CHANGES IN GAIT DURING COMMUNITY BASED WEIGHT LOSS AND EXERCISE IN OBESE OLDER ADULTS WITH CARDIOVASCULAR DISEASE OR METABOLIC SYNDROME

BY

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ABSTRACT

Objective: The purpose of this study was to compare the effects of Weight Loss (WL) + Aerobic Training (AT), WL + Resistance Training (RT), and WL-only on mobility in obese older adults with Cardiovascular Disease (CVD) and/or Metabolic Syndrome (MetS) over an 18-month intervention period.

Methods: Two hundred forty nine obese older adults were randomized into WL + AT, WL + RT or WL-only. Treatment was split into three 6-month phases; an adoption phase, a transition phase, and a maintenance phase. Mobility was assessed by usual and fast pace gait speed and the spatiotemporal parameters (stride length, stride width, single/double support time, cycle/swing time) and were measured on a GAITRITE instrumented walkway at baseline, 6-month and 18-month follow-up. All comparisons were performed as the average of the 6 and 18-month follow-ups.

Results: Usual and fast pace gait speed, step length, and single support time all significantly increased while usual and fast pace double support time significantly decreased in the WL + AT group. Fast pace gait speed and usual and fast pace single support significantly increased, while double support time significantly decreased in the WL + RT group. There were no significant differences between the WL + AT and WL + RT groups. Step width did not significantly change in any of the groups. Gait speed or spatiotemporal parameters did not change significantly in the WL-only group.

Conclusion: WL + AT and WL + RT increased gait speed, step length, and single support, and decreased double support compared to WL-only. Exercise is an important component in a weight loss intervention if a goal is to improve gait and mobility.
INTRODUCTION

The number of elderly Americans with CVD is alarming; 69.1% of males and 67.9% of females aged 60-79 had some form of CVD from 2009-2012 (Mozaffarian et al., 2015). MetS is also more prevalent in older adults over the age of 60, with 52% of males and 54% of females receiving a MetS diagnosis from 2003-2006 (O’Neill & O’Driscoll, 2015). Those with MetS are at a two-fold increased risk for a CVD diagnosis (Mozaffarian et al., 2015). Aerobic training (i.e., walking programs) to improve cardiovascular function and reduce risk factors has been standard treatment for those with CVD or MetS (Audelin, Savage, & Ades, 2008; Balady et al., 2007; Franklin, Hall, & Timmis, 1997). Recently, the need to incorporate treatments to promote weight loss has increased due to the higher prevalence of obesity in the elderly (Rejeski et al., 2011; Rejeski, Ip, Marsh, Zhang, & Miller, 2008). Obesity has a substantial impact on one’s ability to move and can lead to mobility disability especially in older adults with CVD or MetS (Ferrucci & Guralnik, 2013; Jensen et al., 2006). Mobility disability is defined as the difficulty to move around independently, and it is a major concern for older adults (Marsh et al., 2013). Improvement of mobility in obese elderly adults with CVD or MetS may lead to increased quality of life and better overall health (Ades et al., 2002).

Recent studies on the elderly population have focused on gait speed and its relationship between survival rates, incidence of dependence, and other adverse outcomes (Okoro, 2006; Perera et al., 2016; Studenski et al., 2011). Studies have not examined spatiotemporal parameters of gait, which could provide greater insight into how CVD, MetS, and obesity affects mobility. Spatiotemporal parameters include step length, step width, single/double support time, cycle time, and swing time (Menz, Latt, Tiedemann,
Kwan, & Lord, 2004). These measurements can be useful in assessing gait disorders, mobility difficulty, and evaluating specific therapeutic interventions (Menz et al., 2004). Increased age is consistently associated with decreased gait speed while spatiotemporal parameters such as single and double support, stance, and swing time have not been found to change due to increased age alone. This is a substantial benefit when examining gait changes due to chronic disease or obesity in older adults (Patterson, Nadkarni, Black, & McIlroy, 2012).

The focus of this study was to compare the effects of Weight Loss (WL) + Aerobic Training (AT), WL + Resistance Training (RT), and WL-only on gait speed at usual and fast pace gait speed as well as spatiotemporal parameters of gait at usual and fast pace in a community-based setting. Exercise, either AT or RT, in addition to weight loss could have positive effects on gait characteristics and improve mobility. One of the aims of this study was to identify if either WL + AT or WL + RT had a significant impact on spatiotemporal parameters compared to WL-only. Gait measures were assessed at baseline, 6 months, and 18 months using a GAITRite mat, a reliable method that has also been shown to be sensitive to the effects of exercise interventions (Marsh et al., 2013). Assessing gait speed and spatiotemporal parameters illustrates greater detail about improvements in gait caused by interventions, which is important because gait is fundamental to mobility. Comparing the effects of WL-only, WL + AT, and WL + RT on spatiotemporal parameters could aid in determining the most effective method to improve gait, and therefore mobility. Improvements in mobility could decrease disability, enhance independence, and overall quality of life in older adults.
REVIEW OF LITERATURE

The Burden of Cardiovascular Disease in Older Adults

Cardiovascular disease (CVD), which includes coronary heart disease, peripheral arterial disease, heart failure, valvular heart disease, and stroke causes a substantial burden on the health of older adults (Yazdanyar & Newman, 2009). CVD is responsible for significant mortality, morbidity, disability, functional decline, and increased health care costs in the elderly (Yazdanyar & Newman, 2009). In the US during the period of 2009-2012, 69.1% of elderly males and 67.8% of elderly females had some form of CVD (Mozaffarian et al., 2015). In 2015, at least 85.6 million Americans have at least one form of CVD, and 43.7 million of those were 60 years or older in 2015 (Mozaffarian et al., 2015). CVD also accounted for 34% of all deaths in those 75 or younger in 2011, and was responsible for more deaths in that age group than cancer (Mozaffarian et al., 2015).

The burden of CVD has remained high over time and may rise further with the projected growth of the elderly population (Go, Mozaffarian, & Roger, 2013; Yazdanyar & Newman, 2009). The distribution of age in the US population is changing and it has been projected that there will be a two-fold increase of those 65 or older by 2050 which will account for 16% of the total population (Yazdanyar & Newman, 2009). This will increase the burden of morbidity, mortality and costs related to CVD in this population (Yazdanyar & Newman, 2009). CVD is a significant factor in self-reported health decline and is the second leading cause of disability in older adults. (Yazdanyar & Newman, 2009). The number of successful years of life decrease substantially when older adults have high levels of risk factors for common chronic diseases as well as low levels of physical and cognitive functioning (Newman et al., 2003). Successful years of life is
defined as the absence of chronic disease risk factors. Older adults with subclinical
measures of CVD report decreased quality of life, meaning that even nonfatal conditions
can be disabling in old age (Newman et al., 2003). In 2006, CVD accounted for 6.2
million hospital diagnoses at discharge, represented by a major cardiac-related procedure,
and over half of the initial hospitalizations in adults 65 years or older (Lloyd-Jones et al.,
2009). In 2011, total direct and indirect costs due to CVD were estimated at $320.1
billion and by 2030 those costs are projected to increase to $918 billion (Mozaffarian et
al., 2015). In summary, these statistics underscore the huge burden CVD places on public
health and, in particular, older adults (Yazdanyar & Newman, 2009).

**Metabolic Syndrome and Its Association with Cardiovascular Disease in the Elderly**

Metabolic syndrome (MetS) is a term that is used to describe the co-occurrence of
five conditions that include abdominal obesity, insulin resistance, impaired glucose
metabolism, dyslipidemia, and high blood pressure (McNeill et al., 2006). Increased
levels of triglycerides, cholesterol, and low density lipoproteins in the blood can lead to
plaque build-up and forms of CVD. At least 45% of Americans aged 50 or older have
MetS by the definition of the National Heart, Lung and Blood Institute (Third Report of
NCEP, 2002). Further, 52% of males and 54% of females above 60 years of age have
MetS, illustrating the increased prevalence of MetS in older populations and the
increased risk for CVD (O’Neill & O’Driscoll, 2015).

Individuals with MetS have a 61% increased risk for developing CVD compared
to those without MetS (Galassi, Reynolds, & He, 2006). Those with 4 or 5 metabolic
abnormalities are 2.2-2.4 times as likely to suffer an event due to CVD than those with
none of the abnormalities, but each individual MetS component also increases the risk for
CVD (McNeill et al., 2006). McNeill and colleagues reported that the presence of two of the components involved in MetS increased the risk of CVD and that high blood pressure was found to have the highest association (McNeill et al., 2006). Those with MetS are also at an increased risk of mortality from CVD and patients with other chronic diseases such as diabetes and cancer and are more likely to be obese (Ford, Giles, & Dietz, 2002; McNeill et al., 2006; O’Neill & O’Driscoll, 2015).

*Obesity in Conjunction with CVD and MetS*

Obesity is defined as an unhealthy, excess of body weight, and is associated with a myriad of health complications, including CVD and MetS (Okoro, 2006). Body mass index is widely used as a surrogate measure of body fat percentage (Rejeski, Marsh, Chmelo, & Rejeski, 2010). BMI is calculated by dividing body weight, in kilograms, by the square of body height in meters and it takes into account both fat mass and lean body mass. When using BMI, individuals are categorized as underweight, normal, overweight, or obese. Obesity is categorized as having a BMI of ≥ 30 kg/m$^2$, and overweight is categorized as having a BMI of ≥ 25 kg/m$^2$. A high BMI has been associated with poor health and negative outcomes, including increased risk of CVD and MetS (Ortega, Sui, Lavie, & Blair, 2016). Ortega and colleagues reported that a combination of high fat free mass and fat mass is a better predictor of cardio-metabolic risk than fat mass alone (Ortega et al., 2016). Despite its limitations and controversy, BMI remains a simple and inexpensive way to assess body mass, and can accurately categorize individuals into risk categories for CVD and MetS. Obesity is considered fundamental to the diagnoses of MetS and is known to precede other risk factors of MetS (O’Neill & O’Driscoll, 2015). It is also a strong predictor of cancers, increased blood lipids and inflammatory proteins,
sleep disorders, altered glucose metabolism, and musculoskeletal disorders (Mozaffarian et al., 2015). The elderly are more significantly impacted by excess body weight due to decreased strength and muscle quality, changes in body composition, and increased risk for chronic diseases.

The increase in the prevalence of obesity in all age groups, including older adults, in the population has created a substantial concern in both the scientific literature and the press (Okoro, 2006; Rejeski et al., 2010). The number of older adults classified as obese has increased; in 2007-2010 more than one-third of older adults aged 65 and over were obese (Fakhouri, Ogden, Carroll, Kit, & Flegal, 2012). The obesity epidemic, in conjunction with the increase in metabolic disorders (i.e. MetS and diabetes), contributes substantially to increased mortality and diagnoses of CVD and cancer (Okoro, 2006). Obese older adults are at a 50% increased risk of CHD (Osher & Stern, 2009), and metabolic abnormalities are highly prevalent in this population (Rejeski et al., 2010). Obesity is also associated with limitations in physical function. For example, Jensen and colleagues reported that a BMI of > 35 kg/m² in older adults increased the risk for functional decline and for becoming homebound (Jensen et al., 2006).

The Effect of CVD, MetS, and Obesity on Mobility and Physical Capacity

Mobility has been defined as the ability to move around independently, and is a unifying concept of disease, physical decline, and independence in older adults. Mobility limitations are often seen in older patients who have diminished exercise capacities, as well as higher rates of disability (Ades et al., 2002). Aging alone causes mobility loss and a sharp decrease in gait speed begins at the age of 60 years old. Mobility loss and impairment are caused by a combination of exposure to behavioral risk factors, chronic
disease, loss of muscle quality, and increased fat mass (Ferrucci et al., 2016). Those exposed to more negative factors will see a more rapid loss of mobility than those who avoid chronic disease and obesity (Ferrucci et al., 2016). Older patients who are diagnosed with CVD have an increased risk for mobility disability, as diseases of the heart and circulatory system run second only to arthritis as a cause of mobility problems in those ages 60 and older (Pinsky, Jette, Branch, Kannel, & Feinleib, 1990).

Cross-sectional studies have linked MetS and CVD with poor physical performance (Everson-Rose et al., 2011; Penninx et al., 2009; Sayer et al., 2007). Obese older adults with MetS have longer 400m walk times, and slower 20m walking speeds compared to those without MetS (Beavers et al., 2012). Lower physical performance in those objective measures can be used as a predictor of mobility disability and mobility problems, especially if one is also burdened with obesity (Beavers et al., 2012). Obesity in conjunction with MetS increases the risk of functional impairments and mobility disability due to the compromising effects of added fat mass on ambulation and overall physical function (Everson-Rose et al., 2011; Penninx et al., 2009). Obesity has also been reported as an independent risk factor for mobility disability in the elderly (Ferrucci & Guralnik, 2013). Ageing alone causes significant changes in body composition including a decrease in muscle mass and strength (Villareal et al., 2005). A decrease in muscle quality (volume/force ratio) is also seen in obese older individuals, which is an independent predictor of mobility disability, and is further aggravated by chronic disease (Newman et al., 2006; Russ, Gregg-Cornell, Conaway, & Clark, 2012). Obese older adults also experience a discrepancy between the amount of mass that needs to be moved, and the available amount of strength to do so (Ferrucci et al., 2016). This in particular
makes older adults more susceptible to the functional limitations caused by obesity (Villareal et al., 2005).

Interventions to Improve Mobility in the Elderly

There is evidence that a decline in mobility is not inevitable for older adults with chronic disease, and that mobility can be improved through exercise interventions and weight loss (Daley & Spinks, 2000). However, it has been noted that older adults have limited access to formal prevention programs that could improve mobility (Franklin et al., 1997; Gordon et al., 2002). Interventions that incorporate AT or RT in addition to WL can improve mobility and decrease the risk of adverse health outcomes that result from poor physical function. A few interventions have reported improved mobility through WL and exercise in obese older adults (Anton et al., 2011; Messier et al., 2004; Miller et al., 2006; Villareal et al., 2011; Villareal, Banks, Sinacore, Siener, & Klein, 2006). These interventions were all performed in university research lab settings and used combinations of AT, RT, and flexibility in addition to WL. Most were shorter term interventions lasting about 6-months and had smaller sample sizes (Anton et al., 2011; Miller et al., 2006; Villareal et al., 2006). The studies used performance based outcomes such as the 400-m walk and 6-minute walk to measure mobility improvements, and did not specifically measure spatiotemporal parameters. Though WL and exercise did significantly increase gait speed in all the interventions, none were performed in community-based settings and therefore are not as generalizable (Anton et al., 2011; Messier et al., 2004; Miller et al., 2006; Villareal et al., 2011, 2006).

Interventions that include increased physical activity and caloric restriction can reduce poor health due to chronic disease and can reduce cardiovascular risk factors as
well as cardio metabolic parameters (Dattilo & Kris-Etherton, 1992; Whelton, Appel, Espeland, & Applegate, 1998; Wing, Koeske, & Epstein, 1987). Aerobic training has been the most common mode of physical activity used during a WL intervention. A 10% weight loss over a period of 3-12 months has improved cardiometabolic outcomes, CVD risk, and physical function in older adults (Kalish, 2016). The effects of such interventions on CVD risk and MetS are well known, but little is known about the effects on mobility. Several studies reported that restrictive diets do cause fat mass loss but they also may exaggerate lean mass and bone mineral density loss as well as increase the risk of sarcopenia (muscle wasting) and frailty (Darmon, 2013; Mathus-Vliegen, 2012; Rejeski et al., 2010; Villareal et al., 2005). Muscle mass loss and decreased bone density has the potential to decrease functional ability, independence, and further impair mobility.

RT can lead to increases in lean muscle mass, strength, and improvement in physical function even in the oldest of the old (Fiatarone et al., 1990; Latham, Bennett, Stretton, & Anderson, 2004). It can also improve performance of activities of daily living and increase endurance in older adults (Ades et al., 2003). As previously stated, AT has been the primary mode of exercise with WL, but RT has provided similar caloric benefit and can equally modify risk factors for CVD and MetS in the older population (Ferrara, Goldberg, Ortmeyer, & Ryan, 2006). RT has also been shown to increase total lean mass in older adults who are 65 years or older, but it has not been well established if it can reduce the amount of lean mass lost during weight loss in obese older adults (Shea et al., 2011). Three studies in particular investigated RT in the obese elderly to determine if the loss of lean mass could be prevented (Frimel, Sinacore, & Villareal, 2008; Nicklas et al.,
Investigators from those studies compared a WL only arm to a WL + RT arm. Frimel and colleagues, Shea and colleagues, and Nicklas and colleagues reported that participants in both WL-only and WL + RT treatment arms lost significant fat mass (Frimel et al., 2008; Nicklas et al., 2015; Shea et al., 2011). The addition of RT, however, prevented or attenuated the loss of lean muscle mass that is normally associated with WL interventions in obese elderly populations (Frimel et al., 2008; Nicklas et al., 2015; Shea et al., 2011). These studies illustrate that RT in addition to WL can greatly improve health and mobility in the elderly by decreasing CVD and MetS risk factors, removing excess body fat, and preventing the loss of muscle mass and improving strength. The positive results shown on mobility due to WL and exercise in overweight/obese adults in research based settings should be implemented and studied in community-based settings so that interventions can become readily available to the increasingly old and chronically diseased population (Kahn, Robertson, Smith, & Eddy, 2008).

**Measures of Mobility and Physical Function**

Both self-report and performance based measures can be used to assess mobility. (Marsh, Ip, Barnard, Wong, & Rejeski, 2010). Self-report measures are completed by an individual subject, involve self-perception, and self-evaluation of physical function, mobility, and performance of activities (Latham et al., 2008). The most common way to collect self-report data is by utilizing a survey. Two commonly used surveys are the physical function subscale of the Short Form-36 and the Global Mobility Change Rating (Guyatt, Townsend, Berman, & Keller, 1987; Ware & Sherbourne, 1992). The results from self-report measures can be affected by environmental, personal, social, and cultural
factors but have been shown to correlate well with performance based measures (Latham et al., 2008). Performance based measures include the short physical performance battery (SPPB) (Guralnik et al., 1994), the 400 meter walk test (Simonsick, Montgomery, Newman, Bauer, & Harris, 2001), and the 6 minute walk test (American Thoracic Society, 2002; Guralnik et al., 2000). These measures depend on an analysis of the subject’s performance of physical activities. Performance of activities of daily living, and activities that require one to move from one location to another have been used to assess function. (Stalvey, Owsley, Sloane, & Ball, 1999). Other performance based measures involve stair climbing or walking, and are accurate ways to assess mobility, especially when looking at independence and self-care (Stalvey et al., 1999). Gait, which is the specific pattern of movement used during ambulation, can be used to assess mobility. Gait has not been as widely used in this population to determine effects of chronic disease or interventions on mobility, but gait is fundamental to one’s ability to navigate different environments and is therefore critical to understanding mobility. Gait and mobility problems often emerge before problems with ADL’s and IADL’s due to the increased challenge of moving one’s body mass.

_Gait Speed and Mobility Assessment_

Though mobility has been defined differently in many studies, gait, which is the biomechanical pattern with which someone walks, remains fundamental in all definitions. Gait speed requires the neurological, musculoskeletal, and cognitive systems to work together, so it can be useful in detecting small changes in health that may otherwise go unnoticed (Ostir et al., 2015). Gait speed alone has been shown to predict disability, future health status, functional decline, and morbidity, and has been called the sixth vital
sign (Studenski et al., 2011). Guralnik and colleagues reported that gait speed declines with increasing age and that decline accelerates significantly in older adults affected by chronic disease (Ferrucci & Guralnik, 2013). Faster gait speed in older adults is associated with increased health status and higher levels of physical function. In one large cohort study, an increase in gait speed of just 0.1 m/s was associated with a hazard ratio of 0.88, or a 12% reduced mortality risk (Perera et al., 2016). This provides some evidence that a faster gait speed is associated with a lower risk of incident disability and functional decline (Perera et al., 2016).

Measuring slow and fast gait speeds can be especially useful in determining overall physical capacity. One might be rather high functioning when asked to walk at a slow pace, but their range of ability may become apparent when asked to walk at a fast pace (Ostir et al., 2015; Perera et al., 2016). In other words, fast pace gait speed may be more indicative of one’s highest or true functioning capacity (Guralnik et al., 2000). Assessing slow and fast pace may provide insight into one’s functional reserve which represents the difference between usual pace, or normal functioning, and the maximal physical capacity (Soares, Lima, Ferrioli, Dias, & Perracini, 2015). Functional reserve represents the ability an individual has to respond to acute challenges, recover from a traumatic event, and compensate for effects of chronic disease to maintain physical function for daily activities including usual pace gait speed (Ferrucci et al., 2016). In other words, the inability to accomplish a fast pace gait speed is representative of challenged physical systems and mobility disability (Ferrucci et al., 2016).

In the current literature gait speed is a common measure to assess mobility, morbidity, and overall health in older adults. A slower gait speed has been associated
with MetS and CVD (Blazer, Hybels, & Fillenbaum, 2006; Okoro, 2006; Yazdanyar & Newman, 2009). Gait speed is the product of stride rate and stride length which both represent spatiotemporal parameters (Kressig et al., 2004). Other parameters include step width, single support, double support time, cycle time, stance time, and swing time. Spatiotemporal parameters provides greater detail about the specific aspects of gait that improve in older adults as the result of an intervention (Kressig et al., 2004). Spatiotemporal parameters are often examined to determine gait impairments and improvements in populations with orthopedic, musculoskeletal, or neurologic problems but not in those with CVD, MetS and who are obese. More recently, Kressig and colleagues combined data from several studies and established “normative” values for certain subsets of older adults. (Kressig et al., 2004). This data provides a baseline and a comparison for gait speed and spatiotemporal parameters in older adults ranging from frail to vigorous. The studies presented by Kressig and colleagues were all observational and did not investigate the effects of chronic disease or interventions on the parameters of gait. Studying gait is essential for understanding particular impairments in older adults, guiding clinical decisions, and determining what interventions have the greatest effects on specific parameters of gait (Patterson et al., 2012).

Measurement of Spatiotemporal Parameters

Spatiotemporal parameters of gait are useful in quantifying gait and examining changes in mobility due to interventions that target walking, but the methods to do so are often not practical for clinical use (Webster, Wittwer, & Feller, 2004). Three-dimensional motion analysis systems measure parameters with high precision but are expensive, technically involved, and require a lot of labor (Webster et al., 2004). Visual observation
has been used to measure gait spatiotemporal parameters with slight to moderate reliability, but has not been validated against other kinematic analyses (Eastlack, Arvidson, Snyder-Mackler, Danoff, & McGarvey, 1991; Krebs, Edelstein, & Fishman, 1985). Using a stopwatch and manual counting to quantify gait speed, stride length, and cadence have moderate to high reliability, but only mean values are obtained for each parameter and user error is high (Youdas et al., 2000). Chalk and ink-pad methods have been used in certain studies and produced reliable data but were reported as time consuming and burdensome (Bilney, Morris, & Webster, 2003).

The GAITRite system is a portable, computer-based instrumented walkway that is designed to analyze the spatiotemporal parameters of gait and address the limitations of these approaches. The instrumented mat includes pressure sensors that detect footfalls of the subject walking across the mat. The GAITRite software is installed on a laptop computer and is able to collect data from the mat and then calculate a wide range of spatiotemporal parameters, including gait speed, stride length, stride rate, stride width, single/double support time, cycle time, swing time, and stance time.

The GAITRite is portable, less expensive than 3D video methods, is easy to operate, store and is valid and reliable when compared to other direct measures. (McDonough, Batavia, Chen, Kwon, & Ziai, 2001). McDonough and colleagues compared the GAITRite system to the paper and chalk method to measure spatiotemporal parameters of gait and concluded that the GAITRite was valid and accurate (McDonough et al., 2001). Webster and colleagues concluded that the GAITRite system was a valid tool for measuring spatiotemporal parameters in an older adults, that it was easy to use, and could be placed into clinical settings (Webster et al., 2004).
In a reliability study, Menz and colleagues illustrated that the GAITRite produced highly reliable test-retest measures of gait speed, cadence, and step length in older adults (Menz et al., 2004). Some parameters, like base of support and toe-in/out angles, were not as reliable, but those parameters are inherently more variable in older adults. (Menz et al., 2004). Bilney and colleagues reported good concurrent validity compared to pressure sensing foot beds in shoes, and that there was good consistency in all variables measured at usual and fast paced speeds (Bilney et al., 2003). Overall the GAITRite system is a valid, reliable, and clinically applicable method to measure spatiotemporal parameters at usual and fast pace speeds in older adults compared to other methods (McDonough et al., 2001). Table 1 shows how the spatiotemporal parameters are defined and measured in the GAITRite software.
<table>
<thead>
<tr>
<th>Spatiotemporal Characteristic</th>
<th>Definition</th>
<th>GAITRite Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Speed (cm/s)</td>
<td>Stride rate \times stride length</td>
<td>Amount of distance traveled divided by total amount of time.</td>
</tr>
<tr>
<td>Step Length (cm)</td>
<td>Distance between two consecutive heel strikes of the same foot.</td>
<td>Measured on line progression between heel points of two consecutive footprints of same foot (left to left, right to right).</td>
</tr>
<tr>
<td>Step Width (cm)</td>
<td>Distance between the midpoints of the right and left feet.</td>
<td>Distance from the heel center of one foot to the line of progression formed by two footprints of the opposite foot.</td>
</tr>
<tr>
<td>Stance (% gait cycle)</td>
<td>Time period when one foot is in contact with the ground.</td>
<td>Weight bearing portion of each gait cycle. Initiated by heel contact and ends with toe-off of same foot. Time between first contact and last contact of two consecutive footfalls on the same foot.</td>
</tr>
<tr>
<td>Swing (% gait cycle)</td>
<td>Time period that begins with the toe off of one foot and ends with the heels strike of the other foot.</td>
<td>Initiated with toe off and ends with heel strike. Time elapsed between the last contacts of current footfall to first contact of next footfall on same foot.</td>
</tr>
<tr>
<td>Single Support (% gait cycle)</td>
<td>Time period when one foot is in contact with the ground.</td>
<td>Time elapsed between last contact of current footfall to first contact of next footfall on same foot.</td>
</tr>
<tr>
<td>Double Support (% gait cycle)</td>
<td>Time period when both feet are in contact with the ground.</td>
<td>Two periods when both feet are on the floor, called initial double and terminal double support.</td>
</tr>
<tr>
<td>Gait Cycle Time (sec)</td>
<td>Time period from heel strike to heel strike of the same foot.</td>
<td>Time elapsed between the first contacts of two consecutive footfalls on the same foot.</td>
</tr>
</tbody>
</table>
LIMITATIONS IN CURRENT LITERATURE

Current literature focuses on gait speed as a primary outcome to assess mobility, and has been used as a sixth vital sign in predicting disability and morbidity in older adults. It is very well established that slow gait speed is associated with decreased physical function, increased morbidity, and dependence but little is known about the effects of WL + AT, WL + RT, and WL-only interventions on gait speed or spatiotemporal parameters in older adults with chronic disease. Mechanisms by which specific chronic diseases affect mobility, and reciprocally how the decline in mobility further aggravates the severity and evolution of those diseases has only been addressed superficially (Ferrucci & Guralnik, 2013). There are many gaps in the current literature related to spatiotemporal parameters and the effects of chronic disease on gait and mobility. Interventions to improve mobility have been performed in university research lab settings with good results, but no large scale trials have been performed in community-based settings. In the present study, we have used a GAITRite to assess gait speed, step length, step width, single/double support, cycle, swing, and stance times at both a usual and fast pace at baseline, 6- and 18-months to assess the impact of three community-based interventions designed to improve mobility in older adults. This approach will provide a detailed assessment of the effect of chronic disease on gait, as well as the impact of interventions focused on improving mobility.

PURPOSE OF THIS PRESENT STUDY

The purpose of this study was to compare the effects of WL-only to WL + AT and WL + RT, and WL + AT to WL + RT on gait speed and spatiotemporal parameters as the change from baseline to the average of the 6- and 18-month follow-up.
HYPOTHESES

WL + AT will significantly increase usual and fast pace gait speed, step length, single support time, and swing time and will significantly decrease step width, double support time, cycle time, and stance time compared to WL-only at the end of the intervention. WL + RT will significantly increase usual and fast pace gait speed and step length compared to WL-only. The changes in gait speed and spatiotemporal parameters in the WL + AT group will be more pronounced compared to WL + RT.

METHODS

Overview

This analysis used data from the Cooperative Lifestyle Intervention Program-II (CLIP-II), a RCT that investigated the effects of WL + AT, WL + RT, and WL-only on mobility in overweight or obese older adults with CVD and/or MetS (Marsh et al., 2013). The Wake Forest IRB approved the study and all participants provided written informed consent. CLIP-II recruited 249 participants across 8 waves and 3 sites.

Eligibility

Detailed study inclusion and exclusion criteria have been published. Individuals were eligible to participate if they were 60-79 years of age, identified as overweight or obese (BMI of >28 and <42) were community-dwelling, and had either CVD or Metabolic Syndrome (MetS) along with self-reported mobility limitations (Marsh et al., 2013). Participants must have reported low levels of structured physical activity (PA) which was defined as less than 60 min of moderate intensity PA per week (Marsh et al., 2013). Participants with a variety of co-morbidities such as osteoarthritis or peripheral artery disease were not excluded to increase generalizability and translational
significance. Each participant's primary care physician was provided with a description of the study’s weight loss and physical activity program, as well as the study inclusion/exclusion criteria and were asked to approve or disapprove her/his patient for participation (Marsh, et al., 2013).

Recruitment and Screening

Participants were recruited in the Winston-Salem, NC area by direct mailings to community dwelling men and women. Respondents were initially screened for eligibility by telephone. After the phone screen, eligible participants were invited to attend an initial baseline visit at Wake Forest Baptist Medical Center’s Clinical Research Unit. The following assessments were performed after the informed consent process was completed: medical history, cognitive function assessed with the Montreal Cognitive Assessment (MoCA-11) (Nasreddine, Phillips, & Chertkow, 2012), fasting blood draw to determine CVD or MetS eligibility, body mass, height, waist circumference, resting blood pressure, BMI, Short Physical Performance Battery (SPPB) (Guralnik et al., 1994), and 400 m Walk Test (Gabriel et al., 2010). After the first baseline visit, eligible participants were asked to return for a second baseline visit to Wake Forest University Health and Exercise Science Department labs where gait spatiotemporal parameters (e.g. step length, stride time, step width, single/double support time, cycle, swing, stance) were measured on a GAITRite instrumented mat (Marsh et al., 2013).

Randomization

Following the collection of all baseline data, participants were randomized to one of the three treatment arms using a stratified block randomization scheme. Participants
were asked to return for follow-up visits at the end of 6-months and 18-months (Marsh et al., 2013).

**Primary Outcomes**

Gait speed as well as gait spatiotemporal parameters; stride length, stride time, stride width, single/double support time, cycle time, swing time, and stance time were collected. All measurements were collected during usual and fast pace walking using a GAITRite instrumented mat at baseline, 6-, and 18-months. Technicians who conducted the assessments were blinded to the treatment condition. It has previously been shown that the GAITRite system has good validity and reliability (Bilney et al., 2003; McDonough et al., 2001; Menz et al., 2004; Webster et al., 2004). The GAITRite is a portable computer based electronic walkway. The instrumented mat is connected to a computer containing software that records and calculates gait speed and spatiotemporal parameters. The active area of the walkway contains a total of 13,824 sensors arranged in a grid pattern (Menz et al., 2004). The GAITRite mat is 460 cm long with an active sensor area that is 366 cm long and 61 cm wide with a spatial resolution of 1.27 cm (Menz et al., 2004). Data is collected at a frequency of 80 Hz (Menz et al., 2004). As a participant walks across the walkway, pressure exerted by the feet activates the sensors and provides information about the geometry and relative arrangements of those sensors (GAITRite, 2013). The GAITRite has algorithms built into the system’s software that allows the system to isolate exerted pressure as footprints (GAITRite, 2013).

The participants were set up in the GAITRite system at the baseline visit and were later recalled at 6- and 18-months by selecting either New Patient, or Recalling a patient that was already entered into the system. Once New Test was selected, participants were
told they were going to be watched walking at a usual pace. They were instructed to stand behind a line and walk across the carpet to the line on the other side of the carpet. Once they arrived at the second line, they were instructed to turn around and wait for the cue to walk back. Usual pace was described as a pace that felt comfortable, as if one was walking to the mailbox or window shopping at the mall. Participants made 4 passes at this speed. Each pass was collected individually and footfall data was collected as the participant walked over the carpet on each pass. Each pass was accepted and saved for later analysis. After usual pace data was collected participants were told they were going to be watched walking at a fast pace. They were given the same instructions on where to start and end their passes across the carpet. Fast pace was described as walking as quickly as one could, without running. Participants also made 4 passes across the carpet at a fast pace. Each pass was collected individually and footfall data was collected as the participant walked over the carpet on each pass. All passes were accepted and saved for later analysis. Once all passes of usual and fast pace were collected, all fast pace walk trials were grouped together as Test #1 and all usual pace walk trials were grouped together as Test #2 so that average data for both speeds were analyzed separately. All data was exported and saved for later analysis in SPSS.

Study Interventions

Weight Loss Only

All three treatment groups received the same weight loss intervention. This 18-month WL intervention was divided into three 6-months phases: intensive (months1-6), transition (months 7-12), and maintenance (months 13-18). During the intensive phase participants met at the YMCA for 3 group sessions and 1 individual session per month
Group sessions tapered off to two per month in the transition phase and then one per month in the maintenance phase with individual sessions as needed. All group sessions had a duration of 60 minutes (Marsh et al., 2013). Weight loss program content was modeled after previous successful WL interventions that focused on self-regulation (Rejeski et al., 2011).

The primary objectives of the WL intervention were to decrease caloric intake in a manner to elicit a 0.3 kg/week weight loss in the intensive phase (Rejeski et al., 2011). The total weight loss goal for the 18-month study was 7-10% body mass (Rejeski et al., 2011). The aims of the transition phase were dependent on the individual while the focus changed to maintenance (12 to 18 months). Participants were encouraged to seek ways to increase spontaneous physical activity like taking the stairs instead of the elevator and parking farther away from destinations, but no formal exercise program was prescribed and exercise was not discussed with participants. The calorie goal for individuals was 1200-1800 kcal/day with less than 30% of those calories from fat (Marsh et al., 2013). Participants were encouraged to aim for a goal of 1.0 g/kg of protein, but the minimum requirement for protein each day was 0.8 g/kg. Participants were encouraged to track their calories and fat grams daily as well as weigh themselves regularly at home.

**Weight Loss +Aerobic Training**

The AT group used the same WL protocol as the WL-only group but AT was integrated into the group discussion sessions and each participant was prescribed an AT program. AT was individualized by YMCA intervention staff following the American College of Sports Medicine (ACSM) recommendations and occurred 4 days/week. The primary mode of AT was walking on an indoor cushioned track at the YMCA. All
sessions were supervised by YMCA staff and monitored using FitLinxx, a software package used by the YMCA to capture information on mode, intensity, duration, and frequency of exercise. The sessions were shaped towards a goal of 45 min/session with a walking intensity of 12-14 on the Borg RPE scale. Participants were told to increase or decrease their walking speed to adjust their RPE to a moderate intensity (Marsh, Janssen, et al., 2013). RPE was used to measure exercise intensity in both exercise groups. RPE provides a subjective measure that can be taught to participants so that they provide a self-reported measure of intensity. YMCA staff continuously monitored the participants by educating them on RPE, walking with them, and challenging them with new goals as they improved.

**Weight Loss + Resistance Training**

The RT group used the same WL protocol as the WL-only group but RT exercise was integrated into the group discussion sessions and each participant was prescribed a RT program. Participants randomized to the RT intervention also trained 4 days per week to ensure that the time devoted to RT and AT was comparable. The RT portion was shaped towards a duration of 45 minutes including weight lifting and rest periods between sets of exercises. The participants used Cybex resistance machines with weight stacks instrumented with FitLinxx hardware and software. The FitLinxx software tracked the exercise, number of repetitions, and number of sets completed. YMCA staff held individual orientations and all sessions were monitored. The RPE goal intensity level was 15-18. Starting resistance for the machines was determined by 1 repetition maximum (RM) testing at the initial orientation session. The RT program progressed slowly to allow time for the musculoskeletal system to adapt to new activity and for the participant
to learn the new exercises. Intensity increased progressively from 40 to 50% of 1RM with 1 set of 10-12 repetitions in week 1, to 50-60% of 1RM with 2 sets of 10-12 repetitions in week 2, and 70% of 1RM with 3 sets of 10-12 repetitions in weeks 3-12 (Marsh et al., 2013). From week 13 onwards the intensity increased to 75% of 1RM. Participants performed the full range of motion for the concentric movement in 0.5 s and 2.0 s for the eccentric movement. To avoid the need for 1RM testing and to mimic procedures typically used in community-based settings, from week 13 onward, participants performed 2 sets of 10-12 repetitions followed by a third set in which the goal was to perform as many repetitions as possible. Once the participant reached >12 repetitions on the third set on two consecutive days the resistance was increased to ensure overload of the musculoskeletal system (Marsh et al., 2013). To assist with recovery time, participants performed exercises using the same muscle groups on different days. Day 1 involved seated-row, pec fly, shoulder press, rotary torso, leg press, hip adduction, hip abduction and calf-extension and Day 2 involved seated chest press, lateral raise, bicep curl, triceps extension, abdominal crunch, leg extension, leg curl, and lateral pull down.

Setting goals for participants and communicating when goals were met was a critical component of the intervention (Marsh et al., 2013). Participants in the WL + AT group received direct feedback and encouragement from YMCA staff (Marsh et al., 2013). They also received verbal support, RPE monitoring, and assistance with walking progression and goal-setting. Participants in the WL + RT group received feedback from their YMCA staff interventionist in the form of verbal encouragement, checking proper form, and RT progression. The FitLinxx system provided participants in the WL + RT
group with immediate feedback on their effort for each machine they used (completing the full range of motion, number of sets, repetitions and weight) (Marsh et al., 2013).

**STATISTICAL ANALYSES**

The primary comparisons were between WL + AT and WL-only, WL + RT and WL-only and WL + AT and WL + RT. Paired t-tests were used for each primary outcome variable at each time-point to test whether values were different between the right and left feet. It was determined that there were no statistically significant differences between either side so each spatiotemporal parameter was analyzed as the average of the right and left sides. Between-group comparisons were made by mixed-model repeated measures analysis of covariance, where the subject was used as a random effect to account for the fact that multiple measurements for a participant over time were not independent. Covariates included time, sex, YMCA site, wave within each site, and baseline measures of the primary outcome. All P values and tests of hypotheses were two-sided and based on intent to treat analysis. No adjustments were performed to take into account multiple between group comparisons.

**RESULTS**

*Participant Characteristics*

Table II provides the baseline descriptive characteristics of the participants for the entire sample and for each treatment group. Overall, our sample’s average age was 66.8 years, was 71% female and 32% African American. 26% had a history of CVD and 84% of the participants had MetS. There was also a burden of other comorbidities, including an average BMI of 34.3 kg/m², 58% reporting arthritis in the hip or knee, and 74% with hypertension. All three treatment groups were similar in baseline characteristics. Tables 3
and 4 provide baseline usual and fast pace gait speed and spatiotemporal parameters for all three treatment groups. All baseline primary outcome data was similar between all groups.

**Adverse Events**

There were seven serious adverse events reported over the 18-months of the study. No single participant had more than one adverse event. Four of the seven events were possibly related to the study interventions but none were definitely linked to treatment as determined by review by the study data and safety monitoring board. The four events included a torn meniscus in WL + AT, a bulging vertebral disk and a rotator cuff injury in the WL + RT, and one report of low blood glucose of 11 discovered at a follow-up visit in a WL-only participant.

**Retention and Adherence**

As shown in the CONSORT Diagram (Figure 1), 249 total participants who met the inclusion/exclusion criteria were randomized into the three treatment arms, which was 12.1% of the original number phone screened. At the 6-month assessment 90.4% returned, whereas this was 77.1% at the 18-month assessment. There was no differential loss to follow-up as a function of any of the treatment arms.

**Weight Loss**

Data related to weight loss is illustrated in Figure 2. All three treatment groups lost a significant amount of body mass from baseline to 18-months. There was an average adjusted change of -8.12% [95%CI: -9.41, -6.83] for WL + AT, -9.07% [-10.36, -7.77] for WL + RT and -5.33% [-7.16, -4.50] for WL-only at FU18. WL + AT (P = 0.0013) and WL + RT (P < 0.0001) lost more weight than WL-only from baseline to FU18. WL +
AT and WL + RT did not regain any weight from FU6 to FU18 while WL-only group experienced an average 1% gain from FU6 to FU18.

**Outcomes: Summary**

Data related to usual and fast pace gait speed and other spatiotemporal parameters is presented in Tables 5 and 6 and Figures 3-16. Primary outcome data is shown as an average adjusted change of 6-month and 18-month follow-ups. Usual and fast pace gait speed, usual pace spatiotemporal parameters, and fast pace spatiotemporal parameters are presented separately in the results. Overall, significant changes occurred as a result of the WL + AT and WL + RT treatment arms from baseline in gait speed and all spatiotemporal parameters except for usual pace step width (p = 0.10) and fast pace step width (p = 0.78) compared to WL-only. There were no significant differences in gait speed or spatiotemporal parameters between the WL + AT and WL + RT treatment arms months except for fast pace cycle time (p = 0.04). No significant changes occurred for gait speed and spatiotemporal parameters in the WL-only group.

**Gait Speed: Usual and Fast Pace**

There was a significant difference in usual pace gait speed between the WL+AT group and the WL-only group (p = 0.0034). Usual pace gait speed increased 6.95 cm/s [95% CI; 4.49, 9.41] from baseline in the WL + AT group and 2.08 cm/s [-0.46, -4.61] in the WL-only group. Significant increases in fast pace gait speed occurred in both WL + AT (p = 0.031) and WL + RT (p = 0.009) compared to WL-only. Fast pace gait speed increased 9.04 cm/s [4.90, 13.19] in the WL + AT group and 9.87 cm/s [5.75, 13.99] in the WL + RT group compared to 4.90 cm/s [0.70, 9.11] in the WL-only group from
baseline. Both usual and fast pace gait speed increased from baseline to FU6 in both the WL + AT and WL + RT groups compared to WL-only.

**Spatiotemporal Parameters: Usual Pace**

Step length increased significantly in the WL + AT group compared to WL-only (p = 0.0033) with an overall average increase of 2.23 cm [1.41, 3.23]. Step length only increased 0.72 cm [0.21, 1.65] in the WL-only group. Step length did increase from baseline to FU6 in the WL + AT group compared to WL-only. Single support increased significantly in both the WL + AT group (p = 0.012) and the WL + RT (p = 0.0331) group compared to WL-only with an overall average increases of 0.88% [0.64, 1.13] in the WL + AT group and 0.83% [0.59, 1.07] in the WL + RT group compared to 0.55% [0.30, 0.80] in the WL-only group. Single support also increased from baseline to FU6 in both WL + AT and WL + RT. Double support decreased significantly in both the WL + AT (p = 0.02) and the WL + RT (p = 0.0264) groups compared to WL-only with overall average decreases of -1.67% [-2.18, -1.16] in the WL + AT group and -1.65% [-2.15, -1.14] in the WL + RT group compared to -1.08% [-1.60, -0.56] in the WL-only group. Double support did decrease from baseline to FU6 in both WL + AT and WL + RT. Cycle time decreased significantly in both the WL + AT (p = 0.025) and the WL + RT group (p = 0.0388) compared to WL-only with overall average decreases of -0.02 seconds [-0.04, -0.01] in the WL + AT group and -0.02 seconds [-0.03, -0.01] in the WL + RT group compared to -0.00 [-0.02, 0.01] in the WL-only group. Swing time significantly increased in the WL + AT (p = 0.0113) and the WL + RT group (p = 0.033) compared to WL-only with overall average increases of 0.88% [0.64, 1.13] in the WL + AT group and 0.83% [0.59, 1.07] in the WL + RT group compared to 0.55% [0.30, 0.80]
in the WL-only group. Stance time decreased the same amount as swing time increased in all treatment groups.

\textit{Spatiotemporal Parameters: Fast Pace}

Fast pace step length increased significantly in the WL + AT group compared to WL-only (p = 0.0031) with an overall average increase of 2.48 cm [1.53, 3.43]. There was only an increase of 0.86 cm [-0.11, 1.84] in the WL-only group. Step length did increase from baseline to FU6 in both WL + AT and WL + RT, but the increase was only significant in the WL + AT group. Fast pace single support increased significantly in both the WL + AT (p = 0.0111) and WL + RT (p = 0.0008) groups compared to WL-only with overall average increases of 0.89 % [0.64, 1.16] in the WL + AT group and 1.00% [0.75, 1.26] in the WL + RT group compared to 0.54 % [0.28, 0.80] in the WL-only group. Single support increased from baseline to FU6 in both WL + AT and WL + RT. Fast pace double support decreased significantly in both the WL + AT (p = 0.0068) and WL + RT (p = 0.0004) groups compared to WL-only with overall average decreases of -1.17% [-2.25, -1.18] in the WL + AT group, -1.94% [-2.46, -1.18] in the WL + RT group, and -0.98% [-1.52, -0.44] in the WL-only group. Double support did decrease in both WL + AT and WL + RT from baseline to FU6. Cycle time decreased in both WL + AT (p = 0.47) and WL + RT (p = 0.0056) but the decrease was only significant in the WL + RT compared to WL-only. There was a significant difference between the WL + AT and WL + RT groups (p = 0.036). Cycle time decreased by -0.03 seconds [-0.05, -0.02] in the WL + RT compared to -0.02 seconds [-0.03, -0.01] in the WL + AT group, and -0.02 seconds [-0.03, -0.00] in the WL-only group. Swing time increased in both WL + AT (p = 0.0114) and the WL + RT groups (p = 0.0008) compared to WL-only from baseline with average
increases of 0.89% [0.63, 1.14] in the WL + AT group and 1.00% [0.75, 1.25] in the WL + RT group compared to 0.54% [0.28, 0.80] in the WL-only group. Stance time significantly decreased the same amount as swing time increased for all treatment groups.

*Functional Reserve*

Data related to functional reserve are illustrated in Figure 16. Functional reserve increased slightly in the WL + AT and WL + RT groups compared to WL-only. Functional reserve increased from 41.4 cm/s to 43.6 cm/s in the WL + AT group, and from 42.4 cm/s to 49.3 cm/s in the WL + RT group. There was a larger increase in functional reserve in the WL + RT group compared to the WL + AT and WL-only groups. With no change occurring the WL-only group. Functional reserve increased by 7 cm/s in the WL + RT group, and only 2 cm/s in the WL + AT group.
<table>
<thead>
<tr>
<th></th>
<th>WL-only (N=82)</th>
<th>WL + AT (N=86)</th>
<th>WL + RT (N=81)</th>
<th>Combined (N=249)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66.2</td>
<td>67.4</td>
<td>66.9</td>
<td>66.8</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Female</td>
<td>59 (72)</td>
<td>62 (72)</td>
<td>56 (69)</td>
<td>177 (71)</td>
</tr>
<tr>
<td>Male</td>
<td>23 (28)</td>
<td>24 (28)</td>
<td>25 (31)</td>
<td>72 (29)</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>30 (36)</td>
<td>30 (35)</td>
<td>20 (23)</td>
<td>80 (32)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1 (0.01)</td>
<td>1 (0.01)</td>
<td>1 (0.01)</td>
<td>3 (0.01)</td>
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<td>White</td>
<td>49 (59)</td>
<td>55 (64)</td>
<td>58 (67)</td>
<td>162 (65)</td>
</tr>
<tr>
<td>Other</td>
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<td>0</td>
<td>2 (0.02)</td>
<td>4 (0.02)</td>
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<tr>
<td>BMI (kg/m²) (%)</td>
<td>34.7</td>
<td>33.8</td>
<td>34.7</td>
<td>34.3</td>
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<tr>
<td>CVD History (%)</td>
<td>57 (69)</td>
<td>61 (71)</td>
<td>59 (73)</td>
<td>65 (26)</td>
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<tr>
<td>Diabetes (%)</td>
<td>13 (16)</td>
<td>19 (22)</td>
<td>16 (20)</td>
<td>48 (19)</td>
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<td>Arthritis (%)</td>
<td>48 (58)</td>
<td>43 (50)</td>
<td>54 (66)</td>
<td>145 (58)</td>
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<tr>
<td>Hypertension (%)</td>
<td>57 (69)</td>
<td>67 (78)</td>
<td>60 (74)</td>
<td>184 (74)</td>
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<tr>
<td>Cancer (%)</td>
<td>21 (26)</td>
<td>11 (13)</td>
<td>15 (18)</td>
<td>47 (19)</td>
</tr>
<tr>
<td>Metabolic Syndrome (%)</td>
<td>71 (86)</td>
<td>71 (82)</td>
<td>68 (84)</td>
<td>210 (84)</td>
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</table>
Table III: Baseline Usual Pace Gait Speed and Spatiotemporal Parameters

<table>
<thead>
<tr>
<th>Data are mean (SD)</th>
<th>WL-only (N=82)</th>
<th>WL + AT (N=86)</th>
<th>WL + RT (N=81)</th>
<th>Combined (N=249)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Speed (cm/s)</td>
<td>115.1 (1.90)</td>
<td>115.7 (1.81)</td>
<td>113.0 (1.74)</td>
<td>114.6</td>
</tr>
<tr>
<td>Stride Length (cm)</td>
<td>63.6 (0.81)</td>
<td>63.3 (0.77)</td>
<td>62.8 (0.82)</td>
<td>63.5</td>
</tr>
<tr>
<td>Stride Width (cm)</td>
<td>10.0 (0.34)</td>
<td>10.1 (0.32)</td>
<td>10.1 (0.38)</td>
<td>10.0</td>
</tr>
<tr>
<td>Single Support (%)</td>
<td>35.1 (0.18)</td>
<td>35.2 (0.16)</td>
<td>34.9 (0.19)</td>
<td>35.1</td>
</tr>
<tr>
<td>Double Support (%)</td>
<td>30.1 (0.36)</td>
<td>29.7 (0.33)</td>
<td>30.4 (0.39)</td>
<td>30.0</td>
</tr>
<tr>
<td>Cycle Time (sec)</td>
<td>1.11 (0.01)</td>
<td>1.10 (0.01)</td>
<td>1.12 (0.01)</td>
<td>1.11</td>
</tr>
<tr>
<td>Swing Time (%)</td>
<td>35.5 (0.18)</td>
<td>35.3 (0.16)</td>
<td>34.9 (0.20)</td>
<td>35.2</td>
</tr>
<tr>
<td>Stance Time (%)</td>
<td>64.9 (0.18)</td>
<td>64.8 (0.16)</td>
<td>65.1 (0.20)</td>
<td>64.9</td>
</tr>
</tbody>
</table>

Table IV: Baseline Fast Pace Gait Speed and Spatiotemporal Parameters

<table>
<thead>
<tr>
<th>Data are mean (SD)</th>
<th>WL-only (N=82)</th>
<th>WL + AT (N=86)</th>
<th>WL + RT (N=81)</th>
<th>Combined (N=249)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Speed (cm/s)</td>
<td>156.6 (2.32)</td>
<td>157.1 (2.33)</td>
<td>155.4 (2.14)</td>
<td>156.4</td>
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<tr>
<td>Stride Length (cm)</td>
<td>73.2 (0.88)</td>
<td>72.9 (0.87)</td>
<td>72.7 (0.91)</td>
<td>72.9</td>
</tr>
<tr>
<td>Stride Width (cm)</td>
<td>10.3 (0.33)</td>
<td>10.3 (0.31)</td>
<td>10.0 (0.34)</td>
<td>10.2</td>
</tr>
<tr>
<td>Single Support (%)</td>
<td>37.4 (0.19)</td>
<td>37.5 (0.17)</td>
<td>37.5 (0.19)</td>
<td>37.5</td>
</tr>
<tr>
<td>Double Support (%)</td>
<td>25.4 (0.38)</td>
<td>25.3 (0.34)</td>
<td>25.6 (0.38)</td>
<td>25.4</td>
</tr>
<tr>
<td>Cycle Time (sec)</td>
<td>0.94 (0.01)</td>
<td>0.94 (0.01)</td>
<td>0.94 (0.01)</td>
<td>0.94</td>
</tr>
<tr>
<td>Swing Time (%)</td>
<td>37.4 (0.19)</td>
<td>37.5 (0.17)</td>
<td>37.4 (0.19)</td>
<td>37.4</td>
</tr>
<tr>
<td>Stance Time (%)</td>
<td>62.6 (0.19)</td>
<td>62.5 (0.17)</td>
<td>62.6 (0.19)</td>
<td>62.6</td>
</tr>
</tbody>
</table>

Key: SD = standard deviation
Figure 1: CONSORT Diagram

2057 Assessed for Eligibility at Phone Screening

348 Assessed at SV1

253 Further Assessed at SV2

249 Randomized

82 Weight Loss Only

81 Weight Loss + Resistance Training

86 Weight Loss + Aerobic Training

225 at 6 mo follow-up (90.36%)

221 with 400m walk data
215 with HUMAC data

192 at 18 mo follow-up (77.11%)

185 with 400m walk data
183 with HUMAC data

1709 Excluded
1683 Did not meet inclusion criteria
26 Eligible but declined participation

95 Excluded- Top 5 Reasons
31 No CVD or MetS
26 Glucose > 140
13 Eligible but Refused
8 BMI too High
7 No MD Approval

4 Excluded
2 COPD
1 Could not perform knee strength
1 Extreme case of scoliosis

24 Did not complete 6 mo follow-up
11 Unable to contact
9 Dropped/refused
2 Caregiving
1 Moved
1 Medical Complication

57 Did not complete 18 mo follow-up
23 Dropped/refused
12 Medical Complication
7 Caregiving
7 Unable to contact
4 Moved
3 Work Related
1 Death
Figure 2: Weight Loss

Adjusted percent change of WL in obese older adults from baseline to 6-months and 18-months. Data points are average ± SE
### Table V: Usual Pace Gait Speed and Spatiotemporal Parameters average change from baseline

<table>
<thead>
<tr>
<th>Spatiotemporal parameters: average change from baseline adjusted LS Mean (SE) [95% CI]</th>
<th>Treatment Group</th>
<th>P-Value</th>
<th>P-Value</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WL (N=81)</td>
<td>WL+ AT (N=85)</td>
<td>WL+ RT (N=80)</td>
<td>Overall</td>
</tr>
<tr>
<td>Usual Pace Gait Speed (cm/s)</td>
<td>2.08 (1.29) [-0.46, 4.61]</td>
<td>6.95 (1.25) [4.49, 9.41]</td>
<td>4.62 (1.24) [2.18, 7.06]</td>
<td>0.0137</td>
</tr>
<tr>
<td>Usual Pace Step Length (cm)</td>
<td>0.72 (0.47) [0.21, 1.65]</td>
<td>2.32 (0.46) [1.42, 3.23]</td>
<td>1.35 (0.46) [0.46, 2.25]</td>
<td>0.0122</td>
</tr>
<tr>
<td>Usual Pace Step Width (cm)</td>
<td>-0.55 (0.14) [-0.83, -0.26]</td>
<td>-0.45 (0.14) [-0.73, -0.18]</td>
<td>-0.84 (0.14) [-1.12, -0.57]</td>
<td>0.10</td>
</tr>
<tr>
<td>Usual Pace Single Support (% cycle)</td>
<td>0.55 (0.13) [0.30, 0.80]</td>
<td>0.88 (0.12) [0.64, 1.13]</td>
<td>0.83 (0.12) [0.59, 1.07]</td>
<td>0.0259</td>
</tr>
<tr>
<td>Usual Pace Double Support (% cycle)</td>
<td>-1.08 (0.26) [-1.60, -0.56]</td>
<td>-1.67 (0.26) [-2.18, -1.16]</td>
<td>-1.65 (0.26) [-2.15, -1.14]</td>
<td>0.0328</td>
</tr>
<tr>
<td>Usual Pace Cycle Time (%)</td>
<td>-0.00 (0.01) [-0.02, 0.01]</td>
<td>-0.02 (0.01) [-0.04, -0.01]</td>
<td>-0.02 (0.01) [-0.03, -0.01]</td>
<td>0.0464</td>
</tr>
<tr>
<td>Usual Pace Swing Time (%)</td>
<td>0.55 (0.13) [0.30, 0.80]</td>
<td>0.88 (0.12) [0.64, 1.13]</td>
<td>0.83 (0.12) [0.59, 1.07]</td>
<td>0.0255</td>
</tr>
<tr>
<td>Usual Pace Stance Time (%)</td>
<td>-0.55 (0.13) [-0.80, -0.30]</td>
<td>-0.89 (0.13) [-1.14, -0.64]</td>
<td>-0.83 (0.12) [-1.08, -0.59]</td>
<td>0.0209</td>
</tr>
</tbody>
</table>

Footnotes: WL = weight loss; AT = aerobic training; RT = resistance training; SE = standard error; p-value set at <0.05; * denotes statistical significance below .05; ***** denotes no statistically significant changes
Figure 3: Usual Pace Gait Speed

Usual Pace Gait Speed (cm/s)

Follow-up in Months

Adjusted Change

Randomization Group

- Weight Loss (WL)
- WL + Aerobic Training (AT)
- WL + Resistance Training (RT)

Adjusted changes in usual pace gait speed in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 4: Usual Pace Step Length

Adjusted changes in usual pace step length in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 5: Usual Pace Step Width

Adjusted changes in usual pace step width in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 6: Usual Pace Single Support

Adjusted changes in usual pace single support in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 7: Usual Pace Double Support

Adjusted changes in usual pace double support in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Adjusted changes in usual pace cycle time in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SD.
Figure 9: Usual Pace Swing Time

Adjusted changes in usual pace swing time in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
| Spatiotemporal parameters: average change from baseline adjusted LS Mean (SE) [95% CI] | Treatment Group | P-Value |
|---|---|---|---|---|
| | WL (N=81) | WL+ AT (N=85) | WL+ RT (N=80) | Overall | WL vs. WL+AT | WL vs. WL+RT | WL+AT vs. WL+RT |
| Face Pace Gait Speed (cm/s) | 4.90 (2.14) [0.70, 9.11] | 9.04 (2.11) [4.90, 13.19] | 9.87 (2.10) [5.75, 13.99] | 0.0220* | 0.0309* | 0.0093* | 0.66 |
| Fast Pace Step Length (cm) | 0.86 (0.50) [-0.11, 1.84] | 2.48 (0.48) [1.53, 3.43] | 1.58 (0.48) [0.64, 2.53] | 0.0120* | 0.0031* | 0.1829 | 0.09 |
| Fast Pace Step Width (cm) | -0.50 (0.13) [-0.76, -0.24] | -0.62 (0.13) [-0.87, -0.37] | -0.52 (0.13) [-0.77, -0.27] | 0.7772 | ***** | ***** | ***** |
| Fast Pace Single Support (% cycle) | 0.54 (0.13) [0.28, 0.80] | 0.89 (0.13) [0.64, 1.15] | 1.00 (0.13) [0.75, 1.26] | 0.0025* | 0.0111* | 0.0008* | 0.42 |
| Fast Pace Double Support (% cycle) | -0.98 (0.27) [-1.52, -0.44] | -1.71 (0.27) [-2.24, -1.18] | -1.94 (0.27) [-2.46, -1.18] | 0.0011* | 0.0068* | 0.0004* | 0.39 |
| Fast Pace Cycle Time (%) | -0.02 (0.01) [-0.03, -0.00] | -0.02 (0.01) [-0.03, -0.01] | -0.03 (0.01) [-0.05, -0.02] | 0.0149* | 0.4719* | 0.0056* | 0.0364* |
| Fast Pace Swing Time (%) | 0.54 (0.13) [0.28, 0.80] | 0.89 (0.13) [0.63, 1.14] | 1.00 (0.13) [0.75, 1.25] | 0.0025* | 0.0114* | 0.0008* | 0.41 |
| Fast Pace Stance Time (%) | -0.54 (0.13) [-0.80, -0.28] | -0.89 (0.13) [-1.14, -0.64] | -0.99 (0.13) [-1.24, -0.74] | 0.0030* | 0.0114* | 0.0011* | 0.45 |

Footnotes: WL = weight loss; AT = aerobic training; RT = resistance training; SE = standard error; p-value set at <0.05; * denotes statistical significance below .05; ***** denotes no statistical significance in any of the groups
Figure 10: Fast Pace Gait Speed

Adjusted changes in fast pace gait speed in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 11: Fast Pace Step Length

Adjusted changes in fast pace step length in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Adjusted changes in fast pace step width in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 13: Fast Pace Single Support

Adjusted changes in fast pace single support in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Adjusted changes in fast pace in double support in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 15: Fast Pace Cycle Time

Fast Pace Cycle time (sec)

Adjusted changes in fast pace cycle time in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 16: Fast Pace Swing Time

Adjusted changes in fast pace swing time in older obese adults from baseline to 6-months and 18-months. Data point values are average ± SE.
Figure 17: Functional Reserve Change from Baseline

Average change in functional reserve in obese older adults from baseline to 6-months and 18-months. Blue bar values are mean ± SE.
DISCUSSION

Mobility problems in older adults are on the rise due to the increased prevalence of obesity, CVD, and MetS. Few structured interventions have focused on improving mobility through exercise and WL in the community. Even fewer have examined modifications in gait speed and spatiotemporal parameters. Gait patterns and spatiotemporal parameters have been widely examined in several distinct populations such as those with dementia, Parkinson’s, cerebral palsy, and MS but not in older adults with more common reversible chronic diseases. The findings from this randomized controlled trial illustrate that WL + AT and WL + RT improve mobility compared to WL-only. There were significant changes in gait speed and spatiotemporal parameters except step width in WL + AT, and in usual and fast pace single/double support and fast pace gait speed in WL + RT. No significant changes occurred in the WL-only group. This indicates that WL in addition to exercise, either AT or RT, is needed to have a significant impact on gait speed and spatiotemporal parameters of gait. The results of this study also illustrate that community based interventions can improve mobility.

Participants in each of the three treatment arms were similar in age, BMI, race, gender, and co-morbidities. Randomization of all 249 participants was effective and comparisons between each group were made on participants with similar characteristics. Gait speed and spatiotemporal parameters were similar between all groups. Compared to baseline data collected by Kressig and colleagues in a group of older adults “transitioning to frailty”, the participants in CLIP-II were younger in age with an average age of 66.8 years compared to 79.6 years, and had an average baseline gait speed of 1.14 m/s compared to 0.97 m/s. (Kressig et al., 2004). Participants in CLIP-II had a shorter step
length of 0.6 m compared to 1.11 m, and spent less time in double support, 30.1% compared to 32.1%. Kressig did not report baseline step width or single support. Overall, the participants in CLIP-II were less physically disabled than the group examined by Kressig and colleagues, and had gait characteristics similar to those in vigorous older adults.

All three CLIP-II intervention groups consisted of an intensive phase, transition phase, and maintenance phase of WL. All the participants in the WL+ AT and WL + RT groups lost a significant amount of weight from baseline to 6-months and 18-months. Those in the WL-only group did lose a significant amount of weight as well, but were on track for a 1% weigh regain from 6- to 18-months. Though successful weight loss has been reported in overweight/obese older adults, there is still some doubt about the safety and efficacy due to risks of lean mass and bone density loss. (Rejeski et al., 2010). The effects of obesity and WL on mobility are less investigated despite increased rates and costs of disability in obese older adults with chronic disease (Rejeski et al., 2010).

Obesity is defined as $\geq 30 \text{ kg/m}^2$ which has been associated with increased risk for disability, but Jensen and colleagues reported that risk of functional decline significantly increased only when BMI was $\geq 35 \text{ kg/m}^2$ (Jensen et al., 2006). ADL’s and IADL’s have been used to measure functional decline, but other evidence suggests that mobility-related tasks such as walking or climbing stairs, are affected before activities such as eating or bathing (Rejeski et al., 2008). Improving physical function and mobility through WL and exercise in the obese elderly has been examined by three RCT’s in particular (Messier et al., 2004; Miller et al., 2006; Villareal et al., 2006). Overall the studies reported that WL, including intensive WL, improved physical function and mobility in this population. A
large body mass reduction of 8.5% increased self-report and performance measures of mobility in a group of obese older adults despite loss of fat and lean mass (Miller et al., 2006). The larger amount of weight lost was also associated with a greater increase in distance covered during the 6MW test and increased stair climbing ability (Miller et al., 2006). Villareal and colleagues concluded that WL was beneficial in decreasing disability even in a frail, obese population and Messier and colleagues reported an association between increased mobility and WL in obese adults with OA (Messier et al., 2004; Villareal et al., 2006). These RCTs reported that WL in obese older adults was an important factor in improving both self-report and performance measures of mobility. These studies also illustrated that exercise added several benefits like preservation of lean mass and strength. A thorough search of the literature found that no RCT’s to improve mobility in the obese elderly with CVD or MetS have been done, and few large scale interventions to improve mobility have been performed in the community.

The inclusion of the WL + RT treatment arm was an important aspect of this study. Despite the effect of sarcopenia on mobility disability risk, and the unknown effects of WL on obese elderly there are few interventions that investigate RT as the only mode of exercise in addition to WL (Anton, Karabetian, Naugle, & Buford, 2013; Frimel et al., 2008; Nicklas et al., 2015; Shea et al., 2011; Vincent, Raiser, & Vincent, 2012). RT can be very effective in improving mobility in this population due to attenuated lean mass loss, potential gain of muscle mass, and increased muscle strength and quality during a WL intervention (Fiatarone et al., 1990; Frimel et al., 2008; Latham et al., 2004; Shea et al., 2011). In fact, several studies have reported improved overall physical function, and strength and power gains due to RT despite a loss of lean tissue during weight loss.
(Bouchard, Soucy, Sénéchal, Dionne, & Brochu, 2009; Marsh, Shea, et al., 2013; Nicklas et al., 2015; Sartorio, Lafortuna, Conte, Faglia, & Narici, 2001; Wang, Miller, Messier, & Nicklas, 2007). Nicklas and colleagues reported that RT alone decreased intramuscular fat and total fat mass without significant weight loss, further illustrating that RT is important to incorporate into WL programs for older adults (Nicklas et al., 2015). Wang and colleagues reported increases in muscle strength and muscle quality despite the loss of lean mass. They also reported that when more fat mass was lost larger increases in muscle strength and quality were seen (Wang et al., 2007). Marsh and colleagues reported that muscle power significantly increased in a group of overweight/obese, older adults despite the loss of lean body mass in both WL and WL + RT groups (Marsh, Shea, et al., 2013).

Although there is evidence in the current literature that RT can improve overall physical function in older adults across a range of functional abilities from healthy to institutionalized and frail, few studies have investigated WL in combination with RT in obese older adults, and the impact that the intervention has on mobility (Anton et al., 2011; Fiatarone et al., 1990; Marsh, Shea, et al., 2013; Nicklas et al., 2015; Vincent et al., 2012). Studies investigating non-obese older adults have reported improvements in mobility due to WL + RT (Ades, Ballor, Ashikaga, Utton, & Nair, 1996; Brochu, Savage, Lee, & Dee, 2002; Fiatarone et al., 1990). Brochu and colleagues reported that strength, balance, and overall physical function increased as a result of resistance training, and that the ability to climb stairs and ambulate improved (Brochu et al., 2002). Ades and colleagues reported that healthy, community dwelling older adults can improve lower extremity strength and walking endurance through a 12-month RT program (Ades et al.,
Fiatarone and colleagues reported that increased gait speed was correlated with increased lower extremity strength in a group of frail, institutionalized older adults (Fiatarone et al., 1990). Nicklas and colleagues did examine the effects of WL + RT on physical function in a group of obese adults. They reported that WL + RT compared to RT-alone significantly increased 400-m walk times (Nicklas et al., 2015). The current study reported a significant increase in fast pace gait speed and single support, and a decrease in double support in the participants in the WL + RT group, which further supports that RT is an important component of increasing strength and gait speed in older adults and should be included in interventions to improve mobility (Liu & Latham, 2009).

Step width was the only spatiotemporal parameter that did not change in any of the groups. There are a number of potential explanations for this result. Studies that have reported gait characteristics in healthy older adults reported similar step widths to those found in our sample (Hollman, Eric, & Petersen, 2011; Jerome et al., 2015; Verlinden et al., 2013; Wert, Brach, Perera, & Jessie, 2010). At baseline, our participants had a mean step width of 10.05 cm. Jerome and colleagues and Verlindent and colleagues reported a mean step width of 10 cm, Hollman and colleagues reported a step width of 8.95 cm, and Wert and colleagues reported a step width of 9.0 cm (Hollman et al., 2011; Jerome et al., 2015; Verlinden et al., 2013; Wert et al., 2010).

A normal, or more confident gait pattern, in young and older adults is characterized by a narrower but more variable step width (Gabell & Nayak, 1984; MacKinnon & Winter, 1993). Although a wider step width has been thought of as more stable it has been associated with an increased fear of falling, being predictive of falls,
and a low confidence in one’s gait (Maki, 1997). Gabell and colleagues have also suggested that step width is related more to balance control, rather than gait pattern (Gabell & Nayak, 1984). Any deviations from the norm, which is about 10 cm for older adults, could cause instability. An increase or decrease in step width above or below the norm would create a change in the base of support, which would make it more difficult for one to control their center of mass in lateral directions (Gabell & Nayak, 1984).

Despite some mobility difficulties the participants in CLIP-II were not fully disabled and were not experiencing significant declines in function. Participants were independent as they could travel to and from the intervention sites independently, were able to complete 400-m walk unassisted, and received high scores on the SPPB. Unlike participants assessed by Maki and colleagues, the CLIP-II participants were younger and not selected due to previous falls, fear of falling, or instability (Maki, 1997). Our participants also had similar step widths to healthy, older adults without mobility problems. Due to the low fall risk, independence, and general health of the participants in CLIP-II step width was not modified by exercise or weight loss.

Gait speed reflects the health and functional status of older adults and has been suggested as a vital sign for this population (Hardy, Perera, Roumani, Chandler, & Studenski, 2007; Studenski et al., 2011). It is also known to be reliably associated with survival in older adults (Studenski et al., 2011). Hardy and colleagues found that improving gait speed by at least 0.1 m/s over a one-year time period reduced the absolute risk of death in older adults by 17.7% (Hardy et al., 2007). They also found that increasing gait speed decreased mortality even more so than having a faster gait speed at baseline. Meaningful change in usual pace gait speed has been reported as a range from
0.4 m/s – 0.6 m/s, and overall the participants in CLIP-II increased their usual pace gait speed by 0.05 m/s, and their fast pace gait speed by 0.08 m/s (Perera, Mody, Woodman, & Studenski, 2006). A few studies have investigated the effects of improved gait speed on health status, physical function, or mobility disability (Friedman, Richmond, & Baskett, 1988; Hardy et al., 2007; Studenski et al., 2011). Gait speed is commonly used as a predictor of health status and morbidity but it is not often used as a primary outcome in interventions specifically targeting mobility. Increased usual and fast pace gait speed can be used as markers of improved function and mobility, which is associated with decreased risk of frailty, hospitalizations and falls as well as an increase in physiological reserve (Hardy, Perera, Roumani, Chandler, & Studenski, 2007; Studenski et al., 2011). Overall, usual and fast pace gait speed increased as a result of either WL + AT or WL + RT compared to WL-only. This illustrates that gait speed can be improved in elderly, obese adults with either CVD or MetS through weight loss and exercise. It also indicates that mobility and physiological reserve can be improved in this population through a WL and exercise intervention.

Physiological or functional reserve refers to the “buffer” or overall ability one has to respond to adverse events, recover from a chronic disease or hospitalization and maintain function in normal life (Ferrucci et al., 2016). It can also be defined as the difference between one’s normal functioning and their highest physical capacity. Physiological reserve decreases with age, which means older adults have a decreased ability to respond to those stressors, such as exercise, an illness, or a fall (Guralnik, Ferrucci, Balfour, Volpato, & Iorio, 2001; Kemp & Mosqueda, 2004). Mobility disability can also exacerbate the loss of functional reserve due to physical inactivity (Xue, 2011).
For example, a decrease in physical activity causes rapid deconditioning, and loss of strength, which can decrease the amount of reserve one has to maintain normal function (Xue, 2011). The smaller functional reserve and excess capacity the less capable one is able to achieve a higher capacity of work. One way to assess functional reserve is to examine the difference between usual and fast pace gait speed (Hardy, Concato, & Gill, 2004; Soares et al., 2015). Originally we expected a significant increase in functional reserve in both WL + AT and WL + RT, but this was not seen in our data. One reason for these results may have been due to the high usual pace gait speeds (> 1 m/s) observed in all of these participants. The trends that we did observe were similar in both the WL + AT and WL + RT groups.

Faster walking speed may be a better representation of one’s maximal or true functioning capacity than usual pace walking speed. If one is incapable of reaching a faster gait speed it may put them at higher risk for loss of mobility (Guralnik et al., 2000; Ostir et al., 2015; Perera et al., 2016). Though physiological reserve is indicative of mobility impairments, the degree of impairment is dependent on the speed of usual pace gait. If an older adults usual pace gait speed is at or above 1.2 m/s it suggests high overall health and wellbeing and is similar to gait speeds seen in 25 year olds (Abellan van Kan et al., 2009). A large differential between usual and fast pace is not as critical in those with faster gait speeds, but if usual pace gait speed is below 1.0 m/s in older adults it suggests pre-clinical impairments and a higher functional reserve would be more important (Abellan van Kan et al., 2009). A higher functional reserve despite a slower walking speed indicates a higher capacity and wider range of ability to respond to increased physical demands.
The results of the current study illustrate that there are several ways functional reserve can be increased. There was a greater increase in functional reserve in the WL + RT group compared to the WL + AT and WL-only groups due to a greater increase in fast pace gait speed in addition to a slower usual pace than WL + AT. As seen in Figure 3, WL + AT achieved a faster usual pace gait speed than WL + RT but the difference was not significant between groups. Despite this both WL + AT and WL + RT did result in an increase in functional reserve. As stated previously, all groups had a usual pace gait speed around 1.2 m/s, so a high functional reserve is not as critical for the participants in CLIP-II but can still provide a “buffer” for one to recover from stressful events. An increase in functional reserve can also decrease the risk for loss of mobility despite aging and chronic disease (Buchner & Wagner, 1992; Guralnik, Ferrucci, Balfour, Volpato, & Iorio, 2001).

An important aspect of our study was that it was delivered in the community by YMCA staff at 3 different YMCA sites with our study staff acting as advisors. The adherence rates were 90.4% at the 6-month follow-up and 77.1% at the 18-month follow-up. This illustrates that the protocols in all three intervention arms were well tolerated by the participants. It also indicates that the YMCA staff were responsive to training and capable of delivering the interventions. There were 7 serious adverse events but none of them were definitively linked to the intervention arms. This indicates that the intervention arms were safe for this population of older adults. The implementation of the interventions at different YMCA sites indicates the potential for the programs to be used at similar sites. Our study also illustrates that gait speed and spatiotemporal parameters can be improved in this population of older adults and that mobility loss is not inevitable.
despite aging, chronic disease and being overweight or obese. The safety of weight loss and exercise, specifically resistance training, was also further proven by the small number of adverse events.
IMPLICATIONS

In this study, we found that WL combined with either AT or RT leads to increases in gait speed, step length, and single support time, and decreases in double support time compared to WL-only in this cohort of overweight/obese older adults with CVD and/or MetS. WL + AT and WL + RT significantly improved gait speed and spatiotemporal parameters which results in improved mobility and overall function. This large scale trial illustrates that similar types of intervention arms might be successfully delivered at sites like the YMCA, and that YMCA staff can be trained to deliver WL and exercise interventions. The high attendance and low drop-out rates over 18-months indicate that the intervention arms were well tolerated by the participants. The detailed information provided by gait speed and spatiotemporal parameters is very important for overweight/obese older adults with CVD and/or MetS. Improving mobility is critical in preventing loss of independence, frailty, and worsening of chronic disease.

LIMITATIONS

Like all studies, there were several limitations in this study. Because there was no re-examination after the 18-month period we could not determine if modifications in gait speed were maintained over longer time periods or if differences between the WL +AT and WL + RT might have become apparent with more follow-up. Participants could not be blinded to their treatment arm due to the structure of the intervention. No adjustments were made to account for multiple between group comparisons that is the alpha value was not adjusted for the multiple dependent and independent statistical tests that were run simultaneously. Lastly, the GAITRite mat was only 4-m long which may be too short to
stress all the systems of the body and may have diminished differences between the WL + AT group and the WL + RT group.

**STRENGTHS**

The study was a randomized control trial, with an 18-month intervention period in a relatively large sample of 249 participants that has not been widely studied in the context of WL interventions. It was effectively delivered at three different YMCA sites and delivered by successfully trained YMCA staff. This RCT consisted of three different treatment arms all using the same weight loss protocol. The use of RT in combination with WL loss was an important intervention to study in this population because RT is not as commonly used as AT. WL + RT and WL + AT were found to be similarly effective in causing and maintaining weight loss, and in improving mobility. Lastly, the use of the GAITRite instrumented mat to examine changes in gait speed and spatiotemporal parameters as a primary outcome provided more information on specific improvements of gait.

**CONCLUSIONS**

In conclusion, WL + AT and WL + RT compared to WL-only improved gait speed and spatiotemporal parameters in overweight/obese older adults diagnosed with CVD and/or MetS. Those in WL + AT and WL + RT lost a significant amount of weight, and maintained weight loss at the 18-month follow-up. Significant increases in usual and fast pace gait speed, step length, single support, and swing time, and decreases in double support, time, and stance time occurred in the WL + AT group at the end of the 18-month intervention. The participants in WL + RT also improved gait significantly with increases in fast pace gait speed, as well as usual and fast pace single support, and swing time and
decreases in usual and fast pace double support, cycle time, and stance time. The participants in the WL-only group did not improve either gait speed or spatiotemporal parameters from baseline, indicating that WL combined with exercise (AT or RT) is necessary to improve gait in this group of older adults. WL + RT is not as commonly prescribed in this population, but was shown to have similar effects on gait compared to WL + AT. CLIP-II also successfully implemented all three interventions arms at three different YMCA sites, making this the largest trial on this population in a community-based setting. The rising number of the elderly population who are overweight/obese and burdened with chronic disease makes findings like these critical to developing programs that can improve gait and mobility.
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APPENDIX

Appendix 1: Inclusion/Exclusion Criteria for CLIP-II

**Inclusion Criteria:**
- Community dwelling men and women from the county of interest
- Between 60 and 79 years of age
- Low levels of PA (less than 60 minutes of moderate intensity structure PA each week; occurs in no less than 10 minute blocks)
- BMI $\geq 28$ and $< 42$
- Documented evidence of an MI, PCTI, chronic stable angina, cardiovascular surgery, or an ATP II diagnosis of MetS
- Disability defined as self-reported difficulty with walking $\frac{1}{4}$ mile, climbing stairs, lifting and carrying groceries, or performing other household chose (cleaning, yard work)
- Does not plan to move out of the county of residence for duration of the study
- Willing to give consent and sign an informed consent/HIPAA authorization form

**Exclusion Criteria:**
- Severe symptomatic heart disease: evidence of unstable angina, symptomatic congestive heart failure, or exercise induced complex ventricular arrhythmias
- MI or cardiovascular procedure within the last 3 months
- Resting BP $>160/100$ mm Hg
- A fasting blood glucose $\geq 140$ mg/dL, diagnosis of type 1 diabetes, or diagnosis of type 2 diabetes and on insulin therapy
- Diagnosis of Parkinson’s disease, chronic liver disease (cirrhosis, chronic hepatitis, etc), systemic rheumatic condition (rheumatoid arthritis, psoriatic arthritis, Reiter’s disease, systemic lupus, erythematosus, etc), end stage renal disease or other systemic diseases or abnormal laboratory values which would preclude participants from safely participating in the protocol or impair their ability to complete the study
- Active treatment for cancer other than non-melanotic skin cancer
- Significant visual or hearing impairments that cannot be corrected and results in the inability to use the telephone or hear normal conversation
- Bipolar depression or schizophrenia (define as self-reported treatment for these conditions), currently received lithium or neuroleptics
- Currently participating in or planning to participate in another medical intervention study
- Consuming more than 14 alcoholic drinks per week or alcoholism
- Unable to walk unassisted
- Unable to speak or read English
- Working $\geq 21$ hours per week
- Judged to be unsuitable for the trial for any reason by the clinic staff. A participant can be excluded prior to randomization because of some unspecified health problem that has been identified that would put the patient at risk for adherence or retention. These cases are discussed with a recruitment team consisting of the person who has raised the concern, an MD, and the study PIs.
Appendix 2: GAITRite Screen Shots
CURRICULUM VITAE

Cate B Glendenning

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Education

Graduate
Wake Forest University, M.S. (Health and Exercise Science)
2015-2016
Winston-Salem, NC
(graduating December 30, 2016)

Thesis: Changes in Gait during Community-based Weight Loss and Exercise in Obese Older Adults with Cardiovascular Disease or Metabolic Syndrome

Undergraduate
University of North Carolina at Charlotte; B.S. Exercise Science
2013-2015
Kinesiology, Nutrition with Honors
Charlotte, NC

Pfeiffer University – Transfer
2011-2013
Exercise Science with Honors

Research

2015-Present
Wake Forest University
Department of Health and Exercise Science
Research Assistant
Dr. Anthony Marsh, Supervisor

CLIP-II Study: Cooperative Lifestyle Intervention Program – II
The purpose of this study was to investigate the effects of weight loss and weight loss
combined with two different forms of exercise on changes in mobility and function in overweight/obese older adults at risk for cardiovascular disease and metabolic syndrome.

**Responsibilities:** Analyze and study one of the secondary outcomes in the CLIP-II data. These outcomes were gait speed and spatiotemporal parameters. Study the GAITRite, its use and analyze data pertaining to the effects of weight loss and weight loss combined with exercise on gait speed and spatiotemporal parameters.

**Spring 2015 ASU Human Performance Lab Laboratory Research Intern**

Endurance running study: Placebo vs. supplement and the effect on glycogen content after 2 hours of flat running on treadmill and 20 minutes of negative incline.

**Responsibilities:** Performing VO2 max testing on treadmill and Lode bikes, body composition measurements using the BodPod, BIA, and skin folds, power testing using Wingate protocol, leg and back strength tests. Conducting my own research by investigating the correlation between utilizing an Ultrasound machine and the BodPod to determine percent body fat.

**Professional**

2015-2016 **Personal Training and ECG Monitoring**

**Graduate Assistant**

Healthy Exercise & Lifestyle Programs (HELPS) – Winston-Salem, NC

**Responsibilities:** Aided participants in adjusting to new weights and exercise machines. Obtained blood pressure readings, ECG readings, HR and monitored for any significant changes. Engaged participants to discuss current goals as well as attempted to motivate them to challenge themselves and create new goals. Set up new exercise prescriptions based on current fitness level, maximal testing results, and increased strength and endurance. Reported any complaints, new medications, adverse events, etc. to Senior Staff, Doctors or to the Program Coordinator.

2014-2015 **Personal Training**

Lean Teen Exercise Program – Charlotte, NC

**Responsibilities:** Instructed children and young teens on how to use exercise equipment, weights and perform cardiovascular exercises. Taught group classes to groups of 6 or
larger. Classes were based on fitness level, weight loss goals, and interest. Motivated the participants to reach their goals, keep exercising, create healthy habits and discovered what made exercise more fun for each participant. Assisted in group classes that aided participants with self-esteem, confidence, nutrition etc. Measured body composition using a Tanita scale, and took body measurements to track weight loss progress.

Certifications

2017  
ACSM Certified Clinical Exercise Specialist

2015  
ACSM Clinical Exercise Specialist

2015  
CPR and AED Certified, American Heart Association

Memberships

2015-present  
American College of Sports Medicine

Affiliations

Organizational Affiliations

• Alpha Delta Pi Alumnae
• Golden Key Honor Society at UNCC
• Tau Sigma Honor Society at UNCC
• Kinesiology Student Organization UNCC