Improving Maintenance of Physical Activity Trial – Pilot (IMPACT-P)

DISSERTATION

Presented in Partial Fulfillment of the Requirements for the Degree Doctor of Philosophy
in the Graduate School of The Ohio State University

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Graduate Program in Education

The Ohio State University
2011

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Abstract

Osteoarthritis (OA) is a chronic, degenerative disease afflicting millions of older adults. Knee OA (KOA), specifically, is a leading cause of functional limitation in aged persons. With multiple etiologies and no cure, strategies to mitigate progression, improve physical function and ameliorate pain symptoms are of utmost importance in helping patients to maintain functional ability and independence. Physical activity (PA) is an efficacious, adjuvant treatment approach that is highlighted in literature as having high-quality evidence for improving pain symptoms and increasing functional ability. Indeed, exercise interventions consistently result in clinically meaningful improvements in salient outcomes for KOA patients. Despite these established benefits, successfully promoting maintenance of regular PA participation remains a daunting challenge.

PURPOSE: The purpose of the Improving Maintenance of Physical Activity Trial – Pilot (IMPACT-P), a single-blind, randomized controlled pilot trial, was to compare the efficacy of a traditional exercise training (TRAD) and a group-mediated cognitive-behavioral (GMCB) exercise intervention in producing increased PA participation, improving functional ability, increasing self-efficacy (SE) and improving pain symptoms in older, KOA patients. METHODS: Eighty KOA patients (mean age = 63 years) were randomly assigned to GMCB (n = 40) or TRAD (n = 40) interventions. Self-reported (Community Health And Maintenance Program for Seniors) PA participation,
acclerometer-determined (Lifecorder) PA participation, pain symptoms (Western Ontario McMasters University Osteoarthritis Index), functional ability (stair climb and 400-meter walk) and self-efficacy measures for stair climb and 400-meter walk performances were obtained at baseline and 3-month follow-up assessments. Analysis was completed with 2 (Treatment) x 2 (Time) ANCOVA controlling for age.

RESULTS: The GMCB approach was found to result in significant improvements (both CHAMPS and Lifecorder) in short-term, moderate or greater intensity exercise participation ($PA_{\text{Mod}+}$) when compared with a TRAD exercise intervention approach receiving the same exercise prescription and equivalent contact hours. While performance outcomes were not different, subjects were more confident in their ability to complete the functional tasks at the 3-month time point. Of great importance, the TRAD and GMCB interventions promoted decreased pain symptoms after only 3-months of exercise engagement.

CONCLUSION: When considered in aggregate, the present findings demonstrate that the GMCB intervention can result in similar improvements in pain symptoms and confidence for completing various functional tasks while promoting more favorable changes in short-term $PA_{\text{Mod}+}$ participation when compared with a standard exercise approach. Consequently, an exercise intervention designed to provide training and practice in activity-related behavioral self-regulatory skills may augment changes associated with exercise participation. Evidence from IMPACT-P may serve to promote the GMCB approach as a valuable intervention strategy for the design and delivery of future interventions targeting the promotion of PA participation in older, KOA patients.
This document is dedicated to my wife, Justine, and my precious little Ava Marie
Acknowledgments

Only a great blend of drive and support could have allowed this day to arrive. I am cognizant that often my support was greater than my drive and I am blessed to have been surrounded by individuals who have given of their time. It is with utmost appreciation that I take a minute to recognize some of the many people who have made this journey valuable and worthwhile.

I would first like to thank my wife, Justine. You have been beside me in the easiest of times and longest of nights. Your love and support for our beautiful little girl is inspiring and liberating. During my long hours I know that our family is well intact. Beautiful little Ava – you are a joy to my heart and a sparkle in my eye.

Mom and dad – you let me dream as a child and you were a constant backing during my formative years. You gave me a solid foundation on which to stand and then you set me free. I owe much to you. Thank you. Mike and Susan – You were a match made in heaven. One day, you will be reunited there. Susan, I wish you could have met Ava and seen my graduation – I miss the smile that I know both would have produced. Mike, you are a father in law that any man would be lucky to have. Aunts, Uncles, Grandparents – I am blessed to have a close family. Brian, Kurtis and Stephanie – you are tremendous siblings and amazing people.
I would like to thank Dr. Steven T. Devor for assisting in my maturation as a person and teacher. I am indebted to you for your time, energy and passion. You have taught me what being a great teacher is all about – I inspire to be on your level. These have been five special years that we have spent together. Your timely advice will not be forgotten.

Dr. Brian Focht, I never could have guessed that a short meeting in your office, in Cunz Hall, in 2006, would have developed into such a meaningful partnership and mentorship. I am grateful to have been given the opportunity to work alongside and under your guidance. You have made me a better scientist and you are the inspiration for my favorite (retired) password – Fochtman1.

Dr. Hackshaw, you are a true gentlemen and great professional. Your knowledge and availability have been remarkable. I will remember you most for the short conversation that we had outside of your house. You have survived pain and you still smile – I will not forget your strength. It is my benefit that I have had the chance to have you on my committee.

The list of individuals to whom I am appreciative goes on: Drs. Kirby, Buckworth, Buell and Swain, (Future) Drs. Dials and Rose (M.D.) – Thank you all!

I would like to thank you, Kay Yeager. You are simply the best secretary. I have called on you many a time – never to be failed. You are a wonderful person.

To each graduate student over the last five years – it has been a great ride. The collegiality and collective knowledge has been inspirational.

FOREVER A BUCKEYE, Thank you Ohio State University!
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CHAPTER 1: INTRODUCTION

Osteoarthritis: The Societal Burden

Osteoarthritis (OA) is the most common form of arthritis and a leading cause of disability in older adults in the United States and around the world (36, 156). It is predicted that 60 million Americans will suffer from the disease by the year 2020. Currently, 40 million are afflicted (156). Knee osteoarthritis (KOA) accounts for more limitations in walking, stair climbing and other daily activities than any other disease (66). In 2003, the total medical expenditures for arthritis and other rheumatic conditions was estimated to exceed $321.8 billion (159). Clearly, the individual, societal and financial burdens of this disease warrant rigorous scientific investigation in order to further understand mechanisms and identify coping strategies for those afflicted.

While often characterized by joint space narrowing (51, 81), OA is a disease with multiple etiologies and it has an impact on the entire effected joint (26). Several pathophysiological disorders accompany OA: muscle weakness, decreased joint range of motion, joint instability, fatigue, stiffness and pain. This situation is strikingly grave and the maladies of symptomatic KOA are associated with activity avoidance, muscle atrophy, difficulty in performing functional tasks involving ambulation and transfer and reduced quality of life (QOL). The results of inactivity – muscular weakness,
atrophy and deconditioning – have been hypothesized to exacerbate pain symptoms, accelerate disease progression and hasten physical disability. In line with this hypothesis, KOA is cited as a primary cause for activity restriction and physical disability among older adults (42, 91). Preventing the onset of physical disability is one of the most pressing public health issues of the new millennium. As older individuals represent the fastest growing segment of the United States population (139), consideration of the impact of this demographic shift is paramount.

**Diarthrosis Joints, Articular Cartilage and Osteoarthritis Risk Factors**

Diarthrosis joints, such as the knee, are characterized by the ability to move freely in a range of motion. For the knee specifically, articular cartilage lines the inferior portion of the femur, the posterior portion of the patella and the superior portion of the tibia – the tibial plateau. Naturally aneural and avascular, insults to cartilage can be hazardous as recovery and healing are retarded by these intrinsic properties. Insults to cartilage take on many fashions and indeed the risk factors for OA are well-documented and numerous. Age, gender, race, genetic factors, dietary factors, smoking, bone density and estrogen deficiency are all considered systemic factors for the development of KOA. Local factors include: obesity, knee alignment, proprioception, laxity, muscular weakness, occupational stresses and previous injury (66).
Nonpharmacological, Pharmacological and Surgical Interventions

The risks for the development of OA certainly abound. Unfortunately, there is no cure. Depending on the joint affected and the disease progression, therapeutic options often include nonpharmacological and pharmacological means. When not amenable to medical therapies, physical function, functional mobility and QOL may be compromised. Surgical interventions are recommended and/or required when severely debilitating, non-responsive, symptomatic KOA limits one’s ability to complete activities of daily living. Under this scenario, a more aggressive treatment approach is necessary and referral to an orthopedic surgeon for evaluation is common (31). Surgical options often involve either osteotomy or total joint arthroplasty. Under the appropriate circumstances, both have favorable outcomes in the majority of patients (89, 107).

Pain reduction and increased function are two of the primary goals of any intervention. Nonpharmacological interventions are preferred but they are not always successful. Pharmacological interventions should be considered subsequent to or in combination with nonpharmacological strategies. While NSAID usage is a commonly employed method of pain reduction, the documented side effects demand judicious use of these agents (25). Self-care, patient education, weight-loss, occupational therapy, physical therapy and exercise are considered primary lines of defense. Recent evidence (76) from an overview of systematic reviews highlights the particularly efficacious and well-supported role of exercise as a strategy to deal with KOA-related maladies. A total of 23 systematic reviews on physical therapy interventions for KOA patients were
included in the overview conducted by Jamtvedt and colleagues (76). Exercise and weight-loss were the only two interventions specifically highlighted as having high-quality evidence for favorable changes in pain symptoms and physical function (76). The role of physical activity (PA) as an effective behavioral strategy to ameliorate pain and improve functional status warrants considerable attention.

**Exercise Interventions and the Treatment of Knee Osteoarthritis**

Research examining the benefits of PA interventions in older adults with KOA has proliferated in recent years. Findings from several randomized controlled trials (RCT) suggest that structured PA interventions produce significant improvements in pain symptoms, aerobic capacity and self-reported indices of physical function, muscular strength and QOL in older, KOA patients (46, 63, 100, 115). Both home-based (6, 115, 120) and center-based (46, 49, 50, 63, 86, 98, 100, 134, 138) PA interventions have been found to be effective and aerobic training (86, 98), strength training (6, 100, 115, 120, 134, 138, 150), and interventions combining strength and aerobic training (49, 50, 108) result in improvements in salient functional and pain-symptom outcomes. The overwhelming majority of scholarly work supports the premise that PA produces favorable changes in pain and function. Indeed, reviews, meta analyses and expert panels show substantial agreement (18, 29, 30, 45, 56, 64, 65, 76, 99, 118, 133). A trial by trial synopsis of some of the pertinent studies examined under the breadth of scholarly reviews can be found in chapter II. Consistent with the mounting evidence of the
effectiveness of PA as a vehicle of favorable change, PA is now advocated as an essential portion of the medical management of knee OA in recent treatment guidelines (1, 3, 113).

**Long-Term Efficacy of Physical Activity Interventions: The Concern of Maintenance**

Due to the chronic, progressive, degenerative nature of KOA, sustained treatment approaches must be employed. While PA has been shown to be a promising lifestyle intervention in the treatment of KOA, evidence of the long-term improvements in OA outcomes following PA interventions is limited. For example, the majority of relevant trials have examined PA interventions lasting less than 6 months and even fewer trials have evaluated the long-term maintenance of treatment effects. Disconcertingly, results from the few trials that do employ post-treatment follow-up assessments demonstrate that significant improvements in OA outcomes accompanying PA interventions dissipate considerably over time (46, 86, 115). Messier and colleagues (2004) found that sustained participation in exercise was associated with better outcomes than inconsistent participation (108). Ettinger and colleagues also suggest that long-term compliance to PA may be a more important predictor of outcomes than the type of exercise performed (49). Indeed, mounting evidence suggests that the deterioration of these benefits is related to patients’ post-intervention non-compliance to PA prescriptions (46, 49, 86, 115, 123). Strategies such as positive reinforcement, goal setting, and choice of activity have frequently been incorporated into structured PA interventions in an attempt to enhance the compliance to the exercise prescription. Nevertheless, the high rates of
recidivism evident in prior PA-KOA trials suggest that promoting long-term PA participation remains a challenge. Enhanced scheduling self-efficacy (SE) has been associated with greater rates of participation and persons that recognize the importance of exercise are more likely to engage in and maintain exercise programs (104). Lack of understanding (34), apathy (155), prevailing detriments in QOL (123) and a lack of time are common reasons not to participate in and/or maintain exercise regimens.

In spite of the growing recognition of the precipitous effects of non-compliance, attrition from supervised PA programs targeting older, KOA patients remains high. Traditional approaches to promoting PA participation often fail to provide systematic instruction and practice in developing skills necessary for independent maintenance of PA. In line with these concerns, PA interventions for older, KOA patients are often designed and implemented without targeting any behavioral or motivational processes which are known to underlie PA behavior change (27). In effect, participants are left inadequately prepared to maintain independent, long-term exercise participation at the culmination of structured, center-based interventions.

Overall, standard PA interventions may not be sufficient to produce long-term PA participation or sustained improvements in clinically relevant OA outcomes for many older, KOA patients (78, 125). Given the significance of long-term maintenance of PA in the treatment of KOA, it is essential to examine innovative interventions for promoting PA in this population. This need has been underscored by Rheumatologists and OA researchers (133) as a primary objective for future research - The MOVE consensus 2005. Undeniably, there are few intervention strategies which have been targeted at
helping subjects to develop the self-regulatory skills necessary to maintain exercise adherence once supervised phases of traditional PA interventions end. In this regard, one emerging position is that the efficacy of PA interventions in older adults with chronic disease can be enhanced through the addition of targeted, cognitive-behavioral activity counseling strategies (28, 126, 128).

Enhancing Exercise Participation: The Theoretical Foundations of Cognitive-Behavioral Activity Counseling Strategies

Rejeski and Brawley recently developed and implemented a group-mediated cognitive-behavioral (GMCB) intervention for promoting regular PA participation in older adults (28). The theoretical foundation for the cognitive-behavioral portion of the GMCB intervention was based upon social cognitive theory (SCT) (7) whereas the group motivational aspect was derived from the group dynamics literature (35). The theoretical foundations have multifold importance. Chiefly, use of these theories to promote adherence to PA is consistent with recommendations in the exercise psychology literature (28). In addition, application of a theoretical framework provides a means to develop a more comprehensive understanding of the mechanisms through which interventions may alter relevant physiologic, behavioral and QOL outcomes.

SCT draws from the fields of operant learning, social psychology and cognitive psychology (10). SCT is the theoretical foundation underlying the development of many commonly employed lifestyle behavior change strategies and an accepted framework for application within exercise interventions (7-10). The core of this theory avows that
behavior influences and is influenced by reciprocally deterministic relationships that exist among personal, social, and environmental factors. An inseparable crux of this theory is the concept of SE – the belief in one’s ability to successfully manage situation-specific demands (7). In the context of this theory, SE is gathered through mastery experiences, social persuasion, psychological understanding and modeling (7). This construct has been shown to be essential in behavioral change processes (7, 102, 119). Moreover, this “active agent” has been shown to be an important determinant, mediator and outcome within exercise interventions (49, 59, 60, 79, 82, 101, 103, 105, 126). Capitalizing on this recognized relationship is a key aim of the cognitive-behavioral aspect of the exercise intervention.

The delivery of the cognitive-behavioral intervention in a small group format was purposefully intended to motivate behavior change within group members. Exercise companionship is a known stimulus for the adoption and maintenance of an exercise program (37) and group cohesion and enjoyment can assist in the adoption of exercise (39). Certainly, group dynamics literature attest to the favorable changes that small group interactions initiate (35). Specifically, group interactions are known to foster cohesion, common attitudes and goals, persistence to achieve group goals, and motivation to maintain group behavior outside of the group setting (35). Ironically, few attempts have been made to purposefully and orderly utilize these social forces in the design and implementation strategies of exercise interventions in older, KOA patients (27, 84).

Within the framework of group dynamics, the GMCB intervention intentionally used cognitive-behavioral techniques to help older adults identify, monitor and achieve
important outcomes associated with a physically active lifestyle (27, 28, 126, 128) 
GMCB sessions targeted the development of self-regulatory skills necessary to assist 
persons with maintaining long-term PA. More specifically, participants were:

- Taught how to apply self-monitoring, self-evaluation and self-reinforcement 
  through goal setting, positive self-talk and problem solving in order to 
  incorporate a greater frequency and total volume of PA in their daily lives 
- Provided with experience in designing an active lifestyle using different 
  modes of activity 
- Phased from a center-based program into home-based training 
- Provided with the principles from group dynamics (e.g., group problem 
  solving, buddy systems, group reinforcement, and group goals) so that the 
  center-based groups served as an additional agent for behavioral change 

**Exercise Interventions and the Employment of Cognitive-Behavioral Activity 
Counseling Strategies: Evidence of Effectiveness in Older Populations**

The Fitness and Arthritis in Seniors Trial (FAST) was an 18-month, single-blind, 
RCT comparing the effects of exercise (aerobic or resistance exercise training) and a 
health education program on physical disability in older adults with KOA (49). An initial 
three-month, center-based training period was followed by a 15-month, home-based 
phase. Results revealed that both aerobic and resistance exercise programs produced 
significantly greater improvements in measures of pain, physical function, and physical
disability compared with the health education intervention. Adherence to the prescribed exercise regimen was found to be an important predictor of pain and self-reported difficulty (49). Unfortunately, compliance to exercise decreased across the trial and a 50% adherence rate was evident at the 18-month follow-up point (49).

The Arthritis, Diet and Activity Promotion Trial (ADAPT) was a single-blind, 18-month, randomized clinical trial exploring the effect of four treatments: exercise-only, dietary weight-loss only, exercise plus dietary weight-loss, and a healthy lifestyle control condition on function, HRQOL and pain symptoms in a total of 316 overweight, or obese older adults with KOA. Members of the weight-loss and combination groups lost more weight than those in the control or exercise-only treatments (108). By contrast, participants in the exercise-only and combination treatment demonstrated significant improvements in 6-minute (min.) walk performance when compared to the control condition. Furthermore, these same interventions resulted in significant improvements in mobility-related SE for walking and stair climbing (60). The combination treatment of exercise and dietary weight-loss consistently produced the most favorable effects on HRQOL outcomes as scored by the validated and reliable Short Form-36 (SF-36) Medical outcomes questionnaire (108). Analysis revealed that adherence in the exercise-inclusive arms was only 60%.

Results from FAST (49, 110) and ADAPT (60, 108) provide a compelling support for the position that older adults with KOA experience favorable changes in a variety of clinically-relevant outcomes when undergoing an exercise intervention. Unfortunately, the results of FAST and ADAPT also emphasis the importance of exercise adherence and
the challenge of combating the dissipation of exercise adherence over the long-term among previously sedentary older adults with KOA. The application of a GMCB approach to combat these specific issues is addressed below with results from the SALE (Shaping Active Living in the Elderly) and the CHAMP (Cardiovascular Health and Activity Maintenance Program) trials.

SALE was a randomized trial conducted to examine the impact of a GMCB intervention on helping to produce significantly greater volumes of PA engagement in asymptomatic, older adults (28). With the exercise stimulus being identical, a total of 60, sedentary, healthy, older adults were randomly assigned to a GMCB PA intervention, a traditional exercise intervention or a wait-list control condition. The purpose and goals of the GMCB component were discussed previously but briefly, the development of self-regulatory skills was the primary aim. A scheduled phasing from center-based to home-based activity occurred across the initial 3-month period of the trial. Both interventions were successful at promoting exercise engagement as illustrated by similar, significant increases in weekly PA participation of moderate intensity or greater PA after the 3-month exercise training. Participants in each group received phone contacts on a monthly basis during months 3-6 to provide support and encouragement to continue their involvement in home-based PA. At the 9-month follow-up assessment, the GMCB group members demonstrated a higher weekly frequency (5.3 vs. 2.5 sessions) and volume (160 vs. 103 min.) of moderate or greater PA engagement compared to the traditional exercise intervention.
Following the promising results of the SALE trial (28), the GMCB PA intervention was subsequently applied to older adults with or at high-risk for cardiovascular disease in the CHAMP trial (126). CHAMP was a single-blind, 12-month trial employing a total of 147 older adults randomized to either a 3-month standard exercise therapy or the GMCB intervention. While all participants were provided 36 total contact hours during the trial, the employment of the GMCB intervention within one arm inherently altered the purpose and structure between the interventions. Participants in the standard exercise therapy group received all contact hours within the initial 3-month phase while the contact hours for the participants in the GMCB intervention were delivered over a 9-month period. In accordance with aforementioned purposes, the GMCB intervention was intended to provide group-mediated counseling to enhance self-regulatory skills and promote decreasing dependence on center-based activity while simultaneously increasing the importance and frequency of independent PA engagement.

Analysis of adherence during the initial 3-month intensive phase showed that participants in the GMCB intervention demonstrated significantly better compliance than the standard therapy group participants. Significant treatment effects were also observed for the three primary outcomes. Members of the GMCB intervention realized superior improvements in aerobic capacity, engagement in moderate or greater PA and SE when compared to members of the standard exercise therapy. Improvements in barrier management (as indicated by a barrier SE measure) were related to the improvements in the primary outcomes. Correlation analyses revealed significant, positive correlations between confidence in participants’ ability to successfully overcome barriers to PA and
their aerobic fitness and self-reported weekly amount of PA participation. This finding is consistent with the predictions of SCT and corroborates findings in literature that SE is a mediator of changes in response to PA interventions (7, 59, 60, 82, 101-104, 131). Subsequent analysis revealed that women in the GMCB treatment with the lowest initial HRQL scores demonstrated more favorable changes in HRQOL outcomes across the trial as compared to similarly-functioning women assigned to the standard therapy. Moreover, analysis of self-reported function revealed that participants reporting the greatest difficulty with performing daily physical tasks at baseline who were assigned to the GMCB intervention demonstrated the greatest improvements after 3-months of treatment. The results of the CHAMP trial (125, 126) demonstrate the feasibility and efficacy of a GMCB intervention to promote PA among older adults with cardiovascular disease.

**Summary and Direction**

The benefits of increased PA participation as a treatment modality for KOA are well-established. Unfortunately, poor exercise adherence continues to undermine the true efficacy of PA interventions among older, asymptomatic persons (28) and older persons within clinical populations (125, 126). While the benefits of traditional exercise interventions are undeniable, the long-term efficacy is dubious (64). Traditional interventions appear to provide participants with an exercise experience rather than a motivation for maintenance. In other words, there appears to be a disconnect between the
purpose for center-based activity and life thereafter. Several features of the GMCB intervention make it promising for satisfying key limitations in promoting regular PA among older, KOA patients once center-based PA has concluded:

- The cognitive-behavioral counseling component emphasizes the development and practice of individual and peer-initiated problem-solving strategies designed to overcome KOA-specific barriers
- The tapering of center-based PA and use of behavioral homework assignments facilitates the transition to independent PA participation
- The social forces of the group-based intervention serve as a source of motivation for the development and practice of the self-regulatory skills training (group problem solving, buddy systems, group reinforcement and group goals) in order to facilitate the behavior change process

Indeed, the importance of the transition from center-based, supervised activity to independent, long-term PA participation cannot be over emphasized. Due to the chronic nature of the disease, long-term treatment adherence is integral to sustaining the benefits of PA participation for older, knee OA patients.

Results from recent investigations support the utility of the GMCB approach among older, KOA patients. Findings from SALE revealed that participants randomly assigned to the GMCB intervention demonstrated a greater frequency of PA participation and enhanced HRQOL when compared to a traditional center-based exercise program or
wait-list control condition (28). Furthermore, the GMCB intervention was found to be beneficial in a 12-month, randomized clinical trial employed within a cardiac rehabilitation setting. In a sample of older adults, the GMCB intervention produced significantly greater outcomes (PA participation, exercise adherence, barrier SE and HRQOL) at the 12-month follow-up assessment (57, 126, 132). These results provide support that the GMCB intervention may be a more efficacious means to promote long-term PA engagement among older, KOA patients when compared to a standard exercise therapy.

**Primary Purpose**

Therefore, the primary purpose of the Improving Maintenance of Physical Activity Trial – Pilot (IMPACT-P) was to address some of the gaps that remain in the extant KOA-literature (133):

- How do we best deliver exercise as an intervention?
- What approaches best promote adherence and the maintenance of PA engagement?
- What strategies best increase the long-term adherence to exercise?
Objectives and Hypothesis

The primary objective of IMPACT-P was to compare the effects of the GMCB intervention with those observed with a traditional (TRAD) PA intervention upon the weekly volume of participation in moderate or greater intensity exercise (PA^{Mod+}) engagement in min. Secondary objectives were to examine differences in physical function, mobility-related SE and reported pain-symptoms between these contrasting intervention strategies and to also explore the relationships among changes in select primary and secondary outcomes. These objectives, and the associated hypothesis, are described in greater detail below.

- **Objective #1**: Compare the effects of the GMCB intervention with those observed with a TRAD PA intervention upon the weekly volume (minutes) of PA^{Mod+} participation.
  - **Hypothesis 1**: Both the TRAD and GMCB interventions will result in similar, significant increases in self-reported and objectively-measured PA^{Mod+} participation at the 3-month follow-up relative to baseline level.
  - **Hypothesis 2**: The GMCB intervention will result in greater self-reported and objectively-determined PA^{Mod+} participation relative to the TRAD intervention at the 12-month follow-up assessment.
• **Objective #2:** Examine differences in the effects of the GMCB and TRAD interventions upon change in physical function, mobility-related SE and reported pain-symptoms

  o **Hypothesis 3:** Both the TRAD and GMCB interventions will result in comparable improvements in physical function, mobility-related SE and self-reported pain symptoms at the 3-month follow-up assessment relative to baseline level.

  o **Hypothesis 4:** The GMCB intervention will result in greater improvements in physical function, mobility-related SE and self-reported pain symptoms relative to the TRAD intervention at the 12-month follow-up assessment.

• **Objective #3:** Determine the relationships between variables related to the primary and secondary outcomes.

  o **Hypothesis 5:** Self-reported and objectively-determined PA measures will be significantly related when collapsing groups. These results will hold true for the baseline, 3-month and 12-month assessments.

  o **Hypothesis 6:** Baseline mobility-related SE values for the stair climb and 400-meter walk tasks will be significantly related with objective measures of
physical function (stair-climb and 400-meter walk performance), respectively when collapsing groups. These results will hold true for the baseline, 3-month and 12-month assessments

**Definitions**

*Accelerometer* – Removable, electromechanical device provided to participants in order to objectively measure frequency, volume and intensity of exercise participation

*Aerobic Training* – A type of exercise (commonly walking or cycling) which is sustained and increases the heart rate to moderately-intense levels

*Body Mass Index (BMI)* – Method of determining degree of obesity. A function of weight in kilograms divided by height in meters squared

*Cartilage* – A flexible, connective tissue that lines bones at articular regions in order to protect the joint and promote smooth, fluid movement patterns

*Cardiovascular Health and Activity Maintenance Program (CHAMP)* – Single-blind, 12-month trial employing a total of 147 older adults randomized to either a 3-month standard exercise therapy or the GMCB intervention. Primary purpose was to determine if the
GMCB strategy was efficacious for increasing long-term compliance to exercise among patients within cardiac rehabilitation.

*Community Health Activities Model Program for Seniors (CHAMPS) Physical Activity Questionnaire for Older Adults* – A questionnaire employed to measure self-report PA participation. CHAMPS was designed with specificity and sensitivity to changes in physical activity levels for underactive older men and women.

*Disability* – Limitation in a person's physical movements or functions

*Exercise* – A subset of physical activity that is planned, structured and repetitive for the purpose of improvement or maintenance of one or more of the major components of physical fitness.

*Exercise Prescription* – A recommended course of exercise intervention inclusive of directions for frequency, intensity, timing and type of exercise with specific intentions geared towards a particular person.

*Functional Mobility* – An individual’s ability to use the joint – specifically the knee – through a range of motion in order to ambulate.
Group-Mediated Cognitive Behavioral (GMCB) Modification – A behavioral counseling component which emphasizes the development and practice of individual and peer-initiated problem-solving strategies designed to overcome KOA-specific barriers and enhance exercise participation

Kellgren-Lawrence Scale – A classification schema developed to serve as a tool to evaluate radiographic changes in the cartilage of articular joints

Knee Osteoarthritis (KOA) – A chronic condition that is most-readily associated with loss of joint cartilage. It is a disease with multiple etiologies, a multiplicity of risk factors and serious consequences

Malalignment – Abnormal positioning of the femoral condyles in relationship to the tibial plateau (varus or valgus alignment)

Mobility-Related SE – Confidence of one’s ability to successfully complete a specific movement task such as climbing 10 stairs or walking 100 meters

Moderate intensity or greater physical activity participation ($PA^{Mod+}$) – Determined by perceived exertion, $PA^{Mod+}$ was considered engagement any activity in which the intensity was rated as moderate or greater
Obesity – Overabundance of adipose tissue

Physical Activity – Bodily movements produced by skeletal muscles and which result in energy expenditure

Physical Function – Abilities related to physical processes required for normal operation

Quality of Life (QOL) – An umbrella term representing many aspects of life but particularly health-related QOL for the present study

Radiographic KOA – The presence of abnormalities in the knee indicated by primarily joint space narrowing and assessed by radiograph

Randomized Controlled Trial (RCT) – Research design strategy in which subjects are placed into groups by chance and in which some control serves as comparison. A powerful research design to delineate effects of a particular intervention on outcomes

Repetition Max (RM) – Maximal amount of weight that a person can lift in a single repetition for a particular exercise

Repetition – A single complete lifting cycle through an exercise which consists of both concentric and eccentric phases
Social Cognitive Theory (SCT) – A theory which draws from the fields of operant learning, social psychology and cognitive psychology and asserts that behavior is influenced by reciprocally deterministic relationships that exist among personal, social and environmental factors

Self-Efficacy (SE) - Confidence of one’s ability to successfully complete a specific task

Short Form 36 (SF-36) – A valid, reliable and commonly used medical outcomes questionnaire designed purposefully to determine HRQOL characteristics

Sedentary – Physically inactive. For inclusionary purposes, engaging in less than 20 minutes of exercise 3 days a week

Symptomatic KOA – Osteoarthritis of the knee that is detectable by radiograph and results in complaints of pain for the inflicted person

Traditional (TRAD) – The control arm of the intervention trial employing a common exercise prescription (3 days/week for 12 weeks) and provided normal exercise educational instruction

Western Ontario McMaster Osteoarthritis Index (WOMAC) – A valid and reliable measurement tool to assess pain, stiffness and functional limitation in OA patients
Knee Osteoarthritis: The Problem Defined

Osteoarthritis (OA) is the most common form of arthritis and a leading cause of disability in older adults in the United States and around the world (36, 156). The current definition of OA was the result of a joint initiative between the National Institutes of Health (114) and the American Academy of Orthopedic Surgeons (1).

“OA diseases are a result of both mechanical and biologic events that destabilize the normal coupling of degradation and synthesis of articular cartilage chondrocytes and extracellular matrix, and subchondral bone. Although they may be initiated by multiple factors, OA diseases involve all of the tissues of diarthrodial joint. Ultimately, OA diseases are manifested by morphologic, biochemical, molecular, and biomechanical changes of both cells and matrix which lead to a softening, fibrillation, ulceration, loss of articular cartilage, sclerosis and eburnation of subchondral bone, osteophytes, and subchondral cysts. When clinically evident, OA diseases are characterized by joint pain, tenderness, limitation of movement, crepitus, occasional effusion, and variable degrees of inflammation without systemic effects. (87)”
Clearly, OA is a disease with multiple etiologies and which is dynamic in nature. While it is often histopathologically characterized by the loss of joint cartilage (51, 81), it is better viewed as a disease of the whole joint (26).

The Kellgren-Lawrence scale was established to assist with diagnosing the severity of OA. Although it is frequently used throughout literature, its efficacy for determining the severity of OA is questionable. Indeed, studies have reported a discordance between radiographic assessment and symptomatic complaints (12, 51). Barker and colleagues sought to add clarity to whether there was an association between radiographic joint space narrowing and the outcome measures of function, pain and muscle power (12). Anterior-posterior radiographs were evaluated in a blinded fashion and joint space narrowing (Kellgren-Lawrence scale), function, pain and muscle power were assessed with commonly employed techniques. When comparing 123 patients stratified by Kellgren and Lawrence delineation, there was no association found between radiographic change and the measures of function, pain or muscle power (12). Radiographic evaluation appears overvalued.

Several pathophysiological disorders accompany OA: muscle weakness, decreased joint range of motion, joint instability and inflammation. It is predicted that 60 million Americans will suffer from the disease by the year 2020 and currently 40 million are afflicted (156). The primary symptoms include joint pain and stiffness as well as decreased mobility. Early in the disease process, pain is often reported intermittently and associated with specific use pattern (65). In some persons, the disease progresses and pain becomes a more chronic issue. In later stages of the disease, pain is associated not
only with normal movement patterns but more disconcertingly, is present at rest and during the night (65). Women report increasingly greater pain throughout the day as compared with males although both groups report their greatest pain in the evening (80). Pain is thought to be fundamental in initiating the disuse-associated issues prevalent in KOA patients. Among community dwelling OA patients, 20% report functional limitations. Furthermore, 40% of OA patients age 51-61 report work-related disabilities (66). Most telling; however, is that fact that knee osteoarthritis (KOA) accounts for more limitations in walking, stair climbing and other daily activities than any other disease (66). In 2003, the total medical expenditures for arthritis and other rheumatic conditions was estimated to exceed $321.8 billion (159). Clearly, given the financial and societal burdens of this disease, KOA represents a profound public health issue.

**Mechanobiology of the Knee Joint and Chondrocytes and Collagen**

Several scholarly publications were the focus for ascertaining details for the following two paragraphs under the headings shown immediately above:

- “The Basic Science of Articular Cartilage: Structure, Composition, and Function”
  - Sophia Fox et al. 2009 (144)
- “Measures of Molecular Composition and Structure in Osteoarthritis”
  - Burstein et al. 2009 (33)
Mechanobiology of the Knee Joint

Diarthrosis joints, such as the knee, are characterized by the ability to move freely in a range of motion. Articular cartilage acts in a protective manner and lines the inferior portion of the femur, the posterior portion of the patella and the superior portion of the tibia – the tibial plateau. Cartilage is naturally aneural and avascular and consists of gliding, middle and deeper layers. Cartilage is dependent on a squishing motion and diffusive movements for exchange of gases and nutrients. Articular cartilage is comprised of approximately 70% water and 30% matrix material in terms of wet weight. Aggrecan and type 2 collagen make up the bulk of the dry weight. Aggrecan is a proteoglycan – a protein core to which multiple glycosaminoglycans are attached. Aggrecan has three distinct globular domains to which keratin sulfate and chondroitin sulfate are attached. The glycosaminoglycan region confers aggrecan with its negativity. The chondrocytes, which play a vital role in the control of synthesis and degradation of the extracellular matrix, contribute minimally to weight (approximately ~1% of the dry weight). The type 2 collagen forms a lattice-like network and provides cartilage with its tensile strength. Within the framework of these interlaced collagen strands reside the negatively-charged aggrecan molecules and the chondrocytes. A linking protein connects
aggrecan molecules to a central running hyaluronate molecule at approximately 90°. The microscopic appearance might be likened to a bottle brush with a skinny central metal line off of which small arms and bristles stick. Due to their interconnectedness and position within the confines of the collagen framework, the long-stranded proteoglycans are not able to be pulled into the surrounding space to associate with water. Consequently, the glycosaminoglycans draw water into the tissue via an electrical attraction. Aggrecan is therefore responsible for the overall hydration of the cartilage. Depletion of the glycosaminoglycans, which results in the exposure of the central protein core, is an early event in the destruction of cartilage.

During periods of mechanical loading, the pressure exerted on the cartilage results in the expulsion of water from the matrix. As the water shifts through the matrix and into the surrounding synovial fluid, metabolic products are swept away. Although the compressive forces drive water from the area, the electrostatic repulsion of the negatively-charged glycosaminoglycans acts to limit the extent of compression. Consequently, collagen provides cartilage with its tensile strength while aggrecan provides collagen compressive resistance. During the unloading phase, water is drawn back into the matrix and the diffusive movements concurrently assist the avascular cartilage with retrieval of nutrients and gases. In this manner, mechanical loading is more than advantageous for cartilage – it is imperative.
Chondrocytes and Collagen

Chondrocytes are phenotypically differentiated based on collagen production. Normal adult chondrocytes produce a II-B collagen while the production of type I, III and X collagen occurs by dedifferentiated (I and III) and hypertrophic (X) chondrocytes. Under normal conditions, cartilage is comprised of approximately 15% type II-B collagen and there is little expression of type I or III collagen. During the early stages of OA, aggregan expression is reduced by nearly 50%, collagen orientation is altered and proteoglycan content is decreased in the superficial layers. In advanced OA, collagen production by both progenitor (II-A) and dedifferentiated (I and III) chondrocytes is increased multifold and overall collagen content is decreased. Clearly, these biological occurrences are not without consequence and evidence of apoptosis is obvious in late-stage OA.

The role of the zinc-containing matrix metalloproteinases (MMP’s) in degradation of the cartilage and extracellular matrix is significant. The superfamily of MMP’s collectively cleave nearly all components of the extracellular matrix (17). The complexity of this superfamily in regards to substrate specificity, mode of activation and regulation is well beyond the scope of this review. Nevertheless, it should be understood that MMP’s are expressed differentially in normal and OA cartilage (92). The predominant MMP found in normal cartilage (MMP-3) is replaced in diseased cartilage by variants such as MMP-2, MMP-11 and MMP-13. Specifically, MMP-13 has a high affinity for II-B collagen. There is recent evidence from an animal model to suggest that
this MMP may be a key player in the destructive effects seen in the cartilage of OA patients. Knockout mice, deficient in producing MMP-13, were compared with wild type mice after surgically-created OA. After a 2-month period, wild type rodents demonstrated greater cartilage erosion (p < 0.05) compared with knockout mice (92). There were no differences in the presence or severity of osteophytes or the presence of hypertrophic chondrocytes. Authors speculate that MMP-13 may be especially deleterious and contribute substantially to the erosive-like properties characteristic of the degenerative OA disease (92). MMP-13 upregulation in later-stage OA may indicate an increased degradation of a number of structural units of the cartilage and inhibition of this MMP may be crucial to curtailing the degeneration of cartilage (92).

**Introduction to Knee Osteoarthritis Risk Factors**

There are numerous risk factors which impact OA in general and KOA in particular. OA may be defined by radiographic or symptomatic means. Evaluation of radiographic OA was first described by Kellgren and Lawrence (1957) some years ago (81). Identification of OA includes the presence of osteophytes, changes in bone shape and joint space narrowing. In addition to radiographic changes, symptomatic OA includes the report of pain. Literature attests to the discrepancy between radiographic assessment and symptomatic severity (12) and nearly 50% of individuals with radiographically-defined KOA do not report pain (66).
Regardless of this inconsistency, one author (52) has categorically arranged the risk factors for OA as follows:

- Joint vulnerabilities (previous injury, malalignment, loss of proprioception and muscle weakness)
- Systemic vulnerabilities (age and genetic predisposition)
- Extrinsic/OA factors (obesity and injurious loading)

Although other classification schemes exist (Fu and Browner (66); systemic versus local factors), most experts would agree that the factors listed by Felson (52) do play key roles in incident KOA and in some cases disease progression as well.

**Joint Vulnerabilities: Previous Injury**

In a prospective, population-based study, Cooper and colleagues enrolled several hundred members of a local community willing to complete medical history questionnaires and knee radiographs (38). From the initial sample of entrants 55 and older, 350 persons completed both a baseline test and a follow-up 5 years later. Based on questionnaire responses, previous knee injury was strongly linked to incident KOA while reported pain was strongly associated with disease progression (38).

A retrospective cohort study clearly indicates the propensity of injury to initiate the development of KOA (94). Twelve years after ACL injury, females 26-40 years old
were likely to display signs of radiographic (82%) OA and have complaints of symptomatic (75%) OA (94). All scores on a knee injury-related scale indicated detrimental outcomes in relation to an age-matched cohort. Furthermore, the physical-functioning subscale of the SF-36 was found to be significantly decreased for these women. Moreover, these women reported more pain and decreased QOL compared with the age-matched controls (94). More recently (2007), the same lab sought to clarify the literature regarding the consequences of ACL and meniscal injury as they relate to KOA (95). Substantiating their findings in females, although males tended to have injuries a little later in life (19 vs. 23 years of age), the development of OA in male soccer players with previous ACL injuries was alarmingly high. Among individuals having undergone meniscectomy, nearly 50% were reported to have radiographic symptoms of KOA within two decades (95). The trauma required to injure a healthy ACL is substantial. Concurrent injury to the cartilage, menisci, bone and other ligaments might represent a debilitating series of factors which eventually lead to the development of KOA (95). The involvedness of these interactions, many of which are singularly correlated with KOA, are responsible for the “young person old knee” syndrome present in the subjects represented within these studies. Injuries to the ACL and menisci are strongly correlated with further development of KOA (94, 95).
Joint Vulnerabilities: Malalignment

An investigation of nearly 200 older persons conducted by Sharma and colleagues (2001) underscores the potential impact of malalignment on the diagnosis of KOA and progression of the disease (142). Post-test radiographs were obtained on subjects after an 18-month follow-up period. Compared to post-trial, baseline varus and valgus malalignment were associated with medial (30%) and lateral (20%) joint space narrowing over the trial-period. Furthermore, fifteen persons were found to have developed a malalignment issue with an associated narrowing of either the medial or lateral joint space. Bearing great significance, the severity of the malalignment at baseline was highly predictive of physical function at post-test (142). While varus and valgus forces may either be a cause or a result of KOA, once present, they aggravate the issue and to a greater extent in the medial compartment (141, 142). Malalignment can lead to unequal and undue stress on particular regions of the cartilage. With worsening severity, and in combination with obesity and muscle strength decreases, malalignment can be particularly compromising to cartilage health (141, 142).

Joint Vulnerabilities: Proprioceptive Acuity

Proprioceptive acuity diminishes with age (74) and in KOA patients (140). A loss of timely muscle activation may result in transient spikes in loading. In individuals lacking proprioceptive acuity, forces of 60-65 times the body weight have been recorded
(24, 122) at heel strike. This is a substantial loading volume. Whether worsening proprioceptive sharpness is contributory in the development of KOA is not fully elucidated. There is support of this relationship in literature. Work by Vilensky (154) is a particular interest to this area. Ipsilateral surgical denervation of the hind limb of mongrel dogs was used to initiate a loss of proprioceptive acuity. An ACL transection was completed two weeks thereafter. When animals were recorded trotting on a treadmill, surgically blocked proprioceptive feedback was found to result in greater tibial translation and ankle instability. More telling, animals displayed signs of advanced KOA as early as 3 weeks later (154).

Muscle strength is vital for joint protection but this strength must be combined with appropriate awareness and timely activation. This lack of awareness has been noted in literature as “micro klutziness” (26). In at least one study, patients exhibiting diminished acuity showed greater functional limitation (153). Although research has found that KOA is accompanied by deficiencies in proprioceptive ability, whether the neurological abnormality is a consequence of the pathology or the primary initiator of the disease is still in question (23).

**Joint Vulnerabilities: Muscle Weakness**

The knee joint relies on ligamentous integrity and muscular support for stability in the sagittal, frontal and transverse planes. Laxity is known to induce joint instability and serves as a risk factor for KOA (38). The role of muscle in joint movement is understood
but the role that muscle plays in force distribution across a joint is less well-recognized. During knee extension and flexion, muscle strength is a necessary for both movement and braking of the joint. Muscle’s role in braking and distributing shock is pertinent to the current discussion. Adequate muscle strength is imperative to joint and cartilage health and muscles are able to move injurious loads of force without consequence to ligaments and cartilage. An age-related decline in muscle mass and strength is well-documented and evident during the shuffling pattern seen when many elderly persons transfer bipedally. Regardless of the reason, decreased strength has serious implications for normal physical functioning.

Several studies have investigated the relationship between muscle strength and KOA (93). Slemenda and colleagues enrolled over 400 persons age 65 and older to determine the role that quadriceps strength (KinCom) and mass (DXA) had with KOA. Most revealing, extensor leg strength was 20% lower in those with radiographic KOA and after adjusting for body weight, age and sex, quadriceps strength remained predictive for radiographic and symptomatic KOA. These results are further substantiated by Ikeda and colleagues (75). With data collected by computed tomography, authors were quick to point out that it was quadriceps dominant atrophy (evidenced by a high H: Q ratio) which was predictive of the development of KOA among the cross sectional participants ages 30 or 60.

One could logically make the argument that quadriceps atrophy occurred secondary to the development of KOA pain and thus use of muscle mass and strength are not good indicators of the risk of development of KOA. There is some research to refute
this premise. Providing evidence to the contrary, decreased muscle strength in older persons at baseline was correlated with subsequent development of KOA over a period of three years when subjects were compared with age-matched controls of normal strength (93). Furthermore, Hurley makes note that declines in muscle strength is often one of the earliest complaints associated with KOA (73) and quadriceps weakness is a better determinant of pain and disability in patients than radiographic state (73).

As mentioned, it could be argued that muscle atrophy is secondary to some alternate, primary pathology. Perhaps patients who present with KOA already experience pain. It is also plausible to argue that this pain might lead to the disuse atrophy seen within literature. What is more, decreased strength may lead to increased trauma and exacerbate the pathology. Particularly in combination with obesity or malalignment, secondary atrophy could certainly result in serious and rapid loss of QOL and radiographic disease progression. Nevertheless, the following could also be true: loss of knee extension strength with aging (and certainly physical inactivity) might be the initiator of the KOA (75). As previously reported, aging-related quadriceps-dominate atrophy is documented and predictive of KOA. Patients with higher hamstring to quadriceps ratios are significantly more likely to display radiographic signs of KOA (75). Moreover, pain and disability are associated with loss of quadriceps strength (73). It must not be dismissed that muscle weakness may precede and initiate the steps leading to KOA.

Sarcopenia is more evident with age. OA is more evident with age. Could this be more than just coincidence? Certainly, the role of decreased muscle strength warrants
serious consideration in its causative role in both diagnosis of incident KOA and disease progression.

**Systemic Vulnerabilities: Age**

The prevalence (5) and incidence (116) of OA increases with age and to a greater extent in women than in men (5, 66, 116). It must be understood that aging does not cause the disease; rather, age-related factors appear to contribute to the susceptibility for the disease. Indeed, a number of factors associated with aging (decrease in proprioception, muscle atrophy, ligamentous laxity, declining physical activity, increasing body weight, changes in dietary habits and injury) are also correlates of KOA. Many of these factors are described presently.

**Systemic Vulnerabilities: Genetics**

Several epidemiological and twin studies have helped carve out evidence for a genetic link for incident OA and progression of the disease. Nearly 1000 monozygotic and dizygotic female twin participants from the TwinsUK Registry were employed to investigate joint-specific heritability for OA. Data indicated a strong genetic link between OA in joints of the hand but evidence for a common genetic pathway to explain the co-occurrence at multiple sites was lacking (97). Authors noted that while genetics are implicated in the pathogenesis of OA, there is no evidence that common or shared
genetic factors govern occurrence of the disease across all skeletal sites (97). Heritability estimates of medial osteophyte formation (69%) and joint space narrowing (80%) are clear-cut (160). These convincing values were reduced only moderately (7–15%) after accounting for contributing covariates such as age and BMI. There is evidence of substantial genetic influence on the progression of knee OA (160).

Overall, epidemiological studies, twin studies and exploration of genetic disorders suggest that there is a strong genetic component in the development and progression of OA (146) and the heritability is site specific (54, 66, 97). Collectively, estimates suggest a heritability of more than 50% - approximately half of the variation in susceptibility to OA is explained by genetic factors (146).

**Extrinsic Factors: Unsafe Loading Patterns**

While articular cartilage functions well under cyclical, low-impact, loading states, unequally-distributed and abnormally high shear stress can be injurious. In addition, the rate of loading is critical as well. It must be understood that the joint feels far more force than that carried by the body during heel striking motions (122). Several conditions can precipitate situations under which the brunt force felt by the cartilage is beyond what is desirable. For instance, a misjudged step (which involves a fall of less than an inch) results in inadequate time to correct for landing. Under such a condition, an unsafe loading rate and absolute load can occur (122). In combination with malalignment or obesity, such an occurrence could be particularly damaging.
While cartilaginous squishing is important to joint health, improper loading rates and absolute loads can be damaging. In addition to landings from jumps or misjudged steps, unsafe patterns can occur due to traumas such as malalignment (141, 142), muscle weakness (73, 75, 143) and a loss of proprioceptive acuity (23, 24, 140, 153, 154) as have been previously described.

**Extrinsic Factors: Obesity**

Discussed previously, Cooper et al. conducted a study among members of a local community (38). Several hundred members were enrolled and approximately 350 persons returned at a five-year follow-up point. Medical history questionnaires and knee radiographs were completed at baseline. From the sample of persons 55 and older, pain-negative subjects were matched with pain-positive KOA patients. After a period of 5 years, the subjects were contacted again to complete radiographs and questionnaires. In a bias-protective move, radiographs from the two occasions were read in pairs, by a single investigator, who was blinded to chronology. Obesity was predictive of both incidence KOA (P < 0.001) and progression (P < 0.05) of KOA even after statistical consideration of age and sex.

Interestingly, there is some indication that the effect of obesity may be compartment specific – primarily due to the equitability of load distribution on the lateral versus the medial side of the tibia. Indeed, researchers found that BMI was related to the severity of KOA in persons with varus but not valgus malalignment (141). Even after
controlling for sex, medial tibiofemoral OA was explained by the occurrence of varus forces. Alternatively, weight-loss has been found to result in decreased risk of symptomatic KOA in women (55).

Not to be dismissive of the other factors, obesity is recognized as one of the strongest risk factors for KOA (38, 53, 54, 145). The association is stronger for bilateral disease than unilateral disease (43, 66) and stronger in women than in men (43, 53). Although malalignment appears to be more perilous in varus-situations than valgus (141), weight-loss may be an amenable means to reduce risk for symptomatic KOA (55).

**Knee Osteoarthritis – Nonpharmacological and Pharmacological Therapies and Surgical Treatments**

**Nonpharmacological Therapy**

While treatment options must be individualized, self-care, patient education, weight-loss, occupational therapy, physical therapy and exercise are currently considered the primary line of defense against dealing with the effects of OA (25). The role of exercise in the management of OA pain and function will be discussed in subsequent sections. Overall, exercise is an effective means to help reduce pain and increase function. For individuals carrying excess weight, weight-loss can be particularly helpful in combating these same issues. Physical and occupational therapy can greatly assist in the management of OA as well (46, 71). In addition, proper use of a cane can help to reduce loading forces on the joint. Cane usage is associated with improved function and
decreased pain in the knee joint (20). Shoe insertions (137), shock-absorbing shoes, patellar taping (41) and the use of knee braces may also be beneficial but they are less well-researched. Therapies involving diet and supplement have mixed results or are unproven (71). Overwhelmingly, nonpharmacological interventions are effective countermeasures to assist the vast majority of OA patients with pain and functional limitations.

**Pharmacologic Therapy**

Although nonpharmacological interventions are preferred, they are not always followed or effective. Pharmacological interventions should be considered subsequent to or in combination with nonpharmacological strategies. Corticosteroid injections are effective for short-term pain relief (16) but injections should not occur more than 3-4 times in a given year. Individuals requiring more than 3 or 4 intraarticular injections annually are probably candidates for joint lavage or surgical intervention (71). Should chronic analgesic usage be required, some evidence suggests that acetaminophen is a better option that ibuprofen and naproxen (4, 22, 158). More recent evidence contradicts these findings; however, and suggests that NSAIDs are the most effective at reducing resting and walking pain (90). In either case, the use of topical analgesics is indicated before the employment of chronic NSAID usage (44). NSAID usage is common, but due to the well-established adverse side effects documented with long-term NSAID treatment, judicious use of these agents is critical for patient health (25).
Surgical Treatment

Symptomatic OA is not always alleviated by nonpharmacological or pharmacological interventions. When severe, symptomatic OA is not amenable to medical therapies, physical function, functional mobility and QOL are compromised. Under this scenario, an aggressive approach is necessary and referral to an orthopedic surgeon for evaluation is advisable (31). Osteotomy may provide decades of pain relief and prevent disease progression in appropriately selected individuals (85). Osteotomy may be particularly successful in patients with varus malalignment (117) Total joint arthroplasty appears to provide obvious pain relief and functional improvement in the preponderance of KOA patients when appropriate care is taken before and after surgery (89, 107).

Knee Osteoarthritis – Pain and Coping Strategies?

Literature is replete with evidence that attests to the fact that OA is tied closely with pain (12, 38, 52, 54, 66, 94, 122). Keefe and colleagues recognized that while pain is closely linked with OA, knowledge about reports of pain and coping mechanisms to deal with pain was not known. Specifically, authors were interested in the dynamic interaction between males and females during a within-day analysis approach (80). While the within day-analysis is simplistic, it would provide preliminary evidence
regarding the congruent or divergent manners in which men and women manage their pain symptoms day to day and even within a given day (80).

One hundred patients were recruited and asked to complete an assessment of pain and a brief questionnaire at two points during the day (between 12 and 1 PM and 8 and 9 PM) over a period of 30 days. Questionnaires included the Rapid Assessment of Disease scale (pain), inventory of mood states-B scale (mood) and a coping inventory (coping skills). From these assessments, coping mechanisms, mood aspects and tendency to catastrophize were determined. Both males and females reported their greatest pain in the evening and women reported increasingly worsening pain throughout the day. Women worked through intense pain with more problem focused coping mechanisms while males reported more emotion-based coping mechanisms. Persons reporting better coping efficacy in the first diary entry reported more positive mood states in the evening. Subjects prone to catastrophizing were likely to report higher levels of pain, lower coping efficacy, decreased positive mood states and increased negative mood states.

Clearly, methods to deal with pain are divergent between males and females. With pain being a commonality for patients presenting symptomatically, this type of understanding is important. Determination and implementation of appropriate strategies to deal with pain is crucial. More work is needed in this area.
Pain Relief and NSAID Usage

Complaints of OA pain have historically been combated with NSAID usage (25). While the effectiveness of these agents is documented, this practice is not without consequence. The potential for adverse consequences was first investigated in the 1930’s (47) and these agents are now known to be deleterious to the gastrointestinal (GI) tract (19, 69) and potentially even cartilage metabolism (70). NSAID usage is notoriously linked with the minor side effects of abdominal pain and vomiting and more serious issues of erosion and the development of ulcers. Mucosal damage often heals spontaneously with assistance from the mucosal defenses despite continued use of the inciting agents (67). Epidemiological evidence suggests that NSAID users are at a 3-4 times greater risk for suffering from upper GI bleeding and perforation than non-users with higher usage carrying more risk than lower usage (67). Complications associated with NSAID are a common serious adverse drug reaction event worldwide (121) and particularly in the elderly (135). In combination with the fact that they may not be more effective than other pain relievers for many OA patients (4, 22, 158), current recommendations are being refocused (25). The primary lines of defense are now considered to be nonpharmacological interventions such as patient education, weight-loss, physical therapies and exercise (25).

Rather than considering exercise an efficacious and safe method of pain reduction, patients often associate exercise with wear and tear and increased pain (68). These types of misinformed and misplaced beliefs are inconsistent with literature and
would seemingly jeopardize a patient from experiencing there potential efficacy. After all, why would a patient do something that they think will directly aggravate their already ailing knee? It is for reasons such as this that patient education is one of the primary means to address pain (25). Patients should be directed away from NSAID usage and towards other means of intervention.

**Knee Osteoarthritis – Exercise and Pain**

**Aerobic Exercise and Pain Symptoms**

A number of studies have investigated the effects of exercise in ameliorating knee pain symptoms. Kovar and colleagues (1992) compared the effects of an 8-week fitness walking program with a usual care treatment among 102 older adults (86). The 90-minute sessions included supervised walking and psychoeducational training and resulted in a greater reduction in pain symptoms (AIMS) then did the usual care treatment. Unfortunately, at the one-year follow-up point, self-reported PA participation was found to have declined such that there were no differences in total walking volume between groups. Moreover, the significant reductions in pain observed at the end of the 8-week walking program were not maintained (86).

Mangione and colleagues (1999) examined the effect of 10 weeks of aerobic cycling on pain outcomes (98). The aerobic intervention involved 25 minutes of stationary cycling at either 40% or 70% of heart rate reserve three times per week. While
not different from each other, both cycling intensities were found to have resulted in significant reductions in pain compared with baseline. Importantly, neither the high nor the low intensity cycling exercise exacerbated acute pain symptoms when analyzed with the visual analog scale (VAS).

Findings from these trials indicate that engagement in aerobic exercise interventions can result in small to moderate, yet statistically significant, improvements in knee pain among older adults with KOA (98). Both the walking and cycling interventions were of short duration and results in pain reduction were in conjunction with supervised sessions. Consequently, the impact over the long-term is in question and the effectiveness of non-supervised sessions cannot be answered. Disconcerting, neither walking participation nor pain-related symptoms were maintained after just one year (86). This does not bode well for persons who are transient exercisers. Thus, while it appears that both modes of aerobic exercise yield benefits for easing pain symptoms (86, 98), the effects over time and any effects on other outcomes (muscle mass maintenance muscle strength etc.) are not known. Furthermore, evidence for determination of the more optimal modality and dose-response relationships for either modality are lacking.

Strength Training Exercise and Pain Symptoms

The effects of strength training on pain symptoms have been investigated by a number of researchers (6, 100, 115, 120, 134, 138, 152). Schilke et al. (138) and Rogind et al. (134) found favorable results for strength training versus usual care over 8-week
Eight weeks of progressive strength training resulted in a significant within group difference between baseline and post-intervention pain symptoms in the strength-training intervention (138). In addition, three months of lower body strength training was associated with reductions in pain experienced at night and during weight-bearing activities – an outcome that was found to persist at a one-year follow-up assessment (134).

VanBaar (152) and colleagues found improvements in pain symptoms following a 12-week, center-based exercise therapy. Sadly, outcomes were found to decline by a 24-week post treatment assessment and they continued to dissipate such that there was no difference at a 36-week assessment when comparing between an exercise group and participants undergoing usual care (152). A lack of long-term change is not surprising but certainly concerning.

Compared to a short duration health education intervention, Maurer (100) found a greater reduction in pain symptoms with 8 weeks of strength training (10% versus. 23% respectively). Although not directly supervised, home-based strength training intervention strategies appear more efficacious when compared with usual care (115), non-exercise controls (150), nutritional intervention (6) and even medicinal therapy when medicinal therapy is used alone (120). More specifically, six months of quadriceps strength training resulted in improvements in pain during walking and stair climbing (115) and a two-year home-based intervention showed significantly greater reductions in pain for exercise-group members compared with members of the telephone contact and control arms (150). In addition, a short-term, home-based, strength training program was
more effective at relieving pain symptoms (38%) than was a nutritional intervention (10%)(6). Perhaps most interesting, a combination of home-based exercise and NSAID usage was more effective at improving pain symptoms when compared with persons engaging in NSAID usage alone (120).

Both dynamic and isometric strengthening exercises are capable of mitigating self-reported pain symptoms (WOMAC). Among 102 older adults divided into either dynamic strength training, isometric strength training or the control group, improvements in pain were greater with dynamic (14%) and isometric strength training (12%) compared with the control group (0%)(151).

Despite variability in the magnitude of pain reduction, results overwhelmingly indicate that compared with baseline values and when compared with non-strength training intervention control groups at baseline and post-intervention periods, resistance training interventions result in more favorable changes in pain reduction (6, 98, 100, 115, 120, 134, 138, 150-152). The results reported are inclusive of studies employing isokinetic, dynamic and isometric exercises. Future studies are needed to determine which mode of resistance training may be most efficacious for time investment to pain reduction outcomes. Presently, evidence suggests that resistance training, regardless of type, can favorably alter pain symptoms when employed with appropriate frequency, intensity and duration such as employed in the studies reviewed.

Additional studies are needed to help establish dose response relationships and specific, exercise-related characteristics described by the FITT principle. Several investigators have found that the extent of pain relief is related to exercise compliance.
and the most favorable changes in pain accompany the higher adherence rates. Accordingly, the value of regular exercise cannot be overstated. Helping participants successfully maintain involvement in an exercise program is problematic. To this end, Thomas et al. (150) found that less than half of the participants in the exercise intervention were successfully complying with an exercise prescription at a 2-year follow-up point. These same subjects reported significantly less pain during the exercise intervention portion of the trial which makes this result more confounding. Nevertheless, this is a commonly reported outcome in literature.

**Combined Aerobic and Strength Training Exercise Interventions and Pain Symptoms**

Several trials have investigated the combined effect of aerobic and strength training exercise interventions on pain outcomes. Compared with baseline, Evcik and Sonel (50) found that both a 3-month, center-based and a 3-month, home-based exercise intervention resulted in greater reductions in pain than did a usual care approach. Furthermore, a combined exercise intervention resulted in significant and meaningful reductions in pain symptoms at a six-month follow-up (72) compared with a control group.

In combination with manual physical therapy, combined exercise programs help to alleviate pain symptoms compared to baseline (46). What is more, both individualized and group-based physical therapy conditions promote improvements in pain symptoms compared with a usual care group (63) and authors found this favorable changes in pain
to persist after a 16-week follow-up (63). Unfortunately, the favorable changes found by others (Deyle and colleagues (2000); 52% improvement in pain symptoms) deteriorated substantially by a one-year follow-up point (46). This result underscores the importance of continual commitment to exercise – a primary issue cited in exercise behavior literature.

Messier and colleagues enrolled 24, obese, older adults in a six-month study comparing an exercise intervention with a combined exercise and nutritional intervention strategy (109). While both tactics produced significant improvements in pain during ambulation and transfer at a six-month follow-up appointment, the combination intervention resulted in significantly greater changes in weight loss and stair climb performance (109). The addition of nutritional strategies to combined exercise programs may yield more desirable changes in pain (WOMAC), disability (WOMAC) and performance (6-min and stair climb tasks) in this population (109).

It seems clear that changes in pain symptoms are a salient determinant of the fortuitous effects associated between PA engagement and physical function outcomes. Overall, there is agreement that a combined exercise program results in fortuitous adaptations in pain symptoms and other measures. These results have been found for both center-based and home-based interventions and results from Messier (108, 109) demonstrate that a weight-loss component may result in greater adaptation. Differences in pain reduction, which have been found to range from small (49) to large (50) may be explained partly by methodological (i.e. location of intervention, frequency of engagement, modality and intensity among other things) differences between studies.
Exercise and Pain Symptoms: Summary of Research Trials

One of the primary questions arising out of the 2005 MOVE consensus revolved around the relationship between exercise and pain responses, “Which exercise reduces pain symptoms the most? (133)” While this relationship is not necessarily clarified, results from randomized controlled trials consistently demonstrate that engagement in aerobic exercise (86, 98), resistance exercise (6, 100, 115, 120, 134, 138, 152) and combined exercise interventions (46, 49, 50, 63, 72, 108, 109) result in favorable changes in OA-related pain symptoms. Based on a solid set of evidence, Focht suggests that aerobic training, strength training and combined interventions are effective for improving pain symptoms in this clinical population (56). Certainly, exercise is an effective, but undervalued, behavioral pain management strategy within patients. While there is great intratrial variability for the effect sizes accompanying the improvements of pain, the effects are statistically significant and clinically meaningful.

Knee Osteoarthritis – Exercise, Functional Outcomes and Health-Related Quality of Life

Two common complaints among knee osteoarthritis patients are pain (1, 36, 52, 54, 56, 66, 113, 114, 156) and muscle weakness (1, 36, 73, 74, 113, 114, 156). Furthermore, these same issues are linked with activity avoidance and disability (66, 91) and both are well-recognized risk factors for KOA (1, 12, 38, 75, 94, 143). The favorable impact of exercise on pain symptoms is well documented (6, 46, 49, 50, 56, 63, 72, 86,
There is also evidence to suggest that appropriately tailored exercise is effective for increasing muscle strength in KOA patients (51, 63, 100, 148, 149). Accordingly, engagement in exercise can favorably impact two primary complaints of KOA patients. Perhaps, it is favorable changes in these salient complaints which allow exercise to beneficially increase functional performance (49, 63, 86, 120, 148) and improve health-related QOL (HRQOL) (51, 63). A recent review on PA, disability and HRQOL reports that strong evidence exists for the positive effects of PA on both function and HRQOL (112). Unfortunately, the effects of PA on QOL and disability are not as well-established (112).

It is common practice to concurrently investigate a multiplicity of variables within research trials. This aspect makes it more simplistic, and to some degree, more reasonable, to discuss physical functioning, disability, HRQOL and other outcomes simultaneously. As it is relevant to the outcomes, improvements in pain will be mentioned as well. The inclusion of these variables in one discussion should not be taken to indicate that these variables change together in response to exercise. This has been shown to be otherwise (78, 83). Furthermore, even if multiple outcomes were to change, one would be remiss to assume that they change to the same magnitude (46, 49, 86, 108, 115, 138) or in the same course of time (124). Certainly, though, the possibility of synchronized changes in a similar time-course and to a similar magnitude is not impossible (46, 49). Much of the supporting evidence for this section comes from research which has been discussed in some fashion elsewhere in this introduction. Rather than being segregated, one should consider the findings in aggregate.
The work of Kovar (1992) was previously discussed (86). Briefly, 102 older adults were enrolled into either an eight-week fitness walking program or a usual care treatment. As already mentioned, the short-duration, supervised walking and psychoeducational training program was effective at relieving knee pain symptoms. Furthermore, pre to post-test comparison indicated that these same patients had an 18.4% increase in walking distance (+ 70 meters) over 6 mins (86). Concurrently, functional status, as measured by AIMS, was significantly improved. Although ancillary, it is interesting to note that the use of medication was decreased in the walking group at post-test when compared with the control group (86). The significant reduction in pain, as reported, coincides nicely with this finding.

The Fitness and Arthritis in Seniors Trial (FAST) was an 18-month, single-blind, multicenter study comparing the effects of aerobic and resistance exercise programs with those of a health education group (49). A total of 365 participants completed the 18-month trial. A three-month, center-based exercise training period occurred prior to a 15-month, home-based phase. Pain symptoms were improved in the aerobic and strength training groups when compared with the health education intervention. Participants in the aerobic and resistance exercise groups scored lower on the physical disability questionnaire (10% and 8%, respectively) and on the knee pain questionnaire (12% and 8%, respectively) post intervention – both positive outcomes (49). Members of both exercise groups performed better on the 6-minute walk test, time to lift and carry 10 pounds and mean time to get in and out of a car when compared with the health education group (49). Again, these are fortuitous. Older patients hampered with KOA
can clearly benefit by engaging in exercise. Substantiating this claim, the walking and weight-training participants were found to have significantly improved postural sway which authors reported would likely decrease sway disturbances (110).

Individuals exhibiting the greatest attendance rates (frequency) exhibited the greatest reductions in pain. Interestingly, individuals completing the most exercise time per session (duration) did not experience pain reductions compared with the health education group (49). In particular, individuals attaining greater than 40 minutes of exercise per session reported pain scores which were similar to those reported by members of the health education group (49). This finding naturally breeds curiosity and even concern. Perhaps exercise frequency is a more potent determinant of pain outcomes compared with exercise duration. Perhaps as duration exceeds some unknown threshold, it becomes agitating rather than alleviating. Perhaps the outcomes were linked to baseline function and pain values. Maybe those members completing 40 minutes of exercise per session were those with the least pain and highest function at baseline. In this sense, the extent of change in functional improvement and pain reduction might be blunted. Accordingly, maybe these subjects were rendered incapable of seeing significantly greater reductions in pain compared with the health education group. While these statements are speculative, there is no doubt that this finding warrants investigation. Improvements in mobility-related self-efficacy and knee pain symptoms mediated changes in function (49).

The impact of a 16-wk, group-based physical therapy was compared with vs. individually-attended treatment (63). Primary measures included reports of pain,
physical function (WOMAC), HRQOL (SF-36) and physical performance (muscle strength) among 126 KOA patients. Physical therapy, regardless of delivery method, was advantageous. There were no differences between groups but both groups were found to have significant improvements in pain, physical function and HRQOL (63). Knee extensor strength increased significantly and changes in pain and function correlated with self-report measures as determined by WOMAC. Due to the similar responses to several clinically relevant outcomes, group-based therapies appear a cost-effective means of delivering effective therapy as compared with physical therapy delivered individually. The generalizability of these findings is assisted by the fact that 24 therapists were involved in the delivery of the group-based (4 persons) and individually-attended (20 persons) sessions (63).

Maurer and colleagues enrolled over one hundred thirteen men and women to elucidate the impact of an isokinetic exercise compared with a patient education program on pain and function (100). Patients were either in an 8-week, thrice-weekly regimen of isokinetic quadriceps muscle strengthening or a 4-part education series led by health care professionals. Quadriceps strength (isometric and isokinetic) and pain (WOMAC) were important outcome variables. Both treatment groups showed significant strength gains, positive functional outcomes and improved moods (100). Pain scores were improved for more of the measured variables within the exercise group than in the education group. As muscle weakness can be combated with appropriate strength training regimens, the fact that isokinetic exercise training was well-tolerated in these patients was a key finding.
With regards to isokinetic strength training, 6-weeks of progressive resistance exercise have been found to be more effective than an equal length isokinetic training protocol (51). Forty subjects, 40-70 years of age underwent 6 weeks of either progressive strength training on a knee extension machine (10 reps at 50, 75 and 100% 10 repetition max) or leg extensions on the isokinetic dynamometer (60, 90, 120 and 180°/sec). Pain symptoms were decreased and leg strength increased in both groups after 6 weeks (51). More favorable changes were found in HRQOL (SF-36) for progressive resistance exercise members although both groups experienced significant increases in multiple subscales of the assessment (51). Due to the equipment cost and the complex nature of isokinetic strength training and assessment, progressive resistance protocols may be a preferred and efficacious strategy for application within this clinical population.

O’Reilly et al. sought to determine the effect of a 6-month, home-based quadriceps strengthening program on reported physical function tasks and knee pain during walking and stair climbing tasks (115). Researchers randomized 191 individuals to either the daily exercise (n=113) or no intervention (n=78) group. Pain reductions (WOMAC) were significantly more favorable in the exercise group than the control group (22.5% vs. 6.2% decrease). Persons within the exercise group realized significant improvements in physical function (WOMAC) scores (17.4% reduction) which the control-group members did not experience (115).

Petrella and Bartha found the combination of home-based exercise and treatment with a nonsteroidal medication to be of greater benefit for effects on pain and physical functioning compared with the use of medication alone (120). The significant reduction
in pain was discussed in more detail earlier. In tandem with these activity-related reductions in pain, both groups were found to have experienced a significant reduction in time to complete self-paced walking and self-paced stepping tasks. Both passive range of motion and reported PA (physical activity scale for the elderly) were also found to increase. The combination of exercise and medication resulted in significantly more favorable changes (p < 0.05) for the aforementioned variables (120) – a salient outcome for the masses of OA persons.

The large-scale, 18-month, Arthritis, Diet and Activity Promotion (ADAPT) trial was undertaken by Messier and colleagues (108). ADAPT consisted of four arms into which subjects were randomly divided: diet only, exercise only, diet plus exercise or healthy control (108). Each arm consisted of approximately 80 individuals and follow-ups occurred at months 6 and 18. Members within the exercise only group experienced a significant increase in 6-min walk distance at the 18-month follow-up compared with the healthy controls (108). Members of the combined diet and exercise group realized significant improvements in physical function, 6-min walk distance, stair climb time and reported knee pain compared to the healthy controls (108). These results were independently mediated by changes in pain and SE (60). The combined exercise plus weight-loss group was clearly superior for changes in HRQOL (129). Surprisingly, the diet only group saw no differences at the 18-month follow-up compared with the healthy controls (108). Consequently, although exercise resulted in a meaningful increase in walk distance, the combination intervention was found to be more effective for performance (108) and HRQOL (129). A subgroup of the ADAPT trial patients were
selected and included in a secondary investigating examining within days pain symptom responses (58). Pain reports obtained immediately post-exercise were found to indicate greater pain symptoms compared with similar times of the day on non-exercise days. These significant increases in pain were found to be transient and they dissipated rapidly after the completion of exercise. Similar results were found with reported fatigue which increased post-exercise but then dissipated rapidly upon cessation of activity (58). While these findings might be worrisome to both clinician and patient, the documented benefits of PA – even for KOA patients – should prompt clinicians to support and patients to engage in exercise. In other words, the transient nature of these symptoms should not overshadow the multitude of health-related and function-related responses associated with chronic engagement in exercise.

While the majority of research trials are center-based, home-based programs can be an efficacious means for KOA patients to gain the benefits of exercise (49, 56, 115, 120, 150). Interestingly, Creamer and colleagues found threshold to pain to be inversely, but significantly-related to reported disability (40). The old adage surfaces – “No pain, no gain.” Persons with the highest pain thresholds reported the least disability (40). This last comment needs to be taken with caution – this population is very susceptible to injurious loading patterns for a number of reasons. Also of interest, Wilder and colleagues found that pain reductions in response to exercise participation continued over the course of a two-year program (157). Divided into 2, 12-month sections, subjects reported greater pain reduction (WOMAC) in months 13-24 (10.7% decrease) than in the
first 12 months (7.8% decrease). Perhaps “motion” truly is “lotion” as the authors note (157).

While there is not complete agreement (6, 88, 148), the overwhelming majority of research supports the effectiveness of exercise in improving function and/or decreasing pain. This claim is substantiated by scholarly reviews (29, 56, 64, 99, 133), meta analysis (30, 45, 65, 118), expert panels and opinion (18, 133) and an overview of systematic reviews (76) of the existing, relevant literature.

**The Psychological Aspect of Exercise Interventions**

One of the major sentiments highlighted by exercise behaviorists is the call for researchers to incorporate a theoretical model into their exercise interventions (11). Doing so would provide a more accurate method to help elucidate the mechanisms through which interventions are altering both psychological and physical outcomes. Bandura’s social cognitive theory (SCT) is an accepted framework for application within exercise interventions (7-10). The “active agent” in the framework of the SCT is the concept of SE – the belief in oneself to accomplish a specific task (7). Data have shown that SE mediates a number of the outcomes associated with exercise interventions (49, 59, 60, 79, 82, 101, 103, 105, 126). Mediators are proximal outcomes which, when changed, cause change in more distal outcomes (13). Thus, when an exercise intervention enhances SE, changes in more distal outcomes (pain, function etc) might be expected. As SE is task specific, engaging in a given task has the ability to facilitate
greater efficacy for the task. In this manner, SE may result in the undertaking of a task which, after completed successfully, may increase efficacy for the task – a reciprocal relationship. In a cohort of low-functioning, older Netherlanders, higher SE was linked with less physical decline over a 2-year period (82). Furthermore, in a follow up of participants having undergone a 6-month exercise intervention, SE at the conclusion of the intervention was predictive of exercise adherence at both 2 (103) and 5 (105) year check points. In the context of the SCT, SE is gathered through mastery experiences, social persuasion, psychological understanding and modeling (7). Higher levels of SE not only mediate adoption of a program but also foster greater long-term maintenance as well. Furthermore, SE has been found to be predictive of exercise behavior at follow-up even when controlling for other behavioral characteristics (101). Meditation analysis is investigated statistically and acknowledged as having occurred when the following hold true: an intervention significantly alters a selected outcome, the intervention significantly alters a potential mediator such as SE, the change in the mediator is significantly related to the selected outcome and when adjusting statistically for the mediator, the intervention is no longer significantly related to the outcome.

**Influence of Behavioral Modification Strategies in Interventions with Clinical Populations**

Deaths related to coronary disease have decreased drastically over the last 30 years (61). This decrease is explained primarily by improvements in diagnosis and treatment (47%) and changes in the risk factors associated with the disease (44%) (61).
Regardless, cardiovascular disease is still a leading cause of death and disability in America (77). Cardiac rehabilitation is a multidimensional (pharmacotherapy, educational effort, counseling and exercise intervention) approach to assisting patients with successful recovery. While cardiac rehabilitation results in favorable changes in disease status (Focht, in press), few studies with this population have included HRQOL as an outcome. The Cardiovascular Health and Physical Activity Maintenance Program (CHAMP) trial (57, 125, 126) speaks to this need. CHAMP was a single-blind trial enrolling nearly 150 persons age 50-80. Participants had either suffered or were at risk for suffering an event related to cardiovascular disease. Persons were divided randomly (in blocks and by gender) into either a traditional exercise group or an exercise group with additional mediated cognitive behavioral strategies utilized. Behavioral strategies were structured around the social cognitive theory (125). Both the traditional and GMCB groups were given equal stimulus in terms of contact hours. A combined aerobic and strength training program was employed for both exercise arms. In addition, the GMCB strategy included a short group meeting after each exercise session in which relevant and important topics were discussed – short-term goals, long-term goals, gauging exercise intensity, overcoming barriers to activity, preventing relapse, dealing with relapse etc. Both exercise groups realized improvements in functional tasks at the post-intervention period (125). At the 12-month follow-up, members of the GMCB intervention scored higher on the vitality and mental health subscales of the SF-36 (126). Mastery experience and social modeling could certainly be involved in this outcome but both groups were afforded this experience. Purposefully, self-regulatory skills were targeted
to the GMCB group but not the traditional group. Authors concluded that a GMCB strategy provided subjects with more than an exercise experience but rather gave them skills to adequately incorporate greater levels of activity into their everyday life (57, 125, 126).

Cognitive behavioral strategies have been implemented successfully in a number of different populations for a number of reasons: within diabetics to assist with decreasing depressive symptoms (96), within chronic obstructive pulmonary disease persons to assist with physical function and energy expenditure (62) and within cancer patients to assist in decreasing insomnia (48). Behavioral modification strategies structured within the confines of a well-established theoretical framework appear an important addition to facilitate the initiation and maintenance of regular PA participation (48, 57, 62, 96, 125, 126).

**Influence of Group-Mediated Cognitive-Behavioral Modification Approaches in Knee Osteoarthritis Patients**

As described previously, there is strong evidence that SE is an important mediator of change in response to exercise interventions and task-specific SE for exercise engagement (49, 59, 60, 79, 82, 101, 103, 105, 126). When considering findings from the CHAMP trial – the GMCB arm was structured to specifically target self-regulatory skills to participants in a straightforward manner. There is evidence to suggest that the differences noted at the 12-month follow-up were a result of a skill-set revolving around, among other factors, increased exercise SE (57). Cognitive restructuring strategies
within the confines of exercise interventions have been targeted towards the KOA population. Hughes et al. (2004) examined the effects of a center-based GMCB intervention strategy in 150 subjects with lower extremity OA (72). Control-group members were provided self-care and educational materials. The cognitive modification was an adapted from previous work (86) with the intent of increasing exercise efficacy. The 30 min. psychoeducational training program was employed following the exercise sessions. At a six-month time point, members of the treatment group were found to have significant and meaningful reductions in pain symptoms compared with the control subjects (72).

**Issues and Limitations in Exercise-Related Literature**

There have been significant strides in the application of theoretical foundations within exercise research (Focht, in press). It often appears as PA interventions operate on there intended targets through psychological variables – chiefly SE (49, 59, 60, 79, 82, 101, 103, 105, 126). This type of understanding should drive the methodology framework around which exercise interventions are structured. While it is well established that lifelong PA can slow the disablement process, whether activity interventions can do so, is not well-established (112). This is still an area that warrants attention. Primary issues include combating attrition and employing robust, statistical methods to handle drop outs (56). Furthermore, there is a pressing need for longer, longitudinal interventions with greater lengths of follow-up (56). While trials capable of
answering these latter issues require substantial perseverance and financial backing to undertake, they are imperative to delineate the efficacy of exercise over time and on the disablement process. As the volume of research begins to accumulate, evidence to clarify dose-response relationships and optimal exercise strategies will be available. Currently, minimal evidence exists regarding these types of relationships in association with pain relief and functional outcomes. In fact, presently, there is inconsistency regarding this topic. While one researcher suggests that higher doses of exercise are more effective for alleviating pain symptoms (111) findings from another trial indicate that patients achieving the greatest volumes of PA were not the ones realizing the greatest decreases in pain symptoms (49). This underscores the importance of judicious investigation and evidence-based conjectures. Certainly, there is no single exercise prescription that would suffice for all patients with KOA. In many ways, exercise is a matter of initial functioning and personal preference and thus responsiveness to exercise will shape the dose-response outcomes (56). To assume that each participant will respond similarly to an exercise stimulus is especially remiss (56). Mounting evidence does suggest; however, that pain relief and functional benefits are related to exercise adherence and maintenance (46, 49, 56, 86, 115). Assisting patients with adoption of an active lifestyle will continue to be a primary push in the future. Disconcertingly, in a review of the effects of PA on various functional outcomes, Fransen was quick to point out that the most strictly controlled studies were also the least effective (65).
Key Voids in the Literature:

- How do we best deliver exercise as an intervention?
- What approaches best promote adherence and the maintenance of PA engagement?
- What strategies best increase the long-term adherence to exercise?
CHAPTER 3: METHODS

Study Approval and Subject Recruitment

The Improving Maintenance of Physical Activity Trial – Pilot (IMPACT-P) was originally approved by the Institutional Review Board of the Ohio State University (OSU) in November, 2007, (Appendix A and B) and continuing review approval was obtained in October of each year since the original approval (Appendix C). The majority of participants were recruited from the Ohio State University Medical Center (OSUMC) Rheumatology Clinic under the direction of co-investigator, Dr. Kevin Hackshaw. In addition, participants were recruited via pamphlets designed by the OSU Center for Clinical and Translational Research. Pamphlets were placed alongside preliminary screening forms (Appendix D) at OSUMC-affiliated medical offices and clinics, and primary care settings in the Columbus area. Both “Yes” and “No” responses were required for eligibility. Specifically, participants were required to answer “Yes” to the first three questions, “No” to the next three questions and “Yes” to at least one of the final 9 questions. Pamphlets and screening forms were also placed in areas associated with the central Ohio branch of the Arthritis Foundation. On several occasions, the primary investigator completed a short presentation of the pamphlet at Central Ohio Arthritis Foundation Aquatics’ classes (Appendix E).
Individuals expressing interest in the study underwent a brief telephone screening to further explain study details and confirm eligibility. The phone script (Appendix F) was intended to be followed systematically. As mentioned previously, both “Yes” and “No” responses were required on the screening form (Appendix D) for eligibility which was meant to ensure that each subject was:

- Age 55 or older
- Diagnosed with radiographic evidence of KOA
- Sedentary at study commencement
- Struggling with symptomatic KOA on most days of the month
- Limited in some normal functional activity due to pain symptoms
- Otherwise safe to exercise

Once eligible, participants were scheduled for a baseline screening visit.

**Research Design**

**Generic Description of Baseline and Follow-Up Testing Sessions**

All baseline, 3-month and 12-month visits were conducted on the ground floor of the Physical Activity and Educational Services (PAES) building. Subjects were either mailed (Appendix G) or emailed (Appendix H) a letter which included an overview of the
expectations for the baseline testing session and individually-tailored driving directions. On the day of the baseline testing, each subject was provided a complete overview of the trial prior to engagement in any activities. Once all procedures were described in detail and all subject questions were answered, subjects read through and signed the informed consent (Appendix I). Researchers allotted one hour and 15 minutes for completion of demographic data (Appendix J), medical history information (Appendix K), functional tests [stair climb procedure (Appendix L) and 400-meter walk procedure (Appendix M)], mobility-related SE [stair climb SE (Appendix N) and 400-meter walk performance (Appendix O)], HRQOL (Appendix P) and PA (Appendix Q) questionnaires. The visit was completed as quickly as 50 minutes by the most well-functioning persons. Several subjects required additional time for completion of the tests – mainly due to 1) requiring resting periods during the walking phase or 2) reading more slowly through the questionnaires. When necessary, research assistants read questions aloud to participants. Following successful completion of the baseline testing, subjects were provided with a Lifecorder accelerometer and asked to wear the device from waking until sleeping for the subsequent 7-day period except while showering, bathing and swimming. In addition to the device-stored data, subjects completed a self-reported measure of daily exercise and they logged total hours with the device in place (Appendix R). To ensure appropriate recording, all subjects were given an instruction sheet which provided information regarding correct and incorrect handling and wearing procedures (Appendix S). Subjects were provided with a pre-addressed, pre-stamped envelope to promote quick and efficient return of the devices. Following the screening, subjects were assigned to either the
group-mediated cognitive behavioral modification (GMCB) intervention or a traditional (TRAD) PA intervention in randomized, blocked fashion. At the 3 and 12-month time points, subjects were asked to return and complete the same set of functional tests, SE measures and HRQOL questionnaires. A more detailed description of all baseline tests and the two exercise intervention arms is provided in the ensuing sections.

Description of Baseline Procedures and Measures

After completion of the informed consent, subjects completed demographic information. As a final precaution, a brief series of medical history questions was completed by the subject and reviewed by the researchers prior to commencement of the functional tests.

Functional Tests

The functional tests were completed stair climb first and then 400-meter walk. The timed stair climb and 400-meter walk distance tests were used as objective assessments of participants’ performance on stair climbing and ambulation tasks, respectively. Each task has been shown to have excellent 2-week test-retest reliabilities (> 0.82) and have been found to be sensitive to change with exercise interventions in older adults (125, 126). For convenience, both tests were completed on the ground floor of the PAES building just down the hall from the consultation room.
Subjects walked to the stairwell and were given a full description of the stair climb test. In addition, research assistants provided a demonstration of how the test was to be performed. Subjects confirmed they understood the requirements of the test. After acknowledging understanding, but before beginning the test, subjects completed six, mobility-related SE questions. Stair climbing SE was assessed by asking participants to rate their confidence, on the 0 (No) to 10 (Complete) confidence ladder, in their ability to ascend and descend 8 stairs for 2 trips without stopping. This same confidence ladder was used to assess their confidence at 5 increasingly more challenging stair climbing tasks of 4 trips, 6 trips, 8 trips, 10 trips and 12 trips up and down the steps at a moderate pace without stopping. Stair climbing SE scores were calculated by summing the confidence ratings across all 6 climbing levels (confidence at 2 trips + confidence at 4 trips + confidence at 6 trips etc) dividing by 6 and multiplying by 10 to produce a score ranging from 0 to 100. In this manner, a higher score reflects more confidence in completing the task. An example of how to determine stair climb SE is shown at the end of this paragraph. Once SE scores were recorded, subjects begin the stair climb test. It is important to understand that while participants were asked about increasing more challenging levels of stair climbing tasks, they only ascended and descended the steps a single time for determination of functional ability for stair climb. There was a preset line behind which subjects begin the stair climb. The timed test began with the initial movement of the subject after the words, “Whenever you are ready” where provided by
the research assistants. Subjects moved through the ascending and descending portions of the test as quickly as possible while ensuring safety. The time was stopped when the subjects finished the descent and both feet touched down past the preset line that also functioned as the start point. Subjects were permitted to use the hand rail as deemed necessary. There was a brief turn at the top of the stairs which meant subjects ascended on one side of the stairs (right) and descended on the other (left). The start line and ascent and descent patterns were kept standardized through all testing periods for all subjects.

The stair climb mobility-related SE form used during testing can be found in its totality in the appendix (Appendix N). In short, answers were placed on the exact confidence ladder shown immediately below, albeit, in an abbreviated form.

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<thead>
<tr>
<th>How certain are you that you can walk:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ...for 2 trips up and down the stairs at a moderate pace without stopping.</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>NOT AT ALL</td>
</tr>
<tr>
<td>CERTAIN</td>
</tr>
</tbody>
</table>

Figure 2.1 Abbreviated version of the stair climb mobility-related SE form
For the purposes of explaining the mathematical calculation of SE confidence scores, the illustration below (Figure 2.2) will be used with the shaded circles “representing” fictitious responses.

Figure 2.2 Illustration of the mathematical determination of the stair climb mobility-related SE

Adding the confidence scores (10 + 10 + 8 + 7 + 6 + 3) yields a total of 44. Dividing the sum (44) by the number of scores (6) illustrates that the subject had an average stair climb confidence of 7.33 and multiplying by 10 provides the overall confidence of 73.33 when utilizing the 0-100 confidence scale. Higher scores represent higher task-specific confidence.
Subjects went immediately from the stair climb test to the 400-meter performance walk. A similar instructional order was employed. Subjects were provided a full description and standard demonstration of the test. They acknowledged understanding and then completed mobility-related SE questions. The initial level of walking SE was assessed as confidence in the ability to walk a 20-meter course down and back two times (80 meters total) at a moderate pace without stopping. Again, this confidence was rated on a 0 to 10 confidence ladder and repeated for the increasingly more challenging distances of completing 4 laps, 6 laps, 8 laps, 10 laps and 12 laps at a moderate pace without stopping. Walking SE scores were calculated in the same manner as was shown for the stair climb above. Again, walking scores were determined by summing the confidence ratings across all 6 walking distances dividing by 6 and multiplying by 10 to produce a score ranging from 0 to 100. The walking SE scale has demonstrated adequate psychometric properties in previous PA investigations (104). The walking course was set such that 2 cones were 20 meters apart at opposite ends of the hallway. Subjects begin the walk test on the right side of the course, preceded down the hallway and looped around the cone at the 20-meter point in a counter-clockwise fashion and continued back to the start line having completed 40 meters of the 400 meters required. They continued this pattern for 10 laps. As they passed the start line, they were provided standardized information such as, “1 lap down, 9 laps to go” or, “2 laps down, 8 laps to go.” They were not provided with the current time or any other encouragement. At the 5 and 9 lap
points, subjects were given the following information, “5 laps down, 5 laps to go – you are halfway done” and “9 laps down, 1 lap to go – this is your final lap.” As was necessary for some persons, there was a chair placed at the 10-meter point in the hallway to allow for rest. When subjects choose to rest, the time continued to add up. Subjects were informed of this procedure prior to starting the test. The timing of the test was initiated when the subjects left the starting point and began lap number 1 and ended when the subject walked through the finish line having completed their 10th lap and the full 400 meters.

**Self-Report Physical Activity and Health-Related Quality of Life Questionnaires**

After completion of the functional tasks, subjects returned to the consultation room to finish the remaining questionnaires – CHAMPS (Community Health Activities Model Program for Seniors) Physical Activity Questionnaire for Older adults (147) and the WOMAC (Western Ontario McMaster Universities) Osteoarthritis Index (15).

*Self-Reported Physical Activity Participation*

The CHAMPS self-report questionnaire was used to assess PA_{Mod^+}. Subjects were requested to consider their activities during the previous 4-week period. They were asked to answer questions based on activities that a “normal week” would have entailed. The 41-item measure was developed specifically for the assessment of physical activity
participation in individuals 50 years and older (147). Two-week test-retest reliability has been reported (ranging from 0.62 to 0.76) as moderate to strong and discriminant validity (127, 130) has been established in groups of older adults with varied PA levels.

Health-Related Quality of Life

The pain subscale of the WOMAC self-reported questionnaire was used to determine pain symptoms related to specific activities and movement patterns. Participants recorded pain characteristics on a 0 (none) to 4 (extreme) scale. In accordance with the design of the measure, participants were asked to consider the previous 48 hours when reporting the WOMAC responses. The pain subscale consisted of 5 items and total scores ranged from 0 to 20 with higher scores indicating greater pain symptoms. The reliability, validity and responsiveness of the pain subscale has been demonstrated not only in KOA patients but across a range of intervention strategies and patient groups (106). As exemplified by its extensive use and publication in over 65 languages, the WOMAC is an almost inseparable component in rheumatologic settings for determination of OA-related, pain symptoms (2).

Objectively-Measured Physical Activity: The Lifecorder Accelerometer

When subjects finished HRQOL questionnaires, self-reported age and height were recorded and weight was determined on a calibrated, standard medical-grade scale. All
of these data were entered into the Lifecorder accelerometer along with the date and time. For delineation of \( \text{PA}^{\text{Mod}+} \), PA patterns were stratified into light [0-3 Metabolic equivalents (METS)], moderate (3-6 METS) and vigorous (6+ METS) intensities by selecting the appropriate cut-off points of 3 and 6 METS to signify the lower and upper end of the moderate-intensity range. All activity occurring outside of this MET range was classified accordingly – either low intensity or high intensity. The goals for each participant were 10,000 steps and 30 minutes or more of \( \text{PA}^{\text{Mod}+} \) most days of the week. Data were retrieved for analysis via a computer interface and a software program provided by the manufacturer with the unit.

**Exercise Intervention Arms: Traditional and Group-Mediated Cognitive-Behavioral Modification**

Once subjects completed the 7-day consecutive recording, they returned the accelerometer and were officially randomized into one of the two study arms – TRAD or GMCB (Appendix T). Each arm is described in greater detail below.

**Tradition Group Exercise Sessions**

Participants within the TRAD exercise intervention were asked to complete center-based exercise on 3 days each week (M, W, and F) over a period of 3 months. In total, sessions lasted for approximately 60 mins and there were 36 sessions over the 12-week period for a total of 36 contact hours. Sessions were conducted by trained research
assistants. Prior to beginning the warm-up phase, subjects completed a TRAD Group check-in form (Appendix U) and had their blood pressure and glucose levels (if applicable) checked. Each session consisted of a warm-up (5 mins), an aerobic stimulus phase (30-35 mins) and a light, progressive resistance training phase (20-25 mins). The warm-up phase was conducted on the treadmill at a self-determined, light intensity – often 1.0 to 1.5 miles per hour. After several minutes, subjects ramped the speed (0.2 to 0.5 miles per hour) to an intermediate level at which they walked for another minute or two. Having completed a light warm-up, subjects moved the grade and speed in some combination to promote a walking intensity equal to between 50% to 85% of heart rate reserve and perceived exertion of 11-14 using Borg’s (21) 6 to 20 rating of perceived exertion (RPE) scale (Appendix V). While it was desired that subjects would ultimately spend 30-35 mins at this intensity by the end of the 12-week exercise intervention, there was some divergence among subjects throughout the training period. In place of continuous work, interval work was employed when necessary and 10-minute interval bouts were encouraged. Several subjects were only capable of completing 2-3 minutes of walking before resting phases were implemented.

Subjects were periodically asked RPE and knee pain symptoms (Appendix W) during the exercise sessions. Knee pain symptoms were rated on a 1-10 scale. If a subject’s RPE was ever rated at 14 or greater, they were instructed to back down on the walking intensity. If a subject’s knee pain symptoms ever reached a 6 or greater, they were asked to either back down on the intensity or take a short break. Of the subjects who were initially limited to less than 30 minutes of walking by either RPE or knee pain
symptoms, many progressed to the point of completing the desired duration by the completion of the 12-week exercise intervention.

Participants followed the aerobic exercise portion with a light, but progressive, lower-body leg-strengthening component. Typically, subjects completed seated leg extensions, standing hamstring curls, standing calf raises and a series of step ups (in that order). On occasion, pain symptoms limited subjects from completing one or more of the exercises. All strengthening exercises were completed using either body weight or a strap-on ankle weight of 2, 5 or 10 lbs. Regardless of the weight lifted, subjects were encouraged to complete 2-3 sets of 8-12 repetitions for each of the four exercises during each session.

**Group-Mediated Cognitive-Behavioral Modification Group Exercise Sessions**

To avoid undue influence and group-affiliation conflicts, group exercise sessions were held on different floors of the PAES building. In essence, apart from subjects being informed that two exercise groups existed, they were unaware of the structure, meeting times or meeting location of their randomized counterparts. Participants within the GMCB exercise intervention completed the same aerobic and leg-strengthening exercise prescriptions. The total contact hours were the same between the two exercise arms (36 hours). Despite these similarities, the structure, timing and goals of the groups differed intentionally. Sessions were conducted by trained research assistants. Prior to beginning
the warm-up phase, subjects completed a GMCB Group check-in form (Appendix X) and had their blood pressure and glucose levels (if applicable) checked.

The warm-up and walking phases were conducted in a large gym and subjects made laps around the area. Generally, subjects would take 1 to 2 minutes to complete a full lap around the walking area. The walking intensity was monitored with use of the RPE scale and intended to elicit an intensity equal to between 50% to 85% of heart rate reserve. The goal was for subjects to complete 30-35 minutes of continuous walking at this intensity by the completion of the exercise intervention. As with TRAD group sessions, subjects were periodically asked RPE and knee pain symptoms. An RPE of greater than 14 or a report of knee pain symptoms over 5 were followed with mitigation strategies – namely taking a rest. GMCB participants sat down in pre-placed chairs when needing to rest. The chairs were intentionally set in each corner of the gym to ensure quick access at all times. When subjects where incapable of completing longer walking durations, these chairs served as resting points for between-exercise rest intervals. Intervals of at least 10-minutes were encouraged when function allowed and pain symptoms were not exacerbated. The light but progressive lower- body weight training phase followed the aerobic portion of exercise.

When the exercise phase was completed, the GMCB members met for a 20-30 minute group-based, cognitive-behavioral activity counseling session. These sessions followed each center-based exercise session and a chronological list of the topics covered as listed below. Due to the extra time allotted for counseling, the GMCB group met with less frequency to standardize total contact hours. Specifically, the GMCB group met
twice weekly during month 1, once weekly during months 2-4, once every other week months 5-6 and they met for a monthly booster session during months 7-8. The purpose of the GMCB counseling was to directly assist participants with the application of greater amounts of purposeful and planned PA into their everyday life. The cognitive-behavioral activity counseling focused specifically on helping participants with the acquisition of self-regulatory skills necessary to be physically active while competing with the challenge of having KOA. Moreover, the group setting was used as an agent of behavioral change to facilitate participants with development and commitment to learning and independently practicing these skills in order to maintain long-term PA participation. While counseling sessions were staff–moderated, participant interaction and discussion was encouraged – and indeed, vital for the process. The basic principle underlying these contacts and their sequencing was to gradually wean participants from dependency on the exercise staff and group program toward independent, self-regulation of PA. In essence, a phased increase in personal responsibility concurrent with a phased decrease in staff, group and clinic dependency was the explicit intention.

**Chronological List of Group-Mediated Cognitive-Behavioral Modification Topics:**

- Group Introduction
- FITT Principles
- Knee Osteoarthritis
- Managing Pain
- Pain Management and Acceptance
- Goal Setting
- Goal Setting and Problem Solving
- Mind Body Self Monitoring
- Social Support
- Stress and Activity
- Emotional Landscape
- Cognitive Restructuring
- Personalized Motivation Plan
- Relapse Prevention
- Identifying Community Resources
- Transition to Independent Exercise

**Sample, Sample Size Justification and Inclusionary/Exclusionary Criteria**

Based upon a priori sample size estimations anticipating an effect size of 0.50 and a correlation of 0.70 between measures, target accrual for IMPACT-P was 90 participants. Participants were randomized into the 2 treatment arms using a standard 1:1 ratio in blocks of 5. A total of 80 participants (89% of target accrual) were recruited and randomized into the two arms (TRAD or GMCB) of the trial.
Inclusion Criteria

- Age ≥ 55 years
- Self-reported knee pain on most days of the month
- Sedentary activity pattern with less than 20 mins of formal exercise per week during the past 6 months
- Self-reported difficulty with at least one of the following activities due to knee pain: walking 0.25 miles (3-4 city blocks), climbing stairs, bending, stooping, kneeling, shopping, housecleaning; or other self-care activities such as getting in or out of bed, standing up from a chair, lifting and carrying groceries or getting in or out of a bathtub
- Radiographic evidence of Kellgren-Lawrence scale stage I or II (mild to moderate) tibiofemoral OA as determined by a single observer on the basis of weight-bearing anteroposterior x-rays
- Willingness to undergo testing and intervention procedure
- Free of any medical contraindications to participation in moderate exercise.

Exclusion Criteria

- Under age 55
- Radiographic but not symptomatic KOA
- Severe radiographic KOA with or without malalignment
- Medial or lateral malalignment issues
- Persons currently engaged in a regular exercise program on 3 or more days a week for more than 20 mins or having recently stopped a program of similar frequency and duration
- Medical conditions warranting the avoidance of moderate intensity exercise
- Neurological complications ranging from cognition to musculoskeletal balance

**Data Analysis**

Separate 2 (Treatment: TRAD and GMCB) x 2 (Time: baseline and 3 months) mixed model analysis of covariance (ANCOVAs) controlling for age were performed for the dependent variable variables of interest (data Appendix Y). The Least Significant Difference (LSD) procedure was conducted as post hoc analysis to determine the presence of significant mean differences. Effect sizes [ES – Cohen's d (d)] accompanying changes in the outcome variables were calculated by taking the mean difference and dividing by the pooled standard deviation. Partial correlation analyses, controlling for age, were conducted to examine relationships between select outcome variables (data Appendix Y).
CHAPTER 4: RESULTS

Special Note

Data collection for the 1-year follow-up period is presently ongoing. The results addressed are based mainly upon data collected at the baseline to 3-month follow-up assessment. Partial correlations are inclusive of currently collected 12-month data.

Characteristics of the Participants

A total of 180 participants contacted the investigators to inquire about participation. Of this applicant pool, fifty-three persons were not eligible for entrance into the study for failing to meet the following inclusion criteria:

- Medical contraindications \( (n = 18; 34\% \text{ of those ineligible}) \)
- Under required age \( (n = 16; 30\% \text{ of those ineligible}) \)
- Current exerciser \( (n = 12; 23\% \text{ of those ineligible}) \)
- Lack of documented KOA \( (n = 7; 13\% \text{ of those ineligible}) \)
Thirty-nine potentially eligible subjects choose not to enter the study due to an overall lack of time or an interfering engagement. While showing initial interest, eight subjects were not screened due to failing to return phone calls from researchers.

A total of 80 older adults (GMCB \( n = 40 \) and TRAD \( n = 40 \)) were eligible and agreed to participate in the IMPACT-P study. Baseline group characteristics are summarized in Table 4.1 and presented as means (M) and standard deviations (SD).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>GMCB Group M ± SD</th>
<th>TRAD Group M ± SD</th>
<th>Range All Subjects</th>
<th>( p ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>63.5 ± 7.1</td>
<td>63.5 ± 6.6</td>
<td>55 - 84</td>
<td>0.974</td>
</tr>
<tr>
<td>BMI (Kg/m(^2))</td>
<td>31.7 ± 8.8</td>
<td>33.0 ± 7.1(^\hat{\phantom{0}})</td>
<td>18.0 - 48.6</td>
<td>0.45</td>
</tr>
<tr>
<td>Stair Climb (sec)</td>
<td>11.87 ± 5.2</td>
<td>12.05 ± 3.7</td>
<td>6.22 - 25.19</td>
<td>0.858#*</td>
</tr>
<tr>
<td>Stair Climb SE</td>
<td>42.8 ± 28.0</td>
<td>41.5 ± 27.9</td>
<td>0 - 100</td>
<td>0.847</td>
</tr>
<tr>
<td>400-m Walk (min)</td>
<td>5.96 ± 1.6</td>
<td>6.43 ± 2.01</td>
<td>3.98 - 13.97</td>
<td>0.256</td>
</tr>
<tr>
<td>400-m Walk SE</td>
<td>73.0 ± 27.6</td>
<td>70.4 ± 27.6</td>
<td>5 - 100</td>
<td>0.677</td>
</tr>
<tr>
<td>CHAMPS PA(^{\text{Mod+}}) (hrs)</td>
<td>3.8 ± 4.8</td>
<td>5.9 ± 5.5</td>
<td>0 - 23.25</td>
<td>0.071</td>
</tr>
<tr>
<td>Lifecorder PA(^{\text{Mod+}}) (min)</td>
<td>53.8 ± 63.5(^\hat{\phantom{0}})</td>
<td>51.7 ± 70.0(^\hat{\phantom{0}})</td>
<td>0.1 - 275.1</td>
<td>0.893</td>
</tr>
</tbody>
</table>

Table 4.1 Baseline group characteristics \( n = 40 \) per group

*Note.* \(^\hat{\phantom{0}} n = 39; \# \text{violation of equal variance}; \# \text{significance level with equal variances not assumed}
Descriptive statistics for primary and secondary outcome measures (see Table 4.2) are presented below as M and SD.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>GMCB Group</th>
<th>TRAD Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline M ± SD</td>
<td>3-Month M ± SD</td>
</tr>
<tr>
<td>CHAMPS PA(^{Mod+}) (hrs)</td>
<td>3.8 ± 4.7</td>
<td>6.0 ± 6.0</td>
</tr>
<tr>
<td>Lifecorder PA(^{Mod+}) (min)</td>
<td>53.8 ± 63.5(^\wedge)</td>
<td>85.0 ± 77.4(^\wedge)</td>
</tr>
<tr>
<td>Stair Climb Task (sec)</td>
<td>11.87 ± 5.2</td>
<td>11.33 ± 5.2</td>
</tr>
<tr>
<td>Stair Climb SE</td>
<td>42.8 ± 28.0</td>
<td>48.7 ± 30.6</td>
</tr>
<tr>
<td>400-m Walk Task (min)</td>
<td>5.96 ± 1.6</td>
<td>5.64 ± 1.8</td>
</tr>
<tr>
<td>400-m Walk SE</td>
<td>73.0 ± 27.6</td>
<td>79.08 ± 29.2</td>
</tr>
<tr>
<td>WOMAC Pain Subscale</td>
<td>7.44 ± 3.5(^\wedge)</td>
<td>6.69 ± 4.1(^\wedge)</td>
</tr>
</tbody>
</table>

Table 4.2 Baseline and 3-month characteristics \(n = 40\) per group  
*Note.* \(^\wedge\) \(n = 39\)
Self-Reported and Objectively-Determined $\text{PA}^{\text{Mod+}}$

Self-Reported $\text{PA}^{\text{Mod+}}$: CHAMPS

Analysis of the CHAMPS data revealed a significant Treatment x Time interaction [$F(1, 76) = 5.259, p < 0.05$]. Main effects for Treatment [$F(1, 76) = 0.488, p = 0.487$] and Time [$F(1, 76) = 3.412, p = 0.069$] were not significant. Post hoc analyses revealed that self-reported $\text{PA}^{\text{Mod+}}$ increased significantly in the GMCB ($d = 0.41$) but did not change in the TRAD ($d = 0.04$) at the 3-month follow-up assessment.

Figure 4.1: Self-reported hours of $\text{PA}^{\text{Mod+}}$ as determined from CHAMPS PA questionnaire for older adults.
* Significant Treatment by Time Interaction ($p < 0.05$)
Objectively-Determined $\text{PA}^{\text{Mod+}}$: Lifecorder Accelerometer

Analysis of the accelerometry data yielded a significant main effect for Time $[F(1, 75) = 4.602, p < 0.05]$ and significant Treatment x Time interaction $[F(1,75) = 11.391, p < 0.05]$. The main effect for Treatment $[F(1, 75) = 2.195, p = 0.143]$ was not significant. Post hoc analyses revealed that objectively-determined $\text{PA}^{\text{Mod+}}$ increased in the GMCB ($d = 0.44$) but did not change in the TRAD ($d = 0.10$) at the 3-month follow-up assessment.

Figure 4.2: Objectively-measured minutes of $\text{PA}^{\text{Mod+}}$ as determined from the Lifecorder accelerometer.
* Significant Treatment by Time Interaction ($p < 0.05$)
Partial Correlation of Self-Reported and Objectively-Determined $PA^{\text{Mod}^+}$

The baseline partial correlation controlling for age indicated that there was a nonsignificant (df = 75, $p = 0.475$), positive, weak (0.083) association between self-reported and objectively-determined $PA^{\text{Mod}^+}$. Conversely, the partial correlations for the same measures at the 3 and 12-month assessments were significant ($p < 0.05$). At the 3-month assessment, the partial correlation (df = 75) was positive and moderate (0.409). At the one-year follow-up point, the association (df = 38) was positive but moderately-weak (0.322).

Stair Climbing Task and Mobility-Related SE for Stair Climb

Analysis of stair climb performance indicated that there were no significant main effects for Treatment [$F(1, 77) = 0.466$, $p = 0.497$] or Time [$F(1, 77) = 0.006$, $p = 0.926$]. The Treatment x Time interaction [$F(1, 77) = 2.877$, $p = 0.094$] was also non-significant. Analysis of mobility-related SE scores for stair climb yielded a significant main effect for Time [$F(1, 77) = 4.863$, $p < 0.05$]. Neither the main effect of Treatment [$F(1, 77) = 0.142$, $p = 0.707$] nor the Treatment x Time interaction [$F(1, 77) = 0.204$, $p = 0.652$] were significant. Post hoc analysis demonstrated that, when collapsed across treatment, mobility-related SE for stair climb significantly increased ($d = 0.17$) from baseline at the 3-month follow-up assessment.
Figure 4.3: Stair climb performance. Treatment by Time Interaction (p = 0.094)
Figure 4.4: Mobility-related SE for stair climb performance.
* Significant Main Effect for Time (p < 0.05)

Partial Correlation for Mobility-Related SE and Stair Climbing Task

Partial correlation controlling for age indicated a significant (p < 0.05), moderate association between mobility-related SE for stair climbing and stair climb performance at all three test-assessment points. The baseline association was moderately-strong and negative (df=77; -0.560). Similar outcomes were found for the 3-month (df=77; -0.501) and 12-month (df=57; -0.390) assessment points.
400-Meter Walking Task and Mobility-Related SE for 400-Meter Walk

Analysis of 400-meter walking performance indicated that there were no significant main or interactive effects – Treatment [F(1, 77) = 2.849, p = 0.095], Time [F(1, 77) = 2.79, p = 0.599] and Treatment x Time [F(1, 77) = 3.233, p = 0.076].

Analysis of mobility-related SE scores for the 400-meter walk yielded a significant main effect for Time [F(1, 77) = 4.010, p < 0.05]. The main effect of Treatment [F(1, 77) = 0.422, p = 0.518] and Treatment x Time interaction [F(1, 77) = 0.230, p = 0.633] were not significant. Post hoc analysis demonstrated that, when collapsed across treatment, mobility-related SE for the 400-meter walk significantly increased (d = 0.18) from baseline at the 3-month follow-up assessment.
Figure 4.5: 400-meter walk performance. Treatment by Time Interaction (p = 0.076)
Partial Correlation for Mobility-Related SE and 400-Meter Walking Task

Partial correlation controlling for age indicated a significant (p < 0.05), moderate association between mobility-related SE for walking performance and 400-m walking performance task at all three test-assessment points. The baseline association (df = 77) was strong and negative (-0.694). Moderately-strong outcomes were found for the 3-month (df = 77; -0.553) and 12-month (df = 56; -0.471) assessment points.
WOMAC Pain Subscale

Analysis of the WOMAC subscale for pain indicated a significant effect for Time [$F(1, 76) = 6.494, p < 0.05$]. The main effect of Treatment [$F(1, 76) = 0.176, p = 0.676$] and Treatment x Time interaction [$F(1, 76) = 0.107, p = 0.745$] were not significant. Post hoc analysis demonstrated that, when collapsed across treatment, WOMAC pain decreased significantly ($d = 0.21$) from baseline at the 3-month follow-up assessment.

Figure 4.7: Reported pain symptoms as determined by the WOMAC pain subscale. * Significant Main Effect Time ($p < 0.05$)
CHAPTER 5: DISCUSSION

KOA accounts for more limitations in the performance of functional daily activities than any other disease (66). Research indicates that the disease has multiple etiologies and that muscle weakness, fatigue, joint stiffness and pain accompany the chronic condition (26, 51, 81). These adverse symptoms facilitate the deleterious, progression of activity avoidance, muscle atrophy and reduced functional ability often seen in this clinical population. Older adults cite KOA pain as a primary cause for activity restriction and physical disability (43, 91). There is mounting evidence that exercise is an efficacious, nonpharmacological behavioral therapy for combating both primary and secondary pathologies (6, 46, 49, 50, 63, 76, 86, 98, 100, 115, 120, 134, 138). Consistent with this claim, PA is now advocated by as an essential portion of the medical management of KOA (1, 3, 113). While PA is a favorable adjuvant behavioral intervention in older, KOA patients, evidence-based best practices for delivering exercise interventions and for promoting PA adoption and long-term adherence are lacking. Evidence of the long-term improvements in OA outcomes following PA interventions is limited. More concerning, improvements in OA outcomes accompanying PA interventions have been shown to dissipate considerably over time (46, 86, 115). As post-intervention non-compliance (46, 49, 86, 115, 123) is highlighted as the key suspect of this detrimental occurrence, targeting this particular issue is paramount. Despite the
employment of strategies such as positive reinforcement and goal setting with exercise trials, the deleterious effects of non-compliance and attrition remain high (46, 86, 108, 115). Determining more efficacious delivery strategies, promoting exercise participation and promoting long-term maintenance of PA in the treatment of KOA are pressing concerns. Results from IMPACT-P provide evidence to address some of the key issues.

**The Effects of the Exercise Interventions on Self-Reported and Objectively-Determined PA$^{\text{Mod+}}$**

Exercise interventions consistently yield meaningful improvements in a variety of clinically relevant outcomes for older, KOA patients. Unfortunately, exercise interventions targeting KOA patients are plagued by high attrition rates and poor long-term adherence. Traditional exercise interventions alone may not be sufficient to assist patients in successfully making the transition from center-based exercise participation to independent PA participation. Several promising results have arisen from recent GM CB trials (28, 125, 126) and, indeed, GM CB interventions appear more-suited at meeting specific needs associated with successfully facilitating this transition and moreover, long-term maintenance (7, 59, 60, 82, 101-104, 131). Accordingly, the primary aim of IMPACT-P was to compare the efficacy of the GM CB intervention with those observed with a TRAD PA intervention upon PA$^{\text{Mod+}}$. In line with the hypothesis, self-reported PA$^{\text{Mod+}}$ increased significantly in the GM CB but not the TRAD group when comparing respective baseline and 3-month follow-ups. In addition, the GM CB, but not the TRAD group, engaged in greater amounts of objectively-determined PA$^{\text{Mod+}}$ at the 3-month
follow-up. An increased volume of self-reported and objectively-determined PA\textsuperscript{Mod+} in the GMCB at the 3-month follow-up is consistent with findings from previous trials employing GMCB interventions (28, 57, 125, 126). The observation of a significant difference in PA\textsuperscript{Mod+} at the 3-month follow-up with the GMCB treatment arm provides further support for the efficacy of the GMCB approach relative to traditional exercise interventions in producing meaningful changes in PA participation among older, KOA patients. This finding directly addresses two of the primary gaps in literature: the GMCB strategy promotes greater levels of PA participation relative to a TRAD approach and the GMCB appears to be a superior method of delivering exercise interventions to older, KOA patients compared with TRAD approaches. Given that both exercise interventions exposed participants to the same exercise prescription and total amount of contact hours, the self-regulatory skills counseling and systematic transition from center-based to home-based exercise participation appears to favorably influence overall PA levels. This skill-set was only provided to the GMCB. Perhaps this divergence in intervention structure is conveyed in these differences in PA\textsuperscript{Mod+} at the 3-month follow-up assessment. SE is a known mediator in behavioral change processes (7, 102, 119) and an important determinant, mediator and outcome within exercise interventions (49, 59, 60, 79, 82, 101, 103, 105, 126). SE is gathered through mastery experiences and social persuasion (7) among other factors. Capitalizing on this recognized relationship was a key aim of the GMCB strategy. It is reasonable to suspect that group motivational aspects, mastery experience and social persuasion helped foster these differences in PA\textsuperscript{Mod+} that were found at 3-months. A survey of literature indicates that GMCB interventions have been
successful at promoting increased exercise engagement when compared with other strategies (57, 125, 126) and present results strengthen the evidence of the effectiveness of this strategy for the KOA population.

Discrepancies between self-report and objectively-determined PA are common in literature with overestimation of self-report PA being frequently observed. The association between reported and actual PA engagement has been shown to be generally modest and quite variable (32). Results of correlation analyses of baseline PA levels in IMPACT-P demonstrated that the baseline relationship between self-reported and objectively-determined PA was low (0.083) and nonsignificant (p = 0.475). Self-report PA^{Mod+} at baseline (M = 4.99 hours) was considerably higher than PA^{Mod+} determined objectively (52.76 minutes). Thus, it appears older adults with KOA may considerably overestimate their time spent participating in PA of moderate intensity or greater. It is also possible that older, sedentary KOA patients may have difficulty distinguishing what constitutes moderate intensity or greater PA. This delineation is, no doubt, difficult for sedentary individuals that do not exercise regularly. These factors may have contributed to the weak relationship observed between self-reported and objectively-determined physical activity observed at baseline in the present pilot trial. Members of both exercise interventions were prescribed moderate-intensity aerobic exercise as the bulk of the exercise session. This afforded each subject multiple occurrences to conceptualize, feel and understand the physical and physiological changes accompanying such PA. In addition, sessions provided subjects with the opportunity to safely and successfully complete an aerobic walking program – mastery experience. It is plausible to speculate
that a better understanding of actual exercise intensity and a greater engagement in exercise is what lead to moderately-strong associations between self-report and objectively-determined PA_{Mod} at the 3-month (0.409) follow-up. Limited data has currently shown the partial correlation at the 12-month follow-up to be weakening (0.322). Whether this might be partially explained by a diminishing acuity of true moderate-intensity exercise is interesting but certainly not demonstrable presently.

**The Effects of the Exercise Interventions on Performance Measures of Physical Function**

Given that both intervention arms were provided with an active exercise intervention, equivalent contact hours and the same exercise stimulus, it was hypothesized that improvements in performance measures of physical function (stair climb and 400-meter walk) would be similar between exercise interventions at the 3-month follow-up assessment. In actuality, the Treatment x Time interaction (p = 0.094) for the stair climb task and the Treatment main effect (p = 0.095) and Treatment x Time interaction (p = 0.076) for the 400-meter performance each approached significance suggesting that there was a trend toward more favorable performance following the GMCB intervention. In interpreting these findings, it should be recognized that IMPACT-P was a pilot study conducted, in part, to determine the effect size differences accompanying the primary and secondary outcomes between the GMCB and TRAD intervention arms. Thus, it is possible that although there was a trend towards more favorable mobility performance following the GMCB intervention, the sample size of 40
participants per treatment arm was insufficient to detect the Treatment main effect and Treatment x Time interactions for the stair climb and 400-meter walk performance. It is also plausible that the baseline levels of function may have curtailed the ability to detect a difference in functional performance at the 3-month follow-up assessment. Prior research has demonstrated that initial levels of physical function are significant predictors of improvements in functional performance following participation in exercise interventions with those participants with the worst functioning at baseline demonstrating the greatest post-exercise improvement in functional performance (57, 60). Thus, improvements in functional performance may be blunted among individuals with more favorable baseline functional status (57, 125). Although methodological and sample differences across studies somewhat limit the ability to directly compare the baseline functional status of IMPACT-P participants to past exercise intervention trials, it appears as though baseline functional performance was reasonably similar. For example, Ettinger (49) and colleagues report results for stair climb tasks (M = 13.23 seconds) and 6-min walk tasks (M = 433 meters walked). Results from IMPACT-P for stair climb (M = 11.96 seconds) and 400-m walk performance (M = 6.2 minutes) are comparable. The comparison of velocity in meters/second (m/s) is precluded. IMPACT-P participants walked a 20-m course down and back 10 times (M = 1.1 m/s) while members in the FAST trial (49) walked at 1.2 m/s but had less turns. Accounting for 2 turns at the end of each 20-m length would decrease the overall velocity of the walk. While a group of older adults from the CHAMP trial averaged 1.4 m/s walking speed for a 6-min trial, these were non-KOA patients (125). The use of baseline pain symptoms to indicate disability is not
appropriate due to among other factors: variation in pain threshold, day-to-day variation in pain and discrepancy in symptomatic reports of KOA and functional outcomes (12).

The Effects of the Exercise Interventions on Mobility-Related Self-Efficacy

Findings from the IMPACT-P trial revealed that the GMCB and TRAD exercise interventions yielded similar improvements in mobility-related SE for stair climb and 400-m walk performance. It is well established that exercise interventions consistently result in significant improvements in exercise and mobility-related SE beliefs (49, 59, 60, 79, 82, 101, 103, 105, 126). Thus, the present findings are consistent with results of prior studies examining the effects of exercise on SE beliefs in older adults.

Task SE has also been shown to be related to performance measures of mobility and/or physical function in prior exercise trials targeting KOA patients (49, 60, 108). Consistent with these findings, correlation analyses demonstrated significant relationships between mobility-related SE beliefs and the respective stair climb and 400-meter walk performance at both baseline and 3-month follow-up assessments. The nature of this relationship revealed that participants reporting the higher task SE demonstrated the greatest performance on each respective mobility task. Several studies have demonstrated that SE is one of the strongest, most consistent correlates of PA participation and improved physical function in older adults (125-128, 131, 132). The present results provide further evidence of the beneficial effect of exercise participation upon SE judgments. These findings also underscore the value of actively targeting
improvements in mobility-related SE beliefs in future exercise intervention trials among older adults burdened with KOA.

**Pain Symptoms**

Pain is one of the main adverse symptoms of KOA and is frequently cited by patients as a primary cause of activity restriction and disability. Consistent with findings of prior exercise-KOA trials (15), the exercise interventions in IMPACT-P resulted in significant improvements in self-reported pain symptoms. As hypothesized, there were no differences between the 2 treatment arms in improvement in pain reported at the 3-month follow-up assessment. Thus, the present findings provide additional support for the efficacy of exercise in alleviating KOA-related pain symptoms (6, 46, 49, 50, 56, 63, 72, 86, 98, 100, 108, 109, 115, 120, 134, 138, 152). The findings also suggest that both the GMCB and traditional approach to exercise therapy yield comparable short-term improvements in pain symptoms among older adults with KOA.

Significant improvements in both pain symptoms and physical function have been reported within the same research trial after exercise interventions (49, 63, 86, 100, 115, 150, 151). Additionally, improvements in pain symptoms without accompanying improvements in physical function (6) or HRQOL (14, 86) have also been shown in the same trial within the extant KOA literature. Consequently, the significant decrease in pain symptoms and the trend towards improvement in climbing and ambulatory functional tasks is consistent with prior findings in the extant KOA literature. Roddy and
colleagues make note that there are no distinguishing characteristics between trials which show improvements in pain and function or pain and HRQOL and those that improve pain symptoms but not another salient outcomes (133). Moreover, even if multiple outcomes were to change, one should not assume that they change to the same magnitude (46, 49, 86, 108, 115, 138) or in the same course of time (124). The lack of significant change in the functional tasks should not overshadow the fact that study subjects realized significant reductions in pain.

**Conclusion**

The objective of the IMPACT-P trial was to examine the comparable efficacy of GMCB and TRAD interventions in producing improvements in PA, physical function, and pain symptoms in a sample of sedentary, older adults with KOA. Exercise has consistently been shown to yield meaningful improvements in a variety of physiologic and QOL outcomes in KOA patients. Given that both treatments in IMPACT-P involved active exercise interventions during the 3-month intensive phase of the trial, it was hypothesized that the interventions would result in comparable improvements in each of the primary and secondary outcomes at 3-month follow-up and that meaningful differences between the 2 interventions would emerge at the more distal 12-month follow-up assessment. In contrast to these hypotheses, the GMCB intervention resulted in superior improvements in self-reported and objectively-determined PA^{Mod+} at the 3-month assessment. Additionally, trends towards superior improvement were also
observed in mobility performance outcomes following the GMCB intervention. These findings suggest that, although the benefits of the GMCB approach were hypothesized to elicit long-term benefits, the GMCB approach may also yield superior short-term improvements in PA participation relative to a traditional approach to exercise therapy.

Both exercise interventions resulted in significant, comparable improvements in physical function, pain symptoms and mobility-related SE. Thus, the present findings provide support for the benefits of exercise therapy in the treatment of KOA patients. However, given that the persisting challenge of promoting regular adherence to exercise undermines the treatment efficacy of exercise therapy, the superior improvements in moderate intensity or greater physical activity participation accompanying the GMCB intervention underscore the potential utility of integrating this intervention in the treatment of KOA patients.

In summary, an exercise intervention designed to provide training and practice in activity-related behavioral self-regulatory skills may enhance short-term maintenance of exercise participation. Evidence from IMPACT-P may serve to promote the GMCB approach as a valuable intervention strategy for the design and delivery of future interventions targeting the promotion of PA participation in older, KOA patients.
REFERENCES

2. ACR. Practice Management - Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [07/05, 2011].


127. Rejeski WJ, Brubaker PH, Goff Jr DC, Bearon LB, McClelland JW, Perri MG, and Ambrosius WT. Translating Weight Loss and Physical Activity Programs Into the Community to Preserve Mobility in Older, Obese Adults in Poor Cardiovascular Health. *Archives of Internal Medicine* 2011.


Appendices
Appendix A

Original Institutional Review Board Document
INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH
The Ohio State University Institutional Review Board
Office of Responsible Research Practice (ORRP)
300 Research Foundation Building 1940 Kenny Road, Columbus, OH 43210
Phone: (614) 292-8537 Fax: (614) 292-8514 www.orrpi.osu.edu

<table>
<thead>
<tr>
<th>NAME</th>
<th>DATE RECEIVED</th>
<th>DATE VERIFIED COMPLETE</th>
<th>OSU PROTOCOL NUMBER</th>
</tr>
</thead>
</table>

1. PROJECT TITLE
Promoting physical activity in older adults with knee osteoarthritis

2. INSTITUTIONAL REVIEW BOARD
Select the Board to review this research
☐ Behavioral and Social Sciences
☐ Biomedical Sciences
☐ Cancer

3. PRINCIPAL INVESTIGATOR (or Advisor) – See Qualifications to serve as PI
Name(s) (Last, First, MD): Focht, Brian C
Department: PhD
University Academic Title: Assistant Professor
Department of: Public Health
Organization Name (TD): Health Behavior and Health Promotion
Department # (TD):
Campus Mail Address: 4450 Senior Hall
841 Neil Ave
Columbus, OH 43210
E-mail: bfocht@ph.osu.edu
Fax: 614-292-3141
Phone: 614-292-3940

4. CO-INVESTIGATORS
Are there any OSU Co-Investigators on this protocol? ☐ Yes ☑ Complete Appendix A1
Original signatures of Co-Investigator(s) are required. ☐ No

5. OTHER KEY PERSONNEL
Are there any OSU key personnel on this protocol? ☐ Yes ☑ Complete Appendix A1

6. ADDITIONAL CONTACT
If further information about the application is needed, specify the contact person other than the PI (e.g., study coordinator, research assistant, etc.).
Name(s) (Last, First, MD):
Phone:
E-mail:
Fax:

7. EDUCATION
Have all OSU investigators and key personnel completed the required web-based course (SSH) in the protection of human research subjects? ☑ Yes ☐ No
8. CONFLICT OF INTEREST

Does any OSU investigator (including principal investigator, key personnel, or their immediate family members) have a significant financial interest (e.g., speaking and consultation fees, travel expenses, patent income) in the related product, stock ownership, or other equity or membership in the sponsor or $10,000 per year expenses for which the investigator may benefit from the research? Enter ORC if appropriate.

Yes $ No

Is the PI a key personnel for the research, but not an investigator? Enter ORC if appropriate.

Yes $ No

9. EXPEDITED REVIEW

Are you requesting Expedited Review? $ Yes ☑️ $ Complete Appendix E $ No

10. FUNDING

Is the research funded or has funding been requested? $ Yes ☑️ $ No $ No

If Yes, specify sponsor and provide OSUF project number

11. OTHER INSTITUTIONAL APPROVALS

Check all that apply and provide applicable documentation:

☐ None
☐ General Clinical Research Center Advisory Committee (GCRC) - for research conducted in the General Clinical Research Center (GCRC). Contact 293-9830 or visit www.osumc.edu
☐ Institutional Review Board (IRB) - for research involving human subjects (capable of providing informed consent), animal subjects, or unusual risks. Contact 293-9830 or visit http://osp.osu.edu/biorec/
☐ James Cancer Center Clinical Scientific Review Committee (JCC) - for research involving human subjects. Contact 293-9740 or visit www.osumc.edu
☐ Maternal Fetal Committee - for research involving human subjects. Contact 293-9578.
☐ Radiation Safety Committee - for research involving radiation or radioactive materials (e.g., MRI scans, X-rays, radionuclides, and CFL bulbs). Contact 293-9784 or visit www.osumc.edu/radiation

*IRB and ORC review may be performed concurrently; ORC approval must be provided to the IRB before you begin the research.

12. LOCATION OF THE RESEARCH

- List the specific site(s) at which the OSU research will be conducted (include both domestic and international locations).

<table>
<thead>
<tr>
<th>Location Name (description)</th>
<th>Street address</th>
<th>City, State or Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>The OSU Center for Wellness and Prevention</td>
<td>2550 Kenny Rd.</td>
<td>Columbus, OH</td>
</tr>
<tr>
<td>The General Clinical Research Center</td>
<td>Davis Medical Research Center 430</td>
<td>Columbus, OH</td>
</tr>
</tbody>
</table>
13. SUMMARY OF THE PROTOCOL

The proposed research will compare the effects of exercise + group-based self-regulatory skills counseling (SREK) intervention with the effects of exercise alone (EX) on physical activity participation, physical function, and quality of life among older adults with knee osteoarthritis. The study will be a randomized controlled investigation consisting of an intervention group (SREK) and a comparison group (EX). The intervention group will participate in an exercise program consisting of walking and lower body strength training for 3 months. Participants will complete 3 exercise sessions/wk in month 1, 2 exercise sessions/wk during month 2, and 1 exercise session/wk during month 3 while progressively increasing their independent knee-based exercise participation. Each exercise session in the SREK intervention will be followed by 20-min of group-based self-regulatory skills counseling, intended to help participants become confident in their ability to exercise independently while concurrently phasing out center-based activity over an initial 3-month period. The comparison group (EX) will participate in the same exercise program 3 times/wk for 3 months but will not receive the self-regulatory skills counseling component. Both groups will participate in 2 screening visits (SV) at baseline and 3-month and 12-month follow-up assessments. During SV1, conducted in the Exercise Behavior Lab at 445 Cunt Hall, participants will complete the all questionnaire measures and tests for six-minute walk and stair climb performance as well as a leg extension strength test. During SV2, conducted at the OSU GRC, participants will complete a graded exercise test under the supervision of trained exercise and medical staff. During the week immediately following SV2, participants will wear an accelerometer to record their physical activity participation and complete a questionnaire assessment of their physical activity on day 7 of this week. All participants will perform the screening visits and week of physical activity assessment at each of the baseline, 3-month and 12-month assessment intervals.

The risk associated with the proposed research is minimal. Participants may feel some discomfort associated with the exercise stress test; muscle aches and joint pain is common. The risk of serious injury due to participation in an exercise test is present but negligible. Only 1 in 10,000 exercise test participants experience a serious injury. There may be mild muscle pain or discomfort associated with participating in both exercise programs. However, participants will receive medical clearance from Dr. Hachshar and/or their primary care physician prior to participating in the exercise program. Participants will also be supervised at all times by trained exercise staff during each center-based exercise session. The benefits associated with the proposed research include aiding in the understanding of how to promote active lifestyles in older adults with knee OA and how exercise enhances quality of life and physical function. The findings have implications for the treatment of older adults burdened with knee OA.
14. SCIENTIFIC BACKGROUND & LITERATURE REVIEW

Summarize existing knowledge and previous work that support the expectations of obtaining useful results without undue risk to human subjects. Use complete sentences (limit 200 words).

Evidence from several randomized controlled trials demonstrates that exercise participation results in significant improvements in physical function and quality of life in older persons with knee OA. Despite the benefits accompanying exercise, maintenance of physical activity participation among older knee OA patients remains problematic. One potential explanation for the excessive attrition from structured exercise programs is that traditional approaches to exercise therapy fail to provide adequate instruction or practice in the self-regulatory skills necessary to maintain independent, long-term participation. Providing older adults with training intended to enhance their self-efficacy to perform regular exercise, improve their ability to set appropriate goals, and effectively problem-solve to overcome common barriers to a physically active lifestyle may aid in promoting physical activity in this population. Therefore, the primary goal of this investigation is to determine if adding a self-regulatory skills training component to a physical activity intervention will result in higher weekly frequency and volume of moderate intensity or greater physical activity (PAHv) at 3 months and 12 month follow-up assessments when compared to a traditional physical activity intervention.

15. RESEARCH OBJECTIVES

List the specific scientific and scholarly aims of the research study.

The specific aims of the research study are to examine the effects of a 3-month SREX and traditional exercise programs on:
1. Total volume of physical activity participation
2. Physical function
3. Mobility-related self-efficacy
4. Quality of life
5. Leg extension strength

16. RESEARCH METHODS & PROCEDURES

a. Identify all procedures that are to be performed solely for the research study. Distinguish between activities from non-research activities.

1. The collection of physical activity participation, physical function performance, and self-reported quality of life data
2. Random assignment of participants to either SREX or traditional exercise programs.

b. Check all research procedures that apply:

- Materials that may be considered sensitive, offensive, threating or disgusting
- Noninvasive medical procedures (e.g., ERG, Doppler)
- Observation of participants (including field notes)
- Oral history (does not include medical history)
- Placebo
- Pregnancy testing
- Program Protocol (Umbrella Protocol)
- Radioactive or other sources of ionizing radiation
- Radioactive materials (require approval from Radiation Safety Committee)
- Randomization
- Record review (which may include PHI)
17. DURATION

Estimate the time required from each participant, including long-term follow-up, if any. Describe the time commitment in detail.

Participants will complete three assessments during the course of the study. Baseline and 3 and 12 month follow-up assessments will require 1.5 hours each. Thus, the assessments will require a total of approximately 4.5 hours. In addition, participants will spend 38 hours (3 hours per week for 13 months) participating in the SNEAK and traditional EX program. The overall total time commitment is approximately 40 hours. At total of approx. 38 hours of participation will occur during the first 3 months of participation with the final 1.5-2 hours of participation occurring at the 12-month follow-up assessment.

18. NUMBER OF PARTICIPANTS

a. Provide the maximum number of participants (or number of participant records, specimen, etc.) for whom you are seeking OSU IRB approval.

   The number of participants is defined as the number of individual whose records are accessed, etc., even if all do not complete the study.

b. Explain how this number was determined.

   A power analysis is used to determine the number of participants needed to detect a meaningful difference in the outcomes of interest between the intervention and standard treatment groups.

c. Is this a multicenter study?  Yes  No

   Indicate the number of sites to be used across all sites:

19. PARTICIPANT POPULATION

a. Specify the age(s) of the individual(s) who may participate in the research:

   Age(s): 21-30

b. Specify the population(s) to be included (check all that apply):

   - Adults
   - Adults unable to consent for themselves
   - Children (<18 years)  Complete Appendix I
   - Healthy volunteers
   - Native English speaking  Complete Appendix J

   - Pregnant Women or Menopausal  Complete Appendix K
   - Prisoners  Complete Appendix L
   - Psychologists
   - Student participants (other than ELP)

   Specify:

   Unknown (e.g., research with secondary data, specimens, hospital census, program files)
a. Describe the characteristics of the population(s) and explain how the nature of the research requires (justifies) the inclusion of the proposed population(s).

The population to be studied consists of healthy, sedentary older adults diagnosed with knee osteoarthritis. This is an ideal population to investigate the effectiveness of exercise as an adjuvant strategy for enhancing physical function and quality of life.

d. If pregnant women are to be excluded, explain how the nature of the research requires (justifies) their exclusion. Address means of pregnancy screening.

Pregnant women will not be specifically excluded. Nevertheless, given the age range of the participants to be included in the present sample, we do not anticipate having any pregnant women, or potentially pregnant women participate in the study.

20. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Describe how potential participants will be identified (e.g., advertising in local newspapers, social media sites). Explain how the method(s) for identifying potential participants respect their privacy.

Participants will be recruited through Dr. Kevin Hackshaw's Rheumatology Clinic located at The Ohio State University. Participation is voluntary, and potential participants will be informed by the Principal Investigator. Dr. Hackshaw will discuss the study with his patients and subsequently refer all sufficiently healthy knee OA patients satisfying the eligibility criteria who express an interest in participating to Dr. Focht. Dr. Focht will contact these patients by phone. During this phone contact, investigators will provide a description of the study and conducting prescreening evaluation of study eligibility.

b. State who (investigators and/or study personnel) will recruit participants and what process will be used to determine participant eligibility.

Dr. Hackshaw and Dr. Focht will be the primary contacts for recruitment. Knee osteoarthritis patients treated in Dr. Hackshaw's office who are sedentary and sufficiently healthy to participate in an exercise program will be recruited to participate in the study. Screenings for medical contraindications to exercise will be conducted via Dr. Hackshaw and his medical staff and reconfirmed by completion of a medical history questionnaire during the baseline assessment.

c. Describe the recruitment process, including how and when recruitment will take place. Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, oral/written scripts).

Recruitment will take place by telephone contact from Dr. Focht's lab.

d. Explain how you will assess that recruitment and selection of participants is equitable.

We will attempt to recruit every potential participant who sites an interest in participating to Dr. Hackshaw. However, given that the majority of patients diagnosed with knee OA are women, we anticipate approximately 25% of our sample will be men.

21. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other inducements (e.g., free samples, cash payments, gift certificates, parking, classroom meals, travel reimbursement) to participate in the research study? Y/N

If Yes: Describe the inducement. Compensation should be proportionate (e.g., per visit) and not unduly encourage study completion.
This payment will be on a scale which will aid in retention. The schedule will be on the 2 screening visits conducted at each of the baseline, 3-month, and 12-month assessments. Participants will receive $50 for each assessment for a total of $150 in incentives during the study. Participants will also receive $4 parking reimbursement and $20 gas reimbursement for each assessment visit.

<table>
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<tr>
<th>22. INFORMED CONSENT PROCESS</th>
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<tbody>
<tr>
<td>a. Indicate the consent process(es) and documentation to be used in the study. Check all that apply. Provide copies of documents (using CSU template) and/or complete relevant appendices, as needed. See <a href="http://form.csueb.edu/consent/medical">http://form.csueb.edu/consent/medical</a> or contact CERP for more information.</td>
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<td>□ Assent - Verbal Script</td>
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<td>□ Informed Consent - Form</td>
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<td>□ Informed Consent - Verbal Script → Complete Appendix M2</td>
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<tr>
<td>□ Informed Consent - Addendum → Complete Appendix M2</td>
</tr>
<tr>
<td>□ Written Consent/Disclosure → Complete Appendix M1</td>
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</table>

b. Describe the consent process. Explain when and where consent will be obtained and how participants and/or their legally authorized representatives will be provided sufficient opportunity to consider participation. Informed consent will occur upon the participant's first visit. The consent form will be given by a member of the investigative team who is familiar with all aspects of the research study. The consent form will be thoroughly explained and the subject will be given ample time to read the consent form and ask questions. Subjects will be given sufficient time to read the document without the presence of a member of the investigative team. In addition, participants will be reassured that there will be no negative consequences if they decide not to participate for any reason.

c. List the investigator(s) and/or personnel who will obtain consent from participants or their legally authorized representatives.

Brian C. Focht

| M/A |

d. Explain how the possibility of coercion and undue influence will be minimized in the consent process.

The consent form will be thoroughly explained and the subject will be given ample time to read the consent form and ask questions. Subjects will be given sufficient time to read the document without the presence of a member of the investigative team. In addition, participants will be reassured that there will be no negative consequences if they decide not to participate for any reason.

a. Will any other book (e.g., patient, visual aids, information sheet) be used during the consent process to assist participants or explain the study? □ Yes → Provide copies of these books. □ No

f. Will any other consent forms be used (e.g., for clinical procedures such as MRIs, surgery, etc.) and/or consent forms from other institutions? □ Yes → Provide copies of these forms. □ No

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<th>23. CAPACITY TO CONSENT</th>
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<tr>
<td>Will adult participants with limited decision making capacity or who lack the ability to consent be recruited in this research study? □ Yes □ No</td>
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</table>
If Yes \( \Rightarrow \) Describe the likelihood of participant impairment and explain how and by whom the capacity to consent/consent will be determined. For adults unable to provide legally acceptable consent, indicate whether consent will be obtained, or if not explain why not.

### 24. PRIVACY & CONFIDENTIALITY

<table>
<thead>
<tr>
<th>a.</th>
<th>Does the research require access to personally identifiable private information?</th>
<th>Yes</th>
<th>No</th>
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<td></td>
<td>If Yes ( \Rightarrow ) Explain the steps you will take to ensure protection of the participants' privacy.</td>
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<td></td>
<td>All personally identifiable information will be kept in a locked filing cabinet under the direct supervision of the principal investigator's supervision.</td>
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<td>b.</td>
<td>Will personal sensitive information (e.g. relating to illegal behaviors, alcohol/drug use, sexual attitudes, mental health, etc.) be assessed or collected from participants?</td>
<td>Yes</td>
<td>No</td>
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<td>If Yes ( \Rightarrow ) Explain information.</td>
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<td>c.</td>
<td>Could disclosure of information be potentially damaging to participants' financial standing, employability or reputation, or place the participant at risk of criminal or civil liability?</td>
<td>Yes</td>
<td>No</td>
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<td>If Yes ( \Rightarrow ) Explain.</td>
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<td>d.</td>
<td>Explain how you will protect the confidentiality of identifiable data, including where data will be stored, what security measures will be applied, and who will have access to the data.</td>
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<tr>
<td></td>
<td>All personally identifiable information will be kept in a locked filing cabinet under the direct supervision of the principal investigator's supervision.</td>
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<td>e.</td>
<td>Why are obtaining a HIPAA Certificate of Confidentiality?</td>
<td>Yes</td>
<td>No</td>
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<td></td>
<td>( \Rightarrow ) Provide a copy before you begin the research.</td>
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<tr>
<td>f.</td>
<td>Explain any circumstances (official or legal) in which it would be necessary to breach confidentiality.</td>
<td>NA</td>
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</tr>
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</table>

| g. | Indicate what will happen to the identifiable data at the end of the study. Check all that apply: |
|    | - [ ] Identify, suspend, or permanently anonymize from the data |
|    | - [ ] Identifiable/linked data is maintained |
|    | - [ ] Other, specify: |
|    | [ ] NA |

| h. | Indicate how study results might be disseminated. Check all that apply: |
|    | - [ ] Conference Presentation |
|    | - [ ] Dissertation/Thesis |
|    | - [ ] Publication/Journal Article |
|    | - [ ] Other, specify: |
25. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements be accessed, used, or disclosed in the research study?

☐ Yes

☐ No → Go to Question 26

If Yes → Will a written authorization be used?

☐ Yes → Provide a copy of the Authorization Form:

a. Describe the PHI involved in the research (e.g., demographic information, health history, diagnosis, treatment). Be as specific as possible. Provide a copy of the data collection form(s) to be used.

b. List the source(s) of the PHI (e.g., OSUMC Information Systems, patient’s own records, etc.), including whether any information will be obtained from sources external to OSU.

☐ No → Indicate the type of waiver or approval requested (check all that apply) and complete Appendix II:

☐ Partial Waiver (research purpose only)

☐ Full Waiver (study not human subjects)

☐ Authorization (written documentation)

26. RISKS, HARMs, & ITS COMPENSATION

a. Indicate all risks/discomfort that may apply to the research study:

☐ Enrichment of confidentiality

☐ Discovery of previously unknown condition

☐ Economic risk

☐ Invasion of privacy (participant or other individual)

☐ Physical injury or discomfort

☐ Psychological stress

☐ Risk to reputation

☐ Social or legal risk

☐ Other

Specify:

b. For each category of risk checked above, describe the specific risk. For physical injury or discomfort include the following:

- Frequency/likelihood of occurrence

- Potential severity of the harm/discomfort

- Possible consequences (including long-term effects)

Refer to the section of this application (e.g., Appendix III, for drugs) if the risks are described elsewhere.

During the exercise test, participants may be told of cardiac irregularity. There is minimal risk of injury to participants during the exercise test. Injuries have occurred in 1 out of 10,000 exercise tests, even in populations with known heart problems. There is a risk of minimal discomfort with the exercise programs being conducted.

c. Describe the specific precautions that will be used to minimize the identified risks and harms.

Trained personnel from the OSU CRC will be present at the time of all exercise testing to minimize the risk of injury. All exercise training sessions will be conducted by qualified personnel who will maintain an open line of communication with participants to ensure that there is no extreme discomfort or strain associated with the exercise.
27. MONITORING

Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected)
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee)
- Timing of monitoring (e.g., at specific points in time, after specific number of participants have been enrolled) and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

All adverse events that occur will be reported immediately to the principal investigator. A written report concerning the incident will be completed within 48 hours and reported to the OSU IRB. When necessary, procedures will be reviewed to determine how to reduce risk without altering the study protocol.

Close contact between the principal investigator and study personnel will occur via regular meetings to ensure strict adherence to the study protocol. All data will be stored in a locked filing cabinet under the principal investigator's supervision.

The exercise testing will be conducted at the OSU GCRC by trained personnel under the supervision of a physician. The questionnaire, physical function (1-minute walk and stair climb tests), and leg strength assessments will be completed in the Exercise Behavior Lab 444 Curt Hall by trained personnel under the supervision of a Dr. Focht. Exercise training will take place at the OSU Center for Wellness and Prevention. All training will be conducted by trained exercise leaders and physician coverage is provided. Participants will have the contact information of the study coordinator so that they can report any adverse events or ask questions at any time. The principal investigator will maintain regular contact with study personnel to monitor participant safety. It is found that the study is having a deleterious effect on participants, then the study will be stopped.

28. REASONTABLY ANTICIPATED BENEFITS

List the potential benefits that participants, society, and/or others may expect as a result of this research study. State if there are no direct benefits to individual participants. Compensation is not to be considered a benefit.

Subjects may experience improved cardiovascular function, motivation for physical activity participation, physical function, and quality of life due to participation in the investigation. The knowledge gained from this study will aid in documenting the potential benefits of exercise and activity counseling interventions for older knee OA patients, which could potentially influence treatment options for this patient population.

29. ASSESSMENT OF RISKS & BENEFITS

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

The risks to subjects are minimal and involve minor discomfort. The benefits to the participants involve improvements in health such as a reduction in stress and improvement in cardiovascular functioning. The knowledge gained from this study will aid in treatment options for sedentary older adults diagnosed with knee OA.

30. ALTERNATIVES TO STUDY PARTICIPATION

Describe how those who choose not to participate, but who could benefit from the alternative procedures or treatments available, will be advised of the opportunity to receive them.

Patients could select several alternative forms of treatment including, but not limited to, pain medication or surgery. Although each alternative form of therapy has some benefits, they are also associated with adverse side effects and this is part of the reason for examining the efficacy of exercise interventions in this population.
31. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

None

b. List any costs to participants that will be covered by the research study.

Gas reimbursement for assessment visits.
### APPLICATION CONTENTS

Indicate what documents are being submitted for this research project. Check all appropriate boxes and provide the version number and date, if available.

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<thead>
<tr>
<th>Document Description</th>
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33. ASSURANCE

PRINCIPAL INVESTIGATOR (or Advisor)

I agree to follow all applicable policies and procedures of the Ohio State University and federal and state, and local law and guidance regulating the protection of human subjects in research, as well as with professional practice standards and generally accepted good research practice guidelines for investigators, including but not limited to, the following:

- The research will be performed as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- The research will not be initiated until written notification of IRB approval has been received;
- Informed consent and HIPAA-research authorization from human subjects (or their legally authorized representatives) will be obtained and documented (unless waived) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
- Adverse, unexpected and related adverse events, unanticipated adverse device effects, and unanticipated problems involving risk to participants or others will be promptly reported to the IRB, as well as any other information necessary for appropriate oversight of the research;
- Significant findings that develop during the course of the study that may affect the risk or benefit of participation will be reported;
- The IRB will be informed of any proposed change in the research or informed consent process before such changes are implemented, and no changes will be made until approved by the CUU IRB (except when necessary to eliminate apparent immediate hazards to participants);
- A Continuing Review of Human Subject Research application will be completed and submitted before the deadline for review was intended determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities;
- Research-related records (and source documents) will be maintained in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Research-related records will be retained and available for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirement), unless it leaves the University;
- If the Office of Responsible Research Practices asks for assistance in assessing (to request a change in Principal Investigator) or monitoring the research ethics, the University is responsible to cooperate and provide the research ethics to the Office of Responsible Research practices;
- A Final Study Report will be provided to the IRB when all research activities have ended (including data analysis with individually identifiable or coded patient information) and
- All Co-Investigators, research staff, employees, and vendors assisting in the conduct of the research will be informed of their obligations in meeting the above commitments.

I verify that the information provided in this Initial Review of Human Subject Research application is accurate and complete.

[Signature]
Principal Investigator (or Advisor)

[Signature]
Department Chair (or Designated Official)
Appendix B

Institutional Review Board – Research Protocol
Research Protocol

I. Objectives

1. First purpose:
   To examine if the a combined exercise + group-based cognitive behavioral counseling (OMCBE) intervention produces significantly higher weekly frequency and volume of moderate-intensity or greater PA participation (PA Mod+) when compared to a traditional exercise intervention in older knee osteoarthritis (OA) patients.

2. Second purpose:
   To compare the effects of the OMCBE and traditional exercise interventions on physical function, quality of life, and self-efficacy.

II. Background and Rationale

Knee OA is a chronic, progressive, degenerative disease that affects over 20 million Americans. The joint damage and symptoms (i.e., pain, stiffness, and fatigue) accompanying symptomatic knee OA result in activity restriction, muscle atrophy, reduced quality of life and difficulty in performance of functional tasks involving ambulation and transfer. Inactivity secondary to the primary symptoms of knee OA results in muscular weakness, atrophy and deconditioning which has been hypothesized to exacerbate pain symptoms and accelerate the progression towards physical disability in arthritic patients. Consequently, OA of the knee is one of the most common chronic diseases affecting older Americans and is cited as a primary cause for activity restriction and physical disability among older adults.

Research examining the benefits of PA interventions in older adults with knee OA has proliferated in recent years. Findings from several randomized controlled trials suggest that structured PA interventions produce significant improvements in pain, performance and self-reported indices of physical function, muscular strength, aerobic capacity, and quality of life in older knee OA patients. Although PA is a promising lifestyle intervention to be incorporated in the treatment of knee OA, evidence of the long-term improvements in OA outcomes following PA interventions is surprisingly limited. For example, a majority of the OA-PA trials have examined short-term PA interventions lasting less than 6 months in duration and few these short-term trials have evaluated the long-term maintenance of treatment effects. Results from the limited number of trials incorporating post-treatment follow-up assessments demonstrate that many patients fail to maintain regular exercise participation after the end of structured exercise programs. Additionally, significant improvements in OA outcomes accompanying PA interventions dissipate considerably over time. Thus, the high rates of recruitment evident in prior PA-knee OA trials suggest that promoting long-term PA participation remains a primary challenge to this line of inquiry.

Anticipated results

The study will expand knowledge of how to most effectively promote exercise participation in older knee OA patients. The study will also advance knowledge regarding the effects of exercise on physical function and quality of life in this population.

Potential pitfalls

Potential pitfalls of the investigation could include lack of subjects' compliance or dropout.

III. Procedures

A. Research Design

The study employs a 2 (Intervention: OMCBE and Traditional Exercise) x 3 (Time of assessment: pre, 3-month, and 12-month) randomized controlled experimental design.

2/16/2006
The dependent variables are: self-reported and objectively measured (accelerometer) physical activity participation, physical function, quality of life, and self-efficacy (SE) for mobility andamine.

B. Sample
The sample consists of 90 participants (43 randomized to GMEF and 47 randomized to traditional exercise). The sample size was determined based on power calculations to find a significant difference in the main variable. According to Dohren's tables and assuming a moderate effect and a moderate correlation between measures, the estimated sample size was 40. Significance was set at a p < .05. The sample was composed of different groups of variables using Cronbach's alpha, which is .70 or greater acceptable (Potvin & Schum, 2000).

The inclusion criteria for the study are: (a) age = 55 years; (b) self-reported knee pain on most days of the month; (c) sedentary activity pattern with less than 20 min of formal exercise per week during the past 6 months; (d) self-reported difficulty with at least one of the following activities due to knee pain: walking 0.3 miles (4 city blocks), climbing stairs, bending, stooping, kneeling, stepping, walking, or other self-care activities, such as getting in or out of bed, standing up from a chair, lifting, and carrying groceries, or getting in or out of a bathtub; (e) radiographic evidence of Hallgren-Lawrence osteoarthritis I or II; (f) mild to moderate global OA, as determined by a single observer in the form of weight-bearing anteroposterior x-rays; and (g) willingness to undergo testing and intervention procedure; (h) free of any medical contraindications to participation in moderate exercise.

Participants will be recruited from OSUMC medical clinics which will be coordinated with Dr. Kevin Bach's lab (Co-investigator) and other physicians interested in collaborating with the recruitment effort. Participants will also be recruited in collaboration with the FHC Center for Clinical and Translational Research via flyers and pamphlets describing the study which will be placed in OSUMC-affiliated medical offices and clinics. Primary care settings in the Columbus area, campus, and local panels, the OSUMC hospital, and OSUMC weekly e-mails, mailings, and newsletter boards affiliated with the central Ohio branch of the Arthritis Foundation.

C. Measurement/Instrumentation
Assessment of physical activity, physical function, and quality of life will be obtained during screening and at baseline and 3-month and 12-month follow-up. The measures are summarized below.

Physical Activity. Self-reported and objective assessment of physical activity participation will be obtained. The CHAMPS Questionnaire will be used to assess physical activity participation. The CHAMPS questionnaire was developed specifically for the assessment of physical activity in adults 30 years and older. The CHAMPS questionnaire yields an estimate of energy expended per week in all physical activities and in activities of moderate (or higher) intensity. Two weeks or more reliability coefficients ranged from .62 to .76, and discriminant validity has been established in groups of older adults with varied physical activity levels.

The Actigraph single-axis accelerometer (model 7164 version, Manufacturing Technology Incorporated, MTI, Fort Walton Beach, FL) will be used to obtain an objective assessment of PA. The Actigraph accelerometer contains a single, vertical-axis piezoelectric sensor element that generates an electrical signal proportional to the force acting on it. The acceleration/deceleration signals are digitized by an analog-to-digital converter and numerically integrated over a pre-programmed epoch interval. At the end of each interval, the integrated value of movement count is stored in RAM and the integrator's reset. The monitor is reprogrammed for start time and data collection interval and data are transmitted for analysis via
PC interface and software provided with the unit. The downloaded data is then entered into Microsoft Excel for data processing. In this study, the epoch will be 1 minute, and the accelerometers will be worn during the waking hours except while showering, bathing, and swimming, for a 7-day period. Waking hours is defined as the moment upon getting out of bed in the morning until the moment of getting into bed in the evening. The accelerometers will not be worn during the night while the participant is asleep. The participant will record the time that the accelerometers were on a log, and this will be verified by inspection of the minute-by-minute accelerometer data. We will conduct data processing in the presence of the accelerometer data across each of the 7 days and then averaging the total daily counts across the 7 days. This will yield accelerometer data in total counts per day with higher counts representing more PA.

WOMAC. Self-reported physical function and pain symptoms will be assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Participants will indicate on a scale of 0 (none) to 10 (extreme), the amount of difficulty they have experienced performing basic physical function tasks in the past 6 weeks due to knee OA. The physical function subscale consists of 47 items that will be averaged to produce a physical function subscore ranging from 0 to 100 with higher scores indicating poorer function. Participants will also indicate the pain severity they have experienced during the past 6 weeks due to knee OA on a scale ranging from 0 (none) to 10 (extreme). The WOMAC pain subscale consists of 5 items and total score ranges from 0 to 20 with higher scores indicating greater pain.

Mobility Performance. A 4-min wall distance test and timed stair climb test will be used as objective assessments of participants' performance on ambulation and transfers. Each test has excellent 2-week test-retest reliability (>0.8) and have been found to be sensitive to changes with some interventions in older adults (7, 8, 10, 15).

SF-36. A generic measure of HRQL, will be obtained using the SF-36. The SF-36 is a generic measure of HRQL, which consists of 2 norm-based composite scales (mental health and physical health) and 8 subscales (mental functioning, mental health, role-physical, role-emotional, bodily pain, general health, vitality, and social functioning). The norm-based composite scales both have a mean of 50 and standard deviation of 10, whereas the subscales range from 0 to 100. The SF-36 has been shown to be sensitive to change with PA interventions in older adults (10, 19).

Satisfaction with physical function and physical appearance. Specific aspects of HRQL will be assessed using the body satisfaction scale. The body satisfaction scale consists of 4 items that assess physical function and 5 items that assess body appearance. Each item is rated on a 7-point scale that ranges from 1 to 7. Number are accompanied by the following verbal anchors: 1 (very dissatisfied), 2 (somewhat dissatisfied), 3 (a little dissatisfied), 4 (neither), 5 (a little satisfied), 6 (somewhat satisfied), 7 (very satisfied). The body satisfaction scale has been shown to possess excellent psychometric properties and has been demonstrated to be sensitive to change with PA interventions (19).

Mobility-Related Self-Efficacy. Participants will complete two mobility-related self-efficacy measures. Walking self-efficacy will be assessed by asking participants to rate their confidence in their ability to walk around the gymnasium two times without stopping. This measurement will subsequently be repeated for additional levels of difficulty for the anticipated distance of completing 4 laps, 6 laps, 8 laps, 10 laps, and 12 laps without stopping. For each level of difficulty, participants are presented with a confidence ladder with 10 steps ranging from 0 (completely uncertain) to 10 (completely certain). Walking self-efficacy is calculated by summing the participants' confidence ratings across the five levels of difficulty and multiplying the result by 2 to produce a score ranging from 0 to 100. The hierarchical measurement protocol consists with the protocols developed by Bandura and the walking self-efficacy scale has demonstrated adequate psychometric properties in several previous physical activity interventions (34). Participants' stair climb self-efficacy will also be assessed. Participants will
rate their levels of certainty on the 0 to 10 confidence ladder that they could complete the stair climb 2 times, 4 times, 6 times, and 10 times without stopping. Stair climb self-efficacy scores were also calculated by summing across the 5 levels of difficulty and multiplying this result by 2 yielding a score ranging from 0 to 100.

Artikls: Related Self-Efficacy. Participants will also complete the Artikls Self-Efficacy Scale (ASES). The ASES is a 20-item scale used to assess patients’ confidence that they can control pain, perform daily activities without assistance, and control related artikls symptoms such as fatigue and inflammation. The ASES has adequate psychometric properties and has been used in previous investigations with artikls patients.

Leg Extension Strength/Flexibility. Participants will also complete an assessment of leg extension strength. Participants will be asked to select a weight they are moderately confident they can lift for 10 repetitions. Consent with procedures indirectly described by Lefevre et al, participants will complete a test of muscle endurance by sitting on a bench and lifting the selected weight for as many repetitions as possible. This same score can be used as assessment will be calculated by multiplying the weight lifted by the number of repetitions completed. This procedure is being used in place of traditional 1RM testing due to concerns as gaiting increased risk of injury for this sample subset for the knee OA patients.

D. Detailed study procedures

Potential participants experiencing an interest in the study will undergo a brief telephone screening. Participants will then be scheduled for a baseline screening visit. Following the screening visit, they will be randomly assigned to the GMCE intervention or a traditional PA intervention. Assistance of the primary investigator will be provided at screening visits are conducted at baseline, 3 months, and 6 month follow-up. During the screening visit participants will complete the HEDL and self-efficacy questionnaires, functional performance, and leg extension strength tests. At the end of the initial screening visit participants will be provided with an exercise kit to wear during the following week. A detailed description of the exercise intervention arms is provided in the following section.

In the traditional arm, participants will exercise 3 days/week over a period of 3 months for a total of 36 sessions. Exercise sessions will be conducted by exercise leaders trained to deliver both the traditional and GMCE intervention. Each exercise session will consist of four phases: a warm-up (3 min), an aerobic stimulus phase involving walking (30-45 min) at an intensity of 60% to 85% of heart rate reserve and maintained sessions of 12-18 using Borg’s 6-20 RPE scale. Participants will also complete a progressive strength training phase targeting the knee extensors and core (hips and abdominals). Participants will also have 2 sets of 8-12 repetitions for each of the leg extension, leg curl, step-up, and calf raise exercises (15 to 20 min). Core exercises will include 2 sets of 12 repetitions for the abdonimal crunch (abdominals) and dynamic weight raised side-leg raises (hips).

The GMCE intervention will involve the same exercise prescription as the traditional PA intervention, will be conducted by the same exercise leaders, and will also consist of the identical total of 36 contact hours spread across 3 months. However, participants in the GMCE intervention will participate in 20-min of group-based cognitive behavioral activity counseling, immediately after each center-based exercise session. The purpose of including this activity is to assist participants in the learning and independent practicing of the skills in order to maintain long-term PA participation. A basic principle underlying the GMCE is that learning and sequencing a set of gradually increasing participants from the dependency on staff and the group program toward independent self-

26/2004

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regulation of physical activity. This process is one of a phased increase in the ratio of personal
responsibility in conjunction with a phased decrease in staff group and clinical dependency. For the first
month, participants will meet at the annex’s facility for center-based training 2 times each week. During
the months 2-8, center-based training will be reduced to 1 time each week. Following each center-based
annex’s sessions, participants will engage in instruction and participant group discussion regarding the
self-regulatory aspects of learning long-term maintenance of PA.

E. Data Analysis

For this final analysis, we will use analysis of covariances and SAS statistical software.

IV. References


Ballany N, Buchanan WW, and Goldsmith CH. Validation study of the WCMAC: a health
state instrument for measuring clinically relevant outcomes to antihypertensive drug therapy in patients

Brawley LR, Rajski WI, and King A. Promoting physical activity for older adults:

Brawley LR, Rajski WI, and Loria LC. Group mediated co provider—behavioral intervention


Focht BC, Brawley LR, Rajski WI, and Ambrose WF. Effects of lifetime physical activity and
traditional exercise therapy programs upon health-related quality of life among older adults in cardiac

Focht BC, Rajski WI, Elsara IA, Ambrose W and Macier SP. Exercise, selfefﬁcacy, and mobility
performance in overweight and older adults with knee osteoarthritis. Arch Phys Med Rehabil 85: 459-463,
2003.

Macier SP, Looser KN, Miller GD et al. Exercise and dietary weight loss in overweight or
obese older adults with knee osteoarthritis: The Arthritis, Diet and Activity Promotion Trial. Arthritis

Rajski WI, Brawley LR, Ambrose WF, Bubak PH, Focht BC, Foy CG, and Fox LD. Older adults
with chronic knee disease: benefits of group mediated counseling in the promotion of physically active

Rajski WI and Focht BC. Aging and physical disability: Can integrating group and

Rajski WI, Focht BC, Macier SP, Morgan J, Fokas M, and Ganemer E. Obese older adults with
Appendix C

Institutional Review Board – Continuing Review
CONTINUING REVIEW OF HUMAN SUBJECTS RESEARCH
The Ohio State University Institutional Review Board

Office of Responsible Research Practices (ORRP)
300 Research North Building 1540 Kenny Rd, Columbus, OH 43210
Phone: (614) 688-9837 Fax: (614) 688-8344 www.orr.state.oh.us

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<tr>
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<td>John Doe <a href="mailto:jdoe@ohstate.edu">jdoe@ohstate.edu</a></td>
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<tr>
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<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. EXTERNAL CO-INVESTIGATORS &amp; KEY PERSONNEL (non-OSU personnel only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there any changes in external study personnel?</td>
<td>Yes</td>
<td>Complete Appendix A</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. ADDITIONAL CONTACTS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If additional contact information has changed since last IRB review, list all current contact(s) below. If no new information, go to Question 6.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name (Last, First, MI):</td>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>Name (Last, First, MI):</td>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>ALL OSU individuals listed on this protocol will have access to information about IRB actions and the completion status of each investigator's administrative and training requirements (CITI, COI declarations). Note: Personal financial information provided in COI declarations is not included.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. EDUCATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the human subject protection education requirements (CITI) current for all OSU investigator(s) and key personnel?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. FINANCIAL CONFLICT OF INTEREST

Do any OSU investigators (including principal or co-investigator), key personnel, or their immediate family members have a financial interest (including salary or other payments for services, equity interest, or intellectual property rights) that would reasonably appear to be affected by the research? Yes No

OSU investigators and key personnel must have current COI disclosure form updated as necessary for the proposed research filed before IRB review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; and patents, copyrights, and royalties from research. For more information, see the Office of Research Compliance COI Overview and COI Form.

8. FUNDING OR OTHER SUPPORT

If the research is federally funded and involves a subcontractor or from another entity, an IRB Authorization Agreement may be required. Contact ORC for more information.

a. What is the current funding status of the research?
   □ No
   □ Funded

   If funded → Specify sponsor
   National Institutes of Health

b. Is any support for research equipment (e.g., drugs, equipment etc.) being provided or for the study?
   □ Yes
   □ No

   If Yes → Specify sponsor and provider:

   c. Is there a new, revised, or renewed application since the last IRB review?
   □ Yes
   □ No

   If Yes → Forward a copy of the current research application with this submission. The University is required to verify that all funding proposals and grants (new or renewed) have been reviewed by the IRB before funds are awarded.

9. LOCATION OF THE RESEARCH

a. List the specific sites at which the OSU research will be conducted. (include both domestic and international locations). Provide copies of all current IRB approvals for non-OSU sites, as applicable.

<table>
<thead>
<tr>
<th>Location (Name and description)</th>
<th>Address (street, city and state, or country)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise Science Labs and facilities</td>
<td>The Extras Building 365 West 17th Ave Columbus OH</td>
</tr>
<tr>
<td>The OSU Center for Wellness and Prevention</td>
<td>2050 Hemenway Road Columbus OH</td>
</tr>
<tr>
<td>The General Clinical Research Center</td>
<td>430 Medical Center Dr, Columbus OH</td>
</tr>
</tbody>
</table>

10. EXPEDITED REVIEW

Are you requesting expedited review?
□ Yes → Complete Appendix P
□ No

11. RESEARCH STATUS

a. Indicate the stage of the OSU research:
   □ No research participants have been enrolled (or participant records, specimen, etc. obtained).
   Explain:
   □ Research participants have been enrolled (or participant records, specimen, etc. obtained)

b. If participants have been enrolled, check all that apply:

Page 107

Page 138
12. SUMMARY OF THE RESEARCH

Summarize the research using non-technical language that can be easily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may be expected to result. Use complete sentences (limit: 300 words).

The proposed research will compare the effects of exercise + group-based self-regulatory skills counseling (SREK) intervention with the effects of exercise alone (EX) on physical activity participation, physical function, and quality of life among older adults with lower extremity arthritis. The study will be a randomized controlled investigation consisting of an intervention group (SREK) and a comparison group (EX). The intervention group will participate in an exercise program consisting of walking and lower body strength training for 3 months. Participants in the EX group will complete 3 exercise sessions/week for 3 months. Participants in the SREK group will participate in progressively more independent exercise across a 6-month period ranging from 2 sessions/week in month 1 to 1 session/week in months 2-6. Each exercise session in the SREK intervention will be followed by 20-min of group-based self-regulatory skills counseling intended to help participants become confident in their ability to exercise independently while nonconsistently phasing out center-based activity over an initial 3-month period. The comparison group (EX) will participate in the same exercise program 3 times/week for 3 months but will not receive the self-regulatory skills counseling component. Both groups will participate in screening visits at baseline and 3-month and 12-month follow-up assessments. During the screening visit, participants will complete all questionnaires and the six-minute walk, stair climb, and leg strength performance tests. During the week immediately following the screening visit participants will wear an accelerometer to record their physical activity participation and complete a questionnaire assessment of their physical activity on day 7 of this week. All participants will perform the screening visits and week of physical activity assessment at each of the baseline, 3-month and 12-month assessment intervals.

The risks involved in the proposed research are minimal. The risk of serious injury due to participation in the moderate intensity exercise program is present but negligible. All participants will receive medical clearance from Dr. Hameh and/or their primary care physician prior to participating in the exercise program. Participants will also be supervised at all times by trained exercise staff during each center-based exercise session. The benefits associated with the proposed research include aiding in the understanding of how to promote active lifestyles in older adults with lower OA and how exercise enhances quality of life and physical function. The findings have implications for the treatment of older adults burdened with knee OA.

13. RESEARCH PROGRESS

a. Summarize the progress of the OSU research, including any interim findings.

The 2-year funding period for this project began in August 2009. Since that time we have enrolled 24 participants in the study. With this pace we are on schedule to meet our target accrual. To date there have been no adverse events or participant complaints. Study-related activities have been very successful and without incident.

b. For multicenter studies, summarize the overall progress of the research:

N/A

c. Summarize any IRB-approved amendments or changes made to the research since last IRB review (initial or continuing). IRB approval was not obtained for changes, provide an explanation.

An IRB amendment was approved prior to the start of data collection in August that involved minor
revisions to the screening process and timing of the intervention, as well as the addition of pamphlets and flyers to aid in participant recruitment efforts. These were minor modifications that did not alter the project objectives or increase risk for the participants.

An amendment to add key personnel was also submitted just prior to the submission of the continuing review materials and is still pending at this time.

d. Summarize recent literature or other information relevant to the research, if any, since last IRE review (initial or continuing).

N/A

a. Discuss significant new findings (e.g., affecting risk, benefits, or alternatives), if any, that could affect participants' willingness to continue in the research and how participants have been and will be informed.

N/A

f. Are you requesting any changes to the research, other than a change in study personnel or participant numbers (e.g., changes to protocol, recruitment or consent processes, change in eligibility criteria)?

No

g. Projected or actual completion date: August 2011 (month and year)

Indicate "ongoing" for ongoing research or program protocols

14. NUMBER OF PARTICIPANTS

The number of participants is derived from the number of individuals who agreed to participate (i.e., those who provided informed consent whose records were accessed, etc.) or all who met the criteria or completed the study. The total number of research participants may be increased only with prior IRE approval.

b. For research approved by an OSU IREB, provide:

1) IRE approved number of participants (per ccords, specimens, etc.): 24
2) Total number of participants enrolled in the research to date: 24
3) Number of participants enrolled since last IRE review (initial or continuing): 24

c. If actual number is less than (14b.1) is significantly different, provide an explanation.

N/A

d. Are you requesting an increase in the total number of participants?

No

15. PARTICIPANT POPULATION

a. Specify the age(s) of the individual who may participate in the research:

Age(s): 55-80
b. Specify the participant population(s) - check all for which you have approval:
   ☐ Adults
   ☐ Developmentally Impaired Adults
   ☐ Children (< 18 years)
   ☐ Healthy Volunteers
   ☐ No name (cannot maintain confidentiality)
   ☐ Non-English Speaking
   ☐ Yes
   ☐ Women
   ☐ Pregnant Women
   ☐ Elderly
   ☐ Persons
   ☐ Students from Participant Pool (e.g., IRB)
   ☐ Specify:
   ☐ Unknown (e.g., research involving human data, specimen, non-targeted surveys, program protocol)

16. RECRUITMENT & INFORMED CONSENT PROCESS
a. Were recruitment materials used to enroll participants? ☐ Yes
   ☐ No
   If Yes ⇒ Are recruitment materials still being used? ☐ Yes
   ☐ No
   ⇒ Provide copies of the current recruitment materials (e.g., radio/TV script, internet advertisements, etc.).
   ☐ No
b. How was informed consent or assent obtained? Check all that apply:
   ☐ Written consent - Form
   ☐ Assent - Verbal Script
   ☐ Informed Consent - Form
   ☐ Informed Consent - Verbal Script
   ☐ Written or Oral Consent
   ☐ Written Consent - Addendum
   If Yes ⇒ Provide copy of current consent script or other informed consent text used to inform participants.

c. Is a description of the research part of the consent? ☐ Yes
   ☐ No

17. HIPAA RESEARCH AUTHORIZATION
   Is individually identifiable protected health information (PHI) accessed, used, or disclosed in the research? ☐ Yes
   ☐ No
   If Yes ⇒ Check all that apply:
   ☐ Written Authorization
   ☐ Partial Waiver (reason for waiver only)
   ☐ Full Waiver (entire research study)
   ☐ Authorization
   ☐ Informed consent (if required) was obtained from all participants prior to April 14, 2003.

18. RISK ASSESSMENT
   a. Since the last IDE review (initial or continuing) did any unanticipated problems involving risk to subjects or others or adverse events occur in research that was not reviewed by an IDE? ☐ Yes
      ⇒ Complete Appendix B
      ☐ No
   b. Was the research subject to Data and Safety Monitoring Board (DSMB) or other similar committees or groups with oversight? ☐ Yes
      ⇒ Provide a copy of the most recent report. The board meets twice a month to review project progress and the first meeting will occur in March 2010 unless there is an external event that requires the board to meet.
19. PARTICIPANT COMPLAINTS & VOLUNTARY WITHDRAWALS

a. Has any participant made complaints about the research since the last IDE review?
   □ Yes
   □ No

   If Yes → List and describe each complaint and any actions taken to resolve the complaint(s).

b. Has any participant voluntarily withdrawn from the research since the last IDE review?
   □ Yes
   □ No

   If Yes → List and describe each withdrawal and any actions taken (e.g., changes to the research or consent process) in response to the withdrawal(s).

20. APPLICATION CONTENTS

Indicate the documents submitted for this continuing review. Check all appropriate boxes.

☑ Continuing Review of Human Subjects Research Application

☐ Appendix C: Changes in Study Personnel (question 3 & 4)

☐ Appendix D: Changed Review—Continuing Review (question 10)

☐ Appendix E: Changes in Number of Participants (question 144)

☐ Appendix F: Reporting—Internal Events (question 184)

☐ Appendix G: Reporting—External Events (question 186)

☐ Appendix I: All Other Research Changes (question 132)

☐ Currently Approved Consent Form(s) (Form(s) Previous Form(s) and Verbal Script) including translated document (question 156)

☐ HIPAA Research Authorization Form(s) (question 177)

☑ Recruitment Materials (e.g., ads, flyers, telephone or other oral script radio/TV script, internet solicitation) – if still being used (question 143)

☐ Script(s) or Information Sheet(s), including Debriefing Materials (question 146)

☐ Instruments (e.g., questionnaires, surveys completed by participants) – if still being used

☐ Current IDE approval status in support of new IDE sites (question 19)

☐ Research Protocol (full description of the research with changes incorporated since initial IDE approval)

☑ Complete Grant Application (new renewal, or renewal only) (question 24)
21. **PRINCIPAL INVESTIGATOR'S (or Advisor's) ASSURANCE**

I agree to follow applicable policies and procedures of The Ohio State University and federal, state, and local laws and guidelines regarding the protection of human subjects in research, as well as with professional practice standards and generally accepted good research practices guidelines for investigators, including but not limited to, the following:

- Perform the research as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- Obtain and document (where needed) informed consent and HIPAA research authorization form humans subject (or their legally authorized representatives) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
- Promptly report to the IRB events that may represent unanticipated problems involving risk to subjects or others;
- Provide significant new findings that may affect the subject's willingness to continue to participate;
- Inform the IRB of any proposed changes in the research or informed consent forms before changes are implemented, and no change will be made until approved by the CE/IRB (except when necessary to eliminate apparent immediate hazards to participants);
- Complete and submit a Continuing Review of Human Subjects Research Application before the deadline for review and approval determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid the expiration of IRB approval and cessation of all research activities;
- Maintain research-related records (and source documents) in a manner that documents the validity of the research integrity of the data collected, while protecting the confidentiality of the data and privacy of the participants;
- Keep research-related materials for a period of at least three years after the research has ended or longer, according to sponsor or public agency requirements, even if I leave the University;
- Contact the Office of Responsible Research Practices for assistance in amending or terminating the research if I leave the University or am no longer a co-investigator or sponsor of any research activities at the University;
- Provide a Final Study Report to the IRB when all research activities have ended (including data analysis) with individually identifiable or de-identified private information, and
- Inform all Co-investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

I verify that the information provided in this Continuing Review of Human Subject Research Application is accurate and complete.

---

**Signature of Principal Investigator (or Advisor)**

**Date**

---

**Printed name of Principal Investigator (or Advisor)**
Appendix D

Preliminary Screening Form
Thank You for Your Interest in the IMPACT Exercise Study!

We are glad that you are interested in possibly participating in the Improving Maintenance of Physical Activity Trial (IMPACT) Exercise Program. My name is Dr. Brian Focht, and I am the principal investigator for this study. We need to get some important information from all volunteers who are interested in participating in the study.

The questions on this and the following pages help us determine if you will be eligible to participate in the study so please complete each question as accurately as possible. Members of the project staff may need to contact you to verify information on these questionnaires or to schedule an assessment if you are eligible for participation so please list your name, preferred phone number to contact you at, and best time to reach you below.

Name

Phone #

Please circle the best time of day to reach you:

Mornings: 8:00-10:00am  10:00am-Noon
Afternoons: Noon-3:00pm  3:00-6:00pm
Evenings: 6:00-9:00pm

We think you will make new friends and learn a great deal about the importance of exercise in managing your knee osteoarthritis.

We also believe your experience in the IMPACT exercise study will be enjoyable and productive. We hope you that you will participate in our important study!
**INCLUSION CRITERIA:** THE QUESTIONS THAT FOLLOW WILL ASK FOR SOME INFORMATION ABOUT YOUR HEALTH HISTORY. PLEASE ANSWER THEM AS COMPLETELY AS POSSIBLE.

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you 60 years of age or older?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Do you experience knee pain on most days of the month?</td>
<td></td>
<td></td>
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<tr>
<td>Has your doctor told you that you have knee osteoarthritis?</td>
<td></td>
<td></td>
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<tr>
<td>Have you participated in a formal exercise program during the past 6 months?</td>
<td></td>
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<tr>
<td>Have you been exercising 3 or more days per week for at least 20 minutes per day during the past 6 months?</td>
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</tr>
<tr>
<td>To your knowledge, do you have any medical conditions that would prevent you from exercising safely?</td>
<td></td>
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<tr>
<td>Do you have difficulty walking a quarter of a mile (3-4 city blocks) due to knee pain?</td>
<td></td>
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<tr>
<td>Do you have difficulty climbing stairs due to knee pain?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Do you have difficulty bending, stooping, or kneeling due to knee pain?</td>
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<tr>
<td>Do you have difficulty with any of the following activities due to knee pain?</td>
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<td></td>
</tr>
<tr>
<td>a. shopping or carrying groceries</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>b. getting in or out of bed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. standing up from a chair</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. getting in or out of bathtub or shower</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. getting in or out of a car</td>
<td></td>
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</tbody>
</table>

Name ________________________________

Date ________________________________
To: Participant’s primary care physician or rheumatologist

RE: Knee Osteoarthritis Exercise Study Participation

A patient presently under your care, (participant’s name), is interested in participating in a study examining the benefits of exercise participation for older, knee osteoarthritis (OA) patients. Exercise will involve light to moderate intensity walking and lower body strength training lasting 3-6 months. Participants will be supervised by trained exercise leaders and will be instructed on how to continue the exercise program independently after the end of the structured program. This is a safe and effective approach to exercise programming that has been used previously in older, knee OA patients. In order to ensure the safety of all potential participants and screen for appropriate inclusion criteria for the present exercise program, we are requiring all volunteers expressing an interest in participating in the study to have their primary care physician and/or rheumatologist verify that the patient meets each of the criteria listed below:

- self-reported knee pain on most days of the month
- self-reported difficulty completing common daily activities due to knee pain
- radiographically documented mild to moderate radiographic knee OA (Kellgren-Lawrence Stage I or II)
- absence of varus or valgus malalignment that would make exam's participation unsafe for the participant
- absence of any serious medical condition that would make mild to moderate exercise participation unsafe for the participant

Please sign below to verify that to the best of your knowledge the potential participant meets the criteria and would be able to safely participate in the exercise study. If you have any questions or require further information please feel free to contact the Principal Investigator of the study, Dr. Brian Keight Assistant Professor, Health and Exercise Science, 414-292-2145, bkeight@uwm.edu

Yes, in my professional medical opinion, the potential participant meets the necessary criteria and can safely participate in the exercise program.

______________________________________________________________________________________________

No, in my professional medical opinion, the potential participant does not meet the necessary criteria and cannot safely participate in the exercise program.

______________________________________________________________________________________________
Appendix E

Arthritis Foundation Class List
Gentle movement is a heated pool keeps knees and wrists painless, with increasing joint flexibility and range of motion. Class participants are not required to know how to swim. All classes are led by Arthritis Foundation certified instructors. Limited to 15 people are available for those with limited mobility.

**NORTHWEST**
Dunham Community Rec. Center
5300 Pool Rd.
Dublin, OH 43017
(614) 464-5520
Water aerobics class required

Batavia Pools
3333 Deer Park Rd.
Batavia, OH 44010
(330) 922-2222
Membership required

Cleveland Heights Community Center
5710 E 107th St.
Cleveland, OH 44103
(216) 661-5600

**CENTRAL**
Alexander Community Rec. Center
255 W 92nd St.
Cleveland, OH 44102
(216) 661-5600

**EAST**
Batavia Community Rec. Center
2500 N. Main St.
Batavia, OH 45103
(513) 932-3232

**SOUTHWEST**
YMCA - North Branch
1540 Sandalwood Pl.
Columbus, OH 43229
(614) 256-2250

**SOUTHEAST**
Columbus Scioto Rec. Center
4950 Olentangy River Rd.
Columbus, OH 43209
(614) 598-3333
Membership required

**SOUTHWEST**
Boys & Girls Clubs of Columbus
3601 Main St.
Columbus, OH 43224
(614) 464-5522

**SOUTHEAST**
YMCA - Hilliard
45100 Quaker Rd.
Hilliard, OH 43026
(614) 328-9999

**SOUTHEAST**
Aquatics Activities
2900 Lyman Dr.
Columbus, OH 43201
(614) 510-0004

**NORTHWEST**
New Albany Community Rec. Center
2500 E. Main St.
New Albany, OH 43054
(614) 562-2222

**SOUTHWEST**
YMCA - Bexley Center
3516 Forest Blvd.
Columbus, OH 43209
(614) 598-3333

**SOUTHWEST**
YMCA - Westwood Center
1900 Bullock Rd.
Columbus, OH 43228
(614) 256-2250

**SOUTHWEST**
YMCA - Park Center
5400 W. Broad St.
Columbus, OH 43207
(614) 256-2250

**SOUTHWEST**
YMCA - Friendship Center
2000 N. High St.
Columbus, OH 43201
(614) 256-2250

**SOUTHWEST**
YMCA - Central Branch
4100 W. 4th St.
Columbus, OH 43205
(614) 256-2250

**SOUTHWEST**
YMCA - Westside Center
3516 Forest Blvd.
Columbus, OH 43209
(614) 598-3333

For those outside Franklin County, call (614) 362-4573.
Appendix F

Phone Script
Prescreening Calls

- Opening
  - Hello, this is __________. I am graduate research associate at The Ohio State University. I received your name and contact information from Dr. Hackshaw as you showed interest in the Improving Maintenance of Physical Activity in Arthritis Trial (IMPACT). The principle investigator is Dr. Brian Focht of the health and exercise science department who is working closely with Dr. Hadshaw. The reason for my call is to follow up on information you previously provided us. Do you have a few minutes to discuss the questionnaires you filled out at Dr. Hackshaw's office, or would there be a better time for me to call back?

- Verbally verify inclusion criteria
  - All yes first set of boxes?
  - All no second set of boxes?
  - At least one yes rest of boxes?

- Review/discuss information from informed consent document
  - Ensure that the subject understands and is willing to comply with all policies and procedures
  - Encourage subject to ask question and ensure all questions have been answered satisfactorily

- Schedule baseline testing
  - Find an appropriate date and record in scheduling log
  - Briefly explain baseline testing procedures (1–1.5 hrs, clothing/shoes, payment)
  - Provide directions to campus parking garage & discuss parking validation procedures
    - Create email/mailing attachment with campus addresses, directions, and student researcher phone numbers
  - Explain shuttling to and from parking location to PAES building

- Explain post-baseline testing timeline for 12 week exercise intervention
- Answer any remaining questions

- Closing
  - Thank you for your time. We look forward to meeting you when you arrive for your baseline testing. Have a nice day.
Appendix G

Subject Mailing
Health & Exercise Science  
PAES Building  
305 West 17th Avenue  
Columbus, OH 43210  
October 16, 2009

???? Carrollton Club Circle  
Columbus, OH 43219

Mrs. [Redacted]

Thank you for your interest in the Improving Maintenance of Physical Activity Trial at The Ohio State University. Your participation in the IMPACT trial may help us understand how exercise can improve the treatment of Knee Osteoarthritis.

Your baseline testing appointment has been scheduled for Wednesday October 21, 2009 at 10:30 am on the ground floor of the PAES Building. It will include physical function testing, strength testing, a physical activity participation assessment and a series of questionnaires. In total the session should last between 1 & 1.5 hours.

Enclosed you will find directions to the PAES building and a map to help you find your way to the parking lot outside. When you arrive, please park in the space marked for exercise science research. One of the graduate associates will be waiting for you and will direct you to the ground floor.

If you have any questions please call one of the graduate research associates, [Redacted] or [Redacted] at 614-292- [Redacted]. The principle investigator, Dr. Brian Focht, can also be reached at either of the following numbers if necessary. (Office – 614-292- [Redacted] or Cell – 614- [Redacted])

Sincerely,

[Redacted]

Graduate Research Associate
Appendix H

Subject Email
Thank you for your interest in the Improving Maintenance of Physical Activity Trial at The Ohio State University. Your participation in the IMPACT trial may help us understand how exercise can improve the treatment of Knee Osteoarthritis.

Your baseline testing appointment has been scheduled for Friday, October 8th, 2010 at 9:30 AM on the ground floor of the PAES Building in room A12. It will include physical function testing, strength testing, a physical activity participation assessment and a series of questionnaires. In total the session should last between 1 & 1.5 hours. Please wear comfortable clothing.

DIRECTIONS:

Please take 315 North to the Lane Ave Exit. Go Right (East) off of the exit towards OSU Campus. Stay on Lane Avenue until you cross the Lane Ave Bridge. At Tuttle Park, the 2nd light after the Bridge, turn right. (You will now be driving South on Tuttle Park)

(Tuttle Park and is just after a big parking lot on your right side)

Once onto Tuttle continue straight through the intersection at Woody Hayes. You will proceed until you stop at a booth in the middle of the road. Inform the booth attendant that you are taking part in a research study. They will allow you through the gate which is up ahead on the left side just around the circle. Go to the first stop sign at the top of the hill and turn Right. (This road is called Millikin Rd but the sign is only on the left side of the street). Follow the roadway around to the Right and go behind our building and we have the last three (3) parking spots down on the Right available for you.

PARKING

When you arrive, please park in one of the four spaces marked for exercise science research. The spots say "RESERVED" in front of them. Enter the double doors directly in front of the parking space and proceed down the steps to the ground floor. Room A12 is on the left inside the doorway at the bottom of the stairs. If you prefer to use the elevator, it is located to the right just inside the next door. Exit to the left on the ground floor, room A12 is just around the corner.

If you have any questions please call [REDACTED] at 614-292- [REDACTED] or at 614-292- [REDACTED] The principle investigator, Dr. Brian Focht, can also be reached at either of the following numbers if necessary (Office - 614-292-[REDACTED] or Cell - 614-[REDACTED])

[REDACTED] Graduate Research Associate Health & Exercise Science
A12 or A48 PAES Building
305 West 17th Avenue
Columbus, OH 43210
Appendix I

Informed Consent
The Ohio State University Consent to Participate in Research
Promoting physical activity participation in knee osteoarthritis patients.

Principal Investigator: Brian Focht, PhD, CSCS, FACSM

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the signed form.

1. Why is this study being done?

The study is designed to provide information on how to increase exercise participation in knee osteoarthritis patients over a period of one year. It is also designed to increase knowledge of the health and quality of life benefits of regular exercise for knee osteoarthritis patients.

Volunteers for this study will be randomly assigned (“like a flip of a coin”) to either an exercise and educational counseling group or a traditional exercise program group. During the study, participants will be asked to exercise 3 times per week for 3 months and will also be requested to complete assessments of physical activity participation, exercise performance, functional performance, muscular strength, and quality of life. These assessments will be completed at the beginning of the study as well as 3 months and 12 months later.
2. How many people will take part in this study?

90 healthy sedentary knee osteoarthritis patients will be recruited for participation in this study.

3. What will happen if I take part in this study?

You will be asked to participate in a 3 month exercise program and to complete 3 assessments during the course of the study. These assessments will be conducted during a single screening visit at each of 3 different time points: the beginning of the study (baseline), 3 months into the study (1st follow-up) and 12 months into the study (2nd follow-up). Following the baseline assessment, you will be randomly assigned ("like a flip of a coin") to either a 3 month combination exercise + educational counseling program or a standard exercise program. Both exercise programs involve exercising for an hour 3 times per week. Each exercise session will involve walking and/or stationary cycling for 30 minutes and 20 minutes of lower body weight lifting. Participants assigned to the combination group will also receive 20 minutes of educational counseling immediately following each exercise session and will gradually be transitioned to performing independent, home-based exercise across the exercise program. This educational counseling component is designed to enhance participants to develop the ability to exercise independently once the program is over.

At the baseline, 3-month, and 12-month assessments, you will be asked to complete 10 questionnaires. These questionnaires will take approximately 30 minutes to complete. The questionnaires will be evaluating your physical activity participation habits, quality of life, confidence and/or ability to perform common daily activities, and mood. In addition, you will complete a leg strength test, and functional performance test (walking and stair climbing ability) at the baseline, 3-month and 12-month assessments.

If you are assigned to the exercise and educational counseling group, you will be asked to exercise 1 hour per day, 1-2 days/weeks for a period of 6 months. You will also participate in 20 minutes of group-based educational training immediately after each center-based exercise session. During the weeks 1 to 4 of the program, you will do 2 exercise sessions at the PAES Building on the OSU campus and 1 session independently. During weeks 5 to 24 of the program you will exercise with the rest of the group 1 time per week at this facility while completing 2 exercise sessions at the center or at home independently. The exercise sessions will be conducted at the PAES Building on the OSU campus. If you are assigned to traditional exercise program you will be asked to exercise for 1 hour 3 days/week for a period of 3 months. Sessions will be held at the PAES Building on the OSU campus. At each session a record will be kept noting your activity, body weight, blood pressure, and heart rate which will be assessed by the session leader.
CONSENT

IRB Protocol Number:

IRB Approval Date:

Version:

No information regarding your physical function test results or exercise performance will be placed in your medical records. If any discovery of previously unknown conditions are identified as a result of your participation in this research study, you will be notified of the results. With your permission, test results will also be shared with your primary care physician or an appropriate health care professional. It is important for you to know that participation in this research study is not meant to replace your usual health care.

A table outlining the assessments you will be asked to complete during the course of the study is provided below.

<table>
<thead>
<tr>
<th>Time</th>
<th>Assessments</th>
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<tbody>
<tr>
<td></td>
<td>Leg Strength Test</td>
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<tr>
<td></td>
<td>6-Minute Walk Test</td>
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<tr>
<td>Baseline</td>
<td>Star-Climb Test</td>
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<td></td>
<td>10 Activity and Quality of Life Quest</td>
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<td></td>
<td>Exercise Stress Test</td>
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<td>Leg Strength Test</td>
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<td>6-Minute Walk Test</td>
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<td>Star-Climb Test</td>
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<td></td>
<td>10 Activity and Quality of Life</td>
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<tr>
<td>3-months</td>
<td>Questionnaires</td>
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<tr>
<td></td>
<td>Leg Strength Test</td>
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<td></td>
<td>6-Minute Walk Test</td>
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<td></td>
<td>Star-Climb Test</td>
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<tr>
<td>12-Months</td>
<td>10 Activity and Quality of Life</td>
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<tr>
<td>Months</td>
<td>Questionnaires</td>
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4. How long will I be in the study?

Over a period of 1 year, you will complete the exercise program and 3 assessments: baseline, month 3, and month 12. The baseline, 3-month, and 12-month assessments will be conducted in a single screening visit to OSU labs and/or centers. These visits will each require approximately an hour and a half to complete. Assessments will take place at the Exercise Physiology Labs in A-22 in the PAES Building.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.
6. **What risks, side effects or discomforts can I expect from being in the study?**

   For the exercise training: Minor muscle aches and joint pain are common but usually time-limited. The risk of serious injury or death during exercise training is minimal. Even in populations with established heart problems, death occurs in less than 1 of 10,000 exercise tests, and at a rate of less than 1 per 100,000 hours of exercise training.

   For the quality of life questionnaires: Possible emotional upset resulting from questionnaires or fatigue resulting from completing the questionnaires.

7. **What benefits can I expect from being in the study?**

   You will be contributing to society’s knowledge of the benefits of exercise for knee osteoarthritis patients and how we might develop more effective exercise programs. You will have the opportunity to receive free supervised training for a period of 3-6 months and free fitness assessments at each of the baseline, 3-month and 12-month assessments.

8. **What other choices do I have if I do not take part in the study?**

   You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. **Will my study-related information be kept private?**

   Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your research may be reviewed by the following groups (as applicable to the research):
   - Office for Human Research Protections or other federal, state, or international regulatory agencies;
   - U.S. Food and Drug Administration;
   - The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
   - The sponsor supporting the study, their agents or study monitors; and
   - Your insurance company (if charges are billed to insurance).

   If the study involves the use of your protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.
10. What are the costs of taking part in this study?

There are no costs related to participation in this study.

11. Will I be paid for taking part in this study?

Yes, a payment of $75 will be made for completing each of the assessment visits conducted at baseline, 3-months, and 12-months of the study. The $75 payment will be distributed as 3 smaller payments of $25 given after the completion of each assessment. By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.
14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the Principal Investigator, Dr. Brian Focht at 614-292-2165.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-0251.

If you are injured as a result of participating in this study or for questions about a study-related injury, contact Brian Focht at 614-292-2165.
15. Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this signed form.

<table>
<thead>
<tr>
<th>Printed name of subject</th>
<th>Signature of subject</th>
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<td>Date</td>
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<tr>
<th>Printed name as verified on consent form (if applicable)</th>
<th>Signature of person authorized to consent for subject (if applicable)</th>
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<tr>
<th>Relationship to the subject</th>
<th>Date</th>
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**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or his/her representative.

<table>
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<th>Printed name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
<th>AM/PM</th>
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<td>Date</td>
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**Witness(es)** - May be left blank if not required by the IRB

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<th>Printed name</th>
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<td>Date</td>
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Page 7 of 7 Form date: 07/26/05
Appendix J

Demographic Questionnaire
THE EXERCISE OF A STUDY INVESTIGATORS WOULD LIKE TO KNOW ABOUT SOME BASIC BACKGROUND INFORMATION ABOUT YOU. IT MAY HELP US TO UNDERSTAND YOUR RESPONSES TO THIS PROGRAM. ALL OF YOUR ANSWERS ARE CONFIDENTIAL.

1. What is your birthdate?  Month   Day   Year
2. What is your gender?  Male, Female

3. Check the one box below that best describes your ethnic background.
   - Hispanic or Latino (A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.)
   - Not Hispanic or Latino

4a. Do you consider yourself to be of mixed racial background?  Yes, No

   If your answer to question 4a (above) is YES, skip question 4b and answer question 4c.

   If your answer to question 4a (above) is NO, answer question 4b and skip question 4c.

4b. Check the one box below that best describes your racial background.
   - American Indian or Alaska Native (A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
   - Asian (A person having origins in any of the original peoples of the Far East, southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.)
   - Black or African American (A person having origins in any of the black racial groups of Africa.)
   - Native Hawaiian or Other Pacific Islander (A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.)
   - White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.)
4c. If you are of mixed racial/ethnic background, write a "1" in the category you most identify with, a "2" in the next, etc. Leave blank any categories that you do not identify with.

- American Indian or Alaska Native (A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.)
- Asian (A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.)
- Black or African American (A person having origins in any of the black racial groups of Africa.)
- Native Hawaiian or Other Pacific Islander (A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.)
- White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.)

5. Please check the ONE response below that BEST describes the highest level of formal education you have completed.

- No formal education
- Some grade school (1-4 years)
- Grade school (5-8 years)
- Some high school (9-11 years)
- High school graduate or graduate equivalent
- Vocational or training school after high school
- Some college
- Associate degree (A.D. or A.A.)
- College graduate (B.A. or B.S.)
- Some college or professional school after college
- Completed a master's degree
- Completed a doctoral degree (Ph.D., M.D., D.D.S., J.D.)

6. Roughly how much income from all sources (including earnings, pensions, investments, etc.) did your household have last year, before taxes?

- Less than $5,000
- $5,000 to $9,999
- $10,000 to $14,999
- $15,000 to $24,999
- $25,000 to $24,999
- $35,000 to $49,999
- $50,000 to $74,999
- $75,000 or more
PLEASE ANSWER SOME GENERAL QUESTIONS ABOUT YOUR JOB/WORK HISTORY. YOU ONLY NEED TO ANSWER THE QUESTIONS THAT APPLY TO YOU.

7. Would you describe yourself primarily as a homemaker?  
   Yes, ☐  ☐  
   No, ☐  ☐

8. Which of the following best describes your CURRENT employment status?  
   ☐ 1. Currently employed, full-time (at least 35 hours per week)  
   ☐ 2. Currently employed part-time (less than 35 hours per week)  
   ☐ 3. Employed in the past (full- or part-time), but now retired)  
   ☐ 4. Never employed for salary or wages
Appendix K

Medical History
THE QUESTIONS THAT FOLLOW WILL ASK FOR SOME INFORMATION ABOUT YOUR HEALTH HISTORY. PLEASE ANSWER THEM AS COMPLETELY AS POSSIBLE. AFTER YOU HAVE COMPLETED THE QUESTIONNAIRE, A CLINIC STAFF MEMBER WILL GO OVER IT WITH YOU.

<table>
<thead>
<tr>
<th>1. Has a doctor ever told you that you have diabetes?</th>
<th>YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you do have diabetes, do you use insulin to control your diabetes?</td>
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<tr>
<td>If you do have diabetes, have you required help from other people, or needed medical attention from a doctor, for low blood sugar (hypoglycemia) or high blood sugar (hyperglycemia) within the past 6 months?</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Has a doctor ever told you that you have high blood pressure (hypertension)? ...</th>
<th>YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you do have high blood pressure, do you take medication for your high blood pressure?</td>
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<tr>
<td>If you take medication for your high blood pressure, have you been taking the same medication(s) and the same dosage(s) for the past 3 months?</td>
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<tr>
<th>3. Have you ever been diagnosed with, or treated for, cancer?</th>
<th>YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
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</thead>
<tbody>
<tr>
<td>If you have been diagnosed or treated for cancer, are you being treated for cancer at the present time (now) or have you been treated for cancer within the past 6 months?</td>
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<thead>
<tr>
<th>4. Has a doctor ever told you that you have had a heart attack?</th>
<th>YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
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<tbody>
<tr>
<td>If a doctor has told you that you have had a heart attack, did your heart attack occur within the past 6 months?</td>
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<thead>
<tr>
<th>5. Has a doctor ever told you that you may have any of the following:</th>
<th>YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
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</thead>
<tbody>
<tr>
<td>a. Angina (chest pain, discomfort, pressure or heaviness due to a blocked or clogged blood vessel in your heart)?</td>
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<td>b. Heart failure or congestive heart failure?</td>
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<td>c. Heart rhythm problem or irregular heartbeat?</td>
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<td>d. Heart conduction problem or heart block?</td>
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<td>e. Heart valve problem?</td>
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<tr>
<th>6. Have you ever had any of the following surgeries or operations for your heart?</th>
<th>YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Surgery or blocked or clogged arteries in your heart (bypass surgery)?</td>
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<tr>
<td>b. Balloon angioplasty for your heart (opening the arteries of the heart with a balloon or other device, sometimes called PTCA)?</td>
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<tr>
<td>c. Heart valve replacement?</td>
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</table>

| 7. Has a doctor ever told you that you had a stroke or transient ischemic attack? | YES | NO | DON'T KNOW |

169
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Don't Know</th>
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<tbody>
<tr>
<td>8. Has a doctor ever told you that you have a blood circulation problem in any of the following areas:</td>
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<tr>
<td>a. in your head or neck?</td>
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<td>b. in your legs or feet (peripheral vascular disease (PVD) or peripheral arterial disease (PAD))?</td>
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<td>c. in any other part of your body?</td>
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<td>9. Has a doctor ever told you that you have emphysema, chronic bronchitis, chronic obstructive pulmonary disease (COPD), or lung disease?</td>
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<td>10. Has a doctor ever told you that you have arthritis?</td>
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<tr>
<td>a. neck</td>
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<tr>
<td>b. hands</td>
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<td>c. feet</td>
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<td>d. back</td>
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<td>e. shoulders</td>
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<td>f. hips</td>
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<td>g. knees</td>
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<td>11. Has a doctor ever told you that you have kidney disease?</td>
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<td>12. Has a doctor ever told you that you have liver disease?</td>
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<td>13. Have you been treated in the last 2 years by a doctor or other health care professional for any either:</td>
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<td>a. major depression?</td>
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<td>b. other psychiatric problem?</td>
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<td>15. Which of the following best describe how often you drink wine, beer, whiskey, or liquor? (please mark only one)</td>
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<td>Never drank</td>
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<td>Used to drink, but don’t drink now</td>
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<td>One or two times a year, or very occasionally</td>
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<td>Less than once a week or only at parties</td>
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<td>Once or twice a week</td>
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<td>Three or four times a week</td>
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16. Which of the following best describes your cigarette smoking history?
   a. At the present time (now), I smoke cigarettes regularly
   b. I do not smoke at the present time (now), but I smoked cigarettes regularly in the past
   c. I have never smoked cigarettes regularly

17. a. How old were you when you began smoking cigarettes regularly?
   b. On an average day, how many cigarettes do you smoke?

18. a. How old were you when you began smoking cigarettes regularly?
   b. How old were you when you quit (stopped) smoking?
   c. When you were smoking, on an average day how many cigarettes did you smoke?

19. Have you been hospitalized within the past 12 months? If “YES”, please record the reason, date of hospitalization, and name and location of hospital.

<table>
<thead>
<tr>
<th>Date of Hospitalization</th>
<th>Hospital Name</th>
<th>City &amp; State</th>
<th>Reason</th>
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<td>1.</td>
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<td>4.</td>
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<td>5.</td>
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20. Are you presently under a doctor’s care for any medical problems or conditions not listed in the previous questions?
Appendix L

Functional Task: Stair Climb Procedures
Stair Climb Test

Procedures

1) Accompany the participant to the starting line to bottom of the stairs.

2) Describe the stair climb and then demonstrate the test for the participant.

Script: "This is a stair-climb test and it is important that you give a good effort. You will be timed as you walk up and down this flight of stairs one time. You may use the handrail for support. Try to complete the task as quickly as you can but be cautious as climb the stairs. Be particularly careful when you turn at the top of the stairs."

"Stand here and watch me demonstrate how to walk the flight of stairs."

When I say: "Go climb the stairs as quickly as you and while still being safe. Do you have any questions? Ok. Are you ready to begin? Ready, Go."

3) Start the stopwatch when the participant takes the 1st step.

4) Offer appropriate encouragement during the test.

"Keep up the good work." "You are doing well." "Good job."

If a participant is having difficulty, encourage him/her to complete the test.

5) Stop the stopwatch to end the test when the participant's foot crosses the starting line at the bottom of the stairs.
Appendix M

Functional Task: 400-Meter Walk
400 Meter Fitness Walk

Procedures

1) Accompany the participant to the starting line for the 400-m walk.

2) Describe the 400-m walk and then demonstrate the walk for the participant.

Script: "This is a fitness walk and it is important that you give a good effort. You will be walking 10 complete laps around the course, which is about 5 miles. Please walk as quickly as you can without running. At a pace you can maintain for 10 laps. After you complete the 10 laps, I will tell you to stop."

"Stand here and watch me demonstrate how to walk a lap around the course."

3) Walk completely around the course and describe to the participant to walk at a pace they can maintain for 10 laps.

4) Describe to the participant that you will count aloud the number of laps they have completed and how many laps they have left each time they finish a lap.

5) Describe to the participant the purpose of the chairs at each end of the course and the fact that you will be moving behind them as they walk the course to be certain that the test is being conducted safely and properly. However, there can be no conversation taking place during the test.

"The chairs that you will see at each end of the course are only there if you feel you are getting in trouble (feel dizzy or too tired to go on). You may sit down in the chair to rest but please understand that I will still have to keep the watch running if you choose to sit down until you finish the 10 laps."

"At the end of the last lap, please keep walking until I tell you to stop. Once I tell you to stop, I ask that you walk one slow lap and we cool down."

"Ok, are you ready to begin? Ready, Go."

6) Start the stop watch when the participant's first footfall crosses the starting line.

7) At the end of each lap offer standard encouragement, and call out the number of laps completed and the number remaining. Record each lap on the form.

"Keep up the good work!" "You are doing well!" "Good job."

If a participant is getting off course, encourage him/her to stay on course.

8) Stop the stop watch when the participants' first footfall crosses the finish line. Record time.

When the participant completes the 400-m fitness walk (10 laps), tell the participant they have finished, but ask them to walk an additional lap at a slower pace to cool off.
Appendix N

Stair Climb Performance and Mobility-Related Self-Efficacy Recording Form
This questionnaire is designed to measure how confident or certain you are in your ability to complete the walking task. Please indicate below, how certain you are that you can successfully carry out each walking activity listed below at the PRESENT TIME.

How certain are you that you can walk:

1. ... for 2 trips up and down the stairs at a moderate pace **without stopping**.
   - [ ] 0 NOT AT ALL CERTAIN
   - [ ] 1
   - [ ] 2
   - [ ] 3
   - [ ] 4 MODERATELY CERTAIN
   - [ ] 5
   - [ ] 6
   - [ ] 7
   - [ ] 8
   - [ ] 9 HIGHLY CERTAIN
   - [ ] 10

2. ... for 4 trips up and down the stairs at a moderate pace **without stopping**.
   - [ ] 0 NOT AT ALL CERTAIN
   - [ ] 1
   - [ ] 2
   - [ ] 3
   - [ ] 4 MODERATELY CERTAIN
   - [ ] 5
   - [ ] 6
   - [ ] 7
   - [ ] 8
   - [ ] 9 HIGHLY CERTAIN
   - [ ] 10

3. ... for 6 trips up and down the stairs at a moderate pace **without stopping**.
   - [ ] 0 NOT AT ALL CERTAIN
   - [ ] 1
   - [ ] 2
   - [ ] 3
   - [ ] 4 MODERATELY CERTAIN
   - [ ] 5
   - [ ] 6
   - [ ] 7
   - [ ] 8
   - [ ] 9 HIGHLY CERTAIN
   - [ ] 10

4. ... for 8 trips up and down the stairs at a moderate pace **without stopping**.
   - [ ] 0 NOT AT ALL CERTAIN
   - [ ] 1
   - [ ] 2
   - [ ] 3
   - [ ] 4 MODERATELY CERTAIN
   - [ ] 5
   - [ ] 6
   - [ ] 7
   - [ ] 8
   - [ ] 9 HIGHLY CERTAIN
   - [ ] 10
How certain are you that you can walk:

5. ... for 10 trips up and down the stairs at a moderate pace without stopping.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT AT ALL CERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MODERATELY CERTAIN</td>
</tr>
</tbody>
</table>

6. ... for 12 trips up and down the stairs at a moderate pace without stopping.

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<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT AT ALL CERTAIN</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>MODERATELY CERTAIN</td>
</tr>
</tbody>
</table>

Stair Climb Performance (Record performance time in seconds below)

______________ Seconds
Appendix O

400-Meter Walk Performance and Mobility-Related Self-Efficacy Recording Form
This questionnaire is designed to measure how confident or certain you are in your ability to complete the walking task. Please indicate below, how certain you are that you can successfully carry out each walking activity listed below at the PRESENT TIME.

How certain are you that you can walk:

1. ... for **2 laps around the track** at a moderate pace without stopping.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT AT ALL CERTAIN</td>
<td>MODERATELY CERTAIN</td>
<td>HIGHLY CERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. ... for **4 laps around the track** at a moderate pace without stopping.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT AT ALL CERTAIN</td>
<td>MODERATELY CERTAIN</td>
<td>HIGHLY CERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. ... for **6 laps around the track** at a moderate pace without stopping.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT AT ALL CERTAIN</td>
<td>MODERATELY CERTAIN</td>
<td>HIGHLY CERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. ... for **8 laps around the track** at a moderate pace without stopping.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT AT ALL CERTAIN</td>
<td>MODERATELY CERTAIN</td>
<td>HIGHLY CERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
How certain are you that you can walk:

5. ... for 10 laps around the track at a moderate pace **without stopping**.

   | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
---|---|---|---|---|---|---|---|---|---|---|----|
NOT AT ALL CERTAIN | | | | | | | | | | | |
MODERATELY CERTAIN | | | | | | | | | | | |
HIGHLY CERTAIN     | | | | | | | | | | | |

6. ... for 12 laps around the track at a moderate pace **without stopping**.

   | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
---|---|---|---|---|---|---|---|---|---|---|----|
NOT AT ALL CERTAIN | | | | | | | | | | | |
MODERATELY CERTAIN | | | | | | | | | | | |
HIGHLY CERTAIN     | | | | | | | | | | | |

**400M Walk Performance** (Record performance time in minutes below)
Appendix P

Western Ontario McMaster’s University Osteoarthritis Index
Please select the one answer that comes closest to the way you have been feeling during the past 48 hours by circling the appropriate number.

<table>
<thead>
<tr>
<th></th>
<th>Extreme</th>
<th>Severe</th>
<th>Moderate</th>
<th>Slight</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please indicate the amount of pain you have experienced due to arthritis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Walking on a flat surface</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2. Going up or down stairs</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. At night while in bed</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4. Sitting or lying</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>5. Standing upright</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Please indicate the amount of joint stiffness you have experienced</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. After first awakening in the morning</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2. After sitting, lying, or resting, later in the day</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Please indicate the amount of difficulty you have due to arthritis:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Extreme</th>
<th>Severe</th>
<th>Moderate</th>
<th>Slight</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Descending (going down) stairs</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2. Ascending (going up) stairs</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. Rising from sitting (standing up from a chair)</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4. Standing</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>5. Bending to the floor</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>6. Walking on flat surfaces</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>7. Getting in or out of a car</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>8. Going shopping</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>9. Putting on socks</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>10. Rising (getting out of) from bed</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>11. Taking off your socks</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>12. Lying in bed</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>13. Getting in or out of the bath/shower</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>14. Sitting</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Score 1</td>
<td>Score 2</td>
<td>Score 3</td>
<td>Score 4</td>
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<tr>
<td>---</td>
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</tr>
<tr>
<td>15</td>
<td>Getting on or off the toilet</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>16</td>
<td>Heavy domestic duties</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>17</td>
<td>Light domestic duties</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
Appendix Q

Community Health Activities Model Program for Seniors – CHAMPS PA Questionnaire
**Champs Activities Questionnaire for Older Adults**

**Champs Community Health Activities Model Program for Seniors**

The following questions ask you about various activities that you may have done in the past four weeks; for those activities that you have done, they also ask you how many times you have done the activity and how many total hours you spent doing the activity. There are no "right" or "wrong" responses, so please answer each question as honestly and accurately as you can. (For Follow-Up Visits Only) Although for scientific reasons, I ask that you not tell me to which of the two exercise groups you were assigned, when responding to these questions, please report only your actual activity, whether the activity is or is not part of the exercise program. As long as you do not tell me what group you are in, this information will not un-blind me. Do you have any questions? (Assessment Note: If the participant cannot respond or answers the questions, go to question 7.c.)

<table>
<thead>
<tr>
<th>Activity Description</th>
<th>Yes</th>
<th>No</th>
<th>1 hour</th>
<th>1.5 hours</th>
<th>2 hours</th>
<th>2.5 hours</th>
<th>3 hours</th>
<th>3.5 hours</th>
<th>4 hours</th>
<th>4.5 hours</th>
<th>5 hours</th>
<th>5.5 hours</th>
<th>6 hours</th>
<th>6.5 hours</th>
<th>7 hours</th>
<th>7.5 hours</th>
<th>8 hours</th>
<th>8.5 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Visit with friends or family? (Other than those you live with)</td>
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<tr>
<td>2. Go to the senior center?</td>
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<td>3. Do volunteer work?</td>
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<td>4. Attend club or take part in club activities?</td>
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<tr>
<td>5. Attend other club or group meetings?</td>
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<tr>
<td>6. Use a computer?</td>
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<tr>
<td>7. Dance? (e.g., square, line, ballroom, do not count aerobic dance here)</td>
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</tr>
</tbody>
</table>
## CHAMPS PA Questionnaire Baseline

<table>
<thead>
<tr>
<th>In a typical or normal week during the past 4 weeks, did you...</th>
<th>No</th>
<th>Yes</th>
<th>If you, how many times a week did you usually do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Do woodwork, needlework, drawing, or other arts or crafts?</td>
<td></td>
<td></td>
<td>1 hour</td>
</tr>
<tr>
<td>9. Play golf, carrying or pulling your equipment? (count walking the entire course)</td>
<td></td>
<td></td>
<td>3 METS; Mode rate</td>
</tr>
<tr>
<td>10. Play golf, using a cart? (count walking the entire course)</td>
<td></td>
<td></td>
<td>2 METS; Light</td>
</tr>
<tr>
<td>11. Attend a concert, movie, lecture, or sports event?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Play cards, bingo, or board games with other people?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Shoot pool or billiards?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Play singles tennis? (do not count doubles)</td>
<td></td>
<td></td>
<td>6 METS; Mode rate</td>
</tr>
<tr>
<td>15. Play doubles tennis? (do not count singles)</td>
<td></td>
<td></td>
<td>4 METS; Mode rate</td>
</tr>
<tr>
<td>16. Skate? (ice, roller, etc.)</td>
<td></td>
<td></td>
<td>4.5 METS; Mode rate</td>
</tr>
<tr>
<td>17. Play a musical instrument?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Read?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Do heavy work around the house, such as washing windows, cleaning gutters?</td>
<td></td>
<td></td>
<td>3 METS; Mode rate</td>
</tr>
<tr>
<td>20. Do light work around the house? (such as sweeping or vacuuming)</td>
<td></td>
<td></td>
<td>2.5 METS; Light</td>
</tr>
</tbody>
</table>

188
**CHAMPS PA Questionnaire Baseline**

<table>
<thead>
<tr>
<th>No.</th>
<th>Activity</th>
<th>METS</th>
<th>Light Activity</th>
<th>1 hour</th>
<th>1.25 hours</th>
<th>2 hours</th>
<th>2.5 hours</th>
<th>3 hours</th>
<th>3.5 hours</th>
<th>4 hours</th>
<th>5 hours</th>
<th>6 hours</th>
<th>7.25 hours</th>
<th>8 hours</th>
<th>8.5 hours</th>
<th>9 hours</th>
<th>10 hours</th>
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<tr>
<td>21</td>
<td><strong>Do heavy gardening?</strong> (e.g., weeding, raking)</td>
<td>4 ME</td>
<td>Moderate</td>
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<td>22</td>
<td><strong>Do light gardening?</strong> (e.g., weeding, raking)</td>
<td>2.25 ME</td>
<td>Light</td>
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<td>23</td>
<td><strong>Work on your car, truck, lawn mower, or other machinery?</strong></td>
<td>3 ME</td>
<td>Moderate</td>
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<td>24</td>
<td><strong>Jog or run?</strong></td>
<td>7 ME</td>
<td>Moderate</td>
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<td>25</td>
<td><strong>Walk uphill or hike uphill?</strong></td>
<td>6 ME</td>
<td>Moderate</td>
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<td>26</td>
<td><strong>Walk fast or briskly for exercise?</strong></td>
<td>3.5 ME</td>
<td>Moderate</td>
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<td>27</td>
<td><strong>Walk to school?</strong></td>
<td>2.5 ME</td>
<td>Light</td>
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<td>28</td>
<td><strong>Walk to park or exercise playground?</strong></td>
<td>2.5 ME</td>
<td>Light</td>
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<td>29</td>
<td><strong>Ride a bicycle or stationary cycle?</strong></td>
<td>4 ME</td>
<td>Moderate</td>
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<td>30</td>
<td><strong>Do other aerobic machines such as running, or non-machine?</strong></td>
<td>5 ME</td>
<td>Moderate</td>
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<td>Activity Description</td>
<td>Yes</td>
<td>No</td>
<td>Less than 1 hour</td>
<td>1-1.5 hours</td>
<td>1.6-2.4 hours</td>
<td>2.5-4 hours</td>
<td>4.1-5.8 hours</td>
<td>5.9-7.5 hours</td>
<td>7.6+ hours</td>
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<td>37. Do water exercises? (Do not count swimming)</td>
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<td>32. Swim moderately or fast?</td>
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<td>33. Swim rapidly?</td>
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<td>34. Do fast or fast walking exercise? (Do not count yoga or Tai Chi)</td>
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<td>35. Do yoga or Tai Chi?</td>
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<td>36. Do aerobics or aerobic dance?</td>
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<td>37. Do aerobics or easy strength training? (Such as body weight or more than 5 lbs. weight machines or pulleys)</td>
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<td>38. Do weight training? (Such as body weight or 5 lbs. or less or elastic bands)</td>
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<td>39. Do relaxation or mind body relaxation exercise? (Do not count strength training)</td>
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<td>40. Play basketball, soccer, or racquetball? (Do not count time on sides)</td>
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In a typical or normal week during the past 4 weeks, did you...

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<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>If yes, how many total hours a week did you usually do it?</th>
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<td>Low: 1 hour</td>
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<td>41. Do other types of physical activity not previously mentioned? (please specify)</td>
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<td>42. Do other types of physical activity not previously mentioned? (please specify)</td>
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<td>43. Do other types of physical activity not previously mentioned? (please specify)</td>
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Evaluator Note: Do feel this was a valid assessment? Yes □ No □

Specify:

__________________________
__________________________

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Appendix R

Lifecorder Log Recording Sheet
Participant Instructions for Wearing the Accelerometer

1. Wear on the hip at the waistline, either on the right or left side of the body. Beginning tomorrow, wear the unit on the same side and location during all waking hours each day for 7 consecutive days. Securely clip the sensor onto a belt or waistband; it should not jiggle around.

2. Put the accelerometer on while dressing in the morning and do not remove it until undressing at night for bed. This includes wearing the device during exercise or while engaging in other activities. If changing clothes during the day, be sure to put the sensor back on.

3. Use the Activity Monitor Log to document when the accelerometer is worn during the 7 days. This includes the day and the time the monitor is put on and when it is removed. Typically, once it is put on in the morning, it will not need to be removed except for bathing and swimming. In the case of rain, please make sure the accelerometer is fully covered or removed. Taking it off for a few minutes while bathing or changing clothes does not need to be recorded in the diary. If you have to take off the Lifecorder during the day for any reason please record the amount of time it was not worn in the Time Not Worn column. Record any problems you have in the Problems/Comments column on the right of the Activity Monitor Log.

4. The Lifecorder Plus motion sensor is vulnerable to being dropped or submerged in water. It cannot be worn in a shower or pool. Care should be taken to cover it with a jacket or other protective clothing while active in the rain. Make sure the device is removed before clothing is laundered. At bedtime, or during other extended periods of non-use, the motion sensor should be stored in a safe location where it will not be damaged by water or falling to the floor, or accessible to young children or pets.

5. The device and Activity Monitor Log should be returned to the IMPACT staff at the end of the seven-day wear period in person or mailed in the pre-postage paid and envelope provided. Since the life of the battery is short, the device should be returned promptly following the seventh day. Questions about the device should be directed to Dr. Brian Reehl, IMPACT Principal Investigator, at 292-2165.
Appendix S

Lifecorder Instruction Sheet
The IMPACT Study

LIFECORDER Activity Monitor Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Start Time</th>
<th>Finish Time</th>
<th>Minutes of Exercise</th>
<th>Time Off</th>
<th>Time On</th>
<th>Time Off</th>
<th>Time On</th>
<th>Time Off</th>
<th>Time On</th>
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Special Notes (Please include date with any notes)
Appendix T

Randomization Order
IMPACT Trial
Randomization Schedule (Intended 4 Waves of at least 12)

1. GMCB
2. Traditional
3. Traditional
4. GMCB
5. GMCB
6. Traditional
7. GMCB
8. Traditional
9. GMCB
10. GMCB
11. Traditional
12. GMCB
13. Traditional
14. GMCB
15. GMCB
16. Traditional
17. Traditional
18. GMCB
19. Traditional
20. GMCB
21. GMCB (Intended Wave 1 – GMCB = 12; Traditional = 9)
22. Traditional
23. GMCB
24. GMCB
25. Traditional
26. GMCB
27. Traditional
28. Traditional
29. GMCB
30. Traditional
31. GMCB
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37. Traditional
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39. GMCB
40. Traditional
41. Traditional
42. GMCB
43. Traditional
44. GMCB
45. Traditional
46. Traditional
47. GMCB (Intended Wave 2 – GMCB = 24; Traditional = 23)
48. Traditional
49. GMCB
50. GMCB
51. Traditional
52. Traditional
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54. Traditional
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63. GMCB
64. GMCB
65. Traditional
66. Traditional
67. GMCB
68. GMCB
69. Traditional
70. GMCB
71. GMCB (Intended Wave 3 – GMCB = 36; Traditional = 35)
72. Traditional
73. GMCB
74. Traditional
75. GMCB
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91. Traditional
92. Traditional
93. GMCB
94. Traditional
95. GMCB (Wave 4 – GMCB = 48; Traditional = 46)
96. Traditional
97. GMCB
98. Traditional
99. GMCB
100. Traditional
101. GMCB
102. GMCB
103. Traditional
104. GMCB
105. Traditional (Supplemental Wave 5 – GMCB = 53; Traditional = 51...if necessary)
IMPACT Trial
Health & Exercise Science
The Ohio State University
Baseline Randomization Form

Participant name: ____________________________

Participant ID#: ____________________________

Randomized to: GMCB, Traditional

Date: ____________________________

________________________________________
Principal Investigator
Appendix U

Traditional Check-In Form
IMPACT Study – Daily Check In Form

1. Blood Pressure - ____________
   Pulse - ____________
   Glucose level (if diabetic) - ____________
   Do you have any symptoms or problems that may affect your ability to exercise today?

2. Please list the barriers, if any, you experienced in exercising this week:

3. Exercising this week is:
   ___ Very Hard
   ___ Hard
   ___ Somewhat Easy
   ___ Easy
   ___ Very Easy

4. When exercising this week I generally felt ____________
   ___ Very Good
   ___ Good
   ___ Neutral (Neither Good or Bad)
   ___ Bad
   ___ Very Bad

5. I felt ____________ to walking this week:
   ___ Strongly Committed
   ___ Committed
   ___ Somewhat committed
   ___ Not Committed
Appendix V

Borg’s Rating of Perceived Exertion
PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you answer yes to any of the questions in the box, tell your doctor if you should check with your doctor before you start. If you are over 65 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly. Check YES or NO.

YES

1. Have you recently had a heart attack or other heart condition?

2. Have you had any heart or lung problems?

3. Have you been diagnosed with a lung or heart problem?

4. Have you had any recent heart problems or other heart conditions?

5. Have you had a lung or heart condition?

6. Have you been diagnosed with a lung or heart condition?

7. Do you have any other medical conditions that could affect your physical activity?

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active. If you are unsure, it is best to talk with your doctor BEFORE you start.

If you answered yes to any of the questions, see your doctor before you start.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you are reasonably sure that you are ready to start becoming much more physically active. It is always best to start slowly and build up gradually.

Delay may be needed due to age:

If your doctor has advised you to delay because of age or other health conditions, please follow their advice.

Please note: If you have any doubts or concerns, please consult your doctor before starting.

No changes permitted. You are encouraged to photostat the PAR-Q but only if you add it to the entire form.

If you made any changes to the PAR-Q, please print your name and date on the form.

If you have any questions, please consult your doctor before starting.

Note: This physical activity questionnaire is valid for 12 months from the date it is completed and becomes invalid if you need to change any of the answers or if you are no longer physically active.

204
Appendix W

Knee Pain Ratings
I. Exercise Intensity: How hard are you working?

If you experience discomfort, pain, tightness, or fatigue in your legs when exercising, use the **Knee Pain Scale** as one way to determine the intensity of your exercise.

**KNEE PAIN SCALE**

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Exercise until your pain, discomfort, tightness, or fatigue gets so great that you no longer can walk. Then, rest and continue exercising as soon as you can!
Appendix X

Group-Mediated Cognitive-Behavioral Check-In Form
IMPACT Study - Daily Check In Form

1. Blood Pressure - ___________
   Pulse - ___________
   Glucose level (if Diabetic) - ___________
   Do you have any symptoms or problems that may affect your ability to exercise today?

2. Please list the barriers, if any, you experienced in meeting your most recent exercise goals:

3. Trying to achieve my most recent exercise goals was:
   ___ Very Hard
   ___ Hard
   ___ Somewhat Easy
   ___ Easy
   ___ Very Easy

4. When walking this past week I generally felt ___________
   ___ Very Good
   ___ Good
   ___ Neutral (Neither Good or Bad)
   ___ Bad
   ___ Very Bad

5. I felt ____________ to achieving my most recent exercise goals.
   ___ Strongly Committed
   ___ Committed
   ___ Somewhat committed
   ___ Not Committed

6. Write one thing that helped you reach one of your daily walking goals.
Appendix Y

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