A Thesis

entitled

Effects of Therapeutic Exercise on Functional Performance, Self-Reported Outcomes and Physical Activity in Female Patients with Knee Osteoarthritis

by

Bradley M. Stempky

Submitted to the Graduate Faculty as partial fulfillment of the requirements for the Master of Science Degree in Exercise Science

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An Abstract of

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Those who are affected by osteoarthritis (OA) of the knee have shown decreased levels of functional capacity and quality of living. This disability has been linked to decreased levels of strength and physical activity caused by pain or fatigue. Resistance training and increased levels of physical activity have shown to improve these deficits. However, an efficient way to treat a large number of patients by increasing physical activity levels has not yet been determined. Furthermore, it is unknown if a simple, body weight-based exercise program is capable of achieving similar gains as previously-developed, machine-based programs. This thesis examined the effects of a group-based, eight-week therapeutic exercise regimen on functional performance, self-reported outcomes and physical activity levels in elderly female patients with knee OA.

The study design for this pilot project was that of an observational study with an embedded case series. Seven patients (mean age = 56.0±5.42) were included in the group exercise regimen. The exercise regimen was performed once a week and included body weight exercises, balancing, and walking. Self-reported outcomes and pain were measured via the Western Ontario McMaster Universities Osteoarthritis Index
(WOMAC) and Numeric Pain Rating Scale (NPRS). Functional performance was measured by use of the chair stand test (CST), timed up and go test (TUG), stair climb test (SCT), and the six-minute walk test (6MW). Physical activity levels were measured by use of accelerometers and the UCLA activity scale. All measures were collected one week previous to the eight-week exercise regimen and one week following the exercise regimen.

Overall, WOMAC (34.57±15.52 to 23.42±11.96) and NPRS (5.43±1.81 to 2.29±2.93) scores improved as a result of the exercise regimen. Also, the CST (10.21±1.07 reps to 12.00±1.61 reps), TUG (9.65±1.42s to 8.23±1.44s), SCT (13.03±0.70s to 11.6±1.07s) and 6MW (454.09±59.77m to 504.21±54.64m) functional performance measures all improved as a result of the exercise regimen. All measures of self-reported outcomes, pain, and functional performance showed moderate to large effect sizes. However, only the NPRS, CST, and SCT had associated confidence intervals that did not cross zero. In general, physical activity levels did not show overall improvements as a result of the intervention. Only improvements seen in moderate levels of physical activity (211.08±68.57 min to 272.21±97.05 min) were distinguishable from the intervention.

In conclusion, the implementation of an eight-week therapeutic exercise regimen resulted in gains in functional performance and self-reported outcomes. However, these gains did not translate to improvements in physical activity levels. This type of intervention shows promise in improving symptoms for women with knee OA.
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List of Abbreviations

6MWT ...................... Six minute walk test
ACL ......................... Anterior Cruciate Ligament
CST .......................... Chair stand test
LCL .......................... Lateral Collateral Ligament
MCL .......................... Medial Collateral Ligament
NHANES III ........... The National Health and Nutrition Examination Survey that
assesses the health and nutritional status of adults and children in the United States that was
done between the years of 1991 and 1994.
OA: Osteoarthritis
PCL .......................... Posterior Cruciate Ligament
SCT .......................... Stair climb test
TKA .......................... Total knee arthroplasty. Surgery involving the replacement of
damaged bone and cartilage with an artificial joint to relieve pain and restore function.
TUG .......................... Timed up and go test
Chapter 1

Introduction

Osteoarthritis (OA) is the most common form of arthritis in western societies, characterized by degeneration of joint cartilage and marginal and central new bone formation. Furthermore, data from NHANES III (1991-1994) have shown that 37% of US individuals ages 60 and above show evidence of definite knee OA. Additionally, it has been predicted that the prevalence of OA likely increased due to the dramatic increase of body mass index (BMI) in the US since the data from NHANES III. 1 Specifically, disability caused by OA of the knee is as great as that caused by cardiac disease, and greater than any other medical disorder in the elderly, with the most disability seen in tasks of stair climbing, walking a mile, housekeeping, and carrying objects. 2 Upon this, OA affects men and women differently, with women being more commonly affected by OA (42.1% of women to 31.2% of men ages 65-74) and being more greatly affected in aspects of quality of life such as pain, disability, and mood. 1,3 These attributions could be linked to men having substantially higher knee cartilage volumes than women, specifically in those above the age of 50. Causes of differing cartilage volumes are partially explained by body and bone size. 4 It is also commonly known that women, on average, have larger Q angles in comparison to men. Larger Q
angles can correlate to higher levels of knee valgus positioning, which has been shown to lead to further osteoarthritis progression.\textsuperscript{5} In contrast, Brouwer \textit{et al.} \textsuperscript{6} found that only those with a varus alignment were at an increased risk of developing OA, with no association of a valgus alignment with OA. These findings highlight the need to research both the cause of OA and interventions that may help reduce symptoms of OA to improve self-reported outcomes in symptomatic individuals, particularly in females.

Functional performance of individuals with OA of the knee has been closely linked to muscular strength, accounting for 15-20\% of the variance in disability. Strength is more closely related to functional performance than other OA-related factors, including pain, age or radiographic score.\textsuperscript{7-9} Along with this, it has also been found that poor quadriceps strength accounted for the progression of damage to articular cartilage of the knee and could cause more frequent pain. Routine strength training, specifically of the quadriceps, has proven to be very beneficial in improving functional movements.\textsuperscript{7,10-12}

Along with strength training, increases in physical activity alone have been shown to help combat disability and pain associated with OA of the knee.\textsuperscript{13} Unfortunately, several studies have also shown that those who suffer from OA have decreased levels of physical activity, possibly caused by pain and fatigue.\textsuperscript{14-16} An increase in daily walking has been shown to enhance the pace of walking for those with OA of the knee.\textsuperscript{17} Chmelo \textit{et al.}\textsuperscript{18} even found that higher levels of spontaneous activity in general have beneficial affects on physical function, more so than those who engage in less activity. Specific guidelines made for knee OA management support the idea that both aerobic and resistance training can be advantageous in fighting the disability caused by OA.\textsuperscript{19,20}
In a randomized control clinical trial that compared a group exercise intervention to an individual exercise intervention, both forms of intervention demonstrated significant improvements in pain, physical function, and quality of life. The group intervention format required fewer human-resources than the individual treatments, making it much more convenient to clinicians.\textsuperscript{21} Similar research has also shown comparable findings between the two different types of intervention delivery methods and a positive correlation with the amount of directly supervised occasions of exercise and the magnitude of the treatment effect.\textsuperscript{13} This suggests that higher levels of physical activity with a weekly, supervised class to monitor progress may be suitable to increase functional performance. These findings must be further researched to determine if similar intervention methods can improve objective measures of physical capacity.

1.1 Statement of the Problem

Those who are affected by OA of the knee have shown decreased levels of functional capacity in activities of daily living compared to healthy counterparts. This disability has been linked to one’s muscular strength and decreased levels of physical activity caused by either pain or fatigue as seen in patients with knee OA. Resistance training and increased levels of physical activity have been shown to combat these disabilities. Although it is well understood that individualized therapeutic exercise helps improve functional capacity amongst patients with symptomatic knee OA, an efficient way to treat a large number of patients by increasing levels of physical activity has yet to be determined. Further, it is unknown if a simple, body weight-based exercise program is capable of achieving these same gains in functional performance as previously-developed, machine-based programs.
1.2 Statement of the Purpose

The purpose of this pilot investigation is to examine the effects of a group-based therapeutic exercise regimen on functional performance, self-reported outcomes and physical activity levels in female patients with knee OA.

1.2.1 Specific Aim #1

To examine the effects of a weekly exercise intervention on physical activity levels in patients with knee OA.

1.2.1.1 Hypothesis #1

Physical activity levels will increase, as demonstrated by activity monitor and UCLA activity scale measures, following completion of the intervention.

1.2.2 Specific Aim #2

To examine the effects of a weekly exercise intervention on functional performance measures in patients with knee OA.

1.2.2.1 Hypothesis #2

It is hypothesized that all functional performance measures will improve, as demonstrated by the Chair Stand Test (CST) and the 6 Minute Walk Test (6MWT) increasing in scores and the Timed Up and Go (TUG) Test and the Stair Climb Test (SCT) decreasing in scores.

1.2.3 Specific Aim #3

To examine the effects of a weekly exercise intervention on self-reported outcome measures in patients with knee OA.

1.2.3.1 Hypothesis #3
It is hypothesized that self-reported outcome measures will improve, as demonstrated by reduced Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) and Numeric Pain Rating Scale (NPRS) scores.

1.3 Significance of the Study

OA is a very prevalent disease seen within the United States, showing evidence in 37% of US individuals ages 60 and older. This prevalence, along with the $60 billion spent in healthcare costs and extreme disability caused by OA calls for the need to investigate and implement strategies to combat this disease. If the hypotheses of this study hold true, an economically friendly solution will have presented itself in treating large numbers of individuals at once to decrease symptoms, healthcare costs, and disability.

1.4 Operation Definitions

Body Mass Index (BMI): An indicator of body fatness measured by the equation of mass/height$^2$ (kg/m$^2$).

Q-Angle: The angle formed from the anterior superior iliac spine to the midpoint of the patella and then to the tibial tubercle.

Valgus: A term to indicate the outward angulation of the distal segment.

Varus: A term to indicate the inward angulation of the distal segment.
Chapter 2

Literature Review

The purpose of this literature review is to review: 1) the prevalence, anatomy, etiology, pathology, and consequences of knee osteoarthritis (OA); 2) current treatment strategies for patients with knee OA and their impact on functional performance and self-reported outcomes; and 3) methods for assessing functional performance and self-reported outcomes in patients with knee OA.

2.1 Prevalence

Knee OA is a very common disease seen in elderly populations, with 12% of people, ages 60 and older, showing symptoms of knee OA, including severe disability, pain and a decreased general well-being of individuals or quality of life.\textsuperscript{1,3} Dillon \textit{et al.} \textsuperscript{1} found that females have a higher prevalence of knee OA than males, with 42% of women ages 65-74 showing radiographic signs of knee OA compared to 31% of males in the same age group. It was also found that an increasing age, increasing body mass index, and being of a non-Hispanic Black race/ethnicity was linked with increased disease prevalence. Rosemann \textit{et al.} \textsuperscript{3} investigated 1311 male and female patients with OA of the hip or knee and found differences between men and women in aspects of quality of life. Women were more greatly affected in terms of physical disability than men assessed by the AIMS2-SF lower body scale (women: 2.98; men: 2.39; $P<0.01$).
Furthermore, women showed significantly lower mood and significantly higher pain in comparison to men, assessed by the AIMS2-SF affect scale (women: 3.10; men: 2.60; \( P<0.01 \)) and symptom scale (women: 5.12; men: 4.49; \( P<0.01 \)).

### 2.2 Tibiofemoral Joint Anatomy

#### 2.2.1 Musculature

The tibiofemoral joint is classified as a synovial joint that allows for flexion and extension motions to occur at the knee. Musculature that crosses the tibiofemoral joint includes the quadriceps and hamstrings muscle groups, the two heads of the gastrocnemius, and the popliteus. The quadriceps muscle group extends the knee and is comprised of the rectus femoris, vastus lateralis, vastus medialis, and the vastus intermedius muscles, all of which insert onto the tibial tuberosity via the patellar ligament. The hamstrings muscle group flexes the knee and is comprised of the biceps femoris, semitendinosus, and the semimembranosus. The biceps femoris is located laterally, originates on the ischial tuberosity and lateral lip of the linea aspera, and inserts onto the head of the fibula. The semitendinosus and semimembranosus are both located medially, originate on the ischial tuberosity, and insert onto the proximal, medial shaft of the tibia and the posterior aspect of the medial condyle of the tibia, respectively. The quadriceps and hamstrings muscle groups also help to provide stabilization of the tibia against translation forces alongside the anterior cruciate ligament (ACL) and the posterior cruciate ligament. (PCL) The quadriceps limit posterior movement of the tibia relative to the femur, while the hamstrings limit anterior translation of the tibia on a fixed femur, serving as an agonist to the ACL. Furthermore, the quadriceps and hamstrings muscle
groups provide dynamic knee stabilizing factors in the frontal plane. Due to their adduction and abduction moment arms, the co-activation of these muscles are the primary strategy to provide stability against varus and valgus moments at the knee. Frontal plane stabilization is important since instability has been shown to be a risk factor for the progression of knee OA.

The gastrocnemius muscle originates on the condyles of the posterior femur and crosses the knee to insert onto the calcaneus via the Achilles tendon. The gastrocnemius' main function is to plantar flex the talocrural joint but also to flex the knee. In patients with knee OA, elevated levels of gastrocnemius muscle activity have been observed compared to healthy persons. Specifically, patients demonstrate increased quadriceps/gastrocnemius muscle co-activation. It is believed that this increase in co-activation stabilizes the tibiofemoral joint in patients who experience joint laxity. The popliteus muscle originates on the lateral epicondyle of the femur and inserts onto the proximal, posterior aspect of the tibia. The popliteus aids in flexion at the knee. The popliteus muscle has not been implicated in the initiation or progression of tibiofemoral OA.

2.2.2 Ligaments

Ligaments of the tibiofemoral joint include the ACL and PCL and the medial and lateral collateral ligaments, which all act to provide stabilization to the knee. The ACL is an intra-articular ligament that is composed of two different bundles, the anteromedial and posterolateral bundle, and attaches anteriorly to the intercondylar eminence of the tibia and posteriorly on the posteromedial portion of the lateral femoral condyle.
ACL acts primarily to resist forces of anterior translation onto the tibia and secondly to resist internal rotation and abduction forces at the knee.\textsuperscript{25} The PCL is also an intra-articular ligament that attaches from the lateral aspect of the medial femoral condyle to a posterior and inferior position on the tibia plateau. Like the ACL, the PCL also consists of two bundles, the anterolateral bundle and a posteromedial bundle. The PCL primarily functions to resist forces of posterior translation onto the tibia and secondarily functions to stabilize against external rotation and excessive adduction and abduction of the knee.\textsuperscript{26}

The medial collateral ligament (MCL) is separated into a superficial and deep bundle. The superficial bundle attaches from the distal femur on the posterior surface of the medial epicondyle and joints to the posteriomedial tibia and also blends with the fascia of the semimembranosus tendon.\textsuperscript{27} The deep bundle blends with the joint capsule and spans from the distal femur to the medial meniscus. The MCL primarily functions to resist valgus forces. The lateral collateral ligament (LCL) attaches from the distal epicondyle of the femur to the head of the fibula. The LCL averages 66 mm in length and functions to resist adduction forces along with internal rotation forces at certain degrees of knee flexion.\textsuperscript{28}

Patients with knee OA are at risk for laxity seen at the tibiofemoral joint. Wada et al.\textsuperscript{29} reported increased anterior laxity at the tibiofemoral joint in patients with knee OA compared to healthy control subjects. Damage of the ACL was found to contribute to this laxity. Furthermore, Lee et al.\textsuperscript{30} found deficiencies of the ACL in patients about to undergo TKA surgery, without any history of injury or instability. These findings imply that severe OA causes degenerative effects to the ACL. Similarly, Sharma et al.\textsuperscript{31} found that varus and valgus laxity increased with the decrease of joint space found in knee OA.
patients. It was concluded that the ligamentous attachments of the collateral ligaments moved closer together as a result of bone loss and cartilage degeneration and created a pseudo laxity for the MCL and LCL. This laxity can then further contribute to progression of osteoarthritis.

2.2.3 Cartilaginous Structures

The menisci of the tibiofemoral joint function to increase stability for articulations, distribute loading factors, absorb shock, and lubricate the joint. The menisci are crescent in shape and are located on the medial and lateral aspects of the tibiofemoral joint. The medial meniscus measures approximately 35 mm in diameter and attaches anteriorly to the tibia plateau and posteriorly to the posterior intercondylar fossa. The lateral meniscus covers a larger portion of the articular surface than the medial meniscus and attaches anteriorly, adjacent to the attachment site of the ACL on the tibia, and posteriorly, just posterior to the lateral tibial spine. The peripheries of the menisci are thick and have limited vascular capabilities while the inner portions are thinner and are avascular. Blood supply to the periphery includes the medial, lateral, and middle geniculate arteries. The menisci have poor healing capabilities due to their avascular characteristics. Long-term damage to the menisci may lead to degeneration of the joint, joint space narrowing, and symptomatic OA.\textsuperscript{32}

The tibiofemoral joint uses articular cartilage to allow a smooth and lubricated surface for articulations and the transmission of loads without interference. Articular cartilage is 2 to 4 mm thick and does not contain blood vessels, nerves, or lymphatics, which creates a poor healing environment. A dense, extracellular matrix allows articular
cartilage to retain water, which is key for its mechanical properties. Articular cartilage is separated into four unique zones: the superficial zone, the middle zone, the deep zone, and the calcified zone. The superficial zone is thin and makes up 10% to 20% of the articular cartilage. The main function of the superficial zone is to protect against shear forces. Collagen fibers of the superficial zone are tightly compacted and are aligned parallel to the articular surface, which allow this protection against shear forces. Beneath the superficial zone is the middle zone. The middle zone is the largest zone that makes up 40% to 60% of the articular cartilage. The middle zone functions to withstand compressive forces. It can withstand these forces since it is made of thicker collagen fibrils, which are organized obliquely while the chondrocytes of this layer are spherical, and at a low density. The third zone of articular cartilage is that of the deep zone which contains the largest diameter collagen fibrils, the highest proteoglycan content, and the lowest water concentration. The deep zone makes up approximately 30% of the articular cartilage in which the collagen fibrils are arranged perpendicular to the articular surface. The deep zone functions as the primary resistance against compressive forces, and can do this given the high proteoglycan content and perpendicular fiber alignment. The last zone of articular cartilage is that of the calcified zone, which functions to anchor the collagen fibers of the deep zone to the subchondral bone.33

2.3 Osteoarthritis Etiology and Pathology

2.3.1 Multifactorial Etiology
Knee osteoarthritis has a multifactorial etiology including obesity, aging, and injury. Other less established risk factors include genetics, bone density, metabolic, and biomechanical implications.

Neame et al. found that siblings of those with OA had double the risk of having knee OA themselves compared to siblings of those who do not have OA, with 62% of the disease variance being genetically determined. Similarly, Chitnavis et al. reported significant familial tendencies for symptomatic knee OA with siblings of those with OA showing two to five times the risk of needing a TKR due to idiopathic, end-stage OA. The study also found that one-third of the variance of OA seemed to be genetically determined. Finally, Spector et al. investigated the genetic variance of hand and knee OA in identical and non-identical twins. Genetic effects were found to explain 39-65% of the variance for hand and knee OA.

Sowers found that nutrients may influence knee OA. Oxidative damage, implications of inflammatory responses, cellular differentiation, and problems with bone and collagen synthesis may all be affected by inadequate intake of nutrients. A study by McAlindon and Felson did not find any significant associations with micronutrients for the development of radiographic knee OA. However, for those already burdened with radiographic knee OA, a threefold reduction in the progression of OA was found in those with a high intake of vitamin C. The progression of OA was also minimally reduced with an adequate intake of beta-carotene and vitamin E. These nutrients provide antioxidant effects, which react against the oxidative damage seen at the knee from reactive oxygen species. The study also suggests that vitamin E acts against synovial inflammation that
accompanied OA by forming arachidonic acid from phospholipids and inhibits lipoxygenase activity.

Sowers\textsuperscript{36} suggested that the pathology of OA has a relation to skeletal calcification, with OA patients showing higher levels of bone mineral density than those without the disease. Similarly, Hart \textit{et al.}\textsuperscript{37} found increases in mean bone density for those with early radiological knee OA, showing that the two are inversely related. Higher levels of bone mineral density leading to knee OA is further confirmed by Hochberg \textit{et al.}\textsuperscript{42}, who found that higher levels of bone mineral density at the lumbar spine was associated with an increased risk of developing radiographic knee OA. This may suggest that although one may be protected from osteoporosis with higher bone forming tendencies, the same bone forming tendencies may actually increase the risk of developing OA.

Altered biomechanics due to injury of the knee poses as a risk factor for knee OA. Chaudhari \textit{et al.}\textsuperscript{43} investigated biomechanics of the knee in patients with an ACL injury and concluded that ACL deficiencies alter biomechanics, which then leads to the initiation of OA. Differing tibiofemoral contact patterns, anterior tibial translation, and altered tibial internal and external rotation may occur in the presence of an ACL injury. These changes cause a kinematic shift at the knee in which degenerative forces are placed upon the cartilage. Areas of cartilage that are not conditioned to handling loads, along with reduced loading in areas of the cartilage that are conditioned to loading, may occur due to this shift, causing tissue breakdown. Lomander \textit{et al.}\textsuperscript{44} researched female soccer players who had sustained ACL injuries and found that 12 years after the injury 51% of the females had radiographic knee OA.
2.3.2  Articular Cartilage Degeneration

Knee OA is characterized by articular cartilage degeneration.\textsuperscript{45} Early OA shows mostly changes in the superficial zone of articular cartilage. These changes include changes in collagen orientation and proteoglycan content. This progresses into deeper zones of articular cartilage as the state of OA develops in which changes of collagen content take place.\textsuperscript{46} The main areas of the knee that could develop articular cartilage deformities include the medial and lateral tibiofemoral and the patellofemoral compartments, with the patellofemoral compartment experiencing full thickness defects of cartilage in as high as 30\% of osteoarthritic knees.\textsuperscript{45,47}

2.3.3  Bone Marrow Edema

Subchondral trabecular bone marrow edema (BME) is also a consequence of knee OA, with some studies\textsuperscript{45,47} showing BME lesions in 57\% of evaluated osteoarthritic knees. The presence of osteophytes, synovitis, subchondral cysts, and subchondral sclerosis has also been identified as physical markers of OA.\textsuperscript{45,47} A study examining subchondral bone abnormalities and bone marrow edema for over the course of a year found that the absence of these two markers corresponded with a lack of deterioration of chondropathy.\textsuperscript{48} Furthermore, although the exact source of the pain seen in OA patients is unclear, it is suggested that bone and bone marrow edema are the main culprits since these structures are rich in nociceptive fibers, whereas cartilage lacks fibers that produce pain. This is supported by Sowers \textit{et al.}\textsuperscript{49} who confirmed more BME among persons with painful OA than in those with non-painful OA. A similar study expands on this,
specifying that the pain exhibited by BME is compartment-specific, with pain being associated with the medial or lateral tibiofemoral compartments and poorly associated with the patellofemoral compartment. However, Link et al. contradict the explanation of pain caused by BME. These authors reported that significantly lower WOMAC pain and function scores were associated with smaller cartilage defects in patients with knee OA.

2.4 Consequences of Knee Osteoarthritis

2.4.1 Quadriceps Weakness

Quadriceps weakness is the primary clinical sign of knee OA. Quadriceps strength is critical to the performance of activities of daily living and those with quadriceps weakness have difficulty performing daily activities such as walking and stair climbing. Slemenda et al. reported that weakness of the quadriceps muscle group exists in those who have knee OA and that this weakness may occur in the absence of detectable atrophy of the muscle or joint pain. Also, these authors suggest that this quadriceps weakness may be a mark of the possible initiation or progression of the disease. In addition to this, Palmieri-Smith et al. illustrated that quadriceps weakness is present very early in the disease process when other signs such as radiographic and cartilaginous factors were classified as “mild.” These findings may warrant the use of determining one’s quadriceps strength as a clinical marker when identifying possible radiographic knee osteoarthritis. McAlindon et al. further researched the role of quadriceps weakness as a determinant linked to knee OA and found that it was more important than both knee pain and increasing age in causing disability. Similarly, Segal
et al.\textsuperscript{57} established that not only is quadriceps weakness linked to disability but also is a precursor to symptomatic knee OA. Since quadriceps muscle activity plays a key role in protecting against symptoms of knee osteoarthritis and general disability, an intervention to work against decreasing quadriceps strength may prove to be beneficial.

2.4.2 Decrease in Physical Activity

Patients with knee OA have decreased levels of physical activity in comparison to their healthy counterparts.\textsuperscript{14,58,59} De Groot \textit{et al.}\textsuperscript{58} found that patients with both end-stage knee and hip OA had significantly lower physical activity levels, as measured by activity monitors, than healthy controls. These authors also observed that pain was not associated with the reduction in physical activity levels. Similarly, Farr \textit{et al.}\textsuperscript{59} compared activity levels of patients with early-stage knee OA, measured by accelerometry, with recommendations made by Centers of Disease Control and the American College of Sports Medicine and found that only 30\% of these patients achieved the physical activity recommendations. Rosemann \textit{et al.}\textsuperscript{14} revealed that reasons of decreased PA levels in patients with knee OA were due to physical limitations to the lower limb, social contacts, pain, age, and body mass index. Steultjens \textit{et al.}\textsuperscript{60} considered an avoidance model affecting disability and found that an avoidance of OA-related painful activities leads to muscle weakness, which then causes further disability.

2.5 Current Treatment Practices

Current treatments to alleviate the symptoms of knee OA include both conservative and surgical measures. Conservative treatment often includes non-
pharmacological treatments of weight loss, exercise and education as well as pharmacological treatments of oral analgesic and non-steroidal anti-inflammatory drugs (NSAIDS) and injections of corticosteroids or hyaluronic acid. Surgical intervention is in the form of unicompartmental or total knee arthroplasty (TKA). Collectively, these treatments aim to educate the patient, alleviate the pain, improve function, and prevent the progression of the disease. Treatment methods must also be tailored to the patient’s specific needs and situations.

2.5.1 Exercise Training

Certain methods of exercise therapy can be beneficial for treating osteoarthritis of the knee. Van Baar et al. assessed different methods of exercise treatment and concluded that exercise therapy in general is effective in treating patients with knee OA, although insufficient evidence did not allow them to conclude which interventions were optimal. Exercise therapy methods included aerobic exercises, resistance exercises, and a mixture of several types of exercise therapy. Outcome parameters included pain, self-reported disability, observed disability in walking, and patient’s global assessment of effect, which all showed improvement with the different exercise therapies. Davis et al. concluded that the use of therapeutic exercise as a non-pharmacological treatment method has shown promise as an effective approach to conservatively treat the disease.

A systematic review assessing home based strength training has shown that strength training specifically targeting the quadriceps can be beneficial at reducing pain and disability in patients with knee osteoarthritis. The review, however, states that the best way to deliver strengthening exercises is still unclear, with differing variations of
content and duration of exercise programs included. Length of these exercise programs included ranged from eight weeks to two years and varied in the interventions that were combined with strengthening exercises. Mikesky et al. 62 examined the effects of a strength training regimen conducted over a 12 week period, followed by a 12 month home-based exercise program versus a control group. The results showed a trend toward a reduction in the mean rate of joint space narrowing in the strength training group by 26%, although joint space narrowing that exceeded 0.50 mm was found to be 79% more common in the strength training group than the control group. Furthermore, the study revealed that the strength training regimen increased isotonic hamstring strength, while slowing the reduction of quadriceps isokinetic strength loss. King et al. 63 evaluated the response to a 12 week, high intensity, knee extensor and knee flexor resistance training program in those with advanced knee OA. Significant improvements were found in knee extensor and knee flexor strength without significant increases of knee pain during exercise or activities of daily living. Adherence was shown to be high during the 12 week program. Fisher et al. 64 found benefits of a quantitative progressive exercise rehabilitation program in terms of functional performance and muscle functioning in those plagued with knee OA. Benefits of resistance training are also shown by Ciolac and Greve 10 who found that a twice-weekly resistance training program lasting for 13 weeks showed improved muscle strength of older women with total knee arthroplasty (TKA) and knee OA.

2.5.2 Increase in Physical Activity
Increases in physical activity (PA) can help increase functionality and performance in male and female patients with OA across all ages.\textsuperscript{15,18} The American Geriatrics Society Panel on Exercise and Osteoarthritis supplied a consensus practice recommendation for exercise prescription for those with OA,\textsuperscript{65} highlighting the importance of maintaining high levels of PA to reduce pain and morbidity. Dunlop \textit{et al.}\textsuperscript{15} used prospective data from a cohort of patients with radiographically confirmed knee OA and found that those with increased levels of PA had significantly greater objective measures of gait speed. Also, data showed this relation consistently throughout differing levels of knee OA. Bossen \textit{et al.}\textsuperscript{66} investigated the effects of a web-based nine week physical activity program in patients with knee OA that focused around the patient’s favorite recreational activity. The activity was gradually increased in terms of time contingency as the study progressed. It was found at 3- and 12-month follow-ups that PA levels rose 1\% and 6\%, respectively. Furthermore, measures of physical functioning and the patient’s self-perceived degree of change improved with the increase in PA.

Evidence has begun to show that PA correlates with quadriceps strength, an important determinant in knee OA patients. Pietrosimone \textit{et al.}\textsuperscript{67} found this correlation in a study reviewing thirty-six patients with radiographically diagnosed knee OA. The study found that increases in PA correlated with higher quadriceps strength although the relation could not be reversed because higher quadriceps strength was not correlated with increased PA levels. These results could suggest that higher levels of PA could help maintain strength in patients with knee OA.

\textbf{2.5.3 Group Treatment Sessions}
Radiographic knee OA affects approximately 37% of Americans and combined with hip OA, result in some $42.3 billion spent annually in the United States on joint replacement surgery alone. These high statistics require the need to evaluate less human resource intensive treatment methods. Fransen et al. compared individual physical therapy techniques to a group format of physical therapy and concluded that similar benefits of self-reported pain, physical function, and health related qualify of life were found between the two techniques. Upon this, the group format of physical therapy was less human resource intensive. Seven half-hour individual treatment sessions allowed an average of 3.5 hours of one-on-one treatment whereas 16 hours with 6 patients for the group treatment sessions allowed for an average of 2.7 hours of one-on-one treatment.

2.5.4 Pharmacological Treatments

The European League Against Rheumatism (EULAR), American College of Rheumatology (ACR), and Royal College of Physicians (RCP) recommend paracetamol, an oral analgesic, as the first attempt of treating moderate knee pain in those with OA of the knee. Paracetamol has been tested in random clinical trials, which have shown significant improvements over a placebo group in terms of pain. Furthermore, it was established that paracetamol could effectively treat OA-related knee pain for up to two years, while taking doses up to 2600 mg/day. When the use of paracetamol shows unresponsiveness to treating knee pain, the use of a non-steroid anti-inflammatory may be warranted. Bradley et al. researched the use of the non-steroid anti-inflammatory (NSAID), ibuprofen, against the analgesic, paracetamol, and found similar results in
treats knee pain. Williams et al. further demonstrate the efficacy of using NSAIDs in the treatment of knee OA symptoms. However, it is important to note that NSAID use presents an increased risk of gastrointestinal side effects. Evidence has shown that the risk of developing serious gastrointestinal complications is nearly three times greater in NSAID users compared to nonusers. The period of greatest risk of establishing gastrointestinal problems occurs during the first 3 months of NSAID treatment. In cases where NSAIDs present with gastrointestinal side effects, the switch to a cyclooxygenase-2 (COX-2) inhibitor may help relieve symptoms. COX-2 inhibitors do not contain the mechanism-based gastrointestinal toxicity that conventional NSAIDs have but are able to mediate pain and inflammation just as well. McKenna et al. compared the effectiveness and safety in celecoxib (a COX-2 inhibitor) and diclofenac (a conventional NSAID) in a randomized, double-blind comparison. The study found that celecoxib was equally effective as the conventional NSAID but presented with a superior tolerability and safety profile.

2.5.5 Intra-articular Injections

Intra-articular injection of corticosteroids is indicated as an agent to relieve pain and inflammation. Dieppe et al. confirmed short term benefits of steroids, in showing an increased effectiveness in pain relief over a period of seven days while compared to a placebo group. This is furthered by Ravaud et al. who concluded that benefits of intra-articular corticosteroids lasted up to four weeks and were maximal during the first week following injection in a randomized control trial. Lastly, Gaffney et al. also confirms
the short term pain relief benefits of intra-articular corticosteroids with the injection of triamcinolone hexacetonide into osteoarthritic knees.

Intra-articular injections of hyaluronic acid (HA), similar to corticosteroid injections, have been shown alleviate symptoms related to knee OA.\textsuperscript{79, 80} Vincent \textit{et al.} \textsuperscript{79} performed HA intra-articular knee injections on 53 patients with knee osteoarthritis and concluded that the injections increased the quality of movement and functional activity by modifying functional pain severity. Improvements in gait and walking velocity scores were visible upwards of six months post-injection. Similarly, DeCaria \textit{et al.} \textsuperscript{80} compared 15 knee OA patients that received HA injections with 15 knee OA patients that received a placebo injection. The HA injection group showed significantly improved levels of pain, stiffness and physical function, along with improved gait velocity over the duration of the study. However, improvements in gait velocity, stiffness, and physical function levels were not significantly different when compared to the placebo group.

2.5.6 Invasive Treatment

If non-pharmacological and pharmacological treatment methods fail, the use of invasive techniques may be required. In a survey of orthopaedic surgeons,\textsuperscript{81} the general consensus is that pain, functional limitation, and evidence of joint space narrowing are the primary indications of total knee arthroplasty (TKA). However, the severity of disease progression for which surgical intervention should be considered is still debated. A TKA procedure involves the resurfacing of damaged bone and cartilage of the knee via metal or plastic implants. A systematic review by Ethgen \textit{et al.} \textsuperscript{82} found TKAs to be
quite effective in improving quality of life with pain, mobility, mental health, and self care all showing improvements for upwards of five years post-operatively.

2.6 Self-Reported Treatment Outcome Measures

2.6.1 Numeric Pain Rating Scale

The Numeric Pain Rating Scale (NPRS) is a subjective assessment of one’s level of pain for the past 24 hours or during the performance of a particular activity. The scale ranges from 0 to 10, with scores of zero representing no pain and scores of 10 representing the worst pain possible. Joos *et al.* 83 researched the results of a numeric rating scale in 30 individuals with rheumatic pain. The research concluded that the numeric rating scale was useful, reliable, and reproducible for measuring pain for individual patients.83

2.6.2 Western Ontario McMaster Universities Osteoarthritis Index

The Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) questionnaire is a validated, reliable, self-administered questionnaire to assess symptoms and functional capacity.84 Questions of the WOMAC include topics of pain, stiffness, and physical function that are recorded using a 5-point Likert scale. A low score of 0 represents no symptoms/limitations and a high score of 4 corresponds to severe symptoms/limitations. There are 96 total possible points calculated from the WOMAC in which 20 possible are recorded for pain, eight possible are recorded for stiffness, and 68 possible are recorded for physical function. The higher the overall score, the more symptomatic and physically limited the patient is.
2.6.3 UCLA Activity Scale

The UCLA activity scale is a reliable and valid scale used to assess one’s physical activity level. The scale ranges from 1 to 10, with 1 representing “no physical activity, dependent upon others” and 10 representing “regularly participates in full impact sports.” Higher scores indicate higher levels of activity. Naal. et al. concluded that the UCLA activity scale was superior to the Tegner scale and to the Activity Rating Scale due to better metric properties and the population involved.

2.7 Functional Performance Measures

2.7.1 Stair Climb Test

A major burden for elderly, disease-ridden populations is that of stair climbing. This activity may become a heavy burden, especially when facing areas without handicap access points. Stair negotiations are a common rehabilitation goal and are important in order to gain functional independence. Specifically, quadriceps strength is a key factor in successfully ascending and descending stairs and has been shown to be negatively associated with the time to complete stair climbing, such that lower strength values are associated with increased stair climb times. Dobson et al. recommended clinicians use a stair negotiations test in assessing functional performance and concluded that the test may vary in amount of steps taken, according to the setting. Kennedy et al. found that the reliability coefficient of the stair climb test (SCT) measured 0.90 (0.79, 0.96), meeting the study’s cutoff for making clinical decisions at an individual patient level of 0.90 and recommending it as a highly reliable measure of functional capacity.
2.7.2 Chair Stand Test

An activity of daily living that cannot be avoided is that of a sit-to-stand transition. It is an activity that must be able to be performed unaided and efficiently to live an independent lifestyle. This transition from a sitting to a standing position involves increased joint forces and moments that may cause an osteoarthritic knee to experience problems in completing the task. Su et al. 88 found that those who have knee OA and those who have undergone a TKA have shown an increase in time with the transition of rising from a seated position to a standing position. This task, similar to stair climbing, places a large demand on the quadriceps musculature and is difficult to perform in the presence of quadriceps weakness. Patients following TKA and those with OA compensate for quadriceps weakness by leaning forward and placing their center of gravity anterior to their hip and ankle. The forward leaning helps decrease the stresses placed on the quadriceps muscle group, allowing individuals with muscle weakness to still successfully rise from a seated position. Similarly, Turcot et al. 89 found that an increase in knee pain was positively correlated with increased trunk flexion and average time to perform a sit-to-stand task. Increases in time of completing this task for those with knee OA may, therefore, dictate using this sit-to-stand task as an appropriate measure of functional capacity.

A systematic review of performance-based measures by Dobson et al. 90 concluded that a 30 second chair stand test (CST), along with the timed up and go test are optimal for measuring performance in knee OA patients for all sit to stand tests. The test showed positive intra- and inter-rater reliability for the knee and hip. Positive results for measurement error, responsiveness, and interpretability of the test were found for those
with hip OA. No information on validity and retest reliability was found. Similarly, Gill et al. \textsuperscript{91} reported that the 30s CST can be a reliable measure of physical performance and the Osteoarthritis Research Society International (OARSI) recommends the use of the 30s CST to assess physical function in those with diagnosed knee OA.\textsuperscript{86}

2.7.3 Timed Up and Go

Similar to the 30s CST, the timed up and go (TUG) test also encompasses the activity of making a sit-to-stand transition. Originally, the TUG was used as a balance measure in elderly people but was modified into a timed test and used as a test of basic mobility skills.\textsuperscript{92} As stated previously, the sit-to-stand transition involves increased joint forces and moments that cause an osteoarthritic knee to experience difficulties in completing the task. Dobson et al. \textsuperscript{90} determined the TUG and chair stand test to be the best performance-based measures for all sit-to-stand tests for patients with hip or knee OA. The TUG shows positive inter-rater reliability for hip OA along with positive measurement error for hip OA. It also showed positive interpretability for hip OA and positive validity for knee OA.

2.7.4 Six Minute Walk Test

An important functional measure that needs to be taken into consideration for overall functional capacity is that of walking speed. Walking speed has been shown to be negatively associated with quadriceps weakness, which is a consequence of knee OA.\textsuperscript{52-54} Furthermore, Purser et al. \textsuperscript{93} found that slower walking speeds were correlated with a higher incidence of symptomatic knee OA and those with faster walking speeds showed
lower incidences of OA. The reason for this may be explained by Teixeira-Salmela et al. 94 who showed that higher cadence levels of walking necessitated greater contributions from the knee and overall greater moments placed on the joint. Although Dobson et al. 90 concluded that evidence for the six minute walk test (6MWT) has yet to be determined as an objective tool of functional performance in people with knee OA, evidence of the test has been determined in similar populations. Jakobsen et al. 95 concluded that the intra-tester reliability of the 6MWT was high in the TKA population and that the length of the exam was enough to find a true change in these patients. Similarly, Kennedy et al. 87 found that the 6MWT met standards for making clinical decisions at an individual patient level. The intra-correlation coefficient for the 6 MWT in those who have undergone TKA was 0.94 (0.88, 0.98), meeting the study’s cutoff for making decisions at 0.90.

2.7.5 Activity Monitor

Patients with knee osteoarthritis have decreased levels of physical activity in comparison to healthy counterparts.14,58,59 Due to this, collecting data as to how much physical activity patients with knee OA are achieving can be used as a functional performance measure. Accelerometers have been commonly used as accurate measures of physical activity96-98 and have been used effectively in the knee OA populations.58,99 The ActiGraph GT3X (ActiGraph Corporation, Pensacola, FL, USA) is a triaxial accelerometer that records activity intensity levels with estimates of count steps and energy expenditure, while being worn at the hip. Accuracy of ActiGraph accelerometers have been shown with physical activity types of sitting, standing, walking, running, walking stairs and cycling.97 A study by Eston et al. 100 compared accelerometers to
other objectives measures of physical activity and found that accelerometers accounted for 82% of the variance of energy expenditure while heart rate monitors and pedometers accounted for 64% and 65% of the variance respectively. This verifies the use of accelerometry over that of pedometry for predicting physical activity levels.

2.8 Summary

Knee osteoarthritis is an extremely prevalent disease \(^1\) that is characterized by joint space narrowing,\(^{62}\) degeneration of articular cartilage,\(^{45-47}\) and bone marrow edema.\(^{45,47-49}\) Furthermore, consequences of knee OA include decreases in levels of physical activity\(^{14,58-60}\) and quadriceps weakness.\(^{9,51,55-57}\) Methods attempted to reverse the progression of knee OA include medications,\(^{69-72,74,75}\) strength training,\(^{10,11,62-64,101}\) increases in physical activity,\(^{15,65-67}\) intra-articular injections,\(^{76-80}\) and surgery.\(^{81,82}\) The conservative approaches of an increase in physical activity and strength training have shown potential as being low-cost and timely \(^21\) intervention methods to help alleviate symptoms of knee OA.

In assessing the functional capacity and the treatment progress of a patient with knee OA, there are several self-reported treatment outcome measures and functional performance measures that should be performed which encompass many activities of daily living that may be compromised. Self-reported measures that include the NPRS,\(^{83}\) WOMAC,\(^{84}\) and the UCLA activity scale\(^{85}\) report measures of the general well-being of the patient to the tester. Objective functional performance measures that include the 6MWT,\(^{87,90,95}\) 30s CST,\(^{86,90,91}\) TUG,\(^{90,92}\) SCT,\(^{86,87}\) and the use of an activity monitor\(^{96-99}\) suffice for reporting data on changes in functional capacity from the treatment session.
Chapter 3

Methodology

3.1 Study Design/Setting:

The study design for this pilot project was that of an observational study with an embedded case series, in which functional testing was conducted in the Musculoskeletal Health and Movement Sciences (MHMS) Laboratory in the Health and Human Services Building at the University of Toledo and the intervention was conducted at the Friendship Baptist Church (FBC) or the MHMS lab in Toledo, OH. Female patients with diagnosed knee osteoarthritis were taken through several functional measures, treated with an 8-week group exercise intervention, and then taken through the same functional measures that were tested before the intervention at the end of 8 weeks.

3.2 Participation:

This study was part of a larger investigation examining not only functional outcomes but also neuromuscular and gait adaptations following exercise in patients with knee OA. Inclusion criteria were that the patients must be female, between 50-65 years of age\textsuperscript{102,103} and have symptomatic knee OA (as defined by American College of Rheumatology).\textsuperscript{102,103} A power analysis conducted on previous data presented a need to collect data from 22 participants to determine a 15% difference in transcranial magnetic
stimulation measures over time (power: 0.8, effect size: 0.5). Also, previous research has shown that 30% of individuals will not have recordable TMS measures. To counter this and an estimated 20% dropout rate, we will look to enroll 34 participants in this study (17 per group).

Exclusion criteria include: 1) any history of cardiovascular disease or any other medical condition that may preclude safe participation in exercise; 2) any history of illicit drug use, alcohol abuse, or anyone currently withdrawing from an abused substance; 3) an inability to accurately perform the exercises or follow directions regarding details of the study; 4) impaired balance; and 5) a history of neurological disorder, fibromyalgia, peripheral neuropathy, or rheumatoid arthritis. Since this was part of a larger study that includes transcranial magnetic stimulation, exclusion criteria specific to this testing was also used, which include: 1) metal implants in the head, neck, or shoulders (excluding dental work); 2) personal or familial history of seizures or epilepsy; 3) implanted foreign objects including ocular foreign objects, cochlear implants, brain stimulator, aneurysm clip, medication pumps, intra-cardiac lines, or cardiac pacemakers; 4) currently taking medications that lower seizure threshold (e.g. tricyclic antidepressants, neuroleptic agents, Baclofen, Tramadol, etc.); 5) history of serious head injury or increased intracranial pressure; 6) history of back/lower extremity surgery or back/lower extremity orthopedic injury in the past 6 months; 7) pregnant females; 8) body mass index (BMI) $\geq 40$ kg/m$^2$; and 9) current smokers.

Patients were recruited from a Friendship Baptist Church social group that fit inclusion criteria. Patients received an 8-week group exercise training program, between their pre-and post-test measures, conducted by the investigators. The testing order at the pre-test
session was maintained at the post-test session. The treatment was conducted once a week for a total of 8 treatment sessions. Each intervention session was estimated to last approximately one hour.

The study was approved by the University of Toledo Biomedical Institutional Review Board (#108105) and patients signed a consent form before engaging in any tests or exercises, informing the patient of any benefits or risks of the study.

3.3 Procedures Timeline:

![Visit 1 (~4 Hours)]
- Informed Consent
- Patient Demographics
- WOMAC, NPRS, UCLA Completion
- Stair Climb Test, Sit to Stand, TUG, 6 Minute Walk
- Accelerometer Hand Out

![Visit 2-9 (~1 Hour)]
- Collect Accelerometer and Measures (Visit 2)
- NPRS Completion
- Strengthening Exercises
- Walking
- Accelerometer Hand Out (Visit 9)

![Visit 10 (~4 Hours)]
- Collect Accelerometer and Measures
- Patient Demographics
- WOMAC, NPRS, UCLA Completion
- Stair Climb Test, Sit to Stand, TUG, 6 Minute Walk
- Feedback On Intervention

Figure 3-1. Procedures Timeline

3.4 Primary Outcome Measures:

3.4.1 Self-Reported Measures

These questionnaires were administered before and one week after the 8-week intervention.

**Numeric Pain Rating Scale (NPRS):** The NPRS was used to subjectively assess one’s level of pain of the past 24 hours. The scale ranged from 0 to 10, with lower scores representing minimal to no pain and higher scores representing more and higher pain.
The NPRS was administered during pre- and post-test measures, as well as prior to all intervention sessions.

**Western Ontario McMaster Universities Osteoarthritis Index (WOMAC):** The WOMAC questionnaire is a validated, reliable, self-administered questionnaire to assess functional capability. Questions regarding pain, stiffness, and physical function will be recorded using a 5-point Likert scale in which a score of 0 corresponds to no limitations and a score of 4 corresponds to severe limitations. All scores are calculated out of a total possible 96 points in which 20 possible are recorded for pain, eight possible are recorded for stiffness, and 68 possible are recorded for physical function. The higher the overall score, the worse the state of OA. Refer to appendix B for a copy of the WOMAC.

**UCLA activity scale:** The UCLA activity scale is a reliable and valid scale used to assess one’s physical activity level. The scale ranges from 1 to 10, with 1 representing “no physical activity, dependent upon others” and 10 representing “regularly participates in full impact sports.” Higher scores indicate higher levels of activity. Refer to appendix B for a copy of the UCLA activity scale.

### 3.4.2 Functional Performance Measures

Functional performance were evaluated before, and one week following the 8-week intervention. A standard stopwatch will be used for all timed measures.
**Stair Climb Test:** The stairwell outside of the MHMS Laboratory was used for the stair climb test (SCT). The stairwell consists of 10 steps measuring 18 cm high per step. The patient will be asked to “go up the stairs and then come back down at a quick but safe and comfortable pace.” The patient will be allowed to use aid for balance purposes only in ascending and descending the stairs but will be recorded in doing so. The total time taken to ascend and descend the stairs was recorded in hundredths of seconds. The same stairs was used for pre- and post-test measures. The stair climb test was recommended as a consistent and reliable performance-based outcome measure for clinicians and researchers.  

86, 87

**Chair Stand Test:** Participants completed a 30s chair stand test (30CST) and used the Invacare CareGuard Tool-Less Shower Chair (Without Back) (Invacare Corporation, Elyria, Ohio). The shower chair was adjusted so that the patient was seated with 90° of knee flexion as measured with a standard inclinometer. The patient performed the test by sitting comfortably in the shower chair, which was positioned against a wall for safety purposes, with feet shoulder width apart and flat on the floor. Arms were crossed to limit accessory motion. The patient performed the test by completely standing from the chair, so that knees and hips were fully extended, and then completely sit back into the chair, back to the original resting position. The patient did this repeatedly for 30 seconds and the amount of full sit to stands will be recorded. The shower chair used was armless so that patients were not tempted to use aid. If the patient was not able to accomplish a standing position, the patient placed his/her hands on the knees to help the movement and was recorded as an adapted test score. The same chair was used for pre- and post-test
measures in which seat height was again adjusted to allow 90° of knee flexion. The chair stand test was recommended as a consistent and reliable performance-based outcome measure for clinicians and researchers.\textsuperscript{86,88,89,91}

**Timed Up and Go:** The timed up and go (TUG) test used the same shower chair as previously described. The investigator placed a mark 3m in front of the chair using a standard tape measure. The patient was fully seated comfortably in the middle of the chair. Arms were placed at the patient’s knees as the patient stood up, walked to a mark 3m away, turned around, and came back to the chair to sit and return to the original resting position. The amount of time to complete the entire test was recorded in hundredths of seconds. Two trials were performed and the fastest time was utilized. The same chair was used for pre- and post-test measures in which the seat height was again adjusted to allow 90° of knee flexion. The timed up and go test was recommended as a consistent and reliable performance-based outcome measure for clinicians and researchers.\textsuperscript{86,92}

**Six Minute Walk:** Participants completed a six-minute walk (6MW) test in the hallway outside the MHMS Laboratory. A distance of 25 meters was marked and the patients walked back and forth along this distance for the entirety of the six minutes. The total distance walked by the patient over the six minute period was recorded. The hallway was marked every 5 meters for measurement accuracy. The patients were encouraged to walk continuously for the entire test. Rest was allowed; however, the time was not stopped. Assistive device use was permitted and documented as necessary. The six-minute walk
was recommended as a consistent and reliable performance-based outcome measure for clinicians and researchers.\textsuperscript{86,87,92}

**Activity Monitor:** Patients were given an activity monitor (ActiGraph, GT3X, ActiGraph Corporation, Pensacola, FL, USA) immediately following the pre-test measurements. Patients were asked to wear the activity monitor for one week. The patients were instructed to wear the activity monitor throughout the entirety of each day, beginning from when they wake to when they sleep, only removing the activity monitor for occasions of bathing, showering, and swimming. Investigators urged the patients to go about their day, as they normally would while wearing the activity monitor. Instructions of proper activity monitor placement were given to the patient at the time of activity monitor distribution. The activity monitor measures were taken between pre-test and first intervention period and between last intervention and post-test period.\textsuperscript{104-106} Levels of activity were distinguished according to classifications established by Freedson et al.\textsuperscript{107} Activity counts less than 1952 per minute were classified as light activity, between 1952 and 5724 were classified as moderate activity, between 5725 and 9498 were classified as vigorous activity, and above 9498 were classified as very vigorous activity.

3.5 **Intervention/Strength Training:**

**Warm-up:** A five-minute period that encompasses walking and general lower extremity stretching served as appropriate warm-up to the exercise intervention.
**Knee Extension**: Patients were instructed to sit comfortably in a standard chair so that their feet are flat on the ground. They then performed the exercise by extending their respected knee to achieve as much extension as possible. This was done in a slow and controlled manner in which they paused briefly once fully extended, and then returned to the starting position. The exercise was progressed, when tolerated, up to four sets of 20 repetitions.

**Sit-to-Stand**: Patients were instructed to sit comfortably in a standard chair so that their feet were flat on the ground. They then performed the exercise by rising from the chair into a standing position. They paused briefly and then returned to a seated position. The exercise was progressed, when tolerated, up to four sets of 20 repetitions.

**Hip Extension**: Patients were instructed to stand on one limb and extend at their hip with the free limb. They attempted to achieve as much extension as possible, pause briefly, and then return to the starting position. The exercise was progressed, when tolerated, up to four sets of 20 repetitions.

**Hip Abduction**: Patients were instructed to stand on one leg and abduct at their hip with the other leg. They attempted to achieve as much abduction as possible, pause briefly, and then return to the starting position. The exercise was progressed, when tolerated, up to four sets of 20 repetitions.
Heel Raises: Patients were instructed to stand on both legs with feet hip width apart. They raised their heels off of the ground by plantar flexing their ankles and coming up onto their toes. They paused briefly and then returned to the starting position. The exercise was progressed, when tolerated, up to four sets of 20 repetitions.

Balance: Patients were instructed to stand on both legs with arms crossed over their chest. The difficulty of the exercise was increased as needed by progressing to standing on a single leg and closing of the eyes during the activity. Up to four 60-second repetitions were performed.

Walking: Patients were instructed to walk at a comfortable pace for 30 minutes during each exercise session. This took place either inside of the Friendship Baptist Church or in the Health and Human Services building at the University of Toledo. An investigator accompanied the patients during this task.

Exercises that compromised stability were allowed near a stable platform (i.e. table or counter) to reduce the chance of a fall. Intensity of the exercises were patient driven and were done bilaterally when applicable. Exercises were performed in the supervision of an investigator to ensure good form. The patients were also asked to keep a running log of any home exercise or physical activity they engage in outside of the supervised sessions. Illustrations and directions for all exercises are further presented in appendix D.

3.6 Statistical Analyses
The independent variable for this study was time (pre- and post-intervention). Dependent variables included self-report measures (UCLA, NPRS and WOMAC), functional performance measures (CST, SCT, TUG, and 6MWT scores), and physical activity levels. Averages with associated standard deviations and mean differences were calculated for all pre- and post-intervention measures. Effect sizes with associated 95% confidence intervals were also calculated for all pre- to post-intervention differences.
Chapter 4

Results

Twelve patients with osteoarthritis, defined by the American College of Rheumatology, were accepted into the 8-week therapeutic exercise intervention and performed functional and self-reported outcome assessments. Upon completion of the baseline measures, five patients dropped out of the study at varying time points due to scheduling conflicts. Furthermore, three out of the seven patients were disqualified from using the activity monitors due to an excessive body mass index (>40 kg/m²). However, the functional and self-reported outcome measures of these individuals were still used in this study.

Demographic data for these patients can be found in Table 4.1.

<table>
<thead>
<tr>
<th>Table 4.1</th>
<th>Demographics of patients with knee osteoarthritis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age (years)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>56.0 (5.42)</td>
</tr>
</tbody>
</table>

4.1 Self-Reported Outcomes and Pain

Seven patients qualified to take part in the WOMAC and NPRS self-reported measures. Overall, improvements were seen for both self-reported assessments from baseline to follow-up (Table 4.2). These improvements also demonstrated moderate to large effect sizes. However, the effect sizes recorded for the total WOMAC scores and all subcategories of the WOMAC had associated confidence intervals that crossed zero.
4.2 Functional Outcome Measures

Seven patients qualified to take part in the functional outcome measures. Overall, improvements were seen for all functional outcome measures from baseline to follow-up. These improvements also demonstrated moderate to large effect sizes. However, the associated confidence intervals for the TUG and 6MW crossed zero (Table 4.2).

Table 4.2 Patients with knee osteoarthritis, before and after 8-week intervention (Self-Reported Outcomes & Function)

<table>
<thead>
<tr>
<th></th>
<th>Baseline Mean (SD)</th>
<th>Follow-up Mean (SD)</th>
<th>Mean Difference</th>
<th>Cohen's d - Effect Size - Control SD</th>
<th>CI 95% (lower)</th>
<th>CI 95% (upper)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOMAC (Total)</td>
<td>34.57 (15.52)</td>
<td>23.42 (11.96)</td>
<td>-11.14</td>
<td>-0.72</td>
<td>-1.80</td>
<td>0.36</td>
</tr>
<tr>
<td>WOMAC (Pain)</td>
<td>7.42 (2.94)</td>
<td>4.57 (3.10)</td>
<td>-2.86</td>
<td>-0.97</td>
<td>-2.08</td>
<td>0.13</td>
</tr>
<tr>
<td>WOMAC (Stiffness)</td>
<td>4.28 (1.50)</td>
<td>3.14 (1.68)</td>
<td>-1.14</td>
<td>-0.76</td>
<td>-1.85</td>
<td>0.32</td>
</tr>
<tr>
<td>WOMAC (Disability)</td>
<td>22.85 (11.71)</td>
<td>15.71 (9.48)</td>
<td>-7.14</td>
<td>-0.61</td>
<td>-1.68</td>
<td>0.46</td>
</tr>
<tr>
<td>NPRS (Score 0-10)</td>
<td>5.43 (1.81)</td>
<td>2.29 (2.93)</td>
<td>-3.14</td>
<td>-1.73</td>
<td>-2.96</td>
<td>-0.51</td>
</tr>
<tr>
<td>CST (Repetitions)</td>
<td>10.21 (1.07)</td>
<td>12 (1.61)</td>
<td>1.79</td>
<td>2.28</td>
<td>2.88</td>
<td></td>
</tr>
<tr>
<td>TUG (Seconds)</td>
<td>9.65 (1.42)</td>
<td>8.23 (1.44)</td>
<td>-1.42</td>
<td>0.22</td>
<td>-2.11</td>
<td>0.11</td>
</tr>
<tr>
<td>SCT (Seconds)</td>
<td>13.03 (0.70)</td>
<td>11.6 (1.07)</td>
<td>-1.43</td>
<td>0.84</td>
<td>0.25</td>
<td>1.93</td>
</tr>
<tr>
<td>6MW (Meters)</td>
<td>454.09 (59.77)</td>
<td>504.21 (54.64)</td>
<td>50.11</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index; NPRS = Numeric Pain Rating Scale; CST = Chair Stand Test; TUG = Timed Up and Go; SCT = Stair Climb Test; 6MW = 6 Minute Walk; SD = Standard Deviation; CI = Confidence Interval

4.3 Physical Activity Measures

4.3.1 Activity Monitor

Four patients qualified to wear the ActiGraph, GT3X (ActiGraph Corporation, Pensacola, FL, USA) activity monitor for a total period of seven consecutive days, before and after introduction of the exercise regimen (Table 4.3). Overall,
patients increased their average steps per day as well as the peak number of steps taken per day following the intervention. However, these increases from baseline to follow-up sessions resulted in trivial to small effect sizes and had corresponding confidence intervals that crossed zero.

Table 4.3 Patients with knee osteoarthritis, before and after 8-week intervention (Physical Activity Scores)

<table>
<thead>
<tr>
<th></th>
<th>Baseline Mean (SD)</th>
<th>Follow-up Mean (SD)</th>
<th>Mean Difference</th>
<th>Cohen's d - Effect Size (Control SD)</th>
<th>CI 95% (lower)</th>
<th>CI 95% (upper)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Steps/Day</td>
<td>6323.78 (1685.11)</td>
<td>6859.29 (2025.72)</td>
<td>535.51</td>
<td>0.32</td>
<td>-1.08</td>
<td>1.71</td>
</tr>
<tr>
<td>Peak Steps (for all days)</td>
<td>10139.5 (2979.45)</td>
<td>10944.25 (3320.40)</td>
<td>804.75</td>
<td>0.27</td>
<td>-1.12</td>
<td>1.66</td>
</tr>
<tr>
<td>Sedentary (min)</td>
<td>3669.33 (1044.34)</td>
<td>3887.83 (1163.49)</td>
<td>218.50</td>
<td>0.21</td>
<td>-1.18</td>
<td>1.60</td>
</tr>
<tr>
<td>Light Activity (min)</td>
<td>1589.58 (524.62)</td>
<td>1475.04 (355.38)</td>
<td>-114.54</td>
<td>-0.22</td>
<td>-1.61</td>
<td>1.17</td>
</tr>
<tr>
<td>Moderate Activity (min)</td>
<td>211.08 (68.57)</td>
<td>272.21 (97.05)</td>
<td>61.12</td>
<td>0.89</td>
<td>-0.56</td>
<td>2.34</td>
</tr>
<tr>
<td>Vigorous Activity (min)</td>
<td>4.08 (1.5)</td>
<td>4.38 (2.59)</td>
<td>0.29</td>
<td>0.19</td>
<td>-1.19</td>
<td>1.58</td>
</tr>
<tr>
<td>Very Vigorous Activity (min)</td>
<td>0.88 (0.60)</td>
<td>0.71 (0.88)</td>
<td>-0.17</td>
<td>-0.28</td>
<td>-1.67</td>
<td>1.11</td>
</tr>
<tr>
<td>UCLA Activity Scale</td>
<td>5 (2)</td>
<td>5.5 (1.73)</td>
<td>0.50</td>
<td>0.25</td>
<td>-1.14</td>
<td>1.64</td>
</tr>
</tbody>
</table>

*UCLA = University of California-Los Angeles; SD = Standard Deviation; CI = Confidence Interval
Patients demonstrated minimal change in the time spent doing sedentary, light, moderate, vigorous, and very vigorous activity from baseline to follow-up (Table 4.3). All changes in activity levels, except for changes in moderate activity, displayed trivial to small effect sizes and have associated confidence intervals that crossed zero. The raw mean difference of moderate to vigorous physical activity from baseline to follow-up (Figure 4-1) did represent a noticeable improvement.

4.3.2 UCLA Activity Scale

The UCLA activity score did not significantly increase as a result of the intervention. The 0.5 point increase in UCLA activity scale scores from baseline to follow-up sessions resulted in minimal effect sizes with corresponding confidence intervals that crossed zero. UCLA activity scale data are further represented in table 4.3.
The current study was able to identify physical activity levels, functional performance, and self-reported outcome measures, before and after an 8-week exercise regimen, for females with knee osteoarthritis.

Physical activity levels did not exhibit meaningful changes from the introduction of the exercise regimen. This is demonstrated by trivial to small effect sizes for nearly all physical activity measures, with associated confidence intervals that crossed zero. Unfortunately, the patients, following the exercise regimen, demonstrated a small increase in sedentary behavior, along with a decrease in light activity. There are several reasons that may explain the minimal changes. Firstly, the limited improvements could be explained by the timing of the intervention. The start of the intervention took place during the summer while some of the patients were not presently working and ended during a time when they had resumed working again. Therefore, the patient’s work environment may not have allowed them to ambulate as much during the end of the intervention. Also, as shown in Table 4.2, patients on average still had symptoms of pain in their respected osteoarthritic knee. This pain may have inhibited motivations to engage in physical activity. However, this was countered by an overall increase of moderate to vigorous physical activity (MVPA) for patients, after completing the exercise
regimen (Figure 4-1). Possible reasoning for these patterns may be explained if patients desired to relax after participating in moderate to vigorous intensity exercise. Furthermore, the average steps taken per day also support this theory, as the patients also demonstrated a small increase in steps taken each day following the exercise regimen. Patients are not necessarily becoming more sedentary following the exercise regimen, but may require a sufficient amount of rest following an increase in activity level intensity. The American College of Sports Medicine has recommended that adults, ages 18-65, should engage in moderate intensity activity for a minimum of 30 minutes per day over a 5 day span. Higher intensity exercise can be coupled with the moderate intensity activity to meet these recommendations. Those who participated in this study met these recommendations during baseline testing and surpassed even that during follow-up testing, after the 8-week intervention.

Although physical activity levels did not increase as a whole because of the exercise intervention, patients demonstrated a strong clinical improvement in functional performance as evidenced by large effect sizes. Specifically, patients demonstrated the greatest improvements in CST and SCT performance. SCT performance, in particular, has been shown to be associated with quadriceps strength with increasing in strength corresponding to faster SCT performance. Thus, it is possible that patients increased their muscle strength as a result of the intervention and that translated to improvements in functional performance testing from baseline to follow-up. Regarding the CST, it is possible that there was a learning effect, as the sit-to-stand exercise in the intervention was a similar motion to that performed in the CST. Despite improvements in functional performance, these improvements did not translate to increased physical activity levels.
Given the importance of physical activity in preventing chronic disease including obesity and cardiovascular disease, future investigations are needed to determine interventions that are capable of improving both functional performance and physical activity level.

By comparing the present data to that of minimum clinically important differences (MCID) previously reported in similar populations, we can determine the clinical impact of changes in functional outcome measures. A study by Wright et al. established MCIDs for the TUG and CST. Their findings showed that an increase equal to or greater than 2.0, 2.6, and 2.1 repetitions for the CST and a decrease equal to or greater than 0.8, 1.4, and 1.2 seconds for the TUG were associated with major improvements patient self-reported function. In the present study, the average mean difference from baseline to follow-up testing sessions for the CST was 1.79 repetitions and a mean difference of -1.42 seconds for the TUG. Although the mean difference for the CST did not meet the reported MCID, the TUG did. A study by Perera et al. investigated the magnitude of meaningful changes in the 6MW test. These authors found that an increase of 50 meters during the 6MW correlated with a substantial improvement in self-reported function for elderly individuals. The present study found an average mean difference from baseline to follow-up testing sessions for the 6MW was 50.11 meters, just matching that of the MCID in the Perrera et al. study. Reported MCIDs for the SCT could not be found. Collectively, these findings show that improvements made in the 6MW and the TUG after the completion of the 8-week exercise intervention may be important to the patient.

The average mean differences for all WOMAC subcategories, along with the WOMAC as a whole, improved after completion of the 8-week exercise intervention,
with moderate to large effect sizes. However, all associated confidence intervals to the effect sizes also crossed zero. Furthermore, although improvements were seen from baseline to follow-up sessions for the WOMAC as a whole, the improvements did not meet the reported MCID. A study by Angst et al. found that changes larger than 12% of the baseline score were considered the MCID for the WOMAC. The present study found an average change of 11.6% from the baseline to follow-up scores for all patients on the WOMAC. Although, as a whole, the patients displayed an average change in WOMAC scores that fell just below the MCID threshold, some patients did display larger changes from baseline to follow-up scores that were deemed important.

Throughout the exercise intervention, the patients’ progression in exercise was based solely on each patient’s own motivations, including the capacity of exercise for the first week. For every exercise within the intervention, the patients were always told the amount they had performed during the previous week and were told to try and exceed that amount, but only if that amount fell within a comfortable range of effort. This method in the progression of exercises is more comparable to that of a patient implementing exercise into their daily routine, outside of the study, rather than if the patients were given a predetermined exercise amount that they needed to reach each week. The patients responded well with this style of progression, always attempting to surpass their previous exercise amounts. It is possible, however, that had we controlled the amount of sets and repetitions by which each exercise had to progress, the results of the present study could have been different. Further study is needed to determine the best way to progress exercises to improve outcomes without exacerbating pain.
Similar studies have distinguished the effects of exercise on physical functioning and self-reported outcomes. A systematic review by Fransen et al. extracted data from 54 studies comparing some form of land-based therapeutic exercise with a non-exercise group for patients with knee osteoarthritis. Their findings were similar to those of the current study, indicating that therapeutic exercise provides at minimum, short-term benefits in reducing knee pain and improving physical functioning among patients with knee OA. However, the review did not report on direct causes of the improvements in physical functioning and self-reported outcomes. The current study attempted to establish whether these improvements were caused by a general increase in physical activity levels, which were motivated by engaging in a therapeutic exercise regimen. Nevertheless, activity levels measured during pre- and post-intervention did not change in the current study, even though improvements were still made in physical functioning and self-reported outcome measures. This indicates a need for further investigation as to the specific reasoning for why improvements in physical functioning and self-reported outcome measures are made after the completion of an exercise regimen in patients with knee osteoarthritis.

The outcomes found in the current study are comparable to other group-based interventions within the OA population. A randomized control trial by Fransen et al. compared the results of a group-based therapy intervention to that of individualized treatments and found similar short term benefits of pain, physical functioning and self-reported outcomes. As in the current study, their study found the group-based intervention method to be effective in treating OA and to be much less human resource intensive. Another study by Phillips et al. investigated motivations to initiate in and
maintain exercise in elders. A large contributing factor found was that of promoting socialization within exercise. The study suggests that elders are more likely to be active in exercise if they have other people to be active and socialize with. This factor becomes even more important for those living in isolation or without a spouse. Also, the study suggests that seeing those placed in similar circumstances achieve success enhances one’s perceived chance of improving their own success and also improves upon their motivation to engage in exercise.

The completion of multiple functional tasks to measure functional outcomes is a strength of this study. The chosen functional tasks cover a wide range of activities of daily living skills necessary for people of this population. A limitation of this study is that of a small sample size and lack of a control group. The small sample size hindered the ability to observe changes over time.

Although the direct causes of improved functional performance and self-reported outcomes were not recognized, the gains made from participating in the 8-week therapeutic exercise regimen for those with knee OA must not be undervalued. Whether the improvements observed were due to strength gains, from learned movements, or from some other contributing factor from the exercise program, the implementation of a group-based exercise regimen resulted in progress made for fighting symptoms related to knee OA. These findings further support the introduction of an exercise regimen to treat functional performance and self-reported outcome deficits for those plagued by OA of the knee.

In conclusion, the implementation of an 8-week therapeutic exercise regimen resulted in gains in functional performance and self-reported outcomes. However, these
gains did not translate to improvements in physical activity levels. This type of intervention shows promise in improving symptoms for women with knee osteoarthritis. However, further research is needed to determine the optimal intervention by which to improve functional performance, self-reported outcomes, and physical activity levels for patients with knee osteoarthritis.
References


90. Dobson F, Hinman RS, Hall M, Terwee CB, Roos EM, Bennell KL. Measurement properties of performance-based measures to assess physical function in hip and


111. Angst F, Aeschlimann A, Stucki G. Smallest detectable and minimal clinically important differences of rehabilitation intervention with their implications for required sample sizes using WOMAC and SF-36 quality of life measurement.

Appendix A

Consent Form

ADULT RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Exercise To Improve Knee and Hip Pain in Adults

Principal Investigator: Abbey Thomas, PhD, ATC
Other Staff (identified by role): Patricia Hogue, PhD, PA-C (Co-investigator)
Michelle McLeod, MA, ATC (Coordinator)
Devon Eley, ATC (Coordinator)
Allison Schutz (Coordinator)
Bradley Stemply, ATC (Coordinator)

Contact Phone number(s): (419) 530-4501

What you should know about this research study:

- We give you this consent/authorization form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will be communicated to you verbally by the research staff as well.
- Routine clinical care is based upon the best known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- We cannot promise that this research will benefit you. Just like routine care, this research can have side effects that can be serious or minor.
- You have the right to refuse to take part in this research, or agree to take part now and change your mind later.
- If you decide to take part in this research or not, or you decide to take part now but change your mind later, your decision will not affect your routine care.
- Please review this form carefully. Ask any questions before you make a decision about whether or not you want to take part in this research. If you decide to take part in this research, you may ask any additional questions at any time.
- Your participation in this research is voluntary.

PURPOSE (WHY THIS RESEARCH IS BEING DONE)

You are being asked to take part in a research study of exercise for people with knee and hip osteoarthritis. The purpose of the study is to learn if a series of muscle strengthening exercises and walking in a group setting can improve pain and symptoms in people suffering from osteoarthritis. This information will help the researchers determine the best way to treat knee and hip osteoarthritis.

You were selected as someone who may want to take part in this study because you have knee or hip osteoarthritis. Up to 75 people from the University of Toledo and surrounding community will participate in this study.
DESCRIPTION OF THE RESEARCH PROCEDURES AND DURATION OF YOUR INVOLVEMENT
If you decide to take part in this study, you will be asked to report to the Musculoskeletal Health and Movement Sciences Laboratory at the University of Toledo on 2 occasions, once at the beginning and once at the end of the study. Each visit will last approximately 3 hours. Friendship Baptist Church in Toledo, OH on up to 8 occasions (once per week for 9 weeks). Each session will last approximately 1 hour. Your participation in this study will last 9 weeks.

Each session may include the following exercises to treat pain associated with osteoarthritis.
1) Symptom and activity level assessment
2) Gait assessment
3) Strength and neuromuscular activation assessment
4) Functional assessment
5) Muscle strengthening
6) Walking

Symptom and Activity Level Assessment
You will be asked to complete a series of questionnaires regarding your knee or hip symptoms. The questionnaires ask about any pain you may be experiencing and how that pain influences your daily activities and overall function. You will also be asked to disclose any medications you are taking for knee or hip pain. Lastly, you will be asked to complete a brief survey indicating your current level of physical activity. This will take approximately 5 minutes.

Gait Assessment
Prior to performing these tasks, a series of joint markers will be placed on your legs and trunk. Joint markers are Styrofoam balls covered in tape. They allow researchers to recreate your joint motion on a computer. You will be asked to walk approximately 30 ft on a level floor. As you walk, you will step on a force plate (scale). A force plate allows researchers to understand the loads being placed on your joints as you walk. You will be asked to perform this task at two different speeds, your comfortable walking pace and a speed equivalent to normal, human walking speed. You will also be asked to go up and down a custom-made staircase. This staircase has four steps. You will be asked to go up at a comfortable pace. You will pause briefly at the top and then be asked to go down the stairs at a comfortable pace. These tasks will take approximately 30 minutes to complete.

Strength and Neuromuscular Activation Assessment
Muscle Strength Testing
This test helps the researchers determine how strong your thigh muscles are. This will be used to determine how hard you need to contract your thigh muscle during the magnetic stimulation testing. For this test, you will be asked to contract your thigh muscle as hard as you can and hold it for 5 seconds. You will be asked to perform this test no more than 5 times. You will be provided a warm up period and ample rest time between efforts. This test will take approximately 10 minutes.

Muscle Activation Testing
This test helps researchers determine if you are using your thigh muscles to their full potential. This test is similar to the strength testing, except you will have two electrodes (stickers) placed over your thigh muscles. These electrodes will deliver a brief, mild electrical stimulus to your leg while you contract your thigh muscles as hard as possible. You will be asked to perform this test no more than 5 times. You will be provided a warm up period and ample rest time between efforts. This test will take approximately 10 minutes.

Brain Mapping
This process helps the researchers find the spot on your scalp that best corresponds to your thigh muscle. This spot is called your optimal stimulating point and it is where researchers will place the coil for the rest of the testing. For this test, you will sit quietly in a chair and the coil will be moved around on your scalp until the researchers generate a consistent contraction in your thigh muscle. This process will take approximately 10 minutes.

**Motor Threshold Determination**

This process helps the researchers determine at what machine intensity to perform the testing. For this test, you will sit quietly in a chair while the researcher places the coil over your optimal stimulating point. Sets of 8 stimuli will be delivered. The intensity of the stimulus will be varied up and down with each set until the researchers find the lowest intensity possible that makes your muscle contract 4 out of 8 times during a set. You may be asked to lightly (20%) contract your thigh muscle during this test. This process will take approximately 30 minutes.

**Single Pulse Testing**

The data collected during this test are used to normalize the rest of the data collected. Your thigh muscle contractions during this test help the researchers to interpret the data collected during your thigh muscle contractions in the other tests. The researcher will place the coil over your optimal stimulating point. Sets of 8 stimuli will be delivered. The intensity of the stimulus will be set to approximately 120% of your motor threshold. You may be asked to lightly (20%) contract your thigh muscle during this test. This process will take approximately 20 minutes.

**Paired Pulse Testing**

The data collected during this test tell the researchers about how your brain is controlling your thigh muscles. The researcher will place the coil over the optimal stimulating point. Sets of 8 pairs of stimuli will be delivered. The intensity of the stimuli will be based on your motor threshold and the time between the stimuli will vary between 1 and 100 milliseconds. You may be asked to lightly (20%) contract your thigh muscle during this test. This process will take approximately 30 minutes.

**Functional Assessment**

You may be asked to complete a series of activities to measure your physical function. These tests will be similar to things you do every day, including rising from a chair and walking down a hallway. These tests may be timed. These tests will take approximately 10 minutes to complete.

**Muscle Strengthening**

When you report to Friendship Baptist Church, you will be asked to perform a series of exercises to strengthen your leg muscles. A member of the study team will demonstrate the exercises to you and talk you through the process of performing them. Exercises will be performed using your own body weight to provide resistance. You will perform up to 6 different exercises. Up to 4 sets of 20 repetitions of each exercise may be performed. You will be provided a warm-up period and ample rest time between sets. These exercises are standard physical therapy exercises for people with osteoarthritis. These exercises will take approximately 20 minutes to complete.

**Walking**

A member of the study team will accompany you as you walk in the church building or around the property. You will walk at a comfortable pace for up to 45 minutes.

**RISKS AND DISCOMFORTS YOU MAY EXPERIENCE IF YOU TAKE PART IN THIS RESEARCH**

**Likely Risks**

- Muscle soreness as a result of strengthening exercises.
- Mild, temporary discomfort in the scalp.
Less Likely Risks
- Muscle soreness as a result of strength testing
- Mild, temporary skin irritation from the electrodes
- Minor discomfort from noise associated with the TMS pulse. To minimize this risk, you will be offered ear plugs to wear during testing. Hearing loss has also been reported, but only in patients given repetitive magnetic stimulation to treat disorders such as depression. You will not be receiving repetitive magnetic stimulation.
- Mild headache lasting a few hours after testing. If you have a history of headache disorders, magnetic stimulation may aggravate your headaches.

Unlikely Risks
- There is a risk for seizures with magnetic stimulation of the brain, especially if you have had a seizure before or are taking medication that increases your seizure risk. Seizures have only been reported in people given repetitive magnetic stimulation. You will not be receiving repetitive magnetic stimulation.
- Loss of confidentiality
- There may be risks that are unknown to the researchers at this time

Exercise is the standard of care treatment for osteoarthritis. But, your condition may not get better or may become worse while you are in this study. Magnetic stimulation of the brain is safe, however, it may have short or long-term risks associated with it that are not presently known or suspected. If you become pregnant, the particular procedures involved in the study may involve risks to the embryo or fetus that are currently unknown.

POSSIBLE BENEFIT TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH
As a result of participating in this study, you may notice less pain in your knees or hips. Also, you may notice that the muscles you exercised are stronger and your overall fitness is improved. However, we cannot and do not guarantee or promise that you will receive any benefits from this research.

COST TO YOU FOR TAKING PART IN THIS STUDY
There is no cost to you for taking part in this study.

PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH
You will not receive financial compensation for participating in this study.

ALTERNATIVE(S) TO TAKING PART IN THIS RESEARCH
This study is designed to relieve pain in your knees or hips related to osteoarthritis. Physical therapy, including exercises that are a part of this study, combined with pain relieving medications prescribed by your physician are the current standard of care for people with osteoarthritis. Your alternative to participating in this study is not to participate.

CONFIDENTIALITY - (USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION)
By agreeing to take part in this research study, you give to The University of Toledo (UT), the Principal Investigator and all personnel associated with this research study your permission to use or disclose health information that can be identified with you that we obtain in connection with this study. We will use this information for the purpose of contacting you and conducting the research study as described in the research consent/authorization form.
Under some circumstances, the Institutional Review Board, or the Research and Sponsored Programs of the University of Toledo may review your information for compliance audits. If you receive any payments for taking part in this study, your personal information and limited information about this study will be given to The University of Toledo’s accounts payable department as necessary to process payment to you. We may also disclose your protected health information when required by law, such as in response to judicial orders.

The University of Toledo is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. There is a possibility that the information we disclose may be re-disclosed by the persons we give it to, and no longer protected. However, we will encourage any person who receives your information from us to continue to protect and not re-disclose the information.

Your permission for us to use or disclose your protected health information as described in this section is voluntary. However, you will not be allowed to participate in the research study unless you give us your permission to use or disclose your protected health information by signing this document.

You have the right to revoke (cancel) the permission you have given to us to use or disclose your protected health information at any time by giving written notice to Abbey Thomas, PhD, ATC. However, a cancellation will not apply if we have acted with your permission, for example, information that already has been used or disclosed prior to the cancellation. Also, a cancellation will not prevent us from continuing to use and disclose information that was obtained prior to the cancellation as necessary to maintain the integrity of the research study.

Except as noted in the above paragraph, your permission for us to use and disclose your protected health information will stop at the end of the research study. A more complete statement of University of Toledo’s Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo’s Privacy Officer at 419-383-6933.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

IN THE EVENT OF A RESEARCH-RELATED INJURY
In the event of injury resulting from your taking part in this study, treatment can be obtained at a health care facility of your choice. You should understand that the costs of such treatment will be your responsibility. Financial compensation is not available through The University of Toledo or The University of Toledo Medical Center.

By signing this form you are not giving up any of your legal rights as a research subject. In the event of an injury, contact the investigators for this study: Abbey Thomas, PhD, ATC at 419-530-4501.

VOLUNTARY PARTICIPATION
Taking part in this study is voluntary. You may refuse to participate or discontinue participation at any time without penalty or a loss of benefits to which you are otherwise entitled. If you decide not to participate or to discontinue participation, your decision will not affect your future relations with the University of Toledo or The University of Toledo Medical Center.
NEW FINDINGS
You will be notified of new information that might change your decision to be in this study if any becomes available.

OFFER TO ANSWER QUESTIONS
Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over. If you have questions regarding the research at any time before, during or after the study, you may contact the investigators for this study, Abbey Thomas, PhD, ATC at 419-536-4501.

If you have questions beyond those answered by the research team or your rights as a research subject or research-related injury, please feel free to contact the Chairperson of the University of Toledo Biomedical Institutional Review Board at 419-383-6796.

SIGNATURE SECTION (Please read carefully)
YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE INFORMATION PROVIDED ABOVE, YOU HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND YOU HAVE DECIDED TO TAKE PART IN THIS RESEARCH.

BY SIGNING THIS DOCUMENT YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION AS DESCRIBED IN THIS FORM.

The date you sign this document to enroll in this study, that is, today’s date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. These dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study. Each page of this Consent/Authorization Form is stamped to indicate the form’s validity as approved by the UT Biomedical Institutional Review Board (IRB).

Name of Subject (please print)  Signature of Subject or Person Authorized to Consent  Date

Relationship to the Subject (Healthcare Power of Attorney authority or Legal Guardian)  Time  p.m.

Name of Person Obtaining Consent (please print)  Signature of Person Obtaining Consent  Date

Name of Witness to Consent Process (when required by ICH Guidelines)  Signature of Witness to Consent Process (when required by ICH Guidelines)  Date

YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.
Appendix B

Circle the number that best describes your current activity level.

1. Wholly inactive, dependent on others, and cannot leave residence
2. Mostly inactive or restricted to minimum activities of daily living
3. Sometimes participates in mild activities, such as walking, limited housework and limited shopping
4. Regularly participates in mild activities
5. Sometimes participates in moderate activities such as swimming or could do unlimited housework or shopping
6. Regularly participates in moderate activities
7. Regularly participates in active events such as bicycling
8. Regularly participates in active events, such as golf or bowling
9. Sometimes participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor or backpacking
10. Regularly participates in impact sports
**Numeric Pain Rating Scale (NPRS)**

<table>
<thead>
<tr>
<th>Weeks 1-9 – NPRS/Left Knee</th>
<th>Weeks 1-9 – NPRS/Right Knee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1 = _____________</td>
<td>Week 1 = _____________</td>
</tr>
<tr>
<td>Week 2 = _____________</td>
<td>Week 2 = _____________</td>
</tr>
<tr>
<td>Week 3 = _____________</td>
<td>Week 3 = _____________</td>
</tr>
<tr>
<td>Week 4 = _____________</td>
<td>Week 4 = _____________</td>
</tr>
<tr>
<td>Week 5 = _____________</td>
<td>Week 5 = _____________</td>
</tr>
<tr>
<td>Week 6 = _____________</td>
<td>Week 6 = _____________</td>
</tr>
<tr>
<td>Week 7 = _____________</td>
<td>Week 7 = _____________</td>
</tr>
<tr>
<td>Week 8 = _____________</td>
<td>Week 8 = _____________</td>
</tr>
<tr>
<td>Week 9 = _____________</td>
<td>Week 9 = _____________</td>
</tr>
</tbody>
</table>

*The NPRS rates the amount of pain the patient has experienced for the past 24 hours
Patient rates the pain of their respected knee from 0-10
0 = No pain
10 = Worst pain imaginable*
WOMAC OSTEOARTHRITIS INDEX

1. **PAIN:** The following questions concern the amount of pain you are currently experiencing in your knees. For each situation, please enter the amount of pain you have experienced in the **past 48 hours**.

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Walking on a flat surface</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>B. Going up or down stairs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>C. At night while in bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>D. Sitting or lying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E. Standing upright</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

2. Please describe the level of pain you have experienced in the past 48 hours for each one of your knees.

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Right knee</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>B. Left knee</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

2. **STIFFNESS:** How **severe** is your stiffness after **first awakening** in the morning?

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

4. **DISABILITY:** The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours, in your knees.

What degree of difficulty do you have with:

<table>
<thead>
<tr>
<th>Activity</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Descending (going down) stairs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>B. Ascending (going up) stairs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>C. Rising from sitting</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>D. Standing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E. Bending to floor</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F. Walking on a flat surface</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>G. Getting in/out of car</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>H. Going shopping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I. Putting on socks/stockings</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>J. Rising from bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>K. Taking off socks/stockings</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>L. Lying in bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>M. Getting in/out of bath</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>N. Sitting</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>O. Getting on/off toilet</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P. Heavy domestic duties (mowing the lawn, lifting heavy grocery bags)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Q. Light domestic duties (such as tidying a room, dusting, cooking)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix C

Data Collection Form

<table>
<thead>
<tr>
<th>Demographic Information</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session:</strong></td>
<td><strong>Age:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Height:</strong></td>
<td><strong>Mass:</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Functional Performance</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SCT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assistive Device</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TUG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assistive Device</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>30sec CBT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assistive Device</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6MW</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Distance:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Biomechanics Trials    |          |          |

**Walking**

<table>
<thead>
<tr>
<th>Left Limb</th>
<th>Right Limb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial #</td>
<td>Speed (m/s)</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>
### Stairs- Ascent

<table>
<thead>
<tr>
<th>Trial #</th>
<th>Left Limb Speed (m/s)</th>
<th>Right Limb Speed (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>3</td>
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<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>

### Stairs- Descent

<table>
<thead>
<tr>
<th>Trial #</th>
<th>Left Limb Speed (m/s)</th>
<th>Right Limb Speed (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td></td>
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<td>4</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>
Appendix D

Therapeutic Exercises

Instructions:

1. Perform exercises 8-10 times for each leg (when applicable)
2. Repeat 2-3 times throughout the day
3. Complete exercises 3 days per week

Seated Exercises
Knee extension

1. Sit in a chair
2. Slowly straighten your knee
3. Hold for 3-5 seconds
4. Slowly return to start position

Sit-to-Stand

1. Sit in a chair
2. Slowly rise to a standing position
3. Slowly sit down in the chair
Side-lying Exercises

**Hip abduction**

1. Lie on your side with trunk and legs in a straight line
2. Bend your bottom knee
3. Keep top knee straight and toes pointing forward
4. Slowly lift top leg toward the ceiling
5. Hold for 3-5 seconds
6. Slowly return to start position

**Hip extension**

1. Lie on your stomach
2. Bend your knee
3. Slowly raise your thigh off the table
4. Hold for 3-5 seconds
5. Slowly return to start position
Standing Exercises

Heel raises

1. Find a chair, wall, or doorway that you can use to help you balance
2. Start with your feet hip width apart and flat on the floor
3. Slowly raise yourself up on your toes
4. Hold for 3-5 seconds
5. Slowly lower yourself to the ground

Balance

1. Find a chair, wall, or doorway that you can use to regain your balance if necessary
2. Raise one foot off the floor by bending your knee
3. Balance on one leg for 30-45 seconds
4. Lower your foot to the floor