STRENGTH TRAINING AND PHYSICAL FUNCTION: ROLE OF SELF-EFFICACY

BY

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LIST OF ABBREVIATIONS

Osteoarthritis	OA
World Health Organization	WHO
Social Determinants of Health	SDOH
Magnetic Resonance Imaging	MRI
Kellgren and Lawrence	K-L
Joint Space Narrowing	JSN
Body Mass Index	BMI
Osteoarthritis Research Society International	OARSI
Activities of Daily Living	ADL
American College of Sports Medicine	ACSM
Six-Minute Walk	6MW
Western Ontario and McMaster Universities Osteoarthritis Index	WOMAC
Short Form-36; Short Form-36 Physical Component Score	SF-36; SF-36 PCS
Social Cognitive Theory	SCT
Strength Training for Arthritis Trial	START
High Intensity	HI
Low Intensity	LI
One Repetition Maximum	1RM

ABSTRACT

Background: The occurrence of knee osteoarthritis (OA) poses a significant problem for individuals' physical function. Strength training impacts physical function through improvements at the muscular level, where activities of daily living may feel easier to accomplish and may also positively impact perceptions of ability and physical symptoms. Therefore, this study aims to explore whether a strength training intervention leads to changes in self-efficacy and whether changes in self-efficacy mediate the effects of strength training on physical function.

Methods: The Strength Training for Arthritis Trial (START) included 377 community-dwelling adults (≥ 50 years) with a body mass index ranging from 20 to 45, knee pain, and radiographic knee OA, who self-reported disability due to knee OA. Measures of Adherence Self-Efficacy, 6-minute Walk Distance, Western Ontario and McMaster Universities OA Index for physical function, and the SF-36 Physical Component Score were collected before randomization and again at an 18-month follow-up in adults who were assigned to 1 of 3 treatment conditions: high-intensity strength training, low-intensity strength training, or attention control.

Results: Among 377 randomized participants (mean age, 65 years; 151 women [40%]), 320 (85%) completed the trial. The intervention had a significant positive effect on self-efficacy across all outcomes ($\beta = 0.24$-0.26, $p < 0.001$). Self-efficacy significantly mediated treatment effects on strength training and physical function across all measures (SF-36 PCS, WOMAC Function, and 6MWD; $p < .05$).

Conclusions: Results supported that a strength training intervention led to improvements in self-efficacy and that self-efficacy mediated the relationship between strength training and physical function. Strength training programs designed to influence aspects of physical function should consider methods to improve self-efficacy and assist individuals with managing physical symptoms. This study was supported by grants 1R01AR059105-01 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases and P30 AG21332 from the National Institute on Aging.

INTRODUCTION

Osteoarthritis is the most common type of arthritis, affecting millions of individuals globally (Neogi, 2013), and is the leading cause of disability worldwide due to the chronic and progressive nature of the disease (Osteoarthritis Action Alliance, 2019). Osteoarthritis prevalence increases as the population ages and is more prevalent in females than males (Felson et al., 2000). Approximately 528 million people have osteoarthritis worldwide (Long et al., 2022). About 73 percent of those individuals are over the age of 55, with 60% of them being female. The prevalence of OA has increased by over 113% from 1990 to 2019, with the highest number of prevalent cases observed in China (132.81 million), India (62.36 million), and the US (51.87 million) (Long et al., 2022).

OA is a prevalent condition across the United States, affecting people from all backgrounds. Social factors may play a causal role in cultivating illness and disability but can also promote disease prevention and health maintenance. The World Health Organization (WHO) defines social determinants of health (SDOH) as "the conditions in which people are born, grow, work, live, and age, and the set of forces and systems shaping the conditions of daily life" (CDC, 2024). When one or multiple of these conditions pose a challenge, the conditions can become risk factors for poor health outcomes (Whitman et al., 2022). Results of a study by Vennu et al. (2020) revealed that social factors (such as being aged ≥ 65 years, men, non-Caucasian; unmarried, widowed, or separated; less educated, being unemployed, having less than 50,000-dollar annual income, being overweight or obese, being a current or former smoker, and consuming alcohol) were associated with chronic conditions, including arthritis.

According to the Osteoarthritis Research Society International (OARSI; Standardization of Osteoarthritis Definitions, 2015), the definition of OA encompasses the involvement of movable joints characterized by cell stress and extracellular matrix degradation which is started by micro- and macro-injury that activates dysfunctional repair responses. These responses include pro-inflammatory pathways of natural immunity. This condition can involve molecular, anatomic, and or physiological changes which can be characterized by cartilage degradation, bone remodeling, the formation of osteophytes, inflammation of the joint, and the loss of normal joint function.

OA most commonly affects the hands, knees, hips, and back (CDC, 2024), with the knee being the most common OA site, accounting for over 60% of the prevalent cases in 2019 (Long et al., 2022). Over time, OA can cause changes in bone, cartilage, and other joint tissues that can result in disability or make it challenging for someone to complete their daily tasks. There is a layer of smooth, rubbery tissues at the end of bones called cartilage to protect the bones as they move. This protective layer reduces friction where the bones meet, allowing the joints to move more easily. When the cartilage gets damaged, it can wear away, causing the bones to rub together, leading to pain and inflammation (Cleveland Clinic, 2021).

Impact of Knee OA: Economic, Function, and Public Health

Economic

Recognizing the risk factors for knee OA highlights the significant costs and burdens associated with the condition. According to OARSI and Yelin et al. (2007), in 2003, the total costs attributable to arthritis and rheumatic conditions in the United States was approximately 128 billion dollars, with direct costs (medical expenditures) totaling

$80.8 billion and indirect costs (lost earnings) totaling $47 billion. This group also discussed a study from 2009 in the United States, where estimated costs due to hospital expenditures from total knee joint replacement surgeries totaled $28.5 billion. The OARSI reported that when patients with OA were compared to age and gender-matched peers, the patients with OA had much higher out-of-pocket health-related expenditures, with the direct costs of OA per patient estimated at an average of $2,600 per year.

Function

Guccione et al. (1994) investigated the effects of medical conditions on functional limitations in older adults, specifically looking at several functional activities of daily living (ADLs) such as stair climbing, carrying groceries, home chores, and cooking. The authors compared the risks of physical disability associated with all comorbid conditions, controlling for age, sex, and presence of all other comorbid conditions, using data from the Framingham Study Cohort. The authors used two clinical definitions for knee osteoarthritis: at least grade two radiographic changes according to the Kellgren and Lawrence criteria with pain in or around the knee lasting at least a month in the year before examination, or at least grade three radiographic changes (JSN plus osteophytes) with infrequent pain. They were looking at ten prevalent medical conditions, including knee OA. The authors found that knee OA contributes to functional limitations and that the proportions of disability in the elderly attributable to knee osteoarthritis were greater than those attributable to other conditions. Clynes et al. (2019) also found that OA diagnoses were associated with difficulties in mobility, the ability to self-care, and performing usual activities.

Public Health

Furthermore, the high prevalence of knee OA makes it a major public health burden globally. Physical disability from knee OA involves the interaction of severity of the disease process, pain, comorbid medical conditions, loss of physical capacity (muscle strength, aerobic work capacity, and joint function), psychological, social, and environmental factors (Ettinger & Afable, 1994), where the degree of disability is related to the severity of the condition and pain. OA's impact on these physical capacities may lead to the avoidance of activities, further resulting in the disuse of muscles, exacerbating muscle weakness, increasing pain, and limiting physical function (Ettinger & Afable, 1994), ultimately impairing quality of life (Clynes et al., 2019). Physical function refers to the ability to perform basic and instrumental ADLs (Garber et al., 2010). As individuals experience declines in physical functioning, there may be increased difficulty performing these ADLs, which may lead to avoiding or limiting these activities.

Diagnosis and Symptoms of Knee Osteoarthritis

Knee osteoarthritis can be diagnosed as radiographic or symptomatic. Radiographic knee OA can be determined by an X-ray or magnetic resonance imaging (MRI) and is frequently graded in severity using the Kellgren and Lawrence (K-L) system. The K-L system is a method of classifying the severity of osteoarthritis using five grades, where a score of two or higher represents osteoarthritis (Kellgren & Lawrence, 1957). This system ranges from grade zero (none), which is a definite absence of x-ray changes, to grade one (doubtful), having doubtful joint space narrowing (JSN; the distance between the bones in a joint decreases) and a possible overgrowth of the bone around the joint. Grade two (minimal) shows definite osteophytes (bone spurs) and possible JSN. Grade three (moderate) shows multiple osteophytes, definite JSN, some sclerosis (the bone beneath the cartilage becomes thick and dense), and possible deformity on the bone ends. Grade four (severe) shows large osteophytes, noticeable JSN, severe sclerosis, and definite deformity of the bone ends. Breaking down the stages of knee OA can help individuals manage the progression of their condition over time.

Symptomatic knee OA is defined as radiographic OA in the knee with symptoms occurring in the same knee. OA symptoms include pain, joint stiffness (less than or equal to thirty minutes), swelling in and around the joint, and changes in the range of motion of the affected joint (Branch, 2017). A primary symptom of this disabling condition includes pain (Neogi, 2013) and may influence a person's ability to engage in normal activities of daily living. Pain is subjective and ranges in intensity, quality, and duration, and has multiple pathophysiologic mechanisms and meanings (Raja et al., 2020) and can be defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage (Gebhart, 2000).

The causes of pain in OA are multifactorial due to both intra-articular and extra-articular risk factors. Hawker et al. (2008) examined the pain experience in OA and explore pain-related distress and changes over time. These researchers found that more intense but less frequent pain, particularly when unpredictable, had a larger impact on quality of life than background aching pain. The study participants described the more intense and unpredictable pain as having negative effects on their mood and their ability to participate in social and recreational activities with confidence. Additionally, many study participants described how they had reduced participation in typical activities to avoid triggering pain. While the experiences of pain and other physical symptoms is complete, numerous risk factors have been identified to aid in the understanding of pain, function and knee OA.

Risk Factors of Knee Osteoarthritis

There are systemic (genetics, diet, hormones, and bone density) and biomechanical (muscle weakness, joint laxity, repeated forces to the joint, and obesity) risk factors that are important to consider, and modifying them may help prevent or delay the onset of osteoarthritis-related pain and disability (Felson et al, 2000). An article by Segal & Glass (2011) highlighted the role of the quadriceps acting with other lower limb muscles and ligaments to provide stability to the knee joint. Their results suggested that greater quadriceps muscle strength was associated with a lower risk for incident symptomatic knee OA, and additionally, a lower risk of progression of JSN and cartilage loss in women.

With a growing population of overweight and obese individuals in the United States (Fryar & Afful, 2021), it is important to consider the effects weight gain has on the joints. Increased body weight leads to increased force placed on the weight-bearing joints such as the knee, spine, hip, and ankle (Lementowski & Zelicof, 2008). Over time, overloading of the knee joint could cause cartilage breakdown, where a one-pound increase in body weight increases the force placed across the knee during a single-leg stance by two to three pounds (Felson et al., 2000), which might explain the increased risk for knee OA among overweight or obese individuals. Data from NHANES showed that individuals with obesity (Body Mass Index (BMI) ≥ 30 kg/m^2) were 55% more likely to develop any kind of arthritis compared to non-obese individuals (Baah & Kohlmeier, 2024).

Physical Function

The International Classification of Functioning, Disability, and Health (ICF) acts as a framework to describe and organize information on functioning and disability (WHO, 2001). This framework conceptualizes an individual's level of functioning as an interaction between their health conditions, environmental factors, and personal factors. Functioning, according to the ICF, acts as an umbrella term for body function, body structures, activities, and participation. According to Garber et al. (2010) physical functioning includes the ability to perform ADLs, where the ability of individuals to reside in their community independently largely depends on their level of physical function. Where the ability to perform tasks in daily life involves the integration of multiple physiological systems, including the neuromotor and musculoskeletal systems which can be altered by the presence of a disease, ultimately leading to changes in physical function. When assessing physical function, both performance-based and subjective measures can be used to evaluate an individual's ability to carry out their ADLs. Performance-based measures help quantify the participants capacity to perform certain tasks while subjective measures help gather information regarding the participants perception of their functioning and how it impacts their life (Ward, 2007).

As previously stated, osteoarthritis is one of the leading causes of disability worldwide. Individuals with knee OA often experience joint damage and symptoms that interfere with their ability to complete everyday tasks and engage in routine activities, which in turn can worsen their condition. Research has highlighted the fact that osteoarthritis poses a significant public health impact due to its prevalence and impact on pain and is often associated with functional impairment and disability (Luong et al., 2012; Botha-Scheepers et al., 2006).

Guccione et al. (1994) aimed to identify associations between medical conditions in the elderly and limitations in functional tasks to compare the risks of disability across medical conditions; and to determine the proportion of disability attributable to each condition. Members from the Framingham Heart Study were included to explore the degree to which the association of knee OA with physical disability changes with different definitions of OA, asymptomatic or symptomatic. In a sample of 1060 women and 709 men, knee OA was among the most prevalent of the included diseases and was found to contribute to limitations in at least four of seven functional activities (such as stair climbing, walking a mile, heavy home chores, housekeeping, cooking, grocery shopping, carrying bundles).

Properly assessing an individual's physical function through performance-based measures and or self-reported questionnaires can help determine the burden of the disease placed on the individual (White & Master, 2016). Commonly used physical function tests in research include the six-minute walk test (6MWT) and self-reported questionnaires such as the WOMAC, the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the Patient Reported Outcomes Measurement Information System (PROMIS) (White & Master, 2016).

The 6MWT measures functional exercise capacity. Messier et al. (2013) conducted a randomized clinical trial (RCT), the Intensive Diet and Exercise for Arthritis (IDEA) trial. They found that the exercise group, who completed aerobic and strength training, could walk over 20 meters further than the diet-only group. However, those in the combined diet and exercise group had better clinical outcomes (pain, mobility, and function) and improved walking speed and distance during the 6MWT.

The WOMAC is a self-administered, disease-specific, health status instrument that measures pain, stiffness, and physical function (Bellamy et al., 1988). Using the WOMAC scale, patients who perceived their chronic OA diagnosis as having a large impact on their functioning had a higher risk of reporting more activity limitations compared to those who viewed their diagnosis as having a smaller functional impact (Botha-Scheepers et al., 2006).

The short form-36 (SF-36) is the most widely used and validated measure of health-related quality of life and is used to yield two broad summary scores: physical and mental component scores. Yokota et al. (2023) aimed to identify which physical function measures were associated with health-related quality of life in adults with knee OA. The physical function measures included grip strength, one-leg standing time, sit-to-stand-5, times up and go, and maximum walking speed. The researchers found that the OA group had significantly shorter one-leg standing time ($p < 0.01$), significantly slower maximum walking speed ($p < 0.01$), and took significantly longer to complete the sit-to-stand-5 ($p < 0.01$) and timed up and go test ($p < 0.01$). The OA group with lower physical function performance also had significantly lower SF-36 scores than the control group for the physical component summary (PCS; $p < 0.01$).

A cross-sectional study by Wang et al. (2024) aimed to observe the predictors of self-reported and performance-based physical function in patients with knee OA and found that pain intensity and knee flexor muscle strength were the main predictors of self-reported physical function and both knee extensor and flexor muscle strength were the primary determinants of performance-based measurements.

Individuals with knee OA often experience joint damage and symptoms that interfere with their ability to complete everyday tasks and engage in routine activities, which in turn can worsen their condition. A cross-sectional study by Obara et al. (2023) compared the QoL of individuals with knee OA versus age-matched asymptomatic individuals to determine the impact of OA on the affected population. The results showed that individuals with knee OA had worse perceived QoL than the asymptomatic individuals across all domains of the 36-item Short-Form Health Survey. The lowest-scoring domains were physical functioning and functional limitations. Additionally, the researchers found that quality of life was influenced by BMI, age, sex, and the grade of osteoarthritis. An assessment by Kawano et al. (2015) concluded that individuals with osteoarthritis have a lower perception of their QoL in the categories of functional capacity, limitation, and pain. They also found a strong association between low levels of education and low perception of QoL. Various training options have been shown to have positive, therapeutic effects on knee OA (Zeng et al., 2021), but some may carry more beneficial effects than others.

Management of Knee Osteoarthritis

Arthritis is a chronic condition requiring patients to learn the most effective way to manage and cope daily. While knee osteoarthritis has no cure, multiple treatment methods exist to manage symptoms. Management of OA from providers can include physical therapy to strengthen muscles that surround the affected joint, the use of over-the-counter pain relievers or prescribed medications, the use of a supportive device such as a crutch, cane, brace, or Kinesio taping, or if other treatments do not work effectively, a joint replacement surgery (CDC, 2024; Kolasinski et al., 2020).

Managing osteoarthritis symptoms should include the implementation of exercise as it is a strongly recommended strategy for all OA patients, where physician recommendations should focus on their patients' preferences, accessibility, and affordability, which may be potentially important barriers to participation (Kolasinski et al., 2020). However, a detrimental coping strategy for individuals with knee OA is avoiding physical activity to prevent pain.

Physical inactivity is a contributing factor to many chronic conditions that affect individuals globally and is associated with increasing health costs (Thompson et al., 2020); while other determinants of health also influence health outcomes, individual lifestyle and behavior are among the most important factors to consider. Baah & Kohlmeier, (2024) reported that individuals who did not engage in moderate work activity (which was indicated by individuals reporting they were involved in at least a moderate-intensity activity that caused small increases in breathing or heart rate for at least ten minutes continuously) had 24% increased odds of developing arthritis compared to those who did. Physical inactivity among arthritic adults is associated with health consequences, including pain, functional limitations, loss of independence in ADLs, and a decreased quality of life (Penninx et al., 2001). Managing hip and knee OA through regular physical activity has been positively associated with long-term improvements in physical function and health-related quality of life (Lopes et al., 2023). Implementing various types of exercise (planned or structured physical activity) into daily life improves physical and mental health.

Thompson et al. (2020; page 512) shared that “exercise is a 'medicine' that can prevent and treat chronic disease; those who 'take it' live longer and with a higher quality of life.” The ACSM physical activity guidelines recommend that adults aged 18-65 years should participate in moderate-intensity aerobic physical activity for at least thirty minutes, five days per week or vigorous-intensity aerobic physical activity for at least twenty minutes on three days per week and that adults should participate in activities to maintain or increase muscular strength for at least two days per week. Aerobic activity involves the body’s large muscles moving rhythmically for a sustained period, with walking, running, biking, and swimming being examples (*Physical Activity Guidelines for Americans, 2nd Edition*, 2018). Muscle-strengthening activities include resistance/strength training, which can be defined as a form of physical activity that is designed to improve muscular fitness by exercising a muscle or muscle group against an external resistance (Fiataraone Singh, Maria et al., 2019; *Physical Activity Guidelines for Americans, 2nd Edition, 2018).* Because physical functioning is basic to maintaining independence in adults with chronic conditions, it is important to investigate whether exercise interventions are related to improvements in ADLs. Data from Penninx et al. (2001) suggested that an aerobic and strength training program may significantly reduce the 18-month incidence of ADL disability in older adults with knee OA. When compared to the attention control group, the relative risk of incident ADL disability in the exercise group was 0.57 (95% confidence interval, 0.38-0.85; $p = .006$). Indicating that participating in exercise programs may be an effective strategy for reducing the risk of ADL disability and may help an individual maintain independence.

The Arthritis, Diet, and Activity Promotion Trial (ADAPT) revealed that those receiving a combined dietary weight loss and exercise intervention experienced more weight loss, had greater improvements in self-reported physical function ($p < 0.05$) and pain ($p < 0.05$) symptoms, and had greater performance measures of mobility (six-minute walk test (6MWD), $p < 0.05$) in adults with knee osteoarthritis compared with those receiving dietary weight loss alone, exercise alone, or healthy lifestyle education (Messier et al., 2004). Messier et al. (2022) conducted another clinical trial to determine if a weight loss and exercise program in community settings across North Carolina would improve knee pain in patients with osteoarthritis and overweight or obesity. They found that the combined diet and exercise (aerobic and strength training) intervention had a small but statistically significant difference in knee pain ($p = 0.02$), a significantly better Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function score ($p < 0.001$), and a further 6MWD ($p < 0.001$), over eighteen months compared to a control group with no diet or exercise intervention. In support of those findings, weight loss was found to be protective for those with knee OA. Messier et al.'s (2005) clinical trial with diet and exercise found that for every pound of weight lost, there was a four-pound reduction in knee-joint load per step. Further, Messier et al.'s (2013) study revealed that participants who lost ten percent or more of their body weight had improved function and reduced pain compared to those who did not.

A systematic review explored various modes of exercise training and their impact on knee OA. The researchers (Zeng et al., 2021) concluded that aerobic training is the most widely used exercise therapy and can help alleviate pain and improve physical function. In comparison, strength training, which targets muscle weakness, is another effective exercise therapy. Quadriceps muscle weakness has been associated with knee pain and impaired function (O’Reilly et al., 1998; Muraki et al., 2015). The quadriceps act as the stabilizer of the knee joint and are important for walking, standing, and climbing stairs. Weakness in this muscle group may directly cause impaired function and be a reason someone would experience pain, with reason to believe that strengthening the quadriceps through strength training would mitigate pain and improve physical function.

Strength Training Interventions

Strength training in particular is a valuable intervention for aging adults or adults with chronic conditions (*Physical Activity Guidelines for Americans, 2nd Edition*, 2018; Fiataraone Singh et al., 2019); benefits include but are not limited to increased muscle strength, endurance, and power, improved communication between brain and muscle, increased bone, muscle and connective tissue growth and durability, and improved blood glucose regulation. Resistance training provides many benefits patients with mild to moderate OA, including physical symptom relief, less disability, improved functional capacity, improved overall health, and restored muscle strength (Zeng et al., 2021; Vincent & Vincent, 2012). A systematic review and meta-analysis analyzed the effectiveness of resistance exercise in the treatment of knee OA on pain, stiffness, and physical function. Data from 17 RCTs were included and results suggested that resistance training relieved pain (standard mean difference [SMD]: -0.43; 95% confidence interval [CI]: -0.57 to -0.29; $p < 0.001$), alleviated stiffness (SMD: -0.53; 95% CI: -0.56 to -0.05; $p = 0.02$), and improved physical function (SMD: -0.53; 95% CI: -0.70 to -0.37; $p < 0.001$) in people with knee OA (Li et al., 2016); specifically, if there was a high-intensity resistance training focus and included exercises for the glutes, quadriceps, and hamstrings. Vincent & Vincent (2012) suggest that the improvement in physical function may come from restoring muscle strength and joint mechanics and may additionally normalize muscle activation patterns and joint biomechanics, which can lead to reductions in joint pain and cartilage degradation.

Fransen and colleagues (2015) reviewed a total of 54 studies that examined the effects of exercise for individuals with knee OA. Evidence from 44 trials indicated that exercise reduced pain (SMD: -0.49, 95% CI: -0.39 to -0.59) immediately after treatment and participants who completed an exercise program rated their pain 12 points lower following their program compared to those who did not exercise on a zero to one hundred self-reported pain scale (95% CI: 10 to 15 points). Additionally, exercise improved physical function (SMD: -0.52, 95% CI: -0.39 to -0.64) after treatment, with physical function improved by 10 points (95% CI: 8 to 13 points) on a zero-to-one-hundred-point scale. This review also included results that found those who participated in quadricep strengthening had a 15-point increase in self-reported physical function (SMD: 0.74). Vincent and Vincent (2012) conducted a meta-analysis to provide potential mechanisms behind why physical functioning can improve with strength training, and reported that the implementation of resistance training led to physiological and physical changes (increased muscle strength, improvements in articular surface loading, and rebalanced leg muscle activation patterns) which in turn provided knee OA symptom relief (including pain), leading to increases in physical ability, confidence, and self-efficacy. Improvements in these factors can all contribute to an individual with knee OA maintaining their independence.

Knee OA's Impact: A Summary

In summary, knee osteoarthritis is a highly prevalent and disabling condition primarily affecting older adults, leading to pain, physical function limitations, and disability. Resistance training interventions can increase muscle strength, rebalance leg muscle activation patterns, and improve articular surface loading, all of which can provide knee OA symptom relief, leading to an improvement in physical function, increased confidence, and increased self-efficacy (Vincent & Vincent, 2012); with psychological well-being as another benefit of initiating a resistance training program.

While studies consistently show that strength training improves physical function in individuals with knee OA, it's crucial to understand the underlying factors that may explain why these improvements occur. A strong conceptual framework would guide this explanation. One promising theoretical construct for understanding this relationship is self-efficacy, the core of the social cognitive theory (SCT).

CONCEPTUAL THEORY

SCT provides the framework for understanding and modifying behavior. SCT identifies factors that direct the learning of capabilities that can affect physical and emotional well-being, including the self-regulation of healthy habits (Bandura, 1998). Bandura (1986) proposes that human behavior is a product of personal factors, environmental influences, and behavioral patterns, where people are neither driven by inner forces nor controlled by external stimuli. SCT includes the idea that there is a continuous interaction between personal factors (such as thoughts and beliefs), environmental factors, and behavior, where each element is influenced by the other. Furthermore, SCT assumes that people are capable of self-regulation and personal agency. As such, self-perceptions of personal agency are critical in the control of human behavior. Self-efficacy, a situation specific perception of control, is a critical personal factor within the social cognitive theory that plays a role in behavior change.

Self-Efficacy

Self-efficacy refers to a person's confidence in their ability to perform a specific task or achieve a goal (Bandura, 1997). These beliefs determine how people behave, think, and feel, and play a role in the self-regulation of motivation. Bandura states that people can exercise influence over what they do based on their understanding of what is within their power and beliefs about their capabilities. For example, individuals with an efficacious mindset will behave differently from those with an inefficacious one, where someone with an efficacious mindset would actively seek out challenges and work through difficulties, someone with an inefficacious mindset might avoid challenges or give up easily.

There are four sources of information on which self-efficacy expectations are based: mastery experience, vicarious experience, verbal persuasion, and the interpretation of physiological and emotional states (Bandura, 1977). Mastery experiences serve as the most effective way of increasing self-efficacy. Successes and failures while performing a task or engaging in a behavior influence future attempts at performing the task again, where successes will build up self-efficacy and failures will lower it. Bandura states that people who experience easy successes come to expect quick results and are more easily discouraged by failures, but difficulties provide people with the opportunities to learn how to turn failures into successes with consistent efforts.

Vicarious experience, also referred to as social modeling, is another effective tool to promote a stronger sense of personal self-efficacy. This can be defined as "seeing or visualizing people similar to oneself performing successfully typically raises efficacy beliefs in observers that they themselves possess the capabilities to master comparable activities" (Bandura, 1977, p. 87). Vicarious experiences have the potential to alter efficacy beliefs where seeing people like oneself typically raises efficacy beliefs in observers that they also possess the ability to master a comparable activity, and the more similarities there are between the people, the more persuasive the models' successes and failures will be (Bandura, 1977).

Verbal persuasion is an effective way to increase a person's confidence in their ability to complete a task. It involves convincing an individual to complete a task by encouraging them and reinforcing them that they are capable (Bandura, 1998). The impact verbal persuasion has on self-efficacy may vary depending on the perceived credibility of who is persuading the individual and their reputation, trustworthiness, expertise, and assuredness. Additionally, those who are verbally persuaded that they possess the ability to master a task are likely to sustain a greater effort and be consistent in their efforts compared to those with self-doubt.

The interpretation of physiological and emotional states means that a person will rely on the state of their physiological sensations and feelings by judging their anxiety as an indicator of their ability to perform a task (Bandura, 1977), where positive physical sensations and emotions will increase self-efficacy, and negative ones will decrease it. Bandura states that somatic self-efficacy indicators are primarily relevant in domains including physical accomplishments, health functioning, and coping with stressors.

Affective or emotional states can include mood. Moods can act as a source of affective information for judging self-efficacy because they can play a role in the quality of functioning.

The 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis was put together to summarize the evidence supporting the benefits and harms of the available educational, behavioral, psychosocial, physical, mind-body, and pharmacologic therapies for OA. The authors of this review (Kolasinski et al., 2020) discuss the importance of taking the personal beliefs and preferences of the patient, as well as the patient's medical status, into consideration when developing a treatment plan. The inclusion of self-efficacy and self-management practices using a multidisciplinary group-based approach with sessions focusing on skill building, education about the disease, medication effects and side effects, joint protection measures, fitness, and exercise goals and approaches is strongly recommended for patients with OA. The authors reported that exercise programs are more effective if supervised rather than when performed by the individual at home and tend to be more effective when combined with self-efficacy and self-management interventions or weight loss programs. An effective tool to assess the beliefs a person has in their ability to exercise at various intensities and frequencies can be assessed through a self-reported self-efficacy questionnaire.

An example from Rejeski (1996) involved asking participants to rate their self-efficacy for functional tasks (stair climbing and lifting/carrying) on a confidence ladder with ten steps ranging from zero (completely uncertain) to ten (completely certain), the level of certainty that they could complete each task two times to ten times without stopping. Results showed that pre-task self-efficacy beliefs had influenced task performance, and that higher self-efficacy was associated with faster task completion, lower perceived difficulty, and greater confidence in their physical ability (all p-values $< .001$).

Efficacy beliefs can affect people's thought patterns that can either enhance or undermine their performance (Bandura, 1997), where the stronger a person's efficacy beliefs are before beginning an exercise program, the greater the physiological benefits that are derived from it. Managing OA through exercise has the potential to enhance both physical and mental well-being. Baghbani et al. (2023) conducted a systematic review and meta-analysis to establish the impact of exercise interventions on perceived self-efficacy among adult populations. Their data demonstrated that exercise did significantly improve perceived self-efficacy (SMD: 0.536, 95% CI: 0.119 to 0.952; $p = 0.012$) when compared to a control condition.

Focht and colleagues (2005) explored the influence of the ADAPT intervention on changes in mobility-related self-efficacy beliefs. This group was specifically interested in whether changes in self-efficacy beliefs and pain were independent predictors of change in performance measures of function. Analyses from this investigation showed that exercise alone and the combined diet and exercise groups significantly increased their walking self-efficacy. These results suggest that exercise alone can increase self-efficacy for walking ($p = 0.00031$), but dietary weight loss must be combined with exercise to influence efficacy beliefs for the more challenging mobility task of stair climbing ($p = 0.0249$). The findings from this study add to evidence that demonstrates how a sense of control and physical symptoms, such as pain, are crucial for understanding and intervening in the process of physical dysfunction.

Another important example includes the Intensive Diet, Exercise, and Activity (IDEA) trial. This was an 18-month, single-blind RCT including 454 overweight/obese individuals (Messier at al., 2013; Mihalko et al., 2018). A social cognitive framework was used for each of the three groups: diet-induced weight loss (D), exercise (E; consisting of aerobic and resistance training), or a combination of both (D+E) to maximize self-efficacy beliefs in the process of behavior change. The objectives of the study were to examine the associations among self-efficacy and physical activity, function, and pain at baseline, to examine changes in self-efficacy over the 18-month intervention. Significantly ($p < .005$) higher self-efficacy for gait, walking duration, and balance were found in the D+E group following the intervention when compared with the D- or E-only groups. Specifically, the exercise only group had significant increases in self-efficacy as measured by a gait efficacy scale ($p < .03$) and walking efficacy for duration scale ($p < .001$) following the 18-month intervention. These findings support the idea that engaging in a structured exercise intervention improves individuals' self-efficacy, especially when combined with other health interventions.

Self-efficacy as a Mediator

A mediator is a variable that helps explain how or why two variables are related, or in other words, is a variable on the causal pathway that helps explain the relationship between the independent and dependent variables (MacKinnon et al., 2008). A simple mediation model, as described by MacKinnon, involves an independent variable (X), a mediating variable (M), and a dependent variable (Y). Mediation then represents the addition of a third variable (M) to the X → Y relation so that the causal sequence can be labeled as X causes the mediator, M, and M causes Y (X → M → Y).

McAuley et al. (2011) published a review looking at the relationship between physical activity and functional performance in older adults, specifically focusing on self-efficacy's potential role as a mediator for this relationship. McAuley states that it is first important to acknowledge the consistent relationship between physical activity and self-efficacy before making inferences regarding self-efficacy's potential mediating effect on health outcomes. Self-efficacy is hypothesized to be reciprocally related to physical activity behavior; older adults with a higher sense of exercise self-efficacy are more likely to engage in physical activity. This reciprocal relationship can be understood by considering the more active that a person becomes, the more confident in their physical ability they might feel, which would then encourage them to participate in more physical activity. In turn, successful exercise experiences are effective in building a stronger sense of self-efficacy.

Additionally, McAuley et al. (2011) highlight that evidence exists to suggest that efficacy expectations are associated with physical function performance. One example by Rejeski and colleagues (1998) includes an 18-month, RCT examining the effects of aerobic and resistance training exercise programs on self-efficacy beliefs and pain in older adults with knee OA. They examined whether self-efficacy and knee pain mediated the effects of the treatments on stair climb time and health perceptions. Participants were randomized into either an aerobic, resistance, or health education control group. The treatment was found to have a significant effect on the baseline-adjusted 18-month stair climb time and self-efficacy scores. They used a linear model to test the effects of knee pain and self-efficacy on baseline-adjusted 18-month stair climb time and a model to test the effect of the treatment on 18-month stair climb time after controlling for baseline knee pain and self-efficacy. After controlling for baseline knee pain and self-efficacy, adjusted 18-month scores for both knee pain ($p < 0.01$) and self-efficacy ($p < 0.001$) were significant, independent predictors of the baseline adjusted 18-month stair climb time. When the variables were controlled, the intervention no longer accounted for significant variance in stair climb time. That is, self-efficacy and knee pain mediated the effects that the exercise training programs had on stair climb time.

ADAPT (Messier et al., 2004) was an 18-month RCT that was designed to determine whether long-term exercise and dietary weight loss were more effective separately or in combination, compared to usual care, in improving physical function, pain, and mobility in older overweight and obese adults with knee OA. In addition to Focht and colleagues (2005) exploring the influence of the ADAPT intervention on changes in mobility-related self-efficacy beliefs, the researchers were also interested in whether self-efficacy would mediate the effect of the interventions on performance-based measures of function. Self-efficacy was found to partially mediate the influence of the interventions on stair climb performance for the combined exercise and dietary weight loss group only. Both examples support the idea that self-efficacy plays a role in explaining functional performance.

Another study by Maly et al. (2007) examined whether self-efficacy mediated the effect of age, psychosocial factors, impairment (such as pain or stiffness), and mechanical factors (such as strength or obesity) on walking performance measured through the 6MWT. They found that the effects of strength were partially mediated by self-efficacy and concluded that mechanical factors like strength may better represent a person's capabilities and interact with other variables to influence physical measures in adults with knee OA. These researchers shared that their results are consistent with SCT in that physical capabilities are likely not as influential on performance as an individual's perception of their capabilities.

Summary, Purpose, and Hypotheses

Research has demonstrated the benefits of strength training for improving physical function in individuals with knee osteoarthritis, but the mechanisms that drive these outcomes remain unknown. A strong conceptual framework is needed for understanding the relationship, as it can help to clarify the underlying mechanisms. Specifically, the role of self-efficacy as a potential mediator has not yet been fully explored. While previous researchers have explored associations between exercise, self-efficacy, and physical function in knee OA, few have tested the mediating role of self-efficacy using a structured model with defined paths to help provide evidence for a causal pathway. This is important as various studies have discussed self-efficacy in the context of OA and exercise but fewer specifically test whether self-efficacy is the reason why strength training leads to better physical function outcomes.

Many previous studies looking at self-efficacy in individuals with OA combine aerobic and strength training interventions or include other interventions (such as dietary weight loss), making unclear what strength training alone can contribute to self-efficacy and physical function changes. Therefore, the purpose of this study was to test if a strength training intervention leads to changes in self-efficacy and whether self-efficacy mediates the impact of a strength training intervention on improvements in physical function outcomes. Through investigating these gaps, we'll hypothesize that:

1. A strength training intervention will lead to increases in self-efficacy, such that HI and LI participants will have more positive changes than control participants.
2. The intervention will be related to changes in physical functioning, such that HI and LI participants will experience more positive changes in physical functioning than control participants.
3. Changes in self-efficacy will be positively related to changes in physical functioning.
4. The impact on physical function outcomes through strength training will be explained through the effects of self-efficacy, meaning that changes in self-efficacy will mediate the impact of strength training on physical function.

METHODS

This study will analyze data from START (Strength Training for Arthritis Trial; (Messier et al., 2021)), an 18-month RCT examining the effects of high-intensity (HI) and low-intensity (LI) strength training on knee OA. The purpose of the overall study was to determine whether HI strength training would reduce knee pain and knee joint compressive forces more than LI strength training and attention control in patients with knee OA. The secondary aim was to compare the intervention effects on additional clinical measures of disease severity, such as function and mobility. For this study, the impact of strength training on physical function will be examined by combining the HI and LI strength training interventions.

START Primary Outcomes

START primary outcome measures included WOMAC pain (0 best – 20 worst) and knee joint compressive forces (defined as the maximal tibiofemoral contact force exerted on the long axis of the tibia while walking). At the 18-month follow-up, there was no statistically significant difference between groups in mean WOMAC pain. The HI group had a score of 5.1 compared to the control group with a score of 4.9 (adjusted difference, 0.2; 95% CI, -0.6 to 1.1; $p = .61$) and 4.4 in the LI group (adjusted difference, 0.7; 95% CI, -0.1 to 1.6; $p = .08$). Additionally, the mean maximum knee joint compressive force was not statistically significantly different between the HI and the other two groups: HI compared to the control group, 2453 N vs 2512 N (adjusted difference, -58; 95% CI, -282 to 165 N; $p = .61$) and HI compared to LI, 2453 N vs 2475 N (adjusted difference, -21 N; 95% CI, -235 to 193; $p = .85$). Primary outcomes at 18 months can be found in Table 1. Knee extensor (quadriceps), knee flexor, and hip abductor strength were measured using the Humac NORM isokinetic dynamometer. Mean knee extensor strength was statistically significantly greater in the HI group (98.5 Newton meter [Nm]) than in the control group (88.5 Nm) at 18 months (adjusted difference, 10.0 Nm; 95% CI: 3.8 to 16.2; $p = 0.002$) but was not statistically significantly different than the LI group (93.2 Nm; adjusted difference, 5.3 Nm; 95% CI: -0.8 to 11.4; $p = 0.09$). The mean hip abductor strength for the HI group was 74.6 Nm vs 69.5 Nm in the control group (adjusted difference, 5.0 Nm; 95% CI: 0.7 to 9.3; $p = 0.02$) but was not statistically significantly different from the LI group (adjusted difference, 0.0 Nm; 95% CI: -4.3 to 4.2; $p = 0.99$). Lastly, the mean knee flexor strength at 18 months was statistically significantly greater in both strength training groups compared with the control group. The mean HI group measured 51.5 Nm compared with 43.8 Nm in the control group (adjusted difference, 7.6 Nm; 95% CI: 3.6 to 11.7; $P < .001$). The LI group measured 52.6 Nm, and compared with the control group had an adjusted difference of 8.7 Nm (95% CI: 4.7 to 12.7; $P < .001$). However, knee flexor strength was not statistically significantly different between the HI and LI group (adjusted difference, −1.1 Nm; 95% CI: −5.1 to 2.9; $P = .59$).

Table 1. Primary Outcomes at 18-Month Follow-up in a Study of the Effect of High-Intensity Strength Training on Knee Pain and Knee Joint Compressive Forces Among Patients With Knee Osteoarthritis					
	Intensity			Mean difference	*P value*
Outcome	High	Low	Control	(95% CI)	
Primary Outcomes					
WOMAC pain (0-20)					
Baseline mean (SD)	7.0 (2.7)	7.4 (2.6)	7.2 (2.7)		
18-mo follow-up, unadjusted mean (SD)	4.9 (3.2)	4.5 (3.4)	4.8 (2.9)		
18-mo absolute change (95% CI)	-2.0 (-2.6 to -1.4)	-2.8 (-3.5 to -2.2)	-2.3 (-2.9 to -1.6)		
No.	108	104	99		
High intensity vs control				0.3 (-0.6 to 1.2)	0.56
High intensity vs low intensity				0.8 (-0.1 to 1.7)	0.07
Low intensity vs control				-0.6 (-1.5 to 0.3)	0.22
18-mo adjusted means (95% CI)	5.1 (4.5 to 5.7)	4.4 (3.8 to 4.9)	4.9 (4.3 to 5.5)		
No.	91	86	84		
High intensity vs control				0.2 (-0.6 to 1.1)	0.61
High intensity vs low intensity				0.7 (-0.1 to 1.6)	0.08
Low intensity vs control				-0.5 (-1.4 to 0.3)	0.22
Knee joint compressive force, N					
Baseline mean (SD)	2326 (727)	2335 (782)	2261 (691)		
18-mo follow-up, unadjusted mean (SD)	2448 (783)	2498 (813)	2456 (844)		
18-mo absolute change (95% CI)	89 (-59 to 237)	116 (-6.2 to 238)	162 (10 to 314)		
No.	65	64	63		
High intensity vs control				-73 (-271 to 124)	0.47
High intensity vs low intensity				-27 (-223 to -170)	0.79
Low intensity vs control				-46 (-245 to 152)	0.65
18-mo adjusted means (95% CI)	2453 N (2296 to 2611	2475 (2325 to 2625	2512 (2352 to 2672)		
No.	50	55	48		
High intensity vs control				0.2 (-0.6 to 1.1)	0.61
High intensity vs low intensity				0.7 (-0.1 to 1.6)	0.85
Low intensity vs control				-0.5 (-1.4 to 0.3)	0.74

<u>Recruitment</u>

Participants in START included ambulatory, community-dwelling adults aged fifty years or older with self-reported disability due to their knee OA. Inclusion criteria included: mild to moderate radiographic medial tibiofemoral osteoarthritis (K-L score, two or three) in at least one knee associated with radiographic skyline views that demonstrated patellofemoral arthritis (none to moderate severity); neutral (-2º valgus to 2º varus), or varus (< 10º varus) mechanically aligned knee; BMI (calculated as weight in kilograms divided by height in meters squared) ranging from twenty to forty-five kg/m^2; and no participation in formal strength training more than thirty minutes per week in the past six months. All participants could continue their medications, including nonsteroidal anti-inflammatory drugs (NSAIDs). Participants were excluded from START if they had severe patellofemoral osteoarthritis (joint space width, three using the Osteoarthritis Research Society International atlas from skyline x-ray views); lateral more than medial tibiofemoral osteoarthritis; or less than twenty on the Montreal Cognitive Assessment. Participants were randomly assigned to groups through a computer-generated permuted block randomization scheme with randomly selected-sized blocks of three, six, nine, or twelve stratified by sex and baseline BMI. The informed consent can be found in Appendix A.

Intervention Groups

372 ambulatory, community-dwelling adults with knee OA were included, with 124 randomized into each group (HI, LI, or attention control). The participants in both the HI and LI strength training groups performed six lower-body and four upper-body exercises (e.g. leg press, hip abduction, hid adduction, leg curl, leg extension, seated calf extension, compound row, chest press, lower back, and abdomen) for sixty minutes (five-minute warm-up, forty-minute strength training, and fifteen-minute cool down) for three days per week over eighteen months. Following the first four sessions with participants learning proper technique, the maximum amount a participant could lift in a single repetition was measured (one repetition maximum (1RM)) to determine their starting resistance. Both strength training groups progressively increased intensity over eight weeks, followed by a taper week to re-establish their 1RM. The LI strength training group performed each exercise at 30-40% of their 1RM, and the HI strength training group performed each exercise at 75-90% of their 1RM.

The attention control group served as the control group, providing attention, social interaction, and health education. Participants attended 60-minute workshops biweekly for the first six months and then one time per month for the remaining twelve months. This arm aimed to control for attention from study staff and general levels of participant time; to encourage recruitment, adherence, and benefit; and not to influence the primary outcomes directly. Interactive presentations covering topics such as foot care, nutrition, managing medication, and sleep practices were covered over 18 months. Participants were asked to complete homework, review topics, and engage in small group discussions to increase their involvement in this study arm. Lastly, workshops ended with seated upper body stretching to enhance adherence and increase perceived benefit without directly affecting the knees.

Techniques to Improve Adherence

Behavioral studies that range over multiple months require significant commitment. START's study design evolved from SCT, group dynamics, and the study teams' extensive experience in RCTs.

Interventionists were trained in behavioral techniques developed in the SCT framework, including frequent contact during the intervention, positive feedback, incentives to reach attendance and performance goals, establishing commitment to the project, promoting a sense of community, and targeted mechanisms for behavioral adherence, including self-efficacy and self-regulatory skills. This approach helps tailor the intervention to each participant's needs by identifying a problem, finding a solution, and testing it for a specific period until the problem is resolved. Table 2 represents some of the strategies used within the intervention to increase self-efficacy overtime.

Table 2. Sample of Behavioral Strategies to Increase Self-Efficacy	
Mastery Experience	- Intervention intensity was tailored to the participants ability and gradually increased over time - Periodic individual updates on the participant's overall progress - Use of logs reflecting achievements in exercise
Vicarious Experience	- Participants were assigned to a group where they attended exercise sessions with other individuals with knee osteoarthritis
Verbal Persuasion	- Built-in pattern of frequent contact where personal interest in the participant was demonstrated - Interventions were supervised by interventionists who encouraged participants
Physiological Cues / Psychological States	- Interventionists helped participants interpret physiological responses (such as pain or soreness) to starting an exercise program - Participants in the exercise intervention were shown how to monitor heart rate and complete training logs - Interventionists talked with participants about their stress and anxiety around making lifestyle changes

Measures

The following measures were taken at baseline, six, twelve, and eighteen months. Data collection was made by staff who were blinded to the group assignment.

Demographics: Age, sex, race and ethnicity, education level, and annual household income level were self-reported.

Function: Physical function was assessed using an objective, 6MWT, and subjective, self-report measures, the WOMAC, and the SF-36 PCS.

Subjective Measures:

The WOMAC is a self-reported questionnaire that can be used to assess pain, stiffness, and physical function in patients with knee OA (Bellamy et al., 1988). The purpose of the WOMAC physical function scale is for participants to indicate on a scale the degree of difficulty they experienced while participating in activities within the past forty-eight hours due to their knee OA. The activities include descending and ascending stairs, rising from sitting, standing, bending to the floor, walking on a flat surface, getting in/out of the car, going shopping, putting on socks, rising from bed, taking off socks, lying in bed, getting in/out the bath, sitting, getting on/off toilet, heavy domestic duties, and light domestic duties and are scored on a zero to four scale where zero = none, one = slight, two = moderate, three = very, and four = extreme. The WOMAC physical function scale includes a seventeen-item subscale that is totaled to generate a summary score ranging from zero to sixty-eight, with a higher score indicating poorer function.

The SF-36 is the most widely used and validated measure of health-related quality of life and is used to yield two broad summary scores: physical and mental health. The purpose of the SF-36 is to assess the functional health and well-being from the individual's perspective (Cornish, 2021). For our purposes, the physical subscale was used. Participants were asked a series of questions related to how they view their health and if or how their health might limit physical activities. For example, participants were asked to indicate on a scale of 1 (yes, limited a lot) to 3 (no, not limited at all) how their health limits them in activities, including vigorous activities, moderate activities, lifting or carrying groceries, or climbing several flights of stairs, where a higher score indicates better function. The measures for physical function can be found in Appendix B.

Objective Measure:

The purpose of the 6MWT was to determine how many meters the participants were able to walk in six minutes. As previously mentioned, the 6MWT is an easy-to-administer tool to measure an individual's functional exercise capacity (Matos Casano & Anjum, 2024). For this task, the participants should walk around the track as quickly as they can to complete as many laps as they can in six minutes, pacing themselves so that they can walk the entire six minutes. The number of laps and distance walked were recorded.

Self-Efficacy: Self-efficacy was assessed through a self-reported measure for Adherence Self-Efficacy. The purpose of this questionnaire was to assess the participants' beliefs in their ability (confidence) to continue exercising at a moderate intensity for various durations. This questionnaire included eight items rating one's ability to exercise over a specific length of time. For example, participants were asked to indicate how confident they were in their abilities to continue exercising three times per week at a moderate intensity, for 15-30 minutes without quitting, for the next week through eight weeks. Responses could be on a scale from zero percent (not at all confident) to one hundred percent (completely confident), in increments of ten. The self-efficacy scale score ranges from zero to one hundred, with a higher score indicating higher self-efficacy. To score, all eight items were added together and then divided by eight. The Adherence Self-efficacy measure can be found in Appendix B.

Statistical Analysis

Participants were analyzed according to the intention-to-treat principle. Means and standard deviations were used to compute descriptive statistics of baseline measures. The variables of interest include age and sex; dependent variables of 6MWD, WOMAC, SF-36 PCS; and an independent variable of exercise self-efficacy. Linear models were used to test whether self-efficacy mediates the effect of strength training on physical function outcomes.

The analytic plan addresses two key research questions: First, does the intervention lead to changes in self-efficacy? Second, does a change in self-efficacy mediate the effect of the intervention on changes in physical function as measured by the SF-36 PCS, 6MWD, and WOMAC Function? Change is defined as the 18-month outcome value minus the baseline value. The high and low-intensity strength training groups were combined in the present analysis because there were no statistically significant differences between the HI, LI, and control groups. Additionally, for the purpose of exploring if there are significant effects when considering all participants as a single intervention group and can increase statistical power to help detect differences between the combined intervention and the control. The path diagram in Figure 1 represents the mediation model.

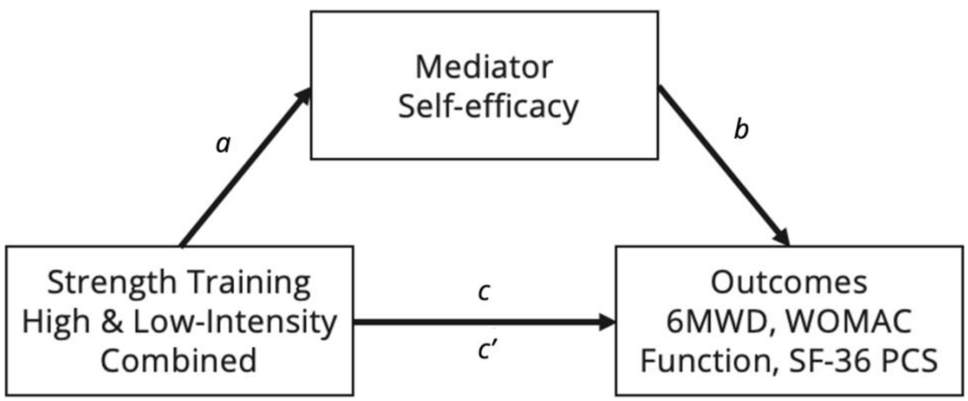


Figure 1. Path diagram for a model showing self-efficacy mediating the intervention on outcomes of interest.

This study used standard notation and denoted the effects (standardized regression coefficient) of the intervention on self-efficacy as *a*, the effect of self-efficacy changes on outcome changes as *b*, and the direct effect of the intervention on outcome changes as *c'*. The indirect effect can be computed under a classical single-mediator (self-efficacy) model as $a \times b$. The total effect, denoted by c, is the sum of the direct and indirect effects, i.e., $c = c' + a \times b$. To establish an intervention effect in the present mediation analysis, the intervention must significantly affect the mediator (*a*), the mediator must significantly affect the outcome (*b)* and calculate, the product of the *a* and *b* coefficients as that represents the extent to which the intervention influences the outcome through the mediating variable. Lastly, demonstrating a lack of the direct effect (*c'*) of the intervention on the outcome should not be significant, meaning that the intervention's influence is explained by its effect on the mediator.

We separately assessed the mediation model for each of the three outcome variables: SF-36 PCS, WOMAC Function, and 6-minute walk. The covariates included the baseline value of the outcome variable, demographic variables (age, gender, race/ethnicity), and socioeconomic factors (education and income). These covariates were included in all regression paths and were consistently used for all outcomes.

RESULTS

Study Cohort

Table 3 shows the characteristics of randomized participants by group. Of the 377 participants randomized (mean age, 65 years; 40% women), 320 (85%) attended the 18-month visit (HI, 109; LI, 108; control, 103). At 18 months, 308 participants contributed data for the outcome of WOMAC Function, 250 participants contributed data for the 6MWD, and 275 participants contributed data for the SF-36 PCS.

Table 3. Demographic and Clinical Characteristics of the Study Participants at Baseline

Basline Characteristics	**No. (%)**	
	High + Low-Intensity	**Control**
No.	253	124
Age, mean (SD), y	65.5 (8.5)	64 (7)
Weight, mean (SD), kg	89 (18.5)	89 (16)
Height, mean (SD), m	1.6 (0.1)	1.6 (0.1)
BMI, mean (SD)	31 (6)	32 (5)
Sex		
Female	103 (41)	48 (39)
Male	150 (59)	76 (61)
Race		
White	202 (80)	94 (76)
Black	44 (17.5)	26 (21)
Asian	2 (1)	1 (1)
> 1 Race	5 (2)	3 (2)
Annual Household Income, $		
No.	247	121
< 20,000	19 (7.5)	7 (6)
20,000-49,999	67 (12.5)	27 (11)
50,000-99,999	103 (21)	53 (22)
≥ 100,000	58 (23.5)	34 (28)
Education		
No.	248	122
< High School	2 (2)	1 (1)
High School	26 (10.5)	5 (4)
Vocational School	21 (8.5)	9 (7)
Some College/Community College	60 (24)	33 (27)
≥ College	139 (18.5)	74 (20.3)
WOMAC		
Function (range 0-68)	26.0 (10.5)	25.0 (10.3)
SF-36		
Physical	41.7 (5.1)	42.2 (5.3)
Self-Efficacy Adherence	90.6 (13.9)	90.5 (15.5)
6MWD, mean (SD), m	472.5 (90.5)	490 (92)

At baseline, the average WOMAC function score was 26.05 for HI and LI and 25.0 for the control group. Higher scores indicate worse functional limitations. At 18 months, the average WOMAC score for HI and LI was 16.35 and 16.4 for the control group. On average, participants walked 472.5 meters in the HI and LI groups and 490 meters in the control group at baseline. At 18 months, the average distance walked for the HI and LI groups was 511 meters and 515 meters for the control group. At baseline, the average SF-36 PCS score for the HI and LI group was 41.7 and 42.4 for the control group. At 18 months, the HI and LI group PCS score was 43.15, and the control group was 43.8. Lastly, for self-efficacy at baseline, the average score for the HI and LI group was 90.6 and 90.6 for the control group. At 18 months, the HI and LI group average scores were 90.6 and 80.1 for the control group; path *a* (β = 0.24-0.26; $p < .001$) represents the between-group differences for self-efficacy. Descriptive statistics can be found in Table 4.

Table 4. Mean (95% C1) Adjusted (baseline value, gender, BMI) Outcomes at Baseline (0), and 18-month Follow-up by Group.

	Control		Low Intensity		High Intensity		P value at18 months
	0	18	0	18	0	18	
6-minute walk (m)	490	512	479	504	466	507	0.76
95% CI		497,526		491,518		494,521	
N	114		116		115		
WOMAC Function	25.0	16.3	26.6	14.8	25.5	17.7	0.06
95% CI		14.5,18.1		13.1,16.6		16.0,19.4	
N	124		126		127		
SF-36 PCS	42.2	43.8	41.4	43.8	42.0	42.5	0.10
95% CI		42.8,44.8		42.8,44.7		41.5,43.3	
N	122		121		120		
Self-Efficacy	90.5	80.1	91.1	91.0	90.2	90.2	<0.001
95% CI		76.5,83.6		87.5,94.5		86.8,93.6	
N	123		123		123		

Effects of a Strength Training Intervention on Self-Efficacy

All three outcomes (SF-36 PCS, WOMAC Function, and 6MWD) had significant a paths (β = 0.251, 0.245, 0.257; *p < .001*), indicating that the independent variable (strength training) significantly predicts the mediator (self-efficacy).

This can be seen in Figure 2.

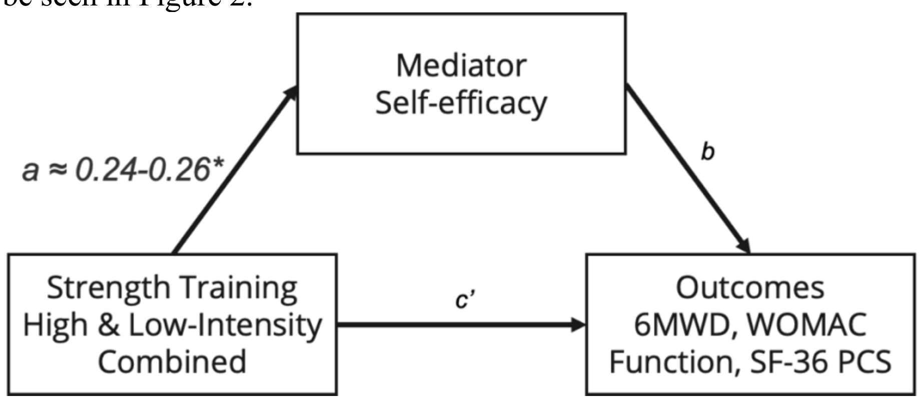


Figure 2. Path diagram for model showing the interventions impact on self-efficacy.

Mediation Effects

Significant mediation effects were observed for the outcomes of SF-36 PCS, WOMAC Function, and 6MWD, suggesting that the strength training intervention improves physical function through its effect on self-efficacy.

SF-36 PCS

Self-efficacy mediated SF-36 PCS: a = 0.251 and b = 0.218, both of which were significant ($p < 0.001$). Both the total effect (c = -0.021) and direct effect (c' = -0.076) were not significant ($p = 0.687$; $p = 0.152$). The indirect effect (β = 0.055; $p < 0.01$) was significant, suggesting that PCS was mediated by self-efficacy (see Figure 3).

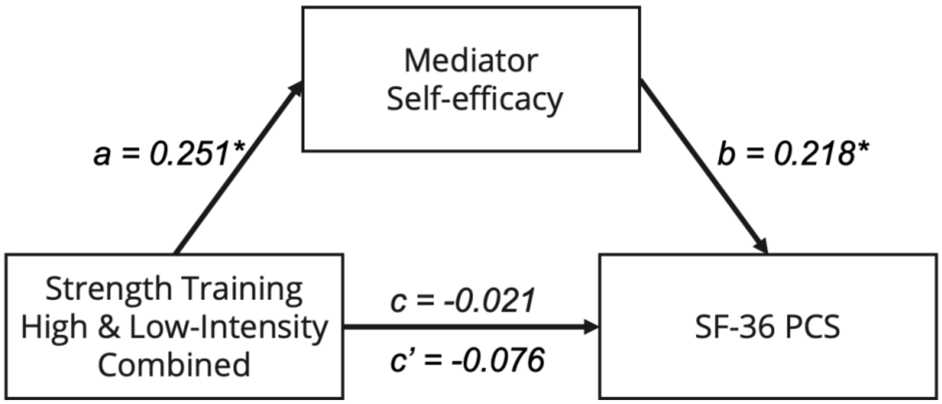


Figure 3. Path diagram for model showing self-efficacy's mediating impact between the intervention and SF-36 PCS.

WOMAC Function

Self-efficacy mediated WOMAC Function: a = 0.245 and b = -0.230, both of which were significant ($p < 0.001$). Both the total effect (c = -0.026) and direct effect (c' = 0.031) were not significant ($p = 0.611$; $p = .544$). The indirect effect ($\beta = -0.056$; $p < 0.01$) was significant, suggesting that WOMAC Function was mediated by self-efficacy (see Figure 4).

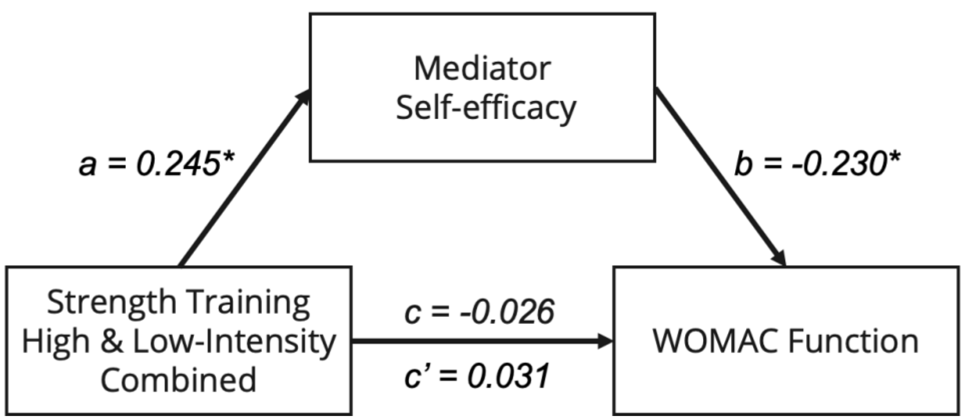


Figure 4. Path diagram for model showing self-efficacy's mediating impact between the intervention and WOMAC Function.

6MWD

Lastly, self-efficacy mediated 6MWD: a = 0.257 ($p < 0.001$) and b = 0.200 ($p < 0.01$), both of which were significant. Both the total effect (c = -0.003) and direct effect (c' = -0.055) were not significant ($p = 0.957$; $p = .375$). The indirect effect ($\beta = 0.051$; $p < .05$) was significant, suggesting that 6MWD was mediated by self-efficacy (see Figure 5).

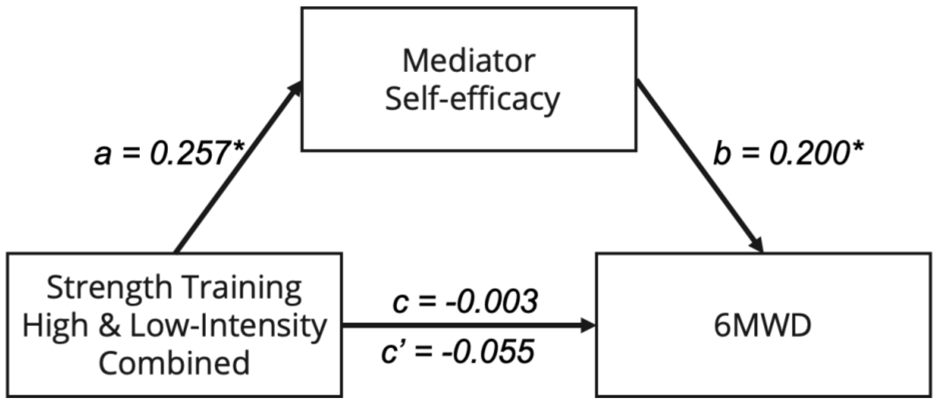


Figure 5. Path diagram for model showing self-efficacy's mediating impact between the intervention and 6MWD.

There were significant indirect effects ($a \times b$) found in each model, and no significant direct effects were observed, meaning that the intervention effects listed were considered mediated by self-efficacy. The mediation table showing these effects can be found in Table 5.

Table 5. Mediation Analysis Results with Path Coefficients										
Outcome	a path	p-value	b path	p-value	c' path (direct effect)	p-value	c path (total effect)	p-value	Indirect effect	p-value
SF-36 PCS	β = 0.251 (0.051)	< .001	β = 0.218 (0.058)	< .001	β = -0.076 (0.053)	.152	β = -0.021 (0.052)	.687	β = 0.055 (0.019)	< .01
WOMAC Function	β = 0.245 (0.051)	< .001	β = -0.230 (0.058)	< .001	β = 0.031 (0.051)	.544	β = -0.026 0.050)	.611	β = -0.056 (0.019)	< .01
6MWD	β = 0.257 (0.053)	< .001	β = 0.200 (0.073)	< .01	β = -0.055 (0.062)	.375	β = -0.003 (0.060)	.957	β = 0.051 (0.022)	< .05

Note: Standard Errors in parentheses. P-values show for each path coefficient. The a path represents the effect of the intervention on self-efficacy. The b path represents the effect of self-efficacy on the physical function outcome. The c path represents the total effect of the intervention on the physical function outcomes, while c' represent the direct effect controlling for the mediator (self-efficacy. Lastly the indirect effect is represented by path a x path b.

DISCUSSION

The purpose of this study was to examine the effect of a strength training intervention on self-efficacy and to examine self-efficacy as a mediator for the relationship between a strength training intervention and self-reported and performance-based physical function outcomes in adults with knee osteoarthritis. Data from this investigation demonstrate that the strength training intervention positively influenced self-efficacy, which in turn mediated improvements in physical function. These findings highlight the importance of self-efficacy for improving physical function from a strength training program. Results showed that the intervention had a significant effect on self-efficacy between groups, indicating that when compared to the attention control group, those individuals receiving the intervention showed higher self-efficacy.

Hypothesis One

The hypothesis that a combined high- and low-intensity strength training intervention would lead to changes in self-efficacy was supported. Results showed that the intervention had a significant effect on self-efficacy. These findings align with prior research examining the effects of exercise training on self-efficacy. A meta-analysis by Baghbani et al. (2023) supports this conclusion, revealing that exercise training programs (aerobic, strength, or combined) significantly improve perceived self-efficacy and found evidence that the self-efficacy improvements due to participating in exercise training could be beneficial for populations with knee osteoarthritis. Similarly, Lawford et al. (2023) found that a strengthening and physical activity program led to improvements in self-efficacy when compared to a control program.

Additional support for this relationship comes from the Intensive Diet, Exercise, and Activity (IDEA) trial, which examined the associations among self-efficacy and physical activity, function, and pain at baseline, to examine changes in self-efficacy over the 18-month interventions (Mihalko et al., 2018). Participants were placed into one of three groups: diet-induced weight loss (D), exercise (E), or a combination of both (D+E). The exercise sessions consisted of aerobic and resistance training. Significantly ($p < .005$) higher self-efficacy for gait, walking duration, and balance were found in the D+E group following the intervention when compared with the D- or E-only groups. Specifically, the exercise only group had significant increases in self-efficacy as measured by a gait efficacy scale ($p < .03$) and walking efficacy for duration scale ($p < .001$) following the 18-month intervention. These findings support the idea that engaging in a structured exercise intervention improves individuals' self-efficacy, especially when combined with other health interventions.

Hypothesis Two: Mediation Effects

Our results also support the hypothesis that changes in self-efficacy would act as a mediator for the relationship between a strength training intervention and physical function outcomes in adults with knee osteoarthritis.

While the intervention did not directly improve physical function, the mediation analysis revealed that improvements in self-efficacy were associated with better physical function outcomes. Specifically, self-efficacy mediated the relationships between strength training and improvements in 6MWD, WOMAC Function, and SF-36 PCS scores, meaning that the intervention did not directly improve physical function outcomes in the absence of self-efficacy. These findings suggest that increased confidence in one's ability to adhere to a strength training intervention is a key mechanism through which improvements in physical function are achieved.

Although it may seem counterintuitive to suggest mediation in the absence of a direct effect. MacKinnon et al. (2009) stated that there are cases where significant mediation exists even when a direct relationship between the independent variable (strength training) and the dependent variable (physical function) is not observed.

MacKinnon et al., (2000) referred to the concept of suppression to describe "a variable which increases the predictive validity of another variable (or set of variables) by its inclusion in a regression equation." In other words, including a third variable (self-efficacy) helped reveal a relationship that was hidden without it. Results revealed that the directions of the direct and indirect effects were opposite, which suggests a suppressor effect, where the beneficial impact of the intervention on physical function through increased self-efficacy may be hidden by the negative and non-significant direct effect. A negative direct effect would indicate an inverse relationship, meaning that as an independent variable increases, the dependent variable tends to decrease. In simple terms, improvements in physical function were seen when self-efficacy increased, but the relationship was not detectable when considering the direct effect of the intervention alone. This further highlights the importance of considering psychological measures such as self-efficacy.

Although few studies have looked specifically at self-efficacy as a mediator in strength training interventions and physical function outcomes, existing research aligns with the current findings. For example, Rejeski et al. (1998) conducted an 18-month RCT where 357 older adults with knee OA were randomized into one of three groups: resistance exercise, aerobic exercise, or attention control. They aimed to determine whether self-efficacy mediates the effects of the treatments on stair climb time. Their results were consistent with our findings, demonstrating that both resistance and aerobic exercise have the potential to enhance performance-related self-efficacy beliefs. The authors discuss how the mediational role played by self-efficacy in explaining the effects of aerobic and resistance exercise on stair-climb time (an objective index of disability) suggests that the health benefits of exercise therapy are linked to perception. Their study was similar to the present study in that there was a large sample size participating in a long-term exercise training program. However, their study had an additional mode of aerobic training compared to only resistance training in the present study.

Similarly, the ADAPT trial (Messier et al., 2004) examined the effects of exercise and dietary weight loss interventions on mobility-related self-efficacy. Focht et al. (2005) conducted a follow-up analysis and examined whether self-efficacy and pain mediated the beneficial effects of the interventions on performance measures such as the 6MWD. Their results had comparable results to the present study, with improvements in self-efficacy and functional measures such as stair climb time and 6-minute walk performance when compared to the healthy lifestyle control intervention. Results examining change in 6-minute walk performance demonstrated that baseline self-efficacy was a significant predictor of change in baseline-adjusted 6MWD ($p < .0001$). Results of the model examining change in stair climb performance demonstrated that baseline stair climb self-efficacy ($p = .0053$) and change in stair climb self-efficacy ($p < .0001$) were significant predictors of baseline-adjusted change in stair climb time. These findings demonstrated that self-efficacy was an independent predictor of change in walking and stair climb performance. Their results supported self-efficacy as a partial mediator in the relationship between the interventions and change in stair climb performance, but not for the 6-minute walk.

Further supporting these findings, the Intensive Diet, Exercise, and Activity (IDEA) trial examined whether changes in self-efficacy mediated the relationship between treatment effects and clinical outcomes at 18 months (Mihalko et al., 2018). Results revealed that self-efficacy significantly ($p < .05$) mediated the effects of diet and exercise on the primary clinical outcomes of physical activity, function, and pain. Change in walking self-efficacy significantly mediated ($p < .05$) the relationship between D+E versus E (and D+E versus D) and 6MWT, gait speed, WOMAC function, and WOMAC pain. Change in balance efficacy also significantly mediated ($p < .05$) the relationship between D+E versus E (and D+E versus D) and WOMAC function, and between D+E versus E and WOMAC pain. Lastly, gait self-efficacy only mediated WOMAC function for D+E versus E ($p < .05$). While this study included a dietary weight loss component in some groups, its findings align with the present study, demonstrating the role of self-efficacy as a mediator for functional improvements.

Looking at changes in subjective measures of physical function (as measured by the WOMAC), Lawford et al. (2023) conducted a secondary analysis of RCTs evaluating the mediators of two telehealth-delivered exercise programs on pain and physical function in patients with knee OA. They found that increased arthritis self-efficacy mediated the effects of exercise and diet and exercise, on improvements in pain and physical function. For WOMAC function scores, self-efficacy accounted for 1.66 units of a 4.99-unit reduction total in the exercise group. While their focus was on telehealth-based programs with a shorter duration (six months versus eighteen months in the present study), their findings aligned with the findings of the present study and further support the role of self-efficacy in driving improvements in physical function from exercise interventions.

Future Directions and Implications

Knee osteoarthritis is a leading cause of disability for individuals worldwide, where the impact on physical capacities may lead to the avoidance of activities, and eventually lead to limited physical function. Results from the present study support the idea that self-efficacy plays a key role in mediating the effects of strength training on physical function for adults with knee osteoarthritis, suggesting that interventions should include strategies to enhance self-efficacy.

Interventions moving forward would benefit from targeting the four sources of self-efficacy (mastery experiences, modeling, verbal persuasion, and the interpretation of physiological and emotional states (Bandura, 1977). Incorporating techniques such as verbal encouragement, goal setting, or progress feedback might help to optimize study outcomes such as physical function by reinforcing participants' confidence in their physical abilities.

In addition to research studies, community-based exercise programs and senior centers should consider incorporating the previously mentioned self-efficacy-enhancing techniques to support long-term engagement. Additionally, including a variety of people from different ethnic and minority groups, those experiencing health disparities, or socioeconomically disadvantaged populations is important in research as all people experience chronic conditions differently and can all benefit from possible advances.

The findings in the present study found self-efficacy to be a causal link between strength training and physical function throughout the 18-month study duration. Future research should investigate the role of self-efficacy in this relationship beyond the intervention period to examine how long self-efficacy improvements persist and whether they help participants maintain physical function improvements over time.

In the future, the exploration of additional psychosocial mediators such as fear of movement, pain, or social support might provide insight into how strength training influences physical function in adults with knee osteoarthritis. Further research exploring additional mediators can help tailor interventions towards special considerations of the population being studied.

Strengths and Limitations

The strengths of this study include the use of a large sample (n = 377) and long-term duration (18 months) in a community facility that was equipped with resistance training machines. Additionally, the use of both subjective (WOMAC Function and SF-36) and objective (6MWD) physical function measures provides a more comprehensive understanding of an individual's capabilities. Both subjective measures are widely used and validated questionnaires that assess health-related components such as function in adults with chronic conditions. The six-minute walk is also a validated and widely used test that measures functional exercise capacity for various populations, including those with chronic conditions.

A few limitations should also be considered. First, the study sample was comprised mostly of male, white, obese individuals who had completed more than a high school education, which limits the generalizability of the findings. The range of eligible frontal plane knee angles was -2º valgus to 10º varus, making these results more generalizable to those with alignments within this range. While objective measures of physical function used alongside subjective measures may be a strength, the use of self-reported physical function measures introduces the possibility of bias, where someone may over- or underreport how they perceive their functional ability. An osteoarthritis-specific self-efficacy measure, such as the Arthritis Self-Efficacy Scale should be considered as it is used to self-report the measure of beliefs reflecting confidence in one's capacity to function despite pain or other arthritis symptoms compared to the Adherence Self-Efficacy scale used in the present study. Additionally, the lack of a no-treatment control group is another limitation. START's control group had improvements in multiple measures which can make it challenging to interpret the results of the study and make it difficult to determine if observed changes are due to the intervention itself or other factors.

Conclusion

In conclusion, these findings suggest that a combined high- and low-intensity strength training intervention improves self-efficacy, and that self-efficacy is a causal mechanism through which strength training leads to improvements in self-reported and performance-based measures of physical function for adults with knee osteoarthritis. While the present study focused on self-efficacy's role as a mediator, prior findings from

START (Messier et al., 2018) indicate that muscle strength (specifically the knee extensors/quadriceps) also significantly improved in both strength training groups. This suggests that more than one pathway, including physiological and psychological factors may contribute to functional improvements, which was also supported by Vincent and Vincent (2012). The incorporation of behavioral strategies to enhance self-efficacy in exercise interventions should be a priority moving forward. An additional focus on social determinants and health outcomes, such as physical function, in individuals with knee OA can help provide a deeper understanding of how people from all social gradients are affected by this chronic condition.

Appendix A. Informed Consent

9.A.2.b. Informed Consent

Wake Forest™
School of Medicine

Department/Section of *Department of Health & Exercise Science*

STRENGTH TRAINING FOR ARTHRITIS TRIAL (START)
Informed Consent Form to Participate in Research
Stephen Messier, Ph.D., Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have *Knee Osteoarthritis*. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

Osteoarthritis (OA) is the most common form of arthritis. It is very common to get arthritis in your knee. While there are no cures for OA, treatment usually combines therapies, for example, exercise combined with a medication. The purpose of this research study is to determine whether intensive strength training could be used as an effective mechanism for the treatment of knee osteoarthritis.

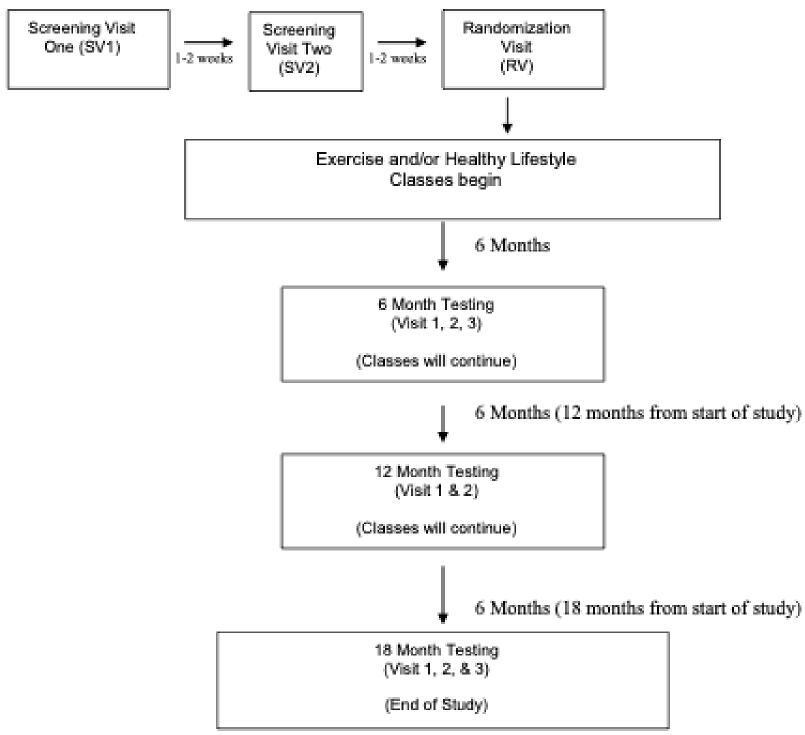
HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 372 people will take part in this study at this research site (this is the only site in the study). In order to identify the 372 subjects needed, we may need to screen as many as 780 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

If you qualify to participate, you will undergo screening and baseline testing. The following scheduled visits and procedures will be performed.

Time line (A detailed description of the visits can be found following this figure).



Baseline Visits:

Screening Visit 1 (SV1):

- *Reynolds Gym at Wake Forest University*: The study will be described in detail and you will be asked to sign this consent form and give the staff member your medication use and medical history forms that were previously mailed to you. The staff will review the forms with you to make sure everything is correct. Your height and weight will be taken and you will complete questionnaires, including general background, knee pain, physical disability, physical function, physical activity history, mental state, depression, and health status. The distance you can walk in 6 minutes will be measured and your leg will be moved throughout a normal range of motion to test your sensory level.

- *Geriatric Clinical Research Unit (CRU) at Wake Forest University School of Medicine (directions will be given)*: Upon your arrival you will meet with a healthcare professional (either the study physician, Jeff Williamson, or his designee). He/she will review your forms and perform a brief physical exam.
- *Outpatient Radiology Center at Wake Forest University Baptist Medical Center:* You will next have x-rays taken of your knees and legs.
- This first visit will take approximately 2 to 2.5 hours to complete.

Screening Visit 2 (SV2): If you remain eligible to participate in the study you will be invited for a second visit about one to two weeks after your first visit.

- *Reynolds Gym at Wake Forest University*: Your height, weight, waist and hip sizes will also be measured. A gait analysis (measurement of how you walk) will be performed. This involves videotaping you walking. The videotape only records markers that will be placed on your body and cannot see a person's actual face or body. The strength in your legs will also be measured. During this test you will be asked to push and/or pull your leg as hard as you can. The strength in your arms will also be measured. You will also perform a short testing battery consisting of walking, balance, and strength tests.
- This second visit will take approximately 2 to 2.5 hours to complete.

Randomization Visit (RV): You will be asked not to eat any food or beverages other than water for 12 hours prior to this visit. In addition you will be asked to only use the bathroom once upon waking up. For this visit, you will be asked to drive to the medical center (WFUBMC) campus and then afterwards to the WFU campus.

- *Geriatric Clinical Research Unit Main (CRU) at Wake Forest University School of Medicine*: Your height and weight will be measured. You will have a small amount of blood withdrawn from a vein (3.5 tablespoons). The total amount of blood withdrawn during the entire study will be approximately 10.5 tablespoons. In addition we will collect a urine sample (approximately 2 tablespoons). The blood and urine tests will help us to assess your general health and to measure proteins in the blood and urine that may be related to arthritis. Once the tests are complete you will be given a snack. Afterwards, you will undergo a CT scan. The computed tomography (CT) scan is a special type of x-ray examination that will measure the amount of various types of tissues in your thigh. You will be asked to lie on a table with the lower portion of your body inside the CT scanner. You will need to remain still when the CT technician requests this. The CT scan should take no more than 30 minutes.
- The strength in your leg will be measured on a bicycle like device. Next, you will have a Dual Energy X-Ray Absorptiometry (DXA) scan, which is a painless scan of your body that tells how much bone, fat, and muscle you have.
- This visit will take approximately 2 – 2.5 hours to complete. At the completion of this visit you will be randomized to one of the 3 study group assignments described below. You will remain in this group for the entire study. Randomization means that you are put into a group by chance by a special computer program, similar to flipping a coin. This is done so that a fair evaluation of results can be made. You will have a one in three chance of being placed in any one group.

- Below is a description of the 3 different study groups (you will be randomized into <u>one</u> of these groups):

- ***Group 1***
  - You will begin coming to the *Clinical Research Center located near the undergraduate campus at Wake Forest University* for exercise classes 3 days per week for about one hour each day. The class will consist of 5 minutes of warm-up walking exercise (stationary bikes are available), followed by 40 minutes of strength training on Nautilus machines involving muscle groups of the lower body, upper body, and core region. This will be followed by 15 minutes of cool-down exercises and stretching.
  - At the beginning of the study and then every 9 weeks until the end of the study your 1 repetition max (1RM) will be measured. This is the maximum amount you can lift. Your exercise instructor will set a goal for you to lift each week based on the amount you are able to lift in the 1RM test. Both groups will have the same workload however participants in this group will lift a low number of repetitions with higher weight. Your exercise instructor will monitor your progress. These regular exercise classes at Wake Forest will go on for 18 months.

- ***GROUP 2***
  - Participants in this group will also meet 3 days per week at the *Clinical Research Center located near the undergraduate campus at Wake Forest University* for about an hour each day. The class will consist of a 5 minute warm-up phase, a 40 minute strength training phase on the same Nautilus machines as Group 1, followed by a 15 minute cool-down phase.
  - Your maximum strength will also be measured with a 1RM test at the beginning of the study and then every 9 weeks until the end of the study. Your exercise instructor will set a goal for you to lift each week based on the amount you are able to lift in the 1RM test. Both groups will have the same workload however participants in this group will lift a high number of repetitions with lower weight. Your exercise instructor will monitor your progress. These regular exercise classes at Wake Forest will continue for 18 months.

- ***GROUP 3***
  - You will attend regular classes at Wake Forest twice a month for about an hour for the first six months afterwards you will attend classes once a month for the remainder of the study. The classes will take place at the *Winston-Salem Senior Center*.
  - Class topics include: foot care, nutrition, managing medication, and sleep practices, and experts will give wide-ranging lectures. You may be asked to complete homework assignments and engage in small group. Each class will end with seated upper body stretching.

6 Month Follow-up (FU6): You will return for a follow up visit after 6 months (split into 3 separate visits).

Visit 1 (Reynolds Gym): You will be given the questionnaires that were given at baseline to complete. Your level of depression will be measured. You will perform the 6-minute walk test. Afterwards your knee sensory will be measured. This visit should last approximately 2 hours.

Visit 2 (Reynolds Gym): You will have your height, weight, hip, and waist sizes measured. You will perform the gait analysis. Your strength will be measured. You will also perform a short testing battery consisting of walking, balance, and strength tests. This visit should last approximately 2 – 2.5 hours.

Visit 3 (Geriatric CRU): You will be asked not to consume any foods/beverages other than water for 12 hours prior to this visit. In addition you will be asked to only use the bathroom once upon waking up. You will have approximately 3.5 tablespoons of blood withdrawn from a vein. In addition we will collect a sample of your urine (approximately 1 cup). Once these tests are complete, you will be given a snack. Your leg strength will also be measured. This visit will take approximately 1 hour to complete. The purpose of repeating these tests and measures at 6 months is to see if there are differences between the 3 groups.

12 Month Follow-up (FU12): You will return for a follow up visit after 12 months (split into 2 separate visits).

Visit 1 (Reynolds Gym): You will be given the questionnaires that were given at baseline to complete. Your mental status, level of depression, the distance you walk in 6 minutes, and knee sensory will be measured. This visit should last approximately 2 hours.

Visit 2 (Reynolds Gym): You will have your height, weight, hip and waist sizes measured. The gait analysis and strength tests will also be performed. You will also perform a short testing battery consisting of walking, balance, and strength tests. This visit should last approximately 1.5 hours.

18 Month Follow-up (FU18): You will return for a follow up visit after 18 months (split into 3 separate visits):

Visit 1 (Reynolds Gym): You will be given the questionnaires that were given at baseline to complete. Your mental status and level of depression will be measured. You will perform the 6-minute walk test. Your knee sensory will also be measured. This visit should last approximately 2 – 2.5 hours.

Visit 2 (Reynolds Gym): You will have your height, weight, hip, and waist sizes measured. Afterwards you will have a gait analysis and your strength will be measured. This visit should last approximately 2 – 2.5 hours.

Visit 3 (Geriatric CRU): You will be asked not to consume any foods/beverages other than water for 12 hours prior to this visit. In addition you will be asked to only use the bathroom once upon waking up. You will have approximately 3.5 tablespoons of blood withdrawn from a vein. In addition we will collect a sample of your urine (approximately 1 cup). Once these tests are complete, you will be given a snack. Your leg strength will be measured. Afterwards you will have a DXA scan and CT scan done. You will then go to *Outpatient Radiology* for a knee x-ray. This visit should last approximately 2.5 - 3 hours.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No ___________ Initials

Storage of Biological Tissue

If you agree to participate in this study, we will draw 10.5 tablespoons of blood to use for future research. This sample will be kept and may be used in future research to learn more about knee osteoarthritis and/or other diseases. Your sample will be obtained by the Clinical Research Unit Main (CRU) at Wake Forest University Baptist Medical Center. The sample will be stored in the WFUSM Cytokine Core laboratory and access will be given only to researchers approved by (Stephen Messier). An Institutional Review Board (IRB) must also approve any future research study using your tissue sample. <u>In order to participate in this study, you must be willing to provide this sample for future research.</u>

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about *<u>20 months</u>* including testing visits.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. There are no serious health or safety consequences that will occur if you choose to stop participating.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. The followings risks and side effects are related to the study:

- There may be muscle or joint soreness following the physical performance test (six minute walk) and the exercise. These symptoms usually go away quickly and are usually not serious.
- It is possible to have a more serious injury, such as a torn ligament or sprain from these tests,

but this is extremely rare. Your tests will be monitored very closely to provide a high degree of safety for you. During the strength-training portion of a recent study of 316 subjects with Knee Osteoarthritis, we had no serious accidents.

- There is a slight risk of falling during the walking portion of testing and training. Rarely, 1-2%, of older people with arthritis who exercise will suffer a more serious injury such as a broken bone from a fall.
- There may be an increase in blood pressure while performing the strength training exercises. Your blood pressure will be measured prior to and after each exercise session. If your blood pressure is high you will not be allowed to perform any exercise that day or may be allowed to perform some exercise but on a limited basis.
- You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia). The total amount of blood that you will be donating throughout the study is approximately 10.5 tablespoons.
- If you participate in this study, you will be exposed to amounts of radiation above what you would normally receive in daily life. To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure. The maximum total amount of radiation exposure that you will receive from the x-rays, CT scans and DXA scans is equivalent to a uniform whole body exposure of 334 millirem. This is equal to 1.11 times the amount of background radiation that the average person in the United States receives each year {annual background = 300 millirem}.
- There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.
- Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be any direct benefit to you. We hope the information learned from this study will benefit other people in the future. You may benefit by having reduced pain and improved physical function.

Based on experience with exercise in other studies with persons with knee osteoarthritis, researchers believe that exercise is important in preventing disease and disability. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

What Other Choices Are There?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have the option of being treated with conventional medical therapy or participating in community lifestyle programs.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: [name, address, telephone number, birthdate, and health status].

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research.
2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it might no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study will be kept in the research records for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Stephen Messier that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Stephen P. Messier
Wake Forest University
Dept. of Health & Exercise Science
P.O. Box 7868

Winston-Salem, NC 27109

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in a special section of your medical record. This part of the medical record will only be available to people involved in the research study or persons treating you at this Medical Center. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

Information about this clinical trial will be placed in the clinical trial registry maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM).

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

This authorization is valid for six years or five years after the completion of the study, whichever is longer.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by *the National Institutes of Health, Wake Forest University*

Health Science, and Wake Forest University. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at (336) 716-3467.

If you are injured, the sponsor may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the sponsor is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call *Dr. Stephen P. Messier* at *(336) 758-5849 (after 7pm call, 774-6628)*.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because but not limited to, not following the study schedule; it is in your best medical interest, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Stephen P. Messier at (336) 758-5849 (after 7pm call, 774-6628) or the project manager at (336) 758-3969.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a copy of this signed consent form.

SIGNATURES

a. I agree that Stephen P. Messier or someone whom he chooses may contact me in the future to ask me about taking part in more research. (*You may still participate if you do not wish to be contacted in the future.*) Yes __ No __

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

____
Subject Name (Printed)

____ _______________
Subject Signature Date

____ _______________
Person Obtaining Consent Date

Appendix B. Adherence Self-Efficacy

9.B.2.I. ADHERENCE SELF-EFFICACY

Data Collection Visit:	This questionnaire will be collected at SV2, FU6, FU12, and FU18.
Purpose:	This questionnaire is designed to assess beliefs in one's ability (confidence) to continue exercising at various intensities and frequencies. The questionnaire also measures beliefs in one's confidence to perform physical activity during the treatment recovery period. Locus of control indicates whether or not an individual attributes the cause of certain obstacles to oneself or to one's surroundings. Measuring locus of control may help to discern why or why not an individual is adhering to an exercise program.
Scaling:	8 items rating one's ability to exercise over a specific length of time. Responses are on a scale ranging from 0% "not at all confident" to 100% "highly confident," in increments of 10.
Scoring:	Add all eight items and divide by 8.
Range:	0-100. A higher score indicates higher self-efficacy.

The following section asks your beliefs in your ability to exercise on a <u>three time per week</u> basis at moderate intensities (upper end of your perceived exertion range), for 15-30 minutes per session in the future.

INSTRUCTIONS: Using the scales listed below, please indicate how confident you are that you will be able to continue to exercise in the future.

0	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Not at all confident	→				**Somewhat Confident**	→				**Completely Confident**

1. I am able to continue to exercise three times per week at moderate intensity, for <u>15-30 minutes</u> without quitting for the <u>NEXT WEEK</u>

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

2. I am able to continue to exercise three times per week at moderate intensity, for <u>15-30 minutes</u> without quitting for the <u>NEXT TWO WEEKS</u>

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

3. I am able to continue to exercise three times per week at moderate intensity, for <u>15-30 minutes</u> without quitting for the <u>NEXT THREE WEEKS</u>

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

4. I am able to continue to exercise three times per week at moderate intensity, for <u>15-30 minutes</u> without quitting for the <u>NEXT FOUR WEEKS</u>

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

0	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Not at all confident	→				**Somewhat Confident**	→				**Completely Confident**

5. I am able to continue to exercise three times per week at moderate intensity, for 15-30 minutes without quitting for the NEXT FIVE WEEKS

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

6. I am able to continue to exercise three times per week at moderate intensity, for 15-30 minutes without quitting for the NEXT SIX WEEKS

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

7. I am able to continue to exercise three times per week at moderate intensity, for 15-30 minutes without quitting for the NEXT SEVEN WEEKS

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

8. I am able to continue to exercise three times per week at moderate intensity, for 15-30 minutes without quitting for the NEXT EIGHT WEEKS

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Appendix C. Six-Minute Walk (6MW)

9.B.3.b. 6-Minute Walk

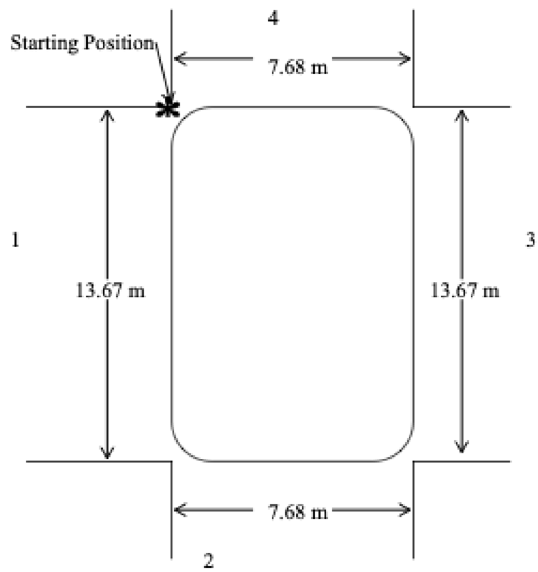
The 6-minute walk test will be performed around a track in Reynolds Gymnasium room 402 (Figure1). The number of laps and distance walked on the final lap will be recorded. The total distance the participant walked will be entered onto the online database.

"For this task, you will be asked to walk as far as you can in six minutes. This means that you should walk around the track as quickly as you can in order to complete as many laps as you can in six minutes, pacing yourself, however, so that you can walk the entire six minutes. You should turn as tightly as possible (*demonstrate*).

The chair is here just in case you experience chest pain, or significant knee pain, or you become dizzy or too winded to continue. Use it if necessary, by all means, but please try very hard to continue walking the entire six minutes. You will begin when I say 'GO' and continue until I say 'STOP.' At that point, STAY EXACTLY WHERE YOU ARE and I will record your total distance. Notice the doors and windows around the room. Do not be distracted by others who may come in to the room during your test. Do not speak to anyone during the test, including me. Do not look at a watch. Stay focused on the task. The important thing is to finish the test. I will tell you when your time is up. Do you have any questions? Are you ready? 'GO.'

Reynolds Gym 402

* measured from the edge of the carpet



1 lap = 42.7 m
2 laps = 85.4 m
3 laps = 128.1 m
4 laps = 170.8 m
5 laps = 213.5 m
6 laps = 256.2 m
7 laps = 298.8 m
8 laps = 341.6 m
9 laps = 384.3 m
10 laps = 427.0 m
11 laps = 469.7 m
12 laps = 512.4 m
13 laps = 555.1 m
14 laps = 597.8 m
15 laps = 640.5 m
16 laps = 683.2 m
17 laps = 725.9 m
18 laps = 768.6 m
19 laps = 811.3 m
20 laps = 854.0 m

Side 1 – 13.67 m
Side 2 – 7.68 m
Side 3 – 13.67 m
Side 4 – 7.68 m

Figure 1. Reynolds Gym 402 track dimensions.

Appendix D. Short-Form 36

Date : ___/___/___
ID #:__________
Visit: ☐ SV2
☐ FU6
☐ FU18

START Form 10
Acrostic :__________

The following section asks your views about your health.

Instructions: Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (check one)

	Excellent (1)
	Very Good (2)
	Good (3)
	Fair (4)
	Poor (5)

2. COMPARED TO ONE YEAR AGO, how would you rate your health in general NOW? (check one)

	Much better now than one year ago (1)
	Somewhat better now than one year ago (2)
	About the same now as one year ago (3)
	Somewhat worse now than one year ago (4)
	Much worse now than one year ago (5)

Date :___/___/___
ID #:__________
Visit: ☐ SV2
☐ FU6
☐ FU18

START Form 10
Acrostic :__________

3. The following items are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

(Mark one box only for each activity)

Activities	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			
B. **Moderate Activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
C. Lifting or carrying groceries			
D. Climbing **several** flights of stairs			
E. Climbing **one** flight of stairs			
F. Bending, kneeling or stooping			
G. Walking **more than a mile**			
H. Walking **several blocks**			
I. Walking **one block**			
J. Bathing or dressing yourself			

4. During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF YOUR PHYSICAL HEALTH?

(Mark one box only for each activity)

	YES (2)	NO (1)
A. Cut down on the **amount of time** you spent on work or other activities		
B. **Accomplished less** than you would like		
C. Were limited in the **kind** of work or other activities		
D. Had **difficulty** performing the work or other activities (for example, it took extra effort)		

Date :___/___/___
ID #:__________
Visit: ☐ SV2
☐ FU6
☐ FU18

START Form 10
Acrostic :__________

5. During the PAST 4 WEEKS, 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)?

(Mark one box only for each activity)

	YES (2)	NO (1)
A. Cut down on the **amount of time** you spent on work or other activities		
B. **Accomplished less** than you would like		
C. Didn't do work or other activities as **carefully** as usual		

6. During the PAST 4 WEEKS, to what extent has your physical health or emotional health problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Mark one box only)

	Not at all (1)
	Slightly (2)
	Moderately (3)
	Quite a bit (4)
	Extremely (5)

7. How much BODILY pain have you had during the PAST 4 WEEKS?

(Mark one box only)

	None (1)
	Very mild (2)
	Mild (3)
	Moderate (4)
	Severe (5)
	Very severe (6)

Date :___/___/___ START Form 10
ID #:__________ Acrostic :__________
Visit: ☐ SV2
☐ FU6
☐ FU18

8. During the PAST 4 Weeks, how much did PAIN interfere with your normal work (including both work outside the home and house work)?

(Mark one box only)

	Not at all (1)
	A little bit (2)
	Moderately (3)
	Quite a bit (4)
	Extremely (5)

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 answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS…

(Mark one box only on each line)

	All of the Time (1)	Most of the Time (2)	A Good Bit of the Time (3)	Some of the Time (4)	A Little of the Time (5)	None of the Time (6)
A. Did you feel full of pep?						
B. Have you been a very nervous person?						
C. Have you felt so down in the dumps that nothing could cheer you up?						
D. Have you felt calm and peaceful?						
E. Did you have a lot of energy?						
F. Have you felt downhearted and blue?						
G. Did you feel worn out?						
H. Have you been a happy person?						
I. Did you feel tired?						

Date : ___/___/___
ID #:__________
Visit: ☐ SV2
☐ FU6
☐ FU18

START Form 10
Acrostic :__________

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.)?

(Mark one box only)

	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)

11. How TRUE or FALSE is each of the following statements for you?

(Mark one box only 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					
B. I am as healthy as anybody I know					
C. I expect my health to get worse					
D. My health is excellent					

Appendix E. Western Ontario and McMaster Universities (WOMAC)

Date : ___/___/___ START Form 9

ID #:__________ Acrostic :__________

Visit: ☐SV1

☐ FU6

☐ FU12

☐ FU18

The following section asks you about knee pain, stiffness, and activities of daily living.

INSTRUCTIONS: In Section A, B, and C, Questions will be asked in the following format. Please indicate your answer by marking an "X" inside the box located below the answer options.

1. Example: **If you put your "X" in the left-hand box, i.e.**

None	Mild	Moderate	Severe	Extreme
X				

Then you are indicating that you have NO **pain**

2. Example: **If you put your "X" in the right-hand box, i.e.**

None	Mild	Moderate	Severe	Extreme
				X

Then you are indicating that your pain is EXTREME

PLEASE NOTE:

1. **That the further to the right you place your "X" the** MORE **pain, joint stiffness, or disability you are experiencing.**
2. **That the further to the left you place your "X", the** LESS **pain, joint stiffness, or disability you are experiencing.**
3. PLEASE DO NOT PLACE YOUR "X" OUTSIDE THE BOX.

You will be asked to indicate on this type of scale the amount of pain, stiffness or disability you have experienced in the last 48 hours.

Remember, the further you place your "X" to the right, the more pain, stiffness or disability you are indicating that you experienced. Finally, please note that you are to complete the questionnaire with respect to your study joint(s). You should think about your study joint(s) when answering the questionnaire, i.e., you should indicate the severity of your pain, stiffness and physical disability that you feel is caused by arthritis in your study joint(s). Your study joint(s) has been identified for you by your health care professional. If you are unsure which joint(s) is your study joint, please ask before completing the questionnaire.

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Date :___/___/___ START Form 9
ID #:__________ Acrostic :__________
Visit: ☐SV1
☐ FU6
☐ FU12
☐ FU18

SECTION A

(Please mark an "X" in the box that best indicates your answer.)

Question: How much pain do you have…

1. when walking on flat surfaces?

None	Mild	Moderate	Severe	Extreme

2. when going up or down stairs?

None	Mild	Moderate	Severe	Extreme

3. when at night while in bed?

None	Mild	Moderate	Severe	Extreme

4. when sitting or lying down?

None	Mild	Moderate	Severe	Extreme

5. when standing upright?

None	Mild	Moderate	Severe	Extreme

Date :___/___/___ START Form 9
ID #:__________ Acrostic :__________
Visit: ☐SV1
☐ FU6
☐ FU12
☐ FU18

SECTION B

(Please mark an "X" in the box that best indicates your answer.)

6. How severe is your stiffness after first awakening in the morning?

None	Mild	Moderate	Severe	Extreme

7. How severe is your stiffness after sitting, lying down, or resting later in the day?

None	Mild	Moderate	Severe	Extreme

SECTION C

(Please mark in "X" in the box that best indicates your answer.)

Question: What degree of difficulty do you have…

8. when descending stairs?

None	Mild	Moderate	Severe	Extreme

9. when ascending stairs?

None	Mild	Moderate	Severe	Extreme

10. when rising from sitting?

None	Mild	Moderate	Severe	Extreme

11. when standing?

None	Mild	Moderate	Severe	Extreme

Question: What degree of difficulty do you have…

Date :___/___/___
ID #:__________
Visit: ☐SV1
☐ FU6
☐ FU12
☐ FU18

START Form 9
Acrostic :__________

12. when bending to the floor?

None	Mild	Moderate	Severe	Extreme

13. when walking on flat surfaces?

None	Mild	Moderate	Severe	Extreme

14. when getting in or out of a car?

None	Mild	Moderate	Severe	Extreme

15. when going shopping?

None	Mild	Moderate	Severe	Extreme

16. when putting on socks/stocking?

None	Mild	Moderate	Severe	Extreme

17. when rising from bed?

None	Mild	Moderate	Severe	Extreme

18. when taking off socks/stocking?

None	Mild	Moderate	Severe	Extreme

19. when lying in bed?

None	Mild	Moderate	Severe	Extreme

Question: What degree of difficulty do you have…

20. when getting in/out of the bathtub?

None	**Mild**	**Moderate**	**Severe**	**Extreme**

21. when sitting?

None	**Mild**	**Moderate**	**Severe**	**Extreme**

22. when getting on/off the toilet?

None	**Mild**	**Moderate**	**Severe**	**Extreme**

23. when carrying out heavy domestic duties?

None	**Mild**	**Moderate**	**Severe**	**Extreme**

24. when carrying out light domestic duties?

None	**Mild**	**Moderate**	**Severe**	**Extreme**

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Curriculum Vitae

Education

Wake Forest University — Winston Salem, NC
Master of Science — Expected May 2025
Major Field of Study: Exercise Science
Department of Health and Exercise Science

Advisor: Dr. Shannon Mihalko
Thesis: Strength Training and Physical Function: Role of Self-efficacy, Knee Pain, and Social Determinants

Ithaca College — Ithaca, NY
Bachelor of Science, Cum Laude — May 2023
Major Field of Study: Exercise Science, Minor in Nutrition Promotion

RESEARCH EXPERIENCE

Wake Forest University

The Osteoarthritis Prevention Study (TOPS)
Student Interventionist — Jan 2024 – Present

- Administered pre-screening questionnaires to identify suitable research subjects based on their health history
- Led weekly exercise sessions, guiding participants through weight training while ensuring proper form, motivation, and adherence to study protocols
- Conducted monthly one-on-one dietary sessions, reviewing progress, identifying challenges, and setting goals to support the participants' weight loss

Physical Activity and Lifestyle Study (PALS)
Student Interventionist — Jan 2024 – Present

- Led and assisted one-hour long educational sessions about healthy living topics such as nutrition, stress management, blood pressure, and sleep for participants with lymphoma and breast cancer
- Led and assisted zoom and in-person physical activity sessions for participants, tailored to prevent declines in exercise capacity, cardiovascular performance, cognitive function, and quality of life
- Assisted baseline study visits using magnetic resonance cardiopulmonary exercise treadmill testing to assess the participants exercise capacity

Breast Cancer Strength and Range of Motion Study
Student Interventionist — Jan 2024 – Present

- Administered physical assessments including shoulder range of motion and upper body strength assessed with a handgrip dynamometer
- Administered questionnaires to assess physical activity levels, physical function, self-reported pain and stiffness, and self-efficacy
- Entered and analyzed data in SPSS, ensuring accurate record-keeping

CLINICAL EXPERIENCE

Wake Forest University

Health and Fitness Programming Aug 2023 – Present

Graduate Assistant

- Designed and implemented personalized exercise programs tailored to clients' fitness levels and limitations
- Fostered a motivating and supportive environment to help clients achieve their fitness goals
- Coordinated small group and individual training sessions, ensuring a motivating experience for all participants

Healthy Exercise & Lifestyle ProgramS (HELPS)

Graduate Exercise Specialist Aug 2023 – Present

- Supervised exercise sessions for older adult and clinical population
- Assessed and monitored vitals such as heart rate, blood pressure, and oxygen saturation
- Ensured safety by assisting members on the correct performance of exercises

Laboratory Coordinator Mar 2024 – Present

- Conducted physician-supervised CPETs using a 12-lead electrocardiogram (ECG) to monitor the participants heart rhythms while exercising
- Performed body composition assessments include anthropometrics, pulmonary function, and lipid profile
- Scheduled consultation appointments to analyze and update participants exercise prescription based on their results

Ithaca College

Robert R. Colbert Sr Wellness Clinic

Fitness Specialist Jan 2021 – May 2023

- Screened clients for medical and health risks through consultations and questionnaires
- Conducted fitness evaluations and exercise orientations in a clinical setting, providing tailored recommendations based on individual needs
- Developed and delivered personalized exercise programs, monitoring client progress to ensure continuous improvement and goal achievements

Cayuga Center for Healthy Living Cardiac Rehabilitation

Intern Jan 2023 – May 2023

- Monitored blood pressure and heart rhythm under the supervision of nursing and exercise physiology staff
- Provided individualized fitness programming and lifestyle education to participants to maximize recovery from cardiac events

INVOLVEMENT

Ithaca College

Vice President - Exercise Science Student Association Aug 2022 – May 2023

- Managed social media to promote meetings and events
- Organized activities such as group exercise classes and exercise physiology themed trivia to engage members
- Collaborated with executive board members to bring in guest speakers on exercise science topics

Vice President – Nutrition Club Aug 2021 – May 2023

- Developed informational presentations highlighting nutrition for personal health
- Promote and encourage a healthy food environment on Ithaca's campus and within the community

PROFESSIONAL DEVELOPMENT

Southeast American College of Sports Medicine Regional Conference (SEACSM)

Accepted Presenter Feb 2025

- "Strength Training and Physical Function: Role of Self-efficacy, Knee Pain, and Social Determinants"

Attendee

HONORS AND AWARDS

Ithaca College

Professional Excellence Award in Exercise Science, Clinical Exercise & Wellness May 2023

Dean's List Spring 2020, Spring 2021, Fall 2022