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Relationship Between Arthritis and Muscular Strength in Older Women with Symptoms of Sarcopenia

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RELATIONSHIP BETWEEN ARTHRITIS AND MUSCULAR STRENGTH IN OLDER WOMEN WITH SYMPTOMS OF SARCOPENIA

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ABSTRACT

Grip strength has been identified as a valid predictor of frailty and disability and has been shown to be a cost-effective method to assess muscular strength in older populations. Grip strength is also used in working definitions for sarcopenia classification. However, various forms of arthritis have been shown to negatively impact grip strength scores, which could potentially lead to misclassification. Therefore, the aim of this study was to investigate if hand arthritis is related to sarcopenia classification in a group of older women with or without symptoms of sarcopenia and if arthritis is related to upper and lower body muscular strength. Sarcopenia status was based on established working definitions that use grip strength or chair stands, physical function, body composition measures in a sample of 61 (71.9±4.6) and a sub-sample of 25 (72.3±4.6 years) older women. Arthritis status was based on self-report and grip strength was measured using a hand dynamometer. Upper body muscular strength was assessed with a one repetition maximum (1RM) test on a chest press machine, while lower body muscular strength was assessed with a 1RM test on a leg press machine. Characteristics of both samples were expressed as mean±SD and frequencies. A Fisher's exact test assessed the relationship between non-specific arthritis and hand arthritis to sarcopenia status. Pearson's correlation coefficients were used to assess the strength of the relationship between grip strength, chest press 1RM (CP1RM), and leg press 1RM (LP1RM) in those with hand arthritis and non-specific arthritis. Non-specific arthritis and hand arthritis were not related to sarcopenia status ($p=0.36$, $p=0.44$). There was no relationship between grip strength and CP1RM, grip strength and LP1RM, and CP1RM and LP1RM for those with non-

specific arthritis or hand arthritis. Although non-specific arthritis and hand arthritis were not related to sarcopenia status via grip strength or failure to complete a single chair stand in this sample, studies with larger sample sizes should be done to assess how arthritis is related to sarcopenia status in older women and what forms are related to sarcopenia status.

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PREFACE

This thesis is written to comply with the University of Rhode Island graduate school manuscript format. The thesis document contains one manuscript: *Relationship between Arthritis and Muscular Strength in Older Women with Symptoms of Sarcopenia*. The manuscript has been written in a form formatted for publication in the Journal of Aging Research.

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The Relationship between Arthritis and Muscular Strength in Older Women with Symptoms of Sarcopenia

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ABSTRACT

Grip strength is identified as a cost-effective, valid measure to assess muscular strength in older populations and is also used in the working definitions for sarcopenia. Various forms of arthritis impact grip strength scores, which could potentially lead to misclassification. The aim of this study was to investigate if hand arthritis is related to sarcopenia classification in a group of older women with or without symptoms of sarcopenia and if arthritis is related to upper and lower body muscular strength. Sarcopenia status was based on established working definitions that use grip strength or chair stands, gait speed, and body composition measures in a sample of 61 older women (71.9±4.6 years) screened for a randomized controlled trial and 25 of those 61 (72.3±4.6 years) who partook in baseline testing for that randomized controlled trial. Arthritis status was based on self-report and grip strength was measured using a hand grip dynamometer. Hand arthritis and non-specific arthritis were not related to sarcopenia status. No relationship between grip strength and chest press one repetition maximum (CP1RM), grip strength and leg press one repetition maximum (LP1RM), or CP1RM and LP1RM was observed. Further studies should address how specific forms of arthritis are related to sarcopenia status.

INTRODUCTION

Sarcopenia is defined as the loss of muscular strength, functionality, and lean mass seen with aging [1,2] that is related to the development of functional limitations [3]. In the United States in 2000, the estimated health care costs of sarcopenia for women were $29.5 billion [4]. Sarcopenia is a public health problem that will continue to be an economic burden as the older population continues to increase [5]. Moreover, women have a greater life expectancy and are at higher risk for functional disability due to their quicker decline in muscular strength when compared to men [5]. Additionally, there is currently no universally accepted sarcopenia classification system, but national and international organizations have established working classification systems that include measures of muscular strength, physical functioning, and lean mass [6-9].

While organizations have various criteria for sarcopenia, muscular strength is often assessed using grip strength test because it is considered a valid measure to predict overall muscular strength [6,10-12]. Using a hand grip dynamometer instead of the current gold standard, isokinetic dynamometry is easier to administer to large populations as it is more portable and compact than an isokinetic dynamometer [11-13]. Additionally, grip strength is predictive of health outcomes including frailty, disability, and mortality since naturally, muscular strength declines with age [10,13-18].

However, using grip strength as a measure of muscular strength based on the current sarcopenia working definitions may not be the best measure when functional limitations such as arthritis are present. Arthritis is a chronic disease characterized by

joint stiffness and inflammation, which can often result in joint deformities from swelling and osteophyte formation as well as decreased functionality [19-22]. In the United States, arthritis is the most common cause of disability and between 2013 and 2015, approximately 54.4 million adults were diagnosed with arthritis [23]. Older adults account for 49.6% of the 54.4 million adults diagnosed and arthritis was more prevalent in women than men [24]. Arthritis also leads to pain as well as poor physical functioning in the affected joint(s) and can make various physical assessments difficult, including evaluations in grip strength [27-32] and gait speed [31,32]. Additionally, arthritis has been shown to be associated with decreases in lean mass [31,33].

There are over 100 different types of arthritic disease including osteoarthritis, rheumatoid arthritis, gout, and fibromyalgia [21]. Osteoarthritis and rheumatoid arthritis are two forms of arthritis that commonly affect the joints of the hand and are also some of the most common forms [24-26]. Since the older population continues to increase and arthritis is more prevalent with increasing age and amongst women, arthritis may be related to sarcopenia status.

A potential misclassification of sarcopenia due to arthritis, but not a lack of overall body strength, has not been addressed in the literature. Therefore, the purpose of this study was to determine if hand arthritis is related to sarcopenia classification in older women with or without symptoms of sarcopenia. A secondary aim was to assess if grip strength was related to measures of upper and lower body muscular strength in a group of older women with symptoms of sarcopenia by hand arthritis status.

MATERIALS AND METHODS

Study Design

The study utilized a cross-sectional analysis to assess the potential effects of hand arthritis on sarcopenia status from grip strength measurements or from failure to rise from a chair unassisted in 61 community-dwelling older women. A second cross sectional analysis of 25 women from the 61, who partook in baseline testing for the 10-week, University of Rhode Island Institutional Review Board approved, Resistance Exercise Study to Reclaim Lean Muscle and Strength (URI RESTORE ME Project IRB # HU1415-168) assessed grip strength in relation to upper and lower body muscular strength. The 61 women were screened prior to the baseline testing session for potential enrollment into the URI RESTORE ME project, and of those 61, only 25 women partook in the baseline testing for the URI RESTORE ME intervention phase.

Participants

This study included 61 women (71.9±4.6 years) screened as potential participants for the URI RESTORE ME randomized controlled trial and 25 women (72.3±4.6 years) of those 61 who were selected for that trial and who also exhibited at least one symptom or sign of sarcopenia defined by various working group definitions. These community-dwelling older women were recruited from southern Rhode Island via flyers, community talks, and word of mouth, and were initially phone screened for study eligibility. The inclusion and exclusion criteria for the study are presented in Table 1. Participants who initially qualified based on the inclusion and exclusion criteria provided written informed consent and were screened for sarcopenia using the European Working Group on Sarcopenia in Older People (EWGSOP), the

International Working Group (IWG), and the Foundation for the National Institutes of Health Sarcopenia Project (FNIHSP) criteria. They were assessed on their performance in gait speed, grip strength, a single chair stand, height, weight, and lean mass measured via segmental multi-frequency bioelectrical impedance analysis (SMF-BIA). Based on the established criteria, 38 participants were qualified for the randomized controlled trial but only 25 were selected for participation into the study based on their pre-screening results, medical histories, and a physical activity readiness questionnaire (PAR-Q). The other 13, who were eligible, were eliminated due to time commitment issues or orthopedic concerns. Figure 1 depicts a flow chart of the subject recruitment process.

Outcome Measures

Sarcopenia Status: Prior to the beginning of baseline testing, participants completed pre-screening assessment to determine their sarcopenia status. The EWGSOP [6], the IWG [7], and the FNIHSP [8,9] working definitions were applied to each participant to determine their sarcopenia status based on their performance in a hand grip strength test, a single chair stand, gait speed, and their appendicular lean mass measured using a segmental multi-frequency bioelectrical impedance analysis (InBody 570 SMF-BIA, Biospace Co, Ltd, Korea) device. The following cut-points were used: <20 kg for grip strength or inability to complete a single chair stand, a gait speed <0.8m/s, and an ALM < 5.67 kg/m^2 or ALM/BMI <0.512. Women were then classified as having low muscular strength, low lean mass, or low physical functioning (gait speed), or all three aspects.

Determining Arthritis Presence: Arthritis was based on self-report noted in

participants' phone screening interviews and medical history questionnaires administered during pre-screening sessions. The phone screening interview specifically asked about osteoarthritis/degenerative arthritis and the disease duration and severity. The medical history questionnaire used a "yes/no" question to identify if the participant had arthritis as well as a separate "yes/no" question for gout. Neither questionnaire asked about which joints were affected or for specifications on other types of arthritis (e.g. rheumatoid arthritis, fibromyalgia). However, some participants chose to report what joints were affected by arthritis on the phone screening interview despite not being asked. Participants were categorized as having non-specific arthritis if they reported arthritis (any kind affecting any joint(s)) and were also categorized into a subset for hand arthritis.

Grip Strength: Hand grip strength is used to identify muscular strength [34] and is a good predictor of frailty and disability with increasing age [13,17]. Grip strength is also a key factor in the current working definitions for sarcopenia [6,9]. Grip strength was assessed using a hand grip dynamometer (Jamar Hydraulic Dynamometer, J.A. Preston, Corp., Jackson, MS) and was performed on both hands for two trials each with the highest score out of all four total trials being recorded in kilograms. Participants were seated with the elbow flexed at 90 degrees. The hand grip dynamometer was adjusted for each participant by ensuring all four fingers have the second knuckle placed flat on the handle. Grip strength was measured during pre-screening sessions and at the baseline assessment.

Single Chair Stands: Muscular strength was also assessed using a single chair stand during the pre-screening sessions. Failure to rise from a chair unassisted is used

in the IWG working definition as criteria for identifying weakness [7]. The IWG recognizes that chair stands are considered an activity of daily living and require adequate muscular strength to complete this task [7,35].

Gait Speed: The assessment of physical functioning is crucial as it characterizes an individual's functional status and can determine mortality risk [36]. A four meter gait speed assessment was done twice with participants walking at a normal pace and the best score was used in determining sarcopenia status.

Body Composition: Body composition was assessed using an InBody 570 SMF-BIA (Biospace Co, Ltd, Korea) device during the pre-screening visit as well as during baseline testing according to the manufacturer's instructions. The SMF-BIA is an accepted valid device used to estimate lean mass and is safe to use in older populations [37]. Measurements were taken at the right and left arms, the right and left legs, as well as for the trunk using 8 electrodes specifically placed and 6 different frequencies (1 kHz, 5 kHz, 50 kHz, 250 kHz, 500 kHz, 1000 kHz) which gave a total of 30 impedance measurements for each participant. The SMF-BIA uses electrical conductivity to estimate lean mass after traveling through various tissues and differentiates between the tissues depending on their water content. Lean mass contains higher amounts of water when compared to adipose tissue and therefore is a better conductor. To standardize the assessment, all participants were asked to be hydrated and fasted for at least four hours.

Anthropometrics: Participants had their height, weight, and waist and hip circumferences measured twice. Participants wore surgical scrubs for the waist and hip circumference measurements and a standard tape measure with a tensometer

(Gulick Tape Measure, Japan) was used to measure both the waist and hip. The average of the two scores was used to calculate each participant's BMI and waist-to-hip ratio.

Strength Measures: A chest press machine (Cybex International, Inc., Medway, MA) was used to assess upper body strength of each participant through methods previously published [38]. From a seated position, participants had their head, shoulders, and back against a seat back and held onto handles positioned at chest height. Participants then extended their elbows fully and then returned to the starting position. After a standard warm up, participants completed 3-5 sets of one repetition with gradually increasing weight and a three minute rest period between sets until their one repetition maximum (1RM) for chest press (CP1RM) was determined. A 1RM for lower body muscular strength for each participant was determined using seated leg press machine (Cybex International, Inc., Medway, MA) using methods previously published [39]. Participants were seated and then extended their knees from the starting position (~90 degrees) by pushing against a platform with their feet until their knees were close to full extension but not locked. After a standard warm up, participants completed 3-5 sets of one repetition with gradually increasing weight and a three minute rest period between sets until their 1RM for leg press (LP1RM) was determined.

Other Measures

Physical Activity: The Yale Physical Activity Survey (YPAS) questionnaire was administered to evaluate participants' physical activity levels and has been shown to be a valid assessment for determining physical activity levels among older adults. This questionnaire was used for describing participants' baseline physical activity

levels [40].

Dietary Intake: The Dietary Screening Tool (DST) was administered to participants at baseline testing to assess their dietary patterns at to determine their level of nutritional risk [41]. There are three levels of nutritional risk that are used to identify if older adults are at risk including: at risk (<60), at possible risk (60-75), and not at risk (>75) [42]. This questionnaire was used to describe the baseline characteristics for the participants who partook in baseline testing for the randomized controlled trial.

Arthritis Medications and Analgesics: Arthritis and painkiller medication was based on self-report noted in each participant's phone screening interviews and medical history questionnaires administered during pre-screening sessions. Table 2 depicts the number of participants who used each.

Statistical Analysis

Estimated sample size for this study was determined based on anticipated between-group changes in lean mass rather than change in sarcopenia status by arthritis status. This analysis is considered a pilot study to determine the potential for periodized resistance training to impact sarcopenia status and therefore could be underpowered.

The demographic and clinical characteristics for participants are expressed as mean ± standard deviation and frequencies. A Shapiro-Wilk test was completed to ensure the data for the primary and secondary outcome variables were normally distributed. Participants were grouped by non-specific arthritis status as well as well as a subset of that for hand arthritis status. Independent samples t-tests were used to

compare those with and without non-specific arthritis to each other as well as those with and without hand arthritis to each other. A Fisher's exact test was used to assess hand arthritis status and its relationship to sarcopenia status, as well as non-specific arthritis status to sarcopenia status for the women who partook in screening measurements for the study (n=61). To test the secondary hypothesis, a Pearson correlation was used to assess the relationship between grip strength, and upper and lower body muscular strength in those with hand arthritis, as well as those with non-specific arthritis from participants who partook in the baseline assessments (n=25). Potential outliers were identified using a box-and-whisker plot and Tukey's method. An alpha of $p \leq 0.05$ was used for all statistical analyses and all analyses were performed using both SPSS software (IBM SPSS, Version 22, Armonk, NY, 2013) and SAS software (SAS Institute, Cary, North Carolina).

RESULTS AND DISCUSSION

Results

Figure 1 depicts the flow of subject recruitment. The analytical sample included 61 women (mean age=71.89±4.60 years) who were screened for participation in the randomized controlled trial. There were 35 women who had non-specific arthritis and 26 women without arthritis. Twelve of the 61 participants had hand arthritis, a subset of the non-specific arthritis, while 49 did not have hand arthritis.

Also, there were 25 women (mean age=72.23±4.63 years) selected from the 61 women who completed all baseline measurements. Of the 25 women, 15 women had non-specific arthritis and 10 did not have any arthritis. In addition, there were 10 women who had hand arthritis while there were 15 women who did not have hand arthritis.

In Tables 3 and 4, each group's demographic characteristics, anthropometric measurements, performance based measures, and physical activity levels are presented. For both the 61 women screened for the randomized controlled trial, and the 25 who partook in baseline measurements for the randomized controlled trial, they were divided into groups including those with non-specific arthritis and a subgroup for those with hand arthritis. There were no significant differences in characteristics between those with non-specific arthritis to those without non-specific arthritis or those with hand arthritis and those without hand arthritis.

Mean grip strength for those with non-specific arthritis for participants who partook in screening assessments for the randomized controlled trial was 16.61±4.06 kg (n=35), while those without arthritis had a mean grip strength of 18.88±5.29 kg

(n=26; p=0.063). Mean grip strength was 17.58±4.72 kg overall and was 16.00±3.72 kg for those with hand arthritis (n=12) and 17.97±4.89 kg (n=49; p=0.198) for those without hand arthritis for participants who partook in screening assessments for the randomized controlled trial.

. When comparing hand arthritis to sarcopenia status via grip strength and ability to perform a single chair stand, the Fisher's exact test highlighted in Table 5, indicates that non-specific arthritis was not significantly related with sarcopenia status for participants who partook in the screening measurements for the randomized controlled trial (p=0.36). In addition, in Table 6, the Fisher's exact test indicates that hand arthritis was not significantly related with sarcopenia status (p=0.44) as well. Participants were considered to have grip dependent inclusion if their grip strength score was <20kg or if they cannot complete a single chair stand. Non grip dependent inclusion described participants who had a grip strength score of >20kg or ALM/m^2 <5.67 or ALM/BMI <0.512 or gait speed <0.8m/s or met no sarcopenia criteria.

A Pearson's correlation coefficient assessed the strength of the relationship between grip strength, CP1RM, and LP1RM for those with non-specific arthritis to those without arthritis for the participants who completed baseline measurements for the randomized controlled trial. There were no significant relationships between grip strength and CP1RM (r=-0.183, p=0.515), grip strength and LP1RM (r=-0.330, p=0.230), and CP1RM and LP1RM (r=0.389, p=0.152). However, if one outlier were removed whose grip strength score was >2.7 SD according to the box and whisker plot and Tukey method [43], grip strength and CP1RM, grip strength and LP1RM, and CP1RM and LP1RM still had no significant relationship (r=-0.226, p=0.438; r=-0.118,

p=0.688; r=0.389, p=0.152 respectively). While for those with hand arthritis, there was also no relationship between grip strength and CP1RM (r=-0.212, p=0.556), grip strength and LP1RM (r=-0.521, p=0.122), and CP1RM and LP1RM (r=0.129, p=0.723). Also, when removing the same outlier from those with non-specific arthritis, the results were not significantly altered as well (grip strength and CP1RM: r=-0.471, p=0.200, grip strength and LP1RM: r=-0.399, p=0.288, CP1RM and LP1RM: r = 0.129, p=0.723).

Discussion

The major finding of this study was that hand arthritis was not related to sarcopenia status in this population of older women. Grip strength was not significantly different between groups for those with non-specific arthritis compared to those without and it was also not significantly different between those with hand arthritis and those without arthritis. To our knowledge, this present study is the first to address hand arthritis to sarcopenia status in older women with or without symptoms of sarcopenia.

Although this study found no relationship between hand arthritis and sarcopenia status via grip strength or failure to perform a single chair stand, it was hypothesized that there may be a relationship based on findings in recent literature. Muscular strength is a component of the working definitions for sarcopenia and is often assessed using a grip strength test. Many studies have reported that grip strength is negatively affected by various forms of arthritis [28-32]. A study by Bagis et al. (2003) compared the relationship between osteoarthritis and grip strength scores in postmenopausal women. In that study, those with osteoarthritis had significantly

decreased grip strength scores for both hands when compared to those without osteoarthritis (19.57±6.16 kg versus 21.88±5.51 kg, 19.16±6.16 kg versus 22.11±5.67 kg, right and left hand respectively, $p<0.05$). Also, with increasing severity of osteoarthritis (based on the grade of osteoarthritis 0-4), the highest grade osteoarthritis was significantly associated with lower grip strength scores than healthy individuals and those with other grades of osteoarthritis ($p<0.001$). The average grip strength scores of those with osteoarthritis on both hands were significantly lower than those without osteoarthritis and would meet the sarcopenia criteria used by the EWGSOP for muscular strength (grip strength <20kg) [6]. Therefore, since a cut-point of <20kg was used to classify participants used in our study, it was hypothesized that arthritis may be related to sarcopenia status.

Also, the IWG sarcopenia working definition utilizes an alternative measure for quantifying muscular strength. Instead of grip strength, the IWG uses the ability to perform a single chair stand as their measure since the ability to rise from a chair is an important activity of daily living and requires adequate muscular strength [35]. However, osteoarthritis in the knee and hip are related to lower, lower extremity muscular strength and could make it more difficult to perform lower body assessments [44].

This study also suggests that grip strength and upper and lower body muscular strength for those with non-specific arthritis as well as hand arthritis were not related to each other. However, other studies have reported that grip strength and lower body muscular strength are related, and that using grip strength as a measure for overall muscular strength is an adequate alternative for older individuals [11,46]. Grip

strength is also known to be a good indicator of upper body strength as well [11,47]. However, given the results of this study, grip strength may not be a valid tool for overall muscular strength for those with arthritis since there was no relationship between grip strength and other measures of upper and lower body strength. Additionally, arthritis is known to cause pain and pain attenuates muscular strength ability [44]. It is unknown to what extent our population of women were experiencing arthritis related pain and if analgesics and arthritis medication helped relieve any symptoms. Therefore it makes it difficult to conclude the reason for a lack of relationship between grip strength, CP1RM, and LP1RM, in this population of older women.

Also, other studies have demonstrated that various forms of arthritis are related to other sarcopenia criteria [31,33,44,45]. In a study conducted by Kemmler et al. (2016), they found that participants with osteoarthritis at the hip and lower limbs were more likely to be classified as sarcopenic according to the EWGSOP working definition. Those with osteoarthritis performed more poorly when assessed for gait speed and grip strength ($p<0.001$). However, lean mass in those with osteoarthritis was higher than those without osteoarthritis [31]. This is different than findings from two studies that looked at body composition in those with rheumatoid arthritis [33,45]. The study by Dogan et al. (2015), assessed sarcopenia in women with rheumatoid arthritis and found that those with rheumatoid arthritis had lower ALM than their normal counterparts [33]. Similarly, in a study by Giles et al. (2008), men and women with rheumatoid arthritis had lower ALM compared to those without rheumatoid

arthritis as well [45]. Various forms of arthritis should be addressed to all components of sarcopenia criteria to see if there is a relationship.

This study has a few strengths worth noting. First, this study included a homogenous sample cohort of community-dwelling older women. Second, to our knowledge this is the first study to assess hand arthritis and its relationship to sarcopenia status in older women with or without symptoms of sarcopenia based on newly established sarcopenia guidelines. Finally, this study used measures of muscular strength that have been standardized and validated for older populations [38,39].

Despite these study strengths, there were some limitations. First, the sample size of our study was small and was not designed to specifically examine the relationship between hand arthritis to sarcopenia status. Therefore, the results may not adequately reflect this relationship. In addition, we did not ask participants to specify on the type of arthritis that they had except for osteoarthritis/degenerative arthritis or what areas of the body were affected but some chose to report it. Therefore, these data on hand arthritis and association with physical functioning should be approached degree of a caution.

CONCLUSION

This is the first study to evaluate hand arthritis to sarcopenia status via grip strength or failure to complete a single chair stand in a population of older women with or without symptoms of sarcopenia. Although the present study found that non-specific arthritis and the subset, hand arthritis, were not significantly related to sarcopenia status, additional studies with a larger sample size and clearly defined arthritis status are needed to determine if these variables are linked. Osteoarthritis and rheumatoid arthritis are two common forms of arthritis known to affect the joints of the hand and are reported to affect grip strength scores [24,26,30,31]. Other common forms of arthritis including gout [51], which primarily affects the metatarsophalangeal joint, and fibromyalgia [52-54], which is characterized by widespread pain, do not commonly affect the hand joints. Therefore, those two forms of arthritis should be evaluated for their relationship to sarcopenia status as well as if disease severity and duration affect sarcopenia classification.

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TABLES

Table 1. Inclusion and exclusion criteria used for study recruitment

Inclusion Criteria
Women, ages 65-84 years
Low physical functioning, and/or low lean muscle mass based on current sarcopenia guidelines
Currently (≥6 months) not engaged in regular exercise programs
Post-menopausal by self-report
BMI 18.5-45.0 kg/m^2
Exclusion Criteria
Failure to provide informed consent
Significant or suspected cognitive impairment
Severe hearing loss, speech disorder, language barrier, or visual impairment
Progressive or degenerative neurological disease
Severe pulmonary disease, uncontrolled diabetes, blood pressure, or anemia
Any medication changes within the past 3 weeks, or lipid lowering medication changes within the past 6 months
Major joint, vascular, abdominal, or thoracic surgery within the past 6 months
Significant cardiovascular disease or implanted pacemaker or defibrillator
Inability to safely engage in mild to moderate exercise with muscular exertion
Inability to speak and read in English

Table 2. Arthritis and analgesic medication use for women screened for the randomized controlled trial and the women who partook in baseline testing for the randomized controlled trial.

Type of Medication	Over the Counter (OTC)/ Supplements	Prescribed (oral and topical)	Not specified- OTC/Supplements
Arthritis Medication	2	4	1
Painkiller Medication - NSAID	6	1	0
Abbreviation: NSAID, nonsteroidal anti-inflammatory drug			

Table 3. Characteristics of those without non-specific or hand arthritis, non-specific arthritis, and hand arthritis in participants who completed the screening measurements for the randomized controlled trial (n=61).

	Mean ± (SD)	Non-specific Arthritis (n=35, 57.4%)	Non-Arthritis (n=26, 42.6%)	P- value	Hand Arthritis (n=12, 19.7%)	Non Hand Arthritis (n=49, 80.3%)	P-value
Age (yrs)	71.89± 4.60	72.03± 4.68	71.69± 4.58	0.780	71.50± 4.21	71.98± 4.73	0.749
Weight (kg)	70.88± 15.19	70.87± 15.06	70.87± 15.64	0.999	75.60± 18.82	69.71± 14.15	0.232
Height (cm)	160.84± 5.64	160.11± 5.29	161.81± 6.04	0.247	160.48± 4.10	160.92± 5.99	0.810
BMI (kg/m^2)	27.31± 5.96	27.65± 5.83	27.09± 6.02	0.717	29.40± 7.64	26.93± 5.34	0.194
% Body Fat	40.05± 7.60	40.62± 7.95	39.29± 7.19	0.505	41.56± 8.24	39.69± 7.48	0.449
Grip Strength (kg)	17.58± 4.72	16.61± 4.06	18.88± 5.29	0.063	16.00± 3.72	17.97± 4.89	0.198
Gait Speed (meters/ second)	1.02± 0.17	0.99± 0.17	1.06± 0.17	0.131	1.04± 0.18	1.02± 0.17	0.685

Abbreviation: BMI, Body Mass Index
% Body Fat measured using InBody 570 SMF-BIA, Biospace Co, Ltd, Korea
P-values were obtained using independent samples t-tests

Table 4. Characteristics of those without non-specific or hand arthritis, non-specific arthritis, and hand arthritis for participants who completed baseline measurements for the randomized controlled trial (n=25).

	Mean ± (SD)	Non-specific Arthritis (n=15, 60.0%)	Non-Arthritis (n=10, 40.0%)	P-value	Hand Arthritis (n=10, 40.0%)	Non Hand Arthritis (n=15, 60.0%)	P-value
Age (yrs)	72.23± 4.63	71.93± 4.57	72.90± 4.89	0.619	73.10± 4.12	71.80± 5.00	0.503
Weight (kg)	65.36± 13.47	62.89± 10.87	69.06± 16.57	0.271	61.25± 9.66	68.10± 15.20	0.220
Height (cm)	159.78± 5.15	159.87± 4.81	159.64± 5.90	0.915	159.54± 4.97	159.94± 5.44	0.855
BMI (kg/m^2)	25.70± 5.86	24.63± 4.31	27.30± 7.61	0.274	24.06± 3.67	26.79± 6.86	0.263
Waist to Hip Ratio	0.87± 0.10	0.88± 0.11	0.86± 0.09	0.745	0.84± 0.09	0.89± 0.10	0.150
% Body Fat	37.14± 7.66	36.03± 7.74	38.82± 7.62	0.383	34.76± 6.98	38.73± 7.91	0.211
Grip Strength (kg)	16.64± 3.74	16.60± 4.01	16.70± 3.51	0.949	16.30± 4.81	16.87± 3.00	0.719
Gait Speed (meters/ second)	1.05± 0.14	1.07± 0.15	1.02± 0.13	0.359	1.04± 0.12	1.05± 0.16	0.813
Chest Press 1 RM (kg)	17.01± 6.64	15.38± 3.93	19.46± 9.09	0.136	14.21± 3.73	18.89± 7.57	0.084
Leg Press 1 RM (kg)	46.34± 16.13	41.91± 7.51	52.98± 22.91	0.093	40.01± 6.46	50.56± 19.28	0.111
Physical Activity (kcals/ week)	7302± 3030	7107± 2663	7574± 3615	0.719	7162± 2753	7386± 3275	0.866
Physical Activity Index	49.46± 21.89	50.79± 20.06	47.60± 25.22	0.734	47.70± 20.19	50.71± 23.69	0.747
DST	69.2±7.8	70.85± 8.99	67.10± 5.61	0.262	69.56± 9.75	69.00± 6.62	0.872

Abbreviation: BMI, Body Mass Index, DST, Dietary Screening Tool
% Body Fat measured using InBody 570 SMF-BIA , Biospace Co, Ltd, Korea
Physical Activity (PA) from the Yale Physical Activity Survey (YPAS)
YPAS and PA Index mean±SD reflect n=24 due to incomplete/missing surveys
Dietary Screening Tool: At Risk (<60), Possible risk (60-75), Not at risk (>75), mean±SD reflect n=23 due to incomplete/missing surveys
P-values were obtained using independent samples t-tests

Table 5. Fisher's exact test for non-specific arthritis and its relationship to sarcopenia status in older women with or without symptoms of sarcopenia

	Arthritis – Yes	Arthritis – No	*Total*
Grip Dependent Inclusion	18	10	28
Non Grip Dependent Inclusion	17	16	33
Total	35	26	61

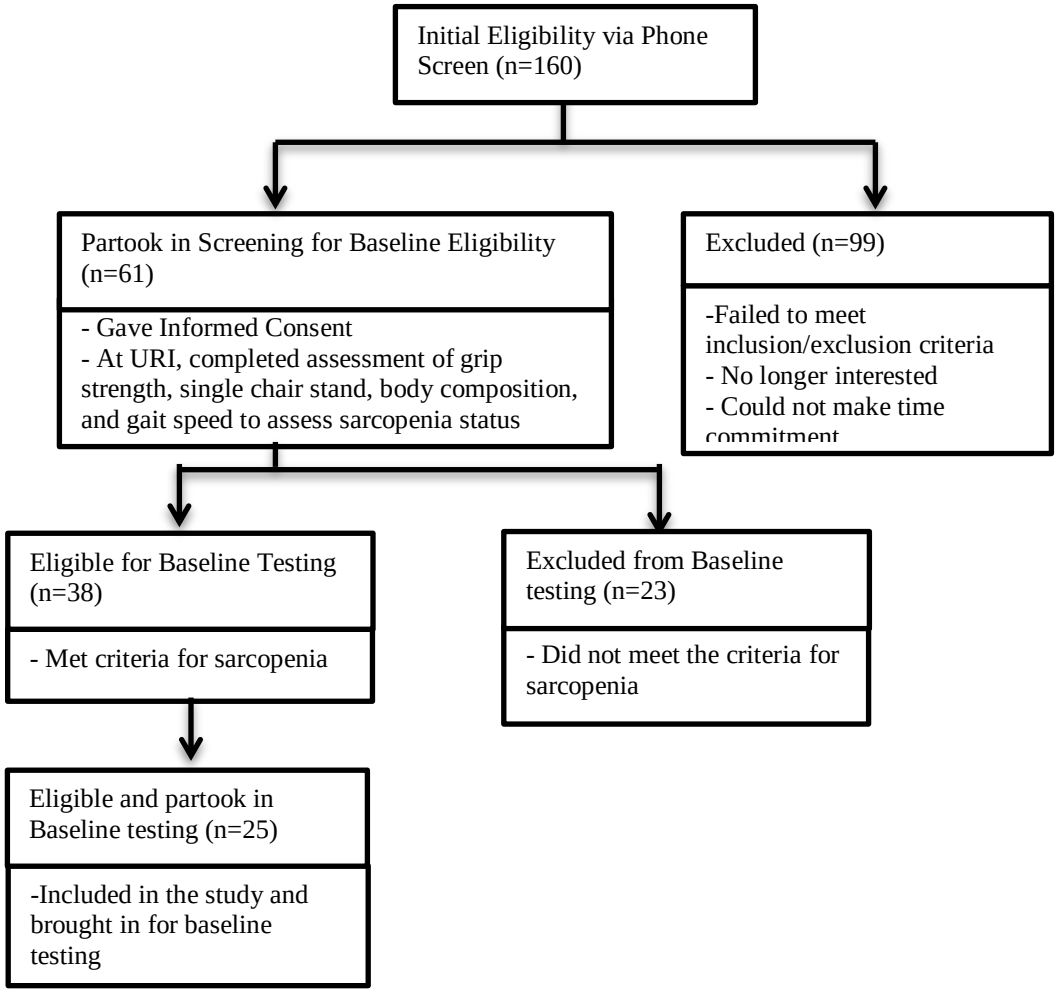
Grip Dependent Inclusion, Grip Strength <20kg or failed to complete a single chair stand
Non Grip Dependent Inclusion, Grip Strength >20kg or ALM/m^2 <5.67 or ALM/BMI <0.512 or gait speed <0.8m/s or no criteria met
NOTE: No differences between groups (p=0.36)

Table 6. Fisher's exact test for hand arthritis and its relationship to sarcopenia status in older women with or without symptoms of sarcopenia.

	Hand Arthritis – Yes	Hand Arthritis – No	*Total*
Grip Dependent Inclusion	7	21	28
Non Grip Dependent Inclusion	5	28	33
Total	12	49	61
Grip Dependent Inclusion, Grip Strength <20kg or failed to complete a single chair stand Non Grip Dependent Inclusion, Grip Strength >20kg or ALM/m^2 <5.67 or ALM/BMI <0.512 or gait speed <0.8m/s or no criteria met NOTE: No differences between groups (p=0.44)			

FIGURES

Figure 1. Study Flow Chart



APPENDICES

APPENDIX A: Review of the Literature

Abstract

The loss of muscular strength, physical functioning, and lean mass with age that contributes to disability and frailty is designated as sarcopenia. Older women are at an increased risk for developing sarcopenia compared to men due to faster declines in muscular strength and lean mass that assist in developing physical disabilities. There is no universally accepted working definition for sarcopenia but many organizations have established their own working definitions based on low lean mass, slowness, and weakness to deem individuals as sarcopenic. Muscular strength is a key component of sarcopenia and is measured via grip strength. While using grip strength to assess overall muscular strength is a common practice, potential challenges may arise when conditions that limit hand functionality, such as arthritis, are present. Arthritis is characterized by inflammation and joints stiffness, which can cause deformities to develop as well as decrease overall hand functionality. Therefore the limited hand functionality due to arthritis may impair grip strength scores and affect sarcopenia classification despite adequate muscular strength and physical functioning in other areas of the body. No study to date has assessed if hand arthritis is related to sarcopenia classification in older women with symptoms of sarcopenia.

Introduction

Sarcopenia is characterized by a loss of muscular strength, functionality, and lean mass with increasing age (Manini & Clark, 2012; Rosenberg, 1989) that is related to the development of functional limitations (Beaudart, Rizzoli, Bruyère, Reginster, & Biver, 2014). This geriatric disease is multifactorial and develops from muscle disuse, nutritional deficiencies, dysfunction of the endocrine system, and chronic diseases identified with muscle loss (Fielding et al., 2011). This promotes muscular atrophy and a reduction in type II muscle fibers (Alchin, 2014; Delmonico & Beck, 2015; Maltais, Desroches, & Dionne, 2009). After the age of 50, lean mass is lost at approximately a rate of 1-2% per year (Marcell, 2003). This decline in lean mass is associated with many adverse health outcomes including an increased risk for fractures and falls, a decrease in physical functionality, decreased independence, and declines in muscular strength (Melton et al., 2000; Scott et al., 2014; Zeng et al., 2016). In addition, in 2000, the estimated health care costs of sarcopenia for women alone were $29.5 billion and were $12.6 billion for older men (Janssen, Shepard, Katzmarzyk, & Roubenoff, 2004). Sarcopenia is a public health problem that will continue to be an economic burden as the older population continues to increase. Women make up the majority of the elderly population worldwide due to their greater life expectancy and they have an increased risk for functional disability due to quicker declines in muscular mass and strength (Borst, 2004; Centers for Disease Control and Prevention (CDC), 2016c; Idland, Pettersen, Avlund, & Bergland, 2013).

Currently, there is no universal working definition for sarcopenia but national and international organizations have established their own criteria used for sarcopenia

and vary depending on the organization (Cruz-Jentoft et al., 2010). Among these several organizations that have established their own working definitions, there are The European Working Group on Sarcopenia in Older People (EWGSOP), the International Working Group (IWG), and The Foundation for the National Institutes of Health Sarcopenia Project (FNIHSP). These three groups all use similar criteria in their working definitions, including measures of muscular strength, gait speed, and a measure of lean mass to confirm sarcopenia status (Cruz-Jentoft et al., 2010; Fielding et al., 2011; McLean et al., 2014).

While there are various techniques to assess muscular strength and there exist variations with how it is assessed in the working definitions, grip strength is a commonly used test for muscular strength. It is considered a valid measure of overall muscular strength and is predictive of health outcomes including frailty, disability, and mortality (Bohannon, 2008; C. Cooper et al., 2013; Rantanen et al., 1999a; Syddall, Cooper, Martin, Briggs, & Aihie Sayer, 2003; Visser, Deeg, Lips, Harris, & Bouter, 2000). However, functional limitations from diseases in the hand such as arthritis are known to be associated with decreased grip strength scores (Bagis, Sahin, Yapici, Cimen, & Erdogan, 2003; Cardoso Fde, Curtolo, Natour, & Lombardi Junior, 2011; Dedeoğlu, Gafuroğlu, Yilmaz, & Bodur, 2013; Huang et al., 2013; Kemmler et al., 2015; Koca et al., 2016). The limited hand functionality due to arthritis may therefore influence sarcopenia classification via grip strength measures despite adequate muscular strength in other major muscle groups and physical functioning. While some studies have shown that hand arthritis does influence grip strength, it has not been addressed how hand arthritis may influence sarcopenia classification.

. **Sarcopenia in Older Women**

Older adults are at a higher risk for sarcopenia, especially women because they make up the majority of the elderly population due to their longer life expectancy of approximately 4.8 years (Centers for Disease Control and Prevention (CDC), 2016c). Women have higher prevalence for declines in muscular strength, functional impairments, and declines in lean mass when compared to men and often occur earlier in life due to menopause. Menopause leads to various changes in hormonal concentrations and causes estrogen levels to decline (Batsis, Mackenzie, Barre, Lopez-Jimenez, & Bartels, 2014; Carriere et al., 2005; Maltais et al., 2009).

Declines in estrogen are accompanied by declines in IGF-1, a protein involved in muscle protein synthesis, which in turn cause pro-inflammatory cytokines levels to increase. Pro-inflammatory cytokines are known to contribute to muscle breakdown and sarcopenia (Ferrucci et al., 2002; Maltais et al., 2009; Visser et al., 2002). Additionally, there is an increase in visceral fat mass and decreases in bone mineral density, as well as atrophy of type II muscle fibers which causes a diminished power output with increasing age among older women (Maltais et al., 2009).

Muscular strength plays a key role in physical functioning as well as overall quality of life (Maltais et al., 2009). Therefore, it is important that early identification of decreased physical function is recognized so proper intervention can be implicated to prevent the development of further functional disability. For example, a nine year prospective cohort study in Norway assessed modifiable risk factors for activities of daily living (ADL) disability in 113, non-disabled community-dwelling older women (mean age=79.5 years) from a census file of women who had randomly been selected

for a separate study on falls. At baseline, the participants completed a comfortable walking speed test, a step climbing test, and a functional reach test to assess physical performance. To assess ADL disability, a modified Avlund PADL-H scale was used with questions pertained to needing assistance in five basic ADL categories at baseline and follow-up (9.3 years). After adjusting for all three measures in the same model, comfortable walking speed was significantly associated with the onset of ADL disability (OR=0.4, 95% CI:0.02-0.69). However, both the step climbing and functional reach tests were not significantly associated with the onset of ADL disability after adjusting for all three performance measures in the same model (OR=0.97, 95% CI:0.93-1.02, OR=0.94, 95% CI:0.89-1.02 respectively). In addition, for every 0.1 m/s slower walking speed, the risk for ADL disability increased by 60% (Idland et al., 2013). Other measurements to predict disability onset from should be employed as well (Rantanen et al., 1999a; Rantanen et al., 1999b).

Working Definitions for Sarcopenia

Sarcopenia is complicated as it is a multifactorial disease with no established universal definition. Currently, there are only working definitions for sarcopenia due to the lack of a widely accepted clinical definition (Cruz-Jentoft et al., 2010). Several organizations have established their own working definitions for sarcopenia but vary slightly in their criteria which presents a challenge when determining which individuals are at risk. Additionally, sarcopenia is sometimes classified based on its severity in various definitions due to its prolonged development over extended periods of time (Cruz-Jentoft et al., 2010; McLean et al., 2014). Previously, the criteria for sarcopenia were based on muscular mass alone compared to a reference population.

However, now the sarcopenia working definitions include performance criteria as well (Correa-de-Araujo & Hadley, 2014). In clinical practice, muscular mass can be assessed using various techniques including dual energy x-ray absorptiometry (DXA), segmental multi-frequency bioelectrical impedance analysis (SMF-BIA), as well as anthropometry measurements. Hand grip strength is assessed via a handheld dynamometer and is used to assess overall muscular strength. It is a good measure of strength and correlates well other parts of the body (Cruz-Jentoft et al., 2010; Lauretani et al., 2003; Visser et al., 2000). In addition, physical functioning is assessed using gait speed, the short physical performance battery (SPPB) test, as well as the get up and go test (Working Group on Functional Outcome Measures for Clinical Trials, 2008). National and international organizations that define sarcopenia based on muscular mass and performance criteria include the EWGSOP, the IWG, and the FNIHSP. While previous working definitions only used measurements of muscular mass, current working definitions, including the EWGSOP, IWG, and FNIHSP, use measurements of muscular mass as well as performance criteria to determine sarcopenia status (Cruz-Jentoft et al., 2010; Fielding et al., 2011; McLean et al., 2014; Studenski et al., 2014).

The EWGSOP working definition states that to be sarcopenic, low lean mass as well as slowness or weakness must be present (Correa-de-Araujo & Hadley, 2014; Cruz-Jentoft et al., 2010). The EWGSOP quantifies low lean mass using appendicular lean mass (ALM) divided by height squared (ALM/ht^2) and uses the criteria of $<5.67 kg/m^2$ for women. In regards to muscular strength, the EWGSOP uses a grip strength test and has a cutpoint of <20 kg for women. To be considered slow, the

EWGSOP uses a gait speed of <0.8 meters per second (m/s) as the criteria for women. Also, the EWGSOP characterizes the severity of sarcopenia and classifies individuals as having presarcopenia, sarcopenia, or severe sarcopenia. Presarcopenia requires individuals to have just low lean mass, while sarcopenia again, requires individuals to have low lean mass and either be slow or weak. To be classified as severely sarcopenic, individuals must present with all three criteria: low lean mass, slowness, and weakness (Correa-de-Araujo & Hadley, 2014; Cruz-Jentoft et al., 2010)

The IWG working definition describes sarcopenia as complex disease that encompasses a decline in physical functioning as well as a decline in muscular mass (Fielding et al., 2011). The IWG therefore states that older individuals who are weak, have low physical functioning or poor health should be evaluated (Fielding et al., 2011). In addition, the IWG suggests evaluating older individuals who have difficulty performing activities of daily living such as rising from a chair or walking for sarcopenia (Fielding et al., 2011). Performing such activities of daily living require adequate muscular strength (Rolland et al., 2008) and is reflected in their measures of muscular strength and physical functioning (Fielding et al., 2011). To assess muscular strength, the IWG uses a failure to complete an unassisted single chair stand as its criteria (Fielding et al., 2011). If an individual can complete a chair stand unassisted, then the IWG states they should complete a gait speed test (Fielding et al., 2011). The criteria for gait speed is <1.0 m/s for women which is slightly slower than what the EWGSOP uses (<0.8 m/s) (Cruz-Jentoft et al., 2010; Fielding et al., 2011). In addition, if an individual's gait speed is <1.0m/s, their lean mass should be assessed

and is considered low lean mass for women if their ALM/ht^2 is <5.67 kg/m^2 (Fielding et al., 2011).

Unlike the EWGSOP, the FNIHSP does not characterize individuals as sarcopenic or severely sarcopenic, but either as those with "weakness with low lean mass," or "weakness and slowness with low lean mass" (McLean et al., 2014). The FNIHSP suggests based on their clinical model that individuals be screened for physical functioning limitations followed by weakness and low lean mass (Studenski et al., 2014). To assess physical functioning, the FNIHSP uses a gait speed cut off of <0.8 m/s for women, which is similar to what the EWGSOP uses. The FNIHSP also uses grip strength like the EWGSOP to assess muscular strength, but has a more conservative cut point of <16 kg for women compared to <20 kg (Alley et al., 2014; Cruz-Jentoft et al., 2010). Also, unlike both the EWGSOP and IWG, the FNIHSP characterizes low lean mass by the ratio of ALM to BMI instead of height squared and uses an established cut point for <0.512 for women (McLean et al., 2014).

The inability to agree on a universal working definition has made determining sarcopenia status and incidence and prevalence rates difficult to compare across groups. Depending on the working definitions used, prevalence numbers vary. In a review conducted by Dam, et al. (2014), they compared prevalence in the EWGSOP, IWG, and FNIHSP working definitions. When applying the EWGSOP definition, more women and men (13.3% and 5.3%) were considered sarcopenic when compared to the FNIHSP (2.3% and 1.3%) and IWG (11.8% and 5.1%) criteria. Additionally they found that the EWGSOP and FNIHSP criteria were more similar to each other due to their working definitions including measures in lean mass, muscular strength,

and/or physical functioning (Dam et al., 2014). While the IWG includes measures of low lean mass in conjunction with declines in function. Additionally, the IWG uses <1.0m/s instead of <0.8m/s, which is used by both the EWGSOP and FNIHSP, and assesses muscular strength differently than those two working groups (Dam et al., 2014; Fielding et al., 2011). However, when comparing the EWGSOP and IWG to the FNIHSP, the FNIHSP quantifies lean mass differently than the EWGSOP and IWG and uses ALM/BMI rather than ALM/ht2 (Dam et al., 2014). The lack of a general consensus makes assessing those for sarcopenia difficult and establishing effective interventions challenging.

Muscular strength is included in the EWGSOP, IWG, and FNIHSP sarcopenia working definitions. Although it is thought that declines in muscular strength should be characterized separately (i.e. dynapenia from sarcopenia), dynapenia is similar to sarcopenia in that both are multifactorial conditions that are age related. In addition, it is suggested that muscular strength is closely related to muscle mass and the working definitions for sarcopenia include measures of muscular strength and muscle mass (Clark & Manini, 2008).

Grip Strength

Hand grip strength is a common measure used in sarcopenia classification and has been associated with increased risks for frailty and mortality (Bohannon, 2008; Rantanen et al., 1999a; Rantanen et al., 1999b; Syddall et al., 2003). To assess muscular strength, isokinetic dynamometry can be used or a hand-held dynamometer can be used (Stark, Walker, Phillips, Fejer, & Beck, 2011). However, hand grip strength as a measure of muscular strength has been validated to the current gold

standard which is isokinetic dynamometry (C. Cooper et al., 2013; Stark et al., 2011). A review conducted by Stark, T., et al. (2011), found minor differences between hand-held dynamometry and isokinetic dynamometry and concluded that a hand-held dynamometer is a reliable and valid instrument (Stark et al., 2011). In addition, compared to isokinetic dynamometry, using a hand grip dynamometer is more cost effective and is easy to administer to large populations due to its compact size and portability allowing for clinical use (C. Cooper et al., 2013; Rantanen et al., 1999a; Stark et al., 2011). Grip strength should be used frequently as it is highly predictive and is pertinent to specific populations such as middle-aged and older adults where the risk for developing functional issues and frailty are high (Bohannon, 2008; Syddall et al., 2003).

Numerous studies have shown the ability of hand grip strength to predict adverse health outcomes including mortality and frailty. In a longitudinal study that used 3,075 men (n=1124, mean age=73.7±2.9 years) and women (n=1168, mean age=73.4±2.8 years) from the from the Health, Aging and Body Composition (ABC) study and followed them for approximately 4.9±0.9 years. At baseline, participants were assessed on hand grip strength and other measures. That study found decreased grip strength was significantly related to increased mortality risk for men (HR=1.36, 95% CI:1.13-1.64) and for women (HR=1.84, 95% CI:1.28-2.65) (Newman et al., 2006).

Similar results were seen in a meta-analysis conducted by Cooper, R. et al. (2010), that included 13 studies which used 44,636 participants, evaluated physical capabilities in relation to mortality in community-dwelling populations as well. It was

found that with every increase in grip strength by 1 kg, there was a decrease in mortality risk and that the mortality summary hazard ratio (HR) was 1.67 (95% CI:1.45-1.93) when comparing the strongest and weakest quarter for grip strength (R. Cooper, Kuh, Hardy, Mortality Review Group, & FALCon and HALCyon Study Teams, 2010).

Future disability can also be predicted via grip strength and numerous studies have evaluated this (Rantanen et al., 1999a; Rantanen et al., 1999b). A 25 year prospective cohort study that looked at grip strength and disability was done by Rantanen, et al. (1999a), and evaluated healthy Japanese American men who resided in Oahu, Hawaii. Their aim was to see if grip strength during mid-life could predict functional disability with increasing age in healthy men. That study used 6,089 men (mean age=54.0±5.5 years) from both the Honolulu Heart Program and Honolulu-Asia Aging Study. The participants completed a hand grip strength assessment at multiple time points as well as a gait speed assessment and an unassisted chair stand test. To assess each participant's disability status, questions on heavy household work, self-care, and mobility were asked. Only 3,218 participants completed follow up tests and the participants were divided into three groups (tertiles) based on their baseline hand grip strength scores. That study found that lower baseline hand grip strength scores (lowest tertile) were associated with an increased risk for functional limitations and disability over the 25 year period. The lowest tertile had an adjusted HR for a walking speed $\leq$ 0.4m/s of 2.77 (95% CI:1.70-4.54) and an adjusted HR of 2.73 (95% CI:1.19-6.27) for unable to rise from a chair. That study concluded that middle-aged men with higher grip strengths at baseline were at a decreased risk for disability and functional

limitations into old age (Rantanen et al., 1999a). While that study adequately showed that grip strength could predict disability and functional limitations, it only used older Japanese-American men.

Another study that evaluated how grip strength predicts disability was a cross-sectional analysis study that looked at 1,002 disabled women age 65 years and older (mean age=78.3±8.1 years) from The Women's Health and Aging Study. To assess muscular strength, hand grip and knee extension strength were assessed using hand-held dynamometers. Disability was assessed via self-reported challenges with specific activities such as walking across a small room, walking a quarter mile, as well as doing heavy housework. In addition, participants were asked about their current physical activity levels via questionnaire and other chronic diseases they have. That study found that with increased disability levels, grip strength and knee extension strength scores decreased ($p<0.001$). In addition, age was negatively correlated with grip strength ($r=-0.092$, $p=0.005$) and knee extension strength ($r=-0.082$, $p=0.0.14$), but positively correlated with disability ($r=0.075$, $p=0.019$). That study concluded that the findings suggested that increases in disability were likely related to muscular strength (grip strength and knee extension strength) decline (Rantanen et al., 1999b). Both of these studies reflect the ability of hand grip strength to predict future disability.

Additionally, there are also many types of hand grip dynamometers protocols that can be used to assess hand grip strength (Innes, 1999; Roberts et al., 2011). According to a review conducted by Roberts, et al. (2011), the Jamar hand grip dynamometer is the most widely used in the literature and concluded that it is likely

the gold standard (Roberts et al., 2011). Some protocols address hand size and hand dominance which influence the results and make comparing different hand dynamometers difficult (Roberts et al., 2011). In addition, there are hand grip dynamometers that can assess both static and dynamic muscular strength but static measurements are more commonly used (Innes, 1999). Hand grip dynamometers can be classified in four categories including hydraulic, pneumatic, mechanical, and strain instruments. The Jamar hand grip dynamometer is an example of a hydraulic dynamometer and assess the amount of force applied (Innes, 1999). Hand-held dynamometers are commonly used and a recommended tool to assess muscular strength but a lack of a standardized protocol makes comparing grip strength between studies difficult. In addition, grip strength may not be the best measurement to use when functional limitations such as arthritis are present and alternative dynamometers more suitable should be used.

Arthritis

Arthritis is a chronic musculoskeletal disease that is characterized by joint stiffness and inflammation, which can often result in deformities of the joint from alterations of the joint structure (i.e. bone, ligaments, joint capsule). This also leads as decreased functionality of the affected joint (Cima, Barone, Porto, & de Abreu, 2013; Hootman, Helmick, & Brady, 2012; Johnsson & Eberhardt, 2009; Osteras et al., 2014). In 2003, arthritis cost the US $128 billion in direct and indirect costs (Centers for Disease Control and Prevention (CDC), 2013). It is likely that those costs are higher as that with increasing age, arthritis prevalence gradually increases and will continue to be more abundant due to older adults living longer (Hootman et al., 2012).

On average in 2013-2015, approximately 54.4 million adults had arthritis and it was more prevalent in women than men (Barbour, Helmick, Boring, & Brady, 2017). It is expected that by 2040, approximately 78.4 million U.S. adults will have doctor-diagnosed arthritis (Hootman, Helmick, Barbour, Theis, & Boring, 2016).

Arthritis is also the leading cause of disability in the U.S. and can decrease overall quality of life (Hootman et al., 2012; Song, Chang, & Dunlop, 2006). In addition, there are over 100 types of arthritic diseases that affect the tendons, ligaments, muscles, and the joints, including osteoarthritis (OA), rheumatoid arthritis (RA), gout, and fibromyalgia (FM) (Hootman et al., 2012). While the most common form of arthritis is osteoarthritis, rheumatoid arthritis, gout, and fibromyalgia are common as well (Centers for Disease Control and Prevention (CDC), 2017a; Hootman et al., 2012).

Types of Arthritis:

Osteoarthritis is a multifactorial disease that leads to pain, a decline in functionality, as well as deformity (Berenbaum, 2013; Centers for Disease Control and Prevention (CDC), 2017b; Loeser, Goldring, Scanzello, & Goldring, 2012). Sex, previous injury to a joint, genetics, obesity, as well as other mechanical factors, and age, which is the strongest risk factor, all contribute to the development of OA (Centers for Disease Control and Prevention (CDC), 2017b; Loeser et al., 2012; Neogi & Zhang, 2013). In addition, the development of OA stems from many pathological changes that occur in the joint cavity and include changes to the articular cartilage, changes to the subchondral bone, as well as inflammation to the synovial lining (Berenbaum, 2013; Loeser et al., 2012). Changes in subchondral bone elements affect

the calcified cartilage, which lies between the subchondral bone and articular cartilage, and causes it to extend into the articular cartilage. This leads to thinning of the articular cartilage. In addition, articular cartilage matrix proteins are degraded and can cause increased matrix degradation from a positive feedback loop that includes pieces of proteins that lead to inflammatory cytokine and chemokine production which contribute to synovitis (Loeser et al., 2012). Synovitis is inflammation of the synovial lining which occurs after a joint injury and is also a contributor to the development of OA early on but is not as severe as seen in RA (Loeser et al., 2012). In addition, for those with knee OA, pathological changes in the menisci and ligaments contribute to the development of OA and occur from disruption of the extracellular matrix as well as calcification of the meniscus and the articular cartilage (Loeser et al., 2012; Molloy & McCarthy, 2006).

There are also three ways OA can be classified including radiographic OA, symptomatic OA, or clinical OA (Neogi & Zhang, 2013; Zhang & Jordan, 2010). Radiographic OA is based on a radiograph grading scale (Kellgren-Lawrence grading scale) that assesses osteophyte presence, deformities, joint space narrowing, cysts, and sclerosis. The system uses five levels (0-4) to classify the severity of the radiographic OA and is used to identify OA at the hands, hips, and the knee (Kellgren & Lawrence, 1957; Neogi & Zhang, 2013; Zhang & Jordan, 2010). Symptomatic OA differs slightly from radiographic OA in that symptomatic OA includes frequent pain, stiffness of the joint, and aching with radiographic OA. The number of individuals with symptomatic OA is therefore often lower since characteristics of both symptomatic OA and radiographic RA must be present (Lawrence et al., 2008; Neogi

& Zhang, 2013; Zhang & Jordan, 2010). In addition, clinical OA is diagnosed based on the results from a physical examination as well as the assessment of symptoms (Lawrence et al., 2008). OA is often diagnosed via a physical examination, radiography, lab assessments, as well as reviewing the symptoms presented (Centers for Disease Control and Prevention (CDC), 2017b; Lawrence et al., 2008).

Rheumatoid arthritis is another form of arthritis that also includes a synovitis component similar to that of OA, but is more severe (Araki & Mimura, 2016; Firestein, 2003; Loeser et al., 2012). It is a multifactorial disease that has a complicated etiology but is includes a combination of environmental factors, genetics, as well as epigenetics (Araki & Mimura, 2016; Gibofsky, 2014). Rheumatoid arthritis is a chronic inflammatory autoimmune disease that is characterized by inflammation of the synovial lining with a progressive destruction of the affected joints that leads to pain and disability (Araki & Mimura, 2016; Gibofsky, 2014). Normally, the synovial lining is only 2-3 cells thick but in RA, the lining becomes 10-15 cells thick due to synovial fibroblasts and synovial macrophages causing hyperplasia. Rheumatoid arthritis synovial fibroblasts (RASF) secrete cytokines and chemokines, which contribute to inflammation. In addition, a pannus, which is aggressive tissue formed by RASFs and macrophages, degrades articular cartilage and the subchondral bone within the joint (Araki & Mimura, 2016; Firestein, 2003). Also, RA commonly affects the feet and hands small diarthrodial joints (Firestein, 2003). All of these factors contribute to the development of RA and the worsening of symptoms.

Fibromyalgia (FM) is another common form of arthritis found in mainly older adults, specifically women. It is characterized by widespread pain throughout the body, which causes tenderness (Lawrence et al., 2008; Panton et al., 2006; Wolfe, Ross, Anderson, Russell, & Hebert, 1995). Symptoms of FM include pain when pressure is applied to various tender points, stiffness, as well as mental impairments (i.e. anxiety, mental fogginess) (Panton et al., 2006). Individuals are diagnosed with FM if they have widespread pain for at least three months in at least three out of four body quadrants. In addition, they must have localized pain in at least eleven of eighteen tender points or at muscle-tendon junctions (Wolfe et al., 1990).

Gout is another common form of arthritis that is prevalent in older adults (typically men) and is characterized by inflammation that occurs from monosodium urate monohydrate crystals that undergo phagocytosis. This causes elevated levels of uric acid in the blood leading to hyperuricemia, which is defined as serum uric acid levels surpassing urate blood solubility (>6.8 mg/dl) (Burke et al., 2015; De Avila Fernandes et al., 2017; Lawrence et al., 2008; Wertheimer, Morlock, & Becker, 2013). Uric acid concentrations that exceed blood solubility levels lead to the formation of crystals, which deposit in fibrous tissues that create a gouty tophus and in turn ultimately lead to inflammation (Wertheimer et al., 2013). The gouty tophus can cause damage to skin, bones, tendons, bursas, and organs. Gout also occurs in flares or episodes and leads to disability and pain and can be characterized into four phases as well (Burke et al., 2015; Centers for Disease Control and Prevention (CDC), 2016b; Wertheimer et al., 2013). These phases include asymptomatic tissue deposition, acute flare episodes, intercritical segments post flare, and chronic gout. During

asymptomatic tissue deposition, there are no symptoms of gout but the individual does have hyperuricemia and crystals begin depositing into tissues. During the acute flares, the crystals cause joint inflammation. Typically, the lower extremities are affected first and inflammation is commonly seen in the metatarsophalangeal joint. Post flare, gout enters an inactive phase despite the continuing deposition of crystals from hyperuricemia. Finally, chronic gout is accompanied by pain, aches, and the presence of tophi (Centers for Disease Control and Prevention (CDC), 2016b). Gout is typically diagnosed by clinical criteria and by examining the synovial fluid for monosodium urate crystals via various techniques (Centers for Disease Control and Prevention (CDC), 2016b; De Avila Fernandes et al., 2017).

There are many other forms of arthritis including polymyalgia rheumatica (PMR) and its sister disease giant cell (temporal) arteritis (GCA) (Cutolo, Cimmino, & Sulli, 2009; Lawrence et al., 2008). Polymyalgia rheumatica is another form of arthritis that occurs mainly in those age $\geq$ 50 years and is characterized by acute musculoskeletal inflammation (Cutolo et al., 2009; Lawrence et al., 2008). It causes morning stiffness and aches in the pelvic girdle, the shoulder joint, and neck (Cutolo et al., 2009; Gonzalez-Gay, 2004). GCA, which closely related to PMR, also occurs in the older population but causes vasculinitis in the cranial arteries causes symptoms such as including visual disturbances and headaches. GCA can also cause limb claudication as well as polymyalgia (Dejaco, Duftner, Buttgereit, Matteson, & Dasgupta, 2016; Gonzalez-Gay, 2004). Overall, arthritis is known to limit functionality and lead to disability (Hootman et al., 2012; Song et al., 2006). In a cross sectional analysis using a cohort from the Cardiovascular Health Study, 49% of

the participants (n=5201, age ≥65 years) stated that arthritis and other musculoskeletal diseases were the main cause of their inability to perform physical functioning activities (Ettinger et al., 1994). Other studies have shown similar results as well (Hochberg, Kasper, Williamson, Skinner, & Fried, 1995; Song et al., 2006).

A longitudinal study that evaluated how arthritis affects disability in older U.S. adults (n=7,758, age ≥ 65 years) used participants from the Health and Retirement Study (1998-2000). The participants had to have no ADL disability at the baseline measurement and included participants with and without arthritis. At baseline, arthritis was assessed via self-report. Disability was assessed after two year follow up period and was based on participants' self-reported ability to perform specific ADL tasks. That study used a multiple logistic regression analysis to assess disability presence based on arthritis status at baseline. It was found that compared to those participants without arthritis, those with arthritis had a higher two year incident ADL disability rate (9.3% versus 4.5%) and an odds ratio (OR) of 2.16 (95% CI:1.80-2.60). In addition, the incident rate for disability for women with arthritis increased by 2.2 times when compared to those without arthritis (10.7% versus 5.1%), and was higher than the incident rate of disability for men with and without arthritis (6.8% versus 3.9%) (Song et al., 2006). Therefore, since arthritis leads to disability, it is important that methods and techniques to predict incident disability are available for various areas of the body that are affected.

Arthritis and Grip Strength

Various forms of arthritis have been evaluated on their effect on grip strength including the most common forms (OA, RA, FM, gout) (Bagis et al., 2003; Burke et

al., 2015; Cardoso Fde et al., 2011; Dedeoğlu et al., 2013; Huang et al., 2013; Kemmler et al., 2015; Koca et al., 2016; Panton et al., 2006). In a case-control study conducted by Panton, et al. (2006), that study evaluated how FM affected muscular strength and physical functioning. That study compared 29 women (mean age=46.0±7.0 years) to 12 age and weight matched women who did not have FM (mean age=44.0±8.0 years) and additionally to 38 healthy older women (mean age=71.0 ± 7.0 years). To assess lower body muscular strength, peak isokinetic knee extension and flexion torque were measured using a Biodex Isokinetic Machine. While to assess upper body muscular strength a hand grip dynamometer was used. Physical functioning was assessed using the Continuous Scale-Physical Function Performance Test (CS-PFP). The CS-PFP test uses sixteen activities and assess them based on time, distance, and weight. To measure FM weekly, a fibromyalgia impact questionnaire (FIQ) was given to those with FM. In addition, the number and sensitivity of tender points was assessed for those with FM. That study found that there was no significant difference between the women with and without FM in regards to grip strength, but the older women had significantly lower grip strength scores when compared to the two other groups ($p \leq 0.025$). However, the FM group and older women group had significantly lower scores for isokinetic knee extension and flexion when compared to the control group ($p \leq 0.025$). That study displayed how women with FM have decreased lower body muscular strength but did not differ with the controls for upper body strength. Although FM is a form of arthritis, it may not affect grip strength scores because tender points for those with FM are generally in the shoulder and neck regions (Panton et al., 2006). In addition, the closest tender point to

the hand that is assessed in those with FM is the forearm (Wolfe et al., 1990). However, although FM does not affect grip strength scores, other forms of arthritis may.

In a prospective cohort study that assessed gout and hyperuricemia in older adults (≥65 years) and its effect on physical function, similar results in regards to FM and grip strength were found. That study used 5,819 participants (mean age=75.5 years) with and without gout and hyperuricemia that are part of the Atherosclerosis Risk in Communities Study. That study had five examination periods between 1987 and 2013 and participants were also contacted annually for a follow-up. Gout was assessed via self-reported, physician diagnosis during visit four or during the annual follow-up contact period. Upper extremity function was assessed using a hand grip strength test via a hand grip dynamometer. Lower extremity function was also assessed via the short physical performance battery assessment (SPPB). The SPPB encompasses assessments in balance, gait speed, and repeated chair stands. In addition, that study used prevalence ratios (PR) to assess if gout or hyperuricemia were associated with poor physical function. That study found that when after adjusting for potential confounders, low grip strength was not significantly affected by gout status (PR=1.04, 95% CI:0.92-1.18, P=0.49). In addition, after adjusting for potential confounders, low grip strength was not significantly affected by hyperuricemia status as well (PR=0.98, 95% CI:0.89-1.07, P=0.60). However, SPPB was affected by both gout (PR=1.18, 95% CI:1.07-1.32, P=0.002) and hyperuricemia (PR=1.09, 95% CI:1.00-1.19, P=0.048). Therefore, that study concluded that lower

extremity physical functioning is poorer in those with gout and hyperuricemia but not for grip strength (Burke et al., 2015).

Although, that study did not show grip strength scores being affected by gout status, another study conducted by Huang, C, et al. (2013), showed the opposite. They found that participants with hyperuricemia (associated with gout) had lower grip strength scores than those without hyperuricemia (40.3 kg, 95% CI:39.2-41.3 kg versus 41.9kg, 95% CI:41.3-42.5 kg, P=0.01) and concluded that hyperuricemia is associated with poor muscle strength. However, that study only used male participants and could have affected their results since hyperuricemia and gout are more prevalent in males. In addition that study used a cross-sectional design and a study that uses a prospective design needs to be executed to assess the causality of the two variables (Huang et al., 2013). Other studies that have used female participants have seen similar results as well (Cardoso Fde et al., 2011). Aside from gout and FM, other forms of arthritis may affect grip strength.

Unlike gout, which commonly affects the metatarsophalangeal joint (Centers for Disease Control and Prevention (CDC), 2016b) and FM, which leads to widespread pain (Lawrence et al., 2008; Panton et al., 2006; Wolfe et al., 1995) , RA commonly affects the joints of the hand (Firestein, 2003). A cross sectional study that assessed RA in the hands for its effect on grip strength and pinch strength, as well as disease activity, hand functionality, disability, and pain, used 78 female and 24 male participants (mean age=52.83±10.50 years). Hand grip strength was measured using a hand-held dynamometer and pinch strength was measured using a hydraulic pinch gauge. Disease activity was assessed using the Disease Activity Score 28 joints (DAS

28). Hand functionality was assessed using the Duroz Hand Index (DHI) and the Signals of the Functional Impairment (SOFI) index. Disability level was assessed using the Health Assessment Questionnaire (HAQ) and pain was measured using the Visual Analog Scale (VAS). Articular damage was also assessed using the Rheumatoid Arthritis Articular Damage score (RAAD) as well as the Modified Sharp Score (MSS). That study found that the grip strength and pinch strength scores were significantly negatively correlated with DAS 28, HAQ, SOFI index, DHI, RAAD scores, VAS, MSS, and disease duration ($p<0.001$). Therefore in individuals with RA, grip strength and pinch strength are decreased and are affected by many aspects of RA . Although this study showed that RA affects grip strength scores, it does not address the most common form of arthritis, OA, and also used both men and women (Dedeoğlu et al., 2013).

Similar to RA, OA also affects the joints of the hand and has led to decreased grip strength scores (Bagis et al., 2003; Kemmler et al., 2015; Neogi & Zhang, 2013). In a case-control study that used postmenopausal women, that study evaluated how OA affected hand function and used a grip strength test as a measure. That study included 100 women who had OA (mean age=61.47±8.21 years) and 70 healthy women (mean age=60.47±7.54 years) who acted as controls. The women were assessed on grip strength, pinch strength, hand function via survey, and on their OA symptoms including pain, nodules, and tenderness. Grip strength was measured using a Jamar hand grip dynamometer and pinch strength was measured using a hydraulic pinch gage. Hand function was assessed using the Dreiser's functional index and pain was assessed using a visual analog scale. The KL scale was used to assess and grade

radiographs (hand OA grade 2 or higher) (Kellgren & Lawrence, 1957) and joints were assessed via palpation. That study found that grip and pinch strength scores were significantly lower ($p<0.05$) in the participants with OA compared to those who were healthy while the Dreiser's Functional Index scores were significantly higher among those with OA compared to the healthy participants ($p<0.001$). In addition, those who were considered with grade 4 OA had significantly lower grip and pinch strength scores than those in the control group or grade 2 OA or grade 3 OA groups ($p<0.05$). Participants who had Herberden and Bouchard nodules had lower grip ($p=0.039$, $p=0.050$) and pinch strength ($p=0.050$, $p=0.015$) scores compared to the healthy counterparts as well. Also, participants were more likely to have significantly decreased hand function with increased pain and tenderness ($p<0.05$). That study concluded that OA significantly impairs hand function as well as grip and pinch strength (Bagis et al., 2003).

Arthritis and Sarcopenia

Numerous studies have evaluated the effect of different forms of arthritis on grip strength scores but did not assess arthritis to sarcopenia status. A study that did assess FM in relation to sarcopenia status was conducted by Koca et al. (2016), using a cross-sectional, case controlled design. That study used women between the ages of 18-60 years and included 82 participants with FM (mean age=40.7±2.0 years) and 38 healthy control female participants (mean age=38.8±2.8 years). Participants with FM were evaluated with the FIQ to evaluate each participant's severity of FM. In addition, these participants completed a visual analog scale questionnaire to quantify their level of pain as well as other questionnaires. To assess sarcopenia status,

muscular strength, body composition, and a physical functioning assessment. Muscular strength was assessed using a hand grip dynamometer for three trials with the average score being recorded. That study used a cut point of <22.5kg. Body composition was assessed using BIA and height and weight were assessed to calculate BMI. A skeletal muscle index (SMI) (appendicular skeletal muscle mass/height^2) of <6.75 kg/m^2 was used and was based of the reference data by the EWGSOP (Cruz-Jentoft et al., 2010). Physical functioning was assessed using a six meter gait speed test and a cutoff of ≤0.8m/s was used. Participants were also classified as presarcopenic, sarcopenic, or severely sarcopenic based on the EWGSOP staging (Cruz-Jentoft et al., 2010). That study found that overall, there were nine participants with sarcopenia and four with presarcopenia in the FM group and two participants with presarcopenia in the control group as well. Also, grip strength scores and gait speed scores were significantly lower in the FM group when compared to the control group ($p=0.023$, $p<0.001$ respectively). For body composition there was no significant difference between the FM participants and the control participants (Koca et al., 2016). However, this study did not address if sarcopenia status was affected by the presence of FM, rather it addressed if components of sarcopenia could be affected by FM. Also, that study did not use older women but used a wider age range and younger population of women.

Another study that assessed arthritis to sarcopenia status was conducted by Kemmler, et al. (2015). A cross-sectional study was used to assess data from the FORMosa Project (Bavarian Research Association – Sarcopenia and Osteoporosis) to evaluate the prevalence of sarcopenia in people with and without OA. That study took

place in Erlangen, Germany and used only Caucasian women (n=1,325) who were age 70 years and older (mean age=76.4±4.9 years). There were 232 participants who had OA that was confirmed by questionnaires and a physician. In regards to sarcopenia status, there were 21 out of 232 women (9.1%) with OA who were classified as sarcopenic while only 38 women (3.5%) out of 1,502 who did not have OA were classified as sarcopenic. In addition, significantly more OA participants had a grip strength less than 20 kg when compared to the non-arthritic counterparts (29.9% and 16.6% respectively) (p=0.001). The OA participants were also significantly slower (p=0.001) and had more participants with low lean mass than the non-arthritic counterparts (p=0.327). However, that study only evaluated the influence of OA on sarcopenia status as an exploratory aim and only asked about OA in the knee and hip and not the hands (Kemmler et al., 2015). To address the current gap in the literature, future studies should address how sarcopenia status may be influenced by various forms of arthritis and their impact on the components of sarcopenia criteria including muscular strength, physical functioning, and body composition.

Conclusion

While other studies have shown that various forms of arthritis affect grip strength, others have reported conflicting results. Grip strength is also a key aspect of many national and international organizations working definitions for sarcopenia. Therefore, it is possible that grip strength could impact sarcopenia status when hand arthritis is present and potentially misclassify people. This may be more true among older women since arthritis is prevalent in that population and they experience faster declines in muscular strength than men. No study has evaluated the effect of hand

arthritis on sarcopenia classification in older women based on current working definitions. Future studies addressing hand arthritis to overall muscular strength in older women with symptoms of sarcopenia are needed as well. Components of arthritis such as severity, pain, type, and joints affected should be considered when addressing arthritis to sarcopenia criteria and should be evaluated to see if those variables would affect sarcopenia status.

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APPENDIX B: Phone Screen Interview

URI Resistance Exercise Study to Reclaim Lean Muscle and Strength (URI RESTORE ME Project)
Data Sheet for Detailed Subject Telephone Interview

⑥ **Brief Explanation of Study**
⑥ **Permission to Conduct Interview?** _____Yes _____No
Comment:_____

Name: Dr./Ms./Mrs._____

Address: _____

_____

Phone #:_____

E-Mail:_____

Best Way and Time to Contact:_____

- **Time Commitment** – Available
  ____Yes ____No Wants to be contacted after _____ (Date)

Comment:_____

- ***Proximity to URI***
  Length of commute: miles or minutes
  Within reasonable commute_____ Willing to make unreasonable commute_____
  Too far to commute_____
- **Age**
  Age: _____ yrs Date of Birth: _____/_____/_____
  MM DD YY
  Approximate Height: _____ Approximate Weight: _____
  BMI: _____
- **Race**
  ___ American Indian or Alaskan Native
  ___ Asian or Pacific Islander
  ___ Black, not of Hispanic origin
  ___ Hispanic
  ___ White, not of Hispanic origin
  ___ Other/Unknown
- **Highest level of education completed**
  ___ Less than high school
  ___ High school or GED
  ___ Some college
  ___ Two-year college degree (e.g. Associates)
  ___ Four-year college degree (e.g. B.S., B.A.)

___ Masters degree

___ Doctoral degree

___ Professional degree (e.g. M.D., J.D.)

___ Other (please specify) _____

- **Have you attained menopause?** Yes _____ No_____

  If Yes, for how long? _____

- **Smoking**

  Always Non-Smoker_____ Non-Smoker for _____
  Smoker_____

- **Physical Activity**

  Participates in regular (>1x/wk for past 3 months) exercise? ____Yes
  _____No

  If yes, describe in <u>detail</u> (e.g. frequency, intensity, duration, mode)

_____
_____
_____
_____

Describe other non-structured physical activity (e.g. leisure time, gardening, occupational, or other)

_____
_____
_____

- **Cardiovascular (heart, blood, or blood vessel) conditions?**

  ____No ____Yes (Record on Medical History/Treatment Form)
  Comments:_____

  _____

- **Respiratory Conditions?**

  ____No ____Yes (Record on Medical History/Treatment Form)
  Comments:_____

  _____

- **Osteoarthritis/Degenerative Arthritis**

  ___No ___Yes
  If yes, how long and what was the
  severity_____
  _____

- **High Blood Pressure**

  No_____
  Yes_____ Controlled (Record High BP and Treatment on Medical History/Treatment Form)

Yes_____ Uncontrolled
Comments:_____
_____

- **Orthopedic conditions (knee, neck, or other back pain)**
  ___No ___Yes
  If yes, describe in detail including severity
  _____
  _____
  _____

- **Diabetes**
  _____No
  _____Yes – Type 2. If type 2, taking insulin now?
  _____
  _____Yes – Type 1 (Insulin Dependent)
  Comments:_____

  _____

- **Any major surgeries as an adult?**
  ___No ___Yes
  If yes, what type (e.g. surgeries of the joints, heart surgeries, angioplasty, bypass surgery, pacemakers, etc.) and date(s)
  _____
  _____
  _____
  _____

- **Other Medical Conditions (especially those that would make exercise difficult or unsafe)**
  _____No
  _____Yes (Record on Medical History/Treatment Form)
  Comments:_____

_____

- **Medication Info – See last page**
  _____No
  _____Yes (Record on Medical History/Treatment Form)
  Comments:_____

_____

- **Personal Physician Info**
  Name of Physician:

_____

  Specialty of Physician:

_____

Phone Number:_____

Fax Number:

_____

Address (if phone and fax unknown):

_____

_____

_____

- **Summary**

Interviewer Printed Name: _____

Interviewer Signature: _____

Questions/Comments:_____

_____

Reviewer Initials: _____

_____Appears to Qualify _____Need More Information
_____Needs Drs. Delmonico, Hatfield, Xu, or Lofgren to review
_____ Not Qualified

Questions/
Comments:_____

Medication/Dietary Supplement Form

Name	
Date	

Condition/Reason	Severity	Name of Medication/Supplement	Date started	Dose (mg/times/day)	Expected to Change?

APPENDIX C: Consent Form for Research

THE UNIVERSITY OF RHODE ISLAND
COLLEGE OF HUMAN SCIENCE AND SERVICES

THINK BIG WE DO

Department of Kinesiology
25 West Independence Way, Kingston, RI 02881 USA p: 401.874.2976 f: 401.874.4215

CONSENT FORM FOR RESEARCH

Title of Project: Effects of a Resistance Training Program in Older Women with Sarcopenia

You are invited to take part in a research project described below. The researchers will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, Drs. Matthew Delmonico (Phone: 401-874-5440) and Ingrid Lofgren (401-874-5706) from the Departments of Kinesiology and Nutrition and Food Sciences at the University of Rhode Island (URI), the persons mainly responsible for this study, will discuss them with you. The general eligibility criteria for inclusion to this study include having/being 1) a woman with low physical function and/or low lean mass, 2) age 65-84 years, 3) no recent medication changes, 4) post-menopausal, 5) the ability to speak and read English, 6) a body mass index of 18.5 – 45.0 kg/m^2 and 6) free of diseases or conditions that would prevent reasonably safe participation in an exercise program.

Description of the project:

You understand that the primary purpose of this study is to assess the role that a 12-week resistance exercise training program plays in improving muscle mass, physical functioning, and sarcopenia (the age-related loss of muscle mass) classification factors. Resistance training is has been shown to be effective for improving health outcomes in older women, including physical functioning but has not been tested in women who have been identified by new guidelines as having low muscle mass and physical functioning. Another purpose of the study will be to assess the influence resistance training on changes in bone density, blood pressure, muscle function, health indicators, blood lipids (fats) and sugar, fat and protein metabolism. Your participation time will vary depending on which group to which you are randomized and can range from 3-4 hours per week. All of the testing and intervention sessions will take place on the URI Kingston campus (Independence Square building, and you are responsible for your own transportation to all of the testing and intervention sessions).

What will be done:

You understand that if you choose to participate, the study potentially requires your involvement in five phases.

PHASE 1: During Phase 1, you will undergo a screening visit to determine if you meet the criteria for sarcopenia which include low muscle mass and either 1) slow normal walking speed or 2) low grip strength. The muscle mass test simply requires you to stand barefoot on a device with metal conducting pads while holding onto another set of conducting pads with

your hands. This will tell us in less than one minute how much arm and leg muscle you have. This device uses a very low electrical current in order to estimate muscle and fat mass on your body. This test only takes about one minute to complete but is a valid and reliable measure of body composition with very few risks. The walking test simply requires you to walk four meters (about 15 feet) at your normal walking pace. The hand grip strength test only takes a couple of minutes and you will be asked to squeeze a device two times with both hands (separately) as hard as you can. Your height and weight will also be measured at this visit. If you meet the criteria that identify you as having sarcopenia, then you will be invited to take part in the project. If you do not meet these criteria, we will provide you with information about your muscle mass and physical functioning, along with information about how you can maintain or improve these health aspects on your own.

PHASE 2: If you are identified as having sarcopenia, then you will be invited to take part in the research trial. Preliminary testing (four visits of ~ 1–1.5 hours per visit) will be necessary. In addition to a repeat of some of the measures in Phase 1, your , waist and hip girths will be measured and you will be asked to complete some tasks to measure your ability to carry out normal daily activities at the Independence Square building. These tasks include a usual pace 400 meter (~ ¼ mile) walk, rising from a chair, standing balance tests, and short walks. Any risk of injury during the completion of these tasks will be minimized by having all sessions supervised by an exercise physiologist qualified to direct this type of testing. In addition, you will be asked to complete several health questionnaires. These include sleep quality, general health, food intake, a dietary screening tool, a balance survey, and physical activity habits.

You understand that your percent body fat and bone density will be performed using dual energy x-ray absorptiometry (DXA) located in room 129 of the Independence Square building. This will require you to lay on a table a wearing hospital scrubs for about 20 minutes for the entire procedure. A licensed radiology technician will perform the DXA scans. There is no cost to you or your insurance for these scans.

The flexibility of your leg muscles will be tested by using a simple test that requires you to attempt to touch your toes while seated. You also understand that strength assessments will be performed on machines or devices that measure how much force and how fast you can exert force through a typical range of leg, back, chest and knee extension motion. Leg strength testing will be performed by measuring the maximal amount of force that you can move through the full range of an exercise. You may experience some temporary muscle soreness as a result of the testing sessions. There is also a risk of muscle soreness or skeletal injury from strength and testing as well as from the exercise training. The investigators of this study will use procedures designed to minimize this risk.

A blood test will be done that will include two blood draws to analyze blood sugar, lipids (fats), and other blood proteins. You understand that there is a risk of bruising, pain, and in rare cases, infection or fainting as a result of blood sampling. However, these risks to you will be minimized by allowing only qualified people to draw your blood. Your blood pressure will also be assessed during this first phase.

At the end of the Phase 2 (testing), you will be randomly assigned (like a flip of a coin) to either a resistance training group or a general physical activity group for Phase 3. You understand that you are not allowed to choose which group you will be assigned.

PHASE 3: INTERVENTION

Resistance Training Sessions (Resistance Training Group)

If you are randomized to the resistance training exercise group, you will also be asked to participate in three (3) supervised exercise sessions per week (~ 45 minutes per visit) for the 12-week intervention in the Independence Square building, room 190. During each resistance training session you will be asked to exercise on machines or free weights that offer resistance against extending and flexing your arms, legs, and trunk region. All sessions will start with a resting blood pressure and a brief warm-up. The first several resistance training sessions will begin with lighter resistances to get you used to the resistance training program. The resistances will be gradually increased based on individual progress. The resistance will always be adjusted so that you are exercising at near maximal effort. You will be able to provide feedback using standardized pain and discomfort rating scales. Your overall progress will be monitored by an exercise specialist so that you are able to tolerate the exercise. Each session will end with a cool-down and a final blood pressure measurement. No special clothing is required, but you should dress in clothing that is comfortable and that allows you to move freely. You will also be instructed to stop exercising immediately if you experience chest pain, muscle injuries, or any other unexpected symptoms. Although you will always have supervision when doing exercise training during this study, if you ever experience chest pain while exercising at other times, you should immediately call 911 to seek emergency care and notify your primary care physician. If you have any problems or injuries, you should also notify a member of the study team. Study team members and their phone numbers are noted on the first page of this consent form.

General Physical Activity Sessions (Active Control Group)

If you are assigned to the active control group, you will also be asked to participate in three (3) supervised exercise sessions per week (~ 45 minutes per visit) for the 12-week intervention in the Independence Square building, room 190. During each general physical activity session, you will engage in individual and group exercise sessions to increase your overall weekly physical activity. Activity sessions will vary but will include activities recommended by the American College of Sports Medicine for adults 65 years and older. Some of these activities may include walking, Tai Chi, light calisthenics, and stretching. All sessions will start with a resting blood pressure and a brief warm-up. The first several exercise sessions will begin with very light activities to get you used to the training program. The difficulty of the exercises will be gradually increased based on individual progress. You will be able to provide feedback using standardized pain and discomfort rating scales. Your overall progress will be monitored by an exercise specialist so that you are able to tolerate the exercise. Each session will end with a cool-down and a final blood pressure measurement. No special clothing is required, but you should dress in clothing that is comfortable and that allows you to move freely. You will also be instructed to stop exercising immediately if you experience chest pain, muscle injuries, or any other unexpected symptoms. Although you will always have supervision when doing

exercise training during this study, if you ever experience chest pain while exercising at other times, you should immediately call 911 to seek emergency care and notify your primary care physician. If you have any problems or injuries, you should also notify a member of the study team. Study team members and their phone numbers are noted on the first page of this consent form.

PHASE 4: Phase 4 will be a repeat of previously taken measures at the mid-point (week 6) and at the end (after week 12) of the 12-week exercise intervention.

PHASE 5: Phase 5 (the final phase) of the project will be six month follow-up testing session after Phase 4. You do not need to do any special activity or diet during this period.

Risks or discomfort:

You understand that it is possible that heart or blood vessel problems could arise during your participation in the testing or training involved in this study. Although highly unusual, it is possible that these problems could lead to a heart attack, stroke or even death. Therefore, prior evaluation and written clearance with a signature from your personal physician is strongly encouraged for you to participate in this study. You also understand that 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 will likely outweigh any potential risks. Additionally, you understand that with the testing described above, resistance training and exercise in general there is a risk of muscle soreness or other muscle injury as well as skeletal injury. Because exercise in this study does require some degree of balance, there is also a risk of falling associated with exercise. However, the investigators will take precautions in order to reduce the likelihood that these adverse events will occur.

You understand that there will also be a very low total radiation dose for the DXA scans (~39 millirem), which is about one-fifth the radiation dose of a standard chest X-ray and 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 due to 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 those 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 that required medical attention becomes your financial responsibility. You understand that 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.

You understand that if you are injured while participating in this research project as a result of negligence of all state employees who are involved in this research project, you may be able to be compensated for your injuries in accordance with the requirements of the Federal

Tort Claims Act. If you are a federal employee acting within the scope of your employment, you may be entitled to benefits in accordance with the Federal Employees Compensation Act.

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 study office (Independence Square building, Suite P, room 119).

Benefits of this study:

You understand that this study is not designed to help you personally, but may help the investigators better understand which interventions are the most effective in helping women who have sarcopenia improve their muscle mass and physical function. However, because of what is already known regarding the effects of resistance training and exercise in general, it is likely that you will notice some benefits. These potential benefits include improved strength, mobility and blood pressure.

For your participation in the study and after the study is completed, you will receive, free of charge, information about your blood pressure, blood test results, body composition, muscle strength, and physical function.

Decision to quit at any time:

You understand that is your decision and your decision alone whether or not you consent to participate in this study. You are free to ask questions about this study before you decide whether or not to consent to participate in it. Also, if you consent to participate in the study you are free to withdraw from participation at any time without penalty or coercion, or without any requirement that you provide an explanation to anyone of your decision to withdraw. You or your insurance company will not be charged for the classes or training sessions.

Rights and Complaints:

If you are not satisfied with the way this study is performed, you may discuss your complaints with the principal investigators, Drs. Matthew Delmonico at (401) 874-5440, Disa Hatfield at (401) 874-5183, Ingrid Lofgren at (401) 874-5869, or Furong Xu (401) 874-2412 (anonymously, if you choose). 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.

Alternatives to study participation: If you choose not to participate in this study, you are encouraged to discuss with your physician about exercise strategies.

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	Signature of Researcher
_____	_____
Typed/printed Name	Typed/printed name
_____	_____
Date	Date

By signing again below you give permission for the investigators to store and use your blood samples for future research only related to the study objectives.

_____	_____
Signature of Participant	Signature of Researcher
_____	_____
Typed/printed Name	Typed/printed name
_____	_____
Date	Date

Please sign both consent forms, keeping one for you.

APPENDIX D: Medical Clearance Form

THE UNIVERSITY OF RHODE ISLAND
COLLEGE OF HUMAN SCIENCE AND SERVICES

Medical Clearance to Participate in Exercise Research Project

THINK BIG WE DO

_____ has volunteered to participate in an exercise study entitled **"**URI Resistance Exercise Study to Reclaim Lean Muscle and Strength (URI RESTORE ME Project)" It is strongly recommended that volunteers have the clearance of her physician to participate in this study.

The aim of this study is to evaluate the impact of a 12-week resistance training exercise vs. a light physical activity program on muscle mass and physical functioning in older women aged 65-84 years who need improvements their muscle mass and physical functioning.

Exclusionary criteria for eligibility (Please check any that apply):

____ Significant or suspected cognitive impairment

____ Significant cardiovascular disease

____ Severe hearing loss, speech disorder, language barrier or visual impairment

____ Progressive, degenerative neurologic disease

____ Severe pulmonary/cardiovascular disease, uncontrolled diabetes, blood pressure, or anemia

____ Inability to safely engage in mild to moderate exercise with muscular exertion

____ Not within age range for study (65-84 years)

____ Medications not taken for > 3 weeks, lipid lowering medications for > 6 months

____ Major joint, vascular, abdominal, or thoracic surgery within six months

Although we are unaware of any cardiac complications that have resulted from resistance training, strength or physical functioning testing, there is only a limited amount of data available in older adults.

Please check one of the following:

____ **Clearance granted**

____ **Clearance not granted**

____ **Please send me the following information about the study:**

_____

_____

_____

Volunteers will either participate (at the URI campus) in 1) a full-body 12-week resistance exercise training program or 2) a light physical activity (e.g. stretching, Tai Chi, walking, light calisthenics, etc.) group. Both groups will be under the supervision of exercise specialists trained specifically for this study under the direction of the Principal Investigators, Matthew J. Delmonico, PhD, MPH, Ph: (401) 874-5440, Disa Hatfield, PhD, Ph: (401) 874-5183; Furong Xu, PhD, Ph: (401) 874-2412 - Department of Kinesiology, University of Rhode Island; Ingrid E. Lofgren, PhD, MPH, RD, Department of Nutrition and Food Sciences, University of Rhode Island, Ph: (401) 874-5706

Physician's name: _____

Physician's signature: _____ **Date**_____

APPENDIX E: Medical History Questionnaire

PHYSICAL FITNESS ACTIVITY 2.2

Medical/Health Questionnaire

According to the American College of Sports Medicine, a medical examination and clinical exercise test is recommended prior to (1) moderate or vigorous exercise training for those at high risk for disease, and (2) vigorous exercise training for moderate-risk individuals. The ACSM recommends that the pretest medical history be thorough and include 11 components: medical diagnoses, previous physical examination findings, history of symptoms, recent illness, hospitalization or surgical procedures, orthopedic problems, medication use and drug allergies, lifestyle habits, exercise history, work history, and family history of disease. The following medical and health questionnaire meets these criteria and can be used to gain a useful history on clients at fitness-testing facilities located in worksites, hospitals, and universities. In this activity, select a faculty member or member of the community that you feel would benefit from this process. Have the person answer the questions in the medical questionnaire, and then summarize important findings in the following blanks.

1. Symptoms or signs of disease: _____
2. Chronic disease risk factors: _____
3. Personal and family medical history: _____
4. Medications: _____
5. Summary of lifestyle habits: _____

Medical/Health Questionnaire

Personal Information

Today's date _____ Please print your name _____

How old are you? _____ years Sex ❑ Male; ❑ Female

Please circle the highest grade in school you have completed:

Elementary school	1	2	3	4	5	6	7	8
High school	9	10	11	12				
College/Postgrad	13	14	15	16	17	18	19	20+

What is your marital status? ❑ Single; ❑ Married; ❑ Widowed; ❑ Divorced/Separated

Race or ethnic background:

❑ White, not of Hispanic origin	❑ American Indian/Alaskan native	❑ Asian
❑ Black, not of Hispanic origin	❑ Pacific Islander	❑ Hispanic

What is your job or occupation? Check the one that applies to the greatest percentage of your time.

❑ Health professional	❑ Disabled, unable to work	❑ Service
❑ Manager, educator, professional	❑ Operator, fabricator, laborer	❑ Unemployed
❑ Skilled crafts	❑ Homemaker	❑ Student
❑ Technical, sales, support	❑ Retired	❑ Other

Symptoms or Signs Suggestive of Disease

Place a check in the box if your answer is "yes."

❑ **1.** Have you experienced unusual pain or discomfort in your chest, neck, jaw, arms, or other areas that may be due to heart problems?

❑ **2.** Have you experienced unusual fatigue or shortness of breath at rest, during usual activities, or during mild-to-moderate exercise (e.g., climbing stairs carrying groceries, brisk walking, cycling)?

❑ **3.** Have you had any problems with dizziness or fainting?

❑ **4.** When you stand up, or sometimes during the night while you are sleeping, do you have difficulty breathing?

❑ **5.** Do you suffer from swelling of the ankles (ankle edema)?

❑ **6.** Have you experienced an unusual and rapid throbbing or fluttering of the heart?

❑ **7.** Have you experienced severe pain in your leg muscles during walking?

❑ **8.** Has a doctor told you that you have a heart murmur?

Chronic Disease Risk Factors

Place a check in the box if your answer is "yes."

❑ **9.** Are you a male over age 45 years, or a female over age 55 years, or a female who has experienced premature menopause and is not on estrogen replacement therapy?

❑ **10.** Has your father or brother had a heart attack or died suddenly of heart disease before age 55 years; has your mother or sister experienced these heart problems before age 65 years?

❑ **11.** Are you a current cigarette smoker?

❑ **12.** Has a doctor told you that you have high blood pressure (more than 140/90 mm Hg), or are you on medication to control your blood pressure?

❑ **13.** Is your total serum cholesterol greater than 240 mg/dl, or has a doctor told you that your cholesterol is at a high-risk level?

❑ **14.** Do you have diabetes mellitus?

❑ **15.** Are you physically inactive and sedentary (little physical activity on the job or during leisure time)?

❑ **16.** During the past year, would you say that you experienced enough stress, strain, and pressure to have a significant effect on your health?

❑ **17.** Do you eat foods nearly every day that are high in fat and cholesterol such as fatty meats, cheese, fried foods, butter, whole milk, or eggs?

❑ **18.** Do you tend to avoid foods that are high in fiber such as whole-grain breads and cereals, fresh fruits, or vegetables?

❑ **19.** Do you weigh 30 or more pounds more than you should?

❑ **20.** Do you average more than two alcoholic drinks each day?

Medical History

21. Please check which of the following conditions you have had or now have. Also check medical conditions in your family (father, mother, brother[s], or sister[s]). Check as many as apply.

Personal	Family	Medical Condition
❑	❑	Coronary heart disease, heart attack, coronary artery surgery
❑	❑	Angina
❑	❑	High blood pressure
❑	❑	Peripheral vascular disease
❑	❑	Phlebitis or emboli
❑	❑	Other heart problems (specify: _____)
❑	❑	Lung cancer
❑	❑	Breast cancer
❑	❑	Prostate cancer
❑	❑	Colorectal cancer (bowel cancer)
❑	❑	Skin cancer
❑	❑	Other cancer (specify: _____)
❑	❑	Stroke
❑	❑	Chronic obstructive pulmonary disease (emphysema)
❑	❑	Pneumonia
❑	❑	Asthma
❑	❑	Bronchitis
❑	❑	Diabetes mellitus
❑	❑	Thyroid problems
❑	❑	Kidney disease
❑	❑	Liver disease (cirrhosis of the liver)
❑	❑	Hepatitis
❑	❑	Gallstones/gallbladder disease
❑	❑	Osteoporosis
❑	❑	Arthritis
❑	❑	Gout
❑	❑	Anemia (low iron)
❑	❑	Bone fracture
❑	❑	Major injury to foot, leg, knee, hip, or shoulder
❑	❑	Major injury to back or neck
❑	❑	Stomach/duodenal ulcer
❑	❑	Rectal growth or bleeding
❑	❑	Cataracts
❑	❑	Glaucoma
❑	❑	Hearing loss
❑	❑	Depression
❑	❑	High anxiety, phobias
❑	❑	Substance abuse problems (alcohol, other drugs, etc.)
❑	❑	Eating disorders (anorexia, bulimia)
❑	❑	Problems with menstruation

❑	❑	Hysterectomy
❑	❑	Sleeping problems
❑	❑	Allergies
❑	❑	Any other health problems (please specify, and include information on any recent illnesses, hospitalizations, or surgical procedures):

_____

_____

22. Please check any of the following medications you currently take regularly. Also give the name of the medication.

	Medication	**Name of Medication**
❑	Heart medicine	_____
❑	Blood pressure medicine	_____
❑	Blood cholesterol medicine	_____
❑	Hormones	_____
❑	Birth control pills	_____
❑	Medicine for breathing/lungs	_____
❑	Insulin	_____
❑	Other medicine for diabetes	_____
❑	Arthritis medicine	_____
❑	Medicine for depression	_____
❑	Medicine for anxiety	_____
❑	Thyroid medicine	_____
❑	Medicine for ulcers	_____
❑	Painkiller medicine	_____
❑	Allergy medicine	_____
❑	Other (please specify)	_____

Physical Fitness, Physical Activity/Exercise

23. In general, compared to other persons your age, rate how physically fit you are:

1❑ 2❑ 3❑ 4❑ 5❑ 6❑ 7❑ 8❑ 9❑ 10❑

Not at all physically fit — Somewhat physically fit — Extremely physically fit

24. Outside of your normal work or daily responsibilities, how often do you engage in exercise that at least moderately increases your breathing and heart rate and makes you sweat, for at least 20 minutes (such as brisk walking, cycling, swimming, jogging, aerobic dance, stair climbing, rowing, basketball, racquetball, vigorous yard work).

❑ 5 or more times per week ❑ 3–4 times per week ❑ 1–2 times per week
❑ Less than 1 time per week ❑ Seldom or never

25. How much hard physical work is required on your job?

❑ A great deal ❑ A moderate amount ❑ A little ❑ None

26. How long have you exercised or played sports regularly?

❑ I do not exercise regularly ❑ Less than 1 year ❑ 1–2 years
❑ 2–5 years ❑ 5–10 years ❑ More than 10 years

Diet

27. On average, how many servings of fruit do you eat per day? (One serving = 1 medium apple, banana, orange, etc.; ½ cup of chopped, cooked, or canned fruit; ¾ cup of fruit juice.)
    ❑ None ❑ 1 ❑ 2 ❑ 3 ❑ 4 or more
28. On average, how many servings of vegetables do you eat per day? (One serving = ½ cup cooked or chopped raw, 1 cup raw leafy, ¾ cup of vegetable juice.)
    ❑ None ❑ 1–2 ❑ 3 ❑ 4 ❑ 5 or more
29. On average, how many servings of bread, cereal, rice, or pasta do you eat per day? (One serving =1 slice of bread, 1 ounce of ready-to-eat cereal, ½ cup of cooked cereal, rice, or pasta.)
    ❑ None ❑ 1–3 ❑ 4–6 ❑ 7–9 ❑ 10 or more
30. When you use grain and cereal products, do you emphasize:
    ❑ Whole grain, high fiber ❑ Mixture of whole grain and refined ❑ Refined, low fiber
31. On average, how many servings of red meat (not lean) do you eat per day? (One serving = 2–3 ounces of steak, roast beef, lamb, pork chops, ham, burgers, etc.)
    ❑ None ❑ 1 ❑ 2 ❑ 3 ❑ 4 or more
32. On average, how many servings of fish, poultry, lean meat, cooked dry beans, peanut butter, or nuts do you eat per day? (One serving = 2–3 ounces of meat, ½ cup of cooked dry beans, 2 tablespoons of peanut butter, or ⅓ cup of nuts.)
    ❑ None ❑ 1 ❑ 2 ❑ 3 ❑ 4 or more
33. On average, how many servings of dairy products do you eat per day? (One serving = 1 cup of milk or yogurt, 1.5 ounces of natural cheese, 2 ounces of processed cheese.)
    ❑ None ❑ 1 ❑ 2 ❑ 3 ❑ 4 or more
34. When you use dairy products, do you emphasize
    ❑ Regular ❑ Low fat ❑ Nonfat
35. How would you characterize your intake of fats and oils (e.g., regular salad dressings, butter or margarine, mayonnaise, vegetable oils)?
    ❑ High ❑ Moderate ❑ Low

Body Weight

36. How tall are you (without shoes)? _____ feet _____ inches
37. How much do you weigh (minimal clothing and without shoes)? _____ pounds
38. What is the most you have ever weighed? _____ pounds
39. Are you *now* trying to
    ❑ Lose weight ❑ Gain weight ❑ Stay about the same ❑ Not trying to do anything

Psychological Health

40. How have you been feeling in general during the past month?
    ❑ In excellent spirits ❑ In very good spirits
    ❑ In good spirits mostly ❑ I've been up and down in spirits a lot
    ❑ In low spirits mostly ❑ In very low spirits
41. During the past month, would you say that you experienced _____ stress?
    ❑ A lot of ❑ Moderate ❑ Relatively little ❑ Almost no
42. In the past year, how much effect has stress had on your health?
    ❑ A lot ❑ Some ❑ Hardly any or none
43. On average, how many hours of sleep do you get in a 24-hour period?
    ❑ Less than 5 ❑ 5–6.9 ❑ 7–9 ❑ More than 9

Substance Use

44. Have you smoked at least 100 cigarettes in your entire life?

❑ Yes ❑ No

45. How would you describe your cigarette smoking habits?

❑ Never smoked

❑ Used to smoke

How many years has it been since you smoked? _____ *years*

❑ Still smoke

How many cigarettes a day do you smoke on average? _____ *cigarettes/day*

46. How many alcoholic drinks do you consume? (A "drink" is a glass of wine, a wine cooler, a bottle/can of beer, a shot glass of liquor, or a mixed drink.)

❑ Never use alcohol ❑ Less than 1 per week ❑ 1–6 per week

❑ 1 per day ❑ 2–3 per day ❑ More than 3 per day

Occupational Health

47. Please describe your main job duties.

_____

_____

	All of the time	Most of the time	Some of the time	Rarely or never
48. After a day's work, do you often have pain or stiffness that lasts for more than 3 hours?	❑	❑	❑	❑
49. How often does your work entail repetitive pushing and pulling movements or lifting while bending or twisting, leading to back pain?	❑	❑	❑	❑

APPENDIX F: Orientation/Screening Checklist and Data Collection Sheet

URI RESTORE ME Study: Orientation Checklist/Screening

Name: Date:

Participant ID:

CHECKLIST

Item	Yes	No	Initial
Consent Teach Back Complete	☐	☐	
Consent Form Signed	☐ 6/ /2015	☐	
Time of Last Meal			
Hydration Status			
Current Illness (Sx's)			
Recent Vigorous Exercise (Comments)	☐	☐	

SCREENING INFORMATION Initial

In-Body: BIA				
Pacemaker or Internal Defibrillator?		Yes ☐	No ☐	
Height:	**Weight:**	**BMI:**		
R Arm LM:	**L Arm LM:**	**R Leg LM:**	**L Leg LM:**	
		Total ALM:		
Grip Strength				
Dynamometer Setting:		**Best Grip Trial:**		
Grip R1:	**Grip R2:**	**Grip L1:**	**Grip L2:**	
4m Gait Speed		**Time 1:**	**Time 2:**	
Ability to Perform Chair Stand?		Yes ☐	No ☐	

APPENDIX G: Baseline Data Collection Sheet

THE UNIVERSITY OF RHODE ISLAND
COLLEGE OF HUMAN SCIENCE AND SERVICES

THINK BIG WE DO

URI RESTORE ME Study Data Sheet

BaselineTesting Day 1
Participant ID #: **Date:**

Measurements	Baseline Testing Day 1	Initial
Resting Heart Rate 1 (bpm)		
Resting Heart Rate 2 (bpm)		
Resting Blood Pressure 1		
Resting Blood Pressure 2		

Grip Strength (kilograms)			
Dynamometer Setting:		Best Grip Trial:	
Grip R1:	Grip R2:	Grip L1:	Grip L2:

Baseline Testing Day 1
Participant ID#: Date:

SPPB

BALANCE SCORING:

- **A. Side-by-side-stand**
  - Held for 10 sec 1 point
  - Not held for 10 sec 0 points
  - Number of seconds held if less than 10 sec:____sec
  - Not attempted 0 points
  - If participant did not attempt test or failed, check why:
  - Participant could not walk unassisted
  - Not attempted, you felt unsafe
  - Not attempted, participant felt unsafe
  - Participant unable to understand instructions
  - Other (Specify)
  - Participant refused
  - **If 0 points, end Balance Tests**

- **B. Semi-Tandem Stand**
  - Held for 10 sec 1 point
  - Not held for 10 sec 0 points
  - Number of seconds held if less than 10 sec:____sec
  - Not attempted 0 points
  - If participant did not attempt test or failed, check why:
  - Participant could not walk unassisted
  - Not attempted, you felt unsafe
  - Not attempted, participant felt unsafe
  - Participant unable to understand instructions
  - Other (Specify)
  - Participant refused
  - **If 0 points, end Balance Tests**
- **C. Tandem Stand**
  - Held for 10 sec 2 points
  - Held for 3 to 9.99 sec 1 point
  - Held for < than 3 sec 0 points
  - Not attempted 0 points
  - If participant did not attempt test or failed, check why:
  - Participant could not walk unassisted
  - Not attempted, you felt unsafe
  - Not attempted, participant felt unsafe
  - Participant unable to understand instructions
  - Other (Specify)
  - Participant refused
- **D. Total Balance Tests score _____(sum points)**
- **For 4-Meter Walk:**
  - If time is more than 8.70 sec: **1 point**

- If time is 6.21 to 8.70 sec: **2 points**
- If time is 4.82 to 6.20 sec: **3 points**
- If time is less than 4.82 sec: **4 points**

CHAIR SCORING:

- **Single Chair Stand Test:**
  - Safe to stand without help YES NO
  - Participant stood without using arms YES NO → If yes go to repeated stand
  - Participant used arms to stand YES NO → If yes end test; score as 0 points
  - Test not completed → End test; score as 0 points
  - If participant did not attempt test or failed, check why:
  - Tried but unable
  - Participant could not walk unassisted
  - Not attempted, you felt unsafe
  - Not attempted, participant felt unsafe
  - Participant unable to understand instructions
  - Other (Specify)
  - Participant refused

- **Repeated Chair Stand Test**
  - Safe to stand five times Yes No → If five stands completed record time
  - Time to complete five stands ___sec
  - If participant did not attempt test or failed, circle why:
  - Tried but unable
  - Participant could not walk unassisted
  - Not attempted, you felt unsafe
  - Not attempted, participant felt unsafe
  - Participant unable to understand instructions
  - Other (Specify)
  - Participant refused

- **Scoring the Repeated Chair Test**
  - Participant unable to complete 5 chair stands or completes stands in >60 sec: 0 points
  - If chair stand time is 16.70 sec or more: 1 points
  - If chair stand time is 13.70 to 16.69 sec: 2 points
  - If chair stand time is 11.20 to 13.69 sec: 3 points
  - If chair stand time is 11.19 sec or less: 4 points

- **Scoring for Complete Short Physical Performance Battery**
- **Total Balance Test score _____ points**
- **Gait Speed Test score _____ points**
- **Chair Stand Test score _____ points**
- **Total Score _____ points (sum of points above)**

Test	Result	Date Completed	Initial
400m walk (sec)			
SPPB	points scored		
Single Leg Stand, 10 sec			
Sit and Reach (+/- cm)			
Timed Up and Go 1 (sec)			
Timed Up and Go 2 (sec)			

Baseline Testing
Participant ID #: **Date:**

Measurements	Date	Initial
Resting Heart Rate 1 (bpm)		
Resting Heart Rate 2 (bpm)		
Resting Blood Pressure 1		
Resting Blood Pressure 2		
Blood Draw 1		

Anthropometrics	Measurement 1	Measurement 2	Average	Initial
Height (inches)				
Weight (lbs)				
Waist Circumference (inches)				
Hip Circumference (inches)				
BMI (kg/m^{2})		Waist to Hip Ratio		

Notes:

Baseline Testing
Participant ID#: **Date:**

Measurements	Baseline Testing Day 1	Initial
Resting Heart Rate 1 (bpm)		
Resting Heart Rate 2 (bpm)		
Resting Blood Pressure 1		
Resting Blood Pressure 2		
Blood Draw 2		

	Results collected	Date	Initial
DEXA			

In-Body: BIA		Date:	
Voided Bladder		Yes	No
Height:	Weight:	BMI:	
R Arm LM:	L Arm LM:	R Leg LM:	L Leg LM:
		Total ALM:	

APPENDIX H: Yale Physical Activity Scale Questionnaire

YALE PHYSICAL ACTIVITY SCALE

Interviewer: I will ask you about some common types of physical activities. Please tell me if you did them during a **typical week in the last month**. Our interest is learning about the types of physical activities that are a part of your regular work and leisure routines.
For each activity you did, please tell me how many **hours** you spent doing the activity **during a typical week.**

Work: (Number of hours per week)

1. _____ Shopping (e.g., grocery, clothes)

2. _____ Stair climbing while carrying a load

3. _____ Laundry (time loading, unloading, hanging, folding only)

4. _____ Light housework: tidying, dusting, sweeping; collecting trash in home; polishing; indoor gardening; ironing

1. _____ Heavy housework: vacuuming, mopping; scrubbing floors and walls; moving furniture, boxes, or garbage cans

6. _____ Food preparation (10+ minutes in duration): chopping, stirring, moving about to get food items, pans

7. _____ Food service (10+ minutes in duration):setting table; carrying food; serving food

8. _____ Dish washing (10+ minutes in duration): clearing table; washing/drying dishes, putting dishes away

9. _____ Light home repair: small appliance repair; light home maintenance/repair

10. _____ Heavy home repair: painting, carpentry, washing/polishing car

11. _____ Other: _____

Yard work: (Number of hours per week)

12. _____ Gardening: planting, weeding, digging, hoeing

13. _____ Lawn mowing (walking only)

14. _____ Clearing walks/driveway: sweeping, shoveling, raking

15. _____ Other: _____

YALE PART 2

Now I would like to ask about certain types of activities that you have done *during the past month.* I will ask you about how much vigorous activity, leisurely walking, sitting, standing, and other things that you usually do.

32. About how many times during the month did you participate in *vigorous* activities that lasted at least *10 minutes* and caused large increases in breathing, heart rate, or leg fatigue *or* caused you to sweat?

Not at all *(**go to Q34**)*	1-3 Times Per Month	1-2 Times Per Week	3-4 Times Per Week	5 or more Times Per Week

33. About how long do you do this vigorous activity each time?

Not applicable	10-30 minutes	31-60 minutes	60 or more minutes

34. Think about the walks you have taken during the past month. About how many times per month did you walk for *at least 10 minutes* or more *without stopping* which *was not* strenuous enough to cause large increases in breathing, heart rate, or leg fatigue *or* cause you to sweat?

Not at all *(**go to Q36**)*	1-3 Times Per Month	1-2 Times Per Week	3-4 Times Per Week	5 or more Times Per Week

35. When you did this walking, for how many minutes did you do it?

Not applicable	10-30 minutes	31-60 minutes	60 or more minutes

36. About how many hours a day do you spend moving around on your feet while doing things? Please report only the time that you are *actually moving.*

Not at all	Less than 1 hr per day	1 to less than 3 hrs per day	3 to less than 5 hrs per day	5 to less than 7 hrs per day	7 + hrs per day

37. Think about how much time you spend standing or moving around on your feet on an average day during the past month. About how many hours per day do you *stand*?

Not at all	Less than 1 hr per day	1 to less than 3 hrs per day	3 to less than 5 hrs per day	5 to less than 7 hrs per day	7 + hrs per day

38. About how many hours did you spend sitting on an average day during the past month?

Not at all	Less than 3hrs	3 hrs to less than 6 hrs	6hrs to less than 8 hrs	8 + hrs

39. About how many flights of stairs do you climb *up* each day?
(Let 10 steps = 1 flight)_____

40. Please compare the amount of physical activity that you do during other seasons of the year with the amount of activity you just reported for a typical week in the past month. For example, in the summer, do you do more or less activity than what you reported doing in the past month?
(Interviewer – mark the right category for each season)

	Lot more	Little more	Same	Little less	Lot less
Spring	1.3	1.15	0	.85	.7
Summer	1.3	1.15	0	.85	.7
Fall	1.3	1.15	0	.85	.7
Winter	1.3	1.15	0	.85	.7

APPENDIX I: Dietary Screening Tool

DIRECTIONS: Please check one response to each question that best describes how you eat.

How often do you usually eat fruit as a snack?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you usually eat whole grain breads?
____ Never **or** less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you usually eat whole grain cereals?
____ Never **or** less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you usually eat candy or chocolate?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat crackers, pretzels, chips, or popcorn?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat cakes or pies?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat cookies?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat ice cream?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat cold cuts, hot dogs, lunchmeats or deli meats?
____ Never **or** less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat bacon or sausage?
____ Never **or** less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat carrots, sweet potatoes, broccoli, or spinach?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 or more times a week

How often do you eat fruit (not including juice)? Please include fresh, canned or frozen fruit.
____ Never **or** Less than once a week
____ 1 or 2 times a week
____ 3 to 5 times a week
____ Every day or almost every day

How often do you eat hot or cold breakfast cereal?
____ Never
____ Less than once a week
____ 1 or 2 times a week
____ 3 to 5 times a week
____ Every day or almost every day

How often do you drink some kind of juice at breakfast?
____ Never **or** Less than once a week
____ 1 or 2 times a week
____ 3 to 5 times a week
____ Every day or almost every day

How often do you eat chicken or turkey?
____ Never **or** less than once a week
____ 1 or 2 times a week
____ More than 3 times a week

How often do you drink a glass of milk?
____ Never **or** Less than once a week
____ 1 or 2 times a week
____ 3 to 5 times a week
____ Every day or almost every day
____ More than once every day

Do you usually add butter or margarine to foods like bread, rolls, or biscuits?
____ Yes
____ No

Do you usually add fat (butter, margarine or oil) to potatoes and other vegetables?
____ Yes
____ No

Do you use gravy (when available) at meals?
____ Yes
____ No

Do you usually add sugar or honey to sweeten your coffee or tea?
____ Yes
____ No

Do you usually drink wine, beer or other alcoholic beverages?
____ Yes
____ No

How often do you eat fish or seafood that IS NOT fried?

___ Never
___ Less than once a week
___ Once a week
___ More than once a week

How many servings of milk, cheese, or yogurt do you usually have each DAY?

___ None
___ One
___ Two or more

How many different vegetable servings do you usually have at your main meal of the day?

___ None
___ One
___ Two
___ Three or more

Which of the following best describes your nutritional supplement use?

___ I don't use supplements
___ I use supplements other than vitamins and mineral
___ I use a multivitamin/mineral preparation (e.g. Centrum)