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Effects of Generic Group-Based Versus Personalized Individual-Based Exercise Programs on Balance, Gait, and Functional Performance of Older Adults with Mild Balance Dysfunction and Living in Residential Care Facilities - A Randomized Controlled Trial

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by

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Abstract

Background and Purpose: To investigate the effect of an individualized exercise program versus a generic group-based exercise program on balance, gait, and functional performance of older adults categorized as having mild balance dysfunction and living in residential care facilities. **Methods:** Single blind randomized control design. One hundred-twenty residents fulfilled screening criteria for mild balance dysfunction based on the BioSway™ balance and the Multi-Directional Reach Test (MDRT) primary outcome measures. Secondary assessment was completed using the Modified Physical Performance Test (PPT), hand-held dynamometer (lower-limb muscle strength testing), and gait speed analysis. Sixty subjects received individualized treatment from physical therapists (8 weeks). Another sixty subjects received generic group-based exercises (8 weeks). All outcome measures were collected at baseline and post-intervention (ninth week); and BioSway™ and PPT measures at follow-up (thirteenth week) for the individualized group. **Results:** Individualized group (n=60) showed significant improvement compared to the group-based group (n=60) on the two BioSway™ scores (limits of stability, $p < .001$; and postural stability, $p = .016$), the MDRT scores (forward reach, $p < .001$; backward reach, $p = .007$; right lateral reach, $p < .001$; and left lateral reach $p < .001$), the strength scores (hip flexors, $p = .010$; knee extensors, $p = .002$; hip abductors, $p = .009$; and ankle dorsiflexors, $p = .025$), the PPT outcomes ($p < .001$), and the gait scores ($p = .012$). Effect sizes ranged from small to large, with the largest sizes for limits of stability and MDRT. There were no significant differences between groups for the mCTSIB ($p = .538$). However, 96.7% of subjects in the individualized group scored within one SD of the reference mean, relative to 75% in the group-based group. At follow-up, the individualized group showed significant differences over time with medium to large effect sizes on the PPT ($p < .001$), limits of stability ($p < .001$), postural stability ($p < .001$), and mCTSIB ($p = .005$) measures. Post-hoc analysis revealed retention of gains for all measures at follow-up, except the mCTSIB. **Conclusion:** The individualized group showed significant improvements in the areas of balance, strength, mobility, and functional outcomes.

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"Action should culminate in wisdom." – Gita

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Chapter 1: Introduction

Introduction to the Chapter

This chapter will provide general information regarding the relevance and significance of mild balance dysfunction in older adults living in residential care facilities, and the need for the proposed research. It also includes the problem statement, study purpose, research question, and definition of key terms.

Problem Statement

Falls are common among older adults. This is a serious public health problem, with a substantial impact on health and healthcare costs.[1] In the United States, older adults living in residential care facilities are three times more likely to fall when compared to their counterparts living in the community.[1] Old age is associated with reduced function in a wide range of organ systems and functional capacities.[2,3] Physical limitations related to aging include reduction in lower-limb muscle strength, joint range of motion, reaction time, and changes in sensory systems and aerobic capacity.[4-7]

Impairments in balance, mobility, and lower-limb strength are associated with an increased risk of dramatic consequences for the individual, such as dependency in activities of daily living (ADL), falls and fractures, hospitalization, and admission to a nursing home.[1] Psychological consequences of falls are also of critical relevance in this population, since one third of older adults who sustain a fall are apprehensive of falling again.[7] Fear of falling leads to an increased risk of inactivity and a reduction in the ability to perform activities of daily living.[2,7] Therefore, managing balance dysfunction in older adults plays a key role in fall prevention.

Published trials have shown that exercise interventions with balance and strengthening components are effective in reducing falls and improving physiological and functional performance in older adults.[5-9] However, most of the available studies evaluated the effectiveness of exercise programs for older adults living in the community with moderate to severe levels of balance dysfunction[1,6,7,9]; or for healthy, active adults without a clear classification of balance dysfunction.[5,8,10] In addition, only a few studies are available on older adults living in residential care facilities with mild levels of balance dysfunction, and the effectiveness of individualized and group exercise interventions in this population remains unexplored.[1,4,5]

In an attempt to limit physical impairments associated with an increased fall risk, most residential care facilities offer some type of non-structured group exercises facilitated by activity directors, or through pre-recorded exercise programs on television.[5,8,11] Nonetheless, residents with mild balance dysfunction may require and benefit more from personalized interventions instead of non-structured group exercises.[5,8,12,13] Without a timely skilled assessment and an individualized intervention, their mild balance dysfunction and fall risk status may likely advance to moderate or high level of fall risk.[1,8] A customized approach with evidence-based evaluation, assessment, and intervention could efficiently improve balance performance and reduce risk factors for falls.[8,14-16]

Relevance and Significance

Fall-related injuries are a major cause of pain, disability, loss of independence, and even premature death.[1,3,16] Fall occurrence is directly related to balance control, which is complex and multifactorial. Physiological and pathological changes related to aging have potential negative effects on balance control and lead to balance dysfunction at varying severity levels.[2,16] Physical limitations related to aging are the primary risk factors for falls that have been shown to be modifiable with timely exercise interventions that may include balance exercises, strengthening, coordination, etc.[1,5,7] In addition, the occurrence of falls in older adults may be related to psychosocial issues, including limited financial resources and social support.[2] However, these factors have been shown to be resolvable through activation and establishment of community resources.[7,11,16]

Falls are often used as a trigger to review risk factors (including balance impairment) to determine whether interventions are needed.[3] Ideally, however, problems contributing to falls should be identified and addressed before a fall occurs, so that preventative measures can be implemented.[6,8] Multiple studies have identified that early identification of fall risk factors and exercise implementation are effective in fall prevention and enhancement of functional performance.[1,5,12,14] However, most studies have included frail older adults residing in the community with comorbidities and multiple functional limitations[6,16] and moderate to severe levels of balance dysfunction,[13,17] older adults with specific conditions such as stroke or Parkinson disease,[17,18] or healthy/active older adults.[1,5,18,19] Even in those studies, the focus was placed on generic home-based and long-term group exercises rather than individualized sessions.[1,5, 16-19]

While there are many published studies regarding the effects of exercise programs on the improvement of balance in adults living in the community (with just a sample set cited here),[7,11,14,16,20] only a small number of studies support the effectiveness of exercise in reducing the fall risk of adults living in residential care facilities.[1-5] In particular, there is a lack of research investigating the impact of exercises on decreasing fall risk factors for older adults with mild levels of balance dysfunction and living in residential facilities (assisted living/ senior care/ independent living).[2,5]

It is apparent that this population at mild risk for falls tends to seek professional care only after a serious fall/injury, or once they have reached an advanced fall risk stage.[6] Therefore, early identification and timely intervention are vital to address balance issues when it is at a mild stage. For an accurate prediction of mild fall risk, a battery of clinical tools and equipment will be required.[1] Residential care facilities should provide an individualized therapy assessment/evaluation during their initial admission process. This will ultimately help to identify fall risk status in newly admitted residents, and to implement appropriate individualized exercise interventions in a timely manner when the fall risk status is still mild and reversible.

Furthermore, early intervention has the potential to improve performance in activities of daily living, cognitive function, and overall quality of life.[2,3,7,11] If fall risk factors could be reduced in this group, this would subsequently lower the utilization of healthcare and the cost of healthcare services.[1,5] Therefore, from an economic, health promotion and prevention perspective, it is important to resolve balance impairments at an early stage when it is mild and reversible,[1,3,9] before a likely progression towards a moderate to high fall risk stage, which will require complex and multifactorial interventions.

Purpose of the Study

The purpose of this study was to examine the effect of the individualized exercise program in comparison to the generic group-based exercise programs on balance, gait, and functional performance of older adults categorized as having mild balance dysfunction and living in residential care facilities.

Hypotheses

The primary hypothesis of this study was that an individualized exercise program would be more effective in improving balance performance when compared to a generic facility-offered group-based exercise program, when used in older adults with identified mild balance dysfunction and living in residential care facilities.

The secondary hypothesis was that the individualized exercise program would be more effective in improving functional scores, muscle strength, and gait performance when compared to a generic group-based exercise program in the same population.

Definitions of Terms

Activities of Daily Living (ADL) - consist of daily self-care activities such as bathing and showering, toileting, dressing, self-feeding, transferring, and walking.[5,21]

Alzheimer's disease - a progressive neurodegenerative disorder with characteristic neuropathological changes of the brain that can occur in middle or old age.[22] It is the most common cause of premature senility (dementia).[22]

Stroke- rapidly developed clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than of vascular origin.[23]

Balance - refers to an individual's ability to maintain the line of gravity within the base of support (BOS).[24] It can also be described as the ability to maintain equilibrium, where equilibrium can be defined as any condition in which all acting forces are cancelled by each other resulting in a stable balanced system.[24]

BioSway™ - a portable balance system that provides standardized testing environments and advanced training features including the Clinical Test for Sensory Integration of Balance (CTSIB), fall risks screening, Limits of Stability (LOS), Balance Error Scoring System (BESS) test of postural stability, and multiple interactive training modes.[25,26]

Comfortable gait speed (6MCWT 6-meter comfortable walk test) - a subject's self paced walking speed across a straight walkway of 10m; the time taken to walk the middle 6m is then expressed in meters divided by seconds.[1,5] The first and last 2 meters of warm-up and cool-down are not included in the calculation.

Fear of Falling (FOF) - defined as an exaggerated concern about falling or the belief that one cannot prevent a fall.[27]

Frailty – is a state of vulnerability to poor resolution of homeostasis following a stress and is a consequence of cumulative decline in multiple physiological systems over a lifespan.[28] Frailty is a syndrome commonly associated with aging, includes several characteristics such as muscle weakness, low physical activity, fatigue or poor endurance, many complex medical problems, unintentional weight loss, impaired mental abilities, and often require assistance for daily activities.[28]

Generic Group-Based Exercises – consists of simultaneous treatment of two or more subjects. They will receive some general instructions regarding the exercises, dividing attention and only brief, intermittent personal contact from the facilitator as applicable.

Individualized or Individual-Based Exercise Program – an intervention that is delivered one-on-one and customized to the specific strengths and challenges of an individual.

Hand-held dynamometer (HHD) - a portable device used to obtain discrete, quantitative, and objective measure of isometric muscular strength of the lower and upper extremities.[29] This device is a reliable and valid assessment tool for measuring strength at the hip and knee in older adults, and greater strength in these muscles is associated with longer step length and decreased reaction time, which are important components of balance recovery in older adults.[30]

Instrumental Activities of Daily Living (IADL) – are key life tasks that let an individual live independently in a community. They include shopping, housekeeping, accounting, food preparation, managing medications, telephone use, and transportation.[5, 21]

Mild Balance Dysfunction – falls under "good" category in the functional balance grades. *In which* a subject able to maintain balance without handhold support, however may present with some postural sway during static stance.[24] During dynamic state of balance the subject may accept moderate challenge, however may present with difficulty during weight shifting within full range in all directions.[24]

Modified Physical Performance Test (PPT) - a performance-based measurement tool used to measure the simulated activities of daily living of various degrees of difficulty in elderly persons. [31-33] The PPT incorporates multiple physical domains into the assessment including activities of daily living (ADLs), gross motor activities, fine motor control, balance, and walking.[31] Scores for the 9-item test range from 0–36 with higher scores indicating better performance.[32,33]

Multi-Directional Reach Test (MDRT) - a simple, inexpensive, reliable and valid screening tool to determine the limits of stability in the anteroposterior and mediolateral directions.[34,35] It measures how far an individual can voluntarily reach, there by shifting the center of gravity to the limits of the base of support with the feet stationary.[36]

Short Test of Mental Status (STMS) - a dementia assessment tool used in inpatient and outpatient settings. It contains items that test orientation, attention, immediate recall, arithmetic, abstraction, construction, information, and delayed recall (approximately 3 minutes).[37,38]

Parkinson's disease - a neurodegenerative disorder that leads to progressive deterioration of motor function due to loss of dopaminergic neuronal cells.[39]

Residential Care Facilities for the Elderly (RCFE) - (sometimes called Assisted Living/ Senior Care/ Independent Living/ Board and Care facilities) are nonmedical facilities that provide room and board, meals, recreational and social activities, protective supervision, and some assistance with daily living as needed.[5,40]

Visual Health Information (VHI) Geriatric Strengthening (Frail through Fit) and Complete Balance and Vestibular Exercise Kit - an online/computer-based exercise database tool. Health care professionals use this database to create educational materials and exercise handouts for their clients and patients.[1,41] This kit offers an extensive number of strength, power, and balance exercise options to treat and challenge the geriatric patients with acute and chronic diseases, and/or pursuing preventive health.[41,42]

Summary

This study aimed to provide evidence as to whether an individual-based physical therapy intervention has a different impact compared to unstructured group-based therapy in improving balance, lower-limb muscle strength, functional performance, and gait performance in older adults with mild balance dysfunction and living in residential care facilities. There is a paucity of research involving the best approach to address mild balance dysfunction in this population.

Chapter 2: Review of the Literature

Introduction to the Chapter

This chapter will provide an analysis and comprehensive review of relevant literature related to this study. A review of residential care facilities, falls, and related risk factors for falls among residents are discussed; and age-related effects on muscle strength (power), balance and gait factors are presented. A review of literature on effective balance and functional assessment tools, and analysis of efficient therapeutic interventions for older adults with mild balance dysfunction and living in residential care facilities, will also be discussed.

Residential Care Facilities and their Residents

As per the National Survey of Residential Care Facilities (NSRCF), the number of people in the United States who need residential care is expected to increase to 27 million in 2050.[43] The latest report from the United States government estimated that there are 30,200 residential care facilities in the United States (compared to 15,600 nursing homes), and that 1,000,000 people are residents of these facilities.[44] Residential care facilities provide room, meals, housekeeping, supervision, storage, and distribution of medication, and some personal care assistance (hygiene, dressing, eating, bathing, and transportation) as needed.[5,45] These facilities usually serve persons 60 years of age and older who are unable to live by themselves but do not need 24-hour nursing care.

Residential care facilities must meet care and safety standards set by the state and national licensing agencies (Department of Social Services, and Community Care Licensing -CCL).[43,45] These facilities typically provide supervision and monitoring of resident activities to help to ensure their health, safety, and well-being; as well as coordination of services with outside health care providers.[45,46]

Most community-dwelling older adults over the age of 65 years experience some difficulty in the performance of basic activities of daily living (ADLs) and instrumental activities of daily living (IADLs).[5,44,47] The likelihood of having difficulty with activities of daily living and instrumental activities of daily living increases with age.[5,47,48] Approximately 12% of older adults 65 to 74 years of age have trouble with both ADLs and IADLs.[5] This level increases to 22% at 75-84 years of age and rises to 40% at 85 years and above.[5] The loss of functional independence and the subsequent degree of dependency are the key factors that will determine choices for safe living arrangements for older adults.[48] For community-dwelling older adults who experience some difficulties with basic life activities and household chores, the first choice would be a non-medical residential care facility.

In general, many residential care facilities preferentially admit only high-functioning and ambulatory individuals, in order to reduce their administrative burdens and specialized work force requirements.[43,45] Further, these facilities tend to charge higher rates for individuals who require more assistance and care with both ADLs and IADLs.[43,45] Additionally, after admission, residents often experience further functional decline due to the biological aging process.[5] When normal aging is compounded with any accidental falls or subsequent injuries, this may not only affect an individual's current living situation, functional independence, and mobility; but also augment their financial burden and public health care costs.[48]

Falls and Risk Factors

Age, functional impairment, and disability are important factors that contribute to an increased risk of falling.[49] Older adults are particularly vulnerable to falls owing to age-related biological, pathophysiological, and musculoskeletal changes.[49] Fall-related injuries may cause restricted mobility and functional decline in elderly individuals, and individuals who have fallen in the past year are more likely to fall again [likelihood ratio range: 2.3–2.8].[49,50] Approximately 5% to 10% of falls result in serious injuries such as fractures (e.g., hip fractures), head trauma, or joint dislocations requiring hospitalization.[51] In fact, 25% to 75% of elderly fallers who sustained a femoral neck fracture do not regain their pre-fracture level of functional mobility.[49,51] The key factors responsible for this high variability in recovery are age-related somatosensory changes, cognitive decline, depressive symptoms, and lack of available psychosocial support systems.[51] In addition, age and post-surgical intervention related effects can influence associations between strength/power, balance performance, and walking ability.[49,51]

Falls and fractures are the major reason for high health care costs in the elderly.[49,52] Prospective studies indicate that 30% to 60% of community-dwelling older adults fall each year.[49,53,54] This rate increases by an additional 20% for individuals living in residential care facilities.[49] Among older adults living in residential care facilities, almost two thirds fall each year.[49,55]

In addition, the incidence rates for both fall-related major soft tissue injuries and fractures are more than twice as high for this group of older adults.[49] Falls account for 40% of all injury-related deaths in residential care facilities, and interestingly, women suffer more falls compared to men.[49] A study found that approximately 30–50% of residents aged 65 years and older in care facilities have fallen at least once in the past year, and 12–40% of them have experience recurrent falls.[56] Another study estimates 21% of residents in care facilities had one fall at least every 3 months, and that 29% of residents require the use of an assistive device (walker or cane) for mobility.[52]

Apart from the physical burden of a fall, older adults who survive falls tend to also experience anxiety, loss of confidence, and fear of falling again.[57,58] Fear of falling may lead to subsequent activity restriction, muscular atrophy and weakness, and associated depressive symptoms.[57] Studies have found that these psychological consequences of falls are common, and one third of older people who sustain a fall are worried about falling again.[49,57] The psychological impact often translates into restriction or avoidance of daily activities, loss of independence, and reduced social activity or quality of life.[55,58] It is important to note that older adults living in residential care facilities face more health problems and falls when compared to community-dwelling adults of the same age.[47,49] In general, the presence of multiple health problems, and frail nature of individuals may contribute for a higher rate of falls in the institutional setting. However, another key contributing factor to this higher incidence may also be that there is more accurate reporting and monitoring of falls in the institutional setting.[44]

Older adults who live alone often avoid reporting falls or soft tissue injuries to their caregivers (family members) or health care providers from fear of losing their independence and be placed in a nursing facility. Therefore, fall-related data could be difficult to track and document accurately in older adults living in the community.

Fall risk factors are often categorized as an individual-specific and environment-specific (Table 1). The individual-specific or intrinsic factors include age, gender, balance issues, generalized muscle weakness, decline in functional and mental status, chronic diseases, psychosocial issues, lower extremity sensation and proprioception issues, and gait disturbances (dual tasking).[59,60] Environment-specific or extrinsic factors are mostly modifiable and may include medications (polypharmacy), low income, limited access to health and social services, low literacy levels, lack of social support, fall hazards in and around the living environment, and the type of footwear used.[59,60]

The risk of falls increases with age and with the presence of more risk factors.[61] In a systematic literature review, Rubenstein and Josephson reported that intrinsic factors (i.e., muscle weakness, sensation issues, gait, and balance disorders) are the second most common cause for falls in older adults.[49,62] Except for gender and age, most of the other intrinsic and extrinsic risk factors are reversible and manageable with appropriate and timely interventions,[59] such as referral to physical therapy or other community-based fall prevention programs, environmental modifications, etc. Residential care facilities are required to implement fall prevention practices that include following strict building codes, proper lighting, avoiding the use of tripping hazards (loose rugs and wires), and installation of non-slippery floors, grab bars and railings.[44,49]

Table 1. Fall risk factors[59,60]

Intrinsic (Individual-Specific)			Extrinsic (Environment-Specific)	
Demographic	**Systems**	**Health Issues**	**Socioeconomic Issues**	**Other Issues**
• Age • Sex	• Strength • Balance • Gait • Vision	• Cognition • Dementia • Psychosocial • Musculoskeletal • Lower Extremity Sensation and Proprioception • Cardiovascular • Neurological • Vestibular	• Low Income • Low Literacy Levels • Limited Health Care Access • Lack of Social Support • Living Situation	• Medications – (Polypharmacy) • Footwear

Age-Related Effects on Balance and Gait

Balance control is complex and multifactorial. Balance is achieved by the complex integration and coordination of multiple body systems including the vestibular, visual, auditory, musculoskeletal, and neurological (sensory) systems.[63] Aging-related physiological changes include reduction in muscle strength and joint range of motion, worsened reaction time, and changes in sensory systems.[1,61] These physiological factors can interact and may lead to complex balance dysfunction at various levels, especially when compounded with pathological processes.[5,63] Age-related degenerative changes in the peripheral and the central nervous system may also cause balance and gait issues.[49]

Individuals with neurological and or musculoskeletal disorders are even more likely to have balance problems that affect safe performance of daily functional tasks and mobility.[7,8,11] The postural control system can also be affected by aging (decline in trunk muscle strength, sensory function, and speed of sensorimotor responses).[63] This system will reach an optimum stage in early adult life and start to deteriorate from approximately the age of 50 onwards.[59,63] As age advances, individuals rely more on proprioceptive senses than on visual input.[49] Postural sway increases linearly with age and this difference is not affected by gender.[49]

Intact balance control is required to not only maintain postural stability but also to ensure safe mobility.[63] Gait and balance disorders in older adults are specifically manifested as an impaired ability to compensate for both reactive balance and steady-state balance.[64] These so-called multitask situations occur frequently during everyday life. For example, standing and removing a coat, rising from a chair and talking, walking and turning around with a cup in hand, etc. It has been reported that deficits in reactive and steady state balance performance put older adults at an increased risk of falling.[61,65] Several studies found that a large number of falls in the elderly occur during ambulation (steady-state balance) or during slipping and tripping events (reactive balance).[65-67]

During static standing, older adults appear to compensate for greater instability by applying different balance strategies (e.g. hip strategy) and by increasing muscle activity.[64,67] A study found that greater postural sway (balance) and gait decrements occur during the concurrent performance of attention-demanding dual tasks.[66]

Another study observed that elderly subjects who stopped walking when talking had a significantly increased risk of sustaining a fall within the next six months.[68] This increase in fall risk status is probably due to age-related dysfunction in the balance control system, and to the inability to allocate attention properly between steady-state balance and a cognitive and/or motor interference task.[64,66] Therefore, it is important to focus on age-related effects which impact dynamic steady state and reactive balance.[66]

When determining an individual's functional ability and balance skills, there are several areas that can be evaluated. Gait speed is an easily measureable, clinically interpretable, potentially modifiable, and useful "vital sign" for older adults.[69] Muscle force (strength and power) generation is essential for increasing an individual's gait speed. Gait speed may also vary depending on muscle strength, range of motion (particularly at the ankle joint), body mass index, age, stature, and environmental factors (walking surface).[70,71] Gait speed values can be used to predict walking ability, fall risk, suitable living situations, and functional independence in the community (Table 2).[70] The factors that influence the determinants of gait speed are classified as modifiable and non-modifiable.[70]

Table 2. Gait Speed Interpretation[72]

Gait Speed	Functional Category
Less than 0.4 m/s	Household Ambulator
0.4 to 0.8 m/s	Limited Community Ambulator
0.8 to 1.2 m/s	Community Ambulator
1.2 m/s and above	Able to Safely Cross Streets

Research in older adults has shown that they can improve their gait speed following muscle strength training.[73] Table 3 provides the summary of comfortable gait speed (m/sec) stratified by gender, use of an assistive device, and age 60 and above.[74] Comfortable gait speed normative values have been noted as 0.72 m/s to 1.26 m/s for males and 0.71 m/s to 1.25 m/s for females.[74] Literature review confirms that older age, female gender, lesser stature, lower knee extension force, and greater adiposity are associated with slower gait speeds.[70,73]

Table 3. Lusardi et al's Comfortable Gait Speed Values: Means, Standard Deviations, & Confidence Intervals by Age, Gender, & Use of Assistive Device[74]

Age Range (years)	Group	Mean (m/s)	SD (m/s)	CI
60-69	Male	1.26	–	0.84 – 1.67
	Female	1.24	0.12	1.05 – 1.42
	Overall	1.24	0.10	1.13 – 1.35
70-79	Male	1.25	0.23	1.11 – 1.39
	Female	1.25	0.18	1.10 – 1.38
	Overall	1.25	0.20	1.15 – 1.34
80-89	Male	0.88	0.24	0.75 – 1.01
	Female	0.80	0.20	0.72 – 0.89
	No Device	0.91	0.16	0.84 – 0.98
	Device	0.63	0.17	0.52 – 0.74
	Overall	0.82	0.21	0.75 – 0.90
90-101	Male	0.72	0.14	0.43 – 1.02
	Female	0.71	0.23	0.60 – 0.82
	No Device	0.88	0.23	0.76 – 1.01
	Device	0.59	0.10	0.48 – 0.70
	Overall	0.71	0.22	0.60 – 0.82

(Only subjects 80 and older used an assistive device in this study sample)

Gait speed can also be used to predict functional ability, falls, and the need for therapy services.[5,75] A study by Potter et al[71] found that gait speeds of less than

0.25 m/s in older adults were associated with dependence in activities of daily living, whereas gait speeds of 0.35-0.55 m/s were associated with independence in activities of daily living. Brown et al[72] noted that a necessary mean speed, as set by crosswalk signals, was 1.2 m/s. This speed is beyond the normal capabilities of many older adults (Table 3). Several studies have shown a strong relationship of gait performance (including speed) with balance ability, indicating that as balance ability improves, so does gait speed.[71,75]

Gait speeds of less than 0.56 m/s (sensitivity=72% and specificity=74%) have been associated with risk of recurrent falling.[75] Harada et al[5] reported a cut-off score of 0.57 m/s to identify individuals living in residential care facilities that may benefit from physical therapy. In addition, a gain of 0.1 m/s is a predictor of meaningful functional improvement and this change could be used for setting patient goals.[69]

Age-Related Effects on Muscle Strength/Power

Biological aging, particularly when coupled with physical inactivity, results in decreased maximal isometric, concentric, and eccentric force, and rate of force development (RFD - muscle power).[49] More specifically, the capacity to generate force rapidly (muscle power) declines at a faster rate than the ability to produce maximal strength.[49,64] Lower-limb muscle strength (force-generating capacity of muscle) and muscle power (product of force and velocity of movement) are two closely related aspects of muscle function that seem to play a central role in the maintenance of mobility (gait ability) and balance function.[49,64,76] Therefore, a small gain in muscle strength may result in a significant improvement in functional activities.[49] Research in both men and women shows that at 60-70 years of age, maximal strength is reduced by 20-40% from younger norms; and at 80 years and over, it is decreased by at least 50% and the decline in muscle power is even greater.[49,64,76]

Ongoing physical training and keeping good muscle strength are critical for older adults to stay active and maintain independence with all functional tasks.[4] In a longitudinal study, older adults (mean age 68 years) who regularly carried out strength training had strength similar to that of sedentary young adults.[77] An important fact to consider is that older women have around 40% less absolute lower-limb strength and power when compared to older men of the same age when adjusted for body weight.[77,78] This emphasizes the extra importance for women to retain their muscle strength and muscle power since they are, in general, closer to the thresholds for impaired mobility and disability.[77,78] The ability to generate force rapidly declines more precipitously in advancing age than maximal strength.[49] Generalized weakness induces reduced levels of muscle strength and power, especially in the extremities.[49] Therefore, maintenance of optimal muscle strength and power in the extremities is critical to preserve independence in activities of daily living.

Effective Assessment Tools and Effective Interventions

A comprehensive clinical and functional assessment of balance is important for both diagnostic and therapeutic purposes.[63] Objective measures of balance using computerized systems and functional measures can bring more sensitive, specific, and responsive balance testing to clinical practice.[63] Clinical assessments of balance are easy to use, do not require expensive equipment, are usually quick to administer, and have also been shown to predict fall risk and, thus, need for therapy, such as physical or occupational therapy.[63] However, the results obtained are subjective, show ceiling effects, and are usually not responsive enough to measure small progress or deterioration in a subject's ability to balance.[63,79] Therefore, it is important to have both laboratory and clinical balance measures to predict mild balance dysfunction.

Balance and postural sway (center of pressure displacements) can be analyzed using computerized biomechanical testing equipment such as the BioSway™ and the force plate. The BioSway™ unit is comprised of a stable balance platform along with a memory foam attachment,[25] whereas the Balance Master® force plate unit consists of a moving type platform and a dynamic visual surrounding.[80] Both units are effective in measuring, analyzing, and interpreting balance measures along with optional retraining capabilities using visual biofeedback.[81,82] However, the BioSway ™ unit is portable and versatile to use in different testing sites when compared to the force place unit. The most commonly used balance testing patterns include bipedal stance, step stance, tandem stance, or one-leg stance, with eyes open and closed, on stable or unstable (balance pad) surfaces, under single or multi-task conditions.[83] A study which investigated healthy subjects aged over 63 years found that postural sway (horizontal movement speed around the center of gravity) during bipedal stance with eyes opened and closed was significantly greater for those who fell one or more times in a year than for those who did not fall.[83] Tucker et al[84] were also recently able to identify community-dwelling older adults with a fall history by using different postural sway (balance) measures.

The multidirectional functional reach test is a clinical-based balance measure., which consists of identifying how far subjects can move their center of mass over their base of support in multiple directions, and can predict fall risk.[34,35] The functional reach test was initially developed to evaluate the maximum limits of stability in stance when leaning forward.[63] Later, reaching in the sideways and backward directions were added to construct a multidirectional reach test.[34,36] The subject has to reach as far forward, backward, and sideways as they can while standing independently with their feet not moving, and their arm horizontal and parallel to the ground.[35]

When voluntarily moving the center of gravity toward the limits of stability (with feet not moving), a greater excursion is expected in the forward and lateral directions when compared to the backward direction.[34-36] This is because of the biomechanics of the ankle and foot joints, and age-related decline linked to loss of stability and worsened reaction time.[34,35] In addition, high routine forward and medio-lateral oriented functional activities and their interrelationship with visual and peripheral nervous systems.[34-36] The multidirectional functional reach test is useful for assessment of postural control and balance in adults aged 60 years and over (intraclass correlation coefficient [ICC >.80] in all four directions).[34,36] When compared to other tests, the advantage of the multidirectional functional reach test is that it can specify what directions the individual has trouble with, in order to direct specific treatment.[35,36]

The prime purpose of a functional assessment is to determine the underlying causes of the balance deficit in order to treat it effectively.[31] To measure the multiple dimensions of physical function in older adults, a performance-based test like the

Modified Physical Performance Test (PPT) is helpful.[32,85] This test is an efficient performance-based measurement tool that combines systemic movement and functional-based tasks to characterize the underlying cause of impaired balance control.[33,86] The PPT incorporates multiple physical domains into the assessment, including tasks involved in basic and complex activities of daily living, balance, and walking components.[31,32] Because items on the PPT include commonly performed functional skills, older adults may follow directions easily and complete the tasks without difficulty.[32] Other assessment tools such as the Berg Balance Scale would present greater challenges to postural control and are more complex to implement.[87,88] Therefore, the performance-based PPT measure has good potential for use in older adults.[31]

The ability of the PPT to assess ADL functions and fall risk makes it a very useful tool in the assessment of balance dysfunction during functional activities in older adults.[32] The validity of the PPT to assess functional performance, measure change, and identify fall risk among older adults has been established (Table 4).[31,86] The PPT focuses on identifying multiple dimensions of physical function using either 7-item or 9-item scales.[32,85] In the 9-item version of the PPT, the clinician records the time it takes for the subject to write a sentence, spoon beans from a bowl into a coffee can (simulated eating), lift a book onto a shelf above shoulder height, put on and remove a jacket, pick up a penny from the floor, chair rise, turn 360°, progressive Romberg test, and walk fifty feet. The tasks in the test are scored 0–4 based on performance time. The score range is 0–36, with higher scores indicating better performance.[32,88]

Table 4. Vidoni et al's PPT Test Scores: Mean, SD, & CI values by Age, Gender, & use of Assistive Device[86]

Age (y)	Group	N	Mean	SD	CI
60-69	Male	1	26.0	-	17.9 - 34.1
	Female	5	26.4	0.9	22.8 - 30.0
	Overall	6	26.3	0.8	25.5 - 27.2
70-79	Male	9	24.6	1.7	21.9 - 27.2
	Female	10	25.1	0.9	22.5 - 27.7
	Overall	19	24.8	1.3	24.2 - 25.5
80-89	Male	10	20.4	4.8	17.8 - 23.0
	Female	24	19.5	3.8	17.9 - 21.2
	No Device	24	21.3	3.2	19.9 - 22.2
	Device	10	16.1	3.6	13.9 - 18.3
	Overall	34	19.8	4.1	18.4 - 21.2
90-101	Male	2	16.5	6.4	10.8 - 22.2
	Female	15	16.2	6.0	14.1 - 18.3
	No Device	7	18.9	6.4	16.2 - 21.5
	Device	10	14.4	4.8	12.2 - 16.6
	Overall	17	16.2	5.8	13.3 - 19.2

The reliability of the PPT has been established in subjects without known cognitive deficits.[33,85,86] The PPT allows for assessment of older adults with a broad range of functional abilities,[31] and it is less frequent for subjects to achieve ceiling scores on the PPT when compared to self-report measures.[31,32] Scores on the PPT are associated with significantly different frequencies of medical diagnoses, somatic symptoms, medication intake, and number of co-morbidities.[31,33,86] The PPT has also been found to have predictive validity.[85,88] In community-dwelling older adults, lower scores on the PPT were a significant predictor of death or institutionalization 18–24 months later.[31,32]

The PPT has also been identified as an independent predictor of recurrent falls in older adults without specified dementia.[31] Studies have shown that the 7-item PPT with a cut-off score of 15 was an independent factor in predicting fall risk.[31,33] Delbaere et al[32] studied multiple intrinsic risk factors in an attempt to construct a risk model to identify frequent fallers. Authors noted that a cut-off score of <19 for the 7-item PPT or < 25 for the 9-item PPT was found to significantly increase the odds of the person being a frequent faller, compared to being a non-faller, by four times.[32] Brown et al[88] used the modified PPT-9 version to describe a "frailty" classification in which 32–36 = not frail; 25–31 = mild frailty; 17–24 = moderate frailty; and <17 = unlikely to be able to function in the community (Table 5).

Table 5. Brown et al's Modified PPT Frailty Classification[88]

9-item PPT Scores	Functional Status
32–36	Not Frail
25–31	Mild Frailty
17–24	Moderate Frailty
Less than 17	Not Able to Function in the Community

Algahtani et al[89] noted that an increase in lower extremity strength was associated with increased grip strength and gait speed. Lower extremity muscle strength is an important factor that greatly affects gait and determines an individual's level of activities of daily living.[89,90] The current gold standard method to measure lower extremity muscle strength is using computerized isokinetic dynamometry.[49]

The high cost, low portability, and time consumption are drawbacks that have limited the application of computerized isokinetic dynamometry in a wide range of settings.[49] An alternative method to assess strength in a clinical setting is manual muscle testing using portable handheld computerized equipments.[29,91] Hand-held dynamometers have been commonly used in different settings to objectively quantify muscle strength.[91] Studies have found that a hand-held dynamometer was a very reliable tool (ICC>0.9) for lower extremity muscle strength assessment of healthy adults,[90] and concurrent validity with functional tests was good when tested in community-dwelling older adults.[29] The measurement process is simple to use with good reliability in different populations, and low ceiling effect.[49,91]

The measurement of gait velocity (time required to walk) is a simple and inexpensive test that can be used in a clinical setting to detect mobility problems and to predict adverse outcomes (hospitalizations, falls, and caregiver requirements) in older adults.[49] The functional implications of gait velocity have frequently been described and discussed in older adults.[49,92]Hollman et al[92] presented normative spatiotemporal gait parameters (stride time/length, stride time/length variability, gait speed, cadence, etc.) in older men and women that can be used as a reference tool to identify subjects with gait disorders.

Gait speed can be measured at self-selected (comfortable) speed or maximum (fast) speed; however, comfortable gait speed is more responsive to age-related changes.[72,93] Comfortable gait speed is measured by walking at a self-selected speed for a pre-determined distance, and reported in terms of feet or meters divided by time in seconds. This study will use meters for measuring distance and seconds for measuring time. An advantage to gait speed measurement is that data is continuous and thus subject to mathematical procedures such as addition and averaging. This type of data is appropriate to analyze with parametric statistics.

Exercise interventions focusing on gait, balance, strength, and functional training components are an important part of multifactorial interventions.[56,94] Exercise may reduce muscle loss and improve muscle strength, gait, balance, endurance, and mood.[48,95] In addition, regular exercising in older adults has produced positive results by increasing aerobic capacity, reducing depressive symptoms, and increasing cognitive function.[48,49,96] Furthermore, physical activity is important in preventing and treating many disability-related diseases and syndromes including diabetes mellitus type II, hypertension, coronary heart disease, and osteoporosis.[78,83,97]

Routine physical activities may enable older adults to perform daily activities without falling or fear of falling.[56] Sensitivity analyses indicate that exercise interventions result in reduced numbers of recurrent falls in frail adults (RR = 0.71, 95% CI = 0.53 - 0.97).[56,94] Multifactorial intervention programs based on assessment of individual risk factors have been shown to be beneficial when compared to generic home-based exercise programs.[1,5,20,97] Further, individualized therapy is effective in reducing falls and improving overall functional status of older adults living in the community.[1,11,12,98]

However, until now there has been no conclusive evidence on the effectiveness of exercise interventions for preventing falls in residential care facilities.[1,5,56] Several systematic reviews found that therapeutic interventions had inconclusive evidence on reducing rate of falls or risk of falling in residential care facilities.[99,100] Another study showed that exercise programs that included strength, endurance, and balance training resulted in reduced fall rates in physically frail older people; however, the review included heterogeneous groups of residents in community and care facilities.[96] There is little information on the type of therapy interventions necessary to prevent falls in frail older adults, especially those living in residential care facilities.

Rationale

Falls are usually the main triggering factor for patients and caregivers to accept the need for further balance risk assessment/analysis, and to determine whether interventions are needed or not.[1,101] Recent studies stress the need for laboratory and functional tests that discriminate performance for individuals functioning on the upper end of the functional spectrum.[102,103] This approach will help in identifying problems at an early stage, before they become more marked stage (high fall risk level), and a fall occurs.[1,103] Responsive balance tests are critical to identifying mild levels of balance dysfunction on high-functioning individuals because without interventions, fall risk status may advance.[1,103] Therefore, managing balance dysfunction would be more effective and less expensive when the risk status is mild.[1,102] There is a lack of research in older adults with mild balance dysfunction and living in residential care facilities, and the effectiveness of exercise interventions in this subgroup has not been well studied either.[1,5,77]

It is important to investigate fall risk factors among individuals living in residential care facilities, since this subgroup may transition from required mild care level (i.e. seeking intermittent assistance for ADLs and IADLs) to an advanced care level (high-level assistance) at anytime.[1,2,4] Research related to balance and mobility in older adults has been conducted primarily in laboratory settings with individuals residing in the community.[1,5,11,98] Although many studies have examined hospitalizations among community-dwelling older adults and nursing home residents, fewer studies have looked at the relationship between falls and hospitalizations among residents in assisted living and other residential care facilities.[56,104,105] Laboratory-based tests are usually expensive and not portable, so the application of these tests has been limited to large institutional based studies.[56] Recent technological advancements have provided inexpensive and portable quantitative tools to assess balance, such as accelerometers, the BioSway™ and force plate balance instruments.[63,81] Little data are available on the use of these technologies to assess balance and gait stability in older adults living in residential care facilities.[1,5,63]

Risk for falls can be predicted by a comprehensive assessment of common fall causes such as reduced muscle strength, impaired balance, and unsteady gait. The choice of appropriate therapeutic interventions can reduce risk factors for a fall.[89,100,104] Existing guidelines recommend that exercise should be an individual-specific intervention, or as combined/ tailored interventions to prevent falls among frail older adults living in the community.[96] Individual-specific balance assessment and exercise programs that are tailored by the therapist to improve balance skills would be effective on frail older adults with functional limitations in institutional settings.[1,5]

When compared to non-structured home based exercise programs, high-intensity individual based exercise programs have been shown to improve strength, balance and gait ability in older adults with moderate to high impairments.[2,104] Multifactorial interventions have been successful in preventing falls among older people living in the community.[20,106] Community-based studies recommend that in order to achieve a positive effect, exercises should be individually tailored, they should target functional impairments, and they should be mainly performed in weight-bearing positions.[2,7,49] An improvement in physical function might be of great importance for individuals in residential care facilities; through which they can effectively achieve or maintain their functional independence, psychosocial wellness, and reduce falls.[56,104,107]

Summary

It is vital for clinicians to have knowledge about the use of robust tests and measures to assess balance control, muscle strength/power, and gait parameters. This foundation provides a solid scientific rationale to assess fall risk, as well as to develop customized fall prevention and rehabilitation programs for older adults. In all published studies looking at various types of exercise programs for older adults, the participants were either healthy older adults or others with moderate to severe balance issues and living in the community.[1,11] Thus, there is a need for exercise studies targeting older adults living in residential care facilities and with mild balance dysfunction. This study aimed to provide an important basis for analyzing effective and evidence-based exercise intervention protocols, in individual or group formats, for older adults with identified mild balance dysfunction and living in residential care facilities.

Chapter 3: Methodology

Introduction to the Chapter

This chapter discusses methodology related to the research study. This was a single-blind randomized control study of older adults living in residential care facilities, age 60 years or older, and with mild balance dysfunction. The study procedures, outcome measures, and data collection methods are outlined, including sampling and recruitment of participants, training of investigators, implementation of interventions, and detailed data analysis plan.

Research Methods

Study design

This study was a single-blind randomized control design, in which selected subjects were randomized into two groups (individualized exercise group or generic group-based exercise group) by using concealed envelopes. The primary investigator who performed all the assessments and the secondary investigators who provided treatment were blinded to each other's data. Clinical measures of balance, gait, muscle strength, and physical function were assessed at pre-intervention (baseline) and post-intervention (ninth week). Additionally, the BioSway™ (balance) and the Physical Performance Test - PPT (physical function) measures were repeated for the individual-based group only at the one-month follow-up period (thirteenth week). The short-term retention effect was assessed only for the individual-based group due to effective time and cost management strategies. Fall history data was collected from facility records and patient interview at baseline (retrospective recall of fall history in last 6 months) and follow-up.

Sample Size Justification

A previous study of older subjects with mild balance dysfunction compared the effectiveness of a home balance and strength exercise intervention with a control group who simply continued with their usual activities.[1] The Limits of Stability (LOS), the Step Test and the Functional Reach Test balance measures were found to be responsive to structured exercises.[1] The authors used one of the primary outcome measures on the NeuroCom force platform, i.e. the Limits of Stability (LOS) measures, to calculate the sample size.[1] A post hoc power analysis of the mean baseline Limits of Stability (LOS) maximum excursion score from a pilot study on 12 subjects with mean age of 76 years was estimated as 81% (SD=15%).[1] The authors reported that in order to detect an expected improvement associated with the interventions, a sample size of 57 participants per group was required with 80% power, alpha of 0.05.[1] Review of relevant literature in this topic was also supported with a sample size of 57 per group.[1,5] Based on the findings of previous research and considering the possibility of attrition, a sample size of 60 subjects in each group was proposed for the current study.

Subject Recruitment

Volunteer residents (subjects) from residential care facilities were recruited through a sample of convenience via advertisements, health fairs, and wellness events. The subjects were recruited from eleven different residential care facilities (assisted living/ senior care/ independent living) located in the State of Michigan and urban locations including Battle Creek, Marshall, Coldwater, Portage, and Kalamazoo. 120 subjects were recruited based on eligibility criteria, for a total of 60 in each group after randomized assignment.

Inclusion and Exclusion Criteria

All subjects who showed interest for participation in the study and provided informed consent underwent a screening session based on predetermined inclusion and exclusion criteria. Participants were not included or excluded based on whether or not they used an assistive device. The inclusion criteria for the research subjects were: (1) age 60 years or over; (2) achievement of a 30 or above score on the Short Test of Mental Status (STMS);[37] and (3) currently not receiving physical therapy.

The following criteria excluded potential subjects from screening and subsequent study participation: (1) Alzheimer's disease; (2) Parkinson's disease with lower extremity impairments and noticeable tremors; (3) cardiac and respiratory conditions that limit exercise participation; (4) legal blindness; (5) multiple joint arthritis with limited mobility; (6) vestibular issues; (7) more than one fall in the last three months; and (8) medication-related recent multiple falls (2 to 3 in the last three months).

All subjects who fulfilled the inclusion criteria underwent a comprehensive balance assessment by using two primary outcome measures: the BioSway™, and the Multi-Directional Reach Test (MDRT). Subjects were classified into the mild balance dysfunction category based on the cutoff scores from the two primary outcome measures (explained in detail in the outcome measurements section). Subjects classified as having mild balance dysfunction became eligible to participate in the full study. Each subject's primary care physician was notified about this study and subject's interest by fax or telephone, and medical clearance was obtained for inclusion.

Informed Consent

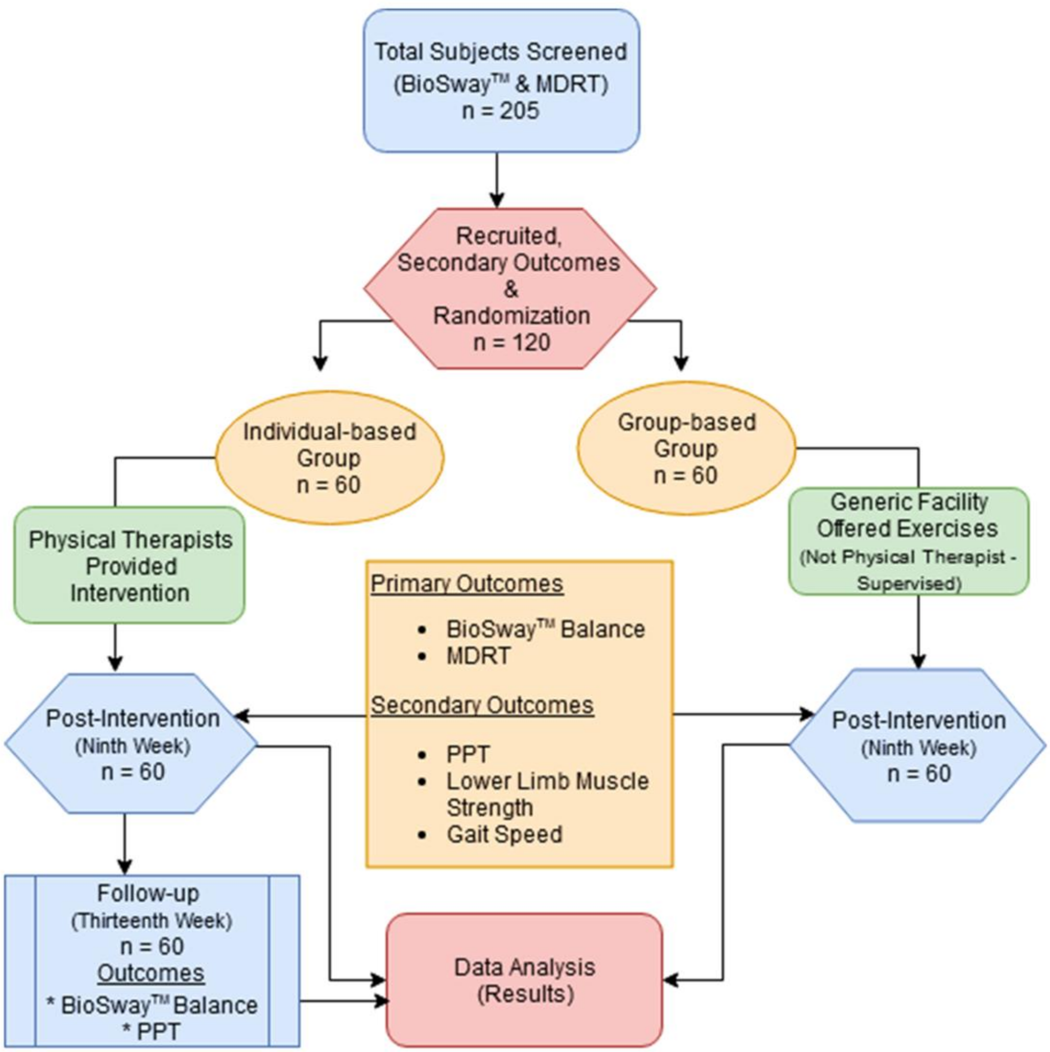
Institutional review board (IRB) approval for this study was obtained from Nova Southeastern University (NSU) on October 2017. Information about the purpose of the research, potential risks and benefits, and activities to be performed was discussed with each subject during the initial contact and at subsequent visits as needed. All subjects who showed interest for participation in this study voluntarily reviewed and signed the consent form, and received copies for their file.

Experimental Procedures

Figure 1 illustrates the steps in the experimental protocol. The primary investigator performed all the initial screening tests, pre-assessment (baseline) and post-assessment (ninth week) for all subjects, and follow-up assessment (thirteenth week) for the individual-based group. The primary investigator was blinded to group allocation and collected data at pre-assessment, post-assessment, and follow-up assessment (Figure 1). Five licensed physical therapists (secondary investigators) with at least 3 years of geriatric home care experience and a clerical assistant were recruited for this study. The secondary investigators provided all the therapeutic interventions. No incentive was provided to the subjects, research assistant, or secondary investigators for participation in the study.

A training session for the secondary investigators was conducted before the start of the study, where the study protocol was explained in detail and a reference manual was distributed to the secondary investigators. The training session included a theoretical explanation of study methodology, procedures, and overview of treatment interventions to improve interrater reliability. The clerical assistant also completed a training session on study protocols and data management skills; and was provided access only to de-identified data. After completion of all the training sessions, participant recruitment commenced.

Figure 1: Participant Flow Diagram from Allocation to Analysis



Abbreviations: MDRT - Multi-Directional Reach Test; PPT - Modified Physical Performance Test

Data Management

Each subject's data and private health information was kept confidential and de-identified during the data collection process. Each subject received an individual specific research number / identification code. The primary investigator assigned those numbers and retained the master list of matching codes and related names in a password-protected computer. Screening forms, test results, evaluation and visit notes, and data sheets were collected and saved in specific folders. All files and research laptop were locked in a secured file cabinet to protect the private health information, and for safety/security reasons. Data collection took place from October 2017 to October 2018.

Procedures

The primary outcome measures of the trial were comprised of three measures from the BioSway™ portable balance system (limits of stability, postural stability, and modified clinical test of sensory integration of balance) and four measures from the Multi-Directional Reach Test (forward reach, backward reach, right lateral reach, and left lateral reach). The secondary outcome measures included the scores on the Modified Physical Performance Test (PPT),[32] lower extremity muscle strength testing using a hand-held dynamometer (Commander Muscle Tester, JTech, USA),[30,90] and gait speed analysis using a speedometer (FitSense FS-1).[1,5,108]

All selected subjects were assessed and classified as mild balance dysfunction category based on the composite scores from the two primary outcome measures. Subjects underwent further assessment with secondary outcome measures (gait, muscle strength, and physical function component). After completion of all the preliminary tests, concealed envelopes were used to randomize the selected subjects into two groups: an individual-based exercise group and a group-based exercise group.

Further, subjects in the individual-based exercise group were randomly assigned to secondary investigators (physical therapists). Each secondary investigator completed an initial evaluation and assessment of all subjects assigned to them, and the therapists developed and implemented functional impairment-based interventions.[5] They referred to the Visual Health Information (VHI) exercise kit provided to them in the training as needed, and prescribed individual specific therapeutic and balance exercises. In contrast, subjects in the generic group-based exercise group were only provided with a fall prevention information booklet, and were signed up to participate in their facility-offered non-structured generic group exercise program. Information was collected from the facility activity directors about their facility-offered group exercise programs to fully understand the type of activities and parameters.

Training Protocol for the Individual-based Therapy Group

Physical therapy for the individualized group involved a detailed evaluation and identification of physical and functional limitations that were addressed during subsequent treatment sessions.[1] Physical therapists were provided with a generalized treatment protocol manual adopted from the Visual Health Information (VHI) Geriatric Strengthening (Frail through Fit)[42] and Complete Balance and Vestibular Exercise Kit.[1,5,109] They were encouraged to use the kit for reference as needed and developed individualized treatment options based on their evaluation findings. The focus was aimed at addressing the subjects' gait, balance, and functional deficits. Individualized direct contact treatment sessions occurred once or twice per week for 4 to 8 weeks, depending on individualized patient needs.[2,5] The duration of each treatment session was at least 45 minutes including the documentation time. The frequency and duration guidelines were chosen based on general Medicare home health care reimbursement guidelines.[110] Each subject received the balance exercises booklet and an activity log. The treating therapists were required to document the assessment, progression, and interventions provided during each session.[5,14]

Although the physical therapy program was individualized for each subject, the plan of care focused on common themes that addressed mobility, stability, controlled mobility and functional specific deficits.[5,9,13,14] The exercise program was progressed according to the subject's tolerance levels (increased repetitions, added resistance, added new exercises, and positional changes).[5,14] The type of functional activity performed during each session was modified depending on the ability of subjects.[5,9]

Training Protocol for the Generic Group-based Exercise Group

Each subject in the facility offered generic group-based exercise group received a fall prevention information booklet and an activity log. They were explicitly signed up for participation in the group exercise program offered at the facilities where they reside, led by activity directors or community volunteers, once or twice per week for 4 to 8 weeks. The duration of each group therapy session was noted as 45 to 60 minutes. The study subjects were asked to fill out an activity log regarding the exercise activities they performed, including the date, type, and duration of activities. The primary investigator reviewed all the participant activity logs, as well as the activity manuals of all the participating facilities, and collected general information regarding their generic exercise programs including the types of exercises offered. Each facility continued to offer their usual exercise programs (sitting, standing, and balance exercises) for the duration of the study, and no modifications were made in these programs as a result of participating in the study.

Outcome Measurements

The primary investigator was responsible for performing all the testing. Initial testing was completed for both groups by using the primary and the secondary outcome measures at pre-intervention (baseline), and then it was repeated again for both the groups at post-intervention (ninth week). A follow-up assessment also occurred one month after the end of the intervention (thirteenth week) only for the individual-based therapy group. At this data collection point, just the BioSway TM balance and the Modified Physical Performance Test (PPT) measures were repeated, with the rationale for this choice of follow-up tests discussed below.[1,32]

Balance performance has been shown to be multidimensional, including domains of static and dynamic balance.[1] Both the MDRT and the BioSwayTM (instrument-based) tests used in this study addressed and assessed all the static and dynamic balance performance domains. In particular, BioSway TM test measures are more sensitive in identifying mild balance dysfunction and intervention effects.[1,3] The BioSwayTM tool is reliable in predicting any minor balance changes and it is not limited by the ceiling effect as the other tests.[1,25,81] The choice of utilizing both clinical and instrument-based measures to assess balance dysfunction was significant, because studies have reported ceiling effects on simple clinical test measures when used in older adults with high levels of functional independence.[1,111] Therefore, a combination of testing tools were required for an accurate identification of “mild balance dysfunction” in high-functioning subjects.[1,111]

The maintenance of good balance and high functional scores are vital in decreasing fall risk factors and promoting overall quality of life.[1,3,5] The Modified Physical Performance Test (PPT) contains a 50-ft walking component that is similar to the comfortable gait speed test, and most of the other functional testing components in the PPT require good muscle strength for optimal performance. In addition, for cost and time effectiveness the individual muscle strength testing, and comfortable gait speed analysis were eliminated during the one-month follow-up assessment. Therefore, a short-term (one month) retention of intervention effects on balance and functional performance measures was only assessed using the BioSway ™ and the Modified Physical Performance Test (PPT).[25,33,81,86]

Table 6 describes the equipment utilized in the different measurement tools proposed in this study.

Table 6. Required Measurement Tools and Equipment

Measurement Tool	Equipment Required
Multi-Directional Reach Test (MDRT)	➢ Yardstick ➢ Duct tape (to stick the yardstick to the wall) ➢ Paper and pen
Physical Performance Test (PPT)	➢ Stopwatch ➢ Paper and pen ➢ 5 kidney beans ➢ A teaspoon ➢ An empty coffee can ➢ A heavy book (7 lbs) ➢ Shelf ➢ Jacket, cardigan sweater, or lab coat ➢ A penny ➢ A chair with seat height of 16 inches
Comfortable Gait Speed (6MCWT 6-meter comfortable walk test)	➢ Stopwatch ➢ Duct tape (for markings) ➢ Tape measure

Primary Outcome Measures

BioSway™

The BioSway™ is a computerized, portable, and versatile balance assessment and training device.[26] The BioSway™ unit has a data set with age- and sex-adjusted normative values.[26] Evidence shows that computerized balance measures are more sensitive in identifying mild balance dysfunction and intervention effects.[1,25,81] High test-retest reliability of several of these tests has been reported previously (ICC>.75).[1] The BioSway™ unit was used in this study to assess the postural stability test, the limits of stability (LOS), and the Modified Clinical Test of Sensory Integration of Balance (mCTSIB).[1,25]

Figure 2: BioSway^{TM} Unit

The Postural Stability test emphasizes a subject's ability to maintain center of balance. The subject's performance is noted as a stability index (in degrees from level) and it represents the variance of platform displacement in the forward, backward, left, and right directions.[26,81] The scores on this test assess deviations from the center, thus a lower score is more desirable than a higher score. A composite (overall) score across the forward/backward and left/right directions was used for analysis in this study.

The limits of stability (LOS) is a test of dynamic bilateral stance balance within the sway envelope. The limits of stability quantifies the maximum distance the subject can intentionally displace their center of gravity (COG) in the four cardinal directions and the four diagonal directions, and maintain stability at those positions.[25,26] The test measures the subject's ability to voluntarily control weight shift in 8 directions (forward, backward, right, left, forward/right, forward/left, backward/right, and backward/left) and to hold as close as possible to a target set at 100% of limits of stability in each direction.[1] Measured parameters are test duration (in seconds), directional control displayed as sway Angle (^{0}), and % of Standard (standardize sway envelope).[26,81] The composite score (Avg.) in the 8 directions was used for analysis.

The Modified Clinical Test of Sensory Integration of Balance (mCTSIB) is a simplified derivative of the Sensory Organization Test (SOT) that provides objective evidence of static standing balance measures under four different sensory conditions.[1,81] This includes standing on a firm surface with eyes open and eyes closed, and standing on a foam surface with eyes open and eyes closed. This test quantifies postural sway velocity with the subject standing steady on the firm and foam surfaces. A composite score (combining the 4 conditions) of center of gravity (COG) sway velocity/index (in degrees per second) was used for analysis. A total of 16 individual scores were derived from all the above mentioned BioSway™ tests. Within those 16 individual measures, if a subject secured between 3 and 5 scores outside the normative limits that was considered as an indicator of mild balance dysfunction.[1]

Multi-Directional Reach Test (MDRT)

The Multi-Directional Reach Test (MDRT) is a modified version of the Functional Reach test (FRT).[34-36] It is an inexpensive, reliable, and valid tool for measuring the dynamic balance and limits of stability (LOS) as derived by reach in the forward, backward, left, and right directions.[34-36] This test measures how far a subject can voluntarily reach in four different directions with stationary feet, shifting the center of gravity (COG) to the limits of the base of support (BOS).[34,36]

The ruler was positioned at the level of the subject's shoulder height. Then, the subject was instructed to stretch the arm in all four directions as far as possible along the ruler (without leaning against the wall) and without feet raised off the floor.[34,36] The subject was allowed and performed one practice and one trial session in each direction.[35] The maximum reach score was comprised of the difference between the initial reach while standing straight and the stretch reach.

In this study, the following criteria were used in classifying participants with mild balance dysfunction:

1. Participants with abnormal scores on the Multi-Directional Reach Test (MDRT), defined as worse than 1 standard deviation from the mean scores published for community-dwelling elderly.[34] A score between 9.4 and 10.2 inches (24 to 26 cm) on the forward reach,[1] and 7.1 to 8.0 inches (18 to 20 cm) on the left or right reach was categorized as mild balance dysfunction category.[34,36]
2. Participants with 3 to 5 abnormal scores on the BioSway™ test measures were classified as mild balance dysfunction category.[1]

All subjects who fulfilled at least one of these score ranges were included in this study.

Rationale for a Dual Test Approach

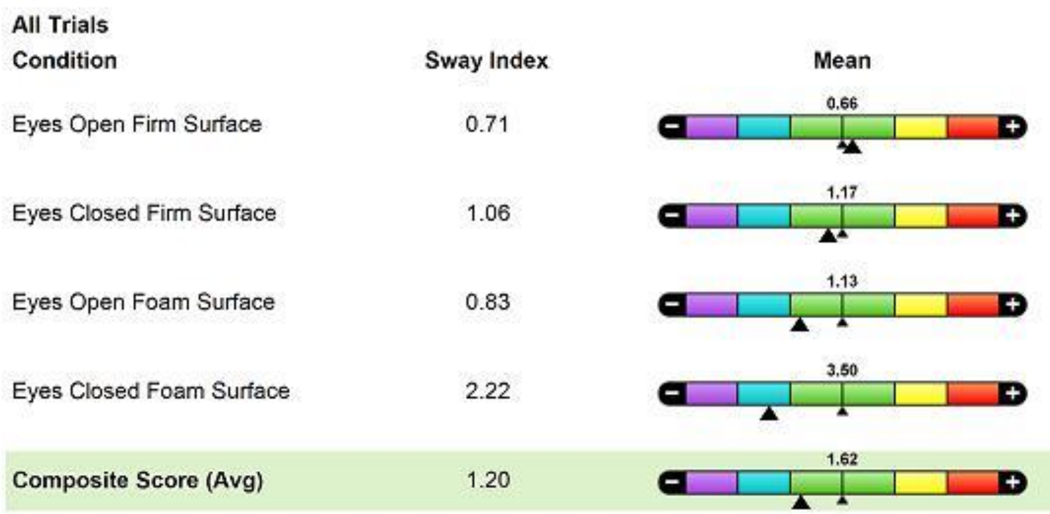
The computerized BioSway™ unit and a clinical multi-directional reach test were used as primary testing tools because the information they provide about an individual's balance can complement one another. Results from both tests were analyzed to identify and categorize individuals with mild balance dysfunction, who were then offered to participate in the study.

CTSIB Standard Scores Interpretation

The BioSway™ unit provides the modified Clinical Test of Sensory Integration of Balance (CTSIB) scores in the raw format relative to the selected normative database. The CTSIB report includes line graphs and a black triangle mark depicting the location of a subject's CTSIB scores relative to the reference normative database (age-related).[25,26] The middle vertical lines provide an indication of the reference database mean and the colored bars represent one, two, and three standard deviation units from the reference database mean.[26] Thus, if the triangle is located to the right of the black vertical line, the subject scored higher than the reference database mean, which suggests poorer balance performance.[26] Further, if the triangle appears in the green zone, the subject is within one standard deviation of the mean, which represents good balance status.[26]

If the triangle appears in the yellow or blue zone, the subject is between one and two standard deviation units worse than the mean, and if the triangle appears in the red or purple zone, the individual scored between two and three standard deviation units worse than the mean.[26] Thus, the report will help to interpret whether an individual score better or worse than the reference database mean, and also shows an indication regarding the magnitude of the distance.[26]

Figure 3: Modified Clinical Test of Sensory Integration of Balance Test Report



Secondary Outcome Measures

Modified Physical Performance Test (PPT)

The Modified Physical Performance Test (PPT) is a functional performance-based measure that assesses activities of daily living (ADLs), gross motor activities, fine motor control, balance, and walking.[31] The PPT offers the advantage of objective assessment of functional performance during everyday tasks, and is easy to administer in all settings.[32,33] The validity and reliability of the PPT to assess functional performance, measure change, and fall risk identification among older adults has been established.[31-33,85,86] Subjects less frequently achieve ceiling scores on the PPT when compared to self-report measures.[32] The PPT 9-item version was used in this study (Table 7).

Table 7. Modified Physical Performance Test Items[88]

1. Write a sentence – 'Whales live in the blue ocean' Scores are based on the time required to complete the task.
2. Simulated eating – Subjects pick up five kidney beans from a bowl using a teaspoon and put them in a coffee can. Scores are based on the time required to complete the task.
3. Book lift - A heavy book with 7-lbs is lifted from waist height to a shelf of 12 inches above shoulder level. Scores are based on the time required to complete the task.
4. Simulated dressing - Subjects put on and take off a standard lab coat or a jacket of appropriate size as quickly as able. Scores are based on the time required to complete this item.
5. Pick up penny - Subjects pick up as quickly as possible a penny that is located at 12 inches in front of the foot. Scores are based on the time required to complete the task.
6. 50-ft. walk - Subjects walk 25 ft in a straight line, turn, and return to the initial starting place as quickly as possible, safely.
7. Turn 360° - Subjects turn both clockwise and counterclockwise quickly but safely. They are subjectively graded on steadiness and ability to produce continuous turning movement.
8. Chair rise - Subjects sit in a chair that has a seat height of 16 inches. They then stand fully and sit back down, without using the hands, five times, as quickly as possible.
9. Progressive Romberg test - Subjects are scored according to their ability to maintain a reduced base of support: feet together, semi-tandem, and full tandem, for a maximum of 10 seconds.

Note: Maximum score is 36; 4 points per item

The primary investigator recorded the time required for the subjects to write a sentence, simulate eating, lift a book onto a shelf above shoulder height, simulate dressing, pick up an item from the floor, walk 50 feet, turn in a circle, rise up from a chair five times, and a progressive Romberg test of balance (i.e. standing with feet side-by-side, semi-tandem and tandem).[32] All the performance tasks in the test were scored from 0–4, based on the timing to complete the task, except the 360° turn.[88]

This 360° turn was rated as either zero or two, for continuity of steps and for steadiness.[32,88] Scores for the 9-item test range from 0–36 with higher scores indicating better performance.[32,88] The reader is referred to appendix C for further scoring details.

Hand-Held Dynamometry

A hand-held dynamometer (Commander Muscle Tester, JTech, USA – Figure 4) is an advanced computerized tool useful for quantitative and objective measure of isometric muscular strength.[29,90]

Figure 4: Commander Wireless Console and Manual Muscle Tester

Key muscle groups that are responsible for safe functional transfers and mobility are hip flexors, hip abductors, knee extensors, and ankle dorsiflexors.[1,90] A handheld dynamometer was used to measure the isometric strength of those four lower extremity muscle groups bilaterally, i.e. hip flexors, hip abductors, knee extensors, and ankle dorsiflexors.[1,30,90] The standardized strength measure was derived by dividing the average score by the subject's weight.[1,90] Assessment of isometric muscle strength and power was performed with the subject in two positions (seated and supine).[30] Hip flexors and knee extensors were assessed in a seated position; hip abductors and ankle dorsiflexors in a supine position.

Detailed testing positions for the four lower limb muscle segments were as follows:

1. Hip flexors were tested with the subject in a seated position with hips and knees flexed at 90°. The hand-held dynamometer was placed on the anterior aspect of the thigh, proximal to the knee joint.[30]
2. Knee extensors were tested with the subject in a seated position with hips and knees flexed at 90°. The hand-held dynamometer was placed on the anterior aspect of the shank, proximal to the ankle joint.[30]
3. Hip abductors were tested with the subject lying in the supine position with hips and knees extended. The hand-held dynamometer was placed on the lateral aspect of the shank, proximal to the ankle joint.[30]
4. Ankle dorsiflexors were tested with the subject lying in supine with hips and knees extended, and ankles in a relaxed position. The hand-held dynamometer was placed over the metatarsal heads on the dorsum of the foot.[30]

Subjects were manually stabilized during the test and the peak force (maximal voluntary isometric contraction) during the middle portion of their range was recorded (i.e. final 4-6 seconds of maximal effort).[30] An average of trials 2 and 3 on the worse side was noted for the four groups of muscles[1] and reported for analysis.

Gait Speed

Comfortable gait speed is a valid and reliable tool to measure walking ability in older adults.[69,93] Comfortable gait speed was measured in this study using a foot pod speedometer system called the FitSense (FS-1, Figure 4).[1,5,108] This 6-meter comfortable walk test (6MCWT) has been shown to be responsive to strength training and balance interventions.[69,71,75] The subjects were encouraged to walk at their comfortable pace across a pre-specified straight walkway of 10m.[5,108] The foot pod recorded cadence, pace and gait speed.[108,112,113] The central 6 meter portion was timed and considered for analysis.[1,5]

Figure 5: FitSense (FS-1) Speedometer

Data Analysis

Data was analyzed using IBM SPSS Analysis Package 25 (Armonk, NY: IBM Corporation), with the level of significance set as 0.05. Baseline demographic and clinical characteristics (age, height, weight, mental status score, and medical diagnosis/conditions) for the two groups were analyzed and summarized using descriptive statistics (mean, median, standard deviation, and interquartile range). Frequency distribution was used to describe categorical data (sex and fall history).

Balance, gait, muscle strength, and physical function variables were analyzed separately using mixed-model analyses of variance (ANOVAs). The primary outcome measures tested were the BioSway™ balance performance and the multi-directional reach test; and the secondary outcome measures tested were the modified physical performance test, the 6-meter comfortable walk test, and the lower-limb muscle strength test. The change in both the primary and secondary outcome measures between the individual-based exercise group and the group-based exercise group were analyzed using separate 2-by-2 mixed-model analyses of variance (ANOVAs), using the two groups as between-subjects factors and two time points (pre-intervention and post-intervention) as within-subjects factors.

The change over time in the BioSway™ balance measures and the modified physical performance test measure in the individual-based therapy group were analyzed by utilizing separate one-way repeated measures analyses of variance (ANOVAs) for BioSway™ and PPT, using three time points as the repeated measures for each tool (pretreatment, post treatment, and one-month follow-up). Normality assumptions were tested using Shapiro-Wilk test followed by visual examination of box plots, histogram graphs and the Normal Q-Q plots. Sphericity assumptions were tested for the repeated-measures ANOVA using Mauchly's test. A Bonferroni method was used in post-hoc analysis. Effect size (Partial Eta Squared) values were presented for all the measures that change significantly with the intervention. Effect was labeled as small (0.01-0.05), medium (0.06-0.13), and large (0.14 or more).[114] As per Cohen, for the eta-square statistic (indexing the amount of variance accounted for by an effect in an ANOVA), effect sizes of 0.01, 0.06, and 0.14 are considered to be small, medium, and large, respectively.[115]

Resources

Resources utilized for successful completion of this study included physical therapists, a clerical assistant, and other substantial materials. The facility hallways were used for comfortable gait speed assessment, and activity (exercise) rooms were used for all screening and testing procedures. Refer to appendix M for the summary of items used for testing and data collection.

The primary investigator purchased all of the required equipment; and furnished all of the protocol manuals, consent forms, and data collection sheets. The primary investigator was also responsible for all document maintenance, data management, post analysis, and submission. The primary investigator maintained contact with all the facility activity directors/staff in-charge and secondary investigators at least twice per week during the data collection period, either by phone or in person.

Chapter 4: Results

Introduction to the Chapter

This chapter provides an overview of the analysis of the data collected and findings of this study. Basic demographic and clinical characteristics for the two groups are summarized using descriptive statistics and the outcome measures are presented based on inferential statistical analysis. Supplementary materials can be found in the appendices for reference.

Participants

A total of two hundred and five (205) subjects were screened initially from eleven different residential care facilities. Out of the screening pool, one hundred and twenty (120) subjects were consented for this study based on the eligibility and selection criteria for mild balance dysfunction. Sixty (60) subjects were randomly assigned to the group-based therapy and sixty (60) subjects were randomly assigned to the individual-based therapy. There was no subject attrition during the studies, and no adverse events of exercise were reported by any of the subjects during the entire study period. Sixty subjects (100%) in the group-exercise group completed the pre- and post-assessment, and sixty subjects (100%) in the individual-exercise group completed pre-, post-, and follow-up assessment.

Overall, seventy-nine percent (n = 95) of the subjects were female with mean age of 79.3 ± 9.1 years old and twenty-one percent (n = 25) of the subjects were male with mean age of 77.3 ± 10.2 years old. Based on ethnicity, there were ninety percent (n = 108) white subjects and ten percent (n = 12) black or African American subjects. Ninety-five percent (n = 114) of subjects had at least a high-school education and the mean length of stay in the residential care facilities was 4.1 $\pm$ 2.1 years. Five percent (n = 6) of the subjects had reported a fall in the last three months, and twenty percent (n = 24) of the subjects used a walker or cane. Fifty-five percent (n = 66) of the subjects had at least 2-3 medical diagnoses/conditions and forty-five percent (n = 54) of the subjects had 4 or more medical diagnoses/conditions. The most common medical diagnoses reported were arthritis, hypertension, diabetes, coronary artery disease, anemia, depression, hyperthyroidism, hypothyroidism, and osteoporosis.

Four subjects (3.3%) in the group-based exercise group experienced a fall during the study term, whereas no falls were reported in the individual-based exercise group. Four facilities offered pre-recorded exercise programs on television twice per week, and two facilities offered non-structured group exercises facilitated by activity directors or community volunteers, once per week. Other five facilities offered both television and activity-director organized exercise programs, once per week. In general, the group-based exercise group reported completion of about 8 to 16 group exercise sessions and each session lasted for 45 to 60 minutes. Each subject in the individual-based exercise group received an average of 8 to 10 sessions and each individual therapy session lasted for 45 minutes.

Subjects in the group-based exercise group were also requested to maintain a record of exercises and walking activities, they performed in an exercise log sheet, and fifty-five subjects (91.6%) completed this task. Nine subjects in the group-based exercise reported regular walking activity inside the facility hallways for 15 minutes, three times per week. Two other subjects reported walking for 20 to 25 minutes, twice per week. Further, seven subjects reported using a recumbent cross trainer bicycle for 15 to 20 minutes, at least once or twice per week. Fifty-eight subjects (96.6%) maintained activity logs in the individual-based group. Given that, six subjects reported walking on the facility hallways for 15 to 20 minutes, twice per week, and two subjects reported using a recumbent bike for about 15 minutes, once per week. Other subjects in both the groups did not report and specify performing any other specific physical activities.

A summary of the subject characteristics by group can be found in Table 8. The distributions of baseline characteristics were similar between the individual-based exercise and group-based exercise groups.

Table 8: Baseline Characteristics of Subjects in the Individual-Based Exercise Group and the Group-Based Exercise Group

Subject Characteristics	**Individual-Based Exercise Group (n = 60)**	**Group-Based Exercise Group (n = 60)**
Age (SD)	80.2 (9.2)	77.6 (9.4)
Female n (%)	48 (80%)	47 (78%)
Male n (%)	12 (20%)	13 (22%)
Height in meters (SD)	1.6 (0.1)	1.6 (0.1)
Weight in kg (SD)	69.4(12.0)	75.7 (17.7)
Short Test of Mental Status (SD)	33.5 (1.9)	33.7 (1.9)
Past History of Falls (within last 3-months) n (%)	4 (66.7%)	2 (33.3%)
Mean Number of Medical Diagnoses/Conditions (25^{th} & 75^{th} Percentiles)	3.3 (3-4)	3.2 (3-4)

Study outcomes

To briefly recapitulate, the primary outcome measures of the trial were the three scores on the BioSway™ balance performance (limits of stability, postural stability, and modified clinical test of sensory integration of balance) and four scores on the Multi-Directional Reach Test (forward reach, backward reach, right lateral reach, and left lateral reach).

The secondary outcome measures were the four scores on the lower-limb muscle strength testing (hip flexors, knee extensors, hip abductors, and ankle dorsiflexors), the Modified Physical Performance Test (PPT), and the 6-meter Comfortable Walk Test.

The change in both the primary and secondary outcome measures between the individual-based exercise group and the group-based exercise group were analyzed using separate 2-by-2 mixed-model analyses of variance (ANOVAs), using the two groups as factors and time (pre-intervention and post-intervention).

Table 9 shows the pre-intervention and post-intervention results for primary and secondary outcome measures, including BioSway™ balance performance scores, multi-directional reach test scores, lower-limb muscle strength scores, modified physical performance test scores, and 6-meter comfortable walk test scores. Means and standard deviations were reported. There were no significant differences between groups in subject performance at baseline for any of the measures ($p>0.05$).

Table 9: Pre- and Post-Intervention Performance on Primary and Secondary Outcome Measures Based on Group^

Outcome Measures	Group-Based Group Pre-Intervention	Individual-Based Group Pre-Intervention	Group-Based Group Post-Intervention	Individual-Based Group Post-Intervention	Mixed-ANOVA Results (Change Between Groups)	Partial Eta Squared
<u>Primary</u>						
BioSway™ Measures						
LOS	3.74 (0.77)	3.94 (0.66)	3.86 (0.81)	4.78 (0.61)	$F(1, 118) = 23.38$ $p < .001$	0.16
PS*	1.51 (0.88)	1.72 (0.84)	1.47 (0.69)	0.79 (0.38)	$F(1, 118) = 5.95$, $p = .016$	0.05
mCTSIB	1.38 (0.30)	1.25 (0.33)	1.31 (0.28)	1.39 (0.21)	$F(1, 118) = 0.38$, $p = .538$	0.00
Multi-Directional Reach Test (MDRT)!						
FR	25.20 (0.81)	25.27 (0.79)	25.27 (1.28)	28.44 (1.46)	$F(1, 118) = 81.53$, $p < .001$	0.41
BR	17.15 (2.38)	17.07 (2.28)	17.13 (2.43)	19.54 (2.53)	$F(1, 118) = 7.41$, $p = .007$	0.06
RLR	19.39 (0.81)	19.37 (0.80)	19.73 (0.97)	21.59 (1.13)	$F(1, 118) = 32.07$, $p < .001$	0.21
LLR	18.90 (0.81)	19.03 (0.75)	19.25 (0.90)	21.11 (1.13)	$F(1, 118) = 40.30$, $p < .001$	0.25
<u>Secondary</u>						
Lower Extremity Muscle Strength						
Hip Flexors+	0.07 (0.01)	0.07 (0.01)	0.07 (0.01)	0.09 (0.02)	$F(1, 118) = 6.90$, $p = .010$	0.06
Knee Extensors+	0.08 (0.01)	0.08 (0.01)	0.08 (0.01)	0.09 (0.02)	$F(1, 118) = 9.95$, $p = .002$	0.08
Hip Abductors+	0.06 (0.01)	0.06 (0.01)	0.06 (0.01)	0.07 (0.01)	$F(1, 118) = 7.11$, $p = .009$	0.06
Ankle Dorsiflexors+	0.06 (0.01)	0.06 (0.01)	0.06 (0.01)	0.07 (0.01)	$F(1, 118) = 5.12$, $p = .025$	0.04
PPT	25.98 (2.90)	25.67 (2.97)	26.28 (3.15)	30.50 (2.83)	$F(1, 118) = 14.03$, $p < .001$	0.11
6MCWT#	0.75 (0.09)	0.74 (0.07)	0.78 (0.09)	0.86 (0.09)	$F(1, 118) = 6.50$, $p = .012$	0.05

^ Values are mean (SD), * Smaller value represents better performance, + Muscle strength measured (kilograms) divided by total body weight (kilograms), # MCWT measured in meters/sec, Multi-Directional Reach Test measured in centimeters. PS – Postural Stability, LOS – Limits of Stability, mCTSIB - Modified Clinical Test of Sensory Integration of Balance, FR – Forward Reach, BR – Backward Reach, RLR – Right Lateral Reach, LLR – Left Lateral Reach, PPT - Modified Physical Performance Test, 6MCWT - 6-meter comfortable walk test.

Evaluation of Parametric Assumptions

Parametric assumptions, such as normality and homogeneity of variance for the between-group variable (individual vs group-based exercise) were evaluated prior to conducting the separate mixed-model analyses of variance (ANOVAs). Normality was evaluated through consideration of descriptive statistics, visual inspection of score distributions for outliers, and computation of normality statistics. Initially, the normality assumption was analyzed using the Shapiro-Wilk's test, and then graphical evaluation was completed using box plots, histogram graphs, and the Normal Q-Q plots for variables that were flagged as significant. Any deviations from normality, even for significant Shapiro results, were small upon further inspection. The ANOVA procedure is robust against small deviations from normality, in the presence of larger and equal samples. Therefore, a parametric approach was retained for all analyses. The Levene's test homogeneity of variance assumption was met for all the measures ($p > 0.05$), except for post postural stability, post hip flexion, and post knee extension measures. The usual sphericity assumption did not apply when comparing pre- and post-assessment, as there were only two repeated measurements.

Analysis of Study Outcomes

Limits of Stability

According to the primary hypothesis of the study, the BioSway™ limits of stability balance scores were expected to be higher for the individual-based exercise group when compared to the group-based exercise group after completion of the intervention.

The findings supported the hypothesis, and the individual-based exercise group received a significantly higher score on the limits of stability measure ($F(1, 118) = 23.38$ $p < .001$) compared to the group-based exercise group after the intervention (Tables 9 and 10). The effect size was large (Partial Eta Squared = 0.16). Thus, there was a large difference in the limits of stability scores of the individual-based exercise group (Mean, $M = 4.78$) compared to the group-based exercise group ($M = 3.86$). The main effect for the within-subjects factor was also significant [$F(1, 118) = 59.91$, $p < .001$], indicating there were significant differences between the values of pre-limits of stability and post-limits of stability within the groups, with a large effect (Partial Eta Squared = 0.34). Combined limits of stability after the intervention ($M = 4.32$) were significantly higher than before the intervention ($M = 3.84$).

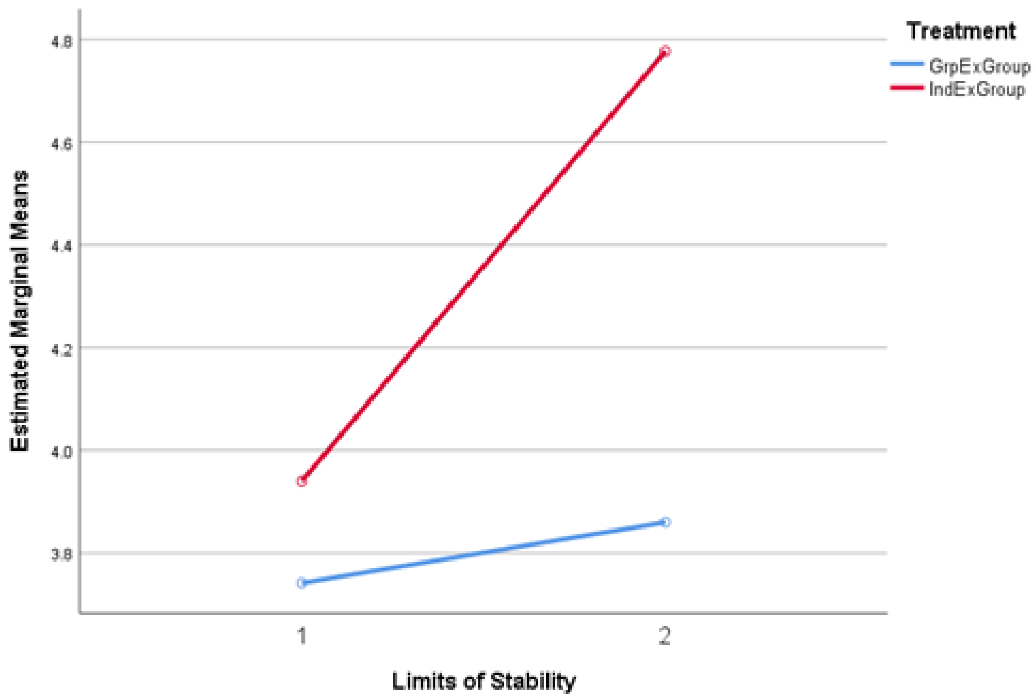
Table 10: ***ANOVA Results for Treatment Group and Limits of Stability Variables***

Source	***df***	***SS***	***MS***	***F***	***p***	***Partial Eta Squared***
			Between Subjects			
Group	1	18.65	18.65	23.38	<.001	.16
Error 1	118	94.14	.798			
			Within Subjects			
Time	1	13.68	13.68	59.91	<.001	.34
Group x Time	1	7.74	7.74	33.90	<.001	.22
Error 2	118	26.95	.228			

Note: *$p < .05$, **$p < .01$, ***$p < .001$.

In addition, the interaction effect between the limits of stability factor and the type of therapy was significant, $F(1, 118) = 33.90$, $p < .001$, with a large effect (Partial Eta Squared = 0.22). This indicates that the overall limits of stability scores were increased significantly more for the individual-based exercise group over time than the group-based exercise group (Figure 6)

Figure 6: Limits of Stability Scores for Both Groups



A large increase was observed in the mean scores for limits of stability in the individual-based exercise group from pre-intervention (*M* = 3.94) to post-intervention (*M* = 4.78), whereas the group-based exercise group had a smaller change in the limits of stability scores from pre-intervention (*M* = 3.74) to post-intervention (*M* = 3.86).

Before the intervention, the individual-based exercise group had slightly higher limits of stability scores (*M* = 3.94) than the group-based exercise group (*M* = 3.74). However, this initial advantage does not account for the difference at post-intervention.

Postural Stability

A lower mean score in the BioSwayTM postural stability balance measure signifies improved postural stability and overall balance. The individual-based exercise group received a significantly lower score on the postural stability measure (F(1, 118) = 5.95, p = .016), compared to the group-based exercise group after intervention (Table 11). The effect size was small (Partial Eta Squared = 0.05). Thus, there was a large difference (decrease) in the postural stability scores of the individual-based exercise group (M = 0.79) compared to the group-based exercise group (M = 1.47). The main effect for the within-subjects factor was significant [F(1, 118) = 29.83, p < .001], indicating there were significant differences between the values of pre-postural stability and post-postural stability, and this was a large effect (Partial Eta Squared = 0.20). Overall postural stability scores after intervention (M = 1.13) were significantly lower than before the intervention (M = 1.61). In addition, the interaction effect between the postural stability factor and the type of therapy was significant, [F(1, 118) = 25.96, p < .001], indicating that the postural stability scores were decreased significantly more for the individual-based exercise group over time than the group-based exercise group (Figure 7), and this was a large effect (Partial Eta Squared = 0.18).

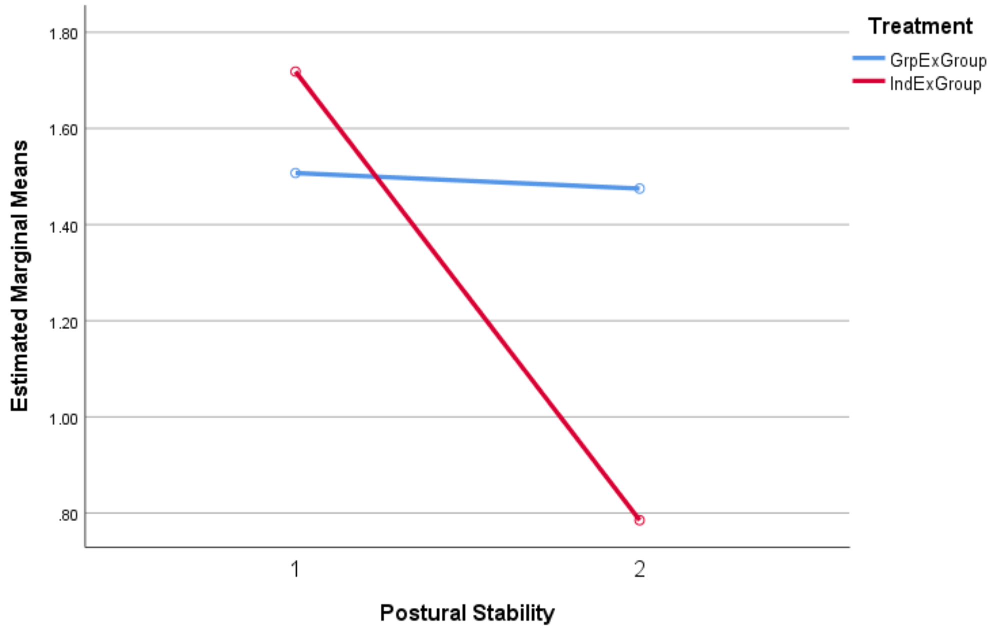
Table 11: ANOVA Results for Treatment Group and Postural Stability Variables

Source	*df*	*SS*	*MS*	*F*	*p*	*Partial Eta Squared*
			Between Subjects			
Group	1	451.30	451.30	5.95	.016	.05
Error 1	118	68.26	.578			
			Within Subjects			
Time	1	13.98	13.98	29.83	<.001	.20
Group x Time	1	12.17	12.17	25.96	<.001	.18
Error 2	118	55.32	.469			

Note: **p* < .05, ***p* < .01, ****p* < .001.

A large decrease was observed in postural stability mean scores for the individual-based exercise group from pre-intervention (*M* = 1.72) to post-intervention (*M* = 0.79), whereas the group-based exercise group demonstrated a considerably smaller change in the postural stability scores from pre-intervention (*M* = 1.51) to post-intervention (*M* = 1.47). Before the intervention, the individual-based exercise group had higher postural stability scores (*M* = 1.72) than the group-based exercise group (*M* = 1.51). In contrast, after the intervention the postural stability scores were lower for the individual-based exercise group (*M* = 0.79) than the group-based exercise group (*M* = 1.47).

Figure 7: Postural Stability Scores for Both Groups



Modified Clinical Test of Sensory Integration of Balance (CTSIB)

Based on the analysis, there was no significant main effect difference in CTSIB scores after intervention between the individual-based exercise group and the group-based exercise group $F(1, 118) = 0.38$, $p = .538$, indicating the CTSIB values of both groups were all similar (Tables 9 and 12). The CTSIB scores of the individual-based exercise group after intervention ($M = 1.39$) were very similar to the group-based exercise group ($M = 1.31$). The main effect for the within-subjects factor was not significant $F(1, 118) = 1.62$, $p = .205$, indicating there were no significant differences between the values of pre-CTSIB and post-CTSIB.

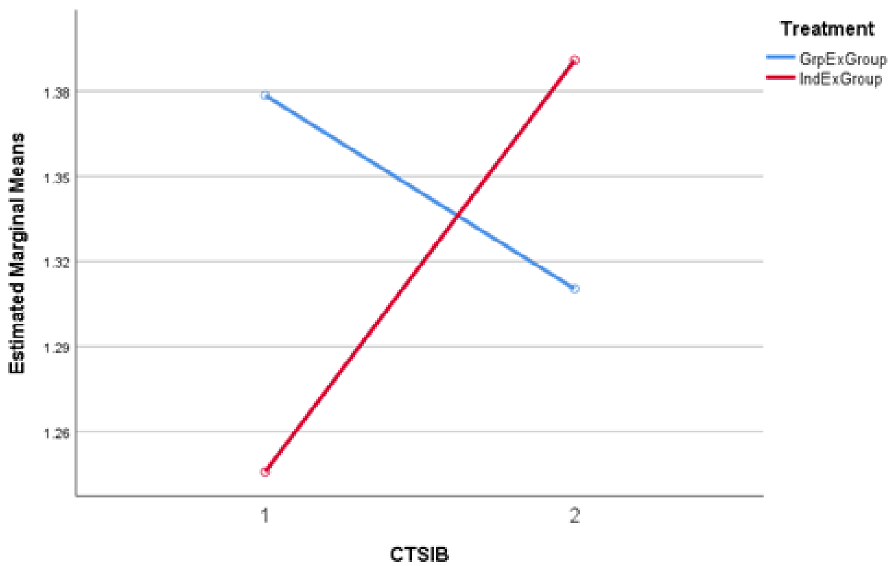
Overall CTSIB scores after the intervention (*M* = 1.35) were not significantly changed from before the intervention (*M* = 1.31). However, the interaction effect between the CTSIB factor and the type of therapy was significant, $F(1, 118) = 12.50$, $p < .001$, and this was a medium effect (Partial Eta Squared = 0.10). This is consistent with the fact that the scores of the individual-based group increased over time, whereas the scores of the group-based group decreased over time, giving rise to the observed crossover interaction effect (Figure 8).

Table 12: *ANOVA Results for Treatment Group and* CTSIB *Variables*

Source	***df***	***SS***	***MS***	***F***	***p***	***Partial Eta Squared***
			Between Subjects			
Group	1	.041	.041	0.38	.538	.00
Error 1	118	12.60	.107			
			Within Subjects			
Time	1	.089	.089	29.82	.205	.01
Group x Time	1	.682	.682	25.96	.001	.10
Error 2	118	6.43	.055			

Note: *$p < .05$, **$p < .01$, ***$p < .001$. CTSIB - Modified Clinical Test of Sensory Integration of Balance

Figure 8: Modified Clinical Test of Sensory Integration of Balance Scores for Both Groups



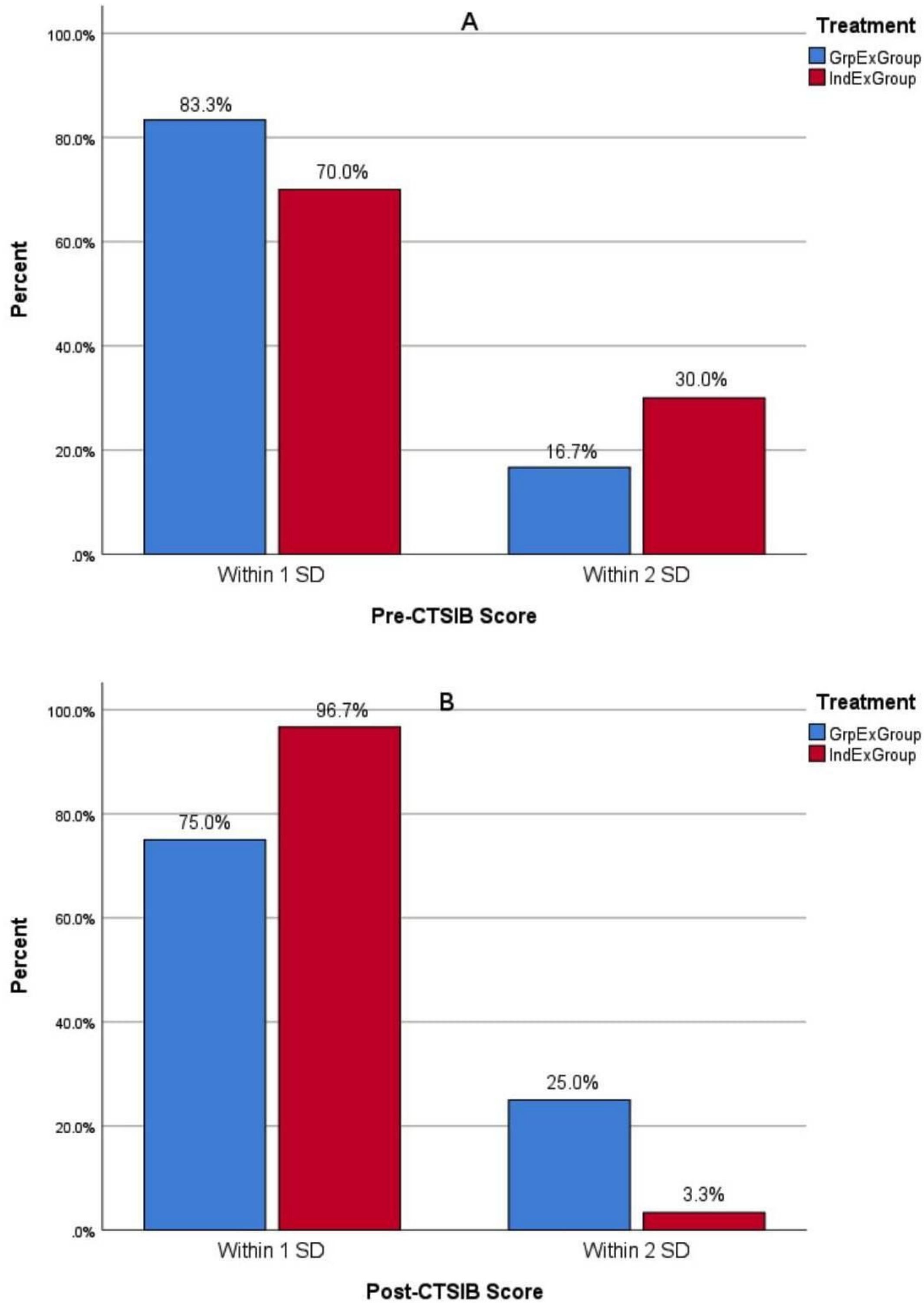
A mild increase was observed in CTSIB mean scores for the individual-based exercise group from pre-intervention (M = 1.24) to post-intervention (M = 1.39), whereas the group-based exercise group showed a mild decrease in the CTSIB scores from pre-intervention (M = 1.38) to post-intervention (M = 1.31). Before the intervention, the individual-based exercise group had slightly lower CTSIB scores (M = 1.24) than the group-based exercise group (M = 1.37). However, after the intervention the CTSIB scores increased for the individual-based exercise group (M = 1.39) to a value over the initial value for the group-based group; whereas in the group-based exercise group there was actually a decrease post-intervention (M = 1.31). The change in CTSIB scores plays a key role in interpreting the results and it will be explained in detail in the CTSIB standard scores interpretation section below.

CTSIB Standard Scores Interpretation

Figure 9A provides information regarding the pre-CTSIB scores for the group-based exercise group and the individual-based exercise group, based on the standard rating method relative to the reference normative database mean. At this time point, 70.0% of subjects in the individual-based exercise group scored within one standard deviation of the reference mean (i.e. green zone), and 30.0% of subjects in the individual-based exercise group scored between one and two standard deviation units from the mean (i.e. yellow or blue zone, M = 1.30, SD =0.46). In the group-based exercise group, 83.3% of subjects scored within one standard deviation to the reference data mean (i.e. green zone), and 16.7% of subjects scored between one and two standard deviation units from the mean (i.e. yellow or blue zone), M = 1.17, SD = 0.38.

In addition, Figure 9B also provides information regarding the post-CTSIB scores for the group-based exercise group and the individual-based exercise group, based on the standard rating method relative to the reference normative database mean. The data shows that 96.7% of subjects in the individual-based exercise group scored within one standard deviation of the reference mean (i.e. green zone), and 3.3% of subjects in the individual-based exercise group scored between one and two standard deviation units from the mean (i.e. yellow or blue zone), M = 1.03, SD = 0.18.

Figure 9: Modified Clinical Test of Sensory Integration of Balance Standard Scores Rating (Pre and Post)



In the group-based exercise group, 75.0% of subjects scored within one standard deviation from the reference data mean (i.e. green zone), and 25.0% of subjects scored between one and two standard deviation units from the mean (i.e. yellow or blue zone), $M = 1.25$, $SD = 0.44$.

Multi-Directional Reach Test (MDRT)

The multi-directional reach test (MDRT) is comprised of four tests: the forward reach (FR), backward reach (BR), right lateral reach (RLR), and left lateral reach (LLR). In the primary hypothesis, all MDRT scores were expected to be higher for the individual-based exercise group when compared to the group-based exercise group.

As shown in Tables 9 and 13, the individual-based exercise group received significantly higher scores than the group-based exercise group on all the MDRT measures after intervention: forward reach ($F(1, 118) = 81.53$, $p < .001$), backward reach ($F(1, 118) = 7.41$, $p = .007$), right lateral reach ($F(1, 118) = 32.07$, $p < .001$), and left lateral reach ($F(1, 118) = 40.30$, $p < .001$). The effect size was large for the forward reach (Partial Eta Squared = 0.41), medium for the backward reach (Partial Eta Squared = 0.06), large for the right lateral reach (Partial Eta Squared = 0.21), and large for the left lateral reach (Partial Eta Squared = 0.25).

Thus, there were large differences in the MDRT scores of the individual-based exercise group (forward reach: $M = 28.44$, backward reach: $M = 19.54$, right lateral reach: $M = 21.59$, and left lateral reach: $M = 21.11$) compared to the group-based exercise group after intervention (forward reach: $M = 25.27$, backward reach: $M = 17.13$, right lateral reach: $M = 19.73$, and left lateral reach: $M = 19.25$).

The main effect for the within-subjects factor was significant for forward reach ($F(1, 118) = 348.85$, $p < .001$, Partial Eta Squared = 0.75 - large effect), backward reach ($F(1, 118) = 144.82$, $p < .001$, Partial Eta Squared = 0.55 - large effect), right lateral reach ($F(1, 118) = 520.12$, $p < .001$, Partial Eta Squared = 0.81 - large effect), and left lateral reach ($F(1, 118) = 500.62$, $p < .001$, Partial Eta Squared = 0.81 - large effect), indicating there were significant changes over time between the values of pre-MDRT and post-MDRT.

The interaction effect between the MDRT factor and the type of therapy was significant, indicating that the subjects in the individual-based exercise group had greater gains in all four directions over time when compared with the group-based exercise group (Figure 10). Specifically: forward reach ($F(1, 118) = 318.14$, $p < .001$, Partial Eta Squared = 0.73 - large effect), backward reach ($F(1, 118) = 148.33$, $p < .001$, Partial Eta Squared = 0.55 - large effect), right lateral reach ($F(1, 118) = 277.95$, $p < .001$, Partial Eta Squared = 0.70 - large effect), and left lateral reach ($F(1, 118) = 252.93$, $p < .001$, Partial Eta Squared = 0.68 - large effect)

Table 13: ***ANOVA Results for Treatment Group and* MDRT *Variables***

Forward Reach

Source	*df*	*SS*	*MS*	*F*	*p*	*Partial Eta Squared*
			Between Subjects			
Group	1	23.88	23.88	81.53	<.001	.41
Error 1	118	34.56	.293			
			Within Subjects			
Time	1	23.75	23.75	348.85	<.001	.78
Group x Time	1	21.66	21.66	318.14	<.001	.73
Error 2	118	8.03	.068			

Backward Reach

Source	*df*	*SS*	*MS*	*F*	*p*	*Partial Eta Squared*
			Between Subjects			
Group	1	12.61	12.61	7.41	.007	.06
Error 1	118	200.73	1.70			
			Within Subjects			
Time	1	14.03	14.03	144.82	<.001	.55
Group x Time	1	14.37	14.37	148.33	<.001	.56
Error 2	118	11.43	.097			

Right Lateral Reach

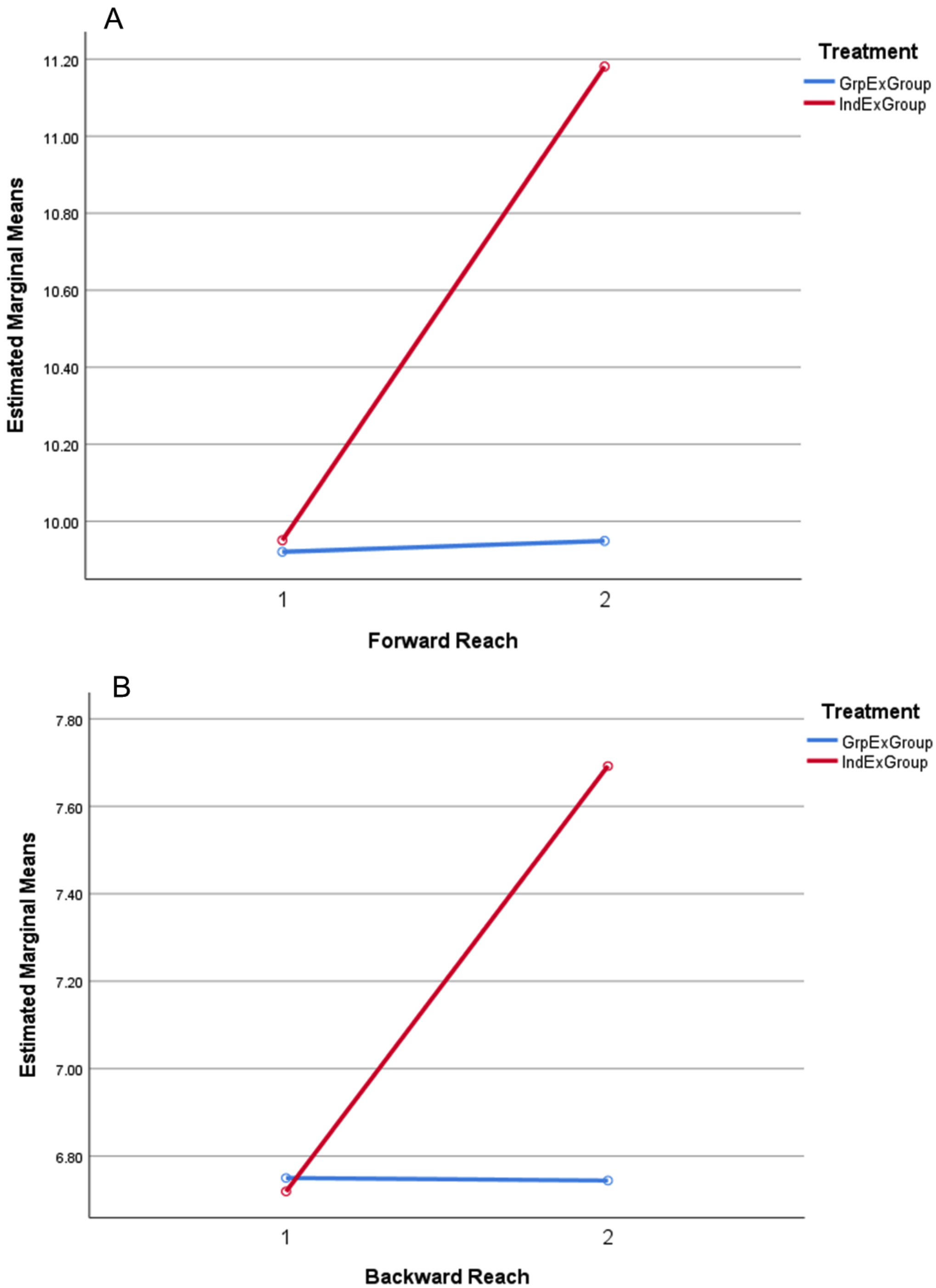
Source	*df*	*SS*	*MS*	*F*	*p*	*Partial Eta Squared*
			Between Subjects			
Group	1	7.81	7.81	32.07	<.001	.21
Error 1	118	28.74	.244			
			Within Subjects			
Time	1	15.30	15.30	520.12	<.001	.81
Group x Time	1	8.18	8.18	277.95	<.001	.70
Error 2	118	3.47	.029			

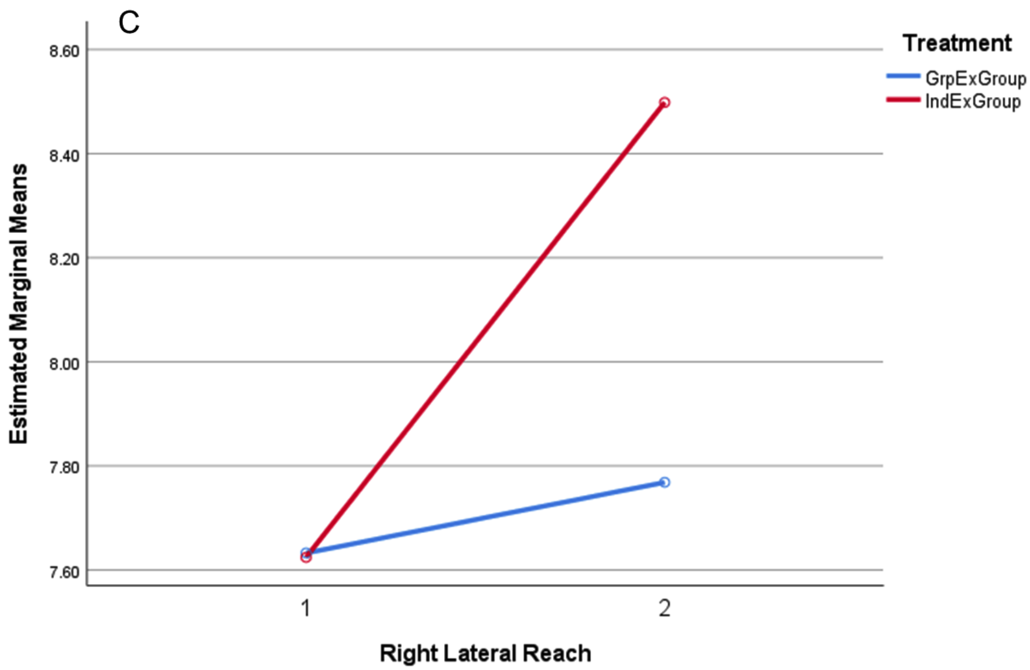
Left Lateral Reach

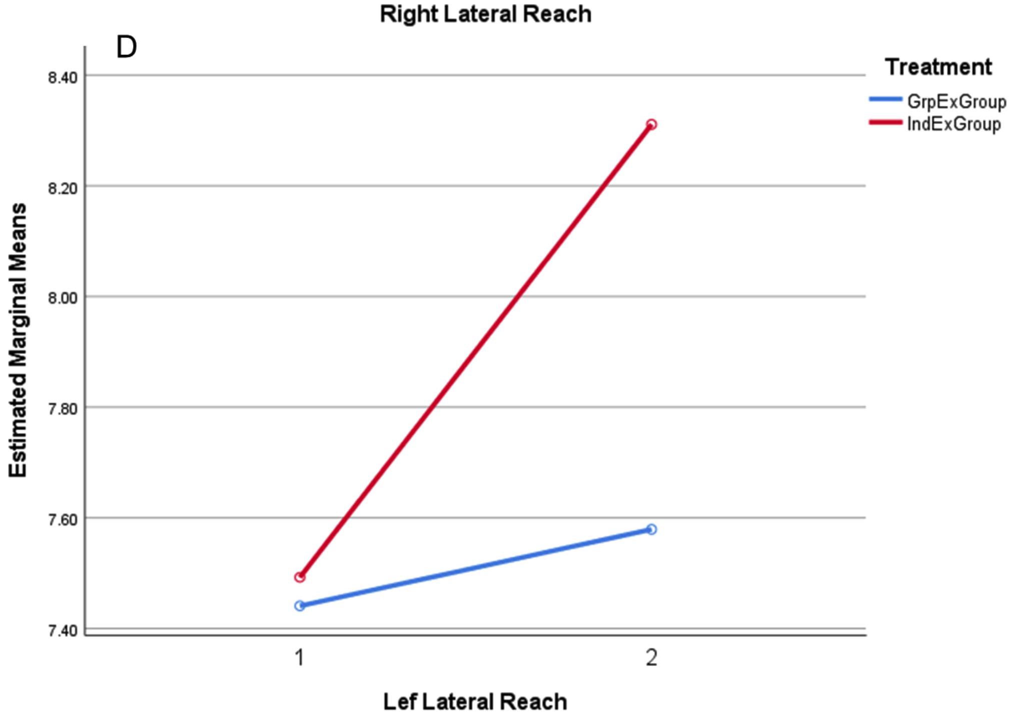
Source	*df*	*SS*	*MS*	*F*	*p*	*Partial Eta Squared*
			Between Subjects			
Group	1	9.20	9.20	40.30	<.001	.25
Error 1	118	26.95	.228			
			Within Subjects			
Time	1	13.73	13.73	500.62	<.001	.81
Group x Time	1	6.94	6.94	252.93	<.001	.68
Error 2	118	3.23	.027			

Note: *p < .05, **p < .01, ***p < .001.

Figure 10: Multi-Directional Reach Test (MDRT) Scores for Both Groups




C
Treatment
GrpExGroup
IndExGroup
Estimated Marginal Means
8.60
8.40
8.20
8.00
7.80
7.60
1
2
Right Lateral Reach


D
Treatment
GrpExGroup
IndExGroup
Estimated Marginal Means
8.40
8.20
8.00
7.80
7.60
7.40
1
2
Lef Lateral Reach

A large increase was observed in MDRT mean scores for the individual-based exercise group from pre-intervention to post-intervention, whereas the group-based exercise group showed a very mild change in the MDRT scores from pre-intervention to post-intervention (Figure 10, Table 9). This means that the within-group gains that were observed stem mainly from the individual-based group.

Lower-Limb Muscle Strength - Hand-Held Dynamometry

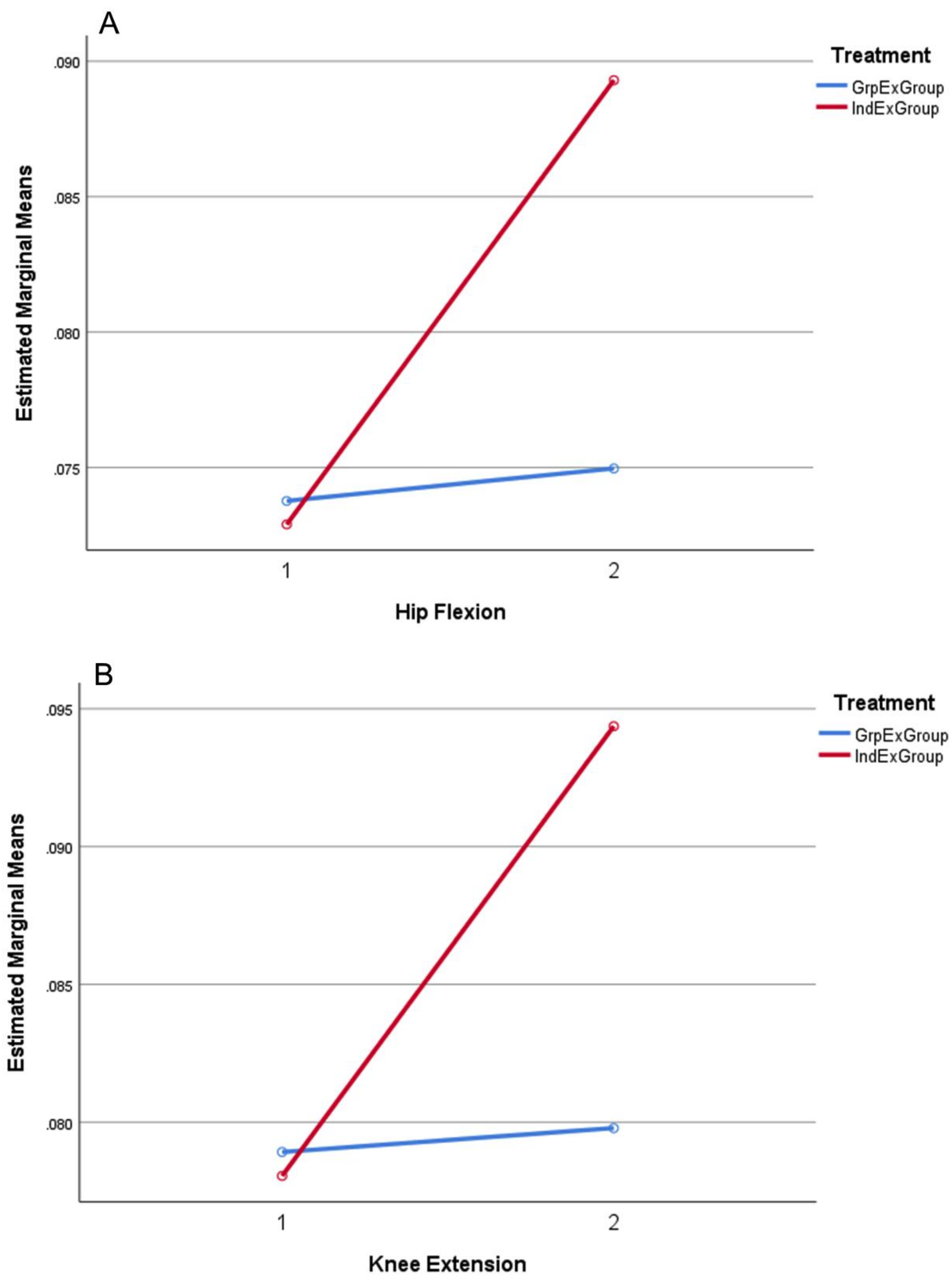
Lower-limb muscle strength was measured using hand-held dynamometry and the key muscle groups tested were hip flexors, hip abductors, knee extensors, and ankle dorsiflexors. According to our secondary hypothesis, all lower-limb muscle strength scores were expected to be significantly higher for the individual-based exercise group when compared to the group-based exercise group. This was the case for all the lower-limb muscle strength measures (Tables 9 and 14): hip flexor strength ($F(1, 118) = 6.90$, $p = .010$), knee extensor strength ($F(1, 118) = 9.95$, $p = .002$), hip abductor strength ($F(1, 118) = 7.11$, $p = .009$), and ankle dorsiflexor strength ($F(1, 118) = 5.12$, $p = .025$). In contrast to the group-based exercise group, the subjects in the individual-based exercise group showed significant improvement in lower extremity muscle strength after two months of individualized therapeutic interventions (Figure 11).

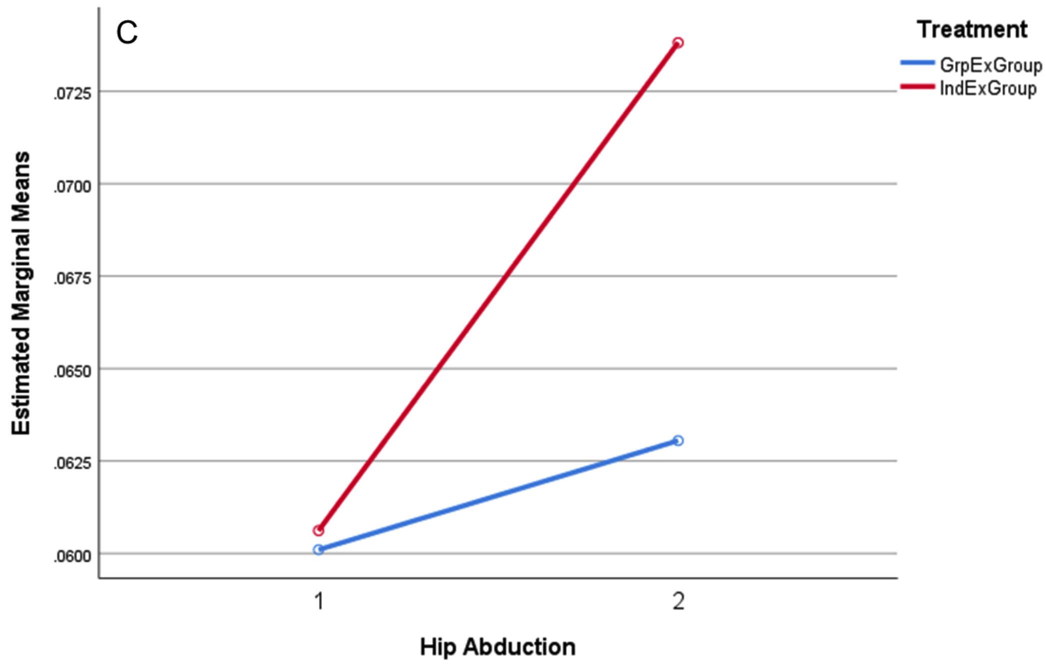
The effect size was medium for hip flexor strength (Partial Eta Squared = 0.06), medium for knee extensor strength (Partial Eta Squared = 0.08), medium for hip abductor strength (Partial Eta Squared = 0.06), and small for ankle dorsiflexor strength (Partial Eta Squared = 0.04).

Thus, there were large differences in the lower-limb muscle strength scores of the individual-based exercise group (hip flexors: M = 0.09, knee extensors: M = 0.09, hip abductors: M = 0.07, and ankle dorsiflexors: M = 0.07) compared to the group-based exercise group (hip flexors: M = 0.07, knee extensors: M = 0.08, hip abductors: M = 0.06, and ankle dorsiflexors: M = 0.06).

The main effect for the within-subjects factor was significant for hip flexors ($F(1, 118) = 238.07$, $p < .001$, Partial Eta Squared = 0.67 - large effect), knee extensors ($F(1, 118) = 147.26$, $p < .001$, Partial Eta Squared = 0.55 - large effect), hip abductors ($F(1, 118) = 241.17$, $p < .001$, Partial Eta Squared = 0.67 - large effect), and ankle dorsiflexors ($F(1, 118) = 189.50$, $p < .001$, Partial Eta Squared = 0.62 - large effect), indicating there were significant differences between the values of pre and post lower-limb muscle strength measures. These within-group gains, however, stem mainly from the individual-based group as can be seen in Figure 11.

Figure 11: Lower-Limb Muscle Strength Scores for Both Groups




C
Treatment
GrpExGroup
IndExGroup
Estimated Marginal Means
.0725
.0700
.0675
.0650
.0625
.0600
1
2
Hip Abduction

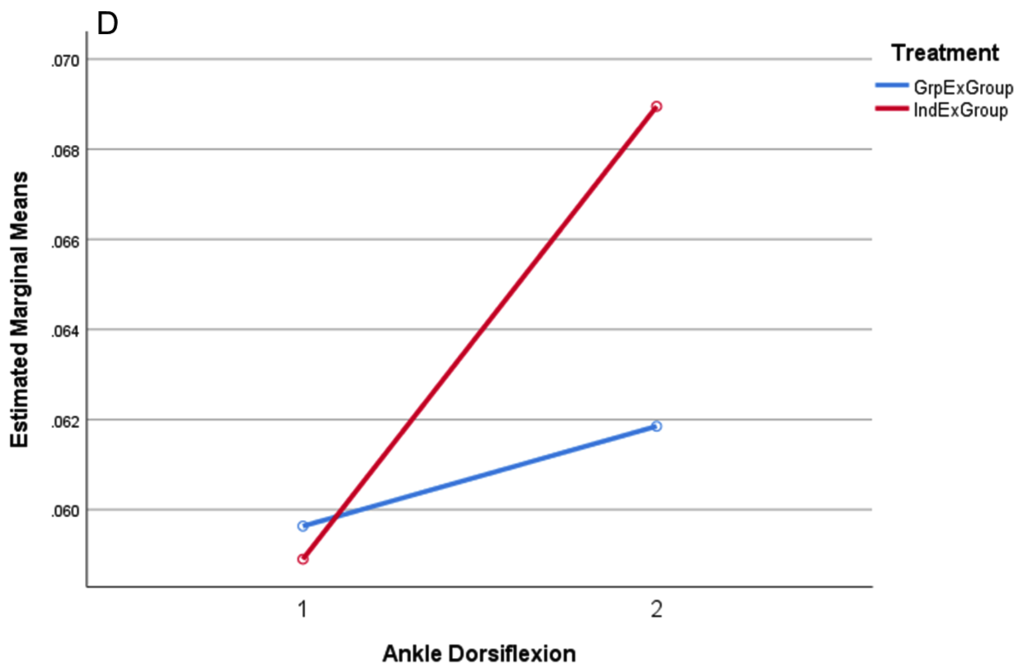

D
Treatment
GrpExGroup
IndExGroup
Estimated Marginal Means
.070
.068
.066
.064
.062
.060
1
2
Ankle Dorsiflexion

Table 14: *ANOVA Results for Treatment Group and* Lower-Limb Muscle Strength *Variables*

Hip Flexor Strength

Source	df	SS	MS	F	p	Partial Eta Squared
			Between Subjects			
Group	1	.003	.003	6.90	.010	.06
Error 1	118	.047	.000			
			Within Subjects			
Time	1	.005	.005	238.07	<.001	.67
Group x Time	1	.003	.003	177.57	<.001	.60
Error 2	118	.002	1.95			

Knee Extensor Strength

Source	df	SS	MS	F	p	Partial Eta Squared
			Between Subjects			
Group	1	.003	.003	9.95	.002	.08
Error 1	118	.033	.000			
			Within Subjects			
Time	1	.004	.004	147.26	<.001	.56
Group x Time	1	.004	.004	119.05	<.001	.50
Error 2	118	.004	3.00			

Hip Abductor Strength

Source	df	SS	MS	F	p	Partial Eta Squared
			Between Subjects			
Group	1	.002	.002	7.11	.009	.06
Error 1	118	.032	.000			
			Within Subjects			
Time	1	.004	.004	241.17	<.001	.68
Group x Time	1	.002	.002	97.15	<.001	.45
Error 2	118	.002	1.62			

Ankle Dorsiflexors Strength

Source	df	SS	MS	F	p	Partial Eta Squared
			Between Subjects			
Group	1	.001	.001	5.12	.025	.04
Error 1	118	.014	.000			
			Within Subjects			
Time	1	.002	.002	189.50	<.001	.62
Group x Time	1	.001	.001	77.27	<.001	.40
Error 2	118	.001	1.19			

Note: *p < .05, **p < .01, ***p < .001.

A large increase was observed in lower-limb muscle strength mean scores for the individual-based exercise group from pre-intervention to post-intervention, whereas the group-based exercise group had a very mild change in lower-limb muscle strength scores from pre-intervention to post-intervention (Table 9, Figure 11). The interaction effect between lower-limb muscle strength and the type of therapy was significant, indicating that subjects in the individual-based exercise group improved more over time for all tested muscle groups when compared with the group-based exercise group (Table 14, Figure 11). Specifically: hip flexors ($F(1, 118) = 177.57$, $p < .001$, Partial Eta Squared = 0.60 - large effect), knee extensors ($F(1, 118) = 119.05$, $p < .001$, Partial Eta Squared = 0.50 - large effect), hip abductors ($F(1, 118) = 97.15$, $p < .001$, Partial Eta Squared = 0.45 - large effect), and ankle dorsiflexors ($F(1, 118) = 77.27$, $p < .001$, Partial Eta Squared = 0.40 - large effect).

Modified Physical Performance Test (PPT)

According to the secondary hypothesis, a higher score on the PPT, which directly reflects a higher level of functional independence, would be observed for the individual-based exercise group. The individual-based exercise group did indeed achieve a significantly higher score on the PPT ($F(1, 118) = 14.03$, $p < .001$) compared to the group-based exercise group (Tables 9 and 15). The effect size was medium (Partial Eta Squared = 0.11) for this difference in PPT scores of the individual-based exercise group ($M = 30.50$) compared to the group-based exercise group ($M = 26.28$) after intervention.

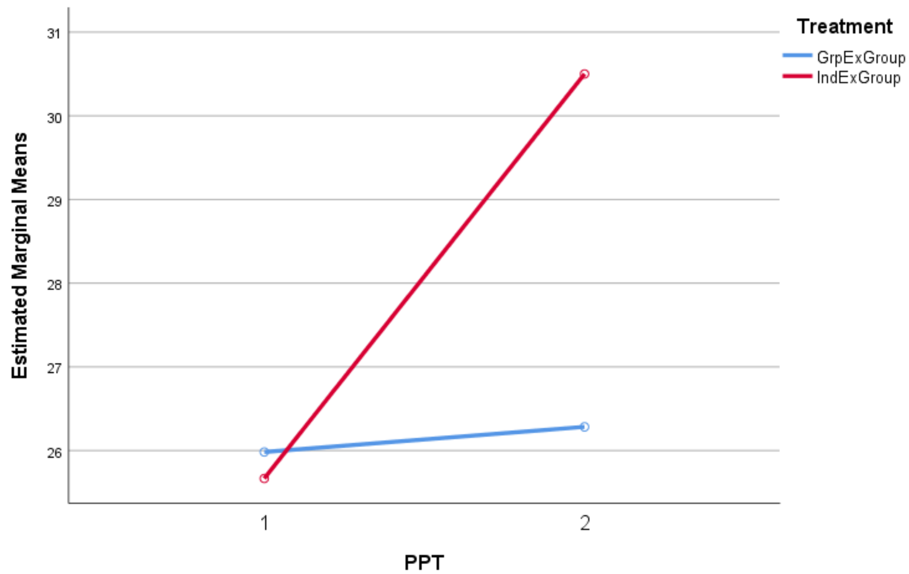
Table 15: ***ANOVA Results for Treatment Group and PPT Variables***

Source	*df*	*SS*	*MS*	*F*	*p*	*Partial Eta Squared*
			Between Subjects			
Group	1	228.15	228.15	14.03	<.001	.11
Error 1	118	1919.03	16.26			
			Within Subjects			
Time	1	395.27	395.27	309.98	<.001	.72
Group x Time	1	308.27	308.27	241.75	<.001	.67
Error 2	118	150.47	1.27			

Note: **p* < .05, ***p* < .01, ****p* < .001. PPT - Modified Physical Performance Test

The main effect for the within-subjects factor was significant $F(1, 118) = 309.98$, $p < .001$, indicating there were significant differences between the values of pre-PPT and post-PPT, and this was a large effect (Partial Eta Squared = 0.72). Overall PPT after the intervention ($M = 28.40$) were significantly higher than before the intervention ($M = 25.82$). In addition, the interaction effect between the PPT factor and the type of therapy was significant, $F(1, 118) = 241.75$, $p < .001$, and this was a large effect (Partial Eta Squared = 0.67). A large increase was observed in PPT mean scores for the individual-based exercise group from pre-intervention ($M = 25.67$) to post-intervention ($M = 30.50$), whereas the group-based exercise group had a mild change in PPT scores from pre-intervention ($M = 25.98$) to post-intervention ($M = 26.28$). Before the intervention, both the individual-based exercise group ($M = 25.67$) and the group-based exercise group ($M = 25.98$) had similar scores. However, over time, the PPT scores in the individual-based exercise group increased more ($M = 30.50$) than the group-based exercise group scores (*M* = 26.28). When compared to the group-based exercise group, the subjects in the individual-based exercise group showed significant improvement in overall functional status after eight weeks of individualized structured therapy (Figure 12).

Figure 12: Modified Physical Performance Test (PPT) for Both Groups



Gait Speed 6-Meter Comfortable Walk Test (6MCWT)

The subjects' overall functional mobility was assessed using the 6-meter comfortable walk test. The individual-based exercise group received a significantly higher score on the 6-meter comfortable walk test ($F(1, 118) = 6.50$, $p = .012$) than the group-based exercise group (Tables 9 and 16). The effect size was small (Partial Eta Squared = 0.05).

Thus, there was a small significant difference in the 6-meter comfortable walk test scores of the individual-based exercise group (*M* = 0.86) compared to the group-based exercise group (*M* = 0.78). The main effect for the within-subjects factor was significant $F(1, 118) = 599.50$, $p < .001$, indicating there were significant differences between the values of pre-6MCWT and post-6MCWT, and this was a large effect (Partial Eta Squared = 0.87). The overall 6MCWT scores after the intervention (*M* = 0.82) were significantly higher than before the intervention (*M* = 0.75).

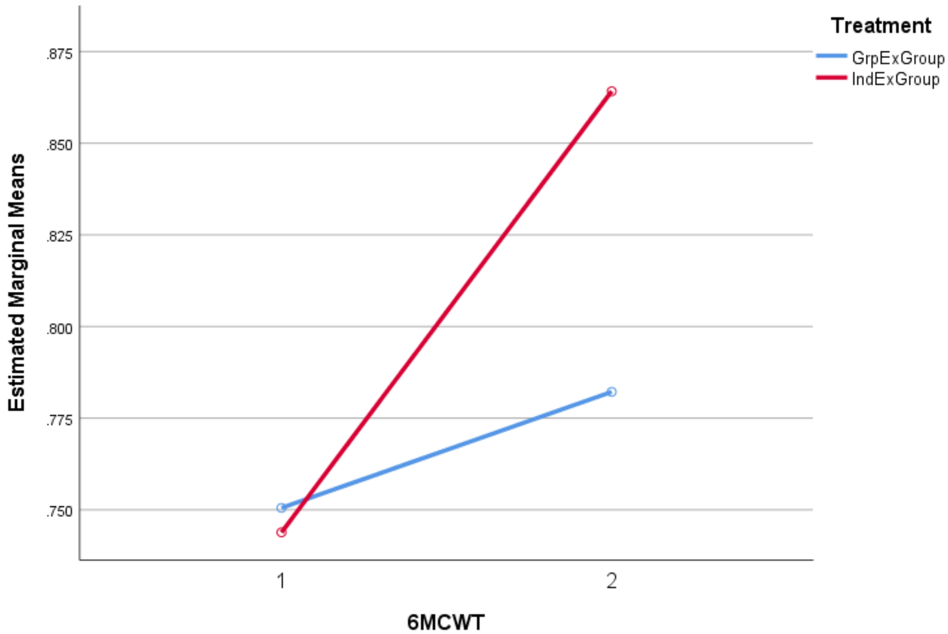
Table 16: ***ANOVA Results for Treatment Group and 6MCWT Variables***

Source	***df***	***SS***	***MS***	***F***	***p***	***Partial Eta Squared***
			Between Subjects			
Group	1	.085	.085	6.50	.012	.05
Error 1	118	1.55	.013			
			Within Subjects			
Time	1	.347	.347	599.50	<.001	.84
Group x Time	1	.118	.118	203.10	<.001	.63
Error 2	118	.068	.001			

Note: **p* < .05, ***p* < .01, ****p* < .001. 6-Meter Comfortable Walk Test (6MCWT)

In addition, the interaction effect between the 6MCWT factor and the type of therapy was significant, $F(1, 118) = 203.10$, $p < .001$, and this was a large effect (Partial Eta Squared = 0.63). When compared to the group-based exercise group, subjects in the individual-based exercise group showed significant improvement in overall gait speed after two months of individualized structured therapy (Figure 13).

Figure 13: Gait Speed 6-meter Comfortable Walk Test (6MCWT) Scores for Both Groups



A large increase was observed in 6MCWT mean scores for the individual-based exercise group from pre-intervention (*M* = 0.74) to post-intervention (*M* = 0.86), whereas the group-based exercise group had a mild change in the 6MCWT scores from pre-intervention (*M* = 0.75) to post-intervention (*M* = 0.78). Before the intervention the group-based exercise group had a slightly higher 6MCWT score (*M* = 0.75) than the individual-based exercise group (*M* = 0. 74). However, after the intervention the individual-based exercise group achieved higher 6MCWT scores (*M* = 0.86) than the group-based exercise group (*M* = 0.78).

Individual-based Exercise Group Follow-up Findings

The change over time in BioSway™ balance measures and the PPT measures for the individual-based exercise group were analyzed with separate one-way repeated measures analyses of variance (ANOVAs), using three time points as the repeated measures for each tool (pre-intervention scores, post-intervention scores, and one-month follow-up scores). The sphericity assumption was met for the limits of stability measure and violated for the postural stability, the CTSIB, and the modified physical performance test measures. Therefore, the repeated measures ANOVA for these variables were calculated using the Greenhouse-Geisser correction to adjust for the violation of the sphericity assumption.

Retention Effects

The results of the separate one-way repeated measures analyses of variance (ANOVAs) were significant for the modified physical performance test ($F(1.07, 63.22) = 487.30$, $p < .001$, $\eta_p^2 = .90$), and all the three BioSway™ balance measures (limits of stability - $F(2, 118) = 71.14$, $p < .001$, $\eta_p^2 = .55$; postural stability - $F(1.67, 98.25) = 48.04$, $p < .001$, $\eta_p^2 = .45$; and modified clinical test of sensory integration of balance - $F(1.67, 98.78) = 6.06$, $p = .005$, $\eta_p^2 = .09$). The results indicate that there were significant differences among the values of pre-intervention, post-intervention, and follow-up balance and functional performance scores (Table 17, Figure 14). The effect size was large for the PPT, the limits of stability, and the postural stability measures; and a medium effect size was noted for the CTSIB measure.

Table 17: *Repeated Measures ANOVA Results for PPT & BioSway™ Balance Scores*

Pre-LOS, Post-LOS, and Follow-up-LOS

Source	df	SS	MS	F	p	Partial Eta Squared
Within-Subjects	2	25.95	12.97	71.14	<.001	.55
Error	118	21.52	.182			

LOS – Limits of Stability

Pre-PS, Post-PS, and Follow-up-PS

Source	df	SS	MS	F	p	Partial Eta Squared
Within-Subjects	1.67	29.59	17.77	48.04	<.001	.45
Error	98.25	36.34	.370			

PS – Postural Stability

Pre-CTSIB, Post-CTSIB, and Follow-up-CTSIB

Source	df	SS	MS	F	p	Partial Eta Squared
Within-Subjects	1.67	.632	.377	6.06	.005	.09
Error	98.78	6.15	.062			

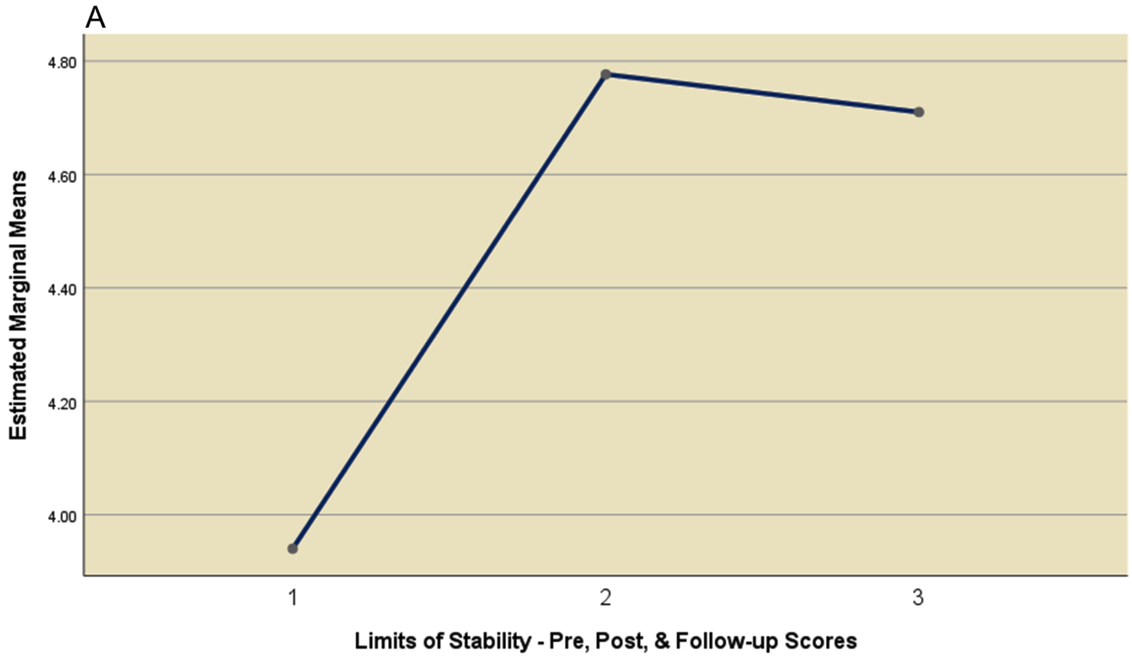
CTSIB - Modified Clinical Test of Sensory Integration of Balance

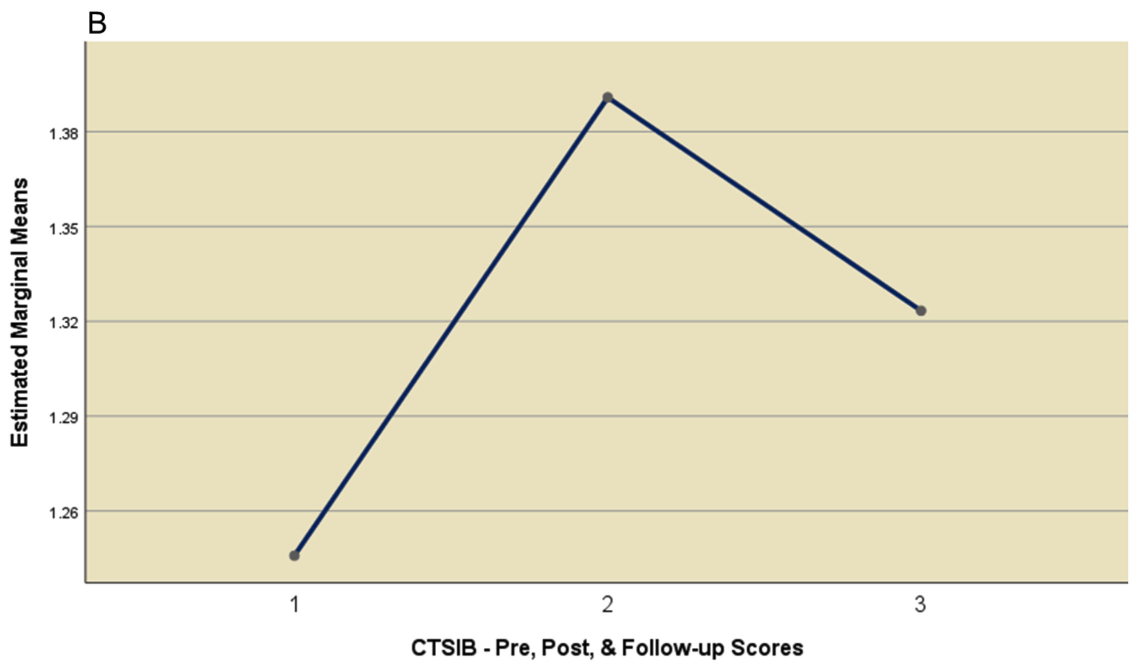
Pre-PPT, Post-PPT, and Follow-up-PPT

Source	df	SS	MS	F	p	Partial Eta Squared
Within-Subjects	1.07	921.73	860.15	487.30	<.001	.90
Error	63.22	111.60	1.76			

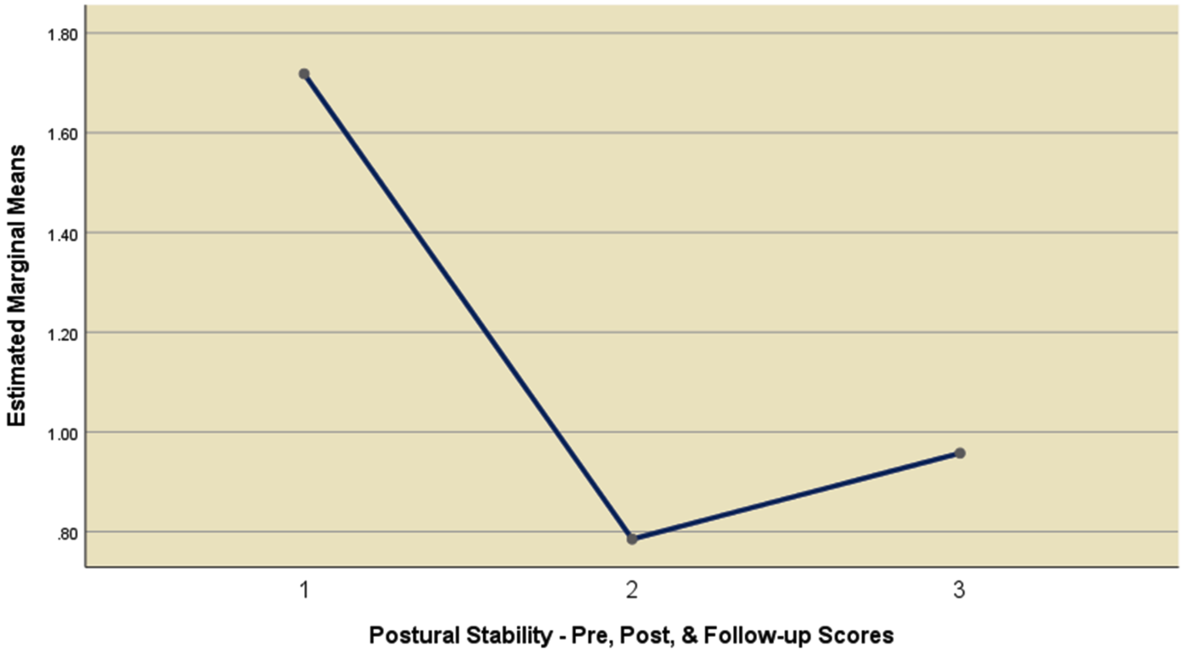
PPT - Modified Physical Performance Test

Figure 14: Individual-based Exercise Group PPT & BioSway™ Balance Scores



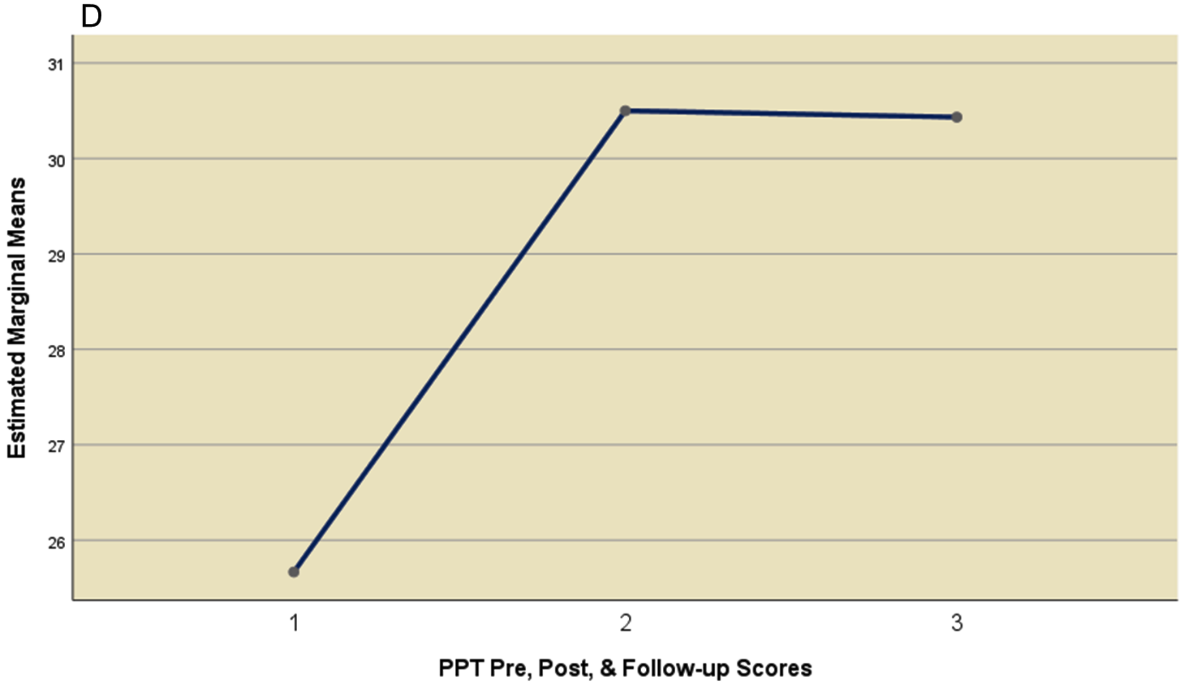


C



1.80
1.60
1.40
1.20
1.00
.80
Estimated Marginal Means
1
2
3
Postural Stability - Pre, Post, & Follow-up Scores

D



31
30
29
28
27
26
Estimated Marginal Means
1
2
3
PPT Pre, Post, & Follow-up Scores

Post-hoc Analysis

To further examine the differences among the variables, the Bonferroni method was used for post-hoc analysis (Table 18). This is a conservative way to analyze the means of pairwise comparisons. Higher physical performance and limit of stability scores represent better balance and functional performance; whereas a lower score in postural stability represents improved stability.

Limits of Stability**:** The mean value of pre-intervention limits of stability (*M* = 3.94, *SD* = 0.66) was significantly less than post-intervention limits of stability (*M* = 4.78, *SD* = 0.61) and follow-up limits of stability (*M* = 4.71, *SD* = 0.65), *p* < .001. The mean value of follow-up limits of stability (*M* = 4.71, *SD* = 0.65) was not significantly different from the post limits of stability (*M* = 4.78, *SD* = 0.61), *p* = .998*,* indicating retention of gains.

Table 18: Post-hoc Results^

Outcome Measures	Pre-Intervention	Post-Intervention	Follow-up Assessment	Pre to Post (Sig.)	Pre to Follow-up (Sig.)	Post to Follow-up (Sig.)
BioSway™ Measures						
LOS	3.94 (0.66)	4.78 (0.61)	4.71 (0.65)	*p* < .001	*p* < .001	*p* = .998
PS*	1.72 (0.84)	0.79 (0.38)	0.95 (0.50)	*p* < .001	*p* < .001	*p* = .079
mCTSIB	1.25 (0.33)	1.39 (0.21)	1.32 (0.27)	*p* = .005	*p* = .327	*p* = .109
PPT	25.67 (2.97)	30.50 (2.83)	30.43 (2.88)	*p* < .001	*p* < .001	*p* = .477

^Values are mean (SD), * Smaller value represents better performance, LOS – Limits of Stability, PS – Postural Stability, mCTSIB - Modified Clinical Test of Sensory Integration of Balance, & PPT - Modified Physical Performance Test.

Postural Stability**:** The mean value of pre-intervention postural stability (M = 1.72, SD = 0.84) was significantly greater than post-intervention postural stability (M = 0.79, SD = 0.38) and follow-up postural stability (M = 0.95, SD = 0.50), $p < .001$. The mean value of follow-up postural stability (M = 0.95, SD = 0.50) was not significantly different from the post postural stability (M = 0.79, SD = 0.38), p = 0.079, indicating retention of gains.

CTSIB**:** The mean value of pre-intervention CTSIB (M = 1.25, SD = 0.33) was significantly less than post-intervention CTSIB (M = 1.39, SD = 0.21), p = .005. The mean value of pre-CTSIB (M = 1.25, SD = 0.33) was not significantly different from the follow-up CTSIB (M = 1.32, SD = 0.27), p = .327. The mean value of follow-up CTSIB (M = 1.32, SD = 0.27) was not significantly different from the post-CTSIB (M = 1.39, SD = 0.21), p = .109, which theoretically indicates retention of gains. However, because the post-hoc results also tell us that there is no significant difference between pre and follow-up measures, but there is a difference between pre and post measures, the interpretation of the post-hoc results is problematic. Conservatively, we have to conclude that we cannot conclude retention of gains, since the pre and follow-up scores are not statistically different. Based on the uncertainty with CTSIB post-hoc values, further exploration was performed using other posthoc techniques including Sidak and Fisher's LSD. Sidak results confirmed Bonferroni findings; whereas LSD detected a difference between the pre-CTSIB and follow-up CTSIB values. Given that LSD may not properly account for multiple comparisons, and Sidak agreed with Bonferroni, the final interpretation was completed based on Bonferroni, and retention was considered inconclusive.

***PPT*:** The mean value of pre-intervention PPT (M = 25.67, SD = 2.97) was significantly less than post-intervention PPT (M = 30.50, SD = 2.83) and follow-up PPT (M = 30.43, SD = 2.88), p < .001. The mean value of follow-up PPT (M = 30.43, SD = 2.88) was not significantly different from the post-PPT (M = 30.50, SD = 2.83), p = .477, indicating retention of gains.

Summary

This study included volunteer subjects recruited from eleven different residential care facilities. Based on the eligibility criteria and preliminary balance screening, 120 subjects were identified as having mild balance dysfunction and participated in the full study. Over three-quarters of the subjects were female (79%) and they were almost equally distributed between the individual-based exercise group (50.5%), and the group-based exercise group (49.5%). The baseline characteristics were similar between the two groups. Both groups completed the eight weeks of their respective interventions and all 120 subjects were able to complete the post-assessment (ninth week). The thirteenth week follow-up assessment was completed only for the individual-based exercise group, and all 60 subjects in that group were able to complete this assessment.

When compared to the group-based exercise group, the individual-based exercise group showed significant improvement on all the primary and secondary outcome measures except the BioSway™ CTSIB balance measure. However, as per the standard score comparison, 96.7% of subjects in the individual-based group scored within one standard deviation to the reference normative data mean, that is, 21.7% more than the group-based exercise group. At the thirteenth week follow-up, the individual-based exercise group showed significant differences on the PPT and all the three BioSway™ balance repeated measures. Post-hoc analysis revealed that the post-intervention mean scores were significantly greater than the pre-intervention scores for all measures. Gains were retained at follow-up, as there were no significant differences between post and follow-up scores, with the exception of the BioSway™ CTSIB balance measure, which cannot be unequivocally concluded to have retained gains.

Chapter 5: Discussion

Introduction to the Chapter

This chapter discusses the key study findings in the context of current evidence, and the implications of the results to physical therapy practice. Limitations and delimitations of the study, clinical implications, and recommendations for future research are discussed. A summary of the study conclusion is also provided.

Main Findings of the Study

The results of this study demonstrated an overall greater improvement in balance, physical function, gait speed, and lower extremity muscle strength following individualized therapeutic interventions as compared to group based exercises. The improvement in balance and strength appears to be clinically meaningful, as it was also accompanied by significant improvements in functional performance scores. The majority of previous research has provided evidence that therapeutic exercises can improve balance and functional performance in older adults with high risk of falls, who are living in the community or in residential care facilities.[1,2,5,16] However, there is a paucity of research about individuals with mild balance dysfunction. The current study adds to existing research on mild balance dysfunction in older adults, such as the study by Yang, et al.[1] that targeted community-dwelling older people with mild balance dysfunction and evaluated the effectiveness of a home exercise intervention. To our knowledge, our study is the first one to focus on older adults living in residential care facilities with identified mild balance dysfunction, and to investigate the effectiveness of individualized therapy versus generic group-based exercises in this population.

Individuals living in residential care facilities require ongoing attention to promote health and fall prevention, as many of them seek medical assistance only after a fall and serious injury has occurred. Any functional decline in these individuals affects the degree of caregiver dependency related to functional ADLs and IADLs; and possible further institutionalization to seek high-level care.[1,7,11] Early identification and timely intervention for mild balance dysfunction is critical in this group, because it may effectively halt the progression from a mild fall risk stage to a high-risk stage, increasing the chances of possible subsequent injuries.[1,5] In addition, therapeutic exercises may have a positive impact on overall physical and mental health and functional independence related to ADLs and IADLs.[1,15] This study demonstrated that an individual-based exercise program is more effective than a generic group-based exercise program in improving balance, gait, and functional performance of older adults with mild balance dysfunction and living in residential care facilities. A critical point to make is that individual-based therapy was provided by physical therapists who are experts in movement science. In contrast, the facility activity directors or community volunteers facilitated the group exercise sessions. The results strongly suggest that individuals with mild balance dysfunction can highly benefit from a structured individualized exercise program rather than a generic group-based exercise program, along with the fact that it is important to have a physical therapist design and supervise such program. Because of the way the study was designed, the effect of physical therapy expertise and the effect of customization versus generic intervention cannot really be separated from one another, and future studies may want to explore them independently.

The effect of the individual-based intervention versus group-based intervention was assessed through primary and secondary outcome measures, which included the BioSway™ balance performance, the multi-directional reach test, the lower-limb muscle strength test, the modified physical performance test, and the 6-meter comfortable walk test. The results showed that the individual-based exercise group achieved significant improvements on all the outcome measures except the BioSway™ Clinical Test of Sensory Integration of Balance (CTSIB) measure, after eight weeks of structured therapy. The effect size was large to medium for most of these outcome measures, suggesting meaningful clinical change. Regarding the CTSIB, a high number of subjects in the individual-based group achieved CTSIB scores within one standard deviation based on the reference normative data interpretation. So even though the CTSIB measure did not show a statistically significant change from pre- to post- intervention, the trend in the change of standard scores (from within two standard deviation to within one standard deviation) was evident. This might be directly related to advanced individualized sensory and balance training. It was obvious that the individual-based exercise group showed high static standing balance, as per preferred low postural stability scores; and dynamic bilateral standing balance within the sway envelope, as per high limits of stability scores. At the thirteenth week follow-up, the individual-based exercise group maintained a significant difference on the PPT and the BioSway™ balance measures with baseline scores. In addition, gains were retained for the majority of the outcome measures at the one-month follow-up assessment. (Table 18). Any lack of retention could be related to patients not following up with prescribed home exercises and post discharge instructions.

To date, there have only been a few community and institutional-based studies that assessed older adults with mild balance dysfunction. Yang, et al.[1] utilized a combination of clinical and laboratory (NeuroCom Balance Master with long plate) measures for screening mild levels of balance impairment in elderly adults living in the community. They developed specific criteria for classifying balance performance of elderly adults as 'within normal limits" or "mild balance impairment".[1] Their study noted that laboratory force platform test measures were effective and more sensitive than clinical measures in identifying mild balance dysfunction, and they were also more responsive to intervention effects.[1] In addition, the authors provided evidence that one or more clinical test measures may be used in combination to detect early signs of balance dysfunction in older adults (sensitivity of 82%).[1]

Muir et al.[103] also reported the need for laboratory and functional tests to discriminate the performance of community-dwelling older adults functioning on the upper end of the functional spectrum. The multi-directional reach test is efficient to identify the direction of functional reach deficit, fall risk prediction, and intervention effect.[35,36] Tantisuwat, et al.[34] conducted a study on the multi-directional reach test and provided useful information regarding the assessment of postural and balance control in older adults with high intraclass correlation.

All baseline characteristics were similar between the two groups in our current study. In line with previous research findings and national data, which show that the majority of individuals living in residential care facilities are elderly women, [5,6,15,17,43,44] the study recruited more women (79%) than men (21%), and their average age was 78.3 ± 9.6 years. Based on the evidence and the necessity to use responsive balance tests to identify and categorize mild balance dysfunction, this study utilized both the BioSway™ and the multi-directional reach test measures. Subjects were classified as having mild balance dysfunction based on 3 to 5 abnormal scores on the combined BioSway™ test measures; and/or abnormal scores on the multi-directional reach test, as defined by one standard deviation below the mean scores related to normative data available for community-dwelling elderly. [34,36] All recruited subjects fulfilled at least one or both of the defined criteria for mild balance dysfunction and participated in the full study.

The BioSway™ balance unit is versatile, portable, and effective in measuring, analyzing, and interpreting balance measures along with optional retraining capabilities. This unit assessed the balance performance between the groups using the limits of stability, the postural stability, and the modified clinical test of sensory integration of balance test measures. For instance, the subjects in the individual-based group scored higher on the limits of stability test, which signifies their ability in controlled weight shifting and stability (sway) in all eight directions without loss of balance. This test is a good indicator of dynamic balance control within a normalized sway envelope.[26] Poor control, inconsistent, or increased time during the test protocol indicates further assessment for lower extremity muscle strength, proprioception, vestibular, or visual issues.[26] The postural stability test assesses the center of balance with desired minimal deviations. The individual-based therapy group showed considerable progress after the two months of structured therapeutic interventions. In addition, a one-month retention effect of the gained progress was evident as per the post-hoc results. Therefore, exercise adherence is a critical factor that can affect treatment outcomes.

The modified Clinical Test of Sensory Integration of Balance (CTSIB) test provides a generalized assessment of how well a subject can integrate various senses with respect to balance, and compensate when one or more of these senses are compromised.[26] The CTSIB is well documented in the literature as an effective test for identifying individuals with mild to severe balance problems.[26] Normal balance includes the ability to hold still in various situations depending on the activity or circumstance demands.[26] The BioSway™ unit displays the CTSIB scores in a format comparative to a selected normative database.[26] It is evident that the CTSIB mean scores changed more for the individual-based exercise group over time than the group-based therapy. After intervention, 96.7% of subjects in the individual-based exercise group were in the green zone, which is defined as within one standard deviation of the reference normative data mean. In contrast, 8.3% of subjects in the group-based exercise group showed a decline from their baseline. The fact that we did not observe statistically significant improvements despite this may be because of the CTSIB tasks are more challenging than the other two BioSway™ balance measures, as they are related to the addition of sensory perturbation in both eyes open and closed conditions.

Maintaining good balance and high physical performance scores is vital in order to reduce the risk factors for falls, and to promote functional independence and overall quality of life.[1,3] The BioSway™ balance test can replicate the modified functional reach test, especially the limits of stability test format and output variables. The Modified Physical Performance Test (PPT) component also includes gait speed testing and strength-related functional tasks. Therefore, retention of the intervention effect was assessed only with the BioSway™ balance and the Modified Physical performance Test (PPT) measures. Further, to control the overall study cost and time, the one-month follow-up assessment was completed only for the individual-based exercise group.

The multi-directional reach test is an inexpensive screening tool to measure the limits of stability in four directions. The subjects in the individual-based exercise group scored better (reached further) at the post-intervention assessment on the multi-directional reach test when compared to the subjects in the group-based exercise group (Table 9). These findings confirmed our primary hypothesis that older adults with mild balance dysfunction can benefit from a structured individual-based exercise program. The results were also in alignment with previous research studies performed in older adults with balance deficits.[1,3,5,15-17]

The limits of stability, postural stability, and multi-directional reach test measures showed statistically significant improvements in the individual-based group over time when looking at the pre-intervention, post-intervention (ninth week) and follow-up assessment (thirteenth week). However, the group-based exercise group generally demonstrated not-significant improvement and even some deterioration on the above-mentioned measures from baseline to post-intervention (Table 9). Although the CTSIB scores were not statistically significantly different between the two groups after intervention, the majority of the subjects in the individual-based exercise group demonstrated improvement by scoring within one standard deviation to the reference normative data mean (green zone – Figures 8, 9, 10). A possible explanation for this change in the primary outcome measures may relate to the specificity of individualized structured training. The exercise program was designed to specifically address mobility, stability, controlled mobility, and functional specific deficits in a manner tailored to individual patient needs. Further, it emphasized and included functional-focused customized training to maximize potential outcomes. As previously discussed, the expertise of the physical therapist most likely played an additional role in optimizing the intervention.

Lower extremity muscle strength is an active factor, which directly influences a subject's functional mobility and independence.[89,90] Computerized dynamometers are sophisticated enough to provide valuable, accurate, reliable, and objective muscle strength measurements. Hand-held portable dynamometers are low cost and suitable alternatives to isokinetic dynamometers, and they are a reliable and valid tool with low ceiling effects for community-dwelling older adults.[29,49,91] Lower-limb muscle strength scores were measured on both sides, however, the weaker side's scores were considered for analysis after divided by the subject's weight.[1,90] The subjects in the individual-based exercise group scored significantly higher on all four lower-limb muscle strength outcomes relative to the group-based exercise group. This result further confirmed previous evidence that an increase in muscle strength can ideally translate into a significant improvement in functional activities.[49]

Gait speed is a vital functional outcome that directly correlates with an individual's muscle strength, power, balance ability, fall risk prediction, assessment of living situations, functional mobility, and therapy considerations. [5,75] Structured strengthening exercises and balance training can improve an individual's gait speed and functional performance. When compared to the group-based exercise group, subjects in the individual-based exercise group significantly improved their performance in the six-meter comfortable walk test after the intervention.

Brown, et al.[72] provided gait speed interpretation (Table 2) and established functional categories for older adults living in the community based on their gait speed. Subjects in the current study had a baseline gait speed score of 0.74 ± 0.07 m/s (individual-based exercise group) and 0.75 ± 0.09 m/s (group-based exercise group) at pre-intervention, which would categorize them as "limited community ambulators." This functional status was not significantly improved in the group-based exercise group; however, the individualized exercise group showed significant improvement after intervention and their status progressed to the "safe community ambulators" category (52 subjects – 86.7%). Based on the study results of Hardy, et al.,[69] even a gain of 0.1 m/s in gait speed is a predictor of meaningful functional improvement. The group-based exercise group showed 0.3 m/s improvement from baseline scores, so there was still a benefit from exercising in this setting. In addition to participating in the facility-offered group exercise program, 18 subjects (30%) in the group-based exercise group reported performing regular walking and recumbent bicycle use. The mild progression of gait scores in this group might be related to their activity adherence, which translated into mild functional improvements.

Performance-based functional assessments are critical to properly evaluate balance, systemic movement, and functional deficits in older adults.[31,32] The modified physical performance test is comprised of physical and functional domains, which mimic the commonly performed activities of daily living. This is a valid tool useful in fall risk prediction and functional limitations assessment.[31,86] The components of the physical performance test are helpful to determine and develop customized plans of care and goals, so that clinicians can focus on interventions that specifically address functional deficits. The 9-item version of the physical performance test was used in this study. At post-intervention, subjects in the individual-based exercise group showed significantly higher physical performance test scores compared to baseline. In contrast, the group-based exercise group was not significantly improved from baseline. At the thirteenth week follow-up assessment, the individual-based exercise group showed a slight decline from their post-assessment scores, but it was not statistically significant. When compared to other self-reported tests, this physical performance test is valid, reliable, and less frequently reaches a ceiling effect.[31,32] Brown et al[88] provided a "frailty classification" based on the physical performance test scores. According to that classification, for the individualized group in the current study at baseline, 17 of the subjects (28.3%) were considered "moderate frail"; 42 subjects (70%) "mild frail"; and 1 subject (1.67%) as "non-frail". However, at post intervention the individualized therapy group showed significant progress (26 subjects (43.3%) - "non-frail" and 34 subjects (56.7%) - "mild frail"), maintaining the same classification at the 13-week follow-up assessment. In contrast, for the group-based exercise group at baseline, 18 subjects (30%) were considered "moderate frail" and 42 subjects (70%) "mild frail"; but there was no noticeable progress at post-intervention (17 subjects (28.3%) - "moderate frail" and 43 subjects (71.7%) - "mild frail").

The primary investigator performed identical screening and testing at different points between the two groups. The secondary investigators were trained and blinded to the baseline assessment values to minimize confounding variables and to improve validity. The primary investigator collected and reviewed information about group exercise programs in all participating facilities. Fall data was obtained from facility directors at the end of primary data collection (9 weeks). All subjects in the group-based exercise group received a fall prevention information booklet and an activity log. The subjects expressed complete gratitude and displayed positive feedback regarding the information booklet; and they even requested permission to reproduce it.

The group-based exercise group maintained an activity log of exercises and walking activities that they performed during the 8 weeks. Fifty-five subjects (91.6%) returned the log sheet and five subjects did not complete the log, even though they participated in the group exercises. This information was collected and confirmed from the facility records. Eleven subjects in the group-based exercise were compliant with regular walking inside the facility for 15 to 25 minutes, two or three times per week. Seven other subjects regularly used a recumbent bicycle, mild intensity, 15 to 20 minutes, once or twice per week. In the individual-based group, six subjects reported walking on the facility hallways, 15 to 20 minutes, twice per week and two other subjects used a recumbent bike for 15 minutes, once per week. The rest of the subjects in both groups did not perform any other specific exercise activities, except as part of the study interventions.

At baseline, six subjects had reported a fall within last three months. During randomization, four of those subjects were assigned to the individual-based exercise group, and two to the group-based exercise group. However, at post-intervention, no falls were reported in the individual-based group and four subjects reported a fall in the exercise-based group. All those falls occurred at nighttime and were isolated incidents inside their facility rooms/apartments; they did not occur during the group exercise sessions. As per the facility incident reports, one fall was related to poor illumination in the bathroom, two falls were related to not using the recommended assistive device at night, and another one was related to a cluttered environment.

The group-based exercises organized by the directors were mainly comprised of chair-based sitting and standing general balance, strengthening, and motion exercises. The facilities used video-based “Sit and be Fit” and “Stronger Seniors - Balance and Posture” core fitness, stretching, balance, standing yoga, and strengthening exercise programs. The secondary investigators (physical therapists) performed a detailed evaluation and assessment of all the subjects assigned to them. The physical therapists identified and addressed individual-specific physical and functional limitations. They developed a patient-centered plan of care and established goals that targeted mobility, stability, controlled mobility, and functional deficits. They further utilized the general treatment protocol manual for reference, exercise prescription, and progression. In this study, the group-based group received a specialized fall prevention booklet. A fall prevention booklet was provided only to the group-based group and not to the individual-based group. This was mainly intended to reproduce common clinical practice, where clients receiving one-on-one physical therapy intervention would get that information as part of their patient education protocol. It is interesting to note that, despite this advanced educational material, the group-based group was the only one that had reported falls during the study.

Clinical Implications and Recommendations

The findings from this study suggest that early identification of mild balance dysfunction in older adults living in residential care facilities can lead to effective and timely interventions. More importantly, individualized therapeutic assessment and targeted interventions are more effective than a generic approach in addressing balance problems, and can impact balance issues when they are still mild and reversible. Results from the individual-based therapy group demonstrate that physical performance scores, gait speed, lower extremity muscle strength, balance measures, and multi-directional reach components were improved significantly after two months of structured therapy provided by physical therapists in the subject's living environment at the residential care facility. The group-based exercise group, whose sessions were not led by physical therapists, did not show as much improvement. In summary, the subjects who participated in individualized exercise supervised by a physical therapist significantly enhanced their functional ability compared to those who participated in a generic exercise program.

Overall, therapeutic exercises provide a wide range of health benefits at any age, but we have shown that they can be applied successfully to address mild balance dysfunction with a customized approach. Very few studies have previously explored mild balance dysfunction in older adults;[1,5,16,17] and this study is the first of its kind to focus on mild balance dysfunction among individuals living in residential care facilities. The presence of mild balance dysfunction in this subgroup of individuals might not be noticed or identified until they have a fall or injury and seek expert consultation. An important take-away message is that balance screening upon admission into residential care facilities should be done routinely, as it will assist in identifying balance dysfunction when it is in its early stages, and still potentially reversible and manageable. If mild balance dysfunction is identified during admission, then residents can easily coordinate with their primary care physicians for possible referral to physical therapy. The facility medical staff can also assist in directing the identified subjects to appropriate referral sources. Ideally, a routine physical therapy evaluation upon admission would be an excellent approach to identifying balance issues. The need to prevent the progression of mild balance dysfunction to moderate or severe levels is critical for improved patient outcomes, and physical therapists can play a key role in the process of timely identification and management of balance dysfunction.

It may seem obvious to expect that an individualized treatment with a physical therapist would outperform a group-based generic intervention that is not supervised by a physical therapist; however, there has been no published research on this specific population living in residential care facilities with mild balance dysfunction. In addition, the positive reinforcement effects of being in a group may have some potential benefits[6,17], so it is not such an obvious assumption to say that the individualized group would be better than the group-based group. Therefore, this study is important in providing evidence for individualized physical therapy in this population. The individual-based exercise group's treatment protocol, scheduling, and patient management followed the general Medicare home health care reimbursement guidelines. This alignment with Medicare guidelines may assist with replication and feasibility of the treatment protocol in a home health care setting.

Individuals living in residential care facilities may not always want to be “labeled” as having balance dysfunction, even if mild, as this would signify admitting decline in their overall function, loss of functional independence, or could imply the need for more supervised care and possible change to a more controlled living environment. Therefore, it is vital to increase awareness among older adults regarding the importance of early screening and identification of balance disorders; and of seeking professional physical therapy care when the problem is mild and easily reversible with timely interventions.

This study utilized both the computerized BioSway™ balance test and clinical measures to identify mild balance dysfunction. Most of the simple clinical balance measures are not responsive enough to measure small progress or deterioration in a subject’s ability to balance, due to ceiling effects and variation in reliability.[63,79] Therefore, considering a combination of both clinical and computerized balance measures is usually a good option.[1] Research in the area of further validation and simplified classification of mild balance dysfunction category in high-functioning older adults is needed. In particular, an ideal test should be accurate, portable, convenient, and cost-effective so that it can be used in multiple settings. The use of force platform units in the community and home settings is cumbersome and not readily available.[1,80] The BioSway™ unit from Biodex Medical Systems is a good alternative that is reliable, portable, and versatile to use in any setting.[26] However, it can be difficult to afford such equipment in some community and home health care settings. Therefore, further studies need to evaluate the effectiveness of clinical balance assessment tools, and perhaps enhance their measurement robustness versus expensive computerized units.

The current study results also suggest that the multi-directional reach test alone can detect and identify early signs of balance dysfunction in older adults. The multi-directional reach test appears to be effective in distinguishing intervention effects.[1,34] Further, the research works of Yang, et al.[1] and Tantisuwat, et al.[34]; provide evidence that the functional reach test and the multi-directional reach test did not produce any ceiling effects when used in elderly people at high functioning levels. A detailed correlation study is warranted in this area to explore the diagnostic capabilities of clinical balance measures versus computerized balance measures in high-functioning older adults with mild balance dysfunction. A potential expansion from the current study is to explore collected data for correlation between the multi-directional reach test and the BioSway™ balance scores in identifying mild balance dysfunction in older adults living in residential care facilities. As a preventive post discharge measure, it was recommended that all subjects continue with their prescribed home exercises in order to avoid any potential functional and balance decline.

Future studies aiming to evaluate the long-term retention effects of therapeutic intervention in mild balance dysfunction can be carried out in a longitudinal manner using all the primary and secondary outcome measures from the current study, including the BioSway™ balance performance, the multi-directional reach test, the lower-limb muscle strength test, the modified physical performance test, and the 6-meter comfortable walk test. Ideally, longer follow-up periods (such as one month, three months, and six months) would help explore the longer-term impact of balance interventions in this population. In addition, future research should also assess the benefits of periodic assessments at earlier times such as at 5 or 6 weeks (enough for neuroplasticity) to monitor whether the subjects reach a plateau prior to 8 weeks.

During the study, only four falls were reported in the group-based exercise group (based on retrospective recall) and none in the individual-based exercise group. Fall history information was re-confirmed with facility records. This study was not aimed at assessing or monitoring falls, or at measuring the subjects' perception of improvement. Future studies should evaluate the effectiveness of individual-based and group-based exercise programs in reducing falls, as well as the perceived effect of the intervention using tools such as the Activities-Specific Balance Confidence scale (ABC) in older adults with mild balance dysfunction and living in residential care facilities.

Limitations and Delimitations

This study used ANOVA statistical models for testing all the primary and secondary outcome variables. The main limitation of this study was that the Levene's test of homogeneity of variance was violated for post-intervention postural stability, post-intervention hip flexion, and post-intervention knee extension measurement variables.

Initial data inspection revealed that a few subjects scored high on the postural stability, hip flexion, and knee extension measures. The presence of a few high level scores in the data caused this deviation from normality. Therefore, normality was evaluated through visual inspection of frequency histogram and quantile-quantile plot of the residuals. All the three post-intervention variables appeared relatively normal, and therefore an F-test was used, as it remains a valid statistical procedure for large sample sizes and equal groups. The ANOVA procedure is quite robust against deviations from normality, provided that sample sizes are large and equal as discussed by Harwell et al.[116] A recent study report by Blanca et al.[117] confirms the same statement, reporting that the F-test which is the foundation of the ANOVA procedure remains a valid statistical procedure under non-normality in a variety of conditions. Blanca et al also noted that data transformations often cause difficulty in the interpretation of results, while offering no additional benefits over the good control of Type I error achieved by the F-test.[117] There are also disadvantages in choosing non-parametric methods such as the Kruskal-Wallis test, as it converts quantitative continuous data into rank-ordered data, with a consequent loss of information.[117] However, readers may exercise some caution when interpreting and generalizing the postural stability, hip flexion, and knee extension results.

A further limitation was that the study subjects were volunteers from residential care facilities located in urban cities; this may limit the generalizability of the findings to other settings and populations. In addition, all the study subjects received physical therapy for 1 or 2 times per week for 8 weeks provided by an experienced physical therapist. An individualized high level of care is vital in achieving stipulated balance goals, and such a large amount of visits may not always be feasible in other settings such as outpatient, due to insurance coverage limitations and soaring copayments.

Therefore, further explorations of how to translate the current findings into different settings and treatment approaches, particularly in the areas of treatment type and duration, may provide new insight.

During the pre-assessment session, all the study subjects were encouraged not to discuss with other residents any information related to their participation in the study and their exercise programs, in an effort to limit diffusion. In addition, the secondary investigators reiterated this recommendation at every visit to the individual-based therapy group. Despite this recommendation, blinding was compromised slightly as two subjects discussed their exercise program and asked some questions to the primary investigator during post-assessment (ninth week). In community/field or institutional-based research, strict controls of subject interaction, blinding, and stringent research processes are more difficult to execute. Group diffusion due to possible subject interaction inside the facilities is potentially unavoidable. Despite repeated instructions to the subjects and strict study guidelines, social effects could not be controlled completely. This adverse interaction effect can be potentially avoidable in some controlled laboratory settings; or by selecting one residential care facility for individual-based group and another facility for group-based group, in random order. However, this could also introduce extraneous factors that were facility-related.

During the study period, the subject's medical, personal, family, or financial condition could have changed; this could possibly have triggered relocation, and inability to continue in the study. To address these issues, an intention to treat analysis was planned. During the one-month follow-up assessment, two subjects in the individual-based therapy group were moved to a new residential facility and another one relocated to a nearby city. However, the facility directors were helpful enough and contacted them; and those three subjects made a special trip back to their old facilities for study completion.

Subject adherence to a home exercise program is a commonplace concern in research and clinical practice and could not be completely controlled, although reasonable attempts were made to improve and assess compliance. The secondary investigators provided home exercise booklets to all the subjects in the individual-based exercise group; and subjects were requested to maintain activity logs. An additional limitation is that no effort was made to have the different facilities offer substantially similar group exercise programs, as it would not have been practical or accepted by the facilities. However, a review of the exercise programs indicated that they were no major differences between the programs that could introduce significant confounding factors, as most of these programs are created around basic generic exercises to address endurance, flexibility, strength, and balance.

Additional studies could compare the effects of a structured group exercise program with a control group with or without specific interventions. This may provide some interesting insights of community-based preventive care and cost-effective group therapy. The follow-up assessment was limited to the individual-based exercise group to reduce field costs and manage time. Despite the improvement in subject performance and short-term retention of gains in the individualized group, the level of long-term retention effect is unknown and it will require further study. It would also be useful to explore short and long-term retention effects in the group-based exercise group in future studies.

An important consideration is that individual therapy is not always available or affordable, as some people have no medical insurance, high copayments, or insurance coverage limitations (particularly in managed care plans which tightly limit the number of visits that are authorized). Another limitation is that most physicians are not familiar with balance treatment, and may not be likely to prescribe therapy for it, especially when symptoms are mild. As a profession, we need to intercede for subjects who need physical therapy at an early stage for preventive care but are not receiving it.

Physical therapy as a profession should leverage direct access to its full potential, overcome objections, and emphasize the need to primary care physicians. It is important to utilize objective data to support the benefits of ancillary physical therapy care in mild balance dysfunction. Augmenting the evidence base for physical therapy intervention in this area of mild balance dysfunction will not only help in persuading physicians, but is also important in getting insurance companies to decrease coverage barriers and copayments for preventive based physical therapy care in this population. This research supports the necessity of early diagnosis of mild balance dysfunction when it is mild and reversible, and it further signifies the need for structured, individualized, and timely therapeutic care.

Summary

The primary purpose of this study was to examine the effects of an individualized exercise program in improving balance performance in comparison to a generic group-based exercise program, in a sample of older adults with identified mild balance dysfunction and living in residential care facilities. The secondary purpose was to examine the benefits of an individualized exercise program in comparison to a generic-based exercise program in improving functional scores, lower extremity muscle strength, and gait performance in the same population.

Balance assessment using the advanced BioSway^{TM} balance unit and the multi-directional reach test found that many individuals living in residential care facilities had mild un-identified balance problems, even though the residents had no awareness of this existing serious problem. This demonstrates the necessity for the inclusion of a comprehensive balance assessment in the admission checklist of residential care facilities, ideally administered by a physical therapist. Residential care facilities should implement this screening protocol at new resident admissions, and periodically thereafter to promote preventive care. Exercise adherence was good in both groups and there were no dropouts.

All the primary and secondary hypotheses of the study were confirmed with statistically significant improvements for the individual-based exercise group compared to the group-based exercise group. Limits of stability and postural stability improved significantly as measured with the BioSway^{TM} computerized balance unit.

The computerized test of sensory integration of balance was not found to be significantly different between groups after treatment as per the balance score; however, the standardized report interpretation shows considerable progress in the individual-based therapy group. Statistically significant improvements were found on the multi-directional reach test measurement scores in all directions, and on the overall post physical performance tests in the individual-based exercise group, which may be linked to corresponding improvements seen in lower-limb muscle strength and gait speed after structured therapeutic interventions.

Conclusion

Individualized physical therapy, provided in the subjects' living environment for 8 weeks, resulted in improved balance performance, functional reach, physical performance, gait speed, and lower-limb muscle strength, with statistically significant differences when compared to a generic group exercise approach. All the tested post-intervention outcome measures showed progression and significant changes in the individual-based exercise group as compared to the group-based exercise group. The individual-based exercise group also retained some of the gained improvement for one-month after the end of treatment. Findings suggest that structured individual-based therapy can result in positive change in overall functional and balance status. Further studies are needed to determine if individual-based structured therapy can prevent mild balance symptoms from progressing toward moderate and high fall risk levels.

There is a need for standardized, simple, and robust testing tools and criteria to identify mild balance dysfunction in high-functioning individuals living in residential care facilities. Examining and treating subjects in their own living environment is challenging, however, it has a positive impact on functional progress, retention effect, and adherence rate.

In conclusion, an individualized structured therapeutic intervention is superior to a generic group-based approach, as it significantly improved balance (static and dynamic), physical performance, muscle strength, and gait speed measures in older adults with identified mild balance dysfunction and living in residential care facilities. This study provides additional evidence on the assessment of mild balance dysfunction and potentially effective clinical approaches in managing mild balance dysfunction in older adults.

APPENDIX A

Data Collection Form

NSU – Clinical Balance Study

(Data Collection Form)

Date:

Name: ID Code:

Sex: M / F DOB:

Race/Ethnicity: White/Black or African American/Asian/American Indian & Alaska Native/ Native Hawaiian & Other Pacific Islander/Hispanic or Latino

Diagnosis/ PMH:

Contact:

Facility…………………………………………… DPOA:……………………

Phone……………………………………………..

Physician Details:

Height:

Weight:

Comments:

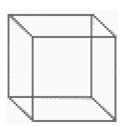
MDRT	Pre	Post
Forward Reach:		
Backward Reach:		
Right Lateral Reach:		
Left Lateral Reach:		

APPENDIX B

Short Test of Mental Status (STMS)

Short Test of Mental Status (STMS)

"I would now like to examine your memory and related items. Please relax, pay attention to the questions I am asking, and answer them as best as you can."

1.	**Orientation (8)**	Name, address, current location (building), city, state, date (day), month, year	
2.	**Attention (7)**	Digit span (present 1/sec; record longest correct span) 2-9-6-8-3, 5-7-1-9-4-6, 2-1-5-9-3-6-2	
3.	**Immediate recall (4)**	Four unrelated words: "apple," "Mr. Johnson," "charity," "tunnel." Number of trials needed to learn all four:	
4.	**Calculation (4)**	5 x 13; 65 - 7; 58/2; 29 + 11	
5.	**Abstraction (3)**	Similarities: orange/banana, dog/horse, table/bookcase	
6.	**Construction (2)** **Copy (2)**	Draw clock face showing 11:15 	
7.	**Information (4)**	President; first President; define an island; number of weeks per year	
8.	**Recall (4)**	The four words: "apple," "Mr. Johnson," "charity," "tunnel"	
	Total Score: (38)	[Raw Score - (number of learning trials - 1)]	

Instructions for Administration and Scoring of the Short Test of Mental Status (STMS)

Orientation: Each correct response is worth 1 point. The maximum score is 8.

Attention: Usually a span of five digits is given to the subject. If the subject responds correctly, the span is increased to six and then to seven. The subject's best performance is then recorded. If the subject is able to repeat seven digits forward, the test is terminated. The number of digits correctly repeated is the score; the maximal score is 7, and the minimal score is 0.

Immediate Recall: If the subject learns the words on the first trial, then the next subtest is given. If the subject is unable to learn all four words, the investigator repeats them for a maximum of 4 trials and records the number of trials that the subject requires to learn all 4 words. If the subject is unable to learn all four words by the end of the fourth trial, the subject's best performance is recorded (the number of words learned and the number of trials required). Learning is scored in two parts. A point is earned for each word learned (a maximum of 4 points). One less than the number of trials (a maximum of 4) required to learn the words was subtracted from the score. Thus, the values that were subtracted were between 0 and 3.

Calculation Each correct answer earns 1 point, and the maximal score is 4.

Abstraction: One point for each word pair is given only for definitely abstract interpretations (for example, horse/dog = animal). Concrete interpretations or inability to see a similarity earns 0 points for that word pair. The maximal score is 3.

Construction and Copying: The subject is able to view the diagram of a cube while drawing his or her own version. For each construction, an adequate conceptual drawing is scored as 2, a less than complete drawing earns a score of 1, and inability to perform the task earns a score of 0. The maximum score for the construction tasks is 4.

Information: Each correct answer earns 1 point, and the maximal score is 4.

Recall: At the end of the test, the subject is asked to recall the four words from the immediate recall subtest. No cues or reminders are provided. The subject earns 1 point for each word recalled, and the maximal score is 4.

Total Score: Total score = sum of subtest scores minus (number of trials for acquisition minus 1). For example, if a subject learned all four words on the first trial, nothing was subtracted from the sum of the subtest scores. If a subject required four trials to learn some or all four words, then 3 was subtracted from the sum of the subtest scores.

APPENDIX C

Modified Physical Performance Test (PPT)

Modified Physical Performance Test

Name/ Code:
Date:

	Test Items		Time	Scoring	Score
1.	**Write a sentence** (Whales live in the blue ocean)	Seconds		≤ 10 sec = 4 10.5-15 sec = 3 15.5 – 20 sec = 2 >20 sec = 1 unable = 0	
2.	**Simulated eating**	Seconds		≤ 10 sec = 4 10.5-15 sec = 3 15.5 – 20 sec = 2 >20 sec = 1 unable = 0	
3.	**Lift a book and put it on a shelf** Book: 7 lbs Bed/ chair height: 23 inches Shelf height: 12 inches above shoulder level.	Seconds		≤ 2 sec = 4 2.5- 4 sec = 3 4.5 – 6 sec = 2 > 6 sec = 1 unable = 0	
4.	**Put on and remove a jacket** In Standing Use a bathrobe; button down shirt; lab coat.	Seconds		≤ 10 sec = 4 10.5-15 sec = 3 15.5 – 20 sec = 2 >20 sec = 1 unable = 0	
5.	**Pick up a penny from floor** Located at 12 inches in front of the foot	Seconds		≤ 2 sec = 4 2.5- 4 sec = 3 4.5 – 6 sec = 2 > 6 sec = 1 unable = 0	
6.	**Turn 360 degrees** Turn clockwise and counterclockwise			Discontinuous steps = 0 Continuous steps = 2 Unsteady (grabs, staggers) = 0 Steady = 2	
7.	**50-foot walk test** Start with sitting for instructions and then proceed to walk.	Seconds		≤ 15 sec = 4 15.5- 20 sec = 3 20.5 – 25 sec = 2 >25 sec = 1 unable = 0	
8.	**Chair rise** Chair height: 16 inches Stand fully & sit down: 5 times No hands use	Seconds		≤ 5 sec = 4 5.5- 10 sec = 3 10.5 – 15 sec = 2 >15 sec = 1 unable = 0	
9.	**Progressive Romberg test** Feet together Semi-tandem (All max 10 sec) Full tandem			Feet together 10 sec = 1 <10 sec = 0 Semi-tandem 10 sec = 1 <10 sec = 0 Full tandem 10 sec = 2 3 to 9.99 sec = 1 <3 sec = 0	

(*Round time measurements to nearest 0.5 seconds)

Total Score (9-item): /36

(Pre/Post/Follow-up)
Comments: Tester Initials:

APPENDIX D

Gait Speed - Comfortable Walk Test (6MCWT)

<u>Gait Speed - Comfortable Walk Test (6MCWT)</u>

Name/ ID Code:

Date:

Test Protocol: Measure and mark a standard distance – 6 meters (19.6 feet).

Then measure and mark 2 m before the start, and 2 m after the end.

Mark the start point and the finish point.

2 meters	**6 meters (19.6 feet)**	**2 meters**
← **Start Line**	← **Begin Timing ……………………Stop Timing** →	**Finish Line** →

Instructions: "Walk at a comfortable pace"

Subject's performance: _________ seconds

Gait Speed = **___meters / __ sec**

(Pre/Post)

Comments:

Tester Initials:

APPENDIX E

Lower-Limb Muscle Strength Testing

(Hand-held Dynamometry)

Lower-Limb Muscle Strength Testing
(Hand-Held Dynamometry)

Name/ ID Code:

Muscle Group		Trial 1		Trial 2		Trial 3	
		Pre R L	Post R L	Pre R L	Post R L	Pre R L	Post R L
1)	**Hip Flexors**						
2)	**Knee Extensors**						
3)	**Hip Abductors**						
4)	**Ankle Dorsiflexors**						

Date:

Tester Initials:

APPENDIX F

BioSway^{TM} – Limits of Stability Test Result

Limit of Stability Test Results

NSU - Clinical Study

PATIENT/ TEST INFORMATION

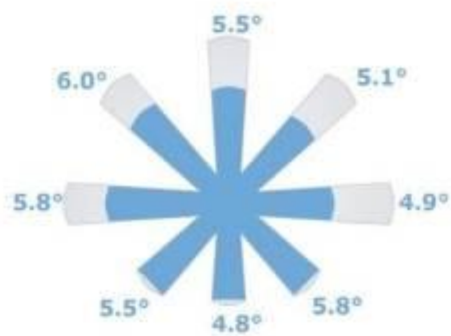
Patient Name	: [redacted]	**Test Date/Time**	: 11/4/2017 4:25:42 PM	**Platform Setting**	: Static
Patient ID	:	**Device**	:	**Test Trials**	: 2
Age	: 65			**Cursor**	: On
Weight (lbs)	: 195			**Pattern**	: Full
Height (ft,in)	: 5'-4"			**CPT Code**	: NONE
Gender	: Female			**ICD Code**	:

FOOT PLACEMENT		LEFT	RIGHT
Foot Angle	:	10	10
Heel Position	:	D6	D16

TEST RESULTS

Direction	Angle (°)	% of Standard
Forward	5.5°	68
Forward/Right	5.1°	64
Right	4.9°	62
Backward/Right	5.8°	96
Backward	4.8°	120
Backward Left	5.5°	92
Left	5.8°	73
Forward Left	6.0°	75
Composite Score (Avg.)	**5.4°**	**68**

0 25 50 75 100 125



COMMENTS

CLINICIAN ______________________

Software Version: 4.0.01 Printed on 11/4/2017

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APPENDIX G

BioSway^{TM} – Postural Stability Test Result

Postural Stability Test Results

NSU - Clinical Study

PATIENT/ TEST INFORMATION

Patient Name	: [redacted]	Test Date/Time	: 11/4/2017 4:16:57 PM		Platform Setting	: Static
Patient ID	:	Device	: Biosway		Test Trial Time	: 00:20
Age	: 65				Test Trials	: 3
Weight (lbs)	: 195	FOOT PLACEMENT	LEFT	RIGHT	Cursor	: On
Height (ft,in)	: 5'-4"	Foot Angle :	10	10	CPT Code	: NONE
Gender	: Female	Heel Position :	D6	D16	ICD Code	:

TEST RESULTS

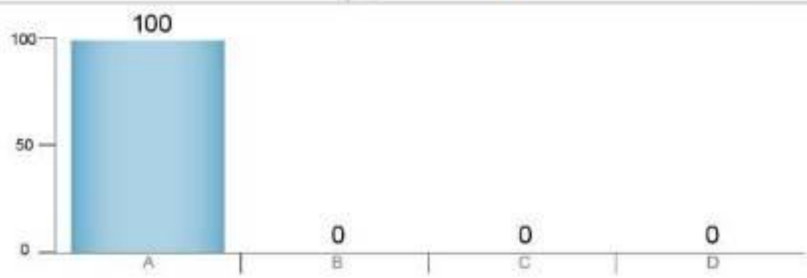
All Trials

Direction	Stability Index	Sway Index
Overall	0.31	0.31
Forward/Backward	0.17	0.23
Left/Right	0.21	0.21

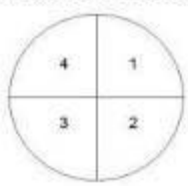
Final Trial

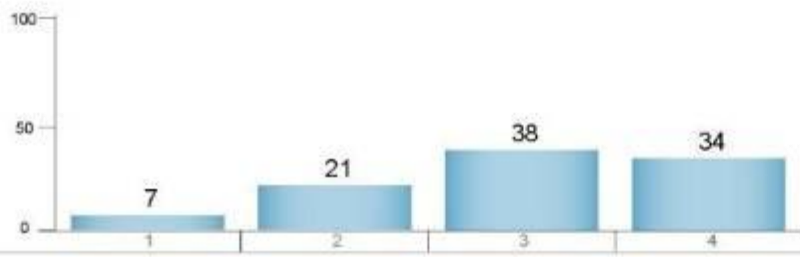
Legend: ● Average Position — Tracing

% Time In Zone



% Time In Quadrant





COMMENTS

CLINICIAN

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APPENDIX H

BioSway^{TM} – Clinical Test of Sensory Integration of Balance Test Result

CTSIB Test Results

NSU - Clinical Study

Clinical Test of Sensory Integration of Balance

PATIENT/ TEST INFORMATION

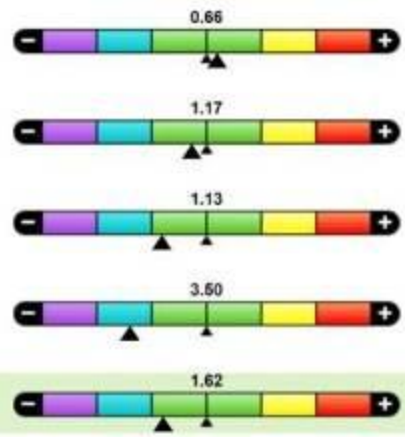
Patient Name	: [redacted]	**Test Date/Time**	: 11/4/2017 4:21:02 PM	**Conditions**	: Modified
Patient ID	:	**Device**	: Biosway	**Test Trial Time**	: 00:30
Age	: 65			**Test Trials**	: 1
Weight (lbs)	: 195			**Cursor**	: Off
Height (ft,in)	: 5'-4"			**CPT Code**	: NONE
Gender	: Female			**ICD Code**	:

FOOT PLACEMENT		LEFT	RIGHT
Foot Angle	:	10	10
Heel Position	:	D6	D16

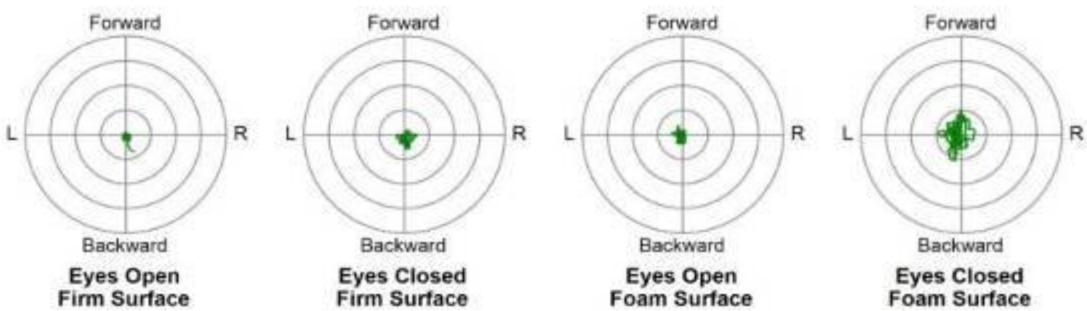
TEST RESULTS

All Trials

Condition	Sway Index	Mean
Eyes Open Firm Surface	0.71	0.66
Eyes Closed Firm Surface	1.06	1.17
Eyes Open Foam Surface	0.83	1.13
Eyes Closed Foam Surface	2.22	3.50
Composite Score (Avg)	1.20	1.62



Final Trial



COMMENTS

CLINICIAN

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APPENDIX I

Fall Prevention Handbook

NOVA SOUTHEASTERN UNIVERSITY

Fall Prevention Handbook

Contents

FALL PREVENTION HANDBOOK

Introduction

Falls are a leading cause of accidental injury and death in the United States, with older adults at the greatest risk. Anyone can fall, but the risk for falls increases as we age. Even falls that do not lead to injury can affect you. The most profound effect of falling is the loss of your independence. After sustaining a fall-related injury, nearly 50% of elderly patients are discharged from the hospital to a nursing home, rather than return home.

The fear of falling itself can lead to loss of self-confidence and inactivity, thereby decreasing your quality of life and increasing your risk of falls. Please take the time to review this book to understand your risk factors for falling, and what you can do to remain active in a safe manner. Some simple precautions and a little preparation can help prevent falls.

Understanding the Risk Factors

More than one-third of people over the age of 60 have at least one fall each year. Sight, hearing, muscle strength, and coordination problems are the key factors which cause falls. Balance can be affected by diabetes and heart disease, or by problems with your circulation, thyroid, or nervous system. Other common medical conditions that increase your risk of falling include arthritis, cataracts, or hip surgery.

Injuries sustained in a fall may range from cuts and bruises to life-threatening trauma. Head injuries and broken bones (fractures) lead the list. Even falls that do not lead to injury can have a negative effect on older adults. After a fall, people often limit their activity because they are afraid they will fall again. When you reduce your exercise and movement, your body becomes weaker, which can, in turn, increase the risk of another fall. Then there is osteoporosis — a disease that makes bones thin and more likely to break. Osteoporosis is a major reason for broken bones in women past menopause, and also affects older men. With more fragile bones, even a minor fall can cause bones to break.

Safety Tips

Most falls occur in the home/ living environment. You can make your home safer by following these tips:

- ✓ Make sure that you have good lighting in your home. Use night-lights in your bedroom, hall, and bathroom. Put night-lights and light switches close to your bed.
- ✓ Rugs and carpets should be firmly fastened to the floor or have nonskid backing. Loose ends should be tacked down.
- ✓ Keep areas where you walk tidy. Rearrange the furniture as needed so your path is clear.
- ✓ Move electrical cords and telephone wires so they are not lying on the floor in walking areas.
- ✓ Pick up things that are on the floor. Always keep objects off the floor such as papers, books, towels, shoes, magazines, boxes, blankets, etc.
- ✓ Put handrails in your bathroom for the bath, shower, and toilet. Do not let your home get too cold or too hot — it can make you dizzy.
- ✓ In the kitchen, make sure items are within easy reach. Do not store things too high or too low. Then you will not have to use a stepladder or a stool to stand on.
- ✓ Keep a telephone near your bed. In the living room, keep a telephone next to your favorite chair.


Action Plan to Avoid Falls

Here are some other actions you can take to avoid falls:

- ✓ Exercise! Exercise will reduce your chances of falling. It makes you stronger and helps you feel better. It helps you react more quickly to obstacles in your path and other potential dangers. Seniors who are less active are more likely to fall because they lack the strength and balance they need to resist falls. To be more active, you can start a regular exercise routine of any kind – even if it is a matter of taking only a few steps a day. Your goal is to improve your strength, balance, and gait. The type of exercise activity is up to you. You may enjoy gardening, walking, or group activities. Choose something that is enjoyable to you so it is easy to make it a regular part of your day.

- ✓ See your doctor if you have dizzy spells or if you fall.
- ✓ See your eye doctor once a year. Have your hearing tested once a year, too.
- ✓ Take good care of your feet. Have them examined if you have pain or difficulty walking.

- ✓ If your doctor suggests that you use a cane or a walker to help you walk, please use it! This will give you extra stability when walking and may help you avoid a bad fall.
- ✓ Do not use stairs without rails on both sides for support. If you must carry something while you are going up or down, hold it in one hand and use the handrail with the other.



- ✓ Do not take chances! Stay away from a freshly washed floor. Never stand on a chair or table to reach something that is too high.
- ✓ Wear shoes with firm non-skid, non-friction soles. Avoid wearing loose-fitting slippers that could cause you to trip.
- ✓ When you get out of bed in the morning or at night to use the bathroom, sit on the side of the bed for a few minutes before standing up. Moving too quickly can make you dizzy, and you might lose your balance and fall.
- ✓ Consider a Medical Alert System - it provides prompt help with a press of a button 24 hours a day. Please connect to a local

provider and they will explain the costs associated with the services.

- ✓ Understand and manage your medications. Many types of drugs can contribute to falls by reducing mental alertness, affecting balance and gait, and causing drops in blood pressure while standing. People taking multiple medications are also at greater risk of falling.

- ✓ Keep a complete, dated list of the medications you take and bring it on every doctor's visit for a medication review. The list should include both prescriptions and non-prescription drugs you take. Take medications as directed and use a medicine organizer to help properly manage them. Know the common side effects of all the medications you are taking. Share any side effects you are experiencing with your doctor.
- ✓ Stay hydrated! Remember to drink plenty of fluids and stay hydrated to prevent blood pressure drops that can result in falling. If you have a medical condition that limits your fluid intake, check with your physician for the appropriate amount that is safe for you.

What to Do If You Fall

- Getting up quickly or the wrong way could make an injury worse. If you are within reach of a phone, call for help; if have a personal transmitter pendant, press the button for help.

- Sit for a few minutes before you try to move from the fall position. If you need to get yourself up and you do not appear to be injured, try to move to a sturdy chair, sofa, or bed. Roll onto your hands and knees and use the furniture to pull yourself up.

Personal Fall Prevention Plan

- Falls are not a normal part of aging. Take the responsibility to understand your risk factors and the best ways to prevent a fall from happening. This will help you gain the confidence to stay active in a safe manner, preserving your independence and quality of life.


- Please share this information with your family so they can help with the changes necessary to make your home a safer place as well as support you in adopting lifestyle changes that can decrease fall risk.

Resources

1. What you can do to prevent falls. Centers for Disease Control and Prevention Web site. https://www.cdc.gov/homeandrecreationalsafety/pubs/English/brochure_Eng_desktop-a.pdf May 17, 2017. Accessed Jun 10, 2017
2. Falls and home safety. Practicing Physician Education in Geriatrics Web site. http://www.gericareonline.net/tools/eng/prevention/attachments/PRE_PDF/Individual_Tools/Patient_Handouts/2_HO_Lifestyle/5A_TL_PRE_Falls.pdf Accessed Jun 10, 2017
3. Fall prevention handbook. VNA of Middlesex-East, Home health and Hospice Web site. http://www.vnaofme.org/wp-content/uploads/2014/02/fall_prevention.pdf Accessed Jun 10, 2017

APPENDIX J

Balance Exercises Booklet

BALANCE EXERCISES

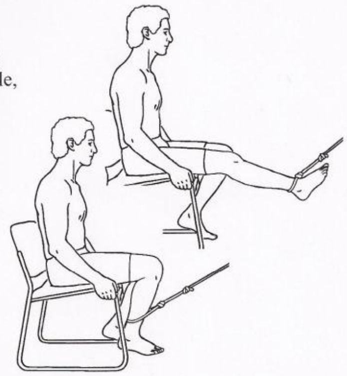
Name________________________________

GENERAL INSTRUCTIONS

1. In general, do not hold your breath. This may voluntarily reduce air intake (causing less oxygen supply to the body) and elevate your blood pressure.
2. Breathe deeply before the start of an exercise. When you are not breathing enough, your respiratory rate slows down, and total oxygen levels in the body can decrease. Your whole body needs oxygen to function optimally and properly.
3. Breathe consistently while performing exercises. When exercising, your muscles burn oxygen and demand more air supply. If there is not enough oxygen available to muscles, the level of waste products (acid) may increase and it may cause muscle soreness.
4. Breathe after the end of exercise. This will help oxygen levels in the body to stay in a healthy range and keep the whole system safe.
5. Breathe deeply for a few times whenever you feel any muscle soreness. When oxygen rushes into sore muscles, it will neutralize accumulated waste acids and will help to clear muscle soreness.
6. During exercise, move your body parts smoothly and with control. Do not jerk, twist, snap or torque your joints and muscles.
7. When exercising, move through your easily available range of motion, then gently attempt to go into your weaker/ more difficult range of motion before smoothly returning to the starting position.
8. Fully release and relax the muscles between each repetition of an exercise to allow blood to flow through the muscles and nourish them. Always remember to take a breath in between each repetition as well.
9. Build up slowly. If you have been inactive for a long while, remember it will take time to get into shape. Just remember that you will feel more fit after a few weeks than when you first started.
10. Dress properly based on the climate (cold days/hot and humid days). Drink lots of fluid, particularly water.

HIP / KNEE - 44 Hamstring Curl: Resisted (Sitting)

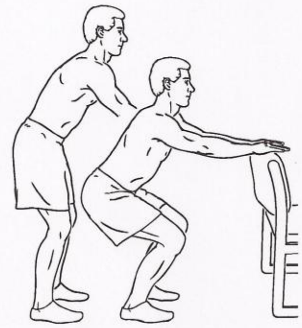
Facing anchor with tubing on right ankle, leg straight out, bend knee.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 78 Functional Quadriceps: Chair Squat

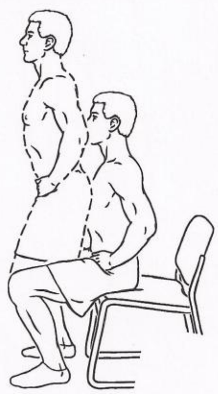
Keeping feet flat on floor, shoulder width apart, squat as low as is comfortable. Use support as necessary.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 77 Functional Quadriceps: Sit to Stand

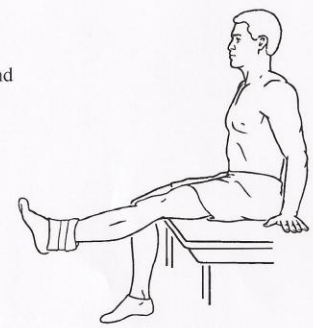
Sit on edge of chair, feet flat on floor. Stand upright, extending knees fully.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 76 Knee Extension (Sitting)

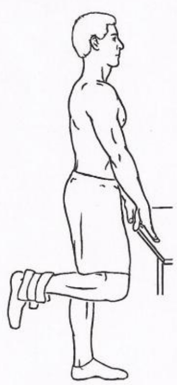
Place _____ pound weight on left ankle and straighten knee fully, lower slowly.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 80 Knee Flexion: Resisted (Standing)

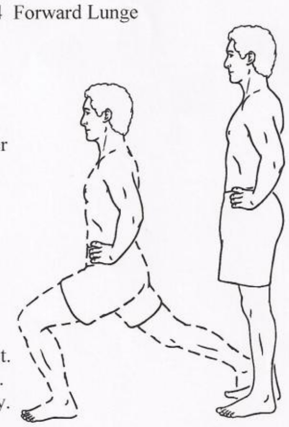
With support, _____ pound weight around right ankle, slowly bend knee up. Return slowly.



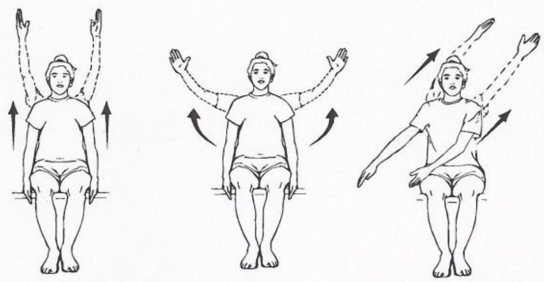
Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

TRUNK STABILITY - 34 Forward Lunge

Standing with feet shoulder width apart and stomach tight, step forward with left leg.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

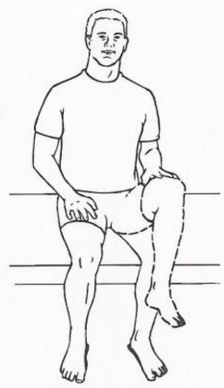


SITTING - 7
Lateral Weight Shift: Upper Trunk Leading

Sit with feet flat on floor. Bring right shoulder, head and arm toward the right side until forearm just touches the sitting surface, return to upright.

SITTING - 15
Leg Lift

With hands on thighs and feet flat on floor, raise left knee toward ceiling.



SITTING - 14
Reaching / Placing Objects in Diagonal Pattern

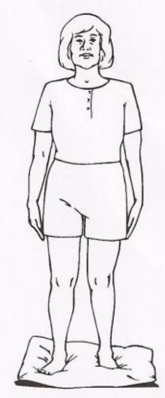
Pick up object located down on right and place up on left. Then pick up object located down on left and place up on right.

SITTING - 4
Supported Anterior / Posterior Weight Shift: Lower Trunk Leading

Sit with feet flat on floor, hands on support. Lean forward through hips bringing nose over knees. Return. Then lean backward through hips.

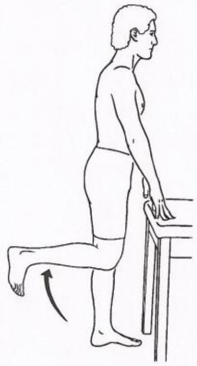
STANDING STATIC - 5
Feet Apart (Compliant Surface)

.



HIP / KNEE - 24 Strengthening: Knee Flexion (Standing)

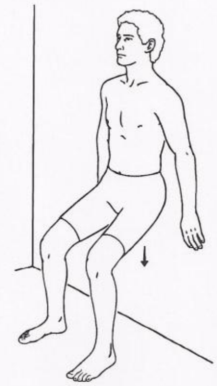
With support, bend right knee as far as possible.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 25 Strengthening: Wall Slide

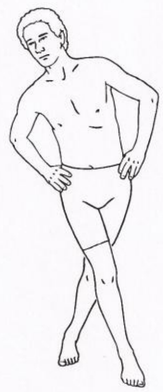
Leaning on wall, slowly lower buttocks until thighs are parallel to floor. Hold _____ seconds. Tighten thigh muscles and return.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 36 Stretching: Tensor

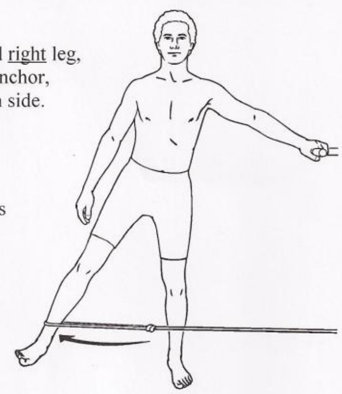
Cross right leg over the other, then lean to same side until stretch is felt on other hip. Hold _____ seconds.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 27 Strengthening: Hip Abduction – Resisted

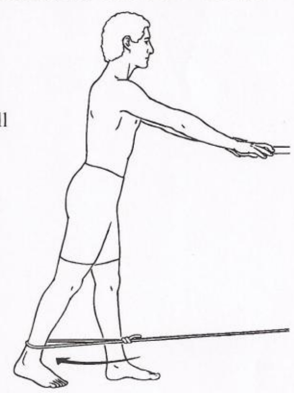
With tubing around right leg, other side toward anchor, extend leg out from side.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

HIP / KNEE - 28 Strengthening: Hip Extension – Resisted

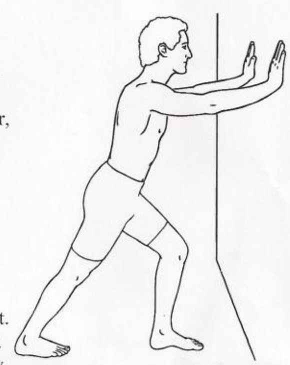
With tubing around right ankle, face anchor and pull leg straight back.



Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

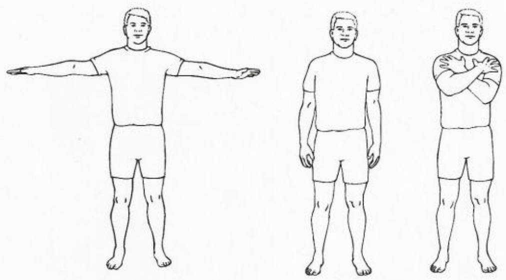
HIP / KNEE - 41 Stretching: Gastroc

Stand with right foot back, leg straight, forward leg bent. Keeping heel on floor, turned slightly out, lean into wall until stretch is felt in calf.
Hold _____ seconds.



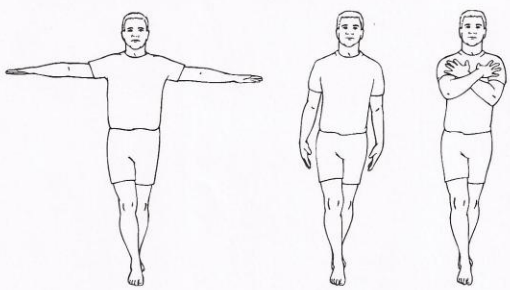
Repeat _____ times per set.
Do _____ sets per session.
Do _____ sessions per day.

STANDING STATIC - 1
Feet Apart: Varied Arm Positions



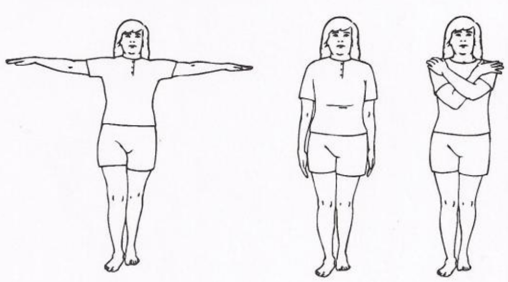
With feet shoulder width apart and arms ____out____, look straight ahead at a stationary object.

STANDING STATIC - 4
Feet Heel-Toe "Tandem": Varied Arm Positions



With right foot directly in front of the other, and arms ____out____, look straight ahead at a stationary object.

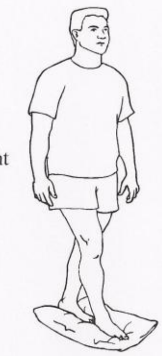
STANDING STATIC - 3
Feet Partial Heel-Toe: Varied Arm Positions



With right foot partially in front of the other and arms ____out____, look straight ahead at a stationary object.

STANDING STATIC - 8
Feet Heel-Toe "Tandem"
(Compliant Surface)

Stand on __________ with right foot directly in front of the other. Look straight ahead at stationary object. Perform with arms __at sides__.

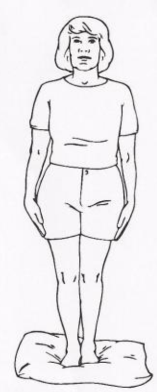


STANDING STATIC - 7
Feet Partial Heel-Toe (Compliant Surface)

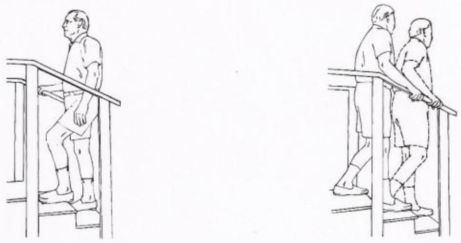
Stand on __________ with left foot partially in front of the other. Look straight ahead at stationary object. Perform with arms __at sides__.

STANDING STATIC - 6
Feet Together (Compliant Surface)

Stand on __________ with feet together. Look straight ahead at stationary object. Perform with arms __at sides__.



STANDING DYNAMIC - 20
Stair Climbing

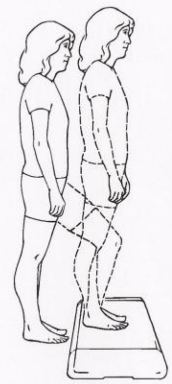


Leading with ___left___ leg, climb a flight of stairs ___with___ hand support. Descend leading with ___right___ leg.

___ Repeat in dimly lit room.
___ Repeat moving head in varied directions.

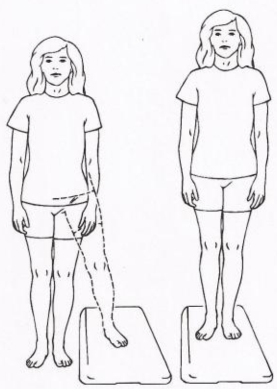
STANDING DYNAMIC - 15
Step-Ups: Forward

Leading with right leg, bring both feet onto a ______ inch step.
Return to starting position, leading with right leg.



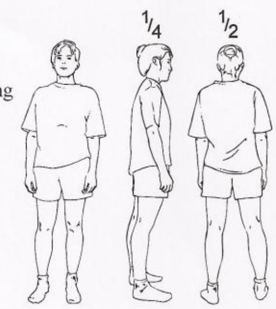
STANDING DYNAMIC - 16
Step-Ups: Lateral

Step up to side with _left_ leg. Bring other foot up onto ______ inch step.
Return to floor position with right leg.



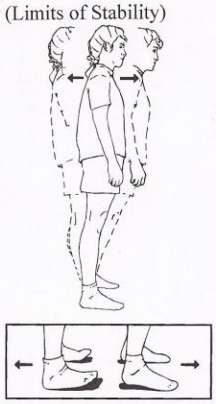
STANDING DYNAMIC - 8
Turning in Place: Solid Surface

Standing in place, lead with head and turn _slowly_ making quarter turns toward right.



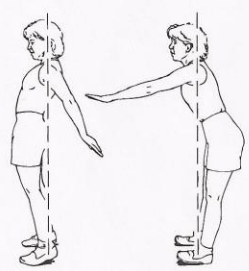
STANDING DYNAMIC - 1
Weight Shift: Anterior / Posterior (Limits of Stability)

Slowly shift weight backward until toes begin to rise off floor.
Return to starting position.
Shift weight forward until heels begin to rise off floor.



STANDING DYNAMIC - 4
Weight Shift: Anterior / Posterior (Righting / Equilibrium)

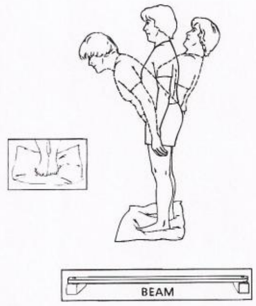
Slowly shift weight forward while bringing arms back and hips forward over toes until heels rise off floor. Return to starting position. Shift weight backward bringing arms forward and hips back over heel until toes rise off floor.



Repeat ______ times per session.
Do ______ sessions per day.

STANDING DYNAMIC - 26
Postural Strategies: Hip

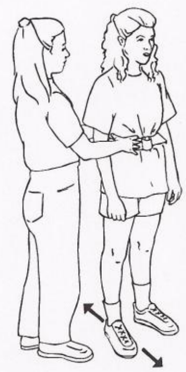
Standing with feet _apart_ on a _compliant_ surface, slowly bend forward through hips. Return to upright position and then slowly bend backward through hips.



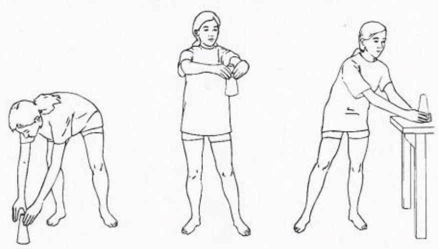
STANDING DYNAMIC - 27
Postural Strategies: Stepping

Stand with feet apart. Have someone push you unexpectedly through trunk, forward or backward. Attempt to maintain balance by taking one quick step.

Exercise must be performed next to counter top for safety.



STANDING DYNAMIC - 14
Reaching / Placing Objects: in Diagonal Pattern

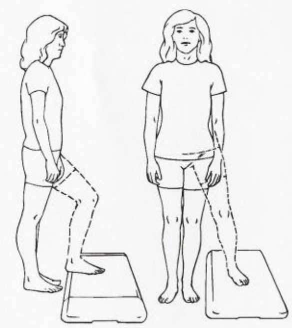


With feet _apart_ pick up object located down to the right side and place on surface up on the _left_ side.

___ Repeat on compliant surface __________.
___ Repeat sequence to opposite side.

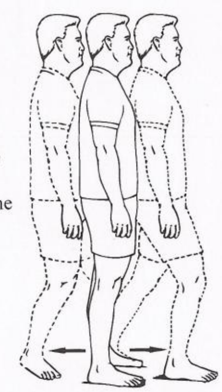
STANDING DYNAMIC - 17
Single Leg: Opposite in Motion

Slowly place right foot lightly on a _____ inch step placed in front. Maintain balance by centering weight over standing leg.



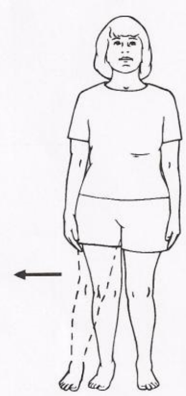
STANDING DYNAMIC - 6
Single Step: Forward / Backward

Lifting foot off floor, take one step _slowly_ forward with right leg. Return to starting position. Take one step backward and return.

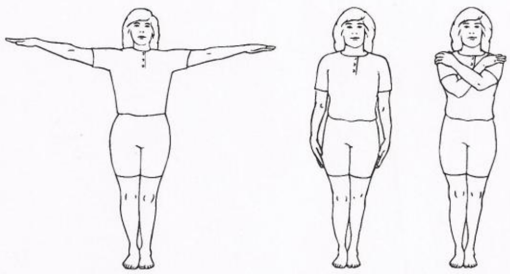


STANDING DYNAMIC - 7
Single Step: Side

Lifting foot off floor, take one step _slowly_ to right side. Return to starting position.



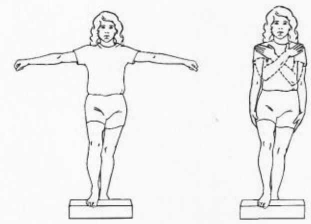
STANDING STATIC - 2
Feet Together: Varied Arm Positions



With feet together and arms ____out____, look straight ahead at a stationary object.

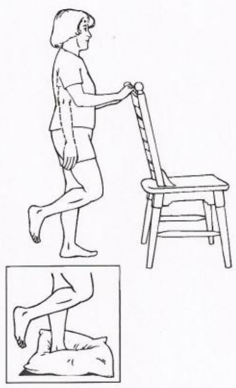
STANDING STATIC - 18
Foot on Step

Stand with one foot on ______ inch step and arms ____out____.

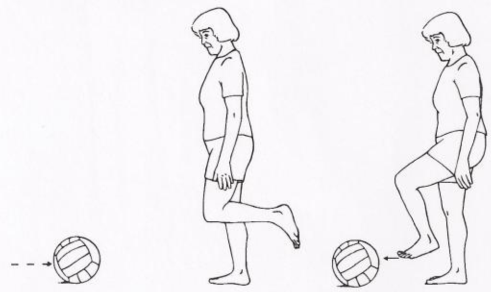


STANDING STATIC - 19
Single Leg (Varied Surfaces)

Holding on to support, lift right leg up while maintaining balance over single leg. Progress to removing hands from support surface for longer periods of time.



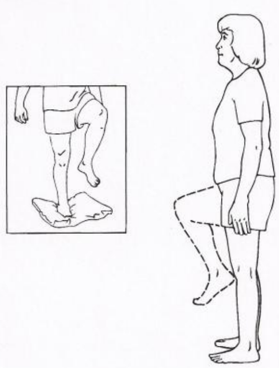
STANDING DYNAMIC - 24
Ball Kick: Single Leg



Standing on right leg, have person roll a ball toward raised leg. Kick it back while maintaining balance over standing leg.

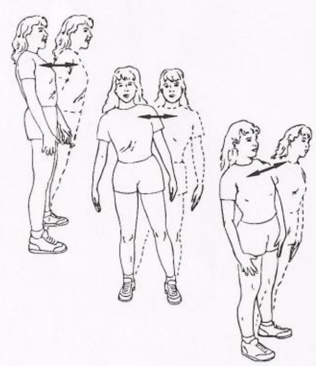
STANDING DYNAMIC - 12
Marching in Place: Varied Surfaces

March in place, slowly lifting knees toward ceiling.



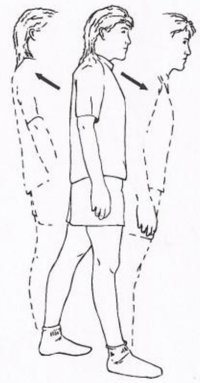
STANDING DYNAMIC - 25
Postural Strategies: Ankle

Keeping feet flat on floor, shoulder width apart, shift weight forward-backward through ankles.



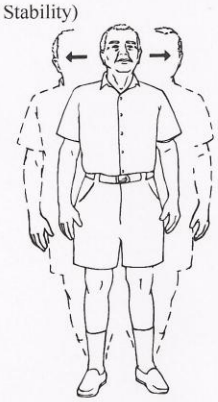
STANDING DYNAMIC - 3
Weight Shift: Diagonal

Slowly shift weight forward over right leg. Return to starting position. Shift backward over left leg.



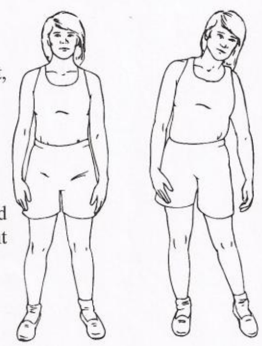
STANDING DYNAMIC - 2
Weight Shift: Lateral (Limits of Stability)

Slowly shift weight to right as far as possible, without taking a step. Return to starting position.



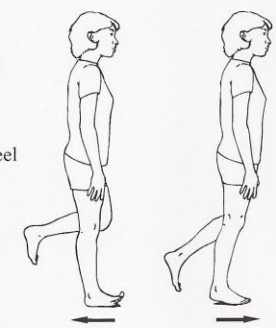
STANDING DYNAMIC - 5
Weight Shift: Lateral (Righting / Equilibrium)

With feet shoulder width apart, slowly shift weight over right leg, bending head and trunk slightly to left. Let left arm hang out from side. Return to starting position. Shift weight over left leg, bending head and trunk slightly to right. Let right arm hang out from side.



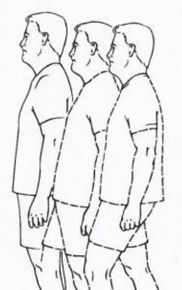
STANDING DYNAMIC - 23
Weight Shifting: Single Leg: Varied Surfaces

Standing on right leg slowly shift weight backward until toes begin to rise off floor. Return to starting position. Shift weight forward until heel begins to rise off floor.

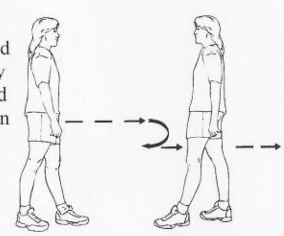


GAIT - 7
Backward

Walk backward with eyes open. Take even steps, making sure each foot lifts off the floor. Turn and walk backward to starting place. Arm supported as needed



On solid ground, walk making a slow half turn in place, leading with head and eyes, toward the right every _____ steps. Walk forward and backward continuing on a straight path between turns.

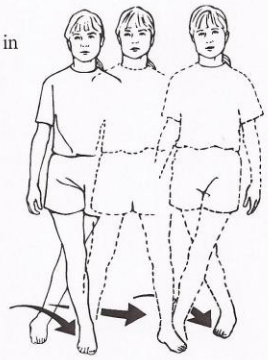


GAIT - 15
Braiding

Move to side: cross right leg in front of left, bring left out to side, then cross right leg behind left leg and so on. Repeat toward opposite direction.

Repeat sequence _____ times.
Do _____ sessions per day.

__ Repeat with eyes closed.
__ Repeat on __________ surface.

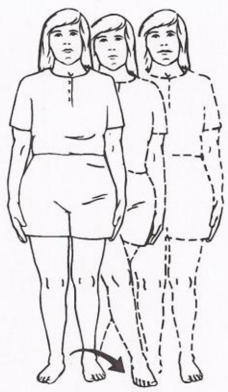


GAIT - 16
Crossovers

Move to side: cross <u>right</u> leg in front, bring back leg out to side. Repeat, progressing in same direction. Move in opposite direction using other leg in front.

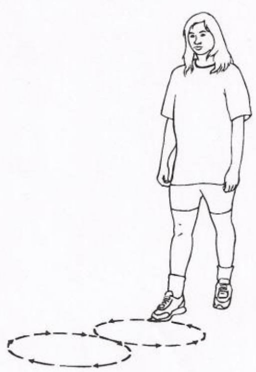
Repeat sequence _____ times.
Do _____ sessions per day.

__ Repeat with eyes closed.
__ Repeat on __________ surface.



GAIT - 20
Figure Eight

Walk making a figure eight pattern.



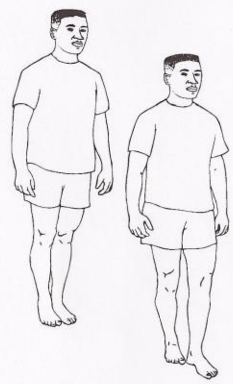
GAIT - 19
Circle

Walk initially making a large circle toward the <u>right</u> and then progressively decreasing size to a smaller circle.

GAIT - 9
Feet Close Together

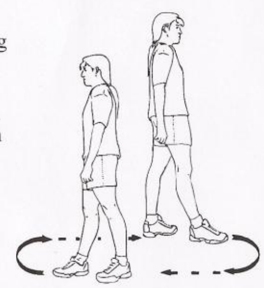
Place feet closer together than normal width and walk while maintaining a straight path.

__ Repeat while moving head <u>side to side</u>.

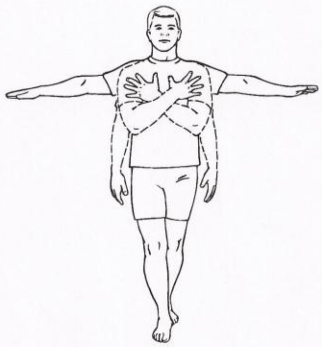


GAIT - 12
Forward Progression With 180° (Half) Turns

On solid ground, walk making a <u>slow</u> half turn in place, leading with head and eyes, toward the <u>right</u> every _____ steps. Walk in a straight path forward between turns.

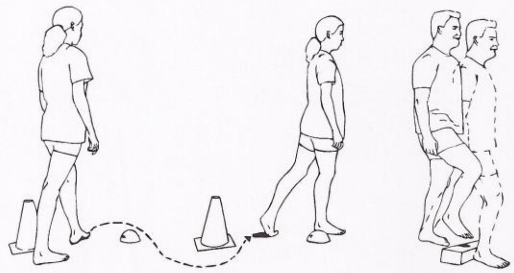


GAIT - 10
Heel-Toe "Tandem"



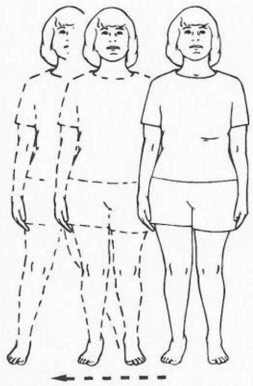
With arms outstretched walk a straight line. Bringing one foot directly in front of the other.

GAIT - 11
Obstacle Course (Over / Around Objects)



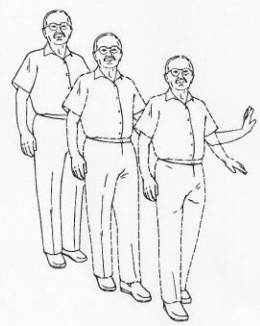
Walk, stepping around objects of various height and size placed on floor.

GAIT - 8
Side-Stepping



Walk to right side with eyes open. Walk evenly, leading with same foot.
Make sure each foot lifts off the floor. Arm supported as needed.

GAIT - 1
Walking



Walk on solid surface with hand close to a wall. Attempt to keep hand away from wall for longer periods of time, keeping a straight path.

APPENDIX K

Activity Log

ACTIVITY LOG

Name: ________________

Date	Type of Activity	Duration

APPENDIX L

Study Flyer

NOVA SOUTHEASTERN UNIVERSITY

A Clinical Study on Balance and Fall Risk Assessment and Effectiveness of Physical Therapy

You are eligible to take part in this community based study, if you are

- ✓ **60 years or over**
- ✓ **Verbal report of fear of falling**
- ✓ **Currently not receiving any other therapy**

Purpose: The goal of this study is to understand whether older adults with mild balance dysfunction benefit from structured or non-structured therapy

Contact: Varatharajan (Physical Therapist), if you are interested and would like to know further about this balance study.

Location: Facility Activity or Exercise Room

Cell: 269-830-3519 **Email:** vl272@mynsu.nova.edu

*************Advanced high-tech BioSway™ balance unit will be used for testing***************

APPENDIX M

Resources Utilized

Resources Utilized

<u>Physical Location for Screening and Testing</u>

- Facility Activity/Exercise Room

<u>Personnel</u>

- Primary investigator
- Five physical therapists (secondary investigators)
- One clerical assistant

<u>Office supplies</u>

- Paper bundle
- Pens/ pencils
- Plastic files
- File folders
- Portable file cabinet with locks
- SPSS software, laptop and printer

<u>Equipment/ Testing Materials</u>

- BioSway ™ - Balance testing unit
- Commander Muscle Tester - Hand-held dynamometer
- FitSense - Speedometer system
- Yardstick
- Duct tape
- Kidney beans
- Teaspoon
- Bowel and coffee can
- Heavy book (7 lbs)
- Shelf
- Jacket, cardigan sweater, or lab coa
- Coins (Pennies)
- Stopwatches and tape measure
- Armless chairs

APPENDIX N

Informed Consent

NSU
NOVA SOUTHEASTERN UNIVERSITY
College of Health Care Sciences
Department of Physical Therapy

Informed Consent

Consent Form for Participation in the Research Study

Effects of Generic Group-based versus Personalized Individual-based Exercise Program on Balance, Gait, and Functional Performance of Older Adults with Mild Balance Dysfunction and Living in Residential Care Facilities – A Randomized Controlled Trial

Funding Source: None

IRB approval #: Pending

Principal investigator
Varatharajan Lingam, PT, DPT
3200 South University Drive
Fort Lauderdale, FL 33328
(954) 262-1967

Co-investigator
Alicia Fernandez Fernandez, PT, DPT, PhD
3200 South University Drive
Fort Lauderdale, FL 33328
(954) 262-1967

What is the study about?

You are invited to participate in a research study. The goal of this study is to understand whether older adults with mild balance dysfunction benefit from structured or non-structured therapy.

Why are you asking me?

We are inviting you to participate because you are 60 years or above, and have concerns about your balance, and fit the criteria for either the control group or the research group of this study.

Health Professions Division
College of Health Care Sciences • Physical Therapy Department
3200 South University Drive • Fort Lauderdale, Florida 33328-2018
(954) 262-1662 • 800-356-0026 ext. 21662 • Fax: 954-262-1783 • www.nova.edu/pt

What will I be doing if I agree to be in the study?

During the course of the study, you will complete a series of tests, which measure your balance, reaching distance, functional tasks, leg muscles strength, and ability to walk. The primary investigator (physical therapist) will administer all these tests. The first test requires you to stand on a fixed instrumental platform and a foam pad of a balance unit. Your physical therapist will then rate your balance, stability, and postural control based on your performance during the procedure and how much assistance you need. The second test will help us to identify about how far you can reach in the front, backward and sideways. During the third test, your physical therapist will assist you through a series of tasks to identify your functional performance that are mostly like your routine daily activities. The fourth test will require you to push your legs in different directions against a small hand-held device to test your leg muscles strength. Final test will requires your physical therapist to use a stopwatch to time how long it takes you to walk 10 meters at a comfortable pace. The tests will be given after you signed this consent form, and again during the ninth week. After one month (around thirteenth week), your retention effect will be assessed using the balance unit and functional based daily tasks test. If you are selected under experimental group, you will receive one-on-one physical therapy including an initial evaluation and subsequent treatment sessions, once or twice per week for 4 to 8 weeks from a licensed physical therapist. If you are selected under control group, you will get the fall prevention information booklet and required to enroll and participate in the facility offered group exercise sessions. In addition, you will be required to keep an exercise diary. You will also be asked to report falls, if any occur during the entire study period.

What are the dangers to me?

Risks to you are minimal, meaning they are not greater than other risks you experience every day during exercise sessions. If you agree to participate, you will be asked questions about your memory, balance, and fall history. If at any time you feel that you no longer wish to spend the time necessary to complete the study, you are allowed to opt out at anytime. Every precaution will be taken during testing to ensure your safety. The primary investigator (trained physical therapist) will administer the initial screening and all other tests. He will explain the procedures in detail to you prior to screening and testing, and give you the opportunity to ask questions and clarify all your doubts. You have all the rights to decline to participate if you feel uncomfortable at any time.

All testing will occur in the activities center of your facility. Participating in this study also may result in some loss of your privacy. You will be asked to perform tests in the activity center, which is a location accessible to other residents living the facility. Thus, other residents will be able to see you participate in testing and may determine that you are participating in a study. It is your choice whether you discuss your participation with others or not. We will not identify you as a study participant to others without your permission.

Initials: ________ **Date:** ________

Are there any benefits to me for taking part in this research study?

The tests performed during this study will give valuable information regarding your balance, strength, walking ability, fall risk, and overall functional status. Potential benefits of participating in physical therapy include decreased fall risk, improved balance and mobility, and increased awareness about fall prevention and therapeutic exercises.

For any questions or concerns about this study or your research rights, you can contact Varatharajan Lingam, PT, DPT, PhD (C) or the IRB office, Nova Southeastern University. Toll free: (866) 499-0790 (IRB@nsu.nova.edu).

Will I get paid for being in the study? Will it cost me anything?

There are no costs to you or payments made for participating in this study.

How will you keep my information private?

Any information that you provide will be kept confidential, only the primary researcher and other members of the study team will have access to the information. Screening forms, test results, evaluation, and data collection sheets will be stored as both paper and electronic records. Your private health information will only be shared with those who are directly involved in your health care and the researchers involved in this study. To ensure your privacy and protection, your health information will be recorded on a data collection form that will be coded and not contain your name or any other information that may identify you. Only the researchers will be able to access your identity and health information by using ID codes. All paper documents and research computer will be locked in a secure file cabinet to protect the identity and privacy of all the study participants. The IRB, Dr. Fernandez-Fernandez and regulatory agencies may review research records as needed. Participant records and signed consents will be destroyed 5 years after the study ends.

What if I want to leave the study?

Your participation in this study is voluntary. You have the right to leave at any time, or to refuse to participate without penalty. If you choose to withdraw, your data will be retained for 36 months from the conclusion of the study and may be used as a part of the research.

Other Considerations:

If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the researchers.

Initials: ________ **Date:** ________

Voluntary Consent by Participant:

By signing below, you indicate that

- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel for any questions about your study rights
- you are entitled to a copy of this form after you have read and signed it
- you voluntarily agree to participate in the study entitled **"**Effects of Generic Group- based versus Personalized Individual-based Exercise Program on Balance, Gait, and Functional Performance of Older Adults with Mild Balance Dysfunction and Living in Residential Care Facilities – A Randomized Controlled Trial**"**

Participant Signature ___________________________________ **Date** ____________

Participant Name (Print) _______________________________________

Signature of Person Obtaining Consent ________________________ **Date** ___________

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