The Effect of Balance-Based Torso-Weighting on Mobility, Gait, Balance, Postural Control, and Falls Efficacy in Mobility Limited Older Adults

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The Effect of Balance-Based Torso-Weighting on Mobility, Gait, Balance, Postural Control, and Falls Efficacy in Mobility Limited Older Adults
The Effect of Balance-Based Torso-Weighting on Mobility, Gait, Balance, Postural Control, and Falls Efficacy in Mobility Limited Older Adults

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Kinesiology

by

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Abstract

Exercise is a known intervention to prevent fall risk among older adults; however, adherence is poor. Therefore, it is of interest to determine if other interventions improve function and decrease fall risk among older adults. Balance-Based Torso-Weighting (BBTW) is a non-exercise intervention that improves functional measures among adults with multiple sclerosis, yet the effectiveness of BBTW has not been assessed among older adults without progressive neurological disorders. We conducted a double-blind, randomized study to analyze the effect of BBTW on functional measures and falls efficacy among community-dwelling, mobility limited older adults after 5 days of wearing BalanceWear® for 4 hours per day. Participants were aged 86.00 (6.05) years. Individuals were randomized into a weighted group (WG, n = 17) or a sham weighted group (SWG, n = 16). Repeated-measures analyses of variance indicated a significant group x time interaction on mobility variables (p = .096). The WG improved in Short Physical Performance Battery scores (1.25 points, p < .05) compared to the SWG, who was unchanged. There was a significant effect of time for the Five-Times Sit-to-Stand Test (p = .01), with greater mean improvements in the WG (23%) compared to the SWG (17%). There was a not a significant interaction for the gait variables (p = .45), but there was a moderate effect size (η² = .06) as well as a significant main effect of time (p = .02). A significant effect of time was observed for the Functional Gait Assessment (FGA, p = .01) with the WG demonstrating greater mean improvements in the FGA (WG 14%, SWG 6%). Gait speed trended towards a significant effect of time (p = .06), with the WG improving by 0.06 m/s compared to the SWG by 0.04 m/s. There were no interactions or main effects between groups for the Timed Up and Go, tandem stance, the Functional Reach Test, the instrumented modified Clinical Test on Sensory Interaction and Balance, or falls efficacy. This study indicates that wearing BalanceWear® for 4
hours a day over 5 days decreases potential fall risk by improvements in mobility, gait, and chair stands in mobility impaired older adults.
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Dedication

To my husband, Ryan, for your patience, love, and support ever since we first met. Thank you for believing in me sometimes more than I believe in myself. You make me a better person so that I may help better others as well.

To my boys, Anders and Hudson, for being patient and understanding (most of the time!) when mommy needed to go study.

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List of Abbreviations (In order of appearance)

1. BBTW - Balance-Based Torso-Weighting
2. COM – Center of mass
3. BOS – Base of support
4. APA - Anticipatory postural adjustments
5. CPA - Compensatory postural adjustments
6. SPPB - Short Physical Performance Battery
7. FES-I - Falls Efficacy Scale-International
8. mCTSIB - Modified Clinical Test of Sensory Interaction on Balance
9. FGA – Functional Gait Assessment
10. FTSST – Five-Times Sit-to-Stand Test
11. TUG – Timed Up and Go Test
12. BBS – Berg Balance Scale
13. FRT – Functional Reach Test
14. POMA – Tinetti Performance Oriented Mobility Assessment
15. DGI – Dynamic Gait Index
16. CTSIB – Clinical Test of Sensory Interaction on Balance
17. EO – eyes open on firm surface
18. EC – eyes closed on firm surface
19. EOF – eyes open on foam surface
20. ECF – eyes closed on foam surface
21. WG – experimental group receiving strategically weighted BalanceWear®
22. SWG – control group receiving sham weighted BalanceWear®
Chapter I
Introduction

The population, as well as life expectancy, of adults over the age of 65 years continues to increase (Tarver, 2013). Older adults comprised 13.7% of the U.S population in 2012 and that number is expected to increase to 21% by 2040 (U.S. Department of Health and Human Services, Administration of Aging, 2013). The Centers for Disease Control and Prevention (2013) predicts that by the year 2030, one in five Americans will be age 65 years or older. One of the major public health concerns among older adults is the prevalence and complications of falls.

The incidence of falls among community-dwelling adults aged 65 years and older is approximately 28-35%, increasing to 32%-42% in those aged 70 years and greater. Moreover, 10-31% of community-dwelling older adults suffer recurrent falls (The American Geriatrics Society Foundation for Health in Aging, 2011). Falls are the most prevalent cause of emergency department visits and injury-related mortality (Centers for Disease Control and Prevention, 2013) and the highest cause of accidental death among older adults (Centers for Disease Control and Prevention, 2006). Falls may also result in morbidity, decreased quality of life, and increased healthcare utilization (Stevens, Corso, Finkelstein, & Miller, 2006). The economic cost of falls is upwards of $20 billion dollars a year (Stevens et al., 2006). Furthermore, 85% of falls occur in the home (Abreu, Hutchins, Matson, Polizzi, & Seymour, 1998) and the majority of falls occur while walking or performing daily activities (Nachreiner, Findorff, Wyman, & McCarthy, 2007). Approximately 40% of adults over the age of 65 years have difficulty with mobility and daily activities (Tarver, 2013). A recent literature review identified impaired balance and mobility, such as gait, as two major risk factors for falls (Ambrose, Paul, & Hausdorff, 2013).
Physiological changes with age that contribute to limitations in balance and mobility include declines in vision, muscle mass, power, and reaction time as well as postural and neuromuscular changes (Gillespie et al., 2012). Furthermore, chronic disease processes that are more prevalent with aging, such as diabetes, can affect sensation and vision, which assist with balance maintenance (Horak, 2006). Balance, or postural control, is maintained by complex interactions between sensory, motor, and neurologic systems (O'Sullivan, Schmitz, & Fulk, 2013). In general, three main sensory systems contribute to providing information to the central nervous system about postural control: somatosensory, vestibular, and visual systems, with consideration given to musculoskeletal, neuromotor systems and biomechanical constraints (Horak, 2006; O'Sullivan et al., 2013). A healthy person, standing in a well-lit environment on a firm surface, relies on the somatosensory system to maintain postural control, while a person with a somatosensory impairment will rely more on the vestibular or visual systems (Abreu et al., 1998). Impairment in any of the systems, or subsystems, may result in balance and mobility impairments and subsequently falls (Peterka, 2002). Considering the multitude of changes affecting balance that occur with aging and diseases, as well as the impact of falls in this population, it is imperative that effective intervention strategies be determined to improve function and reduce falls.

The U.S Preventive Services Task Force recommends vitamin D, physical therapy, or exercise as effective interventions to prevent falls among at risk community-dwelling adults over the age of 65 (Moyer, 2012). Exercise, as well as regular physical activity, has been shown to decrease falls. Older adults who are physically active have less of a decline in function and a lower incidence of falls than those who are not physically active (World Health Organization, 2008). Furthermore, in a global report on falls prevention in older adults, the World Health
Organization (2008) suggests physical activity is one of the most important factors to maintain health, well-being, and prevent falls.

Exercise, a planned form of physical activity, can prevent many of the modifiable risk factors that cause falls, including but not limited to decreased strength, power, and balance (Howe, Rochester, Neil, Skelton, & Ballinger, 2011). In individuals with balance and mobility limitations as risk factors, 42% of falls can be prevented by participation in appropriate exercise programs (Sherrington, Tiedemann, Fairhall, Close, & Lord, 2011). A recent meta-analysis, compiled best practice recommendations on exercise to prevent falls among older adults (Sherrington et al., 2011). Specifically, it is suggested in order to decrease fall risk, exercise must be ongoing, can take place in any setting, and must have a high-dose balance training component (at least 50 hours, or 2 hours a week for 6 months).

Unfortunately, current physical activity and exercise habits among older adults are poor. Approximately 28-44% of older adults do not engage in physical activity (National Center for Health Statistics, 2007) and only 11% of adults aged 65 years and older report participating in aerobic and muscle strengthening activities that meet federal guidelines (Tarver, 2013). Moreover, there are likely even fewer older adults that engage in balance exercises (Clemson et al., 2012). Low levels of exercise and physical activity are major limitations to the implementation of exercise-based fall-risk prevention programs (Simek, McPhate, & Haines, 2012). Furthermore, education as a sole intervention is not effective at reducing the rate or risk of falls (Gillespie et al., 2012). Therefore, other means to improve balance and mobility deficits and decrease fall risk among at-risk older adults are needed.

Investigations indicate non-exercise interventions addressing modifiable fall risk factors, such as polypharmacy, environment, and vision issues decrease the incidence of falls (Gillespie
et al., 2012; Stevens, 2010; World Health Organization, 2008). For example, reducing psychotropic medications decreases the rate, but not risk of falls (Campbell, Robertson, Gardner, Norton, & Buchner, 1999). In a recent Cochrane review, it was determined that home safety modifications were most efficacious in reducing falls in older adults with a high fall risk as well as those with severe visual impairment (Gillespie et al., 2012). Vision-specific interventions to decrease falls have mixed results depending on the subpopulation targeted. Cataracts surgery in the first eye, but not the second eye, decreases falls among women (Harwood et al., 2005). Changing from multifocal to single lens eyewear decreased falls outside the home in older adults who regularly took part in activities outside and actually increased falls outside the home for a subgroup of older adults who did not usually take part in outside activities. There are few successful non-exercise interventions to reduce fall rate and fall risk, more importantly, none directly address balance and mobility. Therefore, it is necessary to investigate if other interventions, such as Balance-Based Torso-Weighting (BBTW) with BalanceWear®, decreases fall risk by improving balance, functional mobility, and falls-efficacy among older community-dwelling adults.

BBTW is a patented evaluation and treatment method consisting of a clinical assessment procedure that results in a custom weighted patient garment, specifically BalanceWear® (Gibson-Horn, 2014). The evaluation and treatment method is performed by a clinician, often a physical or occupational therapist, who is trained in the method. The clinician assesses an individual’s balance via elicited anticipatory and compensatory postural adjustments, to find deficits in accordance with the Balance-Based Torso-Weighting Assessment method. Based on the assessment, the clinician strategically places small non-obtrusive weights on a vest on the torso to improve balance.
Currently the mechanism behind the therapeutic effects of the BBTW is unknown. One theory is that it improves sensory input in the area of weighting thereby augmenting awareness and muscle activation to increase postural control and subsequently balance and mobility (Widener, Allen, & Gibson-Horn, 2009b). In a randomized controlled trial of people with multiple sclerosis, the group with BBTW demonstrated significant improvements in a functional mobility task as well as gait speed (Widener et al., 2009b). Gait parameters also improved in another investigation after BBTW in people with multiple sclerosis (Gorgas, Widener, Allen, & Gibson-Horn, 2014). These promising results warrant investigations into the effectiveness of BBTW and BalanceWear® to improve postural control among older adults with mobility and balance impairments at risk of falls.

**Purpose of the Study**

The purpose of this study was to determine the effect of BalanceWear®, worn for 5 days, on mobility, gait, balance, postural control, and falls-efficacy in balance and mobility-limited adults over the age of 65 years residing in a retirement community.

**Research Hypotheses**

1. Older adults in the strategically weighted BalanceWear® group will have improvements in balance, as measured by tandem stance time and functional reach, compared to older adults with the sham (unweighted) BalanceWear®.

2. Older adults in the strategically weighted BalanceWear® group will have improvements in gait, as measured by habitual gait speed and the Functional Gait Assessment, compared to older adults with the sham (unweighted) BalanceWear®.
3. Older adults in the strategically weighted BalanceWear® group will have improvements in mobility as measured by the Five-Times Sit-to-Stand Test, the total SPPB score, and the Timed Up and Go compared to older adults with the sham (unweighted) BalanceWear®.

4. Older adults in the strategically weighted BalanceWear® group will have improvements in postural control as measured by the instrumented modified Clinical Test of Sensory Interaction on Balance compared to older adults with the sham (unweighted) BalanceWear®.

5. Older adults in the strategically weighted BalanceWear® group will have improvements in falls-efficacy, as measured by the Falls Efficacy Scale-International, compared to older adults with the sham (unweighted) BalanceWear®.

Limitations

1. There is no information on the reliability and validity of Balance-Based Torso-Weighting assessment and strategic weighting protocol.

2. BalanceWear® has been studied in adults with multiple sclerosis (Crittendon, O'Neill, Widener, & Allen, 2014; Gibson-Horn, 2008; Gorgas et al., 2014; Widener, Allen, & Gibson-Horn, 2009a; Widener et al., 2009b) and Parkinson’s disease, (Lazaro, Tanasescu, Widener, & Burke-Doe, 2011), but not specifically an older adult population with mobility and balance impairments.

3. The mechanism of action of BalanceWear® is unclear at this time. An investigation has shown that it does not have a biomechanical mechanism of action (Crittenden et al., 2014).

4. The study sample is limited to a retirement community in Pennsylvania, which may make the study less generalizable to all community-dwelling older adults.

5. The Balance-Based Torso-Weighting evaluation and intervention is conducted while a participant is standing without an assistive device. However, during daily activities,
participants used their usual assistive device. Balance and perturbation response was not tested with an assistive device, which may have limited translation of the intervention to daily function.

6. There are limitations within the functional measures; individuals were asked to not use an assistive device during the tests, if possible. This may not allow for accurate functional results for individuals who normally use an assistive device for functional balance.

**Functional Definitions**

1. Older adult - Adult aged 65 years and older.

2. Community-dwelling older adults - Adults aged 65 years and older who do not reside in a nursing home or hospital.

3. Fall - An event which results in a person coming to rest inadvertently on a lower surface (World Health Organization, 2008).

4. Center of mass (COM) - An arbitrary midpoint of the body mass, located about two thirds of the body height above the base of support (O'Sullivan et al., 2013).

5. Base of support (BOS) - The area of the body that is in contact with the supporting surface (e.g., the feet in standing or the buttocks in sitting; Lippert, 2011).

6. Limits of stability (LOS) - The greatest distance an individual is capable or willing to lean in any direction without losing balance or changing the base of support such as lean, reach, and shift weight without moving feet if in standing (O'Sullivan et al., 2013).

7. Balance - A condition where all the forces acting on the body are balanced; where the center of mass is within the limits of stability and base of support (O'Sullivan et al., 2013).

9. Perturbation - A ‘nudge’ or external force that induces motion between the center of mass and base of support, displacing balance (Gorgas et al., 2014; Mansfield, Peters, Liu, & Maki, 2010).

10. Somatosensory - Refers to sensory input received by the central nervous system from the skin and musculoskeletal systems (O'Sullivan et al., 2013).

11. Sensory integration - The ability of the brain to process and organize different information from different senses and develop appropriate perceptions to respond to changes in the body and environment (O'Sullivan et al., 2013).

12. Anticipatory postural adjustments (APAs) - A postural response that occurs in anticipation of internally generated forces that may destabilize the body due to movement, such as preparing to move an extremity or walk (Horak, 2006; O'Sullivan et al., 2013).

13. Compensatory postural adjustments (CPAs) - Also known as reactive postural adjustments; a postural control response that occurs in response to external forces, such as perturbations, acting on the body to displace the center of mass (O'Sullivan et al., 2013).

14. Assistive device - any device used to help with gait; including a cane, walker, crutches, walking poles, walking sticks, or similar devices (O'Sullivan et al., 2013).

15. Balance-Based Torso-Weighting (BBTW) - A patented evaluation and treatment method consisting of an assessment process that results in a custom weighted patient garment, specifically BalanceWear®.

16. BalanceWear® - Vest-like garment that individual wears over clothing to enable clinician to Velcro® small, non-obtrusive weights on the trunk based on the BBTW assessment. The BalanceWear® also comes with an option for a lumbosacral orthotic attachment (Gibson-Horn, 2014; see Appendix A).
17. Lumbosacral orthotic - A semi-rigid brace that has a component over the abdomen and low back that can be added to the BalanceWear® to provide extra stability and sensory augmentation to the trunk (Gibson-Horn, 2014).

18. Falls efficacy - Construct of self-efficacy related to fear of falling while performing daily activities (Delbaere et al., 2010).

19. Short Physical Performance Battery (SPPB) - Assessment of lower extremity performance and mobility consisting of performing a sit to stand from a chair without using arms 5-times, standing balance tasks (feet together, semitandem, tandem) each for 10 seconds without upper extremity support, and an 8 ft or 4 m usual walking speed test. Ordinal subscales (from 0-4) for chair stand performance, balance, and gait, are totaled to obtain a composite score for the test (0-12). Higher scores indicate better performance (Guralnik et al., 1994).

20. Mobility disability and mobility limited - As defined by the SPPB; a score of \( \leq 9 \) indicates mobility-deficits and risk of disability (Guralnik et al., 2000).

21. Falls Efficacy Scale-International (FES-I) - A 16-item self-report questionnaire regarding an individual’s perception of their fear of falling while performing daily physical and social activities. It is moderately correlated with the ABC (Smee, Berry, Anson, & Waddington, 2015).

22. Modified Clinical Test of Sensory Interaction on Balance (mCTSIB) - An assessment of balance and different sensory inputs involved in postural control under four different conditions: (1) standing on a firm surface, such as the floor, with eyes open; (2) standing on a firm surface with eyes closed; (3) standing on a foam surface, eyes open; and (4) standing on a foam surface, eyes closed (Trueblood, Hodson-Chennault, McCubbin, & Youngclarke, 2015).
2001). The test can be conducted by measuring seconds that each position is able to be held or via instrumentation measuring postural sway.

23. Functional Gait Assessment (FGA) - An assessment that measures balance during gait-related activities by manipulating visual input, base of support, and head movements (Wrisley, Marchetti, Kuharsky, & Whitney, 2004).

24. Tandem stance - Static standing test of balance, synonymous with the sharpened Romberg test, measuring the time in seconds that an individual is able to stand with one foot directly in front of the other (Jonsson, Seiger, & Hirschfeld, 2005).

25. Five-Times Sit-to-Stand Test (FTSST) - The test involves time taken to stand up and sit down from a standard chair 5-times, with arms across the chest (Tiedemann, Shimada, Sherrington, Murray, & Lord, 2008). Both lower extremity strength (Bohannon, 1995) and balance (Whitney et al., 2005) affect test performance.

26. Habitual gait speed - Speed calculated in m/s on an individuals’ usual pace walking speed during a fixed gait parameter, such as 4 m (Van Kan et al., 2009).

27. Timed Up and Go (TUG) - An assessment of balance, walking, and fall risk among older adults. The timed test involves having a person stand up from a chair (with armrests if needed), walk 3 meters as quickly and safely as possible, cross a line or cone on the floor, turn around, walk back and sit down (Podsiadlo & Richardson, 1991).

**Significance of Study**

The population of older adults in the U.S is increasing exponentially every year (U.S. Department of Health and Human Services, 2013). Many physical changes occur with age, among them impaired balance and mobility (Center for Disease Prevention, 2013). Approximately 40% of adults over the age of 65 years have difficulty with mobility and daily
activities, increasing their risk of falling (Tarver, 2013). The incidence of falls among community-dwelling adults aged 65 years and older is 28-42%, which increases with age (The American Geriatrics Society Foundation for Health in Aging, 2011). Even more concerning, falls are the leading cause of accidental death among older adults (Centers for Disease Control and Prevention, 2006), also resulting in injuries, morbidity, and loss of independence (Stevens et al., 2006).

Exercise-based interventions decrease falls up to 42% (Sherrington et al., 2011), however many older adults do not exercise or are not willing to begin exercising (Ruchlin & Lachs, 1999; Tarver, 2013). Therefore, it is important to determine if other interventions can improve balance and mobility, thereby decreasing fall risk. Balance-Based Torso-Weighting has shown significant improvements in functional mobility and gait parameters in patients with multiple sclerosis (Gorgas et al., 2014; Widener et al., 2009b). Ascertaining the effect BalanceWear® has on mobility and balance in older adults is the first step to determine if it may be an effective intervention in falls prevention in this population.
Chapter II

Literature Review

Introduction

As the population of older adults rises, it is necessary to address declines in function and subsequently increases in falls that occur with age (Center for Disease Prevention, 2013; Tarver, 2013). Although the cause of a fall is often multifactorial, physiological changes that occur with age contribute to limitations in balance and mobility relating to falls and (Miszko et al., 2003). These changes include, but are not limited to, impaired vision and balance, decreases in muscle mass, power, and reaction time, and postural and neuromuscular changes (Horak, 2006). First, this literature review will discuss the significance and the risk factors of falls among older adults. Next, mechanisms of balance and postural control as well as age-related changes that contribute to postural control and balance and mobility dysfunction will be covered. Subsequently, assessments of postural control, balance, mobility, and fall risk will be discussed. Current interventions to improve balance, function, and/or decrease falls will also be reviewed. Lastly, the literature review will focus on Balance-Based Torso Weighting assessment and intervention, current evidence on BBTW in the neurological population, and implications for BBTW among older adults.

Falls among Older Adults

Falls among older adults are considered a major public health concern (Kelsey, Procter-Gray, Hannan, & Li, 2012). The prevalence of falls increases with age. Approximately 30% of community-dwelling adults over the age of 65 years suffers at least one fall a year, increasing to approximately 40% over the age of 70 years. Furthermore, it is estimated that 10-31% of older
adults suffer recurrent falls (The American Geriatrics Society Foundation for Health in Aging, 2011).

The incidence of falls are concerning as falls are a principal cause of emergency department visits, injury-related mortality (Centers for Disease Control and Prevention, 2013), morbidity, and disability among older adults (Stevens et al., 2006). Falls are not only detrimental to an older adult’s function and independence, they are also costly to society. A systematic review found that the average economic cost of a fall in the U.S ranged from $3,476 per fall not requiring a hospitalization to $26,483 per fall requiring a hospitalization (Davis et al., 2010).

Considering individual and societal consequences of falls, addressing this public health problem is of utmost importance. In order to address the issue of falls, the risk factors that lead to falls need to be considered.

**Risk factors for falls.** There are many risk factors for falls among older adults. Advanced age and impairments in strength, power, mobility, balance, and cognition have been implicated in increasing fall risk among older adults. Other factors related to falls include environmental factors, medications, and visual deficits (Ambrose et al., 2013).

Age alone is a risk factor for increased fall risk. Approximately 30% of adults over the age of 65 years suffer from a fall, increasing by approximately 10% in those over the age of 70 years (The American Geriatrics Society Foundation for Health in Aging, 2011). Impairments in balance, which can be quantified through a multitude of measures including mobility assessments, are risk factors for falls (Muir, Berg, Chesworth, Klar, & Speechley, 2010). Mobility and balance impairments are also related to muscular strength and power deficits in older adults (Puthoff & Nielsen, 2007). The odds of falling are 1.76 times greater among older adults with lower extremity weakness (Moreland, Richardson, Goldsmith, & Clase, 2004). Older
adults with lower extremity weakness are also more likely to have to use multiple, rather than a single step to recovery from a forward loss of balance (Carty, Barrett, Cronin, Lichtwark, & Mills, 2012). Furthermore, muscular power is a purported strong predictor of functional mobility performance (Reid & Fielding, 2012). Not only is physical function related to falls, cognitive function is related to falls as well. Older adults with cognitive impairment perform worse on functional tests (Atkinson et al., 2007; Herman, Giladi, & Hausdorff, 2011; Power, Van De Ven, Nelson, & Clifford, 2014) and are more likely to suffer from future falls (Herman, Mirelman, Giladi, Schweiger, & Hausdorff, 2010).

Environmental factors are also related to falls; throw rugs and poor lighting have been implicated in increasing falls (O'Sullivan et al., 2013), especially in visually-impaired older adults (Stevens, 2010). Older adults with vision deficits, such as cataracts, blindness, or those that use multi-focal lenses, have demonstrated higher rates of falls. This is due to the primary role of vision in balance, postural control, and mobility (Gillespie et al., 2012). Lastly, medications that increase fall risk include anti-hypertensives as well as general polypharmacy. Anti-hypertensives have side effects of orthostatic hypotension, which may cause a person to suffer from syncope and fall (Gribbin, Hubbard, Gladman, Smith, & Lewis, 2010). Polypharmacy, taking multiple different medications, is common among older adults and may result in medication interactions and deleterious side effects, increasing the risk of falls. An older adult taking greater than four medications is considered to be at an increased risk of falling (Gnjidic et al., 2012). While there are numerous risk factors for falls, impaired balance and mobility are among the highest risk factors (Ambrose et al., 2013). The following sections will describe normal aspects and age-related changes related to balance and postural control.
**Balance and Postural Control**

Postural control, or balance, consists of complex interactions between sensory and motor systems involving perceptions of stimuli, responses to changes in the body’s position in the environment, and maintenance of the body’s center of mass within the base of support (Horak & Macpherson, 1996; Horak, 2006). It can be further described within the terms center of mass (COM), base of support (BOS), and limits of stability (LOS); where the COM is within the BOS and LOS. The COM is the arbitrary midpoint of the mass of the body in standing, located about two thirds of the body height above the base of support, which is at approximately at the second sacral segment (Lundy-Ekman, 2013; O'Sullivan et al., 2013). The BOS refers to the area of the body that is in contact with the supporting surface (e.g., the feet in standing or the buttocks and feet in sitting; Lippert, 2011). Lastly, the LOS refer to the greatest distance an individual is capable or willing to move in any direction without loss of balance or changing the base of support (i.e. lean, reach, and shift weight without moving feet if standing; O'Sullivan et al., 2013). Sensory systems provide input to the CNS to initiate neuromuscular activation to maintain and regain balance within and outside of the LOS to prevent falls.

**Sensory systems in postural control.** Sensory systems, specifically the somatosensory, visual, and vestibular systems, use feedback mechanisms to interpret and integrate the body’s position in space in order maintain posture and balance. Somatosensory information on light touch and pressure from body parts in contact with support surfaces (including hands on an assistive device) as well as muscle and joint proprioceptors that detect movement, provide information on the relative orientation and movement of the body in space (Lundy-Ekman, 2013; O'Sullivan et al., 2013). The visual system also perceives body orientation and movements as well as changes in the environment. The vestibular system, through sensory organs located in the
inner ears, detects linear and angular movement of the head to stabilize eye movement via the vestibulo-ocular reflex. Finally, the vestibulo-spinal reflex assists in regulation of muscle tone for postural control (O'Sullivan et al., 2013). These systems all work together to facilitate sensory awareness of postural position.

A healthy young adult integrates sensory inputs from all three systems in order to determine posture and body position. This process is described as sensory weighting or sensory integration. When standing on a firm surface a healthy adult relies primarily on somatosensory input to determine the position of the body in space (Peterka, 2002). However, if one system is unavailable (i.e., vision in a dark room) or inaccurate (i.e., somatosensory on uneven surfaces), sensory reweighting will occur, thereby adjusting the relative contributions of each system to effectively maintain postural control. This is evident in a study where healthy, young adults stood on an unstable surface, causing inaccuracy in somatosensory input at the feet. The young adults’ nervous systems demonstrated reweighting of sensory information to rely primarily on vestibular, rather than somatosensory input to maintain postural control (Peterka & Loughlin, 2004). Hence, sensory weighting or reweighting relies on internal adjustments and reliance on accurate information from sensory systems on postural position.

While there is some redundancy across the sensory information supplied by the different systems, each system contributes unique information to postural control. Therefore, an impairment in any one system is likely to decrease balance, and an impairment in two or more systems will result in balance deficits (O'Sullivan et al., 2013a Peterka, 2002). Older adults are prone to deficits in the sensory systems that control posture. Vision often declines with age, and chronic diseases such as diabetes may cause decreased sensation in the feet, affecting the somatosensory system (Horak, 2006; O'Sullivan et al., 2013a). Therefore, it is necessary to
optimize balance and postural control in older adults as one or many of the systems contributing to balance may be impaired. Moreover, postural control not only relies on sensory systems for detecting body and head orientation in the environment, but the neuromotor system to maintain the COM over the BOS during static and dynamic conditions based on the sensory input.

**Neuromotor system in postural control.** Sensory systems provide feedback on the orientation of the body in space to the CNS in order to initiate responses to maintain posture that are task and environment specific. Responses include goal-directed conscious and automatic unconscious alterations to maintain balance in the context of an activity. Reactions vary from simple stretch reflexes to specific movement strategies, such as taking a step to regain balance (O'Sullivan et al., 2013). Postural strategies are constantly used during daily activities in anticipation and reaction to movement.

Anticipatory postural control or adjustments (APAs) include the ability to adjust posture prior to a voluntary movement in order to maintain balance (Lundy-Ekman, 2013). Compensatory postural adjustments (CPAs) are the body’s response to outside forces acting on the body, including a perturbation, slip, trip, or fall (O'Sullivan et al., 2013). CPAs can be further classified as ankle, hip, or stepping strategies. Ankle strategies, or activation of the ankle musculature to maintain balance, are used with small postural deviations, hip strategies are used with larger balance perturbations, and stepping strategies are used to change the BOS when the aforementioned fixed-support strategies are not sufficient to maintain posture (Horak, 2006; O'Sullivan et al., 2013; Torres-Oviedo & Ting, 2007). In order to be effective, all of these movement strategies require adequate muscular strength, muscular power, timing, and amplitude (Horak, 2006; Izquierdo et al., 1999; Maki & McIlroy, 2006). Unfortunately, many of the sensorimotor factors that assist with postural control may be affected with age (Maki & McIlroy,
The next section will outline the physiologic changes that occur with age that affect postural control.

**Age-Related Physiological Changes that Affect Balance and Postural Control**

**Sensory changes with age.** Sensory systems provide information to the CNS on the body position and movement in space through tactile stimuli, proprioception, vision, and vestibular input (O'Sullivan et al., 2013). Multiple physiological changes occur with age to the sensory systems that affect postural control. With regards to the somatosensory aspects of postural control; muscle spindle function, distal sensation (Swash & Fox, 1972), and joint proprioception (Wingert, Welder, & Foo, 2014) have shown impairments with age. Deficits in any of these areas may lead to inability to determine the body’s position in space, and therefore decreased postural control and balance. Vision also declines with age, negatively affecting balance (Lee & Scudds, 2003). A decline in vestibular function sensing head position and movement can occur with age, which has been shown to increase fall risk (Herdman, Blatt, Schubert, & Tusa, 2000). Notably, postural awareness is impaired in older adults with balance deficits, demonstrating impaired trunk flexion proprioception compared to older adults who do not have balance deficits (Goldberg, Hernandez, & Alexander, 2005). The perception of vertical posture is also significantly impaired in older adults compared to younger. Older adults demonstrate twice the amount of backward shift of vertical posture compared to younger counterparts (Barbieri, Gissot, & Pérennou, 2010). If perception of vertical posture or trunk flexion is already impaired, the ability to maintain balance may be affected.

**Neuromotor changes with age.** Maintenance of balance relies on adequate neuromuscular function, however the neuromotor system is also affected with age. A decline in muscle mass, strength, and power is noted among aging adults (Doherty, 2003). Moreover, loss
of power is more profound than loss of strength (Izquierdo et al., 1999). This is an important consideration as power is a greater determinant of functional mobility and balance in older adults (Orr, 2010; Reid & Fielding, 2012). Declines in power in the aging population are likely due to greater decreases in type II as compared to type I muscle fibers (Lexell, 1995). This especially occurs in older adults who are not physically active (Grimby, 1995). It is also suggested that motor neurons and motor units decline in number with age (Galea, 1996). Additionally, reaction times (Cohen, Nutt, & Horak, 2011; Fozard, Vercryssen, Reynolds, Hancock, & Quilter, 1994) and neuromuscular activation slows with age (Clark et al., 2011), further affecting muscular performance. Adequate reaction time and neuromuscular activation are especially important to respond to losses of balance, when speed and force of movement are imperative to regain balance and prevent falls. Impairments in force resistance and initiation of stepping to perturbations (Sturnieks et al., 2013) are seen in older adults who fall versus those who do not. Any and all of these age-related changes contribute to postural control impairments.

**Anticipatory and compensatory postural control changes with age.** As a result of the previously mentioned sensory and neuromotor changes with age, impairment of postural control is seen among older adults. APAs and CPAs have both been shown to be impaired among older adults (Kanekar & Aruin, 2014). Increases in postural sway (Era et al., 2006) and muscular latencies with perturbations and sway (Lin & Woollacott, 2002; Woollacott, 1993) are also evident with age. Consequently, these impairments have been related to an increase in falls. It has been determined that older adults with a history of falls demonstrate significantly greater anteroposterior postural sway as well as muscle activation when compared to younger adults (Laughton et al., 2003). Other comparisons indicate that APAs are larger and sway trajectories greater with reaching tasks in the older population regardless of history of falls (Huang &
Brown, 2013). A study on aging and anticipatory and reactive postural control during predictable anteroposterior perturbations indicated older adults exhibited increased sway, delayed anticipatory muscle activity, and greater compensatory muscle activity compared to younger adults (Kanekar & Aruin, 2014).

Older adults may also use inappropriate CPAs to maintain and regain balance inconsistent with strategies among younger cohorts (Kanekar & Aruin, 2014). When visual and somatosensory inputs are manipulated, older adults use hip and stepping strategies for smaller balance perturbations compared to younger adults, who use ankle strategies (Manchester, Woollacott, Zederbauer-Hylton, & Marin, 1989). However, it is important to note that although APAs are delayed and less effective in older adults, the ability to activate muscles in anticipation of movement is still preserved (Kanekar & Aruin, 2014). Therefore, improving anticipatory or compensatory postural control is possible and warrants further investigation.

Horak (2006) cautions that postural control is even more complex than the aforementioned primary systems that contribute to it. Constraints in other subsystems will affect postural maintenance and must be considered, such as limitations in range of motion or cognition as well as issues with chronic disease processes. Furthermore, movement is a complex physiologic process and many systems contribute to a person’s ability to stand, walk, and interact with the environment in a safe and effective manner. This is why balance can be difficult to quantify and measure effectively, especially with regards to interpolation of fall risk among older adults.

**Relationship of Balance, Function, and Falls**

Regardless of the many systems and contributions to balance maintenance, research has demonstrated that impaired balance is a risk factor of falls. Root cause analysis of a fall may be
analyzed following the disablement model originally developed by Nagi (1976) where a pathology, such as diabetes may result in peripheral neuropathy. This may lead to an impairment of decreased sensation in the feet. Subsequently, the functional limitation is difficulty maintaining balance when relying mostly on somatosensory input. Finally, the disability would be inability to maintain balance well enough to stand without falling to continue employment (Jette, 1994). We can quantify possible deficits at the pathology level, again using diabetes as an example. With diabetes, adults are at risk of retinopathy and peripheral neuropathy, among many other complications. However, not all adults that have diabetes get those complications (O'Sullivan et al., 2013). Therefore, it cannot be assumed, but must be evaluated if a person has sensory or visual impairments as a result of the pathology. However, even in the presence of one or both impairments, balance may or may not be affected in an individual. Thus, it cannot be inferred that someone with a particular pathology or impairment will present with balance deficits. This is why clinicians often assess balance along with performing a functional mobility task, which is the most likely time for a fall to occur (Abreu et al., 1998). Of importance, considerations must be taken with regards to intervening at the individual impairment level to address the root cause of the balance impairment, if possible.

**Functional Assessments, Confidence, and Efficacy Measures of Fall Risk**

There are many contributions to balance maintenance, subsequently there are many lab and field based tests to assess balance as well. Scores on balance tests are significantly associated with mobility in older adults (Shubert, Schrodt, Mercer, Busby-Whitehead, & Giuliani, 2006), which is why many assessments of fall risk include functional mobility or gait tasks. Functional assessments quantify the impact balance and other impairments have on physical performance (Guralnik & Ferrucci, 2003). Impaired mobility and slower gait speed were both significantly
associated with a higher relative risk of falling in a large longitudinal study of older adults (Stenhagen, Ekström, Nordell, & Elmståhl, 2013). Furthermore, studies have indicated that most falls occur during walking or daily functional activities (Berg, Alessio, Mills, & Tong, 1997; Nachreiner et al., 2007); therefore it is most useful to assess balance during those activities.

It is essential for balance and functional assessments to be reliable, valid, sensitive to change, and have predictive ability. While most widely used tests exhibit good to excellent reliability, the predictive ability of tests varies between populations and investigations (Muir et al., 2010). A prospective study indicated the Berg Balance Scale (BBS), Short Physical Performance Battery (SPPB), Timed Up and Go (TUG), gait speed, and grip strength were all predictive of difficulties in daily activities in community-dwelling older adults over an 18-month follow-up period (Wennie Huang, Perera, VanSwearingen, & Studenski, 2010). The SPPB is also predictive of mortality and nursing home admission risk (Guralnik et al., 1994). Although physical performance measures detect change and different adverse health outcomes (Guralnik & Ferrucci, 2003), the usefulness in predicting falls is generally inconclusive. In the current literature there are few prospective studies on the incidence of falls in older adults related to functional assessment scores. Furthermore, there are limitations in generalizability due to sample size, heterogeneity of subjects, methods, and differences in statistical analysis (Muir et al., 2010).

The usefulness and predictability of a functional test relies on many factors. Sensitivity and specificity are used to determine cut-off scores to predict falls. Sensitivity refers to the proportion of the time that a test correctly identifies an impairment that is actually present. Specificity refers to the proportion of the time a test correctly identifies an impairment as being absent when it is truly absent (O'Sullivan et al., 2013). Besides sensitivity and specificity, there are other determinants of the usefulness of functional tests, such as ceiling and floor effects.
Ceiling effects refer to the proportion of people achieving a maximal score on a functional test despite having impairments. A test with ceiling effects may not accurately quantify current ability or response to an intervention because an individual already achieved the highest score. Conversely, floor effects are a potential problem when the lowest scores on a test are obtained due to inability to perform tasks. Floor effects also impede the ability of a test to accurately identify current level of function or improvement (VanSwearingen & Brach, 2001). Although there are many factors to determine the effectiveness of a functional assessment tool, self-report instruments can also be useful tools to assess perceived function and fall risk. Self-report questionnaires of balance confidence and perceived fall risk are independent predictors of falls among older adults (Delbaere, Close, Brodaty, Sachdev, & Lord, 2010). The following sections will review the most widely used self-report instruments and functional assessments of balance in the literature to determine fall risk of community dwelling older adults based on prospective studies.

**Gait speed.** Often considered the ‘sixth vital sign’ (Fritz & Lusardi, 2009), gait speed is a reliable (ICC = 0.90; Bohannon, 1997), simple, and quick measure shown to have independent ability to predict health-related outcomes (Van Kan et al., 2009). Habitual gait speed is commonly measured at an individual’s usual pace over distances as short as 4-m (Van Kan et al., 2009) to as long as 20-m (Atkinson et al., 2007). Habitual gait speeds of $> 1.0$ m/s indicates higher functioning and less risk for adverse health events, while speeds $< 0.8$ m/s are indicative of increased risk of adverse health events and decreased survival of adults over the age of 65 years (Cesari et al., 2005; Montero-Odasso et al., 2005; Studenski et al., 2011; Van Kan et al., 2009). Even a small decrement of 0.1 m/s predicts higher mortality among older adults (Studenski et al., 2011). Habitual gait speed is the strongest independent predictor of self-
reported physical function in community-dwelling older adults (Cress et al., 1995) and predicts future mobility disability as well as the composite SPPB score (Guralnik et al., 2000). Gait speed of < 0.7 m/s indicates high relative risk of hospitalization (RR = 5.9), requiring the assistance of a caregiver (RR = 9.5) and suffering from falls (RR = 5.4; Montero-Odasso et al., 2005). Another investigation found that slower gait speed is associated with a higher risk of multiple falls, but not single falls among older adults (Callisaya et al., 2011). Moreover, even individuals with quicker gait speed have elevated risk for falls, especially outdoors during strenuous activities (Kelsey et al., 2012). An investigation found that gait speed improved in adults with multiple sclerosis after BBTW compared to a non-weighted control group (Widener et al., 2009a).

Gait speed can also be measured as fast gait speed, which is ambulating as quickly and safely as possible, rather than at usual pace (Bohannon, 1997). Fast gait speed shows greater declines with age than habitual gait speed, and is suggestive of reserve to maintain usual gait speed and function in the community (Ko, Hausdorff, & Ferrucci, 2010). In a 12-year longitudinal study, fast gait speed declined more rapidly in older adults who died during follow up compared to habitual gait speed (Studenski et al., 2011). Furthermore, a recent investigation on the effect of BBTW on gait parameters in people with multiple sclerosis and healthy adult controls found that fast gait speed improved in both groups after BBTW (Gorgas et al., 2014).

**Timed Up and Go.** While gait speed is a useful and important measure, the TUG (Podsiadlo & Richardson, 1991) is also a well-recognized assessment by the U.S. Preventive Services Task Force (Moyer, 2012) and the CDC (Stevens & Phelan, 2013) to assess balance, walking, and fall risk among older adults. The timed test involves having a person stand up from a chair (with armrests if needed), walk 3 meters as quickly and safely as possible, cross a line or cone on the floor, turn around, walk back and sit down. TUG performance is worse in
individuals with impairments in vision, cognition, strength, and balance (Mun-San Kwan, Lin, Chen, Close, & Lord, 2011).

Most studies on TUG performance cut-offs for fall risk are not prospective, which limits the predictive validity of the TUG at this time (Beauchet et al., 2011; Schoene et al., 2013). For example, a common cut-off of TUG time > 14 s, for fall risk among older adults was based on a retrospective study by Shumway-Cook and colleagues (Shumway-Cook, Brauer, & Woollacott, 2000) that discriminated among, not predicted, older adults with a history of falls versus without a history of falls with both a sensitivity and specificity of 87%. Other issues with using the TUG include lack of standardization of test conditions. For example, different versions of the TUG in research include usual gait speed versus fast gait speed, or walking to a line on the floor and turning around versus walking around a cone (Beauchet et al., 2011; Bohannon, 1997). To address these issues, normative values with similar methodologies should be compared so cut-off values are representative of the population and procedure by which the TUG was measured.

Two recent reviews on TUG time and falls among community-dwelling older adults have indicated cut-off scores based on prospective studies. One systematic review and meta-analysis indicates cut-offs between 11.0 – 13.5 s for community-dwelling older adults with moderate specificity and sensitivity to predict falls (Schoene et al., 2013). This cut-off range is further supported by another review that determined TUG time of > 12.34 s had the best sensitivity and specificity in predicting falls among community-dwelling older adults (Lee, Geller, & Strasser, 2013). While there are other measures to predict falls, a research study determined the TUG was superior to the BBS and static posturography in predicting falls from induced slips, or losses of balance, during gait (Bhatt, Espy, Yang, & Pai, 2011a). Considerations regarding the benefits of the TUG are that it is a quick assessment, requires minimal equipment, does not have a ceiling
effect and is normally distributed, unlike the BBS and dynamic gait index (Herman et al., 2011). Furthermore, the TUG significantly improved in a prior investigation on the effect of BBTW in adults with multiple sclerosis (Widener et al., 2009a).

**Functional Reach Test.** The functional reach test (FRT; Duncan, Weiner, Chandler, & Studenski, 1990) assesses anterior LOS by measuring how far a person can reach forward with one arm while standing without changing their feet position. Investigations support the use of the FRT in predicting falls among older adults. Butler and associates (Butler, Lord, & Fitzpatrick, 2011) found that maximal reach distance for an object is associated with falls among older adults, while Duncan and colleagues (Duncan, Studenski, Chandler, & Prescott, 1992) determined that a functional reach of less than 10 inches indicates increased likelihood of multiple falls in older male veterans. A cut-off score of <7.3 inches was indicated as increasing fall risk in a study on frail older adults from a day hospital, however, the odds ratio only trended towards significance (Thomas & Lane, 2005a).

Notably similar to other functional measures, cut-off scores vary with regards to ability of the FRT to predict falls in older adults. Considering this and that an investigation on kinematics of FRT indicated functional reach is not a good predictor of falls as older adults often use compensatory movement, rather than reaching LOS, to perform the test (Jonsson, Henriksson, & Hirschfeld, 2003), caution should be taken in using this test solely for fall risk. The benefits of the FRT is that it is quick, easy to assess and requires minimal equipment.

**Berg Balance Scale.** The Berg Balance Scale (BBS) is a commonly used tool to assess balance and fall risk among community-dwelling older adults (Berg, Wood-Dauphinee, & Williams, 1995; Berg, Maki, Williams, Holliday, & Wood-Dauphinee, 1992). It is also predictive of onset of difficulty in activities of daily living within an 18-month period (Wennie-
Huang et al., 2010). The test consists of 14 static and dynamic activities assessing daily function and balance during task performance. Each item of the BBS is scored on a 0 to 4 scale, with 4 indicating no balance dysfunction on that particular item and 0 indicating loss of balance or inability to complete the task. The maximum total score of the BBS is 56 and it has an excellent intrarater reliability (ICC = 0.98; Berg, Wood-Dauphinee, & Williams, 1995).

Although the BBS is frequently used to predict fall risk, there is no uniform cut-off score currently identified (Neuls et al., 2011). For example, one investigation in community-dwelling older adults found a cut-off score of <45/56 indicates a greater risk of falling with a 54% sensitivity (Bogle Thorbahn & Newton, 1996), while Shumway-Cook and colleagues (1997) noted scores of <42/56 and self-reported history of imbalance had a 91% sensitivity and 82% specificity of identifying community-dwelling older adults with and without a history of falls. Inconsistencies are likely due to heterogeneity of subjects, methodology, and differences in statistical analysis (Muir et al., 2010). Due to the inconsistencies and different cut-off scores, it is currently recommend that the BBS be used along with other assessments to better predict falls in older adults (Neuls et al., 2011). Other concerns with using the BBS are that it has a ceiling effect, is longer than most of the other available functional balance assessments, does not have a gait component, and must be performed without an assistive device. The Tinetti Performance Oriented Mobility Assessment addresses some of these issues.

**Performance Oriented Mobility Assessment.** Unlike the BBS, the Tinetti Performance Oriented Mobility Assessment (POMA; Tinetti, 1986) can be used with an assistive device and has both a balance and gait subscale. The balance and gait subscales can be combined or used independently. The 16 item tool is based on an ordinal scale, with some measures scored as 0 or 1 and other measures scored between 0-2. The maximal score of the full POMA is 28, with the
balance subscale contributing 16, and the gait scale, 12. Similar to other measures, the cut-off of the POMA depends on the study and type of population assessed. An investigation using the balance subscale of the POMA found that individuals who score < 11/16 have an 18 times higher risk of falling, with a sensitivity of 83% and specificity of 72% (Thomas & Lane, 2005a). A clinimetric analysis of the POMA indicates good reliability, validity for mobility, and detection to change. However, the overall test had poor ability to predict falls with a cut-off of 19/28, sensitivity of 64% and specificity 66.1%; (Faber, Bosscher, & van Wieringen, 2006). Furthermore, a one-year prospective study found that even individuals with high scores suffered falls (Raîche, Hébert, Prince, & Corriveau, 2000). Another study found that one out of three individuals with a slow gait speed (< 0.7 m/s) still had normal range scores on the POMA, indicating a potential ceiling effect. This is concerning considering that gait speeds of < 0.7 m/s are indicative of falls (Montero-Odasso et al., 2005). Other concerns of using the POMA include that the ordinal score is 0-2, therefore there is less ability to detect changes in function, as opposed to ordinal tests with more score options, such as the BBS or short physical performance battery, which is scored ordinally from 0-4.

**Short Physical Performance Battery.** The short physical performance battery (SPPB) is often used as a measure of lower extremity performance and mobility disability (Guralnik et al., 1994). A recent systematic review concluded that the SPPB was the only test that demonstrated good reliability, validity, and responsiveness to change when compared to other physical performance batteries, such as the POMA (Freiberger et al., 2012). It consists of three subscales; balance, chair stand, and gait. The balance subscale contains three increasingly difficult static stances over 10 s each, the chair stand subscale tests time to stand from a chair without upper extremity support five-times, and the gait subscale assesses time to walk a fixed
distance of either 8 ft or 4 m. Each subscale item is scored ordinally on a 0-4-point scale, and combined to add up to a total score of 12. A higher score indicates better function. Functional descriptors based on SPPB score include: a) 10-12 indicates mild mobility disability, b) 7–9 indicates moderate mobility disability, and c) 4-6 indicates severe mobility disability (Guralnik, Ferrucci, Simonsick, Salive, & Wallace, 1995a; Guralnik et al., 1994) The relative risk of mobility disability increases as the score on the test decreases (Guralnik et al., 2000).

Lower scores on the SPPB are also associated with morbidity, mortality, and hospitalization (Guralnik et al., 1995; Studenski et al., 2011; Wennie-Huang et al., 2010). Scores of ≤ 6 are associated with a higher rate of falls among older adults (Guralnik et al., 2000). Furthermore, difficulty completing a chair stand without arm support (Nevitt, Cummings, Kidd, & Black, 1989) and tandem stance of less than 10 s (Stel, Smit, Pluijim, & Lips, 2003) both have individual predictive validity of multiple falls in the following year.

*Tandem stance.* Tandem stance time, also synonymous with the sharpened Romberg test, is a widely-used independent assessment of postural steadiness (Jonsson et al., 2005) that is also an item on both the BBS and SPPB (Shubert et al., 2006). It predicts recurrent fallers as accurately as postural sway analyses (Stel et al., 2003). The quick assessment primarily tests lateral postural stability, which is related to falls among older individuals (Rogers & Mille, 2003). Timed anywhere from 10 s to 60 s, individuals stand with one foot directly in front of the other touching the heel of the front foot to the toes of the back foot. Recommended as a fall risk assessment by the CDC, a tandem stance time of less than 10 s indicates a higher risk of falls (Stevens & Phelan, 2013) and disability (Guralnik et al., 1994). Differences in tandem stance performance are noted especially after 60 years of age (Era et al., 2006). Although this assessment is widely used as an outcome measure for the effectiveness of interventions (Hile et
al., 2012; Judge, 2003; Nnodim et al., 2006), few studies indicate the predictive ability of tandem stance time among older individuals other than fall risk (Pajala et al., 2008; Sherrington et al., 2010; Stel et al., 2003).

**Five-Times Sit-to-Stand Test.** The Five-Times Sit-to-Stand Test (FTSST) constitutes a portion of the SPPB and is also an independent functional assessment tool (Tiedemann et al., 2008). The test involves time taken to stand up and sit down from a standard chair 5-times, with arms across the chest. It has a moderate association with the TUG ($r = .64$; Nitz, Stock, & Khan, 2013). Performance on the FTSST is effected by both lower extremity strength (Bohannon, 1995) and balance (Whitney et al., 2005). Individuals who have balance impairment take longer to perform chair stands compared to those who do not. The test is also predictive of falls, although recommended cutoff times vary. One investigation indicated taking greater than 12 s to complete five chair stands predicts falls (Tiedemann et al., 2008), while a systematic review found that 15 s was the most useful cutoff predicting fall risk (Power et al., 2014). However, Zhang and colleagues found a marginal association of STS performance with falls over 3 years (Zhang et al., 2013). As with many physical assessments, performance on this test declines with age (Bohannon, 2006).

**Dynamic Gait Index.** The dynamic gait index (DGI) consists of 8 tasks challenging gait via speed, head movements, and obstacles, each over a 7 m distance. Tasks are rated on a 0-3 point scale as described by pace, balance during gait, and deviation from a straight path. The maximal score is 24 (Wrisley & Kumar, 2010). The DGI has good concurrent validity with the BBS ($r = 0.67$; Shumway-Cook et al., 1997). The test also has high intrarater and interrater reliability among community-dwelling older adults with balance impairments (Jønsson, Kristensen, Tibaek, Andersen, & Juhl, 2011).
Most studies using the DGI are conducted on individuals with vestibular disorders, however one study found that a cut-off score of ≤ 19 is indicative of falls within 6 months among older adults with 59% sensitivity and 64% specificity (Wrisley & Kumar, 2010). In an investigation on an exercise intervention in mobility limited older adults, it was noted that the DGI and POMA had larger ceiling effects compared to the BBS, but that all demonstrated poor sensitivity to change (Pardasaney et al., 2012). The DGI was revised to address ceiling effects among older adults and recreated as the Functional Gait Assessment (Wrisley et al., 2004).

**Functional Gait Assessment.** Similar to the DGI, the Functional Gait Assessment (FGA) measures balance during gait-related activities. The FGA was developed to ameliorate ceiling effects of the DGI (Wrisley et al., 2004). The test has the same components of the DGI, but adds additional challenging gait components, including tandem gait, walking backwards, and walking with eyes closed. The FGA has demonstrated concurrent validity with BBS, TUG, and DGI. It is noted that, like most functional tests, performance declines with age and normative scores for those over the age of 70 years are often less than optimal (Walker et al., 2007), which should be considered when analyzing scores. One investigation indicated scores of < 22/30 provided 100% sensitivity and 72% specificity in predicting prospective falls in sample of 35 community-dwelling older adults (Wrisley & Kumar, 2010). While the FGA targets balance during gait and manipulates some sensory systems, another assessment tool, the Clinical Test of Sensory Interaction on Balance, targets balance during standing while manipulating one or more of the sensory systems involved in postural control.

**Clinical Test of Sensory Interaction on Balance.** The Clinical Test of Sensory Interaction on Balance (CTSIB) is a timed test of six various conditions used to identify the effect of visual, vestibular, and somatosensory input on postural control (Cohen, Blatchly, &
Gombash, 1993). The test consists of six static standing conditions that manipulate sensory input, maintained for 30 s each: (1) eyes open on a firm surface, (2) eyes closed on a firm surface, (3) visual-conflict dome with eyes open on a firm surface, (4) eyes open on a compliant surface, (5) eyes closed on a compliant surface, and (6) visual dome on a compliant surface. A decrease in composite time to maintain each position indicates a risk of falls among older adults (Di Fabio & Anacker, 1996). Moreover, older people suffering recurrent falls demonstrate less ability to perform conditions 4-6, compared to individuals suffering one or no falls (Ricci, de Faria Figueiredo Gonçalves, Daniele, Coimbra, & Coimbra, 2009).

**Modified Clinical Test of Sensory Interaction on Balance.** The modified Clinical Test of Sensory Interaction on Balance (mCTSIB) omits the visual conflict dome conditions of the full CTSIB. Each position is held for 30 s for the non-instrumented version (Whitney & Wrisley, 2004) and 10-30 s for the instrumented versions (Mancini, 2011). Conditions are designed to assess the input and use of the somatosensory, visual, and vestibular systems to maintain postural control. Conditions include: (1) standing on a firm surface, such as the floor, with eyes open; (2) standing on a firm surface with eyes closed; (3) standing on a foam surface, eyes open; and (4) standing on a foam surface, eyes closed (Trueblood et al., 2001).

An investigation using the mCTSIB program on the Balance Master™ found that increased sway on a firm surface with eyes open, combined with limits of stability tests, were predictive of future falls (Trueblood et al., 2001). Decreased stability while standing on foam, eyes closed also indicates future falls (Nitz et al., 2013). Furthermore, considering the somatosensory and visual systems are manipulated on this test, vestibular integration was proposed to be the best functional predictor of future falls when compared to the TUG. Although performance on any of the aforementioned physical assessments are related to falls, fear of
falling and balance confidence also independently predict future falls (Delbaere et al., 2010). Therefore, it is important to assess both constructs.

**Activities Specific Balance Confidence Scale.** The Activities Specific Balance Confidence Scale is a 16-item self-administered questionnaire on a person’s confidence to maintain balance during specified daily activities (Powell & Myers, 1995). Each item is rated on a 0-10 scale, with 0 indicating no confidence, and 10 indicating high confidence. The total score is out of 100 and the reliability of the test is high ($r = 0.92$; Powell & Myers, 1995). A score of $\leq 67\%$ indicates increased risk of falls with $84\%$ sensitivity and $88\%$ specificity (Lajoie & Gallagher, 2004). A score of $50-80\%$ suggests a moderate level of functional mobility (Myers, Fletcher, Myers, & Sherk, 1998). However, one concern with the scale is that some of the tasks are more appropriate questions for high functioning community-dwelling older adults, such as the item “how confident are you that you will not lose your balance or become unsteady when you step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing?”. Therefore, this test may not represent appropriate activities among already mobility-limited older adults.

**Falls Efficacy Scale-International.** The Falls Efficacy Scale-International (FES-I) is a 16-item questionnaire regarding an individual’s perception of their fear of falling while performing daily physical and social activities. It is moderately correlated with the ABC (Smee et al., 2015) and has high test-retest reliability ($ICC = 0.96$; Yardley et al., 2005). In a large longitudinal study, the cut-off scores of $\geq 23/64$ indicate high concern about falling and are related to future falls (Delbaere et al., 2010). The FES-I has demonstrated a better association with functional and health-related characteristics compared to the ABC (Smee et al., 2015). It is also related to self-reported balance problems, and difficulty standing from a chair (Kumar,
Carpenter, Morris, Iliffe, & Kendrick, 2014). Consequently, fear of falling leads to declines in physical, functional, and psycho-social health among older adults (Scheffer, Schuurmans, van Dijk, van der Hooft, & de Rooij, 2008). Therefore, fear of falling and efficacy of not falling are important constructs to assess in older adults.

Interventions to Improve Balance and Function and Decrease Falls

Physical performance tests and confidence and concern for falling quantify balance and gait impairments and fall risk. Interventions to address balance and falls are numerous. Medication management, home safety modification, vision improvement, and exercise are some of the most effective interventions cited in a recent Cochrane review (Gillespie et al., 2012). For the purpose of this literature review, interventions will be grouped into targeted (non-exercise) and exercise intervention.

**Targeted interventions.** Targeted impairment-based exercise interventions have been useful in special populations to modify risk factors for falls. Special populations that benefit from targeted interventions include older adults taking psychotropic medications, or those who have cataracts, cardioinhibitory syndrome, or severe visual impairment. For example, a study on home modification versus home exercise in older adults with severely impaired vision indicated home modification resulted in 41% fewer falls while exercise resulted in 15% greater falls (Campbell et al., 2005). This is likely because vision was the primary impairment causing falls, rather than strength in this particular cohort of older adults. A different cohort of older adults on psychotropic medications demonstrated a lower fall risk with a targeted intervention of withdrawal of psychotropic medications, as compared to an exercise intervention Campbell, Robertson, Gardner, Norton, & Buchner, 1999b).
Other targeted interventions also decreased falls, but were not compared to exercise as an intervention. For example, older adults at risk of falls due to icy conditions in the northern U.S. during winter were 60% less likely to fall when a traction device was placed on their footwear (McKiernan, 2005). Targeted corrections of disease-related issues also decreases falls among older adults. Pacemaker placement in adults with cardio-inhibitory syndrome decreases rate of falls. Corrective cataracts surgery in one eye, but not in the second eye, also decreases fall rate (Harwood et al., 2005). Vitamin D supplementation in older adults has mixed results in decreasing falls (Bischoff et al., 2003; Gillespie et al., 2012). While targeted interventions to address medical or other related factors of falls are beneficial, there is no current non-exercise intervention available that directly improves balance or mobility among older adults.

**Exercise-based interventions.** Balance and mobility deficits that increase fall risk among older adults are often addressed via exercise interventions and have shown positive results in most investigations (Gillespie et al., 2012; Sherrington et al., 2011; Stevens, 2010). Exercise program effectiveness varies, which is likely due to the many factors that contribute to balance maintenance, measurement of balance, and exercise parameters. Exercise-based interventions target presumed impairments in the neuromotor systems such as balance, postural control, strength, power (Henwood & Taaffe, 2005; Izquierdo et al., 1999; Orr, 2010), as well as tasks to improve motor learning and postural adaptation strategies (Granacher, Muehlbaue, Zahner, Gollhofer, & Kressig, 2011). For example, perturbation-based training programs (Bieryla & Madigan, 2011; Mansfield et al., 2010), and combination programs of strength and balance training (Campbell et al., 2005; Skelton, Dinan, Campbell, & Rutherford, 2005) have all demonstrated effectiveness in decreasing fall rate and risk.
Many other programs, such as the Otago Exercise Program, combine strength and balance training. This program has been shown to decrease fall rate by 35% in older adults and is particularly beneficial among older adults who have fallen and are over 80 years of age (Campbell et al., 1997; Campbell et al., 1999a; Campbell et al., 2005). The program institutes strength, flexibility, balance, and, if appropriate, walking exercises in a home-based program over one year. Strengthening activities include sitting and standing exercises with ankle weights. Flexibility exercises target the neck and trunk, and balance exercises increase in difficulty from a wide to more narrow BOS, continuing to more challenging dynamic activities (Campbell et al., 1999a).

A meta-analysis of the Otago exercise program indicated a significant decline in risk of death (risk ratio = 0.43-0.48) and fall rates (risk ratio = 0.68) among older adults who completed the program (Thomas, Mackintosh, & Halbert, 2010). In the “Compendium of Effective Fall Interventions” for community-dwelling older adults (Stevens, 2010) the CDC recommended the Otago program as well other combination exercise programs such as the Stay Safe Stay Active Program (40% reduction in fall risk; Barnett, Smith, Lord, Williams, & Baumand, 2003), Falls Management Exercise Intervention (31% reductions in falls; Skelton et al., 2005), and multiple Tai Chi programs (Voukelatos, Cumming, Lord, & Rissel, 2007) as effective interventions to decrease fall risk. Tai Chi has demonstrated effectiveness as an exercise-based program to decrease fall risk and rates likely due to the propensity to challenge balance (Lin, Hwang, Wang, Chang, & Wolf, 2006; Low, Ang, Goh, & Chew, 2009). Multifactorial interventions that include exercise and address other individual fall risk factors, such as vision or polypharmacy, appear to be as effective as exercise-based interventions to decrease fall rate (Gillespie et al., 2012; Sherrington et al., 2011; Shubert, 2011; Stevens, 2010).
While exercise interventions that improve strength (Latham, Bennett, Stretton, & Anderson, 2004), power (Orr et al., 2006), and function (Clemson et al., 2012; Skelton et al., 2005) are effective at decreasing falls, exercise programs that specifically target balance appear to be the most effective at reducing fall risk (Sherrington et al., 2011). This is likely because motor learning is task specific (Green & Bavelier, 2008). In a recent meta-analysis of 54 randomized-control trials (Sherrington et al., 2011), it was concluded that the exercise must provide moderate to high challenges to balance, must be of high dose (generally over 50 hours over the trial), must be ongoing, and can be group or home based to be the most efficacious in fall prevention. Of importance, exercise that included walking programs actually increased falls among already high-risk individuals. Therefore, addressing balance impairments is of utmost importance in decreasing fall risk among older adults.

Exercise is an effective intervention to improve balance and function and prevent falls among older adults, however adherence to exercise varies. In a recent meta-analysis of older adults’ adherence to home exercise programs to prevent falls, only 21% of older adults were fully adherent with the exercise regimen (Simek et al., 2012). Individual characteristics related to low exercise adherence include having impaired physical abilities and higher fear of falling (Spink et al., 2011). This is concerning as individuals with these particular characteristics are at the highest risk of falls. While the relationship of adherence of an exercise program to efficacy in decreasing fall risk or rate is currently unclear (McPhate, Simek, & Haines, 2013; Simek et al., 2012), poor adherence may inhibit benefits of fall reduction interventions (Sjosten et al., 2007). Therefore, it is necessary to investigate means other than exercise to improve balance and functional mobility and decrease fall risk among older adults.
Balance-Based Torso Weighting

Balance-Based Torso Weighting (BBTW) is a means other than exercise that has shown ability to increase functional mobility in adults with multiple sclerosis (Gorgas et al., 2014; Widener et al., 2009b). Since impaired function and balance are related to fall risk among older adults, it is of interest if BBTW affects balance and function among older adults, thereby decreasing fall risk. The basis of BBTW is to improve anticipatory and compensatory postural adjustments (APAs and CPAs) to trunk perturbations by strategic torso weighting, thereby improving balance and function. The function of the trunk musculature is important for maintenance of posture and recovery from loss of balance. Older adults exhibit impaired APAs, CPAs, and balance strategies (Kanekar & Aruin, 2014; Woollacott, 1993); therefore, addressing these impairments by BBTW and improving function may decrease fall risk.

In the Balance-Based Torso-Weighting evaluation (Appendix B), a clinician trained in the method provokes threats to balance through perturbations at the upper and lower trunk to elicit APAs and CPAs. The clinician grades those responses then strategically weights each individual based on the quantity and quality of their postural adjustments. The participant donns BalanceWear®, a vest-like garment that allows various weights to be placed via Velcro on the trunk, and the clinician weights the participant per protocol to address postural deficits (Gibson-Horn, 2014). The goal is to weight the trunk of the individual with less than 1.5% of their body weight and improve responses on APAs and CPAs (Gibson-Horn, 2014). After weighting achieves optimal postural responses, a lumbosacral orthotic is donned to determine if it will further improve responses to perturbations. The orthotic is only retained as part of the individualized BalanceWear® orthotic if it further improves postural responses. A non-extensible lumbosacral orthotic increases trunk stiffness and decreases trunk displacement by
14% following a perturbation (Cholewicki, Lee, Peter Reeves, & Morisette, 2010). Using the orthotic, if indicated, should therefore decrease fall risk if it decreases trunk movement with perturbations since increased trunk movement is related to increased falls (Grabiner et al., 2008).

Control of trunk function and movement is imperative to maintain posture and regain balance. Voluntary speed of trunk movement has been significantly related to functional mobility in older adults, regardless of the direction of movement (Iwata et al., 2014). Ability to limit trunk motion during trips and slips discriminates older adults who have fallen from older adults who have not (Grabiner et al., 2008), indicating appropriate postural responses are important for balance maintenance and fall avoidance.

Impaired postural responses to trunk perturbations are related to falls among older adults. Older adults suffering future falls had lower force thresholds causing stepping reactions in posteriorly directed perturbations as compared to older adults who did not suffer a fall (Sturnieks et al., 2013). Moreover, older adults with slower posterior step initiation time have twice the risk of falling at home compared to those with faster step times. Lastly, taking multiple steps when recovering from lateral balance perturbations at the waist are significantly associated with falls (Hilliard et al., 2008). Therefore, improving the reaction to perturbations in the BBTW evaluation and strategic weighting should, theoretically, decrease the risk of falls.

Postural responses at the trunk as well as trunk proprioception are associated with balance and falls. An investigation found that, compared to younger and older adults without balance impairment, older adults with balance impairment demonstrate errors in trunk repositioning accuracy (Goldberg et al., 2005). Improvements in trunk proprioception, balance, and functional mobility were seen after a balance-exercise intervention among older adults with diabetic neuropathy (Song, Petrofsky, Lee, Lee, & Yim, 2011). This indicates that improving
trunk proprioception can effect balance even in the presence of impaired foot sensation, the largest somatosensory input for balance maintenance. Therefore, implications for the use of BBTW in balance and sensory impaired older adults warrants further investigation.

Although the effect of BBTW on balance-impaired older adults has yet to be investigated, studies have found functional and balance improvements after BBTW in people with multiple sclerosis. After BBTW, people with multiple sclerosis significantly improved performance in the TUG, 25-foot walk, sharpened Romberg, and 360-degree turns. These changes were not seen in a comparative control group that did not have BalanceWear® (Widener et al., 2009a). Another investigation found that both people with multiple sclerosis and healthy individuals demonstrated improvements in fast gait velocity, cadence, and double- and single-limb support parameters during fast gait with BBTW (Gorgas et al., 2014). The potential to improve gait among older adults with BBTW has implications of decreasing fall risk in this population since slower gait velocity and increased gait variability is related to falls among older adults (Hausdorff, Rios, & Edelberg, 2001; Studenski et al., 2003).

Besides investigations on BBTW, the use of weighting to improve balance, function, and movement has mixed results and has historically been evaluated in individuals with neurologic disorders. A prior investigation found that applying various weights to an extremity significantly decreased intention tremors in people with neurological disorders (Hewer, Cooper, & Morgan, 1972). Conversely, another study found that weighted utensils or wrist cuff weights did not improve postural hand tremor in people with Parkinson’s disease (Meshack & Norman, 2002). Lower limb ataxia (incoordination related to a neurologic disorder) during gait improved in some individuals after weights were applied to the lower extremities (Okajima, Chino, Noda, & Takahashi, 1990), however another study indicated that weighting bilateral shoulders or at the
waist did not improve gait characteristics of ataxic individuals (Clopton, Schultz, Boren, Porter, & Brillbart, 2003). The effect of weighting the extremities or trunk has not been studied in older adults without progressive neurologic disorders. Traditionally, symmetrically weighted vests of various loads have been used during exercise in the older adult population for means of increasing bone density, balance, power, and function (Bean et al., 2004; Jessup, Horne, Vishen, & Wheeler, 2003). No studies have investigated the effect of a vest with strategic weighting, without combined exercise, on balance, function, and mobility among older adults.

While the mechanism of action of BBTW is unknown at this time, it does not appear to alter COM biomechanically. A recent study indicated that direction of the greatest weight placement with BBTW only matched center of pressure changes ~ 20% of the time (Crittendon et al., 2014). Interestingly, the same participants (both healthy adults and individuals with multiple sclerosis) were able to resist a greater rotational force for a longer period of time when strategically weighted and also demonstrated a significant improvement in gait velocity immediately after BBTW. These results demonstrate that there is a positive therapeutic effect of the intervention, albeit not biomechanical.

Theories on the therapeutic effect of BBTW are mostly related to augmenting sensory stimulus to the trunk where the weights are placed. Possible mechanisms of action are joint compression, increased conscious awareness of the weighted area, or increased sensory input integrated by the central nervous system to modify motor output (Crittendon et al., 2014; Widener et al., 2009a). Joint and skin sensory input stimulate receptors that provide information to the central nervous system on the relative orientation and movement of the body in space in order to maintain or modify posture (Lundy-Ekman, 2013; O'Sullivan et al., 2013). Regardless of the reason BBTW is effective, studies show it improves function, gait, and balance in individuals
with multiple sclerosis. Considering that older adults, especially those at risk of falls, have sensory, neuromotor, and postural control decrements with age and BBTW has shown improvements in function, balance, and gait in individuals with multiple sclerosis, it is of interest to investigate if BBTW will improve these measures, thereby reducing fall risk among mobility-impaired older adults.
Chapter III
Methodology

Introduction

Falls among older adults are a public health issue related to morbidity, mortality, and high health care utilization (Center for Disease Prevention, 2013). Impaired balance, gait, and mobility are prominent risk factors for falls (Nachreiner et al., 2007). The only current intervention to address these impairments is exercise (Sherrington et al., 2011), however, exercise adherence is poor among older adults (McPhate et al., 2013). BBTW is a non-exercise intervention that has shown improvements in gait and mobility among adults with multiple sclerosis (Gorgas et al., 2014; Widener et al., 2009a; Widener et al., 2009b), but has not been studied in older adults with mobility or balance impairments without progressive neurological diseases. Therefore, the purpose of this study was to examine the effects of BBTW on gait, functional mobility, balance, and falls efficacy in adults over the age of 65 years.

Pilot Study

A pilot study was approved by the Institutional Review Board of the University of Arkansas (Appendix C). The investigation was conducted prior to the dissertation to assess the potential of BalanceWear® in improving mobility, balance, gait, and falls efficacy in older adults. The usefulness and feasibility of the assessments were also considered during the pilot study. Adults over the age of 65 years were recruited from a local senior center via fliers. Twenty-five individuals volunteered to participate in the study and 13 met inclusion criteria. The functional and falls efficacy measures were assessed pre BBTW and again post BBTW while wearing the BalanceWear®. Limitations noted included fatigue due to same day pre- and post-testing and BBTW evaluation either limiting performance or inability to complete all tests.
Notably, the two participants who scored less than four on the SPPB were most affected by fatigue during the BBTW evaluation and post-testing conducted in the same day. Other limitations included pain; one individual had to stop the post-testing due to increased pain in the knee during weight bearing activities. Based on these issues, modifications were made to the methodology, inclusion, and exclusion criteria to avoid limitations seen in the pilot study.

**Participants and Recruitment**

Forty older adults over the age of 65 years with mobility or balance impairments were recruited via fliers (Appendix D) and word of mouth from three Country Meadows Retirement facilities in Pennsylvania. The sample size of 40 participants for the study (20 per group) was based on a prior study on BBTW in individuals with multiple sclerosis, where 17 participants was an adequate group size to detect significant changes in gait velocity (Gorgas et al., 2014; Widener et al., 2009b) with 80% statistical power at $\alpha = 0.05$. Additionally, an investigation conducted on sample size needed to determine meaningful change in physical performance measures in older adults indicated 23 individuals per group was adequate to identify 0.10 m/s as a meaningful change in 4-m gait speed (Perera, Mody, Woodman, & Studenski, 2006). Therefore, the sample size of 20, which is an average of the two investigations, selected to achieve statistical power for 4-m gait velocity. Available resources also pre-determined the sample size. The CEO of Country Meadows Retirement facilities funded 40 BalanceWear® orthotics for this investigation (Appendix E). There were two groups; an experimental group that received strategically weighted BalanceWear® (WG) and a blinded placebo group that received a BalanceWear® orthotic with sham weights (SWG). Specific inclusion and exclusion criteria were used to assist with selection of homogeneous groups to maximize the ability to detect changes.
Inclusion and exclusion criteria. Prior to participation in the study approved by the University of Arkansas Institutional Review Board (Appendix F), individuals were provided and signed written informed consent (Appendix G). In order to ensure understanding of the informed consent and the investigation, participants were prescreened for cognitive impairment using the Mini Mental State Examination (Appendix H; Cockrell & Folstein, 2002). The cognitive assessment includes 11 questions that assess organization, registration, attention, calculation, recall, and language abilities. A cut-off score less than ≤ 23/30 on the Mini Mental State Examination indicates cognitive impairment, and therefore served as exclusion criteria.

Participants were also prescreened with a health history questionnaire (Appendix I) for medical issues that would potentially exacerbate conditions and preclude participation in the study (American College of Sports Medicine, 2013). Such conditions were uncontrolled cardiovascular disease, uncontrolled diabetes, or current pain or injury inhibiting mobility or that worsens during mobility. Individuals were also excluded from this investigation if they were told by their physician that they could not perform physical activity, had a progressive neurological disorders (such as Parkinson’s disease or multiple sclerosis) or current complaints of dizziness since these issues can cause or exacerbate balance and mobility problems and were not the focus of this investigation (Stevens, Lang, Guralnik, & Melzer, 2008). Older adults were also excluded from the study if they had severe visual impairment preventing them from being able to navigate the assessment area without bumping into equipment, walls, or other individuals. Individuals with strength deficits less than 2/5 in the hip musculature via a manual muscle test (Clarkson, 2000), or foot drop not corrected by an orthotic were excluded from the study since anecdotal clinical evidence has shown these participants do not benefit from BBTW (personal communication, C. Gibson-Horn, June 10, 2014).
Participants who met inclusion criteria were age 65 years and older, had the ability to tolerate one hour of testing at a time, and ambulate at least 30 feet repeatedly with or without an assistive device in order to complete the pre- and post-tests. Participants meeting inclusion criteria also exhibited evidence of mobility or balance impairments, as defined by an SPPB score of 4-9/12 (Guralnik et al., 1994). The SPPB was conducted per previous investigations (Guralnik et al., 1994) and for the inclusion SPPB, the individual was allowed to use an assistive device to ambulate for the gait subtest. The cut-off of 4-9/12 was effective in the pilot study for this investigation as adults who scored greater than 9/12 did not have obvious evidence of balance or mobility impairments and those that scored less than 4/12 were significantly impaired and had difficulty completing the assessments (Vincenzo, unpublished data, 2014).

Assessments. Fitness and therapy staff at Country Meadows retirement facilities were trained by the primary investigator on inclusion and exclusion criteria, informed consent, and administering the assessments and pre- and post-tests. Staff were also educated on measuring, donning, and doffing BalanceWear ® by the BBTW physical therapist. The comorbidity index was used to provide baseline information on the overall health of the participant. Other physical demographics, including weight and height were collected.

Assessments that may affect balance and mobility, including lower extremity sensation, strength, and proprioception testing, were completed by physical therapists that worked in each facility. Light touch and pressure sensation in the feet were assessed with the participant seated, eyes closed, indicating verbally where they detected the input. Proprioception at the great toe, ankle, knee, and hip were tested with the individual seated, eyes closed, verbalizing the position that the therapist placed their joint in (such as knee straight or bent). Lastly, lower extremity strength was assessed per manual muscle testing protocol (Clarkson, 2000). Recruitment,
assessments, and administration of patient questionnaires, were completed within the month prior to pre-testing and BBTW intervention. However, due to unforeseen circumstances occurring with the therapist at one of the three retirement facilities, participants in one facility did not receive sensation, proprioception, and strength assessment prior to pre-testing. Nevertheless, because anecdotal evidence was utilized for hip strength measure as an inclusion criteria, these participants were still included in the investigation due to meeting all other criteria. Refer to Appendix J for assessments and test forms.

**Experimental Design**

This study was a randomized double blind, placebo controlled investigation with two groups. Participant recruitment, assessments for inclusion and exclusion criteria, and self-administered questionnaires were completed in the month prior to pre-testing after Institutional Review Board approval from the University of Arkansas. All participants performed the same pre-tests at the start of the investigation, followed by the BBTW evaluation and administration of either a weighted or sham weighted BalanceWear® garment. Participants were blinded to group placement and were not told there were both treatment and control groups. The weighted group (WG) received the strategically weighted BalanceWear®, and the sham weighted group (SWG) received BalanceWear® with sham weights placed on the bilateral lateral torso. Sham weights were pieces of Styrofoam® with the same dimensions as the weights encased in the same fabric as the BalanceWear® weights. After 5 days of wearing the garment for 4 hours per day, participants completed the post-tests without having worn the garment for at least 8-hours.

On the first day of pre-testing, participants completed the mobility, gait, and balance pre-tests in a randomized order, followed by BBTW and administration of BalanceWear®. Sealed envelopes were shuffled and chosen from a box by the BBTW therapist, who was in a separate
room, to randomly allocate group assignment. Only the therapist weighting the participants was privy to the group allocation and was not involved in pre- and post-testing. Researchers involved in pre- and post-testing continued to be blinded to group allocation. The permanent BalanceWear® orthotic included the weights and optional lumbosacral orthotic on the inside of the vest therefore, blinding of group allocation to the pre- and post-testers remained consistent. The BalanceWear® was worn for 2 hours in the morning and 2 hours in the afternoon. Participants were recommended to don BalanceWear® during the times of day they were most active in daily activities. A daily calendar was provided to participants to track wear time and all participants followed recommended wear time. Post-tests were conducted 5 days after administration of BalanceWear® as directed. Participants were instructed to not wear their BalanceWear® on the 5th day and did not have the BalanceWear® garment on during post-testing.

**Pre-tests and post-tests.** Assessments completed prior to pre-testing to determine baseline participant information included body weight, height, sensation, strength, proprioception, a health history questionnaire, and the comorbidity index. Due to unforeseen circumstances, participants at one facility were not assessed on strength, sensation, or proprioception prior to commencement of the pre-tests. The SPPB was used for both inclusion criteria of mobility disability and pre- and post-tests. The same pre and post-test measures of gait, functional mobility, balance, and falls efficacy were conducted at the start of the investigation and after 5 days of wearing BalanceWear® to determine the effect of the intervention. Participants were guarded by a trained clinician for safety during all activities and no adverse events occurred. Pre-testing was completed all in one session prior to the BBTW protocol. Post-testing was conducted again 5 days after participants were administered the
BalanceWear® and followed the wear time schedule. Pre-tests were randomly conducted. Gait was evaluated by the 4-m walk speed and the FGA. Functional mobility was assessed by FTSST from the SPPB, total SPPB score, and the TUG. Balance was assessed by tandem stance time and the FRT. Postural control was assessed by the instrumented mCTSIB. Participants were asked to not use their assistive device, if possible, during their functional assessments. Finally, falls efficacy was measured by the FES-I.

**Short Physical Performance Battery.** Mobility disability, defined by an SPPB score of 4-9/12, served as the main functional inclusion and exclusion criteria as well as a pre-test and post-test of the effectiveness of the intervention (Guralnik, et al., 1995). The SPPB consists of three sub-scales; balance, gait, and lower-body strength. The balance test sub-scale consists of timed (up to 10 s), side-by-side, semitandem, and tandem stances. Participants are allowed to use initial support of the researcher, but not an assistive device, to obtain the position. Performance on these three balance stances combine to obtain an ordinal score between 0-4. Although the SPPB was scored with the 10 s performance per protocol, tandem stance time was recorded for up to 30 s to provide another extended balance measure and eliminate potential ceiling effects (Hile et al., 2012). Tandem stance has high test-retest reliability in older women ($r = .90$; Franchignoni, Tesio, Martino, & Ricupero, 1998).

The gait subscale of the SPPB consists of the timed 4-m walk test to determine an ordinal score of 0-4 based on time to walk 4-m at usual pace. Participants were asked to complete the walk without an assistive device if able. Habitual gait speed was also measured at this time during the SPPB 4-m walk. Per SPPB protocol, no time was allowed for acceleration or deceleration (Guralnik et al., 1994). Participants were given a practice trial before the timed trial was recorded. Due to issues concerning fatigue with multiple assessments, only one trial of gait
speed was conducted. Gait speed is valid and predictive of morbidity, mortality, and falls among older adults (Callisaya et al., 2011; Studenski et al., 2011; Van Kan et al., 2009). The reliability of this test is high (ICC = 0.90 usual gait speed, 0.91 fast gait speed; Bohannon, 1997).

Lastly, the FTSST in the SPPB consists of an ordinal score obtained from the time it took the participant to stand up five-times from a standard height chair, without upper extremity support. A standard height, firm chair was used in each facility with the back of the chair supported against the wall. Although different chairs were used across facilities, the same chair was within each facility for the pre- and post-tests. Participants were instructed to stand up as quickly and safely as possible, five-times, with their arms across their chest. Time started when the individual lifted the body off the chair and stopped when the individual stood erect for the fifth time. The time to complete the FTSST was also used as a continuous, separate variable. A systematic review indicated that the FTSST test has moderate reliability (mean ICC = 0.81; Bohannon, 2011).

Three sub-scale scores combine to determine an overall score on the SPPB, with the maximum score being 12, indicating no mobility disability. The SPPB is quick, easy to administer, reliable, valid, and responsive to change (Freiberger et al., 2012). The 1-week test-retest coefficient is high (ICC = 0.88 – 0.92; Studenski et al., 2003).

Timed Up and Go. The TUG (Podsiadlo & Richardson, 1991) is commonly used to assess balance, walking, and fall risk among older adults. Participants were instructed to walk as ‘quickly and safely’ as possible around a cone on the floor 3 m away and return to a seated position in the chair. The timed test began with the individual seated with their back against the chair. On the researcher’s command of ‘go’, the stopwatch was started. Participants were given one practice trial followed by two timed trials that were averaged. Participants were asked to not
use an assistive device if possible. Increased time to complete the test is significantly related to decreased mobility (Bischoff et al., 2003b) and is correlated with the BBS and gait speed (Podsiadlo & Richardson, 1991). The test-retest reliability is high (ICC = 0.97; Steffen, Hacker, & Mollinger, 2002).

**Functional Reach Test.** The FRT (Duncan et al., 1990) assesses anterior limits of stability and balance by measuring how far a person can reach forward with one arm while standing. The participant stood with feet together and one arm lifted to 90 degrees of shoulder flexion with the elbow straight. The fingers started at the zero position of the mounted measuring tape and the person reached forward as far as they could without changing the position of their feet. Two trials were conducted and averaged. The test has been associated with falls among older adults (Butler et al., 2011) and has high test-retest and intrarater reliability (ICC = 0.92, 0.98, respectively; Duncan et al., 1990).

**Functional Gait Assessment.** The FGA was administered as an outcome measure of balance during gait-related activities (Wrisley et al., 2004). The FGA consists of 10 tasks challenging gait via speed, head movements, base of support, occlusion of vision, and obstacles, each over a 7 m distance. Tasks are rated on a 0-3 point scale as described by pace, balance during gait, and deviation from a straight path. Participants were asked to not use an assistive device, if possible, during the test. The FGA has demonstrated concurrent validity with BBS ($r = 0.84$), TUG ($r = 0.84$; Wrisley & Kumar, 2010), and DGI ($r = 0.80$; Wrisley et al., 2004). The test has good intrarater and interrater reliability (ICC = 0.83, 0.93, respectively; Walker et al., 2007; Wrisley et al., 2004). To avoid increased interrater variability, the primary investigator was the sole, blinded clinician that conducted the FGA on all participants.
Modified Clinical Test of Sensory Interaction on Balance. The instrumented modified clinical test of sensory interaction on balance (mCTSIB; APDM™, Portland, OR) was used to evaluate postural control under four different sensory conditions for 30 s each. Wireless sensors were placed on the lumbar area to measure postural sway while the individual was standing in the following successively difficult conditions (1) eyes open on a firm surface (EO), (2) eyes closed on a firm surface (EC), (3) eyes open on a foam surface (ECF), and (4) eyes closed on a firm surface (ECF). For standardization, the same foam Airex® pad (Magister corp; Chatanooga, TN) was used for all testing. Foot position was normalized by using the footplate provided with the Ambulatory Parkinson’s Disease Monitoring (APDM™; Portland, OR) mobility lab. The system has been validated with a force plate in measuring postural sway (Mancini et al., 2012; Mancini, 2011). During testing, if an individual touched a researcher or a researcher needed to assist the individual to prevent falling, the test was stopped manually by another researcher controlling the computer. If this occurred and a condition was aborted prior to 5 s, the software did not record or process the data and this condition on the test data was recorded as missing.

The CTSIB has a test-retest reliability of $r = .75$ for community-dwelling older adults (Anacker & Di Fabio, 1992). One-week test-retest reliability of the mCTSIB on the NeuroCom Balance Master was high. Accelerometry measures at the pelvis have moderate to high test-retest reliability across different sensory assessments (Whitney et al., 2011).

Falls Efficacy Scale-International. The falls efficacy scale-international (FES-I) was utilized to assess concern of falling considering perceived risk of falling is independently related to falls, yet not always related to functional ability (Delbaere et al., 2010; Yardley et al., 2005). The FES-I is a subjective questionnaire regarding an individual’s perceived fall risk while performing everyday tasks (Yardley et al., 2005). Examples of tasks include getting dressed,
cleaning the house, walking in a place with crowds, and going to a social events. Each item on the 16-item test is scored on a 1-4 scale, with 1 being not concerned about falling performing the stated activity and 4 being very concerned about falling performing the stated activity. The items are combined to obtain a single score to determine concern of falling. The higher the total test score, the greater the fear of falling. Scores greater than 23/64 indicate high concern about falling. It has high test-retest reliability (ICC = 0.96; Yardley et al., 2005) and convergent and predictive validity for functional ability and future fall risk (Delbaere et al., 2010).

**Intervention**

**Balance-Based Torso-Weighting.** After the pre-tests were conducted, participants completed the BBTW evaluation in a separate location to maintain blinding of group allocation to researchers who conducted the pre- and post-tests. The clinician conducting the BBTW intervention picked sealed envelopes out of a box to randomize group allocation and did not assist with pre- or post-testing of participants. The BBTW evaluation and treatment method is performed by a clinician, such as a physical or occupational therapist, who has attended a training in the method (Gibson-Horn, 2014). For this investigation, the developer of BBTW, who is a physical therapist, conducted the BBTW evaluation and weighting on the WG and SWG. For all groups, the clinician assessed the individual’s postural control in accordance with the BBTW assessment method while the individual was standing feet together, eyes open without an assistive device. The clinician systematically applied brisk perturbations at the trunk, shoulders, and pelvis in anterior, posterior, and lateral directions noting latencies and qualities of postural responses to perturbations. Lastly, the clinician applied a strong rotational force in both directions at the shoulders and pelvis, and graded asymmetries and responses per the BBTW evaluation grading criteria.
Based on the individual’s postural deficits in the WG, the clinician strategically placed small, non-obtrusive weights on the torso to enhance sensory input and muscle activation in that area of the trunk. Per the protocol of the developer, weighting to address rotational deficits was completed first, then individuals were retested in their postural responses. Following correction of abnormal responses to rotation, the most impaired balance responses were addressed via weighting, in the area of the trunk that musculature needed to be activated in order to improve postural adjustments to perturbations (Gibson-Horn, 2014). Individual weights $\frac{1}{8}$ lb (0.057 kg), $\frac{1}{4}$ lb (0.11 kg), and $\frac{1}{2}$ lb (0.23 kg); and any combination of weights were placed in different positions on the BalanceWear® based on an individual’s responses. The clinician repeated the perturbations where deficits were noted and changed or added weights until the individual’s postural responses, as well as resistance to rotational forces, improved (Gibson-Horn, 2014; Gibson-Horn, 2008; Gorgas et al., 2014). On average, 25 perturbations are required to appropriately evaluate and weight and individual with the BBTW method (Widener & Gibson-Horn, unpublished data, 2014). Once the clinician determined that the weighting was optimal, a lumbosacral orthotic was added to discern if it would further improve responses to perturbations. Whether the LSO was retained as part of the individualized BalanceWear® orthotic depended on the patient and clinician’s judgment of the usefulness of the lumbosacral orthotic in further improving postural responses in addition to the weighting strategy.

The clinician also conducted the perturbation assessment as described in the SWG group, but applied the sham fabric encased Styrofoam® on the bilateral lateral insides of the BalanceWear®. Reassessment perturbations were also conducted and at least 25 perturbations were administered to account for possible fatigue or motor learning effects (Bhatt, Yang, & Pai,
2012) with perturbations. The LSO was not used in the SWG as it can change postural responses (Cholewicki et al., 2010).

All participants were instructed to wear the BalanceWear® for 2 hours in the morning and 2 hours in the afternoon daily, preferably during daily non-sedentary activities, and record this on a daily calendar. Five-days after wearing the BalanceWear®, participants completed the post-tests in a randomized order without their BalanceWear® garment on (SPPB, usual gait speed, TUG, DGI, FGA, FRT, mCTSIB, and the FES-I).

*Exclusion based on BBTW intervention*. If an individual did not demonstrate improvements in perturbations after strategic weighting with the BBTW protocol in the WG, they were excluded from the study. Individuals who worsened in perturbation response, balance, mobility, or pain with strategic weighting or SWG were also excluded as worsening of these factors would put them at a higher risk of falls.

**Statistical Analysis**

Data were analyzed using SPSS version 22 (IBM; Armonk, NY). Group means (SD) were reported for demographics, specific health characteristics and assessments. Although random group allocation was used to facilitate similar characteristics between groups at baseline, groups were compared for baseline differences using different statistical analyses. Fishers’ exact test was conducted to analyze differences among groups for health characteristics. Significance was set at $\alpha \leq .05$. Between group differences of potential confounding factors of daily pre- and post-test pain, mental fatigue, and physical fatigue levels were analyzed each by one-way analysis of variance (ANOVA).

Group differences on pre-tests were analyzed using ANOVA and multivariate analysis of variance (MANOVA). Prior to all analyses, model assumptions of homogeneity of variance and
covariance and normality of data distribution analysis were assessed. Brown and Forsythe’s test was used to examine univariate homogeneity of variance and Box’s M test was used to analyze multivariate homogeneity of covariance. Significance for violation of the model assumption was set at $\alpha \leq .01$. Univariate normality of data were analyzed using Shapiro-Wilks test with significance set at $\alpha \leq .01$ and box plots to identify outlying values. Significant multivariate outliers were detected by Mahalanobis distance, with a Chi Square statistical significance of a model violation at $\alpha \leq .01$. Although MANOVA is robust to violations of normality (Mardia, 1971), and model assumptions can be presumed to be met with fairly equal group sizes (Leech, Barrett, & Morgan, 2012), analyses were conducted with and without outliers to determine if results would be altered.

Pre-test differences between groups on the independent construct of falls efficacy (FES-I) were analyzed via a one-way ANOVA with a significance set at $\alpha \leq .05$. The FTSST was also analyzed separately considering that 12 participants were unable to complete a chair stand on the pre-test, which would result in a large amount of missing data if this variable was included in a MANOVA. Software constraints for the instrumented CTSIB resulted in a full data set including only 18 of the 33 older adults in the study if conducted as a (MANOVA). Therefore, multiple one-way ANOVAs were conducted to determine if there were pre-test differences on the FTSST, and postural control variables [sway during conditions of eyes open (EO), eyes closed (EC), eyes open on foam (EOF), eyes closed on foam (ECF)]. Statistical significance for each ANOVA was set at $\alpha \leq .05$. Finally, three separate multivariate analyses of variance (MANOVAs) were conducted to analyze differences on pre-tests between groups among the constructs with statistical significance set at $\alpha \leq .10$. A bonferonni correction was applied for follow-up analyses. Construct groupings were as follows:
- Mobility (SPPB, TUG)
- Balance (tandem, FRT)
- Gait (gait speed, FGA)

Following analyses of pre-tests for baseline differences, statistical analyses for the effects of the intervention were conducted. Model assumptions were also checked prior to analyses. A repeated-measures ANOVA was conducted on the independent construct of falls-efficacy (FES-I) as well as the FTSST with statistical significance set at $\alpha \leq .05$. Multiple repeated-measures ANOVAs were conducted to capture data available in each of the postural control assessments. An experiment-wide significance level was set at $\alpha \leq 10$ for each set of repeated measures. The liberal alpha level was chosen as in a prior experiment on BBTW (Widener et al., 2009b) considering risking a type I error in a low risk intervention is less of an issue clinically compared to missing a potentially useful treatment among individuals with mobility disability. The bonferroni correction was applied for each repeated-measures ANOVA with a significance set at $\alpha \leq .025$.

Finally, three separate repeated-measures MANOVAs were conducted on the similar constructs (mobility, balance, and gait) each with significance set at $\alpha \leq .10$. In the event the overall MANOVA was significant, the bonferonni correction was applied for follow-up analyses as $[\alpha \leq .10/\text{number of dependent variables}]$. Effect size was calculated as $\eta^2$. A small effect size was defined as .01, medium effect size as .06, and large effect size as .14 (Leech, Barrett, & Morgan, 2015). Observed power was also estimated.
Chapter IV

Results

Participant Information

The purpose of this investigation was to determine the effect of BalanceWear®, worn for 5 days, on mobility, gait, balance, postural control, and falls efficacy in balance and mobility limited adults over the age of 65 years residing in a retirement community. Residents were recruited from three retirement community campuses under the same administration; resulting in 9-14 participants per facility. Thirty-nine older adults originally volunteered to participate in this investigation and met the inclusion and exclusion criteria. Of those volunteers, two withdrew prior to the pre-tests conducted on day one of the investigation. Three participants had issues with pain inhibiting their mobility during the investigation, unrelated to the intervention. Two participants were in the weighted group (WG) and one participant was in the sham-weight group (SWG). Due to exclusion criteria of pain exacerbated by activity, analyses were conducted without these participants. Finally, during day five post-testing, one participant from the sham-weight group (SWG) stated she had been practicing the pre-test activities performed since the first day in order to improve her performance on the day five assessments. Data were analyzed without this participant since greater frequency of practice can improve performance (Nakamura, Tanaka, Yabushita, Sakai, & Shigematsu, 2007). This resulted in an entire sample of 33 participants (SWG = 16, WG = 17).

Participants age ranged from 68 to 96 years with the average age of the sample at 86.00 (6.05) years. Thirty-three percent of the participants were male. Eighty-five percent of the older adults in this sample used an assistive device during daily activities. Sixty-seven percent used a
walker, 18% used a cane, and 15% did not use any assistive device regularly. Based on information gathered from the health history questionnaire and the comorbidity index, there were no differences between groups for history of cardiovascular disorders, joint or bone disorders, or impaired sensation. The WG had an approximately three-times greater history of falls compared to the SWG (see Table 1). There were no non-responders to the BBTW intervention in the WG. Participants in the WG were weighted, on average, with 1.24 lbs (0.56 kg), which is less than 1.00% of the average body weight. Only three participants were given a lumbosacral orthotic with the BBTW intervention.

Table 1

<table>
<thead>
<tr>
<th>Demographic Variables</th>
<th>Sham-Weighted Group</th>
<th>Weighted Group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 16)</td>
<td>(n = 17)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>85.25 (6.89)</td>
<td>86.76 (5.24)</td>
<td>.48</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>161.71 (9.50)</td>
<td>161.66 (9.37)</td>
<td>.88</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>72.76 (18.54)</td>
<td>70.03 (26.34)</td>
<td>.69</td>
</tr>
<tr>
<td>Male (n)</td>
<td>3</td>
<td>8</td>
<td>.26</td>
</tr>
<tr>
<td>Female (n)</td>
<td>13</td>
<td>9</td>
<td>.26</td>
</tr>
<tr>
<td>Walker (n)</td>
<td>9</td>
<td>13</td>
<td>.28</td>
</tr>
<tr>
<td>Cane (n)</td>
<td>4</td>
<td>2</td>
<td>.69</td>
</tr>
<tr>
<td>No device (n)</td>
<td>3</td>
<td>2</td>
<td>.34</td>
</tr>
<tr>
<td>Cardiovascular Disorders (n)</td>
<td>9</td>
<td>15</td>
<td>.06</td>
</tr>
<tr>
<td>Joint/Bone Disorders (n)</td>
<td>13</td>
<td>11</td>
<td>.44</td>
</tr>
<tr>
<td>Fall History (n)</td>
<td>3</td>
<td>10</td>
<td>.01*</td>
</tr>
<tr>
<td>Impaired Sensation (n)</td>
<td>5</td>
<td>5</td>
<td>.72</td>
</tr>
</tbody>
</table>

*Note. Age, height, and weight presented as mean (SD). Other variables represented as number of participants with condition.* Fisher’s exact test, *p* ≤ .05.
Functional and Falls-Efficacy Baseline Differences

Baseline differences on pre-tests were analyzed between groups. Functional variables were grouped into similar constructs (mobility, balance, gait) and conducted as three separate repeated measures multivariate analyses of variance (MANOVA). Analyses revealed that there were no differences between the SWG and WG on the three pre-test construct groupings ($p \geq .10$). Multiple one-way ANOVAs on postural control with the bonferroni correction indicated no between-group differences on the pre-tests ($p \geq .025$). One-way ANOVA revealed no baseline group differences on falls-efficacy score ($p \geq .05$). Functional and falls efficacy measures are reported in Table 2.

Pain, mental fatigue, and physical fatigue ratings were analyzed for between group differences by one-way ANOVAs to accounting for these being potential confounding variables. There were no differences on these measures before and after functional testing on each day between groups ($p \geq .05$). Refer to Table 3 for results.
Table 2.

### Functional and Falls Efficacy Measures

<table>
<thead>
<tr>
<th></th>
<th>Sham-Weighted Group (n = 16)</th>
<th>Weighted Group (n = 17)</th>
<th>Interaction (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
</tr>
<tr>
<td><strong>Mobility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPPB (au)</td>
<td>5.94 (2.32)</td>
<td>5.94 (2.52)</td>
<td>5.63 (2.63)</td>
</tr>
<tr>
<td>TUG (s)</td>
<td>17.80 (8.73)</td>
<td>15.15 (5.27)</td>
<td>19.25 (10.15)</td>
</tr>
<tr>
<td>FTSST (s)</td>
<td>21.61 (7.32)</td>
<td>18.02 (8.03)†</td>
<td>20.24 (7.36)†</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = 21</td>
<td></td>
</tr>
<tr>
<td><strong>Balance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FRT (cm)</td>
<td>20.98 (5.76)</td>
<td>20.58 (8.27)</td>
<td>20.58 (8.43)</td>
</tr>
<tr>
<td>Tandem (s)</td>
<td>6.59 (8.33)</td>
<td>8.35 (9.04)</td>
<td>5.13 (7.85)</td>
</tr>
<tr>
<td><strong>Gait</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GS (m/s)</td>
<td>0.61 (0.26)</td>
<td>0.65 (0.18)</td>
<td>0.63 (0.19)</td>
</tr>
<tr>
<td>FGA (au)</td>
<td>14.50 (5.88)</td>
<td>15.38 (5.24)††</td>
<td>13.67 (4.42)††</td>
</tr>
<tr>
<td><strong>Postural Control</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EO (m²/s⁴)</td>
<td>0.07 (0.05)</td>
<td>0.06 (0.06)</td>
<td>0.12 (0.17)</td>
</tr>
<tr>
<td></td>
<td>n = 33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC (m²/s⁴)</td>
<td>0.24 (0.30)</td>
<td>0.11 (0.11)</td>
<td>0.40 (1.24)</td>
</tr>
<tr>
<td></td>
<td>n = 33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EOF (m²/s⁴)</td>
<td>0.34 (0.28)</td>
<td>0.29 (0.30)</td>
<td>0.30 (0.19)</td>
</tr>
<tr>
<td></td>
<td>n = 32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECF (m²/s⁴)</td>
<td>1.22 (0.98)</td>
<td>0.60 (0.59)</td>
<td>0.49 (0.29)</td>
</tr>
<tr>
<td></td>
<td>n = 18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FES-I (au)</td>
<td>37.73 (9.12)</td>
<td>39.27 (13.68)</td>
<td>33.67 (7.41)</td>
</tr>
</tbody>
</table>

**Note.** Values presented as mean (SD). SPPB = Short Physical Performance Battery; au = arbitrary units; TUG = Timed Up and Go; FTSST = Five-Times Sit-to-Stand Test; GS = Gait Speed; FRT = Functional Reach Test; FGA = Functional Gait Assessment; FES-I= Falls Efficacy Scale-International; EO = postural sway eyes open on a stable surface; EC = postural sway eyes closed on a stable surface; EOF = postural sway eyes open on a foam surface; ECF = postural sway eyes closed on a foam surface. No significant difference between groups on pre-test scores, p ≥ .05. *Indicates significant group x time interaction on pre- to post- tests analyzed by repeated measures multivariate analysis of variance, p ≤ .10. **Indicates significant group x time interaction on follow-up repeated measures analyses, p ≤ .05. †Indicates significant main effect of time on repeated measures analysis of variance, p ≤ .10. ††Indicates significant simple effect of time on repeated measures analysis of variance, p ≤ .05.
Table 3.

Pain and Fatigue Levels Before and After Testing Day 1 and Day 5

<table>
<thead>
<tr>
<th></th>
<th>Sham-Weighted Group (n = 16)</th>
<th>Weighted Group (n = 17)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Day 1 Testing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre Pain</td>
<td>0.25 (0.77)</td>
<td>0.24 (0.75)</td>
<td>.96</td>
</tr>
<tr>
<td>Post Pain</td>
<td>0.00 (0.00)</td>
<td>0.47 (1.70)</td>
<td>.29</td>
</tr>
<tr>
<td>Pre Mental Fatigue</td>
<td>0.56 (1.21)</td>
<td>0.35 (0.86)</td>
<td>.57</td>
</tr>
<tr>
<td>Post Mental Fatigue</td>
<td>0.44 (1.75)</td>
<td>1.24 (2.14)</td>
<td>.25</td>
</tr>
<tr>
<td>Pre Physical Fatigue</td>
<td>1.25 (1.84)</td>
<td>1.59 (2.32)</td>
<td>.65</td>
</tr>
<tr>
<td>Post Physical Fatigue</td>
<td>3.25 (2.18)</td>
<td>2.12 (2.47)</td>
<td>.87</td>
</tr>
<tr>
<td><strong>Day 5 Testing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre Pain</td>
<td>1.56 (3.22)</td>
<td>2.12 (2.96)</td>
<td>.61</td>
</tr>
<tr>
<td>Post Pain</td>
<td>0.44 (1.21)</td>
<td>1.53 (2.67)</td>
<td>.15</td>
</tr>
<tr>
<td>Pre Mental Fatigue</td>
<td>0.81 (1.64)</td>
<td>0.24 (0.66)</td>
<td>.19</td>
</tr>
<tr>
<td>Post Mental Fatigue</td>
<td>0.81 (1.91)</td>
<td>0.18 (0.53)</td>
<td>.20</td>
</tr>
<tr>
<td>Pre Physical Fatigue</td>
<td>2.00 (2.31)</td>
<td>1.35 (1.66)</td>
<td>.36</td>
</tr>
<tr>
<td>Post Physical Fatigue</td>
<td>3.38 (2.03)</td>
<td>2.71 (1.49)</td>
<td>.29</td>
</tr>
</tbody>
</table>

*Note.* Pre indicates values on a 0 – 10 scale before indicated day of testing, post indicates values on a 0 – 10 scale after indicated day of testing. No differences between groups on measures as analyzed by one-way analyses of variance, *p* ≥ 0.05.
Functional and Falls Efficacy Pre- to Post-test Results

Mobility assessments. The set of mobility variables that were analyzed as a repeated measures MANOVA included the Short Physical Performance Battery (SPPB) and Timed Up and Go (TUG). Results revealed a significant group x time interaction ($F[2, 29] = 2.54, p = .096$). Follow-up univariate analyses indicated a significant group x time interaction on the SPPB assessment only ($F[1, 30] = 4.87; p = .04$). Scores increased 1.25-points in the WG, while scores remained unchanged from pre- to post-test among the SWG (see Figure 1). Finally, follow-up univariate analyses revealed there was no group x time interaction on the TUG ($F[1, 30] = 0.02, p = .89$) and both groups improved by approximately 2.50 s after the intervention (see Figure 2).

A repeated measures ANOVA on the Five-Times Sit-to-Stand Test (FTSST) was conducted. There was one statistical outlier in the SWG that took 87.00 s to perform the FTSST, which was two times greater than the next highest value in either group; therefore, this outlier was removed from analyses. Results indicated there was no group x time interaction on the FTSST ($F[1, 17] = 0.14, p = .72$). However, there was a significant main effect of time ($F[1, 17] = 9.02, p = .01$). The WG improved by 23% and the SWG improved by 17% on the FTSST (see Figure 3).
Figure 1. Short Physical Performance Battery (SPPB) scores in arbitrary units (au) between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. 

**Indicates significant group x time interaction on repeated measures analysis of variance, $p \leq .05$. 

*Pre-SPPB  
Post-SPPB*
Figure 2. Timed Up and Go (TUG) in seconds between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; \( p \geq .05 \).
Figure 3. Five-Times Sit-to-Stand Test (FTSST) in seconds between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. †Indicates significant time effect on repeated measures analysis of variance, $p \leq .05$. 
**Balance assessments.** The set of balance variables that were analyzed as a repeated measures MANOVA included tandem stance and the Functional Reach Test (FRT). Results revealed there was not a significant group x time interaction on the set of balance variables ($F[2, 27] = 0.05$, $p = .95$). There were also no significant main effects of group ($F[2, 27] = 0.16$, $p = .86$) or time ($F[1, 27] = 1.17$, $p = .33$). Both groups similarly increased tandem stance time between pre- and post-tests (see Figure 4) and did not change in FRT distance (see Figure 5).

*Figure 4.* Tandem stance time in seconds between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; $p \geq .05$. 
Figure 5. Functional Reach Test (FRT) in centimeters between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; $p \geq .05$.

**Gait assessments.** The set of gait variables that were analyzed as a repeated measures MANOVA included gait speed and the Functional Gait Assessment (FGA). Results were conducted without one multivariate outlier. This outlier had the lowest score on all of the pre- and post-tests. Results revealed there was no group x time interaction ($F[2, 28] = 0.82, p = .45$), yet there was a moderate effect size ($\eta^2 = .06$) with results favorable for the WG, improving 9%
compared to 6% in the SWG. There was not a main effect of group ($F[2, 28] = .26, p = .77$) however, there was a significant main effect of time ($F[2, 28] = 4.32, p = .02$).

Follow-up univariate analyses on the main effect of time indicated a trend towards significance in gait speed ($F[1, 29] = 3.81, p = .06$; see Figure 6) and significant simple effect of time for the FGA ($F[1, 29] = 8.44, p = .01$; see Figure 7). Gait speed improved in the WG by 0.06 m/s and the SWG improved by 0.04 m/s. The WG improved in the FGA by 14% and the SWG improved by 6%.

*Figure 6.* Gait speed in m/s between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. Time effect on repeated measures analysis of variance, $p = .06$. 
Figure 7. Functional Gait Assessment (FGA) scores in arbitrary units (au) between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. ††Indicates significant time effect on repeated measures analysis of variance, \( p \leq .05 \).
**Postural control assessments.** Variables included in the postural control analyses on the modified Clinical Test of Sensory Interaction on Balance (mCTSIB) were postural sway eyes open (EO), eyes closed (EC), eyes open on foam (EOF), and eyes closed on foam (ECF). These were conducted as four, separate repeated measures ANOVA. Homogeneity of covariance was violated with and without outliers for EO and EC measures on a stable surface, but tenable for EOF and ECF measures. Results indicated there was not a significant group x time interaction for EO ($F[1, 31] = 1.06, p = .31$). Main effects of group ($F[1, 31] = 0.83, p = .37$) and time ($F[1, 31] = 2.44, p = .13$) for EO were also not significant, although there was a moderate effect size for time ($\eta^2 = .07$). The WG decreased sway by 0.06 m$^2$/s$^4$ and the SWG decreased by 0.01 m$^2$/s$^4$, although the variability was three times larger in the WG pre-test compared to the SWG pre-test (see Figure 8). Analysis of the EC condition indicated there was not a significant group x time interaction ($F[1, 29] = 0.31, p = .59$; see Figure 9). Main effects of group ($F[1, 31] = 0.19, p = .67$) and time ($F[1, 29] = 1.89, p = .18$) were not significant, however there was a moderate effect size for time ($\eta^2 = .06$). The WG improved sway by 0.31 m$^2$/s$^4$ and the SWG improved by 0.13 m$^2$/s$^4$ however, there was much greater variability again in the WG.
Figure 8. Postural sway eyes open (EO) in m²/s⁴ between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; $p \geq .05$. 
Figure 9. Postural sway eyes closed (EC) in m²/s⁴ between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; \( p \geq .05 \).

Repeated measures ANOVA for EOF indicated there was no group x time interaction \((F[1, 30] = 0.02, p = .90)\). Main effects of group \((F[1,30] = 0.48, p = .50)\) and time \((F[1, 30] = 1.87, p = .18; \text{see Figure 10})\) for EOF were also not significant. Repeated measures ANOVA for ECF indicated there was no group x time interactions of ECF \((F[1, 16] = 4.11, p = .06)\), but effect size was large \((\eta^2 = .20)\) and results trended towards significance \((p = .06)\). The SWG
demonstrated a decrease in postural sway during ECF by 0.62 m²/s⁴, whereas sway increased in the WG by 0.10 m²/s⁴. Main effects of group (F[1, 16] = 1.48, p = .24) and time (F[1, 16] = 2.13, p = .16; see Figure 1) for ECF were also not significant, however, there was a moderate effect size for the main effect of group (η² = .08) and large effect size for the main effect of time (η² = .12). Notably, the SWG pre-test sway was more than two-times greater than the WG and variability was high.
Figure 10. Postural sway eyes open on foam (EOF) in m²/s⁴ on instrumented modified Clinical Test of Sensory Interaction on Balance between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; \( p \geq .05 \).
Figure 11. Postural sway eyes closed on foam (ECF) in m$^2$/s$^4$ on instrumented modified Clinical Test of Sensory Interaction on Balance between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; $p \geq .05.$

Falls-efficacy assessment. A repeated measures ANOVA was utilized to determine group x time differences on the Falls-Efficacy Scale-International (FES-I). There was no significant group x time interaction ($F[1, 28] = 0.15$). Main effects of group ($F[1, 28] = 1.91, p = .18$) and time ($F[1, 28] = 1.13, p = .30$) also were not significantly different. Both groups similarly increased by approximately two points in FES-I scores over time (see Figure 12).
Figure 12. Falls Efficacy Scale-International (FES-I) scores in arbitrary units (au) between weighted group (WG) and sham-weighted group (SWG) after 5 days of BalanceWear®. No significant effects on repeated measures analysis of variance; $p \geq .05$. 
Chapter V
Discussion

The purpose of this investigation was to determine the effect of BalanceWear®, worn for 5 days, on mobility, gait, balance, postural control, and falls efficacy in balance and mobility limited adults over the age of 65 years residing in a retirement community. The investigation found that there was only a statistically significant group x time interaction for SPPB; the WG improved by 18%, while the SWG had no improvement. Assessments of balance, gait, postural control, and falls efficacy did not result in statistically significant differences between groups over time. However, FTSST and FGA significantly improved for both groups between pre- and post-test with moderate to large effect sizes and greater mean changes in the WG. Gait speed had clinically significant improvements over time in both groups with a trend towards statistically significant improvement over time. Finally, ability to perform a chair stand without the use of the upper extremities and ability to stand for at least 5 s on a compliant surface improved in the WG compared to the SWG.

Although statistical changes are important, it is also essential to evaluate clinically significant changes as well as effect sizes. Whereas the minimal detectable change is the minimal amount of change between a test conducted at two different time points that indicates a true statistical difference, other values to determine noticeable clinical significance are also useful (Huang et al., 2011). Criteria of minimal and substantial change are recommended to assess the clinical significance of an intervention, rather than solely the statistical significance (Perera et al., 2006). A minimally clinically significant change is defined as having a small effect size (Cohen’s $d = 0.2, \eta^2 = .01$), whereas a substantial change is defined as having a moderate effect size (Cohen’s $d = 0.8-1.0, \eta^2 = .06$) (Leech et al., 2015; Perera et al., 2006). Both are attributed to
a level of change in a clinical assessment where a person or a proxy to that person, notices a significant improvement in function (Haley & Fragala-Pinkham, 2006). Considering this investigation, a substantial clinical change was noted in the SPPB scores of the WG only while a greater clinical change was noted in the WG compared to the SWG for gait speed. This is the first investigation analyzing the effects of BalanceWear® on mobility, balance, gait, postural control, and falls-efficacy over multiple days as well as among older adults.

**Mobility assessments**

Results from this investigation support the hypothesis that mobility improved over time in the WG compared to the SWG after 5 days of wearing strategically weighted BalanceWear® for 4 hours per day. Initial scores on the SPPB assessment of functional ability for both groups averaged 6 out of 12, indicating a high risk of falls (Guralnik et al., 2000). After only 5 days of wearing BalanceWear®, the WG significantly improved in SPPB score by 1.25 units, which is in the range of substantial clinical improvement of 0.4 - 1.5 points (Kwon et al., 2009; Perera et al., 2006), and indicates a reduction in risk of falls (Guralnik et al., 2000). Comparatively, the SWG scores remained unchanged. Considering lower SPPB scores are related to increased risk of morbidity, mortality, institutionalization, and falls (Guralnik et al., 1995b; Guralnik et al., 1994; Guralnik et al., 2000) improvement in the WG only indicates a potential clinical reduction in risks associated with lower SPPB scores. Furthermore, a score of 4-6, as in the SWG post-test, is considered severely impaired in mobility, while a score of 7-9, approximating the WG post-test, is considered moderately impaired mobility (Guralnik et al., 2000). The relative risk of mobility disability is 2-times greater in individuals scoring in the range of 4-6 versus 7-9 points on the SPPB. Longitudinal studies would be beneficial to determine if the increase in SPPB score in
the WG, as a result of wearing BalanceWear® for 4 hours a day over 5 days, decreases longitudinal risks of morbidity, mortality, institutionalization, and falls among older adults.

Exercise-based interventions also have demonstrated effectiveness in improving SPPB scores among older adults. A prior investigation found that 16 weeks of high and low velocity resistance exercise resulted in improvements in SPPB score by 1.4 – 1.8 units (Reid et al., 2014). Another investigation established that older community-dwelling adults in a self-administered, 6-month long, DVD exercise group improved by 0.52 points on the SPPB compared to a slight decline in a control group (McAuley et al., 2013). Importantly, the improvements of 0.52 points and 1.4 points in SPPB scores were a result of longitudinal exercise interventions, compared to our investigation where the WG improved by 1.25 points in SPPB scores solely from wearing BalanceWear® for 4 hours per day over a 5-day time period. This indicates that short-term use of strategically weighted BalanceWear® may be as effective as long-term exercise in improving mobility as measured by SPPB score.

While SPPB scores improved greater in the WG compared to the SWG, FTSST scores improved in both groups, with a greater mean improvement in the WG. Performance on the FTSST is indicative of both lower extremity function (Bohannon, 1995) and balance (Whitney et al., 2005). The WG improved in time to complete the FTSST by 4.59 s and the SWG improved by 3.59 s. Both groups exceeded the minimal detectable change for the FTSST among older females of 2.50 s (Goldberg, Chavis, Watkins, & Wilson, 2012). Additionally, the WG had considerable improvements in the number of participants that were able to complete 5 sit to stands without upper extremity support after 5 days of wearing BalanceWear®. Initially, six participants in each group were unable to perform the task. On the post-test, 33% of individuals who were unable to perform the task on pre-test were able to in the post-test in the WG.
Conversely, no participants in the SWG who were unable to perform the FTSST on the pre-test were able to on the post-test. Difficulty completing a chair stand without arm support is suggestive of risk of multiple falls in the following year (Nevitt et al., 1989).

Few studies evaluate change in ability to perform a chair stand without upper extremity support after an intervention (Alexander et al., 2001; Olivetti et al., 2007). However, of the studies found, change in ability to perform a chair stand without upper extremity support was favorable for a 2-week weight bearing strength training program (Olivetti et al., 2007) as well as a 12-week functional, task-specific exercise training regimen (Alexander et al., 2001). The 2-week program yielded an improvement in ability to stand from a chair of a lower height (Olivetti et al., 2007), which we are unable to compare to our results as we did not assess chair stands from different height surfaces. The task-specific exercise program resulted in 21% more participants being able to complete a chair stand without upper extremity support versus a 15% improvement in ability among a control group that received a flexibility intervention (Alexander et al., 2001). Comparatively, 5 days of the BBTW intervention resulted in 33% more individuals in the WG able to complete five chair stands without upper extremity support compared to no improvement in the SWG. This indicates that the BBTW intervention may be as or more effective than a 12-week task specific exercise program in improving ability to stand up from a chair without upper extremity support. Further research is necessary to test this hypothesis as well as implications of a decrease in risk of multiple falls related to improvements in ability to stand from a chair after 5 days of wearing BalanceWear® for 4 hours per day.

Although the WG had greater mean improvements in the FTSST, both groups yielded similar improvements in TUG scores by approximately 2.50 s over the 5-day intervention. Outcomes for this investigation are in contrast to another investigation resulting in significant
improvements on same day TUG times among adults with multiple sclerosis (MS) administered BBTW versus controls who had standard weight placement (Widener et al., 2009b).

Inconsistencies between results may be due to differences in the time periods of the testing, whether the BalanceWear® garment was donned during post-testing, or the sample populations. The current investigation had a sample of older adults without progressive neurologic impairments while the prior investigation had a sample of adults with MS. Furthermore, in the study among adults with MS, participants were post-tested on the same day as the pre-test and while wearing the BalanceWear®. In our investigation, participants had been wearing the BalanceWear® for 5 days but were not wearing the BalanceWear® for the post-testing. Lastly, the control group had standard weight placement of 1.5% of their body weight versus our control group that received sham weights. It is unclear if results would have been different in our study if participants had the BalanceWear® on for post-testing, had standard weight placement, or were tested on the same day.

Investigations on changes in TUG times among older adults undergoing various interventions have found differing results. A 6-month intervention of the OTAGO exercise program versus standard care among two groups of older adults who have fallen revealed no change in TUG performance, yet a reduction in falls over the 6 months of the program for the treatment group (Liu-Ambrose et al., 2008). Conversely, a similar, 4-month multi-component exercise program resulted in improvements in TUG time by 3.00 s compared to 2.00 s in a psychomotor group and no change in a control group among older, physically active adults (Freiberger, Menz, Abu-Omar, & Rutten, 2007). The improvements in TUG times among the psychomotor and exercise intervention groups over 4 months are similar to those seen in the WG and SWG over our 5-day intervention. Further research would be beneficial to determine
differences in functional abilities among a variety of sample populations with BBTW versus controls using similar study methodologies. This would help determine in which populations and functional tasks BBTW may be most useful as well as carryover and abilities with and without wearing the BalanceWear®.

**Balance assessments**

Results indicate that BBTW does not have an effect on functional reach distance or tandem stance time measures of balance among older adults. Furthermore, effect sizes were low. FRT was generally unchanged for both groups and tandem stance similarly increased for both groups by approximately 2.00 s. Additionally, pre- and post-test tandem stance times for both groups remained < 10.00 s, which is indicative of an increased risk of falls among older adults (Stevens & Phelan, 2013).

Outcomes from this investigation are in contrast to a prior investigation resulting in same day improvements on the sharpened Romberg test (similar to tandem stance) after BBTW in adults with MS (Widener et al., 2009a). Differences may be attributed to methodologies. The prior study population consisted of adults with MS with the BalanceWear® on, while the current investigation was among older adults without a progressive neurological disorder who were not wearing BalanceWear® during the assessments. Also, in the prior investigation, subjects served as their own controls, whereas the current investigation had a control group. Lastly, the sharpened Romberg test was performed with arms across the chest and total time was summed with a trial of each foot in front. In this investigation, the arms were free and one trial of tandem stance was conducted with the participants’ preferred foot in front. It would be useful to determine if there are differences in tandem stance time with and without wearing BalanceWear® during testing and after a number of days of wearing it regularly. This may help
determine if BalanceWear® has an effect on specific balance measures over time only when
donned versus doffed.

Among balance-specific tests, tandem stance time similarly improved for both groups,
however FRT remained unchanged. An investigation among older adults participating in either a
low-intensity supervised exercise program or an unsupervised home-based flexibility exercise
program demonstrated no change in the FRT over the course of the intervention, but a significant
increase in tandem stance for the supervised group and a decrease in tandem stance for the
control group (Brown et al., 2000). In contrast, another investigation on the impact of the
Alexander Technique on improving body mechanics indicated improvements in FRT in an
experimental group compared to a control group (Dennis, 1999). This indicates that both tandem
stance and FRT performance improvements may be affected by the specifics of the intervention;
where it appears flexibility based programs improve tandem stance, but body mechanics based
programs improve FRT. The BBTW intervention does not address flexibility or body mechanics,
which may be why there was no change in tandem stance or FRT in this investigation.

It should also be considered that while FRT is a measure of balance (Duncan et al.,
1990), there are limitations to performing a forward reach. Restrictions include tightness in the
trunk, arms, and lower extremities, which are common among older adults and associated with
functional abilities (Beissner, Collins, & Holmes, 2000). Investigations indicate that the FRT is
most influenced by movement at the trunk, rather than displacement of the limits of stability
(Jonsson et al., 2003) and that FRT distance is not able to discriminate fall history among older
adults (Thomas & Lane, 2005b). Considering these confounding issues, the FRT may not have
been the most sensitive test to assess balance in this population of mobility limited older adults.
Gait assessments

While there was no significant group x time interaction on the set of gait variables, moderate effect sizes were noted with more clinically significant changes among the WG compared to the SWG after wearing BalanceWear® for 5 days. A significant time effect was observed for both groups on the FGA and trends towards significance were seen on gait speed. The WG demonstrated greater mean improvements compared to the SWG in both assessments. The SWG improved by 0.04 m/s, which is in lower end of the small meaningful change range of 0.03 – 0.06 m/s for gait speed (Kwon et al., 2009; Perera et al., 2006). The WG improved by 0.06 m/s, which is at the high end of the range (0.03 – 0.06 m/s) for small meaningful clinical changes in gait speed (Kwon et al., 2009; Perera et al., 2006).

Exercise programs with various components have resulted in increases in gait speed ranging from 0% - 16%, with an average increase of 5% (VanSwearingen, Perera, Brach, Wert, & Studenski, 2011a). In our investigation, the WG improved by 9% in gait speed compared to a 6% improvement in the SWG. Results of our study are congruent with an investigation among adults with MS who received BBTW or standard weighting laterally at the trunk. Both groups demonstrated improvements in usual gait speed after BBTW when compared to unweighted controls (Widener et al., 2009a). The BBTW group improved by 9%, while the standard weighting group improved by 8%, compared to no change in a control group. These results suggest that increasing sensory input at the lateral trunk, via weighting or even sham weights, may result in improvements in gait speed. It should be distinguished that in both studies, BBTW resulted in greater mean improvements in gait speed compared to the standard or sham weighted groups. Future research is necessary to determine if improvements in gait speed as a result of
increased sensory input to the lateral trunk or BBTW translates to lowering associated risks of slow gait speed (Montero-Odasso et al., 2005).

While clinically, but not statistically significant changes were observed among both groups in gait speed, the converse was true for the FGA. There was a significant time effect for both groups and a 14% improvement in scores for the WG compared to a 6% improvement in scores for the SWG. However, while the WG improved by 2.3 points, neither group improved by the 4-point minimally clinically important difference considered for the FGA (Beninato, Fernandes, & Plummer, 2014). Mean scores for both groups (< 17 points) were also lower than the cut-off score of 22/30 for fall risk (Wrisley & Kumar, 2010) and the published normative values of 20.8 for adults in the ninth decade of life (Walker et al., 2007). Scores in our sample may be lower than average considering only older adults with mobility disability were included in our study. The effect of interventions on FGA scores among older adults in an experimental versus a control group has not been investigated, therefore we cannot compare the results of our study to other investigations.

**Postural control assessments**

There were no group x time interactions between postural control measures on the instrumented mCTSIB. However, the WG demonstrated greater mean improvements for EO, EC, and EOF compared to the SWG and effect sizes were moderate. Conversely, in the ECF condition, effect sizes were large and the SWG improved while the WG declined in postural control. Of note, the number of people who were able to maintain ECF for 5.00 s improved by 100% in the WG and 33% in the SWG.

Limitations existed in the software for this instrumented test, decreasing the amount of valid data that were available to analyze. Specifically, data were only processed and valid if the
test was conducted for at least 5.00 s. Therefore, if a subject did not maintain a position for at least 5.00 s, no value would be calculated for postural sway in that condition. For example, the condition most often not completed was ECF. If an individual could stand for just 1.00 s in the ECF condition on the pre-test, but 4.00 s in the ECF condition on the post-test, neither test would be registered by the program and the improvement in ability would not be available for analyses. This may have led to an invalid sample of postural control measures for data analyses. Also taking into consideration the large variability of the available data, we are cautious in analyzing solely the postural sway values.

A recent study in people with MS and healthy controls analyzed postural control variables including non-linear measures of movement variability via a force plate. They found that postural control became more normalized in people with MS after BBTW (Hunt, Widener, & Allen, 2014). Comparatively, potential reasons for lack of differences statistically in the postural control data we collected may be due to how postural control was measured. The mobility lab system we used measured postural sway area, and was not capable of quantifying sway variability. Considering that increased postural sway is associated with a greater risk of falls (Laughton et al., 2003), future research may be beneficial to analyze postural sway via a force plate as well as changes in sway variability among older adults after BBTW.

Regardless of the limitations in the equipment we used to measure postural control, we found that there was an improvement in ability to maintain the ECF position among the WG compared to the SWG. Of the seven individuals unable to complete ECF for 5.00 s to obtain data on the pre-test, all were able to complete the ECF condition on the post-test. In contrast, of the three adults who were unable to complete the pre-test ECF in the SWG, only one was able to complete that condition on the post-test. This indicates an improvement in postural control
among the WG via either a potential increase in the ability to integrate vestibular information (Allum & Carpenter, 2005), or an improvement in neuromuscular responses to sensory input. Future investigations would be useful to gather time a stance is maintained as well as sway.

Standing on a compliant surface, eyes closed, decreases accurate somatosensory and visual input, therefore an individual must rely on vestibular input for sensory feedback on the orientation of the body in space (Cohen et al., 1993). Subsequently, appropriate neuromuscular responses based on sensory input are also necessary to maintain postural control (Horak, 2006). While it is unclear which system may have been affected by the BBTW, improvement of ability to stand on foam, eyes closed in the WG may have implications of improved function and decreased fall risk. Older adults with a history of falls are able to stand for less time on a compliant surface, eyes closed, compared to those without a history of falls (Anacker & Di Fabio, 1992). Additionally, another investigation using the mCTSIB program on the Balance Master™ (Natus Medical Incorporated; Pleasanton, CA) found that decreased ability to stand on foam with eyes closed was more indicative of future falls than the time to complete the TUG (Nitz et al., 2013). Importantly, interventions have successfully improved postural control among older adults at risk of falling. This was evident in a study on older adults at risk of falling where 81% of the individuals who received home health therapy improved the number of mCTSIB conditions they could complete upon discharge (Whitney, Marchetti, Ellis, & Otis, 2013). Considering that seven of the 10 participants who were unable to stand for at least 5.00 s on the pre-test ECF condition had a history of falls, future research should analyze if a change in ability to perform this task after BBTW impacts longitudinal falls.
Falls-Efficacy Assessment

There were no differences between groups on FES-I pre- or post-tests. In fact, both groups scored in the range of high fear of falling on the pre-test and increased by approximately 2-points on the FES-I on the post-test. This indicates a potential increase in fear of falling regardless of the intervention. We hypothesize scores may have increased due to participants completing the functional assessments without their assistive device and potentially realizing they had more balance impairments than before testing commenced. We also noted that during the investigation, participants were quickly answering the questionnaire, rather than spending time considering their answers. This may have affected the validity of the results. A systematic review found that there are numerous factors in self-reported fear of falling, including older age, suffering at least one fall, and female sex (Scheffer et al., 2008). A systematic review on the effectiveness of interventions to reduce fear of falling found that home exercise programs, multifactorial exercise programs, and group tai chi all decrease fear of falling in community-dwelling older adults (Zijlstra et al., 2007). This indicates that longitudinal exercise programs may be more effective than 5 days of the BBTW intervention in reducing fear of falling.

Finally, it should also be considered that although the WG demonstrated greater clinical improvements in SPPB and gait speed, this may not have translated to changes in fear of falling over a 5 day period. There have also been disparities noted in physical ability and perceived fall risk based on personality traits (Delbaere et al., 2010). This potential confounder could be addressed by future investigations by measuring perceived ability or perceived changes in ability in a control group versus BBTW intervention compared to actual changes in function while considering personality traits.
Justification

The intervention of 5 days of BalanceWear® appears as effective as prior investigations implementing longitudinal exercise programs (Alexander et al., 2001; McAuley et al., 2013; Reid et al., 2014; VanSwearingen, Perera, Brach, Wert, & Studenski, 2011) in inducing changes in certain assessments of mobility and gait among older adults. Although the exact mechanism of action is unclear, the premise of BBTW is to improve anticipatory and compensatory postural adjustments through strategic sensory weighting to the trunk (Widener et al., 2009b). All participants in the WG improved in their postural adjustment responses to perturbations after weighting, as determined by the therapist who developed and performed the BBTW intervention. Although the SWG did not receive weighting, they did receive the BBTW evaluation that consisted of an average of 25 perturbations. A single perturbation training session has been shown to effectively improve postural control response to an induced balance loss up to 6 months (Bhatt, Espy, Yang, & Pai, 2011b). Because of this, both groups, rather than just the WG, received perturbations to ensure that the only potential intervention differences in the intervention was the strategically weighted BalanceWear®. Although the methodologies of perturbations were different between our investigation and the prior investigation; in our investigation perturbations were applied to the trunk and hips and in the prior investigation a platform caused the perturbations at the base of support via an induced slip, there is a possibility that the SWG improved in some areas of function and balance similarly to the WG simply due to the single session of perturbation training.

Perturbation training may improve postural control by translating motor learning to similar tasks (Rose & Clark, 2000). Taking this into consideration, the BBTW evaluation position is conducted while standing with feet together and perturbations are performed at the
trunk. Although no functional assessment in this study exactly mimicked that position, similar standing positions in which feet remained static were in the mCTSIB, tandem stance, and FRT, all of which did not show any statistical differences between groups. Therefore, it is possible that the effects of the perturbations translated for both groups similarly in these static standing postural tasks.

Although the WG demonstrated improvements in perturbation responses after BBTW, the amount of time and types of activities necessary to translate those improvements to functional activities may vary. Motor learning and postural control is individualized and task specific (Green & Bavelier, 2008). Therefore, we recommended that all participants wear the BalanceWear® during the times of day they were performing the most functional activities. In mobile individuals, gait is a necessity to get from one point to another. Not including the TUG, the functional assessments that showed either statistical or greater mean improvements in the WG compared to the SWG all included gait tasks; specifically gait speed, SPPB, and FGA. In contrast, standing activities where the base of support was unchanged, such as tandem stance and FRT did not show any changes with BBTW. This suggests that wearing BalanceWear® during functional tasks likely to be performed during daily activities may result in an improvement in ability to perform those tasks. Improvements in functional tasks as compared to static postural control may be due to translational motor learning occurring with task-specific practiced tasks, with gait being a common task to perform daily activities (Lord et al., 2011). We postulate that performing daily activities with strategically weighted BalanceWear® on may have improved sensory input and postural control during those commonly performed activities. Tandem stance, standing on foam, and standing in one spot reaching anteriorly in one plane as in the FRT, are not functional activities performed on a daily basis.
Participants were told to don BalanceWear® during functional tasks. Interestingly, improvements in gait and function in the WG compared to SWG were observed on post-testing at least 8 hours after removal of BalanceWear®. This indicates that not only is BalanceWear® effective in improving functional mobility, but there is carry-over and BalanceWear® does not need to be donned at all times to improve functional abilities. Improvements in mobility, gait, and ability to maintain posture while ECF may be due to carry-over of the sensory augmentation provided by the strategically weighted BalanceWear®. Still, it is possible that some participants in the WG had carry-over, while others did not. This should be considered since the effectiveness of strategic weighting is evaluated by improvements in perturbations with BalanceWear® on, but we conducted the post-test assessments with BalanceWear® off for at least 8 hours. Anecdotal clinical evidence suggests that just as people are individuals, the amount of time carry-over of improvements in functional tasks and postural control occurs after removal of the BalanceWear® is individual (C. Gibson-Horn, personal communication, February, 6, 2014).

A difference in general carry-over effects was evident in an investigation that studied the longitudinal effects of a lumbosacral orthoses worn for 3 weeks on trunk proprioception and determined that passive trunk proprioception tested without the orthoses on improved, but active proprioception was better with the orthoses (Cholewicki, Shah, & McGill, 2006). Although we did not evaluate trunk proprioception in our investigation, we did see improvements in the intervention group on functional mobility tasks that require adequate proprioceptive sensory information to perform successfully. Consequently, it should be also taken into consideration that the SWG still received sensory input via the sham, Styrofoam® weights on the lateral trunk. This small amount of sensory input may have affected their postural stability and functional mobility. The effects of different sensory input on performance has been seen in an investigation.
comparing BBTW strategic weighting to standard weighting at the waist and a control group among adults with MS (Widener et al., 2009b). Both the BBTW and standard weight groups improved in gait speed compared to the control group, but the BBTW group was the only group that improved in TUG performance. We did not have an additional control group without any sensory input in our investigation to evaluate if the sham weights affected function. Further research would be beneficial in determining if there is a difference in postural control and functional mobility in individuals who receive different sensory inputs at the trunk as well as necessary wear time for carry-over effects.

Limitations

There are limitations that should be considered regarding the results of this study. First, although a large portion of individuals used an assistive device at baseline, all but one agreed to complete pre- and post-testing without their device. Considering participants are more familiar performing daily activities with a device, it is unclear if results would have been different if tested with and without an assistive device. This was evident where some participants scored lower than 4 on the pre-test SPPB, likely because they were asked to perform it without their assistive devices, compared to when they performed the inclusion SPPB. A future investigation may consider testing with and without an assistive device to address these potential differences.

Further considering the use of assistive devices as a limitation, the BBTW evaluation and BalanceWear® garment were applied while the participant was standing without an assistive device. This was true whether they used one or not during usual activities. However, during daily activities participants used their usual assistive device whether they were wearing the garment or not. The use of an assistive device increases the base of support, which may also vary an individual’s center of mass when standing with or without the device (Bateni & Maki, 2005).
change in center of mass with an assistive device may affect posture. For example, a person using a walker will likely have their center of mass more anterior than if they were standing upright without a walker. The BBTW intervention improves postural responses to perturbations with strategically placed weights while the participant is standing without a device. Postural responses were not reassessed while individuals were standing with their usual assisted devices. Therefore, center of mass and postural responses may have been different with or without a device. Although pre- and post-tests were conducted without the use of an assistive device, weighting without an assistive device and not reassessing postural responses with an assistive device may have affected the outcomes of the study. Furthermore, utilizing an assistive device throughout the day with the BalanceWear® on may have also affected the outcomes of this investigation. It would be beneficial to assess postural responses with and without assistive devices to determine if the use of a device changes an individuals’ responses to perturbations and weighting strategy.

Wear time of the BalanceWear® should also be considered as a potential limitation. Participants wore the vest 4 hours per day for 5 days. They did not wear the vest for at least 8 hours prior to testing. Based on the results of this investigation, it appears that this amount of wear time is adequate to promote improvements in functional activities considering the WG had greater improvements in SPPB and clinically significant increases in gait speed compared to the SWG after not wearing the BalanceWear® for at least 8 hours. These promising results also suggest that carry-over of functional improvements last at least 8 hours after removal of the BalanceWear®. Future investigations should focus on evaluating wear time needed for effect and carry-over time of those effects.
Other potential limitations to be considered include that there are numerous issues that could contribute to deficits in mobility, balance, and gait, of which postural control is only one. However, ROM, sensation, and strength were evaluated prior to the intervention and there were no differences between the two groups that were assessed prior to the study. Due unforeseen circumstances, participants in one facility were not assessed on ROM, sensation, and strength prior to the start of the study. Results also indicated similar levels of comorbidities and demographics between treatment groups. Importantly, the amount of people who reported a history of falls was 3 times greater in the WG. Although older adults with a history of falls have greater impairments in balance and mobility (Ambrose et al., 2013), there were no differences between groups on any of the assessments prior to the intervention, therefore it is unlikely that this affected the results.

We did consider that pain or fatigue may also be confounding factors in the results. Increased pain is associated with increased fall risk (Foley, Lord, Srikanth, Cooley, & Jones, 2006) and muscle fatigue results in detriments in postural control (Papa, Garg, & Dibble, 2014). While muscle fatigue was not an outcome measure, we measured pain, physical and mental fatigue before and after testing each day. However, we questioned the accuracy of this measure considering that many older adults did not admit to physical fatigue even when they appeared fatigued, or had fatigue before performing the assessments. Interestingly, very few older adults admitted to mental fatigue throughout the testing and some were offended when asked to rate their mental fatigue. The majority of older adults rated that they had no mental fatigue throughout the testing. Regardless of these potential limitations, results were consistent across groups; there were no differences in pain, mental, or physical fatigue before and after testing each day.
Finally, there were some difficulties in donning and wearing the BalanceWear® in this population of older adults regardless of group allocation. Approximately 15% of the participants required assistance donning the vest, most often due to limited shoulder mobility. Although participants were measured for BalanceWear® prior to the investigation, body habitus of a larger abdomen also caused difficulty with fit in the chest as well as complaints of the vest occasionally riding up while sitting. Individual adjustments were made to improve fit. Since the premise of BBTW is to provide sensory input to a specific part of the trunk, an ill-fitting orthotic may result in the weight on the vest being over a different portion of the trunk musculature as the garment shifts and result in changes to postural control. Based on these issues and participant feedback, Motion Therapeutics™ is developing a different BalanceWear® vest for older adults.

Conclusion

Results of this investigation found statistically and clinically significant improvements in the SPPB scores for the WG compared to the SWG. Although both groups improved in FTSST and FGA, greater mean improvements were noted among the WG. Clinically significant, but not statistically significant improvements were seen in both groups for gait speed. Finally, the WG also demonstrated improvements in ability to perform a chair stand and stand eyes closed on a compliant surface. This indicates that BalanceWear® worn for 4 hours a day for 5 days has a positive effect on mobility, gait, and postural control among balance and mobility impaired older adults.
References


Dennis, R. J. (1999). Functional reach improvement in normal older women after alexander technique instruction. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 54(1), M8-M11.


Iwata, A., Higuchi, Y., Sano, Y., Ogaya, S., Kataoka, M., Okuda, K., . . . Fuchioka, S. (2014). Quickness of trunk movements in a seated position, regardless of the direction, is more important to determine the mobility in the elderly than the range of the trunk movement. Archives of Gerontology and Geriatrics, 59(1), 107-112.


Lajoie, Y., & Gallagher, S. (2004). Predicting falls within the elderly community: Comparison of postural sway, reaction time, the berg balance scale and the activities-specific balance confidence (ABC) scale for comparing fallers and non-fallers. *Archives of Gerontology and Geriatrics, 38*(1), 11-26.


doi:0733464815570669


doi:10.1177/1524839912463576 [doi]


Appendices

Appendix A

BalanceWear® Orthotic

Reprinted with permission from MotionTherapeutics®

a. vest orthotic

b. with lumbo-sacral orthotic
## Appendix B

**Balance-Based Torso-Weighting Evaluation Form**

### E. Identify Reactive/Anticipatory Control Impairment

<table>
<thead>
<tr>
<th>BBTW Scale</th>
<th>No loss</th>
<th>Minimum loss</th>
<th>Moderate loss</th>
<th>Moderate+ Severe</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Severe, falls or complete ability to turn body</td>
</tr>
<tr>
<td>Rent response</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**Upper**
- Anterior
- Posterior
- Lateral Right
- Lateral Left
- Right Rotation
- Left Rotation

**Lower**
- Anterior
- Posterior
- Lateral Right
- Lateral Left
- Right Rotation
- Left Rotation
Appendix C

Pilot Study Institutional Review Board Approval

MEMORANDUM

TO: Jennifer Vincenzo
   Michelle Gray

FROM: Ro Windwalker
   IRB Coordinator

RE: New Protocol Approval

IRB Protocol #: 14-05-712

Protocol Title: The Effect of Balance-Based Torso-Weighting on Functional Measures and Balance in Older Adults with Mobility or Balance Impairments

Review Type: FULL IRB

Approved Project Period: Start Date: 05/23/2014 Expiration Date: 05/15/2015

May 23, 2014

Your protocol has been approved by the IRB. Protocols are approved for a maximum period of one year. If you wish to continue the project past the approved project period (see above), you must submit a request, using the form Continuing Review for IRB Approved Projects, prior to the expiration date. This form is available from the IRB Coordinator or on the Research Compliance website (http://vpred.uark.edu/210.php). As a courtesy, you will be sent a reminder two months in advance of that date. However, failure to receive a reminder does not negate your obligation to make the request in sufficient time for review and approval. Federal regulations prohibit retroactive approval of continuation. Failure to receive approval to continue the project prior to the expiration date will result in Termination of the protocol approval. The IRB Coordinator can give you guidance on submission times.

This protocol has been approved for 80 participants. If you wish to make any modifications in the approved protocol, including enrolling more than this number, you must seek approval prior to implementing those changes. All modifications should be requested in writing (email is acceptable) and must provide sufficient detail to assess the impact of the change.

If you have questions or need any assistance from the IRB, please contact me at 210 Administration Building, 5-2208, or irb@uark.edu.
Appendix D

Recruitment Fliers

*PARTICIPANTS NEEDED*

To try Balancewear

➢ Requirements:
  ○ 65 years or older, able to walk 30 feet, with balance or mobility difficulties

➢ Physical Assessments:
  *All performed HERE at Hershey*
  ○ Balance, mobility, and fall risk assessment

➢ Benefits for you:
  ○ Find out your risk of falling and if BalanceWear will work for you, for FREE!
  ○ Help out and be a part of cutting edge fall prevention research for older population!
  ○ Free BalanceWear Vest, yours to keep!

➢ Contact:
  ○ Kim Eichinger
  ○ KEichinger@countrymeadows.com
Appendix E

Country Meadows Letter of Support

September 3, 2014

Jennifer Vincenzo, PT, MPH, GCS, CHES
Ph.D. Candidate, Exercise Science
University of Arkansas

Subject: Research Project with seniors fitted with Weighted Vests

Dear Jennifer:

This will confirm that Country Meadows Retirement Communities is committed to being a sponsor of your research with seniors fitted with weighted vests.

The purpose of this project will be to evaluate how seniors with balance and ambulation problems respond to wearing micro-weighted vests. Participants will be individually fitted for a vest by a therapist trained in this function. The project will document each participant’s balance before and after the vest is introduced to him or her.

The role of Country Meadows in your project is to provide residents who will participate. We will also purchase the vests from their manufacturer. Approximately 40 vests will be needed. Finally, our senior living community in Hershey, Pennsylvania, with a population of 250, will serve as the principal location for the research study. Our representative will be Kim Eichinger, the company’s Executive Director of Fitness.

Other principal participants in the project are Genesis Rehabilitation Services, Inc. of Kennett Square, PA and Balance Wear, the supplier of the micro-weighted vests, based in California. Genesis provides physical and occupational therapy services for residents of Country Meadows. They will be represented in the research study by Dawn Beiber, OT. Cindy Horn, PT, Vice President of Balance Wear, will be on-site representing Balance Wear throughout the project.

We look forward to your cutting edge research this fall, because it has potential to offer an affordable way to help seniors with balance and ambulation problems to avoid falls that too often result in very serious injuries and even death.

Very truly yours,

G. Michael Leader
President & CEO

cc: Kim Eichinger
Mandi Block

Country Meadows Home Office
830 Cherry Drive | Hershey, PA 17033

PHONE: 717.533.2474 | FAX: 717.533.6202
www.countrymeadows.com
Appendix F
University of Arkansas Institutional Review Board Approval

October 6, 2014

MEMORANDUM

TO: Jennifer Vincenzo          Michelle Gray
    Cindy Gibson-Horn           Hasan Askari
    Heather Carabin            Andy Lesher
    Christine Tilburg

FROM: Ro Windwalker
      IRB Coordinator

RE: New Protocol Approval

IRB Protocol #: 14-09-085

Protocol Title: The Effect of Balance-Based Torso-Weighting after 1 Day, 5 Days, and 4 Months of Wear, on Functional Measures, Balance, Falls, Pain, Cognition, and Falls Efficacy in Older Adults with Mobility or Balance Impairments

Review Type: □ EXEMPT   □ EXPEDITED   ☒ FULL IRB

Approved Project Period: Start Date: 10/02/2014   Expiration Date: 09/09/2015

Your protocol has been approved by the IRB. Protocols are approved for a maximum period of one year. If you wish to continue the project past the approved project period (see above), you must submit a request, using the form Continuing Review for IRB Approved Projects, prior to the expiration date. This form is available from the IRB Coordinator or on the Research Compliance website (http://vpred.uark.edu/210.php). As a courtesy, you will be sent a reminder two months in advance of that date. However, failure to receive a reminder does not negate your obligation to make the request in sufficient time for review and approval. Federal regulations prohibit retroactive approval of continuation. Failure to receive approval to continue the project prior to the expiration date will result in termination of the protocol approval. The IRB Coordinator can give you guidance on submission times.

This protocol has been approved for 60 participants. If you wish to make any modifications in the approved protocol, including enrolling more than this number, you must seek approval prior to implementing those changes. All modifications should be requested in writing (email is acceptable) and must provide sufficient detail to assess the impact of the change.

If you have questions or need any assistance from the IRB, please contact me at 210 Administration Building, 5-2208, or irb@uark.edu.
Appendix G

Informed Consent

Title: THE EFFECT OF BALANCE-BASED TORSO-WEIGHTING ON FUNCTIONAL MEASURES, PAIN, FALLS, FALLS-EFFICACY, AND BALANCE IN OLDER ADULTS WITH MOBILITY AND BALANCE IMPAIRMENTS

Researchers:
Jennifer Vincenzo, PT, MPH, GCS, PhD candidate
Michelle Gray, Ph.D.
University of Arkansas
Department of Health, Human Performance,
and Recreation

Administrative Contact Person:
Iroshi Windwalker
Compliance Coordinator
210 Administration Building

Purpose: The purpose of this project is to determine the effect of Balance-Based Torso-Weighting on function, balance, pain, cognition, falls, and falls-efficacy in older adults with mobility or balance problems.

Inclusion/Exclusion Criteria: You must be at least 65 years of age to participate in the study with no memory problems, able to walk at least 30 feet, in relatively good health (no known uncontrolled heart disease, uncontrolled diabetes, uncontrolled high blood pressure, progressive neurologic disease [Parkinson’s, multiple sclerosis], or currently experiencing bouts of dizziness). If you have pain that gets worse with activity you may be excluded from the study. If your doctor has ever said you should not participate in physical activity, you will be excluded from participation for your safety.

Description: Testing will be completed at the site of your choice at a Country Meadows retirement facility. Before any physical assessment is conducted, you will be asked to complete a cognition test. If your score is ≤ 23/30, additional testing will not be performed unless you have spouse or caregiver able to provide consent with you. A health history questionnaire will be completed to ensure you are not at increased risk of injury when performing the physical measurements. Body weight and height will be taken with standard equipment.

You will perform a physical test called the Short Physical Performance Battery (SPPB). A researcher will be standing next to you at all times. This tests consists of completing the following tasks without using a cane or walker:

- Chair stand - time to complete 5 chair stands without using your arms
- Balance tasks – each for 10 seconds
  - Stand with feet together
  - Stand with the heel of one foot placed by the big toe of the other foot
  - Stand with the heel of one foot placed in front of toes of other foot
- Walking speed - time to walk 12 feet at your usual pace
*If you score between 4-9/12 on the test, you will qualify as having balance or mobility impairment and continue with the study. If you score > 9 or < 4, then you will not qualify for the study.

If you qualify for the study, you will complete the following other assessments:

- You will then complete a 1-page, 16-item questionnaire on your fear of falling called
  - Falls Efficacy Scale- International (FES-I)
- You will complete the comorbidity index
- A clinician will check the sensation in your legs by touching your legs with your eyes closed
- A clinician will check the strength in your legs by seeing if you can lift them up in different directions. They may apply a pressure on your leg to see if you can hold your leg up against a force.
- A clinician will check your position sense awareness of your legs by having your eyes closed and moving your leg in different positions and asking you how it moves.
- We will be asking you to tell us if you have pain and to rate that pain.
- These preassessments are expected to take approximately 1 hour total.
- You will also complete a series of functional tests to assess mobility and balance. There will be a trained clinician next to you at all times for your safety.

On a separate day, you will complete functional assessments as follows:

**A 4-meter walk test** – timed walking at your usual and fast walking speeds.

**Functional reach test (FRT)** – in standing, the distance you can reach forward without moving your feet or losing your balance.

The **Dynamic Gait Index (DGI) and Functional Gait Assessment (FGA)** = Walking (and timed) tests consisting of walking 20 feet multiple times:

- Walking at regular pace
- Walking with changing speeds
- Walking with head turns both horizontally and vertically
- Walking while stepping over and around obstacles
- Pivoting while walking
- Stair climbing
- Walking with eyes closed
- Walking backwards
- Walking heel to toe

**Timed-up and Go (TUG)** = A timed task consisting of standing up from a chair, walking 10 feet, turning around a cone, and sitting back down.
Balance-Based Torso Weighting

- Participants will then be evaluated for the balance-based torso weighting vest. This consists of a certified physical therapist assessing your balance in multiple directions. You will be briskly pushed on the upper torso and pelvis. The physical therapist will be right next to you at all times to ensure safety. Based on your balance assessment, you will receive individualized BalanceWear®: a vest with small, strategically placed weights on the vest on your torso (no more than 1.5% of your body weight).

- You may take rest breaks at your discretion throughout the entire testing session and may refuse any tasks or tests at any time.

- The total time this day is expected to take approximately 1 hour 30 minutes.

The day after you receive your BalanceWear®, and after at least wearing the BalanceWear® for one hour that same day, you will be asked to return to complete the tests again. This will take about 30 minutes.

Participants will repeat the questionnaire and functional tests again as listed above (pain scale, 4-meter walk, FES-I, SPPB, FRT, DGI, FGA, and TUG).

You will be expected to wear your BalanceWear® for 2 hours in the morning and 2 hours in the afternoon. You will be provided a calendar to mark down the times you wear it, as well as any pain you have and if you have any falls. This calendar will be collected at the end of the study.

5 days after getting BalanceWear®, you will perform the same tests again: (pain scale, 4-meter walk, FES-I, SPPB, FRT, DGI, FGA, and TUG). This will take about 1 hour total.

4 months after getting BalanceWear®, you will perform the same tests again: (pain scale, 4-meter walk, FES-I, SPPB, FRT, DGI, FGA, and TUG). This will take about 1 hour total.

*If you feel like your movement has gotten worse at any time, a physical therapist at Country Meadows will assess if you need your BalanceWear® positions changed. Please contact xxx.

The study will be completed after 4 months. The BalanceWear® will be yours to keep. In the event that you do not want it, please donate it to Country Meadows.

Potential Risks: All tests are designed to assess functional fitness and balance, specifically, among older adults. However, with any physical assessment there is a chance of muscle soreness, loss of balance, or falls. Every effort will be made by the research team to decrease the incidence of injury. Each assessment will be thoroughly explained and demonstrated by a member of the research team. You will be briskly pushed on your torso and pelvis to determine
balance loss as part of the evaluation for the strategic vest weighting. Older adults may be at an increased risk of falls during these tasks, however the strategic weighting evaluation is done on adults at risk of falls and the other tests are common measures in rehabilitation to assess function, balance, and fall risk. All proper precautions will be taken in order to ensure your safety during the test such as having a member of the research team next to the participants during all assessments.

**Benefits:** Benefits associated with being in the study include a free assessment of leg strength, function, and balance. You will also receive your own BalanceWear® device to keep.

The University of Arkansas does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

**Confidentiality:** After initial contact with the primary investigator, a code number (e.g. 100,101, etc.) will be assigned to you. All data collection sheets and electronic data files will only have the code number to identify you. All information collected will be kept confidential to the extent allowed by law and University policy.

**Right to withdraw:** Your involvement in this research study is completely voluntary, and you may discontinue your participation in the study at any time without penalty.

**Questions Regarding the Study:** If you have any questions about the research study you are encouraged to ask the researcher; the phone number is at the top of this form. You will be given a copy of this signed and dated consent form to keep, upon request.

**Participant:** I, __________________________, have read the description and information above.

Each of these items has been read and explained to me by the investigator. The investigator has answered all of my questions regarding the study, and I believe I understand what is involved. My signature below indicates that I freely agree to participate in this experimental study and that I have received a copy of this agreement from the investigator.

Signature: __________________________  Date: _______________
Appendix H

Mini Mental State Examination

<table>
<thead>
<tr>
<th>The Mini-Mental State Exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
</tr>
<tr>
<td>Maximum</td>
</tr>
</tbody>
</table>

**Orientation**
- What is the (year) (season) (date) (day) (month)?
- Where are we (state) (country) (town) (hospital) (floor)?

**Registration**
- Name 3 objects: 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until he/she learns all 3. Count trials and record.
  - Trials ______

**Attention and Calculation**
- Serial 7’s. 1 point for each correct answer. Stop after 5 answers.
  - Alternatively spell “world” backward.

**Recall**
- Ask for the 3 objects repeated above. Give 1 point for each correct answer.

**Language**
- Name a pencil and watch.
- Repeat the following “No ifs, ands, or buts”
- Follow a 3-stage command:
  - “Take a paper in your hand, fold it in half, and put it on the floor.”
- Read and obey the following: CLOSE YOUR EYES
- Write a sentence.
- Copy the design shown.

---

*Note.* The rights to the Mini Mental State Examination were purchased for use in this investigation.
Appendix I

Health History Questionnaire

<table>
<thead>
<tr>
<th>Health History Questionnaire</th>
<th>Participant Code: ____________</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Please answer the following questions.</strong></td>
<td><strong>Today's Date: ____________</strong></td>
</tr>
<tr>
<td>Weight</td>
<td>Height</td>
</tr>
<tr>
<td><em>(1) Age</em> Date of Birth</td>
<td><em>What is your current age?</em> ____________</td>
</tr>
</tbody>
</table>

*(2) No diagnosis of unstable or unmanaged cardiovascular disease, hypertension, or diabetes;*

**Have you ever had any of the following conditions? Check yes or no. If yes, explain.**

- Heart Disease              | ☐ Yes ☐ No
- Heart Attack               | ☐ Yes ☐ No
- Angina (Chest Pain)        | ☐ Yes ☐ No
- Peripheral Artery Disease  | ☐ Yes ☐ No
- Stroke                     | ☐ Yes ☐ No
- High Cholesterol (>220)    | ☐ Yes ☐ No
- High Blood Pressure (>140/90) | ☐ Yes ☐ No
- Diabetes                   | ☐ Yes ☐ No
- Rheumatic Fever            | ☐ Yes ☐ No
- Aneurysm                   | ☐ Yes ☐ No
- Neuropathy                 | ☐ Yes ☐ No
- Pain                       | ☐ Yes ☐ No

If yes, where?
If yes, does it get worse with activity?

*(3) Lack of progressive neuromuscular or musculoskeletal disease or injury that prohibits participation in activities*

**Have you ever had any of the following conditions? Check yes or no. If yes, explain.**

- Multiple sclerosis          | ☐ Yes ☐ No
- Parkinson's disease         | ☐ Yes ☐ No
- Arthritis, rheumatism, or gout | ☐ Yes ☐ No
- Any joint, bone, or muscle pain | ☐ Yes ☐ No
- Any joint, bone, or muscle injury | ☐ Yes ☐ No
- Any physical disability     | ☐ Yes ☐ No

*(4) Fall history*

**Have you fallen in the past 12 months?** ☐ Yes ☐ No  **How many times?**  **If yes, explain.**
(5) Additional information

Have you experienced any of these symptoms? Check yes or no. If yes, explain.

- Pain and/or discomfort in the chest, neck, jaw, or arms  □ Yes □ No
- Shortness of breath at rest or with mild exertion  □ Yes □ No
- Dizziness  □ Yes □ No
- Ankle edema (swelling)  □ Yes □ No
- Rapid or irregular beating heart  □ Yes □ No
- Leg pain, cramping, or tightness during exercise  □ Yes □ No
- Heart murmur  □ Yes □ No
- Fatigue or shortness of breath during the day  □ Yes □ No

Do you smoke?  □ Yes □ No  □ Quit

Have you gained or lost weight in the past year?  □ Yes □ No

Vision problems  □ Yes □ No

Wear glasses  □ Yes □ No

Sensation problems in the legs or feet  □ Yes □ No

(7) Please attach a list of all medication (prescription or over-the-counter) you are currently taking or use the form below.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Reason Prescribed</th>
<th>When do you take this medication?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(check all that apply)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Morning □ Mid-Day □ Evening □ Bedtime</td>
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<tr>
<td></td>
<td></td>
<td>□ Morning □ Mid-Day □ Evening □ Bedtime</td>
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<td>□ Morning □ Mid-Day □ Evening □ Bedtime</td>
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<td>□ Morning □ Mid-Day □ Evening □ Bedtime</td>
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<td>□ Morning □ Mid-Day □ Evening □ Bedtime</td>
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<td>□ Morning □ Mid-Day □ Evening □ Bedtime</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Morning □ Mid-Day □ Evening □ Bedtime</td>
</tr>
</tbody>
</table>
Appendix J

Assessment and Test Forms

Preassessments

Inclusion criteria:
- Over the age of 65 years
- Be able to walk at least 30 feet repeatedly with or without an assistive device
- Evidence of mobility or balance impairments, as defined by an SPPB score of 4-9/12

Exclusion criteria:
- Cognitive impairment (MMSE ≤ 23/30)
- < 2/5 strength in the hip musculature as determined by manual muscle testing
- Uncontrolled knee hyperextension during stance
- Uncorrected foot drop/unable to maintain neutral dorsiflexion during swing phase of gait
- Current uncontrolled cardiovascular disease, hypertension, diabetes
- Exclusion from physical activity per physician orders
- Current complaints of dizziness
- A progressive neurological disorder (such as Parkinson’s disease or multiple sclerosis)
- Current pain or injury inhibiting mobility or that worsens with greater than 30 min of activity
- Unwilling to wear the BalanceWear® orthotic
  - These participants may opt to be in non-treatment group we are following for 4 mo.
- Unwilling to undergo balance perturbation testing
- Severe visual impairment preventing them from being able to navigate the assessment area without bumping into equipment, walls, or other individuals.

Order of Preassessments

1. Informed Consent □

2. Health History Questionnaire □
   a. Check for exclusion criteria

3. Mini-Mental State Exam
   a. Must score > 23/30 □

4. Conduct Short Physical Performance Battery
   a. Must score between 4 – 9 out of 12 to be included □

5. Conduct Comorbidity Index □

6. Conduct Falls Efficacy Scale □

7. Check Sensation in Feet
a. Light touch Left foot □ Light touch Right foot □  
b. Pressure Left foot □ Pressure Right foot □  
c. Document any abnormalities __________________________________________

8. Check Strength/ROM in Legs

<table>
<thead>
<tr>
<th></th>
<th>Right LE ROM</th>
<th>Right LE MMT -/-5</th>
<th>Left LE ROM</th>
<th>Left LE MMT -/-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hip flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip abduction</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Hip adduction</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Hip Extension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee Extension</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Knee Flexion</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Ankle Dorsiflexion</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Ankle Plantarflexion</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Ankle Eversion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ankle Inversion</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Check Proprioception in great toe, ankle, knee, and hip (absent, inaccurate, intact)

<table>
<thead>
<tr>
<th></th>
<th>Right LE</th>
<th>Left LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Great toe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ankle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>knee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>hip</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Co-morbidity index

Since age 55, has a doctor told you that you had (e.g.) congestive heart failure? If Yes, how much does it limit you to do your daily activities? Please check the corresponding box of None  A little bit  Somewhat  Quite a bit?

<table>
<thead>
<tr>
<th>Condition</th>
<th>None</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angina</td>
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<td></td>
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<tr>
<td>Congestive Heart Failure</td>
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<tr>
<td>Heart Attack</td>
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<tr>
<td>Lung disease</td>
<td></td>
<td></td>
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<tr>
<td>Arthritis</td>
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<td></td>
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<tr>
<td>Osteoporosis</td>
<td></td>
<td></td>
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<tr>
<td>Broken bone</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Joint Replacement</td>
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<tr>
<td>Joint fusion</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Amputation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parkinson’s disease</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression, anxiety, emotional problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic pain syndrome</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Glaucoma</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Cataract</td>
<td></td>
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</tbody>
</table>
Between each functional assessment tool, ask level of mental fatigue and level of physical fatigue 0-10 scale

**Mental fatigue __/10**  **Physical Fatigue ___/10**

**Short Physical Performance Battery**

**Balance Subscale**
Side by side –Time _______  Semi-tandem –Time _______  Tandem – Time _______

[0] Unable to hold side by side stance for > 9 seconds
[1] Side by side stance for 10 sec, but unable to hold semitandem for 10 sec
[2] Semitandem for 10 sec, unable to hold full tandem for > 2 sec
[3] Full tandem for 3-9 sec
[4] Full tandem for 10 sec

**Balance Score ________/4**

**Four Meter Walk Subscale**
Walk Score (4 Meter or 13.12 feet)  Time 1:________  Time 2:________

[0] Unable to walk
[1] If time is more than 8.70 seconds
[2] If time is 6.21 to 8.70 seconds
[3] If time is 4.82 to 6.20 seconds
[4] If time is less than 4.82 seconds

**Total walk score______/4**

**Sit to Stand Subscale**
Number of Stand completed______  Time______

[0] If the participant was unable to complete the 5 chair stands
[1] If chair stand time is 16.7 seconds or more
[2] If chair stand time is 13.7 to 16.6 seconds
[3] If chair stand time is 11.2 to 13.6 seconds
[4] If chair stand time is 11.1 seconds or less

**Chair Stand Score ________/4**

**Total Score SPPB ________________/12**
Functional Gait Assessment

1. Gait on Level Surface

Equipment: measuring tape, masking tape for floor

Setup: A 23-ft distance is needed for this test. Mark the beginning of the walking course with a piece of tape. Place a piece of tape at the 10-ft and 20-ft points; participant should be instructed to continue walking another 3 ft past the 20-ft point another.

Instructions to Participant: Begin with your toes on this line. When I tell you “Begin,” start walking at your normal pace from here to past this line (point out the 20-ft line to the participant). Make sure you continue to walk past this line. Do you understand what I want you to do? Are you ready? Begin.

Gait Pattern:
(3) Normal: Walks 20 ft, normal gait pattern, no evidence for imbalance.
(2) Mild Impairment: Walks 20 ft, mild gait deviations or mild imbalance.
(1) Moderate Impairment: Walks 20 ft, moderate gait deviations, clear evidence for imbalance, but recovers independently.
(0) Severe Impairment: Cannot walk 20 ft, walks with severe gait deviations, or cannot maintain

2. Change in Gait Speed

Instructions to Participant: Begin with your toes on this line. When I tell you “Begin,” start walking at your normal pace. When I say “Go fast,” I want you to walk as quickly and safely as you can until I tell you to stop. Do you understand what I want you to do? Are you ready? Begin.

Gait Pattern:
(3) Normal: Able to smoothly change walking speed without loss of balance or gait deviation. Shows a significant difference in walking speeds between normal and fast speeds.
(2) Mild Impairment: Is able to change speed but demonstrates mild gait deviations or mild imbalance.
(1) Moderate Impairment: Makes only minor adjustments to walking speed with significant gait deviations or loses balance but is able to recover and continue walking.
(0) Severe Impairment: Cannot change speeds or loses balance and is unable to recover independently.

3. Gait With Horizontal Head Turns

Setup: Same as item 1.

Instructions to Participant: Begin with your toes on this line. When I say “Begin,” start walking at your normal pace. When I tell you “Look right,” keep walking straight but turn your head to the right. Keep looking right until I tell you “Look left,” then keep walking straight and turn your head to the left until I tell you “Look straight,” then keep walking straight but return your head to the center. Do you understand what I want you to do? Are you ready? Begin.
**Gait Pattern:**
(3) Normal: Performs head turns smoothly with no change in gait pattern or evidence of imbalance.
(2) Mild Impairment: Mild reduction in head motion or performs head turns with mild changes in gait pattern, or minor disruption to gait path or mild imbalance.
(1) Moderate Impairment: Moderate reduction in head motion or performs head turns with moderate change in gait pattern, or moderate imbalance but recovers independently.
(0) Severe Impairment: Unable to turn head or performs head turns with severe disruption of gait (ie, staggers outside 15-in path) or stops, or loses balance and is unable to recover independently.

**4. Gait With Vertical Head Turns**
Set up: Same as item 1.
Instructions to Participant: Begin with your toes on this line. When I tell you “Begin,” start walking at your normal pace. When I tell you “Look up,” keep walking straight but tilt your head and look up to the ceiling. Keep looking up until I tell you “Look down,” then keep walking straight and tilt your head down and look at the floor until I tell you “Look straight,” then keep walking straight but return your head to the center. Do you understand what I want you to do? Are you ready? Begin.

**Gait Pattern:**
(3) Normal: Performs head turns smoothly, with no change in gait pattern or evidence of imbalance.
(2) Mild Impairment: Turns using 4 to 5 steps and shows mild gait deviations or imbalance before, during, or after turning.
(1) Moderate Impairment: Turns using 5 steps and has moderate gait deviation or imbalance before, during, or after turning but is able to recover independently.
(0) Severe Impairment: Cannot turn safely, loses balance, and is unable to recover independently.

**5. Gait and Pivot Turn:**
Set up: Place a piece of tape at the end of the 10 ft; participant will be asked to turn around at the 10-ft point.
Instructions to Participant: Begin with your toes on this line. When I tell you “Begin,” start walking at your normal pace. When I tell you “Turn around,” turn around as quickly and safely as you can and walk back to the starting point. Do you understand what I want you to do? Are you ready? Begin.

**Gait Pattern:**
(3) Normal: Pivot turns safely using _3 steps and continues walking in opposite direction with no gait deviations and no imbalance.
(2) Mild Impairment: Turns using 4 to 5 steps and shows mild gait deviations or imbalance before, during, or after turning.
(1) Moderate Impairment: Turns using 5 steps and has moderate gait deviation or imbalance before, during, or after turning but is able to recover independently.
(0) Severe Impairment: Cannot turn safely, loses balance, and is unable to recover independently.
6. Step Over Obstacle
Equipment: Measuring tape, masking tape for floor, stopwatch, 2 semirigid pieces of foam rectangles (dimensions: 76 cm long, 12 cm wide, 5 cm thick).
Setup: A 23-ft distance is needed for this test. Mark the beginning of the walking course with a piece of tape. Place the first obstacle with the 12-cm side flat on the floor at 8 ft from the start. Place the second obstacle with the 12-cm side up 8 ft past the first obstacle (about 16 ft from the start). Place a piece of tape at the end of the 20-ft distance.
Instructions to Participant: Begin with your toes on this line. When I tell you “Begin,” start walking at your normal pace. When you come to each obstacle, step over and keep walking to past this line (point out the 20-ft line on the floor). Do you understand what I want you to do? Are you ready? Begin.

Gait Pattern:
(3) Normal: Is able to step over and clear both obstacles without changing gait speed, no evidence for gait deviations or imbalance.
(2) Mild Impairment: Is able to step over and clear both obstacles but with mild gait deviations (eg, slowing down and adjusting steps to clear obstacles) or mild imbalance.
(1) Moderate Impairment: Is able to step over the obstacles but must stop, then step over, or strikes an obstacle or is significantly unsteady when crossing but able to recover without assistance.
(0) Severe Impairment: Cannot step over one or both obstacles or loses balance and is unable to recover independently.

8. Up Stairs:
Equipment: 10 steps with railing, stopwatch.
Setup: Position participant at the bottom of the stairs.
Instructions to Participant: When I tell you “Begin,” start walking up the stairs as you would at home or in the community. If you normally use a rail, do so. Walk to the top of the stairs and stop. Do you understand what I want you to do? Are you ready? Begin.

Gait Pattern:
(3) Normal: Alternating feet, no rail.
(2) Mild Impairment: Alternating feet, must use rail.
(1) Moderate Impairment: Two feet to a stair, must use rail.
(0) Severe Impairment: Cannot do safely.

9. Gait with narrow base of support
Instructions: Walk on the floor with arms folded across the chest, feet aligned heel to toe in tandem for a distance of 3.6 m (12 ft). The number of steps taken in a straight line are counted for a maximum of 10 steps.

Grading: _______
[3] Normal – Is able to ambulate for 10 steps heel to toe with no staggering.
[1] Moderate impairment – Ambulates 4-7 steps.
[0] Severe impairment – Ambulates less than 4 steps heel to toe or cannot perform without assistance.

10. Gait with eyes closed
Instructions: Walk at your normal speed from here to the next mark (6 m or 20 ft) with your eyes closed.

**Grading:**
[3] Normal – Walks 6 m (20 ft), no assistive devices, good speed, no evidence of imbalance, normal gait pattern, deviates to more than 15.24 cm (6 in) outside 30.48 (12 in) walkway width. Ambulates 6 m (20 ft) in less than 7 seconds.
[2] Mild impairment – Walks 6 m (20 ft), uses assistive device, slower speed, mild gait deviations, deviates 15.24-25.4 cm (6-10 in) outside 30.48 (12 in) walkway width. Ambulates 6 m (20 ft) in less than 9 seconds but greater than 7 seconds.
[1] Moderate impairment – Walks 6 m (20 ft), slow speed, abnormal gait pattern, evidence for imbalance, deviates 25.4-38.1 cm (10-15 in) outside 30.48 cm (12 in) walkway width. Requires more than 9 seconds to ambulate 6 m (20 ft).
[0] Severe impairment – Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 38.1 cm (15 in) outside 30.48 cm (12 in) walkway width or will not attempt task.

11. Ambulating backwards
Instructions: Walk backwards until I tell you to stop.

**Grading:**
[3] Normal – Walks 6 m (20 ft), no assistive devices, good speed, no evidence of imbalance, normal gait pattern, deviates no more than 15.24 (6 in) outside of 30.48 (12 in) walkway width.
[2] Mild impairment – Walks 6 m (20 ft), uses assistive device, slower speed, mild gait deviations, deviates 15.24-25.4 cm (6-10 in) outside 30.48 (12 in) walkway width.
[1] Moderate impairment – Walks 6 m (20 ft), slow speed, abnormal gait pattern, evidence for imbalance, deviates 25.4-38.1 cm (10-15 in) outside 30.48 (12 in) walkway width.
[0] Severe impairment – Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 38.1 cm (15 in) outside 30.48 cm (12 in) walkway width or will not attempt task.

Score ______/30

**Gait speed** 4 meters **normal pace**  trial 1 ___________sec  trial 2 ___________sec

**Timed Up and Go Testing Form:**  Assistive Device and/or Bracing ____________
TUG Time practice:__________  TUG time 1: ____________  TUG time 2: ____________

**Functional Reach Test:**
Functional Reach Test 1 ___________ cm  Functional Reach Test 2 ___________ cm
Now we would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don’t do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling if you did the activity. For each of the following activities, please tick the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Not at all concerned</th>
<th>Somewhat concerned</th>
<th>Fairly concerned</th>
<th>Very concerned</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cleaning the house (e.g. sweep, vacuum or dust)</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>2</td>
<td>Getting dressed or undressed</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>3</td>
<td>Preparing simple meals</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>4</td>
<td>Taking a bath or shower</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>5</td>
<td>Going to the shop</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>6</td>
<td>Getting in or out of a chair</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>7</td>
<td>Going up or down stairs</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>8</td>
<td>Walking around in the neighbourhood</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>9</td>
<td>Reaching for something above your head or on the ground</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>10</td>
<td>Going to answer the telephone before it stops ringing</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>11</td>
<td>Walking on a slippery surface (e.g. wet or icy)</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>12</td>
<td>Visiting a friend or relative</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>13</td>
<td>Walking in a place with crowds</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>14</td>
<td>Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>15</td>
<td>Walking up or down a slope</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
<tr>
<td>16</td>
<td>Going out to a social event (e.g. religious service, family gathering or club meeting)</td>
<td>1 ☐</td>
<td>2 ☐</td>
<td>3 ☐</td>
<td>4 ☐</td>
</tr>
</tbody>
</table>