# BIOPSYCHOSOCIAL MEASURES RELATED TO POSTURAL CONTROL IN OLDER ADULTS

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#### Abstract

This study examined the biopsychosocial measure related to postural control in the growing population of older adults (i.e., 60 years and older). The sample of the study consisted of 129 older adults (M = 74.45, SD = 6.95), with 34 males and 95 females, and 36 classified with chronic low-back pain (CLBP) and 93 without chronic low-back pain (NCLBP). Physical and psychosocial constructs were analyzed as predictors for postural control measures. Also gender and classification of low-back pain were examined as moderators for all physical and psychosocial measures. Results supported that physical and psychosocial measures were able to significantly predict composite, visual, and vestibular balance measures, but not somatosensory or preference balance measures. The chair stand test, modified sit-and-reach test, sleep disturbance, and balance efficacy were all identified as individual significant predictors. Gender and CLBP did not moderate the utility of any predictor variables. Results of the current study support of utilizing the biopsychosocial approach for future research examining postural control in older adults.

Keywords: biopsychosocial, older adults, physical, postural control, balance

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## LIST OF ABBREVIATIONS

BE	balance efficacy
BES	Balance Efficacy Scale
САТ	computer-automated-test
CDC	Centers for Disease Control and Prevention
CFRSI	Comprehensive Falls Risk Screening Instrument
CHLL	Center for Healthy Living and Longevity
CLBP	chronic low-back pain
COG	center of gravity
CS	chair stands
FSC	factor score coefficient
IRB	Institutional Review Board
NCLBP	without chronic low-back pain
NIH	National Institute of Health
PROMIS	Patient Reported Outcome Measurement Information System
SFT	Senior Fitness Test
SLD	sleep disturbance
SNR	modified sit-and-reach
SOT	sensory organization test
SPSS	Statistical Package for Social Science

## BIOPSYCHOSOCIAL MEASURES RELATED TO POSTURAL CONTROL IN OLDER ADULTS

Biopsychosocial distress associated with slips and falls, such as anxiety of falling, evading activities due to anxiety of falling, and decreased postural control efficacy, are often taxing phenomena among older adults (Deshpande et al., 2008; Greenberg, 2012: Kempen et al., 2009). Fall-risk can be intrinsic or extrinsic in nature. Intrinsic factors of fall-risk include advanced age, previous falls, muscle weakness, gait and balance problems, poor vision, postural hypotension, chronic illness such as arthritis, diabetes, stroke, Parkinson's, and fear of falling. Extrinsic factors include environmental risks such as a lack of handrails, stairs, a lack of bars in the bathroom, dim lighting, slippery and uneven surfaces, psychoactive medications, and improper use of assistive device (CDC, n.d.). Fall-risk is increased in the older adult population due to psychosocial risk factors, including anxiety and depression (Hughes et al., 2015). Fear of falling has been generally defined as an enduring worry about falling that causes an individual to avoid performing activities he or she has the ability to do (Tinetti & Powell, 1993). An intense anxiety of falling can be experienced by older adults that have or have not fallen. Awareness of the severity of falls may instill a fear in individuals, leading to behavior changes that limit functional capacity (Center for Gerontology at Virginia Tech, 2013). In contrast, there are beneficial health advantages that older adults may experience with increased physical activity (Pahor et al., 2006).

With the population of older adults increasing in the United States at a rapid pace, the country has entered what is sometimes referred to as a "longevity revolution" or "graying of America". This increase can be a catalyst of healthcare economic stress due to physical and psychosocial vulnerabilities of older adults. Older adults are at higher risk of sustaining physical injury and psychosocial trauma from a slip or fall (Evans & Ness, n.d.).

Identifying objective variables related with fall-risk would be beneficial in order to diminish an individual's threat of sustaining a fall. Because experiencing a fall can be a "shattering" experience" on the mental well-being, physical functioning, and overall quality-of-life of older adults, it is crucial that convenient, economical, and easy administered tests are accessible for routine clinical use (Swanenburg et al., 2015). As an initial step in this progression of these methods, this study evaluated what biopsychosocial variables were related to postural control in older adults. The current study examined the following biopsychosocial variables: physical function, sleep disturbance, fatigue, pain interference, depression, and anxiety (all measured by the Patient Reported Outcome Measurement Information System (PROMIS; Bajaj et al., 2011)); balance efficacy as measured by the *Balance Efficacy Scale* (BES; Lee et al., 2015); and physical measures of cardiovascular endurance (six-minute walk test), lower body muscular endurance (chair-stand test), lower body flexibility (modified and sit-and-reach test), and agility (8 ft. getup and go test) measured through the Senior Fitness Test (Rikli & Jones, 2001). Diagnosis of CLBP (classified by the NIH definition of CLBP) and gender were expected to moderate the utility of any of the aforementioned physical or psychosocial predictors while controlling for age (self-report), calculated environmental fall-risk, and medication fall-risk by the subscales of the Comprehensive Fall Risk Screening Instrument (CSFRI). It was expected that the aforementioned physical and psychosocial measures would predict overall NeuroCom composite, visual, vestibular, somatosensory, and preference scores of the sensory organization test (SOT) as measured by the *NeuroCom Balance System* (a computerized dynamic posturography device; Natus Medical Incorporated, n.d.). The current study was innovative because very few studies have examined physical and psychosocial measures in association with the multiple components of that are involved in balance.

The 2010 U.S. Census reported that, from the 2000 through 2010 decade, the older adult population in America (65 years and older specifically) increased exponentially more (15.1 %) than the total U.S population (9.7%). The population of Americans 65 years or older recorded 40.3 million in April in 2010 (Werner, 2011). In the year of 2014, 15% of Americans were 65 years or older. In 2030 that number is expected to increase to 20%, and by 2060, it is projected that 24% of Americans will be 65 years or older (Colby & Ortman, 2014: Hetzel & Smith, 2001; Institute of Medicine, 2011; Marcus, 2009). Falls and fall-related injuries can lead to extensive hospital visits, and are one of the principle reasons of diminished health and function in community-dwelling older adults (Englander et al., 1996). Falls can be a precursor to physical impairment, pain, chronic pain, fractures, disability, lower-quality-of-life, and in more extreme cases, are a significant cause of injury-related death in the elderly population (Halvarsson et al., 2015; D'Arcy, 2010; Englander et al., 1996). The older adult population is more vulnerable to falls because of age-associated ailments that include declining vision, absence of physical activity, weakening neuromuscular factors, cognitive deficiencies, osteoarthritis, and the use of diuretic and psychotropic medications (DePasquale, 2014). These ailments result in roughly onefourth of older adults falling every year, with one-fifth of them needing medical attention and resulting in serious injury (Cumming et al., 1997). Older adults who have experienced a fall are twice as likely to experience another fall in contrast to their counterparts without a previous fall (Alexander et al., 1992; Lee et al., 2015; O'Loughlin, 1993; Sterling et al., 2001; Stevens et al., 2012). Annually one in three older adults over the age of 65 fall, and 50% over the age of 80 will sustain a fall each year (Bishop et al., 2010; Donath et al., 2016).

One contributing factor to fall risk is poor balance. In a study by Hageman and colleagues (1995), older adults' demonstrated greater sway in balance measures when compared to younger

adults, but gender had no significant effect on balance. In a study by Wolfson and colleagues (1994), older adult females had worse postural sway (balance) than did older adult males when taking measurements with eyes closed, but no significant differences were observed between genders when taking measurements in eyes open conditions.

Maintaining postural control involves three body systems: the visual, vestibular, somatosensory (proprioception) systems (Fitzpatrick and McCloskey, 1994). The visual system allows the body to register position and movement in an environment, allowing an individual to receive information on how to control movement and balance (Lee, 1978). An individual gages distance of upcoming obstacles with optic flow. Optic flow is the phenomenon in which moving forward rays move outward expanding the visual image, and moving backwards the rays contract inward (Lee, 1980). When vision is removed, individuals can still perceive movement through the proprioceptive and vestibular system. Proprioceptors that are primarily located in the body's muscles and tendons (particularly in the hips and ankles) are sensory nerve endings that give information involving the body's position and it's movements regarding feedback to the body's shift in space (Lee & Aronoson, 1974). When standing, the body is making constant compensatory adjustments of the musculature through a process of feedback control. Any sway of the body away from one's center of gravity has to be detected and compensated with muscular adjustments or balance will be lost (Lee & Aronoson, 1974). The vestibular system consists of the inner ear, and is a complex structure of fluid filled tubes and chambers. Specialized nerve endings inside the canals sense the position and movement of the head and detect direction of gravity. Signals sent from nerves of the vestibular system that control eye movement are critically important for the brain's ability to control balance when standing and walking (Schoenewald & Bailey, n.d.). Anatomical studies have shown that the number of nerve cells in

the vestibular system decrease after the age of 55, usually associated with a decrease of blood flow to the inner-ear (Schoenewald & Bailey, n.d.). Studies have shown vestibular stimulation with performed pirouettes increased static sway in female dancers (Hopper et al., 2014). In other research, unilateral vestibular-defective patients have been known to constitute one of the largest group of patients with a falling tendency that suffer from symptoms that include vertigo, dizziness, and hearing loss from excessive fluid in the inner-ear (Allum & Adkin, 2003; Schoenewald & Bailey, n.d.).

With balance, two discrete strategies are dominant in controlling posture based on EMG activations, body kinematics, and ground reaction forces (Nashner & McCollum, 1985). Nashner and McCollum (1985) identified the ankle and hip strategies of postural control. Ankle strategy is characterized by body sway resembling a single-segment-inverted pendulum, whereas hip strategy is characterized by body sway resembling a double-segment inverted pendulum divided at the hip (Horak & Nashner, 1986). Mixed postural control strategies on flat support surfaces have been reported in patients with loss of somatosensation in the feet due to ischemia and in patients with Parkinson's disease (Diener et al., 1984; Horak et al., 1990; Horak et al., 1992).

Twenty to thirty percent of individuals who fall suffer an injury (i.e. low back pain) that will reduce mobility and independence and increase the risk of premature death (Freeman et al., 2002). If older adults experience a fall, they can be at a higher-risk for a fall in the future. It has been supported that restricting one's physical activity for fear of an increased risk of sustaining a fall may be beneficial in the short term. When physical activity becomes limited, and is disproportionate to an individual's physical capabilities, sensorimotor deconditioning, reduced postural control, decreased muscular strength, decreased muscular flexibility, decreased muscular and cardiovascular endurance, and increased risk-of-falls can be a consequence from

avoidance of activity (Daniel, 2012; Delbaere et al., 2004; Hull et al., 2012; Moore & Ellis, 2008). Consequently falls are the leading cause of injury deaths among individuals over the age of 65.Half of the falls experienced will occur in an individual's own home (Lord et al., 1992; Tinetti, 2003). Prior studies have demonstrated how range of motion in the hamstrings can increase with improved postural control (Kuszewski et al., 2009), and agility has been shown to be a reliable and valid predictor of fall risk among adults (Botolfsen et al., 2006). Even though psychosocial concerns are predominant in individuals who have sustained a fall, people who have had no history of a previous fall can also be negatively affected. For example, in a large population-based investigation involving 926 elderly individuals, found that 70% of individuals who reported having a fear-of-falling had no history of falls within the prior year (Deshpande et al., 2008). Consequently, the effects of restrictive movement does not just influence physical deconditioning, but studies have found that avoiding activities due to fall-related anxiety can exacerbate social isolation, diminish quality-of-life, and is associated with depressive symptoms (Boyd & Stevens, 2009; Hull et al., 2012; Moore et al., 2011).

Within the scientific literature, an array of psychosocial factors associated with falls has been acknowledged. Factors such as anxiety from fear of falling, avoiding activities due to fear-of-falling, a decline in balance efficacy, and an unrealistic fear about the consequences of falling have all been shown to be influenced by the experience of a fall (Moore et al., 2008; Moore et al., 2011; Jorstad et al., 2005). The psychosocial occurrence of having a persistent fear-of-falling could contribute to exacerbating the threat for later falls, thus further hampering physical activity (Boyd & Stevens, 2009) as well as being an initiator for deviations in gait mechanics that follow disorganized gait features (i.e. exaggerated shorter strides; Toebes et al., 2015). Disorganized gait features and fear of physical activity further intensifies the threat of a fall. For example,

Petrella and colleagues (2000) found that the focused-avoidance of physical activity was associated in those who had a fear-of-falling. Relatedly, a decrease in muscle mass (a marker of physical frailty, often from inactivity) is often seen in older adults with chronic low back pain (CLBP; Hanada et al., 2011). Physical activity, in contrast, has been established to improve physiological measures, such as muscle tone, balance, and flexibility, making the possibility of experiencing a fall less likely (Pike, 2011).

Older adults often evade physical activity, making their risk for a fall greater (Arfken et al., 1994). Not only does declining physical function influence postural control, but evidence also suggests that decreased physical function has an impact on psychosocial health (Stubbs, 2015). Evasion from physical movement adversely affects an older adult's postural control, and also diminishes the quality of mental well-being. For example, research conducted by Morgan and colleagues (2013) found a strong relation among physical activity and psychological wellbeing, demonstrating that older adults who are consistent in being physically active are less susceptible to suffer depression, and have improved psychological wellbeing. Balance efficacy, can be defined as a person's perceived self-confidence regarding their ability to avoid falls while performing identified activities (Bishop et al., 2010). Balance efficacy has been supported to be a predictor of sustained falls in individuals (Carpenter et al., 2006), poor postural control, reduced physical function, and increased fall risk (Lee et al., 2016). Klima and colleagues (2012) found that balance efficacy was significantly correlated with balance ability and functional mobility in older adult men. Also, a great body of research reveals that a lack physical activity, or living a sedentary lifestyle, leads to a decline in postural control and, therefore, increasing fall risk (Stubbs et al., 2015). Adequate exercise can have an influence in reducing falls in older adults by enhancing biopsychosocial functioning (Stubbs et al., 2015).

The relationship among psychosocial constructs (i.e. anxiety, depression, and sleep disturbance), low-back pain, and falls, is not comprehensively understood. Therefore, research still needs to delineate the associations among psychosocial measures, CLBP, recent falls sustained, fall-risk, and exercise interventions efficacy to positively impact these aforementioned variables. To date, pain has been documented to have a relationship with mobility restrictions (Karttunen et al., 2012), as well as balance and gait deficits (Leveille et al., 2001; Leveille et al., 2002; Lamb et al., 2000). Other research has found pain to be associated with fear of falling (Scheffer et al., 2008), and actual falls (Deandrea et al., 2010; Stubbs et al., 2014). Fear of movement, and specifically fear avoidance, has been documented to also be associated with pain (Vlaeyen & Linton, 2000; Sions & Hicks, 2011). A study conducted by Hulla and colleagues (2016) provides an example of these new important issues. The study found in demographicallymatched elderly individuals, those with CLBP were significantly worse on constructs of physical function, fatigue, pain interference, and approached significance for sleep disturbance. It was also found that *NeuroCom balance measures* (a force plate that measures center of gravity in several different conditions in which the surrounding wall and a force plate move in relation to the sway of the participant) and psychosocial measures did significantly predict CLBP. In another study, pain was a significant predictor in "fall efficacy" or an individual's perception of confidence in avoiding a fall, balance confidence, fear-of-falling, and perceived consequences of falling in the community-dwelling older population (Stubbs et al., 2014).

Older adults also are more vulnerable to experiencing psychosocial ailments because of their susceptibility to pain disorders. For example Bradbeer and colleagues (2003) found that older adults who demonstrated signs of depression were more likely to have symptoms of chronic pain than their counterparts who are not depressed. Like depression, anxiety can

influence the experience of chronic pain (Van Haastregt et al., 2008). The older adult population tends to have greater anxiety, especially in regards to fear-of-falling (Howland et al., 1993). This fear can lead to limited movement (Van Haastregt et al., 2008), which as mentioned previously can intensify pain and weaken balance capabilities. In general the compounding problem with chronic pain and aging affecting psychosocial well-being has been well-supported by a body of evidence. For example, in cases of chronic osteoarthritis, pain has been associated with physical inactivity, which was then followed by further avoiding physical activity (Messier et al., 2000). Such a cycle of reduced participation in physical activity and increased pain further increases the risk of future falls and serious injury due to frailty from a decrease in physical function, intensified aliments of sarcopenia (Toebes et al., 2015) and osteoporosis (Halvarsson et al., 2015), and stiffening of skeletal muscles (Mazzeo et al. 1998).

Studies have supported that fatigue impairs sensorimotor performance, reduces spinal reflexes and compromises the interaction of antagonistic muscles (Ritzmann, 2015), which can directly be related to an individual's postural control. Studies done by Lepers and colleagues (1997) and Burdet and Rougier (2004) examined fatigue induced by cardiovascular activities of cycling and running and found significant effects on an individual's ability to maintain postural control. Other studies have examined cardiovascular induced fatigue in older adults specifically and have found that after performing tasks, such as bicycling and walking, balance performance has decreased (Donath et al., 2012; Donath et al., 2015; Stemplewski et al., 2012). Donath and colleagues (2015) suggested that having a superior endurance capacity might attenuate fatigue induced declines in postural control in general activities of daily living. A study by Hopper and colleagues (2014) found that induced lower body fatigue through repetitive jumps increased static sway in dancers. Yaggie and McGregor (2002) conducted a study of induced fatigue

through resisted muscular contractions with isokinetic exercises of the plantarflexors and dorsiflexors of the ankles, and found greater mediolateral sway in participants after the isokinetic ankle exercises were performed. A study observing balance training found that improved postural control also enhanced rate of force development in leg extensors (Granacher et al., 2010), suggesting that increasing leg strength may coincide with enhancing an individual's postural control. Cardiovascular endurance measured by the 6-minute walk and 2-minute step test, and agility as measured by the 8ft. get-up-and-go test have been significantly associated with balance efficacy (Lee et al., 2016). In contrast, chronic fatigue patients have been found to score worse on balance measures in comparison to healthy controls (Rasouli et al., 2015).

Pain also has been shown to influence sleep quality (Lautenbacher et al., 2006). Sleep quality intern, influenced balance capabilities. For example, a study conducted by Furtado and colleagues (2016) demonstrated the individuals with worse sleep quality perform worse on a balance test with eyes closed. Jorgensen and colleagues (2012) found that participants who described being "sleepy" had increased postural sway than participants who reported being wellrested. Other research has shown that sleep disorders have a negative impact on postural control. Balance deterioration can occur just after one night without sleep and can be responsible for work accidents and falls among older adults (Aguiar & Barela, 2014; Aguiar & Barela, 2015; Albuquerque et al., 2012; Bougard & Davenne, 2014; Gauchard et al., 2008; Gomez et al., 2008; Gribble & Hertel, 2004; Karita et al., 2006; Ku et al., 2012; Kurz et al., 2013; Patel et al., 2008).

It should also be noted that the economic impact of pain and falling is critical when projecting future costs, treatment, and detection methods for fall-risk and pain. More recently, the 2011 Institute of Medicine Report highlighted that musculoskeletal pain is the most common type of chronic pain, with CLBP being the most prevalent type of chronic pain documented. Gaskin and Richard (2012) also found the economic cost of pain in America fluctuated from \$560 to \$635 billion in 2010, and encompassed health care cost and loss of work productivity associated to pain, which is a greater annual cost than heart disease (\$309 billion), cancer (\$243 billion) and diabetes (\$188 billion). As importantly, pain is vastly rampant in the communitydwelling elderly population, with up to 76% affected by pain (Abdulla et al., 2013; Patel et al., 2013). The nation spends \$30 billion a year treating older adults for the effects of falls, and if the rate of falls does not start decreasing, it is projected that direct treatment costs will reach 59.6 billion by 2020, additionally a quarter of hip-fracture patients will be in nursing homes for at least a year, further adding to Medicaid costs (National Council of Aging, n.d.). Low-back pain affects more than 30% of community-dwelling older adults (Weiner et al., 2003), and is one of the most common reasons for physician visits (Hart et al., 1995). Therefore, with the "graving of America", or the current "longevity revolution" happening in America, the economic burden of CLBP and falls will increase in the future if other approaches to manage the illness are not developed. Awareness of the older-population trends contributes to amplified issues about healthcare concerns among elderly adults, including CLBP.

## **Study Overview**

The aim of the study was to examine if biopsychosocial measures (psychosocial measures from the PROMIS and BES, and physical measures from SFT) would predict overall balance (composite score), and individual systems of balance (vestibular, visual, somatosensory, and preference scores) in community-dwelling older adults.

## Hypotheses

**H**<sub>01</sub>: Physical variables of sit-and-reach, chair stands, 8ft.-get-up-and-go, and six minute walk test as measured by the SFT, while controlling for the aforementioned psychosocial measures

(physical function, anxiety, depression, fatigue, sleep disturbance, pain interference, balance efficacy) from the PROMIS and BES, age (self-report), calculated environmental fall-risk and medication use (from the CFRSI) as covariates would predict the *NeuroCom balance system* composite scores. It was also hypothesized that the diagnosis of CLBP and gender will moderate the utility of the predictor variables.

Statistical Analysis: A multiple hierarchical multiple regression model was conducted with composite balance scores as the sole dependent variable. Psychosocial measures of physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, as measure by the PROMIS and balance efficacy as measured by the BES, were calculated into a factor score coefficient (FSC) with a principal component analysis that was used as a covariate in order to measure the predictability of the physical variables, while controlling for psychosocial measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the psychosocial measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the four physical predictor variables (sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests) were introduced. For step three of the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**H**<sub>02</sub>: Physical variables of sit-and-reach, chair stands, 8ft.-get-up-and-go, and six minute walk test while controlling for the aforementioned psychosocial measures, age, calculated environmental fall-risk, and medication use as covariates would predict the *NeuroCom balance* 

*system* visual scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables.

*Statistical Analysis:* A multiple hierarchical multiple regression model was conducted with visual balance scores as the sole dependent variable. Psychosocial measures of physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the physical variables, while controlling for psychosocial measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the psychosocial measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model, the four physical predictor variables (sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests) were introduced. For step three of the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**H**<sub>03</sub>: Physical variables of sit-and-reach, chair stands, 8ft.-get-up-and-go, and six minute walk test, while controlling for the aforementioned psychosocial measures, age, calculated environmental fall-risk and medication use as covariates would predict the *NeuroCom balance system* vestibular scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables.

*Statistical Analysis:* A multiple hierarchical multiple regression model was conducted with vestibular balance scores as the sole dependent variable. Psychosocial measures of physical

function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the physical variables, while controlling for psychosocial measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the psychosocial measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the four physical predictor variables (sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests) were introduced. For step three of the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**Ho4**: Physical variables of sit-and-reach, chair stands, 8ft.-get-up-and-go, and six minute walk test, while controlling for the aforementioned psychosocial measures, age, calculated environmental fall-risk and medication use from the CFRSI as covariates would predict the *NeuroCom balance system* somatosensory scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables.

*Statistical Analysis:* A multiple hierarchical multiple regression model was conducted with somatosensory balance scores, as the sole dependent variable. Psychosocial measures of physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the physical variables, while controlling for psychosocial measures and maintaining the proper amount of predictors for the models' power. Along with the

FSC of the psychosocial measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the four physical predictor variables (sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests) were introduced. For step three of the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**H**<sub>05</sub>: Physical variables of sit-and-reach, chair stands, 8ft.-get-up-and-go, and six minute walk test as measured by the SFT, while controlling for the aforementioned psychosocial measures from the PROMIS and BES, age, calculated environmental fall-risk and medication use from the CFRSI as covariates would predict the *NeuroCom balance system* preference scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables.

*Statistical Analysis*: A multiple hierarchical multiple regression model was conducted with preference balance scores, as the sole dependent variable. Psychosocial measures physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, as measure by the PROMIS and balance efficacy as measured by the BES, were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the physical variables, while controlling for psychosocial measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the psychosocial measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were

entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the four physical predictor variables (sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests) were introduced. For step three of the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**H**<sub>06</sub>: Psychosocial variables of physical function, sleep disturbance, fatigue, pain interference, depression, and anxiety as measured by the PROMIS, and balance efficacy as measured by the BES, while controlling for the aforementioned physical measures from the SFT, age, calculated environmental fall-risk and medication use from the CFRSI as covariates would predict the *NeuroCom balance system* composite scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables.

*Statistical Analysis:* A multiple hierarchical multiple regression model was conducted with composite balance scores as the sole dependent variable. Physical measures of the sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests, were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the psychosocial variables, while controlling for physical measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the physical measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the six psychosocial predictor variables (physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy) were introduced. For step three of

the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

Ho7: Psychosocial variables of physical function, sleep disturbance, fatigue, pain interference, depression, and anxiety, and balance efficacy as, while controlling for the aforementioned physical measures, age, calculated environmental fall-risk and medication use as covariates would predict the *NeuroCom balance system* visual scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables. Statistical Analysis: A multiple hierarchical multiple regression model was conducted with visual balance scores as the sole dependent variable. Physical measures of the sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests, were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the psychosocial variables, while controlling for physical measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the physical measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the six psychosocial predictor variables (physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy) were introduced. For step three of the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**H**<sub>08</sub>: Psychosocial variables of physical function, sleep disturbance, fatigue, pain interference, depression, and anxiety, and balance efficacy, while controlling for the aforementioned physical measures, age, calculated environmental fall-risk and medication use as covariates would predict the *NeuroCom balance system* vestibular scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables.

*Statistical Analysis:* A multiple hierarchical multiple regression model was conducted with vestibular balance scores as the sole dependent variable. Physical measures of the sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests, were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the psychosocial variables, while controlling for physical measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the physical measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the six psychosocial predictor variables (physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy) were introduced. For step three of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**H**<sub>09</sub>: Psychosocial variables of physical function, sleep disturbance, fatigue, pain interference, depression, and anxiety, and balance efficacy, while controlling for the aforementioned physical measures, age, calculated environmental fall-risk and medication use as covariates would predict

the *NeuroCom balance system* somatosensory scores. It was also hypothesized that the diagnosis of CLBP and gender would moderate the utility of the predictor variables.

*Statistical Analysis:* A multiple hierarchical multiple regression model was conducted with somatosensory balance scores as the sole dependent variable. Physical measures of the sit-and-reach, chair stand, 8ft.-get-up-and-go, and six minute walk tests, were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the psychosocial variables, while controlling for physical measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the physical measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the six psychosocial predictor variables (physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy) were introduced. For step three of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

**H**<sub>10</sub>: Psychosocial variables of physical function, sleep disturbance, fatigue, pain interference, depression, and anxiety, and balance efficacy, while controlling for the aforementioned physical measures, age, calculated environmental fall-risk and medication use as covariates will predict the *NeuroCom balance system* preference scores. It is also hypothesized that the diagnosis of CLBP and gender will moderate the utility of the predictor variables.

*Statistical Analysis:* Using multiple hierarchical multiple regression model preference balance scores, was the sole dependent variable. Physical measures of the sit-and-reach, chair stand, 8ft.-

get-up-and-go, and six minute walk tests, were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the psychosocial variables, while controlling for physical measures and maintaining the proper amount of predictors for the models' power. Along with the FSC of the physical measures, age, calculated environmental fall risk, and calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model the covariates were entered into step one of the model to measure. In step two of the hierarchical multiple regression model, the six psychosocial predictor variables (physical function, sleep disturbance, fatigue, pain interference, depression, anxiety, and balance efficacy) were introduced. For step three of the hierarchical multiple regression model, the moderators of CLBP and gender were introduced. Finally, in step four of the hierarchical multiple regression model, the interaction among the moderators and predictor variables were introduced.

#### **METHODS**

## Database

Participants consisted of older adults (age 60 and older) from the *Center for Healthy Living and Longevity* (hereafter, to be referred to as CHLL) who had participated in the CHLL program from August 2015 through May 2017 at the University of Texas at Arlington. All measurements were taken prior to participants' participation in the CHLL program each semester. Participants were recruited from the local community through scheduled presentations about the CHLL (located at the University of Texas at Arlington) at various places: retired faculty gatherings, word-of-mouth from friends, churches, and even doctor recommendations. The Office of Justice Programs released a report titled *Our Aging Population: Promoting Empowerment, Preventing Victimization, and Implementing Coordinated Interventions* in the year 2000 that focused on older adults of 60 years or older, which is why the definition of older adults in this study was 60 years and older. All participants will have provided informed consent to participate per the Institutional Review Board (IRB) at the University of Texas at Arlington. Sample demographics are displayed in *table 1*.

 Table 1. Sample Descriptives

Measure	М	SD	Ν
Age	74.45	6.95	129
Male	-	-	34
Female	-	-	95
CLBP	-	-	36
NCLBP	-	-	93

#### Instruments

The PROMIS was a computer-adaptive test, designed to measure the following 7 psychosocial constructs: physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, and pain interference (Bajaj et al., 2011). The PROMIS has been tested and validated for concurrent and discriminant validity, test-retest reliability, as well as participant preference for measuring health-related quality-of-life (Bajaj et al., 2011). The computer-adaptive aspect of the PROMIS provides the advantage in that information was drawn from a large database, and was formatted to a specific individual, based on the individual's response to the previous question (Bajaj et al., 2011). The NIH has been encouraging its use and has extensively developed it to achieve validation in the general population. Each participant was assigned a computer, and a test profile was created before taking the assessment.

The dimensions of the PROMIS item banks have been specifically developed using patients' representative of the 2000 United States census (Baja et al., 2011). There are subsequent

question banks for each distinctive domain (anxiety, depression, fatigue, pain-interference, sleep disturbance, and physical function). There were 95 questions pertaining to fatigue; 124 questions regarding physical function; 28 questions with respect to depression; 41 in the pain-interference bank; 39 questions with regards to pain-behavior; 29 questions each in the anxiety and fear domains; 27 questions about sleep disturbances; 12 and 14 in the social impairment and social roles dimensions, respectively; and 16 questions in the sleep impairment construct. The PROMIS was a computer-automated-test (CAT) that selected a group of questions from the item bank for the participants to respond to, generally 4–12 questions per construct. The CAT presented the first question and, based on the individual's answer, selected following questions from the question pool, until the answers satisfied the precision criteria of 80% reliability (Baja et al., 2011). The consequential outcome was a score and standard deviation based on the standardized United States population. The mean score is 50, and the standard deviation is 10. An individual score is given per each dimension. Each dimension provides a total score, a score compared with the general United States population, a score compared with patients in the same age group, and a score compared with non-patients in the same age group. Each score is reported as either better or worse than the United States population norms (Baja et al., 2011).

The NIH case-definition of CLBP inventory was be used to classify participants into having or not having CLBP. The criteria for having CLBP included having low-back pain for greater than three months; and having low-back pain at a frequency of at least half the days in the past six months.

The *NeuroCom Balance System* detected any changes in an individuals' balance over time by evaluating their aptitude to regulate their center of gravity in various motor and sensory conditions. The participant stood on a force plate, facing into a three-sided surround. The visual surround and force plate moved in reaction to the participants' forwards and backwards sway, generating a distorted proprioceptive or visual input to the brain. This alteration caused the participant to rely greatly on alternate senses to maintain equilibrium. Body sway referred to changes in the center of the persons applied force as a result of moving forwards or backwards. Postural control was measured using the sensory organization test (SOT) and strategy analysis under six conditions, with a *NeuroCom Balance System* SOT. The SOT procedure accurately identified aberrations in the participant's use of the three sensory systems that encompassed postural control: somatosensory, visual, and vestibular (Ritchie & Palomaki, 2004). Throughout the assessment, inaccurate information was delivered to the participant's eyes, feet, and joints through "sway referencing" of the support surface and/or the visual surround. The participants will be fitted with a cushioned vest that is attached to the NeuroCom Balance System outerstructure in order to prevent the participant from experiencing an actual fall. Each condition was executed three times. Outcome measures for this test included: (1) Strategy Analysis, which measured the relative amount of movement of ankle-strategy and hip-strategy the participant used to maintain balance throughout each trial; (2) Equilibrium Score, which quantified the center of gravity (COG) sway or postural stability; (3) Sensory Analysis ratios, which were used in conjunction with the participant's equilibrium scores to detect deficiencies of the participant's sensory systems; and (4) COG alignment, which plotted the individual's COG position at the beginning of each trial of the SOT, in which each mark determined COG alignment during a single SOT trial, relative to the center of the base of support. The four measures were then combined for use as a composite score. Along with a composite score, the NeuroCom Balance System also provides separate scores for the somatosensory, visual, and vestibular systems, as well as preference (hip-to-ankle dominance).

Assessing physical measures for the participants was conducted through the SFT. After the participants' postural control was assessed with the *NeuroCom Balance System*, participants were be assessed for the components of physical fitness in upper- and lower-limb muscular strength, endurance and flexibility, and cardiovascular endurance through the Senior Fitness Test published by Human Kinetics, which evaluated functional fitness performance of elderly adults (Rikli & Jones, 2001). The battery of physical tests that participants completed in the SFT were: chair-stands (number of stands in 30-seconds); arm curls (number of reps in 30-seconds); 6minute walk (distance in yards); 2-minute step test (number of steps); chair sit and reach (modified sit and reach) in inches; back scratch in inches; and the 8ft.-get-up-and-go in seconds. Participants were then questioned on the amount of falls they had in the past year and six months. For the current study, the physical measures that will be examined from the SFT will be lower body measures in nature, and included chair stands completed in 30-seconds; a 6-minute walk test that measured how far the participants could walk in 6-minutes; an 8ft.-get-up-and-go agility test (which consisted of the participants standing up out of a chair and moving around a marker that was eight-feet from the chair and then sitting back down); and a modified sit and reach test to measure lower body flexibility. All physical fitness scorecards, NIH CLBP definition inventories, and consent forms have been stored in a locked file cabinets, and locked in the lab, and later de-identified and coded into IBM's Statistical Package for Social Science (SPSS).

To obtain demographic information that included the CFRSI included five subscales the American and British Geriatric Society (2011) identified fall-risk factors (history of falls, the use of an assistive device, arthritic diagnosis, and age of an individual), a physical risk subscale (mobility and agility/speed test scores), a medication subscale (information regarding the use of high-risk medication, such as psychotropic, anti-arrhythmic, digoxin/lanoxin, and diuretics, information of multiple pharmacists, and the experience of medication side-effects), a vision subscale (visual acuity, visits to the optometrists, the use of prescription lenses) and an environment subscale (calculated with information regarding hazards that exist in the participants home). The relative risk ratio and odds ratio (developed by Fabre et al., 2010) were used to weigh each and calculate each fall-risk subscale, and all five of the subscale scores were averaged for a total fall-risk score.

To measure the participant's perceived confidence in their balance the BES was used. The BES is an 18 question psychometric assessment of balance confidence survey developed by the California State University at Fullerton's Center for Successful Aging.

#### Scoring

During the SOT, participants will be assessed under 6 conditions (three trials per condition), for a total of 18 trials. Each duration of the trial was 30 seconds. The force plate and visual surround shifted in response to the participant's center of gravity sway. The inclusive composite score provided an overall score of the participant's ability to endure postural stability throughout all conditions. The individual's' sensory system scores (vestibular, visual, somatosensory) were derived from the overall pattern of scores in each of the six conditions. The composite score was the weighted average that encompassed the average scores of conditions 1–6 (Biggan et al., 2014).

The strategy analysis score or preference was computed by plotting the data from the force plate and the equilibrium scores together, in order to quantify the amount of movement of the ankles or the hips. The strategy analysis score reflected the extent of movement concerning the ankles (ankle-dominant strategy) and hips (hip-dominant strategy) that was used to sustain postural stability throughout each trial. The closer the scores were to 100, the more ankledominant strategy was used to maintain stability. Conversely, scores closer to zero reflected a more hip-dominant strategy used to maintain postural control. Typically, as stability was sustained, individuals utilized primarily an ankle-dominant strategy, shifting to a more hipdominant strategy under conditions where postural control was more difficult to maintain (Biggan et al., 2014).

## Procedures

Participants first consented to the IRB-approved protocol of the current study. After consent, participants completed the NIH case-definition of CLBP inventory, with paper and pencil. The PROMIS was then be administered, followed the CFRSI and then the BES. When the participants finish the PROMIS, CFSRI, and BES they were logged out of their profile and results were saved, to be accessed later in order to be de-identified and transferred and coded into SPSS.

After the PROMIS, CFSRI, and BES were administered, participants completed the SOT on The *NeuroCom Balance System* to acquire postural control scores. The scores were de-identified and transferred into an SPSS for statistical analysis.

The last test administered was the SFT. All measures were collected on a score sheet, and then again de-identified and inputted into SPSS for statistical analysis. All tests were administered by a senior graduate student, and graduate and undergraduate research assistants.

The current study examined the following biopsychosocial variables: physical function, sleep disturbance, fatigue, pain interference, depression, and anxiety, as measured by the PROMIS; balance efficacy as measured by the BES; and physical measures of cardiovascular endurance (six-minute walk test), lower body muscular endurance (chair-stand test), lower body flexibility (modified and sit-and-reach test), and agility (8 ft. get-up and go test) measured by the SFT. It also examined if CLBP and gender moderated the utility of any of the aforementioned biopsychosocial predictors, while controlling for age (self-report), calculated environmental fall-risk, and medication fall-risk measured by the subscales of the CSFRI. The assumption was that the aforementioned biopsychosocial measures would predict overall NeuroCom composite, visual, vestibular, somatosensory, and preference scores of the SOT, as measured by the NeuroCom Balance System using several multiple regression models.

### **Power Analysis**

Using a *priori* multiple regression G\*Power (Faul et al., 2009), with 12 predictor variables requiring a medium effect size of  $f^2 = .15$ , and a regression critical coefficient of F = 1.84, a sample size of N = 127, was needed to find significance at a probability error of  $\alpha = .05$ . With a sample size of N = 129, the study had the power to use up to 12 predictors in the regression models.

## Statistical Analysis for Physical Predictors

Second order principal components analysis was conducted on psychosocial and physical variables separately, and the first factor score for each was saved and used as covariates in the multiple hierarchical multiple regression models that examined psychosocial and physical measures separately as the predictor variables, while maintaining a proper power for the analyses.

Using hierarchical multiple regression models composite, visual, vestibular, somatosensory, and preference balance scores as measured by the *NeuroCom Balance System*, were the sole dependent variables for each multiple hierarchical multiple regression model. Psychosocial measures of the anxiety, depression, fatigue, sleep disturbance, pain interference, and balance efficacy as measured by the PROMIS and BES respectively, were calculated into a FSC with a principal component analysis that was used as a covariate in order to measure the predictability of the physical variables while controlling for psychosocial measures and maintaining the proper amount predictors for the models power. Along with the FSC of the psychosocial measures, age, calculated environmental fall risk, calculated medication fall risk were covariates in the analysis. In the first-step of each hierarchical multiple regression model (five separate models to measure the predictability of composite, visual, vestibular, somatosensory, and preference balance scores) the covariates were entered in to step one of the model. In step two of each hierarchical multiple regression model, the four physical predictor variables (modified sit-and-reach, chair stands, 8ft.-get-up-and-go, and six minute walk) were introduced. Step three of each hierarchical multiple regression model the moderators CLBP and gender were introduced. Finally in step four of each hierarchical multiple regression model, the interaction between the moderators and predictor variables were introduced.

## Statistical Analysis for Psychosocial Predictors

Using multiple hierarchical multiple regression models composite, visual, vestibular, somatosensory, and preference balance scores as measured by the *NeuroCom Balance System*, were the sole dependent variables for each multiple hierarchical multiple regression models. Physical measures of the six-minute walk test, chair-stand test, modified sit-and-reach test, and 8 ft. get-up and go test, as evaluated by the SFT, were calculated into a FSC with a principal component analysis that were used as a covariate in order to measure the predictability of the psychosocial variables while controlling for physical measures and maintaining the proper number of predictors for the model's power. Along with the FSC of the physical measures, age, calculated environmental fall risk, calculated medication fall risk were covariates in the analysis.

In the first-step of each hierarchical multiple regression model (five separate models to measure the predictability of composite, visual, vestibular, somatosensory, and preference balance scores) the covariates were entered in to step one of the model. In step two of each hierarchical multiple regression model the six psychosocial predictor variables (anxiety, depression, fatigue, pain interference, sleep disturbance, and balance efficacy) were introduced. Step three of each hierarchical multiple regression model, the moderators CLBP and gender were introduced. Finally, in step four of each hierarchical multiple regression model, the interaction between the moderators and predictor variables were introduced.

### Results

## Factor Analyses

For the models containing physical measures as the predictor variables, initially the factorability of the six psychosocial items were examined. The Kaiser-Meyer-Olkin measure of sampling adequacy was .76, above the recommended value of .60, and Bartlett's test of sphericity was significant  $\chi^2(21) = 250.84$ , p < .001. Given the overall indicators, a factor analysis was conducted with all six psychosocial constructs.

A principal components analysis was used because the purpose was to compute a composite psychosocial score to use as a covariate in the multiple hierarchical multiple regression models that examined physical measures as the predictor variables while maintaining proper power for the analyses. The initial eigen values showed that the first factor explained 44.98% of the variance, and the second factor 16.48% of the variance. All psychosocial constructs were most heavily loaded in the first factor: anxiety (r = .65), depression (r = .65), fatigue (r = .82), pain interference (r = .70), physical function (r = .71), sleep disturbance (r = .45), and balance efficacy (r = .66). Since all constructs were most heavily weighted in the first

factor, the first factor coefficient was used as the covariate in the hierarchical multiple regression models that examined physical measures as the predictor variables. For the models containing psychosocial measures as the predictor variables, initially the factorability of the four physical measures were examined. The Kaiser-Meyer-Olkin measure of sampling adequacy was .75, above the recommended value of .60, and Bartlett's test of sphericity was significant  $\chi^2$  (21) = 145.27, *p* < .001. Given the overall indicators, a factor analysis was conducted with all four physical measurements. The initial eigenvalues showed that the first factor explained 61.44% of the variance. All psychosocial constructs were most heavily loaded in the first and only factor produced: 8ft.-get-up-and-go (*r* = .88), six minute walk (*r* = .81), modified sit-and-reach (*r* = .59), and chair stands (*r* = .83). Because all constructs were most heavily weighted on the first factor, the first factor coefficient was used as the covariate in the multiple hierarchical regression models that examined psychosocial constructs as the predictor variables.

### Hierarchical Multiple Regression Analyses Physical Measures

Results of the hierarchical multiple regressions for the covariates (psychosocial variables, age, medication use, and environmental risk) in the first-step did not predict composite, visual, vestibular, somotasensory, or preference balance scores. In the second step, physical measures (i.e. sit-and-reach test, chair stands test, 8ft.-get-up-and-go test, six minute walk test) were significant over and beyond the covariates in the first-step for predicting NeuroCom composite  $F(8, 89) = 4.57, p < .001; \Delta R^2 = .25, \Delta F(4, 89) = 7.84, p < .001$  and vestibular balance scores  $F(8, 89) = 2.83, p = .008; \Delta R^2 = .19, \Delta F(4, 89) = 5.29, p = .001$ , and approached significance in for visual balance scores  $F(8, 89) = 1.85, p = .078; \Delta R^2 = .13, \Delta F(4, 89) = 5.29, p = .013$ . Physical measures did not yield statistically significant predicting results for the NeuroCom somatosensory, or preference scores. The physical measures that were significant variables for

predicting composite balance scores were the sit-and-reach measure b = .39, SE = .18, t(89) = 2.14, p = .035,  $sr^2 = .22$  and the chair stand measure b = .86, SE = .24, t(89) = 3.51, p = .001,  $sr^2 = .35$ . The six minute walk and 8ft.-get-up-and-go test were not found to be statistically significant as individual predictors for composite balance scores. All physical predictor variables were analyzed if they are were moderated by gender or CLBP. No interactions were significant in predicting composite balance scores. In regards to physical measures that were significant individual predictors for vestibular scores were also the sit-and-reach measure b = .83, SE = .39, t(89) = 2.12, p = .037,  $sr^2 = .22$  and the chair stand measure b = 1.31, SE = .52, t(89) = 2.50, p = .014,  $sr^2 = .26$ . The six minute walk and 8ft.-get-up-and-go test were not found to be statistically significant as individual predictors for vestibular balance scores. Gender and CLBP were also examined as moderators of physical predictor variables as in the previous model, however, no interactions were significant when predicting vestibular balance scores. All Tolerance (>.01) and variance inflation factor (VIF) (< 10.00) measures were within acceptable limits indicating no issues with multicollinearity in any of the analyzed models.

## Hierarchical Multiple Regression Analyses Psychosocial Measures

Results of the hierarchical multiple regressions for the covariates in the first-step (physical variables, age, medication use, and environmental risk) significantly predicted composite ( $R^2 = .20$ , F(4, 92) = 5.73, p < .001) and vestibular ( $R^2 = .12$ , F(4, 92) = 3.20, p = .017) balance scores in the first-step, but did not predict visual, somatosensory, or preference balance scores. In the second step of the hierarchical multiple regression models, psychosocial measures were introduced (anxiety, depression, fatigue, pain interference, physical function, sleep disturbance, and balance efficacy), and when controlling for the covariates, the psychosocial measures yielded significant results over and beyond the covariates for predicting

NeuroCom composite, F(11, 85) = 3.98, p < .001;  $\Delta R^2 = .14$ ,  $\Delta F(7, 85) = 2.58$ , p = .018, and visual balance scores, F(11, 85) = 2.27, p = .017;  $\Delta R^2 = .15$ ,  $\Delta F(7, 85) = 2.34$ , p = .031, with vestibular balances measures approaching significance F(11, 85) = 2.53, p = .008;  $\Delta R^2 = .12$ .  $\Delta F(7, 85) = 2.01, p = .064$ . Psychosocial variables did not significantly predict results for the NeuroCom somatosensory or preference scores. The psychosocial measures that were significant for predicting composite balance scores were sleep disturbance, b = -.36, SE = .09, t(85) = -3.81, p < .001,  $sr^2 = -.38$  and balance efficacy approaching significance b = -.09, SE = .05, t(85) = -1.82, p = .072,  $sr^2 = -.19$ . Anxiety, depression, fatigue, pain interference, and physical function were not found to be statistically significant as individual predictors. In regards to visual balance scores, significant individual predictors were also sleep disturbance b = -.41, SE = .12, t(85) = -3.31, p = .001,  $sr^2 = -.34$  and balance efficacy b = -.14, SE = .07, t(85) = -2.12, p = .037,  $sr^2 = -$ .22. All psychosocial predictor variables were analyzed if they are were moderated by gender or CLBP in predicting visual balance scores and no interactions were statistically significant predicting visual balance scores. All Tolerance (> .01) and VIF (< 10.00) measures were within acceptable limits indicating no issues with multicollinearity. Descriptive NeuroCom data compared to low and high groups of each significant predictors (sit and reach, chair stands, sleep disturbance, and balance efficacy) are shown in tables 2-5.

# Table 2.

Low BE (n = 24) Mean BE (n = 90) High BE (n = 10)

Neurocom Data Descri	iptives Comparea	l with Low, Mean,	and High Balar	<i>ice Efficacy</i>
	First			J

Measure	М	SD	М	SD	М	SD
Composite	71.08	8.73	74.02	7.28	75.10	6.79

## **BIOPSYCHOSOCIAL MEASURES OF POSTURAL CONTROL**

Visual	84.29	7.17	86.57	9.09	87.00	11.33
Vestibular	61.92	19.40	65.47	14.29	66.10	8.01
Somatosensory	92.54	7.49	94.57	3.86	97.10	4.33
Preference	97.46	11.01	98.59	10.09	95.40	7.53

*Note.* Balance efficacy is represented by BE. The low group consisted of scores less than one standard deviation from the mean. The mean group consisted of scores that fall within one standard deviation of the mean. The high group consisted of scores greater than one deviation from the mean.

# Table 3.

	Low SLD	( <i>n</i> = 22)	Mean SLD $(n = 80)$		n = 22) Mean SLD ( $n = 80$ ) High SLD ( $n =$			D ( <i>n</i> = 21)
Measure	М	SD	М	SD	М	SD		
Composite	77.23	6.84	73.38	7.39	71.62	8.61		
Visual	89.45	7.97	85.75	9.18	85.10	9.14		
Vestibular	71.00	10.78	64.92	14.18	59.48	20.06		
Somatosensory	95.59	4.55	94.16	4.05	94.19	7.64		
Preference	100.73	8.90	97.73	10.09	99.33	8.39		

Neurocom Data Descriptives Compared with Low, Mean, and High Sleep Disturbance

*Note*. Sleep disturbance is represented by SLD. The low group consisted of scores less than one standard deviation from the mean. The mean group consisted of scores that fall within one standard deviation of the mean. The high group consisted of scores greater than one deviation from the mean.

# Table 4.

Neurocom Data Descriptives Compared with Low, Mean, and High Modified Sit and Reach

Low SNR ( <i>n</i> = 20)	Mean SNR $(n = 93)$	High SNR( $n = 16$ )

Measure	М	SD	М	SD	М	SD
Composite	70.20	8.10	73.82	7.45	77.56	5.91
Visual	83.10	8.88	86.67	9.17	88.75	6.34
Vestibular	59.35	20.71	65.16	13.65	71.94	10.36
Somatosensory	92.30	6.94	94.55	4.31	96.38	4.00
Preference	100.85	14.25	97.70	9.00	97.75	8.53

*Note*. Sit and Reach is represented by SNR. The low group consisted of scores less than one standard deviation from the mean. The mean group consisted of scores that fall within one standard deviation of the mean. The high group consisted of scores greater than one deviation from the mean.

# Table 5.

	Low CS	( <i>n</i> = 18)	Mean C	Mean CS $(n = 80)$		S ( <i>n</i> = 22)
Measure	М	SD	М	SD	М	SD
Composite	70.44	6.72	73.58	6.96	78.68	7.27
Visual	84.44	7.23	86.45	9.23	90.14	8.12
Vestibular	57.11	19.30	65.53	13.32	71.09	11.56
Somatosensory	94.17	4.45	94.23	4.33	96.55	3.33
Preference	99.39	15.71	97.74	9.41	99.50	5.99

Neurocom Data Descriptives Compared with Low, Mean, and High Chair Stands

*Note.* Chair Stands is represented by CS. The low group consisted of scores less than one standard deviation from the mean. The mean group consisted of scores that fall within one standard deviation of the mean. The high group consisted of scores greater than one deviation from the mean.

# DISCUSSION

The purpose of this study was to examine the usefulness of biopsychosocial measures in predicting postural control. Results of the current study found that physical measures significantly predicted composite and vestibular balance scores, and approached statistical significance for visual balance scores. Physical measures did not significantly predict somatosensory or preference balance scores. Examination the physical measures found that both poorer composite and vestibular balance scores were predicted by fewer chair stands and a greater distance measured from the fingertip to the toe on the modified sit-and-reach test. The psychosocial measures were significant in predicting composite and visual balance scores, and approached statistical significance for vestibular balances scores. Specifically, greater sleep disturbance and lower balance efficacy were significant individual predictors for worse score in composite and visual balance measures.

The results of the present study indicated that the chair stand test was a significant individual predictor in balance scores. This supported the previous findings of Granacher and colleagues (2010) in which postural control was found to coincide with an increased rate of force development in lower body extensor muscles, and the Hopper and colleagues (2014) study of inducing lower body muscular fatigue through 60 seconds of repetitive jumping. It could be that the neuromuscular adaptations that occur in muscle strength gains in the lower body could be what was influencing participant's ability in postural control. It has been well known that muscular responses to training are adapted and maintained by specific changes occurring within the neural control circuits (Felici, 2006). In normal conditions strength training may elicit adaptations along the neuromuscular chain from the higher brain centers down to individual muscle fibers, and this neural drive is thought to increase in agonist muscle recruitment, neural firing rate, enhanced motor neuron synchronization during muscular contractions, increase length

of nerve terminal branching, and increase motor neuron end-plate perimeter length, and a reduction in inhibitory mechanisms from the Golgi tendon organs (Deschenes et al., 1993; Deschenes et al., 2000; Felici, 2006; Ratamess, 2008). A study by Adams and colleagues (1993) found using magnetic resonance imaging that only 71% of muscle tissue was activated during maximal effort in untrained individuals, and it has been found that training can greatly reduce this deficit (Pensini et al., 2002). A systematic review of balance training on neuromuscular control by Zech and colleagues (2010) found that balance training effects on muscular strength increase muscular activity for the lower body muscles of the soleus, gastrocnemius medialis, and quadriceps muscles. The enhancement in neuromuscular system could be why participants who performed more repetitions on the chair stand test were predicted to have better overall composite, vestibular, and visual balance scores in the current study.

Previous studies have found musculoskeletal tightness and muscle strains to influence muscular strength (Orchard et al., 1997; Tyler et al., 2001). In this study, the chair-stand test and modified sit-and-reach were both individual significant predictors of balance scores. The results of this study also support Taylor-Piliae and colleagues (2006) who found a Tai Chai exercise program over a 12 week period enhanced balance, strength, and flexibility measures. The influence of muscular strength and flexibility on postural control is well documented in the aforementioned previous studies, as well as in the current study.

In further analysis of this study, sleep disturbance was a significant individual predictor for balance scores. This supported the findings of Jorgensen and colleagues (2012) that found participants who described themselves as being "sleepy" had increased postural sway than did participants who reported being well-rested. Furtado and colleagues (2016) demonstrated that individuals with worse sleep quality performed worse on a balance test with eyes closed, a finding supported by the present study. Various other research supports the present study finding that sleep disorders have had a negative impact on postural control and balance deterioration, are responsible for work accidents and falls among older adults, and can occur just after one night without sleep (Aguiar & Barela, 2014; Aguiar & Barela, 2015; Albuquerque et al., 2012; Bougard & Davenne, 2014; Gauchard et al., 2008; Gomez et al., 2008; Gribble & Hertel, 2004; Karita et al., 2006; Ku et al., 2012; Kurtz et al., 2013; Patel et al., 2008). A study of older adult participating in Tai chi classes for six months found that compared to controls those who participated in six months of Tai chi classes had a significantly lower fear of falling and improved sleep quality (Nguyen & Kruse, 2012), further supporting the findings of the current study. Previous studies have found evidence to support that lower sleep quality in older adults was related to impaired health status, decreased physical activity, lowered levels of physical functioning, and increase prevalence of chronic diseases (Newman et al., 2000; Gooneratne et al., 2003). Exercise regiments, such as Tai chi, have been found to improve sleep quality, sleeponset latency, sleep duration, sleep efficiency, and sleep disturbance (Li et al., 2004). The effect of participants being generally more physically active may be responsible for not only better scores in regards to the chair stand test, but also better self-reported sleep disturbance scores, both of which were significant individual predictors of balances scores in the current study.

Balance efficacy was also an individual significant predictor of balance score. Of the psychosocial constructs that had been associated with falls, some of the most common factors are increased anxiety from fear of falling and a reduction in balance efficacy (Moore et al., 2008; Moore et al., 2011; Jorstad et al., 2005). This study partially supported the previous finding by identifying balance efficacy as a significant predictor in balance scores, but anxiety was not a

significant predictor in the current study. Indeed, the study still supports the biopsychosocial approach associated with falls and fall-risk.

It should be known that in any clinical research study of this sort, a potential for some confounds may or may not have influenced the results. For example, testing procedures were carried out by numerous graduate and undergraduate research assistants, and even though all research assistants were trained before any data collection, the research assistants could have influenced the effort or performance of the participant based on gender, familiarity with research assistants, or strictness in the testing protocol. Also selection of participants was not randomized, and was purely volunteers that had interest in participating in the current study. These confounds are acknowledged in the current study and they may or may not have influenced any results.

### Conclusion

Overall, the major aims of the present study embraced a *biopsychosocial* model. Indeed, there is a need to not just to consider physical measures when assessing postural control, but to simultaneously evaluate psychosocial constructs with physical measures when examining fallrisk in older adults. A major innovation of the study was the use of a relatively new physical measure of postural control, and the examination of its relationship to other physical, psychosocial, and pain measures in the older adult population. This study can conclude that psychosocial and physical measures, specifically sleep disturbance, balance efficacy, lower body strength, and lower body flexibility, did influence over all balance, and vestibular and visual systems involved in balance.

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# **Appendix A: NIH Definition of CLBP**

# NIH DEFINITON OF CLBP

A response of greater than 3 months to Question 1

# and

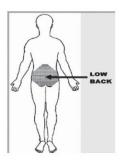
A response of "at least half the days in the past 6 months" to Question 2

1. How long has low-back pain been an ongoing problem for you?

- Less than 1 month
- 1–3 months
- □ 3–6 months
- 6 months-1 year
- □ 1–5 years
- □ More than 5 years

2. How often has low-back pain been an ongoing problem for you over the past 6 months?

- Every day or nearly every day in the past 6 months
- At least half the days in the past 6 months
- □ Less than half the days in the past 6 months



Appendix B:PROMIS-29

# PROMIS-29 Profile v2.0

Please respond to each question or statement by marking one box per row.

	Physical Function	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
1	Are you able to do chores such as vacuuming or yard work?					
2	Are you able to go up and down stairs at a normal pace?					
з	Are you able to go for a walk of at least 15 minutes?					
4	Are you able to run errands and shop?					
	<u>Anxiety</u> In the past 7 days	Never	Rarely	Sometimes	Often	Always
5	I felt fearful					
6	I found it hard to focus on anything other than my anxiety					
7	My worries overwhelmed me					
8	I felt uneasy					
	Depression In the past 7 days	Never	Rarely	Sometimes	Often	Always
9	I felt worthless					
10	I felt helpless					
11	I felt depressed					
12	I felt hopeless					
	Fatigue During the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
13	I feel fatigued					
14	I have trouble <u>starting</u> things because I am tired					

PROMIS-29 H	Profile v2.0
-------------	--------------

	<u>Fatigue</u> In the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
15	How run-down did you feel on average?					
16	How fatigued were you on average?					
	<u>Sleep Disturbance</u> In the past 7 days	Very poor	Poor	Fair	Good	Very good
17	My sleep quality was					
	In the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
18	My sleep was refreshing					
19	I had a problem with my sleep					
20	I had difficulty falling asleep					
	Ability to Participate in Social Roles and Activities	Never	Rarely	Sometimes	Usually	Always
21	I have trouble doing all of my regular leisure activities with others					
22	I have trouble doing all of the family activities that I want to do					
23	I have trouble doing all of my usual work (include work at home)					
24	I have trouble doing all of the activities with friends that I want to do					
	Pain Interference In the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much
25	How much did pain interfere with your day to day activities?					
26	How much did pain interfere with work around the home?					
27	How much did pain interfere with your ability to participate in social activities?.					
28	How much did pain interfere with your household chores?					

# PROMIS-29 Profile v2.0

	Pain Intensity In the past 7 days										
29	How would you rate your pain on average?	0 No pain	2	3	4	5	6	7	8	9	10 Worst imaginable pain

# Appendix C: Comprehensive Fall Risk Screening Instruement

# Comprehensive Falls Risk Screening Instrument (CFRSI)

<center>Please answer the following questions to the best of your ability. Ask the Research Assistant for help if needed.</center>

#### \* Required

#### Participant Number \*

Please enter the participant number given to you by the Research Assistant.

Date

#### Gender

- Male
- Female

#### Marital Status

- Single
- Married
- Widowed
- Divorced
- Decline to Answer

#### Ethnicity

- White of Caucasian
- Black or African American
- Hispanic or Latino (Mexican, Puerto Rican, Cuban, Other)
- Asian (Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Other)
- Native Hawaiin or other Pacific Islander
- Declined to Answer
- Other:

#### .

#### Income

- \$776 or less monthly
- \$1041 or less monthly
- \$1306 or less monthly
- \$1571 or less monthly
- \$1836 or less monthly
- Annual \$25,000 to \$34,999
- Annual \$35,000 to \$49,999
- Annual \$50,000 or greater
- Output Decline to Answer

Household Size
1 person
2 people
3 people
4 people
5 people
<ul> <li>Decline to Answer</li> </ul>
Other:

# Education Level

- Less than 9th grade
- High School Graduate/GED
- Some College/No Degree
- Associate's Degree
- Bachelor's Degree
- Graduate or Professional Degree
- Declined to Answer

# History of Diseases

Continue »

# Comprehensive Falls Risk Screening Instrument (CFRSI)

# Medical/Fall History

Please answer the following questions to the best of your ability. Ask the Research Assistant for help if needed.

# Have you fallen in the past 3 years?

- Yes
- No

# If yes, were any in the last 12 months?

- Yes
- No
- N/A

# Do you use any walking aids (cane walker, etc...)?

- Yes
- No

# Do you have Arthritis?

- Yes
- 🔘 No

« Back Continue »

# Comprehensive Falls Risk Screening Instrument (CFRSI)

# Mobility/Balance

The Research Assistant will enter values for the following questions.

Functional Reach Test (inches)

# Expanded Timed Up and Go (seconds)

« Back Continue »

# Comprehensive Falls Risk Screening Instrument (CFRSI)

# Medications

Please answer the following questions about any medications you are taking to the best of your ability. Ask the Research Assistant for help if needed.

# Known Medications

Check all that apply

- More than 4 prescription meds
- Psychotropic meds
- Anti-arrhythmic meds
- Digoxin/Lanoxin
- Diuretics
- None of the above

# Have you experienced any side-effects due to your medications (e.g. Drowsiness, Dizziness, Impaired balance)?

- Yes
- No
- N/a

### Do you fill ALL of your prescriptions at the same pharmacy?

- Yes
- No
- N/a

« Back Continue »

## Comprehensive Falls Risk Screening Instrument (CFRSI)

## Vision

Please answer the following questions about your vision to the best of your ability. Ask the Research Assistant for help if needed.

## Do you have a prescription for corrective lenses?

- Yes
- No

## If yes, do you wear your corrective lenses as prescribed?

- Yes
- 🔘 No
- N/A

## Have you had a vision test in the past 12 months?

- Yes
- No

## Snellen Score w/lenses

The Research Assistant will enter the value.

« Back Continue »

# Comprehensive Falls Risk Screening Instrument (CFRSI)

## Environmental Survey

Please answer the following questions about your home to the best of your ability. Ask the Research Assistant for help if needed.

If you have stairs within your home or to enter your home answer questions 1, 2, and 3. If not, skip to 4.

## Do you have handrails on both sides of all the stairways in your home, including the outside stairs?

- Yes
- No
- N/A

#### Do the stair rails extend the full length of the stairway?

- Yes
- No
- N/A

### Are the stairways well lit with lights at the top and bottom of the stairs?

- Yes
- No
- N/A

## Do you have nightlights to help light your bathrooms, bedrooms, and hallways during the evening hours?

- Yes
- No

#### Are you able to turn on a light immediately upon entering a room?

- Yes
- No

#### Do you have grab bars in your bath and shower stalls as well as on the sides of the toilet?

- Yes
- No

#### Do you have a non-slip mat or safety decals in your bath and shower?

- Yes
- No

### Do you remove soap build-up in the tub and shower on a regular basis to avoid slipping?

- Yes
- No

If you have area rugs, do they have rug-liners underneath, dual-sided tape, or non-skid backs?

- Yes
- No
- N/A

## Are your steps, landings, and floors clear of clutter?

- Yes
- No

## Do you keep floors clean by promptly wiping up grease, water, and other spills?

- Yes
- No

## Are things you use often stored on easy-to-reach shelves, so that you don't need to reach too high or bend too low to get them?

Yes

No

« Back Submit

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## **Balance Efficacy Scale (BES)**

Listed below are a series of tasks that you may encounter in daily life. Please indicate how confident you are, today, that you can complete each of these tasks without losing your balance. Your answers are confidential. Please answer as you feel, not how you think you should feel.

<center><b>(From 0 to 100%)</center></b>

\* Required

#### Participant Number \*

Please enter the participant number given to you by the Research Assistant.

## How confident are you that you can get up out of a chair (using your hands) without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

## How confident are you that you can get up out of a chair (NOT using your hands) without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

## How confident are you that you can walk up a flight of ten stairs (using the handrail) without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

## How confident are you that you can walk up stairs (NOT using the handrail) without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

#### How confident are you that you can get out of bed without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

## How confident are you that you can get into or out of a shower or bathtub (with the assistance of a handrail or support wall) without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

How confident are you that you can get into or out of a shower or bathtub (with NO ASSISTANCE from a handrail or support wall) without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

## How confident are you that you can walk down a flight of ten stairs (using the handrail) without losing your balance?

0%=Not at all confident; 50%=Somewhat confident; 100%=Absolutely confident

How confident are you that y without losing your balance?	ou can walk down a flight of ten stairs (NOT using the handrail)
	Somewhat confident; 100%=Absolutely confident
is level with your shoulder w	ou can remove an object from a cupboard located at a height that ithout losing your balance? Somewhat confident; 100%=Absolutely confident
head without losing your bala	
0%=Not at all confident; 50%=	Somewhat confident; 100%=Absolutely confident
is good lighting available wit	
0%=Not at all confident; 50%=	Somewhat confident; 100%=Absolutely confident
there is good lighting availab	ou can walk across uneven ground (with NO ASSISTANCE) when ole without losing your balance? Somewhat confident; 100%=Absolutely confident
	Somewhat confident, 100%-Absolutely confident
How confident are you that y without losing your balance?	ou can walk across uneven ground (with assistance) at night
	Somewhat confident; 100%=Absolutely confident
	ou can walk across uneven ground (with NO ASSISTANCE) at
night without losing your bal 0%=Not at all confident: 50%=9	ance? Somewhat confident; 100%=Absolutely confident
of trousers without losing yo	
0%=Not at all confident; 50%=	Somewhat confident; 100%=Absolutely confident
How confident are you that y pair of trousers without losin	ou could stand on one leg (with NO SUPPORT) while putting on a
	Somewhat confident; 100%=Absolutely confident
	ou could complete a daily task quickly (e.g., answer a ringing
	r that is boiling over on stove, etc.) without losing your balance? Somewhat confident; 100%=Absolutely confident

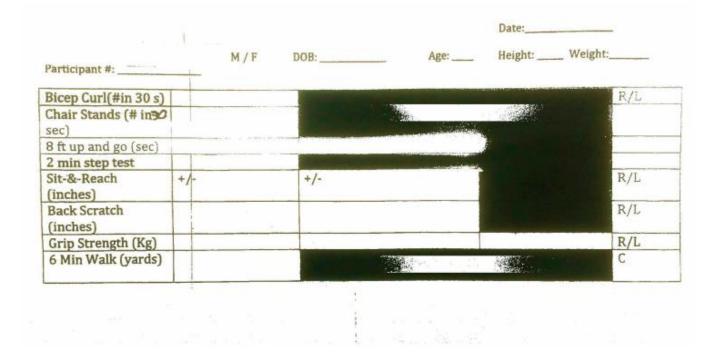
Lastly, we are interested in understanding what factors affect your confidence levels. Please provide reasons for why you answered the way you did. For example, if you answered that you were not very confident, why do you feel that way? If you were not very confident about an activity because you no longer do it very often e.g., climb stairs, walk on uneven ground, etc... we would like to know that also.



Submit

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## **Appendix E: Senior Fitness Test Scorecard**



## **Appendix F: Informed Consent Document**

## UT Arlington Informed Consent Document

### PRINCIPAL INVESTIGATOR

Dr. Robert J. Gatchel, Department of Psychology, College of Science, 817-272-2541, Gatchel@uta.edu

## TITLE OF PROJECT

Effects of a seated exercise intervention simulating activities of daily living on factors associated with fall risk.

## INTRODUCTION

Before you say that you will be in this research study, you need to read this Form. It is important for you to understand all the information in this Form. This Form will tell you what the study is about and how it will be done. It will tell you about some problems that might happen for you during the study. When you read a paper like this to learn about a research study, it is called "Informed Consent". The people who are doing this research study are giving you very important information about the study. When you give your consent for something, it is the same as giving your permission. This Consent Form may contain words that you do not understand. Please talk to someone from the research staff if you have questions. Do not sign this Consent Form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the Form to keep.

### PURPOSE

The specific purposes of this research study are as follows:

We want to learn about the role of exercise in preventing falls in healthy older adults.

We want to observe if fall-risk and pain are related.

We want to observe if exercise is an effective way to manage pain.

#### DURATION

You will be in the study for approximately 16 weeks, with those in the Exercise Group receiving 13-weeks of intervention. However, due to Holiday/University breaks, there may be fewer interventions sessions (however, that will not affect your continued participation in the study).

## NUMBER OF PARTICIPANTS

1

The number of anticipated participants in this research study is 500.

### PROCEDURES

All of the procedures that are being done in this study are approved for healthy older adults: nothing is considered experimental. Before you can participate in the study, you must get your medical doctor's written permission for you to participate.

If you qualify to be in the study and consent to take part in it, you will be given an appointment to return. On that day, you will be asked to complete questionnaires, which will ask you questions about your health and about how and when you interact with others. On the same day, you will be asked to complete initial baseline testing of your strength, weight, balance, walking speed, cognitive ability, environment that you live in, sociability, social support, and demographics. We are also interested in individual differences that are related to the way you move.

### Comprehensive Fall Risk Screening Instrument (CFRSI)

The CFRSI includes five falls- risk subscales. The History Risk sub-scale includes identified falls- risk factors of history of falls, assistive device usage (such as a cane or walker), diagnosis of arthritis, and self-reported age. The Physical Risk subscale includes measures of balance and mobility, and the Medication Risk subscale includes information regarding high-risk medication use, use of multiple pharmacists, and medication side effects. The Vision Risk subscale encompasses visual acuity, optometry visits, and use/compliance of prescription lens, and the Environment Risk subscale is calculated, using information regarding hazards in the home.

## PROMIS-29

Psychosocial outcomes are measured using the PROMIS-29, a 29-item questionnaire with 8 components, including physical function, anxiety, depression, fatigue, and sleep disturbance, satisfaction with social role, pain interference, and pain intensity. The questions on the PROMIS 29 focus on the previous 7-days. This tool is scored on a 5-point Likert scale, similar to a perceived pain scale ("on a scale of 1-5, what is your pain level?") Two of the components of the PROMIS-29 evaluate your pain (pain interference and pain intensity).

Sensory Organization Test (SOT) on the Neurocom Balance Master

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The SOT consists of six conditions (each of which is designed to test balance by challenging one of the three sensory systems used to maintain balance): eyes opened on a firm surface; eyes closed on a firm surface; eyes opened with the wall moving, based on individual sway; eyes opened on a sway- referenced support surface; eyes closed on a sway- referenced support surface; and eyes opened on a sway- referenced support surface and surround. "Sway-referenced" refers to the Neurocom's function that responds to your body's natural forward/backward sway to maintain balance.

## Gait Analysis

Researchers will also be doing a gait analysis using the Protokinetics Zeno Walkway. A gait analysis provides information on the way you walk, and may help to identify inefficiencies and weaknesses in the way you walk. You will be asked to walk normally on a pressure-sensitive walkway, where data will be collected regarding specific details of your gait. Information gained during this procedure could provide insight on the role of gait dynamics on postural control.

## Lower Extremity Dexterity (LED)

You will also be asked to control a platform attached to a spring placed on a force plate, and then compress the spring as much as possible while retaining control. This will give us information on how your feet and legs interact with, and respond to, the ground.

## Senior Fitness Test (SFT)

The Senior Fitness Test (SFT) consists of chair stands, arm curls, a timed 6-minute walk, a 2-minute step test, a seated sit-and-reach test, a "back scratch" range-of-motion test, and the 8-feet up-and-go test. Participants in the exercise intervention will experience mild physical stress as they participate in exercise. Participants in the No-SFT comparison group will not be under any added stress.

You will be randomly assigned to one of two groups:

Group 1: No-Exercise Comparison Group	Group 2: Group Exercise
--	-------------------------

IRB Expiration Date: JAN 2 0 2018

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Informed Consent Document			
No changes to daily activity. You will take part in the initial and final study visits (questionnaires and pre- screening physical exams), but will not take part in the exercise programs which are part of this study.	Exercise (seated and standing activities) for 45-minutes, 3-times per week, for approximately 16 weeks by an instructor in the Department of Kinesiology Biomechanics and Movement Studies Lab and the adjoining gym. You will be physically monitored by a member of the research team while doing this exercise. You will also take part in the initial and final study visits (questionnaires and physical exams).		

# **UT** Arlington

## BENEFITS

Participating in this study will give participants in the exercise group the opportunity to participate in regular physical activity, which has been shown to have significant health benefits (including potential weight loss, and muscle strengthening) and improved quality-of-life. Participants in the comparison group, through pre- and post- data collection, will be given valuable information about their postural control, muscular strength, and cardiovascular endurance.

## RISKS

You might experience standard muscle soreness associated with regular physical activity during this research study. To mitigate this, all exercise sessions will include an appropriate warm-up and cool-down period, which has been shown to help alleviate muscle soreness. Another risk in participating is the risk of falling during exercise. Safeguards to prevent this include having a chair available for you to rest, should you become fatigued during exercise. Trained volunteers will also be present to assist should you lose your balance.

You have the right to quit any study procedures at any time at no consequence, and may do so by informing the researcher.

## OUESTIONS

Dr. Robert Gatchel (817-272-2541), or Tyler Garner, Research Assistant (817-272-3288)

## VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. You can decide, at any time, not to perform the exam, but still participate in the study.

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## ACKNOWLEDGMENT OF RISK

By signing this acknowledgement of risk form, I acknowledge that I have been cleared by my physician to engage in physical activity. I also acknowledge that I have been made aware of any risks involved in participating in this study.

I certify that I am aware of the risks involved in participating in this study

Subject's Name (print), Signature, Date Operator's Name, Signature, Date **COMPENSATION** No compensation is available for this project.

### FINANCIAL COSTS

There are no costs to you for being in the study.

## ALTERNATIVE PROCEDURES

Another option is taking part in a rehabilitation or exercise program on your own without being in the study. Your other option is to not be in the study.

### CONFIDENTIALITY

Every attempt will be made to see that your study results are kept confidential. A copy of the records from this study will be stored in a locked office or another locked area in the Department of Kinesiology for at least three (3) years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a subject. Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, the University of Texas at Arlington Institutional Review Board, and personnel particular to this research have access to the study records. Your medical records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as stated above.

## CONTACT FOR QUESTIONS

If you have any questions, problems, or research-related medical problems at any time, you may call the Principal Investigator, Dr. Robert Gatchel, at 817-272-2541.. Any questions you may have about your rights as a research subject or a research-related injury may be directed to the Office of Research Administration; Regulatory Services at 817-272-2105 or regulatoryservices@uta.edu.

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As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

Signature and printed name of principal investigator or person obtaining consent Date

## CONSENT

By signing below, you confirm that you are 18 years of age or older and have read or had this document read to you. You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this Form. You have been given the opportunity to ask questions before you signed, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this Form, you are not waiving any of your legal rights. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

## SIGNATURE OF VOLUNTEER

DATE

## **Appendix G: Institutional Review Board Letter of Approval**



January 20, 2017

Dr. Robert J. Gatchel Psychology The University of Texas at Arlington Box 19498

 
 IRB No.:
 2016-0108

 Title:
 The Effectiveness of Objective Monitoring and Exercise Intervention for Chronic Low-Back Pain Management

Original Approval Date: January 20, 2016 Continuing Review with Modification Approval Date: January 20, 2017 Expiration Date: January 20, 2018

## EXPEDITED CONTINUING REVIEW WITH MODIFICATION APPROVAL

The Chair (or designee) of the University of Texas at Arlington Institutional Review Board (IRB) reviewed and approved the status of *continuing/revised* for the above study for a period not to exceed one year, expiring on **January 20, 2018** [45 CFR 46.109(e)]. In order for the research to continue, Continuing (annual) Review must be completed within the month preceding the expiration date indicated above. Although a reminder notice will be forwarded to the attention of the Principal Investigator (PI) at a time sufficient enough to allow for the continuation review to occur, it is the PI's responsibility to submit a Continuing Review for approval in the Profiles system prior to the expiration date.

The approved protocol modifications are as follows:

Remove Dr. Gian-Luca Mariottini from protocol personnel

## The approved number of participants for this study is 50 (Do not exceed without prior IRB approval).

## INFORMED CONSENT DOCUMENT:

The IRB approved version of the informed consent document (ICD) must be used when prospectively enrolling volunteer participants into the study. All signed consent forms must be securely maintained on the UT Arlington campus for the duration of the study plus a minimum of three years after the completion of all study procedures (including data analysis). The complete study record is subject to inspection and/or audit during this time period by entities including but not limited to the UT Arlington IRB, Regulatory Services staff, OHRP, FDA, and by study sponsors (if the study is funded).

## MODIFICATION TO AN APPROVED PROTOCOL:

Pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB *any* proposed changes in the research activity, and to ensure that such changes in approved

REGULATORY SERVICES SERVICES The University of Texas at Arlington, Center for Innovation 202 E. Border Street, Ste. 201, Arlington, Texas 76010, Box#19188 (T) 817-272-3723 (F) 817-272-5808 (E) regulatoryservices@uta.edu (W) www.uta.edu/rs



research, during the period for which IRB approval has already been given, are **not initiated without prior IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject." Modifications include but are not limited to: Changes in protocol personnel, number of approved participants, and/or updates to the protocol procedures or instruments. All proposed changes must be submitted via the electronic submission system prior to implementation. Failure to obtain prior approval for modifications is considered an issue of non-compliance and will be subject to review and deliberation by the IRB which could result in the suspension/termination of the protocol.

### ANNUAL CONTINUING REVIEW:

Continuing review of the protocol serves as a progress report and provides the researcher with an opportunity to make updates to the originally approved protocol. Failure to obtain approval for a continuing review will result in automatic *expiration of the protocol* all activities involving human subjects must cease immediately. The research will not be allowed to commence by any protocol personnel until a new protocol has been submitted, reviewed, and approved by the IRB. Per federal regulations and UTA's Federalwide Assurance (FWA), there are no exceptions and no extensions of approval granted by the IRB. The continuation of study procedures after the expiration of a protocol is considered to be an issue of non-compliance and a violation of federal regulations. Such violations could result in termination of external and University funding and/or disciplinary action.

## ADVERSE EVENTS:

Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to The UT Arlington Office of Research Administration; Regulatory Services within 24 hours of the occurrence or upon acknowledgement of the occurrence.

## TRAINING AND CONFLICT OF INTEREST DISCLOSURES:

All investigators and key personnel identified in the protocol must have documented Human Subjects Protection (HSP) training on file AND must have filed a current Conflict of Interest Disclosure (COI) with The UT Arlington Office of Research Administration; Regulatory Services. HSP completion certificates are valid for 2 years from the completion date.

#### COLLABORATION:

If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to: <u>http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm</u>

## CONTACT FOR QUESTIONS:

The UT Arlington Office of Research Administration; Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Regulatory Services at <u>regulatoryservices@uta.edu</u> or 817-272-2105.

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OFFICE OF RESEARCH ADMINISTRATION **REGULATORY SERVICES** 

Sincerely,



Digitally signed by Deborah Behan BC, o=UTA, ou=IRB Chair, email=dbehan@uta.edu, c=US Date: 2017.01.22 16:46:39 -06'00'

Deborah Behan, PhD Associate Clinical Professor, Nursing UT Arlington IRB Chair

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