeated measures modeling using SAS 9.4 to deal with correlated measurement at different time points within participants. In particular, PROC MIXED in SAS will be used to fit the mixed model to investigate the relationship between three groups of non-pharmacologic pain management strategies prescribed by the study interventionist and outcomes. All testing will be two-sided, with a significant level of $p < 0.05$ and a trend level of $0.05 \leq p < 0.10$.

The first step is to determine if random coefficient is needed in the model. Random intercept model with time and baseline outcome score as covariates, and random coefficient model including random effect for time and baseline outcome as covariates will be fitted. Fit indices (e.g., Akaike's information criterion, Schwarz's Bayesian information criterion) will be used to evaluate the repeated measures models estimated assuming different covariance structures to identify the most appropriate model. Likelihood-ratio Chi-square test will be used to check the difference between the random intercept model and the random coefficient model. If the result is significant, the random coefficient model will be used in the next step. If the result is not significant, the random intercept model will be used in the next step.

The second step is to determine the significant covariates in the model, potential demographic and clinical covariates identified as having effects on outcomes would be added into the linear mixed model one by one, which include age, sex, race/ethnicity, marital status, education, employment status, and duration of having OA and comorbid HTN. Wald test will be

used to test the main effects included in the model. The covariate will be kept in the model if the p-value is smaller than 0.05.

The third step is to determine the significance of interaction terms between three groups of non-pharmacologic pain management strategies prescribed by the study interventionist and time. Wald test will be used to test the interaction effects. The interaction will be kept in the model if the p-value is smaller than 0.05. Since demographic and clinical characteristics are not the focus of this dissertation study, the interaction term between three groups of non-pharmacologic pain management strategies prescribed by the study interventionist and the clinical and demographic factors will not be tested in the model.

The final model should only include the three groups of non-pharmacologic pain management strategies prescribed by the study interventionist, time, baseline outcome values, and significant covariates and interaction term. Standardized regression coefficients, coefficients' p-value calculated by Wald test, and their confidence interval will be reported.

1.6.8.2.5 Statistical Analysis of Hypothesis 2.2

To address Hypothesis 2.2 (Changes in arthritis pain self-efficacy will mediate the effect of the pain management strategies prescribed by PTs on changes in pain), the PhD candidate will perform a simple mediation analysis using the change scores from baseline to immediate post-intervention and from baseline to 6 months post-intervention for WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, and Arthritis Pain Self-efficacy subscale scores. StataSE 15 will be used to implement the mediational analyses (UCLA Institute for Digital Research & Education Statistical Consulting). Significance level will be set to $p < 0.05$ and a trend will be set to $0.05 \leq p < 0.10$.

Three linear mixed model will be fitted as the first step for the mediation analysis (Baron & Kenny, 1986; Hayes, 2009). In these models Y_O is the dependent variable, X_I is the independent variable and X_M is the mediator. γ_1, γ_2, and γ_3 represent the intercepts for each model, while ε_1, ε_2, and ε_3 represent the error term for each equation. 1) The first linear mixed model is to examine the association between categories of pain management strategies prescribed by PTs (independent variable) and changes in pain from baseline to immediate post-intervention and from baseline to 6 months post-intervention (dependent variable): $Y_O = \gamma_1 + \tau X_I + \varepsilon_1$. 2). The second linear mixed model is to examine the association between categories of interventionist-prescribed pain management strategies (independent variable) and changes in pain self-efficacy from baseline to immediate post-intervention and from baseline to 6 months post-intervention (mediator): $X_M = \gamma_2 + \alpha X_I + \varepsilon_2$. 3). The third linear mixed model is to examine the association between categories of pain management strategies prescribed by study PTs (independent variable), the changes in arthritis pain self-efficacy (mediator) and the changes in pain from baseline to immediate post-

intervention and from baseline to 6 months post-intervention (dependent variable): $Y_O = \gamma_3 + \tau' X_I + \beta X_M + \varepsilon_3$.

The second step is to measure if there is mediation effect of change in pain self-efficacy between categories of pain management strategies prescribed by study PTs and change in pain The mediation effect is significant if the mediator is significantly related with the independent variable in both model 2 and model 3, and at the same time τ' in model 3 is smaller in absolute value than the original effect for the independent variable (τ in model 1) (Hayes, 2009). Sobel test will be also used to check the full mediation or partial mediation (Sobel, 1982; Sobel, 1986). The output will include the indirect, direct, and total effects. To obtain the standard errors and 95% confidence intervals for the indirect effect, 1000 bootstraps will be used in this dissertation study (Hayes, 2009).

1.6.9 Study Limitations, Potential Problems with Procedures, and Alternative Approaches to Achieve Specific Aims

1.6.9.1 Study Limitations

There are four limitations in this dissertation study. 1) A study limitation is that secondary data analysis could decrease the validity of the study, since this proposed study will use existing data to describe the non-pharmacological pain management strategies people with knee OA and HTN use in their daily life and examine the effect of pain management strategies prescribed by study PTs on changes in pain and changes in arthritis pain self-efficacy. However, although the parent study was designed to measure the effectiveness of the STAR intervention on clinical outcomes for older adults with knee OA and HTN, the interview questionnaire during Unit 4 was designed to measure the pain and pain management people used and intend to use in their daily

life, which was not analyzed during the parent study and has good face validity to assess pain and pain control strategies. 2) Since observational data will be used in this dissertation study, the results cannot be used to make causal inferences. The results can only be interpreted as the relationship between pain management strategies and outcomes evaluated in this dissertation study, if such a relationship is demonstrated. 3) Participants' usage and adherence to the pain management strategies prescribed by study PTs was not recorded by the study. Participants may not use the pain management strategies suggested by study PTs. The PhD candidate assumes that participants did use pain management strategies prescribed by PTs with similar frequency. 4) The effectiveness of pain management strategies prescribed by the PT is dependent on whether or not the strategies are already used (past or currently) by the patient. They would not prescribe as new a strategy that is already used. Therefore, some participants may receive a few new 'prescriptions'. Participants' different current pain management experience will affect the effectiveness of this 'new prescriptions' variable. 5) The sample size is small for the mediation analysis. Partial mediation might be reported in the study, but this relationship should be confirmed using a larger sample. Latent growth curves model could be used in the future if the sample size would be larger.

1.6.9.2 Potential Problems with Procedures

There might be two potential problems in the procedure. First, in Aim 2, it is expected that similar pain management strategies prescribed by study PTs will be collapsed into three categories and participants will be divided into these three groups. However, it is possible that there will be imbalance between these three different groups, which could cause small group sizes and low power. Second, the STAR intervention in the parent study may have an influence on the effectiveness of the pain management strategies prescribed by study PTs.

1.6.9.3 Alternative Approaches to Achieve Specific Aims

For the first potential problem, if any group's sample size is smaller than 10, the PhD candidate will consider combining it with another non-pharmacological management category based on their similarity. For the second potential problem, since the proposed study will only use the data collected from participants in the parent study's intervention group, the influence of the STAR intervention could be regarded as a controlled factor, which would not affect the results of this dissertation study.

1.6.10 Time Line

The PhD candidate has already started data analysis for the qualitative part of this dissertation study. The data analysis for the qualitative part will be completed during Fall term 2021. The data analysis for the quantitative portion of this dissertation study will be completed at the beginning of Spring term 2022. The PI will complete the dissertation writing and hold the defense in Summer term 2022. Three manuscripts, two for the qualitative part and one for quantitative part, will be written after completing the data analysis. The PhD candidate plans to graduate in Summer term 2022.

2.0 Summary of Study

2.1 Introduction

The results of this study are presented in two qualitative manuscripts and one quantitative manuscript. The manuscripts were developed sequentially as subsequent manuscripts built upon findings reported in a previous manuscript.

1. Descriptive qualitative analysis of pain and pain management strategies in participants with knee osteoarthritis and hypertension
2. Content analysis of non-pharmacological pain management strategies used by participants with knee osteoarthritis and hypertension
3. Association between types of pain management strategies, knee osteoarthritis outcomes, and arthritis pain self-efficacy

Appropriate journals will be selected for each manuscript. The manuscripts will be formatted for the selected journals, which may slightly change the presentation and style seen here.

2.2 Changes to Aims

2.2.1 New Aim

One more aim was added before the original Aim 1. The new Aim 1 was to use the qualitative data, collected during interview of Unit 4 in the parent study, to identify and describe

characteristics of pain and pain management strategies used by older adults with knee OA and hypertension in the course of daily life.

2.2.2 Aim 1 Change

Part c of the original Aim 1 was removed from Aim 1. Part c of Aim 1 was to identify, and categorize, pain management strategies prescribed by PTs for participants to consider using for everyday pain and severe pain. However, many of the tailored interviews did not ask this question. Further, the original Aim 2 was also changed as discussed below, which affected Part c of Aim 1. Pain management strategies prescribed by PTs for participants to consider using for everyday pain and severe pain was no longer of interest. Therefore, Part c of Aim 1 was removed from this study.

Part a of the original Aim 1 was also removed. Part a of Aim 1 was to identify and categorize characteristics of pain including causes of pain, conditions that increase pain, activities that are discontinued due to pain, and responses to pain and participants' satisfaction with the pain management. Since we added a new aim to use the constant comparative analysis method to describe the characteristics of pain and pain management strategies, it is not necessary to report similar findings again. This aim would only focus on classifying pain management strategies participants used for everyday pain and severe pain into categories and types in preparation for the quantitative analysis for the new Aim 3.

Since one more aim was added before original Aim1, original Aim 1 became Aim 2. Therefore, the original Aim 1 (now Aim 2) was changed to using qualitative constant comparative analysis to identify patterns in the use of pain management strategies and describe the number and types of pain management strategies used by participants with knee OA and hypertension.

2.2.3 Aim 2 Change

The original second Aim (now Aim 3) proposed in the dissertation proposal was to examine the effect of the pain management strategies prescribed by study PTs on changes in pain and changes in arthritis pain self-efficacy. However, the number of missing values of pain management strategies prescribed by study PTs was larger than 1/3 of the sample size, and many participants preferred to continue to use their previous pain management strategies. Additionally, pain management strategies participants used had no missing values. Therefore, the new Aim 3 was changed to examine the effect of pain management strategies participants used on changes in pain and changes in arthritis pain self-efficacy from baseline to immediate post-intervention and from baseline to 6 months post-intervention in the parent study.

2.3 Changes to Main Variables

The independent variable in original Aim 2 in the dissertation proposal was pain management strategies prescribed by the study PTs. However, more than 1/3 of the tailored interviews did not cover the topic about the pain management strategies prescribed by study PTs. Therefore, the independent variable in original Aim 2 was changed to the pain management strategies used by participants. The qualitative results indicated that strategies could be categorized into two types based on the reasons for using the strategies: to prevent pain before having pain or to treat pain while having pain.

2.4 Changes to the Statistical Power Analysis for the Study

The statistical power calculated in the dissertation proposal was based on assuming three balanced pain management strategy groups would result from the qualitative analysis. However, the qualitative results indicated that pain management strategies used by participant meaningfully collapsed into two groups and the sample sizes for the two groups were not similar. Therefore, the power analysis for new Aim 3 was modified as two pain management strategy groups with the observed unbalanced sample size. The intra-class correlation coefficient, total sample size, alpha level, and standard deviation remained the same.

2.5 Addition of Two Analyses

2.5.1 Exploratory Analysis: Examine the Association between Number of Pain Management Strategies and Outcomes Including Pain and Self-efficacy

The results of the qualitative study showed that all participants were using multiple pain management strategies at the same time to treat and/or prevent the pain caused by knee OA. The number of pain management strategies participants used at the same time might influence the participants' pain and pain self-efficacy. Therefore, an exploratory analysis was added into the study to examine the association between number of pain management strategies and outcomes (pain and pain self-efficacy). The hypothesis was that as the number of pain management strategies increase, the participant would have lower pain and higher pain self-efficacy. A similar analysis

procedure as in original Aim 2 Hypothesis 2.1 was used, except the independent variable was changed from pain management strategy groups to numbers of strategies. Number of strategies participants used was considered as a continuous variable. The manuscript would not report the results if there was a non-significant relationship.

2.5.2 Comparison of the Study Samples and Dropouts

The sample for this proposed study was comprised of 70 community-living participants in the intervention arm of the parent study who completed Unit 4. There were 21 participants excluded from the study because of dropout. Comparison between the study sample and the dropouts was added into the study as a check of internal validity. T-test was used to compare participants' and dropouts' continuous demographic factors including age, education, duration of having hypertension, and duration of having knee OA, and baseline value of the outcomes including pain and pain self-efficacy. Pearson Chi-square test was used to compare participants' and dropouts' categorical demographic factors including gender, race, marital status, and employment status.

2.5.3 Constant Comparative Analysis for New Aim

Constant comparative analysis was used to identify and describe the causes of pain, responses to pain, and pain management strategies participants used in daily life. The procedure was similar with the data analysis for original Aim 1, but the count for each code would not be reported, pain management strategies would not be categorized, and the study would only focus on describing the causes of pain, responses to pain, and pain management strategies.

2.6 Changes to Statistical Data Analysis Plan

2.6.1 Original Aim 2, Hypothesis 2.1 Change

Based on the qualitative study results, pain management strategies were categorized into two types. Therefore, the participants were divided into two groups instead of three proposed in the dissertation proposal and the sample sizes for the two groups were not the same. The model and statistical procedure were not changed.

2.6.2 Original Aim 2, Hypothesis 2.2 Change

The dissertation proposal reported that linear mixed model would be used in original Aim 2, Hypothesis 2.2 to examine the mediating role of self-efficacy between pain management strategy groups and participants' pain level. However, since the sample size was small in this study, two simple mediation analyses using simple linear regression were completed to examine the role of self-efficacy (Figure 4). The change in scores of pain self-efficacy from baseline to immediate post-intervention and immediate post-intervention to 6 months post-intervention were calculated as mediators for the two simple mediation analysis models. The change scores of pain from immediate post-intervention to 6 months post-intervention were calculated as the outcome variable.

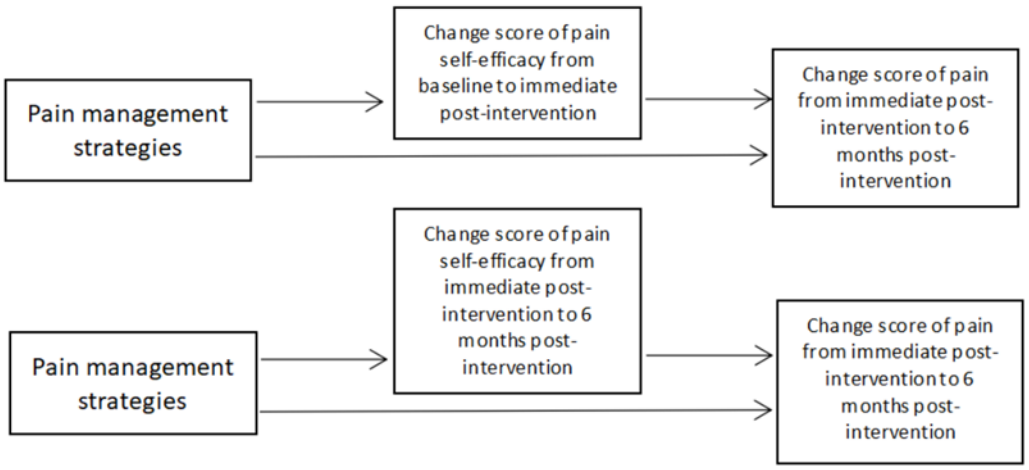


Figure 4 Models for simple mediation analysis

2.7 Strengths and Limitations

The strengths of the study for new Aims 1 and 2 include: 1) this study used rich and detailed data provided by multiple participants during the interviews; 2) the sample had good representation of the non-white population; 3) qualitative descriptive analysis plus content analysis is an effective way to determine the types of non-pharmacological strategies used and number of strategies used compared with just qualitative methods used in previous studies. The limitations of the study for new Aim 1 are: 1) this study was a secondary data analysis, and the parent study was not designed for understanding participant's pain and pain management strategies used in daily life; 2) all participants were recruited in one geographic area and most of them were female, so the results cannot be generalized to the general population of patients with knee OA and hypertension.

There are a few limitations for new Aim 3. First, this was an observational study with a small sample size, so casual relationships cannot be inferred and adequate power to find significant associations was limited. Second, participants' usage of and adherence to the pain management

strategies was not recorded by the parent study, which could influence the effectiveness of the strategies reported. However, this study had two strengths supporting new Aim 3. Most of participants completed all three measurement of the outcomes, so missing values was small. The sample had good representation of non-white population.

2.8 Implications for Global Health

Knee OA pain is a global health issue affecting 527.81 million people all over the world in 2019 (Long et al., 2022). This number is still increasing due to rising obesity and aging of the population. Knee OA pain can contribute to physical, psychological, and financial burden (Jackson et al., 2020; Litwic et al., 2013). Understanding characteristics of pain and pain management strategies patients used in daily life is an important step to develop effective non-pharmacological pain management strategies, which can be used by many patients nationally and internationally. These non-pharmacological strategies can effectively control patients' pain, improve quality of life, and decrease the usage of pain medication and side effect caused by pain medication globally.

2.9 Impact on the Science and Practice of Nursing

Understanding the characteristics of pain and pain management strategies patients used in daily life can assist health care providers to recognize the feasibility of pain management strategies and develop an effective and practical pain management strategy. The results can direct providers to suggest a bundle of treatment strategies when patients are having pain. Health care providers

can suggest preventative strategies that are evidenced-based and that patients find effective to control their pain. This study did not show a significant mediating effect of self-efficacy on the relationship between pain management strategies and pain outcomes, which was likely due to the small sample size.

2.10 Future Studies

The first step should focus on exploring specific strategies or combination of preventative and treatment strategies that are acceptable and feasible to a diverse sample of community dwelling older adults with knee OA and hypertension. The second step should focus on using small clinical trials to examine the efficacy of the specific strategies or combination of preventative and treatment strategies on pain and pain self-efficacy. For the third step, a study with a larger sample size should be done to examine the efficacy of specific strategies or combination of strategies on patients' pain and pain self-efficacy since this study found significant difference between two types of strategies with treatment strategies being more effective in controlling pain than the combination of treatment and preventative strategies. It is also necessary to validate findings in a larger group of patients, adjusted for more clinical covariates such as medication use, and severity of knee OA. At the same time, a study with large sample size should be done to check the mediation effect of self-efficacy in the association between pain management strategies and pain. Then, an effectiveness study could be conducted to examine real world applications of the specific strategies or combination of strategies on patients' pain and pain self-efficacy,

3.0 Dissertation Manuscripts

3.1 Paper 1: Pain and Pain Management Strategies in Patients with Knee Osteoarthritis and Hypertension

3.1.1 Introduction

Knee osteoarthritis (OA) is one of the most common types of OA, affecting more than 19% of American adults older than 45 years (Centers for Disease Control and Prevention, 2020). This number is still increasing as the number of older people increases (Deshpande et al., 2016). Chronic pain caused by knee OA has significant negative impacts on health-related quality of life including physical limitations and psychological burden, and it is a leading risk factor for disability (Helminen et al., 2016; Litwic et al., 2013; Zhang & Jordan, 2010). Patients often have negative responses to the pain such as depression, anxiety, and low self-efficacy, and these negative responses can also increase their pain (Axford et al., 2010; Linton et al., 2011; Rosemann et al., 2007; Somers et al, 2008). People with both knee OA and hypertension (HTN) reported higher pain levels than people with only knee OA, and the prevalence of HTN among older people with knee OA is much higher than the general population, with more than half of OA patients having a concomitant HTN diagnosis. Given the prevalence and burden of knee OA, specific pain management strategies are needed for patients to maintain optimal quality of life.

Possible pain management strategies for knee OA pain including taking medication such as acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs) (Crofford, 2013), but long-term use of any NSAIDs can increase people's blood pressure and the risk of having HTN

(Aljadhey et al., 2012). Although some studies demonstrated the prevalence of use of non-pharmacologic pain management strategies in older adults such as physical activity (Arthritis Foundation, n.d.), there is limited evidence demonstrating which categories of non-pharmacologic pain management strategies older adults with both knee OA and HTN use and the effectiveness of these categories, making it difficult for health care professionals to make recommendations.

Understanding characteristics of pain and strategies patients used to manage knee OA pain is an important step to identifying effective non-pharmacological pain management strategies, but there is little data describing pain and non-pharmacological pain management strategies used in daily life by patients with both knee OA and HTN. This lack of knowledge limits the recommendations for non-pharmacological approaches that health care providers can offer patients to control pain and may increase the usage of medication, thereby increasing the risk of cardiovascular diseases caused by taking pain medication. Therefore, the purpose of this study was to use the qualitative data, collected as part of a randomized controlled trial of a physical activity intervention, to identify, categorize, and describe characteristics of pain and pain management strategies used by older adults with knee OA and HTN during daily life.

3.1.2 Methods

This study was a secondary analysis of data collected during semi-structured interviews conducted as part of the parent study, which was a randomized controlled trial to examine the effectiveness of a self-efficacy based physical activity intervention on knee OA pain among older people with both knee OA and HTN (Schlenk et al., 2020). These interviews were conducted during the fourth intervention session at week 4 of the 24-week parent intervention. Throughout the interview, the interventionist delivered tailored educational content about non-pharmacological

pain management strategies in an interactive format based on participants' reactions to interventionists' questions. Constant comparative analysis was used to identify, categorize, and identify broader themes related to pain and pain management strategies among older adults with knee OA and HTN.

3.1.2.1 Setting and Participants

A total 70 out of 91 community-living participants in the intervention arm of the parent study were included in this study. To be included in this study, participants needed to complete Unit 4 of the parent intervention, Being Physically Active When You Have Pain, and the baseline assessment in the parent study. Eligible criteria for the parent study included the following: (1) is age 50 years or older, (2) has OA of the knee defined as knee pain lasting at least a month within the previous year, and (3) has HTN for which anti-hypertensive monotherapy or combination pharmacological treatment is prescribed. People who received cortisone or Synvisc injection in the past 6 month or were scheduled to undergo a major surgical procedure in the next 13 months were excluded from the study.

3.1.2.2 Data Collection

Three trained interventionists conducted the interviews based on a semi-structured interview guide, which included 12 open-ended questions and 5 yes-or-no questions. The interview questions asked during this unit were designed to understand participants' description of OA knee pain and pain management strategies participants used in daily life. At the same time the interventionist provided the participants with education about using non-pharmacological strategies to control pain when exercising and therefore increase participants' physical activity level.

The semi-structured individual interviews were conducted in a private room during a study visit that included a discussion about the pain and pain management strategies and a physical therapy session. All interviews were audio recorded after obtaining written consent. Participants were asked to talk freely about the major topics including: (1) causes of pain, conditions that increase pain, and activities and responses when having pain, and (2) evaluation of pain management, such as satisfaction, intention to modify pain management strategies, and personal goals for pain management. After participants answered these questions, the interventionist would provide participants with suggestions on pain management strategies based on the participants' answers to these questions. Then participants responded with their reaction to the suggestions and indication of intention to use the suggestions.

This data provided a rich source for expanding our understanding about the characteristics of pain, context of pain, and strategies participants utilized to manage pain. Approval for this study (PRO18060232) was obtained from the University of Pittsburgh Institutional Review Board.

3.1.2.3 Data Analysis

The interview audio recordings (N=70) were transcribed verbatim by trained transcriptionists at the University Center for Social and Urban Research (UCSUR), and any identifying information was redacted during transcription. The transcripts were reviewed to ensure they were accurate and complete; then they were uploaded into Nvivo qualitative data analysis software (version 12.0; 2018; QSR International Pty Ltd, Doncaster, Australia).

Two coders (J.S. and X.S.) read through five of the transcripts together using a constant comparative approach to identify emergent themes and develop a preliminary codebook (Miles et al., 1994). The coders then randomly selected five transcripts, stratified by gender and study time period, and independently coded each, assessing after each for intercoder reliability and revising

the codebook to clarify codes that were a source of disagreement. Independent coding then proceeded when a percent agreement ≥ 95% and Cohen's κ = 0.60 (Viera et al., 2005) for five serial transcripts were achieved. (The kappa for the fifth co-coded transcript was 0.05; therefore, we chose to co-code an additional transcript, for which the kappa was 0.75). The principal investigator (X.S.) then proceeded to code the remaining transcripts, with reliability checks performed on 10% of transcripts, selected at random, to ensure ongoing reliability. Members of the team met regularly to discuss any newly emergent codes; the codebook was updated as new codes were identified; and discrepancies were resolved by consensus, in consultation with members of the team.

3.1.3 Results

The demographic characteristics of the participants are summarized in Table 2. Participants were on average white, female, and 65 years old with OA and HTN for over 10 years. In their responses to the questions posed by the interventionists, participants described their reactions to pain, the activities they had to forego because of pain, the conditions and activities that caused them pain, and the multiple strategies they employed to manage pain on a daily basis.

Table 2 Participants' Demographic and Clinical Characteristics

Characteristic	Value
Age in years [Range]	65.50 [50, 86]
Female n (%)	52 (74%)
White n (%)	53 (76%)
Years of education [Range]	15.47 [7, 20]
Employed n (%)	36 (51%)
Married n (%)	35(50%)
Duration of having OA in years [Range]	11.94 [1, 37]
Duration of having HTN in years [Range]	14.73 [1, 38]

Note. HTN=hypertension, OA=osteoarthritis.

3.1.3.1 Responses to Pain

Many participants described negative emotional responses to the experience of chronic pain. They described being frustrated, sad, depressed, and tired. Many participants believed pain was a sign of aging and weakness, and it caused them to worry about loss of independence.

> *"Well, there's a psychological effect – it sort of makes me feel I guess weak and unable to take care of myself, even if it's just very temporary. That makes me wonder if, you know, how long I'm going to be able to stay independent…It's frustrating."*

However, there were also many participants' responses focused on maintaining a positive attitude to the pain. They stated that, "pain is just pain", "a part of aging" and they just wanted to "keep going".

> *"I look at it the same way I look at Crohn's pain. I mean, I've got Crohn's but it doesn't have me, so I've got arthritis but it's not going to control my life. It does make me alter things, but not change everything."*

For some participants, instead of focusing on the negative psychological reactions to pain, they considered pain as a kind of challenge and were actively engaged in efforts to reduce their pain, so they were more interested in how to decrease the pain or avoid the situation that could cause pain.

> *"It's not gonna stop me. Cause I'm thinking, everybody has some ache or pain of one kind or another, and…Not to be able to deal with it is, like, the worst thing that…could happen. You gotta deal with it, some way."*

3.1.3.2 Activities Stopped

Having pain can cause participants to limit or completely forego activities in which they previously engaged. These activities ranged from their occupational to recreational activities. These activities included instrumental activities of daily living (IADLs) such as working, gardening, and washing the floor, and recreational activities such shopping, golf, riding bikes, and skiing. Some participants expressed frustration at having to forego something they used to do or liked to do because of pain.

"I used to be able to ride a bike, and since the arthritis got really bad, I haven't been able to ride, which is sad, because that was a really good exercise, too."

However, for the majority of people, their previous activity habits or volume were not changed nor did they give up any activities in which they were interested. While some participants had to completely forego previous activities due to pain, others reported that they were able to continue activities if they modified the volume or intensity of the activity.

"Well, sometimes I don't go places because of the amount of walking. And even when I'm going to go, say, for shopping, I try to anticipate how I can handle it. Is there a place to sit down?"

3.1.3.3 Causes of Pain

Participants shared how their pain was caused by the type, timing, or intensity of different activities. Many participants described how maintaining a position or activity that involves increased weight bearing by the knee caused them to have pain or increased their pain level. These activities included going up or going down the stairs, bending the knee and lifting weights.

"I think my ma – weight's a major factor…Going up and down the steps a lot, and I will have some pain."

Too much time in one position (inactivity), such as getting up in the morning, sitting or standing for a long time, changing position after keeping one position for a long time, was commonly cited as a cause of pain. Many participants conveyed a good understanding of the causes of their pain and were thereby able to employ preventative strategies such as to "not sit too much".

"like you said, if I sit too long, definitely. And then get up. So that's why I don't sit too much…"

"I'm stiff in the morning…Even when I get up from here, I might be stiff in a few steps…But it's kind of like everything [unintelligible, laughs]is…is stiff."

In addition, too much activity (overuse) and being overtired in general could also cause or intensify pain.

"If I've been doing a lot of, like, the moving of boxes and things and I've been going up and down the steps a lot, because I'm on a second-floor apartment. I seem to be able to get enough adrenaline going to get it – do it while I'm doing it, but afterwards, I'm really uncomfortable."

"And other times when I'm just not getting enough rest, I – yeah, things do seem to ache."

Psychological stress can "contribute to increased pain", "but not that often". Although many participants had a good understanding of the causes of their pain, there were some participants that reported that the cause of pain was "not predictable" or "it's (pain) constant".

3.1.3.4 Ways of Managing Pain

In general, participants endorsed good effectiveness using the pain management strategies they described. Few participants utilized a single strategy, and most used several. Some of these strategies were used to prevent pain such as avoiding activities that could cause pain, avoiding

overusing, and exercising, and some of them were used to treat pain such as using support devices to protect the knee.

> *"I have two flights of stairs in my house, and generally I just take one flight at a time, and once in a while I have to do the two flights, but I try to avoid that…so I will not have lots of pain."*
>
> *"I usually have more pain in the morning, that's the reason I do those exercises before I have pain. I do those first thing as I get up and it helps."*
>
> *"I wear my knee brace today while I walked, and that helped! So I'll not have so much pain. Once I put that ankle brace on, it's – it feels good, but it, you know, you just can't move."*

Regarding the effectiveness of each individual pain management strategy, participants described widely varying success with the same strategy. For example, many participants reported that using cold or heat "helps" them control the pain, but there were still several people who reported that heat and cold strategies they were using were "not useful" or even "made pain worse".

Several participants reported that they would visit specialists when they had severe pain, such as a chiropractor, and specialist treatment was successful in eliminating their pain.

> *"And I called this friend of mine who's a chiropractor. And I gotta tell you something, it was like throwing a light switch. He threw—I'm t—literally, that's what it is. But (it is?)…[Interviewer laughs] he did it and the pain stopped!"*

However, as participants described their self-care strategies, some people reported that that the same treatment by specialists provided no relief, or even worsened their pain.

Participants described foregoing strategies, not because they were ineffective, but due to financial, logistical, or safety reasons.

"I used to walk track…quit secondary to time constraints of work and extra family responsibilities."

"Going for therapy…helped…but you can't do that for the rest of your life…Insurance isn't going [laughs] to cover it for the rest of your life. And it did improve, it actually did improve my pain. It actually did, but I can't…"

"I'm just afraid that when I'm exhausted and I get in that tub, I can't get out by myself. So I don't get in. So those hot treatments that could really help, I can't do it, you know. I don't want to always alert somebody."

3.1.4 Discussion

This study identified and described characteristics of pain, responses to pain, and pain management strategies that individuals with OA and HTN used in their daily life. Pain was a daily experience: some participants described negative psychological effects, although many held a positive outlook and "pushed through" their discomfort. Participants described having to limit or forego both ADLs and recreational activities. Participants reported multiple daily activities that can cause pain. Not only can too much activity cause participants to have pain, but also inactivity can cause participants to have pain. Participants employed multiple pain management strategies to control their pain. The effectiveness of pain management strategies was different for different people, but most participants reported satisfaction with their pain management strategies.

The pain related to OA has a variety of negative psychological effects such as depression and anxiety, a finding from our study as well as many other studies (Marszaleck et al., 2017; Tighe et al., 2020; Zheng et al., 2021). Our study summarized multiple conditions that could cause pain or increase pain, such as increasing weight bearing exercises, overuse or being overtired after

activities, and long periods of inactivity and feeling depressed, conditions which have been reported in previous studies (Arthritis Foundation, n.d.; Gooberman-Hill, et al, 2009; Johns Hopkins Medicine, n.d.; Mayo Clinic, 2021; Sharma et al.2016). Our study described multiple pain management strategies participants used to manage pain, which were also reported by previous studies, including using assistive devices to protect the knees, decreasing the weight borne by the knee, using one side more, and avoiding stairs (activity that could cause pain) (Hasegawa et al, 2010; Van der Esch et al., 2003; Yakhdani et al. 2010). Our findings regarding the reported effectiveness of exercise and psychological coping skills in controlling pain mirror those reported in previous studies (DiRenzo & Finan, 2019; Ismail et al. 2017; Kraus et al., 2019;).

A finding in our study that is not reported in previous studies involves the barriers to using or accessing pain management strategies that participants found detrimental. Participants gave up a strategy not because it was not effective, but for other reasons. It is necessary to optimize and develop personalized pain management plans based on participants' different backgrounds, health conditions, and responses. Providers need to ensure that there are no financial or time-related barriers to implementing effective strategies. For participants who reported safety concerns about the strategy, health care providers can consider ways to improve the accessibility and adherence to these strategies, which is an important factor affecting the strategy's outcomes (Marks, 2012; Pisters et al., 2010;).

There are a few limitations in our study. First, this is a secondary data analysis. Although the interview was designed to assess the pain and pain management people used in daily life, using existing data could decrease the validity of the study. Second, the sample was recruited from one geographic area, so the results cannot be generalized to individuals in other areas. This study also

has two strengths. Sample size was large for a qualitative study, and the sample had a good representation of the non-white population.

This study gave us a general idea about the pain management strategies participants used in daily life to manage knee OA pain, but which strategies were used most widely and their effectiveness are still not clear. A future study can focus on finding the most commonly used strategies by reporting the number of participants using each strategy and using quantitative methods to compare the effectiveness of different pain management strategies on knee OA symptoms.

In conclusion, chronic knee OA pain could have different meanings for different people. People with knee OA pain used multiple non-pharmacological pain management strategies to control their pain, and most of them showed satisfaction of these strategies. Since different people could have different reactions to the treatment, as health care providers, we should tailor approaches to include serially trialing strategies, combining these effective strategies together, and personalizing strategies for participants based on their situation. Healthcare providers should conduct more research about tailored pain management strategies to develop guidelines.

3.2 Paper 2: Non-pharmacological Pain Management for Patients with Knee Osteoarthritis and Hypertension Using a Content Analysis Approach

3.2.1 Introduction

Knee osteoarthritis (OA), a joint degenerative disease, is one of the most common chronic diseases affecting 19% of US adults older than 65 years (Deshpande et al., 2016). Knee pain is the

key concern among people with knee OA (Centers for Disease Control and Prevention, 2020). Previous studies indicated that OA pain can have a significant negative impact on patients' quality of life and leads to multiple physical and psychological burdens (Farr et al., 2013; Jackson et al., 2020). Therefore, it is necessary for people with OA to find approaches to control the pain.

Treatments for knee OA pain can be divided into two types: pharmacological and non-pharmacological interventions. Long-term use of pharmacological treatments such as non-steroidal anti-inflammatory drugs (NSAIDs) can increase the risk of cardiovascular diseases such as hypertension (HTN) (Bhala et al., 2013; Ray, 2011). The prevalence of HTN among patients with OA is much higher than populations without HTN (Zhang et al., 2017). Therefore, guidelines for controlling knee OA pain suggest non-pharmacological treatments such as physical exercise and cognitive behavior therapy (Kolasinski et al., 2020). Previous studies have shown non-pharmacological treatment can effectively decrease pain and improve function and self-efficacy (Benyon et al., 2010; Helminen et al., 2015; O'Moore et al., 2018; Uritani et al., 2021). Although health care providers give patients many suggestions about pain control techniques, it is not clear what strategies patients use in daily life and, of these, what strategies are the most practical and effective in controlling pain.

Our prior descriptive qualitative work (Shi et al., 2022a) showed that participants with knee OA and HTN used combinations of pain management strategies, including those to prevent and those to treat pain. Furthermore, participants offered widely varied endorsement of commonly cited strategies. A more in-depth examination of the data (in this instance, participant interviews) using qualitative content analysis provides the opportunity to identify patterns in the use of pain management strategies and yields participant-level quantitative data that can then be compared to measures of pain and pain self-efficacy (Elo & Kyngäs, 2008). The purpose of this study was to

use deductive qualitative content analysis to describe the number and types of pain management strategies used by participants with knee OA and HTN.

3.2.2 Methods

This study was a secondary analysis of qualitative data collected as part of a randomized controlled clinical trial. The parent study examined the effectiveness of a self-efficacy based physical activity intervention on knee OA pain among older people with both knee OA and HTN (Schlenk et al., 2020). Qualitative content analysis was used to identify patterns in the use of pain management strategies, describing the number and types of pain management strategies used by participants diagnosed with both knee OA and HTN.

3.2.2.1 Setting and Participants

The sample for this analysis were 70 community-living participants who were enrolled in the intervention arm of the parent study, a randomized clinical trial of an exercise intervention. All participants completed Unit 4 of the physical activity intervention and baseline assessment of the parent study (Schlenk et al., 2020). All participants were > 50 years of age and had a diagnosis of both knee OA and HTN.

3.2.2.2 Data Collection

The data were collected by individual semi-structured interviews with study participants, during Unit 4 at week 4 of the 24-week intervention in the parent study. Three trained interventionists conducted the interviews. Each interview included 12 open-ended questions and 5 yes-or-no questions and was designed to explore participants' responses to pain and pain

management strategies participants used in daily life. All interviews were audio-recorded and were later transcribed by trained research transcriptionists. We reported the details of data collection in our previous qualitative descriptive study (Shi et al., 2022a).

3.2.2.3 Data Analysis

The semi-structured interviews explored multiple aspects of participants' experiences with pain including causes of pain, responses to pain, pain control strategies, and activities that participants had stopped due to pain. This study focused exclusively on the strategies participants used to control knee OA pain. Specifically, this study evaluated participants' responses to two open-ended questions about pain management strategies from the parent study interviews. These two questions were "what methods do you use now to control your everyday pain" and "what methods do you use at the times when your pain is more severe". Since many participants reported using the same pain management strategies for both everyday pain and severe pain, responses for these two questions were combined. In this work, we identified two main approaches (types) to pain management for everyday pain and severe pain--treating pain and preventing pain. Under each of these main approaches (types), we categorized strategies by sub-type. We then counted number of strategies each participant reported using and the frequency with which each sub-type was used by participants. The classification of strategies was reviewed and discussed by the investigators, and any discrepancies were resolved by consensus.

3.2.3 Results

3.2.3.1 Pain Management Strategies and Categories

In Table 3, we summarize the pain management strategies participants used to control knee OA pain, organized by type and sub-type, along with the number of participants that endorsed using each sub-type and unique strategy. Participants described a total of 31 different pain management strategies used to control daily knee OA pain. These pain management strategies were categorized into 14 sub-types (7 treatment sub-types and 7 preventative sub-types) shown in Table 3. Physical self-care activities were the most commonly used strategy sub-type reported by participants, which includes strategies such as cold therapy (n=27), heat therapy (n=29), massage (n=21), and having a rest/lying down (n=19). Psychological self-care activities were also widely used including distraction (n=10) and keeping a positive attitude and ignoring/pushing through the pain (n=13). Participants described various ways to be active such as engaging in any activity that kept them moving (n=10), and planned, structured and purposeful physical activity (n=10). In addition, changing position (n=18) and avoiding overusing the knee (n=17) were also reported by participants.

3.2.3.2 Number of Pain Management Strategies

Participants described using multiple strategies to manage pain (Figure 5). The mean and median number of strategies participants used for controlling pain were 5.31 ± 3.5 and 5 (1-11), respectively. Only one participant endorsed using just a single strategy to manage pain.

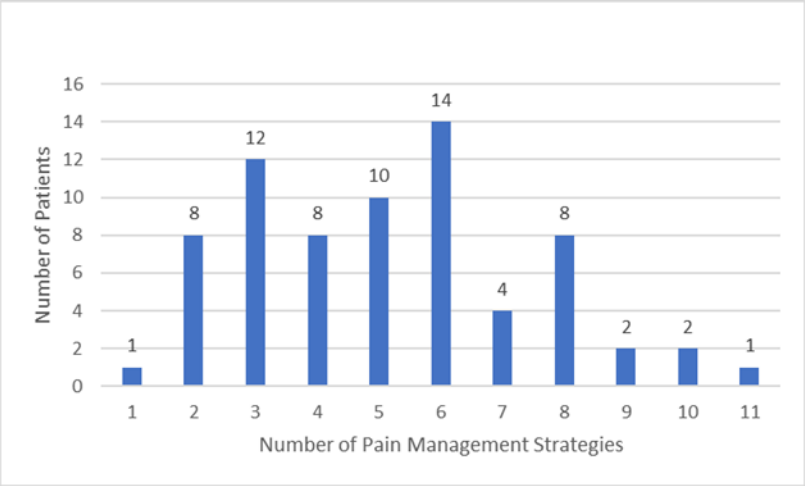


Figure 5 Number of Pain Management Strategies Participants Used for Pain (N=70)

3.2.3.3 Two Types of Pain Management Strategies

We observed two main types of pain management strategies: treatment strategies and preventative strategies (Table 3). The strategies were categorized as treatment or preventative based on the context in which they were used since a few strategies can be used for either treatment or prevention of pain, such as stretching and physical self-care activities. If participants considered the strategy as a routine procedure, or use it to prevent pain before having pain, it was categorized as a preventative strategy. If participants used the strategy to treat pain after feeling pain, it was categorized as a treatment strategy. Most of the participants used both treatment and preventative strategies to control pain (n=45, 64.3%); 25 (35.7%) participants only used treatment strategies and there were no participants who only used preventative strategies (Figure 6).

Table 3 Pain Management Strategy Types and Sub-types*

Type	Sub-type (n)	Pain Management Strategy (n)
Treatment strategies	Positions/activities that decrease pressure on the knee joint (8)	Elevating legs or feet (8)
	Integrated therapy provider delivered (10)	Acupuncture (2)
		Acupressure (2)
		Chiropractor (5)
		Psychotherapy (1)
		Reflexology (1)
	Changing position (18)	Changing position (18)
	Stretching to treat pain (10)	Stretching to treat pain (10)
	Physical self-care activity (50)	Cold therapy (27)
		Heat therapy (29)
		Having a rest/lying down (19)
		Massage (21)
	Psychological self-care activity (24)	Distraction (10)
		Meditation (4)
		Keep a positive attitude, ignore the pain, push through (13)
	Stop doing activities that typically cause pain (16)	Stop doing activities that are causing pain (16)
Preventative strategies	Positions/activities that decrease pressure on the knee joint (8)	Lose weight (4)
		Using the unaffected side more (4)
	Being active (22)	Keep moving (10)
		Doing exercise (10)
		Aquatic therapy (3)
	Stretching/warming up (7)	Stretching/warming up (7)
	Avoid overusing (17)	Decreasing the volume or speed of doing activity (17)
	Physical self-care activity (14)	Achieving good sleep (6)
		Wearing comfortable clothes and shoes (8)
	Avoid doing activity that could cause pain (11)	Avoid doing activity that could cause pain (11)
	Using tools to support the knee (11)	Holding handrail/cane (2)
		Cushion (5)
		Put pillow/pad between legs (2)
		Using brace (4)
		Using cane (2)

Note. n = number of participants who used each sub-type and pain management strategy.
*Pain management strategies may sum to more than the sub-types if more than one strategy was used.

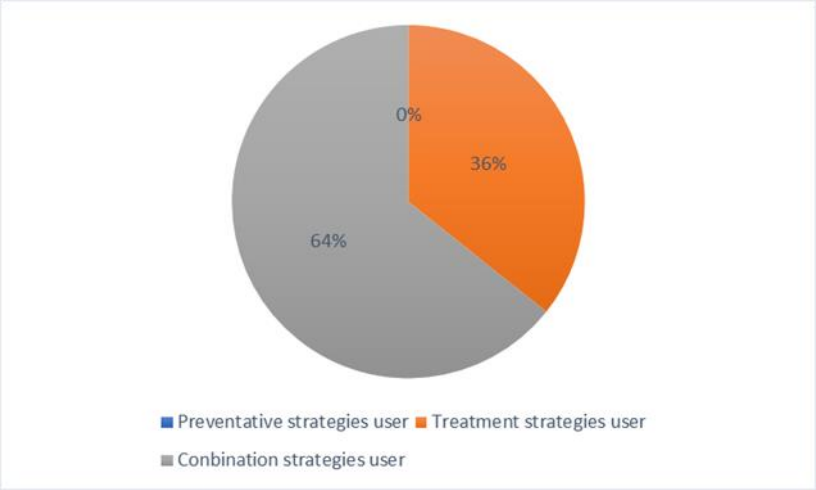


Figure 6 Percentage of Participants Who Used Different Type of Pain Management Strategies

3.2.4 Discussion

This study identified, categorized, and counted pain management strategies individuals with knee OA and HTN used in their daily life. The most commonly used sub-types were physical self-care activities, psychological self-care activities, being active, changing position, and avoiding overusing. Almost all participants simultaneously applied more than one pain management strategy to control pain. Pain management strategies were categorized into treatment strategies and preventative strategies. About two thirds of participants used both treatment and preventative strategies to manage pain at the same time.

Non-pharmacological pain management strategies were widely used in daily life to help participants control chronic pain caused by OA, which was also indicated by many previous studies (Albert et al., 2008; Lavender et al., 2022). Physical self-care activities such as applying heat/cold, using massage, and having a rest are suggested by numerous guidelines for controlling knee OA pain (Buelt & Narducci., 2021; Kolasinski et al., 2020). Some self-care psychological activities

such as meditation and cognitive therapy have also been shown to help patients improve self-efficacy and decrease patients' depression and stress (Iijima et al., 2018; Keefe et al., 1987). Similar to previous research, the most common self-care activities included hot/cold treatment and exercise/movement management (Albert et al., 2008; Lavender et al., 2022). Just a few participants reported using over-the-counter dietary supplements to control pain in our study, which was indicated by many participants in a previous study (Albert et al., 2008). Psychological self-care activities were also widely used among participants in our study but were rarely mentioned in the study by Albert et al. (2008). The reason is Albert's study only focused on meditation, which is one of the psychological self-care activities, but many other psychological self-care activities such as distraction and keeping a positive attitude were also commonly used by participants to control pain. Our study measured participants' usage of multiple types of psychological self-care activities.

Participants used multiple non-pharmacological strategies in combination to manage pain; findings also reported by previous studies (Albert et al., 2008; Jordan et al., 2000). However, prior studies reported the median number of strategies participants used to be only two (Albert et al., 2008), which is a much lower number than in our study, indicating that participants had already started to pay more attention to the usage of self-care pain management strategies over time because of more guideline suggestions. Most forms of self-care were significantly more common among people facing more severe symptoms and arthritis-related disruptions in daily life (Jordan et al., 2000).

Preventative strategies played an important role in controlling chronic pain and were used by many participants in daily life to control pain (Ali et al., 2012; Lavender et al., 2022), which was also seen in our study. Preventative strategies have shown good effectiveness in managing

knee OA pain in previous studies. For example, engaging in physical activities is a good way to increase muscle support for the knee and therefore decrease the chronic pain and increase function (Escalante et al. 2010; Kolasinski et al., 2020). In addition, because many participants express a reluctance to take pain medication, preventative pain management offers an approach to avoid medicines (Ali et al., 2012). Health care providers can suggest that patients engage in more preventative strategies such as routine physical activity to increase muscle strength, improve support of the knee, and prevent chronic pain.

There were a few limitations in this study. First, generalization of the results was limited because our sample was primarily non-Hispanic white women with a history of over a decade of OA and HTN and multiple comorbidities. More studies should be done using more diverse samples with regards to gender and race/ethnicity, as gender and race could be important factors influencing people's expression and understanding of pain. Second, our study did not inquire about the influence of having HTN as a comorbidity on their usage of pain management strategies (Allen et al., 2010; Tschon et al., 2021). HTN could influence participants' physical activities. There was no interview question asking participants to describe any strategies they used to control blood pressure and HTN, which could also be an effective way to control pain (Shi & Schlenk, 2022).

In conclusion, various non-pharmacological pain management strategies were used by participants to control knee pain. These strategies were divided into two types and 14 sub-types. The most commonly used categories were physical self-care activities, psychological self-care activities, and being active. Participants used multiple strategies at the same time to control knee OA pain.

3.3 Paper 3: Associations among Types of Pain Management Strategies, Pain, and Arthritis Pain Self-Efficacy

3.3.1 Introduction

Knee osteoarthritis (OA) is one of the most common chronic diseases among older people, affecting more than 32.5 million US adults (Centers for Disease Control and Prevention, 2020). A recent study indicated that the prevalence of knee OA in the US has been underestimated, especially among adults younger than age 65 years old (Deshpande et al., 2016). Chronic pain caused by knee OA results in significant physical and psychological burden for patients and is an important factor contributing to disability.

Pharmacological pain management is one of the most common strategies used by patients to control knee OA pain (Crofford, 2013), but long-term use of pain medication, such as non-steroidal anti-inflammatory drugs (NSAIDs), can increase patients' blood pressure and risk of developing hypertension (HTN) (Aljadhey et al., 2012). Additionally, the prevalence of HTN is much higher among people with knee OA (Veronese et al., 2018). Therefore, non-pharmacological pain management strategies play important roles in controlling knee OA pain.

Previous studies indicated that non-pharmacological treatments can effectively improve patients' self-efficacy (Olsson et al., 2020), which is an important predictor influencing patients' arthritis pain (Somers et al., 2012). Understanding the role of self-efficacy in OA pain management can help health care researchers to develop effective interventions to help patients control pain.

Our qualitative study indicated that patients use multiple different pain management strategies to control knee OA pain, and these pain management strategies can be divided into two types: preventative strategies, which patients employed specifically to avoid experiencing pain,

and treatment strategies, which are used when having pain (Shi et al., 2022b). Previous studies demonstrated greater effectiveness of preventative strategies compared with treatment strategies, but all of the studies focused only on pharmacological treatments (Mohan et al., 2013). Therefore, the aim of this study was to examine the effectiveness of non-pharmacological preventative strategies and treatment strategies on knee OA pain, and their relationship with participants' pain self-efficacy. We proposed two hypotheses: 1) we posit that patients who used combined strategies (treatment plus preventative) strategies will have lower pain and higher self-efficacy compared to patients who used treatment strategies alone; 2) we posit that self-efficacy is a mediator between types of strategies (treatment strategies and treatment plus preventative strategies) and knee OA pain. Our exploratory aim was to examine if the number of pain management strategies was inversely associated with participants' pain and positively associated with participants' self-efficacy.

3.3.2 Methods

This study was a secondary analysis of data from the Staying Active with Arthritis (STAR) Study dataset. The parent study was a randomized controlled trial of a 6-month self-efficacy based physical activity intervention with 6-month follow-up delivered in 6 weekly face-to-face sessions with physical therapists and 9 bi-weekly telephone sessions with nurses to 182 older adults with both knee OA and HTN (Schlenk et al., 2020). The present study used a longitudinal comparative design to examine the effect of the types of pain management strategies on participants' pain and pain self-efficacy.

3.3.2.1 Setting and Sample

The sample for the present study consisted of parent study participants in the intervention arm (N=70) who completed Unit 4 (15 Units total), Being Physically Active When You Have Pain, and their respective baseline assessments of pain and arthritis pain self-efficacy. All participants in the parent study (1) were 50 years or older, (2) had OA of the knee defined as knee pain lasting at least a month within the previous year, and (3) had HTN for which anti-hypertensive monotherapy or combination pharmacological treatment was prescribed. Participants who received cortisone or Synvisc injection in the past 6 months or were scheduled to undergo a major surgical procedure in the next 13 months were excluded from the parent study.

3.3.2.2 Measurement

3.3.2.2.1 Pain Management Strategies

Pain management strategies were measured by two interview questions during Unit 4 at week 4 of the 24-week intervention in the parent study. These two questions were “what methods do you use now to control your everyday pain” and “what methods do you use at the time when your pain is more severe. The number and types of pain management strategies participants used were evaluated by content analysis. The content analysis procedure included transcribing audio recordings, developing a codebook, performing reliability checks on 10% of transcripts, and resolving discrepancies by weekly team meetings. The detailed content analysis procedure was reported in our qualitative study (Shi et al., 2022b). Pain management strategies were categorized into two types: preventative strategies and treatment strategies. Preventative strategies represent the strategies participant used before they had pain, and treatment strategies represent the strategies participant used when they had pain. Based on the kind of pain management strategies participants reported using, there were no participants who only used preventative strategies. Thus, participants were divided into two groups based on whether participants used preventative strategies: participants who only used treatment strategies (n=25) and participants who used both preventative and treatment strategies (combined strategy) (n=45).

3.3.2.2.2 Pain

OA-related knee pain was evaluated by the pain subscale of the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index at baseline, immediate post-intervention, and 6 months post-intervention. The WOMAC Osteoarthritis Index Pain subscale consists of 5 items, each with 5-point Likert scaling. Items are summed to yield the pain subscale scores, ranging from 0 to 20 with higher scores indicating higher pain. Scores for each knee are averaged to yield an overall pain subscale score. The WOMAC Pain subscale has good construct validity, adequate 1-week test-retest reliability (r = .68), and moderate internal consistency reliability (Cronbach's alpha = .86) (Bellamy, 2002; Bellamy et al., 1988). The internal consistency reliability of the WOMAC Pain subscale was very good in this study (Cronbach's alpha = 0.87).

Bodily pain was measured by the Bodily Pain subscale of the Short Form-36v2 (SF-36v2) at baseline, immediate post-intervention, and 6 months post-intervention. The SF-36v2 Bodily Pain subscale consists of two items, one on a 5-point Likert scale and the other on a 6-point Likert scale. Scores are standardized; possible scores were transformed with range from 0 to 100 with higher scores indicating lower pain. The SF-36v2 Bodily Pain subscale has good construct validity and moderate internal consistency reliability (Cronbach's alpha = .82) (McHorney et al., 1994; McHorney et al., 1993; McHorney et al., 1992). The internal consistency of the SF-36v2 Bodily Pain subscale was moderate in this study (Cronbach's alpha = 0.79).

3.3.2.2.3 Arthritis Pain Self-efficacy

Arthritis pain self-efficacy was measured by self-report using the Arthritis Pain Self-efficacy subscale at baseline, immediate post-intervention, and 6 months post-intervention. The Arthritis Pain Self-Efficacy subscale consists of a 5-item, 10-point Likert scale. The score range is 10 to 100 with higher scores indicating better self-efficacy (Lorig et al., 1989). The Arthritis Pain Self-Efficacy subscale has adequate construct validity, internal consistency reliability of 0.76, and test-retest reliability of 0.87 (Brady, 2011). The internal consistency reliability was very good in this study (Cronbach's alpha = 0.85).

3.3.2.2.4 Demographic and Clinical Characteristics

Demographic variables included age, sex, race/ethnicity (non-Hispanic white and others), marital status (married/partnered or not), education (as years of formal education), and employment status (full-time/part-time working or not working/retired). Clinical characteristics included the years of having OA and years of having comorbid HTN.

3.3.2.3 Statistical Analysis

Analyses were conducted using Stata SE 14 (STATA Corp, College Station, TX). The statistical significance level was two-tailed and set to $p < 0.05$; a trend was two-tailed and set to $0.05 \leq p < 0.10$. Data were first screened for any anomalies (i.e., missing data, outliers, non-normality of residuals, etc.). Missing values were handled by multiple imputation using multivariate normal distribution. Multiple imputation using multivariate normal distribution was recommended to handle missing values for normally distributed variables in a clinical trial study (European Medicine Agency, 2010). There were no missing values for the baseline outcome values. Variables used to impute the missing values for all three outcome variables at immediate post-intervention and 6 months post-intervention include age, gender, race, and baseline outcome value. Outliers were checked by boxplots and residual plots for each outcome variable by types of pain management strategies. If the residual plot was not normally distributed, data transformations of the outcome variable were considered to “normalize” the residual distribution.

3.3.2.3.1 Descriptive Analysis

Descriptive statistics (means, standard deviations, frequency counts, and percentages) were computed for demographic factors, clinical characteristics, and baseline values of the outcomes among participants who participated in this study and participants who dropped out. Continuous variables and categorical variables between participants who participated in this study and participants who dropped out were compared by independent-samples t-test and Pearson Chi-square test of independence or Fisher exact test, respectively.

Continuous demographic factors, clinical characteristics, and baseline values of outcome variables (WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, Arthritis Pain Self-efficacy subscale scores) were summarized by means and standard deviations and compared using two sample t-test between participants who used only pain treatment strategies and participants who used both preventative and treatment strategies for pain. Categorical demographic factors were summarized by frequency counts and percentages and compared by Pearson chi-square test of independence or Fisher's exact test between participants who only used the treatment strategies and those who used both preventative and treatment strategies for pain.

Participants' outcome variables (WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, Arthritis Pain Self-efficacy subscale scores) at baseline, immediate post-intervention and 6-month post-intervention stratified by type of strategy used were summarized by means and standard deviations. Participants' outcome variables at 3 time points within each type of strategy group were compared by one-way analysis of variance.

The total number of strategies used among participants who only used treatment strategies and participants who used both preventative and treatment strategies were summarized by means and standard deviations. For participants who used both preventative and treatment strategies,

means and standard deviations of the number of preventative strategies and the number of treatment strategies were also reported.

3.3.2.3.2 Hypothesis 1

For hypothesis 1, linear mixed modeling to deal with correlated measurement at different time points within participants was used to examine if those who used both preventative and treatment strategies have lower pain and higher self-efficacy compared with those who only used the treatment strategies. The base model fitted in this study was *Outcome = group (participants who used treatment strategies, participants who used both preventative and treatment strategies) + time (immediate post-intervention, and six months post-intervention) + baseline value*. Time was considered as a continuous variable, since the sample size was small. Baseline value was added into the model to decrease the bias (Senn, 2006). Since baseline value was added into the model as a covariate, the time in the model only include immediate post-intervention and 6 months post-intervention. Interaction terms between intervention group and time, and potential demographic and clinical covariates were added into the linear mixed model one by one and tested by Wald test to determine their importance. Baseline self-efficacy was also considered as a covariate and added into models for knee pain and bodily pain since it was significantly different among participants who only used the treatment strategies and participants who used both treatment and preventative strategies, based on previous studies showing a significant relationship between pain and self-efficacy (Benyon et al., 2010; Degerstedt et al., 2020). The interaction terms and covariates were kept in the model if the corresponding p-value was smaller than 0.05.

3.3.2.3.3 Hypothesis 2

For hypothesis 2, three simple mediation analysis models using Mplus were used to investigate the mediating effect of pain self-efficacy on the relationship between the type of pain management strategies used and pain (Muthén et al., 2017). The changes of Arthritis Pain Self-efficacy subscale scores and pain scores (WOMAC Pain subscale scores and SF-36v2 Bodily Pain subscale scores) from the immediate post-intervention to 6 months post-intervention as well as from baseline to 6 months post-intervention were calculated. Arthritis Pain Self-efficacy change score and pain change scores were considered as the mediator and outcomes in the first mediation analysis linear model, respectively. Changes of Arthritis Pain Self-efficacy scores and changes of pain scores from baseline to 6 months post-intervention were considered as the mediator and outcomes in the second mediation analysis linear model, respectively. To check the lagged mediating effect of pain self-efficacy on the relationship between pain management and pain, the third mediation analysis linear models with the change score of Arthritis Pain Self-efficacy scores from baseline to immediate post-intervention as mediator and the change scores of pain from immediate post-intervention to 6 months post-intervention as outcomes were also created. To obtain the standard errors and 95% confidence intervals for the indirect effect, bootstrapping was used in this study with 1000 bootstraps (Hayes, 2009).

3.3.2.3.4 Exploratory Aim

For the exploratory aim, a similar analysis procedure to that of hypothesis 1 was used to examine if the number of pain management strategies was negatively associated with participants' pain and positively associated with participants' self-efficacy. The linear mixed model fitted for this aim for each outcome was *Outcome =number of pain management strategies used + time (immediate post-intervention, and 6 months post-intervention) + baseline value*. Interaction terms between number of pain management strategies and time, and potential demographic and clinical covariates were added into the model one by one. Only significant interaction terms and covariates tested by the Wald test were retained in the model.

3.3.3 Power Analysis

For hypothesis 1, with 25 participants in the treatment strategies group and 45 participants in the combined strategies group, the minimum mean difference of pain measured by WOMAC Pain subscale that can be detected is 0.85 with sufficient power (0.80) when testing hypotheses at a significance level of 0.05, and standard deviation reported in the parent study being about 3.0 (Schlenk et al., 2020). A previous study results reported that the effect size of non-pharmacological treatment strategies on pain was 0.89 (Helminen et al., 2015). For hypothesis 2, based on a study by Cheng et al. (2018), the correlation between self-efficacy and pain intensity was r = -0.50. Inclusion of 70 participants will permit sufficient power (.80) to detect an association as small as r = -.327 between the changes in arthritis pain self-efficacy and pain scores from baseline to immediate post-intervention and from baseline to 6 months post-intervention when testing hypotheses at a significance level of 0.05.

3.3.4 Results

3.3.4.1 Description of the Sample

Demographic and clinical characteristics for the total sample of participants who completed Unit 4 (N = 70) and the total subsample who dropped out from the study before completing Unit 4 (n = 19) were reported in Table 4. Participants who were married and had higher knee pain at baseline were significantly more likely to drop out from the study before completing Unit 4. The differences in knee pain and marital status between the study sample and the dropouts cause the study sample to be biased, which could affect the results. There were no significant differences between those who completed Unit 4 and those who dropped out on other characteristics between the two groups ($p \geq .05$).

Table 4 Demographic and Clinical Characteristics of Participants and Dropouts

Characteristic	Study Sample (*N*=70)	Dropouts (*n*=19)	P-value*
Age (years), mean (SD)	65.50 (8.43)	62.33 (7.58)	0.15
Gender (Female), *n* (%)	52 (74.31)	13 (72.45)	0.76
Race (White), *n* (%)	53 (76.23)	12 (67.41)	0.18
Marital status (Married), *n* (%)	35 (50.01)	13 (71.98)	0.004
Education (years), mean (SD)	15.47 (2.97)	15.22 (0.68)	0.75
Employment status (Employed), *n* (%)	39 (56.62)	7 (39.46)	0.13
Duration of having HTN (years), mean (SD)	14.73 (9.05)	12.83 (2.58)	0.45
Duration of having OA (years), mean (SD)	11.94 (9.96)	10.72 (10.05)	0.65
Baseline WOMAC knee pain, mean (SD)	5.31 (3.63)	7.61 (4.55)	0.03
Baseline SF-36v2 bodily pain, mean (SD)	58.13 (19.38)	60.31 (20.31)	0.26
Baseline arthritis pain self-efficacy, mean (SD)	73.31 (17.28)	76.00 (15.64)	0.30
Note. *Comparison of participants in the study and dropouts without controlling for potential confounders; HTN=hypertension; OA=osteoarthritis; SF-36v2=Short Form-36 version 2; WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index.			

Demographic and clinical characteristics for the total sample of participants (N = 70) for this study and the sample stratified by type of pain management strategies are summarized in Table 5. The total sample was primarily female (74%), non-Hispanic white (76%), married/partnered (50%), and not working/retired (51%). The mean (± standard deviation) age of the participants was 65.50 ± 8.43 years. The mean length of time having knee OA and HTN were 11.94 ± 9.96 years and 14.73 ± 9.05 years, respectively. At baseline, participants in the two groups had on average low to moderate levels of knee pain, moderate bodily pain, and moderate to high pain self-efficacy. The mean baseline knee pain, bodily pain, and pain self-efficacy were 5.31 ± 3.63, 58.13 ± 19.38, and 73.31 ± 17.36, respectively. There were no significant differences in demographic characteristics between participants who only used treatment strategies and participants who used both preventative and treatment strategies; however, participants who used both preventative and treatment strategies had significantly higher pain self-efficacy compared with participants who only used treatment strategies ($p < .01$).

Table 5 Demographic and Clinical Characteristics of Participants by Type of Pain Strategies Used

Characteristic	Total (*N*=70)	Participants Only Used Treatment Strategies (*n*=25)	Participants Used Both Treatment and Preventative Strategies (*n*=45)	P-value*
Age (years), mean (SD)	65.50 (8.43)	66.68 (10.08)	64.84 (7.41)	0.39
Female, *n* (%)	52 (74.29)	20 (80.00)	32 (71.11)	0.42
Non-Hispanic white, *n* (%)	53 (75.71)	16 (64.00)	37 (82.22)	0.09
Education (years), mean (SD)	15.47 (2.97)	15.36 (3.17)	15.53 (2.88)	0.82
Not working/retired, *n* (%)	36 (51.43)	12 (48.00)	24 (53.33)	0.93
Married/partnered, *n* (%)	35 (50.00)	12 (48.00)	23 (51.11)	0.80

Duration of having OA (years), mean (SD)	11.94 (9.96)	10.40 (9.50)	12.8 (10.23)	0.34
Duration of having HTN (years), mean (SD)	14.73 (9.05)	13.20 (9.79)	15.58 (8.61)	0.30
Baseline WOMAC knee pain, mean (SD)	5.31 (3.63)	4.98 (3.16)	5.50 (3.84)	0.32
Baseline SF-36v2 bodily pain, mean (SD)	58.13 (19.38)	59.6 (20.98)	57.31(18.43)	0.41
Baseline arthritis pain self-efficacy, mean (SD)	73.31 (17.36)	68.72 (20.27)	75.87(14.84)	0.002
Note. *Comparison of participants who only used treatment strategies and participants who used both treatment and preventative strategies without controlling for potential confounders; SD=standard deviation; HTN=hypertension; OA=osteoarthritis; SF-36v2=Short Form-36 version 2; WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index.				

The descriptive statistics of number of pain management strategies used are shown in Table 6. The mean number of pain management strategies used among participants who only used treatment strategies (3.48 ± 1.59) was significantly less than the mean number of pain management strategies used among participants who used both preventative and treatment strategies (6.09 ± 2.01) ($p<0.001$).

Table 6 Number of Pain Management Strategies Participants Used by Type of Pain Strategies

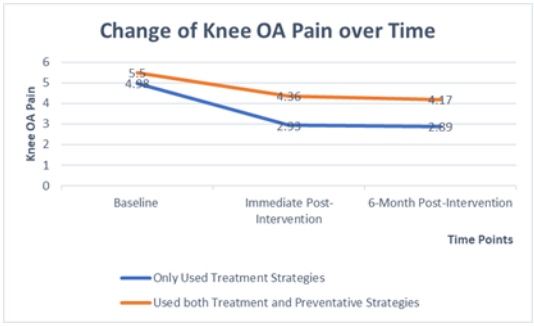
Number of Strategies	Participants Only Used Treatment Strategies (n=25)	Participants Used Both Treatment and Preventative Strategies (n=45)	P-value*
Number of Treatment Strategies Used	3.48 (3.12)	4.16 (4.02)	<0.001
Number of Preventative Strategies Used	--	1.28 (2.44)	--
Total Number of Strategies Used	3.48 (1.59)	6.09 (2.01)	<0.001
Note. *Comparison of participants who only used treatment strategies and participants who used both treatment and preventative strategies without controlling for potential confounders			

Participants' outcomes at baseline, immediate post-intervention, and 6 months post-intervention for participants who only used treatment strategies and those who used both preventative and treatment strategies to control pain are presented in Table 7 and Figure 7. Participants who only used the treatment strategies showed a significant decrease in WOMAC knee pain over time (p=0.017). Bodily pain (p=0.899) and arthritis pain self-efficacy (p=0.762) appear to remain stable over time for participants who used both types of interventions. Participants who only used treatment strategies seem to have lower bodily pain, and higher arthritis pain self-efficacy over time, but the changes were not significant (p=0.261, p=0.589, respectively).

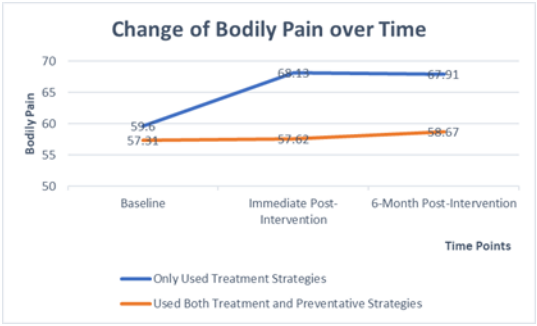
Table 7 Descriptive Analysis of the Outcomes by Type of Pain Strategies Used

Outcomes	Type of Pain Strategies	Baseline Mean (SD)	Immediate Post-intervention Mean (SD)	6 months post-intervention Mean (SD)	P-value*
WOMAC Knee Pain	Only Used Treatment Strategies	4.98 (3.16)	2.93 (2.66)	2.89 (2.54)	0.017
	Used Both Treatment and Preventative Strategies	5.50 (3.84)	4.36 (3.36)	4.17 (3.17)	0.202
SF-36v2 Bodily Pain	Only Used Treatment Strategies	59.60 (20.98)	68.13 (17.80)	67.91 (22.23)	0.261
	Used Both Treatment and Preventative Strategies	57.31 (18.43)	57.62 (20.28)	58.67 (18.09)	0.899
Arthritis Pain Self-efficacy	Only Used Treatment Strategies	68.72 (20.27)	77.42 (20.41)	76.36 (20.16)	0.589
	Used Both Treatment and Preventative Strategies	75.87 (14.84)	75.73 (14.39)	74.14 (16.32)	0.762
Note. *Comparison of outcomes at baseline, immediate post-intervention, and 6-month post-intervention					

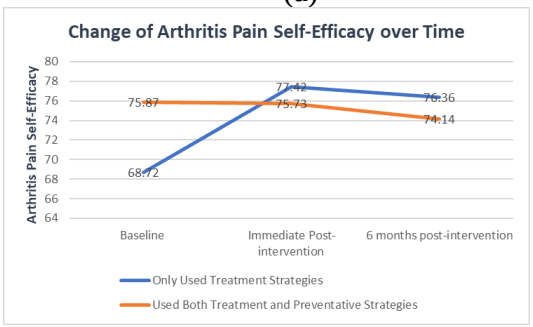
Figure 7 Change in Knee OA Pain, Bodily Pain and Pain Self-Efficacy over Time



(a)



(b)



(c)

3.3.4.2 Hypothesis 1

As shown in Table 8, interaction terms between the type of pain management strategies and time for WOMAC Pain subscale scores, SF-36v2 Bodily Pain subscale scores, and Arthritis Pain Self-efficacy subscale scores were not significant ($p > 0.05$). After removing the interaction terms from these models, participants who only used treatment strategies for pain reported on average significantly lower bodily pain ($b = -7.94$, $p = .017$) compared with the participants who used both preventative and treatment strategies for pain. There was a trend that knee pain reported by participants who used only treatment strategies for pain was lower than knee pain reported by participants who used both treatment and preventative strategies ($b = 1.13$, $p = .051$). There was also a trend that participants who used only treatment strategies for pain reported higher pain self-efficacy comparing with participants who used both treatment and preventative strategies ($b = -5.37$, $p = .090$). Time was not significant in all models.

Table 8 Linear Mixed Modeling Results for the Relationships between Type of Pain Management Strategies Used and Outcomes[1]

	Pain Management Group		Time		Pain Management Group*Time	
Outcome	Coefficient	P-value	Coefficient	P-value	Coefficient	P-value
WOMAC Knee Pain[2]	1.16 (-0.09, 2.41)	0.068	-0.02 (-0.95, -0.91)	0.965	-0.08 (-1.22, 1.07)	0.894
WOMAC Knee Pain[3]	1.13 (-0.01, 2.25)	0.051	-0.07 (-0.62, 0.47)	0.796		
SF-36v2 Bodily Pain[2]	-8.88 (-16.38, -1.38)	0.020	-0.96 (-7.40, 5.48)	0.770	2.00 (-5.96, 9.96)	0.622
SF-36v2 Bodily Pain[4]	-7.94 (-14.43, -1.45)	0.017	0.35 (-3.44, 4.14)	0.856		
Arthritis Pain Self-efficacy[5]	-5.29 (-12.03, 1.45)	0.124	-1.76 (-6.37, 2.86)	0.456	-0.17 (-5.87, 5.53)	0.953
Arthritis Pain Self-efficacy[6]	-5.37 (-11.57, 0.83)	0.090	-1.87 (-4.58, 0.84)	0.176		

Note. SF-36v2=Short Form-36 version 2; WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index.

[1]Participants who only used treatment strategies was reference group.

[2]Model with baseline value of outcome, time, pain management strategies group, and interaction between group and time. Other covariates including baseline self-efficacy were removed from model because of non-significance.

[3]Model with baseline value of outcome, time, pain management strategies group, and race. Other covariates including baseline self-efficacy were removed from model because of non-significance.

[4]Model with baseline value of outcome, time, and pain management strategies group. Other covariates including baseline self-efficacy were removed from model because of non-significance.

[5]Model with baseline value of outcome, time, pain management strategies group, and interaction between group and time. Other covariates were removed from model because of non-significance.

[6]Model with baseline value of outcome, time, and pain management strategies group. Other covariates were removed from model because of non-significance.

3.3.4.3 Hypothesis 2

As shown in Tables 9 and 10, type of pain management strategy was not significantly associated with change of pain self-efficacy from immediate post-intervention to 6 months post-intervention (b = 0.42, p = 0.89). For knee OA pain, the association between type of pain management strategy and change of knee pain from immediate post-intervention to 6 months post-intervention was not significant (b = -0.08, p = 0.89). For bodily pain, the association between type of pain management strategy and change of bodily pain from immediate post-intervention to 6 months post-intervention was also not significant (b = 2.18, p = 0.61). Therefore, we do not have sufficient evidence to show that changes of self-efficacy from immediate post-intervention to 6 months post-intervention mediated the association between the type of pain management strategies and change of knee pain from immediate post-intervention to 6 months-post-intervention or the association between the type of pain management strategies and change of bodily pain from immediate post-intervention to 6 months post-intervention.

As shown in Tables 11 and 12, the relationship between type of pain management strategy and change of pain self-efficacy from baseline to 6 months post-intervention was significant (b = -9.44, p = 0.02). However, the coefficients for all other paths were not significant. Therefore, change of pain self-efficacy from baseline to 6 months post-intervention was not a significant mediator mediating the association between the type of pain management strategies and change of knee pain from baseline to 6 months-post-intervention or the association between the type of pain management strategies and change of bodily pain from baseline to 6 months post-intervention.

Table 9 Mediation Analysis Results for Knee Pain with Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention as Mediator

a: Estimated path coefficients, standard errors (SE) and P-values for predictors in each model path					
Path			Estimate	SE	P-value
Predictor		Outcome			
Type of Pain Management Strategy Used	→	Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention	0.42	2.97	0.89
Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention	→	Change of Knee Pain from Immediate Post-intervention to 6 Months Post-intervention	-0.02	0.03	0.55
Type of Pain Management Strategy Used	→	Change of Knee Pain from Immediate Post-intervention to 6 Months Post-intervention	-0.08	0.60	0.89
Type of Pain Management Strategy Used	→	Change of Knee Pain from Immediate Post-intervention to 6 Months Post-intervention	-0.08	0.60	0.90
Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention	→	Change of Knee Pain from Immediate Post-intervention to 6 Months Post-intervention	-0.02	0.03	0.56

b: Indirect, direct, and total effects between type of pain strategies used and change of knee pain from immediate post-intervention to 6 months post-intervention			
Effect	Estimate (95% CI)	P-value	% of Mediation
Indirect	-0.01 (-0.20, 0.12)	0.85	7.15
Direct	-0.08 (-1.20, 1.07)	0.88	92.85
Total	-0.09 (-1.21, 1.06)	0.84	100

Table 10 Mediation Analysis Results for Bodily Pain with Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention as Mediator

a: Estimated path coefficients, standard errors (SE) and P-values for predictors in each model path

Path			Estimate	SE	P-value
Predictor		Outcome			
Type of Pain Management Strategy Used	→	Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention	0.42	2.97	0.89
Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention	→	Change of Bodily Pain from immediate Post-intervention to 6 months Post-intervention	0.26	0.18	0.15
Type of Pain Management Strategy Used	→	Change of Bodily Pain from Immediate Post-intervention to 6 Months Post-intervention	2.18	4.21	0.61
Type of Pain Management Strategy Used	→	Change of Bodily Pain from Immediate Post-intervention to 6 Months Post-intervention	2.07	4.17	0.62
Change of Arthritis Pain Self-efficacy from Immediate Post-intervention to 6 Months Post-intervention	→	Change of Bodily Pain from Immediate Post-intervention to 6 Months Post-intervention	0.26	0.18	0.16

b: Indirect, direct, and total effects between type of pain strategies used and change of knee pain from immediate post-intervention to 6- months post-intervention

Effect	Estimate	P-value	% of Mediation
Indirect	0.11 (-1.69, 1.97)	0.98	4.90
Direct	2.07 (-5.40, 9.76)	0.61	95.10
Total	2.18 (-5.57, 10.30)	0.61	100

Table 11 Mediation Analysis Results for Knee Pain with Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention as Mediator

a: Estimated path coefficients, standard errors (SE) and P-values for predictors in each model path					
Path			Estimate	SE	P-value
Predictor		Outcome			
Type of Pain Management Strategy Used	→	Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention	-9.44	3.96	0.02
Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention	→	Change of Knee Pain from Baseline to 6 Months Post-intervention	-0.04	0.03	0.16
Type of Pain Management Strategy Used	→	Change of Knee Pain from Baseline to 6 Months Post-intervention	0.87	0.92	0.35
Type of Pain Management Strategy Used	→	Change of Knee Pain from Baseline to 6 Months Post-intervention	0.54	0.96	0.58
Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention			-0.04	0.03	0.24

b: Indirect, direct, and total effect between types of pain strategies used and change of knee pain from immediate post-intervention to 6- months post-intervention			
Effect	Estimate	P-value	% of Mediation
Indirect	0.33(-0.09, 1.10)	0.16	37.93
Direct	0.54(-1.32, 2.40)	0.56	62.07
Total	0.87(-0.73, 2.52)	0.27	100.00

Table 12 Mediation Analysis Results for Bodily Pain with Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention as Mediator

a: Estimated path coefficients, standard errors (SE) and P-values for predictors in each model path					
Path			Estimate	SE	P-value
Predictor		Outcome			
Type of Pain Management Strategy Used	→	Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention	-9.44	3.96	0.02
Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention	→	Change of Bodily Pain from Baseline to 6 Months Post-intervention	0.17	0.14	0.23
Type of Pain Management Strategy Used	→	Change of Bodily Pain from Baseline to 6 Months Post-intervention	-5.63	4.57	0.22
Type of Pain Management Strategy Used	→	Change of Bodily Pain from Baseline to 6 Months Post-intervention	-4.41	4.78	0.36
Change of Arthritis Pain Self-efficacy from Baseline to 6 Months Post-intervention			0.13	0.15	0.38

b: Indirect, direct, and total effect between type of pain strategies used and change of knee pain from immediate post-intervention to 6- months post-intervention			
Effect	Estimate	P-value	% of Mediation
Indirect	-1.22(-4.34, 0.70)	0.22	21.67
Direct	-4.41(-13.94, 5.25)	0.38	78.33
Total	-5.63(-14.97, 3.02)	0.19	100.00

For lagging mediating effect of change of pain self-efficacy from baseline to immediate post-intervention, there was a significant relationship between change of pain self-efficacy from baseline to immediate post-intervention and change of knee pain from immediate post-intervention to 6 months post-intervention ($b = -7.63$, $p = .05$) (Table 13); there was also a significant relationship between change of pain self-efficacy from baseline to immediate post-intervention and change of bodily pain from immediate post-intervention to 6 months post-intervention ($b = -9.87$, $p = .02$) (Table 14); however, coefficients for all other paths were not significant (Table 13, Table 14). Therefore, change of self-efficacy from baseline to 6 months post-intervention was not a significant mediator between intervention and change of knee pain or bodily pain from immediate post-intervention to 6 months post-intervention.

Table 13 Mediation Analysis Results for Knee Pain with Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention as Mediator

a: Estimated path coefficients, standard errors (SE) and P-values for predictors in each model path					
Path			Estimate	SE	P-value
Predictor		Outcome			
Type of Pain Management Strategy Used	→	Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention	-0.17	0.13	0.19
Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention	→	Change of Knee Pain from Immediate Post-intervention to 6 Months Post-intervention	-7.63	3.84	0.05
Type of pain Management Strategy Used	→	Change of Knee Pain from Immediate Post-intervention to 6 Months Post-intervention	-0.08	0.60	0.89
Type of Pain Management Strategy Used	→	Change of Knee Pain from Immediate Post-intervention to 6 Months Post-intervention	0.09	0.63	0.88
Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention			0.02	0.02	0.36

b: Indirect, direct, and total effects between type of pain strategies used and change of knee pain from immediate post-intervention to 6 months post-intervention			
Effect	Estimate (95% CI)	P-value	% of Mediation
Indirect	-0.18 (-0.70, 0.12)	0.28	66.67
Direct	0.09 (-1.04, 1.36)	0.82	33.33
Total	-0.08 (-1.14, 1.14)	0.92	100

Table 14 Mediation Analysis Results for Bodily Pain with Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention as Mediator

a: Estimated path coefficients, standard errors (SE) and P-values for predictors in each model path					
Path			Estimate	SE	P-value
Predictor		Outcome			
Type of Pain Management Strategy Used	→	Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention	-0.17	0.13	0.19
Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention	→	Change of Bodily Pain from Immediate Post-intervention to 6 Months Post-intervention	-9.87	3.94	0.02
Type of Pain Management Strategy Used	→	Change of Bodily Pain from Immediate Post-intervention to 6 Months Post-intervention	2.18	4.21	0.61
Type of Pain Management Strategy used	→	Change of Bodily Pain from Immediate Post-intervention to 6 Months Post-intervention	0.54	4.40	0.90
Change of Arthritis Pain Self-efficacy from Baseline to Immediate Post-intervention			-0.16	0.14	0.23

b: Indirect, direct, and total effects between type of pain strategies used and change of knee pain from immediate post-intervention to 6 months post-intervention			
Effect	Estimate (95% CI)	P-value	% of Mediation
Indirect	1.63 (-0.84, 4.28)	0.170	74.87
Direct	0.55 (-7.14, 8.64)	0.920	25.13
Total	2.18 (-5.65, 9.64)	0.630	100

3.3.4.4 Exploratory Analysis

A shown in Table 15, the interaction term between number of pain management strategies participants used and two time points was significant (b = -0.30, p = 0.011) in the model with WOMAC Knee Pain as the outcome, which means the association between number of pain management strategies and participants' knee OA pain depended on the time point. At 6 months post-intervention, the participants who used multiple different pain management strategies reported less knee OA pain, but at immediate post-intervention, the participants who used multiple different pain management strategies reported higher knee OA pain. Interaction terms between number of pain management strategies participants used and two time points for SF-36v2 Bodily Pain (b = 1.24, p = 0.855), and for Arthritis Pain Self-efficacy (b = -0.61, p = 0.319) were not significant. There was a trend that participants who used more pain management strategies reported higher Bodily Pain (b = -1.37, p = .064).

Table 15 Linear Mixed Modeling Results for the Relationships between Number of Pain Management Strategies Used and Outcomes

	Number of Pain Management Strategies		Time		Number of Pain Management Strategies*Time	
Outcome	Coefficient	P-value	Coefficient	P-value	Coefficient	P-value
WOMAC Knee Pain[1]	0.19 (-0.08,0.46)	0.172	1.47 (0.18, 2.76)	0.026	-0.30 (-0.54, -0.07)	0.011
WOMAC Knee Pain[2]	0.05 (-0.20, 0.30)	0.691	-0.07 (-0.61, 0.48)	0.807		
SF-36v2 Bodily Pain[1]	-1.93 (-3.56, -0.29)	0.021	-6.03 (-15.32, 3.26)	0.203	1.24 (-0.44, 2.91)	0.855
SF-36v2 Bodily Pain[2]	-1.37 (-14.43, -1.45)	0.064	0.25 (-3.54, 4.05)	0.896		
Arthritis Pain Self-efficacy[1]	-0.68 (-2.10, 0.73)	0.350	1.19 (-5.50, 7.87)	0.726	-0.61 (-1.82, 0.59)	0.319

Pain Self-efficacy[2]	-0.96 (-2.27, 0.35)	0.153	-0.92 (-4.61, 0.97)	0.166		

Note. SF-36v2=Short Form-36 version 2; WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index.
[1]Model with baseline value of outcome, time, number of pain management strategies participants used, and interaction between number of pain management strategies participants used and time. Other covariates were removed from model because of non-significance.
[2]Model with baseline value of outcome, time, and number of pain management strategies participants used. Other covariates were removed from model because of non-significance.

3.3.5 Discussion

This study examined the effectiveness of two types of pain management strategies on participants' knee OA pain, bodily pain, and arthritis pain self-efficacy. Contrary to our hypothesis, participants who only used treatment strategies had lower bodily pain compared with participants who used both treatment and preventative strategies. There was no significant difference between two types of pain management strategies on knee OA pain and pain self-efficacy. Pain self-efficacy was not a significant mediator of the association between types of pain management strategies and knee OA pain or bodily pain. This study also explored the effectiveness of the number of pain management strategies used on participants' pain and self-efficacy. At the 6-month post-intervention time point, there was a positive association between number of pain management strategies used and participants' knee OA pain, but at immediate post-intervention, this relationship was inverse.

Previous studies indicated that preventative strategies, such as avoiding overusing and doing exercise, can effectively improve patients' muscle strength and increase muscle support for joints, which can control the knee OA pain (Bijlsma et al. 2007; Harris et al., 2015). However, our study indicated opposite results, which was participants who used both preventative strategies and treatment strategies reported more bodily pain compared to participants who only used treatment

strategies. Previous studies showed treatment strategies such as meditation, heat therapy, and cold therapy can effectively control pain (Ahn et al., 2019; Nurcan et al., 2015), which is similar to our study results.

There are four potential explanations for these results. The first is that the sample in our study was not randomized into two intervention groups, so there could be some potential confounders that influence the relationship between pain management strategies and outcomes. Second, some strategies could be more effective in controlling pain compared with others. It was not clear which pain management strategy effectively improved chronic pain because participants were using multiple different strategies at the same time. It is possible that over-reliance on preventative strategies and insufficient use of treatment strategies may not provide adequate pain control in an older adult sample with average OA duration of nearly 12 years and HTN of almost 15 years. Our sample size was unfortunately too small to permit the examination of effectiveness for each pain management strategy or a bundle of strategies on participants' pain. At the same time, participants who used both preventative and treatment strategies might lack confidence in treatment strategies, which could also influence the effectiveness of combined strategies. Third, some preventative strategies do not have an immediate effect on pain and involve lifestyle change so participants may not consider them as preventative. Only long-term use of some preventative strategies could help participants to effectively control pain. For example, exercise is an effective preventative strategy that should be recommended by health care providers (Bannuru et al., 2019) and long-term adherence is important for its effectiveness on pain. Finally, adherence is an important factor that could influence the relationship between type of pain management strategies participants used and pain. It is possible that participants who only used treatment strategies were more adherent than participants who used both preventative strategies and treatment strategies.

Previous studies indicated self-efficacy was significantly negatively associated with knee OA pain (Benyon et al., 2010; Degerstedt et al., 2020), which was similar to our study results. Previous studies also indicated that use of pain management strategies can effectively improve patients' self-efficacy (Helminen et al., 2015; Lee et al., 2019), but our study did not find similar results; our sample size was too small to test the association between pain management strategies and self-efficacy. A larger study could be done in the future to examine the association between pain management strategies, self-efficacy, and pain.

Treatment strategies are effective in managing knee OA symptoms. Health care providers can suggest that patients try more various pain management strategies to give them some time to practice different combinations of strategies and determine the most effective personalized pain management strategies. A future study can focus on examining specific treatment strategies or combination of strategies that are effective in controlling pain.

There are several limitations in this study. First, this is an observational study. Therefore, the results cannot be used to make causal inferences. The results can only be interpreted as the relationship between pain management strategies and outcomes evaluated in this study. Second, participants' usage of strategies was from self-report and adherence to the pain management strategies was not recorded by the parent study. This study assumed that participants did use pain management strategies with similar frequency. Third, the sample size was small for the mediation analysis. Relationships found in this study should be confirmed using a larger sample. Latent growth curves modeling could be used in the future if the sample size was larger. Fourth, usage of pain medication was not controlled in the model, which could be an important factor influencing effectiveness of non-pharmacological strategies, since almost all participants were using pain medication as needed. Although the parent study collected data on prescription and over-the-

counter drugs at the three time points, a pain medication diary was not used to determine changes in amount of pain medication over time. A future study could examine the effectiveness of non-pharmacological strategies adjusted by the amount of pain medication used. Fifth, the differences in knee pain and marital status between the study sample and the dropouts caused the study sample to be biased, which could affect the results. Sixth, since participants had low to moderate levels of knee pain and moderate bodily pain, future studies can include people with a wider range of pain levels, stratify by pain levels, and examine the effectiveness of strategies on participants with different pain levels.

In conclusion, treatment strategies showed better effectiveness on controlling bodily pain compared with combined strategies. The greater number of pain management strategies participants used, the better participants control knee OA pain in the long term. Self-efficacy was not a significant mediator mediating the association between pain management strategies and pain but more studies with larger sample size should be done to verify these results.

Appendix A Design, Variables and Data Analysis Method

Appendix Table 1 Design, Variables and Data Analysis Method of Aim 1

Aim 1: Identify, categorize, and describe characteristics of pain and pain management using content analysis collected by a structured questionnaire			
Study design	Descriptive qualitative design		
Data analysis method	Content analysis		
Variable and collection	**Variable**	**Collection**	**Content**
	Pain	20- to 30-minute interview in the parent study using 12 open-ended questions and 5 yes-or-no questions	Perceived causes of pain
			Conditions increasing pain
			Activities discontinued due to pain
			Responses to pain
			Satisfaction with baseline pain management
			Intention to improve pain management
			Goals to improve pain management during which times of day and which activities
	Pain management strategies	20- to 30-minute interview in the parent study using 12 open-ended questions and 5 yes-or-no questions	Strategies tried in the past to improve the pain
			Strategies used in the past that did not work
			Strategies currently used for everyday pain
			Strategies used for severe pain
			Effectiveness of strategies
	Interventionist-prescribed pain management strategies	20- to 30-minute interview in the parent study using 12 open-ended questions and 5 yes-or-no questions	The interventionists prescribed pain management strategies based on participants' response

Appendix Table 2 Design, Variables and Data Analysis Method of Aim 2

Aim 2: Examine the effect of the pain management strategies prescribed by PTs on changes in pain and changes in arthritis pain self-efficacy from baseline to immediate post-intervention and from baseline to 6 months post-intervention in the parent study			
Study design	Longitudinal comparative design		
Data analysis methods	**Hypothesis 1:** There will be differences in changes in pain and changes in arthritis pain self-efficacy among the different pain management strategies prescribed by PTs		Linear mix model
	Hypothesis 2: Changes in arthritis pain self-efficacy will mediate the effect the pain management strategies prescribed by PTs have on changes in pain		Mediation analysis
Variable and measurement	**Variable**	**Measurement**	**Level**
	Independent variable		
	Interventionist-prescribed pain management strategies	20- to 30-minute interview in the parent study using 12 open-ended questions and 5 yes-or-no questions	Categorical
	Dependent variable		
	Pain	WOMAC Pain subscale	Continuous
		SF-36v2 Bodily Pain subscale	Continuous
	Dependent variable mediator		
	Pain self-efficacy	Arthritis Pain Self-efficacy subscale	Continuous
	Potential covariate		
	Age	Questionnaire	Continuous
	Gender	Questionnaire	Categorical
	Race/ethnicity	Questionnaire	Categorical
	Marital status	Questionnaire	Categorical
	Education	Questionnaire	Continuous
	Employment status	Questionnaire	Categorical
	Duration of having OA	Questionnaire	Continuous
	Duration of having HTN	Questionnaire	Continuous

Appendix B Human Research Protection Office Approval Letters

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Xiaojun Shi

From: IRB Office

Date: 9/10/2018

IRB#: PRO18060232

Subject: Pain Management Strategies for Knee Osteoarthritis: Use, Intention to Use, and Differences in Pain and Arthritis Pain Self-Efficacy

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The above-referenced project has been reviewed by the Institutional Review Board. Based on the information provided, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section

45 CFR 46.101(b)(4)

Please note the following information:

- Investigators should consult with the IRB whenever questions arise about whether planned changes to an exempt study might alter the exempt status. Use the "**Send Comments to IRB Staff**" link displayed on study workspace to request a review to ensure it continues to meet the exempt category.
- It is important to close your study when finished by using the "**Study Completed**" link displayed on the study workspace.
- Exempt studies will be archived after 3 years unless you choose to extend the study. If your study is archived, you can continue conducting research activities as the IRB has made the determination that your project met one of the required exempt categories. The only caveat is that no changes can be made to the application. If a change is needed, you will need to submit a NEW Exempt application.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

Appendix C Unit 4: Being Physically Active When You Have Pain

UNIT 4: BEING PHYSICALLY ACTIVE WHEN YOU HAVE PAIN

Step 1: **Blood pressure check.**

Focus: This unit is about being physically active when you have pain.

Goal: The main goal of this unit is to learn about ways to manage knee pain so that you can continue to do your physical activity. You will do knee exercise, and we will walk together during today's session.

Step 2: You completed Unit 3 last session. Let's take some time to think about Unit 3.

1. Did Unit 3 increase your confidence in getting started with walking?	YES	NO
2. Do you have questions about Unit 3? What questions do you have? _____ _____	YES	NO

Step 3: You have been keeping a daily diary about your physical activity since the last session. Let's take some time to review your daily diary entries. If you did not complete your diary, let's take a moment to recall your physical activity since the last session.

Look in your diary at what you noted about your physical activity.

How many days did you do range of motion/stretching exercise? _____out of _____days

4.0 Number of sets? _____ Number of repetitions? _____

How many days did you do strengthening exercise? _____out of _____days

5.0 Number of sets? _____ Number of repetitions? _____ Weight added? _____

How many days did you do aerobic exercise? _____out of _____days

6.0 Types of aerobic activity? _____

7.0 Number of sessions per day? _____ Number of minutes per session? _____

Your goal was to:

1. Complete 2 sets of 5-15 repetitions on 2-3 days during the week with 0.0 to 0.5 lb weight added to some of the exercises.

Or, if goal was reduced:_____

2. Walk 5-10 minutes on 5 days for a total of 25-50 minutes each week.

You:

- Met your goal (if attained at least 75% of the goal). Congratulations! Keep it up.
- Made a good attempt (if did not tolerate the goal or did not attain at least 75% of the goal). Let's discuss the problems that kept you from achieving your goal and try to find ways for you to have success in the coming week. Examples:
    - Too much risk due to musculoskeletal problems. Modify the knee exercise (see below).
    - Too many symptoms and medication side effects with physical activity. Get medical advice.
    - Too hard to do. Set lower goal.
    - Too hard to get started. Take a rest before physical activity. Take a warm bath or shower before physical activity. Reinforce yourself when you are done.
    - Too busy to do. Do physical activity at specific times each day. Do physical activity in several sessions. Build physical activity into your daily life by parking further from a store entrance or substituting walking for something else, such as a television show.
    - Too boring. Do physical activity to music or a favorite TV program. Count the repetitions down instead of up (10, 9, 8 etc.). Ask someone to do physical activity with you.
    - Did not feel well, e.g., too much pain. We will discuss pain management strategies this week.
    - Other. Specify_____

Step 4: Identify the purpose and causes of pain in osteoarthritis.

Before we look at specific ways that people can manage pain, let's review what pain is and what causes the pain in osteoarthritis.

Pain is the body's warning system that tells you that something is wrong. Chronic pain, which occurs in osteoarthritis, is not easy to relieve. Learning to manage this type of pain can improve your quality of life.

The pain of osteoarthritis comes from a number of sources:

- Inflammation in the joint lining when the cartilage breaks down and pieces of cartilage and bone float loosely in the joint.
- Damage to joint tissues from osteoarthritis or from stress on the joint.
- Pain is increased if muscles around the joint become weak or are tense.

Some other things that can cause increased pain in osteoarthritis are:

- Staying too long in one position.
- Putting too much stress on some joints during daily activities.
- Overdoing it by exercising too hard, too often, or too long.

Also, a number of things can make pain seem worse. Some of these are:

- Getting too tired.
- Being under increased stress.
- Spending too much time thinking about the pain.
- Feeling anxious or depressed.

When you start a physical activity program, you may have muscle soreness after physical activity. Muscle soreness is normal and is relieved with rest and stretching. Pain in your joint after physical activity is not normal and means you have overdone physical activity and need to cut back. We will talk more about normal body signals and warning signs in a later session.

Very often, people forget that pain can be related to a variety of factors. The more you understand the particular reasons for your own pain, the more confident you will feel in managing it.

Give some thought now to the causes of your pain and the factors that may increase pain, such as overusing a certain joint during your daily activities or becoming overtired.

What do you think are the causes of your pain?

_____

_____

Under what conditions is your pain most likely to increase?

_____

_____

Step 5: Explore the meaning of pain to you.

Pain is a *personal experience* that means different things to different people. The same amount of pain may cause one person to decrease activities while another person continues to do daily activities. It is important to identify how your pain affects *you* and what pain means to *you*.

Have you stopped doing things that you enjoy because of pain? What activities have you stopped doing because of pain? _____ _____ What feelings do you have in response to having pain? _____ _____	YES	NO

Remember these effects of pain as we continue this session. It is important to realize that pain affects you more than physically, it affects what you do every day and how you think and feel.

Step 6: Identify ways to relieve pain.

People can help to avoid unnecessary pain by preparing for physical activity:

- Do gentle warm-up stretches.
- Engage in deep breathing.
- Wear comfortable clothes and shoes.
- Plan your physical activity when your arthritis medication begins to work.
- Ask your doctor if you can take an analgesic half an hour before you do physical activity.

Warm-up prepares the body for more vigorous activity. Warm-up increases the blood flow to the muscles, decreases the risk of sudden stress on the heart, and decreases the risk of injuring muscles and joints. We do a 5-minute warm-up together before we start exercising.

Deep breathing fills the lungs with air and gets more oxygen from the lungs into the blood where it can be taken to the muscles. The muscles use the oxygen to let you move and be active. We do deep breathing together before we start exercising.

Comfortable clothes and shoes are important. Clothes should fit loosely so you can move easily. Wearing layers of clothes lets you adapt to changes in temperature and activity; for example you can remove a jacket if you get too warm. Shoes should provide good support with soles that are non-slip and absorb shock, for example athletic shoes.

Plan your physical activity when your arthritis medication begins to work, which is about 30 minutes after taking the medication, because you may have less pain and stiffness at that time.

If your doctor approves, an *analgesic* 30 minutes before physical activity may increase your comfort. However, you have to be careful that you do not overdo physical activity after taking an analgesic.

A number of osteoarthritis medications help to control pain. Sometimes it is tempting for people to increase medication when they have more pain. This procedure can backfire. Medication is most effective at a certain level in the body. Extra medication may not give any extra pain relief, but it could cause more side effects. Be sure to talk to your doctor about your pain, and ask your doctor for advice. Don't make medication decisions on your own.

Taking medication is only one of many ways to control pain. There are many other effective strategies you can use. For example:

- Be physically active.
- Find ways to relax.
- Use massage.
- Find ways to distract yourself from the pain.
- Use a heated pool, bath, or shower.
- Use heat or cold treatments on painful joints.
- Find ways to balance activity with rest.
- Get enough sleep.
- Find ways to decrease stress and depression.

Physical activity can help with pain in several ways. During physical activity, your body releases natural pain relievers called endorphins, which act in the brain to make pain less noticeable. Physical activity also keeps joints more flexible, helps to keep muscles around the joints strong, reduces pain and stiffness, increases energy, and lifts mood. In a later session, we will talk about any discomfort you have during or after physical activity.

Relaxation can help control pain by reducing the muscle tightness and overall feeling of stress that pain can cause. When muscles are tighter, pain is increased. Relaxing should involve both your body and your mind. Deep breathing, meditation, and prayer are some methods to use. Some people find that relaxation audiotapes available in many bookstores help them to get into a relaxed state.

Massage can reduce muscle aches and tension. You can self-massage to increase blood flow and relax a muscle by lightly stroking, squeezing, or pressing down on a muscle making a deep round motion with the heel of your hand or palm. Stroking should be done towards the heart. You can use lotion or oil to help your hands move easily over your skin. Do not massage a joint that is painful or swollen or a limb that has blood clots. Stop massaging if you feel pain. If you go to a massage therapist, be sure the therapist has experience working with people with arthritis.

Distraction can be very helpful in blocking some of the signals of pain that reach your brain. When you are absorbed in something else, pain is less noticeable. Some examples of ways to distract yourself are staying involved with friends, having an interesting hobby, and listening to music.

A heated pool, bath, or shower helps by relaxing your whole body and also gives you an opportunity to move sore joints through their range of motion.

Heat and cold treatments are helpful when certain joints are more inflamed and will be discussed at the next session.

Getting enough *rest* is an important way to control your pain. The "4 P's" of rest are:
PPlanning: Do only what is realistic and ask for help when you need it.
PPositioning: Avoid staying in one position for too long or overusing certain joints.
PPacing: Balance rest with activity.
PPrioritizing: Decide what is most important and avoid taking on too much.

A good night's *sleep* is important to your overall well-being and attitude. Pain will seem magnified if you are overtired. If sleep is a problem for you, be sure to avoid caffeine and alcohol, especially in the late afternoon and evening. If you often have trouble sleeping, you should discuss this with your doctor. Your doctor can help to pinpoint the cause of your sleep problems and suggest remedies. A warm bath, soft music, and light reading help some people fall asleep.

Stress can contribute to increased pain. Try to identify the causes of your particular stress. Planning and prioritizing can reduce stress if it is caused by too many demands. What may seem overwhelming can be made more manageable by setting smaller goals and concentrating on taking each day one at a time.

Depression can also increase pain. Besides the feelings of sadness and hopelessness, depression is often associated with poor appetite and sleep. If you are troubled with these complaints for more than one or two weeks, you should let your doctor know so your doctor can recommend the best treatment for you.

When you have several different ways to control pain, you will feel more confident and less likely to feel overwhelmed by it.

What methods do you use now to control your everyday pain? Do they work?	Effective?	
1. _____	YES	NO
2. _____	YES	NO
3. _____	YES	NO

Now recall what you identified about the times when your pain is increased.

What methods do you use at the times when your pain is more severe? Do they work?	Effective?	
1. _____	YES	NO
2. _____	YES	NO
3. _____	YES	NO

Are you satisfied with your pain management?	YES	NO
Would you like to improve your pain management?	YES	NO
If YES, during what times of the day would you like to have better pain management strategies? _____ _____		
If YES, during what activities would you like to have better pain management strategies? _____ _____		

Step 7: Identify ways to improve your pain management strategies.

Let's take a look at the pain control methods you are using now. Let's first take the ones you already find helpful. Are there ways that you could increase the helpfulness of these methods?

If you are satisfied with your pain management, congratulations! In this case, let's complete the rest of this session with the idea of continuing to use your strategies successfully or considering new strategies you may also find helpful in the future.

Let's brainstorm ideas to make your current non-medication pain management work better:
_____ _____

Are there pain management strategies you used at one time but now have discarded? What interfered with your use of these methods? For example:

- Did you lack the time to carry them out?
- Were you unsure of how to do a method?
- Did you become discouraged because the strategy wasn't very effective?

What pain management strategies did you try and give up on?

_____

_____

Step 8: Identify new strategies for pain management.

Let's take another look at the pain control techniques we talked about earlier. Which ones have you never tried? Would you like to try some of these strategies? Think about the level of pain and the circumstances surrounding the pain as you consider these new strategies.

What are some additional strategies you would consider trying:

for everyday pain?

_____

_____

for increased pain?

_____

_____

Step 9: We will warm up together first. Then, you will do the knee exercises. After the knee exercises, we walk together for 10-15 minutes.

Let's do a 5-minute warm up, e.g., Joint Check Activity, deep breathing, and walking in place with small arm swings.
Did you have any problems after doing the knee exercises, such as muscle soreness or cramping or knee or hip pain? If YES, modify the exercises by:

- ❑ Reducing the number of sets, repetitions, and/or weight. Specify_____
- ❑ Dropping an exercise. Specify_____

- ❑ Doing submaximal contractions. Specify_____

- ❑ Other. Specify_____

Today, you will do 2 sets of 5-15 repetitions with 0.5-1.0 lb weight added to some of the exercises depending on your capability. If you have sharp pain or pain more than 2 hours after exercise, then you need to cut back. I will count the number of seconds to hold the position. Remember, move gently and slowly, do not overstretch, and do not bounce. Keep breathing regularly. Do not bear down like you are going to the bathroom as this can raise your blood pressure. Do the exercises in your range of motion that is free of pain.

Range of Motion/Stretching Exercises:

- Hamstring stretch (2 options: supine or seated) (precautions: muscle cramp)
- Calf stretch (precautions: muscle cramp)
- Heel slide (precautions: muscle cramp, joint surgery)

Strengthening Exercises:

- Quad set (precautions: none)
- Straight leg raise (precautions: osteoporosis) with 0.5-1.0 lb weight
- Hip abduction (2 options: side lying or standing) (precautions: joint surgery) with 0.5-1.0 lb weight
- Short arc quad (precautions: muscle cramp) with 0.5-1.0 lb weight
- Standing heel raise (precautions: balance, muscle cramp, joint surgery)
- Standing wall slide (precautions: balance). This is an intermediate exercise that should be used with discretion.
- Balance exercise (precautions: balance) (not shown on videotape)

Step 10: We will now walk for 10-15 minutes together, depending on your capability.

Did you have any problems with walking, such as muscle soreness or cramping, knee or hip pain, dizziness, or lightheadedness? If YES, modify walking by:

- ❑ Reducing the frequency and/or duration. Specify_____

- ❑ Getting a blood pressure check.

Let's do a brief cool down.

Step 11: Let's complete your diary to show the knee exercises you have just done.

Step 12: Your goal for the next week is to:

	Knee Exercise Goal

O	Do 2 sets of 5-15 repetitions of these knee exercises 2-3 days during the coming week with 0.5-1.0 lb weight added to some of the exercises.
O	Recommend a lower goal if the subject did not tolerate the last goal or did not attain at least 75% of the last goal: _____

	Walking Goal
O	Walk 10-15 minutes on 5 days for a total of 50-75 minutes each week.
O	Recommend a lower goal if the subject did not tolerate the last goal or did not attain at least 75% of the last goal: _____

You can do the knee exercises in one session or divide them into several sessions each day. You should have at least one day of rest in-between knee exercise. Keep track of the knee exercise, walking, and any other physical activity in your diary and bring your diary with you to the next session.

Wrapping Up: Congratulations on completing Unit 4!

- Motivation/Persistence: Your participation shows that you want to improve your osteoarthritis and high blood pressure. You have also evaluated your current pain management and learned how to manage knee pain so you can continue to do your physical activity. Your perseverance shows that you are someone who can stick to something in which you believe.
- Social persuasion: You are progressing with your physical activity program. You have shown that you can do these knee exercises.

Thank you for your participation in the STAR Study. Your help is greatly appreciated.

Appendix D Parent Study Questionnaires

Appendix D.1 Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index

Instrument Number: 127

Please use BLACK Pen Only!

Study ID: 172

STAR Study

WOMAC™ OSTEOARTHRITIS INDEX VERSION LK 3.1

ID Number: _____ Administration Date: ___ / ___ / ____ (month) (day) (year)

Visit Number: 0 ○ 1 ○ 2 ○

(FOR STAFF USE ONLY)

Shade circles like this: ●
Not like this: ⊗ ✓

Think about the following joint as you complete this questionnaire:

For Staff Use Only ___

Joint: _____

Side:
- ○ **1 Right**
- ○ **2 Left**
- ○ **3 Not applicable**

Section A: **Pain**

Think about the **pain** you felt in your joint caused by your arthritis ***during the last 48 hours***.

QUESTION: How much pain have you had . . . .

	None 0	*Mild* 1	*Moderate* 2	*Severe* 3	*Extreme* 4
1. when walking on a flat surface?	○	○	○	○	○
2. when going up or down stairs?	○	○	○	○	○
3. at night while in bed? (that is - pain that disturbs your sleep)	○	○	○	○	○
4. while sitting or lying down?	○	○	○	○	○
5. while standing?	○	○	○	○	○

48140

ID Number: _ _ _ _ _ _ _ _ _ _ _ _ (for internal use only) Date: _ _ / _ _ / _ _ (for internal use only) Study ID: 1 7 2

WOMAC™ OSTEOARTHRITIS INDEX VERSION LK 3.1

Section B: **Stiffness**

Think about the **stiffness** (not pain) you felt in your joint caused by the arthritis ***during the last 48 hours***. [Stiffness is a sensation of ***decreased*** ease in moving your joint.]

	None	Mild	Moderate	Severe	Extreme
	0	1	2	3	4
6. How **severe** has your stiffness been **after you first woke up** in the morning?	○	○	○	○	○
7. How **severe** has your stiffness been after sitting or lying down or while resting **later in the day**?	○	○	○	○	○

Section C: **Difficulty Performing Daily Activities**

Think about the difficulty you had in doing the following daily physical activities caused by the arthritis in your joint ***during the last 48 hours***. [By this we mean **your ability to move around and take care of yourself**.]

QUESTION: How much difficulty have you had . . . .

	None	Mild	Moderate	Severe	Extreme
	0	1	2	3	4
8. when going down the stairs?	○	○	○	○	○
9. when going up the stairs?	○	○	○	○	○

ID Number: _ _ _ _ _ _ _ _ _ _ _ _ (for internal use only) Date: _ _ / _ _ / _ _ (for internal use only) Study ID: 1 7 2

WOMAC™ OSTEOARTHRITIS INDEX VERSION LK 3.1

Section C: **Difficulty Performing Daily Activities (continued)**

QUESTION: How much difficulty have you had . . . .

	None	Mild	Moderate	Severe	Extreme
	0	1	2	3	4
10. when getting up from a sitting position?	O	O	O	O	O
11. while standing?	O	O	O	O	O
12. when bending to the floor?	O	O	O	O	O
13. when walking on a flat surface?	O	O	O	O	O
14. getting in or out of a car, or getting on or off a bus?	O	O	O	O	O
15. while going shopping?	O	O	O	O	O
16. when putting on your socks or pantyhose or stockings?	O	O	O	O	O
17. when getting out of bed?	O	O	O	O	O
18. when taking off your socks or pantyhose or stockings?	O	O	O	O	O
19. while lying in bed?	O	O	O	O	O
20. when getting in or out of the bathtub?	O	O	O	O	O
21. while sitting?	O	O	O	O	O
22. when getting on or off the toilet?	O	O	O	O	O
23. while doing heavy household chores?	O	O	O	O	O
24. while doing light household chores?	O	O	O	O	O

Appendix D.2 Short Form-36v2 (SF-36v2)

Instrument Number: 4 0 4

Please use BLACK Pen Only!

Study ID: 1 7 2

STAR Study

SF-36v2™ HEALTH SURVEY

ID Number: _____ Administration Date: ___ / ___ / _____ (month) (day) (year)

Visit Number: 0 1 2

(FOR STAFF USE ONLY)

Shade circles like this: ●
Not like this: ⊗ ✓

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

1. In general, would you say your health is: (Choose one response only.)

   - 1 excellent
   - 2 very good
   - 3 good
   - 4 fair
   - 5 poor

2. **Compared to one year ago**, how would you rate your health in general **now**? (Choose one response only.)

   - 1 much better now than one year ago
   - 2 somewhat better now than one year ago
   - 3 about the same as one year ago
   - 4 somewhat worse now than one year ago
   - 5 much worse now than one year ago

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3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much? (Choose one response on each line.)

	Yes, limited a lot 1	Yes, limited a little 2	No, not limited at all 3
a. **vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	O	O	O
b. **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O	O	O
c. lifting or carrying groceries	O	O	O
d. climbing **several** flights of stairs	O	O	O
e. climbing **one** flight of stairs	O	O	O
f. bending, kneeling, or stooping	O	O	O
g. walking **more than a mile**	O	O	O
h. walking **several hundred yards**	O	O	O
i. walking **one hundred yards**	O	O	O
j. bathing or dressing yourself	O	O	O

4. **During the past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? (Choose one response on each line.)

	All of the time 1	Most of the time 2	Some of the time 3	A little of the time 4	None of the time 5
a. cut down on the **amount of time** you spent on work or other activities	O	O	O	O	O
b. **accomplished less** than you would like	O	O	O	O	O
c. were limited in the **kind** of work or other activities	O	O	O	O	O
d. had **difficulty** performing the work or other activities (for example, it took extra effort)	O	O	O	O	O

5. **During the past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? (Choose one response on each line.)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	1	2	3	4	5
a. cut down on the **amount of time** you spent on work or other activities	O	O	O	O	O
b. **accomplished less** than you would like	O	O	O	O	O
c. did work or other activities **less carefully than usual**	O	O	O	O	O

6. **During the past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Choose one response only.)

O 1 not at all
O 2 slightly
O 3 moderately
O 4 quite a bit
O 5 extremely

7. How much **bodily** pain have you had **during the past 4 weeks**? (Choose one response only.)

O 1 none
O 2 very mild
O 3 mild
O 4 moderate
O 5 severe
O 6 very severe

8. **During the past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)? (Choose one response only.)

O 1 not at all
O 2 a little bit
O 3 moderately
O 4 quite a bit
O 5 extremely

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. (Choose one response on each line.)
How much of the time **during the past 4 weeks** . . . .

	All of the time 1	Most of the time 2	Some of the time 3	A little of the time 4	None of the time 5
a. did you feel full of life?	O	O	O	O	O
b. have you been very nervous?	O	O	O	O	O
c. have you felt so down in the dumps that nothing could cheer you up?	O	O	O	O	O
d. have you felt calm and peaceful?	O	O	O	O	O
e. did you have a lot of energy?	O	O	O	O	O
f. have you felt downhearted and depressed?	O	O	O	O	O
g. did you feel worn out?	O	O	O	O	O
h. have you been happy?	O	O	O	O	O
i. did you feel tired?	O	O	O	O	O

10. **During the past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? (Choose one response only.)

O 1 all of the time
O 2 most of the time
O 3 some of the time
O 4 a little of the time
O 5 none of the time

11. How **TRUE** or **FALSE** is <u>each</u> of the following statements for you?
(Choose one response on each line.)

	Definitely TRUE 1	Mostly TRUE 2	Don't Know 3	Mostly FALSE 4	Definitely FALSE 5
a. I seem to get sick a little easier than other people.	O	O	O	O	O
b. I am as healthy as anybody I know.	O	O	O	O	O
c. I expect my health to get worse.	O	O	O	O	O
d. My health is excellent.	O	O	O	O	O

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Appendix D.3 Arthritis Pain Self-Efficacy Subscale

Instrument Number: 364

Please use BLACK Pen Only!

Study ID: 172

STAR Study

ARTHRITIS SELF- EFFICACY SCALE

ID Number: _____ Administration Date: ___ / ___ / _____ (month) (day) (year)

Visit Number: 0 1 2

(FOR STAFF USE ONLY)

Shade circles like this: ●
Not like this: ⊗ ✓

In the following questions, we'd like to know how your arthritis pain affects you. For each of the following questions, please fill in the circle that corresponds best to your certainty that you can now perform the following tasks.

	Very Uncertain				Moderately Uncertain					Very Certain
	10	20	30	40	50	60	70	80	90	100
1. How certain are you that you can decrease your pain quite a bit?	○	○	○	○	○	○	○	○	○	○
2. How certain are you that you can continue most of your daily activities?	○	○	○	○	○	○	○	○	○	○
3. How certain are you that you can keep arthritis pain from interfering with your sleep?	○	○	○	○	○	○	○	○	○	○
4. How certain are you that you can make a small-to-moderate reduction in your arthritis pain by using methods other than taking extra medication?	○	○	○	○	○	○	○	○	○	○
5. How certain are you that you can make a large reduction in your arthritis pain by using methods other than taking extra medication?	○	○	○	○	○	○	○	○	○	○

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We would like to know how confident you are in performing certain daily activities. For each of the following questions, please fill in the circle that corresponds to your certainty that you can perform the tasks as of now, without assistive devices or help from another person. Please consider what you routinely can do, not what would require a single extraordinary effort.

As of now, how certain are you that you can....

	Very Uncertain				Moderately Uncertain					Very Certain
	10	20	30	40	50	60	70	80	90	100
6. walk 100 feet on flat ground in 20 seconds?	○	○	○	○	○	○	○	○	○	○
7. walk 10 steps downstairs in 7 seconds?	○	○	○	○	○	○	○	○	○	○
8. get out of an armless chair quickly, without using your hands for support?	○	○	○	○	○	○	○	○	○	○
9. button and unbutton 3 medium-size buttons in a row in 12 seconds?	○	○	○	○	○	○	○	○	○	○
10. cut 2 bite-size pieces of meat with a knife and fork in 8 seconds?	○	○	○	○	○	○	○	○	○	○
11. turn an outdoor faucet all the way on and all the way off?	○	○	○	○	○	○	○	○	○	○
12. scratch your upper back with both your right and left hands?	○	○	○	○	○	○	○	○	○	○
13. get in and out of the passenger side of a car without assistance from another person and without physical aids?	○	○	○	○	○	○	○	○	○	○
14. put on a long-sleeve front-opening shirt or blouse (without buttoning) in 8 seconds?	○	○	○	○	○	○	○	○	○	○

In the following questions, we'd like to know how you feel about your ability to control your arthritis. For each of the following questions, please fill in the circle that corresponds best to your certainty that you can now perform the following activities or tasks.

	Very Uncertain				Moderately Uncertain					Very Certain
	10	20	30	40	50	60	70	80	90	100
15. How certain are you that you can control your fatigue?	○	○	○	○	○	○	○	○	○	○
16. How certain are you that you can regulate your activity so as to be active without aggravating your arthritis?	○	○	○	○	○	○	○	○	○	○

	Very Uncertain									Moderately Uncertain	Very Certain
	10	20	30	40	50	60	70	80	90	100
17. How certain are you that you can do something to help yourself feel better if you are feeling blue?	○	○	○	○	○	○	○	○	○	○
18. As compared with other people with arthritis like yours, how certain are you that you can manage arthritis pain during your daily activities?	○	○	○	○	○	○	○	○	○	○
19. How certain are you that you can manage your arthritis symptoms so that you can do the things you enjoy doing?	○	○	○	○	○	○	○	○	○	○
20. How certain are you that you can deal with the frustration of arthritis?	○	○	○	○	○	○	○	○	○	○

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