EFFECTS OF INTENSIVE DIET AND EXERCISE ON SELF-EFFICACY IN OVERWEIGHT AND OBESE ADULTS WITH KNEE OSTEOARTHRITIS

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ABSTRACT

PURPOSE: Although moderate physical activity decreases the risk of arthritis-related disability by 47%, pain and lack of confidence are often cited barriers to physical activity participation among older adults with knee osteoarthritis (OA). The purpose of this study was to examine changes in self-efficacy over the course of the Intensive Diet and Exercise (IDEA) trial in obese older adults with knee OA.

METHODS: IDEA was a single-blind, randomized controlled trial with 454 obese older adults (M age=65.6 years) with radiographic evidence of knee OA. Participants were randomized to one of three interventions: exercise-only (E-only); intensive dietary weight loss-only (D-only); or intensive dietary weight loss-plus-exercise (D+E). Self-efficacy for walking ability, balance, walking duration and exercise adherence were assessed at baseline, 6 and 18 months. Baseline associations were tested using Pearson correlations, and group least squares means were compared using mixed linear models at 6 and 18 months, adjusted for multiple comparisons.

RESULTS: At baseline, participants with higher self-efficacy reported significantly better function and less pain, walked farther on the six-minute walk, and were more physically active (all |r| > 0.12, all p < .01). At 18 months, significant differences between groups were detected for all self-efficacy measurements, such that the D+E group was significantly (all p < .005) higher than either D or E groups alone for gait efficacy, walking duration efficacy, and balance, whereas D+E was significantly greater in exercise adherence efficacy when compared to D-only, but not E-only.

CONCLUSIONS: Treatments for knee OA should include both intensive dietary weight loss and exercise to have the greatest impact on self-efficacy.
INTRODUCTION

Knee Osteoarthritis

Osteoarthritis is a degenerative disease that occurs when cartilage in a joint breaks down causing bone to rub against bone. This degeneration of cartilage often leads to swelling, pain, and limited mobility. Osteoarthritis can occur in any joint, but it is more prevalent in the knee joint affecting 9.3 million adults (Lawrence et al., 2008). Prevalence increases with age affecting 37% of those 60 years and older (Dillon, Rasch, Gu, & Hirsch, 2006) making knee osteoarthritis the most common source of disability among older adults (Guccione et al., 1994). On the basis of gender, knee osteoarthritis favors women more than men (Dillon et al., 2006).

Critical to daily functioning, the knee is a load-bearing joint that brings together the femur, tibia and patella. Articular cartilage, a smooth, slick substance covers the end of bones limiting friction during movement. Menisci between the femur and tibia cushion the joint and lessen the impact on the joint through its shock absorbing properties. Knee osteoarthritis occurs when the cartilage in the knee gradually breaks down, the joint space narrows and bone rubs against bone.

Diagnosis of Knee Osteoarthritis

Knee osteoarthritis can be diagnosed as radiographic or symptomatic. Radiographic knee osteoarthritis is determined by an x-ray or similar diagnostic test and is commonly graded in severity using the Kellgren and Lawrence (KL; 1957) scale. Grade 1 indicates doubtful knee osteoarthritis. As the joint space narrows, osteophytes develop, and other radiographic evidence is present the grade increases from mild (KL-2;
grade 2) to moderate (KL-3; grade 3) and severe (KL-4; grade 4). Some adults with radiographic knee osteoarthritis are asymptomatic and rarely limited by the disease; however those that are symptomatic can be greatly affected by the disease.

Symptomatic knee osteoarthritis is characterized by the presence of pain on most days of the week in addition to radiographic evidence. Pain is the hallmark of symptomatic knee osteoarthritis and is often accompanied by stiffness and swelling. Pain is positively correlated with BMI (Garver et al., 2014) and disability (Creamer, Lethbridge-Cejku, & Hochberg, 2000). Pain causes individuals to seek treatment, take medication, and in the end stages of the disease, undergo a knee replacement (Zhang et al., 2008). Knee pain, either mild or moderate/severe, is a strong predictor of disability among older adults (Jordan et al., 1997). Pain associated with knee osteoarthritis is often debilitating and creates great burden upon society and individuals.

**Impact of Knee Osteoarthritis**

While there are no current epidemiological studies on the direct and indirect cost of knee osteoarthritis, there are some large studies that examine the cost of osteoarthritis as a whole without discerning the affected joint. Through a recent survey of the literature, Ma et al. (2014) estimated that the total cost of osteoarthritis of all joints in the United States surpasses $140 billion annually, of which knee osteoarthritis is likely to account for a large proportion. In a matched control study of private sector employees, researchers found that those with osteoarthritis missed almost twice as many days of work, had 3.5 times greater direct costs, and had twice the indirect costs of matched controls with no osteoarthritis (Maetzel, Li, Pencharz, Tomlinson, & Bombardier, 2004).
Of great concern and central to the problem of symptomatic knee osteoarthritis is the functional burden placed on those with the disease. Older adults with knee osteoarthritis report increased difficulty in performing critical daily tasks when compared to peers without knee osteoarthritis (Salaffi, Carotti, Stancati, & Grassi, 2005). Tasks include getting up and down from a chair, lifting and carrying groceries, walking short distances, and getting in and out of a bathtub (Davis, Ettinger, Neuhaus, & Mallon, 1991; Dillon et al., 2006). In the Johnston County Osteoarthritis Project, 43% of adults reported difficulty with at least one physical task (Jordan et al., 1997). The Third National Health and Nutrition Examination Survey (NHANES III) noted that tasks involving the bending of the knee were most problematic with 42% reporting difficulty with or the inability to kneel, stoop, or crouch (Dillon et al., 2006). To escape the constant pain and disability, many seek total knee replacement. Between 1993 and 2006 total knee replacements increased 148% and are forecast to increase 9 fold by 2030 (Kurtz, Ong, Lau, & Manley, 2011). Total knee replacement carries a certain risk and various epidemiological studies conclude that one in five patients who have a knee replaced are dissatisfied with the outcome (Bourne, Chesworth, Davis, Mahomed, & Charron, 2010).

Underlying disability is pain. Pain perception is difficult to quantify due to personal differences in its perception. Qualitative studies are instrumental to understanding the full impact of knee osteoarthritis and are the foundation for many quantitative measurements of pain. Those with knee osteoarthritis describe pain in two ways: a predictable, aching pain that develops over time or a sharp, intense unpredictable pain (Hawker et al., 2008). A 62-year-old female described her pain: “It's awful because you like to be active. I mean I used to go on a treadmill and do all these kinds of things.
Can't do it. Can't do it anymore. And you depend more on people. Like, I depend on my husband a lot more now. You just, you know, you don't like to be that way” (Hawker et al., 2008). Knee pain intensity, along with BMI and age, have been shown to increase the risk of a poor physical function outcome (Sharma et al., 2003).

**Obesity: A Key Risk Factor**

For those without injury to the knee, the etiology of knee osteoarthritis includes several risk factors including age, female gender, muscle weakness, and obesity (Heidari, 2011). Most investigators believe that daily stresses on the knee joint caused by excessive loading plays an important role in the development and progression of knee osteoarthritis (Wearing, Hennig, Byrne, Steele, & Hills, 2006). Throughout the literature obesity presents itself as a key modifiable and independent risk factor (Cooper et al., 2000; Koonce & Bravman, 2013; Manek, Hart, Spector, & MacGregor, 2003; Niu et al., 2009). Excessive body weight is thought to increase joint loads across the knee and to decrease articular cartilage (Baliunas et al., 2002; Bennell et al., 2011; Messier, Gutekunst, Davis, & DeVita, 2005; Mündermann, Dyrby, & Andriacchi, 2005; Wearing et al., 2006). Obese individuals have greater lifetime risk (60%) of developing knee osteoarthritis than those that are overweight (47%) or normal weight (30%) (Murphy et al., 2008). While the biomechanical relationship between joint loads and knee osteoarthritis is well established, research has begun to examine the systemic effects of obesity within the context of knee osteoarthritis etiology. For those that have knee osteoarthritis reducing body weight is critical in the management of the disease.
Management of Knee Osteoarthritis

Currently there is no cure for knee osteoarthritis. Management of the disease includes pharmacologic, education and lifestyle modifications. Pharmacological treatments are used to alleviate pain and reduce swelling. Pain defines symptomatic knee osteoarthritis and pharmacological treatments should be included when needed, however medications carry short and long-term risks. Education gives patients access to information about the disease, treatment, pain management, self-care and encourages patients to make necessary lifestyle modifications. Combined, pharmacological and education treatment regimes can aid people in managing knee osteoarthritis, however, maximum benefit occurs when lifestyle changes are made.

To manage knee osteoarthritis, the American College of Rheumatology strongly recommend that patients with knee osteoarthritis participate in exercise and lose weight (Hochberg et al., 2012). Based on the available evidence, exercise and weight loss are superior in the management of knee osteoarthritis when compared to other non-pharmacological treatment options (Brand, Nyland, Henzman, & McGinnis, 2013; Ettinger et al., 1997; Messier et al., 2004; Zhang et al., 2007, 2008).

Weight reduction decreases the load placed on the knee. As demonstrated by Messier et al. (2005), each pound reduction in weight equates to a four-fold reduction of forces upon the knee. In addition, pain, function and disability all improve with weight loss (Christensen, Bartels, Astrup, & Bliddal, 2007). Inflammation, an important link between obesity-related pathologies like type 2 diabetes and osteoarthritis, also decreases in obese and overweight adults after structured exercise and weight loss (Nicklas et al., 2004).
Exercise indirectly treats knee osteoarthritis by facilitating weight loss. Programs incorporating resistance or aerobic training reduce pain and improve physical function, aerobic capacity and quality of life (Ettinger & Afable, 1994; Roddy et al., 2005). Much interest has developed around the exercise induced pathways that treat knee osteoarthritis. In a recent review of the literature, Beckwée et al. (2013) found that exercise produces both local effects around the knee and global, full body effects that treat knee osteoarthritis through many different pathways. Local pathways include strengthening muscles acting at the knee, stimulating connective tissue, and improving joint stability. Those with knee osteoarthritis have been shown to have weak muscles around the knee (Pisters, Veenhof, van Dijk, & Dekker, 2014). Strong knee muscles are critical to movement and daily function, including both dynamic and static balance (Jadelis, Miller, Ettinger, & Messier, 2001; Steultjens, Dekker, & Bijlsma, 2002). Exercise has been shown to effect psychosocial components by decreasing depression and increasing well-being and self-efficacy (Motl & McAuley, 2010).

In summary, knee osteoarthritis is a disabling disease that primarily affects older adults causing pain, functional impairment and disability. Prevalence increases with age and women carry more risk than men. Despite the evidence to support weight loss and exercise as a viable management option, adoption and adherence is daunting. The next section will explore barriers to exercise in older adults with knee osteoarthritis.

**Barriers to Exercise as a Treatment for Knee Osteoarthritis**

As a whole the United States is trending upwards in body weight and down in physical activity and exercise (Manson, Skerrett, Greenland, & VanItallie, 2004). An individual seeking relief from knee osteoarthritis not only has to overcome social
pressures, they must also change ingrained behavior that brought them to an overweight and inactive state. From the perspective of the older adult, this section will first cover the state of physical inactivity and unhealthy weight in the United States and will continue to explore barriers unique to exercise as a treatment for knee osteoarthritis.

**Physical Activity and Obesity in the United States.** Despite the benefits of physical activity, 42% of older adults report no leisure time activity, and only 12% meet the 2008 Physical Activity Guidelines for Americans (U.S. Department of Health and Human Services, n.d.; US Department of Health and Human Services, 2008). Benefits of physical activity include reducing all-cause mortality, treating and preventing chronic diseases, decreasing physical impairment, and increasing quality of life (Chodzko-Zajko et al., 2009; Lee & Skerrett, 2001; Motl & McAuley, 2010; Wen, Li, & Su, 2014). Just as discouraging, 71% of older adults (>60) are overweight (BMI > 25) or obese (BMI > 30; 31%) (Ogden et al., 2006). Low levels of physical activity and high states of obesity in older adults have resulted in a sizable public health issue.

From a lifespan perspective several age specific barriers to physical activity have been identified. The Canadian Fitness and Lifestyle Research Institute (1998) lists lack of energy, motivation and illness or injury as common barriers in adults 65 years and older. In their review of the literature, Brawley, Rejeski, and King (2003) recognize many other barriers to physical activity including environment, socioeconomic status and misconceptions about physical activity. One of the greatest predictors of physical activity in old age is past physical activity (Golubic et al., 2014).

**Barriers in Older Adults with Knee Osteoarthritis.** A typical person with knee osteoarthritis is obese, over the age of 65, sedentary and experiences pain on most days of
the week (D T Felson & Zhang, 1998; D T Felson, 1990; David T Felson, Anderson, Naimark, Walker, & Meenan, 1988). Pain during activity often leads to fear of pain and avoidance of activity. As illustrated by the avoidance model (Dekker, Tola, Aufdemkampe, & Winckers, 1993; Holla et al., 2012; Pisters et al., 2014; Somers et al., 2009; Steultjens et al., 2002), pain leads to low physical activity, the weakening of muscles, instability of the joints and disability. Uninterrupted, this cycle leads to progressively worse stages of functional disability. Pain discourages exercise, however those that overcome pain, experience the benefits of exercise and become more motivated to do so (Wilcox et al., 2006). The challenge is to get those that are in pain and that have symptomatic knee osteoarthritis to begin an exercise program.

Of great assistance to overcoming the barriers posed by knee osteoarthritis, social cognitive theory provides an important framework for understanding and modifying human behavior. Self-efficacy, the belief in one’s ability to accomplish a task, is one such construct that has gained considerable attention in knee osteoarthritis research over the past decade (Marks, 2012). In persons with knee osteoarthritis, higher levels of domain specific self-efficacy is associated with higher levels of functioning (Focht, Rejeski, Ambrosius, Katula, & Messier, 2005; Rejeski, Miller, Foy, Messier, & Rapp, 2001; Sharma et al., 2003) and lower levels of pain (Somers et al., 2009; Wright, Zautra, & Going, 2008). To aid in this discussion, self-efficacy will be defined within the larger framework of Social Cognitive Theory followed by a literature review of self-efficacy studies specific to knee osteoarthritis, exercise, and weight loss in older adults.
SOCIAL COGNITIVE THEORY AND SELF-EFFICACY

Social Cognitive Theory (SCT) posits that behavior is learned through the continuous reciprocal interactions among person, environment and behavior (Bandura, 1986, 1997). For example, participant involvement and performance (behavior) in an exercise intervention are influenced by how the person feels (person) about the location and personnel involved in the intervention (environment). Social Cognitive Theory emphasizes that individual behavior is complex and that one does not simply respond to the environment.

Underlying this model of causation are two basic cognitions: outcome expectations and efficacy cognitions. Outcome expectations are the beliefs held about the likelihood that a particular outcome might result from a behavior. Efficacy cognitions are the beliefs one holds about the ability to perform a task or behavior. According to Bandura (1997), “People take action when they hold efficacy beliefs and outcome expectations that make the effort seem worthwhile. They expect given actions to produce desired outcomes and believe that they can perform those actions” (p. 24). To carry out a behavior one needs to hold both positive outcome expectations and efficacy beliefs. Perceiving that a behavior will work, but lacking the ability or confidence to carry out the behavior, will often lead to unsuccessful behavior modification. While both outcome expectations and efficacy beliefs are important, self-efficacy has consistently been shown to predict behavior across a wide range of health behaviors including physical activity.

Sources of Self-Efficacy

Self efficacy is defined as “people’s judgments of their capabilities to organize and execute courses of action required to attain designated types of performances”
Self-efficacy in itself does not imply ability, but only belief that one can execute a behavior. There are four main sources of information that impact self-efficacy perceptions: mastery experience, vicarious experience, verbal persuasion, and interpretation of physiological and affective states.

Mastery experience is the most important source of self-efficacy. Previous successes and failures performing a task or behavior greatly influence future attempts at performing a task. Successes build up efficacy while failures undermine it. Older adults are susceptible to having fewer mastery experiences by stereotyping, age-related physical and cognitive declines, and loss of autonomy during the aging process (Rodin & Langer, 1980; Welch & West, 1995).

Vicarious experience, also known as social modeling, involves observing or imagining the execution of a task. Efficacy judgments are made when perceived abilities are compared to others. As people age, comparisons are often made to individuals outside of their peer group, which leads to unrealistic ability appraisals. Older adults need to be encouraged to make social modeling decisions based on comparable peers.

Verbal persuasion in the form of encouragement, coaching, feedback and other motivational techniques can boost self-efficacy by causing individuals to put forth more effort. While generally not as robust as mastery experience, verbal persuasion can be very useful especially when the source is credible. Encouragement carries more weight when it is specific. For example, “You just lifted 20 pounds, you can lift 22 pounds” is better than “You can do it.” Encouragement from experts, especially in interventions, must be careful not to unintentionally undermine self-efficacy by encouraging one to fail.
The final source of self-efficacy involves the interpretation of physiologic and affective states. The body is constantly adapting to the environment it is placed in and these physiological adaptations can be interpreted both positively and negatively. Emotional expression of physiological states has the potential to greatly bolster or undermine self-efficacy. Older adults beginning a physical activity regime for the first time will often feel pain, fatigue, and other physiological changes that are unfamiliar to them. Emotional response to physiological states and perceived stress alters one’s perception of their abilities and outcomes.

**Measurement of Self-Efficacy**

To accurately ascertain one’s perception of capabilities, scales should use phrases like “can do” as opposed to “will do” which implies intention. Scales are constructed using a Likert scale starting at 0 (not confident), progressing by ten’s and ending at 100 (completely confident). Some simplify the scale with a range from 0 to 10 and then convert the score to a 100-point scale. According to McAuley et al. (2012), self-efficacy measures can be categorized into barriers, task-specific, or adherence self-efficacy. Items on a scale are often graduated to reflect increasing difficulty of a task. For example, a graduated walking self-efficacy measurement might ask a person, “How confident are you that you can walk for 2 minutes without stopping?” The next item would increase the time to 4 minutes. In the context of mobility related self-efficacy, measurements are employed when investigating determinants of physical activity and effectiveness of interventions on self-efficacy.

According to Bandura (2006), an individual’s efficacy beliefs vary in generality, strength and level. Design of measurement scales should speak to these three factors.
Generality implies that efficacy beliefs can be applied to other tasks, and vice versa. Scales are designed to either measure one specific task or a group of similar tasks. Strength of the efficacy belief is the degree to which an individual perceives his or her ability and is reflected in the response given on the Likert scale. Level refers to the level of difficulty of a task or group of tasks. Task specific scales are often designed to rate perception of ability at increasingly difficult levels.

Accurate measurements of self-efficacy are task specific and speak to one’s perception of their capability. Scales used to assess self-efficacy are often developed for the task at hand. Bandura (Bandura, 2006) cautions that there is “no all-purpose measure of perceived self-efficacy.” Broad domain self-efficacy scales have limited predictive value to how one might complete a specific task. The Arthritis Self Efficacy Scale (ASES) is one such tool. Developed by Lorig and colleagues (1989), this measurement is frequently used in knee osteoarthritis studies (Brand et al., 2013). As a global measurement, this scale has twenty items divided into pain, function and other symptoms subscales. In an attempt to be an all-purpose measure the ASES includes such questions as, “How certain you are that you can cut 2 bite-size pieces of meat with a knife and fork in 8 seconds?” It is obvious that this question does not measure a functional limitation imposed by knee osteoarthritis. Questions on domain self-efficacy scales need to be relevant, correlated and internally valid.

**Self-Efficacy: Determinant, Outcome and Mediator**

In two thorough reviews of the literature, McAuley et al. (2000; 2013) present compelling evidence based on cross-sectional, longitudinal and intervention studies to suggest that self-efficacy is an important determinant, outcome and mediator of physical
activity. As a determinant, self-efficacy molds behavioral intentions and is correlated with present physical activity. In a large observation of older adults, Harris et al. (2009) demonstrated that exercise self-efficacy was a strong predictor of individual steps after wearing an accelerometer for seven days. Self-efficacy at baseline is also a strong predictor of adherence during an intervention. Older, sedentary adults asked to initiate and maintain a moderate intensity exercise program were more likely to adhere to the program if their baseline and 6-month self-efficacy was high (Garcia & King, 1991). Those with low self-efficacy at the start are at greatest risk for low adherence, however, there is a strong relationship between greater self-efficacy and physical activity participation.

Through the provision of mastery experiences and verbal persuasion, self-efficacy is often increased, which may be accompanied by positive physical performance outcomes. After 12-weeks of strength training, older adults randomized to high intensity and low intensity weight training significantly increased their task specific exercise self-efficacy and at the same time experienced significant changes in arm and leg strength when compared to a control group (Tsutsumi, Don, Zaichkowsky, & Delizonna, 1997). As an outcome, self-efficacy is important in aging populations and is related to increased physical function and quality of life.

In social cognitive theory, self-efficacy is also conceptualized to mediate behavior outcomes. An individual’s journey from suggestions (i.e. prescription from doctor) to habitual behavior is greatly influenced by cognitions about the behavior. Mediators have great potential to increase physical activity adoption and maintenance. In a comparison of cognitive and social mediating variables in older adults, Brassington et al. (2002)
concluded that self-efficacy and outcome expectations mediated the relationship between the exercise counseling intervention and exercise adherence. Beyond intervention outcomes, self-efficacy mediates the relationship between physical activity and quality of life, fear of falling and disability.

Self-efficacy, within the larger context of Social Cognitive Theory, provides a firm foundation upon which many lifestyle interventions are built. There is a growing body of evidence to support the use of self-efficacy theory in diabetes management (Krichbaum, Aarestad, & Bueth, 2003), physical activity (Ashford, Edmunds, & French, 2010), and chronic disease management and disability (Marks, Allegrante, & Lorig, 2005a, 2005b). Within the older adult population, McAuley’s contributions to health psychology, both in original research and synthesis of available research, is invaluable to understanding self-efficacy theory as it applies to exercise and health promotion (McAuley & Courneya, 1993; McAuley & Elavsky, 2007; McAuley, 1993). Using this foundational work, the following section will examine self-efficacy as a determinant, outcome, and mediator of physical activity and function in older adults with knee osteoarthritis.

**ROLE OF SELF-EFFICACY IN TREATING KNEE OSTEOARTHRITIS**

Self-efficacy has been shown to be a determinant, outcome and mediator of physical activity in older adults, however, those with knee osteoarthritis face unique challenges that can impact the effect of self-efficacy. Evidence suggests that increasing age is accompanied by decreasing physical activity, function, and self-efficacy. Knee osteoarthritis further exacerbates functional decline and introduces daily joint pain. Together these barriers, pain and functional disability, can greatly confound the role of
self-efficacy in treating knee osteoarthritis. Over the past two decades, as the prevalence of knee osteoarthritis has grown to affect over a third of older adults, researchers have focused on self-efficacy and its effect on treatment outcomes. An overview of the studies that will be discussed below can be found in Appendix A.

Rejeski and co-investigators (1996) carried out one of the first investigations to examine self-efficacy as a predictor of functional performance in older adults with knee osteoarthritis. Using stair climb and lift/carry tasks as a performance outcome, the investigators found that self-efficacy predicted performance on both tasks. In addition, they found that pain during performance acted independently to mediate the effects of pre-performance self-efficacy. Similar results were found by Maly, Costigan, & Olney (2006). Looking at hamstring and quadriceps strength, functional self-efficacy correlated with strength, pain, stiffness and BMI in older adults with knee osteoarthritis. As a risk factor for knee osteoarthritis the relationship between weight status (BMI) and self-efficacy is important to consider. Garver et al. (2014) observed that as weight status increased, walking self-efficacy decreased. Since the majority of these studies have been cross-sectional, it is important to examine self-efficacy dynamically as an interventional outcome.

Observing the long-term relationship between efficacy beliefs and functional disability, two large epidemiological studies stand out. Rejeski et al. (2001) gave 480 older adults baseline measures of self-efficacy, knee pain, knee strength, physical performance and self-reported disability. After 30-months, the researchers brought the participants back, finding that self-efficacy predicted self-reported disability. In a slightly longer observational study of three years, Sharma et al. (2003) found that higher self-
efficacy reduced the likelihood of having a poor function outcome as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Used extensively in the literature, the WOMAC is a 24 item self-report assessment of pain, stiffness, and physical function in patients with hip or knee osteoarthritis (Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988; McConnell, Kolopack, & Davis, 2001). These results indicate that self-efficacy is protective against poor functional outcomes.

Logically, if self-efficacy protects from functional decline, the next step would be to explore if efficacy cognitions could be increased through treatment interventions. Rejeski et al. (1998) found that older adults with knee osteoarthritis who were randomized to an aerobic or resistance training group significantly increased self-efficacy at follow-up when compared to an education control group. One limitation lies within the measurement used for self-efficacy, which involved climbing stairs as opposed to intervention specific tasks. With self-efficacy and pain both found to mediate stair climb performance times, it is possible that pain confounded the efficacy measurement. Additionally, it is possible that increases in walking self-efficacy were transferred to stair climb performance. In efficacy theory, generality occurs when task specific self-efficacy leads to increased confidence in related tasks. Nevertheless, without a direct measurement of task specific walking self-efficacy it is uncertain generality occurred.

Using a task specific self-efficacy scale which reflected the primary intervention task, Focht and colleagues (2005) investigated the impact of weight loss and/or exercise on self-efficacy. Sedentary, overweight and obese older adults (n = 316) were randomly assigned to exercise alone, weight loss alone, combined weight loss plus exercise, or a healthy lifestyle control group. Walking self-efficacy increased significantly in the
exercise alone and exercise plus weight loss groups when compared to the control group. In addition, increases in self-efficacy were accompanied by increases in walking distance. This study underscores the importance of constructing and using task specific measures of self-efficacy.

Unfortunately, given the overwhelming public health implications, there are few other studies to highlight. In a small (n=46) short duration study, Baker et al. (2001) demonstrated modest improvements in self-efficacy following a four month at home strength training program. A handful of single arm studies also showed similar results, with small to large effect sizes for self-efficacy, after 8 to 12 weeks of structured exercise treatments (Brooks et al., 2014; Lamb, Toye, & Barker, 2008; Sullivan, Allegrante, Peterson, Kovar, & MacKenzie, 1998). Clearly there is a need for high quality, randomized trials that explore the effect of exercise treatments for knee osteoarthritis on self-efficacy in older adults.

Limitations of the Literature

During this review of the literature, two limitations of the research become apparent. First, the measurement of self-efficacy used in the research is inconsistent. Commonly used, the ASES is too broad of a measurement for self-efficacy in knee osteoarthritis individuals. Domain self-efficacy scales must have items that are correlated with each other and are specific to the population. For example, the FAST trial (Rejeski et al., 1998) used aerobic and resistance treatment arms, but the primary outcome was stair climb self-efficacy. The authors hypothesize that task specific self-efficacy transfers to other like movements in the same domain, however, self-efficacy measurement must at minimum reflect the primary mode used in the intervention. Domain self-efficacy
measurements are useful, but they are not a substitute for one-task measurements that reflect intervention tasks.

Second, the strength of the evidence supporting the role of self-efficacy in the treatment of older adults with knee osteoarthritis is quite low. The majority of studies have been cross-sectional, observational, or single arm trials which make it difficult to determine how self-efficacy changes over time. Focht et al. (2005), Rejeski et al. (1998) and Baker et al. (2001) stand alone as the only randomized control trials investigating the impact of exercise on self-efficacy in older adults with knee osteoarthritis.
OBJECTIVES

These limitations highlight the need for further investigation into the effect of exercise interventions on self-efficacy, with specific attention on task specific, gait and adherence self-efficacy in older adults with knee osteoarthritis. The Intensive Diet and Exercise for Arthritis (IDEA) trial aims to support the findings of the current literature and add to the body of evidence by speaking to the limitations above. This thesis has three objectives:

1. To describe the sample at baseline by assessing levels of self-efficacy, physical activity, physical function, and pain.

2. To examine the association between self-efficacy, physical function, physical activity, and pain at baseline.

   **Hypothesis:** At baseline, participants with low self-efficacy will have low physical activity, lower physical function and higher levels of pain when compared to those with higher self-efficacy.

3. To examine changes in self-efficacy over the course of and following exercise and dietary weight loss interventions.

   **Hypothesis 3A:** Having received different interventions, the diet only group, exercise only group, and combined intensive diet and exercise group, will experience different changes from each other in self-efficacy over the course of the interventions.

   **Hypothesis 3B:** Interventions of exercise and combined diet and exercise will have significant positive changes in self-efficacy. The diet only group will not show significant changes in our measures of self-efficacy because this
group will not build gait, duration, exercise adherence, or balance self-efficacy during the intervention.
METHODS

The present study was conducted as part of a randomized control trial that examined the effects of long term (18-month) intensive dietary weight loss and exercise on knee compressive forces and the clinical outcomes of mobility, pain and function (Messier et al., 2009, 2013). Participants were randomized into an intensive dietary weight loss group, exercise only group, or a combined group that received both intensive dietary weight loss and exercise. To elicit behavior modification and adherence, the intervention was purposely designed around social cognitive theory, with the goal of increasing self-efficacy over time.

Recruitment

Community-dwelling, overweight and obese older adults, age 55 or older, and living in greater Winston-Salem, North Carolina were recruited using mass mailings, newspaper advertisements, community centers and physician referrals from 2006 to 2009. The study sample included 454 adults who met the following eligibility requirements: (1) grade II-III (mild to moderate) radiographic tibiofemoral OA or tibiofemoral plus patellofemoral OA of one or both knees with pain on most days of the week; (2) $27.0 \leq \text{BMI} \leq 41 \text{ kg/m2}$; (3) a sedentary lifestyle, defined as less than 30 minutes of formal exercise per week; and (4) lived within 50 miles of the research site. Participants were excluded if: (1) they were unwilling or unable to commit to the 18-month intervention, to include the willingness to modify diet; (2) had a significant comorbid disease that prevented safe participation in an exercise program; or (3) had significant cognitive impairment or depression.
Potential participants were identified by phone screen and scheduled for two in-person screening visits to establish eligibility, with informed consent obtained during the first screening visit (see Appendix B). Eligibility questionnaires assessed joint pain, physical function, activity level, cognitive function, and depression. As a safety measure and for exercise prescription, a symptom-limited graded exercise test was used to exclude those with coronary disease. If the individual remained eligible, they were randomized into one of three groups.

**Intervention Groups**

*Diet Only (D-only).* Weight loss of at least 10% of baseline weight was the goal of the dietary intervention group. To accomplish the desired weight loss, participants were instructed to restrict calories to a minimum of 1100 kcal for women and 1200 kcal for men. This restriction resulted in a calorie deficit of 800 to 1000 kcal per day with a calorie distribution of 15% to 20% from protein, less than 30% from fat, and 45% to 60% from carbohydrates. Dietary plans based on partial meal replacement shakes were individually tailored to the individual. Nutritional counseling was provided by trained staff members and tapered over time. For the first 6 months participants attended 1 individual session and 3 group sessions per month, and for months 7 through 18, participants attended biweekly group sessions and an individual session every 2 months.

*Exercise Only (E-only).* Participants in the exercise only group were asked to attend a facility based, supervised program for one hour, three days a week. Primarily consisting of aerobic activity, the hour was broken down as follows: aerobic walking (15 minutes), strength training (20 minutes), a second aerobic phase (15 minutes), and cool-down (10 minutes). After six months, participants were given an option to transition to
home-based exercise or a combination of home and facility based exercise. Walking, with an exercise intensity of 50-75% of heart rate reserve, was the primary mode of exercise; however, participants were allowed to use a recumbent bike if walking was troublesome. In this study exercise only was the comparison group since a previous study identified aerobic or resistance training as standard treatment for knee osteoarthritis patients (Ettinger et al., 1997).

Combined Diet and Exercise (D+E). Participants in this group received both the exercise and dietary interventions described above. To minimize the number of sessions attended, dietary counseling was conducted prior to or after the exercise session.

Techniques to Improve Adherence

Social Cognitive Theory provided a theoretical framework for implementation of the dietary weight loss and exercise interventions. To promote behavior change in the exercise groups, participants exercised in small groups with the support of an exercise interventionist. Similarly a trained interventionist facilitated small group meetings in the diet groups to encourage participants to share techniques and challenges to caloric restriction. Small groups foster an environment where participants can develop mastery experiences, share in accountability, and provide motivation to each other. All interventionists received training in behavioral techniques from a health psychologist. Frequent meetings were conducted with the intervention team and the health psychologist. In these meetings the staff developed courses of action to aid participants that experienced difficulty making behavior modification. Low adherers were identified and additional support, including counseling and phone call reminders, were provided. Table 1 outlines additional techniques used for each of the four sources of self-efficacy.
**Table 1. Sample of behavioral techniques used to enhance self-efficacy**

<table>
<thead>
<tr>
<th>Sources of Self-Efficacy</th>
<th>Intervention Techniques and Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mastery Experience</td>
<td>• program was tailored to the participant's ability and gradually increased over time</td>
</tr>
<tr>
<td></td>
<td>• periodic individual updates on the participants overall progress (i.e. progress charts)</td>
</tr>
<tr>
<td>Vicarious Experience</td>
<td>• participants were assigned to a group where they attended diet counseling and exercise sessions together with other older, overweight and obese individuals with knee osteoarthritis</td>
</tr>
<tr>
<td>Verbal Persuasion</td>
<td>• built-in pattern of frequent contact that demonstrated personal interest in the participant</td>
</tr>
<tr>
<td></td>
<td>• exercise was supervised by interventionists who encouraged participants</td>
</tr>
<tr>
<td></td>
<td>• interventionists helped participants create measurable and obtainable goals</td>
</tr>
<tr>
<td>Physiological Cues</td>
<td>• interventionists helped participants interpret physiological responses to starting an exercise program (i.e. pain, soreness)</td>
</tr>
<tr>
<td></td>
<td>• participants were shown how to monitor heart rate and complete activity logs</td>
</tr>
<tr>
<td></td>
<td>• in the diet intervention groups, participants received specific counseling in adapting to a lower calorie diet</td>
</tr>
</tbody>
</table>

**Measurements**

All measurements were taken at baseline, 6 months, and 18 months. Data collection was made by personnel that were blinded to group assignment.

*Demographics.* Age, gender, and completed years of formal education were self-reported. Height and weight were obtained using standard measures to obtain BMI.

*Mobility, pain and function.* Mobility, pain and function were assessed using the six-minute walk test (6MW), Physical Activity Scale for the Elderly (PASE) and the Western Ontario McMasters Universities Osteoarthritis Index (WOMAC). For the 6MW, participants were instructed to walk as far as possible in six minutes on an indoor, level course. No encouragement was provided during the walking test.
Validated and shown reliable in older adults with knee osteoarthritis, the PASE (Martin et al., 1999; Washburn, McAuley, Katula, Mihalko, & Boileau, 1999), comprised of items measuring self-reported occupational, household and leisure activity, was used to measure the level of self-reported physical activity in participants over a 7-day period. Total score for the PASE ranges from 0-400 or more and is calculated using hours of time spent in each activity, assigning item weights to an activity from empirical evidence, and then summing the overall activity scores.

Specific to individuals with knee or hip osteoarthritis, the WOMAC pain and function subscales were used to assess self-reported knee pain and function in the previous 48 hours (Bellamy et al., 1988). For the pain scale participants indicated level of pain, on a 0 (none) to 4 (extreme) scale, experienced during daily activities. The pain subscale consisted of 5 questions resulting in a range of 0-20, with a higher score indicating greater pain. Using 17 common mobility related tasks, the function subscale asked participants to rate difficulty on a scale from 0 (none) to 4 (extreme). Individual item scores are summed to give a range of 0 to 68, with a higher score reflecting worse function.

*Self-efficacy measurements.* Self-efficacy was measured using the activities-specific balance confidence scale (ABC), a walking efficacy for duration scale, the gait efficacy scale, and an adherence self-efficacy scale. Each item asks the participant to rate their confidence in the completion of a task ranging from 0% (not at all confident) to 100% (completely confident), in increments of 10. Scales were scored individually by computing the average of all items on the scale yielding a range from 0 to 100 with a higher score indicating higher self-efficacy.
Using 16 common mobility related activities, the ABC asks participants to rate their confidence in performing various ambulatory activities without falling or experiencing a sense of unsteadiness (Powell & Myers, 1995). Demonstrating strong internal consistency (Huang & Wang, 2009), the ABC incorporates activities in and outside the home including: walking across a parking lot, walking in crowded places and getting in and out of a car.

To ascertain the participant’s belief in their ability to walk at a moderately fast pace for increasingly longer time increments, a walking efficacy for duration scale was constructed. Starting at 5 minutes, advancing in increments of 5 minutes and ending at 40 minutes, participants were asked to rate their confidence in walking without stopping.

Walking rarely is without obstacles. To measure confidence in navigating obstacles while walking, to include ascending and descending stairs, the gait self-efficacy scale was used (McAuley, Mihalko, & Rosengren, 1997; Rosengren, McAuley, & Mihalko, 1998). This scale was slightly modified to remove the last two items (Cronbach’s $\alpha = .93$).

An adherence self-efficacy scale asked participants to rate their confidence in their ability to continue moderate intensity exercise three times a week, for 15-30 minutes without quitting for the next week, next two weeks, … and progressing to eight weeks.

**Analytic Plan**

Descriptive statistics of baseline measures were computed using means and standard deviations for continuous measures and frequencies and percentages for discrete measures. Variables of interest include age, gender, BMI, PASE, WOMAC, 6MW, ABC, gait efficacy scale, walking duration efficacy scale, and exercise adherence efficacy scale.
Prior to analysis all measures were inspected for normality and no skewedness was noted. Pearson correlation coefficients were used to test for significant correlations between measures of self-efficacy and the independent variables at baseline. Repeated measures analysis of covariance (ANCOVA) controlling for baseline values of the outcome, baseline BMI, and gender was conducted to examine the impact of the intervention on self-efficacy at 6 and 18 months. Visit-specific group comparisons were deemed significant at the 0.05 level, and post-hoc pairwise comparisons were conducted at a Bonferroni-adjusted 0.0167 level of significance. All analyses were performed using SAS v9.4 (SAS Institute, Cary, NC).
RESULTS

Participant Characteristics

Randomized participants (n = 454, female = 72%) were older (M = 66, SD = 6), obese and overweight (BMI, M = 33.6, SD = 3.7) adults. Demographics and clinical variables of interest at baseline are displayed in Table 2. No significant differences between groups were noted at baseline. Of the randomized participants, 399 (88%) completed the study by returning for 18-month follow-up testing with no difference between participants who completed the study and those that did not. Adherence to exercise sessions was 60% for the exercise only group and 64% for the combined group. The diet session adherence rate was 61% and 63% for the diet only group and the combined group, respectively.

Participants reported moderate to high levels of self-efficacy, as measured by the ABC (M = 78.06), gait efficacy scale (M = 51.87), walking duration efficacy scale (M = 77.11), and exercise adherence efficacy scale (M = 86.71) at baseline. On average participants walked 473.8 meters (SD = 86.7) and reported lower physical activity levels (PASE, M = 114.24, SD = 52.3) than comparable community dwelling adults (Washburn et al., 1999, M = 132, SD = 70.4). Mean scores for WOMAC function and pain were 24.2 (SD = 10.9) and 6.5 (SD = 3.1), respectfully.
Table 2. Demographic and clinical characteristics of the study participants at baseline*

<table>
<thead>
<tr>
<th></th>
<th>Overall N = 454</th>
<th>D-only N=152</th>
<th>E-only N=150</th>
<th>D+E N=152</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>66.0 (6.0)</td>
<td>65.8 (6.2)</td>
<td>65.5 (6.4)</td>
<td>65.4 (6.0)</td>
</tr>
<tr>
<td>Female</td>
<td>325.0 (72.0)</td>
<td>108.0 (71.0)</td>
<td>108.0 (72.0)</td>
<td>109.0 (72.0)</td>
</tr>
<tr>
<td>Nonwhite</td>
<td>85.0 (19.0)</td>
<td>25.0 (16.0)</td>
<td>30.0 (20.0)</td>
<td>30.0 (20.0)</td>
</tr>
<tr>
<td>BMI</td>
<td>33.6 (3.7)</td>
<td>33.7 (3.8)</td>
<td>33.5 (3.7)</td>
<td>33.6 (3.7)</td>
</tr>
<tr>
<td>WOMAC-Function</td>
<td>24.2 (10.9)</td>
<td>24.82 (10.4)</td>
<td>23.1 (10.3)</td>
<td>24.6 (11.4)</td>
</tr>
<tr>
<td>WOMAC-Pain</td>
<td>6.5 (3.1)</td>
<td>6.6 (2.9)</td>
<td>6.1 (2.9)</td>
<td>6.7 (3.4)</td>
</tr>
<tr>
<td>ABC</td>
<td>78.1 (18.5)</td>
<td>76.1 (19.5)</td>
<td>80.49 (16.6)</td>
<td>77.7 (19.1)</td>
</tr>
<tr>
<td>Duration Efficacy</td>
<td>51.9 (28.8)</td>
<td>52.7 (28.4)</td>
<td>56.3 (28.5)</td>
<td>46.7 (28.8)</td>
</tr>
<tr>
<td>Gait Efficacy</td>
<td>77.1 (22.4)</td>
<td>74.7 (22.9)</td>
<td>79.4 (21.0)</td>
<td>77.3 (23.0)</td>
</tr>
<tr>
<td>Adherence Self-Efficacy</td>
<td>86.2 (18.7)</td>
<td>86.1 (18.2)</td>
<td>87.9 (17.9)</td>
<td>86.1 (20.1)</td>
</tr>
<tr>
<td>PASE</td>
<td>114.2 (52.3)</td>
<td>115.3 (53.2)</td>
<td>110.8 (47.7)</td>
<td>116.6 (55.8)</td>
</tr>
<tr>
<td>6MW</td>
<td>473.8 (86.7)</td>
<td>457.4 (81.7)</td>
<td>479.7 (89.9)</td>
<td>466.5 (88.5)</td>
</tr>
</tbody>
</table>

*unless noted results are: mean (SD); ⁴results are: No. (%); ⁵meters

Baseline Correlations

To examine baseline relationships among measures of self-efficacy and the dependent variables a correlation matrix was constructed (Table 3). At baseline, participants who reported greater self-efficacy had significantly better function and less pain and walked farther on the 6MW. Of note, strong positive relationships were seen between 6MW and all efficacy measurements (r = 0.38, p < .0001). Based on self-reported physical activity, the PASE had a weak, but significant relationship (r = 0.12-0.17, p < .05) with each measure of self-efficacy.

WOMAC function and pain subscales, however, displayed a moderate negative relationship (r = -0.26-0.50, p < .0001) with all self-efficacy measurements indicating that participants who reported higher self-efficacy had less pain and better function.
Table 3. Pearson correlations at baseline

<table>
<thead>
<tr>
<th></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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>ABC</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Exercise Adherence Efficacy</td>
<td>.56 *</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Walking for Duration Efficacy</td>
<td>.48 *</td>
<td>.51 *</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Gait Efficacy</td>
<td>.78 *</td>
<td>.52 *</td>
<td>.45 *</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>WOMAC-Function</td>
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<td>-.26 *</td>
<td>-.34 *</td>
<td>-.47 *</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>WOMAC- Pain</td>
<td>-.37 *</td>
<td>-.20 *</td>
<td>-.21 *</td>
<td>-.32 *</td>
<td>.77 *</td>
<td>1.00</td>
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<td></td>
</tr>
<tr>
<td>7</td>
<td>6MW</td>
<td>.50 *</td>
<td>.37 *</td>
<td>.50 *</td>
<td>.51 *</td>
<td>-.31 *</td>
<td>-.23 *</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>PASE</td>
<td>.17 *</td>
<td>.12 *</td>
<td>.14 *</td>
<td>.12 *</td>
<td>.04</td>
<td>.03</td>
<td>.19 *</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Age</td>
<td>-.16 *</td>
<td>-.14 *</td>
<td>-.23 *</td>
<td>-.21 *</td>
<td>.04</td>
<td>.04</td>
<td>-.32 *</td>
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<td>-.15 *</td>
<td>-.12 *</td>
<td>.08</td>
<td>.03</td>
<td>-.19 *</td>
<td>-.07</td>
<td>-.13 *</td>
</tr>
</tbody>
</table>

* = p < .001; ** = p < .05

Effects of Exercise and Dietary Weight Loss on Self-Efficacy

Mean changes from baseline to 6 and 18 months for each measure of self-efficacy are depicted in Figure 1.

**ABC.** At 6 months all groups had a significant increase on the ABC when compared to baseline. At 18 months only D+E remained significantly increased on the ABC when compared to baseline with a mean change of +6.43 (SE = 1.08, p < .0001).

**Gait efficacy scale.** All groups significantly increased perception of gait efficacy at 6 and 18-months. At 18-months, D+E experienced the greatest mean change (+8.43, SE = 1.35, p < .0001), followed by E-only (+3.12 SE = 1.35, p < .05) and D-only (+2.96, SE = 1.37, p < .05).

**Walking duration efficacy scale.** All groups experienced significant changes in walking duration efficacy at 6-months (p < .0001) and 18 months (p < .05) when
compared to baseline. Mean changes from baseline at 18-months are as follows: D-only = +7.29 (2.13); E-only = +13.56 (2.11); D+E = 21.70 (2.09).

*Exercise adherence efficacy scale.* At 6-months, E-only had a mean change +4.75 (SE = 1.97, p < .0001) and at 18-months changes were not significant when compared to baseline. Change in exercise adherence efficacy in the D+E group was significant at 6-months (mean change = +8.59, SE = 1.93, p < .0001) but was not significant at 18-months. D-only reported significant decreases (p < .0001) at 6-months (mean change = -9.11, SE = 2.03) and 18-months (mean change = -9.22, SE = 1.99) when compared to baseline.
Figure 1. Changes in self-efficacy by scale and intervention group

Note: Changes in self-efficacy as measured by (a) Activities-Specific Balance Confidence Scale, (b) Gait Efficacy Scale, (c) Exercise Adherence Efficacy Scale, (d) Walking for Duration Efficacy Scale. All 6 & 18 month means are adjusted for baseline values, baseline BMI & gender. * = value significantly differs from baseline, p < .05. Error bars are SE. Total scores range from 0 to 100 for all measures.

Differences Between Groups

Results of the ANCOVA revealed a significant difference between groups with regards to exercise adherence efficacy, walking duration efficacy, and gait efficacy at 6-months. At 18-months, significant differences between groups were detected for all four self-efficacy measurements. Between group changes can be seen in Figure 2.
ABC. At 6-months the groups were not significantly different from each other. At 18-months, D+E was significantly higher than E-only (M = 4.54, p < .05) and D-only (M = 4.62, p < .05).

Gait efficacy scale. At 6-months, D-E was borderline significantly greater than D-only (M = 4.20, p < .05) and E-only (M = 4.29, p < .05). At 18-months, D+E was significantly greater than E-only (M = 5.31, p < .05) and D-only (M = 5.47, p < .05).

Walking duration efficacy scale. At 6-months, D-only was significantly less than E-only (M = 9.72, p < .05) and D+E (M = 15.29, p < .0001). At 18-months, D-only was significantly less than E-only (M = 6.28, p < .05) and D+E (M = 14.41, p < .0001); E-only was significantly less than D+E (M = 8.14, p < .05).

Exercise adherence efficacy scale. At 6-months, D+E was significantly greater than D-only (M = 17.70, p < .0001) and E-only was significantly greater than D-only (M = 9.72, p < .05). At 18-months, D+E was significantly greater than D-only (M = 12.07, p < .0001) and E-only was significantly greater than D-only (M = 8.73, p < .05)
Note: Adjusted means for self-efficacy measures for the three intervention groups as measured by the (a) Activities-Specific Balance Confidence Scale, (b) Walking for Duration Efficacy Scale, (c) Gait Efficacy Scale, (d) Exercise Adherence Efficacy Scale. All 6 & 18 month means are adjusted for baseline values, baseline BMI & gender. Error bars are SE. Total scores range from 0 to 100 for all measures.
DISCUSSION

To our knowledge this is the only study that examines the effects of intensive weight loss (≥ 10%) and exercise on self-efficacy in older adults with knee osteoarthritis. All groups experienced significant changes in mobility related self-efficacy, however, when compared to the diet only and the exercise only groups, participants in the diet plus exercise group had significantly greater increases as measured by the ABC, gait efficacy, and walking for duration scales. As previously reported (Messier et al., 2013), the D+E group also had less pain, better function, and faster walking speed when compared to the other treatment arms. These findings lead us to conclude that a combined intervention of diet and exercise is a superior treatment for knee osteoarthritis than exercise or diet alone.

Baseline Relationships

As hypothesized, we found that participants with higher self-efficacy were higher functioning, as evidenced by significant correlational relationships among self-efficacy, WOMAC and 6MW. Function, as measured by the 6MW and WOMAC function subscale showed a moderate relationship to all four efficacy measurements. The 6MW is a direct reflection of physical capacity to accomplish tasks needed in everyday life. Shorter walking distances positively correlate with the presence of disease risk factors (Enright et al., 2003). In our study, participants walked an average of 474 meters which demonstrated lower function when compared to healthy older adults (Camarri, Eastwood, Cecins, Thompson, & Jenkins, 2006; Enright & Sherrill, 1998; Steffen, Hacker, & Mollinger, 2002). Self-reported function via the WOMAC was similar to other knee osteoarthritis samples (Messier et al., 2004; Pisters et al., 2014). Functional capacity reflects the ability to accomplish tasks. Repeated efforts to accomplish difficult tasks that
were once done with ease likely erode self-efficacy. Prospective studies have shown that baseline self-efficacy is protective against future functional decline (Sharma et al., 2003).

Closely tied with functional capacity in knee osteoarthritis patients is pain perception. Pain often leads to avoidance of activity that causes pain. Avoidance of activity decreases functional capacity. Pain not only effects speed and perception of task difficulty, but also impacts self-efficacy (Rejeski et al., 1996). We observed a moderate inverse relationship between self-efficacy and pain perception. Pain and self-efficacy have both been found to mediate physical performance in exercise interventions (Rejeski et al., 1998).

Self-reported physical activity (PASE) had a small, but significant positive association with all four measures of self-efficacy. The PASE has been shown to be a valid measure of physical activity in older adults with knee pain, capturing a wide array of physical activity levels (Martin et al., 1999). Our measurements of self-efficacy were specific to gait, balance, and exercise adherence. This specificity may have contributed to the lower than expected correlations between the PASE and self-efficacy measures. Furthermore, McAuley et al. (2005) suggests that the concept of “exercise” might not be relevant to older adults and instead essential activities of daily living should be the focus of quantifying physical activity.

**Self-Efficacy Changes Between Groups**

*Gait efficacy and walking duration efficacy.* Contrary to what was hypothesized, the diet only group experienced significant increases in gait efficacy and walking duration efficacy without having the benefit of an exercise intervention. This finding combined with the significantly greater increase in self-efficacy evidenced by the D+E
group compared to D-only and E-only leads us to consider the impact of weight status on self-efficacy. Examining the relationship between weight status, mobility related tasks and self-efficacy, Garver et al. (2014) observed that weight status in older adults with knee osteoarthritis directly impacts walking self-efficacy and walking performance as measured by accelerometry over a 7-day period. In our study, those in the diet only group experienced similar changes to the exercise only group in gait efficacy and self-efficacy for walking duration, which underscores the impact that weight reduction has on self-efficacy. Given the D+E group experienced greater changes in mobility related self-efficacy than D-only and E-only, the combined impact of weight loss and exercise on mobility related self-efficacy deserves greater attention.

ABC. Participant’s beliefs in their ability to maintain balance during static and dynamic movement, as measured by the ABC, increased for all groups at 6-months and remained significant for D+E at 18-months when compared to baseline. ABC scores less than 67 represent poor balance confidence (Hill, 2005). Participants in our study had moderate balance confidence at baseline (M = 78.1), 6 and 18-months. Aerobic and strength training exercise programs designed for knee osteoarthritis participants have led to improvements in proprioception and balance (Beckwée et al., 2013). Significant increases in balance efficacy in all groups at 6-months likely result from establishing a new diet or exercise regime, however, a combined intervention was necessary to sustain this change at 18-months. At 18-months the D+E group was significantly greater than the D-only and E-only groups in balance efficacy. Improvements in ABC as experienced by D+E from baseline to 18-months lead us to believe that weight reduction coupled with exercise reduces loads placed upon the joint and strengthens muscles that act upon the
knee, resulting in increased joint stability, and reinforced the belief in the participant’s ability to maintain balance during activities of daily living.

*Exercise adherence self-efficacy.* With regards to participant’s willingness to adhere to an exercise program without quitting, the two exercise groups increased from baseline to 6-months but then tapered from 6 to 18-months. Low confidence in the ability to continue an exercise regime following the conclusion of the formal intervention shows how reliant the participants were on intervention staff and the established routine. Participants randomized to the diet only group were not encouraged, nor discouraged, to exercise and due to the blinding of our testers, all groups received the same set of questionnaires. Participants in the exercise groups rated their confidence in ability to adhere to an exercise program following the intervention at or below baseline levels suggesting that participants lacked belief in their abilities to exercise without the structure and support provided by an intervention. The D-only group, receiving no exercise component, saw significant decreases in exercise adherence self-efficacy at 6 and 18-months, showing the value that structured exercise programs have on increasing and/or maintaining self-efficacy. Compared to the D-only group, both exercise groups were significantly greater at 18-months. Self-efficacy, as a part of social cognitive theory, is developed best in social settings that provide mastery experiences, vicarious experiences, verbal persuasion, and help interpreting physiological cues.

*Self-efficacy changes over time.* In all groups, gait efficacy, walking duration efficacy and ABC significantly improved at 6-months and then slightly tapered or remained the same at 18-months. Exercise adherence efficacy, at 6-months significantly increased in E-only and D+E, becoming insignificant at 18-months. The diet only group
significantly decreased exercise adherence efficacy at 6 and 18-months when compared to baseline. Physical capacity and mobility restrictions imposed by knee osteoarthritis possibly caused the plateau seen from 6 to 18-months in gait and walking duration efficacy. It may also be that participants had moderate to high levels of balance, gait and walking duration self-efficacy at 6-months leaving little room for significant growth. Gains in self-efficacy in the first 6-months reflect the transitioning of a sedentary population to exercise. In addition, weight loss was accelerated in the first part of the intervention and most neurological and strength gains occur rapidly at the start of an intervention. Increases in mobility related self-efficacy and 6MW are comparable to those found by Focht et al. (2005) where self-efficacy and 6MW times significantly increased over 18-months in older adults with knee osteoarthritis when compared to baseline.

**Summary**

In sum, at baseline, participants with higher self-efficacy reported significantly better function and less pain (WOMAC), walked farther on the six-minute walk test, and were more physically active (PASE) (all $|r|>0.12$, all $p<.01$). Although efficacy for walking duration, balance, and walking tasks increased in all three groups at 18 months, the D+E group had a significantly (all $p<.005$) greater increase in self-efficacy than either D or E groups alone. These findings lead us to conclude that a combined intervention of diet and exercise should be considered as a method to increase self-efficacy and, as shown by Messier et al. (2013), increase function and decrease pain.

**LIMITATIONS AND FUTURE DIRECTIONS**

When considering the results of this study it is important to consider several limitations. Self-efficacy was measured at baseline, 6 and 18-months. Due to the lack of
self-efficacy measurements at other time points, the trajectory of self-efficacy throughout the intervention is unknown. For example, it is possible that gait efficacy and walking duration efficacy continued to increase past 6-months, only to decline in months 17 and 18 as a result of the intervention ending. McAuley et al. (1999; 2003; 1993) contends that exercise interventions produce a curvilinear pattern of self-efficacy growth. Older adults in a six month long walking intervention reported increases in self-efficacy from baseline to 2 months, only to decline in months 4 and 6 (McAuley et al., 1993). Future studies should assess self-efficacy at frequent time points to help determine the changes that occur in self-efficacy over the course of an intervention.

In our study, participants were asked to lose 10% of their body weight. Initial weight reduction and subsequent weight reduction is challenging, with a success rate of <32% after five years (Anderson, Konz, Frederich, & Wood, 2001; Wadden, Foster, Letizia, & Stunkard, 1992). Weight self-efficacy has been shown to be a predictor of successful weight loss and maintenance (Rodin, Elias, Silberstein, & Wagner, 1988). Weight self-efficacy was not measured in the present study and it is uncertain what effect the study had on the participants belief in their abilities to lose and maintain weight. Utilizing the Weight Efficacy Life-Style Questionnaire (Clark, Abrams, Niaura, Eaton, & Rossi, 1991), Somers et al. (2012) found that a combined intervention of behavioral weight loss and pain coping skills training in knee osteoarthritis patients resulted in a significant reduction in weight and an increase in weight-management self-efficacy when compared to each treatment alone or to a control group. More research needs to be done to determine the impact weight loss interventions have on weight self-efficacy and the role weight self-efficacy plays as a predictor of weight loss and maintenance.
In addition, the delivery of the intervention changed at 6 months. Participants receiving the intensive weight loss intervention tapered contact as follows: from months 1 through 6, 1 individual session and 3 group sessions per month, and from months 7 through 18, biweekly group sessions and an individual session every 2 months. Participants receiving the exercise intervention were given the opportunity to exercise at home some or all of the time starting at 6-months. While few participants chose to exercise at home, the reduction in contact hours with intervention staff could have possibly dampened the effect of the intervention on self-efficacy.

Last, this study was limited by the use of an active comparison group in the place of an attention control group. Previous work by Messier et al. (2004) identified aerobic or resistance training as the standard of care for knee osteoarthritis patients. If a true control group would have been used, it is possible that there would have been even greater between group differences. Despite the fact that all groups received an intervention, the D+E group still showed significantly greater improvements than D-only or E-only in self-efficacy as measured by the ABC, gait efficacy, and walking for duration scales at 18-months.

Few studies have examined the impact of combined weight loss and exercise on self-efficacy in older adults with knee osteoarthritis. In the Arthritis, Diet, and Activity Promotion Trial (ADAPT), Focht (2005) demonstrated a significant increase in mobility related self-efficacy in a combined intervention of modest weight loss (5% of body weight) and exercise when compared to a healthy education control group in a sample of sedentary, overweight and obese older adults with knee osteoarthritis. Somers et al. (2012) found that a combined intervention of pain coping skills training and behavioral
weight management significantly increased self-efficacy over a 12-week long intervention in overweight and obese adults with knee osteoarthritis when compared to receiving pain coping training only, behavioral weight loss only, or a standard care control group. Together, the studies above, along with the present study suggest that interventions seeking to improve the lives of those with knee osteoarthritis should explicitly focus on exercise, weight reduction, pain management and self-efficacy.

**Implications**

Overall, these findings add to the earlier work of Messier and colleagues (2004, 2013) by strengthening the idea that a combined intervention of exercise and intensive weight loss built on social cognitive theory increases self-efficacy, physical function, physical activity and decreases pain. Our study demonstrates that an intervention based on self-efficacy theory enhances the beliefs held by knee osteoarthritis patients in their ability to maintain balance during activities of daily living, adhere to an exercise program, walk while navigating obstacles and walk at increasingly challenging distances.

More effective interventions that serve to enhance self-efficacy may lead to increased physical activity levels, improved pain management and ultimately, empower individuals to take better control of their health care while decreasing the toll on the healthcare system. Participants, diagnosed with one or more chronic diseases, who received a 7-week chronic disease self-management program based on self-efficacy theory managed their health care better, improved clinical outcomes (i.e. pain), had fewer visits to the emergency room and higher self-efficacy levels when compared to pre-intervention (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001). Based on this study, and a
previous randomized control trial (Lorig et al., 1999), the investigators conclude that intervention delivery cost was $200 per participant.

Interventions built on self-efficacy theory that focus on equipping knee osteoarthritis patients with the tools to manage their disease through weight loss, exercise and pain coping might very well be affordable alternatives to current management regimes. On an individual level, knee osteoarthritis patients that exercise and reduce weight experience global changes like increased health related quality of life and better mental functioning (Messier et al., 2013; Rejeski et al., 2002) that better their lives. Future research is needed to determine the viability of delivering this intervention within the confines of the U.S healthcare system. In the end, interventions seeking to improve the lives of patients with knee osteoarthritis should be designed to explicitly focus on self-efficacy for exercise, pain management, and weight loss.
WORKS CITED


Appendix A – Select Studies Exploring Exercise and Self-Efficacy

Selected studies showing the relationship between functional self-efficacy and pain, psychosocial factors and performance in samples of adults with knee osteoarthritis

<table>
<thead>
<tr>
<th>Authors</th>
<th>Level research evidence (I-V)*</th>
<th>Sample size</th>
<th>Study length</th>
<th>SE Measure</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baker et al. (2001)</td>
<td>I</td>
<td>46</td>
<td>4m</td>
<td>Ewart’s for lifting, climbing, walking, jogging, pushups</td>
<td>Walking SE correlated with knee strength</td>
</tr>
<tr>
<td>Brooks et al. (2014)</td>
<td>II</td>
<td>65</td>
<td>8w</td>
<td>Knee Self Efficacy Scale (K-SES) scale daily activities subscale (1-5)</td>
<td>SE increased after 8 week program</td>
</tr>
<tr>
<td>Focht et al. (2005)</td>
<td>II</td>
<td>316</td>
<td>18m</td>
<td>Walking SE Stair climb SE</td>
<td>SE mediated effect of exercise + weight loss</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SE improved with exercise + weight loss</td>
</tr>
<tr>
<td>Garver et al. (2014)</td>
<td>IV</td>
<td>80</td>
<td>12m</td>
<td>Walking SE Stair climb SE</td>
<td>Large effect for weight status on walking SE</td>
</tr>
<tr>
<td>Lamb et al. (2008)</td>
<td>IV</td>
<td>121</td>
<td>12w</td>
<td>ASES</td>
<td>SE increased with a small effect size People who declined treatment had lower SE</td>
</tr>
<tr>
<td>Maly et al. (2006)</td>
<td>IV</td>
<td>54</td>
<td>-</td>
<td>ASE</td>
<td>Functional SE highly correlated with performance measures</td>
</tr>
<tr>
<td>Rejeski et al. (2001)</td>
<td>II</td>
<td>480</td>
<td>30m</td>
<td>SE for stair climb</td>
<td>SE predicted disability at 30-months SE correlated with stair climb time</td>
</tr>
<tr>
<td>Rejeski et al. (1998)</td>
<td>I</td>
<td>439</td>
<td>18m</td>
<td>SE for stair climb</td>
<td>SE increased in treatment groups Compliance did not moderate effect on SE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improvement in SE correlated with stair climb time Baseline SE was a significant predictor of stair climb time</td>
</tr>
<tr>
<td>Sharma et al. (2003)</td>
<td>II</td>
<td>285</td>
<td>3y</td>
<td>ASES function subscale</td>
<td>SE reduced poor function outcome SE protected against poor WOMAC</td>
</tr>
<tr>
<td>Sullivan et al. (1998)</td>
<td>IV</td>
<td>102</td>
<td>8w</td>
<td>ASES</td>
<td>No difference from control in SE at 1-year follow-up after 8-week intervention.</td>
</tr>
</tbody>
</table>

*Levels of evidence based on the American Academy of Orthopedic Surgeons (AAOS), 2005: I = high quality RCT; II = lower quality RCT, prospective study; III = case control, retrospective; IV = observational, single arm treatment
Appendix B – Informed Consent

INTENSIVE DIET AND EXERCISE FOR ARTHRITIS
Informed Consent Form to Participate in Research
Stephen Messier, Ph.D., Principal Investigator

Introduction
You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any benefit from being part of the study. There may also be risks associated with being part of research studies. You are being asked to take part in this study because you have Knee Osteoarthritis. Your participation is voluntary. Please take your time to make your decision, and ask the study staff or the study doctor to explain any words or information that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?
Osteoarthritis (OA) is the most common form of arthritis. It is very common to get arthritis in your knee. While there are no cures for OA, treatment usually combines therapies, for example, exercise combined with a medication. The purpose of this research study is to compare exercise alone, diet alone, and a combination of exercise and diet on joint inflammation, walking mechanics, pain, and physical function to see how these relate to knee osteoarthritis.

How Many People Will Take Part in the Study?
A total of 850 older adults in the study, all from Forsyth County and the surrounding area will participate in the screening for the IDEA Study. Only those who complete and pass the screening visits as listed below will be randomized into the study. A total of 470 persons will be randomized to the study. Each of the three study groups (exercise, diet, and exercise + diet) will have 156-157 participants.

What Is Involved in the Study?
If you qualify to participate, you will undergo screening and baseline testing. The following scheduled visits and procedures will be performed.
Time line (A detailed description of the visits can be found following this figure):

Screening Visit One (SV1) → 1-2 weeks → Screening Visit Two (SV2) → 1-2 weeks → Randomization Visit (RV) → 1-2 weeks → % of participants → MRI Visit (MR0) → Only % of study participants will perform this 4th visit.

Exercise and/or Diet Classes begin

6 Months

6 Month Testing (Visit 1, 2, & 3)
(Exercise & Diet Classes will continue)

Continue with Exercise and Diet Classes!

18 Months (from start of study)

18 Month Testing (Visit 1, 2, & 3)
(Exercise & Diet Classes will continue until testing is complete).

Screening Visit 1 (SV1):
• Clinical Research Center in the Department of Health and Exercise Science at Wake Forest University, Reynolda Campus: The study will be described in detail and you will be asked to sign this consent form and give the study coordinator your medication use and medical history forms that were previously mailed to you. The study coordinator will review the forms with you to make sure everything is correct. Your height and weight will be taken and you will undergo a brief physical exam, including a knee exam to determine the cause of your knee pain. Your mental status and level of depression will be measured. You will undergo a Graded Exercise Test (GXT), which is a supervised walking test on a treadmill. You will not be required to undress for this exam. The purpose of the treadmill test is to make sure it is safe for you to begin an exercise.

Page 2

Subject’s Initials __________

«ApproveAt»
«ApproveBy»
IRB Number: «IRBNo»
Meeting Date Approved: «ApproveDate»
Version Valid Until: «ExpiryDate»
program and to determine your target heart rate. If you are not cleared for exercise, you will not be able to participate in the study.

- Outpatient Radiology Center at Wake Forest University Baptist Medical Center (WFUBMC; directions will be provided): You will next have x-rays taken of your knees. The results of your x-rays will be reviewed by the rheumatologist, Dr. Richard Loeber.
- Afterwards you will meet with a nutritionist from the General Clinical Research Center (GCRC). The GCRC nutritionist will instruct you on how to properly record the foods you eat. You will be given a food diary to record the foods that you eat for 3 days. The nutritionist will contact you after the 3 days to review your food diary with you.
- Not counting the time needed to go from one campus to the other, (a 3 mile drive) this first visit will take approximately 1.5 to 2 hours to complete.

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

- Reynolds Gym in the Department of Health & Exercise Science at Wake Forest University (directions will be given): The study coordinator and study physician, Jeff Williamson will review your forms that you were given at Screening Visit 1. Your height, weight, waist and hip sizes will also be measured. You will perform a 6-minute walk test (where we measure the distance you walk in 6 minutes). A gait analysis (measurement of how you walk) will be performed. This involves videotaping you walking. The videotape only records markers that will be placed on your body and does not show a person’s actual face or body. You will also perform a balance test (where we study how well you are able to balance yourself). During the balance test, you will be wearing a harness attached to the ceiling of the room. This is to protect you from falling in case you lose your balance. You will complete questionnaires, including general background, knee pain, physical disability, physical function, physical activity history, mental state and health status.
- Not counting the time needed to go from one campus to the other, (a 3 mile drive) this visit will take approximately 2 - 2.5 hours to complete.
- Ten percent of participants (45 persons) will be asked to come back in approximately a week following their Screening Visit 2 to repeat the gait analysis procedures. This second gait analysis will be used to test the reliability in the data collected during screening visit 2.
  - Participants will be contacted by phone to be asked to participate in this additional testing.
  - This visit is optional, if you do not wish to participate in this additional gait analysis, you can still participate in the rest of the study.

Randomization Visit (RV): You will be asked not to eat any food or beverages other than water for 12 hours prior to this visit. For this visit, you will need to allow for extra time to get from the medical center (WFUBMC) campus to the WFU campus.

- General Clinical Research Center (GCRC) at Wake Forest University School of Medicine: Your height and weight will be measured. You will have a small amount of blood withdrawn from a vein (7 tablespoons). The total amount of blood withdrawn during the entire study will be approximately 21 tablespoons. In addition we will collect
a urine sample (approximately 1 cup). The blood and urine tests will help us to assess your general health and to measure proteins in the blood and urine that may be related to arthritis. Once the tests are complete you will be given a snack. If you have not yet met with a nutritionist from the General Clinical Research Center (GCRC) you will do this at this time. The GCRC nutritionist will instruct you on how to properly record the foods you eat. You will be given a food diary to record the foods that you eat for 3 days. The nutritionist will contact you after the 3 days to review your food diary with you.

- **Sticht Center at Wake Forest University Baptist Medical Center:**
  - You will have a Dual Energy X-Ray Absorptiometry (DXA) scan, which is a painless scan of your body that tells how much bone, fat, and muscle you have.
  - At the completion of this visit you will be randomized to one of the 3 study group assignments described below: diet, exercise, or diet + exercise. You will remain in this group for the entire study. Randomization means that you are put into a group by chance by a special computer program, similar to flipping a coin. This is done so that a fair evaluation of results can be made. You will have a one in three chance of being placed in any one group.
  - This visit will take approximately 1.5 to 2 hours to complete.
  - Below is a description of the 3 different study groups (you will be randomized into one of these groups):

**DIET GROUP**

- If you are randomly assigned to the diet only group, you will be asked to carefully monitor how much you eat and to follow a low-calorie diet designed for you, with the goal of losing weight. The diet will include up to 2 meal replacements per day, similar to Slim Fast liquid supplements. For the third meal, you will follow a weekly menu plan and recipes composed of traditional foods. The nutritionist will help you to develop a food plan for the third meal that is modified to your individual preferences. This third meal will contain 500-750 calories and be low in fat and high in vegetables.
- You will attend regular classes at Wake Forest once a week for about one hour over 6 months to help you with your diet program. The classes will consist of 1 individual and 3 group sessions monthly. (Group sessions will take place at the Clinical Research Center at Wake Forest University).
- During the remaining 12 months of the study, you will come to Wake Forest for classes twice a month. You will have an individual appointment once every month.
- Class topics include: changing eating habits to lower caloric intake, information regarding what food changes to make, how to make them, and why they are important. Each group session will include problem solving, review of a specific food topic, and tasting of several well-balanced, low-fat, foods. During the individual sessions, the nutritionist will review individual progress, solve problems, answer questions, and help you to set your program goals. The minimal weight loss goal is 10% of your body weight (approximately 20 pounds for a 200 pound person) with an optimal goal of 15% (approximately a 30 pound weight loss for a 200 pound person). Some people will lose more weight than that, and others will lose less.
EXERCISE GROUP

- If you are in the exercise only group, you will begin coming to the Clinical Research Center at Wake Forest University for exercise classes 3 days per week for an hour each day. The class will consist of 15 minutes of walking (stationary bikes are available for those unable to walk for long periods of time), followed by 20 minutes of strength training involving leg weights and/or machines, followed by 15 minutes of walking/biking, and 10 minutes of cool-down exercises. The goal of the exercise program is to improve your fitness. Your exercise instructor will monitor your progress and will help you reach your fitness goals. These regular exercise classes at Wake Forest will go on for at least six (6) months.

- In the first 6 months, but typically during months 7 and 8, you will have a choice of remaining in the exercise classes at the Clinical Research Center or beginning a transitional phase. During transition, you will split your exercise time between the gym and your home or another location of your choosing. Your group leader will monitor your progress and assist you in making your exercise choices. If you choose to exercise at home or at another location an exercise staff member will contact you every other week by telephone during the first 2 months to monitor your progress. Afterwards you will be contacted every third week during the next 2 months and then once a month thereafter.

DIET AND EXERCISE GROUP

- If you are assigned to the diet and exercise group, you will participate in both the exercise and diet classes as outlined in the previous sections. Your nutrition classes will be held before or after your exercise classes to make participation easier for you.

MRI Visit (MR0)

- One-half of all study participants (225) will be assigned in a random fashion to receive additional testing. If you are assigned to receive additional testing (225 persons), you will return for this 4th visit, which will take place at the Center for Biomolecular Imaging, Outpatient Radiology, and the Sticht Center at Wake Forest University Baptist Hospital (directions will be given).

- This visit will take approximately 4 to 4.5 hours to complete.

- You will undergo the following types of tests at this visit:
  - MRI scan: The MRI uses a strong magnet instead of X-ray energy to take electronic pictures of your knees. During the scan, you will lie on your back on a gurney (cot or bed) that will slowly glide into the MRI machine. The scanner makes loud noises, but you will wear headphones with built-in ear plugs to protect your ears. You will have constant contact with the MRI technician and can request that the scan be stopped if you are feeling claustrophobic and uncomfortable. Your head will not be in the MRI scanner. During the MRI scan, you will need to keep still. The MRI scan will take about 50 minutes. People with pacemakers, aneurysm clips, cochlear implants or metal foreign objects implanted in their bodies cannot undergo this procedure.
  - CT scan: After the MRI, you will undergo a CT scan. The computed tomography
(CT) scan is a special type of x-ray examination that will measure the amount of various types of tissues in your abdomen and thigh. You will be asked to lie on a table with the lower portion of your body inside the CT scanner. You will need to remain still and you will need to hold your breath when the CT technician requests this. The CT scan should take no more than 20 minutes.

- **Full Length X-Ray** - After the CT scan is complete you will go to Outpatient Radiology for an x-ray. You will be asked to stand and an x-ray will be taken of your entire leg. This x-ray should take no more than 5 minutes.

- **Leg Power** - After the x-ray we will test the strength in your leg on a bicycle like device.

- **Accelerometer (physical activity monitor)** - You will be asked to wear a small device that will be attached to your waistband or belt. You will wear this device during all your waking hours for 7 full days, starting today. This device will allow the researchers associated with this study to learn more about individual physical activity patterns and the relationship to other measures of interest in this study. You will be given a self-addressed stamped envelope to mail the device back once the 7 days are complete.

- **Reynolds Gym in the Department of Health & Exercise Science at Wake Forest University (directions will be given).**
  - Your height, weight, leg and hand strength will be measured.
  - Your balance will be measured.
  - In addition you will perform a short performance test that includes the following measures: balance, walking speed, and ability to rise from a chair will be measured.
  - Your motor coordination, response speed, and motor persistence will also be measured.

- As a reminder only one-half of all study participants (225) will have this visit.

6 Month Follow-up Visit (FU6): You will return for a follow up visit after 6 months (split into 2 separate visits).

**Visit 1 (Reynolds Gym)**: You will have your height, weight, and waist size measured. You will perform 6-minute walk and the balance, walking speed, and chair rise tests that were performed at baseline. Your mental status will be measured. Afterwards you will have a gut analysis. You will be given a food diary and the questionnaires that were given at baseline to complete at the end of this visit. You will return your questionnaires to the study coordinator. If you wore an accelerometer at baseline (one-half of all participants) you will be given the accelerometer (physical activity monitor) to wear for 7 days. This visit should last approximately 1.5 hours.

**Visit 2 (GCRC)**: You will be asked not to consume any foods/beverages other than water for 12 hours prior to this visit. Your height and weight will be measured. You will have approximately 7 tablespoons of blood withdrawn from a vein. In addition we will collect a sample of your urine (approximately 1 cup). Once these tests are complete, you will be given a snack. Your leg strength will also be measured. You will give your 3-day food record to the nutritionist. This visit will take approximately 1 hour to complete. The
purpose of repeating these tests and measures at 6 months is to see if the intervention
(diet and/or exercise) helped to improve them.

Visit 3 (Reynolds Gym & Sticht Center): If you were assigned to have additional testing
at the beginning of the study, you will return for a third visit. You will first go to
Reynolds Gymnasium to have your height and weight measured. Afterwards the balance
and strength tests will be performed and you will return your accelerometer to the study
staff. You will then go to the Sticht Center to have your leg power measured. This visit
will last approximately 1.5-2 hours.

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

Visit 1 (Reynolds Gym): Your height, weight, and waist size will be measured. You will
perform the 6-minute walk, and mental status test. You will be given a food diary and
questionnaires given at baseline to complete at the end of this visit. You will also have a
gait analysis. If you wore an accelerometer during baseline testing (one-half of all
participants) you will be given the accelerometer to wear for 7 days. This visit will last
approximately 2 hours.

Visit 2: The 2nd visit will begin at the GCRC. Your height and weight will be measured.
You will be asked to not consume any foods/beverages other than water for 12 hours
prior to this visit. You will have approximately 7 tablespoons of blood withdrawn. In
addition we will collect a urine sample (approximately 1 cup). Once these tests are
complete, you will be given a snack. You will give your 3-day food record to the
nutritionist. This visit will take approximately 1 hour to complete. You will return the
physical activity monitor to the staff. Afterwards you will go to the Sticht Center at
Wake Forest University Baptist Medical Center for a DXA scan and to have your leg
strength measured. You will then go to Outpatient Radiology for a knee x-ray. Not
counting the time it takes to go from one part of the medical center to another, this visit
will last approximately 1.5 - 2 hours.

Visit 3: If you were assigned to have additional testing at the beginning of the study, you
will return for a third visit. You will first go to Reynolds Gym for the following tests:
balance, walking speed, chair rise, and strength tests. You will return the accelerometer
to the testing staff. Afterwards you will go to the Center for Biomolecular Imaging to
have MR, x-ray, I and CT scans. You will then go to the Sticht Center to have your leg
power measured. Your height and weight will also be measured. This visit will last
approximately 1.5 hours.

Storage of your Blood Samples

- You may choose not to allow the long-term storage of your blood. However, long term
  storage of the blood is a requirement of this study so you will not be able to participate in
  the study if you do not want your blood stored.
- You may request at any time that your sample be discarded.
- A portion of your blood sample will be kept indefinitely in a freezer for future tests that
become available. Your samples will be stored at the Cytokine Core Laboratory at Wake Forest University Baptist Hospital under the supervision of Drs. Stephen Messier (Principal Investigator of this study, Department of Health & Exercise Science) and Barbara Nicklas, Director of the laboratory. These future analyses will include testing of other inflammatory markers (substances in the blood that can predict certain types of pain and stiffness), DNA testing of pain and stiffness, and yet undetermined testing procedures. (DNA is the genetic material inside your cells.)

- Only laboratory personnel under the supervision of Drs. Stephen Messier and Barbara Nicklas will have access to these blood samples.
- An identification number will code the samples and all results. Neither your name nor any other personal identifiers will be used to code the samples.
- The results from future tests will only be used for research purposes and will not be given to you or to your physician.
- It is very unlikely, but if future testing of your stored sample has commercial value, there are no plans to provide financial compensation to you, should this occur.
- There is a small risk that your private health information could be seen by your employer or your medical insurer and could result in loss of insurance coverage and/or employment. The chance that this information will be given to someone else is very small. Drs. Stephen Messier and Barbara Nicklas and his/her research staff will protect your records so that all your identifying information (name, address, phone number, information in your health record) is kept private. The chance that this information will be found out by someone else is very small.

How Long Will I Be in the Study?
You will be in the study for about 20 months including testing visits.

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

What Are the Risks of the Study?
The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

- There may be muscle or joint soreness following the physical performance test (six minute walk) and the treadmill (graded exercise) test. These symptoms usually go away quickly and are usually not serious.
- It is possible to have a more serious injury, such as a torn ligament or sprain from these tests, but this is extremely rare. Your tests will be monitored very closely to provide a high degree of safety for you.
- There is a small chance that exercise could lead to symptoms of heart disease or minor injury. Some examples of these symptoms include shortness of breath, irregular heart beats, skipped beats, a “flip-flop” feeling in your chest, weakness or dizziness, upset stomach, or a painful, heavyness, or discomfort feeling in your chest. There is a slight risk of falling during the walking portion of testing and training. Rarely, 1-2%, of older people with arthritis who
exercise will suffer more serious injury such as a broken bone from a fall. Exercise participants will have continuous safety monitoring during all training and testing, which will help make sure participants will exercise safely. Pain associated with exercise usually goes away after a few days.

- A small amount of pain is sometimes associated with drawing blood. You may experience discomfort, bruising, and/or bleeding where the needle is inserted. Occasionally some people become dizzy, lightheaded, or feel faint. Infection may occur on rare occasions. The total amount of blood that you will be donating throughout the study is approximately 21 tablespoons.
- There is a chance that you may experience some discomforts as a result of dieting such as hunger or a feeling of less energy. The meal plan will be developed by the nutrition staff to meet your individual needs and will consist of a balanced diet to minimize these discomforts. In addition, the meal plan will include snacks between your meals to minimize the feeling of hunger.
- There is a small risk that participants may lose too much weight. Your weight will be monitored regularly to reduce the chances of this occurring. In addition, some persons who diet might have dietary deficiencies; your food diaries will be reviewed weekly to make sure that you are getting all the nutrients you need.
- This research study involves exposure to radiation from the x-rays of your knees. The risk of this procedure is very small and is similar to that received from clinical x-ray and nuclear medicine studies.
- The maximum total amount of radiation exposure that you may receive from the x-rays, CT scans and DXA scans is equivalent to a uniform whole body exposure of approximately 587 millirem. This is equal to 12% of the yearly limit for radiation workers in North Carolina (5000 millirem) and is about 1.957 times the amount of background radiation that the average person in the United States receives each year (annual background = 0.30 rem).
- The risk of these procedures is small. Please be aware that the radiation exposure is necessary for this research study only and is not essential for your medical care. The Wake Forest University/Baptist Medical Center’s Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being necessary to obtain the research information desired. The potential long-term risk from these radiation doses is uncertain, but these doses have never been associated with any definite adverse effects. Thus, the risk to you, if any, is estimated to be slight.
- There is no known health risk associated with exposure to magnetic fields during an MRI (this type of scan involves no radiation). There are minimal risks from the loud noise associated with the MRI scanner and from the discomfort of lying on a hard surface. Efforts will be provided to ensure your comfort (protective earplugs, blankets, etc.). Some people become anxious in the closed space of the scanner. If this happens, we will remove you from the scanner immediately.
- There also may be other side effects that we cannot predict. You should tell the research staff about any medicine, vitamins, or supplements you take and any medical problems you have. This may help avoid side effects and other risks.
- Taking part in this research study may involve providing information that you consider confidential or private. Stephen Messier, Ph.D., and his research staff will protect your records so that all your identifying information (name, address, phone number, information
in your health record) is kept private. In addition video data that will be kept in a secure location (locked computer and office). The chance that this information will be found out by someone else is very small. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. In addition a Data Safety and Monitoring Committee or a safety monitor, not involved with the research study, will be reviewing the data from this research throughout the study.

Are There Benefits to Taking Part in the Study?
If you agree to take part in this study, there may or may not be any direct benefit to you. We hope the information learned from this study will benefit other people in the future. You may benefit by having reduced pain, improved physical function, and/or weight loss. Participation in this study will also provide you with close medical attention at no cost to you. There is no charge to you for any of the tests or exercise/diet classes included in this study.

Based on experience with diet and exercise in other studies with persons with knee osteoarthritis, researchers believe that diet and exercise are important in preventing disease and disability. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. Important medical findings will be sent to your primary care physician (if you select us to do so). In addition, each participant will contribute to our knowledge about osteoarthritis and may aid in our attempt to reduce or eliminate some disabilities associated with the disease. Previous studies have shown that weight loss helps to decrease pain and improve function in persons with knee osteoarthritis.

What Other Choices Are There?
You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. The tests and medications provided are available in the community, these usually involve a charge to participants. Instead of being in this study, you have the option of being treated with conventional medical therapy.

What about the Use, Disclosure and Confidentiality of Health Information?
By taking part in this research study, your personal health information, as well as information that directly identifies you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth.
Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care.
Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, and information from study visits, phone calls, surveys, and physical examinations.
Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsors; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research (Paul DeVita, Ph.D., Study Consultant, East Carolina University; Felix Eckstein M.D. Study Consultant, Paracelsus Private Medical University Salzburg, Austria); central laboratories, reading centers or analysis centers; the Institutional Review Board, representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

If this research study involves the treatment or diagnosis of a medical condition, then information collected or created as part of the study may be placed in your medical record and discussed with individuals caring for you who are not part of the study. This will help in providing you with appropriate medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care.

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

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. This authorization is valid for six years or five years after the completion of the study, whichever is longer. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Stephen P. Messier
Wake Forest University
Dept. of Health & Exercise Science
P. O. Box 7868
Winston-Salem, NC 27109

If you withdraw your authorization you will not be able to be in this study. If you withdraw your
authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study.

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

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

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

Will I receive Transportation or Free Parking?
If you are unable to provide or arrange for transportation to and from study visits and classes, transportation will be provided for those persons living in Forsyth County. Free parking will be provided to persons providing or arranging their own transportation for all study visits and classes.

Will You Be Paid for Participating?
You will receive no payment or other compensation for taking part in this study.

Who is Sponsoring this Study?
This study is being sponsored by the National Institutes of Health, the Department of Health & Exercise Science at Wake Forest University, the General Clinical Research Center at Wake Forest University Health Science, and General Nutrition Centers, Inc. The sponsors are providing money or other support to Wake Forest University and Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

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

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Stephen P. Messier at (336) 758-5849 (after 7pm call, 774-6628) or the project manager at (336) 758-3969.

What Are My Rights as a Research Study Participant?
Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because but not limited to, not following the study schedule; a change in your medical condition; or new information that necessitates study closure.

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

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

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, you should contact the Chairman of the IRB at (336) 716-4542.

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

a. I agree that my blood samples and health records may be kept for use in research
   on knee osteoarthritis. Yes __ No __

b. I agree that my blood samples and health records may be kept for use for other
   research purposes related to other conditions besides knee osteoarthritis.
   Yes __ No __

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

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

Do you request that we send important medical findings from your study tests/exams to your
personal physician? If you do not wish to have any of your medical information sent to your
physician, you can still participate in this research study.

[ ] Yes [ ] No ____________ Initials

Subject Name (Printed)

Subject Signature __________________________ Date ____________

Person Obtaining Consent __________________________ Date ____________

Time __________________________

Version: 10/27/09
Subject’s Initials ____________
Appendix C – Self-Efficacy Measurements

C.1. Gait Efficacy Scale

Date: _____/____/____
ID #: ______________________
Visit: SV2
FU3
FU4

This section asks you to rate your level of confidence in carrying out the listed task.

Instructions: For each item below, please circle the percentage that best corresponds to the extent to which you agree with each statement.

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

I BELIEVE THAT I CAN SUCCESSFULLY:

1. Walk up a flight of stairs using a handrail
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

2. Walk down a flight of stairs using a handrail
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

3. Walk up a flight of stairs without using a handrail
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

4. Walk down a flight of stairs without using a handrail
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

5. Walk over obstacles in my path (obstacles that are 8 inches in height)
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

6. Step over an obstacle in my path without tripping or falling
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
C.2. Walking for Duration Scale

In the following items you are asked to rate your level of confidence in carrying out the listed task.

INSTRUCTIONS: For each item below, please circle the percentage that corresponds to how confident you are that you can successfully carry out each of the activities listed below.

<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>Somewhat Confident</th>
<th>Completely Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>10% 20% 30% 40% 50% 60% 70% 80% 90% 100%</td>
<td></td>
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I BELIEVE THAT I CAN WALK:

1. For 5 minutes at a moderately fast pace without stopping.
   
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

2. For 10 minutes at a moderately fast pace without stopping.
   
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

3. For 15 minutes at a moderately fast pace without stopping.
   
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

4. For 20 minutes at a moderately fast pace without stopping.
   
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

5. For 25 minutes at a moderately fast pace without stopping.
   
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

6. For 30 minutes at a moderately fast pace without stopping.
   
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
I BELIEVE THAT I CAN WALK:

7. For **35 minutes at a moderately fast pace** without stopping.

8. For **40 minutes at a moderately fast pace** without stopping.
C.3. Exercise Adherence Efficacy Scale

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

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

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

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

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

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

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

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

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

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

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
<table>
<thead>
<tr>
<th>Not at all confident</th>
<th>0%</th>
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<tr>
<td>Somewhat confident</td>
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5. I am able to continue to exercise three times per week at moderate intensity, for 15-30 minutes without quitting for the **NEXT FIVE WEEKS**

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

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

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

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

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

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

   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%
C.4. Activities-Specific Balance Confidence Scale (ABC)

The following section asks you to indicate your level of confidence in doing a variety of activities without losing your balance or becoming unsteady.

INSTRUCTIONS: For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady by circling one of the percentage points on the scale from 0% to 100%. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports.

How confident are you that you will not lose your balance or become unsteady when you....

1. ... walk around the house?
   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%

2. ... walk up and down the stairs?
   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%

3. ... bend over and pick up a slipper from the front of a closet floor?
   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%

4. ... reach for a small can off a shelf at eye level?
   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%

5. ... stand on your tiptoes and reach for something above your head?
   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%

6. ... stand on a chair and reach for something?
   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%
How confident are you that you will not lose your balance or become unsteady when you ....

7. ...sweep the floor?
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

8. ...walk outside the house to a car parked in the driveway?
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

9. ...get into or out of a car?
   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

10. ...walk across a parking lot to the mall?
    0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

11. ...walk up or down a ramp?
    0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

12. ...walk in a crowded mall where people rapidly walk past you?
    0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

13. ...are bumped into by people as you walk through the mall?
    0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

14. ...step onto or off of an escalator while holding onto a railing?
    0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
How confident are you that you will not lose your balance or become unsteady when you ....

15. ...step onto or off of an escalator while holding onto parcels such that you cannot hold onto the railing?

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</table>

16. ...walk outside on icy sidewalks?

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<th>100%</th>
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</thead>
</table>
SCHOLASTIC VITA
PHILLIP COX

Personal Information
Birthplace: Hayward, CA
Birthdate: October 2, 1980

Undergraduate Study
1998-2001 Trinity Life Bible College
Sacramento, CA
BA Ministerial Studies

2009-2012 Cerro Coso Community College
Ridgcrest, CA
AS Digital Media Arts

Graduate Study
2004-2006 Liberty University
Lynchburg, VA
Master of Business Administration

2006-2008 Liberty University
Lynchburg, VA
MA Christian Leadership

2013-2015 Wake Forest University
Winston Salem, NC
MS Health and Exercise Science
Advisor: Shannon L. Mihalko, Ph.D.
Thesis: Effects of Intensive Diet and Exercise on Self-Efficacy in Overweight and Obese Older Adults with Knee Osteoarthritis
Professional Experience

2013-2015  Exercise Interventionist  
            Strength Training for Arthritis Trial (START)  
            Wake Forest University  
            Winston Salem, NC

2013-2015  Program Coordinator  
            Healthy and Exercise Lifestyle Programs (HELPS)  
            Wake Forest University  
            Winston Salem, NC

2013-2015  Graduate Teaching Assistant  
            Department of Health and Exercise Science  
            Wake Forest University  
            Winston Salem, NC

Memberships

2013-      American College of Sports Medicine (ACSM)
2013-      Southeast American College of Medicine (SEACSM)

Certifications

2013-      Certified Exercise Physiologist, ACSM
2010-2014  Personal Trainer, American Council on Exercise (ACE)