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The Impact of Body Composition on Physical Function Performance in Middle-Aged Women

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THE IMPACT OF BODY COMPOSITION ON PHYSICAL FUNCTION PERFORMANCE IN MIDDLE-AGED WOMEN

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ABSTRACT

Research in older adults suggests that percent body fat may be most strongly associated with physical function performance, resulting in increased risk for disability and loss of independence; however, the component of body composition that is most strongly associated with physical function in middle-aged females is incompletely characterized. This cross-sectional study examined the impact of lean mass and percent fat on physical function performance in middle-aged females. Eighty females (ages 52.58 ± 6.10 years) were assessed for body composition (lean mass, percent fat) via dual-energy x-ray absorptiometry, physical activity and sedentary time via accelerometer (steps per day, minutes per day), and physical function via Timed Up-And-Go, 30-Second Chair Stand, Transfer Task, Six-Minute Walk and Lift and Carry. Lean mass (total mass, lean mass index) was not related to any measure of physical function (all $p > 0.05$), while percent fat was related to Transfer Task, 30-Second Chair Stand, and Six-Minute Walk performance (all $p \leq 0.05$). Hierarchical linear regression analyses revealed: (1) age, steps per day, and percent fat were related to Transfer Task, 30-Second Chair Stand, and Six-Minute Walk performance (all $p \leq 0.05$); (2) age, sedentary minutes per day, and percent fat were related to Timed Up-And-Go; (3) age, and average steps per day, but not percent fat, were associated with Lift and Carry performance ($p > 0.05$). In middle-aged women, percent fat was most strongly associated with physical function performance, suggesting that modifying percent fat via intervention may be a method for improving functional performance.

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Because of the guidance and support of the aforementioned, I have been able to expand on the field of physical function and body composition and complete this thesis.

PREFACE

This thesis was written to comply with the University of Rhode Island Graduate School manuscript format. The thesis document contains one manuscript: *The Impact of Body Composition on Physical Function Performance in Middle-Aged Women*. The manuscript has been written in a form formatted for publication in Maturitas.

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MANUSCRIPT

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ABSTRACT

Research in older adults suggests that percent body fat may be most strongly associated with physical function performance, resulting in increased risk for disability and loss of independence; however, the component of body composition that is most strongly associated with physical function in middle-aged females is incompletely characterized. This cross-sectional study examined the impact of lean mass and percent fat on physical function performance in middle-aged females. Eighty females (ages 52.58 ± 6.10 years) were assessed for body composition (lean mass, percent fat) via dual-energy x-ray absorptiometry, physical activity, and sedentary time via accelerometer (steps per day, minutes per day), and physical function via Timed Up-And-Go, 30-Second Chair Stand, Transfer Task, Six-Minute Walk and Lift and Carry. Lean mass (total mass, lean mass index) was not related to any measure of physical function (all $p > 0.05$), while percent fat was related to Transfer Task, 30-Second Chair Stand, and Six-Minute Walk performance (all $p \leq 0.05$). Hierarchical linear regression analyses revealed: (1) age, steps per day, and percent fat were related to Transfer Task, 30-Second Chair Stand, and Six-Minute Walk performance (all $p \leq 0.05$); (2) age, sedentary minutes per day, and percent fat were related to Timed Up-And-Go; (3) age, and average steps per day, but not percent fat, were associated with Lift and Carry performance ($p > 0.05$). In middle-aged women, percent fat was most strongly associated with physical function performance, suggesting that modifying percent fat via intervention may be a method for improving functional performance.

INTRODUCTION

Older women, or women over the age of 65 years, are at the highest risk for poor physical function outcomes compared to age-matched men [28]. This is a concern as decreased physical function ability is related to increased risk for physical frailty, physical disability, and early mortality [5, 37, 41, 42]. It was recently reported that physical function limitations may actually begin in middle-age [36], as 9% of women ages 40 to 55 years report experiencing substantial physical function limitations [36] and other data estimates that 25% of middle-aged women, or those between the ages of 40 and 64, experience moderate to severe disability in areas such as self-care, work related activities, and ambulation [22]. The decline in physical function in middle-aged women may be attributed to lower levels of physical activity, increased amounts of adipose tissue, and lower amounts of lean mass; changes that typically occur with aging [31]. Due to the adverse outcomes associated with poor physical function ability, including lower quality of life, increased financial strain placed on the healthcare system, and increased risk for chronic disease and mortality, it is critical to identify modifiable factors that most strongly influence physical function [48]. Developing interventions to address these factors in midlife may help to improve quality of life in older age.

The influence of body composition on physical function in older adults has been widely studied [3, 4, 6, 10, 17,19, 20, 24, 25]. This is an important area of investigation as an estimated 38.1% of American females over the age of 60 years old are classified as obese [29], and therefore, more than one third of the American population may be at risk for physical disability due to a modifiable condition.

In older adults, obesity has been associated with greater likelihood of physical disability [3, 17, 29, 38, 39]. The negative effects of obesity may more strongly impact females, rather than males, as females typically have less lean muscle mass available to move their total body mass, resulting in poorer physical function performance and relatedly, higher risk for physical disability [39]. Zoico *et al.* [49] reported that obese females were in the 50th percentile of body fat to height ratio or a body mass index (BMI) ≥ 25.0 kg/m^2, were 3 to 5 times more likely to experience limitations while performing physical tasks such as kneeling, bending and climbing stairs compared to age-matched females with less body fat. In addition, Riebe *et al.* [33] found that older females who were obese (BMI ≥ 30.0 kg/m^2) had higher Timed-Up-and-Go times, indicating poorer physical function performance. Furthermore, Leigh *et al.* [24] reported that older females who were obese (BMI ≥ 30.0 kg/m^2) were more likely to self-report lower physical function ability compared to women who were not obese.

While the relationship between body fat and physical function performance in older women has been examined in a large number of studies [3, 17, 24, 33, 41, 49], these relationships have not been thoroughly assessed in middle-aged females. Middle age is a critical time period for women as this time frame typically coincides with the transition from pre-menopausal to post-menopausal status. The menopausal transition is associated with a number of lifestyle and physical changes, including decreased physical activity levels, increased percent body fat, and decreased lean body mass [26]. The body composition changes that accompany menopause may be partially responsible for initiating a decline in physical function performance [17, 39, 47, 48]. If lifestyle changes that improve physical activity levels and body composition are not maintained or adopted in middle-age, physical functional performance may continue to decline with advancing age.

It has also been proposed that low amounts of lean muscle mass, rather than high levels of body fat, may be primarily responsible for poor physical function performance [44]. Fantin *et al.* [10] found that a during a period of weight loss in 97 older women (71.4 ± 2.2 years), a reduction in lean muscle mass rather than change in fat mass, body weight, or BMI was more strongly associated with poorer physical function performance as assessed by the Six-Minute Walk and self-reported ability to complete activities of daily living. Furthermore, Janssen *et al.* [19] reported that women who had the lowest amounts of lean muscle mass had the most disability when performing activities of daily living and physical function tasks including the tandem stand and Repeated Chair Stand test. These results support that further research is needed to determine the component of body composition most strongly associated with physical function performance.

It is well established that physical activity and exercise influence body composition outcomes, including lean mass and percent body fat, as higher volumes of physical activity are associated with increased lean muscle mass and lower body fat percentages [37]. Physical activity has also been shown to be significantly and independently associated with physical function performance in middle-aged females [48]. The benefits of adequate physical activity in regards to delaying decline in physical function ability last well into older age [14].

Therefore, the primary aim of this study was to objectively assess physical function and body composition in a cohort of middle-aged females and to examine the impact of body composition (lean mass and percent body fat) on physical function performance, controlling for age and physical activity level. It is hypothesized that lean mass, rather than percent body fat or total body weight is most strongly associated with physical function performance, when controlling for age and physical activity level.

METHODOLOGY

Study Design

This study included a subset of participants from the Women's Health Improvement Initiative Study, led by Dr. Christie Ward-Ritacco and Dr. Natalie Sabik (WHII Research Project IRB #HU1516-206). This study utilized a cross-sectional design to assess the relationship between body composition and physical function in 80 female participants, ages 40-64 years. Participants were recruited from the University of Rhode Island faculty and staff, and from the surrounding community via flyers, e-mail advertisements, word of mouth, and social media postings.

Participants

Interested participants were required to complete an online screening survey (Appendix B). Inclusion and exclusion criteria is presented in Table 1. A total of 80 participants (52.58 ± 6.10 years) completed all measures. In addition to being a female between the ages of 40 and 64 years, inclusion criteria were: living independently, having the ability to read and speak English, being weight stable for the past 3 months (~5lbs), BMI between 18.5 and 45.0 kg/m^2, willing to undergo a DXA scan, willing to wear an Actigraph Accelerometer, being a non-smoker or smoke free for at least one year, and being free of any diseases or conditions that prevent safe participation in physical activity (such as balance impairments or severe orthopedic limitations).

Participants who were eligible to be a part of the research study were required to report to the Department of Kinesiology at the University of Rhode Island for two visits, which were conducted 7-10 days apart. During Visit 1, participants provided informed consent (Appendix C) and completed the Physical Activity Readiness

Questionnaire (Appendix D). Participants then completed anthropometric measurements, including measurements of height and weight. Body composition was assessed via dual-energy x-ray absorptiometry (DXA). Physical function performance was assessed using the Transfer Task, 30-Second Chair Stand, Six-Minute Walk, Timed Up-and-Go, and Lift and Carry Task. At the end of the first testing visit, participants received an ActiGraph Accelerometer to wear each day in between visits (Appendix E) and an activity log to record the number of hours per day they wore the monitor and physical activities they participated in while not wearing the monitor (Appendix F). During the second testing visit, the ActiGraph Accelerometer and activity log were collected and reviewed for completeness.

Health History: Participants were asked to report all dietary supplements, prescription and over the counter medications. In addition, they were asked to report the presence of chronic health conditions, including arthritis, asthma, cardiovascular disease, peripheral artery disease, depression, diabetes and degenerative disc disease.

Anthropometric Assessment: Weight of each participant was measured in kilograms using a digital scale (TANITA WB-100, Arlington Heights, IL). Height was measured to the nearest 0.5cm using a stadiometer (Seca 213, Chino, CA).

Body Composition: Total body composition, including percent body fat (%Fat) and total lean mass was measured using DXA (GE Lunar iDXA, Waukesha, WI). To complete the body composition analysis, the subject lay flat on the surface of the DXA while wearing loose clothing containing no metal. A trained and licensed radiology technician was present for all DXA scans.

Physical Function Assessments: Physical function was measured objectively via Transfer Task, 30-Second Chair Stand, Six-Minute Walk, Timed Up-and-Go, and Lift and Carry Task. The Transfer Task and 6-Minute Walk were used to assess overall functional ability and cardiorespiratory fitness, respectively. The 30-Second Chair Stand was used to determine lower body muscular endurance and the Timed Up-And-Go was be used to assess muscle power and gait. The Lift and Carry Task was used to assess whole body functional ability. Throughout each test time was kept with a stopwatch (Accusplit Pro Survivor a601x, Pleasanton, CA).

Transfer Task: The Transfer Task (SIT) began with the participant standing. On the word "go," the participant transferred from a standing position to a seated position and then returned to standing in any way, as quickly as possible. This test was performed twice. The best time was kept and used for analysis.

30-Second Chair Stand: The 30-Second Chair Stand Test (CHR) began with a participant sitting in an armless chair on a flat, hard surface. On the word "go," the participant moved to a standing position and returned to a seated position with buttocks firmly on the chair, as quickly as possible. This motion was repeated as many times as possible within 30 seconds. This test was performed twice and the highest repetitions was used for analysis.

6-Minute Walk: The 6-Minute Walk Test (WALK) required participants to walk as many laps as quickly as possible around two cones placed 24.4 meters apart during a six-minute period. Participants were asked to cover as much distance as possible during the six minutes, while also pacing themselves so they did not become too fatigued to finish the test. However, if the participants needed to terminate the test or sit down, they could. This test was performed once and distance covered during the 6 minutes was recorded.

Timed Up-And-Go: The Timed Up-And-Go Test (UPGO) began with the participant sitting in an armless chair on a flat, hard surface. On the word "go," the participant stood up from the chair, walked around a cone that was 8 feet away and sat back down, all as quickly as possible. This test was performed twice and the best time was used for analysis.

The Lift and Carry: The Lift and Carry Test (LIFT) began with participants lifting a crate that contained a 10-pound weight to waist level. They then carried it 20 feet and set it on a shelf that was 51.5 inches high. The participant then picked the crate up again, carried it at waist level for 20 feet and safely set it back on the floor at the original starting point. This test was repeated for a total of 5 repetitions and the time required for the 5 repetitions was recorded and used in analysis.

Physical Activity Measurement: While at home, participants were asked to wear an ActiGraph Accelerometer (Actigraph GT9X LINK, Pensacola, FL) for at least 10 hours per day for 7-10 days on the waistband of the non-dominant hip, except while swimming or bathing, prior to engaging in their second testing visit. A valid wear day included at least 10 hours of wear time. Participant data was included in analyses if monitor was worn for at least 4 valid days. Step counts (steps per day) were calculated on using the mean step count on all valid wear days. Minutes of moderate to vigorous physical activity (MVPA) were calculated as mean time spent in MVPA on all valid wear days. MVPA was defined as physical activity at a moderate and intensity, which was determined by the ActiGraph Accelerometer as 1952 – 5724 and 5725 – 9498 counts per minute respectively. Sedentary time was defined as the total time in minutes spent seated and inactive. It was quantified by the ActiGraph Accelerometer as no movement in the Y axis for at least 10 minutes.

Statistical Analysis: Data was analyzed using IBM SPSS Statistics for Windows version 24.0 (IBM Corp, Armonk, NY). All data are presented as means ± SD unless otherwise stated. Statistical significance was set at $p \leq 0.05$. First, descriptive analysis including means and standard deviations of the study sample characteristics and outcome variables were calculated. Variables were analyzed for normality to ensure that the data was normally distributed. A 3-way analysis of variance (ANOVA) was conducted to determine if physical function performance differed by menopausal status (i.e. pre, peri, postmenopausal). Pearson correlations were conducted to examine bivariate associations between measures of demographic characteristics, physical activity, body composition variables, and physical function outcomes.

To assess the independent contributions of body composition on measures of physical function, hierarchical linear regression analyses were performed to determine the contribution of body composition on measures of physical function while controlling for age and activity level. Correlation analysis found that percent body fat was most strongly associated with physical function performance (SIT, CHR, and

WALK), therefore, this variable was used in regression analyses for these outcomes. Additionally, steps per day was the physical activity variable most strongly associated with physical function performance (SIT, CHR, WALK and LIFT), therefore, the average number of steps per day were used in the analyses for these outcomes. For UPGO, sedentary time was significantly associated, therefore, it was used in the regression analysis for that outcome. Regression analyses were performed in the following order, Step 1: age; Step 2: age and activity level or sedentary time; Step 3: age, activity level or sedentary time, and %Fat. As lean mass was not significantly related to functional performance, this outcomes was not included in the regression models.

RESULTS

A total of 134 females were screened as potential participants and 88 qualified for participation. Reasons for exclusion included: not responding to follow-up contact (33), decline Visit 1 (6), currently smoking (2), not living independently (2), not weight stable (1), outside BMI range (1), and severe musculoskeletal disorder prohibiting safe physical activity participation (1). Of the 87 participants who completed Visit 1, eight participants were excluded from the final data analysis because of the following: incomplete objective physical activity data (5), not medically cleared to participate (1), time commitment too great (1), and BMI outside of the range (too low; 1). Therefore, 80 participants were included in the final data analysis. Figure 1 depicts the subject inclusion process.

The sample was 99% white. Nineteen participants self-identified pre-menopausal, 20 as perimenopausal, and 41 as postmenopausal. Participant characteristics are shown in Table 2. Participants self-reported medical conditions included: hypertension (21%), arthritis (20%), cancer (18%), anxiety (18%), and high cholesterol (16%). The sample was classified as "overweight" based on BMI category (27.46 ± 5.2 kg/m^2). Percent body fat of the sample was 38.9 ± 7.4% and total lean mass was 42.26 ± 5.41kg. Average daily MVPA was 30.31 minutes and 42.5% of participants met the recommended 30 minutes of MVPA per day. Only 44% of participants wore the ActiGraph Accelerometer for 7 or more days between Visits 1 and 2, and average weekly MVPA for those participants was 242.31 ± 163.88 minutes (approximately 64% of participants who wore the ActiGraph Accelerometer for at least seven days met the recommended 150 minutes of MVPA per week). Of the total sample, participants took an average of 7,711 ± 2838 steps per day and 13% of the sample met the recommended guideline of 10,000 steps per day [32].

Physical function performance is presented in Table 3. Participants completed the SIT task in 4.00 ± 1.17 seconds, completed 20.00 ± 5.00 repetitions during the CHR task, and walked 565.75 ± 68.48 meters during the WALK task. The UPGO task was completed in 5.35 ± .86 seconds and completed the LIFT took participants an average of 59.00 ± 10.28 seconds. There was no significant differences in physical function performance based on menopausal status (See Figure 2a-2e).

Bivariate associations between age, body composition, physical activity, and physical function in middle-aged women are presented in Table 4. Menopausal status, number of medical conditions and number of medications were not associated with physical function performance (all $p > 0.05$; data not shown), therefore these variables were excluded from further analysis. In addition, lean mass was examined a number of ways and it was found that lean mass was not significantly associated with physical function outcomes, therefore, lean mass was excluded from further analysis ($p > 0.05$). Age was associated with body weight (kg) and lean mass (kg) (both $p \leq 0.001$). Age was also related to SIT ($p \leq 0.001$) and LIFT ($p \leq 0.05$). Steps/day was associated with SIT, CHR and LIFT performance (all $p \leq 0.001$) and with WALK performance ($p \leq 0.05$). Steps/day was not significantly associated with UPGO performance ($p > 0.05$). Total physical activity per day was not significantly associated with SIT, UPGO or LIFT performance (all $p > 0.05$). Total physical activity was associated with CHR ($p \leq 0.001$) and WALK ($p \leq 0.05$) performance. MVPA/day was significantly associated with SIT, CHR, and WALK performance (all $p \leq 0.05$) but not UPGO or LIFT performance (both $p > 0.05$). Sedentary time/day was significantly associated with UPGO performance ($p \leq 0.05$) but not SIT, CHR, WALK, or LIFT performance (all $p > 0.05$). %Fat was significantly associated with steps per day ($p \leq 0.05$), but not with MVPA per day or total activity per day (both $p > 0.05$). In addition, %Fat was strongly associated with SIT, CHR, WALK, and UPGO performance (all $p \leq 0.001$). %Fat was not related to LIFT performance ($p > 0.05$). Surprisingly, lean mass (kg) was unrelated to performance on all physical function performance tasks (all $p > 0.05$). To fully examine lean mass and its potential contribution to physical function performance, lean mass index (lean mass/height in m^2) and fat-free mass (i.e. lean mass plus bone mass) index (fat-free mass/ height in m^2) were calculated. These outcomes were also not significantly related to physical function perfromance (data not shown). As no indicators of lean mass were related to physical function performance, this element of body composition was not evaluated further using regression analyses.

Hierarchical regression analyses determined that age ($p \leq 0.05$), steps/day ($p \leq 0.05$), and %Fat ($p \leq 0.001$) were independently related to SIT performance, explaining 40.2% of the total variance (Table 5a). %Fat explained 20% of the variance in SIT performance. Both steps/day ($p \leq 0.001$) and %Fat ($p \leq 0.05$) were independently related to CHR performance and the full model containing age, steps/day, and %Fat explained 25.4% of the total variance in CHR performance (Table 5b). %Fat explained 6.4% of the variance in CHR performance. Steps/day ($p \leq 0.05$) and %Fat ($p \leq 0.001$) were also related to WALK performance. The full model containing age, steps/day, and %Fat explained 25.4% of the total variance, with %Fat responsible for 17.6% of the variance (Table 5c). Sedentary time/day ($p \leq 0.05$) and

%Fat ($p \leq 0.001$) were also related to UPGO, which explained 18.2% of the total variance, and the model containing age, sedentary time/day and %Fat explained 18.2% of the total variance in UPGO performance (Table 5d). %Fat was responsible for 10.8% of the variance in UPGO performance. Finally, age ($p \leq 0.05$), and steps/day ($p \leq 0.05$), were independently related to the LIFT task explaining 10.6% of the total variance (Table 5e). However, %Fat ($p > 0.05$) was not related to LIFT performance; therefore, the final model was not significant.

DISCUSSION

The present study addresses the influence of body composition on physical function performance in middle-aged women and contributes to our understanding of these relationships in an understudied population. The results of the study refute the hypothesis that lean mass, rather than %Fat or total body weight, was most strongly associated with physical function performance. Instead, the results of the study suggest that %Fat has the strongest association with physical function performance compared to measures of lean mass and body weight. While body composition and physical function have been extensively analyzed in older adults [3, 4, 6, 10, 17-20, 24, 26], few studied have examined the relationship between body composition and physical function in middle-aged women [1, 10, 11, 14, 15, 22]. It is crucial to determine the component of body composition that most strongly predicts physical function as it is projected that in 2050, 55.1% of the population over the age of 65 will be female, and these females will live to be on average 86.2 years of age, outliving their male counterparts by an average of 4 years across all ethnicities [30]. Determining the component of body composition that most strongly influences physical function in middle-aged women is important because modifying this factor, specifically %Fat in midlife may increase the likelihood of maintaining functional ability and independence in older age [6, 11]. The current findings support research that has been conducted with older adults that have concluded that body fat is most strongly associated with physical function performance [2, 3, 17, 33, 49].

Our results indicate that individuals with higher %Fat had slower SIT performance times. A longitudinal study conducted by de Brito *et al.* [8] that included males and females aged 51 – 80 years found that at baseline and 6.3 years later, individuals who had better SIT times (i.e. performed quickly and did not use a chair to help stand up) had lower BMI values, increased likelihood of preserved functional independence, and decreased risk for falls in older age. Individuals who were obese as defined by a BMI $\geq$ 30 kg/m^2 had longer SIT times and had 2 – 5 times higher death rates over the 6.3-year period. This may be because excess %Fat is highly associated with higher body weight, resulting in greater energy expenditure needed to accomplish physical tasks while carrying an increased load [9]. In addition, Galli *et al.* [13] suggested that obese individuals may experience fatigue when rising from the floor, causing it to take the individuals longer to rise from the floor, resulting in functional limitations all due to moving an increased load.

Percent body fat rather than lean mass, was found to be more highly associated with CHR task performance. Sibella *et al.* [35] analyzed the biomechanics of 40 obese participants and 10 normal weight participants and found that obese individuals had poorer biomechanical strategies during the CHR task which contributed to fewer chair stands. It was reported that obese individuals who performed the CHR task had minimal trunk flexion and moved their feet backwards underneath their body while rising from the chair which increased the amount of knee flexion necessary to stand compared to normal weight participants stood from the chair by using forward trunk flexion and keeping their feet in front of their body, directly underneath their knee [35]. It was proposed that obese participants stood from the chair in that fashion because the increased volume of body fat surrounding the abdomen and hip regions did not allow for as much forward trunk flexion during the task [35]. Because the obese individuals relied more heavily on the musculature within their lower body to stand, rather than using the musculature within the whole body like the normal weight individuals, CHR task times were compromised. Additionally, because the CHR task is associated with lower body endurance, and higher %Fat is associated with increased body weight, it is disadvantageous to have higher %Fat when trying to move a heavier load repeatedly and may result in poorer CHR performance [13, 35].

Individuals with higher %Fat covered less distance during the WALK task. Donini *et al.* [9] found that both males and females (48.5±14 years) who were obese, as defined by a BMI > 40 kg/m^2, were more likely to experience self-reported disability and to perform more poorly during the WALK task. It was proposed that physical function tasks that rely on the lower body to support and move the body, such as the WALK task, are most impacted by excess body fat, causing large decrements in performance [9, 49]. Adipose distribution in the lower half of the body (gynoid adiposity) may result in decrements in physical function in females caused by a biomechanical disadvantage [7]. Adipose deposits in the leg may alter the weight required to be moved by the knee joint, consequently, walking speed is reduced, resulting in decreased functional ability [7]. Furthermore, excess body fat may be associated with inefficient gait patterns, which may cause inefficient movement patterns related to a limited range of motion as a result of the concentration of body fat in the hip and thigh region [9, 23]. This may lead to functional limitations and disability [9, 23]. Due to inefficient gait patterns, energy expenditure during physical function tasks is increased compared to individuals with normal %Fat, which may cause muscular fatigue, yielding further decrements in physical function ability [34].

Interestingly, sedentary time, rather than steps per day, was most strongly associated with UPGO performance. Leung *et al.* [25] found that older individuals who were more sedentary had poorer UPGO scores compared to individuals who were less sedentary. In addition, Leung found that individuals who were more sedentary accumulated sedentary time in fewer but longer sedentary bouts compared to more active individuals. This means the sedentary participants stood up and moved only a few times a day and spent the majority of their day seated [25], resulting in less time practicing activities involving speed and agility, such as getting up from a chair [48]. In addition, the relationship between sedentary behaviors and higher %Fat especially with advanced age is highly related and has been studied extensively [21, 32, 40]. Visser *et al.* [43, 44, 45, 46] suggested that the relationship between increased sedentary times and higher %Fat were resulted in slower walking speeds because of the increased energy expenditure and resulting fatigue caused by moving a heavy load. These statements made by Visser *et al*. support the results from our study.

It was determined that %Fat was unrelated to LIFT times. Naugle *et al.* [27] supported our finding that %Fat is not related to LIFT performance in older adults. They found that there was no difference in LIFT performance times between individuals of different body composition but suggested that individuals with higher %Fat are more likely to experience difficulty performing tasks that primarily require the use of the lower-body and that lower-body functionality is typically the first to decline with age. It was further suggested that it is easier to maintain functionality of the upper-body compared to the lower-body. Because the LIFT task requires the use of both the upper and lower-body, it is possible that decrements in physical function cannot be determined using this task until individuals begin experiencing severe declines in upper- and lower-body physical function. Further studies should examine the component of body composition that is most strongly associated with functional limitation in the upper-extremities as the component of body composition most strongly associated with the LIFT task remains elusive.

The data suggests that it is vital to maintain a healthy level of body fat throughout middle and older age in an attempt to delay and prevent physical function decline, in an effort to maintain one's independence and related quality of life. Interventions focusing on helping middle-aged and older women reach and maintain a healthy level of body fat are important to implement as females tend to report experiencing declines in functional ability before their age-matched male counterparts, then live longer, causing females to spend more of their lifetime disabled [16]. It may be important for future research to determine the upper and lower limits of body fat percentages that are most strongly associated with poor physical function performance and therefore poor prognosis into older age as that number currently remains elusive. Therefore, individuals may take part in a diet and exercise program that targets decreasing percent body fat, therefore improving physical function outcomes and quality of life [5, 37, 41, 42].

This study found that lean mass was not related to any physical function tasks. A similar study by Visser *et al.* [43] found that muscle strength, but not muscle size was related to physical function performance. The current study did not assess muscular strength. Therefore, future studies should include a component of lower limb strength, as previous research has shown that muscle strength and relatedly, muscle quality, may be more strongly associated with physical function performance, rather than muscle mass or size [9].

The present study is not without limitations. First, due to the cross-sectional design, we are unable to draw inferences about causality. Second, the study included only middle-aged women who were community-dwelling, non-smokers, and had no orthopedic limitations, therefore the findings of the study may only be applied to non-smoking, able-bodied individuals within this same age range. Third, 99% of the participants self-identified as Caucasian, thus, the results of the study may not reflect the general middle-aged female population. In addition, muscle strength and muscle quality were not assessed in this study. Future studies should include measures of body composition, including %Fat and lean mass, and both muscle strength and muscle quality to determine their influences on physical function performance.

CONCLUSION

In conclusion, %Fat, rather than lean mass, was most strongly associated with physical function performance in middle-aged women. With 44.6% of middle-aged women living the United States having obesity and transitioning to older age [12], it is crucial that exercise and dietary interventions begin in middle-age and focus on decreasing %Fat. Our research suggests that exercise interventions that focus on decreasing %Fat in middle-aged females should increase the number of steps per day of each participant accumulates, as steps per day was most strongly associated with physical function performance. In addition, improvement of body composition (i.e. decreasing %Fat) in middle-aged women may delay development of or minimize the impact of age-related development of physical disabilities, which is associated with improved quality of life.

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TABLES

Table 1. Participant demographics (n = 80)

Characteristic	Mean ± SD	Range
Age (years)	52.58 ± 6.10	40.00 – 63.00
Total number of medical conditions*	3.00	0.00 – 10.00
Number of medications*	2.00	0.00 – 10.00
Height (m)	1.64 ± 0.06	1.51 – 1.78
Weight (kg)	73.08 ± 14.93	49.40 – 118.30
Body mass index (kg/m^2)	27.46 ± 5.20	20.10 – 42.90
Body fat (%)	38.90 ± 7.40	22.96 – 54.57
Lean mass (%)	58.93 ± 7.60	43.15 – 75.63
Fat-free (%)	62.23 ± 8.01	45.50 – 79.51
Lean mass (kg)	42.26 ± 5.41	33.17 – 59.79
Fat-free lean mass (kg)	44.62 ± 5.70	34.86 – 62.82
Lean index (kg/m^2)	15.69 ± 1.60	12.74 – 21.75
Appendicular skeletal muscle index (kg/m^2)	7.06 ± 0.90	5.17 – 9.72
Appendicular fat-free index (kg/m^2)	7.49 ± 0.93	5.50 – 10.21
Physical activity: Steps/day	7711.00 ± 2838.00	2183.00 – 15954.00
Meeting 10,000 steps per day (%)	13.00	
Physical activity: Low + MVPA per day (min)	319.50 ± 68.50	149.50 – 489.17
Physical activity: MVPA per day (min)	30.31 ± 21.66	1.00 – 112.00
Meets 30 MVPA min per day (%)	42.50	
Physical activity: MVPA per week (min)**	242.31 ± 163.88	17.00 – 787.00
Meeting 150 MVPA per week (%)**	63.90	
Physical activity: Sedentary time per day (min)	564.69 ± 142.37	292.80 – 1130.90

Data is presented as mean ± SD unless stated otherwise.
MVPA, moderate to vigorous physical activity.
* Median
**n = 36, 44.44% of participants wore the ActiGraph Accelerometer for 7 or more days.

Table 2. Physical function performance (n = 80)

Characteristic	Mean ± SD	Range
SIT (sec)	4.00 ± 1.17	1.85 – 8.19
CHR (repetitions)	20.00 ± 5.00	10.00 – 31.00
WALK (m)	565.75 ± 68.48	429.30 – 732.00
UPGO (sec)	5.35 ± .86	2.38 – 7.37
LIFT (sec)	59.00 ± 10.28	39.09 – 80.66

Data is presented as mean ± SD unless stated otherwise.
SIT, Transfer Task, where faster times indicate better performance.
CHR, 30-Second Chair Stand; where more repetitions indicate better performance.
WALK, 6-Minute Walk, where larger distance indicates better performance.
UPGO, Timed Up-and-Go; where faster times indicate better performance.
LIFT, Lift and Carry, where faster times indicate better performance.

Table 3. Bivariate associations between age, body composition, physical activity, and physical function in middle-aged women (n = 80)

	Age	Wt	%Fat	LM	Steps	Act	MVPA	Sedentary	SIT	CHR	WALK	UPGO	LIFT
Age	1.0	-.324**	.085	-.558**	.036	.015	-.013	.042	.310**	-.146	-.046	.145	.226*
Wt		1.0	.723**	.756**	-.223*	-.254*	-.067	-.021	.392**	-.317**	-.413**	.267*	.143
%Fat			1.0	.119	-.234*	-.259	-.179	.084	.534**	-.354**	-.476**	.321**	.217
LM				1.0	-.057	-.080	.125	-.0117	.022	-.115	-.111	.052	-.067
Steps					1.0	.633**	.863**	-.116	-.314**	.405**	.274*	-.202	-.226*
Act						1.0	.445**	-.204	-.203	.339**	.224*	-.211	-.083
MVPA							1.0	-0.71	-.239*	.272*	.235*	-.094	-.151
Sedentary								1.0	.148	-.102	.026	-.223*	.067
SIT									1.0	-.542**	-.491**	.386**	.566**
CHR										1.0	.411**	-.465**	-.607**
WALK											1.0	-.406**	-.577**
UPGO												1.0	.553**
LIFT													1.0

Age, years of age; Wt, total body weight in kg; %Fat, whole body adiposity; LM, total body muscle mass; Steps, steps per day; Act, total light, moderate and vigorous physical activity per day; MVPA, moderate to vigorous physical activity per day; Sedentary, sedentary time per day; SIT, Transfer Task; UPGO, Timed Up-and-Go; LIFT, Lift and Carry; CHR, 30-Second Chair Stand; WALK, 6-Minute Walk.

*$p \leq 0.05$

**$p \leq 0.001$

Table 4a. Regression analysis: SIT

		R^2	β	95% CI
Step 1				
	Age	.096*	.320*	0.18 - .100
Step 2				
	Age	.202*	.322*	.022 - .101
	Steps/day		-.326*	.000 - .000
Step 3				
	Age	.402**	.282*	.020 - .088
	Steps/day		-.215	.000 - .000
	%Fat		.462**	.045 - .105

Analyses were conducted in this order: Step 1, age; Step 2, Steps/day (steps per day); Step 3, %Fat (whole body adiposity).
β = Standardized regression coefficient
*$p \leq 0.05$
**$p \leq 0.001$

Table 4b. Regression analysis: CHR

		R^2	β	95% CI
Step 1				
	Age	.021	-.146	-.327 - .068
Step 2				
	Age	.190**	-.160	-.323 - .039
	Steps/day		.411**	.000 - .001
Step 3				
	Age	.254*	-.136	-.296 - .055
	Steps/day		.349**	.000 - .001
	%Fat		-.261*	-.339 - -.042

Analyses were conducted in this order: Step 1, age; Step 2, Steps/day (steps per day); Step 3, %Fat (whole body adiposity).
β = Standardized regression coefficient
*$p \leq 0.05$
**$p \leq 0.001$

Table 4c. Regression analysis: WALK

		R^2	β	95% CI
Step 1				
	Age	.002	-.046	-3.049 – 2.029
Step 2				
	Age	.078*	-.054	-3.064 – 1.852
	Steps/day		.275*	.001 - .012
Step 3				
	Age	.254**	-.016	-.2414 – 2.057
	Steps/day		.171	-.001 - .009
	%Fat		-.434**	-5.887 - -2.104

Analyses were conducted in this order: Step 1, age; Step 2, Steps/day (steps per day); Step 3, %Fat (whole body adiposity).
β = Standardized regression coefficient
*$p \leq 0.05$
**$p \leq 0.001$

Table 4d. Regression analysis: UPGO

	R^2	β	95% CI
Step 1			
Age	.021	.145	-.011 - .052
Step 2			
Age	.074*	.154	-.009 - .053
Sedentary time/day		-.230*	-.003 - .000
Step 3			
Age	.182*	.127	-.011 - .047
Sedentary time/day		-.257*	-.003 - .000
%Fat		.332*	.014 - .063

Analyses were conducted in this order: Step 1, age; Step 2, Sedentary time/day (average minutes of sedentary time per day); Step 3, %Fat (whole body adiposity).
β = Standardized regression coefficient
*$p \leq 0.05$
**$p \leq 0.001$

Table 4e. Regression analysis: LIFT

		R^2	β	95% CI
Step 1				
	Age	.051*	.226*	.009 - .751
Step 2				
	Age	.106*	.234*	.030 - .756
	Steps/day		-.233*	-.002 - .000

Analyses were conducted in this order: Step 1, age; Step 2, Steps/day (steps per day).
β = Standardized regression coefficient
*p ≤ 0.05
**p ≤ 0.001

FIGURES

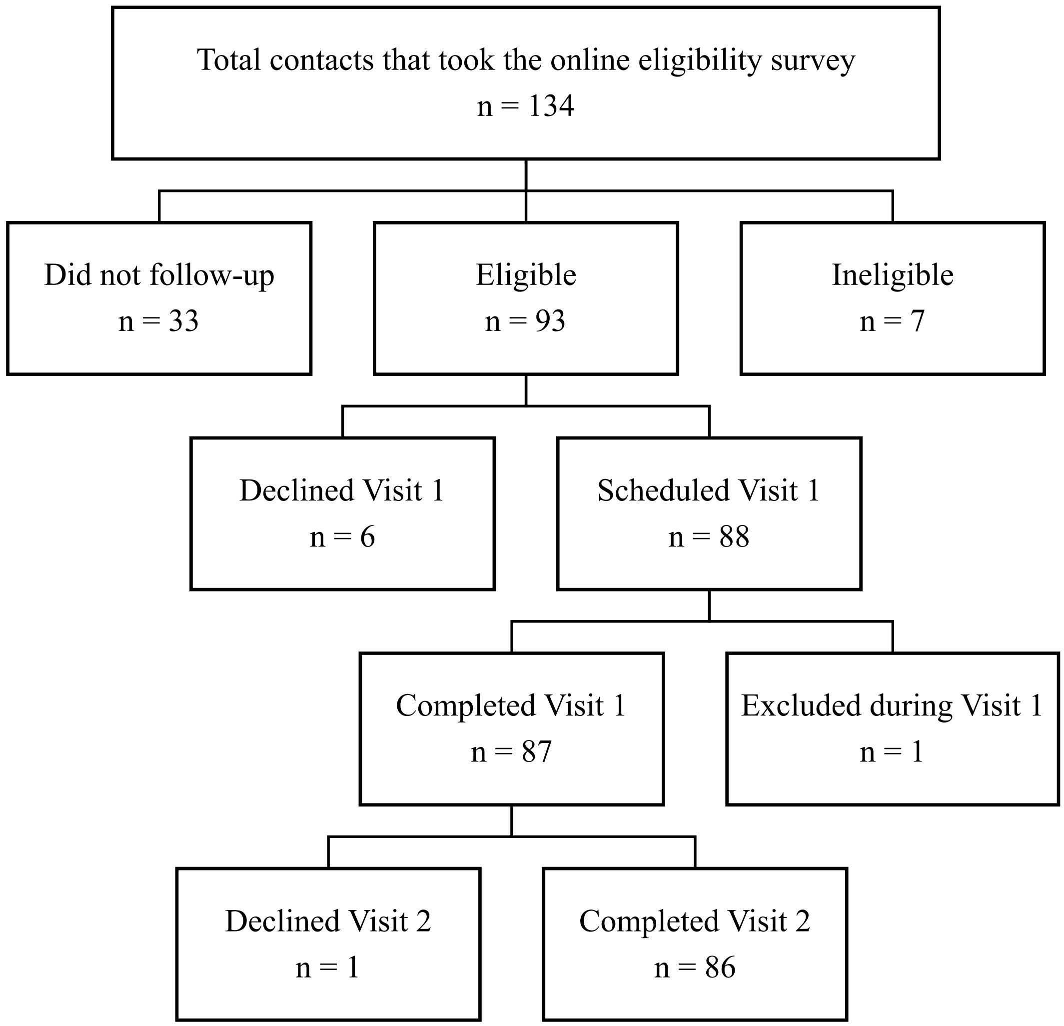

Figure 1. Study Flow Chart

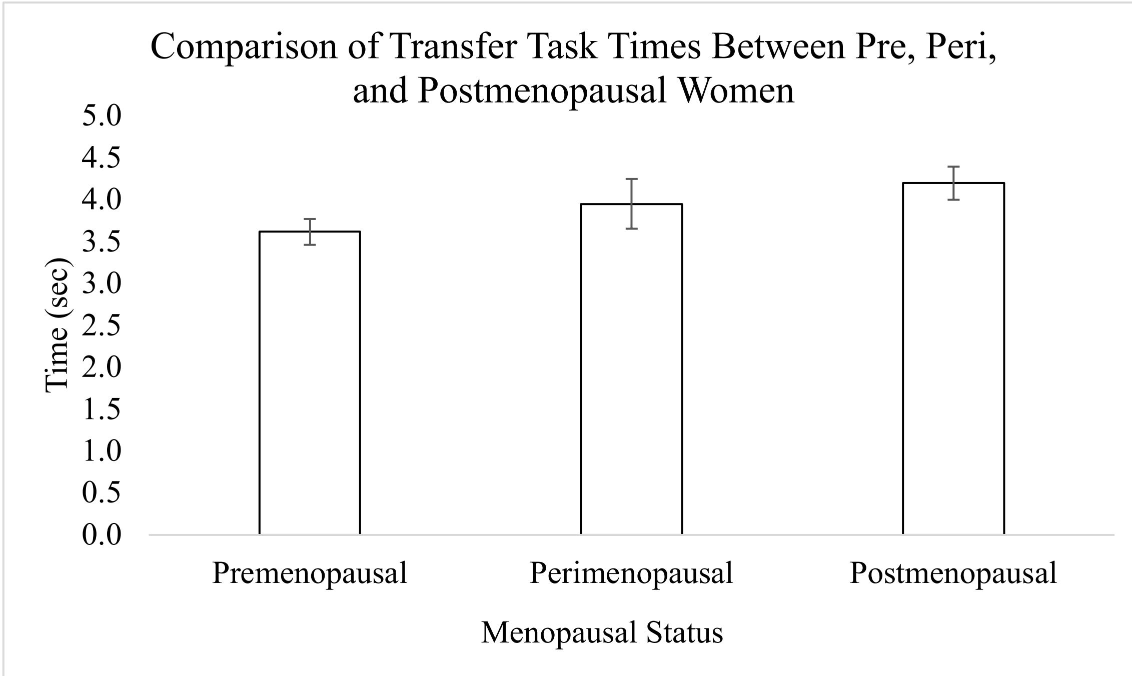

Figure 2a. ANOVA: SIT
Transfer Task Performance by Menopausal Status.

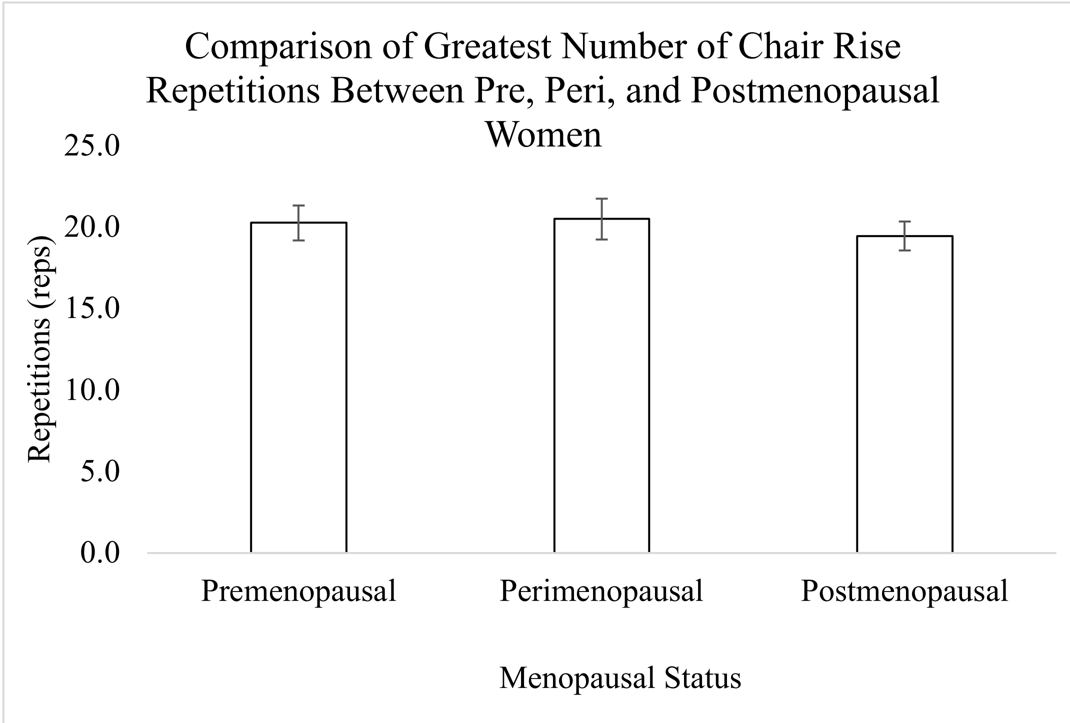

Figure 2b. ANOVA: CHR
Chair Rise Performance by Menopausal Status.

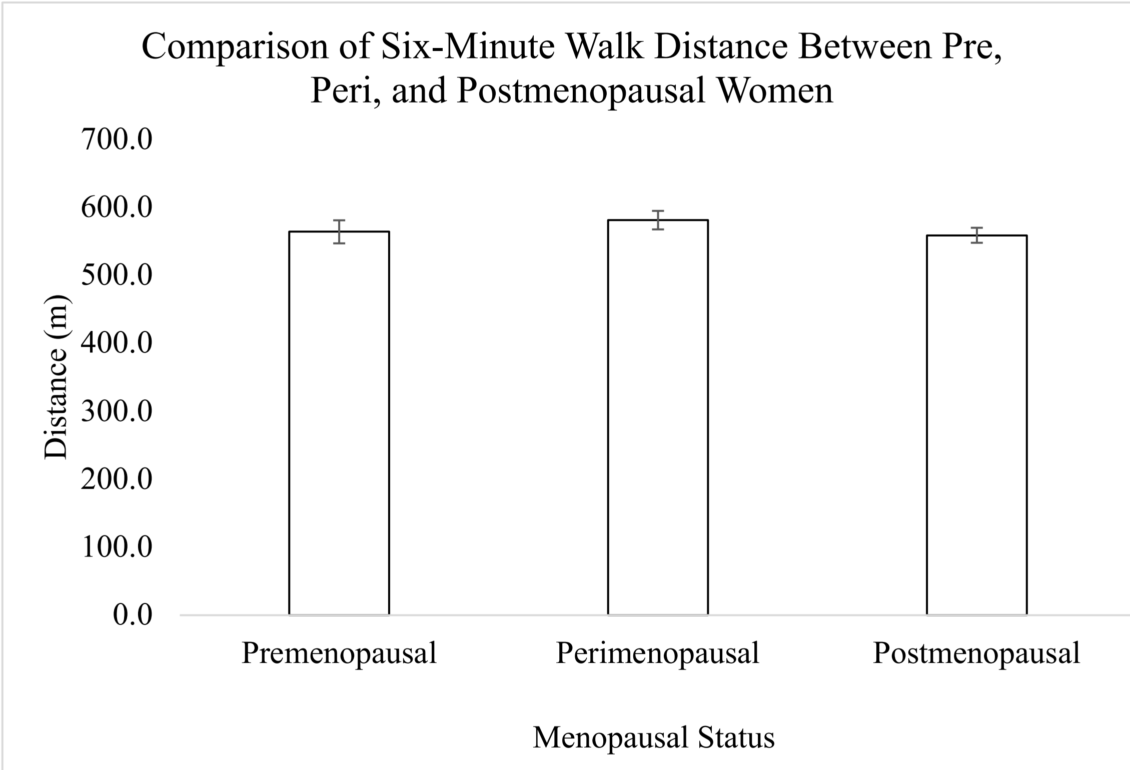

Figure 2c. ANOVA: WALK
Six Minute Walk Performance by Menopausal Status.

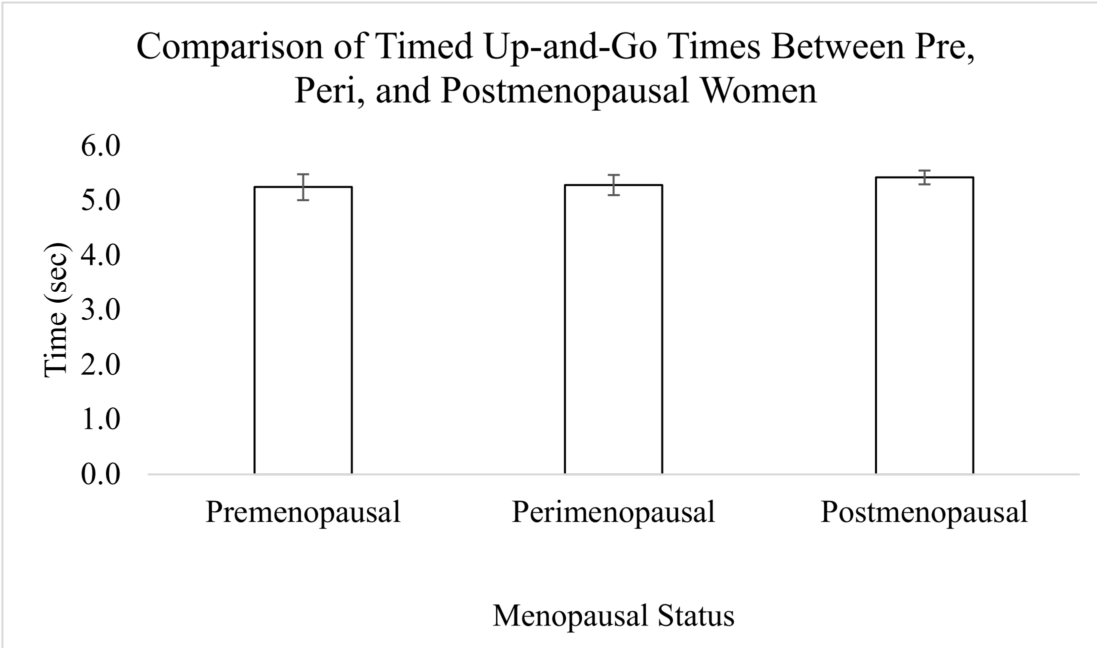

Figure 2d. ANOVA: UPGO
Timed Up-and-Go Performance by Menopausal Status.

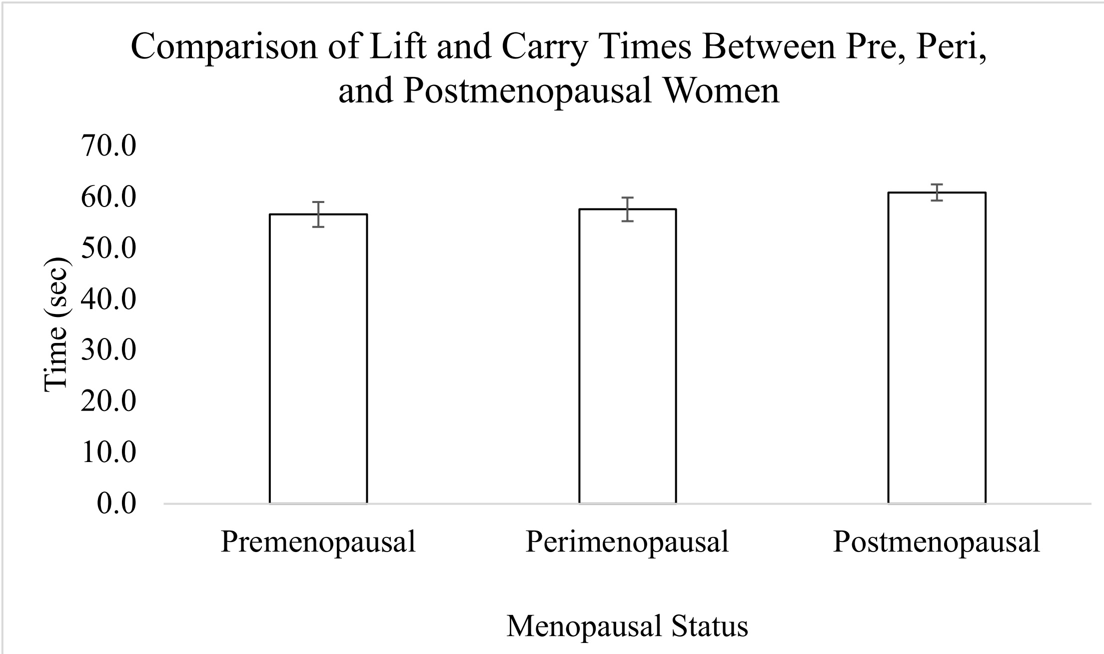

Figure 2e. ANOVA: LIFT
Lift and Carry Performance by Menopausal Status.

APPENDICES

APPENDIX A – Review of the Literature

Abstract

Body composition is defined as the proportion of fat free mass (muscles, bones and organs) and adipose tissue mass within the body. Lean muscle mass is defined as the proportion of mineral-free, fat-free tissue within the body. Generally, as individuals age, a decrease in lean mass occurs with a concomitant increase in fat mass, even in those who remain are weight stable. When compared to their age-matched male counterparts, females are at an increased risk for low levels of lean mass and higher than optimal levels of body fat. This transition to less than optimal body composition (i.e. low volumes of lean mass and high volumes of adipose) is associated with lower levels of physical function performance. This is problematic as poor physical function has been linked to poorer quality of life. While a number of studies have been complete examining relationships between body fat, lean mass, and physical function in older women, these relationships are still not well characterized in middle-aged women.

Introduction

Older adults, or those ages 65 and older, are the most rapidly growing population within the United States [24]. In 2014, there were nearly 46.2 million older adults living in the United States [34]. That number is expected to increase to 77 million by 2020 as the "Baby Boomer" generation transitions from middle to older age. It is also predicted that in 2050, the number of older adults will increase to 83.7 million [31]. It is also predicted that in 2050, 55.1% of the population over the age of 65 will be female, and these females will live to be on average 86.2 years of age, outliving their male counterparts by an average of 4 years across all ethnicities [28].

Historically, the majority of health-related studies have been conducted exclusively in males, for three primary reasons [25]. The first reason that women have been excluded from participation is because of chance of exposure to experimental risk during childbearing years [25]. The second reason women are often excluded from research is because of the perception that females are less affected by particular disorders or conditions and often times go undiagnosed [25]. Cardiovascular disease is the leading cause of death among women [25, 32], however, women are underrepresented in literature relating to cardiovascular disease, potentially because females are less likely to be diagnosed due to differences in signs and symptoms between the sexes. The third reason women are often underrepresented within scientific literature is that the introduction of hormonal changes (including the menstrual cycle and menopausal status changes) decrease homogeneity within the sample and may introduce confounding variables and a source of error [25]. As a result, women are often underrepresented in scientific literature. In terms of understanding the influences of physical function limitations and physical disability, it is disadvantageous for women to be underrepresented in the literature as women are at a greater risk for having functional limitations and less than optimal body composition compared to age-matched males [16].

The current state of the literature suggests the need for more research concerning middle-aged and older women and causes of disability, as the prevalence of individuals who are older, female, and have a high percentage of body fat is increasing [36]. It is well established that increasing age is associated with decreasing functional ability and relatedly, poorer quality of life [51]. The majority of studies examining these outcomes involve older adults because the transition from young to older age is complete. Older adults are also more susceptible to declines in physical function, leading to physical disability and institutionalization compared to young and middle-aged individuals, representing a significant public health concern [42]. Additionally, older adults currently account for nearly 15% of the population and that number is projected to continue increase by 2050 [12]. As the number of middle-aged adults transitioning into older age at this time will significantly increase the percentage of American classified as older adults, it is crucial to examine health outcomes in middle-aged individuals to determine which steps may be taken during the middle-age timeframe to improve health and quality of life in older adulthood. Intervening in middle-age may allow for preservation of independence among older adults and its associated benefits, including decreased risk for physical disability, delayed admittance into nursing homes, decreased health care costs, decreased risk for disability and decreased risk for early mortality [47]. Research examining differences among the sexes have shown that females are at a greater risk for having less than optimal body composition, including higher percentages of body fat and lower volumes of lean mass [17, 36, 42, 46]. These poorer body composition outcomes place women at a higher risk for adverse health outcomes, including disability and institutionalization compared to their age-matched male counterparts [42]. This indicates a critical need for examination of these outcomes in females.

It has been demonstrated that body composition is associated with physical function performance in older age [17, 36, 42, 46], and while intervening to improve these outcomes in older age has been done, it may be more effective to begin these types of interventions during middle-age. Therefore, examining body composition outcomes during middle-age may be crucial, as examination of the relationships between body composition and physical function, and relatedly, to design effective interventions may delay physical disability and institutionalization [43]. The benefits of intervening during middle-age may last into older adulthood. Relatedly, determining the body composition component of body composition that is most highly related to physical function performance is important because interventions designed to change lean mass and adipose tissue mass would differ in their design [9]. Interventions for preserving or improving lean mass would focus on increasing levels of physical activity and exercise, specifically resistance training, while those targeting improvements in adipose tissue mass would focus on adipose tissue loss and would need to include diet modification. These interventions may be able to preserve independence, delay admittance into nursing homes, and decrease risk for early mortality [30, 35]. To date, it is still not well established how body weight and body composition measures, including percent body fat and lean tissue mass, impact physical function performance in middle-aged women.

Physical Functioning

Physical function denotes an individual's capacity to perform various activities that require physical capability including activities to maintain independent living status [29]. The inability to perform physical function tasks, such as standing up from a chair or sitting on the ground and standing up, is defined as physical disability. Physical disability is associated with a number of health outcomes [13], including frailty. Physical disability increases one's risk for institutionalization [9, 13, 42]. While poor physical function and physical disability are widely thought to be "older adult" issues because older women typically report higher levels of physical disability in areas such as ambulation and self-care than middle-aged females [38, 52], it has been reported that middle-aged women also experience limitations in function [38, 52]. One study from 2006 estimated that nearly 10% of females ages 40 – 55 years have experienced some limitations in self-reported physical function ability and an additional 9% of females have reported substantial limitations in self-reported physical function [38, 52]. In 2017, The Study of Women's Health Across the Nation found that 29.6% of middle-aged women report moderate functional limitations and 11.0% report severe functional limitations [40]. If a greater number of women are experiencing physical disabilities in middle-age, theoretically the number of women experiencing physical disability in older adulthood will increase as these women transition from one age group to the next. Additionally, females report longer periods of physical disability compared to males, 4.5 years compared to 2.9 years, respectively [16]. Therefore, it is important to examine the factors associated with poor physical function and physical disability in women across the lifespan.

Body Composition

Body composition is defined as the proportion of fat free mass (muscles, bones and organs) and adipose tissue mass within the body [35]. Obesity is currently defined by having a body mass index (BMI) above 30.0 kg/m^2 and is associated with increased body mass and high volumes of adipose tissue [30, 35]. In 1994, 30.3% of females ages 40-59 were obese [14]. Currently, 44.6% of females living within the United States ages 40-59 are classified obese [14]. It is estimated that globally from 1975 to 2014, the prevalence of obesity has increased from 6.4% to 14.9% [27]. It is further predicted that by 2025, 21% of females throughout the world will be obese [27]. The increase in obesity rates within this group over time is alarming as obesity is associated with increased risk for chronic diseases, including cardiovascular disease, hypertension, metabolic disease, stroke, Type II diabetes mellitus, and early mortality [36, 42, 51, 52]. Obesity has been associated with decreased physical function capacity in middle-aged adults and is associated with increased risk of disability in older adults [9, 42]. It has been reported that weight loss in older adults may be associated with improved physical function performance, however, the benefits of a weight loss programs targeted at older adults are somewhat controversial [33, 37]. Some research indicates that maintaining body weight in older age may be more favorable with increasing age [37] because decreases in body weight are associated with decreased volumes of lean muscle, which may be associated with poorer physical function ability [5]. In addition, caloric deficits are associated decrease in nutrient intake. It is detrimental to decrease intake of nutrients such as calcium is essential for bone health and bone mineral density. Poor bone mineral density is associated with osteopenia and osteoporosis, both of which are related to higher risk for broken bones, causing loss of independent living status [5]. This indicates that middle-age may be an optimal window to intervene for positive body composition changes, with the goal of preventing or delaying physical function decrements with age.

There has been an extensive amount of research done examining the influence of body composition on physical function performance in older adults, however, it has yet to be determined which component of body composition is most strongly associated with physical function ability [52]. Riebe *et al.* [36] investigated the relationship between obesity, age, physical activity and physical function performance in 821 older males and females age 76.9 $\pm$ 6.3 years. Each participant had their BMI calculated based on self-reported height and weight measurements. Participants completed the Yale Physical Activity Survey, which estimated time spent active during a typical week of the last month. Objective physical function was examined via the Timed-Up-and-Go. This study found that participants who were female, spent the most time sitting, were older than 85 years, or were obese, had higher Timed-Up-and-Go times indicating poorer physical function performance.

The purpose of a longitudinal study conducted by Batsis *et al.* [6] was to determine if participants age 60 years and older with above average BMI and large waist circumference were at a greater risk of functional decline over a 6-year period compared to participants with a normal BMI and normal waist circumference. Male and female participants (n = 2,210) were placed into one of six categories based on both their waist circumference measurement and BMI. Functional ability and disability were assessed subjectively using a number of self-report measures and objectively using a 20m walk test. The data was corrected for age, sex, education, race, smoking status and osteoarthritic status. It was found that participants who had a BMI above normal (>24.9 kg/m^2) and large waist circumference (>88cm for females and >102cm for males) at baseline had significantly greater declines in physical function, demonstrated by poorer gait speed, compared to those with a normal BMI and normal waist circumference measures over the 6-year follow up. This study indicates that a high BMI and large waist circumference are important predictors for poor physical function performance. However, this study did not examine body composition objectively and therefore, were unable to determine if lean mass or percent body fat was more likely to be associated with poor physical function. This indicates a need for further examination of the association between objectively measured body composition and physical function outcomes. Additionally, this study was conducted with both males and females and did not examine the impacts of BMI and waist circumference on physical function based on gender, highlighting the need for further investigation in females. Furthermore, this study was conducted on adults over the age of 60, emphasizing the need for further investigation on body composition on physical function performance in ages younger than 60 years, so that efforts may be made earlier in life to prevent poor physical performance in older adulthood.

A cross-sectional observation study by Baldwin *et al.* [4] found that middle-aged and older individuals with a lower body weight, BMI and waist circumference had a higher self-reported physical function ability, and performed better on objective physical function tasks, such as the Six-Minute Walk. This study did not examine their results by sex, indicating that the results may be applied to the age-matched population as a whole, but cannot be applied specifically to men and women separately. In addition, the specific component of body composition that was associated with physical function performance was not identified, indicating that further research should include measurement of these components so that these relationships can be examined.

Zoico *et al.* [54] examined the body composition and physical function of a cohort of 177 females between the ages of 66 and 78. To be eligible for participation, participants had to have no physical function limitations at baseline. The study found that over a 2-year period, even though body mass did not change, only 47% of females were still free of physical function limitations, 48.2% of females developed mild disability, and 2.4% of females developed moderate to severe disability in activities of daily life. After adjusting for age, number of diseases, osteoarthrosis status, and lean mass, individuals who had a fat mass index above the 50% percentile for their age range were more 3 – 5 times more likely to have an increased risk for physical function limitation compared to individuals with normal body fat percentages. This study is valuable because it determines the independent component of body composition that may be associated with poor physical function performance, however, this study was done in a cohort of older females. Therefore, the conclusions made during the study cannot be applied to the middle-aged female population.

Jankowski *et al.* [17] examined body composition, including fat mass, lean muscle mass and BMI, and its relationship with objective physical function in a cohort of older adults. One-hundred nine male and female participants (69 $\pm$ 7 years) completed the Continuous Scale-Physical Functional Performance test, were classified as normal weight, overweight or obese based on their BMI, and underwent a DXA scan. The fat index (the amount of fat each participant relative to height) and appendicular skeletal muscle index (the sum of mineral-free, fat-free tissue of the arms and legs) of each participant was determined using DXA. Individuals who were classified as obese or who had a high fat index performed more poorly on the objective physical function tasks. Appendicular skeletal muscle index was not related to objective measure of physical function performance. This study is important because it examines a variety of body composition variables and their impact on physical function, but this study was performed in an older men and women and therefore the results of the study cannot be applied to middle-aged adults.

A cross-sectional study by Ward-Ritacco *et al.* [52] examined the impact of body composition, physical activity, muscle capacity, and muscle quality on physical function performance in 64 postmenopausal females, aged 58.6 $\pm$ 3.6 years. Analyses were controlled for physical activity level (steps per day and objectively quantified moderate to vigorous physical activity levels). Body composition was measured via DXA. Physical activity was assessed via Accelerometer, and muscle capacity (strength and power of the knee extensors and flexors) was assessed using isokinetic dynamometry and the Nottingham Leg Extensor Power Rig. Muscle quality was determined by the ratio of isokinetic dynamometry values to upper leg lean mass, and the ratio of leg power to lower body lean mass. Physical function was objectively assessed using the Six-Minute Walk, 30-Second Chair Stand, and Timed Up-And-Go. This study found that individuals who had greater adiposity, took fewer steps per day, and those who engaged in fewer minutes of moderate to vigorous physical activity had poorer physical function outcomes. This study reported that individuals who had more favorable body composition (i.e. high lean mass), fewer medical conditions, and high muscle quality performed better on physical function tasks. Additionally, individuals with a high percent body fat performed more poorly on all physical function tasks but especially the Six-Minute Walk. It was also determined that females who had higher volumes of lean thigh muscle mass and had higher strength and power values when performing isokinetic tests of the knee flexors and extensors, performed better on all physical function tasks relating to explosive movements (i.e. the 30-Second Chair Stand and the Timed Up-And-Go) compared to females with lower volumes of lean thigh muscle mass and lower strength and power values during the same tasks. This study highlights the needs for further assessment of the same variables with a larger sample size, and while including pre- and perimenopausal participants within the middle-age group. This study used only postmenopausal females, which is disadvantageous because the results of this study may only be applied to females of the same age-range who are post-menopausal.

As a part of the Health Aging and Body Composition Study, Tseng *et al.* [45] examined the sex-related relationships between physical function ability, muscle strength, muscle mass, and adipose tissue mass (determined via DXA) in a cohort of 2,863 males and females ages 70 – 79 years. Although this study found that females have poorer physical function scores compared to their age-matched male counterparts due to higher adipose mass and higher volumes of intermuscular adipose tissue and lower volumes of lean mass, the study suggested that in *absolute* terms, high volumes of adipose tissue mass may be associated with poor physical function performance, but that lean mass may be important *relative* to the amount of adipose tissue an individual has. As females carry a higher portion of their body weight as adipose tissue mass and consequently have less lean muscle mass, they have a biomechanical disadvantage because of lower volumes of lean mass relative to the volumes of adipose tissue mass. While these findings may be true in the older population, the conclusions may not be applied to the middle-aged female population, highlighting the need for further investigation into the specific, modifiable component of body composition that is most associated with physical function performance.

Although the association between adipose tissue mass and physical function has been well-established in the older female population, there has been less research examining the association between lean muscle mass and physical function, specifically in the middle-aged female population. Due to the lack of research attempting to determine which objective component of body composition is most closely related to physical function performance, the relationship between objective body composition and objective physical function performance is incompletely characterized and in need of further investigation.

Lean muscle mass defined as the proportion of fat-free, mineral-free muscle within the body [9]. It is well known that with advancing age, even if an individual is weight stable, there is a progressive loss of muscle mass, accompanied by an increase in adipose tissue mass leading to disproportionately large amounts of adipose tissue and disproportionately small amounts of lean muscle mass [2]. It is estimated that 3 – 8% of skeletal muscle mass is lost every decade after the age of 30 [3, 49] and no one, including Master Athletes, is immune [11]. This transition to a less than optimal body composition (i.e. high volumes of adipose tissue mass, low volumes of lean tissue mass) may have detrimental impacts on physical function performance, which consequently may negatively impact independent living status and lead to early admittance to nursing homes, and higher rates of morbidity [9]. In addition, females are more likely to report physical limitations across all age groups which contributes to the loss of independent living status and early institutionalization compared to age-matched males [9].

Physical function limitations and physical disability may be associated with inadequate muscle mass [18, 19, 23]. The effects of muscle mass on physical functioning performance in middle-aged women is largely understudied and requires further examination, as middle-age may represent a critical period in time where less than optimal body composition (i.e. high volumes of adipose tissue mass, low volumes of lean tissue mass) can be improved upon, consequently positively impacting health and economic outcomes of older women.

Janssen *et al.* [19] found that low skeletal muscle mass was related to functional impairment and disability amongst a cohort of 4,502 males and females over the age of 60 years. During home interviews, participants were asked to determine their level of difficulty and whether or not they needed help when performing a series of activities of daily living. Each participant was also asked to perform a series of physical function tasks, including the tandem stand, Repeated Chair Stand test and an eight-foot walk. BMI was used to classify obesity status and bio-electrical impedance analysis was used to determine muscle mass. Females who had the lowest percentages of muscle mass had the highest BMIs and reported the most disability in performing activities of daily living and physical function tasks. Conversely, females with the highest percentages of muscle mass had the lowest BMIs and low levels of disability in performing activities of daily living and physical function tasks. Although this study did not determine the component of body composition that had the largest influence on physical function performance, this study does highlight the need for further research to determine the body composition variable that has the most influence on physical functioning performance.

Visser *et al.* [50] reported that muscle mass and size, rather than adipose tissue mass was most highly related to physical function scores in females between the ages of 70 and 79 years, suggesting that the age-related decline in muscle mass is more detrimental to independent living status, disease status and morbidity than the age-related increase in adipose tissue mass. The study also highlights the need for further body composition research in both the middle-aged population and older adults to determine the most optimal intervention strategies for maintaining and improving physical function ability through the delay or prevention of age related muscle loss.

Maltais *et al.* [23] proposed that the loss of lean muscle mass may be caused by an age-related denervation of type I muscle fibers, a transition from type II muscle fibers to predominantly type I muscle fibers, atrophy of pre-existing type I muscle fibers, and the inability to recruit all motor units innervating the muscle fibers [11, 23, 26], rather than the age-related increase of adipose tissue volume. Stanley *et al.* [39] supported the claim and proposed that the transition from type II fibers to predominantly type I muscle fibers resulting in lower power output, causing individuals to be weaker and slower. In turn, the physical function tasks that are associated with power, such as the Timed Up-and-Go, Transfer Task or the 30 Second Chair Stand, are negatively impacted [1].

Findings from a cross-sectional study by Lebrun *et al.* [21] support the claim that increased muscle mass is associated with better physical function. It was also suggested that high volumes of adipose tissue are associated with impairment during activities of daily living [21]. In this study, 396 postmenopausal, independently living females aged 56-73 years old had body composition examined via DXA and muscular strength (grip strength, quadriceps strength) via dynamometry. Physical function performance was assessed subjectively using a number of surveys. Results indicate that females with higher volumes of lean mass had higher muscular strength and reported less disability in activities of daily living compared to individuals with high volumes of adipose tissue. Additionally, higher volumes of adipose tissue mass were associated with poorer physical performance and increased frequencies of disability. However, a limitation of this study is that participants were all postmenopausal, and their results do not examine these outcomes in pre- or perimenopausal as well.

Additionally, this investigation has a wide age range, 56-73, which crosses both the middle and older age group definitions, making it difficult to draw conclusions about each age group.

Fantin *et al.* [10] followed 97 females ages 71.4 $\pm$ 2.2 years over a 5.5-year period. Participants underwent a Six-Minute Walk and DXA at baseline and at the conclusion of the study. It was reported that individuals who lost lean muscle mass in their legs had a two-fold greater risk of becoming disabled compared to individuals who did not lose lean mass. Individuals who had either positive or negative changes in adipose tissue mass did not experience changes in disability status, suggesting that exercise interventions in older populations should focus on increasing muscle mass size, rather than losing weight [9, 42].

Sternfeld *et al.* [41] examined the sex-stratified associations between adipose tissue mass, lean tissue mass (determined by bioelectrical impedance analysis), lean-to-fat ratio (determined by lean mass divided by fat mass) and physical function performance (determined via walking speed) in a cohort of 1,655 males and females ages 55 and older. This study found that adipose tissue mass was most strongly associated with slower walking speeds and greater incidence of self-reported physical function limitation in females. Higher volumes of lean mass on the other hand were associated only with grip strength values. However, when examining lean-to-fat mass ratio, individuals who had a higher ratio had faster walking speeds and fewer incidences of self-reported physical function limitation compared to those with lower lean-to-fat mass ratios, suggesting an important relationship between the lean and fat mass. The findings of this study imply that improvement of lean-to-fat mass ratio through a combination of resistance training, aerobic exercise, and diet changes may delay disability in older age. This study is also important because it examines the contributions of lean and fat mass in the middle-aged population, however it does not evaluate the results of the study based on middle and older age, therefore, the conclusions of the study may not be applied to only the middle-aged female population.

The research conducted by Sternfeld *et al.* [41] is also important because it was one of the first to attempt to analyze the relationship between lean muscle mass and disability in the older population. Another study that attempted to examine the same relationship was by Visser *et al* [48]. A total of 732 males and females between the ages of 72 and 95 years participated in the Framingham Heart Study. It determined that in both males and females, physical disability was related to adipose tissue mass, but not lean tissue mass, and that individuals with higher volumes of lean mass had the smallest self-reported incidences of physical disability.

Findings from Bouchard *et al.* [8] supported the findings of Sternfeld and Visser [8, 41, 48]. Obese females between the ages of 55 – 75 years old who participated in resistance training and caloric restriction had improved physical function scores compared to individuals who participated in only caloric restriction. Individuals who participated only in caloric restriction saw decreases in lean muscle mass and did not improve physical function scores, which stresses the need for inclusion of resistance training bouts in exercise routines as females age.

Physical Function Performance and Physical Activity

Physical activity is defined as any movement produced by the body that results in a significant increase in caloric expenditure above that of the resting levels [30, 35]. According to the American College of Sports Medicine, adequate physical activity is equivalent to 150 minutes of moderate aerobic physical activity per week, 75 minutes per week of vigorous physical activity or a combination of the two [30, 35]. Due to the dose-response relationship between physical activity and health outcomes, such as decreased risk for chronic disease, improved mental health outcomes and increased quality of life, individuals should exceed the minimum physical activity guidelines [30, 35]. In addition, it is recommended that individuals engage in at least two days of resistance training, involving all major muscle groups [30, 35, 51]. Physical activity levels have been shown to decrease, while sedentary time has been shown to increase over the course of the lifespan [7, 42], and relatedly risk for chronic disease and poor quality of life, including physical function increases with age [53].

It has been shown that individuals who have higher physical activity levels have higher volumes of lean muscle mass [40]. In turn, these individuals may have lower levels of physical disability as measured by physical function tasks [40]. This may be because physical function tasks such as the 30-Second Chair Stand and the Timed Up-And-Go require lower body mobility and strength, both of which are improved by physical activity [40]. One study exploring the relationship between physical activity and years of disability in individuals ages 65 years or older for 25 years or until the end of life was conducted by Jacob *et al* [16]. They found that for every 25 city blocks walked per week (equal to 1.25 miles) individuals were statistically more likely to live free of disability in their activities of daily living in their observed lifespan compared to individuals who walked fewer city blocks [16].

Many studies examining the effects of physical activity on physical functioning in females have been conducted in the older population [7, 13, 15, 16, 22, 24, 36, 44, 52, 53]. Leigh *et al.* [22] assessed the patterns of physical activity and physical functioning every 3 years over a 15-year period in cohort of 12,432 older women. BMI of each participant was calculated based on self-report height and weight. Physical activity was determined using self-reported levels of activity and estimated MET-minutes. Participants were classified as either sedentary, low, moderate, high, or very high active. Physical function of each participant was evaluated using the Medical Outcomes Study 36-item Short Form Health Survey. This study found physical function scores worsened with advancing age, regardless of BMI classification. Additionally, females who were classified as obese were more likely to belong to the low physical function group and were more likely to be sedentary. Being in the “low” activity group, rather being in the sedentary group, reduced the odds of having low physical functional ability. While this study demonstrates the benefits of physical activity on self-reported physical function when examining body composition, the study used BMI which is typically considered to be a surrogate indicator of body composition, particularly in the aging population. As aging is associated with stable body weight and reduced height caused by vertebral compression, BMI classifications may not be reliably and validly reflective of body composition [2]. Additionally, this study did not objectively quantify physical function or physical activity in each participant. Although self-report physical function and physical activity data has been correlated with objective physical function and physical activity data, self-report data may be influenced by cognition, language barriers and the administrator's expectations of the participant [4], thus, objective physical function and physical activity data is the preferred method of data collection.

The implications of the study by Leigh *et al.* [22] are far reaching. The study demonstrates the need for objective measurement of physical activity, body composition, and physical function outcomes in an effort to examine the relationships among these variables and determine their contribution to physical function outcomes. This study suggests that high volumes of regular physical activity should be implemented before reaching older age in an effort to prevent detrimental decreases in physical function [22]. Furthermore, individuals should make an effort to reduce BMI before entering older age as a method for reducing the effects of aging on physical function ability.

Few studies have assessed the relationship between physical activity and physical function in middle-aged females. One available study examined the physical function outcomes in 1,771 females ages 42 – 52 years, once a year for 13 consecutive years [31]. Participants reported their physical activity levels using the Kaiser Physical Activity Survey. They also recorded up to two sports or exercise activities (≥3 METs) that they engaged in most during the previous year, including details about the perceived intensity, frequency and duration of the activities. This data was used to create physical activity groups including highest, middle, increasing, decreasing or lowest activity levels. Participants were also classified as being under or normal weight (≤24.9 kg/m^2), overweight (25.0 – 29.9 kg/m^2) or obese (≥30.0 kg/m^2).

Participants also completed the 40-Foot Walk, the 4-Meter Walk, the Repeated Chair Stands Test, and two grip strength measurements of each hand. It was determined that individuals in the highest and middle groups of activity had the fastest 40-Foot Walk times and 4-Meter Walk times. Individuals who were in the highest, middle or increasing groups had the shortest time on the Repeated Chair Stands Test. Additionally, individuals who were in the highest, middle or decreasing physical activity groups had the highest hand grip strength values. Finally, this study found that individuals who were in the lowest or decreasing groups for physical activity were classified as being obese. This study indicates that physical activity may be an important factor in determining physical function performance when transitioning from middle to older age and is strong in its design as it uses objectively measured physical function tasks to measure physical function ability. Its conclusions are only limited by its use of self-reported methods to measure physical activity and BMI as an indicator of body composition. The study does not use a more advanced body composition measurement tool that would allow for examination of body both fat and lean mass, and therefore cannot identify the specific component of body composition most related to physical activity and physical function performance. Nonetheless, the work done by Pettee *et al.* [31] did emphasize the need for further quantification of objective physical activity and body composition measures in the middle-aged female same population.

Conclusion

In conclusion, while some studies have shown that percent body fat is most strongly associated with physical function performance in older adults, others have reported conflicting results, such as lean mass or BMI are most strongly related. In addition, most studies have been conducted only in the older population, even though previous studies have shown that functional limitations and disability are prevalent at midlife. Furthermore, women are typically an understudied population, however, females experience functional decline before their age-matched counterparts and live longer lives on average, resulting in more time spent in disability. Therefore, future studies should examine the influence of body composition, specifically percent body fat and lean mass, on physical function in middle-aged women so that interventions may be developed to delay and prevent this functional decline.

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APPENDIX B - Screening Questionnaire for the Evaluating Physical Function and Self Perception in Middle-Aged Women Research Study

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***

If an individual selects no: Thank you very much for your time.

If an individual selects yes: 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.

Name:____

Phone Number: cell____________________________

home____

Email: ______________________________

Preferred Method of Contact:

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***

If no: Thank you very much for your time.
If yes: Thank you, we will now redirect you to the survey.

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***

Are you between the ages of 40 and 64 years?

Yes ***No***

What is your date of birth?
_____ / _____ /_____

Do you understand spoken and written English?
Yes ***No***

What is your current height in feet and inches?
_______ ft ______ inches

What is your current weight in pounds?
______ pounds

What is your highest weight in past 3 months in pounds?
________ pounds

What is your lowest weight in past 3 months in pounds?
________ pounds

Do you live independently?
Yes ***No***

Are you able to transport yourself or obtain transportation to the URI campus for 2 measurement visits?
Yes ***No***

Do you currently smoke or have you smoked within the past 6 months?
Yes ***No***

Have you recently experienced cardiovascular disease event (e.g. recent myocardial infarction, stent placement) or do you have unstable cardiovascular disease (e.g. unstable angina)?
Yes ***No***

Do you have a history of COPD (e.g. chronic bronchitis, emphysema) or severe asthma?
Yes ***No***

Do you have a history of severe orthopedic/musculoskeletal or neuromuscular impairments that would contraindicate exercise (including severe arthritis)?

Yes ***No***

If yes, please provide us with some information about these conditions:

Have you been diagnosed with Type 1 or Type 2 Diabetes mellitus?
Yes ***No***

If yes, how well controlled is your DM?

If yes, Is your medication stabilized?

Have you been diagnosed with HIV?
Yes ***No***

Do you have a history of dizziness or balance disorders?
Yes ***No***

Have you ever been diagnosed with mental illness, clinical depression or dementia
Yes ***No***

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

Do you use an assistive device to help you walk (e.g. canes, crutches, walkers, braces)?
Yes ***No***

Have you ever been diagnosed with any of the following?		
	Yes	**No**
1. High blood pressure (hypertension)?	1	2
2. High blood cholesterol?	1	2
3. Cardiovascular disease (such as heart disease; heart attack (myocardial infarction), congestive heart failure (CHF), heart rhythm disorders (arrhythmias), heart murmur, chest pain (angina)	1	2
4. Cerebrovascular disease (such as a stroke, transient ischemic attack (TIA)?	1	2
5. Peripheral Vascular Disease (PVD)?	1	2
6. Chronic Obstructive Pulmonary Disease (such as emphysema, chronic bronchitis)?	1	2
7. Asthma?	1	2
8. Arthritis (such as osteo-arthritis, degenerative joint disease, rheumatoid arthritis)?	1	2
9. Upper gastrointestinal disease (such as ulcer, hiatal hernia, gastroesophageal reflux disease (GERD)?	1	2
10. Chronic liver disease (such as chronic or persistent hepatitis, cirrhosis)?	1	2
11. Cancer?	1	2
a) If yes, please specify type: ________________________________ b) If yes, please specify date of diagnosis: _________________________		
12. Anorexia nervosa (not eating and losing extreme amounts of weight)?	1	2
13. Bulimia (eating, sometimes large amounts of food and then vomiting)?	1	2
14. Degenerative disc disease?	1	2
15. Depression?	1	2
16. Anxiety?	1	2

17. Visual impairment (such as cataracts, glaucoma, macular degeneration)?	1	2
18. Hearing impairment?	1	2
19. Thyroid dysfunction (such as hyperthyroidism, hypothyroidism)?	1	2
20. Fibromyalgia?	1	2
21. Chronic fatigue syndrome?	1	2
22. Anemia?	1	2
23. Hashimodo's disease?	1	2
24. Epilepsy?		
25. Lupus (SLE)?		
26. Endometriosis?		
27. Moderate to severe back pain?		
28. Frequent and/or severe headaches?		
29. Environmental allergies?		
30. Do you have a history of having broken bones?		
31. Have you had any surgeries as an adult?		
a) If yes, please provide information about the nature of the surgery below.		

Do you have any other health issues you would like to disclose?
If yes, please provide information in the space below.

Do you take any medications or supplements?

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.

Which of the following racial or ethnic groups best describes you? (Please check all categories that apply.)
_____ Asian/Pacific
_____ Black
_____ Hispanic
_____ Indian/Alaskan
_____ White
_____ Other: Please describe

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)

If you are post menopausal, was your menopause:

- ☐ Spontaneous (natural)
- ☐ Surgical (removal of both ovaries)
- ☐ Due to chemotherapy or radiation therapy
- ☐ Other, please explain:

____

If not still having periods, what was your age when you had your last period?

_______ years

If still having periods, how often do they occur?

____

How many days does your period last?

____

Are your periods painful?

Yes No

If yes, how painful?

Mild Moderate Severe

Do you have any problems with PMS?

Yes No

How would you rate your knowledge about menopause?

☐ Very Good
☐ Fair
☐ Moderately Good
☐ Little Knowledge

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

☐ Books
☐ Internet
☐ Magazines
☐ Friends
☐ TV
☐ Health care providers

How do you view menopause?

☐ Positively. For example, menopause means no more periods and no more worry about contraception

☐ Negatively. For example, menopause means a loss of fertility and loss of youth.

☐ Other: ____

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

What are your current views regarding hormone therapy for menopause?

☐ Positive. Hormone therapy is appropriate for some women

☐ Negative. I don't support the use of hormone therapy.

What concerns you most about hormone replacement therapy? Please provide any of your thoughts in the space provided.

Please mark the appropriate box with an X to record your response to the following:

How often do you engage in each of the following behaviors?	Never	Every 2 years	Once a year	Every 6 months
See a health care professional for a general physical				
See a health care professional for a women's health exam?				
See a dental professional for a dental				
See a health care professional for an eye exam?				

Please mark the appropriate box with an X to record your response to the following:

How often do you engage in each of the following behaviors?	Never	Every 2 years	Once a year	Every 6 months
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?				

Do you currently smoke cigarettes or cigars or other tobacco products?

Yes **No**

If so, what tobacco products do you use?

———

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 C – Informed Consent

THE UNIVERSITY OF RHODE ISLAND
COLLEGE OF HEALTH SCIENCES

THINK BIG WE DO™

HEALTH STUDIES PROGRAM
25 Independence Way, Suite P, Kingston, RI 02881 USA p: 401.874.7499 f: 401.874.4215 web.uri.edu/health-studies

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/m^2, 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.

THE UNIVERSITY OF RHODE ISLAND

IRB NUMBER:	HU1516-206
IRB APPROVAL DATE:	October 23, 2017
IRB EXPIRATION DATE:	October 19, 2018

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 an 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 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. 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

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: ______________________________

Email: ______________________________

☐ No

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.

THE UNIVERSITY OF RHODE ISLAND

IRB NUMBER:	HU1516-206
IRB APPROVAL DATE:	October 23, 2017
IRB EXPIRATION DATE:	October 19, 2018

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 and 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 any other reason 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.

Informed Use of 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 ____ WITNESS ______________________________
or GUARDIAN (for participants under the age of majority)

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.

 Supported by: Health Canada Santé Canada

continued on other side...

APPENDIX E - ActiGraph Accelerometer Instructions

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 | POST

Day of the week							
	Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Date (month/day)	_____/______	_____/______	_____/______	_____/______	_____/______	_____/______	_____/______
Time On	___:___ AM or PM	___:___ 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	___:___ 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	___:___ 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	___:___ 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	___:___ 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	___:___ AM or PM
List any exercise you performed while NOT wearing the monitor (e.g., walking, jogging, swimming, cycling, aerobics):							
1. Exercise Type:							
1. Exercise Start:	___:___ AM or PM	___:___ 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	___:___ 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	___:___ AM or PM
2. Exercise Stop:	___:___ AM or PM	___:___ 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	___:___ 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	___:___ 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	___:___ AM or PM
Walk 2 Stop Time:	___:___ AM or PM	___:___ AM or PM	___:___ AM or PM	___:___ AM or PM	___:___ AM or PM	___:___ AM or PM	___:___ AM or PM