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EXAMINING THE ASSOCIATIONS BETWEEN LEAN MASS, MUSCULAR
STRENGTH, MUSCLE QUALITY AND PHYSICAL FUNCTION

BY

SYDNEY REIGLE

A THESIS SUBMITTED IN FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF

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UNIVERSITY OF RHODE ISLAND

2020

MASTER OF SCIENCE THESIS

OF

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2020

ABSTRACT

Objective: The determinants of physical function are not well characterized among middle-aged women. The primary aim of this cross-sectional study was to determine the strength of the associations between lean mass, muscular strength, muscle quality, and physical functional ability in a cohort of middle-aged women. The secondary aim was to determine the measure of muscle quality most highly associated with measures of physical function.

Methods: Middle-aged women (N=111, age, 53.14 ± 6.15 years) had body composition (via dual energy x-ray absorptiometry), physical activity (via accelerometer), and physical function (via Transfer Task (TRANSFER), 30-Second Chair Stand (30-CS), 6-Minute Walk Test (6MWT), 8-Foot-Up-And-Go (UP-GO)) assessed objectively. A lower body physical function composite score was also calculated. Lower body strength was measured using isokinetic dynamometry for isometric knee flexion and extension at 60 degrees, isokinetic flexion and extension at 60 degrees per second, and isokinetic flexion and extension at 180 degrees per second. Muscle quality was defined as muscular strength normalized for upper leg lean mass and calculated using: 1) isometric knee flexion and extension at 60 degrees (MQ-ISO), 2) isokinetic knee flexion and extension at 60 degrees per second (MQ-KN60), 3) isokinetic knee flexion and extension at 180 degrees per second (MQ-KN180).

Results: The lower body physical function composite score was significantly associated with percent lean mass, MQ-ISO, MQ-KN60, and MQ-KN180. Partial correlations, controlled for age and average steps per day, found that MQ-KN60 was the variable most highly associated with the physical function composite score. Results from a hierarchical linear regression showed that 1) age, average steps per day, and MQ-KN60 are

independently associated with physical function composite score, explaining 3%, 18.1% and 14.3% respectively, and 2) age, average steps per day, MQ-KN60 were significantly associated with , TRANSFER, 30-CS, and 6MWT.

Conclusion: In middle-aged women, percent lean mass, muscular strength, and muscle quality were all significantly associated with physical functional ability. The association between MQ-KN60 and the physical function composite score was stronger than all other measured variables. This data provides insight into the most relevant measures to consider when examining the independent contributors to physical functional ability in middle-aged women.

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PREFACE

This thesis document contains one manuscript: Examining the Associations Between Lean Mass, Muscular Strength, Muscle Quality and Physical Function. This document complies with the University of Rhode Island Graduate School Manuscript format, with a form formatted for publication in Menopause.

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MANUSCRIPT

Examining The Associations Between Lean Mass, Muscular Strength, Muscle Quality and Physical Function

This manuscript is prepared for submission to: Menopause

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Riebe

CHAPTER 1

INTRODUCTION

In 2014, 83 million Americans were between the age of 45 and 64 years, and it is projected by 2060 the number of Americans who are middle-aged will increase to 100 million (1). Recent studies report that middle-aged adults, specifically middle-aged women, self-report difficulties performing daily activities and have poor physical function (2–4), where up to 25% of women between the age of 42 and 52 years old (2). Physical function performance is an aspect of quality of life, defined as the ability to perform the basic actions that are essential for maintaining independence (5). Extensive research assessing physical function in older adults demonstrates that physical function performance is associated with physical activity level (6), lean mass, and muscular strength (5,7–10), however significantly less is known about physical function in middle-aged adults.

While lean mass and muscular strength are independently associated with physical function, examining a measure that accounts for both variables may be the most comprehensive approach to understanding the association between these variables and physical function outcomes. One way to examine the association between lean mass and muscular capacity is by calculating muscle quality. Muscle quality is defined as the ratio of muscular capacity to lean mass (11). Muscle quality assesses the association between muscular strength and lean mass, therefore it may be an optimal independent variable to examine when evaluating determinants of the changes in physical function, compared to lean mass and muscular strength alone (12).

Previous research in older adults has examined how lean mass, muscular strength, and muscle quality, change with age and how these variables are associated with physical function (13–15). Limited research has examined these associations in middle-aged adults, especially middle-aged women (4,16). This is significant because in previous studies, as many as 25% of women are reporting physical functional limitations during mid-life (2). Additionally, negative changes in body composition and muscular capacity often begin during middle-age (5,8,9,11,17) making it important to understand how the associations develop and which factors most affect physical function. Analyzing these factors during middle-age would allow for better understanding of the association between muscle mass, muscular strength, muscle quality and physical functional ability.

Therefore, the primary aim of this study is to examine the strength of the associations between muscle mass, muscular strength, muscle quality and objective measures of physical function performance in a cohort of middle-aged females, when controlling for age and physical activity level. It is hypothesized that measures of muscle quality will be more strongly related to measures of physical function performance compared to measures of muscle mass and muscular strength. As muscle quality takes into consideration both the structural and functional ability of the muscle, it may have the strongest impact on physical function performance compared to muscular strength or lean mass alone.

The secondary aim of the study is to compare muscle quality calculated using three different muscular strength measures, to determine which measure is most highly associated with objective measures of physical function, when controlling for age and physical activity level. Strength will be measured by isometric knee strength at 60

degrees (MQ-ISO), isokinetic knee strength measured at 60 degrees per second (MQ-KN60), and isokinetic knee strength at 180 degrees per second (MQ-KN180), all normalized for lean mass. It is hypothesized that the MQ-KN180 will be most highly related to physical function compared to other measures of muscle quality in middle-aged women. This is predicted because 180 degrees per second most resembles the speed at which daily activities occurs (20–23), thus it may be the most appropriate when examining associations with physical function.

CHAPTER 2

REVIEW OF LITERATURE

Introduction

The US Census Bureau estimated that in 2014, 83 million Americans were between the age of 45 and 64 years old (1). While middle-aged women make up a significant portion of the population, they are significantly under-represented in research, even with recent efforts to correct this imbalance (18). In general, the hormonal changes associated with menopause are often cited as the primary challenge for including middle-aged women in research (18).

Most women go through menopause between 45 and 55 years of age and undergo significant hormonal changes including decreases in estrogen, IGF-1 and DHEA (19). These hormonal changes are associated with several negative health outcomes, including a decrease in muscle mass (19–21). Changes in muscular capacity, including muscular strength, endurance and power, have also been associated with age-related changes in sex hormones (19–22). Due to the current life expectancy, it is possible that a woman could spend 30 or more years with a decreased level in sex hormone compared to younger levels, resulting in a significant reduction in muscle mass and muscular capacity (20,21,23), which puts women at a high risk for disability and other health conditions.

Menopause has been associated with declines in physical function performance (24,25). This is concerning because low levels of physical function are associated with an increased risk of developing chronic health conditions (3,24,26). Therefore, it would be prudent to assess physical function during this time period. Currently there is a significant

gap in the literature regarding objective physical function performance in middle-aged women, as the majority of the work examining physical function in this age group relies on self-report measures (3,27,28).

It is important to understand the factors that independently contribute to physical function in order to understand changes in physical functional ability across the lifespan. Factors related to muscular capacity such as muscular strength, muscle mass and muscle quality are important to consider when assessing physical function. Muscle quality, a unique measurement that considers both measures of muscle mass and muscular strength, may be more strongly related to physical function performance compared to the assessment of muscle mass or muscular strength alone (11). The associations between muscle mass, muscular strength, muscle quality and physical functional ability have been well established in older populations (11,29–32), but a significant gap in the literature exists when it comes to these associations in middle-aged women. Therefore, analyzing the factors associated with physical function during middle-age would allow for better understanding of the significance of these associations and may allow for early intervention before the onset of physical limitations.

Physical Function

Physical function is the ability to perform the basic actions essential for maintaining independence (5). Physical function has been previously associated with the ability to perform activities of daily living, chronic health conditions, and overall health status across the lifespan (3,24,33).

Physical function can be assessed both subjectively and objectively. The most common subjective measure of physical function is the Medical Outcomes Survey Short Form 36

(SF-36) questionnaire (34). The portion of the SF-36 that assesses physical function includes 10-items which evaluate activities ranging from limitations during daily tasks such as carrying groceries or climbing stairs, to the ability to perform moderate and vigorous activities (35). The most common objective measures of physical function include the Short Physical Performance Battery Test (SPPB), the Timed Up-and-Go (TUG), Gait Speed, 5-Chair Stand, and the 6-Minute Walk test (6MWT) (36). Each of these physical function assessments is associated with an aspect of health-related physical fitness. For example, the time it takes to complete 5 consecutive chair stands is highly associated with muscular strength, and both gait speed and 6MWT have been highly associated with cardiorespiratory fitness levels (36). Commonly used physical function assessments are described below:

Short Physical Performance Battery (SPPB): The SPPB consists of three tasks: 4-Meter Gait Speed, Balance Assessment (which includes tandem and semi-tandem stance), and a 5-Chair Stand. This assessment is predictive of fall risk and disability in adults over the age of 70 years (36). The SPPB was specifically designed for older adults and is not appropriate for assessing physical functional ability in middle-aged adults.

Timed-Up-and-Go (TUG): The TUG measures the amount of time it takes a participant to stand up from a chair without the use of their arms, walk 3 meters, and return to a seated position in the chair (36). The TUG is associated with muscle power and balance (37), and is also predictive of fall risk in older adults (36).

6 Minute Walk Test (6MWT): The 6MWT measures the total distance a participant can walk on a premeasured course in 6 minutes. The 6MWT assesses both cardiorespiratory fitness and muscular endurance. An average distance traveled in healthy

middle to older-age adults (age range of 40 to 79) is 400 to 700 meters (38). In older adults, the distance tends to decline to 200 to 300 meters (36).

30-Second Chair Stand (30-CS): The 30-CS assesses lower body muscular strength by determining the number of times a participant can stand up and sit down in a 30 second time period (39).

Transfer Task (TRANSFER): The TRANSFER assesses strength, flexibility and function by measuring the amount of time it takes for the participant to transition from a standing position, to a seated position on the floor and back to a standing position (40).

These physical function tests are commonly used in older adults and may not be appropriate for middle-aged adults. Middle-aged adults typically have higher physical functional status compared to older adults, therefore the intensity of some of these assessments may not be high enough to see the slight changes in physical functional ability experienced in middle-age.

Physical Function and Health Status

Poor physical functional ability is associated with the development of chronic health conditions (41) and increased risk of physical disability (41,42) later in life, however, most of this research has been conducted with older adults.

One of the few studies that addressed physical function and health status in middle-age women was completed by Karvonen-Gutierrez et al. (2). This secondary analysis of the Study of Women Across the Nation (SWAN) data assessed the risk of disability in 326 women between the age of 55 and 68 years. Self-reported disability was measured using the World Health Organization-Disability Assessment Schedule (WHO-DAS), an international standardized measure of disability designed to compare the prevalence and

determinants of disability across different populations. Twenty-five percent of the cohort reported moderate, severe, or extreme disability, which indicates that middle-age may be an appropriate time to assess factors affiliated with physical disability so that effective interventions aimed at improving these outcomes in middle-age can be designed and implemented (2,24).

Another study which examined the association between physical function and disability is a secondary analysis of a larger longitudinal study(28). Men and women (n = 30,097) aged 45-82 years completed an adapted version of the Older Americans Resources and Services Multidimensional Assessment Questionnaire which measures disability and physical function and completed the 4-Meter Walk test, TUG, Single Leg Stance, 5-Chair Rise test at baseline and at an 18 month follow-up. The prevalence of disability increased with age and was more prevalent in women compared to men. Additionally, having lower levels of physical functional was strongly associated with an increased risk of development of functional limitations and disabilities. Falling in the lowest quintile for any one of the five objective physical function assessments increased the odds of having functional limitations and disability by 1.53 times and falling in the lowest quintile for all five tests increased the odds of having a functional limitation or disability by 14.91 times. Because this study found that women reported higher levels of disability compared to males, and a significant association existed between physical functional and disability, it suggests that physical functional ability should be further studied in women.

The association between physical functional ability and health status is well represented in the older adult literature (10,21), but significantly less is known about this association in middle-aged adults. However, studies that assess the association between

physical function and health status in middle-aged adults agree that lower physical functional ability is associated with an increased risk of disability (2,28).

Aging and Physical Function

Overall, previous research agrees that a significant association between age and physical functional ability exists. However, these studies primarily focus on physical function in older adults and use physical function assessments that have been validated for that population (27,29,43).

A 5-year study by Bouchard et al (43) supports the association between age and physical function in older adults. In both sexes, age was the most important contributor to balance performance measured by the Romberg test. Woods et al. (29) supports the association between physical function and age; women with lower physical function (measured via TUG and 6-Meter Walking Speed) were significantly older than the women with higher levels of physical function.

One of the few studies assessing physical function exclusively in middle-aged adults determined the association between physical functional ability (measured via 30-CS, UP-GO, 6MWT) and age in women between 45 to 65 years (44). This study found an independent association between age, UP-GO, and the 30-CS, in which older age was independently associated with lower physical function performance. Even at mid-life, physical function is significantly associated with age and those who are older perform more poorly on objective measures of physical function.

Another study which assesses middle-aged adults is using the U.S. National Health and Nutrition Examination Survey (NHANES) data, Bouchard et al. (27) explored the association between age and physical functional ability in adults over the age of 55 years.

There were differences in physical functional ability between age groups (55-64 years, 65-74 years, and ≥ 75 years), with older groups performing poorer than younger groups. When assessing subjective data, the 65-74-year-old age group reported poorer physical function compared to the 55-64-year-old age group.

Body Composition, Physical Activity, and Physical Function

Previous research demonstrates an association between measures of body composition, physical activity and physical functional ability (6,43,45).

Bouchard et al. (27) found that physical activity level was independently associated with walking speed in older men and women. Similarly, Savikangas et al. (6) determined that the time spent in either light or moderate to vigorous physical activity was positively associated with performance on the 6MWT, 10-Meter Walk, and SPPB. Since physical activity levels are associated with physical function, physical activity level should be considered a control variable when examining the determinants of physical function.

Another variable associated with physical functional ability is body composition, specifically percent body fat. Savikangas et al. (6) examined body composition and physical functional ability in a cohort of 293 sedentary older adults between the age of 70 and 85 years and found that percent body fat was negatively associated with 6MWT, 10-Meter Walk, and SPPB performance. Sternfeld et al. (45) supports the association between body composition and physical function. In the cross-sectional analysis of 2,092 men and women 55 years and older (mean of 59.3 years), body fat mass was found to be significantly associated with lower walking speeds. These studies demonstrate the importance of measuring body composition when assessing physical function as higher levels of fat mass

has been associated with reduces physical functional ability. Fat mass is important to consider as it may explain some of the variance in the performance of the tasks because the individual is required to move around a larger mass during the physical functional assessments requiring a higher strength or power to perform the tasks.

Muscle Mass and Physical Functional Ability

Aging

A significant body of research examining the changes that occur in muscle mass with age exists (7,8,10,31,46,47). Typically, muscle mass begins to decrease around the age of 20 for women and declines at a rate between 0.4 and 0.8 kg per decade (30,56); the rate of decline significantly increases to 1.1 kg per decade after the age of 60 (36).

Kyle et al. (31) assessed body composition using dual energy x-ray absorptiometry in a cohort of 433 men and women between the age of 19 and 94 years divided into 4 age groups: 18-34, 35-49, 50-74, and 75 and older. Appendicular muscle mass was highest in the 35-49 age group for men and the 18-34 age group for women. Differences in skeletal muscle mass was calculated to compare individuals < 60 years and $\geq$ 60-years. It was found that skeletal muscle mass declined from peak muscle mass until the age of 60 in both men and women (men: 1.5 kg/decade, women: 0.8 kg/decade). This was followed by a steeper decline in both men and women $\geq$ 60 years of age (men: 1.7 kg/decade, women: 1.1 kg/decade). This study demonstrated that the age-related decline in muscle mass differs between men and women and that muscle mass peaks earlier than mid-life in women.

Results from a cross-sectional study performed by Janssen et al. (48) supports the association between age and skeletal muscle mass. They found that age was negatively

associated with total and upper body muscle mass. When examining difference between upper and lower body muscle mass between age groups (both sexes were divided into: 18-44 years and ≥ 45 years old), both upper and lower body muscle mass were significantly associated with age (lower body: $r = -.48$, upper body: $r = -.26$) in women, but was only significantly associated with lower body muscle mass ($r = -.48$) in men. However, for both sexes, age was more highly associated with lower body muscle mass compared to upper body muscle mass.

Physical Function

The majority of the studies examining the association between muscle mass and physical function have been conducted with older adults (49–52). For example, Visser et al. (50) found a significant association between leg muscle mass and lower extremity physical performance in both men and women between the ages of 70 and 79 years. A study by Buford et al. (49) examined the association between body composition and physical function in a cohort of young (18-35 years) and older adults (>70 years). Physical function was assessed using the SPPB in the older adults, and muscle mass of the femoral and tibiofibular regions were assessed via magnetic resonance imaging (MRI). The amount of lower body muscle mass was negatively associated with age and functional status within the older adults.

A cross-sectional study performed by Reid et al. (51) assessed the association between total leg lean mass and physical ability in a cohort of 57 older adults (mean age of 74.2 years). Total lean leg mass was independently associated of mobility disability after correcting for confounding variables, such as chronic medical diagnoses, bone mineral density, body weight, total body fat, and habitual physical activity ($p < 0.05$).

Another study which supports the association between muscle mass, mobility limitations, and disability was a secondary analysis assessing a cohort of 2,631 older adults from the Health ABC study (52). Lower muscle mass (those in the lowest quartile of muscle mass cross sectional area) at baseline increased the risk of developing mobility limitations within the 3 year follow up, as men with lower muscle mass were 2.25 times and women were 1.7 times more likely to develop mobility limitations at follow-up compared to individuals in the highest quartile of muscle mass. The results from this study indicate that low muscle mass significantly effects mobility over a relatively short period of time.

The association between low muscle mass and poorer physical functional ability has been well established in older adults (49–52). However, literature assessing the association between muscle mass and physical function in middle-age adults is limited (24).

Muscular Strength

Muscular Strength Across the Lifespan

The age associated change in muscular strength (27), defined as the force producing capacity of muscle (11), has been assessed in depth in previous research (13,32,47,53–56).

In a cross-sectional study performed by Charlier et al. (56) significant associations between age and measures of strength were observed in both sexes. In women, skeletal muscle strength was 28.7% lower in the 60-70-year-olds compared to 18-29-year-olds. After the age of 70, muscular strength was 52.2% lower compared to the 18-29-year-old group.

A 3-year longitudinal study by Goodpaster et al. (15), also supports the association

between muscular strength and age. Baseline body weight and measures of total lean mass, leg regional lean mass, and thigh cross-sectional area were negatively correlated with the changes in muscular strength at follow-up.

Work by Delmonico et al. (13) supports the association between muscular strength and physical function older adults. Significant declines in average torque of the knee extensors measured at 60 degrees per second were seen in both men and women over the 5-year time period, where men lost an average of 24.5 N-m (16.1% change) and women lost an average of 12.7 N-m (13.4% change).

Muscular Strength and Physical Function

A significant body of literature exists addressing the association between muscular strength and physical function in older adults. A meta-analysis summarized the literature that assessed the longitudinal changes of muscular strength and physical function in older adults (53). The studies included muscular strength of the upper and lower body and demonstrated a consensus establishing an association between low muscular strength and functional decline in older adults. This is an important analysis as it examined the research assessing the associations between upper body muscular strength, lower body muscular strength, and physical functional ability (11,54,57–59). This meta-analysis found poorer upper and lower body muscular strength to be significantly associated with overall physical functional performance, however some studies reported that upper body muscular strength was not significantly associated with gait speed.

A secondary analysis of the Health ABC study by Cawthon et al. (47) supports the association between muscular strength and physical functional ability. The study found that knee strength was significantly correlated with walking speed and the timed 5-Chair Stand

in both men and women.

Barbat-Artigas et al. (54) performed a cross-section analysis to determine the association between physical function and upper and lower body muscular strength in 1,462 women aged 75 years and older. Lower body muscular strength was more highly associated with physical functional ability, compared to upper body muscular strength. The results of this study are significant as it supports the use of lower body physical function tasks when assessing physical functional performance.

A cross-sectional study performed by Ferrucci et al. (32) supports the association between lower body muscular strength and physical functional performance in older adults. This study examined 985 women aged 65 years and older, who completed objective measures of physical function. Muscular strength and physical function performance were significantly associated and women who were unable to walk, need an assistive device, or were unable to perform the balance test had significantly lower knee extension and hip flexion strength compared to those who were able to perform the tasks.

Research performed by Miljkovic et al. (8) also supports the association between muscular strength and physical ability. Older adults who had low muscular strength increased their risk of mobility limitations by 2.6 times, slow gait speed by 4.3 times, and mortality by 2.1 times compared to older adults with higher muscular strength.

The association between muscular strength and physical functional ability in middle-age is not well examined, but the association exists in older adults. Understanding the association between muscular strength and physical functional ability in middle-age would allow insight into a possible explanation why physical function declines in middle-age. If an association is established, it could provide a possible intervention strategy to help

reduce the decline of physical function later in life.

Muscle Strength and Physical Function in Middle-Aged Adults

The small body of literature that assesses muscular strength and physical function in middle-age adults supports the association between muscular strength and physical function. Ward-Ritacco et al. (16) examined the association between muscular strength and physical function in a cohort of 64 women between the ages of 50 and 65 years old. Muscular strength was assessed at 60 degrees per second using isokinetic dynamometry. Physical function was assessed objectively through the use of UP-GO, 30-CS, and 6MWT. Muscular strength was found to be highly associated with all physical performance assessments.

Muscular strength and physical function (measured by 12.3-meter walk, stair climb, and stair descent, and isometric knee extension) was assessed in a cohort of 880 middle-aged women by Sowers et al. (4). Gait speed decreased with age, and a significant number of women has a gait speed below 1.0 m/s, which is problematic because the federal standard for crossing an intersection is 1.22 m/s. The 12.3-meter walk was significantly associated with quadriceps strength. While gait speed was not assessed in this study, it does demonstrate that some common measures of physical functional are sensitive enough to identify changes in physical functional ability in middle-age women.

With the decline in muscular strength starting at an earlier age and declining at a faster rate at the end of mid-life for women, the assessment of muscular strength with physical function is important when assessing health risks and disability. Thus, understanding the best method for strength assessment and how muscular strength relates to physical functional performance is important to examine in cohorts of middle-aged

women.

Muscle Quality

Defining Muscle Quality

Muscle quality is a unique measurement that does not yet have a universal definition (60). In exercise science, muscle quality is often defined as a measure of muscular strength or power normalized for muscle mass (54,60). Muscle quality combines both measures of muscle capacity and muscle mass and may be more highly related to physical function ability compared to the measurement of muscle mass or muscular strength alone (11,60).

In a symposium report from the 2016 International Conference on Frailty and Sarcopenia Research, Correa-de-Araujo et al. (60) commented on the need for a standardized measurement of muscle quality, and increased research to be conducted assessing the strength of the associations between muscle quality and physical function performance. Barbat-Artigas et al. (11) stated that muscle quality may better explain differences in physical function compared to muscle mass or muscle strength alone, because muscle mass and muscular strength are potentially interrelated and the combination of both would account for most changes in skeletal muscle properties. However, the lack of a universal definition has led to inconsistent findings in the literature (61,62).

Age-Associated Decline in Muscle Quality

A cross-sectional analysis of objectively measured muscle mass, muscular strength and muscle quality in 654 participants between the ages of 18 and 93 years found significant

age and gender associations with measures of muscle quality ($p < 0.001$) (63). Muscle quality decreased with age, and women had significantly lower muscle quality compared to men. This demonstrates the age and sex differences in muscle quality, suggesting the importance of understanding muscle quality in both men and women across the lifespan.

In a longitudinal study by Metter et al. (61), age-related declines in muscle mass, muscle strength and muscle quality ($p < 0.001$) were evident. However, muscle quality stayed relatively constant after 30-39-years of age. This differs from previous work examining these variables across time, as one study found an age associated decline in muscle quality starting at age 20 (63), demonstrating disagreement among studies examining age-related changes in muscle quality.

Muscle Quality and Physical Function

Evidence supports the association of muscle quality and physical function across the lifespan. Previous literature assessing muscle quality and physical functional ability in older adults exist (5,10,54,61,62,64), yet there is significantly less information available addressing muscle quality and physical functional ability during middle-age (16).

A literature review by Straight et al. (64) found that lower body muscle quality explained between 29% and 42% of the variance in physical function tests (Stair Ascent/Decent, Timed-Up-And-Go, and 7- Meter Walk) (65). This literature review supports the assessment of muscle quality as it explained a high percent of the variance in physical function score.

Straight et al. (66) assessed body composition, muscular power, muscle quality and lower extremity physical function in 94 women aged 65 years and older. Muscle quality,

defined as muscular power (assessed via Nottingham Power Rig) normalized for lower body mineral free muscle mass, was independently associated with physical function performance and explained 17% of the variance in performance. Additionally, a cross sectional study by Straight et al. (67) supports the association between of muscle quality and physical function. Muscle quality was defined in two ways: leg extension power normalized for mineral free lean mass of the lower body, and hand grip strength normalized for body size. Muscle quality defined as leg extension power normalized for mineral free lean mass of the lower body was more highly related to measures of physical function compared to the other definition of muscle quality, however, both muscle quality measurements were significant predictors of physical function outcomes. The research assessing the association between muscle quality and physical functional ability in older adults all conclude that measures of muscle quality explain a significant amount of the changes in physical function. Only a small amount of literature exists examining the association between muscle quality and physical functional ability in middle-aged women.

Ward-Ritacco et al. (16) assessed body composition via dual energy x-ray absorptiometry, physical activity via accelerometer, muscular strength at the knee joint via isokinetic dynamometry at 60 degrees per second, and muscle quality in a cohort of 64 post-menopausal women between the age of 45 and 65 years old. Muscle quality was a significant predictor of the 30-CS and the 6MWT, but not the 8-Foot-Up-And-Go. This study is one of the few studies assessing muscle quality and physical function in a cohort of middle-age women, and the significant findings demonstrate the importance of assessing each of these factors in middle-aged women.

Conclusion

Poor physical function ability is associated with an increased risk for the development of chronic diseases and disability (28,41,42). Physical function has been studied extensively in older adults, but significantly less research has been done examining physical function in middle-aged adults. In order to fully understand physical function and its determinants in middle-aged adults, muscle mass, muscular strength, and muscle quality should all be assessed, as all have been found to be independently associated with physical functional ability (13,49,66,68) and each have been separately associated with adverse health outcomes (8,50,51,64,69).

CHAPTER 3

METHODOLOGY

Study Design: This is a secondary analysis from a larger cross-sectional study (WHII Research Project IRB #HU1516-206) designed to examine the impact of physical and psychological factors on quality of life in middle-aged women. Participants were recruited by word of mouth, fliers, and e-mail from the University of Rhode Island and surrounding community.

Procedures: Interested participants completed an online survey to determine eligibility. To be eligible, participants had to be a woman between the ages of 40 and 64 years old. Additionally, all participants were required to speak and read English, be weight stable (~5 pounds for the past 3 months), have a body mass index (BMI) between 18.5 and 45.0 kg/m², be a non-smoker, not be pregnant, be living independently, be free of diseases or conditions that would prevent reasonably safe participation in the study, be willing to wear a physical activity monitor for 7-10 days, and be willing to have a Dual Energy X-ray Absorptiometry scan.

Once determined to be eligible, participants scheduled two laboratory-based visits separated by 7-10 days. During the first visit, informed consent, the Mini-Mental State Examination (MMSE) (80,81) and Physical Activity Readiness Questionnaire (82,83) were completed. During Visit 1 participants also completed all physical function assessments, a Dual Energy X-ray Absorptiometry exam, and were provided with an ActiGraph accelerometer (ActiGraph GT9XLink, Pensacola, FL) to wear and a physical

activity log to complete in between visits. During Visit 2, participants completed muscular strength assessments via a Biodex Isokinetic Dynamometer (Biodex System 4 Pro, Biodex Medical Systems, Inc., Shirley, NY) and physical activity logs were collected and reviewed.

Anthropometric Assessment: Body weight was assessed via digital scale (Tanita WB-100, Arlington Heights, IL), and height was assessed via stadiometer (Seca 213, Chino, CA).

Menopausal Status: Menopause status was obtained by self-report, and then classified according to the SWAN criteria (24,25).

Body Composition: Dual Energy X-ray Absorptiometry (GE Lunar iDXA, Waukesha, WI) was used to assess body composition (fat mass, percent body fat, and lean mass).

Upper leg lean mass was also assessed and was defined as lean mass contained within the area between the neck of the femur and the medial and lateral condyles of the femur.

Muscular Strength: Muscular strength was assessed using an isokinetic dynamometer (Biodex, system 4 Pro, Shirley, NY). Participants underwent bilateral testing for isometric knee flexion and extension at 60 degrees with 3 sets (holding for 5 seconds each). Bilateral isokinetic knee extension and flexion at 60 degrees per second and 180 degrees per second were assessed with 2 sets of 4 repetitions. All muscular strength assessments were conducted in a randomized fashion. The trials that resulted in the greatest peak torque for the right and left limbs were summed to calculate total peak torque for the muscular strength assessment of interest.

Assessment of Muscle Quality: Muscle quality was calculated as muscular strength normalized for upper leg lean mass. Measures of right and left upper leg lean mass were summed and muscle quality was calculated in three ways: 1) the ratio of upper leg lean

mass to isometric knee flexion and extension at 60 degrees (MQ-ISO), 2) the ratio of upper leg lean mass to isokinetic knee flexion and extension at 60 degrees per second (MQ-KN60), and 3) the ratio of upper leg lean mass to isokinetic knee flexion and extension at 180 degrees per second (MQ-KN180).

Physical Activity: Physical activity was assessed by accelerometry (Actigraph GT9X LINK, Pensacola, FL) over a 7 to 10-day period. Participants were asked to wear the accelerometers on their non-dominant hip for at least 10 hours per day. To be included in the final analysis participants had to meet the 10-hour goal for at least 4 days. Step count was calculated using the mean step count on all days which the criteria of 10 hours of wear time was met. Minutes of moderate to vigorous physical activity was calculated as the mean time spent in moderate to vigorous physical activity on the days that participants met the 10-hour wear time goal.

Physical Function: Physical function was assessed using five objectively measured tests including, the Transfer Task (TRANSFER), the 8-Foot-Up-And-Go (UP-GO), 30 Second Chair Stand (30-CS), Lift and Carry, and Six- Minute Walk Test (6MWT). TRANSFER required participants to transfer from a standing position to a seated position on the floor and then back to a standing position as quickly as possible. The amount of time it took the participant to perform this task was measured and recorded. The UP-GO test required participants to stand up from a chair without using their arms, walk as quickly as they could around a cone paced 8 feet in front of the chair and return to the chair. The amount of time that it took the participant to perform this task was measured and recorded. The 30-CS required the participant, while keeping their arms crossed against their chest, to stand up and sit down as many times as possible in 30 seconds. The number of times the

participant stood was recorded. The 6MWT test required the participant to walk up and down the hallway on a pre-marked course (15.2 meters for one pass, 30.4 meters for one lap), turning around at the cones for a total of 6 minutes. The distance covered over the 6 minutes was measured and recorded.

Physical Function Composite Score: A composite score of lower body physical function assessment was calculated using the results from the TRANSFER, UP-GO the 30-CS, and 6MWT. To complete this calculation: 1) Z-scores were calculated for each physical function task, 2) Inverse z-scores were calculated for the UP-GO and the TRANSFER, as a lower score reflects better performance, 3) finally, the sum of z- scores for the 30-CS, 6MWT, and inverse z-scores for the UP-GO, and TRANSFER were added together for the final physical function composite score.

Statistical Analysis: All statistical analysis was performed with IBM SPSS Statistics software, version 26.0 (IBM Corporation, Armonk, NY). Means and SDs were calculated for all participant characteristics and data was confirmed for normal distribution.

Outlying values were identified as greater or less than 3 SD from the mean.

Pearson correlations were conducted to examine the associations between age, BMI, percent fat mass, percent lean mass, average moderate and vigorous physical activity per day, average steps per day, isokinetic peak torque at 180 degrees/second, isokinetic peak torque at 60 degrees/second, isometric peak torque at 60 degrees, MQ-ISO, MQ-KN180, MQ-KN60, TRANSFER, UP-GO, 30-CS, 6MWT, and the physical function composite score.

Next, partial correlations, controlling for age and average steps per day, were conducted to assess the strength of the associations between muscle quality and measures

of physical function. Finally, linear regression was used to identify the independent contribution of muscle quality to physical function (composite score and individual assessments of physical function), while controlling for age and physical activity (steps/day). Regression analyses were conducted in the following order, with the addition of a new variable with each step: 1) age; 2) steps/day; 3) specific measure of muscle quality. All data are presented as mean (SD) and all statistical significance were set at $p < 0.05$.

CHAPTER 4

FINDINGS

Participant characteristics (n=111) are presented in Table 1. The current sample was 53.14 (± 6.15) years of age, 97.3% white and consisted of 20.7% premenopausal, 23.4% perimenopausal, and 55.9% post-menopausal women.

The physical function composite score was significantly associated with BMI ($r=-0.39$), percent body fat ($r=-0.50$), percent lean mass ($r=0.50$), average moderate to vigorous physical activity ($r=0.38$), average steps per day ($r=0.39$), KN-180 ($r=0.33$), KN-60 ($r=0.31$), MQ-ISO ($r=0.25$), MQ-KN60 ($r=0.45$), MQ-KN180 ($r=0.44$) (all $p \leq 0.01$). TRANSFER was significantly associated with age ($r=0.25$), BMI ($r=0.29$), percent body fat ($r=0.45$), percent lean mass ($r=-0.45$), average moderate to vigorous physical activity ($r=-0.25$), average steps per day ($r=-0.24$), KN-180 ($r=-0.38$), KN-60 ($r=-0.34$), ISO ($r=-0.24$), MQ-ISO ($r=-0.27$), MQ-KN60 ($r=-0.40$), and MQ-KN180 ($r=-0.44$) (all $p \leq 0.01$). UP-GO was significantly associated with BMI ($r=0.21$), percent body fat ($r=0.28$), percent lean mass ($r=-0.28$), average moderate to vigorous physical activity ($r=-0.23$), average steps per day ($r=-0.23$), MQ-KN60 ($r=-0.20$)) (all $p \leq 0.05$). The 30-CS was significantly associated with BMI ($r=-0.26$), percent body fat ($r=-0.34$), percent lean mass ($r=-0.34$), average moderate to vigorous physical activity per day ($r=0.30$), average steps per day ($r=0.31$), KN-180 ($r=0.21$), KN-60 ($r=0.21$), MQ-ISO ($r=0.23$), MQ-KN60 ($r=0.34$), MQ-KN180 ($r=0.33$, $p<0.001$) (all ≤ 0.05). 6MWT was significantly associated with BMI ($r=-0.45$), percent body fat ($r=-0.47$), percent lean mass ($r=0.47$), average moderate to vigorous physical activity ($r=0.38$), average steps per day ($r=0.39$), KN-180 ($r=0.28$),

KN-60 ($r=0.26$), MQ-ISO ($r=0.27$), MQ-KN60 ($r=0.45$), MQ-KN180 ($r=0.45$) (all $p \leq 0.01$).

To determine which physical activity measurement to use when controlling for physical activity level, average daily minutes of moderate to vigorous activity and average steps per day were both examined. Average steps per day was slightly more strongly correlated with the physical function composite score ($r=0.39$, $p<0.001$) compared to average daily minutes of moderate to vigorous physical activity ($r=0.38$, $p<0.001$), and therefore used in further analyses.

Partial correlations, controlled for age and average steps per day, are presented in Table 2. Both MQ-KN60 and MQ-KN180 were significantly associated with physical function composite score ($p<0.001$), however MQ-KN60 was more strongly associated with the physical function composite score ($r=0.43$) compared to MQ-KN180 ($r=0.40$). As both muscle quality measurements were significantly correlated with physical functional ability, a regression analysis for each measurement of muscle quality was performed to assess the independent associations with physical function measurements.

Tables 3 and 4 provide the results for the hierarchical linear regression assessments for muscle quality and physical function. Table 3 shows that age, steps per day and MQ-KN60 are independently associated with physical function composite score, TRANSFER, 30-CS, and UP-GO. For the physical function composite score ($F_{105}^3=19.143$, $p<0.001$), age, steps/day and MQ-KN60 explained 3%, 18.1% and 14.3% of the variance, respectively. Age, steps/day and MQ-KN60 explained 6%, 8.1% and 11.7% of the variance in TRANSFER ($F_{106}^3=12.29$, $p<0.001$), 2.1%, 6.7% and 2.3% of the variance in UP-GO ($F_{107}^3=4.43$, $p=0.006$), 1.7%, 11.4% and 7.9% of the variance for 30-CS ($F_{107}^3=9.52$,

p<0.001), and 0%, 15.8% and 15.9% of the variance in 6MWT ($F_{106}^3=16.46$, p<0.001).

Table 4 presents the associations between age, steps per day and MQ-KN180 and physical function performance. Age, steps/day, and MQ-KN180 explained 3%, 18.1% and 12.8% of the variance in the physical function composite score ($F_{105}^3=17.932$, p<0.001), respectively. Age, steps/day, and MQ-KN180 explained 6%, 8.1% and 13.6% of the variance in TRANSFER ($F_{106}^3= 13.559$, p<0.001), 2.1%, 6.7%, 0.7% of the variance for UP-GO ($F_{107}^3=3.717$, p=0.014), 1.7%, 11.4%, 6.8% of the variance for 30-CS ($F_{107}^3=8.868$, p<0.001), and 0%, 15.8%, 15.7% of the variance for 6MWT ($F_{107}^3=16.251$, p<0.001).

CHAPTER 5

CONCLUSION

The current study assessed the associations between measures of muscle mass, muscular strength, muscle quality, and physical functional ability in middle-aged women. The major findings from this analysis were that: 1) muscle quality is more highly associated with physical function than measures of muscular strength alone; 2) MQ-KN60 is more highly related to a lower body physical function composite score compared to MQ-KN180 and MQ-ISO60; and 3) MQ-KN60 explained additional variance in performance on the majority of physical function measures compared to MQ-KN180.

The current study supports the association between lower body muscular strength (both isometric and isokinetic measurements of knee flexors and extensors) and physical functional ability. When examining measures of isokinetic strength and their associations with functional performance, our findings suggest that isokinetic strength of the knee extensors and flexors at 60 degrees per second is more highly related to physical function tasks that require muscular endurance, strength and flexibility, while isokinetic strength of the knee extensors and flexors at 180 degrees per second are more highly associated with activities related to power and balance. This finding supports previous research in which Ward-Ritacco et al. (16) found isokinetic muscular strength at 60 degrees per second was significantly associated with UP-GO, 30-CS, and 6MWT in a cohort of middle-aged women. The results from the current study could be explained by the force-velocity curve, where lower angular velocity allow higher levels of force to be produced. Previous research has suggested that the harder the task is, the more force is required to perform that

task, thus the angular velocity of that motion occurs at a slower rate (11,63,70). This is important because if slower angular velocities require higher percentage of maximal voluntary contractions, then assessing at slower angular velocity would allow ability to see the decline in the ability to perform tasks that require higher percentage of maximal voluntary contraction.

In the current study, isometric knee strength was also significantly associated with measures of physical function. This is in agreement with Sowers et al. (4) who found that isometric knee strength was associated with gait time and the time it takes to ascend and descend stairs. Additionally, Landers et al. (59), found that measurements of isometric strength of the lower body were significantly associated with standing from a chair. While these function measures differ from those in the present study, it is important to note that isometric strength is indicative of functional ability. However, in our study the strength of the association between isometric strength and physical function was lower than between isokinetic strength and physical function. Further, during activities of daily living, individuals are less likely to perform isometric contractions, but typically move through a range of motion, suggesting that isokinetic strength measures may be more appropriate.

Additionally, the current study found that MQ-KN60 is most highly related to a lower body physical function composite score, as well as individual physical function tasks including TRANSFER, 30-CS, and 6MWT, compared to other measures of muscle quality. Similar to the present findings, Ward-Ritacco et al. (16), found that MQ-KN60 was significantly associated with 30-CS and 6MWT performance, indicating that higher MQ is associated with better functional ability. Ward-Ritacco et al. (16) also found that MQ-KN60 was significantly associated with UP-GO performance, while the present study did

not. In the study by Ward-Ritacco et al. (16) all study participants were postmenopausal, indicating that this assessment may not be appropriate for pre and peri menopausal samples of middle-aged women. Additionally, Ward-Ritacco et al. (16) only assessed MQ-KN60, therefore present study provides a more comprehensive assessment of the associations between muscle quality calculated with isometric strength and isokinetic strength at varying speeds. The present study found that MQ-KN180 was more highly associated with UP-GO when compared to MQ-KN60. UP-GO assesses both muscular power and balance (36). A key component of the development of muscular power is the activation time of the contraction (11,71). Using the force-velocity relationship, peak power occurs at a higher percentage of maximum velocity (11,70), demonstrating that measurements using higher velocity would be more highly associated with measures of muscular power than muscular strength. Because the measurement of muscular strength at 180 degrees per second required a shorter duration of muscle activation, it makes sense that this measurement would be more highly related to muscular power compared to measurement of muscle strength at 60 degrees per second.

The results from this study also suggest that when resistance training, designing a program for both increase muscular strength as well as endurance is important as both measures of muscular strength were associated with physical functions tasks that assess these components. Additionally, multi-joint exercises should be focused on as most activities of daily living requires this.

The present study supports support the use of the MQ-KN60 and MQ- KN180 when examining determinants of physical functional ability that address muscular endurance, strength and power. The reason why MQ-KN60 is thought to be more highly related to

tasks that assess endurance and strength is because the measurement of isokinetic muscular strength at 60 degrees per second has a longer duration to produce the max contraction causing it to be more strongly associated with endurance and measures of muscular strength instead of tests that assess muscular power. These results also provide insight into intervention design, as resistance training programs should be designed to improve isokinetic strength at 60 degrees per second and at 180 degrees per second, while also focusing on improving lean mass. Improving muscle quality in these domains should improve functional performance across the spectrum.

One of the strengths of the current investigation is the use of objective measures when assessing physical activity (15,27,72). While both subjective and objective methods have been validated, participants tend to overestimate their levels of physical activity when using self-report methods (73). The measurement of physical activity in this current study is also a strength because physical activity level has been reported to affect physical function performance (6,16). As all analysis of the association between muscular strength, muscle quality and physical functional ability were controlled for physical activity levels, the results found in this study are representative of a more accurate measurement of the association between muscular strength, muscle quality and physical function in middle-aged women. An additional strength related to measuring physical activity is the inclusion of both steps per day and the amount of moderate to vigorous physical activity achieved by participants. Our results indicate that average steps per day are just slightly more highly related to a lower body physical function composite score. This supports the use of simple step counters if more expensive technology such as, accelerometry is unavailable or not feasible, when designing interventions or crafting behavior change messaging to help

individuals improve their physical functional ability.

No study is ever without limitations. The current study's population is not diverse, where a majority of the study population were Caucasian, and were relatively active with a mean average steps per day of 8,176.55. Compared to current large studies of physical activity in adults, it is suggested that the average adults walks on average 6,927 steps per day (74). Therefore, the results of this study can only truly be applied to the current population and not generalized for all middle-aged women. The current study also did not include a measurement of muscular power, which has been shown to have a higher age related rate of decline compared to muscle mass and muscular strength (9,11), and has previously been more highly related to physical functional ability compared to muscular strength (11,17,55). Therefore, it is important to consider this in future studies examining the determinants of physical function in middle-aged women. Thirdly, while DXA scans are a highly validated tool for measuring body composition, DXA technology does not measure intramuscular fat mass, which may be a contributing factor to decreased physical functional ability (52,53). Thus, studies also assessing body composition using either computed tomography or MRI, when feasible and warranted, may be beneficial (11,75,76). The last limitation of this study is that physical functional ability was not examined by menopausal status groups. Previous research has assessed the association between menopausal status and physical functional ability (25,33,77), and have found some differences based on menopausal group. Therefore, examining the data in this manner would add to the existing body of literature.

To conclude, in relatively healthy middle-aged women, MQ-KN60 is most-highly associated with physical functional ability compared to other measures of muscle quality

and muscular strength, even when controlling for age and physical activity level. This data provides insight into the most appropriate measures to consider when examining the independent contributors to physical functional ability in middle-aged women. Future research can build on these results by measuring isokinetic muscular strength and calculating muscle quality using isokinetic measurements. Based on these results, exercise interventions focusing on improving muscle quality could be implemented in hopes to help improve physical function across the lifespan.

TABLES

Table 1. Participant Characteristics

Demographics	Sample Mean $\pm$ SD (n = 111)	Range	Pre- Menopausal (n = 23)	Peri- Menopausal (n = 26)	Post- Menopausal (n = 62)
Age (years)	53.14 $\pm$ 6.15	40.00 – 64.00	45.91 $\pm$ 3.49	49.81 $\pm$ 3.72	57.22 $\pm$ 4.09
Height (cm)	163.47 $\pm$ 5.54	150.60 – 177.60	164.74 $\pm$ 6.06	164.64 $\pm$ 5.49	162.51 $\pm$ 5.25
Weight (kg)	70.41 $\pm$ 15.09	44.30 – 118.30	72.59 $\pm$ 14.71	75.15 $\pm$ 17.71	67.62 $\pm$ 13.60
Body mass index (kg/m ²)	26.31 $\pm$ 5.54	17.63 – 42.93	26.70 $\pm$ 5.03	27.64 $\pm$ 5.91	25.60 $\pm$ 5.00
Body fat (%)	37.98 $\pm$ 8.06	18.99 – 55.84	37.26 $\pm$ 7.64	38.42 $\pm$ 7.92	38.18 $\pm$ 8.49
Lean mass (%)	62.01 $\pm$ 8.06	44.16 – 81.01	62.74 $\pm$ 7.64	61.58 $\pm$ 7.92	61.82 $\pm$ 8.49
PA: Steps/day	8176.55 $\pm$ 3329.15	2183 – 20301.83	7637.34 $\pm$ 2765.46	7240.75 $\pm$ 2725.27	8769.02 $\pm$ 3653
PA: MVPA/day (min)	31.90 $\pm$ 24.29	1.00 – 113.14	29.71 $\pm$ 20.64	24.04 $\pm$ 21.06	36.00 $\pm$ 26.14
Physical Function	Mean $\pm$ SD	Range			
Transfer Task (sec)	3.89 $\pm$ 1.13*	1.53 – 8.19	3.63 $\pm$ 1.25	3.77 $\pm$ 1.05	4.04 $\pm$ 1.12
30 Second Chair Stand (reps)	20.14 $\pm$ 5.34	10.0 – 38.0	20.91 $\pm$ 5.67	20.38 $\pm$ 5.70	19.74 $\pm$ 5.11
6 Minute Walk (m)	574.28 $\pm$ 67.88*	429.3 – 734.3	570.53 $\pm$ 74.31	580.78 $\pm$ 56.93	572.92 $\pm$ 70.50
8 foot Up and Go (sec)	5.21 $\pm$ 0.89	2.38 – 7.37	5.00 $\pm$ 1.11	5.16 $\pm$ 0.79	5.34 $\pm$ 0.84
Lift and Carry (sec)	58.61 $\pm$ 10.81*	38.8 – 104.9	57.74 $\pm$ 11.05	58.31 $\pm$ 13.07	59.07 $\pm$ 9.80
PF-Composite Score	0.00 $\pm$ 3.01**	-9.06 – 8.34	0.54 $\pm$ 3.07	0.29 $\pm$ 2.89	-0.33 $\pm$ 3.04

Note. Data is presented as mean $\pm$ SD unless stated otherwise, MVPA = moderate to vigorous physical activity, *n=110, **n=109

Table 2. Partial Correlations, Controlled for Age and Average Steps Per Day, Examining Associations Between Muscular Strength, Muscle Quality, And Physical Function

	KN180	KN60	ISO	MQ-ISO	MQ-KN60	MQ-KN180	TRANS	UP- GO	30-CS	6MWT	PFCS
KN180	1.00	.84**	.70**	.46**	.74**	.74**	-.29*	-.03	.11	.29*	.25*
KN60		1.00	.80**	.53**	.53**	.53**	-.25*	-.08	.11	.28*	.25*
ISO			1.00	.78**	.60**	.45**	-.15	.07	.06	.13	.09
MQ-ISO				1.00	.79**	.69**	-.25*	.02	.19*	.24*	.23*
MQ-KN					1.00	.82**	-.37**	-.15	.28*	.42**	.43**
MQ-KN180						1.00	-.40**	-.08	.27*	.42**	.40**
TRANS							1.00	.13	-.50**	-.44**	-.72**
UP-GO								1.00	-.35**	-.33*	-.64**
30-CS									1.00	.36**	.77**
6MWT										1.00	.74**
PFCS											1.00

Note. * $p < 0.05$, ** $p < 0.001$, KN180 = Isokinetic 180 degrees/second, KN60= Isokinetic 60 degrees/second, ISO= Isometric 60 degrees, MQ-ISO = Muscle quality isometric 60 degrees, MQ-KN60= Muscle quality 60 degrees/second, MQ-KN180= Muscle quality at 180 degrees/second, TRANS = Transfer Task, UP-GO= 8-Foot-Up-And-Go, 30-CS= 30-Second Chair Stand, 6MWT= 6-Minute Walk Test, PFCS= Physical Function Composite Score

Table 3. Regression Analysis Summary for Variables Associated with Physical Function Performance

Variables	B	SEB	p	β	95% CI
(a) Physical Function Composite Score ($R^2 = .350$, $p < .001$)					
Age	-.09	.04	.02	-.18	[-.16, -.01]
Steps/Day	.34	.07	<.001	.38	[.19, .48]
MQ-KN60	.20	.04	<.001	.38	[.12, .28]
(b) Transfer Task ($R^2 = .258$, $p < .001$)					
Age	.05	.02	.005	.24	[.01, .08]
Steps/Day	-.08	.03	.005	-.24	[-.14, -.03]
MQ-KN60	-.07	.02	<.001	-.35	[-.10, -.04]
(c) 30 second Chair Stand ($R^2 = .211$, $p = .001$)					
Age	-.13	.08	.10	-.15	[-.28, .03]
Steps/Day	.49	.14	.001	.30	[.21, .77]
MQ-KN60	.27	.09	.001	.29	[.11, .43]
(d) 6-minute Walk ($R^2 = .318$, $p < .001$)					
Age	-.05	.91	.96	-.004	[-1.84, 1.75]
Steps/Day	7.09	1.67	<.001	.35	[3.79, 10.39]
MQ-KN60	4.81	.97	<.001	.41	[2.90, 6.73]
(e) 8-foot Up and Go ($R^2 = .110$, $p = .099$)					
Age	.02	.01	.08	.17	[-.003, .05]
Steps/Day	-.06	.03	.01	-.24	[-.11, -.02]
MQ-KN60	-.02	.01	.01	-.16	[-.05, .01]

Note. Age (years); Steps (PA; Steps/day per 1000 steps); B = Unstandardized regression coefficient; β = Standardized regression coefficient

Table 4. Regression Analysis Summary for Variables Associated with Physical Function Performance

Variables	B	SEB	p	β	95% CI
(a) Physical Function Composite Score ($R^2=.339$, $p<0.001$)					
Age	-.08	.04	.02	-.19	[-.17, -.01]
Steps/Day	.33	.07	<.001	.37	[.19, .48]
MQ-KN180	.26	.06	<.001	.37	[.15, .38]
(b) Transfer Task ($R^2 = .277$, $p < .001$)					
Age	.04	.02	.01	.24	[.01, .07]
Steps/Day	-.08	.03	.01	-.23	[-.13, -.02]
MQ-KN180	-.10	.02	<.001	-.38	[-.15, -.06]
(c) 30 second Chair Stand ($R^2 = .199$, $p = .003$)					
Age	-.13	.08	.10	-.15	[-.28, .03]
Steps/Day	.48	.14	.001	.30	[.20, .76]
MQ-KN180	.34	.11	.003	.27	[.12, .56]
(d) 6-minute Walk ($R^2 = .315$, $p < .001$)					
Age	-.06	.91	.949	-.005	[-1.86, 1.74]
Steps/Day	6.83	1.68	<.001	.34	[3.51, 10.15]
MQ-KN180	6.52	1.33	<.001	.40	[3.89, 9.15]
(e) 8-foot Up and Go ($R^2 = .094$, $p = .365$)					
Age	.03	.01	.07	.17	[-.002, .05]
Steps/Day	-.07	.03	.01	-.25	[-.12, -.02]
MQ-KN180	-.02	.02	.37	-.09	[-.06, .02]

Note. Age (years of age); Steps (PA; Steps/day per 1000 steps); B = Unstandardized regression coefficient; β = Standardized regression coefficient

FIGURES

Figure 1: Study Flow Chart

APPENDICES

Appendix A: Participant Screening

Questionnaire Appendix B: Informed

Consent

Appendix C: Mini-Mental State Examination

Appendix D: Physical Activity Readiness

Questionnaire

Appendix E: ActiGraph Accelerometer Instructions

Appendix F: ActiGraph Accelerometer Record of

Wear Appendix G: Biodex Strength and Endurance

Data Sheet

Appendix H: Physical Function Data Sheet

Appendix A: Participant Screening Questionnaire

WHII Screening Questionnaire

Start of Block: Default Question Block

Q1 Thank you for your interest in our research study.

The purpose of this research study is to assess markers of physical and mental health and quality of life among middle-aged women. We are asking eligible participants to come to the Department of Kinesiology at the University of Rhode Island for two measurement visits that will be completed 7-10 days apart. If you participate in the study, we will measure your body composition, ask you questions about yourself, such as questions about your body perceptions, personality, and well-being, assess your physical function, muscular strength, and assess your levels of physical activity and levels of stress. We will also ask you to wear a physical activity monitor clipped to your waist during all waking hours for 7 days, provide us with saliva samples and answer some questionnaires at home during the time between your visits.

Do you think you might be interested in participating in this study?

☐ Yes

☐ No

Skip To: Q2 If Thank you for your interest in our research study. The purpose of this research study is to asses... = Yes

Skip To: End of Survey If Thank you for your interest in our research study. The purpose of this research study is to asses... = No

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Q2 Before enrolling you in our study, we need to ask you some questions to determine if you are eligible. Please answer the following questions about yourself and your health history. This should only take about 15 minutes of your time. Some of these questions pertain to sensitive topics and therefore there is a possibility that some of these questions may make you uncomfortable. If so, you can skip any questions you do not choose to answer.

All information that you share in this screening process, including your name and any other information that can possibly identify you, will be strictly confidential and will be kept under lock and key. If after completion of this screening process it is determined that you are not eligible for the study then, if you grant us permission, we will keep your screening information in a password protected computer file in the event our eligibility criteria change and you then become eligible for participation in the current study.

If you do not want us to keep your information on file, we will record the reason for your ineligibility, without any of your identifying information and then destroy your screening information. If you are eligible for the study and you decide to participate, your information will be coded with an identifying number and we will contact you to schedule your first visit. Remember, your participation is voluntary; you can refuse to answer any questions or stop the screening process at any time without penalty or loss of benefits to which you are otherwise entitled.

Do we have your permission to ask you these questions?

☐ Yes

☐ No

Skip To: Q4 If Before enrolling you in our study, we need to ask you some questions to determine if you are elig... = Yes

Skip To: End of Survey If Before enrolling you in our study, we need to ask you some questions to determine if you are elig... = NoQ4 This study includes the administration of bone and body composition scan, using Dual Energy

X-ray Absorptiometry, commonly referred to as a DXA scan or a bone scan. This scan uses a

small amount of radiation to assess your body composition including your fat mass,

muscle

mass and bone density. The three scans that we are administering together amount to approximately 1/6 of the amount of radiation used during one traditional x-ray.

Are you willing to undergo a DXA scan?

☐ Yes

☐ No

Skip To: Q5 If This study includes the administration of bone and body composition scan, using Dual Energy X-ray... = Yes

Skip To: End of Survey If This study includes the administration of bone and body composition scan, using Dual Energy X-ray... = No

---

Q5 Are you between the ages of 40 and 64 years?

☐ Yes

☐ No

Skip To: Q6 If Are you between the ages of 40 and 64 years? = Yes

Skip To: End of Survey If Are you between the ages of 40 and 64 years? = No

---

Q6 What is your date of birth?

Please enter below

Month

Date

Year

Q47 What is your current age in years?

▼ 30 ... 80

Q7 Do you understand spoken and written English?

☐ Yes

☐ No

Q8 What is your current height in feet and inches?

Feet

▼ 0 ... 11

Inches

▼ 0 ... 11

Q9 What is your current weight in pounds?

Q10 What is your highest weight in the past 3 months in pounds?

Q11 What is your lowest weight in the past 3 months in pounds?

Q12 Do you live independently?

☐ Yes

☐ No

Q13

Are you able to transport yourself or obtain transportation to the URI Kingston
campus for

2

measurement visits?

☐ Yes

☐ No

Q14 Do you currently smoke or have you smoked within the past 6 months?

☐ Yes

☐ No

Q15

Have you recently experienced a cardiovascular disease event (e.g. recent myocardial infarction, stent placement) or do you have unstable cardiovascular disease (e.g.

unstable angina)?

☐ Yes

☐ No

Q16 Do you have a history of COPD (e.g. chronic bronchitis, emphysema) or severe asthma?

☐ Yes

☐ No

Q17

Do you have a history of severe orthopedic/musculoskeletal or neuromuscular

impairments that would contraindicate exercise (including severe arthritis)?

☐ Yes

☐ No

Display This Question:

If Do you have a history of severe orthopedic/musculoskeletal or neuromuscular impairments that woul... = Yes

Q18 If you answered yes above, please provide us with some information about these conditions:

Q19 Have you been diagnosed with Type 1 or Type 2 Diabetes mellitus?

☐ Yes

☐ No

Display This Question:

If Have you been diagnosed with Type 1 or Type 2 Diabetes mellitus? = Yes

Q20 Have you been diagnosed with Type 1 or Type 2 Diabetes mellitus?

☐ Type 1

☐ Type 2

Display This Question:

If Have you been diagnosed with Type 1 or Type 2 Diabetes mellitus? = Yes

Q21 Is your medication stabilized?

Q22 Have you been diagnosed with HIV?

☐ Yes

☐ No

Q23 Do you have a history of dizziness or balance disorders?

☐ Yes

☐ No

Q24 Have you ever been diagnosed with mental illness, clinical depression or dementia?

☐ Yes

☐ No

Display This Question:

If Have you ever been diagnosed with mental illness, clinical depression or dementia? = Yes

Q25 If yes, can you tell us more about your diagnosis and treatment plan:

Q26 Do you use an assistive device to help you walk (e.g. canes, crutches, walkers, braces)?Y

Yes

☐ No

Q27 Have you ever been diagnosed with any of the following?

	Yes	No
High blood pressure (hypertension)?	☐	☐
High blood cholesterol?	☐	☐
Cardiovascular disease (such as heart disease; heart attack, myocardial infarction), congestive heart failure (CHF), heart rhythm disorders (arrhythmias), heart murmur, chest pain (angina)?	☐	☐
Cerebrovascular disease (such as a stroke, transient ischemic attack (TIA))?	☐	☐
Peripheral Vascular Disease (PVD)?	☐	☐
Chronic Obstructive Pulmonary Disease (such as emphysema, chronic bronchitis)?	☐	☐
Asthma?	☐	☐
Arthritis (such as osteoarthritis, degenerative joint disease, rheumatoid arthritis)?	☐	☐
Upper gastrointestinal disease (such as an ulcer, hiatal hernia, gastroesophageal reflux	☐	☐

disease (GERD)?		
Chronic liver disease (such as chronic or persistent hepatitis, cirrhosis)?	☐	☐
Cancer?	☐	☐
a) If yes, please specify type:	☐	☐
b) If yes, please specify date of diagnosis:	☐	☐
Anorexia nervosa (not eating and losing extreme amounts of weight)?	☐	☐
Bulimia (eating, sometimes large amounts of food and then vomiting)?	☐	☐
Degenerative disc disease?	☐	☐
Depression?	☐	☐
Anxiety?	☐	☐
Visual impairment (such as cataracts, glaucoma, macular degeneration)?	☐	☐
Hearing impairment?	☐	☐
Thyroid dysfunction (such as hyperthyroidism, hypothyroidism)?	☐	☐

Fibromyalgia?	☐	☐
Chronic fatigue syndrome?	☐	☐
Anemia?	☐	☐
Hashimoto's disease?	☐	☐
Epilepsy?	☐	☐
Lupus (SLE)?	☐	☐
Endometriosis?	☐	☐
Moderate to severe back pain?	☐	☐
Frequent and/or severe headaches?	☐	☐
Environmental allergies?	☐	☐
Do you have a history of having broken bones?	☐	☐
Have you had any surgeries as an adult?	☐	☐
a) If yes, please provide information about the nature of the surgery below.	☐	☐

Q28

Do you have any other health issues you would like to disclose?

☐ Yes

☐ No

Display This Question:

If Do you have any other health issues you would like to disclose? = Yes

Q48

If yes, please provide information in the space below.

Q29

Do you take any medications or supplements?

☐ Yes

☐ No

Display This Question:

If Do you take any medications or supplements? = Yes

Q49

If yes, please list these in the space below, and indicate the dose (amount) you take, what

you take the medication to treat, and the frequency with which you take this

medication.

Q53

Which of the following racial or ethnic groups best describes you? (Please select all

categories that apply.)

- ☐ Asian/Pacific
  - ☐ Black
  - ☐ Hispanic
  - ☐ Indian/Alaskan
  - ☐ White
  - ☐ Other: Please describe
-

Q54 How many alcoholic beverages do you drink (includes wine, beer and hard liquor)?

- ☐ None
- ☐ Less than once a week
- ☐ 1-3 drinks per week
- ☐ 4-6 drinks per week
- ☐ 1 drink daily
- ☐ 2 drinks daily
- ☐ 3 drinks daily
- ☐ More than 3 drinks daily

Q55 How many caffeinated beverages do you drink (includes coffee, soda, energy drinks)?

- ☐ None
- ☐ Less than once a week
- ☐ 1-3 drinks per week
- ☐ 4-6 drinks per week
- ☐ 1 drink daily
- ☐ 2 drinks daily
- ☐ 3 drinks daily
- ☐ More than 3 drinks daily

Q56 On average, how many meals do you consume each day?

	▼ 0 ... 12

Q57 Do you try to eat a special diet?

- ☐ Low fat
- ☐ Low carbohydrate
- ☐ High protein
- ☐ Vegetarian
- ☐ Other: _____

Q58 How many servings of dairy do you consume each day?

▼ 0 ... 9

Q59 How many servings of fruits do you consume each day?

▼ 0 ... 9

Q60 How many servings of vegetables do you consume each day?

▼ 0 ... 9

Q61 How many servings of fish do you consume each week?

▼ 0 ... 9

Q62 Please describe your current employment.

_____

Q63 Would you describe your current employment as:

- ☐ Full time – working at least 35 hours/week
- ☐ Part time – working less than 35 hours/week
- ☐ Laid-off or unemployed, but looking for work
- ☐ Laid-off or unemployed, but not looking for work
- ☐ Retired, not working at all
- ☐ Retired, working part-time
- ☐ Disabled
- ☐ Full time homemaker
- ☐ Other, _____ please _____ specify:

Q64 If you are retired, please describe your primary occupation when you were working.

Q65 Please tell us about your highest level of education:

- ☐ Less than a high school diploma
- ☐ High school diploma or equivalent
- ☐ Some College
- ☐ Graduated from college
- ☐ Graduate or professional degree

Q66 Have you ever been married or lived with a partner?

☐ Yes

☐ No

Q67 Have you ever been divorced or had a live-in relationship end?

☐ Yes

☐ No

Q68 Have you ever been widowed or had a live-in partner die?

☐ Yes

☐ No

Q69 Do you now live with a partner or spouse?

☐ Yes

☐ No

Q70 If you currently live with a partner or spouse, what is your partner's highest level of education (last grade completed or degree(s) received):

☐ Less than a high school diploma

☐ High school diploma or equivalent

☐ Some college

☐ Graduated from college

☐ Graduate or professional degree

Q71 Your total yearly household income (includes income from all sources):

☐ \$0-14,999

☐ \$15,000-29,999

☐ \$30,000-44,999

- ☐ \$45,000-59,999
- ☐ \$60,000-74,999
- ☐ \$75,000-99,999
- ☐ \$100,000-149,999
- ☐ \$150,000-199,999
- ☐ \$200,000-249,999
- ☐ \$Over 250,000

Q72 Other than yourself, how many people live in your household?

	▼ 0 ... 10

Q73 Do you have children (biological, adopted or extended family)?

- ☐ Yes
- ☐ No

Q74 If yes, how many?

	▼ 1 ... N/A

Q75 How many (if any) currently live with you?

	▼ 0 ... N/A

Q76

What are the current major stressors or life changes in your life?

Please provide an explanation here:

Q78

Any major changes in family health during the past year?

If yes, please explain:

Q79 How would you describe your sexual orientation?

☐ Heterosexual

☐ Lesbian

☐ Bisexual

☐ Other (please specify:)

Q31 How would you describe your current menstrual status?

☐ Premenopause (before menopause; having regular periods)

☐ Perimenopause/menopause transition (changes in periods, but have not gone 12 months in a row without a period)

☐ Postmenopause (after menopause)

Q32 If you are post menopausal, was your menopause:

☐ Spontaneous (natural)

☐ Surgical (removal of both ovaries)

☐ Due to chemotherapy or radiation therapy

☐ Other, _____ please _____ explain:

☐ Not applicable

Q33

If you are no longer having periods, what was your age when you had your last period?

	▼ 20 ... 65

Q34 If you are still having periods, how often do they occur?

Q35 On average, how many days does your period last?

Q36 Are your periods painful?

- ☐ Yes
- ☐ No
- ☐ Not applicable

Q37 If yes, how painful?

- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Not applicable

Q38 Do you have any problems with PMS?

- ☐ Yes
- ☐ No

Q39 How would you rate your knowledge about menopause?

- ☐ Very good
- ☐ Moderately good
- ☐ Fair
- ☐ Little Knowledge

Q40 Where do you get your information about menopause (mark all that apply)

- ☐ Books
- ☐ Internet
- ☐ Magazines
- ☐ Friends
- ☐ TV
- ☐ Health care providers
- ☐ Other _____

Q41 How do you view menopause?

- ☐ Positively. For example, menopause means no more periods and no more worry about contraception.
- ☐ Neutral.
- ☐ Negatively. For example, menopause means a loss of fertility and loss of youth.
- ☐ Other: _____

Q42

What concerns you about menopause? Please provide any of your thoughts in the space

provided.

Q43 What are your current views regarding hormone therapy for menopause?

- ☐ Positive. Hormone therapy is appropriate for some women.
- ☐ Neutral.
- ☐ Negative. I don't support the use of hormone therapy.

Q44

What concerns you most about hormone replacement therapy? Please provide any of

your thoughts in the space provided.

Q45 Please mark the appropriate box with to record your response to the following:
How often do you engage in each of the following behaviors?

	Every 6 months	Once a year	Every 2 years	More than every 2 years	Never
See a health care professional for a general physical exam?	☐	☐	☐	☐	☐
See a health care professional for a women's health exam?	☐	☐	☐	☐	☐
See a dental professional for a dental exam/cleaning?	☐	☐	☐	☐	☐
See a health care professional for an eye exam?	☐	☐	☐	☐	☐

Q46 Please mark the appropriate box to record your response to the following: How often do you engage in each of the following behaviors?

	Every month	Every 6 months	Once a year	Every 2 years	More than every 2 years	Never
How often do you have a pap smear?	☐	☐	☐	☐	☐	☐
How often do you have breast exams by a doctor or nurse?	☐	☐	☐	☐	☐	☐
How often do you have mammograms?	☐	☐	☐	☐	☐	☐
How often do you breast self-examine?	☐	☐	☐	☐	☐	☐

Q50 What is the best way to contact you?

☐ Phone

☐ Email

☐ Mail

☐ Other _____

Q51 Please enter the following contact information:

☐

Full Name _____

Q86 Please provide us with a phone number to reach you (including area code)

☐ Phone Number _____
_____

Q87 Please provide us with an email address (if you have one)

☐ Email Address _____

Q88 Please provide us with a mailing address, including Street, City/Town, Zip Code

☐ Address _____

Q52 Thank you very much for your time. Based on the information you provided us in this questionnaire, we will determine your eligibility to participate in the study. We will be contacting you in the near future to schedule your first visit to the research lab at the University of Rhode Island. If you have any questions about this research project, please feel free to contact our Principal Investigator, Dr. Sabik by email at sabik@uri.edu or by phone at (401) 874-5439. You can contact Dr. Ward-Ritacco by email christieward@uri.edu or by phone at (401) 874-5638.

Appendix B: Informed Consent

DEPARTMENT OF KINESIOLOGY

25 West Independence Way, Suite P, Kingston, RI 02881 USA p: 401.874.2976 f: 401.874.4215 web: uri.edu/kinesiology

Project Title: Evaluating Physical Function and Self Perception in Middle-Aged Women

CONSENT FORM FOR RESEARCH

You have been invited to take part in the research project described below. A member of the research team will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, Dr. Natalie Sabik and Dr. Christie Ward-Ritacco, the persons mainly responsible for this study, will be happy to talk with you about them. You can contact Dr. Sabik by email at sabik@uri.edu or by phone at (401) 874-5439. You can contact Dr. Ward-Ritacco by email christieward@uri.edu or by phone at (401) 874-5638.

Inclusionary Criteria

To be a candidate for this study you must 1) be able to speak and read English, 2) be a woman, 3) be between 40 - 64 years of age, 4) have no recent changes in your body weight (within ~5 pounds for the past 3 months), 5) have a body mass index of 18.5 – 45.0 kg/m², 6) be a non-smoker, 7) not be pregnant, 8) be willing to have a dual energy X-ray absorptiometry (DXA) scan, 9) be free of diseases or conditions that would prevent reasonably safe participation in study related testing, and 10) be living independently.

Project Description

The main purpose of this study is to assess how physical factors, such as exercise, body composition, and muscular strength, relate to well-being among middle-aged women. We want to learn about how these factors are related because physical changes during midlife place women at increased risk of poorer quality of life, including increased functional limitations and decreased psychological well-being. A growing number of middle-aged Americans are reporting decreases in their physical health, mental health, ability to perform activities of daily living, and ability to work. Examining the associations between these factors will help us to understand barriers to health and will allow us to design effective interventions to improve quality of life in middle-aged women.

Your participation will include coming to the URI Kingston campus for two testing visits and completing a series of tasks at home in between your visits. All of the testing will take place on the URI Kingston campus in Independence Square. You are responsible for your own transportation to all of the testing visits.

Time Commitment

Interested women will complete a short online screening questionnaire. Women who qualify to take part in the research study will be asked to come to the Department of Kinesiology at the University of Rhode Island for two visits that will occur 7-10 days apart. During the time

between visits you will complete a series of questionnaires. The total time commitment for this study is 7 hours.

What Will I Do As a Participant in This Study?

If you choose to participate in the study you will be asked complete two in person visits and complete a series of tasks at home between the two visits.

Visit 1:

First we will check your interest and ability to take part in this study. Then we will review and sign this form. Next, we will complete a paper and pencil administered questionnaire making sure that you are able to engage in physical activity safely and one to examine your cognitive performance.

Next, a qualified member of the research team will collect 160 microliters (about a half a teaspoon) of your blood using a finger stick technique. Your blood sample will be analyzed for hemoglobin and hematocrit, to assess your risk for anemia.

After your blood sample is taken, we will measure your height and weight, your waist circumference, and take your heart rate and blood pressure. Then you will have a DXA scan in room 129 of the Independence Square building. A DXA scan is a body scan that tells us information about your body fat, your muscle mass, and your bone density. We will provide you with medical "scrubs" to wear during scanning if you are wearing clothing that would interfere with the scan. You will lie on a padded table that remains stationary as the scanning arm moves over your body. Total scanning time, complete with positioning, takes approximately 20 minutes. A licensed radiology technician will perform the DXA scans. There is no cost to you or your insurance for these scans. If you are pre-menopausal (not self-identified as post-menopausal or otherwise unable to become pregnant), you will complete a pregnancy test prior to completing your DXA scan. One will be provided to you with no cost to you or your insurance company. You will provide a small urine sample by peeing in a cup and then provide the sample to the researcher, who will conduct the pregnancy test to confirm that you are not pregnant prior to having the DXA scan.

In addition we will ask you to complete several questionnaires using a computer in our laboratory. The questionnaires will ask you about your quality of life, your feelings of energy and fatigue, your sleep quality, your stress levels, your physical activity history, and will also contain questions about your emotional and physical health and well-being. Next you will complete a series of tasks to measure your physical functional ability. These include sitting in chair and standing up as many times as you can in 30 seconds, standing from seated position and walking around a cone placed in front of you as quickly as possible, lifting a weighted crate and carrying it through a marked course, getting up and off the floor as quickly as possible, and walking for 6 minutes as quickly as you can. During the functional assessments we will ask you to rate your feelings of effort, fatigue, and pain. You can rest between each activity. Any risk of injury during the completion of these tasks will be minimized by having all sessions supervised by a research team member qualified to direct this type of testing.

Before you leave for the day, we will review how to wear your physical activity monitoring device for 7-10 days while you go about your normal daily routine. We will ask you to wear your physical activity monitor during all waking hours except when showering or swimming. We will also show you how to fill out your physical activity log. This will require you to write down the type of activity, the time of the activity, and how many minutes you completed of during each

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bout of planned, structured physical activity (e.g. 30 minutes of walking outside at 3:30 pm). We will also review how to provide saliva samples and review the questionnaires that you will be asked to fill out at home in the time between visits 1 and 2.

In between Visits 1 and 2:

You will be asked to complete a series of questionnaires asking you about your physical activity history, your menopausal symptoms, how you feel about your body and age, social activities, and your daily feelings of energy at home. If you would like to complete these on your home computer, we will email a link to you from Qualtrics, an online survey tool, containing the questionnaires. If however, you would prefer to answer offline or do not have access to a computer, we will provide you with hard copies of all of the questionnaires. You will wear your physical activity monitor and record any planned physical activity/exercise sessions on your physical activity log. You will bring your completed physical activity log, your physical activity monitor, and completed questionnaires (if applicable) to the lab when you return for Visit 2. You will also be asked to provide us with 10 saliva samples total (5 per day for 2 days). The saliva sample will provide us with information about how your body responds to stress. To create these samples you will simply chew on a cotton swab provided by the researchers and will spit it into a tube to be stored in the refrigerator. You will be asked to bring these with you to the lab on Visit 2.

Visit 2:

At Visit 2, we will collect your physical activity monitor and check and collect your physical activity log. If there are any missing information on your physical activity log we will ask you to try and fill it in as best as you can remember. We will also collect your saliva samples. We will also ask you to complete any unfinished questionnaires in our laboratory. When this is finished, we will test your hand grip strength by squeezing the lever on a small hand-held device, known as a hand grip dynamometer. This task is repeated three times with both the right and left hands. We will then test the strength of your upper leg. This involves being seated in a special machine that controls the speed with which you can move your leg and measures how much force you are able to produce while you kick and pull with your knee. Then we will check your muscular endurance. During each task you will receive real-time visual feedback on a computer monitor and verbal encouragement to help you. During the strength and endurance tests we will ask you to rate your feelings of effort, fatigue and pain. You can rest between each exercise.

Risks or Discomfort

It is possible that heart or blood vessel problems could arise during your participation in the study testing. Although highly unusual, it is possible that these problems could lead to a heart attack, stroke or even death. It is possible that these risks will not be eliminated completely, even with a medical evaluation prior to participation in the study. However, the investigators believe the risk of harm from study participation is relatively small and that the benefits of the study to you individually will likely outweigh any potential risks. You may experience some temporary muscle soreness as a result of the testing sessions. There is also a risk skeletal injury from testing. The investigators will use procedures designed to minimize this risk. Because some of the physical function tasks require some degree of balance, there is a risk of falling associated with completing these tasks. However, the investigators will take precautions to reduce the chance of falling.

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There is a risk of bruising, pain, and in rare cases, infection or fainting as a result of finger stick blood sampling. However, these risks to you will be minimized by allowing only qualified people to use the finger stick technique to take a small sample of your blood.

You understand that there will also be a very low total radiation dose for the DXA scans (~9 millirem), which is well below the maximal annual radiation dose (5 rems) allowed for exposure in the workplace. Naturally occurring radiation (cosmic radiation, radon gas, etc.) gives each person a whole body radiation dose of about 300 millirems per year. Therefore, the total dose of radiation exposure from DXA is considered low. The major risk from high radiation exposure is passing on damaged genes (genetic mutations) to offspring. Therefore, this risk is of primarily a concern for women who are of childbearing age.

In case there is any injury to the subject:

In the event of physical injury resulting from participation in this study, upon your consent, emergency treatment will be available at South County Hospital with the understanding that any injury requiring medical attention becomes your financial responsibility. URI will not provide any medical or hospitalization insurance coverage for participants in this research study, nor will they provide compensation for any injury sustained as a result of this research study, except as required by law.

Benefits of this study:

This study may help the investigators better understand which factors are most important in determining quality of life in middle-aged women. The results of this study may be used in the future to design effective interventions for improving physical and psychological health in middle-aged women. Additionally, as a participant in this study you will be provided with the results of your hemoglobin and hematocrit testing, a copy of your DXA scan, and the results of your muscular strength and physical function testing.

Participant Compensation:

For your participation in the study and after the study is completed, you will receive, free of charge, information about your blood test results, body composition, muscle strength, and physical function. Participants will be compensated \$100 total in the form of gift cards upon completion of all study requirements. For participants that withdraw from the study early, compensation will be prorated based on the time spent completing study materials. Pro-rating will occur as follows: for completion of the initial laboratory visit, you will receive \$30. For completion of at-home activities (questionnaires, wearing and returning accelerometer, collecting saliva samples) and visit 2, participants will receive \$70. For participants that withdraw early from the study, study equipment must be returned to receive payment.

Confidentiality:

All information collected in this study is confidential, and your name will not be identified and linked to any electronic study data at any time to anyone other than the principal investigators of the study. Your data will be coded with an ID number only, which will be linked back to you only by the principal investigators of the study. Your part in this study is confidential within legal limits. The researchers and the University of Rhode Island will protect your privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name.

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All study data, including this consent form, will be locked in a file cabinet and also stored in a study computer with a password secured in our locked study office (Independence Square building, Suite P, room 225). All study data will be kept for three years after study completion

Decision to Quit at any Time:

It is your decision alone whether or not you participate in this study. You are free to ask questions about this study before you decide whether or not to participate. Also, if you consent to participate in the study you are free to quit at any time without penalty, or without any requirement that you provide an explanation about your decision to withdraw.

Rights and Complaints:

If you are not happy with the way this study was done, you may talk with Dr. Natalie Sabik or Dr. Christie Ward-Ritacco. They can be reached at (401) 874-5439 or (401) 874-5638, respectively. You can talk to either of them anonymously if you want to. In addition, if this study causes you any injury or if you have questions about your rights as a research subject you may contact the office of the Vice President for the Division of Research and Economic Development, Carlotti Administration Building, 2nd Floor, 75 Lower College Road, Suite 2, University of Rhode Island, Kingston, Rhode Island; telephone: (401) 874-4576.

Further, we would like to know if we can retain your contact information to potentially contact you to provide the opportunity to participate in future research. You can choose to participate in the current study and can opt to not be contacted in the future.

I would like to provide my contact information to be contact for future research studies.

☐ Yes   Phone: _____

☐ No   Email: _____

You have read and understand the above information in the Consent Form and have been given adequate opportunity to ask the investigators any questions you have about the study. Your questions, if any, have been answered by the investigators to your satisfaction. Your signature on this form means that you understand the information and you agree to voluntarily participate in this study.

_____
Signature of Participant

_____
Date

_____
Signature of Researcher

_____
Date

_____
Typed/printed Name

_____
Typed/printed name

Please sign both consent forms, the research team will keep one copy and you will be given one for yourself.

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Appendix C: Mini-Mental State Examination

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

Instructions: Ask the questions in the order listed. Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

Appendix D: Physical Activity Readiness Questionnaire

Physical Activity Readiness
Questionnaire - PAR-Q
(revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

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

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

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

YES	NO	
☐	☐	1. Has your doctor ever said that you have a heart condition <u>and</u> that you should only do physical activity recommended by a doctor?
☐	☐	2. Do you feel pain in your chest when you do physical activity?
☐	☐	3. In the past month, have you had chest pain when you were not doing physical activity?
☐	☐	4. Do you lose your balance because of dizziness or do you ever lose consciousness?
☐	☐	5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?
☐	☐	6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
☐	☐	7. Do you know of <u>any other reason</u> why you should not do physical activity?

If you
answered

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active — begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal — this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever — wait until you feel better; or
- if you are or may be pregnant — talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Important Note: The PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____

DATE _____

SIGNATURE OF PARENT
or GUARDIAN (for participants under the age of majority) _____

WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

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continued on other side...

Appendix E: ActiGraph Accelerometer Instruction

ActiGraph Accelerometer Instructions

Thank you for participating in our study!

What is an accelerometer?

This activity meter records general movement and will allow us to get a better idea of your overall activity level. This device will measure the physical activity you perform by detecting the movements that are made as well as the acceleration of those movements, but will not be able to tell us exactly what activity you are doing. It is easy to use and can be worn on your belt or on the waist band of your clothing. It may feel slightly awkward at first, but after a few hours you will barely know it's there. They are also quite pricey, so please be careful!

Instructions:

You will be given an accelerometer at your study visit by your assigned number. Please do **NOT** switch accelerometers with anyone!

Please wear the ActiGraph with the belt clip fastened around the waist with the unit positioned over the **right** hip bone.

You can wear your activity monitor over or under clothing, whichever is most comfortable to you! The meter does not need to be in direct contact with the body. However, it is essential that the ActiGraph be positioned snugly enough against the body that it cannot flop around.

If you take it off for any reason, please write that on your tracking log. You will keep track of the time the accelerometer was worn using the Accelerometer Log form.

Please do not wear this device in any other way, including:

- NOT in any pockets of clothing
- NOT in a backpack or handbag
- NOT in a car glove compartment or trunk

During the week-long wear period, you will be given the accelerometer at your first visit. You will wear it during the visit and for the rest of the day. For the rest of the week it will be worn during all waking hours until you return it at your second study visit.

Appendix F: ActiGraph Accelerometer Record of Wear

Accelerometer Record of Wear

Subject ID: _____

Week: _____

PRE

Day of the week						
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
Date (month/day)	____/____	____/____	____/____	____/____	____/____	____/____
Time On	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
Time Off	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
If the monitor was removed during waking hours, list the times and reasons for each removal:						
1. Time Took Off:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
1. Reason Took Off:						
1. Time Back On:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
2. Time Took Off:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
2. Reason Took Off:						
2. Time Back On:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
List any exercise you performed while NOT wearing the monitor (e.g., walking, jogging, swimming, cycling, aerob						
1. Exercise Type:						
1. Exercise Start:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
1. Exercise Stop:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
2. Exercise Type:						
2. Exercise Start:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
2. Exercise Stop:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
Walking Diary: List any brisk walks you took that were at least 10 minutes long:						
Walk 1 Start Time:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
Walk 1 Stop Time:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM
Walk 2 Start Time:	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM	____:____ AM or PM

Appendix G: Biodex Strength and Endurance Data Sheet

WHII Project: Muscular Strength and Endurance Recording Form

Subject No.	Date of Visit	Visit	Form filled out by:	Data entered by:
____	____	____	____	____
	MM DD YYYY			

Knee EXT/FLEX Settings

Dynamometer Orientation 90°; DynaTilt 0°; Seat Orientation 90°; Seatback Tilt 70-85°

Chair Height:	Chair Position:	Dynamometer Position:

Knee Extension: [Isometric Unilateral; Knee (Extension/Flexion); Away: Test: 60; (BRCX Knee EXT)]

RIGHT				LEFT			
Trial 1	RPE	PAIN	FATIGUE	Trial 1	RPE	PAIN	FATIGUE
Trial 2	RPE	PAIN	FATIGUE	Trial 2	RPE	PAIN	FATIGUE
Trial 3	RPE	PAIN	FATIGUE	Trial 3	RPE	PAIN	FATIGUE

Notes: _____

Knee Flexion: [Isometric Unilateral; Knee (Extension/Flexion); Toward: Test: 60; (BRCX Knee FLEX)]

RIGHT				LEFT			
Trial 1	RPE	PAIN	FATIGUE	Trial 1	RPE	PAIN	FATIGUE
Trial 2	RPE	PAIN	FATIGUE	Trial 2	RPE	PAIN	FATIGUE
Trial 3	RPE	PAIN	FATIGUE	Trial 3	RPE	PAIN	FATIGUE

Notes: _____

Knee Ext/Flex @ 60 deg/sec: [Isokinetic Unilateral; Knee (Ext/Flex); Con/Con: Test: 60/60, 60/60; (BRCX Knee EXT/FLEX 60)]

RIGHT				LEFT			
Trial 1	RPE	PAIN	FATIGUE	Trial 1	RPE	PAIN	FATIGUE
Trial 2	RPE	PAIN	FATIGUE	Trial 2	RPE	PAIN	FATIGUE

Notes: _____

Knee Ext/Flex @ 180 deg/sec: [Isokinetic Unilateral; Knee (Ext/Flex); Con/Con: Test: 180/180, 180/180; (BRCX Knee EXT/FLEX 180)]

RIGHT				LEFT			
Trial 1	RPE	PAIN	FATIGUE	Trial 1	RPE	PAIN	FATIGUE
Trial 2	RPE	PAIN	FATIGUE	Trial 2	RPE	PAIN	FATIGUE

Notes: _____

Knee Ext/Flex 25 REPETITIONS @ 180 deg/sec: [Isokinetic Unilateral; Knee (Ext/Flex); Con/Con: Test: 180/180; (BRCX Knee EXT/FLEX 180 25 REPS)]

RIGHT				LEFT			
Trial 1	RPE	PAIN	FATIGUE	Trial 1	RPE	PAIN	FATIGUE

WHII Project: Muscular Strength and Endurance Recording Form

Subject No.

Date of Visit

MM		DD		YYYY			

Visit

Form filled
out by:

Data entered by:

Notes: _____

Appendix H: Physical Function Data Sheet:

Functional Testing Recording Form											
Subject No.		Date of Visit				Visit		Form filled out by:		Data entered by:	
		MMDDYYYY									
Transfer Task		Time				RPE		Pain		Fatigue	
Trial 1 (seconds)											
Trial 2 (seconds)											
Transfer Task Fastest Time (seconds)											
Notes: _____											
8 foot up-and-go		Time				RPE		Pain		Fatigue	
Trial 1 (seconds)											
Trial 2 (seconds)											
8 foot up-and-go Fastest Time (seconds)											
Percentile Rank											
Notes: _____											
Lift & Carry		Time				RPE		Pain		Fatigue	
Trial 1: Time (seconds)											
Trial 2: Time (seconds) OPTIONAL											
Notes: _____											
30-second chair rise						RPE		Pain		Fatigue	
Trial 1: Number of stands											
Trial 2: Number of stands OPTIONAL											
Greatest Number of stands											
Notes: _____											

MODIFIED: 06/24/16

Functional Testing Recording Form

Subject No.	Date of Visit	Visit	Form filled out by:	Data entered by:																												
<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td colspan="2">MM</td><td colspan="2">DD</td><td colspan="4">YYYY</td></tr></table>									MM		DD		YYYY				<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td></td></tr></table>			
MM		DD		YYYY																												

6-minute walk test

Walking Path Distance – one way (m)	<table border="1"><tr><td></td><td></td><td></td></tr></table>				X	Total Passes	<table border="1"><tr><td></td><td></td><td></td></tr></table>				=	<table border="1"><tr><td></td><td></td><td></td></tr></table>			
Use this area to keep track of passes (one tick mark = one trip down)		Partial Pass Distance (m)		<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>											
Total Distance (m)		<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>													

RPE	Pain	Fatigue	Notes

MODIFIED: 06/24/16

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