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The Effects of Partial Body Weight Support for Gait in Patients with Neurological Dysfunction: A Case Study Approach

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This Scholarly Project, submitted by Sarah Hammers, Alecia Herring, Amanda Olson, and Mandy Runyan in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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PERMISSION

Title	The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction: A Case study Approach
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TABLE OF CONTENTS

LIST OF FIGURES

Figure Page

LIST OF TABLES

Table Page

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ABSTRACT

Cerebrovascular accident (CVA) is the primary cause of disability in the United States.[1] It is estimated that 75% of those who have a CVA survive and function with multiple degrees of impairments. These impairments impact their activities of daily living in a variety of ways. One of the goals of rehabilitation is to minimize the negative effects a CVA has on the functioning of an individual and allow each person to reach his or her maximum potential. Limited research has been conducted exploring the positive outcomes of partial body weight support treadmill training (PBWSTT) in those who have experienced a neurological insult. More research is needed to discover the effects partial body weight support has on individuals. If this training is found to be beneficial in a population of clients with a CVA, then there is a possibility that the effects could carry over to other neurological populations. **Purpose:** The purpose of this study is to determine if partial body weight support system improves the quality of gait, postural control, and speed in adults diagnosed with a CVA over a period of six weeks, attending sessions three times per week. **Subjects & Methods:** The four subjects who participated in this study all have the neurological diagnosis of CVA. They ranged in age from 50 to 78 years old. Four methods were used to gather initial and final data for the six-week study to illustrate outcomes gained. The methods utilized were the Berg Balance Measure, a template recording of footprints, the gait portion of the Tinetti Assessment Tool, and the 10-Meter Timed Walk. **Results:** Results of this study were more apparent

qualitatively than quantitatively. Each individual demonstrated improvements in one or more categories in the areas of postural control, gait quality, and speed. The most significant improvements were seen in gait speed and symmetry. **Conclusion:** Following a review of literature, the participation in the six-week study, and analyzing its results, we concluded that PBWSTT is indeed a beneficial rehabilitation tool for the population that has experienced a CVA. The researchers feel that the improvements in our subjects will increase functional capacities leading to a better quality of life.

CHAPTER 1

INTRODUCTION

Cerebrovascular accident (CVA) is the primary cause of disability in the United States.[1] It is estimated that 75% of those who have a CVA survive and function with multiple degrees of impairments. These impairments impact their activities of daily living in a variety of ways. One of the goals of rehabilitation is to minimize the negative effects a CVA has on the functioning of an individual and allow each person to reach his or her maximum potential.

Most neurological impairments, including a CVA, interfere with the brain's ability to coordinate the lower extremities during gait, one of the main output features of the central nervous system.[2] The goals of gait retraining include proper timing, weight shifting, and symmetry. These goals are challenging to achieve using current treatment techniques. Numerous clients do not receive training for ambulation until later in their rehabilitation for this reason. Failing to initiate gait training earlier may limit a client's long-term functional improvements.

Through use of devices for partial body weight support (PBWS), a person is able to initiate gait training earlier in the rehabilitation process. It is believed that the sooner gait retraining is initiated, the better the long-term outcomes will be. Even though partial body weight support is thought to demonstrate positive benefits, it has been slow to be accepted. More research is needed to familiarize health care professionals with the

benefits of partial body weight support and its use in gait training in clients who have had a CVA.

Problem Statement

Limited research has been conducted exploring the positive outcomes of partial body weight support treadmill training in those who have experienced a neurological insult. More research is needed to discover the effects partial body weight support has on individuals. If this training is found to be beneficial in a population of clients with a CVA, then there is a possibility that the effects could carry over to other neurological populations.

Purpose

The purpose of this study is to determine if partial body weight support system improves the quality of gait, postural control, and speed in adults diagnosed with a CVA over a period of six weeks, attending sessions three times per week.

Significance

As there becomes an increasing number of neurological impairments, physical therapists need to expand their scope of practice to enhance each patients' ability to reach their goals in the most time efficient manner. A physical therapist with varied treatment options has more to offer a client with a neurological deficit. It is important to realize that individualizing each treatment program will achieve maximum benefit for the client.

This study will help determine if partial body weight support treadmill training is effective in improving gait, postural control, and speed in individuals who have had a CVA. If PBWS is found to be effective in the population that has had a CVA, further

research is warranted in this area for those with other neurological limitations. With the knowledge gained, it can be added to a physical therapist's options for treatment.

Research Questions

1. What is the effect of six weeks of partial body weight support treadmill training on gait quality in subjects with a CVA diagnosis, ages 50-80?
2. What is the effect of six weeks of partial body weight support treadmill training on postural control in subjects with a CVA diagnosis, ages 50-80?
3. What is the effect of six weeks of partial body weight support treadmill training on speed in subjects with a CVA diagnosis, ages 50-80?

Hypothesis

H_O: Partial body weight support treadmill training will have no effect on gait quality, postural control, or speed in subjects with CVA after participating three times per week for six weeks.

H_A: Partial body weight support treadmill training will have an effect on gait quality, postural control, or speed in subjects with CVA after participating three times per week for six weeks.

CHAPTER 2

LITERATURE REVIEW

Cerebral Vascular Accident

Incidence

A cerebral vascular accident (CVA) occurs in approximately 600,000 people per year in the United States alone.[3] The incidence of CVA increases significantly as a person ages, doubling each decade after 55 years. African American men have a 50% higher risk of having a CVA than Caucasian men have. Also, African American women have a 130% risk of having a stroke than Caucasian women. Overall, men have a 30-80% increased risk of having a CVA as compared to women.

Pathology of a CVA

Pathology is defined as the study of the nature and cause of disease, which involves changes in structure and function.[4] As defined by O'Sullivan and Schmitz,[3] CVA is an acute onset of neurological dysfunction due to an abnormality in cerebral circulation. CVA is the most common cause of disability in adults in the United States today[1,5] and is also the third leading cause of death among adults in the United States.[3] Many processes, all of which involve blood vessels in the brain, cause CVA. A CVA may originate within the brain or possibly as an embolus from the heart. Symptoms result corresponding to the area of the brain affected by the abnormal circulation. Sensory, motor, language, cognitive, and perceptual deficits are all possible. These

impairments will be discussed later on in the chapter. To be classified as a CVA, neurological deficits must last at least 24 hours. Typically, motor deficits are distinguished by hemiplegia, which is paralysis to one side of the body or hemiparesis, which is weakness on one side of the body.

The human brain requires a supply of glucose and oxygen to function appropriately.[5] This is delivered via the blood stream accounting for 15% of resting cardiac output and 20% of the total body capacity. The brain is a highly aerobic tissue. Thus, an interruption in the vascular system that inhibits oxygen and glucose intake warrants a devastating disorder.

A CVA can be categorized into many different groups.[3] The most common are ischemic and hemorrhagic. An ischemic CVA is the most common type occurring 61-81% of the time. The occlusion of major arteries is the likeliest cause of an ischemic CVA, while a thrombus or embolus produces ischemic strokes. This occlusion disrupts blood flow in the brain robbing it of needed oxygen and glucose that leads to death of tissues. The middle cerebral artery is the most commonly involved site where ischemia takes place. A hemorrhagic CVA occurs 12-24% of the time. In this type of CVA, abnormal bleeding into areas of the brain emerges secondary to trauma or from an aneurysm. These result due to an increase in pressure within the brain that restricts blood flow. There are a few types of hemorrhages that can occur within the brain to lead to a CVA. Intracerebral hemorrhage is the rupture of a blood vessel with bleeding into the brain. Cerebral hemorrhage is a non-traumatic bleeding that is spontaneous in occurrence. Oftentimes, this takes place in small blood vessels. Subarachnoid

hemorrhage is a bleeding into the subarachnoid space within the brain. There are many causes of hemorrhages in the brain, but chronic hypertension is closely linked to this.

Normal blood pressure is considered to be 120/80.[5] Hypertension is the elevation of blood pressure to 140/90. This elevation accelerates changes in the vessel walls. These changes within the vessels potentiate a CVA, either ischemic or hemorrhagic. In a study done by Lammie et al,[6] vessel changes as a result of hypertension were observed only in the brain and not in other organs of the body. They hypothesized that cerebral vessels were somehow vulnerable to the effects of hypertension.

Impairments Accompanying a CVA

Impairments are defined as any loss or abnormality of psychological, physiological, or anatomical structure or function.[4] The effects of a CVA may be life-long since it is impossible to replace dead brain cells. Depending on the part of the brain involved, a CVA can affect many different parts of the body, including the senses, vision, motor activity, speech, behavior, thoughts, and memory.

Throughout the United States, 53% percent of people who experience a CVA have some sort of sensory impairment.[3] The extent of the deficit is related to the location and how severe the lesion is on the brain. Most serious impairments are found in the unilateral face, upper extremity, and lower extremity pattern. Different variations such as face with contralateral upper extremity and lower extremity involvement are found but are much less common. Sensation loss can range from superficial to deep. Different types include, but are not limited to: proprioceptive deficits, numbness, dysesthesias (abnormal sensation), hyperesthesia (increased sensation), pain, and temperature changes.

Visual deficits are often attributed to the patients affected side.[3] Homonymous hemianopsia, found in 26% of patients with a CVA, is a loss of vision in the contralateral half of each eye in the patient's visual field. Other impairments include visual neglect, depth perception, problems with spatial relationships, forced gaze deviation, diplopia, vertigo, oscillopsia, and visual distortions.

Motor impairments vary as a CVA progresses. According to Post-Stroke Rehabilitation,[7] 70-85% of clients experience some sort of hemiplegia. Initially, flaccidity without any normal movements is common.[3] In time mass patterns of movements called synergies often appear which include spasticity and hyperreflexia. They can either take form in extension or flexion patterns. As recovery moves along, these synergies are decreased in intensity and more normal movement patterns can be obtained. The neurodevelopmental (NDT) approach encompasses this process into three main stages: (1) initial flaccid stage, (2) spasticity stage, and (3) stage of relative recovery. Depending on the severity of the involvement, a client may plateau at any of these stages and not recover entirely. Disruption of a client's postural control and balance is common and can lead to falls and other injuries that further complicate rehabilitation. Other motor impairments included for those who have experienced a CVA may include: incoordination from loss of proprioception (ataxia), ideomotor and ideational apraxia, motor impersistence, motor weakness, dyssynergia, bradykinesia, and adventitious movements. Adaptation to and determination of the client can have a huge impact on the outcome of his or her motor rehabilitation.

Clients who have a lesion in the cortex often demonstrate impairments in their speech.[3] Aphasia (an impairment in language understanding, composition, and use) has

been shown in 30-36% of all clients with a CVA. Aphasia can be receptive where they can speak but do not understand others, or expressive, in which they understand others but cannot speak. Global aphasia is a combination of both deficits. Difficulty swallowing, called dysphagia, is found in 12% of clients with lesions in the medullary brainstem. Dysphagia can lead to a swallowing reflex, drooling, difficulty ingesting food, dehydration, or aspiration.

Perceptual impairments, discovered with lesions within the cortex, occur most often with clients who have had right-sided lesions.[3] Disorders involved with perceptual dysfunction are body image disorders, spatial relations disorder, agnosias (inability to recognize incoming information), and apraxia (lack of voluntary, controlled movement). Ipsilateral pushing, where the client leans to his or her hemiplegic side is much less common, but is also found in the realm of perceptual impairments.

Cognitive impairments are revealed in lesions anywhere in the brain and comprise problems with attention, memory, and decision-making functions.[3] Affective disorders are found with lesions in the right hemisphere and impact emotional functioning. They can experience extreme mood changes varying from intense laughing to uncontrollable crying. These variations often lead to depression, which is found in 33% of all cases. Clients with left sided lesions are found to commonly be apprehensive, guarded, and disorganized while those with right sided lesions are often described as sudden and impulsive who have difficulties with grasping the concept of an idea in its entirety and in spatial-perceptual tasks.

Other impairments, such as seizures are produced in a small percentage of people who have had a CVA.[3] These can tend to be life threatening and are controlled with anti-

seizure medications as soon as they are discovered. Problems with bowel and bladder are more frequent during the acute phase and tend to get better as rehabilitation continues. Physical activity is thought to help these problems and is controlled in early stages with toileting schedules.

Indirect impairments can be just as serious as those direct impairments mentioned above.[3] Some indirect impairments include deep vein thrombosis, skin break down, and decreased flexibility from loss of voluntary movement and immobilization. Shoulder subluxation and pain may result from flaccidity of muscle and ligaments surrounding the joint capsule. Regional pain complex occurs in 12 to 25% of clients and is a problem with the autonomic nervous system. Regional pain complex is defined as pain from an unidentifiable source than can occur in one or all four of the extremities.

In an article done by Patel, Coshall, Rudd et al,[8] the factors associated with cognitive impairments were discussed. Age, sex, ethnicity, socioeconomic class, past medical history, initial impairments, and level of consciousness were all taken into consideration. The factors found to be independently associated with cognitive impairments were as follows: older than 75 years, ethnicity, low socioeconomic class, left hemisphere lesions, urinary incontinence, and visual field defects. The study also showed that if cognitive impairments exist three months post stroke, this could be associated with a poor long-term outcome, greater severity of disabilities, and higher institutional rates.

Neurological impairments were taken into consideration in another study done by Han, Law-Gibson, and Reding.[9] This study focused on the impact on function related groups outcomes. It was found that key neurological impairments had an effect on

functional independent measure (FIM) scores completed at discharge from their hospital stay. These key impairments included motor, somatosensory, and hemianopic visual impairments. With greater number of these key neurological impairments established, a less complete neurological recovery was expected.

Functional Limitations Accompanying a CVA

Functional limitations are defined as the inability of the individual to perform a task or activity in the way that it is usually done.[10] Many functional limitations can occur as a result from a CVA. A person who has experienced a CVA may have difficulties with many of the activities that he or she was able to do before the incident occurred. Several lifestyle adjustments may be necessary in order to accommodate to the changes that have affected his or her body.

Rozzini et al[11] performed a study on the effect of chronic conditions, including CVA, on physical functioning. They assessed their subjects by giving them the Katz Basic Activities of Daily Living (BADL) and the Lawton and Brody Instrumental Activities of Daily Living (IADL) scales to complete by self-report. The Katz BADL scale assesses bathing, dressing, toileting, mobility, continence, and feeding. The Lawton and Brody IADL scale evaluates using the telephone, using transport, managing money, shopping, taking drugs, cooking, housekeeping, and doing laundry. The final three items on this IADL scale were not taken into consideration for elder men living with their wife or for women who have had their housekeeping done by another person. All subjects were also tested using the Physical Performance Test (PPT). This test consists of performing timed tasks simulating activities of daily living, including eating, turning 360 degrees, writing a sentence, walking 15 meters, etc. A score of zero would indicate the

worst performance and a score of 28 would be the best performance. Of the results obtained on the BADL scale, almost three-fourths of the population reported they were independent in all activities, with the remainder of the people being dependent in one function or two or more functions. Reports of the IADLs included almost half of the subjects independent in all activities, one-fifth were dependent in one function, and one-third were dependent in two or more functions. Almost half of the subjects scored greater than 20 on the PPT, with one-third scoring in the range of 11 to 20 and the rest of the subjects scoring less than 11. The authors compared the results from the self-reported tests to the results of the PPT. The outcomes demonstrated that the chronic diseases including CVA, Parkinson's Disease, and heart diseases were associated with a lower PPT score, illustrating decreased functioning, however, these subjects did not report any problem in their ADLs. The authors discuss that this may be due to the compensatory tactics, which a person with a chronic condition may use. Additionally, the client may not take into account that he or she may require more time to accomplish an activity.

Another study done by Mayo and company[12] looked at functional limitations of people who have had a CVA as compared to people who did not. People who had experienced their first CVA were given a telephone interview every six months for two years following the incident. Telephone interviews were also given to people in the same age group who did not have a CVA every six months for two years. Of those people who have had a CVA, many stated that they experienced a limitation in functional activities. A little more than half reported a limitation with high-level activities, such as housekeeping and shopping, and well over half mentioned that they had difficulty re-entering community activities. All those interviewed by telephone were also given the

Medical Outcomes 36-Item Short-Form health Survey (SF-36). Those who had experienced a CVA rated their physical health seven points lower than those who had not had a CVA. The people who had experienced a CVA demonstrated that seven out of the eight subscores on the SF-36 were affected by their condition. It was also noted that approximately half of those who experienced a CVA required a caregiver or some other form of home health for their activities of daily living. Many of the people who had a CVA also stated that they felt that this had a lack of significant activity and that there was a need for CVA support groups to prevent depression, prevent decreased function, and improve quality of life.

Disability Resulting from a CVA

Disabilities are defined as any physical, mental or functional impairment that limits a major activity.[4] Several of these functional limitations can result in a disability in a person who has had a CVA. The difficulties that he or she has with activities of daily living may cause problems for this person in his or her family, social life, and community. For example, if a person who has had a CVA has difficulty using transportation, he or she might not be able to go to the grocery store without assistance from another person. A person may not even be able to live on his or her own if they are unable to perform several of the tasks that are required for daily living.

A person who experiences a CVA may have many social issues to deal with following discharge from a rehabilitation facility. Teasell, McRae, and Finestone[13] did a study on social factors and outcomes in people who have had a CVA who are under the age of 50. The researchers investigated marital and employment status upon admission into the hospital and at three months following discharge, discharge destination, number

of children who were under the age of 16, and psychosocial difficulties observed by the staff at the hospital. Of those discharged, less than one-fifth of the subjects with spouses were separated within three months of discharge, were unable to live in the previous home, and were placed in an institution. At three months following discharge, only one-fifth of the subjects were able to return to work and less than 10% of them who previously worked full time, were able to return to this status. The authors concluded that several unique social problems such as relating to peers occur with the onset of a CVA in this young age group.

The welfare of people who experienced a CVA and who live in the community was studied by Clarke, et al.[14] The authors analyzed the results from a previous study called the Canadian Study of Health and Aging, which was termed a second wave (CSHA-2). A portion of this study included the administration of the Ryff Measure of Psychological Well-being, measuring self-acceptance, autonomy, environmental mastery, purpose in life, personal growth, and positive relations with others. The subjects rated themselves on the items in these areas from "strongly agree" to "strongly disagree". Subjects were also asked about information on demographics, health, and socioeconomic factors affecting their lives. The subjects' cognitive function was also assessed using the Modified Mini-Mental State Examination. It is scored from 0 to 100, with a higher score meaning higher cognitive function. Each subject was also questioned on seven of his or her basic activities of daily living and seven of his or her complex instrumental activities of daily living. Subjects were given a score of two if they could carry out the activity independently, a one if they needed some help, and a zero if they could not perform the activity. All scores were added together, with a highest possible score of fourteen in each

category. A higher score meant more independence in function. Subjects were also questioned regarding their education, annual income, and social support. They were asked how many people they could depend on for help, if needed. Depression was assessed using five of the questions on the SF-36. A higher score on these five questions indicated better mental health. The authors concluded that a CVA could significantly compromise the well-being of the person who experiences it. Additionally, he or she may experience more difficulty with ADLs, feel as though he or she has lost control of his or her life, and have fewer perceived opportunities for personal growth. Decreased cognitive function can also have a negative impact on how a person who has had a CVA functions. However, it was found that those who had more educational background did not have as many adverse effects as a result of a CVA. Also, those who have more social support were more likely to have a better sense of well-being than those who do not have the social support. The authors did conclude that there was a decreased well-being amongst those who have had a CVA.

There are a variety of issues to deal with when a person has a CVA. Many new functional limitations are presented as well as the disability that occurs as a result of these new concerns. Many adaptations need to be made in order to ensure a person with a diagnosis of CVA can return to the quality of life that he or she was experiencing prior to the incident.

Focus of Rehabilitation

Balance

When a person has a CVA, his or her balance can be greatly affected. This is especially common when a hemorrhage occurs in the cerebellar region of the brain.[15]

Balance is essential in many of the normal activities of daily living, and when balance is affected, people who have had a CVA have difficulty with many everyday activities that they were able to do before the incident.

There are many ways that physical therapists help to retrain balance in people who had a CVA. It is uncertain which method is the most beneficial since one method may benefit an individual client and not help another. The investigators will discuss several studies that have been done on retraining balance in people who have had a CVA and/or are elderly.

It has been in question whether conventional physical therapy methods versus other methods of instruction are more appropriate when retraining balance in a person who has had a CVA. Geiger et al[16] investigated the difference in people's balance following a CVA when conventional physical therapy was done versus conventional therapy and force plate training and biofeedback on the Balance Master. Each group underwent 50-minute training sessions two to three times per week. Those that were included in the Balance Master group had 35 minutes of conventional therapy and 15 minutes of force plate training. The conventional therapy consisted of mat activities (stretching & strengthening), weight-shifting, lower extremity exercises in the parallel bars, and balance activities (rocker-board, unilateral stance, braiding, balance beam, etc.). Measures of balance were taken initially and after four weeks of treatment using the Berg Balance Scale and the Timed "Up & Go" Test. Significant improvement was shown on both scales in both groups, but neither group progressed further than the other.

Another method of rehabilitation following a CVA includes the use of visual feedback when attempting to regain balance. Walker, Brouwer, and Culham[17] used the

Balance Master to provide visual feedback to the client about his or her center of gravity in addition to his or her conventional physical and occupational therapy based on a neurodevelopmental approach. These results were compared with the results of those receiving just balance training in addition to his or her conventional physical and occupational therapy based on an NDT approach. The control group was receiving the conventional physical and occupational therapy based on the NDT approach. The additional training in the first two groups was given for 30 minutes a day for five days a week for three to eight weeks, depending on the length of stay in the rehabilitation center. Each subject was scored on the Berg Balance Scale, Timed "Up & Go" Test, and gait speed at the beginning of the study, after completion of study, and at one-month follow-up. The baseline measures indicated similar ability across the three groups. All three groups improved in the Berg Balance Scale, Timed "Up & Go" Test, and gait speed by the end of therapy and again at the one-month follow-up. However, no single group demonstrated marked improvement over another. Visual feedback did not advance the progression of regaining balance as predicted by the authors.

Verbal instructions are very commonly used during therapy sessions. It is a concern that this may interfere with a client's ability to concentrate on the task at hand. Bowen and company[18] studied the effect of dual tasking while walking on clients' balance and velocity after he or she has experienced a CVA. They used the GaitMatII to measure double support time (DST), the time a client spends with both feet on the ground during walking, as a measure of balance and gait speed. All participants in the study performed trials of just walking and trials walking while saying 'yes' or 'no' as instructed before beginning. If DST as a percentage of stride time increased, a client's balance was

found to be decreased. DST as a percentage of stride time and gait velocity was found to be significantly decreased in most clients during the dual-task activity of walking and talking. However, there was no control group for this study and there may be other contributing factors to the decreased balance and velocity found.

Yet, another approach to retraining balance in clients who have had a CVA includes the use of body weight support while walking. Nilsson et al[19] did a study comparing body weight support while walking on the treadmill versus walking on the ground without support. The treatment group walked on the treadmill with body weight support for 30 minutes five days a week. They were given manual assistance as needed. The control group was given walking training for 30 minutes a day five days a week using the Motor Relearning method, which consisted of transfer training, range of motion exercises, and strengthening. Both groups were also given an additional 30-minute rehabilitation session five days a week. The following measures were taken initially one time per month until discharge, and 10 months following the CVA: Fugl-Meyer Stroke Assessment, Functional Ambulation Classification (FAC), walking test for ten meters, and Berg Balance Scale. Both groups improved significantly in all assessment areas between initial assessment and discharge. Improvements were made until the 10-month follow-up but were not as significant. The authors concluded that these two methods of treatment are comparable choices to use in the rehabilitation following a CVA.

A study of balance training for people who are elderly done by Wolf and company[20] suggested that an individualized exercise program improved functional balance. They divided their subjects into two groups. The experimental group had an exercise program to retrain their balance that was developed specifically for each subject

within the group based on the system approach. This program included balance activities in sitting and standing, as well as during activities of daily living. These subjects were seen for a total of twelve sessions each. The control group also had individual activity for each subject, but it did not contain balance training. These individual activities consisted of handicraft, music, board games, discussion groups, etc. The Berg Balance Scale and the Dynamic Gait Index were given to each subject initially, after the study was done, the fourth week following the study, and at a one-year follow-up. The results demonstrated that an individualized exercise program to train balance can be very effective and remained effective through the four-week follow-up. However, at the one-year follow-up the improvement found had diminished, suggesting that ongoing training may be required to maintain balance in people who are elderly.

Gait

A recent study done by Friedman[21] stated that immobility the first weeks following a CVA is common. Approximately 27% of those who experience a CVA walk within the first week. After three weeks, 60% walk independently. By the time the six-month mark comes, 85% are able to ambulate on their own. Although they may be able to walk independently, many times they do not have the correct gait pattern. The normal gait pattern is often altered due to a number of factors following a CVA including impairments in mobility, sensation, perception, and motor control. The restoration of gait is one of the main goals during rehabilitation and achieving a functional gait pattern is essential to the safety and well being of the patient. For those who only achieve a partial recovery, problems often remain with ambulation and completion of their activities of daily living.

In people with a normal gait pattern, a certain sequence of repetitive movements is attained.[22] The gait cycle is divided into two phases, stance and swing, as well as two periods of double support where both extremities are in contact with the ground to exchange the weight of the body. The stance phase makes up 60% of the gait cycle and is divided into initial contact, foot flat, midstance, heel off, and toe off. The swing phase constitutes the other 40% and is divided into three phases including acceleration, midswing, and deceleration. Any alteration of the joint rotation or time spent within each phase can cause a major deviation in the way a person ambulates.

For people who have experienced a CVA, their gait pattern is almost always altered.[3] The uninvolved leg will exhibit a shorter step length while the weaker, affected leg has a longer one. This causes the gait to become asymmetrical and a number of deficits may occur at each section of the body. Typically there is poor pelvic rotation with inadequate hip flexion causing the individual to hike his or her hip. This substitution allows the individual to clear the swing phase portion of his or her gait. Poor ankle dorsiflexion is also seen which can cause foot drag and a decrease in heel strike.

There are many different treatment approaches a physical therapist can choose from to assist his or her clients in achieving independence. Many studies have examined the outcomes of different intervention approaches to ensure the best rehabilitation potential for those who have experienced a CVA. These different intervention approaches include but are not limited to: treadmill training, conventional intervention including traditional exercises and functional activities, proprioceptive neuromuscular facilitation techniques, the NDT approach, motor relearning, partial body weight support treadmill training, and electrical stimulation.

Treadmill training is commonly used in therapy for the rehabilitation of clients with hemiparesis and an impaired gait pattern. However, the type of treadmill training to use is sometimes in question. In a study conducted by Marcus, Mehrholz, Ritschel et al,[23] a randomized control trial was completed on patients with hemiparesis to compare the effectiveness of speed-dependent treadmill training (STT) against limited progressive treadmill training (LTT) and conventional gait training (CGT). The goal of STT was to increase the clients walking time each session. Their maximum speed was found and then halved for a warm up session. The speed was then increased to the highest setting tolerable by the client. If the client maintained that speed and felt comfortable then it would increase by 10% for 10 seconds during the next attempt. LTT was similar but never progressed more than 5% of their maximum walking velocity each week. CGT was based on the principles of proprioceptive neuromuscular facilitation and NDT concepts by skilled therapists. After six weeks of training, the trial suggested that the speed-dependent training is more effective in improving gait parameters than training without any specific changes in speed. Although the results of this study demonstrated that STT was superior to others in gait velocity, it still cannot replace conventional rehabilitation. It should always be used in conjunction with other strategies because of the task specific nature of the technique.

Many exercise programs are used during the rehabilitation process. Langhammer and Stanghelle[24] compared the NDT concept versus motor relearning to determine if either method caused a difference in the outcome in rehabilitation after an acute CVA. To determine their effectiveness, the following parameters were used: length of stay in the hospital, use of assistive devices for mobility, and the client's accommodation after

discharge from the hospital. Although there was no significant difference in the use of assistive devices or accommodation after discharge, there was a difference in the length of stay at the hospital. Those who received motor learning stayed on average 14 days shorter than those using the NDT concept.

In another study done by Dickstein, Hochemar and Pillar et al,[25] three different exercise approaches were examined to determine the best therapeutic benefit for a client who experienced a CVA. The three treatments consisted of the following: conventional intervention including traditional exercises and functional activities, proprioceptive neuromuscular facilitation techniques, and the NDT approach. Following six weeks of treatment, the client's walking ability was re-assessed. It was concluded that there was no significant difference in the outcome of rehabilitation between the three different strategies. Since there was no difference between these interventions, more studies are needed to further investigate the optimal therapeutic procedure provided for a person who experiences a CVA.

Conventional physical therapy relies on the use verbal instructions, gait initiation and turning, postural alignment, balance reactions, and interventions for specific components of the altered gait. In a study done by Lison, Mickelborough, Harris, et al[26] a comparison of conventional physical therapy and treadmill training without partial body weight support for higher-level gait disorders for those who experienced a CVA was completed. Although there were trends to suggest that treadmill re-training would have better outcomes, results found there be no difference between the outcomes of these two types of interventions. They did suggest, however, that more trials be conducted because of the small group size in this study.

Another study completed by Hesse, Bertlelt, Jahnke, et al[27] also compared treadmill training this time with a partial body weight support and physical therapy in non-ambulatory clients who have hemiparesis. In this study, physical therapy was considered a combination of neurofacilitaion techniques such as the Brunnstrom technique with synergistic movements, proprioceptive neuromuscular facilitation with spiral and diagonal movements and neurodevelopmental therapy with reflex inhibitory movements. Each of these methods are complicated and do not focus on gait. The treatment approach was done in the following procedure: thirty minutes of partial body weight support treadmill training, followed by forty-five minutes of physical therapy as explained above and ended with another thirty minutes of partial body weight support treadmill training. It was concluded that treadmill training was more effective than physical therapy when looking a gait recovery and walking velocity. Like the previous study, based on the sample size it was suggested that more studies with a variety of treatment parameters be conducted to ensure that partial body weight support treadmill training could become an effective tool in regaining walking ability in a shorter time.

In another study prepared by Filho, Lim, Qureshy, et al,[28] there was a comparison of regular rehabilitation and traditional rehabilitation with supported treadmill ambulation training for clients who suffered an acute CVA. Regular rehabilitation was defined as regular session of physical therapy, kinesiotherapy and occupational therapy three hours daily. Physical therapy primarily worked on general strengthening and function as well as mobility issues. Clients underwent kinesiotherapy to help increase strength and endurance, while occupational therapy concentrated on activities of daily living. The results demonstrated those involved in supported treadmill ambulation training had a

higher oxygen consumption compared to those who completed only regular rehabilitation. No other physiologic or functional measurements were found. This study also suggested that larger trials were needed to determine the value of this intervention.

Since one of the main focuses of rehabilitation following a CVA is gait, a study done by Visitin, Barbeau, Korner-Bitensky, et al[29] examined retraining gait through body weight support and treadmill training versus treadmill training alone. The strategy during this study focused on a straight trunk and limb alignment along with proper weight shifting and weight bearing of the hemiparetic limb during stance phases as well as being able to advance the limb forward during swing phases. The study lasted six weeks, with sessions four times per week. The results demonstrated that gait training on a treadmill with partial body weight support resulted significantly better in balance and walking abilities than that of treadmill training alone. Approximately 79% of the clients progressed to at full weight bearing by the end of the six-week period. Although an increase in balance and walking abilities were obtained, the article suggested further studies should be done to perfect the art of partial body weight support treadmill training in combination with other rehabilitation strategies.

Recapturing independence after a stroke is a main priority for those who want to get back to a functional life. Gaining the knowledge necessary to give the best rehabilitation possible to those who experience a CVA is critical to achieving a functional gait pattern as soon as possible. Once this task is achieved, the increased safety and well being of these clients will enhance the quality of their life and allow them to reclaim their independence.

Partial Body Weight Support Training

Losing the ability to ambulate is an extremely incapacitating effect that occurs as a result to a neurological disorder such as a CVA. As one of the most fundamental motor tasks, this functional limitation is a devastating reality for many people.[30] The initiation of gait retraining is often slow and controlled following an extensive period of strength training, tone inhibiting maneuvers and training of balance.[31,32] Gait training in these individuals typically utilizes techniques such as NDT, proprioceptive neuromuscular facilitation (PNF), Brunnstrom, motor control, neurophysiology, and clinical observation to accomplish the individual tasks needed to ambulate.[33] However, these techniques are limited to the deficits their diagnosis, biomechanical and neurological, and exclude gait practice as a whole.[27,33] Often deficits exclude training in a well-defined and task-specific environment. For example, gait training is commonly broken down into individual components such as heel strike, weight acceptance, stance phase, toe off, and swing phase. Poor muscular activation hinders the client's ability to ambulate effectively after he or she has experienced a neurological deficit.[34] Individual muscles are recruited throughout the gait cycle that are often separated and worked on independently. Individualized muscle strengthening however has not been found to be effective in gait retraining.[27,35] Research shows that muscles are better trained in a more functional environment to facilitate movements needed to complete the task of ambulation. By reducing these preparatory activities clients can begin gait retraining sooner, and can increase the degree of mobility.[32]

In the past few decades, attention has been given to a new approach in gait training of clients with a multitude of diagnoses including neurological disorders. This

new approach allows simultaneous retraining of various aspects of ambulation. Earlier initiation of gait retraining is also allowed through stabilization of the trunk via the partial body weight support harness. Finch and Barbeau[34] suggest that removal of body weight allow gait patterns to surface. Body weight supported gait appears to present sequential and kinematic patterns that are beneficial in gait retraining. Decreasing the weight bearing decreases the amount of stretch put on a muscle. Controlling the weight bearing status then in turn controls the stretch allowing the client to work in his ability level. With balance and posture provided from the harness, the client is free to feel safe, thus allowing his attention to be focused primarily on walking.[35] However, the ability to load the affected limb can be accomplished gradually at the client's speed by decreasing the BWS.

Partial body weight support (PBWS) treadmill training has been found to be effective in populations diagnosed with a neurological impairment. Outcomes include increases in gait symmetry, velocity, postural control, cadence, and stride length.[30,32,35] Other results include a decrease in the stance phase of the unaffected limb while the swing phase of the affected limb is prolonged.[35] In a single subject study by Gardner et al,[36] PBWS treadmill training was found to increase gait speed with an average of 70% in an individual with a spinal cord injury. Factors that have been found to influence locomotor capacities maximally are as follows:

1) Increased loading ability of the lower limbs is facilitated in PBWS
2) A decrease in manual assistance needed
3) Swing phase of the gait cycle facilitated through the unloading ability of the limb at the end of the stance phase

4) Without the use of an assistive device such as parallel bars, quad cane, or a walker allows a reciprocating arm swing which in turn facilitated stepping.[37]

In the population of persons diagnosed with CVA and resultant hemiplegia, PBWS has been found to be especially effective.[38] This new treatment strategy targets simultaneous muscle activation to allow all the components of the gait pattern to occur in the proper order. Weight bearing tolerance and weight acceptance can also be facilitated in PBWS with treadmill training. In a study done by Hesse et al,[27] treadmill training with PBWS was found to restore gait ability and walking velocity. Other motor functions have also found to be improved through use of PBWS treadmill training. Standing balance, stride length, stance time on the affected limb increased while it decreased on the unaffected limb, over ground walking speed also increased.[32,34,39,40] Symmetry was noted throughout the gait cycle as well in a number of studies.[27,41,42] Additionally, Hesse et al[27] noted the client's ability to sit up, stand up, and transfer improved.

With conventional therapeutic interventions regarding gait retraining, considerable efforts have been made by therapists to facilitate ambulation. Therapists have been involved with helping clients balance and maintain postural control.[32] Treadmill training with PBSW significantly decreases the amount of assistance the client requires as he or she completes the gait cycle by providing trunk stabilization.[27,39] PBWS treadmill training also allows the ability for numerous repetitions to be completed within the gait cycle to occur early on in the rehabilitation process.[41]

PBWS may normalize the gait patterns of clients with neurological deficits enhancing the chance of full recovery of locomotion.[34,41] In a study by Visintin et al,[32] the benefits of gait retraining with partial body weight support were derived from the

effects of body weight support. With PBWS treadmill training, clients are allowed to practice a more favorable and appropriate gait pattern. Relief of balance problems and fall risks allows spasticity and synergies to be avoided. This allows the correct muscular pattern to be trained efficiently and consistently.

A person's life is greatly affected following a CVA. The pathology, impairments, functional limitations, and disabilities all result in profound changes in a person's physical, emotional, and social life. Accomplishing many of the activities of daily living require key components, which encompass balance and gait. Partial body weight support treadmill training systems have been shown to improve these factors therefore influencing a person's daily functional tasks. Based on the findings of the previously mentioned studies, further research is warranted to better educate rehabilitation teams to enhance the recovery period following a CVA.

CHAPTER 3

METHODOLOGY

Final approval for this study was received from Altru Health System Institutional Review Board for the use of human subjects. Copies of the Human Subjects Review form and application form to conduct research at Altru Health Systems facilities are located in Appendix A. During the recruitment of subjects, all individuals were informed of the components of the study as well as the criteria for inclusion. All the subjects were informed that participation in this study was strictly voluntary and they may withdraw at anytime without prejudice. Each subject signed the consent form before participation in this study. The consent form informed subjects of the requirements for participation, and the risks and benefits of this study. The results of this study will be secured in the Physical Therapy Department at the University of North Dakota. Unless these records are required for future studies, they will be destroyed three years following the completion of this study. A copy of the consent form is located in Appendix A.

Subjects

In order to study the effects of partial body weight support on gait for patients with neurological dysfunction, this case study describes four subjects. Cindy Flom-Meland MPT, a physical therapist at Altru Health Institute in Grand Forks, ND and instructor within the Department of Physical Therapy at the University of North Dakota, recruited these subjects. The criteria required to participate in this study consisted of the following:

1. Subject must be older than 20 years of age and weigh less than 250 pounds.
2. Subject must have a neurological diagnosis, such as stroke, traumatic brain injury, multiple sclerosis, etc.
3. Subject must be living in the community.
4. Subject's blood pressure must be within normal limits. A blood pressure of 160/90 mmHg or less was used as an acceptable guideline noted by a blood pressure screen.
5. Subject must be able to attend both initial and final testing sessions, as well as a majority of the training sessions.
6. Subject must have an understanding that this study is a large time commitment (six weeks) and is strictly voluntary.

The four subjects who participated in this study all have the neurological diagnosis of Cerebral Vascular Accident (CVA). They ranged in age from 50 to 78 years old. A history of each subject is located in Appendix B.

Instrumentation

Data was collected from the initial and final testing sessions. Each subject completed the Berg Balance Measure, a 10 meter timed walk, the gait portion of the Tinetti Assessment Tool, and a template recording of each subject's footprints during ambulation for both the initial and final testing sessions. The initial testing session also included a blood pressure screen and measurement of weight for each subject. Following the initial testing, subjects received body weight support (BWS) treadmill gait training for six weeks on the LiteGait™. Each subject was assigned to one student researcher that

performed both the testing and BWS treadmill gait training to ensure the best accuracy and reliability in the results. Below is a description of the assessment tools used.

Blood Pressure and Measurement of Weight

Blood pressure and weight were assessed during the initial testing session. The Critikon Dinamap 8100, a standardized blood pressure machine from Altru Health Institute, took each subject's blood pressure. A reading of 160/90 mmHg or less was considered acceptable and was used as the guideline for participation in this study. Each subject was also weighed on a standard scale from Altru Health Institute. All subjects were required to weigh less than 250 pounds to participate in the study, and their weight was used to determine the appropriate amounts of body weight support during BWS treadmill gait training.

Berg Balance Measure

The Berg Balance Measure is a test that was designed to measure the subject's level of balance.[43] This test consists of fourteen balance tasks that the subjects must perform. Each task is then scored on a five point ordinal scale. A score of zero indicates the subject is not able to perform the task and a score of four indicates the subject is able to perform the task independently. Each score is then added together to achieve a total score. Thus the higher the score the more independent the subject is. The researchers chose this test because it is highly reliable. The Berg Balance Measure is found to have a value of .96 for Cronbach's alpha and a range of .72 to .90 for task to total correlations. These values indicate a high level of reliability and that the total score provides a stronger measure of balance than each individual task. A copy of this test is located in Appendix C.

10-Meter Timed Walk

The 10-meter timed walk test was selected to measure each subject's gait velocity. Ten meters were marked on a hard flat surface by two pieces of tape. The subject was instructed to stand behind the first piece of tape with their head forward and to begin walking. The researcher used a standard stop watch to determine the amount of time it took the subject to walk from the first piece of tape to the second piece of tape that was 10 meters away. The subject was informed before the test that this test was being performed to determine the speed in which they are able to ambulate.

Tinetti Assessment Tool

The Tinetti Assessment Tool measures gait and balance. The test is scored by a person's ability to perform individual tasks.[43] For this study, the researchers had the subjects complete only the gait portion of the test. This test uses a three point ordinal scale to score each specific task. A score of zero indicates the most impairment, and a score of two indicates independence in that specific task. The individual scores are then summed together to create an overall gait assessment score. The maximum score for the gait portion of the test is twelve points. The Tinetti Assessment Tool has been found to have good interrater reliability. A study was performed on fifteen patients in which a physician and a nurse administered this test at the same time. They agreed on a score for over 85% of the specific tasks and when they differed it was never by more than 10%. A copy of the gait portion of the Tinetti Assessment Tool is located in Appendix C.

Template Recording of Footprints

A template recording of each subject's footprints was used to determine stride length, step length, walking angle, and base of support. This was accomplished by having

the subject walk across a WriteStep™ that displayed each footprint. The subject was instructed to stand several feet behind the WriteStep™ and begin ambulating across the entire mat with his/her head facing forward. Then using a tape measure and goniometer, an average of the stride length, step length, walking angle, and base of support were determined for each foot. A diagram of how each measurement was determined is located in Appendix C.

LiteGait 1™

The LiteGait 1™ is a partial weight bearing gait therapy device that is used to improve balance, posture, and gait.[44] This device is used to keep people in a proper upright position and in an environment free from falling during ambulation. This device enables the person and therapist to concentrate on improving gait at an earlier stage in the rehabilitation process. The LiteGait 1™ is used to enable therapists to observe gait patterns, and make manual adjustments such as limb placement, symmetry, weight shifting, and gait timing. The LiteGait 1™ can be used over ground or with a treadmill. In this study, the researchers used the LiteGait 1™ in conjunction with a GateKeeper™ treadmill at Altru Health Institute. The LiteGait 1™ consists of five important features.

1. Yoke: A Y-shaped piece with four buckles that supports the subject from over each shoulder, maintaining his/her balance and posture.
2. Overhead Straps: Four adjustable straps that may be used to correct an asymmetric upper body posture.
3. Harness/Groin Strap: Securely wraps around the subject's pelvis. It allows the subject to transfer weight into the abdomen and groin area while still allowing full leg extension for walking.

4. Base: The base has wheels and is designed to fit over treadmills and walking on ground.

5. Actuator/BiSym: The actuator is the lift function that raises and lowers the yoke and the BiSym is a box on top of the actuator that provides a display of the pounds of support the actuator is lifting for each arm of the yoke.

A diagram of the LiteGait 1™ device is located in Appendix D.

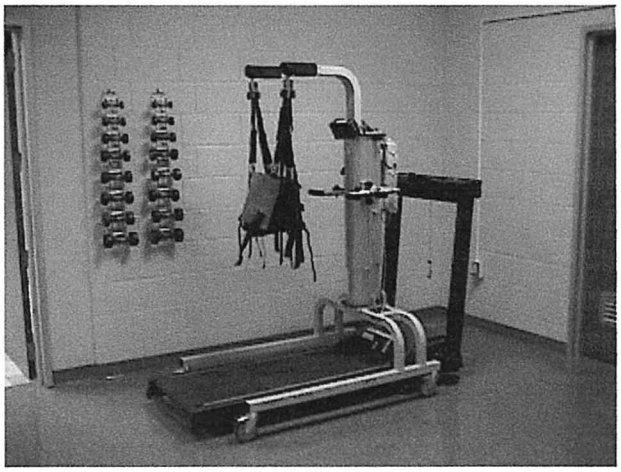

Figure 1. Photograph of the LiteGait 1™

Procedure

After recruiting the four subjects for this study, each subject was assigned to a student researcher. All subjects initially completed the Berg Balance Measure, 10-meter timed walk test, the gait portion of the Tinetti Assessment Tool, and a template recording of the subject's footprints. A baseline for heart rate and blood pressure was also recorded. Following the initial testing, each subject participated in BWS treadmill gait training two to three times per week for six weeks. Each session consisted of three bouts of ambulation using the LiteGait 1™ with a five-minute rest break between bouts. Duration of each bout of ambulation was determined by the subject's tolerance or to a maximum of

ten minutes. Initially, 40% of each subject's body weight was supported during the BWS gait training. The treadmill was started at .5 mph. There were three levels of body weight support (40%, 20%, and 0%) and treadmill speed (.5mph, .7mph, 1.0mph). A decrease in body weight support to the next level was made when the subject demonstrated fairly symmetrical step length, cadence, foot clearance, and the ability to support weight on the affected limb without buckling. The speed was increased to the next level when the subject demonstrated adequate endurance, which was measured by the tolerance of walking at least five minutes in at least two of the three bouts of ambulation. Any changes in body weight support or speed were always initiated at the next session. At the end of six weeks, all subjects completed the final testing. The final testing session consisted of the subjects repeating the same tests given during the initial testing session. All testing and gait training sessions were completed at Altru Health Institute.

Data Collection

Data was collected during initial testing, final testing, and each session of Partial Body Weight Support Treadmill Training (PBWSTT). The researchers created a form to record this data. This form kept record of the subject's results for the Berg Balance Measure, 10-meter timed walk, Tinetti Assessment Tool, and measurement of footprints for initial and final testing sessions. The subject's blood pressure, heart rate and weight were also included. For each PBWSTT session, the time and distance walked, percent body weight supported, speed, and technique and facilitation points were recorded for each bout of PBWSTT. A copy of this form is located in Appendix E.

Data Analysis

Simple descriptive statistics were used to analyze the data for this study. Comparisons were made between the scores from the initial and final testing results. Simple addition and subtraction were used to determine if the subject's scores had improved following six weeks of PBWSTT. Each subject's qualitative results were based on observations by the researcher and the progression noted on the data record form. The data record forms revealed the subject's progression by the change and or reduction of facilitation. Changes in endurance, speed, and body weight support were determined by simple subtraction to identify the differences between bouts and or sessions of PBWSTT.

Reporting of Results

Upon completion of this study, a summary of the results were given to the University of North Dakota Physical Therapy Department, the Harley E. French Library of Health Sciences, and to all researchers and subjects that participated in this study. This study was completed as partial fulfillment of requirements needed for the University of North Dakota School of Medicine and Health Sciences Physical Therapy Program.

CHAPTER 4

RESULTS

All subjects demonstrated better scores in one or all tests at the final testing date (Table 1). Initial testing scores of each subject are recorded in Table 2. Individual final testing scores are shown in Table 3. The greatest improvements were seen in the ten-meter timed walk (seventy-five percent), the gait assessment followed (fifty-two percent) and balance (twelve percent) (Table 1). All subjects showed improvements in their foot template measurements dependent on their impairments demonstrated at the beginning of the six-week trial (Tables 4-7).

Table 1. Percent Change of Improvements

	Berg Balance	Tinetti-Gait Portion	10-Meter Walk
Subject A	2%	0%	15%
Subject B	0%	7%	-15%
Subject C	0%	25%	15%
Subject D	10%	20%	58%
Total	12%	52%	75%

Table 2. Test Scores Prior to 6-week trial

	Berg Balance	Tinetti-Gait Portion	10-Meter Walk
Subject A	48/56	8/12	21.40 seconds
Subject B	54/56	11/12	7.06 seconds
Subject C	49/56	9/12	14.03 seconds
Subject D	45/56	8/12	27.29 seconds

Table 3. Test Scores Following 6-week trial

	Berg Balance	Tinetti-Gait Portion	10-Meter Walk
Subject A	49/56	8/12	18.18 seconds
Subject B	54/56	12/12	8.27 seconds
Subject C	49/56	12/12	11.92 seconds
Subject D	50/56	10/12	15.72 seconds

Subject A improved by two percent in balance and fifteen percent in gait velocity (Table 1). No improvements were made quantitatively in gait assessment. Step length increased and became more consistent and symmetrical (Table 5). Stride length also increased (Table 5). Her walking angle increased by one degree and her base of support increased by two percent (Table 6 & 7).

Subject B showed the strongest improvement in gait assessment by seven percent (Table 1). However, his ten-meter timed walk decreased by fifteen percent and there were no changes in his balance abilities (Table 1). Stride length increased and also became equal bilaterally (Table 4). Step length became more consistent as well as symmetrical (Table 5). His base of support decreased by thirty-three percent and his walking angle improved to seven degrees bilaterally (Table 6 & 7).

Subject C showed great improvements in the gait assessment and ten-meter timed walk at increases of twenty-five percent and fifteen percent respectively (Table 1). Her balance showed no changes quantitatively. Step length and stride length increased however both became more asymmetrical (Table 4 & 5). Her walking angle decreased to within normal limits (three to four degrees) becoming more symmetrical as well (Table 6). Her base of support showed an eighteen percent increase (Table 7).

Subject D showed the most gains. He improved in all assessments; ten percent for balance, twenty percent for gait assessment, and fifty-eight percent in gait velocity (Table 1). Step length and stride length both increased in distance but became more asymmetrical (Table 4 & 5). His walking angle decreased on the right side by fifteen degrees (Table 6) while his base of support increased by thirteen percent (Table 7).

Change in Foot Template Measurements:

Table 4. Stride Length

	Before		After	
	Left	Right	Left	Right
A	61.5 cm	61.7 cm	64.5 cm	61.7 cm
B	108.0 cm	107.9 cm	114.3 cm	114.3 cm
C	82.87 cm	81.28 cm	87.0 cm	84.3 cm
D	41.67 cm	40.63 cm	52.63 cm	49.0 cm

Table 5. Step Length

	Before		After	
	Left	Right	Left	Right
A	41.8 cm	31.2 cm	29.5 cm	37.8 cm
B	59.0 cm	51.3 cm	54 .0 cm	57.0 cm
C	41.0 cm	40.3 cm	42.97 cm	44.35 cm
D	21.9 cm	18.8 cm	29.6 cm	19.48 cm

Table 6. Walking Angle

	Before		After	
	Left	Right	Left	Right
A	5°	5°	6°	6°
B	7°	5°	7°	7°
C	17°	13°	3°	1°
D	11°	24°	11°	9°

Table 7. Base of Support

	Before	After	% Change
A	14.5 cm	14.8 cm	+ 2%
B	15.24 cm	10.16 cm	- 33%
C	12.1 cm	14.81 cm	+18%
D	10.83 cm	12.4 cm	+ 13%

Results of this study were more apparent qualitatively than quantitatively. To better relay the improvements gained throughout this study each subject's qualitative results are provided below. Due to the methods in which the subjects were tested before and after the six-week trial, these results were not as evident quantitatively as qualitatively.

Qualitative Results: Subject A

This six-week trial involving body weight supported treadmill ambulation provided the subject with positive qualitative results such as a more symmetrical gait pattern, better timing and sequencing reduced the subject's tendency to over compensate for the affected limb. Due to the methods in which the subject was tested before and after the six-week trial, these results were not as evident quantitatively as qualitatively as the tests used to measure the improvements were not as sensitive as they needed to be as the subject was a high functioning individual prior to the trial.

The subject's results of initial testing were as follows: Berg 48/56, Tinetti 9/12, and ten meter timed walk of 21.40 seconds. Initial testing demonstrated an average left step length of 41.8 centimeters and left stride length of 61.5 centimeters. The average right step length was 31.2 centimeters and right stride length was 61.7 centimeters. Although the averages such as stride length seem symmetrical as in stride length, the three to four individual measurements for the right stride length were quite varied while the individual left stride measurements were consistent. The individual right stride measurements were 57,68,53, and 69 centimeters. Her base of support measured 14.5 centimeters and her degree of toe out was five degrees bilaterally.

Following the six-week trial, the same assessments were repeated. The subject recorded an improvement in balance and gait velocity with a decrease in the gait portion of the Tinetti. The Berg test was 49/56, Tinetti was 8/12, and the ten-meter timed walk was 18.18 seconds. Measurements were taken again as well for gait. Base of support had decreased to 14.8 cm and her degree of toe out had changed to six degrees bilaterally. The final average left step length was 29.5 centimeters and left stride length was 64.5

centimeters. The average right step length was 37.8 centimeters and the average right stride length was 68.1 centimeters. The individual measurements for the final right stride length were 74.6,61.4, and 68.3 centimeters. Although the averages demonstrate a more symmetrical gait pattern initially, the final individual measurements demonstrate that the subject's gait pattern became less varied and more symmetrical on the right following the six-week trial of body weight supported treadmill ambulation.

Throughout the six-week trial the subject demonstrated consistent and positive improvements throughout the duration of the experiment. She was able to complete all sessions walking ten minutes three times a session without rest. The subject initially started at 40 percent body weight supported and .5 miles per hour on the treadmill. The assistance of two people was needed to facilitate a correct gait pattern. One person's hands were placed on the heel and dorsum of the left foot to facilitate a heel strike, proper timing and prevent excess toeing out. The other person had hands on the ilia to stabilize the right hip and facilitate the left hip forward at heel strike. The subject also required consistent verbal cueing. Commands such as "keep your head up," "take a larger step on the right," and "take a wider step on the right," were frequent verbal cues used in addition to the manual facilitation. These techniques were only utilized for the first week of the six-week trial.

During the second week of the experiment, the subject's gait timing was better and facilitation was reduced to one person at the pelvis. Facilitation at the pelvis consisted of stabilizing the right hip and facilitating the left hip forward at heel strike. The subject continued the need for verbal cueing, but to a lesser degree. At the end of the second week, the subject was walking with a more symmetrical gait pattern and required

minimal assistance and cueing. At that point, the subject graduated to the next level. The subject began to ambulate at 20 percent body weight supported and .7 miles per hour on the treadmill.

The initial session at this new level required the assistance of two people once again. One person to facilitate a heel strike, correct timing, and prevent excessive toe out on the left, and the other person to facilitate at the pelvis. Following the initial session at this new level, the subject demonstrated continued, gradual improvement. Assistance was once again only needed at the pelvis and verbal cues were minimal. The subject stayed at this level for weeks three and four of the experiment. At the end of week four, the subject was demonstrating symmetrical steps, and correct timing and patterning with minimal assistance and verbal cues.

At the start of week five the subject was placed at the next level, zero percent body weight and 1.0 mile per hour. At this new level, the subject required facilitation at the pelvis and the toes on the left appeared to drag, however, following this initial session the subject demonstrated improvement. The subject's toes did not drag as often and only stabilization at the pelvis was needed to facilitate a normal gait pattern. The subject remained at this level for the remainder of the six-week experiment. Throughout the last two weeks of the experiment the subject seldom needed verbal cues and demonstrated a more symmetrical gait pattern along with better timing and patterning while ambulating on the treadmill.

Qualitative Results: Subject B

A six-week trial utilizing partial body weight support treadmill training methods afforded the subject with small quantitative improvements but large qualitative results.

At the end of this six-week trial, a more symmetrical gait pattern was noted as well as improved balance.

A Berg Balance score of 54/56 was found indicating no significant risk of falls. The gait portion of the Tinetti was scored an 11/12. A template of his footprints was taken of the subject during gait to determine what deviations the subject had left to right. Step length and stride length was measured and an average of three to four steps was recorded. The subjects left step length had an average of 59 centimeters whereas the right step length averaged to be 51.3 centimeters. Left stride length averaged to be 108 centimeters as compared to the right at 107 centimeters. The subject's base of support was approximately six inches. Left walking angle was found to be seven degrees whereas right walking angle was only five degrees. A ten meter timed walk was administered as well to determine the subject's functional gait at a safe speed. The subject completed ten meters in 7.06 seconds.

Following the six-week trial, the subject's Berg Balance score remained the same but the gait portion of the Tinetti improved to 12/12. Left step length averaged 54 centimeters while right step length averaged 57 centimeters. The template of his footprints revealed many changes in gait quality. The subject did demonstrate equal step length during gait in one of the three trials total. Equal stride length of 114.3 centimeters was acquired. Walking base decreased to four inches, while walking angle became equal bilaterally at seven degrees. A ten meter timed walk was administered again and was found to have slightly decreased in time to 8.27 seconds.

Positive improvements were demonstrated throughout the entire trial time. The subject was able to complete all sessions without any rest periods, walking ten minutes,

three times each session. The subject began the six-week trial at 40 percent his body weight walking .5 miles per hour. The subject often demonstrated foot drag of the outside border throughout the entire swing phase of his gait cycle. Facilitation at the calcaneous was given to keep the foot in the proper everted position to allow the swing phase of gait to complete without foot drag. Reciprocal pelvic rotation was elicited with facilitation at both hips during entire gait pattern. The subject responded well to this facilitation.

Beginning the third session the subject's body weight support was decreased to 20 percent supported and increased his speed to .7 miles per hour. Left foot eversion was facilitated only during the swing phase of the left side. This facilitation technique was coupled with verbal cues for heel strike and no circumduction. By the third week the subject was able to keep his left foot everted while exhibiting an adequate heel strike at weight acceptance. At this time the subject reported that he could single leg stand longer on the left side than previously. Also, he stated that his left foot was not dragging as much while walking. Left anterior pelvic rotation was initiated during the swing phase while providing left pelvic stability during mid swing at the last session at 20 percent body weight support and .7 miles per hour. The subject was able to complete an almost perfect gait pattern with only small deviations in left foot eversion and some instability during weight acceptance in that his left knee extension was poorly controlled. By the end of this session verbal cues were the main facilitating factor.

At the end of week three the subject was decreased to zero percent body weight support and a walking speed of 1.0 mile per hour. At this setting the subject began to veer off to the right of the treadmill so appropriate facilitation techniques were brought

in. Pelvic rotation was still facilitated while providing left anterior protraction during the swing phase. Following two sessions utilizing these techniques, decreased circumduction, improved quality during heel strike, decreased limp on the left, and an improved push off with the left was observed during gait. During the fifth week of the trial, facilitation was given for adequate weight shift onto the left leg. Verbal cues were given for pelvic rotation, shoulder symmetry, left foot eversion, and left foot heel strike. During the last week of the trial, facilitation decreased significantly as there were great qualitative improvements. By the last session, no facilitation was needed and therefore not used. At the end of the last session, following all post-trial measurements, the subject was observed during normal gait. Decreased speed was noted but the quality of walking had greatly improved. The subject was able to lift his left leg through the swing phase without dragging the left foot on the floor. Also, the subject appropriately rotated his hips throughout the entire gait cycle while weight shifting evenly onto both the right and the left side equally. The gait pattern had normalized throughout the six-week trial into a more functional quality that was evident throughout his entire gait pattern.

Qualitative Results: Subject C

Throughout the six weeks of testing, it was shown that both qualitatively and quantitatively, the subject's gait and balance improved. It was observed that she had a straighter hip and knee during the stance phase of her gait, increased stride length and increased heel strike. Her confidence level also seemed to increase as the sessions progressed.

Upon initial observation the subject was noted to have a shuffle type gait with her left stride length being shorter than her right. She had a decreased heel strike bilaterally and did not reach full extension in her knees bilaterally during the stance phase.

Her initial score for the Berg Balance was 49/56, which showed mild balance impairment. Her Tinetti score was a 9/12, which indicated a mild to moderate impairment in her gait. Her ten-meter walk was 14.03 seconds. Measurements from her foot prints were averaged and found to be as follows: left step length 41 centimeters, right step length 40.3 centimeters, left stride length 82.87 centimeters, right stride length 81.28 centimeters, walking base 4.75 inches, left walking angle seventeen degrees and right walking angle of thirteen degrees.

Following the six-week trial the subject's Berg Balance test and score was 49/56, the same score she received initially. Her Tinetti score was a 12/12. This indicated that the quality of her gait and balance had improved significantly. Measurements from her foot prints were averaged and found to be as follows: left step length 42.97 centimeters, right step length 44.35 centimeters, left stride length 87 centimeters, right stride length 84.3 centimeters, walking base improved to 5.83 inches, left walking angle 3 degrees and right walking angle one degree. These measurements showed that bilaterally her step and stride length increased. Her walking base also increased showing an increase in her balance. Her toe measurements revealed a more normalized base of support as well as being more symmetrical. Her ten meter walk time was 11.92 seconds. This was an improved time of 2.11 seconds from her initial testing.

Partial body weight support treadmill sessions began on the same day as the evaluation. She underwent three bouts of up to ten minutes each on the treadmill with 5

minute breaks in between each bout. Initially, 40 percent of her body weight was supported and she walked at a speed of .5 mph. Bilateral facilitation points initially included the anterior superior iliac spines (ASIS) because her hips were not reciprocating with her walk. She completed the full ten minutes for each bout and only seemed slightly fatigued at the end of her session. Upon her next visit, all parameters were kept the same except facilitation was added to the dorsum of her left foot to enhance stride length as well as facilitation of her lower legs. It was noted that her reciprocal hip movement improved since her first session.

During her third session, her body weight support was decreased to 20 percent of her body weight because of her marked improvement. Her speed was also increased to .7 miles per hour. Once again, the subject walked for the full ten minutes for each bout. Alternating bilateral facilitation was needed at the feet and the hips to help increase her stride length. The increase in speed and decrease in weight altered her gait pattern during her first bout but improved during her second and third. It was observed that the subject tended to "sit" in the harness when she fatigued. Frequent verbal cues were needed to stand up straight and to keep her eyes straight ahead so she would not look at her feet. A slight sway in her gait was still observed and so slight stabilization was given at hips. At the end of the treatment the subject complained of pain in her right shoulder radiating to her hand. The subject rested and the pain subsided within a few minutes.

The subject missed her fourth session because of miscommunication with her transportation to the session. During her fifth session, the subject remained at the previous parameters. She fatigued quickly during her first session and had to stop at seven minutes and twenty seconds. A slight shake in her right hand was noticed.

Stabilization was again needed at the ASIS to decrease her sway. Manual cues were given at her low back and upper chest to facilitate standing up straight along with frequent verbal cues. The patient complained of soreness and increased fatigue during her first bout but improved during her last two with a more consistent stride length and upright stance. The same parameters and facilitation techniques were used during her sixth session and the subject consistently had good stride length and increased heel strike with verbal cues. As a result the researchers decreased their stabilization at the hips.

For the seventh session, the parameters were changed because of the patients increased efficiency of gait and endurance. The new parameters were set at zero percent body weight support and a speed of 1.0 mile per hour. The subject had a hard time standing up straight during her first bout and once again was observed to be sitting in her harness. Her body was in a flexed posture at approximately 15-20 degrees. Facilitation was given at her chest and low back to stand up straight. The subject stopped her first bout at four minutes and fifteen seconds secondary to fatigue. During her second bout she appeared more upright. Facilitation remained the same but the bout was terminated at three minutes forty-five seconds because subject was out of breath and complained that her left leg was tired. The patient endured five minutes and ten seconds during her third and final bout of the day. Facilitation remained the same in conjunction with verbal cues for her posture and to increase her stride length bilaterally.

At the beginning of the subject's eighth session the testers were informed that she went to the emergency room the evening prior because the subject experienced disorientation and confusion. There was evidence that she suffered a transient ischemic attack (TIA). The doctor gave permission for her to continue the study as long as she felt

fine. Due to the TIA, it was decided to revert her parameters back to 20 percent body weight and .7 miles per hour speed. Blood pressures were taken at the beginning of the session as well as after each bout of exercise to ensure patient safety. Her blood pressure elevated to a high of 161/57 after her second session but came down nicely within five minutes to 145/56. During her first bout, stabilization was given at the hips to decrease her sway and verbal cues to increase her left stride length. The bout ended at six minutes and thirty-three seconds secondary to patient's complaint of being out of breath and her left leg pain. During her second and third walk, the same facilitation was given and she went the full 10 minutes for each bout. At this time the subject corrected her gait independently an approximated 75 percent of the time.

The subject stayed at the same parameters during her ninth session. Blood pressures were taken prior to and following each bout of exercise. All measurements were within normal limits. It was observed that the subject was very fatigued and moving slowly with more pronounced deficits in her gait on this day. During her first bout, she lasted eight minutes and four seconds with complaints of her knees feeling weak and shortness of breath. Facilitation remained the same throughout all three bouts to maintain stabilization at her hips and keep her body upright. The subject lasted seven minutes two seconds during her second bout and seven minutes fifty-five seconds during her third bout.

The subject was much improved during her tenth session. Parameters remained the same secondary to her recent medical complications. During all three bouts, she walked the full ten minutes. Slight facilitation was given at her hips to decrease her sway

and occasional verbal cues given to increase her stride length and keep an upright posture.

During her eleventh session, the parameters remained the same and the subject completed three bouts of ten minutes each. No stabilization was needed at the hips. Slight verbal cues were rarely given to increase her left stride length. Her blood pressures were taken after each bout of exercise and were found to be within normal limits until the final bout when her blood pressure rose to 196/92. At this point the subject was sent to the emergency room whereupon it lowered back to normal limits.

Through out her five final sessions, the subject remained at 20 percent body weight support and .7 miles per hour for safety reasons. She visited her doctor two days following her emergency room visit and was discovered that she had an incredibly high caffeine intake that was causing her high blood pressure. She decreased her intake and an immediate drop in her blood pressure was noted where it remained stabilized throughout the rest of the trials. Stabilization at her hips was occasionally needed to decrease her left-sided sway. Verbal cues decreased each session until the subject corrected her posture and stride length independently. With the exception for two bouts where she complained of leg soreness, she completed the full ten minutes for each session. Upon her last session of the supported treadmill walking, she reached a stage of independent walking with 20 percent body weight support going .7 miles per hour.

Qualitative Results: Subject D

Subject D exhibited positive results from this six-week trial of body-weight supported treadmill training. He achieved a more symmetrical gait pattern, with increased stride length bilaterally. His gait velocity increased, and his balance improved

following the six weeks of training. Subject D also verbally expressed that he felt his walking had improved and had become easier by the end of the study.

Upon initial observation of his gait, Subject D was found to have a very short step length bilaterally, a narrow base of support, and a greater degree of a walking angle on the right. His right swing foot did not pass his left step foot and vice versa. He did not achieve heel strike on the right, and his right toe would catch on the floor, especially carpet, frequently.

His initial score on the Berg Balance Scale was 45/56 which showed an increased risk of falling. His Tinetti Assessment Tool (gait portion) score was 8/12 which demonstrated a moderate impairment in his gait. His ten meter walk test revealed a gait velocity of 27.29 seconds. Template measurements were averaged, using three to four steps from the template. Subject D's left step length was found to be 21.88 centimeters and left stride was 41.67 centimeters. His right step length was 18.75 centimeters, and right stride was found to be 40.63 centimeters. These averages were fairly symmetrical. However, the individual measurements of his left stride length were inconsistent. These measurements were as follows: 43.13, 47.19, and 34.69 centimeters. His average base of support was 10.83 cm. Left walking angle was eleven degrees compared with the right, which was twenty-four degrees.

At six weeks his Berg Balance scale was 50/56. The Tinetti Assessment Tool (gait portion) score was 10/12. His ten meter timed walk test improved to 15.72 seconds. The foot template was assessed and measurements were taken. Average left step length was 29.6 centimeters, and average left stride length was 52.63 centimeters. Average right step and stride lengths were 19.48 cm and 49.0 centimeters, respectively. His step and

stride lengths continued to be symmetrical, and his left stride length became more consistent with individual measurements of: 53, 53.9, 51 centimeters. His left swing foot would now pass his right stance leg, but his right swing foot would not pass his left stance leg. This is an improvement from the initial measure. His base of support averaged out to be 12.4 centimeters. Left walking angle was eleven degrees, and right walking angle was 9.2 degrees.

The subject was able to complete ten-minute bouts three times per session for the entire six-week trial. Subject D began his body weight support treadmill training on his next session. He began with 40 percent of his body weight supported and a speed of 0.5 miles per hour on the treadmill. He was able to walk for the full ten minutes on each of the three bouts. The assistance of two people was required to facilitate a correct gait pattern. One person placed her hands on the heel and dorsum of the right foot to facilitate heel strike, toe in, and increased stride length. The other person placed her hands on the heel of the left foot to facilitate an increased stride length. Verbal cues were also given consistently to take a larger step with the left. He also held on to the handle bilaterally 85 percent of the time he was on the treadmill. These methods were used for the first two and a half weeks of the six-week trial.

By the middle of the third week, Subject D was able to walk for the last two minutes of each ten-minute session without any facilitation on the left. He also only required bilateral upper extremity support for 50 percent of the time he was on the treadmill. He did however require verbal cues for increased stride on the left, as well as all of the facilitation on the right. His symmetry had improved without the facilitation on the left, so it was decided that the last session of the third week would be at the next

level. He would now ambulate with 20 percent body-weight support and a speed of 0.7 miles per hour.

At this new level, Subject D continued to require the assistance of two people for facilitating his correct gait pattern. He was able to walk without facilitation on the left for the last two minutes of each ten-minute session, requiring upper extremity support only 30 percent of the time. He continued to require facilitation for heel strike, toe in and increased stride on the right throughout the next three sessions. At the next session, Subject D only required verbal cues for increased stride length on the left, with no manual facilitation. His gait pattern was improving and it was decided he would be moved up to the next level of zero percent body weight support and 1.0 mile per hour at the next session.

At the beginning of week five, the next level of zero percent body weight support at 1.0 mile per hour was initiated. Subject D only required facilitation on the right for heel strike, toe in, and increased stride. He required verbal cues for increased stride on the left. For session two of week five, he received no manual facilitation, with only verbal cues for heel strike and increased stride, for the last two minutes of the last two ten minute sessions. It was only during these last two minutes that he required upper extremity support 75 percent of the time. Approximately 40 percent of the time his right toe would drag on the treadmill causing him to stutter-step. This facilitation was continued throughout the remainder of the study. On the last day of treadmill training, Subject D was only catching his toe on the treadmill approximately 20 percent of the time when he was not receiving manual facilitation. He only used the upper extremity support for roughly ten seconds after his toe caught on the treadmill, until he regained his

balance. By this last session, his gait was more symmetrical, and he required less verbal cues for increased stride and heel strike.

CHAPTER 5

DISCUSSION

The purpose of this study was to determine of PBWSTT improves the quality of gait, postural control, and gait speed in adults diagnosed with a CVA. Patients attended three sessions per week for a period of six weeks. There were qualitative and quantitative improvements in the subjects who participated in the six-week study.

Discussion

The results demonstrated that two of the four subjects improved in the Berg Balance Measure, three of the four subjects in the gait portion of the Tinetti Assessment Tool, and three of the four in the 10-meter timed walk. In analyzing the foot template measurement all four of the subjects showed an increased step and stride length, and three of the four decreased their walking angle, but all were within normal limits. The base of support (BOS) increased in three of the four subjects, which was determined to have a positive outcome.

There are many contributing factors to the outcomes of balance testing. In the subjects who showed a low percentage or no improvement, the researchers feel that this was a result of intertester reliability and validity, as there were two different supervisors accompanying the student tester at the initial and final sessions. The researchers also believe that the test was too insensitive for the level of function the subjects demonstrated, secondary to specific factors such as young age, cognitive level, chronic status of their diagnosis, or medical complications. The researchers think that large

improvements were made in one of the subjects due to the fact that the CVA was more acute allowing spontaneous neurological recovery to become a factor, as well as prior experience with PBWSTT, high cognition level, and a high rate of carry-over.

There are many aspects that contributed to the results of the gait portion of the Tinetti. The test did not appropriately represent the more chronic status of two of the subjects. It is not sensitive enough to detect the small qualitative changes that were observed by the tester. Improvements made could be attributed to age, increased prior level of function, extra-curricular activities such as aerobic/strength training, increased confidence, and repetition of facilitation, which in turn increased carry-over.

Some changes in velocity can be accredited to increased quality of gait, motivational factors, and the time of day test was performed. Speed, BWS, and duration at which they practiced also played a role in the positive improvements made. Interpretation of directions prior to initial and final testing may have inhibited the speed at which it was performed due to the fact that the directions were not standardized.

Due to the various ages of the subjects, decreases and increases in the (BOS) demonstrated positive improvements. In the subject who was youngest, a decrease in BOS was noted. The researchers feel that this is credited to the fact that this subject's initial BOS was wider than normal in order to compensate for his decreased balance so improvements would decrease his BOS. In older individuals a smaller BOS may be due to decreased balance. Therefore, the researchers feel that the increases in BOS resulted from a better ability to balance demonstrated in prior testing. Some other causes for changes in other foot measurements may be error on the part of the tester in assessing the template, a more symmetrical gait quality, and changes in foot wear.

Limitations

Limitations of this study include not training over ground with BWS. This decreased the desired carry-over effects needed for the normalization of gait. The researchers' tests were not sensitive enough to measure the subtle qualitative changes observed by the testers. Also, different testers were with each subject utilizing their own facilitation techniques, which were limited by their experience. Comparison between subjects was restricted due to various ages, location of the CVA, functional impairments, length of time that has passed since the CVA, and the small sample size used.

Suggestions for Further Research

The researchers recommend further studies in this area to include over-ground PBWS training to improve the carry-over effect. In a study performed by Nilsson et al[19] the effect of PBWS treadmill training versus walking training on the ground during the acute stage of rehab was studied. There were no significant differences found between the two groups. Hesse et al[41] studied PBWSTT versus floor walking. The researchers found that clients did not practice an abnormal physiological gait with PBWSTT versus floor walking. Similar to these studies, this study did not attempt to use over-ground BWS gait training. The researchers feel that the results may have demonstrated a more significant improvement in the PBWSTT clients if this method was utilized.

According to *Statistics for the Behavioral Sciences*,[45] the law of large numbers states that as sample size increases, the error between sample and population mean should decrease. Therefore, an increase in sample size will allow a more accurate comparison of results between the clients. The researchers feel that decreasing the variability among the subjects in this study would have allowed a more accurate comparison of outcomes.

Generally, decreased variability allows patterns to be clearly recognized versus increased variability, which tends to disguise existing patterns.

Conclusion

Following a review of literature, the participation in the six-week study, and analyzing its results, the researchers concluded that PBWSTT is indeed a beneficial rehabilitation tool for the population that has experienced a CVA. This study demonstrated improvements within each subject in the areas of postural control, gait quality and speed. The researchers feel that the improvements in our subjects will increase functional capacities leading to a better quality of life.

APPENDIX A

X EXPEDITED REVIEW REQUESTED UNDER ITEM 3, 7 (NUMBER[S]) OF HHS REGULATIONS

___ EXEMPT REVIEW REQUESTED UNDER ITEM ___ (NUMBER[S]) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

Please include ALL information and check ALL blanks that apply.

PRINCIPAL INVESTIGATOR: Cindy Flom-Meland, MPT, Michelle LaBrecque, MPT, Beth Enerson, Becky Fuhrer, LaRae Haas, Sarah Hammers, Alecia Herring, Amanda Olson, Mandy Schumacher **TELEPHONE:** 777-2831 **DATE:** 4-9-02

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: Cindy Flom-Meland or Michelle LaBrecque Box 9037 PT

SCHOOL/COLLEGE: Medicine (E.g., A&S, Medicine, EHD, etc.) **DEPARTMENT:** Physical Therapy **PROPOSED PROJECT DATES:** 04-02 to 05-03 (Month/Day/Year)

PROJECT TITLE: The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction – A Case Study Approach

FUNDING AGENCIES (IF APPLICABLE): ___

TYPE OF PROJECT (Check ALL that apply):

X NEW PROJECT ___ CONTINUATION ___ RENEWAL ___ DISSERTATION OR THESIS RESEARCH X STUDENT RESEARCH PROJECT

___ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: ___

PROPOSED PROJECT: ___ INVOLVES NEW DRUGS (IND) ___ INVOLVES NON-APPROVED USE OF DRUG X INVOVLES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATION, PLEASE INDICATE THE CLASSIFICATION(S):

☐ MINORS (<18 YEARS) ☐ PREGNANT WOMEN ☐ MENTALLY DISABLED ☐ FETUSES ☐ PERSONS WITH MENTAL RETARDATION

☐ PRISONERS ☐ ABORTUSES ☐ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE ___

IF YOUR PROJECT HAS BEEN\WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE LIST NAME OF BOARD(S): Altru Health System

Status: ___ Submitted; Date 2-22-02 ___ Approved; Date ___ ___ Pending

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.)

Loss of independence in gait is a common functional limitation following a neurological incident; such as a cerebrovascular accident or traumatic brain injury. This study will investigate whether or not use of body weight supported treadmill ambulation can improve quality of gait, postural control, and speed.

This study will follow a case study format, requiring up to 7 subjects over the age of 20 years with a neurological diagnosis, such as stroke, traumatic brain injury, multiple sclerosis, etc. All subjects will initially undergo a standard balance test, 10 m timed walk test, standard gait test, and a recording of a template of each subjects' footprints, along with resting heart rate and blood pressure. Each subject will participate in body weight supported treadmill ambulation 2-3x/week for 6 weeks. Following this period, all subjects will repeat the initial testing procedures again. Findings within each subject will be compared using traditional descriptive statistics. The results from this study will add to the current body of knowledge regarding gait with body weight supported. The information will be reported in a scholarly project with a case study format.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary. Attach any surveys, tests, questionnaires, interview questions, examples of interview questions (if qualitative research), etc., the subjects will be asked to complete.)

Recruitment: Subjects will be recruited from the city of Grand Forks, ND and surrounding communities. Cindy Flom-Meland will be responsible for recruitment of subjects via contacting local support groups (i.e. Stroke Support Group, MS Support Group, etc.). Contact will be made in person or via telephone, at the desire of the potential subjects. A total of 7 subjects are required for this study.

Selection: Subjects must be older than 20 years of age and have a neurological diagnosis, such as stroke, traumatic brain injury, multiple sclerosis, etc. and be living in the community. Subjects will be excluded if found to have abnormally high or uncontrolled blood pressure, noted by a blood pressure screen (using 160/90 mmHg or less as a guideline for acceptance).

Procedure: All subjects will initially complete a standard balance test (the Berg Balance Measure), 10 meter timed walk test for gait velocity, a standard gait test (the gait portion of the Tinetti Test of Balance and Mobility), and a recording of a template of each subjects' footprints. This will be completed by having each subject walk at a comfortable speed over a piece of black paper (baby powder on the bottom of their shoes), which will allow stride length, step length, and base of support to be measured. A baseline for heart rate and blood pressure will also be recorded initially. Each subject will be assigned to one of the student researchers and will participate in body weight support (BWS) treadmill gait training 2-3 times per week for 6 weeks. Each session will consist of 3 bouts of ambulation with a 5 minute rest break between bouts. The bouts will be limited in duration by subject tolerance or to a maximum of 10 minutes. Initially, 40% of each subject's body weight will be supported during BWS gait training and the speed will started at .5 mph. There will be three levels of body weight support (40%, 20%, and 0%) and treadmill speed (.5 mph, .75 mph, and 1.0 mph). A decrease in body weight support will be made when the subject is observed to demonstrate adequate gait technique (fairly symmetrical step length, cadence, and foot clearance and the ability to support weight on affected limb without buckling). The speed will be increased when the subject demonstrates adequate endurance, which be measured by the tolerance of walking at least 5 minutes in at least 2 of the 3 bouts. The changes in body weight support and treadmill speed would be made at the next session. During the final week of the study, the BWS will be decreased to 0% to assist with transition back to ambulation without BWS. Multiple bouts of walking, be it on a treadmill or on land, is typically incorporated into physical therapy intervention programs. At the end of the 6 week time period, all subjects will repeat the initial testing. All testing and training will take place at the Altru Health Institute.

Informed Consent: This will be obtained through an information and consent form (see attached form). All individuals participating in this study will be competent and independent in their decision-making and will sign the consent form in relation to participation in this study. Subjects will be provided with a copy at the initial test session. Once the subject and one of the investigators sign the form, a photo copy will be made and then given to the subject.

Risk: Walking on a treadmill is a form of exercise, so therefore there is some degree of risk. However, the investigators feel this risk is minimal, as walking is a part of daily function and is very much a part of physical therapy intervention programs. If injury does occur, the individual will be encouraged to seek medical attention. All medical expenses will be the responsibility of the individual and his/her third party payer. Subjects will be excluded if found to have uncontrolled blood pressure or abnormally high blood pressure, as noted by a blood pressure screen. Subject and result information will not be linked from the consent form in order to in sure the confidentiality of all subjects. The results of this study will be secured in the Physical Therapy Department at the University of North Dakota. Unless theses records are required for future studies, they will be destroyed 3 years after the study has ended. Only the principal investigators will have access to this information.

3. **BENEFITS:** (Describe the benefits to the individual or society.)

Being able to walk independently is a naturally assumed function of most people. When someone has a stroke or a traumatic brain injury, this assumed part of normal function can be disrupted.

The purpose of this study is to determine whether or not use of body weight supported treadmill ambulation can improve quality of gait, postural control, and speed for subjects with a physical therapy diagnosis of Impaired Motor Function and Sensory Integrity Associated With Nonprogressive Disorders of the Central Nervous System – Acquired in Adolescence or Adulthood. Research, though is limited, has demonstrated that BWS training is beneficial to people with neurological diagnoses. The goal of this study is to provide further information and to increase the awareness of BWS as an alternative and/or additional tool to use of gait training in the physical therapy clinic.

Further benefits for the subjects include social interaction, an increase in self-confidence with walking, and the promotion of general health and well-being.

4. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to protect the confidentiality of data obtained, debriefing procedures, storage of data, how long date will be stored (must be a minimum of three years), final disposition of data, etc.)

Walking on a treadmill is a form of exercise, so therefore there is some degree of risk. However, the investigators feel this risk is minimal, as walking is a part of daily function and is very much a part of physical therapy intervention programs. If injury does occur, the individual will be encouraged to seek medical attention. All medical expenses will be the responsibility of the individual and his/her third party payer. Subjects will be excluded if found to have uncontrolled blood pressure or abnormally high blood pressure, as noted by a blood pressure screen. Subject and result information will not be linked from the consent form in order to in sure the confidentiality of all subjects. The results of this study will be secured in the Physical Therapy Department at the University of North Dakota. Unless theses records are required for future studies, they will be destroyed 3 years after the study has ended. Only the principal investigators will have access to this information.

5. **CONSENT FORM:** Attach a copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

   Describe where signed consent forms will be kept and for how long (must be a minimum of 3 years), including plans for final disposition or destruction.

Informed consent will be obtained through an information and consent form (see attached form). All individuals participating in this study will be competent and independent in their decision-making and will sign the consent form in relation to participation in this study. Subjects will be provided with a copy at the initial test session. Once the subject and one of the investigators sign the form, a photo copy will be made and then given to the subject.

6. For **FULL IRB REVIEW** forward a signed original and fifteen (15) copies of this completed form, including fifteen (15) copies of the proposed consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to the address below. An original and 19 copies are required for clinical medical projects. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

   Office of Research & Program Development
   University of North Dakota
   Grand Forks, North Dakota 58202-7134

   On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

   For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original, including a copy of the consent form, questionnaires, examples of interview questions, etc. and any supporting documentation to one of the addresses above. In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES: Sarah Hammers, Amanda Olson, Mandy Schumacher, LaRae Haas, Beth Erickson, Becky Fuhrer, Alicia Hering

Cindy Flom-Meland, Michelle LaBrecque — Principal Investigator — 4-9-02 — Date

Cindy Flom-Meland, Michelle LaBrecque — Project Director or Student Adviser — 4-9-02 — Date

Training or Center Grant Director — Date

(Revised 2/2000)

STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD[1]

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is The Effects of Partial Body Weight Support for Gait for Patients With Neurological Dysfunction – A Case Study Approach

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I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

4-9-02
Date

Beth Energen, Becky Fabre, Alicia Herring
Mandy Schumacher, Sara Haas
Jenn Hammers, Amanda Olson
Signature of Student Researcher

[1]Consent required by 20 U.S.C. 1232g.

ALTRU HEALTH SYSTEM

APPROVAL TO CONDUCT RESEARCH STUDY AT ALTRU HEALTH SYSTEM

Name: Cindy Flom-Melland Date: April 1, 2002

Address: 513 Evergreen Drive, Grnad Forks, ND 58201

Telephone Numbers: Work 777-4130 Home 775-2476

Department/College Physical Therapy/UND

Project Title : The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction: A Case Study Approach

Your request to conduct the above named study at an Altru Health System facility involving employees or patients as participants, and/or requiring facility resources has been reviewed. The following action has been taken:

✓ Permission to conduct the study is granted

_____ Permission to conduct the study will be granted upon completion of the following:

_____

_____

_____ Permission to conduct the study is denied for the following reason(s):

_____

_____

_____

RECOMMENDATIONS/REMARKS:

Signature	Title	Date
[signature]	Manager, Research	4-2-02

word\research\prmsnfrm

Copy to Cindy 4/12/02

Altru Health System

Institutional Review Board

Research Project Action Report

Date: April 11, 2002 IRB # UND-18

Principal Investigator: Cindy Flom-Meland & Michelle La Brecque

Department: Physical Therapy Phone # 777-2831

Address to which notice of approval should be sent: UND Department of Medicine, P.O. Box 9037 PT, Grand Forks

Research Coordinator: Phone # 780-1751

Project Title: The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction – A Case Study Approach.

The above referenced project protocol and informed consent was reviewed by the Altru Health System Institutional Review Board on _____ and the following action was taken:

CONDITIONAL APPROVAL:

☐ Project conditionally approved on _____ pending modifications. This study cannot be started until revisions have been made and submitted, and final approval has been granted.

FINAL APPROVAL:

☐ Final project approval granted on _____ Next scheduled review is on _____
If no date is given, then review will be required in 12 months. (See REMARKS SECTION for any special conditions.

☒ Project approved. **EXPEDITED REVIEW NO.** 3, 7 Next scheduled reviewed is on _____

☐ Project approved. **EXEMPT CATEGORY NO.** _____ No periodic review scheduled unless so stated in REMARKS SECTION.

☐ Project approval deferred. (See REMARKS SECTION for further information)

☐ Project approval denied. (see REMARKS SECTION for further information)

☐ Amendment approved _____

☐ Administrative change approved _____

☐ Protocol revision approved _____

☐ Revised consent form approved _____

☒ Other **New Study.**

REMARKS:
Any changes in protocol, adverse occurrences or deaths in the course of the research project must be reported immediately to the IRB chairperson or the IRB office (780-6161).

Signature of Chairperson or Designated IRB Member
Altru Health System Institutional Review Board

4/12/02
Date

If the proposed project is to be part of a research activity funded by a federal agency, a special assurance statement or a completed 596 Form may be required. Contact the IRB office to obtain the required documents.

MLR 12/11/01 *Completed by:* _____

Copy to Cindy + Renee 4/12/02

LEAD IRB DESIGNATION SHEET

I have reviewed the proposal received from Cindy Flom-Meland and Michelle La Brecque from the Department of Physical Therapy (School of Medicine and Health Sciences at the University of North Dakota) entitled "The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction - A Case Study Approach"

and recommend that the ☒ Altru Health System ☐ University of North Dakota Institutional Review Board be the lead IRB because subjects will be accrued at their institution.

John P. Madden

John P. Madden, Ph.D., Chair
University of North Dakota
Institutional Review Board

3-11-02
Date

Kevin J. Tveter, M.D., Chair
Altru Health Systems
Institutional Review Board

4/12/02
Date

Altru Health System

APPLICATION TO CONDUCT RESEARCH AT ALTRU HEALTH SYSTEM FACILITIES

Any researcher proposing to conduct research using patients, staff, or records of Altru Health System must obtain organizational approval as well as IRB approval. Complete this application form and submit it along with a brief summary of the study, including consent and instruments to: Virginia Esslinger, MS, RN, Altru Health Research Center, P.O. Box 6002, Grand Forks, ND 58206-6002

Name Cindy Flom-Meland Date 3-19-03
Address 513 Evergreen Drive, Grand Forks
Telephones numbers: Work 777-4130 Home 775-2476
Department/College: Physical Therapy / UND
Project Title: The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction: A Case Study Approach.

Status of applicant (check all that apply):

✓ Altru physician/staff member

____ Student — Department PT (Flex-time)
Advisor Steve Rood
Relationship to Altru, if any
____ Coursework ____ Thesis ____ Dissertation

____ Other

X Faculty — College/Department UND / Physical Therapy
Relationship to Altru, if any Flex-time employee

____ Other — Organization
Position
Relationship to Altru, if any

Please answer the following questions:

1. Describe the nature and extent of involvement expected of Altru staff with your project (include specific staff members by name and/or title, specific activities requested of them and an estimate of the amount of their time that would be required).
None. My students and myself will be using the LiteGait device and treadmill (which are both owned by the PT depart. at UND that are located within the department of PT at AHI.

2. Describe the nature of patient contact required by your project, if applicable (i.e. access to medical records, patient interviews, etc.) The subjects for this project will not be recruited through Altru, but through the Grand Forks community and surrounding areas, for example at support group meetings.

3. Describe how patient/subject confidentiality will be protected and how patients/subjects in the study will be assured of anonymity. The subjects name will be kept separate from the data that is collected, no identifying information will be available to link the subjects with their data.

4. List any supplies, equipment or other resources provided by Altru that would be required to carry out your project (i.e. photocopying, computer access, etc. Describe funding available, if any, to cover these expenses). None.

5. Identify any space requirements that would be needed to carry out your project.
The equipment is already located within the PT department, would not need any other additional space.

6. Projected start of project activities at Altru March 2003 (as soon as given approval)
Projected completion of project activities at Altru August 2003
Projected completion date of entire project May 2003

7. Source of funding sought or received Not applicable

8. Other information/comments
Please see IRB form & consent form that were previously sent.

Cindy Flom-Meland
Signature of Applicant

Cindy Flom-Meland
Signature of Faculty Advisor

Information and Consent Form

The Effects of Partial Body Weight Support for Gait for Patients With Neurological Dysfunction – A Case Study Approach

You are being invited to participate in a study conducted by Beth Enerson, Becky Fuhrer, LaRae Hass, Sarah Hammers, Alecia Herring, Amanda Olson, and Mandy Schumacher, students in the Master's of Physical Therapy Program at the University of North Dakota. The purpose of this study is to determine the effects of partial body weight support treadmill walking on quality of walking, balance, and speed.

The requirements of the study are as follows: over 20 years of age, be a community dweller, and have a medical history of having a neurological insult, i.e. stroke, traumatic brain injury, etc. You will be excluded if they are found to have abnormal or uncontrolled blood pressure.

If eligible, you will be required to partake in initial testing, which will include a standard balance test (Berg Balance Measure), standard gait test (walking portion of the Tinetti Test of Balance and Mobility), timed walking for 10 meters, and footprint analysis. This initial testing will take approximately 45 minutes. You will be assigned to one researcher whom will work with you 2-3 times per week for 6 weeks on body weight supported treadmill walking. Each session will be of approximately 45 minutes in duration. Following the 6 week period, you will repeat the initial tests. All testing and training will take place at Altru Health Institute.

This form of exercise is considered a low risk activity, but as with any type of physical exercise there is some risk of injury. If physical injury does occur, during or as a result of the research, medical assistance will be available to you. You and/or your insurance company will cover the cost of medical expenses. Coverage will not be provided through this research project.

The information obtained through this study will be kept confidential. Your name and personal information will not be revealed at any time through out this study. The results of this study will be secured in the Physical Therapy Department at the University of North Dakota. Unless theses records are required for future studies, they will be destroyed 3 years after the study has ended. Neither the researchers nor yourself will receive any compensation associated with involvement of this study.

Participation in this study is entirely voluntary, and you may withdraw consent and discontinue participation at any time until the final data has been collected, without prejudice.

The investigators can be reached at University of North Dakota, Department of Physical Therapy at (701)777-2831 or by contacting our preceptors, Cindy Flom-Meland, MPT (701)777-4130 or Michelle LaBrecque, MPT (701)777-6389. Please feel free to contact any one of us with any questions or concerns.

We realize that your time is valuable, and the time commitment of participating in this study is substantial, but we believe that your result will make it well worth your time. Not only do we expect to find improvement in your testing scores, but we also expect that you will notice an improvement in your activities of daily living as well.

If you have any other questions or concerns, please call the Office of Research and Program Development at the University of North Dakota at 777-4279 and/or Altru Institutional Review Board at 780-6161.

I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND AGREE TO THE COMMITEMTN OF PARTICIPATING IN THIS RESEARCH STUDY. I REALIZE THAT IF I HAVE ANY QUESTIONS OR CONCERNS AT ANY TIME DURING THIS STUDY, I AM ENCOURAGED TO CONTACT THE RESEARHERS. A COPY OF THIS CONSENT FORM HAS BEEN GIVEN TO ME.

_____

Participant's Signature Date

_____

Investigator's Signature Date

APPENDIX B

SUBJECT HISTORY

SUBJECT A

Subject A was a 73-year old woman who experienced a right-sided CVA with left-sided involvement on June 29, 1996. Her past medical history was unremarkable and had no history of smoking. At the time of this study, the subject was currently taking the following medications: aspirin, vitamins, Fosamax, and Lanoxin.

Following her CVA, subject A received rehabilitation services in an acute hospital, six weeks were spent in a rehabilitation facility, and two months in an outpatient facility. During her rehabilitation, subject A's treatment consisted of exercise, weights (free weights, machines, resistive band strengthening), home exercise program and an ankle-foot orthosis. Subject A also received two tendon lengthening surgeries, one in her left hand and one in her left foot. Subject A has been out of rehabilitation services for six years but continues to perform home exercises on her own as well as working out at a local fitness center in her community. At her local fitness center she walks on a treadmill and exercises with weights.

At the time of this study, the subject stated her current activity level was at about 75% and that ambulation was still difficult. Subject A has participated in alternative therapies such as acupuncture and chiropractics. She has also participated in several studies by the University of North Dakota Physical Therapy Department but did not state which ones in particular.

SUBJECT B

Subject B was a 50-year old male who experienced a right-sided CVA with left-sided involvement in September 2000. His past medical history was unremarkable and had no history of smoking. At the time of this study, the subject was currently taking Agronoz daily.

Following his CVA, subject B spent one week in an acute hospital, one month in a rehabilitation facility and participated in outpatient physical therapy services for two months. The subject also received occupational therapy at these times. Subject B's rehabilitation treatments consisted of Nautilus™ weight lifting, resistive band strengthening, treadmill walking, electrical stimulation, and occupational therapy for constraint-induced training. He utilized an everter brace on his left foot for the first two months following his outpatient physical therapy. At the time of this study, Subject B was participating in a home exercise program and exercise at a local fitness center in the community. Subject B stated he tried to work out 2-3 times per week. His workouts consisted of walking for 30 minutes at a speed of 3mph and using all Nautilus™ weight machines.

Subject B stated that he currently had problems with lifting and had some work limitations at the time of the study. He reported he has not participated in any alternative therapies. He has participated in a previous study, however neglected to indicate the type of study.

SUBJECT C

Subject C was a 78-year old female who experienced a right-sided CVA with left-sided involvement on September 9, 2000. The CVA occurred while she was at her local therapeutic pool. Subject C's past medical history includes hypertension, diabetes, left hip plate, mastectomy in 1989, heart valve replacement in 1991 and a back surgery in 2000. She smoked cigarettes for approximately one year as a teenager. Subject C is also legally blind in her left eye. Her medications and doses per day are as follows: Verapamil (24 mg), Metoprolol (100 mg), Lovastatin (20 mg), Coumadin (1.5 mg), Hydrochlorothiazide (25 mg), Amaryl (25 mg), flaxseed oil (1000 mg), vitamin C (500 mg), multivitamin, Cranberry, Zinc, and Tylenol (2000 mg).

Following her CVA, Subject C fell out of her bed during her stay in the acute hospital. This resulted in a broken hip, requiring a left hip plate and therefore delaying her rehabilitation. Subject C's rehabilitation course included an initial stay in an acute hospital, followed by treatment in a rehabilitation facility, and outpatient physical therapy. Subject C's treatment included free weights, resistive band strengthening, and treadmill gait training. At the time of this study, Subject C had been out of rehabilitation for over a year and a half and participated in an exercise program that included walking 2-3 miles every other day and was independent in activities of daily living. Prior to her CVA, Subject C exercised in a therapeutic pool and walked. She reported never participating in previous studies or alternative therapies.

SUBJECT D

Subject D was a 70-year old male who experienced a left-sided CVA with right-sided involvement on November 6, 2001. His past medical history was unremarkable and had no history of smoking. Subject D reported that the only medication he was currently taking was a sleeping pill. He did not report the name of the medication.

Following his CVA, subject D underwent a three-week stay in an acute hospital, followed by a two-month stay in a rehabilitation facility. Throughout his stay, his training included exercises, resistive band strengthening, and gait training. He also received an ankle-foot orthosis (AFO) he used until his discharge from the rehabilitation facility. Subject D then received fourteen weeks of physical therapy in an outpatient facility. He worked on exercises in treadmill training for gait prior to discharge. At the time of this study, subject D had been out of rehabilitation one week. The subject reported that he was currently having the most functional difficulty with ambulation. Subject D has not been involved in previous studies or any alternative therapies.

APPENDIX C

Berg Balance Measure

Population: Elderly patients, balance

Description: The Berg Balance Measure was designed to test elderly patients level of balance. The test consists of 14 balance items which have been deemed safe for elderly patients to perform.

Mode of Administration: The Berg Balance Measure is a task performance exam.

Completion:

Time to Complete: 15 to 20 minutes

Time to Score: The test is scored while it is administered.

Scoring: The independent items are scored on a five point ordinal scale; where 0 indicates the patients inability to perform the task and 4 represents independence. The individual points are then summed to achieve a total score.

Interpretation: The higher the patients score on the balance measure the more independent the patient is.

Reliability: In order to test various components of reliability 14 elderly patients with varying levels of balance impairment were videotaped performing the tasks of the measure.

The Berg Balance Measure was found to be an internally consistent measure with Cronbach's alpha at a value of .96. The item to total correlations had a range of .72 to .90, all consistently high. The item to total correlations also further demonstrate that the Berg Balance Measure as a whole provides a stronger measure of balance than the individual items.

A high degree of interrater reliability was found with the intraclass coefficients ranging from .71 to .99. The intraclass coefficient for the total measure was .98 demonstrating a very strong degree of agreement.

Intrarater reliability was measured by having four of the original raters return one week later to watch the videotaped patients again. The intraclass coefficient of the second testing ranged from .71 to .99 for the individual items and the total test had a value of .99. These coefficients indicate that the Berg Balance Measure is a reliable tool.

Validity:

Content validity of this measure was established through the manner in which it was constructed. The Berg Balance Measure began as a series of 38 balance items which were tested on patients. The study went through three phases which involved dropping the items that were the least accurate. The resulting tool is the 14 items which are included on the Berg Balance Measure.

Reference:

Berg K, Wood-Dauphinee S, Williams JI, Gayton D. Measuring balance in the elderly: preliminary development of an instrument. *Physiotherapy Canada* 1989; 41(6):304-311.

BALANCE SCALE

Name_____ Date_____

Location_____ Rater_____

ITEM	DESCRIPTION	SCORE (0-4)
1.	Sitting to standing	_____
2.	Standing unsupported	_____
3.	Sitting unsupported	_____
4.	Standing to sitting	_____
5.	Transfers	_____
6.	Standing with eyes closed	_____
7.	Standing with feet together	_____
8.	Reaching forward with outstretched arm	_____
9.	Retrieving object from floor	_____
10.	Turning to look behind	_____
11.	Turning to 360 degrees	_____
12.	Placing alternate foot on stool	_____
13.	Standing with one foot in front	_____
14.	Standing on one foot	_____
	TOTAL	_____

GENERAL INSTRUCTIONS

Please demonstrate each task and/or give instruction as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for specific time. Progressively more points are deducted if the time or distance requirements are not met, if the subject's performance warrants supervision, or if the subject touches an external support or receives assistance from the examiner. Subjects should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing are a stopwatch or watch with a second hand, and a ruler or other indicator of 2,5 and 10 inches. Chairs used during testing should be of reasonable height. Either a step or a stool (of average step height) may be used for item #12.

1. SITTING TO STANDING

INSTRUCTIONS: Please stand up. Try not to use your hands for support.

( )4 able to stand without using hands and stabilize independently
( )3 able to stand independently using hands
( )2 able to stand using hands after several tries
( )1 needs minimal aid to stand or to stabilize
( )0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED

INSTRUCTIONS: Please stand for two minutes without holding.

( )4 able to stand safely 2 minutes
( )3 able to stand 2 minutes with supervision
( )2 able to stand 30 seconds unsupported
( )1 needs several tries to stand 30 seconds unsupported
( )0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL

INSTRUCTIONS: Please sit with arms folded for 2 minutes.

( )4 able to sit safely and securely 2 minutes
( )3 able to sit 2 minutes under supervision
( )2 able to sit 30 seconds
( )1 able to sit 10 seconds
( )0 unable to sit without support 10 seconds

4. STANDING TO SITTING

INSTRUCTIONS: Please sit down.

( )4 sits safely with minimal use of hands
( )3 controls descent by using hands
( )2 uses back of legs against chair to control descent
( )1 sits independently but has uncontrolled descent
( )0 needs assistance to sit

5. TRANSFERS

INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.

( )4 able to transfer safely with minor use of hands
( )3 able to transfer safely definite need of hands
( )2 able to transfer with verbal cuing and/or supervision
( )1 needs one person to assist
( )0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED

INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.

( )4 able to stand 10 seconds safely
( )3 able to stand 10 seconds with supervision
( )2 able to stand 3 seconds
( )1 unable to keep eyes closed 3 seconds but stays safely
( )0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER

INSTRUCTIONS: Place your feet together and stand without holding.

( )4 able to place feet together independently and stand 1 minute safely
( )3 able to place feet together independently and stand for 1 minute with supervision
( )2 able to place feet together independently but unable to hold for 30 seconds
( )1 needs help to attain position but able to stand 15 seconds feet together
( )0 needs help to attain position and unable to hold for 15 seconds

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( )4 can reach forward confidently 25 cm (10 inches)
( )3 can reach forward 12 cm safely (5 inches)
( )2 can reach forward 5 cm safely (2 inches)
( )1 reaches forward but needs supervision
( )0 loses balance while trying/requires external support

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.

( )4 able to pick up slipper safely and easily
( )3 able to pick up slipper but needs supervision
( )2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently
( )1 unable to pick up and needs supervision while trying
( )0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

( )4 looks behind from both sides and weight shifts well
( )3 looks behind one side only other side shows less weight shift
( )2 turns sideways only but maintains balance
( )1 needs supervision when turning
( )0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

( )4 able to turn 360 degrees safely in 4 seconds or less
( )3 able to turn 360 degrees safely one side only 4 seconds or less
( )2 able to turn 360 degrees safely but slowly
( )1 needs close supervision or verbal cuing
( )0 needs assistance while turning

12. PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.

( )4 able to stand independently and safely and complete 8 steps in 20 seconds
( )3 able to stand independently and complete 8 steps > 20 seconds
( )2 able to complete 4 steps without aid with supervision
( )1 able to complete > 2 steps needs minimal assist
( )0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width

( )4 able to place foot tandem independently and hold 30 seconds
( )3 able to place foot ahead of other independently and hold 30 seconds
( )2 able to take small step independently and hold 30 seconds
( )1 needs help to step but can hold 15 seconds
( )0 loses balance while stepping or standing

14. STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding.

( )4 able to lift leg independently and hold > 10 seconds
( )3 able to lift leg independently and hold 5-10 seconds
( )2 able to lift leg independently and hold = or > 3 seconds
( )1 tries to lift leg unable to hold 3 seconds but r remains standing independently
( )0 unable to try or needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

Tinetti Assessment Tool

Population: Adult population, elderly patients

Description: The Tinetti Assessment Tool is a simple, easily administered test that measures a patients gait and balance. The test is scored on the patients ability to perform specific tasks.

Mode of Administration: The Tinetti Assessment Tool is a task performance exam.

Completion:

Time to Complete: 10 to 15 minutes

Time to Score: Time to score is included in time to complete.

Scoring: Scoring of the Tinetti Assessment Tool is done on a three point ordinal scale with a range of 0 to 2. A score of 0 represents the most impairment while a 2 would represent independence of the patient. The individual scores are then combined to form three measures; an overall gait assessment score, an overall balance assessment score, and a gait and balance score.

Interpretation: The maximum score for the gait component is 12 points. The maximum score for the balance component is 16 points. The maximum total score is 28 points. In general, patients who score below 19 are at a high risk for falls. Patients who score in the a range of 19-24 indicate that the patient has a risk for falls.

Reliability: Interrater reliability was measured in a study of 15 patients by having a physician and a nurse test the patients at the same time. Agreement was found on over 85% of the items and the items that differed never did so by more than 10%. These results indicate that the Tinetti Assessment Tool has good interrater reliability.

Validity: not reported

References:

Lewis C. Balance, Gait Test Proves Simple Yet Useful. *P.T. Bulletin* 1993; 2/10:9 & 40.

Tinetti ME. Performance-Oriented Assessment of Mobility Problems in Elderly Patients. *JAGS* 1986; 34:119-126.

TINETTI ASSESSMENT TOOL

Gait Tests

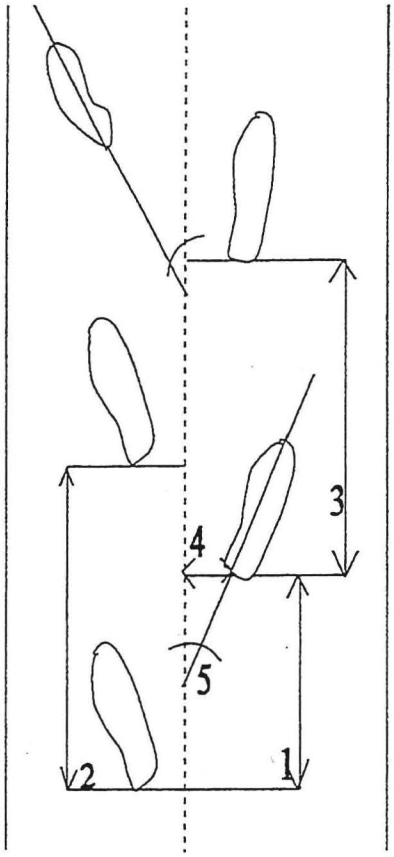
Initial Instructions: Subject stands with examiner, walks down hallway or across room, first at "usual" pace, then back at "rapid, but safe" pace (using usual walking aids)

10. Initiation of gait (immediately after told to "go")			
	Any hesitancy or multiple attempts to start	= 0	_____
	No hesitancy	= 1	_____
11. Step length and height			
	a. Right swing foot		
	Does not pass left stance foot	= 0	_____
	Passes left stance foot with step	= 1	_____
	Right foot does not clear floor completely with step	= 0	_____
	Right foot completely clears floor	= 1	_____
	b. Left swing foot		
	Does not pass right stance foot	= 0	_____
	Passes right stance foot with step	= 1	_____
	Left foot does not clear floor completely with step	= 0	_____
	Left foot completely clears floor	= 1	_____
12. Step Symmetry	Right and left step length not equal (estimate)	= 0	_____
	Right and left step appear continuous	= 1	_____
13. Step Continuity	Stopping or discontinuity between steps	= 0	_____
	Steps appear continuous	= 1	_____
14. Path (estimated in relation to floor tiles, 12-inch diameter; observe excursion of 1 foot over about 10 ft. of the course)			
	Marked deviation	= 0	_____
	Mild/moderate deviation or uses walking aid	= 1	_____
	Straight without walking aid	= 2	_____
15. Trunk	Marked sway or uses walking aid	= 0	_____
	No sway but flexion of knees or back or spread arms out while walking	= 1	_____
	No sway, no flexion, no use of arms, and no use of walking aid	= 2	_____
16. Walking Stance	Heels apart	= 0	_____
	Heels almost touching while walking	= 1	_____

Gait Score: _____: 12
Balance + Gait Score _____: 28

Reprinted with permission. Tinetti ME: Performance Oriented Assessment of Mobility Problems in Elderly Patients. JAGS 1986; 34(2): 119-126.

ELGAM



ELGAM measures: 1 = step length; 2 = left stride; 3 = right stride; 4 = walking base; 5 = walking angle

These ELGAM measurements were utilized as a reference for creating the template recording of footprints.

The ELGAM gait assessment was not performed in this study.

Reprinted with permission. Fried AV, Cwikel J, Ring H, Galinsky D. ELGAM--Extra Laboratory Gait Assessment Method: Identification for Risk Factors for Falls Among the Elderly at Home. *International Disabilities Studies* 1990; 12(4):161-164.

APPENDIX D

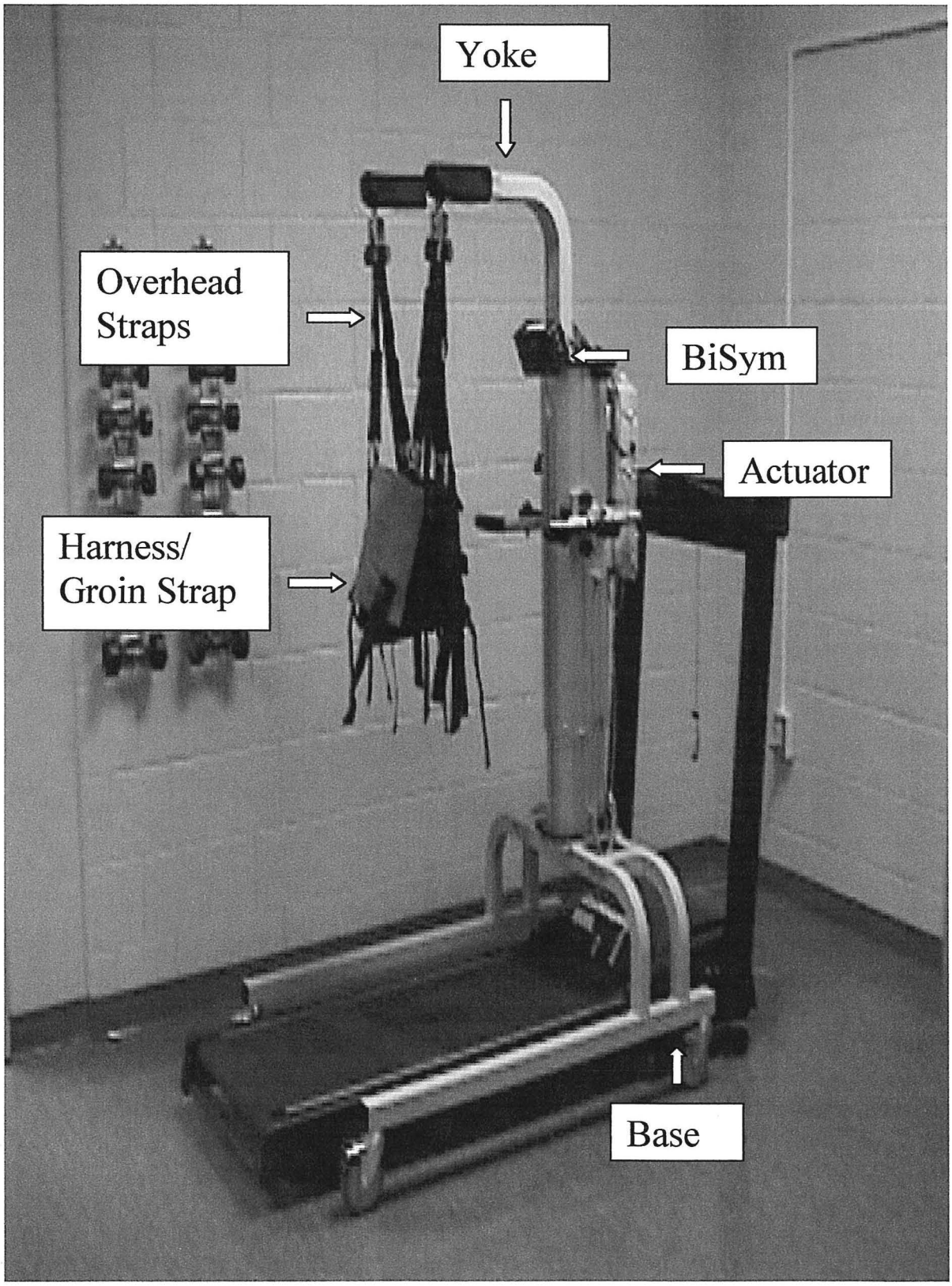


Figure 2. Diagram of LiteGait 1™

APPENDIX E

Scholarly Project: Clinical Research

Name:_____

BP/HR:_____ Weight:_____

Assessment:

	Date	Berg Balance (?/56)	Tinetti (?/12)	ELGAM	10 Meter Walk
Initial:				(L) Step Length: (R) Step Length: (L) Stride: (R) Stride: Walking Base: (L) Toe Out: (R) Toe Out:	
Final:				(L) Step Length: (R) Step Length: (L) Stride: (R) Stride: Walking Base: (L) Toe Out: (R) Toe Out:	

Additional Comments:

INDIVIDUAL TREATMENTS:

Date:

Time:	Distance: (feet/miles)	% Body weight: (lbs)	Speed: (mph)	Technique/Facilitation Point:

Date:

Time:	Distance: (feet/miles)	% Body weight: (lbs)	Speed: (mph)	Technique/Facilitation Point:

Date:

Time:	Distance: (feet/miles)	% Body weight: (lbs)	Speed: (mph)	Technique/Facilitation Point:

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