# Effect of a Wii Fit® Intervention on Balance, Muscular Fitness, and Bone Health in Middle-aged Women

by

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ABSTRACT

Sustaining a fall can be hazardous for those with low bone mass. Interventions exist to reduce fall-risk, but may not retain long-term interest. “Exergaming” has become popular in older adults as a therapy, but no research has been done on its preventative ability in non-clinical populations. The purpose was to determine the impact of 12-weeks of interactive play with the Wii Fit® on balance, muscular fitness, and bone health in peri-menopausal women**.** METHODS: 24 peri-menopausal-women were randomized into study groups. Balance was assessed using the Berg/FICSIT-4 and a force plate. Muscular strength was measured using the isokinetic dynamometer at 60°/180°/240°/sec and endurance was assessed using 50 repetitions at 240°/sec. Bone health was tracked using dual-energy x-ray absorptiometry (DXA) for the hip/lumbar spine and qualitative ultrasound (QUS) of the heel. Serum osteocalcin was assessed by enzyme immunoassay. Physical activity was quantified using the Women’s Health Initiative Physical Activity Questionnaire and dietary patterns were measured using the Nurses’ Health Food Frequency Questionnaire. All measures were repeated at weeks 6 and 12, except for the DXA, which was completed pre-post. RESULTS: There were no significant differences in diet and PA between groups. Wii Fit® training did not improve scores on the Berg/FICSIT-4, but improved center of pressure on the force plate for Tandem Step, Eyes Closed (p-values: 0.001-0.051). There were no significant improvements for muscular fitness at any of the angular velocities. DXA BMD of the left femoral neck improved in the intervention group (+1.15%) and decreased in the control (-1.13%), but no other sites had significant changes. Osteocalcin indicated no differences in bone turnover between groups at baseline, but the intervention group showed increased bone turnover between

weeks 6 and 12. CONCLUSIONS: Findings indicate that WiiFit® training may improve balance by preserving center of pressure. QUS, DXA and osteocalcin data confirm that those in the intervention group were experiencing more bone turnover and bone formation than the control group. In summary, twelve weeks of strength /balance training with the Wii Fit® shows promise as a preventative intervention to reduce fall and fracture risk in non-clinical middle aged women who are at risk.

# DEDICATION

This dissertation is dedicated to my parents, Tim, Lori, Cindy, and Fred, for their constant support and encouragement through all of my endeavors.

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# Chapter 1

# INTRODUCTION

Falls can result in muscular injury, head injury, or other impairments, but sustaining a fall for those who have weak bone can have serious, if not fatal, consequences. At the onset of menopause, there is typically an accelerated bone loss that makes some women even more susceptible, or "at risk", for serious consequences related to loss of balance and falls, such as a hip or vertebral fracture (Downey, Perry, & Anderson, 2012). Currently, the medical costs related to falling are approximately $25 billion, and by 2020, the healthcare costs associated with falling are estimated to exceed $54.9 billion (Stevens, Corso, Finkelstein, & Miller, 2006; Englander, Hodson, & Terregrossa, 1996). This estimate includes both direct costs, such as medical treatment and rehabilitation, and indirect costs, such as lost work time or impairments in quality of life.

A resulting fracture, particularly hip fracture, is the major direct medical expenditure that occurs from a fall. Approximately 1/3 of nonfatal fall injuries are fractures and the medical costs of fracture accounts for 61% of all nonfatal fall healthcare expenditures (Stevens et al., 2006). So while fracture only comprises a third of fall-related injuries, it is responsible for greater than 50% of the medical expenses associated with falls. One of the greatest predictors of suffering a fall-related fracture is low bone mineral density (BMD), which is often observed in older women, following the onset of menopause (Downey et al., 2012).

Fall risk is a multi-faceted problem, involving physiological, psychological, and neurocognitive changes that influence a person's ability to properly interact with his or her environment. However, one suggested technique for preventing falls is to improve whole body balance. While many exercise programs and interventions currently exist with the goal of improving balance and decreasing fall risk, many of them are hospital/clinic-based, and typically target geriatric populations (Howe, Rochester, Neil, Skelton, & Ballinger, 2011). In addition, these interventions typically require fairly monotonous exercise procedures that fail to arouse enough long-term interest to elicit the intended improvements. In other words, while the exercise intervention may be beneficial, participants quit before they can realize substantial gains.

The Wii Fit® game and balance board includes various strength and balance exercises integrated into games and competitions which are intended for the participant to have fun and retain interest, while also improving fitness. Its interactive game system includes many exercises that are typically included in traditional rehabilitation or therapy-based balance and muscular endurance improvement programs, but it uses an interactive interface. The Wii Fit® requires the participant to practice controlling their movement and center of pressure (balance) while using a fun, gaming-type interactive approach which makes completing exercise training goals more appealing. The system also provides immediate feedback to the user, which can take the form of tips, suggestions, encouraging phrases, or actual visual depictions of the user's movements.

Currently, no evidence exists regarding the efficacy of the Wii Fit® as a means to improve balance, strength and bone health in a middle-aged, non-clinical population. This study proposes to utilize the Wii Fit® balance game as an exercise intervention to improve balance and bone health of those at-risk for age related bone loss. This novel, technology-based intervention has clear public health importance as it can be easily used at home for primary fall prevention or integrated into standard rehabilitation and treatment practices. Long-term, it could be developed as a community-based intervention tool to promote balance and fitness training in a preventative sense, potentially reducing the healthcare burden related to falls and fracture later in life.

## PURPOSE

To evaluate changes in balance and muscular endurance in middle-aged women with low bone mass randomly assigned to a 12-week home-based exercise intervention incorporating the Wii Fit® balance game as compared to a sedentary control group.

## SPECIFIC AIMS

**Primary Aim**. To determine the effectiveness of interactive play using the Wii Fit® game system over a 12-week study period on balance in middle-aged women as compared to a randomly assigned control group.

**Secondary Aim 1**. To determine the effectiveness of interactive play using the Wii Fit® game system over a 12-week study period on muscular strength and endurance of the leg extensors and flexors in middle-aged women as compared to a randomly assigned control group.

**Secondary Aim 2**. To assess potential changes in bone formation through bone stiffness index as measured by qualitative ultrasound of the Os Calcis (heel).

**Secondary Aim 3**. To assess potential changes in bone turnover (formation and breakdown) through biochemical analyses of serum osteocalcin and c-telopeptide (CTX).

## HYPOTHESES

**Primary Aim 1**. 12 weeks of interactive play will significantly improve balance in middle-aged women as compared to a randomly assigned control group.

**Secondary Aim 1**. 12 weeks of interactive play will significantly increase muscular strength and endurance of the leg extensors and flexors in middle-aged women as compared to a randomly assigned control group.

**Secondary Aim 2**. 12 weeks of interactive play will significantly increase bone health parameters at the Os Calcis, as measured by qualitative ultrasound, and site-specific measures of bone health, as measured by DXA, in middle-aged women as compared to a randomly assigned control group

**Secondary Aim 3**. 12 weeks of interactive play will significantly increase bone turnover (increase serum osteocalcin) in middle-aged women as compared to a randomly assigned control group.

## DELIMITATIONS

The study was delimited to peri-menopausal women between the ages of 45-60 who did not have a diagnosis of osteoporosis but who had indications of low bone mass based on a DXA t-score of less than 0. Participants were able-bodied and could not have contraindications to standing or walking. No women in the study were to take any hormone replacement therapy drugs. Participants were required to have transportation,

have a TV set in their home that is appropriate for use with the Wii Fit® device, and have enough room in their home to have the device set up to be played daily. All had to be able to read and write in English.

## LIMITATIONS

The study was a convenience sample of volunteers. Study participants were asked not to change their daily physical activity, other than that prescribed to those in the intervention group, for the 12 weeks of the study. Study participants were asked not to change their medications, supplement use, or general diet for the 12 weeks of the study. However this was only validated with a verbal confirmation and the Food Frequency Questionnaire.

## DEFINITIONS

**Area Effective:** the area that encompasses 66% of the total balance ellipsis.

**Berg Balance Scale:** an assessment tool used to estimate fall risk and dynamic balance. A score of less than 45 out of 54 is considered to be "at-risk" for sustaining a fall.

**Broadband Ultrasound Attenuation (BUA):** the relationship between the dampening of the amplitude of the qualitative ultrasound sound wave in conjunction with the decrease in wave speed, and is expressed as dB/MHz

**DXA:** dual-energy x-ray absorptiometry is a skeletal imaging and assessment tool to measure bone density and skeletal health.

**Dynamic Balance:** is the ability to manage center of gravity and total body balance while moving.

**Exergaming:** is participating in physical activity- or exercise-based video games (Wii Fit®, Xbox Kinect®, etc.).

**Fatigue Index:** drop in peak torque from the first knee extension-flexion cycle to the last.

**FFQ:** Food Frequency Questionnaire is a brief battery of questions used to assess typical dietary patterns.

**FICSIT-4:** Frailty and Injuries: Cooperative Studies of Intervention Techniques is an assessment tool used to estimate fall risk and static balance. The test is scored out of 28, but there are no cut-off criteria to define fall-risk, although higher numbers are associated with lower risk.

**Major Axis:** the length of the major axis of movement within the overall center of pressure ellipsis.

**Menopause:** process by which menarche ceases for reasons other than dietary issues, underlying medical conditions, or surgical removal of reproductive organs.

**Osteoblast:** bone cell responsible for the deposition of skeletal tissue and minerals during bone formation.

**Osteocalcin:** a metabolic marker representative of osteoblastic cellular activity and bone formation.

**Osteoclast:** bone cell responsible for the breakdown and resorption of skeletal tissue and minerals during bone remodeling.

**Osteopenia:** lower than "normal" bone mass, but not progressed enough to diagnose osteoporosis; at-risk for osteoporosis.

**Osteoporosis:** a clinical diagnosis of a weakening of the skeletal system; clinically low bone mass.

**Perimenopausal:** women between the ages of 45-65 who are either a) within one year of beginning menopause, b) currently experiencing menopause, or c) one year post-menopause.

**Qualitative Ultrasound (QUS):** qualitative ultrasound is a form of bone imaging technology that uses ultrasound waves to measure bone quality.

**Remodeling:** the breakdown and rebuilding of skeletal tissue.

**Resorption:** the process of bone tissue breakdown and the release of skeletal minerals in the bloodstream.

**Speed of Sound (SOS):** the change in the velocity of the ultrasound sound wave, and is expressed in m/s.

**Static Balance:** the ability to manage center of gravity and total body balance while standing or remaining still.

**Stiffness Index (SI):** is a measure of bone quality, and is a mathematical derivation using both BUA and SOS.

**T-score:** A standard deviation from the mean for young adults, adjusted for gender and ethnicity. It is derived from bone mineral density value from DXA and from stiffness index value from QUS.

**Z-score:** A standard deviation from the mean for a particular age group, adjusted for gender and ethnicity. It is derived from bone mineral density value from DXA and from stiffness index value from QUS.

Chapter 2

# REVIEW OF LITERATURE

## FALL-RISK

**Multi-faceted aspects of falling.** With age, there are a variety of physiological changes that may occur that can impact balance. Approximately 130 independent risk factors have been identified as contributors to changes in balance and age-associated fall-risk (Carter, Kannus, & Khan, 2001). Generally speaking, the elements that seem to have the greatest influence on balance ability are declines in the visual/ vestibular/ somatosensory systems along with declines in lean muscle mass (Carter et al., 2001). These changes can create problems with older adults in regards to interacting with the environment and identifying/avoiding obstacles, such as curbs or debris on walkways. Even if the visual system is still functioning adequately, musculoskeletal declines can decrease total-body balance and increase the risk of sustaining a balance-related fall (Carter et al., 2001).

One of the more obvious manifestations of declining balance is postural sway, or a large degree of postural instability, while walking or standing. One explanation for postural sway is related to the decrease in neuromuscular tone that accompanies aging. A reduction in neuromuscular tone results in an overall greater need for muscle activation and increased muscle fiber recruitment to initiate or sustain any movement (Laughton et al., 2003). This excess energy expended for any muscular movement then limits the amount of energy available for continuous or sustained muscular control that is necessary

for stable, upright posture (Laughton et al., 2003). Additionally, greater motor recruitment and limited neural availability can decrease reaction time and reduce muscular force production (Patla et al., 1993).Thus, in those with reduced neuromuscular tone, even if an obstacle is identified appropriately, the declines in neuromuscular activity may hamper the ability to react and lessen the ability to make quick directional changes to avoid an obstacle while maintaining balance (Patla et al., 1993).

**Exercise and balance/fall risk.** Evidence for the use of exercise interventions to treat balance impairments and prevent fall-risk appears to be promising. Current research indicates that for a balance intervention to be successful, it needs to target several aspects related to balance and falls. Traditionally, balance therapy consisted of standardized balance exercises (standing on one foot, tandem walking, standing with eyes closed, etc.) and resistance training along with activities to improve spatial awareness are also recommended (Chang et al., 2004). Howe, Rochester, Jackson, Banks, and Blair (2007) concluded that such interventions, when put into either home-based or rehab-based programs, are successful in reducing balance-related falls. Specifically, therapies that included a strength or resistance training exercise program in addition to standard balance training significantly improve balance outcomes over standard balance therapy alone (Howe et al., 2007).

However, changes in muscular strength may not be necessary for improvements in balance and fall-risk. Barnett, Smith, Lord, Williams, and Baumand (2003) developed a year-long stepping, throwing, and Tai Chi intervention for older adults to improve

balance and decrease falls. At the end of the intervention, those in the exercise group had improved balance and spatial awareness compared to the control group, although there were no changes in muscular strength or lean muscle mass. Despite this, those in the intervention group had a 44% lower incidence of falls than the control during study follow-up (Barnett et al., 2003).

**Components of falling.** As previously noted (Carter et al., 2001), there are several components related to fall-risk. Figure 1 displays the major categorical components and some interactions between the factors related to fall-risk. Some factors are known to be directly associated with falling such as motor control and muscular fitness, while other physiological and psychological factors may indirectly influence falling by influencing gait or mobility. In addition most risk factors are inter-related.

Two components that are strongly inter-related in regards to fall-related fracture are muscular fitness (strength and endurance) and balance. Figure 1 depicts a feedback system between muscular fitness and balance indicating that physical inactivity and deconditioning lead to muscular impairment which negatively impacts neural control resulting in disrupted joint movements and gait patterns. Disrupted gait patterns as a result of weak muscles, can result in gait instability, which can lead to an increased risk for falls.

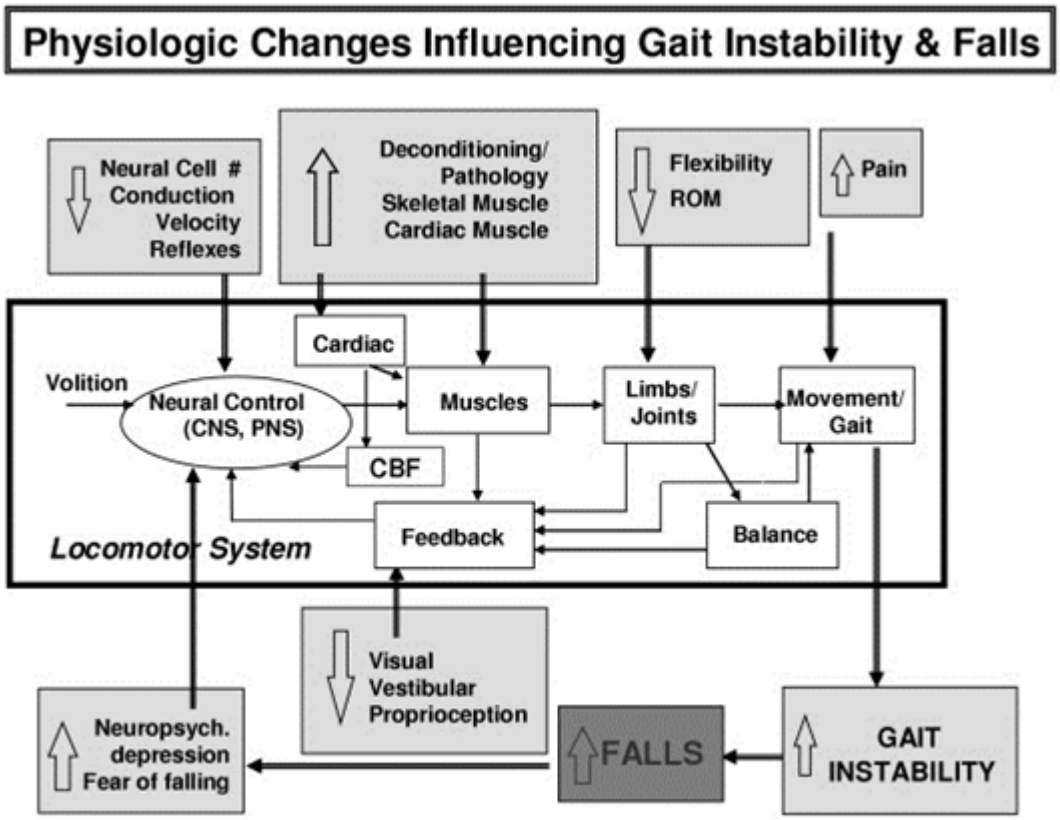


*Figure 1*. Components of Fall-Risk

Adapted from: Hausdorff, J. M. (2005). Gait variability: methods, modeling and meaning. *Journal of NeuroEngineering and Rehabilitation*, *2*(1), 19. doi:10.1186/1743-0003-2-19.

Additionally, it is known that a history of previous falls increases the subsequent fear of falling (Tsur et al., 2013. This fear of falling can lead to heightened anxiety with physical activity in general. This resulting inactivity leads to a negative cycle of further deconditioning and further muscle loss, resulting in more gait instability and more falls. At the core of this negative behavioral spiral is a person's underlying bone health. As seen in Figure 1, bone health may also be an important predictor of falling as it is considered be a component of the "limbs/joints" subsection. While it is true that low

bone mass may not necessarily cause a fall, it is known that a weak skeleton is clearly more likely to fracture as the result of the fall and will require increased recovery time after sustaining a fall. Thus in one with low bone mass, a previous fall may not only increase their fear of falling, but when coupled with a lengthening of the recovery period, further increases inactivity and deconditioning thereby perpetuating and elevating the risk for future falls.

## MUSCULAR STRENGTH AND ENDURANCE

Muscular strength and endurance are two components of muscular fitness that have been implicated as necessary for maintaining independence and completing activities of daily living. Simple tasks, such as climbing a flight of stairs, require muscular endurance, while opening a jar is more dependent on muscular strength. While younger adults typically do not struggle with these sorts of tasks under normal conditions, the muscle loss that accompanies aging can make these everyday tasks challenging or near impossible to complete without assistance.

**Sarcopenia.** One of the issues related to a loss of balance and falls is the age-related decline in muscle mass, or sarcopenia. As addressed previously, older adults lack neuromuscular tone as compared to younger adults, which can make balance and maintaining posture difficult (Laughton et al., 2003). However, declines in muscle mass can also decrease muscular strength and endurance, which could also lead to difficulties in completing activities of daily living, as well as contributing to mobility and balance issues.

Generally defined, sarcopenia is the slow and progressive loss of lean muscle mass associated with the aging process (Ryall, Scherter, and Lynch, 2008). Unlike other age-related conditions, there is currently no medically accepted diagnostic definition of sarcopenia. Because loss of muscle mass is relative to a person's frame size, gender, and activity level, it is difficult to quantify an amount of loss that would be classified as significant or as impairing daily function. However, the European Working Group on Sarcopenia in Older People (EWGSOP) has developed a working definition that encompasses total lean mass in conjunction with low muscular strength and endurance (Cruz-Jentoft et al., 2010).

**Exercise for improving muscular strength and endurance.** Sedentary behavior and a lack of weight-bearing or resistance exercise are both considered to be risk-factors for the development of sarcopenia. Like many of the declines in function related to aging, proper exercise or physical activity can help slow the progression, but not eliminate the condition completely. Even those who remain highly physically active through the lifespan, such as Master class athletes, will still progressively lose muscle mass with age (Ryall et al., 2008). However, those who do participate in load-bearing activity through older adulthood typically experience better health outcomes than those who do not and are able to slow muscle loss (Shephard, Park, Park, & Aoyagi, 2013)

Longitudinal data in older Japanese adults (65-84 y.o.) demonstrated that those who were walking 7000-8000 steps/day, or participating in a minimum 15-20 minutes of structured

exercise per day at an intensity greater than 3 METs, were 2.3-3.0 times less likely to develop sarcopenia than those who were sedentary or had less activity that those threshold values (Shephard et al., 2013). Similarly, participants enrolled in the Research on Osteoarthritis/osteoporosis Against Disability (ROAD) study found that exercise habits beginning in middle-age were strong predictors of sarcopenia risk. In 1000 older adults, while lean muscle decreased across all study participants, those who reported regular physical activity in middle-age experienced less impairment, and had greater handgrip strength ($p < 0.001$) and one-leg standing time ($p = 0.005$) (Akune et al., 2013).

Structured activity also has been shown to not only maintain some lean mass, but also increase muscle size and strength in older adults. Eighteen older adults were randomized into one of two groups: Group 1 performed very low-intensity (30% 1-repition max (1RM) knee extension exercise with continuous muscle contraction (3-second (3-s) eccentric, 3-s concentric, and 1-s isometric actions with no rest between reps). Group 2 performed intermittent muscle contraction (1-s concentric and 1-s eccentric actions with 1-s rest between each rep) for the same time period. Both groups performed these exercises twice a week over the course of 12 weeks (Watanabe, Madarame, Ogasawara, Nakazato, & Ishii, 2013). At the end of the study, those in the low intensity group increased their muscle size as compared to the control, although the exercise load was considered to be very low.

The activity can even be as infrequent as once per week, and still demonstrate some improvement in lean muscle mass. Thirty-three older adult men were randomly assigned

to either an intervention group, which consisted of completing seven exercises once per week (bench press, leg press, latissimus dorsi pull-down, leg extension, military press, leg curl, and arm curl) at 65-75% of one-repetition max (1-RM) or to a control group (Sousa, Mendes, Abrantes, Sampaio, & Oliveira, 2013). At the end of the 32-week study period, those in the intervention group had a cumulative strength gain exceeding 67% at the 32-week period, and 2.9% decrease in body fat from weeks 8-32 (Sousa et al., 2013).

## BONE HEALTH

The aging process is associated with a variety of physiological changes that can increase the likelihood of sustaining a fall, such as declines in muscular strength and endurance and loss of regulation of center of pressure. However, the risk of sustaining a fracture as a result of a fall is often a function of bone mass at the site of impact (Christen et al., 2013). Bone loss typically occurs at the onset of menopause for women and after the age of 65 for men, and both incidences may be due to disruptions in estrogen signaling and production (Khosla, 2012). The pathogenesis of bone loss is not identical for all individuals, but is a combination of dietary deficiencies, hormonal disruptions, lack of weight-bearing exercise, metabolic disorders, or other underlying disease states (Khosla, 2012). However, regardless of the physiological reason, the mechanism behind age-related bone loss is the uncoupling of the cellular balance between osteoblastic and osteoclastic cells. Especially in women, age impairs osteoblast differentiation and cellular activity, partially due to hormonal deficiencies, and increased osteoclastic activity (Chan & Duque, 2002).

**Bone remodeling regulation.** Bone tissue is extremely metabolically active, yet slow-moving, in regards to cell turnover and remodeling. While many may view the skeletal system as static, bone undergoes multiple regenerative cycles over the course of a lifetime. The actual process of bone remodeling involves both the breakdown/resorption and the replacement of pockets of old/damaged bone tissue, and it is estimated that the entire skeleton is remodeled every 10 years (Manolagas, 1999). There are two major cell types involved in the regulation and process of bone remodeling: osteoclasts and osteoblasts. Osteoclastic cells are responsible for bone breakdown and resorption, while osteoblasts re-ossify the skeletal matrix and deposit new bone tissue. While the process of "building up" and "breaking down" bone may seem relatively straightforward, it is actually an incredibly complex and dynamic system that requires "cross-talk" between cell types as well as a variety of mechanical and hormonal cues.

During the developmental years, the skeleton is soft and somewhat pliable. This is necessary to allow for the rapid growth necessary to support an adult-sized frame. In childhood, the osteoblastic activity greatly outpaces the osteoclastic activity, due to the high rate of skeletal deposition to allow for the ossification of the skeletal system (Frost, 1985). Once peak bone mass is achieved (typically at the end of puberty), there is a tight regulation between the osteoclasts and osteoblasts that maintain skeletal mass. However, with age, osteoclastic activity becomes more prominent, leading to increased bone breakdown that is not as easily matched by osteoblastic cells. This can lead to loss of bone mass and weak/brittle skeletal tissue (Frost, 1990). Although bone resorption is increased, the system is still tightly maintained to attempt to prevent excessive and rapid

bone loss. The only exception to this is in the case of metabolic bone disorders or the use of osteoporotic drugs, which inhibit bone turnover at both the osteoblastic and osteoclastic level.

The cues for bone turnover are related to many factors including hormonal signals and mechanical strain. In regards to mechanical load and strain, such as from bone loading forces or from small microfractures within the osteocyte, the regulatory system is able to target a specific site for remodeling (Hadjidakis & Androulakis, 2006). During the remodeling process, Basic Multicellular Units (BMUs), which are comprised of both osteoblasts and osteoclasts, form tunnels in the portions of bone that need repair. Ten osteoblastic cells dig a small circle in the surface of the bone that needed to be repaired, and that area is then filled with thousands of osteoblastic cells (Frost, 1997). Regardless of whether the turnover is initiated by hormones or mechanical forces, the process of bone remodeling is identical.

***Cellular signaling.*** The major signal to start the process of remodeling is osteocyte death within the skeletal matrix, which often results from the formation of microcracks within the osteocyte itself (Martin & Seeman, 2008). The actual process of bone remodeling occurs in three phases: resorption, reversal, and formation. The resorption phase is activated by the migration of partially differentiated mononucleated preosteoclasts to the bone surface. At the surface of the bone, the cells become multinucleated and begin the actual process of bone resorption (Hadjidakis & Androulakis, 2006). Dead cells and deposited minerals are broken down and released into

the blood stream by the now-nucleated osteoclast cells. Following the resorption of all targeted tissues, the reversal phase is activated by the presence of mononuclear osteoblast cells. These cells signal osteoblast activity and osteoblast formation/differentiation. After the activation of the osteoblastic cells, the formation phase begins. This involves the saturatation of the exposed bone matrix with mature osteoblastic cells, which replace all minerals and structural cells that were lost during resorption. Flattened lining cells then coat the bone surface, and remain in a dormant phase until another remodeling cycle at that site is activated (Hadjidakis & Androulakis, 2006). The entire process from signaling of resorption to the deposition of flattened lining cells takes approximately 4 months.

To ensure that the osteoblastic and osteoclastic cells work in equilibrium, a complex coupling system exists. The actual resorption phase is activated by osteoclasts at either the cell surface or the marrow, which signal the migration of the partially differentiated preosteoclasts to the cell surface. These signaling cells then change shape and secret enzymes that digest the proteins that are bound to the cell surface, in addition to secreting r eceptor activator of nuclear factor kappa-B ligand (RANKL). RANKL is responsible for the differentiation to multi-nucleated osteoclasts, which are the cells actually responsible for the resorption of bone (Hsu et al., 1999). At some point during the resorption phase, osteoprotegerin (OPG) is produced by the osteoblasts and preosteoblasts, which blocks RANKL and activates osteoblast apoptosis (Hofbauer & Schoppet, 2004). The exact mechanism behind the onset of secretion of OPG is not entirely understood, but the current hypothesis is that there may be metabolic markers of bone resorption that activate osteoblasts within the marrow at high levels (Hadjidakis & Androulakis, 2006). Once

OPG is secreted and RANKL activity is blocked, the mononuclear osteoblast cells are able to migrate to the bone surface to begin the reversal and formation phases.

***Hormonal and protein influence: systemic and local regulation*.** In general, bone remodeling at the systemic level is controlled through a variety of hormonal pathways. The hormone with perhaps the greatest impact of skeletal health is parathyroid hormone (PTH), which is directly implicated in calcium homeostasis. PTH signals bone resorption and renal calcium uptake during times of low blood calcium levels, but it is also able to stimulate bone formation. Continuously elevated PTH activates calcium uptake and bone resorption, while intermittent PTH spikes signal bone formation (Kim 2003). Also at the systemic level, calcitonin, calcitriol, and thyroid hormones all impact calcium regulation via absorption in the intestines and the kidneys. The other hormone group most directly related to bone turnover is the estrogens. Specifically, estrogens decrease osteoclast progenitor cells' responsiveness to RANKL, thereby decreasing osteoclast formation and bone resorption. Additionally, estrogens stimulate osteoblast formation and suppress osteoblast apoptosis (Manolagas, 2000).

Local regulation, as mentioned previously, is controlled via RANKL and OPG activity at the cellular surface. However, cytokines are necessary for appropriate cellular coupling and protein regulation. The primary cytokines necessary for the cross-talk are tumor necrosis factor α (TNF-α) and interleukin-10 (IL-10). These work by activated macrophage colony stimulating factor (MCSF), which is necessary for osteoclast differentiation (Hofbauer et al., 1999). Another important cytokine is interleukin-6 (IL-6),

which is secreted by both osteoblastic and osteoclastic cells. IL-6 typically stimulates bone resorption by the osteoclasts, but under the condition of high bone resorption, IL-6 is also able to promote bone osteoblast formation and differentiation (Moonga et al., 2002).

**Genetic and modifiable osteoporotic fracture risk factors.** With increasing age, the risk of osteoporotic fracture generally increases due to a variety of physiological changes. The population considered to be most at-risk for developing a non-traumatic fracture is typically post-menopausal Caucasian and Asian women (Cumming & Klineberg, 1994), but osteoporosis can impact all ethnicities, genders, and ages. The risk for sustaining a fracture is multi-faceted, involving a combination of physiological changes, lifestyle factors, and genetic predisposition. Of all of the risk factors for osteoporotic fracture, the one most often associated with increased risk is impaired bone health or low bone mass.

***Bone mass*.** Both bone mass and bone quality change with age. Throughout life, a complex system of mechanical and hormonal signals maintains skeletal structure, constantly turning over old cells. The process of "breaking down" and "building up" of skeletal tissue is referred to as remodeling. During development and ossification of soft skeletal tissues, the "building up" tends to outpace the "breaking down," which allows for gains in skeletal strength. Through young adulthood, the processes are closely matched to maintain peak bone mass. However, after menopause for women and in the elderly years for men, the coupling system can become disrupted, which leads to more bone being

resorbed than is replaced (Frost, 1985). This can lead to weakening of the skeletal structure, and eventually, osteoporotic fracture. Bone health is typically tracked via dual-energy x-ray absorptiometry (DXA), which provides information regarding both bone mineral density (BMD) and bone mineral content (BMC). BMD is often the variable more closely associated with impaired bone health.

There is a large body of work to suggest that low BMD is a cause for concern in regards to sustaining an osteoporotic fracture. For both men and women, some evidence suggests that the relative risk (RR) of sustaining an osteoporotic fracture increases by 3-4 fold for every one standard deviation (SD) decrease in femoral neck BMD (Nguyen, Pongchaiyakul, Center, Eisman, & Nguyen, 2005). Similarly, Johnell et al. (2005) showed that in a population of approximately 40,000 older adults across 12 prospective cohort studies, the RR of sustaining a hip fracture increased by 1.4 for every one SD decrease in BMD at the femoral neck.

***Body size and lifestyle factors.*** Despite the clear importance of bone mass, the risk of sustaining an osteoporotic fracture is more complicated than BMD alone. The Fracture Risk Assessment Score (FRAX) was developed to screen for a variety of clinical and epidemiological risk factors to assess for true fracture risk over a 10-year period (Fardellone, 2008). The proponents of the assessment tool noted that the women who were sustaining osteoporotic fracture were often not the ones with the lowest BMD scores, indicating that other factors may play an equally important role in fracture risk (Fardellone, 2008). The FRAX was developed using over 60,000 older adults from 12

prospective cohort studies, and it currently screens for total body BMD, height, weight, gender, age, family history, smoking status, alcohol use, and glucocorticoid use (Fardellone, 2008).

Each of these risk factors identified in the FRAX have evidence to support their implication in osteoporotic fracture risk. To date, most clinicians and researchers are well aware that age, gender, family history, and BMD are highly associated with fracture risk. However, recent research has indicated that body size and body mass may play a critical role as well. De Laet et al. (2005) studied the same 60,000 adults from the 12 prospective cohort studies used to develop the FRAX, and found that body mass index (BMI) had a large impact on lifetime fracture risk. Those with a BMI of 20 had a 2-fold greater risk of sustaining a hip fracture than those with a BMI of 25. Other research has shown that body size may actually be more critical than body mass. Sordia et al. (2004) found that in a population of post-menopausal women, low height and low weight were associated with greater fracture risk, regardless of BMI. Maintaining weight and weight loss are also of concern. In a study population consisting of both older men and women, losing weight as an older adult was more likely to result in an osteoporotic fracture than remaining weight stable or losing weight (Cumming & Klineberg, 1994).

Lifestyle factors, such as smoking status and alcohol use, also appear to play a large role in lifetime fracture risk. Several studies have documented the detrimental impact of smoking on bone health, but the largest study to date, analyzing over 60,000 older adults, found that the RR of sustaining any fracture for smokers was 1.25, with non-smokers

serving as the reference group. This risk was lowered to 1.13 once adjustments for BMD were made, but the risk remaining significantly elevated over that of non-smokers (Kanis, Johnell et al., 2005). The results for alcohol consumption, using the same 60,000 older adults from the 12 prospective cohort studies, also found a detrimental effect. High alcohol consumption, defined as drinking greater than two units per day, had a RR of 1.38 for both men and women as compared to moderate drinkers and abstainers (Kanis, Johansson et al., 2005). A unit can range from 25ml to 284 ml depending on the type of alcoholic beverage, which hard alcohols having less volume per unit that beer or wine. However, age and BMD did not influence the model, indicating that alcohol consumption appears to affect fracture risk in ways aside from decreasing BMD (Kanis, Johansson et al., 2005).

The last screening criterion on the FRAX, glucocorticoid use, also appears to negatively impact bone health. It has been shown that premenopausal women (18-45 y) who used glucocorticoid inhalers in the treatment of asthma had impaired BMD at the femoral neck (Israel et al., 2001). For every puff per year, the women on the glucocorticoid therapy lost approximately 0.00044 g/cm$^2$ of bone mass at the proximal femur. The study was controlled for oral glucocorticoid use, and none of the women suffered from any condition known to impair bone metabolism.

***Physiological changes.*** Another main risk factor for sustaining osteoporotic fracture is changes in physiology, such as loss of muscular strength and endurance or cognitive decline. Older men and women (>60 y) were followed for a total of 12 years to

determine which factors were most associated with fracture risk. The authors found that quadriceps/lower limb weakness and high degree of postural sway were highly correlated with fracture (Nguyen et a., 2005). In regards to cognitive function, first-time, non-traumatic fracture patients and healthy, age-matched controls were assessed to identify any physiological differences that may explain the fracture. Poor scores on the mini-mental state examination, along with poor handgrip strength and low BMD, were associated with increased fracture risk (Lan et al., 2010).

**Nutritional Deficiencies.** Due to the fact that skeletal tissue is constantly undergoing resorption and remodeling, the appropriate intake of a variety of vitamins and minerals are necessary to maintain skeletal integrity. Several nutrients have been identified as contributing to skeletal health, and their roles vary from actually composing the skeletal matrix to regulating cellular activity and mineral deposition. More vitamins and minerals are determined to be "bone essential" as more research is conducted, but currently there is evidence to confirm the importance of three vitamins and minerals: calcium, vitamin D, and phosphorus.

***Calcium, vitamin D, and phosphorus.*** Perhaps the mineral most often associated with bone health is calcium. The importance of calcium is due to the fact that it comprises the majority of the structural integrity of the skeleton. Hydroxyapatite, the naturally-occurring mineral form of calcium apatite, is responsible for approximately 40% of skeletal mass and is the major form of stored calcium (Zhu & Prince, 2012).

However, calcium ions have a variety of functions in the body, aside from lending strength to bone, that require appropriate circulating levels in the bloodstream. In childhood, calcium deficiency has an obvious visual manifestation through the development of rickets, but adult deficiency can often go undetected and result in impaired bone structure or osteoporosis (Price, Langford, & Liporace, 2012).

The pathophysiology of the development of osteoporosis is due to increased bone resorption and inadequate bone deposition. When calcium levels in the bloodstream are low, parathyroid hormone (PTH) sends a signal to increase renal calcium uptake/resorption. If calcium needs are still not met, further PTH stimulation signals for calcium release from the long bones (Zhu & Prince, 2012). If the calcium deficiency is quickly addressed via dietary replacement, there is no long-term damage to the skeleton. If deficiency is long-term then bone is not properly remodeled and bone can become brittle (Zhu & Prince, 2012). When PTH signals for calcium release, it targets healthy, strong bones to meet calcium needs rather than weaker sites that may require remodeling. Therefore, healthy sites are weakened and unhealthy sites remain impaired as cellular activity is focused on release rather than repair (Zhu & Prince, 2012). Once the formation stage of remodeling begins, if there is not sufficient calcium available, the site is remodeled without an equivalent calcium replacement for what was lost.

The next nutrient closely associated with bone health and osteoporosis is vitamin D. Unlike calcium, vitamin D is not necessary for skeletal structure, but instead has a regulatory role for calcium uptake and homeostasis (Dawson-Hughes & Bischoff-Ferrari,

2007). Like calcium, vitamin D deficiency can result in rickets or osteoporosis, but the disease state is a result of a secondary calcium deficiency rather than a vitamin D deficiency, per se. Insufficient vitamin D impairs calcium uptake, which then reduces calcium availability for other functions, such as skeletal deposition. Also, if calcium levels in the bloodstream are low, low vitamin D could result in bone resorption, even if dietary calcium intake is sufficient (Price et al., 2012). Aside from vitamin D's role in calcium uptake, it may also be important for calcium/phosphorus homeostasis. Vitamin D may influence activation of vitamin D receptor signaling for fibroblast growth factor (fgf) 23 (Lieben & Carmeliet, 2013). fgf 23 has been implicated in the maintenance of appropriate calcium/phosphorus levels to ensure appropriate mineral uptake, transport, and deposition in the skeleton (Lieben & Carmeliet, 2013).

The last major identified nutrient for bone health is phosphorus. Like vitamin D, phosphorus and calcium metabolism and uptake are very closely linked. However, high calcium intake actually suppresses phosphorus uptake (Heaney & Nordin, 2002). Results from supplementation studies have shown that when calcium intake is high and phosphorus intake is low, net phosphorus excretion is increased. However, when phosphorus intake is increased while calcium remains static, net excretion of calcium is unchanged (Spencer 1978). Due to the composition of hydroxyapatite, phosphorus is also a major contributor to skeletal strength and deficiency could potentially result in a weakened lattice (Heaney & Nordin, 2002). Additionally, phosphorus also has a regulatory cellular role in addition to composing the skeletal structure. Phosphorus is necessary for osteoblast differentiation and proliferation, so impaired phosphorus status

via increased calcium intake or through dietary phosphorus deficiency could result in impaired bone formation (Bonjour, 2011). In the diet, calcium and phosphorus should be in appropriate ratios as to not disrupt uptake of either mineral, but calcium supplements that lack phosphorus could create a potentially unfavorable environment (Bonjour, 2011).

***Vitamin K, magnesium, and boron*.** There is a large body of epidemiological work linking vitamin K status with markers of bone health, but the exact mechanism behind the relationship is only hypothesized at this point. Like vitamin D, vitamin K's role seems to be primarily regulatory. There are two key components of bone remodeling that are vitamin K dependent: bone GLA protein and carboxylated osteocalcin (Chan, Leung, & Woo, 2012). GLA protein may have calcium-binding properties, which would be important for calcium transport and deposition during bone remodeling (Ahmadieh & Arabi, 2011). Additionally, osteocalcin, once carboxylated, binds to calcium for proper bone mineralization during the formation stage. During the carboxylation of osteocalcin, vitamin K is necessary component; vitamin K deficiency appears to disrupt the carboxylation process (Chan et al., 2012). While research is still on-going, vitamin K appears to impact bone health via calcium transport and regulation, with deficiency impairing calcium deposition during the formation stage.

Like vitamin K, the mechanism by which magnesium influences bone health is poorly understood, with only some epidemiological and animal model studies linking magnesium deficiency and osteopenia/osteoporosis (Nieves, 2013). In some supplementation studies, magnesium supplementation did improve markers of bone

health. However, this only appears to serve as a benefit for those who are already magnesium deficient, and supplementation may not have any positive impact for the average population (Nieves, 2013). In murine models, induced magnesium deficiency can result in impaired bone health. Over 16 weeks, controlled magnesium deficiency resulted in the disruption of the tightly regulated system between the osteoclastic and osteoblastic cells, leading to impaired bone remodeling (Rude et al., 1999). While similar studies have not been conducted in humans due to ethical considerations, it appears that magnesium may be essential for maintaining the cellular signaling system for bone turnover.

The effect of boron on bone is not entirely understood, as research dealing with boron and bone health status has only emerged within the last 15 years. Some controlled supplementation studies in humans using 3 mg of boron supplementation daily (average intake is 1 mg/daily) have shown positive effects on metabolic markers of bone health, such as osteocalcin (Nieves, 2013). The proposed mechanism for the importance of boron is related to renal clearance. The main site of boron homeostasis in the kidney; as boron intake increases, boron excretion increases. However, in relation to calcium, increased boron excretion results in reduced calcium excretion when calcium intake remains static (Hunt, Herbel, & Nielsen, 1997). More research is needed to better understand the importance of boron as it relates to bone health, but it appears that it works by increasing calcium availability in the bloodstream, reducing the need to resorb calcium from the bone (Hunt et al., 1997).

## HOME-BASED EXERCISE

Home-based exercise intervention programs are being recommended more frequently by rehabilitation and clinical specialists because participation is not contingent on attending a fitness center, gym, or other facility to complete an activity.

One concern with a home based program is compliance; participants are not able to be regularly monitored when they exercise outside of the rehab facility. A pilot study that assessed compliance to a home-based exercise program in cardiac patients noted that after 72 months, approximately 50% of those originally enrolled were still participating (Marzolini, Mertens, Oh, & Plyley, 2010). While this is not necessarily limited compliance, it may still impact overall outcomes, especially if compliance continues to decline with time. However, research using home-based exercise in women diagnosed with osteoporosis found that home-based interventions are at least effective as long as participants can comply with the intervention. For example, following a 12-month home-based, resistance training program, those in the intervention group significantly improved markers of muscular strength and endurance over baseline values and the control group (Kanemaru et al., 2010).

## EXERGAMING

The use of exercise video games, or "exergaming," has gained increasing popularity in both clinical and long-term care facilities. Its interactive interface is believed to increase enjoyment and compliance, and prevents participants from becoming bored. It has been used predominantly in older, clinical populations, but no work has been published

supporting its use in middle aged adults as a means of preventative therapy. Most of the existing literature focuses primarily on balance outcomes. Limited information is provided regarding any impact of exergaming on muscular fitness. Currently, there are no published reports available regarding the use of exergaming to positively influence skeletal health in any population.

**Acceptability.** The Wii Fit® system has been successfully implemented in older adult populations. Several studies indicate that older adults enjoy this form of novel exercise technology. Agmon, Perry, Phelan, Demiris, and Nguyen (2011) used the system as a balance therapy with seven older adults over a three month study period. These participants rated high enjoyment with using the system and expressed an interest in using the system with their grandchildren within their homes. A recent separate study that also gauged enjoyment with using the WiiFit®in older adults, found similar results (Meldrum, Glennon, Herdman, Murray, & McConn-Walsh, 2012). In this study, 26 older adults played with the Wii Fit® system one time for 30 minutes and then rated their enjoyment. The mean enjoyment score was 82 out of 100 (i.e., 100 being the highest enjoyment possible) and only two participants rated the system below 50. Additionally, 73% of the participants indicated that they enjoyed the Wii Fit® system more than traditional balance therapy (Meldrum et al., 2012).

There is some discrepancy in the literature about older adults' preference of an exergaming system over traditional clinic-based therapy. After completing several physical therapy sessions that included using the Wii Fit®, 21 older adult participants

completed a discrete choice experiment regarding using the system in comparison to typical balance rehabilitation programs. Unlike the participants in the Meldrum et al. (2012) study, this group of participants preferred traditional therapy. They cited concerns regarding cost, ease of use, and percentage of recovery made as reasons why they did not find the Wii® system appealing (Laver, Ratcliffe, George, Burgess, & Crotty, 2011). A major difference between these studies was the number of times the participants played the game. It may be that for some of these older adults the novelty and fun of the game "wears off" over time.

**Balance Outcomes in Older Adults.** Exergaming, especially the Wii Fit® system, is comprised of mainly balance games intended to improve center of pressure in users. This feature was identified as a potential tool to improve balance in older adults, especially those who may suffer from balance impairment or considered high fall-risk. In two separate intervention trials using older adults, both comprised of 30 minutes of Wii exercise twice per week, there is some evidence to suggest that balance improvements may be possible. A study by Nitz, J.C., Kuys, S., Isles, R., and Fu, S. (2010) indicated a that those who participated in a WiiFit® balance program showed non-significant improvements in the Berg Balance Test over the control group. However, this study was underpowered, limiting the ability to detect any significant outcomes. Franco et al. (2012) also reported a non-significant but positive trend in balance improvement with the WiiFit® intervention in a group of older men and women. However, their study was also underpowered and lasted only three weeks, compared to ten for the Nitz et al. (2010)

study. Nevertheless, they suggested that significant changes may have been detected with a longer intervention period (Franco et al., 2012).

In older adults with a known balance impairment, which was defined at a score of < 52 of the Berg Balance Scale, the Wii® system did appear to improve balance (Agmon et al., 2011). The play time was similar to other interventions, 30 minutes, but the gameplay was done three times per week instead of two. Also, the total study time was longer, lasting three months. Seven older adults completed the study, without a control group, and at the end of the study period, several markers of balance improved (Agmon et al., 2011). The Berg Balance results increased from 49 (SD ± 2.1) to 53 (SD ± 1.8), and walking speed improved by approximately 0.3 m/s.

In general, the Wii Fit® system does not appear to be better than standard treatment alone in improving balance for older adults. Seventeen older adults were randomized into one of three groups: Physical Therapy, Wii Fit®, and Combined Wii® and Therapy. Following four weeks of training consisting of three visits per week, there was no significant difference between the combined group and the therapy alone group, but both were significantly better than the Wii® system alone (Bateni, 2012).

# Chapter 3

# METHODOLOGY

## STUDY DESIGN

12 Week, randomized, home based, controlled, pre-post intervention of 24 peri-menopausal middle-aged women with low bone mass.

## RECRUITMENT

Middle aged women were recruited from the ASU campuses and greater Phoenix metropolitan area via listserves sent to faculty, staff, and local downtown businesses. Women who participated in pilot testing who indicated that they would be willing to participate in research using the Wii Fit® were contacted if they met all inclusion criteria. All recruitment materials can be found in Appendix A.

## ELIGIBILITY

**Inclusion Criteria**. Eligible participants were apparently healthy, sedentary women between the ages of 45-60. Sedentary was defined as accumulating fewer than 60 minutes per week of purposeful light to moderate physical activity. Volunteers could not have contraindications to walking or standing. They could not be on hormonal replacement therapy or any medications or supplements (except for calcium, daily multivitamin, vitamin D) that affect the bone. Any vitamin supplements were to be over-the-counter (OTC) and could not

be prescription-grade. Participants were to have access to an available TV within their home that can be used with the Wii Fit® system.

**Exclusion Criteria.** Those who responded "yes" to any of the questions on the PAR-Q+, and/or did not have any underlying conditions that are well-managed, were excluded. Any woman who had an exergaming system (Wii Fit®, Xbox Kinect®) in her home was excluded. Those who indicated plans to travel for more than 5 days over the 4 months of the study were also excluded. If a prospective participant had a DXA total hip or spine t-score of ≤0 but not lower than -1.5, then they were deemed eligible. Eligible participants were then randomized into one of the two groups (Wii Fit® or control). (Note: any woman who had a DXA t-score less than -1.5 was referred to their health care provider for further follow up and was not allowed into the study without the approval of their health care professional).

## PROCEDURES

All volunteers were informed of the study requirements and asked to sign the informed consent form. Screening for eligibility consisted of completing a PAR-Q+ and health history questionnaire, and assessing bone density using the QUS and DXA. After initial eligibility assessment was determined, women were tested for whole body balance, bone density, and muscular strength and endurance of the lower limbs. All testing was conducted in the Healthy Lifestyles Research Center (HLRC) on the Downtown Phoenix Campus (DPC) of Arizona State University

(ASU) in Phoenix, AZ. Once randomized, the intervention group was given a WiiFit® system, to take home to complete their training sessions. At 6 weeks (mid-intervention) and 12-weeks (posttest) testing all outcome variables except the DXA was reassessed. A copy of the consent form can be found in Appendix B.

**Health history questionnaire.** All volunteers completed the Physical Activity Readiness+ Questionnaire (PAR-Q+) and a health history questionnaire. The PAR-Q+ was used to screen for any health issues that would contraindicate physical activity. Potential participants who answered "yes" to any of the questions were required to provide further information regarding health status to determine inclusion. The Health History Questionnaire served to identify any familial or personal bone-related issues. The Par-Q+ is considered to be highly reliability, with a three-month score correlation of 0.99 (Warburton, Bredin, Jamnik, & Gledhill, 2011). A copy of both the PAR-Q+ and the Health History Questionnaire can be found in Appendix C.

**Food frequency questionnaire.** All participants completed a Food Frequency Questionnaire (FFQ) at baseline, 6-weeks, and 12-weeks to assess if dietary habits changed over the course of the study. Special attention was given to dietary increases in vitamin K, vitamin D, and calcium. Any vitamins/minerals from supplements were included in calculating total daily vitamin/mineral intake. The FFQ used has been shown to have an intra-class correlation coefficient of

0.59 when the questionnaire is taken twice with one year between sessions (Morris, Tangney, Bienias, Evans, & Wilson, 2003). The questionnaire can be found in Appendix D.

**Qualitative Ultrasound (QUS) and Dual-Energy X-ray Absorptiometry (DXA) to assess low bone mass eligibility.** To determine bone-specific inclusion criteria, participants completed a heel scan of the Os Calcis using the Achilles InSight Qualitative Ultrasonometer (GE Lunar, Madison, WI). Participants placed their bare foot into the ultrasonometer, which transmited a harmless ultrasound wave through the Os Calcis. If the stiffness index (SI) t-score from the device was above 1.0, the participant was excluded from the study. If the t-score was equal to or below 1.0, they were asked to continue to have a whole body DXA scan to confirm low bone mass. Total hip and/or spine bone mineral density (BMD) from the DXA was to be below 0, but not lower than -1.5. (Note: any woman who had a DXA t-score less than -1.5 was referred to her health care provider and was not admitted to the study without physician consent.) The Achilles InSight QUS has a coefficient of variation (CV%) of 2.0% when used following manufacturer guidelines (Cepollaro et al., 2005).

**Physical activity questionnaires.** Eligible women completed the Women's Health Initiative Physical Activity Questionnaire (WHI-PAQ) to assess baseline physical activity levels, as well as additional questions from the Rapid Physical Activity Assessment regarding strength, yoga, and flexibility exercise.

These questionnaires were completed every two weeks via phone call to track changes in physical activity habits of both groups over the 12-week intervention. This questionnaire has been shown to have an interclass correlation coefficient of 1.91 ($p<0.0001$) when measured 1 week apart, and a weighed kappa statistic between 0.53 and 0.72 when given 3 months apart (Pettee Gabriel et al., 2009). A copy of the questionnaire can be found in Appendix E.

**Biochemical indices of bone turnover.** A 10 ml venous blood sample was taken to measure serum osteocalcin, a marker of bone formation. Participants did not need to be fasted. All blood draws were done by a certified phlebotomist. Serum was separated from the blood prior to storage using a centrifuge. Samples were stored at -20°C until all blood samples were collected at the end of the study. Blood cell precipitate was also stored separately for future analysis.

For analysis, serum samples were allowed to thaw to room temperature, standards were prepared, and the plates were prepped for use. Samples were only thawed once as they cannot be re-frozen after being thawed. All procedures for preparing the kit and the sample were followed for the osteocalcin ELISA assay (Biomedical Technologies, INC, catalogue number: BT-460) . Full procedures and considerations were conducted per manufacturer's protocol, and can be found in Appendix F. Coefficients of variation (CV%) were determined for each sample. If CV% exceeded 7%, the sample was re-run and analysis repeated.

**Body composition testing**. Bioelectrical impedance (BIA) analysis was conducted at both baseline and 12 weeks to measure any changes in body composition (Tanita TBF-300WA, Arlington Heights, IL) . The areas of interest were total body fat mass and total body lean mass. No site-specific measures were analyzed. BIA has an ICC of 0.93 under ideal conditions and under same-day testing, but the ICC can be as low as 0.71 (or greater than a 2% difference) when tested across days (Loenneke et al., 2013).

**Balance testing.** All screened and eligible participants completed two balance test batteries to assess total body static and dynamic balance (Appendix G). All of the standing exercises were done on the AMTI force plate (Watertown, MA) which collected data on the area and velocity of shifts in center of balance. The within-day ICC using the AMTI for mean velocity was between 0.67 and 0.84, and it was approximately 0.70 for between-day (Lin, Seol, Nussbaum, & Madigan, 2008).

***Foot Positions*.** All measurements were taken for 10 seconds or until loss of balance, unless noted otherwise. The standing positions included:

*Open Base, Eyes Open*. The feet are placed approximately hip-distance apart and eyes are open. Participants look straight ahead with the head upright, focusing on a black dot placed on the wall in front of them. This position is maintained for two minutes

*Closed Base, Eyes Open.* The feet are together with medial sides of the feet in contact. Participants look straight ahead with the head upright, focusing on a black dot placed on the wall in front of them.

*Closed Base, Eyes Closed.* The feet are together with medial sides of the feet in contact. Eyes are closed with the head upright.

*Semi-Tandem, Eyes Open.* The heel of one foot is placed next to the first toe of the opposite foot. The participant gets to choose which foot is placed in front. Participants look straight ahead with the head upright, focusing on a black dot placed on the wall in front of them.

*Semi-Tandem, Eyes Closed.* The heel of one foot is placed next to the first toe of the opposite foot. The participant gets to choose which foot is placed in front. Eyes are closed with the head upright.

*Tandem Step, Eyes Open.* The heel of one foot is placed directly in front of the first toe of the opposite foot. The participant gets to choose which foot is placed in front. Participants look straight ahead with the head upright, focusing on a black dot placed on the wall in front of them. This position is done twice: once for 10 seconds and once for 30 seconds.

*Tandem Step, Eyes Closed.* The heel of one foot is placed directly in front of the first toe of the opposite foot. The participant gets to choose which foot is placed in front. Eyes are closed with the head upright.

*Single-leg Stand, Eyes Open.* The participants raise one foot off of the ground while supporting weight on the adjacent leg. The foot that is raised cannot rest against the standing leg and must be held independently. The participant gets to choose which foot is raised. Participants look straight ahead with the head upright, focusing on a black dot placed on the wall in front of them.

*Open Base, Eyes Closed.* The feet are placed approximately hip-distance apart. Eyes are closed with the head upright.

**Balance Scales.**

***The Berg Balance Scale.*** This scale is a 14-item test that measures fall-risk during usual activities. Some examples of test procedures are "sitting to standing," "standing unsupported," and "turning 360 degrees." Each test is scored on a scale from 0-4, with 0 being unable to complete the test, and 4 representing full ability. The test has a total of 56 points, with a higher score indicating a decreased fall-risk (Berg, 1989). Any score below 40 points is considered to be at an elevated risk of falling, and any score below 20 is considered high risk. The Berg Balance Scale has been shown to have an inter-rater interclass correlation

coefficient (ICC) of 0.98, and an intra-rater ICC of 0.97 (Berg, Wood-Dauphinee, & Williams, 1995).

***The Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT)-4.*** This scale is a 7-item test that assesses static balance. While some items are similar to the Berg, the FICSIT-4 includes tandem standing with eyes both open and closed, and other more complex challenges to balance. Test-retest reliability was assessed and was acceptable ($r = 0.66$, $p<0.001$), and does not appear to be influenced by age (Rossiter-Fornoff, Wolf, Wolfson, & Buchner, 1995).

**Muscular testing.** Muscular strength, power and endurance of knee extensors and flexors was measured using an isokinetic dynamometer (HUMAC NORM, Stoughton, MA). Strength (peak torque) was measured at three speeds: 60°/sec, 180°/sec, and 240°/sec. Two repetitions at each speed were assessed. Muscular endurance was assessed using 50 repetitions at 240°/sec. Muscular endurance was quantified using a fatigue index score, calculated as peak power minus minimum power, divided by the time (seconds) between peak and minimum power. The ICC for peak torque varies from 0.95 to 0.97, depending on the angular velocity, and the ICC for muscular endurance values ranged from 0.96 to 0.97 (Feiring, Ellenbecker, & Derscheid, 1990).

**Randomization.** Eligible participants were assigned using the random number generator program included in Microsoft EXCEL. Study participant numbers were created up to 30, and EXCEL produced an equal number of even and odd decimal values. A separate investigator chose which set of numbers (even or odd) corresponded to the intervention group and assigned participant numbers appropriately. Group assignment was sealed in an envelope labeled with the participant number so that the researcher was blinded to group assignment during baseline testing. Following baseline testing the envelope was opened so that the primary investigator and the participant learned their group assignment at the same time.

**Control group.** Those assigned to the control group were asked to not change their dietary or physical activity habits over the 12-week study period. They were not given any equipment during the intervention however, the control group did have the opportunity to use Wii Fit® system once the study was over.

**Exercise intervention.** Participants assigned to the intervention group were familiarized with the Wii® console. The intervention group was taught how to play various exercises on the Wii Fit®. After familiarization, participants in the intervention group were assigned a Wii console and a Wii Fit® balance board. They were also be given the option of having a member of the research team come to their home to install the gaming system if they did not feel comfortable with setting the system up on their own. Participants were provided an e-mail

address and phone number where they could report any technical problems with the equipment, or could request additional assistance in set-up, use, or exercise instructions.

The intervention group was asked to use only the participant profile pre-programmed for them. Participants were asked to play the Wii Fit® games for 30 minutes, 3 times per week. They completed yoga poses and strength training exercises for the first 10 minutes. These exercises included warrior pose, half-moon pose, torso twists, lunges, and side lunges. For the remaining 20 minutes, participants completed balance games such as Soccer Heading, Ski Slalom, and Table Tilt. They were asked to avoid Ski Jump. They were asked to complete each exercise at least twice, preferably by cycling through all exercises. Participants were asked to do all of the exercises in one 30-minute session, rather than breaking them up throughout the day. Screenshots of the included Wii exercises can be found in Appendix H.

***Half-moon pose***. Participants will stand on the balance board with their feet together. Their will extend their arms above their hand with their palms together. They will bend at the waist to the right as far as is comfortable, and hold for 15 seconds. They will repeat this same pose on the left.

***Warrior pose***. The right foot will be placed on the balance board and the left foot will be on the ground. Participants will be in a side lunge position, with the leg on the

balance board flexed at the knee. Participants will lean into the lead/balance board leg and hold this position for 15 seconds. They will repeat this on the left leg.

***Standing knee***. Participants will stand on the balance board with their feet together. They will extend their arms above their hand with their palms together. They will bend at the waist to the right as far as is comfortable, and hold for 15 seconds. They will repeat this same pose on the left.

***Torso twists***. Participants will stand on the balance board with feet hip-distance apart. They will extend their arms outward into a "T" shape. They will rotate to the right at the waist as far as is comfortable and return to center. They will repeat this on the left side. They will complete 5-10 left/right rotations.

***Lunges***. Participants will stand with one foot on the balance board and one foot on the ground behind them. They will flex both knees, and drop the rear knee as close to the ground as possible. They should reach a 90 degree flexion at the front knee. They will repeat this position with both the right and the left leg as the lead leg.

***Soccer Heading***. Participants will shift their weight from right to left to guide a soccer player on the screen. The goal is to move the soccer player so that he fields the soccer balls with his head, but avoids incoming obstacles, such as soccer cleats. The game is over once time has expired, or the player has hit too many obstacles.

***Balance Bubble***. Participants will shift their weight from left to right and from front to back to maneuver an avatar through a river obstacle course. The goal is to avoid the river banks, various obstacles in the water (rocks, whirlpools) and to avoid airborne obstacles (bees).

***Table Tilt***. Participants will shift their weight from left to right, or from front to back, to move a table with various obstacles. The goal is to guide a ball on the table into a hole by moving the table accordingly.

All participants were asked to keep a record of which games they play and for how long. Participants were provided a journal and will be asked to record the time of day, type, and duration of activity for all purposeful exercise, including time spent using the Wii Fit®. The Wii Fit® software also keeps a digital record of which exercises were completed and how long they were performed. At the end of the intervention the investigator was able to use the information stored in the Wii, as well as activity logs, to assess compliance. Participants were permitted to play games other than those prescribed, but they were asked to do so outside of the 30 minute daily game play time. Any additional games they played was to be included in the exercise log. A copy of the exercise log can be found in Appendix I.

**Reminder phone calls/emails.** Study personnel telephoned or emailed the participants (based on participant preference) every two weeks to ask them to complete the physical activity questionnaire (WHI-PAQ) and to allow participants

to voice any concerns they may have about the equipment. Any health or physical activity changes will be noted.

**Mid-intervention testing (6 weeks).** At week 6, participants returned to the lab to complete the FICSIT-4, Berg Balance Test, the Women's Health Initiative Physical Activity Questionnaire, a blood draw, muscular fitness testing, and an ultrasound heel scan.

**Post-test (12 weeks).** During the week 12 post-test visit, participants completed the same measures as the 6-week visit, as well as a final DXA measure, and returned the Wii Fit® equipment.

**Incentives.** Participants had their parking costs covered during testing at the lab. In addition each participant received $25 in cash for completing the 12 weeks. All subjects names were also entered into a drawing to win one of two (2) Wii Fit® consoles and balance boards. One was raffled to the intervention group, and the other to the control group. Lastly, when the study was complete anyone in the control group was provided instruction on the Wii Fit® should she want it.

**Sample Size Calculation.** Based on current literature utilizing the Wii Fit® in balance interventions, a sample size of 24 was determined to be appropriate. Previous studies have reported significant changes in balance test

scores with using 8-10 subjects (Nitz et al., 2010; Meldrum et al., 2012). No data on subject drop out could be found.

An analysis powered for the effects of exergaming on balance indicated that a minimum of 22 participants are needed to detect any statistically significant change. The SAS macro "PROC POWER" was used to determine sufficient group numbers. The mean difference and standard deviation from Bateni (2012) was used for sample size calculation (n=17, $\beta = 0.80$, Cohen's d= 0.5656). Thus, two groups of 14 were determined appropriate to allow for enough power to detect significant changes in balance and to allow for about a 25% drop out. 25% dropout was anticipated based on previous experience conducting exercise studies that involve a longer time frame.

**Data analysis.** Data was entered into an Excel spreadsheet, which then was imported for analyzing in PASW Statistics 22 (SPSS/IBM, Quarry Bay, Hong Kong). Data was checked for normality and then differences between the intervention and control group analyzed using two-way repeated measures analysis of variance (ANOVA). Changes in body weight, several indices of balance, muscular strength/endurance, physical activity, QUS indices of bone quality, and osteocalcin, were compared between groups and any time x group interactions was assessed. Alpha was set at 0.05 for determining significance. Proper checks and corrections were conducted for all outcome variables (normality, sphericity, homogeneity), and no transformations were necessary for any of the data.

# Chapter 4

# RESULTS

Twenty-four peri or post-menopausal women were deemed eligible to participate in the study. Of the 24 women, 22 women completed the baseline and follow-up visits for the study. Reasons for dropout included a family medical emergency and not being interested in participating in the control group. All statistics were run in IBM SPSS 22. Figure 2 provides the screening, recruitment, and dropout sequence.

Participants in the intervention group were 92% compliant. 100% compliance was defined as completing all prescribed exercises for at least 30 minutes for all 36 exercise sessions. The participants completed all exercises for a full 30 minutes on all days that they played the Wii system, but not all participants completed all 36 exercise sessions. Three participants exceeded 36 sessions, and were over 100% compliant. Only two of the total 11 intervention participants were less than 80% compliant.

Descriptive data, nutritional data, and physical activity habits at baseline are presented in Table 1, Table 2, and Table 3, respectively. There were no significant differences between groups at baseline.

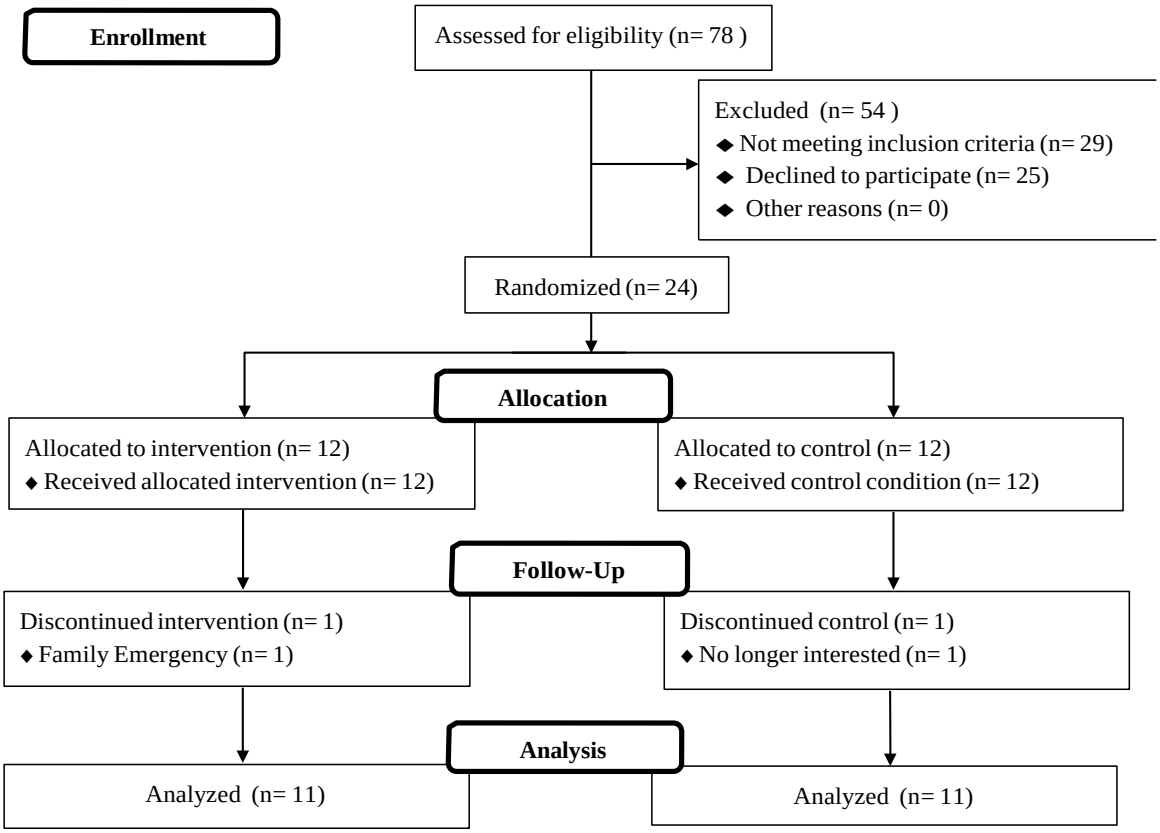


*Figure* 2. Flow Diagram of Participant Recruitment and Retention

**BASELINE DATA**

Table 1

*Descriptive Characteristics*

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| Age (years) | 54.82 ± 4.75 | 52.36 ± 5.94 | 0.297 |
| Weight (lbs) | 158.10 ± 13.95 | 168.00 ± 37.24 | 0.415 |
| Body fat (%) | 37.68 ± 3.25 | 33.94 ± 6.76 | 0.119 |
| Height (in) | 63.31 ± 1.95 | 64.91 ± 2.66 | 0.127 |
| | Intervention N (%) | Control N (%) | Total N (%) |
| Ethnicity | | | |
| Caucasian | 8 (73) | 9 (82) | 17 (77) |
| African American | 1 (9) | 1 (9) | 2 (9) |
| Asian | 1 (9) | 0 (0) | 1 (5) |
| Hispanic | 1 (9) | 1 (9) | 2 (9) |
| Other | 0 (0) | 0 (0) | 0 (0) |
| Total | 11 (100) | 11 (100) | 22 (100) |

Table 2

*Baseline Dietary Patterns from Harvard Food Frequency Questionnaire (n=22)*

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| Protein Servings/Month | 45 ± 31 | 47 ± 33 | 0.859 |
| Vegetable Servings/Month | 138 ± 54 | 106 ± 74 | 0.133 |
| Calcium Intake (mg/day)[¤] | 936 ± 600 | 877 ± 467 | 0.707 |

[¤]Combined dietary and supplement intake

Table 3

*Baseline Physical Activity Habits (n=22)*

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| Walking (min/week) | 34.55 ± 23.81 | 25.45 ± 18.10 | 0.325 |
| MVPA (min/week) | 1.82 ± 6.03 | 7.27 ± 13.48 | 0.235 |
| Mild(min/week) | 0 | 0 | -- |
| Strength Training (min/week) | 0 | 0 | -- |
| Flexibility/Balance Training (min/week) | 0 | 0 | -- |

There were no significant differences between the Intervention and Control groups in regards to any descriptive information (age, height, weight, body fat percentage), nutritional intake, or physical activity habits at baseline. Repeated Measures ANOVAs for all descriptive and baseline characteristics can be found in Table 5, Table 7, and Table 9, for weight/body fat, dietary patterns, and physical activity habits, respectively. Means and standard deviations for each group across study visits can be found in Table 4 (weight/body fat), Table 6 (dietary patterns), and Table 8 (physical activity habits).

## CHANGE IN BASELINE DESCRIPTIVE DATA

Table 4

*Means and Standard Deviations across Visits for Body Weight and Body Fat Percentage (n=22)*

| | Visit 1 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|
| Weight (lbs) | | |
| Intervention (n=11) | 158.10 ± 13.95 | 159.22 ± 15.24 |
| Control (n=11) | 168.00 ± 37.24 | 169.05 ± 37.18 |
| Body Fat % | | |
| Intervention (n=11) | 37.68 ± 3.25 | 37.20 ± 5.59 |
| Control (n=11) | 33.94 ± 6.76 | 37.04 ± 7.26 |

Table 5

*RM-ANOVA for Body Weight (lbs) and Body Fat Percentage (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Weight | | | | |
| Time | 3.22 | 1 | 0.088 | 0.139‡ |
| Time*Group | 0.01 | 1 | 0.908 | 0.001 |
| Body Fat | | | | |
| Time | 3.69 | 1 | 0.069 | 0.156‡ |
| Time*Group | 1.68 | 1 | 0.210 | 0.077‡ |

‡ effect size > 0.06

Table 6

*Means and Standard Deviations across Visits for Dietary Patterns Assessed via Food Frequency Questionnaire (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Protein Servings/Month | | | |
| Intervention (n=11) | 45 ± 31 | 46 ± 31 | 47 ± 31 |
| Control (n=11) | 47 ± 33 | 48 ± 33 | 49 ± 33 |
| Vegetable Servings/Month | | | |
| Intervention (n=11) | 138 ± 54 | 144 ± 55 | 143 ± 57 |
| Control (n=11) | 105 ± 74 | 103 ± 68 | 104 ± 67 |
| Calcium Intake (mg/day)¤ | | | |
| Intervention (n=11) | 936 ± 600 | 918 ± 354 | 945 ± 372 |
| Control (n=11) | 877 ± 467 | 863 ± 412 | 859 ± 474 |

¤Combined dietary and supplement intake

Table 7

*RM-ANOVA for Dietary Patterns as Assessed via Food Frequency Questionnaire (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Protein Servings-Month | | | | |
| Time | 0.40 | 2 | 0.537 | 0.019 |
| Time*Group | 0.14 | 2 | 0.710 | 0.007 |
| Vegetable Servings/Month | | | | |
| Time | 0.64 | 2 | 0.434 | 0.031 |
| Time*Group | 1.91 | 2 | 0.182 | 0.087‡ |
| Calcium Intake (mg/day)¤ | | | | |
| Time | 1.80 | 2 | 0.195 | 0.083‡ |
| Time*Group | 0.20 | 2 | 0.660 | 0.010 |

¤Combined dietary and supplement intake
‡ effect size > 0.06

Table 8

*Means and Standards Deviations across Visits 1, 2, and 3 for Physical Activity Habits* ¤ *from the Women's Health Initiative Physical Activity Questionnaire (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Walking (min/week) | | | |
| Intervention (n=11) | 34.55 ± 23.81 | 34.00 ± 21.19 | 34.00 ± 21.25 |
| Control (n=11) | 25.45 ± 18.10 | 28.89 ± 17.64 | 26.67 ± 20.00 |
| MVPA (min/week) | | | |
| Intervention (n=11) | 1.82 ± 6.03 | 2.22 ± 6.67 | 6.67 ± 14.14 |
| Control (n=11) | 7.27 ± 13.48 | 8.00 ± 19.32 | 8.00 ± 19.32 |
| Mild (min/week) | | | |
| Intervention (n=11) | 0.00 ± 0.00 | 94.00 ± 35.024 | 85.50 ± 34.12 |
| Control (n=11) | 0.00 ± 0.00 | 0.00 ± 0.00 | 0.00 ± 0.00 |

¤No strength training or flexibility training was reported at any study visit

Table 9

*RM-ANOVA for Physical Activity Habits from the Women's Health Initiative Physical Activity Questionnaire (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Walking (min/week) | | | | |
| Time | 0.71 | 2 | 0.498 | 0.040 |
| Time*Group | 0.24 | 2 | 0.789 | 0.014 |
| MVPA (min/week) | | | | |
| Time | 0.45 | 2 | 0.450 | 0.046 |
| Time*Group | 2.22 | 2 | 0.138 | 0.115‡ |
| Mild (min/week) | | | | |
| Time | 58.39 | 2 | 0.000† | 0.775‡ |
| Time*Group | 58.39 | 2 | 0.000† | 0.775‡ |

† p-value < 0.05

‡ effect size > 0.06

There were no significant main effects or interactions for weight/body fat or dietary patterns across the 12-week study period. There was a significant main effect for time and a significant time*group interaction for mild physical activity. Only the intervention group increased total mild activity time during the study period by using the Wii Fit® device, and no other physical activity habits were significantly difference at baseline or any subsequent visit. All physical activity times were reported using the Women's Health Initiative Physical Activity Questionnaire (WHI-PAQ), except for Mild activity in the intervention group; that was tracked use actual play time logged on the Wii Fit® console.

**PRIMARY HYPOTHESIS**

12 weeks of interactive play will significantly improve balance in middle-aged women as compared to a randomly assigned control group. Independent samples t-tests were conducted to determine any differences between groups at baseline across all measures (Table 10 (balance scales) and Table 13 in Appendix J (force plate)). Repeated Measures Analysis of Variance (RM-ANOVA) were run to assess a main effect for time and any time*group interaction (Table 12 (balance scales) and Tables 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 (force plate)). Means and standards deviations for each group at each study visit can be found in Table 11 (balance scales) and Tables 14, 16, 18, 20, 22, 24, 26, 28, 30, 32 (force plate).

Baseline data for the balance scales is presented first, followed by the means and standard deviations for all study visits and the Repeated Measures Analysis of Variance (RM-ANOVA) for the balance scales. A brief interpretation of the outcomes is located below the tables for the balance scales.

For the force plate outcomes, the tables follow the same table pairing, with each table pair representing the means and standard deviations across all three visits for the intervention and the control group as well as the RM-ANOVA for the 10 individual foot positions. The tables progress as follows: Means and Standard Deviations for first foot position, RM-ANOVA for first foot position; Means and Standard Deviations for second foot position, RM-ANOVA for second foot position, etc. The brief interpretation for each position follows each table pair for the given foot position. Any pertinent figures will

follow the table pairs, but precede the interpretation. The upcoming foot positions will progress in the following order: Open Base, Eyes Open; Closed Base, Eyes Open; Closed Base, Eyes Closed; Semi-Tandem, Eyes Open; Semi-Tandem, Eyes Closed; Tandem Step, Eyes Open (10 second); Tandem Step, Eyes Closed; Single Leg, Eyes Open; Open Base, Eyes Closed; Tandem Step, Eyes Open (30 second).

**Balance scales.**

Table 10

*Baseline Score Results for Balance Scales (Berg and FICSIT-4*) across Groups (n=22)*

| | Intervention (M ± SD) | Control (M ± SD) | p- |
|---|---|---|---|
| Berg (Raw Score) | value 54.73 ± 2.24 | 55.36 ± 1.50 | 0.443 |
| FICSIT-4 (Raw Score) | 26.91 ± 1.81 | 26.18 ± 1.60 | 0.331 |

*Frailty and Injuries: Cooperative Studies of Intervention Techniques

Table 11

*Means and Standard Deviations across Visits for Balance Scales (Berg and FICSIT-4*, n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Berg | | | |
| Intervention (n=11) | 54.73 ± 2.24 | 55.91 ± 0.30 | 56.00 ± 0.00 |
| Control (n=11) | 55.36 ± 1.50 | 55.45 ± 1.04 | 55.45 ± 1.51 |
| FICSIT | | | |
| Intervention (n=11) | 26.80 ± 1.87 | 27.90 ± 0.32 | 27.60 ± 0.84 |
| Control (n=11) | 26.00 ± 1.66 | 26.22 ± 2.33 | 27.33 ± 1.00 |

*Frailty and Injuries: Cooperative Studies of Intervention Techniques

Table 12

*RM- ANOVA for Balance Scales (Berg and FICSIT-4*, n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Berg | | | | |
| Time | 2.223 | 2 | 0.121 | 0.133‡ |
| Time*group | 1.654 | 2 | 0.204 | 0.085‡ |
| FICSIT-4 | | | | |
| Time | 3.061 | 2 | 0.060 | 0.365‡ |
| Time*group | 1.340 | 2 | 0.275 | 0.135‡ |

*Frailty and Injuries: Cooperative Studies of Intervention Techniques
‡ partial eta squared > 0.06

There were no significant main effects for time or any time*group interactions for the Berg or the FICSIT-4. The main effect for Time for the FICSIT-4 was trending toward significance and has a large effect size, indicating that both groups improved their scores across visits. There were also large effect sizes for the main effect for Time (Berg) and the Time*Group interaction (FICSIT-4). There was a medium effect size for the Time*Group interaction (Berg).

**Force plate.**

Table 14

*Means and Standard Deviations across Visits for Open Base, Eyes Open Assessed via the AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=11) | 3.96 ± 2.43 | 2.79 ± 0.75 | 3.37 ± 1.38 |
| Control (n=11) | 2.51 ± 0.70 | 2.53 ± 0.92 | 2.81 ± 1.81 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=11) | -3.34 ± 1.49 | -2.75 ± 1.01 | -3.07 ± 0.70 |
| Control (n=11) | -3.43 ± 1.90 | -2.89 ± 1.29 | -2.89 ± 1.33 |
| Average Velocity (mm/s) | | | |
| Intervention (n=11) | 0.83 ± 0.21 | 0.82 ± 0.17 | 0.96 ± 0.25 |
| Control (n=11) | 0.88 ± 0.22 | 0.89 ± 0.21 | 0.86 ± 0.17 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=11) | 1.37 ± 0.56 | 1.36 ± 0.47 | 1.67 ± 0.65 |
| Control (n=11) | 1.25 ± 0.39 | 1.24 ± 0.31 | 1.12 ± 0.16 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=11) | 1.30 ± 0.94 | 1.24 ± 0.71 | 1.98 ± 1.45 |
| Control (n=11) | 0.99 ± 0.57 | 0.97 ± 0.49 | 0.82 ± 0.18 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=11) | 2.44 ± 1.43 | 2.58 ± 1.06 | 3.43 ± 1.69 |
| Control (n=11) | 1.77 ± 0.92 | 1.89 ± 0.87 | 1.71 ± 0.51 |

Table 15

*RM-ANOVA for the Open Base, Eyes Open Position for the Parameters from the AMTI Force Plate (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 0.78 | 2 | 0.466 | 0.044 |
| Time*Group | 1.63 | 2 | 0.212 | 0.087‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time*Group | 0.08 | 2 | 0.928 | 0.004 |
| Average Velocity (mm/s) | | | | |
| Time | 0.82 | 2 | 0.451 | 0.046 |
| Time*Group | 1.69 | 2 | 0.199 | 0.091‡ |
| Major Axis ($mm^{2)}$ | | | | |
| Time | 0.32 | 2 | 0.726 | 0.019 |
| Time*Group | 1.76 | 2 | 0.187 | 0.094‡ |
| Area Effective ($mm^2$) | | | | |
| Time*Group | 1.99 | 2 | 0.160 | 0.102‡ |
| Area 95 ($mm^2$) | | | | |
| Time | 1.06 | 2 | 0.360 | 0.062‡ |
| Time*Group | 1.88 | 2 | 0.170 | 0.105‡ |

† p-value < 0.05
‡effect size > 0.06

There was no significant main effect for time or any significant group*time interaction for any of the balance parameters in the open base, eyes open position. All mean velocities for each group were in the range of what is considered “stable”. There were medium effect sizes for the Time*Group interaction (Average Velocity), the Time*Group interaction (Major Axis), the Time*Group interaction (Area Effective), the main effect for time (Area 95), and the Time*Group Interaction (Area 95). All other effect sizes were small.

Table 16

*Means and Standard Deviations across Visits for Closed Base, Eyes Open Assessed via the AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=11) | 4.42 ± 2.14 | 5.76 ± 2.10 | 4.84 ± 1.48 |
| Control (n=11) | 4.44 ± 3.02 | 5.10 ± 1.54 | 5.17 ± 2.33 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=11) | -4.17 ± 1.66 | -5.67 ± 2.61 | -4.98 ± 2.48 |
| Control (n=11) | -3.84 ± 1.13 | -5.87 ± 2.03 | -5.49 ± 2.51 |
| Average Velocity (mm/s) | | | |
| Intervention (n=11) | 1.48 ± 0.40 | 2.03 ± 0.74 | 1.76 ± 0.44 |
| Control (n=11) | 1.55 ± 0.54 | 1.86 ± 0.28 | 1.85 ± 0.48 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=11) | 1.26 ± 0.54 | 1.267 ± 0.48 | 1.26 ± 0.42 |
| Control (n=11) | 1.11 ± 0.36 | 1.25 ± 0.33 | 1.32 ± 0.45 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=11) | 1.34 ± 0.99 | 1.38 ± 1.04 | 1.29 ± 0.76 |
| Control (n=11) | 0.98 ± 0.57 | 1.25 ± 0.56 | 1.35 ± 0.76 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=11) | 3.25 ± 1.66 | 3.82± 2.94 | 3.37 ± 1.82 |
| Control (n=11) | 2.61 ± 1.33 | 3.45 ± 1.45 | 3.41 ± 1.88 |

Table 17

*RM-ANOVA for the Closed Base, Eyes Open Position for the Parameters from the AMTI Force Plate (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 1.41 | 2 | 0.258 | 0.044 |
| Time*Group | 0.35 | 2 | 0.689 | 0.087‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time | 5.21 | 2 | 0.011† | 0.049 |
| Time*Group | 0.29 | 2 | 0.752 | 0.004 |
| Average Velocity (mm/s) | | | | |
| Time*Group | 0.58 | 2 | 0.566 | 0.091‡ |
| Major Axis ($mm^{2)}$ | | | | |
| Time | 0.26 | 2 | 0.771 | 0.019 |
| Time*Group | 0.28 | 2 | 0.757 | 0.094‡ |
| Area Effective ($mm^2$) | | | | |
| Time | 0.26 | 2 | 0.771 | 0.042 |
| Time*Group | 0.30 | 2 | 0.743 | 0.102‡ |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 0.16 | 2 | 0.850 | 0.105‡ |

† p-value < 0.05
‡effect size > 0.06

There was a significant main effect for time for the Maximum Velocity Y and the Average Velocity measures, indicating that both groups improved across the study period. There was no other significant main effects for time or any significant group*time interactions for any of the balance parameters in the closed base, eyes open position. All average velocities for each group fell into the range of what is considered “stable”. There were medium effect sizes for the Time*Group interaction (Maximum Velocity X), the Time*Group interaction (Average Velocity), and Time*Group interaction (Major Axis), the main effect for time (Area 95), and the Time*Group interaction (Area 95). All other effect sizes were small.

Table 18

*Means and Standard Deviations across Visits for Closed Base, Eyes Closed Assessed via the AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=11) | 8.06 ± 4.79 | 8.72 ± 6.56 | 8.23 ± 2.19 |
| Control (n=11) | 6.12 ± 2.65 | 7.23 ± 2.03 | 6.58 ± 3.16 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=11) | -7.72 ± 5.83 | -8.44 ± 6.48 | -9.24 ± 3.93 |
| Control (n=11) | -6.15 ± 2.16 | -7.90 ± 2.60 | -6.80 ± 5.36 |
| Average Velocity (mm/s) | | | |
| Intervention (n=11) | 2.66 ± 1.16 | 2.64 ± 1.40 | 2.71 ± 0.74 |
| Control (n=11) | 2.03 ± 0.33 | 2.41 ± 0.65 | 2.42 ± 1.04 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=11) | 1.66 ± 0.51 | 1.83 ± 0.59 | 1.72 ± 0.51 |
| Control (n=11) | 1.36 ± 0.41 | 1.62 ± 0.44 | 1.66 ± 0.61 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=11) | 2.35 ± 1.27 | 2.84 ± 1.95 | 2.64 ± 1.69 |
| Control (n=11) | 1.48 ± 0.91 | 2.05 ± 0.92 | 2.41 ± 1.83 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=11) | 5.02 ± 2.14 | 6.83 ± 5.07 | 7.01 ± 3.23 |
| Control (n=11) | 3.96 ± 2.41 | 5.29 ± 2.10 | 6.78 ± 5.12 |

Table 19

*RM-ANOVA for the Closed Base, Eyes Closed Position for the Parameters from the AMTI Force Plate (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 0.36 | 2 | 0.701 | 0.021 |
| Time*Group | 0.02 | 2 | 0.976 | 0.001 |
| Maximum Velocity Y (mm/s) | | | | |
| Time | 0.67 | 2 | 0.520 | 0.038 |
| Time*Group | 0.33 | 2 | 0.722 | 0.019 |
| Average Velocity (mm/s) | | | | |
| Time*Group | 0.58 | 2 | 0.566 | 0.033 |
| Major Axis ($mm^{2)}$ | | | | |
| Time | 0.88 | 2 | 0.425 | 0.033 |
| Time*Group | 0.21 | 2 | 0.423 | 0.038 |
| Area Effective ($mm^2$) | | | | |
| Time | 1.35 | 2 | 0.275 | 0.083‡ |
| Time*Group | 0.39 | 2 | 0.681 | 0.025 |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 0.19 | 2 | 0.829 | 0.013 |

† p-value < 0.05
‡effect size > 0.06

There were no significant main effects for time or any significant group*time interactions for any of the balance parameters in the closed base, eyes closed position. There was a medium effect size for the main effect for time (Area Effective) and a large effect size for the main effect for time (Area 95). All other effect sizes were small.

Table 20

*Means and Standard Deviations across Visits for Semi-Tandem, Eyes Open Assessed via the AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=11) | 5.42 ± 1.64 | 5.59 ± 2.60 | 5.56 ± 1.33 |
| Control (n=11) | 32.83 ± 81.8 | 6.18 ± 1.83 | 5.57 ± 1.78 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=11) | -5.32 ± 1.36 | -5.81 ± 2.56 | -6.16 ± 1.41 |
| Control (n=11) | -17.37 ± 34.88 | -6.14 ± 2.03 | -6.34 ± 3.83 |
| Average Velocity (mm/s) | | | |
| Intervention (n=11) | 2.06 ± 0.37 | 2.05 ± 076 | 2.09 ± 0.36 |
| Control (n=11) | 3.72 ± 5.09 | 2.34 ± 0.69 | 2.09 ± 0.37 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=11) | 1.36 ± 0.29 | 1.37 ± 0.45 | 1.38 ± 0.26 |
| Control (n=11) | 2.52 ± 3.24 | 1.48 ± 0.26 | 1.40 ± 0.25 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=11) | 1.44 ± 0.51 | 1.48 ± 0.92 | 1.51± 0.48 |
| Control (n=11) | 9.14 ± 22.75 | 1.56 ± 0.48 | 1.50± 0.60 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=11) | 3.87 ± 1.18 | 3.84 ± 2.39 | 4.13 ± 1.33 |
| Control (n=11) | 15.53 ± 35.38 | 3.89 ± 1.39 | 4.09 ± 1.80 |

Table 21

*RM-ANOVA for the Semi-Tandem, Eyes Open Position for the Parameters from the AMTI Force Plate (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 1.09 | 2 | 0.348 | 0.060‡ |
| Time*Group | 1.11 | 2 | 0.340 | 0.062‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time*Group | 1.11 | 2 | 0.341 | 0.061‡ |
| Average Velocity (mm/s) | | | | |
| Time | 0.83 | 2 | 0.446 | 0.046 |
| Time*Group | 0.85 | 2 | 0.438 | 0.047 |
| Major Axis ($mm^{2)}$ | | | | |
| Time*Group | 1.10 | 2 | 0.344 | 0.061‡ |
| Area Effective ($mm^2$) | | | | |
| Time*Group | 1.12 | 2 | 0.339 | 0.062‡ |
| Area 95 ($mm^2$) | | | | |
| Time | 1.01 | 2 | 0.374 | 0.056 |
| Time*Group | 1.05 | 2 | 0.361 | 0.058 |

† p-value < 0.05
‡effect size > 0.06

There were no significant main effects for time or any significant group*time interactions for any of the balance parameters in the semi-tandem, eyes open position. At baseline, the control group had values that were considered “abnormal” for Maximum Velocity X and Y. These values fell within the normal range at all subsequent visits. All of the other mean values were within the range of what is considered “stable” for both the intervention and the control groups. There were medium effect sizes for the main effect for time (Maximum Velocity X), the Time*Group interaction (Maximum Velocity X), the Time*Group interaction (Maximum Velocity Y), the Time*Group interaction (Major Axis), the main effect for time (Area Effective), and the Time*Group interaction (Area Effective). All other effect sizes were small.

Table 22

*Means and Standard Deviations across Visits for Semi-Tandem, Eyes Closed Assessed via the AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=11) | 12.60 ± 4.46 | 10.48 ± 4.91 | 10.20 ± 4.02 |
| Control (n=11) | 38.50 ± 85.07 | 8.23 ± 1.88 | 9.88 ± 4.07 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=11) | -12.21 ± 5.05 | -10.11 ± 5.14 | -10.83 ± 4.68 |
| Control (n=11) | -20.20 ± 36.45 | -8.88 ± 2.62 | -8.73 ± 2.45 |
| Average Velocity (mm/s) | | | |
| Intervention (n=11) | 3.83 ± 1.21 | 3.45 ± 1.35 | 3.61 ± 1.35 |
| Control (n=11) | 4.55 ± 5.21 | 3.13 ± 0.68 | 3.06 ± 0.88 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=11) | 2.29 ± 1.05 | 2.36 ± 0.89 | 2.18 ± 1.19 |
| Control (n=11) | 2.98 ± 3.33 | 1.99 ± 0.44 | 1.92 ±0.41 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=11) | 4.35 ± 3.51 | 4.22 ± 2.49 | 4.31 ± 5.26 |
| Control (n=11) | 10.92 ± 23.84 | 2.98 ± 1.29 | 2.82 ± 0.91 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=11) | 10.79 ± 7.28 | 9.99 ± 5.31 | 11.30 ± 13.06 |
| Control (n=11) | 19.31 ± 36.76 | 7.90 ± 3.62 | 7.40 ± 2.60 |

Table 23

*RM-ANOVA for the Semi-Tandem, Eyes Closed Position for the Parameters from the AMTI Force Plate (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 1.42 | 2 | 0.256 | 0.082‡ |
| Time*Group | 1.05 | 2 | 0.363 | 0.061‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time*Group | 0.70 | 2 | 0.506 | 0.042 |
| Average Velocity (mm/s) | | | | |
| Time*Group | 0.51 | 2 | 0.605 | 0.031 |
| Major Axis ($mm^{2)}$ | | | | |
| Time | 0.80 | 2 | 0.459 | 0.053 |
| Time*Group | 0.70 | 2 | 0.506 | 0.051 |
| Area Effective ($mm^2$) | | | | |
| Time*Group | 1.05 | 2 | 0.363 | 0.042 |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 0.87 | 2 | 0.430 | 0.061‡ |

† p-value < 0.05
‡effect size > 0.06

There were no significant main effects for time or any significant group*time interactions for any of the balance parameters in the semi-tandem, eyes closed position. The mean values for both the intervention and the control were considered “abnormal” for the Maximum Velocity X and Y outcomes. These values came into the “stable” range for all remaining study visits. The other parameters were considered “stable” across all visits for both study groups. There was a medium effect size for the main effect for Time (Maximum Velocity X), the Time*Group interaction (Maximum Velocity X), the main effect for Time (Maximum Velocity Y), the main effect for Time (Average Velocity), the main effect for time (Area 95), and the Time*Group interaction (Area 95). All other effect sizes were small.

Table 24

*Means and Standard Deviations across Visits for Tandem Step, Eyes Open (10 sec) Assessed via the AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=11) | 12.99 ± 6.25 | 11.24 ± 2.96 | 12.24 ± 3.63 |
| Control (n=11) | 18.87 ± 15.70 | 12.65 ± 4.23 | 12.24 ± 3.86 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=11) | -12.17 ± 6.25 | -12.59 ± 5.69 | -11.06 ± 4.01 |
| Control (n=11) | -19.17 ± 19.73 | -11.17 ± 1.99 | -11.78 ± 5.23 |
| Average Velocity (mm/s) | | | |
| Intervention (n=11) | 4.12 ± 1.21 | 3.99 ± 1.01 | 4.00 ± 1.16 |
| Control (n=11) | 4.92 ± 2.48 | 4.37 ± 1.34 | 4.34 ± 1.44 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=11) | 1.79 ± 0.66 | 2.22 ± 0.98 | 2.12 ± 0.84 |
| Control (n=11) | 3.60 ± 4.00 | 1.92 ± 0.56 | 1.97 ± 0.67 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=11) | 2.56 ± 1.42 | 4.05 ± 3.06 | 3.63 ± 2.53 |
| Control (n=11) | 16.18 ± 32.19 | 3.02 ± 1.95 | 3.03 ± 2.01 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=11) | 6.53 ± 3.44 | 8.04 ± 5.94 | 9.28 ± 6.20 |
| Control (n=11) | 30.46 ± 57.03 | 10.28 ± 6.76 | 7.83 ± 4.96 |

Table 25

*RM-ANOVA for the Tandem Step, Eyes Open (10 sec) Position for the Parameters from the AMTI Force Plate (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 1.69 | 2 | 0.199 | 0.091‡ |
| Time*Group | 0.81 | 2 | 0.453 | 0.045 |
| Maximum Velocity Y (mm/s) | | | | |
| Time | 1.32 | 2 | 0.281 | 0.072‡ |
| Time*Group | 0.72 | 2 | 0.495 | 0.040 |
| Average Velocity (mm/s) | | | | |
| Time*Group | 1.04 | 2 | 0.363 | 0.058 |
| Major Axis ($mm^{2)}$ | | | | |
| Time*Group | 2.29 | 2 | 0.117 | 0.119‡ |
| Area Effective ($mm^2$) | | | | |
| Time | 1.32 | 2 | 0.280 | 0.072‡ |
| Time*Group | 1.95 | 2 | 0.157 | 0.103‡ |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 1.94 | 2 | 0.160 | 0.102‡ |

† p-value < 0.05
‡ partial eta squared > 0.06

There was no significant main effect for time or a significant group*time interaction for any of the balance parameters in the tandem step, eyes open (10 sec) position. The Maximum Velocity X and Y values were considered "abnormal" for both the intervention and the control group across all study visits. All other outcome measures fell within the "stable" range for both groups. There was a medium effect size for the main effect for time (Maximum Velocity X), the main effect for time (Maximum Velocity Y), the Time*Group interaction (Major Axis), the main effect for Time (Area Effective), the Time*Group interaction (Area Effective), the main effect for Time (Area 95), and the Time*Group interaction (Area 95). All other effect sizes were small.

Table 26

*Means and Standard Deviations across Visits for Tandem Step, Eyes Closed Assessed via the AMTI Force Plate (n=10)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=5) | 20.84 ± 7.04 | 14.95 ± 4.96 | 16.13 ± 5.07 |
| Control (n=5) | 9.60 ± 11.57 | 19.05 ± 5.43 | 22.96 ± 6.35 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=5) | -19.67 ± 6.45 | -14.26 ± 4.48 | -19.25 ± 4.34 |
| Control (n=5) | -8.15 ± 9.84 | -17.98 ± 3.24 | -16.72 ± 1.13 |
| Average Velocity (mm/s) | | | |
| Intervention (n=5) | 6.31 ± 1.33 | 4.90 ± 1.21 | 5.21 ± 0.92 |
| Control (n=5) | 2.64 ± 2.64 | 5.26 ± 1.16 | 7.43 ± 1.35 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=5) | 2.68 ± 0.82 | 2.15 ± 0.65 | 2.90 ± 0.39 |
| Control (n=5) | 1.73 ± 1.25 | 2.97 ± 0.05 | 3.96 ± 3.15 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=5) | 5.49 ± 2.63 | 3.48 ± 1.81 | 6.40 ± 1.75 |
| Control (n=5) | 2.55 ± 3.02 | 5.77 ± 3.21 | 2.35± 3.11 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=5) | 14.34 ± 6.77 | 8.54 ± 3.26 | 17.24 ± 5.49 |
| Control (n=5) | 6.31 ± 7.96 | 16.17 ± 3.97 | 36.21 ± 41.76 |

Table 27

*RM-ANOVA for the Tandem Step, Eyes Closed Position for the Parameters from the AMTI Force Plate (n=10)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 0.74 | 2 | 0.499 | 0.110‡ |
| Time*Group | 3.72 | 2 | 0.051† | 0.383‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time | 1.13 | 2 | 0.355 | 0.148‡ |
| Time*Group | 3.99 | 2 | 0.047† | 0.400‡ |
| Average Velocity (mm/s) | | | | |
| Time*Group | 14.28 | 2 | 0.001† | 0.741‡ |
| Major Axis ($mm^{2)}$ | | | | |
| Time*Group | 2.11 | 2 | 0.164 | 0.260‡ |
| Area Effective ($mm^2$) | | | | |
| Time | 0.49 | 2 | 0.622 | 0.091‡ |
| Time*Group | 2.49 | 2 | 0.133 | 0.332‡ |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 2.72 | 2 | 0.106 | 0.312‡ |

† p-value < 0.05
‡ partial eta squared > 0.06

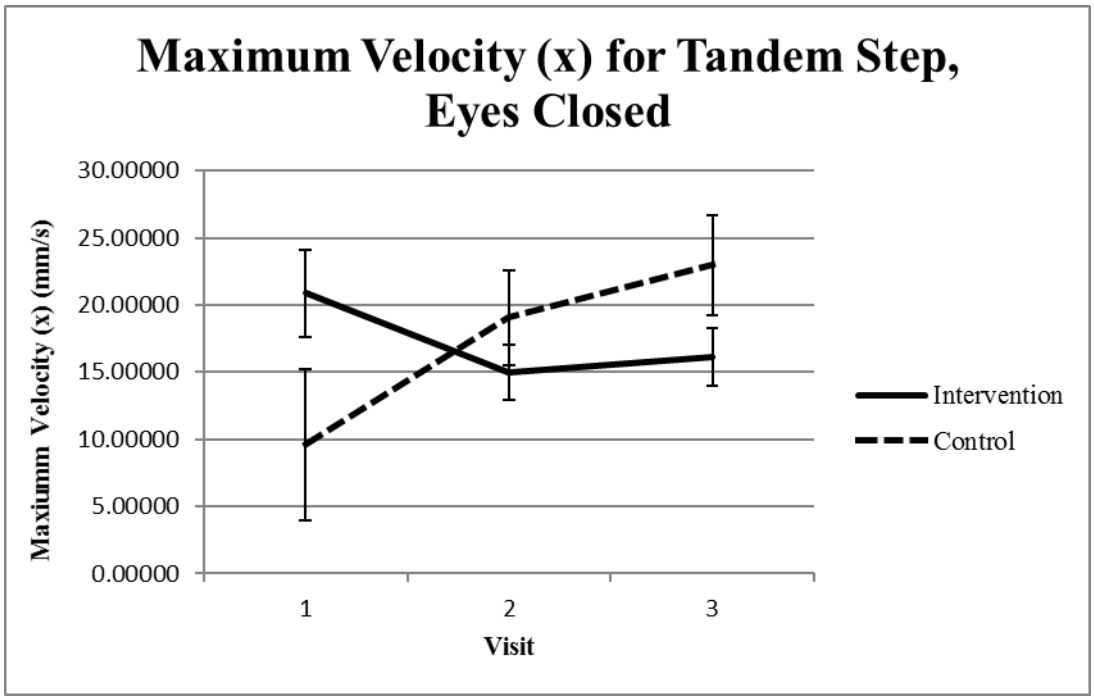


*Figure 3*. Group Means for Maximum Velocity (x) across Study Visits (n=10)

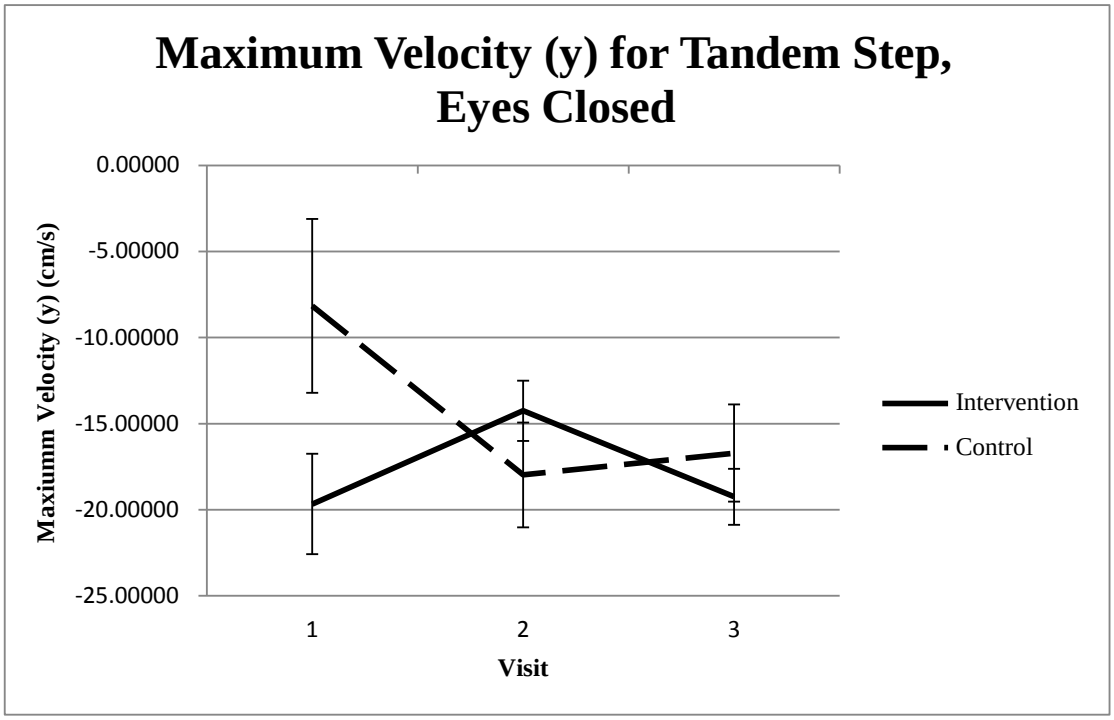


*Figure 4*. Group Means for Maximum Velocity (y) across Study Visits (n=10)

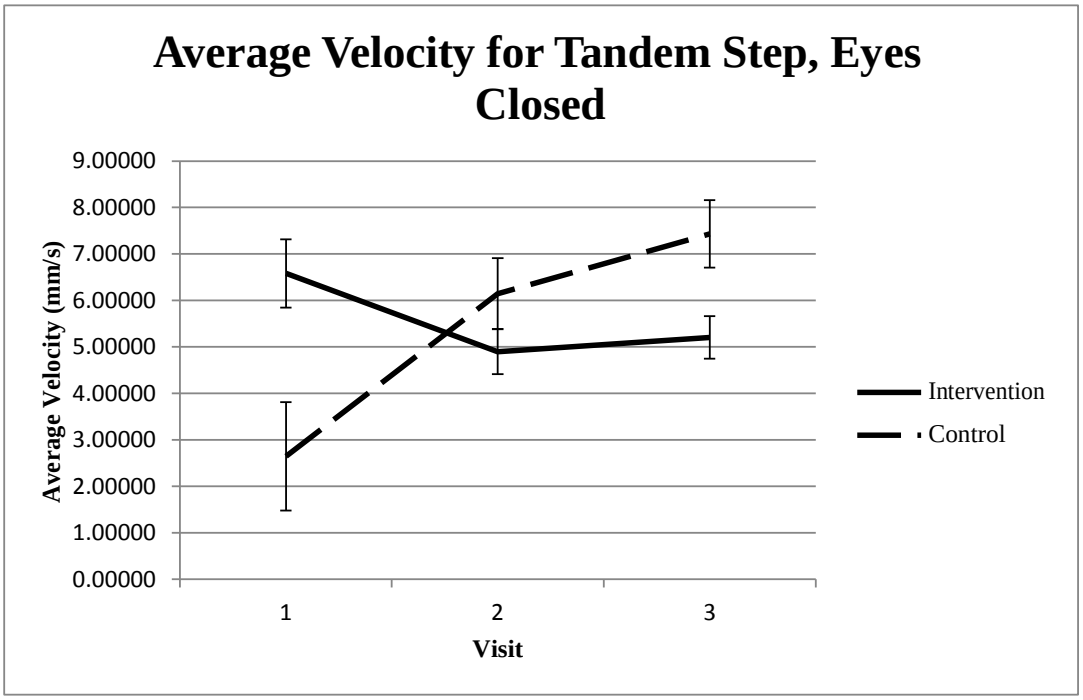


*Figure 5*. Group Means for Average Velocity across Study Visits (n=10)

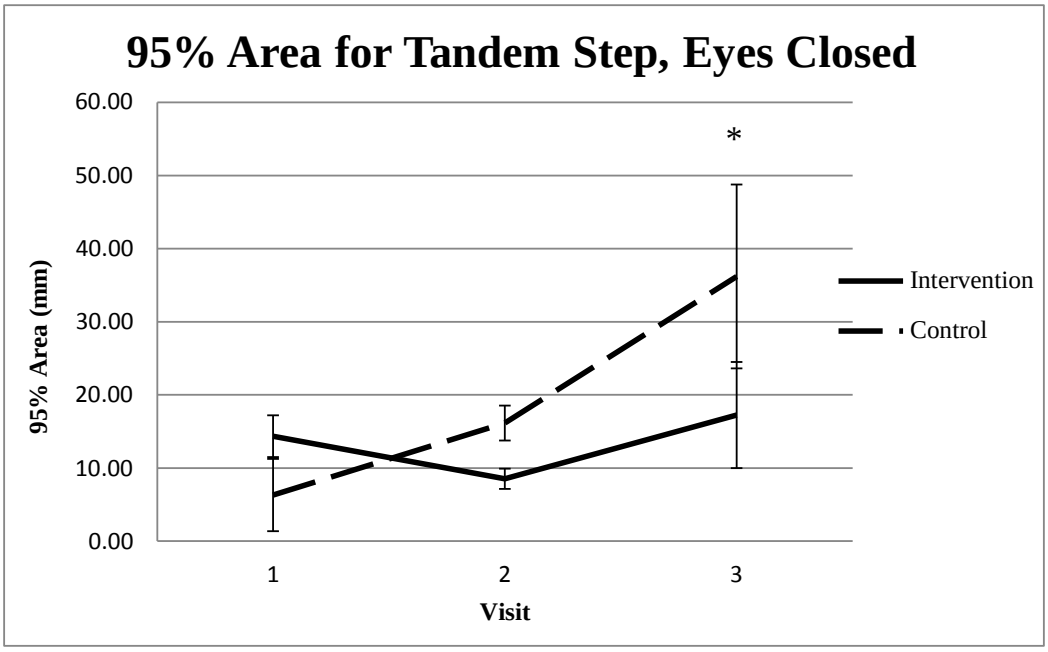


*Figure 6*. Group Means for 95% Area across Study Visits (n=10). *Indicates a statistically significant difference from visit 2 ($p < 0.05$, control group only).

There was a significant group*time interaction and large effect sizes for all of the velocity parameters (main effect for Time and Time*Group interaction). For maximum x velocity, maximum y velocity, and average velocity, the intervention group's values remained stable, indicating maintained balance along the anteroposterior and mediolateral axes, while the control group's velocities increased.

The main effect for time in the average velocity parameter is trending toward significance and has a large effect size, indicating that all groups changed throughout the course of the study period. The major axis also has a large effect size, but the main effect was not significant. There was a main effect for time and a large effect size for 95% area. Both groups did have a greater area change over the course of the study period, but there was also a large effect size for the time*group interaction. The control group had a much greater area change than the intervention group, with a significant area difference between visits 2 and 3. A large effect size was calculated for the time*group interaction for area effective, although the interaction was not statistically significant.

Table 28

*Means and Standard Deviations across Visits for Single Leg, Eyes Open Assessed via the AMTI Force Plate (n=19)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=10) | 16.53 ± 8.96 | 21.95 ± 8.76 | 16.61± 10.21 |
| Control (n=9) | 18.14 ± 8.05 | 20.44 ± 6.96 | 16.56 ± 4.54 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=10) | -18.44 ± 10.47 | -19.68 ± 5.50 | -13.81 ± 5.98 |
| Control (n=9) | -14.21 ± 7.55 | -17.29 ± 5.26 | -14.03 ± 3.79 |
| Average Velocity (mm/s) | | | |
| Intervention (n=10) | 6.00 ± 2.99 | 6.39 ± 1.48 | 4.78 ± 1.51 |
| Control (n=9) | 5.13 ± 2.31 | 5.27 ± 1.36 | 4.66 ± 0.77 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=10) | 2.01 ± 1.22 | 1.98 ± 0.29 | 1.48 ± 0.37 |
| Control (n=9) | 1.74 ± 0.53 | 1.73 ± 0.51 | 1.63 ± 0.34 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=10) | 3.84 ± 4.32 | 3.29 ± 0.79 | 1.94 ± 0.83 |
| Control (n=9) | 2.68 ± 1.56 | 2.93 ± 1.19 | 2.24 ± 0.94 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=10) | 10.21 ± 10.81 | 9.39 ± 2.23 | 5.61 ± 2.38 |
| Control (n=9) | 7.64 ± 4.69 | 7.53 ± 3.88 | 6.35 ± 2.68 |

Table 29

*RM-ANOVA for the Single Leg, Eyes Open Position for the Parameters from the AMTI Force Plate (n=19)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 1.09 | 2 | 0.350 | 0.068‡ |
| Time*Group | 1.54 | 2 | 0.230 | 0.093‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time | 0.14 | 2 | 0.867 | 0.009 |
| Time*Group | 1.50 | 2 | 0.240 | 0.091‡ |
| Average Velocity (mm/s) | | | | |
| Time*Group | 1.49 | 2 | 0.242 | 0.090‡ |
| Major Axis ($mm^{2)}$ | | | | |
| Time | 0.25 | 2 | 0.784 | 0.016 |
| Time*Group | 2.37 | 2 | 0.111 | 0.136‡ |
| Area Effective ($mm^2$) | | | | |
| Time | 0.73 | 2 | 0.490 | 0.046 |
| Time*Group | 1.63 | 2 | 0.213 | 0.098‡ |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 1.47 | 2 | 0.246 | 0.111‡ |

† p-value < 0.05
‡ partial eta squared > 0.06

There was no significant main effect for time or a significant group*time interaction for any of the balance parameters in the single leg, eyes open position. There values for Maximum Velocity X and Maximum Velocity Y were considered to be in the "abnormal" range for both the intervention and the control, and remained within that range at all study visits. There was a medium effect size for the main effect for Time (Maximum Velocity X), the Time*Group interaction (Maximum Velocity X), the Time*Group interaction (Maximum Velocity Y), the Time *Group interaction (Average Velocity), the Time*Group interaction (Area Effective), the main effect for Time (Area 95), and the Time*Group interaction (Area 95). There was a large effect size for the Time*Group interaction (Major Axis). All other effect sizes were small.

Table 30

*Means and Standard Deviations across Visits for Open Base, Eyes Closed Assessed via the AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention | 5.79 ± 9.01 | 2.05 ± 0.45 | 3.15 ± 1.91 |
| Control | 2.02 ± 0.81 | 2.14 ± 0.78 | 2.95 ± 1.89 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention | -4.43 ± 6.47 | -2.54 ± 1.08 | -3.08 ± 1.49 |
| Control | -1.94 ± 0.54 | -2.84 ± 2.17 | -2.82 ± 0.95 |
| Average Velocity (mm/s) | | | |
| Intervention | 2.82 ± 4.73 | 1.26 ± 0.31 | 1.18 ± 0.26 |
| Control | 1.13 ± 0.23 | 1.39 ± 0.27 | 1.38 ± 0.39 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention | 1.73 ± 1.62 | 1.11 ± 0.31 | 1.08 ± 0.22 |
| Control | 1.02 ± 0.24 | 1.35 ± 0.47 | 1.34 ± 0.77 |
| Area Effective ($mm^2$) | | | |
| Intervention | 3.95 ± 8.89 | 0.77 ± 0.39 | 0.73 ± 0.25 |
| Control | 0.65 ± 0.26 | 1.24 ± 1.07 | 1.31 ± 1.59 |
| Area 95 ($mm^2$) | | | |
| Intervention | 10.52 ± 25.61 | 1.38 ± 0.72 | 1.41 ± 0.37 |
| Control | 1.14 ± 0.53 | 2.54 ± 3.03 | 1.97 ± 1.98 |

Table 31

*RM-ANOVA for the Open Base, Eyes Closed Position for the Parameters from the AMTI Force Plate*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 1.09 | 2 | 0.350 | 0.068‡ |
| Time*Group | 1.54 | 2 | 0.230 | 0.093‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time | 0.14 | 2 | 0.867 | 0.009 |
| Time*Group | 1.50 | 2 | 0.240 | 0.091‡ |
| Average Velocity (mm/s) | | | | |
| Time*Group | 1.49 | 2 | 0.242 | 0.090‡ |
| Major Axis ($mm^{2)}$ | | | | |
| Time | 0.25 | 2 | 0.784 | 0.016 |
| Time*Group | 2.37 | 2 | 0.111 | 0.136‡ |
| Area Effective ($mm^2$) | | | | |
| Time | 0.73 | 2 | 0.490 | 0.046 |
| Time*Group | 1.63 | 2 | 0.213 | 0.098‡ |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 1.47 | 2 | 0.246 | 0.111‡ |

† p-value < 0.05
‡ partial eta squared > 0.06

There were no significant main effects for time or any significant group*time interactions for any of the balance parameters in the open base, eyes closed position. All parameters were in the range of what is considered “stable”. There was a medium effect for the main effect for Time (Maximum Velocity X), the Time*Group interaction (Maximum Velocity X), the Time*Group interaction (Maximum Velocity Y), the Time*Group interaction (Average Velocity), the Time*Group interaction (Major Axis), the Time*Group interaction (Area Effective), the main effect for time (Area 95), and the Time*Group interaction (Area 95).

Table 32

*Means and Standard Deviations across Visits for Tandem Step, Eyes Open (30 sec)*

*Assessed via AMTI Force Plate (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Maximum Velocity X (mm/s) | | | |
| Intervention (n=11) | 14.15 ± 3.06 | 14.07 ± 6.13 | 14.37 ± 3.73 |
| Control (n=11) | 20.64 ± 10.38 | 13.06 ± 1.78 | 14.53 ± 5.19 |
| Maximum Velocity Y (mm/s) | | | |
| Intervention (n=11) | -13.17 ± 2.38 | -13.45 ± 5.10 | -12.94 ± 3.26 |
| Control (n=11) | -21.95 ± 15.10 | -12.76 ± 3.86 | -13.14 ± 7.22 |
| Average Velocity (mm/s) | | | |
| Intervention (n=11) | 3.74 ± 0.80 | 4.00 ± 1.24 | 3.55 ± 0.61 |
| Control (n=11) | 4.50 ± 1.65 | 3.43 ± 0.73 | 3.49 ± 1.08 |
| Major Axis ($mm^{2)}$ | | | |
| Intervention (n=11) | 1.87 ± 0.29 | 2.23 ± 0.94 | 1.90 ± 0.53 |
| Control (n=11) | 2.41 ± 0.86 | 1.76 ± 0.14 | 2.06± 0.97 |
| Area Effective ($mm^2$) | | | |
| Intervention (n=11) | 2.79 ± 0.81 | 4.00 ± 3.09 | 3.02 ± 1.48 |
| Control (n=11) | 4.63 ± 3.07 | 2.45 ± 0.47 | 3.81 ± 4.00 |
| Area 95 ($mm^2$) | | | |
| Intervention (n=11) | 7.83 ± 2.29 | 9.56 ± 5.12 | 8.34 ± 3.79 |
| Control (n=11) | 11.79 ± 7.42 | 6.81 ± 1.66 | 10.41 ± 10.74 |

Table 33

*RM-ANOVA for the Tandem Step, Eyes Open (30 sec) Position for the Parameters from the AMTI Force Plate (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Maximum Velocity X (mm/s) | | | | |
| Time | 2.48 | 2 | 0.102 | 0.151‡ |
| Time*Group | 2.51 | 2 | 0.100 | 0.152‡ |
| Maximum Velocity Y (mm/s) | | | | |
| Time*Group | 2.18 | 2 | 0.132 | 0.135‡ |
| Average Velocity (mm/s) | | | | |
| Time*Group | 1.19 | 2 | 0.173 | 0.118‡ |
| Major Axis ($mm^{2)}$ | | | | |
| Time | 0.29 | 2 | 0.751 | 0.020 |
| Time*Group | 2.43 | 2 | 0.107 | 0.148‡ |
| Area Effective ($mm^2$) | | | | |
| Time*Group | 2.13 | 2 | 0.138 | 0.132‡ |
| Area 95 ($mm^2$) | | | | |
| Time*Group | 1.51 | 2 | 0.238 | 0.098‡ |

† p-value < 0.05
‡ partial eta squared > 0.06

There were no significant main effects for time or any significant group*time interactions for any of the balance parameters in the tandem step, eyes open (30 second) position. There are no guidelines for this position to establish what is considered “stable” versus “abnormal”. There was a large effect size for the main effect for Time (Maximum Velocity X), the Time*Group interaction (Maximum Velocity X), the main effect for Time (Maximum Velocity Y), the Time*Group interaction (Maximum Velocity Y), the main effect for Time (Average Velocity), the Time*Group interaction (Average Velocity), the Time*Group interaction (Major Axis), the Time*Group interaction (Area Effective), and the Time*Group interaction (Area 95).

**SECONDARY HYPOTHESIS 1**

12 weeks of interactive play will significantly increase muscular strength and endurance of the knee extensors and flexors in middle-aged women as compared to a randomly assigned control group. Independent samples t-tests were conducted to determine any differences between groups at baseline across all measures (Table 34 (knee extensors), Table 35 (knee flexors)). Repeated Measures Analysis of Variance (RM-ANOVA) were run to assess a main effect for time and any time*group interaction (Table 37 (knee extensors), Table 39 (knee flexors)). There were no significant differences between groups at baseline. Means and standard deviations across study visits for each group can be found in Table 36 (knee extensors) and Table 38 (knee flexors).

Baseline data is presented first, followed by table pairs for the flexor and extensor groups. The table pairs consist of the means and standard deviations for both groups across all visits and the repeated measures analysis. These table pairs are followed by any necessary figures and the brief interpretation of the data. The table pairs will proceed as follows: Extensor Peak Torque and Endurance; Flexor Peak Torque and Endurance.

Table 34

*Baseline Knee Extensor Results across Groups for All Angular Velocities and Endurance Outcomes (n=22)*

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| 60 degrees/sec | | | |
| Right (ft·lb) | 29.63 ± 9.30 | 34.90 ± 13.81 | 0.37 |
| Left (ft·lb) | 27.75 ± 9.34 | 35.20 ± 8.62 | 0.098 |
| 180 degrees/sec | | | |
| Right (ft·lb) | 14.09 ± 8.92 | 16.10 ± 8.67 | 0.607 |
| Left (ft·lb) | 16.36 ± 14.39 | 16.50 ± 7.76 | 0.979 |
| 240 degrees/sec | | | |
| Right (ft·lb) | 8.09 ± 3.51 | 9.30 ± 5.27 | 0.540 |
| Left (ft·lb) | 6.91 ± 3.23 | 9.50 ± 5.27 | 0.198 |
| Endurance | | | |
| Right | 1.81 ± 36.47 | 2.00 ± 56.11 | 0.993 |
| Left | 12.63 ± 39.14 | 3.60 ± 47.87 | 0.640 |

Table 35

*Baseline Knee Flexor Results across Groups for All Angular Velocities and Endurance Outcomes (n=22)*

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| 60 degrees/sec | | | |
| Right (ft·lb) | 14.75 ± 6.31 | 10.80± 7.04 | 0.234 |
| Left (ft·lb) | 12.12 ± 4.39 | 11.70 ± 7.57 | 0.890 |
| 180 degrees/sec | | | |
| Right (ft·lb) | 8.45 ± 4.45 | 8.00 ± 5.64 | 0.840 |
| Left (ft·lb) | 4.00 ± 13.87 | 8.10 ± 5.99 | 0.399 |
| 240 degrees/sec | | | |
| Right (ft·lb) | 5.27 ± 3.32 | 6.00 ± 3.68 | 0.860 |
| Left (ft·lb) | 6.09 ± 3.91 | 6.30 ± 4.87 | 0.914 |
| Endurance | | | |
| Right | -7.72 ± 30.73 | -7.70 ± 36.78 | 0.999 |
| Left | 9.91 ± 36.84 | 3.40 ± 23.44 | 0.639 |

There were no statistically significant differences between groups at baseline for either the knee extensor or the knee flexor muscle groups.

Table 36

*Means and Standard Deviations across Visits for Peak Torque and Fatigue for Knee Extensor Group Assessed via the Isokinetic Dynamometer (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| 60 degrees/sec | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | 29.63 ± 9.30 | 31.06 ± 5.68 | 28.10 ± 14.49 |
| Control (n=11) | 34.90 ± 13.81 | 30.65 ± 10.86 | 27.37 ± 9.03 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 27.75 ± 9.34 | 25.69 ± 13.00 | 27.50 ± 12.33 |
| Control (n=11) | 35.20 ± 8.61 | 34.85 ± 14.07 | 26.00 ± 7.73 |
| 180 degrees/sec | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | 14.09 ± 8.91 | 18.14 ± 6.49 | 17.64 ± 8.45 |
| Control (n=11) | 16.10 ± 8.67 | 16.65 ± 9.32 | 17.70 ± 11.85 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 16.36 ± 14.39 | 17.45 ± 6.97 | 16.91 ± 8.47 |
| Control (n=11) | 16.50 ± 7.67 | 17.30 ± 9.21 | 17.40 ± 11.45 |
| 240 degrees/sec | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | 8.09 ± 3.51 | 12.55 ± 5.63 | 11.55 ± 6.58 |
| Control (n=11) | 9.30 ± 5.27 | 10.60 ± 7.71 | 11.80 ± 6.65 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 6.91 ± 3.23 | 11.96 ± 6.67 | 12.18 ± 6.29 |
| Control (n=11) | 9.50 ± 5.27 | 10.91 ± 7.13 | 12.20 ± 8.01 |
| Endurance | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | 1.81 ± 36.47 | 7.41 ± 57.45 | 24.27 ± 37.68 |
| Control (n=11) | 2.00 ± 56.11 | 1.5 ± 41.46 | 4.20 ± 38.05 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 12.63 ± 39.14 | 0.955 ± 53.58 | 2.82 ± 44.73 |
| Control (n=11) | 3.60 ± 47.87 | 0.250 ± 63.12 | 15.60 ± 35.04 |

Table 37

*RM-ANOVA for Peak Torque and Fatigue for Knee Extensor Group for All Angular Velocities (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| 60 degrees/sec | | | | |
| Right | | | | |
| Time | 1.456 | 2 | 0.250 | 0.083‡ |
| Time*Group | 0.615 | 2 | 0.547 | 0.037 |
| Left | | | | |
| Time | 1.895 | 2 | 0.167 | 0.106‡ |
| Time*Group | 1.271 | 2 | 0.294 | 0.074‡ |
| 180 degrees/sec | | | | |
| Right | | | | |
| Time | 0.855 | 2 | 0.421 | 0.044 |
| Time*Group | 0.340 | 2 | 0.714 | 0.018 |
| Left | | | | |
| Time | 0.116 | 2 | 0.891 | 0.006 |
| Time*Group | 0.015 | 2 | 0.985 | 0.001 |
| 240 degrees/sec | | | | |
| Right | | | | |
| Time | 2.503 | 2 | 0.095 | 0.116‡ |
| Time*Group | 0.573 | 2 | 0.569 | 0.029 |
| Left | | | | |
| Time | 4.861 | 2 | 0.013† | 0.204‡ |
| Time*Group | 0.953 | 2 | 0.395 | 0.048 |
| Endurance | | | | |
| Right | | | | |
| Time | 1.034 | 2 | 0.365 | 0.052 |
| Time*Group | 0.41 | 2 | 0.667 | 0.021 |
| Left | | | | |
| Time | 0.476 | 2 | 0.625 | 0.024 |
| Time*Group | 0.623 | 2 | 0.542 | 0.032 |

† p-value < 0.05
‡ partial eta squared > 0.06

There was a significant main effect for time for the left 240°/sec peak torque. There were no significant main effects for time or any significant group*time interactions for any of the other angular velocities in either leg or for the endurance outcome. There was a medium effect size for the main effect for Time (right 60°/sec), the main effect for Time (left 60°/sec), the Time*Group interaction (left 60°/sec), the main effect for time (right 240°/sec), and the main effect for time (left 240°/sec). All other effect sizes were small.

Table 38

*Means and Standard Deviations across Visits for Peak Torque and Fatigue for Knee Flexor Group Assessed via the Isokinetic Dynamometer (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| 60 degrees/sec | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | 14.75 ± 6.31 | 17.56 ± 6.31 | 13.25 ± 5.80 |
| Control (n=11) | 10.80 ± 7.04 | 17.90 ± 20.01 | 9.00 ± 4.42 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 12.12 ± 4.39 | 12.94 ± 5.36 | 13.00 ± 6.34 |
| Control (n=11) | 11.70 ± 7.57 | 14.65 ± 12.33 | 11.00 ± 7.24 |
| 180 degrees/sec | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | 8.45 ± 4.52 | 9.59 ± 4.17 | 7.82 ± 4.40 |
| Control (n=11) | 8.00 ± 5.63 | 6.35 ± 3.40 | 6.80 ± 5.53 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 4.00 ± 13.87 | 8.18 ± 4.35 | 8.64 ± 5.10 |
| Control (n=11) | 8.10 ± 5.99 | 6.00 ± 3.46 | 7.30 ± 4.81 |
| 240 degrees/sec | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | 5.27 ± 3.32 | 8.91 ± 4.28 | 6.45 ± 2.73 |
| Control (n=11) | 6.00 ± 3.68 | 5.00 ± 2.75 | 6.00 ± 3.32 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 6.09 ± 3.91 | 6.32 ± 3.91 | 6.36 ± 3.56 |
| Control (n=11) | 6.30 ± 4.87 | 5.95 ± 3.46 | 6.60 ± 3.72 |
| Endurance | | | |
| Right (ft·lb) | | | |
| Intervention (n=11) | -7.72 ± 30.73 | 4.64 ± 33.08 | 10.18 ± 19.64 |
| Control (n=11) | -7.70 ± 36.78 | -12.35 ± 40.61 | -22.40 ± 49.02 |
| Left (ft·lb) | | | |
| Intervention (n=11) | 9.91 ± 36.84 | -7.05 ± 44.15 | 0.18 ± 36.10 |
| Control (n=11) | 3.40 ± 23.44 | 0.350 ± 25.76 | 2.80 ± 34.29 |

Table 39

*RM-ANOVA for Peak Torque and Fatigue for Knee Flexor Group for All Angular Velocities (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| 60 degrees/sec | | | | |
| Right | | | | |
| Time | 3.054 | 2 | 0.061 | 0.162‡ |
| Time*Group | 0.425 | 2 | 0.657 | 0.026 |
| Left | | | | |
| Time | 0.487 | 2 | 0.619 | 0.030 |
| Time*Group | 0.375 | 2 | 0.690 | 0.023 |
| 180 degrees/sec | | | | |
| Right | | | | |
| Time | 0.520 | 2 | 0.598 | 0.027 |
| Time*Group | 1.258 | 2 | 0.296 | 0.062‡ |
| Left | | | | |
| Time | 0.472 | 2 | 0.627 | 0.024 |
| Time*Group | 1.488 | 2 | 0.239 | 0.073‡ |
| 240 degrees/sec | | | | |
| Right | | | | |
| Time | 0.916 | 2 | 0.409 | 0.046 |
| Time*Group | 3.705 | 2 | 0.034† | 0.163‡ |
| Left | | | | |
| Time | 0.151 | 2 | 0.860 | 0.008 |
| Time*Group | 0.128 | 2 | 0.881 | 0.007 |
| Endurance | | | | |
| Right | | | | |
| Time | 0.157 | 2 | 0.855 | 0.008 |
| Time*Group | 2.787 | 2 | 0.074 | 0.128‡ |
| Left | | | | |
| Time | 0.672 | 2 | 0.516 | 0.034 |
| Time*Group | 0.335 | 2 | 0.717 | 0.017 |

† p-value < 0.05
‡ partial eta squared > 0.06

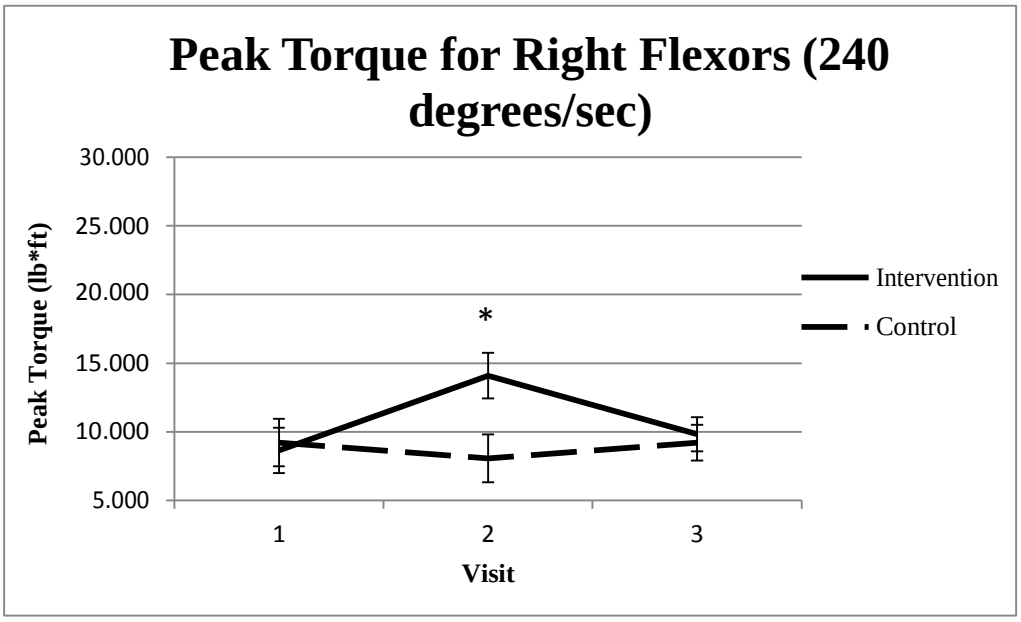


*Figure 7.* Change in peak torque for the right knee flexors at 240 degrees/sec (n=22). *Indicates a statistically significant difference between groups ($p < 0.05$).

There was a significant time*group interaction for peak torque in the right leg at 240 degrees/sec. The intervention group improved their peak torque at visit 2, but any gain was lost at visit 3. There were no significant main effects for time and no other time*group interactions in any of the angular velocities in either leg. There was a medium effect size for the main effect for Time (right 60°/sec), the Time*Group interaction (right 180°/sec), the Time*Group interaction (left 180°/sec), the Time*Group interaction (right 240°/sec), and the Time*Group interaction (right fatigue index). All other effects sizes were small.

**SECONDARY HYPOTHESIS 2**

12 weeks of interactive play will significantly increase bone health parameters at the Os Calcis, as measured by qualitative ultrasound (QUS), and site-specific measures of bone health, as measured by dual-energy x-ray absorptiometry (DXA), in middle-aged women as compared to a randomly assigned control group. Independent samples t-tests were conducted to determine any differences between groups at baseline across all measures (Table 40 (QUS), Tables 41-43 (DXA)). Repeated Measures Analysis of Variance (RM-ANOVA) were run to assess a main effect for time and any time*group interaction (Table 45 (QUS), Tables 47, 49, 51 (DXA)). There were no significant differences at baseline between groups. Means and standard deviations for each group can be found in Table 44 (QUS) and Tables 46, 48, 50 (DXA).

Baseline data is presented first for the QUS and DXA, followed by the table pairs for the QUS and the DXA. The table pairs consist of the means and standard deviations across all visits and the RM-ANOVA results. Individual change data for the DXA results follow the DXA table pairs, but come before the interpretation. Any necessary figures will follow the tables, but precede the brief interpretation.

Table 40

*Baseline Qualitative Ultrasound (QUS) Parameters across Groups (n=22)*

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| T-score | | | |
| Right | -0.76 ± 0.77 | -0.48 ± 0.98 | 0.502 |
| Left | -0.84 ± 0.91 | -0.20 ± 0.82 | 0.142 |
| Z-score | | | |
| Right | 0.21 ± 0.77 | 0.41 ± 0.93 | 0.622 |
| Left | 0.10 ± 1.09 | 0.70 ± 0.85 | 0.222 |
| Broadband Ultrasound Attenuation (BUA) | | | |
| Right | 113.48 ± 8.22 | 112.16 ± 15.29 | 0.817 |
| Left | 109.72 ± 14.24 | 118.39 ± 11.76 | 0.186 |
| Speed of Sound (SOS) | | | |
| Right | 1544.28 ± 28.14 | 1563.75 ± 38.19 | 0.231 |
| Left | 1547.30 ± 36.54 | 1566.39 ± 27.72 | 0.240 |
| Stiffness Index (SI) | | | |
| Right | 87.80 ± 12.16 | 92.38 ± 15.39 | 0.491 |
| Left | 86.20 ± 14.86 | 97.538 ± 13.43 | 0.118 |

Table 41

*Baseline Dual-Energy X-ray Absorptiometry (DXA) Parameters across Groups (n=22)*

| | Intervention (M ± SD) | Control | p-value |
|---|---|---|---|
| Total Hip | | | |
| t-score | -0.63 ± 0.54 | -0.636 ± 1.00 | 0.979 |
| z-score | -0.10 ± 0.50 | -0.345 ± 1.09 | 0.504 |
| Lumbar Spine | | | |
| t-score | -1.00 ± 1.17 | -0.38 ± 1.01 | 0.200 |
| z-score | -0.39 ± 1.05 | -0.38 ± 2.18 | 0.303 |

Table 42

*Baseline Dual-Energy X-ray Absorptiometry (DXA) Parameters for Femoral Neck (n=22)*

| | | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|---|
| Right Femoral Neck | | | | |
| | BMD | 0.94 ± 0.07 | 0.93 ± 0.14 | 0.979 |
| | T-score | 0.56 ± 0.58 | -0.64 ± 1.06 | 0.979 |
| | Z-score | 0.03 ± 0.54 | -0.36 ± 1.12 | 0.979 |
| Left Femoral Neck | | | | |
| | BMD | 0.92 ± 0.07 | 0.93 ± 0.12 | 0.676 |
| | T-score | -0.71 ± 0.59 | -0.61 ± 0.94 | 0.700 |
| | Z-score | 0.16 ± 0.54 | -0.36 ± 1.04 | 0.575 |

Table 43

*Baseline Dual-Energy X-ray Absorptiometry (DXA) Parameters for Lumbar Spine (n=22)*

| | | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|---|
| L1 | | | | |
| | BMD | 1.07 ± 0.15 | 1.15 ± 0.12 | 0.146 |
| | T-score | -1.38 ± 0.93 | -0.78 ± 0.67 | 0.109 |
| | Z-score | 0.79± 0.81 | -0.49 ± 1.01 | 0.459 |
| L2 | | | | |
| | BMD | 1.02 ± 0.14 | 1.09 ± 0.08 | 0.165 |
| | T-score | -1.31 ± 1.36 | -0.60 ± 0.88 | 0.159 |
| | Z-score | -0.73 ± 1.28 | -0.30 ± 0.99 | 0.406 |
| L3 | | | | |
| | BMD | 1.05 ± 0.14 | 1.12 ± 0.09 | 0.162 |
| | T-score | -0.89 ± 1.20 | -0.25 ± 0.84 | 0.178 |
| | Z-score | -0.29 ± 1.04 | -0.07 ± 1.28 | 0.669 |
| L4 | | | | |
| | BMD | 1.10 ± 0.16 | 1.15 ± 0.09 | 0.446 |
| | T-score | -0.65 ± 0.96 | -0.78 ± 1.06 | 0.787 |
| | Z-score | -0.06 ± 1.08 | -0.50 ± 1.2 | 0.394 |

**Qualitative ultrasound (QUS).**

Table 44

*Means and Standard Deviations across Visits for Qualitative Ultrasound (QUS) (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| T-score | | | |
| Right | | | |
| Intervention (n=11) | -0.76 ± 0.77 | -0.52 ± 1.24 | -0.57 ± 1.06 |
| Control (n=11) | -0.48 ± 0.98 | -0.68 ± 1.06 | -0.43 ± 1.07 |
| Left | | | |
| Intervention (n=11) | -0.84 ± 0.91 | -0.27 ± 1.19 | -0.37 ± 0.99 |
| Control (n=11) Z-score | -0.20 ± 0.82 | -0.44 ± 1.03 | -0.10 ± 1.41 |
| Right | | | |
| Intervention (n=11) | 0.21 ± 0.77 | 0.43 ± 1.25 | 0.38 ± 1.07 |
| Control (n=11) | 0.41 ± 0.93 | 0.18 ± 1.04 | 0.08 ± 0.100 |
| Left | | | |
| Intervention (n=11) | 0.11 ± 1.03 | 0.67 ± 1.28 | 0.58 ± 1.08 |
| Control (n=11) | 0.70 ± 0.85 | 0.425 ± 1.03 | 0.79 ± 1.52 |
| Broadband Ultrasound Attenutation (BUA) | | | |
| Right | | | |
| Intervention (n=11) | 113.48 ± 8.22 | 111.53 ± 23.13 | 112.95 ± 14.79 |
| Control (n=11) | 112.16 ± 15.29 | 107.26 ± 17.01 | 114.53 ± 21.54 |
| Left | | | |
| Intervention (n=11) | 109.28 ± 14.24 | 120.09 ± 16.24 | 119.21 ± 12.92 |
| Control (n=11) | 118.39 ± 11.76 | 112.86 ± 13.05 | 118.17 ± 16.25 |
| Speed of Sound (SOS) | | | |
| Right | | | |
| Intervention (n=11) | 1544.28 ± 28.14 | 1561.76 ± 39.31 | 1556.34 ± 31.22 |
| Control (n=11) | 1563.75 ± 38.19 | 1562.99 ± 44.62 | 1569.25 ± 44.01 |
| Left | | | |
| Intervention (n=11) | 1547.30 ± 36.54 | 1556.57 ± 36.53 | 1553.44 ± 30.82 |
| Control (n=11) | 1566.39 ± 27.72 | 1563.39 ± 38.95 | 1570.18 ± 45.09 |
| Stiffness Index (SI) | | | |
| Right | | | |
| Intervention (n=11) | 87.80 ± 12.16 | 91.40 ± 19.89 | 90.90 ± 17.41 |
| Control (n=11) | 92.38 ± 15.39 | 89.13 ± 16.84 | 79.50 ± 30.29 |
| Left | | | |
| Intervention (n=11) | 86.20 ± 14.86 | 95.67 ± 18.94 | 94.33 ± 16.13 |
| Control (n=11) | 97.538 ± 13.43 | 93.00 ± 17.02 | 98.88 ± 22.47 |

Table 45

*RM-ANOVA for the Bone Parameters from Qualitative Ultrasound (QUS) (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| T-score | | | | |
| Right | | | | |
| Time | 0.67 | 2 | 0.521 | 0.040 |
| Time*Group | 2.39 | 2 | 0.118 | 0.125 |
| Left | | | | |
| Time | 1.10 | 2 | 0.346 | 0.068 |
| Time*Group | 2.27 | 2 | 0.121 | 0.131 |
| Z-score | | | | |
| Right | | | | |
| Time | 0.54 | 2 | 0.591 | 0.032 |
| Time*Group | 2.12 | 2 | 0.137 | 0.117‡ |
| Left | | | | |
| Time | 1.36 | 2 | 0.272 | 0.083‡ |
| Time*Group | 3.02 | 2 | 0.064 | 0.168‡ |
| Broadband Ultrasound Attenuatio (BUA) | | | | |
| Right | | | | |
| Time | 0.95 | 2 | 0.397 | 0.056 |
| Time*Group | 0.39 | 2 | 0.681 | 0.024 |
| Left | | | | |
| Time | 0.95 | 2 | 0.398 | 0.060 |
| Time*Group | 2.99 | 2 | 0.081 | 0.155‡ |
| Speed of Sound (SOS) | | | | |
| Right | | | | |
| Time | 2.53 | 2 | 0.095 | 0.137‡ |
| Time*Group | 2.20 | 2 | 0.127 | 0.121‡ |
| Left | | | | |
| Time | 0.31 | 2 | 0.736 | 0.020 |
| Time*Group | 0.77 | 2 | 0.471 | 0.049 |
| Stiffness Index (SI) | | | | |
| Right | | | | |
| Time | 0.66 | 2 | 0.526 | 0.039 |
| Time*Group | 1.28 | 2 | 0.293 | 0.074‡ |
| Left | | | | |
| Time | 1.42 | 2 | 0.259 | 0.162‡ |
| Time*Group | 3.02 | 2 | 0.064 | 0.309‡ |

‡ partial eta squared > 0.06

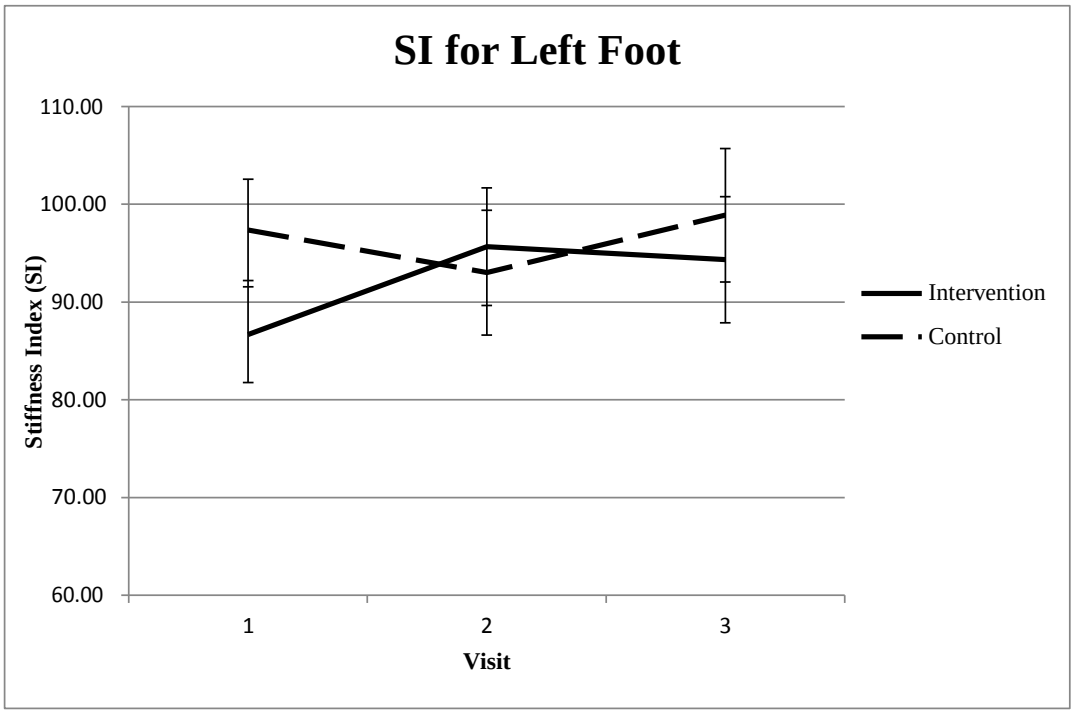


*Figure 8.* Change in stiffness index (SI) of the left foot (n=22).

There were no significant main effects for time for any of the QUS parameters, and there were no significant time*group interactions. There was a medium effect size for the Time*Group interaction (right z-score), the main effect for time (left z-score), and the Time*Group interaction (right SI). There was a large effect size for the Time*Group interaction (left z-score), the Time*Group interaction (left BUA), the main effect for Time (right SOS), the Time*Group interaction (right SOS), the main effect for Time (left SI), and the left Time*Group interaction (left SI). All other effect sizes were small.

**Dual-energy x-ray absorptiometry (DXA).**

Table 46

*Means and Standard Deviations across Visits for Dual-Energy X-ray Absorptiometry (DXA) for Total Hip and Lumbar Spine (n=22)*

| | Visit 1 (M ± SD) | Visit 3 (M ± SD) | % Change |
|---|---|---|---|
| Total Hip BMD | | | |
| Intervention (n=11) | 0.85 ± 0.26 | 1.02 ± 0.31 | 16.66† |
| Control (n=11) | 0.93 ± 0.13 | 0.93 ± 0.12 | 0.26 |
| Total Hip T-score | | | |
| Intervention (n=11) | 0.63 ± 0.54 | -0.60 ± 0.54 | -- |
| Control (n=11) | -0.64 ± 1.00 | -0.60 ± 0.98 | -- |
| Total Hip Z-score | | | |
| Intervention (n=11) | -0.10 ± 0.50 | -0.04 ± 0.48 | -- |
| Control (n=11) | -0.35 ± 1.09 | -0.32 ± 1.06 | -- |
| Lumbar Spine BMD | | | |
| Intervention (n=11) | 1.07 ± 0.15 | 1.07 ± 0.14 | 0.17 |
| Control (n=11) | 1.15 ± 0.12 | 0.16 ± 0.12 | 0.77 |
| Lumbar Spine T-score | | | |
| Intervention (n=11) | -1.00 ± 1.17 | -0.98 ± 1.16 | -- |
| Control (n=11) | -0.38 ± 1.01 | -0.31 ± 1.00 | -- |
| Lumbar Spine Z-score | | | |
| Intervention (n=11) | -0.39 ± 1.05 | -0.36 ± 0.99 | -- |
| Control (n=11) | -0.38 ± 2.18 | -0.04 ± 1.15 | -- |

† % change > ± 1.00%

Table 47

*RM-ANOVA for Dual-Energy X-ray Absorptiometry (DXA) for Total Hip and Lumbar Spine (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Total Hip | | | | |
| T-score | | | | |
| Time | 1.96 | 1 | 0.177 | 0.089 |
| Time*Group | 0.04 | 1 | 0.844 | 0.002 |
| Z-score | | | | |
| Time | 4.39 | 1<br>0.049† | | 0.180‡ |
| Time*Group | 0.70 | 1 | 0.412 | 0.034 |
| Lumbar Spine | | | | |
| T-score | | | | |
| Time | 0.50 | 1 | 0.490 | 0.024 |
| Time*Group | 0.18 | 1 | 0.678 | 0.009 |
| Z-score | | | | |
| Time | 0.56 | 1 | 0.464 | 0.027 |
| Time*Group | 0.72 | 1 | 0.405 | 0.035 |

† $p < 0.05$
‡ partial eta squared > 0.06

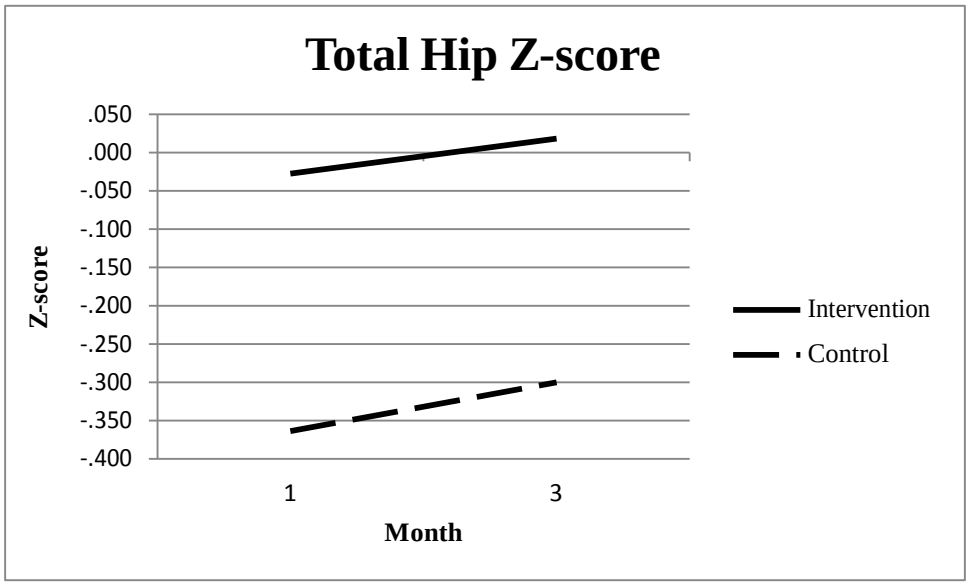


*Figure 9.* Change in z-score for the total hip (n=22).

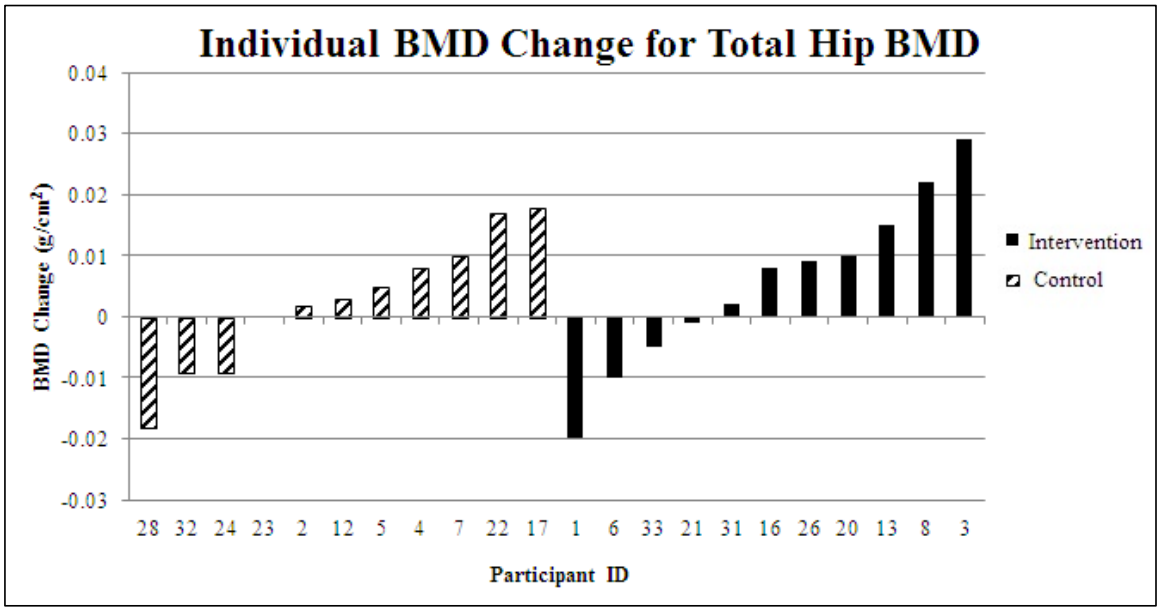


*Figure 10. Individual raw BMD change for total hip (n=22).*

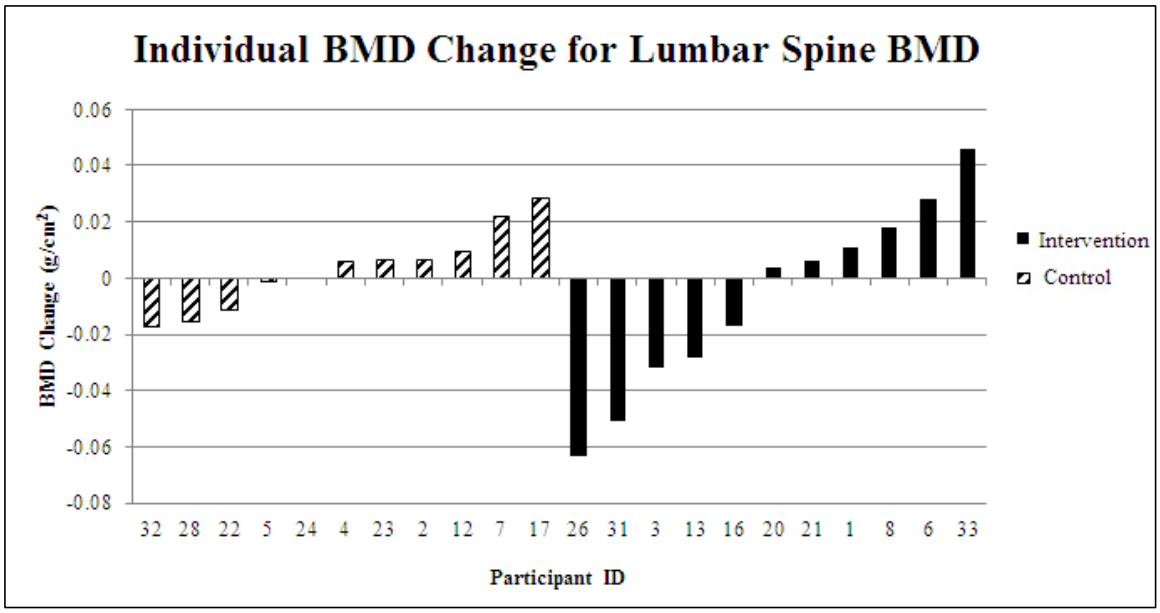


*Figure 11. Individual raw BMD change lumbar spine (n=22).*

There was a significant main effect for time for the z-score of the total hip. Both groups increased across the study period. There were no other main effects for time and there were no time*group interactions for the total hip or the lumbar spine. There was a large effect size for z-score (total hip). All other effect sizes were small. Both groups were similarly active in regards to individual change for the total hip (Figure 10), but the intervention group was much more active than the control for the lumbar spine (Figure 11).

Table 48

*Means and Standard Deviations across Visits for Dual-Energy X-ray Absorptiometry (DXA) for the Right and Left Femoral Neck (n=22)*

| | Visit 1 (M ± SD) | Visit 3 (M ± SD) | % Change |
|---|---|---|---|
| Right Femoral Neck BMD | | | |
| Intervention (n=11) | 0.94 ± 0.07 | 0.94 ± 0.07 | 0.18 |
| Control (n=11) | 0.93 ± 0.14 | 0.93 ± 0.13 | 0.38 |
| Right Neck T-score | | | |
| Intervention (n=11) | 0.56 ± 0.58 | -0.55 ± 0.58 | -- |
| Control (n=11) | -0.64 ± 1.06 | -0.59 ± 1.04 | -- |
| Right Neck Z-score | | | |
| Intervention (n=11) | 0.027 ± 0.54 | 0.18 ± 0.50 | -- |
| Control (n=11) | -0.364 ± 1.12 | -0.30 ± 0.1.09 | -- |
| Left Femoral Neck BMD | | | |
| Intervention (n=11) | 0.92 ± 0.07 | 0.93 ± 0.07 | 1.15† |
| Control (n=11) | 0.93 ± 0.12 | 0.92 ± 0.11 | -1.13† |
| Left Neck T-score | | | |
| Intervention (n=11) | -0.71 ± 0.59 | -0.65 ± 0.55 | -- |
| Control (n=11) | -0.61 ± 0.94 | -0.62 ± 0.94 | -- |
| Left Neck Z-score | | | |
| Intervention (n=11) | 0.16 ± 0.54 | -0.09 ± 0.51 | -- |
| Control (n=11) | -0.36 ± 1.04 | -0.32 ± 1.02 | -- |

† % change > ±1.00%

Table 49

*RM-ANOVA for Dual-Energy X-ray Absorptiometry (DXA) for the Right and Left Femoral Neck (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Right Neck | | | | |
| T-score | | | | |
| Time | 0.04 | 1 | 0.836 | 0.002 |
| Time*Group | 0.70 | 1 | 0.412 | 0.034 |
| Z-score | | | | |
| Time | 0.79 | 1 | 0.385 | 0.038 |
| Time*Group | 0.94 | 1 | 0.344 | 0.045 |
| Left Neck | | | | |
| T-score | | | | |
| Time | 0.17 | 1 | 0.687 | 0.008 |
| Time*Group | 5.04 | 1 | 0.036† | 0.201‡ |
| Z-score | | | | |
| Time | 0.14 | 1 | 0.709 | 0.007 |
| Time*Group | 4.35 | 1 | 0.050† | 0.158‡ |

† $p < 0.05$
‡ partial eta squared > 0.06

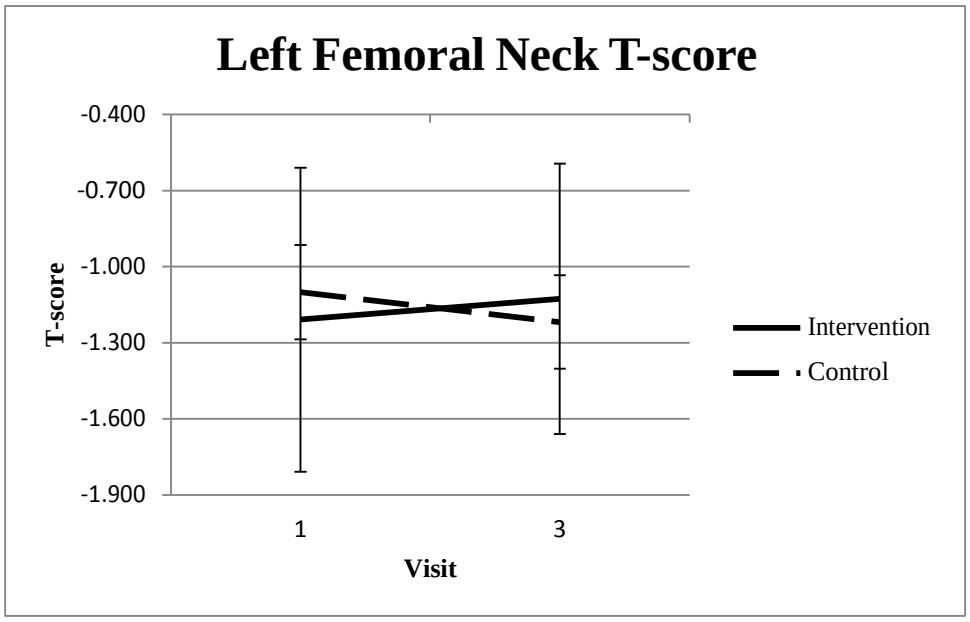


*Figure 12.* Change in left femoral neck t-score (n=22).

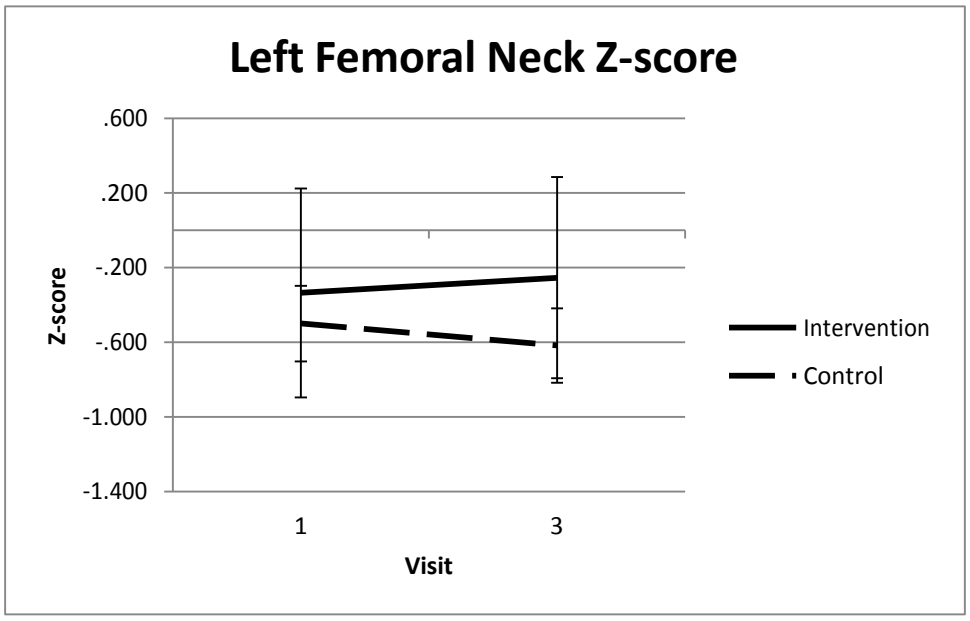


*Figure 13.* Change in left femoral neck z-score (n=22).

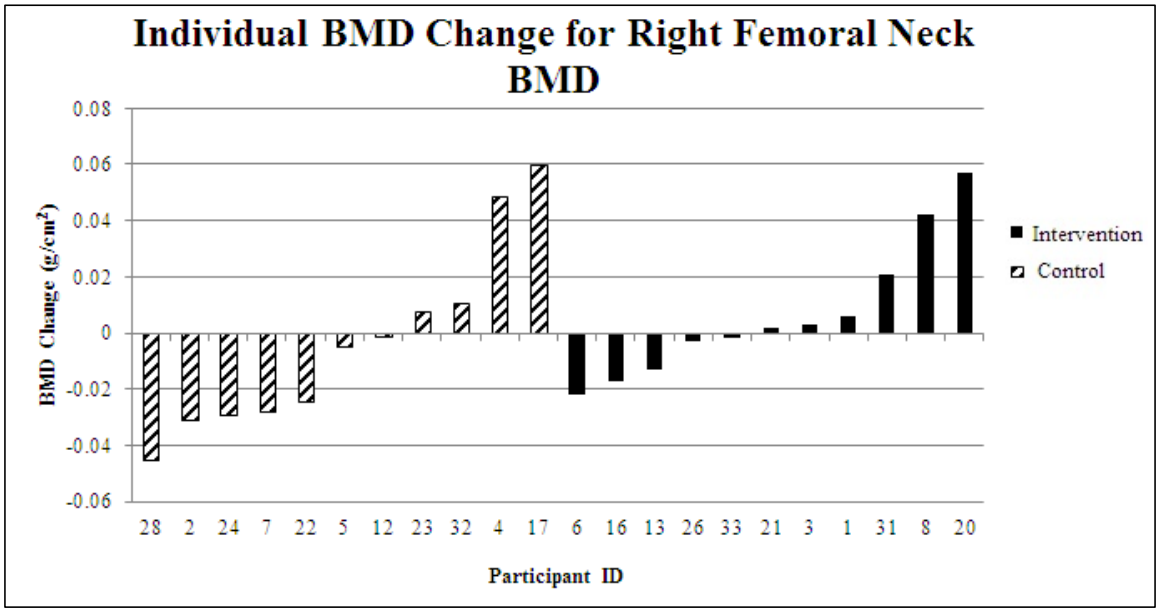


*Figure 14.* Individual raw BMD change for right femoral neck (n=22).

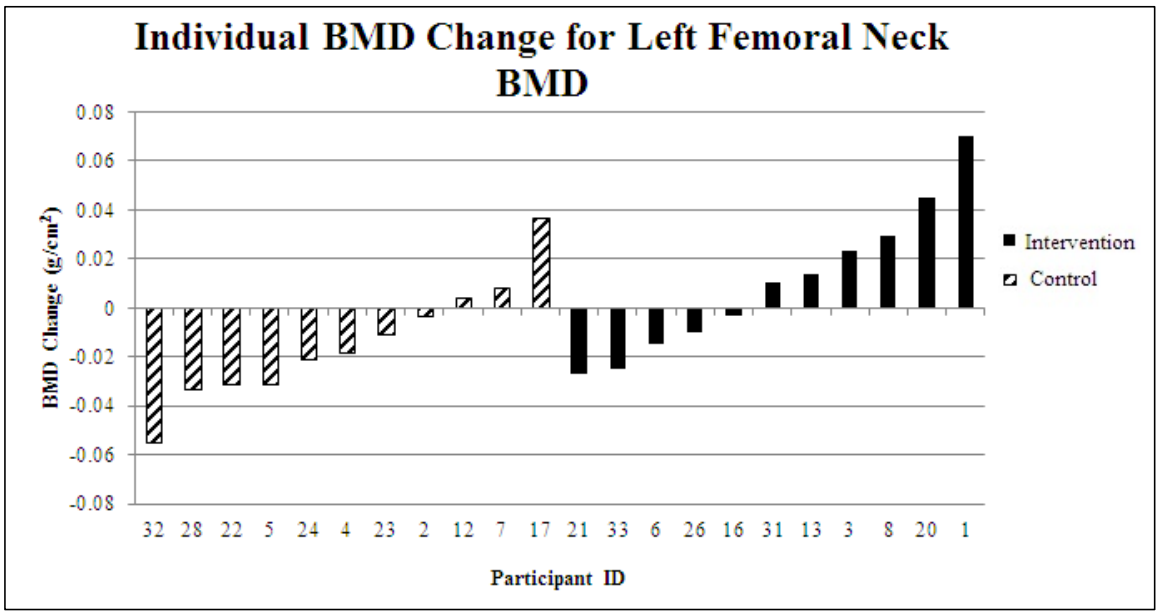


*Figure 15.* Individual raw BMD change for left femoral neck (n=22).

There was a significant time*group interaction for the t- and z-scores of the left femoral neck. For both t-score and z-score, the intervention group improved while the control group lost bone mass. There were no main effects for time across either the right or left femoral neck. There was a large effect size for the Time*Group interaction (left femoral t-score) and the Time*Group interaction (left femoral neck z-score). All other calculated effect size estimates were small.

There was a clinically significant increase (> 1.00%) in BMD at the total hip for the intervention. There was also a clinically significant (> 1.00%) change in bone mass at the left femoral neck for both the intervention and the control group. The intervention group gained BMD and the control group lost BMD at that skeletal site.

Table 50

*Means and Standard Deviations across Visits for Dual-Energy X-ray Absorptiometry (DXA) for the Lumbar Vertebrae*

| | Visit 1 (M ± SD) | Visit 3 (M ± SD) | % Change |
|---|---|---|---|
| L1 | | | |
| BMD | | | |
| Intervention (n=11) | 1.07 ± 0.15 | 1.07 ± 0.14 | 0.78 |
| Control (n=11) | 1.15 ± 0.12 | 1.16 ± 0.14 | 0.17 |
| T-score | | | |
| Intervention (n=11) | -1.38 ± 0.93 | -1.33 ± 0.92 | -- |
| Control (n=11) | -0.78 ± 0.67 | -0.65 ± 0.77 | -- |
| Z-score | | | |
| Intervention (n=11) | 0.79± 0.81 | -0.74 ± 0.76 | -- |
| Control (n=11) | -0.49 ± 1.01 | -0.56 ± 0.80 | -- |
| L2 | | | |
| BMD | | | |
| Intervention (n=11) | 1.02 ± 0.14 | 1.01± 0.13 | 0.36 |
| Control (n=11) | 1.09 ± 0.08 | 1.09 ± 0.09 | -0.72 |
| T-score | | | |
| Intervention (n=11) | -1.31 ± 1.36 | -1.45 ± 1.28 | -- |
| Control (n=11) | -0.60 ± 0.88 | -0.67 ± 0.88 | -- |
| Z-score | | | |
| Intervention (n=11) | -0.73 ± 1.28 | -0.83 ± 1.21 | -- |
| Control (n=11) | -0.30 ± 0.99 | -0.36 ± 1.19 | -- |
| L3 | | | |
| BMD | | | |
| Intervention (n=11) | 1.05 ± 0.14 | 1.05 ± 0.06 | 0.16 |
| Control (n=11) | 1.12 ± 0.09 | 1.13 ± 0.09 | 0.38 |
| T-score | | | |
| Intervention (n=11) | -0.89 ± 1.20 | -0.75 ± 1.31 | -- |
| Control (n=11) | -0.25 ± 0.84 | -0.18 ± 0.91 | -- |
| Z-score | | | |
| Intervention (n=11) | -0.29 ± 1.04 | -0.14 ± 1.17 | -- |
| Control (n=11) | -0.07 ± 1.28 | -0.12 ± 1.28 | -- |
| L4 | | | |
| BMD | | | |
| Intervention (n=11) | 1.10 ± 0.16 | 1.10 ± 0.15 | 0.09 |
| Control (n=11) | 1.15 ± 0.09 | 0.15 ± 0.11 | 0.15 |
| T-score | | | |
| Intervention (n=11) | -0.65 ± 0.96 | -0.62 ± 0.99 | -- |
| Control (n=11) | -0.78 ± 1.06 | -0.68 ± 1.20 | -- |
| Z-score | | | |
| Intervention (n=11) | -0.06 ± 1.08 | -0.07 ± 1.07 | -- |
| Control (n=11) | -0.50 ± 1.2 | -0.32 ± 1.24 | -- |

Table 51

*RM-ANOVA for Dual-Energy X-ray Absorptiometry (DXA) for the Lumbar Vertebrae (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| L1 | | | | |
| T-score | | | | |
| Time | 0.77 | 1 | 0.391 | 0.039 |
| Time*Group | 0.18 | 1 | 0.677 | 0.009 |
| Z-score | | | | |
| Time | 0.86 | 1 | 0.365 | 0.043 |
| Time*Group | 0.14 | 1 | 0.708 | 0.008 |
| L2 | | | | |
| T-score | | | | |
| Time | 0.95 | 1 | 0.341 | 0.048 |
| Time*Group | 0.10 | 1 | 0.757 | 0.005 |
| Z-score | | | | |
| Time | 0.60 | 1 | 0.448 | 0.031 |
| Time*Group | 0.04 | 1 | 0.848 | 0.002 |
| L3 | | | | |
| T-score | | | | |
| Time | 1.23 | 1 | 0.281 | 0.061 |
| Time*Group | 0.15 | 1 | 0.702 | 0.008 |
| Z-score | | | | |
| Time | 3.40 | 1 | 0.081 | 0.152‡ |
| Time*Group | 0.04 | 1 | 0.852 | 0.002 |
| L4 | | | | |
| T-score | | | | |
| Time | 0.51 | 1 | 0.483 | 0.026 |
| Time*Group | 1.29 | 1 | 0.270 | 0.064‡ |
| Z-score | | | | |
| Time | 1.12 | 1 | 0.304 | 0.055 |
| Time*Group | 1.37 | 1 | 0.257 | 0.067‡ |

† $p < 0.05$
‡ partial eta squared > 0.06

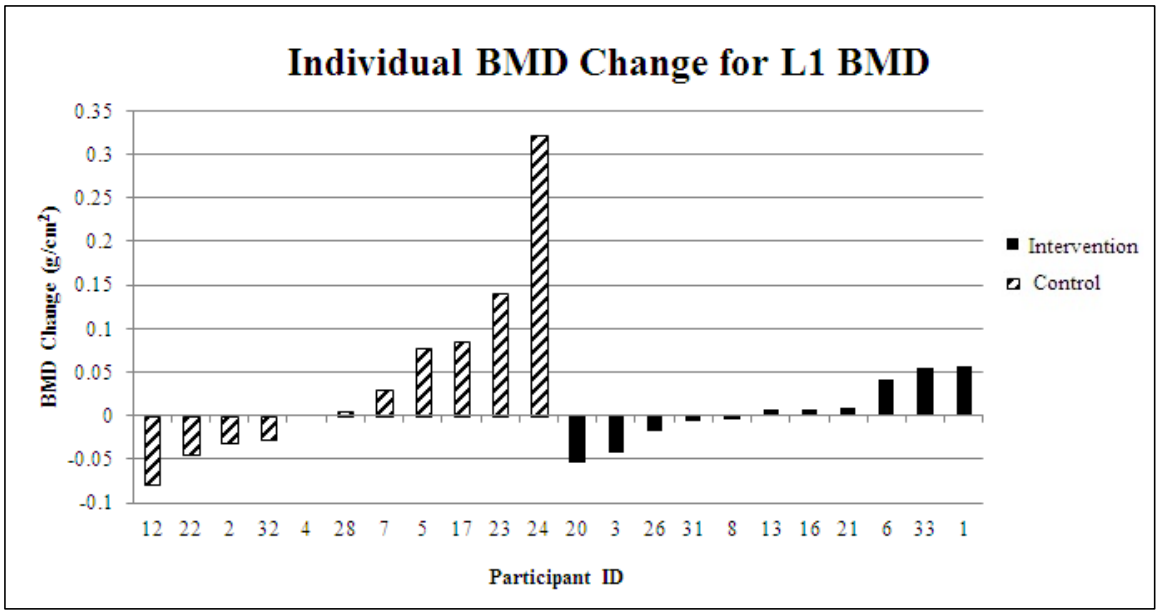


*Figure 16.* Individual raw BMD change for L1 vertebra (n=22).

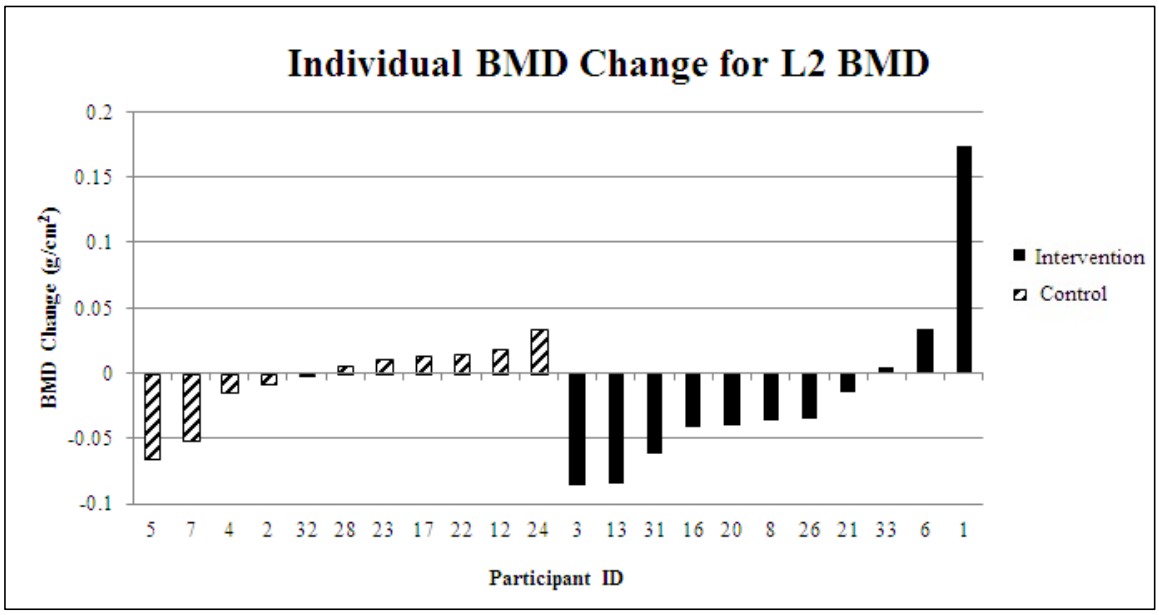


*Figure 17.* Individual raw BMD change for L2 vertebra (n=22).

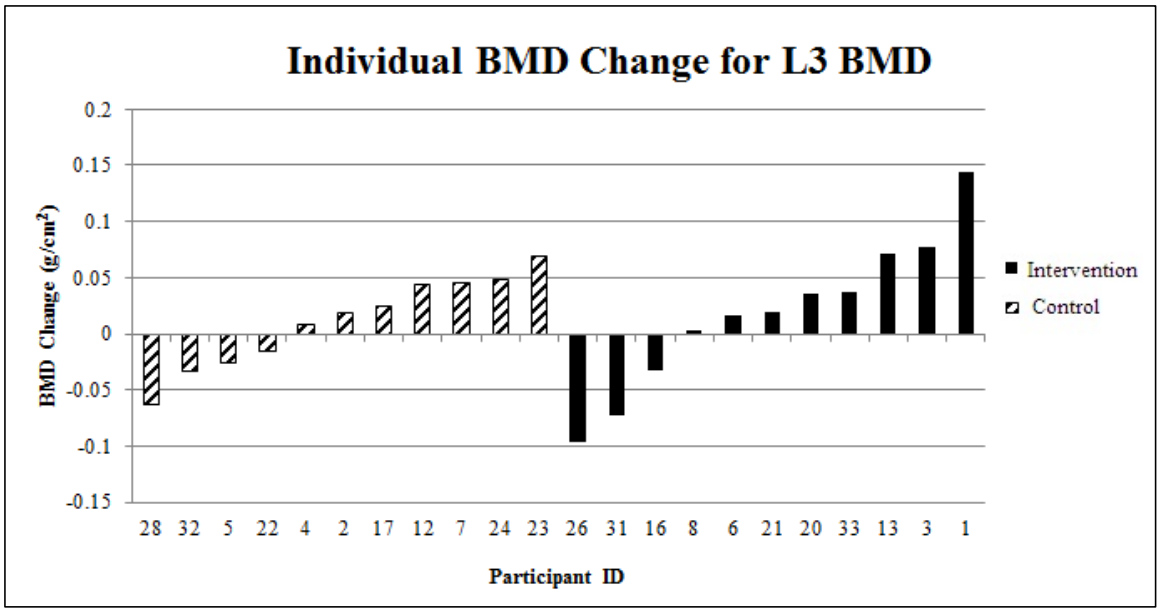


*Figure 18.* Individual raw BMD change for L3 vertebra (n=22).

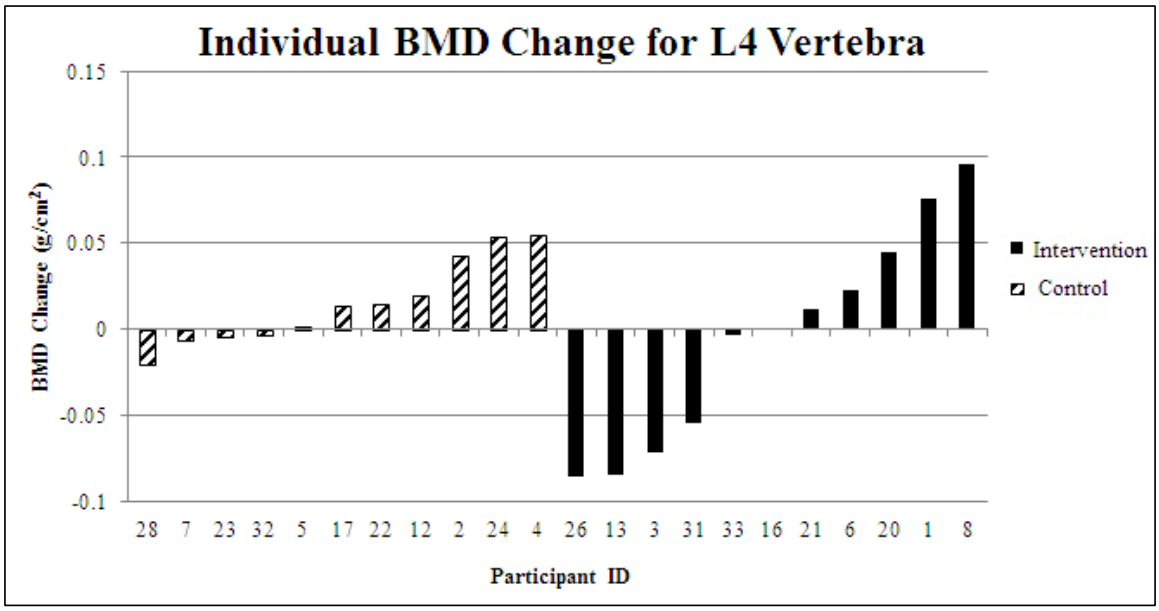


*Figure 19.* Individual raw BMD change for L4 vertebra (n=22).

There were no significant main effects for time or any time*group interactions for any of the lumbar vertebrae. There was a large effect size for the main effect for Time (L3 z-score). There was a medium effect size for the main effect for Time (L4 z-score) and the Group*Time interaction (L4 z-score). The control group was more variable in regards to individual change for L1, but the intervention group was more active for the remaining load-bearing lumbar vertebrae (L2-L4).

**SECONDARY HYPOTHESIS 3**

12 weeks of interactive play will significantly increase bone turnover (increase serum osteocalcin) in middle-aged women as compared to a randomly assigned control group. Independent samples t-tests were conducted to determine any differences between groups at baseline across all measures (Table 52). Repeated Measures Analysis of Variance (RM-ANOVA) were run to assess a main effect for time and any time*group interaction (Table 54). Means and standard deviations across study visits can be found in Table 53.

Baseline data is presented first, followed by the means and standard deviations across visits and the RM-ANOVA. Any necessary figures follow the table pairs but precede the brief interpretation.

Table 52

*Baseline Osteocalcin across Groups (n=22)*

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| Osteocalcin | 3.06 ± 0.82 | 2.84 ± 0.77 | 0.526 |

There was no significant difference between groups at baseline. Both groups had values within the range of what is considered normal for their age and gender.

Table 53

*Means and Standard Deviations across Visits for Osteocalcin as Assessed via Venipuncture (n=22)*

| | Visit 1 (M ± SD) | Visit 2 (M ± SD) | Visit 3 (M ± SD) |
|---|---|---|---|
| Osteocalcin | | | |
| Intervention (n=11) | 3.06 ± 0.82 | 3.18 ± 0.64 | 3.29 ± 0.63 |
| Control (n=11) | 2.84 ± 0.77 | 2.53 ± 0.44 | 2.74 ± 0.48 |

Table 54

*RM-ANOVA for Osteocalcin (n=22)*

| | F | df | p-value | partial eta squared |
|---|---|---|---|---|
| Osteocalcin | | | | |
| Time | 0.79 | 2 | 0.46 | 0.040 |
| Time*Group | 1.53 | 2 | 0.230 | 0.075‡ |

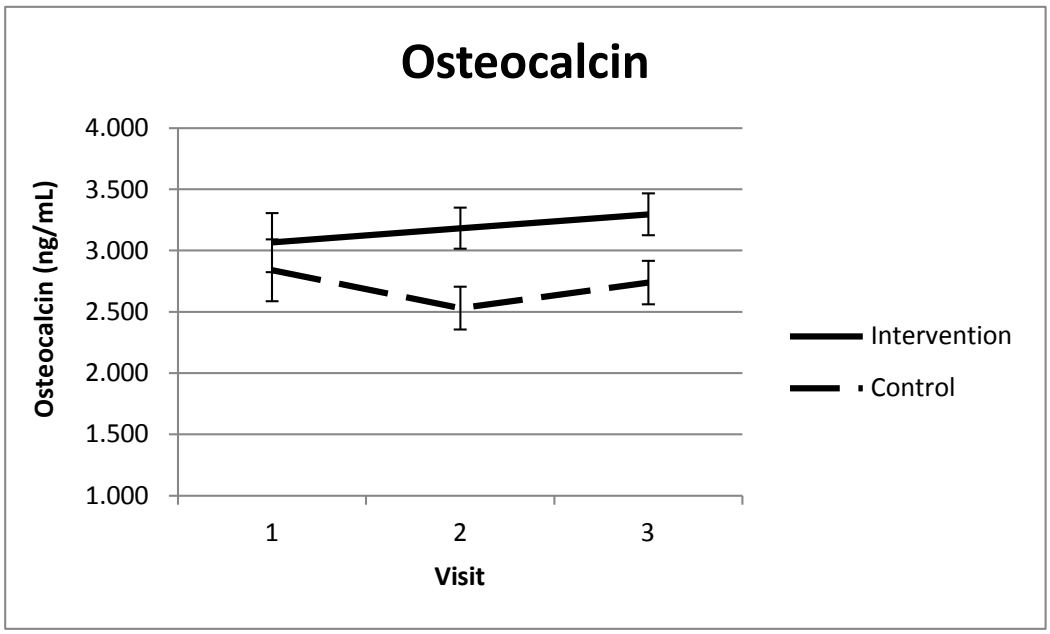


*Figure 20.* Change in Osteocalcin (n=22).

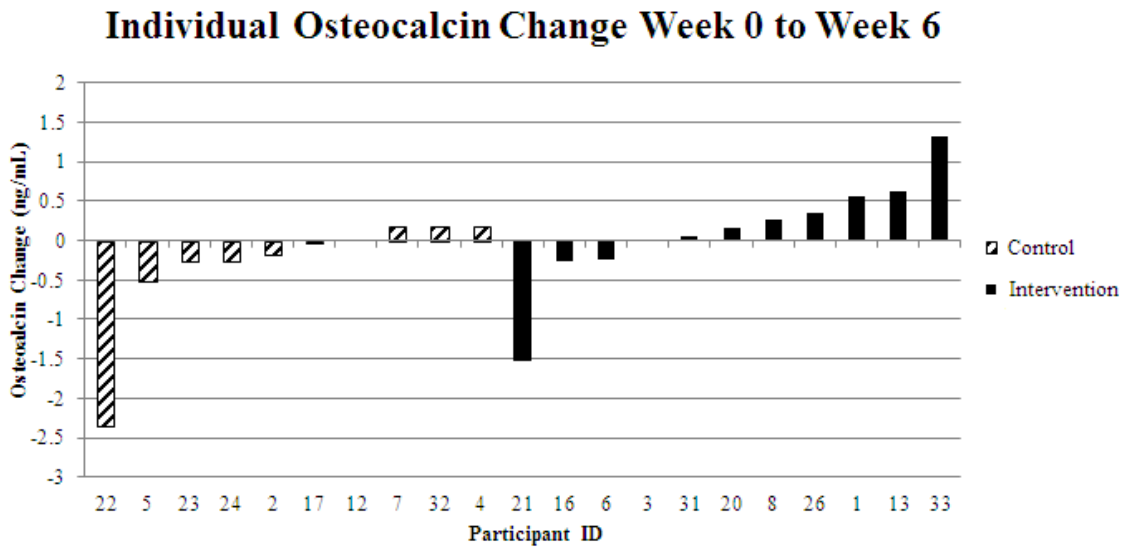


*Figure 21.* Individual Osteocalcin Change from Week 0 to Week 6 (n=22).

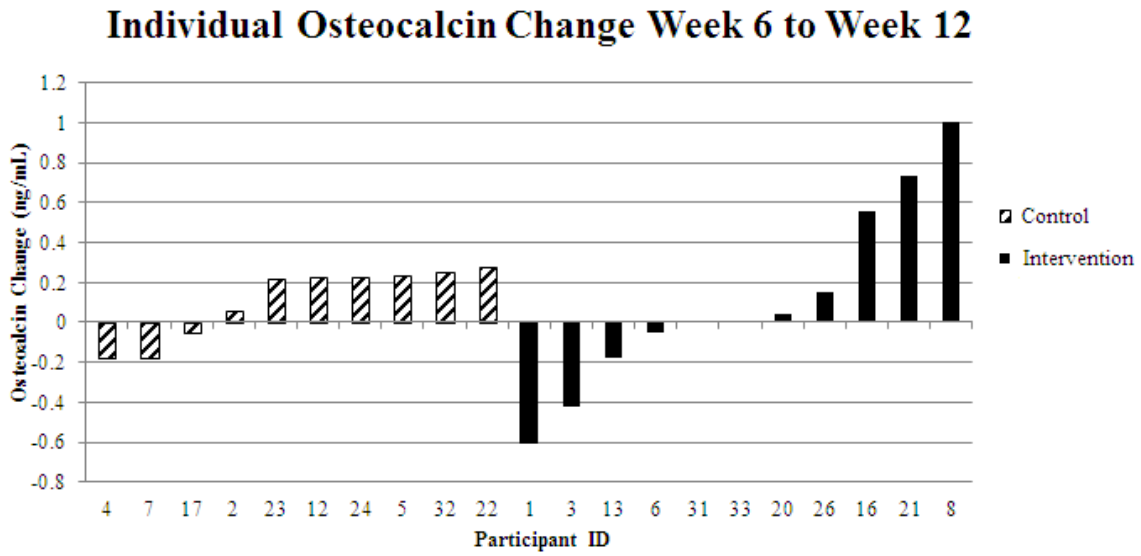


*Figure 22.* Individual Osteocalcin Change from Week 0 to Week 6 (n=22).

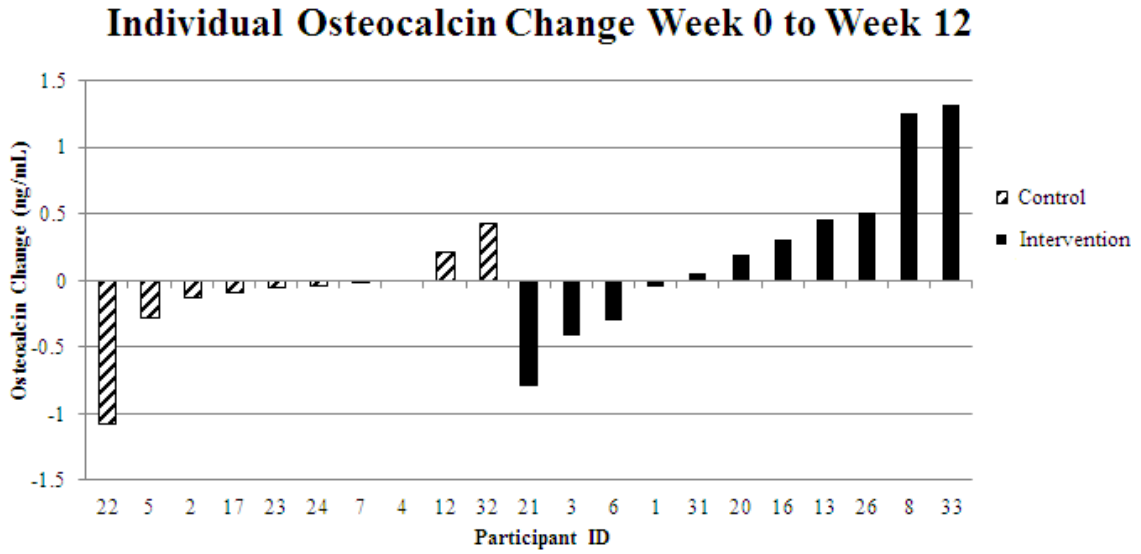


*Figure 23.* Individual Osteocalcin Change from Week 0 to Week 12 (n=22).

There was no significant main effect for time or a time*group interaction for osteocalcin. There was a medium effect size for the Time*Group interaction. The intervention group's overall mean increased during each visit, and the individual change data shows greater increases in the intervention group over the control. All coefficients of variability (CV%) were below 7%, which is considered to be in the desirable range for the kit used.

# CHAPTER 5

# DISCUSSION

## BASELINE CHANGES

Throughout the duration of the study period, the women were weight stable, with little to no change in total body weight. They were not statistically different at baseline (Table 1) and there was no main effect for time or a time*group interaction for either body weight or body fat percentage (Table 5). While there was more variation in body fat percentage than there was in weight, the methodology used is not considered reliable for tracking body composition changes over time. The Tanita (Arlington Heights, IL) can be influenced by several factors, such as hydration status, recent food intake, time of day, and recent physical activity (Loenneke et al., 2013). While precautions were taken to try to schedule all visits at the same time of the day, bioelectrical impedance (BIA) still has an error of 5-13% under prime conditions (Loenneke et al., 2013), which exceeds what would be expected in such a short time frame.

Overall, the participants in this study did not change their baseline dietary patterns, which could potentially influence any losses or gains over the duration of the study period (Table 7). At the beginning of the study, the mean calcium intake from both food and supplements was lower than 1200 mg/day, which is the current Recommended Daily Allowance (RDA) for peri- and post-menopausal women (Pinheiro et al., 2009). Some women did meet or exceed the RDA for calcium in both study groups, but there was no statistically significant difference in intake between the two. To assure that any bone

changes were not due to calcium status, change in bone mass was correlated with calcium intake, and there was no correlation between the two variables. The groups were also equivalent in their protein and vegetable intake, although neither group was meeting the recommended three or more servings/day of vegetables. However, the questionnaire used did not account for all vegetables that may be included in the diet, so it is not a comprehensive measure of total intake. Like calcium, protein intake was correlated with changes in muscular fitness, and there was no relationship.

There were changes in physical activity habits, but any statistically significant changes were due to the inclusion of the exercise program in the intervention group. At baseline, the women were considered extremely sedentary, with less than 40 minutes of walking per week, and little to no moderate-to-vigorous physical activity (MVPA). There was no statistically significant different between groups at baseline (Table 3), and there was no main effect for time or a time*group interaction for walking or MVPA (Table 9). When provided with the questionnaire at Visits 2 and 3, the women were instructed to report all physical activity excluding the Wii Fit®, if applicable. The increase in time spent in mild activity was entered manually using the electronic and paper exercise logs completed by the women. While questionnaires do have some error in reporting and are subject to bias, the raw time changes seen in the mild category are coming from direct measures of activity time logged by the gaming system. Screenshots of the exercise time reported by the Wii System can be found in Appendix K.

## PRIMARY HYPOTHESIS

**Balance Scales.** The results from this study do not support the hypothesis that 12-weeks of interactive play would improve performance on either the Berg or the FICSIT-4 balance scales as compared to a control. This is in part due to an insufficient sample size and a ceiling effect among the participants. The study was powered on previous research that predominantly used older adults, as there is no research is this area that has studied the effect on peri-menopausal women. Using the results from Bateni (2012), it was anticipated that the effect size would be close to 0.25, but the observed effect size estimate was 0.133 for time and 0.085 for time*group for the Berg Scale (Table 12). However, there was a medium effect size for time with the FICSIT-4 scale, and the p-value was trending toward significance. These results indicate that all participants were improving with each visit, and that any gains cannot be attributed to participation in the exercise intervention. Running a sample size analysis in SAS using the observed effect sizes for the Berg and FICSIT-4 interactions, a sample size of 54+ would have been necessary to detect any significant differences.

The other potential issue was the fact that none of the women who participated in the study were what would be considered "fall-risk." The Berg is scored out of 56 and the FICSIT-4 is scaled out of 28, and both groups had means in the upper range. The Berg requires a score of below 40 to be considered "at-risk" for falling, but no women in either group scored below a 48 (Berg, 1989). Previous research in older adults has shown score changes in the range of 5-7 points on the Berg, which were used to determine the sample size, but such gains would not have been possible with this group (Bateni, 2012; Nitz et

al., 2010). It is possible that the Wii Fit® system may be able to improve and maintain balance long-term as these women age, but the study population and study duration were not sufficient to determine any benefits of improving balance when using a validated balance scale.

**Force plate.** The results from this support the hypothesis that 12-weeks of interactive play will improve balance over a control group, at least in part. There were 10 individual foot positions that were performed on the force plate, but improvement was not consistent across all of the foot positions. Similar to the balance scales, it appears that a lack of improvement may be due to a ceiling effect. Pajala et al. (2008) used force plate parameters as a predictor of falls and found that average velocity in most positions exceeded ±9 mm/sec, whereas the women in the study were typically near ±4 mm/sec. The authors of the study also used older, community-dwelling seniors, like most balance research, which potentially explains why the women used in this study performed much better overall that what has been reported in other studies.

Another potential explanation is that the balance positions, in general, were not challenging enough to disturb balance or center of pressure. These women were likely already stable and had not yet experienced the age-related decline in neuromuscular tone. That decline rapidly increases after age 60 for most adults, and the upper age cut-off was 60 years (Laughton et al., 2003). If they were not experiencing a loss of control over center of pressure due to maintaining a large degree of their neuromuscular tone, many of the foot positions would not be considered difficult. For example, standing with the feet

hip-distance apart and the eyes open would only show improvement or impairment if they experienced a large degree of postural sway at any given visit. Being that these women were extremely stable at baseline, there was no room for gross improvements in those types of situations.

The more challenging foot positions, such as Tandem Step, Eyes Open or the Single Leg Stand, still did not show an improvement across the study period. However, that may be because of removed data points for certain participants. The force plate is not equipped to truncate data at the point of a fall and make it comparable to someone who completed the full 10-second or 30-second trial. Therefore, power was lost for several of the more challenging data points because participants' results had to be removed. If a woman fell at her first visit but was able to complete the remaining trials, it was not possible to include her baseline visit, which ultimately removed her from the analysis. Missing data point analysis would not be appropriate in such a situation because each participant who fell does have a physiologically valid data point; there just has not been a commonly accepted method developed yet to deal with the velocity and area measures that result from such an occurrence.

However, there was one foot position in particular that did elicit an improvement across the study period. This was the "tandem step, eyes closed" position, which proved to be the most challenging position of all that were tested. Several participants had to be excluded due to falling, but even in those who were retained for analysis, there was an improvement in the intervention group across several of the force plate parameters. In the

case of maximum velocity (x), the intervention group's average velocity (x) decreased from Visit 1 to Visit 2, and this decrease was maintained through Visit 3 (Figure 3). The control group's average velocity (x) continued to increase across all 3 study visits. This trend was repeated for average velocity overall (Figure 5). The outcomes were not as clear for average velocity (y). The control group seemed to improve, while the intervention group remained stable (Figure 4).

In the case of the area outcomes for Tandem Step, Eyes Closed, it also appears that the intervention group improved as compared to the control. For 95% area, the intervention group remained stable throughout the study period, while the control group because less stable (Figure 6). There was even a statistically significant difference for the control group from Visit 2 to Visit 3, with a change of nearly 20 mm. Nearly all of the time*group interactions had medium to large estimates of effect size, and when analyzed using PROC POWER in SAS, the sample size was appropriate for this given foot position. Similarly to the balance scales, the effect sizes were too small for any significant change to be detected in any of the other foot positions. A sample size analysis using the effect sizes found in this study resulted in a necessary study population exceeding 60 participants.

The improvement in the Tandem Step, Eyes Closed position is surprising because that position was not one that was practiced in any of the Wii Fit games. While balance training seeks to improve whole body balance, not just the position practiced, a tandem step is not a natural foot position and is typically very challenging. Several of the games

used an open and closed base stance, as well as a single leg stand, so it would be expected that those would improve due to a training effect. As was mentioned previously, this could be due to little room for improvement or a ceiling effect. Because these women were not balanced impaired, it would be expected that only the most difficult positions would improve, which would explain the change in that specific foot position.

To date, no other study has reported a change in tandem step force plate outcomes following an exercise intervention, only changes in the foot positions that were part of the exercise program. The participants in this study were not balanced impaired, as assessed by the balance scales, so they likely were not suffering from a drastic loss of neuromuscular tone. However, they are within the age range that begins to experience the age-related loss of balance, which supports why only the most challenging activity was difficult to complete (Laughton et al., 2003). This intervention was designed from a preventative standpoint, so there is at least some evidence that it may help in reducing age-related declines in balance, as the intervention typically improved or remained stable while the control group declined.

**Strengths.** One of the major strengths of this study is that it has good ecological validity. These women were given very brief instructions on how to use the system and were encouraged to try to solve problems on their own before contacting research staff. The home-based exercise set-up is very similar to what a person would experience should they decide to purchase a Wii Fit® system on their own, with the major difference being that an exercise prescription was provided for them. Savvy users can look up exercise

programs on the Wii®, and several exercise protocols come pre-programmed into the system, with the major difference being that the pre-programming options do not include balance games.

**Limitations.** One limitation of this study is that it is a convenience sample and was full of women who did not necessarily need balance training. Therefore, it is difficult to truly assess the impact that such an intervention would have on this age group had they been more unstable. Another limitation was that the timeframe was relatively short, being only 12 weeks. Had the study been conducted over a longer period of time, the differences in balance outcomes may have been different. Women were also permitted to play additional balance games, if they chose. They were asked to report all additional activity, but the inclusion of extra game time prevented consistency across all participants for balance training.

**Future directions.** More research is needed in this age group as a means to determine the importance or utility of the Wii Fit® as a means to deliver a preventative balance intervention. Preferably, future studies should be conducted over longer time frames or aim to recruit only women who are beginning to show balance impairments.

## SECONDARY HYPOTHESIS 1

**Peak Torque.** The results of this study did not support the hypothesis that 12 weeks of interactive play would improve peak torque of the knee flexors and extensors as compared to a control group. This is partially due to being underpowered, given the sample size, as all effect sizes were small for both the knee flexors and the knee extensors. However, the main issue may be that the women were not performing to their full ability.

Other results assessing peak torque of older women found that elderly women had a peak torque of the knee extensors at 60 degrees/sec around 56 ft•lb on the dominant side and 37 ft•lb on the non-dominant side (Aquino et al., 2002). There was no difference in the dominant versus non-dominant side in the women who were studied, and their peak values at 60 degrees/sec were near 30 ft•lb. At baseline, these women were already performing worse than sedentary women who were at least 15 years older. Due to what is known about aging and a loss of muscular strength and lean muscle mass, the women in the Wii Fit® should have performed better than the elderly women from the Aquino et al. (2002) study just as a function of where they are in their life cycle (Shephard et al., 2013).

The low values could be a function of the women not performing to their full potential. Anecdotally, many of the women expressed being intimidated by the equipment or the protocol. It is possible that they did not flex and extend at the knee to their full ability because they were trying to preserve energy or strength for subsequent angle speeds and

for the muscular endurance component of the testing. This is especially likely under the 60 degree/sec condition, as the order of speeds was randomized. Following the first visit, most women commented on remembering the most challenging of the three speeds that were used, and had a fear of injury or not being able to complete the trial. Practice trials were provided prior to each measured angle speed, but it may not have been enough to ease tension or anxiety about performing the activity.

Another explanation is that the activity in the intervention was not sufficient to induce any change in muscular strength. The majority of the activities were balance-oriented rather than being strength activities, but there were two exercises built into the intervention aimed at improving lower limb strength, specifically the knee extensors. Those exercises were the lunge and the warrior pose. Both of these exercises are body weight lunges, and if someone was completing all three sessions per week, she would be doing a minimum of 90 body weight lunges/week. Research in adults aged 30-58 found that 30-minutes of Wii Fit® play twice per week was enough to improve lower limb strength (Nitz et al., 2010), although this study did not confirm these results. Many of the women in the intervention group complained of muscle soreness in the first few weeks of training, but that could be a function of their sedentary lifestyle rather than any major improvements occurring in muscular strength.

There was a significant main effect for time at 240 degrees/sec for the left knee extensors, indicating a practice effect, but there were no other significant main effects for time or any time*group interactions (Table 37). A significant time*group interaction for the right

knee flexors at 240 degrees/sec was observed (Table 39). However, when looking at the means across visits (Table 38) and the mean change for each group (Figure 7), it is unclear if any change observed was a result of the intervention or just a random occurrence. The intervention group does change from Visit 1 to Visit 2, but any gain is lost by Visit 3, which does not make sense intuitively given that all women were still participating in the intervention at a level of at least 75% compliance. All estimated effects sizes for the knee extensor and flexor groups were small, so a larger sample size would be needed to detect a significant change. However, other possible explanations for the lack of change in the intervention group will be discussed below.

**Muscular fatigue.** The hypothesis was not supported that 12 weeks of interactive play would improve muscular fatigue over a control group. Like the outcomes for peak torque/muscular strength, the lack of difference could be due to the participants not working to their full potential, or the Wii Fit® system being ineffective for improving fatigue in this population.

The raw data seems to suggest that the women were not performing to their full capacity. While not published research exists regarding what is considered a "normal" fatigue index for this, or a similar, population, the numbers themselves indicate a lack of full exertion. Larger numbers are better, indicating more ability to continue peak torque over an extended time, whereas negative numbers mean that a participant was performing a greater torque near the end of the 50 repetitions than she was at the onset (Brown, Miller, & Eason, 2006). In Table 36, many of the values for the knee extensors are near zero,

which would suggest that many of the women in both groups had negative fatigue index scores at each visit. This is confirmed when looking at the raw data, as nearly 50% of all participants are negative at any one visit, the only exception to that being the intervention group at Visit 3 for the right extensors. More women in that group moved above the positive-negative threshold at that visit, but many of the values were still very small.

This is similar to the pattern observed for the knee flexors. In Table 38, five of the group means were negative, indicating better performance at the end of the trial than at the beginning. For the right flexor, the control group was consistently negative across all three visits. When the values were positive, they were also close to zero, suggesting a large portion of the group was negative. When looking at the raw data, like what was observed for the knee extensors, at least 50% of each group was negative. The only exception was the control group for the right flexor, where close to 75% of the group was negative at any one visit.

Another possibility is that the intervention was just not effective for improving muscular fatigue. None of the activities prescribed were specifically tailored to improve fatigue, but the women were completing 30 minutes of continuous weight-being activity three times per week, which included activity of both the knee flexors and the knee extensors. No published research has investigated the effect of s Wii Fit® intervention on fatigue outcomes, so there is no available comparison, but 90 minutes/week of weight-bearing activity would be expected to contribute to improvements in fatigue, especially in a sedentary population (Bogdanis, 2012).

**Strengths.** One strength of this portion of the study is that the muscular fitness testing always occurred at the same point in each visit, eliminating the possibility that performance could be influenced by when the muscular testing happened. Additionally, the order of the peak torque trials was randomized, also eliminating the impact of order on performance. The muscular endurance testing always came last to diminish the impact of fatigue on peak torque measures. Which leg was performed first was also randomized to minimize the impact of order of testing. Another major strength is that the prescribed strength program was the same across all participants. Previous work gauging muscular strength let participants play whatever games they chose, so it cannot be determined which activities are effective, or if all participants respond in a similar fashion.

**Limitations.** The women in this study were from a sample of convenience, and did not have much exposure to strength training. Their lack of experience with traditional resistance training equipment may have made the protocol intimidating or prevented them from being able to appropriately gauge how to pace themselves in the muscular fatigue portion.

**Future research.** More research in needed in this population, especially since prior evidence has suggested that improvements can be observed with Wii Fit® training in a similar population (Nitz et al., 2010). Future research should allow for more practice sessions with the isokinetic dynamometer to reduce any fear of anxiety regarding the equipment, as well as more instruction on peak force and pacing for each of the speeds

and the fatigue portion. Finally, other strength training games and poses should be incorporated to help determine which activities are most effective in increasing muscular strength and endurance of the lower limb.

## SECONDARY HYPOTHESIS 2

**Qualitative Ultrasound (QUS).** The hypothesis was supported, in part, that 12 weeks of interactive play would improve QUS parameters as compared to a control group. While all the individual components of stiffness index (SI) were not independently significant, there was a significant time*group interaction for the SI of the left foot, and a medium effect size.

There is some discrepancy over what QUS actually measures, and it is known that certain parameters, mainly SOS, can be highly variable and not always dependent on bone structure (Njeh, Fuerst, Diessel, & Genant, 2001). It has been suggested that BUA is the best predictor of overall bone health, instead of SI, but BUA has a non-linear relationship with BMD, so it can be difficult to definitely determine what any specific measure means in regards to bone health (Njeh et al., 2001; Bauer et al., 1997). In this study, BUA was stable for the right foot, but highly variable in the left, in comparison. SOS was stable for both feet across both visits (Table 44). While not statistically significant, BUA had a time*group interaction p-value of 0.081, which is trending toward significance (Table 45). This could be indicative of a bone quality change occurring at the left heel, but the sample size was insufficient to detect the change. Because BUA mathematically contributes to SI, it is expected that SI should then also be influenced. The time*group interaction for the left SI has a p-value of 0.064, which is also trending toward significance. When the group means are plotted, the intervention group increases then remains stable, while the control group decreases and then increases, although not

statistically significant. The changes observed could be a function of bone remodeling or may be due to the variability of QUS outcomes.

QUS has never been used in a long-term intervention before, so it is unclear what degree of change would be expected. However, the variability in one foot suggests that there is some remodeling occurring at that skeletal site. QUS typically correlates with changes in the femoral neck, as both experience similar load-bearing forces during activity, so it is also expected that there will be improvements in the left femoral neck as well (Njeh et al., 2001). Those results will be discussed later on. While none of the parameters were considered to be statistically significant, which may be due to a small sample size, the differences in right foot consistency compared to left foot variability seem to indicate that greater skeletal activity is occurring in the intervention group.

**Dual-energy X-ray Absorptiometry (DXA).** The results of this study support the hypothesis that 12-weeks of interactive play using the Wii Fit® will improve BMD as compared to a control group. The prominent changes occurred at the hip, with little to no change at the lumbar spine.

When analyzing only the percent change of BMD at the total hip and spine, none of the changes were considered to be clinically significant (Table 46). While there is a change of 16.6% for the total hip, that value is outside the realm of what is considered physiologically possible for that time frame, and is being driven by one participant. This may be due to an alignment issue during the scan and the removal of this participant as an

outlier reduces the percent change at the total hip to less than one percent. There was a significant main effect for time for the z-score or the total hip, and both groups improved over time (Table 47, Figure 9). There were no significant time*group interactions for any of the t- or z-scores of the total hip or the lumbar spine. RM-ANOVAs were not run for BMD because BMD alone is a meaningless value, and determining osteoporosis risk is dependent on age, gender, and ethnicity.

When looking at the individual change data for the total hip, both groups experienced gains and losses of BMD, with no clear trend (Figure 10). However, there was a more obvious trend for individual change data for the lumbar spine (Figure 11). The intervention group was much more metabolically active, experiencing greater losses and gains than the control group, which may be indicative of more bone remodeling activity.

There is a more obvious trend that appears when the femoral neck is isolated from the total hip. For BMD, there was a clinically significant percent change at the left femoral neck (Table 48). Clinical significance is determined as a change of greater than one percent at an individual skeletal site (Hangartner, 2007). However, the same cannot be said about the right femoral neck BMD, where the change was minimal. There were no main effects for time for either the right or left t- and z-scores, but there were two significant time*group interactions for the left neck t- and z-scores (Table 49). For the left neck t-score, the intervention group increased while the control group decreased (Figure 12), and this pattern was similar for the left neck z-score (Figure 13).

For the individual change data at the right femoral neck, there is no clear trend (Figure 14). Both groups experienced gains and losses of BMD at the right neck, but it appears that the control group was more active overall. However, for the left neck, an obvious trend appears. Overall, the intervention group gained BMD while, in general, the control group was losing bone mass (Figure 15).

The mechanism behind one hip being remodeled while the other stayed static is related to the body's protection of skeletal sites during remodeling. In general, the body will not remodel contralateral skeletal sites at the same time as a means to maintain skeletal integrity (Jordan et al., 2000). These women were considered extremely sedentary, so they likely were not experiencing much weight-bearing activity in their daily life. These women were also predominantly right-footed, meaning they favor the right foot when walking, standing, etc. In most normal adults, one hip will always be denser than the other, even if marginally, and the denser side is the one that is favored. Because these women mostly favored the right side, the left hip was likely weaker, and would have been targeted first for remodeling. When looking at the means for each group for BMD, the left hip is consistently weaker, supporting the idea that it would be targeted first (Table 48).

The skeleton also responds to loading signals coming from weight-bearing physical activity. As mentioned previously, these women were very sedentary, and engaged in very little activity during the course of the week. For those who were introduced into the intervention, both hips were now experiencing loads that they were not accustomed to,

which is a primary signal to remodel a skeletal site (Frost, 1997). Combined with the concept that the left hip was already impaired in comparison to the right, it would be targeted first to be able to adapt to the new load being placed on the skeleton.

The losses that were seen in the control group are also consistent with what has been reported as typical bone loss with age. Post-menopausal women, on average, lose upwards of 2.5% within a year, without pharmacological or exercise interventions (Martin & Seeman, 2008). What is important to note is that bone resorption does not necessarily need to be followed by bone formation, especially following menopause. As was noted before, most of these women could be considered calcium deficient. The body will signal for calcium release from the skeleton to maintain serum calcium levels, so these women may have been losing bone mass from calcium leeching and there was not enough in the diet to replace what was being released, leading to the bone loss observed.

Interestingly, the QUS and the DXA tracked together, which has never previously been reported. The changes seen in the left femoral neck correspond to the changes in the left heel, which assists in validating the QUS's ability to track bone health changes over time. The fact that both moved in a similar direction, as well as both right hip and right heel staying stable, may be important in future research to confirm or add more information to changes seen in the DXA alone.

The lumbar spine did not behave in the same way as the femoral necks. Looking at raw BMD change in Table 50, none of the lumbar vertebrae experienced a BMD change

greater than 1%. There were also no main effects for time and any time*group interactions for the t- and z-scores of the lumbar vertebrae. Additionally, all effect sizes were very small (Table 51). For individual change at each of the lumbar vertebrae, each one responded differently. For L1, there was no clinically significant change for the intervention group, but the control group was much more metabolically active (Figure 16). However, this could be a function of where they were in the remodeling cycle at the time of measurement, which could explain the gains observed. Any gains in the control group are being driven by the top two individuals, whereas the remainder of the change seen is within the range of error of the DXA.

The opposite occurred for the L2 vertebrae (Figure 17). The control group was stable, whereas the intervention group experienced both significant gains and losses. Similar to the control group, this could be a function of where they were in the remodeling cycle at the time of measurements. L3 responded similarly, with the intervention group being much more metabolically active (Figure 18). L4 had large changes both positively and negatively for the intervention group while the control stayed stable (Figure 19). While such great losses appear to be concerning, they may actually be an artifact of the bone remodeling cycle. L4 experiences the most loading during activity, and is also typically the weakest when a person is sedentary, so it would be the vertebrae most likely to undergo remodeling (Martin & Seeman, 2008).

All of the activities included in the intervention were standing, which would place a large load on the lumbar vertebrae in comparison to sitting or lying down. Like the hip, it is

expected that one vertebra would remodel during a turnover cycle. The body will only target one portion of one vertebral group at a time to help to maintain skeletal integrity along the spinal column (Jordan et al., 2000). Although there was such great variability in the L4 vertebra, no clinically significant change was detected during raw BMD change analysis. Looking at each individual change, it is because the entire group is not moving in a uniform direction. The majority of the individuals were experiencing greater than a 1% change in their bone mass, but the opposite directions caused the average gross change to be less than 1%.

**Strengths.** A major strength of this study is that skeletal health was assessed in a variety of ways. The combination of the DXA and the QUS serves to cross-validate the changes seen in both pieces of equipment, creating a more definite picture of the skeletal changes occurring over the course of the intervention. Another strength is that individual skeletal sites were analyzed, rather than the skeleton as a whole. Often in bone interventions, a total body t-score or BMD is used to assess skeletal health, which is not informative regarding specific sites of fracture. Having site-specific changes, especially at the femoral neck, is extremely important because hip fracture most often occurs at the neck (Christen et al., 2013). While total hip is more informative than total body, femoral neck is much more specific to fracture. For example, in this study, not change was detected when the total hip was analyzed, but assessment of the femoral neck alone detected a meaningful change that may have otherwise been missed.

**Limitations.** A limitation of this study is the short time-frame. Three months is the absolute minimum to detect change in bone health parameters using the DXA, so the pattern of BMD gain of loss may change over an extended timeframe. Because bone is influenced by a variety of factors, it is not possible to predict from the data available if bone would have continued to improve past the intervention period. While blood biomarkers provide some insight, which will be discussed later, it is unclear if the gains seen in the intervention group are the threshold, or if continued activity would produce greater bone deposition during a following turnover cycle. It is also not possible to predict if the right hip would ever remodel to the extent that the left did without directly tracking bone change with DXA.

**Future research.** More research in this area is warranted, especially since such large gains in such a small timeframe have not been previously reported. A longer study period under the same conditions would help to answer questions about how bone will respond as the intervention continues. Especially in reference to the sites that appeared to be individually active, it is important to know if these large changes seen in individuals would lead to greater bone loss or gain over time.

**SECONDARY HYPOTHESIS 3**

The results of this study support, in part, the hypothesis that 12-weeks of interactive play using the Wii Fit® will improve markers of bone turnover (increased osteocalcin) as compared to a control group. While the results were not statistically significant, likely due to a lack of power, there is a clear trend that emerges for both the group means and the individual responses.

There is no clinical cutoff for osteocalcin to determine whether someone is healthy or at-risk for osteoporosis, but many studies have used osteocalcin as a means to track bone health in comparison to DXA. Generally, increases in osteocalcin tend to correlate well with improvements in BMD, as measured via DXA (Bharadwaj, Naidu, Betageri, Prasadarao, & Naidu, 2009). The results from this study did not wield statistically significant results for the change in osteocalcin (Table 54), but there is a clear trend to suggest that those in the intervention group had a greater improvement in bone formation over those in the control.

Looking at the means across study visits (Table 53, Figure 20), the intervention group consistently increased while the control group remained somewhat static. In the individual change data, the trend is not as obvious when comparing week 6 to week 0 (Figure 21) and week 12 to week 6 (Figure 22), but the overall change from week 0 to week 12 (Figure 23) showed a marked increase in the intervention over the control. This variability in the increase is to be expected based on the timing of the bone remodeling cycle. The remodeling cycle itself lasts 3-4 months, with bone resorption dominating

during the first 6-8 weeks (Frost, 1997). This explains why individual change is minimal when comparing week 6 to week 0, as at that point, the skeleton was likely undergoing bone resorption (Figure 21). The shift in cellular dominance is then more prominent as the intervention appears to be more metabolically active than the control from week 6 to week 12 (Figure 22). The fact that the intervention group is much more variable helps to justify the hypothesis from the DXA results that the intervention group was much more active overall in regards to bone turnover.

These results also confirm what is seen in the femoral neck DXA results. While osteocalcin cannot be site-specific, as it indicates bone formation on a systemic level, it is expected that increases in osteocalcin should be seen in the group that is experiencing increases in bone mass. While the control group was also highly varied in the DXA results for some of the skeletal markers, many of the variations were within the range of error of the DXA equipment and were not clinically significant. Within that group, there were also a few women who did experience BMD gains and had some osteocalcin variability.

**Strengths.** A major strength of this study is that the analysis of osteocalcin helps to support any changes seen in the DXA or QUS results. Without corresponding biomarker analysis, it would be difficult to definitively state that changes in bone mass were due to increased skeletal activity rather than issues with site alignment, technician error, or other sources or error associated with DXA analysis. Also, the use of three time

points  instead of the typical pre-post collection helps to determine how long an intervention would need to be to influence bone deposition following bone resorption.

**Limitations.** A limitation of this study is the short time-frame. Osteocalcin appears to increase linearly, but without further time points, it is difficult to determine if the intervention group is at the end of bone formation, or if bone mass would continue to increase with time. Another limitation is the small sample size. Changes in osteocalcin levels were very small, so a larger sample size would have been necessary to detect any statistically significant changes, although there was a clear trend. Additionally, none of these women had osteocalcin levels that were abnormally low, which could indicate a metabolic disruption in bone formation, such as what happens in osteoporosis. It is difficult to say that such metabolic activity would be the same for women who may already be experiencing impaired bone metabolism as a result of age. There was also no analyzed marker of bone resorption to help determine skeletal metabolic activity, which could help to identify the location in the bone turnover cycle for each woman.

**Future research.** Future research should focus on recruiting a more diverse study population over a longer period of time. The recruitment and inclusion of women with true osteoporosis would be more informative as to the utility of the Wii Fit® to prevent and treatment bone impairments during the aging process. A longer timeframe would also help to identify the extent to which bone mass can be improved or maintained following the initial improvements seen over a 12-week period.

## CONCLUSION

The Wii Fit® system does show some promise as a preventative tool for fall-risk, but more research needs to be done to determine any long-term benefits of using the system. Balance was improved in the most challenging foot position, which suggests that training on the gaming system may help to maintain or improve balance outcomes during the aging process. However, since none of the women enrolled in the study suffered from balance impairments, it is difficult to fully quantify the impact of the equipment on balance and center of pressure. More longitudinal research using the Wii Fit® is necessary to determine how it may function as a preventative therapy as individuals age, especially as usage and interest in engaging with the system may decrease with time.

While muscular fitness was not improved, other research had indicated that similar interventions have been successful in improving peak torque of the knee flexors with less game time. With the raw data suggesting that the women participating in the study did not engage in the testing portion to their full potential, it is likely that the expected gains were lost. Like the balance portion, long-term studies are needed to determine if the Wii Fit can at least maintain muscular fitness with age, especially as participants begin to lose lean muscle mass and neuromuscular function.

The most promise seems to be in the improvement of skeletal health. 12 weeks of game play resulted in unprecedented BMD gains that were supported by the results from all three measures (DXA, QUS, and osteocalcin). Because bone formation does not occur uniformly across contralateral skeletal sites (i.e., left and right femoral neck

simultaneously), future research is necessary to determine how skeletal remodeling occurs with continued engagement in the exercise program. Additionally, markers of bone resorption would help in further identifying the current stage of the bone remodeling cycle at each of the study visits. Such information could be informative regarding the bone turnover activity in the control group to see if the bone loss observed in that group could be a combination of muted bone formation in conjunction with increased bone resorption over time.

While the Wii Fit® has been used extensively in older adults for the treatment of balance impairments, this study is the first of its kind to show that a 12 week intervention of an interactive gaming technology may be a valuable intervention for fall and fracture prevention as women age. This is especially relevant in regards to changes in bone health over time. The changes seen in this study exceed what is typically expected, and the values observed are similar across all the measures taken that assess bone health; this limits the possibility that what was observed occurred via change or problems with x-ray alignment. While changes in balance were minimal, the major health and financial risk from sustaining a fall is the fracture. If bone health was improved in such a short time frame, women may at least reduce their fracture risk even if the system was not able to improve actual fall risk. Overall this innovative technology holds great promise for improving bone health and decreasing fall risk in women as they age.

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# APPENDIX A

# RECRUITMENT FLYER

ASU School of Nutrition & Health Promotion

# **Female Volunteers Needed for Wii Fit Study**

## Strength and Balance Study for Middle-aged Women

The Exercise and Wellness Program is recruiting middle-aged women (45-60 y of age) who are willing to participate in a 12-week exercise study.

**Time Commitment:** Three (3) study visits lasting approximately one hour each (in addition to weekly exercise time if assigned to the exercise group). The study visits involve the following measures at the Downtown Phoenix Campus:

- Height/weight
- Body fat %
- Bone health
- Balance
- Strength
- Short physical activity questionnaire
- Blood draw

Women between the ages of 45-60 who are not on any hormone replacement therapy or osteoporotic drugs, willing to volunteer their time, and willing to complete study procedures may be eligible to participate.

For more information, please contact:

Sarah Wherry
swherry@asu.edu
814-932-7481

# APPENDIX B

# IRB APPROVAL AND INFORMED CONSENT

ASU Knowledge Enterprise Development

Office of Research Integrity and Assurance

| | |
|---|---|
| **To:** | Pamela Swan<br>ABC Room 2 |
| **From:** | for Carol Johnston, Chair<br>Bioscience Full Board |
| **Date:** | 05/16/2013 |
| **Committee Action:** | Approval |
| **IRB Action Date** | 05/16/2013 |
| **Approval Date** | 05/15/2013 |
| **IRB Protocol #** | 1304009123 |
| **Study Title** | Effect of Wii Fit Intervention on Balance in Middle-Aged Women |
| **Expiration Date** | 05/14/2014 |

The above-referenced protocol has been APPROVED following Full Board Review by the Institutional Review Board.

This approval does not replace any departmental or other approvals that may be required. It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date noted above. Please allow sufficient time for continued approval. Research activity of any sort may not continue beyond the expiration date without committee approval. Failure to receive approval for continuation before the expiration date will result in the automatic suspension of the approval of this protocol on the expiration date. Information collected following suspension is unapproved research and cannot be reported or published as research data. If you do not wish continued approval, please notify the Committee of the study termination.

Adverse Reactions: If any untoward incidents or severe reactions should develop as a result of this study, you are required to notify the Bioscience Full Board immediately. If necessary a member of the Committee will be assigned to look into the matter. If the problem is serious, approval may be withdrawn pending IRB review.

Amendments: If you wish to change any aspect of this study, such as the procedures, the consent forms, or the investigators, please communicate your requested changes to the Bioscience Full Board. The new procedure is not to be initiated until the IRB approval has been given.

**EFFECT OF WII FIT INTERVENTION ON BALANCE IN MIDDLE-AGED WOMEN**
**CONSENT FORM**

## INTRODUCTION

The purpose of this form is to provide you (as a prospective research study participant) information that may affect your decision as to whether or not to participate in this research and to record the consent of those who agree to be involved in the study.

## RESEARCHERS

Dr. Pamela Swan, Associate Professor in the School of Nutrition and Health Promotion, and Sarah Wherry, Doctoral Student in the School of Nutrition and Health Promotion, have invited your participation in a research study.

## STUDY PURPOSE

The purpose of the research is to evaluate changes in balance and muscular endurance in middle-aged women with low bone mass over a 12-week home-based exercise intervention incorporating the Wii Fit balance games.

## DESCRIPTION OF RESEARCH STUDY

If you decide to participate, then as a participant you will join a study involving research of the Wii Fit. Your total time commitment in the lab will include three (3) study visits (each lasting approximately one hour). Each study visit will involve completing questionnaires, testing your bone quality and quantity by taking an ultrasound of the heel of your foot and a DEXA scan of your hip and spine, measuring your balance, your lower limb muscular strength and a measure of your percent body fat. In addition, you will be asked to provide a small blood sample. Should you be assigned to the control group, your total time commitment will only involve the 3 study visits. Should you be assigned to the intervention group, you will be provided a WiiFit machine for your use and you will be expected to play the exercise games at home 30 minutes 3 days per week for a total of 90 minutes/week.

During the initial visit, you will complete a short physical activity questionnaire and have an ultrasound scan of the bone in your heel to determine bone health. If your heel scan shows that you have low bone mass (i.e., a t-score of less than 1), you will complete a DXA (dual energy xray absorptiometry) scan to confirm low bone density. If the DXA also indicates that you have evidence of slightly low bone (i.e., a total hip and/or spine t-score of less than 0), then you will be randomly assigned to one of two groups. You will not have a choice of which group you will be assigned. If you decide to continue in the study, then you will have your blood drawn to measure osteocalcin and C-telopeptide,

which are biochemical markers of bone turnover. Also, you will have your balance and muscular fitness assessed. Balance tests involve activities such as standing on one leg. Muscular fitness is assessed by getting up from a chair and with an automated machine that measures the strength of your legs as you extend or bend your knees.

Should you be assigned to the intervention group, you will be provided a Wii Fit game console and balance board to be set up in your house. First we need to confirm that you have adequate space in your home and that you have a TV set that can be equipped to use the Wii system. One of the investigators will come to your house to help set the system up for you and make sure it works. Over the 12-week study, you will be asked to play exercise games on the Wii Fit system 3 times a week for 30 minutes each session. These games include strength, balance, and coordination movements. You will be given detailed instructions on which games to play and how to play them. In addition, you will be asked to keep a playing log recording the time at which you played and the duration. If you have any problems with using the Wii Fit system, an investigator will try to help you troubleshoot and/or come to your home and help you, should you need it. At the conclusion of the study, you will need to return the Wii Fit and balance board to the study personnel.

Should you be assigned to the control group, DO NOT change your current physical activity habits. You will be asked to keep a physical activity journal recording any exercise you do. All participants will be contacted by study staff every 2 weeks via email or phone to complete the physical activity questionnaire and to track your progress. If at any time you encounter problems or issues, you will be provided a "HOT LINE" phone number where you can contact the study staff for assistance.

**RISKS**

Due to the DEXA scan, there is a small risk of radiation exposure. The DEXA scan will expose you to a small amount of radiation. We take all precautions to make this risk as minimal as possible. If you have not completed menopause, you will be asked to take a pregnancy test before your DXA scan as a precaution.

The blood draw may cause some bruising or discomfort at the needle site as well as the risk of nausea or fainting.

There are no risks associated with the ultrasound measurement.

The risk of the exercise portion does not exceed those of daily living, such as muscle strain/pull or fatigue. However, there may be a chance of falling when using the Wii Fit system at home. In order to reduce this risk, follow all safety instructions provided by the research staff and in the Wii Fit manual that will be provided with the Wii Fit. If you fall and get injured, please contact your health care provider and contact the researchers after your visit with your physician. However, as with any research, there is some possibility that you may be subject to risks that have not yet been identified.

**BENEFITS**
The possible benefit of your participation in the research is receiving information regarding information about your balance and bone health. While the tools used cannot be used for diagnostic purposes, they may help you identify any weaknesses you have so that you can pursue further testing with your physician.

**NEW INFORMATION**
If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you.

**CONFIDENTIALITY**
All information obtained in this study is strictly confidential unless disclosure is required by law. The results of this research study may be used in reports, presentations, and publications, but the researchers will not identify you. In order to maintain confidentiality of your records, study personnel will provide you with a participant number that will be used on all documents. No research documents will ever include your name, and the key containing which name belongs to which number will be kept in a locked file that is only accessible to the study researchers. Additionally, all research documents containing your participant number (but not your name) will also be kept in a locked file accessible only to those conducting this study.

**WITHDRAWAL PRIVILEGE**
It is okay for you to say no. Even if you say yes now, you are free to say no later and withdraw from the study at any time.

Your decision will not affect your relationship with Arizona State University or otherwise cause a loss of benefits to which you might otherwise be entitled.

If you are a student or employee at Arizona State University, your participation is completely voluntary, and any decisions to withdraw will not impact your grade or employment status.

**COSTS AND PAYMENTS**
All parking costs will be covered, and you will receive $25 in cash should you complete the full 12-week study. In addition, if you complete the study, you will be entered into a drawing to win one of two (2) Wii Fit consoles and balance boards. One will be raffled to the intervention group, and the other to the control group.

**COMPENSATION FOR ILLNESS AND INJURY**
If you agree to participate in the study, then your consent does not waive any of your legal rights. However, no funds have been set aside to compensate you in the event of injury.

**VOLUNTARY CONSENT**

Any questions you have concerning the research study or your participation in the study, before or after your consent, will be answered by Sarah Wherry at swherry@asu.edu or 814-932-7481.

If you have questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at 480-965-6788.

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given (offered) to you.

Your signature below indicates that you consent to participate in the above study.

| _____ | _____ | _____ |
|---|---|---|
| Subject's Signature | Printed Name | Date |

**INVESTIGATOR'S STATEMENT**

"I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided (offered) the subject/participant a copy of this signed consent document."

Signature of Investigator_____ Date_____

# APPENDIX C

## HEALTH HISTORY SCREENING QUESTIONNAIRES

# 2013 PAR-Q+

The Physical Activity Readiness Questionnaire for Everyone

The health benefits of regular physical activity are clear; more people should engage in physical activity every day of the week. Participating in physically active is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

## GENERAL HEALTH QUESTIONS

| Please read the 7 questions below carefully and answer each one honestly: check YES or NO. | YES | NO |
|---|---|---|
| 1) Has your doctor ever said that you have a heart condition ☐ OR high blood pressure ☐ ? | ☐ | ☐ |
| 2) Do you feel pain in your chest at rest, during your daily activities of living, **OR** when you do physical activity? | ☐ | ☐ |
| 3) Do you lose balance because of dizziness **OR** have you lost consciousness in the last 12 months? Please answer **NO** if your dizziness was associated with over-breathing (including during vigorous exercise). | ☐ | ☐ |
| 4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? **PLEASE LIST CONDITION(S) HERE:** _____ | ☐ | ☐ |
| 5) Are you currently taking prescribed medications for a chronic medical condition? **PLEASE LIST CONDITION(S) AND MEDICATIONS HERE:** _____ | ☐ | ☐ |
| 6) Do you have a bone or joint problem that could be made worse by becoming more physically active? Please answer **NO** if you had a joint problem in the past, but it *does not limit your current ability* to be physically active. For example, knee, ankle, shoulder or other. **PLEASE LIST CONDITION(S) HERE:** _____ | ☐ | ☐ |
| 7) Has your doctor ever said that you should only do medically supervised physical activity? | ☐ | ☐ |

**If you answered NO to all of the questions above, you are cleared for physical activity.**
**Go to Page 4 to sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.**

- Start becoming much more physically active – start slowly and build up gradually.
- Follow International Physical Activity Guidelines for your age (www.who.int/dietphysicalactivity/en/).
- You may take part in a health and fitness appraisal.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
- If you have any further questions, contact a qualified exercise professional.

**If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.**

**Delay becoming more active if:**

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at **www.eparmedx.com** before becoming more physically active.
- Your health changes - answer the questions on Pages 2 and 3 of this document and/or talk to your doctor or a qualified exercise professional before continuing with any physical activity program.



20-05-2013

Participant Number:_____ Date:_____

Health History Questionnaire

Wt. (lbs)_____Ht.(in)_____Birthdate mm/dd/year):_____

Ethnic Background (circle):
Caucasian African American Asian Hispanic Other

Do you have any pre-existing conditions that would limit your ability to participant in an exercise program involving prolonged standing? (circle one) Yes No

Have you begun menopause? (circle one) Yes No

Have you lost height? (circle one) Yes No

If so, by how many inches? (circle one) _____

Are you a current smoker? (circle one) Yes No

Are you on any hormone replacement therapy medications? Yes No

If yes, which medications/therapies are you taking, and how long have you been taking them? _____

Have you fractured your hip, back, shoulder, or wrist as an adult? Yes No

If so, please describe how the fracture occurred (eg: fall, accident etc.) and at what age?

_____

Have either of your parents fractured a hip? (circle one) Yes No

Do you have a family history of osteoporosis? (circle one) Yes No

Have you had a bone density test before? (circle one) Yes No

If yes, when did you have the bone density test? _____

What was the result (circle one): Normal Osteopenia Osteoporosis

Have you had any ankle/heel injuries, aside from mild sprains? (circle one) Yes No

If yes, what was the injury, and which foot was impacted? _____

_____

# APPENDIX D

# FOOD FREQUENCY QUESTIONNAIRE

HARVARD UNIVERSITY — Page 3 — NURSES' HEALTH STUDY II

**19.** Do you currently take a multi-vitamin? (Please report other individual vitamins in Question 20.)

○ Yes → a) How many do you take per week? ○ 2 or less ○ 3–5 ○ 6–9 ○ 10 or more

○ No

b) What specific brand (or equivalency) do you usually take?

○ Centrum Silver ○ Centrum ○ Theragran M
○ One-A-Day Women's ○ One-A-Day Essential
○ Shaklee Vita-Lea ○ Nutrilite Double X ○ Other →

Ex: AARP Alphabet II Formula 643 Multivitamins and Minerals

**20.** Do you take the following separate preparations? (DO NOT report the contents of multi-vitamins reported above.)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| a) Vitamin A ○ No | ○ Yes, seasonal only<br>○ Yes, most months | If Yes, Dose per day: | ○ Less than 8,000 IU | ○ 8,000 to 12,000 IU | ○ 13,000 to 22,000 IU | ○ 23,000 IU or more | ○ Don't know | |
| b) Vitamin C ○ No | ○ Yes, seasonal only<br>○ Yes, most months | If Yes, Dose per day: | ○ Less than 400 mg. | ○ 400 to 700 mg. | ○ 750 to 1250 mg. | ○ 1300 mg. or more | ○ Don't know | |
| c) Vitamin $B_6$ ○ No | ○ Yes → | If Yes, Dose per day: | ○ Less than 10 mg. | ○ 10 to 39 mg. | ○ 40 to 79 mg. | ○ 80 mg. or more | ○ Don't know | |
| d) Vitamin E ○ No | ○ Yes → | If Yes, Dose per day: | ○ Less than 100 IU | ○ 100 to 250 IU | ○ 300 to 500 IU | ○ 600 IU or more | ○ Don't know | |
| e) Calcium ○ No (Include elemental Calcium in Tums, etc.) | ○ Yes → | If Yes, Dose per day (elemental calcium): | ○ Less than 400 mg. | ○ 400 to 900 mg. | ○ 901 to 1300 mg. | ○ 1301 mg. or more | ○ Don't know | |
| f) Vitamin D ○ No (In calcium supplement or separately) | ○ Yes → | If Yes, Dose per day: | ○ Less than 300 IU | ○ 300 to 500 IU | ○ 600 to 900 IU | ○ 1,000 IU or more | ○ Don't know | |
| g) Selenium ○ No | ○ Yes → | If Yes, Dose per day: | ○ Less than 80 mcg. | ○ 80 to 130 mcg. | ○ 140 to 250 mcg. | ○ 260 mcg. or more | ○ Don't know | |
| h) Niacin ○ No | ○ Yes → | If Yes, Dose per day: | ○ Less than 50 mg. | ○ 50 to 300 mg. | ○ 400 to 800 mg. | ○ 900 mg. or more | ○ Don't know | |
| i) Zinc ○ No | ○ Yes → | If Yes, Dose per day: | ○ Less than 25 mg. | ○ 25 to 74 mg. | ○ 75 to 100 mg. | ○ 101 mg. or more | ○ Don't know | |

**Are there other supplements that you take on a regular basis?**

○ Metamucil/Citrucil ○ Lutein ○ Chromium ○ Folic Acid ○ DHEA ○ Other (Please specify)
○ Cod Liver Oil ○ Magnesium ○ Lecithin ○ B-Complex ○ Iron
○ Vitamin $B_{12}$ ○ Melatonin ○ Beta-carotene ○ Ginkgo Biloba
○ Coenzyme Q10 ○ Fish Oil ○ Glucosamine ○ Garlic Supplements
○ Ginseng ○ St. John's Wort ○ Chondroitin ○ Lycopene

**21.** How many teaspoons of sugar do you add to your beverages or food each day? → _____ tsp.

**22.** What brand and type of cold breakfast cereal do you usually eat? → Specify cereal brand & type

○ Don't eat cold breakfast cereal.

**23.** What form of margarine do you usually use? →

○ None Form? ○ Stick ○ Tub ○ Spray ○ Squeeze (liquid)
Type? ○ Reg ○ Light ○ Extra Light ○ Nonfat

What specific brand & type of margarine (e.g., Blue Bonnet Lower Fat Spread)?

**24.** For each food listed, fill in the circle indicating how often on average you have used the amount specified during the past year.

| DAIRY FOODS | | AVERAGE USE LAST YEAR: Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day |
|---|---|---|---|---|---|---|---|---|---|---|
| Milk (8 oz. glass) | Skim milk | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| | 1 or 2 % milk | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| | Whole milk | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| | Soy milk | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Cream, e.g., coffee, whipped or sour cream (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Non-dairy coffee whitener (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Frozen yogurt, sherbet or non-fat ice cream (1 cup) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Regular ice cream (1 cup) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Yogurt | Artificially sweetened or plain (1 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| | Sweetened-with fruit or other flavoring (1 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Margarine (pat), added to food or bread; exclude use in cooking | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Butter (pat), added to food or bread; exclude use in cooking | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Cottage or ricotta cheese (1/2 cup) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Cream cheese (1 oz.) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Other cheese, e.g., American, cheddar, etc., plain or as part of a dish (1 slice or 1 oz. serving) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |

→ What type of cheese do you usually eat? ○ Regular ○ Low fat or Lite ○ Nonfat ○ None

**24.** For each food listed, fill in the circle indicating how often on average you have used the amount specified during the past year.

Please try to average your seasonal use of foods over the entire year. For example, if a food such as cantaloupe is eaten 4 times a week during the approximate 3 months that it is in season, then the average use would be once per week.

| FRUITS | Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day |
|---|---|---|---|---|---|---|---|---|---|
| Raisins (1 oz. or small pack) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Grapes (1 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Prunes (7 prunes or 1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Prune juice (glass) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Bananas (1) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Cantaloupe (1/4 melon) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Applesauce (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Fresh apples or pears (1) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Apple juice or cider (glass) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Oranges (1) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Orange juice (glass) — Calcium fortified | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Orange juice (glass) — Regular (not fortified) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Grapefruit (1/2) or grapefruit juice (glass) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Other fruit juices (glass) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Strawberries, fresh, frozen or canned (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Blueberries, fresh, frozen or canned (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Peaches, apricots or plums (1 fresh, or 1/2 cup canned) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |

| VEGETABLES | Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day |
|---|---|---|---|---|---|---|---|---|---|
| Tomatoes (3 slices or 1/2 small tomato) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Tomato or V-8 juice (small glass) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Tomato sauce (1/2 cup) e.g., spaghetti sauce | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Salsa, picante or taco sauce (1/4 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Tofu, soy burger or other soy protein | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| String beans (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Beans or lentils, baked or dried (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Peas or lima beans (1/2 cup fresh, frozen, canned) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Broccoli (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Cauliflower (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Cabbage or coleslaw (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Brussels sprouts (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Carrots, raw (1/2 carrot or 2–4 sticks) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Carrots, cooked (1/2 cup) or carrot juice (2–3 oz.) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Corn (1 ear or 1/2 cup frozen or canned) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Mixed vegetables, stir-fry, vegetable soup (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Yams or sweet potatoes (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Dark orange (winter) squash (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Eggplant, zucchini or other summer squash (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Kale, mustard greens or chard (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Spinach, cooked (1/2 cup) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Spinach, raw as in salad (serving) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Iceberg or head lettuce (serving) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Romaine or leaf lettuce (serving) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Celery (4" stick) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Green or red peppers (3 slices or 1/4 pepper) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Onions as a garnish or in salad (1 slice) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Onions as a vegetable, rings or soup (1 onion) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |

| EGGS, MEAT, ETC. | Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day |
|---|---|---|---|---|---|---|---|---|---|
| Egg Beaters or egg whites only (1/4 cup or 1 egg) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Eggs including yolk (1) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Beef or pork hot dogs (1) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Chicken or turkey hot dogs (1) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Chicken/Turkey sandwich or frozen dinner | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Other chicken or turkey, with skin (3 oz.) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Other chicken or turkey, without skin (3 oz.) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |
| Bacon (2 slices) | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ |

**24.** For each food listed, fill in the circle indicating how often on average you have used the amount specified during the past year.

| EGGS, MEAT, ETC. | Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day |
|---|---|---|---|---|---|---|---|---|---|
| Salami, bologna, or other processed meat sandwiches | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Other processed meats, e.g., sausage, kielbasa, etc. (2 oz. or 2 small links) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Hamburger (1 patty) — Lean or extra lean | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Hamburger (1 patty) — Regular | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Beef, pork, or lamb as a sandwich or mixed dish, e.g., stew, casserole, lasagna, frozen dinner, etc. | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Pork as a main dish, e.g., ham or chops (4–6 oz.) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Beef or lamb as a main dish, e.g., steak, roast (4–6 oz.) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Canned tuna fish (2–3 oz.) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Breaded fish cakes, pieces, or fish sticks (1 serving, store bought) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Shrimp, lobster, scallops as a main dish | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Dark meat fish, e.g., mackerel, salmon, sardines, bluefish, swordfish (3–5 oz.) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Other fish, e.g., cod, haddock, halibut (3–5 oz.) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |

| BREADS, CEREALS, STARCHES | Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day |
|---|---|---|---|---|---|---|---|---|---|
| Cold breakfast cereal (1 cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Cooked oatmeal/cooked oat bran (1 cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Other cooked breakfast cereal (1 cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Bread (1 slice) — White bread, including pita | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Bread (1 slice) — Rye/Pumpernickel | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Bread (1 slice) — Whole wheat, oatmeal, other whole grain | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Bagels, English muffins, or rolls (1) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Muffins or biscuits (1) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Pancakes or waffles (2 small pieces) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Brown rice (1 cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| White rice (1 cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Pasta, e.g., spaghetti, noodles, etc. (1 cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Tortillas (1) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| French Fries (4 oz. or 1 serving) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Potatoes, baked, boiled (1) or mashed (1 cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Potato chips or corn chips (small bag or 1 oz.) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Crackers (6) — Fat free or light | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Crackers (6) — Regular | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| Pizza (2 slices) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |

| BEVERAGES | | Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day |
|---|---|---|---|---|---|---|---|---|---|---|
| CARBONATED BEVERAGES. Consider the serving size as 1 glass, bottle or can for these carbonated beverages. | Low-Calorie (sugar-free) types | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Low-calorie beverage with caffeine, e.g., Diet Coke, Diet Mt. Dew | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Other low-cal bev. without caffeine, e.g., Diet 7-Up | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Regular types (not sugar-free) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Carbonated beverage with caffeine & sugar, e.g., Coke, Pepsi, Mt. Dew, Dr. Pepper | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Other carbonated beverage with sugar, e.g., 7-Up, Root Beer, Ginger Ale | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| OTHER BEVERAGES | Punch, lemonade, other non-carbonated fruit drinks, or sugared ice tea (1 glass, bottle, can) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Beer, regular (1 glass, bottle, can) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Light Beer, e.g., Bud Light (1 glass, bottle, can) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Red wine (5 oz. glass) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | White wine (5 oz. glass) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Liquor, e.g., vodka, gin, etc. (1 drink or shot) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Plain water, bottled, sparkling, or tap (1 cup or glass) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Herbal tea or decaffeinated tea (8 oz. cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Tea with caffeine (8 oz. cup), including green tea | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Decaffeinated coffee (8 oz. cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |
| | Coffee with caffeine (8 oz. cup) | ○ | ○ | (W) | ○ | ○ | (D) | ○ | ○ | ○ |

**24.** *(continued)* For each food listed, fill in the circle indicating how often on average you have used the amount specified during the past year.

| SWEETS, BAKED GOODS, MISCELLANEOUS | | Never, or less than once per month | 1–3 per month | 1 per week | 2–4 per week | 5–6 per week | 1 per day | 2–3 per day | 4–5 per day | 6+ per day | P |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Chocolate (bar or packet) e.g., Hershey's, M & M's | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Candy bars, e.g., Snickers, Milky Way, Reese's | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Candy without chocolate (1 oz.) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Cookies (1) | Fat free or reduced fat | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| | Other ready made/frozen dough | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| | Home baked | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Brownies (1) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Doughnuts (1) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Cake, ready made (slice) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Cake, home baked (slice) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Pie, homemade or ready made (slice) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Jams, jellies, preserves, syrup, or honey (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Peanut butter (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Popcorn (3 cups) | Fat free or light | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| | Regular | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Sweet roll, coffee cake or other pastry (serving) | Fat free or reduced fat | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| | Other ready made | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| | Home baked | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Pretzels (1 small bag or serving) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Peanuts (small packet or 1 oz.) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Walnuts (1 oz.) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Other nuts (small packet or 1 oz.) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Oat bran, added to food (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Other bran (e.g., wheat), added to food (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Wheat germ (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Chowder or cream soup (1 cup) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Ketchup or red chili sauce (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Salt added at table (1 shake) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Nutrasweet or Equal (1 packet) NOT Sweet 'N Low | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Garlic (1 clove or 4 shakes) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Olive oil added to other food or bread (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Low-fat or fat-free mayonnaise (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Regular mayonnaise (1 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |
| Salad dressing (2 Tbs) | | ○ | ○ | W | ○ | ○ | D | ○ | ○ | ○ | ○ |

Type of salad dressing: ○ Nonfat ○ Low-fat ○ Olive oil ○ Other vegetable oil

**25.** Liver: beef, calf or pork (4 oz.) ○ Never ○ Less than 1/mo ○ 1/mo ○ 2-3/mo ○ 1/week or more
Liver: chicken or turkey (1 oz.) ○ Never ○ Less than 1/mo ○ 1/mo ○ 2-3/mo ○ 1/week or more

**26.** How much of the visible fat on your beef, pork or lamb do you remove before eating?
○ Remove all visible fat ○ Remove most ○ Remove small part of fat ○ Remove none ○ Don't eat meat

**27.** How often do you eat food fried, stir-fried or sautéed at home?
○ Never ○ Less than once a week ○ Once per week ○ 2–4 times/wk ○ 5–6 times/wk ○ Daily

**28.** What kind of fat is usually used for frying and sautéing at home? ○ Any "Pam"-type spray
○ Real butter ○ Margarine ○ Olive oil ○ Vegetable oil ○ Vegetable shortening ○ Lard

**29.** What kind of fat is usually used for baking at home?
○ Real butter ○ Margarine ○ Olive oil ○ Vegetable oil ○ Vegetable shortening ○ Lard

**30.** What type of cooking oil is usually used at home? (e.g., Mazola Corn Oil) Specify brand and type →

**31.** How often do you eat deep fried chicken, fish, shrimp or clams away from home?
○ Never ○ Less than once a week ○ 1–3 times per week ○ 4–6 times per week ○ Daily

**32.** What percent of your noon and evening meals are prepared at home? (exclude commercially prepared meals)
○ Almost none ○ 25% ○ 50% ○ 75% ○ Almost all

**33.** Are there any other important foods that you usually eat at least once per week?
Include for example: Avocados, mushrooms, bulgur, couscous, radish, horseradish, dried apricots, dates, figs, mango, mixed dried fruit, papaya, rhubarb, custard, venison, hot peppers, pickles, olives, Slim-Fast, Ensure (regular, plus or light), PowerSports bars.
(Do not include dry spices.)

| Other foods that you usually eat at least once per week | Servings per week |
|---|---|
| (a) | |
| (b) | |
| (c) | |

# APPENDIX E

## WOMEN'S HEALTH INITIATIVE PHYSICAL ACTIVITY QUESTIONNAIRE

The following questions are about your usual physical activity and exercise. This includes walking and sports.

1. Think about the walking you do outside the home. How often do you walk outside the home for more than 10 minutes without stopping? (Mark only one.)

- Rarely or never
- 1-3 times each month
- 1 time each week
- 2-3 times each week
- 4-6 times each week
- 7 or more times each week

1.1 When you walk outside the home for more than 10 minutes without stopping, for how many minutes do you usually walk?

- Less than 20 min.
- 20-39 min.
- 40-59 min.
- 1 hour or more

1.2 What is your usual speed?

- Casual strolling or walking (less than 2 miles an hour)
- Average or normal (2-3 miles an hour)
- Fairly fast (3-4 miles an hour)
- Very fast (more than 4 miles an hour)
- Don't know

2.1 STRENUOUS OR VERY HARD EXERCISE (You work up a sweat and your heart beats fast.) For example, aerobics, aerobic dancing, jogging, tennis, swimming laps.

- None
- 2 days per week
- 3 days per week
- 4 days per week
- 5 or more days per week

2.2 How long do you usually exercise like this at one time?

- Less than 20 min.
- 20-39 min.
- 40-59 min.

- 1 hour or more

2.3 MODERATE EXERCISE (Not exhausting). For example, biking outdoors, using an exercise machine (like stationary bike or treadmill), calisthenics, easy swimming, popular or folk dancing.

- None
- 2 days per week
- 3 days per week
- 4 days per week
- 5 or more days per week

2.4 How long do you usually exercise like this at one time?

- Less than 20 min.
- 20-39 min.
- 40-59 min.
- 1 hour or more

2.5 MILD EXERCISE. For example, slow dancing, bowling, golf

- None
- 2 days per week
- 3 days per week
- 4 days per week
- 5 or more days per week

2.6 How long do you usually exercise like this at one time?

- Less than 20 min.
- 20-39 min.
- 40-59 min.
- 1 hour or more

3. I do activities to increase muscular strength, such as lifting weights or calisthenics, once a week or more.

- No
- Yes

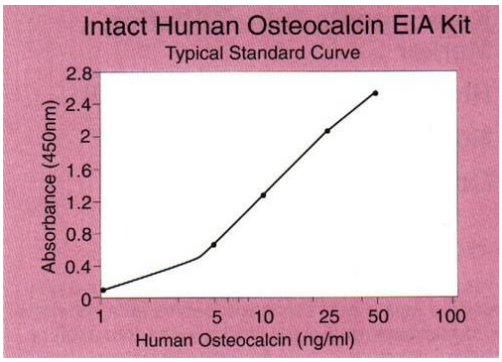
4. I do activities to increase flexibility, such as stretching or yoga, once a week or more.

- No
- Yes

# APPENDIX F

# BLOOD BIOMARKER ELISA INSTRUCTIONS

**Intact Human Osteocalcin EIA Kit**




About The Assay

Osteocalcin (5800 daltons) is a specific product of the osteoblast. It is primarily deposited into the ECM of bone and only a small amount of newly synthesized osteocalcin is released directly into the circulation. Studies suggest that there are various forms of osteocalcin in the circulation and that different antibodies detect both intact and fragments of osteocalcin. The physiological significance of osteocalcin fragments is unclear but they may be derived from resorption, osteoblastic synthesis, systemic catabolism or all of these. Since serum proteases may also degrade the intact osteocalcin, it is recommended that blood samples be processed quickly in the presence of protease inhibitors.

The BTI Intact Osteocalcin EIA measures only intact osteocalcin which is synthesized de novo by the osteoblast and it eliminates any interference by circulating fragments. The assay is a sandwich EIA which employs two monoclonal antibodies directed towards the amino-and the carboxy-terminal regions of the human osteocalcin. It recognizes only intact osteocalcin, requiring the full 49 residue protein for detection. This assay reacts with human, bovine, monkey and dog osteocalcin.

The assay is highly sensitive (Range: 1-50ng/ml) and requires only a 25ul sample. All the necessary reagents, a 96-well strip plate, and a complete 3½ hour protocol are included with the kit.

Procedural Outline

1. Add 25ul standard/sample. Add antibody and gently swirl. Incubate 2½ hours at 37$^{o}$C.

2. Aspirate and wash 3 times with wash buffer.

3. Add Strep-Av-HRP, swirl, incubate ½ hour at room temperature.

4. Repeat Step 2. Then add 100ul of substrate, swirl, develop 10 minutes in the dark. Add 100ul stop solution, swirl, measure absorbance at 450nm.

References

1. Gundberg C.M., Weinstein R.S. Multiple immunoreactive forms of osteocalcin in uremic serum. J. Clin Invest 77: 1762-67, 1986.

2. Power M.J., Gosling J.P., Fotrell P.F. Radioimmunoassay of osteocalcin with polyclonal and monoclonal antibodies. Clin Chem 35: 1408-15, 1989.

3. Calvo M.S., Eyre D.R., and Gundberg C.M. Molecular Basis and Clinical Application of Biological Markers of Bone Turnover. Endocrine Reviews 17 (4): 333-364, 1996.

4. Bodine, P.V.N., Trailsmith, M. and B.S. Komm. Development and Characterization of a Conditionally Transformed Adult Human Osteoblastic Cell Line. J. of Bone & Miner. Res. 11: 806-819, 1996.

5. Nutall, M.E., Patton, A. J., Olivera, D.L. Nadeau, D.P., & M. Gowen. Human Trabecular Bone Cells are able to Express Both Osteoblastic and Adipocytic Phenotype: Implications for Osteopenic Disorders. J. of Bone & Miner. Res. 13: 371-382, 1998.

**BTI Intact Osteocalcin EIA Kit**
Catalog No: BT-460
(sufficient reagents and precoated 96-well strips)
Quantity: 1 kit

Specifications:
Sample Size: 25ul
Assay Time: 3.5 hours
Sensitivity: 0.5 ng/ml
Range: 1.0- 50 ng/ml
Intraassay Variation: 7%
Interassay Variation: 10.5%

FOR RESEARCH USE ONLY. NOT FOR USE IN HUMANS OR AS AN IN-VITRO DIAGNOSTIC.

# APPENDIX G

## BALANCE SCALES (BERG AND FICSIT-4)

Name: _____ Date:_____

Rater: _____

# BERG BALANCE SCALE

## 14-Item Long Form Original Version

**1. SITTING TO STANDING**
*INSTRUCTIONS: Please stand up. Try not to use your hands for support.*
(4) able to stand without using hands and stabilize independently
(3) able to stand independently using hands
(2) able to stand using hands after several tries
(1) needs minimal aid to stand or to stabilize
(0) needs moderate or maximal assist to stand

**2. STANDING UNSUPPORTED**
*INSTRUCTIONS: Please stand for two minutes without holding.*
(4) able to stand safely 2 minutes
(3) able to stand 2 minutes with supervision
(2) able to stand 30 seconds unsupported
(1) needs several tries to stand 30 seconds unsupported
(0) unable to stand 30 seconds unassisted If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

**3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL**
*INSTRUCTIONS: Please sit with arms folded for 2 minutes.*
(4) able to sit safely and securely 2 minutes
(3) able to sit 2 minutes under supervision
(2) able to sit 30 seconds
(1) able to sit 10 seconds
(0) unable to sit without support 10 seconds

**4. STANDING TO SITTING**
*INSTRUCTIONS: Please sit down.*
(4) sits safely with minimal use of hands
(3) controls descent by using hands
(2) uses back of legs against chair to control descent
(1) sits independently but has uncontrolled descent
(0) needs assistance to sit

**5. TRANSFERS**
*INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.*
(4) able to transfer safely with minor use of hands
(3) able to transfer safely definite need of hands
(2) able to transfer with verbal cueing and/or supervision
(1) needs one person to assist
(0) needs two people to assist or supervise to be safe

**6. STANDING UNSUPPORTED WITH EYES CLOSED**
*INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.*
(4) able to stand 10 seconds safely
(3) able to stand 10 seconds with supervision
(2) able to stand 3 seconds
(1) unable to keep eyes closed 3 seconds but stays steady
(0) needs help to keep from falling

**7. STANDING UNSUPPORTED WITH FEET TOGETHER**
*INSTRUCTIONS: Place your feet together and stand without holding.*
(4) able to place feet together independently and stand 1 minute safely
(3) able to place feet together independently and stand for 1 minute with supervision
(2) able to place feet together independently but unable to hold for 30 seconds
(1) needs help to attain position but able to stand 15 seconds feet together
(0) needs help to attain position and unable to hold for 15 seconds

( ) TOTAL SCORE (Maximum = 56) ,a person scoring below 45 is considered to be at risk for falling.

**8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING**
*INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reaches while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.).*
(4) can reach forward confidently >25 cm (10 inches)
(3) can reach forward >12 cm safely (5 inches)
(2) can reach forward >5 cm safely (2 inches)
(1) reaches forward but needs supervision
(0) loses balance while trying/requires external support

**9. PICK UP OBJECT FROM FLOOR FROM A STANDING POSITION**
*INSTRUCTIONS: Pick up shoe/slipper which is placed in front of your feet.*
(4) able to pick up slipper safely and easily
(3) able to pick up slipper but needs supervision
(2) unable to pick up but reaches 2-5cm (1-2 inches) from slipper and keeps balance independently
(1) unable to pick up and needs supervision while trying
(0) unable to try/needs assist to keep from losing balance or falling

**10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING**
*INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.*
(4) looks behind from both sides and weight shifts well
(3) looks behind one side only other side shows less weight shift
(2) turns sideways only but maintains balance
(1) needs supervision when turning
(0) needs assist to keep from losing balance or falling

**11. TURN 360 DEGREES**
*INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.*
(4) able to turn 360 degrees safely in 4 seconds or less
(3) able to turn 360 degrees safely one side only in 4 seconds or less
(2) able to turn 360 degrees safely but slowly
(1) needs close supervision or verbal cueing
(0) needs assistance while turning

**12. PLACING ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED**
*INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.*
(4) able to stand independently and safely and complete 8 steps in 20 seconds
(3) able to stand independently and complete 8 steps >20 seconds
(2) able to complete 4 steps without aid with supervision
(1) able to complete >2 steps needs minimal assist
(0) needs assistance to keep from falling/unable to try

**13. STANDING UNSUPPORTED ONE FOOT IN FRONT**
*INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width).*
(4) able to place foot tandem independently and hold 30 seconds
(3) able to place foot ahead of other independently and hold 30 seconds
(2) able to take small step independently and hold 30 seconds
(1) needs help to step but can hold 15 seconds
(0) loses balance while stepping or standing

**14. STANDING ON ONE LEG**
*INSTRUCTIONS: Stand on one leg as long as you can without holding.*
(4) able to lift leg independently and hold >10 seconds
(3) able to lift leg independently and hold 5-10 seconds
(2) able to lift leg independently and hold = or >3 seconds
(1) tries to lift leg unable to hold 3 seconds but remains standing independently
(0) unable to try or needs assist to prevent fall

# FICSIT-4

*(Frailty and Injuries: Cooperative Studies of Intervention Techniques)*

INSTRUCTIONS: Demonstrate each position to the subject, then ask them to perform and time.

F-1. **FEET CLOSELY TOGETHER**, UNSUPPORTED, **eyes open** (ROMBERG POSITION)
INSTRUCTIONS: Stand still with your feet together as demonstrated for 10 seconds.
☐4 able to stand 10 seconds safely
☐3 able to stand 10 seconds with supervision
☐2 able to stand 3 seconds
☐1 unable to stand 3 seconds but stays steady
☐0 needs help to keep from falling
If subject is able to do this, proceed to the next position, if not, stop.

F-2. **FEET CLOSELY TOGETHER**, UNSUPPORTED, **eyes closed** (ROMBERG POSITION)
INSTRUCTIONS: Please close your eyes and stand still with your feet together as demonstrated for 10 seconds.
☐4 able to stand 10 seconds safely
☐3 able to stand 10 seconds with supervision
☐2 able to stand 3 seconds
☐1 unable to keep eyes closed 3 seconds but stays steady
☐0 needs help to keep from falling
If subject is able to do this, proceed to the next position, if not, stop.

F-3. **SEMI-TANDEM**: **eyes open** HEEL OF 1 FOOT PLACED TO THE SIDE OF THE 1$^{ST}$ TOE OF THE OPPOSITE FOOT (SUBJECT CHOOSES WHICH FOOT GOES FORWARD)
INSTRUCTIONS: Please stand still with your feet together as demonstrated for 10 seconds.
☐4 able to stand 10 seconds safely
☐3 able to stand 10 seconds with supervision
☐2 able to stand 3 seconds
☐1 unable to stand 3 seconds but stays steady
☐0 needs help to keep from falling
If subject is able to do this, proceed to the next position, if not, stop.

F-4. **SEMI-TANDEM**: **eyes closed** HEEL OF 1 FOOT PLACED TO THE SIDE OF THE 1$^{ST}$ TOE OF THE OPPOSITE FOOT (SUBJECT CHOOSES WHICH FOOT GOES FORWARD)
INSTRUCTIONS: Please close your eyes and stand still with your feet together as demonstrated for 10 seconds.
☐4 able to stand 10 seconds safely
☐3 able to stand 10 seconds with supervision
☐2 able to stand 3 seconds
☐1 unable to keep eyes closed 3 seconds but stays steady
☐0 needs help to keep from falling
If subject is able to do this, proceed to the next position, if not, stop.

F-5. **FULL TANDEM**: **eyes open** HEEL OF 1 FOOT DIRECTLY IN FRONT OF THE OTHER FOOT (SUBJECT CHOOSES WHICH FOOT GOES FORWARD)
INSTRUCTIONS: Please stand still with your feet together as demonstrated for 10 seconds.
☐4 able to stand 10 seconds safely
☐3 able to stand 10 seconds with supervision
☐2 able to stand 3 seconds
☐1 unable to stand 3 seconds but stays steady
☐0 needs help to keep from falling
If subject is able to do this, proceed to the next position, if not, stop.

F-6. **FULL TANDEM**: **eyes closed** HEEL OF 1 FOOT DIRECTLY IN FRONT OF THE OTHER FOOT (SUBJECT CHOOSES WHICH FOOT GOES FORWARD)
INSTRUCTIONS: Please stand still with your feet together as demonstrated for 10 seconds.
☐4 able to stand 10 seconds safely
☐3 able to stand 10 seconds with supervision
☐2 able to stand 3 seconds
☐1 unable to stand 3 seconds but stays steady
☐0 needs help to keep from falling
If subject is able to do this, proceed to the next position, if not, stop

F-7. **STANDING ON ONE LEG**: **eyes open**
INSTRUCTIONS: Stand on one leg as long as you can without holding.
☐4 able to lift leg independently and hold >10 seconds
☐3 able to lift leg independently and hold 5-10 seconds
☐2 able to lift leg independently and hold = or >3 seconds
☐1 tries to lift leg unable to hold 3 seconds but remains standing independently
☐0 unable to try or needs assist to prevent fall

Total FICSIT-4 Static Balance score =_____/ 28

# APPENDIX H

## WII FIT® EXERCISE LOG

**Wii Fit Study Exercise Log** **Participant:** **Date:**

**Yoga**

| | | |
|---|---|---|
| Half-Moon | ☐ Yes | ☐ No |
| Warrior | ☐ Yes | ☐ No |
| Standing Knee | ☐ Yes | ☐ No |

**Muscular Strength/Endurance**

| | | |
|---|---|---|
| Torso Twists | ☐ Yes | ☐ No |
| Lunges | ☐ Yes | ☐ No |

**Balance Games**

| | | |
|---|---|---|
| Tilt City | ☐ Yes | ☐ No |
| Balance Bubble Plus | ☐ Yes | ☐ No |
| Soccer Heading | ☐ Yes | ☐ No |

**Additional Games**

| | | |
|---|---|---|
| Did you play any games not included above? | ☐ Yes | ☐ No |

Which ones?

**Comment**

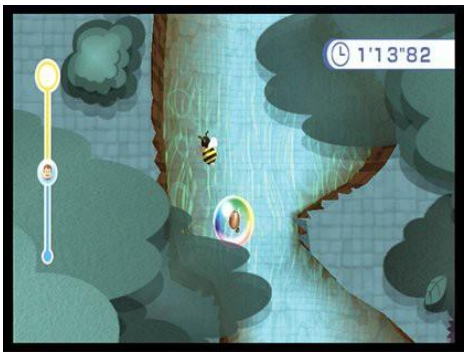
# APPENDIX I

# EXERCISE SCREENSHOTS

**Balance Games:**

Tilt City/Table Tilt

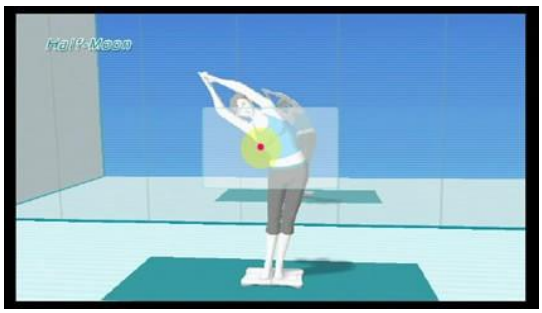
Balance Bubble



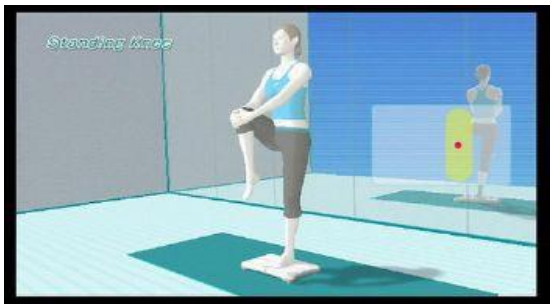

Soccer Heading


**Yoga Poses:**

Half-moon



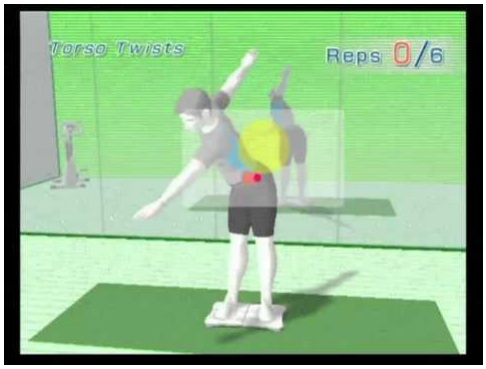

Standing Knee



Warrior


**Strength Training:**

Torso Twists




Lunges

# APPENDIX J

## TABLE 13: BASELINE BALANCE PARAMETERS (FORCE PLATE)

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| Open Base, Eyes Open | | | |
| Max Velocity X (mm/s) | 3.96 ± 2.43 | 2.51 ± 0.70 | 0.102 |
| Max Velocity Y (mm/s) | -3.34 ± 1.49 | -3.43 ± 1.90 | 0.910 |
| Average Velocity (mm/s) | 0.83 ± 0.21 | 0.88 ± 0.22 | 0.61 |
| Major Axis ($mm^2$) | 1.37 ± 0.56 | 1.25 ± 0.39 | 0.602 |
| Area Effective ($mm^2$) | 1.30 ± 0.94 | 0.99 ± 0.57 | 0.418 |
| Area 95 ($mm^2$) | 2.44 ± 1.43 | 1.77 ± 0.92 | 0.251 |
| Closed Base, Eyes Open | | | |
| Max Velocity X (mm/s) | 4.42 ± 2.14 | 4.44 ± 3.02 | 0.987 |
| Max Velocity Y (mm/s) | -4.17 ± 1.66 | -3.84 ± 1.13 | 0.619 |
| Average Velocity (mm/s) | 1.48 ± 0.40 | 1.55 ± 0.54 | 0.721 |
| Major Axis ($mm^2$) | 1.26 ± 0.54 | 1.11 ± 0.36 | 0.492 |
| Area Effective ($mm^2$) | 1.34 ± 0.99 | 0.98 ± 0.57 | 0.373 |
| Area 95 ($mm^2$) | 3.25 ± 1.66 | 2.61 ± 1.33 | 0.365 |
| Closed Base, Eyes Closed | | | |
| Max Velocity X (mm/s) | 8.06 ± 4.79 | 6.12 ± 2.65 | 0.294 |
| Max Velocity Y (mm/s) | -7.72 ± 5.83 | -6.15 ± 2.16 | 0.457 |
| Average Velocity (mm/s) | 2.66 ± 1.16 | 2.03 ± 0.33 | 0.135 |
| Major Axis ($mm^2$) | 1.66 ± 0.51 | 1.36 ± 0.41 | 0.210 |
| Area Effective ($mm^2$) | 2.35 ± 1.27 | 1.48 ± 0.91 | 0.118 |
| Area 95 ($mm^2$) | 5.02 ± 2.14 | 1.36 ± 0.41 | 0.376 |
| Semi-Tandem, Eyes Open | | | |
| Max Velocity X (mm/s) | 5.42 ± 1.64 | 32.83 ± 81.8 | 0.259 |
| Max Velocity Y (mm/s) | -5.32 ± 1.36 | -17.37 ± 34.88 | 0.289 |
| Average Velocity (mm/s) | 2.06 ± 0.37 | 3.72 ± 5.09 | 0.317 |
| Major Axis ($mm^2$) | 1.36 ± 0.29 | 2.52 ± 3.24 | 0.275 |
| Area Effective ($mm^2$) | 1.44 ± 0.51 | 9.14 ± 22.75 | 0.299 |
| Area 95 ($mm^2$) | 3.87 ± 1.18 | 15.53 ± 35.38 | 0.311 |

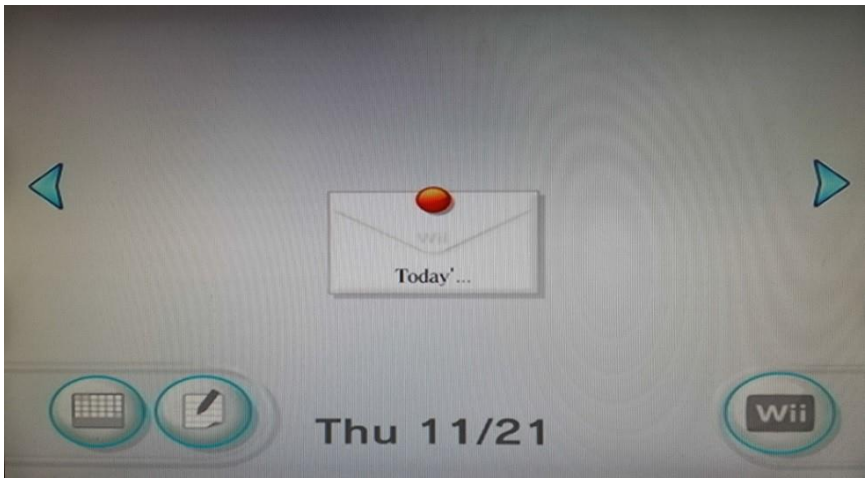
| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| Semi-Tandem, Eyes Closed | | | |
| Max Velocity X (mm/s) | 12.60 ± 4.46 | 38.50 ± 85.07 | 0.347 |
| Max Velocity Y (mm/s) | -12.21 ± 5.05 | -20.20 ± 36.45 | 0.500 |
| Average Velocity (mm/s) | 3.83 ± 1.21 | 4.55 ± 5.21 | 0.673 |
| Major Axis ($mm^2$) | 2.29 ± 1.05 | 2.98 ± 3.33 | 0.546 |
| Area Effective ($mm^2$) | 4.35 ± 3.51 | 10.92 ± 23.84 | 0.399 |
| Area 95 ($mm^2$) | 10.79 ± 7.28 | 19.31 ± 36.76 | 0.482 |
| Tandem, Eyes Open | | | |
| Max Velocity X (mm/s) | 12.99 ± 6.25 | 18.87 ± 15.70 | 0.317 |
| Max Velocity Y (mm/s) | -12.17 ± 6.25 | -19.17 ± 19.73 | 0.304 |
| Average Velocity (mm/s) | 4.12 ± 1.21 | 4.92 ± 2.48 | 0.377 |
| Major Axis ($mm^2$) | 1.79 ± 0.66 | 3.60 ± 4.00 | 0.217 |
| Area Effective ($mm^2$) | 2.56 ± 1.42 | 16.18 ± 32.19 | 0.240 |
| Area 95 ($mm^2$) | 6.53 ± 3.44 | 30.46 ± 57.03 | 0.244 |
| Tandem, Eyes Closed | | | |
| Max Velocity X (mm/s) | 20.84 ± 7.04 | 9.60 ± 11.57 | 0.383 |
| Max Velocity Y (mm/s) | -19.67 ± 6.45 | -8.15 ± 9.84 | 0.321 |
| Average Velocity (mm/s) | 6.31 ± 1.33 | 2.64 ± 2.64 | 0.281 |
| Major Axis ($mm^2$) | 2.68 ± 0.824 | 1.73 ± 1.25 | 0.248 |
| Area Effective ($mm^2$) | 5.49 ± 2.63 | 2.55 ± 3.02 | 0.230 |
| Area 95 ($mm^2$) | 14.34 ± 6.77 | 6.31 ± 7.96 | 0.209 |
| Single Leg, Eyes Open | | | |
| Max Velocity X (mm/s) | 16.53 ± 8.96 | 18.14 ± 8.05 | 0.737 |
| Max Velocity Y (mm/s) | -18.44 ± 10.47 | -14.21 ± 7.55 | 0.416 |
| Average Velocity (mm/s) | 6.00 ± 2.99 | 5.13 ± 2.31 | 0.567 |
| Major Axis ($mm^2$) | 2.01 ± 1.22 | 1.74 ± 0.53 | 0.604 |
| Area Effective ($mm^2$) | 3.84 ± 4.32 | 2.68 ± 1.56 | 0.521 |
| Area 95 ($mm^2$) | 10.21 ± 10.81 | 7.64 ± 4.69 | 0.580 |

| | Intervention (M ± SD) | Control (M ± SD) | p-value |
|---|---|---|---|
| Open Base, Eyes Closed | | | |
| Max Velocity X (mm/s) | 5.79 ± 9.01 | 2.02 ± 0.81 | 0.228 |
| Max Velocity Y (mm/s) | -4.43 ± 6.47 | -1.94 ± 0.54 | 0.267 |
| Average Velocity (mm/s) | 2.82 ± 4.73 | 1.13 ± 0.23 | 0.298 |
| Major Axis ($mm^2$) | 1.73 ± 1.62 | 1.02 ± 0.24 | 0.215 |
| Area Effective ($mm^2$) | 3.95± 8.89 | 0.65 ± 0.26 | 0.280 |
| Area 95 ($mm^2$) | 10.52 ± 25.61 | 1.14 ± 0.53 | 0.335 |
| Berg Tandem, Eyes Open | | | |
| Max Velocity X (mm/s) | 14.15 ± 3.06 | 20.64 ± 10.38 | 0.155 |
| Max Velocity Y (mm/s) | -13.17 ± 2.38 | -21.95 ± 15.10 | 0.176 |
| Average Velocity (mm/s) | 3.74 ± 0.80 | 4.50 ± 1.65 | 0.241 |
| Major Axis ($mm^2$) | 1.87 ± 0.29 | 2.41 ± 0.86 | 0.156 |
| Area Effective ($mm^2$) | 2.79 ± 0.81 | 4.63 ± 3.07 | 0.170 |
| Area 95 ($mm^2$) | 7.83 ± 2.29 | 11.79 ± 7.42 | 0.215 |

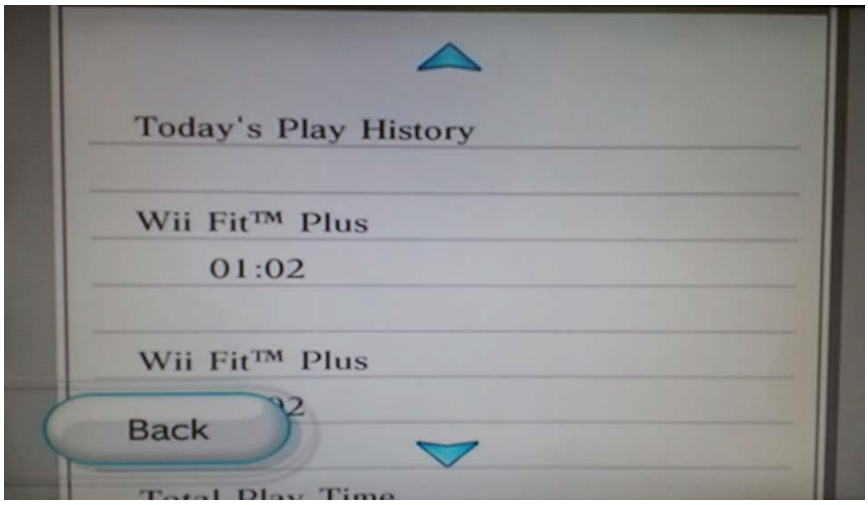
# APPENDIX K

## SCREENSHOTS OF ELECTRONIC RECORD

Welcome Screen:




Time Log:



# BIOGRAPHICAL SKETCH

Sarah Jo Wherry was born in Mesa, Arizona and relocated to Altoona, Pennsylvania with her family when she was three years old, where she received her high school education at Altoona Area High School. She completed her undergraduate studies at the Pennsylvania State University in University Park, PA, earning her BS in Life Science with a Psychology Minor. Upon graduation she moved to Scranton, PA to earn her MS in Sports Nutrition and Exercise Science at Marywood University. During her MS, she became a member of Kappa Omicron Nu Nutrition Honor Society and was the Graduate Assistant for the Human Physiology Lab. In 2011, she entered Arizona State University to begin her doctoral studies in Physical Activity, Nutrition and Wellness. During her time at ASU, she was accepted to the Phi Kappa Phi Honor Society, served as the President of the Exercise and Wellness Club, and was elected to the role of College Representative of the Graduate Women's Association for the College of Health Solutions. She also received two grants from the Graduate and Professional Student Association to assist in funding her pilot work and the blood assays for her dissertation research as well as received an American College of Sports Medicine (ACSM) Foundation Doctoral Student Research Grant to fund the majority of her dissertation work. She has accepted a postdoctoral fellow position at the University of Colorado Denver Anschutz Medical Center studying bone physiology beginning Summer 2014.